HOW TO TREAT

1/19
Kobe Edition

EDUCATION
FROM THE INDUSTRY
FABRICATION
BIOMECHANICS

PROSTHETICS
OSSEOINTEGRATION
INSOLES
3D PRINTING

Peer-Reviewed Papers

Partners:

2019 JAPAN

ISPO JAPAN
International Society for Prosthetics and Orthotics
Japanese National Member Society

Orthopädie.Technik
Bundesinnungsverband

www.howtotreat.world

Visit us at ISPO Kobe

Stand G19, Hall 3

Blatchford is a multi-award winning manufacturer of some of the world's most advanced prosthetic technology, bespoke seating solutions and orthotic devices.

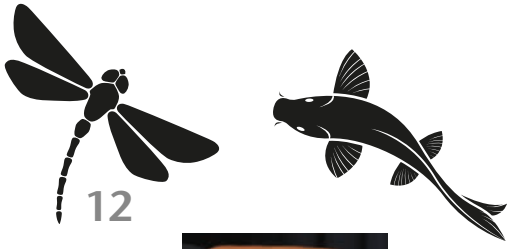
Endolite is now Blatchford

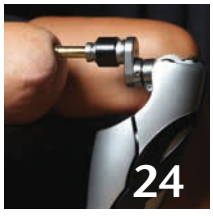
We combine expertise and pioneering innovation to redefine mobility, helping people get more out of every day.

@blatchfordgrp | blatchford.co.uk

Blatchford

Contents





Not to know is bad; not to wish to know is worse

An African proverb states: "Not to know is bad; not to wish to know is worse." This proverb is significant for everyone who is involved in the many aspects of practice related to assistive technology, mobility devices, prosthetics and orthotics. There are always gaps in our knowledge and we are always looking for ways in which we can address and bridge these gaps. As clinicians we have a constant desire to improve our practice and the outcomes for our patients. In order to do this successfully, we need to be able to share our experiences and knowledge and learn from each other and together.

For many years there have been discussions within ISPO, the German Association of Orthopaedic Technology and other circles regarding the challenges of disseminating information which does not fit into the traditional scientific literature. We have an excellent array of scientific journals including Prosthetic and Orthotics International which are an excellent way of sharing knowledge but not everything which is worthwhile sharing is appropriate for an academic scientific journal.

ISPO was delighted to receive the invitation form the German Association of Orthopaedic Technology to work in partnership in the support of a new publication aimed specifically at practitioners in prosthetics and orthotics. We hope that this will fill the current void of communication particularly related to the technical and practical aspects of the art of being a practitioner in orthopaedic technology.

It is envisaged that the journal be available free of charge as a digital version for all members of ISPO and the German Association of Orthopaedic Technology. Special editions in printed copy will also be available at the biennial ISPO World Congress and in the alternating years at the biennial OT World Congress.

On behalf of ISPO I would like to thank the German Association of Orthopaedic Technology for making this journal possible and for all the work associated with the production of this journal. I am very confident that it will be popular as a resource among the prosthetic and orthotic practitioners in the field.

I am very pleased to welcome the readers to this first edition of "HowToTreat" and wish you much enjoyment as you read it and much success in your careers.

Photo: Friedbert Kohler

Friedbert Kohler OAM,
President International Society for Prosthetics and Orthotics (ISPO)

Share experience

Since 1949, the German Association of Orthopaedic Technology has been publishing its monthly expert magazine ORTHOPÄDIE TECHNIK, which has been the industry's leading trade journal for prosthetists and orthotists for the German-speaking world.

Established as the mouthpiece for the industry shortly after World War II, the magazine has continued to evolve for 70 years. Our goal is to keep our readers informed of the latest, state-of-the-art orthopaedic devices and share the expertise on 'how to treat'.

Even though the issue of healthcare is strongly influenced by the national health services of each individual country, we are united across all borders and frontiers by a single question: How can we improve the quality of care for our patients? And, indeed, the requisite progress today needs, more than ever, both global and interdisciplinary networks where we can exchange ideas and experiences.

This magazine HowToTreat aims at actively contributing to this global exchange of experience. I feel proud to say that we have been able to win a truly international team for this magazine.

Special thanks go to ISPO International, with whom we have been preparing the launch of a magazine focusing on the practical work of the prosthetists and orthotists for a very long time.

HowToTreat strives to support the exchange of experience: What could be more appropriate than its launch at the ISPO World Congress in Kobe, where all the experts come together? A digital edition will be made available to the members of the associations free of charge. The next print issue will be published together in May 2020 at the OTWorld 2020, where the experts will meet for the World Congress in Leipzig.

We are very pleased that we have also been able to gain additional international partners. For example, both the Bundesfachschule für Orthopädie-Technik (BUFA) and Human Study will contribute their know-how. The latter are particularly proficient in teaching prosthetists and orthotists worldwide and contribute to the fact that we can publish relevant content in the HowToTreat across borders.

I look forward to launching HowToTreat at the World Congress in Kobe – Let's start and share experience worldwide.

Photo: BIV-OT/Ebbert

Klaus-Jürgen Lotz
President Bundesinnungsverband für Orthopädie-Technik
(German Association of Orthopaedic Technology)

3D-printed prosthetic foot:

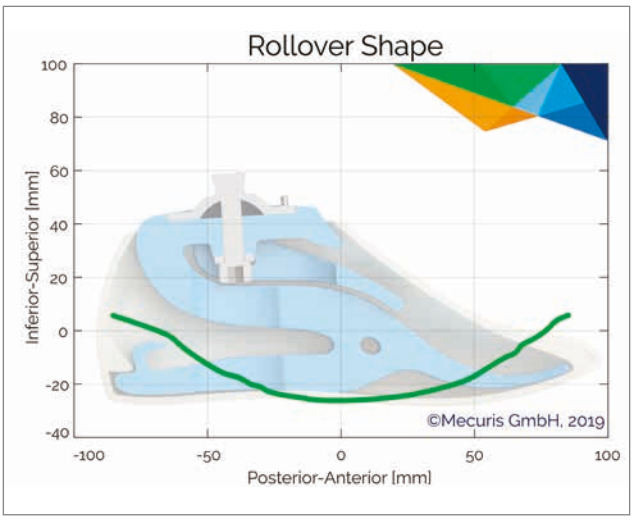
"The foot walks when it is supposed to walk and stands when it is supposed to stand"

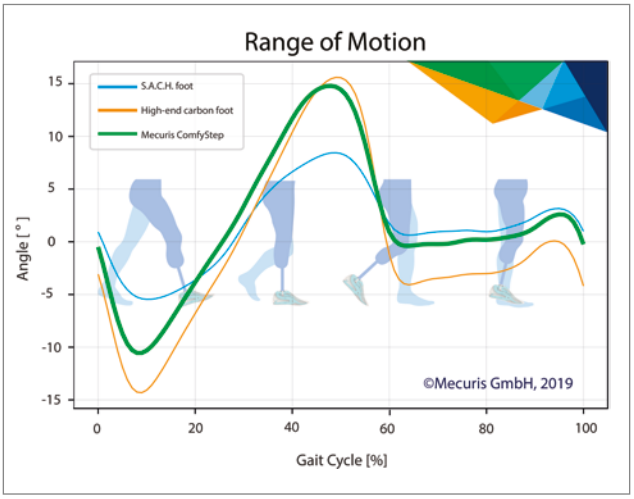
With the Munich based medical technology company, Mecuris GmbH is bringing a new prosthetic foot to market. It is a 3D-printed prosthetic foot to be optimised for both a particularly smooth rollover-shape and a high range of motion in the ankle area. It has been specially developed for all those wearers who want a prosthetic foot for slow to moderate walking speeds or for long periods of standing. It offers good control and a high feeling of safety even on uneven ground.

The approaches to replace the human foot and ankle can hardly be more diverse. It is a highly complex mechanism whose biomechanical properties are difficult to imitate. After the success with the tailor-made 3D-printed pediatric prosthetic foot FirStep and the water-resistant, sauna-proof NexStep, the company has reached a new level of digital product development in the prosthetic foot sector with the Mecuris ComfyStep – developments that Mecuris is driving forward together with partners in the medical supply industry.

The ComfyStep's innovative design has been developed from a highly complex metamodel based on Finite Element (FE) Simulations and has been validated and certified by virtual and physical tests. The resulting model is optimised for a particularly smooth rollover-shape and also offers a high range of motion in the ankle area (dorsiflexion-plantarflexion), completely without complex hydraulics or other sensitive technology. The prosthesis is designed to initiate the rollover immediately upon heelstrike and provides smooth progression to terminal stance without additional energy from the wearer. In addition, the precise control over the foot is perceived by wearers as positive in their own walking comfort: "The foot walks when it is supposed to walk and stands when it is supposed to stand" describes a test wearer. It is 3D-printed in one piece with four interlocking spring systems.

Photos: MECURIS GmbH





The split-toe design offers high stability (medial-lateral) and provides safety, even on uneven terrain. "It's even possible to walk backward easily and balance on one leg – I couldn't do that for a long time," another test wearer was pleased to confirm.

In summary, the foot contributes to a natural walking and standing feeling at moderate speeds or when standing for long periods of time. This is rated by numerous users as particularly pleasant and relieving for knees and hips and is currently being validated in a gait lab study. Due to its construction and performance, the foot is suitable for both transtibial and transfemoral amputees in mobility class 2–3 (K2–3). It is worn in a foot shell (10mm heel height) and available in the lengths 23–29cm (EU) for patients with a maximum weight of up to 125 kg.

