

# ORTHOPÄDIE TECHNIK

O&P · REHABILITATION · HOME HEALTH CARE

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Quarterly

## Calendar

**September 29 – October 2, 2010**  
AOPA National Assembly, Rosen Shingle Creek Resort, Orlando, FL, USA.  
Info: [www.aopanet.org](http://www.aopanet.org)

**September 30 – October 2, 2010**  
Orto Pro Care 2010, Trade Fair for Orthopedic Technical Aids and Professional Care, IFEMA Recinto Ferial Juan Carlos I, Madrid, Spain.  
Info: [www.orto-procare.com](http://www.orto-procare.com)

**October 19-22, 2010**  
Medical Fair, Brno, Czech Republic.  
Info: [www.bvv.cz/hospimedica-gb](http://www.bvv.cz/hospimedica-gb)

**October 27-29, 2010**  
People & Health, 15th Russian National Congress, St. Petersburg, Russia.  
Contact: [ph@peterlink.ru](mailto:ph@peterlink.ru)

**November 4-6, 2010**  
20th Argentinian Rehabilitation Congress, SAMFYR, Mar del Plata, Argentina.  
Info: [www.samfyr.org](http://www.samfyr.org)

**November 6-8, 2010**  
China International Rehabilitation and Special Equipment Expo, Nanchang, China.  
Info: [www.crda.com.cn](http://www.crda.com.cn)

## Imprint

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## CP

J. R. Fisk

## Cerebral Palsy – A Global Perspective

### Literature Review

The literature review was not an arduous task. It is almost non-existent. I found four clinically based papers, fewer epidemiological papers and none having to do with orthotic management. I enlisted the reference librarians at my medical school library and they assured me that they went to non-standard sources.

According to Msall and Hogan, four million of the 130 million infants born each year around the world die during the first four weeks of life. Major associations with these early deaths include preterm birth, severe infections, and asphyxia, which in aggregate contribute to 80 per cent of these deaths. They note that the historic assumption has been that if one sequentially applies advances in preventive health, then the presence of child disability will be substantially reduced. In the preschool years, this has happened with reduction of motor disability from polio and cerebral palsy from iodine deficiency; and other infectious diseases from vaccination. In low income countries in south Asia and sub-Saharan Africa, 200 million children under five years of



age fail to reach their cognitive potential because of poverty, poor health and nutrition and the sub-optimal home environment.

The current knowledge on child disability in low-income (less than \$875 gross national income) and middle-income countries (\$875-\$3465 gross national income) is woefully inadequate. Two diseases causing an increase in childhood encephalitis and resultant upper motor neuron dysfunction about which there is some data are HIV-AIDS and Malaria. In 2006, the



estimated number of children younger than 15 years infected with AIDS was 2.3 million. In Zimbabwe 150 per cent of children, in as much as many have two infections, contract Malaria.

Cerebral palsy is five to ten times more common in poorer countries. Disorders of the nervous system account for at least 15 per cent of the global burden of disease and at least 27 per cent of average years lived with disability. These numbers refer only to disorders that arise within the brain. If we add the impact of the many conditions that damage the brain as part of their overall effect such as noted previously, the numbers become much larger approaching 30 per cent of the global burden of disease (6). Brain health and disease may be the best overall indicator of a nation's success in promoting health.

It is often noted that the majority of related causes for cerebral palsy in developed countries is idiopathic. The incidence of CP in very low birth weight children is consistent at 7.7 per cent for children born at less than 1000 grams. Most of the identified pathologies in these children are periventricular leukomalacia and proencephaly. Increased survival rates as a result of improved neonatal

intensive care units have not increased the numbers of children thus affected. In a study from Soweto similar findings have been reported. Survivability was increased from 24 per cent to 66 per cent for children under 1500 grams. They did not have sufficient respirator facilities for children under 1000 grams. Similar survival figures in the United States between 1960 and 1983 rose from 43 per cent to 85 per cent. Rates for cerebral palsy in both populations remained similar.

Hagberg reported that „the prevalence

of cerebral palsy in preterms is no longer increasing, in spite of additional improvements in survival“. In a similar manner, Fanaroff et al., reporting on prospective observations from twelve US centers, in 1995 concluded that the increase in survival of very-low-birth-weight infants seen after the introduction of surfactant therapy in the 1080's „was not accompanied by an increase in medical morbidity.“

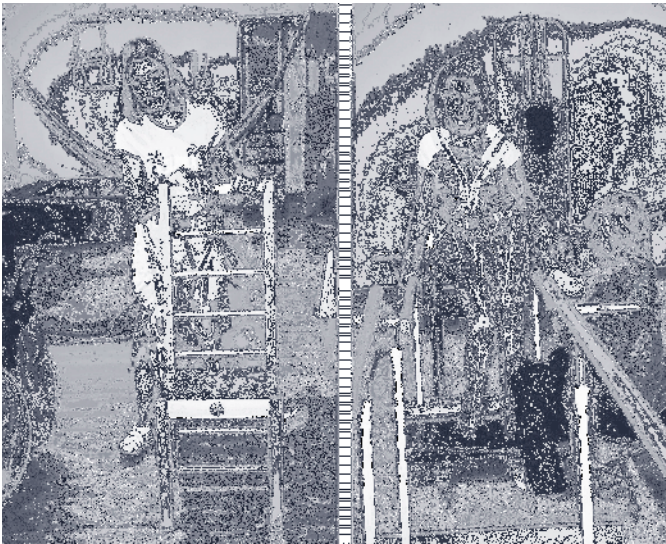
Over all global rates of Cerebral Palsy are between two and three per 1000 life births. Although these figures are not available in low income countries there is data on the types of involvement in children with spasticity. Ozmen reported from Turkey that the types encountered according to Hagberg's categorization were similar to developed countries. My own unscientific observations in

southern Asia and sub-Saharan Africa is that there are more dyskenitic types perhaps from untreated ABO incompatibility and resultant kernicterus.

