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nternationality and interprofessionalism – these are two ingredients in OTWorld's recipe for success. Every two years, it is the industry's number one meeting place and it offers a unique platform in Leipzig for everyone who is involved in the daily provision of medical aids. Here, orthopaedic technicians, orthopaedic shoemakers, rehab technicians, specialist dealers, engineers, doctors and physiotherapists come together to exchange ideas about improved supply options for patients and to share experiences and knowledge.

With the successful digital edition "OTWorld.connect" in 2020, our industry has proven that it is flexible, well-connected and at the cutting edge of technology. Now, I am very much looking forward to seeing you again at the fair. The congress and trade fair programme guarantee a top-class selection of specialist and exciting lectures. Personal discussions will also have their space at OTWorld. This is where representatives from politics, industry, science, research, medicine, neighbouring associations as well as from professional societies, health insurance companies and service providers will come together and talk. I am sure that we will talk constructively, and as equals, about quality improvements in patient care/everyday care.

ISPO (International Society for Prosthetics and Orthotics) and the German Association of Orthopaedic Technology (Bundesinnungsverband für Orthopädie-Technik, BIV-OT) have enjoyed a close partnership for many years, which I greatly appreciate. As a national and international forum, OTWorld offers the appropriate setting to get together with colleagues from ISPO again, without a screen. With the high standard of hygiene at OTWorld, nothing stands in the way of a carefree face-to-face reunion. There will be an exciting exchange of views concerning the different challenges faced by the aids industry at an international level. In this context, OTWorld is the perfect opportunity to set further goals for future cooperation. This is because it is a symbol for interdisciplinary cohesion – even across national borders.

This is also reflected again in the new issue of the international magazine "How To Treat" (HTT): We get the best results in patient care when we think outside the box and seek mutual networking/discourse. With HTT, ISPO and BIV-OT have succeeded in providing substantial evidence of close cooperation.

I hope that we will continue on our common path successfully and that we will be perceived as a role model for international cohesion. OTWorld puts the key to these cross-border friendships in our hands. It is up to us what we make of this opportunity – where the world is our guest.

Yours,

MAT

Alf Reuter, President of German Association of Orthopaedic Technology





Removing Barriers

A ssistive technology includes the systems and services by which people obtain assistive products. Assistive products are external products used by persons with functional difficulties to enable and enhance their participation and inclusion in all domains of life. Mobility products such as prostheses, orthoses and wheelchairs improve people's ability to function and enable them to live independent lives and participate in desired activities.

However, despite evidence that using mobility products can improve quality of life, the World Health Organization (WHO) estimates that globally only 10% of people in need of assistive technology actually has access to it. As populations age globally and the prevalence of noncommunicable diseases increase, the need for assistive technology will continue to rise exacerbating the already wide gap in access. Several factors hamper access to mobility products including (but not exclusively) the lack of trained professionals, lack of service points and the cost of services.

The provision of high-quality mobility products depends on the availability of a competent, adequately trained workforce. Without a well-trained workforce within the mobility products environment, poor fitting, discomfort and abandonment of devices becomes a real issue, which is very costly to the patient and the health system. At present, the availability of trained workforces are inadequate to meet the actual demand and there are too few training institutions to train the required number of competent staff. Potential solutions to overcome this barrier could include collaboration among training institutions to ensure the quality of the training and support in the establishment of new training programmes. The use of digital technologies can also be part of the solution enabling to establish e-training.

Although it would be financially impossible to have complete mobility products service units in all cities and communities in a country, the services must be made accessible for people in remote and rural areas. Training more professionals alone will not increase access to services if this is not accompanied by the increase of service points. Integration and decentralisation of service delivery are important considerations and can help improve the availability, accessibility, and affordability of services. Digital assessment and follow-up, by using desktop conferencing, smartphones, and other communication technologies, could be part of the solution to work beyond barriers presented by distance restrictions.

Affordability has been highlighted as one of the main reasons why people with functional limitations do not receive needed mobility products. The costs of mobility product provision are mainly driven by the cost of the products (for the users) and/or of the components (for the service provider) which influence the cost of the final product. A range of affordable, durable and quality components should be available and supported by optimal visibility into supplier offerings, prices, and quality.

To remove barriers, a coordinated effort is needed to tackle all barriers hampering the development of the mobility products sector and restricting access to appropriate services.

Claude Tardif, President of International Society for Prosthetics and Orthotics



Offizielles Fachorgan des Bundesinnungsverbandes für Orthopädie-Technik



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ollowing the purely digital edition OTWorld.connect as a result of the coronavirus pandemic: "Welcome back" is the motto from 10 to 13 May 2022 in Leipzig. The global industry for modern assistive technology will once again meet in person at OTWorld 2022 for an interdisciplinary exchange of knowledge and experience. The focus of the world congress and the world's leading trade fair will be on the entire range of advanced processes, products and technologies that enable people with mobility impairments and disabilities to enjoy greater independence and participation. These include digital assistance systems, care concepts for cerebral palsy or diabetic foot syndrome as well as children's neuro-orthopaedics, robotics, 3D printing, high-tech prosthetics and orthotics. One of the most important topics this year is ensuring professional help, as well as in times of crisis and in war zones.



Skateboarder Eric Dargent was a guest at OTWorld in the past.

A global discussion among professionals is more important than ever

As Martin Buhl-Wagner, Managing Director of Leipziger Messe emphasises, "Rarely has OTWorld, the global meeting place for the industry, been as important as it is today. In uncertain times marked by crises and war, a global discussion among professionals about the best possible assistance for people with reduced mobility and disabilities at a personal level is more important than ever. We are pleased to be able to offer all stakeholders a platform for exchange." The great international interest in OTWorld is also reflected in ticket purchases from Ghana, Iraq and Lebanon, New Caledonia and Norway, among others.

Finally in person again!

"The supply of assistive technology is associated with close personal exchange and contact, which can only be depicted to a limited extent in video sessions," adds Alf Reuter, President of the German Association of Orthopaedic Technology (Bundesinnungsverband für Orthopädie-Technik, BIV-OT), the conceptual sponsor of OTWorld. As Reuter goes on to say, "Together with leading international professional societies and aid organisations, we want to use the intensive worldwide connections of our profession to dedicate ourselves to the topic of support for Ukraine at OTWorld." In this context, he said, the Industry and Politics Forum will especially serve to network politics and industry.

Industry and Politics Forum: Global responsibility

The OTWorld Industry and Politics Forum focuses on the supply of aids in crises and places the issue of responsibility at the centre. Experts from politics, science, medicine, health insurance companies, associations and organisations such as the International Society for Prosthetics and Orthotics (ISPO) and the United Nations (UN) will have their say in eight panel discussions. For example, the discussion will focus on the responsibility of the assistive technology industry to enable people with mobility impairments and disabilities to participate on an equal footing. This is especially put to the test in times of crisis.

In one-hour talk formats over the entire duration of OTWorld, questions will be answered such as: Who bears the responsibility for a quality-assured supply of assistive technology? How can professional assistance be ensured, even in times of crisis and in war zones? What opportunities and challenges do digitalisation, e-health and 3D technology entail?

In the "Showing responsibility: Does the international supply of assistive technology know (any) borders?" session, the podium will, for example, feature ISPO President Claude Tardif, Hans-Jörg Strohmeyer from the Office for the Coordination for Humanitarian Affairs (OCHA) of the UN, the physician Professor Yasuhito Tanaka MD PhD from the Department of Orthopaedic Surgery at Nara Medical University, Japan, as well as PD Dr. Casper Grim, Head Orthopaedic Surgeon of the German Olympic team, Head Physician of the Triathlon Union and Vice-President of the Society for Orthopaedic-Traumatological Sports Medicine Prof. Dr. Martin Engelhardt, Congress President of the World Congress 2022.



(GOTS e V.). Among other things, they will examine the supply of assistive technology in crisis situations as well as the supply to poorer countries. For example, ISPO is working together with the United States Agency for International Development (USAID).

Lighthouses in the congress programme

Two outstanding approaches to care concerning the topics of diabetic foot and leg prosthetics will be presented by interdisciplinary care teams from the Netherlands and the USA as interdisciplinary lighthouses at the OTWorld Congress. The programme highlights also include the "Rehabilitation of Veterans and the Importance of Sports" block of lectures with Rory Cooper, PhD, from the Human Engineering Research Laboratories (HERL) at the University of Pittsburgh with himself being a US war veteran. A total of 280 speakers from more than 30 countries are expected in Leipzig. The languages of the congress are German and English, simultaneous translation will be provided. Parts



Kenton Kaufman, PhD, PE, a researcher at the Mayo Clinic and head of the US registry project LLPR, aims to fill data gaps. He will speak at OTWorld 2022 on the subject of "Evidence for amputation and limb preservation – establishing a registry in the US".

of the programme will be streamed and made available in a media library after OTWorld.

The congress presidents will also provide focuses: The sports physician Prof. Martin Engelhardt, Medical Director of the Osnabrück Clinic and Head of the Clinic for Orthopaedics and Sports Medicine as well as a member of the Executive Committee of the Society for Orthopaedic-Traumatological Sports Medicine GOTS e. V., will focus on the care of athletes in competitive and popular sports. Dipl.-Ing. Merkur Alimusaj, Head of Technical Orthopaedics at the Clinic for Orthopaedics and Trauma Surgery at Heidelberg University Hospital, will focus on digitalisation, new manufacturing methods and the care of children with congenital or acquired deformities and impairments such as infantile cerebral palsy. More than 20 courses and workshop discussions complement the range, including new workshops concerning materials science in the field of technical orthopaedics.

As the presidents of the congress explain, "Despite all the pitfalls and concerns related to the pandemic, we have been able to attract top-class national and international experts to the congress - this speaks for the format of OTWorld and the networking of all participants!" As Alimusaj says, "Internationality and networking are essential in a globalised structure. We learn from each other - the excellent training related to trades in Germany and, for example, the high academic content relating to the subject in the USA can lead to forward-looking synergies." In addition to internationality, the presidents of the congress attach great importance to strengthening interdisciplinary cooperation for the benefit of patients. As Prof. Engelhardt emphasises, "Our goal with the congress is to improve the interdisciplinary teamwork of orthopaedic technicians, doctors and therapists."

Groundbreaking keynotes: Outstanding approaches to research

Traditional congress highlights are the four groundbreaking keynotes concerning the latest trends in the industry, which once again this year represent outstanding approaches in the field of research and lead the international exchange:

Prof. Kenton Kaufman from the W. Hall Wendel Jr. Musculoskeletal Center at the Mayo Clinic, Minnesota, USA, will speak on: "Evidence for amputation and limb preservation – establishing a registry in the US". Despite the burden of disease, little is known about the effectiveness of practices and technologies used after limb loss, writes Prof Kaufman ahead of his keynote speech. "A similar medical situation exists in



the United States. The Limb Loss and Preservation Registry (LLPR) was created to advance scientific developments," said the expert, who specialises in musculoskeletal rehabilitation research and is leading the project to develop the US National LLPR Limb Loss and Preservation Registry. As Kaufman goes on to say, the LLPR collects information concerning the causes, treatment processes and outcomes of more than 500 amputations performed per day in the US. The LLPR was developed to standardise, measure and report patient data and treatment outcome data. The aim is to support evidence-based decision making and improve health care and/or prevention, treatment and rehabilitation efforts for these patients.

Prof. Bertolt Meyer, Professor of Labour, Organisational and Economic Psychology at the Chemnitz University of Technolo*gy*, will look at stereotypes in his keynote speech "Digitalisation: Opportunities and risks for people with impairments." He himself wears a bionic prosthetic hand from Össur. He is not only no stranger to the field of science, but he is also active in the club scene as a DJ. Meyer agrees that increasing digitalisation opens up completely new possibilities for people with disabilities. Thanks to digitalisation, paraplegics can now walk temporarily with exoskeletons, and people with multiple disabilities can control assistive devices via eye-tracking, to name just a few examples. As Meyer explains, "Our research shows that the new technology not only has a functional advantage, but also a psychological one." This is because, in addition to the opportunities offered by prosthetics, he is also confronted with the prejudices of non-prosthesis wearers. He investigated the question of stereotypes towards wearers of bionic prostheses in his current research work and he will present the first results.

