March 13, 2012

Laurence Wilson
Director, Chronic Care Policy Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard, Mail Stop C5-02-23
Baltimore, Maryland 21244-1850

Via Overnight Delivery and E-mail

Dear Mr. Wilson:

The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with a national membership that draws from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss, or limb impairment resulting from a chronic disease or health condition. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

We are writing today to submit comments with respect to the list, published via the CMS website in February, of devices being considered by CMS as possible off-the-shelf orthotic devices. We are concerned about this list because we believe it deviates substantially from the statutory definition which Congress articulated in 2003 and which binds the agency. Any efforts by CMS to implement such a list for purposes of a possible extension of competitive bidding would have serious potential impact on patients with limb loss and limb impairment, and the professionals who provide these patients with the prosthetic and orthotic devices that help restore their mobility at over 2,000 patient care facilities across the United States.

AOPA is aware of, and participated in the formulation of a separate set of comments that will be submitted on this topic by the O&P Alliance. AOPA is one of the five members of the O&P Alliance, and we want to state that AOPA is 100% supportive of the separate comments being submitted in the name of the five O&P organizations represented in the O&P Alliance.

We need to underscore that AOPA believes that fixing this very aberrant listing by CMS is a priority of the highest order. The list published by the agency is completely misguided, and its impact on patient care, were it to advance any farther, would be devastating. In large measure our response to this list, below and attached, is divided into two subdivisions – (1) patient harm and (2) the clear violation of the law.

Historically, on August 23, 2011, CMS announced its plans for Round II of competitive bidding, and made clear that it did not intend to include off-the-shelf (OTS) orthotics with Round II. That was the right decision for several reasons and we applaud it. CMS does possess statutory authority to conduct competitive bidding as to OTS orthoses. However, if the agency observes the statutory definition of off-the-shelf orthoses articulated by Congress, we believe the number of eligible devices and the volume of their usage by Medicare beneficiaries are sufficiently small that any very modest 'savings' that might be generated via competitive bidding would be more than offset by the agency's costs in conducting the program. We believe the San Antonio pilot project and similar trial runs over the past ten years or so have demonstrated that fact.

However, in June, 2011, AOPA became aware that some CMS officials had circulated to one or more Senate offices, a document stating that CMS, with assistance from its contractors, had identified a list of over 100 potential OTS orthotic devices, with a total Medicare annual financial impact in the range of $200 million. AOPA spent a significant amount of time reviewing orthotic devices and concluded that there was no way that either the number of devices, or the Medicare dollar volume telegraphed to Hill staffers on this topic could be correct if the very explicit statutory definitional terms for off-the-shelf orthotics were observed by CMS. After the August 23 decision was finalized, requests from some parties within the orthotics field were generated to CMS, asking for the opportunity to review its list of OTS orthotics, and this resulted in placement of the list on the CMS website last month.

On August 15, representatives from AOPA and others in the O&P field, under the aegis of the O&P Alliance, met with Jonathan Blum, CMS Deputy Administrator and Director, Medicare Center, and other CMS officials in a discussion that included competitive bidding. At that meeting, CMS raised the question essentially of "what harm would come if CMS were to expand the envelope for off-the-shelf orthotics a bit beyond the strict statutory definition." AOPA responded by saying that while CMS does have statutory authority to conduct competitive bidding of OTS orthotics within the boundaries of the strict statutory definition of that term, if CMS ventured at all beyond the strict words and clear meaning of that definition: (1) patients would be very significantly harmed; and (2) CMS would be violating the law. The AOPA comments that follow are organized around those two principles.

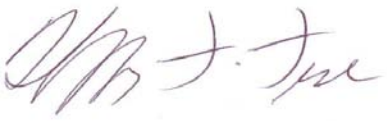
(1) Patient Harm. We will share with CMS the results of our examining every device on the CMS list. In instances where AOPA disagrees with the CMS OTS classification, we show what it looks like, explain how it is used and with what patients, in many cases supported by the pertinent medical literature. Our comments also articulate the harm that can come to patients/Medicare beneficiaries if, as a result of OTS designation, these devices were distributed to patients without attendant clinical care by an appropriately trained, qualified (and in many states licensed) orthotist or health professional with comparable training who can assure that the device is properly formed and adjusted to the unique anatomical features of the patient and suitable to that patient's medical condition/needs. There are, of course, some instances in which we agree with the CMS thinking that some of the devices do belong on any legitimate OTS list. These codes are clearly identified in the enclosed document that indicates AOPA's agreement or disagreement with the CMS OTS classification for each code.

(2) Violation of Law. Turning to the second point, the violation of the law that would attend any decision by CMS to go beyond the strict terms and clear meaning of the statutory definition of OTS orthotics, AOPA submits a legal memorandum prepared by outside counsel from the law

firm, Winston and Strawn, which examines the statutory language, legislative history and legal precedents in interpreting the definition, and particularly the unambiguous, but pivotal phrase "minimal self adjustment."

AOPA appreciates the opportunity to express the concerns of its members regarding the CMS proposed list of off-the-shelf orthoses and looks forward to continuing to work with CMS to ensure that Medicare beneficiaries continue to receive quality healthcare from properly trained providers.

Sincerely,



Thomas F Fise, JD
Executive Director

CMS Off-The-Shelf Orthotics HCPCS Codes

HCPCS Code	Descriptor	AOPA Agrees it is an OTS item	AOPA Disagrees that it is an OTS item	Summary of Rationale	For Full Rationale See Page
L0120	CERVICAL, FLEXIBLE, NON-ADJUSTABLE (FOAM COLLAR)	X			
L0160	CERVICAL, SEMI-RIGID, WIRE FRAME OCCIPITAL/MANDIBULAR SUPPORT		X	The device comes in multiple sizes and the patient must be measured and the correct size provided and fit. Once selected the device must be contoured to fit the patient, avoiding excessive pressure on the bony anatomy, especially the clavicle. It may also be necessary to adjusted the collar to provide the desired flexion/extension position of the cervical spine Improper fitting may cause mal-alignment resulting in nerve impingement; movement of skeletal fragments and puts the patient at further risk of spinal cord injury. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device.	1

HCPCS Code	Descriptor	AOPA Agrees it is an OTS item	AOPA Disagrees that it is an OTS item	Summary of Rationale	For Full Rationale See Page
L0172	CERVICAL, COLLAR, SEMI-RIGID THERMOPLASTIC FOAM, TWO PIECE		X	This device describes a collar that stabilizes the cervical spine, decreasing motion. This class of device requires a choice between 4 to 15 sizes to provide appropriately size and fit. This device is typically provided for stabilization of the cervical spine where moderate stabilization is required. The stabilization applied by the device needs to be evaluated by a professional to ensure proper clearance over bony prominences in order to prevent skin breakdown and adequate control of motion. Improper fitting may cause mal-alignment resulting in nerve impingement or movement of skeletal fragments. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device.	5

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L0174	CERVICAL, COLLAR, SEMI-RIGID, THERMOPLASTIC FOAM, TWO PIECE WITH THORACIC EXTENSION		X	The device is available in separate component parts requiring appropriate size selection and fitting. The sizing chart demonstrates the typical devices. When necessary the fronts and backs can be mixed to optimize fit for non-standard heights, circumferences or to achieve non-neutral flexion angles. Once applied the anterior mandibular and posterior occipital sections are adjusted to balance forces on the skeletal structures and provide well-distributed support of the spine. This device offers increased stabilization over other cervical orthoses as an anterior extension reduces flexion, due to its longer stabilization on the sternum. Improper fitting may cause mal-alignment resulting in poor healing, nerve impingement, and movement of skeletal fragments or spinal column damage. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device.	16
L0450	TLSO, FLEXIBLE, PROVIDES TRUNK SUPPORT, UPPER THORACIC REGION, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISKS WITH RIGID STAYS OR PANEL(S), INCLUDES SHOULDER STRAPS AND CLOSURES, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	This consists of a flexible material, which provides stabilization to the upper thoracic spine. . It requires, bending of the posterior stays or shaping of the rigid panel to optimize fit. These devices are often provided to persons who would have difficulty with more rigid type devices and who may have difficulty with pressure on sensitive skin. Additionally they would need instruction, often repetitively, to ensure application of the device for appropriate function. Improper fitting may lead to exacerbation of orthopedic condition and issues with skin that can lead to breakdown. Follow up care is essential following fitting of these types of devices.	27

HCPCS Code	Descriptor	AOPA Agrees it is an OTS item	AOPA Disagrees that it is an OTS item	Summary of Rationale	For Full Rationale See Page
L0454	TLSO FLEXIBLE, PROVIDES TRUNK SUPPORT, EXTENDS FROM SACROCOCCYGEAL JUNCTION TO ABOVE T-9 VERTEBRA, RESTRICTS GROSS TRUNK MOTION IN THE SAGITTAL PLANE, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISKS WITH RIGID STAYS OR PANEL(S), INCLUDES SHOULDER STRAPS AND CLOSURES, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	This TLSO is determined by multiple measurements, providing stabilization to the thoracic and lumbar spine. Sizing allows fitting of both neutral and pendulous patients, requiring the fitter to have more than a passing knowledge of anatomy for application. The devices come in 6 circumferences. Height of the devices must be properly selected to allow for standing and sitting without compromising overall fit and function of the device. Improper fitting may lead to exacerbation of orthopedic condition and issues with skin that can lead to breakdown. Follow up care is essential following fitting of these types of devices. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device.	28
L0456	TLSO, FLEXIBLE, PROVIDES TRUNK SUPPORT, THORACIC REGION, RIGID POSTERIOR PANEL AND SOFT ANTERIOR APRON, EXTENDS FROM THE SACROCOCCYGEAL JUNCTION AND TERMINATES JUST INFERIOR TO THE SCAPULAR SPINE, RESTRICTS GROSS TRUNK MOTION IN THE SAGITTAL PLANE, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISKS, INCLUDES STRAPS AND CLOSURES, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	This TLSO consist of a full-length posterior section that is secured with straps that attached to a rigid anterior apron front. The device requires measurements to select the appropriate size, bending of the posterior stabilizing portion of the device and trimming of the straps to achieve an optimal fit. The fitting of this device cannot be done without assistance and requires the fitter applies adjustment after the device to the patient. Once applied, the straps typically need to be further tuned to allow for standing and sitting without compromising the device function. As this patient typically has limited mobility often techniques need to be developed to permit device application. Follow up instructions are commonly required. It would not be possible for this device to be fit by someone with an understanding of basic skeletal anatomy to appropriately position the device, to assure stabilization and to accommodate the variation in sitting and standing postural changes without causing irritation.	29

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L0460	TLSO, TRIPLANAR CONTROL, MODULAR SEGMENTED SPINAL SYSTEM, TWO RIGID PLASTIC SHELLS, POSTERIOR EXTENDS FROM THE SACROCOCCYGEAL JUNCTION AND TERMINATES JUST INFERIOR TO THE SCAPULAR SPINE, ANTERIOR EXTENDS FROM THE SYMPHYSIS PUBIS TO THE STERNAL NOTCH, SOFT LINER, RESTRICTS GROSS TRUNK MOTION IN THE SAGITTAL, CORONAL, AND TRANSVERSE PLANES, LATERAL STRENGTH IS PROVIDED BY OVERLAPPING PLASTIC AND STABILIZING CLOSURES, INCLUDES STRAPS AND CLOSURES, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	Representative of two shelled TLSO that overlaps to interlock on the torso. Multiple measurements are required to ensure an appropriately sized module. Sizing chart demonstrates both neutral and pendulous design, requiring the fitter to have knowledge of anatomy for application. Modules are designed to be modified by the use of heat to compensate for potential areas of pressure. Plastic can be cut, and cut edges must be properly smoothed which cannot be done without training and proper tools. Trim lines must be properly configured to allow for standing and sitting without compromising overall fit and function of the device. Improper fitting may lead to exacerbation of orthopedic condition and issues with skin that can lead to breakdown. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device.	30
L0466	TLSO, SAGITTAL CONTROL, RIGID POSTERIOR FRAME AND FLEXIBLE SOFT ANTERIOR APRON WITH STRAPS, CLOSURES AND PADDING, RESTRICTS GROSS TRUNK MOTION IN SAGITTAL PLANE, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON INTERVERTEBRAL DISKS, INCLUDES FITTING AND SHAPING THE FRAME, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	A rigid posterior paneled TLSO made of either metal or plastic with an apron front with multiple sized options. Posterior section must be appropriately shaped to ensure contact with torso. Depending on the design selected, modifications to ensure an appropriate fit must be done via heat for the plastic model or bending irons or other orthotic specific tools for the metal model. Shaping and contouring require an eye towards clinical need and familiarity in working with different materials. Improper application can result in less than proper function, adverse pressure applied to the spine and surrounding tissue, which could lead to skin breakdown and exacerbation of existing clinical issues. Application of such an orthosis may require follow up care to ensure proper functioning.	36

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L0468	TLSO, SAGITTAL-CORONAL CONTROL, RIGID POSTERIOR FRAME AND FLEXIBLE SOFT ANTERIOR APRON WITH STRAPS, CLOSURES AND PADDING, EXTENDS FROM SACROCOCCYGEAL JUNCTION OVER SCAPULAE, LATERAL STRENGTH PROVIDED BY PELVIC, THORACIC, AND LATERAL FRAME PIECES, RESTRICTS GROSS TRUNK MOTION IN SAGITTAL, AND CORONAL PLANES, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON INTERVERTEBRAL DISKS, INCLUDES FITTING AND SHAPING THE FRAME, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	A rigid posterior paneled TLSO made of either metal or plastic with an apron front and the additional support of rigid lateral frames to increase the functional stability, this rigid posterior paneled TLSO is made of either metal or plastic with an apron front with multiple sized options. Posterior section must be appropriately shaped to ensure contact with torso. Depending on the design selected, modifications to ensure an appropriate fit must be done via heat for the plastic model or bending irons or other orthotic specific tools for the metal model. Shaping and contouring require an eye towards clinical need and familiarity in working with different materials. Improper application can result in less than proper function, adverse pressure applied to the spine and surrounding tissue, which could lead to skin breakdown and exacerbation of existing clinical issues. Application of such an orthosis may require follow up care to ensure proper functioning.	42
L0621	SACROILIAC ORTHOSIS, FLEXIBLE, PROVIDES PELVIC-SACRAL SUPPORT, REDUCES MOTION ABOUT THE SACROILIAC JOINT, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT	X			
L0623	SACROILIAC ORTHOSIS, PROVIDES PELVIC-SACRAL SUPPORT, WITH RIGID OR SEMI-RIGID PANELS OVER THE SACRUM AND ABDOMEN, REDUCES MOTION ABOUT THE SACROILIAC JOINT, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	There are a range of sizes. It includes anterior and posterior panels, which must be positioned properly and would provide more restrictive in motion. This device must be worn properly in order for it to function. Proper sizing is important and the patient must be educated on this proper positioning and warning signs.	48

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L0625	LUMBAR ORTHOSIS, FLEXIBLE, PROVIDES LUMBAR SUPPORT, POSTERIOR EXTENDS FROM L-1 TO BELOW L-5 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PENDULOUS ABDOMEN DESIGN, SHOULDER STRAPS, STAYS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	There is a large surface area of contact, and with that greater area is a broader range of sizing that must be properly evaluated. Items in this code category must also be provided based upon a patient's shape which will vary by length, circumference and contours of the abdomen and spine. As the items in this category are essentially non-elastic, there is less "forgiveness" of material, hence the importance of an appropriate fit. Also present may be stainless steel stays, which must be properly shaped, not only for comfort but for appropriate control of the lumbar portion of the spine. Often times these items will be provided in a post surgical situation, requiring appropriate clinical understanding of mechanics in the application both standing and supine to ensure no injury during the fitting.	54
L0626	LUMBAR ORTHOSIS, SAGITTAL CONTROL, WITH RIGID POSTERIOR PANEL(S), POSTERIOR EXTENDS FROM L-1 TO BELOW L-5 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, STAYS, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	Note this style orthoses may require heating and contouring of the rigid material in the posterior panel. This technique is specialized to the trained orthotist. If not, edges may be left sharp without proper cutting and sanding equipment.	60
L0627	LUMBAR ORTHOSIS, SAGITTAL CONTROL, WITH RIGID ANTERIOR AND POSTERIOR PANELS, POSTERIOR EXTENDS FROM L-1 TO BELOW L-5 PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES,VERTEBRA, PRODUCES INTRACAVITARY MAY INCLUDE PADDING, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	The forces implemented by the brace to control sagittal control with this bi-valve rigid device need to be evaluated by a professional. If the forces are not directed in the appropriate anatomical location to prevent unwanted motion direction then the patient puts them self at a higher risk of injury. The trimlines of posterior and anterior rigid panel and pressures over bony prominences encompassed by the brace needs to be evaluated by a professional to ensure maintain skin integrity and prevent skin breakdown. The amount of intracavitary pressures provide by the brace needs to be assessed to ensure an appropriate amount of force is being applied and abdominal structures and internal organs are not being constricted due to excessive pressures. The strapping configuration and appropriate tightness of the straps needs to be review with the patient. Poorly adjusted straps decrease the overall effectiveness of the brace and increase the risk of injury with poorly directed strap forces.	66

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L0628	LUMBAR-SACRAL ORTHOSIS, FLEXIBLE, PROVIDES LUMBO-SACRAL SUPPORT, POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE STAYS, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	This orthoses requires exact sizing and measurements. When fit incorrectly, the orthoses will be extremely difficult to tolerate and would cause discomfort to the lumbar spine as well as cause skin irritation. Heat molding and bending of the posterior panel requires specific training.	72
L0630	LUMBAR-SACRAL ORTHOSIS, SAGITTAL CONTROL, WITH RIGID POSTERIOR PANEL(S), POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, STAYS, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	The forces implemented by the brace to control sagittal control with this rigid device need to be evaluated by a professional. If the forces are not directed in the appropriate anatomical location to prevent unwanted motion direction then the patient puts them self at a higher risk of injury. The trimlines of posterior and anterior rigid panel and pressures over bony prominences encompassed by the brace needs to be evaluated by a professional to ensure maintain skin integrity and prevent skin breakdown. The amount of intracavitary pressures provide by the brace needs to be assessed to ensure an appropriate amount of force is being applied and abdominal structures and internal organs are not being constricted due to excessive pressures. The strapping configuration and appropriate tightness of the straps needs to be review with the patient. Poorly adjusted straps decrease the overall effectiveness of the brace and increase the risk of injury with poorly directed strap forces.	78

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L0631	LUMBAR-SACRAL ORTHOSIS, SAGITTAL CONTROL, WITH RIGID ANTERIOR AND POSTERIOR PANELS, POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	The forces implemented by the brace to control sagittal control with this rigid device need to be evaluated by a professional. If the forces are not directed in the appropriate anatomical locations to prevent unwanted motion direction then the patient puts them self at a higher risk of injury. The trimlines of posterior and anterior rigid panel and pressures over bony prominences encompassed by the brace needs to be evaluated by a professional to ensure maintain skin integrity and prevent skin breakdown. The amount of intracavitary pressures provide by the brace needs to be assessed to ensure an appropriate pressure. The strapping configuration and appropriate tightness of the straps needs to be review with the patient. Poorly adjusted straps decrease the overall effectiveness of the brace and increase the risk of injury with poorly directed strap forces.	84
L0633	LUMBAR-SACRAL ORTHOSIS, SAGITTAL-CORONAL CONTROL, WITH RIGID POSTERIOR FRAME/PANEL(S), POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, LATERAL STRENGTH PROVIDED BY RIGID LATERAL FRAME/PANELS, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, STAYS, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	This orthoses requires specific sizing, heating, and bending during the initial fitting. A trained orthotist will be able to manage the fitting, but a non-orthotist will not have the tools required to do the job, and they do not have the traing to safely manage the patient to protect them from sharp edges or poor alignment.	90

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L0637	LUMBAR-SACRAL ORTHOSIS, SAGITTAL-CORONAL CONTROL, WITH RIGID ANTERIOR AND POSTERIOR FRAME/PANELS, POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, LATERAL STRENGTH PROVIDED BY RIGID LATERAL FRAME/PANELS, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	The forces implemented by the brace to control sagittal and coronal control with this bi-valve rigid device need to be evaluated by a professional. If the forces are not directed in the appropriate to prevent unwanted motion direction then the patient puts them self at a higher risk of injury. The trimlines of posterior, anterior, and lateral rigid panels and pressures over bony prominences encompassed by the brace needs to be evaluated by a professional to ensure maintain skin integrity and prevent skin breakdown. The amount of intracavitary pressures provided by the brace needs to be assessed to ensure an appropriate amount of force is being applied and abdominal structures and internal organs are not being constricted due to excessive pressures. The strapping configuration and appropriate tightness of the straps needs to be review with the patient. Poorly adjusted straps decrease the overall effectiveness of the brace and increase the risk of injury with poorly directed strap forces.	96
L0639	LUMBAR-SACRAL ORTHOSIS, SAGITTAL-CORONAL CONTROL, RIGID SHELL(S)/PANEL(S), POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, ANTERIOR EXTENDS FROM SYMPHYSIS PUBIS TO XYPHOID, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, OVERALL STRENGTH IS PROVIDED BY OVERLAPPING RIGID MATERIAL AND STABILIZING CLOSURES, INCLUDES STRAPS, CLOSURES, MAY INCLUDE SOFT INTERFACE, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	The Lumbar-sacral orthosis is a rigid device which limits motion. This device provides circumferential support and total contact which requires the following: accurate measurement, proper device assessment, and skilled fitting and delivery. The critical areas of fit involve angle of lordosis, assessment of existing deformity, and proper height. In the event of poor assessment and fit, the result could be pain, open wounds, or additional negative outcomes.	97
L0980	PERONEAL STRAPS, PAIR				
L0982	STOCKING SUPPORTER GRIPS, SET OF FOUR (4)				
L0984	PROTECTIVE BODY SOCK, EACH				

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L1600	HIP ORTHOSIS, ABDUCTION CONTROL OF HIP JOINTS, FLEXIBLE, FREJKA TYPE WITH COVER, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	The Frejka pillow is a thick, layered or padded material with adjustable shoulder straps. It is designed to reduce stresses across the affected hip joint or joints of newborns and infants. It is designed to maintain the femoral head to be contained within the acetabulum, while the hip joint is stabilized bilaterally at the end desired degrees of abduction as well as the desired degrees of internal rotation. Professional fit is essential for the proper degrees and limited range of motion. Inappropriate fit can result in inability to ambulate, painful ambulation, required surgical intervention or multiple poor outcomes.	98
L1610	HIP ORTHOSIS, ABDUCTION CONTROL OF HIP JOINTS, FLEXIBLE, (FREJKA COVER ONLY), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	The Frejka pillow is a thick, layered or padded material with adjustable shoulder straps. It is designed to reduce stresses across the affected hip joint or joints of newborns and infants. It is designed to maintain the femoral head to be contained within the acetabulum, while the hip joint is stabilized bilaterally at the end desired degrees of abduction as well as the desired degrees of internal rotation. Professional fit is essential for the proper degrees and limited range of motion. Inappropriate fit can result in inability to ambulate, painful ambulation, required surgical intervention or multiple poor outcomes. In the event of cover change, the same fitting criteria are required. The replacement of the cover requires reapplication and same fitting criteria as with the original device.	133

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L1620	HIP ORTHOSIS, ABDUCTION CONTROL OF HIP JOINTS, FLEXIBLE, (PAVLIK HARNESS), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT			The Pavlik harness is made of webbing, straps, foam and Velcro. It is designed to reduce stresses across the affected hip joint or joints of newborns and infants. It is designed to maintain the femoral head to be contained within the acetabulum, while the hip joint is stabilized bilaterally at the end desired degrees of abduction as well as the desired degrees of internal rotation. Professional fit is essential for the proper degrees and limited range of motion. Biomechanically correct strap position is required for maximum effectiveness in treating hip dysplasia. If straps are applied incorrectly it will prevent the hip from forming in the correct alignment which can result in dislocation, inability to ambulate, painful ambulation, or required surgical intervention.	168
L1810	KNEE ORTHOSIS, ELASTIC WITH JOINTS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	The knee orthosis is made of elastic, neoprene or like materials with hinged joints medially and laterally positioned over the knee joint. This device provides mild medio-lateral stabilization, circumferential support and resists hyperextension. The metal knee joints require proper adjustments to accommodate anatomical angles. Inappropriate fit puts the patient at risk of tourniquet injury and wounds resulting from inappropriate pressure on bony prominences and other negative outcomes	203
L1830	KNEE ORTHOSIS, IMMOBILIZER, CANVAS LONGITUDINAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT	X			
L1832	KNEE ORTHOSIS, ADJUSTABLE KNEE JOINTS (UNICENTRIC OR POLYCENTRIC), POSITIONAL ORTHOSIS, RIGID SUPPORT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	This device is indicated for locked or limited motion control of knee during rehabilitation after operative procedures or injury to knee ligaments, cartilage, or stable or internally fixed fractures of tibial plateau, condyles, or proximal tibia and distal femur. The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for stabilization needed to facilitate healing. Failure to properly align/apply this device may lead to further injury of the knee.	204
L1836	KNEE ORTHOSIS, RIGID, WITHOUT JOINT(S), INCLUDES SOFT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	To allow for functional ROM by maintaining knee position.	205

HCPCS Code	Descriptor	AOPA Agrees it is an OTS item	AOPA Disagrees that it is an OTS item	Summary of Rationale	For Full Rationale See Page
L1843	KNEE ORTHOSIS, SINGLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT (UNICENTRIC OR POLYCENTRIC), MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	This orthosis is designed to unload/stabilize the knee joint. A proper understanding of the diagnosis, knowledge of the anatomy of the knee joint and proper understanding of the knee orthosis and how to fit this and adjust the settings is crucial to proper functioning of the orthosis. Without this knowledge the orthosis would not be fit properly and the proper unloading effects would not be experienced. Knowledge and experience with these orthoses would allow the professional to know whether this orthosis will fit properly and control the excessive knee motion.	206
L1845	KNEE ORTHOSIS, DOUBLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT (UNICENTRIC OR POLYCENTRIC), MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	This orthosis is designed to unload/stabilize the knee joint. A proper understanding of the diagnosis, knowledge of the anatomy of the knee joint and proper understanding of the knee orthosis and how to fit this and adjust the settings is crucial to proper functioning of the orthosis. Without this knowledge the orthosis would not be fit properly and the proper unloading effects would not be experienced. Knowledge and experience with these orthoses would allow the professional to know whether this orthosis will fit properly and control the excessive knee motion.	231
L1847	KNEE ORTHOSIS, DOUBLE UPRIGHT WITH ADJUSTABLE JOINT, WITH INFLATABLE AIR SUPPORT CHAMBER(S), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	This orthosis is used to provide stability to an injured knee and requires knowledge of the anatomy of the knee as well as the knowledge of the injury type to understand how the knee joint should be adjusted as well as how much air pressure should be added to the orthosis. Improper fitting of this orthosis could cause further damage to the knee. A trained person should fit this and also provide follow-up as needed.	265
L1850	KNEE ORTHOSIS, SWEDISH TYPE, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	This orthosis is prescribed to provide posterior control of the knee joint which could be caused by a variety of injuries. Improper alignment of the knee joints could allow further damage to the knee or injuries to the soft tissue if the uprights are not contoured correctly. If the orthosis is adjusted improperly, and keeps the knee to extended, injury could result if the patient fell from lack of knee stability. Proper fitting in adjusting of this orthosis is crucial to proper function.	266
L1902	ANKLE FOOT ORTHOSIS, ANKLE GAUNTLET, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT	X			

HCPCS Code	Descriptor	AOPA Agrees it is an OTS item	AOPA Disagrees that it is an OTS item	Summary of Rationale	For Full Rationale See Page
L1906	ANKLE FOOT ORTHOSIS, MULTILIGAMENTUS ANKLE SUPPORT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT	X			
L3100	HALLUS-VALGUS NIGHT DYNAMIC SPLINT	X			
L3170	FOOT, PLASTIC, SILICONE OR EQUAL, HEEL STABILIZER, EACH	X			
L3650	SHOULDER ORTHOSIS, FIGURE OF EIGHT DESIGN ABDUCTION RESTRAINER, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT	X			
L3660	SHOULDER ORTHOSIS, FIGURE OF EIGHT DESIGN ABDUCTION RESTRAINER, CANVAS AND WEBBING, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	Proper application of this device involves appropriate knowledge of a qualified practitioner on patient positioning of the elbow and shoulder to protect the patient from compromising the post surgical healing process. The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for stabilization needed to facilitate healing. Failure to properly align/apply this device may lead to further injury of the shoulder.	267
L3670	SHOULDER ORTHOSIS, ACROMIO/CLAVICULAR (CANVAS AND WEBBING TYPE), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	This brace is intended to stabilize the acromioclavicular joint to reduce pain and joint motion. Proper fit and adjustment of straps is required for stabilization. The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for stabilization needed to facilitate healing. Failure to properly align/apply this device may lead to further injury of the shoulder and increased pain potentially leading to surgery. Proper application of this device involves appropriate knowledge of a qualified practitioner on patient positioning of the elbow and shoulder to protect the patient from compromising the post surgical healing process or from further damaged to the rotator cuff that could lead to further surgical intervention.	268
L3675	SHOULDER ORTHOSIS, VEST TYPE ABDUCTION RESTRAINER, CANVAS WEBBING TYPE OR EQUAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	The device is designed to protect and stabilize the shoulder post-injury and post-operatively. The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for immobilization needed to facilitate healing. Casual application by an inexperienced individual could place the involved shoulder at risk.	287

HCPCS Code	Descriptor	AOPA Agrees it is an OTS item	AOPA Disagrees that it is an OTS item	Summary of Rationale	For Full Rationale See Page
L3677	SHOULDER ORTHOSIS, SHOULDER JOINT DESIGN, WITHOUT JOINTS, MAY INCLUDE SOFT INTERFACE, STRAPS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for immobilization needed to facilitate healing. Casual application by an inexperienced individual could place the involved shoulder at risk. Requires appropriate application and fitting and trimming of plastic material to customize fit and achieve desired level of motion restriction.	306
L3710	ELBOW ORTHOSIS, ELASTIC WITH METAL JOINTS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	The elbow orthosis described by this code offers adjustable elbow joint components that are too complex for patient self-adjustment and would require the presence of a qualified individual to properly determine both the appropriate range of motion settings and the amount of contouring required to apply corrective forces or stabilization of the elbow. There is a dramatic range of orthopedic diagnoses of patients who would be candidates for this orthosis. Because of the complexity of the orthosis and the vast array of clinical applications this should not be considered for OTS. The elbow orthosis is made of a combination of elastic, neoprene or similar materials with associated metal stays or hinges that are located medially and laterally and positioned over the elbow joint to control motion or to stabilize the soft tissue and boney anatomy that surround the elbow. This device provides medial and lateral stabilization and restricts unwanted motion through circumferential support and compression and immobilization. The metal joints require contouring and bending that is specific to the anatomy and must accommodate anatomical angles and	307

HCPCS Code	Descriptor	AOPA Agrees it is an OTS item	AOPA Disagrees that it is an OTS item	Summary of Rationale	For Full Rationale See Page
L3762	ELBOW ORTHOSIS, RIGID, WITHOUT JOINTS, INCLUDES SOFT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	A rigid elbow orthosis without joints is indicated for post-surgical immobilization or immobilization to prevent injury to oneself in some cases. A static elbow brace is used to properly align or position the elbow joint and associated bones after surgery. This ensures proper healing of a fracture or surgical site. Without proper fitting and adjustments by a credentialed professional, the joint could heal in malalignment, which may indicate a surgical revision or deformity that the patient must live with. In some cases where a child is inflicting injury on itself, a rigid elbow orthosis is indicated to restrict that movement. Without proper fitting and adjustments, these individuals and their caretakers may place themselves at risk for injury if the device is not performing its intended purpose. This device clearly does not meet the criteria in statute associated with "minimal patient self-adjustment." The metal stays or thermoplastic components require contouring and bending that is specific to the anatomy and must accommodate anatomical angles and deformities as well as not contact	332
L3807	WRIST HAND FINGER ORTHOSIS, WITHOUT JOINT(S), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENTS, ANY TYPE		X	A wrist hand finger orthosis without joints is indicated for a person who does not have optimum neuromuscular-skeletal function of the wrist, hand, or fingers. This type of brace is used for static positioning of the wrist, hand, and fingers. The brace provides corrective forces or tension to the flexors and extensors to prevent shortening of the ligaments and/or muscles to prevent or correct contractures. Some users of this brace have no sensation in their hand or fingers and must use this brace to prevent damage to their skin or joints. These braces provide sagittal and frontal plane stability for the flail wrist and hand. Proper evaluation and fitting is required to ensure an optimal fit to prevent skin break down, ligament damage or joint contracture. The length of this orthosis and the fit of the straps are critical to the success of the brace in protecting the patient. Due to the nature of the typical user of this orthosis, self-adjustment may be impossible as well as dangerous for the patient.	357
L3908	WRIST HAND ORTHOSIS, WRIST EXTENSION CONTROL COCK-UP, NON MOLDED, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT	X			

HCPCS Code	Descriptor	AOPA Agrees it is an OTS item	AOPA Disagrees that it is an OTS item	Summary of Rationale	For Full Rationale See Page
L3912	HAND FINGER ORTHOSIS, FLEXION GLOVE WITH ELASTIC FINGER CONTROL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT	X			
L3915	WRIST HAND ORTHOSIS, INCLUDES ONE OR MORE NONTORSION JOINT(S), ELASTIC BANDS, TURNBUCKLES, MAY INCLUDE SOFT INTERFACE, STRAPS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	A prefabricated wrist hand orthosis with joints is indicated for a person who does not have optimum function of the wrist joint. A weak or misaligned wrist decreases the patient's ability to position the hand and fingers in a functional position to use for ADL's. The joints associated with this orthosis can assist the wrist and fingers in performing tasks, which require three-point prehension. If these joints are not fit and adjusted by a credentialed individual, they could cause pain or decrease function of the patient's hand, preventing them from performing their ADL's, which are essential to functional independence. Improper fit of this orthosis can lead to contractures of the ligaments and tendons of the hand and fingers due to the lack of range of motion on a regular basis.	364
L3917	HAND ORTHOSIS, METACARPAL FRACTURE ORTHOSIS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	A hand orthosis, which is used to heal metacarpal fractures, immobilizes the bones of the hand to prevent met movement and allow healing. A hand orthosis is the primary treatment method of a metacarpal fracture. Without professional fitting and evaluation by a credentialed individual, the fracture site may close in malalignment and cause deformity of the bone. This would lead to decreased function of the hand, which is necessary for proper performance of ADL's.	371
L3923	HAND FINGER ORTHOSIS, WITHOUT JOINTS, MAY INCLUDE SOFT INTERFACE, STRAPS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	A hand finger orthosis without joints is used to protect and immobilize the bones and ligaments of the hand and fingers. It places the hand in a safe position to prevent injury while wearing. The brace places the thumb and hand in a position for 3-point prehension for ADL's. Without proper fitting and evaluation by a credentialed individual, the orthosis could cause shortening of ligaments, which would decrease range of motion and function of the fingers. It could also cause ligamentous laxity or weakness in the hand or fingers and may allow unwanted motions of the fingers or hand, which would prolong the healing process.	372

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L3925	FINGER ORTHOSIS, PROXIMAL INTERPHALANGEAL (PIP)/DISTAL INTERPHALANGEAL (DIP), NON TORSION JOINT/SPRING, EXTENSION/FLEXION, MAY INCLUDE SOFT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	This finger orthosis is used to protect and immobilize the DIP and/or PIP joints of the finger after injury or surgery. It provides minimal compression and prevents motion of the PIP and DIP joints, which aids in the healing process. A finger splint that is improperly fitted could be too restrictive and decrease circulation to the finger. If the patient fit this device loosely, it would allow motion at the DIP and PIP, which would decrease the healing processes, it was intended to assist.	373
L3927	FINGER ORTHOSIS, PROXIMAL INTERPHALANGEAL (PIP)/DISTAL INTERPHALANGEAL (DIP), NON TORSION JOINT/SPRING, EXTENSION/FLEXION, MAY INCLUDE SOFT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	A qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Adjustments to the orthosis which could be detrimental to the fit and function should only be performed by a qualified professional.	392
L3929	HAND FINGER ORTHOSIS, INCLUDES ONE OR MORE NONTORSION JOINT(S), TURNBUCKLES, ELASTIC BANDS/SPRINGS, MAY INCLUDE SOFT INTERFACE MATERIAL, STRAPS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	A qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Adjustments to the orthosis which could be detrimental to the fit and function should only be performed by a qualified professional.	411
L4350	ANKLE CONTROL ORTHOSIS, STIRRUP STYLE, RIGID, INCLUDES ANY TYPE INTERFACE (E.G., PNEUMATIC, GEL), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT	X			

HCPCS Code	Descriptor	AOPA Agrees it is an OTS item	AOPA Disagrees that it is an OTS item	Summary of Rationale	For Full Rationale See Page
L4360	WALKING BOOT, PNEUMATIC AND/OR VACUUM, WITH OR WITHOUT JOINTS, WITH OR WITHOUT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	A qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Other issues include proper height (distal to the fibular head to avoid peroneal nerve pressure, proper foot plate length/adjustments, proper vacuum/pneumatic adjustments, contour changes for anatomical shape). When the pneumatic device is properly inflated, it decreases pain and swelling around the surgical or injury site. An improperly inflated device can cause excessive swelling and pain around the site being protected, prolonging the healing process and possibly require further intervention. Adjustments to the orthosis which could be detrimental to the fit and function should only be performed by a qualified professional.	423
L4370	PNEUMATIC FULL LEG SPLINT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT	X			
L4380	PNEUMATIC KNEE SPLINT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT	X			
L4386	WALKING BOOT, NON-PNEUMATIC, WITH OR WITHOUT JOINTS, WITH OR WITHOUT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	A qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Other issues include proper height (distal to the fibular head to avoid peroneal nerve pressure, proper foot plate length/adjustments, contour changes for anatomical shape). Adjustments to the orthosis which could be detrimental to the fit and function should only be performed by a qualified professional.	431

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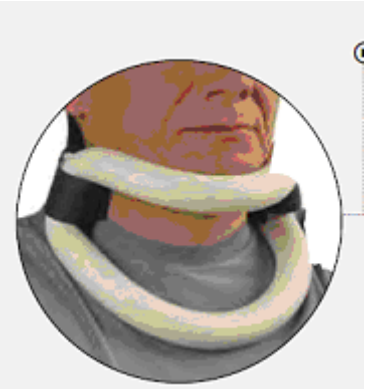
L4396	STATIC OR DYNAMIC ANKLE FOOT ORTHOSIS, INCLUDING SOFT INTERFACE MATERIAL, ADJUSTABLE FOR FIT, FOR POSITIONING, MAY BE USED FOR MINIMAL AMBULATION, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT		X	A qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Other issues include proper height (distal to the fibular head to avoid peroneal nerve pressure, proper footplate length/adjustments, contour changes for anatomical shape. An improper fitting PRAFO can decrease healing time or even prevent healing which can, in some cases, lead to amputation. A qualified professional should only perform adjustments to the orthosis, which could be detrimental to the fit and function.	439
L4398	FOOT DROP SPLINT, RECUMBENT POSITIONING DEVICE, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT	X			

HCPCS:	Descriptor:
L0160	CERVICAL, SEMI-RIGID, WIRE FRAME OCCIPITAL/MANDIBULAR SUPPORT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
NO	YES	NO	NO	YES

Sample Diagnosis (Not Inclusive)	Neuromuscular weakness
Medically Necessary Argument	The device comes in multiple sizes and the patient must be measured and the correct size provided and fit. Once selected the device must be contoured to fit the patient, avoiding excessive pressure on the bony anatomy, especially the clavicle. It may also be necessary to adjusted the collar to provide the desired flexion/extension position of the cervical spine Improper fitting may cause mal-alignment resulting in nerve impingement; movement of skeletal fragments and puts the patient at further risk of spinal cord injury. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device.
References	1

RESEARCH

The Incidence of Skin Breakdown Associated With Use of Cervical Collars

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ABSTRACT
The most common adverse complication associated with cervical immobilization is skin breakdown. The purpose of this prospective, descriptive study was to assess the incidence of tissue breakdown associated with cervical immobilization. In this convenience sample of 484 patients, skin breakdown was noted in 33 (6.8%) patients. All cases of documented skin breakdown were stage I or II, with only 2 (0.4%) patients having stage III breakdown. Days in the cervical collar is a significant predictor of skin breakdown, along with presence of edema. Results from this study demonstrate that there is a very low incidence of complications of skin breakdown associated with the use of Aspen cervical collars. The collars are safe and effective to use in patients with actual or suspected head or spine injuries.

KEY WORDS
Cervical collars, Immobilization, Skin breakdown

Cervical immobilization with the use of cervical collars is a common and necessary practice associated with the care of trauma patients. Cervical immobilization is required until cervical spine or ligament injury can be completely ruled out. This is often difficult to accomplish in patients in the intensive care unit setting. It is difficult to clear patients clinically when they have a concomitant head injury and are unable to communicate cervical pain. This is even more challenging in pediatric patients for whom spinal cord injury without radiographic abnormality is a more common occurrence. One of the most common, yet preventable, adverse problems associated with cervical collar use is skin or tissue breakdown.

The goal of cervical immobilization is to restrict cervical mobility and avoid any further damage to the spine. There are 4 cervical collars that are routinely used in practice: Stiff-neck, Philadelphia, Miami-J, and Aspen. It is not the goal of this article to address the mobility restrictions of these collars because these have been documented in studies on motion restriction that have been completed previously.[1,2] However, very few studies have addressed skin breakdown, the most common adverse complication of cervical collars. It has been reported that up to 55% of patients in a cervical collar for 5 days or greater develop skin breakdown, specifically occipital, chin, mandibular, ears, and shoulders, as well as macerated skin.[2–6] Skin breakdown can be quite severe, even progressing to stage IV pressure ulcers, requiring plastic surgery for repair and reconstruction of the area damaged by pressure ulcers.[5,6] This can significantly affect patient morbidity and length of stay and add significant cost to hospitalization. Previous studies have reported increased hospital costs ranging from $4,323 to $30,000.[7,8]

Plaisier et al[7] measured the capillary closure pressure of 4 different cervical collars. The collars evaluated in this study were Stiff-neck, Philadelphia, Miami-J, and Aspen (previously known as Newport) cervical collars. The cervical collars were tested on 20 healthy subjects, and capillary closure pressure was measured on various areas of the scalp and face. Increased capillary closure pressure is known to be associated with soft-tissue breakdown.[7] The findings from this study demonstrated an increased capillary closure pressure exerted by the Stiff-neck and the Philadelphia collars and pressures exerted by Miami-J and Newport (Aspen) to be well below capillary closure pressures associated with tissue breakdown.[7]

Powers[8] reported a decreased incidence of skin breakdown from 19 ulcers to 0 with improved process of care

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and a change to Aspen cervical collars for cervical immobilization. This project, completed with 76 adult patients, demonstrated that with optimal skin care and the change to a collar that had a lower capillary closure pressure, skin breakdown associated with cervical collar use was essentially eliminated. In this initiative, protocols were established for routine care and changing of the cervical collars. A protocol was also established to decrease the length of time the patients were immobilized in cervical collars. The average time that patients were in cervical collars decreased from an average of 14.4 days before this initiative to 7.7 days after the implementation.

Similar results were reported by Blaylock[9] in 20 patients at a level 1 trauma center. Patient collar use ranged from 1 to 37 days. A change to Aspen cervical collars using a continuous quality improvement model resulted in zero incidence of skin breakdown associated with cervical collars.

These are the only reports in the literature, other than case reviews, concerning incidence of skin breakdown with cervical collar use. These manuscripts discuss skin breakdown in an adult population using a quality improvement process. To date, there have been no large studies identifying risk or incidence of tissue breakdown associated with cervical collar use or studies that have included pediatric patients. The purpose of this research study was to assess the incidence of tissue breakdown associated with cervical immobilization.

METHODS

This prospective, descriptive study was designed to assess the incidence of tissue breakdown associated with cervical immobilization. Aspen cervical collars are the standard collar used for cervical immobilization at the institution where this study was conducted; therefore, these were the collars used for the study. A convenience sample of adult and pediatric patients admitted to 3 critical care units at a large urban level 1 trauma center and tertiary referral center was included in the study. Only patients who had a cervical collar in place at the time of admission and who had a cervical collar for longer than 24 hours were included in the study. Patients were excluded if they began their hospital stay on a medical-surgical unit and then were transferred into one of the critical care units. The study was approved by the institutional review board. A waiver of informed consent was granted owing to the descriptive nature of the study.

The critical care units included were the neuroscience critical care, the adult critical care, and the pediatric critical care units, where most trauma patients are admitted. Standard practice for care of patients in cervical collars was not altered. Standard practice includes cleaning and assessing skin under the cervical collar every 12 hours and changing the pads in the collar every 24 hours. The use of a small back panel for any patient using an adult-sized cervical collar and who was on bedrest is recommended by the manufacturers to decrease potential skin breakdown caused by pressure on the occipital area.

Patients who met the inclusion criteria of being placed in a cervical collar were followed for the duration of their hospital stay while in a cervical collar. Patients were examined by 1 of 4 trained investigators, and all potential pressure areas on the head, face, neck, and chest were assessed daily for pressure breakdown for the first 7 days and then on days 10 and 14. If the patients remained in a cervical collar for more than 14 days, they were then examined weekly for the extent of their stay in the cervical collar while they were hospitalized. Variables collected included height and weight for body mass index, age, time from admission to placement in Aspen collar, vasopressor use, appropriate fit, extent of edema, activity level, use of a small back panel, length of time in collar, and length of stay in the intensive care unit. Data were collected on a manual tracking form and then entered into an SPSS database by a trained assistant. All data entry was double checked for accuracy by one of the investigators.

The sample consisted of 484 patients during a 1-year time period. The mean age of the patients was 37.8 years (range, 2–94 years), with an SD of 20.4 years. Gender was not collected as part of the data. All patients were trauma patients with actual or suspected head or spine injuries.

RESULTS

The standard practice for this institution is to change collar use from the traditional Stiff-neck collar used by the pre-hospital personnel to an Aspen cervical collar in the emergency department or in the intensive care unit. Most of the patients (70.8%) were changed from a hard cervical collar to an Aspen collar, within 8 hours of admission to the intensive care unit, and an additional 22.4% had an Aspen collar placed within 24 hours, for a total of 93.2% with placement of Aspen cervical collars within 24 hours. Of the 484 patients, only 46.7% had a small back panel in use for the majority of time in the collar.

Patients had the cervical collar in place for an average of 10.3 days (range, 1–61 days), with an SD of 11.4 days.

Skin breakdown was noted in 33 (6.8%) patients. Of these, our highest concern is for occiput breakdown, which only occurred in 6 (1.2%) patients. All cases of documented skin breakdown were stage I or II, with only 2 (0.4%) patients having stage III breakdown. The 2 patients with stage III breakdown were in the collars for 12 and 43 days, respectively, and had a body mass index of 33 and 35, as well as 2+ and 3+ edema. These factors would potentially lead to an increased skin breakdown, although with only 2 cases, it is impossible to draw any definitive conclusions. Most of the skin breakdown (5.5%) occurred on the shoulders, chin, and back, generally from

plastic edges not being covered entirely by foam, not a true pressure breakdown.

Logistic regression was chosen for statistical analysis because the outcome variable of skin breakdown is a dichotomous categorical variable (either there is breakdown present or there is none). The predictor variables or independent variables can be continuous or categorical in nature. The predictor variables used for this analysis are age, body mass index, length of time in collar, length of time to application, appropriate fit, small back panel, activity, and degree of edema present. A forced entry method was used for the logistic regression analysis.

Days in the cervical collar was found to be a significant predictor of skin breakdown, as well as length of time to application of the Aspen collar. Time in the cervical collar was the most significant predictor, with a P value <.0001. There is an increase in odds of breakdown related to the number of days in a cervical collar. There is also an increase in the odds of breakdown when edema is added as an additional predictor variable in this equation. No other variables evaluated in this study seem to have a significant impact on the incidence of skin breakdown associated with cervical collars.

The results of this study show the safety of these collars along with the proven efficacy of cervical immobilization from other studies. There was no correlation between the use of the small back panels and a decrease in the incidence of skin breakdown. Our institution does adhere to strict care with collars that requires the changing of pads every 24 hours and inspecting and cleaning the skin every 12 hours. If these were not done meticulously, the associated problems/incidence of skin breakdown would possibly be much greater.

DISCUSSION

The results of this study show an extremely low incidence of soft-tissue breakdown associated with the use of cervical collars. Implications for the healthcare practitioner based on this study are that the results of this study show the safety of these collars along with the proven efficacy of cervical immobilization from other studies.

There is no support offered for the use of small back panels to decrease the incidence of skin breakdown. The standard practice at this institution is adherence to strict care with skin cleansing, inspecting, and changing of pads. If these were not done meticulously, the associated problems and incidence of skin breakdown may be much greater. A potential limitation of this study is the assumption that standard practice was followed according to institutional policy. The actual practice and adherence to the policy were not assessed or monitored as part of the data collection process.

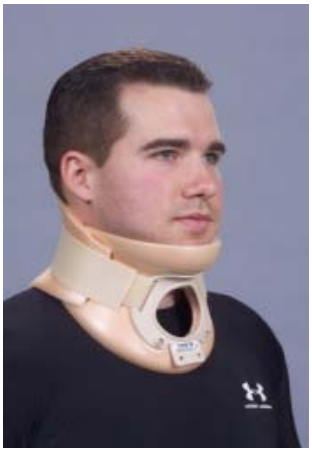
This evaluation of the incidence of skin breakdown was limited to those patients in Aspen cervical collars. This collar is the standard collar used for cervical immobilization at this institution; thus, other collars were not evaluated. Future research should explore tissue breakdown incidence with other comparable cervical collars and explore possible relationships between collar/skin care and skin breakdown.

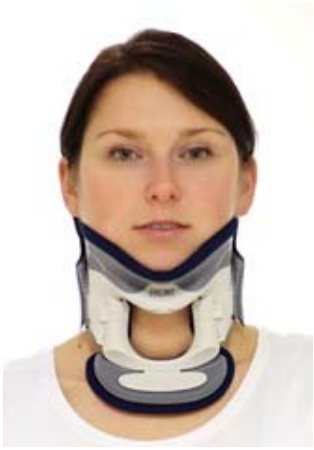
There is a very low incidence of complications of skin breakdown associated with the use of Aspen cervical collars. These collars are safe and effective to use in patients with actual or suspected head or spine injuries.

REFERENCES

1. Askins V, Eismont F. Efficacy of five cervical orthoses in restricting cervical motion. *Spine*. 1997;22:1193–1198.
2. Clancy M. Clearing the cervical spine of adult victims of trauma. *Clin Manage*. 1999;16:208–214.
3. Davis J, Parks S, Detlefs C, Williams G, Williams J, Smith R. Clearing the cervical spine in obtunded patients: the use of dynamic fluoroscopy. *J Trauma*. 1995;39:435–438.
4. Webber-Jones JE, Thomas CA, Bordeaux RE. The management and prevention of rigid cervical collar complications. *Orthop Nurs*. 2002;21:19–27.
5. Hewitt S. Skin necrosis caused by a rigid cervical collar in a ventilated patient with multiple injuries. *Injury*. 1994;25:323–324.
6. Liew S, Hill D. Complication of hard cervical collars in multi-trauma patients. *Aust N Z J Surg*. 1994;64:139–140.
7. Plaisier B, Gabram SG, Schwartz RJ, Jacobs LM. Prospective evaluation of craniofacial pressure in four different cervical orthoses. *J Trauma*. 1994;37:714–720.
8. Powers J. A multidisciplinary approach to occipital pressure ulcers related to cervical collars. *J Nurs Care Qual*. 1997;12(1):46–52.
9. Blaylock B. Solving the problem of pressure ulcers resulting from cervical collars: a step-by-step approach. *Ostomy Wound Manage*. 1996;42:26–33.

HCPCS:	Descriptor:
L0172	CERVICAL, COLLAR, SEMI-RIGID THERMOPLASTIC FOAM, TWO PIECE





Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	NO	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Cervical neck injury, Distal fracture of the skull, Post surgical, Traumatic stabilization, Cervical Strain/Sprain, Severe soft tissue injury
Medically Necessary Argument	This device describes a collar that stabilizes the cervical spine, decreasing motion. This class of device requires a choice between 4 to 15 sizes to provide appropriately size and fit. This device is typically provided for stabilization of the cervical spine where moderate stabilization is required. The stabilization applied by the device needs to be evaluated by a professional to ensure proper clearance over bony prominences in order to prevent skin breakdown and adequate control of motion. Improper fitting may cause mal-alignment resulting in nerve impingement or movement of skeletal fragments. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device.
References	1, 2

RESEARCH

The Incidence of Skin Breakdown Associated With Use of Cervical Collars

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Dawn Daniels, DNS, RN
Carolyn McGuire, RN
Chris Hilbish, RN, ACNP, CCRN, CNRN

ABSTRACT
The most common adverse complication associated with cervical immobilization is skin breakdown. The purpose of this prospective, descriptive study was to assess the incidence of tissue breakdown associated with cervical immobilization. In this convenience sample of 484 patients, skin breakdown was noted in 33 (6.8%) patients. All cases of documented skin breakdown were stage I or II, with only 2 (0.4%) patients having stage III breakdown. Days in the cervical collar is a significant predictor of skin breakdown, along with presence of edema. Results from this study demonstrate that there is a very low incidence of complications of skin breakdown associated with the use of Aspen cervical collars. The collars are safe and effective to use in patients with actual or suspected head or spine injuries.

KEY WORDS
Cervical collars, Immobilization, Skin breakdown

Cervical immobilization with the use of cervical collars is a common and necessary practice associated with the care of trauma patients. Cervical immobilization is required until cervical spine or ligament injury can be completely ruled out. This is often difficult to accomplish in patients in the intensive care unit setting. It is difficult to clear patients clinically when they have a concomitant head injury and are unable to communicate cervical pain. This is even more challenging in pediatric patients for whom spinal cord injury without radiographic abnormality is a more common occurrence. One of the most common, yet preventable, adverse problems associated with cervical collar use is skin or tissue breakdown.

The goal of cervical immobilization is to restrict cervical mobility and avoid any further damage to the spine. There are 4 cervical collars that are routinely used in practice: Stiff-neck, Philadelphia, Miami-J, and Aspen. It is not the goal of this article to address the mobility restrictions of these collars because these have been documented in studies on motion restriction that have been completed previously.[1,2] However, very few studies have addressed skin breakdown, the most common adverse complication of cervical collars. It has been reported that up to 55% of patients in a cervical collar for 5 days or greater develop skin breakdown, specifically occipital, chin, mandibular, ears, and shoulders, as well as macerated skin.[2–6] Skin breakdown can be quite severe, even progressing to stage IV pressure ulcers, requiring plastic surgery for repair and reconstruction of the area damaged by pressure ulcers.[5,6] This can significantly affect patient morbidity and length of stay and add significant cost to hospitalization. Previous studies have reported increased hospital costs ranging from $4,323 to $30,000.[7,8]

Plaisier et al[7] measured the capillary closure pressure of 4 different cervical collars. The collars evaluated in this study were Stiff-neck, Philadelphia, Miami-J, and Aspen (previously known as Newport) cervical collars. The cervical collars were tested on 20 healthy subjects, and capillary closure pressure was measured on various areas of the scalp and face. Increased capillary closure pressure is known to be associated with soft-tissue breakdown.[7] The findings from this study demonstrated an increased capillary closure pressure exerted by the Stiff-neck and the Philadelphia collars and pressures exerted by Miami-J and Newport (Aspen) to be well below capillary closure pressures associated with tissue breakdown.[7]

Powers[8] reported a decreased incidence of skin breakdown from 19 ulcers to 0 with improved process of care

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and a change to Aspen cervical collars for cervical immobilization. This project, completed with 76 adult patients, demonstrated that with optimal skin care and the change to a collar that had a lower capillary closure pressure, skin breakdown associated with cervical collar use was essentially eliminated. In this initiative, protocols were established for routine care and changing of the cervical collars. A protocol was also established to decrease the length of time the patients were immobilized in cervical collars. The average time that patients were in cervical collars decreased from an average of 14.4 days before this initiative to 7.7 days after the implementation.

Similar results were reported by Blaylock[9] in 20 patients at a level 1 trauma center. Patient collar use ranged from 1 to 37 days. A change to Aspen cervical collars using a continuous quality improvement model resulted in zero incidence of skin breakdown associated with cervical collars.

These are the only reports in the literature, other than case reviews, concerning incidence of skin breakdown with cervical collar use. These manuscripts discuss skin breakdown in an adult population using a quality improvement process. To date, there have been no large studies identifying risk or incidence of tissue breakdown associated with cervical collar use or studies that have included pediatric patients. The purpose of this research study was to assess the incidence of tissue breakdown associated with cervical immobilization.

METHODS

This prospective, descriptive study was designed to assess the incidence of tissue breakdown associated with cervical immobilization. Aspen cervical collars are the standard collar used for cervical immobilization at the institution where this study was conducted; therefore, these were the collars used for the study. A convenience sample of adult and pediatric patients admitted to 3 critical care units at a large urban level 1 trauma center and tertiary referral center was included in the study. Only patients who had a cervical collar in place at the time of admission and who had a cervical collar for longer than 24 hours were included in the study. Patients were excluded if they began their hospital stay on a medical-surgical unit and then were transferred into one of the critical care units. The study was approved by the institutional review board. A waiver of informed consent was granted owing to the descriptive nature of the study.

The critical care units included were the neuroscience critical care, the adult critical care, and the pediatric critical care units, where most trauma patients are admitted. Standard practice for care of patients in cervical collars was not altered. Standard practice includes cleaning and assessing skin under the cervical collar every 12 hours and changing the pads in the collar every 24 hours. The use of a small back panel for any patient using an adult-sized cervical collar and who was on bedrest is recommended by the manufacturers to decrease potential skin breakdown caused by pressure on the occipital area.

Patients who met the inclusion criteria of being placed in a cervical collar were followed for the duration of their hospital stay while in a cervical collar. Patients were examined by 1 of 4 trained investigators, and all potential pressure areas on the head, face, neck, and chest were assessed daily for pressure breakdown for the first 7 days and then on days 10 and 14. If the patients remained in a cervical collar for more than 14 days, they were then examined weekly for the extent of their stay in the cervical collar while they were hospitalized. Variables collected included height and weight for body mass index, age, time from admission to placement in Aspen collar, vasopressor use, appropriate fit, extent of edema, activity level, use of a small back panel, length of time in collar, and length of stay in the intensive care unit. Data were collected on a manual tracking form and then entered into an SPSS database by a trained assistant. All data entry was double checked for accuracy by one of the investigators.

The sample consisted of 484 patients during a 1-year time period. The mean age of the patients was 37.8 years (range, 2–94 years), with an SD of 20.4 years. Gender was not collected as part of the data. All patients were trauma patients with actual or suspected head or spine injuries.

RESULTS

The standard practice for this institution is to change collar use from the traditional Stiff-neck collar used by the pre-hospital personnel to an Aspen cervical collar in the emergency department or in the intensive care unit. Most of the patients (70.8%) were changed from a hard cervical collar to an Aspen collar, within 8 hours of admission to the intensive care unit, and an additional 22.4% had an Aspen collar placed within 24 hours, for a total of 93.2% with placement of Aspen cervical collars within 24 hours. Of the 484 patients, only 46.7% had a small back panel in use for the majority of time in the collar.

Patients had the cervical collar in place for an average of 10.3 days (range, 1–61 days), with an SD of 11.4 days.

Skin breakdown was noted in 33 (6.8%) patients. Of these, our highest concern is for occiput breakdown, which only occurred in 6 (1.2%) patients. All cases of documented skin breakdown were stage I or II, with only 2 (0.4%) patients having stage III breakdown. The 2 patients with stage III breakdown were in the collars for 12 and 43 days, respectively, and had a body mass index of 33 and 35, as well as 2+ and 3+ edema. These factors would potentially lead to an increased skin breakdown, although with only 2 cases, it is impossible to draw any definitive conclusions. Most of the skin breakdown (5.5%) occurred on the shoulders, chin, and back, generally from

plastic edges not being covered entirely by foam, not a true pressure breakdown.

Logistic regression was chosen for statistical analysis because the outcome variable of skin breakdown is a dichotomous categorical variable (either there is breakdown present or there is none). The predictor variables or independent variables can be continuous or categorical in nature. The predictor variables used for this analysis are age, body mass index, length of time in collar, length of time to application, appropriate fit, small back panel, activity, and degree of edema present. A forced entry method was used for the logistic regression analysis.

Days in the cervical collar was found to be a significant predictor of skin breakdown, as well as length of time to application of the Aspen collar. Time in the cervical collar was the most significant predictor, with a P value <.0001. There is an increase in odds of breakdown related to the number of days in a cervical collar. There is also an increase in the odds of breakdown when edema is added as an additional predictor variable in this equation. No other variables evaluated in this study seem to have a significant impact on the incidence of skin breakdown associated with cervical collars.

The results of this study show the safety of these collars along with the proven efficacy of cervical immobilization from other studies. There was no correlation between the use of the small back panels and a decrease in the incidence of skin breakdown. Our institution does adhere to strict care with collars that requires the changing of pads every 24 hours and inspecting and cleaning the skin every 12 hours. If these were not done meticulously, the associated problems/incidence of skin breakdown would possibly be much greater.

DISCUSSION

The results of this study show an extremely low incidence of soft-tissue breakdown associated with the use of cervical collars. Implications for the healthcare practitioner based on this study are that the results of this study show the safety of these collars along with the proven efficacy of cervical immobilization from other studies.

There is no support offered for the use of small back panels to decrease the incidence of skin breakdown. The standard practice at this institution is adherence to strict care with skin cleansing, inspecting, and changing of pads. If these were not done meticulously, the associated problems and incidence of skin breakdown may be much greater. A potential limitation of this study is the assumption that standard practice was followed according to institutional policy. The actual practice and adherence to the policy were not assessed or monitored as part of the data collection process.

This evaluation of the incidence of skin breakdown was limited to those patients in Aspen cervical collars. This collar is the standard collar used for cervical immobilization at this institution; thus, other collars were not evaluated. Future research should explore tissue breakdown incidence with other comparable cervical collars and explore possible relationships between collar/skin care and skin breakdown.

There is a very low incidence of complications of skin breakdown associated with the use of Aspen cervical collars. These collars are safe and effective to use in patients with actual or suspected head or spine injuries.

REFERENCES

1. Askins V, Eismont F. Efficacy of five cervical orthoses in restricting cervical motion. *Spine*. 1997;22:1193–1198.
2. Clancy M. Clearing the cervical spine of adult victims of trauma. *Clin Manage*. 1999;16:208–214.
3. Davis J, Parks S, Detlefs C, Williams G, Williams J, Smith R. Clearing the cervical spine in obtunded patients: the use of dynamic fluoroscopy. *J Trauma*. 1995;39:435–438.
4. Webber-Jones JE, Thomas CA, Bordeaux RE. The management and prevention of rigid cervical collar complications. *Orthop Nurs*. 2002;21:19–27.
5. Hewitt S. Skin necrosis caused by a rigid cervical collar in a ventilated patient with multiple injuries. *Injury*. 1994;25:323–324.
6. Liew S, Hill D. Complication of hard cervical collars in multi-trauma patients. *Aust N Z J Surg*. 1994;64:139–140.
7. Plaisier B, Gabram SG, Schwartz RJ, Jacobs LM. Prospective evaluation of craniofacial pressure in four different cervical orthoses. *J Trauma*. 1994;37:714–720.
8. Powers J. A multidisciplinary approach to occipital pressure ulcers related to cervical collars. *J Nurs Care Qual*. 1997;12(1):46–52.
9. Blaylock B. Solving the problem of pressure ulcers resulting from cervical collars: a step-by-step approach. *Ostomy Wound Manage*. 1996;42:26–33.

ELSEVIER

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Assessing range of motion to evaluate the adverse effects of ill-fitting cervical orthoses

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Abstract

BACKGROUND CONTEXT: Although previous studies have primarily focused on testing the effectiveness of cervical orthoses under properly fit conditions, this study focuses on analyzing the effects of an ill-fitted cervical orthosis (Miami J). This may have significance to health-care providers in understanding the effects of an improperly fitted neck brace.

PURPOSE: The aims of this study were threefold: first, to apply virtual reality (VR) feedback control to repeatedly measure orthoses effectiveness in the primary motions; second, to use this control methodology to test the orthoses ability to restrict flexion/extension (FE) as a function of axial rotation (AR); third, to test the effects of an ill-fitting Miami J on cervical motion.

STUDY DESIGN/SETTING: This study combines six degrees of freedom electromagnetic trackers and VR feedback to analyze the effectiveness of common cervical orthoses under less than optimal conditions.

PATIENT SAMPLE: Twelve healthy male subjects aged 21 to 35 (mean 29.44 years, SD 6.598) years with no previous spinal cord injuries or current neck pain participated in the study.

OUTCOME MEASURES: Cervical range of motion (CRoM) measurements were used to determine the amount of motion restriction for each of the fitted (too small, correct size, and too big) Miami J orthoses.

METHODS: One Nest of Birds (NOB) electromagnetic sensor (Ascension Technology) was placed on the head and another on the upper back to measure motion of the head relative to the torso. The VR goggles (i-O Display Systems) were worn so that real-time feedback was available to the subject for motion control. The subject executed the primary motions of FE, AR, and lateral bending (LB) in separate sets of five trials each. Next, in combined motion, the subject axially rotated to a set point and then FE to his maximums. This entire set of motions was repeated for each (soft collar, Miami J, Miami J with chest extension, Sternal Occipital Mandibular Immobilizer (AliMed, Inc.), (SOMI and Halo) as well as the Miami J (one size too small and one size too big); the fitting of each brace was done by a board certified orthotist. A repeated measures analysis of variance was used to determine differences between the tested states (*p=.05).

RESULTS: For the validation test, the primary motions recorded for subjects wearing each cervical brace, which demonstrated that the various orthoses all restricted CRoM. The soft collar restricted less motion than the other devices, whereas the Halo restricted the most motion throughout.

FDA device/drug status: not applicable.

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For the ill-fitting cervical collar comparison, motion in the correct size collar was normalized to 1.0, and the correct size allowed less motion than either the too big or too small braces. In FE, the too big brace tended to allow more motion than the too small, but only the too big brace in extension was significantly different from the correct size. In AR, the too small brace seemed to allow more motion than the too big. Both the too big and too small braces were significantly different than the correct size in both left and right AR. In LB, the too big brace and too small brace were very similar in the amount of motion they were able to restrict. Both braces were significantly different than the correct size in right LB, whereas only the too small brace was significantly different from the correct size in left LB. In the combined motion data, both the too big and too small braces allowed more motion than the correct size. The too small brace seemed to allow more FE at all degrees of AR except for extreme right AR.

CONCLUSIONS: To our knowledge, the effects of improperly fitted cervical orthoses on CRoM are still unknown. Using the NOB electromagnetic tracking system combined with VR feedback, we were able to consider the motion restriction of ill-fitting Miami J orthoses for both primary and combined motions. For both motion types, increased motion was possible when the subject was improperly fitted with the Miami J. If not considered, these excessive motions could potentially have detrimental effects on patient satisfaction, clinical outcomes, or even lead to increased secondary injury.

Keywords: Cervical spine; Range of motion; Orthoses; Virtual reality; Electromagnetic tracking; Ill-fitting

Introduction

Previous research studies analyzing the effectiveness of cervical orthoses at restricting cervical range of motion (CRoM) have primarily focused on testing orthoses under ''optimal'' conditions (ie, properly fit braces restricting primary motions) [1–9]. Unfortunately, these optimal testing conditions are not a realistic model for many clinical situations. Therefore, orthosis selection based solely on data obtained under optimal conditions could be insufficient and potentially harmful to the involved patient.

In general, cervical orthoses are used in the prehospital stabilization of trauma patients as well as a part of the definitive treatment of an injured cervical spine, in the weeks and months postsurgery. The objectives for spinal orthoses applications include correction of spinal deformity and misalignment, intervertebral segmental immobilization, regional stabilization, specific posture maintenance, and protection from damaging stresses [10].

However, because of limited availability, emergency applications, and financial constraints, it is not uncommon that a patient is fitted with a cervical orthosis that is not optimal for his or her size and body type. Ill-fitting braces are most commonly applied in a trauma setting, where care is given away from the health-care facility and access to a variety of sizes of orthoses is impossible. Ill-fitted braces could also be applied erroneously because of limited training or experience. Additionally, ill-fitting braces may be used in rural or other low-volume health-care facilities where it is unreasonable to have all possible brace sizes available.

To date, little work has been done to study the effects of ill-fitting cervical orthoses. However, it is reported that between 3% and 25% of spinal cord injuries occur after the initial cervical injury (secondary injuries), suggesting that the spinal cord injury originates either during transport or in the early course of treatment [2]. Thus, the structural integrity and ability of a cervical orthosis to provide effective and rigid immobilization is of paramount importance [2]. Therefore, we have found it necessary to examine the effectiveness of an ill-fitting cervical orthosis in restricting cervical motion.

This study uses a virtual reality (VR) feedback system to control the subjects' motion allowing for a more comprehensive and repeatable testing system. In addition, a six-degrees of freedom electromagnetic tracking system accurately measures positions and orientations of the head without visual estimation or radiation exposure as developed by previous research [11]. The aims of this study were to apply VR feedback control to repeatedly measure the primary motions and flexion/extension (FE) as a function of axial rotation (AR) with the goal of ultimately testing the effectiveness of an ill-fitting cervical orthosis at restricting CRoM.

Methods

Subjects

Twelve healthy male subjects aged 21 to 35 (mean 29.44 years, SD 6.598) years with no previous spinal cord injuries or current neck pain participated in the study. Before any data collection, all subjects signed an informed consent form, approved by the Institutional Review Board at the University of Pittsburgh.

Electromagnetic tracking

The Nest of Birds (NOB) (Ascension Technology Corp., Burlington, VT), a six-degrees of freedom electromagnetic measurement system, was used to measure cervical spine motion in this study. The NOB comprises a transmitter

and two sensors. One sensor is affixed to the headpiece securing the VR goggles. The other sensor is fixed to the upper back by means of a harness. The relative motion of the head with respect to the torso is recorded with these two sensors. The NOB detects and records both the positions and orientations of the sensors relative to the fixed transmitter.

Virtual reality feedback

VR feedback was provided so that the subject could visually limit any extraneous motion, resulting in what is defined as "pure" FE, AR, and lateral bending (LB). The VR component allows for repeatable motions both within a single subject and between different subjects. The software was developed in our lab exclusively for this purpose using MATLAB (Mathworks, Natick, MA).

For all testing cases, the subject's field of view was immersed in a globe where a horizontal and vertical line defined pure AR and FE, respectively. A crosshair was set on top of these lines and would move in real-time with the subject's movement. LB was defined as rotating the crosshair around the intersection of the two lines. One of the advantages of the VR system is the ability to prescribe repeatable combined motion. When testing a combined motion scenario, an additional vertical line was added at a specified degree of AR (Fig. 1).

Orthoses testing validation

To first validate our system, we tested a spectrum of cervical braces (soft collar, Miami J, Miami J with chest extension, Sternal Occipital Mandibular Immobilizer (SOMI, AliMed, Inc., Dedham, MA) (SOMI, and Halo) to ensure our system measured decreasing motion as widely reported [1,2,6,8,12]. Each brace was fit by a clinically licensed orthotist, according to the specifications provided by the manufacturer. However, the Halo device was fit with four pins onto plastic tip covers, which attached the orthosis to the skull in a noninvasive manner, reducing the overall rigidity of this brace.

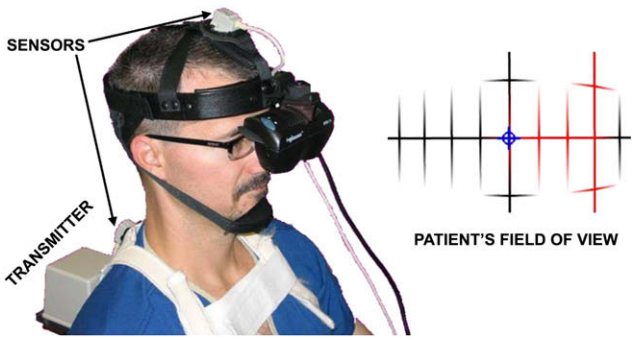

Fig. 1. The virtual reality goggles and electromagnetic tracking set up display. As the subject moves his or her head, the blue crosshair traces the lines in real-time.

EVIDENCE & METHODS

Context

Cervical orthoses, as routinely applied, often fit improperly. Little is known regarding the resulting kinematic effects.

Contribution

Using novel technologies to afford well-controlled active cervical motions and to assess kinematics, the authors have demonstrated that ill-fitting Miami-J collars result in increased motions relative to properly fitted collars.

Implications

The clinical implications of increased motion despite orthosis treatment remain unknown. Patient dependent factors including cervical pathology (injury pattern, underlying stenosis, etc.) will determine the degree of risk. Greater risk regarding potential motion may convince the clinician to aim for more rigid devices.
That said, the same clinician often aim to provide adequate control with the least cumbersome orthosis and the Miami-J collar, especially at many major trauma centers, is frequently employed. This study serves as a reminder that fit matters and that a slap it on technique may sabotage an expected and necessary stabilization effect. Orthopaedic, neurosurgical and emergency medicine trainees are responsible for placement of these orthosis. This paper should serve to encourage appropriate training to determine proper fit and placement of cervical orthoses.

—The Editors

Ill-fitting cervical collar testing

Each subject was tested wearing three different Miami J collars fit by a clinically licensed orthotist. Brace selection started by measuring and applying the properly fit brace first. According to the instructions accompanying each Miami J brace and confirmed by the orthotist, 1) selecting the right sized collar and 2) correctly fitting it to the patient are the two essential points for properly fitting a Miami J collar.

The Miami J collar sizes are determined by the shape of the subject's neck and shoulders. Sizing silhouettes and sample sizing questions are provided to aid the caregiver in determining the appropriate collar size. Collar size is

best determined by observing the vertical distance between the highest point of the trapezius and the tip of the chin when the head is in the desired treatment alignment.

While the subject is seated upright, the collar back is held steadily at the back of the patient's neck, and the sides of the collar front are flared out. It is then slid up the chest wall and scooped up under the chin. When properly placed, the sides are oriented up, off the trapezius, and toward the ears. While holding the front securely, the ends are curled snugly against the patient's neck. The Velcro straps are used to secure the collar back by tightening straps alternately to an equal length on both sides. When the patient is properly fit, there should be equal amounts of excess Velcro overhanging the front adhesive sections.

After the initial fitting, collar adjustments must be made to ensure proper fit. According to the Miami J sizing and application instructions, it is nearly impossible to fit a properly sized collar too tightly. Therefore, before motion was recorded, the subject was asked to attempt to slip his chin inside the correct size brace, and the brace was tightened until this was no longer possible.

After the process of properly fitting the correctly sized brace (defined as ''correct size''), the ill-fitting braces were selected by increasing one size and decreasing one size (defined as ''too big'' and ''too small'', respectively). Because the incorrect size braces could not be fit properly, the orthotist fit the braces to the subject as if it were a trauma case in the field and the brace size being used were the only one available. This helped to normalize the ill-fitting brace application (Fig. 2).

Experimental protocol

The order of the protocol was the same for all subjects. After being fit with the harness and VR goggles, subjects sat upright in a chair with their back firmly against the back support. The subject was asked to follow the prescribed FE, AR, and LB (the primary motions) VR motions paths. In each individual case, the desired motion path was highlighted in red to eliminate any possible confusion over the appropriate path. In the FE trials, the subject was instructed to move his chin as far toward his chest as possible (flexion) and to rotate his head as far back as possible (extension). In the AR trials, the subject was instructed to turn his head as far to the left and to the right as possible, In the LB trials, the subject was instructed to move his head like he was following the hands of a clock with his nose. The subject moved counter-clockwise to his left shoulder, and clockwise to his right shoulder.

Next, the subject executed combined motion, axially rotating to one of three set points in directions, then maximally flexing and extending. The software required that the point of FE be a multiple of nine degrees; the amount of AR was set at the multiple of nine degrees closest to 25%, 50%, and 75% of maximum AR. In these trials, an extra red vertical line was added to the VR display to explicitly prescribe the desired path, informing the subject how far to axially rotate before performing FE. Lastly, the subject would fully extend and ''roll'' his head throughout the entire range of motion to yield an overall score, which is a calculated sum of the average maximal primary motions achieved during this circumduction motion, normalized to 90 degrees of rotation.

Each of these motions was repeated five times, stopping only between different types of motion. This entire set of motions was repeated for each brace (soft collar, Miami J [including correct size, too big and too small-sized brace], Miami J with chest extension, SOMI, and Halo). Before each different motion path, the subject returned his head to a neutral position and the NOB was reset to a zero position. During all motions, the subject was asked to move as far as possible without substantial discomfort and pause for a full second at this point. This standard for end of range of motion was chosen to most closely resemble motion of everyday life.

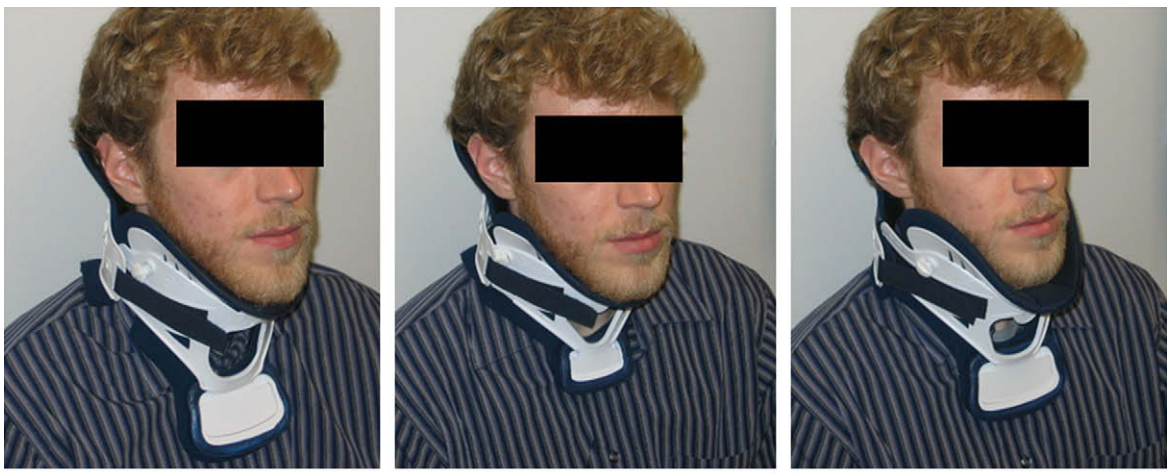

Fig. 2. The Miami J orthosis fitted for each of the different sized parameters: correct fit, too small, and too big.

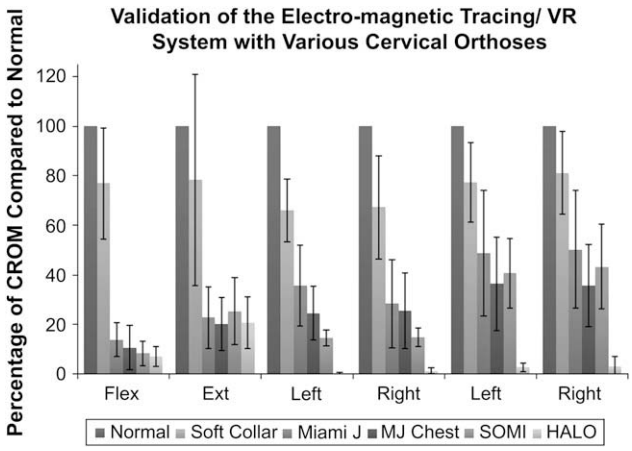

Fig. 3. The amount of restriction for each of the cervical orthoses (soft collar, Miami J, Miami J with chest extension, SOMI, and Halo) plotted as bar graphs compared with normal, uninhibited motion.

Data processing and analysis

The Euler angle coordinates of the electromagnetic sensors were recorded in MATLAB. An algorithm was developed to average the five peaks of each of the trials. All of this data was then imported into Microsoft Excel where the averages from all of the subjects were combined and a student *t* test (*p≤.05) was used to determine significant differences between the study groups.

Results

For the validation test, the primary motions recorded for subjects wearing each cervical brace (soft collar, Miami J, Miami J with chest extension, SOMI, and Halo) was normalized with the ''uninhibited'' motion in those not wearing an orthosis. As seen in Fig. 3, the various orthoses all restricted CRoM. The soft collar restricted less motion than the other devices, whereas the Halo restricted the most motion throughout.

For the ill-fitting cervical collar comparison, motion in the correct size collar was normalized to 1.0. Motion allowed from the too big and too small braces was then normalized and compared with the correct size. In all of the primary motions (Fig. 4), the correct size allowed less motion than either the too big or too small braces.

In FE, the too big brace tended to allow more motion than the too small, but only the too big brace in extension was significantly different from the correct size. In AR, the too small brace seemed to allow more motion than the too big. Both the too big and too small braces were significantly different than the correct size in both left and right AR. In LB, the too big brace and too small brace were very similar in the amount of motion they were able to restrict. Both braces were significantly different than the correct size in right LB, whereas only the too small brace was significantly different from the correct size in left LB.

In combined motion (Fig. 5), both the too big and too small braces allowed more motion than the correct size. The too small brace seemed to allow more FE at all degrees of AR except for extreme right AR.

Discussion

The purpose of cervical collars is to firmly support patients' heads and to minimize the risk of injury associated with movement of the neck, mitigating pain, and myopalmus caused by incremental movements of cervical vertebrae [2,8,12–16]. Numerous types of cervical orthotic devices are available to meet the variety of patient needs and are specifically designed to restrict different amounts of range of motion. Our validation of the electromagnetic VR system assessed this diversity and was consistent with previously reported CRoM comparisons of these devices [1–9].

To minimize variability, we tested just the Miami J collar to determine the effects of ill fitting on CRoM. However, it should be noted that our selection of the Miami J for investigation does not imply that the authors or their institution perceive any superiority of this device. Additionally, although the Miami J was selected as a representative cervical orthosis for the purposes of this study and we feel that the findings should raise awareness of ill-fitting orthoses in the clinical community, in general, the results are not directly translatable to other cervical orthotic devices. With this in mind, the Miami J is highly used by physicians at this institution, and it is concluded by many researchers to be restrictive in all primary degrees of freedom [6]. Previous studies of the Miami J, and other cervical orthoses, have concentrated on measuring the amount of motion the orthosis is able to restrict. However, results from previous cervical orthoses range of motion studies have been inconsistent, and results from study to study are difficult to compare. Table 1 shows how our data compares with previous studies involving the Miami J and also illustrates the differences in results between different researchers.

A probable reason for these large discrepancies is that no method was used to control subjects' motion in previous studies. Our novel tracking system provides the subject with a real-time VR feedback, enabling the subject to exactly repeat his motions. Additionally, this system provides the ability to prescribe combined motions. In everyday activities, cervical motion is not restricted to just FE, AR, and LB, rather it is a constant combination of the three primary motions. Because of the VR feedback, we can measure combined motions such as a subject's motion as they axially rotate and then flex and extend. FE in AR is an apt model of a cervical motion that is repeated many times throughout the day in activities such as driving a car, looking at a clock on a wall, or placing something on a high shelf.

Within the primary motions, the correct size brace functionally constrains the range of motion more effectively

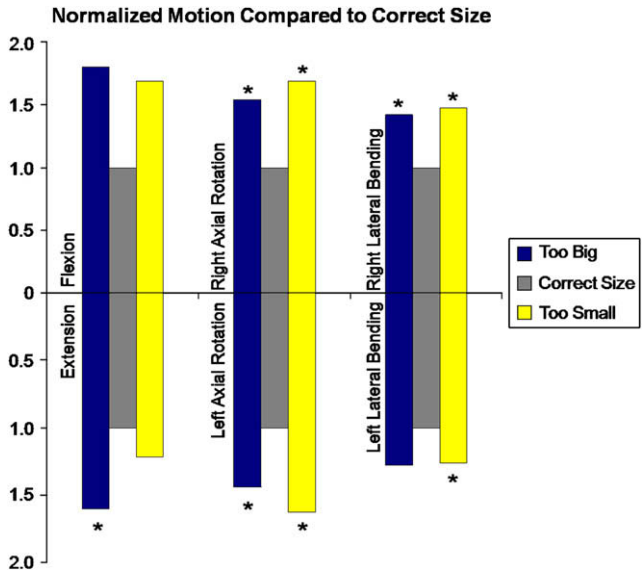

Fig. 4. Primary motions: bar graphs comparing amount of motion restriction for the too small and too big Miami J brace compared with the correct fit Miami J. The averages from all of the subjects were combined. Significant differences were determined using a student *t* test (*p≤.05).

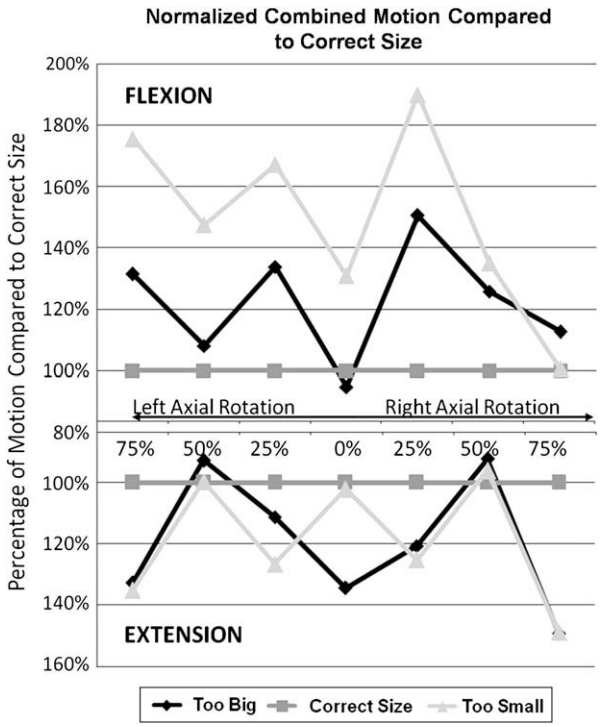

Fig. 5. Combined motions: data plot of motion percentage of flexion/extension while axially rotated for ill-fitting Miami J compared with correctly fitting Miami J.

than those fitted too loosely (big) and too tightly (small). Comparable with previous research, this control of motion allows for the restriction of cervical vertebrae movement: FE, AR, and LB. As hypothesized, the ill-fitted cervical orthoses were unable to service appropriate restriction of CRoM compared with the properly fitted device. This suggests that after a cervical injury, a patient wearing a collar that is either too big or too small could experience added cervical impairment because of the lack of restriction and under-restrained motion of the neck.

Combined motions performed with each of the improperly fitted orthoses showed percentages of motion greater than 100% compared with the correctly fitted brace. Moreover, the randomness and inconsistency of the results raises some concern. Variability in the degree to which a brace is capable of restricting motion when a patient's head is turned could make brace selection difficult or ultimately lead to increased occurrence of secondary injuries.

A notable limitation of this study was its inability to quantitatively create an end point for physical exertion. Subjects were told to move until they reached a point of maximum muscle exertion, which may not be repeatable between trials or consistent between subjects. Additionally, the use of healthy subjects is not directly representative of the injured population which typically would not be able to exert as much force against the brace. However, this model of maximum muscle exertion could be representative of the efficacy of the brace at restricting high loading conditions that could be experienced through involuntary motions, which could lead to secondary injury.

The negative effects of ill-fitting cervical orthoses from uninhibited CRoM have significant clinical implications. Patient care could be compromised as a result of the increased motion permitted by improper fitting of cervical orthoses. Other researchers investigating clinical implications of ill-fitting orthoses have shown that dermal contact with an ill-fitted cervical brace can cause skin lesions and affect CRoM and patient satisfaction [17,18]. The results show that the ill-fitting Miami J does not restrict motion as completely as the correctly sized Miami J, potentially adding to the 3% to 25% of spinal cord injuries that occur after the initial injury [2]. As previously noted, there is a wide range of cervical collars, none of which should be inferred as definitive treatment for unstable injuries. In addition, the use of Miami J itself is at the discretion of the individual (emergency medical provider, trauma specialist, or certified orthotist) applying the brace. Although this study used a qualified orthotist, this ideal situation is less likely to occur in trauma situations where a qualified orthotist may be unavailable; nonetheless, the professional fitting of a brace one size larger or smaller has statistically significant differences from the correctly fitted size.

Therefore, this study highlights the importance of understanding the effect of ill-fitting orthoses and should be considered when applying orthoses in clinical settings.

This study also presented a novel VR feedback system to control the subject's motion. Utilization of this technology for investigation of cervical kinematics enabled consistent motion paths within and between subjects as well as for ''more realistic'' combined motion paths to be recorded—desirable outcomes for any kinematic study. Therefore, this system is being implemented for ongoing investigations of

Table 1
Reported differences in the percentages of ‘‘unrestricted’’ motion allowed by the Miami J

Author	Flexion (%)	Extension (%)	Axial rotation (%)	Lateral bending (%)	Measurement type
Donaldson	18.8	30.0	32.5	54.4	Electromagnetic and VR
Zhang [19]	15.2	44.5	34.6	62.1	Vicon optical tracking
Askins and Eismont [2]	24.0	30.0	35.0	49.0	Radiographs, compass goniometer
Gavin et al. [7]	40.0	46.0	n/a	n/a	Video fluoroscopy
Richter [20]	68.1*		n/a	n/a	Radiography/photography

* Percentage of unrestricted motion allowed by the Miami J for overall flexion/extension in a cadaver study.

cervical disorders and surgical procedures in our laboratory, and it is recommended that similar methodologies be implemented in other laboratories as well. Additionally, future work is planned to improve the computer-user interface whereby creating a more interactive and user-friendly environment that will hopefully enable a more effective and varied application of this technology.

Acknowledgments

The financial support of the Albert B. Ferguson, Jr. MD Orthopaedic Fund of The Pittsburgh Foundation and Stryker Corp. is gratefully recognized. We would also like to acknowledge Hanger Orthopedic Group, Inc. for their generous donation of orthotic devices used in this study.

References

[1] Alberts LR, Mahoney CR, Neff JR. Comparison of the Nebraska collar, a new prototype cervical immobilization collar, with three standard models. J Orthop Trauma 1998;12:425–30.
[2] Askins V, Eismont FJ. Efficacy of five cervical orthoses in restricting cervical motion. A comparison study. Spine 1997;22:1193–8.
[3] Bearden BG, Conrad BP, Horodyski M, Rechtine GR. Motion in the unstable cervical spine: comparison of manual turning and use of the Jackson table in prone positioning. J Neurosurg Spine 2007;7:161–4.
[4] Bruns W, Von Salis-Soglio G, Plitz W. Cervical collars: a clinical and biomechanical study. Z Orthop Ihre Grenzgeb 2004;142:421–7.
[5] Carter VM, Fasen JA, Roman JM Jr, Hayes KW, Petersen CM. The effect of a soft collar, used as normally recommended or reversed, on three planes of cervical range of motion. J Orthop Sports Phys Ther 1996;23:209–15.
[6] Garth GC. Efficacy of five cervical orthoses in restricting cervical motion: a comparison study. Spine 1998;23:961–2.
[7] Gavin TM, Carandang G, Havey R, Flanagan P, Ghanayem A, Patwardhan AG. Biomechanical analysis of cervical orthoses in flexion and extension: a comparison of cervical collars and cervical thoracic orthoses. J Rehabil Res Dev 2003;40:527–37.
[8] Hart DL, Johnson RM, Simmons EF, Owen J. Review of cervical orthoses. Phys Ther 1978;58:857–60.
[9] Schneider AM, Hipp JA, Nguyen L, Reitman CA. Reduction in head and intervertebral motion provided by 7 contemporary cervical orthoses in 45 individuals. Spine 2007;32:E1–6.
[10] Stuber K. Cervical collars and braces in athletic brachial plexus injury and excessive cervical motion prevention: a review of the literature. JCCA J Can Chiropr Assoc 2005;49:216–22.
[11] LoPresti E, Brienza DM, Angelo J, Gilbertson L, Sakai J. Neck range of motion and use of computer head controls. In: Fourth International ACM Conference on Assistive Technologies. Arlington: Virginia, United States, 2000.
[12] Manix T, Gunderson MR, Garth GC. Comparison of prehospital cervical immobilization devices using video and electromyography. Prehospital Disaster Med 1995;10:232–7; discussion 237, 238.
[13] Hartman JT, Palumbo F, Hill BJ. Cineradiography of the braced normal cervical spine. A comparative study of five commonly used cervical orthoses. Clin Orthop Relat Res 1975;109:97–102.
[14] Hughes SJ. How effective is the Newport/Aspen collar? A prospective radiographic evaluation in healthy adult volunteers. J Trauma 1998;45:374–8.
[15] Johnson RM, Hart DL, Owen JR, Lerner E, Chapin W, Zeleznik R. The yale cervical orthosis: an evaluation of its effectiveness in restricting cervical motion in normal subjects and a comparison with other cervical orthoses. Phys Ther 1978;58:865–71.
[16] Sandler AJ, Dvorak J, Humke T, Grob D, Daniels W. The effectiveness of various cervical orthoses. An in vivo comparison of the mechanical stability provided by several widely used models. Spine 1996;21:1624–9.
[17] Duhem R, Tonnelle V, Vinchon M, Assaker R, Dhellemmes P. Unstable upper pediatric cervical spine injuries: report of 28 cases and review of the literature. Childs Nerv Syst 2007;24:343–8.
[18] Powers J, Daniels D, McGuire C, Hilbish C. The incidence of skin breakdown associated with use of cervical collars. J Trauma Nurs 2006;13:198–200.
[19] Zhang S, Wortley M, Clowers K, Krusenklaus JH. Evaluation of efficacy and 3D kinematic characteristics of cervical orthoses. Clin Biomech (Bristol, Avon) 2005;20:264–9.
[20] Richter D, Latta LL, Milne EL, et al. The stabilizing effects of different orthoses in the intact and unstable upper cervical spine: a cadaver study. J Trauma 2001;50:848–54.

HCPCS:	Descriptor:
L0174	CERVICAL, COLLAR, SEMI-RIGID, THERMOPLASTIC FOAM, TWO PIECE WITH THORACIC EXTENSION

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	NO	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Post surgical stabilization, Traumatic stabilization, Cervical Fractures, Cervical Neck Injury, and High Thoracic Vertebral Fractures
Medically Necessary Argument	The device is available in separate component parts requiring appropriate size selection and fitting. The sizing chart demonstrates the typical devices. When necessary the fronts and backs can be mixed to optimize fit for non-standard heights, circumferences or to achieve non-neutral flexion angles. Once applied the anterior mandibular and posterior occipital sections are adjusted to balance forces on the skeletal structures and provide well-distributed support of the spine. This device offers increased stabilization over other cervical orthoses as an anterior extension reduces flexion, due to its longer stabilization on the sternum. Improper fitting may cause mal-alignment resulting in poor healing, nerve impingement, and movement of skeletal fragments or spinal column damage. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device.
References	1, 2

RESEARCH

The Incidence of Skin Breakdown Associated With Use of Cervical Collars

Jan Powers, RN, MSN, CCRN, CCNS, CNRN, CWCN
Dawn Daniels, DNS, RN
Carolyn McGuire, RN
Chris Hilbish, RN, ACNP, CCRN, CNRN

ABSTRACT
The most common adverse complication associated with cervical immobilization is skin breakdown. The purpose of this prospective, descriptive study was to assess the incidence of tissue breakdown associated with cervical immobilization. In this convenience sample of 484 patients, skin breakdown was noted in 33 (6.8%) patients. All cases of documented skin breakdown were stage I or II, with only 2 (0.4%) patients having stage III breakdown. Days in the cervical collar is a significant predictor of skin breakdown, along with presence of edema. Results from this study demonstrate that there is a very low incidence of complications of skin breakdown associated with the use of Aspen cervical collars. The collars are safe and effective to use in patients with actual or suspected head or spine injuries.

KEY WORDS
Cervical collars, Immobilization, Skin breakdown

Cervical immobilization with the use of cervical collars is a common and necessary practice associated with the care of trauma patients. Cervical immobilization is required until cervical spine or ligament injury can be completely ruled out. This is often difficult to accomplish in patients in the intensive care unit setting. It is difficult to clear patients clinically when they have a concomitant head injury and are unable to communicate cervical pain. This is even more challenging in pediatric patients for whom spinal cord injury without radiographic abnormality is a more common occurrence. One of the most common, yet preventable, adverse problems associated with cervical collar use is skin or tissue breakdown.

The goal of cervical immobilization is to restrict cervical mobility and avoid any further damage to the spine. There are 4 cervical collars that are routinely used in practice: Stiff-neck, Philadelphia, Miami-J, and Aspen. It is not the goal of this article to address the mobility restrictions of these collars because these have been documented in studies on motion restriction that have been completed previously.[1,2] However, very few studies have addressed skin breakdown, the most common adverse complication of cervical collars. It has been reported that up to 55% of patients in a cervical collar for 5 days or greater develop skin breakdown, specifically occipital, chin, mandibular, ears, and shoulders, as well as macerated skin.[2–6] Skin breakdown can be quite severe, even progressing to stage IV pressure ulcers, requiring plastic surgery for repair and reconstruction of the area damaged by pressure ulcers.[5,6] This can significantly affect patient morbidity and length of stay and add significant cost to hospitalization. Previous studies have reported increased hospital costs ranging from $4,323 to $30,000.[7,8]

Plaisier et al[7] measured the capillary closure pressure of 4 different cervical collars. The collars evaluated in this study were Stiff-neck, Philadelphia, Miami-J, and Aspen (previously known as Newport) cervical collars. The cervical collars were tested on 20 healthy subjects, and capillary closure pressure was measured on various areas of the scalp and face. Increased capillary closure pressure is known to be associated with soft-tissue breakdown.[7] The findings from this study demonstrated an increased capillary closure pressure exerted by the Stiff-neck and the Philadelphia collars and pressures exerted by Miami-J and Newport (Aspen) to be well below capillary closure pressures associated with tissue breakdown.[7]

Powers[8] reported a decreased incidence of skin breakdown from 19 ulcers to 0 with improved process of care

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and a change to Aspen cervical collars for cervical immobilization. This project, completed with 76 adult patients, demonstrated that with optimal skin care and the change to a collar that had a lower capillary closure pressure, skin breakdown associated with cervical collar use was essentially eliminated. In this initiative, protocols were established for routine care and changing of the cervical collars. A protocol was also established to decrease the length of time the patients were immobilized in cervical collars. The average time that patients were in cervical collars decreased from an average of 14.4 days before this initiative to 7.7 days after the implementation.

Similar results were reported by Blaylock[9] in 20 patients at a level 1 trauma center. Patient collar use ranged from 1 to 37 days. A change to Aspen cervical collars using a continuous quality improvement model resulted in zero incidence of skin breakdown associated with cervical collars.

These are the only reports in the literature, other than case reviews, concerning incidence of skin breakdown with cervical collar use. These manuscripts discuss skin breakdown in an adult population using a quality improvement process. To date, there have been no large studies identifying risk or incidence of tissue breakdown associated with cervical collar use or studies that have included pediatric patients. The purpose of this research study was to assess the incidence of tissue breakdown associated with cervical immobilization.

METHODS

This prospective, descriptive study was designed to assess the incidence of tissue breakdown associated with cervical immobilization. Aspen cervical collars are the standard collar used for cervical immobilization at the institution where this study was conducted; therefore, these were the collars used for the study. A convenience sample of adult and pediatric patients admitted to 3 critical care units at a large urban level 1 trauma center and tertiary referral center was included in the study. Only patients who had a cervical collar in place at the time of admission and who had a cervical collar for longer than 24 hours were included in the study. Patients were excluded if they began their hospital stay on a medical-surgical unit and then were transferred into one of the critical care units. The study was approved by the institutional review board. A waiver of informed consent was granted owing to the descriptive nature of the study.

The critical care units included were the neuroscience critical care, the adult critical care, and the pediatric critical care units, where most trauma patients are admitted. Standard practice for care of patients in cervical collars was not altered. Standard practice includes cleaning and assessing skin under the cervical collar every 12 hours and changing the pads in the collar every 24 hours. The use of a small back panel for any patient using an adult-sized cervical collar and who was on bedrest is recommended by the manufacturers to decrease potential skin breakdown caused by pressure on the occipital area.

Patients who met the inclusion criteria of being placed in a cervical collar were followed for the duration of their hospital stay while in a cervical collar. Patients were examined by 1 of 4 trained investigators, and all potential pressure areas on the head, face, neck, and chest were assessed daily for pressure breakdown for the first 7 days and then on days 10 and 14. If the patients remained in a cervical collar for more than 14 days, they were then examined weekly for the extent of their stay in the cervical collar while they were hospitalized. Variables collected included height and weight for body mass index, age, time from admission to placement in Aspen collar, vasopressor use, appropriate fit, extent of edema, activity level, use of a small back panel, length of time in collar, and length of stay in the intensive care unit. Data were collected on a manual tracking form and then entered into an SPSS database by a trained assistant. All data entry was double checked for accuracy by one of the investigators.

The sample consisted of 484 patients during a 1-year time period. The mean age of the patients was 37.8 years (range, 2–94 years), with an SD of 20.4 years. Gender was not collected as part of the data. All patients were trauma patients with actual or suspected head or spine injuries.

RESULTS

The standard practice for this institution is to change collar use from the traditional Stiff-neck collar used by the pre-hospital personnel to an Aspen cervical collar in the emergency department or in the intensive care unit. Most of the patients (70.8%) were changed from a hard cervical collar to an Aspen collar, within 8 hours of admission to the intensive care unit, and an additional 22.4% had an Aspen collar placed within 24 hours, for a total of 93.2% with placement of Aspen cervical collars within 24 hours. Of the 484 patients, only 46.7% had a small back panel in use for the majority of time in the collar.

Patients had the cervical collar in place for an average of 10.3 days (range, 1–61 days), with an SD of 11.4 days.

Skin breakdown was noted in 33 (6.8%) patients. Of these, our highest concern is for occiput breakdown, which only occurred in 6 (1.2%) patients. All cases of documented skin breakdown were stage I or II, with only 2 (0.4%) patients having stage III breakdown. The 2 patients with stage III breakdown were in the collars for 12 and 43 days, respectively, and had a body mass index of 33 and 35, as well as 2+ and 3+ edema. These factors would potentially lead to an increased skin breakdown, although with only 2 cases, it is impossible to draw any definitive conclusions. Most of the skin breakdown (5.5%) occurred on the shoulders, chin, and back, generally from

plastic edges not being covered entirely by foam, not a true pressure breakdown.

Logistic regression was chosen for statistical analysis because the outcome variable of skin breakdown is a dichotomous categorical variable (either there is breakdown present or there is none). The predictor variables or independent variables can be continuous or categorical in nature. The predictor variables used for this analysis are age, body mass index, length of time in collar, length of time to application, appropriate fit, small back panel, activity, and degree of edema present. A forced entry method was used for the logistic regression analysis.

Days in the cervical collar was found to be a significant predictor of skin breakdown, as well as length of time to application of the Aspen collar. Time in the cervical collar was the most significant predictor, with a P value <.0001. There is an increase in odds of breakdown related to the number of days in a cervical collar. There is also an increase in the odds of breakdown when edema is added as an additional predictor variable in this equation. No other variables evaluated in this study seem to have a significant impact on the incidence of skin breakdown associated with cervical collars.

The results of this study show the safety of these collars along with the proven efficacy of cervical immobilization from other studies. There was no correlation between the use of the small back panels and a decrease in the incidence of skin breakdown. Our institution does adhere to strict care with collars that requires the changing of pads every 24 hours and inspecting and cleaning the skin every 12 hours. If these were not done meticulously, the associated problems/incidence of skin breakdown would possibly be much greater.

DISCUSSION

The results of this study show an extremely low incidence of soft-tissue breakdown associated with the use of cervical collars. Implications for the healthcare practitioner based on this study are that the results of this study show the safety of these collars along with the proven efficacy of cervical immobilization from other studies.

There is no support offered for the use of small back panels to decrease the incidence of skin breakdown. The standard practice at this institution is adherence to strict care with skin cleansing, inspecting, and changing of pads. If these were not done meticulously, the associated problems and incidence of skin breakdown may be much greater. A potential limitation of this study is the assumption that standard practice was followed according to institutional policy. The actual practice and adherence to the policy were not assessed or monitored as part of the data collection process.

This evaluation of the incidence of skin breakdown was limited to those patients in Aspen cervical collars. This collar is the standard collar used for cervical immobilization at this institution; thus, other collars were not evaluated. Future research should explore tissue breakdown incidence with other comparable cervical collars and explore possible relationships between collar/skin care and skin breakdown.

There is a very low incidence of complications of skin breakdown associated with the use of Aspen cervical collars. These collars are safe and effective to use in patients with actual or suspected head or spine injuries.

REFERENCES

1. Askins V, Eismont F. Efficacy of five cervical orthoses in restricting cervical motion. *Spine*. 1997;22:1193–1198.
2. Clancy M. Clearing the cervical spine of adult victims of trauma. *Clin Manage*. 1999;16:208–214.
3. Davis J, Parks S, Detlefs C, Williams G, Williams J, Smith R. Clearing the cervical spine in obtunded patients: the use of dynamic fluoroscopy. *J Trauma*. 1995;39:435–438.
4. Webber-Jones JE, Thomas CA, Bordeaux RE. The management and prevention of rigid cervical collar complications. *Orthop Nurs*. 2002;21:19–27.
5. Hewitt S. Skin necrosis caused by a rigid cervical collar in a ventilated patient with multiple injuries. *Injury*. 1994;25:323–324.
6. Liew S, Hill D. Complication of hard cervical collars in multi-trauma patients. *Aust N Z J Surg*. 1994;64:139–140.
7. Plaisier B, Gabram SG, Schwartz RJ, Jacobs LM. Prospective evaluation of craniofacial pressure in four different cervical orthoses. *J Trauma*. 1994;37:714–720.
8. Powers J. A multidisciplinary approach to occipital pressure ulcers related to cervical collars. *J Nurs Care Qual*. 1997;12(1):46–52.
9. Blaylock B. Solving the problem of pressure ulcers resulting from cervical collars: a step-by-step approach. *Ostomy Wound Manage*. 1996;42:26–33.

ELSEVIER

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Assessing range of motion to evaluate the adverse effects of ill-fitting cervical orthoses

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Abstract

BACKGROUND CONTEXT: Although previous studies have primarily focused on testing the effectiveness of cervical orthoses under properly fit conditions, this study focuses on analyzing the effects of an ill-fitted cervical orthosis (Miami J). This may have significance to health-care providers in understanding the effects of an improperly fitted neck brace.

PURPOSE: The aims of this study were threefold: first, to apply virtual reality (VR) feedback control to repeatedly measure orthoses effectiveness in the primary motions; second, to use this control methodology to test the orthoses ability to restrict flexion/extension (FE) as a function of axial rotation (AR); third, to test the effects of an ill-fitting Miami J on cervical motion.

STUDY DESIGN/SETTING: This study combines six degrees of freedom electromagnetic trackers and VR feedback to analyze the effectiveness of common cervical orthoses under less than optimal conditions.

PATIENT SAMPLE: Twelve healthy male subjects aged 21 to 35 (mean 29.44 years, SD 6.598) years with no previous spinal cord injuries or current neck pain participated in the study.

OUTCOME MEASURES: Cervical range of motion (CRoM) measurements were used to determine the amount of motion restriction for each of the fitted (too small, correct size, and too big) Miami J orthoses.

METHODS: One Nest of Birds (NOB) electromagnetic sensor (Ascension Technology) was placed on the head and another on the upper back to measure motion of the head relative to the torso. The VR goggles (i-O Display Systems) were worn so that real-time feedback was available to the subject for motion control. The subject executed the primary motions of FE, AR, and lateral bending (LB) in separate sets of five trials each. Next, in combined motion, the subject axially rotated to a set point and then FE to his maximums. This entire set of motions was repeated for each (soft collar, Miami J, Miami J with chest extension, Sternal Occipital Mandibular Immobilizer (AliMed, Inc.), (SOMI and Halo) as well as the Miami J (one size too small and one size too big); the fitting of each brace was done by a board certified orthotist. A repeated measures analysis of variance was used to determine differences between the tested states (*p=.05).

RESULTS: For the validation test, the primary motions recorded for subjects wearing each cervical brace, which demonstrated that the various orthoses all restricted CRoM. The soft collar restricted less motion than the other devices, whereas the Halo restricted the most motion throughout.

FDA device/drug status: not applicable.

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doi:10.1016/j.spinee.2008.03.010

For the ill-fitting cervical collar comparison, motion in the correct size collar was normalized to 1.0, and the correct size allowed less motion than either the too big or too small braces. In FE, the too big brace tended to allow more motion than the too small, but only the too big brace in extension was significantly different from the correct size. In AR, the too small brace seemed to allow more motion than the too big. Both the too big and too small braces were significantly different than the correct size in both left and right AR. In LB, the too big brace and too small brace were very similar in the amount of motion they were able to restrict. Both braces were significantly different than the correct size in right LB, whereas only the too small brace was significantly different from the correct size in left LB. In the combined motion data, both the too big and too small braces allowed more motion than the correct size. The too small brace seemed to allow more FE at all degrees of AR except for extreme right AR.

CONCLUSIONS: To our knowledge, the effects of improperly fitted cervical orthoses on CRoM are still unknown. Using the NOB electromagnetic tracking system combined with VR feedback, we were able to consider the motion restriction of ill-fitting Miami J orthoses for both primary and combined motions. For both motion types, increased motion was possible when the subject was improperly fitted with the Miami J. If not considered, these excessive motions could potentially have detrimental effects on patient satisfaction, clinical outcomes, or even lead to increased secondary injury.

Keywords: Cervical spine; Range of motion; Orthoses; Virtual reality; Electromagnetic tracking; Ill-fitting

Introduction

Previous research studies analyzing the effectiveness of cervical orthoses at restricting cervical range of motion (CRoM) have primarily focused on testing orthoses under ''optimal'' conditions (ie, properly fit braces restricting primary motions) [1–9]. Unfortunately, these optimal testing conditions are not a realistic model for many clinical situations. Therefore, orthosis selection based solely on data obtained under optimal conditions could be insufficient and potentially harmful to the involved patient.

In general, cervical orthoses are used in the prehospital stabilization of trauma patients as well as a part of the definitive treatment of an injured cervical spine, in the weeks and months postsurgery. The objectives for spinal orthoses applications include correction of spinal deformity and misalignment, intervertebral segmental immobilization, regional stabilization, specific posture maintenance, and protection from damaging stresses [10].

However, because of limited availability, emergency applications, and financial constraints, it is not uncommon that a patient is fitted with a cervical orthosis that is not optimal for his or her size and body type. Ill-fitting braces are most commonly applied in a trauma setting, where care is given away from the health-care facility and access to a variety of sizes of orthoses is impossible. Ill-fitted braces could also be applied erroneously because of limited training or experience. Additionally, ill-fitting braces may be used in rural or other low-volume health-care facilities where it is unreasonable to have all possible brace sizes available.

To date, little work has been done to study the effects of ill-fitting cervical orthoses. However, it is reported that between 3% and 25% of spinal cord injuries occur after the initial cervical injury (secondary injuries), suggesting that the spinal cord injury originates either during transport or in the early course of treatment [2]. Thus, the structural integrity and ability of a cervical orthosis to provide effective and rigid immobilization is of paramount importance [2]. Therefore, we have found it necessary to examine the effectiveness of an ill-fitting cervical orthosis in restricting cervical motion.

This study uses a virtual reality (VR) feedback system to control the subjects' motion allowing for a more comprehensive and repeatable testing system. In addition, a six-degrees of freedom electromagnetic tracking system accurately measures positions and orientations of the head without visual estimation or radiation exposure as developed by previous research [11]. The aims of this study were to apply VR feedback control to repeatedly measure the primary motions and flexion/extension (FE) as a function of axial rotation (AR) with the goal of ultimately testing the effectiveness of an ill-fitting cervical orthosis at restricting CRoM.

Methods

Subjects

Twelve healthy male subjects aged 21 to 35 (mean 29.44 years, SD 6.598) years with no previous spinal cord injuries or current neck pain participated in the study. Before any data collection, all subjects signed an informed consent form, approved by the Institutional Review Board at the University of Pittsburgh.

Electromagnetic tracking

The Nest of Birds (NOB) (Ascension Technology Corp., Burlington, VT), a six-degrees of freedom electromagnetic measurement system, was used to measure cervical spine motion in this study. The NOB comprises a transmitter

and two sensors. One sensor is affixed to the headpiece securing the VR goggles. The other sensor is fixed to the upper back by means of a harness. The relative motion of the head with respect to the torso is recorded with these two sensors. The NOB detects and records both the positions and orientations of the sensors relative to the fixed transmitter.

Virtual reality feedback

VR feedback was provided so that the subject could visually limit any extraneous motion, resulting in what is defined as "pure" FE, AR, and lateral bending (LB). The VR component allows for repeatable motions both within a single subject and between different subjects. The software was developed in our lab exclusively for this purpose using MATLAB (Mathworks, Natick, MA).

For all testing cases, the subject's field of view was immersed in a globe where a horizontal and vertical line defined pure AR and FE, respectively. A crosshair was set on top of these lines and would move in real-time with the subject's movement. LB was defined as rotating the crosshair around the intersection of the two lines. One of the advantages of the VR system is the ability to prescribe repeatable combined motion. When testing a combined motion scenario, an additional vertical line was added at a specified degree of AR (Fig. 1).

Orthoses testing validation

To first validate our system, we tested a spectrum of cervical braces (soft collar, Miami J, Miami J with chest extension, Sternal Occipital Mandibular Immobilizer (SOMI, AliMed, Inc., Dedham, MA) (SOMI, and Halo) to ensure our system measured decreasing motion as widely reported [1,2,6,8,12]. Each brace was fit by a clinically licensed orthotist, according to the specifications provided by the manufacturer. However, the Halo device was fit with four pins onto plastic tip covers, which attached the orthosis to the skull in a noninvasive manner, reducing the overall rigidity of this brace.

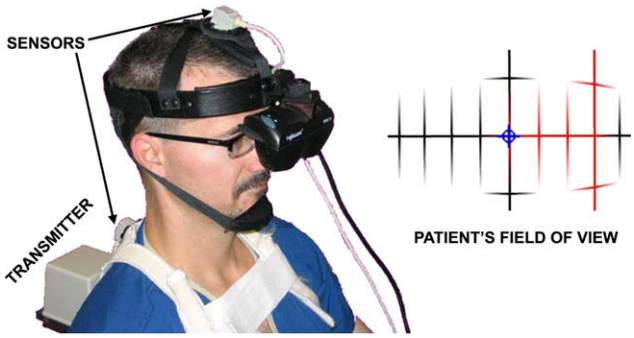

Fig. 1. The virtual reality goggles and electromagnetic tracking set up display. As the subject moves his or her head, the blue crosshair traces the lines in real-time.

EVIDENCE & METHODS

Context

Cervical orthoses, as routinely applied, often fit improperly. Little is known regarding the resulting kinematic effects.

Contribution

Using novel technologies to afford well-controlled active cervical motions and to assess kinematics, the authors have demonstrated that ill-fitting Miami-J collars result in increased motions relative to properly fitted collars.

Implications

The clinical implications of increased motion despite orthosis treatment remain unknown. Patient dependent factors including cervical pathology (injury pattern, underlying stenosis, etc.) will determine the degree of risk. Greater risk regarding potential motion may convince the clinician to aim for more rigid devices.
That said, the same clinician often aim to provide adequate control with the least cumbersome orthosis and the Miami-J collar, especially at many major trauma centers, is frequently employed. This study serves as a reminder that fit matters and that a slap it on technique may sabotage an expected and necessary stabilization effect. Orthopaedic, neurosurgical and emergency medicine trainees are responsible for placement of these orthosis. This paper should serve to encourage appropriate training to determine proper fit and placement of cervical orthoses.

—The Editors

Ill-fitting cervical collar testing

Each subject was tested wearing three different Miami J collars fit by a clinically licensed orthotist. Brace selection started by measuring and applying the properly fit brace first. According to the instructions accompanying each Miami J brace and confirmed by the orthotist, 1) selecting the right sized collar and 2) correctly fitting it to the patient are the two essential points for properly fitting a Miami J collar.

The Miami J collar sizes are determined by the shape of the subject's neck and shoulders. Sizing silhouettes and sample sizing questions are provided to aid the caregiver in determining the appropriate collar size. Collar size is

best determined by observing the vertical distance between the highest point of the trapezius and the tip of the chin when the head is in the desired treatment alignment.

While the subject is seated upright, the collar back is held steadily at the back of the patient's neck, and the sides of the collar front are flared out. It is then slid up the chest wall and scooped up under the chin. When properly placed, the sides are oriented up, off the trapezius, and toward the ears. While holding the front securely, the ends are curled snugly against the patient's neck. The Velcro straps are used to secure the collar back by tightening straps alternately to an equal length on both sides. When the patient is properly fit, there should be equal amounts of excess Velcro overhanging the front adhesive sections.

After the initial fitting, collar adjustments must be made to ensure proper fit. According to the Miami J sizing and application instructions, it is nearly impossible to fit a properly sized collar too tightly. Therefore, before motion was recorded, the subject was asked to attempt to slip his chin inside the correct size brace, and the brace was tightened until this was no longer possible.

After the process of properly fitting the correctly sized brace (defined as ''correct size''), the ill-fitting braces were selected by increasing one size and decreasing one size (defined as ''too big'' and ''too small'', respectively). Because the incorrect size braces could not be fit properly, the orthotist fit the braces to the subject as if it were a trauma case in the field and the brace size being used were the only one available. This helped to normalize the ill-fitting brace application (Fig. 2).

Experimental protocol

The order of the protocol was the same for all subjects. After being fit with the harness and VR goggles, subjects sat upright in a chair with their back firmly against the back support. The subject was asked to follow the prescribed FE, AR, and LB (the primary motions) VR motions paths. In each individual case, the desired motion path was highlighted in red to eliminate any possible confusion over the appropriate path. In the FE trials, the subject was instructed to move his chin as far toward his chest as possible (flexion) and to rotate his head as far back as possible (extension). In the AR trials, the subject was instructed to turn his head as far to the left and to the right as possible, In the LB trials, the subject was instructed to move his head like he was following the hands of a clock with his nose. The subject moved counter-clockwise to his left shoulder, and clockwise to his right shoulder.

Next, the subject executed combined motion, axially rotating to one of three set points in directions, then maximally flexing and extending. The software required that the point of FE be a multiple of nine degrees; the amount of AR was set at the multiple of nine degrees closest to 25%, 50%, and 75% of maximum AR. In these trials, an extra red vertical line was added to the VR display to explicitly prescribe the desired path, informing the subject how far to axially rotate before performing FE. Lastly, the subject would fully extend and ''roll'' his head throughout the entire range of motion to yield an overall score, which is a calculated sum of the average maximal primary motions achieved during this circumduction motion, normalized to 90 degrees of rotation.

Each of these motions was repeated five times, stopping only between different types of motion. This entire set of motions was repeated for each brace (soft collar, Miami J [including correct size, too big and too small-sized brace], Miami J with chest extension, SOMI, and Halo). Before each different motion path, the subject returned his head to a neutral position and the NOB was reset to a zero position. During all motions, the subject was asked to move as far as possible without substantial discomfort and pause for a full second at this point. This standard for end of range of motion was chosen to most closely resemble motion of everyday life.

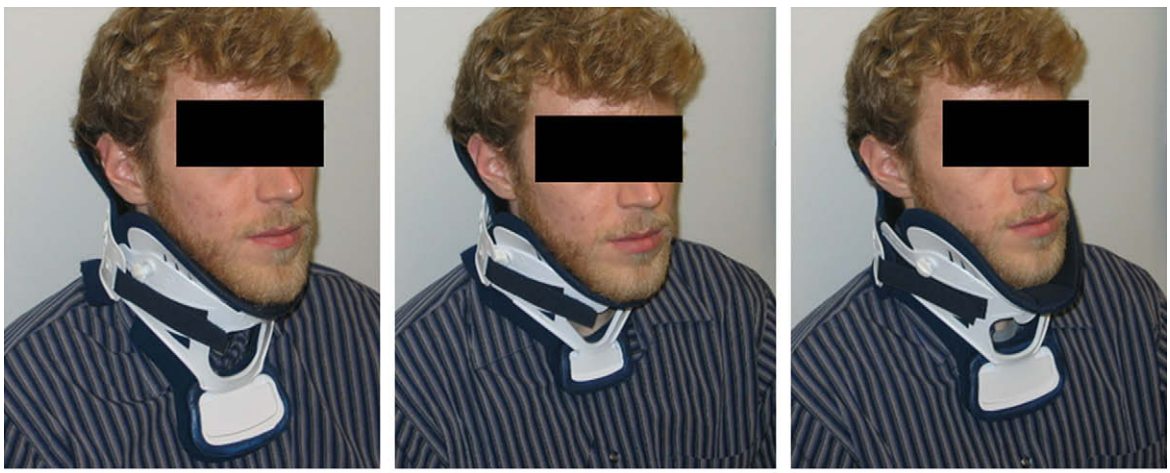

Fig. 2. The Miami J orthosis fitted for each of the different sized parameters: correct fit, too small, and too big.

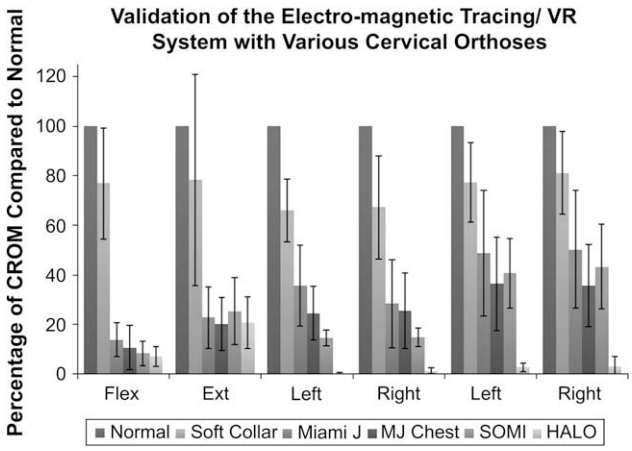

Fig. 3. The amount of restriction for each of the cervical orthoses (soft collar, Miami J, Miami J with chest extension, SOMI, and Halo) plotted as bar graphs compared with normal, uninhibited motion.

Data processing and analysis

The Euler angle coordinates of the electromagnetic sensors were recorded in MATLAB. An algorithm was developed to average the five peaks of each of the trials. All of this data was then imported into Microsoft Excel where the averages from all of the subjects were combined and a student *t* test (*p≤.05) was used to determine significant differences between the study groups.

Results

For the validation test, the primary motions recorded for subjects wearing each cervical brace (soft collar, Miami J, Miami J with chest extension, SOMI, and Halo) was normalized with the ''uninhibited'' motion in those not wearing an orthosis. As seen in Fig. 3, the various orthoses all restricted CRoM. The soft collar restricted less motion than the other devices, whereas the Halo restricted the most motion throughout.

For the ill-fitting cervical collar comparison, motion in the correct size collar was normalized to 1.0. Motion allowed from the too big and too small braces was then normalized and compared with the correct size. In all of the primary motions (Fig. 4), the correct size allowed less motion than either the too big or too small braces.

In FE, the too big brace tended to allow more motion than the too small, but only the too big brace in extension was significantly different from the correct size. In AR, the too small brace seemed to allow more motion than the too big. Both the too big and too small braces were significantly different than the correct size in both left and right AR. In LB, the too big brace and too small brace were very similar in the amount of motion they were able to restrict. Both braces were significantly different than the correct size in right LB, whereas only the too small brace was significantly different from the correct size in left LB.

In combined motion (Fig. 5), both the too big and too small braces allowed more motion than the correct size. The too small brace seemed to allow more FE at all degrees of AR except for extreme right AR.

Discussion

The purpose of cervical collars is to firmly support patients' heads and to minimize the risk of injury associated with movement of the neck, mitigating pain, and myopalmus caused by incremental movements of cervical vertebrae [2,8,12–16]. Numerous types of cervical orthotic devices are available to meet the variety of patient needs and are specifically designed to restrict different amounts of range of motion. Our validation of the electromagnetic VR system assessed this diversity and was consistent with previously reported CRoM comparisons of these devices [1–9].

To minimize variability, we tested just the Miami J collar to determine the effects of ill fitting on CRoM. However, it should be noted that our selection of the Miami J for investigation does not imply that the authors or their institution perceive any superiority of this device. Additionally, although the Miami J was selected as a representative cervical orthosis for the purposes of this study and we feel that the findings should raise awareness of ill-fitting orthoses in the clinical community, in general, the results are not directly translatable to other cervical orthotic devices. With this in mind, the Miami J is highly used by physicians at this institution, and it is concluded by many researchers to be restrictive in all primary degrees of freedom [6]. Previous studies of the Miami J, and other cervical orthoses, have concentrated on measuring the amount of motion the orthosis is able to restrict. However, results from previous cervical orthoses range of motion studies have been inconsistent, and results from study to study are difficult to compare. Table 1 shows how our data compares with previous studies involving the Miami J and also illustrates the differences in results between different researchers.

A probable reason for these large discrepancies is that no method was used to control subjects' motion in previous studies. Our novel tracking system provides the subject with a real-time VR feedback, enabling the subject to exactly repeat his motions. Additionally, this system provides the ability to prescribe combined motions. In everyday activities, cervical motion is not restricted to just FE, AR, and LB, rather it is a constant combination of the three primary motions. Because of the VR feedback, we can measure combined motions such as a subject's motion as they axially rotate and then flex and extend. FE in AR is an apt model of a cervical motion that is repeated many times throughout the day in activities such as driving a car, looking at a clock on a wall, or placing something on a high shelf.

Within the primary motions, the correct size brace functionally constrains the range of motion more effectively

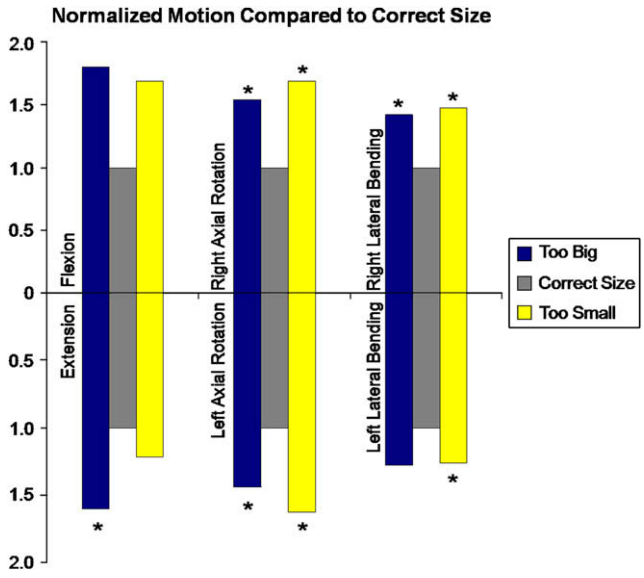

Fig. 4. Primary motions: bar graphs comparing amount of motion restriction for the too small and too big Miami J brace compared with the correct fit Miami J. The averages from all of the subjects were combined. Significant differences were determined using a student *t* test (*p≤.05).

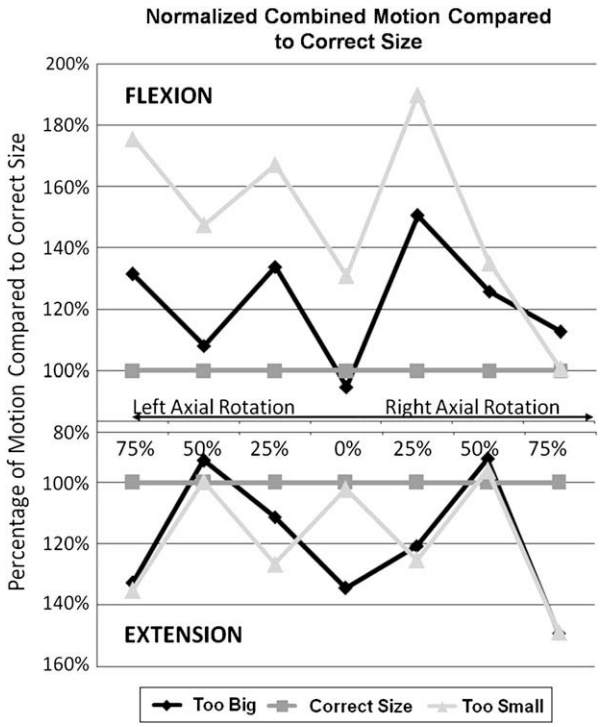

Fig. 5. Combined motions: data plot of motion percentage of flexion/extension while axially rotated for ill-fitting Miami J compared with correctly fitting Miami J.

than those fitted too loosely (big) and too tightly (small). Comparable with previous research, this control of motion allows for the restriction of cervical vertebrae movement: FE, AR, and LB. As hypothesized, the ill-fitted cervical orthoses were unable to service appropriate restriction of CRoM compared with the properly fitted device. This suggests that after a cervical injury, a patient wearing a collar that is either too big or too small could experience added cervical impairment because of the lack of restriction and under-restrained motion of the neck.

Combined motions performed with each of the improperly fitted orthoses showed percentages of motion greater than 100% compared with the correctly fitted brace. Moreover, the randomness and inconsistency of the results raises some concern. Variability in the degree to which a brace is capable of restricting motion when a patient's head is turned could make brace selection difficult or ultimately lead to increased occurrence of secondary injuries.

A notable limitation of this study was its inability to quantitatively create an end point for physical exertion. Subjects were told to move until they reached a point of maximum muscle exertion, which may not be repeatable between trials or consistent between subjects. Additionally, the use of healthy subjects is not directly representative of the injured population which typically would not be able to exert as much force against the brace. However, this model of maximum muscle exertion could be representative of the efficacy of the brace at restricting high loading conditions that could be experienced through involuntary motions, which could lead to secondary injury.

The negative effects of ill-fitting cervical orthoses from uninhibited CRoM have significant clinical implications. Patient care could be compromised as a result of the increased motion permitted by improper fitting of cervical orthoses. Other researchers investigating clinical implications of ill-fitting orthoses have shown that dermal contact with an ill-fitted cervical brace can cause skin lesions and affect CRoM and patient satisfaction [17,18]. The results show that the ill-fitting Miami J does not restrict motion as completely as the correctly sized Miami J, potentially adding to the 3% to 25% of spinal cord injuries that occur after the initial injury [2]. As previously noted, there is a wide range of cervical collars, none of which should be inferred as definitive treatment for unstable injuries. In addition, the use of Miami J itself is at the discretion of the individual (emergency medical provider, trauma specialist, or certified orthotist) applying the brace. Although this study used a qualified orthotist, this ideal situation is less likely to occur in trauma situations where a qualified orthotist may be unavailable; nonetheless, the professional fitting of a brace one size larger or smaller has statistically significant differences from the correctly fitted size.

Therefore, this study highlights the importance of understanding the effect of ill-fitting orthoses and should be considered when applying orthoses in clinical settings.

This study also presented a novel VR feedback system to control the subject's motion. Utilization of this technology for investigation of cervical kinematics enabled consistent motion paths within and between subjects as well as for ''more realistic'' combined motion paths to be recorded—desirable outcomes for any kinematic study. Therefore, this system is being implemented for ongoing investigations of

Table 1
Reported differences in the percentages of ‘‘unrestricted’’ motion allowed by the Miami J

Author	Flexion (%)	Extension (%)	Axial rotation (%)	Lateral bending (%)	Measurement type
Donaldson	18.8	30.0	32.5	54.4	Electromagnetic and VR
Zhang [19]	15.2	44.5	34.6	62.1	Vicon optical tracking
Askins and Eismont [2]	24.0	30.0	35.0	49.0	Radiographs, compass goniometer
Gavin et al. [7]	40.0	46.0	n/a	n/a	Video fluoroscopy
Richter [20]	68.1*		n/a	n/a	Radiography/photography

* Percentage of unrestricted motion allowed by the Miami J for overall flexion/extension in a cadaver study.

cervical disorders and surgical procedures in our laboratory, and it is recommended that similar methodologies be implemented in other laboratories as well. Additionally, future work is planned to improve the computer-user interface whereby creating a more interactive and user-friendly environment that will hopefully enable a more effective and varied application of this technology.

Acknowledgments

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References

[1] Alberts LR, Mahoney CR, Neff JR. Comparison of the Nebraska collar, a new prototype cervical immobilization collar, with three standard models. J Orthop Trauma 1998;12:425–30.
[2] Askins V, Eismont FJ. Efficacy of five cervical orthoses in restricting cervical motion. A comparison study. Spine 1997;22:1193–8.
[3] Bearden BG, Conrad BP, Horodyski M, Rechtine GR. Motion in the unstable cervical spine: comparison of manual turning and use of the Jackson table in prone positioning. J Neurosurg Spine 2007;7:161–4.
[4] Bruns W, Von Salis-Soglio G, Plitz W. Cervical collars: a clinical and biomechanical study. Z Orthop Ihre Grenzgeb 2004;142:421–7.
[5] Carter VM, Fasen JA, Roman JM Jr, Hayes KW, Petersen CM. The effect of a soft collar, used as normally recommended or reversed, on three planes of cervical range of motion. J Orthop Sports Phys Ther 1996;23:209–15.
[6] Garth GC. Efficacy of five cervical orthoses in restricting cervical motion: a comparison study. Spine 1998;23:961–2.
[7] Gavin TM, Carandang G, Havey R, Flanagan P, Ghanayem A, Patwardhan AG. Biomechanical analysis of cervical orthoses in flexion and extension: a comparison of cervical collars and cervical thoracic orthoses. J Rehabil Res Dev 2003;40:527–37.
[8] Hart DL, Johnson RM, Simmons EF, Owen J. Review of cervical orthoses. Phys Ther 1978;58:857–60.
[9] Schneider AM, Hipp JA, Nguyen L, Reitman CA. Reduction in head and intervertebral motion provided by 7 contemporary cervical orthoses in 45 individuals. Spine 2007;32:E1–6.
[10] Stuber K. Cervical collars and braces in athletic brachial plexus injury and excessive cervical motion prevention: a review of the literature. JCCA J Can Chiropr Assoc 2005;49:216–22.
[11] LoPresti E, Brienza DM, Angelo J, Gilbertson L, Sakai J. Neck range of motion and use of computer head controls. In: Fourth International ACM Conference on Assistive Technologies. Arlington: Virginia, United States, 2000.
[12] Manix T, Gunderson MR, Garth GC. Comparison of prehospital cervical immobilization devices using video and electromyography. Prehospital Disaster Med 1995;10:232–7; discussion 237, 238.
[13] Hartman JT, Palumbo F, Hill BJ. Cineradiography of the braced normal cervical spine. A comparative study of five commonly used cervical orthoses. Clin Orthop Relat Res 1975;109:97–102.
[14] Hughes SJ. How effective is the Newport/Aspen collar? A prospective radiographic evaluation in healthy adult volunteers. J Trauma 1998;45:374–8.
[15] Johnson RM, Hart DL, Owen JR, Lerner E, Chapin W, Zeleznik R. The yale cervical orthosis: an evaluation of its effectiveness in restricting cervical motion in normal subjects and a comparison with other cervical orthoses. Phys Ther 1978;58:865–71.
[16] Sandler AJ, Dvorak J, Humke T, Grob D, Daniels W. The effectiveness of various cervical orthoses. An in vivo comparison of the mechanical stability provided by several widely used models. Spine 1996;21:1624–9.
[17] Duhem R, Tonnelle V, Vinchon M, Assaker R, Dhellemmes P. Unstable upper pediatric cervical spine injuries: report of 28 cases and review of the literature. Childs Nerv Syst 2007;24:343–8.
[18] Powers J, Daniels D, McGuire C, Hilbish C. The incidence of skin breakdown associated with use of cervical collars. J Trauma Nurs 2006;13:198–200.
[19] Zhang S, Wortley M, Clowers K, Krusenklaus JH. Evaluation of efficacy and 3D kinematic characteristics of cervical orthoses. Clin Biomech (Bristol, Avon) 2005;20:264–9.
[20] Richter D, Latta LL, Milne EL, et al. The stabilizing effects of different orthoses in the intact and unstable upper cervical spine: a cadaver study. J Trauma 2001;50:848–54.

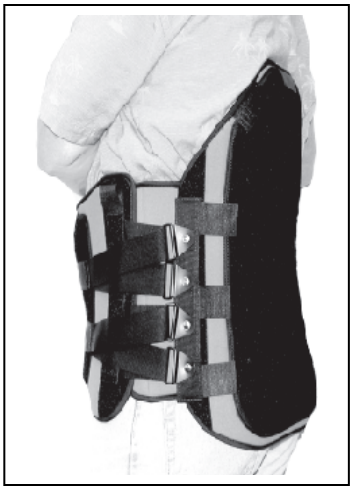
HCPCS:	Descriptor:
L0450	TLSO, FLEXIBLE, PROVIDES TRUNK SUPPORT, UPPER THORACIC REGION, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISKS WITH RIGID STAYS OR PANEL(S), INCLUDES SHOULDER STRAPS AND CLOSURES, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	NO	YES	YES

Sample Diagnosis (Not Inclusive)	Osteoporosis, Compression fractures
Medically Necessary Argument	This consists of a flexible material, which provides stabilization to the upper thoracic spine. . It requires, bending of the posterior stays or shaping of the rigid panel to optimize fit. These devices are often provided to persons who would have difficulty with more rigid type devices and who may have difficulty with pressure on sensitive skin. Additionally they would need instruction, often repetitively, to ensure application of the device for appropriate function. Improper fitting may lead to exacerbation of orthopedic condition and issues with skin that can lead to breakdown. Follow up care is essential following fitting of these types of devices.
References	

HCPCS:	Descriptor:
L0454	TLSO FLEXIBLE, PROVIDES TRUNK SUPPORT, EXTENDS FROM SACROCOCCYGEAL JUNCTION TO ABOVE T-9 VERTEBRA, RESTRICTS GROSS TRUNK MOTION IN THE SAGITTAL PLANE, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISKS WITH RIGID STAYS OR PANEL(S), INCLUDES SHOULDER STRAPS AND CLOSURES, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Post surgical, Traumatic stabilization, mid thoracic to high lumbar vertebral fractures, abdominal pain, and activity induced back pain.
Medically Necessary Argument	This TLSO is determined by multiple measurements, providing stabilization to the thoracic and lumbar spine. Sizing allows fitting of both neutral and pendulous patients, requiring the fitter to have more than a passing knowledge of anatomy for application. The devices come in 6 circumferences. Height of the devices must be properly selected to allow for standing and sitting without compromising overall fit and function of the device. Improper fitting may lead to exacerbation of orthopedic condition and issues with skin that can lead to breakdown. Follow up care is essential following fitting of these types of devices. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device.
References	

HCPCS:	Descriptor:
L0456	TLSO, FLEXIBLE, PROVIDES TRUNK SUPPORT, THORACIC REGION, RIGID POSTERIOR PANEL AND SOFT ANTERIOR APRON, EXTENDS FROM THE SACROCOCCYGEAL JUNCTION AND TERMINATES JUST INFERIOR TO THE SCAPULAR SPINE, RESTRICTS GROSS TRUNK MOTION IN THE SAGITTAL PLANE, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISKS, INCLUDES STRAPS AND CLOSURES, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Osteoporosis, Compression fractures, mid thoracic to high lumbar vertebral fractures, and induced back pain.
Medically Necessary Argument	This TLSO consist of a full-length posterior section that is secured with straps that attached to a rigid anterior apron front. The device requires measurements to select the appropriate size, bending of the posterior stabilizing portion of the device and trimming of the straps to achieve an optimal fit. The fitting of this device cannot be done without assistance and requires the fitter applies adjustment after the device to the patient. Once applied, the straps typically need to be further tuned to allow for standing and sitting without compromising the device function. As this patient typically has limited mobility often techniques need to be developed to permit device application. Follow up instructions are commonly required. It would not be possible for this device to be fit by someone with an understanding of basic skeletal anatomy to appropriately position the device, to assure stabilization and to accommodate the variation in sitting and standing postural changes without causing irritation.
References	

HCPCS:	Descriptor:
L0460	TLSO, TRIPLANAR CONTROL, MODULAR SEGMENTED SPINAL SYSTEM, TWO RIGID PLASTIC SHELLS, POSTERIOR EXTENDS FROM THE SACROCOCCYGEAL JUNCTION AND TERMINATES JUST INFERIOR TO THE SCAPULAR SPINE, ANTERIOR EXTENDS FROM THE SYMPHYSIS PUBIS TO THE STERNAL NOTCH, SOFT LINER, RESTRICTS GROSS TRUNK MOTION IN THE SAGITTAL, CORONAL, AND TRANSVERSE PLANES, LATERAL STRENGTH IS PROVIDED BY OVERLAPPING PLASTIC AND STABILIZING CLOSURES, INCLUDES STRAPS AND CLOSURES, PREFABRICATED, INCLUDES FITTING AND ADUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Post-surgical stabilization, Traumatic stabilization, Osteoporosis, spinal fractures
Medically Necessary Argument	Representative of two shelled TLSO that overlaps to interlock on the torso. Multiple measurements are required to ensure an appropriately sized module. Sizing chart demonstrates both neutral and pendulous design, requiring the fitter to have knowledge of anatomy for application. Modules are designed to be modified by the use of heat to compensate for potential areas of pressure. Plastic can be cut, and cut edges must be properly smoothed which cannot be done without training and proper tools. Trim lines must be properly configured to allow for standing and sitting without compromising overall fit and function of the device. Improper fitting may lead to exacerbation of orthopedic condition and issues with skin that can lead to breakdown. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device.
References	3

The Effect of Four Types of Support on the Segmental Mobility of the Lumbosacral Spine

BY M. W. FIDLER, F.R.C.S.*, AND C. M. T. PLASMANS, M.D.†, AMSTERDAM, THE NETHERLANDS

From the Slotervaart Ziekenhuis and O.L.V. Gasthuis, Amsterdam

ABSTRACT: **With the aid of flexion-extension lateral radiographs, we investigated the effect of the canvas corset, the Raney and Baycast jackets, and the Baycast spica on the segmental sagittal mobility of the lumbosacral spine in separate groups of five volunteers each. The canvas corset reduced the mean angular movements at each level to two-thirds of normal. The Raney and Baycast jackets reduced the mean angular movements in the middle of the lumbar spine to approximately one-third of normal. The Baycast spica was the most effective in restricting angular movements below the third lumbar vertebra, and especially at the fourth lumbar-fifth lumbar level and the lumbosacral level.**

Lumbosacral corsets have been in use at least since the Minoan period, some 2000 years B.C.[2]. The function of those corsets was primarily to mold and enhance the female form, but their construction could also have served to support the lumbosacral spine. The first surgical corset that was specifically designed to support the lumbar spine was probably that made in 1530 for Catherine of Medici[3]. This was an iron corset, extending from the mid-part of the thorax to over the iliac crests, hinged down one side and fastened by a clasp on the other.

Lumbosacral supports are now commonly prescribed in the management of low-back pain[1,7] and are used to judge the effect of immobilization when considering spine fusion or postoperatively to support the spine until fusion occurs. By means of a questionnaire, Perry reviewed the use of supports in America and found that the lumbosacral corset was the most widely used, followed closely by the chairback brace. The effect most often expected from a brace was restriction of lumbosacral motion — this in spite of the fact that Norton and Brown as well as Lumsden and Morris had observed that in some patients a support actually could lead to an increase in movement at the lumbosacral level. It seems that there is still a tendency to prescribe a support for the lumbosacral spine without focusing attention specifically on the level concerned.

We use mainly four types of lumbosacral support. The lumbosacral canvas corset with posterior steel supports (Fig. 1), the Raney[8] flexion jacket (Fig. 2), and the Baycast (Cuttercast) jacket (Fig. 3) are used principally in the treatment of low-back pain, and the Baycast jacket with inclusion of the left thigh (Baycast spica) (Fig. 4) is used chiefly when considering fusion and postoperatively. The thigh is included in order to improve control of the pelvis.

The purpose of this investigation was to assess and compare the effects of these supports on the segmental sagittal mobility of the lumbosacral spine.

Material

Each type of support was assessed on five healthy male volunteers, none of whom had a history of low-back pain.

The canvas lumbosacral corsets were made to measure for each volunteer in the routine manner used for patients with lumbosacral disorders by the orthotist in the Slotervaart Hospital. The pattern used was a minor modification of that described in the spinal orthotics manual of the New York University Post-Graduate Medical School[5]. The lower edge of the corset was trimmed posteriorly at seat level with the subject sitting on a stool, thus avoiding the uncomfortable curled lip that can occur with the slightly lower edge described in the manual. The corset extended from around the lower ribs to over the iliac crest laterally, to just above the symphysis pubis anteriorly, and included the sacrum and upper part of the buttocks posteriorly. Each corset was reinforced with two posterior vertical steel stays stitched between the layers of the canvas.

The Raney flexion jackets were standard models of appropriate size for the volunteers.

The Baycast jackets were applied on standing volunteers by the same orthotist. These jackets extended from two centimeters below the shoulder blades to the mid-part of the sacrum posteriorly, from the xiphisternum to just above the pubis anteriorly, and from around the lower ribs to three centimeters below the level of the anterior superior iliac spines laterally. The left thigh was subsequently included to produce the Baycast spica on these same volunteers. The thigh-piece extended to five centimeters proximal to the patella and was added with the hip in 20 degrees of flexion in order to prevent any fixed lumbar lordosis and to facilitate sitting.

Method

Using a uniform technique lateral radiographs of the lumbosacral spine were made in maximum flexion and extension, first without and then with the support so that each

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TABLE I

MOVEMENT IN THE CANVAS CORSET FOR FIVE VOLUNTEERS (CASES 1 THROUGH 5)

Level	Movement with No Support (*Degrees*)					Movement in the Canvas Corset (*Degrees*)					Percentage Permitted Movement in the Canvas Corset					
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	Mean
L1-L2	15			11	17	9	13		4	10	60			36	59	52*
L2-L3	21	16	11	12	10	11	12	9	10	3	52	75	82	83	30	64†
L3-L4	18	13	17	12	3	7	10	17	10	0	39	77	100	83	0	60‡
L4-L5	15	21	20	13	7	10	10	17	10	2	67	48	85	77	29	61†
L5-S1	13	14	15	14	15	6	7	9	13	10	46	50	60	93	67	63*

* $0.005 > p > 0.001$.
† $0.05 > p > 0.01$.
‡ $0.1 > p > 0.05$.

volunteer acted as his own control. Segmental movement during flexion and extension was determined by means of corresponding lines drawn along the end-plates of each vertebra. The angles between adjacent vertebrae were measured in flexion and in extension, and the difference was recorded as the movement occurring at that level. These segmental angular movements, without and with a support, were determined at each level for all of the volunteers. In order to facilitate comparison of one type of support with another, the angular movements that were permitted by a support were expressed as percentages of the corresponding control unrestricted angular movements and then, for each type of support, the averages (arithmetical means) of these percentages were calculated for each level.

We found that the most accurate method of drawing corresponding lines on the radiographs was first to draw all of the lines on one radiograph. The second radiograph was then placed on top of the first and the shadow of each vertebral body was superimposed in turn over that of the same vertebra on the underlying radiograph while the corresponding lines were traced onto the upper radiograph.

We did not assess the reproducibility of the measurements because it would have been necessary to repeat at least one set of flexion and extension radiographs for the volunteers. In view of the extra radiation involved, we did

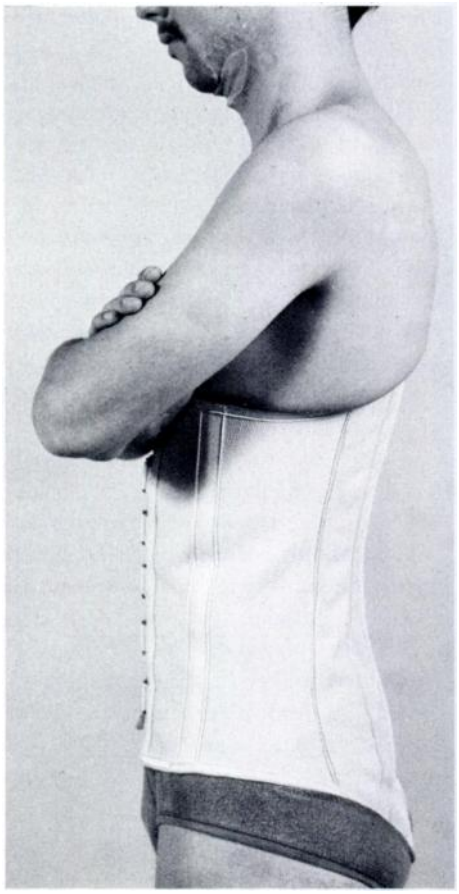


FIG. 1

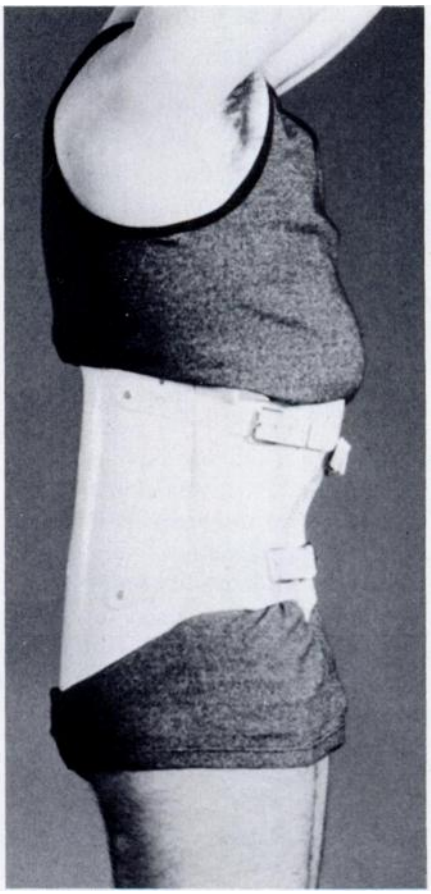


FIG. 2

Fig. 1: Canvas lumbosacral corset.
Fig. 2: Raney flexion jacket.

TABLE II

MOVEMENT IN THE RANEY JACKET FOR FIVE VOLUNTEERS (CASES 6 THROUGH 10)

Level	Movement with No Support (*Degrees*)					Movement in the Raney Jacket (*Degrees*)					Percentage Permitted Movement in the Raney Jacket					
	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10	Mean
L1-L2	15	11	6			2	5	5	7	2	13	45	83			47*
L2-L3	13	15	12	8	15	5	4	1	3	7	38	27	8	38	47	32†
L3-L4	12	12	17	13	13	6	2	1	2	10	50	17	6	15	77	33‡
L4-L5	20	16	15	17	11	6	7	8	12	3	30	44	53	71	27	45§
L5-S1	18	11	13	22	18	13	12	6	5	10	72	109	46	23	56	61¶

* $0.1 > p > 0.05$.
† $0.001 > p$.
‡ $0.01 > p > 0.005$.
§ $0.005 > p > 0.001$.
¶ $0.05 > p > 0.01$.

not think that this was justifiable. Tanz, who also used a superimposition method to calculate the segmental angular movements, found that the results of repeat radiographic examinations usually agreed to within 2 degrees. We assumed that this 2-degree error would be applicable to our series.

Radiation Precautions

The volunteers were healthy thin men whose gonads were screened. They had had minimum previous exposure to radiation and did not come into contact with x-rays during their routine work. One radiographer in each hospital made all of the radiographs to minimize the chance of error. An off-center radiograph was not repeated. This explains the absence of readings at the level of the disc between the first and second lumbar vertebrae for Cases 2, 3, 9, 10, and 11 in Tables I, II, and III. Copies of the radiographs were subsequently given to the volunteers for possible future reference in case they ever had low-back pain in the future. The radiation dose to the lumbar spine was approximately 250 millirads and to the shielded gonads it was ten millirads per radiograph. Baycast absorbs virtually no radiation. Thus, lower radiation doses were possible than would have been necessary if plaster of Paris had been used.

Results

The effect of the supports is shown in Tables I through IV. Almost all of the supports reduced the segmental angular movements of the lumbosacral spine. The exceptions were the canvas corset on Case 3, in whom movement at the third lumbar-fourth lumbar level was unaffected; the Raney jacket on Case 7, in whom there was a 1-degree (9 per cent) increase in angular movement at the

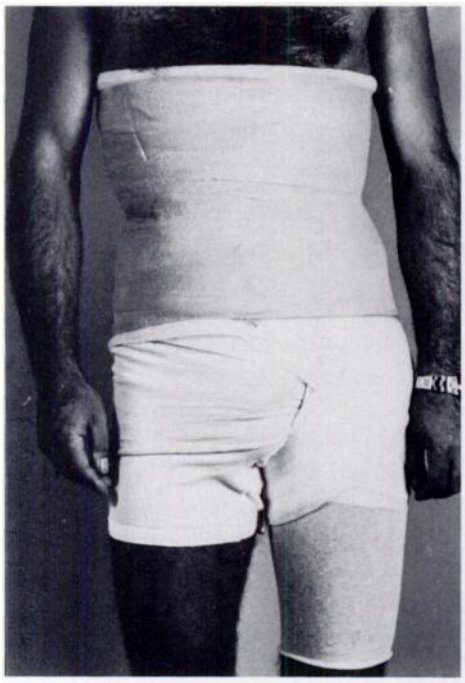


FIG. 3

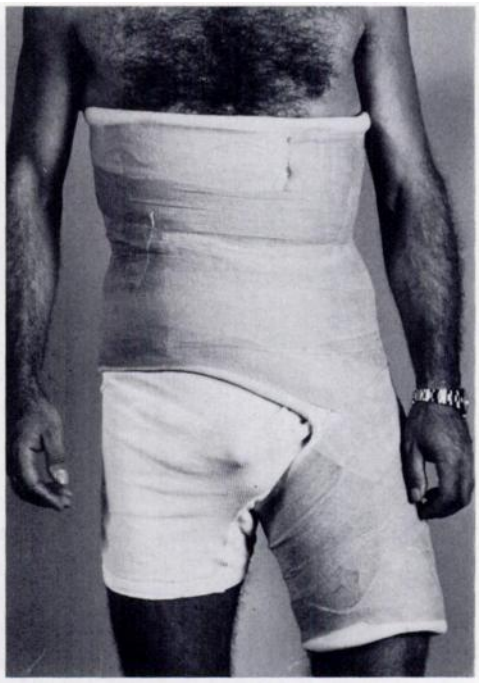


FIG. 4

Fig. 3: Baycast jacket.
Fig. 4: Baycast spica.

TABLE III

MOVEMENT IN THE BAYCAST JACKET AND BAYCAST SPICA FOR FIVE VOLUNTEERS (CASES 11 THROUGH 15)

Level	Movement with No Support (Degrees)					Movement in the Baycast Jacket (Degrees)						Movement in the Baycast Spica (Degrees)					
	11	12	13	14	15	11	12	13	14	15	Mean	11	12	13	14	15	Mean
L1-L2		16	10	10	12	2	7	3	7	8	53%*	4	10	3	7	4	49%†
L2-L3	20	16	17	13	13	2	8	11	5	4	39%‡	2	1	4	12	4	33%†
L3-L4	16	16	11	10	13	2	4	6	6	6	40%†	0	2	6	6	1	27%†
L4-L5	18	22	18	20	12	0	6	13	6	4	32%‡	2	0	3	3	2	12%§
L5-S1	23	22	14	16	17	10	11	14	16	10	70%*	2	0	1	1	3	8%§

* $0.05 > p > 0.01$.
† $0.01 > p > 0.005$.
‡ $0.005 > p > 0.001$.
§ $0.001 > p$.

lumbosacral level; and the Baycast jackets on Cases 13 and 14, in whom the angular movements at the lumbosacral level were unaffected. Although the results showed considerable variation between individuals with regard to the effect of the supports, certain general trends could be discerned. Table IV and Figure 5 summarize the effect of each type of support at each level in the form of the mean percentage of angular movement permitted.

The canvas corset reduced angular movement at each level to approximately two-thirds of normal. The Raney and Baycast jackets were reasonably effective in the mid-part of the lumbar spine, where they reduced the angular movement to about one-third of normal, but at the first lumbar-second lumbar level and the lumbosacral level they had the same effect as the canvas corset. The Baycast spica was the most efficient below the third lumbar vertebra, and was progressively more efficient the lower the level. At the fourth lumbar-fifth lumbar level the Baycast spica permitted an average angular movement of only 2 degrees, or 12 per cent of normal, and a maximum angular movement of 3 degrees. At the lumbosacral level it was even more efficient, permitting an average angular movement of only 1.4 degrees, or 8 per cent of normal, and a maximum angular movement of only 3 degrees. The beneficial effect of the Baycast spica compared with the Baycast jacket in reducing angular movement at the lumbosacral level was statistically significant ($p < 0.001$).

TABLE IV

MEAN AND RANGE OF PERCENTAGE PERMITTED MOVEMENT

Level	Canvas Corset	Raney Jacket	Baycast Jacket	Baycast Spica
L1-L2	52 (36-60)	47 (13-83)	53 (30-70)	49 (30-70)
L2-L3	64 (30-83)	32 (8-47)	39 (10-65)	33 (6-92)
L3-L4	60 (0-100)	33 (6-77)	40 (13-60)	27 (0-60)
L4-L5	61 (29-85)	45 (27-71)	32 (0-72)	12 (0-17)
L5-S1	63 (46-93)	61 (23-109)	70 (43-100)	8 (0-18)

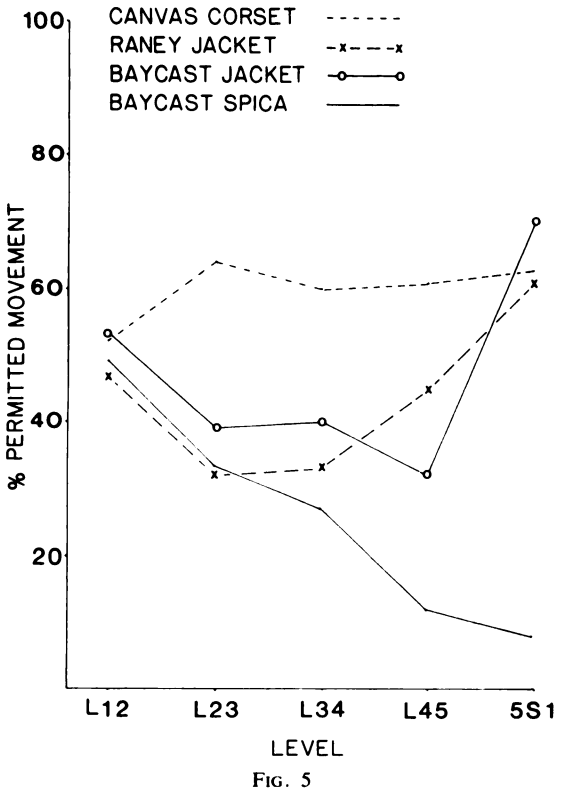


FIG. 5

Graph illustrating the percentage of movement permitted at each level by each type of support.

Discussion

The lumbosacral spinal vertebrae can undergo both translation and angular motion. The latter is caused by lateral bending and flexion-extension or axial rotation movements. Restriction of axial rotation at the lumbosacral level was observed by Lumsden and Morris in subjects wearing a chairback brace, but the effects of lumbosacral canvas corsets were varied and unpredictable. It is probable that the Raney and Baycast jackets, like the chairback brace, would adequately fix the pelvis and similarly control rotation. The cross section of the torso is oval and hence the lateral sides of a spinal support, being farther away from the spine than the back and front, should be more efficient in restricting lateral bending movement than the back and front are in restricting flexion and extension movement. Unless the sides are inadequate, it therefore seems likely that a support that restricts flexion-extension movement would be at least as effective in restricting lateral bending movement. In order to obtain the maximum

information from the minimum amount of radiation, we therefore limited this comparative study to motion in the sagittal plane.

Like Tanz, we found considerable variation in lumbar spinal movements between normal individuals, and so each volunteer had to act as his own control. However, because of the radiation involved it was not possible to do a radiographic assessment of four supports in flexion and extension, as well as to make control radiographs, for each volunteer. Norton and Brown circumvented this problem by measuring the angles between Kirschner wires in the spinous processes after making preliminary radiographic measurements, and Lumsden and Morris measured rotation by inserting Steinmann pins in the spinous processes alone. We used different groups of volunteers for the canvas, Raney, and Baycast supports.

A rigid support works on the principle of three-point fixation; optimum restriction of movement is likely to be achieved about halfway along and to decrease toward the ends. This effect is illustrated by the graphs for the Raney and Baycast jackets (Fig. 5). At the caudal end, for example, the pelvis is not effectively controlled by the supports and considerable lumbosacral motion is still possible. The extension of the jacket to include the hip and thigh provides the necessary control of the pelvis and accounts for the effectiveness of the Baycast spica in restricting the movement of the lower part of the lumbosacral spine.

Although only five volunteers were examined, the Baycast spica had a consistent and statistically significant effect on the fourth lumbar-fifth lumbar level ($p < 0.001$) and the lumbosacral level ($p < 0.0005$). At other levels, and at all levels with the other supports, there was great variation between individuals. In these situations, we recommend that, if a support is to be used in the expectation of a particular effect on segmental mobility, the appropriate check radiographs be made, as pointed out by Norton and Brown.

If one of these supports is to be used in the treatment of low-back pain, then the canvas corset has the advantage of comfort while providing abdominal support and some restriction of angular movements of the lumbar spine. There is little to choose between the Raney and Baycast jackets regarding their effect on segmental movements, but the Raney jacket is designed to reduce the lumbar lordosis and can be easily removed. The Baycast spica can be worn for a few weeks to break a painful vicious circle, but for more prolonged use it is too cumbersome. However, the Baycast spica was the most effective in restricting the mobility of the lower part of the lumbosacral spine. This is particularly important if a lumbosacral support is used in the preoperative assessment or postoperative management of a patient with a low-back disorder.

For the best restriction of movement at the fourth lumbar-fifth lumbar level or at the lumbosacral level, preoperatively or postoperatively, we now routinely include the thigh (Baycast spica). Because our study has shown this device to be consistently effective, and also for the purpose of avoiding unnecessary radiation, routine check radiographs in flexion and extension are not made. For restriction of movement at the third lumbar-fourth lumbar level, a carefully molded Baycast jacket is applied but, because of the variation between individuals in our study, we do make flexion-extension radiographs. If these do not show the desired effect, the jacket is replaced by a spica and flexion-extension radiographs are again made for comparison and future correlation. For restriction of movement at the second lumbar-third lumbar level, a Baycast jacket is used along with check radiographs. Plaster of Paris can be substituted for the Baycast jacket, but the weight of the plaster is a particular disadvantage for the spica.

Conclusions

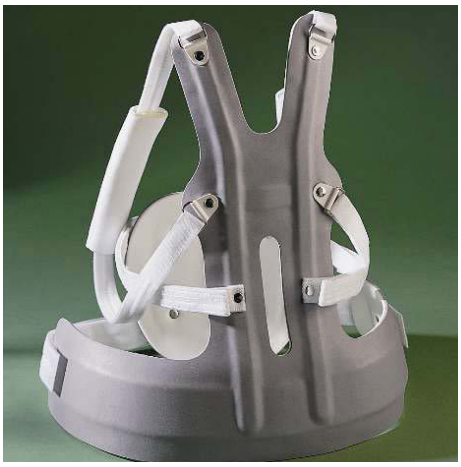
All of the supports that we tested restricted the segmental sagittal movements of the lumbosacral spine, although there was considerable variation between individuals for the canvas corset and for the Raney and Baycast jackets at all levels. Similarly, the Baycast spica showed some variation in its effects at the first lumbar-second lumbar, the second lumbar-third lumbar, and the third lumbar-fourth lumbar levels. However, the Baycast spica was consistent in significantly limiting movement at the fourth lumbar-fifth lumbar level and especially at the lumbosacral level. Furthermore, it was the most effective of the supports that we tested in limiting movement below the third lumbar vertebra, particularly at the fourth lumbar-fifth lumbar level and at the lumbosacral level.

NOTE: The authors would like to thank Dr. B. van der Ende and Dr. van der Stadt for their statistical help, as well as Bayer for supplying the Baycasts and Camp for providing the Raney flexion jackets, and especially the volunteers without whose participation the study would not have been possible.

References

1. AHLGREN, S. A., and HANSEN, T.: The Use of Lumbosacral Corsets Prescribed for Low Back Pain. Prosthet. and Orthot. Internat., **2:** 101-104, 1978.
2. EVANS, ARTHUR: The Palace of Minos at Knossos. Vol. 1, p. 503. London, Macmillan, 1921.
3. EWING, ELIZABETH: Fashion in Underwear, p. 13. London, Batsford, 1971.
4. LUMSDEN, R. M., and MORRIS, J. M.: An *In Vivo* Study of Axial Rotation and Immobilization at the Lumbosacral Joint. J. Bone and Joint Surg., **50-A:** 1591-1602, Dec. 1968.
5. NEW YORK UNIVERSITY, POST-GRADUATE MEDICAL SCHOOL: Prosthetics and Orthotics; Measurement, Layout and Pattern Design for Lumbosacral F-E and L Corsets. Spinal Orthotics including Orthotists' Supplement, pp. 167-196. New York, 1975.
6. NORTON, P. L., and BROWN, THORNTON: The Immobilizing Efficiency of Back Braces. Their Effect on the Posture and Motion of the Lumbosacral Spine. J. Bone and Joint Surg., **39-A:** 111-138, Jan. 1957.
7. PERRY, JACQUELIN: The Use of External Support in the Treatment of Low-Back Pain. Report of the Subcommittee on Orthotics of the Committee on Prosthetic-Orthotic Education, National Academy of Sciences, National Research Council. J. Bone and Joint Surg., **52-A:** 1440-1442, Oct. 1970.
8. RANEY, F.: Royalite Flexion Jacket. Report on the Spinal Orthotics Workshop, pp. 85-91. Sponsored by the Committee on Prosthetics Research and Development of the Division of Engineering of the National Research Council. Washington, D.C., National Research Council, 1969.
9. TANZ, S. S.: Motion of the Lumbar Spine. A Roentgenologic Study. Am. J. Roentgenol., **69:** 399-412, 1953.

HCPCS:	Descriptor:
L0466	TLSO, SAGITTAL CONTROL, RIGID POSTERIOR FRAME AND FLEXIBLE SOFT ANTERIOR APRON WITH STRAPS, CLOSURES AND PADDING, RESTRICTS GROSS TRUNK MOTION IN SAGITTAL PLANE, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON INTERVERTEBRAL DISKS, INCLUDES FITTING AND SHAPING THE FRAME, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Post-surgical stabilization, Traumatic stabilization, Osteoporosis, Compression fractures
Medically Necessary Argument	A rigid posterior paneled TLSO made of either metal or plastic with an apron front with multiple sized options. Posterior section must be appropriately shaped to ensure contact with torso. Depending on the design selected, modifications to ensure an appropriate fit must be done via heat for the plastic model or bending irons or other orthotic specific tools for the metal model. Shaping and contouring require an eye towards clinical need and familiarity in working with different materials. Improper application can result in less than proper function, adverse pressure applied to the spine and surrounding tissue, which could lead to skin breakdown and exacerbation of existing clinical issues. Application of such an orthosis may require follow up care to ensure proper functioning.
References	3

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Method

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TABLE I

MOVEMENT IN THE CANVAS CORSET FOR FIVE VOLUNTEERS (CASES 1 THROUGH 5)

Level	Movement with No Support (*Degrees*)					Movement in the Canvas Corset (*Degrees*)					Percentage Permitted Movement in the Canvas Corset					
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	Mean
L1-L2	15			11	17	9	13		4	10	60			36	59	52*
L2-L3	21	16	11	12	10	11	12	9	10	3	52	75	82	83	30	64†
L3-L4	18	13	17	12	3	7	10	17	10	0	39	77	100	83	0	60‡
L4-L5	15	21	20	13	7	10	10	17	10	2	67	48	85	77	29	61†
L5-S1	13	14	15	14	15	6	7	9	13	10	46	50	60	93	67	63*

* $0.005 > p > 0.001$.
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volunteer acted as his own control. Segmental movement during flexion and extension was determined by means of corresponding lines drawn along the end-plates of each vertebra. The angles between adjacent vertebrae were measured in flexion and in extension, and the difference was recorded as the movement occurring at that level. These segmental angular movements, without and with a support, were determined at each level for all of the volunteers. In order to facilitate comparison of one type of support with another, the angular movements that were permitted by a support were expressed as percentages of the corresponding control unrestricted angular movements and then, for each type of support, the averages (arithmetical means) of these percentages were calculated for each level.

We found that the most accurate method of drawing corresponding lines on the radiographs was first to draw all of the lines on one radiograph. The second radiograph was then placed on top of the first and the shadow of each vertebral body was superimposed in turn over that of the same vertebra on the underlying radiograph while the corresponding lines were traced onto the upper radiograph.

We did not assess the reproducibility of the measurements because it would have been necessary to repeat at least one set of flexion and extension radiographs for the volunteers. In view of the extra radiation involved, we did

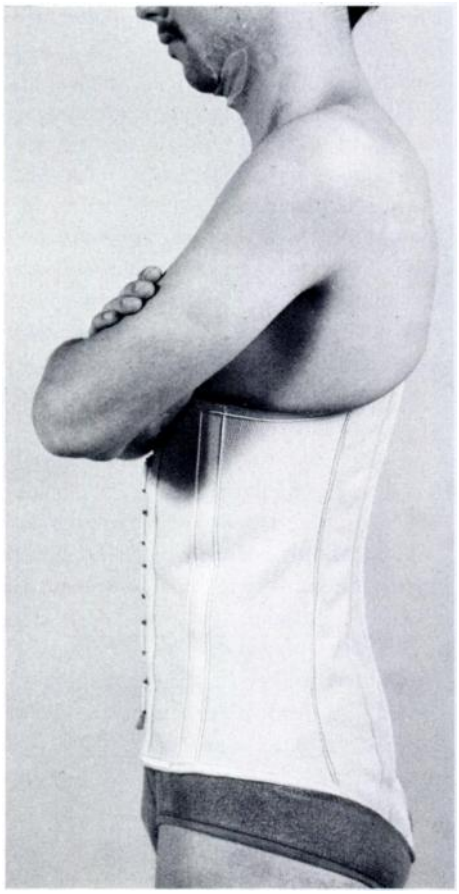

FIG. 1

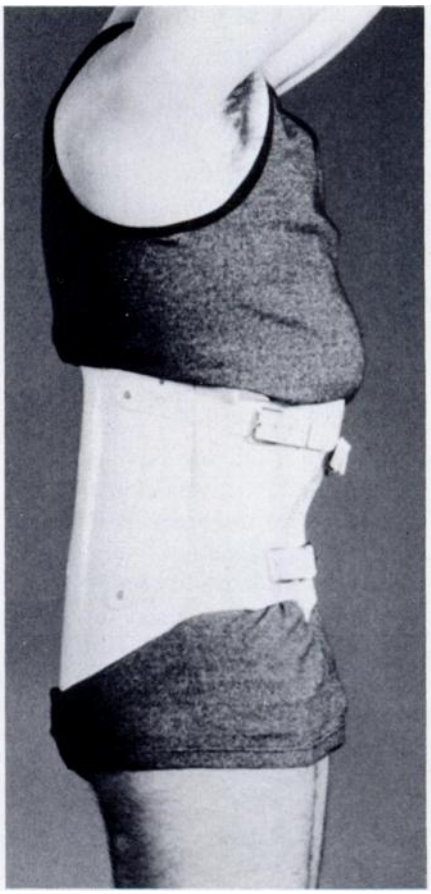

FIG. 2

Fig. 1: Canvas lumbosacral corset.
Fig. 2: Raney flexion jacket.