New Brand, New Values

Blatchford presents its new brand at ISPO World Congress, Kobe

For over 20 years, Blatchford has operated under the Endolite brand for the distribution of its prosthetic components in the US, France, Germany and Russia. What was perhaps lesser known was that Endolite was a subsidiary of Blatchford, the second largest provider of prosthetic care in the UK and a leading prosthetic manufacturer. Over the last five years, the company has continued to expand, establishing subsidiaries in both Norway and Turkey, as well as increasing its distributor network around the world.

In 2015, Blatchford set goals to double its turnover by 2020 and again by 2025, with the aim of becoming a top 3 global supplier of prosthetic components. In late 2018, in order to support this investment in growth, Blatchford agreed the sale of a majority interest to CBPE Capital, with Stephen Blatchford taking up a role as a non-executive director and the company continuing to be led by CEO Adrian Stenson.

The company underscores this ambitious step with a brand relaunch that aligns Endolite under the single worldwide Blatchford name, redefines its focus on its business values and the introduction of new innovations.

Kirsten Abel, editor of 'HowToTreat', visited Blatchford and spoke with Adrian Stenson about Blatchford's plans for the future. 'HowToTreat' publishes a section of the interview here:

Kirsten Abel: Let's speak about your company values. Values form the foundation of the company culture and help position you in your stated ambition of becoming a top 3 global supplier. How are things changing?

Adrian Stenson: The values are very important to how we define ourselves as a business. 'Integrity', 'Innovation', 'Collaboration' remain as strong as ever, but we have updated 'Excellence' to 'Performance', reflecting better the passion and drive within the organisation and our continued commitment to every customer. In the past we saw the values more as an internal tool: how we work with and treat one another within the business. We are now extending the values out to our customers as an external reflection of who we are. We strive to have the highest performing products and want to be measured on that by our customers, whether that's delivery performance, the quality and reliability of the product, or the outcome it achieves for the wearer.

Kirsten: To re-establish the values was an important step in the new branding. What does a renewed focus on 'Innovation' mean to Blatchford?

Adrian: The fabulous idea generation in our Research & Development team has allowed us to produce award-winning products like Echelon, Elan and Linx, the world's first and only fully integrated limb system. While we are particularly strong in innovating ideas, we intend to get better at harnessing those ideas and bringing them to fruition as new products more efficiently than we have in the past. We have always been very patient-driven and make no apology for that, but we also need to remain mindful of the needs of the whole market – the clinician, the payer and so on.

Adrian Stenson, *CEO of the Blatchford Group: After qualifying in Prosthetics and Orthotics in 1986, Adrian has worked in both the private sector and within the NHS as an orthotist. He currently represents the Prosthetic and Orthotic sections of the British Healthcare Trades Association (BHTA); chairing the Orthotic section and leading the subgroup on orthotic tariffs. He is a former Treasurer and Executive Committee member of the British Association of Prosthetists and Orthotists (BAPO) and a former Chairman of the Trustees of the Orthotic Education Training Trust. In addition to his clinical qualification, Adrian holds a Diploma in Company Direction and is a Fellow of the Institute of Directors.* Photo: Blatchford Group

Kirsten: In today's world of 'innovation', the term 'big data' plays a very important role. How do you see developments regarding this?

Adrian: There is an understandable and increasing requirement within the medical devices arena to ensure everything we do is safe, appropriate and represents value for money. While we'd all agree with the principles, much of the testing involved, by its nature, is standardised and somewhat artificial. For example, we may cycle-test an item 3 million times, but we know it is unlikely this accurately reflects real life. Every wearer is an individual; they have their own unique walking style, their own activities. Some may go up and down stairs a lot, others live in a hilly environment or on the flat. With connected microprocessor products, we have enormous potential to collect information and design limbs for the way people actually use them.

There is the potential for all the suppliers to contribute to a vast source of data that could provide compelling evidence around the benefits prosthetic components can provide, for example reduced trips, stumbles and falls. Our challenge as manufacturers is to do that in a safe, responsible and ethical way in an area that is just evolving. We should use the information to better inform payer decision-making, as well as helping us to design ever-improving products and enhance quality of life for the wearer.

Kirsten: Adrian, thank you for the interview.

Blatchford

The new company logo

Today

More than **1 billion** people in the world need assistive technology

970 million need glasses and low vision aids

35 million people need prostheses or orthoses

75 million people need wheelchairs

94 million people need hearing aids

150 million people need mobility aids

150 million people need cognitive aids

but only **1** in **10** have access to the products they need.

Why ?

High cost of products

Lack of skilled workforce

Lack of policy & standards

By 2030

More than **2 billion** people will need assistive technology

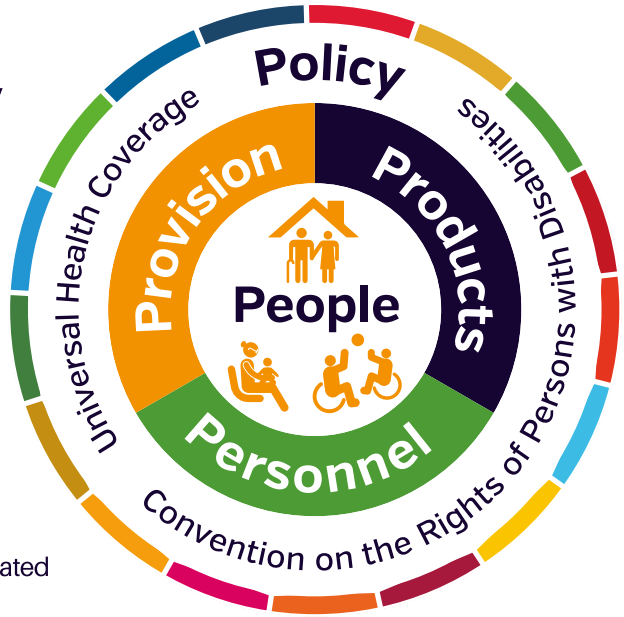
WHO is making UHC inclusive

Policy Support countries in developing national policy and standards

Products Support countries in developing a list of national priority assistive products

Personnel Support countries in building the capacity of their community-level workforce

Provision Support countries in developing integrated models of service provision



to ensure access to assistive technology for everyone, everywhere

The GATE Initiative

World Health Organization

Photo: AdobeStock: skylarkstudio

SAVE THE DATE!

2021 MÉXICO

ISPO

18TH WORLD CONGRESS
Guadalajara, Mexico

19 - 22 April 2021

ISPO
INTERNATIONAL SOCIETY FOR PROSTHETICS AND ORTHOTICS

www.ispo-congress.com

Yukio Agarie

Introduction of the Department of Prosthetics & Orthotics and Assistive Technology in Niigata University of Health and Welfare

Photos: Niigata University of Health and Welfare

Niigata University of Health and Welfare was founded in April 2001, for the purpose of training professionals in the fields of health, medicine, welfare, and sports, not only for Niigata but for the future of Japan. The university was founded on the spirit of fostering qualified QOL supporters. The Department of Prosthetics & Orthotics and Assistive Technology was created in 2007 as the 9th prosthetics and orthotics training school in Japan. Each class has a capacity of 40, and there are currently 159 students enrolled. As of April 1, 2019, the department has graduated a total of 379 students over 9 graduating classes. At the graduate school, there are international students enrolled in the master's course and in the doctoral course. In addition, since 2006 Niigata University of Health and Welfare has created an academic exchange agreement with a variety of universities and hospitals and is putting effort into the international exchange.

At the Department of Prosthetics & Orthotics and Assistive Technology, we aim for students to acquire a wide range of cultivation and specialised knowledge and skills necessary for prosthetists and orthotists. In addition, we also foster skills to interpret the role and necessity of prosthetics, orthotics, assistive products and machines based on the mental and physical condition of the subject as well as lifestyle and societal factors, to logically consider the influence they will have on the QOL of the subject, and the ability to explain specifically as well as basic manufacturing, adjustment, and adaptation skills.

The special feature of the Department of Prosthetics & Orthotics and Assistive Technology is that we conduct courses in prosthetics, orthotics, assistive products, wheelchairs and seating, and shoes based on the current situation of an aging society with a low birthrate. The qualifications students aim to acquire start with the Prosthetist & Orthotist National Qualification, and they are working to acquire certification for Assistive Products Planner, Assistive Products Consultant, Housing Environment Coordinator (Level 2), and Wheelchair Safety Mechanic. Furthermore, we are also striving to teach team medicine and foster talent relevant to the time.

Our university was inspected to obtain the ISPO School of Prosthetist and Orthotist qualification on March 2019. We raise prosthetist and orthotist educational training in Japan to the international standard and to foster talent that will contribute to improving the QOL of disabled persons not only in Japan but worldwide who require prosthetics and orthotics as well as assistive products.

Shin Sasaki

Introduction to Kobe College of Medical Welfare (KCMW) Sanda Campus

KCMW (Kobe College of Medical Welfare) Sanda Campus is the only ISPO recognised school in Japan among 10 schools in the country (4 universities and 6 colleges) as ISPO Prosthetist & Orthotist (formerly Category I) since its first recognition in 2012.

KMCW was established in 1997 with several programs including a Prosthetist & Orthotist 3 year program, and a Prosthetist & Orthotist 4 year program was also established in 2008 which is currently an ISPO recognised program.