Prof. Oskar C. Aszmann, Head of the Centre for Limb Reconstruction and Rehabilitation and Deputy Head of the Department of Plastic and Reconstructive Surgery at the Medical University of Vienna, will give the first "Tandem keynote speech" of the World Congress on "TMR and Osseointegration" together with physiotherapist Dr. Agnes Sturma. The interdisciplinary focus will be on amputations above the elbow. The professor will present the latest research on targeted muscle reinnervation (TMR), the transfer of unused nerves to the residual limb, and osseointegration, the direct anchoring of the prosthesis in the bone. As Prof. Aszmann emphasises, af-

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fected persons control the prosthesis by means of TMR, but they have to be neurologically introduced to this new reality following a nerve transfer. Dr. Sturma will show how this works and how users learn to perceive their prosthesis as authentic. The focus of the tandem keynote speech is on practical relevance. As Aszmann explains, "Because many people injure their hands as a result of accidents at work or even lose them, the aim is to help them back into everyday working life in the best possible way. For example, how does our research support the forest worker after

an arm amputation so that he get back to his work environment and cut down a tree?"

How does robotics approximate human performance? "Intelligent control processes and learning in



Univ. Prof. Dr. Oskar C. Aszmann, Head of the Centre for Limb Reconstruction and Rehabilitation and Deputy Head of the University Clinic for Plastic and Reconstructive Surgery at the Medical University of Vienna, is one of the keynote speakers at OTWorld 2022 in Leipzig. Together with Dr. scient. med. Agnes Sturma, BSc MSc, he will speak on the topic of "TMR and osseointegration". prosthetics" is the topic of the keynote speech by Prof. Dr.-Ing. Sami Haddadin, Chair of Robotics and Systems Intelligence and Director of the Munich Institute of Robotics and Machine Intelligence (MIRMI) at the Technical University of Munich (TUM). He will focus on machine intelligence to improve prostheses: As Prof. Haddadin explains, "We want to develop mathematical algorithms and ultimately derive new technologies that, for example, achieve the flexibility of the human wrist." The development of artificial muscles that approach human performance is also conceivable. We are working with the methods used in machine learning and/ or machine intelligence to ensure that, for example, a prosthesis is a predictive human extension of the body - just as legs or arms do not just function mechanically. Instead, complex adaptive processes take place." A paradigm shift has taken place in recent years: The still relatively mechanistic view of prosthetics is on its way to intelligent systems. However, it is still a long time before they are used in industrial products. In Leipzig, Haddadin reports on progress that has been made in research and takes a look into the future.

Exhibition: People in focus & Innovation Talks

At the world's leading trade fair OTWorld, more than 400 exhibitors from 28 countries will showcase new products, innovative care concepts and services for people with limited mobility and disabilities. Among them are companies from Australia, France, Canada, Sweden, Spain, South Korea, Taiwan and the USA. A new feature is a presentation in the nine care areas of mobility impairments, diabetes and vascular diseases, arthrosis and diseases related to wear and

tear, stroke, sports prophylaxis and accident injuries, back, movement disorders and paralysis, cancer related diseases and prevention. The focus is on the needs of those affected.

Special spotlights are cast on new worlds of care focusing on "cerebral palsy", "lymphatic diseases" and "orthoses", which provide diverse insights into modern and evidence-based care options. Also new is the online format "Innovation Talks", where exhibitors present their innovations in a livestream.

Jugend.Akademie TO: Keeping an eye on the next generation

In order to offer trainees and students from the fields of orthopaedic technology, orthopaedic shoe technology, the medical supplies trade, medicine and physiotherapy an overview of the latest innovations, results from research and further training opportunities around the world in the constantly growing market for assistive technology, OTWorld is organising the Youth.Academy Technical Orthopaedics (Jugend.Akademie TO) for the fifth time. Around 500 young professionals from Germany and abroad are expected to attend this special programme. The training meeting point has also been newly established in the area of further education and training. There, schools for master craftspeople, universities of applied sciences and other educational institutions from all over the world will

Prof. Dr.-Ing. Sami Haddadin, Chair of Robotics and Systems Intelligence at the Technical University of Munich, will speak on "Intelligent control processes and learning in prosthetics" at OTWorld 2022. provide information about their further education and training programmes in technical orthopaedics.

MOOC: Learning from the best

For the first time, an international offer will be continued beyond OTWorld for the next generation of professionals: In the new free "Massive Open Online Course" (MOOC) you can learn from the best. In over ten 20-minute learning videos in English, experts from Germany, El Salvador, Thailand and the USA will showcase successful examples of interdisciplinary work concerning the care of people with amputations. After OTWorld, the content will be available worldwide and free of charge in the media library. "For good patient care, various experts must work as closely as possible," emphasises Dr. Urs Schneider, Director of Life Sciences at the Fraunhofer Institute for Manufacturing Engineering and Automation IPA and Head of Human-Technology Interaction at the Institute of Industrial Manufacturing and Management IFF at the University of Stuttgart. "This works best if, during their training, they learn which other occupational groups these are and which functions and competences they each bring with them." Dr. Schneider is one of the initiators of the MOOC together with Prof. Levi Hargrove, Director and Scientific Chair at the Shirley Ryan AbilityLab in Chicago (USA), and Prof. Michael Goldfarb, Professor of Mechanical Engineering at Vanderbilt University Medical Centre in Nashville Tennessee (USA). Schneider: "Interdisciplinary work is mandatory for all professionals in assistive technology, whether in wealthy or poorer countries."



Osseointegration

A. Sturma, C. Gstöttner, St. Salminger, O. C. Aszmann

Osseointegration in Patients with Transhumeral Amputation: Benefits, Challenges and Limitations

The treatment of high arm amputations continues to pose a great challenge for the medical and orthopaedic technology team. Although in general, surgeons, therapists and orthopaedic technicians invest a great deal of time and energy in a good prosthetic solution, patients are often dissatisfied with the end result and do not wear their prosthesis regularily. One of the main reasons for this is that it is uncomfortable to wear and the socket limits shoulder mobility. For several years, osseointegration has been one approach to counteract this problem. An implant is surgically anchored in the residual humerus. This implant then perforates the skin and makes it possible to attach the prosthesis directly to the external part (abutment). This means that the prosthesis can be anchored to the bone by the implant and a conventional socket is no longer needed. This is also termed an endo-exo prosthesis. As described in detail in this article, a stable connection of the prosthesis to the residual limb and preservation of shoulder mobility can be achieved through osseointegration. However, the procedure requires a surgical intervention, an extensive and structured rehabilitation and specific special skills in orthopaedic technology. The procedure is also associated with the risk of superficial or deep infections and loosening of the implant. In the worst case, this can lead to removal of the implant and re-shortening of the residual limb. Before making the decision for osseointegration, patients must be aware of these risks. In general, it is recommended that osseointegration be offered primarily to young and healthy patients while simultaneously evaluating their motivation, realistic expectations and compliance. Osseointegration is therefore a useful option for improving the prosthesis connection in a selected group of patients. However, because of the risks, the use of this invasive technique should be considered carefully with respect to personal preferences and expectations.

Key words: osseointegration, transhumeral amputation, arm prosthesis, endo-exo prosthesis, TMR

Introduction

Amputations above the elbow traditionally present a great challenge with regard to their prosthetic fitting. Compared to amputations below the elbow, it is much more difficult to replace the lost arm function and, at the same time, ensure a stable and comfortable connection of the prosthesis to the residual limb. This often leads to user dissatisfaction and as such, to a relatively high rejection rate with regard to the fittings [1]. This problem of a possibly uncomfortable socket that restricts shoulder mobility is particularly relevant for very short upper arm amputations. In these cases, it is often necessary to resort to a socket design for a glenohumeral amputation. As such, these patients lose the possibility of using their shoulder movement with the prosthesis. In addition, socket fittings often require straps to the contralateral, healthy side. This further restricts patients in their everyday life, which contributes to the fact that the prosthesis is increasingly perceived as a burden instead of an aid.

Benefits, risks and associated education of patients

Osseointegration offers several advantages, especially in the case of short transhumeral amputations. In this invasive method, an implant is surgically inserted into the humerus, which passes through the skin and protrudes a few centimetres beyond the end of the residual limb as a so-called abutment (Fig. 1). A prosthesis can be fixed to this abutment, which is thus directly connected to the bone via the implant [2]. In principle, conventional socket construction can therefore be omitted. By eliminating the need for a socket and, above all, any straps or shoulder caps, this direct connection to the skeleton allows movements in the shoulder joint to be transferred directly to the prosthesis. This also makes precise rotational movements in the shoulder as well as movements to the side of the body and in the overhead area possible with the prosthesis, as is shown in Fig. 2. With conventional fittings, this can usually only be achieved to a limited extent.

This preservation of mobility in the shoulder joint, especially with short humeral residual limbs, is the greatest advantage compared to conventional socket fittings. The length of the remaining humerus bone and the bone quality determine which implant can be chosen. Recent studies have also shown that patients that have had os-

seointegration report positive effects that go beyond pure functionality. For example, an improved quality of life is reported after osseointegration, and patients also state that they tend to perceive the prosthesis as a part of their own body [3]. This is also in line with the experience of the author's team. In addition, the so-called osseoperception - the improved perception of movements and the substrate through the implant - is described positively, especially in osseointegrations in the lower extremity [4]. How relevant this also is for the upper extremity is the subject of current research.

Due to all the advantages mentioned above, osseointegration, which has been used for much longer in the lower extremity, is also becoming increasingly popular in the upper extremity. Nevertheless, it should not be forgotten that this procedure involves at least one surgical intervention and as such, it also entails some risks. These range from superficial to deep soft tissue infections, which, if the bone is involved, can lead to implant loosening and subsequent removal of the implant. Superficial infections are relatively common, but can be treated well with antibiotics. Deep infections, i.e. in the bone, are rarer and more difficult to treat. In the worst case, the implant may have to be removed and the residual limb may have to be shortened [5].

However, in view of the small number of cases regarding osseointegrations at the humeral level to date, the actual complication rates are still difficult to estimate. Tsikandylakis et al. followed up complication rates in transhumeral amputees over 5 years. Overall, the implant had to be removed again in 20% of patients; 38% were affected by an infection at least once [6]. It should be noted, however, that some of the patients were provided with a new implant again after explantation and that infections could usually be treated well. Likewise, it can be assumed that complication rates will decrease with increased experience at international centres due to continuous improvements relating to implants, surgical techniques and rehabilitation [6].

Nevertheless, these relatively high complication rates indicate that patients who decide to undergo osseointegration must be aware of these *Fig. 1* Schematic representation of an osseointegration system. Source: [15].



risks. Accordingly, it is imperative to address these possible complications, the management of the complications and the patient's responsibility regarding abutment cleaning and timely reporting of problems in the discussion relating to the education on medical issues [7]. Rehabilitation and its duration must also be addressed. In addition, as described below, together with the patient, it is necessary to consider whether osseointegration is really the treatment of choice.

Patient selection

As with any medical intervention, osseointegration must be weighed against the potential benefits and risks. As the risk-benefit profile varies greatly between patients with amputations, adequate patient selection is imperative. Classic indications for osseointegration are the following:

- Traumatic amputations in active, young patients;
- Problems with the use of a well-fitted conventional socket, for example due to a very short residual limb;

 Very active patients with high requirements and corresponding motivation and/or compliance [6].

The following are considered contraindications by a majority of experts in the field:

- Low bone density and blood circulation;
- Organisational problems (example: Patient lives far away from the treatment centre and has no local contact person);
- Overestimation of benefits;
- Psychological problems;
- Unstable social environment;
- Low self-drive [7].

Precise criteria for inclusion are currently being developed in an international Delphi study led by the main author of this article.