TABLE II

MOVEMENT IN THE RANEY JACKET FOR FIVE VOLUNTEERS (CASES 6 THROUGH 10)

	Movement with No Support (*Degrees*)					Movement in the Raney Jacket (*Degrees*)					Percentage Permitted Movement in the Raney Jacket					
Level	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10	Mean
L1-L2	15	11	6			2	5	5	7	2	13	45	83			47*
L2-L3	13	15	12	8	15	5	4	1	3	7	38	27	8	38	47	32†
L3-L4	12	12	17	13	13	6	2	1	2	10	50	17	6	15	77	33‡
L4-L5	20	16	15	17	11	6	7	8	12	3	30	44	53	71	27	45§
L5-S1	18	11	13	22	18	13	12	6	5	10	72	109	46	23	56	61¶

* $0.1 > p > 0.05$.
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not think that this was justifiable. Tanz, who also used a superimposition method to calculate the segmental angular movements, found that the results of repeat radiographic examinations usually agreed to within 2 degrees. We assumed that this 2-degree error would be applicable to our series.

Radiation Precautions

The volunteers were healthy thin men whose gonads were screened. They had had minimum previous exposure to radiation and did not come into contact with x-rays during their routine work. One radiographer in each hospital made all of the radiographs to minimize the chance of error. An off-center radiograph was not repeated. This explains the absence of readings at the level of the disc between the first and second lumbar vertebrae for Cases 2, 3, 9, 10, and 11 in Tables I, II, and III. Copies of the radiographs were subsequently given to the volunteers for possible future reference in case they ever had low-back pain in the future. The radiation dose to the lumbar spine was approximately 250 millirads and to the shielded gonads it was ten millirads per radiograph. Baycast absorbs virtually no radiation. Thus, lower radiation doses were possible than would have been necessary if plaster of Paris had been used.

Results

The effect of the supports is shown in Tables I through IV. Almost all of the supports reduced the segmental angular movements of the lumbosacral spine. The exceptions were the canvas corset on Case 3, in whom movement at the third lumbar-fourth lumbar level was unaffected; the Raney jacket on Case 7, in whom there was a 1-degree (9 per cent) increase in angular movement at the

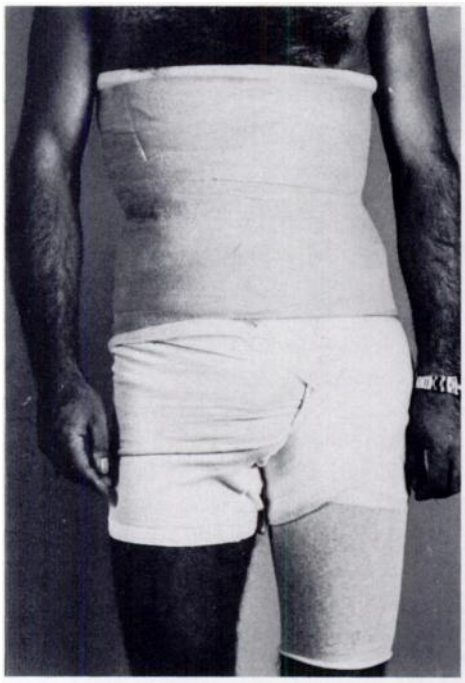

FIG. 3

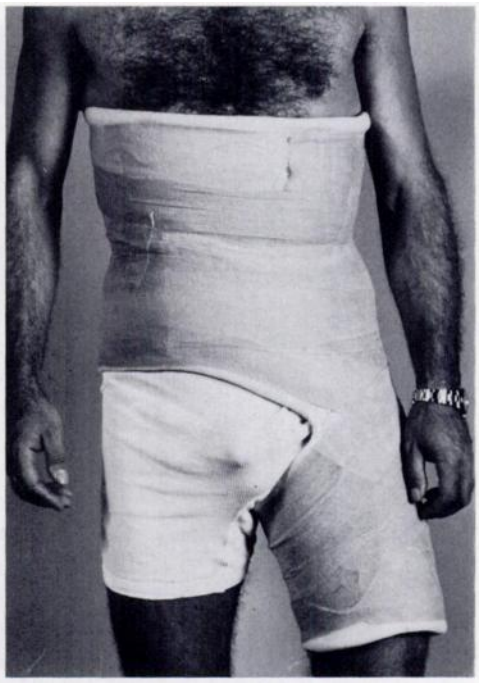

FIG. 4

Fig. 3: Baycast jacket.
Fig. 4: Baycast spica.

TABLE III

MOVEMENT IN THE BAYCAST JACKET AND BAYCAST SPICA FOR FIVE VOLUNTEERS (CASES 11 THROUGH 15)

Level	Movement with No Support (Degrees)					Movement in the Baycast Jacket (Degrees)						Movement in the Baycast Spica (Degrees)					
	11	12	13	14	15	11	12	13	14	15	Mean	11	12	13	14	15	Mean
L1-L2		16	10	10	12	2	7	3	7	8	53%*	4	10	3	7	4	49%†
L2-L3	20	16	17	13	13	2	8	11	5	4	39%‡	2	1	4	12	4	33%†
L3-L4	16	16	11	10	13	2	4	6	6	6	40%†	0	2	6	6	1	27%†
L4-L5	18	22	18	20	12	0	6	13	6	4	32%‡	2	0	3	3	2	12%§
L5-S1	23	22	14	16	17	10	11	14	16	10	70%*	2	0	1	1	3	8%§

* $0.05 > p > 0.01$.
† $0.01 > p > 0.005$.
‡ $0.005 > p > 0.001$.
§ $0.001 > p$.

lumbosacral level; and the Baycast jackets on Cases 13 and 14, in whom the angular movements at the lumbosacral level were unaffected. Although the results showed considerable variation between individuals with regard to the effect of the supports, certain general trends could be discerned. Table IV and Figure 5 summarize the effect of each type of support at each level in the form of the mean percentage of angular movement permitted.

The canvas corset reduced angular movement at each level to approximately two-thirds of normal. The Raney and Baycast jackets were reasonably effective in the mid-part of the lumbar spine, where they reduced the angular movement to about one-third of normal, but at the first lumbar-second lumbar level and the lumbosacral level they had the same effect as the canvas corset. The Baycast spica was the most efficient below the third lumbar vertebra, and was progressively more efficient the lower the level. At the fourth lumbar-fifth lumbar level the Baycast spica permitted an average angular movement of only 2 degrees, or 12 per cent of normal, and a maximum angular movement of 3 degrees. At the lumbosacral level it was even more efficient, permitting an average angular movement of only 1.4 degrees, or 8 per cent of normal, and a maximum angular movement of only 3 degrees. The beneficial effect of the Baycast spica compared with the Baycast jacket in reducing angular movement at the lumbosacral level was statistically significant ($p < 0.001$).

TABLE IV

MEAN AND RANGE OF PERCENTAGE PERMITTED MOVEMENT

Level	Canvas Corset	Raney Jacket	Baycast Jacket	Baycast Spica
L1-L2	52 (36-60)	47 (13-83)	53 (30-70)	49 (30-70)
L2-L3	64 (30-83)	32 (8-47)	39 (10-65)	33 (6-92)
L3-L4	60 (0-100)	33 (6-77)	40 (13-60)	27 (0-60)
L4-L5	61 (29-85)	45 (27-71)	32 (0-72)	12 (0-17)
L5-S1	63 (46-93)	61 (23-109)	70 (43-100)	8 (0-18)

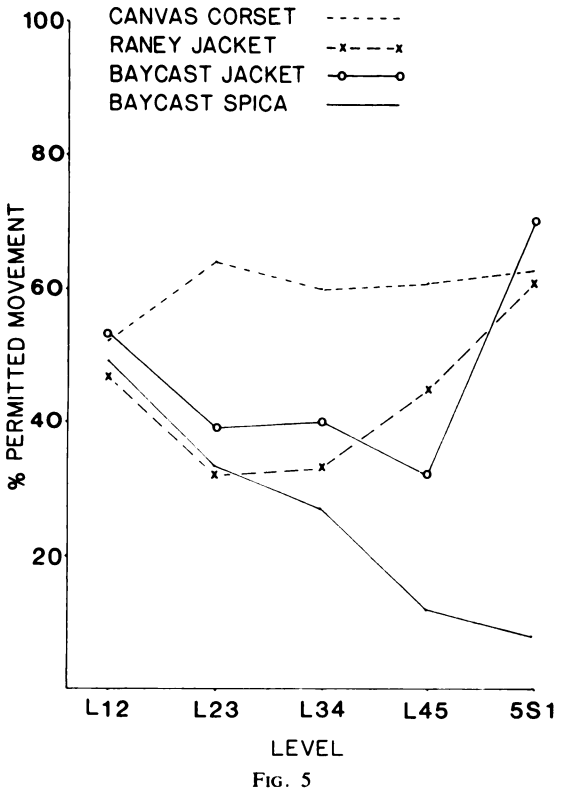

FIG. 5

Graph illustrating the percentage of movement permitted at each level by each type of support.

Discussion

The lumbosacral spinal vertebrae can undergo both translation and angular motion. The latter is caused by lateral bending and flexion-extension or axial rotation movements. Restriction of axial rotation at the lumbosacral level was observed by Lumsden and Morris in subjects wearing a chairback brace, but the effects of lumbosacral canvas corsets were varied and unpredictable. It is probable that the Raney and Baycast jackets, like the chairback brace, would adequately fix the pelvis and similarly control rotation. The cross section of the torso is oval and hence the lateral sides of a spinal support, being farther away from the spine than the back and front, should be more efficient in restricting lateral bending movement than the back and front are in restricting flexion and extension movement. Unless the sides are inadequate, it therefore seems likely that a support that restricts flexion-extension movement would be at least as effective in restricting lateral bending movement. In order to obtain the maximum

information from the minimum amount of radiation, we therefore limited this comparative study to motion in the sagittal plane.

Like Tanz, we found considerable variation in lumbar spinal movements between normal individuals, and so each volunteer had to act as his own control. However, because of the radiation involved it was not possible to do a radiographic assessment of four supports in flexion and extension, as well as to make control radiographs, for each volunteer. Norton and Brown circumvented this problem by measuring the angles between Kirschner wires in the spinous processes after making preliminary radiographic measurements, and Lumsden and Morris measured rotation by inserting Steinmann pins in the spinous processes alone. We used different groups of volunteers for the canvas, Raney, and Baycast supports.

A rigid support works on the principle of three-point fixation; optimum restriction of movement is likely to be achieved about halfway along and to decrease toward the ends. This effect is illustrated by the graphs for the Raney and Baycast jackets (Fig. 5). At the caudal end, for example, the pelvis is not effectively controlled by the supports and considerable lumbosacral motion is still possible. The extension of the jacket to include the hip and thigh provides the necessary control of the pelvis and accounts for the effectiveness of the Baycast spica in restricting the movement of the lower part of the lumbosacral spine.

Although only five volunteers were examined, the Baycast spica had a consistent and statistically significant effect on the fourth lumbar-fifth lumbar level ($p < 0.001$) and the lumbosacral level ($p < 0.0005$). At other levels, and at all levels with the other supports, there was great variation between individuals. In these situations, we recommend that, if a support is to be used in the expectation of a particular effect on segmental mobility, the appropriate check radiographs be made, as pointed out by Norton and Brown.

If one of these supports is to be used in the treatment of low-back pain, then the canvas corset has the advantage of comfort while providing abdominal support and some restriction of angular movements of the lumbar spine. There is little to choose between the Raney and Baycast jackets regarding their effect on segmental movements, but the Raney jacket is designed to reduce the lumbar lordosis and can be easily removed. The Baycast spica can be worn for a few weeks to break a painful vicious circle, but for more prolonged use it is too cumbersome. However, the Baycast spica was the most effective in restricting the mobility of the lower part of the lumbosacral spine. This is particularly important if a lumbosacral support is used in the preoperative assessment or postoperative management of a patient with a low-back disorder.

For the best restriction of movement at the fourth lumbar-fifth lumbar level or at the lumbosacral level, preoperatively or postoperatively, we now routinely include the thigh (Baycast spica). Because our study has shown this device to be consistently effective, and also for the purpose of avoiding unnecessary radiation, routine check radiographs in flexion and extension are not made. For restriction of movement at the third lumbar-fourth lumbar level, a carefully molded Baycast jacket is applied but, because of the variation between individuals in our study, we do make flexion-extension radiographs. If these do not show the desired effect, the jacket is replaced by a spica and flexion-extension radiographs are again made for comparison and future correlation. For restriction of movement at the second lumbar-third lumbar level, a Baycast jacket is used along with check radiographs. Plaster of Paris can be substituted for the Baycast jacket, but the weight of the plaster is a particular disadvantage for the spica.

Conclusions

All of the supports that we tested restricted the segmental sagittal movements of the lumbosacral spine, although there was considerable variation between individuals for the canvas corset and for the Raney and Baycast jackets at all levels. Similarly, the Baycast spica showed some variation in its effects at the first lumbar-second lumbar, the second lumbar-third lumbar, and the third lumbar-fourth lumbar levels. However, the Baycast spica was consistent in significantly limiting movement at the fourth lumbar-fifth lumbar level and especially at the lumbosacral level. Furthermore, it was the most effective of the supports that we tested in limiting movement below the third lumbar vertebra, particularly at the fourth lumbar-fifth lumbar level and at the lumbosacral level.

NOTE: The authors would like to thank Dr. B. van der Ende and Dr. van der Stadt for their statistical help, as well as Bayer for supplying the Baycasts and Camp for providing the Raney flexion jackets, and especially the volunteers without whose participation the study would not have been possible.

References

1. AHLGREN, S. A., and HANSEN, T.: The Use of Lumbosacral Corsets Prescribed for Low Back Pain. Prosthet. and Orthot. Internat., **2:** 101-104, 1978.
2. EVANS, ARTHUR: The Palace of Minos at Knossos. Vol. 1, p. 503. London, Macmillan, 1921.
3. EWING, ELIZABETH: Fashion in Underwear, p. 13. London, Batsford, 1971.
4. LUMSDEN, R. M., and MORRIS, J. M.: An *In Vivo* Study of Axial Rotation and Immobilization at the Lumbosacral Joint. J. Bone and Joint Surg., **50-A:** 1591-1602, Dec. 1968.
5. NEW YORK UNIVERSITY, POST-GRADUATE MEDICAL SCHOOL: Prosthetics and Orthotics; Measurement, Layout and Pattern Design for Lumbosacral F-E and L Corsets. Spinal Orthotics including Orthotists' Supplement, pp. 167-196. New York, 1975.
6. NORTON, P. L., and BROWN, THORNTON: The Immobilizing Efficiency of Back Braces. Their Effect on the Posture and Motion of the Lumbosacral Spine. J. Bone and Joint Surg., **39-A:** 111-138, Jan. 1957.
7. PERRY, JACQUELIN: The Use of External Support in the Treatment of Low-Back Pain. Report of the Subcommittee on Orthotics of the Committee on Prosthetic-Orthotic Education, National Academy of Sciences, National Research Council. J. Bone and Joint Surg., **52-A:** 1440-1442, Oct. 1970.
8. RANEY, F.: Royalite Flexion Jacket. Report on the Spinal Orthotics Workshop, pp. 85-91. Sponsored by the Committee on Prosthetics Research and Development of the Division of Engineering of the National Research Council. Washington, D.C., National Research Council, 1969.
9. TANZ, S. S.: Motion of the Lumbar Spine. A Roentgenologic Study. Am. J. Roentgenol., **69:** 399-412, 1953.

HCPCS:	Descriptor:
L0468	TLSO, SAGITTAL-CORONAL CONTROL, RIGID POSTERIOR FRAME AND FLEXIBLE SOFT ANTERIOR APRON WITH STRAPS, CLOSURES AND PADDING, EXTENDS FROM SACROCOCCYGEAL JUNCTION OVER SCAPULAE, LATERAL STRENGTH PROVIDED BY PELVIC, THORACIC, AND LATERAL FRAME PIECES, RESTRICTS GROSS TRUNK MOTION IN SAGITTAL, AND CORONAL PLANES, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON INTERVERTEBRAL DISKS, INCLUDES FITTING AND SHAPING THE FRAME, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Post-surgical stabilization, Traumatic stabilization, Osteoporosis, Compression fractures
Medically Necessary Argument	A rigid posterior paneled TLSO made of either metal or plastic with an apron front and the additional support of rigid lateral frames to increase the functional stability, this rigid posterior paneled TLSO is made of either metal or plastic with an apron front with multiple sized options. Posterior section must be appropriately shaped to ensure contact with torso. Depending on the design selected, modifications to ensure an appropriate fit must be done via heat for the plastic model or bending irons or other orthotic specific tools for the metal model. Shaping and contouring require an eye towards clinical need and familiarity in working with different materials. Improper application can result in less than proper function, adverse pressure applied to the spine and surrounding tissue, which could lead to skin breakdown and exacerbation of existing clinical issues. Application of such an orthosis may require follow up care to ensure proper functioning.
References	3

The Effect of Four Types of Support on the Segmental Mobility of the Lumbosacral Spine

BY M. W. FIDLER, F.R.C.S.*, AND C. M. T. PLASMANS, M.D.†, AMSTERDAM, THE NETHERLANDS

From the Slotervaart Ziekenhuis and O.L.V. Gasthuis, Amsterdam

ABSTRACT: **With the aid of flexion-extension lateral radiographs, we investigated the effect of the canvas corset, the Raney and Baycast jackets, and the Baycast spica on the segmental sagittal mobility of the lumbosacral spine in separate groups of five volunteers each. The canvas corset reduced the mean angular movements at each level to two-thirds of normal. The Raney and Baycast jackets reduced the mean angular movements in the middle of the lumbar spine to approximately one-third of normal. The Baycast spica was the most effective in restricting angular movements below the third lumbar vertebra, and especially at the fourth lumbar-fifth lumbar level and the lumbosacral level.**

Lumbosacral corsets have been in use at least since the Minoan period, some 2000 years B.C.[2]. The function of those corsets was primarily to mold and enhance the female form, but their construction could also have served to support the lumbosacral spine. The first surgical corset that was specifically designed to support the lumbar spine was probably that made in 1530 for Catherine of Medici[3]. This was an iron corset, extending from the mid-part of the thorax to over the iliac crests, hinged down one side and fastened by a clasp on the other.

Lumbosacral supports are now commonly prescribed in the management of low-back pain[1,7] and are used to judge the effect of immobilization when considering spine fusion or postoperatively to support the spine until fusion occurs. By means of a questionnaire, Perry reviewed the use of supports in America and found that the lumbosacral corset was the most widely used, followed closely by the chairback brace. The effect most often expected from a brace was restriction of lumbosacral motion — this in spite of the fact that Norton and Brown as well as Lumsden and Morris had observed that in some patients a support actually could lead to an increase in movement at the lumbosacral level. It seems that there is still a tendency to prescribe a support for the lumbosacral spine without focusing attention specifically on the level concerned.

We use mainly four types of lumbosacral support. The lumbosacral canvas corset with posterior steel supports (Fig. 1), the Raney[8] flexion jacket (Fig. 2), and the Baycast (Cuttercast) jacket (Fig. 3) are used principally in the treatment of low-back pain, and the Baycast jacket with inclusion of the left thigh (Baycast spica) (Fig. 4) is used chiefly when considering fusion and postoperatively. The thigh is included in order to improve control of the pelvis.

The purpose of this investigation was to assess and compare the effects of these supports on the segmental sagittal mobility of the lumbosacral spine.

Material

Each type of support was assessed on five healthy male volunteers, none of whom had a history of low-back pain.

The canvas lumbosacral corsets were made to measure for each volunteer in the routine manner used for patients with lumbosacral disorders by the orthotist in the Slotervaart Hospital. The pattern used was a minor modification of that described in the spinal orthotics manual of the New York University Post-Graduate Medical School[5]. The lower edge of the corset was trimmed posteriorly at seat level with the subject sitting on a stool, thus avoiding the uncomfortable curled lip that can occur with the slightly lower edge described in the manual. The corset extended from around the lower ribs to over the iliac crest laterally, to just above the symphysis pubis anteriorly, and included the sacrum and upper part of the buttocks posteriorly. Each corset was reinforced with two posterior vertical steel stays stitched between the layers of the canvas.

The Raney flexion jackets were standard models of appropriate size for the volunteers.

The Baycast jackets were applied on standing volunteers by the same orthotist. These jackets extended from two centimeters below the shoulder blades to the mid-part of the sacrum posteriorly, from the xiphisternum to just above the pubis anteriorly, and from around the lower ribs to three centimeters below the level of the anterior superior iliac spines laterally. The left thigh was subsequently included to produce the Baycast spica on these same volunteers. The thigh-piece extended to five centimeters proximal to the patella and was added with the hip in 20 degrees of flexion in order to prevent any fixed lumbar lordosis and to facilitate sitting.

Method

Using a uniform technique lateral radiographs of the lumbosacral spine were made in maximum flexion and extension, first without and then with the support so that each

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	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	Mean
L1-L2	15			11	17	9	13		4	10	60			36	59	52*
L2-L3	21	16	11	12	10	11	12	9	10	3	52	75	82	83	30	64†
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L5-S1	13	14	15	14	15	6	7	9	13	10	46	50	60	93	67	63*

* $0.005 > p > 0.001$.
† $0.05 > p > 0.01$.
‡ $0.1 > p > 0.05$.

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We found that the most accurate method of drawing corresponding lines on the radiographs was first to draw all of the lines on one radiograph. The second radiograph was then placed on top of the first and the shadow of each vertebral body was superimposed in turn over that of the same vertebra on the underlying radiograph while the corresponding lines were traced onto the upper radiograph.

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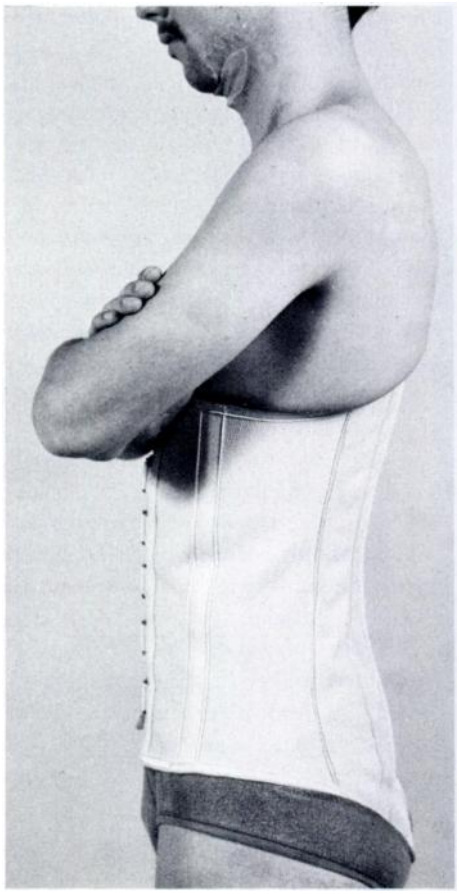

FIG. 1

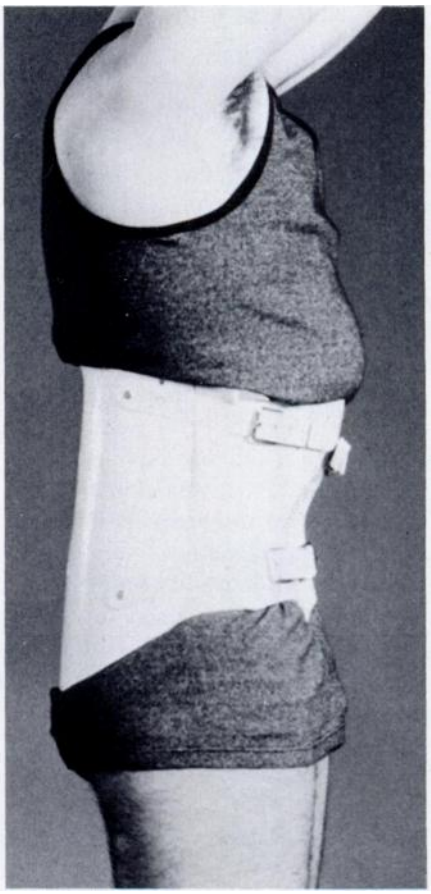

FIG. 2

Fig. 1: Canvas lumbosacral corset.
Fig. 2: Raney flexion jacket.

TABLE II

MOVEMENT IN THE RANEY JACKET FOR FIVE VOLUNTEERS (CASES 6 THROUGH 10)

Level	Movement with No Support (*Degrees*)					Movement in the Raney Jacket (*Degrees*)					Percentage Permitted Movement in the Raney Jacket					
	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10	Mean
L1-L2	15	11	6			2	5	5	7	2	13	45	83			47*
L2-L3	13	15	12	8	15	5	4	1	3	7	38	27	8	38	47	32†
L3-L4	12	12	17	13	13	6	2	1	2	10	50	17	6	15	77	33‡
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Radiation Precautions

The volunteers were healthy thin men whose gonads were screened. They had had minimum previous exposure to radiation and did not come into contact with x-rays during their routine work. One radiographer in each hospital made all of the radiographs to minimize the chance of error. An off-center radiograph was not repeated. This explains the absence of readings at the level of the disc between the first and second lumbar vertebrae for Cases 2, 3, 9, 10, and 11 in Tables I, II, and III. Copies of the radiographs were subsequently given to the volunteers for possible future reference in case they ever had low-back pain in the future. The radiation dose to the lumbar spine was approximately 250 millirads and to the shielded gonads it was ten millirads per radiograph. Baycast absorbs virtually no radiation. Thus, lower radiation doses were possible than would have been necessary if plaster of Paris had been used.

Results

The effect of the supports is shown in Tables I through IV. Almost all of the supports reduced the segmental angular movements of the lumbosacral spine. The exceptions were the canvas corset on Case 3, in whom movement at the third lumbar-fourth lumbar level was unaffected; the Raney jacket on Case 7, in whom there was a 1-degree (9 per cent) increase in angular movement at the

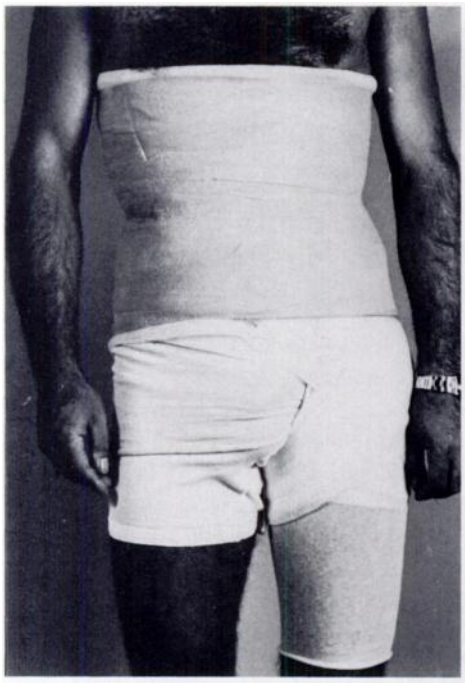

FIG. 3

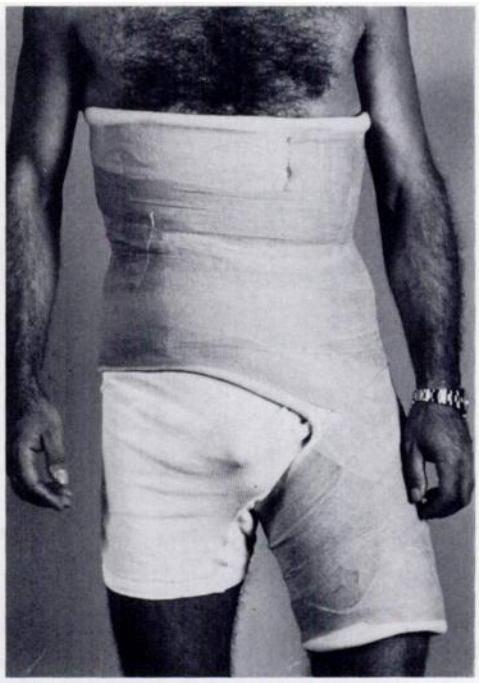

FIG. 4

Fig. 3: Baycast jacket.
Fig. 4: Baycast spica.

TABLE III

MOVEMENT IN THE BAYCAST JACKET AND BAYCAST SPICA FOR FIVE VOLUNTEERS (CASES 11 THROUGH 15)

Level	Movement with No Support (Degrees)					Movement in the Baycast Jacket (Degrees)						Movement in the Baycast Spica (Degrees)					
	11	12	13	14	15	11	12	13	14	15	Mean	11	12	13	14	15	Mean
L1-L2		16	10	10	12	2	7	3	7	8	53%*	4	10	3	7	4	49%†
L2-L3	20	16	17	13	13	2	8	11	5	4	39%‡	2	1	4	12	4	33%†
L3-L4	16	16	11	10	13	2	4	6	6	6	40%†	0	2	6	6	1	27%†
L4-L5	18	22	18	20	12	0	6	13	6	4	32%‡	2	0	3	3	2	12%§
L5-S1	23	22	14	16	17	10	11	14	16	10	70%*	2	0	1	1	3	8%§

* $0.05 > p > 0.01$.
† $0.01 > p > 0.005$.
‡ $0.005 > p > 0.001$.
§ $0.001 > p$.

lumbosacral level; and the Baycast jackets on Cases 13 and 14, in whom the angular movements at the lumbosacral level were unaffected. Although the results showed considerable variation between individuals with regard to the effect of the supports, certain general trends could be discerned. Table IV and Figure 5 summarize the effect of each type of support at each level in the form of the mean percentage of angular movement permitted.

The canvas corset reduced angular movement at each level to approximately two-thirds of normal. The Raney and Baycast jackets were reasonably effective in the mid-part of the lumbar spine, where they reduced the angular movement to about one-third of normal, but at the first lumbar-second lumbar level and the lumbosacral level they had the same effect as the canvas corset. The Baycast spica was the most efficient below the third lumbar vertebra, and was progressively more efficient the lower the level. At the fourth lumbar-fifth lumbar level the Baycast spica permitted an average angular movement of only 2 degrees, or 12 per cent of normal, and a maximum angular movement of 3 degrees. At the lumbosacral level it was even more efficient, permitting an average angular movement of only 1.4 degrees, or 8 per cent of normal, and a maximum angular movement of only 3 degrees. The beneficial effect of the Baycast spica compared with the Baycast jacket in reducing angular movement at the lumbosacral level was statistically significant ($p < 0.001$).

TABLE IV

MEAN AND RANGE OF PERCENTAGE PERMITTED MOVEMENT

Level	Canvas Corset	Raney Jacket	Baycast Jacket	Baycast Spica
L1-L2	52 (36-60)	47 (13-83)	53 (30-70)	49 (30-70)
L2-L3	64 (30-83)	32 (8-47)	39 (10-65)	33 (6-92)
L3-L4	60 (0-100)	33 (6-77)	40 (13-60)	27 (0-60)
L4-L5	61 (29-85)	45 (27-71)	32 (0-72)	12 (0-17)
L5-S1	63 (46-93)	61 (23-109)	70 (43-100)	8 (0-18)

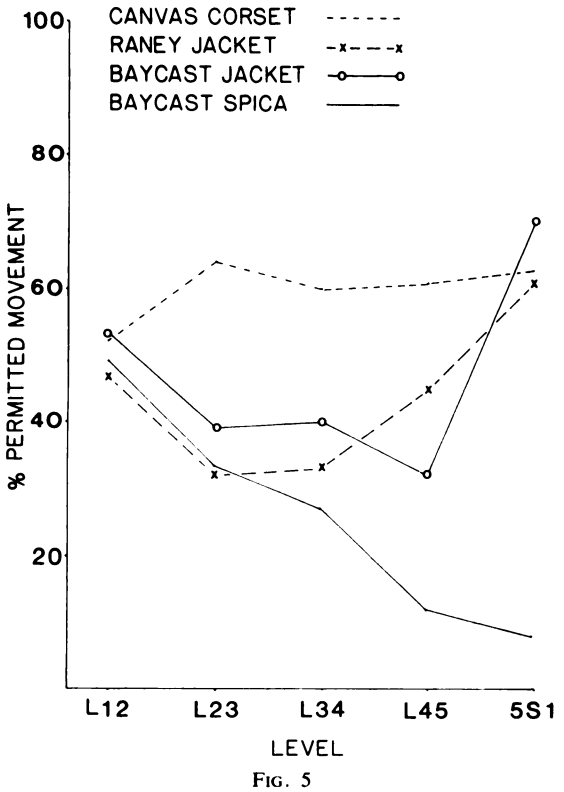

FIG. 5

Graph illustrating the percentage of movement permitted at each level by each type of support.

Discussion

The lumbosacral spinal vertebrae can undergo both translation and angular motion. The latter is caused by lateral bending and flexion-extension or axial rotation movements. Restriction of axial rotation at the lumbosacral level was observed by Lumsden and Morris in subjects wearing a chairback brace, but the effects of lumbosacral canvas corsets were varied and unpredictable. It is probable that the Raney and Baycast jackets, like the chairback brace, would adequately fix the pelvis and similarly control rotation. The cross section of the torso is oval and hence the lateral sides of a spinal support, being farther away from the spine than the back and front, should be more efficient in restricting lateral bending movement than the back and front are in restricting flexion and extension movement. Unless the sides are inadequate, it therefore seems likely that a support that restricts flexion-extension movement would be at least as effective in restricting lateral bending movement. In order to obtain the maximum

information from the minimum amount of radiation, we therefore limited this comparative study to motion in the sagittal plane.

Like Tanz, we found considerable variation in lumbar spinal movements between normal individuals, and so each volunteer had to act as his own control. However, because of the radiation involved it was not possible to do a radiographic assessment of four supports in flexion and extension, as well as to make control radiographs, for each volunteer. Norton and Brown circumvented this problem by measuring the angles between Kirschner wires in the spinous processes after making preliminary radiographic measurements, and Lumsden and Morris measured rotation by inserting Steinmann pins in the spinous processes alone. We used different groups of volunteers for the canvas, Raney, and Baycast supports.

A rigid support works on the principle of three-point fixation; optimum restriction of movement is likely to be achieved about halfway along and to decrease toward the ends. This effect is illustrated by the graphs for the Raney and Baycast jackets (Fig. 5). At the caudal end, for example, the pelvis is not effectively controlled by the supports and considerable lumbosacral motion is still possible. The extension of the jacket to include the hip and thigh provides the necessary control of the pelvis and accounts for the effectiveness of the Baycast spica in restricting the movement of the lower part of the lumbosacral spine.

Although only five volunteers were examined, the Baycast spica had a consistent and statistically significant effect on the fourth lumbar-fifth lumbar level ($p < 0.001$) and the lumbosacral level ($p < 0.0005$). At other levels, and at all levels with the other supports, there was great variation between individuals. In these situations, we recommend that, if a support is to be used in the expectation of a particular effect on segmental mobility, the appropriate check radiographs be made, as pointed out by Norton and Brown.

If one of these supports is to be used in the treatment of low-back pain, then the canvas corset has the advantage of comfort while providing abdominal support and some restriction of angular movements of the lumbar spine. There is little to choose between the Raney and Baycast jackets regarding their effect on segmental movements, but the Raney jacket is designed to reduce the lumbar lordosis and can be easily removed. The Baycast spica can be worn for a few weeks to break a painful vicious circle, but for more prolonged use it is too cumbersome. However, the Baycast spica was the most effective in restricting the mobility of the lower part of the lumbosacral spine. This is particularly important if a lumbosacral support is used in the preoperative assessment or postoperative management of a patient with a low-back disorder.

For the best restriction of movement at the fourth lumbar-fifth lumbar level or at the lumbosacral level, preoperatively or postoperatively, we now routinely include the thigh (Baycast spica). Because our study has shown this device to be consistently effective, and also for the purpose of avoiding unnecessary radiation, routine check radiographs in flexion and extension are not made. For restriction of movement at the third lumbar-fourth lumbar level, a carefully molded Baycast jacket is applied but, because of the variation between individuals in our study, we do make flexion-extension radiographs. If these do not show the desired effect, the jacket is replaced by a spica and flexion-extension radiographs are again made for comparison and future correlation. For restriction of movement at the second lumbar-third lumbar level, a Baycast jacket is used along with check radiographs. Plaster of Paris can be substituted for the Baycast jacket, but the weight of the plaster is a particular disadvantage for the spica.

Conclusions

All of the supports that we tested restricted the segmental sagittal movements of the lumbosacral spine, although there was considerable variation between individuals for the canvas corset and for the Raney and Baycast jackets at all levels. Similarly, the Baycast spica showed some variation in its effects at the first lumbar-second lumbar, the second lumbar-third lumbar, and the third lumbar-fourth lumbar levels. However, the Baycast spica was consistent in significantly limiting movement at the fourth lumbar-fifth lumbar level and especially at the lumbosacral level. Furthermore, it was the most effective of the supports that we tested in limiting movement below the third lumbar vertebra, particularly at the fourth lumbar-fifth lumbar level and at the lumbosacral level.

NOTE: The authors would like to thank Dr. B. van der Ende and Dr. van der Stadt for their statistical help, as well as Bayer for supplying the Baycasts and Camp for providing the Raney flexion jackets, and especially the volunteers without whose participation the study would not have been possible.

References

1. AHLGREN, S. A., and HANSEN, T.: The Use of Lumbosacral Corsets Prescribed for Low Back Pain. Prosthet. and Orthot. Internat., **2:** 101-104, 1978.
2. EVANS, ARTHUR: The Palace of Minos at Knossos. Vol. 1, p. 503. London, Macmillan, 1921.
3. EWING, ELIZABETH: Fashion in Underwear, p. 13. London, Batsford, 1971.
4. LUMSDEN, R. M., and MORRIS, J. M.: An *In Vivo* Study of Axial Rotation and Immobilization at the Lumbosacral Joint. J. Bone and Joint Surg., **50-A:** 1591-1602, Dec. 1968.
5. NEW YORK UNIVERSITY, POST-GRADUATE MEDICAL SCHOOL: Prosthetics and Orthotics; Measurement, Layout and Pattern Design for Lumbosacral F-E and L Corsets. Spinal Orthotics including Orthotists' Supplement, pp. 167-196. New York, 1975.
6. NORTON, P. L., and BROWN, THORNTON: The Immobilizing Efficiency of Back Braces. Their Effect on the Posture and Motion of the Lumbosacral Spine. J. Bone and Joint Surg., **39-A:** 111-138, Jan. 1957.
7. PERRY, JACQUELIN: The Use of External Support in the Treatment of Low-Back Pain. Report of the Subcommittee on Orthotics of the Committee on Prosthetic-Orthotic Education, National Academy of Sciences, National Research Council. J. Bone and Joint Surg., **52-A:** 1440-1442, Oct. 1970.
8. RANEY, F.: Royalite Flexion Jacket. Report on the Spinal Orthotics Workshop, pp. 85-91. Sponsored by the Committee on Prosthetics Research and Development of the Division of Engineering of the National Research Council. Washington, D.C., National Research Council, 1969.
9. TANZ, S. S.: Motion of the Lumbar Spine. A Roentgenologic Study. Am. J. Roentgenol., **69:** 399-412, 1953.

HCPCS:	Descriptor:
L0623	SACROILIAC ORTHOSIS, PROVIDES PELVIC-SACRAL SUPPORT, WITH RIGID OR SEMI-RIGID PANELS OVER THE SACRUM AND ABDOMEN, REDUCES MOTION ABOUT THE SACROILIAC JOINT, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
NO	NO	YES	NO	YES

Sample Diagnosis (Not Inclusive)	Sacroiliac impingement, Sacroiliac syndrome, Sacroiliac joint pain, Sacroiliitis, pregnancy and post pregnancy complications
Medically Necessary Argument	There are a range of sizes. It includes anterior and posterior panels, which must be positioned properly and would provide more restrictive in motion. This device must be worn properly in order for it to function. Proper sizing is important and the patient must be educated on this proper positioning and warning signs.
References	3

The Effect of Four Types of Support on the Segmental Mobility of the Lumbosacral Spine

BY M. W. FIDLER, F.R.C.S.*, AND C. M. T. PLASMANS, M.D.†, AMSTERDAM, THE NETHERLANDS

From the Slotervaart Ziekenhuis and O.L.V. Gasthuis, Amsterdam

ABSTRACT: **With the aid of flexion-extension lateral radiographs, we investigated the effect of the canvas corset, the Raney and Baycast jackets, and the Baycast spica on the segmental sagittal mobility of the lumbosacral spine in separate groups of five volunteers each. The canvas corset reduced the mean angular movements at each level to two-thirds of normal. The Raney and Baycast jackets reduced the mean angular movements in the middle of the lumbar spine to approximately one-third of normal. The Baycast spica was the most effective in restricting angular movements below the third lumbar vertebra, and especially at the fourth lumbar-fifth lumbar level and the lumbosacral level.**

Lumbosacral corsets have been in use at least since the Minoan period, some 2000 years B.C.[2]. The function of those corsets was primarily to mold and enhance the female form, but their construction could also have served to support the lumbosacral spine. The first surgical corset that was specifically designed to support the lumbar spine was probably that made in 1530 for Catherine of Medici[3]. This was an iron corset, extending from the mid-part of the thorax to over the iliac crests, hinged down one side and fastened by a clasp on the other.

Lumbosacral supports are now commonly prescribed in the management of low-back pain[1,7] and are used to judge the effect of immobilization when considering spine fusion or postoperatively to support the spine until fusion occurs. By means of a questionnaire, Perry reviewed the use of supports in America and found that the lumbosacral corset was the most widely used, followed closely by the chairback brace. The effect most often expected from a brace was restriction of lumbosacral motion — this in spite of the fact that Norton and Brown as well as Lumsden and Morris had observed that in some patients a support actually could lead to an increase in movement at the lumbosacral level. It seems that there is still a tendency to prescribe a support for the lumbosacral spine without focusing attention specifically on the level concerned.

We use mainly four types of lumbosacral support. The lumbosacral canvas corset with posterior steel supports (Fig. 1), the Raney[8] flexion jacket (Fig. 2), and the Baycast (Cuttercast) jacket (Fig. 3) are used principally in the treatment of low-back pain, and the Baycast jacket with inclusion of the left thigh (Baycast spica) (Fig. 4) is used chiefly when considering fusion and postoperatively. The thigh is included in order to improve control of the pelvis.

The purpose of this investigation was to assess and compare the effects of these supports on the segmental sagittal mobility of the lumbosacral spine.

Material

Each type of support was assessed on five healthy male volunteers, none of whom had a history of low-back pain.

The canvas lumbosacral corsets were made to measure for each volunteer in the routine manner used for patients with lumbosacral disorders by the orthotist in the Slotervaart Hospital. The pattern used was a minor modification of that described in the spinal orthotics manual of the New York University Post-Graduate Medical School[5]. The lower edge of the corset was trimmed posteriorly at seat level with the subject sitting on a stool, thus avoiding the uncomfortable curled lip that can occur with the slightly lower edge described in the manual. The corset extended from around the lower ribs to over the iliac crest laterally, to just above the symphysis pubis anteriorly, and included the sacrum and upper part of the buttocks posteriorly. Each corset was reinforced with two posterior vertical steel stays stitched between the layers of the canvas.

The Raney flexion jackets were standard models of appropriate size for the volunteers.

The Baycast jackets were applied on standing volunteers by the same orthotist. These jackets extended from two centimeters below the shoulder blades to the mid-part of the sacrum posteriorly, from the xiphisternum to just above the pubis anteriorly, and from around the lower ribs to three centimeters below the level of the anterior superior iliac spines laterally. The left thigh was subsequently included to produce the Baycast spica on these same volunteers. The thigh-piece extended to five centimeters proximal to the patella and was added with the hip in 20 degrees of flexion in order to prevent any fixed lumbar lordosis and to facilitate sitting.

Method

Using a uniform technique lateral radiographs of the lumbosacral spine were made in maximum flexion and extension, first without and then with the support so that each

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† O.L.V. Gasthuis, Amsterdam, the Netherlands.

TABLE I

MOVEMENT IN THE CANVAS CORSET FOR FIVE VOLUNTEERS (CASES 1 THROUGH 5)

Level	Movement with No Support (*Degrees*)					Movement in the Canvas Corset (*Degrees*)					Percentage Permitted Movement in the Canvas Corset					
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	Mean
L1-L2	15			11	17	9	13		4	10	60			36	59	52*
L2-L3	21	16	11	12	10	11	12	9	10	3	52	75	82	83	30	64†
L3-L4	18	13	17	12	3	7	10	17	10	0	39	77	100	83	0	60‡
L4-L5	15	21	20	13	7	10	10	17	10	2	67	48	85	77	29	61†
L5-S1	13	14	15	14	15	6	7	9	13	10	46	50	60	93	67	63*

* $0.005 > p > 0.001$.
† $0.05 > p > 0.01$.
‡ $0.1 > p > 0.05$.

volunteer acted as his own control. Segmental movement during flexion and extension was determined by means of corresponding lines drawn along the end-plates of each vertebra. The angles between adjacent vertebrae were measured in flexion and in extension, and the difference was recorded as the movement occurring at that level. These segmental angular movements, without and with a support, were determined at each level for all of the volunteers. In order to facilitate comparison of one type of support with another, the angular movements that were permitted by a support were expressed as percentages of the corresponding control unrestricted angular movements and then, for each type of support, the averages (arithmetical means) of these percentages were calculated for each level.

We found that the most accurate method of drawing corresponding lines on the radiographs was first to draw all of the lines on one radiograph. The second radiograph was then placed on top of the first and the shadow of each vertebral body was superimposed in turn over that of the same vertebra on the underlying radiograph while the corresponding lines were traced onto the upper radiograph.

We did not assess the reproducibility of the measurements because it would have been necessary to repeat at least one set of flexion and extension radiographs for the volunteers. In view of the extra radiation involved, we did

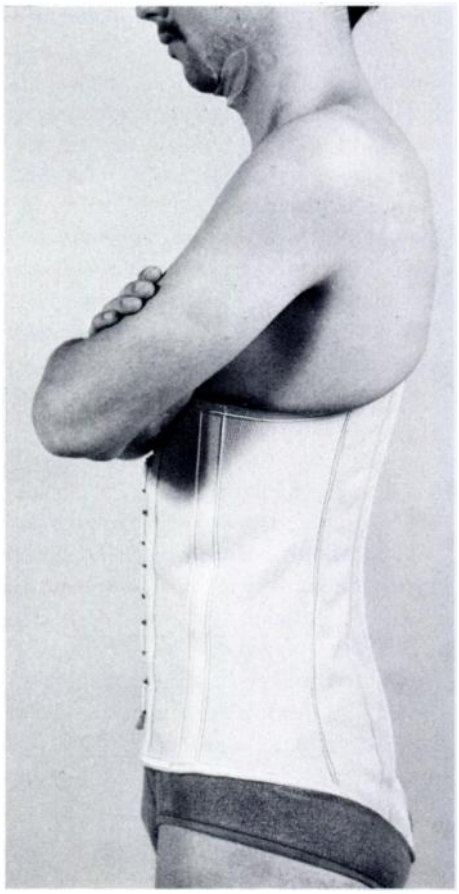

FIG. 1

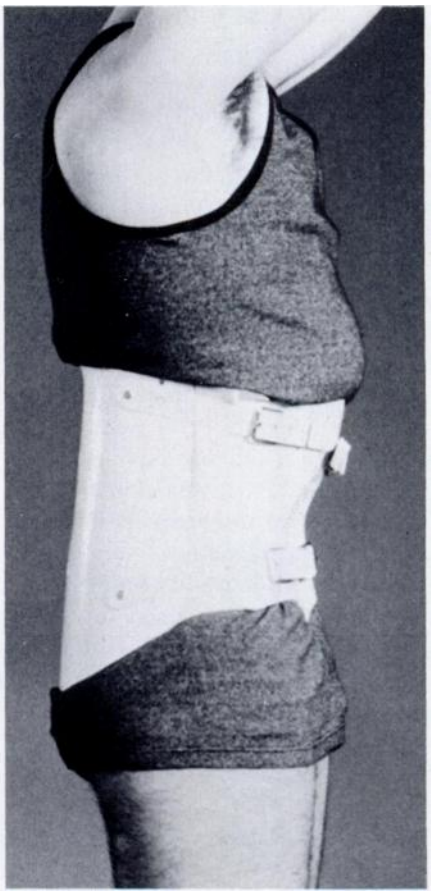

FIG. 2

Fig. 1: Canvas lumbosacral corset.
Fig. 2: Raney flexion jacket.

TABLE II

MOVEMENT IN THE RANEY JACKET FOR FIVE VOLUNTEERS (CASES 6 THROUGH 10)

	Movement with No Support (*Degrees*)					Movement in the Raney Jacket (*Degrees*)					Percentage Permitted Movement in the Raney Jacket					
Level	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10	Mean
L1-L2	15	11	6			2	5	5	7	2	13	45	83			47*
L2-L3	13	15	12	8	15	5	4	1	3	7	38	27	8	38	47	32†
L3-L4	12	12	17	13	13	6	2	1	2	10	50	17	6	15	77	33‡
L4-L5	20	16	15	17	11	6	7	8	12	3	30	44	53	71	27	45§
L5-S1	18	11	13	22	18	13	12	6	5	10	72	109	46	23	56	61¶

* $0.1 > p > 0.05$.
† $0.001 > p$.
‡ $0.01 > p > 0.005$.
§ $0.005 > p > 0.001$.
¶ $0.05 > p > 0.01$.

not think that this was justifiable. Tanz, who also used a superimposition method to calculate the segmental angular movements, found that the results of repeat radiographic examinations usually agreed to within 2 degrees. We assumed that this 2-degree error would be applicable to our series.

Radiation Precautions

The volunteers were healthy thin men whose gonads were screened. They had had minimum previous exposure to radiation and did not come into contact with x-rays during their routine work. One radiographer in each hospital made all of the radiographs to minimize the chance of error. An off-center radiograph was not repeated. This explains the absence of readings at the level of the disc between the first and second lumbar vertebrae for Cases 2, 3, 9, 10, and 11 in Tables I, II, and III. Copies of the radiographs were subsequently given to the volunteers for possible future reference in case they ever had low-back pain in the future. The radiation dose to the lumbar spine was approximately 250 millirads and to the shielded gonads it was ten millirads per radiograph. Baycast absorbs virtually no radiation. Thus, lower radiation doses were possible than would have been necessary if plaster of Paris had been used.

Results

The effect of the supports is shown in Tables I through IV. Almost all of the supports reduced the segmental angular movements of the lumbosacral spine. The exceptions were the canvas corset on Case 3, in whom movement at the third lumbar-fourth lumbar level was unaffected; the Raney jacket on Case 7, in whom there was a 1-degree (9 per cent) increase in angular movement at the

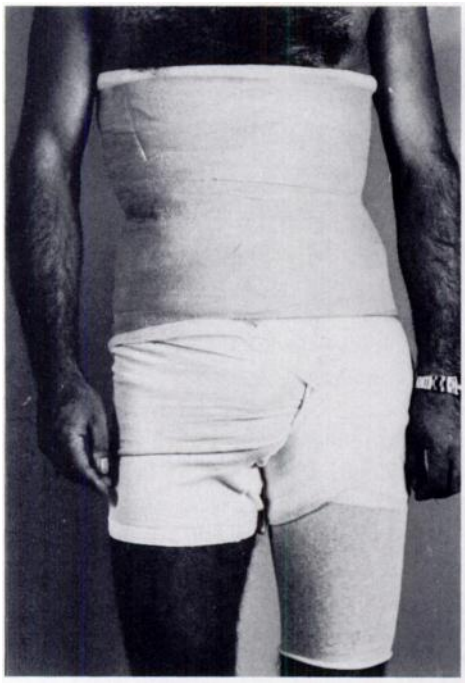

FIG. 3

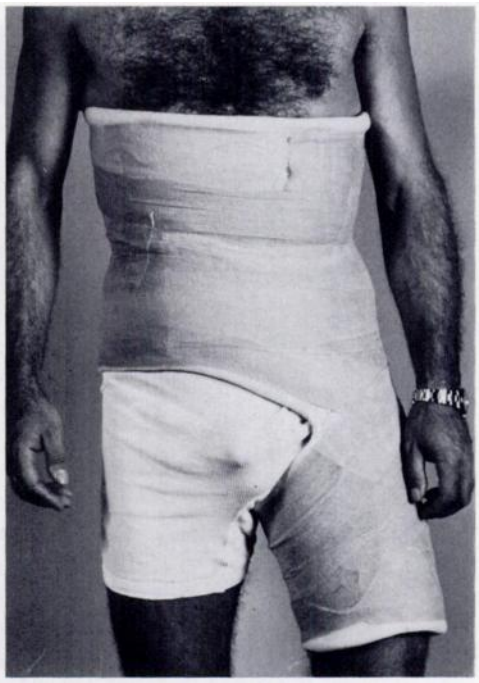

FIG. 4

Fig. 3: Baycast jacket.
Fig. 4: Baycast spica.

TABLE III

MOVEMENT IN THE BAYCAST JACKET AND BAYCAST SPICA FOR FIVE VOLUNTEERS (CASES 11 THROUGH 15)

Level	Movement with No Support (Degrees)					Movement in the Baycast Jacket (Degrees)						Movement in the Baycast Spica (Degrees)					
	11	12	13	14	15	11	12	13	14	15	Mean	11	12	13	14	15	Mean
L1-L2		16	10	10	12	2	7	3	7	8	53%*	4	10	3	7	4	49%†
L2-L3	20	16	17	13	13	2	8	11	5	4	39%‡	2	1	4	12	4	33%†
L3-L4	16	16	11	10	13	2	4	6	6	6	40%†	0	2	6	6	1	27%†
L4-L5	18	22	18	20	12	0	6	13	6	4	32%‡	2	0	3	3	2	12%§
L5-S1	23	22	14	16	17	10	11	14	16	10	70%*	2	0	1	1	3	8%§

* $0.05 > p > 0.01$.
† $0.01 > p > 0.005$.
‡ $0.005 > p > 0.001$.
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lumbosacral level; and the Baycast jackets on Cases 13 and 14, in whom the angular movements at the lumbosacral level were unaffected. Although the results showed considerable variation between individuals with regard to the effect of the supports, certain general trends could be discerned. Table IV and Figure 5 summarize the effect of each type of support at each level in the form of the mean percentage of angular movement permitted.

The canvas corset reduced angular movement at each level to approximately two-thirds of normal. The Raney and Baycast jackets were reasonably effective in the mid-part of the lumbar spine, where they reduced the angular movement to about one-third of normal, but at the first lumbar-second lumbar level and the lumbosacral level they had the same effect as the canvas corset. The Baycast spica was the most efficient below the third lumbar vertebra, and was progressively more efficient the lower the level. At the fourth lumbar-fifth lumbar level the Baycast spica permitted an average angular movement of only 2 degrees, or 12 per cent of normal, and a maximum angular movement of 3 degrees. At the lumbosacral level it was even more efficient, permitting an average angular movement of only 1.4 degrees, or 8 per cent of normal, and a maximum angular movement of only 3 degrees. The beneficial effect of the Baycast spica compared with the Baycast jacket in reducing angular movement at the lumbosacral level was statistically significant ($p < 0.001$).

TABLE IV

MEAN AND RANGE OF PERCENTAGE PERMITTED MOVEMENT

Level	Canvas Corset	Raney Jacket	Baycast Jacket	Baycast Spica
L1-L2	52 (36-60)	47 (13-83)	53 (30-70)	49 (30-70)
L2-L3	64 (30-83)	32 (8-47)	39 (10-65)	33 (6-92)
L3-L4	60 (0-100)	33 (6-77)	40 (13-60)	27 (0-60)
L4-L5	61 (29-85)	45 (27-71)	32 (0-72)	12 (0-17)
L5-S1	63 (46-93)	61 (23-109)	70 (43-100)	8 (0-18)

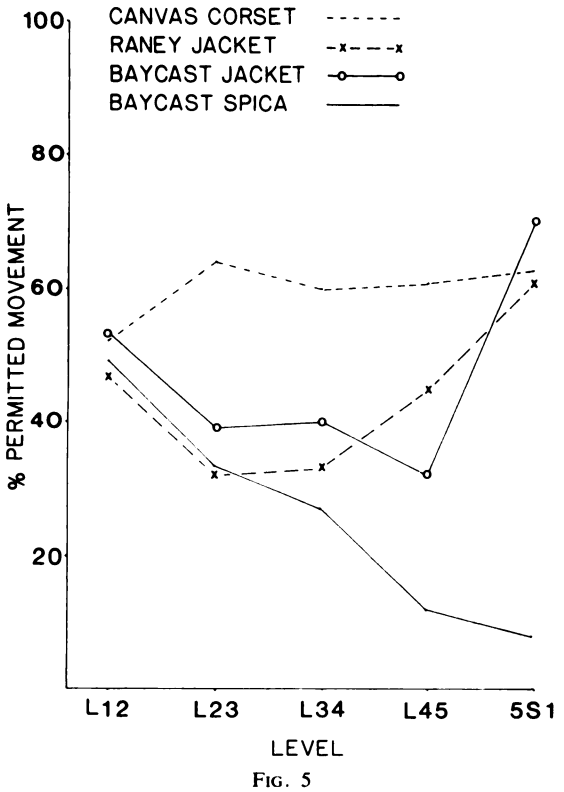

FIG. 5

Graph illustrating the percentage of movement permitted at each level by each type of support.

Discussion

The lumbosacral spinal vertebrae can undergo both translation and angular motion. The latter is caused by lateral bending and flexion-extension or axial rotation movements. Restriction of axial rotation at the lumbosacral level was observed by Lumsden and Morris in subjects wearing a chairback brace, but the effects of lumbosacral canvas corsets were varied and unpredictable. It is probable that the Raney and Baycast jackets, like the chairback brace, would adequately fix the pelvis and similarly control rotation. The cross section of the torso is oval and hence the lateral sides of a spinal support, being farther away from the spine than the back and front, should be more efficient in restricting lateral bending movement than the back and front are in restricting flexion and extension movement. Unless the sides are inadequate, it therefore seems likely that a support that restricts flexion-extension movement would be at least as effective in restricting lateral bending movement. In order to obtain the maximum

information from the minimum amount of radiation, we therefore limited this comparative study to motion in the sagittal plane.

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If one of these supports is to be used in the treatment of low-back pain, then the canvas corset has the advantage of comfort while providing abdominal support and some restriction of angular movements of the lumbar spine. There is little to choose between the Raney and Baycast jackets regarding their effect on segmental movements, but the Raney jacket is designed to reduce the lumbar lordosis and can be easily removed. The Baycast spica can be worn for a few weeks to break a painful vicious circle, but for more prolonged use it is too cumbersome. However, the Baycast spica was the most effective in restricting the mobility of the lower part of the lumbosacral spine. This is particularly important if a lumbosacral support is used in the preoperative assessment or postoperative management of a patient with a low-back disorder.

For the best restriction of movement at the fourth lumbar-fifth lumbar level or at the lumbosacral level, preoperatively or postoperatively, we now routinely include the thigh (Baycast spica). Because our study has shown this device to be consistently effective, and also for the purpose of avoiding unnecessary radiation, routine check radiographs in flexion and extension are not made. For restriction of movement at the third lumbar-fourth lumbar level, a carefully molded Baycast jacket is applied but, because of the variation between individuals in our study, we do make flexion-extension radiographs. If these do not show the desired effect, the jacket is replaced by a spica and flexion-extension radiographs are again made for comparison and future correlation. For restriction of movement at the second lumbar-third lumbar level, a Baycast jacket is used along with check radiographs. Plaster of Paris can be substituted for the Baycast jacket, but the weight of the plaster is a particular disadvantage for the spica.

Conclusions

All of the supports that we tested restricted the segmental sagittal movements of the lumbosacral spine, although there was considerable variation between individuals for the canvas corset and for the Raney and Baycast jackets at all levels. Similarly, the Baycast spica showed some variation in its effects at the first lumbar-second lumbar, the second lumbar-third lumbar, and the third lumbar-fourth lumbar levels. However, the Baycast spica was consistent in significantly limiting movement at the fourth lumbar-fifth lumbar level and especially at the lumbosacral level. Furthermore, it was the most effective of the supports that we tested in limiting movement below the third lumbar vertebra, particularly at the fourth lumbar-fifth lumbar level and at the lumbosacral level.

NOTE: The authors would like to thank Dr. B. van der Ende and Dr. van der Stadt for their statistical help, as well as Bayer for supplying the Baycasts and Camp for providing the Raney flexion jackets, and especially the volunteers without whose participation the study would not have been possible.

References

1. AHLGREN, S. A., and HANSEN, T.: The Use of Lumbosacral Corsets Prescribed for Low Back Pain. Prosthet. and Orthot. Internat., **2:** 101-104, 1978.
2. EVANS, ARTHUR: The Palace of Minos at Knossos. Vol. 1, p. 503. London, Macmillan, 1921.
3. EWING, ELIZABETH: Fashion in Underwear, p. 13. London, Batsford, 1971.
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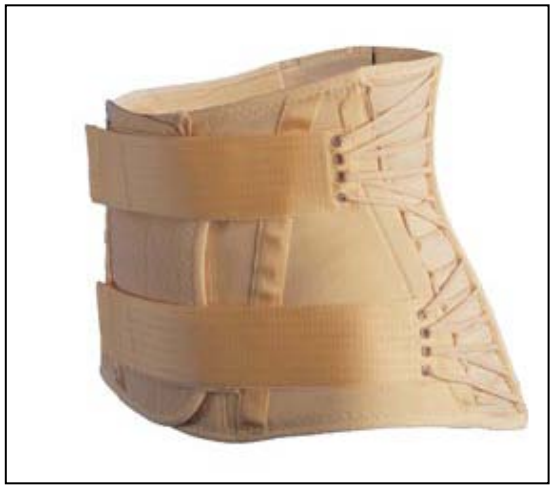
5. NEW YORK UNIVERSITY, POST-GRADUATE MEDICAL SCHOOL: Prosthetics and Orthotics; Measurement, Layout and Pattern Design for Lumbosacral F-E and L Corsets. Spinal Orthotics including Orthotists' Supplement, pp. 167-196. New York, 1975.
6. NORTON, P. L., and BROWN, THORNTON: The Immobilizing Efficiency of Back Braces. Their Effect on the Posture and Motion of the Lumbosacral Spine. J. Bone and Joint Surg., **39-A:** 111-138, Jan. 1957.
7. PERRY, JACQUELIN: The Use of External Support in the Treatment of Low-Back Pain. Report of the Subcommittee on Orthotics of the Committee on Prosthetic-Orthotic Education, National Academy of Sciences, National Research Council. J. Bone and Joint Surg., **52-A:** 1440-1442, Oct. 1970.
8. RANEY, F.: Royalite Flexion Jacket. Report on the Spinal Orthotics Workshop, pp. 85-91. Sponsored by the Committee on Prosthetics Research and Development of the Division of Engineering of the National Research Council. Washington, D.C., National Research Council, 1969.
9. TANZ, S. S.: Motion of the Lumbar Spine. A Roentgenologic Study. Am. J. Roentgenol., **69:** 399-412, 1953.

HCPCS:	Descriptor:
L0625	LUMBAR ORTHOSIS, FLEXIBLE, PROVIDES LUMBAR SUPPORT, POSTERIOR EXTENDS FROM L-1 TO BELOW L-5 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PENDULOUS ABDOMEN DESIGN, SHOULDER STRAPS, STAYS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	NO	NO	YES

Sample Diagnosis (Not Inclusive)	Spondylolysis, Spinal fractures, Muscle spasms, Post surgical applications, Osteoporosis
Medically Necessary Argument	There is a large surface area of contact, and with that greater area is a broader range of sizing that must be properly evaluated. Items in this code category must also be provided based upon a patient's shape which will vary by length, circumference and contours of the abdomen and spine. As the items in this category are essentially non-elastic, there is less "forgiveness" of material, hence the importance of an appropriate fit. Also present may be stainless steel stays, which must be properly shaped, not only for comfort but for appropriate control of the lumbar portion of the spine. Often times these items will be provided in a post surgical situation, requiring appropriate clinical understanding of mechanics in the application both standing and supine to ensure no injury during the fitting.
References	3

The Effect of Four Types of Support on the Segmental Mobility of the Lumbosacral Spine

BY M. W. FIDLER, F.R.C.S.*, AND C. M. T. PLASMANS, M.D.†, AMSTERDAM, THE NETHERLANDS

From the Slotervaart Ziekenhuis and O.L.V. Gasthuis, Amsterdam

ABSTRACT: **With the aid of flexion-extension lateral radiographs, we investigated the effect of the canvas corset, the Raney and Baycast jackets, and the Baycast spica on the segmental sagittal mobility of the lumbosacral spine in separate groups of five volunteers each. The canvas corset reduced the mean angular movements at each level to two-thirds of normal. The Raney and Baycast jackets reduced the mean angular movements in the middle of the lumbar spine to approximately one-third of normal. The Baycast spica was the most effective in restricting angular movements below the third lumbar vertebra, and especially at the fourth lumbar-fifth lumbar level and the lumbosacral level.**

Lumbosacral corsets have been in use at least since the Minoan period, some 2000 years B.C.[2]. The function of those corsets was primarily to mold and enhance the female form, but their construction could also have served to support the lumbosacral spine. The first surgical corset that was specifically designed to support the lumbar spine was probably that made in 1530 for Catherine of Medici[3]. This was an iron corset, extending from the mid-part of the thorax to over the iliac crests, hinged down one side and fastened by a clasp on the other.

Lumbosacral supports are now commonly prescribed in the management of low-back pain[1,7] and are used to judge the effect of immobilization when considering spine fusion or postoperatively to support the spine until fusion occurs. By means of a questionnaire, Perry reviewed the use of supports in America and found that the lumbosacral corset was the most widely used, followed closely by the chairback brace. The effect most often expected from a brace was restriction of lumbosacral motion — this in spite of the fact that Norton and Brown as well as Lumsden and Morris had observed that in some patients a support actually could lead to an increase in movement at the lumbosacral level. It seems that there is still a tendency to prescribe a support for the lumbosacral spine without focusing attention specifically on the level concerned.

We use mainly four types of lumbosacral support. The lumbosacral canvas corset with posterior steel supports (Fig. 1), the Raney[8] flexion jacket (Fig. 2), and the Baycast (Cuttercast) jacket (Fig. 3) are used principally in the treatment of low-back pain, and the Baycast jacket with inclusion of the left thigh (Baycast spica) (Fig. 4) is used chiefly when considering fusion and postoperatively. The thigh is included in order to improve control of the pelvis.

The purpose of this investigation was to assess and compare the effects of these supports on the segmental sagittal mobility of the lumbosacral spine.

Material

Each type of support was assessed on five healthy male volunteers, none of whom had a history of low-back pain.

The canvas lumbosacral corsets were made to measure for each volunteer in the routine manner used for patients with lumbosacral disorders by the orthotist in the Slotervaart Hospital. The pattern used was a minor modification of that described in the spinal orthotics manual of the New York University Post-Graduate Medical School[5]. The lower edge of the corset was trimmed posteriorly at seat level with the subject sitting on a stool, thus avoiding the uncomfortable curled lip that can occur with the slightly lower edge described in the manual. The corset extended from around the lower ribs to over the iliac crest laterally, to just above the symphysis pubis anteriorly, and included the sacrum and upper part of the buttocks posteriorly. Each corset was reinforced with two posterior vertical steel stays stitched between the layers of the canvas.

The Raney flexion jackets were standard models of appropriate size for the volunteers.

The Baycast jackets were applied on standing volunteers by the same orthotist. These jackets extended from two centimeters below the shoulder blades to the mid-part of the sacrum posteriorly, from the xiphisternum to just above the pubis anteriorly, and from around the lower ribs to three centimeters below the level of the anterior superior iliac spines laterally. The left thigh was subsequently included to produce the Baycast spica on these same volunteers. The thigh-piece extended to five centimeters proximal to the patella and was added with the hip in 20 degrees of flexion in order to prevent any fixed lumbar lordosis and to facilitate sitting.

Method

Using a uniform technique lateral radiographs of the lumbosacral spine were made in maximum flexion and extension, first without and then with the support so that each

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TABLE I

MOVEMENT IN THE CANVAS CORSET FOR FIVE VOLUNTEERS (CASES 1 THROUGH 5)

Level	Movement with No Support (*Degrees*)					Movement in the Canvas Corset (*Degrees*)					Percentage Permitted Movement in the Canvas Corset					
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	Mean
L1-L2	15			11	17	9	13		4	10	60			36	59	52*
L2-L3	21	16	11	12	10	11	12	9	10	3	52	75	82	83	30	64†
L3-L4	18	13	17	12	3	7	10	17	10	0	39	77	100	83	0	60‡
L4-L5	15	21	20	13	7	10	10	17	10	2	67	48	85	77	29	61†
L5-S1	13	14	15	14	15	6	7	9	13	10	46	50	60	93	67	63*

* $0.005 > p > 0.001$.
† $0.05 > p > 0.01$.
‡ $0.1 > p > 0.05$.

volunteer acted as his own control. Segmental movement during flexion and extension was determined by means of corresponding lines drawn along the end-plates of each vertebra. The angles between adjacent vertebrae were measured in flexion and in extension, and the difference was recorded as the movement occurring at that level. These segmental angular movements, without and with a support, were determined at each level for all of the volunteers. In order to facilitate comparison of one type of support with another, the angular movements that were permitted by a support were expressed as percentages of the corresponding control unrestricted angular movements and then, for each type of support, the averages (arithmetical means) of these percentages were calculated for each level.

We found that the most accurate method of drawing corresponding lines on the radiographs was first to draw all of the lines on one radiograph. The second radiograph was then placed on top of the first and the shadow of each vertebral body was superimposed in turn over that of the same vertebra on the underlying radiograph while the corresponding lines were traced onto the upper radiograph.

We did not assess the reproducibility of the measurements because it would have been necessary to repeat at least one set of flexion and extension radiographs for the volunteers. In view of the extra radiation involved, we did

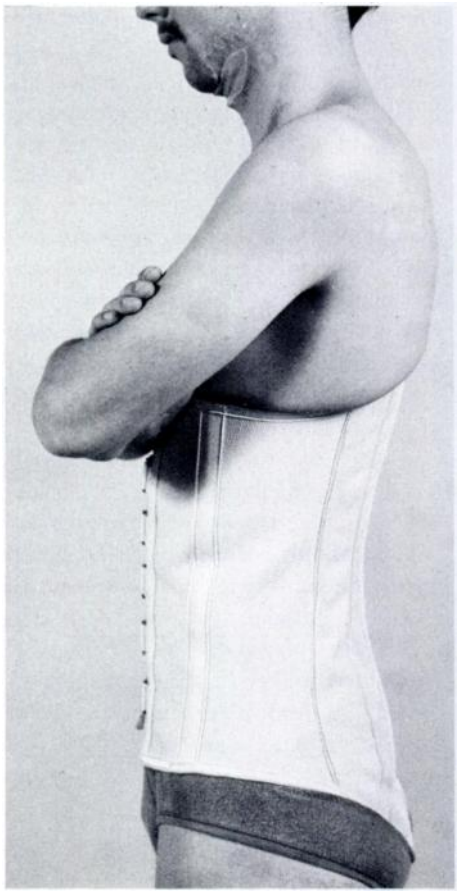

FIG. 1

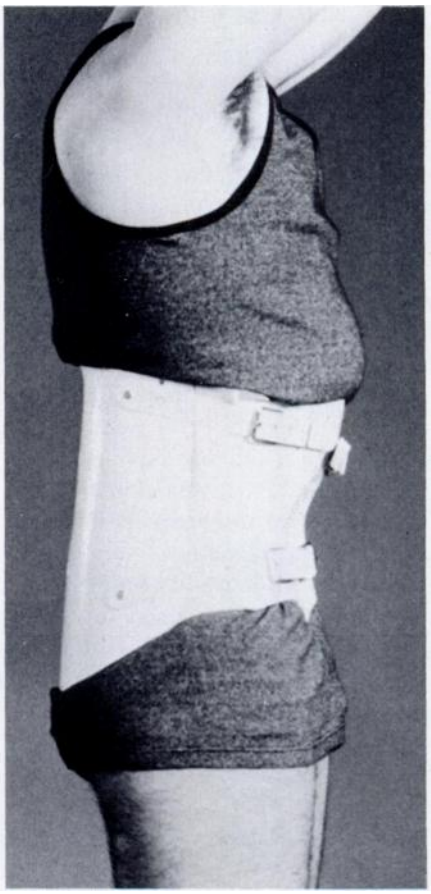

FIG. 2

Fig. 1: Canvas lumbosacral corset.
Fig. 2: Raney flexion jacket.

TABLE II

MOVEMENT IN THE RANEY JACKET FOR FIVE VOLUNTEERS (CASES 6 THROUGH 10)

Level	Movement with No Support (*Degrees*)					Movement in the Raney Jacket (*Degrees*)					Percentage Permitted Movement in the Raney Jacket					
	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10	Mean
L1-L2	15	11	6			2	5	5	7	2	13	45	83			47*
L2-L3	13	15	12	8	15	5	4	1	3	7	38	27	8	38	47	32†
L3-L4	12	12	17	13	13	6	2	1	2	10	50	17	6	15	77	33‡
L4-L5	20	16	15	17	11	6	7	8	12	3	30	44	53	71	27	45§
L5-S1	18	11	13	22	18	13	12	6	5	10	72	109	46	23	56	61¶

* $0.1 > p > 0.05$.
† $0.001 > p$.
‡ $0.01 > p > 0.005$.
§ $0.005 > p > 0.001$.
¶ $0.05 > p > 0.01$.

not think that this was justifiable. Tanz, who also used a superimposition method to calculate the segmental angular movements, found that the results of repeat radiographic examinations usually agreed to within 2 degrees. We assumed that this 2-degree error would be applicable to our series.

Radiation Precautions

The volunteers were healthy thin men whose gonads were screened. They had had minimum previous exposure to radiation and did not come into contact with x-rays during their routine work. One radiographer in each hospital made all of the radiographs to minimize the chance of error. An off-center radiograph was not repeated. This explains the absence of readings at the level of the disc between the first and second lumbar vertebrae for Cases 2, 3, 9, 10, and 11 in Tables I, II, and III. Copies of the radiographs were subsequently given to the volunteers for possible future reference in case they ever had low-back pain in the future. The radiation dose to the lumbar spine was approximately 250 millirads and to the shielded gonads it was ten millirads per radiograph. Baycast absorbs virtually no radiation. Thus, lower radiation doses were possible than would have been necessary if plaster of Paris had been used.

Results

The effect of the supports is shown in Tables I through IV. Almost all of the supports reduced the segmental angular movements of the lumbosacral spine. The exceptions were the canvas corset on Case 3, in whom movement at the third lumbar-fourth lumbar level was unaffected; the Raney jacket on Case 7, in whom there was a 1-degree (9 per cent) increase in angular movement at the

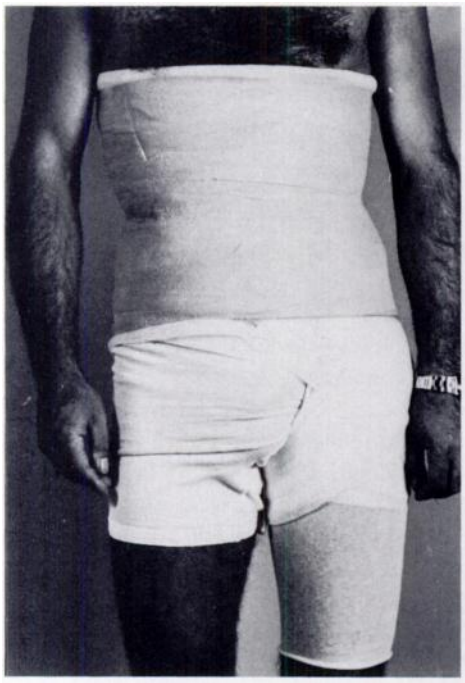

FIG. 3

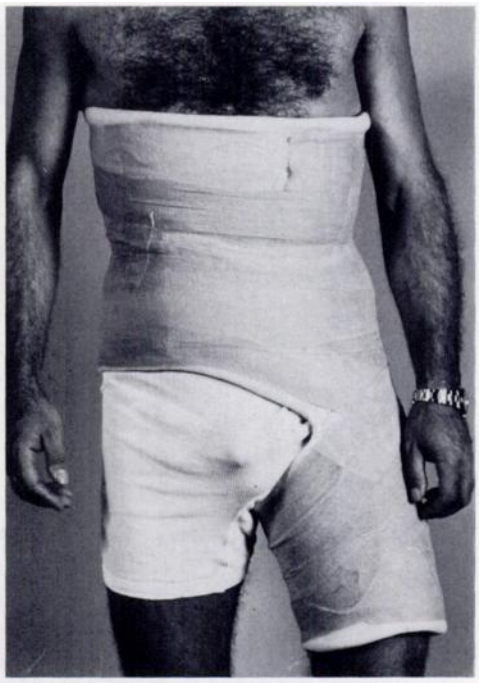

FIG. 4

Fig. 3: Baycast jacket.
Fig. 4: Baycast spica.

TABLE III

MOVEMENT IN THE BAYCAST JACKET AND BAYCAST SPICA FOR FIVE VOLUNTEERS (CASES 11 THROUGH 15)

Level	Movement with No Support (Degrees)					Movement in the Baycast Jacket (Degrees)						Movement in the Baycast Spica (Degrees)					
	11	12	13	14	15	11	12	13	14	15	Mean	11	12	13	14	15	Mean
L1-L2		16	10	10	12	2	7	3	7	8	53%*	4	10	3	7	4	49%†
L2-L3	20	16	17	13	13	2	8	11	5	4	39%‡	2	1	4	12	4	33%†
L3-L4	16	16	11	10	13	2	4	6	6	6	40%†	0	2	6	6	1	27%†
L4-L5	18	22	18	20	12	0	6	13	6	4	32%‡	2	0	3	3	2	12%§
L5-S1	23	22	14	16	17	10	11	14	16	10	70%*	2	0	1	1	3	8%§

* $0.05 > p > 0.01$.
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lumbosacral level; and the Baycast jackets on Cases 13 and 14, in whom the angular movements at the lumbosacral level were unaffected. Although the results showed considerable variation between individuals with regard to the effect of the supports, certain general trends could be discerned. Table IV and Figure 5 summarize the effect of each type of support at each level in the form of the mean percentage of angular movement permitted.

The canvas corset reduced angular movement at each level to approximately two-thirds of normal. The Raney and Baycast jackets were reasonably effective in the mid-part of the lumbar spine, where they reduced the angular movement to about one-third of normal, but at the first lumbar-second lumbar level and the lumbosacral level they had the same effect as the canvas corset. The Baycast spica was the most efficient below the third lumbar vertebra, and was progressively more efficient the lower the level. At the fourth lumbar-fifth lumbar level the Baycast spica permitted an average angular movement of only 2 degrees, or 12 per cent of normal, and a maximum angular movement of 3 degrees. At the lumbosacral level it was even more efficient, permitting an average angular movement of only 1.4 degrees, or 8 per cent of normal, and a maximum angular movement of only 3 degrees. The beneficial effect of the Baycast spica compared with the Baycast jacket in reducing angular movement at the lumbosacral level was statistically significant ($p < 0.001$).

TABLE IV

MEAN AND RANGE OF PERCENTAGE PERMITTED MOVEMENT

Level	Canvas Corset	Raney Jacket	Baycast Jacket	Baycast Spica
L1-L2	52 (36-60)	47 (13-83)	53 (30-70)	49 (30-70)
L2-L3	64 (30-83)	32 (8-47)	39 (10-65)	33 (6-92)
L3-L4	60 (0-100)	33 (6-77)	40 (13-60)	27 (0-60)
L4-L5	61 (29-85)	45 (27-71)	32 (0-72)	12 (0-17)
L5-S1	63 (46-93)	61 (23-109)	70 (43-100)	8 (0-18)

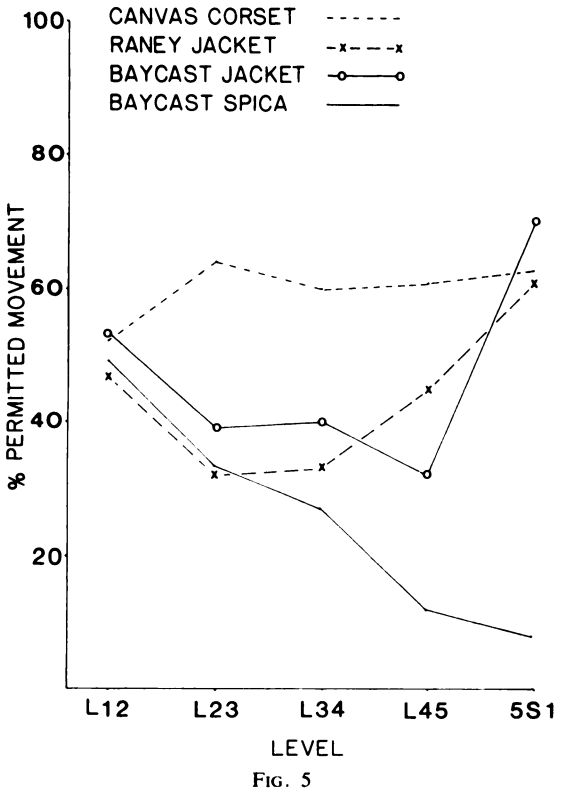

FIG. 5

Graph illustrating the percentage of movement permitted at each level by each type of support.

Discussion

The lumbosacral spinal vertebrae can undergo both translation and angular motion. The latter is caused by lateral bending and flexion-extension or axial rotation movements. Restriction of axial rotation at the lumbosacral level was observed by Lumsden and Morris in subjects wearing a chairback brace, but the effects of lumbosacral canvas corsets were varied and unpredictable. It is probable that the Raney and Baycast jackets, like the chairback brace, would adequately fix the pelvis and similarly control rotation. The cross section of the torso is oval and hence the lateral sides of a spinal support, being farther away from the spine than the back and front, should be more efficient in restricting lateral bending movement than the back and front are in restricting flexion and extension movement. Unless the sides are inadequate, it therefore seems likely that a support that restricts flexion-extension movement would be at least as effective in restricting lateral bending movement. In order to obtain the maximum

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A rigid support works on the principle of three-point fixation; optimum restriction of movement is likely to be achieved about halfway along and to decrease toward the ends. This effect is illustrated by the graphs for the Raney and Baycast jackets (Fig. 5). At the caudal end, for example, the pelvis is not effectively controlled by the supports and considerable lumbosacral motion is still possible. The extension of the jacket to include the hip and thigh provides the necessary control of the pelvis and accounts for the effectiveness of the Baycast spica in restricting the movement of the lower part of the lumbosacral spine.

Although only five volunteers were examined, the Baycast spica had a consistent and statistically significant effect on the fourth lumbar-fifth lumbar level ($p < 0.001$) and the lumbosacral level ($p < 0.0005$). At other levels, and at all levels with the other supports, there was great variation between individuals. In these situations, we recommend that, if a support is to be used in the expectation of a particular effect on segmental mobility, the appropriate check radiographs be made, as pointed out by Norton and Brown.

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For the best restriction of movement at the fourth lumbar-fifth lumbar level or at the lumbosacral level, preoperatively or postoperatively, we now routinely include the thigh (Baycast spica). Because our study has shown this device to be consistently effective, and also for the purpose of avoiding unnecessary radiation, routine check radiographs in flexion and extension are not made. For restriction of movement at the third lumbar-fourth lumbar level, a carefully molded Baycast jacket is applied but, because of the variation between individuals in our study, we do make flexion-extension radiographs. If these do not show the desired effect, the jacket is replaced by a spica and flexion-extension radiographs are again made for comparison and future correlation. For restriction of movement at the second lumbar-third lumbar level, a Baycast jacket is used along with check radiographs. Plaster of Paris can be substituted for the Baycast jacket, but the weight of the plaster is a particular disadvantage for the spica.

Conclusions

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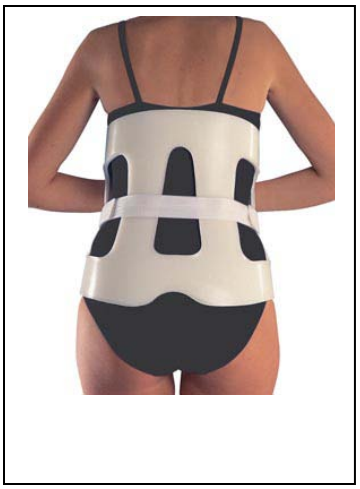
References

1. AHLGREN, S. A., and HANSEN, T.: The Use of Lumbosacral Corsets Prescribed for Low Back Pain. Prosthet. and Orthot. Internat., **2:** 101-104, 1978.
2. EVANS, ARTHUR: The Palace of Minos at Knossos. Vol. 1, p. 503. London, Macmillan, 1921.
3. EWING, ELIZABETH: Fashion in Underwear, p. 13. London, Batsford, 1971.
4. LUMSDEN, R. M., and MORRIS, J. M.: An *In Vivo* Study of Axial Rotation and Immobilization at the Lumbosacral Joint. J. Bone and Joint Surg., **50-A:** 1591-1602, Dec. 1968.
5. NEW YORK UNIVERSITY, POST-GRADUATE MEDICAL SCHOOL: Prosthetics and Orthotics; Measurement, Layout and Pattern Design for Lumbosacral F-E and L Corsets. Spinal Orthotics including Orthotists' Supplement, pp. 167-196. New York, 1975.
6. NORTON, P. L., and BROWN, THORNTON: The Immobilizing Efficiency of Back Braces. Their Effect on the Posture and Motion of the Lumbosacral Spine. J. Bone and Joint Surg., **39-A:** 111-138, Jan. 1957.
7. PERRY, JACQUELIN: The Use of External Support in the Treatment of Low-Back Pain. Report of the Subcommittee on Orthotics of the Committee on Prosthetic-Orthotic Education, National Academy of Sciences, National Research Council. J. Bone and Joint Surg., **52-A:** 1440-1442, Oct. 1970.
8. RANEY, F.: Royalite Flexion Jacket. Report on the Spinal Orthotics Workshop, pp. 85-91. Sponsored by the Committee on Prosthetics Research and Development of the Division of Engineering of the National Research Council. Washington, D.C., National Research Council, 1969.
9. TANZ, S. S.: Motion of the Lumbar Spine. A Roentgenologic Study. Am. J. Roentgenol., **69:** 399-412, 1953.

HCPCS:	Descriptor:
L0626	LUMBAR ORTHOSIS, SAGITTAL CONTROL, WITH RIGID POSTERIOR PANEL(S), POSTERIOR EXTENDS FROM L-1 TO BELOW L-5 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, STAYS, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Fractures, DJD, arthritis, osteoporosis
Medically Necessary Argument	Note this style orthoses may require heating and contouring of the rigid material in the posterior panel. This technique is specialized to the trained orthotist. If not, edges may be left sharp without proper cutting and sanding equipment.
References	3

The Effect of Four Types of Support on the Segmental Mobility of the Lumbosacral Spine

BY M. W. FIDLER, F.R.C.S.*, AND C. M. T. PLASMANS, M.D.†, AMSTERDAM, THE NETHERLANDS

From the Slotervaart Ziekenhuis and O.L.V. Gasthuis, Amsterdam

ABSTRACT: **With the aid of flexion-extension lateral radiographs, we investigated the effect of the canvas corset, the Raney and Baycast jackets, and the Baycast spica on the segmental sagittal mobility of the lumbosacral spine in separate groups of five volunteers each. The canvas corset reduced the mean angular movements at each level to two-thirds of normal. The Raney and Baycast jackets reduced the mean angular movements in the middle of the lumbar spine to approximately one-third of normal. The Baycast spica was the most effective in restricting angular movements below the third lumbar vertebra, and especially at the fourth lumbar-fifth lumbar level and the lumbosacral level.**

Lumbosacral corsets have been in use at least since the Minoan period, some 2000 years B.C.[2]. The function of those corsets was primarily to mold and enhance the female form, but their construction could also have served to support the lumbosacral spine. The first surgical corset that was specifically designed to support the lumbar spine was probably that made in 1530 for Catherine of Medici[3]. This was an iron corset, extending from the mid-part of the thorax to over the iliac crests, hinged down one side and fastened by a clasp on the other.

Lumbosacral supports are now commonly prescribed in the management of low-back pain[1,7] and are used to judge the effect of immobilization when considering spine fusion or postoperatively to support the spine until fusion occurs. By means of a questionnaire, Perry reviewed the use of supports in America and found that the lumbosacral corset was the most widely used, followed closely by the chairback brace. The effect most often expected from a brace was restriction of lumbosacral motion — this in spite of the fact that Norton and Brown as well as Lumsden and Morris had observed that in some patients a support actually could lead to an increase in movement at the lumbosacral level. It seems that there is still a tendency to prescribe a support for the lumbosacral spine without focusing attention specifically on the level concerned.

We use mainly four types of lumbosacral support. The lumbosacral canvas corset with posterior steel supports (Fig. 1), the Raney[8] flexion jacket (Fig. 2), and the Baycast (Cuttercast) jacket (Fig. 3) are used principally in the treatment of low-back pain, and the Baycast jacket with inclusion of the left thigh (Baycast spica) (Fig. 4) is used chiefly when considering fusion and postoperatively. The thigh is included in order to improve control of the pelvis.

The purpose of this investigation was to assess and compare the effects of these supports on the segmental sagittal mobility of the lumbosacral spine.

Material

Each type of support was assessed on five healthy male volunteers, none of whom had a history of low-back pain.

The canvas lumbosacral corsets were made to measure for each volunteer in the routine manner used for patients with lumbosacral disorders by the orthotist in the Slotervaart Hospital. The pattern used was a minor modification of that described in the spinal orthotics manual of the New York University Post-Graduate Medical School[5]. The lower edge of the corset was trimmed posteriorly at seat level with the subject sitting on a stool, thus avoiding the uncomfortable curled lip that can occur with the slightly lower edge described in the manual. The corset extended from around the lower ribs to over the iliac crest laterally, to just above the symphysis pubis anteriorly, and included the sacrum and upper part of the buttocks posteriorly. Each corset was reinforced with two posterior vertical steel stays stitched between the layers of the canvas.

The Raney flexion jackets were standard models of appropriate size for the volunteers.

The Baycast jackets were applied on standing volunteers by the same orthotist. These jackets extended from two centimeters below the shoulder blades to the mid-part of the sacrum posteriorly, from the xiphisternum to just above the pubis anteriorly, and from around the lower ribs to three centimeters below the level of the anterior superior iliac spines laterally. The left thigh was subsequently included to produce the Baycast spica on these same volunteers. The thigh-piece extended to five centimeters proximal to the patella and was added with the hip in 20 degrees of flexion in order to prevent any fixed lumbar lordosis and to facilitate sitting.

Method

Using a uniform technique lateral radiographs of the lumbosacral spine were made in maximum flexion and extension, first without and then with the support so that each

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TABLE I

MOVEMENT IN THE CANVAS CORSET FOR FIVE VOLUNTEERS (CASES 1 THROUGH 5)

Level	Movement with No Support (*Degrees*)					Movement in the Canvas Corset (*Degrees*)					Percentage Permitted Movement in the Canvas Corset					
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	Mean
L1-L2	15			11	17	9	13		4	10	60			36	59	52*
L2-L3	21	16	11	12	10	11	12	9	10	3	52	75	82	83	30	64†
L3-L4	18	13	17	12	3	7	10	17	10	0	39	77	100	83	0	60‡
L4-L5	15	21	20	13	7	10	10	17	10	2	67	48	85	77	29	61†
L5-S1	13	14	15	14	15	6	7	9	13	10	46	50	60	93	67	63*

* $0.005 > p > 0.001$.
† $0.05 > p > 0.01$.
‡ $0.1 > p > 0.05$.

volunteer acted as his own control. Segmental movement during flexion and extension was determined by means of corresponding lines drawn along the end-plates of each vertebra. The angles between adjacent vertebrae were measured in flexion and in extension, and the difference was recorded as the movement occurring at that level. These segmental angular movements, without and with a support, were determined at each level for all of the volunteers. In order to facilitate comparison of one type of support with another, the angular movements that were permitted by a support were expressed as percentages of the corresponding control unrestricted angular movements and then, for each type of support, the averages (arithmetical means) of these percentages were calculated for each level.

We found that the most accurate method of drawing corresponding lines on the radiographs was first to draw all of the lines on one radiograph. The second radiograph was then placed on top of the first and the shadow of each vertebral body was superimposed in turn over that of the same vertebra on the underlying radiograph while the corresponding lines were traced onto the upper radiograph.

We did not assess the reproducibility of the measurements because it would have been necessary to repeat at least one set of flexion and extension radiographs for the volunteers. In view of the extra radiation involved, we did

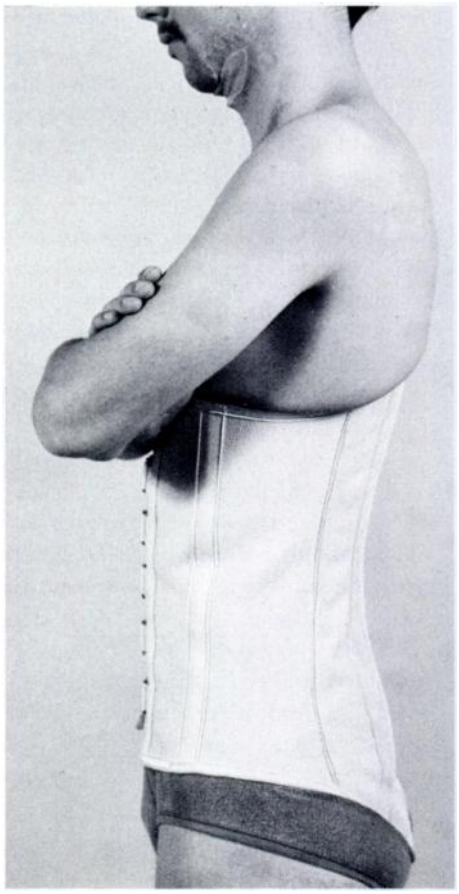

FIG. 1

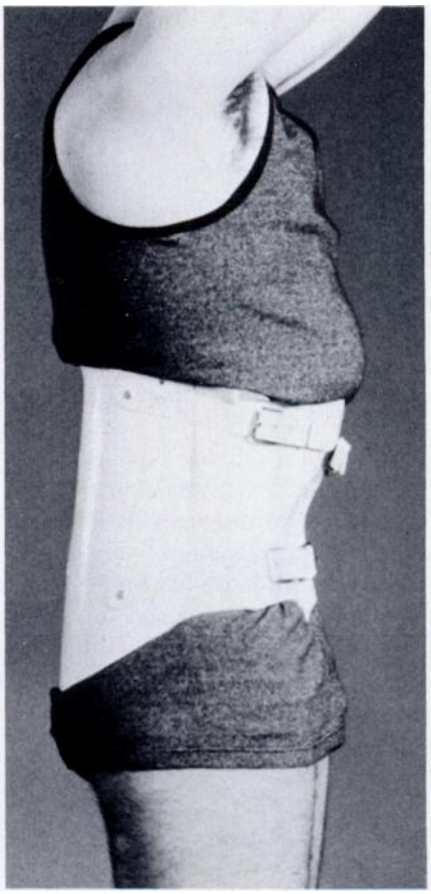

FIG. 2

Fig. 1: Canvas lumbosacral corset.
Fig. 2: Raney flexion jacket.

TABLE II

MOVEMENT IN THE RANEY JACKET FOR FIVE VOLUNTEERS (CASES 6 THROUGH 10)

	Movement with No Support (*Degrees*)					Movement in the Raney Jacket (*Degrees*)					Percentage Permitted Movement in the Raney Jacket					
Level	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10	Mean
L1-L2	15	11	6			2	5	5	7	2	13	45	83			47*
L2-L3	13	15	12	8	15	5	4	1	3	7	38	27	8	38	47	32†
L3-L4	12	12	17	13	13	6	2	1	2	10	50	17	6	15	77	33‡
L4-L5	20	16	15	17	11	6	7	8	12	3	30	44	53	71	27	45§
L5-S1	18	11	13	22	18	13	12	6	5	10	72	109	46	23	56	61¶

* $0.1 > p > 0.05$.
† $0.001 > p$.
‡ $0.01 > p > 0.005$.
§ $0.005 > p > 0.001$.
¶ $0.05 > p > 0.01$.

not think that this was justifiable. Tanz, who also used a superimposition method to calculate the segmental angular movements, found that the results of repeat radiographic examinations usually agreed to within 2 degrees. We assumed that this 2-degree error would be applicable to our series.

Radiation Precautions

The volunteers were healthy thin men whose gonads were screened. They had had minimum previous exposure to radiation and did not come into contact with x-rays during their routine work. One radiographer in each hospital made all of the radiographs to minimize the chance of error. An off-center radiograph was not repeated. This explains the absence of readings at the level of the disc between the first and second lumbar vertebrae for Cases 2, 3, 9, 10, and 11 in Tables I, II, and III. Copies of the radiographs were subsequently given to the volunteers for possible future reference in case they ever had low-back pain in the future. The radiation dose to the lumbar spine was approximately 250 millirads and to the shielded gonads it was ten millirads per radiograph. Baycast absorbs virtually no radiation. Thus, lower radiation doses were possible than would have been necessary if plaster of Paris had been used.

Results

The effect of the supports is shown in Tables I through IV. Almost all of the supports reduced the segmental angular movements of the lumbosacral spine. The exceptions were the canvas corset on Case 3, in whom movement at the third lumbar-fourth lumbar level was unaffected; the Raney jacket on Case 7, in whom there was a 1-degree (9 per cent) increase in angular movement at the

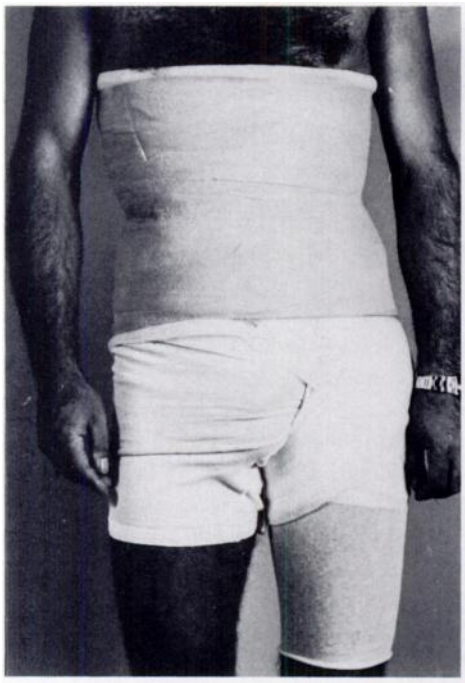

FIG. 3

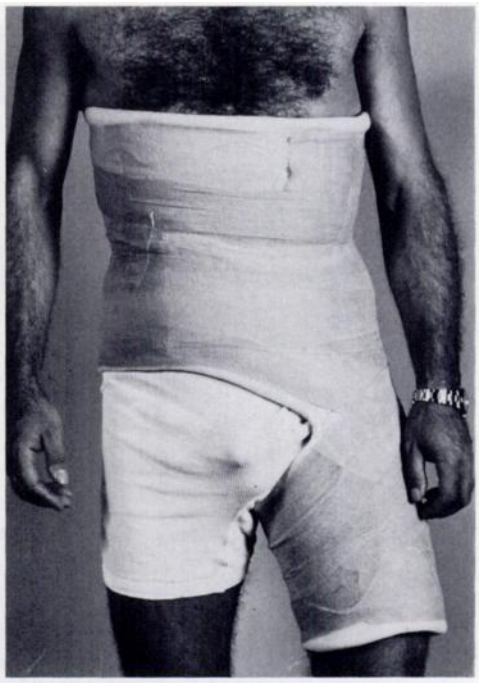

FIG. 4

Fig. 3: Baycast jacket.
Fig. 4: Baycast spica.

TABLE III

MOVEMENT IN THE BAYCAST JACKET AND BAYCAST SPICA FOR FIVE VOLUNTEERS (CASES 11 THROUGH 15)

Level	Movement with No Support (Degrees)					Movement in the Baycast Jacket (Degrees)						Movement in the Baycast Spica (Degrees)					
	11	12	13	14	15	11	12	13	14	15	Mean	11	12	13	14	15	Mean
L1-L2		16	10	10	12	2	7	3	7	8	53%*	4	10	3	7	4	49%†
L2-L3	20	16	17	13	13	2	8	11	5	4	39%‡	2	1	4	12	4	33%†
L3-L4	16	16	11	10	13	2	4	6	6	6	40%†	0	2	6	6	1	27%†
L4-L5	18	22	18	20	12	0	6	13	6	4	32%‡	2	0	3	3	2	12%§
L5-S1	23	22	14	16	17	10	11	14	16	10	70%*	2	0	1	1	3	8%§

* $0.05 > p > 0.01$.
† $0.01 > p > 0.005$.
‡ $0.005 > p > 0.001$.
§ $0.001 > p$.

lumbosacral level; and the Baycast jackets on Cases 13 and 14, in whom the angular movements at the lumbosacral level were unaffected. Although the results showed considerable variation between individuals with regard to the effect of the supports, certain general trends could be discerned. Table IV and Figure 5 summarize the effect of each type of support at each level in the form of the mean percentage of angular movement permitted.

The canvas corset reduced angular movement at each level to approximately two-thirds of normal. The Raney and Baycast jackets were reasonably effective in the mid-part of the lumbar spine, where they reduced the angular movement to about one-third of normal, but at the first lumbar-second lumbar level and the lumbosacral level they had the same effect as the canvas corset. The Baycast spica was the most efficient below the third lumbar vertebra, and was progressively more efficient the lower the level. At the fourth lumbar-fifth lumbar level the Baycast spica permitted an average angular movement of only 2 degrees, or 12 per cent of normal, and a maximum angular movement of 3 degrees. At the lumbosacral level it was even more efficient, permitting an average angular movement of only 1.4 degrees, or 8 per cent of normal, and a maximum angular movement of only 3 degrees. The beneficial effect of the Baycast spica compared with the Baycast jacket in reducing angular movement at the lumbosacral level was statistically significant ($p < 0.001$).

TABLE IV

MEAN AND RANGE OF PERCENTAGE PERMITTED MOVEMENT

Level	Canvas Corset	Raney Jacket	Baycast Jacket	Baycast Spica
L1-L2	52 (36-60)	47 (13-83)	53 (30-70)	49 (30-70)
L2-L3	64 (30-83)	32 (8-47)	39 (10-65)	33 (6-92)
L3-L4	60 (0-100)	33 (6-77)	40 (13-60)	27 (0-60)
L4-L5	61 (29-85)	45 (27-71)	32 (0-72)	12 (0-17)
L5-S1	63 (46-93)	61 (23-109)	70 (43-100)	8 (0-18)

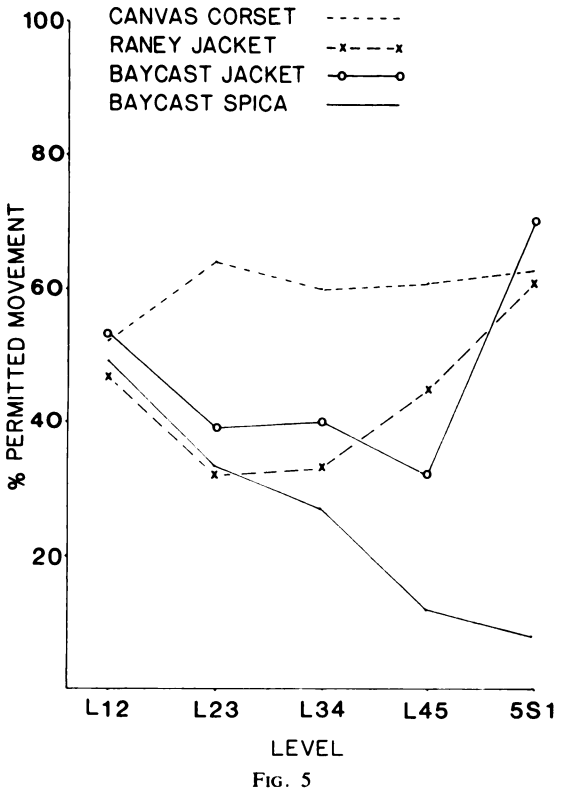

FIG. 5

Graph illustrating the percentage of movement permitted at each level by each type of support.

Discussion

The lumbosacral spinal vertebrae can undergo both translation and angular motion. The latter is caused by lateral bending and flexion-extension or axial rotation movements. Restriction of axial rotation at the lumbosacral level was observed by Lumsden and Morris in subjects wearing a chairback brace, but the effects of lumbosacral canvas corsets were varied and unpredictable. It is probable that the Raney and Baycast jackets, like the chairback brace, would adequately fix the pelvis and similarly control rotation. The cross section of the torso is oval and hence the lateral sides of a spinal support, being farther away from the spine than the back and front, should be more efficient in restricting lateral bending movement than the back and front are in restricting flexion and extension movement. Unless the sides are inadequate, it therefore seems likely that a support that restricts flexion-extension movement would be at least as effective in restricting lateral bending movement. In order to obtain the maximum

information from the minimum amount of radiation, we therefore limited this comparative study to motion in the sagittal plane.

Like Tanz, we found considerable variation in lumbar spinal movements between normal individuals, and so each volunteer had to act as his own control. However, because of the radiation involved it was not possible to do a radiographic assessment of four supports in flexion and extension, as well as to make control radiographs, for each volunteer. Norton and Brown circumvented this problem by measuring the angles between Kirschner wires in the spinous processes after making preliminary radiographic measurements, and Lumsden and Morris measured rotation by inserting Steinmann pins in the spinous processes alone. We used different groups of volunteers for the canvas, Raney, and Baycast supports.

A rigid support works on the principle of three-point fixation; optimum restriction of movement is likely to be achieved about halfway along and to decrease toward the ends. This effect is illustrated by the graphs for the Raney and Baycast jackets (Fig. 5). At the caudal end, for example, the pelvis is not effectively controlled by the supports and considerable lumbosacral motion is still possible. The extension of the jacket to include the hip and thigh provides the necessary control of the pelvis and accounts for the effectiveness of the Baycast spica in restricting the movement of the lower part of the lumbosacral spine.

Although only five volunteers were examined, the Baycast spica had a consistent and statistically significant effect on the fourth lumbar-fifth lumbar level ($p < 0.001$) and the lumbosacral level ($p < 0.0005$). At other levels, and at all levels with the other supports, there was great variation between individuals. In these situations, we recommend that, if a support is to be used in the expectation of a particular effect on segmental mobility, the appropriate check radiographs be made, as pointed out by Norton and Brown.

If one of these supports is to be used in the treatment of low-back pain, then the canvas corset has the advantage of comfort while providing abdominal support and some restriction of angular movements of the lumbar spine. There is little to choose between the Raney and Baycast jackets regarding their effect on segmental movements, but the Raney jacket is designed to reduce the lumbar lordosis and can be easily removed. The Baycast spica can be worn for a few weeks to break a painful vicious circle, but for more prolonged use it is too cumbersome. However, the Baycast spica was the most effective in restricting the mobility of the lower part of the lumbosacral spine. This is particularly important if a lumbosacral support is used in the preoperative assessment or postoperative management of a patient with a low-back disorder.

For the best restriction of movement at the fourth lumbar-fifth lumbar level or at the lumbosacral level, preoperatively or postoperatively, we now routinely include the thigh (Baycast spica). Because our study has shown this device to be consistently effective, and also for the purpose of avoiding unnecessary radiation, routine check radiographs in flexion and extension are not made. For restriction of movement at the third lumbar-fourth lumbar level, a carefully molded Baycast jacket is applied but, because of the variation between individuals in our study, we do make flexion-extension radiographs. If these do not show the desired effect, the jacket is replaced by a spica and flexion-extension radiographs are again made for comparison and future correlation. For restriction of movement at the second lumbar-third lumbar level, a Baycast jacket is used along with check radiographs. Plaster of Paris can be substituted for the Baycast jacket, but the weight of the plaster is a particular disadvantage for the spica.

Conclusions

All of the supports that we tested restricted the segmental sagittal movements of the lumbosacral spine, although there was considerable variation between individuals for the canvas corset and for the Raney and Baycast jackets at all levels. Similarly, the Baycast spica showed some variation in its effects at the first lumbar-second lumbar, the second lumbar-third lumbar, and the third lumbar-fourth lumbar levels. However, the Baycast spica was consistent in significantly limiting movement at the fourth lumbar-fifth lumbar level and especially at the lumbosacral level. Furthermore, it was the most effective of the supports that we tested in limiting movement below the third lumbar vertebra, particularly at the fourth lumbar-fifth lumbar level and at the lumbosacral level.

NOTE: The authors would like to thank Dr. B. van der Ende and Dr. van der Stadt for their statistical help, as well as Bayer for supplying the Baycasts and Camp for providing the Raney flexion jackets, and especially the volunteers without whose participation the study would not have been possible.

References

1. AHLGREN, S. A., and HANSEN, T.: The Use of Lumbosacral Corsets Prescribed for Low Back Pain. Prosthet. and Orthot. Internat., **2:** 101-104, 1978.
2. EVANS, ARTHUR: The Palace of Minos at Knossos. Vol. 1, p. 503. London, Macmillan, 1921.
3. EWING, ELIZABETH: Fashion in Underwear, p. 13. London, Batsford, 1971.
4. LUMSDEN, R. M., and MORRIS, J. M.: An *In Vivo* Study of Axial Rotation and Immobilization at the Lumbosacral Joint. J. Bone and Joint Surg., **50-A:** 1591-1602, Dec. 1968.
5. NEW YORK UNIVERSITY, POST-GRADUATE MEDICAL SCHOOL: Prosthetics and Orthotics; Measurement, Layout and Pattern Design for Lumbosacral F-E and L Corsets. Spinal Orthotics including Orthotists' Supplement, pp. 167-196. New York, 1975.
6. NORTON, P. L., and BROWN, THORNTON: The Immobilizing Efficiency of Back Braces. Their Effect on the Posture and Motion of the Lumbosacral Spine. J. Bone and Joint Surg., **39-A:** 111-138, Jan. 1957.
7. PERRY, JACQUELIN: The Use of External Support in the Treatment of Low-Back Pain. Report of the Subcommittee on Orthotics of the Committee on Prosthetic-Orthotic Education, National Academy of Sciences, National Research Council. J. Bone and Joint Surg., **52-A:** 1440-1442, Oct. 1970.
8. RANEY, F.: Royalite Flexion Jacket. Report on the Spinal Orthotics Workshop, pp. 85-91. Sponsored by the Committee on Prosthetics Research and Development of the Division of Engineering of the National Research Council. Washington, D.C., National Research Council, 1969.
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HCPCS:	Descriptor:
L0627	LUMBAR ORTHOSIS, SAGITTAL CONTROL, WITH RIGID ANTERIOR AND POSTERIOR PANELS, POSTERIOR EXTENDS FROM L-1 TO BELOW L-5 PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES,VERTEBRA, PRODUCES INTRACAVITARY MAY INCLUDE PADDING, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

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Sample Diagnosis (Not Inclusive)	Fractures, DJD, arthritis
Medically Necessary Argument	The forces implemented by the brace to control sagittal control with this bi-valve rigid device need to be evaluated by a professional. If the forces are not directed in the appropriate anatomical location to prevent unwanted motion direction then the patient puts them self at a higher risk of injury. The trimlines of posterior and anterior rigid panel and pressures over bony prominences encompassed by the brace needs to be evaluated by a professional to ensure maintain skin integrity and prevent skin breakdown. The amount of intracavitary pressures provide by the brace needs to be assessed to ensure an appropriate amount of force is being applied and abdominal structures and internal organs are not being constricted due to excessive pressures. The strapping configuration and appropriate tightness of the straps needs to be review with the patient. Poorly adjusted straps decrease the overall effectiveness of the brace and increase the risk of injury with poorly directed strap forces.
References	3

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Using a uniform technique lateral radiographs of the lumbosacral spine were made in maximum flexion and extension, first without and then with the support so that each

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TABLE I

MOVEMENT IN THE CANVAS CORSET FOR FIVE VOLUNTEERS (CASES 1 THROUGH 5)

Level	Movement with No Support (*Degrees*)					Movement in the Canvas Corset (*Degrees*)					Percentage Permitted Movement in the Canvas Corset					
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	Mean
L1-L2	15			11	17	9	13		4	10	60			36	59	52*
L2-L3	21	16	11	12	10	11	12	9	10	3	52	75	82	83	30	64†
L3-L4	18	13	17	12	3	7	10	17	10	0	39	77	100	83	0	60‡
L4-L5	15	21	20	13	7	10	10	17	10	2	67	48	85	77	29	61†
L5-S1	13	14	15	14	15	6	7	9	13	10	46	50	60	93	67	63*

* $0.005 > p > 0.001$.
† $0.05 > p > 0.01$.
‡ $0.1 > p > 0.05$.

volunteer acted as his own control. Segmental movement during flexion and extension was determined by means of corresponding lines drawn along the end-plates of each vertebra. The angles between adjacent vertebrae were measured in flexion and in extension, and the difference was recorded as the movement occurring at that level. These segmental angular movements, without and with a support, were determined at each level for all of the volunteers. In order to facilitate comparison of one type of support with another, the angular movements that were permitted by a support were expressed as percentages of the corresponding control unrestricted angular movements and then, for each type of support, the averages (arithmetical means) of these percentages were calculated for each level.

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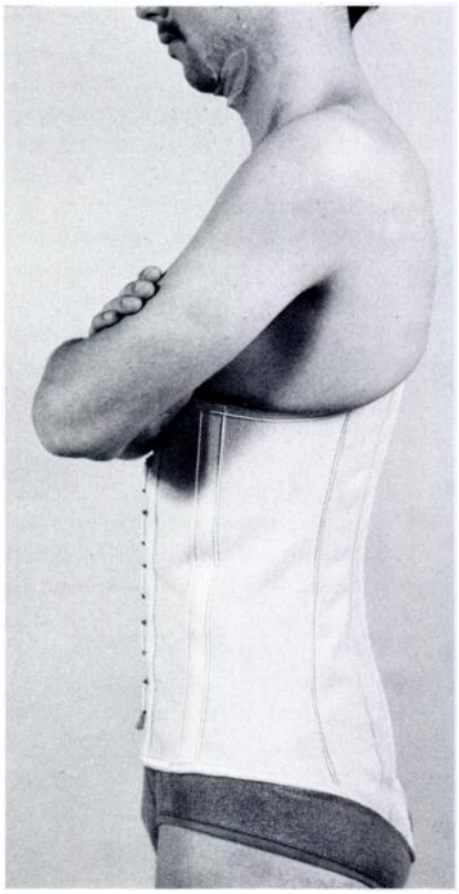

FIG. 1

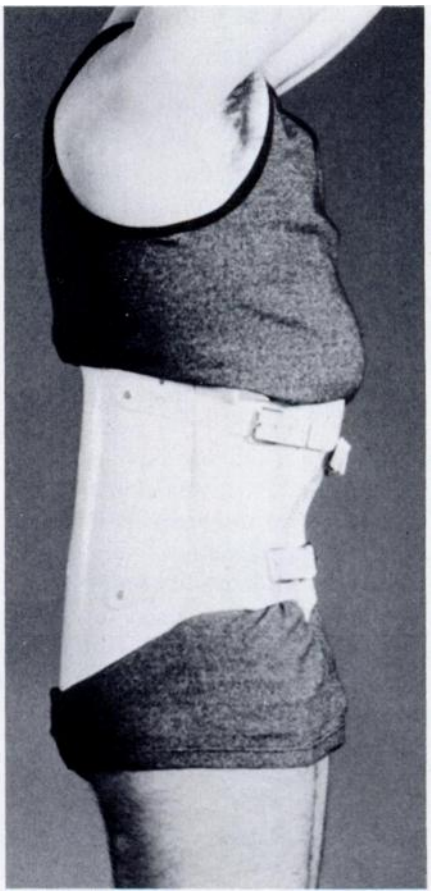

FIG. 2

Fig. 1: Canvas lumbosacral corset.
Fig. 2: Raney flexion jacket.

TABLE II

MOVEMENT IN THE RANEY JACKET FOR FIVE VOLUNTEERS (CASES 6 THROUGH 10)

	Movement with No Support (*Degrees*)					Movement in the Raney Jacket (*Degrees*)					Percentage Permitted Movement in the Raney Jacket					
Level	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10	Mean
L1-L2	15	11	6			2	5	5	7	2	13	45	83			47*
L2-L3	13	15	12	8	15	5	4	1	3	7	38	27	8	38	47	32†
L3-L4	12	12	17	13	13	6	2	1	2	10	50	17	6	15	77	33‡
L4-L5	20	16	15	17	11	6	7	8	12	3	30	44	53	71	27	45§
L5-S1	18	11	13	22	18	13	12	6	5	10	72	109	46	23	56	61¶

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not think that this was justifiable. Tanz, who also used a superimposition method to calculate the segmental angular movements, found that the results of repeat radiographic examinations usually agreed to within 2 degrees. We assumed that this 2-degree error would be applicable to our series.

Radiation Precautions

The volunteers were healthy thin men whose gonads were screened. They had had minimum previous exposure to radiation and did not come into contact with x-rays during their routine work. One radiographer in each hospital made all of the radiographs to minimize the chance of error. An off-center radiograph was not repeated. This explains the absence of readings at the level of the disc between the first and second lumbar vertebrae for Cases 2, 3, 9, 10, and 11 in Tables I, II, and III. Copies of the radiographs were subsequently given to the volunteers for possible future reference in case they ever had low-back pain in the future. The radiation dose to the lumbar spine was approximately 250 millirads and to the shielded gonads it was ten millirads per radiograph. Baycast absorbs virtually no radiation. Thus, lower radiation doses were possible than would have been necessary if plaster of Paris had been used.

Results

The effect of the supports is shown in Tables I through IV. Almost all of the supports reduced the segmental angular movements of the lumbosacral spine. The exceptions were the canvas corset on Case 3, in whom movement at the third lumbar-fourth lumbar level was unaffected; the Raney jacket on Case 7, in whom there was a 1-degree (9 per cent) increase in angular movement at the

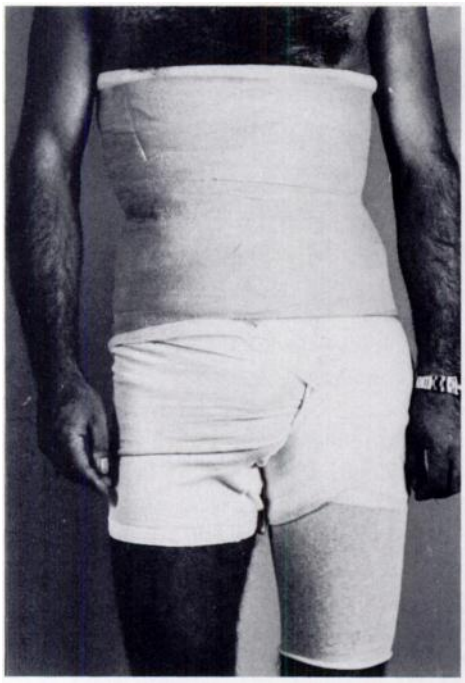

FIG. 3

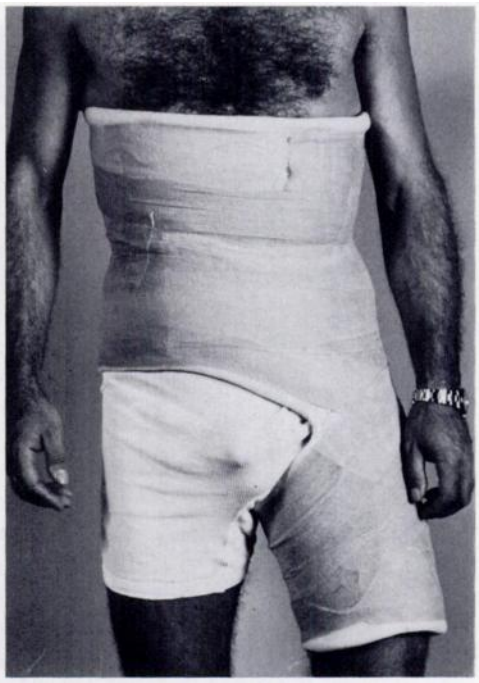

FIG. 4

Fig. 3: Baycast jacket.
Fig. 4: Baycast spica.

TABLE III

MOVEMENT IN THE BAYCAST JACKET AND BAYCAST SPICA FOR FIVE VOLUNTEERS (CASES 11 THROUGH 15)

Level	Movement with No Support (Degrees)					Movement in the Baycast Jacket (Degrees)						Movement in the Baycast Spica (Degrees)					
	11	12	13	14	15	11	12	13	14	15	Mean	11	12	13	14	15	Mean
L1-L2		16	10	10	12	2	7	3	7	8	53%*	4	10	3	7	4	49%†
L2-L3	20	16	17	13	13	2	8	11	5	4	39%‡	2	1	4	12	4	33%†
L3-L4	16	16	11	10	13	2	4	6	6	6	40%†	0	2	6	6	1	27%†
L4-L5	18	22	18	20	12	0	6	13	6	4	32%‡	2	0	3	3	2	12%§
L5-S1	23	22	14	16	17	10	11	14	16	10	70%*	2	0	1	1	3	8%§

* $0.05 > p > 0.01$.
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§ $0.001 > p$.

lumbosacral level; and the Baycast jackets on Cases 13 and 14, in whom the angular movements at the lumbosacral level were unaffected. Although the results showed considerable variation between individuals with regard to the effect of the supports, certain general trends could be discerned. Table IV and Figure 5 summarize the effect of each type of support at each level in the form of the mean percentage of angular movement permitted.

The canvas corset reduced angular movement at each level to approximately two-thirds of normal. The Raney and Baycast jackets were reasonably effective in the mid-part of the lumbar spine, where they reduced the angular movement to about one-third of normal, but at the first lumbar-second lumbar level and the lumbosacral level they had the same effect as the canvas corset. The Baycast spica was the most efficient below the third lumbar vertebra, and was progressively more efficient the lower the level. At the fourth lumbar-fifth lumbar level the Baycast spica permitted an average angular movement of only 2 degrees, or 12 per cent of normal, and a maximum angular movement of 3 degrees. At the lumbosacral level it was even more efficient, permitting an average angular movement of only 1.4 degrees, or 8 per cent of normal, and a maximum angular movement of only 3 degrees. The beneficial effect of the Baycast spica compared with the Baycast jacket in reducing angular movement at the lumbosacral level was statistically significant ($p < 0.001$).

TABLE IV

MEAN AND RANGE OF PERCENTAGE PERMITTED MOVEMENT

Level	Canvas Corset	Raney Jacket	Baycast Jacket	Baycast Spica
L1-L2	52 (36-60)	47 (13-83)	53 (30-70)	49 (30-70)
L2-L3	64 (30-83)	32 (8-47)	39 (10-65)	33 (6-92)
L3-L4	60 (0-100)	33 (6-77)	40 (13-60)	27 (0-60)
L4-L5	61 (29-85)	45 (27-71)	32 (0-72)	12 (0-17)
L5-S1	63 (46-93)	61 (23-109)	70 (43-100)	8 (0-18)

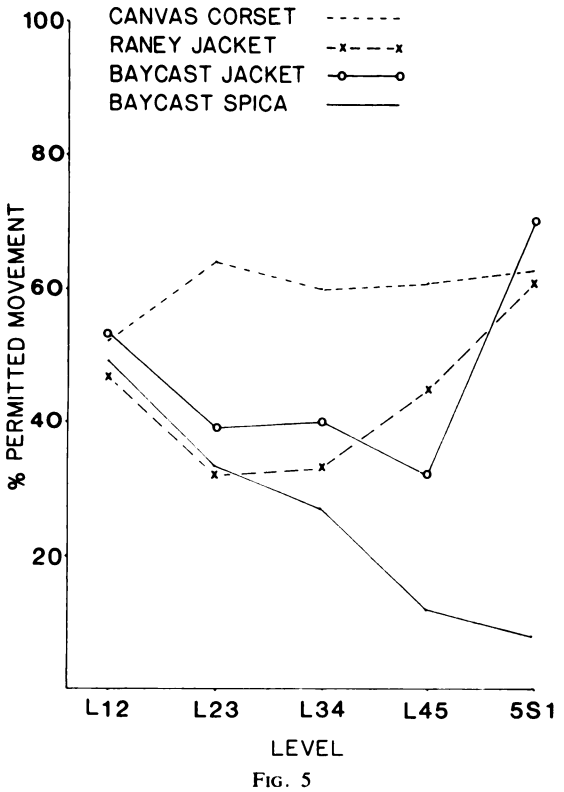

FIG. 5

Graph illustrating the percentage of movement permitted at each level by each type of support.

Discussion

The lumbosacral spinal vertebrae can undergo both translation and angular motion. The latter is caused by lateral bending and flexion-extension or axial rotation movements. Restriction of axial rotation at the lumbosacral level was observed by Lumsden and Morris in subjects wearing a chairback brace, but the effects of lumbosacral canvas corsets were varied and unpredictable. It is probable that the Raney and Baycast jackets, like the chairback brace, would adequately fix the pelvis and similarly control rotation. The cross section of the torso is oval and hence the lateral sides of a spinal support, being farther away from the spine than the back and front, should be more efficient in restricting lateral bending movement than the back and front are in restricting flexion and extension movement. Unless the sides are inadequate, it therefore seems likely that a support that restricts flexion-extension movement would be at least as effective in restricting lateral bending movement. In order to obtain the maximum

information from the minimum amount of radiation, we therefore limited this comparative study to motion in the sagittal plane.

Like Tanz, we found considerable variation in lumbar spinal movements between normal individuals, and so each volunteer had to act as his own control. However, because of the radiation involved it was not possible to do a radiographic assessment of four supports in flexion and extension, as well as to make control radiographs, for each volunteer. Norton and Brown circumvented this problem by measuring the angles between Kirschner wires in the spinous processes after making preliminary radiographic measurements, and Lumsden and Morris measured rotation by inserting Steinmann pins in the spinous processes alone. We used different groups of volunteers for the canvas, Raney, and Baycast supports.

A rigid support works on the principle of three-point fixation; optimum restriction of movement is likely to be achieved about halfway along and to decrease toward the ends. This effect is illustrated by the graphs for the Raney and Baycast jackets (Fig. 5). At the caudal end, for example, the pelvis is not effectively controlled by the supports and considerable lumbosacral motion is still possible. The extension of the jacket to include the hip and thigh provides the necessary control of the pelvis and accounts for the effectiveness of the Baycast spica in restricting the movement of the lower part of the lumbosacral spine.

Although only five volunteers were examined, the Baycast spica had a consistent and statistically significant effect on the fourth lumbar-fifth lumbar level ($p < 0.001$) and the lumbosacral level ($p < 0.0005$). At other levels, and at all levels with the other supports, there was great variation between individuals. In these situations, we recommend that, if a support is to be used in the expectation of a particular effect on segmental mobility, the appropriate check radiographs be made, as pointed out by Norton and Brown.

If one of these supports is to be used in the treatment of low-back pain, then the canvas corset has the advantage of comfort while providing abdominal support and some restriction of angular movements of the lumbar spine. There is little to choose between the Raney and Baycast jackets regarding their effect on segmental movements, but the Raney jacket is designed to reduce the lumbar lordosis and can be easily removed. The Baycast spica can be worn for a few weeks to break a painful vicious circle, but for more prolonged use it is too cumbersome. However, the Baycast spica was the most effective in restricting the mobility of the lower part of the lumbosacral spine. This is particularly important if a lumbosacral support is used in the preoperative assessment or postoperative management of a patient with a low-back disorder.

For the best restriction of movement at the fourth lumbar-fifth lumbar level or at the lumbosacral level, preoperatively or postoperatively, we now routinely include the thigh (Baycast spica). Because our study has shown this device to be consistently effective, and also for the purpose of avoiding unnecessary radiation, routine check radiographs in flexion and extension are not made. For restriction of movement at the third lumbar-fourth lumbar level, a carefully molded Baycast jacket is applied but, because of the variation between individuals in our study, we do make flexion-extension radiographs. If these do not show the desired effect, the jacket is replaced by a spica and flexion-extension radiographs are again made for comparison and future correlation. For restriction of movement at the second lumbar-third lumbar level, a Baycast jacket is used along with check radiographs. Plaster of Paris can be substituted for the Baycast jacket, but the weight of the plaster is a particular disadvantage for the spica.

Conclusions

All of the supports that we tested restricted the segmental sagittal movements of the lumbosacral spine, although there was considerable variation between individuals for the canvas corset and for the Raney and Baycast jackets at all levels. Similarly, the Baycast spica showed some variation in its effects at the first lumbar-second lumbar, the second lumbar-third lumbar, and the third lumbar-fourth lumbar levels. However, the Baycast spica was consistent in significantly limiting movement at the fourth lumbar-fifth lumbar level and especially at the lumbosacral level. Furthermore, it was the most effective of the supports that we tested in limiting movement below the third lumbar vertebra, particularly at the fourth lumbar-fifth lumbar level and at the lumbosacral level.

NOTE: The authors would like to thank Dr. B. van der Ende and Dr. van der Stadt for their statistical help, as well as Bayer for supplying the Baycasts and Camp for providing the Raney flexion jackets, and especially the volunteers without whose participation the study would not have been possible.

References

1. AHLGREN, S. A., and HANSEN, T.: The Use of Lumbosacral Corsets Prescribed for Low Back Pain. Prosthet. and Orthot. Internat., **2:** 101-104, 1978.
2. EVANS, ARTHUR: The Palace of Minos at Knossos. Vol. 1, p. 503. London, Macmillan, 1921.
3. EWING, ELIZABETH: Fashion in Underwear, p. 13. London, Batsford, 1971.
4. LUMSDEN, R. M., and MORRIS, J. M.: An *In Vivo* Study of Axial Rotation and Immobilization at the Lumbosacral Joint. J. Bone and Joint Surg., **50-A:** 1591-1602, Dec. 1968.
5. NEW YORK UNIVERSITY, POST-GRADUATE MEDICAL SCHOOL: Prosthetics and Orthotics; Measurement, Layout and Pattern Design for Lumbosacral F-E and L Corsets. Spinal Orthotics including Orthotists' Supplement, pp. 167-196. New York, 1975.
6. NORTON, P. L., and BROWN, THORNTON: The Immobilizing Efficiency of Back Braces. Their Effect on the Posture and Motion of the Lumbosacral Spine. J. Bone and Joint Surg., **39-A:** 111-138, Jan. 1957.
7. PERRY, JACQUELIN: The Use of External Support in the Treatment of Low-Back Pain. Report of the Subcommittee on Orthotics of the Committee on Prosthetic-Orthotic Education, National Academy of Sciences, National Research Council. J. Bone and Joint Surg., **52-A:** 1440-1442, Oct. 1970.
8. RANEY, F.: Royalite Flexion Jacket. Report on the Spinal Orthotics Workshop, pp. 85-91. Sponsored by the Committee on Prosthetics Research and Development of the Division of Engineering of the National Research Council. Washington, D.C., National Research Council, 1969.
9. TANZ, S. S.: Motion of the Lumbar Spine. A Roentgenologic Study. Am. J. Roentgenol., **69:** 399-412, 1953.

HCPCS:	Descriptor:
L0628	LUMBAR-SACRAL ORTHOSIS, FLEXIBLE, PROVIDES LUMBO-SACRAL SUPPORT, POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE STAYS, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Fractures, DJD, arthritis, osteoporosis
Medically Necessary Argument	This orthoses requires exact sizing and measurements. When fit incorrectly, the orthoses will be extremely difficult to tolerate and would cause discomfort to the lumbar spine as well as cause skin irritation. Heat molding and bending of the posterior panel requires specific training.
References	3

The Effect of Four Types of Support on the Segmental Mobility of the Lumbosacral Spine

BY M. W. FIDLER, F.R.C.S.*, AND C. M. T. PLASMANS, M.D.†, AMSTERDAM, THE NETHERLANDS

From the Slotervaart Ziekenhuis and O.L.V. Gasthuis, Amsterdam

ABSTRACT: **With the aid of flexion-extension lateral radiographs, we investigated the effect of the canvas corset, the Raney and Baycast jackets, and the Baycast spica on the segmental sagittal mobility of the lumbosacral spine in separate groups of five volunteers each. The canvas corset reduced the mean angular movements at each level to two-thirds of normal. The Raney and Baycast jackets reduced the mean angular movements in the middle of the lumbar spine to approximately one-third of normal. The Baycast spica was the most effective in restricting angular movements below the third lumbar vertebra, and especially at the fourth lumbar-fifth lumbar level and the lumbosacral level.**

Lumbosacral corsets have been in use at least since the Minoan period, some 2000 years B.C.[2]. The function of those corsets was primarily to mold and enhance the female form, but their construction could also have served to support the lumbosacral spine. The first surgical corset that was specifically designed to support the lumbar spine was probably that made in 1530 for Catherine of Medici[3]. This was an iron corset, extending from the mid-part of the thorax to over the iliac crests, hinged down one side and fastened by a clasp on the other.

Lumbosacral supports are now commonly prescribed in the management of low-back pain[1,7] and are used to judge the effect of immobilization when considering spine fusion or postoperatively to support the spine until fusion occurs. By means of a questionnaire, Perry reviewed the use of supports in America and found that the lumbosacral corset was the most widely used, followed closely by the chairback brace. The effect most often expected from a brace was restriction of lumbosacral motion — this in spite of the fact that Norton and Brown as well as Lumsden and Morris had observed that in some patients a support actually could lead to an increase in movement at the lumbosacral level. It seems that there is still a tendency to prescribe a support for the lumbosacral spine without focusing attention specifically on the level concerned.

We use mainly four types of lumbosacral support. The lumbosacral canvas corset with posterior steel supports (Fig. 1), the Raney[8] flexion jacket (Fig. 2), and the Baycast (Cuttercast) jacket (Fig. 3) are used principally in the treatment of low-back pain, and the Baycast jacket with inclusion of the left thigh (Baycast spica) (Fig. 4) is used chiefly when considering fusion and postoperatively. The thigh is included in order to improve control of the pelvis.

The purpose of this investigation was to assess and compare the effects of these supports on the segmental sagittal mobility of the lumbosacral spine.

Material

Each type of support was assessed on five healthy male volunteers, none of whom had a history of low-back pain.

The canvas lumbosacral corsets were made to measure for each volunteer in the routine manner used for patients with lumbosacral disorders by the orthotist in the Slotervaart Hospital. The pattern used was a minor modification of that described in the spinal orthotics manual of the New York University Post-Graduate Medical School[5]. The lower edge of the corset was trimmed posteriorly at seat level with the subject sitting on a stool, thus avoiding the uncomfortable curled lip that can occur with the slightly lower edge described in the manual. The corset extended from around the lower ribs to over the iliac crest laterally, to just above the symphysis pubis anteriorly, and included the sacrum and upper part of the buttocks posteriorly. Each corset was reinforced with two posterior vertical steel stays stitched between the layers of the canvas.

The Raney flexion jackets were standard models of appropriate size for the volunteers.

The Baycast jackets were applied on standing volunteers by the same orthotist. These jackets extended from two centimeters below the shoulder blades to the mid-part of the sacrum posteriorly, from the xiphisternum to just above the pubis anteriorly, and from around the lower ribs to three centimeters below the level of the anterior superior iliac spines laterally. The left thigh was subsequently included to produce the Baycast spica on these same volunteers. The thigh-piece extended to five centimeters proximal to the patella and was added with the hip in 20 degrees of flexion in order to prevent any fixed lumbar lordosis and to facilitate sitting.

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L2-L3	21	16	11	12	10	11	12	9	10	3	52	75	82	83	30	64†
L3-L4	18	13	17	12	3	7	10	17	10	0	39	77	100	83	0	60‡
L4-L5	15	21	20	13	7	10	10	17	10	2	67	48	85	77	29	61†
L5-S1	13	14	15	14	15	6	7	9	13	10	46	50	60	93	67	63*

* $0.005 > p > 0.001$.
† $0.05 > p > 0.01$.
‡ $0.1 > p > 0.05$.

volunteer acted as his own control. Segmental movement during flexion and extension was determined by means of corresponding lines drawn along the end-plates of each vertebra. The angles between adjacent vertebrae were measured in flexion and in extension, and the difference was recorded as the movement occurring at that level. These segmental angular movements, without and with a support, were determined at each level for all of the volunteers. In order to facilitate comparison of one type of support with another, the angular movements that were permitted by a support were expressed as percentages of the corresponding control unrestricted angular movements and then, for each type of support, the averages (arithmetical means) of these percentages were calculated for each level.

We found that the most accurate method of drawing corresponding lines on the radiographs was first to draw all of the lines on one radiograph. The second radiograph was then placed on top of the first and the shadow of each vertebral body was superimposed in turn over that of the same vertebra on the underlying radiograph while the corresponding lines were traced onto the upper radiograph.

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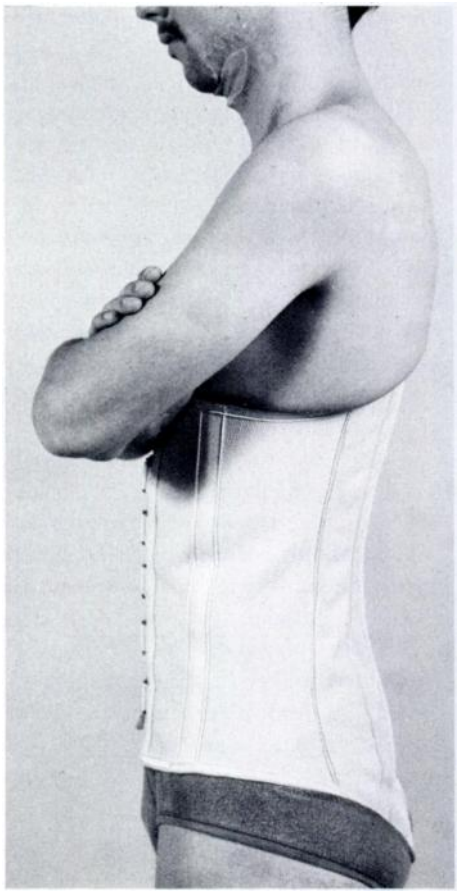

FIG. 1

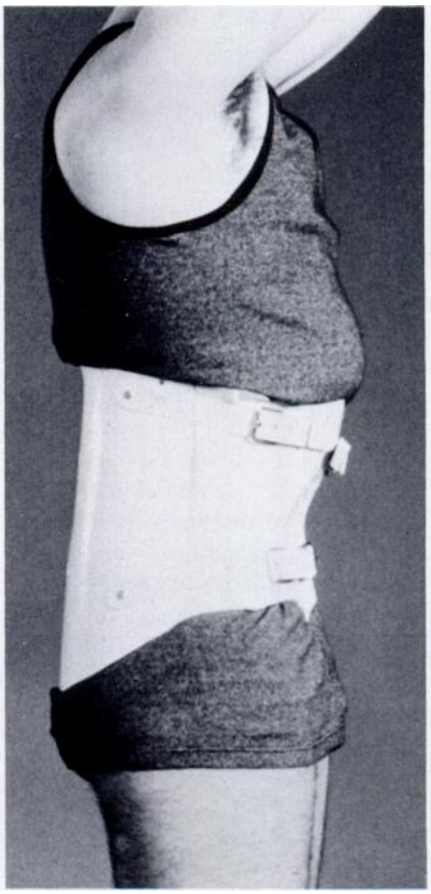

FIG. 2

Fig. 1: Canvas lumbosacral corset.
Fig. 2: Raney flexion jacket.

TABLE II

MOVEMENT IN THE RANEY JACKET FOR FIVE VOLUNTEERS (CASES 6 THROUGH 10)

Level	Movement with No Support (*Degrees*)					Movement in the Raney Jacket (*Degrees*)					Percentage Permitted Movement in the Raney Jacket					
	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10	Mean
L1-L2	15	11	6			2	5	5	7	2	13	45	83			47*
L2-L3	13	15	12	8	15	5	4	1	3	7	38	27	8	38	47	32†
L3-L4	12	12	17	13	13	6	2	1	2	10	50	17	6	15	77	33‡
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L5-S1	18	11	13	22	18	13	12	6	5	10	72	109	46	23	56	61¶

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Results

The effect of the supports is shown in Tables I through IV. Almost all of the supports reduced the segmental angular movements of the lumbosacral spine. The exceptions were the canvas corset on Case 3, in whom movement at the third lumbar-fourth lumbar level was unaffected; the Raney jacket on Case 7, in whom there was a 1-degree (9 per cent) increase in angular movement at the

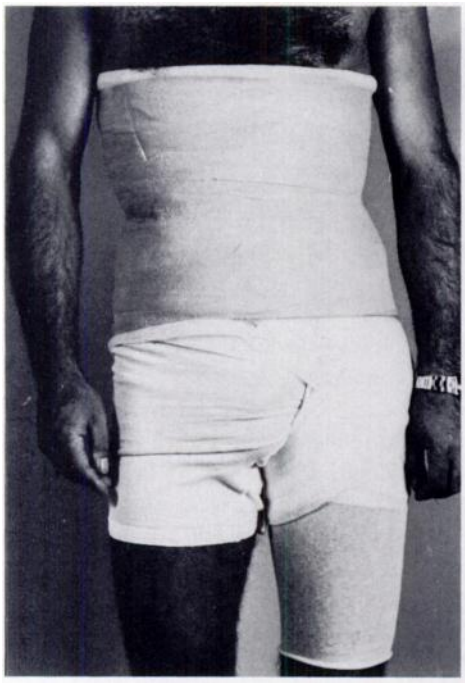

FIG. 3

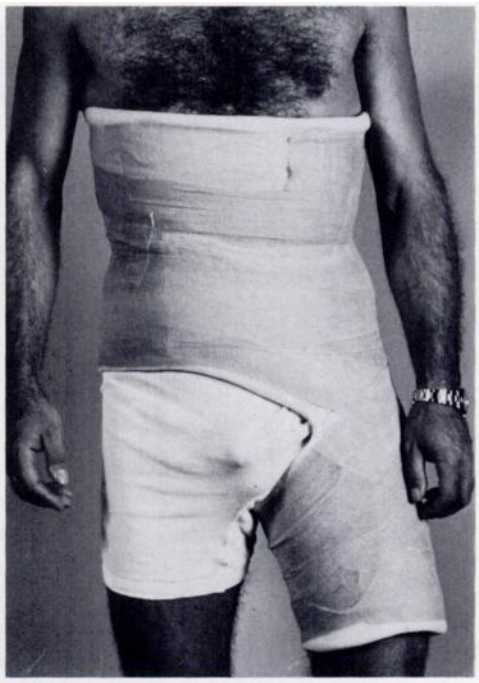

FIG. 4

Fig. 3: Baycast jacket.
Fig. 4: Baycast spica.

TABLE III

MOVEMENT IN THE BAYCAST JACKET AND BAYCAST SPICA FOR FIVE VOLUNTEERS (CASES 11 THROUGH 15)

Level	Movement with No Support (Degrees)					Movement in the Baycast Jacket (Degrees)						Movement in the Baycast Spica (Degrees)					
	11	12	13	14	15	11	12	13	14	15	Mean	11	12	13	14	15	Mean
L1-L2		16	10	10	12	2	7	3	7	8	53%*	4	10	3	7	4	49%†
L2-L3	20	16	17	13	13	2	8	11	5	4	39%‡	2	1	4	12	4	33%†
L3-L4	16	16	11	10	13	2	4	6	6	6	40%†	0	2	6	6	1	27%†
L4-L5	18	22	18	20	12	0	6	13	6	4	32%‡	2	0	3	3	2	12%§
L5-S1	23	22	14	16	17	10	11	14	16	10	70%*	2	0	1	1	3	8%§

* $0.05 > p > 0.01$.
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lumbosacral level; and the Baycast jackets on Cases 13 and 14, in whom the angular movements at the lumbosacral level were unaffected. Although the results showed considerable variation between individuals with regard to the effect of the supports, certain general trends could be discerned. Table IV and Figure 5 summarize the effect of each type of support at each level in the form of the mean percentage of angular movement permitted.

The canvas corset reduced angular movement at each level to approximately two-thirds of normal. The Raney and Baycast jackets were reasonably effective in the mid-part of the lumbar spine, where they reduced the angular movement to about one-third of normal, but at the first lumbar-second lumbar level and the lumbosacral level they had the same effect as the canvas corset. The Baycast spica was the most efficient below the third lumbar vertebra, and was progressively more efficient the lower the level. At the fourth lumbar-fifth lumbar level the Baycast spica permitted an average angular movement of only 2 degrees, or 12 per cent of normal, and a maximum angular movement of 3 degrees. At the lumbosacral level it was even more efficient, permitting an average angular movement of only 1.4 degrees, or 8 per cent of normal, and a maximum angular movement of only 3 degrees. The beneficial effect of the Baycast spica compared with the Baycast jacket in reducing angular movement at the lumbosacral level was statistically significant ($p < 0.001$).

TABLE IV

MEAN AND RANGE OF PERCENTAGE PERMITTED MOVEMENT

Level	Canvas Corset	Raney Jacket	Baycast Jacket	Baycast Spica
L1-L2	52 (36-60)	47 (13-83)	53 (30-70)	49 (30-70)
L2-L3	64 (30-83)	32 (8-47)	39 (10-65)	33 (6-92)
L3-L4	60 (0-100)	33 (6-77)	40 (13-60)	27 (0-60)
L4-L5	61 (29-85)	45 (27-71)	32 (0-72)	12 (0-17)
L5-S1	63 (46-93)	61 (23-109)	70 (43-100)	8 (0-18)

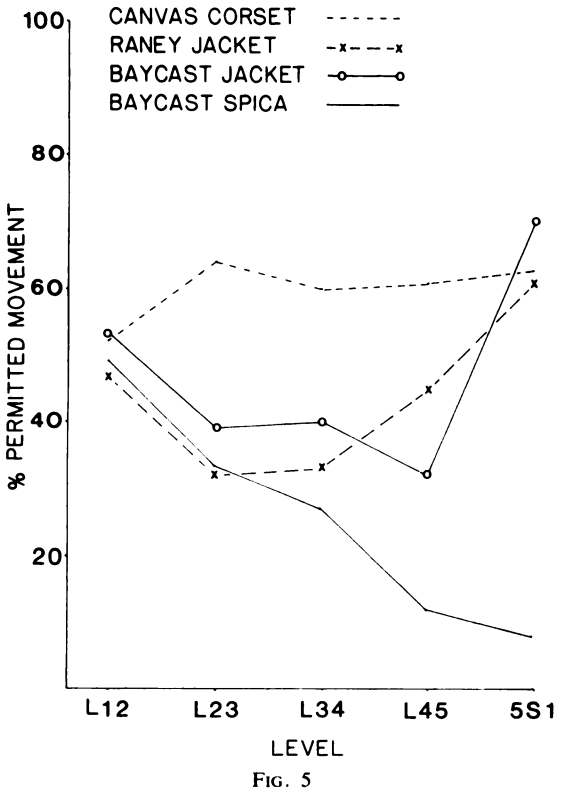

FIG. 5

Graph illustrating the percentage of movement permitted at each level by each type of support.

Discussion

The lumbosacral spinal vertebrae can undergo both translation and angular motion. The latter is caused by lateral bending and flexion-extension or axial rotation movements. Restriction of axial rotation at the lumbosacral level was observed by Lumsden and Morris in subjects wearing a chairback brace, but the effects of lumbosacral canvas corsets were varied and unpredictable. It is probable that the Raney and Baycast jackets, like the chairback brace, would adequately fix the pelvis and similarly control rotation. The cross section of the torso is oval and hence the lateral sides of a spinal support, being farther away from the spine than the back and front, should be more efficient in restricting lateral bending movement than the back and front are in restricting flexion and extension movement. Unless the sides are inadequate, it therefore seems likely that a support that restricts flexion-extension movement would be at least as effective in restricting lateral bending movement. In order to obtain the maximum

information from the minimum amount of radiation, we therefore limited this comparative study to motion in the sagittal plane.

Like Tanz, we found considerable variation in lumbar spinal movements between normal individuals, and so each volunteer had to act as his own control. However, because of the radiation involved it was not possible to do a radiographic assessment of four supports in flexion and extension, as well as to make control radiographs, for each volunteer. Norton and Brown circumvented this problem by measuring the angles between Kirschner wires in the spinous processes after making preliminary radiographic measurements, and Lumsden and Morris measured rotation by inserting Steinmann pins in the spinous processes alone. We used different groups of volunteers for the canvas, Raney, and Baycast supports.

A rigid support works on the principle of three-point fixation; optimum restriction of movement is likely to be achieved about halfway along and to decrease toward the ends. This effect is illustrated by the graphs for the Raney and Baycast jackets (Fig. 5). At the caudal end, for example, the pelvis is not effectively controlled by the supports and considerable lumbosacral motion is still possible. The extension of the jacket to include the hip and thigh provides the necessary control of the pelvis and accounts for the effectiveness of the Baycast spica in restricting the movement of the lower part of the lumbosacral spine.

Although only five volunteers were examined, the Baycast spica had a consistent and statistically significant effect on the fourth lumbar-fifth lumbar level ($p < 0.001$) and the lumbosacral level ($p < 0.0005$). At other levels, and at all levels with the other supports, there was great variation between individuals. In these situations, we recommend that, if a support is to be used in the expectation of a particular effect on segmental mobility, the appropriate check radiographs be made, as pointed out by Norton and Brown.

If one of these supports is to be used in the treatment of low-back pain, then the canvas corset has the advantage of comfort while providing abdominal support and some restriction of angular movements of the lumbar spine. There is little to choose between the Raney and Baycast jackets regarding their effect on segmental movements, but the Raney jacket is designed to reduce the lumbar lordosis and can be easily removed. The Baycast spica can be worn for a few weeks to break a painful vicious circle, but for more prolonged use it is too cumbersome. However, the Baycast spica was the most effective in restricting the mobility of the lower part of the lumbosacral spine. This is particularly important if a lumbosacral support is used in the preoperative assessment or postoperative management of a patient with a low-back disorder.

For the best restriction of movement at the fourth lumbar-fifth lumbar level or at the lumbosacral level, preoperatively or postoperatively, we now routinely include the thigh (Baycast spica). Because our study has shown this device to be consistently effective, and also for the purpose of avoiding unnecessary radiation, routine check radiographs in flexion and extension are not made. For restriction of movement at the third lumbar-fourth lumbar level, a carefully molded Baycast jacket is applied but, because of the variation between individuals in our study, we do make flexion-extension radiographs. If these do not show the desired effect, the jacket is replaced by a spica and flexion-extension radiographs are again made for comparison and future correlation. For restriction of movement at the second lumbar-third lumbar level, a Baycast jacket is used along with check radiographs. Plaster of Paris can be substituted for the Baycast jacket, but the weight of the plaster is a particular disadvantage for the spica.

Conclusions

All of the supports that we tested restricted the segmental sagittal movements of the lumbosacral spine, although there was considerable variation between individuals for the canvas corset and for the Raney and Baycast jackets at all levels. Similarly, the Baycast spica showed some variation in its effects at the first lumbar-second lumbar, the second lumbar-third lumbar, and the third lumbar-fourth lumbar levels. However, the Baycast spica was consistent in significantly limiting movement at the fourth lumbar-fifth lumbar level and especially at the lumbosacral level. Furthermore, it was the most effective of the supports that we tested in limiting movement below the third lumbar vertebra, particularly at the fourth lumbar-fifth lumbar level and at the lumbosacral level.

NOTE: The authors would like to thank Dr. B. van der Ende and Dr. van der Stadt for their statistical help, as well as Bayer for supplying the Baycasts and Camp for providing the Raney flexion jackets, and especially the volunteers without whose participation the study would not have been possible.

References

1. AHLGREN, S. A., and HANSEN, T.: The Use of Lumbosacral Corsets Prescribed for Low Back Pain. Prosthet. and Orthot. Internat., **2:** 101-104, 1978.
2. EVANS, ARTHUR: The Palace of Minos at Knossos. Vol. 1, p. 503. London, Macmillan, 1921.
3. EWING, ELIZABETH: Fashion in Underwear, p. 13. London, Batsford, 1971.
4. LUMSDEN, R. M., and MORRIS, J. M.: An *In Vivo* Study of Axial Rotation and Immobilization at the Lumbosacral Joint. J. Bone and Joint Surg., **50-A:** 1591-1602, Dec. 1968.
5. NEW YORK UNIVERSITY, POST-GRADUATE MEDICAL SCHOOL: Prosthetics and Orthotics; Measurement, Layout and Pattern Design for Lumbosacral F-E and L Corsets. Spinal Orthotics including Orthotists' Supplement, pp. 167-196. New York, 1975.
6. NORTON, P. L., and BROWN, THORNTON: The Immobilizing Efficiency of Back Braces. Their Effect on the Posture and Motion of the Lumbosacral Spine. J. Bone and Joint Surg., **39-A:** 111-138, Jan. 1957.
7. PERRY, JACQUELIN: The Use of External Support in the Treatment of Low-Back Pain. Report of the Subcommittee on Orthotics of the Committee on Prosthetic-Orthotic Education, National Academy of Sciences, National Research Council. J. Bone and Joint Surg., **52-A:** 1440-1442, Oct. 1970.
8. RANEY, F.: Royalite Flexion Jacket. Report on the Spinal Orthotics Workshop, pp. 85-91. Sponsored by the Committee on Prosthetics Research and Development of the Division of Engineering of the National Research Council. Washington, D.C., National Research Council, 1969.
9. TANZ, S. S.: Motion of the Lumbar Spine. A Roentgenologic Study. Am. J. Roentgenol., **69:** 399-412, 1953.

HCPCS:	Descriptor:
L0630	LUMBAR-SACRAL ORTHOSIS, SAGITTAL CONTROL, WITH RIGID POSTERIOR PANEL(S), POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, STAYS, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Fractures, DJD, arthritis, osteoporosis
Medically Necessary Argument	The forces implemented by the brace to control sagittal control with this rigid device need to be evaluated by a professional. If the forces are not directed in the appropriate anatomical location to prevent unwanted motion direction then the patient puts them self at a higher risk of injury. The trimlines of posterior and anterior rigid panel and pressures over bony prominences encompassed by the brace needs to be evaluated by a professional to ensure maintain skin integrity and prevent skin breakdown. The amount of intracavitary pressures provide by the brace needs to be assessed to ensure an appropriate amount of force is being applied and abdominal structures and internal organs are not being constricted due to excessive pressures. The strapping configuration and appropriate tightness of the straps needs to be review with the patient. Poorly adjusted straps decrease the overall effectiveness of the brace and increase the risk of injury with poorly directed strap forces.
References	3

The Effect of Four Types of Support on the Segmental Mobility of the Lumbosacral Spine

BY M. W. FIDLER, F.R.C.S.*, AND C. M. T. PLASMANS, M.D.†, AMSTERDAM, THE NETHERLANDS

From the Slotervaart Ziekenhuis and O.L.V. Gasthuis, Amsterdam

ABSTRACT: **With the aid of flexion-extension lateral radiographs, we investigated the effect of the canvas corset, the Raney and Baycast jackets, and the Baycast spica on the segmental sagittal mobility of the lumbosacral spine in separate groups of five volunteers each. The canvas corset reduced the mean angular movements at each level to two-thirds of normal. The Raney and Baycast jackets reduced the mean angular movements in the middle of the lumbar spine to approximately one-third of normal. The Baycast spica was the most effective in restricting angular movements below the third lumbar vertebra, and especially at the fourth lumbar-fifth lumbar level and the lumbosacral level.**

Lumbosacral corsets have been in use at least since the Minoan period, some 2000 years B.C.[2]. The function of those corsets was primarily to mold and enhance the female form, but their construction could also have served to support the lumbosacral spine. The first surgical corset that was specifically designed to support the lumbar spine was probably that made in 1530 for Catherine of Medici[3]. This was an iron corset, extending from the mid-part of the thorax to over the iliac crests, hinged down one side and fastened by a clasp on the other.

Lumbosacral supports are now commonly prescribed in the management of low-back pain[1,7] and are used to judge the effect of immobilization when considering spine fusion or postoperatively to support the spine until fusion occurs. By means of a questionnaire, Perry reviewed the use of supports in America and found that the lumbosacral corset was the most widely used, followed closely by the chairback brace. The effect most often expected from a brace was restriction of lumbosacral motion — this in spite of the fact that Norton and Brown as well as Lumsden and Morris had observed that in some patients a support actually could lead to an increase in movement at the lumbosacral level. It seems that there is still a tendency to prescribe a support for the lumbosacral spine without focusing attention specifically on the level concerned.

We use mainly four types of lumbosacral support. The lumbosacral canvas corset with posterior steel supports (Fig. 1), the Raney[8] flexion jacket (Fig. 2), and the Baycast (Cuttercast) jacket (Fig. 3) are used principally in the treatment of low-back pain, and the Baycast jacket with inclusion of the left thigh (Baycast spica) (Fig. 4) is used chiefly when considering fusion and postoperatively. The thigh is included in order to improve control of the pelvis.

The purpose of this investigation was to assess and compare the effects of these supports on the segmental sagittal mobility of the lumbosacral spine.

Material

Each type of support was assessed on five healthy male volunteers, none of whom had a history of low-back pain.

The canvas lumbosacral corsets were made to measure for each volunteer in the routine manner used for patients with lumbosacral disorders by the orthotist in the Slotervaart Hospital. The pattern used was a minor modification of that described in the spinal orthotics manual of the New York University Post-Graduate Medical School[5]. The lower edge of the corset was trimmed posteriorly at seat level with the subject sitting on a stool, thus avoiding the uncomfortable curled lip that can occur with the slightly lower edge described in the manual. The corset extended from around the lower ribs to over the iliac crest laterally, to just above the symphysis pubis anteriorly, and included the sacrum and upper part of the buttocks posteriorly. Each corset was reinforced with two posterior vertical steel stays stitched between the layers of the canvas.

The Raney flexion jackets were standard models of appropriate size for the volunteers.

The Baycast jackets were applied on standing volunteers by the same orthotist. These jackets extended from two centimeters below the shoulder blades to the mid-part of the sacrum posteriorly, from the xiphisternum to just above the pubis anteriorly, and from around the lower ribs to three centimeters below the level of the anterior superior iliac spines laterally. The left thigh was subsequently included to produce the Baycast spica on these same volunteers. The thigh-piece extended to five centimeters proximal to the patella and was added with the hip in 20 degrees of flexion in order to prevent any fixed lumbar lordosis and to facilitate sitting.

Method

Using a uniform technique lateral radiographs of the lumbosacral spine were made in maximum flexion and extension, first without and then with the support so that each

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† O.L.V. Gasthuis, Amsterdam, the Netherlands.

TABLE I

MOVEMENT IN THE CANVAS CORSET FOR FIVE VOLUNTEERS (CASES 1 THROUGH 5)

Level	Movement with No Support (*Degrees*)					Movement in the Canvas Corset (*Degrees*)					Percentage Permitted Movement in the Canvas Corset					
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	Mean
L1-L2	15			11	17	9	13		4	10	60			36	59	52*
L2-L3	21	16	11	12	10	11	12	9	10	3	52	75	82	83	30	64†
L3-L4	18	13	17	12	3	7	10	17	10	0	39	77	100	83	0	60‡
L4-L5	15	21	20	13	7	10	10	17	10	2	67	48	85	77	29	61†
L5-S1	13	14	15	14	15	6	7	9	13	10	46	50	60	93	67	63*

* $0.005 > p > 0.001$.
† $0.05 > p > 0.01$.
‡ $0.1 > p > 0.05$.

volunteer acted as his own control. Segmental movement during flexion and extension was determined by means of corresponding lines drawn along the end-plates of each vertebra. The angles between adjacent vertebrae were measured in flexion and in extension, and the difference was recorded as the movement occurring at that level. These segmental angular movements, without and with a support, were determined at each level for all of the volunteers. In order to facilitate comparison of one type of support with another, the angular movements that were permitted by a support were expressed as percentages of the corresponding control unrestricted angular movements and then, for each type of support, the averages (arithmetical means) of these percentages were calculated for each level.

We found that the most accurate method of drawing corresponding lines on the radiographs was first to draw all of the lines on one radiograph. The second radiograph was then placed on top of the first and the shadow of each vertebral body was superimposed in turn over that of the same vertebra on the underlying radiograph while the corresponding lines were traced onto the upper radiograph.

We did not assess the reproducibility of the measurements because it would have been necessary to repeat at least one set of flexion and extension radiographs for the volunteers. In view of the extra radiation involved, we did

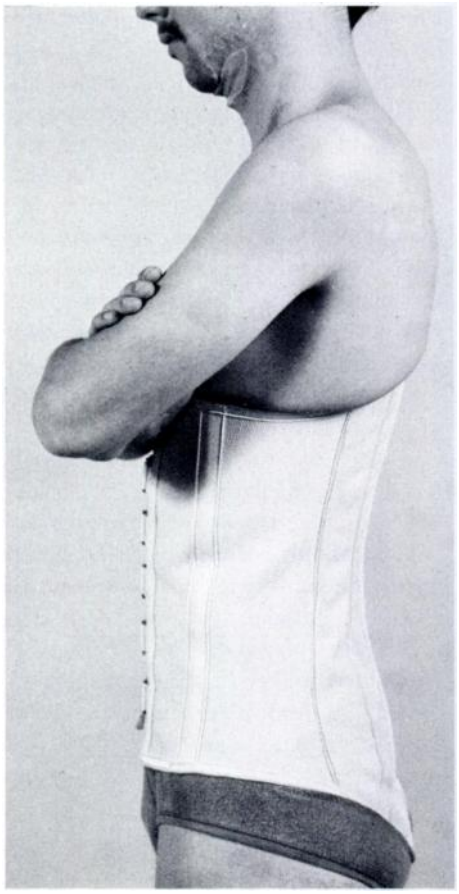

FIG. 1

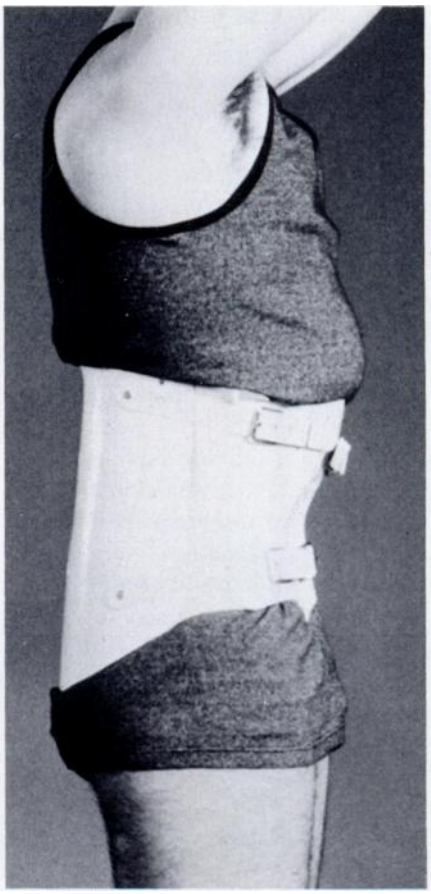

FIG. 2

Fig. 1: Canvas lumbosacral corset.
Fig. 2: Raney flexion jacket.

TABLE II

MOVEMENT IN THE RANEY JACKET FOR FIVE VOLUNTEERS (CASES 6 THROUGH 10)

Level	Movement with No Support (*Degrees*)					Movement in the Raney Jacket (*Degrees*)					Percentage Permitted Movement in the Raney Jacket					
	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10	Mean
L1-L2	15	11	6			2	5	5	7	2	13	45	83			47*
L2-L3	13	15	12	8	15	5	4	1	3	7	38	27	8	38	47	32†
L3-L4	12	12	17	13	13	6	2	1	2	10	50	17	6	15	77	33‡
L4-L5	20	16	15	17	11	6	7	8	12	3	30	44	53	71	27	45§
L5-S1	18	11	13	22	18	13	12	6	5	10	72	109	46	23	56	61¶

* $0.1 > p > 0.05$.
† $0.001 > p$.
‡ $0.01 > p > 0.005$.
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not think that this was justifiable. Tanz, who also used a superimposition method to calculate the segmental angular movements, found that the results of repeat radiographic examinations usually agreed to within 2 degrees. We assumed that this 2-degree error would be applicable to our series.

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The volunteers were healthy thin men whose gonads were screened. They had had minimum previous exposure to radiation and did not come into contact with x-rays during their routine work. One radiographer in each hospital made all of the radiographs to minimize the chance of error. An off-center radiograph was not repeated. This explains the absence of readings at the level of the disc between the first and second lumbar vertebrae for Cases 2, 3, 9, 10, and 11 in Tables I, II, and III. Copies of the radiographs were subsequently given to the volunteers for possible future reference in case they ever had low-back pain in the future. The radiation dose to the lumbar spine was approximately 250 millirads and to the shielded gonads it was ten millirads per radiograph. Baycast absorbs virtually no radiation. Thus, lower radiation doses were possible than would have been necessary if plaster of Paris had been used.

Results

The effect of the supports is shown in Tables I through IV. Almost all of the supports reduced the segmental angular movements of the lumbosacral spine. The exceptions were the canvas corset on Case 3, in whom movement at the third lumbar-fourth lumbar level was unaffected; the Raney jacket on Case 7, in whom there was a 1-degree (9 per cent) increase in angular movement at the

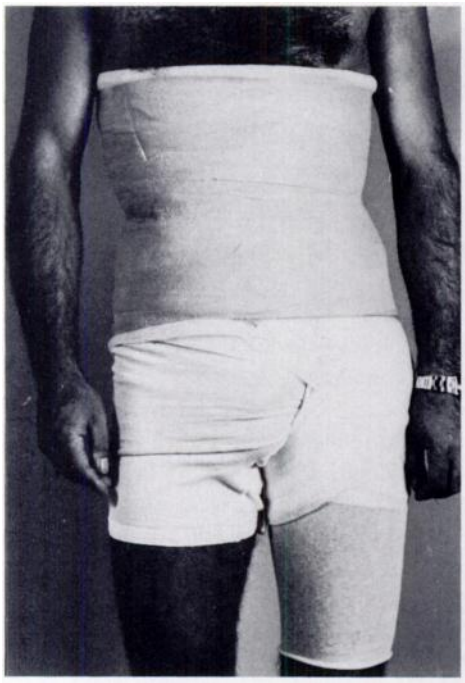

FIG. 3

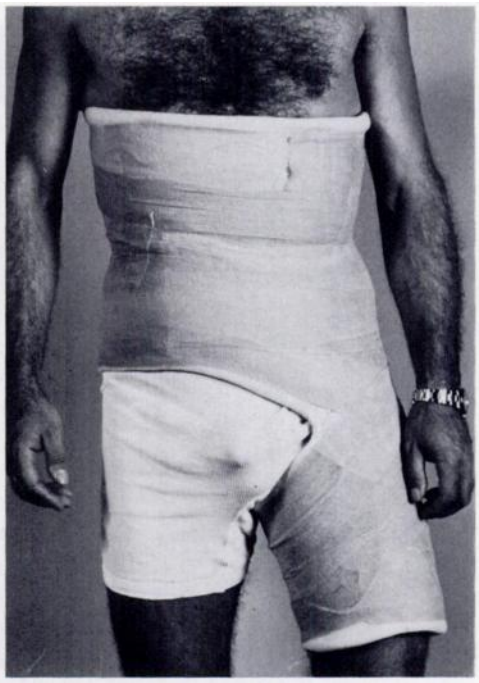

FIG. 4

Fig. 3: Baycast jacket.
Fig. 4: Baycast spica.

TABLE III

MOVEMENT IN THE BAYCAST JACKET AND BAYCAST SPICA FOR FIVE VOLUNTEERS (CASES 11 THROUGH 15)

Level	Movement with No Support (Degrees)					Movement in the Baycast Jacket (Degrees)						Movement in the Baycast Spica (Degrees)					
	11	12	13	14	15	11	12	13	14	15	Mean	11	12	13	14	15	Mean
L1-L2		16	10	10	12	2	7	3	7	8	53%*	4	10	3	7	4	49%†
L2-L3	20	16	17	13	13	2	8	11	5	4	39%‡	2	1	4	12	4	33%†
L3-L4	16	16	11	10	13	2	4	6	6	6	40%†	0	2	6	6	1	27%†
L4-L5	18	22	18	20	12	0	6	13	6	4	32%‡	2	0	3	3	2	12%§
L5-S1	23	22	14	16	17	10	11	14	16	10	70%*	2	0	1	1	3	8%§

* $0.05 > p > 0.01$.
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lumbosacral level; and the Baycast jackets on Cases 13 and 14, in whom the angular movements at the lumbosacral level were unaffected. Although the results showed considerable variation between individuals with regard to the effect of the supports, certain general trends could be discerned. Table IV and Figure 5 summarize the effect of each type of support at each level in the form of the mean percentage of angular movement permitted.

The canvas corset reduced angular movement at each level to approximately two-thirds of normal. The Raney and Baycast jackets were reasonably effective in the mid-part of the lumbar spine, where they reduced the angular movement to about one-third of normal, but at the first lumbar-second lumbar level and the lumbosacral level they had the same effect as the canvas corset. The Baycast spica was the most efficient below the third lumbar vertebra, and was progressively more efficient the lower the level. At the fourth lumbar-fifth lumbar level the Baycast spica permitted an average angular movement of only 2 degrees, or 12 per cent of normal, and a maximum angular movement of 3 degrees. At the lumbosacral level it was even more efficient, permitting an average angular movement of only 1.4 degrees, or 8 per cent of normal, and a maximum angular movement of only 3 degrees. The beneficial effect of the Baycast spica compared with the Baycast jacket in reducing angular movement at the lumbosacral level was statistically significant ($p < 0.001$).

TABLE IV

MEAN AND RANGE OF PERCENTAGE PERMITTED MOVEMENT

Level	Canvas Corset	Raney Jacket	Baycast Jacket	Baycast Spica
L1-L2	52 (36-60)	47 (13-83)	53 (30-70)	49 (30-70)
L2-L3	64 (30-83)	32 (8-47)	39 (10-65)	33 (6-92)
L3-L4	60 (0-100)	33 (6-77)	40 (13-60)	27 (0-60)
L4-L5	61 (29-85)	45 (27-71)	32 (0-72)	12 (0-17)
L5-S1	63 (46-93)	61 (23-109)	70 (43-100)	8 (0-18)

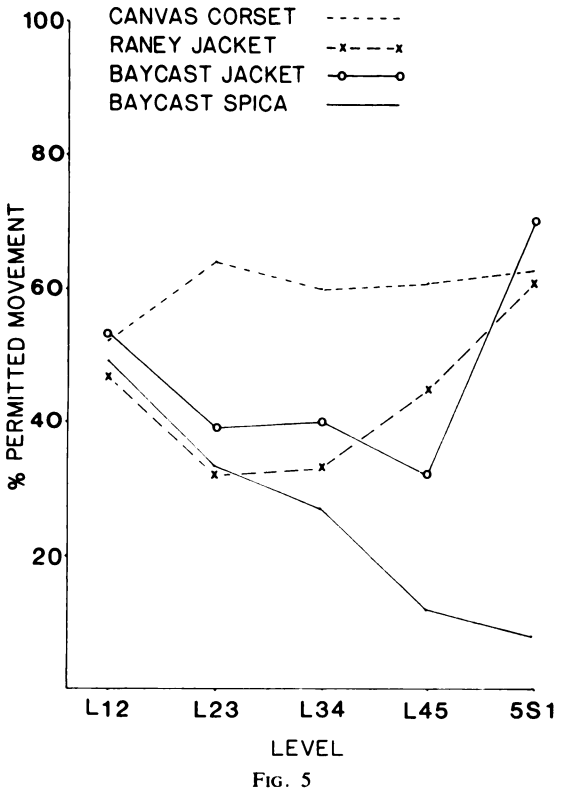

FIG. 5

Graph illustrating the percentage of movement permitted at each level by each type of support.

Discussion

The lumbosacral spinal vertebrae can undergo both translation and angular motion. The latter is caused by lateral bending and flexion-extension or axial rotation movements. Restriction of axial rotation at the lumbosacral level was observed by Lumsden and Morris in subjects wearing a chairback brace, but the effects of lumbosacral canvas corsets were varied and unpredictable. It is probable that the Raney and Baycast jackets, like the chairback brace, would adequately fix the pelvis and similarly control rotation. The cross section of the torso is oval and hence the lateral sides of a spinal support, being farther away from the spine than the back and front, should be more efficient in restricting lateral bending movement than the back and front are in restricting flexion and extension movement. Unless the sides are inadequate, it therefore seems likely that a support that restricts flexion-extension movement would be at least as effective in restricting lateral bending movement. In order to obtain the maximum

information from the minimum amount of radiation, we therefore limited this comparative study to motion in the sagittal plane.