In a clinical study, M.A. Khan reported in 2007 on 85 children treated with single event multiple site surgery. He referenced the suggestions of Eugene Bleck and later of R.S. Paine that a child having spastic diplegia if unable to walk by age seven or eight probably would not walk. Reporting on his work done in Karachi, Pakistan he noted that there is a difference between western nations and his own. The children that the earlier authors were working with received treatment from the age of diagnosis. Khan's patients on the other had presented on average at age 8.5 years. He was able to affect ambulation in all 85 who had not been walking at the time of presentation. 18 (21.2 per cent) attained exercise ambulation, 39 (45.9 per cent) attained household ambulation and 28 (33 per cent) attained community ambulation.

This literature review illustrates the need for improved data but more importantly the desire to identify problems unique to low income countries. As we send our foreign students back to their





home countries we must encourage them to repeat many of the studies performed in our high income countries in their low and middle income countries.

## Survey Results

Early in 2008 a brief questionnaire was sent to a number of treatment facilities in low income countries. The address list of ISPO which consists of all the certified P&O schools, non certified schools and their related workshops was used. The same questioner was also sent to all of the International Committee of the Red Cross P&O workshops. Seven questions were submitted for response. They dealt with requests for data on population incidence, numbers of patients served, types of services and needs for improved services.

Responses were received from eighteen low income countries and twenty-five work treatment facilities. Very few ISPO associated centers responded where as most ICRC workshops sent in their information.

### Question 1: Do you have any data on the incidence of cerebral palsy in your region?

Fourteen facilities reported that no data is kept. One country kept records but would not release it to the public.

### Question 2: Do you provide services to persons having cerebral palsy?

Twenty reported that they do, but that most are very limited.

### Question 3: Which services do

so that they can construct them at home.

### Question 4: What volume of services for CP are you or your facility providing?

Few had any data. One clinic said they saw as many 135 children with CP per month. One clinic fit 168 orthoses in 2007.

### Question 5: What age range are you patients/clients?

Most said all of their CP patients were children, some worked with adults.

### Question 6: What is your ability to address the level of need in your region?

„The ability will be defined according to the parents' attitude to CP and with reference to social stigma which is a problem in my region. It is imperative that the disabled view themselves as functional beings and it is critical that parents do not shy away from seeking professional help for their child.“

There are insufficient personnel to do home visits. Unrealistic expectations of families lead to discouragement. In Kashmir there are only two facilities for 12 million people. There is need for better awareness.

### you or your facility provide?

Physical therapy 16, Orthotics 11, Surgery 5. One said that since „CP is not correctable so they did not provide services“. Another facility said they have examples of equipment available for families to see

### Question 7: What are your needs, what are you lacking to provide services?

There are needs in all areas, infrastructure, manpower, therapy equipment, social workers, CBR, education, transportation, and food. „Lacking is specific training in the care of persons with CP for physicians and therapists.“ Lacking is trust to dispel stigma and money for home services.

One country acknowledged little interest or willingness in the care of people with cerebral palsy.

## Conclusion

With a paucity of scientific literature concerning the adequacy of services for the care of persons with cerebral palsy in low and middle income countries few recommendations on best practices can be made. The World Health Organization

Task Force on Medical Rehabilitation Guidelines met in Geneva in October of 2005. One of the clear recommendations coming from that session was the need for accurate country by country data on the incidence and types of disabilities as a starting point in stimulating local governmental organizations to address service needs. Few Ministries of Health will act without identified needs and top down guidelines.

All of you who have had the privilege to work in low income countries as I have know of the inadequacy of the orthotic services seen there. The fabricator is rarely a consultant and only a technician.



Materials are clumsy. Design is with poor biomechanical understanding and there is very poor understanding of cerebral palsy as a clinical entity. Most of the time treatment is aimed at deformity rather than function.

This paper has attempted to identify available resources on these issues. Clearly they are lacking. A nonscientific survey was added as a means of reporting on some current available services. The primary conclusion that can be drawn from it is that the needs are great. There is need of infrastruc-

ture, education, and public awareness. All of these take money. The most concerning need however was the expressed need for a societal change in attitude to overcome stigma of cerebral palsy for specific and disabled persons in general. We must not lose sight of the goal for this workshop as we consider the medical needs of persons with cerebral palsy, the importance of inclusion of those persons in their society as a whole.

#### **WHO Definition of Disability**

*„Any limitation in performing*

*tasks, activities and roles to levels expected within physical and social context“*

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**This – abridged – article is only an excerpt from the ISPO conference report on CP which can be downloaded for free from [www.ispoint.org](http://www.ispoint.org)**

## Prosthetics

G. Stark

# Clinical Classes of Gel Liners

**Flexible gel liners are currently regarded as the predominant suspension choice for a majority of lower limb prostheses, because they serve multiple purposes such as suspension, shear relief, and cushioning. These needs become especially important at the boundary layer between the interface and the skin, where the sensate limb meets the solid surface of the prosthesis. Historically wool socks, polyethylene foam, urethane foam rubber, silicone, and a variety of other materials have been used to increase load and shear comfort at the skin boundary layer. Gel liners, introduced in the mid 1990's, have been largely successful in accomplishing these various goals and are evolving into various clinical classes based on Material Type, Softness, Construction Matrix, Surface Matching, and Suspension.**