Different systems

While all osseointegration systems are similar in that they connect the prosthesis to the bone, a distinction can be made between two basic designs:



Fig. 2 Osseointegration allows a patient with a transhumeral amputation to fully utilise the range of motion in their shoulder with the prosthesis.

- one in which the implant is screwed into the bone with a thread, and
- one in which the implant is inserted into the bone with high pressure ("press fit").

An example of the former is the socalled OPRA system (Integrum, Sweden). This consists of a relatively short intramedullary implant (length 6-8 cm) with a thread on the surface. This part is screwed to the cortex from the inside to ensure mechanical stability between the implant and the bone.

An implant which follows the press-fit technique and is strongly represented on the German market is the ILP system (ESKA Orthodynamics GmbH, Germany). This is significantly longer and does not require a thread.

While both systems have been used successfully in the lower extremity for many years [7], there are still only a few reports of experience with the ILP system, especially with transhumeral amputations.

Surgical procedure

The surgical procedure for osseointegration basically depends on the type of implant that is used. In this regard, the authors have gathered relevant experience with the use of the OPRA system in the upper extremity, which is why the surgical procedure for this system will be discussed in the following.

For surgical planning, it is useful to perform a computer tomography of the residual limb - on the one hand, to assess the bone quality and, on the other hand, to determine the necessary implant size. In healthy patients with good bone condition and a long residual limb, the authors of this article now perform implantation of the OPRA system as part of a one-stage surgical procedure. On the other hand, in the case of thinner bone or very short residual limbs, it is only recommended that the intramedullary implant is inserted in a first operation. In the course of this, a surgical lengthening of the bone can also be performed, if necessary. For this purpose, bone material is taken from the patient's iliac crest and inserted at the end of the residual limb. After a healing phase of about three months, the skin passage is then created in a second procedure and the external abutment is connected to the intramedullary implant. This step of osseointegration is of utmost importance, as the surgeon can contribute significantly to the success or failure of the subsequent fitting.

In order to keep secretions at the port and the associated risk of infection as low as possible, the soft tissue mantle around the skin passage of the prosthesis must be reduced as much as possible. In contrast to the principles of classical residual limb surgery, the skin around the port should ideally lie directly against the bone so that it can fuse with it. Subcutaneous fat must be removed accordingly and the muscles must be fixed around the bone. The aim is to have as little relative movement as possible between the skin and the prosthesis. This allows a stable connection between the skin and the prosthesis and thus keeps the entry point for germs at a low level. A tight bandage should be applied postoperatively to prevent swelling of the residual limb. To prevent infection, oral antibiotics are given after the operation, usually until the sutures are removed.

Rehabilitation for osseointegration

Rehabilitation measures should begin before the operation and aim at strengthening and increasing mobility in the shoulder area in order to enable optimal use of the prosthesis later on. It is essential that post-operative therapy takes place in close cooperation with the surgical and orthopaedic teams and is based on the recommendations of the respective implant manufacturer. In addition to continuing the programme for maintaining or improving strength and mobility, the focus is on continuously increasing the load. When using the OPRA system, it is recommended that weight-bearing training is started three weeks after the second operation with the help of a special training prosthesis and that this is increased continuously. In this process, 50g to 100g are added to the weight of the load every week. Patients are also instructed to press the implant axially against a scale as the load increases. Usually, therapy starts with a load of 5kg, which is put on the scale ten times a day for ten seconds. The aim of the continuous increase in load is to enable gradual ingrowth of the bone onto the surface of the implant. The most important indicator for the extent of the load is the pain, whereby a an indication of 5 or more on the visual analogue scale (VAS) is interpreted as overload and should therefore not be provoked, as in the worst case, this can lead to a loosening of the implant [8]. In the course of rehabilitation, the load is increased until the weight of the prosthesis including grasped objects is tolerated well. In addition, the patient is informed preoperatively about the hygiene that is necessary when passing through the skin, which is also regularly discussed during rehabilitation. Depending on the condition of the soft tissue mantle, there will either be more or less secretions. If these are pronounced, it makes sense to tie a handkerchief around the abutment, for example. Patients should also clean the skin passage at least twice a day, e.g. with disinfectant (compatible with mucous membranes) or a common saline solution.

After the prosthesis has been fitted, the patient is also trained in how to activate the prosthesis during the course of therapy. Essentially, prosthesis training after osseointegration only differs from conventional prosthesis fitting in that more attention is paid to the ergonomic use of the gained range of motion. Apart from that - as with conventional fittings - the training starts by practising isolated prosthesis movements. Later on, objects are grasped and positioned, and finally, movement sequences and activities relevant to everyday life are trained. In the case of myoelectric prostheses, signal training using EMG biofeedback can also be useful.

Orthopaedic considerations

In general, mechanical, cosmetic and myoelectric prostheses can be combined with osseointegration. The choice of prosthetic fitting after transhumeral osseointegration therefore depends on the needs and requirements of the individual patient. As was already mentioned at the beginning, because the prosthesis can now be fixed to the abutment, no socket has to be adapted. However, suitable connecting parts have to be selected and adjusted if necessary. In most cas-



Fig. 3 Possible design for an "electrode socket" that encloses all necessary surface electrodes for prosthesis control following successful TMR surgery (supplied by OTH Döbling, Vienna, Austria).

es, certification by the implant manufacturer is necessary for this. In the case of myoelectric fitting, it is also necessary to fix the surface electrodes to the residual limb. For this purpose, the electrodes can be built into a short silicone socket that has an opening for the abutment, to which the prosthesis is then attached (Fig. 3). Alternatively, adhesive electrodes can be used. These must then be reattached by the patient after each tightening of the prosthesis. They require a precise marking of the appropriate points in order to ensure stable signals.

According to the authors' experience, after successful surgery and rehabilitation, patients increasingly use their prosthesis in daily life, and possibly, for manual or agricultural activities as well. Frequent and intensive use usually results in more wear and tear on the various components. Where possible, efforts should be made to provide a robust secondary fitting. For example, a myoelectric fitting for everyday use in combination with a robust mechanical fitting for greater use of force and outdoor use can be useful, as can different terminals and adapters. An example of a robust mechanical fitting for agricultural work is shown in Fig. 4. Some patients also want a simple sleep prosthesis that offers protection from the hard abutment and also an appropriate weight, which many patients find comfortable.

Approval of prosthetic fitting parts used in arms

Currently, there is no elbow component on the market that is approved for fittings following osseointegration. All individual parts (implant, adapter, prosthetic fitting parts) are individually CE-certified, but there is no common evaluation as there already is for the lower extremity. However, the prosthesis and implant manufacturers are generally striving for such a solution: an approval of the complete system from the implant to the adapter to the elbow component. This requires close cooperation between all manufacturers and the performance of joint tests and assessments in compliance with all regulatory requirements. Therefore, the authors cannot estimate how long the process of an overall evaluation will take.

Combination with TMR

Selective nerve transfers (also known as "targeted muscle reinnervation", TMR) have become established in recent years in order to improve the control of myoelectric prostheses. TMR has a positive influence on phantom pain. It can also increase the number of simultaneous prosthesis movements and allows for more intuitive control [9, 10]. However, the team of authors was recently able to demonstrate that this method alone has only a limited positive influence on the rejection rate [11]. One of the reasons for this is that nerve transfers do not solve the problem of a possibly uncomfortable socket that restricts shoulder mobility. If TMR is combined with osseointegration, a more intuitive control can be achieved together with a comfortable and functional connection of the prosthesis [12]. A first case series of five people with transhumeral amputation who received both TMR and osseointegration at the authors' centre shows promising results. This indicates that prosthesis control and connection are perceived as significantly more natural and comfortable.

Operatively, the nerve transfers can be performed by appropriately trained surgeons in the course of implantation. The subsequent rehabilitation then covers both the interventions described above to increase strength, mobility and load as well as the TMR-specific training of the newly created myosignals. Structured signal training using EMG biofeedback is particularly important [13]. Because both osseointegration and TMR are very complex in terms of surgery and rehabilitation, the authors recommend that new centres should first gain experience with both techniques separately before using them together. The team of authors had already performed and rehabilitated more than 30 TMR operations before this technique was combined with osseointegration.

In the context of orthopaedic fittings, it is necessary to ensure that all of the (up to six) surface electrodes are precisely placed in a socket. Although in principle, adhesive electrodes can also be used, correct placement becomes more challenging as the number of signals increases. Therefore, a



Fig. 4 Mechanical prosthesis set-up for agricultural activities requiring the fixation of objects with a large amount of force and vibration.

fitting with a small silicone socket has proven better for the authors' patients. Here, too, it is recommended that the fitting is carried out by orthopaedic technicians with previous experience.

Conclusion and outlook

Although osseointegration is a relatively new option for transhumeral amputees, it is very popular because of the clear advantages for the patients. Due to the still limited experience and the risk profile, as well as the relatively complex rehabilitation, it is recommended that the indication is chosen carefully. Patients must meet the relevant health requirements and should be cooperative and sufficiently motivated both to enable rehabilitation with few complications and to comply with the necessary measures such as regular hygiene. If desired and appropriate, combined treatment with targeted muscle reinnervation (TMR) can be performed at the same time. As such, not only the mechanical interface to the prosthesis can be improved, but the prosthesis control can also be made easier and more intuitive.

However for current prosthesis controls with surface electrodes, it is not yet possible to do without some kind of socket to fix the electrodes to the residual limb. In the future, this is where implanted electrodes could provide a remedy. Although some systems are already being tested in research, it is not expected that they will find their way into everyday clinical use in the near future [14].

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For the authors:

Dr. scient. med. Agnes Sturma, MSc Klinisches Labor für Bionische Extremitätenrekonstruktion Medizinische Universität Wien Währinger Gürtel 18–20 1090 Wien, Österreich agnes.sturma@meduniwien.ac.at

Bachelorstudium Physiotherapie FH Campus Wien Favoritenstraße 226 1100 Wien, Österreich agnes.sturma@fh-campuswien.ac.at

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The ICRC Physical Rehabilitation Programme (PRP) strives to meet the basic physical rehabilitation needs of people with disabilities affected by conflict and other situations of violence and to do this in the most prompt, humane and professional way possible. These basic needs include access to high-quality, appropriate and long-term physical rehabilitation services and to effective and comprehensive social inclusion services. In the conflict-racked countries where the ICRC works, it is not only people directly affected by the conflict (those injured by landmines, bombs and other ordnance) who need physical rehabilitation and social inclusion but also people indirectly affected – there is usually an increase in the prevalence of communicable and non-communicable diseases that lead to dis-



PRP has supported more than 300 projects. More than 2 million persons with disabilities have benefited from physical rehabilitation services. ability and people who are or become physically disabled because the breakdown of normal health services prevents them from receiving proper care. The projects assisted by the ICRC offer services to all those in need.

Since 1979, PRP has supported more than 300 projects in over 100 countries. More than 2 million persons with disabilities have benefited from physical rehabilitation services. The PRP employs today over 1.000 staff across 41 countries. Nearly 300.000 persons benefited from the ICRC physical rehabilitation programme in 2021, either through direct support or through partnership with local structures.

Sustainable Humanitarian Impact

PRP accomplishes its mission through a multidisciplinary, twin track approach that focuses on delivery of person-centred services (at the point of delivery) while also, addressing the structural needs of the systems within which it works (national level). At the service level, ICRC staff work on building clinical, technical and managerial competence, within its or its partner's workforce, with the overall aim of improving access to quality services. Furthermore, ICRC recognises that in fragile contexts, social structures can fail to provide assistance to persons with disability, leaving them feeling marginalized and a burden to their family. Hence, the ICRC's social inclusion programme, which complements the physical rehabilitation process, supporting a person's reintegration into society. To help in this journey, the ICRC offers various opportunities including access to education, vocational training, starting



The digital tool DCMS is based on two open source applications.

a business and even sport. Where once, they may have felt a burden, our service users are often the ones supporting their family and contributing to society. At the national level, ICRC works in areas including national legislation, continuum of care, professional recognition, formal education and supply chain. It is only by implementing this multi-level approach that the sector as a whole will be strengthened, and ICRC's interventions may be sustainable.

