ORTHOPÄDIE TECHNIK
O&P · REHABILITATION · HOME HEALTHCARE
English Edition
Quarterly

Editorial

The Publishing House Orthopädie-Technik proudly presents its first English edition. Orthopädie-Technik *Quarterly* contains technical articles that have previously been published in the German Orthopädie-Technik and contributions of international interest. It does not only go back to the desire of our readers for an English edition, but also pays tribute to the fact that the world is rapidly growing together and it has become crucial to think in global terms.
We have kept the layout plain and simple in favour of the content: prosthetic management, dynamic orthotics, standards in O&P, rehabilitation and international co-operation. Please browse through and let us know what you think!

B. Wiegard

Imprint
Published by Bundesinnungsverband für Orthopädie-Technik / Verlag Orthopädie-Technik
Reinoldistr. 7-9
44135 Dortmund, **Germany**
Tel.: +49 (0)231 / 55 70 50-50
Fax: +49 (0)231 / 55 70 50-70
E-mail: wiegard@ot-forum.de
Edited by Beate Wiegard, Dirk Böcker
Published quarterly providing articles from Orthopädie-Technik, German edition,

http://www.ot-forum.de

Co-operation

H. Halbwachs

Orthopaedic Technology in German Technical Co-operation

What is it about?

According to WHO (World Health Organisation) estimations the percentage of physically disabled people who need prosthetics or, more often, orthotics is 0.8% of the total population. In conflict or post-conflict areas this proportion may even be higher. The causes are congenital diseases, malnutrition, infections, bone diseases, violence and war (mines!) and increasingly work and traffic accidents as well as diseases of old age.

In most developing countries there is an enormous backlog with regard to the care of physically disabled. Public health services are, as a rule, entirely overtaxed with this issue so that there is neither systematic early diagnosis nor orthopaedic care. There are either no institutions for orthopaedic care or if skilled staff do exist, they are concentrated in a few larger cities. In addition, most of the patients have enormous difficulties in paying for the manufacture of suitable prosthetic, orthotic or other devices. Especially in the big cities where family relationships are less able to endure social burdens than in rural areas, handicapped people often live a miserable life as beggars.

Grotesquely, there are some regions (especially post-conflict regions) where the problem is oversupply with prostheses. This is due to the financial structure of many NGOs (Non-Governmental Organisations) which puts them under pressure to present prompt success. The donors want to be sure that as many physically disabled as possible are served. Unfortunately, as a result, important aspects of priority setting or the adequacy of the quality get lost. Thus war victims are often treated with preference to the "conventional" disabilities, though the latter normally represent the majority.

Compared to important diseases such as tuberculosis, malaria or

Contents

respiratory diseases the care of physically disabled is rated as being of second rank because of the high cost involved. There are, however, indications that appropriate care is not more expensive than the losses in terms of income, the burden for the families etc.

A special problem is the care of women in some social contexts. The possibilities of health personnel with regard to (inevitable) body contact can be drastically restricted (Purdah), the shortage of female skilled staff being an aggravating factor. On the other hand, however, much is to be learned from many Islamic societies, because they have a remarkably positive attitude towards disabled people.

What does GTZ do?

GTZ (Gesellschaft für Technische Zusammenarbeit) supports projects in dealing with the development of service structures and the training of skilled workers in orthopaedic technology and works in close collaboration with the responsible government authorities, but also with national and international NGOs.

Essential activity areas are:

- Development of appropriate care strategies and guidelines
- Training of orthopaedic technicians
- Standardisation of orthopaedic technology devices (quality norms)
- Development of prosthetic and orthotic care units including private providers
- Development of suitable financing systems
- Counselling of health institutions
- Co-operation in international committees dealing with aspects relating to content and health policy for the care of physically disabled

GTZ has working experience in countries like Angola, Armenia, China, El Salvador, Jordan, Pakistan, Togo, Tunisia, Turkey and Vietnam.

How does GTZ work?

In orthopaedic technology the same common criteria apply as in technical co-operation overall, for example help toward self-help, involvement of target groups, minimum intervention in the structures of the partner organisation and sustainability. Predominantly, we apply the method of providing consultancy wherever possible to all of a country's institutions and individuals involved in orthopaedic technology. Our task is not, therefore, to deal with the care of the physically disabled ourselves or to promote individual service units, but rather our commission is to assist the development of suitable systems that can be applied country-wide.

The training of orthopaedic technicians follows the same logic. With this aim in view we support the establishment of technical colleges or courses of studies in already existing institutions. The training courses are for the most part oriented towards the training category II as proposed by the ISPO (International Society for Prosthetics & Orthotics). This category occupies an intermediate position between theory and practical requirements. Besides sound theoretical and detailed knowledge, the practical skills are imparted that are necessary for the manufacturing of orthotics and prosthetics and other orthopaedic devices. In addition, the technicians receive intensive clinical training in order to exercise how to deal with patients and to be able to manufacture individual appliances and give follow-up assistance.

In its co-operation with other organisations GTZ deals predominantly with the aspects of health and training policy for the care of physically disabled. By harmonising concepts, we participate in the system design process and promote the development of modern strategies in partner countries. On the occasion of an international conference in Wuhan/China in November 1996 the respective principles were jointly formulated in the "Wuhan Declaration".

As a rule, the polypropylene technique as developed by the International Red Cross is chosen as an adapted and appropriate technology approach. More sophisticated techniques, however, are not entirely pushed into the background so that services are still in a position to satisfy the demand of better-off patients. The higher income thus created serves to support the orthopaedic care of poorer patients.

Projects normally work with one to two long-term experts and several short-term expert missions to address special topics. In addition, considerable means for training and further education (specialised teachers, health planners) are available in most cases. Inputs for the development of educational establishments and pilot workshops are made available according to the situation. As a rule, all project work is taken over entirely by the partner after 8 to 12 years.

What type of project do we support?

At present we are participating in 7 orthopaedic projects.

Angola

When the co-operation project started in 1997 it was the first GTZ-supported measure in Angola. As there is a lot to catch up on in the way of orthopaedic care, much room is given to advisory services to the Ministry of Health in close harmonisation with the NGOs working in the country. At the same time, the establishment of an orthopaedic referral centre in Luanda is being promoted where, in addition, national orthopaedic technicians receive further training.

China

In 1992 first in Wuhan and then in 1998 in Beijing the Chinese Centre for Orthopaedic Training (CHICOT) was established. In the meantime, approximately 15 male and female orthopaedic technicians graduate from the school every year (ISPO category II) and start to work at state-run or private production sites. In the meantime, the training centre has become responsible for the certification of skilled orthopaedic workers of the lower level. Besides, greater importance is being given to entrepreneurial con-

sultancy. This generates considerable additional income for CHICOT and which is indispensable for the training activities.

El Salvador

In this project the efforts towards the development of a coherent policy for the physically disabled are well advanced. ISRI (Instituto Salvadoreño de Rehabilitación de los Inválidos), for example, the national authority for physically disabled which is responsible for the project implementation, has in the meantime developed mechanisms which oblige the national and international NGOs to work on the basis of joint concepts with regard to appropriate technologies and price structure. In co-operation with the Catholic University Don Bosco, ISRI trains orthopaedic technicians according to ISPO category II.

Morocco

The project was started in 1999. GTZ's role is to assist in organising a training course for orthopaedic technicians according to ISPO standards in Marrakech. The national partners are the Ministry of Health, a local organisation "Association Le Grand Atlas" and the medical faculty of the University of Marrakech which is presently being built-up. As of 2004 the Moroccan partner is to assume complete responsibility for the training course.

Nigeria

This project, rather atypical for GTZ, has been supporting an orthopaedic clinic (NOHE, National Orthopaedic Hospital Enugu) which, however, being a regional reference centre and training hospital is of central importance for the federal state of Enugu. The predominant task is to improve hospital management including its maintenance and the orthopaedic workshop.

Supraregional

Since 1998 GTZ has been working together with the WHO Disability & Rehabilitation Unit in Geneva on the development of a concept aiming to bring both orthopaedic technology and the care of the physically disabled into the focus of public health. In developing countries at the present time, this field is more or less entirely left to national and international relief organisations and there is little co-ordination. Therefore the project addresses target groups such as health politicians and planners in developing countries but also relief organisations. Within the frame of this measure it is planned to create a database through case studies (for example in El Salvador) which will make it possible to determine the economic losses caused by inadequate care.

Vietnam

In Vietnam a co-operation project was started in 1994. The prime objective is the organisation of a training course according to ISPO category II. In addition, the Ministry of Social Affairs is provided with advisory services on extending the service structures in orthopaedic technology. In the meantime, contacts have been made with the Ministry of Health. This is a sign of successful work in a country where co-operation among the authorities is still in the building up process.

What kind of challenges do we have to face?

Health problems and disproportionate population growth in many developing countries become even more urgent in an era when the industrialised countries are also having to fight against the economic effects of globalisation. This situation means that less resources are being made available for development aid. The sectors that suffer from the consequences are those in the health system (such as the care of the physically disabled) that traditionally were and are the domain of charitable organisations.

GTZ has therefore to ensure that the issue of physical disability is brought into the focus of health politicians and planners. The promoters of "health for all", especially the international community of experts in Public Health, need to deal with the ethical, medical, and health economic (see also co-operation with WHO) effects of physical disabilities in developing countries. Not least the economic aspect should be a strong enough motive to systematically pursue the topic and to comprehend that the care of handicapped people is a task of public health policy. It does not suffice to consider Community Based Rehabilitation (CBR) as the only potential solution as such. Additional measures could be considered, for example:

- Introduction of elements of the care of the physically disabled into the district health system, development of respective referral structures
- Introduction of theoretical and practical curricula into the basic training of physicians and nursing staff.
- Introduction of CAD/CAM technology for long-distance P&O services (minimising social costs for the patients).
- More targeted involvement of private providers in the frame of the piloting function for example of health insurance systems.

The collaboration with WHO with regard to the convergence of physically disabled policy and health policy is forward-looking. Besides the dialogue with the respective technical colleges attempts will be made to integrate orthopaedic technology into those projects that contribute to the national health sector reform. An approach in this direction is being prepared

in form of an orthopaedic regional project in Central America. It is planned to closely collaborate with other organisations with other health projects in implementing all measures of structural development and policy advisory services.

The conclusion is that the gap between resources and needs will grow in the coming years. Orthopaedic technology must therefore move out of its "sectoral corner" and approach the conceptual lines of action of the health sector reform. With this objective in mind, CBR is an important contribution which will, however, lead to an effective strategy only if it is combined with an integrated approach in orthopaedic care.

The author:

Hans Halbwachs
GTZ GmbH
Postfach 5180
65726 Eschborn
Germany

Prosthetics

M. Piro

Possibilities in Fabrication of Sockets for Below-Knee Prostheses

In the manufacture of below-knee prostheses, two areas have to be differentiated or examined independently. These areas are the socket as the embedding of the stump and functional components, e.g. the prosthetic foot and further modular components.

It is not an easy job to differentiate in importance between the prosthetic socket and functional components. Therefore a highly functional foot cannot work well for a BK amputee with an ill fitting prosthetic socket. On the other hand, it is impossible for the BK amputee to convert his dynamic abilities and energy into a well fitting socket which is coupled with components of minimal function, for example the SACH foot, which will restrict his range of action. In order to succeed in prosthetic fitting, both components are of equal importance and significance (Fig. 1).

Obviously, regarding the history of prosthetic fitting, prosthetic fabrication has changed according to new materials and technologies.

Materials like wood, leather and steel were used during the years after the Second World War.

Fig. 1 *Functional components in connection with a well fitting socket have to suit the needs of the BK amputee.*

Together with modular component systems there has been a change within the technical field in the selection of materials for socket fabrication to polymer plastics, silicone or other materials based on gel. These materials have also changed fabrication technologies.