## Clinical need for Comfort

In a often referenced study by Board, Street, and Caspers on vacuum assisted suspension, a total of 528 skin problems were documented from 337 lower extremity limbs. The primary conditions included

ulcers, irritations, cysts, calluses, and verrucous hyperplasia, accounting for 79.5% of the skin disorders. [3] A 2001 study by Ehde, Czerniecki, and Smith surveyed 255 amputees and 74% had residual limb pain with a mean intensity of 5.4 on a 10 point scale. 60% of patients described the pain as being “moderately to severely bothersome”. [6] These repetitive high-magnitude loads are directly related to the shear at the boundary later at the instant of heel strike. Klute in a 2001 paper on shock absorbing pylons relates this rapid deceleration as a high frequency “shock wave” detected in spectral analysis above a frequency of 50Hz. The overall stiffness of the prosthesis is typically arranged in series with the foot providing the dynamic spring, shock absorber acting to dampen impulse load, and the interface material against the skin. The mechanical vibrational system is said to be in series since they are placed in line from most distal to proximal. As Gard notes, a series vibrational system is only as stiff as the softest member which is not the shock absorber, but the soft gel interface. [8] This translates to a large amount of shear and load still being placed at the boundary layer

with the reduces surface area of the residual limb. In a 2008 review by Mc Kenzie, Bosker, and Walden, a survey was done of approximately 1,200 transtibial casts. The average limb was 14 cm long, 31 cm in circumference at MTP and 21 cm in circumference 25 mm proximal to the distal end. [1] This translates into roughly 335 square centimeters of surface area. If total surface bearing was applied this would be about 174 mm-Hg of pressure just in simple loading. [1] Pressures within the interface may be higher than those found at the distal end of the interface. Biel measured these pressure values in 2002 from 31mm-Hg to 89mm-Hg. [1] Arjon Buis, Ph.D. at the University of Strathclyde, Scotland has also mapped these pressure points when comparing standard PTB style sockets with hydrostatic methods during walking. [9] The peak loads of hydrostatic method is concentrated at the fibular head and distal tibial whereas peak load on the PTB are visually more broadly identified. [9] According to the Rogers and Wilson tissue tolerance curve, skin can tolerate high loads of 100 mm-Hg, but only for short periods of time. [10] Pressures as low as 30mm-Hg can produce tissue breakdown in access of 10

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hours. As mentioned by Carlson the presence of shear forces greatly limit the amount of force the skin can tolerate. A reduction of the coefficient of friction by 30% results in triple the amount of load cycles that the skin can tolerate. [11] Anecdotally this shear relief may be one reason fleshy patients experience relief with gel liners even though they have ample subcutaneous padding.

## Evolution of Gel liners

Alleviating friction and load magnitude is nothing new. Wool socks were the first type of cushioning material and provided a modicum of cushioning and shear relief. Kemblo a foam rubber material was paneled on the exterior of a leather liner to provide increased cushioning, but did not conform to shape. Michigan Gel was a PVC gel made in a cookie jar in the late 1960's, was the first gel type material to create cushioning and flow, but had to be sandwiched in a leather liner as well because it had little structural properties. [14] In 1986 Ossur Kristinsson with Bo Klasson developed the ICEROSS system which originally utilized a flexible urethane interface, then later a thin silicone liner. [14] Carlton Fillauer, inspired by Kristinsson's method, developed the 3-S custom liner system in 1987 using a custom laminated silicone, but it was intended for suspension only with no cushioning. [14] Carl Caspers introduced the use of a thicker custom urethane liner that could flow to increase cushion and shear properties with vacuum attachment in 1992. [14] Silicone sheaths and fitting socks with gel sandwiched in between also provided added cushion and shear in the early 90's. Although many prosthetic manufacturers knew of the properties of thermoplastic elastomer it was not viable as a prosthetic interface material because it stretched and tore so easily. With the application of an elastic fabric to the elastomer in the 1994, gel liners became a possibility. [14] Since then a dozens of liners have evolved using different reinforcements and materials evolved to the variety of designs we have presently. While the diversity of designs brings with it many

alternatives, it also can be difficult to choose the best one or compare the range of designs. Liners have differentiated themselves into different clinical design classes based on a variety of factors including: Material Type, Softness, Construction Matrix, Suspension Type, and Degree of Surface Matching. Using these as comparative subsets may be beneficial when making a recommendation.

## Material Types

Liners have developed with three main types of elastic materials: Urethane, Silicone and Thermoplastic Elastomer (TPE) each with different advantages and disadvantages due to different manufacturers formulations.

Urethane elastomer is essentially a man-made form of rubber with a high degree toughness and abrasion resistance. It is usually a simple two-part mixture that does not require injection molding and can be made inexpensively, although air bubbles frequently result in these low-cost slush molds. It has excellent flow characteristics and resists packing out even under a high number of loading cycles so it can be made thinner. It is a thermoset with significant cross-linking so it cannot be reformed nor will it deform. Thermosets will burn at high temperatures and thermoplastics melt due to the presence of cross-linking. However it has a higher density and it is heavier than water with a specific gravity of 1.05-1.25. Urethanes typically discolor and can degrade when exposed to sunlight. Urethanes for prosthetic liners vary in durometer from the mid-30s to the low-50s on the Shore 00 scale. [11]

Silicone rubber is also a thermoset, as are most elastomers, and has even greater elasticity than Urethane although it may not flow as easily. Silicones are more expensive due to their longer cure times and material costs. A two-part material, silicone is extremely sensitive to reactant proportions including water or latex gloves. Once reacted is very elastic and impervious to water or UV damage. Silicones have a less dense specific gravity at .95-1.2, but need to be made thicker because of poor notch sensitivity and tear resis-

tance. Silicones come two main types: Tin catalyst (Condensation cure) and Platinum catalyst (Addition cure). Tin cure included many of the early off-the-shelf liners. Tin cure silicone are basic two part silicones that are less expensive, easier to mix, and have less odor. Tin cure silicones usually have a shorter life span, lose elasticity, and become toughed after 2-4 years. There is slight shrinkage during the manufacturing process. Platinum cure silicones are used in most custom or thick gel-type liners. The curing is internalized, fully cures after 10 minutes, and is only affected by temperature with no shrinkage. Also Platinum cure produces less volatiles or by-products, which can irritate the skin surface. Platinum cured silicones preserve their elasticity, but require attention to proportions to avoid contamination such as latex gloves. Silicone liners have excellent memory and usually have a durometer ranging from the low-30s to mid-40s, but can go to the high-40s to low-50s on the Shore 00 scale. [1]