System strengthening is a marathon rather than a sprint. In order to fulfil its commitment to addressing the needs of people wounded by weapons and persons with disabilities affected by armed conflict and other violence, the ICRC PRP is developing novel funding strategies, and partnerships with other actors from humanitarian and development world to get its programmes running and evolving.

The world is in constant evolution and it is also true in the humanitarian field. New solutions are always needed to constantly better address the specific needs in low- and middle-income countries, and countries affected by conflicts. The ICRC is therefore deeply involved in Research & Development projects for innovative approaches, advanced digital solutions and new Prosthetic & Orthotic products.

Some innovative developments within the ICRC:

A digital solution to support efficiency

The ICRC is developing a comprehensive digital solution to support data management for physical rehabilitation service providers. The digital tool called the Digital Centre Management System (DCMS) is based on two open source applications. It includes an Electronic Medical Record (EMR) on Open-MRS and an Enterprise Resource Planning platform on Odoo (ERP). The EMR allows the collection of a wide range of information about service users, service delivery and referrals, assessment and evaluations, outreach, follow-up and repairs, and provides professional dashboards, work scheduling and tracking, and an appointment system. The ERP supports the management of a physical rehabilitation centre through offering a digital solution for supply chain, stock management and purchases, manufacturing, invoicing, maintenance and human resources management.

The DCMS will offer physical rehabilitation centers the benefit of a digital tool that allows for more efficient and cost-effective management in a transparent, auditable and standardized way.

A partnership with persons with disabilities for persons with disabilities

The ICRC established a new partnership with the foundation Alfaset to manufacture its product range. Alfaset is a non-profit organization, offering socio-professional support by providing workplaces across various fields as well as adapted housing to persons with disabilities. The Rehab Impulse brand was born from this win-win partner-



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ship where persons with disabilities in Switzerland manufacture prosthetic and orthotic components for persons with disabilities in humanitarian settings or development contexts. It aims at consolidating the social business model between our two institutions. The brand, which belongs to the ICRC, is also used as a platform for all commercial activities as well as for manufacturing or research and development partnerships with other actors in the field of rehabilitation or academia. On a long-term perspective this model will ensure the sustainability of ICRC-supported projects as it allows our partners and other actors in the field (governments, NGOs, etc.) to purchase appropriate componentry and equipment at a reasonable price level.

A polycentric knee joint in the spirit of our technology

A newly ISO certified polycentric knee joint is now available for adult amputees. It has been designed to provide improved stability throughout stance phase and smooth progression during swing phase with increased toe-clearance. With integrated extension assistance, it provides an extensive bending angle of up to 165° with increased stability when kneeling. The polycentric knee joint is intended for prosthetic fitting of users with activity level K2 (restricted outdoor walker) and a body weight of up to 80 kg (P4). It is possible to adjust the knee stability by simply removing or adding up to 3 spacers behind the bumper. This device has been designed for a lifespan of up to 3 years and is intended for single use only. The product is already distributed and in use in all our programs worldwide and receiving very positive feedback from users.

The prosthetic foot is composed of an injection-molded ankle part made of an innovative but cheap highperformance material.

tect the rigid elements above, finished with a high-density foam anatomically-formed cover.

The prototype has already been tested by an independent certification laboratory in France that measured its performance and asertained that it corresponds to the targeted 3rd level of the mobility scale (K3). Currently ICRC is conducting long-term large-scale field tests in different contexts to prove its clinical relevance in areas where people cannot afford high-end products. In this regard, 200 prototypes have been produced and trials are proceeding, monitored and documented by ICRC staff and our partners.

These developments are harmonious with the continuity of the ICRC's programmes, and aim to be affordable, of high quality and sustainable. With the support of well qualified rehabilitation professionals, they will contribute to the continuous improvement of services and making a difference to the lives for persons with disabilities in LMICs and places of conflict.

François Friedel PRP Coordinator,ICRC, Genf, Schweiz with the contribution of the ICRC physical rehabilitation team Contact: ffriedel@icrc.org



The ISO certified polycentric knee joint is available for adult amputees.

An affordable dynamic foot, soon to be available

The goal was to develop, industrialize and launch a new dynamic prosthetic foot that will be a real game changer in low-resource settings. A joint project between the Polythechic School in Lausanne, Switzerland and the ICRC, a prototype has been developed that will cost less than 100 CHF (107 USD) to manufacture once industrialized.

This new prosthetic foot is composed of an injectionmolded ankle part made of an innovative but cheap high-performance material, a carbon blade with a very simple shape to keep the cost low, a foam filling to proNearly 300'000 persons benefited from the ICRC physical rehabilitation programme in 2021, either through direct support or through partnership with local structures.



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Prosthetics

K. Stahl

Complications When Controlling Lower Limb Prostheses in Persons with Hypermobility Syndrome

In prosthetic treatment of the lower limb, it is possible - even with technically satisfactory prostheses and uncomplicated residual limb conditions - for the patient to experience unsafe standing and walking. When investigating the causes, the presence of a hypermobility syndrome should not be excluded, which affects all joints in the musculoskeletal system, leading to major problems for the prosthesis wearer. A distinction must be made between the hypermobility spectrum disorder (HSD) and the Ehlers-Danlos syndrome of the hypermobile type (EDS-HT). The respective diagnosis can be made based on the Beighton score.

Key words: lower limb prostheses, standing and walking disorders, hypermobility syndrome, HSD, EDS-HT

Introduction

Nowadays, after an amputation of the lower limb - whether forefoot, lower leg or thigh and regardless of the cause (disease, accident or trauma) - prostheses are usually fitted with very high-quality foot and knee joint techniques, liner techniques as well as materials such as carbon. Normally, every available technique can be used in a targeted manner. The patient is fitted with a prosthesis that is customised and adapted to him or her. However, one must almost always expect that the volume of the residual limb area will change and that the prosthetist will have to continuously adapt the socket to the respective conditions of the residual limb. The activity level of the person with an amputation may also change, e.g. from an indoor to an outdoor walker. This may mean that the fitting parts of the prosthesis have to be replaced. Generally, this takes place under medical supervision. With the help of rehabilitation measures, the patient is prepared and trained for standing and walking with the prosthesis. After a certain "running-in period" (which is different for each patient), the person with an amputation should be able to cope with his or her prosthesis and lead a normal everyday life under the given circumstances.

However, this is still the exception rather than the rule: Many people with amputations do not get along with their prosthetic fitting immediately or at all. Of course, orthopaedic technicians should have made sure in advance that the patient's anatomical conditions have been taken into account and that all regulations have been observed in the construction of the fitting parts. It is true that it always depends on the residual limb conditions,

- whether the socket has a good hold,
- whether the volume is constant,
- whether the prosthesis adheres to the residual limb and does not draw air with every step and
- whether the foot can roll sufficiently and be brought from the swing phase to the stance phase and thus to a secure knee.

However, patients repeatedly describe limitations regarding the handling of the prosthesis that go beyond this: They often find the prosthesis "very heavy" and complain that they can only lift it with great effort. In addition, patients often complain that the prosthesis socket moves and rotates on the residual limb, causing insecurity when standing and walking.

The various femoral socket techniques (for example CAT-CAM or M.A.S. sockets) [3] have different degrees of adduction to pre-tension ligaments and muscles so that improved biomechanics can be achieved. For transtibial sockets, this is condylar socket safety, as is the case with the KBM socket. But liner technology sockets with a lateral, ventrally higher mechanism in order to stabilise the stance phase of the knee joint also have this feature. In forefoot prostheses, the prosthesis is built up more in a pronation position in order to stabilise the ankle joint.

Question

There are, however, cases where one has to pay attention and do more detailed research into the cause. Because often, it is neither the prosthesis socket nor the orthopaedic technical implementation that is responsible for deficiencies related to the control of the prosthesis. Rather, it is necessary to investigate whether the patient with the amputation possibly has a hypermobility syndrome. The following findings suggest that:

 the femoral stump does not cause the desired pretension of the ligaments and muscles due to the position of the prosthesis socket with the prescribed degree of adduction, and circumduction of the hip makes walking unsafe, so crutches must be used.

- the femoral stump moves and twists in the prosthetic socket with each step.
- the knee joint is in valgus or varus malalignment on the amputated or contralateral side.
- due to a knee hyperextension (genu recurvatum), every step becomes uncertain or almost impossible.
- by making an adjustment to the prosthesis or a movement of the prosthesis tube in a lateral direction standing and walking stability cannot be achieved.
- a strong hollow cross formation leads the patient to an unsteady stance or only being able to walk with support(s).
- the ankle joint of both the amputated and the contralateral side is not stable enough and tilts laterally with some steps.

Hypermobility as a possible cause

Both hypermobility syndrome (HMS) [1] and Ehlers-Danlos syndrome of the hypermobile type (hEDS) [1] are characterised by a congenital disorder

in the connective tissue in a heterogeneous group. The exact cause in both groups has not yet been researched. What is known, however, is that the joints of those affected move beyond the normal range and that there can be increased overstretching and luxation of the small and large joints, which is often associated with various organic accompanying symptoms: For example, in some patients the skin can be pulled far away from the body (hypermobile skin). The same group of EDS connective tissue disorders includes both Marfan syndrome and osteogenesis imperfecta. EDS belongs to the group of rare diseases whose incidence in the population is assumed to be 1:5,000. No statistical value currently exists for hypermobility syndrome. While EDS can be diagnosed and categorised by type with the help of a DNA analysis, this is not yet possible for HMS.

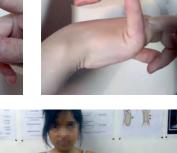
In the field of orthopaedic technology, hardly any publications or studies on the topic of hypermobility syndrome can be identified. Hypomobility, scoliosis [4-7] and hallux valgus are a few topics that have been focused on in recent years [8-12]. At this stage, all that is known is that all soft tissues of the body – especially the ligaments and tendons of the musculoskeletal system – are affected, which means that people with hypermobility syndrome generally have postural abnormalities that are often associated with various dysfunctions.

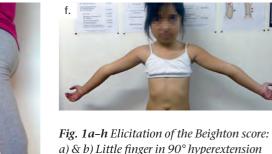
The Beighton Score (Fig. 1) [2], a specific clinical examination, can be used to determine whether there is hypermobility. Eight different joints in the arms and legs as well as one body position are examined – each differentiated into three age groups. If the required number of points are reached according to the respective age group, the hypermobility syndrome can be diagnosed.

Consequences for patients with an amputation

If a patient with a leg amputation has hypermobility, there is an overmovement in all joints of the body. Because of their excess length, tendons and ligaments cannot transmit sufficient force to the muscles, which has conse-







a) & b) Little finger in 90° hyperextension or beyond; c) Body position with palms on floor and knee extended; d) & e) Knee position in recurvatum of 10° and beyond; f) Elbow joints hyperextended of 10° and beyond; g) & h) Thumb parallel to forearm. This results in a total of 9 points on the Beighton score [2].



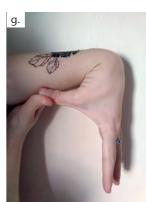






Fig. 2a-e Lower leg prosthesis: a) hypermobility of the ligaments in the knee joint leads to a varus position on the amputated side; b) Bringing the thumb to the forearm; c) Little finger hyperextended in all joints; d) and e) Hypermobile skin that can be pulled away from the body beyond the normal extent.











quences for posture, the residual limb as well as the prosthesis. The adduction position of a femoral socket does not prove useful for the overstretched ligaments and tendons, even if the degree is increased. In addition, lateralisation of the prosthetic tube, including the knee joint, does not allow the transmission of force to the muscular apparatus. The hip can cause circumducted walking on the side with amputation or on the contralateral side in the joint due to its overstretchability. If the skin is affected, socket rotation problems usually occur. The skin can normally be moved longitudinally on the femoral stump by up to 5 cm. In some patients with hypermobility it can be moved up to 10 cm or even beyond this. The rotation of the residual limb in the socket as well as the non-anchoring in the tube area may also be due to the hyper-extensible skin

The hypermobility of the ligaments in the knee joint on the amputated side, as well as on the contralateral side, can lead to a valgus or varus position (Fig. 2a). A hypermobile person with an amputation and a knee hyperextension (genu recurvatum) has problems with knee stability when standing. By adjusting the prosthesis – from the socket to the foot position – attempts are often made to stabilise the knee joint, but this rarely works: So-called "protective limping" can be naturally expected. With a forefoot prosthesis, instability of the ankle joints is usually the problem (Fig. 3). Even if the prosthesis is very well fitted to the residual limb, friction and insecurity can occur with every step. The cause is hypermobility of the ankle joint.