KCMW has been providing unique curricula for P&O students to acquire the basic skills and knowledge for evaluation methods and diagnostic methods in Patient Evaluation in their first year and learn the orthotics design based on diagnoses and evaluations in Seminar for Orthotics Management in the second year. Following their second year of studies, students gain experience performing physical evaluations with actual patients in the course of Clinical Placement. They also consider the patient's orthotics therapy and provide alternative proposals. Students work together with students from other disciplines such as physical therapy, occupational therapy and speech-language-hearing therapy and discuss how each discipline would approach several patients with representative medical conditions. This series of courses is useful in the training of Prosthetists and Orthotists who can provide accurate advice to medical professionals and patients with regards to prescribing P&O devices.

KCMW is also the only school in Japan providing training course of orthopaedic shoemaking, therefore P&O students are also able to learn the techniques of orthopaedic shoemaking as the subject is a part of curricula for the P&O students.

KCMW plays great role for the ISPO World Congress 2019 in October in Kobe. All of the lectures and students from the P&O departments officially registered the congress together with daily volunteer work at each location.

Photos: Kobe College of Medical Welfare

要約

D.ホッホマン
D. Hochmann

整形外科技術における
3Dプリンティングの応用

この記事では、整形外科技術における積層造形プロセス開発の現状と展望について説明しています。顕著な利点の説明に加えて、既存の技術的、素材に起因する、また規制上のリスクに関して論じ、完全にデジタルなプロセスチェーンのビジョンを提示します。

p. 45

L.ブリュックナー、M.シェーファー、その他
L. Brückner, M. Schäfer et. al.

大要「下肢装具の品質基準」
からの抜粋

大要「下肢義肢の品質基準」：整形外科技術の複雑性と進歩、およびそれに伴う治療概念の新しい発展は、現代（義肢装具士の）職業資格および現代のワークショップに求められる機器という観点から新たな課題を提示するものです。この品質基準はそんな今日の観点から、専門家が最先端の下肢治療を提供する、またそれを可能にする方法を定義しています。

p. 34

H.バン・デ・メエント、R.A.レイジェンデッカー、C.ワルレ、J.P.フレルケ
H. van de Meent, R. A. Leijendekkers, M. C. Warlé, J.P. Frölke

大腿切断または下腿切断患者のための骨固定式オッセオインテグレーテッド人工装具
血管疾患患者に重点を置いた適応基準

この記事では、オッセオインテグレーションインプラントまたは「骨固定」人工装具を取り入れた大腿または下腿切断患者の適応プロセスを評価しています。血管疾患の結果として下肢切断を受けた患者に重点を置いて、選択基準と除外基準が議論されています。121のオッセオインテグレーテッドインプラントが埋め込まれている116人の患者グループの予備データを取り上げ、 116人の患者グループのうち17人（14.7%）では、血管疾患により体肢切断が行われていました。これら17人の患者（17のインプラント、平均年齢62歳、年齢範囲44〜75歳、女性4名、脛骨インプラント使用患者5名、調査期間の中央値3年、調査期間1〜5年）のうち1名の脛骨インプラント患者には軟部組織感染を伴う血管病状の進行があり、最終的にはインプラントが使用できない状態となりました。血管疾患が理由ではない下肢切断の99人の患者のグループでは、腐敗/非腐敗を理由としたインプラントの緩みや治療不可能な軟部組織感染は見られませんでした。

p. 24

H.トレントマン、O.バーシュ
H. Trentmann, O. Baasch

糖尿病患者のためのフットベッド

糖尿病患者用フットベッド（DAF）は、解剖学的、生体力学的、また特に圧力ポイントに対する神経障害に起因する感度を考慮しながら、数多くの変化を経験していく糖尿病患者の足のために特にカスタマイズされたフットベッドです。その目的は、怪我をしやすい足を保護しながら、患者のモビリティを確保していくことです。これらの要件を満たすには、設計における数多くのディテールが検証されなければなりません。

p. 50

J.S.シーグルザルドッティル、S.P.シーグトルソン、G.ハルドルスドッティル、G.K.ルードビックスドッティル、Th.ヘルガソン、K.レヒラー、M.オッドソン、Th.イングバルソン、K.クリストヤンソン

J. S. Sigurdardottir, S. P. Sigurthorsson, G. Halldorsdottir, G. K. Ludviksdottir, Th. Helgason, K. Lechler, M. Oddsson, Th. Ingvarsson, K. Kristjansson

下肢装具制御のための表面装着式電極 VS 埋め込み式電極

現在の下肢装具は、人間の脚と比較した場合制限があるものです。これらの装具では、可動範囲が限られており、補助的な力を提供することができず、またユーザーが装具にこう動いて欲しいと直接指示を出すことができないものです。ユーザーの神経系との直接的な繋がりを確立するために筋電信号が使用されてきました。これにより、ユーザーは従来の機器が提供できないような形で義肢を制御することができます。たとえば、歩行中の足首の屈曲を意思で制御することは不可能です。しかし、これが可能になればユーザーにとって極めて大きなメリットとなります。この研究では、下肢装具の制御のために、表面式電極と埋め込み式電極が記録した2つの筋電信号を比較しました。また、筋電制御システムの適用性と実用性に関する検証が行われました。現在の段階では、埋め込み式電極は表面式電極を使用するシステムよりも確実に信号を送信し、実用的な筋電制御を提供することがわかりました。

p. 40

J.P.フレルケ、R.アタラー、R.レイジェンデッカー、L.フェアハメ、H.バン・デ・メエント

J.P. Frölke, R. Atallah, R.Leijendekkers, L. Verhamme, H. van de Meent

下腿切断患者のための骨固定オッセオインテグレイテッドインプラント：外科的側面とインプラントの設計

オッセオインテグレーテッドインプラントによって骨に固定された人工装具は、大腿切断後の患者にとって、従来のライナーシステムと比較し、歩行、装具、クオリティオブライフの向上など、いくつかの実証済みの利点を提示するものです。著者のカスタムメイド脛骨インプラントの目標は、CTスキャンを使い脛骨の骨髄内にぴったりと一致するインプラントの形状を開発することでした。最終的に、インプラントはしずく形状に整えられました。この設計の目標は、骨髄内の空間をぴったりと遮蔽することにより、インプラントのゆるみを最大限に防止し、骨髄内空間への細菌の拡散を防止することでした。

p. 18

ラルフ・ベートマン

Ralph Bethmann

大腿切断における オッセオインテグレーション-概要

ほぼ30年間、オッセオインテグレーション（骨にプロテーゼを固定すること）は、大腿切断の場合、従来の残留肢にソケットを埋め込む手法を取って代わるものとなりました。そして特に感染のリスクやインプラントの強度といった、その長所、そして短所は、議論の対象となってきました。この記事は、現在使用されている手法とその客観的に判断し得る合併症率の概要を説明するものです。

p. 14

illustration: iStock_yod67

Osseointegration in Transfemoral Amputations – An Overview

For nearly thirty years, osseointegration, i.e. anchoring the prosthesis in bone, has been an alternative to conventional residual limb enclosure with a prosthesis socket for transfemoral amputations. The advantages and disadvantages – especially related to the risk of infection and the strength of the implant – have been the subject of some controversy. This article gives an overview of the currently used techniques and their objectifiable complication rates.

The term "osseointegration" describes a method used for transfemoral amputations in which a prosthetic body replacement part is attached to the body not in the usual manner using soft tissue tension in a prosthesis socket, but with a metal connector firmly anchored in the bone of the residual limb (Fig. 1 & 2). The advantage of this method is that the load is transferred directly to the bone designed by nature to assume this load, while, in a conventional socket, a great deal of control is lost due to the soft tissue coverage. Although many changes have taken place in recent years relating to functionality with regard to socket shape and adaptation options, the parameter that the soft tissues within the residual limb are not originally designed for load bearing can lead to damage due to excessive stress or sensitive skin. Volume fluctuations are another parameter that can only be compensated for within the prosthesis socket to a limited extent. Movement restrictions due to the shape of the socket brim and discomfort when sitting caused by the socket enclosing the residual limb are perceived to be unpleasant [1]. All of these problems cannot occur if the residual limb is not enclosed in a socket, but rather the prosthesis can be attached directly to the bone anchor. This direct connection also makes controlling the prosthesis more effective and patients report better ground perception.

When a socket is not required, there are thus several reasons why osseointegration can be superior to the conventional method, but there are also limitations [1]. The primary limitation is the potential infection of the bone or soft tissue. The opening in the skin for the connecting cone is a potential entry port for pathogens that can multiply along the osseous anchorage and soften it. There is also the danger of excessive force acting on the bone, which could lead to a fracture in the implant area.

The advantages and disadvantages of osseointegration have been debated for years. However, we now have many objectifiable long-term results that are presented below. The overview is based on a literature search using the medical database PubMed.