In addition to higher demands for less weight, higher stability and greater durability of the new materials on the one hand, there have also been at the same time higher demands by individuals, for example, for better prosthetic fit; and therefore towards technical fabrication on the other hand. At this point in the orthopedic technical field the classification of age, activity and individual demands of prosthetic users have become an issue. But above all the different requirements, expectations and handicaps, there is this one principle: the socket has to fit.

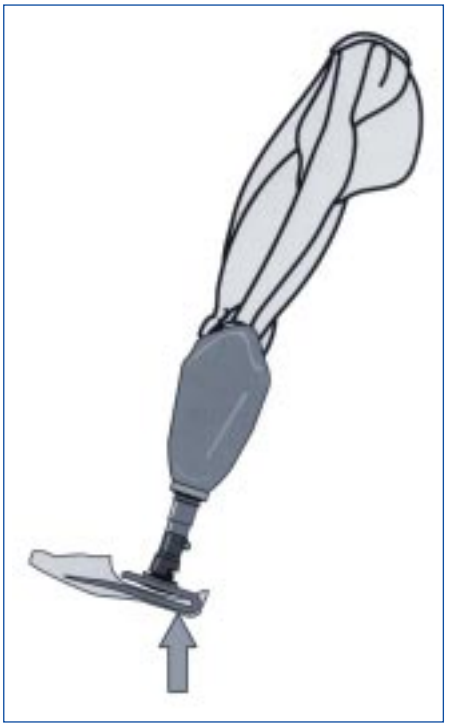


Fig. 2 *The socket is responsible for body weight containment during stance phase and for transferring the forces through the components into the ground.*

As a result it is possible for the individuals to wear the prosthesis without pain and most effectively. Because of individual demands, the different purposes of prosthetic fit, and the differentiation of medical indication, we have to ask the question: which prosthetic socket is the correct or best one for the individual? The biomechanical viewpoint of the two basic functions of the prosthetic socket are, in spite of different demands, still the same.

Stance phase

During stance phase the prosthetic socket has to transfer body weight into the functional components and the floor. For the prosthetic user there has to be a guarantee of a stabilized heel strike and easy rollover of the prosthetic foot. (Fig. 2)

Fig. 3 *This gives an example of the connection between a silicone socket and the residual limb.*

Swing phase

During swing phase the prosthetic socket has the responsibility of maintaining a reliable connection to the residual limb. The suspension has to prevent the prosthesis from working itself loose from the residual limb during swing. (Fig. 3)

The demands of biomechanics and providers lead to the following questions:

- What materials are needed for socket fabrication?
- What are the indications for shape and design of the modified mold?
- How will the prosthesis be suspended from the body?

Fig. 4 *Material generation 1: Moldflex-Inliner, prefab softsockets*

Choice of material

Going back again into the history of prosthetics we can see that for a long time the pelite soft socket was the first and only choice. And even today it is a good choice when quick and effective modifications have to be considered.

These considerations are especially demanded for first fitting. Because of rising costs and short hospitalization, prefab sockets have shown to be useful and for an indicated quick fitting (Fig. 4). Thus the soft socket belongs to the first generation of PTB prosthetics.

Now, for almost ten years, silicon sockets have comprised the second generation. The development of silicon sockets was the beginning of distal end suspension, meaning a fastening of the prosthesis at the end of the residual limb. These suspension possibilities – away from supracondylar support – have provided free knee movement and therefore improved comfort (Fig. 5).

Unfortunately there are not only advantages in suspending the prosthesis at the end of the residual limb. When too much soft tissue covers or hangs over the end of the residual limb, pistoning and a distal progression of the prosthesis can be observed during swing phase.

The third generation – polymer connections based on gel – has been developed and perfected within the last two years. They have the same advantages of adhesion and skin protection as the silicon, but they have much more cushion, elasticity and softer fit than the preceding generation. The softness of the Easy-Gel liner in picture 6 feels very comfortable to the prosthetic user. The highly elastic character of the material enhances the fit, especially in the hollow of the knee. The suspension of the prosthesis with an Easyliner can either occur above, meaning proximal to the knee joint, or below, so to say distal to the residual limb (Fig. 7).

Regarding the author's experiences with the last two years, a prognosis can be determined that Gel-suction-sockets might replace silicon-suction-sockets more and more. This change will not only result-

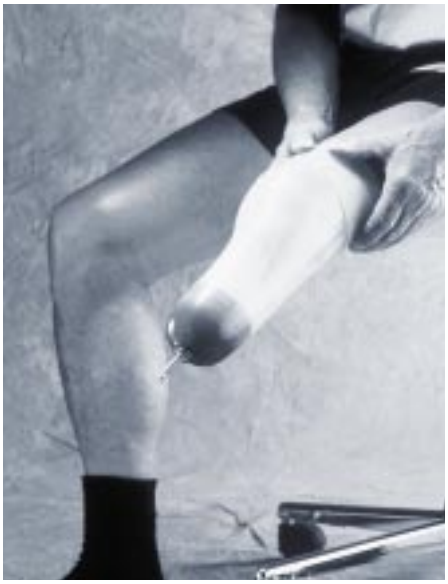


Fig. 5 *Material generation 2: Silicon socket stabilizing the distal end with two layers.*

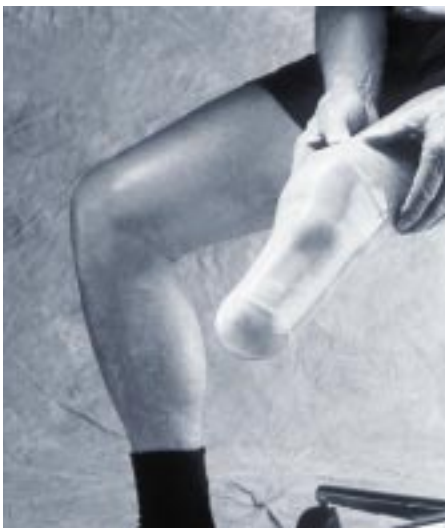


Fig. 6 *Material generation 3: Easyliner PX based on gel.*

Fig. 7 *Material generation 3: Easyliner DT based on gel with web reinforcement and thread for pin adaptation.*

Fig. 8 *Manual fabrication of the cast. Marked areas: non-contact and -pressure.*

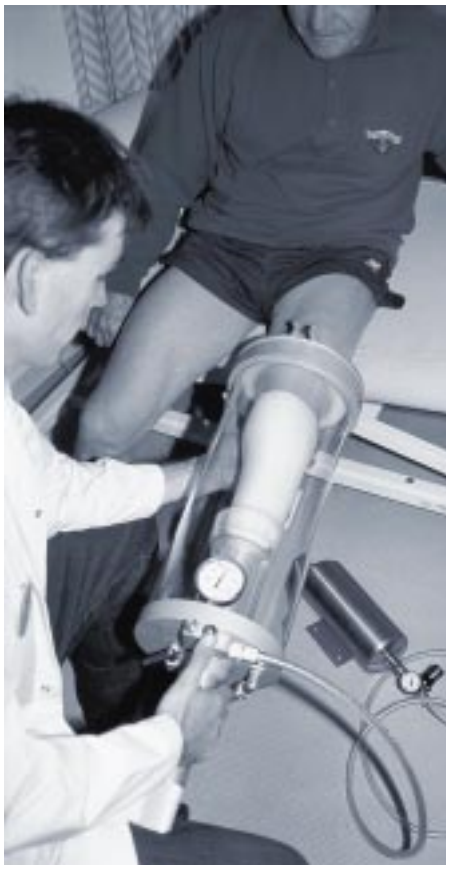


Fig. 9 *Fabrication of the cast with the Castlite Professional.*

from the decision of the prosthetist but mainly will be initiated by the user himself.

The design of the outer socket

The correct choice of material is only one of the critical issues in outer socket fabrication. The design of the prosthetic rigid socket with pressure areas and non-pressure areas is just as important.

For years conventional modifying techniques for prosthetic design have been established in the orthopedic technical field, but a look at recent assessments should be reflected. The intended design of the rigid socket leads to a deformation of the residual limb in an unphysiological manner.

In the orthopedic technical field a BK socket was always considered to have the shape of a triangle to contain sufficient rotational stability. The restriction of muscles (tibialis ant. And gastrocnemius) within their operating range and the atrophy of the residual limb is a result of this triangle formation (Fig. 8).

The procedure of cast fabrication in using a pressurized chamber with adjustable compression allows the exact molding of the natural contours of the residual limb. As a result, furing stance phase pressure and body weight are evenly loaded onto the surface of the residual limb, which is contained within the rigid socket.

The Castlite Professional seen in picture 9 allows this kind of procedure. The residual limb wrapped with plaster is set into the cylinder with a rigid outer wall and an inner membrane made of silicon. For easier entry into the cylinder the air between both partitions is evacuated. By activating a button the vacuum is suspended as soon as the cylinder is fixed to the limb of the amputee.

By activating a second button, compressed air is inserted by the pressure pump. The pressure activation is checked by a manometer. The best results were achieved by pressure conditions of 180 to 240 mm/Hg. When too much pressure is inserted, a safety valve opens automatically at about 265 mm/Hg.

Covering the distal end of the residual limb with a plastic cup for inhibiting pressure on the soft tissue in this area is crucial for cast fabrication. Because of soft tissue displacement, too much compression of the distal end would artificially elongate and taper off the distal end of the socket. This induced deformation leads to a feeling of tightness at the distal end of the socket which cannot be tolerated long term by the prosthetic user.

The experiences of past years have also shown that pressurized chambers without a distal end protection cup do not lead to an acceptable result. The reason for this is that although it seems easier to roll the pressure generating element up from the distal to proximal end, it produces an incongruity of pressure distribution.

In these cases the prosthetic sockets were on the one hand much too tight in the distal end and on the other hand much too wide in the proximal area (Fig. 10). In order to prevent excessive compression of the end of the residual limb, it is necessary to protect it during the procedure of cast fabrication.

Suspension techniques

The suspension of the prosthesis is as crucial as the choice of material and the design of the rigid socket. Regarding the fabrication of a PTB-BK prosthesis there is basically a difference in suspension: one above the knee joint (proximal connection) and the other suspension at the end of the residual limb

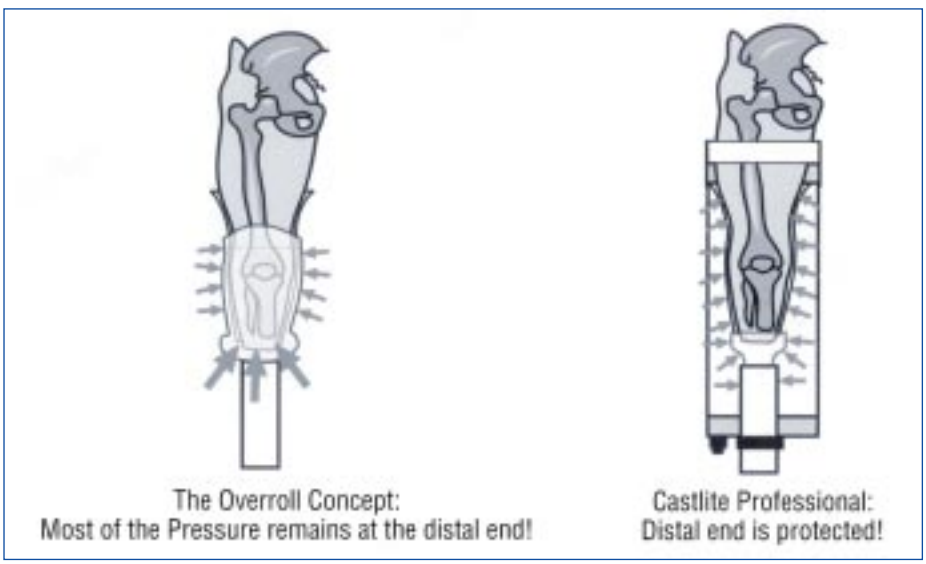


Fig. 10 *Function of different pressurized chambers schematically represented.*

(distal connection). Both suspension techniques are acceptable, and the choice for the prosthetic planning depends on different parameters. These parameters are as follows:

– the patient's dexterity
– the space between distal end of the limb and the foot component
– the condition of the residual limb
– the patient's expectations

Knee sleeves made of silicon or Easy-Gel proved to be good as proximal connection. These kinds of knee sleeves connect the prosthesis to the limb by producing a vacuum between thigh and prosthetic socket. The excessive muscle compression of the thigh resulting from conventional compression sleeves is not present. A further advantage for the patient is the easy handling of this suspension method (Fig. 11).