Hyperlordosis as a result of hypermobility

Hypermobile people often suffer from hyperlordosis or spondylolisthesis of the lumbar spine. Amputation of the lower limb can increase the degree of hyperlordosis, especially in people with a transfemoral amputation. In hypermobile people with a leg amputation, the unilateral, but also bilateral positive Trendelenburg position occurs very frequently, whereby both walking and the prosthesis itself are perceived as too heavy. Then, in the case of a double amputation, most patients only have the use of a wheelchair.

In all hypermobile people with leg amputations, all joints, including those on the contralateral side, are overstretchable. This can lead to the patient finding the prosthesis too heavy, even with correct prosthesis technique, good fit and an exact fit of the prosthesis socket. The residual limb moves in the socket and consequently gait and stance stability are not guaranteed.

Options for intervention

Hypermobility – whether HMS or hEDS – is a diagnosis that is rarely made. In the author's practice, every patient is tested using the Beighton score to diagnose possible HMS. It is undeniable that for people with amputations, a particular problem results from the fact that one leg is no longer available as a measurement parameter. It is even more difficult when there are multiple amputations and therefore it is not possible to test all nine points of the Beighton score. Therefore, the author and her team are currently working on a test specifically for people with amputations, which takes this into account. This is where the "KStahl indication" developed by the author can help. With this, the possible displacement of the sacroiliac joints in the direction of the cranial and caudal can be tested. A conspicuous feature of HMS or hEDS is a displaceability of the two sacroiliac joints by up to 2 cm and more. Therefore, if HMS or hEDS is present and the person with a leg amputation is to be fitted with a prosthesis, hypermobility should also be specifically addressed. Special attention should be paid to ligaments and tendons on both sides of the body so that they are placed in exactly the same relationship regarding the tension.

In the author's practice, the body of all patients is extensively measured. This way, the torsion in the pel-









Fig. 3a-e: Forefoot prosthesis: (a) all fingers can be hyperextended; (b) thumb is parallel to the forearm; (c) on amputated side genu recurvatum of approx.15°, which in turn has implications for ankle instability; (d) hypermobile skin; (e) hyperextended elbow joint.



vis can be eliminated by means of special insoles and a seat cushion that are adapted to the needs of the respective patient. This creates a force amplifier on the muscle complex, whereby this muscle strength in turn enables the person with an amputation to lift and control the prosthesis better.

New tests aimed at stimulating the muscles, ligaments and tendons in the residual limb area via a special liner technique are currently being carried out (as of: June 2020). Stabilisation of the joints via knee or hip splints is not effective, as the overload on the overlying joints is too great in the long term and can cause subsequent complications.

Conclusion

The author's practical experience clearly shows how important it is to examine people with amputations for hypermobility. According to her estimates, there is a large number of unreported cases of patients who cannot use their prostheses or cannot use them properly because they are hypermobile. Therefore, in the future, in order to determine the fitting parts, orthopaedic technology should not limit itself to an examination of the residual limb of a person with an amputation with regard to the construction of a functional prosthetic socket or the determination of the degree of activity. Rather, attention must also, and especially focus on the mobility or hypermobility of the patient in order to ensure that there is sufficient muscle strength to allow the prosthesis to be used without further complications.

The author:

Kristin Stahl, OMM MCT System Schlodderdicher Werg 75 51469 Bergisch Gladbach contact@kristinstahl-consulting.com

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Neuro Mobility: Thinking About **Patient Care** in an Integrated Way

Ottobock wants to combine the segments of neuro-orthoses and wheelchairs with a new approach to patient care. In the OT interview, Philipp Hoefer, Managing Director Sales & Marketing DACH of Ottobock Healthcare Deutschland GmbH, explains the concept called "Neuro Mobility".

OT: What patient care model is behind the Neuro Mobility approach from Ottobock?



Philipp Hoefer, Managing Director Sales & Marketing DACH at Ottobock Healthcare Germany.

Philipp Hoefer: The term results from the merger of the Neuroorthotics and Human Mobility business units. Both focus on solutions for patients with neurological diseases such as cerebral palsy, multiple sclerosis, stroke and spinal cord injuries. By combining our internal and customer-related teams in the Neuro Mobility unit, we focus on fitting as a whole and want to meet individual requirements even better in this way. Because in the course of an illness, the demands on medical aids often change. This requires a holistic model that thinks less in terms of "products" as such.

Focusing on the patient

OT: Why is a new concept necessary for this?

Hoefer: In the past, Ottobock had three areas in the DACH region in its "business-to-business (B2B)" operations: Prosthetics, Rehab and Orthotics – corresponding to around 90 percent of our clientèle in terms of distribution. This product-driven division is still common in the market. We want to accompany this in the direction of an integrative concept – ideally actively – that is not oriented towards unit numbers in individual areas, but rather focuses on the needs of the patients and pursues a modern, combined care approach. To illustrate this, we are combining the business areas related to wheelchairs and neuro-orthotics.

OT: What are the benefits for patients?

Hoefer: Many people with neurological diseases use several aids, including splint systems and wheelchairs. Their use depends on how their individual mobility needs can be compensated. Within the framework of the neuro-mobility concept, we now offer and develop corresponding overall solutions as well as products that complement each other. This is because patients – just like orthopaedic technicians and therapists – are not looking for individual products, but for a solution to their overall problem and flexible, compatible supports in everyday life. This is especially true in primary care. Such holistic offers to our customers make our new orientation possible.

From electrode suits to FES

OT: How are medical supply stores involved in the Neuro Mobility model and which products are the focus?

Hoefer: The medical supply stores are responsible for the actual care of the patients. Their employees can directly define the needs of the patients and develop the appropriate care concept. With our Neuro Mobility approach and the associated products and services, we support them in taking an even more holistic approach. These include the new Exopulse Suit - an electrode suit that releases cramped muscles or spasticity with electrical impulses - as well as our products with functional electrical stimulation (FES), the computer-controlled C-Brace orthosis system and orthosis fittings for the construction of Ankle Foot Orthoses (AFOs) and Knee Ankle Foot Orthoses (KAFOs), seating solutions, buggies and active wheelchairs/power wheelchairs. At the same time, these are the products for a more mobile everyday life, and are most often needed and used in combination by patients with neurological indications.

OT: What do medical supply stores need to be prepared for with regard to Ottobock's product range?

Hoefer: Recognising the mobility needs of neurological patients and compensating for them holistically are central elements. In order to realise this ambition, we must



The Bioness L300 Go foot lifter system from Ottobock based on functional electrical stimulation (FES) and is also part of the Neuro Mobility concept.

work together with the medical supply stores to address all target groups in the multi-professional care environment. This includes doctors, therapists, funding agencies, medical services and relatives in equal measure. Of course, we also offer a wide range of holistic training for medical supply store staff.

New structures

OT: Why is a concept such as Neuro Mobility necessary?

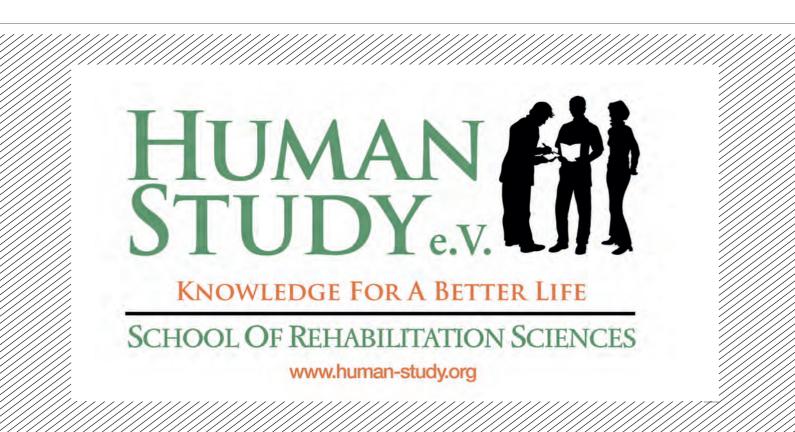
Hoefer: I have been working for Ottobock for 13 years. The demand for integrated concepts has grown strongly, especially in recent years. The patients' demands for mobility in everyday life and social participation have increased – and rightly so. With the Neuro Mobility concept, we meet these needs and we also help medical supply stores and orthopaedic companies to fulfil them in a more solution-oriented manner. The linking of parts for fittings, FES and wheel-chairs is a completely new approach for an industrial sup-

plier. Their combination in individual and adaptable fitting concepts is unique in the market.

OT: How is the Ottobock company changing as a result and what are the next steps?

Hoefer: The associated realignment requires a completely new internal structure in marketing and sales for the DACH region. All processes will be centred on the best possible care for patients. In addition, we see it as our task – together with the medical supply stores and the entire industry – to work for fair and performance-oriented compensation. This is where we as manufacturers can prove the benefits of our concepts with the help of studies. All of us should have the goal of ensuring better care and the participation of patients by means of appropriate aids and as such, to sustainably reduce follow-up costs in the solidarity-based health care system.

Cathrin Günzel asked the questions.



How Can Ankle-Foot Orthoses Improve the Gait Pattern in Children with Cerebral Palsy?

Ankle-foot orthoses are the most frequently used type of orthosis for children with cerebral palsy. The gait of the affected children is quite variable and is determined by the interaction of spasticity, muscle contractures, weakness, compensation mechanisms and changes in bones due to growth. These underlying gait pathologies must be taken into consideration with respect to the alignment and mode of action of the orthosis. This article explains the biomechanics of three common gait problems in cerebral palsy - crouch, equinus and drop foot - and presents the appropriate orthosis for each condition. To achieve the optimal effect of an ankle-foot orthosis on the gait, for crouch gait, it must be noted that the increased knee flexion results primarily from the foot and calf muscles, not from contractures or weakness of the proximal joints. In equinus gait, consistently wearing the orthosis can also lead to improvement when walking without the orthosis. For drop foot gait, the effect of the orthosis stiffness on the proximal joints must also be taken into consideration.

Key words: ankle-foot orthosis, cerebral palsy, ICP, gait analysis, gait pathology, crouch gait, equinus, drop foot

Introduction

Infantile cerebral palsy (ICP) is a movement disorder due to early brain damage, which occurs with a total prevalence of 2-3/1.000 live births [1]. The resulting disability is characterised by primary disorders of the nervous system and, secondarily, of the muscles; it restricts the range of voluntary motor skills and walking ability to varying degrees [2]. Therefore, the affected children and adolescents with ICP are to a greater or lesser extent severely limited in their everyday activities, participation and social life [3]. Functional orthoses are used for persons with ICP to improve their posture and body function and thus to improve activity in everyday life. In children with ICP, ankle-foot orthoses are the most commonly prescribed orthosis types, accounting for 51% [4]. The therapy goals here are the improvement of function (19%), the extent of movement (22%) or both (59%). In principle, the therapeutic goal of the orthoses should be formulated in relation to the individual gait pathology [5]. The most common gait disorder patterns that can be positively influenced by ankle-foot orthoses are crouch, equinus and drop foot (Fig. 1). Of these, crouch is the most common gait disorder, occurring in 72% of bilateral patients [6]. In patients with unilateral pathology, crouch is less common (37%), but walking with drop foot is more frequent in 64% of patients [7]. These three gait disorders described can occur individually, but also in combination.

In the first section of the article, the clinical relevance, biomechanics and underlying causes of the three gait disorders above (crouch, equinus and drop foot) are explained. In the second section, the effect of the appropriate orthoses in changing gait disorder is presented on the basis of the literature and our own data, and the individual indications are discussed.