Thermoplastic elastomer or (TPE) combines the advantages thermoforming like a thermoplastic with the cushion and resiliency of urethane. TPE exhibits elements of an elastomer with thermoplastic binding in a SBS block structure. SBS or styrene-butadiene-styrene creates a structure with butadiene "blocks" in a microscopic cross-linked nanostructure linked by polystyrene clusters linked in a covalent thermoplastic structure. The polystyrene acts as microscopic crosslinks that can be loosened and broken with heat, but reform during cooling. This allows the material to be stretched twice its original length repeatedly and return to the original shape. TPE can be formed in a semi liquid state with high-pressure injection molds and the cross-linking will reform. Although TPE's require very little compounding, they are relatively expensive due to the molding process when compared to urethanes. Being a thermoplastic, TPE can be reformed to a shape using moderate temperature but has the tendency of thinning more than urethane with repeated loading. TPE can be made extremely soft and can be made softer with the addition of skin friendly soft-

ening oils such as mineral oil soften the material further. TPE can be extremely soft from the mid 20s to low 30's on the shore 00 scale. [1] The original use of TPE for prosthetic liners is said to have come from a prosthetic wearer who melted fishing lure worms into a socket shape after being impressed with its softness.

The type of material utilized depends on a variety of factors desired including perceived softness, durability, expense, and thermoformability. The best materials absorb load and shear with little thinning. During normal gait, silicones and urethanes show very similar properties with TPE displacing slightly more. Convery utilized relatively high force loads of 550N to achieve a greater separation material performance with urethane exhibiting the greatest load and shear absorption properties with minimal thinning. However these load forces would primarily be found in high activity athletic activities, which would be 8 times higher than normal ambulation. [1,2]

## Different Softness Measures

With the range and formulation of material design, liners can vary greatly even within the same family of material. Softness is measured in durometer with different scales originally developed by Albert Shore in the 1920's. An instrument called a durometer measures a material's resistance to permanent indentation using a specific presser "foot" and load (Durometer is used with polymers, elastomers, and rubbers whereas Brinell, Rockwell, and Vickers scales are used for metal toughness). There are several scales most notably for prosthetic liners shore A, 0, and 00. The while liner materials can be measured in the Shore A scale, shore 0 and 00 scales are more sensitive to the softest of materials. Human skin is 20 Shore A which would be similar to a very tough "dummy" liner used for fabrication. Chewing gum is softer so it would be a 15 Shore 00. TPE liners would have a 4 Shore A, but the test is really not as sensitive as it should be so the 00 scale is used to have a more accu-

rate 28 Shore 00 value. Softness is can be typically correlated to durability, but not necessarily to thermoformability. Materials that are softer typically have less shear resistance and poor notch sensitivity meaning they tear more easily. TPE for example has a very low durometer, and was not a viable product until it could be reinforced with fabric. Silicone and urethane can be very soft, but because they are thermosets, they will not thermoform even when subjected to heat and pressure.

## Construction Matrix

The construction matrix has historically been the design challenge for elastomeric liner construction. In fact the liner gels have been in existence for some time, but the construction matrix is what makes liners practical. It is the construction matrix that is so valuable and the primary subject of most of the patent protection with liner designs. The Michigan gel material, advanced for its time in 1969, required a traditional material, leather, to provide the construction matrix to hold it together. Ossur Kristinsson's original liner was a supple urethane, but it ripped and tore easily so he needed to develop a silicone liner with an internal matrix. Carlton Fillauer, saw promise Kristinsson's flexible liner system and also improved on the urethane design in a different direction with a custom laminated silicone and nylon stockinette. [12] The addition of elastic external fabric to TPE made off-the-shelf gel liners possible. In a sense all of these designs can be considered a composite or hybrid of materials with flexible interface material proximally and a more structural element distally to bind the interface and provide support for the distal attachment. The matrix was also necessary to limit the periodic distal distraction or "milking sensation" that occurred when the elastic only material was used. The matrix of can be constructed of any fiber nylon, fabric, or polymer mesh and can be external or internal but needs to eliminate longitudinal stretch. This reinforcement does have a rounding effect to the limb shape can be placed at the distal 1/3 where there is less physio-

logic shape. Internal matrices are difficult to manage during the molding process to prevent wrinkles. They must be made in two layers or fixtured in the mold to prevent buckling or wrinkling. An internal fabric matrix has the issue of silicone delaminating and providing a porous surface for bacterial growth. External matrices can be glued to the liner or heat melded to prevent delaminating. These can consist of fabrics with differing amounts of elasticity or composition. Usually stiffer urethane or plastic distal ends are utilized to attach the pin ends. This process of attaching the distal end takes considerable design effort and cost due to the localized load. Some liner designs attempted to eliminate this attachment option to produce a less expensive device, but this excluded too many possible wearers.

## Surface Matching

There was a disadvantage to the addition of fabric matrices; they changed the shape of the liner to a more rounded generic shape. The more stiff the matrix type the greater the affect to the liner and socket shape. The residual limb with its triangular shape would be become more rounded. This was also required by the material, especially TPE, which could not tolerate high localized loading. To insure long term wear, Total Surface Bearing had to be employed to load the entire limb equally even over prominences. This is different than the "Hydrostatic" methods first described by Robin Redhead that advocated elongation to encourage overall circumferential tension. The original proponents of elastic interfaces, notably Bo Klasson and others, spoke of the need for surface matching. [13] This is why the elasticity of the liner was so important to conform to the overall surfaces. With thicker gel liners, especially urethane, material flow became the key to create relief for bony prominences. Without surface matching or material flow, rounded generic shapes actually increase pressure on prominent areas rather than equalize them. Since the bony areas are of much greater density, the ring tension applies greater surface load. Klasson said this was

inversely proportional to the radius of the interface or up to five times more pressure. [13] Fortunately the softness of the material counteracts this affect. Comfort can be achieved with surface matching even with relatively firm surfaces such as arch supports. For example when standing on thick TPE the metatarsal heads and heel feel most of the load instead of the arch, because there is insufficient flow around the bony prominences. It is interesting to consider that musculoskeletal contouring is considered novel in the transtibial brim shape, but outdated for the transtibial interface. In reality most practitioners produce a hybrid design with incorporates more general surface bearing with relief for the fibular head and distal tibia.