The distal connection provides enhanced knee movement. This suspension technique requires the patient's skill to slide the silicon or gel suction socket in a certain position over the residual limb to correctly connect the pin with the locking mechanism integrated into the bottom of the prosthesis.

A further problem is the space needed for the integration of the locking mechanism (Fig. 12). The coordination of the patient's expectations and the possibilities with options in handling and function is important in the selection of the correct suspension components.

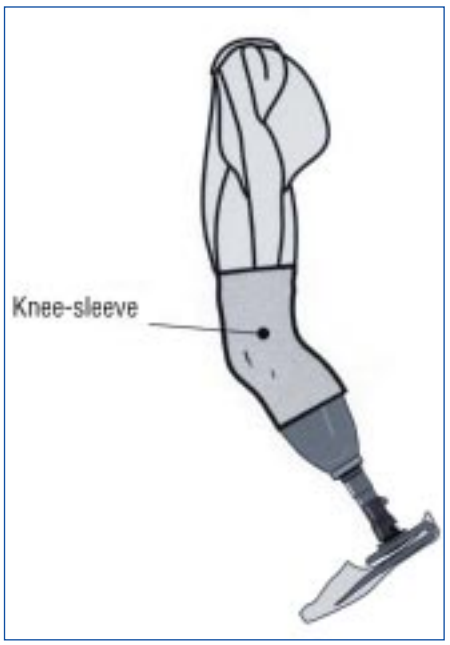


Fig. 11 *The proximal connection: Knee-sleeve made of gel (Easysleeve) to create a vacuum between thigh and prosthetic socket.*

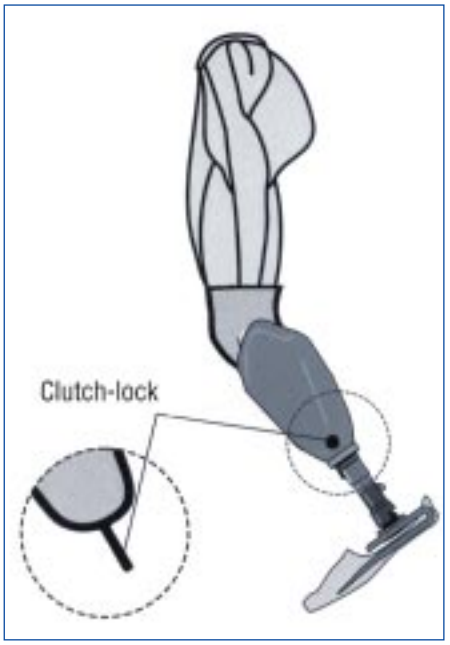


Fig. 12 *The distal connection: Suction socket made of gel, Easyliner DT with pin, the detachment occurs by activating the button.*

Summary

The object of prosthetic fitting for an amputee is a prosthesis which allows activity without pain together with comfortable wear of the prosthetic socket. New liner systems such as the Easy-liner or devices for cast fabrication like the Castlite Professional are helpful for the prosthetist in managing the fabrication effectively and for the comfort of the prosthetic user.

The author:

Markus Piro
L. Biedermann Orthopädie-Technik
Bertha-von-Suttner-Str. 23
78054 Villingen-Schwenningen
Germany

G. Puchhammer

The Tactile Slip Sensor: Integration of a Miniaturized Sensory Device on an Myoelectric Hand

Fig. 1 *Sensor hand with automatic grip stabilizer.*

As a result of the latest developments a new myoelectric had is now available in the orthopedic technology which by means of an integrated sensor system allows a safe and sensible gripping of different objects. The danger slipping of an object is detected by measuring the different force components acting between the fingers and the thumb. Digital closed loop grip control algorithms make sure that the patient can easily and safely operate the artificial hand.

Fig. 2 An empty glass can be held with minimal force.

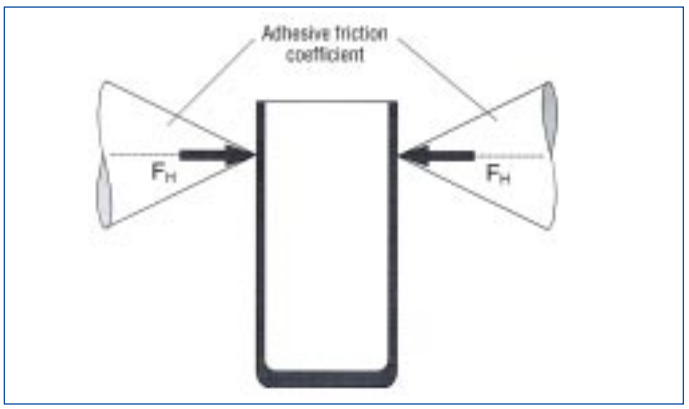


Fig. 3 A schematic outline of forces occurring when a glass is held. An empty glass (glass here described without mass): holding forces F_H are established between thumb and finger.

Four different program versions offer a wide range of applications of the hand. Design and mode of operation of the new designed grip control system are described in this article.

Introduction

The loss of a limb means loss of its sensation at the same time. Especially prosthetic patients of the upper extremities experience this painfully. The function of grip can be more or less well reconstructed with a hand prosthesis mechanically as well as with a myoelectric system. The sensation for instance in form of force feedback to the prosthetic patient does how ever not exist in general. Because of missing the tactile impressions of senses the prosthetic user can become insecure, as he will be informed of the state of grip of his prosthesis hand only indirectly. Nobody likes unintended dropping of objects and increased attention.

The idea of installing additional sensing devices in the hand in order to use some of the former natural impressions of senses for feedback to the prosthetic user or for steering the prosthesis is not new [1, 2, 3, 4, 5, 6]. As substitute for the perception of the senses devices for measuring temperature, force, pressure and noise have already been used, always with different focus. Even today none of these developments has made the hurdle for mass production. The problems in case to process mass production are known: achievement of re-production, of service, reliability, necessary miniaturized sensors as well as high costs are against this last step.

Ten years ago Winkler and Bierwirth in the Swiss Bellikon at SUVA had the idea of feeding measured "impressions of senses" back into the prosthetic hand and utilizing them. Bierwirth was occupied with the idea of which impression of senses one needs in order to characterize the condition of grip of a gripped object and which sensory arrangements a prosthetic hand must have in order to be able to do the same.

With this in mind and with the cooperation with the university-institute of ETH Lausanne four model-hands with integrated force sensors were later created. The first prototype of a functional prosthesis with a "SUVA-sensor" was born. With the desire to bring this hand to market in order to make it available to a wide range of prosthetic users SUVA turned to Otto Bock company for the purpose of final development and for mass production.

After a long phase of transposing this to a mass production for the first time a prosthetic hand is on the market (Fig. 1), which is equipped with an automatic grip control system.

Classification of grip control systems

Grip control systems can be differentiated in terms of recognition of slipping based on different physical principles. It has been tested so far with the following ideas:

1. Formation of noise

Every slipping object causes noise, which can be received by microphone. Noises, which result from ones own movement of the hand can have a negative effect. Also the relative movement between the cosmetic glove and the microphone jack causes an additional source of noise.

2. Visual comparison

Another way of detecting movements in the hand results in a shifted lapse of time of the visual comparison with a subject located in the hand. Digital pictures of a subject located in the hand taken with a CCD sensor through thumb and through a transparent cosmetic are compared. If two pictures taken in succession do not correlate with enough intensity a movement of the object in the hand is the cause. This can but need not indicate a slipping object. Misleading measurements can result from disturbing influences especially with bad light or variable light conditions (for instance neon lighting).

3. Temporal change of force

Changes of the force vector which can emerge by contact between an object and the hand, can well be measured for instance with the help of Piezo-sensors. However it is a disadvantage, that not every change of force derives from a slipping object.

4. Three dimensional measurement

The measurement of vector force components in all three dimensions allows the observation of a

Fig. 4 The same gripping forces are sufficient for stable holding of a half-filled glass.

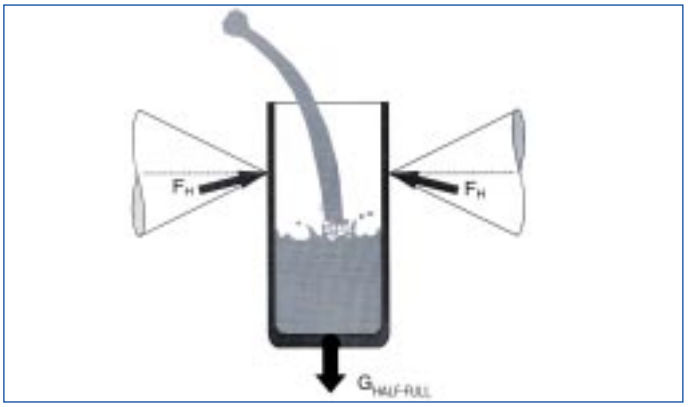


Fig. 5 Schematically shown forces: Resulting holding forces shift towards the limits of the adhesive-friction-cone as soon as the glass is filled "half-full" with the liquid amount G.

gripped object. The tactile slip sensor measures the force which arises from gripping direction and size. The condition between subject and object is thus known, the tendency of slipping can therefore be prevented.

The first measurements are similar in the kind of the point in time of the measurement. Measurements will take place at the moment the object is already slipping. This is too late for starting an automatic process of gripping again, because the object could have already fallen out of the hand. The reasons for that are with the systems 1–3 the detection of movements, which an object carries out. In opposition to that is the function of sensory feeling in the human hand during process of gripping. We are used to holding tighter when we notice that something is about to slip out of our hand.

A signal begins at the moment before something starts to slip out of the hand. The tactile slip sensor-2 makes good use of this fact. The method of measuring is based on the observation of the arising 3-dimensional forces of the gripping process in the same way as the human hand also acts. Not the movement of an object but the condition of the vector force components will be observed. Before the subject starts to slip at all, the tendency to slip causes re-gripping. Because of that, this concept differs essentially with the other systems mentioned above.

The sensor hand

Development into a marketable product and the production of a hand with an integrated tactile slip sensor has been accomplished for the first time with the so called "sensor hand" (Fig. 1). The fundamental concept of this hand is based on the intention to relief a patient of not really necessary observation control functions and to transfer those to an automatically working system. This control system continuously works in the background and without the patient's help. The patient is notably relieved of the supervision of control and for this reason does not experience any additional mental diversions. The absolute reliability of the control function guarantees great ease of use of the hand for the prosthetic wearer. He need not concentrate so much on his hand any more and can participate more in his surroundings.

Gripping is always safe and just strong enough for a secure hold. The patient is relieved of the anxiety of dropping an object unintentionally. In comparison to former hand prostheses, this sensor system offers a physiologically better and higher evaluated replacement. In the daily chores and responsibilities of life such advantages are appreciated in many ways. So far experiences show that the prosthetic wearer accepts it very well and can get used to it very easily.

Fig. 6 Too high loading is caused by filling more liquid into the glass. The glass slips out of the hand, because gripping forces are not sufficient any more.