Crouch gait

Crouch gait is characterised by walking with flexed hip and knee joints [8], shown as an example in Figure 1a. This gait pattern leads to higher energy consumption and is associated with increased stress on the knee joints [9]. Crouch gait in ICP can have many causes, most of which occur in combinations; from distal to proximal:

- walking on the heel (heel foot)
- knee flexion contracture at the knee joint, and/or shortening of the knee flexors, weakness and excess length of the knee extensors and
- flexion contracture of the hip joint [8]

Heel foot in particular can be corrected with ankle-foot orthoses. The heel foot position in the stance phase is mainly caused by a weakness of the calf muscles. This can exist primarily or occur iatrogenically after unnecessary or excessive Achilles tendon lengthening [8]. In the middle of the stance phase, due to the insufficiency of the calf, the forward tilt of the lower leg cannot be controlled and a crouch gait develops. Mechanically, the force vector thus moves behind the knee axis and loses its knee extending effect. The positions of the force vectors during normal and crouch gait are illustrated in Figure 2a and b. This mechanism is known as "plantar flexion knee extension coupling" [10]. A footrelated causal pathogenesis is also given if there is an extreme equinus position or instability in the midfoot or



Fig. **1** *The three most common gait disorder patterns in cerebral palsy: (a) Crouch gait, (b) Equinus gait, (c) Drop foot.*

if the foot is twisted strongly inwards or outwards relative to the direction of gait or the knee axis.

Equinus gait

In equinus gait, there is permanent plantar flexion of the ankle joint in the stance phase. This gait pattern is also known as "toe gait" due to the accentuated forefoot load. However, this term is misleading because although the affected patients step on the forefoot, the toes lie flat on the floor. In addition, the heel can certainly be stressed if the knee is hyperextended. However, this hyperextension of the knee is rarely observed when walking and is most apparent when standing (Fig. 3). The figure also shows that patients with equinus have problems standing upright. In addition, stability is lower due to the reduced support surface. The accentuated forefoot stress during walking leads to an excessive flexural load on the midfoot [11]. If the foot then yields in the sagittal plane, this is called "breakdown" [12]. Similarly, the aforementioned crouch gait can also lead to predominant forefoot loading when walking. A personal experiment can help clarify this: If you squat down low from a standing position, your heels usually lose contact with the floor. For this reason, it is not generally possible to conclude from walking with forefoot contact that this is equinus gait, but rather the position of the knee joint should always be taken into account.

Drop foot while walking

In drop foot gait the foot lift in the swing phase is reduced or absent. This often leads to forefoot contact instead of normal heel-first contact in the subsequent foot strike. The reduced floor clearance in the swing phase increases the risk of tripping. In patients affected unilaterally, compensatory movements of the opposite side

can lead to overloading. The difficulty in foot lift can often be interpreted from the wear on the tip of the shoe. However, increased shoe wear does not always have to be caused by drop foot, but can also be caused by insufficient knee flexion during the swing phase if the gait pattern appears "stiff" [6]. The reduced foot lift in the swing phase is usually also caused by weak foot dorsiflexion. In children with ICP, however, there is no direct correlation with weakness of dorsiflexion of the foot, since the spasticity of the calf muscles with the possibility of contractures also contributes to reduced dorsiflexion in the swing phase [13]. Even strong dorsiflexion muscles can only lift the foot as far as the contracture of the calf muscles allows. However, pronounced contractures of the calf then involve equinus gait as previously described, which dominates both the stance and swing phase. In case of a manually determined weakness of the foot dorsiflexion muscles, it is therefore important to assess not only shoe wear but also foot lift during the swing phase of gait. With reduced selectivity of the foot dorsiflexion muscles, it is quite possible that manual foot lift in a sitting position can only be carried out at all or better with simultaneous hip and knee flexion; this phenomenon is known as the "confusion test" [14]. Despite differentiating clinical testing with the "confusion test", the actual lifting of the foot during walking cannot be predicted in ICP [14]. It has also been shown that the dorsal extension of the foot can be significantly improved during running as compared with walking [7].

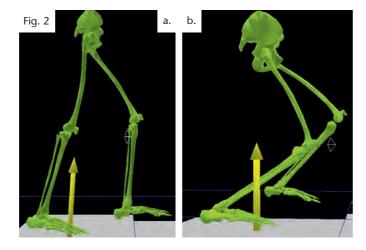




Fig. 2 Position of the force vectors during normal gait (*a*) and crouch gait (*b*).

Fig. 3 Patient with bilateral equinus with problems standing upright. In the left leg the knee is hyperextended and the right leg is kept flexed.



Fig. 4 Floor reaction orthosis with ring-shaped foot receptacle. The red arrows illustrate the effect of the floor reaction forces on the ankle-foot. The release of the joint results from the pathology of the foot: In the case of equinus, plantar flexion is blocked and dorsiflexion is released by 5°. With heel foot, dorsiflexion is blocked and plantar flexion is released by 10°. In combination with the orthotic shoe, the aim is to achieve a 12° forward position when walking.

Orthotic therapy of crouch gait

The functional therapeutic goal of an orthotic appliance in this case is improved straightening from the crouch gait. Especially in patients with weak plantar flexors, an orthosis known as a floor reaction orthosis can support the weak calf muscles. With a floor reaction ankle-foot orthosis (FRAFO), the passive dorsal extension is limited. The forces applied via a rigid foot plate are transmitted to the lower leg via a ventral support (Fig. 4). This controls the forward movement of the lower leg in relation to the foot during walking and shifts the force vector forward so that it has a greater knee-extending effect. The corrective effect of the orthoses may be limited in ICP patients due to spasticity, contractures and weakness of the series of proximal joints [15, 16]. The effect of knee-extending orthoses has been investigated in the literature in four studies on patients with ICP of varying severity [15-18]. In review, it is noticeable that the straightening in the knee joint works better in poor walkers with lower walking speed. According to the data available, a patient with GMFCS III can be expected to improve knee extension by 17° on average, while better walkers with GMFCS II only achieve an average of 4° [16], see the patient example in Figure 5. Several reasons concur to provide an explanation:

- Firstly, the poor walkers in the study had significantly lower plantar flexion strength, showed a helicopod gait and evidence of a decompensated midfoot. These pathologies contribute to crouch gait and can potentially be compensated very effectively by a sufficient angle-foot orthosis.

- Secondly, poorer walkers showed increased knee flexion when walking in the stance phase; despite average straightening of 17°, complete knee extension was not achieved. In good walkers with GMFCS I and II, hip and knee flexion contractures of more than 15° are an exclusion criterion for orthotic therapy, since complete straightening cannot be achieved orthotically [15].

In summary, it is evident that a floor reaction orthosis can achieve good

effects in knee extension with insufficient calf muscles and unfavourable foot lift, but only as far as the individual contractures allow. Furthermore, passive knee extension could be improved with knee-spanning night positioning splints. If this overnight positioning is not accepted and/or does not result in an improvement, surgical bony correction to improve passive knee extension can be considered. A suitable technique in such cases would be growth control by ventral epiphysiodesis or extension osteotomy.

Orthotic therapy of equinus gait

Insoles with heel elevation are advantageous in order to create a larger contact surface with equinus gait and to reduce the pressure on the forefoot as well as the bending loads on the midfoot. In the opinion of the authors, these are indicated when there is bony deformity or equinus without shortening of the calf muscles. With ICP however, the reasons for equinus gait in most cases are shortening and/or spasticity of the calf muscles. The equinus posture can be improved with lower leg orthoses. The orthoses block plantar flexion and are con-

Fig. 5 Patient example of a good effect (a) and a low effect (b) of a floor reaction orthosis for crouch gait.





Fig. 6 Orthoses for correction of equinus with plantar lock for day and/or night therapy. They can be additionally equipped with gas springs to increase the stretching effect in dorsiflexion.

structed with a dorsal support (Fig. 6). With such an orthosis, the equinus posture in the stance phase can be improved by 12° on average [19]. By successive correction and consistent wearing time (more than 6 hours per day, wearing time more than 3 months), the sole angle can be improved in terms of initial floor contact to achieve normal heel contact with barefoot loading [20]. Positive effects have been demonstrated in children with ICP [21], but also with idiopathic equinus gait [22]. The effect on the improvement of dorsiflexion in the stance phase is 2° on average after three months of stretching therapy. In a recent study in the authors' clinic, the same mean value of 2° was confirmed. This sounds like relatively little - in individual cases, however, up to 8° improvement could be demonstrated. But the prerequisite for improvement was consistent wearing time, which could be analysed in the current study using temperature sensors built into the orthosis. The calculated wearing time of the anklefoot orthosis was 6 ± 2 hours per day on average for all subjects. This corresponded on average to the target of 6 hours, but was both lower and higher for some study participants. First results of this study confirm that positive effects of stretching therapy on equinus can only be seen after a wearing time of at least 6 hours; below this duration a deterioration of equinus was in fact observed.

The question now arises as to how the effects of stretching therapy can be explained on the muscular level. After three months of stretching therapy with orthoses, imaging ultrasound was used to determine shortening of the muscle fibres and lengthening of the tendon structures [20]. This is understandable insofar as prolonged immobilisation (e.g. with a plaster cast) leads to atrophy of the muscle fibres. In many cases M. gastrocnemius is shortened. As this is a double-jointed muscle, which is particularly influenced by the knee flexion position, it is advisable to combine the overnight stretching treatment with an extension of the knee joint.

Orthotic therapy of drop foot

A common therapy for drop foot is with prefabricated ankle-foot orthoses made of carbon composite material. Advantages of this material:

- High flexural strength with low weight
- Temperature and chemical resistance
- High energy absorption capacity
- Efficient energy return

In addition, no special orthotic shoes are then required. The orthoses can

be fabricated variably – from flexible to hard; various examples from such a product range from two manufacturers are shown in Figure 7.

Besides in their stiffness, these orthoses differ in the position of the support for the ankle-foot, which is with a support ventrally or a calf strap dorsally. The question arises as to which orthosis best helps the patient to improve the individual gait pattern. Compared to patients with isolated peroneal paresis, the pathology of ICP is more complex: Drop foot can occur either in isolation or together with proximal problems such as the crouch and/or equinus gait. In the case of isolated drop foot without proximal problems, which frequently occurs in unilaterally affected patients [13], the possibility of a equinus gait can be initially ruled out. In this case, an individual, stably fabricated orthosis would be necessary to correct the equinus gait, which is usually also prescribed as overnight therapy to stretch the calf muscles. Moreover, it must be clarified whether foot lift is completely absent or whether there is an incomplete partial paresis of the foot dorsiflexion muscles. Given incomplete foot lift when walking barefoot, simply walking with sturdy shoes can improve the swing phase [22]. One



Fig. 7 Product ranges of two manufacturers of prefabricated ankle-foot orthoses made of carbon composite material for foot lift (above: Camp Skandinavia, below: Ottobock) The orthoses can be manufactured variably from flexible to hard. Stiffer orthoses for knee extension have a ventral support, softer ones have a dorsal calf strap.

possible explanation for this is that any remaining toe lift can be better transferred through the shoe to the whole foot. During initial contact, the rear heel elevation of the shoe or a drag heel can also support heel contact. However, after initial contact while absorbing the load, the subsequent absorption by the foot dorsiflexion muscles is absent, so that a loud thud of the foot can often be heard when walking. In pronounced cases, the prefabricated foot-lifting orthoses described above can provide relief [22]. If foot paralysis does not occur in isolation, but in combination with crouch gait, an orthosis with ventral support and a rigid foot plate can have a knee-extending effect in addition to improving foot lift [22].

Study: Analysis in the gait lab

To determine the effects of orthosis stiffness on foot lift and knee extension, 27 patients with spastic cerebral palsy with two orthoses of different stiffness were analysed in the gait lab [23]. A softer orthosis with dorsal support ("WalkOn Trimable 28U11") was compared with a stiffer orthosis with ventral support ("WalkOn Reaction 28U24"). Both orthoses are distributed by Otto Bock Holding, Duderstadt, and are shown in Figure 7. In accordance with Drewitz's recom-

mendation, the orthoses were fitted with additional wedges under the forefoot or hindfoot in such a way that the force vector came to lie slightly in front of the knee in relaxed standing [24].