When looking at the study results, it must be considered that, except for the meta-analyses, the studies were generally based on only one of the three commercial implants currently available. The oldest and most widespread method is the OPRA system (Osseointegrated Prostheses for the Rehabilitation of Amputees, Integrum AB, Mölndal, Sweden) that was introduced in the early 1990s. Around ten years later, the German endo-exo femur prosthesis (ESKA Ortho-

Fig. 1 *Prosthetic components attached directly to the implant with no socket encompassing the residual limb.*

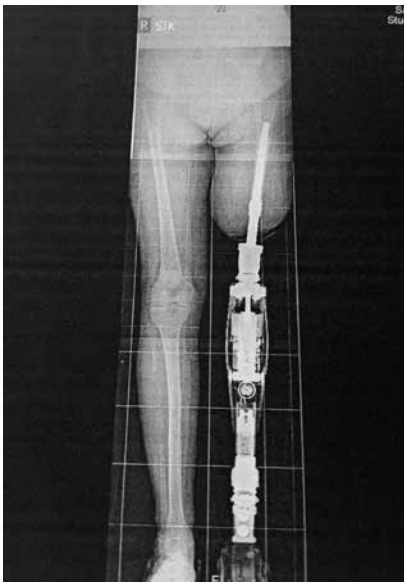


Fig. 2 *X-ray image with implant and attached prosthesis.*

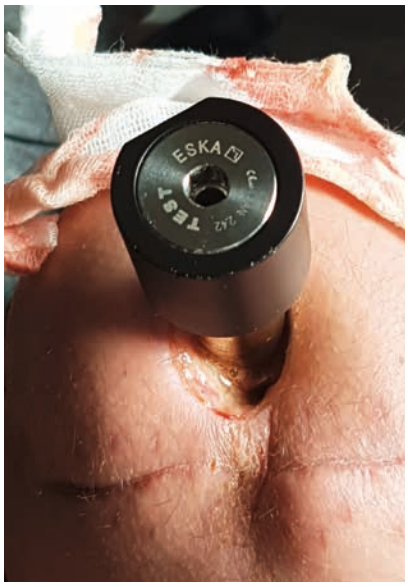


Fig. 3 *Stoma with the exiting implant a few days after surgery; the wound is not yet healed.*

paedic Handels GmbH, Lübeck, Germany) was marketed, sometimes designated in international literature as ILP (Integral Leg Prosthesis). The latest product is the OGAP-OPL System (Osseointegration Group of Australia Osseointegration Prosthetic Limb, Permedica S.p.A., Merate, Italy). The OPRA system stems from the field of dental implants and is therefore screw-anchored, while the other two systems were derived from the method of cementless press-fitting in total hip replacements. In this technique, the implant is covered by a metallic "mesh" into which the cancellous bone can grow. For all of the systems, a two-stage procedure is recommended: In a first operation, the bone anchor is implanted, covered with soft tissue, and then there is a wait until the bone grows into the implant. Only then is the stoma, the opening for passing through the connector, made in a second operation (Fig. 3) and then mobilisation with the prosthesis begun. A waiting period of 6 months between the operations is recommended with the OPRA technique, while this is only 6 weeks for the press-fitting methods. If conditions are optimal, a single-stage method can also be considered. The initial results are promising [2]. Details of study results for the methods:

OPRA

All of the studies cited below on the OPRA system refer mainly to the first 100 patients who were treated with this system in Gothenburg, Sweden, from 1990 to 2008. This period includes experience with the first version, which – like the surgical technique – was later modified and developed several times. In the initial study, relatively high complication rates were reported: Of the 100 patients, only 68 still used their prosthesis regularly at the end of the observation period of 18 years. The failure to use the prosthesis was partly because of the still incomplete, protracted rehabilitation process for this model. In 11 patients, the implants had to be removed permanently; in another 9 patients, the implant was successfully replaced. The total complication rate was thus 20% [3]. After the introduction of a structured rehabilitation protocol in 1999, this rate dropped to 8% [4]. The rate of superficial infections that were treated successfully with antibiotics was 55% [4].

For the patients in this group, data were also collected on the comparison with the previously used socket-mounted prosthesis. They showed better values for the various validated scores for prosthesis use, mobility and quality of life (Questionnaire for Persons with a Transfemoral Amputation [Q-TFA] and Short Form 36 [SF-36]). The score for problems using the prosthesis was reduced significantly [4]. Evidence was found for an improved range of movement in the hip [5] and greater sitting comfort [6]. The use of vibrations under the prosthetic foot showed evidence of improved ground perception [7].

Endo-exo femur prosthesis

The published studies have also shown progress in the endo-exo femur prosthesis, which is used primarily in Germany (Lübeck), but also in the Netherlands (Nijmegen). The implant design was modified significantly twice. While the first version had a rate of infections requiring revision of 77%, in the latest version, this rate has dropped to 0%; however, the observation period of 5 years is still relatively short [8]. The percentage of manageable superficial infections was 55%, exactly the same as with the OPRA system, and makes it clear that the care of the stoma is essential. Cleaning twice a day with mild soap is recommended. The correct assessment of the patient's approach to care can thus be a crucial criterion for determining suitability for osseointegration. The functional benefit for the user is similar to the OPRA system: Compared with conventional socket technique, improvements were found in the 6-minute walking test (423 m instead of 321 m), in the timed-up-and-go-test (8.1 s instead of 15.1 s) and for oxygen consumption (1093 ml/min instead of 1330 ml/min). The duration of prosthesis use and subjective satisfaction also increased considerably [9].

OGAP-OPL

The OGAP-OPL system is a variant of the endo-exo prosthesis that is used mainly in Australia. As this is the latest system to become available, there are not yet any extensive study data for it. The largest study published up to now includes only 22 participants for a period of 2 years. The results are similar to those for the endo-exo prosthesis: There were improvements in the 6-minute walking test (128%) and in the timed-up-and-go test (30%). The scores for quality of life also improved significantly. The rate of superficial infections was 68%; no deep infections, fractures or implant failures were found [10].

Patient selection

Despite the proven advantages for the patients and the now largely manageable risk of infection, none of the authors cited, all of whom come from the corresponding treatment centres, recommended osseointegration as the standard approach. Patients who do not have satisfactory results with conventional socket systems are considered to be the most important group of clients. Prerequisites are that bone maturation must be completed and the femur must have a physiological structure. The users must be willing to agree to the prolonged treatment protocol. In addition, the appearance when the prosthesis is removed needs some getting used to and the care of the stoma is essential for successful treatment. Typical contraindications are serious circulatory disorders and diabetes, although some successful implantations have been reported for these clients. Osteoporosis and high body weight (>100 kg) are sometimes listed as contraindications. Some medically necessary additional treatments are contraindications: osseointegration is not recommended with acute chemotherapy or radiation or if immunosuppression is required [1].

Summary

Studies have shown the improved subjective quality of life in patients fitted with a bone-anchored transfemoral prosthesis. Objectifiable improvement in mobility was also found. It should also be taken into consideration that this technique is used primarily when a conventional socket method has not been satisfactory. The risk of infection for the latest methods is increasingly manageable with corresponding patient compliance. No fractures in the implant area have been reported. However, "defined breaking points" are sometimes integrated into the prosthesis connector so that, in the event of sudden overload, the component fails, not the implant. Impact loads, for example from running or jumping, should therefore be avoided. Another limiting factor is the considerably longer duration of therapy and the associated increased stress for users. Aesthetic or cosmetic reasons have also been suggested to explain why osseointegration has not been established as the standard treatment. It is thus an alternative method for selected indications where the user's personal circumstances allow this method.

Author:
Ralph Bethmann, OTM
Bundesfachschule für Orthopädie-Technik
Schliepstraße 6–8
Dortmund, Germany
R.Bethmann@ot-bufa.de

Reviewed Paper

References:

[1] Hebert JS, Rehani M, Stiegelmar R. Osseointegration for Lower-Limb Amputation: A Systematic Review of Clinical Outcomes. JBJS Rev, 2017; 5 (10): e10

[2] Al Muderis M, Lu W, Tetsworth K, et al. Singlestage osseointegrated reconstruction and rehabilitation of lower limb amputees: the Osseointegration Group of Australia Accelerated Protocol-2 (OGAAP-2) for a prospective cohort study. BMJ Open, 2017; 7: e013508

[3] Hagberg K, Brånemark R. One hundred patients treated with osseointegrated transfemoral amputation prostheses – Rehabilitation perspective. Journal of Rehabilitation Research and Development, 2009; 46 (3): 331–344

[4] Brånemark R, Berlin Ö, Hagberg K, et al. A novel osseointegrated percutaneous prosthetic system for the treatment of patients with transfemoral amputation: A prospective study of 51 patients. Bone and Joint Journal, 2014; 96 B(1): 106–113

[5] Tranberg R, Zügner R, Kärrholm J. Improvements in hip- and pelvic motion for patients with osseointegrated trans-femoral prostheses. Gait and Posture, 2011; 33 (2): 165–168

[6] Hagberg K, Häggström E, Uden M, et al. Socket versus bone-anchored trans-femoral prostheses: Hip range of motion and sitting comfort. Prosthetics and Orthotics International, 2005; 29 (2): 153–163

[7] Häggström E, Hagberg K, Rydevik B, et al. Vibrotactile evaluation: Osseointegrated versus socket-suspended transfemoral prostheses. Journal of Rehabilitation Research and Development. 2013; 50 (10): 1423–1434

[8] Juhnke DL, Beck JP, Jeyapalina S, et al. Fifteen years of experience with Integral-Leg-Prosthesis: Cohort study of artificial limb attachment system. Journal of Rehabilitation Research and Development, 2015; 52 (4): 407–420

[9] Van De Meent H, Hopman MT, Frölke JP. Walking ability and quality of life in subjects with transfemoral amputation: A comparison of osseointegration with socket prostheses. Archives of Physical Medicine and Rehabilitation, 2013; 94 (11): 2174–2178

[10] Al Muderis M, Lu W, Li JJ. Osseointegrated prosthetic limb for the treatment of lower limb amputations: experience and outcomes. Unfallchirurg, 2017; 120 (4): 306–311

The ESKA® **endo**-stem adapted **exo**-prosthesis care concept according

"to Dr. Grundei®"

Enjoy life

ESKA Orthopaedic Handels GmbH

www.eskaorthopaedic.de
info@eskaorthopaedic.de

J. P. Frölke, R. Atallah, R. Leijendekkers, L. Verhamme, H. van de Meent

Bone-Anchored Osseointegration Implants for Transtibial Amputees: Surgical Aspects and Implant Design

Prostheses that are anchored in the bone by an osseointegrated implant have – compared with a conventional liner system – several proven advantages for patients after a transfemoral amputation, for example, improved ability to walk, use of the prosthesis and quality of life. The aim of the authors' custom-made tibia implant was to develop an implant shape based on CT scans that correlates exactly with the intramedullary cavity of the tibia. Ultimately, the implant was given a drop shape. By tightly shielding the intramedullary space, this design was intended to ensure maximum prevention of implant loosening and block the spread of bacteria into the intramedullary space.