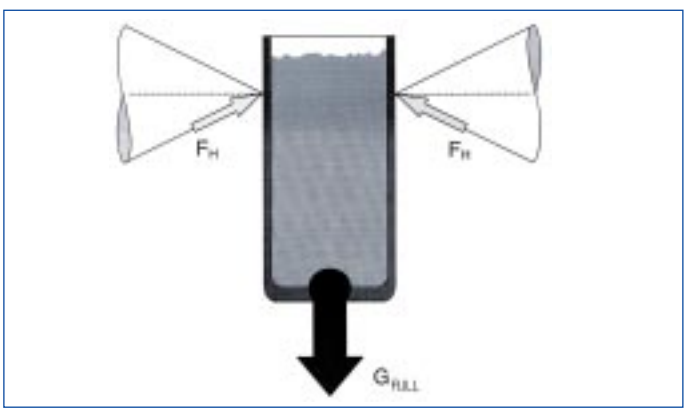


Fig. 7 Schematically shown forces: holding force already settled on the adhesive-friction-cone the force of weight G "full" of the filled glass cannot be compensated by friction. The glass begins to slip.

Fig. 8 The full glass can be held in a more stabilized manner by a firmer grip, i.e. by increasing gripping force.

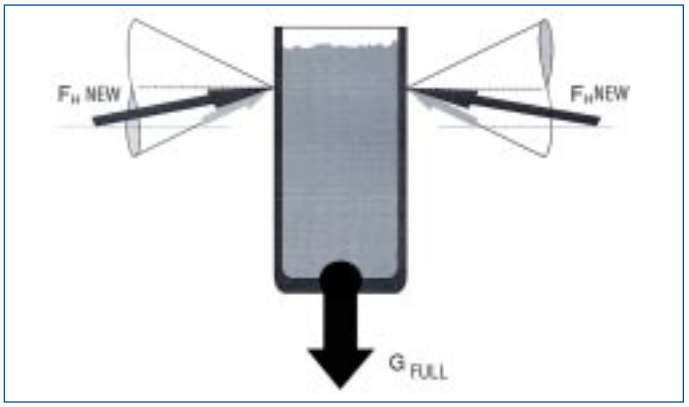


Fig. 9 Schematically shown forces; the increased gripping force directs the resulting holding force "FH-new" in a more horizontal manner. It is again within the adhesive friction cone. A slight free, more stabilized grip is the result.

The grip control systems of the sensor hand

The function of the stabilizing system is to stabilize, to fixate an object in the hand and by not too tight release grip it. This system needs a starting impulse and from that point on runs independently. There is no help necessary from the patient except when he/she wants to open the grip or to stop the automatism. Every regulated system needs sensors, which means measuring components, which give exact information on the gripped object.

In the sensor hand there are two sensors, the "SUVA sensor" built into the thumb and the "finger lever with sensor". The SUVA sensor is steadily metering the direction and the size of the force, which exist between the thumb and the gripped object.

The sensor is in the thumb, because this one is participated in each grip definitely as an opponent of the index and the middle finger. The SUVA sensor will send no signal if, in the case of small objects, the tip of the thumb is not touched. In order to recognize a grip nevertheless a second sensor, the finger lever sensor was built into the sensor hand. With this one also these grips are recognizable and governable.

The grip stabilization is based upon the physical connection of the adhesion and the sliding friction between two frictional partners. The friction is influenced among other things by the surface smoothness, the relative movement of the contact partners to each other and the squeezing force. When a gripped object starts slipping in the artificial hand this is described as the transition from adhering to the sliding friction. The possibility of adhering friction between two bodies is characterized by the adhering friction coefficient. This one indicates up to what amount of friction force adhering is still possible. As long as the size of the friction force (e.g. as the pulling force between thumb and finger) is below this limit, no slipping will occur at an unchanged gripping force. This fundamental principle is used in the case of the tactile slip sensor.

The SUVA sensor measures the amount and direction of the force and in this way also the sideways force components. The grip remains stable under constant grip force as long as the side ways forces remain smaller than the limit force given by the adhesive friction coefficient.

Pictures 2 to 8 show the principle in theory and practice. The forces are pictured which originate in the holding of a glass. As long as the glass is empty (Fig. 2 & 3) the forces are pointing in horizontal direction and the forces are within the adhesive friction cone.

In case of liquid being poured into the glass (Fig. 4 & 5) only the tangential force component and bay this the angle of the contact force is changed as the gripping force remains unchanged. In further filling, the angle of the contact force approaches the one of the adhesive frictional cone, until it reaches it and the object starts slipping (Fig. 6 & 7).

A more stable grip can in this case only be achieved by stronger gripping. The contact force is now directed more in horizontal direction and moved into the region of the adhesive friction cone (Fig. 8 & 9). This stops slippage. The preceded pictured physical principle is transformed by a rule algorithms (Fig. 10).

After the gripping order by the patient the algorithms of grip stabilization is started by the contact of the gripping organs with an object. The measuring data of the SUVA sensor will be read and the amount as well the angle of force is

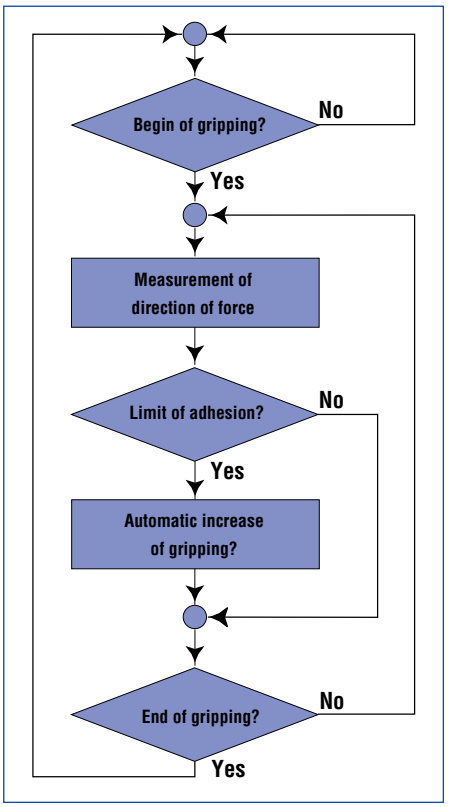


Fig. 10 Bloc circuit diagram of the stabilization of grip.

calculated from the measured force components. As long as this measured angle remains under a critical value the object does not slip from the hand.

The object is held firmly if the grip is sufficiently firm. If, caused by external influences, the angle of the measured power transgresses a certain limit value danger exists, that the object will slip. The size of this limiting value of the angle of force is tuned for smooth objects. This makes a great number of contact situations safe.

At the danger of slipping the hand is just so firmly closed that this will be prevented. Such a regulation check occurs 100x per sec. and continues until the patient gives the command for the hand to open. It is understandable that this type of automatism permits the technical realization of a complete autonomous working hand.

Fig. 11 *Modular exchangeable miniaturized "gliding sensor". For size comparison a match alongside.*

Composition and function of the sensor in the "Sensor Hand"

The tactile glide sensor (Fig. 11) is the central measuring element of the sensor hand. As mentioned with help of the tactile glide sensor the force and its direction (vector), which arises when gripping something between fingers and thumb, is measured. The sensor element itself is built up by bringing together conducting plastic material and sinuous wound electric circuits (Fig. 12). Due to the force on the sensor a mechanical pressure is exerted on the plastic material and the printing plate. The subsequent inner contact of both materials allows their electrical flow-through resistance to be diminished. This change in ohmic resistance stands in a non-linear correlation to the existing force.

Fig. 12 *Mechanical pieces and electronic components of the gliding sensor.*

Fig. 13 *"Finger stirrup with sensor" used for measuring of the gripping force between thumb and fingers.*

By this characteristic above all the smaller forces are more precisely perceived which in turn leads to a better fine feeling hand. The measured ohmic resistance change lets itself easily be transformed with help of a bridge circuit into an electronic measuring signal. In order also to measure three-dimensional forces the sensor itself consists of three separate sensors which are rotationally symmetric incorporated in the overall case. The distribution of the three dimensional thumb force on these three sensors elements is done via a miniaturized mechanical piece (Fig. 12). Only by having the possibility of three-dimensional force measurement allowed tangential forces to be measured which are of utmost importance for the analysis of gliding obstacles. The sensor mechanics were optimized in such a manner that these side forces are measurable in a very high resolution.

Not only the sensor itself but also the interaction of sensor, thumb and the inner part of the hand is decisive for the sensibility of the artificial hand. The construction of the thumb (Fig. 14) was optimized in accordance with the sensor qualities.

This allows the best possible combination of all three components. The necessity of miniaturization of the sensors is predominated by the existing overall volume of the hand. In the hand little unused space is available for incorporating additional sensors. All the needed sensors had to be great-

Fig. 14 *Form design of the thumb adjusted to the sensible interaction of sensor thumb and sensor inner part of the hand*

ly reduced in size. In the final phase the SUVA-sensor had a diameter of only ten millimeters and a height of 7 millimeters respectively.

It can be inserted as a modular piece without the usage of any special tools. Protection from excessive mechanical strain or stress to the small sensor is provided by its construction and its structure. Changes in its characteristic functions, due to continuous mechanical stress could not be found in extended time tests. The characteristics of the sensor are stable, over a multitude of times compared to the normal working lifetime of a human hand.

An additional sensor which measures the hand force between thumb and fingers was built in (Fig. 13). This sensor consists of a special formed finger piece in the form of a stirrup on which a strain gauge foil (DMS) is attached. The forces arising under load causes expansions in the finger stirrup which are measured with the help of a wire resistance bridge and a secondary amplifier.In order to have good interference suppression on the amplifying electronic part was incorporated directly adjacent to a strain gauge foil (DMS) in a small encapsulation attached to the finger stirrup.

Types of control and indicator positioning

In order to have an optimal fit of most often multiple demands due to different degrees or lengths of amputation the automatism of the grip stability was incorporated in the various control types. The possible range of control algorithm varies from EVO (Electronic Voluntary Opening) up to proportional DMC control (Dynamic Mode Control). By inserting colored coding plugs in the housing of the electronic control board the artificial hand is programmed for its future utilization and at the same time is adapted the best possible for the individual needs of the patient. Four different programs are available all of which have the grip stability as a principal part in the program and allow the following functions as well:

Fig. 15 *Miniaturized electronic control unit, programmed via code-plug.*

DMC plus sensors

This control function works like the known DMC-control, however with an superimposed grip stability. It gives the patient complete freedom of steering his artificial (prosthetic) hand. Two electrode and good responding muscle signals are needed.

Auto-Control-Low Input

If the muscle signals are too weak for a fine controllable steering of the artificial hand then this program gives an alternative to the program "DMC plus sensor". Two steering signals are needed which can come from either two electrodes or one electrode and a switch or from a switch only having two switch positions. In this part of the program the closing of the hand is done fully automatically. The closing procedure of the hand is induced by the patient via an impulse which can either be generated by the electrode or via the switch. This electronic impulse starts the grip stabilization. The degree of gripping force automatically adjusts itself to the needs without any further help from the patient.

Auto-Control-EVO

For patients having only one usable muscle and very weak muscle signals as well this program part allows good steering of the prosthesis. As in the program "Auto-Control-Low Input" the closing of the hand and following holding of an object is triggered by either a muscle or switch impulse. Further steering is however done either with an electrode or a switch.

Vario-Control

If at least sufficient good muscle signal is available then with the help of this part of the program a very fine (exact) steering possibility (in comparison to Auto-Control-EVO) with one electrode is available. The sensor hand can, as can be seen from the program variations be activated via single or dual ports. The triggering can be started by an electrode or a switch. Thus multiple possibilities for the best possible accommodation of the patient are available.