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A rigid support works on the principle of three-point fixation; optimum restriction of movement is likely to be achieved about halfway along and to decrease toward the ends. This effect is illustrated by the graphs for the Raney and Baycast jackets (Fig. 5). At the caudal end, for example, the pelvis is not effectively controlled by the supports and considerable lumbosacral motion is still possible. The extension of the jacket to include the hip and thigh provides the necessary control of the pelvis and accounts for the effectiveness of the Baycast spica in restricting the movement of the lower part of the lumbosacral spine.

Although only five volunteers were examined, the Baycast spica had a consistent and statistically significant effect on the fourth lumbar-fifth lumbar level ($p < 0.001$) and the lumbosacral level ($p < 0.0005$). At other levels, and at all levels with the other supports, there was great variation between individuals. In these situations, we recommend that, if a support is to be used in the expectation of a particular effect on segmental mobility, the appropriate check radiographs be made, as pointed out by Norton and Brown.

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For the best restriction of movement at the fourth lumbar-fifth lumbar level or at the lumbosacral level, preoperatively or postoperatively, we now routinely include the thigh (Baycast spica). Because our study has shown this device to be consistently effective, and also for the purpose of avoiding unnecessary radiation, routine check radiographs in flexion and extension are not made. For restriction of movement at the third lumbar-fourth lumbar level, a carefully molded Baycast jacket is applied but, because of the variation between individuals in our study, we do make flexion-extension radiographs. If these do not show the desired effect, the jacket is replaced by a spica and flexion-extension radiographs are again made for comparison and future correlation. For restriction of movement at the second lumbar-third lumbar level, a Baycast jacket is used along with check radiographs. Plaster of Paris can be substituted for the Baycast jacket, but the weight of the plaster is a particular disadvantage for the spica.

Conclusions

All of the supports that we tested restricted the segmental sagittal movements of the lumbosacral spine, although there was considerable variation between individuals for the canvas corset and for the Raney and Baycast jackets at all levels. Similarly, the Baycast spica showed some variation in its effects at the first lumbar-second lumbar, the second lumbar-third lumbar, and the third lumbar-fourth lumbar levels. However, the Baycast spica was consistent in significantly limiting movement at the fourth lumbar-fifth lumbar level and especially at the lumbosacral level. Furthermore, it was the most effective of the supports that we tested in limiting movement below the third lumbar vertebra, particularly at the fourth lumbar-fifth lumbar level and at the lumbosacral level.

NOTE: The authors would like to thank Dr. B. van der Ende and Dr. van der Stadt for their statistical help, as well as Bayer for supplying the Baycasts and Camp for providing the Raney flexion jackets, and especially the volunteers without whose participation the study would not have been possible.

References

1. AHLGREN, S. A., and HANSEN, T.: The Use of Lumbosacral Corsets Prescribed for Low Back Pain. Prosthet. and Orthot. Internat., **2:** 101-104, 1978.
2. EVANS, ARTHUR: The Palace of Minos at Knossos. Vol. 1, p. 503. London, Macmillan, 1921.
3. EWING, ELIZABETH: Fashion in Underwear, p. 13. London, Batsford, 1971.
4. LUMSDEN, R. M., and MORRIS, J. M.: An *In Vivo* Study of Axial Rotation and Immobilization at the Lumbosacral Joint. J. Bone and Joint Surg., **50-A:** 1591-1602, Dec. 1968.
5. NEW YORK UNIVERSITY, POST-GRADUATE MEDICAL SCHOOL: Prosthetics and Orthotics; Measurement, Layout and Pattern Design for Lumbosacral F-E and L Corsets. Spinal Orthotics including Orthotists' Supplement, pp. 167-196. New York, 1975.
6. NORTON, P. L., and BROWN, THORNTON: The Immobilizing Efficiency of Back Braces. Their Effect on the Posture and Motion of the Lumbosacral Spine. J. Bone and Joint Surg., **39-A:** 111-138, Jan. 1957.
7. PERRY, JACQUELIN: The Use of External Support in the Treatment of Low-Back Pain. Report of the Subcommittee on Orthotics of the Committee on Prosthetic-Orthotic Education, National Academy of Sciences, National Research Council. J. Bone and Joint Surg., **52-A:** 1440-1442, Oct. 1970.
8. RANEY, F.: Royalite Flexion Jacket. Report on the Spinal Orthotics Workshop, pp. 85-91. Sponsored by the Committee on Prosthetics Research and Development of the Division of Engineering of the National Research Council. Washington, D.C., National Research Council, 1969.
9. TANZ, S. S.: Motion of the Lumbar Spine. A Roentgenologic Study. Am. J. Roentgenol., **69:** 399-412, 1953.

HCPCS:	Descriptor:
L0631	LUMBAR-SACRAL ORTHOSIS, SAGITTAL CONTROL, WITH RIGID ANTERIOR AND POSTERIOR PANELS, POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Fractures, DJD, arthritis
Medically Necessary Argument	The forces implemented by the brace to control sagittal control with this rigid device need to be evaluated by a professional. If the forces are not directed in the appropriate anatomical locations to prevent unwanted motion direction then the patient puts them self at a higher risk of injury. The trimlines of posterior and anterior rigid panel and pressures over bony prominences encompassed by the brace needs to be evaluated by a professional to ensure maintain skin integrity and prevent skin breakdown. The amount of intracavitary pressures provide by the brace needs to be assessed to ensure an appropriate pressure. The strapping configuration and appropriate tightness of the straps needs to be review with the patient. Poorly adjusted straps decrease the overall effectiveness of the brace and increase the risk of injury with poorly directed strap forces.
References	3

The Effect of Four Types of Support on the Segmental Mobility of the Lumbosacral Spine

BY M. W. FIDLER, F.R.C.S.*, AND C. M. T. PLASMANS, M.D.†, AMSTERDAM, THE NETHERLANDS

From the Slotervaart Ziekenhuis and O.L.V. Gasthuis, Amsterdam

ABSTRACT: **With the aid of flexion-extension lateral radiographs, we investigated the effect of the canvas corset, the Raney and Baycast jackets, and the Baycast spica on the segmental sagittal mobility of the lumbosacral spine in separate groups of five volunteers each. The canvas corset reduced the mean angular movements at each level to two-thirds of normal. The Raney and Baycast jackets reduced the mean angular movements in the middle of the lumbar spine to approximately one-third of normal. The Baycast spica was the most effective in restricting angular movements below the third lumbar vertebra, and especially at the fourth lumbar-fifth lumbar level and the lumbosacral level.**

Lumbosacral corsets have been in use at least since the Minoan period, some 2000 years B.C.[2]. The function of those corsets was primarily to mold and enhance the female form, but their construction could also have served to support the lumbosacral spine. The first surgical corset that was specifically designed to support the lumbar spine was probably that made in 1530 for Catherine of Medici[3]. This was an iron corset, extending from the mid-part of the thorax to over the iliac crests, hinged down one side and fastened by a clasp on the other.

Lumbosacral supports are now commonly prescribed in the management of low-back pain[1,7] and are used to judge the effect of immobilization when considering spine fusion or postoperatively to support the spine until fusion occurs. By means of a questionnaire, Perry reviewed the use of supports in America and found that the lumbosacral corset was the most widely used, followed closely by the chairback brace. The effect most often expected from a brace was restriction of lumbosacral motion — this in spite of the fact that Norton and Brown as well as Lumsden and Morris had observed that in some patients a support actually could lead to an increase in movement at the lumbosacral level. It seems that there is still a tendency to prescribe a support for the lumbosacral spine without focusing attention specifically on the level concerned.

We use mainly four types of lumbosacral support. The lumbosacral canvas corset with posterior steel supports (Fig. 1), the Raney[8] flexion jacket (Fig. 2), and the Baycast (Cuttercast) jacket (Fig. 3) are used principally in the treatment of low-back pain, and the Baycast jacket with inclusion of the left thigh (Baycast spica) (Fig. 4) is used chiefly when considering fusion and postoperatively. The thigh is included in order to improve control of the pelvis.

The purpose of this investigation was to assess and compare the effects of these supports on the segmental sagittal mobility of the lumbosacral spine.

Material

Each type of support was assessed on five healthy male volunteers, none of whom had a history of low-back pain.

The canvas lumbosacral corsets were made to measure for each volunteer in the routine manner used for patients with lumbosacral disorders by the orthotist in the Slotervaart Hospital. The pattern used was a minor modification of that described in the spinal orthotics manual of the New York University Post-Graduate Medical School[5]. The lower edge of the corset was trimmed posteriorly at seat level with the subject sitting on a stool, thus avoiding the uncomfortable curled lip that can occur with the slightly lower edge described in the manual. The corset extended from around the lower ribs to over the iliac crest laterally, to just above the symphysis pubis anteriorly, and included the sacrum and upper part of the buttocks posteriorly. Each corset was reinforced with two posterior vertical steel stays stitched between the layers of the canvas.

The Raney flexion jackets were standard models of appropriate size for the volunteers.

The Baycast jackets were applied on standing volunteers by the same orthotist. These jackets extended from two centimeters below the shoulder blades to the mid-part of the sacrum posteriorly, from the xiphisternum to just above the pubis anteriorly, and from around the lower ribs to three centimeters below the level of the anterior superior iliac spines laterally. The left thigh was subsequently included to produce the Baycast spica on these same volunteers. The thigh-piece extended to five centimeters proximal to the patella and was added with the hip in 20 degrees of flexion in order to prevent any fixed lumbar lordosis and to facilitate sitting.

Method

Using a uniform technique lateral radiographs of the lumbosacral spine were made in maximum flexion and extension, first without and then with the support so that each

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TABLE I

MOVEMENT IN THE CANVAS CORSET FOR FIVE VOLUNTEERS (CASES 1 THROUGH 5)

Level	Movement with No Support (*Degrees*)					Movement in the Canvas Corset (*Degrees*)					Percentage Permitted Movement in the Canvas Corset					
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	Mean
L1-L2	15			11	17	9	13		4	10	60			36	59	52*
L2-L3	21	16	11	12	10	11	12	9	10	3	52	75	82	83	30	64†
L3-L4	18	13	17	12	3	7	10	17	10	0	39	77	100	83	0	60‡
L4-L5	15	21	20	13	7	10	10	17	10	2	67	48	85	77	29	61†
L5-S1	13	14	15	14	15	6	7	9	13	10	46	50	60	93	67	63*

* $0.005 > p > 0.001$.
† $0.05 > p > 0.01$.
‡ $0.1 > p > 0.05$.

volunteer acted as his own control. Segmental movement during flexion and extension was determined by means of corresponding lines drawn along the end-plates of each vertebra. The angles between adjacent vertebrae were measured in flexion and in extension, and the difference was recorded as the movement occurring at that level. These segmental angular movements, without and with a support, were determined at each level for all of the volunteers. In order to facilitate comparison of one type of support with another, the angular movements that were permitted by a support were expressed as percentages of the corresponding control unrestricted angular movements and then, for each type of support, the averages (arithmetical means) of these percentages were calculated for each level.

We found that the most accurate method of drawing corresponding lines on the radiographs was first to draw all of the lines on one radiograph. The second radiograph was then placed on top of the first and the shadow of each vertebral body was superimposed in turn over that of the same vertebra on the underlying radiograph while the corresponding lines were traced onto the upper radiograph.

We did not assess the reproducibility of the measurements because it would have been necessary to repeat at least one set of flexion and extension radiographs for the volunteers. In view of the extra radiation involved, we did

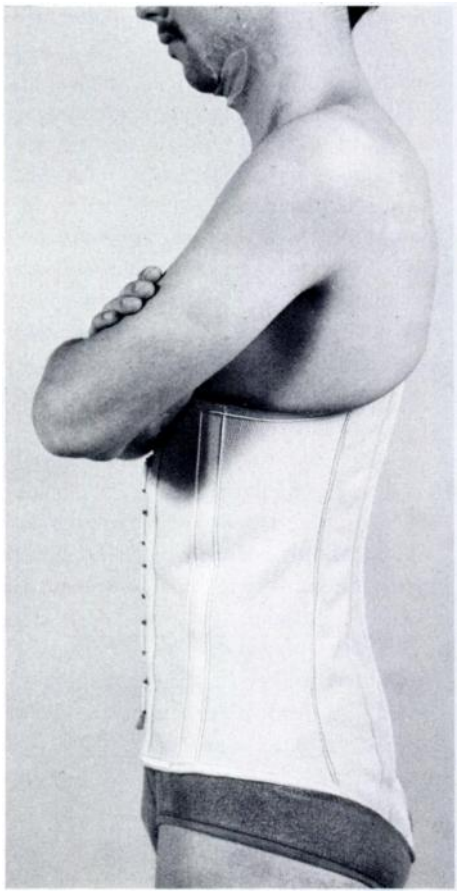

FIG. 1

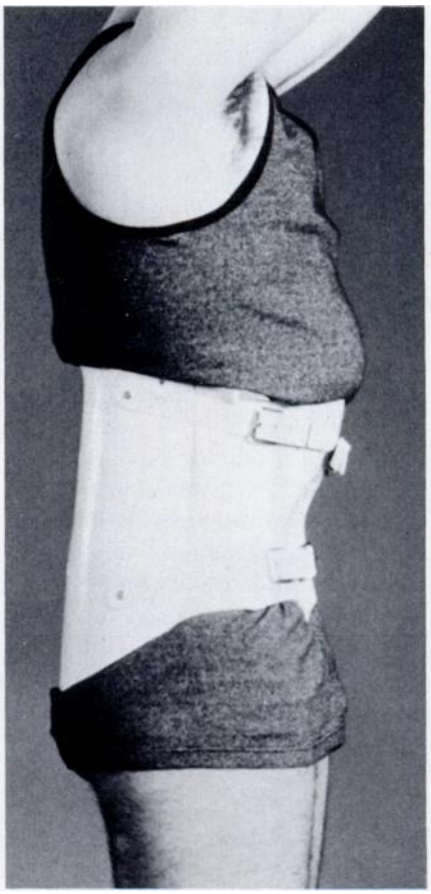

FIG. 2

Fig. 1: Canvas lumbosacral corset.
Fig. 2: Raney flexion jacket.

TABLE II

MOVEMENT IN THE RANEY JACKET FOR FIVE VOLUNTEERS (CASES 6 THROUGH 10)

	Movement with No Support (*Degrees*)					Movement in the Raney Jacket (*Degrees*)					Percentage Permitted Movement in the Raney Jacket					
Level	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10	Mean
L1-L2	15	11	6			2	5	5	7	2	13	45	83			47*
L2-L3	13	15	12	8	15	5	4	1	3	7	38	27	8	38	47	32†
L3-L4	12	12	17	13	13	6	2	1	2	10	50	17	6	15	77	33‡
L4-L5	20	16	15	17	11	6	7	8	12	3	30	44	53	71	27	45§
L5-S1	18	11	13	22	18	13	12	6	5	10	72	109	46	23	56	61¶

* $0.1 > p > 0.05$.
† $0.001 > p$.
‡ $0.01 > p > 0.005$.
§ $0.005 > p > 0.001$.
¶ $0.05 > p > 0.01$.

not think that this was justifiable. Tanz, who also used a superimposition method to calculate the segmental angular movements, found that the results of repeat radiographic examinations usually agreed to within 2 degrees. We assumed that this 2-degree error would be applicable to our series.

Radiation Precautions

The volunteers were healthy thin men whose gonads were screened. They had had minimum previous exposure to radiation and did not come into contact with x-rays during their routine work. One radiographer in each hospital made all of the radiographs to minimize the chance of error. An off-center radiograph was not repeated. This explains the absence of readings at the level of the disc between the first and second lumbar vertebrae for Cases 2, 3, 9, 10, and 11 in Tables I, II, and III. Copies of the radiographs were subsequently given to the volunteers for possible future reference in case they ever had low-back pain in the future. The radiation dose to the lumbar spine was approximately 250 millirads and to the shielded gonads it was ten millirads per radiograph. Baycast absorbs virtually no radiation. Thus, lower radiation doses were possible than would have been necessary if plaster of Paris had been used.

Results

The effect of the supports is shown in Tables I through IV. Almost all of the supports reduced the segmental angular movements of the lumbosacral spine. The exceptions were the canvas corset on Case 3, in whom movement at the third lumbar-fourth lumbar level was unaffected; the Raney jacket on Case 7, in whom there was a 1-degree (9 per cent) increase in angular movement at the

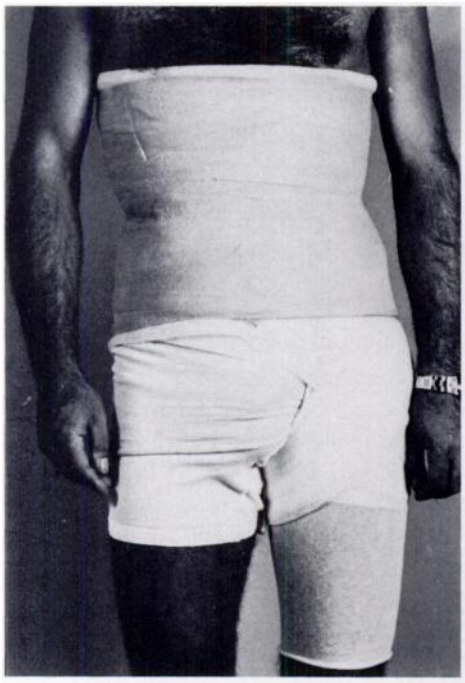

FIG. 3

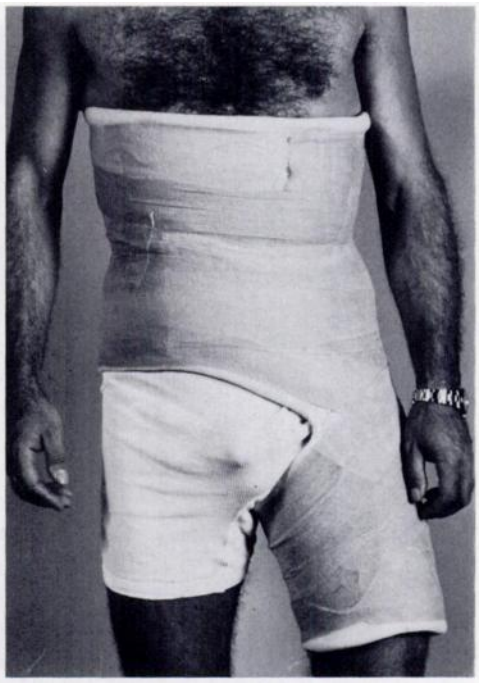

FIG. 4

Fig. 3: Baycast jacket.
Fig. 4: Baycast spica.

TABLE III

MOVEMENT IN THE BAYCAST JACKET AND BAYCAST SPICA FOR FIVE VOLUNTEERS (CASES 11 THROUGH 15)

Level	Movement with No Support (Degrees)					Movement in the Baycast Jacket (Degrees)						Movement in the Baycast Spica (Degrees)					
	11	12	13	14	15	11	12	13	14	15	Mean	11	12	13	14	15	Mean
L1-L2		16	10	10	12	2	7	3	7	8	53%*	4	10	3	7	4	49%†
L2-L3	20	16	17	13	13	2	8	11	5	4	39%‡	2	1	4	12	4	33%†
L3-L4	16	16	11	10	13	2	4	6	6	6	40%†	0	2	6	6	1	27%†
L4-L5	18	22	18	20	12	0	6	13	6	4	32%‡	2	0	3	3	2	12%§
L5-S1	23	22	14	16	17	10	11	14	16	10	70%*	2	0	1	1	3	8%§

* $0.05 > p > 0.01$.
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§ $0.001 > p$.

lumbosacral level; and the Baycast jackets on Cases 13 and 14, in whom the angular movements at the lumbosacral level were unaffected. Although the results showed considerable variation between individuals with regard to the effect of the supports, certain general trends could be discerned. Table IV and Figure 5 summarize the effect of each type of support at each level in the form of the mean percentage of angular movement permitted.

The canvas corset reduced angular movement at each level to approximately two-thirds of normal. The Raney and Baycast jackets were reasonably effective in the mid-part of the lumbar spine, where they reduced the angular movement to about one-third of normal, but at the first lumbar-second lumbar level and the lumbosacral level they had the same effect as the canvas corset. The Baycast spica was the most efficient below the third lumbar vertebra, and was progressively more efficient the lower the level. At the fourth lumbar-fifth lumbar level the Baycast spica permitted an average angular movement of only 2 degrees, or 12 per cent of normal, and a maximum angular movement of 3 degrees. At the lumbosacral level it was even more efficient, permitting an average angular movement of only 1.4 degrees, or 8 per cent of normal, and a maximum angular movement of only 3 degrees. The beneficial effect of the Baycast spica compared with the Baycast jacket in reducing angular movement at the lumbosacral level was statistically significant ($p < 0.001$).

TABLE IV

MEAN AND RANGE OF PERCENTAGE PERMITTED MOVEMENT

Level	Canvas Corset	Raney Jacket	Baycast Jacket	Baycast Spica
L1-L2	52 (36-60)	47 (13-83)	53 (30-70)	49 (30-70)
L2-L3	64 (30-83)	32 (8-47)	39 (10-65)	33 (6-92)
L3-L4	60 (0-100)	33 (6-77)	40 (13-60)	27 (0-60)
L4-L5	61 (29-85)	45 (27-71)	32 (0-72)	12 (0-17)
L5-S1	63 (46-93)	61 (23-109)	70 (43-100)	8 (0-18)

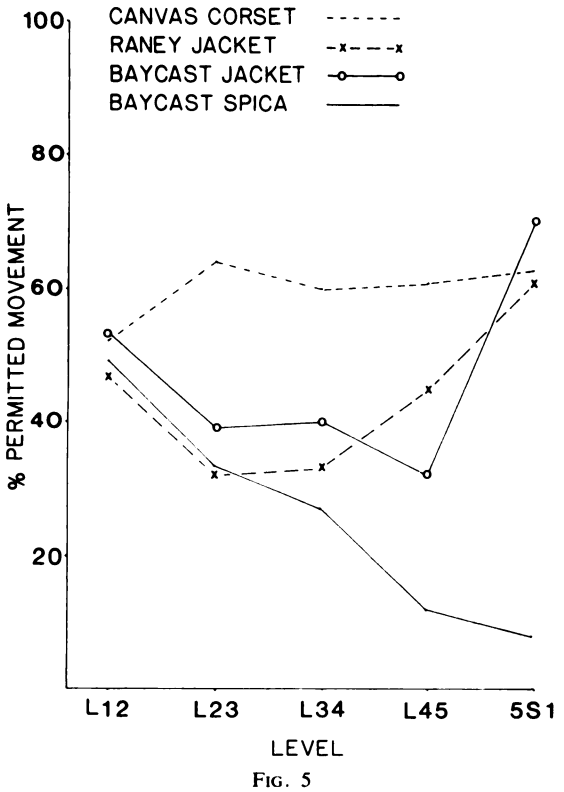

FIG. 5

Graph illustrating the percentage of movement permitted at each level by each type of support.

Discussion

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Although only five volunteers were examined, the Baycast spica had a consistent and statistically significant effect on the fourth lumbar-fifth lumbar level ($p < 0.001$) and the lumbosacral level ($p < 0.0005$). At other levels, and at all levels with the other supports, there was great variation between individuals. In these situations, we recommend that, if a support is to be used in the expectation of a particular effect on segmental mobility, the appropriate check radiographs be made, as pointed out by Norton and Brown.

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For the best restriction of movement at the fourth lumbar-fifth lumbar level or at the lumbosacral level, preoperatively or postoperatively, we now routinely include the thigh (Baycast spica). Because our study has shown this device to be consistently effective, and also for the purpose of avoiding unnecessary radiation, routine check radiographs in flexion and extension are not made. For restriction of movement at the third lumbar-fourth lumbar level, a carefully molded Baycast jacket is applied but, because of the variation between individuals in our study, we do make flexion-extension radiographs. If these do not show the desired effect, the jacket is replaced by a spica and flexion-extension radiographs are again made for comparison and future correlation. For restriction of movement at the second lumbar-third lumbar level, a Baycast jacket is used along with check radiographs. Plaster of Paris can be substituted for the Baycast jacket, but the weight of the plaster is a particular disadvantage for the spica.

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References

1. AHLGREN, S. A., and HANSEN, T.: The Use of Lumbosacral Corsets Prescribed for Low Back Pain. Prosthet. and Orthot. Internat., **2:** 101-104, 1978.
2. EVANS, ARTHUR: The Palace of Minos at Knossos. Vol. 1, p. 503. London, Macmillan, 1921.
3. EWING, ELIZABETH: Fashion in Underwear, p. 13. London, Batsford, 1971.
4. LUMSDEN, R. M., and MORRIS, J. M.: An *In Vivo* Study of Axial Rotation and Immobilization at the Lumbosacral Joint. J. Bone and Joint Surg., **50-A:** 1591-1602, Dec. 1968.
5. NEW YORK UNIVERSITY, POST-GRADUATE MEDICAL SCHOOL: Prosthetics and Orthotics; Measurement, Layout and Pattern Design for Lumbosacral F-E and L Corsets. Spinal Orthotics including Orthotists' Supplement, pp. 167-196. New York, 1975.
6. NORTON, P. L., and BROWN, THORNTON: The Immobilizing Efficiency of Back Braces. Their Effect on the Posture and Motion of the Lumbosacral Spine. J. Bone and Joint Surg., **39-A:** 111-138, Jan. 1957.
7. PERRY, JACQUELIN: The Use of External Support in the Treatment of Low-Back Pain. Report of the Subcommittee on Orthotics of the Committee on Prosthetic-Orthotic Education, National Academy of Sciences, National Research Council. J. Bone and Joint Surg., **52-A:** 1440-1442, Oct. 1970.
8. RANEY, F.: Royalite Flexion Jacket. Report on the Spinal Orthotics Workshop, pp. 85-91. Sponsored by the Committee on Prosthetics Research and Development of the Division of Engineering of the National Research Council. Washington, D.C., National Research Council, 1969.
9. TANZ, S. S.: Motion of the Lumbar Spine. A Roentgenologic Study. Am. J. Roentgenol., **69:** 399-412, 1953.

HCPCS:	Descriptor:
L0633	LUMBAR-SACRAL ORTHOSIS, SAGITTAL-CORONAL CONTROL, WITH RIGID POSTERIOR FRAME/PANEL(S), POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, LATERAL STRENGTH PROVIDED BY RIGID LATERAL FRAME/PANELS, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, STAYS, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Fractures, DJD, arthritis
Medically Necessary Argument	This orthoses requires specific sizing, heating, and bending during the initial fitting. A trained orthotist will be able to manage the fitting, but a non-orthotist will not have the tools required to do the job, and they do not have the traing to safely manage the patient to protect them from sharp edges or poor alignment.
References	3

The Effect of Four Types of Support on the Segmental Mobility of the Lumbosacral Spine

BY M. W. FIDLER, F.R.C.S.*, AND C. M. T. PLASMANS, M.D.†, AMSTERDAM, THE NETHERLANDS

From the Slotervaart Ziekenhuis and O.L.V. Gasthuis, Amsterdam

ABSTRACT: **With the aid of flexion-extension lateral radiographs, we investigated the effect of the canvas corset, the Raney and Baycast jackets, and the Baycast spica on the segmental sagittal mobility of the lumbosacral spine in separate groups of five volunteers each. The canvas corset reduced the mean angular movements at each level to two-thirds of normal. The Raney and Baycast jackets reduced the mean angular movements in the middle of the lumbar spine to approximately one-third of normal. The Baycast spica was the most effective in restricting angular movements below the third lumbar vertebra, and especially at the fourth lumbar-fifth lumbar level and the lumbosacral level.**

Lumbosacral corsets have been in use at least since the Minoan period, some 2000 years B.C.[2]. The function of those corsets was primarily to mold and enhance the female form, but their construction could also have served to support the lumbosacral spine. The first surgical corset that was specifically designed to support the lumbar spine was probably that made in 1530 for Catherine of Medici[3]. This was an iron corset, extending from the mid-part of the thorax to over the iliac crests, hinged down one side and fastened by a clasp on the other.

Lumbosacral supports are now commonly prescribed in the management of low-back pain[1,7] and are used to judge the effect of immobilization when considering spine fusion or postoperatively to support the spine until fusion occurs. By means of a questionnaire, Perry reviewed the use of supports in America and found that the lumbosacral corset was the most widely used, followed closely by the chairback brace. The effect most often expected from a brace was restriction of lumbosacral motion — this in spite of the fact that Norton and Brown as well as Lumsden and Morris had observed that in some patients a support actually could lead to an increase in movement at the lumbosacral level. It seems that there is still a tendency to prescribe a support for the lumbosacral spine without focusing attention specifically on the level concerned.

We use mainly four types of lumbosacral support. The lumbosacral canvas corset with posterior steel supports (Fig. 1), the Raney[8] flexion jacket (Fig. 2), and the Baycast (Cuttercast) jacket (Fig. 3) are used principally in the treatment of low-back pain, and the Baycast jacket with inclusion of the left thigh (Baycast spica) (Fig. 4) is used chiefly when considering fusion and postoperatively. The thigh is included in order to improve control of the pelvis.

The purpose of this investigation was to assess and compare the effects of these supports on the segmental sagittal mobility of the lumbosacral spine.

Material

Each type of support was assessed on five healthy male volunteers, none of whom had a history of low-back pain.

The canvas lumbosacral corsets were made to measure for each volunteer in the routine manner used for patients with lumbosacral disorders by the orthotist in the Slotervaart Hospital. The pattern used was a minor modification of that described in the spinal orthotics manual of the New York University Post-Graduate Medical School[5]. The lower edge of the corset was trimmed posteriorly at seat level with the subject sitting on a stool, thus avoiding the uncomfortable curled lip that can occur with the slightly lower edge described in the manual. The corset extended from around the lower ribs to over the iliac crest laterally, to just above the symphysis pubis anteriorly, and included the sacrum and upper part of the buttocks posteriorly. Each corset was reinforced with two posterior vertical steel stays stitched between the layers of the canvas.

The Raney flexion jackets were standard models of appropriate size for the volunteers.

The Baycast jackets were applied on standing volunteers by the same orthotist. These jackets extended from two centimeters below the shoulder blades to the mid-part of the sacrum posteriorly, from the xiphisternum to just above the pubis anteriorly, and from around the lower ribs to three centimeters below the level of the anterior superior iliac spines laterally. The left thigh was subsequently included to produce the Baycast spica on these same volunteers. The thigh-piece extended to five centimeters proximal to the patella and was added with the hip in 20 degrees of flexion in order to prevent any fixed lumbar lordosis and to facilitate sitting.

Method

Using a uniform technique lateral radiographs of the lumbosacral spine were made in maximum flexion and extension, first without and then with the support so that each

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TABLE I

MOVEMENT IN THE CANVAS CORSET FOR FIVE VOLUNTEERS (CASES 1 THROUGH 5)

Level	Movement with No Support (*Degrees*)					Movement in the Canvas Corset (*Degrees*)					Percentage Permitted Movement in the Canvas Corset					
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	Mean
L1-L2	15			11	17	9	13		4	10	60			36	59	52*
L2-L3	21	16	11	12	10	11	12	9	10	3	52	75	82	83	30	64†
L3-L4	18	13	17	12	3	7	10	17	10	0	39	77	100	83	0	60‡
L4-L5	15	21	20	13	7	10	10	17	10	2	67	48	85	77	29	61†
L5-S1	13	14	15	14	15	6	7	9	13	10	46	50	60	93	67	63*

* $0.005 > p > 0.001$.
† $0.05 > p > 0.01$.
‡ $0.1 > p > 0.05$.

volunteer acted as his own control. Segmental movement during flexion and extension was determined by means of corresponding lines drawn along the end-plates of each vertebra. The angles between adjacent vertebrae were measured in flexion and in extension, and the difference was recorded as the movement occurring at that level. These segmental angular movements, without and with a support, were determined at each level for all of the volunteers. In order to facilitate comparison of one type of support with another, the angular movements that were permitted by a support were expressed as percentages of the corresponding control unrestricted angular movements and then, for each type of support, the averages (arithmetical means) of these percentages were calculated for each level.

We found that the most accurate method of drawing corresponding lines on the radiographs was first to draw all of the lines on one radiograph. The second radiograph was then placed on top of the first and the shadow of each vertebral body was superimposed in turn over that of the same vertebra on the underlying radiograph while the corresponding lines were traced onto the upper radiograph.

We did not assess the reproducibility of the measurements because it would have been necessary to repeat at least one set of flexion and extension radiographs for the volunteers. In view of the extra radiation involved, we did

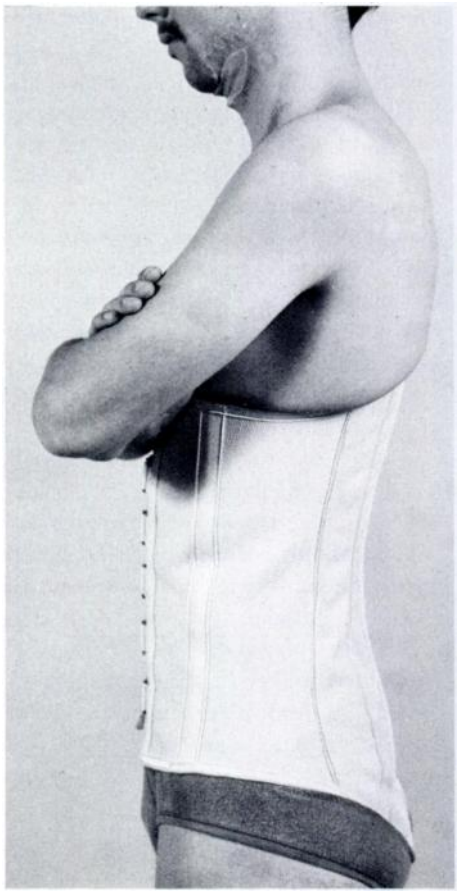


FIG. 1

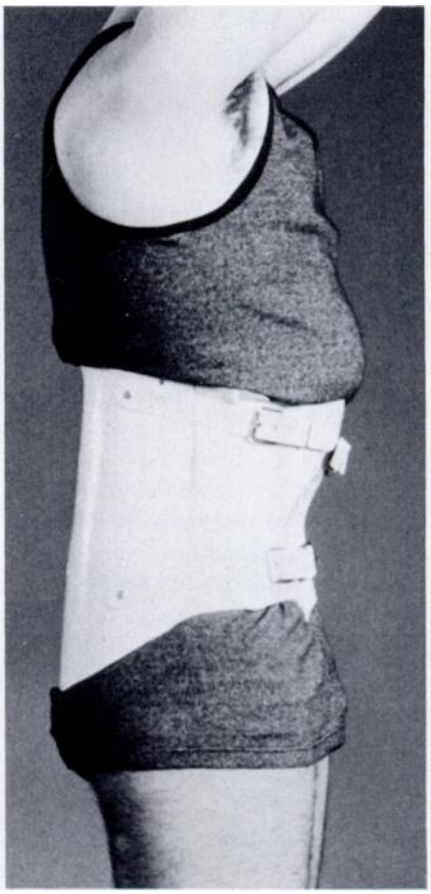


FIG. 2

Fig. 1: Canvas lumbosacral corset.
Fig. 2: Raney flexion jacket.

TABLE II

MOVEMENT IN THE RANEY JACKET FOR FIVE VOLUNTEERS (CASES 6 THROUGH 10)

Level	Movement with No Support (*Degrees*)					Movement in the Raney Jacket (*Degrees*)					Percentage Permitted Movement in the Raney Jacket					
	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10	Mean
L1-L2	15	11	6			2	5	5	7	2	13	45	83			47*
L2-L3	13	15	12	8	15	5	4	1	3	7	38	27	8	38	47	32†
L3-L4	12	12	17	13	13	6	2	1	2	10	50	17	6	15	77	33‡
L4-L5	20	16	15	17	11	6	7	8	12	3	30	44	53	71	27	45§
L5-S1	18	11	13	22	18	13	12	6	5	10	72	109	46	23	56	61¶

* $0.1 > p > 0.05$.
† $0.001 > p$.
‡ $0.01 > p > 0.005$.
§ $0.005 > p > 0.001$.
¶ $0.05 > p > 0.01$.

not think that this was justifiable. Tanz, who also used a superimposition method to calculate the segmental angular movements, found that the results of repeat radiographic examinations usually agreed to within 2 degrees. We assumed that this 2-degree error would be applicable to our series.

Radiation Precautions

The volunteers were healthy thin men whose gonads were screened. They had had minimum previous exposure to radiation and did not come into contact with x-rays during their routine work. One radiographer in each hospital made all of the radiographs to minimize the chance of error. An off-center radiograph was not repeated. This explains the absence of readings at the level of the disc between the first and second lumbar vertebrae for Cases 2, 3, 9, 10, and 11 in Tables I, II, and III. Copies of the radiographs were subsequently given to the volunteers for possible future reference in case they ever had low-back pain in the future. The radiation dose to the lumbar spine was approximately 250 millirads and to the shielded gonads it was ten millirads per radiograph. Baycast absorbs virtually no radiation. Thus, lower radiation doses were possible than would have been necessary if plaster of Paris had been used.

Results

The effect of the supports is shown in Tables I through IV. Almost all of the supports reduced the segmental angular movements of the lumbosacral spine. The exceptions were the canvas corset on Case 3, in whom movement at the third lumbar-fourth lumbar level was unaffected; the Raney jacket on Case 7, in whom there was a 1-degree (9 per cent) increase in angular movement at the

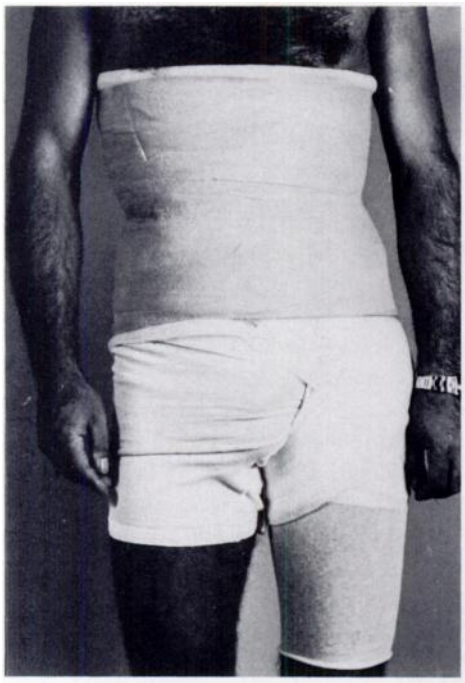


FIG. 3

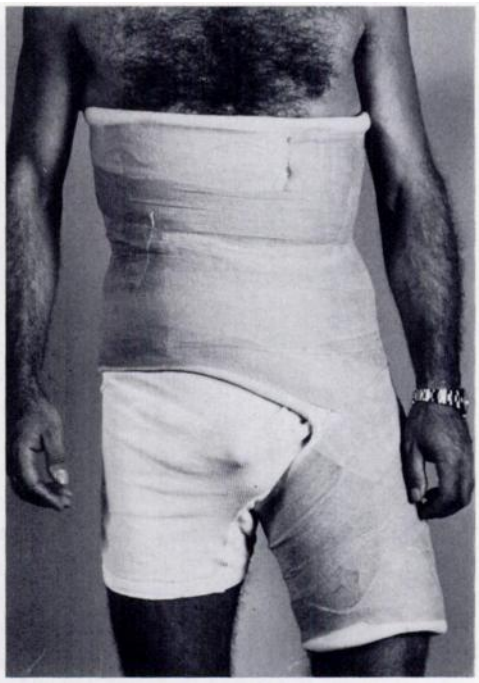


FIG. 4

Fig. 3: Baycast jacket.
Fig. 4: Baycast spica.

TABLE III

MOVEMENT IN THE BAYCAST JACKET AND BAYCAST SPICA FOR FIVE VOLUNTEERS (CASES 11 THROUGH 15)

Level	Movement with No Support (Degrees)					Movement in the Baycast Jacket (Degrees)						Movement in the Baycast Spica (Degrees)					
	11	12	13	14	15	11	12	13	14	15	Mean	11	12	13	14	15	Mean
L1-L2		16	10	10	12	2	7	3	7	8	53%*	4	10	3	7	4	49%†
L2-L3	20	16	17	13	13	2	8	11	5	4	39%‡	2	1	4	12	4	33%†
L3-L4	16	16	11	10	13	2	4	6	6	6	40%†	0	2	6	6	1	27%†
L4-L5	18	22	18	20	12	0	6	13	6	4	32%‡	2	0	3	3	2	12%§
L5-S1	23	22	14	16	17	10	11	14	16	10	70%*	2	0	1	1	3	8%§

* $0.05 > p > 0.01$.
† $0.01 > p > 0.005$.
‡ $0.005 > p > 0.001$.
§ $0.001 > p$.

lumbosacral level; and the Baycast jackets on Cases 13 and 14, in whom the angular movements at the lumbosacral level were unaffected. Although the results showed considerable variation between individuals with regard to the effect of the supports, certain general trends could be discerned. Table IV and Figure 5 summarize the effect of each type of support at each level in the form of the mean percentage of angular movement permitted.

The canvas corset reduced angular movement at each level to approximately two-thirds of normal. The Raney and Baycast jackets were reasonably effective in the mid-part of the lumbar spine, where they reduced the angular movement to about one-third of normal, but at the first lumbar-second lumbar level and the lumbosacral level they had the same effect as the canvas corset. The Baycast spica was the most efficient below the third lumbar vertebra, and was progressively more efficient the lower the level. At the fourth lumbar-fifth lumbar level the Baycast spica permitted an average angular movement of only 2 degrees, or 12 per cent of normal, and a maximum angular movement of 3 degrees. At the lumbosacral level it was even more efficient, permitting an average angular movement of only 1.4 degrees, or 8 per cent of normal, and a maximum angular movement of only 3 degrees. The beneficial effect of the Baycast spica compared with the Baycast jacket in reducing angular movement at the lumbosacral level was statistically significant ($p < 0.001$).

TABLE IV

MEAN AND RANGE OF PERCENTAGE PERMITTED MOVEMENT

Level	Canvas Corset	Raney Jacket	Baycast Jacket	Baycast Spica
L1-L2	52 (36-60)	47 (13-83)	53 (30-70)	49 (30-70)
L2-L3	64 (30-83)	32 (8-47)	39 (10-65)	33 (6-92)
L3-L4	60 (0-100)	33 (6-77)	40 (13-60)	27 (0-60)
L4-L5	61 (29-85)	45 (27-71)	32 (0-72)	12 (0-17)
L5-S1	63 (46-93)	61 (23-109)	70 (43-100)	8 (0-18)

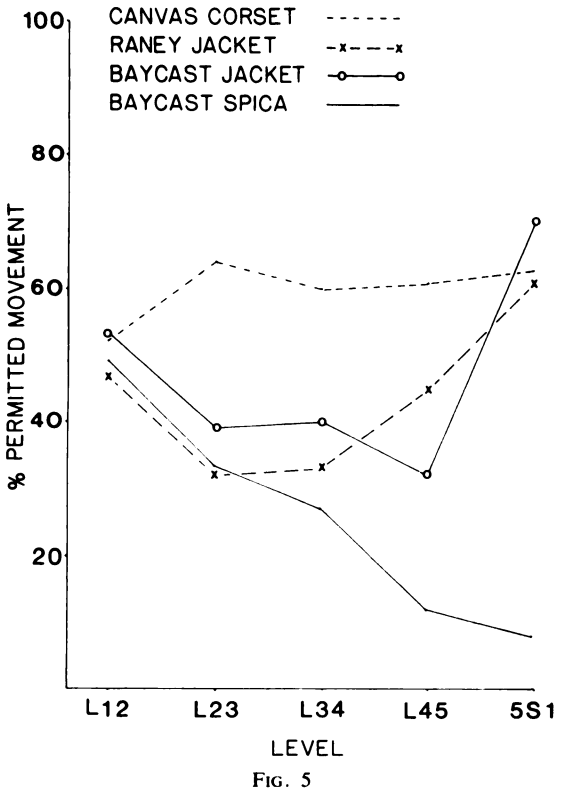


FIG. 5

Graph illustrating the percentage of movement permitted at each level by each type of support.

Discussion

The lumbosacral spinal vertebrae can undergo both translation and angular motion. The latter is caused by lateral bending and flexion-extension or axial rotation movements. Restriction of axial rotation at the lumbosacral level was observed by Lumsden and Morris in subjects wearing a chairback brace, but the effects of lumbosacral canvas corsets were varied and unpredictable. It is probable that the Raney and Baycast jackets, like the chairback brace, would adequately fix the pelvis and similarly control rotation. The cross section of the torso is oval and hence the lateral sides of a spinal support, being farther away from the spine than the back and front, should be more efficient in restricting lateral bending movement than the back and front are in restricting flexion and extension movement. Unless the sides are inadequate, it therefore seems likely that a support that restricts flexion-extension movement would be at least as effective in restricting lateral bending movement. In order to obtain the maximum

information from the minimum amount of radiation, we therefore limited this comparative study to motion in the sagittal plane.

Like Tanz, we found considerable variation in lumbar spinal movements between normal individuals, and so each volunteer had to act as his own control. However, because of the radiation involved it was not possible to do a radiographic assessment of four supports in flexion and extension, as well as to make control radiographs, for each volunteer. Norton and Brown circumvented this problem by measuring the angles between Kirschner wires in the spinous processes after making preliminary radiographic measurements, and Lumsden and Morris measured rotation by inserting Steinmann pins in the spinous processes alone. We used different groups of volunteers for the canvas, Raney, and Baycast supports.

A rigid support works on the principle of three-point fixation; optimum restriction of movement is likely to be achieved about halfway along and to decrease toward the ends. This effect is illustrated by the graphs for the Raney and Baycast jackets (Fig. 5). At the caudal end, for example, the pelvis is not effectively controlled by the supports and considerable lumbosacral motion is still possible. The extension of the jacket to include the hip and thigh provides the necessary control of the pelvis and accounts for the effectiveness of the Baycast spica in restricting the movement of the lower part of the lumbosacral spine.

Although only five volunteers were examined, the Baycast spica had a consistent and statistically significant effect on the fourth lumbar-fifth lumbar level ($p < 0.001$) and the lumbosacral level ($p < 0.0005$). At other levels, and at all levels with the other supports, there was great variation between individuals. In these situations, we recommend that, if a support is to be used in the expectation of a particular effect on segmental mobility, the appropriate check radiographs be made, as pointed out by Norton and Brown.

If one of these supports is to be used in the treatment of low-back pain, then the canvas corset has the advantage of comfort while providing abdominal support and some restriction of angular movements of the lumbar spine. There is little to choose between the Raney and Baycast jackets regarding their effect on segmental movements, but the Raney jacket is designed to reduce the lumbar lordosis and can be easily removed. The Baycast spica can be worn for a few weeks to break a painful vicious circle, but for more prolonged use it is too cumbersome. However, the Baycast spica was the most effective in restricting the mobility of the lower part of the lumbosacral spine. This is particularly important if a lumbosacral support is used in the preoperative assessment or postoperative management of a patient with a low-back disorder.

For the best restriction of movement at the fourth lumbar-fifth lumbar level or at the lumbosacral level, preoperatively or postoperatively, we now routinely include the thigh (Baycast spica). Because our study has shown this device to be consistently effective, and also for the purpose of avoiding unnecessary radiation, routine check radiographs in flexion and extension are not made. For restriction of movement at the third lumbar-fourth lumbar level, a carefully molded Baycast jacket is applied but, because of the variation between individuals in our study, we do make flexion-extension radiographs. If these do not show the desired effect, the jacket is replaced by a spica and flexion-extension radiographs are again made for comparison and future correlation. For restriction of movement at the second lumbar-third lumbar level, a Baycast jacket is used along with check radiographs. Plaster of Paris can be substituted for the Baycast jacket, but the weight of the plaster is a particular disadvantage for the spica.

Conclusions

All of the supports that we tested restricted the segmental sagittal movements of the lumbosacral spine, although there was considerable variation between individuals for the canvas corset and for the Raney and Baycast jackets at all levels. Similarly, the Baycast spica showed some variation in its effects at the first lumbar-second lumbar, the second lumbar-third lumbar, and the third lumbar-fourth lumbar levels. However, the Baycast spica was consistent in significantly limiting movement at the fourth lumbar-fifth lumbar level and especially at the lumbosacral level. Furthermore, it was the most effective of the supports that we tested in limiting movement below the third lumbar vertebra, particularly at the fourth lumbar-fifth lumbar level and at the lumbosacral level.

NOTE: The authors would like to thank Dr. B. van der Ende and Dr. van der Stadt for their statistical help, as well as Bayer for supplying the Baycasts and Camp for providing the Raney flexion jackets, and especially the volunteers without whose participation the study would not have been possible.

References

1. AHLGREN, S. A., and HANSEN, T.: The Use of Lumbosacral Corsets Prescribed for Low Back Pain. Prosthet. and Orthot. Internat., **2:** 101-104, 1978.
2. EVANS, ARTHUR: The Palace of Minos at Knossos. Vol. 1, p. 503. London, Macmillan, 1921.
3. EWING, ELIZABETH: Fashion in Underwear, p. 13. London, Batsford, 1971.
4. LUMSDEN, R. M., and MORRIS, J. M.: An *In Vivo* Study of Axial Rotation and Immobilization at the Lumbosacral Joint. J. Bone and Joint Surg., **50-A:** 1591-1602, Dec. 1968.
5. NEW YORK UNIVERSITY, POST-GRADUATE MEDICAL SCHOOL: Prosthetics and Orthotics; Measurement, Layout and Pattern Design for Lumbosacral F-E and L Corsets. Spinal Orthotics including Orthotists' Supplement, pp. 167-196. New York, 1975.
6. NORTON, P. L., and BROWN, THORNTON: The Immobilizing Efficiency of Back Braces. Their Effect on the Posture and Motion of the Lumbosacral Spine. J. Bone and Joint Surg., **39-A:** 111-138, Jan. 1957.
7. PERRY, JACQUELIN: The Use of External Support in the Treatment of Low-Back Pain. Report of the Subcommittee on Orthotics of the Committee on Prosthetic-Orthotic Education, National Academy of Sciences, National Research Council. J. Bone and Joint Surg., **52-A:** 1440-1442, Oct. 1970.
8. RANEY, F.: Royalite Flexion Jacket. Report on the Spinal Orthotics Workshop, pp. 85-91. Sponsored by the Committee on Prosthetics Research and Development of the Division of Engineering of the National Research Council. Washington, D.C., National Research Council, 1969.
9. TANZ, S. S.: Motion of the Lumbar Spine. A Roentgenologic Study. Am. J. Roentgenol., **69:** 399-412, 1953.

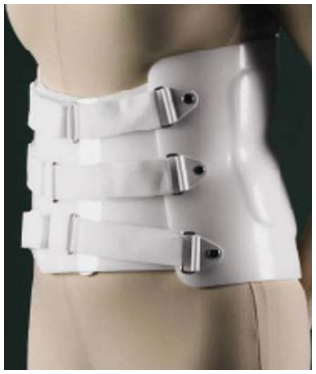
HCPCS:	Descriptor:
L0637	LUMBAR-SACRAL ORTHOSIS, SAGITTAL-CORONAL CONTROL, WITH RIGID ANTERIOR AND POSTERIOR FRAME/PANELS, POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, LATERAL STRENGTH PROVIDED BY RIGID LATERAL FRAME/PANELS, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Back pain, herniated disc, spondylolisthesis, osteoarthritis, and spinal stenosis
Medically Necessary Argument	The forces implemented by the brace to control sagittal and coronal control with this bi-valve rigid device need to be evaluated by a professional. If the forces are not directed in the appropriate to prevent unwanted motion direction then the patient puts them self at a higher risk of injury. The trimlines of posterior, anterior, and lateral rigid panels and pressures over bony prominences encompassed by the brace needs to be evaluated by a professional to ensure maintain skin integrity and prevent skin breakdown. The amount of intracavitary pressures provided by the brace needs to be assessed to ensure an appropriate amount of force is being applied and abdominal structures and internal organs are not being constricted due to excessive pressures. The strapping configuration and appropriate tightness of the straps needs to be review with the patient. Poorly adjusted straps decrease the overall effectiveness of the brace and increase the risk of injury with poorly directed strap forces.
References	

HCPCS:	Descriptor:
L0639	LUMBAR-SACRAL ORTHOSIS, SAGITTAL-CORONAL CONTROL, RIGID SHELL(S)/PANEL(S), POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, ANTERIOR EXTENDS FROM SYMPHYSIS PUBIS TO XYPHOID, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, OVERALL STRENGTH IS PROVIDED BY OVERLAPPING RIGID MATERIAL AND STABILIZING CLOSURES, INCLUDES STRAPS, CLOSURES, MAY INCLUDE SOFT INTERFACE, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Back pain, herniated disc, spondylolisthesis, osteoarthritis, spinal stenosis
Medically Necessary Argument	The Lumbar-sacral orthosis is a rigid device which limits motion. This device provides circumferential support and total contact which requires the following: accurate measurement, proper device assessment, and skilled fitting and delivery. The critical areas of fit involve angle of lordosis, assessment of existing deformity, and proper height. In the event of poor assessment and fit, the result could be pain, open wounds, or additional negative outcomes.
References	

HCPCS:	Descriptor:
L1600	HIP ORTHOSIS, ABDUCTION CONTROL OF HIP JOINTS, FLEXIBLE, FREJKA TYPE WITH COVER, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	NO	NO	YES	YES

Sample Diagnosis (Not Inclusive)	Hip dysplasia
Medically Necessary Argument	The Frejka pillow is a thick, layered or padded material with adjustable shoulder straps. It is designed to reduce stresses across the affected hip joint or joints of newborns and infants. It is designed to maintain the femoral head to be contained within the acetabulum, while the hip joint is stabilized bilaterally at the end desired degrees of abduction as well as the desired degrees of internal rotation. Professional fit is essential for the proper degrees and limited range of motion. Inappropriate fit can result in inability to ambulate, painful ambulation, required surgical intervention or multiple poor outcomes.
References	4

FROM FYLKESSJUKEHUSET (COUNTY HOSPITAL) IN ÅLESUND, NORWAY.
HEAD OF THE SURGICAL DEPARTMENT: DR. HALVARD SKEIE, M.D.
(FROM 1956): DR. KAARE BENDIXEN M.D.
HEAD OF THE RADIOLOGICAL DEPARTMENT: DR. JOHS. SLÖRDAHL, M.D.

EARLY DIAGNOSIS AND TREATMENT OF HIP JOINT DYSPLASIA

By

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Congenital dislocation of the hips has probably been known for thousands of years. Treatment has varied through history. Both the treatment and the results of the treatment have been made the subject of intense interest in medical literature.

In more recent decades it has become more and more obvious that the earlier the treatment begins, the greater is the chance of achieving a good result. It is generally accepted in the literature that the best results are obtained when treatment is started in the neonatal stage. These observations form the background to the study of which an account is given in these pages.

During the years 1950 to 1954 a relatively large number of patients were admitted to Fylkessjukehuset in Ålesund for treatment of congenital hip joint dysplasia (h.d.) at the age of 1–3 years. In the late fall of 1954, therefore, it was decided to begin routine examination of all newborn children in the hospital's maternity department and from the 1st of January, 1955, such an examination was consistently carried out.

SCHEME OF INVESTIGATION

a. Clinical examination:

Examination of the hips was made part of the routine examination of all babies in the maternity ward. Doctors on duty examined the hips of all children when they were 3–5 days old. When somewhat later a pediatrician was added to the hospital staff this series of examinations was so well organised that no reason could be found for changing the routine.

The clinical signs which were looked for were as follows:

1. Ortolani's sign (snapping sign).
2. Instability of the hips (telescoping sign).
3. Limited abduction of the hips.
4. Shortening of the femora.
5. Crepitation sound/feeling in the hip joints on passive abduction.

This last sign has scarcely any pathognomic significance as e.g. 1 and 2, but in certain cases this was the only pathological finding in hips which were undoubtedly dysplastic. We followed up all babies with this sign. In the great majority the hips developed in a completely normal way without any treatment. No exact explanation of the finding can be given. It may possibly be due to a certain looseness of the connective tissue in newborns who are still under the influence of the mother's hormones. In the few cases in which it indicated the presence of a dysplasia the sign was regarded as an abortive Ortolani's sign.

b. Radiological examination:

In the first year of this series X-rays were taken of the hip joints in all babies who were suspected of hip joint dysplasia following clinical examination. X-ray examination was made the day after the clinical examination, i.e., when the baby was 4–6 days old.

In the following two years X-ray examination was only carried out on newborns when convincingly positive symptoms were present on clinical examination. In all cases, however, X-ray examination was undertaken at the age of 3–4 months.

The findings at this time decided the need for future follow up.

We sought to evaluate by means of X-ray pictures taken of newborns the following radiological details:

1. The acetabular index.
2. Lateral position of the diaphysis in relation to the acetabulum.
3. Shenton's line.
4. The development of the anterior and the posterior acetabular rim.
5. The upper, lateral border of the acetabulum.
6. The upper end of the diaphysis in relation to the obturator line.

c. Other data on mother and child:

In connection with the first clinical examination certain data was collected on mother and child so as to determine further factors of etiologic importance.

The following were noted, the child's sex, weight at birth, length,

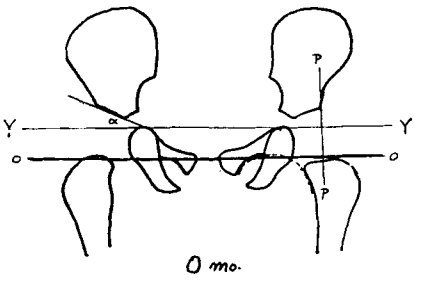


Fig. 1.
Normal pelvis with auxiliary lines.
YY = Y-line. OO = obturator line.
PP = line of gravity through the upper, lateral border of the acetabulum.
a = the acetabular index.

position in womb and order of precedence in the family. In addition the mother's age was recorded and information was sought as to any history of h.d. in the family.

TREATMENT

The principle determining treatment was that this should be initiated as far as possible immediately the diagnosis was made, i.e., in the first week of life.

This was observed with 41 of the 50 babies.

In 7 of the remaining cases treatment was begun along with the first check-up, i.e., at the age of 3–4 months. The cause of this was partly administrative mistakes partly the fact that the diagnosis could only be determined with certainty at this period.

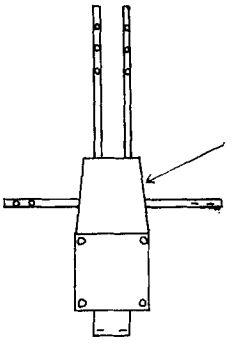
In the last two cases treatment was not started until the age of 7 and 10 months for the last-mentioned reason. One of these cases will be discussed later (case no. 134, Fig. 7).

In the newborns difficulties in reducing the dislocation was never encountered. Frejka's cushion splint was used for immobilisation. See Fig. 2.

For practical reasons the actual cushion in this splint was encased in waterproof material. Thus the individual patient's need for cushions was reduced to 2–3 cushions. The cushion has to be hard to prevent it from being squeezed from one side to the other.

On discharge from hospital each mother received instruction in the use of the splint and got one complete splint as a gift from the hospital so that one should be certain that the remaining splints had the correct dimensions. In our very first case, forming one of the cases in which the treatment is stated to have begun only at the age of 3–4 months an attempt was made to obtain the effect of the Frejka splint by an apparently more easy way.

On discharge the mother was requested to use several diapers at a



Shoulder straps with buttons.

Back support.

Stomach straps with buttons and buttonholes.

Cushion section, size 20 × 20 cm. Thickness about 5 cm.

Flap for fastening shoulderstraps.

Fig. 2.
Frejka's cushion splint, size 1:10.
The buttons in the corners of the cushion section are connected with elastic around the child's thighs.

time thereby achieving the intended abduction position of the hips. This method of treatment proved to be completely useless and at the first follow-up it was replaced by the customary cushion splint delivered and demonstrated for the mother as described above.

Any attempts to replace the original Frejka splint in this way is inadvisable. Regarding the relationship of the patients to the cushion splint and perhaps especially the mother's attitude to this, the following questions were put as routine to the mother at each later check-up:

1. Do you think that the baby suffers any discomfort from the splint?
2. Does it seem to you yourself that it is troublesome to put on the splint?
3. Have you any objections to the splint?

The first question was consistently answered: No.

In reply to the second question a few found that it seemed difficult to put the splint on to begin with. Afterwards all went smoothly and the common answer was that it was not more difficult to put the splint on than to put on ordinary diapers.

In answer to the third question a few brought forward the objection that they did not care for the splint from purely aesthetic reasons. They were reluctant to show the baby to the family and friends because it was so difficult to dress up the child in the way that mothers appreciate. The great majority had, however, no objection to the cushion splint.

In a few individual cases where at the check-up 3 months later no satisfactory reduction had been obtained the cushion splint was replaced by a plaster cast. This enclosed the pelvis and both lower extremities to the knee. The plaster kept the lower extremities fixed at

about 90° flexion and 70° abduction of the hip joints. Corresponding procedures were employed in individual cases where treatment was initiated at the age of 3 months or later, when abduction was hindered to such an extent that the dislocation could not be reduced without recourse to anesthesia. In such cases also immobilisation in a plaster cast was adopted for 3–4 weeks. Afterwards the plaster was removed and replaced by cushion splint. This procedure proved very effective and was clearly much less troublesome to the patient and mother than a lengthy immobilisation in plaster.

Complete immobilisation in the cushion splint was pursued until a clinically stable hip joint was achieved. This was very often the case as early as the first check-up (age: about 3 months). In doubtful cases, especially when the clinical and radiological findings did not correspond, the immobilisation was maintained longer. In the last follow-up period it was recommended that the cushion should only be used in the normal sleeping hours of the baby so that she/he was free to move the lower extremities for some hours every day.

PATIENT MATERIAL

My series comprises all children born in the department during the years 1955–1956–1957. Table 1 records the total of these patients.

As the table shows, the examination comprises 3242 children.

At the clinical examination the findings were negative in 3099 children, but in the remaining 143, findings were made which were regarded primarily as pathological. The latter were all examined once or several times both clinically and radiologically. On the basis of the findings which were made at the first examination or later, 50 children were selected in whom the author believed that clear pathological changes were present in the hips, either in the form of hip joint dislocation or subluxation or a type of h.d. This gives a morbidity of about 1.5 %.

TABLE 1
Survey of children examined.

Year	No of births with children living	Twin births amongst these	Twins living	No of children examined
1955	1035	8	16	1043
1956	1115	14	28	1129
1957	1054	19	35	1070
Total number of children examined				3242

This figure may seen strikingly high and manifests a morbidity in this series which surpasses by far what is commonly thought to occur with h.d. in Norway. The author has observed this point and has repeatedly gone through the series with the aim of reducing the number of probable pathological hips. This attempt was not successful, however, and it was thought that the series should be reported so that it could speak for itself.

It was mentioned above that 143 babies were originally selected who were thought to show pathological changes in the hips on clinical examination, immediately after birth. Of these there were only 50, therefore, in which the primary diagnosis was thought to be correct. The other 93 babies offered at birth only sensations of crepitation in the hip joints on abduction. Radiological confirmation of the disease could not be obtained by pictures taken when the baby was 3–4 days old. At the beginning of the investigation treatment was started in a number of these patients. After more experience was gained this treatment was found unnecessary, so that the great majority were not treated.

In spite of this the diagnosis h.d., could never be confirmed at later clinical and X-ray examination and one must therefore assume that the crepitating sensation on abduction of the hips in newborns may occur without any pathological significance. In a few cases of these babies with crepitation as the sole clinical symptom it has been possible, however, to demonstrate undoubted h.d. at further check-ups (3 months old and later). Attention is therefore drawn to this symptom which in the author's opinion may represent an abortive Ortolani's symptom.

RESULTS OF EXAMINATION AT THE NEW-BORN STAGE

a. Clinical examination:

On examination just after birth the clinical symptoms of the 50 children were as follows:

Ortolani's sign bilaterally	8
Ortolani's sign right hip	16
Ortolani's sign left hip	8
Instability bilaterally	1
Instability right hip	7
Instability left hip	1
Doubtful instability in one or both hips	4
Crepitation in one or both hips on passive abduction	4
No clinical findings	1
	50

Ortolani's sign is only stated positive when one could dislocate and reduce the hip concerned with certainty.

Moreover, it is felt that the instability sign most probably represents a pathological hip. This is stated positive when one could with certainty press the femur so far in the dorsal direction that one would not consider it reasonable that this movement should proceed within a normal joint.

In the four patients where instability is recorded as doubtful, mobility was so small that it was possibly due to general relaxation of the joint in the postnatal period.

Greater doubt may arise concerning the group with crepitation in one or both hips. As stated above, the author believes that this symptom can be regarded as an abortive Ortolani's sign, even if it can be provoked in a number of babies in whom at later examinations h.d. can be excluded.

A good illustration is obtained of a case where such a crepitation on passive abduction movement of the hip joints was the only finding on examination in the newborn stage on studying X-rays of case 36, Fig. 13. Unfortunately the first X-ray examination was undertaken at the age of 3½ months.

The last case, in which nothing pathological was noticed on examination immediately after birth, was discovered when the baby was 7 months old, see case no. 134, Fig. 7.

b. Radiological examination:

The radiological findings in newborns were as follows:

Certain dislocation or subluxation	16
Probable dysplasia	10
Probable negative finding on X-ray examination	19
X-ray exam. not carried out in newborn stage	5
	50

There are scarcely any reasons for general remarks on the above, apart from the fact that the X-ray examination produces far fewer positive findings than the clinical examination. What is most interesting in this connection is whether there is any correspondence between the clinical and the radiological findings.

If one reviews the eight cases with clinical findings:

Ortolani + bilat., the radiological findings are as follows:

Bilateral dislocation or subluxation	5
Bilateral dysplasia	1
Unilateral dysplasia	1
Negative findings	1
	8

The 24 cases with clinical findings: Ortolani positive in right or left hip, show the following X-ray findings:

Dislocation or subluxation same side	11
Dislocation or subluxation opposite side	2
Dysplasia same side or both	5
Negative findings	6
	24

A corresponding summary can be made of the other clinical groups with an increasing failure in the radiological diagnosis.

With regard to the 32 cases with the clinical diagnosis: Ortolani's sign positive, all the cases with radiological findings, dislocation or subluxation, coincide within this group. On the other hand, however, convincingly positive radiological findings were only found in 16 of 32 babies who were declared to have completely reliable positive findings on clinical examination, and in fully 7 cases the X-ray diagnosis was completely negative in a very critical evaluation in spite of the positive clinical findings.

The question may then be put: is not amongst these 7 the clinical diagnosis faulty and the radiological one correct? With this in mind I studied the results of the first follow-up examination of these 7 children. This took place when the child was 3–4 months old.

The findings on clinical and radiological examination were these:

Clin. ex.:	Neg. findings.	
Rad. ex.:	No or doubtful positive findings	2 cases
Clin. ex.:	Neg. findings.	
Rad. ex.:	Delayed development of epiphysis	2 cases
Clin. ex.:	Neg. findings.	
Rad. ex.:	Undoubted dysplasia findings	2 cases
Clin. ex.:	Not performed.	
Rad. ex.:	Neg. findings	1 case
		7 cases

In order to evaluate the above one must bear in mind that all these babies commenced treatment immediately after birth. In the author's experience it rarely or never happens that on examination at 3 months

of age clinical symptoms will be found positive and it is rare that there will be definite pathological findings on X-ray examination. In spite of this, however, pathological findings were made at the first follow-up examination in 4 out of 7; these findings were due in all probability to a hip joint dysplasia or—dislocation. This makes it most likely that the clinical diagnosis at the neonatal examination was correct and that the X-ray diagnosis was at fault.

The conclusions to be drawn from this rather detailed evaluation of the symptoms found on clinical and radiological examination of newborns are that the radiological examination is much inferior to the clinical at this age. In addition I believe to have demonstrated that a positive Ortolani's sign at birth is such a certain symptom of h.d. that it will be a failure of technique if it is not heeded and treatment does not begin with the newborn baby.

c. Other clinical data from the newborn stage.

As stated above the series comprises 3242 children. Based on clinical and radiological examination of the hip joints of these children, it is considered that hip joint dysplasia is present in 50 children.

Below is given more clinical data on these 50.

TABLE 2

Sex distribution.

Sex	No.	No. given in %
Girls	43	86
Boys	7	14

This distribution between the sexes corresponds well with the figures found elsewhere in the literature.

The information collected about the position of the foetus determined in relation to the birth showed nothing unexpected. On the whole the distribution was normal with a certain emphasis on the breech position, since 6 children or 12 % were born in this position.

Nor was anything unusual found in respect to which order in the family these children came.

As far as the mothers were concerned, the mother's age was noted when the child was born. This was on average 29.9 years. In a control series of 93 mothers with normal children born in the same period the average age was 29.3 years.

Finally information was requested about other known cases of h.d.

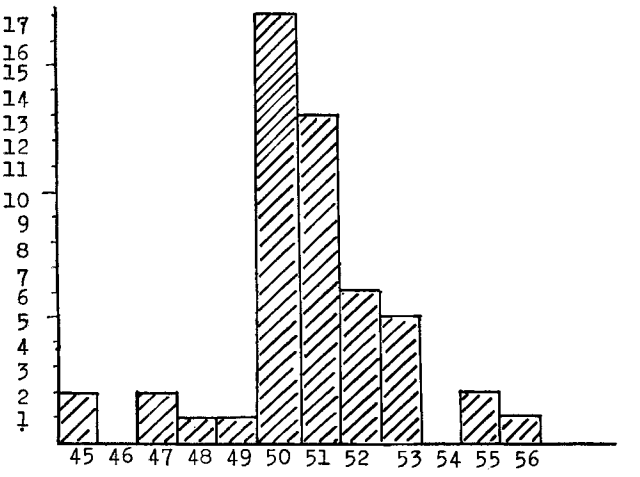


Fig. 3.

Length at birth:

Abscissa: Length at birth given in centimetres.

Ordinate: Number of children.

Each column represents the children whose length at birth lies within the same centimetre. If this graph of length at birth is compared with the corresponding graph in Sundal's normal series from Bergen in 1956, the same pattern is found on the whole. If the average length of the 50 children is calculated, this is 50.74 cms. Sundal states that the average length of boys is 50.9 cms. and of girls 50.2 cms. A series composed of 14 % boys and 86 % girls will then achieve an average length of approx. 50.3 cms., i.e., somewhat less than in my series.

in the family. Here positive information was received in 17 of the 50 children, i.e., 34 %.

RESULTS OF TREATMENT

In the great majority of children the treatment was commenced a few days after birth. As explained above such early treatment was started in 41 out of the 50 children. In the remainder the treatment commenced later, but in all cases before the child had begun to stand or walk.

In order to assess the results of treatment it was decided to divide the children into two groups. Group I comprises the 41 children in whom the treatment was started in the newborn stage. Group II comprises the remaining 9 children.

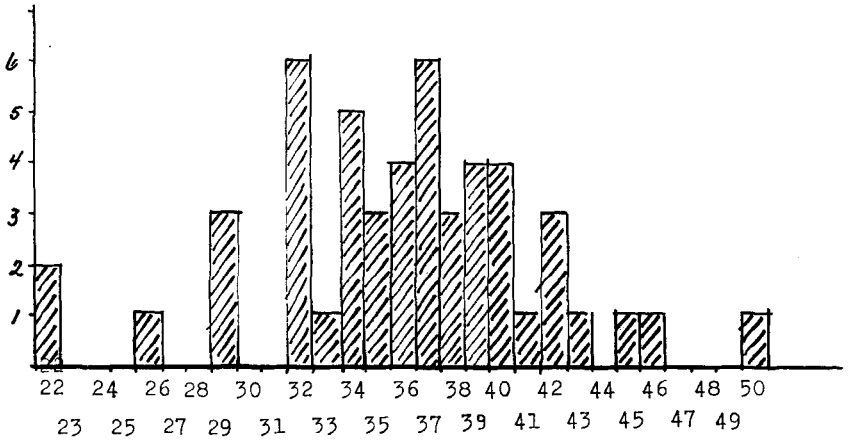


Fig. 4.

Weight at birth:

Abscissa: Weight at birth stated in 100 grams.

Ordinate: Number of children.

Each column represents the children whose weight at birth lies within the same 100 grams. The pattern in this graph of the weight at birth of the 50 children also corresponds with the graph in Sundal's normal series. The average weight at birth is calculated at 3.608 gr. Sundal states the normal weight of boys to be 3.500 gr. and of girls to be 3.400 gr. A group composed of 14 % boys and 86 % girls will then have an average weight of 3.414 gr., i.e., somewhat less than in my series.

GROUP I:

The first control examination within the group took place in 39 cases when the child was between 3 and 4 months old. In the last two cases the age was respectively 5 and 6 months. The results of the clinical examination at this point was as follows:

Negative findings	37 patients
Positive findings	4 patients
	41 patients

Positive findings in this connection mean that the hip could be dislocated and reduced with certainty or that shortening of the extremities could be demonstrated with limited abduction and positive "telescoping sign". In the X-ray examination, which took place the same day, the following was found:

Negative findings	23
Dysplasia signs in one or both hips	11
Dislocation or subluxation in one or both hips	4
No satisfactory X-ray exam.	3
	41

There was very good correspondence here between clinical and X-ray examination, since all in the group "negative findings" in the X-ray examination turned up again in the same group in the clinical examination.

All the dislocation findings in the clinical examination could, as was to be expected, be confirmed at the X-ray examination.

The X-ray symptoms which were given importance in referring a case to the radiological dysplasia group were as follows:

a. Increased relative acetabular index	6
b. Delayed development of epiphysis	3
c. Poor development of the anterior and posterior lips of the acetabulum, and poorly marked upper lateral border of the acetabulum	11

Cf. a: This symptom is relatively easy to evaluate and is only noted positive when there is an obvious increase of the angle of incline on one side in relation to the other.

Cf. b: This symptom is also easy to assess. One cannot, however, expect to find it positive in all cases where the control is undertaken at the age 3–4 months, since the epiphysis normally does not become radiologically visible until the age 3–6 months.

Cf. c: This X-ray symptom may be the subject of considerable subjective assessment, but is on the other hand present in all babies. In 6 out of 11 it is, however, supplemented by one of the above more objective symptoms, so that one may draw the conclusion that the subjective assessment of the acetabulum is probably not too fortuitous.

If the radiological findings in this group are compared with the clinical findings of Ortolani's sign at birth, the following is found:

Of the 32 babies who had positive Ortolani's sign at birth, 30 appear in group 1. In 2 of these the X-rays at the first check-up were of such quality that no X-ray diagnosis may be ventured.

In the remaining 28 the X-ray findings are negative in 15 (over 50 %), 4 have radiological subluxation and 9 have radiological dysplasia. No one has now a complete dislocation. From this it can be concluded that Frejka's cushion splint is very effective and that it is a fundamental advantage to begin treatment at such an early stage.

Final results of treatment:

In assessing the final result of treatment certain difficulties of evaluation are encountered. As stated the children were followed-up until the examiner at the clinical and radiological check-up was of the opinion that the hips were normal and showed no signs of becoming worse after the splint treatment was ended, i.e., the last check-up occurred at least 3 months after the continuous treatment was finished. The end result of the examined babies will be assessed according to this principle at most varying ages, and these lie between 6 and 33 months.

In 26 children the age was from	9–15 months
In 9 children less than	9 months
In 5 children more than	15 months

One child did not return for check-up owing to geographical reasons.
Total 41 children.

A. *Clinical examination.*

No signs of h.d. were found in any of the 40 children. In 19 cases the child was 12 months old on check-up, and all these could walk or stand with or without support. In these cases all had negative Trendelenburg sign as far as could be demonstrated.

It may then be maintained that from a clinical standpoint all the children had normal hips.

B. *Radiological examination.*

This appears more problematic both because the end stage is recorded at ages varying between ½ and almost 3 years and because there is no definite standard for the normal hip in this age group. The results of X-ray examination were judged according to two different principles.

First a general picture was formed of the hip joint, by taking into consideration the mutual development of the osseous parts of the caput and acetabulum and the adjustment of the caput to the acetabulum.

From this point of view an end result was found in 39 of these 40 children which was quite satisfactory. The caput and acetabulum had even contours, the acetabulum's roof had a suitable angle, the anterior and posterior lips were well developed and closed laterally. Moreover, the caput seemed to be well centred in its joint cavity.

A hip joint of normal appearance may thus be said to be present in 39 out of 40 cases. In the last case the caput is placed so far laterally and the acetabular contours are so blurred and uneven that an h.d. is probably still present or possibly a slight subluxation.

This method of assessment must undoubtedly be rather subjectively influenced, since it depends on the general judgement of the examiner.

Secondly these 80 hip joints were assessed strictly geometrically, by drawing up 2 of the previously mentioned auxiliary lines. Even at this point one comes across the first difficulty, since the Y line, judging from the literature, is drawn rather differently by different authors.

It was decided to draw the line as described by *Wiberg*. He draws it as a tangent to the upper contour of the os pubis. Others draw it rather differently, but in all cases it is situated further cranially than that described by *Wiberg*.

The second auxiliary line, called the P line, is drawn through the lateral, osseous border of the acetabulum and vertical to the Y line. Since the above border is often slightly rounded a slight difficulty is encountered in deciding the localisation of the line and the judgement of the examiner again comes into the picture.

After these lines are drawn, all hips are said to be "normal" where the caput in its entirety lies in the lower medial quadrant.

In those cases where 0–2 mm. of the caput lies above the Y line or laterally of the P line, the hips are called "normal?". This method of assessment was chosen because there will always be a certain doubt about the exact localisation of the auxiliary lines described. In no case does the caput lie more than 2 mm. above the Y-line.

In those cases where 3–5 mm. of the caput project laterally of the vertical line, the designation "dysplastic?" is used.

In those cases where the divergence is greater than that stated above, the hip joint is called "dysplastic".

The results of this strict assessment of the babies are as follows:

"Normal" hips	22 babies
"Normal?" hips	12 babies
"Dysplastic?" hips	5 babies
"Dysplastic" hips	1 baby
	40 babies

Much doubt was felt whether it was right to describe pathological conditions in a hip joint so systematically. Firstly, as already mentioned, some doubt was felt where the auxiliary lines were to be drawn. Secondly the question occurs whether here as elsewhere in man's anatomy, one must not make allowances for minor individual variations. Thirdly it was not possible to find anywhere in the literature an account of what should be regarded as the norm for the hip joint in children of

this age group, namely, 1–3 years. Studies were found which stated the normal outer limits for hip joints in adults and children down to 6 years, but not for the younger children.

When the investigation was being pursued *Andrén & von Rosen*'s examination technique was not published and therefore this could not be evaluated.

If the end results of the treatment of these 40 children according to the three procedures described are studied, the following emerges:

Clinical exam.	Normal hips	40 children
General radiological assessment	Normal hips	39 children
	Dysplastic hips	1 child
Radiological assessment in relation to the quadrant division of the hip joint		
	Normal hips	34 children
	Possible dysplastic hips	5 children
	Certain dysplastic hips	1 child

On the basis of the above it is believed that the treatment in 39 of the 40 children has led to the healing of the existing defect in the hip joints, while in one case complete healing has not yet been achieved.

This last case represents undoubtedly an error in treatment on the part of the examiner, in that the whole purpose of the investigation originally was aimed at demonstrating how valuable Frejka's cushion splint was. For this reason splint treatment alone was continued until the child was 14 months old. At this time certain dislocation existed in the right hip. A change was made to plaster and at the next check-up the right hip was reduced very nicely, but as stated, the caput is still placed rather far laterally, nor can one say really that any certain subluxation is present. A more elastic attitude by the author would undoubtedly have produced a better result. In later cases of the series the experience acquired from this lesson was applied. If complete stability was not achieved in the hip during the course of a control period of 3 months, the cushion splint was replaced by plaster administered if necessary under anesthesia. After 3 weeks the plaster was removed and the Frejka treatment was again adopted. In such cases no sign of recurrence was ever seen.

GROUP II:

The group comprises 9 children.

In 7 of these children treatment was begun at the age 3–4 months. In the last two the age was respectively 7 and 10 months.

A. *Clinical examination.*

The last clinical examination of these took place between 1 and 2 years of age. In no case could signs be demonstrated of pathological conditions in the hips. All had started to put weight on their lower extremities in the erect position. In those cases where it was technically possible, Trendelenburg's test was carried out with negative results.

The results of the clinical examination were thus negative in 100 %.

B. *Radiological examination.*

The last X-ray examination was carried out at the same time as the clinical one. On assessing this, uncertainty arises again as described before, since it is not definitely known which radiological standards must be applied to the normal hip in the age group involved here.

The general impression of the examiner in assessing the present X-rays is that in all cases the hip joints concerned under routine conditions would be regarded as normal. The acetabulum is well developed with a centrally placed epiphysis of normal shape.

If the existing pictures from the last check-up are studied strictly geometrically in this group and if the caput's position is assessed in relation to the previously described auxiliary lines in the same way as in Group I, the following end results are obtained:

"Normal" hips	2 children
"Normal?" hips	2 children
"Dysplastic?" hips	5 children

On comparing the clinical and radiological findings this group is believed to have achieved probable normal hips in all cases, i.e., 100 %.

If the strictly geometrical assessment of the end result has any value in comparison between these two groups, it appears that even a postponement of treatment from the birth of the child until he (she) is 3–4 months old, is unfavourable.

COMBINED ASSESSMENT OF GROUP I AND II AT THE CONCLUSION OF TREATMENT

It is the author's opinion that the two groups of results treated here are so small and that the time of initial treatment varies so little that no great mistake will be made if the two groups are combined.

The following total results are given for the 49 children who underwent full follow-ups:

Clinical examination:	Normal hips:	49 children
General radiological assessment:	Normal hips:	48 children
	Dysplastic hips:	1 child
Radiological assessment in relation to the quadrant division of the hip joint:	"Normal" hips:	24 children
	"Normal?":	14 children
	"Dysplastic?" hips:	10 children
	Dysplastic hips:	1 child

Even after the strictest assessment, therefore, 38 children or 77.5 % emerge from their congenital hip joint dysplasia with normal hip joints.

In 10 children or 20.5 % the clinical examination shows a completely normal hip joint, while a strict radiological assessment shows a slightly lateral position of the caput in one or both hip joints, although one cannot definitely say that h.d. exists.

In one child certain dysplasia is present in the one hip joint, while the other lies in the group above.

In 1 child an adequate follow-up could not be pursued owing to geographical conditions.

Seen in relation to the percentage of healing obtained in congenital h.d. when treatment is commenced after the child has started to walk, the results are believed to be so favourable that any postponement at all of the treatment after the newborn stage must be regarded as an error of technique.

PRESENTATION OF CASES

To give the reader a better understanding of the view-points maintained by the author some case-histories with tracings of X-rays are presented. There are three cases from each of the groups: "Normal" hips, "Normal?" hips and "Dysplastic?" hips.

Group: "Normal" hips:

Case No. 30 R.O. b. 25/9.1955. Fig. 5.

Family history:	No known cases of h.d.
Clin. ex. at birth:	Ortolani's sign pos. right hip. Shortening of right femur and assymm. skin folds.
X-ray ex. at birth:	Probable sublux. in right hip.
Treatment and course:	Commenced immediately after birth with Frejka's cushion splint. This was used day and night for 6 months, afterwards at normal sleeping hours for a further 2 months. Walked and stood with support at ca. 10 months.
Last check-up (15 mos.):	Clinical ex.: Completely normal hips.

Walks without limp. Trendelenburg — bilat.
X-ray: normal hips, both caputs in the lower medial quadrant. Right caput insignificantly smaller than the left.

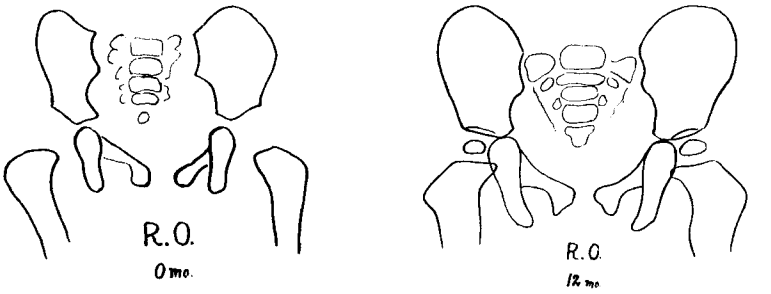


Fig. 5.

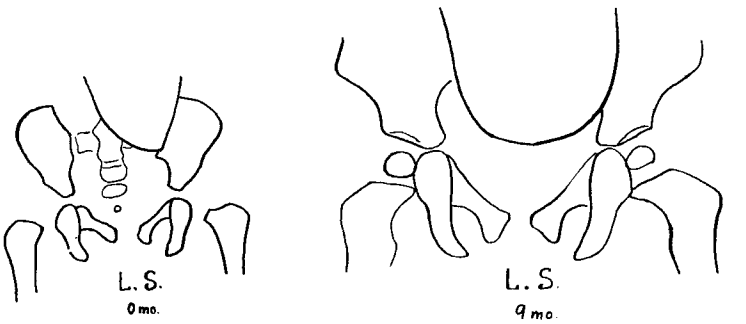


Fig. 6.

Group: "Normal" hips:

Case No. 143 L.S. b. 12/12.1957. Fig. 6.

Family history:	No known cases of h.d.
Clin. ex. at birth:	Ortolani's sign pos. bilat. with relative shortening of the femora.
X-ray ex. at birth:	Probable dysplasia bilat.
Treatment and course:	Frejka's cushion splint treatment started at birth. This was used continuously for 6 months, afterwards during sleeping hours for a further 3 months. Normal development of the hip joints.
Last check-up (9 mos.):	Clin. ex.: normal hips.
	X-ray: normal hip joints. Caput in lower medial quadrant bilat.

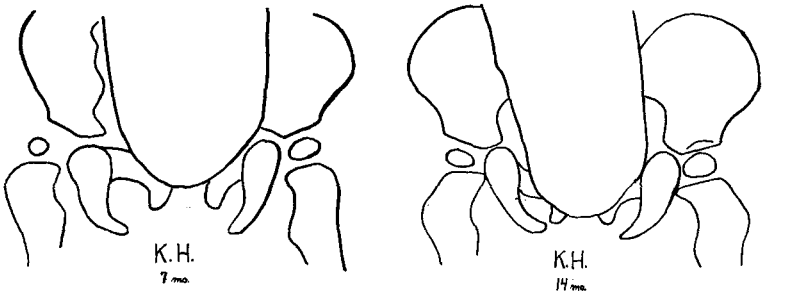


Fig. 7.

Group: "Normal" hips:

Case No. 134 K.H. b. 5/9.1957. Fig. 7.

Family history:	Twin sister with certain clinical and radiological luxation in left hip at birth.
Clin. ex. at birth:	Neg. findings.
X-ray ex. at birth:	Not performed.

Owing to the examiner's interest in twin cases in this series the patient was called for check-up with her sister, 7 months old.

Clin. ex., age 7 months:	Limited abduction in right hip, assymm. skin folds and probable shortening of right femur.
X-ray ex., age 7 months:	Certain dislocation in right hip.
Treatment and course:	Reduction performed under anesthesia without difficulty. Position maintained in plaster. After 3 weeks, plaster-cast replaced by Frejka's cushion splint. This was used continuously for 3 months, afterwards during sleeping hours for a further 3 months.
Last check-up (14 mos.):	Clin. ex.: normal hips.
	X-ray ex.: both hip joints appear normal, but right caput is still a little smaller than the left.

Group: "Normal?" hips:

Case No. 43 S.H. b. 12/4.1956. *Fig.* 8.

Family history:	3 certain cases of h.d. in the father's family.
Clin. ex. at birth:	Ortolani's sign pos. right hip.
X-ray ex. at birth:	Certain lat. position of upper end of femur, right side, with slight uprooting of same and increased acet. incline bilat.
Treatment and course:	Frejka's cushion splint used from birth. The cushion was used continuously for 6 months. Afterwards treatment was concluded. After only 3 months clin. ex. was negative, while there were continued signs of dysplasia in both hips on X-ray ex.—Started to walk without limping at 1 year.

Last check-up (26 mos.): Clin. ex.: completely normal hip joints.

X-ray ex.: at first sight the hips appear completely normal bilaterally, but on both sides the caput projects about 2 mm. above the Y line and about 2 mm. laterally of the P line.

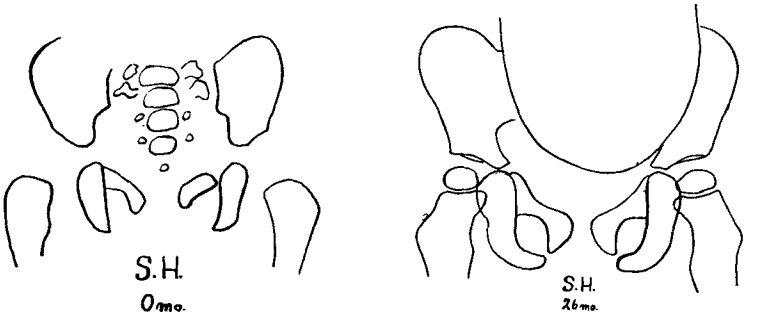


Fig. 8.

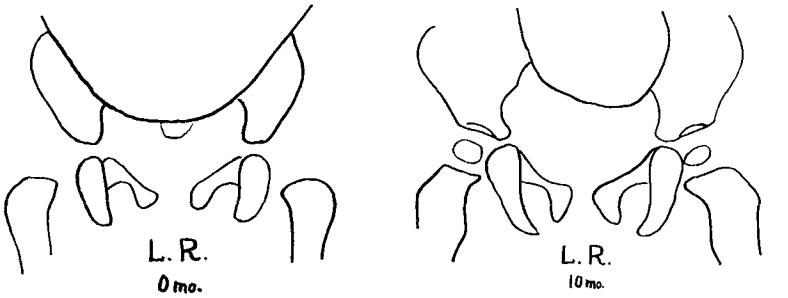


Fig. 9.

Group: "Normal?" hips:

Case No. 118 L.R. b. 8/7.1957. Fig. 9.

Family history: One case known in a distant relative in the mother's family.

Clin. ex. at birth: Ortolani's sign positive bliat. Left hip was so loose that it did in fact dislocate as soon as the baby was laid on its back.

X-ray ex. at birth: Considerable increase in acetabulum's angle of incline bilat.

Treatment and course: Frejka's cushion splint treatment started at birth. At the first check-up certain dislocation continued to be present in the left hip. Easy reduction without anestesia was obtained. Reduction maintained in plaster. After 3 weeks the

plaster was replaced with Frejka's splint. This was used continuously for 3 months. Afterwards again for 3 months with two hours freedom from the splint each day. Could stand with support after 10 months.

Last check-up (10 mos.): Clinical ex.: normal hips.

X-ray ex.: bilat. the caput projects 1 mm. above the Y line and on the right side 2 mm. outside the P line.

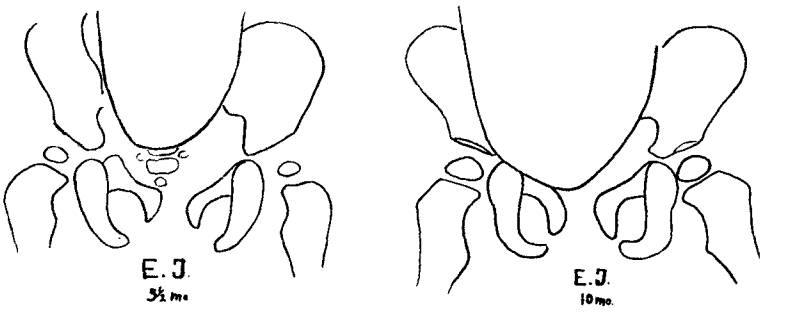


Fig. 10.

Group: "Normal?" hips:

Case No. 79 E.J. b. 5/1.1957. Fig. 10.

Family history: No known cases of h.d.

Clin. ex. at birth: Pronounced crepitation and some looseness in left hip joint. Ortolani's sign neg. No instability.

X-ray ex. at birth: Not performed.

Treatment and course: No treatment begun at birth. At first check-up aged 3½ months limited abd. was found in right hip and definite instability in left hip. X-ray findings: Probable subluxation in both hips. Reduction was undertaken under anesthesia. Stability was easily obtained in the reduced position with Frejka's cushion splint. This was used continuously for 3 months, then at sleeping-hours for a further 3½ months.

Last check-up (10 mos.): Clinical ex.: Normal hip joints.

X-ray ex.: On immediate study both hip joints appear normal, but the caput projects 2 mm. above the Y line bilat. and also 2 mm. outside the P line.

Group: "Dysplastic?" hips:

Case No. 115 J.T.V. b. 28/5.1957. Fig. 11.

Family history: Elder sister had certain bilat. h.d. In addition the child is closely related with another child in the series.

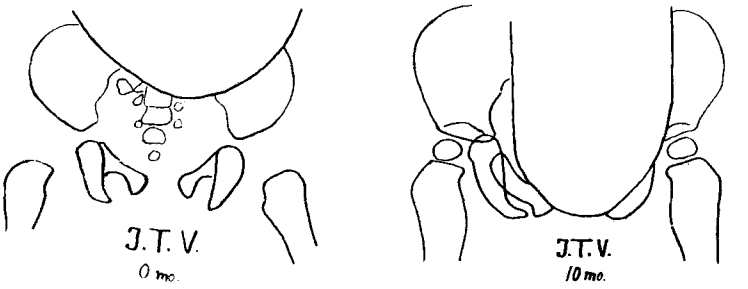


Fig. 11.

Clin. ex. at birth:	Ortolani's sign pos. left hip, probably instability in right hip.
X-ray ex. at birth:	Upper lateral border of acetabulum is not well marked. Rather large angle of incline in left hip. Certain signs of dislocation are not present.
Treatment and course:	Frejka's cushion splint treatment started at birth. In first check-up after 3 months there was probable instability in both hips on clinical ex. X-ray showed certain sublux. in right hip, and somewhat laterally placed caput in left hip. It proved that the cushion used was too thin and soft to obtain the desired effect and it was exchanged. The new cushion was afterwards used day and night for 6 weeks, afterwards omitted 2 hours daily for 6 weeks, and then worn only at night for a further 4 months.
Last check-up (10 mos.):	Clin. ex.: normal hips. X-ray ex.: left hip completely normal, caput on right side projects 3 mm. outside the P line.

Group: "Dysplastic?" hips:

Case No. 10 E.E. b. 8/4.1955. Fig. 12.

Family history:	No known cases of h.d.
Clin. ex. at birth:	Ortolani's sign pos. right hip.
X-ray ex. at birth:	Relatively increased acetabulum angle of incline on right side. Shenton's line broken bilat. Lateral position of both femoral diaphyses.
Treatment and course:	With clinically certain hip joint dislocation on the right side a directive was given that treatment should be started before discharge from the maternity ward. The directive was misinterpreted, however, and no treatment was begun. On the first check-up certain clin. dislocation existed in the right hip, which could be confirmed on X-ray ex. No success was obtained in trying to achieve stable reduction

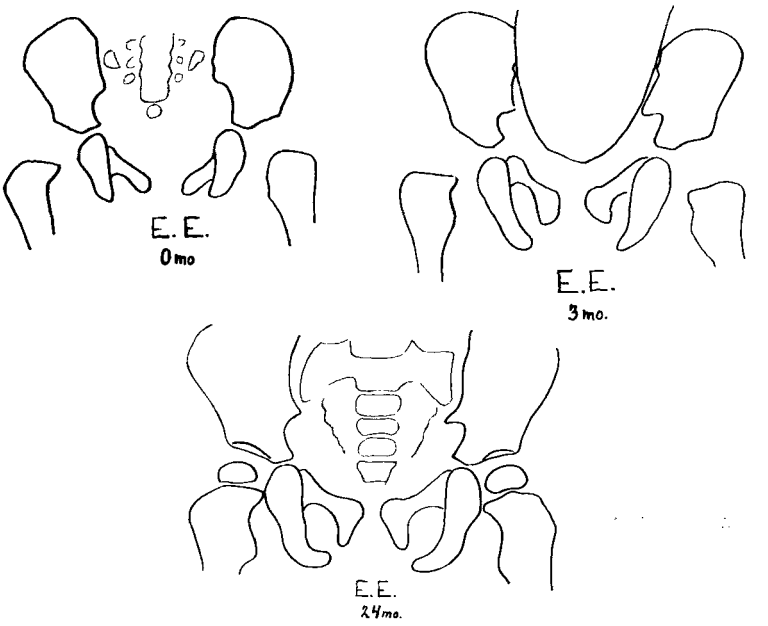


Fig. 12.

without anesthesia. The reduction was maintained in plaster for 3 weeks. Then normal Frejka's splint was used continuously to the age of 6 months and then during sleep to 12 months. Later checks gave normal findings from the right hip, but plain abduction spasm in the left, where the epiphysis as well seemed to be more laterally placed than on the right side. At 14 months tenotomy of the adductors on the left side was performed. Later the course was normal, apart from temporary fragmentation of both caputs. At 14 months she could stand with support. Walked at 16 months.

Last check-up (24 mos.): Clinical ex.: Neg. findings.

Walks freely without limp. Trendelenburg's sign neg. bilat.

X-ray ex.: Well developed acetabulums. Right epiphysis 1 mm. above and 5 mm. laterally of the auxiliary lines. Left epiphysis projects 1 mm. above and 3 mm. laterally of the same lines.

Group: "Dysplastic?" hips:

Case No. 36 G. F. b. 5/1.1956. Fig. 13.

Family history: No known cases of h.d.

Clin. ex. at birth: Slight crepitation on abduction beyond 80° of left hip.

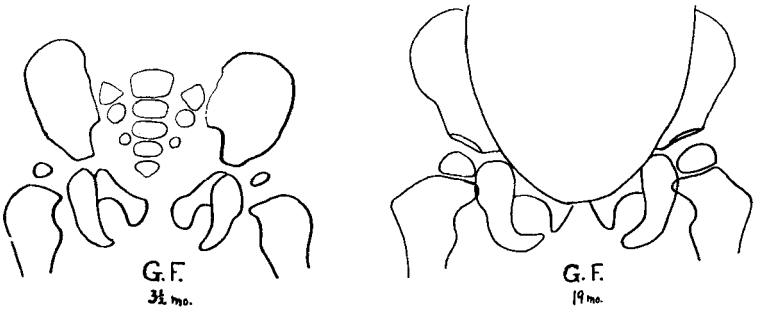


Fig. 13.

X-ray ex. at birth:	Not performed.
Treatment and course:	At the first check-up, age 3½ months, certain clin. dislocation in the right hip, confirmed at X-ray ex. Under anesthesia an easy reduction was carried out. The position was maintained in plaster for 4 weeks. Then the plaster was replaced by Frejka's splint. This was continuously used for 3 months. Then it was used at sleeping hours for a further 6 months. The patient walked without support at the age of 13 months.
Last check-up (19 mos.):	Clin. ex.: walks normally. No pathological findings on ex. of the hips. X-ray ex.: The general impression is that the hip joints are developing normally, but the caput projects respectively 4 and 3 mm. above the Y-line and 4 and 3 mm. laterally of the P line.

DISCUSSION

I have presented the results of a consistently pursued investigation into hip joint dysplasia in 3242 children.

The 50 children whom I believe had h.d. at birth were treated and followed-up until I considered the hips to be normal.

a) *Incidence of h.d. in the series.*

I was very surprised at the high incidence of h.d. According to other studies from the Scandinavian countries the disease occurs to the order of 0.1 % while in this series it shows a figure of 1.5 %. In the Samic population in Finnmark a morbidity of 4–5 % was found, while the Norwegian population in this province has much the same incidence as elsewhere in the country.

According to the research I have made, there are at any rate no official statistics on the occurrence of h.d. The figures presented in the literature are not based then on normal health statistics.

From other parts of the world the morbidity incidence is reported as varying quite considerably from place to place. The interpretation must be that h.d. is a disease which in certain geographical areas arises with great frequency while in others it may be very rare. I therefore satisfied myself with the explanation that Möre and Romsdal county forms just such a geographical area in which h.d. has a higher incidence than in Norway as a whole.

This theory is supported by the fact that before this investigation was commenced a relatively large number of children were admitted to hospital aged 1–3 years, with hip joint dislocation. During the years 1950–54, 4–7 newly-diagnosed cases were admitted each year. Even this number is only a third of the incidence shown in the series. The explanation of this may be partly that some cases of h.d. were referred for treatment to a special clinic instead of to the local hospital. It is also known from the literature that spontaneous healing of h.d. does occur. It is therefore probable that a number of the cases included in the series would also have achieved healing without treatment. The difficulty arises only in that it is not known with certainty who will develop a complete dislocation and who will achieve spontaneous healing.

The few cases in which a certain diagnosis of dysplasia was made at birth but in which treatment was mistakenly not commenced, do not encourage postponement of treatment in the hope of spontaneous healing.

b) *The clinical examination of the hip joint in newborns.*

The examination was undertaken with the baby lying supine. The hip joints were flexed 90°. The examiner placed his thumb over the distal end of the femur and the other fingers over the trochanter region. From this initial position the mobility and stability of the hip joints were examined.

Based on past experience I believe that Ortolani's sign (snapping sign) and instability (telescoping sign) of the hip joints are convincing symptoms of h.d. Using the examination technique described these symptoms are relatively easy to observe even for a less skilled examiner.

I have never observed limited abduction in the newborn stage except as a link in Ortolani's sign, i.e., when the abduction movement is undertaken in a dislocated hip joint, slight resistance to continued abduction

is felt before the caput is tilted into the joint cavity. Afterwards abduction may normally be undertaken to about 70°. For the symptom to appear alone I assume that a better development of the musculature is required than is found in newborns. Later, e.g., at the age of 3 months, the abduction blockage will be an important symptom of hip joint dislocation.

I have also as a matter of routine taken notice of whether asymmetry was present in the thigh, groin or gluteal skin creases.

I should like to draw attention to the crepitation noise to be heard on passive abduction of the hip joint. In a good number of cases where this was observed at the first examination, I checked on the child later without finding signs of pathological development of the joint. In some few cases this was the only clinical symptom of h.d. in the neonatal stage and later examination showed the development of dislocation (see case 36, Fig. 13). I would therefore recommend that children who offer this symptom are examined as routine at the age of about 4 months when the epiphysis is visible on the X-ray pictures.

c) *Hip joint dysplasia in children with negative findings on examination at the newborn stage.*

Among the 3242 children who were examined immediately after birth, and where the primary result of the examination was "Normal hips", only 2 cases occurred which were later to be admitted to hospital with hip joint dysplasia. In both cases only a moderate degree of dysplasia was present without complete dislocation. Both were treated with favourable results.

I take this as indicating that clinical examination at the neonatal stage is very reliable.

Naturally the objection may be made that perhaps there were other cases of which the examiner was not aware. I consider this to be hardly probable because this series of investigations was much publicised by the hospital both amongst the women who were admitted to the maternity ward and amongst the doctors in the district.

The fact that, taken as a whole, overlooked cases do arise is an inspiration towards constant control of the hip joints of infants. Carrying out a hip joint examination is so easy and takes so little time that it ought to be included as a routine examination in all infant check-ups. In particular the examination should apply to girls in families where it is known that h.d. occurs amongst other members of the family.

If this procedure is carried out, all cases of hip joint dysplasia should be discovered and treated before the child begins to walk.

d) *Radiological examination of the hip joint.*

An attempt was made to take all pictures with the patient lying supine in complete rest with straight lower extremities in the neutral position of rotation and centred towards the symphysis. It will be well known to all who have performed such an examination that it can be difficult, not to say impossible, to persuade a patient in the age group involved here to lie in the correct position during the examination. To avoid overlong exposure I therefore approved in a number of cases X-rays which were obviously not taken in an ideal position. This circumstance should be born in mind when assessing a radiological diagnosis on a purely geometrical basis.

As will appear in the assessment of the end results, I found on careful scanning of the X-rays a number of babies who had a very slight lateral dislocation of the caput but at the same time no sign of dysplasia could be detected in the hip joint as a whole, i.e., the caput was normally formed, with entirely normal size and contours. The same applies to the acetabulum, including the angle of incline. The author cannot declare with certainty today that these hips are normal and will develop normally. It is hardly reasonable to believe that the above-mentioned changes are only due to inaccuracies in the radiological technique. A possible explanation is that these cases concern femora with increased anteversion, so that X-rays taken with the lower extremities in the correct position of rotation, really give a very slight lateral projection of the caput in relation to the acetabulum. I consider it very doubtful that a genuine subluxation is involved. Some children in the series who presented such radiological findings were checked again after getting about without any form of treatment. No increased lateral displacement or signs of uprooting were observed.

It is stated in the literature that the hip joint ends its development in persons in the 17 years age group. I assume than the population group from which this series is derived has stable housing conditions so that it would be possible to follow-up these children when they are about 17 years old. Such an investigation is planned. It will possibly give the answer to the question of how much importance a lateral position of the caput may possess in the development of the hip joint.

In this series I have omitted to divide the patients into the usual groups of unilateral and bilateral cases.

In the literature published 20–30 years ago and earlier, a strict differentiation was made between uni- and bilateral cases. On the whole it was agreed that ⅓ were bilateral and ⅔ were unilateral. In later publications this distribution was altered in favour of a larger number of bilateral cases. I am strongly convinced that one should perhaps go further in this direction and say that congenital hip joint dysplasia is a systemic disease which affects the development of the hip joint generally. The degree of dysplasia may vary and this explains why the symptoms found on clinical and radiologacil examination may be localised to one hip only.

With a serious degree of dysplasia at birth, dislocation may occur in one or both hips.

With a slight degree of dysplasia one of two things may happen: either the hip joint will develop so that the child begins to stand and walk with normal hip joints, or the dysplasia will persist or become worse in the first years so that weight bearing on the lower extremity concerned will pass into a genuine dislocation on one or both sides.

If the above view of hip joint dysplasia is correct, then the fact that we constantly examine our children in their younger years and that methods of examination constantly grow better, will provide, in the author's opinion, a good explanation of the tendency found in the literature towards a constant increase in the bilateral cases at the expense of the unilateral.

I have deliberately paid little attention to the importance of the angle of incline of the acetabulum in the radiological assessments.

The reason is partly that more recent literature very decidedly asserts that this angle varies so much individually that no clear boundary can be drawn between normal and pathological values. Nor in this study was any complete correspondence found between the acetabulum's angle of incline and other symptoms utilised to make the diagnosis h.d.

It must be said that the angle of incline in the series as a whole is high. The average figure for normal angles of incline is put in the literature at 28–29° in newborns, but with large individual variations which cannot be designated as pathological.

In this series X-ray pictures of the newborn stage are included of 44 babies, in all 88 hip joints. 68 of these show an angle of incline of 29° and more. An angle of incline less than 25° is found in only 5 hip joints.

These figures should indicate that a large angle of incline certainly is a feature in the picture of a hip joint dysplasia, but as previously stated I would not venture, on the basis of the present radiological findings,

to draw up any boundary between normal and pathological angles of incline.

A circumstance which caused the author somt thought during the collection of the material was the danger of overlong irradiation of the gonads. As the figures from the casepresentation will show, an attempt was made to cover the gonads with lead plate during the exposure.

In this field my experience is that it is difficult to achieve satisfactory covering of the gonads, at any rate in girls, without at the same time covering parts of the hip joints. It may therefore be asked if it is more advisable to take the pictures without covering than to present the patient for two or more exposures in order to include both hip joints.

Skin dosage in exposure of the joints was measured. This is of such a degree that a control examination at intervals of 3 months will scarcely cause any injury to the gonads. I would, however, emphatically warn against exaggerated use of X-ray examination, not least because the clinical examination may be of more value than the radiological examination in newborns.

e) *Treatment with Frejka's cushion splint.*

My experience with Frejka's cushion splint has been very favourable. In the great majority of cases I obtained normal development of the hip joints after 3 month's treatment. In certain cases where instability was unusually large, or where treatment began later than the newborn stage, I utilised plaster immobilisation for a short period. In these cases I replaced the plaster by a cushion splint after 3–4 weeks and found this completely satisfactory.

The advantage of the cushion splint is that it causes the patients little or no inconvenience. It also is simple and cheap to make and easy to take off and put on in the daily care of the baby.

f) *The results of other clinical observations of the child.*

The information which I have collected about the length and weight of the child at birth shows considerable correspondence with the average figures for the country. Length and weight relationships in the series therefore give no support to the theory that space conditions in the womb are an etiologic factor in h.d.

As far as the position of the foetus in the womb is concerned, conditions on the whole agree with what is found in a normal material, with the exception that breech position occurs more often than usual.

6 children or 12 % were born in the breech position. This also corresponds with what is found in other series. It is asserted in the literature that children are born in the breech position because they are not so large and are more delicate than others and that their leg movements in the womb would therefore be less active. I find no support for this theory if length and weight are to form an expression of muscle activity. The average weight of the 6 children born in the breech position is 3560 gr., thus somewhat above the average for the whole series. This is in spite of the fact that one of these 6 children is a twin.

I also noted the mother's age at birth to see if this could have any importance in the etiology. The average age of the mother was 29.9 years. The series includes two cases of twins. In calculating the above figures I included the age of these mothers twice. If this error is corrected, an average age of 29.4 years results. The average age of 93 mothers with normal children amongst the 3242 examined equals 29.3 years, and therefore this forms no reason for the assertion that the mother's age has any significance in the development of h.d.

As with other series, definite information about other cases of h.d. in the family to a high figure were found, in this series the figure was 34 %. Moreover, it may be said that several children in the series are related. Finally it ought to be stated that amongst the 50 children 3 pairs of twins were affected. I found h.d. in both twins in two of the pairs. This also supports the theory of the familiar emergence of h.d.

On the basis of the information gathered about the length and weight of the children at birth, their foetus position, their order of birth in the family, the mother's age at birth and other cases of h.d. in the family, one can only draw the conclusion that h.d. occurs more often in children born in the breech position than in other foetus positions and that the disease seems to be conditioned by the respective family, facts which were well known from previous research.

SUMMARY AND CONCLUSION

The results are presented of an investigation into hip joint dysplasia in all children born at County Hospital in Ålesund, Norway, in the years 1955–57, in all 3242 children. The findings indicate an incidence of morbidity far above the accepted average for Norway.

On the basis of the series presented, it is thought that these conclusions may be drawn:

1. A clinical examination of the hip joints of all newborns should be consistently pursued.
2. A positive Ortolani's sign or a definite instability of the hip, when demonstrated in newborns, is a convincing symptom of hip joint dysplasia which demands treatment. Treatment should be commenced immediately after birth.
3. The normal hip joint in newborns can be moved passively with complete freedom without any form of crepitation. A repeated and constant crepitation in a certain position of the hip joint may indicate the presence of a dysplasia and ought to lead to control examination of the baby at 4 months of age, when the epiphysis is radiologically visible.
4. Limitation of abduction in the hip joint occurs rarely or never in in newborns as a sign of hip joint dysplasia.
5. In newborns clinical examination of the hip joints is so superior to X-ray examination that the latter can be dropped without consequences. It is only when the epiphyses becomes visible radiologically that the X-ray offers more than the clinical examination.
6. The reduction position achieved in the hip joints with a Frejka's cushion splint in children up to 9 months of age, is completely satisfactory and will in the great majority of patients provide recovery.
7. Treatment of hip joint dysplasia with Frejka's splint is so little troublesome to the patient and mother that commencement of treatment is justified even if there may be doubt about the diagnosis.

RESUME ET CONCLUSION

Présentation des résultats de l'examen concernant la dysplasie de l'articulation de la hanche pratiqué chez tous les enfants nés à l'Hôpital Fylke à Ålesund, en Norvège, dans les années 1955–57, en tout chez 3242 enfants. Les trouvailles indiquent une incidence de morbidité beaucoup plus élevée que la moyenne normalement présumée en Norvège.

Sur la base de cette série d'observations, on considère que les conclusions suivantes peuvent être tirées:

1. Il faut continuer à procéder à un examen clinique des articulations de la hanche chez tous les nouveau-nés.

2. Un signe Ortolani positif ou une instabilité définie de la hanche constatée chez un nouveau-né un symptôme certain de dysplasie de l'articulations de la hanche qui demande à être traitée. Le traitement doit être entrepris immédiatement après la naissance.

3. Le mouvement passif d'une articulation normale de la hanche chez les nouveau-nés est entièrement libre sans aucune forme de crépitation. Une crépitation répétée et constantée dans une certaine position de l'articulation de la hanche indique la présence d'une dysplasie et doit engager à un examen de contrôle du bébé à l'âge de 4 mois, lorsque l'épiphyse est radiologiquement visible.

4. La limitation de l'abduction de l'articulation de la hanche est rarement ou jamais constatée chez les enfants comme signe de dysplasie de l'articulation de la hanche.

5. Chez les nouveau-nés, l'examen clinique de l'articulation de la hanche est si supérieur à l'examen aux Rayons X que celui-ci peut être abandonné sans inconvénient. C'est seulement quand l'épiphyse devient visible radiologiquement que les Rayons X donnent plus que l'examen clinique.

6. La position de réduction pratiquée dans les articulations de la hanche au moyen d'une attelle Frejka chez les enfants jusqu'à l'âge de 9 mois est complètement satisfaisante et entraîne la guérison dans la grande majorité des cas.

7. Le traitement de la dysplasie de la hanche par l'attelle Frejka est si peu gênant pour le bébé et sa mère qu'il est justifié de l'entreprendre même si l'on a des doutes concernant le diagnostic.

8. Les résultats obtenus par le traitement conforme de la dysplasie de l'articulation de la hanche chez les enfants sont si bons qu'il devrait être possible dans un proche avenir de rayer les dislocations de la hanche comme problème orthopédique chez les enfants plus âgés ou les adultes.

9. Les données présentées concernant la position de l'enfant dans la matrice, la longueur et le poids après la naissance n'offrent aucune base à l'explication mécanique d'une dysplasie de l'articulation de la hanche.

ZUSAMMENFASSUNG UND SCHLUSSFOLGERUNGEN

Die Ergebnisse einer Untersuchung der Hüftgelenksdysplasien aller Kinder, die in den Jahren 1955–57 am Fylkes (Bezirks) Krankenhaus in Ålesund, Norwegen geboren wurden (insgesamt 3242 Kinder), werden vorgestellt. Die Befunde weisen eine Häufigkeit der Morbiditet auf, die weit höher als der angenommene Durchschnitt für Norwegen ist.

Auf Grund der vorgewiesenen Untersuchungsreihen glaubt man die folgenden Schlussfolgerungen ziehen zu können:

1. Eine klinische Untersuchung der Hüftgelenke aller Neugeborenen sollte konsequent vorgenommen werden.

2. Ein positives Ortolani Zeichen oder eine sichere Unstabilitet der Hüfte sind, sobald sie am Neugeborenen nachgewiesen werden, überzeugende Symptome einer Gelenksdysplasie und erfordern Behandlung. Diese soll unmittelbar nach der Geburt begonnen werden.

3. Das normale Hüftgelenk des Neugeborenen kann passiv vollständig unbehindert und ohne jegliche Krepitation bewegt werden. Eine wiederholte und konstante Krepitation in einer gewissen Stellung des Hüftgelenkes kann das Vorhandensein eine Dysplasie anzeigen und sollte zu einer Kontrolluntersuchung des Kindes im Alter von 4 Monaten, wenn die Epiphyse im Röntgenbilde sichtbar wird, führen.

4. Begrenzung der Abduktion im Hüftgelenk des Neugeborenen ist als ein Zeichen von Dysplasie kaum oder niemals vorhanden.

5. Bei Neugeborenen ist die klinische Untersuchung des Hüftgelenkes der Röntgenuntersuchung weitaus überlegen, so dass die letztere ohne Folgen fallen gelassen werden kann. Nur sobald die Epiphyse röntgenologisch sichtbar wird, bietet das Röntgenverfahren mehr als die klinische Untersuchung.

6. Die Einrenkungsstellung im Hüftgelenk, welche mit Frejkas Polsterschiene erzielt wird, ist bei Kindern bis zu 9 Monaten vollständig zufriedenstellend und wird für die Mehrzahl der Patienten eine Heilung ergeben.

7. Die Behandlung der Hüftgelenksdysplasie mit der Frejka-Schiene stört Kind und Mutter so wenig, dass die Inangriffnahme der Behandlung berechtigt ist selbst wenn Zweifel über die Diagnose bestehen.

8. Die Ergebnisse einer konsequenten Behandlung der Hüftgelenksdysplasie bei Säuglingen sind so gute, dass es möglich sein sollte, Hüftgelenksverrenkungen bei älteren Kindern und Erwachsenen als ein orthopädisches Problem in der nahen Zukunft auszuschalten.

9. Die vorgelegten Daten über die Lage des Kindes im Uterus, ferner über Länge und Gewicht bei der Geburt bieten keine Grundlage für eine mechanische Erklärung der Entwicklung von Hüftgelenksdysplasie.

REFERENCES

Andrén, L. & v. Rosen, S.: Acta Radiologica. Vol. 49. Fasc. 2: 89.
Burman & Clark: Am. J. of Roentgenology. *44*: 37, 1940.
Caffey, J. et al.: Pediatrics, *17*: 632, 1956.
Frejka, B.: Wiener Med. Wochenschrift, 91: 523, 1941.
Getz, B.: Acta Orthop. Scand. Suppl. XVIII, 1955.

Hart, V. L.: Congenital Dysplasia of the Hip Joint and Sequelae. Charles C. Thomas. Springfield, Ill. 1952.

Hilgenreiner, H.: Med. Klinik XXI. 1925. 2: 1385 and 1425.

Jacobson, E.: Sv. Läkartidn., 55: 33, 2427.

Köhler, A. & Zimmer, E. A.: Grenzen des Normalen und Anfange des Pathologischen im Röntgenbild des Skelettes. Georg Thieme Verlag, Stuttgart (10. Aufl.).

Laurenson, R. D.: JBJS. Vol. 41 B No. 4: 702.

Leeftmann, R.: JBJS. Vol. 41 B No. 4: 689.

Martin, H.: Radiology, 56: 842, 1951.

Nyström, B. & Zilliacus, H.: Nord. Med., 12 VII. 1956.

Palmén, K.: Sv. Läkartidn., 54: 1706, 1957.

Ponseti, J.: J. of the Iowa State Med. Society. Nov. 1950.

Ponseti, J.: Am. Academy of Orthop. Surg. Instructional Course Lectures. Vol. X. 1953.

Putti, V.: JBJS. Vol. XV: 16.

v. Rosen, S.: Acta Orthop. Scand. Vol. XXVI: 136.

v. Rosen, S.: Sv. Läkartidn., 54: 2879, 1957.

Severin, E.: Acta Chir. Scand. Vol. 84. Suppl. 63, 1941.

Sundal, A.: Universitetet i Bergen, Årbok 1957. Medisinsk rekke, nr. 1.

Walther, T. & Moe, B.: Tidsskr. for Den norske lægeforening. Nr. 20: 643, 1954.

Wiberg, G.: Acta Chir. Scand. Vol. 83, Suppl. 58, 1938.

HCPCS:	Descriptor:
L1610	HIP ORTHOSIS, ABDUCTION CONTROL OF HIP JOINTS, FLEXIBLE, (FREJKA COVER ONLY), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	NO	NO	YES	YES

Sample Diagnosis (Not Inclusive)	Hip dysplasia
Medically Necessary Argument	The Frejka pillow is a thick, layered or padded material with adjustable shoulder straps. It is designed to reduce stresses across the affected hip joint or joints of newborns and infants. It is designed to maintain the femoral head to be contained within the acetabulum, while the hip joint is stabilized bilaterally at the end desired degrees of abduction as well as the desired degrees of internal rotation. Professional fit is essential for the proper degrees and limited range of motion. Inappropriate fit can result in inability to ambulate, painful ambulation, required surgical intervention or multiple poor outcomes. In the event of cover change, the same fitting criteria are required. The replacement of the cover requires reapplication and same fitting criteria as with the original device.
References	4

FROM FYLKESSJUKEHUSET (COUNTY HOSPITAL) IN ÅLESUND, NORWAY.
HEAD OF THE SURGICAL DEPARTMENT: DR. HALVARD SKEIE, M.D.
(FROM 1956): DR. KAARE BENDIXEN M.D.
HEAD OF THE RADIOLOGICAL DEPARTMENT: DR. JOHS. SLÖRDAHL, M.D.

EARLY DIAGNOSIS AND TREATMENT OF HIP JOINT DYSPLASIA

By

INGULF UTHEIM MEDBÖ

Congenital dislocation of the hips has probably been known for thousands of years. Treatment has varied through history. Both the treatment and the results of the treatment have been made the subject of intense interest in medical literature.

In more recent decades it has become more and more obvious that the earlier the treatment begins, the greater is the chance of achieving a good result. It is generally accepted in the literature that the best results are obtained when treatment is started in the neonatal stage. These observations form the background to the study of which an account is given in these pages.

During the years 1950 to 1954 a relatively large number of patients were admitted to Fylkessjukehuset in Ålesund for treatment of congenital hip joint dysplasia (h.d.) at the age of 1–3 years. In the late fall of 1954, therefore, it was decided to begin routine examination of all newborn children in the hospital's maternity department and from the 1st of January, 1955, such an examination was consistently carried out.

SCHEME OF INVESTIGATION

a. Clinical examination:

Examination of the hips was made part of the routine examination of all babies in the maternity ward. Doctors on duty examined the hips of all children when they were 3–5 days old. When somewhat later a pediatrician was added to the hospital staff this series of examinations was so well organised that no reason could be found for changing the routine.

The clinical signs which were looked for were as follows:

1. Ortolani's sign (snapping sign).
2. Instability of the hips (telescoping sign).
3. Limited abduction of the hips.
4. Shortening of the femora.
5. Crepitation sound/feeling in the hip joints on passive abduction.

This last sign has scarcely any pathognomic significance as e.g. 1 and 2, but in certain cases this was the only pathological finding in hips which were undoubtedly dysplastic. We followed up all babies with this sign. In the great majority the hips developed in a completely normal way without any treatment. No exact explanation of the finding can be given. It may possibly be due to a certain looseness of the connective tissue in newborns who are still under the influence of the mother's hormones. In the few cases in which it indicated the presence of a dysplasia the sign was regarded as an abortive Ortolani's sign.

b. Radiological examination:

In the first year of this series X-rays were taken of the hip joints in all babies who were suspected of hip joint dysplasia following clinical examination. X-ray examination was made the day after the clinical examination, i.e., when the baby was 4–6 days old.

In the following two years X-ray examination was only carried out on newborns when convincingly positive symptoms were present on clinical examination. In all cases, however, X-ray examination was undertaken at the age of 3–4 months.

The findings at this time decided the need for future follow up.

We sought to evaluate by means of X-ray pictures taken of newborns the following radiological details:

1. The acetabular index.
2. Lateral position of the diaphysis in relation to the acetabulum.
3. Shenton's line.
4. The development of the anterior and the posterior acetabular rim.
5. The upper, lateral border of the acetabulum.
6. The upper end of the diaphysis in relation to the obturator line.

c. Other data on mother and child:

In connection with the first clinical examination certain data was collected on mother and child so as to determine further factors of etiologic importance.

The following were noted, the child's sex, weight at birth, length,

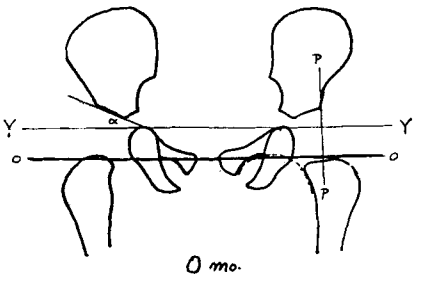


Fig. 1.
Normal pelvis with auxiliary lines.
YY = Y-line. OO = obturator line.
PP = line of gravity through the upper, lateral border of the acetabulum.
a = the acetabular index.

position in womb and order of precedence in the family. In addition the mother's age was recorded and information was sought as to any history of h.d. in the family.

TREATMENT

The principle determining treatment was that this should be initiated as far as possible immediately the diagnosis was made, i.e., in the first week of life.

This was observed with 41 of the 50 babies.

In 7 of the remaining cases treatment was begun along with the first check-up, i.e., at the age of 3–4 months. The cause of this was partly administrative mistakes partly the fact that the diagnosis could only be determined with certainty at this period.

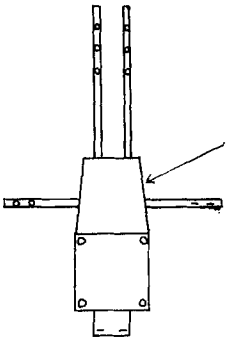
In the last two cases treatment was not started until the age of 7 and 10 months for the last-mentioned reason. One of these cases will be discussed later (case no. 134, Fig. 7).

In the newborns difficulties in reducing the dislocation was never encountered. Frejka's cushion splint was used for immobilisation. See Fig. 2.

For practical reasons the actual cushion in this splint was encased in waterproof material. Thus the individual patient's need for cushions was reduced to 2–3 cushions. The cushion has to be hard to prevent it from being squeezed from one side to the other.

On discharge from hospital each mother received instruction in the use of the splint and got one complete splint as a gift from the hospital so that one should be certain that the remaining splints had the correct dimensions. In our very first case, forming one of the cases in which the treatment is stated to have begun only at the age of 3–4 months an attempt was made to obtain the effect of the Frejka splint by an apparently more easy way.

On discharge the mother was requested to use several diapers at a



Shoulder straps with buttons.

Back support.

Stomach straps with buttons and buttonholes.

Cushion section, size 20 × 20 cm. Thickness about 5 cm.

Flap for fastening shoulderstraps.

Fig. 2.
Frejka's cushion splint, size 1:10.
The buttons in the corners of the cushion section are connected with elastic around the child's thighs.

time thereby achieving the intended abduction position of the hips. This method of treatment proved to be completely useless and at the first follow-up it was replaced by the customary cushion splint delivered and demonstrated for the mother as described above.

Any attempts to replace the original Frejka splint in this way is inadvisable. Regarding the relationship of the patients to the cushion splint and perhaps especially the mother's attitude to this, the following questions were put as routine to the mother at each later check-up:

1. Do you think that the baby suffers any discomfort from the splint?
2. Does it seem to you yourself that it is troublesome to put on the splint?
3. Have you any objections to the splint?

The first question was consistently answered: No.

In reply to the second question a few found that it seemed difficult to put the splint on to begin with. Afterwards all went smoothly and the common answer was that it was not more difficult to put the splint on than to put on ordinary diapers.

In answer to the third question a few brought forward the objection that they did not care for the splint from purely aesthetic reasons. They were reluctant to show the baby to the family and friends because it was so difficult to dress up the child in the way that mothers appreciate. The great majority had, however, no objection to the cushion splint.

In a few individual cases where at the check-up 3 months later no satisfactory reduction had been obtained the cushion splint was replaced by a plaster cast. This enclosed the pelvis and both lower extremities to the knee. The plaster kept the lower extremities fixed at

about 90° flexion and 70° abduction of the hip joints. Corresponding procedures were employed in individual cases where treatment was initiated at the age of 3 months or later, when abduction was hindered to such an extent that the dislocation could not be reduced without recourse to anesthesia. In such cases also immobilisation in a plaster cast was adopted for 3–4 weeks. Afterwards the plaster was removed and replaced by cushion splint. This procedure proved very effective and was clearly much less troublesome to the patient and mother than a lengthy immobilisation in plaster.

Complete immobilisation in the cushion splint was pursued until a clinically stable hip joint was achieved. This was very often the case as early as the first check-up (age: about 3 months). In doubtful cases, especially when the clinical and radiological findings did not correspond, the immobilisation was maintained longer. In the last follow-up period it was recommended that the cushion should only be used in the normal sleeping hours of the baby so that she/he was free to move the lower extremities for some hours every day.

PATIENT MATERIAL

My series comprises all children born in the department during the years 1955–1956–1957. Table 1 records the total of these patients.

As the table shows, the examination comprises 3242 children.

At the clinical examination the findings were negative in 3099 children, but in the remaining 143, findings were made which were regarded primarily as pathological. The latter were all examined once or several times both clinically and radiologically. On the basis of the findings which were made at the first examination or later, 50 children were selected in whom the author believed that clear pathological changes were present in the hips, either in the form of hip joint dislocation or subluxation or a type of h.d. This gives a morbidity of about 1.5 %.

TABLE 1
Survey of children examined.

Year	No of births with children living	Twin births amongst these	Twins living	No of children examined
1955	1035	8	16	1043
1956	1115	14	28	1129
1957	1054	19	35	1070
Total number of children examined				3242

This figure may seen strikingly high and manifests a morbidity in this series which surpasses by far what is commonly thought to occur with h.d. in Norway. The author has observed this point and has repeatedly gone through the series with the aim of reducing the number of probable pathological hips. This attempt was not successful, however, and it was thought that the series should be reported so that it could speak for itself.

It was mentioned above that 143 babies were originally selected who were thought to show pathological changes in the hips on clinical examination, immediately after birth. Of these there were only 50, therefore, in which the primary diagnosis was thought to be correct. The other 93 babies offered at birth only sensations of crepitation in the hip joints on abduction. Radiological confirmation of the disease could not be obtained by pictures taken when the baby was 3–4 days old. At the beginning of the investigation treatment was started in a number of these patients. After more experience was gained this treatment was found unnecessary, so that the great majority were not treated.

In spite of this the diagnosis h.d., could never be confirmed at later clinical and X-ray examination and one must therefore assume that the crepitating sensation on abduction of the hips in newborns may occur without any pathological significance. In a few cases of these babies with crepitation as the sole clinical symptom it has been possible, however, to demonstrate undoubted h.d. at further check-ups (3 months old and later). Attention is therefore drawn to this symptom which in the author's opinion may represent an abortive Ortolani's symptom.

RESULTS OF EXAMINATION AT THE NEW-BORN STAGE

a. Clinical examination:

On examination just after birth the clinical symptoms of the 50 children were as follows:

Ortolani's sign bilaterally	8
Ortolani's sign right hip	16
Ortolani's sign left hip	8
Instability bilaterally	1
Instability right hip	7
Instability left hip	1
Doubtful instability in one or both hips	4
Crepitation in one or both hips on passive abduction	4
No clinical findings	1
	50

Ortolani's sign is only stated positive when one could dislocate and reduce the hip concerned with certainty.

Moreover, it is felt that the instability sign most probably represents a pathological hip. This is stated positive when one could with certainty press the femur so far in the dorsal direction that one would not consider it reasonable that this movement should proceed within a normal joint.

In the four patients where instability is recorded as doubtful, mobility was so small that it was possibly due to general relaxation of the joint in the postnatal period.

Greater doubt may arise concerning the group with crepitation in one or both hips. As stated above, the author believes that this symptom can be regarded as an abortive Ortolani's sign, even if it can be provoked in a number of babies in whom at later examinations h.d. can be excluded.

A good illustration is obtained of a case where such a crepitation on passive abduction movement of the hip joints was the only finding on examination in the newborn stage on studying X-rays of case 36, Fig. 13. Unfortunately the first X-ray examination was undertaken at the age of 3½ months.

The last case, in which nothing pathological was noticed on examination immediately after birth, was discovered when the baby was 7 months old, see case no. 134, Fig. 7.

b. Radiological examination:

The radiological findings in newborns were as follows:

Certain dislocation or subluxation	16
Probable dysplasia	10
Probable negative finding on X-ray examination	19
X-ray exam. not carried out in newborn stage	5
	50

There are scarcely any reasons for general remarks on the above, apart from the fact that the X-ray examination produces far fewer positive findings than the clinical examination. What is most interesting in this connection is whether there is any correspondence between the clinical and the radiological findings.

If one reviews the eight cases with clinical findings:

Ortolani + bilat., the radiological findings are as follows:

Bilateral dislocation or subluxation	5
Bilateral dysplasia	1
Unilateral dysplasia	1
Negative findings	1
	8

The 24 cases with clinical findings: Ortolani positive in right or left hip, show the following X-ray findings:

Dislocation or subluxation same side	11
Dislocation or subluxation opposite side	2
Dysplasia same side or both	5
Negative findings	6
	24

A corresponding summary can be made of the other clinical groups with an increasing failure in the radiological diagnosis.

With regard to the 32 cases with the clinical diagnosis: Ortolani's sign positive, all the cases with radiological findings, dislocation or subluxation, coincide within this group. On the other hand, however, convincingly positive radiological findings were only found in 16 of 32 babies who were declared to have completely reliable positive findings on clinical examination, and in fully 7 cases the X-ray diagnosis was completely negative in a very critical evaluation in spite of the positive clinical findings.

The question may then be put: is not amongst these 7 the clinical diagnosis faulty and the radiological one correct? With this in mind I studied the results of the first follow-up examination of these 7 children. This took place when the child was 3–4 months old.

The findings on clinical and radiological examination were these:

Clin. ex.:	Neg. findings.	
Rad. ex.:	No or doubtful positive findings	2 cases
Clin. ex.:	Neg. findings.	
Rad. ex.:	Delayed development of epiphysis	2 cases
Clin. ex.:	Neg. findings.	
Rad. ex.:	Undoubted dysplasia findings	2 cases
Clin. ex.:	Not performed.	
Rad. ex.:	Neg. findings	1 case
		7 cases

In order to evaluate the above one must bear in mind that all these babies commenced treatment immediately after birth. In the author's experience it rarely or never happens that on examination at 3 months

of age clinical symptoms will be found positive and it is rare that there will be definite pathological findings on X-ray examination. In spite of this, however, pathological findings were made at the first follow-up examination in 4 out of 7; these findings were due in all probability to a hip joint dysplasia or—dislocation. This makes it most likely that the clinical diagnosis at the neonatal examination was correct and that the X-ray diagnosis was at fault.

The conclusions to be drawn from this rather detailed evaluation of the symptoms found on clinical and radiological examination of newborns are that the radiological examination is much inferior to the clinical at this age. In addition I believe to have demonstrated that a positive Ortolani's sign at birth is such a certain symptom of h.d. that it will be a failure of technique if it is not heeded and treatment does not begin with the newborn baby.

c. Other clinical data from the newborn stage.

As stated above the series comprises 3242 children. Based on clinical and radiological examination of the hip joints of these children, it is considered that hip joint dysplasia is present in 50 children.

Below is given more clinical data on these 50.

TABLE 2

Sex distribution.

Sex	No.	No. given in %
Girls	43	86
Boys	7	14

This distribution between the sexes corresponds well with the figures found elsewhere in the literature.

The information collected about the position of the foetus determined in relation to the birth showed nothing unexpected. On the whole the distribution was normal with a certain emphasis on the breech position, since 6 children or 12 % were born in this position.

Nor was anything unusual found in respect to which order in the family these children came.

As far as the mothers were concerned, the mother's age was noted when the child was born. This was on average 29.9 years. In a control series of 93 mothers with normal children born in the same period the average age was 29.3 years.

Finally information was requested about other known cases of h.d.

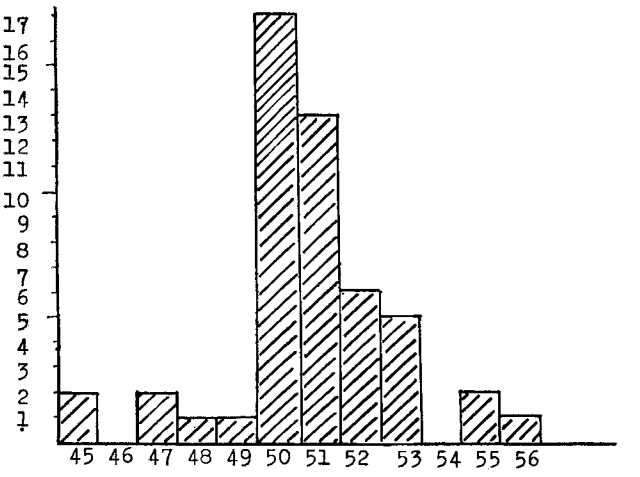


Fig. 3.

Length at birth:

Abscissa: Length at birth given in centimetres.

Ordinate: Number of children.

Each column represents the children whose length at birth lies within the same centimetre. If this graph of length at birth is compared with the corresponding graph in Sundal's normal series from Bergen in 1956, the same pattern is found on the whole. If the average length of the 50 children is calculated, this is 50.74 cms. Sundal states that the average length of boys is 50.9 cms. and of girls 50.2 cms. A series composed of 14 % boys and 86 % girls will then achieve an average length of approx. 50.3 cms., i.e., somewhat less than in my series.

in the family. Here positive information was received in 17 of the 50 children, i.e., 34 %.

RESULTS OF TREATMENT

In the great majority of children the treatment was commenced a few days after birth. As explained above such early treatment was started in 41 out of the 50 children. In the remainder the treatment commenced later, but in all cases before the child had begun to stand or walk.

In order to assess the results of treatment it was decided to divide the children into two groups. Group I comprises the 41 children in whom the treatment was started in the newborn stage. Group II comprises the remaining 9 children.

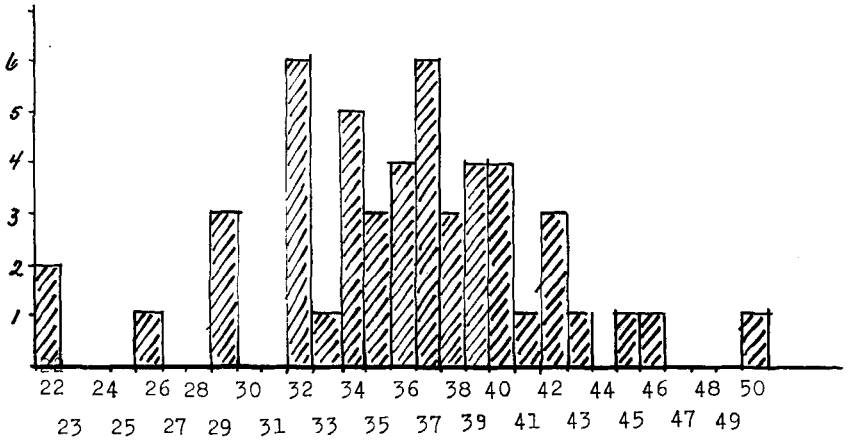


Fig. 4.

Weight at birth:

Abscissa: Weight at birth stated in 100 grams.

Ordinate: Number of children.

Each column represents the children whose weight at birth lies within the same 100 grams. The pattern in this graph of the weight at birth of the 50 children also corresponds with the graph in Sundal's normal series. The average weight at birth is calculated at 3.608 gr. Sundal states the normal weight of boys to be 3.500 gr. and of girls to be 3.400 gr. A group composed of 14 % boys and 86 % girls will then have an average weight of 3.414 gr., i.e., somewhat less than in my series.

GROUP I:

The first control examination within the group took place in 39 cases when the child was between 3 and 4 months old. In the last two cases the age was respectively 5 and 6 months. The results of the clinical examination at this point was as follows:

Negative findings	37 patients
Positive findings	4 patients
	41 patients

Positive findings in this connection mean that the hip could be dislocated and reduced with certainty or that shortening of the extremities could be demonstrated with limited abduction and positive "telescoping sign". In the X-ray examination, which took place the same day, the following was found:

Negative findings	23
Dysplasia signs in one or both hips	11
Dislocation or subluxation in one or both hips	4
No satisfactory X-ray exam.	3
	41

There was very good correspondence here between clinical and X-ray examination, since all in the group "negative findings" in the X-ray examination turned up again in the same group in the clinical examination.

All the dislocation findings in the clinical examination could, as was to be expected, be confirmed at the X-ray examination.

The X-ray symptoms which were given importance in referring a case to the radiological dysplasia group were as follows:

a. Increased relative acetabular index	6
b. Delayed development of epiphysis	3
c. Poor development of the anterior and posterior lips of the acetabulum, and poorly marked upper lateral border of the acetabulum	11

Cf. a: This symptom is relatively easy to evaluate and is only noted positive when there is an obvious increase of the angle of incline on one side in relation to the other.

Cf. b: This symptom is also easy to assess. One cannot, however, expect to find it positive in all cases where the control is undertaken at the age 3–4 months, since the epiphysis normally does not become radiologically visible until the age 3–6 months.

Cf. c: This X-ray symptom may be the subject of considerable subjective assessment, but is on the other hand present in all babies. In 6 out of 11 it is, however, supplemented by one of the above more objective symptoms, so that one may draw the conclusion that the subjective assessment of the acetabulum is probably not too fortuitous.

If the radiological findings in this group are compared with the clinical findings of Ortolani's sign at birth, the following is found:

Of the 32 babies who had positive Ortolani's sign at birth, 30 appear in group 1. In 2 of these the X-rays at the first check-up were of such quality that no X-ray diagnosis may be ventured.

In the remaining 28 the X-ray findings are negative in 15 (over 50 %), 4 have radiological subluxation and 9 have radiological dysplasia. No one has now a complete dislocation. From this it can be concluded that Frejka's cushion splint is very effective and that it is a fundamental advantage to begin treatment at such an early stage.

Final results of treatment:

In assessing the final result of treatment certain difficulties of evaluation are encountered. As stated the children were followed-up until the examiner at the clinical and radiological check-up was of the opinion that the hips were normal and showed no signs of becoming worse after the splint treatment was ended, i.e., the last check-up occurred at least 3 months after the continuous treatment was finished. The end result of the examined babies will be assessed according to this principle at most varying ages, and these lie between 6 and 33 months.

In 26 children the age was from	9–15 months
In 9 children less than	9 months
In 5 children more than	15 months

One child did not return for check-up owing to geographical reasons.
Total 41 children.

A. *Clinical examination.*

No signs of h.d. were found in any of the 40 children. In 19 cases the child was 12 months old on check-up, and all these could walk or stand with or without support. In these cases all had negative Trendelenburg sign as far as could be demonstrated.

It may then be maintained that from a clinical standpoint all the children had normal hips.

B. *Radiological examination.*

This appears more problematic both because the end stage is recorded at ages varying between ½ and almost 3 years and because there is no definite standard for the normal hip in this age group. The results of X-ray examination were judged according to two different principles.

First a general picture was formed of the hip joint, by taking into consideration the mutual development of the osseous parts of the caput and acetabulum and the adjustment of the caput to the acetabulum.

From this point of view an end result was found in 39 of these 40 children which was quite satisfactory. The caput and acetabulum had even contours, the acetabulum's roof had a suitable angle, the anterior and posterior lips were well developed and closed laterally. Moreover, the caput seemed to be well centred in its joint cavity.

A hip joint of normal appearance may thus be said to be present in 39 out of 40 cases. In the last case the caput is placed so far laterally and the acetabular contours are so blurred and uneven that an h.d. is probably still present or possibly a slight subluxation.

This method of assessment must undoubtedly be rather subjectively influenced, since it depends on the general judgement of the examiner.

Secondly these 80 hip joints were assessed strictly geometrically, by drawing up 2 of the previously mentioned auxiliary lines. Even at this point one comes across the first difficulty, since the Y line, judging from the literature, is drawn rather differently by different authors.

It was decided to draw the line as described by *Wiberg*. He draws it as a tangent to the upper contour of the os pubis. Others draw it rather differently, but in all cases it is situated further cranially than that described by *Wiberg*.

The second auxiliary line, called the P line, is drawn through the lateral, osseous border of the acetabulum and vertical to the Y line. Since the above border is often slightly rounded a slight difficulty is encountered in deciding the localisation of the line and the judgement of the examiner again comes into the picture.

After these lines are drawn, all hips are said to be "normal" where the caput in its entirety lies in the lower medial quadrant.

In those cases where 0–2 mm. of the caput lies above the Y line or laterally of the P line, the hips are called "normal?". This method of assessment was chosen because there will always be a certain doubt about the exact localisation of the auxiliary lines described. In no case does the caput lie more than 2 mm. above the Y-line.

In those cases where 3–5 mm. of the caput project laterally of the vertical line, the designation "dysplastic?" is used.

In those cases where the divergence is greater than that stated above, the hip joint is called "dysplastic".

The results of this strict assessment of the babies are as follows:

"Normal" hips	22 babies
"Normal?" hips	12 babies
"Dysplastic?" hips	5 babies
"Dysplastic" hips	1 baby
	40 babies

Much doubt was felt whether it was right to describe pathological conditions in a hip joint so systematically. Firstly, as already mentioned, some doubt was felt where the auxiliary lines were to be drawn. Secondly the question occurs whether here as elsewhere in man's anatomy, one must not make allowances for minor individual variations. Thirdly it was not possible to find anywhere in the literature an account of what should be regarded as the norm for the hip joint in children of

this age group, namely, 1–3 years. Studies were found which stated the normal outer limits for hip joints in adults and children down to 6 years, but not for the younger children.

When the investigation was being pursued *Andrén & von Rosen*'s examination technique was not published and therefore this could not be evaluated.

If the end results of the treatment of these 40 children according to the three procedures described are studied, the following emerges:

Clinical exam.	Normal hips	40 children
General radiological assessment	Normal hips	39 children
	Dysplastic hips	1 child
Radiological assessment in relation to the quadrant division of the hip joint		
	Normal hips	34 children
	Possible dysplastic hips	5 children
	Certain dysplastic hips	1 child

On the basis of the above it is believed that the treatment in 39 of the 40 children has led to the healing of the existing defect in the hip joints, while in one case complete healing has not yet been achieved.

This last case represents undoubtedly an error in treatment on the part of the examiner, in that the whole purpose of the investigation originally was aimed at demonstrating how valuable Frejka's cushion splint was. For this reason splint treatment alone was continued until the child was 14 months old. At this time certain dislocation existed in the right hip. A change was made to plaster and at the next check-up the right hip was reduced very nicely, but as stated, the caput is still placed rather far laterally, nor can one say really that any certain subluxation is present. A more elastic attitude by the author would undoubtedly have produced a better result. In later cases of the series the experience acquired from this lesson was applied. If complete stability was not achieved in the hip during the course of a control period of 3 months, the cushion splint was replaced by plaster administered if necessary under anesthesia. After 3 weeks the plaster was removed and the Frejka treatment was again adopted. In such cases no sign of recurrence was ever seen.

GROUP II:

The group comprises 9 children.

In 7 of these children treatment was begun at the age 3–4 months. In the last two the age was respectively 7 and 10 months.

A. *Clinical examination.*

The last clinical examination of these took place between 1 and 2 years of age. In no case could signs be demonstrated of pathological conditions in the hips. All had started to put weight on their lower extremities in the erect position. In those cases where it was technically possible, Trendelenburg's test was carried out with negative results.

The results of the clinical examination were thus negative in 100 %.

B. *Radiological examination.*

The last X-ray examination was carried out at the same time as the clinical one. On assessing this, uncertainty arises again as described before, since it is not definitely known which radiological standards must be applied to the normal hip in the age group involved here.

The general impression of the examiner in assessing the present X-rays is that in all cases the hip joints concerned under routine conditions would be regarded as normal. The acetabulum is well developed with a centrally placed epiphysis of normal shape.

If the existing pictures from the last check-up are studied strictly geometrically in this group and if the caput's position is assessed in relation to the previously described auxiliary lines in the same way as in Group I, the following end results are obtained:

"Normal" hips	2 children
"Normal?" hips	2 children
"Dysplastic?" hips	5 children

On comparing the clinical and radiological findings this group is believed to have achieved probable normal hips in all cases, i.e., 100 %.

If the strictly geometrical assessment of the end result has any value in comparison between these two groups, it appears that even a postponement of treatment from the birth of the child until he (she) is 3–4 months old, is unfavourable.

COMBINED ASSESSMENT OF GROUP I AND II AT THE CONCLUSION OF TREATMENT

It is the author's opinion that the two groups of results treated here are so small and that the time of initial treatment varies so little that no great mistake will be made if the two groups are combined.

The following total results are given for the 49 children who underwent full follow-ups:

Clinical examination:	Normal hips:	49 children
General radiological assessment:	Normal hips:	48 children
	Dysplastic hips:	1 child
Radiological assessment in relation to the quadrant division of the hip joint:	"Normal" hips:	24 children
	"Normal?":	14 children
	"Dysplastic?" hips:	10 children
	Dysplastic hips:	1 child

Even after the strictest assessment, therefore, 38 children or 77.5 % emerge from their congenital hip joint dysplasia with normal hip joints.

In 10 children or 20.5 % the clinical examination shows a completely normal hip joint, while a strict radiological assessment shows a slightly lateral position of the caput in one or both hip joints, although one cannot definitely say that h.d. exists.

In one child certain dysplasia is present in the one hip joint, while the other lies in the group above.

In 1 child an adequate follow-up could not be pursued owing to geographical conditions.

Seen in relation to the percentage of healing obtained in congenital h.d. when treatment is commenced after the child has started to walk, the results are believed to be so favourable that any postponement at all of the treatment after the newborn stage must be regarded as an error of technique.

PRESENTATION OF CASES

To give the reader a better understanding of the view-points maintained by the author some case-histories with tracings of X-rays are presented. There are three cases from each of the groups: "Normal" hips, "Normal?" hips and "Dysplastic?" hips.

Group: "Normal" hips:

Case No. 30 R.O. b. 25/9.1955. Fig. 5.

Family history:	No known cases of h.d.
Clin. ex. at birth:	Ortolani's sign pos. right hip. Shortening of right femur and assymm. skin folds.
X-ray ex. at birth:	Probable sublux. in right hip.
Treatment and course:	Commenced immediately after birth with Frejka's cushion splint. This was used day and night for 6 months, afterwards at normal sleeping hours for a further 2 months. Walked and stood with support at ca. 10 months.
Last check-up (15 mos.):	Clinical ex.: Completely normal hips.

Walks without limp. Trendelenburg — bilat.
X-ray: normal hips, both caputs in the lower medial quadrant. Right caput insignificantly smaller than the left.

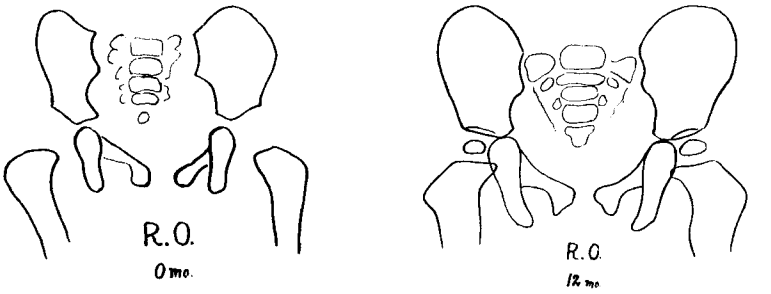


Fig. 5.

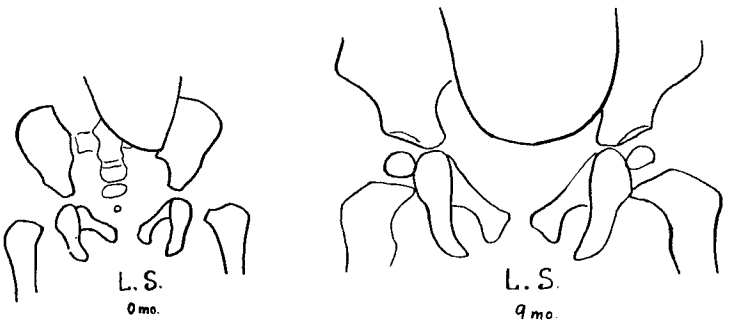


Fig. 6.

Group: "Normal" hips:

Case No. 143 L.S. b. 12/12.1957. Fig. 6.

Family history:	No known cases of h.d.
Clin. ex. at birth:	Ortolani's sign pos. bilat. with relative shortening of the femora.
X-ray ex. at birth:	Probable dysplasia bilat.
Treatment and course:	Frejka's cushion splint treatment started at birth. This was used continuously for 6 months, afterwards during sleeping hours for a further 3 months. Normal development of the hip joints.
Last check-up (9 mos.):	Clin. ex.: normal hips.
	X-ray: normal hip joints. Caput in lower medial quadrant bilat.

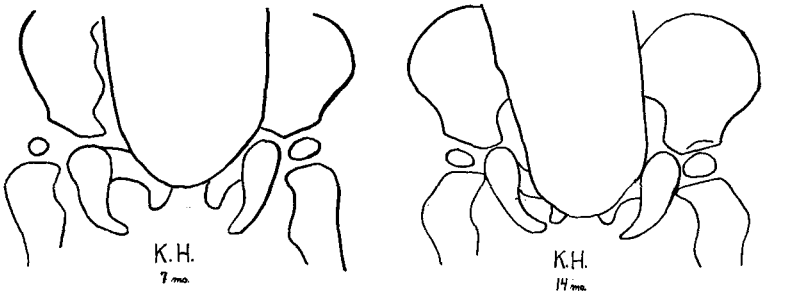


Fig. 7.

Group: "Normal" hips:

Case No. 134 K.H. b. 5/9.1957. Fig. 7.

Family history:	Twin sister with certain clinical and radiological luxation in left hip at birth.
Clin. ex. at birth:	Neg. findings.
X-ray ex. at birth:	Not performed.

Owing to the examiner's interest in twin cases in this series the patient was called for check-up with her sister, 7 months old.

Clin. ex., age 7 months:	Limited abduction in right hip, assymm. skin folds and probable shortening of right femur.
X-ray ex., age 7 months:	Certain dislocation in right hip.
Treatment and course:	Reduction performed under anesthesia without difficulty. Position maintained in plaster. After 3 weeks, plaster-cast replaced by Frejka's cushion splint. This was used continuously for 3 months, afterwards during sleeping hours for a further 3 months.
Last check-up (14 mos.):	Clin. ex.: normal hips.
	X-ray ex.: both hip joints appear normal, but right caput is still a little smaller than the left.

Group: "Normal?" hips:

Case No. 43 S.H. b. 12/4.1956. *Fig.* 8.

Family history:	3 certain cases of h.d. in the father's family.
Clin. ex. at birth:	Ortolani's sign pos. right hip.
X-ray ex. at birth:	Certain lat. position of upper end of femur, right side, with slight uprooting of same and increased acet. incline bilat.
Treatment and course:	Frejka's cushion splint used from birth. The cushion was used continuously for 6 months. Afterwards treatment was concluded. After only 3 months clin. ex. was negative, while there were continued signs of dysplasia in both hips on X-ray ex.—Started to walk without limping at 1 year.

Last check-up (26 mos.): Clin. ex.: completely normal hip joints.

X-ray ex.: at first sight the hips appear completely normal bilaterally, but on both sides the caput projects about 2 mm. above the Y line and about 2 mm. laterally of the P line.

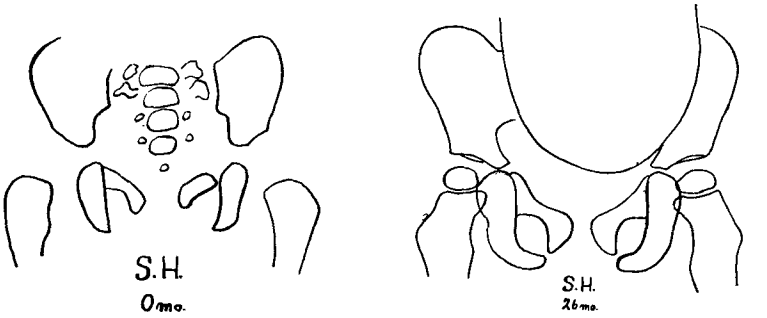


Fig. 8.

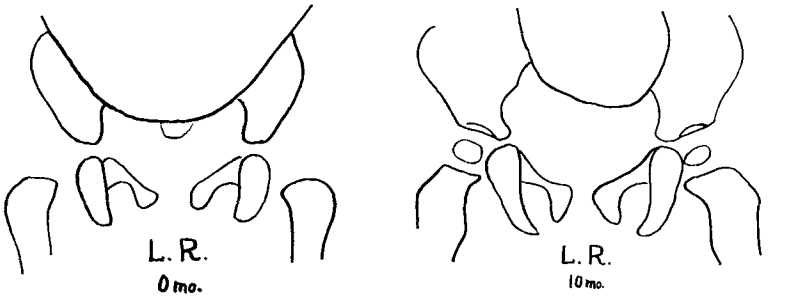


Fig. 9.

Group: "Normal?" hips:

Case No. 118 L.R. b. 8/7.1957. Fig. 9.

Family history:	One case known in a distant relative in the mother's family.
Clin. ex. at birth:	Ortolani's sign positive bliat. Left hip was so loose that it did in fact dislocate as soon as the baby was laid on its back.
X-ray ex. at birth:	Considerable increase in acetabulum's angle of incline bilat.
Treatment and course:	Frejka's cushion splint treatment started at birth. At the first check-up certain dislocation continued to be present in the left hip. Easy reduction without anestesia was obtained. Reduction maintained in plaster. After 3 weeks the

plaster was replaced with Frejka's splint. This was used continuously for 3 months. Afterwards again for 3 months with two hours freedom from the splint each day. Could stand with support after 10 months.

Last check-up (10 mos.): Clinical ex.: normal hips.

X-ray ex.: bilat. the caput projects 1 mm. above the Y line and on the right side 2 mm. outside the P line.

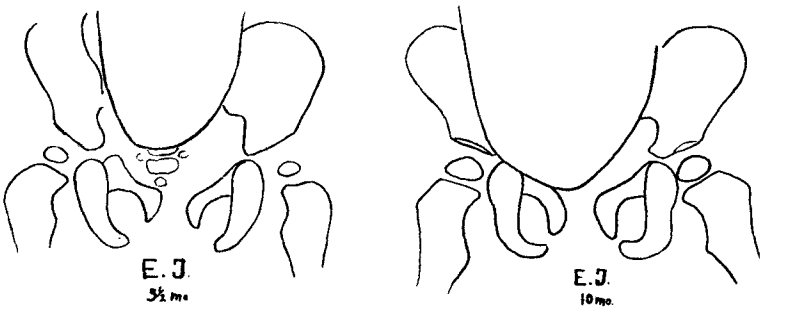


Fig. 10.

Group: "Normal?" hips:

Case No. 79 E.J. b. 5/1.1957. Fig. 10.

Family history: No known cases of h.d.

Clin. ex. at birth: Pronounced crepitation and some looseness in left hip joint. Ortolani's sign neg. No instability.

X-ray ex. at birth: Not performed.

Treatment and course: No treatment begun at birth. At first check-up aged 3½ months limited abd. was found in right hip and definite instability in left hip. X-ray findings: Probable subluxation in both hips. Reduction was undertaken under anesthesia. Stability was easily obtained in the reduced position with Frejka's cushion splint. This was used continuously for 3 months, then at sleeping-hours for a further 3½ months.

Last check-up (10 mos.): Clinical ex.: Normal hip joints.

X-ray ex.: On immediate study both hip joints appear normal, but the caput projects 2 mm. above the Y line bilat. and also 2 mm. outside the P line.

Group: "Dysplastic?" hips:

Case No. 115 J.T.V. b. 28/5.1957. Fig. 11.

Family history: Elder sister had certain bilat. h.d. In addition the child is closely related with another child in the series.

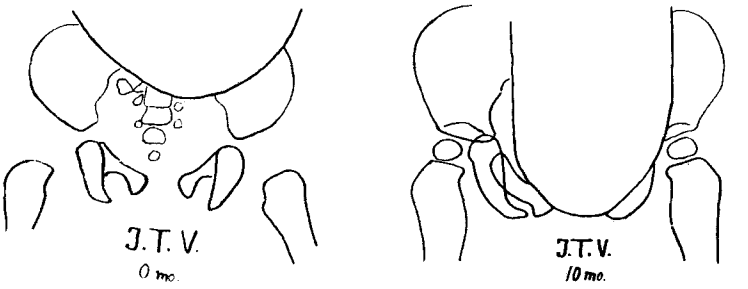


Fig. 11.

Clin. ex. at birth:	Ortolani's sign pos. left hip, probably instability in right hip.
X-ray ex. at birth:	Upper lateral border of acetabulum is not well marked. Rather large angle of incline in left hip. Certain signs of dislocation are not present.
Treatment and course:	Frejka's cushion splint treatment started at birth. In first check-up after 3 months there was probable instability in both hips on clinical ex. X-ray showed certain sublux. in right hip, and somewhat laterally placed caput in left hip. It proved that the cushion used was too thin and soft to obtain the desired effect and it was exchanged. The new cushion was afterwards used day and night for 6 weeks, afterwards omitted 2 hours daily for 6 weeks, and then worn only at night for a further 4 months.
Last check-up (10 mos.):	Clin. ex.: normal hips. X-ray ex.: left hip completely normal, caput on right side projects 3 mm. outside the P line.

Group: "Dysplastic?" hips:

Case No. 10 E.E. b. 8/4.1955. Fig. 12.

Family history:	No known cases of h.d.
Clin. ex. at birth:	Ortolani's sign pos. right hip.
X-ray ex. at birth:	Relatively increased acetabulum angle of incline on right side. Shenton's line broken bilat. Lateral position of both femoral diaphyses.
Treatment and course:	With clinically certain hip joint dislocation on the right side a directive was given that treatment should be started before discharge from the maternity ward. The directive was misinterpreted, however, and no treatment was begun. On the first check-up certain clin. dislocation existed in the right hip, which could be confirmed on X-ray ex. No success was obtained in trying to achieve stable reduction

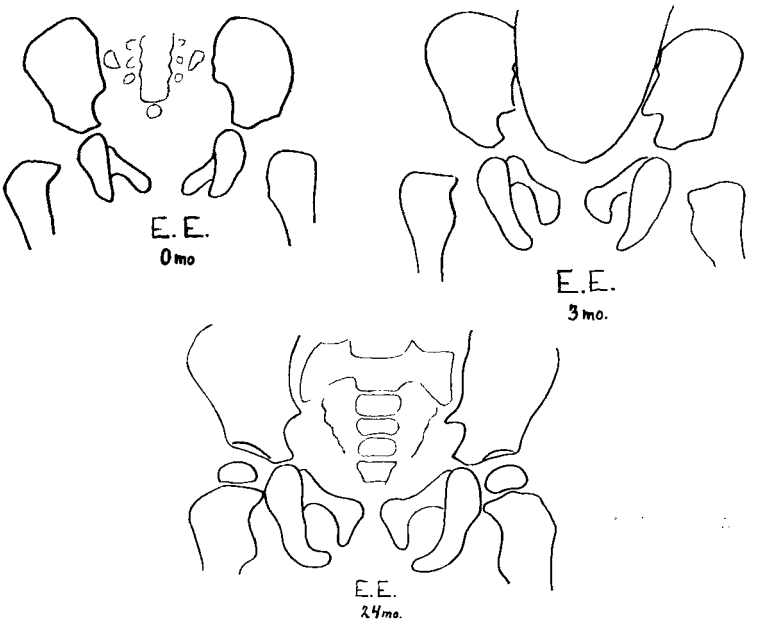


Fig. 12.

without anesthesia. The reduction was maintained in plaster for 3 weeks. Then normal Frejka's splint was used continuously to the age of 6 months and then during sleep to 12 months. Later checks gave normal findings from the right hip, but plain abduction spasm in the left, where the epiphysis as well seemed to be more laterally placed than on the right side. At 14 months tenotomy of the adductors on the left side was performed. Later the course was normal, apart from temporary fragmentation of both caputs. At 14 months she could stand with support. Walked at 16 months.

Last check-up (24 mos.): Clinical ex.: Neg. findings.

Walks freely without limp. Trendelenburg's sign neg. bilat.

X-ray ex.: Well developed acetabulums. Right epiphysis 1 mm. above and 5 mm. laterally of the auxiliary lines. Left epiphysis projects 1 mm. above and 3 mm. laterally of the same lines.

Group: "Dysplastic?" hips:

Case No. 36 G. F. b. 5/1.1956. Fig. 13.

Family history: No known cases of h.d.

Clin. ex. at birth: Slight crepitation on abduction beyond 80° of left hip.

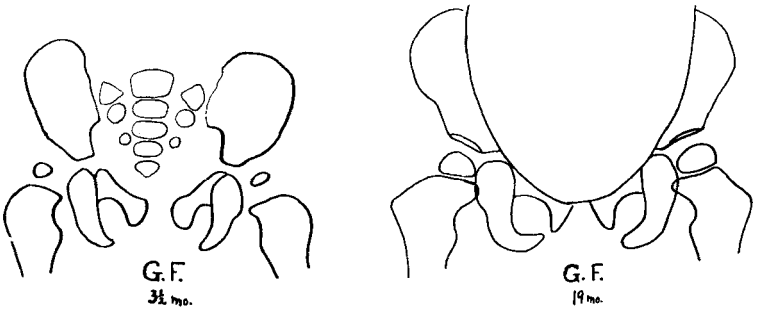


Fig. 13.

X-ray ex. at birth:	Not performed.
Treatment and course:	At the first check-up, age 3½ months, certain clin. dislocation in the right hip, confirmed at X-ray ex. Under anesthesia an easy reduction was carried out. The position was maintained in plaster for 4 weeks. Then the plaster was replaced by Frejka's splint. This was continuously used for 3 months. Then it was used at sleeping hours for a further 6 months. The patient walked without support at the age of 13 months.
Last check-up (19 mos.):	Clin. ex.: walks normally. No pathological findings on ex. of the hips. X-ray ex.: The general impression is that the hip joints are developing normally, but the caput projects respectively 4 and 3 mm. above the Y-line and 4 and 3 mm. laterally of the P line.

DISCUSSION

I have presented the results of a consistently pursued investigation into hip joint dysplasia in 3242 children.

The 50 children whom I believe had h.d. at birth were treated and followed-up until I considered the hips to be normal.

a) *Incidence of h.d. in the series.*

I was very surprised at the high incidence of h.d. According to other studies from the Scandinavian countries the disease occurs to the order of 0.1 % while in this series it shows a figure of 1.5 %. In the Samic population in Finnmark a morbidity of 4–5 % was found, while the Norwegian population in this province has much the same incidence as elsewhere in the country.

According to the research I have made, there are at any rate no official statistics on the occurrence of h.d. The figures presented in the literature are not based then on normal health statistics.

From other parts of the world the morbidity incidence is reported as varying quite considerably from place to place. The interpretation must be that h.d. is a disease which in certain geographical areas arises with great frequency while in others it may be very rare. I therefore satisfied myself with the explanation that Möre and Romsdal county forms just such a geographical area in which h.d. has a higher incidence than in Norway as a whole.

This theory is supported by the fact that before this investigation was commenced a relatively large number of children were admitted to hospital aged 1–3 years, with hip joint dislocation. During the years 1950–54, 4–7 newly-diagnosed cases were admitted each year. Even this number is only a third of the incidence shown in the series. The explanation of this may be partly that some cases of h.d. were referred for treatment to a special clinic instead of to the local hospital. It is also known from the literature that spontaneous healing of h.d. does occur. It is therefore probable that a number of the cases included in the series would also have achieved healing without treatment. The difficulty arises only in that it is not known with certainty who will develop a complete dislocation and who will achieve spontaneous healing.

The few cases in which a certain diagnosis of dysplasia was made at birth but in which treatment was mistakenly not commenced, do not encourage postponement of treatment in the hope of spontaneous healing.

b) *The clinical examination of the hip joint in newborns.*

The examination was undertaken with the baby lying supine. The hip joints were flexed 90°. The examiner placed his thumb over the distal end of the femur and the other fingers over the trochanter region. From this initial position the mobility and stability of the hip joints were examined.

Based on past experience I believe that Ortolani's sign (snapping sign) and instability (telescoping sign) of the hip joints are convincing symptoms of h.d. Using the examination technique described these symptoms are relatively easy to observe even for a less skilled examiner.

I have never observed limited abduction in the newborn stage except as a link in Ortolani's sign, i.e., when the abduction movement is undertaken in a dislocated hip joint, slight resistance to continued abduction

is felt before the caput is tilted into the joint cavity. Afterwards abduction may normally be undertaken to about 70°. For the symptom to appear alone I assume that a better development of the musculature is required than is found in newborns. Later, e.g., at the age of 3 months, the abduction blockage will be an important symptom of hip joint dislocation.

I have also as a matter of routine taken notice of whether asymmetry was present in the thigh, groin or gluteal skin creases.

I should like to draw attention to the crepitation noise to be heard on passive abduction of the hip joint. In a good number of cases where this was observed at the first examination, I checked on the child later without finding signs of pathological development of the joint. In some few cases this was the only clinical symptom of h.d. in the neonatal stage and later examination showed the development of dislocation (see case 36, Fig. 13). I would therefore recommend that children who offer this symptom are examined as routine at the age of about 4 months when the epiphysis is visible on the X-ray pictures.

c) *Hip joint dysplasia in children with negative findings on examination at the newborn stage.*

Among the 3242 children who were examined immediately after birth, and where the primary result of the examination was "Normal hips", only 2 cases occurred which were later to be admitted to hospital with hip joint dysplasia. In both cases only a moderate degree of dysplasia was present without complete dislocation. Both were treated with favourable results.

I take this as indicating that clinical examination at the neonatal stage is very reliable.

Naturally the objection may be made that perhaps there were other cases of which the examiner was not aware. I consider this to be hardly probable because this series of investigations was much publicised by the hospital both amongst the women who were admitted to the maternity ward and amongst the doctors in the district.

The fact that, taken as a whole, overlooked cases do arise is an inspiration towards constant control of the hip joints of infants. Carrying out a hip joint examination is so easy and takes so little time that it ought to be included as a routine examination in all infant check-ups. In particular the examination should apply to girls in families where it is known that h.d. occurs amongst other members of the family.

If this procedure is carried out, all cases of hip joint dysplasia should be discovered and treated before the child begins to walk.

d) *Radiological examination of the hip joint.*

An attempt was made to take all pictures with the patient lying supine in complete rest with straight lower extremities in the neutral position of rotation and centred towards the symphysis. It will be well known to all who have performed such an examination that it can be difficult, not to say impossible, to persuade a patient in the age group involved here to lie in the correct position during the examination. To avoid overlong exposure I therefore approved in a number of cases X-rays which were obviously not taken in an ideal position. This circumstance should be born in mind when assessing a radiological diagnosis on a purely geometrical basis.

As will appear in the assessment of the end results, I found on careful scanning of the X-rays a number of babies who had a very slight lateral dislocation of the caput but at the same time no sign of dysplasia could be detected in the hip joint as a whole, i.e., the caput was normally formed, with entirely normal size and contours. The same applies to the acetabulum, including the angle of incline. The author cannot declare with certainty today that these hips are normal and will develop normally. It is hardly reasonable to believe that the above-mentioned changes are only due to inaccuracies in the radiological technique. A possible explanation is that these cases concern femora with increased anteversion, so that X-rays taken with the lower extremities in the correct position of rotation, really give a very slight lateral projection of the caput in relation to the acetabulum. I consider it very doubtful that a genuine subluxation is involved. Some children in the series who presented such radiological findings were checked again after getting about without any form of treatment. No increased lateral displacement or signs of uprooting were observed.

It is stated in the literature that the hip joint ends its development in persons in the 17 years age group. I assume than the population group from which this series is derived has stable housing conditions so that it would be possible to follow-up these children when they are about 17 years old. Such an investigation is planned. It will possibly give the answer to the question of how much importance a lateral position of the caput may possess in the development of the hip joint.

In this series I have omitted to divide the patients into the usual groups of unilateral and bilateral cases.

In the literature published 20–30 years ago and earlier, a strict differentiation was made between uni- and bilateral cases. On the whole it was agreed that ⅓ were bilateral and ⅔ were unilateral. In later publications this distribution was altered in favour of a larger number of bilateral cases. I am strongly convinced that one should perhaps go further in this direction and say that congenital hip joint dysplasia is a systemic disease which affects the development of the hip joint generally. The degree of dysplasia may vary and this explains why the symptoms found on clinical and radiologacil examination may be localised to one hip only.

With a serious degree of dysplasia at birth, dislocation may occur in one or both hips.

With a slight degree of dysplasia one of two things may happen: either the hip joint will develop so that the child begins to stand and walk with normal hip joints, or the dysplasia will persist or become worse in the first years so that weight bearing on the lower extremity concerned will pass into a genuine dislocation on one or both sides.

If the above view of hip joint dysplasia is correct, then the fact that we constantly examine our children in their younger years and that methods of examination constantly grow better, will provide, in the author's opinion, a good explanation of the tendency found in the literature towards a constant increase in the bilateral cases at the expense of the unilateral.

I have deliberately paid little attention to the importance of the angle of incline of the acetabulum in the radiological assessments.

The reason is partly that more recent literature very decidedly asserts that this angle varies so much individually that no clear boundary can be drawn between normal and pathological values. Nor in this study was any complete correspondence found between the acetabulum's angle of incline and other symptoms utilised to make the diagnosis h.d.

It must be said that the angle of incline in the series as a whole is high. The average figure for normal angles of incline is put in the literature at 28–29° in newborns, but with large individual variations which cannot be designated as pathological.