Key words: amputation, tibia, osseointegration surgery, implant design

Introduction

The conventional way of rehabilitating individuals with lower limb amputation for centuries has been via socket-suspended prostheses [1] and even despite significant technological innovations to both socket materials and design, individuals with amputations still exhibit socket-residuum-interface problems that lead to substantial problems such as reduction in prosthesis use, less ability to mobilise and decreased quality of life [2–4]. These socket-residuum-interface problems include skin problems such as infections, irritation due to mechanical problems such as poor socket fit, pain and pistoning and lastly, problems with balance leading to falls [5–8]. Individuals with lower limb amputations using socket-suspended prostheses account most problems regarding quality of life to physical disability, pain and decreased energy level [2, 9].

Over the last 3 decades a new innovative technology has emerged addressing these socket related problems by eliminating the socket-residuum-interface. This is achieved via the technique of osseointegration, in which prosthetic parts are attached to the skeleton by incorporating an osseointegration implant in living bone [10]. Osseointegration implants have been well established in the field of dentistry for the treatment of edentulous jaws for many years with a 10-year survival of dental implants in mandibular bone of 95 % [11–13]. Since its first introduction in 1990 in individuals with an amputation, bone-anchored prostheses using an osseointegration implant have been predominantly used for the treatment of individuals with above knee amputation (transfemoral amputation; TFA). In patients with socket-related problems, the use of an osseointegration implant demonstrated advantages such as improved daily prosthetic use, reduced energy consumption, osseoperception and improved walking ability possibly leading to increased quality of life [3, 4, 14, 15].

Over the last years multiple studies have been published looking at the safety of this procedure, especially in individuals with TFA. The incorporation of a transcutaneous metal implant into the bone was supposed to give rise to concerns of ascending infections and concomitant implant loosening or sepsis [16]. Multiple studies have now reported that this seldom leads to untreatable infection and/or septic implant loosening despite the inevitable presence of bacterial colonisation around the skin-implant interface [16]. Most encountered complications are soft tissue infections as a result of redundant soft tissue in the skin penetration area. This has led to an adaptation and improvement in the soft tissue surgical technique resulting in a decrease of soft tissue complications (data not published).

Bone-anchored prostheses using osseointegration implants have successfully been used for the treatment of individuals with TFA at a larger scale. We believe there is enough argumentation for an attempt in individuals with transtibial amputation (TTA). When comparing between amputation level, it is clear that the prevalence of transtibial amputation is even higher or at least equal to that of transfemoral amputation, depending on country and etiology of amputation [17,18]. Of these individuals using socket prostheses, 40 % experience at least 1 skin problem, with a rate substantially higher in individuals with TTA (TTA: 45.8 %, TFA: 20 %; OR: 4.1) as well as an increased rate of stump pain [5, 18–29] Meulenbelt et al. [8] even reported on an incidence of skin problems of up to 68 %, equally distributed between individuals with a TTA and a TFA. High frequencies of skin problems and pain are inherently linked to intolerance of the prosthesis and impact the ability to become independently mobile [21]. Poor socket fit occurs both in individuals with a TTA and with a TFA (TTA: 59 %, TFA: 78 %) [22] and dissatisfaction with socket prostheses does not differ when comparing for level of amputation, with only 43 % being satisfied with the comfort of their prosthesis [23–25].

Up to this date, there is very little data assessing the feasibility and potential advantages of osseointegrated implants (OI) in individuals with TTA. Only very small series have been published with variable results [16, 26–28]. Research has to be performed reporting on the surgical approach and implant design of osseointegration for the treatment of individuals with a TTA. The ability to treat these patients with OI brings the potential of significantly reducing socket-residuum-interface problems and improving mobility, functioning and overall quality of life.

Referral and assessment

There are multiple ways of referral to the osseointegration clinics for individuals with transtibial amputation experiencing socket-related problems. Patients return to their prosthetic technician who may send patients back to the rehabilitation physicians. In the Netherlands we have a wide network of rehabilitation physicians specialised in amputation with adequate knowledge of novel treatments such as osseointegration. Since rehabilitation physicians are not registered in Germany, this network includes mostly prosthetic technicians and physical therapists. General practitioners or surgeons also refer patients to the OI clinics. Individuals with amputations are generally very well informed about osseointegration solutions through television, internet and social media; leading to awareness in the patient population.

The assessment of individuals with a TTA is similar to that of individuals with a TFA. Individuals fill in the Questionnaire for Persons with a Transfemoral Amputation (Q-TFA) prior to their visit to the multidisciplinary group clinic. Individuals visiting our clinics undergo standard radiographs and a musculoskeletal CT scan. With a plenary presentation, information is provided regarding selection procedures, surgical outcomes, risks of treatments and standard follow-up schedules. Expert-patients take part of the team and offer their knowledge and experiences with osseointegration to potential candidates. Eventually, every person is individually seen by the entire treatment team for assessment of medical history, physical examination, radiography and Q-TFA in order to reach mutual consensus regarding indication for treatment. We initiated our academic osseointegration centre in the Radboud university medical centre in 2009 and proceeded with the treatment of individuals with transtibial amputation in 2014, including selected patients with peripheral vascular disease. In the past 10 years our practice expanded slowly from a few patients per year to more than 50 per year in 2018. At the time of writing, in April 2019, we have treated 213 patients after lower limb amputation including 165 with transfemoral osseointegration and 48 patients with transtibial osseointegration.

Osseointegration implant systems

Similar to femoral osseointegration systems, screw systems as well as press-fit implants devices are available. Differences between the screw and press-fit systems include the type of attachment, possible in- or on-growth of the bone, time interval between surgeries in the case of 2-stage surgery and rehabilitation protocol. Unlike with femoral OI implants, there are currently no standard CE-certified press-fit tibia osseointegration systems available. For individuals with transtibial amputation, a custom-made implant is manufactured as an intramedullary press-fit device, often including locking screw fixation for enhanced primary stability [10]. Because of the satisfying results of the press-fit transfemoral OI (OFP, OTNimplants Arnhem The Netherlands), we decided to develop a press-fit design tibial implant with anatomical shape to allow solid attachment to the tibial remnant; often being short and irregular, with poor bone quality and vascularisation especially in subjects with peripheral vascular disease [27].

Preoperative planning and implant design

Calibrated radiographs are taken of the residual limb of individuals with transtibial amputation as well as standing full-leg-length radiographs. The minimum length of the residual tibia should be 50–60 mm and no shortening is done unless in case of very long tibia remnants. In those cases, the tibia needs to be shortened to 120 mm calculated from the tibia plafond of the ankle joint. This allows sufficient space for the osseointegration quick-release connector and prosthetic foot. All custom-made implants are based and designed on standard musculoskeletal CT scans according to a preset protocol, which is run through a graphic design program by engineers. The main goal is to design implants with a shape that correlates to the tibial intramedullary canal optimally, which tends to have a drop-like type of shape. With such an optimal shape the goal is to achieve complete press-fit closure of the medullary cavity (Fig. 1); to allow early ingrowth at the level of the bone-implant interface and prevent ascending infections and septic loosening with subsequent failure of the implant [10, 29].

All implants used in individuals with a TTA are custom made and based on computed tomography scans (CT) (Fig. 2). Similar to implants used in individuals with a TFA, all implants have a macroporous coating/structure allowing for osseointegration. When comparing the fixation of tibial implants to femoral implants there are some differences. The femoral implants often have a greater length and thus a larger surface of osseointegration and the femoral implant is inserted in diaphyseal bone which has a fairly circular shape, making implant design less complex. For the tibial implants, a shorter implant is often necessary, resulting in a smaller surface of osseointegration. The tibial implant fixates in the tibial epi- and metaphysis making it necessary, to this day, for a custom implant to be designed, as variations in the shape of the intramedullary canal lead to difficulty in implant design and fixation (Fig. 3).