The author:

Dr. G. Puchhammer
Otto Bock Austria
Kaiserstr. 39
1070 Wien
Austria

Literature:

[1] Boosfeld, C.H.M., C. Jichuan, C. Mingshan, W. Boxiong: Sensory Feedback of the Gripping Force of an EMG Controlled Forearm Prosthesis. Biomedizinische Technik, Band 33 (1988) 172-178

[2] Brittain, R.H., R.N. Scott: Sensory Feedback in a Myoelectric Prosthesis. Univ. of New Brunswick, Bio Engineering Inst., Research Report 78.1, Progress Report No 15, ISSN0380-3066, 1978

[3] Kyberd, P.J., P.H. Chappell, J.M. Nightingale: Sensory Control of a Multifunction Hand Prosthesis, Biosensors 3 (1987/88) 347-357

[4] Melchiorri, C., G. Vassura: The Development of the U.B. Hand Project. Methodological and Practical Aspects of the Acticity. Preprints, Int. Summer School, Computer aided Education in Automation and Control, 1997, 129-134

[5] Patterson, P. E., A., J. Katz: Design and Evaluation of a Sensory Feedback System that Provides Grasping Pressure in a Myoelectric Hand. Journal of Rehabilitation Research and Development Vol. 29 (1992), 1-8

[6] An Artificial Hand with a Sense of Touch, NEWS, Brisbane, Australia, University of Queensland, Acta Chirurgiae plasticae, 21, 4, 1979, 260-262

S. Zahedi

Standards in Prosthetics and Orthotics

Background

Reviewing the history of the development of prosthetics, orthotics and most rehabilitation engineering devices, such as walking aid, or wheelchairs, they all seem to share common stages of evolution. All these devices, such as artificial limbs were made bespoke, measured to fit the individual patient. Hence they were all considered as a craft. The manufacturers were highly specialised craftsman in metal, wood, leather and other readily available materials. During mid 20th century the application of engineering in design and manufacture of all these devices revolutionised their functionality, speed of delivery and choice for the user. The specialist orthopaedic technicians, were able to concentrate more on individual requirements and match the assembled device made up from off the shelve components to satisfy more closely the needs of the individual's life style. With increased popularity of the modular components, mass production of major parts enabled the formation of the new type of Prosthetic & Orthotics and other similar industries, which were even more specialised in particular devices for different types of disability. During the later part of 20th century, the manufacturer of P&O, walking aid, hoist, wheelchairs, etc. not only were using the most advanced materials such as composites, and specialised alloys, but also were using the latest manufacturing technology, with computer numerically controlled machining centre linked directly to latest solid modelling computer aided design tools. Today's new generation of the medical device supplier is as sophisticated as any major manufacturer from automotive, aircraft, or pharmaceutical industry.

Traditionally the P&O industry has operated with a voluntary code of practice, supported by association of industries such as Interbor, or the professional association such as International Society for Prosthetic and Orthotics. In various countries, notably in UK, Germany and Japan, although there has been some regulation set by purchasing authorities, which were mainly government agents, yet, these varied from country to country. The UK example of this has been a well-established procedure for manufacture and fitting of P&O devices by competent professionals ensuring the safety of each device and its fabrication. The safety of the devices until recently were checked by a government body carrying out established structural testing of new designs based on a consensus before allowing components to be made available for the amputees. This procedure however did not quite got implemented for orthotics. In parallel there is a well-established adverse event reporting system, which continuously monitors field performance. This enables the immediate implementation of any corrections as a result of shortcomings discovered in the field. This system has had a major bearing on the refinements of all products supplied in UK. In Germany, the approval took a different approach where by making the industry to take more of the responsibility and restricting the government agencies to the role of approval based on submitted documentation. Here test laboratories at Universities where acting as 3rd party independent evaluator. However these procedures were continuously evolving and by their nature were refining towards a more harmonised approach.

Coincidentally whilst various experts in the field through the industry and professional association were working towards harmonisation and establishments of standards, the European Community was also working on a general harmonisation of laws, social and economic relationship. This was in the form of regulations for various industries to help easier flow of goods across the community. In 1993 this led to publication of European Medical Devices Directive MDD/42/93 which governs the P&O as well as all other medical devices industry.

Medical Devices Directive

The essence of the MDD is to define clearly its objective, which is to care for the user by providing definition of responsibilities, definition of types of medical devices, the minimum requirements, and means of policing it across the community.

The main aim of the directive is to ensure the safety of the medical devices and protect the rights of the user. There are 3 classes of devices, which covers the broad range of medical devices, ranging for example from a walking aid as a class I, to a functional electrical stimulator orthosis as a class IIa, or a pace maker implanted near the heart as class III. These classifications are based on the relative degree of safety or potential risk to the user. Hence the guidelines in the form of flow charts are provided helping the manufacturer to define the classification of their product in a systematic manner. For example the distinction between active, passive, ability to input energy, or effecting the chemical composition, or physiology of the body and their respective risk of influence can determine the class that a device will fall under. The MDD then defines who is considered to be a manufacturer who places the product in the market, and has the legal responsibility for distribution. Other specific responsibilities define the roles of practitioners who use the product, and pending on the class of the product the registration and provision of documents with notified bodies who can provide an independent assessment. The later at present may vary from one member state to the other especially with regard to low risk class I type of product. The directive also describes the role of competent authority in each state

that is responsible for ensuring the implementation of the directive.

The classification of product and means of satisfying the ERs can be challenged in courts provided their sufficient ground to justify alteration to the requirements. The MDD is a specific directive and hence take president on other requirements specified in general Directive for industry.

The directive and the P&O

Almost all devices used in the area of external prosthetics and Orthotics are class I type product. (A member country in mid 1990's disputed this classification, and following a court case the ruling was made to uphold the classification). Hence the manufacturer are responsible for self-certification and CE marking of their own product. This means manufacturer has to provide the technical file for their device within a pre-defined period to the Competent Authority, (which in many countries are agencies of the department of health or social welfare). The content of the file usually includes specification, restrictions, statement of compliance with directive, and evidences of the risk analysis and results of measures undertaken to prove the minimisation of the risk to the user. Other information such as warnings, labelling, instructions for use may be required in various national languages.

European standardisation

The main aim of the European standardisation is to facilitate the exchange of goods and services through the elimination of technical barrier to trade. Hence superseding any previously established local regulation. Although the use of standards is always voluntary, however European standards are sometimes related to European legislation or directives. Hence conformity to such standards may constitute a presumption of the conformity to the legal requirements of the directive, which must be met by the manufacturer before their products can be traded and placed legally within the single European Community market.

The European Committee for Standardisation (CEN) one of the three bodies responsible for implementation of standards to aid the enforcement of the directives is a legal association. The members are made of National Standard Bodies of 19 EU countries, and 6 association representing social and economic interest supported by Central Secretariat based in Brussels. Its Principle objective is to deliver European standard (EN) which is published by the National Bodies in an identical form.

The medical devices EN standard are insured to satisfy all the Essential Requirements of MDD/ 42/93 which could act as a minimal route to compliance and CE marking of the Medical Devices. Hence the task given to the working groups for establishing these standard within their own industry sector is specifically related to the satisfying the ER aspect of the Directive.

The European Standard in P & O is mandatory and therefore there is a legal responsibility with the manufacturer to comply or provide evidence of an equivalent alternative. The Competent Authority in each country is responsible for verifying and enforcing the law. The Medical Devices Directive deals with many details, such as different levels of hazards, recalls, safety precautions, documentation, marking, levels of risk, clinical experimentation and numerous other requirements. In parallel to the directive, the European Standards are produced in 3 levels. A level 1 standard is a generic standard. For example a standard for biocompatability of all Medical Devices which is applicable in most cases is a level 1. Also a standard for devices for disabled people is also a general level 1 standard or some time refereed to as horizontal standard. Where there is a more specific standard such as standard applicable to P&O, it becomes a level 2 or a more vertical standard. A level 3 standard is a very specific standard, which may be applicable to a particular aspect of a product type or industry. Unless is specified, it is assumed that the requirements of all 3 levels do apply when compliance is sought. In the case of P&O, the EN 12523 as a level 2 standard was exceptionally made as stand alone document for present moment. The International and European Normalisation Standards (ISO and CEN) are in many cases a more efficient route for producing safe products.

The extra cost of meeting these new regulations and standards should be reflected in the improvement of service. The level of the cost, however, varies for different manufacturers or workshops. A reputable manufacturer always tests products structurally to establish their safety and ensure total quality of design. The standard of product is therefore at least the same as those tested. Any changes in manufacturing procedure or material is always checked by testing. A certified Prosthetist or Orthotist always uses the correct combination of tested products in accordance with the manufacturers' fabrication procedure. As a consequence there would be added cost of documentation and closer monitoring. However, those manufacturers and Professionals who do not follow these procedures will find themselves facing huge costs of re-organisation, change of practice, loss of sales and penalties.

The modular components, which are mass-produced according to a set procedure for, use in Prosthesis or Orthosis are interpreted as Medical Devices. However, ultimately it is the responsibility of the manufacturer to determine whether the produce they provide is a medical device or a custom built device. Irrespective of classification the manufacturer must satisfy Essential Requirements such as correct strength at the interface and the overall safety of the device. Even for example if a uniform interpretation in the UK has been finalised, an agreement from the remaining European countries would be needed for harmonisation of the interpretation of law and the creation of a level playing field throughout the EU.

There are a few areas, which may appear to be new to this field and need to be studied and rapidly implemented. These are namely

risk analysis for hazards, provision of tractability for the vigilance system, compliance with EMC directives for electrical products, proper labelling and placement of warning signs, adequate instructions by the manufacturer on operation, cleaning procedure and biocompatibility for skin irritation on all new materials. General Standards assisting compliance with these topics are published. These supportive EN standards as far as possible utilise existing European, International and National Standards instead of rewriting new protocols. Obviously in most cases the standards are already validated – providing additional confidence and speeds up the process. An example of adaptation of this strategy in P&O standard is: in order to satisfy the mechanical strength of a prosthesis, it is suggested compliance with ISO 10328 and other recent ISO standards established in P&O.

A manufacturer could also establish his own standards for the structural safety of his prosthesis and certifies compliance with Essential Requirements by self-certification without any reference to the EN route. Naturally, if this is chosen, in the case of a legal dispute, the courts would require access to the manufacturer's in-house records to see how the test procedures were determined and the background to the data collection, validation and long term field experience.

EN 12523 is the main standard in Prosthetics and Orthotics which provides test methods for satisfying the mechanical strength, risk analysis, flammability, biocompatibility, electrical safety, ergonomics, restriction of use, labelling, instructions, packaging and all other applicable topics of MDD's Essential Requirements. Obviously areas such as sterilisation which is not applicable is not dealt with in this document.

This standard as far as possible adopts relevant Medical Devices supportive standard as means of compliance and where possible as guide or recommendations. Hence the overall risk assessment is carried out in line with EN 1441, and from that the general and specific areas of risks are then defined under the following headings.

ISO 10328, Parts 1 to 8 and ISO 15032, which is included in the EN 12523 standard are for structural testing of the lower limb prosthesis and covers Ankle Disarticulation, Prosthetic Feet and Ankles, Trans-Tibia and Trans-Femoral prostheses. Specific test methods for components, such as Knee Lock and Torque Absorbers are covered in part 5 as supplementary tests. The ISO 15032 is also for structural testing of lower limb prostheses and covers the main components of the Hip Disarticulation prosthesis.

The other standards cited in the above tables are either very general and apply to many devices and/or require specialised laboratory or procedure usually outside P&O field to be dealt with.

Already, most manufacturers and prosthetic clinics satisfy the requirements of EN 46000 Series on the quality aspect of the provision of medical devices. This standard is a specific revision of the ISO 9000 series for medical devices.

EN 12182 is the level 1 standard, which is written for general technical aids for the disabled. There are other level 2 standards for wheelchairs, walking aids, hoists, adjustable beds, communication aids, Ostomy and showering aids. For all other devices for the disabled, this level 1 standard will apply.

There are two definitive visible marks of satisfying the Medical Devices Directorate: The CE mark displayed on any medical device and the creation of specific Technical Files for custom built devices. There are still many areas of misinterpretation such as may be thinking that by declaring conventional devices as custom build, there is going to be less work for the manufacturer and less responsibility for the prescriber. To the contrary, the MDD specifies additional requirements to the ERs for these devices. One possible solution is to encourage manufacturers to provide construction of kits, which could be used in the manufacturer of conventional devices.