In the gait analysis of the 27 patients in this study, 15 had an isolated drop foot and 12 of 27 had a combination with a crouch gait. It was shown that the "WalkOn Trimable" orthosis was more suitable for isolated drop foot, since it lifts the foot better in comparison and does not cause knee hyperextension (Fig. 8). However, in the 12 of 27 patients with crouch gait, the "WalkOn Reaction" orthosis was functionally more favourable, since it had an additional knee-extending effect in addition to supported foot lift. The effects on knee extension were, nevertheless, very different, as only patients with calf muscle weakness as the cause of their crouch gait benefited. In patients with a weakness of the plantar flexors, an average of 7° straitening could be achieved with the WalkOn-Reaction orthosis. If, on the other hand, there is an additional weakness of the knee extensors or a shortening of the knee flexors, these cannot be corrected by using a kneefoot orthosis. In general, the weaker the calf muscle strength or the less favourable the foot lift, the better the correction effect of the ankle-foot orthosis.

In summary, it can be concluded that when choosing a ready-made foot lift orthosis, special attention must be paid to its stiffness. An orthosis that is too stiff can possibly also cause unfavourable knee hyperextension. But there is no universal key index for orthosis stiffness – the purpose of use as described by the manufacturer should therefore be followed for orientation. As a simple decision-making aid, the anterior support includes a knee-extending effect. Figure 9 shows a possible therapy scheme for patients with foot lift weakness as a graphical overview.

A disadvantage of all prefabricated ankle-foot orthoses made of carbon composite material is that, when the foot is lifted, they simultaneously restrict plantar flexion while pushingoff with the foot (see Fig. 7). This leads to lower push-off power of the plantar flexors during walking [22]. An alternative therapy option that does not restrict the foot in its movement is the functional electrostimulation orthosis. The foot is lifted in the swing phase by electrical stimulation of the foot's peroneal nerve. In this respect, the results are also promising for longterm training of the muscles and improving the foot position on initial contact [25-27]. In addition, electrostimulation of the tibialis anterior and the peroneus longus / peroneus brevis muscles can improve spastic clubfoot position upon initial contact as well

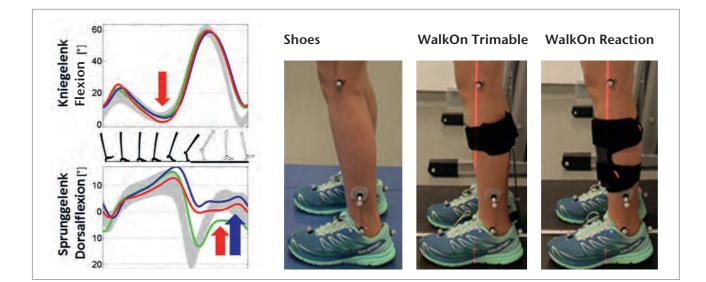


Fig. 8 Knee and ankle joint angles from the gait analysis of 15 patients with isolated drop foot and normal knee extension with shoes (green), and with WalkOn Reaction orthosis (red). The "WalkOn Trimable" orthosis (blue) is more suitable for isolated drop foot, since it lifts the foot better in comparison and does not cause knee hyperextension.

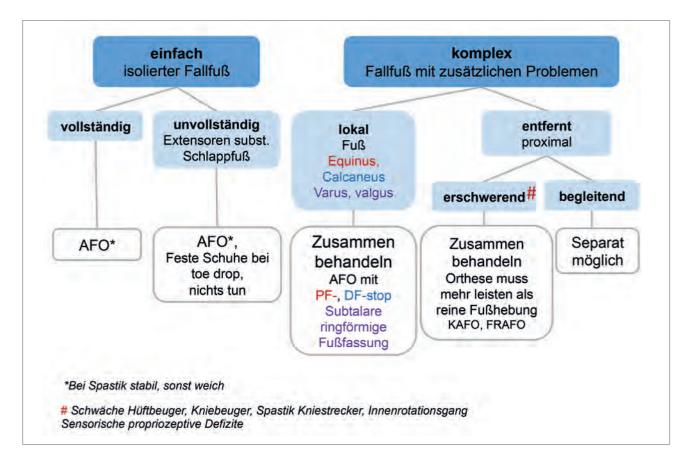


Fig. 9 Therapy scheme for patients with foot lift weakness according to Leonhard Döderlein.

as in the subsequent stance phase [28]. A limiting factor for prescription in practice are the high costs, which are about 10 times higher than those of a prefabricated standard ankle-foot orthosis.

The product range is rounded off by elastic bandages, which also restrict foot movement, but do not have a fixed foot plate and thus may have advantages with regard to sensorimotor function; however, studies on this are not yet known.

Both manufacturers and users also point out that their foot-lift orthoses are particularly suitable for longer walking distances when the ability to actively lift the foot (with support) or their compensation mechanisms for improving floor clearance through muscle exhaustion decline.

Conclusion

To answer the question of what ankle-foot orthoses can do to improve the gait pattern in children with cerebral palsy, the following can be concluded: With pronounced crouch gait and the correct indication (low plantar flexion force and/or unfavourable foot lift), an average 17° improvement in knee extension can be expected with individually manufactured orthoses [16]. In cases of mild crouch gait, a prefabricated orthosis can also improve knee extension by 7° on average if the indication position is correct. [23].

In equinus gait, caused by shortened or spastically overactive calf muscles, individually manufactured orthoses can improve dorsal extension in the stance phase by 12° on average [19]. The associated stretching treatment of the muscle improves the gait pattern when walking without orthoses towards achieving a natural heel strike [20]. Foot-lift orthoses are available in various degrees of stiffness; a stiff appliance can also have a knee-extending effect in addition to foot lift, thus causing unfavourable knee hyperextension during walking in patients with unhindered knee function.

This article describes the improvements in the joint positions during walking; however, it is also important to answer the question of whether improved joint position improves balance, walking speed and endurance and thus extends walking distance. There is good evidence that improvements in walking speed can be achieved, even if only slight, and that energy consumption during walking is reduced [5, 29]. However, ankle-foot orthoses did not improve balance [5]. With all the therapy options presented, three-dimensional foot deformity must not be ignored, but must be included in the design considerations regarding foot receptacle or foot bedding.

For the authors:

Prof. Dr. Harald Böhm Leiter des Ganglabors Orthopädische Kinderklinik Aschau, KIZ-Chiemgau, Bernauer Str. 18, 83229 Aschau im Chiemgau Professur für Biomechanik, Zentrum für Health Care Technology PFH Göttingen, Robert-Koch-Straße 40, 37075 Göttingen h.boehm@kiz-chiemgau.de

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Vocational Training in Germany

Skilled Trades, Technology and Medicine in the **Service of People** in Need of Help

The profession of orthopaedic technician in Germany masters the interface between modern technology and people by combining technology, skilled trades and medicine – including digital process technologies. Working in an interdisciplinary team together with doctors and therapists, orthopaedic technicians provide patients with orthopaedic technical aids. These include artificial limbs



(prostheses), supporting and stabilising splints and bandages worn on the body (orthoses), as well as walking aids and wheelchairs (rehabilitation technology). At the end of their training, assistants can produce state-of-the-art aids themselves, fit industrially prefabricated fitting parts to patients and advise patients and the interdisciplinary team. Applicants for an apprenticeship as an orthopaedic technician should therefore enjoy conscientious work, science and skilled trades using classic and modern materials, and also have a spatial imagination. In addition, they should have a high degree of empathy, with no fear of contact with scars/wounds on the body and the soul of patients. Training companies recommend an intermediate or higher school leaving certificate. However, applicants with a lower secondary school leaving certificate also meet the formal requirements. Those who have already completed a (school) internship in an orthopaedic technology workshop or a medical supply store increase their chances of finding a training place.

Three-year "dual" training as an assistant (on the job vocational training combined with study at a vocational school)

The three-year training to become an orthopaedic technician is classed as "dual" training. The practical part of the training takes place in one of approximately 2,000 training companies that currently provide training in accordance with the German Association of Orthopaedic Technology (Bundesinnungsverband für Orthopädie-Technik, BIV-OT). The theoretical part takes place in one of the 13 vocational schools nationwide.

A training ordinance and a framework curriculum in close coordination

The most recent amendment to the training ordinance dates from 15 March 2013. In the current "Ordinance concerning Vocational Training as a Mechanic in the field of Orthopaedic Technology", the duration of the training is set at three years. It also provides for a two-part examination for assistants and contains the training framework

The practical part of the training takes place in one of approximately 2.000 training companies.



plan, which uniformly specifies the contents of in-company training throughout Germany. In Germany, the federal states have so-called sovereignty regarding cultural matters, which means that each federal state is responsible for legislation concerning schools, higher education and nursery education within its borders. In order to ensure that the training content does not differ too much between the federal states and to guarantee uniformity and comparability of quality standards, the Standing Conference of the Ministers of Education and Cultural Affairs of the federal states (Kultusministerkonferenz) draws up a cross-state framework curriculum for vocationally related teaching at vocational schools. With the resolution of the Standing Conference of the Ministers of Education and Cultural Affairs of 22 March 2015, the "Framework Curriculum for Vocational Training as a Mechanic in the field of Orthopaedic Technology", which is still valid today, came into force. The individual federal states can adopt the framework curriculum one-to-one. Should they prefer to draw up their own curriculum, it must closely follow the guidelines of the Conference of Ministers of Education and Cultural Affairs.

Supplementary industry-wide teaching of apprentices

Because not every training company is able to cover all training contents and incorporate the latest technologies due to its structure, several chamber districts and state guilds for orthopaedic technology offer "industry-wide teaching of apprentices" (ÜLU) as a third training module. Together, companies, vocational schools and – if available – ÜLUs teach occupational and inter-occupational competences that enable the apprentices to fulfil both their specific tasks in the occupation and/or company and to assume social, economic and ecological responsibility (see the diagram on the previous page).

In the second year, the apprentices learn how to make corsages for the trunk.

Planning fittings, manufacturing and adapting

According to the framework curriculum, apprentices also complete 280 hours of instruction per apprenticeship year, mostly in block instruction, i.e. spread over several days or weeks at a time, at one of the 13 vocational schools. The training's 840 teaching hours (in total) is divided into eleven fields of learning. In the first year of training, the following fields of learning are make up the programme: Presenting the profession and the company, manufacturing and fitting orthopaedic foot orthoses, assembling rehabilitation aids and fitting ready-made aids for the lower extremities. In the second year, the apprentices learn how to make and fit individual orthoses for the lower extremities, bandages and corsages for the trunk and orthoses for the upper extremities. They also learn how to make foot and lower leg prostheses. The third and final year of the apprenticeship includes the manufacturing of transfemoral prostheses, the manufacturing and fitting of corsets, the fitting of individual rehabilitation aids as well as the implementation and presentation of individual fittings in the fields of orthotics, prosthetics or rehabilitation technology - depending on the chosen focus.