In this series X-ray pictures of the newborn stage are included of 44 babies, in all 88 hip joints. 68 of these show an angle of incline of 29° and more. An angle of incline less than 25° is found in only 5 hip joints.

These figures should indicate that a large angle of incline certainly is a feature in the picture of a hip joint dysplasia, but as previously stated I would not venture, on the basis of the present radiological findings,

to draw up any boundary between normal and pathological angles of incline.

A circumstance which caused the author somt thought during the collection of the material was the danger of overlong irradiation of the gonads. As the figures from the casepresentation will show, an attempt was made to cover the gonads with lead plate during the exposure.

In this field my experience is that it is difficult to achieve satisfactory covering of the gonads, at any rate in girls, without at the same time covering parts of the hip joints. It may therefore be asked if it is more advisable to take the pictures without covering than to present the patient for two or more exposures in order to include both hip joints.

Skin dosage in exposure of the joints was measured. This is of such a degree that a control examination at intervals of 3 months will scarcely cause any injury to the gonads. I would, however, emphatically warn against exaggerated use of X-ray examination, not least because the clinical examination may be of more value than the radiological examination in newborns.

e) *Treatment with Frejka's cushion splint.*

My experience with Frejka's cushion splint has been very favourable. In the great majority of cases I obtained normal development of the hip joints after 3 month's treatment. In certain cases where instability was unusually large, or where treatment began later than the newborn stage, I utilised plaster immobilisation for a short period. In these cases I replaced the plaster by a cushion splint after 3–4 weeks and found this completely satisfactory.

The advantage of the cushion splint is that it causes the patients little or no inconvenience. It also is simple and cheap to make and easy to take off and put on in the daily care of the baby.

f) *The results of other clinical observations of the child.*

The information which I have collected about the length and weight of the child at birth shows considerable correspondence with the average figures for the country. Length and weight relationships in the series therefore give no support to the theory that space conditions in the womb are an etiologic factor in h.d.

As far as the position of the foetus in the womb is concerned, conditions on the whole agree with what is found in a normal material, with the exception that breech position occurs more often than usual.

6 children or 12 % were born in the breech position. This also corresponds with what is found in other series. It is asserted in the literature that children are born in the breech position because they are not so large and are more delicate than others and that their leg movements in the womb would therefore be less active. I find no support for this theory if length and weight are to form an expression of muscle activity. The average weight of the 6 children born in the breech position is 3560 gr., thus somewhat above the average for the whole series. This is in spite of the fact that one of these 6 children is a twin.

I also noted the mother's age at birth to see if this could have any importance in the etiology. The average age of the mother was 29.9 years. The series includes two cases of twins. In calculating the above figures I included the age of these mothers twice. If this error is corrected, an average age of 29.4 years results. The average age of 93 mothers with normal children amongst the 3242 examined equals 29.3 years, and therefore this forms no reason for the assertion that the mother's age has any significance in the development of h.d.

As with other series, definite information about other cases of h.d. in the family to a high figure were found, in this series the figure was 34 %. Moreover, it may be said that several children in the series are related. Finally it ought to be stated that amongst the 50 children 3 pairs of twins were affected. I found h.d. in both twins in two of the pairs. This also supports the theory of the familiar emergence of h.d.

On the basis of the information gathered about the length and weight of the children at birth, their foetus position, their order of birth in the family, the mother's age at birth and other cases of h.d. in the family, one can only draw the conclusion that h.d. occurs more often in children born in the breech position than in other foetus positions and that the disease seems to be conditioned by the respective family, facts which were well known from previous research.

SUMMARY AND CONCLUSION

The results are presented of an investigation into hip joint dysplasia in all children born at County Hospital in Ålesund, Norway, in the years 1955–57, in all 3242 children. The findings indicate an incidence of morbidity far above the accepted average for Norway.

On the basis of the series presented, it is thought that these conclusions may be drawn:

1. A clinical examination of the hip joints of all newborns should be consistently pursued.
2. A positive Ortolani's sign or a definite instability of the hip, when demonstrated in newborns, is a convincing symptom of hip joint dysplasia which demands treatment. Treatment should be commenced immediately after birth.
3. The normal hip joint in newborns can be moved passively with complete freedom without any form of crepitation. A repeated and constant crepitation in a certain position of the hip joint may indicate the presence of a dysplasia and ought to lead to control examination of the baby at 4 months of age, when the epiphysis is radiologically visible.
4. Limitation of abduction in the hip joint occurs rarely or never in in newborns as a sign of hip joint dysplasia.
5. In newborns clinical examination of the hip joints is so superior to X-ray examination that the latter can be dropped without consequences. It is only when the epiphyses becomes visible radiologically that the X-ray offers more than the clinical examination.
6. The reduction position achieved in the hip joints with a Frejka's cushion splint in children up to 9 months of age, is completely satisfactory and will in the great majority of patients provide recovery.
7. Treatment of hip joint dysplasia with Frejka's splint is so little troublesome to the patient and mother that commencement of treatment is justified even if there may be doubt about the diagnosis.

RESUME ET CONCLUSION

Présentation des résultats de l'examen concernant la dysplasie de l'articulation de la hanche pratiqué chez tous les enfants nés à l'Hôpital Fylke à Ålesund, en Norvège, dans les années 1955–57, en tout chez 3242 enfants. Les trouvailles indiquent une incidence de morbidité beaucoup plus élevée que la moyenne normalement présumée en Norvège.

Sur la base de cette série d'observations, on considère que les conclusions suivantes peuvent être tirées:

1. Il faut continuer à procéder à un examen clinique des articulations de la hanche chez tous les nouveau-nés.

2. Un signe Ortolani positif ou une instabilité définie de la hanche constatée chez un nouveau-né un symptôme certain de dysplasie de l'articulations de la hanche qui demande à être traitée. Le traitement doit être entrepris immédiatement après la naissance.

3. Le mouvement passif d'une articulation normale de la hanche chez les nouveau-nés est entièrement libre sans aucune forme de crépitation. Une crépitation répétée et constantée dans une certaine position de l'articulation de la hanche indique la présence d'une dysplasie et doit engager à un examen de contrôle du bébé à l'âge de 4 mois, lorsque l'épiphyse est radiologiquement visible.

4. La limitation de l'abduction de l'articulation de la hanche est rarement ou jamais constatée chez les enfants comme signe de dysplasie de l'articulation de la hanche.

5. Chez les nouveau-nés, l'examen clinique de l'articulation de la hanche est si supérieur à l'examen aux Rayons X que celui-ci peut être abandonné sans inconvénient. C'est seulement quand l'épiphyse devient visible radiologiquement que les Rayons X donnent plus que l'examen clinique.

6. La position de réduction pratiquée dans les articulations de la hanche au moyen d'une attelle Frejka chez les enfants jusqu'à l'âge de 9 mois est complètement satisfaisante et entraîne la guérison dans la grande majorité des cas.

7. Le traitement de la dysplasie de la hanche par l'attelle Frejka est si peu gênant pour le bébé et sa mère qu'il est justifié de l'entreprendre même si l'on a des doutes concernant le diagnostic.

8. Les résultats obtenus par le traitement conforme de la dysplasie de l'articulation de la hanche chez les enfants sont si bons qu'il devrait être possible dans un proche avenir de rayer les dislocations de la hanche comme problème orthopédique chez les enfants plus âgés ou les adultes.

9. Les données présentées concernant la position de l'enfant dans la matrice, la longueur et le poids après la naissance n'offrent aucune base à l'explication mécanique d'une dysplasie de l'articulation de la hanche.

ZUSAMMENFASSUNG UND SCHLUSSFOLGERUNGEN

Die Ergebnisse einer Untersuchung der Hüftgelenksdysplasien aller Kinder, die in den Jahren 1955–57 am Fylkes (Bezirks) Krankenhaus in Ålesund, Norwegen geboren wurden (insgesamt 3242 Kinder), werden vorgestellt. Die Befunde weisen eine Häufigkeit der Morbiditet auf, die weit höher als der angenommene Durchschnitt für Norwegen ist.

Auf Grund der vorgewiesenen Untersuchungsreihen glaubt man die folgenden Schlussfolgerungen ziehen zu können:

1. Eine klinische Untersuchung der Hüftgelenke aller Neugeborenen sollte konsequent vorgenommen werden.

2. Ein positives Ortolani Zeichen oder eine sichere Unstabilitet der Hüfte sind, sobald sie am Neugeborenen nachgewiesen werden, überzeugende Symptome einer Gelenksdysplasie und erfordern Behandlung. Diese soll unmittelbar nach der Geburt begonnen werden.

3. Das normale Hüftgelenk des Neugeborenen kann passiv vollständig unbehindert und ohne jegliche Krepitation bewegt werden. Eine wiederholte und konstante Krepitation in einer gewissen Stellung des Hüftgelenkes kann das Vorhandensein eine Dysplasie anzeigen und sollte zu einer Kontrolluntersuchung des Kindes im Alter von 4 Monaten, wenn die Epiphyse im Röntgenbilde sichtbar wird, führen.

4. Begrenzung der Abduktion im Hüftgelenk des Neugeborenen ist als ein Zeichen von Dysplasie kaum oder niemals vorhanden.

5. Bei Neugeborenen ist die klinische Untersuchung des Hüftgelenkes der Röntgenuntersuchung weitaus überlegen, so dass die letztere ohne Folgen fallen gelassen werden kann. Nur sobald die Epiphyse röntgenologisch sichtbar wird, bietet das Röntgenverfahren mehr als die klinische Untersuchung.

6. Die Einrenkungsstellung im Hüftgelenk, welche mit Frejkas Polsterschiene erzielt wird, ist bei Kindern bis zu 9 Monaten vollständig zufriedenstellend und wird für die Mehrzahl der Patienten eine Heilung ergeben.

7. Die Behandlung der Hüftgelenksdysplasie mit der Frejka-Schiene stört Kind und Mutter so wenig, dass die Inangriffnahme der Behandlung berechtigt ist selbst wenn Zweifel über die Diagnose bestehen.

8. Die Ergebnisse einer konsequenten Behandlung der Hüftgelenksdysplasie bei Säuglingen sind so gute, dass es möglich sein sollte, Hüftgelenksverrenkungen bei älteren Kindern und Erwachsenen als ein orthopädisches Problem in der nahen Zukunft auszuschalten.

9. Die vorgelegten Daten über die Lage des Kindes im Uterus, ferner über Länge und Gewicht bei der Geburt bieten keine Grundlage für eine mechanische Erklärung der Entwicklung von Hüftgelenksdysplasie.

REFERENCES

Andrén, L. & v. Rosen, S.: Acta Radiologica. Vol. 49. Fasc. 2: 89.
Burman & Clark: Am. J. of Roentgenology. *44*: 37, 1940.
Caffey, J. et al.: Pediatrics, *17*: 632, 1956.
Frejka, B.: Wiener Med. Wochenschrift, 91: 523, 1941.
Getz, B.: Acta Orthop. Scand. Suppl. XVIII, 1955.

Hart, V. L.: Congenital Dysplasia of the Hip Joint and Sequelae. Charles C. Thomas. Springfield, Ill. 1952.

Hilgenreiner, H.: Med. Klinik XXI. 1925. 2: 1385 and 1425.

Jacobson, E.: Sv. Läkartidn., 55: 33, 2427.

Köhler, A. & Zimmer, E. A.: Grenzen des Normalen und Anfange des Pathologischen im Röntgenbild des Skelettes. Georg Thieme Verlag, Stuttgart (10. Aufl.).

Laurenson, R. D.: JBJS. Vol. 41 B No. 4: 702.

Leeftmann, R.: JBJS. Vol. 41 B No. 4: 689.

Martin, H.: Radiology, 56: 842, 1951.

Nyström, B. & Zilliacus, H.: Nord. Med., 12 VII. 1956.

Palmén, K.: Sv. Läkartidn., 54: 1706, 1957.

Ponseti, J.: J. of the Iowa State Med. Society. Nov. 1950.

Ponseti, J.: Am. Academy of Orthop. Surg. Instructional Course Lectures. Vol. X. 1953.

Putti, V.: JBJS. Vol. XV: 16.

v. Rosen, S.: Acta Orthop. Scand. Vol. XXVI: 136.

v. Rosen, S.: Sv. Läkartidn., 54: 2879, 1957.

Severin, E.: Acta Chir. Scand. Vol. 84. Suppl. 63, 1941.

Sundal, A.: Universitetet i Bergen, Årbok 1957. Medisinsk rekke, nr. 1.

Walther, T. & Moe, B.: Tidsskr. for Den norske lægeforening. Nr. 20: 643, 1954.

Wiberg, G.: Acta Chir. Scand. Vol. 83, Suppl. 58, 1938.

HCPCS:	Descriptor:
L1620	HIP ORTHOSIS, ABDUCTION CONTROL OF HIP JOINTS, FLEXIBLE, (PAVLIK HARNESS), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	NO	NO	YES	YES

Sample Diagnosis (Not Inclusive)	Congenital hip dysplasia
Medically Necessary Argument	The Pavlik harness is made of webbing, straps, foam and Velcro. It is designed to reduce stresses across the affected hip joint or joints of newborns and infants. It is designed to maintain the femoral head to be contained within the acetabulum, while the hip joint is stabilized bilaterally at the end desired degrees of abduction as well as the desired degrees of internal rotation. Professional fit is essential for the proper degrees and limited range of motion. Biomechanically correct strap position is required for maximum effectiveness in treating hip dysplasia. If straps are applied incorrectly it will prevent the hip from forming in the correct alignment which can result in dislocation, inability to ambulate, painful ambulation, or required surgical intervention.
References	4

FROM FYLKESSJUKEHUSET (COUNTY HOSPITAL) IN ÅLESUND, NORWAY.
HEAD OF THE SURGICAL DEPARTMENT: DR. HALVARD SKEIE, M.D.
(FROM 1956): DR. KAARE BENDIXEN M.D.
HEAD OF THE RADIOLOGICAL DEPARTMENT: DR. JOHS. SLÖRDAHL, M.D.

EARLY DIAGNOSIS AND TREATMENT OF HIP JOINT DYSPLASIA

By

INGULF UTHEIM MEDBÖ

Congenital dislocation of the hips has probably been known for thousands of years. Treatment has varied through history. Both the treatment and the results of the treatment have been made the subject of intense interest in medical literature.

In more recent decades it has become more and more obvious that the earlier the treatment begins, the greater is the chance of achieving a good result. It is generally accepted in the literature that the best results are obtained when treatment is started in the neonatal stage. These observations form the background to the study of which an account is given in these pages.

During the years 1950 to 1954 a relatively large number of patients were admitted to Fylkessjukehuset in Ålesund for treatment of congenital hip joint dysplasia (h.d.) at the age of 1–3 years. In the late fall of 1954, therefore, it was decided to begin routine examination of all newborn children in the hospital's maternity department and from the 1st of January, 1955, such an examination was consistently carried out.

SCHEME OF INVESTIGATION

a. Clinical examination:

Examination of the hips was made part of the routine examination of all babies in the maternity ward. Doctors on duty examined the hips of all children when they were 3–5 days old. When somewhat later a pediatrician was added to the hospital staff this series of examinations was so well organised that no reason could be found for changing the routine.

The clinical signs which were looked for were as follows:

1. Ortolani's sign (snapping sign).
2. Instability of the hips (telescoping sign).
3. Limited abduction of the hips.
4. Shortening of the femora.
5. Crepitation sound/feeling in the hip joints on passive abduction.

This last sign has scarcely any pathognomic significance as e.g. 1 and 2, but in certain cases this was the only pathological finding in hips which were undoubtedly dysplastic. We followed up all babies with this sign. In the great majority the hips developed in a completely normal way without any treatment. No exact explanation of the finding can be given. It may possibly be due to a certain looseness of the connective tissue in newborns who are still under the influence of the mother's hormones. In the few cases in which it indicated the presence of a dysplasia the sign was regarded as an abortive Ortolani's sign.

b. Radiological examination:

In the first year of this series X-rays were taken of the hip joints in all babies who were suspected of hip joint dysplasia following clinical examination. X-ray examination was made the day after the clinical examination, i.e., when the baby was 4–6 days old.

In the following two years X-ray examination was only carried out on newborns when convincingly positive symptoms were present on clinical examination. In all cases, however, X-ray examination was undertaken at the age of 3–4 months.

The findings at this time decided the need for future follow up.

We sought to evaluate by means of X-ray pictures taken of newborns the following radiological details:

1. The acetabular index.
2. Lateral position of the diaphysis in relation to the acetabulum.
3. Shenton's line.
4. The development of the anterior and the posterior acetabular rim.
5. The upper, lateral border of the acetabulum.
6. The upper end of the diaphysis in relation to the obturator line.

c. Other data on mother and child:

In connection with the first clinical examination certain data was collected on mother and child so as to determine further factors of etiologic importance.

The following were noted, the child's sex, weight at birth, length,

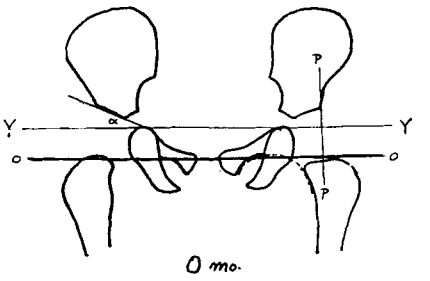


Fig. 1.
Normal pelvis with auxiliary lines.
YY = Y-line. OO = obturator line.
PP = line of gravity through the upper, lateral border of the acetabulum.
a = the acetabular index.

position in womb and order of precedence in the family. In addition the mother's age was recorded and information was sought as to any history of h.d. in the family.

TREATMENT

The principle determining treatment was that this should be initiated as far as possible immediately the diagnosis was made, i.e., in the first week of life.

This was observed with 41 of the 50 babies.

In 7 of the remaining cases treatment was begun along with the first check-up, i.e., at the age of 3–4 months. The cause of this was partly administrative mistakes partly the fact that the diagnosis could only be determined with certainty at this period.

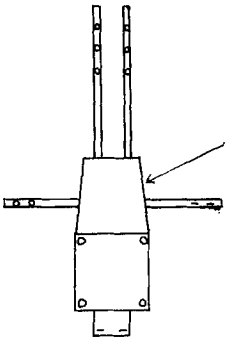
In the last two cases treatment was not started until the age of 7 and 10 months for the last-mentioned reason. One of these cases will be discussed later (case no. 134, Fig. 7).

In the newborns difficulties in reducing the dislocation was never encountered. Frejka's cushion splint was used for immobilisation. See Fig. 2.

For practical reasons the actual cushion in this splint was encased in waterproof material. Thus the individual patient's need for cushions was reduced to 2–3 cushions. The cushion has to be hard to prevent it from being squeezed from one side to the other.

On discharge from hospital each mother received instruction in the use of the splint and got one complete splint as a gift from the hospital so that one should be certain that the remaining splints had the correct dimensions. In our very first case, forming one of the cases in which the treatment is stated to have begun only at the age of 3–4 months an attempt was made to obtain the effect of the Frejka splint by an apparently more easy way.

On discharge the mother was requested to use several diapers at a



Shoulder straps with buttons.

Back support.

Stomach straps with buttons and buttonholes.

Cushion section, size 20 × 20 cm. Thickness about 5 cm.

Flap for fastening shoulderstraps.

Fig. 2.
Frejka's cushion splint, size 1:10.
The buttons in the corners of the cushion section are connected with elastic around the child's thighs.

time thereby achieving the intended abduction position of the hips. This method of treatment proved to be completely useless and at the first follow-up it was replaced by the customary cushion splint delivered and demonstrated for the mother as described above.

Any attempts to replace the original Frejka splint in this way is inadvisable. Regarding the relationship of the patients to the cushion splint and perhaps especially the mother's attitude to this, the following questions were put as routine to the mother at each later check-up:

1. Do you think that the baby suffers any discomfort from the splint?
2. Does it seem to you yourself that it is troublesome to put on the splint?
3. Have you any objections to the splint?

The first question was consistently answered: No.

In reply to the second question a few found that it seemed difficult to put the splint on to begin with. Afterwards all went smoothly and the common answer was that it was not more difficult to put the splint on than to put on ordinary diapers.

In answer to the third question a few brought forward the objection that they did not care for the splint from purely aesthetic reasons. They were reluctant to show the baby to the family and friends because it was so difficult to dress up the child in the way that mothers appreciate. The great majority had, however, no objection to the cushion splint.

In a few individual cases where at the check-up 3 months later no satisfactory reduction had been obtained the cushion splint was replaced by a plaster cast. This enclosed the pelvis and both lower extremities to the knee. The plaster kept the lower extremities fixed at

about 90° flexion and 70° abduction of the hip joints. Corresponding procedures were employed in individual cases where treatment was initiated at the age of 3 months or later, when abduction was hindered to such an extent that the dislocation could not be reduced without recourse to anesthesia. In such cases also immobilisation in a plaster cast was adopted for 3–4 weeks. Afterwards the plaster was removed and replaced by cushion splint. This procedure proved very effective and was clearly much less troublesome to the patient and mother than a lengthy immobilisation in plaster.

Complete immobilisation in the cushion splint was pursued until a clinically stable hip joint was achieved. This was very often the case as early as the first check-up (age: about 3 months). In doubtful cases, especially when the clinical and radiological findings did not correspond, the immobilisation was maintained longer. In the last follow-up period it was recommended that the cushion should only be used in the normal sleeping hours of the baby so that she/he was free to move the lower extremities for some hours every day.

PATIENT MATERIAL

My series comprises all children born in the department during the years 1955–1956–1957. Table 1 records the total of these patients.

As the table shows, the examination comprises 3242 children.

At the clinical examination the findings were negative in 3099 children, but in the remaining 143, findings were made which were regarded primarily as pathological. The latter were all examined once or several times both clinically and radiologically. On the basis of the findings which were made at the first examination or later, 50 children were selected in whom the author believed that clear pathological changes were present in the hips, either in the form of hip joint dislocation or subluxation or a type of h.d. This gives a morbidity of about 1.5 %.

TABLE 1
Survey of children examined.

Year	No of births with children living	Twin births amongst these	Twins living	No of children examined
1955	1035	8	16	1043
1956	1115	14	28	1129
1957	1054	19	35	1070
Total number of children examined				3242

This figure may seen strikingly high and manifests a morbidity in this series which surpasses by far what is commonly thought to occur with h.d. in Norway. The author has observed this point and has repeatedly gone through the series with the aim of reducing the number of probable pathological hips. This attempt was not successful, however, and it was thought that the series should be reported so that it could speak for itself.

It was mentioned above that 143 babies were originally selected who were thought to show pathological changes in the hips on clinical examination, immediately after birth. Of these there were only 50, therefore, in which the primary diagnosis was thought to be correct. The other 93 babies offered at birth only sensations of crepitation in the hip joints on abduction. Radiological confirmation of the disease could not be obtained by pictures taken when the baby was 3–4 days old. At the beginning of the investigation treatment was started in a number of these patients. After more experience was gained this treatment was found unnecessary, so that the great majority were not treated.

In spite of this the diagnosis h.d., could never be confirmed at later clinical and X-ray examination and one must therefore assume that the crepitating sensation on abduction of the hips in newborns may occur without any pathological significance. In a few cases of these babies with crepitation as the sole clinical symptom it has been possible, however, to demonstrate undoubted h.d. at further check-ups (3 months old and later). Attention is therefore drawn to this symptom which in the author's opinion may represent an abortive Ortolani's symptom.

RESULTS OF EXAMINATION AT THE NEW-BORN STAGE

a. Clinical examination:

On examination just after birth the clinical symptoms of the 50 children were as follows:

Ortolani's sign bilaterally	8
Ortolani's sign right hip	16
Ortolani's sign left hip	8
Instability bilaterally	1
Instability right hip	7
Instability left hip	1
Doubtful instability in one or both hips	4
Crepitation in one or both hips on passive abduction	4
No clinical findings	1
	50

Ortolani's sign is only stated positive when one could dislocate and reduce the hip concerned with certainty.

Moreover, it is felt that the instability sign most probably represents a pathological hip. This is stated positive when one could with certainty press the femur so far in the dorsal direction that one would not consider it reasonable that this movement should proceed within a normal joint.

In the four patients where instability is recorded as doubtful, mobility was so small that it was possibly due to general relaxation of the joint in the postnatal period.

Greater doubt may arise concerning the group with crepitation in one or both hips. As stated above, the author believes that this symptom can be regarded as an abortive Ortolani's sign, even if it can be provoked in a number of babies in whom at later examinations h.d. can be excluded.

A good illustration is obtained of a case where such a crepitation on passive abduction movement of the hip joints was the only finding on examination in the newborn stage on studying X-rays of case 36, Fig. 13. Unfortunately the first X-ray examination was undertaken at the age of 3½ months.

The last case, in which nothing pathological was noticed on examination immediately after birth, was discovered when the baby was 7 months old, see case no. 134, Fig. 7.

b. Radiological examination:

The radiological findings in newborns were as follows:

Certain dislocation or subluxation	16
Probable dysplasia	10
Probable negative finding on X-ray examination	19
X-ray exam. not carried out in newborn stage	5
	50

There are scarcely any reasons for general remarks on the above, apart from the fact that the X-ray examination produces far fewer positive findings than the clinical examination. What is most interesting in this connection is whether there is any correspondence between the clinical and the radiological findings.

If one reviews the eight cases with clinical findings:

Ortolani + bilat., the radiological findings are as follows:

Bilateral dislocation or subluxation	5
Bilateral dysplasia	1
Unilateral dysplasia	1
Negative findings	1
	8

The 24 cases with clinical findings: Ortolani positive in right or left hip, show the following X-ray findings:

Dislocation or subluxation same side	11
Dislocation or subluxation opposite side	2
Dysplasia same side or both	5
Negative findings	6
	24

A corresponding summary can be made of the other clinical groups with an increasing failure in the radiological diagnosis.

With regard to the 32 cases with the clinical diagnosis: Ortolani's sign positive, all the cases with radiological findings, dislocation or subluxation, coincide within this group. On the other hand, however, convincingly positive radiological findings were only found in 16 of 32 babies who were declared to have completely reliable positive findings on clinical examination, and in fully 7 cases the X-ray diagnosis was completely negative in a very critical evaluation in spite of the positive clinical findings.

The question may then be put: is not amongst these 7 the clinical diagnosis faulty and the radiological one correct? With this in mind I studied the results of the first follow-up examination of these 7 children. This took place when the child was 3–4 months old.

The findings on clinical and radiological examination were these:

Clin. ex.:	Neg. findings.	
Rad. ex.:	No or doubtful positive findings	2 cases
Clin. ex.:	Neg. findings.	
Rad. ex.:	Delayed development of epiphysis	2 cases
Clin. ex.:	Neg. findings.	
Rad. ex.:	Undoubted dysplasia findings	2 cases
Clin. ex.:	Not performed.	
Rad. ex.:	Neg. findings	1 case
		7 cases

In order to evaluate the above one must bear in mind that all these babies commenced treatment immediately after birth. In the author's experience it rarely or never happens that on examination at 3 months

of age clinical symptoms will be found positive and it is rare that there will be definite pathological findings on X-ray examination. In spite of this, however, pathological findings were made at the first follow-up examination in 4 out of 7; these findings were due in all probability to a hip joint dysplasia or—dislocation. This makes it most likely that the clinical diagnosis at the neonatal examination was correct and that the X-ray diagnosis was at fault.

The conclusions to be drawn from this rather detailed evaluation of the symptoms found on clinical and radiological examination of newborns are that the radiological examination is much inferior to the clinical at this age. In addition I believe to have demonstrated that a positive Ortolani's sign at birth is such a certain symptom of h.d. that it will be a failure of technique if it is not heeded and treatment does not begin with the newborn baby.

c. Other clinical data from the newborn stage.

As stated above the series comprises 3242 children. Based on clinical and radiological examination of the hip joints of these children, it is considered that hip joint dysplasia is present in 50 children.

Below is given more clinical data on these 50.

TABLE 2

Sex distribution.

Sex	No.	No. given in %
Girls	43	86
Boys	7	14

This distribution between the sexes corresponds well with the figures found elsewhere in the literature.

The information collected about the position of the foetus determined in relation to the birth showed nothing unexpected. On the whole the distribution was normal with a certain emphasis on the breech position, since 6 children or 12 % were born in this position.

Nor was anything unusual found in respect to which order in the family these children came.

As far as the mothers were concerned, the mother's age was noted when the child was born. This was on average 29.9 years. In a control series of 93 mothers with normal children born in the same period the average age was 29.3 years.

Finally information was requested about other known cases of h.d.

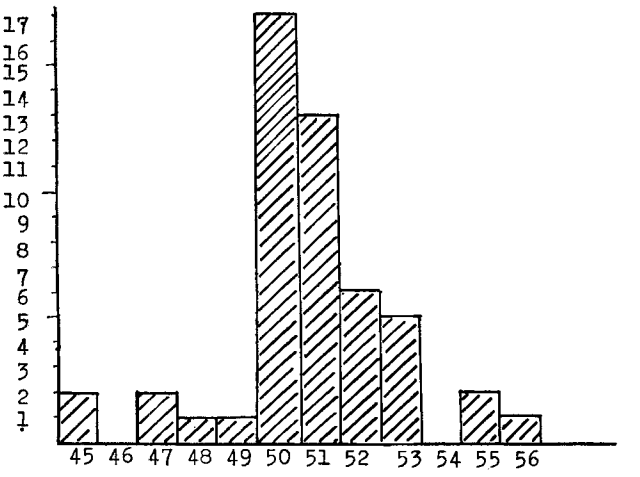


Fig. 3.

Length at birth:

Abscissa: Length at birth given in centimetres.

Ordinate: Number of children.

Each column represents the children whose length at birth lies within the same centimetre. If this graph of length at birth is compared with the corresponding graph in Sundal's normal series from Bergen in 1956, the same pattern is found on the whole. If the average length of the 50 children is calculated, this is 50.74 cms. Sundal states that the average length of boys is 50.9 cms. and of girls 50.2 cms. A series composed of 14 % boys and 86 % girls will then achieve an average length of approx. 50.3 cms., i.e., somewhat less than in my series.

in the family. Here positive information was received in 17 of the 50 children, i.e., 34 %.

RESULTS OF TREATMENT

In the great majority of children the treatment was commenced a few days after birth. As explained above such early treatment was started in 41 out of the 50 children. In the remainder the treatment commenced later, but in all cases before the child had begun to stand or walk.

In order to assess the results of treatment it was decided to divide the children into two groups. Group I comprises the 41 children in whom the treatment was started in the newborn stage. Group II comprises the remaining 9 children.

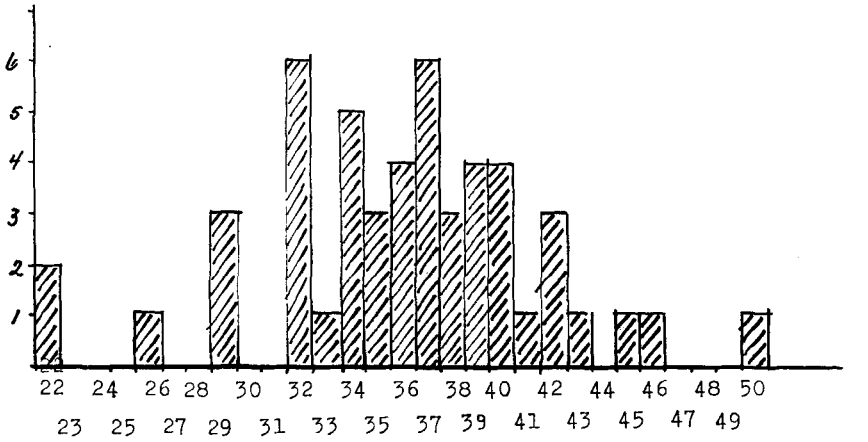


Fig. 4.

Weight at birth:

Abscissa: Weight at birth stated in 100 grams.

Ordinate: Number of children.

Each column represents the children whose weight at birth lies within the same 100 grams. The pattern in this graph of the weight at birth of the 50 children also corresponds with the graph in Sundal's normal series. The average weight at birth is calculated at 3.608 gr. Sundal states the normal weight of boys to be 3.500 gr. and of girls to be 3.400 gr. A group composed of 14 % boys and 86 % girls will then have an average weight of 3.414 gr., i.e., somewhat less than in my series.

GROUP I:

The first control examination within the group took place in 39 cases when the child was between 3 and 4 months old. In the last two cases the age was respectively 5 and 6 months. The results of the clinical examination at this point was as follows:

Negative findings	37 patients
Positive findings	4 patients
	41 patients

Positive findings in this connection mean that the hip could be dislocated and reduced with certainty or that shortening of the extremities could be demonstrated with limited abduction and positive "telescoping sign". In the X-ray examination, which took place the same day, the following was found:

Negative findings	23
Dysplasia signs in one or both hips	11
Dislocation or subluxation in one or both hips	4
No satisfactory X-ray exam.	3
	41

There was very good correspondence here between clinical and X-ray examination, since all in the group "negative findings" in the X-ray examination turned up again in the same group in the clinical examination.

All the dislocation findings in the clinical examination could, as was to be expected, be confirmed at the X-ray examination.

The X-ray symptoms which were given importance in referring a case to the radiological dysplasia group were as follows:

a. Increased relative acetabular index	6
b. Delayed development of epiphysis	3
c. Poor development of the anterior and posterior lips of the acetabulum, and poorly marked upper lateral border of the acetabulum	11

Cf. a: This symptom is relatively easy to evaluate and is only noted positive when there is an obvious increase of the angle of incline on one side in relation to the other.

Cf. b: This symptom is also easy to assess. One cannot, however, expect to find it positive in all cases where the control is undertaken at the age 3–4 months, since the epiphysis normally does not become radiologically visible until the age 3–6 months.

Cf. c: This X-ray symptom may be the subject of considerable subjective assessment, but is on the other hand present in all babies. In 6 out of 11 it is, however, supplemented by one of the above more objective symptoms, so that one may draw the conclusion that the subjective assessment of the acetabulum is probably not too fortuitous.

If the radiological findings in this group are compared with the clinical findings of Ortolani's sign at birth, the following is found:

Of the 32 babies who had positive Ortolani's sign at birth, 30 appear in group 1. In 2 of these the X-rays at the first check-up were of such quality that no X-ray diagnosis may be ventured.

In the remaining 28 the X-ray findings are negative in 15 (over 50 %), 4 have radiological subluxation and 9 have radiological dysplasia. No one has now a complete dislocation. From this it can be concluded that Frejka's cushion splint is very effective and that it is a fundamental advantage to begin treatment at such an early stage.

Final results of treatment:

In assessing the final result of treatment certain difficulties of evaluation are encountered. As stated the children were followed-up until the examiner at the clinical and radiological check-up was of the opinion that the hips were normal and showed no signs of becoming worse after the splint treatment was ended, i.e., the last check-up occurred at least 3 months after the continuous treatment was finished. The end result of the examined babies will be assessed according to this principle at most varying ages, and these lie between 6 and 33 months.

In 26 children the age was from	9–15 months
In 9 children less than	9 months
In 5 children more than	15 months

One child did not return for check-up owing to geographical reasons.
Total 41 children.

A. *Clinical examination.*

No signs of h.d. were found in any of the 40 children. In 19 cases the child was 12 months old on check-up, and all these could walk or stand with or without support. In these cases all had negative Trendelenburg sign as far as could be demonstrated.

It may then be maintained that from a clinical standpoint all the children had normal hips.

B. *Radiological examination.*

This appears more problematic both because the end stage is recorded at ages varying between ½ and almost 3 years and because there is no definite standard for the normal hip in this age group. The results of X-ray examination were judged according to two different principles.

First a general picture was formed of the hip joint, by taking into consideration the mutual development of the osseous parts of the caput and acetabulum and the adjustment of the caput to the acetabulum.

From this point of view an end result was found in 39 of these 40 children which was quite satisfactory. The caput and acetabulum had even contours, the acetabulum's roof had a suitable angle, the anterior and posterior lips were well developed and closed laterally. Moreover, the caput seemed to be well centred in its joint cavity.

A hip joint of normal appearance may thus be said to be present in 39 out of 40 cases. In the last case the caput is placed so far laterally and the acetabular contours are so blurred and uneven that an h.d. is probably still present or possibly a slight subluxation.

This method of assessment must undoubtedly be rather subjectively influenced, since it depends on the general judgement of the examiner.

Secondly these 80 hip joints were assessed strictly geometrically, by drawing up 2 of the previously mentioned auxiliary lines. Even at this point one comes across the first difficulty, since the Y line, judging from the literature, is drawn rather differently by different authors.

It was decided to draw the line as described by *Wiberg*. He draws it as a tangent to the upper contour of the os pubis. Others draw it rather differently, but in all cases it is situated further cranially than that described by *Wiberg*.

The second auxiliary line, called the P line, is drawn through the lateral, osseous border of the acetabulum and vertical to the Y line. Since the above border is often slightly rounded a slight difficulty is encountered in deciding the localisation of the line and the judgement of the examiner again comes into the picture.

After these lines are drawn, all hips are said to be "normal" where the caput in its entirety lies in the lower medial quadrant.

In those cases where 0–2 mm. of the caput lies above the Y line or laterally of the P line, the hips are called "normal?". This method of assessment was chosen because there will always be a certain doubt about the exact localisation of the auxiliary lines described. In no case does the caput lie more than 2 mm. above the Y-line.

In those cases where 3–5 mm. of the caput project laterally of the vertical line, the designation "dysplastic?" is used.

In those cases where the divergence is greater than that stated above, the hip joint is called "dysplastic".

The results of this strict assessment of the babies are as follows:

"Normal" hips	22 babies
"Normal?" hips	12 babies
"Dysplastic?" hips	5 babies
"Dysplastic" hips	1 baby
	40 babies

Much doubt was felt whether it was right to describe pathological conditions in a hip joint so systematically. Firstly, as already mentioned, some doubt was felt where the auxiliary lines were to be drawn. Secondly the question occurs whether here as elsewhere in man's anatomy, one must not make allowances for minor individual variations. Thirdly it was not possible to find anywhere in the literature an account of what should be regarded as the norm for the hip joint in children of

this age group, namely, 1–3 years. Studies were found which stated the normal outer limits for hip joints in adults and children down to 6 years, but not for the younger children.

When the investigation was being pursued *Andrén & von Rosen*'s examination technique was not published and therefore this could not be evaluated.

If the end results of the treatment of these 40 children according to the three procedures described are studied, the following emerges:

Clinical exam.	Normal hips	40 children
General radiological assessment	Normal hips	39 children
	Dysplastic hips	1 child
Radiological assessment in relation to the quadrant division of the hip joint		
	Normal hips	34 children
	Possible dysplastic hips	5 children
	Certain dysplastic hips	1 child

On the basis of the above it is believed that the treatment in 39 of the 40 children has led to the healing of the existing defect in the hip joints, while in one case complete healing has not yet been achieved.

This last case represents undoubtedly an error in treatment on the part of the examiner, in that the whole purpose of the investigation originally was aimed at demonstrating how valuable Frejka's cushion splint was. For this reason splint treatment alone was continued until the child was 14 months old. At this time certain dislocation existed in the right hip. A change was made to plaster and at the next check-up the right hip was reduced very nicely, but as stated, the caput is still placed rather far laterally, nor can one say really that any certain subluxation is present. A more elastic attitude by the author would undoubtedly have produced a better result. In later cases of the series the experience acquired from this lesson was applied. If complete stability was not achieved in the hip during the course of a control period of 3 months, the cushion splint was replaced by plaster administered if necessary under anesthesia. After 3 weeks the plaster was removed and the Frejka treatment was again adopted. In such cases no sign of recurrence was ever seen.

GROUP II:

The group comprises 9 children.

In 7 of these children treatment was begun at the age 3–4 months. In the last two the age was respectively 7 and 10 months.

A. *Clinical examination.*

The last clinical examination of these took place between 1 and 2 years of age. In no case could signs be demonstrated of pathological conditions in the hips. All had started to put weight on their lower extremities in the erect position. In those cases where it was technically possible, Trendelenburg's test was carried out with negative results.

The results of the clinical examination were thus negative in 100 %.

B. *Radiological examination.*

The last X-ray examination was carried out at the same time as the clinical one. On assessing this, uncertainty arises again as described before, since it is not definitely known which radiological standards must be applied to the normal hip in the age group involved here.

The general impression of the examiner in assessing the present X-rays is that in all cases the hip joints concerned under routine conditions would be regarded as normal. The acetabulum is well developed with a centrally placed epiphysis of normal shape.

If the existing pictures from the last check-up are studied strictly geometrically in this group and if the caput's position is assessed in relation to the previously described auxiliary lines in the same way as in Group I, the following end results are obtained:

"Normal" hips	2 children
"Normal?" hips	2 children
"Dysplastic?" hips	5 children

On comparing the clinical and radiological findings this group is believed to have achieved probable normal hips in all cases, i.e., 100 %.

If the strictly geometrical assessment of the end result has any value in comparison between these two groups, it appears that even a postponement of treatment from the birth of the child until he (she) is 3–4 months old, is unfavourable.

COMBINED ASSESSMENT OF GROUP I AND II AT THE CONCLUSION OF TREATMENT

It is the author's opinion that the two groups of results treated here are so small and that the time of initial treatment varies so little that no great mistake will be made if the two groups are combined.

The following total results are given for the 49 children who underwent full follow-ups:

Clinical examination:	Normal hips:	49 children
General radiological assessment:	Normal hips:	48 children
	Dysplastic hips:	1 child
Radiological assessment in relation to the quadrant division of the hip joint:	"Normal" hips:	24 children
	"Normal?":	14 children
	"Dysplastic?" hips:	10 children
	Dysplastic hips:	1 child

Even after the strictest assessment, therefore, 38 children or 77.5 % emerge from their congenital hip joint dysplasia with normal hip joints.

In 10 children or 20.5 % the clinical examination shows a completely normal hip joint, while a strict radiological assessment shows a slightly lateral position of the caput in one or both hip joints, although one cannot definitely say that h.d. exists.

In one child certain dysplasia is present in the one hip joint, while the other lies in the group above.

In 1 child an adequate follow-up could not be pursued owing to geographical conditions.

Seen in relation to the percentage of healing obtained in congenital h.d. when treatment is commenced after the child has started to walk, the results are believed to be so favourable that any postponement at all of the treatment after the newborn stage must be regarded as an error of technique.

PRESENTATION OF CASES

To give the reader a better understanding of the view-points maintained by the author some case-histories with tracings of X-rays are presented. There are three cases from each of the groups: "Normal" hips, "Normal?" hips and "Dysplastic?" hips.

Group: "Normal" hips:

Case No. 30 R.O. b. 25/9.1955. Fig. 5.

Family history:	No known cases of h.d.
Clin. ex. at birth:	Ortolani's sign pos. right hip. Shortening of right femur and assymm. skin folds.
X-ray ex. at birth:	Probable sublux. in right hip.
Treatment and course:	Commenced immediately after birth with Frejka's cushion splint. This was used day and night for 6 months, afterwards at normal sleeping hours for a further 2 months. Walked and stood with support at ca. 10 months.
Last check-up (15 mos.):	Clinical ex.: Completely normal hips.

Walks without limp. Trendelenburg — bilat.
X-ray: normal hips, both caputs in the lower medial quadrant. Right caput insignificantly smaller than the left.

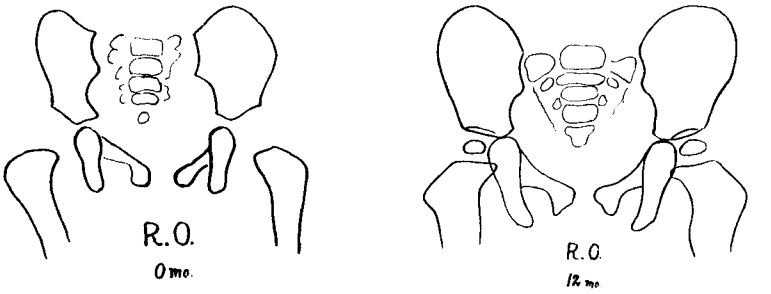


Fig. 5.

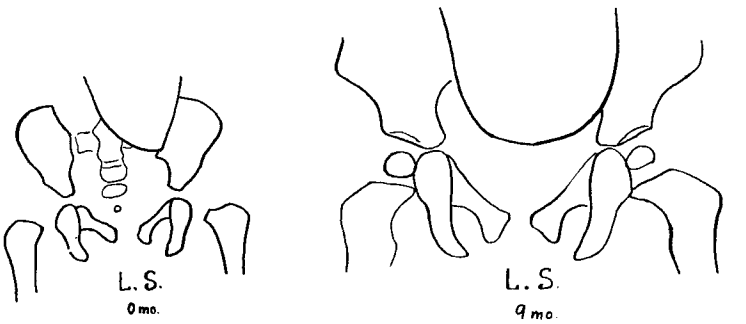


Fig. 6.

Group: "Normal" hips:

Case No. 143 L.S. b. 12/12.1957. Fig. 6.

Family history:	No known cases of h.d.
Clin. ex. at birth:	Ortolani's sign pos. bilat. with relative shortening of the femora.
X-ray ex. at birth:	Probable dysplasia bilat.
Treatment and course:	Frejka's cushion splint treatment started at birth. This was used continuously for 6 months, afterwards during sleeping hours for a further 3 months. Normal development of the hip joints.
Last check-up (9 mos.):	Clin. ex.: normal hips.
	X-ray: normal hip joints. Caput in lower medial quadrant bilat.

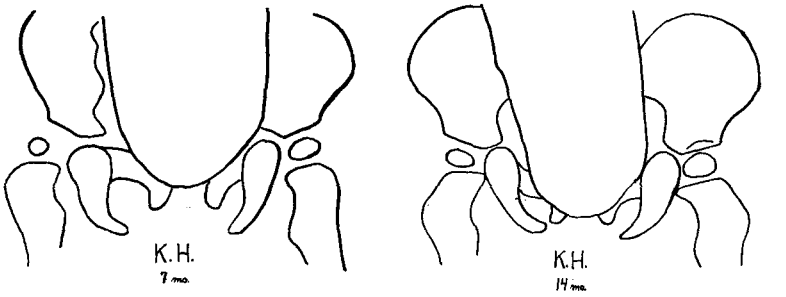


Fig. 7.

Group: "Normal" hips:

Case No. 134 K.H. b. 5/9.1957. Fig. 7.

Family history:	Twin sister with certain clinical and radiological luxation in left hip at birth.
Clin. ex. at birth:	Neg. findings.
X-ray ex. at birth:	Not performed.

Owing to the examiner's interest in twin cases in this series the patient was called for check-up with her sister, 7 months old.

Clin. ex., age 7 months:	Limited abduction in right hip, assymm. skin folds and probable shortening of right femur.
X-ray ex., age 7 months:	Certain dislocation in right hip.
Treatment and course:	Reduction performed under anesthesia without difficulty. Position maintained in plaster. After 3 weeks, plaster-cast replaced by Frejka's cushion splint. This was used continuously for 3 months, afterwards during sleeping hours for a further 3 months.
Last check-up (14 mos.):	Clin. ex.: normal hips.
	X-ray ex.: both hip joints appear normal, but right caput is still a little smaller than the left.

Group: "Normal?" hips:

Case No. 43 S.H. b. 12/4.1956. *Fig.* 8.

Family history:	3 certain cases of h.d. in the father's family.
Clin. ex. at birth:	Ortolani's sign pos. right hip.
X-ray ex. at birth:	Certain lat. position of upper end of femur, right side, with slight uprooting of same and increased acet. incline bilat.
Treatment and course:	Frejka's cushion splint used from birth. The cushion was used continuously for 6 months. Afterwards treatment was concluded. After only 3 months clin. ex. was negative, while there were continued signs of dysplasia in both hips on X-ray ex.—Started to walk without limping at 1 year.

Last check-up (26 mos.): Clin. ex.: completely normal hip joints.

X-ray ex.: at first sight the hips appear completely normal bilaterally, but on both sides the caput projects about 2 mm. above the Y line and about 2 mm. laterally of the P line.

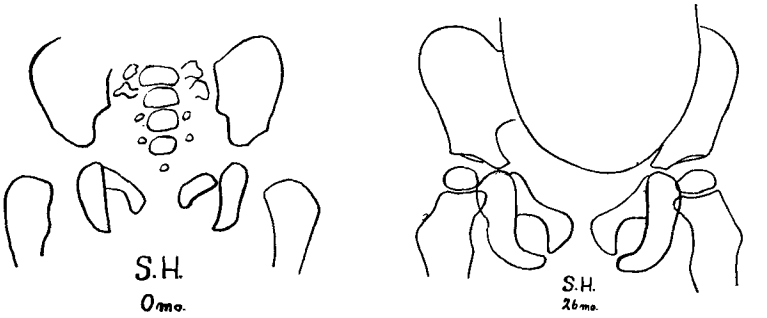


Fig. 8.

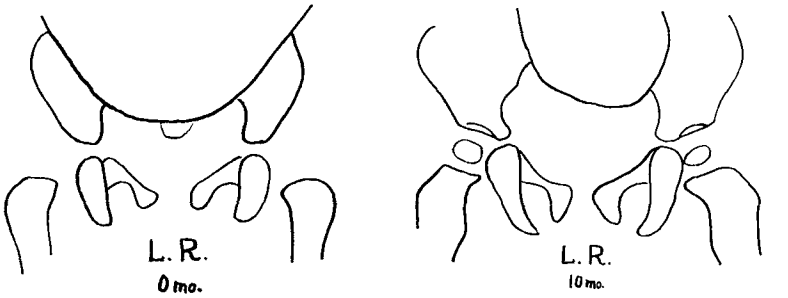


Fig. 9.

Group: "Normal?" hips:

Case No. 118 L.R. b. 8/7.1957. Fig. 9.

Family history: One case known in a distant relative in the mother's family.

Clin. ex. at birth: Ortolani's sign positive bliat. Left hip was so loose that it did in fact dislocate as soon as the baby was laid on its back.

X-ray ex. at birth: Considerable increase in acetabulum's angle of incline bilat.

Treatment and course: Frejka's cushion splint treatment started at birth. At the first check-up certain dislocation continued to be present in the left hip. Easy reduction without anestesia was obtained. Reduction maintained in plaster. After 3 weeks the

plaster was replaced with Frejka's splint. This was used continuously for 3 months. Afterwards again for 3 months with two hours freedom from the splint each day. Could stand with support after 10 months.

Last check-up (10 mos.): Clinical ex.: normal hips.

X-ray ex.: bilat. the caput projects 1 mm. above the Y line and on the right side 2 mm. outside the P line.

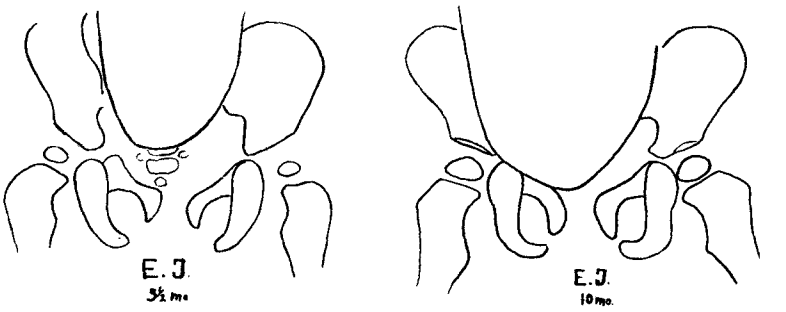


Fig. 10.

Group: "Normal?" hips:

Case No. 79 E.J. b. 5/1.1957. Fig. 10.

Family history: No known cases of h.d.

Clin. ex. at birth: Pronounced crepitation and some looseness in left hip joint. Ortolani's sign neg. No instability.

X-ray ex. at birth: Not performed.

Treatment and course: No treatment begun at birth. At first check-up aged 3½ months limited abd. was found in right hip and definite instability in left hip. X-ray findings: Probable subluxation in both hips. Reduction was undertaken under anesthesia. Stability was easily obtained in the reduced position with Frejka's cushion splint. This was used continuously for 3 months, then at sleeping-hours for a further 3½ months.

Last check-up (10 mos.): Clinical ex.: Normal hip joints.

X-ray ex.: On immediate study both hip joints appear normal, but the caput projects 2 mm. above the Y line bilat. and also 2 mm. outside the P line.

Group: "Dysplastic?" hips:

Case No. 115 J.T.V. b. 28/5.1957. Fig. 11.

Family history: Elder sister had certain bilat. h.d. In addition the child is closely related with another child in the series.

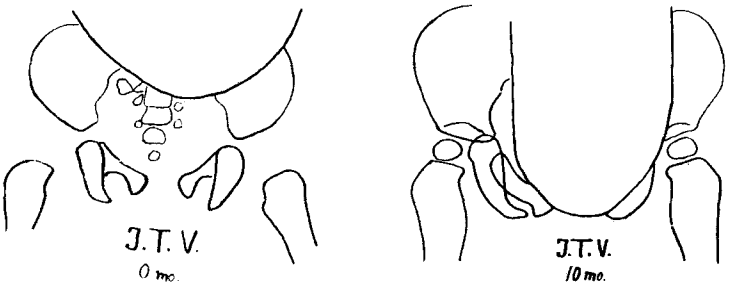


Fig. 11.

Clin. ex. at birth:	Ortolani's sign pos. left hip, probably instability in right hip.
X-ray ex. at birth:	Upper lateral border of acetabulum is not well marked. Rather large angle of incline in left hip. Certain signs of dislocation are not present.
Treatment and course:	Frejka's cushion splint treatment started at birth. In first check-up after 3 months there was probable instability in both hips on clinical ex. X-ray showed certain sublux. in right hip, and somewhat laterally placed caput in left hip. It proved that the cushion used was too thin and soft to obtain the desired effect and it was exchanged. The new cushion was afterwards used day and night for 6 weeks, afterwards omitted 2 hours daily for 6 weeks, and then worn only at night for a further 4 months.
Last check-up (10 mos.):	Clin. ex.: normal hips. X-ray ex.: left hip completely normal, caput on right side projects 3 mm. outside the P line.

Group: "Dysplastic?" hips:

Case No. 10 E.E. b. 8/4.1955. Fig. 12.

Family history:	No known cases of h.d.
Clin. ex. at birth:	Ortolani's sign pos. right hip.
X-ray ex. at birth:	Relatively increased acetabulum angle of incline on right side. Shenton's line broken bilat. Lateral position of both femoral diaphyses.
Treatment and course:	With clinically certain hip joint dislocation on the right side a directive was given that treatment should be started before discharge from the maternity ward. The directive was misinterpreted, however, and no treatment was begun. On the first check-up certain clin. dislocation existed in the right hip, which could be confirmed on X-ray ex. No success was obtained in trying to achieve stable reduction

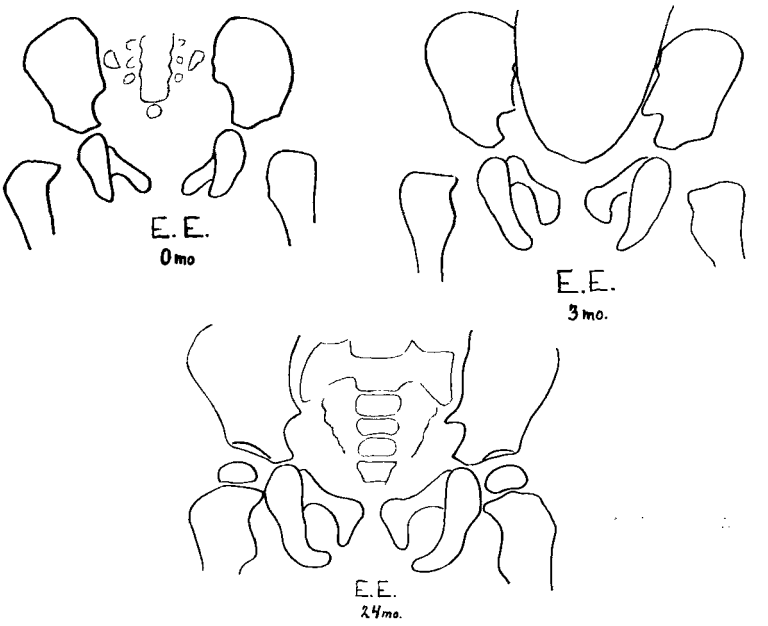


Fig. 12.

without anesthesia. The reduction was maintained in plaster for 3 weeks. Then normal Frejka's splint was used continuously to the age of 6 months and then during sleep to 12 months. Later checks gave normal findings from the right hip, but plain abduction spasm in the left, where the epiphysis as well seemed to be more laterally placed than on the right side. At 14 months tenotomy of the adductors on the left side was performed. Later the course was normal, apart from temporary fragmentation of both caputs. At 14 months she could stand with support. Walked at 16 months.

Last check-up (24 mos.): Clinical ex.: Neg. findings.

Walks freely without limp. Trendelenburg's sign neg. bilat.

X-ray ex.: Well developed acetabulums. Right epiphysis 1 mm. above and 5 mm. laterally of the auxiliary lines. Left epiphysis projects 1 mm. above and 3 mm. laterally of the same lines.

Group: "Dysplastic?" hips:

Case No. 36 G. F. b. 5/1.1956. Fig. 13.

Family history: No known cases of h.d.

Clin. ex. at birth: Slight crepitation on abduction beyond 80° of left hip.

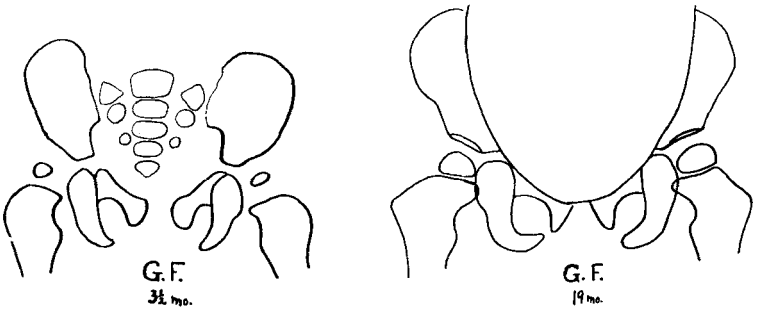


Fig. 13.

X-ray ex. at birth:	Not performed.
Treatment and course:	At the first check-up, age 3½ months, certain clin. dislocation in the right hip, confirmed at X-ray ex. Under anesthesia an easy reduction was carried out. The position was maintained in plaster for 4 weeks. Then the plaster was replaced by Frejka's splint. This was continuously used for 3 months. Then it was used at sleeping hours for a further 6 months. The patient walked without support at the age of 13 months.
Last check-up (19 mos.):	Clin. ex.: walks normally. No pathological findings on ex. of the hips. X-ray ex.: The general impression is that the hip joints are developing normally, but the caput projects respectively 4 and 3 mm. above the Y-line and 4 and 3 mm. laterally of the P line.

DISCUSSION

I have presented the results of a consistently pursued investigation into hip joint dysplasia in 3242 children.

The 50 children whom I believe had h.d. at birth were treated and followed-up until I considered the hips to be normal.

a) *Incidence of h.d. in the series.*

I was very surprised at the high incidence of h.d. According to other studies from the Scandinavian countries the disease occurs to the order of 0.1 % while in this series it shows a figure of 1.5 %. In the Samic population in Finnmark a morbidity of 4–5 % was found, while the Norwegian population in this province has much the same incidence as elsewhere in the country.

According to the research I have made, there are at any rate no official statistics on the occurrence of h.d. The figures presented in the literature are not based then on normal health statistics.

From other parts of the world the morbidity incidence is reported as varying quite considerably from place to place. The interpretation must be that h.d. is a disease which in certain geographical areas arises with great frequency while in others it may be very rare. I therefore satisfied myself with the explanation that Möre and Romsdal county forms just such a geographical area in which h.d. has a higher incidence than in Norway as a whole.

This theory is supported by the fact that before this investigation was commenced a relatively large number of children were admitted to hospital aged 1–3 years, with hip joint dislocation. During the years 1950–54, 4–7 newly-diagnosed cases were admitted each year. Even this number is only a third of the incidence shown in the series. The explanation of this may be partly that some cases of h.d. were referred for treatment to a special clinic instead of to the local hospital. It is also known from the literature that spontaneous healing of h.d. does occur. It is therefore probable that a number of the cases included in the series would also have achieved healing without treatment. The difficulty arises only in that it is not known with certainty who will develop a complete dislocation and who will achieve spontaneous healing.

The few cases in which a certain diagnosis of dysplasia was made at birth but in which treatment was mistakenly not commenced, do not encourage postponement of treatment in the hope of spontaneous healing.

b) *The clinical examination of the hip joint in newborns.*

The examination was undertaken with the baby lying supine. The hip joints were flexed 90°. The examiner placed his thumb over the distal end of the femur and the other fingers over the trochanter region. From this initial position the mobility and stability of the hip joints were examined.

Based on past experience I believe that Ortolani's sign (snapping sign) and instability (telescoping sign) of the hip joints are convincing symptoms of h.d. Using the examination technique described these symptoms are relatively easy to observe even for a less skilled examiner.

I have never observed limited abduction in the newborn stage except as a link in Ortolani's sign, i.e., when the abduction movement is undertaken in a dislocated hip joint, slight resistance to continued abduction

is felt before the caput is tilted into the joint cavity. Afterwards abduction may normally be undertaken to about 70°. For the symptom to appear alone I assume that a better development of the musculature is required than is found in newborns. Later, e.g., at the age of 3 months, the abduction blockage will be an important symptom of hip joint dislocation.

I have also as a matter of routine taken notice of whether asymmetry was present in the thigh, groin or gluteal skin creases.

I should like to draw attention to the crepitation noise to be heard on passive abduction of the hip joint. In a good number of cases where this was observed at the first examination, I checked on the child later without finding signs of pathological development of the joint. In some few cases this was the only clinical symptom of h.d. in the neonatal stage and later examination showed the development of dislocation (see case 36, Fig. 13). I would therefore recommend that children who offer this symptom are examined as routine at the age of about 4 months when the epiphysis is visible on the X-ray pictures.

c) *Hip joint dysplasia in children with negative findings on examination at the newborn stage.*

Among the 3242 children who were examined immediately after birth, and where the primary result of the examination was "Normal hips", only 2 cases occurred which were later to be admitted to hospital with hip joint dysplasia. In both cases only a moderate degree of dysplasia was present without complete dislocation. Both were treated with favourable results.

I take this as indicating that clinical examination at the neonatal stage is very reliable.

Naturally the objection may be made that perhaps there were other cases of which the examiner was not aware. I consider this to be hardly probable because this series of investigations was much publicised by the hospital both amongst the women who were admitted to the maternity ward and amongst the doctors in the district.

The fact that, taken as a whole, overlooked cases do arise is an inspiration towards constant control of the hip joints of infants. Carrying out a hip joint examination is so easy and takes so little time that it ought to be included as a routine examination in all infant check-ups. In particular the examination should apply to girls in families where it is known that h.d. occurs amongst other members of the family.

If this procedure is carried out, all cases of hip joint dysplasia should be discovered and treated before the child begins to walk.

d) *Radiological examination of the hip joint.*

An attempt was made to take all pictures with the patient lying supine in complete rest with straight lower extremities in the neutral position of rotation and centred towards the symphysis. It will be well known to all who have performed such an examination that it can be difficult, not to say impossible, to persuade a patient in the age group involved here to lie in the correct position during the examination. To avoid overlong exposure I therefore approved in a number of cases X-rays which were obviously not taken in an ideal position. This circumstance should be born in mind when assessing a radiological diagnosis on a purely geometrical basis.

As will appear in the assessment of the end results, I found on careful scanning of the X-rays a number of babies who had a very slight lateral dislocation of the caput but at the same time no sign of dysplasia could be detected in the hip joint as a whole, i.e., the caput was normally formed, with entirely normal size and contours. The same applies to the acetabulum, including the angle of incline. The author cannot declare with certainty today that these hips are normal and will develop normally. It is hardly reasonable to believe that the above-mentioned changes are only due to inaccuracies in the radiological technique. A possible explanation is that these cases concern femora with increased anteversion, so that X-rays taken with the lower extremities in the correct position of rotation, really give a very slight lateral projection of the caput in relation to the acetabulum. I consider it very doubtful that a genuine subluxation is involved. Some children in the series who presented such radiological findings were checked again after getting about without any form of treatment. No increased lateral displacement or signs of uprooting were observed.

It is stated in the literature that the hip joint ends its development in persons in the 17 years age group. I assume than the population group from which this series is derived has stable housing conditions so that it would be possible to follow-up these children when they are about 17 years old. Such an investigation is planned. It will possibly give the answer to the question of how much importance a lateral position of the caput may possess in the development of the hip joint.

In this series I have omitted to divide the patients into the usual groups of unilateral and bilateral cases.

In the literature published 20–30 years ago and earlier, a strict differentiation was made between uni- and bilateral cases. On the whole it was agreed that ⅓ were bilateral and ⅔ were unilateral. In later publications this distribution was altered in favour of a larger number of bilateral cases. I am strongly convinced that one should perhaps go further in this direction and say that congenital hip joint dysplasia is a systemic disease which affects the development of the hip joint generally. The degree of dysplasia may vary and this explains why the symptoms found on clinical and radiologacil examination may be localised to one hip only.

With a serious degree of dysplasia at birth, dislocation may occur in one or both hips.

With a slight degree of dysplasia one of two things may happen: either the hip joint will develop so that the child begins to stand and walk with normal hip joints, or the dysplasia will persist or become worse in the first years so that weight bearing on the lower extremity concerned will pass into a genuine dislocation on one or both sides.

If the above view of hip joint dysplasia is correct, then the fact that we constantly examine our children in their younger years and that methods of examination constantly grow better, will provide, in the author's opinion, a good explanation of the tendency found in the literature towards a constant increase in the bilateral cases at the expense of the unilateral.

I have deliberately paid little attention to the importance of the angle of incline of the acetabulum in the radiological assessments.

The reason is partly that more recent literature very decidedly asserts that this angle varies so much individually that no clear boundary can be drawn between normal and pathological values. Nor in this study was any complete correspondence found between the acetabulum's angle of incline and other symptoms utilised to make the diagnosis h.d.

It must be said that the angle of incline in the series as a whole is high. The average figure for normal angles of incline is put in the literature at 28–29° in newborns, but with large individual variations which cannot be designated as pathological.

In this series X-ray pictures of the newborn stage are included of 44 babies, in all 88 hip joints. 68 of these show an angle of incline of 29° and more. An angle of incline less than 25° is found in only 5 hip joints.

These figures should indicate that a large angle of incline certainly is a feature in the picture of a hip joint dysplasia, but as previously stated I would not venture, on the basis of the present radiological findings,

to draw up any boundary between normal and pathological angles of incline.

A circumstance which caused the author somt thought during the collection of the material was the danger of overlong irradiation of the gonads. As the figures from the casepresentation will show, an attempt was made to cover the gonads with lead plate during the exposure.

In this field my experience is that it is difficult to achieve satisfactory covering of the gonads, at any rate in girls, without at the same time covering parts of the hip joints. It may therefore be asked if it is more advisable to take the pictures without covering than to present the patient for two or more exposures in order to include both hip joints.

Skin dosage in exposure of the joints was measured. This is of such a degree that a control examination at intervals of 3 months will scarcely cause any injury to the gonads. I would, however, emphatically warn against exaggerated use of X-ray examination, not least because the clinical examination may be of more value than the radiological examination in newborns.

e) *Treatment with Frejka's cushion splint.*

My experience with Frejka's cushion splint has been very favourable. In the great majority of cases I obtained normal development of the hip joints after 3 month's treatment. In certain cases where instability was unusually large, or where treatment began later than the newborn stage, I utilised plaster immobilisation for a short period. In these cases I replaced the plaster by a cushion splint after 3–4 weeks and found this completely satisfactory.

The advantage of the cushion splint is that it causes the patients little or no inconvenience. It also is simple and cheap to make and easy to take off and put on in the daily care of the baby.

f) *The results of other clinical observations of the child.*

The information which I have collected about the length and weight of the child at birth shows considerable correspondence with the average figures for the country. Length and weight relationships in the series therefore give no support to the theory that space conditions in the womb are an etiologic factor in h.d.

As far as the position of the foetus in the womb is concerned, conditions on the whole agree with what is found in a normal material, with the exception that breech position occurs more often than usual.

6 children or 12 % were born in the breech position. This also corresponds with what is found in other series. It is asserted in the literature that children are born in the breech position because they are not so large and are more delicate than others and that their leg movements in the womb would therefore be less active. I find no support for this theory if length and weight are to form an expression of muscle activity. The average weight of the 6 children born in the breech position is 3560 gr., thus somewhat above the average for the whole series. This is in spite of the fact that one of these 6 children is a twin.

I also noted the mother's age at birth to see if this could have any importance in the etiology. The average age of the mother was 29.9 years. The series includes two cases of twins. In calculating the above figures I included the age of these mothers twice. If this error is corrected, an average age of 29.4 years results. The average age of 93 mothers with normal children amongst the 3242 examined equals 29.3 years, and therefore this forms no reason for the assertion that the mother's age has any significance in the development of h.d.

As with other series, definite information about other cases of h.d. in the family to a high figure were found, in this series the figure was 34 %. Moreover, it may be said that several children in the series are related. Finally it ought to be stated that amongst the 50 children 3 pairs of twins were affected. I found h.d. in both twins in two of the pairs. This also supports the theory of the familiar emergence of h.d.

On the basis of the information gathered about the length and weight of the children at birth, their foetus position, their order of birth in the family, the mother's age at birth and other cases of h.d. in the family, one can only draw the conclusion that h.d. occurs more often in children born in the breech position than in other foetus positions and that the disease seems to be conditioned by the respective family, facts which were well known from previous research.

SUMMARY AND CONCLUSION

The results are presented of an investigation into hip joint dysplasia in all children born at County Hospital in Ålesund, Norway, in the years 1955–57, in all 3242 children. The findings indicate an incidence of morbidity far above the accepted average for Norway.

On the basis of the series presented, it is thought that these conclusions may be drawn:

1. A clinical examination of the hip joints of all newborns should be consistently pursued.
2. A positive Ortolani's sign or a definite instability of the hip, when demonstrated in newborns, is a convincing symptom of hip joint dysplasia which demands treatment. Treatment should be commenced immediately after birth.
3. The normal hip joint in newborns can be moved passively with complete freedom without any form of crepitation. A repeated and constant crepitation in a certain position of the hip joint may indicate the presence of a dysplasia and ought to lead to control examination of the baby at 4 months of age, when the epiphysis is radiologically visible.
4. Limitation of abduction in the hip joint occurs rarely or never in in newborns as a sign of hip joint dysplasia.
5. In newborns clinical examination of the hip joints is so superior to X-ray examination that the latter can be dropped without consequences. It is only when the epiphyses becomes visible radiologically that the X-ray offers more than the clinical examination.
6. The reduction position achieved in the hip joints with a Frejka's cushion splint in children up to 9 months of age, is completely satisfactory and will in the great majority of patients provide recovery.
7. Treatment of hip joint dysplasia with Frejka's splint is so little troublesome to the patient and mother that commencement of treatment is justified even if there may be doubt about the diagnosis.

RESUME ET CONCLUSION

Présentation des résultats de l'examen concernant la dysplasie de l'articulation de la hanche pratiqué chez tous les enfants nés à l'Hôpital Fylke à Ålesund, en Norvège, dans les années 1955–57, en tout chez 3242 enfants. Les trouvailles indiquent une incidence de morbidité beaucoup plus élevée que la moyenne normalement présumée en Norvège.

Sur la base de cette série d'observations, on considère que les conclusions suivantes peuvent être tirées:

1. Il faut continuer à procéder à un examen clinique des articulations de la hanche chez tous les nouveau-nés.

2. Un signe Ortolani positif ou une instabilité définie de la hanche constatée chez un nouveau-né un symptôme certain de dysplasie de l'articulations de la hanche qui demande à être traitée. Le traitement doit être entrepris immédiatement après la naissance.

3. Le mouvement passif d'une articulation normale de la hanche chez les nouveau-nés est entièrement libre sans aucune forme de crépitation. Une crépitation répétée et constantée dans une certaine position de l'articulation de la hanche indique la présence d'une dysplasie et doit engager à un examen de contrôle du bébé à l'âge de 4 mois, lorsque l'épiphyse est radiologiquement visible.

4. La limitation de l'abduction de l'articulation de la hanche est rarement ou jamais constatée chez les enfants comme signe de dysplasie de l'articulation de la hanche.

5. Chez les nouveau-nés, l'examen clinique de l'articulation de la hanche est si supérieur à l'examen aux Rayons X que celui-ci peut être abandonné sans inconvénient. C'est seulement quand l'épiphyse devient visible radiologiquement que les Rayons X donnent plus que l'examen clinique.

6. La position de réduction pratiquée dans les articulations de la hanche au moyen d'une attelle Frejka chez les enfants jusqu'à l'âge de 9 mois est complètement satisfaisante et entraîne la guérison dans la grande majorité des cas.

7. Le traitement de la dysplasie de la hanche par l'attelle Frejka est si peu gênant pour le bébé et sa mère qu'il est justifié de l'entreprendre même si l'on a des doutes concernant le diagnostic.

8. Les résultats obtenus par le traitement conforme de la dysplasie de l'articulation de la hanche chez les enfants sont si bons qu'il devrait être possible dans un proche avenir de rayer les dislocations de la hanche comme problème orthopédique chez les enfants plus âgés ou les adultes.

9. Les données présentées concernant la position de l'enfant dans la matrice, la longueur et le poids après la naissance n'offrent aucune base à l'explication mécanique d'une dysplasie de l'articulation de la hanche.

ZUSAMMENFASSUNG UND SCHLUSSFOLGERUNGEN

Die Ergebnisse einer Untersuchung der Hüftgelenksdysplasien aller Kinder, die in den Jahren 1955–57 am Fylkes (Bezirks) Krankenhaus in Ålesund, Norwegen geboren wurden (insgesamt 3242 Kinder), werden vorgestellt. Die Befunde weisen eine Häufigkeit der Morbiditet auf, die weit höher als der angenommene Durchschnitt für Norwegen ist.

Auf Grund der vorgewiesenen Untersuchungsreihen glaubt man die folgenden Schlussfolgerungen ziehen zu können:

1. Eine klinische Untersuchung der Hüftgelenke aller Neugeborenen sollte konsequent vorgenommen werden.

2. Ein positives Ortolani Zeichen oder eine sichere Unstabilitet der Hüfte sind, sobald sie am Neugeborenen nachgewiesen werden, überzeugende Symptome einer Gelenksdysplasie und erfordern Behandlung. Diese soll unmittelbar nach der Geburt begonnen werden.

3. Das normale Hüftgelenk des Neugeborenen kann passiv vollständig unbehindert und ohne jegliche Krepitation bewegt werden. Eine wiederholte und konstante Krepitation in einer gewissen Stellung des Hüftgelenkes kann das Vorhandensein eine Dysplasie anzeigen und sollte zu einer Kontrolluntersuchung des Kindes im Alter von 4 Monaten, wenn die Epiphyse im Röntgenbilde sichtbar wird, führen.

4. Begrenzung der Abduktion im Hüftgelenk des Neugeborenen ist als ein Zeichen von Dysplasie kaum oder niemals vorhanden.

5. Bei Neugeborenen ist die klinische Untersuchung des Hüftgelenkes der Röntgenuntersuchung weitaus überlegen, so dass die letztere ohne Folgen fallen gelassen werden kann. Nur sobald die Epiphyse röntgenologisch sichtbar wird, bietet das Röntgenverfahren mehr als die klinische Untersuchung.

6. Die Einrenkungsstellung im Hüftgelenk, welche mit Frejkas Polsterschiene erzielt wird, ist bei Kindern bis zu 9 Monaten vollständig zufriedenstellend und wird für die Mehrzahl der Patienten eine Heilung ergeben.

7. Die Behandlung der Hüftgelenksdysplasie mit der Frejka-Schiene stört Kind und Mutter so wenig, dass die Inangriffnahme der Behandlung berechtigt ist selbst wenn Zweifel über die Diagnose bestehen.

8. Die Ergebnisse einer konsequenten Behandlung der Hüftgelenksdysplasie bei Säuglingen sind so gute, dass es möglich sein sollte, Hüftgelenksverrenkungen bei älteren Kindern und Erwachsenen als ein orthopädisches Problem in der nahen Zukunft auszuschalten.

9. Die vorgelegten Daten über die Lage des Kindes im Uterus, ferner über Länge und Gewicht bei der Geburt bieten keine Grundlage für eine mechanische Erklärung der Entwicklung von Hüftgelenksdysplasie.

REFERENCES

Andrén, L. & v. Rosen, S.: Acta Radiologica. Vol. 49. Fasc. 2: 89.
Burman & Clark: Am. J. of Roentgenology. *44*: 37, 1940.
Caffey, J. et al.: Pediatrics, *17*: 632, 1956.
Frejka, B.: Wiener Med. Wochenschrift, 91: 523, 1941.
Getz, B.: Acta Orthop. Scand. Suppl. XVIII, 1955.

Hart, V. L.: Congenital Dysplasia of the Hip Joint and Sequelae. Charles C. Thomas. Springfield, Ill. 1952.

Hilgenreiner, H.: Med. Klinik XXI. 1925. 2: 1385 and 1425.

Jacobson, E.: Sv. Läkartidn., 55: 33, 2427.

Köhler, A. & Zimmer, E. A.: Grenzen des Normalen und Anfange des Pathologischen im Röntgenbild des Skelettes. Georg Thieme Verlag, Stuttgart (10. Aufl.).

Laurenson, R. D.: JBJS. Vol. 41 B No. 4: 702.

Leeftmann, R.: JBJS. Vol. 41 B No. 4: 689.

Martin, H.: Radiology, 56: 842, 1951.

Nyström, B. & Zilliacus, H.: Nord. Med., 12 VII. 1956.

Palmén, K.: Sv. Läkartidn., 54: 1706, 1957.

Ponseti, J.: J. of the Iowa State Med. Society. Nov. 1950.

Ponseti, J.: Am. Academy of Orthop. Surg. Instructional Course Lectures. Vol. X. 1953.

Putti, V.: JBJS. Vol. XV: 16.

v. Rosen, S.: Acta Orthop. Scand. Vol. XXVI: 136.

v. Rosen, S.: Sv. Läkartidn., 54: 2879, 1957.

Severin, E.: Acta Chir. Scand. Vol. 84. Suppl. 63, 1941.

Sundal, A.: Universitetet i Bergen, Årbok 1957. Medisinsk rekke, nr. 1.

Walther, T. & Moe, B.: Tidsskr. for Den norske lægeforening. Nr. 20: 643, 1954.

Wiberg, G.: Acta Chir. Scand. Vol. 83, Suppl. 58, 1938.

HCPCS:	Descriptor:
L1810	KNEE ORTHOSIS, ELASTIC WITH JOINTS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
NO	YES	NO	NO	YES

Sample Diagnosis (Not Inclusive)	Knee sprains, strains, partial tears of the MCL and LCL, arthritics, valgus or varus instability.
Medically Necessary Argument	The knee orthosis is made of elastic, neoprene or like materials with hinged joints medially and laterally positioned over the knee joint. This device provides mild medio-lateral stabilization, circumferential support and resists hyperextension. The metal knee joints require proper adjustments to accommodate anatomical angles. Inappropriate fit puts the patient at risk of tourniquet injury and wounds resulting from inappropriate pressure on bony prominences and other negative outcomes.
References	

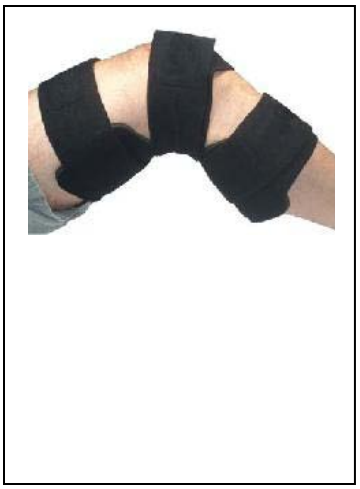
HCPCS:	Descriptor:
L1832	KNEE ORTHOSIS, ADJUSTABLE KNEE JOINTS (UNICENTRIC OR POLYCENTRIC), POSITIONAL ORTHOSIS, RIGID SUPPORT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	ACL tear, post op healing, knee sprain, and other related knee injuries
Medically Necessary Argument	This device is indicated for locked or limited motion control of knee during rehabilitation after operative procedures or injury to knee ligaments, cartilage, or stable or internally fixed fractures of tibial plateau, condyles, or proximal tibia and distal femur. The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for stabilization needed to facilitate healing. Failure to properly align/apply this device may lead to further injury of the knee.
References	

HCPCS:	Descriptor:
L1836	KNEE ORTHOSIS, RIGID, WITHOUT JOINT(S), INCLUDES SOFT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
NO	YES	YES	NO	YES

Sample Diagnosis (Not Inclusive)	Knee flexion contractures, post-op burns
Medically Necessary Argument	To allow for functional ROM by maintaining knee position.
References	

HCPCS:	Descriptor:
L1843	KNEE ORTHOSIS, SINGLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT (UNICENTRIC OR POLYCENTRIC), MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Osteoarthritis, DJD, knee instability, ACL injury, ligamentous injury
Medically Necessary Argument	This orthosis is designed to unload/stabilize the knee joint. A proper understanding of the diagnosis, knowledge of the anatomy of the knee joint and proper understanding of the knee orthosis and how to fit this and adjust the settings is crucial to proper functioning of the orthosis. Without this knowledge the orthosis would not be fit properly and the proper unloading effects would not be experienced. Knowledge and experience with these orthoses would allow the professional to know whether this orthosis will fit properly and control the excessive knee motion.
References	5, 6, 7

American Academy of Orthotists & Prosthetists

Professionals Advancing Care Through Knowledge

Efficacy of the Generation II Unloader Knee Orthosis in improving Lysholm Knee Rating Scale Scores in Patients with Medial Compartment Osteoarthritis

By Donald House, PT, OCS, CO

Abstract

Osteoarthritis of the knee joint can result in pain and instability, thus limiting the functional abilities of those stricken. The percentage of the world's population at risk for suffering pain and limitation due to OA is increasing considerably. These people are typically greater than 50 years old and are at high risk for surgical complications. Patients who are younger than 50 years old are also not optimal surgical candidates due to the high probability that they will require multiple revisions later in life.

Conservative management of mild osteoarthritis with heel wedges and neoprene sleeves has been suggested to be effective. In moderate to severe OA with reduction of the medial tibio-femoral joint space, a valgus inducing orthosis may be the only viable option to unload the medial joint and reduce pain during ADL's.

The purpose of this study was to determine whether patients would report less pain during normal ADL's after 1 month of orthotic treament with a Generation II Medial Unloader Knee Orthosis. The subjects included 9 patients that were referred to our clinic for orthotic management of knee osteoarthritis with c/o medial knee pain, and genuvarus. The subjects were asked to complete a Lysholm Knee Scale Questionnaire at the time of casting, then again at 1 month follow- up. Although 7 out of 9 patients reported improvement in pain and functional ability following treatment, there was no significant difference in functional knee scale scores obtained following orthotic treatment compared to those reported prior to orthotic management.

Introduction and Background:

Osteoarthritis (OA) is the most common disorder affecting synovial joints, with structural changes present in approximately half of the adult population (4). Kellgren and Lawrence performed clinical and roentgenologic assessment and deduced that 80% of persons 55 years or older experienced OA. The knee is the most commonly affected weightbearing joint, and varus deformity is the most common malalignment of the knee associated with osteoarthritis (4). As "baby boomers" are presently reaching this age, we expect that a growing percentage of the American public will be faced with pain and disability due to OA. It has also been documented that this population of patients is at a much

higher risk for complications during surgical procedures, therefore conservative alternatives may be a better option for many of these people (7).

Knee joint loading during walking or other routine ADL's has been shown to reach several times the loading caused by a static standing posture (1). A larger component of this reaction force is born by the medial compartment of the knee. Changes in bony alignment or loss of intrinsic soft tissue stabilizers can lead to increased asymmetry of knee joint loading patterns and cause more rapid progression of degenerative changes. For example, the presence of varus angulation results in approximation of the medial tibial plateau and medial femoral condyle which increases load on the medial compartment and accelerates breakdown of joint surfaces. Further more, the patient will often compensate by attempting to regain stability by forcefully contracting the musculature about the knee. This will also increase the compressive force across the joint. As the patient ambulates, the ground reaction force passes medial to the knee joint thus producing an adduction moment. This adduction moment combined with increased joint play due to loss of joint congruency results in high repetition, ballistic stretch of the surrounding soft tissue stabilizers. Since the bony anatomy of the knee joint does not provide any intrinsic stability, chronic lengthening of the collateral ligaments will result in gross coronal instability, and amplify the varus thrust during stance.

High tibial osteotomy has been used to reduce the varus deformity of the knee in an attempt to normalize bony alignment and reduce loading of the medial compartment. Unfortunately, patients who present with high adduction moments during gait prior to surgery have been shown to maintain that pattern or revert back to it within a few years post surgery (1). Many of these patients progress rapidly to requiring total knee replacement. Even then, a high incidence of component loosening is seen in patients who remain in varus. These unreliable surgical outcomes combined with risk of surgical complications, high cost, and time loss from normal work and activity make conservative treatment options attractive to many patients.

Orthotic treatment has been used as part of the conservative treatment for knee medial compartment osteoarthritis. Most common types or orthoses used include wedged insoles, knee sleeves, and unloading braces. Wedge insole orthoses have been shown to be effective only in early-stage OA; severe OA is not affected (7). Neoprene knee sleeves provide little or no mechanical support to the knee but may have some effect on improved stability and reduction of pain. Kirkley reports that good results have been described anecdotally however no controlled trials have been reported supporting the use of a sleeve. Unloading braces were developed to create a valgus force on the knee and reduce compression of the medial compartment during gait, which can be excessive when genuvarum due to OA is present. One such orthosis, the Generation II (G II) was designed in Canada by Generation II Orthotics Ltd. It is a polyaxial hinged brace that induces an increasing amount of valgus force to the knee as the patient moves from knee extension to flexion. The valgus force is thought to be beneficial in correcting bony alignment, and lessening the effect of the adduction moment placed on the knee in stance thereby reducing compression force in the medial knee compartment. If the medial joint space in OA patients could be enlarged using this orthosis, painful symptoms might be eliminated or decreased affording the patient improved function during ADL's.

Studies supporting Valgus bracing for OA would be useful to many members of the rehabilitation team. Physicians and surgeons can learn whether conservative options can be used instead of, or possibly in conjunction with surgery to correct bony alignment, protect prosthetic implants, improve knee stability and reduce the amplification of forces across the joint surfaces. Physical therapists may be interested in learning whether orthotic treatment can assist in reducing pain, thus allowing patients to maintain their current functional level while performing exercises to strengthen the knee stabilizers. Orthotists can benefit from research that explores not only the use of Valgus bracing for treatment of

knee OA, but also the use of outcome measures to evaluate the effect that orthotic treatment has on the patients perceived level of pain and disability.

The purpose of this study is to evaluate the effectiveness of valgus bracing for medial compartment knee osteoarthritis, to assess the appropriateness of the Generation II Unloader Orthosis in patients with medial knee joint OA, and to examine the use of the Lysholm Knee Rating Scale as a functional outcome measure for support of orthotic treatment of knee osteoarthritis.

Previous Investigations

Matsuno et al. studied 20 subjects who were all >55 y/o with bilateral knee arthritis but retained at least 50% of normal tibio-femoral joint space, and could walk at least 500 meters independent of support. The side experiencing the most severe symptoms was fitted with a Generation II Medial Unloader Knee Orthosis that was worn at all times except for at night.

Clinical Assessments were performed each month following GII application. The functional objective efficacy of the orthosis was assessed utilizing the modified knee scoring system of the Japan Orthopaedic Association, which evaluates pain on walking and on climbing up and down stairs. X-rays were taken both in and out of orthosis every 2 months. Quadriceps muscle strength was assessed isokinetically using a dynamometer. A stabilometer was used to record the excursion of the patients center of gravity during 30 seconds of static standing.

The authors reported that the JOA Knee Scores significantly improved with application of the orthosis and continued to improve throughout the 12 month observation period. The femorotibial angle (genuvarum) decreased after 2 months in the orthosis and remained decreased at 12 month follow-up. The isokinetic quadriceps muscle strength with the brace on increased throughout the full range of motion. Also, decreased total movement of the center of gravity was noted in the orthosis suggesting improvement in the lateral stability of the knee (7).

Hewett, Noyes et al. studied 19 subjects with persistent chronic medial tibiofemoral compartment pain that affected sports or daily activities, arthroscopic or radiographic documentation of medial compartment arthrosis, or varus osseous alignment. Patients were fitted with a valgus inducing orthosis (Bledsoe Brace Systems) and were instructed to wear the brace for as many hours and for as many days of the week as they wished. All patients had undergone multiple operative procedures, including arthroscopies, partial or total meniscectomies, high tibial osteotomies, and anterior cruciate ligament reconstruction. Evaluation was performed before brace wear, after the initial follow-up evaluation (mean: 9 weeks), and after the final follow up evaluation (mean: 46 weeks). Patients completed a Cincinnati Knee Rating System questionnaire, and visual analog scale. They were asked how many minutes they could walk without significant pain, how painful their knee was after 30 and 60 minutes of mall shopping, and whether none, some, or significant pain relief was provided by only the brace, by only the medication, or by both the brace and the medication. Patients were also asked to rate the overall condition of their knee on a 1 to 10 scale with 1 indicating the poorest knee and 10 indicating a normal knee. At the two follow-up evaluations, patients were asked to provide and average of hours per day and days per week that the brace had been worn. X-rays were repeated at follow-up, and 9 patients underwent gait analysis testing.

According to the authors, 78% of the patients reported severe pain with ADL's prior to brace wear, compared to only 39% at the first follow-up and 31% at the final follow-up. Pain analogue scale scores decreased significantly between the pre-orthosis and both follow up evaluations. Reported walking tolerance increased from 51 minutes pre-orthosis to 138 minutes at 9 week follow up. The patients reported average walking tolerance of 107 minutes after 1 year of wearing the valgus

inducing orthosis. Gait evaluation showed no change in the mean value for the knee adduction moment in stance. At pre-brace evaluation, the mean patient's self perception of knee score was 3.4 points out of 10. At the first follow-up evaluation, the mean score had improved to 5.4, and it remained improved at 4.7 at second follow-up (2).

Kirkley et al. randomized 119 patients into 3 groups to compare the effectiveness of valgus bracing (GII) to patients treated with a neoprene sleeve and a control group, which received no orthosis. Two disease specific, health related, quality of life measures and two functional scores were used at the baseline and all follow-up evaluations. The Western Ontario and McMaster University Osteoarthritis Index (WOMAC), and McMaster-Toronto Arthritis Patient Preference Disability Questionnaire (MACTAR) were used to assess the patients perceived functional limitations while a six minute walking test and 30 second stair climbing test were used as functional measures.

The authors reported that patients who underwent valgus bracing showed significantly improved WOMAC scores compared to the group that wore a neoprene sleeve, who in turn improved significantly more than the control group. No significant difference could be detected between the unloader brace group and the neoprene sleeve group, or between the sleeve group and the controls. Distance walked and the number of stairs climbed during functional testing were not statistically different among the three groups at 6 month assessment however pain scores in the valgus braced group were significantly less than those for the neoprene sleeve and control groups following both tests(4).

Lindenfeld et al. examined whether a brace designed to unload varus degenerative knees actually alters medial compartment load by decreasing the knee adduction moment during gait. Eleven patients who had undergone arthroscopic debridement and other associated arthroscopic procedures for persistent medial knee pain during ambulation, but continued to have pain post surgically were used for the study. These patients were fitted with a valgus knee brace (Big Sky Medical, Bozeman, MI) and underwent gait analysis before and after a minimum of 4 weeks wearing the brace. They also completed questionnaires and were interviewed for the assessment of symptoms, sports activities, and functional limitations according to the Cincinnati Knee Rating System. Results were compared to a group of controls without a brace, with no knee injury, that were matched for walking speed and performed identical tests.

Investigators reported that pain symptoms decreased significantly with brace wear. The pain scores recorded from analog pain scale decreased 48% in the brace group, activity level achieved without pain symptoms increased 69%, and function with activities of daily living score of the Cincinnati Knee Rating System increased 79%. Nine of 11 patients had a decrease in the adduction moment of the involve knee when wearing the brace, with the moment decreasing by as much as 32% (5).

Methods:

All patients (n=11) who were referred to our clinic from 1/1/2001 and 6/30/2001 for orthotic treatment secondary to knee osteoarthritis who presented with varus angulation of the knee (varus >0 degrees), and complained of medial knee pain were asked to participate in the study. Patients were excluded from the study if they reported a past medical history that includes: knee surgery, hip surgery, cardiac or respiratory problems, recent lower extremity fractures, loss of sensation in the legs or feet, or open wounds within the trim lines of the orthosis, or if they had ever worn a knee orthosis. No patients were excluded because of age, race, or gender. One patient was excluded from the study due to lack of follow-up, and one additional subject was excluded due to inconsistent responses on his questionnaire compared with his functional level. All patients who were not excluded (appendix A) and agreed to participate were asked to sign a consent form (appendix B). Participants were asked to

complete a Lysholm Knee Scale Questionnaire (appendix C). The Lysholm Knee rating scale is reported to have an intrapersonal and interpersonal coefficient of variation of 3%, and 4% respectively. Test-retest reliability level was excellent with a calculated correlation coefficient of .97 (6). This scale is especially appropriate for self-evaluation of function in the typical OA patient in that unlike most other knee function questionnaires, it assesses normal ADL's rather than sports specific activity. The scale is easy to administer and score. All patients were fitted with a Generation II Medial Unloader Knee Orthosis as per manufacturers specifications (Generation II Orthotics Ltd., Canada). The patients were instructed to wear their orthosis whenever they were active. At 1 month follow-up, the patients were asked about any problems that they may have experienced with the orthosis and whether they had complied with the prescribed wearing schedule. They were also asked to complete another Lysholm Knee Scale Questionnaire.

Knee Scale Scores were calculated as recommended by Lysholm. Pre-orthosis and post-orthosis scores were compared statistically using a paired T-test design with significance level of .05, and were used to prove or disprove the research hypothesis that valgus bracing is effective in reducing the Lysholm Knee Rating Scale Scores in patients with pain and functional limitation due to medial compartment osteoarthritis.

Results:

Initial Lysholm Knee Scale scores ranged from 26% to 64% with a mean score of 45.1%. Treatment time preceding follow-up ranged varied due to patient non-compliance with scheduled follow-up appointments. Mean follow-up time was 10.9 weeks with a range from 4 weeks to 27 weeks. Post-treatment Lysholm Knee Scale scores ranged from 16% to 93% with a mean score of 63% (Table 1).

Table 1

Pre-score	Post-score	Time to follow-up	Change in Score
44%	72%	15 weeks	28%
44%	62%	10 weeks	18%
55%	60%	5 weeks	5%
64%	82%	6 weeks	18%
29%	71%	7 weeks	42%
55%	93%	4 weeks	38%

26%	24%	14 weeks	(-) 2%
36%	16%	10 weeks	(-) 20%
53%	87%	27 weeks	34%

Data was compared using a 2 tailed paired t-test. The t-test indicated that the Lysholm Scale scores at follow-up were not statistically different from those obtained prior to orthotic treatment at a significance level of 0.05.

Conclusion:

The results of this study suggest that although 7 out of 9 subjects reported improvement in pain and functional ability after treatment, there was no significant difference in functional knee scale scores obtained following orthotic treatment compared to those reported prior to orthotic management. The subject sample size utilized in this study was small due to time constraints. Treatment time was not well controlled and varied significantly between subjects. Additional studies with larger sample sizes, better regulation of treatment time, specific patient populations, and the use of other manufacturers orthotic devices for valgus knee bracing are needed to explore the efficacy of this treatment.

APPENDIX A

Name:_____ AGE:_____

Have you ever had any of the following?

Yes No Don't Know

1. Knee Surgery ___ ___ ___
2. Hip Surgery ___ ___ ___
3. Cardiac or Respiratory Problems ___ ___ ___
4. Recent Fractures ___ ___ ___
5. Loss of Sensation in your legs ___ ___ ___
6. Open wounds on your legs or feet ___ ___ ___

Have you ever worn a knee brace? If so what type?

Do you know of any reason that it may be harmful for you to wear a knee brace as prescribed by your physician at this time? If yes, please explain:

_____ _____

Participant Orthotist

Appendix B

Lysholm Knee Rating System

Name_____ Date_____ Therapist_____

By completing this questionnaire, your therapist will gain information as to how your knee functions during normal activities. Mark the box which best describes your knee function today.

1.	LIMP (5 points)	
	☐ None	5
	☐ Slight or periodic	3
	☐ Severe and constant	0
2.	SUPPORT (5 points)	
	☐ None	5
	☐ Cane or crutch needed	2
	☐ Weight bearing impossible	0
3.	LOCKING (15 points)	
	☐ None	15
	☐ Catching sensation, but no locking	10
	☐ Locking occasionally	6
	☐ Locking frequently	2
	☐ Locked joint at examination	0
4.	INSTABILITY (25 points)	
	☐ Never gives way	25
	☐ Rarely during athletic activities/physical exertion	20
	☐ Frequently during athletic activities/physical exertion	15
	☐ Occasionally during daily activities	10
	☐ Often during daily activities	5
	☐ Every step	0
5.	PAIN (25 points)	
	☐ None	25
	☐ Intermittent and light during strenuous activities	20
	☐ Marked during strenuous activity	15
	☐ Marked during or after walking more than 2 km. (1.2 mi.)	10
	☐ Marked during or after walking less than 2 km. (1.2 mi.)	5
	☐ Constant	0
6.	SWELLING (10 points)	
	☐ None	10
	☐ After strenuous activities	6
	☐ After ordinary activities	2
	☐ Constant	0
7.	STAIRS (10 points)	
	☐ No problem	10
	☐ Slight problem	6
	☐ One step at a time	2
	☐ Impossible	0
8.	SQUATTING (5 points)	
	☐ No problem	5
	☐ Slight problem	4
	☐ Not beyond 90° of flexion of the knee (halfway)	2
	☐ Impossible	0

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References

1. Andriacchi T. Dynamics of Knee Malalignment. Orthopedic Clinics of North America 1994; 25: 395-403.

2. Hewett, T.E.; Noyes, F.R.; Barber-Westin S.D.; Heckmann, T.P. Decrease in knee joint pain and increase in function in patients with medial compartment arthrosis: a prospective analysis of valgus bracing. Orthopedics 1998; 21: 131-138.

3. Horlick S; Loomer R. Valgus Knee Bracing for Medial Gonarthrosis. Clin J Sport Med1993; 3: 251-255.

4. Kirkley, M.D., et al. The Effect of Bracing on Varus Gonarthrosis. Journal of Bone and Joint Surgery 1999; 81-A: 539-548.

5. Lindenfeld, Hewett, T.E.; Andriacchi T. Joint Loading with Valgus Bracing in Patients with Varus Gonarthrosis. Clinical Orthopedics and Related Research 1997; 344: 290-297.

6. Lysholm. Rating Systems in the Evaluation of Knee Ligament Injuries. Am J Sports Med. 1982; 10: 150-155.

7. Matsuno, H; Tsuji, H. Generation II Knee Bracing for Severe Medial Compartment Osteoarthritis of the Knee. Arch. Phys. Med. And Rehab.1997; 78: 745-749.

The Effectiveness of Off-Loading Knee Orthoses in the Reduction of Pain in Medial Compartment Knee Osteoarthritis: A Systematic Review

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ABSTRACT

The purpose of this review is to determine the effectiveness of knee orthoses in the treatment of pain in unilateral compartment osteoarthritis (OA). OA is the most common disorder affecting synovial joints, with structural changes of OA present in approximately half of the adults. The knee is the most commonly affected joint. Many treatments have been developed for OA, including the unloader knee orthosis. The principle of the unloader knee orthosis is to create a varus or valgus moment at the knee—theoretically creating additional space in the joint compartment, thus relieving pain caused by bone-on-bone contact. Several studies have been done, but none with a power or number of participants were large enough to demonstrate effective treatment of OA. Using the keywords "knee osteoarthritis" and "orthosis" or "brace," the PubMed, CINAHL, RECAL, and ISI Web of Knowledge electronic databases were searched for randomized control trials with "orthoses" or "braces" for the knee between January 1980 and December 2010. Only studies that dealt with medial unilateral compartment knee OA and the use of a knee orthosis were selected. Of these articles, only experimental trials were selected based on the American Academy of Orthotists and Prosthetists State-of-the-Science Evidence Report Guidelines. A comparative analysis of the articles was used to determine the effectiveness of the orthoses in reducing pain. Forty-six initial articles were found. Of these, 15 articles were ultimately included and reviewed based on the inclusion guidelines. Most of these articles were either single-subject research or before-and-after studies. The majority were of moderate quality. Statistically significant pain reduction was noted by 73% of the studies reviewed, although all showed that there was pain reduction in the patients. Patient function and orthosis efficacy were also briefly examined, showing moderate increases of function. The rate of pain relief was further investigated and revealed that pain relief was almost immediate. OA knee orthoses are a cost-effective way to reduce pain in patients with medial compartment OA. (*J Prosthet Orthot.* 2012;24:39–49.)

KEY INDEXING TERMS: osteoarthritis, knee orthoses, brace, knee, pain, function

Osteoarthritis (OA) is a debilitating disease that affects millions of people worldwide. It is the most common type of arthritis and is a major cause of musculoskeletal pain and disability in elderly populations.[1] In the United States alone, 6% of the adults aged 30 years and older (roughly 10 million individuals) have symptomatic OA of the knee.[2] OA of a single compartment is distinguished from that of both compartments. The single-compartment OA is associated with malalignment and increased risk and progression of knee OA, therefore predicting decline in function. Those with medial compartment OA often have a varus alignment observed during gait evaluation, as the mechanical axis and weightbearing pass through the medial compartment. Patients with OA of the lateral compartment usually have a valgus alignment, and the mechanical axis and weightbearing pass through the lateral compartment.[3] With so many affected, multiple treatment modalities have been developed. There are >50 nonpharmacological, pharmacological, and surgical interventions for the treatment of OA. Nonsurgical treatment methodologies are generally tried first. If these relieve pain, increase function, and slow the progression of the disease, then surgical interventions are delayed. Surgical interventions include knee joint replacement, both full and partial; high tibial osteotomy; and fusion as a last resort when joint replacement has failed.[4]

OA knee bracing is one of these nonsurgical interventions. Introduced in 1989, it has become a popular mode of treatment for the OA knee.[5] The orthoses function by the use of a mechanical lever arm that reduces the forces transferred through the affected compartment, "off-loading" those affected compartments with unilateral OA by creating a valgus or varus moment at the knee depending on the affected compartment. This, in turn, reduces pain and increases function.[6]

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Although some research in OA unloading knee orthoses has demonstrated an increase in function with various scales and measurement tools,[7,8] probably the most practical and easiest way for the orthotists to demonstrate clinical effectiveness through evidence-based practice is by measuring pain. Evidence-based practice seeks to inform clinical decision making by combining a practitioner's training and experience with evidence established through scientific research.[9] If pain reduction is a goal of the orthotic intervention process, using pain as a measurable benchmark can demonstrate that an orthosis is an effective treatment modality. The visual analog scale (VAS) is a common, well-established measuring device to track this.[10]

With the growth and acceptance of the market for these orthoses, there have been multiple articles and studies published on the topic. Although some articles focus on the biomechanical aspects of the knee and its varus and valgus moments, others consider whether or not function is increased by the use of knee orthoses. Other articles reveal the long-term effects of the orthosis; still others investigate pain reduction of the participant with the orthosis. Some articles include various combinations of these aspects of study. By documenting the ability of the unloading knee orthosis to reduce pain in those suffering from unilateral OA of the knee through research, the authors of this article may prove what clinical practice has already shown to be effective: that OA unloading knee orthoses are effective in the relief of medial compartment OA knee pain.

METHODS

Using the keywords "knee osteoarthritis" and "orthosis" or "brace," the PubMed, CINAHL, RECAL, and ISI Web of Knowledge electronic databases were searched for randomized control trials with orthoses or braces for the knee between January 1980 and December 2010. The exact Boolean search phrase used was [(knee osteoarthritis) and (orthosis or brace)]. The RECAL and CINAHL databases were selected for their orthotic-specific search capabilities. The RECAL database was compiled by the National Centre for Prosthetics and Orthotics and the service designed and developed by the Centre for Digital Library Research, both of the University of Strathclyde.[11] CINAHL was selected because it included the *Journal of Prosthetics and Orthotics*.

To standardize the process of literature review and selection, the American Academy of Orthotists and Prosthetists (AAOP) has developed a study design classification scale, which is used to classify the study type when performing a literature review. Research is divided into four categories: structured reviews, (quasi) experimental trials, observational studies, and expert opinion. It was decided that experimental trials would best demonstrate the effectiveness of the OA knee orthosis in relieving pain in the OA knee.[12]

Only those articles that were experimental or quasi-experimental trials were selected, based on the AAOP State-of-the-Science Evidence Report Guidelines. The studies reviewed needed to be prospective research studies with multiple subjects. They must have some comparison, whether it is between conditions or between a control group and an intervention group. The studies must also have had one or more interventions and the data gathered and documented intervals. The five groups established by the AAOP State-of-the-Science Evidence Report Guidelines are randomized control trial (E1), controlled trial (E2), interrupted time series trial (E3), single-subject experimental trial (E4), or a controlled before-and-after trial (E5). The difference between these is the number of subjects, random assignment of the subject(s) and control(s), and the frequency of data collection. A comparative analysis of the studies will be used to determine the effectiveness of the orthoses in the area of pain.[12]

Only studies that dealt with medial unilateral compartment knee OA and the use of a knee orthosis were selected. The medial compartment is involved in 91% of unilateral cases of OA, 10 times more often than the lateral compartment.[13] This can partly be attributed to the increased load carried by the medial compartment. Approximately 60% to 80% of the load across the knee is transmitted through the medial compartment.[14] To keep the demographic population consistent, only those studies that investigated medial compartment OA were evaluated. This eliminated variables associated with varus or valgus moments that affect the biomechanics and function of the orthoses and therefore the effect on pain.[15]

Methodological quality was assessed using a modified version of the State-of-the-Science Evidence Report Guidelines Quality Assessment Form.[12] All items have "yes," "no," or "N/A" answer options. Fourteen questions were asked: six on internal validity and eight regarding external validity (Table 1). Because of the nature of many of the studies and the justification for the literature review, it was thought by the reviewers that external validity should be more heavily favored because of the desire for clinical application.

After the articles were reviewed, they were then scored. Those articles that scored five or below were considered of low quality and were rejected for review. Those articles that scored from 6 to 10 were considered moderate quality, whereas those that scored from 11 to 14 were considered high quality. Both moderate- and high-quality articles were reviewed. A high score indicated that the reviewers evaluated the study to have few to no confounding factors or bias, which would limit the usefulness of the study in its applicability. A study of moderate quality indicated that there are areas of bias introduced into the study, somewhat limiting the value and usefulness of the results. A low score indicated that the reviewers believed that there were many confounding factors and bias introduced in the study and that there were serious problems with the applicability of the study to clinical practice.

RESULTS

The initial Internet database search yielded 306 articles. From CINAHL, 19 articles were located, 64 from the ISI-Web

Table 1. Methodological quality assessment.

	Yes	No	N/A	Comments	
Criterion—internal validity					
IV-1. Control/comparison group appropriate					
IV-2. Inclusion criteria appropriate					
IV-3. Exclusion criteria appropriate					
IV-4. Protocol addresses accommodation and washout					
IV-5. Attrition explained and <20%					
IV-6. Free from conflicts of interest					
Total number of threats identified					
Criterion—external validity					
EV-1. Sample characteristics adequately described					
EV-2. Sample representative of the target population					
EV-3. Outcome measures adequately described					
EV-4. Outcome measures valid for this study					
EV-5. Intervention adequately described					
EV-6. Findings clinically significant/relevant					
EV-7. Conclusions placed in context of existing literature					
EV-8. Conclusions supported by findings					
Total number of threats identified					
Combined total number of threats identified					
Overall assessment of internal and external validity (circle one)	High			Moderate	Low

of Knowledge, 100 from the RECAL database, and 123 from the PubMed database. A review of the titles and abstracts of these initial 306 articles resulted in 265 being excluded based on inclusion and exclusion criteria. The remaining 41 were pearled ("pearling" is a search for additional references within references located for review), and 5 additional articles were located. These remaining 46 articles were reviewed, and 31 were excluded from the study for the following reasons. In 16, pain was not considered in the study; 9 were not level E5 to E1; in one study the knee orthosis was used after knee arthroplasty; in one study no knee orthoses were used, and the study was unclear as to the mode of treatment; in one study the methodology was unclear; one was not in English; one was a meeting abstract; and one was a product development paper (Figure 1). Fifteen articles were included for review.

Of these 15, there were 3 randomized control trials selected (E1), one interrupted time series trial (E3), six single-subject experimental trials (E4), and five before-and-after trials (E5). A quality analysis resulted in nine studies that were of moderate quality and six studies of high quality. Only one study[16] had a perfect score, indicating that the reviewers believed that there was little bias introduced in this study; this study used gait parameters as a primary outcome measure and pain as a side measure. There were no studies of low quality reviewed. Studies tended to score lower on questions of internal validity than external validity. Some of the best organized and well-written studies were funded by manufacturers who introduced additional bias into the studies (Table 2).

A brief summary of the applicable data from each reviewed articles is as follows. If numbers were given in the study, then they are reported below, otherwise statistical significance was considered.

Barnes et al. published "Effect of CounterForce Brace on Symptomatic Relief in a Group of Patients With Symptomatic Unicompartmental Osteoarthritis: A Prospective 2-Year Investigation" in the *American Journal of Orthopedics* in 2002. Thirty patients from the clinical population of Barnes et al. were selected as participants in this study. Patients completed the American Academy of Orthopaedic Surgeons (AAOS) arthritis questionnaire, the short-form SF-36® Health Survey, and VAS on pain levels both on a daily and on a weekly basis. Participants were fitted with the CounterForce ™ (Breg, Vista, CA) orthoses from Breg®. After 8 weeks of treatment, participants again completed the AAOS and SF-36 forms. A follow-up after 2.5 years was also completed. With both the AAOS and SF-36 forms, symptoms improved in all categories during the 8-week period. The patients' responses to questions in the weekly log were also of note. Statistically significant decreases in pain during the duration of that time were documented, as well as a marked decrease in weeks 1 to 3. Pain relief in the orthosis was initially dramatic but seemed to level out after week 3. There was another marked decrease in pain between weeks 7 and 8. There were inconclusive results as to the decreased use of pain medications while using the orthosis. At the long-term follow-up, 21 individuals (73%) indicated that the orthosis was effective in relieving their pain.[17]

Brouwer et al. published "Brace Treatment for Osteoarthritis of the Knee: A Prospective Randomized Multi-Centre Trial" in *Osteoarthritis and Cartilage* in 2006. Participants in this study were originally treated with standard conservative treatments. Patients were either originally fit with an OAsys orthoses from Innovation Sports or were in a control group that was not treated with any orthosis but instead continued with standard treatment. One hundred eighteen

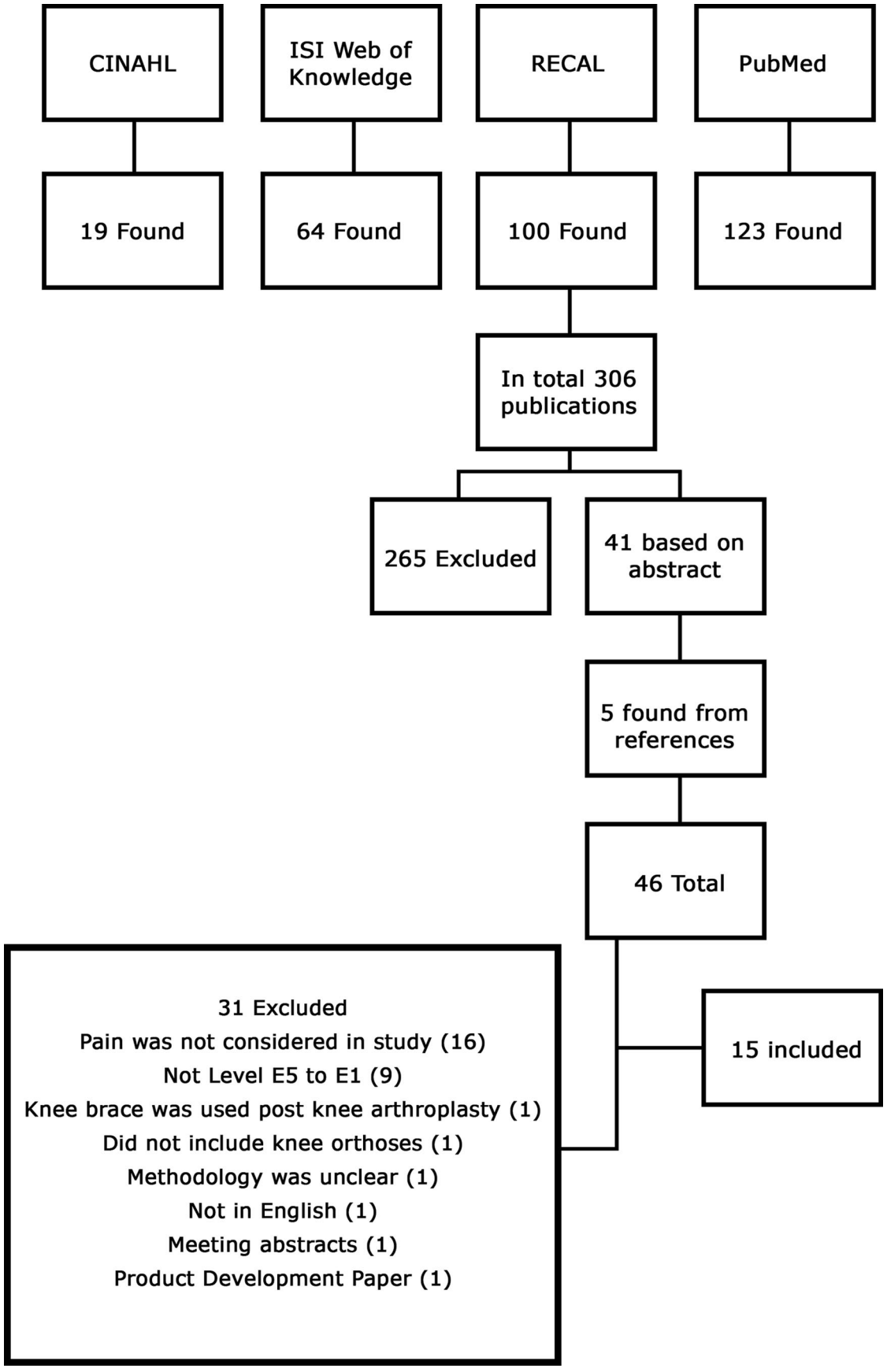

Figure 1. Literature search results.

Table 2. Methodological quality assessment results.

Author	Study level of evidence	Parameters	Participants	Device used	Selection																		0–5 Low, 6–10 moderate, 11–14 high
					Internal validity							External validity									Total score	Quality	
					IV-1	IV-2	IV-3	IV-4	IV-5	IV-6	Total	EV-1	EV-2	EV-3	EV-4	EV-5	EV-6	EV-7	EV-8	Total			
Barnes et al.	E-5	AAOS arthritis questionnaire, SF-36 health survey, VAS	30	Breg Counterforce OA knee brace	1	0	0	1	0	0	2	1	1	1	1	1	1	0	0	6	8	Moderate	
Brouwer et al.	E1	VAS, HSS, Walking distance, EuroQol5D)	117	OAsys brace, Innovation sports	1	1	1	1	0	1	5	1	1	1	1	1	1	1	1	8	13	High	
Dennis et al.	E5	Subjective patient reported measure	45	Bledsoe Thruster 2, DJ OAdjuster, Innovations sports OAsys, Generation II, Ossur	1	1	0	0	1	0	3	1	0	1	1	1	1	1	1	7	10	Moderate	
Draganich et al.	E4	WOMAC	10	OAdjuster AND oa Defiance from DJ	1	1	1	1	0	0	4	1	1	1	1	1	1	1	1	8	12	High	
Finger et al.	E4	VAS	23	OAdjuster DonJoy	1	1	0	1	1	0	4	0	0	1	1	1	1	1	0	5	9	Moderate	
Gaasbeek et al.	E4	WOMAC, VAS	15	SofTec OA brace (Bauerfeind, GmbH)	1	1	1	1	0	0	4	0	1	1	1	1	1	0	1	6	10	Moderate	
Horlick and Lommer	E4	VAS	40	Generation II (Ossur)	1	1	1	1	1	0	5	0	1	1	1	1	1	1	1	7	12	High	
Kirkley et al.	E1	WOMAC	110	Generation II (Ossur)	1	1	1	1	1	0	5	1	1	1	1	1	1	1	1	8	13	High	
Lindenfeld et al.	E4	VAS	11	Generation II (Ossur)	1	0	0	1	0	1	3	0	0	1	1	1	1	1	1	6	9	Moderate	
Matsuno et al.	E5	Self-reported	20	Generation II (Ossur)	1	0	1	1	1	0	4	0	0	1	1	1	1	1	1	6	10	Moderate	
Pagani et al.	E4	WOMAC	11	28K20/21 (Otto Bock)	1	1	0	1	0	1	4	0	0	1	1	1	1	1	1	6	10	Moderate	
Ramsey et al.	E3	Knee injury and Osteoarthritis Outcome Score (KOOS)	16	Generation II (Ossur)	1	1	0	1	1	1	5	0	0	1	1	1	1	0	1	5	10	Moderate	
Richards et al.	E5	VAS, HSS	12	Generation II (Ossur), Bilateral uniaxial hinge B1 (Trulife)	1	1	0	1	1	1	5	0	0	1	1	1	1	1	0	5	10	Moderate	
Schmalz et al.	E5	VAS	16	28K20/21 (Otto Bock)	1	1	1	1	1	1	6	1	1	1	1	1	1	1	1	8	14	High	
van Raaij et al.	E1	VAS, WOMAC	91	MOS Genu (Bauerfeind AG)	1	1	1	1	1	1	6	1	1	0	1	1	1	1	1	7	13	High	
		VAS, HSS, WOMAC	567																				

VAS, visual analog scale; HSS, Hospital for Special Surgery; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

patients were admitted in the study and randomized into two different groups. Patients were assessed using both the VAS and the Hospital for Special Surgery OA form (HSS). Compared with the controls, pain severities on the VAS scale were less in the orthosis group at each of the three assessment points as well as overall during the 12-month follow-up. At 12 months, the difference was borderline significant; however, in both instances, significant pain reduction versus the control group was not found.[3]

Dennis et al. published "An In Vivo Analysis of the Effectiveness of the Osteoarthritic Knee Brace During Heel Strike and Midstance of Gait" in the *Acta Chirurgiae Orthopaedicae Et Traumatologiae Cechoslovaca*, a Czech orthopedic journal, in 1999. In it the researchers analyzed the gait of 40 subjects during heelstrike and midstance, which are both weightbearing conditions, using video fluoroscopy to determine whether unloading knee orthoses actually provide separation of the femoral condyle from the tibial plateau, thereby avoiding excessive loads on the degenerated compartment. Participants were also asked to state if the orthosis reduced their pain, though not rated on a VAS or other measuring device. Thirty-four of the 40 participants indicated that they had pain relief from the orthosis, whereas 6 did not. It was noted by the authors that all of these had a body mass index >20% of their ideal body weight and had no condylar separation. Although the authors documented that lack of subjective pain relief correlated with no condylar separation, no statistical analysis was done to determine whether this was a significant association.[18]

Dennis et al. published his findings again with a parallel study in 2006 in the *Journal of Arthroplasty* under the title, "Evaluation of Off-Loading Braces for Treatment of Unicompartmental Knee Arthrosis." As before, it was documented that 34 of the 40 participants, or 85%, stated they had pain relief from the orthosis, whereas 6 did not. Again, no statistical analysis was done to determine whether this was a significant association between subjective pain relief and condylar separation.[19]

Draganich et al. published "The Effectiveness of Self-Adjustable Custom and Off-the-Shelf Bracing in the Treatment of Varus Gonarthrosis" in the *Journal of Bone and Joint Surgery* in 2006. Ten patients were evaluated in two orthoses in a random order. One was custom fabricated for them and the other was an off-the-shelf model. Pain and function were both assessed using the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) index (which measures pain, stiffness, and physical function).[20] Measurements were taken before application of the orthoses and after 4 to 5 weeks after application of the orthoses. Pain was significantly reduced from an average baseline of 197 to 120 mm with the off-the-shelf model and to an average of 71 mm with the custom orthosis. There was a significant difference between each of the three testing parameters. Function increased significantly only with the custom orthosis over the baseline. The authors attributed this success of the custom model to the better fit of the custom orthosis. The authors further state that their study suggests that an intimate fit is necessary for improved results and increased pain relief.[21]

Finger et al. published "Clinical and Biomechanical Evaluation of the Unloading Brace" in the *Journal of Knee Surgery* in 2002. Twenty-three participants were assessed preapplication of the orthosis and at three months using a 10-point pain scale. At three months, the average resting pain decreased from 4.2 to 1.9, pain with activity decreased from 7.2 to 3.9, and night pain decreased from 3.9 to 2.4. No statistical analysis was done on these numbers to determine whether the changes were significant.[22]

Gaasbeek et al. published "Valgus Bracing in Patients With Medial Compartment Osteoarthritis of the Knee: A Gait Analysis Study of a New Brace" in *Gait and Posture* in 2006. Fifteen patients with medial compartment OA were fit with a pneumatic knee orthosis, which provided a medial force that was designed to off-load the medial compartment of the knee. Baseline measurements were taken before the fit of the orthosis and after 6 weeks of continuous wear. The VAS pain scores showed a statistically significant change. The average score was 6.8 ± 2.5 without the orthosis and 4.7 ± 3.0 with the orthosis. The WOMAC score also showed a statistically significant change. The average score was 50.1 ± 17.6 without the orthosis and 63.0 ± 18.4 with the orthosis.[23]

Horlick et al. published "Valgus Knee Bracing for Medial Gonarthrosis" in the *Clinical Journal of Sports Medicine* in 1993. Thirty-nine participants were fit with the generation II unloader orthosis, some with the hinge on the lateral side and some with the hinge on the medial side. Participants were then randomly assigned to one of four treatment sequences: (a) brace in neutral, brace in valgus, and no brace; (b) brace in neutral, no brace, and brace in valgus; (c) brace in valgus, no brace, and brace in neutral; and (d) brace in valgus, brace in neutral, and no brace. Although an option, Horlick decided not to start participants out in the no-brace stage because it did not differ from the pretreatment status. During the study, participants filled out a daily pain and function log. Twenty participants had laterally hinged orthoses, and 19 participants had medially hinged orthoses. The VAS showed a statistically significant decrease in the pain level from baseline to valgus and a marginally significant decrease from baseline to neutral, using the lateral hinge. Somewhat stronger evidence of differences was seen with the medial hinge. Both baseline to valgus and baseline to neutral were statistically significant. Something that was noted by the authors was a carryover effect of the orthosis into the no-brace, washout phase. Continuing relief of pain was experienced in the no-brace phase of the study by both those with the valgus and neutral orthoses.[24]

Kirkley et al. compared the neoprene knee sleeve, a custom-made unloader orthosis, and no treatment, in their study, "The Effect of Bracing on Varus Gonarthrosis," published in the *Journal of Bone and Joint Surgery* in 1999. One hundred ten patients participated in the study, with 33 in the control group, 36 in the neoprene knee sleeve group, and 41 in the unloader group. The researchers found a significant

difference between treatment groups as far as pain. The six-month assessment showed a significant difference among the treatment groups with regard to the mean aggregate change score for the WOMAC. There was an increase in pain equal to 13.1 mm for the control group, a decrease in pain equal to 13.1 mm with the neoprene sleeve group, and 43.2 mm with the unloader orthosis group. It was remarkable that most of the pain relief came in the first 6 weeks with continued relief tapering off in the following weeks.[25]

In 1997, Lindenfeld et al. published "Joint Loading With Valgus Bracing in Patients With Varus Gonarthrosis" in *Clinical Orthopaedics and Related Research*. The researchers investigated the generation II knee orthosis by applying it to 11 participants. Baseline measurements were taken before applications and after 4 to 6 weeks of orthosis wear using the 10-point VAS. Pain symptoms decreased significantly with brace wear (48%) from 6.3 to 3.6. The authors also noted significant increases in function and activity levels, which they attributed to the decreased pain levels.[26]

Matsuno et al. published "Generation II Knee Bracing for Severe Medial Compartment Osteoarthritis of the Knee" in *Archives of Physical Medical and Rehabilitation* in 1997. Using a modified knee scoring system developed by the Japanese Orthopaedic Association, 20 participants were evaluated before orthosis application and each month thereafter for 1 year. The modified knee scoring scale used in the study considered pain while engaging in walking and stair climbing. Nineteen of the 20 patients (95%) reported decreased pain during activities. All scores significantly improved with the application of the orthosis and continued to improve throughout the observation period. Unfortunately, the results were not clearly stated.[27]

Pagani et al. published "Short-Term Effects of a Dedicated Knee Orthosis on Knee Adduction Moment, Pain, and Function in Patients With Osteoarthritis" in the *Archives of Physical Medical and Rehabilitation* in 2010. Eleven participants were incorporated in this study. Participants were tested in three different sessions by using a crossover design: before orthosis wear, after 2 weeks of wearing the orthosis with a neutral setting, and before and after the orthosis set with 4° of valgus. The order of the two different orthosis conditions was randomly assigned, and patients were blinded to the different adjustments. Before the participant was fitted and wore the orthosis, the researchers used the WOMAC scale to measure pain and function. There were statistically significant improvements in pain from the control group to the orthosis in neutral and from the orthosis in neutral to the 4° of valgus conditions. Each was higher than the previous condition. The same was true for the function measure of the WOMAC scale.[28]

Ramsey et al. published "A Mechanical Theory of the Effectiveness of Bracing for Medial Compartment Osteoarthritis of the Knee" in the *Journal of Bone and Joint Surgery* in 2007. Sixteen participants with medial compartment OA were referred from a local orthopedic practice for participation in the study. Baseline measurements were taken. Each participant was fit with a generation II unloading orthosis with an initial setting of 0° of correction. This was worn for 2 weeks, and measurements were taken again. The orthosis was removed for 2 weeks and then reapplied with 4° of valgus added. There were no significant results between the washout and the valgus condition or between the two bracing conditions with respect to pain and the activities of daily living (ADL). However, the symptoms were worse with the 4° of valgus condition than the initial setting of 0°. The orthoses control condition changes were significantly different than the baseline measurements. The authors attributed this to changes in the muscle action at the knee, which were also measured in this study. The authors concluded that the use of an orthosis was a cost-effective way to relieve pain, while not exclusively recommending the use of an OA unloading orthosis.[29]

Richards et al. published "A Comparison of Knee Braces During Walking for the Treatment of Osteoarthritis of the Medial Compartment of the Knee" in the *Journal of Bone and Joint Surgery* (British Volume) in 2005. Twelve patients were recruited and randomly fit with either a hinged knee orthosis or the generation II knee orthosis. After 6 months, each received the second type of orthosis for another 6 months. Measurements were taken before application and at the end of each 6-month period, using the VAS for resting, standing, walking, and stair climbing. It was discovered that only significant differences were found for the valgus orthosis condition, and no significant difference was discovered between the simple hinged orthosis and the baseline measurements.[30]

Schmalz et al. published "Analysis of Biomechanical Effectiveness of Valgus-Inducing Knee Brace or Osteoarthritis of Knee" in the *Journal of Rehabilitation Research and Development* in 2010. The research included 16 patients who wore a prefabricated knee orthosis for 4 weeks. Although gait parameters were the main focus of this study, pain while walking was assessed using the VAS. The initial pain while walking was 6.4 ± 1.7, which was reduced to 3.3 ± 1.9. This was a significant change. Significant changes in walking speed (meter per second) and cadence (step per minute) were documented; although the step length did not change, both walking speed and cadence increased. This points to a significant increase in function. The authors attributed these gait pattern changes to the lack of a need for protection against pain, therefore increasing function.[16] van Raaij et al. published "Medial Knee Osteoarthritis Treated by Insoles or Braces: A Randomized Trial" in *Clinical Orthopedics and Related Research* in 2010. Ninety-one participants with medial knee OA took part in this study. Of these, 45 were treated with laterally wedged insoles and 46 with the MOS Genu knee orthosis. Although this knee orthosis was not exclusively designed for OA, it has the ability to off-load the medial compartment. In this study, the pain severity in the braced group decreased from a mean 5.6 on the VAS to 4.6, and the WOMAC increased from 46.8 to 50.8. These measurements were taken 6 months after application of the orthosis. Both of these results were statistically significant. It was noted that skin irritation was the main complaint, with 10 participants

reporting skin irritation and seven patients commented on poor fit. Each of these could have contributed to less than ideal results.[31]

DISCUSSION

The importance of pain reduction cannot be underestimated. According to the American Pain Society, "Pain is the leading public health problem in this country and the most common symptom that leads to medical care, resulting in more than 50 million lost workdays each year. The cost of pain, including medical bills and lost workdays, is estimated at $100 billion per year in the United States. Back pain alone produces chronic disability in 1 percent of the U.S. population and is the leading cause of disability in Americans under 45 years old."[32] Because of this, the reduction of pain and its debilitating effects was the goal of this review. The pain caused by knee OA is especially limiting because it affects mobility and walking.

The 15 studies that met the inclusion criteria indicate that there is strong evidence that pain is reduced with the use of unloading osteoarthritic knee orthoses. Only one study, Brouwer et al.,[3] had less than significant results, and several lacked statistical analysis of the data, but data were reported in percentages. It is also interesting to note that the study by Brouwer et al. was also the largest single study with 117 participants. Most studies presented the results of their pain measurements with a mean. Matsuo noted one patient who did not receive any pain relief and Dennis noted six. Only one study reported that all participants noted pain relief.[30] Therefore, of the 567 combined participants of these studies, at least seven of them had no pain relief whatsoever. This was marginally >1% of participants. On the basis of the studies reviewed, 98.6% of patients experienced pain relief when fitted with an unloading knee orthosis.

Because these studies had different measures of pain, VAS scale, WOMAC index or a modified version of that scale, HSS score, and using different orthoses and different methods in the setup of the studies, the authors were not able to perform any meta-analysis of the combined results. Percentages indicate that 76% of those participants in studies who did statistical analysis had significant reductions in pain. Excluding the 88 participants reporting reductions in pain in studies that did not do statistical analysis to determine significance leaves 479 who were involved in studies that did provide statistically significant data. All these patients reported some pain relief. This percentage would undoubtedly be higher if an appropriate statistical analysis was done in each case or a meta-analysis was completed of these compiled studies.

Immediate pain relief would be expected from the application of the unloading knee orthosis. This was demonstrated by three studies in an interesting way. In the study by Barnes et al., pain measurements were taken each week. There was significant improvement until week 3 in each case and a leveling out of relief after that point.[17] Kirkley et al.[25] measured their treatment for a total of 24 weeks and found that pain relief leveled out at 12 weeks with the greatest relief happening in the first 6 weeks. Finally, Brouwer et al. noted that at the 3-month, 6-month, and 12-month follow-up, the difference between the two control groups did not change markedly but rather remained within a 20-point range. Although these were not significant at the studies $p < 0.01$ significance level, most were below $p < 0.053$. These three studies indicate that most of the pain relief applied by the orthosis is immediate. The theory behind the tapering off pain is the reduction in inflammation due to decreased irritation.[33]

Of interest was the pain relief during the no-brace phase of Horlick's study. The researchers noted that although the pain relief was more profound in the valgus bracing phase than the brace in neutral phase of the study, there was relief during the no-brace washout period or the no-brace period after wearing the orthoses.[24] This "carryover" effect has been documented in other orthotic literature, with the effects of the orthosis continuing after discontinuation of the orthosis. With scoliosis orthoses, there is often a carryover effect that is considered during routine radiographs. If the physician chooses to take radiographs of the patient out of his or her orthosis, the physician looks for what the body is doing when the orthosis is not being worn. There is always a time period between the radiograph and the last wearing time to mitigate the residual or carryover effects of the orthosis.[34] A review of ankle-foot orthoses also noted a carryover effect in several studies.[35] This residual effect may be one answer for the carryover effect noted by Horlick in this study.

All but two of the studies were underpowered, meaning that the number of participants was less than ideal and thereby raising the possibility of a type 2 error. This means that the chance of not reporting a difference in the intervention when there was a difference is more likely. Most of the studies were of moderate design, indicating that there were areas that may have introduced bias and therefore affected the outcomes of the studies. Important elements fundamental to randomized control trials, such as blinding and randomization, were not possible or were not provided for in the studies reviewed. Because of this, further bias may have been introduced.

Although not a primary focus in this project, decreased function is a known complication of OA. Some of the studies reviewed investigated increases in function. Eight of the studies in some way investigated function. All of them noted significant increases in the function of participants.[3,16,17,25,26,28,29,31] There were two studies that are of note: studies by Lindenfeld et al. and Schmalz et al. Gait pattern changes seem to be a protective mechanism by the patient with knee OA to reduce knee pain.[36] The study by Schmalz et al resulted in more symmetrical gait patterns in the participants, noting that their gait lab measurements were improved with the unloading knee orthosis. Lindenfeld et al. indicated that the participants in their study went from moderate symptoms with ADLs to walking several hours per day without appreciable symptoms. According to the authors of the studies reviewed, the decrease in pain scores was

attributed to the use of the knee orthosis. The knee orthosis in each case caused an increase in the knee adduction moment at heelstrike and loading response, thereby relieving the pressure on the medial compartment of the knee.

Although the ability of this review to analyze which orthoses were more effective than others is extremely limited, some interesting observations can be made based on the differences in study morphology, pain measurement scales, and interval of measurements. The most common type of orthosis used was the generation II unloader orthosis. This orthosis was among the first commercially available OA knee orthoses, which was undoubtedly the reason it was the most commonly studied orthosis. Horlick[24] and Matsuno et al.[27] were among the first to investigate the use of this unloading orthosis. As the clinical effectiveness of these types of orthoses became known, flurries of articles were published around the turn of the century on a variety of knee orthoses. Two worth mentioning are Dennis and Draganich. Dennis compared the effectiveness of four commercially available off-the-shelf orthoses. The Bledsoe Thruster had the greatest amount of relief of symptoms from medial knee OA.[19] Draganich et al. examined custom versus off-the-shelf models of the unloading knee orthosis and found a significant difference between the two orthoses. Custom knee orthoses provided significantly better relief of symptoms. Draganich et al.[21] attributed this to a better fitting orthosis.

Another interesting observation, and warranting further study, was the importance of patient perception and placebo effect. Demonstrated in both studies done by Brouwer et al.[3] and Kirkley et al.,[25] some participants in the control group of both studies withdrew because they wanted to be in the knee orthosis group rather than in the control group. In the study by Kirkley et al., seven (18%) withdrew from the control group and two (5%) from the neoprene sleeve group. In the study by Brouwer et al., "One patient withdrew immediately because of dissatisfaction with the randomization outcome." Furthermore, no patients withdrew from the unloader orthosis control groups in either study. Patient perception and the placebo effect produce a valid effect on pain perception and play a real part in clinical care. Although it may be part of the results, even if the placebo worked and decreased pain, it should be considered a viable option for the treatment of knee OA.[37]

As insurance companies tighten reimbursement, justifying the use of orthoses over other treatments is important. One thing that was not evaluated in these studies was how many of the participants later underwent corrective surgery, either femoral osteotomy or knee replacement. One way of evaluating the effectiveness of the orthotic intervention is whether or not patients later have to undergo corrective surgery, which always entails risks. In the research by Barnes et al., it was noted how many patients went on to some type of surgery and how many were able to continue using the orthosis to lessen their pain. At a 2-year follow-up, only 24% of the participants had undergone arthroplasty, whereas 41% were still using their orthosis.[17] van Raaij et al. noted that of those participating in their study, three in the no-orthosis group underwent surgery at 6 months, whereas one had undergone surgery in the orthosis group.[31] In the randomized control trial, Brouwer et al.[3] followed up patients for a year and found that in the orthosis group, 11 (18%) patients underwent surgery that year and that in the control group 13 of the remaining 53 (25%) participants underwent some sort of surgery. Each of these studies had similar results of decreased incidence of surgery in the orthosis group versus a control group. Although these numbers are very small, they may signal an interesting trend and warrant further research.

Only a few of the studies reported how the orthoses were fit and if a qualified individual was responsible for fit and follow-up. Most of the studies did not state who fit or how the orthosis was fit. Appropriate fit is an often-heard complaint among wearers of the orthoses.[24,31] A trained orthotist can properly fit an orthosis, increase compliance, and further increase the effectiveness of the orthosis.

The Osteoarthritis Research Society International guidelines for knee OA indicate that "emphasis should be placed on encouraging adherence to the regimen of nonpharmacological therapy" in the treatment of knee OA. It was recommended for patients with mild to moderate knee OA for the reduction of symptoms including pain.[38] These guidelines are consistent with the findings of the literature review in that they would recommend the OA knee orthosis for treatment of knee OA.

Areas of further research are apparent based on the results of this review. Further research on the effectiveness of one orthosis over another by an unbiased source would help practitioners provide the best possible care. The possible carryover effect of the knee unloading orthosis would have implications for the duration of wear time of the orthosis. If there is indeed a carryover effect, then possibly it is not necessary to wear the orthosis full time but only during activities that cause pain. Can the need for patients to receive knee replacements or other invasive surgeries to correct knee OA be lessened by the wearing the unloading knee orthosis? If this is true, then wearing the unloading knee orthosis may indeed reduce the incidence of surgery. This would be a justification for the orthosis, proving that the orthosis would reduce the overall healthcare cost of the treatment of medial compartment OA.

CONCLUSION

OA can be a disabling disease. On the basis of the articles reviewed, an OA or unloading knee orthosis is an effective way to relieve pain in the osteoarthritic knee. Pain relief was documented to help in 98.6% of patients fitted with unloading orthoses for medial compartment OA of the knee. With decreased pain comes increased function and quality of life. When compared with surgery, these orthoses are a cost-effective means of treating OA.

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REFERENCES

1. Peat G, McCarney R, Croft P. Knee pain and osteoarthritis in older adults: a review of community burden and current use of primary health care. *Ann Rheum Dis* 2001;60:91–97.
2. Felson DT, Lawrence RC, Dieppe PA, et al. Osteoarthritis: new insights. Part 1: the disease and its risk factors. *Ann Intern Med* 2000;133:635–646.
3. Brouwer RW, van Raaij TM, Verhaar JAN, et al. Brace treatment for osteoarthritis of the knee: a prospective randomized multicentre trial. *Osteoarthritis Cartilage* 2006;14:777–783.
4. Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, part I: critical appraisal of existing treatment guidelines and systematic review of current research evidence. *Osteoarthritis Cartilage* 2007;15:981–1000.
5. Pollo FE. Bracing and heel wedging for unicompartmental osteoarthritis of the knee. *Am J Knee Surg* 1998;11:47–50.
6. Pollo FE, Jackson RW. Knee bracing for unicompartmental osteoarthritis. *J Am Acad Orthop Surg* 2006;14:5–11.
7. Divine JG, Hewett TE. Valgus bracing for degenerative knee osteoarthritis—relieving pain, improving gait, and increasing activity. *Phys Sportsmed* 2005;33:40–46.
8. Chew KTL, Lew HL, Date E, Fredericson M. Current evidence and clinical applications of therapeutic knee braces. *Am J Phys Med Rehabil* 2007;86:678–686.
9. Geil MD. Assessing the state of clinically applicable research for evidence-based practice in prosthetics and orthotics. *J Rehabil Res Dev* 2009;46:305–313.
10. Price DD, McGrath PA, Rafii A, Buckingham B. The validation of visual analog scales as ratio scale measures for chronic and experimental pain. *Pain* 1983;17:45–56.
11. The Recal Legacy [database on the Internet]. Available at: http://www.strath.ac.uk/cdlr/services/recallegacy/. Accessed March 31, 2011.
12. Hafner BP. American Academy of Orthotists & Prosthetists (AAOP), State-of-the-Science Evidence Report Guidelines. American Academy of Orthotists and Prosthetists; 2008. Available at: http://www.oandp.org/grants/MasterAgenda/AAOP_EvidenceReport Guidlines.pdf. Accessed March 31, 2011.
13. Ahlback S. Osteoarthrosis of the knee. A radiographic investigation. *Acta Radiol Diagn (Stockh)* 1968:Suppl 277:7–72.
14. Prodromos CC, Andriacchi TP, Galante JO. A relationship between gait and clinical changes following high tibial osteotomy. *J Bone Joint Surg Am* 1985;67:1188–1194.
15. Self BP, Greenwald RM, Pflaster DS. A biomechanical analysis of a medial unloading brace for osteoarthritis in the knee. *Arthritis Care Res* 2000;13:191–197.
16. Schmalz T, Knopf E, Drewitz H, Blumentritt S. Analysis of biomechanical effectiveness of valgus-inducing knee brace for osteoarthritis of knee. *J Rehabil Res Dev* 2010;47:419–429.
17. Barnes CL, Cawley PW, Hederman B, et al. Effect of Counter-Force brace on symptomatic relief in a group of patients with symptomatic unicompartmental osteoarthritis: a prospective 2-year investigation. *Am J Orthop (Belle Mead NJ)* 2002;31:396–401.
18. Dennis AD, Komistek RD. An in vivo analysis of the effectiveness of the osteoarthritic knee brace during heel strike and mid-stance of gait. *Acta Chir Orthop Traumatol Cech* 1999;66:323–327. Analyza ucinnosti in vivo ortez pri lecbe gonartrozy behem jednotlivych fazi chuze ("heel-strike" a "mid-stance").
19. Dennis DA, Komistek RD, Nadaud MC, Mahfouz M. Evaluation of off-loading braces for treatment of unicompartmental knee arthrosis. *J Arthroplasty* 2006;21:2–8.
20. Bellamy N, Buchanan WW, Goldsmith CH, et al. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;15:1833–1840.
21. Draganich L, Reider B, Rimington T, et al. The effectiveness of self-adjustable custom and off-the-shelf bracing in the treatment of varus gonarthrosis. *J Bone Joint Surg Am* 2006;88:2645–2652.
22. Finger S, Paulos LE. Clinical and biomechanical evaluation of the unloading brace. *J Knee Surg* 2002;15:155–158; discussion 159.
23. Gaasbeek RDA, Groen BE, Hampsink B, et al. Valgus bracing in patients with medial compartment osteoarthritis of the knee—a gait analysis study of a new brace. *Gait Posture* 2007;26:3–10.
24. Horlick SG. Valgus knee bracing for medial gonarthosis. *Clin J Sports Med* 1993;3:251–255.
25. Kirkley A, Webster-Bogaert S, Litchfield R, et al. The effect of bracing on varus gonarthrosis. *J Bone Joint Surg Am* 1999;81:539–548.
26. Lindenfeld TN, Hewett TE, Andriacchi TP. Joint loading with valgus bracing in patients with varus gonarthrosis. *Clin Orthop Relat Res* 1997;344:290–297.
27. Matsuno H, Kadowaki KM, Tsuji H, et al. Generation II knee bracing for severe medial compartment osteoarthritis of the knee. *Arch Phys Med Rehabil* 1997;78:745–749.
28. Pagani CH, Bohle C, Potthast W, Bruggemann GP. Short-term effects of a dedicated knee orthosis on knee adduction moment, pain, and function in patients with osteoarthritis. *Arch Phys Med Rehabil* 2010;91:1936–1941.
29. Ramsey DK, Briem K, Axe MJ, Snyder-Mackler L. A mechanical theory for the effectiveness of bracing for medial compartment osteoarthritis of the knee. *J Bone Joint Surg Am* 2007;89:2398–2407.

30. Richards JD, Sanchez-Ballester J, Jones RK, et al. A comparison of knee braces during walking for the treatment of osteoarthritis of the medial compartment of the knee. *J Bone Joint Surg Br* 2005;87:937–939.

31. van Raaij TM, Reijman M, Brouwer RW, et al. Medial knee osteoarthritis treated by insoles or braces: a randomized trial. *Clin Orthop Relat Res* 2010;468:1926–1932.

32. Society AP. Media backgrounder. Internet: American Pain Society; 2011. Available at: http://www.ampainsoc.org/press/backgrounder.htm. Accessed May 1, 2011.

33. Marieb ENR, Hoehn KM. *Anatomy & Physiology*. 7th ed. San Francisco, CA: Pearson Benjamin Cummings; 2007:1159.

34. Carol J, Hentges C. The team approach to the orthotic treatment of idiopathic scoliosis and Scheuermann's kyphosis. *J Orthot Prosthet* 2003;15:49–52.

35. Kobayashi TP, Leung AKLP, Hutchins SWP. Design and effect of ankle-foot orthoses proposed to influence muscle tone: a review. *J Orthot Prosthet* 2011;23:52–58.

36. White A, Foster NE, Cummings M, Barlas P. Acupuncture treatment for chronic knee pain: a systematic review. *Rheumatology (Oxford)* 2007;46:384–390.

37. Pagani CHF, Potthast W, Bruggemann GP, et al. The effect of valgus bracing on the knee adduction moment during gait and running in male subjects with varus alignment. *Clin Biomech* 2010;25:70–76.

38. Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis Cartilage* 2008;16:137–162.

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Advancing Orthotic and Prosthetic Care Through Knowledge

Patient Evaluation Of An Unloader Knee Brace: A Prospective Cohort Study

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Introduction

The prevalence of osteoarthritis (OA) is constantly increasing, currently affecting 4.3 million adults in the United States, and making it the most prevalent of the chronic joint disorders worldwide. One contributing factor that may increase the severity of knee OA is knee malalignment.[8] Sharma et al. showed that a compartmental increase in the load of the knee can cause an increase in knee degeneration of that compartment.[12]

Many nonsurgical and surgical treatment options exist that may relieve pain, and therefore increase knee function. Non-surgical treatment options include oral supplementation, such as glucosamine and chondroitin, and corticosteroid and hyaluronic-acid knee injections. Previous studies have shown that oral supplements as well as intra-articular injections may cause a decrease in symptoms such as pain; however, these treatments are temporary and do not change the mechanics of the knee.[9]

Some surgical treatments have been developed to treat malalignment of the knee; however, these procedures are quite invasive and require lengthy recovery times and rehabilitation. And though these operative procedures, which are intended to relieve knee pain by reducing the weight bearing load in the degenerative compartment, are available, there is an increasing desire for non-surgical treatments that address the issue of malalignment.[3]

Unloader braces are specifically designed to decrease the load on the degenerative compartment of the knee in order to improve function and decrease symptoms related to malalignment and OA.[7, 10] The purpose of this study is to document patients' expectations of treatment and outcomes following six months of use of an unloader brace. Outcomes and response to the brace were measured by symptoms such as pain and stiffness, function, use of pain medication, and quality of life.

Methods

Patients were enrolled in an IRB-approved prospective cohort study. Excluded were patients who had any arthroplasty in the knee, or moderate to severe OA in both lateral and medial knee compartments. Inclusion criteria were diagnosis of osteoarthritis of the knee with unicompartmental knee conditions that required load reduction to the affected compartment and a minimum of a six-month prescription in order to allow for sufficient trial of the brace. Patients signed informed consent forms and agreed to complete all mailed questionnaires. At enrollment, three weeks, six weeks, and six months, patients completed a self-administered questionnaire. This questionnaire included the SF-12; the WOMAC score[1]; and a survey of patients' use of both prescription and non-prescription anti-inflammatory drugs. In addition, all patients completed an expectation questionnaire prior to enrollment in the study. Twenty patient expectation domains were measured. The domains were then analyzed individually as "very important" to "of little to no importance." These data were then summed as an expectation score with a range of 20–80, 80 showing no expectation and 20 showing the highest expectation.

Statistical Analysis

Comparisons of scores between pre-brace WOMAC and final time point (six months) were performed using the paired t-test. Comparisons between independent groups were performed using the independent t-test. We used repeated measures analysis to determine if there was a difference between pre-brace, three-week, six-week, and six-month WOMAC pain and function scores. Because the WOMAC scores were assessed on the same patient over time, we used repeated measures analysis to adjust for the within-patient factors.

Results

Thirty-nine patients were enrolled in this study. The average age was 60 years (range 44 to 87). Average body-mass index (BMI) was 26 (range 20 to 37). There were 22 men and 17 women. Twenty-five patients were prescribed a medial unloader brace, and 14 were prescribed a lateral unloader brace. Seven patients (18 percent), five women and two men, discontinued brace wear.

Patient Expectations

Pain relief was very important to only 69 percent of patients and somewhat important to 17 percent. If patients did expect pain relief, 39 percent expected most of the pain to be relieved, and 57 percent expected all pain to be relieved. Seventeen patients (37 percent) also reported stiffness as a primary reason for seeking medical treatment. Eighty-six percent of the patients expected knee stiffness or swelling to stop. Improving their ability to walk was considered very important by 89 percent. Of those who considered walking important, they all expected to walk more than one mile. Improving their ability to go up and down stairs was considered very important to 70 percent. Patients considered return to recreational sports an important expectation. It was considered very important to 83 percent and somewhat important to 17 percent. The most important expectation in this group was to have confidence in their knee (97 percent very important), avoid future degeneration of their knee (90 percent very important), and improve ability to maintain general health (93 percent very important).

The WOMAC scores are shown in the following table. There was significant improvement in pain, stiffness, and function components of the WOMAC score ($p<0.05$). Patients also had a significant improvement in their quality-of-life physical component as shown by the SF-12 ($p<0.05$). As expected, the patient mental component of quality of life remained unchanged.

	WOMAC Pain	WOMAC Stiffness	WOMAC Function	WOMAC	SF-12 PCS	SF-12 MCS
Pre-brace	6.8	3.0	19	28.3	38.6	58.5
3 weeks	3.0	1.4	7.4	10.4	NA	NA
6 weeks	3.4	1.4	9.8	13.5	42.5	56.6
6 months	2.9	1.5	8.6	11.9	46.0	59.4

At three weeks, 24 percent of patients reported a decrease in over-the-counter anti-inflammatory use, and 16 percent reported a decrease in prescription anti-inflammatory use. At six months, 23 percent reported a decrease in over-the-counter anti-inflammatory use and 16 percent reported a decrease in prescription anti-inflammatory use.

Discussion

In this population, patients expected pain relief, improved function, and improved activity level. It was very important for the patients to avoid future degeneration of the knee and to be able to maintain their general health. The unloader brace decreased pain in the initial weeks following bracing and maintained improvement throughout the study. Improved patient function and a decrease in stiffness were also seen in the initial weeks and were maintained at end point as well. Patients reduced medications and had improved overall physical health.

The results of this study are similar to those of Kirkley et al.[7] In the Kirkley et al. study, there was a control group, a neoprene-sleeve group, and an unloader brace group, all of which consisted of patients under 50 years old who had a BMI of less than 35. Patients who used the unloader brace showed less pain than the other two groups after walking for six minutes and climbing for 30 seconds. They also showed a significant increase in quality of life and knee function. And although not significant, there was a strong trend toward a significant difference between the unloader group and neoprene-sleeve group regarding the overall WOMAC score and the functional component of the WOMAC.[7]

Other studies have also shown unloader braces to be effective in not only reducing symptoms, but also in shifting the weight-bearing load.[2,4–6,10–11] Self et al. showed a significant decrease in varus moment during stance, which can contribute to a reduction in pain.[10] And Pollo et al. showed a shift in the center axis of pressure with the use of an unloading brace. Resting pain, night pain, and pain with activity all showed a significant decrease with brace use.[11]

In this patient population, the mean BMI was quite low, which may not be representative of a normally distributed population. Also, many of the patients in this study had a low pre-brace WOMAC score, which may not have allowed for as much improvement.

Overall, patients demonstrated a significant decrease in pain and increase in function and overall physical health. Braces specifically designed to unload the degenerative compartment of the knee may be an effective treatment for pain generated from OA in conjunction with malalignment of the knee.

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References

1. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J., Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol.* 1988;15:1833–1840.

2. Cerejo R, Dunlop DD, Cahue S, Channin D, Song J, Sharma L. The influence of alignment on risk of knee osteoarthritis progression according to baseline stage of disease. *Arthritis Rheum.* 2002;46:2632–2636.

3. Chew KT, Lew HL, Date E, Fredericson M. Current evidence and clinical applications of therapeutic knee braces. *Am J Phys Med Rehabil.* 2007;86:678–686.

4. Draganich L, Reider B, Rimington T, Piotrowski G, Mallik K, Nasson S. The effectiveness of self-adjustable custom and off-the-shelf bracing in the treatment of varus gonarthrosis. *J Bone Joint Surg Am.* 2006;88:2645–2652.

5. Felson DT, Goggins J, Niu J, Zhang Y, Hunter DJ. The effect of body weight on progression of knee osteoarthritis is dependent on alignment. *Arthritis Rheum.* 2004;50:3904–3909.

6. Finger S, Paulos LE. Clinical and biomechanical evaluation of the unloading brace. *J Knee Surg.* 2002;15:155–158; discussion 159.

7. Kirkley A, Webster-Bogaert S, Litchfeld R, Amendola A, MacDonald S, McCalden R, Fowler P. The effect of bracing on varus gonarthrosis. *J Bone Joint Surg Am.* 1999;81:539–548.

8. Miller BS, Joseph TA, Barry EM, Rich VJ, Sterett WI. Patient satisfaction after medial opening high tibial osteotomy and microfracture. *J Knee Surg.* 2007;20:129–133.

9. M–ezzinoğlu S, Bulu– L. The role of nonsteroidal anti-inflammatory drugs, oral preparations, and viscosupplementation in conservative treatment of cartilage lesions. *Acta Orthop Traumatol Turc.* 2007;41:48–53.

10. Pollo FE, Jackson RW. Knee bracing for unicompartmental osteoarthritis. *J Am Acad Orthop Surg.* 2006;14:5–11.

11. Self BP, Greenwald RM, Pfaster DS. A biomechanical analysis of a medial unloading brace for osteoarthritis in the knee. *Arthritis Care Res.* 2000;13:191–197.

12. Sharma L, Song J, Felson DT, Cahue S, Shamiyeh E, Dunlop DD. The role of knee alignment in disease progression and functional decline in knee osteoarthritis. *JAMA.* 2001;286:188–195. Erratum in: *JAMA.* 2001;286:792.

COMING SOON

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HCPCS:	Descriptor:
L1845	KNEE ORTHOSIS, DOUBLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT (UNICENTRIC OR POLYCENTRIC), MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Osteoarthritis, DJD, knee instability, ACL injury, ligamentous injury
Medically Necessary Argument	This orthosis is designed to unload/stabilize the knee joint. A proper understanding of the diagnosis, knowledge of the anatomy of the knee joint and proper understanding of the knee orthosis and how to fit this and adjust the settings is crucial to proper functioning of the orthosis. Without this knowledge the orthosis would not be fit properly and the proper unloading effects would not be experienced. Knowledge and experience with these orthoses would allow the professional to know whether this orthosis will fit properly and control the excessive knee motion.
References	5, 6, 7, 8

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Response of Eight Knee Orthoses to Valgus, Varus and Axial Rotation Loads

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Abstract

Motion restriction of eight knee orthoses were compared for the pathological conditions of valgus, varus and axial rotation. The eight knee orthoses included the Polyaction, Lerman, Lenox Hill, ECKO, DonJoy Analog, Pro Am and CTi. Valgus, varus and axial rotation torques were applied to the test apparatus and corresponding angular deformities were measured.

Analog and CTi provided the most valgus control, Analog the varus control and Lerman and CTi the most axial rotational control. The clinical efficacy of the knee orthoses evaluated depended upon the magnitude of the imposed load and the quality of fit.

Introduction

The Normal Knee

The knee is a modified hinge joint capable of the fundamental motions of flexion and extension in addition to some rotation and gliding motion. Control of knee motion is shared by the capsular structures, intra- and extra-articular ligaments, the joint contours and the muscles with their tendons which cross the joint anteriorly and posteriorly.[1,2] While sagittal plane motion (flexion/extension) consists of a large, free arc of approximately 150 degrees, motion in the coronal and transverse planes are very small and limited by ligamentous and capsular structures.[1,2] In a normal and fully extended knee, axial rotation is less than 20 degrees and combined varus/valgus is less the 5 degrees. [1,3,4] As the knee is flexed towards 90 degrees, increased axial rotation to 90 degrees may be attained,[1,5] while combined varus/valgus is less than 15 degrees.[6] While the knee is most stable when fully extended, it is also in this position that it is most vulnerable to injury, especially from lateral/medial forces.

The Injured Knee

Injury to the knee may exist as fracture of bone or tearing or rupturing of ligaments and menisci. Understanding the role of the bony and soft tissue structure of the knee is mandatory for proper management of the posttraumatized knee.

Specific function of the knee ligaments and the consequence of their injury have been described [7,8,9]as well as tests to determine the extent of each.[10,11] Knee joint instability, secondary to tearing or rupturing of the soft tissue structures, is clinically described by the resulting excessive motion. Varus is an unstable knee in which the tibial plateau leans laterally ("bow-legs") and is the result of disruption of the lateral structures (mid-third capsular ligament, fibulo-collateral ligament, biceps tendon, and ilio-tibial tract, with or without abnormality of the medial meniscus).[8,9] In valgus, the tibial plateau leans medially ("knock-knees") and results from disruption of the medial structures (medial capsular ligament, posterior/anterior cruciates).[8,9] Axial rotation refers to the tibial plateau turning externally or internally with respect to the femur. Rotation injuries can result from almost any combination of structural damage but primarily result from anterior cruciate, medial capsular and tibial collateral ligament damage.[7,9] Drawer sign refers to the tibial plateau sliding anteriorly or posteriorly with respect to the femur while the patient's knee is flexed. The drawer sign is most commonly linked to tear of either the anterior and/or posterior cruciate ligaments. However, some feel that to get a significant anterior drawer sign the medial capsular ligament must also be damaged.[9,11] Lastly, recurvatum is the increased posterior angle of the leg while the patient's knee is hyper-extended. Posterior support of the knee has been found to be offered primarily by the posterior cruciate ligament, posterior capsule and tibial collateral ligament.[7,9]

Treatment

The excessive motions allowed by an injury to the knee need to be controlled via conservative management to enable healing, or to protect the knee following surgical repair. Knee orthoses have been used as an adjunct to the management of the post-traumatized knee and designed to immobilize after surgery or injury, and/or to protect joints that were painful due to trauma or disease.[12] Lately, knee orthoses have been designed to stabilize antero-lateral and antero-medial rotatory motion ,[13] medio-lateral motion,[14,15] and excessive flexion/hyper-extension motions.16 There also have been efforts toward preventing pain by providing positioning support of the patella via an orthosis. [17,18]

Designs have been as simple as those reported by Palumbo[17] and Levine[18] which consist of straps which surround or support the patella to those which are customized with specific biomechanical objectives for individual patients.13'14'15

Evaluation of Orthoses

Although the literature is abundant with information on the anatomy and pathology of the knee, few studies are reported that objectively compare treatment using an orthosis versus no orthosis and even fewer compare knee orthoses. A survey was conducted to determine the outcome of collegiate football players wearing versus not wearing prophylactic knee orthoses.[19] Surprisingly this survey showed a greater incidence of injury in those who wore an orthosis than those who did not, regardless of the type of knee orthosis worn. Butler, et al.[20] described 13 knee orthoses commonly prescribed for patients with ligamentous laxity secondary to rheumatoid arthritis or injury. Butler commented on the "potential function" of these knee orthoses and was critical of the short moment arms, the application of biomechanical forces on compliant soft tissues and suspension. Butler created a prescription guide by subjectively evaluating warmth, comfort, protection against blows and limitation of various deforming motions. Motion restriction was graded as slight, fair or good. A prescriber with specific and subjective treatment goals could use Butler's guide to zero-in on one of the 13 knee orthoses described. Knutzen, et al. ,[21] compared an Ace elastic support (Becton Dickinson Co., Rochelle Park, NJ) to the Lenox Hill derotation knee orthosis (Lenox Hill Brace Shop, 2245 B. 84th St., New York,

NY) on runners for flexion, axial rotation and varus/ valgus using electrogoniometric evaluation of knee joint kinematics. The Lenox Hill derotation knee orthosis restrained axial rotation of surgically repaired runners' knees approximately 2.3 degrees and the Ace support had no effect. Basset evaluated the effectiveness of the Lenox Hill orthosis in controlling anterolateral rotatory instability and combined anteromedial-anterolateral rotatory instability in 36 patients using the standard clinical laxity tests.[13] Patients with isolated anterolateral rotatory instability were generally improved one grade on the Lachman scale while wearing the Lenox Hill knee orthosis. However, when there was combined instability, excessive anterolateral rotatory instability was unchanged. Hoffman, et al.,[12] evaluated six commercially available knee orthoses for their ability to stabilize ligamentous injuries against valgus, axial rotation and the drawer sign symptoms using fresh cadaver specimens by measuring bony displacements as external loads were applied. Of the six knee orthoses evaluated by Hoffman, the 3D 3-Way knee orthosis (3D Orthopedic Inc., Dallas, TX) provided the greatest overall restriction of knee motion.

The American Academy of Orthopedic Surgeons[22] reviewed knee orthoses organized into categories of prophylactic, rehabilitative and functional. Generally very little objective biomechanical or functional data regarding the orthoses were provided by the manufacturers. However, a cadaver study was reported wherein the resistance of four prophylactic orthoses to valgus loads was measured. They also reported that there was no limitation of the drawer sign by any of the four orthoses evaluated. In the category functional knee orthoses, Robert Hunter, M.D., compared the effectiveness of the Lenox Hill and the CTi knee orthoses in protection against the drawer sign in 15 subjects with an absent anterior cruciate ligament in one knee. The results showed that both orthoses held the knee to within normal limits at 15 pounds of anteriorly directed force at both 25 degrees and 90 degrees of knee flexion while neither provided protection at 20 pounds of force.

Purpose

Because performance data are scarce and technical/clinical guidelines unavailable, it is difficult for a clinician to objectively select the appropriate knee orthosis for a given patient/pathology. Therefore, the purpose of this study is to objectively compare eight commonly prescribed knee orthoses for their ability to restrain excessive knee valgus, varus and axial rotation. A follow-up study will be directed at evaluating the drawer sign and recurvatum.

Specific Aims

The specific aims of this study are to:

1. Develop an apparatus for evaluating valgus, varus and axial rotation;
2. Document the mean (+/- sd) of valgus, varus and axial rotation deformity for each of several torque loads for eight knee orthoses;
3. Compare the motion allowed among the eight knee orthoses at each of the torque loads;
4. Define the relationship between the torque and angle for each orthosis tested, in each position.

Method

Materials

To objectively evaluate the eight knee orthoses, a unique testing apparatus was developed (Figure 1) . The apparatus consists of an above-knee prosthesis which had been modified to allow valgus, varus and axial rotation angles much greater than normal. The socket portion of the prosthesis was filled with polyester foam and a mounting pipe was inserted to hold the prosthesis horizontally. This pipe was inserted through two tee-joints, which were attached to a wood base. The prosthetic knee joint was removed and replaced with a custom-made joint constructed of soft crepe. This custom-made crepe knee joint required minimum torque to create valgus, varus and axial rotational deformities.

To simulate natural skin friction, a rubber sleeve was stretched over the prosthesis. This allowed the components and straps of the various knee orthoses to grip the otherwise smooth surface of the prosthesis.

With the test apparatus in the horizontal side-lying position, the tibial portion freely fell into 30 degrees of valgus or varus and 25 degrees of axial rotation (Figure 2 and Figure 3). Axial rotation was indicated by two offset alignment marks on the femoral and tibial sections of the prosthesis. The femoral portion of the AK prosthesis was immobilized and the tibial section was able to angulate medially or laterally independent of the femur when torque was applied. The instrumentation used consisted of a torque wrench (Model 1502DIN, Consolidated Devices Inc., City of Industry, CA), tensiometer (Model DDP-50, John Chatillon & Sons, Inc., Greensboro, NC), electrogoniometer (Neuromuscular Engineering Department, Rancho Los Amigos Medical Center, Downey, CA) and linear scale (Figure 4) . The electrogoniometer, which consisted of a truss assembly connected to a potentiometer and a digital readout, measured and indicated the angular deformities produced. Custom-made mounting brackets were used to secure the electrogoniometer for measuring angular deformity of the test prosthesis (Figure 5) . The brackets could be arranged to accommodate valgus, varus and axial rotation angulation measurements.

The eight knee orthoses selected for testing included the Polyaction, Lerman, Lenox Hill, ECKO, DonJoy, Analog, Pro Am and CTi (Table 1) . These orthoses were either purchased or donated. Although all existing knee orthoses were not evaluated, this group is considered to be representative of the knee orthoses presently available.

Procedure

Preliminary calculations indicated that a 150 pound patient in single limb support with varying degrees of varus/valgus may require a knee orthosis to restrain approximately 500 inch-pounds of torque. Therefore, for the purpose of comparison, the applied valgus and varus torque was set to range from 0 to 650 inch-pounds, in ten 65 inch-pound increments. Similarly, the applied axial rotation torque ranged from 0 to 240 inch-pounds, in 60 inch-pound increments. These ranges of applied torques were selected to represent practical clinical conditions. The extreme torques associated with high level professional sports is unknown.

For each orthosis, the torque application sequence was repeated three times. This loading sequence was also done when no orthosis was on the testing apparatus. All testing took place with the test apparatus in the horizontal supine position.

Once a knee orthosis was placed on the test apparatus, axial rotation torque was applied with a torque wrench with an analog dial indicator, while valgus/varus torque was applied with a constant lever tensiometer. The lever arm for the valgus/varus tests was 13 inches from the point of application of the force to the knee joint axis, thus giving torque (inch-pounds) force (pounds) x 13 inches. Each angular deformity was digitally indicated on the electrogoniometer. This procedure was repeated three times for each deformity for each of the eight knee orthoses. Between trials, slippage and inelastic alignment were corrected.

For each value of valgus, varus or axial rotational torque applied, the angle that the fixture deformed, with or without an orthosis attached, was recorded.

Valgus and varus force was applied with the tensiometer at a point corresponding to the apex of the lateral malleolus (Figure 5) . As the fixture with the orthosis applied began to deform, the resulting angulation was displayed on the electrogoniometer digital readout. After each trial was performed, the electrogoniometer was reset to zero and the leg reset to its original position as indicated by alignment marks on the prosthesis and on the base board.

Axial rotational torque was applied with a torque wrench to a nut welded to the distal margin of the prosthesis (Figure 7) . The electrogoniometer mounting brackets were rotated 90 degrees from the previous location to record the angles produced by the deforming knee orthosis. Anterior alignment marks on the femur and tibia sections of the test fixture were used to reset the fixture to the starting point.

Data Analysis

The data were screened for outliers and summarized. Since only one of each orthosis was tested, the three replicate measurements were averaged and that value used to represent the motion obtained for each orthosis at each position and torque load. Analysis of variance was used to test for variation between the orthoses. This was done separately for each motion at each of the imposed torques. Regression analyses were also used to detect significant linear trends between the variables of torque and angle. As the applied torques caused the apparatus and orthosis to deform, it was obvious that some of the resistance to deformity was caused by the apparatus. To isolate the resistance to motion caused by the orthoses alone, the resistance due to the apparatus was subtracted. This was done by subtracting the torque required by the apparatus alone at a specific angular deformity from the opposite torque required by the apparatus and orthosis being tested. The procedure was repeated at two degree increments from 0 to 50 degrees.

The statistical programming package Crunch (Crunch Software Corp., 5335 College Aye, Oakland, CA 94618) was used to perform the data analysis, and all testing was done at a .05 level of significance.

Results

Valgus

The mean (+/- sd) valgus angle of deformity ranged from a low of 0 degrees for the Polyaction, Lerman, ECKO, Analog and Pro Am orthoses at 65 inch pounds of torque to a high of 46.7 degrees (+/- 1.16) for the ECKO knee orthoses at 650 inch-pounds of torque (Table 2) . Post hoc testing using the Sheffe multiple comparisons test showed the Polyaction, Lerman and Analog knee orthoses had consistently greater ability to resist deformity, than the other five orthoses, through 390 inch-pounds

of torque. At the load of 455 inch-pounds the Analog knee orthosis was joined by the CTi in showing the most significant resistance to deformity through the final load of 650 inch-pounds attaining a valgus angle of 13 degrees (+/- 1), 13 degrees (+/- 0) respectively. The Lennox Hill and ECKO knee orthoses showed the least resistance to deformity, where 6 degrees (+/- 1) and 7 degrees (+/- 1) of valgus motion was noted at 130 inch-pounds of applied torque. At 260 inch-pounds the DonJoy joined these two orthoses and continued to resist valgus motion significantly less than the other five knee orthoses through the final torque load of 650 inch-pounds, attaining 46.7 degrees (+/- 1.16), 42.7 degrees (+/- 1.16) and 38.7 degrees (+/-1.16) for the ECKO, Lenox Hill and DonJoy, respectively. The test prosthesis with no orthosis deformed 49 degrees (+/- 1) into valgus (maximum deformity permissible on the apparatus) at 325 inch-pounds and was significantly more flexible than all of the test orthoses (Table 2) .

The first load of 65 inch-pounds of torque was the only load at which all of the knee orthoses protected the knee to within the maximum comfortable valgus deformity of 3.4 degrees.[4] The Polyaction provided the best protection by allowing less than 3.4 degrees of valgus through 260 inch-pounds of torque. The Polyaction, Lerman, Analog and CTi best restrained valgus to within 8 degrees, through 390 inch-pounds of torque, the angle which corresponds to internal knee disruption.[3](Table 2)

Significant linear trends were detected for torque versus angle for each of the orthoses evaluated, (r .95 to .99). Further regression was applied and the best curve fit to these data were observed with third order regression (r .983 to .998); however, this was not significant (Figure 7) .

Varus

The Polyaction, Lerman, Analog and Pro Am knee orthoses showed significantly greater resistance to varus deformity from 65 to 260 inch-pounds of applied torque; 7 degrees (+/- 0), 9.3 degrees (+/- 2.08), 8.3 degrees (+/- .58), and 9.7 degrees (+/- 1.16), respectively, at 260 inch-pounds (Table 3) . At 325 inch-pounds the Polyaction yielded 11.3 degrees (+/- 1.53) and the Analog yielded 9 degrees (+/- 0) and both were significantly more resistant to varus motion than any of the other orthoses. From 390 to 650 inch-pounds of applied torque the Analog was, alone, significantly more resistant to varus deformity than the other seven orthoses, attaining a maximum varus deformity of 15.7 degrees (+/- .58). The ECKO knee orthosis exhibited the greatest degree of flexibility being significantly more deformed, 49.7 degrees (+/- .58), at the maximum torque load. The ECKO, DonJoy, Lenox Hill, and CTi deformed significantly more than all of the other orthoses for varus loads of 195 inch-pounds to 325 inch-pounds. The test prosthesis, with no orthosis, deformed 50.7 degrees (+/- 1.53) into varus (maximum deformity permissible on the apparatus), at a load of 455 inch-pounds, which was significantly greater than any of the test orthoses.

At the maximum comfortable varus angle, 3.4 degrees,[4] the Polyaction provided the best protection (195 inch-pounds) while the ECKO, Lenox Hill and DonJoy provided the best protection by exceeding the 3.4 degrees maximum comfortable varus range in degrees after only 65 inch-pounds of applied load. At the minimum angle at which internal joint disruption occurs (8 degrees[3]), four orthoses - Polyaction, Lerman, Analog and Pro Am - were stiffer than the others holding through 260 inch-pounds of varus torque. The ECKO provided the least protection by exceeding the 8 degrees after the first torque load.

Again a significant linear trend was observed between the variables of torque and angle for each of the orthoses (r .979 to .99). With third order regression applied, there was an improvement in curve fit (r .991 to .999) which, again, was not significant (Figure 8).

Axial Rotation

There are two groups of applied rotational torques: 0 to 60 inch-pounds, to evaluate the test apparatus with no orthosis; and 30 to 240 inch-pounds used to evaluate the eight knee orthoses.