Surgical protocol

The standard way of osseointegration treatment is performed preferably in two-stage surgery in our centre in the Netherlands with an interval of 6–8 weeks in between. During the first surgery, the implant is inserted in the residual bone. Surgery is performed under spinal or general anesthesia and perioperative antibiotic prophylaxis is administered. Patients are positioned in supine position, alcoholic chlorhex-

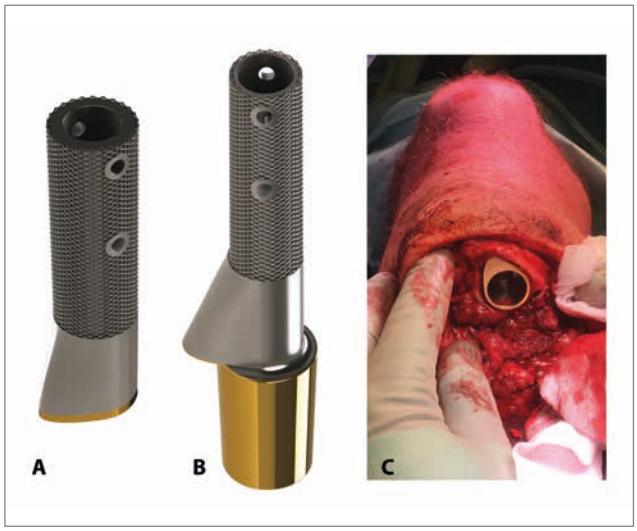


*Fig. 1a–c 3D printed titanium alloy implant with lattice coated stem and drop shape with niobium coated internal **(a)** or external **(b)** taper connection. Complete seal of the medullary cavity of the tibia **(c)**.*

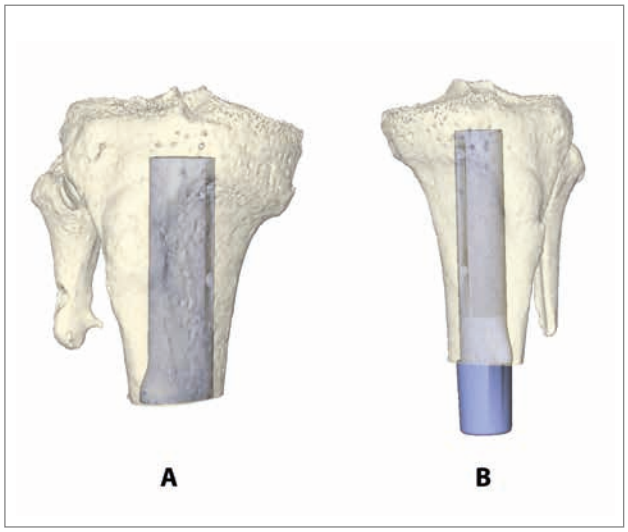


*Fig. 2a und b Preoperative planning of implant with internal **(a)** or external **(b)** taper connection.*

idine is used for disinfection and the extremity is covered with a fenestrated extremity drape. At the level of the distal stump, an incision is made and soft tissue surplus at the distal stump is maximally resected. Whenever indicated, a neurectomy is performed. The medullary canal is retrogradely reamed in a step-wise fashion with radiographic guidance followed by the press fit insertion of the intramedullary component (implant) of the osseointegration device. One or two transverse locking screws are inserted from medial to lateral followed by closure of the wound (Fig. 3.). During the second surgery, a stoma is created using a circular knife which is passed over a guide wire inserted into the intramedullary component. The transcutaneous component of the osseointegration device is inserted into the intramedullary component and secured with an internal locking screw. In some cases surgery is performed in a single stage approach. This might be necessary when there is insufficient skin and soft tissue to cover the intramedullary component. The stoma is then created after the insertion of the implant followed by the attachment of the transcutaneous component. The philosophy of performing osseointegration surgery preferably in two stages is to create a period with a sterile environment for the implant to allow osseointegration with the bone [10].

Rehabilitation protocol

Osseointegration rehabilitation starts one week after second stage surgery, or 3–6 weeks after single stage surgery depending on bone quality [30]. The aim of rehabilitation is to achieve predetermined individualised functional goals such as minimising gait compensation strategies and increasing the level of activity. To reach these goals rehabilitation focuses on increasing hip adductor strength, core stability and gait symmetry.

The rehabilitation team consists of a rehabilitation physician, physical therapist, occupational therapist and a prosthetist. The prosthetist attaches the quick-release osseointegration connector to the transcutaneous component of the osseointegration device and aims to achieve optimal alignment of all external components during the rehabilitation period. To prevent overload of the knee joint due to valgus or varus stress, an optimal frontal plane alignment is of extra importance in individuals with a transtibial OI.

Individuals are instructed by the physical therapist to gradually load the prosthesis, from partial weight bearing between parallel bars and with help of a walking aid to full weight bearing without walking aids. Gait and muscle strength is trained in a functional setting using motor learning principles. The occupational therapist provides instructions for daily stoma care (Fig. 4). The rehabilitation physician supervises the process of rehabilitation and treats initial complaints occurring such as stoma pain due to stoma irritation or infection and muscle pain.

The rehabilitation is given in group sessions two times a week of two hours each and takes 4 weeks in individuals with a transtibial OI. The rehabilitation can be prolonged depending on the progress of the individual and limitations, e.g. due to pain or lack of muscle strength. These limitations may lead to an interlude in the predefined rehabilitation program and result in variability in rehabilitation duration [31] (Fig. 4).

Pre/post outcome measures

Conventional radiographs are evaluated at baseline as well as 1, 2, 5 and 10 years post-surgery [30]. Functional outcomes are measured using the Questionnaire for Persons with a Transfemoral Amputation (Q-TFA) to evaluate prosthetic use, mobility and prosthetic-related quality of life. Up to this date, there is no validated functional outcome questionnaire designed specifically for individuals with a transtibial amputation. However, the Q-TFA assesses aspects that are also meaning-

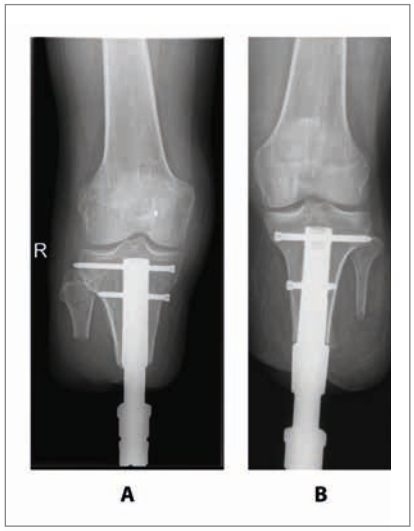


Fig. 3a and b Anteroposterior radiograph of implant with internal (a) and external (b) taper connection.

ful and relevant for individuals with a transtibial amputation. Mobility level is determined using the Time Up and Go (TUG) and walking ability using the Six Minute Walking Test (6MWT). Adverse events related to the osseointegration surgery are monitored by evaluating the medical charts. Infections associated with bone-anchored osseointegration prosthesis are graded as described in our previous article [32].

Future developments

Bone-anchored prostheses using osseointegrated implants are predominantly evaluated in individuals with transfemoral amputation. Over the years a great deal of knowledge has been gathered for further adaptations to implant design and surgical technique, resulting in a low occurrence of major complications in individuals with transfemoral OI. In transtibial amputees there are no large case series assessing functional outcomes and complications up to this date. Therefore, it is unclear whether the same principles apply for individuals with a tibia bone-anchored prosthesis regarding safety and performance. Further research is required to elucidate this.

Future studies also should focus on the application of bone-anchored prostheses simultaneous with initial amputation. Since bone-anchored prostheses are now more and more commonly seen as standard care, there is a growing demand for this technique for patients that are scheduled for amputation. This question particularly concerns people scheduled for lower limb amputation because of peripheral artery occlusive disease or diabetes mellitus. Further studies are desired to define sensible inclusion criteria leading to an acceptable risk/benefit ratio in this group of vascular amputees [27].

For the Authors
Jan Paul Frölke
Orthopaedic Traumasurgeon
Geert Grooteplein Zuid 10 route 618
Nijmegen, Netherlands
janpaul.frolke@radboudumc.nl

Reviewed paper

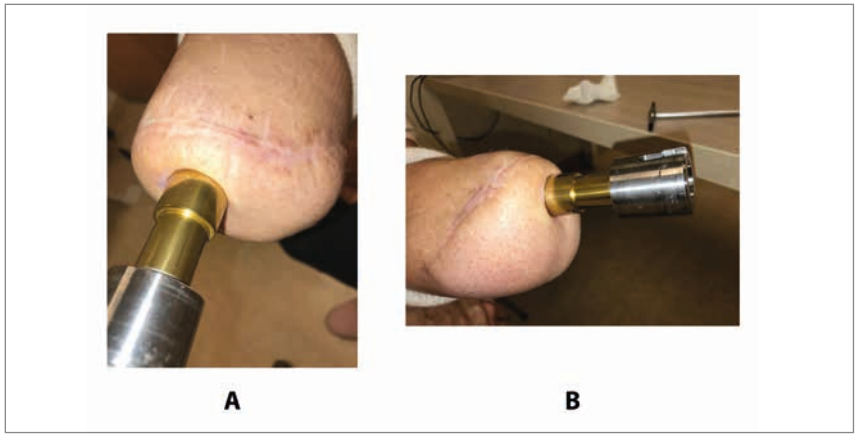


Fig. 4 Stoma of individual with transtibial osseointegration.