## Suspension Method

Suspension type greatly influences liner construction, classification, and choice. Distal pin attachment greatly affects liner construction and volumetric control. This is a result from the pin distracting the liner during stance, which decreases distal circumference and volume. With minimal or no matrix the patient can feel the "milking" sensation of increased distal end suction and shear. Among athletes this can be accentuated during high activity motion, but not as readily apparent to one-speed geriatric ambulators. Distal attachment also increases the localized load on the liner itself, which can result distal material break down and the pin attachment pulling free. Pin attachment is not restricted to a distal pin and can utilize proximally placed pins. The largest difficulty comes in the donning of the device where the patient has circumferential tension applied to the proximal liner. The user must have sufficient balance of forces within the interface to maintain limb position, but so much that they can easily push the pin into the catch distally. If the patient has a fleshy limb or redundant tissue they may not have sufficient substructure to push the limb distal enough to achieve suspension especially in circumferential tension. In these cases a lanyard or pin

guide is required to position and help distract the liner to achieve locking.

Vacuum systems eliminate the need for a distal pin and rely suction fit of the liner to the interface. They can be classified as passive or active in nature. Passive suction can be used in conjunction with pin attachment and involves the use of a passive check valve and proximal seal. The suction is possible to accomplish with cushion gel liners that advocate total surface bearing techniques of a 5-10% reduction in circumference. Active suction uses an electric pump or the secondary action of a distal shock absorber to actively extract air. Board, Street, and Caspers examined volume control comparing passive and active vacuum systems at the University of St. Cloud in 2001 and found that after 30 minutes of walking there was on average -6.5% loss of volume ranging from -1.7 % to -11.3% using a passive check valve. Active vacuum assisted devices provided an average gain of volume from 3.7% ranging from -1.6% to 8.0%.<sup>3</sup> With either system the fit of the prosthesis and the amount of tension applied is crucial. If there is a change of volume or shape the suspension may be compromised. The material must have sufficient flow over the characteristic limb shape and the interface is made more cylindrically to make vacuum possible. Too many contours would create channels where air could re-enter the system during motion. Another disadvantage is the increased limb bulk of the liner interface and proximal seal. This has the affect of increasing proximal limb bulk over 20mm medial and lateral and circumferences over 120mm (using a 9mm liner, 3mm plastic interface, 5mm laminated frame, 6mm suspension liner). This large bulk can also limit motion and increase overall maintenance costs of liner and suspension sleeves. The benefit of vacuum to wound healing and skin condition was analyzed by the University of Texas Health Sciences center measuring transcutaneous skin condition (TcPO<sub>2</sub>) and skin condition continues to be debated. A patient was observed to a change from 40mm-Hg to 50mm-Hg. [1]

Another form of liner adapted

for vacuum suspension uses a flexible silicone baffle that seals itself against the socket wall not proximally where motion occurs, but distally where motion is minimal. This simple suspension that grew from hypobaric socks and membranes, involves relatively few parts and benefits from less proximal limb bulk. The main disadvantage is that the membrane must be accommodated in the socket and spacer socks must also be split.

## Liner Recommendation

Using the main criteria of Material Type, Softness, Construction Matrix, Suspension Type, and Degree of Surface Matching can be utilized to advocate the best liner choice. One of the first determinations is the main type of suspension distal pin or vacuum. This often leads to the construction matrix based on durability needs of the distal attachment. Characteristic limb shape is addressed with greater surface matching and less stiff construction matrix. On the durability scale Urethane may be the most durable for loading and shear with Silicone and TPE behind. TPE is typically the most soft with Silicone and Urethane only slightly harder. Urethane and Silicone can be custom made so surface matching is greatest among these custom devices. Off the shelf TPE may be contoured under slight heat and pressure, but the external matrix prevents dramatic shape contours. Finally the liner should match the suspension choice. Pin locking provides distal locking without proximal bulk, but can be difficult to find the insertion and may place excessive shear on the distal limb. Passive vacuum avoids distal distraction and shear, but depends on the stabilized volume of the prosthesis. Active vacuum increases the ability to expel air and may achieve the quasi-hydrostatic support Robin Redhead suggest years ago, but involves another system the must be maintained.

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## Stroke

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# Clinical and Gait Analysis Data on the Shoulder Orthosis "OmoNeurexa"

First Clinical and Gait Analysis Data on the Shoulder Orthosis OmoNeurexa for the Prevention and Treatment of a Painful Shoulder After Stroke

This article describes first clinical and gait analysis data on the orthosis OmoNeurexa, a new shoulder orthosis to prevent and treat a painful shoulder (PS) after stroke. A shoulder brace of soft material connects to a forearm cuff to promote elbow extension and supination. Out of 13 subjects, ten patients used the device continuously for four weeks and three put the orthosis off within three days (too tight, no effect anticipated, fear of

flexor spasticity). The comfort was good, transpiration minimal, and seven patients reported a beneficial effect of the orthosis on their activities, e.g. they felt more secure during transfer tasks and mobility. Five patients reported a relevant pain reduction. Gait analysis revealed a more dynamic gait pattern reflected by a significant reduction of the relative double stance phase. Furthermore the paretic quadriceps muscle was facilitated during

the initial stance phase in selected patients. The therapists reported that they could intensify their functional therapy approach in seven subjects. The shoulder subluxation decreased, spasticity of the initially plegic patients only slightly increased, and the shoulder range of motion did not change. The orthosis is an interesting component in the prevention and treatment of PS after stroke, controlled trials are justified.

## Introduction

Stroke is the most frequent cause of permanent impairment in the industrialized world. In Germany, the annual incidence of stroke is approx. 180 patients per 100,000 people. A painful shoulder (PS) occurs in about 15 to 40 percent of patients in early rehabilitation [8]. It is associated with an unfavorable and longer period of rehabilitation.