The greatest variation between the eight knee orthoses occurred in axial rotation. The only axial rotation load at which all eight orthoses could be compared was 60 inchpounds (Table 4) . At this axial rotation load, the Polyaction and CTi deformed 2.3 degrees (+/-1.16) and 2.3 degrees (+/-.58), respectively; both of these knee orthoses were significantly more resistant to axial rotation motion than any of the others. The ECKO and DonJoy orthoses allowed significantly more motion, 40.3 degrees (+/- 1.53) and 38.3 degrees (+/- 1.16), respectively, at the first load of 60 inch-pounds, and exceeded the maximum permissible axial rotational deformity at the second rotational torque of 120 inch-pounds. Of the remaining six knee orthoses, the Lennox Hill was significantly more flexible than any of the others, allowing 30.3 degrees (+/-3.51) of axial rotation at 120 inchpounds. At 180 and 240 inch-pounds of applied torque, the CTi and Lerman were significantly more resistant to axial motion, attaining 31 degrees (+/- 1) and 34.7 degrees (+/- 1.53), respectively, at the maximum load.

The maximum comfortable axial rotation angle of 25 degrees5 was maintained up to 180 inch-pounds by only the Lerman and CTi knee orthoses. The axial rotation angle at which internal knee disruption occurs (37 degrees) was maintained up to 240 inch-pounds of applied axial rotation torque by only the Lerman and CTi knee orthoses.[3]

There was significant linear relationship between the applied torque and resulting angle (r .93 to .99) for all of the orthoses tested for rotation, which improved as third order regression was applied (r = .996 to .999). This change was also, not significant.

Discussion

The Analog and CTi knee orthoses exhibited the overall best resistance to high valgus loads (Table 2) . It is interesting to note that although the Analog and CTi knee orthoses offer the greatest resistance to valgus at high loads; the Polyaction, Lerman and Analog were better able to avoid the 3.4 degrees maximum comfortable deformity up to 195 inch-pounds of torque (Table 2 and Figure 7).

The Analog knee orthosis exhibited the overall best resistance to varus torques (Table 3 and Figure 8), especially at the higher varus loads (>325 inch-pounds). As was the case for valgus, the Polyaction knee orthosis was best able to avoid the maximum comfortable varus deformity (3.4 degrees) up to applied loads of 195 inch-pounds.

In general there was a 25 percent greater resistance to valgus than varus; the reason for this is not clear.

The CTi and Lerman knee orthoses exhibited the overall best resistance to axial rotation torques (Table 4 and Figure 9), including the axial angles corresponding to the maximum comfortable rotation (25 degrees) and protected completely against the axial angle at which internal joint disruption occurs (37 degrees). Regression curves of the axial rotation data (Figure 9) show that the CTi and Lerman knee orthoses were 25 to 30 percent better than the other six knee orthoses tested. This study did not support the finding of Knutzen, et al.[21] which showed that the Lenox Hill restricted axial rotation of the knee to approximately 7 degrees, during weight-bearing while walking. While these two studies are not comparable, the Lenox Hill exceeded 7 degrees of axial rotation at the first torque load which is calculated to beless than that experienced during the weight-bearing phase of gait.

Only two of the knee orthoses tested required a plaster impression to be sent to the manufacturer: the Analog and Lenox Hill. The CTi knee orthosis required an outline of the leg be drawn by a company representative. Therefore, these three were considered custom made and all the others were "off the shelf." In spite of being custom fabricated, the Lenox Hill knee orthosis did not fit well, which may account for its poor overall performance. Conversely, the Pro Am knee orthosis was not custom fabricated, did not fit well and performed surprisingly.

In general the more rigid the knee orthosis, the more resistant it was to deforming forces. Rigidity depended upon design (CTi), the use of metal sidebars (Analog, Polyaction and Lerman), and overall length (leverage). If the knee orthosis fits well, then good resistance deformity at small loads was more likely and corrective pressures were less (not measured).

The best knee orthosis in terms of fit and cosmesis, the ECKO, did not perform the best. It remains an obvious problem that the cosmetically "conscious" knee orthosis may not necessarily be functionally capable of doing the job for which it was intended; yet the functionally capable knee orthosis may not be acceptable to the patient or prescriber.

It is the authors' opinion that before a given knee orthosis can be objectively recommended for a given patient/pathology, standards should be devised as to how much knee angle deformity can be tolerated and the magnitude of external loads which must be restrained. It is obvious from Teitz, et al.[19] that the orthoses used by the football players did not provide adequate protection. However, to determine if protection by a knee orthosis is even possible, the specific loads imposed during the activity of football need to be known. It may be that the most restrictive knee orthoses may not be capable of guarding against high deforming torques. Therefore, the best knee orthosis may not be good enough. However, it may be found that the least restrictive knee orthoses may suffice for a wide range of low torque applications.

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References:

1. Rasch, P.J. and R.K. Burke, "The Science of Human Movement," Kinesiology and Applied Anatomy, Lea & Febiger, 1978, pp. 285-310.
2. Welsh, R.P., "Knee Joint Structure and Function," Clinical Orthopaedics and Related Research, Vol. 147, 1980, pp. 7-14.

3. Seering, W.P., R.L. Piziali, DA. Nagel and D.J. Schurman, "The Function of the Primary Ligaments of the Knee in Varus-Valgus and Axial Rotation," Journal of Biomechanics, Vol.13, 1980, pp. 785-794.
4. Markolf, K.L., A. Graff-Radford, and H.C. Amstutz, "In Vivo Knee Stability," Journal of Bone and Joint Surgery, 60A:5, 1978, pp. 664674.
5. Shoemaker, S.C. and K.L. Markolf, "In Vivo Rotatory Knee Stability," Journal of Bone and Joint Surgery, 64A:2, 1982, pp. 208-216.
6. Markolf, K.L., J.S. Mensch and H.C. Amstutz, "Stiffness and Laxity of the Knee - The Contributions of the Supporting Structures," Journal of Bone and Joint Surgery, 58A:5, 1976, pp. 583-593.
7. Kennedy, J.C. and P.J. Fowler, "Medial and Anterior Instability of the Knee," Journal of Bone and Joint Surgery, 53A:7, 1971, pp. 12571270.
8. Hughston, J.C., J.R. Andrews, M.J. Cross and A. Moschi, "Classification of Knee Ligament Instabilities ä Part I. The Medial Compartment and Cruciate Ligaments," Journal of Bone and Joint Surgery, 58A:2, 1976, pp. 159-186.
9. Fowler, P.J. "The Classification and Early Diagnosis of Knee Joint Instability," Clinical Orthopaedics and Related Research, Vol. 147, 1980, pp. 15-21.
10. Gaiway, H.R. and D.L. MacIntosh, "The Lateral Pivot Shift: A Symptom and Sign of Anterior Cruciate Ligament Insufficiency," Clinical Orthopaedics and Related Research, Vol. 147, 1980, pp. 45-50.
11. Torg, J.S., W. Conrad, and V. Kalen, "Clinical Diagnosis of Anterior Cruciate Ligament Instability in the Athlete," The American Journal of Sports Medicine, 4:2, 1976, pp. 84-93.
12. Hofmann, A.A., R.W.B. Wyatt, M.H. Bourne and A.U. Daniels, "Knee Stability in Orthotic Knee Braces," The American Journal of Sports Medicine, 12:5, 1984, pp. 371-374.
13. Bassett, G.S. and B.W. Fleming, "The Lenox Hill Brace in Anterolateral Rotatory Instability," American Journal of Sports Medicine, 11:5, 1983, pp. 345-348.
14. Peizer, E., E.J. Lorenze and M. Dixon, "The Genucentric Joint Orthosis," Medical Instrumentation, 16:4, 1982, pp. 207-208. Cassvan, A., K.E. Wunder and D.M. Fultonberg, "Orthotic Management of the Unstable Knee," Archives of Physical Medicine & Rehabilitation, Vol. 58, 1977, pp. 487-490.
15. Hastings, D.E., "The Non-Operative Management of Collateral Ligament Injuries of the Knee Joint," Clinical Orthopaedics & Related Research, Vol. 147, 1980, pp. 22-28.
16. Palumbo, P.M., "Dynamic Patellar Brace: A New Orthosis in the Management of Patellofemoral Disorders," American Journal of Sports Medicine, 9:1, 1981, pp. 45-49.
17. Levine, J., "A New Brace for Chondromalacia Patella and Kindred Conditions," Journal of Sports Medicine, 6:3, 1978, pp. 137-140.
18. Teitz, C.C., B.K. Hermanson, R.A. Kronmal, and P.H. Diehr, "Evaluation of the Use of Braces to Prevent Injury to the Knee in Collegiate Football Players," The Journal of Bone and Joint Surgery, 69A:1, 1987, pp. 2-9.
19. Butler, P.B., G.A. Evans, G.K. Rose and J.H. Patrick, "A Review of Selected Knee Orthoses," British Journal of Rheumatology, 22, 1983, pp. 109-120.
20. Knutzen, K.M., B.T. Bates and J. Hamill, "Electrogoniometry of Post-Surgical Knee Bracing in Running," American Journal of Physical Medicine, 62:4, 1983, pp. 172-181.
21. Knee Braces," American Academy of Orthopaedic Surgeons: Summer Report, 1984.

American Academy of Orthotists & Prosthetists

Professionals Advancing Care Through Knowledge

Efficacy of the Generation II Unloader Knee Orthosis in improving Lysholm Knee Rating Scale Scores in Patients with Medial Compartment Osteoarthritis

By Donald House, PT, OCS, CO

Abstract

Osteoarthritis of the knee joint can result in pain and instability, thus limiting the functional abilities of those stricken. The percentage of the world's population at risk for suffering pain and limitation due to OA is increasing considerably. These people are typically greater than 50 years old and are at high risk for surgical complications. Patients who are younger than 50 years old are also not optimal surgical candidates due to the high probability that they will require multiple revisions later in life.

Conservative management of mild osteoarthritis with heel wedges and neoprene sleeves has been suggested to be effective. In moderate to severe OA with reduction of the medial tibio-femoral joint space, a valgus inducing orthosis may be the only viable option to unload the medial joint and reduce pain during ADL's.

The purpose of this study was to determine whether patients would report less pain during normal ADL's after 1 month of orthotic treament with a Generation II Medial Unloader Knee Orthosis. The subjects included 9 patients that were referred to our clinic for orthotic management of knee osteoarthritis with c/o medial knee pain, and genuvarus. The subjects were asked to complete a Lysholm Knee Scale Questionnaire at the time of casting, then again at 1 month follow- up. Although 7 out of 9 patients reported improvement in pain and functional ability following treatment, there was no significant difference in functional knee scale scores obtained following orthotic treatment compared to those reported prior to orthotic management.

Introduction and Background:

Osteoarthritis (OA) is the most common disorder affecting synovial joints, with structural changes present in approximately half of the adult population (4). Kellgren and Lawrence performed clinical and roentgenologic assessment and deduced that 80% of persons 55 years or older experienced OA. The knee is the most commonly affected weightbearing joint, and varus deformity is the most common malalignment of the knee associated with osteoarthritis (4). As "baby boomers" are presently reaching this age, we expect that a growing percentage of the American public will be faced with pain and disability due to OA. It has also been documented that this population of patients is at a much

higher risk for complications during surgical procedures, therefore conservative alternatives may be a better option for many of these people (7).

Knee joint loading during walking or other routine ADL's has been shown to reach several times the loading caused by a static standing posture (1). A larger component of this reaction force is born by the medial compartment of the knee. Changes in bony alignment or loss of intrinsic soft tissue stabilizers can lead to increased asymmetry of knee joint loading patterns and cause more rapid progression of degenerative changes. For example, the presence of varus angulation results in approximation of the medial tibial plateau and medial femoral condyle which increases load on the medial compartment and accelerates breakdown of joint surfaces. Further more, the patient will often compensate by attempting to regain stability by forcefully contracting the musculature about the knee. This will also increase the compressive force across the joint. As the patient ambulates, the ground reaction force passes medial to the knee joint thus producing an adduction moment. This adduction moment combined with increased joint play due to loss of joint congruency results in high repetition, ballistic stretch of the surrounding soft tissue stabilizers. Since the bony anatomy of the knee joint does not provide any intrinsic stability, chronic lengthening of the collateral ligaments will result in gross coronal instability, and amplify the varus thrust during stance.

High tibial osteotomy has been used to reduce the varus deformity of the knee in an attempt to normalize bony alignment and reduce loading of the medial compartment. Unfortunately, patients who present with high adduction moments during gait prior to surgery have been shown to maintain that pattern or revert back to it within a few years post surgery (1). Many of these patients progress rapidly to requiring total knee replacement. Even then, a high incidence of component loosening is seen in patients who remain in varus. These unreliable surgical outcomes combined with risk of surgical complications, high cost, and time loss from normal work and activity make conservative treatment options attractive to many patients.

Orthotic treatment has been used as part of the conservative treatment for knee medial compartment osteoarthritis. Most common types or orthoses used include wedged insoles, knee sleeves, and unloading braces. Wedge insole orthoses have been shown to be effective only in early-stage OA; severe OA is not affected (7). Neoprene knee sleeves provide little or no mechanical support to the knee but may have some effect on improved stability and reduction of pain. Kirkley reports that good results have been described anecdotally however no controlled trials have been reported supporting the use of a sleeve. Unloading braces were developed to create a valgus force on the knee and reduce compression of the medial compartment during gait, which can be excessive when genuvarum due to OA is present. One such orthosis, the Generation II (G II) was designed in Canada by Generation II Orthotics Ltd. It is a polyaxial hinged brace that induces an increasing amount of valgus force to the knee as the patient moves from knee extension to flexion. The valgus force is thought to be beneficial in correcting bony alignment, and lessening the effect of the adduction moment placed on the knee in stance thereby reducing compression force in the medial knee compartment. If the medial joint space in OA patients could be enlarged using this orthosis, painful symptoms might be eliminated or decreased affording the patient improved function during ADL's.

Studies supporting Valgus bracing for OA would be useful to many members of the rehabilitation team. Physicians and surgeons can learn whether conservative options can be used instead of, or possibly in conjunction with surgery to correct bony alignment, protect prosthetic implants, improve knee stability and reduce the amplification of forces across the joint surfaces. Physical therapists may be interested in learning whether orthotic treatment can assist in reducing pain, thus allowing patients to maintain their current functional level while performing exercises to strengthen the knee stabilizers. Orthotists can benefit from research that explores not only the use of Valgus bracing for treatment of

knee OA, but also the use of outcome measures to evaluate the effect that orthotic treatment has on the patients perceived level of pain and disability.

The purpose of this study is to evaluate the effectiveness of valgus bracing for medial compartment knee osteoarthritis, to assess the appropriateness of the Generation II Unloader Orthosis in patients with medial knee joint OA, and to examine the use of the Lysholm Knee Rating Scale as a functional outcome measure for support of orthotic treatment of knee osteoarthritis.

Previous Investigations

Matsuno et al. studied 20 subjects who were all >55 y/o with bilateral knee arthritis but retained at least 50% of normal tibio-femoral joint space, and could walk at least 500 meters independent of support. The side experiencing the most severe symptoms was fitted with a Generation II Medial Unloader Knee Orthosis that was worn at all times except for at night.

Clinical Assessments were performed each month following GII application. The functional objective efficacy of the orthosis was assessed utilizing the modified knee scoring system of the Japan Orthopaedic Association, which evaluates pain on walking and on climbing up and down stairs. X-rays were taken both in and out of orthosis every 2 months. Quadriceps muscle strength was assessed isokinetically using a dynamometer. A stabilometer was used to record the excursion of the patients center of gravity during 30 seconds of static standing.

The authors reported that the JOA Knee Scores significantly improved with application of the orthosis and continued to improve throughout the 12 month observation period. The femorotibial angle (genuvarum) decreased after 2 months in the orthosis and remained decreased at 12 month follow-up. The isokinetic quadriceps muscle strength with the brace on increased throughout the full range of motion. Also, decreased total movement of the center of gravity was noted in the orthosis suggesting improvement in the lateral stability of the knee (7).

Hewett, Noyes et al. studied 19 subjects with persistent chronic medial tibiofemoral compartment pain that affected sports or daily activities, arthroscopic or radiographic documentation of medial compartment arthrosis, or varus osseous alignment. Patients were fitted with a valgus inducing orthosis (Bledsoe Brace Systems) and were instructed to wear the brace for as many hours and for as many days of the week as they wished. All patients had undergone multiple operative procedures, including arthroscopies, partial or total meniscectomies, high tibial osteotomies, and anterior cruciate ligament reconstruction. Evaluation was performed before brace wear, after the initial follow-up evaluation (mean: 9 weeks), and after the final follow up evaluation (mean: 46 weeks). Patients completed a Cincinnati Knee Rating System questionnaire, and visual analog scale. They were asked how many minutes they could walk without significant pain, how painful their knee was after 30 and 60 minutes of mall shopping, and whether none, some, or significant pain relief was provided by only the brace, by only the medication, or by both the brace and the medication. Patients were also asked to rate the overall condition of their knee on a 1 to 10 scale with 1 indicating the poorest knee and 10 indicating a normal knee. At the two follow-up evaluations, patients were asked to provide and average of hours per day and days per week that the brace had been worn. X-rays were repeated at follow-up, and 9 patients underwent gait analysis testing.

According to the authors, 78% of the patients reported severe pain with ADL's prior to brace wear, compared to only 39% at the first follow-up and 31% at the final follow-up. Pain analogue scale scores decreased significantly between the pre-orthosis and both follow up evaluations. Reported walking tolerance increased from 51 minutes pre-orthosis to 138 minutes at 9 week follow up. The patients reported average walking tolerance of 107 minutes after 1 year of wearing the valgus

inducing orthosis. Gait evaluation showed no change in the mean value for the knee adduction moment in stance. At pre-brace evaluation, the mean patient's self perception of knee score was 3.4 points out of 10. At the first follow-up evaluation, the mean score had improved to 5.4, and it remained improved at 4.7 at second follow-up (2).

Kirkley et al. randomized 119 patients into 3 groups to compare the effectiveness of valgus bracing (GII) to patients treated with a neoprene sleeve and a control group, which received no orthosis. Two disease specific, health related, quality of life measures and two functional scores were used at the baseline and all follow-up evaluations. The Western Ontario and McMaster University Osteoarthritis Index (WOMAC), and McMaster-Toronto Arthritis Patient Preference Disability Questionnaire (MACTAR) were used to assess the patients perceived functional limitations while a six minute walking test and 30 second stair climbing test were used as functional measures.

The authors reported that patients who underwent valgus bracing showed significantly improved WOMAC scores compared to the group that wore a neoprene sleeve, who in turn improved significantly more than the control group. No significant difference could be detected between the unloader brace group and the neoprene sleeve group, or between the sleeve group and the controls. Distance walked and the number of stairs climbed during functional testing were not statistically different among the three groups at 6 month assessment however pain scores in the valgus braced group were significantly less than those for the neoprene sleeve and control groups following both tests(4).

Lindenfeld et al. examined whether a brace designed to unload varus degenerative knees actually alters medial compartment load by decreasing the knee adduction moment during gait. Eleven patients who had undergone arthroscopic debridement and other associated arthroscopic procedures for persistent medial knee pain during ambulation, but continued to have pain post surgically were used for the study. These patients were fitted with a valgus knee brace (Big Sky Medical, Bozeman, MI) and underwent gait analysis before and after a minimum of 4 weeks wearing the brace. They also completed questionnaires and were interviewed for the assessment of symptoms, sports activities, and functional limitations according to the Cincinnati Knee Rating System. Results were compared to a group of controls without a brace, with no knee injury, that were matched for walking speed and performed identical tests.

Investigators reported that pain symptoms decreased significantly with brace wear. The pain scores recorded from analog pain scale decreased 48% in the brace group, activity level achieved without pain symptoms increased 69%, and function with activities of daily living score of the Cincinnati Knee Rating System increased 79%. Nine of 11 patients had a decrease in the adduction moment of the involve knee when wearing the brace, with the moment decreasing by as much as 32% (5).

Methods:

All patients (n=11) who were referred to our clinic from 1/1/2001 and 6/30/2001 for orthotic treatment secondary to knee osteoarthritis who presented with varus angulation of the knee (varus >0 degrees), and complained of medial knee pain were asked to participate in the study. Patients were excluded from the study if they reported a past medical history that includes: knee surgery, hip surgery, cardiac or respiratory problems, recent lower extremity fractures, loss of sensation in the legs or feet, or open wounds within the trim lines of the orthosis, or if they had ever worn a knee orthosis. No patients were excluded because of age, race, or gender. One patient was excluded from the study due to lack of follow-up, and one additional subject was excluded due to inconsistent responses on his questionnaire compared with his functional level. All patients who were not excluded (appendix A) and agreed to participate were asked to sign a consent form (appendix B). Participants were asked to

complete a Lysholm Knee Scale Questionnaire (appendix C). The Lysholm Knee rating scale is reported to have an intrapersonal and interpersonal coefficient of variation of 3%, and 4% respectively. Test-retest reliability level was excellent with a calculated correlation coefficient of .97 (6). This scale is especially appropriate for self-evaluation of function in the typical OA patient in that unlike most other knee function questionnaires, it assesses normal ADL's rather than sports specific activity. The scale is easy to administer and score. All patients were fitted with a Generation II Medial Unloader Knee Orthosis as per manufacturers specifications (Generation II Orthotics Ltd., Canada). The patients were instructed to wear their orthosis whenever they were active. At 1 month follow-up, the patients were asked about any problems that they may have experienced with the orthosis and whether they had complied with the prescribed wearing schedule. They were also asked to complete another Lysholm Knee Scale Questionnaire.

Knee Scale Scores were calculated as recommended by Lysholm. Pre-orthosis and post-orthosis scores were compared statistically using a paired T-test design with significance level of .05, and were used to prove or disprove the research hypothesis that valgus bracing is effective in reducing the Lysholm Knee Rating Scale Scores in patients with pain and functional limitation due to medial compartment osteoarthritis.

Results:

Initial Lysholm Knee Scale scores ranged from 26% to 64% with a mean score of 45.1%. Treatment time preceding follow-up ranged varied due to patient non-compliance with scheduled follow-up appointments. Mean follow-up time was 10.9 weeks with a range from 4 weeks to 27 weeks. Post-treatment Lysholm Knee Scale scores ranged from 16% to 93% with a mean score of 63% (Table 1).

Table 1

Pre-score	Post-score	Time to follow-up	Change in Score
44%	72%	15 weeks	28%
44%	62%	10 weeks	18%
55%	60%	5 weeks	5%
64%	82%	6 weeks	18%
29%	71%	7 weeks	42%
55%	93%	4 weeks	38%

26%	24%	14 weeks	(-) 2%
36%	16%	10 weeks	(-) 20%
53%	87%	27 weeks	34%

Data was compared using a 2 tailed paired t-test. The t-test indicated that the Lysholm Scale scores at follow-up were not statistically different from those obtained prior to orthotic treatment at a significance level of 0.05.

Conclusion:

The results of this study suggest that although 7 out of 9 subjects reported improvement in pain and functional ability after treatment, there was no significant difference in functional knee scale scores obtained following orthotic treatment compared to those reported prior to orthotic management. The subject sample size utilized in this study was small due to time constraints. Treatment time was not well controlled and varied significantly between subjects. Additional studies with larger sample sizes, better regulation of treatment time, specific patient populations, and the use of other manufacturers orthotic devices for valgus knee bracing are needed to explore the efficacy of this treatment.

APPENDIX A

Name:_____ AGE:_____

Have you ever had any of the following?

Yes No Don't Know

1. Knee Surgery ___ ___ ___
2. Hip Surgery ___ ___ ___
3. Cardiac or Respiratory Problems ___ ___ ___
4. Recent Fractures ___ ___ ___
5. Loss of Sensation in your legs ___ ___ ___
6. Open wounds on your legs or feet ___ ___ ___

Have you ever worn a knee brace? If so what type?

Do you know of any reason that it may be harmful for you to wear a knee brace as prescribed by your physician at this time? If yes, please explain:

_____ _____

Participant Orthotist

Appendix B

Lysholm Knee Rating System

Name_____ Date_____ Therapist_____

By completing this questionnaire, your therapist will gain information as to how your knee functions during normal activities. Mark the box which best describes your knee function today.

1.	LIMP (5 points)	
	☐ None	5
	☐ Slight or periodic	3
	☐ Severe and constant	0
2.	SUPPORT (5 points)	
	☐ None	5
	☐ Cane or crutch needed	2
	☐ Weight bearing impossible	0
3.	LOCKING (15 points)	
	☐ None	15
	☐ Catching sensation, but no locking	10
	☐ Locking occasionally	6
	☐ Locking frequently	2
	☐ Locked joint at examination	0
4.	INSTABILITY (25 points)	
	☐ Never gives way	25
	☐ Rarely during athletic activities/physical exertion	20
	☐ Frequently during athletic activities/physical exertion	15
	☐ Occasionally during daily activities	10
	☐ Often during daily activities	5
	☐ Every step	0
5.	PAIN (25 points)	
	☐ None	25
	☐ Intermittent and light during strenuous activities	20
	☐ Marked during strenuous activity	15
	☐ Marked during or after walking more than 2 km. (1.2 mi.)	10
	☐ Marked during or after walking less than 2 km. (1.2 mi.)	5
	☐ Constant	0
6.	SWELLING (10 points)	
	☐ None	10
	☐ After strenuous activities	6
	☐ After ordinary activities	2
	☐ Constant	0
7.	STAIRS (10 points)	
	☐ No problem	10
	☐ Slight problem	6
	☐ One step at a time	2
	☐ Impossible	0
8.	SQUATTING (5 points)	
	☐ No problem	5
	☐ Slight problem	4
	☐ Not beyond 90° of flexion of the knee (halfway)	2
	☐ Impossible	0

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References

1. Andriacchi T. Dynamics of Knee Malalignment. Orthopedic Clinics of North America 1994; 25: 395-403.

2. Hewett, T.E.; Noyes, F.R.; Barber-Westin S.D.; Heckmann, T.P. Decrease in knee joint pain and increase in function in patients with medial compartment arthrosis: a prospective analysis of valgus bracing. Orthopedics 1998; 21: 131-138.

3. Horlick S; Loomer R. Valgus Knee Bracing for Medial Gonarthrosis. Clin J Sport Med1993; 3: 251-255.

4. Kirkley, M.D., et al. The Effect of Bracing on Varus Gonarthrosis. Journal of Bone and Joint Surgery 1999; 81-A: 539-548.

5. Lindenfeld, Hewett, T.E.; Andriacchi T. Joint Loading with Valgus Bracing in Patients with Varus Gonarthrosis. Clinical Orthopedics and Related Research 1997; 344: 290-297.

6. Lysholm. Rating Systems in the Evaluation of Knee Ligament Injuries. Am J Sports Med. 1982; 10: 150-155.

7. Matsuno, H; Tsuji, H. Generation II Knee Bracing for Severe Medial Compartment Osteoarthritis of the Knee. Arch. Phys. Med. And Rehab.1997; 78: 745-749.

The Effectiveness of Off-Loading Knee Orthoses in the Reduction of Pain in Medial Compartment Knee Osteoarthritis: A Systematic Review

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ABSTRACT

The purpose of this review is to determine the effectiveness of knee orthoses in the treatment of pain in unilateral compartment osteoarthritis (OA). OA is the most common disorder affecting synovial joints, with structural changes of OA present in approximately half of the adults. The knee is the most commonly affected joint. Many treatments have been developed for OA, including the unloader knee orthosis. The principle of the unloader knee orthosis is to create a varus or valgus moment at the knee—theoretically creating additional space in the joint compartment, thus relieving pain caused by bone-on-bone contact. Several studies have been done, but none with a power or number of participants were large enough to demonstrate effective treatment of OA. Using the keywords "knee osteoarthritis" and "orthosis" or "brace," the PubMed, CINAHL, RECAL, and ISI Web of Knowledge electronic databases were searched for randomized control trials with "orthoses" or "braces" for the knee between January 1980 and December 2010. Only studies that dealt with medial unilateral compartment knee OA and the use of a knee orthosis were selected. Of these articles, only experimental trials were selected based on the American Academy of Orthotists and Prosthetists State-of-the-Science Evidence Report Guidelines. A comparative analysis of the articles was used to determine the effectiveness of the orthoses in reducing pain. Forty-six initial articles were found. Of these, 15 articles were ultimately included and reviewed based on the inclusion guidelines. Most of these articles were either single-subject research or before-and-after studies. The majority were of moderate quality. Statistically significant pain reduction was noted by 73% of the studies reviewed, although all showed that there was pain reduction in the patients. Patient function and orthosis efficacy were also briefly examined, showing moderate increases of function. The rate of pain relief was further investigated and revealed that pain relief was almost immediate. OA knee orthoses are a cost-effective way to reduce pain in patients with medial compartment OA. (*J Prosthet Orthot.* 2012;24:39–49.)

KEY INDEXING TERMS: osteoarthritis, knee orthoses, brace, knee, pain, function

Osteoarthritis (OA) is a debilitating disease that affects millions of people worldwide. It is the most common type of arthritis and is a major cause of musculoskeletal pain and disability in elderly populations.[1] In the United States alone, 6% of the adults aged 30 years and older (roughly 10 million individuals) have symptomatic OA of the knee.[2] OA of a single compartment is distinguished from that of both compartments. The single-compartment OA is associated with malalignment and increased risk and progression of knee OA, therefore predicting decline in function. Those with medial compartment OA often have a varus alignment observed during gait evaluation, as the mechanical axis and weightbearing pass through the medial compartment. Patients with OA of the lateral compartment usually have a valgus alignment, and the mechanical axis and weightbearing pass through the lateral compartment.[3] With so many affected, multiple treatment modalities have been developed. There are >50 nonpharmacological, pharmacological, and surgical interventions for the treatment of OA. Nonsurgical treatment methodologies are generally tried first. If these relieve pain, increase function, and slow the progression of the disease, then surgical interventions are delayed. Surgical interventions include knee joint replacement, both full and partial; high tibial osteotomy; and fusion as a last resort when joint replacement has failed.[4]

OA knee bracing is one of these nonsurgical interventions. Introduced in 1989, it has become a popular mode of treatment for the OA knee.[5] The orthoses function by the use of a mechanical lever arm that reduces the forces transferred through the affected compartment, "off-loading" those affected compartments with unilateral OA by creating a valgus or varus moment at the knee depending on the affected compartment. This, in turn, reduces pain and increases function.[6]

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Although some research in OA unloading knee orthoses has demonstrated an increase in function with various scales and measurement tools,[7,8] probably the most practical and easiest way for the orthotists to demonstrate clinical effectiveness through evidence-based practice is by measuring pain. Evidence-based practice seeks to inform clinical decision making by combining a practitioner's training and experience with evidence established through scientific research.[9] If pain reduction is a goal of the orthotic intervention process, using pain as a measurable benchmark can demonstrate that an orthosis is an effective treatment modality. The visual analog scale (VAS) is a common, well-established measuring device to track this.[10]

With the growth and acceptance of the market for these orthoses, there have been multiple articles and studies published on the topic. Although some articles focus on the biomechanical aspects of the knee and its varus and valgus moments, others consider whether or not function is increased by the use of knee orthoses. Other articles reveal the long-term effects of the orthosis; still others investigate pain reduction of the participant with the orthosis. Some articles include various combinations of these aspects of study. By documenting the ability of the unloading knee orthosis to reduce pain in those suffering from unilateral OA of the knee through research, the authors of this article may prove what clinical practice has already shown to be effective: that OA unloading knee orthoses are effective in the relief of medial compartment OA knee pain.

METHODS

Using the keywords "knee osteoarthritis" and "orthosis" or "brace," the PubMed, CINAHL, RECAL, and ISI Web of Knowledge electronic databases were searched for randomized control trials with orthoses or braces for the knee between January 1980 and December 2010. The exact Boolean search phrase used was [(knee osteoarthritis) and (orthosis or brace)]. The RECAL and CINAHL databases were selected for their orthotic-specific search capabilities. The RECAL database was compiled by the National Centre for Prosthetics and Orthotics and the service designed and developed by the Centre for Digital Library Research, both of the University of Strathclyde.[11] CINAHL was selected because it included the *Journal of Prosthetics and Orthotics*.

To standardize the process of literature review and selection, the American Academy of Orthotists and Prosthetists (AAOP) has developed a study design classification scale, which is used to classify the study type when performing a literature review. Research is divided into four categories: structured reviews, (quasi) experimental trials, observational studies, and expert opinion. It was decided that experimental trials would best demonstrate the effectiveness of the OA knee orthosis in relieving pain in the OA knee.[12]

Only those articles that were experimental or quasi-experimental trials were selected, based on the AAOP State-of-the-Science Evidence Report Guidelines. The studies reviewed needed to be prospective research studies with multiple subjects. They must have some comparison, whether it is between conditions or between a control group and an intervention group. The studies must also have had one or more interventions and the data gathered and documented intervals. The five groups established by the AAOP State-of-the-Science Evidence Report Guidelines are randomized control trial (E1), controlled trial (E2), interrupted time series trial (E3), single-subject experimental trial (E4), or a controlled before-and-after trial (E5). The difference between these is the number of subjects, random assignment of the subject(s) and control(s), and the frequency of data collection. A comparative analysis of the studies will be used to determine the effectiveness of the orthoses in the area of pain.[12]

Only studies that dealt with medial unilateral compartment knee OA and the use of a knee orthosis were selected. The medial compartment is involved in 91% of unilateral cases of OA, 10 times more often than the lateral compartment.[13] This can partly be attributed to the increased load carried by the medial compartment. Approximately 60% to 80% of the load across the knee is transmitted through the medial compartment.[14] To keep the demographic population consistent, only those studies that investigated medial compartment OA were evaluated. This eliminated variables associated with varus or valgus moments that affect the biomechanics and function of the orthoses and therefore the effect on pain.[15]

Methodological quality was assessed using a modified version of the State-of-the-Science Evidence Report Guidelines Quality Assessment Form.[12] All items have "yes," "no," or "N/A" answer options. Fourteen questions were asked: six on internal validity and eight regarding external validity (Table 1). Because of the nature of many of the studies and the justification for the literature review, it was thought by the reviewers that external validity should be more heavily favored because of the desire for clinical application.

After the articles were reviewed, they were then scored. Those articles that scored five or below were considered of low quality and were rejected for review. Those articles that scored from 6 to 10 were considered moderate quality, whereas those that scored from 11 to 14 were considered high quality. Both moderate- and high-quality articles were reviewed. A high score indicated that the reviewers evaluated the study to have few to no confounding factors or bias, which would limit the usefulness of the study in its applicability. A study of moderate quality indicated that there are areas of bias introduced into the study, somewhat limiting the value and usefulness of the results. A low score indicated that the reviewers believed that there were many confounding factors and bias introduced in the study and that there were serious problems with the applicability of the study to clinical practice.

RESULTS

The initial Internet database search yielded 306 articles. From CINAHL, 19 articles were located, 64 from the ISI-Web

Table 1. Methodological quality assessment.

	Yes	No	N/A	Comments	
Criterion—internal validity					
IV-1. Control/comparison group appropriate					
IV-2. Inclusion criteria appropriate					
IV-3. Exclusion criteria appropriate					
IV-4. Protocol addresses accommodation and washout					
IV-5. Attrition explained and <20%					
IV-6. Free from conflicts of interest					
Total number of threats identified					
Criterion—external validity					
EV-1. Sample characteristics adequately described					
EV-2. Sample representative of the target population					
EV-3. Outcome measures adequately described					
EV-4. Outcome measures valid for this study					
EV-5. Intervention adequately described					
EV-6. Findings clinically significant/relevant					
EV-7. Conclusions placed in context of existing literature					
EV-8. Conclusions supported by findings					
Total number of threats identified					
Combined total number of threats identified					
Overall assessment of internal and external validity (circle one)	High			Moderate	Low

of Knowledge, 100 from the RECAL database, and 123 from the PubMed database. A review of the titles and abstracts of these initial 306 articles resulted in 265 being excluded based on inclusion and exclusion criteria. The remaining 41 were pearled ("pearling" is a search for additional references within references located for review), and 5 additional articles were located. These remaining 46 articles were reviewed, and 31 were excluded from the study for the following reasons. In 16, pain was not considered in the study; 9 were not level E5 to E1; in one study the knee orthosis was used after knee arthroplasty; in one study no knee orthoses were used, and the study was unclear as to the mode of treatment; in one study the methodology was unclear; one was not in English; one was a meeting abstract; and one was a product development paper (Figure 1). Fifteen articles were included for review.

Of these 15, there were 3 randomized control trials selected (E1), one interrupted time series trial (E3), six single-subject experimental trials (E4), and five before-and-after trials (E5). A quality analysis resulted in nine studies that were of moderate quality and six studies of high quality. Only one study[16] had a perfect score, indicating that the reviewers believed that there was little bias introduced in this study; this study used gait parameters as a primary outcome measure and pain as a side measure. There were no studies of low quality reviewed. Studies tended to score lower on questions of internal validity than external validity. Some of the best organized and well-written studies were funded by manufacturers who introduced additional bias into the studies (Table 2).

A brief summary of the applicable data from each reviewed articles is as follows. If numbers were given in the study, then they are reported below, otherwise statistical significance was considered.

Barnes et al. published "Effect of CounterForce Brace on Symptomatic Relief in a Group of Patients With Symptomatic Unicompartmental Osteoarthritis: A Prospective 2-Year Investigation" in the *American Journal of Orthopedics* in 2002. Thirty patients from the clinical population of Barnes et al. were selected as participants in this study. Patients completed the American Academy of Orthopaedic Surgeons (AAOS) arthritis questionnaire, the short-form SF-36® Health Survey, and VAS on pain levels both on a daily and on a weekly basis. Participants were fitted with the CounterForce ™ (Breg, Vista, CA) orthoses from Breg®. After 8 weeks of treatment, participants again completed the AAOS and SF-36 forms. A follow-up after 2.5 years was also completed. With both the AAOS and SF-36 forms, symptoms improved in all categories during the 8-week period. The patients' responses to questions in the weekly log were also of note. Statistically significant decreases in pain during the duration of that time were documented, as well as a marked decrease in weeks 1 to 3. Pain relief in the orthosis was initially dramatic but seemed to level out after week 3. There was another marked decrease in pain between weeks 7 and 8. There were inconclusive results as to the decreased use of pain medications while using the orthosis. At the long-term follow-up, 21 individuals (73%) indicated that the orthosis was effective in relieving their pain.[17]

Brouwer et al. published "Brace Treatment for Osteoarthritis of the Knee: A Prospective Randomized Multi-Centre Trial" in *Osteoarthritis and Cartilage* in 2006. Participants in this study were originally treated with standard conservative treatments. Patients were either originally fit with an OAsys orthoses from Innovation Sports or were in a control group that was not treated with any orthosis but instead continued with standard treatment. One hundred eighteen

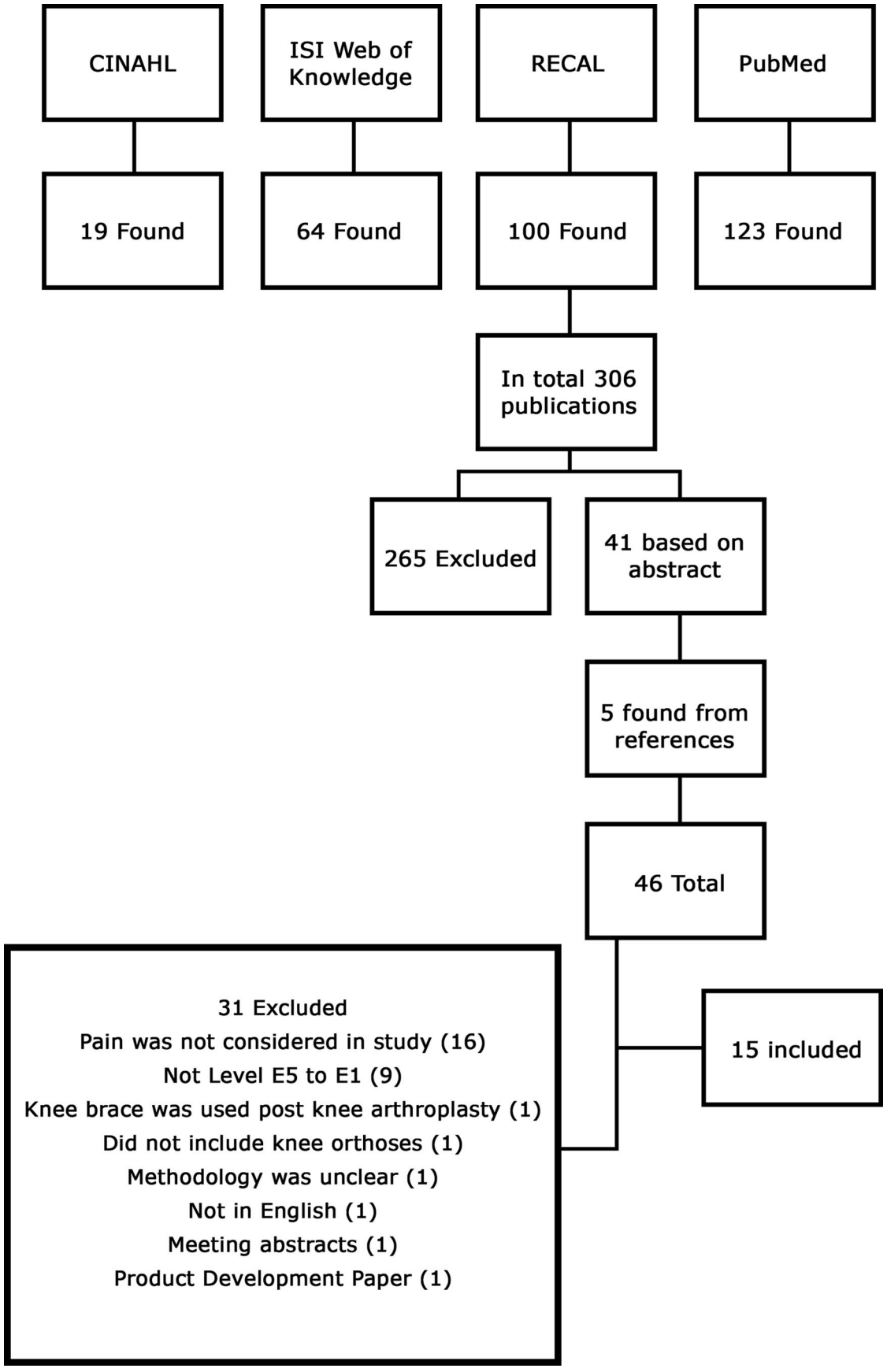

Figure 1. Literature search results.

Table 2. Methodological quality assessment results.

Author	Study level of evidence	Parameters	Participants	Device used	Selection																		0–5 Low, 6–10 moderate, 11–14 high
					Internal validity							External validity									Total score	Quality	
					IV-1	IV-2	IV-3	IV-4	IV-5	IV-6	Total	EV-1	EV-2	EV-3	EV-4	EV-5	EV-6	EV-7	EV-8	Total			
Barnes et al.	E-5	AAOS arthritis questionnaire, SF-36 health survey, VAS	30	Breg Counterforce OA knee brace	1	0	0	1	0	0	2	1	1	1	1	1	1	0	0	6	8	Moderate	
Brouwer et al.	E1	VAS, HSS, Walking distance, EuroQol5D)	117	OAsys brace, Innovation sports	1	1	1	1	0	1	5	1	1	1	1	1	1	1	1	8	13	High	
Dennis et al.	E5	Subjective patient reported measure	45	Bledsoe Thruster 2, DJ OAdjuster, Innovations sports OAsys, Generation II, Ossur	1	1	0	0	1	0	3	1	0	1	1	1	1	1	1	7	10	Moderate	
Draganich et al.	E4	WOMAC	10	OAdjuster AND oa Defiance from DJ	1	1	1	1	0	0	4	1	1	1	1	1	1	1	1	8	12	High	
Finger et al.	E4	VAS	23	OAdjuster DonJoy	1	1	0	1	1	0	4	0	0	1	1	1	1	1	0	5	9	Moderate	
Gaasbeek et al.	E4	WOMAC, VAS	15	SofTec OA brace (Bauerfeind, GmbH)	1	1	1	1	0	0	4	0	1	1	1	1	1	0	1	6	10	Moderate	
Horlick and Lommer	E4	VAS	40	Generation II (Ossur)	1	1	1	1	1	0	5	0	1	1	1	1	1	1	1	7	12	High	
Kirkley et al.	E1	WOMAC	110	Generation II (Ossur)	1	1	1	1	1	0	5	1	1	1	1	1	1	1	1	8	13	High	
Lindenfeld et al.	E4	VAS	11	Generation II (Ossur)	1	0	0	1	0	1	3	0	0	1	1	1	1	1	1	6	9	Moderate	
Matsuno et al.	E5	Self-reported	20	Generation II (Ossur)	1	0	1	1	1	0	4	0	0	1	1	1	1	1	1	6	10	Moderate	
Pagani et al.	E4	WOMAC	11	28K20/21 (Otto Bock)	1	1	0	1	0	1	4	0	0	1	1	1	1	1	1	6	10	Moderate	
Ramsey et al.	E3	Knee injury and Osteoarthritis Outcome Score (KOOS)	16	Generation II (Ossur)	1	1	0	1	1	1	5	0	0	1	1	1	1	0	1	5	10	Moderate	
Richards et al.	E5	VAS, HSS	12	Generation II (Ossur), Bilateral uniaxial hinge B1 (Trulife)	1	1	0	1	1	1	5	0	0	1	1	1	1	1	0	5	10	Moderate	
Schmalz et al.	E5	VAS	16	28K20/21 (Otto Bock)	1	1	1	1	1	1	6	1	1	1	1	1	1	1	1	8	14	High	
van Raaij et al.	E1	VAS, WOMAC	91	MOS Genu (Bauerfeind AG)	1	1	1	1	1	1	6	1	1	0	1	1	1	1	1	7	13	High	
		VAS, HSS, WOMAC	567																				

VAS, visual analog scale; HSS, Hospital for Special Surgery; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

patients were admitted in the study and randomized into two different groups. Patients were assessed using both the VAS and the Hospital for Special Surgery OA form (HSS). Compared with the controls, pain severities on the VAS scale were less in the orthosis group at each of the three assessment points as well as overall during the 12-month follow-up. At 12 months, the difference was borderline significant; however, in both instances, significant pain reduction versus the control group was not found.[3]

Dennis et al. published "An In Vivo Analysis of the Effectiveness of the Osteoarthritic Knee Brace During Heel Strike and Midstance of Gait" in the *Acta Chirurgiae Orthopaedicae Et Traumatologiae Cechoslovaca*, a Czech orthopedic journal, in 1999. In it the researchers analyzed the gait of 40 subjects during heelstrike and midstance, which are both weightbearing conditions, using video fluoroscopy to determine whether unloading knee orthoses actually provide separation of the femoral condyle from the tibial plateau, thereby avoiding excessive loads on the degenerated compartment. Participants were also asked to state if the orthosis reduced their pain, though not rated on a VAS or other measuring device. Thirty-four of the 40 participants indicated that they had pain relief from the orthosis, whereas 6 did not. It was noted by the authors that all of these had a body mass index >20% of their ideal body weight and had no condylar separation. Although the authors documented that lack of subjective pain relief correlated with no condylar separation, no statistical analysis was done to determine whether this was a significant association.[18]

Dennis et al. published his findings again with a parallel study in 2006 in the *Journal of Arthroplasty* under the title, "Evaluation of Off-Loading Braces for Treatment of Unicompartmental Knee Arthrosis." As before, it was documented that 34 of the 40 participants, or 85%, stated they had pain relief from the orthosis, whereas 6 did not. Again, no statistical analysis was done to determine whether this was a significant association between subjective pain relief and condylar separation.[19]

Draganich et al. published "The Effectiveness of Self-Adjustable Custom and Off-the-Shelf Bracing in the Treatment of Varus Gonarthrosis" in the *Journal of Bone and Joint Surgery* in 2006. Ten patients were evaluated in two orthoses in a random order. One was custom fabricated for them and the other was an off-the-shelf model. Pain and function were both assessed using the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) index (which measures pain, stiffness, and physical function).[20] Measurements were taken before application of the orthoses and after 4 to 5 weeks after application of the orthoses. Pain was significantly reduced from an average baseline of 197 to 120 mm with the off-the-shelf model and to an average of 71 mm with the custom orthosis. There was a significant difference between each of the three testing parameters. Function increased significantly only with the custom orthosis over the baseline. The authors attributed this success of the custom model to the better fit of the custom orthosis. The authors further state that their study suggests that an intimate fit is necessary for improved results and increased pain relief.[21]

Finger et al. published "Clinical and Biomechanical Evaluation of the Unloading Brace" in the *Journal of Knee Surgery* in 2002. Twenty-three participants were assessed preapplication of the orthosis and at three months using a 10-point pain scale. At three months, the average resting pain decreased from 4.2 to 1.9, pain with activity decreased from 7.2 to 3.9, and night pain decreased from 3.9 to 2.4. No statistical analysis was done on these numbers to determine whether the changes were significant.[22]

Gaasbeek et al. published "Valgus Bracing in Patients With Medial Compartment Osteoarthritis of the Knee: A Gait Analysis Study of a New Brace" in *Gait and Posture* in 2006. Fifteen patients with medial compartment OA were fit with a pneumatic knee orthosis, which provided a medial force that was designed to off-load the medial compartment of the knee. Baseline measurements were taken before the fit of the orthosis and after 6 weeks of continuous wear. The VAS pain scores showed a statistically significant change. The average score was 6.8 ± 2.5 without the orthosis and 4.7 ± 3.0 with the orthosis. The WOMAC score also showed a statistically significant change. The average score was 50.1 ± 17.6 without the orthosis and 63.0 ± 18.4 with the orthosis.[23]

Horlick et al. published "Valgus Knee Bracing for Medial Gonarthrosis" in the *Clinical Journal of Sports Medicine* in 1993. Thirty-nine participants were fit with the generation II unloader orthosis, some with the hinge on the lateral side and some with the hinge on the medial side. Participants were then randomly assigned to one of four treatment sequences: (a) brace in neutral, brace in valgus, and no brace; (b) brace in neutral, no brace, and brace in valgus; (c) brace in valgus, no brace, and brace in neutral; and (d) brace in valgus, brace in neutral, and no brace. Although an option, Horlick decided not to start participants out in the no-brace stage because it did not differ from the pretreatment status. During the study, participants filled out a daily pain and function log. Twenty participants had laterally hinged orthoses, and 19 participants had medially hinged orthoses. The VAS showed a statistically significant decrease in the pain level from baseline to valgus and a marginally significant decrease from baseline to neutral, using the lateral hinge. Somewhat stronger evidence of differences was seen with the medial hinge. Both baseline to valgus and baseline to neutral were statistically significant. Something that was noted by the authors was a carryover effect of the orthosis into the no-brace, washout phase. Continuing relief of pain was experienced in the no-brace phase of the study by both those with the valgus and neutral orthoses.[24]

Kirkley et al. compared the neoprene knee sleeve, a custom-made unloader orthosis, and no treatment, in their study, "The Effect of Bracing on Varus Gonarthrosis," published in the *Journal of Bone and Joint Surgery* in 1999. One hundred ten patients participated in the study, with 33 in the control group, 36 in the neoprene knee sleeve group, and 41 in the unloader group. The researchers found a significant

difference between treatment groups as far as pain. The six-month assessment showed a significant difference among the treatment groups with regard to the mean aggregate change score for the WOMAC. There was an increase in pain equal to 13.1 mm for the control group, a decrease in pain equal to 13.1 mm with the neoprene sleeve group, and 43.2 mm with the unloader orthosis group. It was remarkable that most of the pain relief came in the first 6 weeks with continued relief tapering off in the following weeks.[25]

In 1997, Lindenfeld et al. published "Joint Loading With Valgus Bracing in Patients With Varus Gonarthrosis" in *Clinical Orthopaedics and Related Research*. The researchers investigated the generation II knee orthosis by applying it to 11 participants. Baseline measurements were taken before applications and after 4 to 6 weeks of orthosis wear using the 10-point VAS. Pain symptoms decreased significantly with brace wear (48%) from 6.3 to 3.6. The authors also noted significant increases in function and activity levels, which they attributed to the decreased pain levels.[26]

Matsuno et al. published "Generation II Knee Bracing for Severe Medial Compartment Osteoarthritis of the Knee" in *Archives of Physical Medical and Rehabilitation* in 1997. Using a modified knee scoring system developed by the Japanese Orthopaedic Association, 20 participants were evaluated before orthosis application and each month thereafter for 1 year. The modified knee scoring scale used in the study considered pain while engaging in walking and stair climbing. Nineteen of the 20 patients (95%) reported decreased pain during activities. All scores significantly improved with the application of the orthosis and continued to improve throughout the observation period. Unfortunately, the results were not clearly stated.[27]

Pagani et al. published "Short-Term Effects of a Dedicated Knee Orthosis on Knee Adduction Moment, Pain, and Function in Patients With Osteoarthritis" in the *Archives of Physical Medical and Rehabilitation* in 2010. Eleven participants were incorporated in this study. Participants were tested in three different sessions by using a crossover design: before orthosis wear, after 2 weeks of wearing the orthosis with a neutral setting, and before and after the orthosis set with 4° of valgus. The order of the two different orthosis conditions was randomly assigned, and patients were blinded to the different adjustments. Before the participant was fitted and wore the orthosis, the researchers used the WOMAC scale to measure pain and function. There were statistically significant improvements in pain from the control group to the orthosis in neutral and from the orthosis in neutral to the 4° of valgus conditions. Each was higher than the previous condition. The same was true for the function measure of the WOMAC scale.[28]

Ramsey et al. published "A Mechanical Theory of the Effectiveness of Bracing for Medial Compartment Osteoarthritis of the Knee" in the *Journal of Bone and Joint Surgery* in 2007. Sixteen participants with medial compartment OA were referred from a local orthopedic practice for participation in the study. Baseline measurements were taken. Each participant was fit with a generation II unloading orthosis with an initial setting of 0° of correction. This was worn for 2 weeks, and measurements were taken again. The orthosis was removed for 2 weeks and then reapplied with 4° of valgus added. There were no significant results between the washout and the valgus condition or between the two bracing conditions with respect to pain and the activities of daily living (ADL). However, the symptoms were worse with the 4° of valgus condition than the initial setting of 0°. The orthoses control condition changes were significantly different than the baseline measurements. The authors attributed this to changes in the muscle action at the knee, which were also measured in this study. The authors concluded that the use of an orthosis was a cost-effective way to relieve pain, while not exclusively recommending the use of an OA unloading orthosis.[29]

Richards et al. published "A Comparison of Knee Braces During Walking for the Treatment of Osteoarthritis of the Medial Compartment of the Knee" in the *Journal of Bone and Joint Surgery* (British Volume) in 2005. Twelve patients were recruited and randomly fit with either a hinged knee orthosis or the generation II knee orthosis. After 6 months, each received the second type of orthosis for another 6 months. Measurements were taken before application and at the end of each 6-month period, using the VAS for resting, standing, walking, and stair climbing. It was discovered that only significant differences were found for the valgus orthosis condition, and no significant difference was discovered between the simple hinged orthosis and the baseline measurements.[30]

Schmalz et al. published "Analysis of Biomechanical Effectiveness of Valgus-Inducing Knee Brace or Osteoarthritis of Knee" in the *Journal of Rehabilitation Research and Development* in 2010. The research included 16 patients who wore a prefabricated knee orthosis for 4 weeks. Although gait parameters were the main focus of this study, pain while walking was assessed using the VAS. The initial pain while walking was 6.4 ± 1.7, which was reduced to 3.3 ± 1.9. This was a significant change. Significant changes in walking speed (meter per second) and cadence (step per minute) were documented; although the step length did not change, both walking speed and cadence increased. This points to a significant increase in function. The authors attributed these gait pattern changes to the lack of a need for protection against pain, therefore increasing function.[16] van Raaij et al. published "Medial Knee Osteoarthritis Treated by Insoles or Braces: A Randomized Trial" in *Clinical Orthopedics and Related Research* in 2010. Ninety-one participants with medial knee OA took part in this study. Of these, 45 were treated with laterally wedged insoles and 46 with the MOS Genu knee orthosis. Although this knee orthosis was not exclusively designed for OA, it has the ability to off-load the medial compartment. In this study, the pain severity in the braced group decreased from a mean 5.6 on the VAS to 4.6, and the WOMAC increased from 46.8 to 50.8. These measurements were taken 6 months after application of the orthosis. Both of these results were statistically significant. It was noted that skin irritation was the main complaint, with 10 participants

reporting skin irritation and seven patients commented on poor fit. Each of these could have contributed to less than ideal results.[31]

DISCUSSION

The importance of pain reduction cannot be underestimated. According to the American Pain Society, "Pain is the leading public health problem in this country and the most common symptom that leads to medical care, resulting in more than 50 million lost workdays each year. The cost of pain, including medical bills and lost workdays, is estimated at $100 billion per year in the United States. Back pain alone produces chronic disability in 1 percent of the U.S. population and is the leading cause of disability in Americans under 45 years old."[32] Because of this, the reduction of pain and its debilitating effects was the goal of this review. The pain caused by knee OA is especially limiting because it affects mobility and walking.

The 15 studies that met the inclusion criteria indicate that there is strong evidence that pain is reduced with the use of unloading osteoarthritic knee orthoses. Only one study, Brouwer et al.,[3] had less than significant results, and several lacked statistical analysis of the data, but data were reported in percentages. It is also interesting to note that the study by Brouwer et al. was also the largest single study with 117 participants. Most studies presented the results of their pain measurements with a mean. Matsuo noted one patient who did not receive any pain relief and Dennis noted six. Only one study reported that all participants noted pain relief.[30] Therefore, of the 567 combined participants of these studies, at least seven of them had no pain relief whatsoever. This was marginally >1% of participants. On the basis of the studies reviewed, 98.6% of patients experienced pain relief when fitted with an unloading knee orthosis.

Because these studies had different measures of pain, VAS scale, WOMAC index or a modified version of that scale, HSS score, and using different orthoses and different methods in the setup of the studies, the authors were not able to perform any meta-analysis of the combined results. Percentages indicate that 76% of those participants in studies who did statistical analysis had significant reductions in pain. Excluding the 88 participants reporting reductions in pain in studies that did not do statistical analysis to determine significance leaves 479 who were involved in studies that did provide statistically significant data. All these patients reported some pain relief. This percentage would undoubtedly be higher if an appropriate statistical analysis was done in each case or a meta-analysis was completed of these compiled studies.

Immediate pain relief would be expected from the application of the unloading knee orthosis. This was demonstrated by three studies in an interesting way. In the study by Barnes et al., pain measurements were taken each week. There was significant improvement until week 3 in each case and a leveling out of relief after that point.[17] Kirkley et al.[25] measured their treatment for a total of 24 weeks and found that pain relief leveled out at 12 weeks with the greatest relief happening in the first 6 weeks. Finally, Brouwer et al. noted that at the 3-month, 6-month, and 12-month follow-up, the difference between the two control groups did not change markedly but rather remained within a 20-point range. Although these were not significant at the studies $p < 0.01$ significance level, most were below $p < 0.053$. These three studies indicate that most of the pain relief applied by the orthosis is immediate. The theory behind the tapering off pain is the reduction in inflammation due to decreased irritation.[33]

Of interest was the pain relief during the no-brace phase of Horlick's study. The researchers noted that although the pain relief was more profound in the valgus bracing phase than the brace in neutral phase of the study, there was relief during the no-brace washout period or the no-brace period after wearing the orthoses.[24] This "carryover" effect has been documented in other orthotic literature, with the effects of the orthosis continuing after discontinuation of the orthosis. With scoliosis orthoses, there is often a carryover effect that is considered during routine radiographs. If the physician chooses to take radiographs of the patient out of his or her orthosis, the physician looks for what the body is doing when the orthosis is not being worn. There is always a time period between the radiograph and the last wearing time to mitigate the residual or carryover effects of the orthosis.[34] A review of ankle-foot orthoses also noted a carryover effect in several studies.[35] This residual effect may be one answer for the carryover effect noted by Horlick in this study.

All but two of the studies were underpowered, meaning that the number of participants was less than ideal and thereby raising the possibility of a type 2 error. This means that the chance of not reporting a difference in the intervention when there was a difference is more likely. Most of the studies were of moderate design, indicating that there were areas that may have introduced bias and therefore affected the outcomes of the studies. Important elements fundamental to randomized control trials, such as blinding and randomization, were not possible or were not provided for in the studies reviewed. Because of this, further bias may have been introduced.

Although not a primary focus in this project, decreased function is a known complication of OA. Some of the studies reviewed investigated increases in function. Eight of the studies in some way investigated function. All of them noted significant increases in the function of participants.[3,16,17,25,26,28,29,31] There were two studies that are of note: studies by Lindenfeld et al. and Schmalz et al. Gait pattern changes seem to be a protective mechanism by the patient with knee OA to reduce knee pain.[36] The study by Schmalz et al resulted in more symmetrical gait patterns in the participants, noting that their gait lab measurements were improved with the unloading knee orthosis. Lindenfeld et al. indicated that the participants in their study went from moderate symptoms with ADLs to walking several hours per day without appreciable symptoms. According to the authors of the studies reviewed, the decrease in pain scores was

attributed to the use of the knee orthosis. The knee orthosis in each case caused an increase in the knee adduction moment at heelstrike and loading response, thereby relieving the pressure on the medial compartment of the knee.

Although the ability of this review to analyze which orthoses were more effective than others is extremely limited, some interesting observations can be made based on the differences in study morphology, pain measurement scales, and interval of measurements. The most common type of orthosis used was the generation II unloader orthosis. This orthosis was among the first commercially available OA knee orthoses, which was undoubtedly the reason it was the most commonly studied orthosis. Horlick[24] and Matsuno et al.[27] were among the first to investigate the use of this unloading orthosis. As the clinical effectiveness of these types of orthoses became known, flurries of articles were published around the turn of the century on a variety of knee orthoses. Two worth mentioning are Dennis and Draganich. Dennis compared the effectiveness of four commercially available off-the-shelf orthoses. The Bledsoe Thruster had the greatest amount of relief of symptoms from medial knee OA.[19] Draganich et al. examined custom versus off-the-shelf models of the unloading knee orthosis and found a significant difference between the two orthoses. Custom knee orthoses provided significantly better relief of symptoms. Draganich et al.[21] attributed this to a better fitting orthosis.

Another interesting observation, and warranting further study, was the importance of patient perception and placebo effect. Demonstrated in both studies done by Brouwer et al.[3] and Kirkley et al.,[25] some participants in the control group of both studies withdrew because they wanted to be in the knee orthosis group rather than in the control group. In the study by Kirkley et al., seven (18%) withdrew from the control group and two (5%) from the neoprene sleeve group. In the study by Brouwer et al., "One patient withdrew immediately because of dissatisfaction with the randomization outcome." Furthermore, no patients withdrew from the unloader orthosis control groups in either study. Patient perception and the placebo effect produce a valid effect on pain perception and play a real part in clinical care. Although it may be part of the results, even if the placebo worked and decreased pain, it should be considered a viable option for the treatment of knee OA.[37]

As insurance companies tighten reimbursement, justifying the use of orthoses over other treatments is important. One thing that was not evaluated in these studies was how many of the participants later underwent corrective surgery, either femoral osteotomy or knee replacement. One way of evaluating the effectiveness of the orthotic intervention is whether or not patients later have to undergo corrective surgery, which always entails risks. In the research by Barnes et al., it was noted how many patients went on to some type of surgery and how many were able to continue using the orthosis to lessen their pain. At a 2-year follow-up, only 24% of the participants had undergone arthroplasty, whereas 41% were still using their orthosis.[17] van Raaij et al. noted that of those participating in their study, three in the no-orthosis group underwent surgery at 6 months, whereas one had undergone surgery in the orthosis group.[31] In the randomized control trial, Brouwer et al.[3] followed up patients for a year and found that in the orthosis group, 11 (18%) patients underwent surgery that year and that in the control group 13 of the remaining 53 (25%) participants underwent some sort of surgery. Each of these studies had similar results of decreased incidence of surgery in the orthosis group versus a control group. Although these numbers are very small, they may signal an interesting trend and warrant further research.

Only a few of the studies reported how the orthoses were fit and if a qualified individual was responsible for fit and follow-up. Most of the studies did not state who fit or how the orthosis was fit. Appropriate fit is an often-heard complaint among wearers of the orthoses.[24,31] A trained orthotist can properly fit an orthosis, increase compliance, and further increase the effectiveness of the orthosis.

The Osteoarthritis Research Society International guidelines for knee OA indicate that "emphasis should be placed on encouraging adherence to the regimen of nonpharmacological therapy" in the treatment of knee OA. It was recommended for patients with mild to moderate knee OA for the reduction of symptoms including pain.[38] These guidelines are consistent with the findings of the literature review in that they would recommend the OA knee orthosis for treatment of knee OA.

Areas of further research are apparent based on the results of this review. Further research on the effectiveness of one orthosis over another by an unbiased source would help practitioners provide the best possible care. The possible carryover effect of the knee unloading orthosis would have implications for the duration of wear time of the orthosis. If there is indeed a carryover effect, then possibly it is not necessary to wear the orthosis full time but only during activities that cause pain. Can the need for patients to receive knee replacements or other invasive surgeries to correct knee OA be lessened by the wearing the unloading knee orthosis? If this is true, then wearing the unloading knee orthosis may indeed reduce the incidence of surgery. This would be a justification for the orthosis, proving that the orthosis would reduce the overall healthcare cost of the treatment of medial compartment OA.

CONCLUSION

OA can be a disabling disease. On the basis of the articles reviewed, an OA or unloading knee orthosis is an effective way to relieve pain in the osteoarthritic knee. Pain relief was documented to help in 98.6% of patients fitted with unloading orthoses for medial compartment OA of the knee. With decreased pain comes increased function and quality of life. When compared with surgery, these orthoses are a cost-effective means of treating OA.

ACKNOWLEDGMENTS

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REFERENCES

1. Peat G, McCarney R, Croft P. Knee pain and osteoarthritis in older adults: a review of community burden and current use of primary health care. *Ann Rheum Dis* 2001;60:91–97.
2. Felson DT, Lawrence RC, Dieppe PA, et al. Osteoarthritis: new insights. Part 1: the disease and its risk factors. *Ann Intern Med* 2000;133:635–646.
3. Brouwer RW, van Raaij TM, Verhaar JAN, et al. Brace treatment for osteoarthritis of the knee: a prospective randomized multicentre trial. *Osteoarthritis Cartilage* 2006;14:777–783.
4. Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, part I: critical appraisal of existing treatment guidelines and systematic review of current research evidence. *Osteoarthritis Cartilage* 2007;15:981–1000.
5. Pollo FE. Bracing and heel wedging for unicompartmental osteoarthritis of the knee. *Am J Knee Surg* 1998;11:47–50.
6. Pollo FE, Jackson RW. Knee bracing for unicompartmental osteoarthritis. *J Am Acad Orthop Surg* 2006;14:5–11.
7. Divine JG, Hewett TE. Valgus bracing for degenerative knee osteoarthritis—relieving pain, improving gait, and increasing activity. *Phys Sportsmed* 2005;33:40–46.
8. Chew KTL, Lew HL, Date E, Fredericson M. Current evidence and clinical applications of therapeutic knee braces. *Am J Phys Med Rehabil* 2007;86:678–686.
9. Geil MD. Assessing the state of clinically applicable research for evidence-based practice in prosthetics and orthotics. *J Rehabil Res Dev* 2009;46:305–313.
10. Price DD, McGrath PA, Rafii A, Buckingham B. The validation of visual analog scales as ratio scale measures for chronic and experimental pain. *Pain* 1983;17:45–56.
11. The Recal Legacy [database on the Internet]. Available at: http://www.strath.ac.uk/cdlr/services/recallegacy/. Accessed March 31, 2011.
12. Hafner BP. American Academy of Orthotists & Prosthetists (AAOP), State-of-the-Science Evidence Report Guidelines. American Academy of Orthotists and Prosthetists; 2008. Available at: http://www.oandp.org/grants/MasterAgenda/AAOP_EvidenceReport Guidlines.pdf. Accessed March 31, 2011.
13. Ahlback S. Osteoarthrosis of the knee. A radiographic investigation. *Acta Radiol Diagn (Stockh)* 1968:Suppl 277:7–72.
14. Prodromos CC, Andriacchi TP, Galante JO. A relationship between gait and clinical changes following high tibial osteotomy. *J Bone Joint Surg Am* 1985;67:1188–1194.
15. Self BP, Greenwald RM, Pflaster DS. A biomechanical analysis of a medial unloading brace for osteoarthritis in the knee. *Arthritis Care Res* 2000;13:191–197.
16. Schmalz T, Knopf E, Drewitz H, Blumentritt S. Analysis of biomechanical effectiveness of valgus-inducing knee brace for osteoarthritis of knee. *J Rehabil Res Dev* 2010;47:419–429.
17. Barnes CL, Cawley PW, Hederman B, et al. Effect of Counter-Force brace on symptomatic relief in a group of patients with symptomatic unicompartmental osteoarthritis: a prospective 2-year investigation. *Am J Orthop (Belle Mead NJ)* 2002;31:396–401.
18. Dennis AD, Komistek RD. An in vivo analysis of the effectiveness of the osteoarthritic knee brace during heel strike and mid-stance of gait. *Acta Chir Orthop Traumatol Cech* 1999;66:323–327. Analyza ucinnosti in vivo ortez pri lecbe gonartrozy behem jednotlivych fazi chuze ("heel-strike" a "mid-stance").
19. Dennis DA, Komistek RD, Nadaud MC, Mahfouz M. Evaluation of off-loading braces for treatment of unicompartmental knee arthrosis. *J Arthroplasty* 2006;21:2–8.
20. Bellamy N, Buchanan WW, Goldsmith CH, et al. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;15:1833–1840.
21. Draganich L, Reider B, Rimington T, et al. The effectiveness of self-adjustable custom and off-the-shelf bracing in the treatment of varus gonarthrosis. *J Bone Joint Surg Am* 2006;88:2645–2652.
22. Finger S, Paulos LE. Clinical and biomechanical evaluation of the unloading brace. *J Knee Surg* 2002;15:155–158; discussion 159.
23. Gaasbeek RDA, Groen BE, Hampsink B, et al. Valgus bracing in patients with medial compartment osteoarthritis of the knee—a gait analysis study of a new brace. *Gait Posture* 2007;26:3–10.
24. Horlick SG. Valgus knee bracing for medial gonarthosis. *Clin J Sports Med* 1993;3:251–255.
25. Kirkley A, Webster-Bogaert S, Litchfield R, et al. The effect of bracing on varus gonarthrosis. *J Bone Joint Surg Am* 1999;81:539–548.
26. Lindenfeld TN, Hewett TE, Andriacchi TP. Joint loading with valgus bracing in patients with varus gonarthrosis. *Clin Orthop Relat Res* 1997;344:290–297.
27. Matsuno H, Kadowaki KM, Tsuji H, et al. Generation II knee bracing for severe medial compartment osteoarthritis of the knee. *Arch Phys Med Rehabil* 1997;78:745–749.
28. Pagani CH, Bohle C, Potthast W, Bruggemann GP. Short-term effects of a dedicated knee orthosis on knee adduction moment, pain, and function in patients with osteoarthritis. *Arch Phys Med Rehabil* 2010;91:1936–1941.
29. Ramsey DK, Briem K, Axe MJ, Snyder-Mackler L. A mechanical theory for the effectiveness of bracing for medial compartment osteoarthritis of the knee. *J Bone Joint Surg Am* 2007;89:2398–2407.

30. Richards JD, Sanchez-Ballester J, Jones RK, et al. A comparison of knee braces during walking for the treatment of osteoarthritis of the medial compartment of the knee. *J Bone Joint Surg Br* 2005;87:937–939.

31. van Raaij TM, Reijman M, Brouwer RW, et al. Medial knee osteoarthritis treated by insoles or braces: a randomized trial. *Clin Orthop Relat Res* 2010;468:1926–1932.

32. Society AP. Media backgrounder. Internet: American Pain Society; 2011. Available at: http://www.ampainsoc.org/press/backgrounder.htm. Accessed May 1, 2011.

33. Marieb ENR, Hoehn KM. *Anatomy & Physiology*. 7th ed. San Francisco, CA: Pearson Benjamin Cummings; 2007:1159.

34. Carol J, Hentges C. The team approach to the orthotic treatment of idiopathic scoliosis and Scheuermann's kyphosis. *J Orthot Prosthet* 2003;15:49–52.

35. Kobayashi TP, Leung AKLP, Hutchins SWP. Design and effect of ankle-foot orthoses proposed to influence muscle tone: a review. *J Orthot Prosthet* 2011;23:52–58.

36. White A, Foster NE, Cummings M, Barlas P. Acupuncture treatment for chronic knee pain: a systematic review. *Rheumatology (Oxford)* 2007;46:384–390.

37. Pagani CHF, Potthast W, Bruggemann GP, et al. The effect of valgus bracing on the knee adduction moment during gait and running in male subjects with varus alignment. *Clin Biomech* 2010;25:70–76.

38. Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis Cartilage* 2008;16:137–162.

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Advancing Orthotic and Prosthetic Care Through Knowledge

Patient Evaluation Of An Unloader Knee Brace: A Prospective Cohort Study

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Introduction

The prevalence of osteoarthritis (OA) is constantly increasing, currently affecting 4.3 million adults in the United States, and making it the most prevalent of the chronic joint disorders worldwide. One contributing factor that may increase the severity of knee OA is knee malalignment.[8] Sharma et al. showed that a compartmental increase in the load of the knee can cause an increase in knee degeneration of that compartment.[12]

Many nonsurgical and surgical treatment options exist that may relieve pain, and therefore increase knee function. Non-surgical treatment options include oral supplementation, such as glucosamine and chondroitin, and corticosteroid and hyaluronic-acid knee injections. Previous studies have shown that oral supplements as well as intra-articular injections may cause a decrease in symptoms such as pain; however, these treatments are temporary and do not change the mechanics of the knee.[9]

Some surgical treatments have been developed to treat malalignment of the knee; however, these procedures are quite invasive and require lengthy recovery times and rehabilitation. And though these operative procedures, which are intended to relieve knee pain by reducing the weight bearing load in the degenerative compartment, are available, there is an increasing desire for non-surgical treatments that address the issue of malalignment.[3]

Unloader braces are specifically designed to decrease the load on the degenerative compartment of the knee in order to improve function and decrease symptoms related to malalignment and OA.[7, 10] The purpose of this study is to document patients' expectations of treatment and outcomes following six months of use of an unloader brace. Outcomes and response to the brace were measured by symptoms such as pain and stiffness, function, use of pain medication, and quality of life.

Methods

Patients were enrolled in an IRB-approved prospective cohort study. Excluded were patients who had any arthroplasty in the knee, or moderate to severe OA in both lateral and medial knee compartments. Inclusion criteria were diagnosis of osteoarthritis of the knee with unicompartmental knee conditions that required load reduction to the affected compartment and a minimum of a six-month prescription in order to allow for sufficient trial of the brace. Patients signed informed consent forms and agreed to complete all mailed questionnaires. At enrollment, three weeks, six weeks, and six months, patients completed a self-administered questionnaire. This questionnaire included the SF-12; the WOMAC score[1]; and a survey of patients' use of both prescription and non-prescription anti-inflammatory drugs. In addition, all patients completed an expectation questionnaire prior to enrollment in the study. Twenty patient expectation domains were measured. The domains were then analyzed individually as "very important" to "of little to no importance." These data were then summed as an expectation score with a range of 20–80, 80 showing no expectation and 20 showing the highest expectation.

Statistical Analysis

Comparisons of scores between pre-brace WOMAC and final time point (six months) were performed using the paired t-test. Comparisons between independent groups were performed using the independent t-test. We used repeated measures analysis to determine if there was a difference between pre-brace, three-week, six-week, and six-month WOMAC pain and function scores. Because the WOMAC scores were assessed on the same patient over time, we used repeated measures analysis to adjust for the within-patient factors.

Results

Thirty-nine patients were enrolled in this study. The average age was 60 years (range 44 to 87). Average body-mass index (BMI) was 26 (range 20 to 37). There were 22 men and 17 women. Twenty-five patients were prescribed a medial unloader brace, and 14 were prescribed a lateral unloader brace. Seven patients (18 percent), five women and two men, discontinued brace wear.

Patient Expectations

Pain relief was very important to only 69 percent of patients and somewhat important to 17 percent. If patients did expect pain relief, 39 percent expected most of the pain to be relieved, and 57 percent expected all pain to be relieved. Seventeen patients (37 percent) also reported stiffness as a primary reason for seeking medical treatment. Eighty-six percent of the patients expected knee stiffness or swelling to stop. Improving their ability to walk was considered very important by 89 percent. Of those who considered walking important, they all expected to walk more than one mile. Improving their ability to go up and down stairs was considered very important to 70 percent. Patients considered return to recreational sports an important expectation. It was considered very important to 83 percent and somewhat important to 17 percent. The most important expectation in this group was to have confidence in their knee (97 percent very important), avoid future degeneration of their knee (90 percent very important), and improve ability to maintain general health (93 percent very important).

The WOMAC scores are shown in the following table. There was significant improvement in pain, stiffness, and function components of the WOMAC score ($p<0.05$). Patients also had a significant improvement in their quality-of-life physical component as shown by the SF-12 ($p<0.05$). As expected, the patient mental component of quality of life remained unchanged.

	WOMAC Pain	WOMAC Stiffness	WOMAC Function	WOMAC	SF-12 PCS	SF-12 MCS
Pre-brace	6.8	3.0	19	28.3	38.6	58.5
3 weeks	3.0	1.4	7.4	10.4	NA	NA
6 weeks	3.4	1.4	9.8	13.5	42.5	56.6
6 months	2.9	1.5	8.6	11.9	46.0	59.4

At three weeks, 24 percent of patients reported a decrease in over-the-counter anti-inflammatory use, and 16 percent reported a decrease in prescription anti-inflammatory use. At six months, 23 percent reported a decrease in over-the-counter anti-inflammatory use and 16 percent reported a decrease in prescription anti-inflammatory use.

Discussion

In this population, patients expected pain relief, improved function, and improved activity level. It was very important for the patients to avoid future degeneration of the knee and to be able to maintain their general health. The unloader brace decreased pain in the initial weeks following bracing and maintained improvement throughout the study. Improved patient function and a decrease in stiffness were also seen in the initial weeks and were maintained at end point as well. Patients reduced medications and had improved overall physical health.

The results of this study are similar to those of Kirkley et al.[7] In the Kirkley et al. study, there was a control group, a neoprene-sleeve group, and an unloader brace group, all of which consisted of patients under 50 years old who had a BMI of less than 35. Patients who used the unloader brace showed less pain than the other two groups after walking for six minutes and climbing for 30 seconds. They also showed a significant increase in quality of life and knee function. And although not significant, there was a strong trend toward a significant difference between the unloader group and neoprene-sleeve group regarding the overall WOMAC score and the functional component of the WOMAC.[7]

Other studies have also shown unloader braces to be effective in not only reducing symptoms, but also in shifting the weight-bearing load.[2,4–6,10–11] Self et al. showed a significant decrease in varus moment during stance, which can contribute to a reduction in pain.[10] And Pollo et al. showed a shift in the center axis of pressure with the use of an unloading brace. Resting pain, night pain, and pain with activity all showed a significant decrease with brace use.[11]

In this patient population, the mean BMI was quite low, which may not be representative of a normally distributed population. Also, many of the patients in this study had a low pre-brace WOMAC score, which may not have allowed for as much improvement.

Overall, patients demonstrated a significant decrease in pain and increase in function and overall physical health. Braces specifically designed to unload the degenerative compartment of the knee may be an effective treatment for pain generated from OA in conjunction with malalignment of the knee.

This research was funded in part by Ossur Americas, Aliso Viejo, California. Address correspondence to Karen K. Briggs, MPH; Steadman Hawkins Research Foundation; Attn: Clinical Research; 181 W. Meadow Dr. Ste. 1000; Vail, CO 81657.

References

1. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J., Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol.* 1988;15:1833–1840.

2. Cerejo R, Dunlop DD, Cahue S, Channin D, Song J, Sharma L. The influence of alignment on risk of knee osteoarthritis progression according to baseline stage of disease. *Arthritis Rheum.* 2002;46:2632–2636.

3. Chew KT, Lew HL, Date E, Fredericson M. Current evidence and clinical applications of therapeutic knee braces. *Am J Phys Med Rehabil.* 2007;86:678–686.

4. Draganich L, Reider B, Rimington T, Piotrowski G, Mallik K, Nasson S. The effectiveness of self-adjustable custom and off-the-shelf bracing in the treatment of varus gonarthrosis. *J Bone Joint Surg Am.* 2006;88:2645–2652.

5. Felson DT, Goggins J, Niu J, Zhang Y, Hunter DJ. The effect of body weight on progression of knee osteoarthritis is dependent on alignment. *Arthritis Rheum.* 2004;50:3904–3909.

6. Finger S, Paulos LE. Clinical and biomechanical evaluation of the unloading brace. *J Knee Surg.* 2002;15:155–158; discussion 159.

7. Kirkley A, Webster-Bogaert S, Litchfeld R, Amendola A, MacDonald S, McCalden R, Fowler P. The effect of bracing on varus gonarthrosis. *J Bone Joint Surg Am.* 1999;81:539–548.

8. Miller BS, Joseph TA, Barry EM, Rich VJ, Sterett WI. Patient satisfaction after medial opening high tibial osteotomy and microfracture. *J Knee Surg.* 2007;20:129–133.

9. M–ezzinoğlu S, Bulu– L. The role of nonsteroidal anti-inflammatory drugs, oral preparations, and viscosupplementation in conservative treatment of cartilage lesions. *Acta Orthop Traumatol Turc.* 2007;41:48–53.

10. Pollo FE, Jackson RW. Knee bracing for unicompartmental osteoarthritis. *J Am Acad Orthop Surg.* 2006;14:5–11.

11. Self BP, Greenwald RM, Pfaster DS. A biomechanical analysis of a medial unloading brace for osteoarthritis in the knee. *Arthritis Care Res.* 2000;13:191–197.

12. Sharma L, Song J, Felson DT, Cahue S, Shamiyeh E, Dunlop DD. The role of knee alignment in disease progression and functional decline in knee osteoarthritis. *JAMA.* 2001;286:188–195. Erratum in: *JAMA.* 2001;286:792.

COMING SOON

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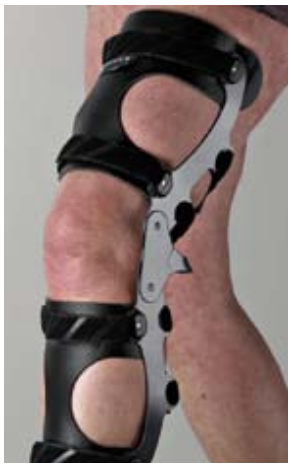
HCPCS:	Descriptor:
L1847	KNEE ORTHOSIS, DOUBLE UPRIGHT WITH ADJUSTABLE JOINT, WITH INFLATABLE AIR SUPPORT CHAMBER(S), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
NO	YES	NO	YES	YES

Sample Diagnosis (Not Inclusive)	Post Op ACL, MCL, PCL, LCL instability
Medically Necessary Argument	This orthosis is used to provide stability to an injured knee and requires knowledge of the anatomy of the knee as well as the knowledge of the injury type to understand how the knee joint should be adjusted as well as how much air pressure should be added to the orthosis. Improper fitting of this orthosis could cause further damage to the knee. A trained person should fit this and also provide follow-up as needed.
References	

HCPCS:	Descriptor:
L1850	KNEE ORTHOSIS, SWEDISH TYPE, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Genu recurvatum
Medically Necessary Argument	This orthosis is prescribed to provide posterior control of the knee joint which could be caused by a variety of injuries. Improper alignment of the knee joints could allow further damage to the knee or injuries to the soft tissue if the uprights are not contoured correctly. If the orthosis is adjusted improperly, and keeps the knee to extended, injury could result if the patient fell from lack of knee stability. Proper fitting in adjusting of this orthosis is crucial to proper function.
References	

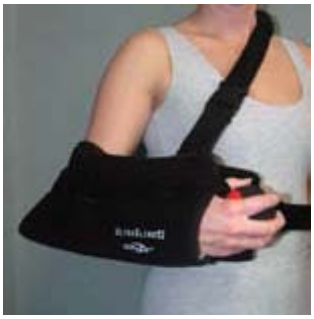
HCPCS:	Descriptor:
L3660	SHOULDER ORTHOSIS, FIGURE OF EIGHT DESIGN ABDUCTION RESTRAINER, CANVAS AND WEBBING, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
NO	NO	NO	YES	NO

Sample Diagnosis (Not Inclusive)	Orthopedic diagnoses and applications are typically post surgical. This device provides immobilization of the shoulder and positions the shoulder at a specified abduction angle and used post surgical for rotator cuff repairs, capsular shifts, Bankhart repairs, glenohumeral dislocations/subluxation and soft tissue repairs/strains, Clavicular fractures
Medically Necessary Argument	Proper application of this device involves appropriate knowledge of a qualified practitioner on patient positioning of the elbow and shoulder to protect the patient from compromising the post surgical healing process. The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for stabilization needed to facilitate healing. Failure to properly align/apply this device may lead to further injury of the shoulder.
References	

HCPCS:	Descriptor:
L3670	SHOULDER ORTHOSIS, ACROMIO/CLAVICULAR (CANVAS AND WEBBING TYPE), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
NO	NO	NO	YES	NO

Sample Diagnosis (Not Inclusive)	Shoulder immobilization and controlled range of motion for anterior, multi-directional, inferior and posterior instabilities, rotator cuff deceleration, shoulder separations and muscle strains
Medically Necessary Argument	This brace is intended to stabilize the acromioclavicular joint to reduce pain and joint motion. Proper fit and adjustment of straps is required for stabilization. The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for stabilization needed to facilitate healing. Failure to properly align/apply this device may lead to further injury of the shoulder and increased pain potentially leading to surgery. Proper application of this device involves appropriate knowledge of a qualified practitioner on patient positioning of the elbow and shoulder to protect the patient from compromising the post surgical healing process or from further damaged to the rotator cuff that could lead to further surgical intervention.
References	9, 10, 11

ORTHOTICS AND DEVICES

Shoulder Subluxation After Stroke: A Comparison of Four Supports

Richard D. Zorowitz, MD, David Idank, DO, Tetsuo Ikai, MD, Mary B. Hughes, OTR, Mark V. Johnston, PhD

ABSTRACT. Zorowitz RD, Idank D, Ikai T, Hughes MB, Johnston MV. Shoulder subluxation after stroke: a comparison of four supports. Arch Phys Med Rehabil 1995;76:763-71.

• *Objective:* Shoulder subluxation is a well-known sequela of stroke. This study quantitatively compares the reduction of shoulder subluxation using four supports: the single-strap hemisling, the Bobath roll, the Rolyan humeral cuff sling, and the Cavalier support. *Design/Setting:* Anteroposterior shoulder radiographs of 20 consecutive first-time stroke survivors in a freestanding rehabilitation hospital were taken within 6 weeks of stroke onset. Vertical, horizontal, and total asymmetries of glenohumeral subluxation compared with the unaffected shoulders were measured before and after fitting of each support. *Main Outcome Measures:* Group means were compared to find which supports altered subluxation asymmetries and approximated the unaffected shoulder. Individual data were tallied to detect how often each support best reduced subluxation asymmetries. *Results:* The single-strap hemisling eliminated the vertical asymmetry of subluxation over the entire study group, but each support corrected the vertical asymmetry best in some subjects (55%, 20%, 40%, and 5%, respectively). The Bobath roll and the Cavalier support produced lateral displacements of the humeral head of the affected shoulder ($p = 0.005$, 0.004, respectively). The Rolyan humeral cuff sling significantly reduced total subluxation asymmetry ($p = 0.008$), whereas the single-strap hemisling, Bobath roll, and Cavalier support did not alter total asymmetry ($p = 0.091$, 0.283, 0.502, respectively). *Conclusion:* When treating shoulder subluxation, several different types of supports should be evaluated to optimize the function of the affected extremity and the reduction of the shoulder subluxation.

The occurrence of subluxation of the humeral head out of the glenoid fossa after stroke has not been disputed. Reported incidences of shoulder subluxation in stroke survivors vary from 17% to 66%.[1-3] Positioning of the limb in abduction and external rotation helps to discourage tone and contracture while the stroke survivor lies in bed. Use of an armboard or lap tray on the affected side provides support to the limb and may overcorrect the subluxation.[4,5] Treatment of the hemiplegic limb in the upright position, however, remains controversial.

Checklists for prescription of shoulder supports for use by the ambulatory stroke survivor have been proposed.[6] Radiographic measurements have been obtained to quantitate the degree of subluxation in acute, subacute, and chronic stroke survivors.[1,3,5,7-9] These works, however, have not examined all commonly used supports together and have averaged subluxation measures across all patients. This approach may be erroneous because it assumes that overcorrection of subluxation in one patient compensates for undercorrection in another.

The present study was designed to measure the ability of four ambulatory shoulder supports to correct subluxation in stroke survivors who still had potential for spontaneous recovery of upper-extremity movement. The four supports were the single-strap hemisling, the Bobath roll, Rolyan humeral cuff sling, and the Cavalier support. Pilot data have suggested that single-strap hemislings most closely approximate the head of the humerus with the glenoid fossa.[10] This study analyzes both group and individual data. As a result, practical guidelines for application of shoulder supports may be recommended based on the individual stroke survivor, and not just on general conclusions.

METHODS

Twenty subjects admitted to a rehabilitation institute between October 15, 1992, and August 9, 1993, for rehabilitation of first thromboembolic or hemorrhagic strokes were enrolled in this study after informed consent was obtained from each subject. The neuroanatomic location of the stroke was recorded from reports of computed tomography (CT) or magnetic resonance imaging (MRI) from the acute care hospital, and the clinical stroke syndrome was recorded from the physical examination performed at admission by each physiatrist. Data were collected using Part J of the National Institute of Neurological Diseases and Stroke (NINDS) Stroke Data Bank.[11]

Exclusion criteria included time from onset of stroke to enrollment in the study more than 6 weeks, history of prior neurological condition resulting in unilateral or bilateral hemiparesis, presence of clinical stroke syndrome undetected by CT or MRI, and neuroanatomic lesions resulting in bilateral hemiparesis. The presence of a pure unilateral lesion allowed each subject to be used as his own control when

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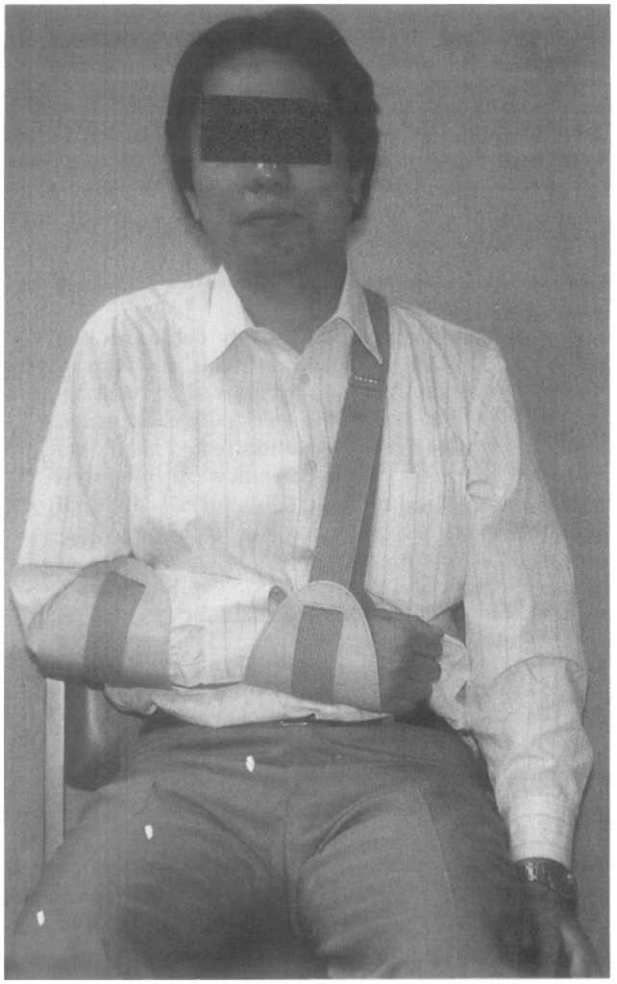

Fig 1—The single-strap hemisling.

the measurements of the affected shoulder unsupported and supported with each support were compared with that of the unaffected shoulder.

Motor recovery of the affected extremity was assessed using the sum of the upper extremity, wrist, and hand scores of the Fugl-Meyer Motor Function Evaluation.[12] The Fugl-Meyer Evaluation is a quantitative application of the Brunnstrom scale of motor recovery[13] based on the description of motor recovery after stroke.[14] An ordinal scale was used to rate various stereotypical movements: 0 for unable to perform, 1 for able to perform partially, and 2 for able to perform completely. It is a reliable method of measuring motor recovery after stroke. The highest possible attainable score was 66.

Application of Shoulder Supports

An occupational therapist applied each shoulder support to each subject in the following order: (1) single-strap hemisling; (2) Rolyan humeral cuff sling; (3) Bobath roll; and (4) Cavalier support. The single-strap hemisling was fitted with one cuff supporting the elbow and a second cuff supporting the forearm, wrist, and hand distally (Fig 1). The strap was fitted on each subject along the unaffected shoulder and across the back so that the line of pull was not across the neck. The resulting position of the shoulder with the single-strap hemisling in place was adduction and internal rotation.

The Bobath roll was fitted to each subject with a foam roll placed in the axilla beneath the proximal humerus (fig 2). Straps were adjusted to provide vertical support of the humerus. The shoulder was maintained in a position of abduction and external rotation.

The Rolyan humeral cuff sling consisted of a figure-eight strap system with an arm cuff sized to fit distally on the humerus of the affected upper extremity (fig 3). The strap and cuff system was designed to allow adjustment of both the vertical and rotational position of the humerus. The therapist fitted the sling after the directions of the manufacturer and adjusted the sling to provide maximum shoulder support on clinical examination. Slight external rotation of the shoulder was obtained when application of the sling was optimized.

The Cavalier shoulder support normally is not used for treatment of shoulder subluxation but was included in this study because it provides bilateral axillary support similar to that of the Bobath roll. It consisted of bilateral straps that positioned along the humeral head and integrated posteriorly with a material brace that rested between the scapulae (fig 4). The straps were adjusted to support the shoulder girdle in external rotation and retraction.

Radiographic Technique

Six anteroposterior radiographs were taken of each subject: (1) unaffected shoulder; (2) affected shoulder, unsupported; (3) affected shoulder, Rolyan humeral cuff sling; (4) affected shoulder, Bobath roll; (5) affected shoulder, single-strap hemisling; and (6) affected shoulder, Cavalier support. A 7-mm lead marker was placed over the distal aspect of the clavicle to correct any variability resulting from magnification of the x-ray. A thyroid shield was placed over the neck of each subject to minimize excessive radiation to the soft tissues of the neck.

Analysis

Radiographs were analyzed on a standard viewing box. Information identifying the radiograph was covered, and the radiographs were analyzed in random order to reduce measurement bias by the analyst. Three reference points were identified, as described by previous investigators[15]: the central point of the glenoid fossa, the central point of the humeral head, and the most inferolateral point of the acromion (fig 5). The central point of the glenoid fossa was defined at the intersection of lines connecting the horizontal and vertical points that produced the greatest width and height of the glenoid fossa, respectively. The central point of the humeral head was defined at the bisection point of the line that measured the greatest distance horizontally across the humeral head. This line was parallel to the horizontal line within the glenoid fossa.

The vertical component of glenohumeral subluxation was determined by measuring the distance between the point on the acromion and a perpendicular horizontal line through the central point of the humeral head. The horizontal component

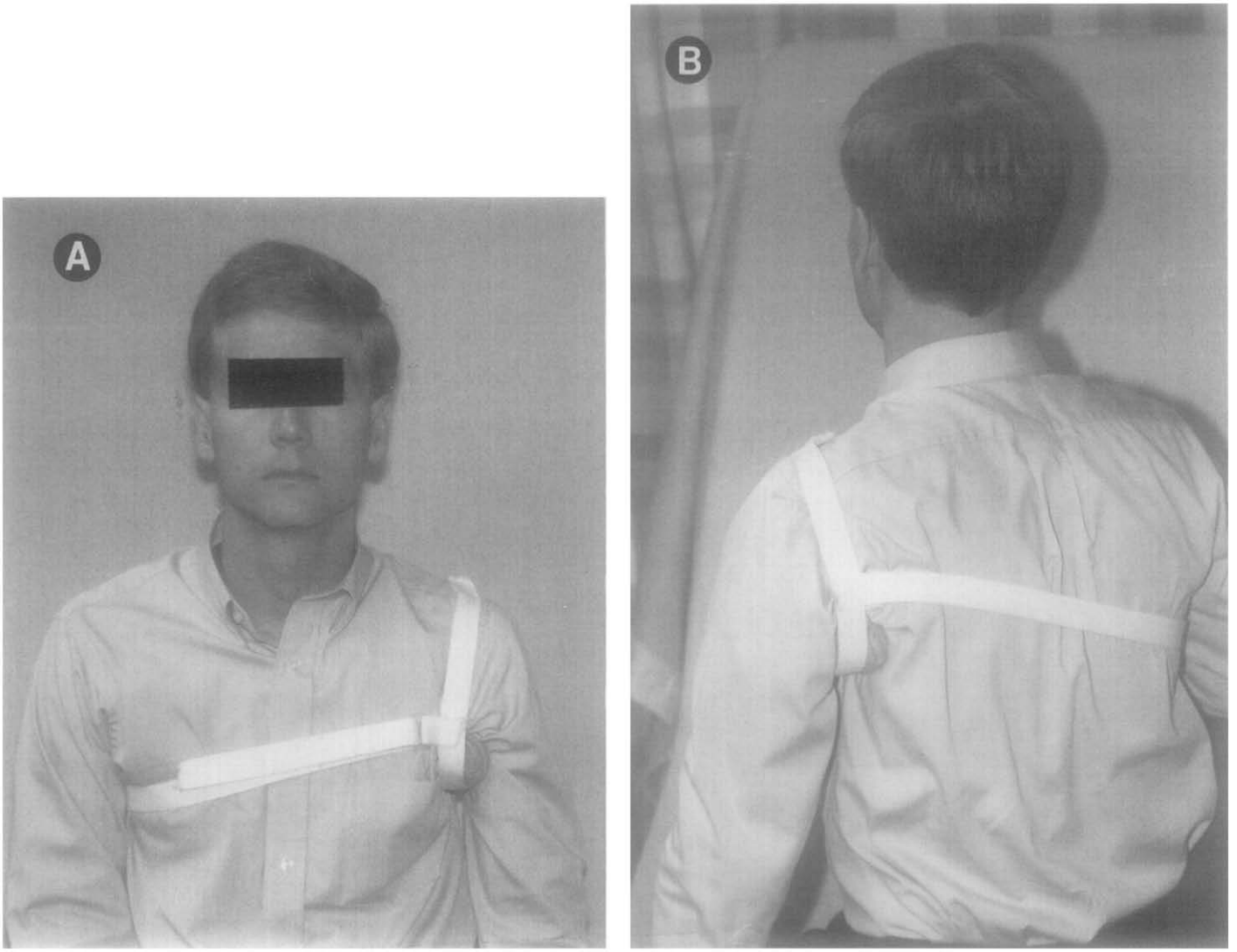

Fig 2—The Bobath roll. (A) Anterior view. (B) Posterior view.

was determined by measuring the distance between the central point of the glenoid fossa and a perpendicular vertical line through the central point of the humeral head.

Asymmetries between the unaffected shoulder and the unsupported affected shoulder were calculated to gauge the degree to which each of the four slings corrected for subluxation. Directional or raw vertical *asymmetry* was calculated by subtracting the vertical displacement of the affected shoulder from the vertical position of the unaffected shoulder. Similarly, raw *horizontal asymmetry* was calculated by subtracting the horizontal displacement of the affected shoulder from the horizontal position of the unaffected shoulder.

Logically, the best single measure of degree of correction should summarize as much of the data on different aspects of error as possible. Vertical and horizontal asymmetry data can be easily summarized by computing total asymmetry along the hypotenuse of the horizontal and vertical asymmetries:

$$\text{Total asymmetry} = \sqrt{[(\text{vertical asymmetry})^2 + (\text{horizontal asymmetry})^2]}$$

Total asymmetry reflects absolute error but not direction of error because squaring yields the same result regardless of whether asymmetry values are positive or negative. Therefore, mean total asymmetry values cannot be calculated from means of raw or absolute vertical and horizontal asymmetry values. Rather, they can be calculated only from individual total asymmetry values.

Group means were analyzed to determine how each support altered subluxation asymmetries and approximated the unaffected shoulder. As the data were not evenly distributed, the 95% confidence intervals for each variable were described instead of standard deviation. A one-sample t test against a test value of 0, which represents complete symmetry, was used to compare the asymmetry measurements using each support with the position of the unaffected shoulder. A paired t test against the asymmetries of the unsupported affected shoulder was used to determine how each support altered subluxation asymmetries. Individual data were analyzed to determine how often each support produced the best fit. The measures of vertical, horizontal, and total asymmetries were listed by individual subjects. The support that provided the least asymmetry for each subject was noted and counted.

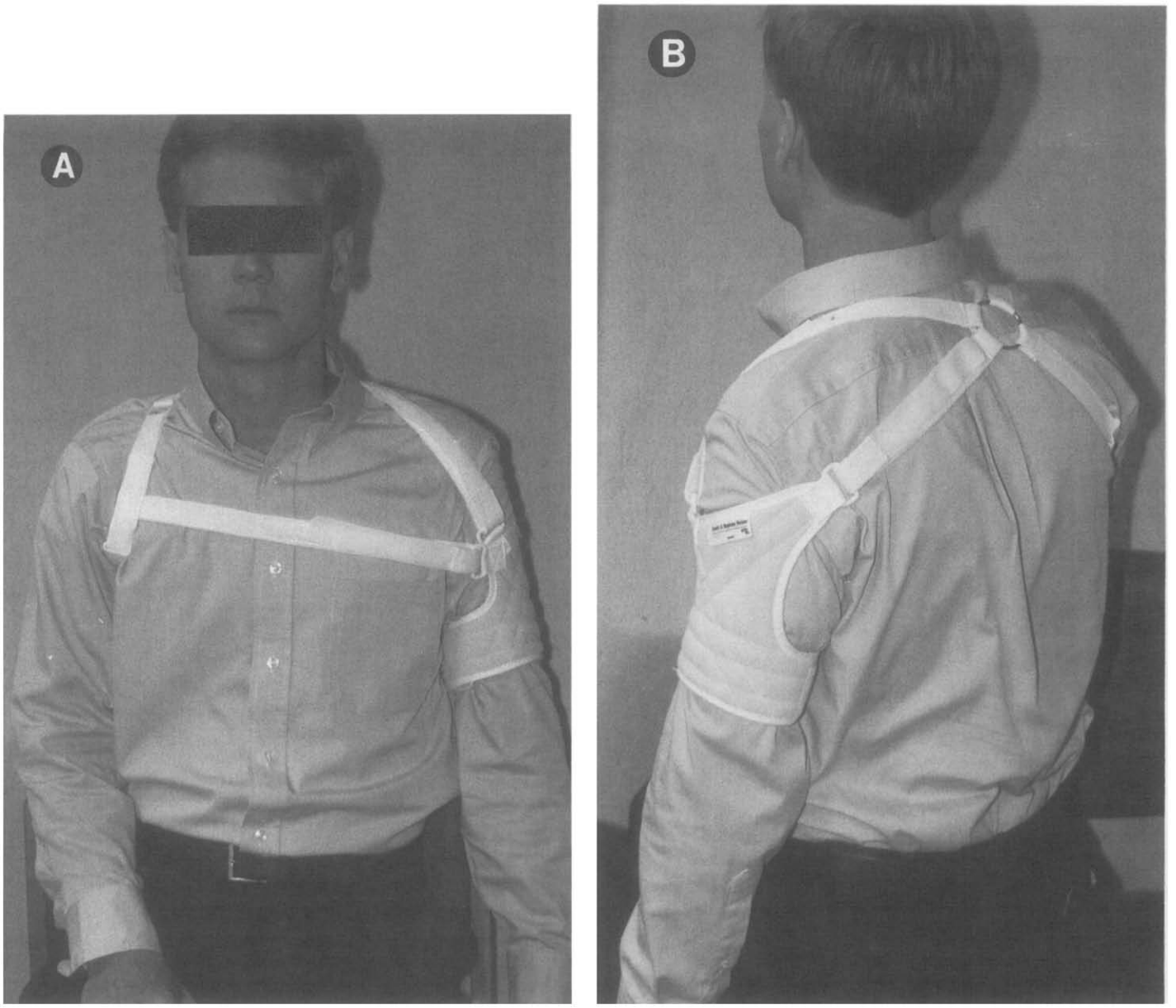

Fig 3—The Rolyan humeral cuff sling. (A) Anterior view. (B) Posterior view.

RESULTS

Two hundred nineteen consecutive patients admitted to the East Orange Facility of the Kessler Institute for Rehabilitation were screened for inclusion into the study. Of these, 26 (12%) met the inclusion criteria for the study. Six of these patients were excluded subsequently when comparison of the radiographs of the unaffected shoulder and unsupported affected shoulder unexpectedly demonstrated no significant subluxation. A total of 20 subjects completed the study.

Table 1 outlines the characteristics of the study population. The mean age of the subjects was 63 years (range 47 to 76). Fourteen (70%) of the 20 subjects were men, and 6 (30%) were women. Thirteen (65%) subjects suffered nonhemorrhagic strokes. Six (30%) subjects had lesions in the left hemisphere, 13 (65%) subjects had lesions in the right hemisphere, and 1 (5%) had a lesion in the brainstem. Eleven (55%) subjects had cortical lesions, whereas 8 (40%) subjects had subcortical lesions.

The average Fugl-Meyer score for the 20 subjects was 8.7 ± 8.4 points. Eight of 20 (40%) subjects were classified in Brunnstrom stage II, 11 (55%) subjects were classified in Brunnstrom stage III, and 1 (5%) subject was classified in Brunnstrom stage IV. Kendall tau correlation coefficients (r_k) did not produce a significant linear correlation between the Fugl-Meyer scores and the vertical asymmetry of subluxation ($r_k = 0.3245$, $p = 0.067$), the horizontal asymmetry of subluxation ($r_k = -0.301$, $p = 0.865$), or the total asymmetry of subluxation ($r_k = 0.2705$, $p = 0.120$).

Table 2 shows the values of vertical asymmetry of the affected shoulder with and without each of the four supports

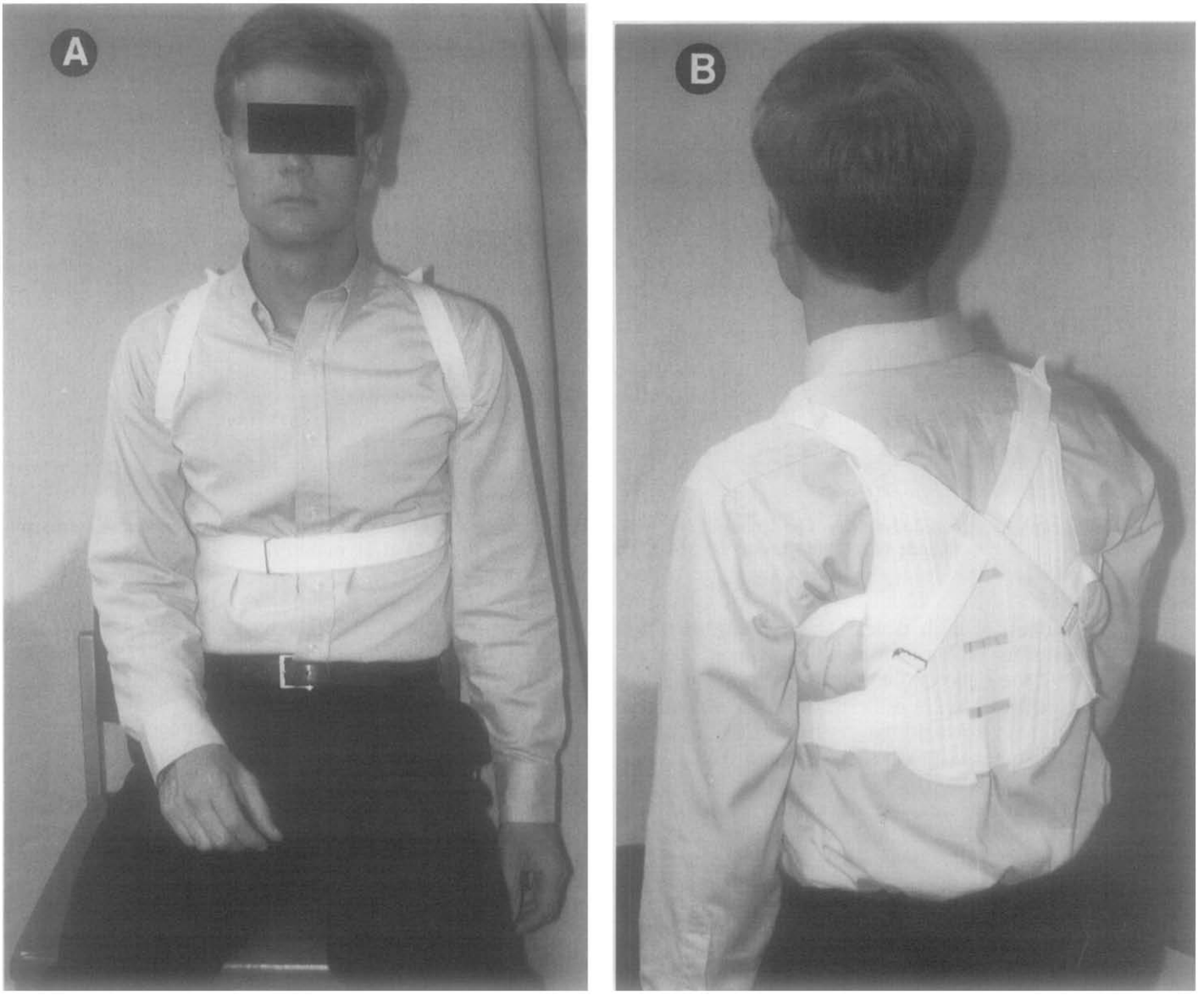

Fig 4—The Cavalier shoulder support. (A) Anterior view. (B) Posterior view.

over the group of 20 subjects. The mean is a negative number if the support undercorrected the subluxation. Tables 2 and 3 describe how each support alters vertical asymmetry with respect to the unsupported affected shoulder and the unaffected shoulder, respectively. The single-strap hemisling corrected the vertical displacement, and the Cavalier support did not significantly alter vertical displacement. The remaining two supports significantly reduced but did not correct vertical displacement.

Table 4 exhibits the horizontal asymmetries of the affected shoulder with and without each of the four supports over the group of 20 subjects. A negative mean indicates lateral displacement of the humeral head. Tables 4 and 5 describe how each support alters horizontal asymmetry with respect to the unsupported affected shoulder and the unaffected shoulder, respectively. On a group basis, there was no significant horizontal asymmetry when no support was applied. Horizontal symmetry was maintained when the single-strap hemisling and the Rolyan humeral cuff sling were used. However, the Bobath roll and the Cavalier support produced a significant lateral displacement of the humeral head of the affected shoulder compared with the unaffected shoulder.

Table 6 displays the total asymmetries of the affected shoulder with and without each of the four supports over the group of 20 subjects. Tables 6 and 7 describe how each support alters total asymmetry with respect to the unsupported affected shoulder and the unaffected shoulder, respectively. The Rolyan humeral cuff sling was the only support that significantly decreased total subluxation asymmetry but did not eliminate it. The remaining three supports did not alter total asymmetry significantly when compared with the unsupported affected shoulder.

Measurements of asymmetries for each subject are listed in tables 8 through 10. The support that reduced the asymmetry most for each subject is highlighted, and the number of individuals for whom each support provided the best correction is

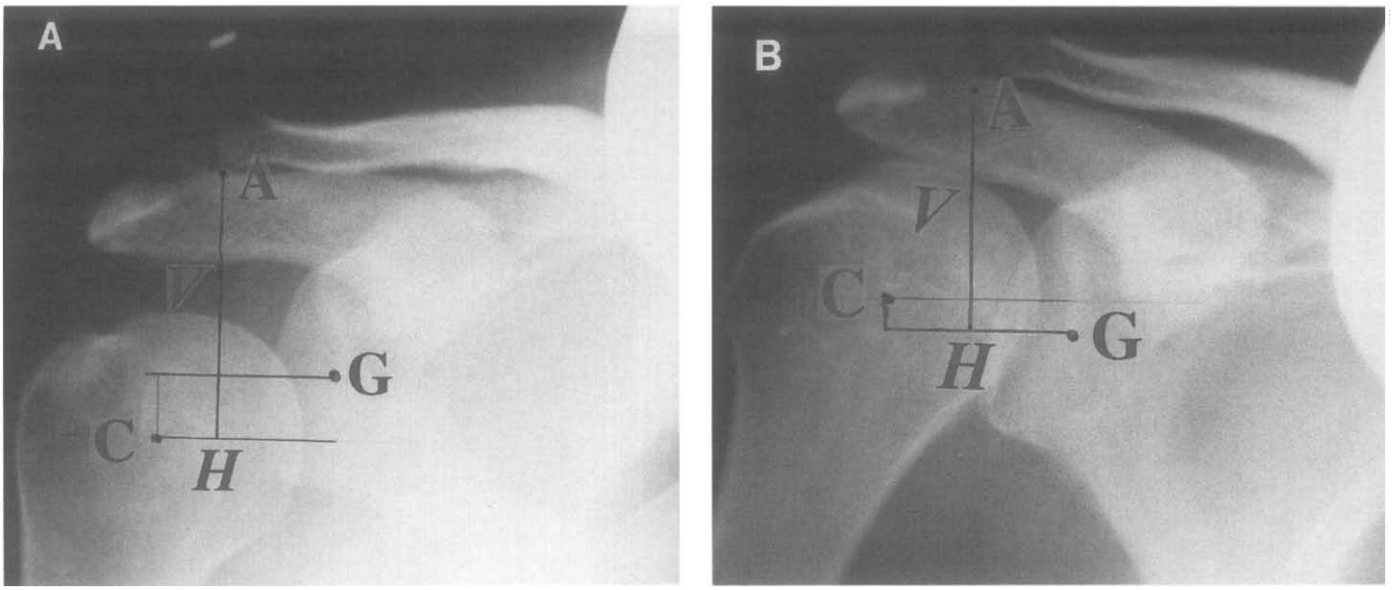

Fig 5—Radiograph of affected shoulder. (A) Unsupported. (B) With single-strap hemisling. A, acromion; C, center of humeral head; G, glenoid fossa; *H*, horizontal asymmetry; *V*, vertical asymmetry.

tallied at the bottom of each table. Table 8 shows that the single-strap hemisling produced a best vertical correction in only 55% (11) of the subjects; the Rolyan humeral cuff sling provided the best correction in 40% (8) of the cases; and the Bobath roll corrected vertical asymmetry best in 20% (4) of the cases. Table 9 illustrates that each support except the Cavalier support produced a best horizontal correction in 25% (5) of the subjects. The Cavalier support provided the best horizontal correction in only 10% (2) of the subjects. Table 10 shows that the Rolyan humeral cuff sling best corrected total asymmetry in 45% (9) of the subjects, the single-strap hemisling provided the best correction of the asymmetry in 40% (8) of the cases, and the Bobath roll corrected total asymmetry best in 20% (4) of the cases. The Cavalier support did not correct total asymmetry best in any subject.

Table 1: Age, Sex, and Type and Site of Lesion of the Study Population

	Age	Sex	Lesion Type	Lesion Site
1.	76	M	Hem	Right thalamus
2.	67	F	Inf	Right frontoparietal
3.	55	M	Hem	Right thalamus
4.	61	M	Inf	Right middle cerebral artery
5.	47	M	Inf	Left temporoparietal
6.	60	M	Inf	Right parietal
7.	83	F	Hem	Right cerebral hemisphere
8.	76	M	Inf	Left temporal
9.	73	F	Inf	Right middle cerebral artery
10.	79	M	Inf	Left frontotemporoparietal
11.	50	M	Hem	Left basal ganglia
12.	66	M	Inf	Midbrain/pons
13.	57	M	Inf	Left middle cerebral artery
14.	63	F	Inf	Right middle cerebral artery
15.	47	M	Hem	Right basal ganglia
16.	75	F	Inf	Right parietal
17.	76	M	Inf	Left basal ganglia
18.	69	F	Inf	Right caudate
19.	42	M	Hem	Right basal ganglia
20.	43	F	Hem	Right cerebral hemisphere

Abbreviations: Inf, Nonhemorrhagic infarct; Hem, Hemorrhagic infract.

DISCUSSION

The use of supports in reducing glenohumeral subluxation in the stroke survivor remains controversial. Some investigators have questioned their use,[2,16-18] whereas others have considered their use contraindicated.[19,20] Researchers have suggested that supports may impair body image.[21] Supports may place the affected extremity in nonfunctional positions that facilitate synergistic patterns and may lead to contracture[19,25] or reflex sympathetic dystrophy.[22] No significant differences in shoulder range of motion between subjects who wear supports and those who do not have been observed.[23] One investigator even believed that it is not necessary to support a painfree shoulder with a support because the support will not prevent or correct a subluxation.[24]

Data from this study indicate that the single-strap hemisling eliminates the vertical asymmetry of subluxed hemiplegic shoulders when group statistics are considered.

Table 2: Vertical Asymmetry (Difference Between Affected and Unaffected Shoulder [cm]) With and Without Supports: One-Value *t* Test, Test Value = 0, Against Unsupported Shoulder

	No Support	Hemisling	Rolyan	Bobath	Cavalier
Mean	−0.99	−0.34	−0.58	−0.62	−0.90
95% CI					
Lower	−1.26	−0.69	−0.95	−0.93	−1.22
Upper	−0.72	0.02	−0.21	−0.32	−0.56
Range					
Lower	−2.30	−1.60	−3.10	−2.20	−2.60
Upper	−0.30	1.20	0.20	0.30	0.10
t value	−7.57	−1.98	−3.31	−4.31	−5.67
2-tail sig	$p < 0.001$	$p = 0.062$	$p = 0.004$	$p < 0.001$	$p < 0.001$

Abbreviations: CI, confidence interval; sig, significance (*p* value).

Table 3: Paired Differences (cm) of Vertical Asymmetry Between Affected Shoulder With Support and Affected Shoulder With No Support: Paired *t* Test

	Hemisling	Rolyan	Bobath	Cavalier
Paired difference	−0.65	−0.40	−0.36	−0.95
95% CI				
Lower	−0.90	−0.59	−0.52	−0.26
Upper	−0.41	0.22	−0.21	−0.07
t value	−5.63	−4.61	−4.95	−1.21
2-tail sig	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p = 0.240$

Abbreviations: CI, confidence interval; sig, significance (*p* value).

Table 5: Paired Differences (cm) of Horizontal Asymmetry Between Affected Shoulder With Support and Affected Shoulder With No Support: Paired *t* Test

	Hemisling	Rolyan	Bobath	Cavalier
Paired difference	−0.08	0.06	0.40	0.37
95% CI				
Lower	−0.29	−0.07	0.22	0.21
Upper	0.12	0.19	0.57	0.53
t value	−0.85	0.96	4.80	4.77
2-tail sig	$p = 0.406$	$p = 0.350$	$p < 0.001$	$p < 0.001$

Abbreviations: CI, confidence interval; sig, significance (*p* value).

However, the results also emphasize that other shoulder supports sometimes may correct asymmetries best. This finding should not be surprising. Many supports designed for reducing shoulder subluxation during ambulation have been described,[25-32] but their effects appear to be variable. In a recent study, the Harris hemisling, which is similar to the single-strap hemisling used in the present study, was found to provide vertical correction better than that of a Bobath roll in 10 hemiplegic subjects.[5] Another study demonstrated radiographic evidence of reduced subluxation when a broad arm sling was applied, but not when a Bobath roll or Hook hemi-harness was used.[4] On the other hand, a third investigator found that only half of the subjects benefited by the use of a standard hemisling or cone sling.[33] A fourth investigator found that the Dennison sling, Dumbbell sling, Harris hemisling, Hook hemi-harness, and Zimmer fashion arm sling all significantly corrected subluxation when correctly applied.[34]

The present study also finds no statistically significant lateral displacement in unsupported subluxed shoulders of stroke survivors. This finding is similar to that of one study that did not report statistical significance of the horizontal measurements between the unaffected and the unsupported and supported affected shoulders.[5] Another group of investigators implied the presence of lateral humeral displacement associated with subluxation when they reported a reduction of lateral displacement of the affected shoulders of 70% of subjects when a standard hemisling was applied.[33] However, the present study supports the findings of researchers who described a creation of horizontal asymmetry when a Bobath roll was applied.[20,26,33] This study also found that the Cavalier support iatrogenically produced horizontal asymmetry of the affected shoulder.

A unique aspect of this study is the use of the measure of total asymmetry of the affected shoulder. Using vertical and horizontal asymmetries, the single-strap hemisling corrected subluxation best because overcorrection in some patients was averaged with undercorrection in others (tables 2 and 4). In contrast, the Rolyan humeral cuff sling was the only support that statistically reduced total asymmetry. The single-strap hemisling did not reduce total asymmetry statistically as well as the Rolyan humeral cuff sling because the values of vertical and horizontal asymmetry were squared and thus became positive. The absolute error produced by the single-strap hemisling was greater than that produced by the Rolyan humeral cuff sling (table 6).

Total asymmetry analyses therefore confirm that the Rolyan humeral cuff sling decreases subluxation on a group basis but suggest that the single-strap hemisling also may be useful in reducing subluxation. During analysis of individual subjects, each support except the Cavalier support provided the best overall total fit in a number of subjects. In future research, the measurement of total asymmetry in three dimensions could be a useful and powerful tool to compare asymmetries of shoulders with inferior and anterior subluxations. Such a calculation would require both anteroposterior and lateral radiographs of the shoulders.

Another interesting observation was that the Fugl-Meyer scores and the vertical asymmetry of subluxation were not statistically correlated. One would expect an association between shoulder subluxation and severity of paralysis. One investigator found that the incidence of subluxation in stroke survivors was 66% in subjects with "complete or severe paralysis," but only 16% in those with "partial paralysis or paresis."[3] This makes sense because functional loss of the

Table 4: Horizontal Asymmetry (Difference Between Affected and Unaffected Shoulder [cm]) With and Without Supports: One-value *t* Test, Test Value = 0, Against Unsupported Shoulder

	No Support	Hemisling	Rolyan	Bobath	Cavalier
Mean	−0.09	0.00	−0.15	−0.49	−0.46
95% CI					
Lower	−0.34	−0.33	−0.43	−0.80	−0.76
Upper	0.16	0.32	−0.13	−0.16	−0.16
Range					
Lower	−1.00	−1.50	−1.70	−1.90	−1.60
Upper	0.60	0.90	0.60	0.30	0.60
t value	−0.76	−0.03	−1.14	−3.16	−3.23
2-tail sig	$p = 0.457$	$p = 0.975$	$p = 0.270$	$p = 0.005$	$p = 0.004$

Abbreviations: CI, confidence interval; sig, significance (*p* value).

Table 6: Total Asymmetry (Difference Between Affected and Unaffected Shoulder [cm]) With and Without Supports: One-value *t* Test, Test Value = 0, Against Unsupported Shoulder

	No Support	Hemisling	Rolyan	Bobath	Cavalier
Mean	1.11	0.93	0.82	1.01	1.16
95% CI					
Lower	0.82	0.68	0.44	0.68	0.82
Upper	1.39	1.17	1.20	1.33	1.51
Range					
Lower	0.30	0.14	0.10	0.14	0.32
Upper	2.51	2.19	3.54	2.91	3.05
t value	8.11	7.98	4.56	6.43	7.05
2-Tail sig	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$

Abbreviations: CI, confidence interval; sig, significance (*p* value).

Table 7: Paired Differences (cm) of Total Asymmetry Between Affected Shoulder With Support and Affected Shoulder With no Support: Paired *t* Test

	Hemisling	Rolyan	Bobath	Cavalier
Paired difference	0.18	0.29	0.10	−0.56
95% CI				
Lower	−0.03	0.09	−0.09	−0.23
Upper	0.40	0.49	0.30	0.12
t value	1.78	2.99	1.11	−0.68
2-tail sig	$p = 0.091$	$p = 0.008$	$p = 0.283$	$p = 0.502$

Abbreviations: CI, confidence interval; sig, significance (*p* value).

supraspinatus and posterior deltoid muscles, which normally support structures across the glenohumeral joint, is associated with inferior glenohumeral subluxation.[35]

An important issue is the relationship between shoulder subluxation and pain. Many authors suggest that shoulder subluxation is a cause of pain.[1,8,30,36-38] Some even advocate that supports may be used to prevent or reduce pain caused by shoulder subluxation, although they have not established any causal relationship between shoulder subluxation and pain.[2,6,16,25] On the other hand, several investigators have found no significant relationship between shoulder subluxation and pain.[39-41] Future research should address whether a causal relationship exists between poststroke shoulder subluxation and shoulder pain.

There is no doubt that appropriately chosen shoulder supports can correct subluxation to varying degrees. However, one should carefully consider whether a support is necessary to treat shoulder subluxation after stroke. If a support is to be used, this study suggests that patients should try several supports appropriate to the motor function of the affected extremity. For example, a patient with a flaccid upper extremity may consider a single-strap hemisling to decrease traction forces while awaiting the development of tone or volitional movement. A patient with some volitional movement may consider a Rolyan humeral cuff sling or Bobath roll to distribute the affected limb's weight to another part of the body. The cognitive status of each stroke survivor should be evaluated to determine whether the patient has unilateral neglect or sensory deficits that place the affected

Table 8: Vertical Asymmetry (Difference Between Affected and Unaffected Shoulder [cm]) During Application of Supports: Best Correction by Subject

	No Support	Bobath	Cavalier	Hemisling	Rolyan
1.	−.90	−.60	−.60	**−.20**	−.40
2.	−.30	**.10**	−.80	1.00	−.20
3.	−1.20	−.90	−.60	**.10**	−.30
4.	−1.50	−.90	−1.20	**−.20**	−.70
5.	−2.30	−2.20	−2.60	**−1.60**	−3.10
6.	−1.40	−1.20	−1.40	**−.90**	−1.50
7.	−.70	**.10**	**.10**	1.20	−.30
8.	−.80	−.50	−.80	**−.40**	−.50
9.	−1.70	−1.20	−2.10	−1.60	**−1.40**
10.	−1.80	−1.60	−1.70	**−1.00**	−1.50
11.	−.40	−.90	−.50	−.30	**−.20**
12.	−.90	−.30	−.50	**.00**	**.00**
13.	−.40	−.60	−.80	−.80	**−.10**
14.	−.60	.30	−.20	**.10**	.20
15.	−.30	−.20	−.30	.50	**.10**
16.	−.60	**−.20**	−.40	−.40	−.30
17.	−.80	**−.20**	−.50	**−.20**	**−.20**
18.	−.30	.30	−.30	**.10**	.20
19.	−1.20	−.70	−.80	−.90	**−.50**
20.	−1.70	−1.10	−1.90	−1.20	**−1.00**
Total best correction: (in bold)		4	1	11	8

Table 9: Horizontal Asymmetry (Difference Between Affected and Unaffected Shoulder [cm]) During Application of Supports: Best Correction by Subject

	No Support	Bobath	Cavalier	Hemisling	Rolyan
1.	.00	−.10	.10	.70	.20
2.	.10	−.10	.60	.10	.40
3.	−.70	−1.50	−1.10	−1.10	**−.50**
4.	.30	**.10**	−.20	.30	.50
5.	−1.00	−1.90	−1.60	−1.50	−1.70
6.	.60	**.20**	**.20**	.40	.50
7.	−.30	−.80	−.60	**.00**	−.30
8.	.20	−1.40	−1.00	−.60	−.50
9.	.60	**.30**	.50	.90	.60
10.	−.90	−1.40	−1.30	**−.40**	−1.00
11.	−.90	−1.00	−1.20	**−.60**	−.80
12.	.40	.30	−.20	.30	**.10**
13.	.10	−.10	−.20	**.00**	.10
14.	.00	−.40	−.40	.10	.20
15.	−.50	−.90	−.90	**.10**	−.60
16.	−.10	**.00**	−.20	.90	**.00**
17.	.60	.20	**.10**	.80	.30
18.	.00	−.40	−.10	.40	.00
19.	.40	**.10**	−.40	.30	**.10**
20.	−.70	−.90	−1.30	−1.20	**−.60**
Total best correction: (in bold)		5	2	5	5

Table 10: Total Asymmetry (Difference Between Affected and Unaffected Shoulder [cm]) During Application of Supports: Best Correction by Subject

	No Support	Bobath	Cavalier	Hemisling	Rolyan
1.	.90	.61	.61	.73	**.45**
2.	.32	**.14**	1.00	1.00	.45
3.	1.39	1.75	1.25	1.10	**.58**
4.	1.53	.91	1.22	**.36**	.86
5.	2.51	2.91	3.05	**2.19**	3.54
6.	1.52	1.22	1.41	**.98**	1.58
7.	0.76	.81	.61	1.20	**.42**
8.	0.82	1.49	1.28	**.72**	**.71**
9.	1.80	**1.24**	2.16	1.84	1.52
10.	2.01	2.13	2.14	**1.08**	1.80
11.	0.98	1.35	1.30	**.67**	.82
12.	0.98	.42	.54	.30	**.10**
13.	0.41	.61	.82	.80	**.14**
14.	0.60	.50	.45	**.14**	.28
15.	0.58	.92	.95	**.51**	.61
16.	0.61	**.20**	.45	.98	.30
17.	1.00	**.28**	.51	.82	.36
18.	0.30	.50	.32	.41	**.20**
19.	1.26	.71	.89	.95	**.51**
20.	1.84	1.42	2.30	1.70	**1.17**
Total best correction: (in bold)		4	0	8	9

extremity at risk of trauma. Supports should minimize vertical and horizontal asymmetries of the affected shoulder. Supports should be easy to don and doff in order for patients to perform range of motion exercises that potentially prevent muscle contractures and other complications. The stroke survivor and his family members should be taught and be able to demonstrate proper use of the support. Future studies need to address the benefits and complications of long-term use of shoulder supports in order to determine whether they have a useful and necessary purpose in stroke rehabilitation.

In conclusion, this study has demonstrated that any of the supports tested, except the Cavalier support, may correct the vertical asymmetry of glenohumeral subluxation but that only the single-strap hemisling corrects vertical asymmetry to any significant degree. Lateral displacement of the humeral head does not appear to result from the subluxation itself but may be caused by application of supports such as the Bobath roll or Cavalier support. Total asymmetry is significantly reduced only with use of the Rolyan humeral cuff sling. Although supports are used commonly during the rehabilitation of stroke survivors, there is no absolute evidence that supports prevent or reduce long-term shoulder subluxation when spontaneous recovery of motor function occurs, or that a support will prevent supposed complications of shoulder subluxation. Without proper training in the use of a support, stroke survivors may face potential complications such as pain or contracture. More research is needed to critically evaluate the presumed benefits of supports in stroke rehabilitation so that the role of supports in correcting shoulder subluxation may be better clarified.

References

1. Fitzgerald-Finch O, Gibson I. Subluxation of the shoulder in hemiplegia. Age Ageing 1975;4:16-8.
2. Smith RG, Cruikshank JG, Dunbar S, Akhtar AJ. Malalignment of the shoulder after stroke. Br Med J (Clin Res) 1982;284:1224-6.
3. Najenson T, Pikielny SS. Malalignment of the glenohumeral joint following hemiplegia. Ann Phys Med 1965;8:96-9.
4. Moodie N, Brisbin J, Margan A. Subluxation of the glenohumeral joint in hemiplegia: evaluation of supportive devices. Physiother Can 1986;38:151-7.
5. Brooke MM, de Lateur BJ, Diana-Rigby GC, Questad KA. Shoulder subluxation in hemiplegia: effects of three different supports. Arch Phys Med Rehabil 1991;72:582-6.
6. Smith RO, Okamoto GA. Checklist for the prescription of slings for the hemiplegic patient. Am J Occup Ther 1981;35:91-5.
7. Carpenter GI, Millard PH. Shoulder subluxation in elderly patients. J Am Ger Soc 1982;30:441-6.
8. Najenson T, Yacubovich E, Pikielm SS. Rotator cuff injury in shoulder joints of hemiplegic patients. Scand J Rehabil Med 1971;3:131-7.
9. Prevost R, Arsenault AB, Dutil E, Drouin G. Shoulder subluxation in hemiplegia: a radiologic correlational study. Arch Phys Med Rehabil 1987;68:782-5.
10. Idank DM, Zorowitz RD, Ikai T, Hughes MB, Johnston MV. Shoulder subluxation after stroke: a pilot study comparing four slings. Arch Phys Med Rehabil 1993;74:1235.
11. Kunitz SC, Gross CR, Heyman A, et al. The pilot stroke data bank: definition, design, and data. Stroke 1984;15:740-5.
12. Fugl-Meyer AR, Jääskö L, Leyman I, Olsson S, Steglind S. The post-stroke hemiplegic patient. 1. A method for evaluation of physical performance. Scand J Rehabil Med 1975;7:13-31.
13. Brunnstrom S. Movement therapy in hemiplegia: a neurophysiological approach. Philadelphia: Harper and Row, 1970.
14. Twitchell TE. The restoration of motor function following hemiplegia in man. Brain 1951;74:443-80.
15. Prevost R, Arsenault A, Dotil E, Drouin G. Rotation of the scapula and shoulder subluxation in hemiplegia. Arch Phys Med Rehabil 1987;68:786-90.
16. Varghese G. Shoulder complications in hemiplegia. J Kansas Med Soc 1981;82:451-3.
17. Voss DE. Should patients with hemiplegia wear a sling? Phys Ther 1969;49:1030.
18. Tepperman PS, Greysen D, Hilbert L, Jimenez J, Williams H. Reflex sympathetic dystrophy in hemiplegia. Arch Phys Med Rehabil 1984;65:442-7.
19. Bobath B. Adult hemiplegia: evaluation and treatment. London: Heinemann, 1978.
20. Irwin-Carruthers S, Runnals MJ. Painful shoulder in hemiplegia - prevention and treatment. South African J Physiother 1980;36:18-23.
21. Miller J. Shoulder pain from subluxation in hemiplegia [letter]. Br Med J 1975;4:345.
22. Flatt A. Shoulder-hand syndrome. Lancet 1974;i:1107-8.
23. Hurd MM, Farrell KH, Waylonis GW. Shoulder sling for hemiplegia: friend or foe? Arch Phys Med Rehabil 1974;55:519-22.
24. Friedland F. Physical Therapy. In: Licht S, editor. Stroke and its rehabilitation. Baltimore: Williams and Wilkins, 1975.
25. Brudny J. New orthosis for treatment of hemiplegic shoulder subluxation. Orthot Prosthet 1985;57:1377-80.
26. Sodring KM. Upper extremity orthosis for stroke patients. Int J Rehabil Res 1980;3:33-8.
27. McCollough NC. Orthotic management in adult hemiplegia. Clin Orthop 1978;131:38-46.
28. Paquin JM, Albert A, Fajai G. Appliances for the hemiplegic patient: prescription and utilization. Prosthet Int 1968;3:22-6.
29. Leddy M. Sling for hemiplegic patients. Br J Occup Ther 1981;44:158-60.
30. Rajaram Y, Holtz M. Shoulder forearm support for the subluxed shoulder. Arch Phys Med Rehabil 1985;66:191-2.
31. Claus SW, Godfrey KJ. A new distal support sling for the hemiplegic patient. Am J Occup Ther 1985;39:536-7.
32. Collins DW. Some attempts to aid surgeons and orthotists in the management of hemiplegics and tetraplegics: upper extremities. Prosthet Int 1968;3:32-6.
33. Kieran OP, Willingham A, Schwarz S, Firooznia H. Radiographic assessment of efficacy of slings in glenohumeral subluxation in hemiplegia. Arch Phys Med Rehabil 1984;65:653.
34. Patterson JR, Zabransky R, Grabois M, Ferro P. Evaluation of the effectiveness of sling orthoses for the correction of glenohumeral subluxation in the hemiplegic. Arch Phys Med Rehabil 1984;65:635.
35. Chaco J, Wolf E. Subluxation of the glenohumeral joint in hemiplegia. Am J Phys Med 1971;50:139-43.
36. van Ouwenaller C, Laplace PM, Chantraine A. Painful shoulder in hemiplegia. Arch Phys Med Rehabil 1986;67:23-6.
37. Tobis JS. Posthemiplegic shoulder pain. NY State J Med 1957;57:1377-80.
38. Moskowitz H, Goodman CR, Smith E, Balthazar E, Mellins HZ. Hemiplegic shoulder. NY State J Med 1969;69:548-50.
39. Van Langenberghe HV, Hogan BM. Degree of pain and grade of subluxation in the painful hemiplegic shoulder. Scand J Rehabil Med 1988;20:161-6.
40. Arsenault AB, Silodeau M, Dutil E, Riley E. Clinical significance of the V-shaped space in the subluxed shoulder of hemiplegics. Stroke 1991;22:867-71.
41. Bohannon RW, Andrews AW. Shoulder subluxation and pain in stroke patients. Am J Occup Ther 1990;44:507-9.

Shoulder Support for Children with Subluxation: A Case Study

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ABSTRACT

Children with brachial plexus injury from birth may present with varying degrees of muscle imbalance, as well as a subluxation of the glenohumeral joint. Shoulder subluxation occurs when the muscles of the shoulder girdle are weak or flaccid. The deltoid and the rotator cuff musculatures are unable to position the humerus appropriately to the glenoid fossa, and there is concurrent stretching of the glenohumeral joint capsule, ligaments, and nonactive muscles. Treatment for reducing the subluxation and positioning the arm typically has involved use of an appropriate sling or humeral cuff support. There are commercially available slings for children but no child-size shoulder support. The purpose of this case study was to design a custom-fitted shoulder support for children that reduces subluxation and maintains alignment through extended periods of the day. A validated radiographic method was used to quantify the subluxation before application of the shoulder support, immediately after applying the shoulder support, and after 3 hours of wear. A motion tracking system objectively quantified active shoulder and elbow movements in the presence and absence of the shoulder support. This case study suggests that the custom-designed child support significantly reduced the subluxation, maintained alignment through extended periods of the day, and maintained the active range in elbow flexion. (*J Prosthet Orthot.* 2005;17:74–79.)

KEY INDEXING TERMS: brachial plexus injuries, pediatric shoulder support, shoulder subluxation

The main causes of damage to the brachial plexus at birth are traction, contusion, and compression during delivery.[1,2] The residual effects on the arm depend on the number of nerve roots involved and severity of the injury. Babies who have had incomplete or poor function from 6 to 18 months after birth and a greater degree of dysfunction are classified as having moderate to severe damage to the nerves of the plexus.[2–4] After the age of 2 years, some degree of residual motor dysfunction may appear. The most common deformity may include all or some of the following: weakness of external rotation, weakness of overhead shoulder movement, scapula instability, subluxation of the humerus, overactivity of the muscles of internal rotation, and weakness of the distal muscles of the forearm and hand.[4]

Children with brachial plexus injury need to receive optimal therapeutic intervention, with the focus on maximizing function and preventing the development of secondary problems such as shoulder subluxation and tightness. Inferior shoulder subluxation occurs when the head of the humerus slides down or inferior in the glenoid fossa and the scapula is in a downwardly rotated position. The secondary problems can interfere with functional use of the affected upper extremity and the child's ability to incorporate the arm to perform self-care. Often shoulder supports are placed on the child without a thorough evaluation. An inappropriate shoulder support can contribute to poor alignment of the humerus into the glenoid fossa, which may cause additional impingement and pain.

Children with birth-related brachial plexus often present with shoulder problems.[4,5] For implementing an appropriate treatment course, a thorough evaluation is critical. The therapist must assess the alignment of the scapula on the rib cage, the alignment and mobility of the glenohumeral joint, passive and active range of motion, and muscle strength. Subluxation often occurs as a result of the loss of balanced muscle firing around the glenohumeral joint and stretching of the ligamentous support structure.[6] The glenohumeral joint must be realigned and is essential for active shoulder movements.

For the adult stroke population there are numerous studies documenting the efficacy in reducing shoulder subluxation with different types of supports for the hemiplegic shoulder.[7–9] Zorowitz et al.[10] described a comparison study using four different types of shoulder support to optimize function and reduce shoulder subluxation for ambulatory adults with stroke. A humeral cuff sling, a figure-8 strap system with a humeral arm cuff to fit on the affected upper extremity, was found to significantly reduce the vertical asymmetry of the

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glenohumeral subluxation. The strap and cuff system allows adjustments to the vertical alignment and rotational position of the humerus.[10]

Brooke et al.[11] measured the effects of three different types of shoulder support for shoulder subluxation in adults with hemiplegia: 1) a hemisling device that positions the involved arm in shoulder adduction, elbow flexion, and internal rotation; 2) a figure-8 support that is applied around the uninvolved shoulder (The rationale for this sling is to avoid internal rotation and the flexed arm position of the conventional sling. However, it did not support the humerus into the glenoid fossa); 3) the arm trough, a device that is attached to the arm of the wheelchair (Shoulder subluxation is corrected by adjusting the height of the armrest or position of the trough). The results of that study supported the use of the hemisling. However, the author reported that other factors need to be considered if using the hemisling. There may be risks for contracture secondary to the position of the arm into internal rotation and elbow flexion.[11]

Children with shoulder girdle weakness may present with potential pain, over-stretching of the joint capsule and ligament, and poor motor control. Limited data exist to support the effectiveness of bracing for children with shoulder subluxation. The primary objective of this case study was to evaluate a custom-fitted, child-size shoulder support that reduced subluxation and maintained alignment through extended periods of the day.

METHODS

The shoulder support is a brace to be worn directly on the skin to provide maximum support, contour, and comfort. It is made from a Velcro-compatible fabric, which is a knitted unbroken loop backed with a perforated neoprene. The material is custom fit over the involved shoulder with the top of the brace formed at the highest point of the shoulder. The shoulder support consists of a humeral cuff, chest straps, and back strap that supports the scapula and assists with the alignment of the humerus. To stabilize the chest and involved scapula, a contoured chest piece with straps is applied that goes under the axilla of the uninvolved shoulder, across the chest, and is pulled through a D-ring. The straps and cuff system are designed to allow adjustments of both the vertical and rotational position of the humerus (Figures 1–4).

The humeral cuff positions and supports the humerus circumferentially with two straps to pull the humerus in a vertical direction back into alignment with the glenoid fossa. A posterior vertical strap assists with pulling the arm up toward the shoulder with the first Velcro tab applied near the axilla and the second Velcro tab on the high point of the shoulder to assist in stabilizing the humerus (Figure 4). The strap is continued down over the chest on a diagonal toward the opposite underarm. An anterior vertical strap also assists with pulling the arm up toward the shoulder with the first Velcro tab applied near the axilla and the second Velcro tab on the high point of the shoulder. The anterior vertical strap continues down toward the back and is pulled on a diagonal to the opposite underarm.

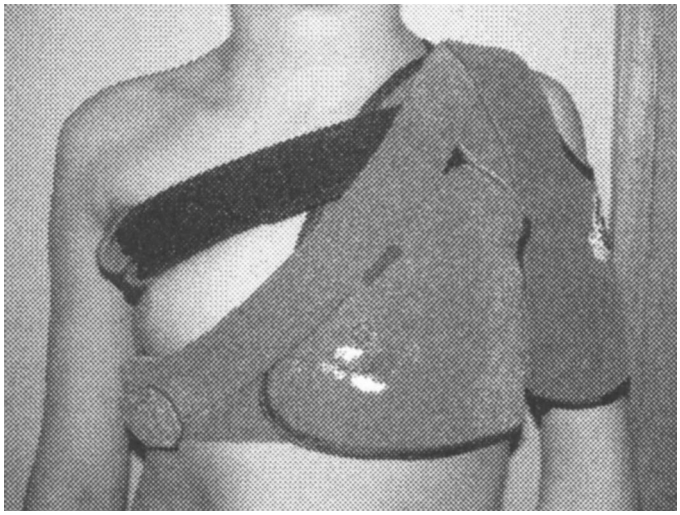

Figure 1. Front view of shoulder support.

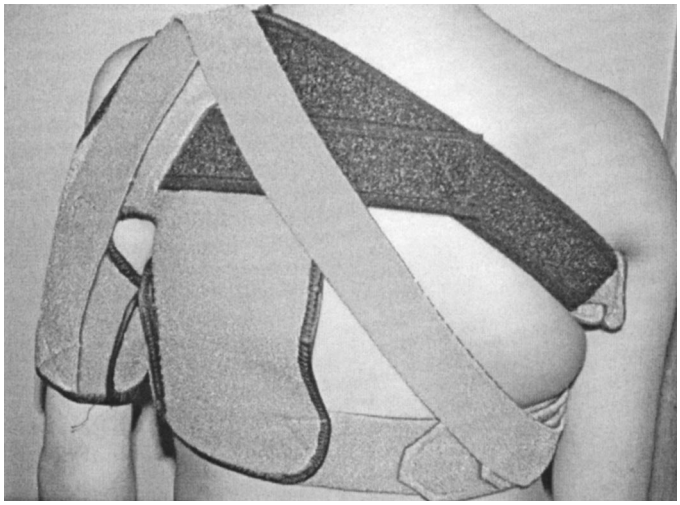

Figure 2. Back view of shoulder support.

The subject's ability to tolerate the brace and alignment must be considered in addition to building a gradual wearing schedule.

SUBJECT

The subject was a 9-year-old boy with left congenital brachial plexus from traction applied to his head and neck during the delivery process, resulting in the avulsion of his 4th, 5th, 6th, and 7th cervical nerves. He presented in the outpatient clinic for occupational therapy evaluation with significant wasting and atrophy of the left shoulder girdle. In addition, his left humerus appeared subluxed about 1 inch, sliding down vertically from the glenoid fossa (Figure 5). The medial border of the scapula was winging with the inferior border tipped. His left shoulder was in a forward position with the left scapula slightly elevated in a downward rotated alignment. The humeral head appeared below the inferior lip of the glenoid

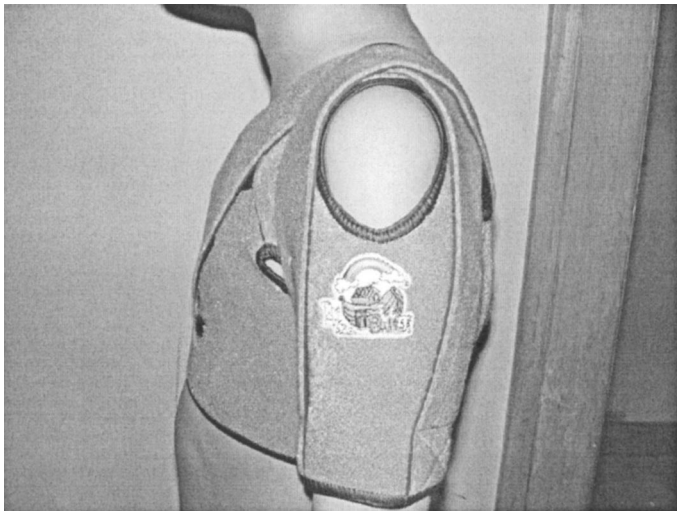

Figure 3. Side view of shoulder support.

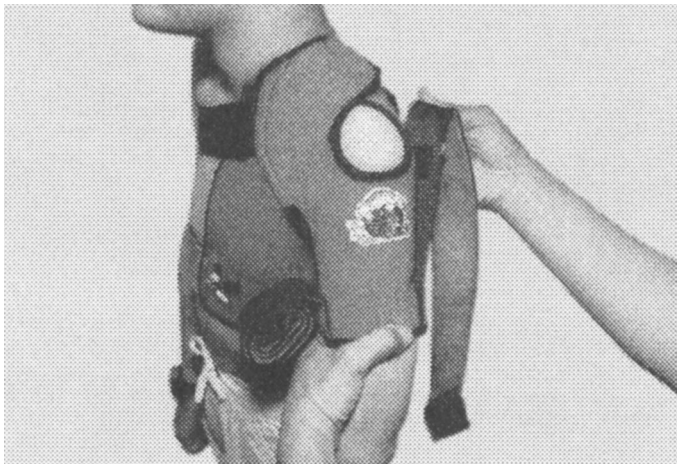

Figure 4. A posterior strap on the humeral cuff is pulled vertically and attached with Velcro to position the humerus.

fossa in an inferior subluxation through clinical palpation. Passive range of motion of his left upper extremity was within functional limits.

He presented with limited scapula and humeral mobility. The strength of the serratus anterior (using a manual muscle test rating of 1 = trace, 2 = poor, 3 = fair, 4 = good, and 5 = normal) was 1/5, upper trapezius 4/5, middle and lower trapezius 1/5, and rhomboids 4/5. The shoulder muscle strength presented with the anterior, middle, and posterior deltoid at 1/5, external rotators 1/5, internal rotator 2/5, and pectoralis major and minor 2/5.

He was able to abduct his arm to 30°, although he also compensated by hyperextending his lower back when attempting to raise his arm. Weak elbow movements were also exhibited with the strength of his elbow flexors and extensors at 2/5. His forearm strength of the supinator and pronators was 4/5, whereas distal control of his wrist and hand also scored a strong 4/5. He demonstrated functional use of his left hand but limited control proximally at the shoulder.

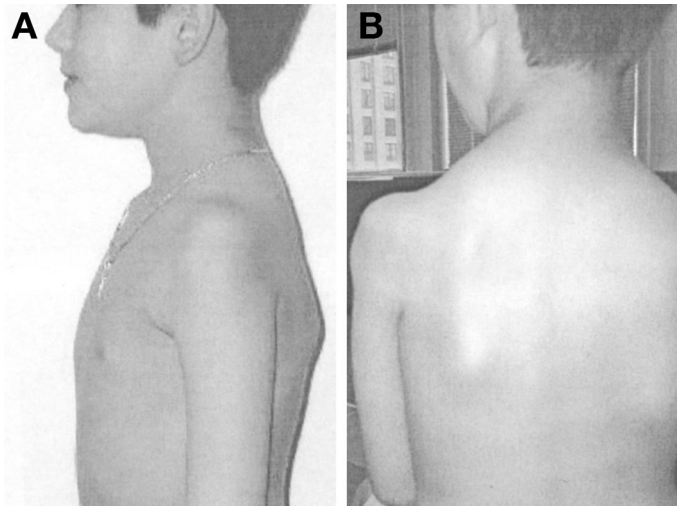

Figure 5. Side view and back view of left inferior subluxation of the humerus.

The subject was very active in sports. He participated in soccer during the time of his assessment and stated that he let his left arm hang while running on the field. He reported pain inconsistently around the shoulder area. A shoulder support of some type was discussed that would maintain the integrity of his ligaments around the shoulder girdle and align the humerus into the glenoid fossa. The shoulder brace was especially important for the subject during contact sports, as well as for maintaining alignment during the day.

RADIOGRAPHIC TECHNIQUE

Three radiographs were taken of both shoulders to quantify and compare the left subluxed shoulder with the unaffected right shoulder:

1. Affected shoulder unsupported (Figure 6).
2. Shoulder support brace applied (Figure 7).
3. After 3 hours of wearing the shoulder support (Figure 8).

The degree of shoulder subluxation found on the radiographs was determined by measuring the vertical and horizontal distances of the glenohumeral axis, as described by Brooke et al.[11]

The central point of the glenoid fossa was determined by measuring the maximum width and height of the fossa (Figure 9). The point at which these two lines intersect is the central point of this fossa (A). The central point of the humeral head was determined by measuring the greatest width of the humerus and then locating its central point (B). Once these points were defined, the vertical distance was measured by the distance from the inferior part of the acromioclavicular joint and the central point of the humerus (V). The horizontal distance was determined by measuring the distance between the central points (H).

FLOCK OF BIRDS

The subject was evaluated using the Flock of Birds electromagnetic motion capture system (Ascension Technologies,

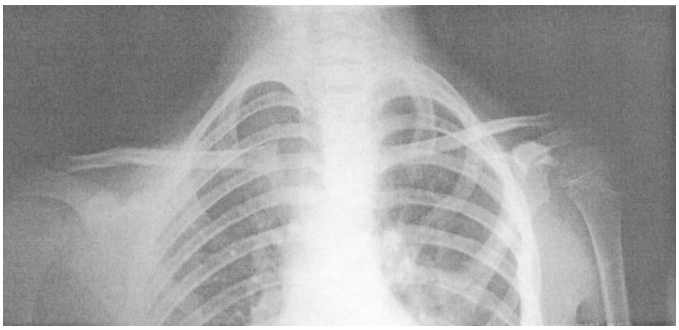

Figure 6. Radiograph of right shoulder and left affected shoulder unsupported.

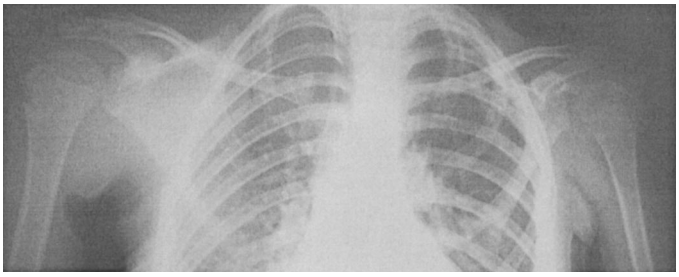

Figure 7. Radiograph of right shoulder and left shoulder in a shoulder support brace.

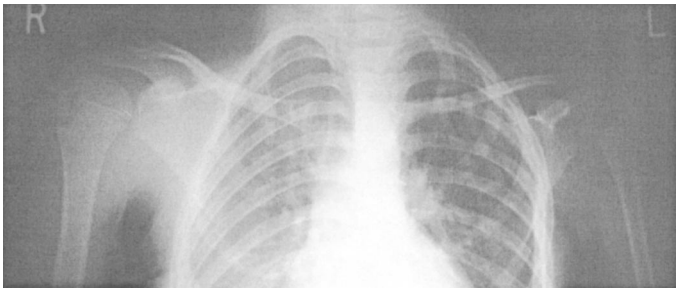

Figure 8. Radiograph of right shoulder and left shoulder in a shoulder support brace after 3 hours of wear.

Inc., Burlington, VT) to objectively measure active movement. The Flock of Birds captured whole limb movements during active shoulder flexion and abduction, and elbow flexion. Markers placed at the subject's thoracic spine (T1 level), humerus, and forearm recorded movement of each segment, and their relative motions revealed joint excursions at the shoulder and elbow. The subject was asked to flex and abduct his humerus with his elbow in an extended position and to flex his elbow. Each of these movements was performed without the shoulder brace and then repeated with the shoulder brace.

RESULTS

Radiographic measurements of the vertical and horizontal alignment of the humerus were taken of the uninvolved and involved left shoulders (Table 1). Initially the patient attempted to lift his involved humeral head actively back into position (25 mm vertical and 32 mm horizontal). It is possible that the clavicle was elevated by the pull of the upper trapezius (4/5 muscle strength) and rhomboids (4/5 muscle strength). The external rotator cuff, middle and lower trapezius, serratus anterior, and the deltoid musculatures were extremely weak, with a strength level of poor to trace. The radiograph demonstrated a superior subluxation of the glenohumeral joint when the humerus moved above the fossa. The patient presented with active motor components of shoulder elevation, minimal shoulder abduction, and internal rotation. This patient typically activated strongly into elevation, causing a superior subluxation position (Figure 6). With the brace in place, the humeral head was positioned back down into the glenoid fossa and both clavicles appeared symmetrical (Figures 7 and 8).

The shoulder brace gave good correction of subluxation as measured in millimeters of the horizontal and vertical distances of the glenohumeral alignment (Table 1). The optimal correction in this case occurred at the vertical component of the glenohumeral alignment. The subluxation was nearly corrected after the immediate application of the brace. Three hours later, the shoulder continued to demonstrate good vertical alignment of the glenohumeral joint.

The motion capture results demonstrated no significant differences in shoulder range of motion between the braced and unbraced conditions. The subject presented poor to trace muscle grade of his deltoid muscles and scapular musculature, which would not have changed with the donning of the shoulder support. However, the brace did not restrict his active range of motion with elbow flexion (Figure 10).

DISCUSSION

The radiographic results support the use of the shoulder brace to minimize subluxation. The glenohumeral joint must be assessed and realigned before the application of a shoulder support. Because the weight of the dangling arm gives a continuous traction to the cord, relief of the pull can increase circulation, which can reduce the potential for pain.

In addition, over-lengthening of the biceps occurs with poor positioning of the humeral head. The biceps traverse the humeral head, such that subluxation will progressively pull the muscle and decrease the ability over the muscle to contract in optimal length tension. Although the biceps strength is dependent on the innervation, length of the muscle affects the muscle strength. The glenohumeral joint integrity is essential before active shoulder movements can be practiced. Family members or caregivers must be instructed in and be able to demonstrate proper use of the support. The shoulder support must also be accepted by the child.

Careful and thorough evaluation is essential for applying the shoulder support. The goal is to provide optimal musculoskeletal alignment to stabilize the shoulder girdle, and maximize motor return and functional performance. The involved shoulder must feel firmly supported to the child.

Strengthening active elbow range should be encouraged

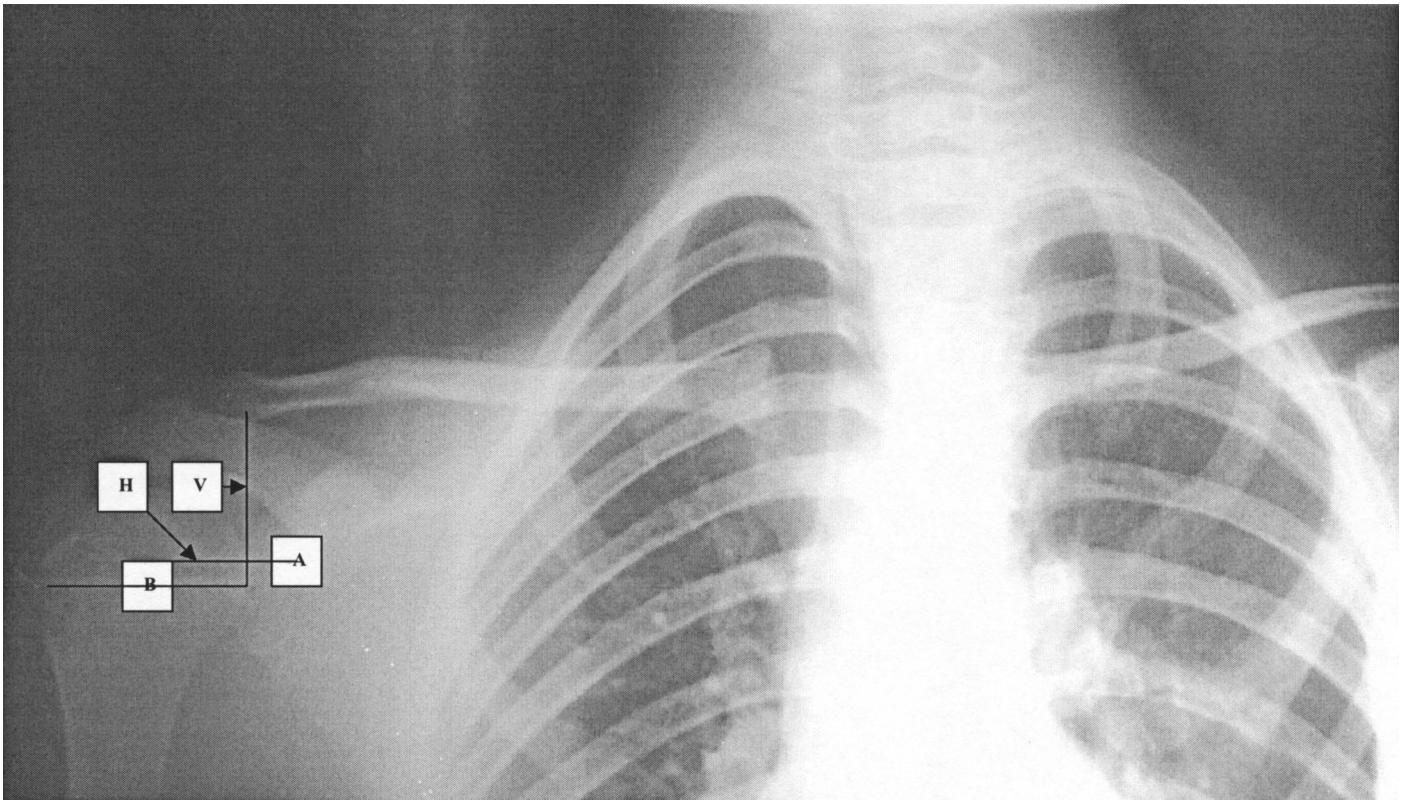

Figure 9. Vertical, horizontal, and total asymmetries of glenohumeral subluxation were compared with the unaffected side.

Table 1. Radiographic measurements (millimeters of the horizontal and vertical distances of glenohumeral alignment) of the uninvolved and involved shoulders

	Right uninvolved		Left involved	
	Vertical (mm)	Horizontal (mm)	Vertical (mm)	Horizontal (mm)
Without brace	39	31	25	32
With brace immediately applied	37	31	36	28
With brace 3 hours after application	36	32	31	32

while the humerus and scapula are stabilized by the brace. The elbow joint is an integral part of the upper extremity kinetic chain. The instability around the shoulder area and over-stretching of the tendons that insert into glenoid fossa and coracoid process may lead to substitution patterns and elbow overuse in a poor position.[12,13] Major extensors and flexors of the elbow, and the triceps and biceps brachii, originate on the scapula and insert on the ulna and radius, respectively. In the presence of these biarticular muscles, pathological conditions at one joint, in this case the shoulder, affect mechanics at the other. Correction of the shoulder alignment and stability provided by the brace may reduce the biomechanical stress at the elbow during use of the arm and help prevent musculotendinous overload at both the shoulder and elbow. The shoulder support brace can potentially provide the stability and alignment in the shoulder area and provide better stabilization for distal control.

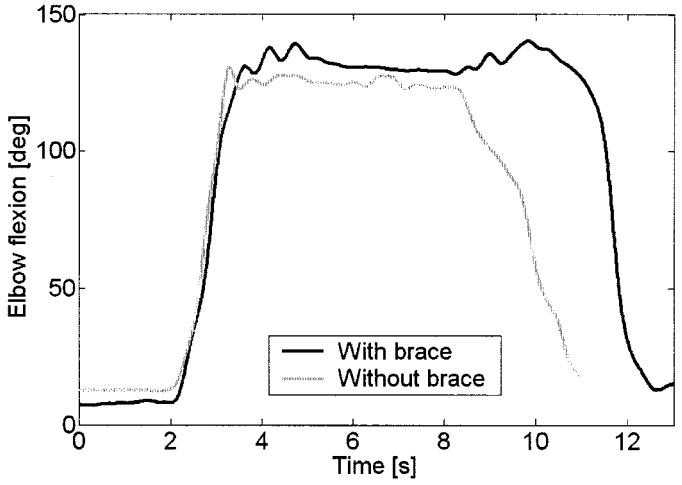

Figure 10. Elbow flexion with and without the shoulder support brace.

SUMMARY

This case study evaluated the efficacy of supporting the subluxed shoulder with a custom-fitted child's size shoulder support. There are no available shoulder braces for children with subluxation except for the sling support. Radiographic methods were used before application of the shoulder support, immediately after applying the shoulder support, and after 3 hours of wear. This case study suggests that the custom-designed child shoulder support significantly reduced the subluxation and maintained alignment through extended periods of the day. The stability at the shoulder area demonstrated potential for providing improved active control of distal movements at the elbow through an ongoing active exercise program.

This case study suggests, for an active child, the shoulder brace effectively reduced subluxation and maintained current active range of motion for distal control of the arm. There is no absolute evidence that supports reduced long-term shoulder subluxation. More research is needed to critically evaluate the benefits of supports with shoulder subluxation in children for assisting with developing a protocol for correcting shoulder subluxation.

REFERENCES

1. Hogan L. OT with obstetric brachial plexus injuries. *Adv Occup Ther* September 1995;19–20.
2. Eng G, Koch B, Smokvina MD. Brachial plexus palsy in neonates and children. *Arch Phys Med Rehabil* 1978;59:458–464.
3. Sundholm LK, Eliasson AC, Forssberg H. Obstetric brachial plexus injuries: assessment protocol and functional outcome at age 5 years. *Dev Med Child Neurol* 1998;40:4–11.
4. Wickstrom J. Birth injuries of the brachial plexus, treatment of defects in the shoulder. *Clin Orthop Rel Res* 1962;23:187–196.
5. Shepherd RB. Brachial plexus injury. In: Campbell S, ed. *Pediatric Neurologic Physical Therapy*. New York: Churchill Livingstone; 1984:141–168.
6. Ryerson S, Levit K. Glenohumeral joint subluxation in CNS dysfunction. *NDTA Newsletter* 1988;115–117.
7. Morin L, Bravo G. Strapping the hemiplegic shoulder: a radiographic evaluation of the efficacy to reduce subluxation. *Physiother Can* 1997;49(2):103–108.
8. Moodie N, Brisbin J, Margan A. Subluxation of the glenohumeral joint in hemiplegia: evaluation of supportive devices. *Physiother Can* 1986;38:151–157.
9. Byrne DP, Ridgeway EM. Considering the whole body in treatment of the hemiplegic upper extremity. *Top Stroke Rehabil* 1998;4(4):14–34.
10. Zorowitz RD, Idank D, Ikai T, et al. Shoulder subluxation after stroke: a comparison of four supports. *Phys Med Rehabil* 1995; 76(8):763–771.
11. Brooke MM, de Lateur BJ, Diana-Rigby GC, Questad KA. Shoulder subluxation in hemiplegia: effects of three different supports. *Arch Phys Med Rehabil* 1991;72:582–585.
12. Kibler WB, Press JM. Rehabilitation of the elbow. In: Lee PA, ed. *Functional Rehabilitation of Sports and Musculoskeletal Injuries*. Gaithersburg, MD: Aspen Publications; 1998:178–181.
13. Dilorenzo CE, Parkes JC, Chmelar RD. The importance of shoulder and cervical dysfunction in the etiology and treatment of athletic elbow injuries. *J Orthop Sports Phys Ther* 1990;11: 402–409.

Overview of Brachial Plexus Management

Gerald Stark, BSME, CP, FAAOP

Management of the Brachial Plexus Injury or BPI is one area where the device created is intended to satisfy both orthotic and prosthetic goals, blurring the lines between support of the limb and functional need. Treatment by the orthotist and prosthetist often differ, but requires a blending of the different philosophies and componentry developed independently in each respective field. The primary goals of a device is ordered in most to least significance: 1) Prevent deformity, 2) Correct deformity, 3) Fix position to obtain maximum function. [1] The main deformity is shoulder subluxation due to muscular flaccidity at the shoulder. Added goals are to treat edema, maintain bimanuality, and ease pain caused by traction.1 These functional goals are influenced by the unilateral/ bilateral involvement, gadget tolerance, donning/ doffing, and wear time. [1] While rejection rate for upper extremity prostheses can be as high as 50 %, the acceptance rate for a brachial plexus orthosis has been estimated as high as 70% after one year of use. [4]

Brachial plexus may be divided into closed or open trauma to nerve branches at the shoulder. In children, 90% of brachial plexus injury is a closed Erb's Palsy which results from birth injury. Injury of the lower brachial plexus is referred to as Kumpke's palsy. This affects nearly 5,000 children per year with an estimate of one to two per 1,000 births. [6] Of those, one in ten require some form of treatment and often involve malpractice litigation. [6] In adults, brachial plexus injury is often the result of traction on the nerve roots C5-C6 as the head is distracted from the shoulder. 4 Lower trauma to nerve roots C8-T1 occur as the arm is brought over the head. [4] These injuries follow Narakus' "law of seven seventies": 70% of traumatic BPI are due to motor vehicle accidents, 70% involve bicycles or motorcycles, 70% have multiple injuries, 70% have subclavicular nerve lesion, 70% have one nerve root avulsed, 70% have lower root (C7, C8, T1 or C8, T1) avulsed, 70% with lower root avulsed experience persistent pain. [4] Other causes for traumatic BPI can be a penetrating stab wound, gunshot, or other open trauma which involves the nerve roots (which may heal faster because there is distinct borders of trauma rather than distraction or tearing). Most patients with traumatic BPI are males, 15-25 years of age. [4]

The first concern with BPI is shoulder subluxation due to muscular flaccidity. As the humeral head subluxes distally it places increasing traction since the nerve roots are held by the clavicle and scaline muscles. [4] Second is the functional positioning of the limb and preservation of extremity function. After WWII this was accomplished surgically with shoulder fusion, elbow bone lock, and finger tenodesis. [4] In the 1960's shoulder fusion in slight abduction and flexion combined with transhumeral amputation with "good" to "fair" functional results. [4] Today surgical management of nerve root avulsions focuses on early, aggressive microsurgical reconstruction of the brachial plexus using nerve donors, grafts, and free vascularized and neurotized muscles. [7] This often results in significant return especially in young patients. Amputation results only when these microsurgical techniques have failed. [7] Surgically the injury is divided into preganglionic or postganglionic. Tendon transfers, pectoralis transfer, and latissimus dorsi transfers cannot be used with C5-C6 avulsions since these muscles are not functional. Transfer of the triceps to biceps is possible only when there is some elbow flexion existing. The nerve tissue for preganglionic injury is not reconstructable and can benefit from an intercostals motor nerve transfer at the 4 rib in which the nerve is routed subcutaneously to the musculocutaneous nerve if 6-12 months post injury. If after 12 months post injury, a gracilis transfer is recommended in which the (Continued from page 7) entire biceps is excised and replaced with the gracilis muscle with the obtuator nerve, artery, and vein. The motor nerves of the 3 rd , 4 th , and 5 th ribs then innervate the gracilis. [4] Postganglionic has shown some recovery up to 3 months after which nerve grafting for the upper trunk is recommended after patient has plateaued. Nerve grafting of the lower trunk presents with mixed results and may require a tendon transfer later. [4] Often stabilization of the humerus in the anesthetic upper limb cannot be achieved due to the weight of the arm, so shoulder fusion is recommended for many patients. [1,4]The recommended position for the shoulder fusion is approximately 20 degree abduction, 30 degree flexion, and 40 degree of internal rotation. [1]

Orthotic/prosthetic management often follows an understanding of the functional levels. C5-C6 presents with a complete loss of shoulder and elbow control. Some wrist extension using finger extensors and extensor carpi ulnaris are still available. [1,4] Thumb and index finger sensation in impaired. C5-C7 also adds radial palsy, increased hand sensory loss, and loss of wrist, hand, and finger extension. [1,4] C7- C8 shows good shoulder and elbow function, but finger flexor weakness, extensors, and intrinsics of the hand. Surgical intervention is fairly successful at this level. Patients do not usually have myosites below the elbow because forearm innervation is lost. [1,4] C8-T1 has lost finger flexors and hand intrinsics, but has good hand sensation except for the 4 th and 5 th finger. This level has the greatest orthotic success. Complete plexus injury has the least amount of success since the arm is completely flail and insensate. Pain is also often present due to nerve traction. [4] Often amputation is recommended for the best functional outcome although not often pursued. Orthotic benefits at this level are

limited to: 1) Protection of the limb, 2) Support to minimize pain, 3) Edema prevention. [1] The following table is presented as a functional guide, but injuries are usually case dependent especially when incomplete. [1]

Photo 1

Level	Motor Deficit	Sensory Loss	Functional Need
C5-C6	Shoulder Abduction	Lateral Arm	Shoulder Support
†	Shoulder Flexion	1st Digit	Prevent Shoulder Subluxation
†	Elbow Flexion	2nd Digit	Elbow Flexion
†	Wrist Extension	†	†
†	†	†	†
C5,C6, C7	Shoulder Abduction	Lateral Arm	†
†	Shoulder Flexion	1st Digit	Shoulder Support
†	Elbow Flexion	2nd Digit	Prevent Shoulder Subluxation
†	Elbow Extension Weakness	3rd Digit	Elbow Flexion
†	Wrist Extension	†	Wrist Support
†	Finger Extension	†	Finger Extension
†	Thumb Extension Weakness	†	1st Extension
†	†	†	†
C8,T1	Wrist Flexors	4th Digit	Wrist Stabilization
†(rare)	Finger Flexors	5th Digit	Finger Flexion
†	Thumb Flexors	Medial Forearm	Some Finger Extension
†	Finger Extensors	†	Intrinsics of Hand
†	Thumb Extensors	†	†
†	†	†	†
C5-T1	Entire Arm	Total Forearm	Shoulder Support
†	May include Scapular Motion	Lateral Arm	Prevent Shoulder Subluxation
†	†	Entire Hand	Protect Limb
†	†	†	Edema Control
†	†	†	Nominal Function
†	†	†	†

Orthotically the first goal is to prevent the subluxation of the shoulder so the weight of the arm must be supported is often supported with the use of a shoulder saddle and an inverted "Y" strap to support the lower forearm also referred to as a hemisling. This is made of padded polyethylene or can be constructed of 2" straps, Spenco Æ , or leather. There is no device as of yet to provide the active shoulder motion although the Rancho Los Amigos Orthosis does aid in flexion/extension and rotation with straps if shoulder movements are poor to trace. [1] A shoulder cap may be used for additional axial support and cable installation, but increases skin coverage and overall bulk. If additional support is required a "gunslinger" or pelvic hemi-girdle variation may be used to support the arm inferiorly. The mechanism is attached to a lower LSO support or to a wheelchair and the positioning joints are mounted inferiorly to provide translational movement.