Finally the practice of mix and match which has been very common in North America and lately in Europe. Apart from the fact that prescription of what is not on the schedule may not necessarily be legal, many prescriber are not in a position to accept the complete responsibility of such a mix and match and take on the official responsibility of a manufacturer. Furthermore, a review of the failures has shown a marked increase in the cases where such combinations are not structurally tested and hence jeopardising amputees' safety. There may be some times a gross misunderstanding that every component, which is CE marked, is safe and therefore can, be combined and assembled together. The EN 12523 requires the manufactu-

Area of risk	Satisfy by compliance or use as a guide
1. Intended performance	Technical documentation
2. Clinical evaluation	EN540
3. Strength	ISO 10328, ISO 15032
4. Flammability	Specified in the standard
5. Restriction of use	Technical documentation
6. Ergonomic principle	Specified in the standard
7. Surface temperature	Technical documentation
8. Mechanical requirements	Specified in the standard
9. Electromagnetic compatibility	EN 60601
10. Biocompatability	EN 10993
11. Manual controls	Specified in the standard
12. Moving parts	Specified in the standard
13. Corrosion	Specified in the standard
14. Electrical safety	EN60601
15. Instruction	EN 1041
16. Packaging	Specified in the standard

rer's technical files to list the particular combination of components that are permissible. However this does not restrict the right of any prescriber to become a manufacturer of a new combination by undertaking to commission test samples to a suitable test house for compliance wish EN 12523.

The author:

Saeed Zahedi
Chas. A. Blatchford & Sons Ltd.
Unit 6, Sherington Way
RG22 4LU Basingstoke, Hants
Great Britain

Discussion

U. Boenick

Standards in Prosthetics and Orthotics: Another View

The article entitled "Standards in Prosthetics and Orthotics" by S. Zahedi mainly refers to the situation in Great Britain. At first the test and evaluation procedures of prosthetic components including clinical tests and the adverse event reporting system which was established in the UK as a supporting measure aimed to continously monitor field experiences before the Medical Devices Directive 93/42 EEC (MDD) was put to practice are reviewed. The main part, however, deals with the situation after the introduction of the MDD. In this context the role of international standards is stressed in particular.

As far as the former evaluation procedure is concerned, the situation in Germany was in fact not so different from the British approach as described by S. Zahedi. The industry had the same responsibilities with regard to the quality of their products as in Britain and the government agencies were not only restricted to the role of approval based on submitted documents. Of course it is true that prior to the MDD there was no legal obligation to submit prosthetic or orthotic components to tests in independent laboratories in Germany i.e. in universities or other recognized test houses, as a prerequisite for their prescription by a physician. Officially, the question of payment for the complete device, a transtibial or a transfemoral prosthesis had to be decided by the social health insurances or by private insurance companies. In practice the situation was in fact completely different as their decision to accept or not to accept the components or the complete artificial limb was based on the issues of the war veterans service which the German Ministry of Labour and Social Affairs was responsible for. For this reason every manufacturer tried to get his components included into the so-called Federal Prosthetic List. Basically this publication was only mandatory for the prescription of prostheses and other technical aids for war victims. In practice the list which was continuously updated had in fact a much broader importance as it was and is still used as a decision tool by all other institutions which are responsible for all groups of amputees i. e civil persons who had lost an extremity for different reasons or labour accidents and others. Before being added to this list the components had to undergo not only safety but also numerous functional tests and a practical trial on a limited number of amputees. This ensured a high quality of the product. In so far the British system was absolutely comparable to the German approach.

When in 1993 the Medical Device Directive was edited by the European Commission all medical devices hat to be labelled with the CE mark. The main aim of this directive is to ensure the safety of the medical devices and to protect the rights of the user. According to the classification in the MDD walking aids, wheel chairs and prosthetic components belong to the lowest risk class I. This enables the manufacturer to place the CE mark on the product without involving external test houses if it meets the essential requirements given in annex 1 of the MDD. It is than assumed that the product is safe for the user and other parties. In other words, the manufacturer himself is responsible for the certification of his own product. The satisfaction of the essential requirements of the MDD is generally assumed if the product is in compliance with the European Standard EN 12523. However, it should be mentioned that this is only a minimum requirement. To ensure an over all quality assessment of the product a lot of additional tests is necessary. This is not as clearly pointed out in the contribution of S. Zahedi as it should be. In Germany the majority of component manufactures therefore prefer CE marking by registered test institutions.

Another fact, which is unfortunately not clearly addressed, is the question of custom built devices. From the view of the author of this comment not only prostheses consisting of components of different manufactures (so called mix and match systems) are custom built devices in which the orthopedic technician has the responsibility of the manufacturer. Even if all components are products of the same industrial company and they are CE marked and listed as a permissible combination the final prosthesis still remains a custom built device as the socket is designed for a specific amputee and the device is based on an individual prescription.

The author:

Prof. Dr.-Ing. Ulrich Boenick
Institut für Mikrotechnik und Medizintechnik
Technische Universität Berlin
Dovestr. 6
10587 Berlin
Germany

N. Hylton

Dynamic AFOs – Therapeutic Orthotics

The development of Dynamic AFOs has always been directly connected to a therapeutic need. In the U.S. this history dates back to 1970 and my earliest exploration with shoe modifications and casting to improve movement and reduce abnormal hypertonus in children with C.P. This exploration occurred in an attempt to find something that would produce similar tone and movement control changes to what I could produce with my hands in therapy. If I could keep the control "my hands" at the feet and still have another pair of hands free to assist movement elsewhere in the body, I could increase the effectiveness of my therapy. Also, if a child could wear these "hands" as they went about daily activities, perhaps they would have more opportunities to move more freely. So began a rather amazing journey which continues today.

The introduction of Dynamic AFOs into Germany came more recently with the first DAFO course at Kinderzentrum Pelzerhaken in 1994. Since that time numerous seminars, basic DAFO courses and DAFO Refresher courses have been offered in Kinderzentrum Pelzerhaken, Kinderzentrum/München, IKE/Hamburg and BUFA/Dortmund. Interest in this orthotic method has continued to increase with many Basic DAFO courses and DAFO Refresher courses and numerous other seminars on the topic given here in Germany in 1998 and 1999 and others planned for year 2000.

AFOs are therapy tools

With this increasing interest it now becomes more necessary to clarify the function and optimal use of DAFOs nach Nancy Hylton. Dynamic AFOs are and have always been designed to be used as "therapy tools". The active participation of knowledgeable therapists is needed, as they are the members of the medical team best able to decide whether this "tool" is working well or needs modification. Ultimately also, the patients themselves should provide the final quality control as to comfort and functional helpfulness of any DAFO. I realize fully that this is a new way of looking at orthotic management, but this is a rather revolutionary orthotic concept and orthosis which requires somewhat different thinking.

DAFOs have developed over a 25 year period as "therapy tools" with patients teaching us some the most important stages of learning and development. They told us what felt good and what did not; what helped their movement and stability and what did not. The orthoses became more and more flexible because of this input. Polypropylene, a very old plastic, was pulled and stretched extremely thin in a new and different way. Trimlines and padding, even modifications to plaster positive molds were done in new ways based on patient needs and feedback. Our therapy emphasis shifted because of this new and more actively stable base of support; children were challenged with greater amounts of movement and needs to adapt their balance; expectations for future function of many children broadened. Therapist, orthotist and doctor must all understand this in order to judge properly whether a DAFO is working well for a specific patient. When deciding to provide a new therapeutic intervention, it is always helpful to have a specific set of functional expectations. Use of the orthosis with then either confirm these expectations or permit a deeper problem-solving if there are surprise results.

Leaving AFOs on children during therapy session is also a new and different idea to some. Because DAFOs were developed as therapeutic tools, using them in therapy seemed a very natural transition for us, even though most of the therapists that I worked with had been trained to remove stiff and restrictive bracing during therapy. DAFOs are different. They enhance movement possibilities rather than restricting them. Taking DAFOs off during therapy is like hammering a nail with a rock; it can be done, but it is much more effective to do it with the tool designed for the job. DAFOs were designed to enhance active midline stability, deep sensory feedback and balance, all of which are prerequisites for improved movement and tone control. If the DAFO is restricting movements which a child is able to control, modification of the trimlines, making the orthosis thinner, even transitioning to a Dynamic FO all must be considered to allow optimal active movement control.

Nancy Hylton has just published a book on dynamic orthoses:

"Dynamic Orthotic Concepts – Background and Experiences / Dynamische Orthesenkonzepte – Hintergrund und Erfahrungen"

Verlag Orthopädie-Technik (Dortmund, Germany), 2000

DAFOs have also always required very close teamwork with prescribing doctor, therapist, orthotist and family in order to achieve best quality of functional improvement from the brace. Though they were originally used to help reduce hypertonus in children with spastic C.P., the responses of these patients made us re-examine our thinking about "why" hypertonus is present. They have also gradually expanded our understanding of patients who can achieve significant functional improvement from this type to enhanced sensory and stability platform. Our thinking in this regard has been modified also by new information about optimal biomechanics, systems of movement and balance control and neural plasticity.

Indications

With this in mind I propose the following proven indications for DAFOs "according Nancy Hylton":

1. To manage improved balance, movement and tone control in children with spastic C.P. We have now over 25 years of experience and expect mild to dramatic reduction in hypertonus and improved movement possibilities with all of these children. Children with severe deep sensory deficits who appear to generate hypertonus "to feel" their bodies better, show the most variable initial response to DAFOs. Though some may have initial difficulties accepting the new feeling in their bodies, they are ultimately helped a great deal by the enhanced deep sensory information provided through this brace.

2. To manage improved stability and movement control in children with fluctuating tone or moderate to severe hypotonia. We have also 15 to 20 years of positive experience in this regard.

3. The other patient groups who have shown improvements in functional movement control using DAFOs include, adults with hypertonus and instability from MS, Head Injury, CVA, Spinal Cord Injury and C.P.

4. Other types of patients who have experienced comfortable wear and excellent alignment control with DAFOs include children with varying problems of joint alignment, stability, muscle weakness and motor control such as Spina Bifida, Arthrogryposis, Muscular Dystrophy.

Indications for custom molded Dynamic FOs include:

1. Children with C.P. with milder stability, tone control, balance and movement control deficits. Children with moderate spasticity are sometimes able to shift to DFO support after 2 or more years of movement training using DAFOs. Children with mild to moderate motor problems may move from DAFO control to DFO within 1 year with specific therapy support directed at managing active ankle/knee/hip control in 1-leg standing.

2. Older free ambulating children with athetoid C.P. who can manage initial foot contact successfully. Children with mild to moderate hypotonia who can manage active ankle/knee/hip control successfully with improved base of support.

3. We have also had success managing mild to moderate hypertonus and stability problems in adults with MS, Spinal Cord Injury and adults with disabling foot pain from instability of hypermobile joints and uneven weight distribution.

Finally, I would like to address the indications for the use of Custom Contoured Pelite FOs and Shoe Modifications. These are very valuable tools for problem solving the potential value of DAFOs or DFOs in all age groups. I see them as a mandatory first step in moving toward successful use of DAFOs in anyone who has used moderate to severe spasticity to function in upright for more than 1 year. This is because the control of a DAFO can cause a severe disruption in a person's sensory-motor organization and function. Pelite systems can be a very powerful help to stability and tone control while permitting a more gradual adjustment to this control.

1. Custom Pelite FOs and Custom Shoe Modifications are the Nancy Hylton orthosis of choice for initiating support in persons with very severe hypertonus and movement control problems who often will not tolerate either the process of molding or a DAFO.

2. Custom Pelite FOs are a significant help to young children with mild to moderate movement and stability problems as they are learning to balance in standing and walking. They can often make the difference whether a child can stand on 1 foot and balance or run or jump.

3. Custom Pelite FOs are the initial orthosis of choice to introduce persons who have been walking and moving for years high tone and abnormal foot ankle positioning before fabricating a DAFO.