Several factors are discussed in the etiopathogenesis. For example, PS is correlated in particular with subluxation of the humeral head, the underlying causal paresis of the shoulder region, spasticity, and limited shoulder movement [10]. The distinction between the flaccid and spastic form has proven helpful; the former is more frequent in early rehabilitation and is generally associated with extreme weakness of the shoulder girdle, subluxation, and resulting injuries to the soft tissues [6, 9]. These injuries occur in particular when the paretic arm is lifted without protection; the lack of movement of the scapula causes the humeral head to strike the acromion. This results in microtraumas causing, inflammation of soft tissues, and bursitis which are by today's understanding a major factor in the pathogenesis of the flaccid form of PS [1].

Correct shoulder handling, administration of non-steroidal pain medication, physical therapy including ultrasound, less frequently electrostimulation [7], and in recent times injections of botulinum toxin A into the subscapularis and pectoral muscles [5, 12] have proven to be effective therapy for PS. Although many shoulder orthoses are available, they have not been widely used. All orthoses share a common goal of recentering the humeral head through traction and/or reducing the weight of the arm (one twelfth of body weight) in the event of subluxation. Another aspect is protecting the paretic arm from abrupt movements during walking. Arguments against prescribing a shoulder orthosis are that it promotes a flexed position of the forearm, risks limiting shoulder movement, is impractical to use, does not fit well,

is uncomfortable to wear on bare skin, and may cause an unpleasant odor.

In this situation, the author's team collaborated with Otto Bock with the intent to design a new orthosis and test it in an initial pilot study in early rehabilitation of patients with severe flaccid paresis of the shoulder girdle. An instrumented gait analysis was conducted with and without the orthosis to examine the effect the orthosis had on gait pattern and muscle activation while walking.

## The Orthosis

The shoulder orthosis weighing approx. 300 g comes in five sizes and for either shoulder (Fig. 1) and consists of a shoulder section with a belt that fits under the contralateral armpit. The belt can be adjusted in the front and back with Velcro fasteners. The second part of the orthosis is a forearm cuff that also has Velcro fasteners. The two

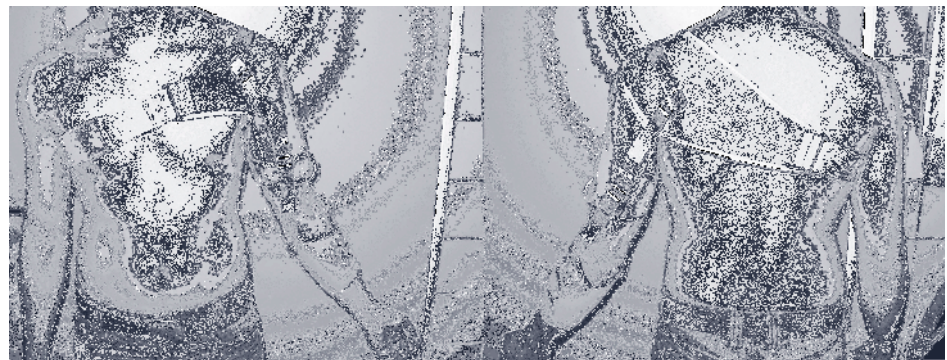


Fig. 1 OmoNeurexa shoulder orthosis

adjustable straps connecting the two parts have different colored snaps to avoid mix-ups.

The orthosis is made of a soft, supple material. All parts that could slip on bare skin are lined with a one-cm strip of silicone. The snaps embedded in the soft Velcro fasteners are padded on the body side to prevent pressure sores points on bare skin. The outer edges of the orthosis are trimmed with soft bias tape and are very elastic. A webbing strap stitched onto the orthosis provides the desired fit and necessary stability.

Nine photographs with written instructions show how the shoulder orthosis is put on. The orthosis is worn on bare skin. After the proper size is selected (based on the

circumference of the thorax under the armpits) the shoulder part is put on so that it lies smoothly over the shoulder joint. Next the axilla underarm strap is fastened either from the front or the back and adjusted if necessary to ensure a proper fit. The perspiration protection must fit under the armpit. The forearm cuff is closed in such a manner that the olecranon is not covered and circulation is not restricted. In the next step, the two parts are connected so that the forearm is slightly supinated and extended. Finally, the fit is optimized once again in a standing position. The orthosis is taken off at night.

## Patients of the Pilot Study

Thirteen hemiparetic patients participated in the pilot study (ten men, three women, mean age  $61.7 \pm 12$  years, six patients with hemi-

paresis on the right and seven on the left, mean interval since stroke before the orthosis was prescribed was  $8.3 \pm 3.8$  weeks, height  $173.5 \pm 11.4$  cm, and weight  $75.8 \pm 9.1$  kg), who fulfilled the following criteria:

- First-time stroke with treatment in inpatient early rehabilitation,
- Non-functioning paretic upper extremity,
- Mobilized in wheelchair, stance and gait already practiced in therapy,
- Able to give verbal or written information in a short interview,
- No major impairment of pain sensory perception in the affected upper extremity,
- Consent given to participation in the study.

## The patient was fitted with an orthosis if

- He or she complained of shoulder pain on his own,
- The team reported on shoulder pain,
- There were clear clinical signs of subluxation (more than one finger width).

At the time they were included in the study, ten of the thirteen patients complained spontaneously of shoulder pain and the team of

- Shoulder pain (impairment dimension)
- Use of the arm for daily activities, participation in physical therapy, competence in activities of daily life, and mobility in the clinic (activities dimension)
- Mood and social contacts (participation dimension)

The patient could respond to each question with "clearly worse" (-2), "worse" (-1), "unchanged" (0), "somewhat better" (1), or "clearly better" (2).