Since the shoulder cannot be used to achieve positional control, elbow joints are available where most of the terminal positioning can be achieved. These range from bilateral friction joints, spring loaded locking joints, and unilateral ratchet joints. Where polymer systems are used, a simple overlap joint can be employed. Bilateral flail arm hinges are available that provide a spring counterbalance laterally and a reciprocating lock medially. Ratchet joints lock the arm when it is manually positioned and unlock it when the arm is flexed completely similar to a lawn chair joint. Instances where transhumeral amputation has been chosen, externally powered electric elbows with corresponding terminal devices can be utilized. Some contend transradial amputation would be a benefit even if the elbow is non-functioning and the skin over the residuum is insensate, because proprioception may be still be present to aid in arm positioning. 4 Where the BPI arm is left intact, humeral and forearm cuffs support the

arm passively with elastic Velcro closures. A fairly cosmetic lightweight orthosis from the Netherlands uses a medially mounted ratchet elbow in a unilateral construction with four small cuffs that wrap from the medial on the humeral and forearm section. A modular system from England referred to as the Stanmore Orthosis incorporates shoulder, locking elbow, and terminal device function with cable control with a shoulder cap and unilateral, medial construction.

Distally the main goal is to protect the limb and hold it anteriorly. If functional prehension is desired, a smaller 9P hook terminal device may be mounted in the palmar area of the hand with an infant wrist, controlled with a standard Bowden cable system. The cabling may also be split to provide assistance lifting the forearm, where needed. Another orthotic option is to use a tenodesis splint that uses the existing hand as the manipulator with body or external power control. While more cosmetic, it must be remembered that the fingers are usually insensate with limited functional prehension. The tenodesis splint may be a metal Rancho type or a lower profile RIC polymer type. These can be cable controlled as a ratchet or to apply the pinch force. External power using myoelectric or switch control may also be employed to apply pinch, but this adds extra weight, bulk, and expense. Earlier designs used pneumatic or a "McKibben" muscle that contracted and pulled the tenodesis splint closed. [2,3] Later designs used linear actuators or rotary worm gears to provide powered pinch. [2,3] Currently only one device which is commercially available for linear actuation which is relatively light weight, uses myo or switch control, and can provide up to 14 lbs. of pinch. [2]Instances that only partially involve the loss of the distal extensors may use a low profile WHO with MP assist.

Harnessing of the "prosthosis" has usually two goals, suspension and operation of terminal device and/or elbow. This may be done with a chest strap or a figure of 8 design. A chest strap has the advantages of axillary comfort, easier donning, and works well with shoulder saddle designs. The figure of 8 captures more of the unilateral scapular abduction and resists migration. An elastic inverted "Y" strap descends distally to support the lower forearm and position it anterior to the trunk. Additional excursion for cable activation can be captured with a shoulder sling over the apex of the contralateral shoulder. While additional harnessing features may be incorporated, this increases the complexity of donning and the likelihood of rejection.

Overall the orthotic goals must first be met, but functional prosthetic goals are still possible for the motivated patient as a result of the variety of componentry.

Fillauer, Inc. Chattanooga, Tennessee

References:

1) Leffert, R., Lowe, C., and Snowden, J., Orthoses for Brachial Plexus Injuries. Atlas of Orthoses and Assistive Devices, Chapter 20, 3rd ed., Mosby Year Book, St. Louis, 1997, pp. 339-347.
2) Slack, M., and Berbrayer, D., A Myoelectrically Controlled Wrist-Hand Orthosis for Brachial Plexus Injury: A Case Study. Journal of Prosthetics and Orthotics, Vol. 4, Num. 3, 1992, pp. 171-174.
3) Benjuya, N., and Kenney, S., Myoelectric Hand Orthosis. Journal of Prosthetics and Orthotics, Vol. 2, Num. 2, 1990, pp. 149-154.
4) Michael, J., and Nunley, J., Brachial Plexus Injuries: Surgical Advances and Orthotic/Prosthetic Management. Atlas of Limb Prosthetics, Chapter 12A, 2nd ed., Mosby Year Book, St. Louis, 1992, pp. 293-310.
5) Brachial Plexus Palsy Foundation, Royersford, PA, http://membrane.com/bpp/overview.html
6) Erbs Palsy and Shoulder Dystocia Birth Injury Center, http://www.erbs-palsy-birth-injuries.com/
7) Terzis, J., Vekris, M., and Soucacos, P, Brachial Plexus Root Avulsions, World Journal of Surgery, DOI: 10.1007/s00268-001-0058-8, Societe Internationale de Chirurge, 2001.

HCPCS:	Descriptor:
L3675	SHOULDER ORTHOSIS, VEST TYPE ABDUCTION RESTRAINER, CANVAS WEBBING TYPE OR EQUAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
NO	NO	NO	YES	YES

Sample Diagnosis (Not Inclusive)	Glenohumeral dislocations/subluxations, rotator cuff tears, and acromioclavicular separations post surgical or orthopedic injuries and provide shoulder immobilization. It provides abduction control, external rotation control and support for acromioclavicular separations.
Medically Necessary Argument	The device is designed to protect and stabilize the shoulder post-injury and post-operatively. The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for immobilization needed to facilitate healing. Casual application by an inexperienced individual could place the involved shoulder at risk.
References	9, 10, 11

ORTHOTICS AND DEVICES

Shoulder Subluxation After Stroke: A Comparison of Four Supports

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ABSTRACT. Zorowitz RD, Idank D, Ikai T, Hughes MB, Johnston MV. Shoulder subluxation after stroke: a comparison of four supports. Arch Phys Med Rehabil 1995;76:763-71.

• *Objective:* Shoulder subluxation is a well-known sequela of stroke. This study quantitatively compares the reduction of shoulder subluxation using four supports: the single-strap hemisling, the Bobath roll, the Rolyan humeral cuff sling, and the Cavalier support. *Design/Setting:* Anteroposterior shoulder radiographs of 20 consecutive first-time stroke survivors in a freestanding rehabilitation hospital were taken within 6 weeks of stroke onset. Vertical, horizontal, and total asymmetries of glenohumeral subluxation compared with the unaffected shoulders were measured before and after fitting of each support. *Main Outcome Measures:* Group means were compared to find which supports altered subluxation asymmetries and approximated the unaffected shoulder. Individual data were tallied to detect how often each support best reduced subluxation asymmetries. *Results:* The single-strap hemisling eliminated the vertical asymmetry of subluxation over the entire study group, but each support corrected the vertical asymmetry best in some subjects (55%, 20%, 40%, and 5%, respectively). The Bobath roll and the Cavalier support produced lateral displacements of the humeral head of the affected shoulder ($p = 0.005$, 0.004, respectively). The Rolyan humeral cuff sling significantly reduced total subluxation asymmetry ($p = 0.008$), whereas the single-strap hemisling, Bobath roll, and Cavalier support did not alter total asymmetry ($p = 0.091$, 0.283, 0.502, respectively). *Conclusion:* When treating shoulder subluxation, several different types of supports should be evaluated to optimize the function of the affected extremity and the reduction of the shoulder subluxation.

The occurrence of subluxation of the humeral head out of the glenoid fossa after stroke has not been disputed. Reported incidences of shoulder subluxation in stroke survivors vary from 17% to 66%.[1-3] Positioning of the limb in abduction and external rotation helps to discourage tone and contracture while the stroke survivor lies in bed. Use of an armboard or lap tray on the affected side provides support to the limb and may overcorrect the subluxation.[4,5] Treatment of the hemiplegic limb in the upright position, however, remains controversial.

Checklists for prescription of shoulder supports for use by the ambulatory stroke survivor have been proposed.[6] Radiographic measurements have been obtained to quantitate the degree of subluxation in acute, subacute, and chronic stroke survivors.[1,3,5,7-9] These works, however, have not examined all commonly used supports together and have averaged subluxation measures across all patients. This approach may be erroneous because it assumes that overcorrection of subluxation in one patient compensates for undercorrection in another.

The present study was designed to measure the ability of four ambulatory shoulder supports to correct subluxation in stroke survivors who still had potential for spontaneous recovery of upper-extremity movement. The four supports were the single-strap hemisling, the Bobath roll, Rolyan humeral cuff sling, and the Cavalier support. Pilot data have suggested that single-strap hemislings most closely approximate the head of the humerus with the glenoid fossa.[10] This study analyzes both group and individual data. As a result, practical guidelines for application of shoulder supports may be recommended based on the individual stroke survivor, and not just on general conclusions.

METHODS

Twenty subjects admitted to a rehabilitation institute between October 15, 1992, and August 9, 1993, for rehabilitation of first thromboembolic or hemorrhagic strokes were enrolled in this study after informed consent was obtained from each subject. The neuroanatomic location of the stroke was recorded from reports of computed tomography (CT) or magnetic resonance imaging (MRI) from the acute care hospital, and the clinical stroke syndrome was recorded from the physical examination performed at admission by each physiatrist. Data were collected using Part J of the National Institute of Neurological Diseases and Stroke (NINDS) Stroke Data Bank.[11]

Exclusion criteria included time from onset of stroke to enrollment in the study more than 6 weeks, history of prior neurological condition resulting in unilateral or bilateral hemiparesis, presence of clinical stroke syndrome undetected by CT or MRI, and neuroanatomic lesions resulting in bilateral hemiparesis. The presence of a pure unilateral lesion allowed each subject to be used as his own control when

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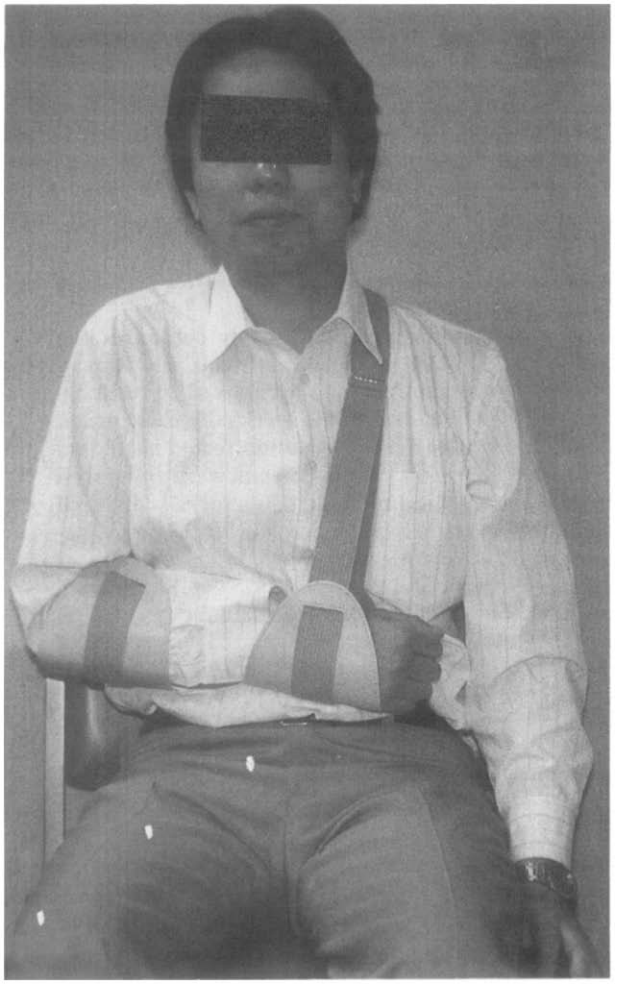

Fig 1—The single-strap hemisling.

the measurements of the affected shoulder unsupported and supported with each support were compared with that of the unaffected shoulder.

Motor recovery of the affected extremity was assessed using the sum of the upper extremity, wrist, and hand scores of the Fugl-Meyer Motor Function Evaluation.[12] The Fugl-Meyer Evaluation is a quantitative application of the Brunnstrom scale of motor recovery[13] based on the description of motor recovery after stroke.[14] An ordinal scale was used to rate various stereotypical movements: 0 for unable to perform, 1 for able to perform partially, and 2 for able to perform completely. It is a reliable method of measuring motor recovery after stroke. The highest possible attainable score was 66.

Application of Shoulder Supports

An occupational therapist applied each shoulder support to each subject in the following order: (1) single-strap hemisling; (2) Rolyan humeral cuff sling; (3) Bobath roll; and (4) Cavalier support. The single-strap hemisling was fitted with one cuff supporting the elbow and a second cuff supporting the forearm, wrist, and hand distally (Fig 1). The strap was fitted on each subject along the unaffected shoulder and across the back so that the line of pull was not across the neck. The resulting position of the shoulder with the single-strap hemisling in place was adduction and internal rotation.

The Bobath roll was fitted to each subject with a foam roll placed in the axilla beneath the proximal humerus (fig 2). Straps were adjusted to provide vertical support of the humerus. The shoulder was maintained in a position of abduction and external rotation.

The Rolyan humeral cuff sling consisted of a figure-eight strap system with an arm cuff sized to fit distally on the humerus of the affected upper extremity (fig 3). The strap and cuff system was designed to allow adjustment of both the vertical and rotational position of the humerus. The therapist fitted the sling after the directions of the manufacturer and adjusted the sling to provide maximum shoulder support on clinical examination. Slight external rotation of the shoulder was obtained when application of the sling was optimized.

The Cavalier shoulder support normally is not used for treatment of shoulder subluxation but was included in this study because it provides bilateral axillary support similar to that of the Bobath roll. It consisted of bilateral straps that positioned along the humeral head and integrated posteriorly with a material brace that rested between the scapulae (fig 4). The straps were adjusted to support the shoulder girdle in external rotation and retraction.

Radiographic Technique

Six anteroposterior radiographs were taken of each subject: (1) unaffected shoulder; (2) affected shoulder, unsupported; (3) affected shoulder, Rolyan humeral cuff sling; (4) affected shoulder, Bobath roll; (5) affected shoulder, single-strap hemisling; and (6) affected shoulder, Cavalier support. A 7-mm lead marker was placed over the distal aspect of the clavicle to correct any variability resulting from magnification of the x-ray. A thyroid shield was placed over the neck of each subject to minimize excessive radiation to the soft tissues of the neck.

Analysis

Radiographs were analyzed on a standard viewing box. Information identifying the radiograph was covered, and the radiographs were analyzed in random order to reduce measurement bias by the analyst. Three reference points were identified, as described by previous investigators[15]: the central point of the glenoid fossa, the central point of the humeral head, and the most inferolateral point of the acromion (fig 5). The central point of the glenoid fossa was defined at the intersection of lines connecting the horizontal and vertical points that produced the greatest width and height of the glenoid fossa, respectively. The central point of the humeral head was defined at the bisection point of the line that measured the greatest distance horizontally across the humeral head. This line was parallel to the horizontal line within the glenoid fossa.

The vertical component of glenohumeral subluxation was determined by measuring the distance between the point on the acromion and a perpendicular horizontal line through the central point of the humeral head. The horizontal component

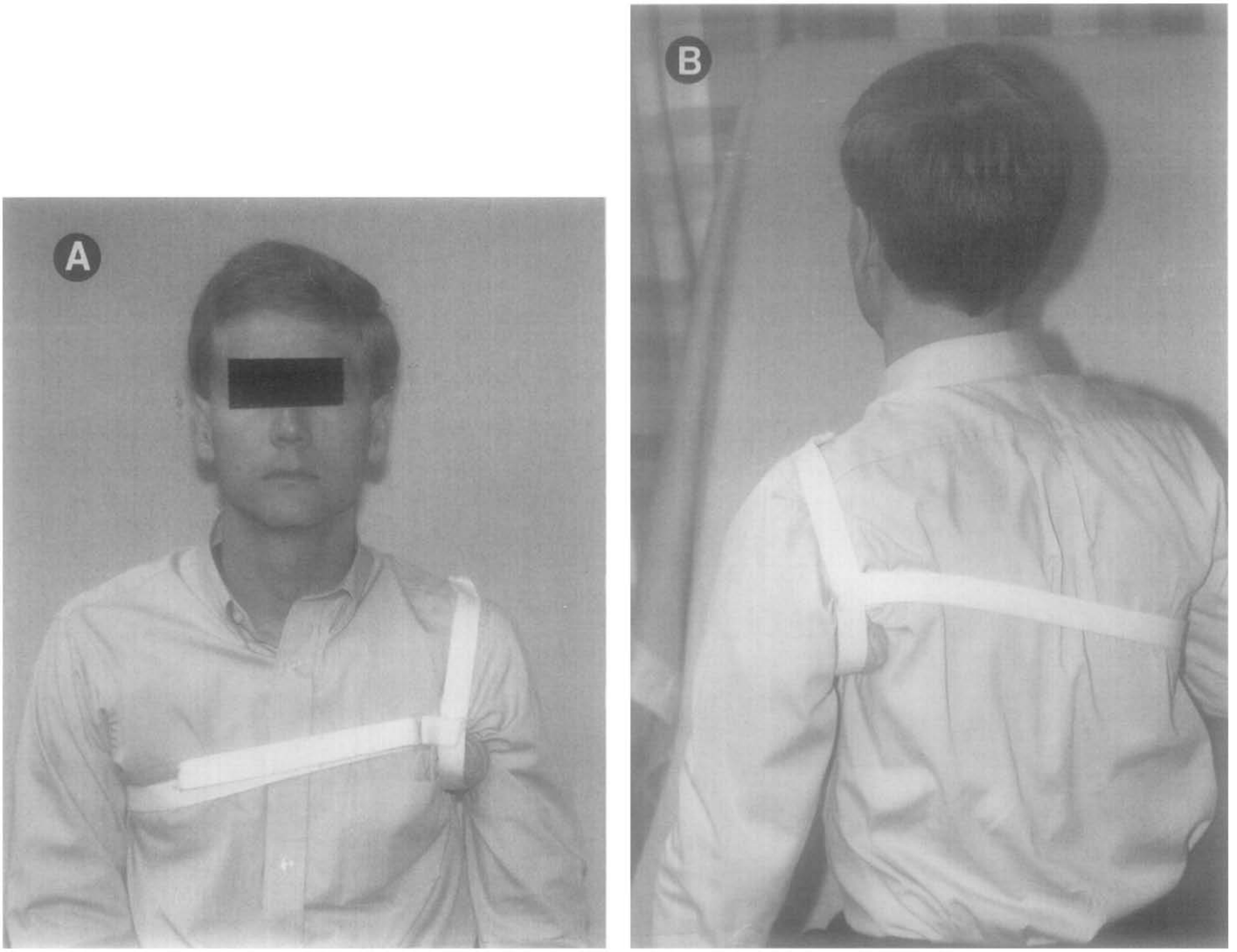

Fig 2—The Bobath roll. (A) Anterior view. (B) Posterior view.

was determined by measuring the distance between the central point of the glenoid fossa and a perpendicular vertical line through the central point of the humeral head.

Asymmetries between the unaffected shoulder and the unsupported affected shoulder were calculated to gauge the degree to which each of the four slings corrected for subluxation. Directional or raw vertical *asymmetry* was calculated by subtracting the vertical displacement of the affected shoulder from the vertical position of the unaffected shoulder. Similarly, raw *horizontal asymmetry* was calculated by subtracting the horizontal displacement of the affected shoulder from the horizontal position of the unaffected shoulder.

Logically, the best single measure of degree of correction should summarize as much of the data on different aspects of error as possible. Vertical and horizontal asymmetry data can be easily summarized by computing total asymmetry along the hypotenuse of the horizontal and vertical asymmetries:

$$\text{Total asymmetry} = \sqrt{[(\text{vertical asymmetry})^2 + (\text{horizontal asymmetry})^2]}$$

Total asymmetry reflects absolute error but not direction of error because squaring yields the same result regardless of whether asymmetry values are positive or negative. Therefore, mean total asymmetry values cannot be calculated from means of raw or absolute vertical and horizontal asymmetry values. Rather, they can be calculated only from individual total asymmetry values.

Group means were analyzed to determine how each support altered subluxation asymmetries and approximated the unaffected shoulder. As the data were not evenly distributed, the 95% confidence intervals for each variable were described instead of standard deviation. A one-sample t test against a test value of 0, which represents complete symmetry, was used to compare the asymmetry measurements using each support with the position of the unaffected shoulder. A paired t test against the asymmetries of the unsupported affected shoulder was used to determine how each support altered subluxation asymmetries. Individual data were analyzed to determine how often each support produced the best fit. The measures of vertical, horizontal, and total asymmetries were listed by individual subjects. The support that provided the least asymmetry for each subject was noted and counted.

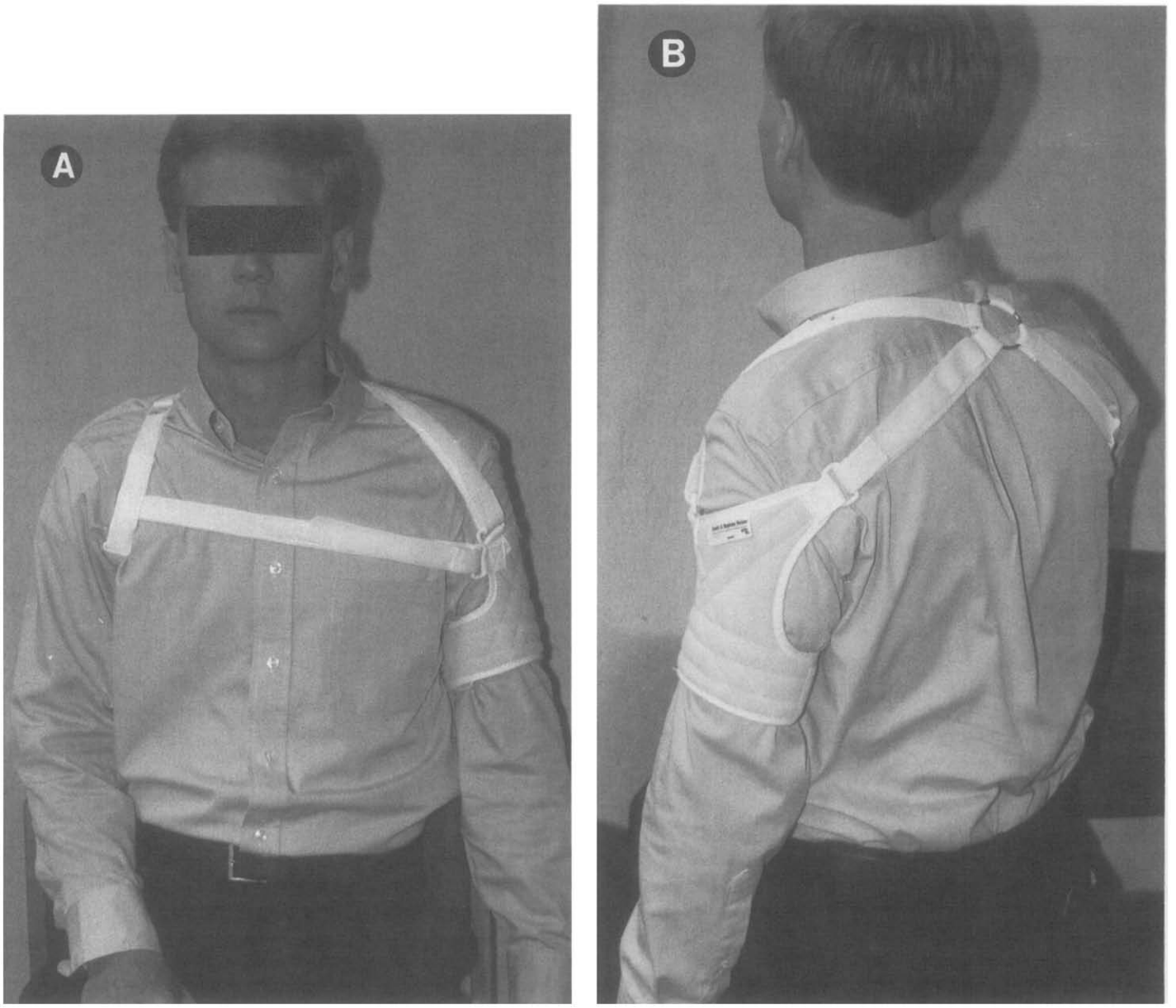

Fig 3—The Rolyan humeral cuff sling. (A) Anterior view. (B) Posterior view.

RESULTS

Two hundred nineteen consecutive patients admitted to the East Orange Facility of the Kessler Institute for Rehabilitation were screened for inclusion into the study. Of these, 26 (12%) met the inclusion criteria for the study. Six of these patients were excluded subsequently when comparison of the radiographs of the unaffected shoulder and unsupported affected shoulder unexpectedly demonstrated no significant subluxation. A total of 20 subjects completed the study.

Table 1 outlines the characteristics of the study population. The mean age of the subjects was 63 years (range 47 to 76). Fourteen (70%) of the 20 subjects were men, and 6 (30%) were women. Thirteen (65%) subjects suffered nonhemorrhagic strokes. Six (30%) subjects had lesions in the left hemisphere, 13 (65%) subjects had lesions in the right hemisphere, and 1 (5%) had a lesion in the brainstem. Eleven (55%) subjects had cortical lesions, whereas 8 (40%) subjects had subcortical lesions.

The average Fugl-Meyer score for the 20 subjects was 8.7 ± 8.4 points. Eight of 20 (40%) subjects were classified in Brunnstrom stage II, 11 (55%) subjects were classified in Brunnstrom stage III, and 1 (5%) subject was classified in Brunnstrom stage IV. Kendall tau correlation coefficients (r_k) did not produce a significant linear correlation between the Fugl-Meyer scores and the vertical asymmetry of subluxation ($r_k = 0.3245$, $p = 0.067$), the horizontal asymmetry of subluxation ($r_k = -0.301$, $p = 0.865$), or the total asymmetry of subluxation ($r_k = 0.2705$, $p = 0.120$).

Table 2 shows the values of vertical asymmetry of the affected shoulder with and without each of the four supports

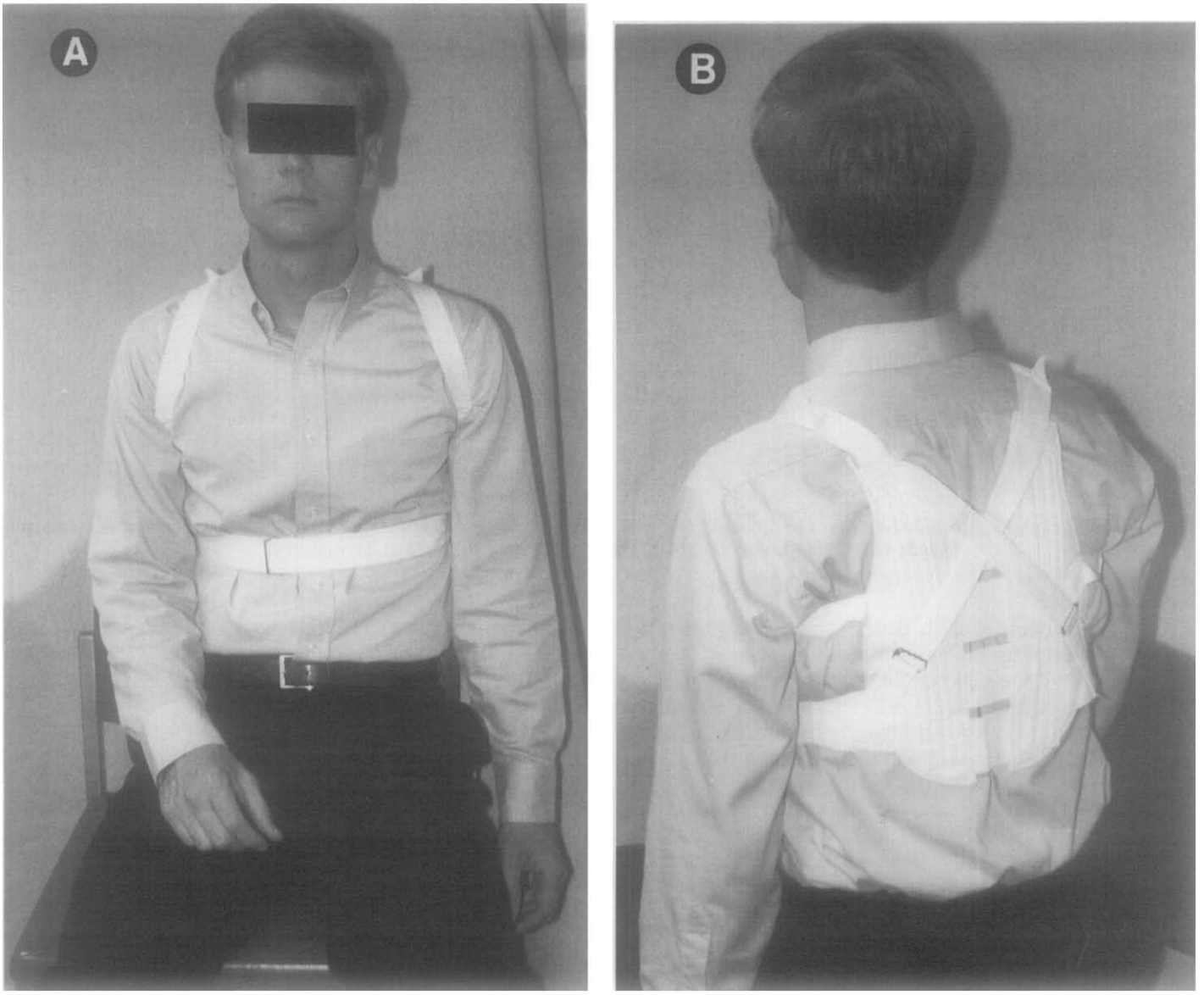

Fig 4—The Cavalier shoulder support. (A) Anterior view. (B) Posterior view.

over the group of 20 subjects. The mean is a negative number if the support undercorrected the subluxation. Tables 2 and 3 describe how each support alters vertical asymmetry with respect to the unsupported affected shoulder and the unaffected shoulder, respectively. The single-strap hemisling corrected the vertical displacement, and the Cavalier support did not significantly alter vertical displacement. The remaining two supports significantly reduced but did not correct vertical displacement.

Table 4 exhibits the horizontal asymmetries of the affected shoulder with and without each of the four supports over the group of 20 subjects. A negative mean indicates lateral displacement of the humeral head. Tables 4 and 5 describe how each support alters horizontal asymmetry with respect to the unsupported affected shoulder and the unaffected shoulder, respectively. On a group basis, there was no significant horizontal asymmetry when no support was applied. Horizontal symmetry was maintained when the single-strap hemisling and the Rolyan humeral cuff sling were used. However, the Bobath roll and the Cavalier support produced a significant lateral displacement of the humeral head of the affected shoulder compared with the unaffected shoulder.

Table 6 displays the total asymmetries of the affected shoulder with and without each of the four supports over the group of 20 subjects. Tables 6 and 7 describe how each support alters total asymmetry with respect to the unsupported affected shoulder and the unaffected shoulder, respectively. The Rolyan humeral cuff sling was the only support that significantly decreased total subluxation asymmetry but did not eliminate it. The remaining three supports did not alter total asymmetry significantly when compared with the unsupported affected shoulder.

Measurements of asymmetries for each subject are listed in tables 8 through 10. The support that reduced the asymmetry most for each subject is highlighted, and the number of individuals for whom each support provided the best correction is

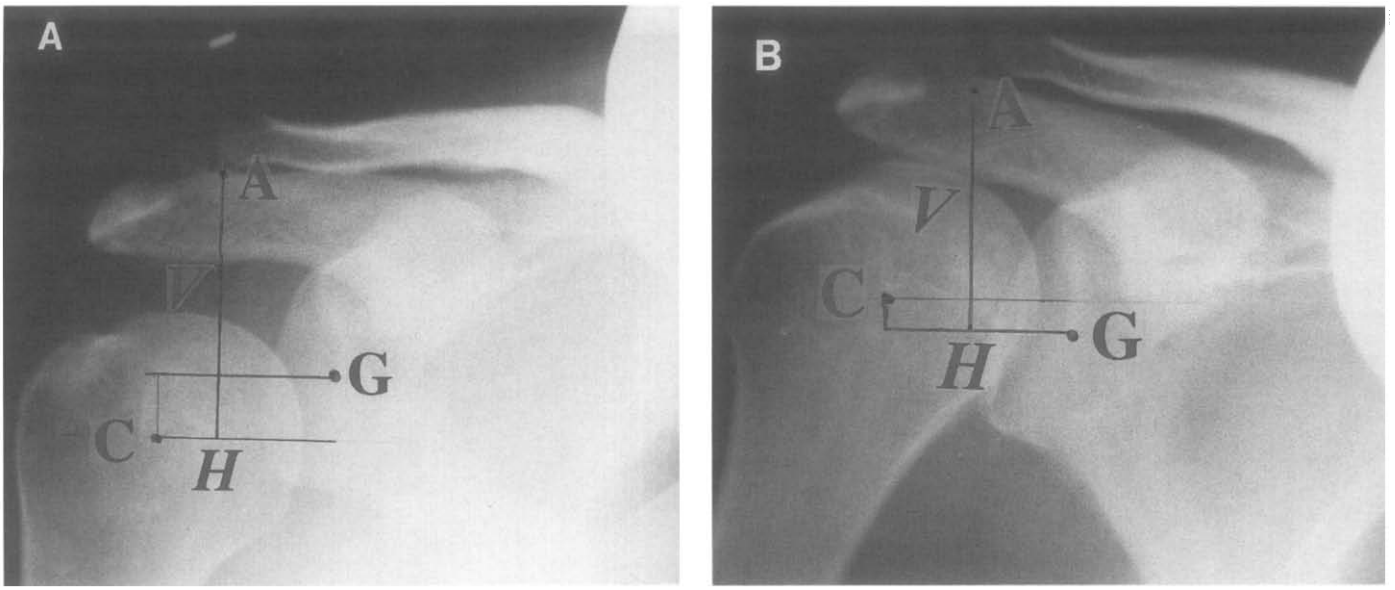

Fig 5—Radiograph of affected shoulder. (A) Unsupported. (B) With single-strap hemisling. A, acromion; C, center of humeral head; G, glenoid fossa; *H*, horizontal asymmetry; *V*, vertical asymmetry.

tallied at the bottom of each table. Table 8 shows that the single-strap hemisling produced a best vertical correction in only 55% (11) of the subjects; the Rolyan humeral cuff sling provided the best correction in 40% (8) of the cases; and the Bobath roll corrected vertical asymmetry best in 20% (4) of the cases. Table 9 illustrates that each support except the Cavalier support produced a best horizontal correction in 25% (5) of the subjects. The Cavalier support provided the best horizontal correction in only 10% (2) of the subjects. Table 10 shows that the Rolyan humeral cuff sling best corrected total asymmetry in 45% (9) of the subjects, the single-strap hemisling provided the best correction of the asymmetry in 40% (8) of the cases, and the Bobath roll corrected total asymmetry best in 20% (4) of the cases. The Cavalier support did not correct total asymmetry best in any subject.

Table 1: Age, Sex, and Type and Site of Lesion of the Study Population

	Age	Sex	Lesion Type	Lesion Site
1.	76	M	Hem	Right thalamus
2.	67	F	Inf	Right frontoparietal
3.	55	M	Hem	Right thalamus
4.	61	M	Inf	Right middle cerebral artery
5.	47	M	Inf	Left temporoparietal
6.	60	M	Inf	Right parietal
7.	83	F	Hem	Right cerebral hemisphere
8.	76	M	Inf	Left temporal
9.	73	F	Inf	Right middle cerebral artery
10.	79	M	Inf	Left frontotemporoparietal
11.	50	M	Hem	Left basal ganglia
12.	66	M	Inf	Midbrain/pons
13.	57	M	Inf	Left middle cerebral artery
14.	63	F	Inf	Right middle cerebral artery
15.	47	M	Hem	Right basal ganglia
16.	75	F	Inf	Right parietal
17.	76	M	Inf	Left basal ganglia
18.	69	F	Inf	Right caudate
19.	42	M	Hem	Right basal ganglia
20.	43	F	Hem	Right cerebral hemisphere

Abbreviations: Inf, Nonhemorrhagic infarct; Hem, Hemorrhagic infract.

DISCUSSION

The use of supports in reducing glenohumeral subluxation in the stroke survivor remains controversial. Some investigators have questioned their use,[2,16-18] whereas others have considered their use contraindicated.[19,20] Researchers have suggested that supports may impair body image.[21] Supports may place the affected extremity in nonfunctional positions that facilitate synergistic patterns and may lead to contracture[19,25] or reflex sympathetic dystrophy.[22] No significant differences in shoulder range of motion between subjects who wear supports and those who do not have been observed.[23] One investigator even believed that it is not necessary to support a painfree shoulder with a support because the support will not prevent or correct a subluxation.[24]

Data from this study indicate that the single-strap hemisling eliminates the vertical asymmetry of subluxed hemiplegic shoulders when group statistics are considered.

Table 2: Vertical Asymmetry (Difference Between Affected and Unaffected Shoulder [cm]) With and Without Supports: One-Value *t* Test, Test Value = 0, Against Unsupported Shoulder

	No Support	Hemisling	Rolyan	Bobath	Cavalier
Mean	−0.99	−0.34	−0.58	−0.62	−0.90
95% CI					
Lower	−1.26	−0.69	−0.95	−0.93	−1.22
Upper	−0.72	0.02	−0.21	−0.32	−0.56
Range					
Lower	−2.30	−1.60	−3.10	−2.20	−2.60
Upper	−0.30	1.20	0.20	0.30	0.10
t value	−7.57	−1.98	−3.31	−4.31	−5.67
2-tail sig	$p < 0.001$	$p = 0.062$	$p = 0.004$	$p < 0.001$	$p < 0.001$

Abbreviations: CI, confidence interval; sig, significance (*p* value).

Table 3: Paired Differences (cm) of Vertical Asymmetry Between Affected Shoulder With Support and Affected Shoulder With No Support: Paired *t* Test

	Hemisling	Rolyan	Bobath	Cavalier
Paired difference	−0.65	−0.40	−0.36	−0.95
95% CI				
Lower	−0.90	−0.59	−0.52	−0.26
Upper	−0.41	0.22	−0.21	−0.07
t value	−5.63	−4.61	−4.95	−1.21
2-tail sig	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p = 0.240$

Abbreviations: CI, confidence interval; sig, significance (*p* value).

Table 5: Paired Differences (cm) of Horizontal Asymmetry Between Affected Shoulder With Support and Affected Shoulder With No Support: Paired *t* Test

	Hemisling	Rolyan	Bobath	Cavalier
Paired difference	−0.08	0.06	0.40	0.37
95% CI				
Lower	−0.29	−0.07	0.22	0.21
Upper	0.12	0.19	0.57	0.53
t value	−0.85	0.96	4.80	4.77
2-tail sig	$p = 0.406$	$p = 0.350$	$p < 0.001$	$p < 0.001$

Abbreviations: CI, confidence interval; sig, significance (*p* value).

However, the results also emphasize that other shoulder supports sometimes may correct asymmetries best. This finding should not be surprising. Many supports designed for reducing shoulder subluxation during ambulation have been described,[25-32] but their effects appear to be variable. In a recent study, the Harris hemisling, which is similar to the single-strap hemisling used in the present study, was found to provide vertical correction better than that of a Bobath roll in 10 hemiplegic subjects.[5] Another study demonstrated radiographic evidence of reduced subluxation when a broad arm sling was applied, but not when a Bobath roll or Hook hemi-harness was used.[4] On the other hand, a third investigator found that only half of the subjects benefited by the use of a standard hemisling or cone sling.[33] A fourth investigator found that the Dennison sling, Dumbbell sling, Harris hemisling, Hook hemi-harness, and Zimmer fashion arm sling all significantly corrected subluxation when correctly applied.[34]

The present study also finds no statistically significant lateral displacement in unsupported subluxed shoulders of stroke survivors. This finding is similar to that of one study that did not report statistical significance of the horizontal measurements between the unaffected and the unsupported and supported affected shoulders.[5] Another group of investigators implied the presence of lateral humeral displacement associated with subluxation when they reported a reduction of lateral displacement of the affected shoulders of 70% of subjects when a standard hemisling was applied.[33] However, the present study supports the findings of researchers who described a creation of horizontal asymmetry when a Bobath roll was applied.[20,26,33] This study also found that the Cavalier support iatrogenically produced horizontal asymmetry of the affected shoulder.

A unique aspect of this study is the use of the measure of total asymmetry of the affected shoulder. Using vertical and horizontal asymmetries, the single-strap hemisling corrected subluxation best because overcorrection in some patients was averaged with undercorrection in others (tables 2 and 4). In contrast, the Rolyan humeral cuff sling was the only support that statistically reduced total asymmetry. The single-strap hemisling did not reduce total asymmetry statistically as well as the Rolyan humeral cuff sling because the values of vertical and horizontal asymmetry were squared and thus became positive. The absolute error produced by the single-strap hemisling was greater than that produced by the Rolyan humeral cuff sling (table 6).

Total asymmetry analyses therefore confirm that the Rolyan humeral cuff sling decreases subluxation on a group basis but suggest that the single-strap hemisling also may be useful in reducing subluxation. During analysis of individual subjects, each support except the Cavalier support provided the best overall total fit in a number of subjects. In future research, the measurement of total asymmetry in three dimensions could be a useful and powerful tool to compare asymmetries of shoulders with inferior and anterior subluxations. Such a calculation would require both anteroposterior and lateral radiographs of the shoulders.

Another interesting observation was that the Fugl-Meyer scores and the vertical asymmetry of subluxation were not statistically correlated. One would expect an association between shoulder subluxation and severity of paralysis. One investigator found that the incidence of subluxation in stroke survivors was 66% in subjects with "complete or severe paralysis," but only 16% in those with "partial paralysis or paresis."[3] This makes sense because functional loss of the

Table 4: Horizontal Asymmetry (Difference Between Affected and Unaffected Shoulder [cm]) With and Without Supports: One-value *t* Test, Test Value = 0, Against Unsupported Shoulder

	No Support	Hemisling	Rolyan	Bobath	Cavalier
Mean	−0.09	0.00	−0.15	−0.49	−0.46
95% CI					
Lower	−0.34	−0.33	−0.43	−0.80	−0.76
Upper	0.16	0.32	−0.13	−0.16	−0.16
Range					
Lower	−1.00	−1.50	−1.70	−1.90	−1.60
Upper	0.60	0.90	0.60	0.30	0.60
t value	−0.76	−0.03	−1.14	−3.16	−3.23
2-tail sig	$p = 0.457$	$p = 0.975$	$p = 0.270$	$p = 0.005$	$p = 0.004$

Abbreviations: CI, confidence interval; sig, significance (*p* value).

Table 6: Total Asymmetry (Difference Between Affected and Unaffected Shoulder [cm]) With and Without Supports: One-value *t* Test, Test Value = 0, Against Unsupported Shoulder

	No Support	Hemisling	Rolyan	Bobath	Cavalier
Mean	1.11	0.93	0.82	1.01	1.16
95% CI					
Lower	0.82	0.68	0.44	0.68	0.82
Upper	1.39	1.17	1.20	1.33	1.51
Range					
Lower	0.30	0.14	0.10	0.14	0.32
Upper	2.51	2.19	3.54	2.91	3.05
t value	8.11	7.98	4.56	6.43	7.05
2-Tail sig	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$

Abbreviations: CI, confidence interval; sig, significance (*p* value).

Table 7: Paired Differences (cm) of Total Asymmetry Between Affected Shoulder With Support and Affected Shoulder With no Support: Paired *t* Test

	Hemisling	Rolyan	Bobath	Cavalier
Paired difference	0.18	0.29	0.10	−0.56
95% CI				
Lower	−0.03	0.09	−0.09	−0.23
Upper	0.40	0.49	0.30	0.12
t value	1.78	2.99	1.11	−0.68
2-tail sig	$p = 0.091$	$p = 0.008$	$p = 0.283$	$p = 0.502$

Abbreviations: CI, confidence interval; sig, significance (*p* value).

supraspinatus and posterior deltoid muscles, which normally support structures across the glenohumeral joint, is associated with inferior glenohumeral subluxation.[35]

An important issue is the relationship between shoulder subluxation and pain. Many authors suggest that shoulder subluxation is a cause of pain.[1,8,30,36-38] Some even advocate that supports may be used to prevent or reduce pain caused by shoulder subluxation, although they have not established any causal relationship between shoulder subluxation and pain.[2,6,16,25] On the other hand, several investigators have found no significant relationship between shoulder subluxation and pain.[39-41] Future research should address whether a causal relationship exists between poststroke shoulder subluxation and shoulder pain.

There is no doubt that appropriately chosen shoulder supports can correct subluxation to varying degrees. However, one should carefully consider whether a support is necessary to treat shoulder subluxation after stroke. If a support is to be used, this study suggests that patients should try several supports appropriate to the motor function of the affected extremity. For example, a patient with a flaccid upper extremity may consider a single-strap hemisling to decrease traction forces while awaiting the development of tone or volitional movement. A patient with some volitional movement may consider a Rolyan humeral cuff sling or Bobath roll to distribute the affected limb's weight to another part of the body. The cognitive status of each stroke survivor should be evaluated to determine whether the patient has unilateral neglect or sensory deficits that place the affected

Table 8: Vertical Asymmetry (Difference Between Affected and Unaffected Shoulder [cm]) During Application of Supports: Best Correction by Subject

	No Support	Bobath	Cavalier	Hemisling	Rolyan
1.	−.90	−.60	−.60	**−.20**	−.40
2.	−.30	**.10**	−.80	1.00	−.20
3.	−1.20	−.90	−.60	**.10**	−.30
4.	−1.50	−.90	−1.20	**−.20**	−.70
5.	−2.30	−2.20	−2.60	**−1.60**	−3.10
6.	−1.40	−1.20	−1.40	**−.90**	−1.50
7.	−.70	**.10**	**.10**	1.20	−.30
8.	−.80	−.50	−.80	**−.40**	−.50
9.	−1.70	−1.20	−2.10	−1.60	**−1.40**
10.	−1.80	−1.60	−1.70	**−1.00**	−1.50
11.	−.40	−.90	−.50	−.30	**−.20**
12.	−.90	−.30	−.50	**.00**	**.00**
13.	−.40	−.60	−.80	−.80	**−.10**
14.	−.60	.30	−.20	**.10**	.20
15.	−.30	−.20	−.30	.50	**.10**
16.	−.60	**−.20**	−.40	−.40	−.30
17.	−.80	**−.20**	−.50	**−.20**	**−.20**
18.	−.30	.30	−.30	**.10**	.20
19.	−1.20	−.70	−.80	−.90	**−.50**
20.	−1.70	−1.10	−1.90	−1.20	**−1.00**
Total best correction: (in bold)		4	1	11	8

Table 9: Horizontal Asymmetry (Difference Between Affected and Unaffected Shoulder [cm]) During Application of Supports: Best Correction by Subject

	No Support	Bobath	Cavalier	Hemisling	Rolyan
1.	.00	−.10	.10	.70	.20
2.	.10	−.10	.60	.10	.40
3.	−.70	−1.50	−1.10	−1.10	**−.50**
4.	.30	**.10**	−.20	.30	.50
5.	−1.00	−1.90	−1.60	−1.50	−1.70
6.	.60	**.20**	**.20**	.40	.50
7.	−.30	−.80	−.60	**.00**	−.30
8.	.20	−1.40	−1.00	−.60	−.50
9.	.60	**.30**	.50	.90	.60
10.	−.90	−1.40	−1.30	**−.40**	−1.00
11.	−.90	−1.00	−1.20	**−.60**	−.80
12.	.40	.30	−.20	.30	**.10**
13.	.10	−.10	−.20	**.00**	.10
14.	.00	−.40	−.40	.10	.20
15.	−.50	−.90	−.90	**.10**	−.60
16.	−.10	**.00**	−.20	.90	**.00**
17.	.60	.20	**.10**	.80	.30
18.	.00	−.40	−.10	.40	.00
19.	.40	**.10**	−.40	.30	**.10**
20.	−.70	−.90	−1.30	−1.20	**−.60**
Total best correction: (in bold)		5	2	5	5

Table 10: Total Asymmetry (Difference Between Affected and Unaffected Shoulder [cm]) During Application of Supports: Best Correction by Subject

	No Support	Bobath	Cavalier	Hemisling	Rolyan
1.	.90	.61	.61	.73	**.45**
2.	.32	**.14**	1.00	1.00	.45
3.	1.39	1.75	1.25	1.10	**.58**
4.	1.53	.91	1.22	**.36**	.86
5.	2.51	2.91	3.05	**2.19**	3.54
6.	1.52	1.22	1.41	**.98**	1.58
7.	0.76	.81	.61	1.20	**.42**
8.	0.82	1.49	1.28	**.72**	**.71**
9.	1.80	**1.24**	2.16	1.84	1.52
10.	2.01	2.13	2.14	**1.08**	1.80
11.	0.98	1.35	1.30	**.67**	.82
12.	0.98	.42	.54	.30	**.10**
13.	0.41	.61	.82	.80	**.14**
14.	0.60	.50	.45	**.14**	.28
15.	0.58	.92	.95	**.51**	.61
16.	0.61	**.20**	.45	.98	.30
17.	1.00	**.28**	.51	.82	.36
18.	0.30	.50	.32	.41	**.20**
19.	1.26	.71	.89	.95	**.51**
20.	1.84	1.42	2.30	1.70	**1.17**
Total best correction: (in bold)		4	0	8	9

extremity at risk of trauma. Supports should minimize vertical and horizontal asymmetries of the affected shoulder. Supports should be easy to don and doff in order for patients to perform range of motion exercises that potentially prevent muscle contractures and other complications. The stroke survivor and his family members should be taught and be able to demonstrate proper use of the support. Future studies need to address the benefits and complications of long-term use of shoulder supports in order to determine whether they have a useful and necessary purpose in stroke rehabilitation.

In conclusion, this study has demonstrated that any of the supports tested, except the Cavalier support, may correct the vertical asymmetry of glenohumeral subluxation but that only the single-strap hemisling corrects vertical asymmetry to any significant degree. Lateral displacement of the humeral head does not appear to result from the subluxation itself but may be caused by application of supports such as the Bobath roll or Cavalier support. Total asymmetry is significantly reduced only with use of the Rolyan humeral cuff sling. Although supports are used commonly during the rehabilitation of stroke survivors, there is no absolute evidence that supports prevent or reduce long-term shoulder subluxation when spontaneous recovery of motor function occurs, or that a support will prevent supposed complications of shoulder subluxation. Without proper training in the use of a support, stroke survivors may face potential complications such as pain or contracture. More research is needed to critically evaluate the presumed benefits of supports in stroke rehabilitation so that the role of supports in correcting shoulder subluxation may be better clarified.

References

1. Fitzgerald-Finch O, Gibson I. Subluxation of the shoulder in hemiplegia. Age Ageing 1975;4:16-8.
2. Smith RG, Cruikshank JG, Dunbar S, Akhtar AJ. Malalignment of the shoulder after stroke. Br Med J (Clin Res) 1982;284:1224-6.
3. Najenson T, Pikielny SS. Malalignment of the glenohumeral joint following hemiplegia. Ann Phys Med 1965;8:96-9.
4. Moodie N, Brisbin J, Margan A. Subluxation of the glenohumeral joint in hemiplegia: evaluation of supportive devices. Physiother Can 1986;38:151-7.
5. Brooke MM, de Lateur BJ, Diana-Rigby GC, Questad KA. Shoulder subluxation in hemiplegia: effects of three different supports. Arch Phys Med Rehabil 1991;72:582-6.
6. Smith RO, Okamoto GA. Checklist for the prescription of slings for the hemiplegic patient. Am J Occup Ther 1981;35:91-5.
7. Carpenter GI, Millard PH. Shoulder subluxation in elderly patients. J Am Ger Soc 1982;30:441-6.
8. Najenson T, Yacubovich E, Pikielm SS. Rotator cuff injury in shoulder joints of hemiplegic patients. Scand J Rehabil Med 1971;3:131-7.
9. Prevost R, Arsenault AB, Dutil E, Drouin G. Shoulder subluxation in hemiplegia: a radiologic correlational study. Arch Phys Med Rehabil 1987;68:782-5.
10. Idank DM, Zorowitz RD, Ikai T, Hughes MB, Johnston MV. Shoulder subluxation after stroke: a pilot study comparing four slings. Arch Phys Med Rehabil 1993;74:1235.
11. Kunitz SC, Gross CR, Heyman A, et al. The pilot stroke data bank: definition, design, and data. Stroke 1984;15:740-5.
12. Fugl-Meyer AR, Jääskö L, Leyman I, Olsson S, Steglind S. The post-stroke hemiplegic patient. 1. A method for evaluation of physical performance. Scand J Rehabil Med 1975;7:13-31.
13. Brunnstrom S. Movement therapy in hemiplegia: a neurophysiological approach. Philadelphia: Harper and Row, 1970.
14. Twitchell TE. The restoration of motor function following hemiplegia in man. Brain 1951;74:443-80.
15. Prevost R, Arsenault A, Dotil E, Drouin G. Rotation of the scapula and shoulder subluxation in hemiplegia. Arch Phys Med Rehabil 1987;68:786-90.
16. Varghese G. Shoulder complications in hemiplegia. J Kansas Med Soc 1981;82:451-3.
17. Voss DE. Should patients with hemiplegia wear a sling? Phys Ther 1969;49:1030.
18. Tepperman PS, Greysen D, Hilbert L, Jimenez J, Williams H. Reflex sympathetic dystrophy in hemiplegia. Arch Phys Med Rehabil 1984;65:442-7.
19. Bobath B. Adult hemiplegia: evaluation and treatment. London: Heinemann, 1978.
20. Irwin-Carruthers S, Runnals MJ. Painful shoulder in hemiplegia - prevention and treatment. South African J Physiother 1980;36:18-23.
21. Miller J. Shoulder pain from subluxation in hemiplegia [letter]. Br Med J 1975;4:345.
22. Flatt A. Shoulder-hand syndrome. Lancet 1974;i:1107-8.
23. Hurd MM, Farrell KH, Waylonis GW. Shoulder sling for hemiplegia: friend or foe? Arch Phys Med Rehabil 1974;55:519-22.
24. Friedland F. Physical Therapy. In: Licht S, editor. Stroke and its rehabilitation. Baltimore: Williams and Wilkins, 1975.
25. Brudny J. New orthosis for treatment of hemiplegic shoulder subluxation. Orthot Prosthet 1985;57:1377-80.
26. Sodring KM. Upper extremity orthosis for stroke patients. Int J Rehabil Res 1980;3:33-8.
27. McCollough NC. Orthotic management in adult hemiplegia. Clin Orthop 1978;131:38-46.
28. Paquin JM, Albert A, Fajai G. Appliances for the hemiplegic patient: prescription and utilization. Prosthet Int 1968;3:22-6.
29. Leddy M. Sling for hemiplegic patients. Br J Occup Ther 1981;44:158-60.
30. Rajaram Y, Holtz M. Shoulder forearm support for the subluxed shoulder. Arch Phys Med Rehabil 1985;66:191-2.
31. Claus SW, Godfrey KJ. A new distal support sling for the hemiplegic patient. Am J Occup Ther 1985;39:536-7.
32. Collins DW. Some attempts to aid surgeons and orthotists in the management of hemiplegics and tetraplegics: upper extremities. Prosthet Int 1968;3:32-6.
33. Kieran OP, Willingham A, Schwarz S, Firooznia H. Radiographic assessment of efficacy of slings in glenohumeral subluxation in hemiplegia. Arch Phys Med Rehabil 1984;65:653.
34. Patterson JR, Zabransky R, Grabois M, Ferro P. Evaluation of the effectiveness of sling orthoses for the correction of glenohumeral subluxation in the hemiplegic. Arch Phys Med Rehabil 1984;65:635.
35. Chaco J, Wolf E. Subluxation of the glenohumeral joint in hemiplegia. Am J Phys Med 1971;50:139-43.
36. van Ouwenaller C, Laplace PM, Chantraine A. Painful shoulder in hemiplegia. Arch Phys Med Rehabil 1986;67:23-6.
37. Tobis JS. Posthemiplegic shoulder pain. NY State J Med 1957;57:1377-80.
38. Moskowitz H, Goodman CR, Smith E, Balthazar E, Mellins HZ. Hemiplegic shoulder. NY State J Med 1969;69:548-50.
39. Van Langenberghe HV, Hogan BM. Degree of pain and grade of subluxation in the painful hemiplegic shoulder. Scand J Rehabil Med 1988;20:161-6.
40. Arsenault AB, Silodeau M, Dutil E, Riley E. Clinical significance of the V-shaped space in the subluxed shoulder of hemiplegics. Stroke 1991;22:867-71.
41. Bohannon RW, Andrews AW. Shoulder subluxation and pain in stroke patients. Am J Occup Ther 1990;44:507-9.

Shoulder Support for Children with Subluxation: A Case Study

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ABSTRACT

Children with brachial plexus injury from birth may present with varying degrees of muscle imbalance, as well as a subluxation of the glenohumeral joint. Shoulder subluxation occurs when the muscles of the shoulder girdle are weak or flaccid. The deltoid and the rotator cuff musculatures are unable to position the humerus appropriately to the glenoid fossa, and there is concurrent stretching of the glenohumeral joint capsule, ligaments, and nonactive muscles. Treatment for reducing the subluxation and positioning the arm typically has involved use of an appropriate sling or humeral cuff support. There are commercially available slings for children but no child-size shoulder support. The purpose of this case study was to design a custom-fitted shoulder support for children that reduces subluxation and maintains alignment through extended periods of the day. A validated radiographic method was used to quantify the subluxation before application of the shoulder support, immediately after applying the shoulder support, and after 3 hours of wear. A motion tracking system objectively quantified active shoulder and elbow movements in the presence and absence of the shoulder support. This case study suggests that the custom-designed child support significantly reduced the subluxation, maintained alignment through extended periods of the day, and maintained the active range in elbow flexion. (*J Prosthet Orthot.* 2005;17:74–79.)

KEY INDEXING TERMS: brachial plexus injuries, pediatric shoulder support, shoulder subluxation

The main causes of damage to the brachial plexus at birth are traction, contusion, and compression during delivery.[1,2] The residual effects on the arm depend on the number of nerve roots involved and severity of the injury. Babies who have had incomplete or poor function from 6 to 18 months after birth and a greater degree of dysfunction are classified as having moderate to severe damage to the nerves of the plexus.[2–4] After the age of 2 years, some degree of residual motor dysfunction may appear. The most common deformity may include all or some of the following: weakness of external rotation, weakness of overhead shoulder movement, scapula instability, subluxation of the humerus, overactivity of the muscles of internal rotation, and weakness of the distal muscles of the forearm and hand.[4]

Children with brachial plexus injury need to receive optimal therapeutic intervention, with the focus on maximizing function and preventing the development of secondary problems such as shoulder subluxation and tightness. Inferior shoulder subluxation occurs when the head of the humerus slides down or inferior in the glenoid fossa and the scapula is in a downwardly rotated position. The secondary problems can interfere with functional use of the affected upper extremity and the child's ability to incorporate the arm to perform self-care. Often shoulder supports are placed on the child without a thorough evaluation. An inappropriate shoulder support can contribute to poor alignment of the humerus into the glenoid fossa, which may cause additional impingement and pain.

Children with birth-related brachial plexus often present with shoulder problems.[4,5] For implementing an appropriate treatment course, a thorough evaluation is critical. The therapist must assess the alignment of the scapula on the rib cage, the alignment and mobility of the glenohumeral joint, passive and active range of motion, and muscle strength. Subluxation often occurs as a result of the loss of balanced muscle firing around the glenohumeral joint and stretching of the ligamentous support structure.[6] The glenohumeral joint must be realigned and is essential for active shoulder movements.

For the adult stroke population there are numerous studies documenting the efficacy in reducing shoulder subluxation with different types of supports for the hemiplegic shoulder.[7–9] Zorowitz et al.[10] described a comparison study using four different types of shoulder support to optimize function and reduce shoulder subluxation for ambulatory adults with stroke. A humeral cuff sling, a figure-8 strap system with a humeral arm cuff to fit on the affected upper extremity, was found to significantly reduce the vertical asymmetry of the

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glenohumeral subluxation. The strap and cuff system allows adjustments to the vertical alignment and rotational position of the humerus.[10]

Brooke et al.[11] measured the effects of three different types of shoulder support for shoulder subluxation in adults with hemiplegia: 1) a hemisling device that positions the involved arm in shoulder adduction, elbow flexion, and internal rotation; 2) a figure-8 support that is applied around the uninvolved shoulder (The rationale for this sling is to avoid internal rotation and the flexed arm position of the conventional sling. However, it did not support the humerus into the glenoid fossa); 3) the arm trough, a device that is attached to the arm of the wheelchair (Shoulder subluxation is corrected by adjusting the height of the armrest or position of the trough). The results of that study supported the use of the hemisling. However, the author reported that other factors need to be considered if using the hemisling. There may be risks for contracture secondary to the position of the arm into internal rotation and elbow flexion.[11]

Children with shoulder girdle weakness may present with potential pain, over-stretching of the joint capsule and ligament, and poor motor control. Limited data exist to support the effectiveness of bracing for children with shoulder subluxation. The primary objective of this case study was to evaluate a custom-fitted, child-size shoulder support that reduced subluxation and maintained alignment through extended periods of the day.

METHODS

The shoulder support is a brace to be worn directly on the skin to provide maximum support, contour, and comfort. It is made from a Velcro-compatible fabric, which is a knitted unbroken loop backed with a perforated neoprene. The material is custom fit over the involved shoulder with the top of the brace formed at the highest point of the shoulder. The shoulder support consists of a humeral cuff, chest straps, and back strap that supports the scapula and assists with the alignment of the humerus. To stabilize the chest and involved scapula, a contoured chest piece with straps is applied that goes under the axilla of the uninvolved shoulder, across the chest, and is pulled through a D-ring. The straps and cuff system are designed to allow adjustments of both the vertical and rotational position of the humerus (Figures 1–4).

The humeral cuff positions and supports the humerus circumferentially with two straps to pull the humerus in a vertical direction back into alignment with the glenoid fossa. A posterior vertical strap assists with pulling the arm up toward the shoulder with the first Velcro tab applied near the axilla and the second Velcro tab on the high point of the shoulder to assist in stabilizing the humerus (Figure 4). The strap is continued down over the chest on a diagonal toward the opposite underarm. An anterior vertical strap also assists with pulling the arm up toward the shoulder with the first Velcro tab applied near the axilla and the second Velcro tab on the high point of the shoulder. The anterior vertical strap continues down toward the back and is pulled on a diagonal to the opposite underarm.

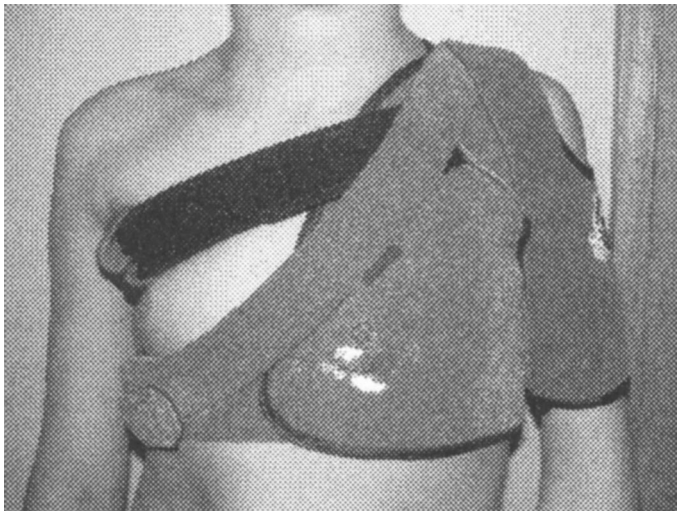

Figure 1. Front view of shoulder support.

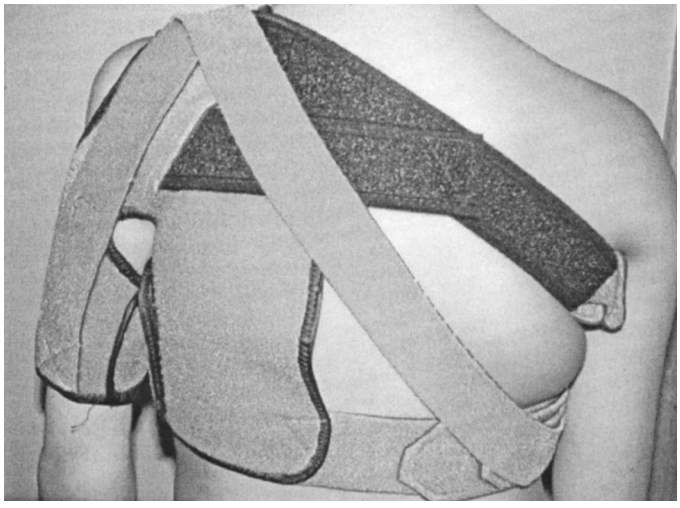

Figure 2. Back view of shoulder support.

The subject's ability to tolerate the brace and alignment must be considered in addition to building a gradual wearing schedule.

SUBJECT

The subject was a 9-year-old boy with left congenital brachial plexus from traction applied to his head and neck during the delivery process, resulting in the avulsion of his 4th, 5th, 6th, and 7th cervical nerves. He presented in the outpatient clinic for occupational therapy evaluation with significant wasting and atrophy of the left shoulder girdle. In addition, his left humerus appeared subluxed about 1 inch, sliding down vertically from the glenoid fossa (Figure 5). The medial border of the scapula was winging with the inferior border tipped. His left shoulder was in a forward position with the left scapula slightly elevated in a downward rotated alignment. The humeral head appeared below the inferior lip of the glenoid

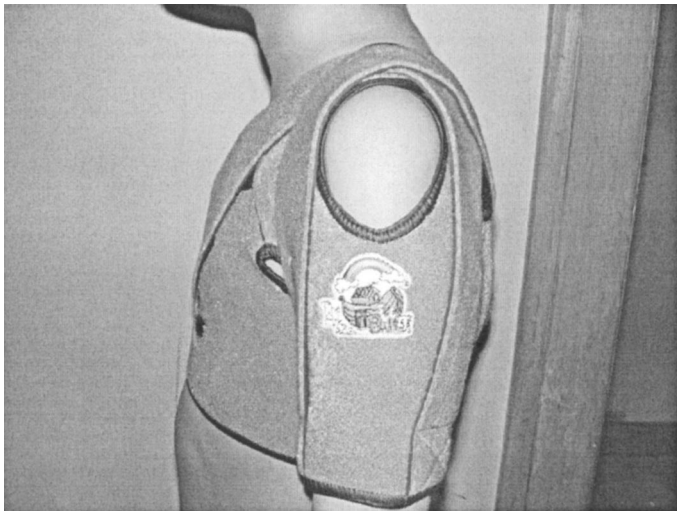

Figure 3. Side view of shoulder support.

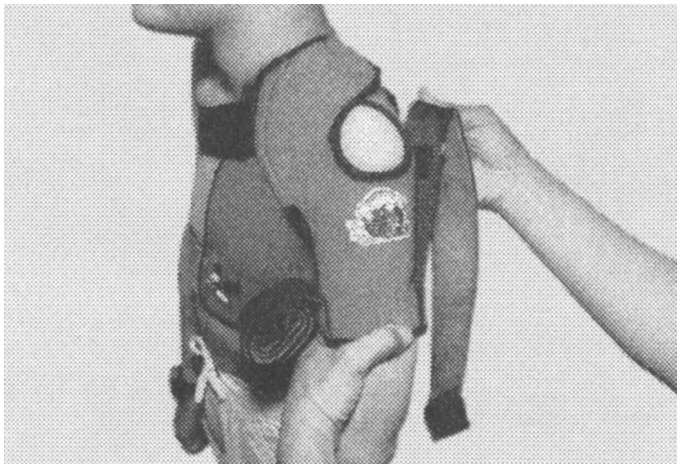

Figure 4. A posterior strap on the humeral cuff is pulled vertically and attached with Velcro to position the humerus.

fossa in an inferior subluxation through clinical palpation. Passive range of motion of his left upper extremity was within functional limits.

He presented with limited scapula and humeral mobility. The strength of the serratus anterior (using a manual muscle test rating of 1 = trace, 2 = poor, 3 = fair, 4 = good, and 5 = normal) was 1/5, upper trapezius 4/5, middle and lower trapezius 1/5, and rhomboids 4/5. The shoulder muscle strength presented with the anterior, middle, and posterior deltoid at 1/5, external rotators 1/5, internal rotator 2/5, and pectoralis major and minor 2/5.

He was able to abduct his arm to 30°, although he also compensated by hyperextending his lower back when attempting to raise his arm. Weak elbow movements were also exhibited with the strength of his elbow flexors and extensors at 2/5. His forearm strength of the supinator and pronators was 4/5, whereas distal control of his wrist and hand also scored a strong 4/5. He demonstrated functional use of his left hand but limited control proximally at the shoulder.

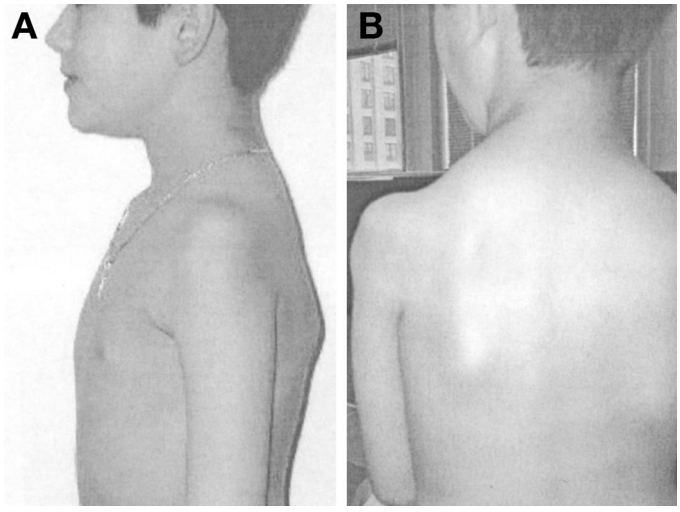

Figure 5. Side view and back view of left inferior subluxation of the humerus.

The subject was very active in sports. He participated in soccer during the time of his assessment and stated that he let his left arm hang while running on the field. He reported pain inconsistently around the shoulder area. A shoulder support of some type was discussed that would maintain the integrity of his ligaments around the shoulder girdle and align the humerus into the glenoid fossa. The shoulder brace was especially important for the subject during contact sports, as well as for maintaining alignment during the day.

RADIOGRAPHIC TECHNIQUE

Three radiographs were taken of both shoulders to quantify and compare the left subluxed shoulder with the unaffected right shoulder:

1. Affected shoulder unsupported (Figure 6).
2. Shoulder support brace applied (Figure 7).
3. After 3 hours of wearing the shoulder support (Figure 8).

The degree of shoulder subluxation found on the radiographs was determined by measuring the vertical and horizontal distances of the glenohumeral axis, as described by Brooke et al.[11]

The central point of the glenoid fossa was determined by measuring the maximum width and height of the fossa (Figure 9). The point at which these two lines intersect is the central point of this fossa (A). The central point of the humeral head was determined by measuring the greatest width of the humerus and then locating its central point (B). Once these points were defined, the vertical distance was measured by the distance from the inferior part of the acromioclavicular joint and the central point of the humerus (V). The horizontal distance was determined by measuring the distance between the central points (H).

FLOCK OF BIRDS

The subject was evaluated using the Flock of Birds electromagnetic motion capture system (Ascension Technologies,

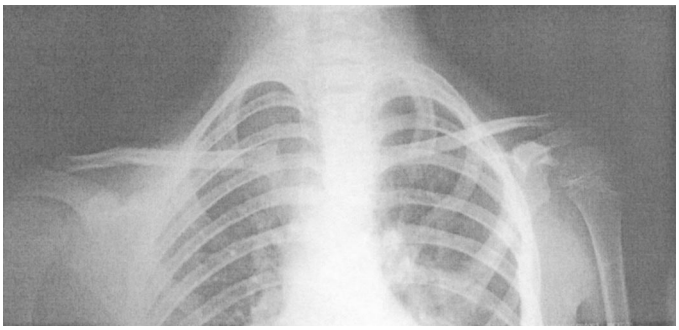

Figure 6. Radiograph of right shoulder and left affected shoulder unsupported.

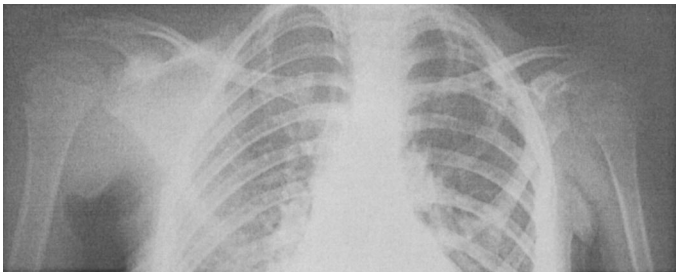

Figure 7. Radiograph of right shoulder and left shoulder in a shoulder support brace.

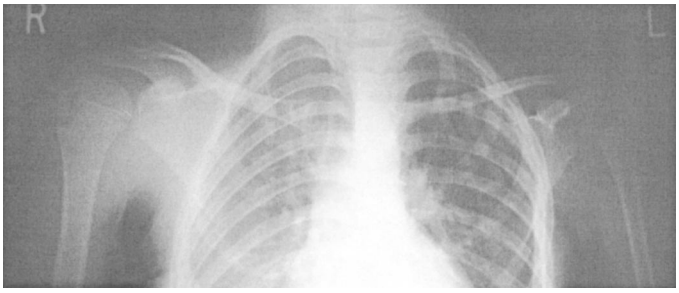

Figure 8. Radiograph of right shoulder and left shoulder in a shoulder support brace after 3 hours of wear.

Inc., Burlington, VT) to objectively measure active movement. The Flock of Birds captured whole limb movements during active shoulder flexion and abduction, and elbow flexion. Markers placed at the subject's thoracic spine (T1 level), humerus, and forearm recorded movement of each segment, and their relative motions revealed joint excursions at the shoulder and elbow. The subject was asked to flex and abduct his humerus with his elbow in an extended position and to flex his elbow. Each of these movements was performed without the shoulder brace and then repeated with the shoulder brace.

RESULTS

Radiographic measurements of the vertical and horizontal alignment of the humerus were taken of the uninvolved and involved left shoulders (Table 1). Initially the patient attempted to lift his involved humeral head actively back into position (25 mm vertical and 32 mm horizontal). It is possible that the clavicle was elevated by the pull of the upper trapezius (4/5 muscle strength) and rhomboids (4/5 muscle strength). The external rotator cuff, middle and lower trapezius, serratus anterior, and the deltoid musculatures were extremely weak, with a strength level of poor to trace. The radiograph demonstrated a superior subluxation of the glenohumeral joint when the humerus moved above the fossa. The patient presented with active motor components of shoulder elevation, minimal shoulder abduction, and internal rotation. This patient typically activated strongly into elevation, causing a superior subluxation position (Figure 6). With the brace in place, the humeral head was positioned back down into the glenoid fossa and both clavicles appeared symmetrical (Figures 7 and 8).

The shoulder brace gave good correction of subluxation as measured in millimeters of the horizontal and vertical distances of the glenohumeral alignment (Table 1). The optimal correction in this case occurred at the vertical component of the glenohumeral alignment. The subluxation was nearly corrected after the immediate application of the brace. Three hours later, the shoulder continued to demonstrate good vertical alignment of the glenohumeral joint.

The motion capture results demonstrated no significant differences in shoulder range of motion between the braced and unbraced conditions. The subject presented poor to trace muscle grade of his deltoid muscles and scapular musculature, which would not have changed with the donning of the shoulder support. However, the brace did not restrict his active range of motion with elbow flexion (Figure 10).

DISCUSSION

The radiographic results support the use of the shoulder brace to minimize subluxation. The glenohumeral joint must be assessed and realigned before the application of a shoulder support. Because the weight of the dangling arm gives a continuous traction to the cord, relief of the pull can increase circulation, which can reduce the potential for pain.

In addition, over-lengthening of the biceps occurs with poor positioning of the humeral head. The biceps traverse the humeral head, such that subluxation will progressively pull the muscle and decrease the ability over the muscle to contract in optimal length tension. Although the biceps strength is dependent on the innervation, length of the muscle affects the muscle strength. The glenohumeral joint integrity is essential before active shoulder movements can be practiced. Family members or caregivers must be instructed in and be able to demonstrate proper use of the support. The shoulder support must also be accepted by the child.

Careful and thorough evaluation is essential for applying the shoulder support. The goal is to provide optimal musculoskeletal alignment to stabilize the shoulder girdle, and maximize motor return and functional performance. The involved shoulder must feel firmly supported to the child.

Strengthening active elbow range should be encouraged

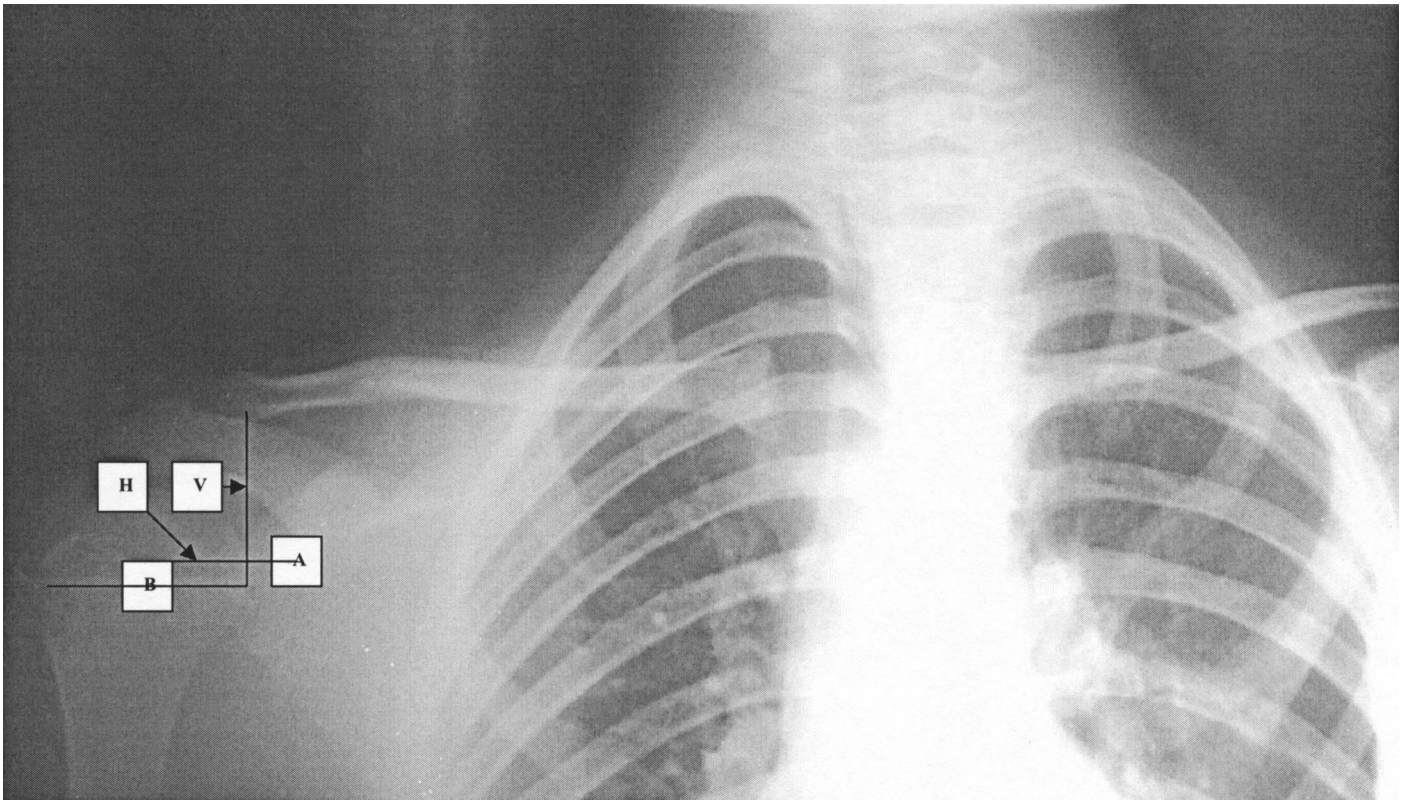

Figure 9. Vertical, horizontal, and total asymmetries of glenohumeral subluxation were compared with the unaffected side.

Table 1. Radiographic measurements (millimeters of the horizontal and vertical distances of glenohumeral alignment) of the uninvolved and involved shoulders

	Right uninvolved		Left involved	
	Vertical (mm)	Horizontal (mm)	Vertical (mm)	Horizontal (mm)
Without brace	39	31	25	32
With brace immediately applied	37	31	36	28
With brace 3 hours after application	36	32	31	32

while the humerus and scapula are stabilized by the brace. The elbow joint is an integral part of the upper extremity kinetic chain. The instability around the shoulder area and over-stretching of the tendons that insert into glenoid fossa and coracoid process may lead to substitution patterns and elbow overuse in a poor position.[12,13] Major extensors and flexors of the elbow, and the triceps and biceps brachii, originate on the scapula and insert on the ulna and radius, respectively. In the presence of these biarticular muscles, pathological conditions at one joint, in this case the shoulder, affect mechanics at the other. Correction of the shoulder alignment and stability provided by the brace may reduce the biomechanical stress at the elbow during use of the arm and help prevent musculotendinous overload at both the shoulder and elbow. The shoulder support brace can potentially provide the stability and alignment in the shoulder area and provide better stabilization for distal control.

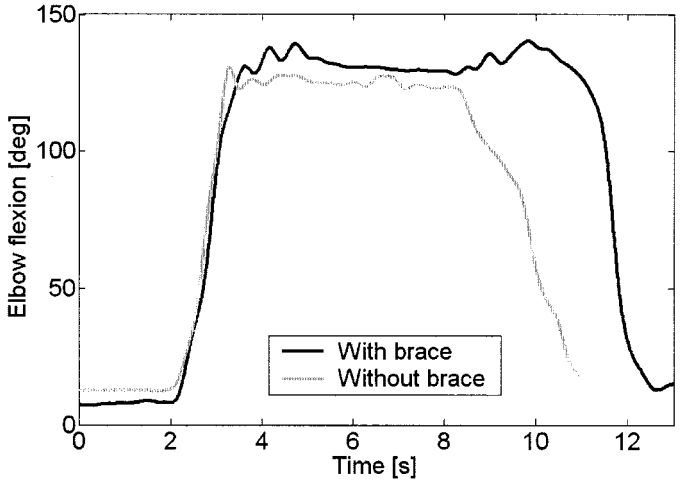

Figure 10. Elbow flexion with and without the shoulder support brace.

SUMMARY

This case study evaluated the efficacy of supporting the subluxed shoulder with a custom-fitted child's size shoulder support. There are no available shoulder braces for children with subluxation except for the sling support. Radiographic methods were used before application of the shoulder support, immediately after applying the shoulder support, and after 3 hours of wear. This case study suggests that the custom-designed child shoulder support significantly reduced the subluxation and maintained alignment through extended periods of the day. The stability at the shoulder area demonstrated potential for providing improved active control of distal movements at the elbow through an ongoing active exercise program.

This case study suggests, for an active child, the shoulder brace effectively reduced subluxation and maintained current active range of motion for distal control of the arm. There is no absolute evidence that supports reduced long-term shoulder subluxation. More research is needed to critically evaluate the benefits of supports with shoulder subluxation in children for assisting with developing a protocol for correcting shoulder subluxation.

REFERENCES

1. Hogan L. OT with obstetric brachial plexus injuries. *Adv Occup Ther* September 1995;19–20.
2. Eng G, Koch B, Smokvina MD. Brachial plexus palsy in neonates and children. *Arch Phys Med Rehabil* 1978;59:458–464.
3. Sundholm LK, Eliasson AC, Forssberg H. Obstetric brachial plexus injuries: assessment protocol and functional outcome at age 5 years. *Dev Med Child Neurol* 1998;40:4–11.
4. Wickstrom J. Birth injuries of the brachial plexus, treatment of defects in the shoulder. *Clin Orthop Rel Res* 1962;23:187–196.
5. Shepherd RB. Brachial plexus injury. In: Campbell S, ed. *Pediatric Neurologic Physical Therapy*. New York: Churchill Livingstone; 1984:141–168.
6. Ryerson S, Levit K. Glenohumeral joint subluxation in CNS dysfunction. *NDTA Newsletter* 1988;115–117.
7. Morin L, Bravo G. Strapping the hemiplegic shoulder: a radiographic evaluation of the efficacy to reduce subluxation. *Physiother Can* 1997;49(2):103–108.
8. Moodie N, Brisbin J, Margan A. Subluxation of the glenohumeral joint in hemiplegia: evaluation of supportive devices. *Physiother Can* 1986;38:151–157.
9. Byrne DP, Ridgeway EM. Considering the whole body in treatment of the hemiplegic upper extremity. *Top Stroke Rehabil* 1998;4(4):14–34.
10. Zorowitz RD, Idank D, Ikai T, et al. Shoulder subluxation after stroke: a comparison of four supports. *Phys Med Rehabil* 1995; 76(8):763–771.
11. Brooke MM, de Lateur BJ, Diana-Rigby GC, Questad KA. Shoulder subluxation in hemiplegia: effects of three different supports. *Arch Phys Med Rehabil* 1991;72:582–585.
12. Kibler WB, Press JM. Rehabilitation of the elbow. In: Lee PA, ed. *Functional Rehabilitation of Sports and Musculoskeletal Injuries*. Gaithersburg, MD: Aspen Publications; 1998:178–181.
13. Dilorenzo CE, Parkes JC, Chmelar RD. The importance of shoulder and cervical dysfunction in the etiology and treatment of athletic elbow injuries. *J Orthop Sports Phys Ther* 1990;11: 402–409.

Overview of Brachial Plexus Management

Gerald Stark, BSME, CP, FAAOP

Management of the Brachial Plexus Injury or BPI is one area where the device created is intended to satisfy both orthotic and prosthetic goals, blurring the lines between support of the limb and functional need. Treatment by the orthotist and prosthetist often differ, but requires a blending of the different philosophies and componentry developed independently in each respective field. The primary goals of a device is ordered in most to least significance: 1) Prevent deformity, 2) Correct deformity, 3) Fix position to obtain maximum function. [1] The main deformity is shoulder subluxation due to muscular flaccidity at the shoulder. Added goals are to treat edema, maintain bimanuality, and ease pain caused by traction.1 These functional goals are influenced by the unilateral/ bilateral involvement, gadget tolerance, donning/ doffing, and wear time. [1] While rejection rate for upper extremity prostheses can be as high as 50 %, the acceptance rate for a brachial plexus orthosis has been estimated as high as 70% after one year of use. [4]

Brachial plexus may be divided into closed or open trauma to nerve branches at the shoulder. In children, 90% of brachial plexus injury is a closed Erb's Palsy which results from birth injury. Injury of the lower brachial plexus is referred to as Kumpke's palsy. This affects nearly 5,000 children per year with an estimate of one to two per 1,000 births. [6] Of those, one in ten require some form of treatment and often involve malpractice litigation. [6] In adults, brachial plexus injury is often the result of traction on the nerve roots C5-C6 as the head is distracted from the shoulder. 4 Lower trauma to nerve roots C8-T1 occur as the arm is brought over the head. [4] These injuries follow Narakus' "law of seven seventies": 70% of traumatic BPI are due to motor vehicle accidents, 70% involve bicycles or motorcycles, 70% have multiple injuries, 70% have subclavicular nerve lesion, 70% have one nerve root avulsed, 70% have lower root (C7, C8, T1 or C8, T1) avulsed, 70% with lower root avulsed experience persistent pain. [4] Other causes for traumatic BPI can be a penetrating stab wound, gunshot, or other open trauma which involves the nerve roots (which may heal faster because there is distinct borders of trauma rather than distraction or tearing). Most patients with traumatic BPI are males, 15-25 years of age. [4]

The first concern with BPI is shoulder subluxation due to muscular flaccidity. As the humeral head subluxes distally it places increasing traction since the nerve roots are held by the clavicle and scaline muscles. [4] Second is the functional positioning of the limb and preservation of extremity function. After WWII this was accomplished surgically with shoulder fusion, elbow bone lock, and finger tenodesis. [4] In the 1960's shoulder fusion in slight abduction and flexion combined with transhumeral amputation with "good" to "fair" functional results. [4] Today surgical management of nerve root avulsions focuses on early, aggressive microsurgical reconstruction of the brachial plexus using nerve donors, grafts, and free vascularized and neurotized muscles. [7] This often results in significant return especially in young patients. Amputation results only when these microsurgical techniques have failed. [7] Surgically the injury is divided into preganglionic or postganglionic. Tendon transfers, pectoralis transfer, and latissimus dorsi transfers cannot be used with C5-C6 avulsions since these muscles are not functional. Transfer of the triceps to biceps is possible only when there is some elbow flexion existing. The nerve tissue for preganglionic injury is not reconstructable and can benefit from an intercostals motor nerve transfer at the 4 rib in which the nerve is routed subcutaneously to the musculocutaneous nerve if 6-12 months post injury. If after 12 months post injury, a gracilis transfer is recommended in which the (Continued from page 7) entire biceps is excised and replaced with the gracilis muscle with the obtuator nerve, artery, and vein. The motor nerves of the 3 rd , 4 th , and 5 th ribs then innervate the gracilis. [4] Postganglionic has shown some recovery up to 3 months after which nerve grafting for the upper trunk is recommended after patient has plateaued. Nerve grafting of the lower trunk presents with mixed results and may require a tendon transfer later. [4] Often stabilization of the humerus in the anesthetic upper limb cannot be achieved due to the weight of the arm, so shoulder fusion is recommended for many patients. [1,4]The recommended position for the shoulder fusion is approximately 20 degree abduction, 30 degree flexion, and 40 degree of internal rotation. [1]

Orthotic/prosthetic management often follows an understanding of the functional levels. C5-C6 presents with a complete loss of shoulder and elbow control. Some wrist extension using finger extensors and extensor carpi ulnaris are still available. [1,4] Thumb and index finger sensation in impaired. C5-C7 also adds radial palsy, increased hand sensory loss, and loss of wrist, hand, and finger extension. [1,4] C7- C8 shows good shoulder and elbow function, but finger flexor weakness, extensors, and intrinsics of the hand. Surgical intervention is fairly successful at this level. Patients do not usually have myosites below the elbow because forearm innervation is lost. [1,4] C8-T1 has lost finger flexors and hand intrinsics, but has good hand sensation except for the 4 th and 5 th finger. This level has the greatest orthotic success. Complete plexus injury has the least amount of success since the arm is completely flail and insensate. Pain is also often present due to nerve traction. [4] Often amputation is recommended for the best functional outcome although not often pursued. Orthotic benefits at this level are

limited to: 1) Protection of the limb, 2) Support to minimize pain, 3) Edema prevention. [1] The following table is presented as a functional guide, but injuries are usually case dependent especially when incomplete. [1]

Photo 1

Level	Motor Deficit	Sensory Loss	Functional Need
C5-C6	Shoulder Abduction	Lateral Arm	Shoulder Support
†	Shoulder Flexion	1st Digit	Prevent Shoulder Subluxation
†	Elbow Flexion	2nd Digit	Elbow Flexion
†	Wrist Extension	†	†
†	†	†	†
C5,C6, C7	Shoulder Abduction	Lateral Arm	†
†	Shoulder Flexion	1st Digit	Shoulder Support
†	Elbow Flexion	2nd Digit	Prevent Shoulder Subluxation
†	Elbow Extension Weakness	3rd Digit	Elbow Flexion
†	Wrist Extension	†	Wrist Support
†	Finger Extension	†	Finger Extension
†	Thumb Extension Weakness	†	1st Extension
†	†	†	†
C8,T1	Wrist Flexors	4th Digit	Wrist Stabilization
†(rare)	Finger Flexors	5th Digit	Finger Flexion
†	Thumb Flexors	Medial Forearm	Some Finger Extension
†	Finger Extensors	†	Intrinsics of Hand
†	Thumb Extensors	†	†
†	†	†	†
C5-T1	Entire Arm	Total Forearm	Shoulder Support
†	May include Scapular Motion	Lateral Arm	Prevent Shoulder Subluxation
†	†	Entire Hand	Protect Limb
†	†	†	Edema Control
†	†	†	Nominal Function
†	†	†	†

Orthotically the first goal is to prevent the subluxation of the shoulder so the weight of the arm must be supported is often supported with the use of a shoulder saddle and an inverted "Y" strap to support the lower forearm also referred to as a hemisling. This is made of padded polyethylene or can be constructed of 2" straps, Spenco Æ , or leather. There is no device as of yet to provide the active shoulder motion although the Rancho Los Amigos Orthosis does aid in flexion/extension and rotation with straps if shoulder movements are poor to trace. [1] A shoulder cap may be used for additional axial support and cable installation, but increases skin coverage and overall bulk. If additional support is required a "gunslinger" or pelvic hemi-girdle variation may be used to support the arm inferiorly. The mechanism is attached to a lower LSO support or to a wheelchair and the positioning joints are mounted inferiorly to provide translational movement.

Since the shoulder cannot be used to achieve positional control, elbow joints are available where most of the terminal positioning can be achieved. These range from bilateral friction joints, spring loaded locking joints, and unilateral ratchet joints. Where polymer systems are used, a simple overlap joint can be employed. Bilateral flail arm hinges are available that provide a spring counterbalance laterally and a reciprocating lock medially. Ratchet joints lock the arm when it is manually positioned and unlock it when the arm is flexed completely similar to a lawn chair joint. Instances where transhumeral amputation has been chosen, externally powered electric elbows with corresponding terminal devices can be utilized. Some contend transradial amputation would be a benefit even if the elbow is non-functioning and the skin over the residuum is insensate, because proprioception may be still be present to aid in arm positioning. 4 Where the BPI arm is left intact, humeral and forearm cuffs support the

arm passively with elastic Velcro closures. A fairly cosmetic lightweight orthosis from the Netherlands uses a medially mounted ratchet elbow in a unilateral construction with four small cuffs that wrap from the medial on the humeral and forearm section. A modular system from England referred to as the Stanmore Orthosis incorporates shoulder, locking elbow, and terminal device function with cable control with a shoulder cap and unilateral, medial construction.

Distally the main goal is to protect the limb and hold it anteriorly. If functional prehension is desired, a smaller 9P hook terminal device may be mounted in the palmar area of the hand with an infant wrist, controlled with a standard Bowden cable system. The cabling may also be split to provide assistance lifting the forearm, where needed. Another orthotic option is to use a tenodesis splint that uses the existing hand as the manipulator with body or external power control. While more cosmetic, it must be remembered that the fingers are usually insensate with limited functional prehension. The tenodesis splint may be a metal Rancho type or a lower profile RIC polymer type. These can be cable controlled as a ratchet or to apply the pinch force. External power using myoelectric or switch control may also be employed to apply pinch, but this adds extra weight, bulk, and expense. Earlier designs used pneumatic or a "McKibben" muscle that contracted and pulled the tenodesis splint closed. [2,3] Later designs used linear actuators or rotary worm gears to provide powered pinch. [2,3] Currently only one device which is commercially available for linear actuation which is relatively light weight, uses myo or switch control, and can provide up to 14 lbs. of pinch. [2]Instances that only partially involve the loss of the distal extensors may use a low profile WHO with MP assist.

Harnessing of the "prosthosis" has usually two goals, suspension and operation of terminal device and/or elbow. This may be done with a chest strap or a figure of 8 design. A chest strap has the advantages of axillary comfort, easier donning, and works well with shoulder saddle designs. The figure of 8 captures more of the unilateral scapular abduction and resists migration. An elastic inverted "Y" strap descends distally to support the lower forearm and position it anterior to the trunk. Additional excursion for cable activation can be captured with a shoulder sling over the apex of the contralateral shoulder. While additional harnessing features may be incorporated, this increases the complexity of donning and the likelihood of rejection.

Overall the orthotic goals must first be met, but functional prosthetic goals are still possible for the motivated patient as a result of the variety of componentry.

Fillauer, Inc. Chattanooga, Tennessee

References:

1) Leffert, R., Lowe, C., and Snowden, J., Orthoses for Brachial Plexus Injuries. Atlas of Orthoses and Assistive Devices, Chapter 20, 3rd ed., Mosby Year Book, St. Louis, 1997, pp. 339-347.
2) Slack, M., and Berbrayer, D., A Myoelectrically Controlled Wrist-Hand Orthosis for Brachial Plexus Injury: A Case Study. Journal of Prosthetics and Orthotics, Vol. 4, Num. 3, 1992, pp. 171-174.
3) Benjuya, N., and Kenney, S., Myoelectric Hand Orthosis. Journal of Prosthetics and Orthotics, Vol. 2, Num. 2, 1990, pp. 149-154.
4) Michael, J., and Nunley, J., Brachial Plexus Injuries: Surgical Advances and Orthotic/Prosthetic Management. Atlas of Limb Prosthetics, Chapter 12A, 2nd ed., Mosby Year Book, St. Louis, 1992, pp. 293-310.
5) Brachial Plexus Palsy Foundation, Royersford, PA, http://membrane.com/bpp/overview.html
6) Erbs Palsy and Shoulder Dystocia Birth Injury Center, http://www.erbs-palsy-birth-injuries.com/
7) Terzis, J., Vekris, M., and Soucacos, P, Brachial Plexus Root Avulsions, World Journal of Surgery, DOI: 10.1007/s00268-001-0058-8, Societe Internationale de Chirurge, 2001.

HCPCS:	Descriptor:
L3677	SHOULDER ORTHOSIS, SHOULDER JOINT DESIGN, WITHOUT JOINTS, MAY INCLUDE SOFT INTERFACE, STRAPS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	NO	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Shoulder subluxation, A-C Joint subluxation, Post-surgical
Medically Necessary Argument	The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for immobilization needed to facilitate healing. Casual application by an inexperienced individual could place the involved shoulder at risk. Requires appropriate application and fitting and trimming of plastic material to customize fit and achieve desired level of motion restriction.
References	

HCPCS:	Descriptor:
L3710	ELBOW ORTHOSIS, ELASTIC WITH METAL JOINTS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	NO	NO	YES

Sample Diagnosis (Not Inclusive)	Tendinitis, bursitis, and arthritis to providing elbow stability for mild to moderate medial/lateral and hyperextension injuries, arthrogryposis, contracture, self-injury, fusion, arthritis, sprain/ strain
Medically Necessary Argument	The elbow orthosis described by this code offers adjustable elbow joint components that are too complex for patient self-adjustment and would require the presence of a qualified individual to properly determine both the appropriate range of motion settings and the amount of contouring required to apply corrective forces or stabilization of the elbow. There is a dramatic range of orthopedic diagnoses of patients who would be candidates for this orthosis. Because of the complexity of the orthosis and the vast array of clinical applications this should not be considered for OTS. The elbow orthosis is made of a combination of elastic, neoprene or similar materials with associated metal stays or hinges that are located medially and laterally and positioned over the elbow joint to control motion or to stabilize the soft tissue and boney anatomy that surround the elbow. This device provides medial and lateral stabilization and restricts unwanted motion through circumferential support and compression and immobilization. The metal joints require contouring and bending that is specific to the anatomy and must accommodate anatomical angles and deformities as well as not contact boney prominences. Inappropriate fitting of the device presents a risk to the patient in achieving functional outcomes and could result in poor healing, wounds, or further deformities that are negative outcomes that could result in further medical interventions.
References	12, 13, 14, 15, 16

THE JOURNAL OF BONE & JOINT SURGERY (B)

The effectiveness of turnbuckle splinting for elbow contractures

J. J. Gelinas, K. J. Faber, S. D. Patterson, G. J. W. King

From the University of Western Ontario, Canada

We have treated 22 patients with an elbow contracture using a static progressive turnbuckle splint for a mean of 4.5 ± 1.8 months. All had failed to improve with supervised physiotherapy and splinting. The mean range of flexion before splintage was from 32 ± 10° to 108 ± 19° and afterwards from 26 ± 10° (p = 0.02) to 127 ± 12° (p = 0.0001). A total of 11 patients gained a 'functional arc of movement,' defined as at least 30° to 130°. In eight patients movement improved with turnbuckle splinting, but the functional arc was not achieved. Six of these were satisfied and did not wish to proceed with surgical treatment and two had release of the elbow contracture. In three patients movement did not improve with the use of the turnbuckle splint and one subsequently had surgical treatment.

Our findings have shown that turnbuckle splinting is a safe and effective treatment which should be considered in patients whose established elbow contractures have failed to respond to conventional physiotherapy.

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Contracture of the elbow is a common complication after trauma or surgery to this joint. The soft tissues surrounding the elbow, including the capsule and collateral ligaments, lose their ability to be stretched, resulting in stiffness of the joint. While early mobilisation and splinting are usually successful in preventing post-traumatic stiffness, the treatment of established contracture may involve both conservative and operative regimes.

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In many cases physiotherapy, both at home and in the clinic, together with splinting, is the first line of treatment for all such contractures. Patients are prescribed static flexion and extension splints to maintain their end range of movement when not exercising. Other forms of static progressive and dynamic splinting have been reported to be beneficial in the treatment of established elbow contractures.[1-5] Manipulation of the elbow under anaesthesia and serial casting may also be useful for resistant contractures.[6,7] The turnbuckle splint is a static progressive method which may be useful in the treatment of an established elbow contracture. It is applied and adjusted incrementally by the patient to cause progressive stretch at the elbow in either flexion or extension. The efficacy of turnbuckle splinting for the treatment of elbow contractures has received little attention.[1,2]

We have assessed the effectiveness of custom-moulded turnbuckle splints in patients with soft-tissue contractures of the elbow which had not responded to standard physiotherapy and static splinting.

Patients and Methods

We have reviewed 22 patients (15 women and 7 men) treated between 1992 and 1995. We excluded those with articular incongruity or heterotopic ossification. Their range of movement at the elbow was less than the functional arc of 30° to 130°, as defined by Morrey et al,[8] despite receiving intensive supervised standardised physiotherapy for at least two months. Their mean age was 39 years (15 to 70). They were placed in a turnbuckle splint after having standard non-operative treatment for a mean of four months (2 to 7). The mean period from the time of the original injury or from surgery was four months (2 to 7). Two patients had isolated postsurgical contractures, five had isolated post-traumatic contractures, and 15 developed their contractures after having open reduction and internal fixation of a fracture, or following release of a surgical contracture after trauma (Table I). Five injuries were work-related. Eleven patients used the turnbuckle splint to improve both flexion and extension, two used the splint primarily to improve elbow extension and nine to improve flexion (Table II). The range of movement was measured by the treating surgeon using a standard goniometer before

Table I. Details of the 22 patients who were treated using a turnbuckle splint

Case	Age (yr)	Gender	Dominance	Injured arm	Injury	Surgery preturnbuckle	Injured at work
1	18	F	Right	Left	T-intercondylar fracture	ORIF*	No
2	45	M	Left	Left	Post-traumatic arthritis	Contracture release	No
3	39	F	Right	Right	Capitellum fracture	ORIF	No
4	41	M	Left	Right	Capitellum fracture	ORIF	Yes
5	48	F	Left	Left	Fracture-dislocation elbow	Contracture release	No
6	15	M	Left	Right	Medial epicondyle fracture	None	No
7	47	M	Right	Right	Post-traumatic arthritis	Contracture release	No
8	30	F	Right	Left	Radial head fracture	ORIF	No
9	15	F	Right	Left	Lateral condyle fracture	None	No
10	45	F	Right	Right	Olecranon fracture	ORIF	No
11	58	F	Right	Right	Distal humeral fracture	ORIF	No
12	31	F	Right	Left	Radial head fracture	None	Yes
13	56	M	Right	Right	Olecranon fracture	ORIF	No
14	48	M	Right	Right	Capitellum fracture	ORIF	No
15	33	F	Right	Right	Radial head fracture	ORIF	No
16	40	F	Right	Left	Capitellum fracture	None	No
17	33	M	Left	Left	Fracture-dislocation elbow	ORIF/contracture release	Yes
18	33	F	Right	Left	Radial head fracture	Contracture release	Yes
19	38	F	Right	Left	Radial neck fracture	ORIF	No
20	60	F	Right	Right	Fracture-dislocation elbow	None	No
21	37	F	Right	Right	Radial head fracture	ORIF	Yes
22	70	F	Right	Right	Capitellum fracture	Contracture release	No

* open reduction and internal fixation

Table II. Results (mean; degrees) in the 22 patients who were treated using a turnbuckle splint

	Presplint			Postsplint			Change in			Follow-up		
Case	Flexion	Flexion contracture	Flexion arc	Flexion	Flexion contracture	Flexion arc	Flexion	Flexion contracture	Flexion arc	Flexion	Flexion contracture	Flexion arc
1	125	40	85	135	25	110	10	15	25	145	43	102
2	125	35	90	130	35	95	5	0	5	120	50	70
3*	100	30	70	105	40	65	5	-10	-5	133	22	111
4*	95	40	55	125	35	90	35	5	35	110	24	86
5	115	30	85	130	30	100	15	0	15	135	35	100
6	115	35	80	140	30	110	25	5	30	130	30	100
7	120	40	80	130	28	102	10	12	22	125	35	90
8	80	30	50	118	34	84	38	-4	34	130	10	120
9	145	35	110	140	15	125	-5	20	15	140	-5	145
10	90	18	72	145	10	135	55	8	63	145	10	135
11	80	45	35	115	45	70	35	0	35	N/A	N/A	N/A
12	150	55	95	140	20	120	-10	35	25	150	0	150
13	100	30	70	130	25	105	30	5	35	135	18	117
14	110	35	75	120	35	85	10	0	10	125	40	85
15	100	25	75	105	10	95	5	15	20	105	15	90
16	115	15	100	130	5	125	15	1 0	25	130	7	123
17	125	35	90	130	25	105	5	10	15	N/A	N/A	N/A
18	95	10	85	113	30	83	18	-20	-2	110	20	90
19*	90	20	70	120	30	90	30	-10	20	N/A	N/A	N/A
20	90	36	54	126	32	94	36	4	40	130	10	120
21	110	35	75	145	28	117	35	7	42	150	22	128
22	107	35	72	120	30	90	13	5	18	N/A	N/A	N/A

*cases 3, 4, and 19 had release of a surgical contracture after use of the turnbuckle splint

and at the end of turnbuckle splinting.[9] We treated the patients by a custom-moulded orthosis (Truppe Orthotics and Prosthetics, Lambeth, Ontario) designed with an adjustable turnbuckle, so that the same splint could be used for flexion and extension (Fig. 1). The splints could be modified as needed, to improve the fit.

The patients wore the splint for 20 hours per day directed to their maximal contracture. It was worn at night in the position requiring the greatest improvement. At breakfast, lunch, dinner, and before bed, the splint was removed for one hour for periods of active movement. Otherwise, it was worn in alternating positions of flexion and extension. The turnbuckle on the splint was tightened by the patient to the point of stretch, but not pain. As load-relaxation of the soft tissues occurred, it was gradually tightened further by the patient during the period of wear. Turnbuckle splinting was carried out as a home programme without the assistance of supplemental physiotherapy. All patients were followed for at least six months after use of the splint had been discontinued.

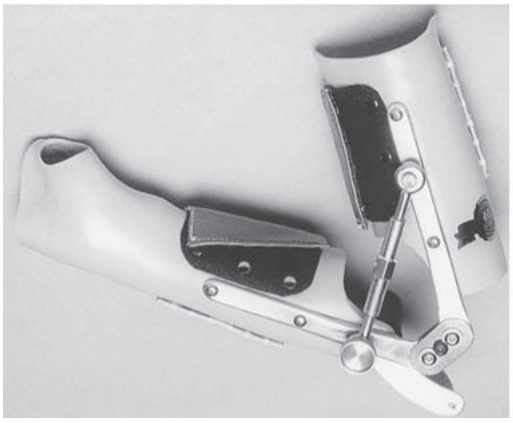

Fig. 1a

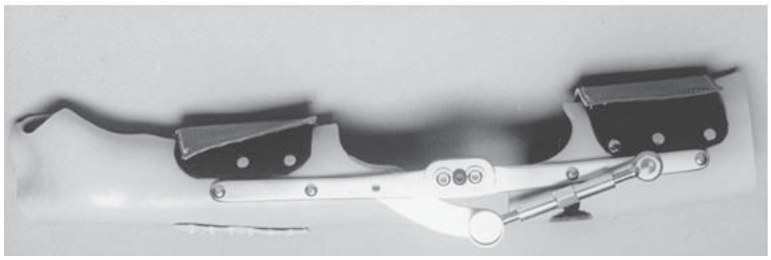

Fig. 1b

The custom-moulded turnbuckle splint. Figure 1a – Using a wrench, the patient adjusts the splint to provide gentle elbow flexion. Figure 1b – The turnbuckle splint with the arm in extension. The attachment site of the bolt is changed to allow controlled passive stretching of the elbow in extension.

We reviewed 18 of the 22 patients (82%) between six and 37 months after use of the turnbuckle splint. One patient could not return for health reasons, one who was one of three who required surgical release of the contracture, was unwilling to return for follow-up and two were not contactable. Patients were examined by an independent observer who was not involved in their care. They completed a questionnaire designed to evaluate subjective satisfaction with the splint and to estimate the duration of time during which it was worn per day. A visual analogue scale was completed summarising the overall satisfaction of each patient.

The change in flexion, flexion contracture, and the total arc of flexion achieved with the turnbuckle splint was compared using a paired Student *t*-test. Univariate linear regression was used to analyse the effects of age, magnitude of contracture and time from injury to application of the splint on the final outcome.

Results

The patients wore their splint for a mean of 4.5 ± 1.8 months. The mean range of flexion before splintage was from 32 ± 10° to 108 ± 19°. After splinting the flexion contracture decreased to a mean of 26 ± 10° ($p = 0.02$) and flexion increased to a mean of 127 ± 12° ($p < 0.0001$). There was a mean gain in flexion of 20 ± 15° and a decrease in the flexion contracture of 5 ± 11°. Before splintage the total arc of elbow flexion was 76 ± 17° and this improved to 100 ± 18°. A total of 11 patients gained a functional arc of movement;[4] eight patients improved but did not achieve this range. Six of these patients were satisfied and did not wish to proceed with surgical treatment; two had a release of their elbow contracture. Three patients showed no improvement with the turnbuckle splint and one of these had a surgical release (Table II).

Neither the age of the patient nor the time between injury and use of the splint had any effect on outcome. There was no correlation between the magnitude of the contracture and the gain in the arc of movement.

Of the 18 patients who returned for an independent follow-up, two had lost more than 10° of movement of the elbow after discontinuing the splint. These patients had post-traumatic arthritis; one had shown no improvement with the turnbuckle and another had improved slightly but had then regressed. Three patients made further gains in their arc of movement after discontinuing splinting.

The mean rating of patient satisfaction on the visual analogue scale was 7.3 ± 1.3, with a score of ten representing very satisfied.

Many patients found difficulty in sleeping and carrying out activities of daily living while wearing the splint. As a result, they could only tolerate wearing the splint for a mean of 15 ± 3 hours daily. Their recall of the number of hours spent daily in the splint was poor and we were therefore not able to correlate compliance with the splinting protocol and the range of movement gained. Two patients reported transient paraesthesiae in the distribution of the ulnar nerve which completely resolved with adjustment of the splint. There was no skin breakdown and no long-term complications were seen.

Discussion

Contracted ligaments, muscles, tendons, or capsule can be corrected using the principle of creep or load-relaxation. Creep occurs when a contracted tissue is placed under a constant load, thereby achieving a change in displacement. Load-relaxation occurs when a contracted tissue is stretched or displaced, thereby creating a load, which dissipates over time.[10,11] Dynamic splinting is based on the principle of creep and static progressive splinting on the principle of

load-relaxation. By tightening the turnbuckle and lengthening the tissues, the splint creates a load which dissipates over time as load-relaxation occurs. The application of prolonged loading to dense connective tissues generates a biological response to modify the length or cross-link integrity of collagen and thereby allows a permanent change in the tissue.[12,13] In static progressive splinting the patient controls the magnitude of the applied load by adjusting the turnbuckle to the maximum load which can be tolerated comfortably. This graduated and prolonged tissue stretching may explain the success of this approach compared with intermittent physiotherapy and static splinting. Dynamic splinting applies a fixed load which may cause pain and diminish compliance with the splinting regime. Soft-tissue damage and inflammation may occur due to overloading of the tissues which may retard remodelling. Dynamic loads which are too small to achieve the desired stretching of the soft tissues may not result in any gains in movement. We know of only two other series reported in the English literature in which static progressive splinting has been used for post-traumatic and postsurgical contractures of the elbow. The most recent review was of 20 patients by Bonutti et al,[1] who used a Joint Active System orthosis. Their mean gain in arc of movement was 31° with approximately equal increase in both flexion and extension. In the other series, Green and McCoy[2] described the results in 15 patients treated by a turnbuckle splint for post-traumatic flexion contractures. They gained a mean of 43° of movement, with 37° of this being in extension.

Our patients did not do as well as those of Green and McCoy[2], possibly because our flexion contractures were less severe being 32° compared with 60° in their series. This probably allowed greater gains in extension, although the final flexion contracture was not considerably different, being 23° in Green and McCoy's patients as opposed to 26° in ours. Our patients had more improvement in flexion by the use of the turnbuckle splint, with a mean improvement of 20°. This may be a reflection of the design of the splint or of the splinting programme, and may be because our patients had only a mean of 108° of flexion before splinting, which is 22° less than was considered functional by Morrey et al.[8] The mean flexion contracture of our patients before splintage was 32° which is close to functional.

Most of our patients were unable to tolerate the splint for 20 hours each day. Unfortunately, due to poor recall of the actual time spent in the splint, we were not able to correlate gains in the range of movement with the number of hours of splintage. The patients of Bonutti et al[1] made their gains by a small number of 30-minute splinting sessions each day. It may therefore be possible to make equal gains with a much less rigorous regime than that used by us. Patient acceptance and satisfaction would be better if this was so. After the application of a load to dense connective tissues, relaxation occurs exponentially.[10,11] The duration for which this stretch has to be applied before biological remodelling of the tissue occurs is unknown.[12,13] Shorter periods of application of the load may achieve the same gains. We found that compliance with the turnbuckle splint tended to decrease as patients approached a functional arc of movement, possibly explaining the ultimate range of flexion achieved with this method of treatment.

A total of 19 of our 22 patients made gains in elbow movement with improvement in the arc of ≥ 10° by the use of a static progressive splint despite not responding to an intensive standardised programme of physiotherapy and static splinting.[9] These improvements in movement were maintained after discontinuation of the splint, except in two patients with post-traumatic arthritis. A functional arc of elbow flexion was achieved in 11 patients, thereby avoiding surgery. Only three of our patients requested surgical release of their residual contracture. No complications were encountered from the use of the splint. In comparison, surgical release of elbow contracture is an expensive undertaking with significant risk to the patient. It also relies on the motivation of the patient and compliance with post-operative rehabilitation to achieve satisfactory results.

Although we could not demonstrate a relationship between time from injury/surgery to improvement in movement after turnbuckle splinting, all our patients were less than seven months from the inital event. While some authors have suggested that turnbuckle splinting may be effective in long-standing elbow contractures this has not been our experience, hence the restricted selection of patients for splinting in our study. We believe that patients in whom turnbuckle splintage is likely to succeed should have some 'springiness' to their extremes of movement, indicating that load-relaxation could occur when the splint is applied. The presence of mild discomfort on stressing the end-ranges is suggestive of ongoing healing of the capsule and ligaments which have the potential for tissue remodelling in response to an applied load. Based on our experience with two patients who had mild post-traumatic arthritis, turnbuckle splinting should be avoided in this group since they did not reliably improve or maintain their range of movement at follow-up. This may be due to the inability of the arthritic joint to tolerate compressive loads generated by the turnbuckle splint and a gradual progression of arthritis over time. There was no correlation between the age of our patients and their response to splinting. Since most of our patients were adults, we cannot comment on this relationship in children.

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References

1. **Bonutti M, Windau JE, Ables BA, Miller BG.** Static progressive stretch to reestablish elbow range of motion. *Clin Orthop* 1994; 303:128-34.
2. **Green DP, McCoy H.** Turnbuckle orthotic correction of elbow-flexion contractures after acute injuries. *J Bone Joint Surg [Am]* 1979; 61-A:1092-5.

3. **Hepburn GR.** Case studies: contracture and stiff joint management with Dynasplint. *J Orthop Sports Phys Therapy* 1987;8:498-504.
4. **Hepburn GR, Crivelli KJ.** Use of elbow Dynasplint for reduction of elbow flexion contractures: a case study. *J Orthop Sports Phys Therapy* 1984;5:269-74.
5. **Karachalios T, Maxwell-Armstrong C, Atkins RM.** Treatment of post-traumatic fixed flexion deformity of the elbow using an intermittent compression garment. *Injury* 1994;25:313-5.
6. **Duke JB, Tessler RH, Dell PC.** Manipulation of the stiff elbow with patient under anaesthesia. *J Hand Surg Am* 1991;16:19-24.
7. **Zander CL, Healy NL.** Elbow flexion contractures treated with serial casts and conservative therapy. *J Hand Surg Am* 1992;17:694-7.
8. **Morrey BF, Askew LJ, An KN, Chao EY.** A biomechanical study of normal functional elbow motion. *J Bone Joint Surg [Am]* 1981; 63-A:872-7.
9. **Armstrong AD, MacDermid JC, Chinchalkar S, Stevens RS, King GJ.** Reliability of range of motion measurement in the elbow and forearm. *J Shoulder Elbow Surg* 1998;7:573-80.
10. **Taylor DC, Dalton JD, Seaber AV, Garrett WE.** Viscoelastic properties of muscle-tendon units: the biomechanical effects of stretching. *Am J Sports Med* 1990;18:300-9.
11. **Woo S.** Mechanical properties of tendons and ligaments. *Biorheology* 1982;19:385-96.
12. **Ilizarov GA.** The tension-stress effect on the genesis and growth of tissues: the influence of rate and frequency of distraction. *Clin Orthop* 1989;239:263-85.
13. **Kottke FJ, Pauley DL, Ptak RA.** The rationale for prolonged stretching for correction of shortening of connective tissue. *Arch Phys Med Rehabil* 1966;47:345-52.

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Post-traumatic contracture of the elbow

OPERATIVE RELEASE USING A LATERAL COLLATERAL LIGAMENT SPARING APPROACH

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We performed a lateral approach for the release of post-traumatic stiffness of the elbow in 22 patients using a modified technique designed to spare the lateral ligaments. They were reviewed after a mean interval of 26 months. The total humeroulnar joint movement had increased from a mean of 74° to 129° and forearm rotation from a mean of 135° to 159°. Both pain and function in the elbow had improved significantly. This modified lateral approach allows release of post-traumatic contracture without disruption of the lateral collateral ligament or the origins of the extensor tendon at the lateral epicondyle of the humerus. The advantages include a simplified surgical procedure, less operative morbidity, and unrestricted rehabilitation.

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Post-traumatic stiffness is common after trauma to the elbow. This has been attributed to fibrosis and thickening of the capsule and periarticular soft tissues.[1-3] Minor degrees of stiffness can be managed by physiotherapy and static or dynamic splinting.[4-6] When this fails and a marked contracture persists, the elbow can be released surgically by a variety of techniques.[1-3,7-10]

One of us (HH) has described the treatment of post-traumatic contracture of the elbow using a lateral approach.[8] An anterior and posterior capsulectomy was performed with release and re-attachment of the lateral collateral ligament and extensor tendon origins at the lateral epicondyle of the humerus. This required postoperative rehabilitation with the shoulder adducted to protect the lateral soft-tissue repair. Two patients developed postero-lateral instability during rehabilitation secondary to avulsion of the soft-tissue structures from the lateral epicondyle (Fig. 1). Surgical repair was required to restore stability to the elbow.

With a greater understanding of the anatomy and role of the lateral collateral ligament,[11,12] we have designed a technique for capsular release and debridement of the elbow to preserve the integrity of these structures. Our aim in this study was to determine if post-traumatic contracture of the elbow can be corrected safely and effectively by a ligament sparing approach.

Patients and Methods

Between December 1988 and April 1995 we operated on 23 patients with post-traumatic contracture of the elbow which had occurred despite a supervised programme including dynamic splinting. They had a flexion contracture of at least 30°, or had less than 100° of flexion or both. Radiologically, all the elbows were congruous with an adequate humeroulnar joint space. We excluded all patients with spasticity, burn contractures, associated injury to the head or spinal cord, rheumatoid arthritis or significant heterotopic ossification. One patient was lost to follow-up, leaving 22 available for evaluation.

There were 12 men and 10 women, with a mean age of 35 years (15 to 72) at the time of operation (Table I). The average length of follow-up was 29 months. In 14 of the patients the dominant limb was affected. The mean interval from the initial injury to surgery was 5.8 years (median 2.1).

The details of the injuries are shown in Table I. Two patients had an associated dislocation of the joint with a periarticular fracture. Four patients with a history of remote trauma had radiological evidence of osteochondritis dissecans of the capitellum. A total of 16 operations had been carried out on the affected elbow in 12 patients (Table I).

The office and hospital charts of each patient were reviewed; all returned for assessment and each completed a detailed questionnaire. Pain was rated according to severity and frequency of occurrence. Visual analogue scales were used to assess peak and general levels of elbow pain on an average day, night pain, the limits of the elbow with respect to hobbies or sports and satisfaction with the surgical

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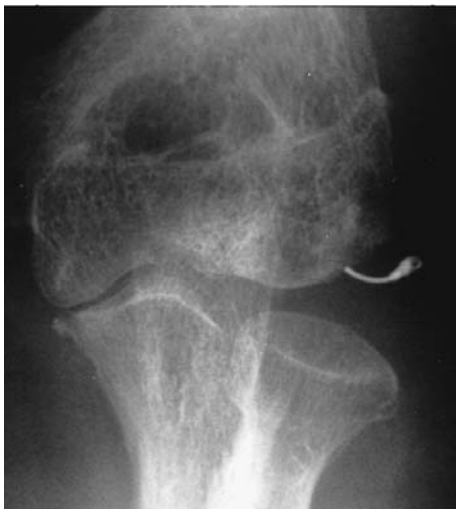

Fig. 1a

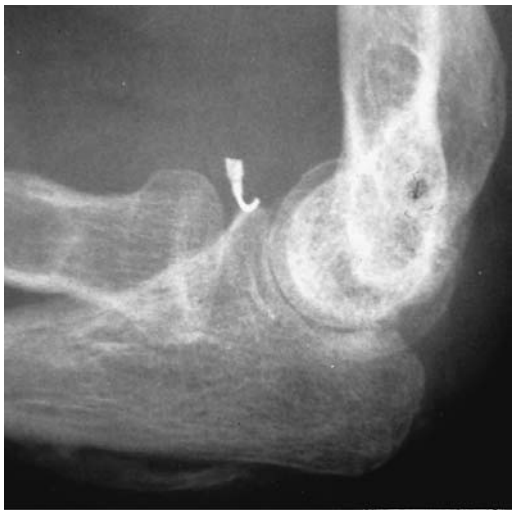

Fig. 1b

Anteroposterior (a) and lateral (b) radiographs of a patient after elbow release through an exposure requiring release and re-attachment of the lateral collateral ligament and the extensor origin.[8] There is avulsion of the bone anchor used to reattach the lateral soft tissues. This patient developed posterolateral instability and required surgery to restore the integrity of the lateral side of the elbow.

result.[13] Elbow function was determined by a questionnaire developed at the Mayo Clinic based on the ability to carry out 12 common tasks.[8,14] Additional questions were included to allow determination of the Mayo Elbow Performance Index for each patient.[2,15]

The recorded physical findings at follow-up consisted of the range of elbow movement, the presence of tenderness or crepitus, medial or posterolateral instability, a careful motor and sensory examination with determination of two-point discrimination, and grip strength. Anteroposterior, lateral and oblique radiographs were taken and examined for the presence of osteophytes, advancement in joint degeneration, loose bodies or heterotopic bone. We performed statistical analysis using the Student's *t*-test on the numerical data and the Wilcoxon rank-sum test on the visual analogue scales. Differences were regarded as significant when $p < 0.05$. The two-tailed test was used in all cases.

Operative technique. Under regional anaesthesia with a long-acting axillary block an extended Kocher incision was used beginning along the lateral supracondylar ridge of the humerus and passing distally in the interval between the anconeus and the extensor carpi ulnaris (ECU).[16] The anconeus was reflected posteriorly with dissection carried out proximally beneath the lateral epicondyle and along the supracondylar ridge of the humerus, thereby reflecting both the anconeus and triceps posteriorly (Fig. 2). A triceps tenolysis was carried out with an elevator, releasing any adhesions between the muscle and the posterior humerus. The humeroulnar joint was identified posteriorly and the olecranon fossa cleared of any fibrous tissue or scar which would restrict terminal extension. The tip of the olecranon was removed if there was evidence of overgrowth or impingement (Fig. 2). The posterior aspect of the radiocapitellar joint was inspected after excision of the elbow capsule just proximal to the conjoined lateral collateral and annular ligament complex through the 'soft spot' on the lateral side of the elbow. The proximal edge of this complex lies along the proximal border of the radial head.[11]

Once the posterior release was completed, dissection was carried anteriorly releasing the brachioradialis and extensor carpi radialis longus (ECRL) from the lateral supracondylar ridge of the humerus (Fig. 3). The brachialis was then mobilised off the humerus and anterior capsule with an elevator, releasing any adhesions between the muscle and the anterior humerus. This dissection was continued distally between the ECRL and extensor carpi radialis brevis (ECRB), allowing exposure of the anterior capsule with preservation of the lateral collateral ligament and the origins of the ECRB, the extensor digitorum communis (EDC) and minimi and the ECU from the lateral epicondyle. Dissection was then carried out beneath the elbow capsule between the joint and the brachialis. The capsule was then excised as far as the medial side of the joint. The radial and coronoid fossae were cleared of fibrous tissue and the tip of the coronoid removed if overgrowth or impingement was noted in flexion. Loose bodies were removed (Fig. 3).

With radiocapitellar degeneration the joint was debrided or the radial head resected through the anterior capsulectomy using an oscillating saw or osteotome without dissection of the lateral collateral ligament complex.[11,12]

After release of the anterior capsule, gentle extension of the elbow with applied pressure would usually bring the joint out to nearly full extension. In longstanding cases of contracture the brachialis muscle can be tight inhibiting full terminal elbow extension. This myostatic contracture could be stretched for several minutes during the procedure and required attention at subsequent physiotherapy. After clo-

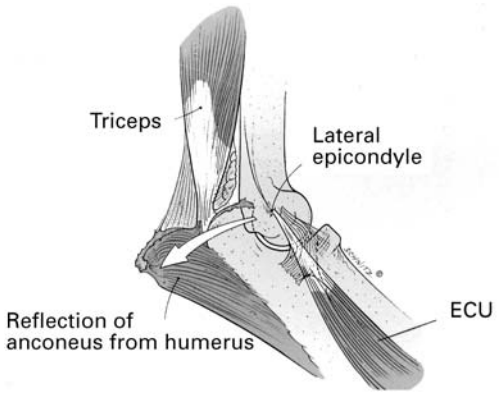

Fig. 2a

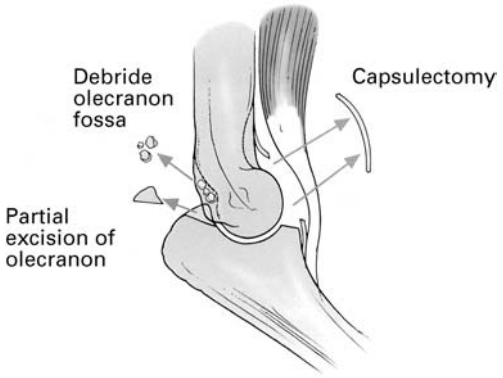

Fig. 2b

Diagrams showing the posterior approach to the elbow for operative debridement and release. The interval between the anconeus and ECU is split and anconeus and triceps reflected posteriorly (a). This allows tenolysis of the triceps, resection of the posterior capsule and debridement of the olecranon and its fossa (b).

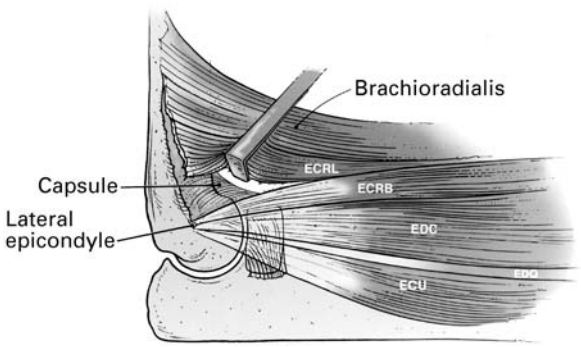

Fig. 3a

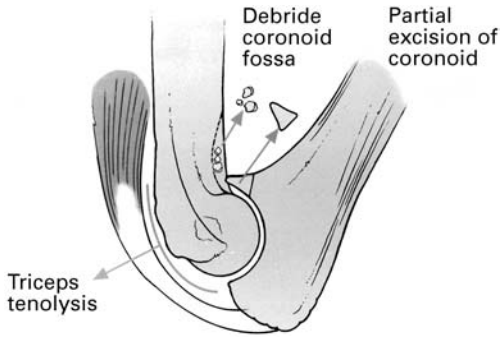

Fig. 3b

Diagrams showing the anterior approach to the elbow for debridement and release. The brachialis and ECRL are released from the supracondylar ridge of the humerus exposing the anterior elbow capsule which is excised (a). The coronoid and radial fossae can then be debrided, the tip of the coronoid removed and the radiocapitellar joint inspected (b).

sure the dressing was cut out over the antecubital fossa to allow elbow flexion. Continuous passive movement was started in the recovery room and maintained until the following morning.

Physiotherapy began on the first postoperative day with active and passive movement, intermittent continuous passive movement and the wearing of a dynamic elbow brace. To gain extension, weighted passive stretches using a wrist weight of 1 or 2 kg with the elbow extended over a bolster were performed several times daily. Since the collateral ligaments were not released, there were no restrictions on movement.

All patients had an anterior and posterior release from the lateral side with excision of bony overgrowth and osteophytes. Three patients had metal removed at the time of the procedure. Five had excision of the radial head for arthritis and in nine, loose bodies were identified and removed. Two patients with ulnar neuropathy had an anterior subcutaneous transposition of the nerve through a second medial incision. In none of these was the joint entered or debridement carried out from the medial side.

The patients remained in hospital for an average of 2.4 days after operation. Outpatient rehabilitation was continued two to three times per week for approximately four to six weeks. Continuous passive movement was continued at home for approximately four weeks. Intermittent dynamic elbow bracing and weighted elbow stretches were continued for eight to 12 weeks and subsequently as required. All patients received oral indomethacin for six weeks after operation as prophylaxis against heterotopic ossification.

Results

Movement. The total elbow movement improved in all patients (Fig. 4; Table I). Extension increased from a mean of 39° to 8°. The mean elbow flexion increased from 113° to 137°, giving a mean increase in the total range of movement in the humeroulnar joint of 55° ($p < 0.001$). Mean supination improved from 68° to 83° and pronation from 67° to 75° ($p < 0.01$).

Pain. As shown in Tables II and III the frequency of elbow pain decreased in all patients ($p < 0.001$). Both peak pain and the general level of pain on an average day diminished significantly at follow-up ($p < 0.001$) as did night pain inhibiting sleep ($p < 0.001$). Ten patients continued to take analgesics. Eight used aspirin or a non-steroidal anti-

Table I. Details of 22 patients with post-traumatic contracture of the elbow

Case	Gender	Age (yr)	Initial injury	Prior treatment	Interval from injury to operation (mth)	Additional procedures	Active extension (degrees)		Active flexion (degrees)		Supination (degrees)		Pronation (degrees)		Complications	Duration of follow-up (mth)
							Preop	Postop	Preop	Postop	Preop	Postop	Preop	Postop		
1	F	37	Radial head, fracture of the capitellum	Excision osteochondral fragments	7	Radial head excision	50	0	120	150	35	90	60	90		15
2	F	39	Supracondylar fracture of the humerus	Cubital tunnel release	14		35	10	90	135	85	95	75	90		35
3	F	44	Ulnar fracture	ORIF*	20	Metal removal	40	10	95	150	50	65	75	70		33
4	F	20	Radial head fracture		7		40	0	120	150	45	90	80	90		73
5	F	72	Radial head fracture		4	Radial head excision	40	10	70	135	20	80	30	70		32
6	M	37	Olecranon fracture	ORIF Metal removal	60		45	25	110	135	90	90	80	85		16
7	F	52	Radial head fracture		6		40	0	120	150	55	85	80	90	Transient ulnar neuritis, late synovitis	30
8	M	19	Supracondylar fracture of the humerus	ORIF	36		40	5	135	145	90	90	90	90	Postop pain	40
9	M	26	OCD† capitellum		192		25	5	120	125	80	75	60	75		36
10	M	40	Radial head fracture		26		30	15	120	120	80	80	80	80		24
11	F	16	Radial head fracture		6		50	10	140	135	90	90	90	90	Transient median neuritis	22
12	F	46	Fracture dislocation	ORIF capitellum	8	Metal removal Anterior transposition ulnar nerve	60	15	105	150	90	90	90	90		15

13	M	15	OCD capitellum	Arthroscopic removal loose bodies	48		30	5	120	130	60	65	80	70		26
14	F	34	Fracture dislocation	ORIF radial head	4	Metal removal Anterior transposition ulnar nerve	45	0	70	140	30	85	50	50		27
15	M	31	Supracondylar and intracon-dylar fracture of the humerus	Cubital tunnel release, radial head excision	204		55	5	110	125	75	80	45	50		28
16	F	21	Supracondylar and intracon-dylar fracture of the humerus	ORIF, metal removal	40		45	10	125	135	90	80	70	45		25
17	M	20	Radial head, coronoid fracture		17		45	10	120	135	80	80	45	70		19
18	M	49	Radial head fracture	Joint debridement	36	Radial head excision	30	15	105	135	60	85	45	65	Transient ulnar neuritis	27
19	M	48	Radial head fracture		24		35	8	120	135	80	80	80	80		25
20	M	30	OCD capitellum	Anterior transportation ulnar nerve joint debridement	180	Radial head excision	35	5	110	135	75	85	45	70		32
21	M	31	Radial head fracture, coronoid fracture		180		30	10	120	135	60	80	50	60	Transient ulnar neuritis	30
22	M	55	OCD capitellum		400	Radial head excision	15	0	130	135	80	85	70	80	Late elbow synovitis	33

* open reduction and internal fixation
† osteochondritis dissecans

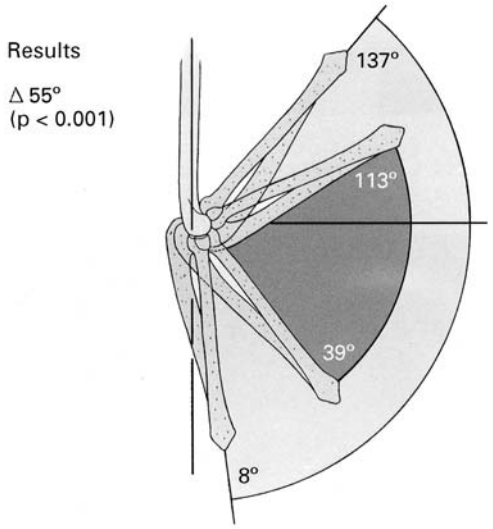

Fig. 4a

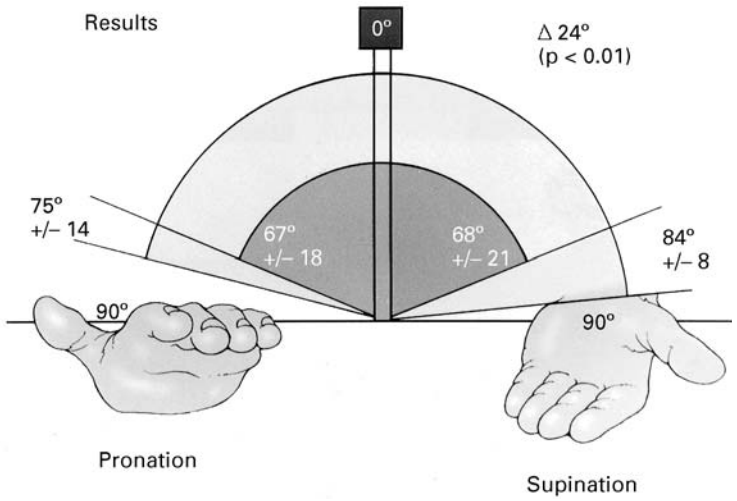

Fig. 4b

Diagram of average active range of elbow flexion and extension (a) and supination and pronation (b) preoperatively and at follow-up.

Table II. Number of patients with elbow pain preoperatively and at follow-up

	Never	Rare (1 to 2 times per year)	Occasional (1 to 2 times per month)	Frequent (every week)	Daily
Preop	0	0	2	4	16
At follow-up	4	8	7	0	3

inflammatory agent, and two intermittently used narcotics. When examined one patient experienced discomfort at the extreme of elbow flexion and another at terminal extension.

Function. The scores in Table IV show a significant improvement, after operation, in elbow function[8,14] ($p < 0.001$). The Mayo Elbow Performance Index ($p < 0.001$), the patient's assessment of how their elbow limited their most strenuous activities ($p < 0.001$), and the reported overall handicap which the affected elbow caused in the patient's lifestyle ($p < 0.001$) were all better. Patient satisfaction was a mean of 8.8 on a score from 0 to 10.

On examination, no patient had clinical evidence of instability of the posterolateral joint.[12] Two had slight laxity of the medial side during stress testing but this was not a functional problem. Four patients had palpable crepitus during active flexion and extension, and one during rotation of the forearm. The mean grip strength of the affected arm was 44.5 kg at follow-up. This compared favourably with the 47.2 kg in the unaffected arm ($p > 0.05$). Preoperative measurements of grip strength were available for 15 patients. In this subset, strength improved from 38.6 kg preoperatively to 49.5 kg at follow-up ($p < 0.002$).

Table III. Level of pain and mean (± SD) pain severity score preoperatively and at follow-up in 22 patients

	Pain severity score	
	Before operation	At follow-up
Pain frequency (1 to 5)	4.6 ± 0.7	2.5 ± 1.2
Peak level of pain (0 to 10)	7.3 ± 2.5	1.3 ± 2.0
General level of pain (0 to 10)	6.4 ± 3.0	0.8 ± 1.3
Night pain (0 to 10)	6.1 ± 3.3	0.7 ± 1.0

Radiological evaluation. Radiological analysis showed that no patient had regrown excised osteophytes or produced further loose bodies. One had mild progression of humeroulnar degenerative changes after 24 months and five had small foci of soft-tissue calcification anteriorly or

Table IV. Mean (± SD) elbow function score and Mayo performance index in 22 patients preoperatively and at follow-up

	Elbow function score	
	Before operation	At follow-up
Mayo performance index[15] (0 to 100)	50 ± 14	89 ± 12
Mayo function task analysis[8,14] (0 to 12)	6.5 ± 2.8	11.1 ± 1.2
Elbow limitation in activities (0 to 10)	7.8 ± 2.0	1.2 ± 2.0
Elbow handicap on lifestyle (0 to 10)	7.1 ± 2.0	1.5 ± 1.7

posteriorly which did not affect elbow movement.

Complications. One patient had severe pain requiring a regional anaesthetic block on the third day after operation. This eventually resolved after six days in hospital. Three patients developed symptoms of ulnar neuritis and one of median nerve dysfunction but none had measurable motor or sensory deficits. All the symptoms were transient and had cleared by three months.

Two patients developed an episode of late pain and synovitis in the elbow associated with increased activity, one after six months and the other after seven. They were treated by an intra-articular injection of cortisone and a period of reduced activity.

Discussion

Loss of movement after injury to the elbow is common and has been attributed to the intrinsic congruity of the joint, the presence of three articulations in a single capsule and the proximity of the articular surface and capsule to the intracapsular ligaments and extracapsular muscles.[2] Prolonged immobilisation of the elbow after trauma may result in stiffness. Once established, minor elbow contractures can often be treated successfully by physiotherapy and the wearing of dynamic splints or braces.[4-6] When conservative measures fail, the elbow can be released by a variety of surgical techniques.[1-3,7-9,17]

The advantages of a lateral exposure include an internervous plane, an incision in the neutral axis of flexion-extension making wound problems less likely with early movement, and the ability to see and treat both the anterior and posterior humeroulnar and the radiocapitellar joints through one incision. This preserves the collateral and annular ligaments and the origins of the extensor complex while allowing complete exposure of the anterior and posterior elbow. The advantages include a simplified surgical dissection, less operative morbidity and the preservation of the lateral ligaments to prevent subsequent instability.

In our series the gains in rotation can be attributed to concomitant resection of the radial head (five patients), removal of metal, debridement of the radiocapitellar joint and pain relief in conjunction with a supervised post-operative physiotherapy programme. Elbow function, as measured by standardised scales, significantly improved (Table IV). Patients reported their elbow to be less of a disturbance and handicap to their most vigorous activities. No patient had clinical or functional evidence of significant joint instability. These results compare favourably with our previous technique for lateral elbow release[8] as well as with reports using anterior or medial approaches.[1,3,10,18]

We assessed pain by a variety of visual analogue scales.[13] The frequency of pain, the peak and general level of pain in the elbow on an average day and night pain all significantly improved after release and debridement (Tables II and III). The relief of symptoms is probably attributable to the removal of osteophytes, loose bodies, degenerative radiocapitellar arthritis, and bony and soft-tissue impingement within the joint. Excision of the anterior and posterior elbow capsule, however, may lead to a partial denervation of the elbow. Radiological evaluation showed slight progression of humeroulnar joint degeneration in only one patient at an average follow-up of two years. Long-term follow-up will be needed to determine if there is any deleterious effect from removal of the joint capsule.

The most common complication was the development of transient paraethesiae in the distribution of the ulnar nerve which was seen in three patients. This may in part be related to improved flexion after surgery. Tension in the ulnar nerve increases in elbow flexion and may lead to symptoms in a nerve which is compromised to a subclinical degree. Trauma can itself lead to oedema and fibrosis in the cubital tunnel with resultant nerve symptoms. Three of the 22 patients in our study had had prior surgery for cubital tunnel syndrome and two had anterior transposition of the ulnar nerve at the time of their elbow release. We now recommend release and transposition of the ulnar nerve in patients with symptoms or in those who have positive provocative tests for impingement of the ulnar nerve (a Tinel's sign or a positive elbow flexion test).[18]

Special mention must be made of the postoperative rehabilitation required after capsular release. The rehabilitation programme consists of daily continuous passive movement at home, weighted elbow stretches, active and passive exercises at home and under supervision, and a dynamic elbow brace. Patients must be motivated and understand the commitment required. Although most improvement occurs within the first six to eight weeks, patients must continue their home programme since movement can continue to improve for up to three to four months after the procedure. This is especially true for longstanding contractures.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References

1. **Gates HS, Sullivan FL, Urbaniak JR.** Anterior capsulotomy and continuous passive motion in the treatment of post-traumatic flexion contracture of the elbow: a prospective study. *J Bone Joint Surg [Am]* 1992;74-A:1229-34.
2. **Modabber MR, Jupiter JB.** Current concepts review: reconstruction for post-traumatic conditions of the elbow joint. *J Bone Joint Surg [Am]* 1995;77-A:1431-46.
3. **Urbaniak JR, Hansen PE, Beissinger SF, Aitken MS.** Correction for post-traumatic flexion contracture of the elbow by anterior capsulotomy. *J Bone Joint Surg [Am]* 1985;67-A:1160-4.
4. **Dickson RA.** Reversed dynamic slings: a new concept in the treatment of post-traumatic elbow flexion contractures. *Injury* 1976;8:35-8.
5. **Green DP, McCoy H.** Turnbuckle orthotic correction of elbow-flexion contractures after acute injuries. *J Bone Joint Surg [Am]* 1979;61-A:1092-5.
6. **Hepburn GR, Crivelli KJ.** Use of elbow dynasplint for reduction of elbow flexion contractures: a case study. *J Orthop Sports Phys Ther* 1984;5:269-74.
7. **Hastings H II.** Elbow contractures and ossification. In: Peimer C, ed. *Surgery of the hand and upper extremity.* New York: McGraw-Hill, 1996:507-34.

8. Husband JB, Hastings H. The lateral approach for operative release of post-traumatic contracture of the elbow. *J Bone Joint Surg [Am]* 1990;72-A:1353-8.

9. Morrey BF. Post-traumatic contracture of the elbow: operative treatment including distraction arthroplasty. *J Bone Joint Surg [Am]* 1990; 72-A:601-18.

10. Willner P. Anterior capsulectomy for contractures of the elbow. *J Internat College Surg* 1948;11:359-61.

11. Cohen MS, Hastings H. Rotatory instability of the elbow: the anatomy and role of the lateral stabilizers. *J Bone Joint Surg [Am]* 1997;79-A:225-33.

12. O'Driscoll SW, Bell DF, Morrey BF. Posterolateral rotatory instability of the elbow. *J Bone Joint Surg [Am]* 1991;73-A:440-6.

13. Huskisson EC. Measurement of pain. *Lancet* 1974;2:1127-31.

14. Morrey BF, An KN, Chao EYS. Functional evaluation of the elbow. In: Morrey BF, ed. *The elbow and its disorders.* Philadelphia: W. B. Saunders, 1985:73-91.

15. Morrey BF, An KN, Chao EYS. Functional evaluation of the elbow. In: Morrey BF, ed. *The elbow and its disorders.* Second edition. Philadelphia: W. B. Saunders, 1993;86-97.

16. Crenshaw AH, ed. Surgical approaches. In: *Campbell's operative orthopaedics.* 7th ed. St Louis, etc: CV Mosby Co, 1987:23-107.

17. Wilson PD. Capsulectomy for the relief of flexion contractures of the elbow following fracture. *J Bone Joint Surg* 1944;26:71-86.

18. Novak CB, Lee GW, MacKinnon SE, Lay L. Provocative testing for cubital tunnel syndrome. *J Hand Surg Am* 1994;19:817-20.

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Static Progressive Forearm Rotation Contracture Management Orthosis Design: A Study of 28 Patients

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Jeffrey C. King, MD

ABSTRACT

*Loss of forearm rotation can lead to significant loss of upper limb function. Operative treatment to improve rotation of the forearm at both the proximal radioulnar joint and distal radioulnar joint has been reported. There are limited orthosis designs available to address this clinical problem and limited information about the efficacy of conservative management of forearm rotation stiffness. A unique orthosis design was fabricated to provide static progressive motion for forearm rotation motion: supination and pronation. The orthosis design consisted of a custom-molded polyethylene hinged elbow orthosis with a dual offset channel overlapping an adjustable rotation component. Attempts were made to align the anatomical axis for forearm rotation motion with the mechanical axis of the orthosis. All orthoses used were adjustable from full supination to full pronation range of motion. A study was carried out to track the progress and results of 28 patients with loss of forearm rotation. Patients with synostosis or malunion of forearm fractures were excluded. Patients were included if they had 50° or less of supination, pronation, or both. Average initial supination was 33.2°, and final supination averaged 68.1°. Average gain was 36.5°. Twenty-three patients (92%) gained motion, 17 (68%) gained a functional arc. Initial pronation averaged 49.3°, and final pronation was 74.0°. Average pronation gain was 25.8°. This report describes the design details and the fit criteria and challenges. It also demonstrates the effectiveness of this type of static progressive stretching to improve forearm stiffness related to soft tissue contracture. (*J Prosthet Orthot. *2006;18:63–67.)*

Designs of upper limb orthoses vary from simple prefabricated three-point pressure systems to more elaborate high temperature (fabricated from plaster mold of patient) designs. All orthosis designs with articulations share a common goal of attempting to match the anatomical axis to the mechanical axis to provide simultaneous movement along the same plane of motion. One of the more difficult upper limb axes of motion to mimic in a mechanical design is the motion of forearm rotation: pronation and supination. The anatomical axis for forearm rotation is defined as a longitudinal axis that extends from the ulnar head to the radial head. The anatomical axis extends the entire length of the forearm (Figure 1). The custommolded orthosis design effectively moved the patient's forearm through the entire range of motion-full supination to full pronation-with adequate limitation of substitution by circumferentially encompassing the forearm with a molded forearm cuff attached to the adjustable rotation component.

Operative treatment to improve rotation of the forearm at both the proximal radioulnar joint (PRUJ) and distal radioulnar joint (DRUJ) has been reported. [1–4] However, there is limited information about the efficacy of conservative management of forearm rotation stiffness. Nonoperative management alone is not effective in loss of forearm rotation related to mechanical malalignment or bony block. [3] Causes of stiffness amenable to conservative treatment include elbow trauma from fracture/ dislocation, isolated radial head injury, and reconstructive procedures, such as radial head resection, arthroplasty, or ligament reconstruction. Distal radius fractures, ulna fractures, DRUJ or wrist ligament reconstruction procedures can lead to rotation stiffness that can be treated with orthoses, provided the limitation is not bony in nature. Although the reported functional range of motion (ROM) for forearm rotation is 100°, centered in neutral rotation, [5] individual needs can vary. For example, the increasing use of keyboards places a premium on forearm pronation, whereas for a guitar player, maximal supination is critical. The concept of positioning the shortened tissue at or near the end of its currently available range of motion is referred to as low load, prolonged stretch therapy, and is most effectively accomplished with the use of orthoses. [6] The force can be applied via different techniques, including static progressive stretching, dynamic splinting, or static serial casting. Technical challenges to designing effective forearm stretching orthoses include difficulty with aligning the axis of rotation, short lever arms with which to apply stretching force, and soft tissue containment.

Connective tissue of the capsule demonstrates viscoelastic properties. [6] The collagen latticework has a high tensile resistance to rapidly applied loads but demonstrates the properties of creep and stress relaxation in response to sustained loads. This plastic elongation has been attributed to the "separation of the attachments at the points of contact of adjacent collagen fibers in the connective tissue meshwork," [7] rather than from the actual ductility of the collagen fibers. This material property of capsular tissue forms the basis for the use of stretching orthoses.

Static progressive orthotic management (SPOM) uses the principle of stress relaxation. By definition, the amount of force required to maintain tissue at a given length decreases with time. [6,8] Serial casting uses the same principles but is much more labor and time intensive. [9,10] An incrementally adjustable orthosis controlled by the patient allows a set force to be applied that slightly exceeds the elastic limit of the tissue, resulting in relaxation and stretch. The tissue elongation occurs via reorganization of the collagen matrix and the breaking and reforming of the attachments of the fibers at greater distances. Properly applied, there is little inflammation of the tissue, resulting in minimal pain, improved compliance, and much better acceptance by the patients. SPOM allows for infinite adjustability and control of tissue tension and joint position compared with dynamic splinting. [6] SPOM has been effectively applied to address elbow flexion contractures [11–13] but has received limited attention for forearm rotation.

Loss of joint motion may be related to capsular contracture, shortening of the musculotendinous units through spasm, cocontraction, or contracture, or changes of the articular surface and/or bony blocks. The latter two causes are not addressed in this study. The connective tissue of the capsule is loose areolar tissue with a meshwork structure. The collagen, elastin, and reticular fibers are loosely connected by ground substance and by chemical bonds. The mobility of this tissue is determined by the distance between the points of attachment of the collagen fibers. [7] There exists potential energy in the collagen lattice with a tendency for the fibers to contract and reorganize unless countered by an opposing force. The normal mobility of the elbow or wrist joint provides the opposing force to these tissue changes. Thus, when the joint is immobilized, these forces are restricted, allowing for shortening, primarily by fiber reorganization, which leads to the thickening and increased stiffness of the capsular tissue readily seen in contracted joint capsule. Trauma, edema, or ischemia exacerbates this process by stimulating the production of additional collagen fibers via active fibroblastic activity.

These conformational changes may occur in as little as 3 days. [7] The purpose of this study is to evaluate the results of the use of a static progressive orthosis for improvement of forearm rotation caused by soft tissue contracture and to demonstrate the effectiveness of this new design of orthosis.

PATIENTS AND METHODS

Twenty-eight patients (15 men, 13 women; average age, 41.2 years; range 23–64 years) received treatment with static progressive orthoses. Half (14) had stiffness related to the PRUJ, 13 had stiffness related to the DRUJ, and 1 had stiffness related to both. Causes of stiffness included elbow fracture/dislocation (6), isolated radial head injury (3), status post radial head resection (5), distal radius fracture (10) wrist ligament reconstruction (2), and ulna fracture (2). Six patients received their orthoses following surgery for postoperative stiffness. Patients with synostosis or malunion of forearm fractures were excluded. Functional range of motion was defined as 50° supination and 50° pronation.[5] Patients were included if they had 50° or less of supination, pronation, or both. All 28 patients were seen initially for evaluation and molding in preparation for fabrication. Average time from date of surgical release or date of injury to placement of orthosis was 7.6 weeks, with a median of 8 weeks (range, 2–12 weeks). Rotation splinting was continued for at least 3 months, or until a plateau was achieved.

Evaluation included determination of elbow joint location at an approximation of the difference between the location of the center of the medial and lateral epicondyles. Any bony abnormalities or prominence of surgical hardware were noted in the mold. The patients underwent the molding process in a position of 80° flexion and neutral forearm rotation (when applicable and patient tolerated this position). If a patient was unable to achieve this molding position, the mold was taken at a position as close to this as possible to facilitate joint alignment of the rotation component. Negative molds were filled and positive molds were modified with minimal plaster addition or removal. Approximation of soft tissue compression, especially on the humeral section, was reduced on the positive mold to achieve an intimate fit. True anatomical shape of the forearm was not compromised with plaster modification.

The mechanical joint at the elbow consisted of two options depending on the presence of a flexion or extension contracture in conjunction with the forearm rotation contracture. If the secondary flexion/extension contracture were present, a static progressive joint was used to address this limitation with the same protocol (Figure 2). If no secondary limitation existed, a free range joint was used at the elbow (Figure 3).

Although unable to directly mimic the anatomical axis of the forearm (Figure 1) with the mechanical axis of the orthosis, the rotation component included movement of the entire forearm component around the static humeral/elbow section of the orthosis. The shape of the forearm section of the orthosis remained accurate to the exact shape of the patient's forearm. The outside of the forearm component had several layers of additional polyethylene added to produce a smooth round surface over which the rotation motion would glide smoothly and without resistance (Figure 4). The total contact nature of the forearm component was used to most closely approximate the anatomical axis of rotation and prevent substitution by radiocarpal rotation, which is likely with a less-than-intimate fit between the forearm component and the patient's forearm. All orthoses were adjustable from full supination to full pronation ROM (Figure 5). Dual offset slots were meticulously cut into the overlapping component to facilitate integrity of the rotation component itself and allow full ROM in directions of both pronation and supination.

Custom orthoses were fit to patients within 1 week of initial presentation. Range-of-motion measurements were taken during each follow-up appointment and entered as data. Patients were seen

at 4-week intervals. Range-of-motion measurements used for data analysis were all performed by one physician with a standard technique. We standardized the measurement of forearm rotation by referencing the longitudinal axis of the humerus, rather than to "vertical," to eliminate the error associated with shoulder internal and external rotation. [14] Patients underwent aggressive hand therapy in conjunction with orthotic management. Passive ROM and/or manipulation were not performed by the therapist. Orthoses were adjusted as needed for fit problems, decreases in swelling, or increases in muscle tone. However, with the use of 1/8-inch polyethylene material for humeral and forearm shells, a certain amount of patient adjustment to compensate for decreases or increases in volume was allowed.

Detailed written donning instructions were provided to all patients. A written wearing schedule was provided and explained verbally at the time of orthosis fitting. The protocol for the determination of the wearing schedule began with the most severe limitation being addressed during sleep (6–8 hour session). Three daily wearing sessions of 3 to 4 hours each were alternated between the more severe limitation and the opposing motion (Table 1). The orthosis was removed for 1 to 2 hours between wearing sessions, and functional use of the forearm and skin maintenance were encouraged. Patients were instructed to apply the orthosis in a neutral, mid-arc position, then apply rotation force in the desired direction until a strong stretching sensation was felt. They were then instructed to relax the stretch slightly, and set the position. This submaximal stretch protocol enhanced patient compliance, while providing for the stress relaxation response. Degree markings were not provided on the orthosis because patients were encouraged to apply the stretch that was tolerable at each session.

RESULTS

Duration of splinting was 12 to 24 weeks. Average initial supination was 33.2° (range, 0° – 48°), and final supination averaged 68.1° (range, 10° –90°). Average gain was 36.5° (range, .20° – 80°). Twenty -three (92%) patients gained motion; 17 (68%) gained a functional arc. Initial pronation averaged 49.3° (range, 0° –90°), and final pronation was 74.0° (range, 40° –90°). Average pronation gain was 25.8° (range, 10° – 69°). All gained pronation, and 87% achieved a functional arc (Table 2). Complications included radial sensory nerve neurapraxia in two patients. Only two patients in this series required surgery for failure to achieve functional rotation.

DISCUSSION

The efficacy of static progressive splinting SPOM for the treatment of elbow flexion/extension contracture has been well documented. [11,12,15] Serial casting is a more labor-intensive form of SPOM, which has been successful as well. [9,16] Despite the documented results of conservative management of elbow flexion/ extension contracture with SPOM, there are no reported results with the use of SPOM to treat rotation contracture of the forearm. We are reporting the only known large series of patients with forearm contracture effectively treated with static progressive orthoses.

Green and McCoy [15] reported the effective treatment of 12 of 15 patients with elbow flexion contracture with turnbuckle splinting. The demographics of the patients are similar to those in this study. Treatment was initiated later, at an average of 5.3 months after injury or operation. Failure to obtain an acceptable correction occurred in three patients, all of whom had intraarticular incongruity. Bonutti et al. [11] reported an average increase of 31° in elbow ROM in 20 patients with elbow flexion/ extension contracture. Only 8 of 20 obtained a "functional" arc of motion (30°–130° of elbow flexion/extension) The static progressive device was worn for only two 30-minute periods per day. Patient compliance and satisfaction were high, despite the limited functional results. More recently, Gelinas et al. [12] reported the result of turnbuckle splinting for the treatment of elbow flexion/extension

contracture in 22 patients. They demonstrated improvement in the ROM of 19 of 22 patients, although a functional arc was obtained in only 11 of 22. Three patients experienced no improvement, with one patient ultimately undergoing surgery to improve ROM.

We are reporting the design of a static progressive orthosis and the only known series of patients treated with SPOM for forearm rotational stiffness. Patients with diminished forearm rotation from PRUJ and/or DRUJ causes have been included, and improvement was noted in each group. Ongoing data collection with more patients is under way, with the hope that these different groups can be compared to determine if efficacy and prognostic differences exist. These orthoses are well tolerated by the patients, and self-reported compliance is high. Although the initial cost of custom-made orthoses can be high, the combination of demonstrated effectiveness, as well as unlimited pre- and postoperative use, make this device cost effective when compared with the monthly rental charges required for commercially available SPOM rotation orthoses. There was noticeable difference in the amount of time required for patients to wear the orthoses. All patients were told the minimum amount of time for orthotic treatment would be 3 months. They were also told that this time would extend until improvements in range of motion plateaued. This time varied between 3 and 12 months.

One potential weakness of the study was the inclusion of multiple diagnoses, including PRUJ and DRUJ causes for rotation loss. Pre- and postoperative orthosis use also is included. Despite this varied population, we thought the universal improvement of forearm rotation across this disparate group warranted the inclusion of these varying diagnoses/situations.

We have demonstrated the ability of this static progressive orthoses to reliably obtain/maintain a functional arc of forearm rotation in a variety of conditions. Treatment with this orthosis is well tolerated by the patients, and patient compliance is high. Additional studies are in progress to evaluate this device for the correction of proximal versus distal forearm rotation problems, as well as the efficacy for specific diagnosis. This static progressive stretching orthosis design provides an effective treatment modality for improving rotation of the forearm axis.

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References:

1. Bell SN, Benger D. Management of radioulnar synostosis with mobilization, anconeus interposition, and a forearm rotation assist splint. *J Shoulder Elbow Surg* 1999;8(6):621–624.

2. Cohen MS, Hastings H II. Post-traumatic contracture of the elbow. Operative release using a lateral collateral ligament sparing approach. *J Bone Joint Surg Br* 1998;80(5):805–812.
3. King GJ, Faber KJ. Posttraumatic elbow stiffness. *Orthop Clin North Am* 2000;31(1):129–143.
4. Kleinman WB, Graham TJ. The distal radioulnar joint capsule: clinical anatomy and role in posttraumatic limitation of forearm rotation. *J Hand Surg [Am]* 1998;23(4):588–599.
5. Morrey BF, Askew LJ, Chao EY. A biomechanical study of normal functional elbow motion. *J Bone Joint Surg Am* 1981; 63(6):872–877.
6. Schultz-Johnson K. Mechanical considerations in splinting to reduce stiffness. Proceedings, "The Stiff Joint." American Association of Hand Surgery Annual Meeting, Kona, Hawaii, January 13-16, 1999.
7. Kottke FJ, Pauley DL, Ptak RA. The rationale for prolonged stretching for correction of shortening of connective tissue. *Arch Phys Med Rehabil* 1966;47(6):345–352.
8. Richard R, Shanesy CP III, Miller SF. Dynamic versus static splints: a prospective case for sustained stress. *J Burn Care Rehabil* 1995;16:284–287.
9. Bennett GB, Helm P, Purdue GF, Hunt JL. Serial casting: a method for treating burn contractures. *J Burn Care Rehabil* 1989;10(6):543–545.
10. Zander CL, Healy NL. Elbow flexion contractures treated with serial casts and conservative therapy. *J Hand Surg* [Am] 1992; 17(4):694–697.
11. Bonutti PM, Windau E, Ables BA, Miller BG. Static progressive stretch to reestablish elbow range of motion. *Clin Orthop* 1994 (303):128–134.
12. Gelinas JJ, Faber KJ, Patterson SD, King GJ. The effectiveness of turnbuckle splinting for elbow contractures. *J Bone Joint Surg Br* 2000;82(1):74–78.
13. Morrey BF. Splinting and bracing at the elbow. In: *The Elbow* , 3rd ed. Philadelphia: Lippincott Raven; 2000:150 –154.
14. Hoppenfeld S. *Physical Examination of the Spine and Extremities.* Norwalk, CT: Appleton & Lange; 1976.
15. Green DP, McCoy H. Turnbuckle orthotic correction of elbow- flexion contractures after acute injuries. *J Bone Joint Surg Am* 1979;61(7):1092–1095.
16. Strang M. The use of dynamic slings to correct elbow flexion contractures. *Orthop Nurs Assoc J* 1977;4(9):224–225.

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Management of radioulnar synostosis with mobilization, anconeus interposition, and a forearm rotation assist splint

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Abstract

Three cases of post-traumatic proximal radioulnar synostosis are presented. Each was treated with surgery with excision of the heterotrophic new bone and mobilization of the proximal radius. The anconeus muscle was mobilized as a vascularized pedicle graft and then interposed between the proximal radius and ulna. Two patients had postoperative radiotherapy. A forearm rotation assist splint was used to augment rehabilitation after surgery. This device consists of an inner sleeve that attaches to the hand and then rotates within a standard turnbuckle flexion/extension assist splint. The overall improvement in forearm rotation in each case was 100°, 140°, and 150°, respectively.

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References

1. EWING, JAMES: Diffuse Endothelioma of Bone. Proc. New York Pathol. Soc., **21:** 17-24, 1921.
2. EWING, JAMES: Further Report on Endothelial Myeloma of Bone. Proc. New York Pathol. Soc., **24:** 93-101, 1924.
3. LANNELONGUE, O. M.: De l'ostéomyélite aiguë pendant la croissance. Paris, Asselin, 1879.
4. TESSARI, L.: L'osteomielite del bacino. Arch. ortop., **74:** 1163-1176, 1961.
5. WELD, P. W.: Osteomyelitis of the Ilium. Masquerading as Acute Appendicitis. J. Am. Med. Assn., **173:** 634-636, 1960.

Turnbuckle Orthotic Correction of Elbow-Flexion Contractures after Acute Injuries

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ABSTRACT: **Fifteen patients with acute flexion contractures of the elbow after injuries or operations were treated with a turnbuckle splint. Satisfactory correction was achieved in twelve patients. An average reduction in deformity of about 37 degrees was recorded after an average treatment period of twenty weeks. The treatment was unsuccessful in three patients with severe intra-articular damage because the splint caused excessive discomfort. The average improvement in the arc of motion of the elbow was approximately 43 degrees.**

Stiffness of the elbow is a relatively common complication following fractures, dislocations, and soft-tissue injuries about the elbow. In most cases the joint will improve with an appropriate exercise program, but occasionally a refractory fixed flexion contracture develops. This paper presents our experience over an eight-year period with a simple orthotic device which has proved quite effective in the management of flexion contractures of the elbow.

Much has been written about surgical treatment of elbow-flexion contractures, but there is very little in the literature regarding non-operative management. Perhaps one reason for this has been the misconception that orthotic devices are ineffectual in dealing with elbow-flexion contractures. This attitude was expressed in the recent American Academy of Orthopaedic Surgeons Atlas of Orthotics, where Perry stated that "restoration of full elbow extension is a strong challenge", and that "recovery of lost arcs of motion with an orthosis is difficult".

The turnbuckle splint is not a new idea. Steindler, in 1947, showed a turnbuckle splint somewhat different in design from the one that we use, although it was identical in principle. The American Academy of Orthopaedic Surgeons Orthopaedic Appliances Atlas, published in 1952, also briefly mentioned the turnbuckle.

Other types of orthotic devices to correct elbow-flexion contractures have been described as well. The use of a dynamic plastic elbow-extension orthosis was reported by Goller and Enders, but the average decrease in flexion contracture in their five patients was only 15 degrees. Dickson's treatment of an elbow-flexion contracture in a single patient yielded an impressive result, but his technique of reversed dynamic splinting required a week of hospitalization. From Russia has come a report[6] of correction of difficult flexion contractures of the knee and elbow with a hinge-distractor apparatus, but this device requires percutaneous pin fixation of bone.

Material and Methods

During the period 1970 to 1978, we used turnbuckle splints in twenty-five patients with flexion contractures of the elbow. Sufficient records of accurate measurements were available for fifteen of these patients, ranging in age from seven to fifty-seven years (average, 24.5 years). Nine patients were male and six were female. Table I summarizes the important clinical data. In ten patients the articular surfaces were undamaged; in two there were intra-articular fractures which were either minimally displaced or reduced accurately; and in three there was severe intra-articular damage.

The lesions that led to the contractures were: six fractures; three dislocations; two fracture-dislocations; and four cases of postoperative stiffness following an osteotomy of the humerus, a medial epicondylectomy, a

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TABLE I

SUMMARY OF CLINICAL DATA

Case	Age/Sex (Yrs.)	Time Since Injury (Mos.)	Cause of Lesion	Elbow Motion (Degrees)									Length of Follow-up (Mos.)	Time in Splint* (Mos.)
				Before Splinting			After Splinting			Results of Treatment				
				Contract.	Flexion	Arc	Contract.	Flexion	Arc	Contract.	Flexion	Arc		
1	17/F	4	3 wks. immob. after open reduction of entrapped medial epicondyle with disloc. of elbow	75	135	60	30	130	100	−45	− 5	+40	72	7
2	14/M	3	4 wks. long cast for open fract. of humerus and radial-nerve palsy	70	135	65	15	135	120	−55	0	+55	52	5
3	53/F	8	6 wks. long cast following operative treatment of tennis elbow	40	150	110	25	150	125	−15	0	+15	36	4
4	10/F	4	8 wks. long cast for supracondylar fract. of humerus	70	110	40	5	130	125	−65	+20	+85	70	10 (night only)
5	39/M	2	Postop. medial epicondylectomy for cubital tunnel syndrome; common flexor-pronator origin reattached with elbow in flexion	55	120	65	0	135	135	−55	+15	+70	84	3
6	7/M	5	Supracondylar fract. with arterial injury requiring exploration	75	115	40	10	110	100	−65	− 5	+60	12	7
7	26/F	3	Transcondylar fract. of distal humerus; accurate reduction by ORIF†	60	85	25	10	90	70	−50	+ 5	+45	24	4
8	13/M	4	Transcondylar fract. of distal humerus treated by closed reduction and percutaneous pinning with accurate reduction	45	135	90	10	135	125	−35	0	+35	27	5
9	13/M	3	Varus osteotomy of distal humerus for cubitus valgus	45	120	75	25	135	110	−20	+15	+35	18	6
10	16/M	22	6 wks. long cast for fract. of medial epicondyle	50	140	90	30	140	110	−30	0	+20	33	4
11	29/F	4	4 wks. long cast for posterior disloc. of elbow	45	135	90	10	135	125	−30	0	+30	12	3
12	17/M	3	3 wks. long cast for repair of lacerated brachial artery	90	100	10	20	115	95	−70	+15	+85	6	5
13	29/F	4	Severely comminuted fract.-disloc.	70	110	30	70	115	45	0	+15	+15	48	6
14	57/M	3	1-wk.-old unreduced medial sublux. of elbow	45	90	45	35	110	75	−10	+20	+30	42	6
15	27/M	3.5	Comminuted fract.-disloc. of elbow	60	90	30	50	100	50	−10	+10	+20	18	4
Average	24.5	5.3		59.6	118	57.6	23	125	100.7	−36.6	+ 7	+43.1	37	5.3

* Includes night-time use after maximum correction was achieved.

† Open reduction and internal fixation.

lacerated brachial artery, and an operation for tennis elbow. Prolonged immobilization of the elbow (four weeks or longer) in a cast was believed to be a factor leading to stiffness in six of the patients.

Ten patients were lost to follow-up during treatment with the turnbuckle splint, and are not included in this study. The etiological factors in those ten were: six, fractures; two, fracture-dislocations; one, dislocation; and one, Erb's palsy.

We have not used this splint in patients with long-standing elbow-flexion contractures that were residua from cerebral palsy, stroke, or congenital lesions (other than Erb's palsy).

The correction of a 70-degree flexion contracture that was attempted in one eleven-year-old child with Erb's palsy resulted in minimum improvement. This patient is not included in the present series, and we do not a vocate the use of the turnbuckle in patients with lon standing contractures.

The turnbuckle splint (Fig. 1) is a double-upright long-arm orthosis with a turnbuckle on the outside upright. The uprights are cut from three by 12.7-millimeter (0.125 by 0.5-inch) 2024-T3 aluminum and the posterior bands, from 0.063-2024-T3 aluminum. Leather cuffs with Velcro straps provide broad, firm control of the upper end of the arm and forearm.