New information in the fields of biomechanics, kinesiology and neurophysiology is continuing to be added daily that will help us to understand the active mechanisms of balance, active stabilization and movement control in much deeper ways. This fact should keep our thinking flexible and dynamic, ever searching for better answers to enable active movement control.

The author:

Nancy Hylton
10820 Oakwood Ave. So.
Seattle, WA 98178
USA

Rehab

K. H. Mauritz

Rehabilitation after Stroke

In stroke rehabilitation several new methods were introduced recently which proved to be effective. However, in this article only methods pertaining to motor rehabilitation are described. Treadmill training with partial body weight support is a new treatment for hemiparetic gait disturbances. Either alone or in combination with functional electrical stimulation is improved ambulation considerably. Botulinum toxin injections in the calf muscles are now widely used in the treatment of the spastic drop foot. Computer controlled biofeedback with music is an innovative method for improving hemiparetic gait. In the treatment of the centrally paretic arm daily repetitive training and emg-initiated electrical stimulation are applied. A new method is the Arm Ability Training which aims also at deficits in higher motor functions. In preliminary studies it has been shown to be useful.

General principles

The incidence in stroke in the Federal Republic is approximately 200.000, prevalence is about 500.000. Many of these patients

- **Spontaneous recovery**
- **Making the advantage of brain plasticity with training methods (physical therapy, occupational therapy, speech therapy, neuropsychology)**
- **Learning of compensatory strategies (e.g. one-hand-training),**
- **Prosthetic and orthotic devices**
- **Adaptation of patient's environment and training the patient's adaptability to the environment**
- **Further treatment methods**

Chart 1 *Mechanisms for regaining functions during CVA-Rehabilitation.*

have motor, sensible, sensory and cognitive fall-outs and deficiencies. Neurological rehabilitation has the task of promoting the recuperation of lost functions, to offer compensatory strategies, to furnish remedies or to achieve functional improvements by change of surroundings [10, 11] (chart 1).

In neurological rehabilitation the recovery of functions is based upon mechanisms which are summed up under plasticity of the nervous system and which are certified neurobiologically. The connections in the motor, visual, auditive and somato-sensory cortex can be influenced by external stimulation. The great chance for rehabilitation in this plasticity lies in training procedures, e.g. by stimulation in physiotherapy, occupational therapy, speech therapy and neuropsychology, to reduce the deficits caused by a stroke.

The learning of compensatory strategies is an important therapeutic object in neurological rehabilitation in addition to the recovery of functions in the framework of plasticity. This is understood as the learning of functions after the irreversible fall-out of certain activities; e.g. it is possible to execute a so called one-hand-training in the case of complete loss of motor hand control. In this case the patient learns how to tie a bow, to eat and to execute other daily work with one hand.

A further mechanism is the training of the patient with devices for eating, walking or dressing. Beyond this an improvement of daily functions can be achieved by a suitable surrounding. The living quarters should be rebuilt in such a way that personal activities become possible. The patient on the other hand must adapt to his surroundings and must learn to bypass his deficiencies and to live with them. This coping mechanism is really important in the framework of neurological rehabilitation.

The most common deficits which remain after a stroke (CVA) are disturbances of walking and gripping, deficits in body awareness like neglect hemianopsias and speech disturbances. This article will deal mainly with the loss (reduction) of motor functions.

Stance and gait functions of the hemiplegic patient

The recovery of standing and walking is a central part of rehabilitation after a stroke. 25% of the patients are forever bound to wheelchair, 50% will have a more or less reduced walking ability and only 25% regain the full walking ability [17]. This means, that with an incidence of 200.000 stroke patients millions of DM will be spent for the recovery of walking. Therefore the control and the choice of efficient therapeutic procedures is of importance.

First standing attempts should be done as soon as possible as the tonic stretching of the muscles in standing counteracts the so-called "spastic pattern". Standing increases also the circulation and prevents contractures, osteoporosis, lung embolisms and pneumonias. From beginning one has to pay attention to a general weight distribution and an upright positioning.

Head and trunk are oriented symmetrically. The therapeutic object for standing are a general weight loading – initially with maximum help from the therapist – afterwards loading and standing on the hemi side with full body weight, while the healthy leg is lifted or placed on a stool. This serves as preparation to stabilize pelvis and trunk in walking during stancephase. In the case of patients with a higher level paralysis in the pelvis and trunk area and patients with an increased flexion of the leg an additional "high-desk-training" is indicated.

Training of gait

Contrary to the healthy gait the hemiparetic gait is asymmetrical, inefficient and characterized by great variability as well inter-individual as intra-individual, which necessitates an individually tuned procedure. The hemiparetic gait is marked by paresis, spasm, synergies, decreased proprioception and eventual contractions. Important therapeutic methods are the reduction of increased hypertonus and induction of movements. Movement guided by the PT counteracts the typical spastic appearance (shortening of the trunk, retraction of the pelvis, external rotation of the hip and knee extension as well plantarflexion and inversion of the subtalarjoint (STG)).

The reduction of muscle tone gives the patient the possibility of applying singular movement activities selectively i.e. independent of synergy of primitive postural reflexes.

Training with partial body weight reduction on the treadmill

Various physical therapy techniques are applied for the usual gait therapy (e.g. Bobath, PNF, Brunström, Voijta) the specific effects of those could not yet be proved [6]. A new attempt is a training on the treadmill with partial reduction of the body weight (Fig. 1). In animal experience it was shown that in the case of cats with spinal or central lesions walking movements could be induced faster on the treadmill by body weight reduction.

This method has been applied during recent years successfully with patients with partial paralysis [2, 4]. The advantage is that training can start very early before the

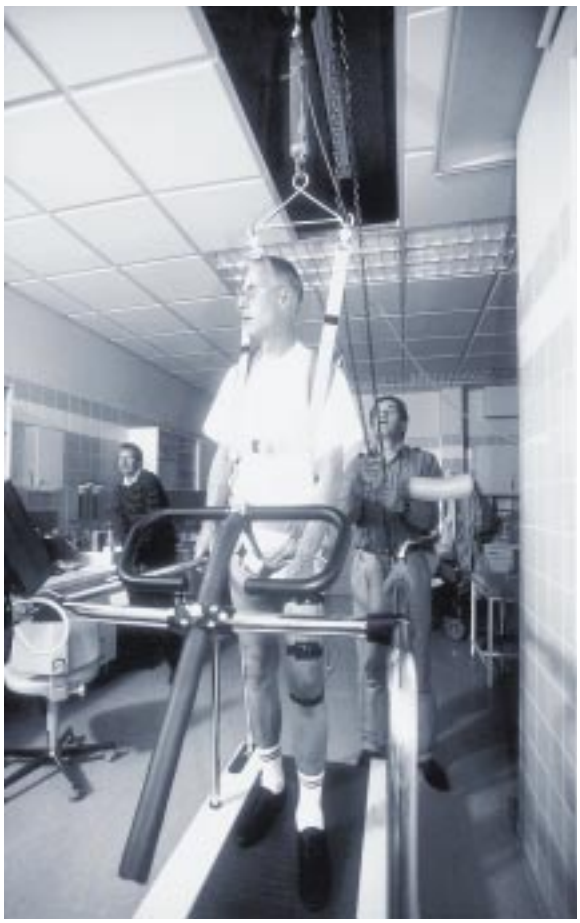


Fig. 1 *Training on the treadmill with partial reduction of body weight. The patient is hanging in a modified parachute strap. In the beginning one applies a large weight reduction and later on increasingly more weight. The belt speed is also increased. In the beginning leg placement by the PT may be necessary.*

patient is able to stand. He is suspended in parachute straps and the body weight is reduced. This load reduction is increasingly diminished according to the state of training. The speed of the treadmill is initially low and is then steadily increased. In several control studies [2, 4] it proves to be a distinct superiority of the treadmill training compared to the standard physical therapy.

This is due to the fact that during training on the treadmill the gait cycle is more physiological and steadier than walking on the surface guided by the PT. The results of a controlled therapeutical test are shown in fig. 2. Patients were trained initially for three weeks on the treadmill then for three weeks treated with Bobath therapy and following within the frame of this A-B-A trials again on the treadmill. All patients measured showed improvements.

Combined treadmill training and functional electrical stimulation

In combination of treadmill training with a functional electrical stimulation the lifting of the foot was improved, the knee stability was secured and the gait cycle was optimized [9] by a cycle-phase governed electrical stimulation.

The stimulation sequences are initiated by foot contacts and are adapted to the gait speed and number of steps by a portable microcomputer. A learning effect can be demonstrated by the afferent and efferent stimulation, which lasts beyond training. In a study with heavily affected patients this combination proved to be very efficient [11]. The method is large-scale and can be practiced only in a few centers.

Music-biofeedback as gait training

An audiovisual feedback of electrical muscle activities of the knee or subtalarjoint angles or from ground forces was used in the so far applied biofeedback procedures with the stroke patient. With biorhythmic stimulation a synchronizing effect on the gait pattern was observed [16]. Most recently rhythmical musical stimulation was tried as a biofeedback.

A "rehab-walkman" was developed which can be carried on the waist belt and on which has been stored numerous melodies. Sensors in the soles can be used as signal donors in order to govern the speed and the correct melody.

The patient causes the melody to play correctly with the best possible symmetrical and fluent gait. The patients must voluntarily change pace duration, loading of body weight and the heel contact. A first study has shown that by these means the symmetry and the walking appearance of stroke patients could be significantly improved and it could be demonstrated, that the training effects are permanent [15].

As opposed to metronomes and external musical sources this method presents a true music biofeedback. A commercial equipment will be marked shortly.

Botulinum toxin in hemispastic walking

The injection of botulinum toxin A in spastic hemiplegia has been used in recent years. Especially in strong inversion and plantarflexion of the foot, which cannot be equalized by splints and which is therapy resistant for antispastic medication, the injection of botulinum toxin into the soleus, tibialis posterior and in both heads of the gastrocnemius results in a considerably improved position and more physiological gait [3, 5]. Spasms could be reduced and the gait was more physiological. Not only the weight transfer over the foot but also the EMG activity of the calf had become more normal after the injection. The stride length had become longer and the pacing speed was increased. The variability in the gait cycle diminished as a sign of higher stability [3, 5].

Repetitive training of the paretic arm

The improvement of arm and hand function is subject of physical therapy and occupational therapy training treatments. Typical treatment focus are reduction of undesirable associated movements, improvement of fine motor abilities, improvement of strength and endurance and tone reduction. The importance of repetition for motor relearning is today sometimes underestimated in the far-flung physical therapy. During recent years it could be demonstrated that a specific, repetitively executed training of the gripping force improves not only the basic parameters of hand motor function,

strength – in isometric dorsal extension of hand – and the acceleration – in isotonic dorsal extension of the hand – but also significantly improves the entire arm function [1].

Forced use

Similar considerations are the basis for the very effective procedure of "forced use" of the paretic arm. In the early phase after a stroke the patient develops a "learnt non usage" (by a disproportionate low usage of the affected arm under circumstances of only mild impairment). Then the patient activates almost only the non-affected side. Therapeutically the "forced use" is the right choice for this phenomenon. In this case the unaffected arm is fixed for several hours per day so that the patient must use the affected side. Bilateral exercises are taken up by therapy only when the motor abilities on the affected side have reached an all day satisfactory level.

EMG triggered stimulation

In the method of EMG triggered electrical stimulation remaining voluntary–potentials are discharged by electrodes attached onto the surface (e.g. onto the paretic extensors of hand and finger). When this voluntary-activity surpasses a certain threshold electrical stimulation is induced into the same muscle, which initiates a distinct movement in the hand joints. Thus a small muscle activity can be technically transformed into a visible movement. In therapy the patient tries repetitively to activate the treated muscle. In this way the voluntary activation of the paretic muscle is practiced. The effectiveness of this method was demonstrated in several therapeutic studies [7, 8]. The successful results of this treatment last over several months.