(Fig. 2). Passive shoulder movement deteriorated for only one patient and improved for three patients. The MRC strength grades of the shoulder-elbow musculature showed increased shoulder strength for three out of ten patients (by one point in two cases and two points in one case) and increased elbow muscle strength for four of ten patients. Four patients developed flexor spasticity in the elbow with the Ashworth score increased by one (two cases), two, and three points respectively;

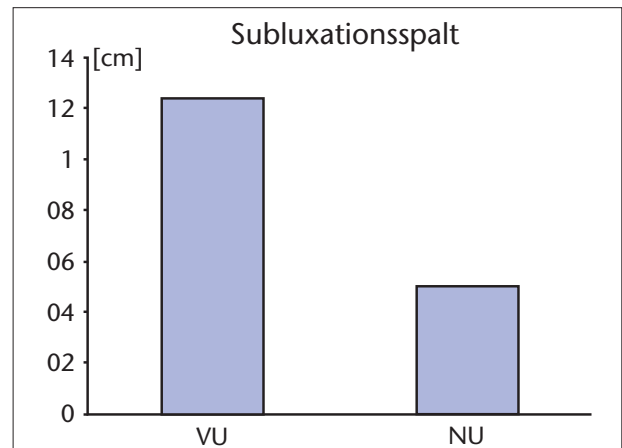
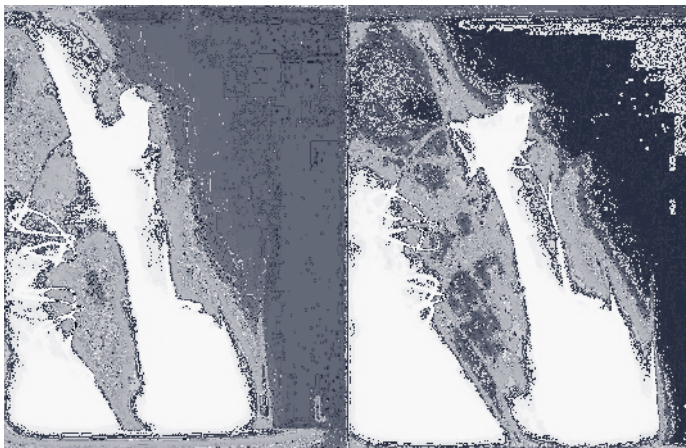


Fig. 2 X-ray images of a subluxated shoulder; a) without the shoulder orthosis (left) and b) with shoulder orthosis (center). Note the large gap between the socket and the humeral head in the left image and the improved position of the humeral head with the shoulder orthosis (center). The diagram shows the average size of the subluxation gap at the beginning and end of the study in centimeters.

physicians and therapists described three cases of acute shoulder pain.

## Dependent Variables of the Pilot Study

An experienced examiner determined the size of the shoulder luxation, the passive range of motion using the Fugl-Meyer Score (Fugl Meyer 1975), and the proximal strength and tone of the upper extremity. With the help of the MRC strength scores (zero to five: 0 = plegia, 5 = full strength), shoulder elevation and abduction and elbow flexion and extension were measured and resistance to passive elbow flexion and extension was tested using a modified Ashworth score (zero to five, 0 = no increase in muscle tone, 5 = rigid). The examinations were made before daily use of the orthosis and four weeks afterwards. The patients assessed the effect of the orthosis in a "patient-reported outcome" with respect to

Patients and therapists were also requested to assess the wearing comfort and potential unpleasant odor. An X-ray of the shoulder with and without the orthosis was made for one patient.

## Results of the Pilot Study

Three out of thirteen patients discontinued use of the orthosis prematurely. The reasons given were unfulfilled expectations (one patient), feeling of constriction (one patient), and the fear, conveyed by the therapist, of developing flexor spasticity. All three patients discontinued use of the orthosis within the first three days.

The other ten patients all assessed wearing comfort as good with minimal odor build-up. The demonstration X-ray images showed that subluxation was reduced; in seven patients, the joint space was reduced by an average of 2.5 cm during the four-week intervention

for each of three patients it decreased by one point.

The patients assessed the orthosis as follows:

- Five patients each described shoulder pain as reduced or unchanged,
- Use of the arm in everyday activities: better for seven, unchanged for three,
- Participation in physical therapy: better for six, unchanged for three, worse for one
- Mobility in everyday activities: better for six, unchanged for four,
- Performing activities of daily life: better for five, unchanged for five,
- Participation and mood: better for three, unchanged for seven.

## Instrumented Gait Analysis

In addition, a gait analysis [3] was performed for all ten patients,



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with and without the orthosis. The Infotronic system was used. It

consists of overshoes in the proper sizes; by means of contact switches embedded in the soles, cycle parameters, stance, swing, and double stance periods are measured separately for each side. The data are saved in a portable data logger. The ten-meter test was used to determine the basal cycle parameters, namely speed, cadence, and step length. The dynamic electromyogram of selected leg muscles on the paretic side (tibialis anterior, gastrocnemius, vastus medialis, vastus lateralis, gluteus medius, and erector spinae muscles)

was recorded from superficial electrodes applied to the body of the muscle following proper cleansing of the skin, pre-amplified, and then also saved in the data logger. The patient walked with and without the orthosis for 30 seconds each, and then the data were transmitted to a computer for further analysis. The cycle parameters for each side were then standardized to the gait cycle (100 percent), symmetry quotients were calculated for the stance

and swing phase periods using the formula: stance (swing) right/stance (swing) left times 100 if the right was less than the left side, otherwise vice versa. The EMG data were rectified, standardized to the gait cycle and filtered. An experienced examiner analyzed the envelope curves determined in this manner quantitatively with respect to amplitude and qualitatively with respect to the pattern.

## Results of the Gait Analysis

There was no difference in the basal cycle parameters between the two conditions; there was a tendency toward a greater step length and lower cadence with the orthosis. With the orthosis, the relative double stance phase was significantly shorter (-17 percent on average,  $p < 0.05$ ), while the relative stance and swing periods of both sides as

well as the symmetry quotients were not significantly different. The analysis of the dynamic EMGs did not yield a uniform result; in four of the ten patients, there was more pronounced activity of the quadriceps femoris muscle, which also commenced earlier in swing phase (Fig. 3).