The splint was fabricated and custom-fitted by the orthotist, and the patient was instructed to wear it as much as was possible, removing it several times each day for range-of-motion exercises of the elbow. An effort was

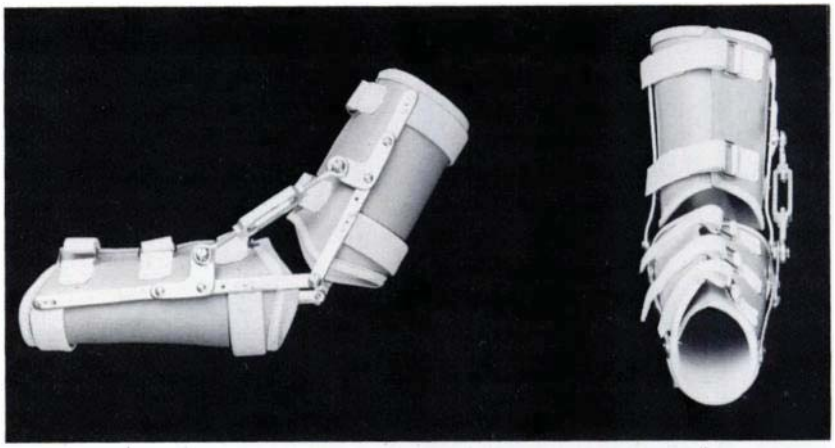

FIG. 1

A turnbuckle splint for the left upper extremity. The turnbuckle is on the outside upright.

made to have the splint worn essentially full-time except for exercise periods, but in most instances compromises were made to allow the patient to be free of the brace several hours each day for work or school. If the flexion contracture did not respond to this regimen, full-time use was strongly encouraged. The patient was taught how to increase the force applied by the turnbuckle to the point of discomfort, but not pain. When the end of the turnbuckle screw was reached, a longer screw was applied by the orthotist.

Results

Treatment with the splint was begun an average of 5.3 months (range, two to twenty-two months) following the injury or operation that caused the flexion deformity. All measurements were made with standard orthopaedic goniometers. The average fixed flexion contracture before the institution of brace treatment was 59.6 degrees (range, 40 to 90 degrees) and the post-treatment average was 23 degrees (range, zero to 70 degrees). The average reduction in fixed flexion contracture at the completion of treatment was 36.6 degrees (range, zero to 70 degrees). If the three patients with severe intra-articular damage (Cases 13, 14, and 15) are excluded, the average reduction in fixed flexion contracture was 43.8 degrees.

Three patients had minimum correction of the contractures, and these warrant further comment. One patient (Case 3), a fifty-three-year-old woman, was seen with a fixed flexion contracture of 40 degrees eight months following an operation for tennis elbow. The elbow had been immobilized for six weeks postoperatively in a long cast. She also had an ulnar-nerve palsy and to further complicate the problem, she sustained an undisplaced surgical fracture of the neck of the ipsilateral humerus during the period of brace treatment (although she was not wearing the brace when she sustained the fracture). Subsequently the shoulder became "frozen". Her contracture was reduced by only 15 degrees.

Case 10, a sixteen-year-old boy, had been treated with a long cast for six weeks for a fracture of the medial epicondyle, and was fitted with the splint twenty-two months after the initial injury. His 50-degree fixed flexion contracture was reduced to 30 degrees within the first three weeks in the brace, but did not respond further despite three additional months of brace treatment.

A fifty-seven-year-old woman (Case 14) was first seen with a one-week-old unreduced medial subluxation of the elbow. A refractory 45-degree fixed flexion contracture developed after closed reduction and three weeks of immobilization in a cast. Even though the turnbuckle was applied just three months after injury, the contracture was reduced only 10 degrees. However, she was able to return to her former job as a waitress.

The length of time required to achieve correction ranged from three weeks to several months, depending on the rigidity of the contracture and the amount of time the splint was worn.

Discussion

The turnbuckle splint that we have used is durable yet relatively simple to fabricate, requires no percutaneous pin fixation or sophisticated mechanical devices and, most importantly, is effective in correcting fixed flexion contractures of the elbow. Local tissue pressure is controlled by the patient, eliminating one objection raised against corrective orthotic devices for the elbow[4].

The appropriate timing for application of the splint is based on the clinical course. Any fracture should of course be healed, and the patient should have had a fair trial with an exercise program. In our patients, the turnbuckle was instituted when improvement in range of motion of the elbow had reached a plateau for at least two to three weeks despite an intensive physical-therapy program.

It is important to note that the splint did not achieve improved extension at the expense of flexion. In fact, there was an average 7-degree increase in elbow flexion. A few patients did lose as much as 5 degrees of active flexion (range, 5 degrees' loss of flexion to 20 degrees' gain). The resulting improvement in arc of motion averaged 43.1 degrees (range, 15 to 85 degrees).

Essentially no correction was lost after the brace was discontinued if the patient was weaned from the splint by gradually decreasing its use over a one-month period after correction had been achieved.

We have learned that the splint is much more successful in patients with joint and soft-tissue contractures than in those with significant intra-articular damage. When there is more than minimum damage in the joint, the splint generally is too painful to wear, and in the three patients with significant intra-articular damage the treatment failed. It was effective, however, in two patients with minimum articular damage. No patient required an operative release of the flexion contracture, but it is anticipated that at least two of the three patients in whom the treatment failed will ultimately require elbow arthroplasty because of severe post-traumatic arthrosis.

References

1. AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS: Orthopaedic Appliances Atlas. Vol. 1, pp. 340-341. Ann Arbor, J. W. Edwards, 1952.
2. DICKSON, R. A.: Reversed Dynamic Slings. A New Concept in the Treatment of Post-Traumatic Elbow Flexion Contractures. Injury, **8:** 35-38, 1976.
3. GOLLER, HERBERT, and ENDERS, MARCH: A Dynamic Plastic Elbow-Extension Orthosis for Reduction of Flexion Contractures. Orthot. and Prosthet., **30:** 47-51, Dec. 1976.
4. PERRY, JACQUELIN: Prescription Principles. *In* American Academy of Orthopaedic Surgeons: Atlas of Orthotics; Biomechanical Principles and Application, pp. 120-122. St. Louis, C. V. Mosby, 1975.
5. STEINDLER, ARTHUR: The Traumatic Deformities and Disabilities of the Upper Extremity, p. 25. Springfield, Illinois, Charles C Thomas, 1946.
6. VOLKOV, M. V., and OGANESIAN, O. V.: Restoration of Function in the Knee and Elbow with a Hinge-Distractor Apparatus. J. Bone and Joint Surg., **57-A:** 591-600, July 1975.

HCPCS:	Descriptor:
L3762	ELBOW ORTHOSIS, RIGID, WITHOUT JOINTS, INCLUDES SOFT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Tendinitis, bursitis, and arthritis to providing elbow stability for mild to moderate medial/lateral and hyperextension injuries, arthrogryposis, contracture, self injury, fusion, arthritis, sprain/ strain
Medically Necessary Argument	A rigid elbow orthosis without joints is indicated for post-surgical immobilization or immobilization to prevent injury to oneself in some cases. A static elbow brace is used to properly align or position the elbow joint and associated bones after surgery. This ensures proper healing of a fracture or surgical site. Without proper fitting and adjustments by a credentialed professional, the joint could heal in malalignment, which may indicate a surgical revision or deformity that the patient must live with. In some cases where a child is inflicting injury on itself, a rigid elbow orthosis is indicated to restrict that movement. Without proper fitting and adjustments, these individuals and their caretakers may place themselves at risk for injury if the device is not performing its intended purpose. This device clearly does not meet the criteria in statute associated with "minimal patient self-adjustment." The metal stays or thermoplastic components require contouring and bending that is specific to the anatomy and must accommodate anatomical angles and deformities as well as not contact boney prominences. Inappropriate fitting of the device presents a risk to the patient in achieving functional outcomes and could result in poor healing, wounds, or further deformities that are negative outcomes that could result in further medical interventions.
References	12, 13, 14, 15, 16

THE JOURNAL OF BONE & JOINT SURGERY (BJ)

The effectiveness of turnbuckle splinting for elbow contractures

J. J. Gelinas, K. J. Faber, S. D. Patterson, G. J. W. King

From the University of Western Ontario, Canada

We have treated 22 patients with an elbow contracture using a static progressive turnbuckle splint for a mean of 4.5 ± 1.8 months. All had failed to improve with supervised physiotherapy and splinting. The mean range of flexion before splintage was from 32 ± 10° to 108 ± 19° and afterwards from 26 ± 10° (p = 0.02) to 127 ± 12° (p = 0.0001). A total of 11 patients gained a 'functional arc of movement,' defined as at least 30° to 130°. In eight patients movement improved with turnbuckle splinting, but the functional arc was not achieved. Six of these were satisfied and did not wish to proceed with surgical treatment and two had release of the elbow contracture. In three patients movement did not improve with the use of the turnbuckle splint and one subsequently had surgical treatment.

Our findings have shown that turnbuckle splinting is a safe and effective treatment which should be considered in patients whose established elbow contractures have failed to respond to conventional physiotherapy.

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Contracture of the elbow is a common complication after trauma or surgery to this joint. The soft tissues surrounding the elbow, including the capsule and collateral ligaments, lose their ability to be stretched, resulting in stiffness of the joint. While early mobilisation and splinting are usually successful in preventing post-traumatic stiffness, the treatment of established contracture may involve both conservative and operative regimes.

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In many cases physiotherapy, both at home and in the clinic, together with splinting, is the first line of treatment for all such contractures. Patients are prescribed static flexion and extension splints to maintain their end range of movement when not exercising. Other forms of static progressive and dynamic splinting have been reported to be beneficial in the treatment of established elbow contractures.[1-5] Manipulation of the elbow under anaesthesia and serial casting may also be useful for resistant contractures.[6,7] The turnbuckle splint is a static progressive method which may be useful in the treatment of an established elbow contracture. It is applied and adjusted incrementally by the patient to cause progressive stretch at the elbow in either flexion or extension. The efficacy of turnbuckle splinting for the treatment of elbow contractures has received little attention.[1,2]

We have assessed the effectiveness of custom-moulded turnbuckle splints in patients with soft-tissue contractures of the elbow which had not responded to standard physiotherapy and static splinting.

Patients and Methods

We have reviewed 22 patients (15 women and 7 men) treated between 1992 and 1995. We excluded those with articular incongruity or heterotopic ossification. Their range of movement at the elbow was less than the functional arc of 30° to 130°, as defined by Morrey et al,[8] despite receiving intensive supervised standardised physiotherapy for at least two months. Their mean age was 39 years (15 to 70). They were placed in a turnbuckle splint after having standard non-operative treatment for a mean of four months (2 to 7). The mean period from the time of the original injury or from surgery was four months (2 to 7). Two patients had isolated postsurgical contractures, five had isolated post-traumatic contractures, and 15 developed their contractures after having open reduction and internal fixation of a fracture, or following release of a surgical contracture after trauma (Table I). Five injuries were work-related. Eleven patients used the turnbuckle splint to improve both flexion and extension, two used the splint primarily to improve elbow extension and nine to improve flexion (Table II). The range of movement was measured by the treating surgeon using a standard goniometer before

Table I. Details of the 22 patients who were treated using a turnbuckle splint

Case	Age (yr)	Gender	Dominance	Injured arm	Injury	Surgery preturnbuckle	Injured at work
1	18	F	Right	Left	T-intercondylar fracture	ORIF*	No
2	45	M	Left	Left	Post-traumatic arthritis	Contracture release	No
3	39	F	Right	Right	Capitellum fracture	ORIF	No
4	41	M	Left	Right	Capitellum fracture	ORIF	Yes
5	48	F	Left	Left	Fracture-dislocation elbow	Contracture release	No
6	15	M	Left	Right	Medial epicondyle fracture	None	No
7	47	M	Right	Right	Post-traumatic arthritis	Contracture release	No
8	30	F	Right	Left	Radial head fracture	ORIF	No
9	15	F	Right	Left	Lateral condyle fracture	None	No
10	45	F	Right	Right	Olecranon fracture	ORIF	No
11	58	F	Right	Right	Distal humeral fracture	ORIF	No
12	31	F	Right	Left	Radial head fracture	None	Yes
13	56	M	Right	Right	Olecranon fracture	ORIF	No
14	48	M	Right	Right	Capitellum fracture	ORIF	No
15	33	F	Right	Right	Radial head fracture	ORIF	No
16	40	F	Right	Left	Capitellum fracture	None	No
17	33	M	Left	Left	Fracture-dislocation elbow	ORIF/contracture release	Yes
18	33	F	Right	Left	Radial head fracture	Contracture release	Yes
19	38	F	Right	Left	Radial neck fracture	ORIF	No
20	60	F	Right	Right	Fracture-dislocation elbow	None	No
21	37	F	Right	Right	Radial head fracture	ORIF	Yes
22	70	F	Right	Right	Capitellum fracture	Contracture release	No

* open reduction and internal fixation

Table II. Results (mean; degrees) in the 22 patients who were treated using a turnbuckle splint

	Presplint			Postsplint			Change in			Follow-up		
Case	Flexion	Flexion contracture	Flexion arc	Flexion	Flexion contracture	Flexion arc	Flexion	Flexion contracture	Flexion arc	Flexion	Flexion contracture	Flexion arc
1	125	40	85	135	25	110	10	15	25	145	43	102
2	125	35	90	130	35	95	5	0	5	120	50	70
3*	100	30	70	105	40	65	5	-10	-5	133	22	111
4*	95	40	55	125	35	90	35	5	35	110	24	86
5	115	30	85	130	30	100	15	0	15	135	35	100
6	115	35	80	140	30	110	25	5	30	130	30	100
7	120	40	80	130	28	102	10	12	22	125	35	90
8	80	30	50	118	34	84	38	-4	34	130	10	120
9	145	35	110	140	15	125	-5	20	15	140	-5	145
10	90	18	72	145	10	135	55	8	63	145	10	135
11	80	45	35	115	45	70	35	0	35	N/A	N/A	N/A
12	150	55	95	140	20	120	-10	35	25	150	0	150
13	100	30	70	130	25	105	30	5	35	135	18	117
14	110	35	75	120	35	85	10	0	10	125	40	85
15	100	25	75	105	10	95	5	15	20	105	15	90
16	115	15	100	130	5	125	15	1 0	25	130	7	123
17	125	35	90	130	25	105	5	10	15	N/A	N/A	N/A
18	95	10	85	113	30	83	18	-20	-2	110	20	90
19*	90	20	70	120	30	90	30	-10	20	N/A	N/A	N/A
20	90	36	54	126	32	94	36	4	40	130	10	120
21	110	35	75	145	28	117	35	7	42	150	22	128
22	107	35	72	120	30	90	13	5	18	N/A	N/A	N/A

*cases 3, 4, and 19 had release of a surgical contracture after use of the turnbuckle splint

and at the end of turnbuckle splinting.[9] We treated the patients by a custom-moulded orthosis (Truppe Orthotics and Prosthetics, Lambeth, Ontario) designed with an adjustable turnbuckle, so that the same splint could be used for flexion and extension (Fig. 1). The splints could be modified as needed, to improve the fit.

The patients wore the splint for 20 hours per day directed to their maximal contracture. It was worn at night in the position requiring the greatest improvement. At breakfast, lunch, dinner, and before bed, the splint was removed for one hour for periods of active movement. Otherwise, it was worn in alternating positions of flexion and extension. The turnbuckle on the splint was tightened by the patient to the point of stretch, but not pain. As load-relaxation of the soft tissues occurred, it was gradually tightened further by the patient during the period of wear. Turnbuckle splinting was carried out as a home programme without the assistance of supplemental physiotherapy. All patients were followed for at least six months after use of the splint had been discontinued.

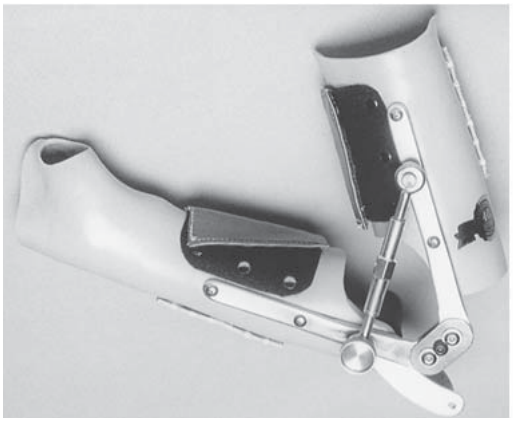

Fig. 1a

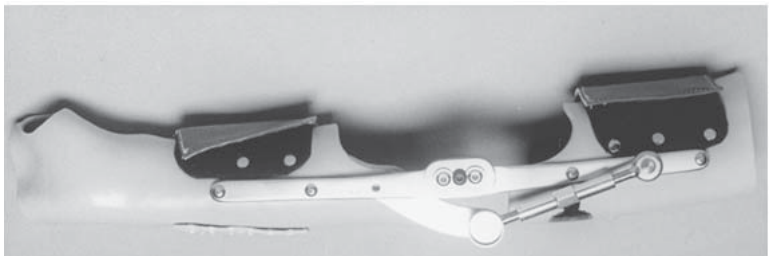

Fig. 1b

The custom-moulded turnbuckle splint. Figure 1a – Using a wrench, the patient adjusts the splint to provide gentle elbow flexion. Figure 1b – The turnbuckle splint with the arm in extension. The attachment site of the bolt is changed to allow controlled passive stretching of the elbow in extension.

We reviewed 18 of the 22 patients (82%) between six and 37 months after use of the turnbuckle splint. One patient could not return for health reasons, one who was one of three who required surgical release of the contracture, was unwilling to return for follow-up and two were not contactable. Patients were examined by an independent observer who was not involved in their care. They completed a questionnaire designed to evaluate subjective satisfaction with the splint and to estimate the duration of time during which it was worn per day. A visual analogue scale was completed summarising the overall satisfaction of each patient.

The change in flexion, flexion contracture, and the total arc of flexion achieved with the turnbuckle splint was compared using a paired Student *t*-test. Univariate linear regression was used to analyse the effects of age, magnitude of contracture and time from injury to application of the splint on the final outcome.

Results

The patients wore their splint for a mean of 4.5 ± 1.8 months. The mean range of flexion before splintage was from 32 ± 10° to 108 ± 19°. After splinting the flexion contracture decreased to a mean of 26 ± 10° ($p = 0.02$) and flexion increased to a mean of 127 ± 12° ($p < 0.0001$). There was a mean gain in flexion of 20 ± 15° and a decrease in the flexion contracture of 5 ± 11°. Before splintage the total arc of elbow flexion was 76 ± 17° and this improved to 100 ± 18°. A total of 11 patients gained a functional arc of movement;[4] eight patients improved but did not achieve this range. Six of these patients were satisfied and did not wish to proceed with surgical treatment; two had a release of their elbow contracture. Three patients showed no improvement with the turnbuckle splint and one of these had a surgical release (Table II).

Neither the age of the patient nor the time between injury and use of the splint had any effect on outcome. There was no correlation between the magnitude of the contracture and the gain in the arc of movement.

Of the 18 patients who returned for an independent follow-up, two had lost more than 10° of movement of the elbow after discontinuing the splint. These patients had post-traumatic arthritis; one had shown no improvement with the turnbuckle and another had improved slightly but had then regressed. Three patients made further gains in their arc of movement after discontinuing splinting.

The mean rating of patient satisfaction on the visual analogue scale was 7.3 ± 1.3, with a score of ten representing very satisfied.

Many patients found difficulty in sleeping and carrying out activities of daily living while wearing the splint. As a result, they could only tolerate wearing the splint for a mean of 15 ± 3 hours daily. Their recall of the number of hours spent daily in the splint was poor and we were therefore not able to correlate compliance with the splinting protocol and the range of movement gained. Two patients reported transient paraesthesiae in the distribution of the ulnar nerve which completely resolved with adjustment of the splint. There was no skin breakdown and no long-term complications were seen.

Discussion

Contracted ligaments, muscles, tendons, or capsule can be corrected using the principle of creep or load-relaxation. Creep occurs when a contracted tissue is placed under a constant load, thereby achieving a change in displacement. Load-relaxation occurs when a contracted tissue is stretched or displaced, thereby creating a load, which dissipates over time.[10,11] Dynamic splinting is based on the principle of creep and static progressive splinting on the principle of

load-relaxation. By tightening the turnbuckle and lengthening the tissues, the splint creates a load which dissipates over time as load-relaxation occurs. The application of prolonged loading to dense connective tissues generates a biological response to modify the length or cross-link integrity of collagen and thereby allows a permanent change in the tissue.[12,13] In static progressive splinting the patient controls the magnitude of the applied load by adjusting the turnbuckle to the maximum load which can be tolerated comfortably. This graduated and prolonged tissue stretching may explain the success of this approach compared with intermittent physiotherapy and static splinting. Dynamic splinting applies a fixed load which may cause pain and diminish compliance with the splinting regime. Soft-tissue damage and inflammation may occur due to overloading of the tissues which may retard remodelling. Dynamic loads which are too small to achieve the desired stretching of the soft tissues may not result in any gains in movement. We know of only two other series reported in the English literature in which static progressive splinting has been used for post-traumatic and postsurgical contractures of the elbow. The most recent review was of 20 patients by Bonutti et al,[1] who used a Joint Active System orthosis. Their mean gain in arc of movement was 31° with approximately equal increase in both flexion and extension. In the other series, Green and McCoy[2] described the results in 15 patients treated by a turnbuckle splint for post-traumatic flexion contractures. They gained a mean of 43° of movement, with 37° of this being in extension.

Our patients did not do as well as those of Green and McCoy[2], possibly because our flexion contractures were less severe being 32° compared with 60° in their series. This probably allowed greater gains in extension, although the final flexion contracture was not considerably different, being 23° in Green and McCoy's patients as opposed to 26° in ours. Our patients had more improvement in flexion by the use of the turnbuckle splint, with a mean improvement of 20°. This may be a reflection of the design of the splint or of the splinting programme, and may be because our patients had only a mean of 108° of flexion before splinting, which is 22° less than was considered functional by Morrey et al.[8] The mean flexion contracture of our patients before splintage was 32° which is close to functional.

Most of our patients were unable to tolerate the splint for 20 hours each day. Unfortunately, due to poor recall of the actual time spent in the splint, we were not able to correlate gains in the range of movement with the number of hours of splintage. The patients of Bonutti et al[1] made their gains by a small number of 30-minute splinting sessions each day. It may therefore be possible to make equal gains with a much less rigorous regime than that used by us. Patient acceptance and satisfaction would be better if this was so. After the application of a load to dense connective tissues, relaxation occurs exponentially.[10,11] The duration for which this stretch has to be applied before biological remodelling of the tissue occurs is unknown.[12,13] Shorter periods of application of the load may achieve the same gains. We found that compliance with the turnbuckle splint tended to decrease as patients approached a functional arc of movement, possibly explaining the ultimate range of flexion achieved with this method of treatment.

A total of 19 of our 22 patients made gains in elbow movement with improvement in the arc of ≥ 10° by the use of a static progressive splint despite not responding to an intensive standardised programme of physiotherapy and static splinting.[9] These improvements in movement were maintained after discontinuation of the splint, except in two patients with post-traumatic arthritis. A functional arc of elbow flexion was achieved in 11 patients, thereby avoiding surgery. Only three of our patients requested surgical release of their residual contracture. No complications were encountered from the use of the splint. In comparison, surgical release of elbow contracture is an expensive undertaking with significant risk to the patient. It also relies on the motivation of the patient and compliance with post-operative rehabilitation to achieve satisfactory results.

Although we could not demonstrate a relationship between time from injury/surgery to improvement in movement after turnbuckle splinting, all our patients were less than seven months from the inital event. While some authors have suggested that turnbuckle splinting may be effective in long-standing elbow contractures this has not been our experience, hence the restricted selection of patients for splinting in our study. We believe that patients in whom turnbuckle splintage is likely to succeed should have some 'springiness' to their extremes of movement, indicating that load-relaxation could occur when the splint is applied. The presence of mild discomfort on stressing the end-ranges is suggestive of ongoing healing of the capsule and ligaments which have the potential for tissue remodelling in response to an applied load. Based on our experience with two patients who had mild post-traumatic arthritis, turnbuckle splinting should be avoided in this group since they did not reliably improve or maintain their range of movement at follow-up. This may be due to the inability of the arthritic joint to tolerate compressive loads generated by the turnbuckle splint and a gradual progression of arthritis over time. There was no correlation between the age of our patients and their response to splinting. Since most of our patients were adults, we cannot comment on this relationship in children.

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References

1. **Bonutti M, Windau JE, Ables BA, Miller BG.** Static progressive stretch to reestablish elbow range of motion. *Clin Orthop* 1994; 303:128-34.
2. **Green DP, McCoy H.** Turnbuckle orthotic correction of elbow-flexion contractures after acute injuries. *J Bone Joint Surg [Am]* 1979; 61-A:1092-5.

3. **Hepburn GR.** Case studies: contracture and stiff joint management with Dynasplint. *J Orthop Sports Phys Therapy* 1987;8:498-504.
4. **Hepburn GR, Crivelli KJ.** Use of elbow Dynasplint for reduction of elbow flexion contractures: a case study. *J Orthop Sports Phys Therapy* 1984;5:269-74.
5. **Karachalios T, Maxwell-Armstrong C, Atkins RM.** Treatment of post-traumatic fixed flexion deformity of the elbow using an intermittent compression garment. *Injury* 1994;25:313-5.
6. **Duke JB, Tessler RH, Dell PC.** Manipulation of the stiff elbow with patient under anaesthesia. *J Hand Surg Am* 1991;16:19-24.
7. **Zander CL, Healy NL.** Elbow flexion contractures treated with serial casts and conservative therapy. *J Hand Surg Am* 1992;17:694-7.
8. **Morrey BF, Askew LJ, An KN, Chao EY.** A biomechanical study of normal functional elbow motion. *J Bone Joint Surg [Am]* 1981; 63-A:872-7.
9. **Armstrong AD, MacDermid JC, Chinchalkar S, Stevens RS, King GJ.** Reliability of range of motion measurement in the elbow and forearm. *J Shoulder Elbow Surg* 1998;7:573-80.
10. **Taylor DC, Dalton JD, Seaber AV, Garrett WE.** Viscoelastic properties of muscle-tendon units: the biomechanical effects of stretching. *Am J Sports Med* 1990;18:300-9.
11. **Woo S.** Mechanical properties of tendons and ligaments. *Biorheology* 1982;19:385-96.
12. **Ilizarov GA.** The tension-stress effect on the genesis and growth of tissues: the influence of rate and frequency of distraction. *Clin Orthop* 1989;239:263-85.
13. **Kottke FJ, Pauley DL, Ptak RA.** The rationale for prolonged stretching for correction of shortening of connective tissue. *Arch Phys Med Rehabil* 1966;47:345-52.

THE JOURNAL OF BONE & JOINT SURGERY (Br)

Post-traumatic contracture of the elbow

OPERATIVE RELEASE USING A LATERAL COLLATERAL LIGAMENT SPARING APPROACH

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We performed a lateral approach for the release of post-traumatic stiffness of the elbow in 22 patients using a modified technique designed to spare the lateral ligaments. They were reviewed after a mean interval of 26 months. The total humeroulnar joint movement had increased from a mean of 74° to 129° and forearm rotation from a mean of 135° to 159°. Both pain and function in the elbow had improved significantly. This modified lateral approach allows release of post-traumatic contracture without disruption of the lateral collateral ligament or the origins of the extensor tendon at the lateral epicondyle of the humerus. The advantages include a simplified surgical procedure, less operative morbidity, and unrestricted rehabilitation.

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Post-traumatic stiffness is common after trauma to the elbow. This has been attributed to fibrosis and thickening of the capsule and periarticular soft tissues.[1-3] Minor degrees of stiffness can be managed by physiotherapy and static or dynamic splinting.[4-6] When this fails and a marked contracture persists, the elbow can be released surgically by a variety of techniques.[1-3,7-10]

One of us (HH) has described the treatment of post-traumatic contracture of the elbow using a lateral approach.[8] An anterior and posterior capsulectomy was performed with release and re-attachment of the lateral collateral ligament and extensor tendon origins at the lateral epicondyle of the humerus. This required postoperative rehabilitation with the shoulder adducted to protect the lateral soft-tissue repair. Two patients developed postero-lateral instability during rehabilitation secondary to avulsion of the soft-tissue structures from the lateral epicondyle (Fig. 1). Surgical repair was required to restore stability to the elbow.

With a greater understanding of the anatomy and role of the lateral collateral ligament,[11,12] we have designed a technique for capsular release and debridement of the elbow to preserve the integrity of these structures. Our aim in this study was to determine if post-traumatic contracture of the elbow can be corrected safely and effectively by a ligament sparing approach.

Patients and Methods

Between December 1988 and April 1995 we operated on 23 patients with post-traumatic contracture of the elbow which had occurred despite a supervised programme including dynamic splinting. They had a flexion contracture of at least 30°, or had less than 100° of flexion or both. Radiologically, all the elbows were congruous with an adequate humeroulnar joint space. We excluded all patients with spasticity, burn contractures, associated injury to the head or spinal cord, rheumatoid arthritis or significant heterotopic ossification. One patient was lost to follow-up, leaving 22 available for evaluation.

There were 12 men and 10 women, with a mean age of 35 years (15 to 72) at the time of operation (Table I). The average length of follow-up was 29 months. In 14 of the patients the dominant limb was affected. The mean interval from the initial injury to surgery was 5.8 years (median 2.1).

The details of the injuries are shown in Table I. Two patients had an associated dislocation of the joint with a periarticular fracture. Four patients with a history of remote trauma had radiological evidence of osteochondritis dissecans of the capitellum. A total of 16 operations had been carried out on the affected elbow in 12 patients (Table I).

The office and hospital charts of each patient were reviewed; all returned for assessment and each completed a detailed questionnaire. Pain was rated according to severity and frequency of occurrence. Visual analogue scales were used to assess peak and general levels of elbow pain on an average day, night pain, the limits of the elbow with respect to hobbies or sports and satisfaction with the surgical

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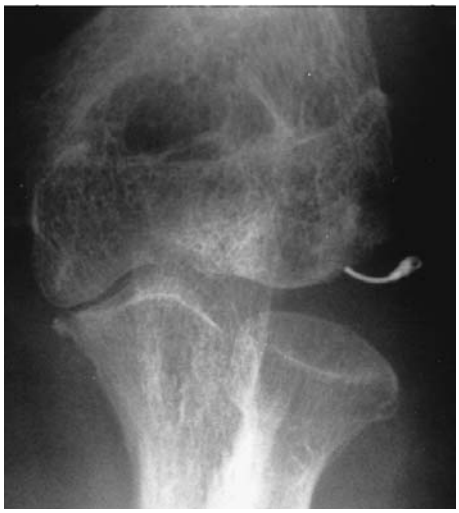

Fig. 1a

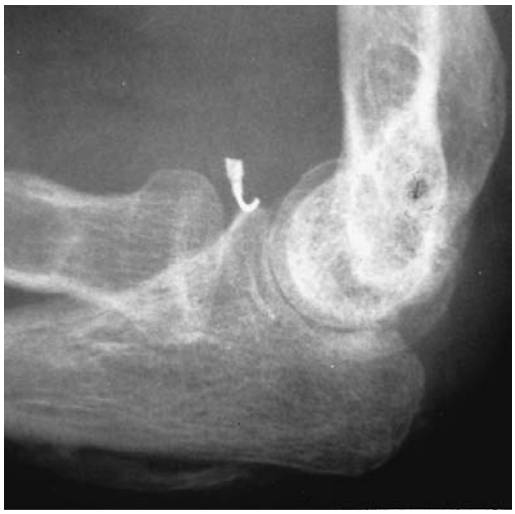

Fig. 1b

Anteroposterior (a) and lateral (b) radiographs of a patient after elbow release through an exposure requiring release and re-attachment of the lateral collateral ligament and the extensor origin.[8] There is avulsion of the bone anchor used to reattach the lateral soft tissues. This patient developed posterolateral instability and required surgery to restore the integrity of the lateral side of the elbow.

result.[13] Elbow function was determined by a questionnaire developed at the Mayo Clinic based on the ability to carry out 12 common tasks.[8,14] Additional questions were included to allow determination of the Mayo Elbow Performance Index for each patient.[2,15]

The recorded physical findings at follow-up consisted of the range of elbow movement, the presence of tenderness or crepitus, medial or posterolateral instability, a careful motor and sensory examination with determination of two-point discrimination, and grip strength. Anteroposterior, lateral and oblique radiographs were taken and examined for the presence of osteophytes, advancement in joint degeneration, loose bodies or heterotopic bone. We performed statistical analysis using the Student's *t*-test on the numerical data and the Wilcoxon rank-sum test on the visual analogue scales. Differences were regarded as significant when $p < 0.05$. The two-tailed test was used in all cases.

Operative technique. Under regional anaesthesia with a long-acting axillary block an extended Kocher incision was used beginning along the lateral supracondylar ridge of the humerus and passing distally in the interval between the anconeus and the extensor carpi ulnaris (ECU).[16] The anconeus was reflected posteriorly with dissection carried out proximally beneath the lateral epicondyle and along the supracondylar ridge of the humerus, thereby reflecting both the anconeus and triceps posteriorly (Fig. 2). A triceps tenolysis was carried out with an elevator, releasing any adhesions between the muscle and the posterior humerus. The humeroulnar joint was identified posteriorly and the olecranon fossa cleared of any fibrous tissue or scar which would restrict terminal extension. The tip of the olecranon was removed if there was evidence of overgrowth or impingement (Fig. 2). The posterior aspect of the radiocapitellar joint was inspected after excision of the elbow capsule just proximal to the conjoined lateral collateral and annular ligament complex through the 'soft spot' on the lateral side of the elbow. The proximal edge of this complex lies along the proximal border of the radial head.[11]

Once the posterior release was completed, dissection was carried anteriorly releasing the brachioradialis and extensor carpi radialis longus (ECRL) from the lateral supracondylar ridge of the humerus (Fig. 3). The brachialis was then mobilised off the humerus and anterior capsule with an elevator, releasing any adhesions between the muscle and the anterior humerus. This dissection was continued distally between the ECRL and extensor carpi radialis brevis (ECRB), allowing exposure of the anterior capsule with preservation of the lateral collateral ligament and the origins of the ECRB, the extensor digitorum communis (EDC) and minimi and the ECU from the lateral epicondyle. Dissection was then carried out beneath the elbow capsule between the joint and the brachialis. The capsule was then excised as far as the medial side of the joint. The radial and coronoid fossae were cleared of fibrous tissue and the tip of the coronoid removed if overgrowth or impingement was noted in flexion. Loose bodies were removed (Fig. 3).

With radiocapitellar degeneration the joint was debrided or the radial head resected through the anterior capsulectomy using an oscillating saw or osteotome without dissection of the lateral collateral ligament complex.[11,12]

After release of the anterior capsule, gentle extension of the elbow with applied pressure would usually bring the joint out to nearly full extension. In longstanding cases of contracture the brachialis muscle can be tight inhibiting full terminal elbow extension. This myostatic contracture could be stretched for several minutes during the procedure and required attention at subsequent physiotherapy. After clo-

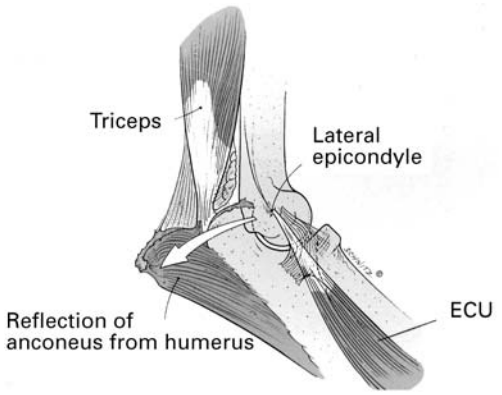

Fig. 2a

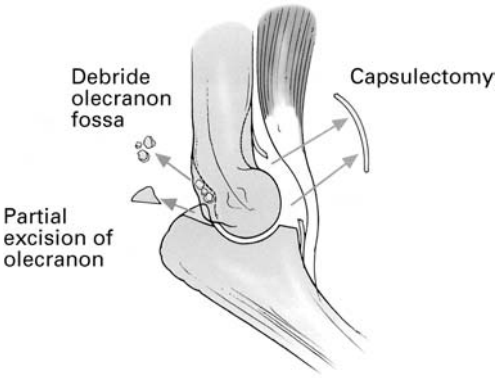

Fig. 2b

Diagrams showing the posterior approach to the elbow for operative debridement and release. The interval between the anconeus and ECU is split and anconeus and triceps reflected posteriorly (a). This allows tenolysis of the triceps, resection of the posterior capsule and debridement of the olecranon and its fossa (b).

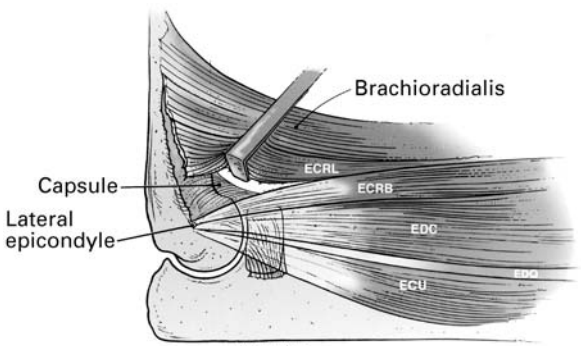

Fig. 3a

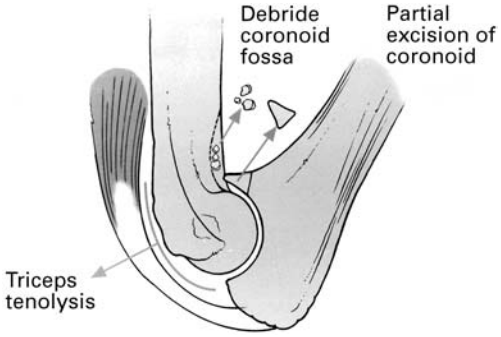

Fig. 3b

Diagrams showing the anterior approach to the elbow for debridement and release. The brachialis and ECRL are released from the supracondylar ridge of the humerus exposing the anterior elbow capsule which is excised (a). The coronoid and radial fossae can then be debrided, the tip of the coronoid removed and the radiocapitellar joint inspected (b).

sure the dressing was cut out over the antecubital fossa to allow elbow flexion. Continuous passive movement was started in the recovery room and maintained until the following morning.

Physiotherapy began on the first postoperative day with active and passive movement, intermittent continuous passive movement and the wearing of a dynamic elbow brace. To gain extension, weighted passive stretches using a wrist weight of 1 or 2 kg with the elbow extended over a bolster were performed several times daily. Since the collateral ligaments were not released, there were no restrictions on movement.

All patients had an anterior and posterior release from the lateral side with excision of bony overgrowth and osteophytes. Three patients had metal removed at the time of the procedure. Five had excision of the radial head for arthritis and in nine, loose bodies were identified and removed. Two patients with ulnar neuropathy had an anterior subcutaneous transposition of the nerve through a second medial incision. In none of these was the joint entered or debridement carried out from the medial side.

The patients remained in hospital for an average of 2.4 days after operation. Outpatient rehabilitation was continued two to three times per week for approximately four to six weeks. Continuous passive movement was continued at home for approximately four weeks. Intermittent dynamic elbow bracing and weighted elbow stretches were continued for eight to 12 weeks and subsequently as required. All patients received oral indomethacin for six weeks after operation as prophylaxis against heterotopic ossification.

Results

Movement. The total elbow movement improved in all patients (Fig. 4; Table I). Extension increased from a mean of 39° to 8°. The mean elbow flexion increased from 113° to 137°, giving a mean increase in the total range of movement in the humeroulnar joint of 55° ($p < 0.001$). Mean supination improved from 68° to 83° and pronation from 67° to 75° ($p < 0.01$).

Pain. As shown in Tables II and III the frequency of elbow pain decreased in all patients ($p < 0.001$). Both peak pain and the general level of pain on an average day diminished significantly at follow-up ($p < 0.001$) as did night pain inhibiting sleep ($p < 0.001$). Ten patients continued to take analgesics. Eight used aspirin or a non-steroidal anti-

Table I. Details of 22 patients with post-traumatic contracture of the elbow

Case	Gender	Age (yr)	Initial injury	Prior treatment	Interval from injury to operation (mth)	Additional procedures	Active extension (degrees)		Active flexion (degrees)		Supination (degrees)		Pronation (degrees)		Complications	Duration of follow-up (mth)
							Preop	Postop	Preop	Postop	Preop	Postop	Preop	Postop		
1	F	37	Radial head, fracture of the capitellum	Excision osteochondral fragments	7	Radial head excision	50	0	120	150	35	90	60	90		15
2	F	39	Supracondylar fracture of the humerus	Cubital tunnel release	14		35	10	90	135	85	95	75	90		35
3	F	44	Ulnar fracture	ORIF*	20	Metal removal	40	10	95	150	50	65	75	70		33
4	F	20	Radial head fracture		7		40	0	120	150	45	90	80	90		73
5	F	72	Radial head fracture		4	Radial head excision	40	10	70	135	20	80	30	70		32
6	M	37	Olecranon fracture	ORIF Metal removal	60		45	25	110	135	90	90	80	85		16
7	F	52	Radial head fracture		6		40	0	120	150	55	85	80	90	Transient ulnar neuritis, late synovitis	30
8	M	19	Supracondylar fracture of the humerus	ORIF	36		40	5	135	145	90	90	90	90	Postop pain	40
9	M	26	OCD† capitellum		192		25	5	120	125	80	75	60	75		36
10	M	40	Radial head fracture		26		30	15	120	120	80	80	80	80		24
11	F	16	Radial head fracture		6		50	10	140	135	90	90	90	90	Transient median neuritis	22
12	F	46	Fracture dislocation	ORIF capitellum	8	Metal removal Anterior transposition ulnar nerve	60	15	105	150	90	90	90	90		15

13	M	15	OCD capitellum	Arthroscopic removal loose bodies	48		30	5	120	130	60	65	80	70		26
14	F	34	Fracture dislocation	ORIF radial head	4	Metal removal Anterior transposition ulnar nerve	45	0	70	140	30	85	50	50		27
15	M	31	Supracondylar and intracon-dylar fracture of the humerus	Cubital tunnel release, radial head excision	204		55	5	110	125	75	80	45	50		28
16	F	21	Supracondylar and intracon-dylar fracture of the humerus	ORIF, metal removal	40		45	10	125	135	90	80	70	45		25
17	M	20	Radial head, coronoid fracture		17		45	10	120	135	80	80	45	70		19
18	M	49	Radial head fracture	Joint debridement	36	Radial head excision	30	15	105	135	60	85	45	65	Transient ulnar neuritis	27
19	M	48	Radial head fracture		24		35	8	120	135	80	80	80	80		25
20	M	30	OCD capitellum	Anterior transportation ulnar nerve joint debridement	180	Radial head excision	35	5	110	135	75	85	45	70		32
21	M	31	Radial head fracture, coronoid fracture		180		30	10	120	135	60	80	50	60	Transient ulnar neuritis	30
22	M	55	OCD capitellum		400	Radial head excision	15	0	130	135	80	85	70	80	Late elbow synovitis	33

* open reduction and internal fixation
† osteochondritis dissecans

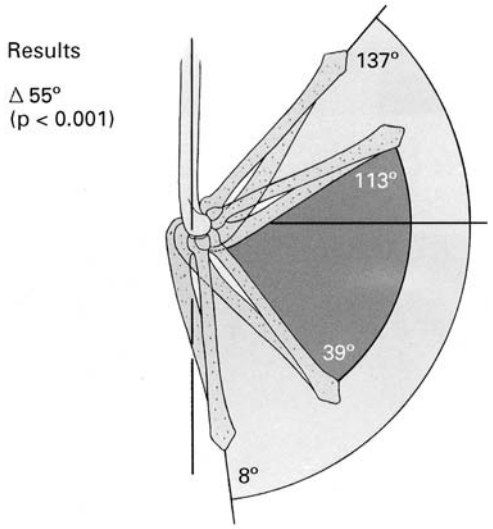

Fig. 4a

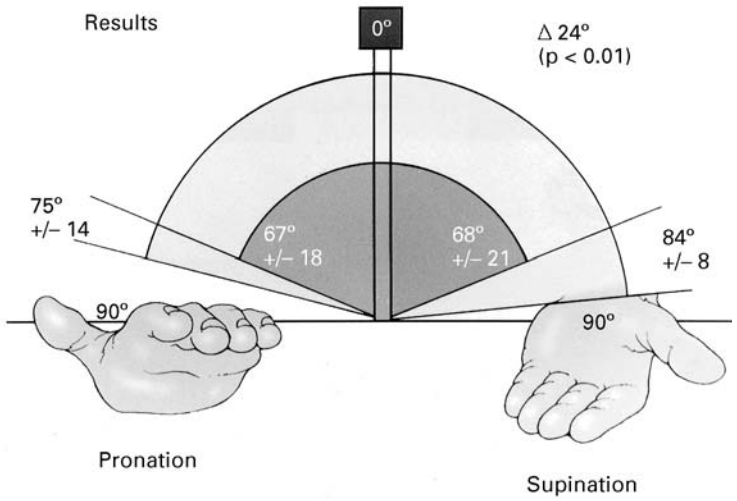

Fig. 4b

Diagram of average active range of elbow flexion and extension (a) and supination and pronation (b) preoperatively and at follow-up.

Table II. Number of patients with elbow pain preoperatively and at follow-up

	Never	Rare (1 to 2 times per year)	Occasional (1 to 2 times per month)	Frequent (every week)	Daily
Preop	0	0	2	4	16
At follow-up	4	8	7	0	3

inflammatory agent, and two intermittently used narcotics. When examined one patient experienced discomfort at the extreme of elbow flexion and another at terminal extension.

Function. The scores in Table IV show a significant improvement, after operation, in elbow function[8,14] ($p < 0.001$). The Mayo Elbow Performance Index ($p < 0.001$), the patient's assessment of how their elbow limited their most strenuous activities ($p < 0.001$), and the reported overall handicap which the affected elbow caused in the patient's lifestyle ($p < 0.001$) were all better. Patient satisfaction was a mean of 8.8 on a score from 0 to 10.

On examination, no patient had clinical evidence of instability of the posterolateral joint.[12] Two had slight laxity of the medial side during stress testing but this was not a functional problem. Four patients had palpable crepitus during active flexion and extension, and one during rotation of the forearm. The mean grip strength of the affected arm was 44.5 kg at follow-up. This compared favourably with the 47.2 kg in the unaffected arm ($p > 0.05$). Preoperative measurements of grip strength were available for 15 patients. In this subset, strength improved from 38.6 kg preoperatively to 49.5 kg at follow-up ($p < 0.002$).

Table III. Level of pain and mean (± SD) pain severity score preoperatively and at follow-up in 22 patients

	Pain severity score	
	Before operation	At follow-up
Pain frequency (1 to 5)	4.6 ± 0.7	2.5 ± 1.2
Peak level of pain (0 to 10)	7.3 ± 2.5	1.3 ± 2.0
General level of pain (0 to 10)	6.4 ± 3.0	0.8 ± 1.3
Night pain (0 to 10)	6.1 ± 3.3	0.7 ± 1.0

Radiological evaluation. Radiological analysis showed that no patient had regrown excised osteophytes or produced further loose bodies. One had mild progression of humeroulnar degenerative changes after 24 months and five had small foci of soft-tissue calcification anteriorly or

Table IV. Mean (± SD) elbow function score and Mayo performance index in 22 patients preoperatively and at follow-up

	Elbow function score	
	Before operation	At follow-up
Mayo performance index[15] (0 to 100)	50 ± 14	89 ± 12
Mayo function task analysis[8,14] (0 to 12)	6.5 ± 2.8	11.1 ± 1.2
Elbow limitation in activities (0 to 10)	7.8 ± 2.0	1.2 ± 2.0
Elbow handicap on lifestyle (0 to 10)	7.1 ± 2.0	1.5 ± 1.7

posteriorly which did not affect elbow movement.

Complications. One patient had severe pain requiring a regional anaesthetic block on the third day after operation. This eventually resolved after six days in hospital. Three patients developed symptoms of ulnar neuritis and one of median nerve dysfunction but none had measurable motor or sensory deficits. All the symptoms were transient and had cleared by three months.

Two patients developed an episode of late pain and synovitis in the elbow associated with increased activity, one after six months and the other after seven. They were treated by an intra-articular injection of cortisone and a period of reduced activity.

Discussion

Loss of movement after injury to the elbow is common and has been attributed to the intrinsic congruity of the joint, the presence of three articulations in a single capsule and the proximity of the articular surface and capsule to the intracapsular ligaments and extracapsular muscles.[2] Prolonged immobilisation of the elbow after trauma may result in stiffness. Once established, minor elbow contractures can often be treated successfully by physiotherapy and the wearing of dynamic splints or braces.[4-6] When conservative measures fail, the elbow can be released by a variety of surgical techniques.[1-3,7-9,17]

The advantages of a lateral exposure include an internervous plane, an incision in the neutral axis of flexion-extension making wound problems less likely with early movement, and the ability to see and treat both the anterior and posterior humeroulnar and the radiocapitellar joints through one incision. This preserves the collateral and annular ligaments and the origins of the extensor complex while allowing complete exposure of the anterior and posterior elbow. The advantages include a simplified surgical dissection, less operative morbidity and the preservation of the lateral ligaments to prevent subsequent instability.

In our series the gains in rotation can be attributed to concomitant resection of the radial head (five patients), removal of metal, debridement of the radiocapitellar joint and pain relief in conjunction with a supervised post-operative physiotherapy programme. Elbow function, as measured by standardised scales, significantly improved (Table IV). Patients reported their elbow to be less of a disturbance and handicap to their most vigorous activities. No patient had clinical or functional evidence of significant joint instability. These results compare favourably with our previous technique for lateral elbow release[8] as well as with reports using anterior or medial approaches.[1,3,10,18]

We assessed pain by a variety of visual analogue scales.[13] The frequency of pain, the peak and general level of pain in the elbow on an average day and night pain all significantly improved after release and debridement (Tables II and III). The relief of symptoms is probably attributable to the removal of osteophytes, loose bodies, degenerative radiocapitellar arthritis, and bony and soft-tissue impingement within the joint. Excision of the anterior and posterior elbow capsule, however, may lead to a partial denervation of the elbow. Radiological evaluation showed slight progression of humeroulnar joint degeneration in only one patient at an average follow-up of two years. Long-term follow-up will be needed to determine if there is any deleterious effect from removal of the joint capsule.

The most common complication was the development of transient paraethesiae in the distribution of the ulnar nerve which was seen in three patients. This may in part be related to improved flexion after surgery. Tension in the ulnar nerve increases in elbow flexion and may lead to symptoms in a nerve which is compromised to a subclinical degree. Trauma can itself lead to oedema and fibrosis in the cubital tunnel with resultant nerve symptoms. Three of the 22 patients in our study had had prior surgery for cubital tunnel syndrome and two had anterior transposition of the ulnar nerve at the time of their elbow release. We now recommend release and transposition of the ulnar nerve in patients with symptoms or in those who have positive provocative tests for impingement of the ulnar nerve (a Tinel's sign or a positive elbow flexion test).[18]

Special mention must be made of the postoperative rehabilitation required after capsular release. The rehabilitation programme consists of daily continuous passive movement at home, weighted elbow stretches, active and passive exercises at home and under supervision, and a dynamic elbow brace. Patients must be motivated and understand the commitment required. Although most improvement occurs within the first six to eight weeks, patients must continue their home programme since movement can continue to improve for up to three to four months after the procedure. This is especially true for longstanding contractures.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References

1. **Gates HS, Sullivan FL, Urbaniak JR.** Anterior capsulotomy and continuous passive motion in the treatment of post-traumatic flexion contracture of the elbow: a prospective study. *J Bone Joint Surg [Am]* 1992;74-A:1229-34.
2. **Modabber MR, Jupiter JB.** Current concepts review: reconstruction for post-traumatic conditions of the elbow joint. *J Bone Joint Surg [Am]* 1995;77-A:1431-46.
3. **Urbaniak JR, Hansen PE, Beissinger SF, Aitken MS.** Correction for post-traumatic flexion contracture of the elbow by anterior capsulotomy. *J Bone Joint Surg [Am]* 1985;67-A:1160-4.
4. **Dickson RA.** Reversed dynamic slings: a new concept in the treatment of post-traumatic elbow flexion contractures. *Injury* 1976;8:35-8.
5. **Green DP, McCoy H.** Turnbuckle orthotic correction of elbow-flexion contractures after acute injuries. *J Bone Joint Surg [Am]* 1979;61-A:1092-5.
6. **Hepburn GR, Crivelli KJ.** Use of elbow dynasplint for reduction of elbow flexion contractures: a case study. *J Orthop Sports Phys Ther* 1984;5:269-74.
7. **Hastings H II.** Elbow contractures and ossification. In: Peimer C, ed. *Surgery of the hand and upper extremity.* New York: McGraw-Hill, 1996:507-34.

8. **Husband JB, Hastings H.** The lateral approach for operative release of post-traumatic contracture of the elbow. *J Bone Joint Surg [Am]* 1990;72-A:1353-8.
9. **Morrey BF.** Post-traumatic contracture of the elbow: operative treatment including distraction arthroplasty. *J Bone Joint Surg [Am]* 1990; 72-A:601-18.
10. **Willner P.** Anterior capsulectomy for contractures of the elbow. *J Internat College Surg* 1948;11:359-61.
11. **Cohen MS, Hastings H.** Rotatory instability of the elbow: the anatomy and role of the lateral stabilizers. *J Bone Joint Surg [Am]* 1997;79-A:225-33.
12. **O'Driscoll SW, Bell DF, Morrey BF.** Posterolateral rotatory instability of the elbow. *J Bone Joint Surg [Am]* 1991;73-A:440-6.
13. **Huskisson EC.** Measurement of pain. *Lancet* 1974;2:1127-31.
14. **Morrey BF, An KN, Chao EYS.** Functional evaluation of the elbow. In: Morrey BF, ed. *The elbow and its disorders.* Philadelphia: W. B. Saunders, 1985:73-91.
15. **Morrey BF, An KN, Chao EYS.** Functional evaluation of the elbow. In: Morrey BF, ed. *The elbow and its disorders.* Second edition. Philadelphia: W. B. Saunders, 1993;86-97.
16. **Crenshaw AH,** ed. Surgical approaches. In: *Campbell's operative orthopaedics.* 7th ed. St Louis, etc: CV Mosby Co, 1987:23-107.
17. **Wilson PD.** Capsulectomy for the relief of flexion contractures of the elbow following fracture. *J Bone Joint Surg* 1944;26:71-86.
18. **Novak CB, Lee GW, MacKinnon SE, Lay L.** Provocative testing for cubital tunnel syndrome. *J Hand Surg Am* 1994;19:817-20.

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Static Progressive Forearm Rotation Contracture Management Orthosis Design: A Study of 28 Patients

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ABSTRACT

*Loss of forearm rotation can lead to significant loss of upper limb function. Operative treatment to improve rotation of the forearm at both the proximal radioulnar joint and distal radioulnar joint has been reported. There are limited orthosis designs available to address this clinical problem and limited information about the efficacy of conservative management of forearm rotation stiffness. A unique orthosis design was fabricated to provide static progressive motion for forearm rotation motion: supination and pronation. The orthosis design consisted of a custom-molded polyethylene hinged elbow orthosis with a dual offset channel overlapping an adjustable rotation component. Attempts were made to align the anatomical axis for forearm rotation motion with the mechanical axis of the orthosis. All orthoses used were adjustable from full supination to full pronation range of motion. A study was carried out to track the progress and results of 28 patients with loss of forearm rotation. Patients with synostosis or malunion of forearm fractures were excluded. Patients were included if they had 50° or less of supination, pronation, or both. Average initial supination was 33.2°, and final supination averaged 68.1°. Average gain was 36.5°. Twenty-three patients (92%) gained motion, 17 (68%) gained a functional arc. Initial pronation averaged 49.3°, and final pronation was 74.0°. Average pronation gain was 25.8°. This report describes the design details and the fit criteria and challenges. It also demonstrates the effectiveness of this type of static progressive stretching to improve forearm stiffness related to soft tissue contracture. (*J Prosthet Orthot. *2006;18:63–67.)*

Designs of upper limb orthoses vary from simple prefabricated three-point pressure systems to more elaborate high temperature (fabricated from plaster mold of patient) designs. All orthosis designs with articulations share a common goal of attempting to match the anatomical axis to the mechanical axis to provide simultaneous movement along the same plane of motion. One of the more difficult upper limb axes of motion to mimic in a mechanical design is the motion of forearm rotation: pronation and supination. The anatomical axis for forearm rotation is defined as a longitudinal axis that extends from the ulnar head to the radial head. The anatomical axis extends the entire length of the forearm (Figure 1). The custommolded orthosis design effectively moved the patient's forearm through the entire range of motion-full supination to full pronation-with adequate limitation of substitution by circumferentially encompassing the forearm with a molded forearm cuff attached to the adjustable rotation component.

Operative treatment to improve rotation of the forearm at both the proximal radioulnar joint (PRUJ) and distal radioulnar joint (DRUJ) has been reported. [1–4] However, there is limited information about the efficacy of conservative management of forearm rotation stiffness. Nonoperative management alone is not effective in loss of forearm rotation related to mechanical malalignment or bony block. [3] Causes of stiffness amenable to conservative treatment include elbow trauma from fracture/ dislocation, isolated radial head injury, and reconstructive procedures, such as radial head resection, arthroplasty, or ligament reconstruction. Distal radius fractures, ulna fractures, DRUJ or wrist ligament reconstruction procedures can lead to rotation stiffness that can be treated with orthoses, provided the limitation is not bony in nature. Although the reported functional range of motion (ROM) for forearm rotation is 100°, centered in neutral rotation, [5] individual needs can vary. For example, the increasing use of keyboards places a premium on forearm pronation, whereas for a guitar player, maximal supination is critical. The concept of positioning the shortened tissue at or near the end of its currently available range of motion is referred to as low load, prolonged stretch therapy, and is most effectively accomplished with the use of orthoses. [6] The force can be applied via different techniques, including static progressive stretching, dynamic splinting, or static serial casting. Technical challenges to designing effective forearm stretching orthoses include difficulty with aligning the axis of rotation, short lever arms with which to apply stretching force, and soft tissue containment.

Connective tissue of the capsule demonstrates viscoelastic properties. [6] The collagen latticework has a high tensile resistance to rapidly applied loads but demonstrates the properties of creep and stress relaxation in response to sustained loads. This plastic elongation has been attributed to the "separation of the attachments at the points of contact of adjacent collagen fibers in the connective tissue meshwork," [7] rather than from the actual ductility of the collagen fibers. This material property of capsular tissue forms the basis for the use of stretching orthoses.

Static progressive orthotic management (SPOM) uses the principle of stress relaxation. By definition, the amount of force required to maintain tissue at a given length decreases with time. [6,8] Serial casting uses the same principles but is much more labor and time intensive. [9,10] An incrementally adjustable orthosis controlled by the patient allows a set force to be applied that slightly exceeds the elastic limit of the tissue, resulting in relaxation and stretch. The tissue elongation occurs via reorganization of the collagen matrix and the breaking and reforming of the attachments of the fibers at greater distances. Properly applied, there is little inflammation of the tissue, resulting in minimal pain, improved compliance, and much better acceptance by the patients. SPOM allows for infinite adjustability and control of tissue tension and joint position compared with dynamic splinting. [6] SPOM has been effectively applied to address elbow flexion contractures [11–13] but has received limited attention for forearm rotation.

Loss of joint motion may be related to capsular contracture, shortening of the musculotendinous units through spasm, cocontraction, or contracture, or changes of the articular surface and/or bony blocks. The latter two causes are not addressed in this study. The connective tissue of the capsule is loose areolar tissue with a meshwork structure. The collagen, elastin, and reticular fibers are loosely connected by ground substance and by chemical bonds. The mobility of this tissue is determined by the distance between the points of attachment of the collagen fibers. [7] There exists potential energy in the collagen lattice with a tendency for the fibers to contract and reorganize unless countered by an opposing force. The normal mobility of the elbow or wrist joint provides the opposing force to these tissue changes. Thus, when the joint is immobilized, these forces are restricted, allowing for shortening, primarily by fiber reorganization, which leads to the thickening and increased stiffness of the capsular tissue readily seen in contracted joint capsule. Trauma, edema, or ischemia exacerbates this process by stimulating the production of additional collagen fibers via active fibroblastic activity.

These conformational changes may occur in as little as 3 days. [7] The purpose of this study is to evaluate the results of the use of a static progressive orthosis for improvement of forearm rotation caused by soft tissue contracture and to demonstrate the effectiveness of this new design of orthosis.

PATIENTS AND METHODS

Twenty-eight patients (15 men, 13 women; average age, 41.2 years; range 23–64 years) received treatment with static progressive orthoses. Half (14) had stiffness related to the PRUJ, 13 had stiffness related to the DRUJ, and 1 had stiffness related to both. Causes of stiffness included elbow fracture/dislocation (6), isolated radial head injury (3), status post radial head resection (5), distal radius fracture (10) wrist ligament reconstruction (2), and ulna fracture (2). Six patients received their orthoses following surgery for postoperative stiffness. Patients with synostosis or malunion of forearm fractures were excluded. Functional range of motion was defined as 50° supination and 50° pronation.[5] Patients were included if they had 50° or less of supination, pronation, or both. All 28 patients were seen initially for evaluation and molding in preparation for fabrication. Average time from date of surgical release or date of injury to placement of orthosis was 7.6 weeks, with a median of 8 weeks (range, 2–12 weeks). Rotation splinting was continued for at least 3 months, or until a plateau was achieved.

Evaluation included determination of elbow joint location at an approximation of the difference between the location of the center of the medial and lateral epicondyles. Any bony abnormalities or prominence of surgical hardware were noted in the mold. The patients underwent the molding process in a position of 80° flexion and neutral forearm rotation (when applicable and patient tolerated this position). If a patient was unable to achieve this molding position, the mold was taken at a position as close to this as possible to facilitate joint alignment of the rotation component. Negative molds were filled and positive molds were modified with minimal plaster addition or removal. Approximation of soft tissue compression, especially on the humeral section, was reduced on the positive mold to achieve an intimate fit. True anatomical shape of the forearm was not compromised with plaster modification.

The mechanical joint at the elbow consisted of two options depending on the presence of a flexion or extension contracture in conjunction with the forearm rotation contracture. If the secondary flexion/extension contracture were present, a static progressive joint was used to address this limitation with the same protocol (Figure 2). If no secondary limitation existed, a free range joint was used at the elbow (Figure 3).

Although unable to directly mimic the anatomical axis of the forearm (Figure 1) with the mechanical axis of the orthosis, the rotation component included movement of the entire forearm component around the static humeral/elbow section of the orthosis. The shape of the forearm section of the orthosis remained accurate to the exact shape of the patient's forearm. The outside of the forearm component had several layers of additional polyethylene added to produce a smooth round surface over which the rotation motion would glide smoothly and without resistance (Figure 4). The total contact nature of the forearm component was used to most closely approximate the anatomical axis of rotation and prevent substitution by radiocarpal rotation, which is likely with a less-than-intimate fit between the forearm component and the patient's forearm. All orthoses were adjustable from full supination to full pronation ROM (Figure 5). Dual offset slots were meticulously cut into the overlapping component to facilitate integrity of the rotation component itself and allow full ROM in directions of both pronation and supination.

Custom orthoses were fit to patients within 1 week of initial presentation. Range-of-motion measurements were taken during each follow-up appointment and entered as data. Patients were seen

at 4-week intervals. Range-of-motion measurements used for data analysis were all performed by one physician with a standard technique. We standardized the measurement of forearm rotation by referencing the longitudinal axis of the humerus, rather than to "vertical," to eliminate the error associated with shoulder internal and external rotation. [14] Patients underwent aggressive hand therapy in conjunction with orthotic management. Passive ROM and/or manipulation were not performed by the therapist. Orthoses were adjusted as needed for fit problems, decreases in swelling, or increases in muscle tone. However, with the use of 1/8-inch polyethylene material for humeral and forearm shells, a certain amount of patient adjustment to compensate for decreases or increases in volume was allowed.

Detailed written donning instructions were provided to all patients. A written wearing schedule was provided and explained verbally at the time of orthosis fitting. The protocol for the determination of the wearing schedule began with the most severe limitation being addressed during sleep (6–8 hour session). Three daily wearing sessions of 3 to 4 hours each were alternated between the more severe limitation and the opposing motion (Table 1). The orthosis was removed for 1 to 2 hours between wearing sessions, and functional use of the forearm and skin maintenance were encouraged. Patients were instructed to apply the orthosis in a neutral, mid-arc position, then apply rotation force in the desired direction until a strong stretching sensation was felt. They were then instructed to relax the stretch slightly, and set the position. This submaximal stretch protocol enhanced patient compliance, while providing for the stress relaxation response. Degree markings were not provided on the orthosis because patients were encouraged to apply the stretch that was tolerable at each session.

RESULTS

Duration of splinting was 12 to 24 weeks. Average initial supination was 33.2° (range, 0° – 48°), and final supination averaged 68.1° (range, 10° –90°). Average gain was 36.5° (range, .20° – 80°). Twenty -three (92%) patients gained motion; 17 (68%) gained a functional arc. Initial pronation averaged 49.3° (range, 0° –90°), and final pronation was 74.0° (range, 40° –90°). Average pronation gain was 25.8° (range, 10° – 69°). All gained pronation, and 87% achieved a functional arc (Table 2). Complications included radial sensory nerve neurapraxia in two patients. Only two patients in this series required surgery for failure to achieve functional rotation.

DISCUSSION

The efficacy of static progressive splinting SPOM for the treatment of elbow flexion/extension contracture has been well documented. [11,12,15] Serial casting is a more labor-intensive form of SPOM, which has been successful as well. [9,16] Despite the documented results of conservative management of elbow flexion/ extension contracture with SPOM, there are no reported results with the use of SPOM to treat rotation contracture of the forearm. We are reporting the only known large series of patients with forearm contracture effectively treated with static progressive orthoses.

Green and McCoy [15] reported the effective treatment of 12 of 15 patients with elbow flexion contracture with turnbuckle splinting. The demographics of the patients are similar to those in this study. Treatment was initiated later, at an average of 5.3 months after injury or operation. Failure to obtain an acceptable correction occurred in three patients, all of whom had intraarticular incongruity. Bonutti et al. [11] reported an average increase of 31° in elbow ROM in 20 patients with elbow flexion/ extension contracture. Only 8 of 20 obtained a "functional" arc of motion (30°–130° of elbow flexion/extension) The static progressive device was worn for only two 30-minute periods per day. Patient compliance and satisfaction were high, despite the limited functional results. More recently, Gelinas et al. [12] reported the result of turnbuckle splinting for the treatment of elbow flexion/extension

contracture in 22 patients. They demonstrated improvement in the ROM of 19 of 22 patients, although a functional arc was obtained in only 11 of 22. Three patients experienced no improvement, with one patient ultimately undergoing surgery to improve ROM.

We are reporting the design of a static progressive orthosis and the only known series of patients treated with SPOM for forearm rotational stiffness. Patients with diminished forearm rotation from PRUJ and/or DRUJ causes have been included, and improvement was noted in each group. Ongoing data collection with more patients is under way, with the hope that these different groups can be compared to determine if efficacy and prognostic differences exist. These orthoses are well tolerated by the patients, and self-reported compliance is high. Although the initial cost of custom-made orthoses can be high, the combination of demonstrated effectiveness, as well as unlimited pre- and postoperative use, make this device cost effective when compared with the monthly rental charges required for commercially available SPOM rotation orthoses. There was noticeable difference in the amount of time required for patients to wear the orthoses. All patients were told the minimum amount of time for orthotic treatment would be 3 months. They were also told that this time would extend until improvements in range of motion plateaued. This time varied between 3 and 12 months.

One potential weakness of the study was the inclusion of multiple diagnoses, including PRUJ and DRUJ causes for rotation loss. Pre- and postoperative orthosis use also is included. Despite this varied population, we thought the universal improvement of forearm rotation across this disparate group warranted the inclusion of these varying diagnoses/situations.

We have demonstrated the ability of this static progressive orthoses to reliably obtain/maintain a functional arc of forearm rotation in a variety of conditions. Treatment with this orthosis is well tolerated by the patients, and patient compliance is high. Additional studies are in progress to evaluate this device for the correction of proximal versus distal forearm rotation problems, as well as the efficacy for specific diagnosis. This static progressive stretching orthosis design provides an effective treatment modality for improving rotation of the forearm axis.

ACKNOWLEDGMENTS

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References:

1. Bell SN, Benger D. Management of radioulnar synostosis with mobilization, anconeus interposition, and a forearm rotation assist splint. *J Shoulder Elbow Surg* 1999;8(6):621–624.

2. Cohen MS, Hastings H II. Post-traumatic contracture of the elbow. Operative release using a lateral collateral ligament sparing approach. *J Bone Joint Surg Br* 1998;80(5):805–812.
3. King GJ, Faber KJ. Posttraumatic elbow stiffness. *Orthop Clin North Am* 2000;31(1):129–143.
4. Kleinman WB, Graham TJ. The distal radioulnar joint capsule: clinical anatomy and role in posttraumatic limitation of forearm rotation. *J Hand Surg [Am]* 1998;23(4):588–599.
5. Morrey BF, Askew LJ, Chao EY. A biomechanical study of normal functional elbow motion. *J Bone Joint Surg Am* 1981; 63(6):872–877.
6. Schultz-Johnson K. Mechanical considerations in splinting to reduce stiffness. Proceedings, "The Stiff Joint." American Association of Hand Surgery Annual Meeting, Kona, Hawaii, January 13-16, 1999.
7. Kottke FJ, Pauley DL, Ptak RA. The rationale for prolonged stretching for correction of shortening of connective tissue. *Arch Phys Med Rehabil* 1966;47(6):345–352.
8. Richard R, Shanesy CP III, Miller SF. Dynamic versus static splints: a prospective case for sustained stress. *J Burn Care Rehabil* 1995;16:284–287.
9. Bennett GB, Helm P, Purdue GF, Hunt JL. Serial casting: a method for treating burn contractures. *J Burn Care Rehabil* 1989;10(6):543–545.
10. Zander CL, Healy NL. Elbow flexion contractures treated with serial casts and conservative therapy. *J Hand Surg* [Am] 1992; 17(4):694–697.
11. Bonutti PM, Windau E, Ables BA, Miller BG. Static progressive stretch to reestablish elbow range of motion. *Clin Orthop* 1994 (303):128–134.
12. Gelinas JJ, Faber KJ, Patterson SD, King GJ. The effectiveness of turnbuckle splinting for elbow contractures. *J Bone Joint Surg Br* 2000;82(1):74–78.
13. Morrey BF. Splinting and bracing at the elbow. In: *The Elbow* , 3rd ed. Philadelphia: Lippincott Raven; 2000:150 –154.
14. Hoppenfeld S. *Physical Examination of the Spine and Extremities.* Norwalk, CT: Appleton & Lange; 1976.
15. Green DP, McCoy H. Turnbuckle orthotic correction of elbow- flexion contractures after acute injuries. *J Bone Joint Surg Am* 1979;61(7):1092–1095.
16. Strang M. The use of dynamic slings to correct elbow flexion contractures. *Orthop Nurs Assoc J* 1977;4(9):224–225.

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Management of radioulnar synostosis with mobilization, anconeus interposition, and a forearm rotation assist splint

Simon N Bell, FRACS, Debra Benger, BAppSci (Phty)

Abstract

Three cases of post-traumatic proximal radioulnar synostosis are presented. Each was treated with surgery with excision of the heterotrophic new bone and mobilization of the proximal radius. The anconeus muscle was mobilized as a vascularized pedicle graft and then interposed between the proximal radius and ulna. Two patients had postoperative radiotherapy. A forearm rotation assist splint was used to augment rehabilitation after surgery. This device consists of an inner sleeve that attaches to the hand and then rotates within a standard turnbuckle flexion/extension assist splint. The overall improvement in forearm rotation in each case was 100°, 140°, and 150°, respectively.

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Volume 8, Issue 6 , Pages 621-624, November 1999

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References

1. EWING, JAMES: Diffuse Endothelioma of Bone. Proc. New York Pathol. Soc., **21:** 17-24, 1921.
2. EWING, JAMES: Further Report on Endothelial Myeloma of Bone. Proc. New York Pathol. Soc., **24:** 93-101, 1924.
3. LANNELONGUE, O. M.: De l'ostéomyélite aiguë pendant la croissance. Paris, Asselin, 1879.
4. TESSARI, L.: L'osteomielite del bacino. Arch. ortop., **74:** 1163-1176, 1961.
5. WELD, P. W.: Osteomyelitis of the Ilium. Masquerading as Acute Appendicitis. J. Am. Med. Assn., **173:** 634-636, 1960.

Turnbuckle Orthotic Correction of Elbow-Flexion Contractures after Acute Injuries

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ABSTRACT: **Fifteen patients with acute flexion contractures of the elbow after injuries or operations were treated with a turnbuckle splint. Satisfactory correction was achieved in twelve patients. An average reduction in deformity of about 37 degrees was recorded after an average treatment period of twenty weeks. The treatment was unsuccessful in three patients with severe intra-articular damage because the splint caused excessive discomfort. The average improvement in the arc of motion of the elbow was approximately 43 degrees.**

Stiffness of the elbow is a relatively common complication following fractures, dislocations, and soft-tissue injuries about the elbow. In most cases the joint will improve with an appropriate exercise program, but occasionally a refractory fixed flexion contracture develops. This paper presents our experience over an eight-year period with a simple orthotic device which has proved quite effective in the management of flexion contractures of the elbow.

Much has been written about surgical treatment of elbow-flexion contractures, but there is very little in the literature regarding non-operative management. Perhaps one reason for this has been the misconception that orthotic devices are ineffectual in dealing with elbow-flexion contractures. This attitude was expressed in the recent American Academy of Orthopaedic Surgeons Atlas of Orthotics, where Perry stated that "restoration of full elbow extension is a strong challenge", and that "recovery of lost arcs of motion with an orthosis is difficult".

The turnbuckle splint is not a new idea. Steindler, in 1947, showed a turnbuckle splint somewhat different in design from the one that we use, although it was identical in principle. The American Academy of Orthopaedic Surgeons Orthopaedic Appliances Atlas, published in 1952, also briefly mentioned the turnbuckle.

Other types of orthotic devices to correct elbow-flexion contractures have been described as well. The use of a dynamic plastic elbow-extension orthosis was reported by Goller and Enders, but the average decrease in flexion contracture in their five patients was only 15 degrees. Dickson's treatment of an elbow-flexion contracture in a single patient yielded an impressive result, but his technique of reversed dynamic splinting required a week of hospitalization. From Russia has come a report[6] of correction of difficult flexion contractures of the knee and elbow with a hinge-distractor apparatus, but this device requires percutaneous pin fixation of bone.

Material and Methods

During the period 1970 to 1978, we used turnbuckle splints in twenty-five patients with flexion contractures of the elbow. Sufficient records of accurate measurements were available for fifteen of these patients, ranging in age from seven to fifty-seven years (average, 24.5 years). Nine patients were male and six were female. Table I summarizes the important clinical data. In ten patients the articular surfaces were undamaged; in two there were intra-articular fractures which were either minimally displaced or reduced accurately; and in three there was severe intra-articular damage.

The lesions that led to the contractures were: six fractures; three dislocations; two fracture-dislocations; and four cases of postoperative stiffness following an osteotomy of the humerus, a medial epicondylectomy, a

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TABLE I

SUMMARY OF CLINICAL DATA

Case	Age/Sex (Yrs.)	Time Since Injury (Mos.)	Cause of Lesion	Elbow Motion (Degrees)									Length of Follow-up (Mos.)	Time in Splint* (Mos.)
				Before Splinting			After Splinting			Results of Treatment				
				Contract.	Flexion	Arc	Contract.	Flexion	Arc	Contract.	Flexion	Arc		
1	17/F	4	3 wks. immob. after open reduction of entrapped medial epicondyle with disloc. of elbow	75	135	60	30	130	100	−45	− 5	+40	72	7
2	14/M	3	4 wks. long cast for open fract. of humerus and radial-nerve palsy	70	135	65	15	135	120	−55	0	+55	52	5
3	53/F	8	6 wks. long cast following operative treatment of tennis elbow	40	150	110	25	150	125	−15	0	+15	36	4
4	10/F	4	8 wks. long cast for supracondylar fract. of humerus	70	110	40	5	130	125	−65	+20	+85	70	10 (night only)
5	39/M	2	Postop. medial epicondylectomy for cubital tunnel syndrome; common flexor-pronator origin reattached with elbow in flexion	55	120	65	0	135	135	−55	+15	+70	84	3
6	7/M	5	Supracondylar fract. with arterial injury requiring exploration	75	115	40	10	110	100	−65	− 5	+60	12	7
7	26/F	3	Transcondylar fract. of distal humerus; accurate reduction by ORIF†	60	85	25	10	90	70	−50	+ 5	+45	24	4
8	13/M	4	Transcondylar fract. of distal humerus treated by closed reduction and percutaneous pinning with accurate reduction	45	135	90	10	135	125	−35	0	+35	27	5
9	13/M	3	Varus osteotomy of distal humerus for cubitus valgus	45	120	75	25	135	110	−20	+15	+35	18	6
10	16/M	22	6 wks. long cast for fract. of medial epicondyle	50	140	90	30	140	110	−30	0	+20	33	4
11	29/F	4	4 wks. long cast for posterior disloc. of elbow	45	135	90	10	135	125	−30	0	+30	12	3
12	17/M	3	3 wks. long cast for repair of lacerated brachial artery	90	100	10	20	115	95	−70	+15	+85	6	5
13	29/F	4	Severely comminuted fract.-disloc.	70	110	30	70	115	45	0	+15	+15	48	6
14	57/M	3	1-wk.-old unreduced medial sublux. of elbow	45	90	45	35	110	75	−10	+20	+30	42	6
15	27/M	3.5	Comminuted fract.-disloc. of elbow	60	90	30	50	100	50	−10	+10	+20	18	4
Average	24.5	5.3		59.6	118	57.6	23	125	100.7	−36.6	+ 7	+43.1	37	5.3

* Includes night-time use after maximum correction was achieved.

† Open reduction and internal fixation.

lacerated brachial artery, and an operation for tennis elbow. Prolonged immobilization of the elbow (four weeks or longer) in a cast was believed to be a factor leading to stiffness in six of the patients.

Ten patients were lost to follow-up during treatment with the turnbuckle splint, and are not included in this study. The etiological factors in those ten were: six, fractures; two, fracture-dislocations; one, dislocation; and one, Erb's palsy.

We have not used this splint in patients with long-standing elbow-flexion contractures that were residua from cerebral palsy, stroke, or congenital lesions (other than Erb's palsy).

The correction of a 70-degree flexion contracture that was attempted in one eleven-year-old child with Erb's palsy resulted in minimum improvement. This patient is not included in the present series, and we do not a vocate the use of the turnbuckle in patients with lon standing contractures.

The turnbuckle splint (Fig. 1) is a double-upright long-arm orthosis with a turnbuckle on the outside upright. The uprights are cut from three by 12.7-millimeter (0.125 by 0.5-inch) 2024-T3 aluminum and the posterior bands, from 0.063-2024-T3 aluminum. Leather cuffs with Velcro straps provide broad, firm control of the upper end of the arm and forearm.

The splint was fabricated and custom-fitted by the orthotist, and the patient was instructed to wear it as much as was possible, removing it several times each day for range-of-motion exercises of the elbow. An effort was

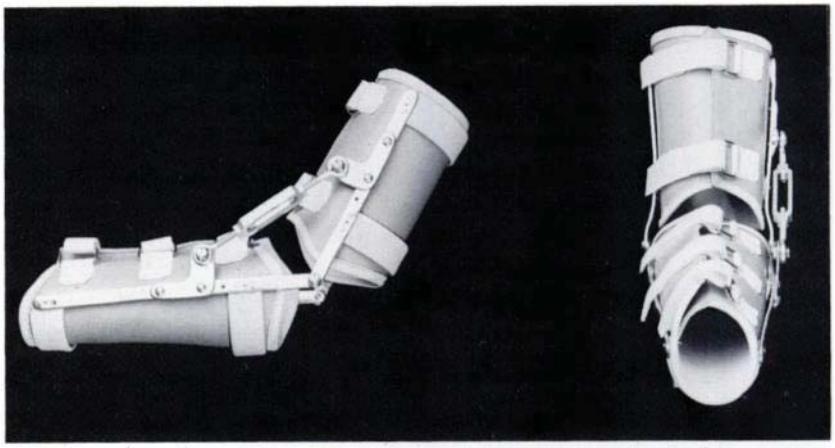

FIG. 1

A turnbuckle splint for the left upper extremity. The turnbuckle is on the outside upright.

made to have the splint worn essentially full-time except for exercise periods, but in most instances compromises were made to allow the patient to be free of the brace several hours each day for work or school. If the flexion contracture did not respond to this regimen, full-time use was strongly encouraged. The patient was taught how to increase the force applied by the turnbuckle to the point of discomfort, but not pain. When the end of the turnbuckle screw was reached, a longer screw was applied by the orthotist.

Results

Treatment with the splint was begun an average of 5.3 months (range, two to twenty-two months) following the injury or operation that caused the flexion deformity. All measurements were made with standard orthopaedic goniometers. The average fixed flexion contracture before the institution of brace treatment was 59.6 degrees (range, 40 to 90 degrees) and the post-treatment average was 23 degrees (range, zero to 70 degrees). The average reduction in fixed flexion contracture at the completion of treatment was 36.6 degrees (range, zero to 70 degrees). If the three patients with severe intra-articular damage (Cases 13, 14, and 15) are excluded, the average reduction in fixed flexion contracture was 43.8 degrees.

Three patients had minimum correction of the contractures, and these warrant further comment. One patient (Case 3), a fifty-three-year-old woman, was seen with a fixed flexion contracture of 40 degrees eight months following an operation for tennis elbow. The elbow had been immobilized for six weeks postoperatively in a long cast. She also had an ulnar-nerve palsy and to further complicate the problem, she sustained an undisplaced surgical fracture of the neck of the ipsilateral humerus during the period of brace treatment (although she was not wearing the brace when she sustained the fracture). Subsequently the shoulder became "frozen". Her contracture was reduced by only 15 degrees.

Case 10, a sixteen-year-old boy, had been treated with a long cast for six weeks for a fracture of the medial epicondyle, and was fitted with the splint twenty-two months after the initial injury. His 50-degree fixed flexion contracture was reduced to 30 degrees within the first three weeks in the brace, but did not respond further despite three additional months of brace treatment.

A fifty-seven-year-old woman (Case 14) was first seen with a one-week-old unreduced medial subluxation of the elbow. A refractory 45-degree fixed flexion contracture developed after closed reduction and three weeks of immobilization in a cast. Even though the turnbuckle was applied just three months after injury, the contracture was reduced only 10 degrees. However, she was able to return to her former job as a waitress.

The length of time required to achieve correction ranged from three weeks to several months, depending on the rigidity of the contracture and the amount of time the splint was worn.

Discussion

The turnbuckle splint that we have used is durable yet relatively simple to fabricate, requires no percutaneous pin fixation or sophisticated mechanical devices and, most importantly, is effective in correcting fixed flexion contractures of the elbow. Local tissue pressure is controlled by the patient, eliminating one objection raised against corrective orthotic devices for the elbow[4].

The appropriate timing for application of the splint is based on the clinical course. Any fracture should of course be healed, and the patient should have had a fair trial with an exercise program. In our patients, the turnbuckle was instituted when improvement in range of motion of the elbow had reached a plateau for at least two to three weeks despite an intensive physical-therapy program.

It is important to note that the splint did not achieve improved extension at the expense of flexion. In fact, there was an average 7-degree increase in elbow flexion. A few patients did lose as much as 5 degrees of active flexion (range, 5 degrees' loss of flexion to 20 degrees' gain). The resulting improvement in arc of motion averaged 43.1 degrees (range, 15 to 85 degrees).

Essentially no correction was lost after the brace was discontinued if the patient was weaned from the splint by gradually decreasing its use over a one-month period after correction had been achieved.

We have learned that the splint is much more successful in patients with joint and soft-tissue contractures than in those with significant intra-articular damage. When there is more than minimum damage in the joint, the splint generally is too painful to wear, and in the three patients with significant intra-articular damage the treatment failed. It was effective, however, in two patients with minimum articular damage. No patient required an operative release of the flexion contracture, but it is anticipated that at least two of the three patients in whom the treatment failed will ultimately require elbow arthroplasty because of severe post-traumatic arthrosis.

References

1. AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS: Orthopaedic Appliances Atlas. Vol. 1, pp. 340-341. Ann Arbor, J. W. Edwards, 1952.
2. DICKSON, R. A.: Reversed Dynamic Slings. A New Concept in the Treatment of Post-Traumatic Elbow Flexion Contractures. Injury, **8:** 35-38, 1976.
3. GOLLER, HERBERT, and ENDERS, MARCH: A Dynamic Plastic Elbow-Extension Orthosis for Reduction of Flexion Contractures. Orthot. and Prosthet., **30:** 47-51, Dec. 1976.
4. PERRY, JACQUELIN: Prescription Principles. *In* American Academy of Orthopaedic Surgeons: Atlas of Orthotics; Biomechanical Principles and Application, pp. 120-122. St. Louis, C. V. Mosby, 1975.
5. STEINDLER, ARTHUR: The Traumatic Deformities and Disabilities of the Upper Extremity, p. 25. Springfield, Illinois, Charles C Thomas, 1946.
6. VOLKOV, M. V., and OGANESIAN, O. V.: Restoration of Function in the Knee and Elbow with a Hinge-Distractor Apparatus. J. Bone and Joint Surg., **57-A:** 591-600, July 1975.

HCPCS:	Descriptor:
L3807	WRIST HAND FINGER ORTHOSIS, WITHOUT JOINT(S), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENTS, ANY TYPE

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	NO	YES

Sample Diagnosis (Not Inclusive)	Wrist injury, contracture, carpal tunnel, instability, paralysis
Medically Necessary Argument	A wrist hand finger orthosis without joints is indicated for a person who does not have optimum neuromuscular-skeletal function of the wrist, hand, or fingers. This type of brace is used for static positioning of the wrist, hand, and fingers. The brace provides corrective forces or tension to the flexors and extensors to prevent shortening of the ligaments and/or muscles to prevent or correct contractures. Some users of this brace have no sensation in their hand or fingers and must use this brace to prevent damage to their skin or joints. These braces provide sagittal and frontal plane stability for the flail wrist and hand. Proper evaluation and fitting is required to ensure an optimal fit to prevent skin break down, ligament damage or joint contracture. The length of this orthosis and the fit of the straps are critical to the success of the brace in protecting the patient. Due to the nature of the typical user of this orthosis, self-adjustment may be impossible as well as dangerous for the patient.
References	17, 18

Impact of Impaired Wrist Motion on Hand and Upper-Extremity Performance

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Purpose: To quantify and compare the disabilities caused by reduced and absent wrist motion using objective measurements of task performance and perceived disability, and to assess the compensatory motions of the shoulder, elbow, forearm, and trunk caused by impaired wrist motion.

Methods: A clinical study of 21 normal subjects was done to measure physical performance and to assess wrist function under conditions of reduced (30° flexion and 30° extension) and nearly absent wrist motion using established physical tests and questionnaires (Disabilities of the Arm, Shoulder, and Hand [DASH], Patient Rated Wrist Evaluation [PRWE], and a study-specific survey). The clinical study also measured compensatory motions of the shoulder, elbow, forearm, and trunk.

Results: Average times to perform the Jebsen test and activities of daily living (ADLs) test increased for both motion-restricted conditions of the wrist but did not differ significantly between the conditions. Questionnaire scores regarding function were significantly worse for both motion-restricted conditions and poorest for nearly absent motion. Average compensatory motions in the extremity and trunk statistically increased for both motion-restricted conditions but were not marked and did not differ between the conditions. High variability among subjects occurred in all physical tests and questionnaires for both motion-restricted conditions.

Conclusions: Perceived disability from reduced wrist motion appeared greater than measured functional loss using common physical tests and outcome surveys. (J Hand Surg 2003;28A: 898–903. Copyright © 2003 by the American Society for Surgery of the Hand.)

Key words: Wrist motion, kinematics, arthritis, wrist.

In the treatment of wrist arthritis motion-preserving procedures commonly are preferred over complete wrist arthrodesis because it is perceived that these procedures provide higher patient satisfaction. Motion-preserving procedures include partial wrist fusions, proximal row carpectomy, isolated carpal bone replacement (eg, scaphoid or lunate implant), and total wrist replacement. Potential reasons for greater satisfaction include better hand function and reduced impact on other joints. Reported risks with motion-preserving procedures include further arthritic changes, failure of fusion, and implant loosening. To justify the risks and added technical challenges associated with these procedures, the benefits should be clear.

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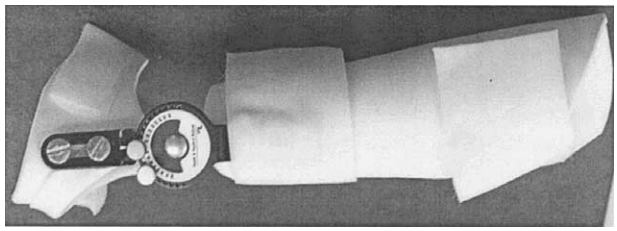

Figure 1. Example of the splint used to restrict wrist motion.

The goals of this study were to quantify and compare the impairment caused by reduced and absent wrist motion using objective measurements of task performance and perceived disability and to assess the compensatory motions of the shoulder, elbow, forearm, and trunk imposed by impaired wrist motion.

Materials and Methods

After obtaining institutional review board approval 21 subjects with normal upper-extremity function were recruited from the local community. Informed consent was obtained from all subjects. They received nominal monetary compensation. Ten subjects were women and 11 were men with an average age of 23.8 years (range, 19–32 y). Each subject was tested on 3 consecutive days. Only the dominant side was tested.

Technique

To restrict wrist motion a custom brace with a single hinge at the wrist was made for each subject. It was constructed in 3 parts, with the first part consisting of a plastic-molded forearm component extending from midforearm to the ulnar styloid with the dorsal, radial, and ulnar forearm surfaces. The brace was secured with 2 hook-and-loop closure straps. The hand-molded plastic component was nearly circumferential at the midpalm and tightened with one strap (Velcro). A wrist hinge (Rolyan Incremental Wrist Hinge; Smith and Nephew, Germantown, WI) joined the 2 components (Fig. 1). The hinge was attached to the radial aspects of the plastic components with its axis aligned just distal to the tip of the radial styloid to allow wrist flexion and extension. It severely restricted wrist radial and ulnar deviation. Proper hinge location was determined by testing wrist flexion/extension of each subject. The hinge was aligned at the flexion extension axis where it was least restrictive to the subject. Minor modifications were made on an individual basis to reduce discomfort. The hinge had a mechanism with built-in stops to variably restrict flexion and extension. Forearm rotation was also restricted minimally by the brace.

An electromagnetic tracking system (mini-BIRDS; Ascension Technology, Inc., Burlington, VT) was used to track wrist, forearm, elbow, and shoulder motions of the tested extremity and the trunk.[1,2] The system included an extended-range transmitter and 5 wired receivers; the latter were fixed to the skin or to the brace with tape. Sites of the receiver units were the middle of the third metacarpal, the distal radioulnar joint, elbow lateral epicondyle, acromion process, and sternum. Receiver sites were marked on the brace to reproduce receiver positions for the duration of the testing. Wrist joint range of motion was determined by the relative change between receiver positions. Before testing, the degree of restricted motion permitted by the brace was measured. Motion was reported as the full range of motion achieved within the arc of motion tested. In testing the accuracy of the rotational measurements made by the motion tracking system, we found a mean error of 8% over a 60° arc of motion.

Task performance was measured under 3 conditions: (1) unrestricted wrist motion without the brace, (2) highly restricted wrist motion with the hinged brace locked in neutral wrist position (11° flexion/extension), and (3) partially restricted wrist motion with the hinge set for a 60° arc of flexion/extension (allowing 62°). The motion selected for the partially restricted wrist was a conservative range chosen from a literature review of common motion-preserving procedures, including proximal row carpectomy, intercarpal fusions, and total wrist arthroplasty.[3–6] The brace allowed for 13° of radioulnar deviation in both settings.

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Difficulty with task performance was measured

Table 1. ADL Tasks

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Unlocking door with a key	DASH
Turning a door knob	Nelson et al,[11] PRWE
Pushing up from a chair	PRWE

Tasks taken from DASH,[9] PRWE,[10] and Nelson et al[11] and Tang et al.[12]

using the DASH, PRWE, and a study-specific questionnaire regarding the tasks in the Jebsen test and the 13 ADLs to assess perceived difficulty with performance. Only those questions in the DASH and PRWE regarding function were included. Responses in the study-specific survey were formatted as in the DASH: no difficulty, mild difficulty, moderate difficulty, severe difficulty, or unable. The PRWE response scale is 1 through 10, from no difficulty to unable to do.

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A baseline DASH and PRWE was completed. The subject practiced the tasks in the Jebsen test and ADL list without wearing the brace to minimize effects from learning. No measurements were taken at that time. The custom brace was fitted and the subject was asked to wear the brace continuously except to bathe until the test session on the next day. Subjects were assigned randomly to an order of brace type (limited hinge motion vs no hinge motion) over the following 2 consecutive days of the study.

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Statistical Analysis

Mixed-model, analysis of variance techniques within the general linear model framework using a software system (SAS version 8.2; SAS Institute Inc., Cary, NC) were used. Tukey grouping also was used to show statistical significance ($p < .05$). Statistical analyses were conducted for individual joints and planes of motion. Both the brace order and task order were considered nuisance conditions and analyzed for their effects. Repeated baseline measurements on days 2 and 3 assessed possible learned effect.

Results

Average time to complete the Jebsen test significantly increased ($p < .05$) for both the highly and partially restricted wrists. Time to completion increased from 41 seconds for the unrestricted wrist to 47 seconds for the partially restricted wrist and to 49 seconds for the highly restricted wrist. Although the increase was greater for the highly restricted wrist, the average time was not statistically different from the partially restricted wrist. Times were highly variable among subjects, with SDs of 4.8, 5.8, and 9.4 seconds, respectively, for the 3 motion conditions.

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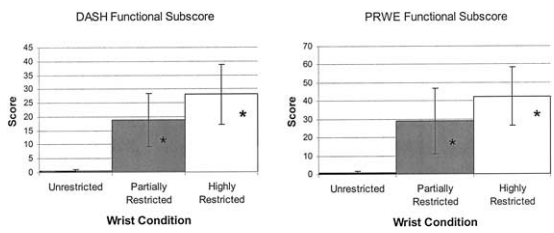


Figure 2. (A) DASH functional subscore and (B) PRWE functional subscore. *Statistically different from unrestricted. The differences between the partially and highly restricted wrists are also statistically significant. Error bars show 1 SD.

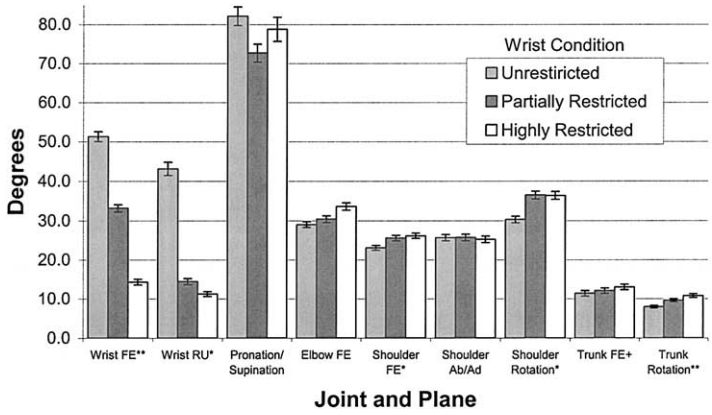


Figure 3. Average motions in degrees for all subjects and all ADLs. Motions are total arcs motion in that plane. *Restricted wrist conditions are significantly different from unrestricted. +Highly restricted wrist condition is significantly different from unrestricted and partially restricted conditions. **All 3 wrist conditions are different than each other. Ab/Ad, abduction-adduction; FE, flexion/extension; RU, radioulnar deviation. Error bars show 1 standard error.

was greater for the highly restricted wrist, but it was not statistically different from the partially restricted wrist. The times were highly variable among subjects, with SDs of 9.3, 11.7, and 16.9 seconds, respectively, for the 3 motion conditions.

DASH and PRWE subscores for function and the survey scores for the ADL test significantly increased ($p < .05$) for both the partially and highly restricted wrists, implying a greater perception of disability (Fig. 2). The differences between the partially and highly restricted wrists were also significant ($p < .05$), with the highly restricted wrist having increased scores in all 3 surveys (Fig. 3). The survey scores for the Jebsen test significantly increased ($p < .05$) for both the partially and highly restricted wrists, but the scores for the 2 restricted wrist conditions were not significantly different from each other.

Both the partially and highly restricted wrists were associated with small average increases in ipsilateral forearm, elbow, and shoulder motions and trunk motion, of which some increases were statistically significant ($p < .05$) (Appendix A; this appendix may be viewed at the *Journal*'s Web site, www.jhandsurg.org). The average differences between the partially and highly restricted wrists were not statistically significant for most of the joints other than the wrist, however, changes in motions were highly variable among subjects and tasks. In both cases, the statistical differences were small and their clinical relevance may be questioned. There was, however, a statistical difference in wrist flexion/extension motion among all 3 bracing conditions (Fig. 3).

The order of bracing and task order had no effects on outcomes of test times, motions, or survey scores. There were no significant interactions between bracing order and task order.

Discussion

Selecting the best surgical treatment for an arthritic wrist often is difficult and imprecise. Although the choice depends on the affected joint, it also is influenced by the patient's activities and the preferences of the surgeon. Priorities regarding grip strength, motion, duration of recovery, reliability, and durability vary among patients. Consequently several options can be considered including wrist joint denervation, radial styloidectomy, proximal row carpectomy, limited wrist fusion, total wrist joint replacement, and complete wrist arthrodesis.

Limited intercarpal fusions and partial carpal resections are commonly chosen motion-preserving treatments for osteoarthritis and posttraumatic arthritis, and total wrist arthroplasty is an alternative for rheumatoid and low-demand patients. These procedures are chosen because of the expectation that there will be better upper-extremity function from retained motion than with a complete wrist arthrodesis.

The relationship between wrist motion and function has been examined from 3 different approaches, with each having its own set of premises and definitions.[11] The first approach equated wrist function with maximum wrist motion, the second equated wrist function with the amount of wrist motion used, and the third equated wrist function with the amount of wrist motion needed. The first approach, which considered wrist function to be almost linearly related to motion, was used commonly in the first half of the past century and was highly criticized for lack

of experimental data.[11] In the second approach, conclusions were reached from tracking wrist motion in normal subjects during ADLs. Brumfield and Champoux[14] reported that 10° flexion and 35° extension were required to accomplish most ADLs. Palmer et al[15] claimed the functional range was 5° flexion, 30° extension, 10° radial deviation, and 15° ulnar deviation for ADLs. Ryu et al[16] found the required range was 60° extension, 54° flexion, 17° radial deviation, and 40° ulnar deviation. They also described a reasonable range needed to accomplish most activities as 40° extension, 40° flexion, 10° radial deviation, and 30° ulnar deviation. The differences between these studies are related to different methods of measurement, the activities tested, and the accepted performance level. Nelson[11] took a third approach by seeking to determine the minimum amounts of motion required to complete tasks. A series of splints that allowed different ranges of motions (flexion/extension 11° to 41°, radial/ulnar deviation 13° to 29°) were applied and the subjects were graded on their abilities to perform each task. The subjects reported very little disability regardless of the degree of wrist motion, including the maximally restricted wrist. From 123 ADLs surveyed for disability, they found only 13 to be impaired at the most restrictive range of motion, and the impairment was minimal according to the scale used. None of these motion studies measured the time to complete tasks or the effect on other joints motions.

In an effort to determine the best position for wrist fusion or splinting, Kraft and Detels[17] immobilized the dominant side of normal subjects using a series of 4 splints holding the wrist in different positions: neutral, 15° extension, 30° extension, and 15° flexion. The effect of wrist position was evaluated by the time required to perform 5 functional activities: simulated feeding, writing, picking up small objects from the floor, combing hair, and toileting. Grip and pinch strength also were measured. They found the flexed position to be worse for writing and picking up small objects from the floor, while the other 3 positions were equal for these tasks. There was no significant difference among the 4 positions for eating, combing hair, and toileting. Task practice had a significant effect ($p < .05$) on measurements of eating, writing, and combing hair. Grip and pinch strength also were measured and found to be similar in neutral, 15°, and 30° extension, but less in flexion.

In this study we sought to identify the potential benefits of motion-preserving procedures using quantitative measures of task performance, perceived disability, and impact on ipsilateral elbow, shoulder, and forearm motions and trunk motion. To measure function, we observed a series of common tasks that were derived from established tests, surveys, and previously reported studies (Table 1). Perceived disability was measured by using validated outcome surveys and questions developed specifically for this study using an established format.

The results show that reduced wrist motion increased the times for task performance. Although the highly restricted wrist had a greater adverse effect than the partially restricted wrist, the difference was not statistically significant using this study protocol. The average impact of restricted wrist motion on other joint and trunk motions was statistically significant but did not appear clinically substantial. The impacts were highly variable among the subjects and tasks; however, this suggests that some individuals can adapt better to lost wrist motion and that some tasks are accommodated more easily. All survey scores were worse for the restricted wrists and poorest for the highly restricted wrist. The sensitivities of the DASH and PRWE in detecting the impact of reduced wrist motion were similar.

There are limitations in applying the results of a clinical study with normal subjects to patients with wrist arthritis. The study does not include other potential influences on the outcome of wrist procedures. Most patients undergo surgery to achieve pain relief and to improve reduced grip, which were not factors in these normal subjects. This difference may have made some of the tasks we chose less effective for this study. The subjects also were younger than most patients treated for wrist arthritis. Older individuals may be less able to compensate for lost motion, especially if other joints are affected by arthritis. Furthermore the study did not consider strenuous or repetitive tasks such as sports or physically demanding occupations that likely would be more affected. Conversely the brace may have created a greater hindrance to hand function than a surgical procedure for a variety of reasons. For example, the brace component in the palm may impair dexterity and the hinge at the wrist limits radioulnar deviation, which is retained partially in most motion-preserving procedures.

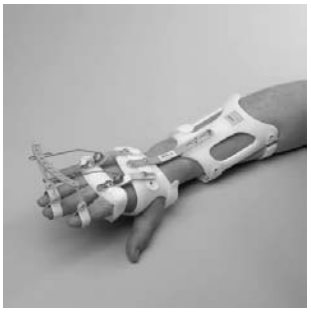
An individual's perceived disability with performance of common tasks appears to be influenced by their available wrist motion, however, there is marked variability in perceptions. The compensatory motions of the shoulder, elbow, forearm, and trunk motions also were highly variable. Simulated mo-

tion-preserving procedures did rate better than simulated arthrodesis by several parameters but the average differences were not as great as we had anticipated. Thus it may be hard to predict a patient's response to reduced wrist motion. The amount of flexion and extension necessary to achieve high patient satisfaction may be greater than that provided by common motion-preserving wrist procedures despite small reductions in physical performance. Similarly, patient satisfaction with function after complete wrist arthrodesis may rank lower than common physical measurements would suggest.

References

1. Meskers CG, Fraterman H, van der Helm FC, Vermeulen HM, Rozing PM. Calibration of the "Flock of Birds" electromagnetic tracking device and its application in shoulder motion studies. J Biomech 1999;32:629–633.
2. Milne AD, Chess DG, Johnson JA, King GJ. Accuracy of an electromagnetic tracking device: a study of the optimal range and metal interference. J Biomech 1996;29:791–793.
3. Divelbiss BJ, Sollerman C, Adams BD. Early results of the Universal total wrist arthroplasty in rheumatoid arthritis. J Hand Surg 2002;27A:195–204.
4. Cohen MS, Kozin SH. Degenerative arthritis of the wrist: proximal row carpectomy versus scaphoid excision and four-corner arthrodesis. J Hand Surg 2001;26A:94–104.
5. Wyrick JD, Stern PJ, Kiefhaber TR. Motion-preserving procedures in the treatment of scapholunate advanced collapse wrist: proximal row carpectomy versus four-corner arthrodesis. J Hand Surg 1995;20A:965–970.
6. Cobb TK, Beckenbaugh RD. Biaxial total-wrist arthroplasty. J Hand Surg 1996;21A:1011–1021.
7. Jebsen RH, Taylor N, Trieschmann RB, Trotter MJ, Howard LA. An objective and standardized test of hand function. Arch Phys Med Rehabil 1969;50:311–319.
8. Vliet Vlieland TP, van der Wijk TP, Jolie IM, Zwinderman AH, Hazes JM. Determinants of hand function in patients with rheumatoid arthritis. J Rheumatol 1996;23:835–840.
9. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measurethe DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). Am J Ind Med 1996;29:602–608.
10. MacDermid JC, Turgeon T, Richards RS, Beadle M, Roth JH. Patient rating of wrist pain and disability: a reliable and valid measurement tool. J Orthop Trauma 1998;12:577–586.
11. Nelson DL. Functional wrist motion. Hand Clin 1997;13:83–92.
12. Tang C, Roidis N, Itamura J, Vaishnau S, Shean C, Stevanovic M. The effect of simulated elbow arthrodesis on the ability to perform activities of daily living. J Hand Surg 2001;26A:1146–1150.
13. Carlson JD, Trombley CA. The effect of wrist immobilization on performance of the Jebsen Hand Function test. Am J Occup Ther 1983;37:167–175.
14. Brumfield RH, Champoux JA. A biomechanical study of normal functional wrist motion. Clin Orthop 1984;187:23–25.
15. Palmer AK, Werner FW, Murphy D, Glisson R. Functional wrist motion: a biomechanical study. J Hand Surg 1985;10A:39–46.
16. Ryu JY, Cooney WP 3rd, Askew LJ, An KN, Chao EY. Functional ranges of motion of the wrist joint. J Hand Surg 1991;16A:409–419.
17. Kraft G, Detels P. Position of function of the wrist. Arch Phys Med Rehabil 1972;53:272–275.

HCPCS:	Descriptor:
L3915	WRIST HAND ORTHOSIS, INCLUDES ONE OR MORE NONTORSION JOINT(S), ELASTIC BANDS, TURNBUCKLES, MAY INCLUDE SOFT INTERFACE, STRAPS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Contracture, arthritis, arthrogryposis
Medically Necessary Argument	A prefabricated wrist hand orthosis with joints is indicated for a person who does not have optimum function of the wrist joint. A weak or misaligned wrist decreases the patient's ability to position the hand and fingers in a functional position to use for ADL's. The joints associated with this orthosis can assist the wrist and fingers in performing tasks, which require three-point prehension. If these joints are not fit and adjusted by a credentialed individual, they could cause pain or decrease function of the patient's hand, preventing them from performing their ADL's, which are essential to functional independence. Improper fit of this orthosis can lead to contractures of the ligaments and tendons of the hand and fingers due to the lack of range of motion on a regular basis.
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Impact of Impaired Wrist Motion on Hand and Upper-Extremity Performance

Brian D. Adams, MD, Nicole M. Grosland, PhD, David M. Murphy, BS, Matthew McCullough, BS, *Iowa City, IA*

Purpose: To quantify and compare the disabilities caused by reduced and absent wrist motion using objective measurements of task performance and perceived disability, and to assess the compensatory motions of the shoulder, elbow, forearm, and trunk caused by impaired wrist motion.

Methods: A clinical study of 21 normal subjects was done to measure physical performance and to assess wrist function under conditions of reduced (30° flexion and 30° extension) and nearly absent wrist motion using established physical tests and questionnaires (Disabilities of the Arm, Shoulder, and Hand [DASH], Patient Rated Wrist Evaluation [PRWE], and a study-specific survey). The clinical study also measured compensatory motions of the shoulder, elbow, forearm, and trunk.

Results: Average times to perform the Jebsen test and activities of daily living (ADLs) test increased for both motion-restricted conditions of the wrist but did not differ significantly between the conditions. Questionnaire scores regarding function were significantly worse for both motion-restricted conditions and poorest for nearly absent motion. Average compensatory motions in the extremity and trunk statistically increased for both motion-restricted conditions but were not marked and did not differ between the conditions. High variability among subjects occurred in all physical tests and questionnaires for both motion-restricted conditions.

Conclusions: Perceived disability from reduced wrist motion appeared greater than measured functional loss using common physical tests and outcome surveys. (J Hand Surg 2003;28A: 898–903. Copyright © 2003 by the American Society for Surgery of the Hand.)

Key words: Wrist motion, kinematics, arthritis, wrist.

In the treatment of wrist arthritis motion-preserving procedures commonly are preferred over complete wrist arthrodesis because it is perceived that these procedures provide higher patient satisfaction. Motion-preserving procedures include partial wrist fusions, proximal row carpectomy, isolated carpal bone replacement (eg, scaphoid or lunate implant), and total wrist replacement. Potential reasons for greater satisfaction include better hand function and reduced impact on other joints. Reported risks with motion-preserving procedures include further arthritic changes, failure of fusion, and implant loosening. To justify the risks and added technical challenges associated with these procedures, the benefits should be clear.

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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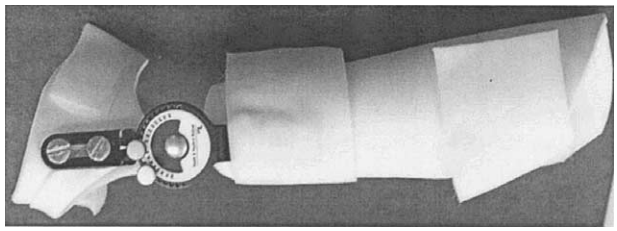

Figure 1. Example of the splint used to restrict wrist motion.

The goals of this study were to quantify and compare the impairment caused by reduced and absent wrist motion using objective measurements of task performance and perceived disability and to assess the compensatory motions of the shoulder, elbow, forearm, and trunk imposed by impaired wrist motion.

Materials and Methods

After obtaining institutional review board approval 21 subjects with normal upper-extremity function were recruited from the local community. Informed consent was obtained from all subjects. They received nominal monetary compensation. Ten subjects were women and 11 were men with an average age of 23.8 years (range, 19–32 y). Each subject was tested on 3 consecutive days. Only the dominant side was tested.

Technique

To restrict wrist motion a custom brace with a single hinge at the wrist was made for each subject. It was constructed in 3 parts, with the first part consisting of a plastic-molded forearm component extending from midforearm to the ulnar styloid with the dorsal, radial, and ulnar forearm surfaces. The brace was secured with 2 hook-and-loop closure straps. The hand-molded plastic component was nearly circumferential at the midpalm and tightened with one strap (Velcro). A wrist hinge (Rolyan Incremental Wrist Hinge; Smith and Nephew, Germantown, WI) joined the 2 components (Fig. 1). The hinge was attached to the radial aspects of the plastic components with its axis aligned just distal to the tip of the radial styloid to allow wrist flexion and extension. It severely restricted wrist radial and ulnar deviation. Proper hinge location was determined by testing wrist flexion/extension of each subject. The hinge was aligned at the flexion extension axis where it was least restrictive to the subject. Minor modifications were made on an individual basis to reduce discomfort. The hinge had a mechanism with built-in stops to variably restrict flexion and extension. Forearm rotation was also restricted minimally by the brace.

An electromagnetic tracking system (mini-BIRDS; Ascension Technology, Inc., Burlington, VT) was used to track wrist, forearm, elbow, and shoulder motions of the tested extremity and the trunk.[1,2] The system included an extended-range transmitter and 5 wired receivers; the latter were fixed to the skin or to the brace with tape. Sites of the receiver units were the middle of the third metacarpal, the distal radioulnar joint, elbow lateral epicondyle, acromion process, and sternum. Receiver sites were marked on the brace to reproduce receiver positions for the duration of the testing. Wrist joint range of motion was determined by the relative change between receiver positions. Before testing, the degree of restricted motion permitted by the brace was measured. Motion was reported as the full range of motion achieved within the arc of motion tested. In testing the accuracy of the rotational measurements made by the motion tracking system, we found a mean error of 8% over a 60° arc of motion.

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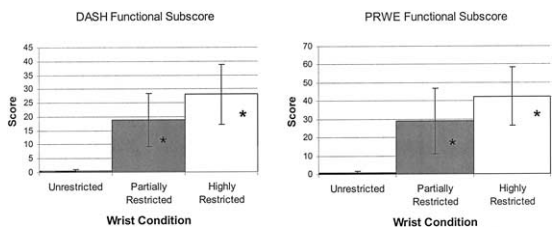

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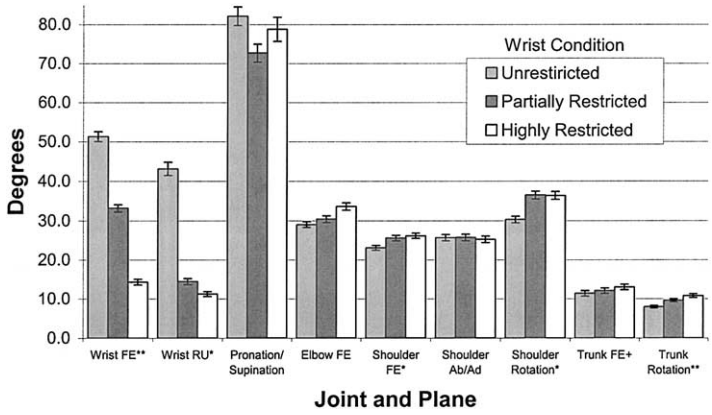


Figure 3. Average motions in degrees for all subjects and all ADLs. Motions are total arcs motion in that plane. *Restricted wrist conditions are significantly different from unrestricted. +Highly restricted wrist condition is significantly different from unrestricted and partially restricted conditions. **All 3 wrist conditions are different than each other. Ab/Ad, abduction-adduction; FE, flexion/extension; RU, radioulnar deviation. Error bars show 1 standard error.

was greater for the highly restricted wrist, but it was not statistically different from the partially restricted wrist. The times were highly variable among subjects, with SDs of 9.3, 11.7, and 16.9 seconds, respectively, for the 3 motion conditions.

DASH and PRWE subscores for function and the survey scores for the ADL test significantly increased ($p < .05$) for both the partially and highly restricted wrists, implying a greater perception of disability (Fig. 2). The differences between the partially and highly restricted wrists were also significant ($p < .05$), with the highly restricted wrist having increased scores in all 3 surveys (Fig. 3). The survey scores for the Jebsen test significantly increased ($p < .05$) for both the partially and highly restricted wrists, but the scores for the 2 restricted wrist conditions were not significantly different from each other.

Both the partially and highly restricted wrists were associated with small average increases in ipsilateral forearm, elbow, and shoulder motions and trunk motion, of which some increases were statistically significant ($p < .05$) (Appendix A; this appendix may be viewed at the *Journal*'s Web site, www.jhandsurg.org). The average differences between the partially and highly restricted wrists were not statistically significant for most of the joints other than the wrist, however, changes in motions were highly variable among subjects and tasks. In both cases, the statistical differences were small and their clinical relevance may be questioned. There was, however, a statistical difference in wrist flexion/extension motion among all 3 bracing conditions (Fig. 3).

The order of bracing and task order had no effects on outcomes of test times, motions, or survey scores. There were no significant interactions between bracing order and task order.

Discussion

Selecting the best surgical treatment for an arthritic wrist often is difficult and imprecise. Although the choice depends on the affected joint, it also is influenced by the patient's activities and the preferences of the surgeon. Priorities regarding grip strength, motion, duration of recovery, reliability, and durability vary among patients. Consequently several options can be considered including wrist joint denervation, radial styloidectomy, proximal row carpectomy, limited wrist fusion, total wrist joint replacement, and complete wrist arthrodesis.

Limited intercarpal fusions and partial carpal resections are commonly chosen motion-preserving treatments for osteoarthritis and posttraumatic arthritis, and total wrist arthroplasty is an alternative for rheumatoid and low-demand patients. These procedures are chosen because of the expectation that there will be better upper-extremity function from retained motion than with a complete wrist arthrodesis.

The relationship between wrist motion and function has been examined from 3 different approaches, with each having its own set of premises and definitions.[11] The first approach equated wrist function with maximum wrist motion, the second equated wrist function with the amount of wrist motion used, and the third equated wrist function with the amount of wrist motion needed. The first approach, which considered wrist function to be almost linearly related to motion, was used commonly in the first half of the past century and was highly criticized for lack

of experimental data.[11] In the second approach, conclusions were reached from tracking wrist motion in normal subjects during ADLs. Brumfield and Champoux[14] reported that 10° flexion and 35° extension were required to accomplish most ADLs. Palmer et al[15] claimed the functional range was 5° flexion, 30° extension, 10° radial deviation, and 15° ulnar deviation for ADLs. Ryu et al[16] found the required range was 60° extension, 54° flexion, 17° radial deviation, and 40° ulnar deviation. They also described a reasonable range needed to accomplish most activities as 40° extension, 40° flexion, 10° radial deviation, and 30° ulnar deviation. The differences between these studies are related to different methods of measurement, the activities tested, and the accepted performance level. Nelson[11] took a third approach by seeking to determine the minimum amounts of motion required to complete tasks. A series of splints that allowed different ranges of motions (flexion/extension 11° to 41°, radial/ulnar deviation 13° to 29°) were applied and the subjects were graded on their abilities to perform each task. The subjects reported very little disability regardless of the degree of wrist motion, including the maximally restricted wrist. From 123 ADLs surveyed for disability, they found only 13 to be impaired at the most restrictive range of motion, and the impairment was minimal according to the scale used. None of these motion studies measured the time to complete tasks or the effect on other joints motions.

In an effort to determine the best position for wrist fusion or splinting, Kraft and Detels[17] immobilized the dominant side of normal subjects using a series of 4 splints holding the wrist in different positions: neutral, 15° extension, 30° extension, and 15° flexion. The effect of wrist position was evaluated by the time required to perform 5 functional activities: simulated feeding, writing, picking up small objects from the floor, combing hair, and toileting. Grip and pinch strength also were measured. They found the flexed position to be worse for writing and picking up small objects from the floor, while the other 3 positions were equal for these tasks. There was no significant difference among the 4 positions for eating, combing hair, and toileting. Task practice had a significant effect ($p < .05$) on measurements of eating, writing, and combing hair. Grip and pinch strength also were measured and found to be similar in neutral, 15°, and 30° extension, but less in flexion.

In this study we sought to identify the potential benefits of motion-preserving procedures using quantitative measures of task performance, perceived disability, and impact on ipsilateral elbow, shoulder, and forearm motions and trunk motion. To measure function, we observed a series of common tasks that were derived from established tests, surveys, and previously reported studies (Table 1). Perceived disability was measured by using validated outcome surveys and questions developed specifically for this study using an established format.

The results show that reduced wrist motion increased the times for task performance. Although the highly restricted wrist had a greater adverse effect than the partially restricted wrist, the difference was not statistically significant using this study protocol. The average impact of restricted wrist motion on other joint and trunk motions was statistically significant but did not appear clinically substantial. The impacts were highly variable among the subjects and tasks; however, this suggests that some individuals can adapt better to lost wrist motion and that some tasks are accommodated more easily. All survey scores were worse for the restricted wrists and poorest for the highly restricted wrist. The sensitivities of the DASH and PRWE in detecting the impact of reduced wrist motion were similar.

There are limitations in applying the results of a clinical study with normal subjects to patients with wrist arthritis. The study does not include other potential influences on the outcome of wrist procedures. Most patients undergo surgery to achieve pain relief and to improve reduced grip, which were not factors in these normal subjects. This difference may have made some of the tasks we chose less effective for this study. The subjects also were younger than most patients treated for wrist arthritis. Older individuals may be less able to compensate for lost motion, especially if other joints are affected by arthritis. Furthermore the study did not consider strenuous or repetitive tasks such as sports or physically demanding occupations that likely would be more affected. Conversely the brace may have created a greater hindrance to hand function than a surgical procedure for a variety of reasons. For example, the brace component in the palm may impair dexterity and the hinge at the wrist limits radioulnar deviation, which is retained partially in most motion-preserving procedures.

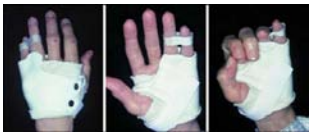
An individual's perceived disability with performance of common tasks appears to be influenced by their available wrist motion, however, there is marked variability in perceptions. The compensatory motions of the shoulder, elbow, forearm, and trunk motions also were highly variable. Simulated mo-

tion-preserving procedures did rate better than simulated arthrodesis by several parameters but the average differences were not as great as we had anticipated. Thus it may be hard to predict a patient's response to reduced wrist motion. The amount of flexion and extension necessary to achieve high patient satisfaction may be greater than that provided by common motion-preserving wrist procedures despite small reductions in physical performance. Similarly, patient satisfaction with function after complete wrist arthrodesis may rank lower than common physical measurements would suggest.

References

1. Meskers CG, Fraterman H, van der Helm FC, Vermeulen HM, Rozing PM. Calibration of the "Flock of Birds" electromagnetic tracking device and its application in shoulder motion studies. J Biomech 1999;32:629–633.
2. Milne AD, Chess DG, Johnson JA, King GJ. Accuracy of an electromagnetic tracking device: a study of the optimal range and metal interference. J Biomech 1996;29:791–793.
3. Divelbiss BJ, Sollerman C, Adams BD. Early results of the Universal total wrist arthroplasty in rheumatoid arthritis. J Hand Surg 2002;27A:195–204.
4. Cohen MS, Kozin SH. Degenerative arthritis of the wrist: proximal row carpectomy versus scaphoid excision and four-corner arthrodesis. J Hand Surg 2001;26A:94–104.
5. Wyrick JD, Stern PJ, Kiefhaber TR. Motion-preserving procedures in the treatment of scapholunate advanced collapse wrist: proximal row carpectomy versus four-corner arthrodesis. J Hand Surg 1995;20A:965–970.
6. Cobb TK, Beckenbaugh RD. Biaxial total-wrist arthroplasty. J Hand Surg 1996;21A:1011–1021.
7. Jebsen RH, Taylor N, Trieschmann RB, Trotter MJ, Howard LA. An objective and standardized test of hand function. Arch Phys Med Rehabil 1969;50:311–319.
8. Vliet Vlieland TP, van der Wijk TP, Jolie IM, Zwinderman AH, Hazes JM. Determinants of hand function in patients with rheumatoid arthritis. J Rheumatol 1996;23:835–840.
9. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measurethe DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). Am J Ind Med 1996;29:602–608.
10. MacDermid JC, Turgeon T, Richards RS, Beadle M, Roth JH. Patient rating of wrist pain and disability: a reliable and valid measurement tool. J Orthop Trauma 1998;12:577–586.
11. Nelson DL. Functional wrist motion. Hand Clin 1997;13:83–92.
12. Tang C, Roidis N, Itamura J, Vaishnau S, Shean C, Stevanovic M. The effect of simulated elbow arthrodesis on the ability to perform activities of daily living. J Hand Surg 2001;26A:1146–1150.
13. Carlson JD, Trombley CA. The effect of wrist immobilization on performance of the Jebsen Hand Function test. Am J Occup Ther 1983;37:167–175.
14. Brumfield RH, Champoux JA. A biomechanical study of normal functional wrist motion. Clin Orthop 1984;187:23–25.
15. Palmer AK, Werner FW, Murphy D, Glisson R. Functional wrist motion: a biomechanical study. J Hand Surg 1985;10A:39–46.
16. Ryu JY, Cooney WP 3rd, Askew LJ, An KN, Chao EY. Functional ranges of motion of the wrist joint. J Hand Surg 1991;16A:409–419.
17. Kraft G, Detels P. Position of function of the wrist. Arch Phys Med Rehabil 1972;53:272–275.

HCPCS:	Descriptor:
L3917	HAND ORTHOSIS, METACARPAL FRACTURE ORTHOSIS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

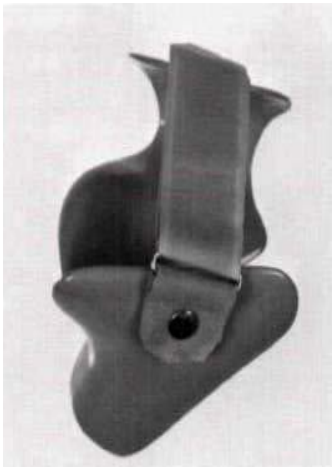


Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Fracture of carpals
Medically Necessary Argument	A hand orthosis, which is used to heal metacarpal fractures, immobilizes the bones of the hand to prevent met movement and allow healing. A hand orthosis is the primary treatment method of a metacarpal fracture. Without professional fitting and evaluation by a credentialed individual, the fracture site may close in malalignment and cause deformity of the bone. This would lead to decreased function of the hand, which is necessary for proper performance of ADL's.
References	

HCPCS:	Descriptor:
L3923	HAND FINGER ORTHOSIS, WITHOUT JOINTS, MAY INCLUDE SOFT INTERFACE, STRAPS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	NO	YES

Sample Diagnosis (Not Inclusive)	Sprains, strains, contracture, paralysis, muscle weakness
Medically Necessary Argument	A hand finger orthosis without joints is used to protect and immobilize the bones and ligaments of the hand and fingers. It places the hand in a safe position to prevent injury while wearing. The brace places the thumb and hand in a position for 3-point prehension for ADL's. Without proper fitting and evaluation by a credentialed individual, the orthosis could cause shortening of ligaments, which would decrease range of motion and function of the fingers. It could also cause ligamentous laxity or weakness in the hand or fingers and may allow unwanted motions of the fingers or hand, which would prolong the healing process.
References	

HCPCS:	Descriptor:
L3925	FINGER ORTHOSIS, PROXIMAL INTERPHALANGEAL (PIP)/DISTAL INTERPHALANGEAL (DIP), NON- TORSION JOINT/SPRING, EXTENSION/FLEXION, MAY INCLUDE SOFT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
NO	YES	NO	YES	YES

Sample Diagnosis (Not Inclusive)	Fracture, sprain, strain, contracture, ligament rupture, surgical repair
Medically Necessary Argument	This finger orthosis is used to protect and immobilize the DIP and/or PIP joints of the finger after injury or surgery. It provides minimal compression and prevents motion of the PIP and DIP joints, which aids in the healing process. A finger splint that is improperly fitted could be too restrictive and decrease circulation to the finger. If the patient fit this device loosely, it would allow motion at the DIP and PIP, which would decrease the healing processes, it was intended to assist.
References	19, 20

Chapter 3

Effectiveness of two finger splints for swan neck deformity in patients with rheumatoid arthritis: a randomized, crossover trial

Arthritis Rheum. 2009; 61:1025-31

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Abstract

Objective To compare the effectiveness and acceptability of silver ring splints (SRS) and commercial prefabricated thermoplastic splints (PTS) in treating swan neck deformities in patients with rheumatoid arthritis (RA).
Methods Consecutive patients with RA and a mobile swan neck deformity were included in a randomized, crossover trial. In 2 different sequences, patients used both splints for 4 weeks, with a washout period of 2 weeks. Afterward, patients used the preferred splint for another 12 weeks. The primary outcome measure was dexterity measured with the Sequential Occupational Dexterity Assessment (SODA). Secondary outcome measures included other measures of hand function, satisfaction with the splints and splint preference.
Results Fifty patients were included, and 47 (94%) of those completed the study. Eighteen patients (36%) had 1 swan neck deformity, whereas the other patients had 2 or more. The improvement of the total SODA score with the SRS (11.2; 95% confidence interval (95% CI) 8.1, 14.3) and PTS (10.8; 95% CI 7.5, 14.1) was similar (difference -0.5; 95% CI -2.2, 1.2). In addition, there were no significant differences in change scores regarding the other clinical outcome measures, or satisfaction. Twenty-four patients preferred the SRS, 21 preferred the PTS, and 2 patients choose neither. A comparison in the 12 week followup period yielded similar clinical outcomes, with the exception of a significantly higher score in 3 items of satisfaction in the SRS group.
Conclusion For patients with RA and a mobile swan neck deformity, SRS and PTS are equally effective and acceptable.

Introduction

The swan neck deformity is a common finger deformity associated with rheumatoid arthritis (RA). The deformity is characterized by flexion at the metacarpophalangeal joint, hyperextension of the proximal interphalangeal joint (PIPJ), and flexion of the distal interphalangeal joint (DIPJ) caused by a dominance of the extensor apparatus, which is not counteracted by flexion forces. This can result in a decreased ability to actively flex the PIPJ, leading to impaired dexterity[1-4]. With conservative treatment, finger splints aiming to prevent hyperextension and allow flexion of the PIPJ can be employed. Currently, 3 types of finger splints are available in the Netherlands: custom-made silver ring splints (SRS), custom-made thermoplastic splints (CTS), and prefabricated thermoplastic splints (PTS). SRS are made of sterling silver and manufactured according to the patient's ring size. The maximum allowed extension of the PIPJ can be can be individually adjusted by bending the splint within material limits. SRS cost approximately €80 (US$126,40) each. CTS are individually fabricated. Their costs depend on the time needed for fabrication, usually ranging between 21 and 44 minutes[5]. PTS are available in kits containing numerous sizes, with minimal time required for individual adjustments. They are made of less material than CTS and their price is approximately €15 (US$23.70), exclusive of the therapist time[6].

To date, studies on the effectiveness of finger splints for swan neck deformity are sparse. In an uncontrolled study with 17 patients who had RA and swan neck deformities[7], SRS improved dexterity but did not have an effect on grip strength, self-reported hand function, or hand pain. In a controlled study comparing SRS and CTS in 18 patients with RA[5], both splints were found to be equally effective with respect to digital stability, grip strength and mobility of the finger joints. However, CTS were considered less comfortable and less attractive. Since PTS appear to be more elegant and comfortable than CTS, they may offer an acceptable, inexpensive alternative to the SRS. Therefore, our study aimed to compare effectiveness, patient satisfaction and patient preferences of PTS and SRS in patients with RA and swan neck deformities.

Patients and Methods

Study design

This study used a multicenter, randomized, crossover design. Patients were randomly assigned to the SRS-PTS or PTS-SRS sequence. Randomization was done with a random digit generator with stratification for center and sex. Blocked randomization of 4 patients per block was used to prevent unbalanced distribution. The randomization procedure was completed by an administrative assistant who was not aware of the block size. Patients used each splint for 4 weeks with a washout period of 2 weeks in between. After both treatment periods, patients chose their preferred splint and were followed up for 12 weeks while wearing the preferred splint.

Patients

From August 2005 through September 2006, consecutive patients with RA and swan neck deformities were recruited one patient at a time until the target sample size was obtained at the outpatient rheumatology clinics of 3 centers in the Netherlands: Leiden University Medical Center (Leiden), Sint Maartenskliniek (Nijmegen) and Reinier de Graaf Gasthuis (Delft). Patients were eligible for the study if they had been diagnosed with RA

according to 1987 criteria of the American College of Rheumatology (formerly, the American Rheumatism Association)[8], were at least 18 years old, had a mobile swan neck deformity that was manually correctable to at least 45° of PIPJ flexion of an index and/or middle finger, had stable disease activity, had received no corticosteroid injections for the previous 3 months, had no planned surgery for the duration of the study, and had not been treated with swan neck finger splints in the past. Exclusion criteria were the presence of a condition other than RA, or other severe finger deformities that interfered with hand function or with the use of finger splints.

The study was approved by the hospital medical ethics committees of the 3 participating hospitals, and all participants gave written informed consent.

Splinting protocol

The study used the SIRIS Swan Neck Splint (Silver Ring Splint Company, Charlottesville, VA) and the Oval-8 Finger Splint (3-Point Products, Stevensville, MD). Both splints were sized according to manufacturer's recommendations by experienced (>5 years) hand therapists (FJvdG and CK-S), and fitted in slight flexion, which corrected the hyperextension of the PIPJ. All the correctable swan neck deformities of the index or middle finger(s) were splinted. The participants were asked to wear the splints as much as possible, removing them only for cleaning. During the crossover period, participants returned the first splint type worn to ensure the consistent wearing of the second splint type.

Measurements

Sociodemographic and disease characteristics were collected at baseline (T0). Outcome measurements were gathered at T0, after the first treatment period (T1), after the washout period (T2), after the second treatment period (T3), and after the 12-week followup period (T4). All measurements were collected with patients wearing the splints, except for the PIPJ hyperextension. Adherence and satisfaction were measured at T1, T3 and T4. The patients' preferences were obtained at T3 and at T4 by asking whether they would continue wearing the splints (yes, unsure, no). All clinical measurements were performed by 2 experienced hand therapists (FJvdG and CK-S). To enhance the intrarater reliability, a training session and calibration meeting was scheduled prior to the start of the study and once during the study.

Sociodemographic and general disease characteristics

Sociodemographic data included sex, age, living status (alone or with others), and paid employment (yes/no and number of hours per week, if applicable). Disease duration was extracted from the patient records. Disease activity was measured with the Disease Activity Score in 28 joints using 4 variables: the 28-joint counts for swelling and tenderness, the erythrocyte sedimentation rate, and the patient's overall assessment of well-being[9]. Functional ability was measured with the Health Assessment Questionnaire (HAQ)[10], which covers 20 activities of daily living in 8 dimensions. The total HAQ score is the average score of the 8 dimensions (where 0 = best possible function and 3 = worst possible function). General health status was measured with a validated version of the Medical Outcomes Study Short Form 36 Health Survey[11], which includes 8 subscales. These subscales can be converted into two summary scales: the physical and mental component summary scales, standardized to a mean ± SD score of 50 ± 10 in the general population. For that purpose, we used the scores from an age- and sex-matched normative sample, which was

drawn from a large, random, nationwide sample of adults (n=1,742) from the general Dutch population[12] and factor score coefficients[13].

Swan neck deformities, splinting protocol, adverse events, and adherence

The number of swan neck deformities, all deviations from the splinting protocol, and adverse events were recorded. Adherence during the first 2 splinting periods was assessed with a diary, in which the participants recorded the number of hours per day that they used the splint(s). Because the prolonged usage of diaries is usually hampered by low compliance, adherence during the followup period was assessed only once at the end of that period, when patients were asked: 'How many days of the week did you wear the splint on average in the past 12 weeks?' and 'When you were wearing the splint, for how many hours per day was this in the past 12 weeks?'. The results of these questions were multiplied to obtain an average number of splint usage hours per week.

Primary outcome measure

The primary outcome measure was dexterity as measured by the Sequential Occupational Dexterity Assessment (SODA)[14-16]. With the SODA, the patient performs 12 standardized tasks and an assessor scores the ability to perform every task (where 4 = able to perform in the requested way, 1 = able to perform in a different way, and 0 = unable to perform) and the level of difficulty in the performance (where 2 = not difficult, 1 = some difficulty, 0 = very difficult). The SODA score range is 0-108, with a higher number indicating better dexterity. The SODA pain score is computed by counting the number of painful tasks (range 0-12).

Secondary outcome measures

The secondary outcome measures included general hand function as measured by the hand and finger function domain of the Dutch Arthritis Impact Measurement Scales 2 (D-AIMS2)[17] and the Michigan Hand Outcomes Questionnaire (MHQ)[18,19]. The hand and finger function subscale of the D-AIMS2 consists of 5 questions regarding the patient's hand function over the previous week. The scores range from 0 (good hand function) to 10 (bad hand function). The MHQ is a questionnaire covering 6 domains: overall hand function, activities of daily living, pain, work performance, esthetics, and satisfaction with hand function. The total score range (average of all domains) is 0-100, with higher scores indicating better hand function.

Passive PIPJ hyperextension of the splinted fingers was measured unsplinted with a goniometer[20]. If more than one finger was splinted, the average of the scores of the fingers involved was used. Cylindrical grip strength and pinch grip strength were determined with a Jamar dynamometer (JA Preston Corporation, Clifton, NJ)[21] and a North Coast hydraulic pinch gauge (Pieksma Medical Supplies, Bussum, the Netherlands), respectively. The patients underwent the tests twice on every side, with the highest score recorded. Scores were obtained for the splinted finger(s) only. In the case of involvement of multiple fingers, average scores were used. After both initial splinting periods, the patient's perceived change in hand function was measured on a 3-point scale (where 1 = worsened, 2 = neither worsened nor improved, and 3 = improved). In the absence of a validated questionnaire to measure the RA patients' satisfaction with hand or finger splints, we used a 13-item questionnaire previously developed by one of the authors (Stern EB: personal communication). Each item was rated on a 5-point Likert scale (where 1 = totally disagree and 5 = totally agree).

Statistical analysis

The sample size was calculated based on the SODA as primary outcome measure and using the formula: $n = (Z_{\alpha/2} + Z_{\beta})^2 * \tau^2 * (r + 1) / v^2 r$. With $\alpha = 0.05$ and 1 minus $\beta = 0.80$, $(Z_{\alpha/2} + Z_{\beta})^2 = 7.85$. In the absence of data on the clinical relevance of SODA change scores, we used the data from a study[7] executed within a context similar to the present study[22] with respect to the patient population (RA patients with finger deformities), the intervention (finger splints), and the primary outcome measure (dexterity). In that uncontrolled study on custom-made silver splints in 17 patients with RA, a median improvement of 5 points on the SODA after 1 month was observed[7], yielding a value of 5 for the mean difference. From the individual data presented in that study, an SD of the SODA change score (τ) of 8.95 was calculated. With a comparison of 2 groups with equal numbers implying that $r = 1$, and using the previously mentioned formula, a total of 50 patients per group would be required. To detect a difference of 6 points on the SODA score, in line with the 12-week difference observed by Zijlstra et al.[7], 36 patients per group would be needed. As in this study, a crossover design was employed, and the total number of patients required for the study was 50.

For all data, we observed the distribution plots. In case of normally distributed data, we presented mean ± SDs or 95% confidence intervals (95% CIs), and in case of a non-normal distribution, we presented median and interquartile range the net result of the 75th percentile minus the 25th percentile.

To determine if a period effect was present, the differences in effect between the 2 periods were compared between the two sequences (SRS-PTS or PTS-SRS). To determine if a carryover effect was present, the change scores of the 2 splints in the 2 periods were averaged for every patient, and the mean change score was then compared between the 2 splinting sequences[23]. These possible effects were tested for all outcome variables by unpaired *t*-tests. In the absence of statistically significant carryover or period effects, the main analysis would pertain to a comparison of the change scores after wearing them for 4 weeks between the 2 splints by means of the paired *t*-test. McNemar's test was used to compare numbers of patients reporting the following categories of perceived changes in hand function between the 2 splints: 'improved' versus both 'neither worsened nor improved' and 'worsened'. In addition, a within-splint analysis was performed using paired *t*-tests to test for significant differences between T0 and followup measurements after 4 weeks. To study the effects after a 12-week followup period, the change scores between T3 and T4 within the groups of patients preferring the SRS and PTS were compared using unpaired *t*-tests. In addition, the chi-square was used to assess a trend in differences in willingness to continue using the splints between patients who chose the SRS or the PTS. For that purpose, the outcomes were dichotomized into 'yes' versus 'unsure and no'. All analyses were computed using the Statistical Package for the Social Siences, version 14.0 (SPSS, Chicago, IL). The level of significance was set at less than 0.05 for all statistical tests.

Results

A total of 83 patients were invited and screened (Figure 1). Eventually, 50 participants entered the study, and 3 of those patients did not complete the study. Table 1 shows the characteristics of the study sample.

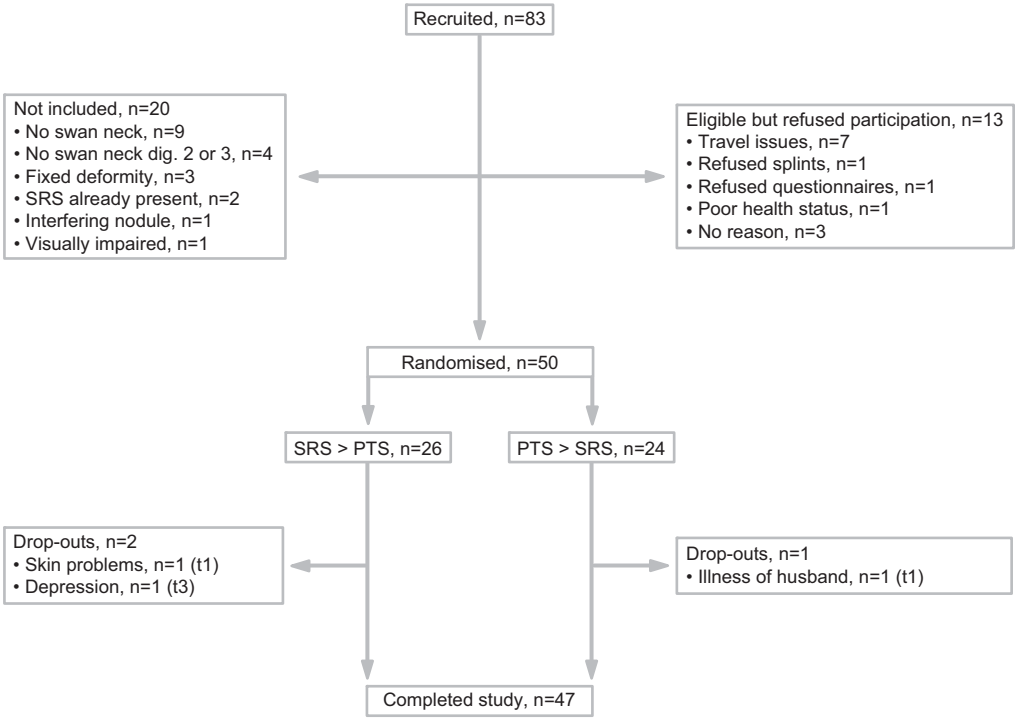

Figure 1. Flow-chart of a randomized crossover study comparing 2 finger splints in 50 patients with reumatoid arthritis and swan neck deformities. SRS = silver ring splint; PTS = prefabricated thermoplastic splint.

Protocol violations, adverse events, and adherence

In the initial 2 treatment periods, 8 patients did not use one or more of their splints for the full study period. Seven patients, all having more than 1 swan neck deformity, could not use 1 splint during 1 period because it was broken (1 SRS), lost (2 SRS and 3 PTS), or did not fit because of local joint inflammation (1 PTS). In one patient, neither the SRS nor the PTS could be used on one finger because of the development of an interfering nodule, but the patient continued using splints on other fingers. One patient developed skin problems on both splinted fingers (SRS), possibly due to the relatively high hyperextension force. This patient refused further participation after 2 weeks. Two patients reported minor skin problems with the PTS due to perspiration in warm weather, but they could continue to wear the splints throughout the assigned period. In the initial treatment periods, 47 of 49 SRS diaries, and 47 of 48 PTS diaries, were filled in. Adherence rates of the SRS group (mean ± SD 15.3 ± 7.4 hours/week) and the PTS group (mean ± SD 15.4 ± 7.4 hours/week) were similar (difference -0.05; 95% CI -2.1, 1.9).

Table 1. Sociodemographic and disease characteristics of 50 patients with reumatoid arthritis and swan neck deformities‡

Characteristics	*Patients*
Sociodemographics	
Male/female, no.	9/41
Age, years	53.8 (21.6)
Living with other(s), no.	45
Not living with other(s), no.	5
Paid employment, no. (%)	13 (26)
Hours of paid employment per week (n=13)	20 (18)
Disease	
Disease duration, years	13.7 (11.5)
DAS28	3.26 (2.1)
HAQ (range 0-3)	1.13 (1.1)
SF-36 Physical Component Summary (range 0-100)	38.3 (15.2)
SF-36 Mental Component Summary (range 0-100)	56.2 (15.9)
Number of swan neck deformities, no. (%) ¥	
1	18 (36)
2	17 (34)
3	2 (4)
4	13 (26)

‡ Values are expressed as the median (interquartile range) unless otherwise indicated. DAS28 = Disease Activity Score in 28 joints; HAQ = Health Assessment Questionnaire; SF-36 = Medical Outcomes Study Short Form 36 Health Survey. ¥ Per patient on the index and/or middle finger.

Outcomes after 4 weeks

None of the outcome measures demonstrated a significant period or carryover effect (P >0.05 for all; data not shown).

As shown in Table 2, after 4 weeks of use there were no differences between the change scores of the 2 finger splints for any of the outcome measures. The number of patients considering their hand function 'worse', 'worse nor improved', or 'improved' were 5, 18 and 21 for the SRS splint, and 2, 21 and 20 for the PTS splint, respectively (P =0.42, by McNemar's test).

Concerning within-group changes with both splints, both SODA scores improved significantly after 4 weeks. Moreover, with the SRS splints, passive PIPJ hyperextension decreased significantly between T0 and 4 weeks. With all other outcomes, a trend toward improvement was seen with both splints; however, none of the changes reached statistical significance.

After using both splints for 4 weeks, 24 patients preferred the SRS, 21 the PTS and 2 choose neither (P =0.66, by chi-square test).

Followup with the preferred splint

After choosing a preferred splint, 3 patients, using more than one splint, did not use one because it was found uncomfortable (2 SRS) or it was lost (1 PTS). In the followup

Table 2. Change scores with SRS and PTS and differences in change scores in 50 patients with reumatoid arthritis and swan neck deformities‡

	SRS (n=50)	*PTS (n=50)*	*Difference between splints*
SODA, range 0-108			
Baseline, mean ± SD	83.7 ± 18.0	84.3 ± 18.8	
Change after 4 weeks	11.2 (8.1; 14.3)¥	10.8 (7.5; 14.1)¥	-0.5 (-2.2; 1.2)
SODA pain, range 0-12			
Baseline, mean ± SD	1.6 ± 2.6	1.7 ± 2.5	
Change after 4 weeks	-0.5 (-0.9; -0.1)¥	-0.5 (-1.0; -0.1;)¥	0.4 (-0.1; 1.0)
D-AIMS2 Hand/finger subscale, range 0-10			
Baseline, mean ± SD	2.72 ± 2.27	3.07 ± 2.26	
Change after 4 weeks	-0.14 (-0.55; 0.27)	-0.21 (-0.62; 0.19)	-0.01 (-0.66; 0.65)
MHQ total score, range 0-100			
Baseline, mean ± SD	60.7 ± 15.6	58.7 ± 13.7	
Change after 4 weeks	-0.1 (-3.0; 2.7)	1.4 (-2.0; 4.8)	-1.3 (-6.4; 3.8)
Passive PIPJ hyperextension, degrees			
Baseline, mean ± SD	27.7 ± 8.2	27.0 ± 9.1	
Change after 4 weeks	-2.1 (-3.3; -1.0)¥	-1.1 (-2.4; 0.1)	-1.1 (-2.6; 0.5)
Cylindrical grip strength, kg			
Baseline, mean ± SD	17.7 ± 9.9	17.5 ± 10.4	
Change after 4 weeks	-0.13 (-1.10; 0.82)	0.39 (-0.36; 1.15)	-0.53 (-1.67; 0.61)
Pinch grip strength, kg			
Baseline, mean ± SD	2.4 ± 1.7	2.3 ± 1.7	
Change after 4 weeks	0.03 (-0.20; 0.26)	0.08 (-0.17; 0.32)	-0.02 (-0.24; 0.21)
Patient preferences, no. (%)	24 (51)	21 (45)	

‡ Values are the mean (95% confidence interval) unless otherwise indicated. SRS = silver ring splint; PTS = prefabricated thermoplastic splint; SODA = Sequential Occupational Dexterity Assessment; D-AIMS2 = Dutch Arthritis Impact Measurement Scales 2; MHQ = Michigan Hand Outcomes Questionnaire; PIPJ = proximal Interphalangeal joint. Positive changes reflect improvement, except for SODA pain, D-AIMS2, and PIPJ hyperextension. Positive differences are in favor of the SRS. ¥P <0.05, paired t-test, comparison within splints (Baseline minus 4 weeks); #P <0.05, paired t-test, comparison between splints (SRS minus PTS).

period, the mean ± SD splinting duration was 11.7 ± 8.1 hours/day with the SRS, and 16.3 ± 6.5 hours/day with the PTS (difference -4.6, 95% CI -9.2, 0.03). Table 3 shows that with 24 patients continuing to wear the SRS and 21 patients the PTS, there are no significant differences between the 2 splints regarding the change scores between 10 and 22 weeks on any of the clinical outcome measures.

For the other outcome measures, there were no significant changes during the 12-week followup between and within the splints, indicating that effects obtained after 4 weeks were sustained after 12 weeks. When asked at followup if they would continue wearing the splints after the study, 21 (91%) of the 23 patients using the SRS answered positively, and 2 (9%) indifferently or negatively. In the PTS group, 11 (61%) patients answered positively, and 7 (39%) answered indifferently or negatively (SRS versus PTS; P =0.79 by chi-square test).

Table 3. Change scores between 10 weeks and 22 weeks (12 week followup) with the finger splint of choice (SRS or PTS) and differences in change scores‡

	SRS (n=24)	*PTS (n=21)*	*Difference between splints*
SODA range, 0-108	-0.4 (-1.8; 0.9)	-0.2 (-3.4; 3.0)	-0.2 (-3.4; 3.0)
SODA pain, range, 0-12	-0.3 (-1.0; 0.5)	0.5 (-0.4; 1.4)	-0.8 (-1.9; 0.4)
D-AIMS2 hand/finger subscale, range 0-10	-0.08 (-0.7; 0.6)	0.00 (-0.6 ; 6.0)	-0.08 (-1.0; 0.8)
MHQ total score, range 0-100	0.6 (-3.2; 4.5)	-2.0 (-7.1; 3.1)	2.6 (-3.4; 8.7)
Passive hyperextension PIPJ, degrees	-1.0 (-4.6; 2.5)	-2.7 (-5.8; 0.5)	1.6 (-3.1; 6.3)
Cylindrical grip strength, kg.	0.2 (-1.7; 2.1)	-0.3 (-2.4; 1.9)	0.5 (-2.3; 3.2)
Pinch grip strength, kg.	0.1 (-0.2; 0.4)	-0.1 (-0.6; 0.4)	0.3 (-0.3; 0.8)

‡ Differences and changes are mean (95% confidence intervals). SRS = silver ring splint; PTS = prefabricated thermoplastic splint; SODA = Sequential Occupational Dexterity Assessment; D-AIMS2 = Dutch Arthritis Impact Measurement Scales 2; MHQ = Michigan Hand Outcomes Questionnaire; PIPJ = proximal interphalangeal joint. Positive changes reflect improvement, except for SODA pain, D-AIMS2 and PIPJ hyperextension. Positive differences are in favor of the SRS. $^{*}P < 0.05$, paired *t*-test, comparison between splints (SRS minus PTS).

Patient satisfaction

Table 4 shows the results of the patient satisfaction questionnaire. Overall, after 4 weeks the scores were higher for the SRS than for the PTS, except for item 12, But only the score on item 1 reached statistical significance.
In the followup period, with the patients using the preferred splint, the scores were significantly higher for the SRS than for the PTS, regarding the items 1, 2 and 9.

Discussion

The current study suggests that SRS and PTS are equally effective and acceptable in patients with RA and mobile swan neck deformities. Both splints improve dexterity (as measured by the SODA) and reduce dexterity-related pain (as measured by the SODA pain score), but only the SRS reduces PIPJ hyperextension. Neither splint significantly improved or interfered with reported hand function, measured grip, or pinch strength. Except for a significantly higher satisfaction score in 3 satisfaction items with the SRS, a followup with the preferred splint yielded equal results with both splints. Almost two-thirds of the patients said they would continue wearing their preferred splints after the study.

With respect to the comparison of the effectiveness of thermoplastic splints with SRS, our results parallel those of the study by Schegget and Knipping[5], where CTS were found to be equally effective as SRS in 18 patients with RA. However, in that study, CTS were found to be far less acceptable than SRS, mainly due to their less attractive appearance and their thickness, making the fingers spread. In contrast, no differences in satisfaction were seen after 4 weeks with the PTS used in the present study, with equal numbers of patients choosing the SRS and the PTS. In the followup period, with the patients wearing the splint of their choice, 2 aesthetics-related items of satisfaction were valued higher in the SRS than in the PTS; however, the absolute difference was small, so that its clinical significance is questionable.

The results of our study suggest that the provision of a PTS is worth considering for patients with a mobile swan neck deformity. This is especially the case since PTS are less expensive than SRS, with similar time needed for the hand therapist to measure and adjust the splint to obtain the optimal fit and allowed extension.

Table 4. Differences in satisfaction in 13 items after 4 weeks and after 12 weeks of followup between 2 swan neck orthoses in patients with rheumatoid arthritis‡

	After 4 weeks			After 12 weeks of followup		
	SRS (n=50)	*PTS (n=50)*	*Differences Mean (95% CI)*	*SRS (n=24)*	*PTS (n=21)*	*Differences Mean (95% CI)*
1. Did you like how the splint looked? (1-5)	4.3 ± 0.6	3.7 ±1.0	0.5 (0.2; 0.8)#	4.5 ± 0.5	3.9 ± 0.6	0.6 (0.2; 0.9)¥
2. Did you like how your fingers looked with the splint on? (1-5)	4.0 ± 0.6	3.8 ± 0.8	0.2 (-0.1; 0.5)	4.2 ± 0.6	3.8 ± 0.6	0.4 (0.0; 0.8)¥
3. Was the splint easy to put on and take off? (1-5)	4.1 ± 0.8	4.0 ± 0.7	0.1 (-0.2; 0.4)	4.3 ± 0.4	4.0 ± 0.9	0.3 (-0.2; 0.7)
4. Was the splint easy to clean? (1-5)	4.4 ± 0.5	4.2 ± 0.6	0.1 (-0.1; 0.3)	4.3 ± 0.4	4.1 ± 0.4	0.2 (-0.1; 0.5)
5. Did the splint relieve your finger joint pain? (1-5)	3.2 ± 0.8	3.0 ± 1.0	0.2 (-0.1; 0.5)	3.1 ± 1.0	2.9 ± 0.8	0.1 (-0.5; 0.8)
6. Did the splint decrease your finger joint swelling? (1-5)	2.9 ± 0.9	2.8 ± 1.1	0.1 (0.1; 0.4)	3.0 ± 0.9	2.8 ± 0.7	0.2 (-0.3; 0.8)
7. Did the splint improve your grasp while you wore it? (1-5)	3.0 ± 0.8	2.9 ± 0.9	0.1 (-0.2; 0.4)	3.6 ± 0.9	3.1 ± 0.9	0.5 (-0.1; 1.1)
8. Was your hand stronger with the splint on?	2.8 ± 0.8	2.7 ± 1.0	0.1 (-0.2; 0.4)	3.0 ± 0.9	2.9 ± 0.8	0.2 (-0.4; 0.7)
9. Did the splints keep your fingers from hyper extending (bending back) the majority of the time? (1-5)	4.1 ± 0.9	3.9 ± 1.2	0.3 (-0.1; 0.6)	4.6 ± 0.6	4.0 ± 1.0	0.6 (0.1; 1.1)¥
10. Did the splint help you manipulate small objects? (1-5)	3.1 ± 0.8	2.9 ± 0.8	0.2 (-0.1; 0.4)	3.3 ± 0.9	3.0 ± 0.7	0.3 (-0.2; 0.8)
11. Was it easier to perform daily activities with the splint on? (1-5)	3.0 ± 0.7	2.9 ± 0.8	0.1 (-0.3; 0.3)	3.3 ± 0.8	2.8 ± 0.8	0.5 (0.0; 1.0)
12. Did the splint stay on your fingers when reaching into tight areas? (1-5)	2.9 ± 1.1	3.0 ± 1.0	-0.1 (-0.5; 0.2)	3.1 ± 1.1	3.2 ± 0.9	-0.1 (-0.8; 0.6)
13. Was the splint comfortable to wear? (1-5)	4.0 ± 1.0	3.3 ± 1.0	0.2 (-0.2; 0.5)	4.0 ± 0.6	3.6 ± 0.8	0.4 (-0.1; 0.8)

‡ Values are the mean ± SD unless indicated otherwise. SRS = silver ring splint; PTS = prefabricated thermoplastic splint; 95% CI = 95% confidence interval. Higher scores indicate more satisfaction.
# P <0.05, paired t-test; ¥ P <0.05, unpaired t-test.

Similar to the results of the present study, significant improvements of the SODA dexterity score with SRS were also seen in a previous observational study[7]. However, the SODA dexterity score improvements of were larger in the current study. Moreover, the SODA pain score improved, whereas in the study by Zijlstra et al. no improvement was seen. The greater improvement in the present study might be explained by the fact that Zijlstra and colleagues included patients with a longer disease duration (median 21 years) and worse hand function, which is reflected by a lower baseline SODA score (median 71). As suggested by the authors of that study, it could be hypothesized that finger splints for swan neck deformity are more effective in the earlier stages of disease, when correction is relatively easy. To date, there are no studies are available with respect to the clinical relevance of the observed changes of the SODA score.

In all other measures of hand function, no improvements were seen either in our study or in the study by Zijlstra et al, except for a significant decrease of passive mobility of the PIPJ in the present study. This latter result is comparable with the outcome of the study by Schegget and Knipping[5], which demonstrated a reduction of passive PIPJ hyperextension of equal magnitude with both SRS and thermoplastic splints after 24 weeks. Since the absolute reduction of passive PIPJ hyperextension was small, its clinical relevance is doubtful.

The absence of effect of finger splints on various outcome measures related to hand function could possibly be explained by the impact of limitations of joints or structures other than the PIPJ and the DIPJ of the index and middle fingers. Although patients with limitations or deformities seriously interfering with hand and finger function were excluded, most patients had mild other limitations such as ulnar deviation, or swan neck or boutonnière deformities of the thumb or fourth and fifth fingers. As these other limitations would probably affect hand function to a similar extent with both splints, they are not likely to have had an impact on the comparisons between the two splints.

Despite the modest effectiveness of both splints, more than 60% of the patients in the current study indicated that they would continue using the splints after the study. This rate is in line with the findings of Zijlstra et al. However, studies with a longer duration of followup assessment would be needed to examine which proportion of the patients would fulfill their intention.

A limitation of the study is its crossover design, where despite statistical testing, carryover or period effects cannot be totally ruled out. Furthermore, when calculating the sample size, we did not take into account a drop-out rate. Since 3 patients left the study prematurely, the possibility that this study did not have sufficient power to detect a difference of 5 points or less on the SODA score can not be totally ruled out. Because it is not possible to blind assessors in this type of research, where measurements are done with splints on, bias toward the effectiveness of finger splints cannot be completely avoided. Nevertheless, having the assessments performed by an independent assessor, rather than 2 of the authors, would probably have been preferable. Another potential source of bias could be the lack of blinding of assessors and patients, due to the nature of the intervention. In addition, we used a satisfaction questionnaire, of which the psychometric properties have not yet been established. Given the fact that specific satisfaction questionnaires for hand and finger splints are scarce, more research into the validation of questionnaires used to evaluate RA patients' satisfaction with orthoses seems justified.

In summary, the results of the present study, and that of the already available evidence[5-7], suggest that wearing SRS or PTS for mobile swan neck deformities is effective in improving dexterity and dexterity-related pain after 4 weeks. The decision about what type of splint to use should therefore not depend on its effectiveness, but merely on patient preferences and costs.

Acknowledgement

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References

1. Boyer MI, Gelberman RH. Operative correction of swan neck and boutonniere deformities in the rheumatoid hand. J Am Acad Orthop Surg 1999; 7:92-100.
2. Eberhardt K, Johnson PM, Rydgren L. The occurrence and significance of hand deformities in early rheumatoid arthritis. Br J Rheumatol 1991; 30:211-213.
3. Laine VA, Sairanen E, Vainio K. Finger deformities caused by rheumatoid arthritis. J Bone Joint Surg [Am] 1957; 39-A:527-533.
4. van der Giesen FJ, Nelissen RG, Rozing PM, Arendzen JH, de Jong Z, Wolterbeek R et al. A multidisciplinary hand clinic for patients with rheumatic diseases: a pilot study. J Hand Ther 2007; 20:251-261.
5. Schegget M, Knipping A. A study comparing use and effects of custom-made versus prefabricated splints for swan neck deformity in patients with rheumatoid artrhritis. Br J Hand Therapy 2000; 5:101-107.
6. Manning J. Perceptions of an inexpensive commercial tripoint (swan neck) splint for individuals with rheumatoid arthritis, a project submitted to the faculty of the graduate School of the University of Minnesota in partial fulfillment of the requirements for the degree of Master of Science. Research advisor: Erica B Stern - Associate Professor of Occupational Therapy. 2003.
7. Zijlstra TR, Heijnsdijk-Rouwenhorst L, Rasker JJ. Silver ring splints improve dexterity in patients with rheumatoid arthritis. Arthritis Rheum 2004; 51:947-951.
8. Arnett FC, Edworthy SM, Bloch DA, McShane DJ, Fries JF, Cooper NS et al. The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. Arthritis Rheum 1988; 31:315-324.
9. Prevoo ML, 't Hof MA, Kuper HH, van Leeuwen MA, van de Putte LB, van Riel PL. Modified disease activity scores that include twenty-eight-joint counts. Development and validation in a prospective longitudinal study of patients with rheumatoid arthritis. Arthritis Rheum 1995; 38:44-48.
10. Siegert CE, Vleming LJ, Vandenbroucke JP, Cats A. Measurement of disability in Dutch rheumatoid arthritis patients. Clin Rheumatol 1984; 3:305-309.
11. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992; 30:473-483.
12. Aaronson NK, Muller M, Cohen PD, Essink-Bot ML, Fekkes M, Sanderman R et al. Translation, validation, and norming of the Dutch language version of the SF-36 Health Survey in community and chronic disease populations. J Clin Epidemiol 1998; 51:1055-1068.
13. Ware JE Jr, Kosinski M, Keller SD. SF-36 Health Survey Manual and Interpretation Guide. Boston, MA: The Health Institute, 1994.
14. van Lankveld W, van't Pad BP, Bakker J, Terwindt S, Franssen M, van Riel P. Sequential occupational dexterity assessment (SODA): a new test to measure hand disability. J Hand Ther 1996; 9:27-32.
15. van Lankveld W, van't Pad BP, van der SD, Dapper M, de Waal MM, van de PL. Evaluating hand surgery in patients with rheumatoid arthritis: short-term effect on dexterity and pain and its relationship with patient satisfaction. J Hand Surg [Am] 2000; 25:921-929.
16. van Lankveld WG, Graff MJ, van 't Pad Bosch PJ. The Short Version of the Sequential Occupational Dexterity Assessment based on individual tasks' sensitivity to change. Arthritis Care Res 1999; 12:417-424.
17. Riemsma RP, Taal E, Rasker JJ, Houtman PM, Van Paassen HC, Wiegman O. Evaluation of a Dutch version of the AIMS2 for patients with rheumatoid arthritis. Br J Rheumatol 1996; 35:755-760.
18. Chung KC, Pillsbury MS, Walters MR, Hayward RA. Reliability and validity testing of the Michigan Hand Outcomes Questionnaire. J Hand Surg [Am] 1998; 23:575-587.
19. Huijsmans R, Sluiter H, Aufdemkampe G. Michigan Hand Outcomes Questionnaire - Dutch Language Version; een vragenlijst voor patienten met handfunctieproblemen. Fysiopraxis 2001; 9:38-41.
20. American Acadamy of Orthopedic Surgeons. Joint Motion; Method of measuring and recording. 1965. ed. Churchill Livingstone, Edinburgh, london and New York.

21. Harkonen R, Harju R, Alaranta H. Accuracy of the Jamar dynamometer. J Hand Ther 1993; 6:259-262.
22. Beaton DE, Boers M, Wells GA. Many faces of the minimal clinically important difference (MCID): a literature review and directions for future research. Curr Opin Rheumatol 2002; 14:109-114.
23. Altman D. Crossover trials. Practical Statistics For Medical Research. Chapman & Hall, 1999: 467-471.

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Case report

Dynamic joint-aligned PIP and DIP corrective-flexion/extension orthosis for post burn finger contractures

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1. Introduction

Patients with hand burns are likely to develop various hand deformities and contractures, the most common of all being the deformities that resemble the Boutonniere deformities of fingers [1]. In contrast to other orthopaedic conditions these deformities in burns are often due to the contracted scar tissue and not solely due to changes in the direction of pull by the muscles of the hand. Therefore, the commonly prescribed splints, the '*Capener*' splint that corrects PIP (Proximal Interphalangeal) deformities alone and the static '*Gutter Splint*' that corrects the hyperextension component of DIP (Distal Interphalangeal) joint but inadequate in addition, its application hinders the functional use of hand, are not sufficient. Thus this paper describes an innovative splint, indigenously designed that stretches both the joints simultaneously.

2. General objective and rationale

- To enhance function.
- To apply gentle, prolonged stretch to a contracted PIP & DIP capsule, ligaments and the other related soft tissues to promote growth of shortened tissues and restore range of motion in both the PIP and DIP joints.

3. Fabrication of the splint

The splint consists of four springs (S1, S2, S3 and S4) and three supports (the proximal support, PS; the intermediate support, IS and the distal support, DS) that are made out of approximately 15 cm of spring wire (Fig. 1). Initially, the outline of the finger that needs to be splinted is drawn and the skin creases of that finger are marked. The spring wire is then bent in such a way that the two springs S1 and S2 are on either sides of the PIP crease and the other two springs S3 and S4 are on either sides of the DIP crease and the three semi-circular supports (PS, IS, and DS) are made in the following pattern.

- The PS rests on the dorsal surface of the finger at the midline between the MP (metacarpophalangeal) crease and the PIP crease.
- The DS rests on the dorsal surface of the finger at the midline between DIP crease and the tip of the finger.
- The IS rests on the volar surface of the finger at the midline between the PIP and DIP crease.

These supports provide the three-point pressure needed to produce the extension force at the PIP and flexion force at the DIP joints (Fig. 2). The finger supports PS, IS, and DS are padded adequately with foam or any padding material in order to avoid any local pressure by increasing the surface area or the area of contact.

4. Advantages

- This splint's best utility would be in those with slipped extensor tendons, where there is difficulty in full PIP extension, due to the mobilizing of both the PIP and the DIP joints at the same time.
- This dynamic functional splint is a day splint, when prescribed concomitantly with static gutter splint as night splint, likely to assist in promoting faster growth of

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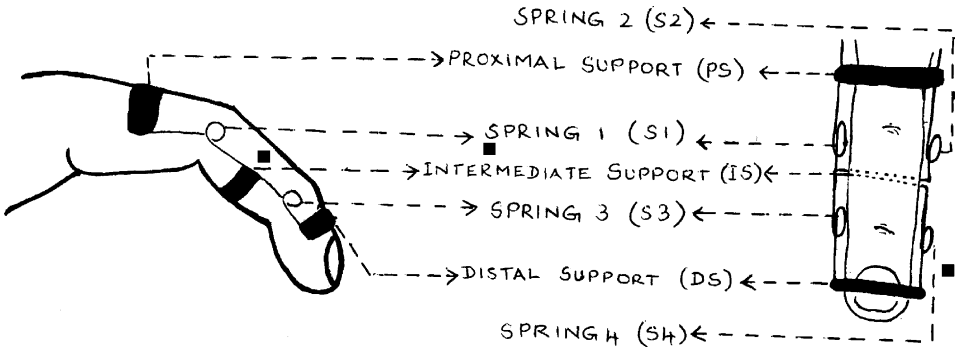


Fig. 1.

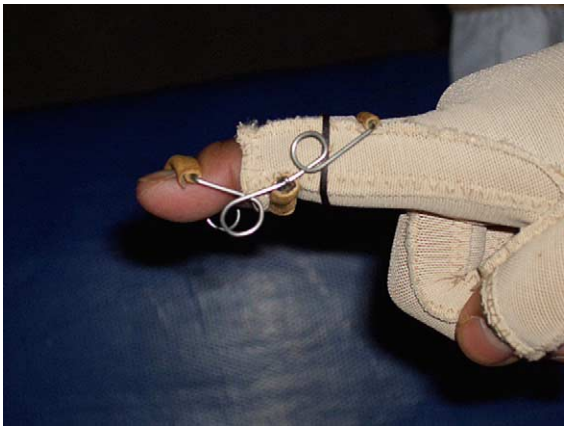


Fig. 2.

shortened tissues and restore range in boutonniere deformity while maintaining the client's functional independence [2]. However, this splint does not replace the static gutter splint that is in use, which allows scarring without flexion at PIP by maintaining it in extension.

- The force produced by the splint to provide prolonged stretch could be easily adjusted by varying the number of coils in the spring and/or by changing the thickness of the spring wire.
- Importantly this orthosis has "no profile" minimizing its visual presence.
- Above all it is cost-effective (less than 25 cents) and very easy to make requiring not more than 15 min per splint.

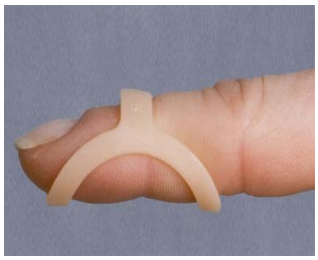
5. Conclusion

This splint provides continuous stretch to both PIP and DIP that is needed for range restorations among one of the commonest post burn contractures of fingers. It has a pleasing look and is also comfortable and easy to use, which enhances the client's compliance. This can become the splint of choice for most of the third world nations especially because of its simple and cost effective nature.

References

[1] Daugherty MB, Carr-Collins JA. Splinting techniques for the burn patient. In: Richard RL, Staley MJ, editors. Burn care and rehabilitation: principles and practice. Philadelphia: FA Davis, 1994. p. 589.
[2] McKee P, Morgan L, editors. Orthotics in rehabilitation. New Delhi: Jaypee Brothers medical Publishers Ltd., 1998.

HCPCS:	Descriptor:
L3927	FINGER ORTHOSIS, PROXIMAL INTERPHALANGEAL (PIP)/DISTAL INTERPHALANGEAL (DIP), NON TORSION JOINT/SPRING, EXTENSION/FLEXION, MAY INCLUDE SOFT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
NO	NO	YES	NO	YES

Sample Diagnosis (Not Inclusive)	Contracture
Medically Necessary Argument	A qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Adjustments to the orthosis which could be detrimental to the fit and function should only be performed by a qualified professional.
References	19, 20

Chapter 3

Effectiveness of two finger splints for swan neck deformity in patients with rheumatoid arthritis: a randomized, crossover trial

Arthritis Rheum. 2009; 61:1025-31

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Abstract

Objective To compare the effectiveness and acceptability of silver ring splints (SRS) and commercial prefabricated thermoplastic splints (PTS) in treating swan neck deformities in patients with rheumatoid arthritis (RA).
Methods Consecutive patients with RA and a mobile swan neck deformity were included in a randomized, crossover trial. In 2 different sequences, patients used both splints for 4 weeks, with a washout period of 2 weeks. Afterward, patients used the preferred splint for another 12 weeks. The primary outcome measure was dexterity measured with the Sequential Occupational Dexterity Assessment (SODA). Secondary outcome measures included other measures of hand function, satisfaction with the splints and splint preference.
Results Fifty patients were included, and 47 (94%) of those completed the study. Eighteen patients (36%) had 1 swan neck deformity, whereas the other patients had 2 or more. The improvement of the total SODA score with the SRS (11.2; 95% confidence interval (95% CI) 8.1, 14.3) and PTS (10.8; 95% CI 7.5, 14.1) was similar (difference -0.5; 95% CI -2.2, 1.2). In addition, there were no significant differences in change scores regarding the other clinical outcome measures, or satisfaction. Twenty-four patients preferred the SRS, 21 preferred the PTS, and 2 patients choose neither. A comparison in the 12 week followup period yielded similar clinical outcomes, with the exception of a significantly higher score in 3 items of satisfaction in the SRS group.
Conclusion For patients with RA and a mobile swan neck deformity, SRS and PTS are equally effective and acceptable.

Introduction

The swan neck deformity is a common finger deformity associated with rheumatoid arthritis (RA). The deformity is characterized by flexion at the metacarpophalangeal joint, hyperextension of the proximal interphalangeal joint (PIPJ), and flexion of the distal interphalangeal joint (DIPJ) caused by a dominance of the extensor apparatus, which is not counteracted by flexion forces. This can result in a decreased ability to actively flex the PIPJ, leading to impaired dexterity[1-4]. With conservative treatment, finger splints aiming to prevent hyperextension and allow flexion of the PIPJ can be employed. Currently, 3 types of finger splints are available in the Netherlands: custom-made silver ring splints (SRS), custom-made thermoplastic splints (CTS), and prefabricated thermoplastic splints (PTS). SRS are made of sterling silver and manufactured according to the patient's ring size. The maximum allowed extension of the PIPJ can be can be individually adjusted by bending the splint within material limits. SRS cost approximately €80 (US$126,40) each. CTS are individually fabricated. Their costs depend on the time needed for fabrication, usually ranging between 21 and 44 minutes[5]. PTS are available in kits containing numerous sizes, with minimal time required for individual adjustments. They are made of less material than CTS and their price is approximately €15 (US$23.70), exclusive of the therapist time[6].