Arm ability training

It could be shown during recent years that higher non-motor deficits are responsible for several rest symptoms after a hemiparetic palsy of the arm, which impacts upon planning, the motor program and the execution of movements [12, 13]. Therefore recently a specific ability and readiness training (arm ability training) was developed in which the patients are training a wide spectrum of abilities. The training is tailored to the individual patient and his motor performance.

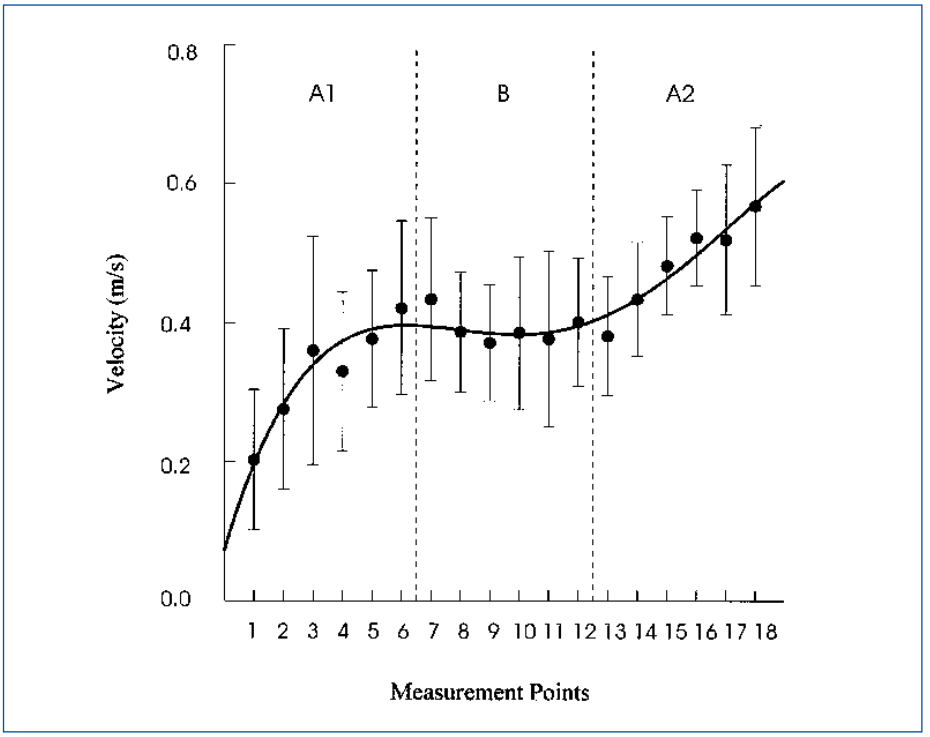


Fig. 2 *Results of a controlled study in which in phase A1 and A2 each three weeks of treadmill training was executed, in between in phase B conventional physical therapy. One can see that during the treadmill phases walking speed increases significantly.*

The author:

Prof. Dr. K. H. Mauritz
Klinik Berlin und
Abt. Neurologische
Rehabilitation
der Freien Universität Berlin
Kladower Damm 223
14089 Berlin
Germany

Literature:

[1] Bütefisch, C., H. Hummelsheim, P. Denzler, K.H. Mauritz: Repetitive training of isolated movements improves the outcome of motor rehabilitation of the centrally paretic hand. J. Neurol. Sciences 130 (1995), 59-68

[2] Hesse, S., C. Bertelt, A. Schaffrin, M. Malezic, K.H. Mauritz: Restoration of gait in nonambulatory hemiparetic patients by treadmill training with partial body weight support. Arch. Phys. Med. Rehabil. 75 (1994), 1087-1093

[3] Hesse, S., D. Luecke, M. Malezic, C. Bertelt, H. Friedrich, M. Gregoric, K.H. Mauritz: Botulinum toxin treatment for lower limb extensor spasticity in chronic hemiparetic patients. J. Neurol. Neurosurg. Psychiatr. 57 (1994), 1321-1324

[4] Hesse, S., C. Bertelt, M.T. Jahnke, A. Schaffrin, P. Baake, M. Malezic, K.H. Mauritz: Treadmill training with partial body weight support compared with physiotherapy in nonambulatory hemiparetic patients. Stroke 26 (1995) 976-981

[5] Hesse, S., J. Krajnik, D. Luecke, M.T. Jahnke, M. Gregoric, K.H. Mauritz: Ankle muscle activity before and after botulinum toxin therapy for lower limb extensor spasticity in chronic hemiparetic patients. Stroke 27 (1996), 455-460

[6] Hummelsheim, H., K.H. Mauritz: Neurophysiologische Grundlagen krankengymnastischer Übungsbehandlung bei Patienten mit zentralen Hemiparesen. Fortschr. Neurol. Psychiat. 61 (1993), 208-216

[7] Hummelsheim, H., S. Amberger, K.H. Mauritz: The influence of EMGinitiated electrical stimulation on motor recovery of the cen-

trally paretic hand. Europan. Journal of Neurology 3 (1996), 245-254

[8] Kraft, G.H., S.S. Fitts, M.C. Hammond M: Techniques to improve function of the arm and hand in ehronic hemiplegia. Arch. Phys. Med. Rehabil. 73 (1992), 220-227

[9] Malezic, M., S. Hesse, H. Schewe, K.H. Mauritz: Restoration of weight shift and gait by multichannel electrical stimulation in hemiparetic patients. Int. J. Rehab. Res. 17 (1994), 169-179

[10] Mauritz, K.H.: Rehabilitation nach Schlaganfall. Kohlhammer Verlag, Stuttgart 1994

[11] Mauritz, K.H., S. Hesse, T. Platz: Late recovery of motor functions. Advances in Neurology 73 (1997), 395-408

[12] Platz, T., K.H. Mauritz: Human motor planning, motor programming, and use of new task relevant information with different apraxic syndromes. European J. of Neurosciences 7 (1995), 1536-1547

[13] Platz, T.: Tactile agnosia. Casuistic evidence and theoretical remarks on modality- specific meaning systems and sensorymotor integration. Brain 119 (1996), 1565 - 1574

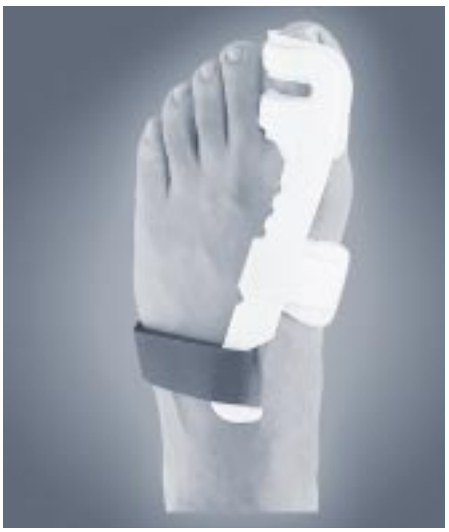
[14] Platz, T., K.H. Mauritz: Syndrome-specific deficits of performance and effects of practice on arm movements with deafferentation due to posterior thalamic lesion. Behavioral Neurology 10 (1997)

[15] Schauer, M., W. Steingrüber, K.H. Mauritz: Die Wirkung von Musik auf die Symmetrie des Gehens von Schlaganfallpatienten auf dem Laufband. Biomed. Technik 41 (1996), 289-294

[16] Thaut, M.H., G.C. Mclntosh, S.G. Prassas, R.R. Ruth: Effect of rhythmic auditory cuing on temporal stride parameters and EMG patterns in hemiparetic gait of stroke patients. J. Neurol. Rehab 7 (1993), 9-16

[17] Wade, D.T., V.A. Wood, A. Heller, J. Maggs, R. Langton Hewer: Walking after stroke. Measurement and recovery over the first 3 months. Scand. J. Rehabil. Med. 19 (1987), 25-30

Product News



Bort Valco – the comfortable solution for hallux valgus

The human foot has to bear the whole weight of the body every day. Deformations of the basic toe joint due to wrong or excessive load are quite frequent, especially with female patients. One of the most common clinical pictures is the hallux valgus, a deformation of the big toe in the shape of an X. Shoes that are too narrow, high-heeled or too small do not give the big toe any room for a natural position. It will be pushed to the side, with the ball strongly protruding. If the foot remains constantly in this unnatural position, a permanent deformation will develop. Without correction, the big toe will not be able to return to its natural position anymore.

The valgus position may then be so marked that in the shoe the big toe will be forced under the neighbouring toes. The consequence: Great pain from putting load on and moving the toe which make natural walking and standing impossible. The BORT Valco Hallux Valgus splint made of unbreakable ABS plastic material is a conservative therapy in the hallux valgus treatment. It corrects the unnatural X-position of the big toe and straightens it.

- The anatomically adapted shape of the splint guarantees the physiological correction of the basic joint of the big toe.
- It affords much comfort thanks to the generously dimensioned foam paddings which safely protect in the critical area of the toe semi-shell and in the ball area.
- To avoid excessive heat, the splint is provided with a ventilation hole in the toe area.
- Two adjustable velcro fasteners allow a precise adjustment of the moments of leverage with the splint remaining in the same optimum position.

Parawalker

The Parawalker permits paraplegic patients with complete thoracic lesions (congenital or acquired) up to T1 to ambulate reciprocally with crutches. The Parawalker consists of a rigid body brace to which are attached long leg calipers via special hip joints to provide the necessary control. The design has been developed to minimise energy expenditure and to ease off and on and transfer. To ensure that this orthosis is built, fitted and used correctly, the kit for it is supplied only to a trained team consisting of a physiotherapist and an orthopaedic technician. Please ask for the training course.

Questionnaire

How do you like our international edition?

Your opinion about our first edition is important to us! Please take a little time and fill in the following questionnaire. It is only with your assistance that we can learn more about your needs! As a little thank-you for your efforts we raffle 5 copies of the bilingual edition of Nancy Hylton's "Dynamic Orthotic Concepts – Konzepte der dynamischen Orthetik" (Verlag Orthopädie-Technik, Dortmund 2000) among all entries that have reached us by 1st August 2000.

Please give marks for the following points (1 = excellent, 5 = poor).

1. How do you mark

	1	2	3	4	5
Scientific character	❑	❑	❑	❑	❑
Practical value	❑	❑	❑	❑	❑
Comprehensibility	❑	❑	❑	❑	❑
Choice of topics	❑	❑	❑	❑	❑

2. Presentation/Layout – Please tick.

- ❑ Clear
- ❑ Confusing
- ❑ Unpretentious
- ❑ Too simple

3. Which specialist topics are of particular interest to you?

- ❑ Orthotics
- ❑ Prosthetics
- ❑ Rehabilitation technology
- ❑ Medical devices and medical technology
- ❑ Orthopaedics, medical topics
- ❑ Design, material and manufacturing procedures
- ❑ Other:

4. Where have you first heard of ORTHOPÄDIE-TECHNIK Quarterly?

- ❑ Trade Fair Orthopädie + Reha-Technik in Leipzig
- ❑ ORTHOPÄDIE-TECHNIK (German edition)
- ❑ Internet
- ❑ Other:

Questionnaire

(continued from p. 23)

5. Which further topics are of interest to you?
   - ❑ Health policy
   - ❑ Foreign aid
   - ❑ Professional training
   - ❑ Portrait of the situation in individual countries
   - ❑ Book reviews
   - ❑ Calendar of events
   - ❑ Coverage of trade shows and congresses
   - ❑ Other:

6. Would you be interested in subscribing to ORTHOPÄDIE-TECHNIK Quarterly?
   - ❑ Yes ❑ No

7. Would you be interested in advertising in ORTHOPÄDIE-TECHNIK Quarterly?
   - ❑ Yes ❑ No

8. Would you be interested in an online edition?
   - ❑ Yes ❑ No

9. What are you missing?

10. Further remarks:

If you want to take part in our raffle, please add your address:

Please fax to: +49-(0)231-55 70 50 70