Skilled trades and state guilds

In 2018, several chambers of skilled trades and state guilds in the field of orthopaedic technology focused on the industry-wide teaching of apprentices (ÜLUs) in addition to company-based and school-based training. They offer industry-wide teaching of apprentices in order to systematically deepen basic and specialised vocational training in workshops. The aim is to achieve a broad, uniform level of training, regardless of the specialisation of the individual training company. The training plan for the industry-wide teaching of apprentices in the field of orthopaedic technology was developed by the Heinz Piest Institute for Craft Technology at Leibniz University Hanover in cooperation with the German Association of Orthopaedic Technology (Bundesinnungsverband für Orthopädie-Technik). The nationwide standardised training plan provides for four course topics: 1) Material processing in the field of orthopaedic technology, 2) handling of patients appropriate to the situation as well as measuring and moulding, 3) modern techniques in the field of prosthetics and orthotics as well as 4) rehabilitation, stoma, incontinence care and anti-decubitus aids. Questions concerning industry-wide

Tools of the trainees.

teaching of apprentices can be answered by the relevant chambers of skilled trades. A list with contact details can be found at: <u>www.zdh.de.</u>

Two examinations – one qualification

Training is deemed to be completed when the two-part assistant's examination has been passed. The first part of the examination is taken at the end of the second year of the apprenticeship and covers the skills, knowledge and abilities learned in the first three semesters of training in the company and at the vocational school. This also includes the preparation of two work samples within six and a half hours. In the second part of the assistant's examination - at the end of the third and final year of the apprenticeship - the trainee must succeed in proving that he or she is able to make and adapt an individual aid, taking into account anatomy, pathology and biomechanics, and to advise patients, doctors and medical, nursing and therapeutic professionals in relation to the aids. In addition to the oral and written tasks, the examinee is given a maximum of 42 hours to carry out an operational assignment raging from planning and implementation to consultation and documentation. In addition, the trainee should be able to present and assess the general economic and social contexts that arise in the world of work. On average, about 400 trainees have passed the assistant's examination every year since 2005 and are allowed to call themselves mechanic in the field of orthopaedic technology. Since 2006, the profession has seen a particularly high increase in the number of graduates. The proportion of female assistants has also developed positively and has recently accounted for 40 percent of the graduates.





Cost expenditure – Earning potential

The expected training allowance is offset by costs for learning materials and travel. The assumption of costs by the public sector for the books that are used in vocational schools varies from federal state to federal state, so that trainees also have to pay different amounts for books and worksheets. In addition to the teaching materials, the main costs include the rent for the flat if the training company is far away from the parents' home, as well as costs for travelling to the training company and to the vocational school. There is no official information concerning training allowances. They are agreed on a company-by-company basis.

Subsidies from the Federal Employment Agency

Trainees can apply to the Federal Employment Agency for vocational training assistance (BAB) if, for example, they cannot live with their parents because of the long distance between their parents' home and the training company. The amount of the vocational training assistance depends on living expenses such as rent, travel costs and work clothes on the one hand and the income of the trainee and his/her parents or partner on the other.

Numerous prospects

National and international labour markets offer numerous opportunities to orthopaedic technicians. Assistants are sought after in orthopaedic workshops all over the world and for international development/cooperation agencies, they are considered an important occupational group in the care of people with limited mobility. At the same time, orthopaedic technicians are in demand as sales staff for manufacturers of medical aids. Those who complete a master craftsman training course after their apprenticeship can become self-employed with their own business/medical equipment supply shop or take on managerial functions in a company. Assistants also have the option of taking up a degree course, for example in business or technical orthopaedics/orthobionics.

On average, about 400 trainees have passed the assistant's examination every year since 2005.

Leadership in a Skilled Trade

A Career with Master Craftsman's Diploma and Seal

Providing patients with assistive technology under one's own responsibility, opening one's own orthopaedic workshop, concluding supply contracts with health insurance companies and taking on management tasks in a large company based on skilled trades or industrial company – the master craftsman's diploma is indispensable for realising these professional ideas. A master craftsman's diploma is awarded to anyone who has passed the master craftsman examination. Those whose qualifications have been recognised as equivalent by the respective master craftsman examination board can also register as entrepreneurs in the register of skilled trades.

The framework for training to become a master orthopaedic technician and master orthopaedic shoemaker is laid down in the Order governing Skilled Trades Act (Gesetz zur Ordnung des Handwerks), better known by the abbreviated term Handwerksordnung (HwO). According to this, both trades are among those which are "subject to registration". Anyone who wants to set up a business must apply for an entry in the register of skilled trades. To do so, the applicant must prove his or her qualification in the form of a master craftsman's diploma for the relevant skilled trade. The master craftsman's diploma not only enables the establishment of an independent business. Anyone who can present a master craftsman's diploma also fulfils the professional requirements to obtain a prequalification – the so-called pre-competitive aptitude test – for the specific field of work of their trade. In turn, pre-qualification is important because health insurance contracts ensure the supply of assistive technology to patients. They also ensure that contracts may only be concluded with contractual partners that "fulfil the requirements for the adequate, appropriate and functionally suitable manufacturing, dispensing and adaptation of assistive technology", as stated in sect. 126 paragraph 1 of the Social Code, book V. Last but not least, the master craftsman's diploma qualifies and allows to properly train apprentices.

Those who do not want to take the risk of starting their own business, but prefer to take on managerial tasks in an existing trade or industrial enterprise, also have the best prerequisites for this with a master craftsman's diploma. This is because training as a master craftsman is not limited to imparting specialist knowledge in the field of orthopaedic technology and technology relating to orthopaedic shoes. It also includes knowledge relating to business management, which is equally indispensable for management tasks as an owner or manager of a company.

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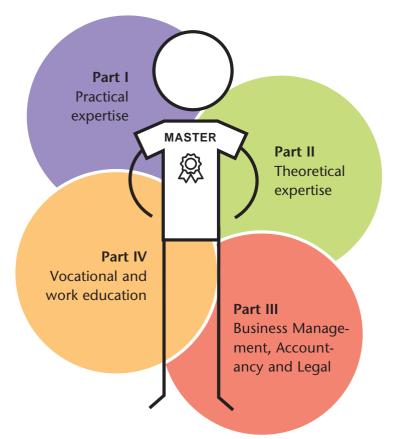
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Master craftsman examination boards are responsible

The Order governing Skilled Trades Act (HwO) (paragraphs 45 to 51) also stipulates the requirements and conditions for master craftsman examinations for trades that are subject to registration. In accordance with the Order governing Skilled Trades, the five-member master craftsman examination boards are responsible for master craftsman examinations. As a rule, they are set up by the chamber of skilled trades of the individual chamber districts and have their main office registered as a state examination body at the respective chamber of skilled trades. In exceptional cases, the supreme authority of the federal state sets up master craftsman examination boards beyond the chamber district borders or several supreme authorities (at the level of the federal state) agree on an examination board across the federal states. The members of the master craftsman examination boards represent the various technical and business competences required in the examination. The committee is chaired by a person who is not a member of the trade being examined. Section 49 of the Order governing Skilled Trades regulates who is admitted to a master craftsman examination. According to this, it is not just mechanics in the field of orthopaedic technology that can take a master craftsman's examination, but also assistants of related trades subject to licencing or corresponding recognised training occupations as well as graduates of technical schools. These must prove their professional experience in the trade that is to be examined. Whether one of these criteria applies to the respective master craftsman examination candidate is checked by the chairperson of the respective master craftsman examination committee following the registration. If the chairman does not admit the candidate, the examination committee decides on the case.



From assistant to master craftsman

The master craftsman training is divided into four topics: Practical technical knowledge (Part I), theoretical technical knowledge (Part II), business administration, accounting and law (Part III) as well as vocational and occupational pedagogy (Part IV). The General Master Craftsman's Examination Ordinance requires candidates in Part III (business administration and law) of the master craftsman's examination to complete complex case-related tasks in writing in the following three fields: a) assessing the competitiveness of companies, b) preparing, implementing and evaluating start-up and takeover activities, and c) developing business management strategies. The examinee is given two hours for each of the three tasks. If Part III is about demonstrating business management knowledge from the point of view of a company owner or manager, in Part IV (vocational and work education) the examinee must demonstrate in writing that he/she is able to independently plan, implement and control the proper training of apprentices. Three hours is allowed for the written paper and 30 minutes for the oral paper. This includes elements that enable the examinees to check training prerequisites on the basis of the applicable company, occupational and legal provisions, recruit the applicant, plan the training accordingly, but also promote the independent learning of the apprentices so that they can successfully complete their apprenticeship.

Upon application by the candidates, the master craftsman examination board may decide to exempt the applicant from individual parts of the examination if the candidate has already passed a comparable examination. This applies, for example, to the courses offered by many institutions, examined specialist in running commercial businesses and "train the trainer" (AdA), which can be recognised on application as a passed examination, part III and/ or IV. Similarly, a master orthopaedic shoemaker, for example, who has already passed parts III and IV as a master craftsman, does not have to repeat these two partial examinations if he is also aiming for a master craftsman title in the field of orthopaedic technology.

Wide range of access routes in preparation for the master craftsman examination

Attending a master craftsman course is not a prerequisite for registering for the master craftsman examination. Candidates can prepare for the four parts of the master craftsman examination on their own or book courses at master craftsman schools or chambers of skilled trades. There is a wide range of continuing education options that are available. At some schools, classes are held full-time from Monday to Friday, while others spread the teaching over evenings and weekends. Some schools only offer courses for the subject-specific parts I and II and refer to the respective competent chamber of skilled trades for part III and part IV. At other institutions, candidates can prepare for all parts of the examination. The number of teaching hours per module and the duration of the continuing education/training courses also varies greatly. The costs for the courses, the examination fees and the materials/learning aids are just as varied.

What is HowToTreat?

"HowToTreat" is the international special edition for professional prosthetists and orthotists exclusively for the world congresses "OTWorld" and "ISPO World Congress". The "HowToTreat" magazine is a special issue with articles specifically for O&P professionals. The special edition will be published at the World Congresses of ISPO International and OTWorld – in close partnership with the organising associations.

"HowToTreat" is supported by the following organisations:

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The German Association of Orthopaedic Technology represents more than 2.500 orthopaedic workshops with around 40.000 employees. Each year, the affiliated companies supply more than 20 million patients with aids. Thus, the association represents service providers throughout Germany who permanently treat their patients with the highest standards, driving innovation in the German healthcare market.

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International Society for Prosthetics and Orthotics (ISPO)



ISPO is a multidisciplinary organisation that promotes access to appropriate and equitable rehabilitation, mobility devices, and other assistive technology to improve the quality of life for people with reduced mobility. Prosthetics and orthotics services enable people with limb amputations or physical impairments of their limbs or spine to achieve greater function and independence to participate in society. Alarmingly, according to the World Health Organization, such services are not available to an estimated 9 out of 10 people with disabilities globally due to a shortage of personnel, service units and health rehabilitation infrastructures. To address this, ISPO has worked to develop the prosthetics and orthotics sector worldwide since its inception in the 1970s. As a global, multidisciplinary, non-governmental organisation aiming to improve the quality of life for persons who may benefit from prosthetic, orthotic, mobility and assistive devices, ISPO provides an effective platform for the exchange and communication on all aspects of the science, practice, and education associated with the provision of prosthetic and orthotic care, rehabilitation engineering, and related areas. ISPO has approximately 3.500 members from different professional disciplines in over 100 countries: prosthetists and orthotists, prosthetic and orthotic (P&O) technicians, orthopaedic surgeons, rehabilitation doctors, physiotherapists, occupational therapists, orthopaedic shoemakers, nurses and biomechanical/rehabilitation engineers. \rightarrow www.ispoint.org

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Human Study is a German-based institution offering a unique model of comprehensive education customtailored for practitioners employed in prosthetic and orthotic workshops and clinics. Human Study offers a range of educational programs that are delivered to students by means of blended learning methodology. The methodology is an effective combination of e-learning practices and on-site clinical training. The blended learning methodology allows students to study and at the same time stay productive in their workshop facilities, treating patients and keeping a regular income. Human Study educational programs are internationally recognised Associate (Cat. II) and Professional (Cat. I / BSc Degree) level programs, accredited by the International Society for Prosthetics and Orthotics (ISPO). In addition, Human Study offers a range of short and specialised courses for continuing education (SCOPe). → www.human-study.org

Bundesfachschule für Orthopädie-Technik e. V. (BUFA) (Federal Academy of Orthopaedic Technology)



BUFA is the leading education centre for professional prosthetists and orthotists in the entire German-speaking area. Each year, more than 2.000 national and international specialists from orthopaedic and rehabilitation technology as well as more than 30 percent of young Certified Prosthetists/Orthotists (CPOs) continue their education in various subject areas in around 170 training continuing education offers. In addition to teaching, the range of services includes application research and the development of courses and new teaching concepts. → www.ot-bufa.de

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