References:

[1] Thurston AJ. Pare and prosthetics: The Early History of Artificial Limbs. ANZ J Surg. 2007; 77 (12): 1114–9

[2] Demet K, Martinet N, Guillemin F, Paysant J, Andre JM. Health Related Quality of Life and Related Factors in 539 Persons with Amputation of Upper and Lower Limb. Disabil Rehabil. 2003; 25 (9): 480–6

[3] Hagberg K, Branemark R. Consequences of non-vascular trans-femoral Amputation: A Survey of Quality of Life, Prosthetic Use and Problems. Prosthet Orthot Int. 2001; 25 (3): 186–94

[4] Van de Meent H, Hopman MT, Frolke JP. Walking Ability and Quality of Life in subjects with transfemoral amputation: a comparison of osseointegration with socket prostheses. Arch Phys Med Rehabil. 2013; 94 (11): 2174–8

[5] Dudek NL, Marks MB, Marshall SC, Chardon JP. Dermatologic conditions associated with use of a lower-extremity prosthesis. Arch Phys Med Rehabil. 2005; 86 (4): 659–63

[6] Hunter SW, Batchelor F, Hill KD, Hill AM, Mackintosh S, Payne M. Risk Factors for Falls in People With a Lower Limb Amputation: A Systematic Review. Pm&R. 2017; 9 (2): 170–80

[7] Lyon CC, Kulkarni J, Zimerson E, Van Ross E, Beck MH. Skin disorders in amputees. J Am Acad Dermatol. 2000;42 (3): 501–7

[8] Meulenbelt HE, Geertzen JH, Jonkman MF, Dijkstra PU. Determinants of skin problems of the stump in lower-limb amputees. Arch Phys Med Rehabil. 2009;90 (1): 74–81

[9] Amtmann D, Morgan SJ, Kim J, Hafner BJ. Health-related profiles of people with lower limb loss. Arch Phys Med Rehabil. 2015; 96 (8): 1474–83

[10] Mavrogenis AF, Dimitriou R, Parvizi J, Babis GC. Biology of implant osseointegration.
Journal Musculoskelet Neuronal Interact. 2009; 9 (2): 61–71

[11] Adell R, Eriksson B, Lekholm U, Branemark PI, Jemt T. Long-term follow-up study of osseointegrated implants in the treatment of totally edentulous jaws. Int J Oral Maxillofac Implants. 1990; 5 (4): 347–59

[12] Branemark PI, Adell R, Albrektsson T, Lekholm U, Lundkvist S, Rockler B. Osseointegrated titanium fixtures in the treatment of edentulousness. Biomaterials. 1983; 4 (1): 25–8

[13] Branemark R, Branemark PI, Rydevik B, Myers RR. Osseointegration in skeletal reconstruction and rehabilitation: a review. J Rehabil Res Dev. 2001; 38 (2): 175–81

[14] Hagberg K, Branemark R, Gunterberg B, Rydevik B. Osseointegrated trans-femoral amputation prostheses: prospective results of general and condition-specific quality of life in 18 patients at 2-year follow-up. Prosthet Orthot Int. 2008; 32 (1): 29–41

[15] Leijendekkers RA, van Hinte G, Frolke JP, van de Meent H, Nijhuis-van der Sanden MW, Staal JB. Comparison of bone-anchored prostheses and socket prostheses for patients with a lower extremity amputation: a systematic review. Disabil Rehabil. 2017; 39 (11): 1045–58

[16] Atallah R, Leijendekkers RA, Hoogeboom TJ, Frolke JP. Complications of bone-anchored prostheses for individuals with an extremity amputation: A systematic review. PLoS One. 2018; 13 (8): e0201821

[17] Fortington LV, Rommers GM, Postema K, van Netten JJ, Geertzen JH, Dijkstra PU. Lower limb amputation in Northern Netherlands: unchanged incidence from 1991–1992 to 2003–2004. Prosthet Orthot Int. 2013;37 (4): 305–10

[18] Dillingham TR, Pezzin LE, MacKenzie EJ. Limb amputation and limb deficiency: epidemiology and recent trends in the United States. South Med J. 2002; 95 (8): 875–83

[19] Walker CR, Ingram RR, Hullin MG, McCreath SW. Lower limb amputation following injury: a survey of long-term functional outcome. Injury. 1994; 25 (6): 387–92

[20] Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the prevalence of limb loss in the United States: 2005 to 2050. Arch Phys Med Rehabil. 2008; 89 (3): 422–9

[21] Butler K, Bowen C, Hughes AM, Torah R, Ayala I, Tudor J, et al. A systematic review of the key factors affecting tissue viability and rehabilitation outcomes of the residual limb in lower extremity traumatic amputees. J Tissue Viability. 2014; 23 (3): 81–93

[22] Hoaglund FT, Jergensen HE, Wilson L, Lamoureux LW, Roberts R. Evaluation of problems and needs of veteran lower-limb amputees in the San Francisco Bay Area during the period 1977–1980. J Rehabil R D. 1983; 20 (1): 57–71

[23] Behr J, Friedly J, Molton I, Morgenroth D, Jensen MP, Smith DG. Pain and pain-related interference in adults with lower-limb amputation: comparison of knee-disarticulation, transtibial, and transfemoral surgical sites. J Rehabil Res Dev. 2009; 46 (7): 963–72

[24] Dillingham TR, Pezzin LE, MacKenzie EJ, Burgess AR. Use and satisfaction with prosthetic devices among persons with trauma-related amputations: a long-term outcome study. Am J Phys Med Rehabil. 2001; 80 (8): 563–71

[25] Pezzin LE, Dillingham TR, Mackenzie EJ, Ephraim P, Rossbach P. Use and satisfaction with prosthetic limb devices and related services. Arch Phys Med Rehabil. 2004;85 (5): 723–9

[26] Aschoff HH, Juhnke DL. Endo-Exo-Prothesen: Osseointegrierte, perkutan ausgeleitete Implantate zur Rehabilitation nach Gliedmaßenamputation. Unfallchirurg. 2016; 119 (5): 421–7

[27] Atallah R, Li JJ, Lu W, Leijendekkers R, Frolke JP, Al Muderis M. Osseointegrated Transtibial Implants in Patients with Peripheral Vascular Disease: A Multicenter Case Series of 5 Patients with 1-Year Follow-up. J Bone Joint Surg Am. 2017;99 (18): 1516–23

[28] Juhnke DL, Aschoff HH. Endo-Exo-Prothesen nach Gliedmaßenamputation. Orthopade. 2015; 44 (69): 419–25

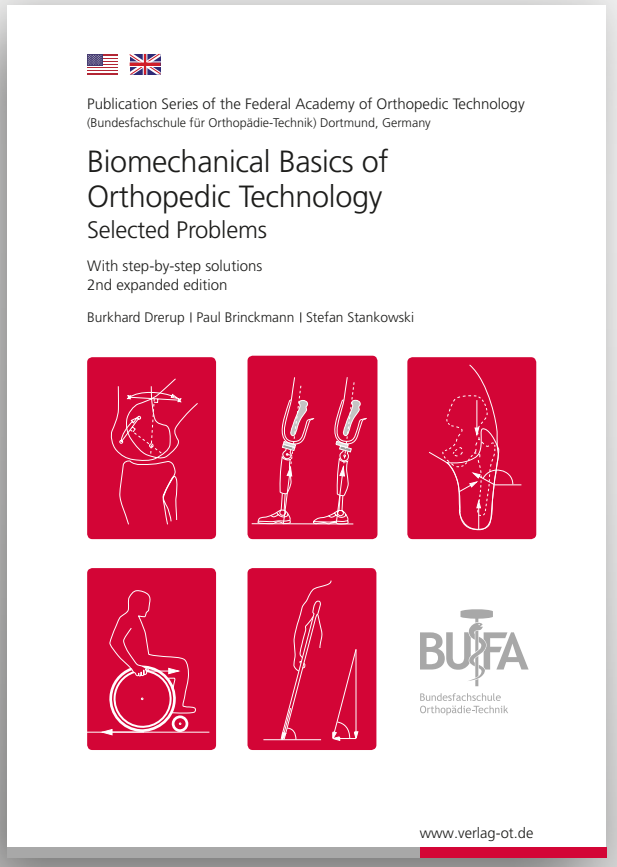
[29] Jeyapalina S, Beck JP, Agarwal J, Bachus KN. A 24-month evaluation of a percutaneous osseointegrated limb-skin interface in an ovine amputation model. J Mater Sci Mater Med. 2017; 28 (11): 179

[30] Leijendekkers RA, Staal JB, van Hinte G, Frolke JP, van de Meent H, Atsma F, et al. Long-term outcomes following lower extremity press-fit bone-anchored prosthesis surgery: a 5-year longitudinal study protocol. BMC Musculoskelet Disord. 2016; 17(1): 484

[31] Leijendekkers RA, van Hinte G, Frolke JP, van de Meent H, Atsma F, Nijhuis-van der Sanden MW, et al. Functional performance and safety of bone-anchored prostheses in persons with a transfemoral or transtibial amputation: a prospective one-year follow-up cohort study. Clin Rehabil. 2019; 33 (3): 450–64

[32] Al Muderis M, Khemka A, Lord SJ, Van de Meent H, Frolke JP. Safety of Osseointegrated Implants for Transfemoral Amputees: A Two-Center Prospective Cohort Study. J Bone Joint Surg Am. 2016; 98 (11): 900–9

Biomechanics? No problem!



Order online:
bestellung@biv-ot.org
www.verlag-ot.de

Can the strength of all muscles that act to straighten the back be combined to a single muscular force? Can you replace the mechanical effect of pressure distribution in the socket of a prosthesis by the action of a single force?