## Discussion

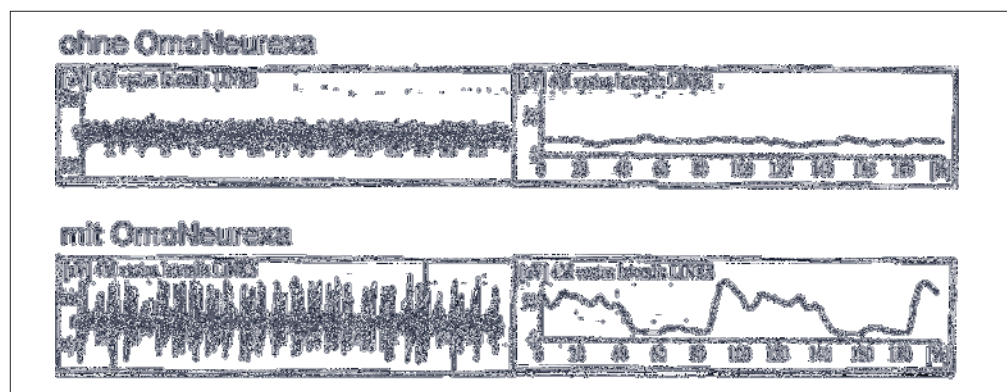
The orthosis proved to be practicable in the clinical setting – fit and wearing comfort were good and there was minimal unpleasant odor from the orthosis worn on the bare

spasticity; passive resistance against extension of the elbow increased slightly in four patients and was even reduced in three patients.

This result must be viewed in the context that acute patients were initially flaccid and thus the development of varying degrees of flexor spasticity would not be unusual.

The specifications of this orthosis recommend extension and supination of the elbow to prevent the development of flexor spasticity.

Aside from one patient, there was no indication of limitation of passive shoulder movement. On



**Fig. 3** The EMG standardized to the gait cycle (left, raw EMG; right, envelope curve) of the paretic vastus lateralis muscle of a left hemiplegic patient without and with the orthosis. Note the increased activity and the earlier onset of the knee extensor in the stance phase (zero to 60 percent of the gait cycle) on the affected side. The finding is consistent with facilitation of the muscle.

skin. No side effects such as chafing or allergies occurred.

The clinical routine quickly showed that ongoing training of the therapy team, especially of nursing personnel, was indispensable for ensuring the desired functionality of the orthosis.

Initially, the most frequent mistakes were loose fit, incorrectly fastened straps, and wearing the orthosis over clothing. It proved to be practicable for therapy that the separate forearm cuff could be taken off quickly, allowing unrestricted mobilization of the upper extremity.

Three patients had discontinued use of the orthosis prematurely – one patient due to a feeling of constriction, one patient did not consider it to be useful after only two days, and one patient, after discussing with his therapist, feared developing flexor spasticity in his elbow.

However, the studies did not justify the fear of developing flexor

the contrary, it was even improved in three patients, certainly the result of multi-professional, inpatient rehabilitation.

The X-ray confirmed that the orthosis when worn properly partially repositioned the humeral head, as previously described by Zorowitz et al. for four different models (including Bobath roll, mitra, and a comparable orthosis) [13].

The joint space was narrowed in seven of ten patients during the four-week intervention. Of course, the aim of therapy was to strengthen the shoulder girdle, but the MRC strength scores documented the known moderate regression of strength in the paretic upper extremity when severe paresis has occurred [2, 4]. Only three patients had minimal improvement of their voluntary shoulder strength, so that it can be assumed that the orthosis contributed to narrowing the joint space.

One important aim of the development of the shoulder orthosis was to reduce shoulder pain, but this was achieved for only half of the patients. However, subjective perception of pain is affected by many factors.

For some patients, fitting was carried out in the phase of uncritical euphoria (everything will be just fine) that is known to occur after brain damage. But the assessment was made four weeks later in a phase in which the patient becomes increasingly aware of the risk of permanent impairment, leading to negative views. This is most likely the reason that a Cochrane meta-analysis also reached the conclusion that no shoulder orthosis was completely convincing with respect to reduction of shoulder pain in controlled studies [7].

On the one hand, this result is an argument against the use of shoulder orthoses only for treating shoulder pain in stroke patients. On the other hand it could be seen as proof that determining pain in this patient group is a difficult task, dependent on many variables.

The patients gave a more positive assessment of the effect of the orthosis on the level of activity. When asked, the patients said that the affected arm was secured and held close to the body by the orthosis, making it lighter so that they were better able to concentrate on gait rehabilitation. They said that made walking safer, as already shown by Yavuzer and Ergin for a simple mitra-shaped device [11]. The present results of the gait analysis showed that patients had a more dynamic gait with the orthosis. The relative duration of the double-stance period was significantly reduced and the patients' steps also tended to become longer, both of which can be assessed as signs of greater gait safety.

At the same time, some patients were apparently able to put more weight on the paretic leg. Unfortunately, ground reaction forces were not measured, but indirect indications were that there was earlier and greater activation of the quadriceps muscle on the paretic side in the initial stance phase. The muscle secures weight transfer in this phase; the results are consis-

tent with the facilitation of the paretic quadriceps muscle by the orthosis.

In summary, the newly developed shoulder orthosis is an interesting component in the prevention and therapy of painful shoulder in severely paretic patients in multi-professional early rehabilitation.

Provided that the nursing staff is given extensive training, good fit, a high level of wearing comfort, and minimal amount of unpleasant odor can be ensured. The open study indicates that the orthosis reduces subluxation and promotes restoration of activity. The results of the gait analysis are consistent with a more safe and dynamic gait; there was also facilitation of the knee extensor on the affected side in some selected patients. A controlled study is indicated.

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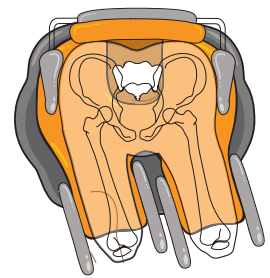
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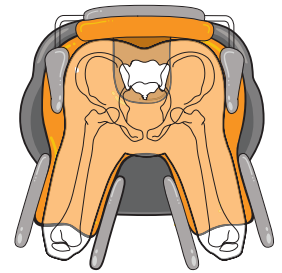


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