To date, studies on the effectiveness of finger splints for swan neck deformity are sparse. In an uncontrolled study with 17 patients who had RA and swan neck deformities[7], SRS improved dexterity but did not have an effect on grip strength, self-reported hand function, or hand pain. In a controlled study comparing SRS and CTS in 18 patients with RA[5], both splints were found to be equally effective with respect to digital stability, grip strength and mobility of the finger joints. However, CTS were considered less comfortable and less attractive. Since PTS appear to be more elegant and comfortable than CTS, they may offer an acceptable, inexpensive alternative to the SRS. Therefore, our study aimed to compare effectiveness, patient satisfaction and patient preferences of PTS and SRS in patients with RA and swan neck deformities.

Patients and Methods

Study design

This study used a multicenter, randomized, crossover design. Patients were randomly assigned to the SRS-PTS or PTS-SRS sequence. Randomization was done with a random digit generator with stratification for center and sex. Blocked randomization of 4 patients per block was used to prevent unbalanced distribution. The randomization procedure was completed by an administrative assistant who was not aware of the block size. Patients used each splint for 4 weeks with a washout period of 2 weeks in between. After both treatment periods, patients chose their preferred splint and were followed up for 12 weeks while wearing the preferred splint.

Patients

From August 2005 through September 2006, consecutive patients with RA and swan neck deformities were recruited one patient at a time until the target sample size was obtained at the outpatient rheumatology clinics of 3 centers in the Netherlands: Leiden University Medical Center (Leiden), Sint Maartenskliniek (Nijmegen) and Reinier de Graaf Gasthuis (Delft). Patients were eligible for the study if they had been diagnosed with RA

according to 1987 criteria of the American College of Rheumatology (formerly, the American Rheumatism Association)[8], were at least 18 years old, had a mobile swan neck deformity that was manually correctable to at least 45° of PIPJ flexion of an index and/or middle finger, had stable disease activity, had received no corticosteroid injections for the previous 3 months, had no planned surgery for the duration of the study, and had not been treated with swan neck finger splints in the past. Exclusion criteria were the presence of a condition other than RA, or other severe finger deformities that interfered with hand function or with the use of finger splints.

The study was approved by the hospital medical ethics committees of the 3 participating hospitals, and all participants gave written informed consent.

Splinting protocol

The study used the SIRIS Swan Neck Splint (Silver Ring Splint Company, Charlottesville, VA) and the Oval-8 Finger Splint (3-Point Products, Stevensville, MD). Both splints were sized according to manufacturer's recommendations by experienced (>5 years) hand therapists (FJvdG and CK-S), and fitted in slight flexion, which corrected the hyperextension of the PIPJ. All the correctable swan neck deformities of the index or middle finger(s) were splinted. The participants were asked to wear the splints as much as possible, removing them only for cleaning. During the crossover period, participants returned the first splint type worn to ensure the consistent wearing of the second splint type.

Measurements

Sociodemographic and disease characteristics were collected at baseline (T0). Outcome measurements were gathered at T0, after the first treatment period (T1), after the washout period (T2), after the second treatment period (T3), and after the 12-week followup period (T4). All measurements were collected with patients wearing the splints, except for the PIPJ hyperextension. Adherence and satisfaction were measured at T1, T3 and T4. The patients' preferences were obtained at T3 and at T4 by asking whether they would continue wearing the splints (yes, unsure, no). All clinical measurements were performed by 2 experienced hand therapists (FJvdG and CK-S). To enhance the intrarater reliability, a training session and calibration meeting was scheduled prior to the start of the study and once during the study.

Sociodemographic and general disease characteristics

Sociodemographic data included sex, age, living status (alone or with others), and paid employment (yes/no and number of hours per week, if applicable). Disease duration was extracted from the patient records. Disease activity was measured with the Disease Activity Score in 28 joints using 4 variables: the 28-joint counts for swelling and tenderness, the erythrocyte sedimentation rate, and the patient's overall assessment of well-being[9]. Functional ability was measured with the Health Assessment Questionnaire (HAQ)[10], which covers 20 activities of daily living in 8 dimensions. The total HAQ score is the average score of the 8 dimensions (where 0 = best possible function and 3 = worst possible function). General health status was measured with a validated version of the Medical Outcomes Study Short Form 36 Health Survey[11], which includes 8 subscales. These subscales can be converted into two summary scales: the physical and mental component summary scales, standardized to a mean ± SD score of 50 ± 10 in the general population. For that purpose, we used the scores from an age- and sex-matched normative sample, which was

drawn from a large, random, nationwide sample of adults (n=1,742) from the general Dutch population[12] and factor score coefficients[13].

Swan neck deformities, splinting protocol, adverse events, and adherence

The number of swan neck deformities, all deviations from the splinting protocol, and adverse events were recorded. Adherence during the first 2 splinting periods was assessed with a diary, in which the participants recorded the number of hours per day that they used the splint(s). Because the prolonged usage of diaries is usually hampered by low compliance, adherence during the followup period was assessed only once at the end of that period, when patients were asked: 'How many days of the week did you wear the splint on average in the past 12 weeks?' and 'When you were wearing the splint, for how many hours per day was this in the past 12 weeks?'. The results of these questions were multiplied to obtain an average number of splint usage hours per week.

Primary outcome measure

The primary outcome measure was dexterity as measured by the Sequential Occupational Dexterity Assessment (SODA)[14-16]. With the SODA, the patient performs 12 standardized tasks and an assessor scores the ability to perform every task (where 4 = able to perform in the requested way, 1 = able to perform in a different way, and 0 = unable to perform) and the level of difficulty in the performance (where 2 = not difficult, 1 = some difficulty, 0 = very difficult). The SODA score range is 0-108, with a higher number indicating better dexterity. The SODA pain score is computed by counting the number of painful tasks (range 0-12).

Secondary outcome measures

The secondary outcome measures included general hand function as measured by the hand and finger function domain of the Dutch Arthritis Impact Measurement Scales 2 (D-AIMS2)[17] and the Michigan Hand Outcomes Questionnaire (MHQ)[18,19]. The hand and finger function subscale of the D-AIMS2 consists of 5 questions regarding the patient's hand function over the previous week. The scores range from 0 (good hand function) to 10 (bad hand function). The MHQ is a questionnaire covering 6 domains: overall hand function, activities of daily living, pain, work performance, esthetics, and satisfaction with hand function. The total score range (average of all domains) is 0-100, with higher scores indicating better hand function.

Passive PIPJ hyperextension of the splinted fingers was measured unsplinted with a goniometer[20]. If more than one finger was splinted, the average of the scores of the fingers involved was used. Cylindrical grip strength and pinch grip strength were determined with a Jamar dynamometer (JA Preston Corporation, Clifton, NJ)[21] and a North Coast hydraulic pinch gauge (Pieksma Medical Supplies, Bussum, the Netherlands), respectively. The patients underwent the tests twice on every side, with the highest score recorded. Scores were obtained for the splinted finger(s) only. In the case of involvement of multiple fingers, average scores were used. After both initial splinting periods, the patient's perceived change in hand function was measured on a 3-point scale (where 1 = worsened, 2 = neither worsened nor improved, and 3 = improved). In the absence of a validated questionnaire to measure the RA patients' satisfaction with hand or finger splints, we used a 13-item questionnaire previously developed by one of the authors (Stern EB: personal communication). Each item was rated on a 5-point Likert scale (where 1 = totally disagree and 5 = totally agree).

Statistical analysis

The sample size was calculated based on the SODA as primary outcome measure and using the formula: $n = (Z_{\alpha/2} + Z_{\beta})^2 * \tau^2 * (r + 1) / v^2 r$. With $\alpha = 0.05$ and 1 minus $\beta = 0.80$, $(Z_{\alpha/2} + Z_{\beta})^2 = 7.85$. In the absence of data on the clinical relevance of SODA change scores, we used the data from a study[7] executed within a context similar to the present study[22] with respect to the patient population (RA patients with finger deformities), the intervention (finger splints), and the primary outcome measure (dexterity). In that uncontrolled study on custom-made silver splints in 17 patients with RA, a median improvement of 5 points on the SODA after 1 month was observed[7], yielding a value of 5 for the mean difference. From the individual data presented in that study, an SD of the SODA change score (τ) of 8.95 was calculated. With a comparison of 2 groups with equal numbers implying that $r = 1$, and using the previously mentioned formula, a total of 50 patients per group would be required. To detect a difference of 6 points on the SODA score, in line with the 12-week difference observed by Zijlstra et al.[7], 36 patients per group would be needed. As in this study, a crossover design was employed, and the total number of patients required for the study was 50.

For all data, we observed the distribution plots. In case of normally distributed data, we presented mean ± SDs or 95% confidence intervals (95% CIs), and in case of a non-normal distribution, we presented median and interquartile range the net result of the 75th percentile minus the 25th percentile.

To determine if a period effect was present, the differences in effect between the 2 periods were compared between the two sequences (SRS-PTS or PTS-SRS). To determine if a carryover effect was present, the change scores of the 2 splints in the 2 periods were averaged for every patient, and the mean change score was then compared between the 2 splinting sequences[23]. These possible effects were tested for all outcome variables by unpaired *t*-tests. In the absence of statistically significant carryover or period effects, the main analysis would pertain to a comparison of the change scores after wearing them for 4 weeks between the 2 splints by means of the paired *t*-test. McNemar's test was used to compare numbers of patients reporting the following categories of perceived changes in hand function between the 2 splints: 'improved' versus both 'neither worsened nor improved' and 'worsened'. In addition, a within-splint analysis was performed using paired *t*-tests to test for significant differences between T0 and followup measurements after 4 weeks. To study the effects after a 12-week followup period, the change scores between T3 and T4 within the groups of patients preferring the SRS and PTS were compared using unpaired *t*-tests. In addition, the chi-square was used to assess a trend in differences in willingness to continue using the splints between patients who chose the SRS or the PTS. For that purpose, the outcomes were dichotomized into 'yes' versus 'unsure and no'. All analyses were computed using the Statistical Package for the Social Siences, version 14.0 (SPSS, Chicago, IL). The level of significance was set at less than 0.05 for all statistical tests.

Results

A total of 83 patients were invited and screened (Figure 1). Eventually, 50 participants entered the study, and 3 of those patients did not complete the study. Table 1 shows the characteristics of the study sample.

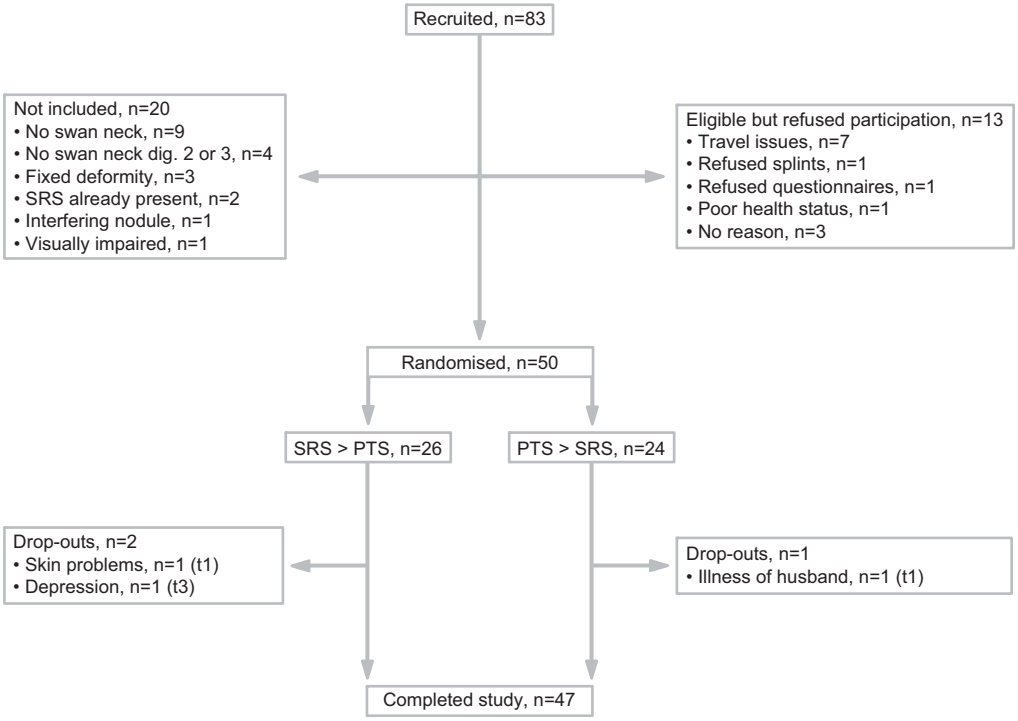

Figure 1. Flow-chart of a randomized crossover study comparing 2 finger splints in 50 patients with reumatoid arthritis and swan neck deformities. SRS = silver ring splint; PTS = prefabricated thermoplastic splint.

Protocol violations, adverse events, and adherence

In the initial 2 treatment periods, 8 patients did not use one or more of their splints for the full study period. Seven patients, all having more than 1 swan neck deformity, could not use 1 splint during 1 period because it was broken (1 SRS), lost (2 SRS and 3 PTS), or did not fit because of local joint inflammation (1 PTS). In one patient, neither the SRS nor the PTS could be used on one finger because of the development of an interfering nodule, but the patient continued using splints on other fingers. One patient developed skin problems on both splinted fingers (SRS), possibly due to the relatively high hyperextension force. This patient refused further participation after 2 weeks. Two patients reported minor skin problems with the PTS due to perspiration in warm weather, but they could continue to wear the splints throughout the assigned period. In the initial treatment periods, 47 of 49 SRS diaries, and 47 of 48 PTS diaries, were filled in. Adherence rates of the SRS group (mean ± SD 15.3 ± 7.4 hours/week) and the PTS group (mean ± SD 15.4 ± 7.4 hours/week) were similar (difference -0.05; 95% CI -2.1, 1.9).

Table 1. Sociodemographic and disease characteristics of 50 patients with reumatoid arthritis and swan neck deformities‡

Characteristics	*Patients*
Sociodemographics	
Male/female, no.	9/41
Age, years	53.8 (21.6)
Living with other(s), no.	45
Not living with other(s), no.	5
Paid employment, no. (%)	13 (26)
Hours of paid employment per week (n=13)	20 (18)
Disease	
Disease duration, years	13.7 (11.5)
DAS28	3.26 (2.1)
HAQ (range 0-3)	1.13 (1.1)
SF-36 Physical Component Summary (range 0-100)	38.3 (15.2)
SF-36 Mental Component Summary (range 0-100)	56.2 (15.9)
Number of swan neck deformities, no. (%) ¥	
1	18 (36)
2	17 (34)
3	2 (4)
4	13 (26)

‡ Values are expressed as the median (interquartile range) unless otherwise indicated. DAS28 = Disease Activity Score in 28 joints; HAQ = Health Assessment Questionnaire; SF-36 = Medical Outcomes Study Short Form 36 Health Survey. ¥ Per patient on the index and/or middle finger.

Outcomes after 4 weeks

None of the outcome measures demonstrated a significant period or carryover effect (P >0.05 for all; data not shown).

As shown in Table 2, after 4 weeks of use there were no differences between the change scores of the 2 finger splints for any of the outcome measures. The number of patients considering their hand function 'worse', 'worse nor improved', or 'improved' were 5, 18 and 21 for the SRS splint, and 2, 21 and 20 for the PTS splint, respectively (P =0.42, by McNemar's test).

Concerning within-group changes with both splints, both SODA scores improved significantly after 4 weeks. Moreover, with the SRS splints, passive PIPJ hyperextension decreased significantly between T0 and 4 weeks. With all other outcomes, a trend toward improvement was seen with both splints; however, none of the changes reached statistical significance.

After using both splints for 4 weeks, 24 patients preferred the SRS, 21 the PTS and 2 choose neither (P =0.66, by chi-square test).

Followup with the preferred splint

After choosing a preferred splint, 3 patients, using more than one splint, did not use one because it was found uncomfortable (2 SRS) or it was lost (1 PTS). In the followup

Table 2. Change scores with SRS and PTS and differences in change scores in 50 patients with reumatoid arthritis and swan neck deformities‡

	SRS (n=50)	*PTS (n=50)*	*Difference between splints*
SODA, range 0-108			
Baseline, mean ± SD	83.7 ± 18.0	84.3 ± 18.8	
Change after 4 weeks	11.2 (8.1; 14.3)¥	10.8 (7.5; 14.1)¥	-0.5 (-2.2; 1.2)
SODA pain, range 0-12			
Baseline, mean ± SD	1.6 ± 2.6	1.7 ± 2.5	
Change after 4 weeks	-0.5 (-0.9; -0.1)¥	-0.5 (-1.0; -0.1;)¥	0.4 (-0.1; 1.0)
D-AIMS2 Hand/finger subscale, range 0-10			
Baseline, mean ± SD	2.72 ± 2.27	3.07 ± 2.26	
Change after 4 weeks	-0.14 (-0.55; 0.27)	-0.21 (-0.62; 0.19)	-0.01 (-0.66; 0.65)
MHQ total score, range 0-100			
Baseline, mean ± SD	60.7 ± 15.6	58.7 ± 13.7	
Change after 4 weeks	-0.1 (-3.0; 2.7)	1.4 (-2.0; 4.8)	-1.3 (-6.4; 3.8)
Passive PIPJ hyperextension, degrees			
Baseline, mean ± SD	27.7 ± 8.2	27.0 ± 9.1	
Change after 4 weeks	-2.1 (-3.3; -1.0)¥	-1.1 (-2.4; 0.1)	-1.1 (-2.6; 0.5)
Cylindrical grip strength, kg			
Baseline, mean ± SD	17.7 ± 9.9	17.5 ± 10.4	
Change after 4 weeks	-0.13 (-1.10; 0.82)	0.39 (-0.36; 1.15)	-0.53 (-1.67; 0.61)
Pinch grip strength, kg			
Baseline, mean ± SD	2.4 ± 1.7	2.3 ± 1.7	
Change after 4 weeks	0.03 (-0.20; 0.26)	0.08 (-0.17; 0.32)	-0.02 (-0.24; 0.21)
Patient preferences, no. (%)	24 (51)	21 (45)	

‡ Values are the mean (95% confidence interval) unless otherwise indicated. SRS = silver ring splint; PTS = prefabricated thermoplastic splint; SODA = Sequential Occupational Dexterity Assessment; D-AIMS2 = Dutch Arthritis Impact Measurement Scales 2; MHQ = Michigan Hand Outcomes Questionnaire; PIPJ = proximal Interphalangeal joint. Positive changes reflect improvement, except for SODA pain, D-AIMS2, and PIPJ hyperextension. Positive differences are in favor of the SRS. ¥P <0.05, paired t-test, comparison within splints (Baseline minus 4 weeks); #P <0.05, paired t-test, comparison between splints (SRS minus PTS).

period, the mean ± SD splinting duration was 11.7 ± 8.1 hours/day with the SRS, and 16.3 ± 6.5 hours/day with the PTS (difference -4.6, 95% CI -9.2, 0.03). Table 3 shows that with 24 patients continuing to wear the SRS and 21 patients the PTS, there are no significant differences between the 2 splints regarding the change scores between 10 and 22 weeks on any of the clinical outcome measures.

For the other outcome measures, there were no significant changes during the 12-week followup between and within the splints, indicating that effects obtained after 4 weeks were sustained after 12 weeks. When asked at followup if they would continue wearing the splints after the study, 21 (91%) of the 23 patients using the SRS answered positively, and 2 (9%) indifferently or negatively. In the PTS group, 11 (61%) patients answered positively, and 7 (39%) answered indifferently or negatively (SRS versus PTS; P =0.79 by chi-square test).

Table 3. Change scores between 10 weeks and 22 weeks (12 week followup) with the finger splint of choice (SRS or PTS) and differences in change scores‡

	SRS (n=24)	*PTS (n=21)*	*Difference between splints*
SODA range, 0-108	-0.4 (-1.8; 0.9)	-0.2 (-3.4; 3.0)	-0.2 (-3.4; 3.0)
SODA pain, range, 0-12	-0.3 (-1.0; 0.5)	0.5 (-0.4; 1.4)	-0.8 (-1.9; 0.4)
D-AIMS2 hand/finger subscale, range 0-10	-0.08 (-0.7; 0.6)	0.00 (-0.6 ; 6.0)	-0.08 (-1.0; 0.8)
MHQ total score, range 0-100	0.6 (-3.2; 4.5)	-2.0 (-7.1; 3.1)	2.6 (-3.4; 8.7)
Passive hyperextension PIPJ, degrees	-1.0 (-4.6; 2.5)	-2.7 (-5.8; 0.5)	1.6 (-3.1; 6.3)
Cylindrical grip strength, kg.	0.2 (-1.7; 2.1)	-0.3 (-2.4; 1.9)	0.5 (-2.3; 3.2)
Pinch grip strength, kg.	0.1 (-0.2; 0.4)	-0.1 (-0.6; 0.4)	0.3 (-0.3; 0.8)

‡ Differences and changes are mean (95% confidence intervals). SRS = silver ring splint; PTS = prefabricated thermoplastic splint; SODA = Sequential Occupational Dexterity Assessment; D-AIMS2 = Dutch Arthritis Impact Measurement Scales 2; MHQ = Michigan Hand Outcomes Questionnaire; PIPJ = proximal interphalangeal joint. Positive changes reflect improvement, except for SODA pain, D-AIMS2 and PIPJ hyperextension. Positive differences are in favor of the SRS. $^{*}P < 0.05$, paired *t*-test, comparison between splints (SRS minus PTS).

Patient satisfaction

Table 4 shows the results of the patient satisfaction questionnaire. Overall, after 4 weeks the scores were higher for the SRS than for the PTS, except for item 12, But only the score on item 1 reached statistical significance.
In the followup period, with the patients using the preferred splint, the scores were significantly higher for the SRS than for the PTS, regarding the items 1, 2 and 9.

Discussion

The current study suggests that SRS and PTS are equally effective and acceptable in patients with RA and mobile swan neck deformities. Both splints improve dexterity (as measured by the SODA) and reduce dexterity-related pain (as measured by the SODA pain score), but only the SRS reduces PIPJ hyperextension. Neither splint significantly improved or interfered with reported hand function, measured grip, or pinch strength. Except for a significantly higher satisfaction score in 3 satisfaction items with the SRS, a followup with the preferred splint yielded equal results with both splints. Almost two-thirds of the patients said they would continue wearing their preferred splints after the study.

With respect to the comparison of the effectiveness of thermoplastic splints with SRS, our results parallel those of the study by Schegget and Knipping[5], where CTS were found to be equally effective as SRS in 18 patients with RA. However, in that study, CTS were found to be far less acceptable than SRS, mainly due to their less attractive appearance and their thickness, making the fingers spread. In contrast, no differences in satisfaction were seen after 4 weeks with the PTS used in the present study, with equal numbers of patients choosing the SRS and the PTS. In the followup period, with the patients wearing the splint of their choice, 2 aesthetics-related items of satisfaction were valued higher in the SRS than in the PTS; however, the absolute difference was small, so that its clinical significance is questionable.

The results of our study suggest that the provision of a PTS is worth considering for patients with a mobile swan neck deformity. This is especially the case since PTS are less expensive than SRS, with similar time needed for the hand therapist to measure and adjust the splint to obtain the optimal fit and allowed extension.

Table 4. Differences in satisfaction in 13 items after 4 weeks and after 12 weeks of followup between 2 swan neck orthoses in patients with rheumatoid arthritis‡

	After 4 weeks			After 12 weeks of followup		
	SRS (n=50)	*PTS (n=50)*	*Differences Mean (95% CI)*	*SRS (n=24)*	*PTS (n=21)*	*Differences Mean (95% CI)*
1. Did you like how the splint looked? (1-5)	4.3 ± 0.6	3.7 ±1.0	0.5 (0.2; 0.8)#	4.5 ± 0.5	3.9 ± 0.6	0.6 (0.2; 0.9)¥
2. Did you like how your fingers looked with the splint on? (1-5)	4.0 ± 0.6	3.8 ± 0.8	0.2 (-0.1; 0.5)	4.2 ± 0.6	3.8 ± 0.6	0.4 (0.0; 0.8)¥
3. Was the splint easy to put on and take off? (1-5)	4.1 ± 0.8	4.0 ± 0.7	0.1 (-0.2; 0.4)	4.3 ± 0.4	4.0 ± 0.9	0.3 (-0.2; 0.7)
4. Was the splint easy to clean? (1-5)	4.4 ± 0.5	4.2 ± 0.6	0.1 (-0.1; 0.3)	4.3 ± 0.4	4.1 ± 0.4	0.2 (-0.1; 0.5)
5. Did the splint relieve your finger joint pain? (1-5)	3.2 ± 0.8	3.0 ± 1.0	0.2 (-0.1; 0.5)	3.1 ± 1.0	2.9 ± 0.8	0.1 (-0.5; 0.8)
6. Did the splint decrease your finger joint swelling? (1-5)	2.9 ± 0.9	2.8 ± 1.1	0.1 (0.1; 0.4)	3.0 ± 0.9	2.8 ± 0.7	0.2 (-0.3; 0.8)
7. Did the splint improve your grasp while you wore it? (1-5)	3.0 ± 0.8	2.9 ± 0.9	0.1 (-0.2; 0.4)	3.6 ± 0.9	3.1 ± 0.9	0.5 (-0.1; 1.1)
8. Was your hand stronger with the splint on?	2.8 ± 0.8	2.7 ± 1.0	0.1 (-0.2; 0.4)	3.0 ± 0.9	2.9 ± 0.8	0.2 (-0.4; 0.7)
9. Did the splints keep your fingers from hyper extending (bending back) the majority of the time? (1-5)	4.1 ± 0.9	3.9 ± 1.2	0.3 (-0.1; 0.6)	4.6 ± 0.6	4.0 ± 1.0	0.6 (0.1; 1.1)¥
10. Did the splint help you manipulate small objects? (1-5)	3.1 ± 0.8	2.9 ± 0.8	0.2 (-0.1; 0.4)	3.3 ± 0.9	3.0 ± 0.7	0.3 (-0.2; 0.8)
11. Was it easier to perform daily activities with the splint on? (1-5)	3.0 ± 0.7	2.9 ± 0.8	0.1 (-0.3; 0.3)	3.3 ± 0.8	2.8 ± 0.8	0.5 (0.0; 1.0)
12. Did the splint stay on your fingers when reaching into tight areas? (1-5)	2.9 ± 1.1	3.0 ± 1.0	-0.1 (-0.5; 0.2)	3.1 ± 1.1	3.2 ± 0.9	-0.1 (-0.8; 0.6)
13. Was the splint comfortable to wear? (1-5)	4.0 ± 1.0	3.3 ± 1.0	0.2 (-0.2; 0.5)	4.0 ± 0.6	3.6 ± 0.8	0.4 (-0.1; 0.8)

‡ Values are the mean ± SD unless indicated otherwise. SRS = silver ring splint; PTS = prefabricated thermoplastic splint; 95% CI = 95% confidence interval. Higher scores indicate more satisfaction.
# P <0.05, paired t-test; ¥ P <0.05, unpaired t-test.

Similar to the results of the present study, significant improvements of the SODA dexterity score with SRS were also seen in a previous observational study[7]. However, the SODA dexterity score improvements of were larger in the current study. Moreover, the SODA pain score improved, whereas in the study by Zijlstra et al. no improvement was seen. The greater improvement in the present study might be explained by the fact that Zijlstra and colleagues included patients with a longer disease duration (median 21 years) and worse hand function, which is reflected by a lower baseline SODA score (median 71). As suggested by the authors of that study, it could be hypothesized that finger splints for swan neck deformity are more effective in the earlier stages of disease, when correction is relatively easy. To date, there are no studies are available with respect to the clinical relevance of the observed changes of the SODA score.

In all other measures of hand function, no improvements were seen either in our study or in the study by Zijlstra et al, except for a significant decrease of passive mobility of the PIPJ in the present study. This latter result is comparable with the outcome of the study by Schegget and Knipping[5], which demonstrated a reduction of passive PIPJ hyperextension of equal magnitude with both SRS and thermoplastic splints after 24 weeks. Since the absolute reduction of passive PIPJ hyperextension was small, its clinical relevance is doubtful.

The absence of effect of finger splints on various outcome measures related to hand function could possibly be explained by the impact of limitations of joints or structures other than the PIPJ and the DIPJ of the index and middle fingers. Although patients with limitations or deformities seriously interfering with hand and finger function were excluded, most patients had mild other limitations such as ulnar deviation, or swan neck or boutonnière deformities of the thumb or fourth and fifth fingers. As these other limitations would probably affect hand function to a similar extent with both splints, they are not likely to have had an impact on the comparisons between the two splints.

Despite the modest effectiveness of both splints, more than 60% of the patients in the current study indicated that they would continue using the splints after the study. This rate is in line with the findings of Zijlstra et al. However, studies with a longer duration of followup assessment would be needed to examine which proportion of the patients would fulfill their intention.

A limitation of the study is its crossover design, where despite statistical testing, carryover or period effects cannot be totally ruled out. Furthermore, when calculating the sample size, we did not take into account a drop-out rate. Since 3 patients left the study prematurely, the possibility that this study did not have sufficient power to detect a difference of 5 points or less on the SODA score can not be totally ruled out. Because it is not possible to blind assessors in this type of research, where measurements are done with splints on, bias toward the effectiveness of finger splints cannot be completely avoided. Nevertheless, having the assessments performed by an independent assessor, rather than 2 of the authors, would probably have been preferable. Another potential source of bias could be the lack of blinding of assessors and patients, due to the nature of the intervention. In addition, we used a satisfaction questionnaire, of which the psychometric properties have not yet been established. Given the fact that specific satisfaction questionnaires for hand and finger splints are scarce, more research into the validation of questionnaires used to evaluate RA patients' satisfaction with orthoses seems justified.

In summary, the results of the present study, and that of the already available evidence[5-7], suggest that wearing SRS or PTS for mobile swan neck deformities is effective in improving dexterity and dexterity-related pain after 4 weeks. The decision about what type of splint to use should therefore not depend on its effectiveness, but merely on patient preferences and costs.

Acknowledgement

We thank participating patients and the Dutch Arthritis Association for financial support (04-2-01). ISRCTN: 55287158.

References

1. Boyer MI, Gelberman RH. Operative correction of swan neck and boutonniere deformities in the rheumatoid hand. J Am Acad Orthop Surg 1999; 7:92-100.
2. Eberhardt K, Johnson PM, Rydgren L. The occurrence and significance of hand deformities in early rheumatoid arthritis. Br J Rheumatol 1991; 30:211-213.
3. Laine VA, Sairanen E, Vainio K. Finger deformities caused by rheumatoid arthritis. J Bone Joint Surg [Am] 1957; 39-A:527-533.
4. van der Giesen FJ, Nelissen RG, Rozing PM, Arendzen JH, de Jong Z, Wolterbeek R et al. A multidisciplinary hand clinic for patients with rheumatic diseases: a pilot study. J Hand Ther 2007; 20:251-261.
5. Schegget M, Knipping A. A study comparing use and effects of custom-made versus prefabricated splints for swan neck deformity in patients with rheumatoid artrhritis. Br J Hand Therapy 2000; 5:101-107.
6. Manning J. Perceptions of an inexpensive commercial tripoint (swan neck) splint for individuals with rheumatoid arthritis, a project submitted to the faculty of the graduate School of the University of Minnesota in partial fulfillment of the requirements for the degree of Master of Science. Research advisor: Erica B Stern - Associate Professor of Occupational Therapy. 2003.
7. Zijlstra TR, Heijnsdijk-Rouwenhorst L, Rasker JJ. Silver ring splints improve dexterity in patients with rheumatoid arthritis. Arthritis Rheum 2004; 51:947-951.
8. Arnett FC, Edworthy SM, Bloch DA, McShane DJ, Fries JF, Cooper NS et al. The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. Arthritis Rheum 1988; 31:315-324.
9. Prevoo ML, 't Hof MA, Kuper HH, van Leeuwen MA, van de Putte LB, van Riel PL. Modified disease activity scores that include twenty-eight-joint counts. Development and validation in a prospective longitudinal study of patients with rheumatoid arthritis. Arthritis Rheum 1995; 38:44-48.
10. Siegert CE, Vleming LJ, Vandenbroucke JP, Cats A. Measurement of disability in Dutch rheumatoid arthritis patients. Clin Rheumatol 1984; 3:305-309.
11. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992; 30:473-483.
12. Aaronson NK, Muller M, Cohen PD, Essink-Bot ML, Fekkes M, Sanderman R et al. Translation, validation, and norming of the Dutch language version of the SF-36 Health Survey in community and chronic disease populations. J Clin Epidemiol 1998; 51:1055-1068.
13. Ware JE Jr, Kosinski M, Keller SD. SF-36 Health Survey Manual and Interpretation Guide. Boston, MA: The Health Institute, 1994.
14. van Lankveld W, van't Pad BP, Bakker J, Terwindt S, Franssen M, van Riel P. Sequential occupational dexterity assessment (SODA): a new test to measure hand disability. J Hand Ther 1996; 9:27-32.
15. van Lankveld W, van't Pad BP, van der SD, Dapper M, de Waal MM, van de PL. Evaluating hand surgery in patients with rheumatoid arthritis: short-term effect on dexterity and pain and its relationship with patient satisfaction. J Hand Surg [Am] 2000; 25:921-929.
16. van Lankveld WG, Graff MJ, van 't Pad Bosch PJ. The Short Version of the Sequential Occupational Dexterity Assessment based on individual tasks' sensitivity to change. Arthritis Care Res 1999; 12:417-424.
17. Riemsma RP, Taal E, Rasker JJ, Houtman PM, Van Paassen HC, Wiegman O. Evaluation of a Dutch version of the AIMS2 for patients with rheumatoid arthritis. Br J Rheumatol 1996; 35:755-760.
18. Chung KC, Pillsbury MS, Walters MR, Hayward RA. Reliability and validity testing of the Michigan Hand Outcomes Questionnaire. J Hand Surg [Am] 1998; 23:575-587.
19. Huijsmans R, Sluiter H, Aufdemkampe G. Michigan Hand Outcomes Questionnaire - Dutch Language Version; een vragenlijst voor patienten met handfunctieproblemen. Fysiopraxis 2001; 9:38-41.
20. American Acadamy of Orthopedic Surgeons. Joint Motion; Method of measuring and recording. 1965. ed. Churchill Livingstone, Edinburgh, london and New York.

21. Harkonen R, Harju R, Alaranta H. Accuracy of the Jamar dynamometer. J Hand Ther 1993; 6:259-262.
22. Beaton DE, Boers M, Wells GA. Many faces of the minimal clinically important difference (MCID): a literature review and directions for future research. Curr Opin Rheumatol 2002; 14:109-114.
23. Altman D. Crossover trials. Practical Statistics For Medical Research. Chapman & Hall, 1999: 467-471.

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Case report

Dynamic joint-aligned PIP and DIP corrective-flexion/extension orthosis for post burn finger contractures

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1. Introduction

Patients with hand burns are likely to develop various hand deformities and contractures, the most common of all being the deformities that resemble the Boutonniere deformities of fingers [1]. In contrast to other orthopaedic conditions these deformities in burns are often due to the contracted scar tissue and not solely due to changes in the direction of pull by the muscles of the hand. Therefore, the commonly prescribed splints, the '*Capener*' splint that corrects PIP (Proximal Interphalangeal) deformities alone and the static '*Gutter Splint*' that corrects the hyperextension component of DIP (Distal Interphalangeal) joint but inadequate in addition, its application hinders the functional use of hand, are not sufficient. Thus this paper describes an innovative splint, indigenously designed that stretches both the joints simultaneously.

2. General objective and rationale

- To enhance function.
- To apply gentle, prolonged stretch to a contracted PIP & DIP capsule, ligaments and the other related soft tissues to promote growth of shortened tissues and restore range of motion in both the PIP and DIP joints.

3. Fabrication of the splint

The splint consists of four springs (S1, S2, S3 and S4) and three supports (the proximal support, PS; the intermediate support, IS and the distal support, DS) that are made out of approximately 15 cm of spring wire (Fig. 1). Initially, the outline of the finger that needs to be splinted is drawn and the skin creases of that finger are marked. The spring wire is then bent in such a way that the two springs S1 and S2 are on either sides of the PIP crease and the other two springs S3 and S4 are on either sides of the DIP crease and the three semi-circular supports (PS, IS, and DS) are made in the following pattern.

- The PS rests on the dorsal surface of the finger at the midline between the MP (metacarpophalangeal) crease and the PIP crease.
- The DS rests on the dorsal surface of the finger at the midline between DIP crease and the tip of the finger.
- The IS rests on the volar surface of the finger at the midline between the PIP and DIP crease.

These supports provide the three-point pressure needed to produce the extension force at the PIP and flexion force at the DIP joints (Fig. 2). The finger supports PS, IS, and DS are padded adequately with foam or any padding material in order to avoid any local pressure by increasing the surface area or the area of contact.

4. Advantages

- This splint's best utility would be in those with slipped extensor tendons, where there is difficulty in full PIP extension, due to the mobilizing of both the PIP and the DIP joints at the same time.
- This dynamic functional splint is a day splint, when prescribed concomitantly with static gutter splint as night splint, likely to assist in promoting faster growth of

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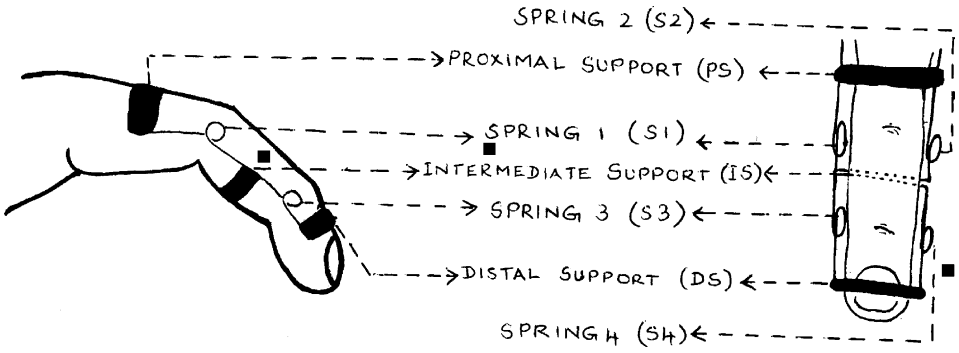

Fig. 1.

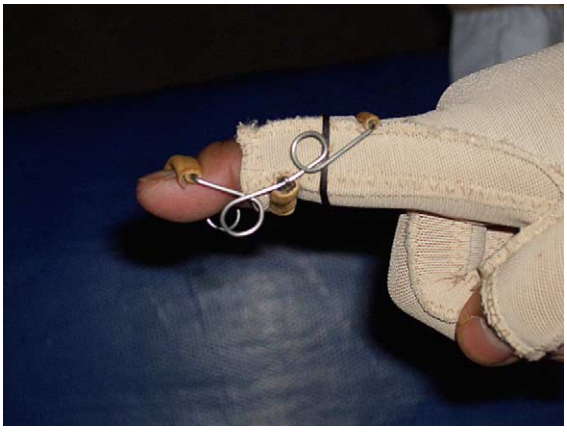

Fig. 2.

shortened tissues and restore range in boutonniere deformity while maintaining the client's functional independence [2]. However, this splint does not replace the static gutter splint that is in use, which allows scarring without flexion at PIP by maintaining it in extension.

- The force produced by the splint to provide prolonged stretch could be easily adjusted by varying the number of coils in the spring and/or by changing the thickness of the spring wire.
- Importantly this orthosis has "no profile" minimizing its visual presence.
- Above all it is cost-effective (less than 25 cents) and very easy to make requiring not more than 15 min per splint.

5. Conclusion

This splint provides continuous stretch to both PIP and DIP that is needed for range restorations among one of the commonest post burn contractures of fingers. It has a pleasing look and is also comfortable and easy to use, which enhances the client's compliance. This can become the splint of choice for most of the third world nations especially because of its simple and cost effective nature.

References

[1] Daugherty MB, Carr-Collins JA. Splinting techniques for the burn patient. In: Richard RL, Staley MJ, editors. Burn care and rehabilitation: principles and practice. Philadelphia: FA Davis, 1994. p. 589.
[2] McKee P, Morgan L, editors. Orthotics in rehabilitation. New Delhi: Jaypee Brothers medical Publishers Ltd., 1998.

HCPCS:	Descriptor:
L3929	HAND FINGER ORTHOSIS, INCLUDES ONE OR MORE NONTORSION JOINT(S), TURNBUCKLES, ELASTIC BANDS/SPRINGS, MAY INCLUDE SOFT INTERFACE MATERIAL, STRAPS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	RA, MCP deviation
Medically Necessary Argument	A qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Adjustments to the orthosis which could be detrimental to the fit and function should only be performed by a qualified professional.
References	19, 21

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MANAGEMENT OF SIMPLE FINGER INJURIES: THE SPLINTING REGIME

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ABSTRACT

Mallet finger injury, ligamentous sprain and dislocation of proximal interphalangeal (PIP) joint of fingers are very common types of simple hand injuries. Immediate correction of alignment and protection of the injured area will facilitate early joint movement while maximising functional recovery. This article is to introduce the fabrication of three simple finger splints to tackle these injuries for quick and effective conservative treatment. They are the mallet finger splint, buddy splint and dorsal finger block splint.

The indications and functions of the three types of splints are discussed. The fabrication process will be illustrated; including materials needed, pattern drafting and steps of molding. Wearing regime and precautions will be highlighted to ensure effective patient compliance to splinting programme for the finger injuries.

Keywords: Simple Finger Injuries; Mallet Splint; Buddy Splint; Dorsal Finger Block Splint; Ligamentous Sprain of PIPJ; Dislocation of PIPJ; Splint Fabrication.

INTRODUCTION

Tendon disconnection or fracture at distal interphalangeal (DIP) joint of finger is a challenge to the splint fabricator as the bones and joint surfaces are small. In the five-year review by Okafor[6] on conservative splintage treatment of patient with mallet finger injury, it is noted that 48% are with osteoarthritic changes, 29% with a swan-neck deformity and 35% with 10° of extension lag. Thus, it is important to ensure the extension support of the distal phalanx and the compliance of client to keep the joint in extension when putting the splint on or off for cleansing. Ligament injury of fingers does not always mean the need for total immobilisation of the joint, which may cause longer post-splinting time to mobilise the joint.[3] A buddy splint allowing the injured finger to move with the adjacent finger can promote early guarded mobilisation and minimise range limitation. Dorsal dislocation of proximal interphalangeal (PIP) joint also indicates the possibility of full flexion after joint reduction while guarding the PIP joint at 30° flexion lag. This again maximises joint range of motion after splintage. These three types of splints are selected for discussion as they involve only quicksteps of fabrication (within 15 minutes) and very common thermoplastic splinting materials. Moreover, quick application of these splints can avoid spontaneous use of the injured hand after injury which may further tear the injured ligaments or joint structure, resulting in unnecessary complications.

MALLET FINGER SPLINT

Indications and Functions

Mallet finger injury is a result of traumatic disruption of the terminal tendon with loss of active extension of the DIP joint.[2] If the mallet finger injury involves only tendon rupture, the splint is designed to over-correct the DIP joint in slight hyperextension (5° to 10°). If the tendon injury involves fracture, the DIP joint is kept by the mallet splint at neutral for alignment of the DIP joint and tendon healing.[5]

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Types of Mallet Finger Splints

For a six-week splintage programme, a short or long mallet finger splint may be applied to the injury. In some local hospitals, a long mallet splint with PIP joint flexion at 70° is preferred in the first two weeks to reduce the tension of the central slip and promote better distal tendon healing[1] (as shown in Fig. 1). On the third week, it is changed to a short mallet finger splint.

Fabrication Process

Pattern drafting and materials

The pattern will be traced on a 2 mm thick low temperature thermoplastic splinting material as shown in Figs. 2a and b. The pattern is cut out by a pair of shears. Perforated material is preferred for better ventilation.

Molding the mallet splint with PIPJ flexion

The cut-out pattern is put into warm water of about 60°C (depending on the working temperature of the material) to allow for it to become soft and malleable. The softened splinting material is wrapped around the affected digit on the palmar side. As shown in Fig. 3, while holding the splinting material in position against the lateral side of the digit, the distal end is also pulled up to fit the distal hemispherical shape of the finger. If hyperextension is indicated, the DIP joint is held slightly at 5° to 10° during molding.

After the material becomes rigid, the extra portion at the distal part is trimmed away. Velcro strap with padding is wrapped around the DIP joint for three-point support, to keep the joint in extension or hyperextension. For mallet splint with PIP joint

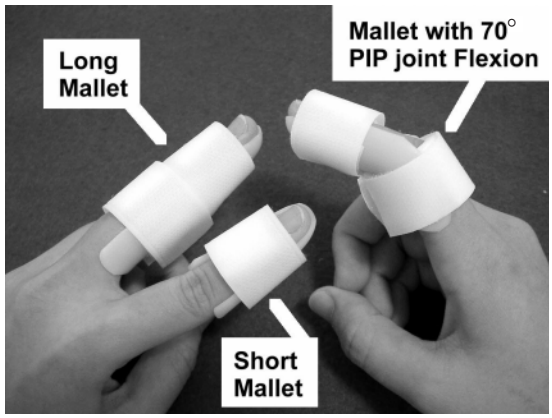

Fig. 1 Different types of mallet splints.

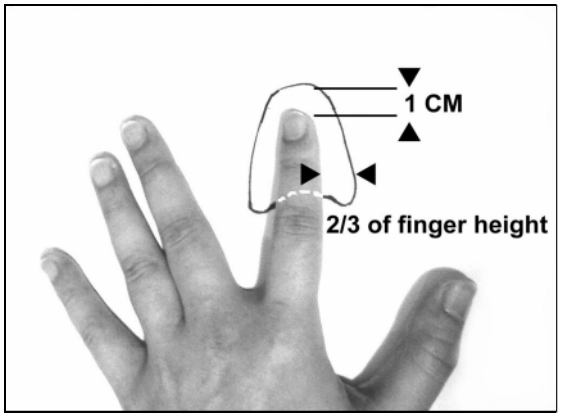

Fig. 2a Short mallet splint pattern.

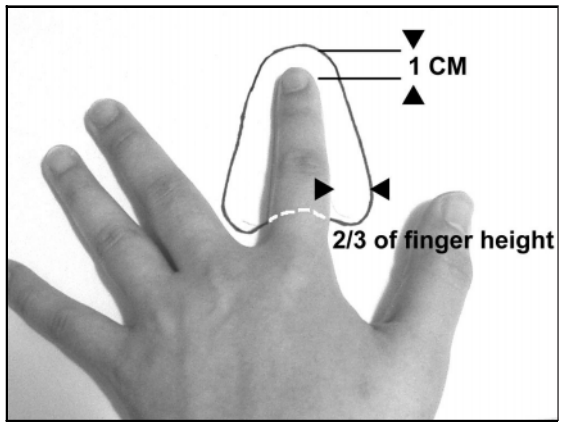

Fig. 2b Long mallet splint patterns.

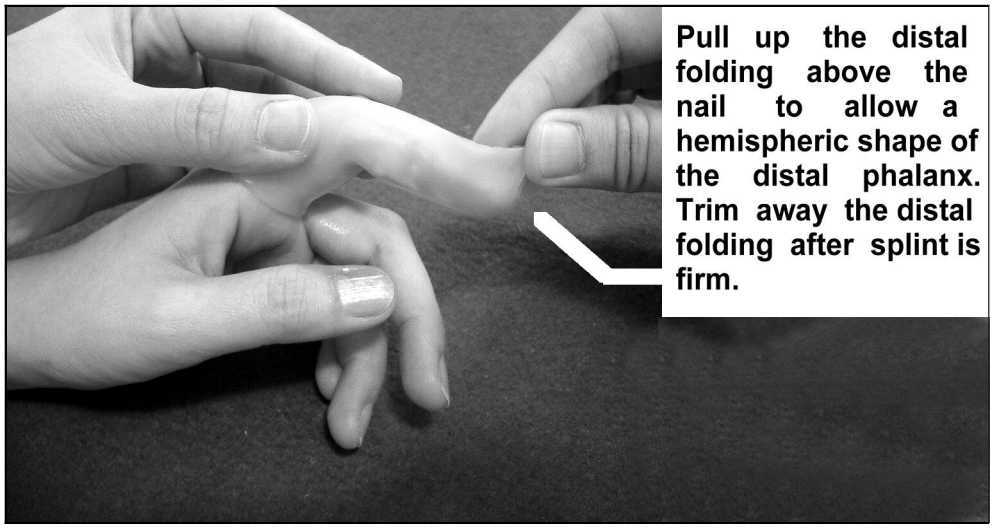

Fig. 3 Molding mallet splint with 70° PIPJ flexion.

flexion, additional Velcro strap is needed to cross over the proximal phalanx (Fig. 1).

Wearing Regime

In local practice, the short mallet splint is worn for 24 hours a day for six weeks. Then the patient is advised to start daytime active mobilisation and continue wearing the mallet splint at night for a further period of three to six weeks. For long mallet finger splint programme, it is applied during the initial two weeks. It is changed to the short mallet finger splint on the third week and is worn for a further period of four weeks. However, the long mallet splint is more preferable for patients with shorter fingers or for the little finger to ensure adequate lever length for more effective three-point support.[7]

Precautions

In order for the patient to fully comply with the whole programme, it is important that the therapist explains clearly to the patient. The patient must learn how to support the DIP joint in extension at all times, even when removing the splint for daily cleansing of the finger.

The hyperextension of the DIP joint and the pressure of the padded Velcro on the DIP joint should be carefully monitored; making sure that the circulation is not jeopardised, especially in the case of fracture.

When molding the long mallet splint, the therapist must position the PIP joint into flexion first before molding the thermoplastic material on the palmer side of the finger. If the PIP joint is flexed after wrapping the material around the palmar side of the digit, the folding at the PIP crease will be too sharp resulting in pressure point to the skin.

BUDDY SPLINT

Indications and Functions

The buddy splint allows the injured finger to move alongside the adjacent non-injured finger. The splint can be used for conditions such as post-close reduction of PIP joint dislocation, minor ligamentous sprain, or post-boutonniere deformity release.[2]

Types of Buddy Splint

The buddy splint can be classified into the tube type, Velcro type and ring type depending on the material used.

Fabrication Process

Tube type

The circumference of the two fingers is measured. A suitable size of elastic tubular bandage is used (Fig. 4a) (usually size A for females and B for males). The position to separate the two fingers is marked on the tubular bandage as shown in Fig. 4b.

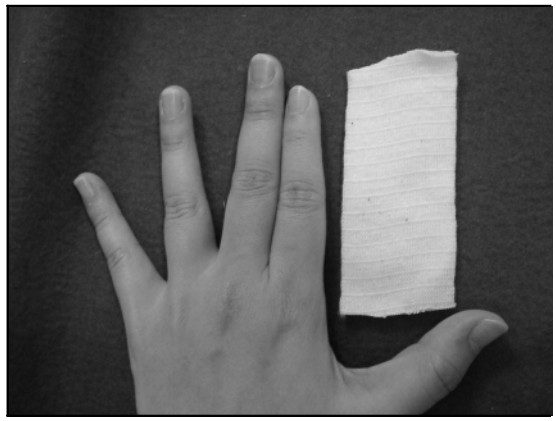

Fig. 4a Elastic tubular bandage.

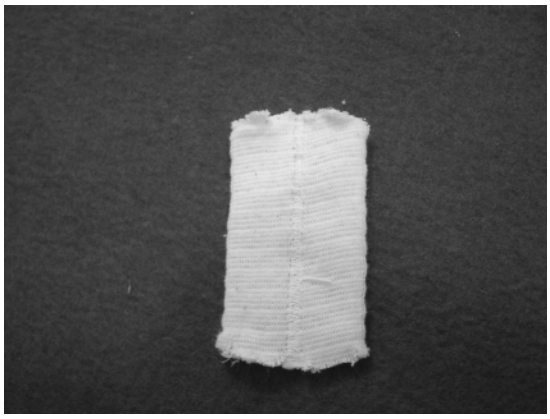

Fig. 4b "Zig-zag" seam to separate the tube.

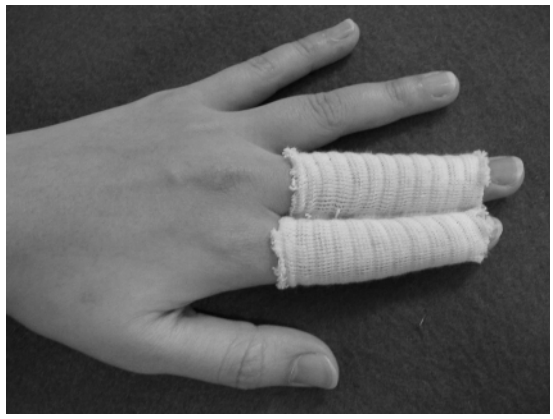

Fig. 4c Tubing in fingers and check circulation.

A wide "zig-zag" seam is sewn on the line marked. The joint alignment and tension of the elastic tube during active flexion and extension are checked after patient has put on the splint (Fig. 4c).

Velcro type

Two pieces of 14 cm Velcro loop straps and two pieces of 8 cm Velcro hook straps are needed to make this splint. With the hook and the loop sides facing up, they are sewn together. At the centre, we use the straight line seam for the pair of straps going around the proximal phalanges and the "zig-zag" seam for the two going around the middle phalanges (Figs. 5a and b).

The edge of the Velcro over the palmar side is trimmed to allow flexion of fingers without pressure edges on the DIP and PIP creases (Figs. 5c and d).

Strap type

Four straps of 2 mm thick and 10 mm wide low temperature thermoplastic material are prepared. The length of the straps is 6 to 8 cm (Fig. 6a).

The straps are softened in hot water at the working temperature of the splinting material. The strips are wrapped around the proximal phalanx and the middle phalanx of the two fingers. The extra length of the strips is trimmed (as in Fig. 6b) to form rings. For cosmetic reasons and for better stability, the trimmed edges of the individual heat strap ring should be joined to form the buddy splint (Figs. 6c and d).

An extra piece of thin splinting material (1.5 or 2 mm) can be added between the buddy rings of the middle phalangeal level before binding them together to fill the gap between the phalanges (Fig. 6e).

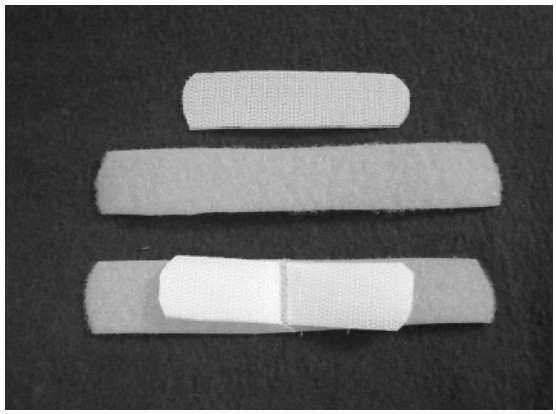

Fig. 5a Prepare buddy Velcro straps.

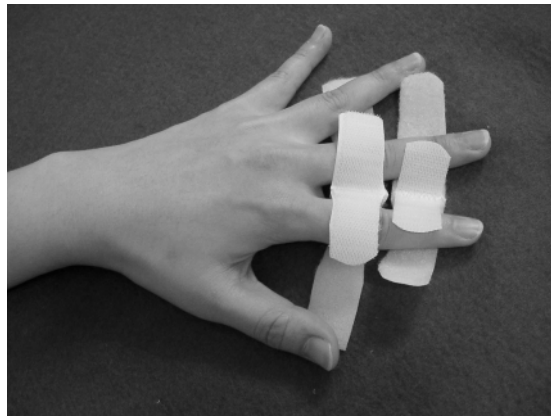

Fig. 5b Adjust Velcro alignment — line seam for proximal and "zig-zag" seam for distal.

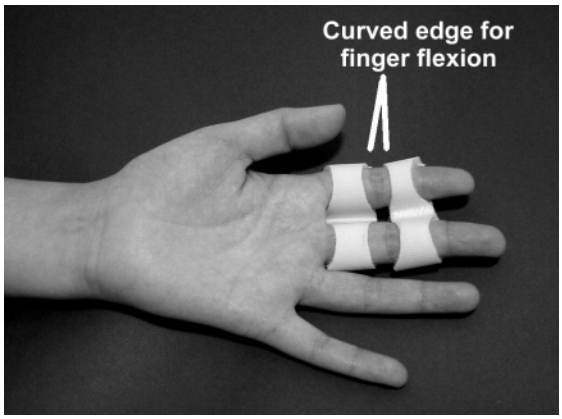

Fig. 5c Trim palmar side of Velcro to allow finger flexion.

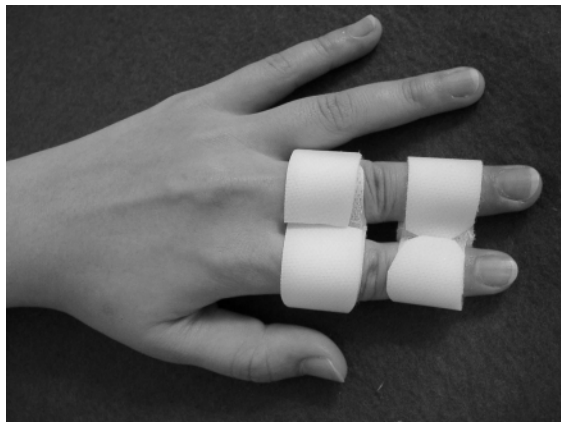

Fig. 5d Check finger circulation.

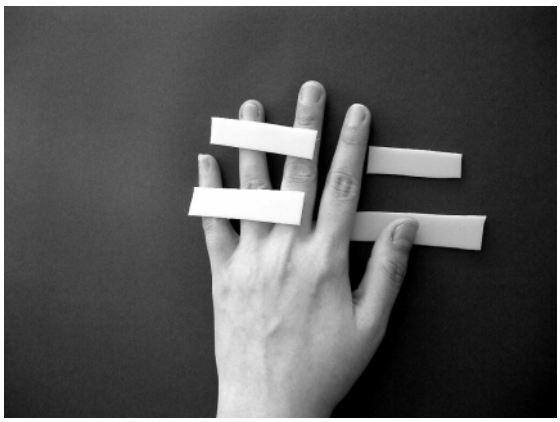

Fig. 6a Prepare four thermoplastic straps.

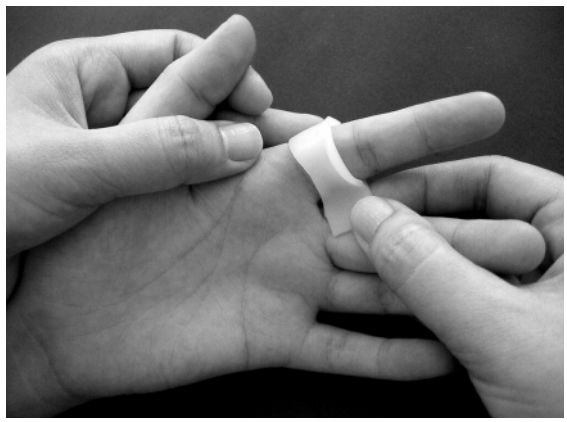

Fig. 6b Mold the straps to become rings and free finger flexion.

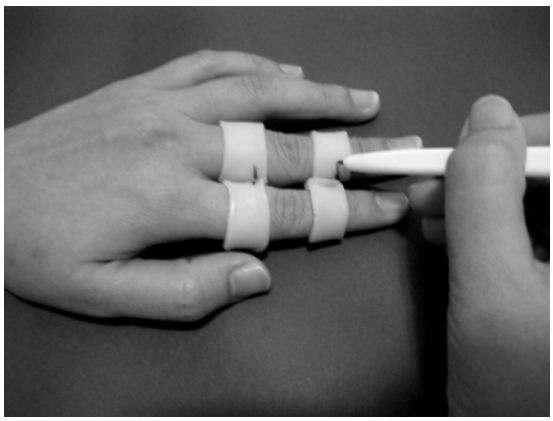

Fig. 6c Mark the contact point of the four buddy rings.

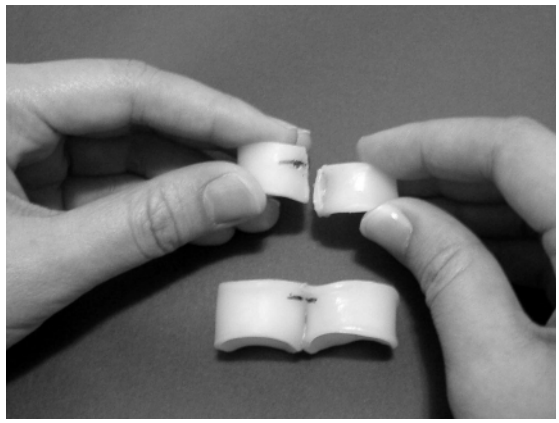

Fig. 6d Fix the rings with heat gun.

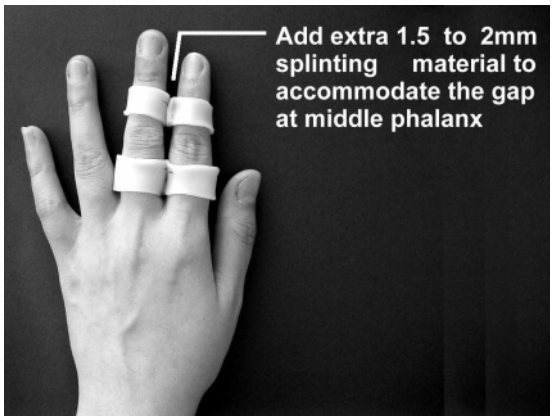

Fig. 6e Check proximal and distal finger alignment and circulation.

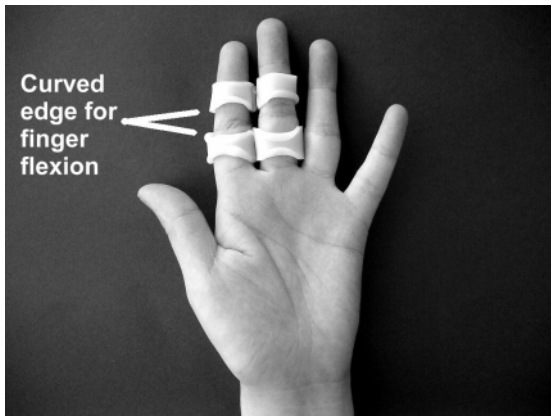

Fig. 6f Ensure buddy splint allows finger flexion.

It is important to make sure that the palmar edges of the rings are trimmed enough to allow free finger flexion (Fig. 6f).

Wearing Regime

The buddy splint should be worn continuously (24 hours a day) for three to four weeks to allow soft tissue healing and full range of motion with the support and assistance from the adjacent finger.

Precautions

The strap, ring or tube types should allow free movements of the DIP and PIP joints to ensure maximal finger flexion and extension[8] (Figs. 7a–c). The splint should not be too tight as it would result in discomfort and swelling of the involved finger.

Buddy strapping is only an option when there is an adjacent finger of approximately equal length to the injured finger, e.g. the index, middle and ring fingers. It is not advisable to use the splint to pair up the injured little finger with the ring finger. Otherwise, the PIP joints will rotate on different axes resulting in deformities.[3]

DORSAL FINGER BLOCK SPLINT

Indications and Functions

The dorsal finger block splint is indicated for post-reduction of dorsal dislocation of the PIP joint of fingers.[4] The PIP joint is usually blocked at 30° short of full extension lag but allow full flexion. If the dislocation is a recurrent one, Seiler[8] recommended blocking at 10° short of full extension.

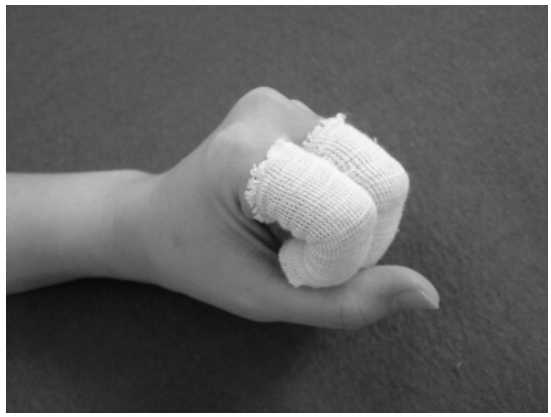

Fig. 7a Tube-type buddy allows full finger flexion.

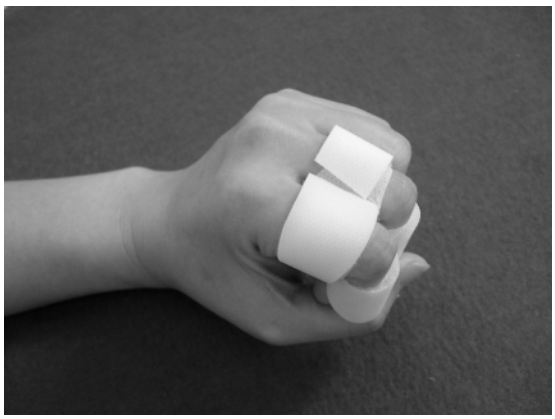

Fig. 7b Velcro-type buddy allows full finger flexion.

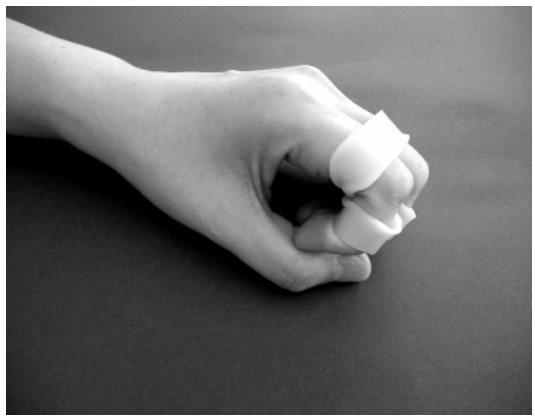

Fig. 7c Strap-type buddy allows full finger flexion.

Fabrication Process

The pattern is drafted and traced on a piece of 2 mm low temperature thermoplastic splinting material as shown in Fig. 8a.

The PIP joint is positioned at 30° short of full extension. The splinting material is wrapped around the dorsal aspect of the finger as shown in Fig. 8b.

The Velcro strap is added to secure the splint round the finger (Fig. 8c).

The Velcro over the palma surface of the injured finger is trimmed to allow full PIP joint flexion (Fig. 8d).

Wearing Regime

The dorsal block splint should be worn throughout day and night for three to four weeks.

Precautions

The Velcro strap should be trimmed to avoid restricting full flexion of the PIP joint, and it should not be wrapped too tightly since it will obstruct circulation. On the other hand, if the Velcro strap is too loose, it fails to keep the finger in the proper position.

CONCLUSION

Simple finger injuries such as mallet finger injury, ligamentous sprain and dislocation of PIP joint of fingers can be treated using very simple finger splints. They are small, easy to make and allow early protected mobilisation, as in the case of buddy splint and dorsal finger block splint. The fabrication steps involved are simple and can be completed in 15 minutes. The effectiveness of the splinting programme depends very much on patient's compliance

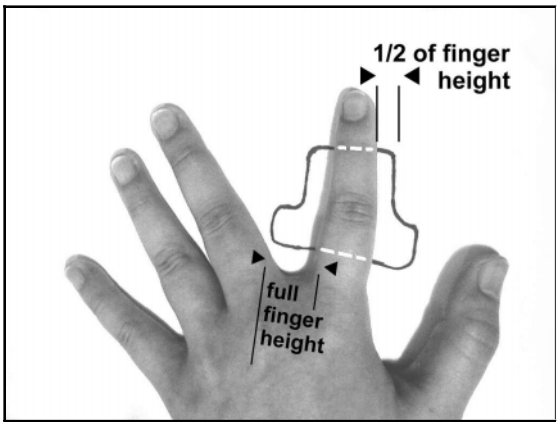

Fig. 8a Pattern of dorsal finger block splint.

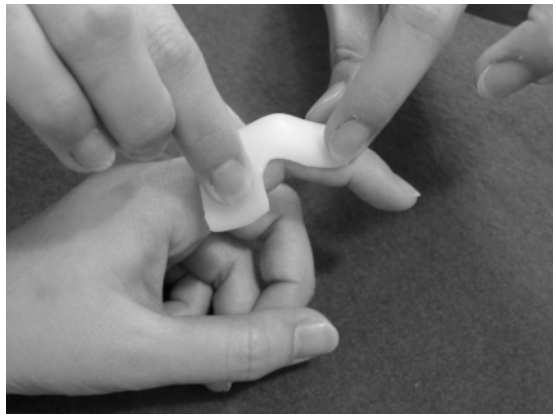

Fig. 8b Molding of dorsal finger block splint.

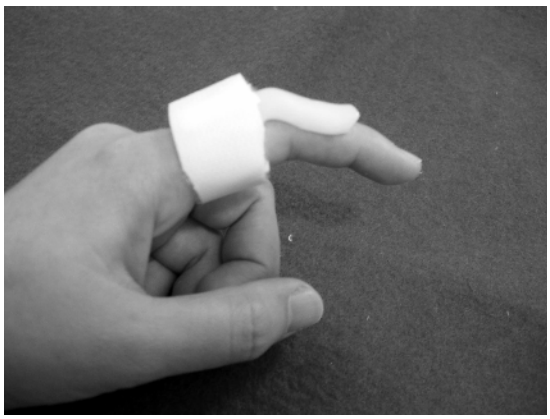

Fig. 8c Velcro strap to reinforce extension block.

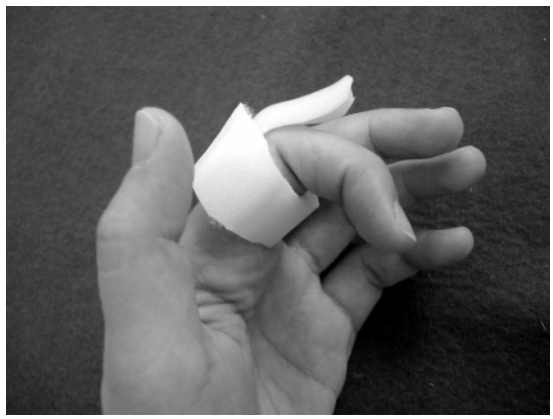

Fig. 8d Trim Velcro at palmar side to encourage finger flexion.

towards treatment. It is, therefore, very important that the patient has a clear understanding of the nature of injury, the function and wearing regime of the splint and the necessary precautions to be taken.

Although the injuries are considered simple, inappropriate handling with delayed treatment or prolonged immobilisation can result in stiff hand, reduced hand function and cosmetically unacceptable deformities.

References

1. Chan YCS *et al. Splint Manual for Occupational Therapist*. Hong Kong: Splint Working Group, Occupational Therapists, 1996: 77.
2. Clark GL *et al. Hand Rehabilitation*. New York: Churchill Livingstone, 1998: 143–149, 358.
3. Concannon MJ. *Common Hand Problems in Primary Care*. Philadelphia: Hanley & Belfus Inc., 1999: 103.
4. Glickel SZ, Barron OA. Proximal interphalangeal joint fracture dislocations. *Hand Clinics* 2000; **16(3)**: 333–344.
5. Lubahn JD, Hood JM. Fractures of the distal interphalangeal joint. *Clin Orthop* 1996; **327**: 12–20.
6. Okafor B, Mbubaegbu C, Munshi L, Williams DJ. Mallet deformity of the finger: Five-year follow-up of conservative treatment. *Br J Bone Joint Surg* 1997; **79(B)**: 544–547.
7. Orthopaedic Working Group. *Position Paper of Hand Therapy*. Hong Kong: Occupational Therapy Coordination Committee, Hospital Authority, 1993: 18–23.
8. Seiler JG. *III. Essentials of Hand Surgery — American Society for Surgery of the Hand*. New York: Lippincott Williams & Wilkins, 2002: 109, 247.

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Case report

Dynamic joint-aligned PIP and DIP corrective-flexion/extension orthosis for post burn finger contractures

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Accepted 11 January 2005

1. Introduction

Patients with hand burns are likely to develop various hand deformities and contractures, the most common of all being the deformities that resemble the Boutonniere deformities of fingers [1]. In contrast to other orthopaedic conditions these deformities in burns are often due to the contracted scar tissue and not solely due to changes in the direction of pull by the muscles of the hand. Therefore, the commonly prescribed splints, the '*Capener*' splint that corrects PIP (Proximal Interphalangeal) deformities alone and the static '*Gutter Splint*' that corrects the hyperextension component of DIP (Distal Interphalangeal) joint but inadequate in addition, its application hinders the functional use of hand, are not sufficient. Thus this paper describes an innovative splint, indigenously designed that stretches both the joints simultaneously.

2. General objective and rationale

- To enhance function.
- To apply gentle, prolonged stretch to a contracted PIP & DIP capsule, ligaments and the other related soft tissues to promote growth of shortened tissues and restore range of motion in both the PIP and DIP joints.

3. Fabrication of the splint

The splint consists of four springs (S1, S2, S3 and S4) and three supports (the proximal support, PS; the intermediate support, IS and the distal support, DS) that are made out of approximately 15 cm of spring wire (Fig. 1). Initially, the outline of the finger that needs to be splinted is drawn and the skin creases of that finger are marked. The spring wire is then bent in such a way that the two springs S1 and S2 are on either sides of the PIP crease and the other two springs S3 and S4 are on either sides of the DIP crease and the three semi-circular supports (PS, IS, and DS) are made in the following pattern.

- The PS rests on the dorsal surface of the finger at the midline between the MP (metacarpophalangeal) crease and the PIP crease.
- The DS rests on the dorsal surface of the finger at the midline between DIP crease and the tip of the finger.
- The IS rests on the volar surface of the finger at the midline between the PIP and DIP crease.

These supports provide the three-point pressure needed to produce the extension force at the PIP and flexion force at the DIP joints (Fig. 2). The finger supports PS, IS, and DS are padded adequately with foam or any padding material in order to avoid any local pressure by increasing the surface area or the area of contact.

4. Advantages

- This splint's best utility would be in those with slipped extensor tendons, where there is difficulty in full PIP extension, due to the mobilizing of both the PIP and the DIP joints at the same time.
- This dynamic functional splint is a day splint, when prescribed concomitantly with static gutter splint as night splint, likely to assist in promoting faster growth of

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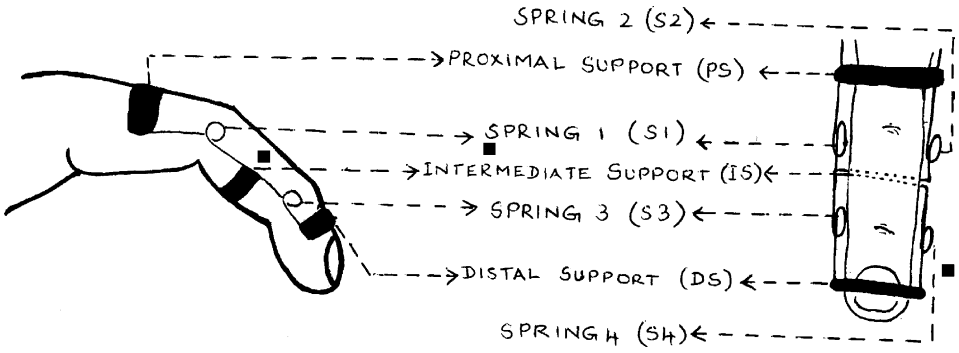

Fig. 1.

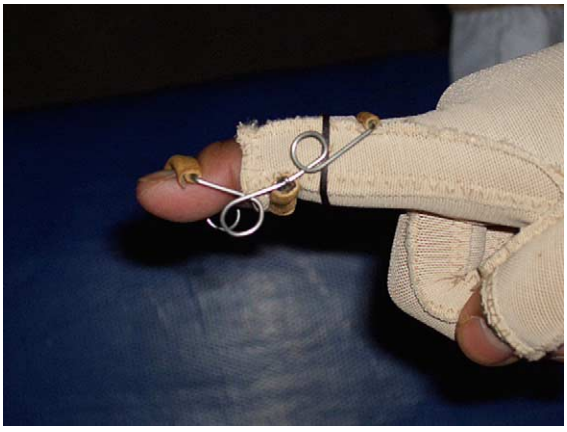

Fig. 2.

shortened tissues and restore range in boutonniere deformity while maintaining the client's functional independence [2]. However, this splint does not replace the static gutter splint that is in use, which allows scarring without flexion at PIP by maintaining it in extension.

- The force produced by the splint to provide prolonged stretch could be easily adjusted by varying the number of coils in the spring and/or by changing the thickness of the spring wire.
- Importantly this orthosis has "no profile" minimizing its visual presence.
- Above all it is cost-effective (less than 25 cents) and very easy to make requiring not more than 15 min per splint.

5. Conclusion

This splint provides continuous stretch to both PIP and DIP that is needed for range restorations among one of the commonest post burn contractures of fingers. It has a pleasing look and is also comfortable and easy to use, which enhances the client's compliance. This can become the splint of choice for most of the third world nations especially because of its simple and cost effective nature.

References

[1] Daugherty MB, Carr-Collins JA. Splinting techniques for the burn patient. In: Richard RL, Staley MJ, editors. Burn care and rehabilitation: principles and practice. Philadelphia: FA Davis, 1994. p. 589.
[2] McKee P, Morgan L, editors. Orthotics in rehabilitation. New Delhi: Jaypee Brothers medical Publishers Ltd., 1998.

HCPCS:	Descriptor:
L4360	WALKING BOOT, PNEUMATIC AND/OR VACUUM, WITH OR WITHOUT JOINTS, WITH OR WITHOUT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Sprain, strain, fracture, soft tissue injuries
Medically Necessary Argument	A qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Other issues include proper height (distal to the fibular head to avoid peroneal nerve pressure, proper foot plate length/adjustments, proper vacuum/pneumatic adjustments, contour changes for anatomical shape). When the pneumatic device is properly inflated, it decreases pain and swelling around the surgical or injury site. An improperly inflated device can cause excessive swelling and pain around the site being protected, prolonging the healing process and possibly require further intervention. Adjustments to the orthosis which could be detrimental to the fit and function should only be performed by a qualified professional.
References	22

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Orthopedic Walkers: Effect on Plantar Pressures

by James A. Birke, P.T., M.S.
Deborah A. Nawoczenski, P.T., M.Ed.

Introduction

Short leg (SLW) and patellar tendon bearing walkers (PTBW) are orthotic appliances† which have been recently designed as alternative devices to traditional plaster cast immobilization. The indications for use of lower leg walkers include severe ankle sprains, and ankle and foot fractures. Orthopedic walkers are convenient to use, lightweight, and removable to perform joint range of motion or inspect the extremity. Short leg walkers have been shown to be as effective as walking casts in healing stable ankle fractures, and patients treated with short leg walkers have shown significantly less edema, tenderness, and joint stiffness after six weeks of immobilization.[13] The authors feel that orthopedic walkers may also prove to be a beneficial alternative to traditional management of neuropathic fractures and plantar ulcerations, which are commonly seen in diabetes mellitus and Hansen's disease.

Neuropathic foot lesions are the result of abnormal or repetitive stress.[3,4,8,10,16] Treatment techniques for neuropathic foot conditions should be effective in reducing pressure and shear stress. Traditional methods of treating neuropathic foot lesions include walking casts, fixed ankle braces, and PTB braces.[1,5,6,7,14,17] Plaster walking casts and PTB braces have been shown to significantly reduce pressure on the plantar surface of the foot during walking.[2,9,11,15] The total contact walking cast is considered effective in reducing pressure on the foot by redistributing forces on the plantar surface of the foot and lower leg. Several features of PTB orthoses shown to be important in achieving maximal weight bearing reduction on the foot include a rigid closure PTB shell, a heel-shoe clearance of ⅜″ to 1″, a fixed ankle joint, and a rocker sole.[11] Orthopedic walkers incorporate these same design features to varying degrees which has generated our interest in studying their effectiveness in reducing pressure on the foot.

The SLW has a fixed ankle joint, rocker sole, and a polyurethane liner which is snugly secured to the leg with Velcro® closures (Figure 1). The PTBW incorporates all the features of the SLW, as well as a non-custom molded, semi-rigid polyethylene PTB shell (Figure 2).

The effectiveness of the SLW or PTBW in reducing pressure or shear stress on the foot has not previously been studied. The potential value of these devices in managing the neuropathic foot may be evaluated by their effectiveness in reducing pressure and shear stress. Currently, there are unreliable methods for measuring shear stress. However, shear is directly related to the perpendicular forces acting on the foot. Pressure equals the perpendicular forces per unit area. Pressure transducers provide a repeatable measurement of relative pressure inside footwear when the material interfacing with the transducers is controlled.[12]

† 3D Orthopedics, Inc., 10520 Olympic Drive, Dallas, Texas 75220.

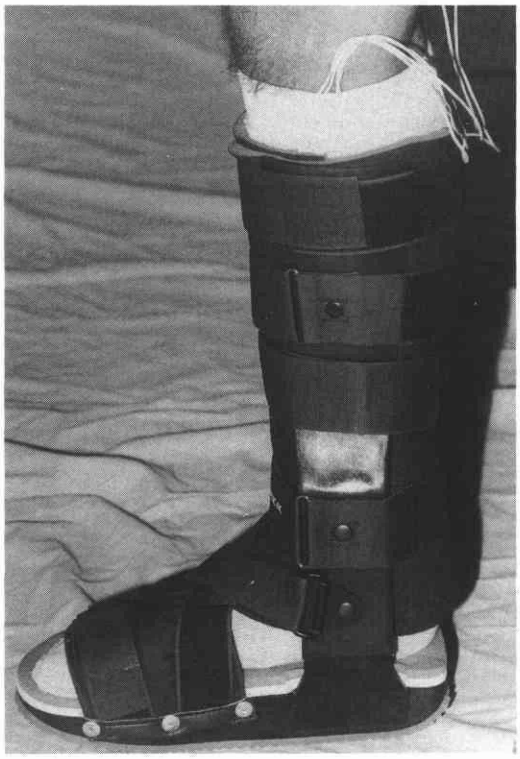

Figure 1. Short Leg Walker.

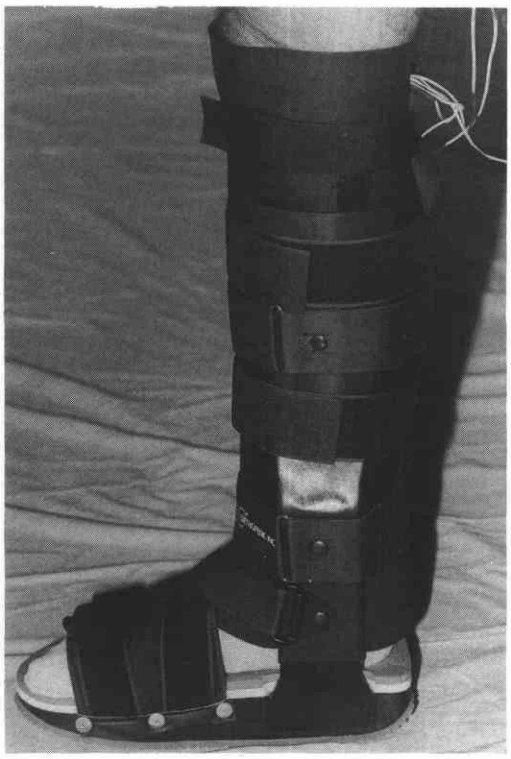

Figure 2. Patellar Tendon Bearing Walker.

Purpose

The purpose of this study was to determine the effectiveness of SLW and PTBW in reducing the pressure distribution on the normal foot during walking.

Method

Ten subjects (6 male and 4 female) without a history of foot pathology participated in this study. Capacitive pressure transducers‡ 2mm thick and 1.5cm in diameter were taped to the first metatarsal head (MTH), third MTH, fifth MTH, and plantar heel of the right foot of each subject (Figure 3). The foot was covered with a thin cotton stockinette which remained undisturbed during the study. Transducers were calibrated according to the manufacturer's instructions prior to testing each subject. Pressure recordings were made using a four-channel capacitive impedance bridge amplifier‡ and oscillographic recorder††† while subjects walked in a cast shoe (CS-1) (Figure 4), short leg walker (SLW), patella tendon bearing walker (PTBW), and again in a cast shoe (CS-2). All the walking devices were fabricated by the same manufacturer.† The cast shoe was identical to the foot component of both the SLW and PTBW, utilizing identical rocker outersoles and 2.4mm polyurethane material insoles. SLW and PTBW were applied to the leg with a ⅜" heel-shoe clearance. Subjects walked a distance of 100 meters for each treatment condition. The testing order of treatments SLW, PTBW, and CS-2 was randomly assigned to eliminate systematic error.

Relative pressure was measured in millimeters of peak to peak chart deflection for 24 steps for each treatment condition. The middle distance of each run was used for analysis in order to eliminate pressure variations due to the acceleration and deceleration phases of each trial. Percent pressure change relative to CS-1

‡ Hercules Orthoflex Data System, Allegany Ballistics Lab, Cumberland, Maryland.

††† Gulton TR-400a, Gulton Industries, Inc., East Greenwich, Rhode Island.

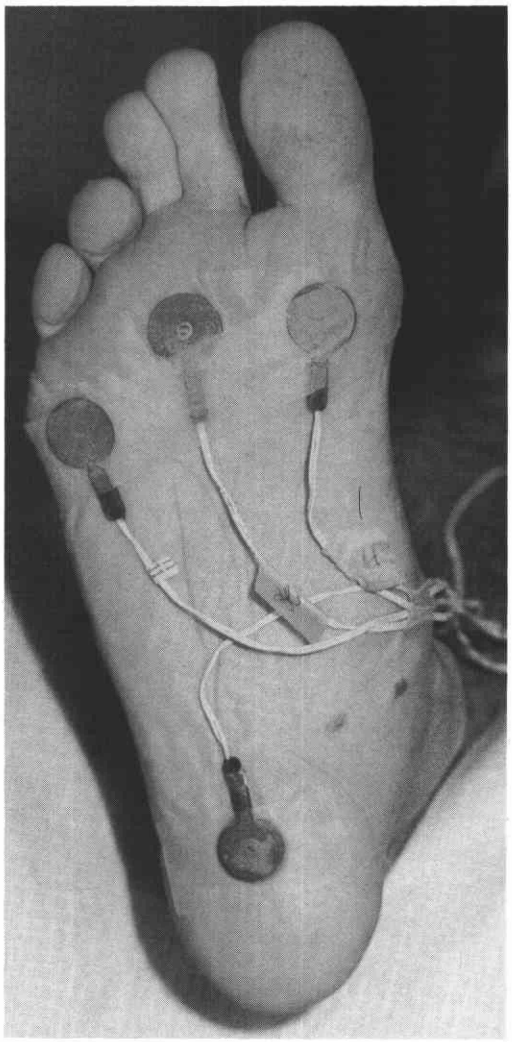

Figure 3. Pressure transducer placement on selected areas of the foot.

was calculated for treatments SLW, PTBW, and CS-2. Means and standard deviations were computed for treatments at each transducer site. An analysis of variance for repeated measures was used to determine whether treatment differences were significant within each site. Duncan's test was used for post-hoc analysis of means. A significance level of 0.05 was used for comparisons.

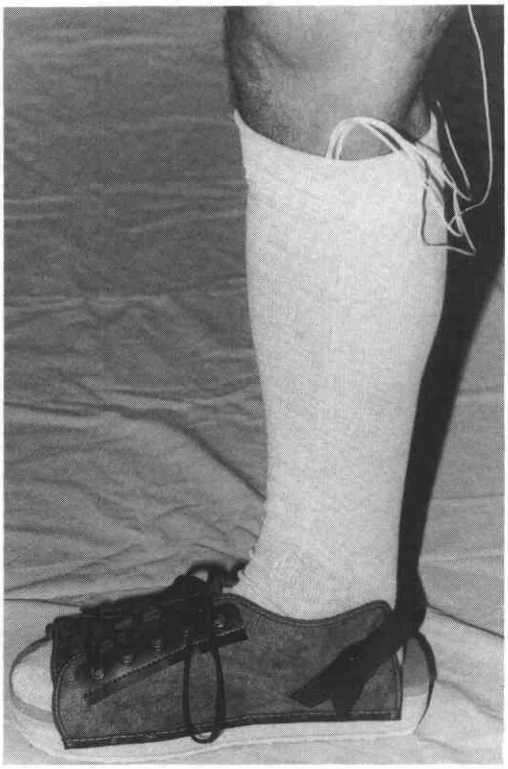

Figure 4. Cast Shoe.

Results and Discussion

An analysis of variance (Table 1) for mean percent reduction in pressure was highly significant at all sites tested (Figures 5, 6, 7, and 8). Duncan's test was performed to establish which treatments differed. Significant differences were found between the percent reduction in pressure walking in SLW and PTBW as compared to the CS-2 at all sites. No difference was found between SLW and PTBW at any site. The percent pressure reduction using the walker devices was comparable at all the sites tested.

This study demonstrated the effectiveness of the short leg and patellar tendon bearing walkers as compared to the cast shoe in reducing plantar pressure on the foot. Since all the devices in this study had the same sole design and insole materials, treatment differences must be attributable to proximal orthotic components including the polyurethane liner, fixed ankle uprights, and Velcro® closures. The SLW and PTBW differed only by the polyeth-

Analysis of Variance of Percent Pressure Reduction

SITE	SOURCE	DF	SS	MS	F
1ST MTH	Treatments	2	1.378	0.689	187.08*
	Subjects	9	0.5468	0.0608	
	Error	18	0.0663	0.0037	
	Total	29	1.9912		
3RD MTH	Treatments	2	2.4045	1.2022	433.8666*
	Subjects	9	0.2841	0.0316	
	Error	18	0.0499	0.0028	
	Total	29	2.7385		
5TH MTH	Treatments	2	1.0142	0.5071	400.0744*
	Subjects	9	0.5052	0.0561	
	Error	18	0.0228	0.0013	
	Total	29	1.5422		
HEEL	Treatments	2	1.2276	0.6138	828.9806*
	Subjects	9	0.1868	0.0208	
	Error	18	0.0133	0.0007	
	Total	29	1.4278		

* $P < .001$.

Table I. Analysis of Variance of Percent Pressure Reduction.

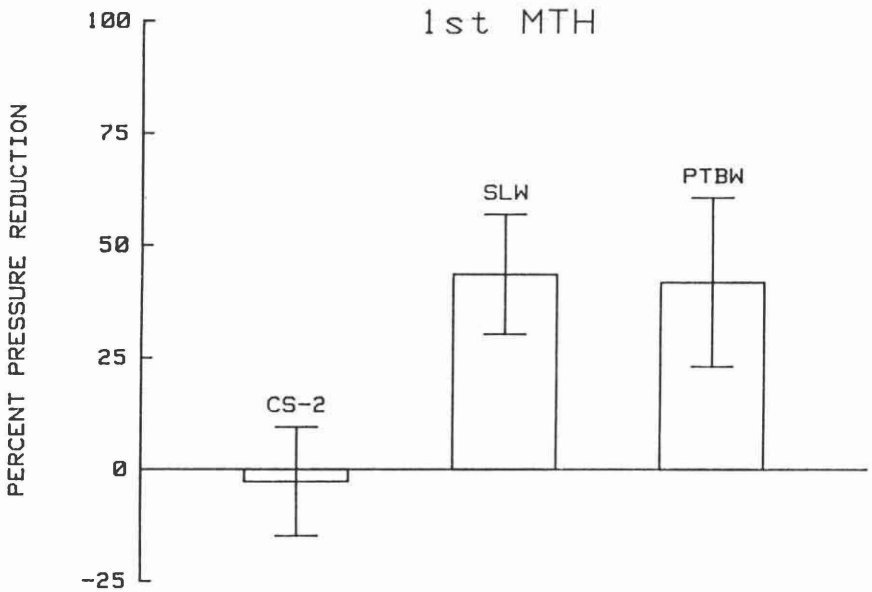

Figure 5. Percent pressure reduction at the first metatarsal head (1 MTH) walking in cast shoe-2 (CS-2), short leg walker (SLW) and patellar tendon bearing walker (PTBW) compared to walking in cast shoe-1.

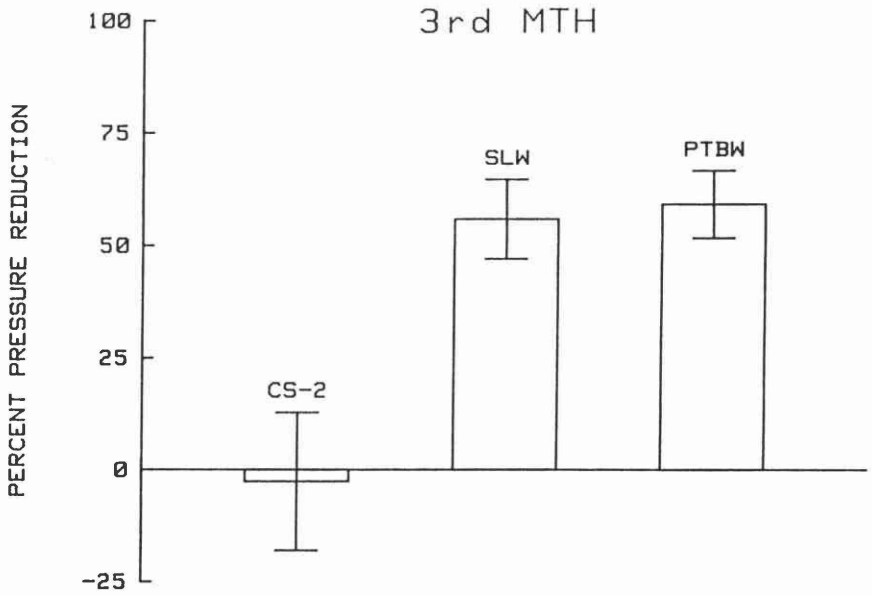

Figure 6. Percent pressure reduction at the third metatarsal head (3 MTH) walking in cast shoe-2 (CS-2), short leg walker (SLW) and patellar tendon bearing walker (PTBW) compared to walking to in cast shoe-1.

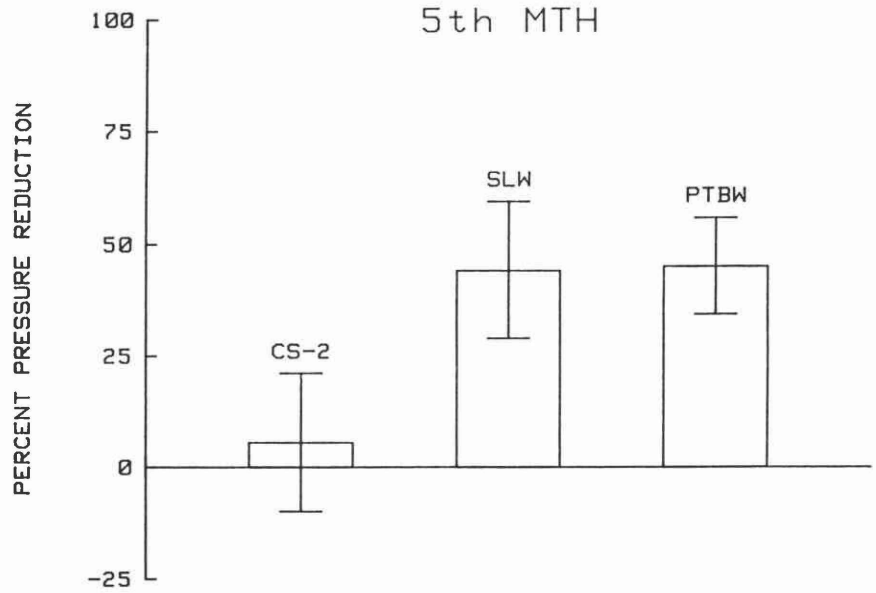

Figure 7. Percent pressure reduction at the fifth metatarsal head (5 MTH) walking in cast shoe-2 (CS-2), short leg walker (SLW) and patellar tendon bearing walker (PTBW) compared to walking in cast shoe-1.

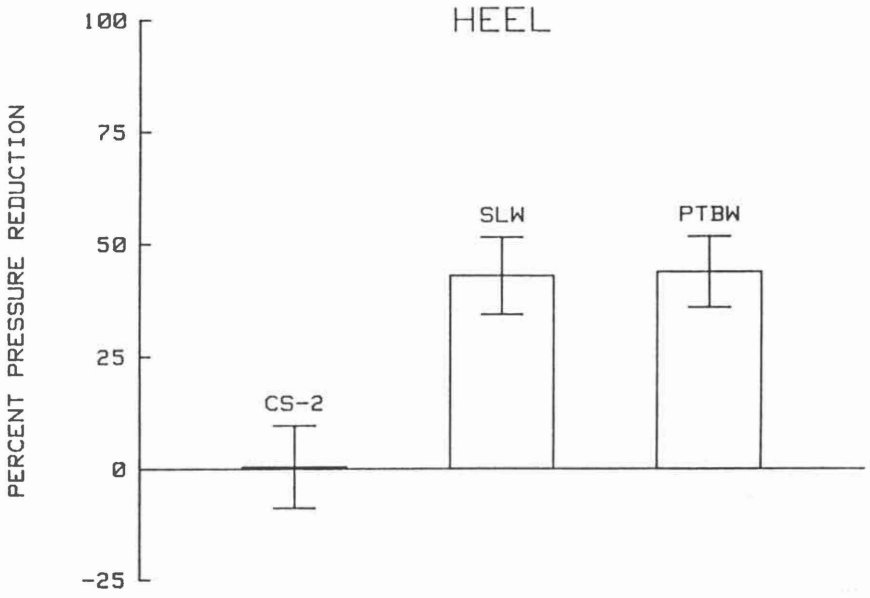

Figure 8. Percent pressure reduction at the heel walking in cast shoe-2 (CS-2), short leg walker (SLW) and patellar tendon bearing walker (PTBW) compared to walking in cast shoe-1.

ylene, non-custom molded patellar tendon cuff. Since no treatment difference was seen between these devices, the PTBW cuff design must not have been effective. However, in follow-up, single subject trials, we were not able to change walking pressures by redesigning the PTBW cuff using polyethylene or plaster custom molded PTB cuffs. An alternative conclusion is that the SLW design alone optimally reduced plantar pressure by the fixed ankle joint and uprights snugly supporting the lower leg and calf.

In this study, orthopedic walkers were equally effective in reducing pressure at all sites tested on the foot. In previous studies, casts were shown to reduce pressure more effectively in the forefoot than the heel, and PTB orthotics reduced pressure more effectively in the heel than the forefoot.[2,11,15]

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Conclusions

Within the scope of this study, it is possible to conclude the following: (1) SLW and PTBW orthopaedic walkers are effective in reducing pressure at the first MTH, third MTH, fifth MTH and heel in normal subjects during walking, and (2) there is no difference in pressure distribution between the SLW and PTBW during walking.

References

[1] Anderson, J.G., "Treatment and Prevention of Plantar Ulcers," *Leprosy Review,* 35, 1964, pp. 251–258.

[2] Birke, J.A. and D.S. Sims, "Walking Casts: Effect on Plantar Foot Pressures," *Journal of Rehabilitation Research and Developement,* 22:3, July, 1985, pp. 18–22.

[3] Brand, P.W., "The Insensitive Foot," Editor M.H. Jahss, *Disorders of the Foot,* Vol. II, W.B. Saunders, 1982, p. 1266.

[4] Cterctecko, G.C., M. Dhanendran, W.S. Hutton, and L.P. LeQuesne, "Vertical Forces Acting on the Foot of Diabetic Patients with Neuropathic Ulceration," *British Journal of Surgery,* 68, 1981, pp. 609–614.

[5] Coleman, W.S., P.W. Brand, and J.A. Birke, "The Total Contact Cast: A Therapy for Plantar Ulceration of the Insensitive Foot," *Journal of the American Podiatric Medical Association,* 74:11, November, 1984, pp. 548–552.

[6] Enna, C.D., P.W. Brand, J.K. Reed, and D. Welch, "The Orthotic Care of the Denervated Foot in Hansen's Disease," *Orthotics and Prosthetics,* 30:1, March, 1976, pp. 33–39.

[7] Gristina, A.G., A.L.W. Thompson, N. Kester, W. Walsh, and J.A. Gristina, "Treatment of Neuropathic Conditions of the Foot and Ankle with a Patellar-Tendon-Bearing Brace," *Archives of Physical Medicine and Rehabilitation,* 54, December, 1973, pp. 562–564.

[8] Hall, O.C. and P.W. Brand, "The Etiology of the Neuropathic Plantar Ulcer," *Journal of the American Podiatric Medical Association,* 69:3, March, 1979, pp. 173–177.

[9] Helm, P.A., S.C. Walker, and G. Pullium, "Total Contact Casting in Diabetic Patients with Neuropathic Foot Ulcerations," *Archives of Physical Medicine and Rehabilitation,* 65, 1984, pp. 691–693.

[10] Lang-Stevenson, A.I., W. Sharrard, R.P. Betts, and T. Duckworth, "Neuropathic Ulcers of the Foot," *Journal of Bone and Joint Surgery,* (British) 67B, 1985, pp. 438–442.

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[12] Patterson, R.P., and S.V. Fisher, "The Accuracy of Electrical Transducers for the Measurement of Pressure Applied to the Skin," *IEEE Transactions on Biomedical Engineering,* 26:8, August, 1979, pp. 450–456.

[13] Polakoff, D.R., S.M. Pearce, D.P. Grogan, and W.Z. Burkhead, "The Orthotic Treatment of Stable Ankle Fractures," *Orthopedics,* 7, 1984, pp. 1712–1715.

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[15] Pollard, J.P., L.P. LeQuesne, and J.W. Tappin, "Forces Under the Foot," *Journal of Biomedical Engineering,* 5, 1983, pp. 37–40.

[16] Sabato, S., Z. Yosipovitch, A. Simkin, and J. Sheskin, "Plantar Trophic Ulcers in Patients with Leprosy," *International Orthopedics,* 6, 1982, pp. 203–208.

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Authors

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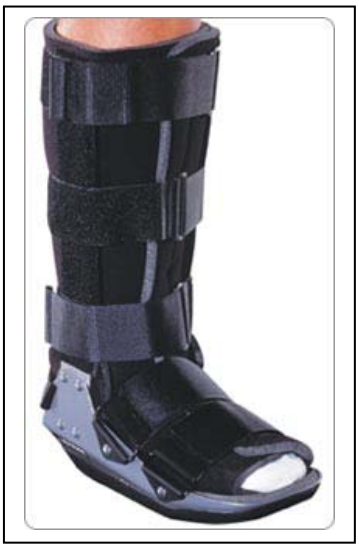
Deborah A. Nawoczenski, P.T., M.Ed., is Assistant Professor at the Department of Physical Therapy for the College of Allied Health Professions at Temple University, Philadelphia, Pennsylvania 19140.

HCPCS:	Descriptor:
L4386	WALKING BOOT, NON-PNEUMATIC, WITH OR WITHOUT JOINTS, WITH OR WITHOUT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT



Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
YES	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Sprain, strain, fracture, soft tissue injuries
Medically Necessary Argument	A qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Other issues include proper height (distal to the fibular head to avoid peroneal nerve pressure, proper foot plate length/adjustments, contour changes for anatomical shape). Adjustments to the orthosis which could be detrimental to the fit and function should only be performed by a qualified professional.
References	22

Clinical Prosthetics and Orthotics, Vol. 12, No. 2, pp. 74–80

Orthopedic Walkers: Effect on Plantar Pressures

by James A. Birke, P.T., M.S.
Deborah A. Nawoczenski, P.T., M.Ed.

Introduction

Short leg (SLW) and patellar tendon bearing walkers (PTBW) are orthotic appliances† which have been recently designed as alternative devices to traditional plaster cast immobilization. The indications for use of lower leg walkers include severe ankle sprains, and ankle and foot fractures. Orthopedic walkers are convenient to use, lightweight, and removable to perform joint range of motion or inspect the extremity. Short leg walkers have been shown to be as effective as walking casts in healing stable ankle fractures, and patients treated with short leg walkers have shown significantly less edema, tenderness, and joint stiffness after six weeks of immobilization.[13] The authors feel that orthopedic walkers may also prove to be a beneficial alternative to traditional management of neuropathic fractures and plantar ulcerations, which are commonly seen in diabetes mellitus and Hansen's disease.

Neuropathic foot lesions are the result of abnormal or repetitive stress.[3,4,8,10,16] Treatment techniques for neuropathic foot conditions should be effective in reducing pressure and shear stress. Traditional methods of treating neuropathic foot lesions include walking casts, fixed ankle braces, and PTB braces.[1,5,6,7,14,17] Plaster walking casts and PTB braces have been shown to significantly reduce pressure on the plantar surface of the foot during walking.[2,9,11,15] The total contact walking cast is considered effective in reducing pressure on the foot by redistributing forces on the plantar surface of the foot and lower leg. Several features of PTB orthoses shown to be important in achieving maximal weight bearing reduction on the foot include a rigid closure PTB shell, a heel-shoe clearance of ⅜″ to 1″, a fixed ankle joint, and a rocker sole.[11] Orthopedic walkers incorporate these same design features to varying degrees which has generated our interest in studying their effectiveness in reducing pressure on the foot.

The SLW has a fixed ankle joint, rocker sole, and a polyurethane liner which is snugly secured to the leg with Velcro® closures (Figure 1). The PTBW incorporates all the features of the SLW, as well as a non-custom molded, semi-rigid polyethylene PTB shell (Figure 2).

The effectiveness of the SLW or PTBW in reducing pressure or shear stress on the foot has not previously been studied. The potential value of these devices in managing the neuropathic foot may be evaluated by their effectiveness in reducing pressure and shear stress. Currently, there are unreliable methods for measuring shear stress. However, shear is directly related to the perpendicular forces acting on the foot. Pressure equals the perpendicular forces per unit area. Pressure transducers provide a repeatable measurement of relative pressure inside footwear when the material interfacing with the transducers is controlled.[12]

† 3D Orthopedics, Inc., 10520 Olympic Drive, Dallas, Texas 75220.

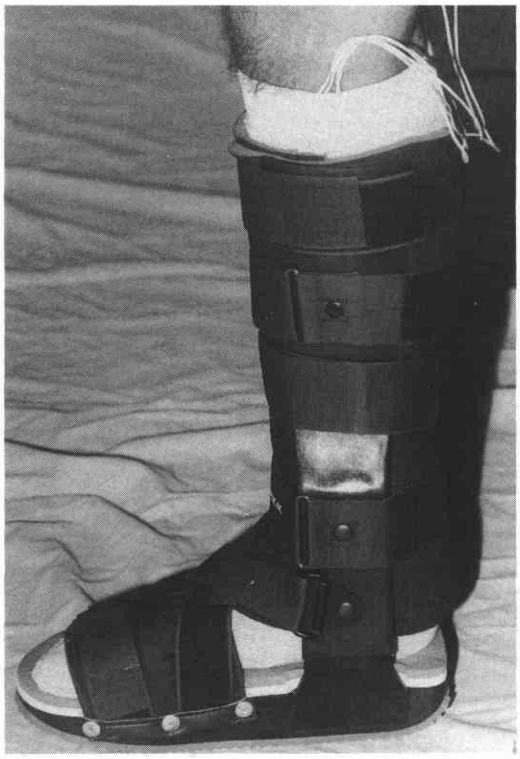


Figure 1. Short Leg Walker.

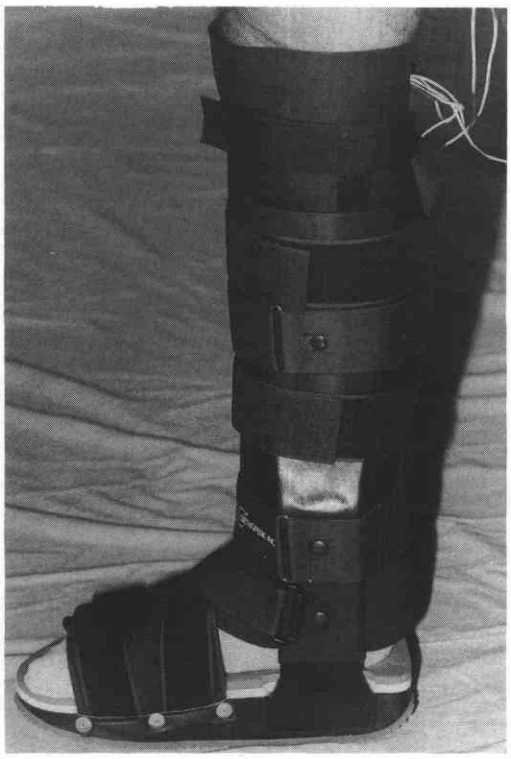


Figure 2. Patellar Tendon Bearing Walker.

Purpose

The purpose of this study was to determine the effectiveness of SLW and PTBW in reducing the pressure distribution on the normal foot during walking.

Method

Ten subjects (6 male and 4 female) without a history of foot pathology participated in this study. Capacitive pressure transducers‡ 2mm thick and 1.5cm in diameter were taped to the first metatarsal head (MTH), third MTH, fifth MTH, and plantar heel of the right foot of each subject (Figure 3). The foot was covered with a thin cotton stockinette which remained undisturbed during the study. Transducers were calibrated according to the manufacturer's instructions prior to testing each subject. Pressure recordings were made using a four-channel capacitive impedance bridge amplifier‡ and oscillographic recorder††† while subjects walked in a cast shoe (CS-1) (Figure 4), short leg walker (SLW), patella tendon bearing walker (PTBW), and again in a cast shoe (CS-2). All the walking devices were fabricated by the same manufacturer.† The cast shoe was identical to the foot component of both the SLW and PTBW, utilizing identical rocker outersoles and 2.4mm polyurethane material insoles. SLW and PTBW were applied to the leg with a ⅜" heel-shoe clearance. Subjects walked a distance of 100 meters for each treatment condition. The testing order of treatments SLW, PTBW, and CS-2 was randomly assigned to eliminate systematic error.

Relative pressure was measured in millimeters of peak to peak chart deflection for 24 steps for each treatment condition. The middle distance of each run was used for analysis in order to eliminate pressure variations due to the acceleration and deceleration phases of each trial. Percent pressure change relative to CS-1

‡ Hercules Orthoflex Data System, Allegany Ballistics Lab, Cumberland, Maryland.

††† Gulton TR-400a, Gulton Industries, Inc., East Greenwich, Rhode Island.

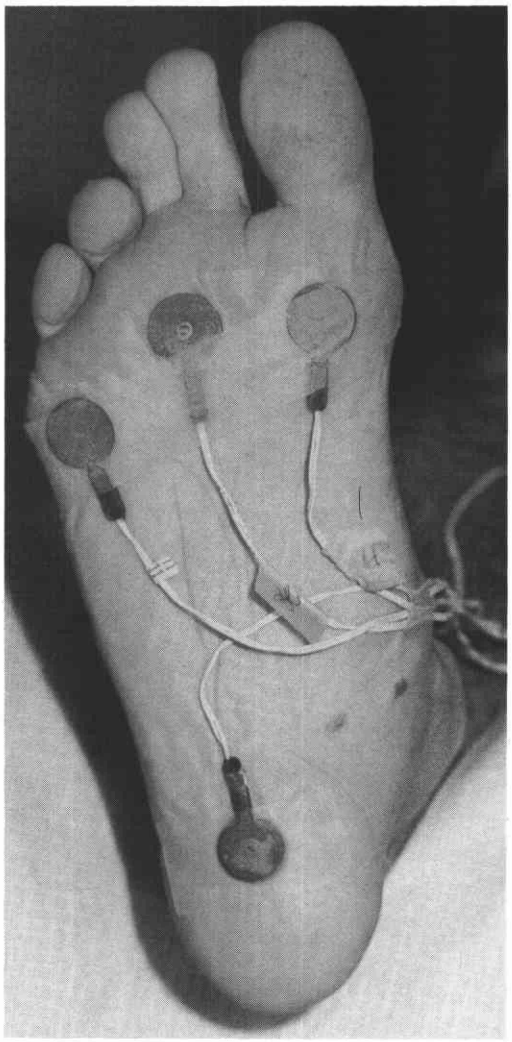


Figure 3. Pressure transducer placement on selected areas of the foot.

was calculated for treatments SLW, PTBW, and CS-2. Means and standard deviations were computed for treatments at each transducer site. An analysis of variance for repeated measures was used to determine whether treatment differences were significant within each site. Duncan's test was used for post-hoc analysis of means. A significance level of 0.05 was used for comparisons.

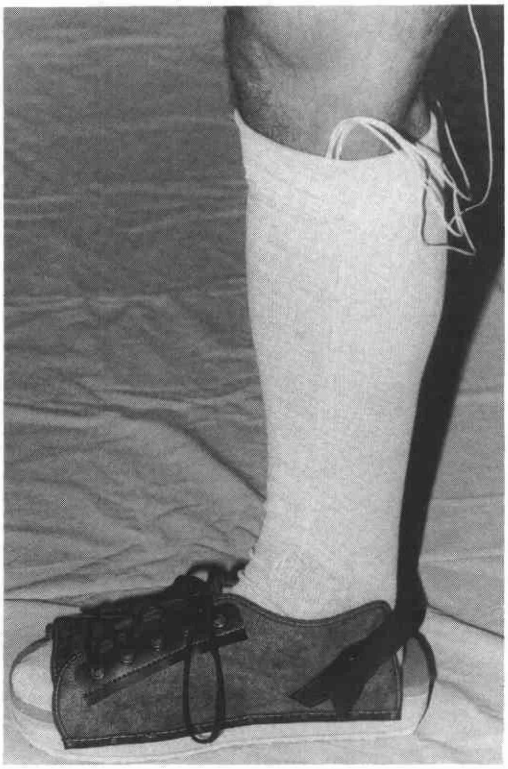


Figure 4. Cast Shoe.

Results and Discussion

An analysis of variance (Table 1) for mean percent reduction in pressure was highly significant at all sites tested (Figures 5, 6, 7, and 8). Duncan's test was performed to establish which treatments differed. Significant differences were found between the percent reduction in pressure walking in SLW and PTBW as compared to the CS-2 at all sites. No difference was found between SLW and PTBW at any site. The percent pressure reduction using the walker devices was comparable at all the sites tested.

This study demonstrated the effectiveness of the short leg and patellar tendon bearing walkers as compared to the cast shoe in reducing plantar pressure on the foot. Since all the devices in this study had the same sole design and insole materials, treatment differences must be attributable to proximal orthotic components including the polyurethane liner, fixed ankle uprights, and Velcro® closures. The SLW and PTBW differed only by the polyeth-

Analysis of Variance of Percent Pressure Reduction

SITE	SOURCE	DF	SS	MS	F
1ST MTH	Treatments	2	1.378	0.689	187.08*
	Subjects	9	0.5468	0.0608	
	Error	18	0.0663	0.0037	
	Total	29	1.9912		
3RD MTH	Treatments	2	2.4045	1.2022	433.8666*
	Subjects	9	0.2841	0.0316	
	Error	18	0.0499	0.0028	
	Total	29	2.7385		
5TH MTH	Treatments	2	1.0142	0.5071	400.0744*
	Subjects	9	0.5052	0.0561	
	Error	18	0.0228	0.0013	
	Total	29	1.5422		
HEEL	Treatments	2	1.2276	0.6138	828.9806*
	Subjects	9	0.1868	0.0208	
	Error	18	0.0133	0.0007	
	Total	29	1.4278		

* $P < .001$.

Table I. Analysis of Variance of Percent Pressure Reduction.

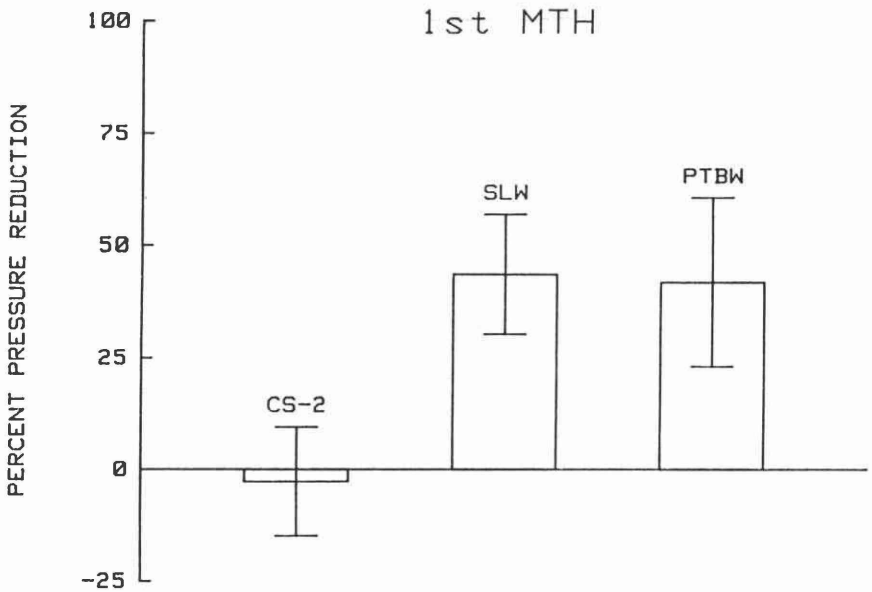


Figure 5. Percent pressure reduction at the first metatarsal head (1 MTH) walking in cast shoe-2 (CS-2), short leg walker (SLW) and patellar tendon bearing walker (PTBW) compared to walking in cast shoe-1.

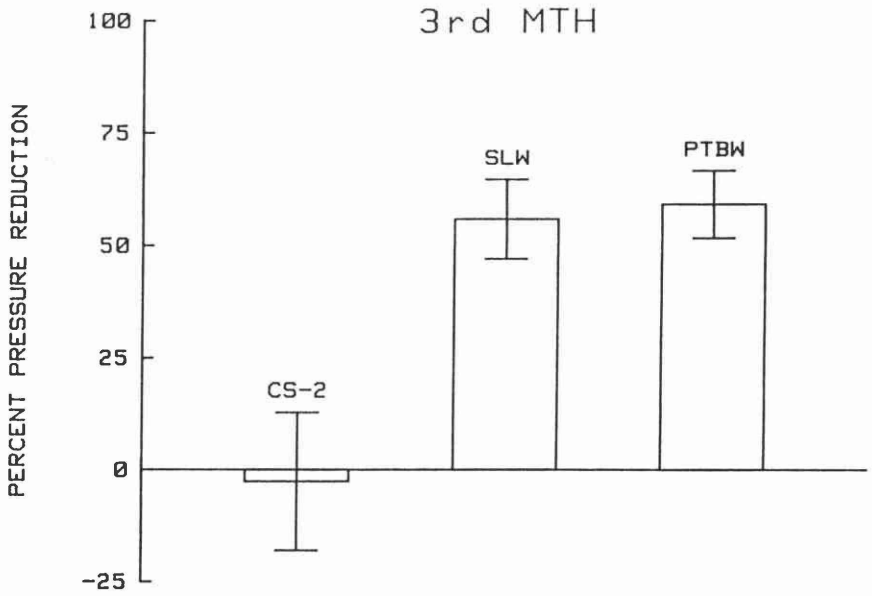
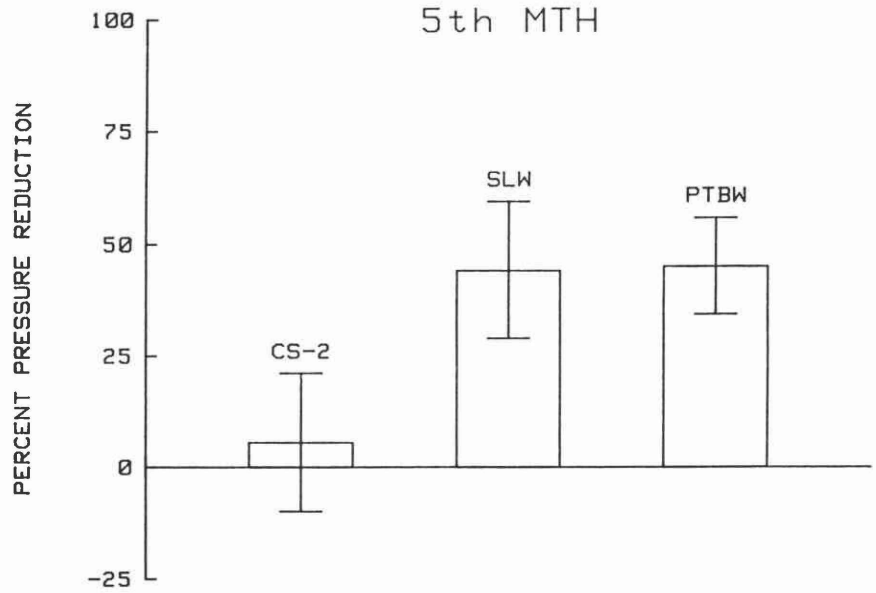


Figure 6. Percent pressure reduction at the third metatarsal head (3 MTH) walking in cast shoe-2 (CS-2), short leg walker (SLW) and patellar tendon bearing walker (PTBW) compared to walking to in cast shoe-1.



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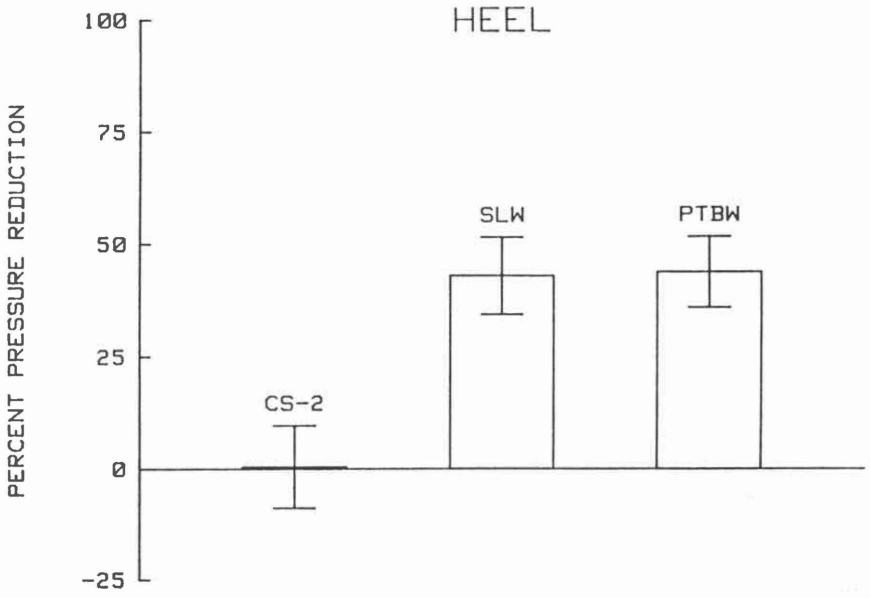

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Conclusions

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HCPCS:	Descriptor:
L4396	STATIC OR DYNAMIC ANKLE FOOT ORTHOSIS, INCLUDING SOFT INTERFACE MATERIAL, ADJUSTABLE FOR FIT, FOR POSITIONING, MAY BE USED FOR MINIMAL AMBULATION, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Violates OTS Policy Rationale

Requires Trimming	Requires Bending	Requires Molding	Requires Assembly	Customized to Individual required
NO	YES	YES	YES	YES

Sample Diagnosis (Not Inclusive)	Sprain, strain, fracture, plantar fasciitis, heel ulcers, ankle contracture, flaccid equinus
Medically Necessary Argument	A qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Other issues include proper height (distal to the fibular head to avoid peroneal nerve pressure, proper footplate length/adjustments, contour changes for anatomical shape. An improper fitting PRAFO can decrease healing time or even prevent healing which can, in some cases, lead to amputation. A qualified professional should only perform adjustments to the orthosis, which could be detrimental to the fit and function.
References	23

Lower Limb Orthotic Management of Duchenne Muscular Dystrophy: A Literature Review

Phillip M. Stevens, MEd, CPO

ABSTRACT

Although currently incurable, Duchenne muscular dystrophy remains treatable. The characteristic gradual loss of functional muscle and the concurrent developments of progressive contracture are often indications for orthotic interventions. As the disease progresses through the abbreviated life of the young man, he will encounter three functional stages: independent ambulation, assisted ambulation, and wheelchair mobility. Although controversy continues as to the appropriate role of orthoses during each of these stages, some generalities may be gleaned from a review of published literature. Specific patterns of weakness, accommodation, and contracture development characterize the initial stage of independent ambulation. Orthotic intervention is often confined to nighttime splints to slow the development of equinus contracture. As weakness and contracture progress, balance becomes increasingly precarious, and independent ambulation is ultimately precluded. Many authors have suggested that a degree of ambulation may be maintained during this phase by combinations of surgery, knee-ankle-foot orthoses and aggressive rehabilitation. The popularity of such procedures has declined since its peak in the 1970s and 1980s. Appropriate timing, patient selection, and rehabilitation appear to be essential in obtaining optimal outcomes. Weakness and contracture continue to progress until even assisted ambulation is precluded and wheelchair confinement ensues. Some authors have suggested a limited role of orthotic intervention in the form of postoperative positional ankle-foot orthoses to prevent recurrence of deformities. The relevance of corticosteroids, fracture incidence, and cognitive ability are also discussed. (J Prosthet Orthot. 2006; 18:111–1119.)

Of the identified muscular dystrophies, the x-linked Duchenne muscular dystrophy (DMD) has been described as the most common and most severe. Although its incidence is still relatively rare, described variously as two to three cases per 10,000 live male births[1] or one in 3,500 live male births,[2] it is encountered with regularity in the orthotic community. Its degenerative processes begin at birth and continue through the next 2 decades, until it ultimately claims the life of the affected young man.[1] Despite the relentless progression of the disease, many efforts have been made to optimize the abbreviated life of the child with DMD. As Siegel[3] accurately reminded the medical community, "incurable is not synonymous with untreatable." The characteristic gradual loss of functional muscle and the concurrent developments of progressive contracture are indications for appropriate intervention from the orthotic community as a part of the global management of this patient population.

The purpose of this report is to describe the physical presentations observed within this patient population during the various stages of disease progression and to review the published literature to date on the use of lower extremity orthoses across these same stages. It is not intended as a consensus of current practice techniques but an evaluation of the methods that have been used during the past several decades.

When treating the patient with DMD, it is helpful to consider the needs of the patient according to three chronologically encountered functional stages: independent ambulation, assisted ambulation, and wheelchair mobility. Perhaps because of the incurable but treatable nature of the disease, controversy exists regarding the appropriate orthotic intervention at each of these three stages. Although several authors have reported the average ages at which patients tend to transition from one stage to the next, there is tremendous heterogeneity from patient to patient.[4,5] In addition, there has been increasing discussion and use of several medications that have been reported to slow muscle degeneration and thereby alter the natural history of the disease process. Therefore, categorizations and generalizations of anticipated function based solely on age should be avoided.

STAGE 1: INDEPENDENT AMBULATION

Affected boys are unremarkable in their presentation at birth and through infancy as early developmental milestones such as rolling, sitting, and standing are reached within normal age limits.[1,6] As toddlers, it is not uncommon for their walking to be delayed until 18 months or older.[2] Deficits in gait are not typically noticed until 3 to 5 years of age.[7,8]When first seeking medical opinions, parents often site clumsiness or an inability of their son to keep up with his peers at school. In the absence of a genetic history that would suggest the presence of DMD, definitive diagnosis is often delayed. In one study, Read and Galasko[9]reported that although the average age of initial referral to an orthopedist was 3 years, the correct diagnosis of DMD was not assigned until an average of 2 years later.

As the disease progresses, functional muscle is incrementally replaced with fibrofatty tissue.[1,10] This results in strength deficits while the muscle bellies may appear to be quite developed. This "pseudohypertrophy" is most commonly noted in the triceps surae. Although this attribute is common among patients with DMD, it is not always present. In addition, its presence may be secondary to other muscular dystrophies and should not, therefore, be considered exclusive to the DMD population.[8]

Weakness always occurs in proximal muscles before distal ones, initially targeting the hip and knee extensors.[8,11] This weakness is often manifested at an early age in the child's employment of the Gowers' maneuver when transitioning from the floor to a standing position. Initially the child will roll onto his hands and knees in the prone position. He will then extend his knees, raising his buttocks upward. Next, he will use his upper limbs to "walk" his hands along his legs until the torso can be brought upright.[1] As with the pseudohypertrophy of the calf muscles, the use of the Gowers' maneuver is not exclusive to the DMD population but is simply a manifestation of weakened gluteal musculature that may be found in spinal muscle atrophies and other myopathies.[1,8]

MECHANICS OF STANCE AND GAIT

During this functional stage, boys with DMD gradually develop a characteristic standing posture (Figure 1). Among the muscles of the lower limbs, hip extensors are the first to demonstrate critical weakness. Increasingly unopposed, the hip flexors contract and draw the pelvis into an anterior tilt. This allows the tensor fascia lata to pass further anterior to the greater trochanter, where it progressively shortens. In addition, as the trunk is drawn forward, aggressive lumbar lordosis and hyperextension of the spine occur. This positions the weight line posterior to the hip joint, thereby establishing passive hip stability and accommodating the weakened hip extensors. Concurrently, as knee extensors become increasingly weaker, the subject relies more on active equinus posturing of the feet and ankles bilaterally to maintain the weight line anterior to the knees and thereby establish a passive knee stability. Unlike hip and knee flexion contractures that usually remain mild as long as the child is ambulatory, equinus contractures continue to progress during this stage, gradually diminishing the child's functional base of support. As balance becomes increasingly precarious, the child establishes a wider base of support by abducting the hips. The result is further shortening of the tensor fascia lata.[12–16]

Ambulation is similarly affected as the proximal weaknesses progress. During early ambulation, gait deviations are subtle. Excessive plantar flexion may be seen in swing phase, with a concomitant increase in hip flexion to assist in toe clearance. Cadence may be reduced, and initial contact is with the entire planar surface of the foot to minimize the early flexion moments experienced at the hip and knee in stance.[5,6]

As muscle weakness progresses, cadence continues to decline and changes are seen in both the coronal and sagittal planes. In the coronal plane, increasing gluteus medius weakness and the progressive shortening of the tensor fascia lata lead to incrementally exaggerated trunk leaning, increased shoulder sway, and the adoption of a wider base of support.[5,6]

In the sagittal plane, boys soon learn to position themselves so the weight line is anterior to the knee throughout single leg support, abandoning early stance phase knee flexion to accommodate their weakening knee extensors.[1,5,6,17] This passive stability of the knee is assisted by the concurrent development of equinus contracture, such that several authors have cautioned against surgical overlengthening of the Achilles during this functional stage.[17–19] Even if equinus contractures are minimal, there is evidence that as the proximal weaknesses progress, the

child actively plantarflexes in stance for stability.[5]Equinus may likewise be manifested in gait as the presence of early heel rise in terminal stance[1] and ultimately as toe-walking.[6,16] Throughout this functional stage, periods of prolonged immobilization secondary to minor trauma or illness should be avoided because the child may deteriorate quickly, losing the ability to walk.[20]

Progressive contracture of the hip and knee flexors is prevented by daily ambulation,[8,18,20,21] and weaknesses can still be accommodated at this functional stage by the outlined compensations. Accordingly, orthotic interventions should be confined to attempts at delaying the development of severe plantarflexion contractures.

ORTHOTIC INTERVENTIONS

Daytime ankle-foot orthoses (AFOs) should generally be avoided because they compromise increasingly precarious ambulation, placing excessive demands on incapable knee extensors during the loading response phase of gait.[1,22] Furthermore, recent literature has drawn attention to the susceptibility of dystrophic muscles to permanent injury when subjected to eccentric contractions.[23–25] Preliminary evidence has verified an increased external flexion moment at the knee when DMD patients ambulate with daytime orthoses.[22] By requiring greater eccentric contractions of proximal extensors, the inappropriate prescription of daytime AFOs during this functional stage may actually further weaken the quadriceps, potentially shortening the child's period of independent ambulation.

Nighttime AFOs are often prescribed at this stage in conjunction with passive stretching regimens.[1,10,20] The effectiveness of night splints in altering the natural history of heel cord contracture formation has been questioned[26,27] and warrants investigation.

In 1981, Scott et al.[21] reported on 59 boys with DMD, in whom assessments of joint contractures and functional abilities were performed at 3- to 4-month intervals during a period of 3 years. The authors reported a delay in the loss of dorsiflexion range of motion among boys who had worn night splints and received regular daily stretching. These same boys were able to walk independently for longer periods. In contrast, boys who did not wear night splints and received no stretching were observed to require wheelchair confinement at earlier ages. The authors concluded that early and persistent splinting slows the development of contracture and enhances walking ability.[21]

In 1985, Seeger et al.[28] reported a smaller case series in which the researchers followed up 12 boys for just more than a year. Reductions in plantar flexion contractures were observed in subjects who were compliant in the use of night splints combined with regular stretching. However, during an 8-week period when physical therapy was suspended and parental compliance with brace wear and home stretching could not be ascertained, equinus contractures increased.

In 1989, Brooke et al.[4] published the broadest evaluation of the effects of passive joint stretching and nighttime AFOs on slowing the development of equinus contractures, reporting on 283 boys with DMD from four different medical centers. No correlation was found between the use of passive joint stretching and joint contracture. However, regular use of night splints was found to have a marked effect in reducing contractures of the heel cord.

In 2000, Hyde et al.[29] reported on a prospective randomized study of 27 boys observed for a period of 30 months. Those treated with a combination of night splints and stretching experienced annual increases in equinus contracture that were 23% less than those treated with stretching alone.

A universal challenge in the provision of nighttime AFOs during this functional stage is the facilitation of compliance on the part of the patient and his family. In the treatment of cerebral palsy and other pediatric neuromuscular disorders, splints are typically molded in relative dorsiflexion to provide the maximum nocturnal stretch of the Achilles tendon. Sussman[1] suggests that among the DMD population, night splints be molded with the ankle at neutral alignment to enhance patient tolerance and ultimately compliance. This is consistent with the observations of several authors that conservative interventions can, at best, only slow the progression of equinus contracture.[1,19,20] Ultimately, the orthoses must be comfortable or they will not be worn.

SUMMARY

Orthotic intervention during the independent ambulation stage is limited to the foot and ankle complex. Although proximal weakness is primarily responsible for the end of a child's independent ambulation, extreme equinus contractures contribute to this eventuality. Daytime AFOs place excessive demands on increasingly weakening quadriceps and should generally be avoided. There is some evidence that compliant use of nighttime AFOs can modify the natural history of the disease process during this stage by slowing the progression of equinovarus deformities. The comfort of the orthoses plays a critical role in facilitating compliance.

STAGE 2: ASSISTED AMBULATION

While contracture of the hip flexors, knee flexors, and plantar flexors may each play a part, it is ultimately the combination of progressive hip and knee extensor weakness that gradually precludes the child's functional abilities.[6,7,15,18] It has been observed that patients with DMD generally lose their ability to rise from the floor, climb stairs, and walk independently, in that order, and at intervals of approximately 1 year between each functional deficit.[4,30] Although there is some variability among authors, the consensus observation is that the natural course of the disease will lead to increasing frequencies of falls, growing uncertainty in walking ability and ultimately the loss of independent ambulation.[7,16,18–20,31]

For a family coping with a disease characterized by a series of crises, the loss of ambulation may represent the biggest crisis since the initial diagnosis. As Gardner-Medwin[15]expressed, "the loss of their boy's ability to walk confirms in a graphic and inescapable way the prognosis they [the parents] had been given and had been hoping against hope might be wrong" (p 659).

ORTHOTIC INTERVENTIONS

Prior to the early 1960s the sole treatment alternative of a child with DMD was temporary prolongation of ambulation through orthotic interventions, soon followed by confinement to a wheelchair.[12,18,30] Then, in 1962, Spencer and Vignos[18] reported the successful preservation of orthoticassisted ambulation in 15 boys through the combination of Achilles tendon release, iliotibial band (ITB) fasciotomy, and the use of double upright knee-ankle-foot orthoses (KAFOs) with locking knee joints. The authors reported that although patients continued to slowly weaken at varying rates, an average of 24 additional months of orthotic-assisted ambulation was observed.[18]

In 1967, observing the unique strength retention of the posterior tibialis among the lower limb muscles, Spencer[32] reported anterior transfer of these tendons through the interosseous membrane attaching to the cuneiform. This was done to restore some degree of muscular balance to the foot and ankle and prevent the recurrence of equinovarus posturing. Three years later, Roy and Gibson[33] reported on 30 children treated according to Spencer's modified protocols, including ITB fasciotomy, Achilles release, and posterior tibialis tendon transfer. In their series, walking was prolonged for a mean value of 25 months.

In 1968, Siegel et al.[34] reported on their protocols in the treatment of 21 boys, incorporating Spencer's original methods[32] with the addition of proximal tenotomies of the sartorius and rectus femoris to address hip flexion contracture. The authors reported that all patients were able to stand without support and walk unassisted for short distances.[34]

Continuing to as recently as 2003, numerous others have reported similar results of an additional 2 to 4 years of orthotic-assisted ambulation using variations from the original surgical protocols of Spencer.[6,14,16,19,31,35–41] The muscles treated surgically by the various authors, along with the mean values of the periods of assisted ambulation observed are summarized in Table 1 . It should be noted that most of these studies were published in the late 1970s and early 1980s, with a limited number occurring in the past 20 years. The prevalence of such assistive procedures in current practice may be justifiably questioned.

There is consensus that if such ambulation-prolonging procedures are to be performed, they should be implemented as soon as the child loses the capability for independent ambulation and requires external assistance.[14,19,31] One author reported increasing the frequencies of follow-up evaluations as gait and balance became increasingly

precarious to ensure appropriate timing of the interventions.[33] Periods of prolonged nonambulation increase disuse atrophy of muscle and contractures of weight-bearing joints, thereby compromising outcomes.[15,18,31,39]

Regardless of the type of surgical procedures performed, rapid and aggressive rehabilitation procedures are required after surgery. Research consistently advocates the immediate application of postoperative casts to allow for early standing and ambulation.[14,16,18,31–36,39] Standing, and in some cases, walking, occurs on the first postoperative day[14,16,31,32,34–36,39] but may begin as early as 12 hours after surgery.[19] In the ensuing weeks, an aggressive physical therapy regimen is undertaken as the child regains balance and learns to ambulate with his new body alignments. Long-leg casts are used until orthoses are provided 1 to 3 weeks later.[14,32,34–36,39] Prolonged postoperative immobilization should be avoided because of the patient's susceptibility to rapid disuse atrophy.[3]

Orthoses should be lightweight, plastic KAFOs. Ischial shelves have been incorporated to allow the child to "sit" into the orthoses.[13,34,36,39] The height of the orthosis is important. If too high, the patient is pushed forward out of balance; if too low, a severe kyphosis may develop.[13] Locking knee joints substitute for weakening quadriceps.[6] It has been suggested that the ankle region of the orthosis should provide a rigid anterior stop, allowing a secondary knee extension force anteriorly[6] and preventing painful stretching of the Achilles tendon.[14] At the ankle, slight dorsiflexion may be needed to facilitate the child's balance of his upper body. Heel wedges can also facilitate this alignment.[6] It has also been suggested that the foot plate of the orthoses should extend only to the metatarsal heads.[39]

Ambulation after such interventions begins with a walker until the child learns to balance with stability in the orthoses. Swing phase is compromised by the locked extension of the knee joints bilaterally, necessitating lateral trunk lean over the stance limb to lift the swing leg. Initial contact is instigated by the heel, translating into forward progression of the locked limb. Hyperlordosis of the lumbar spine and trunk hyperextension persist, keeping the child's weight line posterior to the hip, thereby providing passive stability at that joint.[6,18,36]

RATIONALE FOR ORTHOTIC INTERVENTION

A year is a long time in the life of a child,[16] and the additional period of ambulation afforded by surgery and bracing may represent as much as 20% of that patient's life span.[3,36] Authors have cited numerous benefits associated with the provision of this second functional phase of orthotic-assisted ambulation. Factors associated with wheelchair confinement in the DMD population, such as scoliosis, obesity, disuse atrophy, osteoporosis, pathologic fracture, pressure sores, severe contracture at the hip and knee flexors, and the development of further foot and ankle deformity, may be avoided or postponed.[6,18,35–36,39–42] Additional benefits to both gastrointestinal and pulmonary function have been suggested.[14,42] Psychological benefits have been reported, including enhanced self-sufficiency, selfconfidence, and increased independence,[18] as well as a delay in the lack of motivation that can ensue once a child is confined to a wheelchair.[36]

The effect of prolonged ambulation on spinal deformities warrants individual consideration. In addition to being both unsightly and uncomfortable, scoliosis restricts ventilation and aggravates the respiratory problems that result from weakness of the intercostal muscles and diaphragm.[43] Numerous authors have cited a delay in the onset of severe scoliosis when standing and walking are prolonged,[6,14,39] additionally observing that by slowing the progression of the scoliosis, surgery is postponed until the child is older and more amenable to the procedures.[4]

In a comprehensive evaluation, Rodillo et al.[44] reported on 93 boys who had undergone reambulation procedures. They found a significant difference between the Cobb angles measured in the boys who stopped walking before the age of 13 years (62° ± 32°) and those who ambulated beyond that age (32° ± 22°). The monthly progression in the later group averaged 0.95°, whereas that of the former group averaged 2.4°. A highly significant relationship was found between the Cobb angle and the number of months each boy spent in a wheelchair. The authors concluded that although severe scoliosis was postponed until wheelchair confinement in the boys who discontinued ambulation before age 13, these boys ultimately were more prone to the rapid progression of scoliosis associated with puberty than were those who walked beyond 13 years of age. In this second group, it was hypothesized that the symmetrical

lordosis associated with standing reduced pelvic tilt and stabilized the spine by locking the lumbar facet joints. The lateral flexion of the spine associated with walking was thought to avoid any prolonged fixed positions.[44]

PREDICTING SUCCESS OF REAMBULATION PROCEDURES

Even given the benefits reported with successful orthoticassisted, ambulation-prolonging procedures, the procedures remain controversial, with skeptics arguing that rewards are outweighed by "the frustration, inconvenience and cost involved."[35] Others have raised concerns about the excessive energy cost of braced ambulation and safety concerns in the event of a fall.[10] Although the aggressive procedures outlined earlier have prolonged both independent and assisted ambulation for as many as 62 months and 85 months, respectively,[31] in some cases the same protocols and procedures, performed at the same centers, have prolonged ambulation by only a few months.[31,33,35] For these reasons, there have been several attempts to isolate the factors that might predispose a boy with DMD toward successful outcomes during this second functional stage.

Reporting on their 9 years of operation at the Muscle Clinic at Arkansas Children's Hospital, Bowker and Halpin[14] identified both physical and psychosocial considerations in the selection of patients for reambulation procedures. Positive physical considerations included residual balance and the ability to take a few steps at the time of intervention. Negative considerations were periods of nonambulation exceeding 3 to 4 weeks with concomitant joint contracture and disuse atrophy, and an obese body habitus. Beneficial psychosocial considerations were positive family attitude, family stability, and family understanding of the procedures.[14]

In a more critical evaluation of 17 consecutive patients, Ziter and Allsop[35] reported that bilateral Achilles tenotomy followed by orthosis-assisted ambulation was most effective in boys who ambulated independently until at least the age of 10 years, retained residual muscle strength of at least 50%, and did not show certain competing factors, including obesity, mental retardation, prolonged wheelchair confinement, undue family and psychological stress (such as that caused by parental divorce), or poor compliance. In the cases of more rapidly deteriorating patients who lost the ability to ambulate independently before age 9, patients and families were observed to welcome the mobility of a wheelchair over the orthotic treatment.[35]

Citing the attempts of earlier authors as being based on clinical impressions, rather than systematic analysis of data, Vignos et al.[31] used linear and multiple regression to identify the variables most predictive of bracing outcomes among the DMD population. In that study, published in 1983, five variables were identified, including muscle strength, patient motivation, vital capacity, and certain laboratory indicators. The authors then developed a series of equations that would allow the physician to better predict the expected prolongation of ambulation on a case-by-case basis in the clinic setting. Using the values of each of the five variables on a patient-specific basis, such predictions would then facilitate a more informed decision on the part of the patient and his family when considering the expense and time commitment.[31]

SUMMARY

Multiple authors have reported on the ability to extend the ambulatory period of most boys with DMD by an average of approximately 2 years through surgical contracture management and the fitting of bilateral KAFOs. If the number of published reports is reflective of prescription patterns, these techniques achieved their greatest popularity through the 1970s and 1980s, with declining use since then. These interventions should be timed correctly, immediately at or after the loss of independent ambulation. Once surgical intervention has been performed, the rehabilitation of the child must proceed quickly, with standing and/or walking occurring on the first postoperative day. Not all boys with DMD will benefit from these expensive and intense procedures, and factors such as remaining strength, motivation, and residual walking ability should be considered.

STAGE 3: WHEELCHAIR CONFINEMENT

Once weakness progresses to the point where assisted ambulation is no longer possible, the child is confined to a wheelchair. In the absence of standing, flexion contractures of the hips and knees develop quickly. Equinovarus

deformities are also common during this stage[19,20] and can ultimately progress to painful subluxation of the midtarsal joints.[19]From an orthopedic perspective, most attention is now turned to the spine, where scoliosis is often observed.[1,20] With respect to the lower limbs, preservation of joint range at the hip and knee is no longer feasible or necessary, and any interventions are again directed solely at the foot and ankle complex.

In 1984, Williams et al.[19] reported on the surgical elongation of the Achilles tendon as well as divisions of the tibialis posterior, flexor hallucis, and flexor digitorum longus to restore a neutral foot and ankle alignment. After 6 weeks of postoperative short leg casts, nighttime AFOs were provided. The authors reported compliance to be variable such that it was not possible to draw conclusions about the effect of orthoses in reducing the rate or severity of recurrence.[19]

One year later, Hsu and Jackson[45] outlined the appropriate indications for surgical intervention on the feet of nonambulatory patients with neuromuscular disease. These included the prevention of pressure sores and skin breakdown, particularly on the dorsolateral aspects of the feet, pain, the need to obtain a shoeable foot so as to better protect it from the environment, and the need to facilitate a plantigrade foot so that it can rest on the footplate of the wheelchair and provide stability to the legs. They advocated lengthening the Achilles and anterior transfer of the posterior tibialis tendon in such cases. Following the use of postoperative short leg casts, AFOs were provided to prevent recurrence of deformities.[45]

In 2002, Scher and Mubarak[41] reported on a series of five nonambulatory patients who underwent anterior transfer of the posterior tibial tendon and Achilles lengthenings, indicating that orthoses are not necessary following surgery.[41] In contrast, 3 years later, Leitch et al.[46] reported on 30 nonambulatory patients who underwent similar surgical procedures. As with the study of Hsu and Jackson, after 4 to 6 weeks of postoperative short leg casts, AFOs were routinely fitted. Interestingly, among both those who received and those who declined surgical intervention, the authors reported none of the boys wore his AFO routinely.[46] In addition, the authors found no significant differences with respect to shoe wear, pain, hypersensitivity, or cosmesis between those who accepted and those who declined surgical correction of their feet.

SUMMARY

The role of lower limb orthotic intervention during the wheelchair stage of DMD is limited to the foot and ankle. In the instances in which the need for corrective surgery outweighs the operative risks to the patient, some authors have suggested there is value in the use of postoperative nighttime AFOs to prevent recurrence of the deformity. The orthoses must be comfortable to augment patient compliance.

OTHER CONSIDERATIONS

Although not immediately related to orthotic interventions, there are other factors that warrant awareness among the orthotic community, including the increased use of corticosteroids, the elevated risk of fracture within the patient population, and cognitive understanding.

CORTICOSTEROIDS

As early as 1974, reports were published on the use of corticosteroids to alter the natural history of the muscle disease itself.[47,48] These early reports demonstrated initial improvements in muscle strength and function among ambulatory patients[47] and ultimately a less rapid progression of the disease when compared with that in controls.[48] It is beyond the scope and intent of this paper to review the literature that has been produced since these early studies, as has been done elsewhere[49]; however, some general findings should be considered.

Of relevance to the orthotist is the reality that the use of corticosteroids has consistently been demonstrated to alter the natural history of the muscle disease. Independent ambulation has been prolonged with the use of both prednisone[50] and deflazcort.[51] Other benefits have included improved and temporarily sustained muscle strength, motor function, and pulmonary function.[49] Common side effects to these treatments include weight gain and growth suppression.[49]

The role of orthotic intervention in the treatment of patients treated with corticosteroids undoubtedly will be reexamined in light of these alterations. For some patients, sustained muscle integrity may obviate or postpone the need for orthotic interventions. For others, these interventions may prolong stage 1 and stage 2 functions, making careful orthotic prescription increasingly relevant. Either way, practitioners should appreciate that variations to the natural history of the disease process of DMD may be encountered with increasing regularity.

FRACTURES

Fractures are common in boys with DMD, with reports varying from 21% to 67%.[10,52]This has been attributed to skeletal changes, including osteoporosis and decreased build-up of cortices in long and flat bones.[53] In addition, diminished power and motor agility may predispose the child to an increased susceptibility to injury.[10]

Among boys in stages 1 and 3, fractures are reported most frequently in the lower limbs.[10,52] Subjects in stage 2 are more likely to experience upper limb fractures, presumably in their attempts to prevent a straight leg fall using outstretched arms.[10,52]Although concerns have been raised about the risk of falling during this stage of assisted ambulation, published reports indicate that boys are more likely to injure themselves in a fall from a wheelchair than when wearing lower limb orthoses.[4,10,52]

Even in the early stages of the disease, bone density in the proximal femur is considerably diminished,[52] and unsurprisingly, the femur is the most common sight of fracture.[4,10,52]This is particularly common during wheelchair transfers, and caution should always be used when these types of transfers are undertaken.[54]

COGNITIVE UNDERSTANDING

It has been observed that boys with DMD have lower IQ scores than their peers, with a mean value between 80 and 90.[1,34] However, more detailed analyses have revealed that such figures reflect selected deficits in younger boys. Although lower performances in verbal reasoning, verbal processing, and attentional-organizational skills have been observed in younger populations, older children were less likely to present with these shortcomings.[55,56] Accordingly, just as interactions with younger boys should allow for such cognitive deficits, interactions with older boys should avoid condescension.

CONCLUSION

The role of orthotic intervention in the treatment of patients with Duchenne muscular dystrophy is controversial. Considerable variation has characterized its use regionally, locally, and temporally. This article represents an attempt to synthesize available literature as it relates to the orthotic care of these young men. During independent ambulation, interventions generally should be confined to nighttime AFOs in an attempt to slow the progression of equinus contractures. For carefully selected patients treated at experienced centers, independent ambulation may be prolonged through surgical contracture releases, KAFOs and aggressive rehabilitation. Such exhaustive attempts to prolong an assisted stage of ambulation appear to be less common. Once ambulation ceases, lower limb interventions, if indicated, should be confined to the foot and ankle complex in an attempt to maintain any surgical corrections and deter the progression of deformities.

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References:

1. Sussman M. Duchenne muscular dystrophy. *J Am Acad Orthop Surg* 2002;10(2):138–151.

2. Do T. Orthopedic management of the muscular dystrophies. *Curr Opin Pediatr*2002;14(1):50–53.

3. Siegel IM. The management of muscular dystrophy: a clinical review. *Muscle Nerve*1978;1(6):453–460.

4. Brooke MH, Fenichel GM, Griggs RC, et al. Duchenne muscular dystrophy: patterns of clinical progression and defects of supportive therapy. *Neurology* 1989;39(4):475–481.

5. Sutherland DH, Olshen R, Cooper L, et al. The pathomechanics of gait in Duchenne muscular dystrophy. *Dev Med Child Neurol* 1981;23(1):3–22.

6. Hsu JD, Furumasu J. Gait and posture changes in the Duchenne muscular dystrophy child. *Clin Orthop Relat Res* 1993;288: 122–125.

7. Gardner-Medwin D. Management of muscular dystrophy. *Physiotherapy*1977;62(2):46–51.

8. Moosa A. Muscular dystrophy in childhood. *Dev Med Child Neurol* 1974;16:97–111.

9. Read L, Galasko CS. Delay in diagnosing Duchenne muscular dystrophy in orthopaedic clinics. *J Bone Joint Surg Br* 1986;68: 481–482.

10. McDonald CM. Limb contractures in progressive neuromuscular disease and the role of stretching, orthotics, and surgery. *Phys Med Rehabil Clin N Am* 1998;9(1):187–211.

11. Scott OM, Hyde SA, Goddard C, Dubowitz V. Quantitation of muscle function in children: a prospective study in Duchenne muscular dystrophy. *Muscle Nerve*1982;5(4):291–301.

12. Archibald KC, Vignos PJ A study of contractures in muscular dystrophy. *Arch Phys Med Rehabil* 1959;40(4):150–157.

13. Siegel IM. Pathomechanics of stance in Duchenne muscular dystrophy. *Arch Phys Med Rehabil* 1972;53(9):403–406.

14. Bowker JH, Halpin PJ. Factors determining success in reambulation of the child with progressive muscular dystrophy. *Orthop Clin North Am* 1978;9:431–436.

15. Gardner-Medwin D. Controversies about Duchenne muscular dystrophy (2). Bracing for ambulation. *Dev Med Child Neurol* 1979;21(5):659–662.

16. Smith SE, Green NE, Cole RJ, et al. Prolongation of ambulation in children with Duchenne muscular dystrophy by subcutaneous lower limb tenotomy. *J Pediatr Orthop*1993;13(3):336–340.

17. Khodadadeh S, McClelland MR, Patrick JH, et al. Knee moments in Duchenne muscular dystrophy. *Lancet* 1986;2:544–545.

18. Spencer GE, Vignos PJ. Bracing for ambulation in childhood progressive muscular dystrophy. *J Bone Joint Surg Am* 1962; 44:234–242.

19. Williams EA, Read L, Ellis A, et al. The management of equinus deformity in Duchenne muscular dystrophy. *J Bone Joint Surg Br* 1984;66(4):456–450.

20. Dubowitz V. Analysis of neuromuscular disease. *Physiotherapy* 1977;62(2):38–45.

21. Scott OM, Hyde SA, Goddard C, Dubowitz V. Prevention of deformity in Duchenne muscular dystrophy. A prospective study of passive stretching and splintage.*Physiotherapy* 1981;67(6): 177–180.

22. Thompson N, Robb SA. The orthotic management of gait pathology in Duchenne muscular dystrophy. *Physiotherapy* 1995; 81:459–460.

23. Childers MK, Okamura CS, Bogan DJ, et al. Eccentric contraction injury in dystrophic canine muscle. *Arch Phys Med Rehabil* 2002;83(11):1572–1578.

24. Allen DG. Eccentric muscle damage: mechanism of early reduction of force. *Acta Physiol Scand* 2001;171(3):311–319.

25. Edwards RH, Newham DJ, Jones DA, Chapman SJ. Role of mechanical damage in pathogenesis of proximal myopathy in man. *Lancet* 1984;1(8376):548–552.

26. Vignos PJ. Management of musculoskeletal complications in neuromuscular disease: limb contractures and the role of stretching, bracing and surgery. *Phys Med Rehabil: State of the Art Rev* 1988;2:509–536.

27. Fowler WM Jr. Rehabilitation management of muscular dystrophy and related disorders: II. Comprehensive care. *Arch Phys Med Rehabil* 1982;63:322–328.

28. Seeger BR, Caudry DJ, Little JD. Progression of equinus deformity in Duchenne muscular dystrophy. *Arch Phys Med Rehabil* 1985;66(5):286–288.

29. Hyde SA, Filytrup I, Glent S, et al. A randomized comparative study of two methods for controlling Tendo Achilles contractures in Duchenne muscular dystrophy. *Neuromuscul Disord* 2000:10(4-5):257–263.

30. Vignos PJ, Archibald KC. Maintenance of ambulation in childhood muscular dystrophy. J Chron Dis 1960;12:273–290.

31. Vignos PJ, Wagner MB, Kaplan JS, Spencer GE. Predicting success of reambulation in patients with Duchenne muscular dystrophy. *J Bone Joint Surg Am* 1983;65(6):719–728.

32. Spencer GE Orthopedic care of progressive muscular dystrophy. *J Bone Joint Surg Am*1967;49(6):1201–1204.

33. Roy L, Gibson DA. Psuedohypertrophic muscular dystrophy and its surgical management: review of 30 patients. *Can J Surg* 1970;13(1):13–21.

34. Siegel IM, Miller JE, Ray RD. Subcutaneous lower limb tenotomy in the treatment of pseudohypertrophic muscular dystrophy. Description of technique and presentation of twenty-one cases. *J Bone Joint Surg Am* 1968;50(7):1437–1443.

35. Ziter FA, Allsop KG. The value of orthoses for patients with Duchenne muscular dystrophy. *Phys Ther* 1979;59:1361–1365.

36. Siegel IM. Maintenance of ambulation in Duchenne muscular dystrophy. The role of the orthopedic surgeon. *Clin Pediatr* 1980;19(6):383–388.

37. Miller G, Dunn N. An outline of the management and prognosis of Duchenne muscular dystrophy in Western Australia. *Aust Paediatr J* 1982;18(4):277–282.

38. Miller GM, Hsu JD, Hoffer MM, Rentfro R. Posterior tibial transfer: a review of the literature and analysis of 74 procedures. *J Pediatr Orthop* 1982;2:363–370.

39. Heckmatt JZ, Dubowitz V, Hyde SA, et al. Prolongation of walking in Duchenne muscular dystrophy with lightweight orthoses: review of 57 case. *Dev Med Child Neurol*1985;27 (2):149–152.

40. Vignos PJ, Wagner MB, Karlinchak B, Katirji B. Evaluation of a program for long-term treatment of Duchenne muscular dystrophy. Experience at the University Hospitals of Cleveland. *J Bone Joint Surg Am* 1996;78(12):1844–1852.

41. Scher DM, Mubarak SJ. Surgical prevention of foot deformity in patients with Duchenne muscular dystrophy. *J Pediatr Orthop* 2002;22(3):384–391.

42. Green NE. The orthopaedic care of children with muscular dystrophy. *Instr Course Lect*1988;37:267–274.

43. Aicardi J. The future of clinical child neurology. *J Child Neurol* 1987;2:152–159.

44. Rodillo EB, Fernandez-Bermejo E, Heckmatt JZ, Dubowitz V. Prevention of rapidly progressive scoliosis in Duchenne muscular dystrophy by prolongation of walking with orthoses. *J Child Neurol* 1988;3:269–274.

45. Hsu JD, Jackson R. Treatment of symptomatic foot and ankle deformities in the nonambulatory neuromuscular patient. *Foot Ankle* 1985;5(5):238–244.

46. Leitch KK, Raza N, Biggar D, et al. Should foot surgery be performed for children with Duchenne muscular dystrophy? *J Pediatr Orthop* 2005;25(1):95–97.

47. Drachman DB, Toyka KV, Myer E. Prednisone in Duchenne muscular dystrophy. *Lancet*1974;2:1409–1412.

48. Siegel IM, Miller JE, Ray RD. Failure of corticosteroid in the treatment of Duchenne (pseudohypertrophic) muscular dystrophy: report of a clinically matched three year double-blind study. *Ill Med J* 1974;145:32–36.

49. Wong BL, Christopher C. Corticosteroids in Duchenne muscular dystrophy: a reappraisal. *J Child Neurol* 2002;17(3):183–190.

50. DeSilva S, Drachman DB, Mellits D. Prednisone treatment in Duchenne muscular dystrophy: long term benefit. *Arch Neurol* 1987;44:818–822.

51. Angelini C, Pegoraro E, Turella E. Deflazacort in Duchenne dystrophy: study of long-term effect. *Muscle Nerve* 1994;17: 386–391.

52. Larson CM, Henderson RC. Bone mineral density and fractures in boys with Duchenne muscular dystrophy. *J Pediatr Orthop* 2000;20:71–74.

53. Hsu JD Skeletal changes in children with neuromuscular disorders. In: Alan R, ed. Factors and Mechanisms Influence Bone Growth. New York: Liss; 1982;553–557.

54. Gray B, Hsu JD, Furumasu J. Fractures caused by falling from a wheelchair in patients with neuromuscular disease. *Dev Med Child Neurol* 1992;34:589–592.

55. Cotton SM, Voudouris NJ, Greenwood KM. Association between intellectual functioning and age in children and young adults with Duchenne muscular dystrophy: further results from a meta-analysis. *Dev Med Child Neurol* 2005;47(4):257–265.

56. Sollee ND, Latham EE, Kindlon DJ, Bresnan MJ. Neuropsychological impairment in Duchenne muscular dystrophy. *J Clin Exp Neuropsychol* 1985;7(5):486–496.

Bibliography

1. Pompe, B., and V. Antolič. "Slotted Acetabular Augmentation for the Treatment of Residual Hip Dysplasia in Adults: Early Results of 12 Patients." *Archives of Orthopaedic and Trauma Surgery* 127.8 (2007): 719-23.
2. Carlson JD, Trombly CA. The effect of wrist immobilization on performance of the Jebsen Hand Function Test. *Am J Occup Ther* 1983;37:167–165.
3. Fess EE, Gettle KS, Philips CA, Janson JR, eds. *Hand and Upper Extremity Splinting: Principles and Methods.* 3rd ed. St. Louis, MO: Elsevier/Mosby; 2005.
4. McIntyre, C.P.O., Charles A. "Treatment Of Pediatric Shoulder Subluxation And Paralysis A Case Study." *Journal of Proceedings* (2007).
5. Bos, Renate P.M.J., Joke H. Grady, Pieter A.M. Vierhout, and Jaap De Vries. "A Comparison of Two Custom-Made and Two Off-the-shelf Rigid Knee Orthoses in the Treatment of ACL-Deficient Knees." *JPO Journal of Prosthetics and Orthotics* 9.1 (1997): 25-32
6. Fawcett, Jennifer. "The Best Spinal Orthosis: Deciding Factors." *Best of Resident Directed Studies*.
7. Hoppenfeld S. *Physical Examination of the Spine and Extremities.* Norwalk, CT: Appleton & Lange; 1976.
8. Lubahn JD, Hood JM. Fractures of the distal interphalangeal joint. *Clin Orthop* 1996; 327: 12–20.
9. Soreff J, Axdorph G, Bylund P, Odeen I, Olerud S. Treatment of patients with unstable fractures of the thoracic and lumbar spine: a follow-up study of surgical and conservative treatment. Acta Orthop Scand 1982;53:369–81
10. Yasukawa A, Kahn L, Forney M, Schmit B, Gaebler-Spira D. Measuring change of function in upper extremity use in children with CNS dysfunction. *Dev Med & Child Neurology* 2001; Abstracts 43:6.
11. Zhang S, Wortley M, Clowers K, Krusenklaus JH. Evaluation of efficacy and 3D kinematic characteristics of cervical orthoses. Clin Biomech (Bristol, Avon) 2005;20:264–9
12. Glickel SZ, Barron OA. Proximal interphalangeal joint fracture dislocations. *Hand Clinics* 2000; 16(3): 333–344.
13. Bearden BG , Conrad BP, Horodyski M, and Rechtine GR. "Supplemental Content."*National Center for Biotechnology Information*. U.S. National Library of Medicine. Web. 01 Mar. 2012. http://www.ncbi.nlm.nih.gov/pubmed/17688055 behavior. J Rehabil Res Dev. 1998;35(1):34–42.
14. Palumbo, P.M., "Dynamic Patellar Brace: A New Orthosis in the Management of Patellofemoral Disorders," American Journal of Sports Medicine, 9:1, 1981, pp. 45-49.
15. Clark GL *et al. Hand Rehabilitation*. New York: Churchill Livingstone, 1998: 143–149, 358.
16. Gavin TM, Carandang G, Havey R, Flanagan P, Ghanayem A, Patwardhan AG. Biomechanical analysis of cervical orthoses in flexion and extension: a comparison of cervical collars and cervical thoracic orthoses. J Rehabil Res Dev 2003;40:527–37

17. Adams BD, Grosland NM, Murphy DM, McCullough M. Impact of impaired wrist motion on hand and upper extremity performance. *J Hand Surg* 2003;28A:898 – 903.
18. Pratt, D.J. "Three-dimensional Electrogoniometric Study of Selected Knee Orthoses." *Clinical Biomechanics* 6.2 (1991): 67-72.
19. S. Fishman, N. Berger, J.E. Edelstein and W.P. Springer, Spinal orthoses, in: Atlas of Orthotics, Biomechanical Principles and Application, W.H. Bunch et al., eds, American Academy of Orthopaedic Surgeons, The C.V. Mosby Company, 1985:238–256
20. "Using a Philadelphia collar after spinal cord injury." *CareNotes*. Thomson Healthcare, Inc., 2011. *Health Reference Center Academic*. Web. 1 Mar. 2012.
21. Cawley, P. W., E. P. France, and L. E. Paulos. "The Current State of Functional Knee Bracing Research: A Review of the Literature." *The American Journal of Sports Medicine* 19.3 (1991): 226-33.
22. Beynnon BD, Pope MH, et al. The effect of functional knee braces on strain on the anterior cruciate ligament in vivo. JBJS 1992;74A:9:1298-1312.
23. Stern EB. Stability of the Jebsen-Taylor Hand Function Test across three test sessions. *Am J Occup Ther* 1992;46:647– 649.

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Dear Sir or Madame:

RE: Off-the-Shelf HCPCS Codes Posted February 10, 2012

We write on behalf of our client, the American Orthotic and Prosthetic Association (AOPA) with respect to the proposed list of OTS HCPCS codes posted by the Centers for Medicare & Medicaid Services ("CMS") on February 10, 2012 at http://www.cms.gov/DMEPOSFeeSched/04_OTS_Orthotics.asp. AOPA has asked us to address the legal issues related to CMS' proposed list of OTS Orthotics, as part of it comprehensive submission of comments to CMS.

As an initial matter, we urge CMS to revisit its regulatory definition of "minimal self-adjustment" upon which the current list of OTS orthotics is based. Respectfully, we submit that the regulatory definition departs materially — both as a legal matter, *and* as a therapeutic matter — from the plain words of the statute.

Only "off-the-shelf" ("OTS") orthotics are required to be competitively bid, for obvious reasons: if an orthotic is custom made, or needs to be fitted by someone other than the Medicare beneficiary patient, there can be no commonality to the items being competitively bid. For that reason, Congress defined OTS orthotics to include only orthotics that require "minimal *self*-adjustment." 42 U.S.C. § 1395w-3(a)(2)(C) (emphasis added). To the extent that CMS's proposed HCPCS list includes items for competitive bidding that may require adjustment by *someone other than the person using the orthotics*, the listing is inconsistent with statutory guidelines. We assume the listing is based on CMS's regulatory definition of "minimal self-adjustment":

> an adjustment that the beneficiary, *caretaker for the beneficiary, or supplier of the device can perform* and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and

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> Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training (emphasis supplied).

42 C.F.R. § 414.402 (adopted at 72 Fed. Reg. 17992 (Apr. 10, 2007))(emphasis supplied).

This definition should be modified to incorporate the plain meaning of the statute, which applies competitive bidding only to orthotics actually adjustable by the user himself or herself.

Definition of Self-Adjustment

Under the plain language of the statute, OTS orthotics require "minimal self-adjustment." CMS's definition of self-adjustment simply doesn't make sense; it allows people other than the person using the orthotics to adjust it. But, by no dictionary definition could *self*-adjustment include adjustment by a caretaker or other person. See, *e.g.* Oxford English Dictionary (2d. ed.) (defining "self" as "indicat[ing] emphatically that the reference is to the person ... mentioned and not, or not merely, to some other."); Webster's II New Riverside Dictionary 614-15 (defining prefix "self-" as "oneself" and noun "self" as "[t]he essential being of one person as distinct from any other.").

Construing "self" to mean "self plus others" also violates common canons of interpretation. *First*, statutes should be read "as to avoid rendering superfluous" statutory language. *Astoria Federal Savings & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991). Had Congress intended to allow any untrained person to adjust an orthotic, it could simply have written "minimal adjustment." *Second*, undefined terms in a statute are ordinarily "construe[d] ... in accordance with [their] ordinary and natural meaning." *FDIC v. Meyer*, 510 U.S. 471, 476 (1994). And as discussed above, the term "self" is far from ambiguous. *Finally*, where Congress intends "self" to refer to others besides the actor, it knows how to say it. *E.g.*, 8 U.S.C. §1101(a)(51) (defining "VAWA self-petitioner" to mean "an alien, or a child of the alien ...").

Textually, CMS's definition of minimal self-adjustment does further damage to the statutory scheme by essentially carving out device suppliers as non-specialists. Rather, one would think that if a DMEPOS supplier is necessary to ensure that the device is properly adjusted, the device requires "an individual who has specialized training." Ultimately, this change, though subtle, could reduce patient quality of service by replacing qualified, trained professionals with low-bid company employees and contractors who may not be up to the task. The competitive bidding program focuses on providing products at the lowest cost. It does not require adjustment services.

Practical Effects of Expanding Self-Adjustment, and Thus Competitive Bidding, to Include Adjustment by Caretakers

To our knowledge, CMS has not studied the profound effects of requiring orthotics to be competitively bid where such orthotics cannot be adjusted by the user. If CMS insists on its

existing definition, we urge that it withhold from finalizing those orthotics deemed to be OTS until it studies the impact on the Medicare population. AOPA is submitting a comprehensive list of those orthotics it believes should be reclassified or withheld pending study.

Consider the following scenario: An elderly gentleman, living alone, requires an arm brace. He also has arthritis in his hands or shoulder, and therefore is unable to self-adjust the brace as necessary to fit it on his arm properly. Under the OTS orthotic description currently in the regulations, that man would still have to obtain his arm brace from a competitive bidding supplier because "a caretaker for the beneficiary or supplier of the device" *could* perform the adjustment. But, just because a theoretical beneficiary or supplier could do so, that does not mean, as a practical matter, that each Medicare recipient in need has someone willing to help. Further, to our knowledge, CMS is not proposing that an OTS supplier offer fitting assistance services as a precondition to being a "responsive and responsible bidder". How then can a Medicare beneficiary who cannot himself or herself adjust a needed orthotic be placed in the same position as one who is able to obtain that assistance for free? Either the Medicare beneficiary can adjust the orthotic without another person's assistance or not. One can "self-adjust"; one cannot.

The distinction between *minimal self-adjustment* and *minimal adjustment* is not trivial. For instance, in some cases, self-adjustment is possible because an improper alignment would produce slight pain or discomfort, alerting the user that the device was not properly aligned. But under the Medicare regulatory definition, in cases where the orthotics user has a caretaker because he is mentally challenged, this safeguard in adjustment may not occur—i.e., the mentally challenged user might be unable to express pain, or understand the discomfort is not intended, and therefore may not warn the caretaker that the device has been adjusted improperly. The result might be serious damage but at very least, it is poor medicine and not something Medicare should promote. But, if that person were to receive the orthotic from an orthotic specialist, not a DMEPOS low-bid supplier who has no requirement to provide adjustment assistance, the advanced training would prevent the incorrect adjustment.

We can see no role for supplier adjustment that is compatible with the statutory terminology "minimal self-adjustment." We believe the same result applies to the inclusion of caretaker adjustment, although we could concede an equitable argument for including the same in those instances where a caretaker were actually available. But, as noted, this would require further extensive study by of circumstances noted above, before the agency could legitimately undertake any bidding efforts premised on such an expansion of the definition beyond the crystal clear language of the statute.

Other questions, too, remain unanswered: (1) How large is the Medicare population that lives alone and is personally unable to *self*-adjust as the regulation contemplates?; (2) In the absence of an ability actually to *self*-adjust, what mechanisms exist to ensure that the orthotics-wearer will not continue to wear an improperly fitting orthotic to his or her detriment?; (3) What financial effect will the expansion of the definition of OTS orthotic beyond Congress's intended meaning have? Perhaps a better question is whether CMS anticipates savings by expanding the definition of "minimal self-adjustment" adjustment to mean "self-adjustment-with-a-little-help-from-our-friends" which will justify the anticipated degradation in care for those Medicare

beneficiaries not so fortunate. At the least, CMS should study and consider the long- and short-term effects of its expansion beyond its statutory mandate.

Conclusion

The inclusion in the definition of "minimal self-adjustment" and, thus, the definition of OTS orthotics, those orthotics that the Medicare beneficiary cannot adjust on his or her own could reduce the quality of orthotics to a significant portion of Medicare beneficiaries. CMS should limit the definition of "minimal self-adjustment" to adjustment that the beneficiary can perform by himself or herself. At the very least, CMS should undertake a study to answer the questions posed in this letter.