This practical workbook answers these and many other questions about biomechanics. With detailed instructions for solving.

B. Drerup/P. Brinckmann/S. Stankowski
Biomechanical Basics of Orthopedic Technology.
Selected Problems.
2018, 150 pp., paperback
EUR 24.95
ISBN 978-3-9813221-8-7

Verlag Orthopädie.Technik

H. van de Meent, R. A. Leijendekkers, M. C. Warlé, J. P. M. Frölke

Bone-Anchored Osseointegrated Prostheses for Patients with a Transfemoral or Transtibial Amputation: Indication Criteria with Emphasis on Vascular Patients

This article reviews the indication process for patients with transfemoral or transtibial amputation referred for an osseointegration implant or 'bone-anchored' prosthesis. Inclusion and exclusion criteria are discussed with emphasis on criteria for patients with lower limb amputation as a result of vascular pathology. The preliminary data of a cohort of 116 patients with 121 osseointegrated implants is presented. For 17 of the cohort of 116 patients (14.7%), a vascular pathology was the reason for their amputation. Of those 17 patients (17 implants, average age 62 years, age range 44–75 years, 4 females, 5 tibia implants, median follow-up 3 years, follow-up range 1–5 years), one patient with a tibia implant had a progressive course of vascular pathology with soft tissue infection, eventually leading to implant failure. There were no (a)septic implant loosening or untreatable soft tissue infections in the group of 99 patients without a vascular cause of the lower limb amputation.

Keywords: amputees, osseointegration, peripheral vascular diseases, complications, prosthesis implantation.

Introduction

Referral

In the Netherlands, people with a lower limb amputation who encounter problems with the socket attachment of their prosthesis are referred to our specialised amputee osseointegration centre either by their general practitioner or rehabilitation physician. The existence of our amputee osseointegration centre is known by the broader public because of attention in the media and the work of the Amputee Osseointegration Foundation Europe (AOFE), www.osseointegration.eu, (accessed April 30, 2019). The AOFE is a charity foundation established in 2015 with the aim to promote and improve the quality of osseointegration treatment for people with extremity amputation in Europe. In this way, more and more patients are informed through peer-to-peer contact and ask for a referral to our clinic.

The indication process

The indication process is performed in a multidisciplinary team approach. The osseointegration treatment team consists of an orthopaedic surgeon, a case manager, a rehabilitation physician, a physiotherapist. Patients who are referred for a bone-anchored prosthesis are invited by our case manager to an out-patient group clinic. Prior to their visit, they complete the Questionnaire for Persons with a Transfemoral Amputation (Q-TFA) [1]. The outpatient group clinic starts with radiologic examination of the femur or tibia remnant and a calibrated total view of both lower extremities (Fig. 1a). A CT scan is performed in patients with transtibial amputation or patients with a short femur remnant. This CT scan is used to define the size and design of a custom-made implant. In a plenary session, all the details of the treatment are presented by the surgeon and the rehabilitation physician, followed by individual consultations with the entire osseointegration team. During the individual talks, the rest of the candidates and their relatives are introduced to two individuals with a bone-anchored prosthesis who successfully completed their rehabilitation. They inform new candidates about their experiences and show them their bone-anchored prosthesis. Finally, mutual agreement about the indication for the treatment is achieved based on in- and exclusion criteria [2], medical history, physical examination, Q-TFA results, and radiology. Candidates who reveal unrealistic expectations of their future functioning with a bone-anchored prosthesis are referred to our clinical psychologist for discussion and adjustment of expectations that are probably too high (Fig. 1).

Inclusion and exclusion criteria

In 2009, when we started our specialized amputee osseointegration centre in the Netherland, there were many discussions and doubts among physicians and prosthetists regarding the safety of bone-anchored prostheses (Fig. 1b) particularly regarding the possible risk of septic loosening, osteitis, and osteomyelitis. This encouraged our team to apply a restrained policy regarding inclusion and exclusion criteria [2] and to evaluate thoroughly the post-operative safety and performance results. We assumed that the application of strict in- and exclusion criteria would lead to the best safety-performance ratio. In 2016, together with the OGAAP osseointegration group of Australia, we published the outcome of the first 86 patients with

2 years of follow-up. The study included 86 patients and confirmed that the bone-anchored prostheses treatment was safe. There were no (a)septic loosenings and patients reported an enormous increase in functional performance and quality of life [3]. Bone quality of the residual limb is not an exclusion criteria for bone-anchored prostheses since in general, most amputees suffer from more or less severe disuse osteoporosis. In transfemoral amputees, socket-attached prostheses support the pelvis and unload the femur which results in disuse osteoporosis of the diaphyseal and metaphyseal bone. For subjects with post-traumatic bone deformation, custom-made implants are designed based on the CT scan images.

Vascular patients

Since the osseointegration technique appeared to be safe in a well selected population of amputees, we went on by carefully including candidates with slightly more liberal indication criteria and added criteria to distinguish between patients with severe and mild peripheral arterial disease (Tab. 1 and 2). Patients with a vascular cause of amputation were screened by our vascular surgeon (MW) and for the presence of femoral artery pulsations in the groin area. The criterion palpable femoral artery pulsations was acquired from a study in patients with critical limb ischemia indicating that the presence of palpable pulsations directly proximal of amputation level correlates with 100 % primary wound healing after amputation [4]. Additionally, skin perfusion oxygen pressure measured with laser Doppler at the tip of the residual limb (Fig. 2) was introduced as measure of local microcirculatory blood perfusion. The technique is based on the detection of the oxygen pressure in the skin with a beam of laser light carried by a fibre-optic probe placed on the skin. Transcutaneous oxygen pressure less than 40 mmHg was adopted as an exclusion criterion for osseointegration surgery. An oxygen pressure less than 40 mmHg at the amputation site has been indicated in the literature as a positive predictive value for wound healing failure after amputation in patients with critical limb ischaemia (Fig. 3) [5]. For an osseointegration implant, vital skin and soft tissue conditions with adequate local blood perfusion are necessary for successful osseointegration and sufficient resistance against bacterial infections in the skin penetration area (stoma). We assumed that the skin oxygen perfusion pressure level that guarantees proper amputation wound healing also may guarantee conditions for successful osseointegration in vascular amputees.

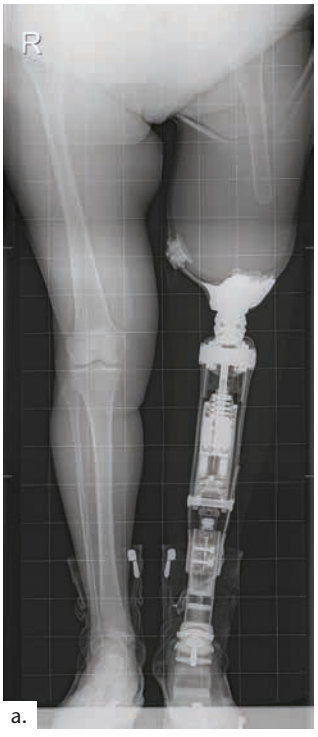
Methods

Patients included for osseointegration treatment are scheduled for two stage surgery with an interval of 6–8 weeks in between. During the first surgery, the medullary canal is retrogradely reamed in a step-wise fashion with radiographic guidance followed by the press-fit insertion of the intramedullary component of the osseointegration device. Soft tissue surplus in the distal stump is resected as much as possible and the wound is closed. During the second-stage surgery, a stoma (Fig. 4) is created and the transcutaneous component of the osseointegration device is attached to the intramedullary component. In selected cases the surgery is performed in a single-stage approach. This might be necessary when there is insufficient skin to cover the implant.

Rehabilitation starts one week after the second surgery, or 3 weeks after single-stage surgery. The aim of rehabilitation is to reach predetermined individualized functional goals [6]. The rehabilitation is given in group sessions two times a week of two hours each and a total duration of 4 weeks and 11 weeks for tibial and femoral bone-anchored prosthesis users, respectively [7]. Follow-up visits including radiologic examination are scheduled at 6 months and thereafter at 1, 2, 5, and 10 years after stage 2 surgery. Side effects and performance are evaluated from the medical charts and with questionnaires. All data are stored and processed using a web-based database (Castor EDC).

Results

Between April 2014 and April 2018, 116 consecutive patients (121 implants; 5 bilateral amputees) with average age at time of implantation of 53.7 years (range 20–86), including 35 females, underwent osseointegration implant surgery in our centre. All candidates met the in- and exclusion criteria and 29 of the 121 implants were tibia implants. One patient with traumatic transtibial amputation and se-



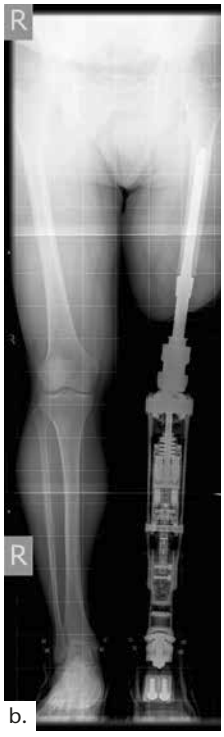


Fig. 1a *X-ray with socket prosthesis.*

Fig. 1b *X-ray with bone-anchored osseointegration prosthesis.*

Tab. 1 Inclusion Criteria:

Inclusion Criteria: osseointegration is indicated when at least one item is answered yes:

- The prosthesis is used less than 50 hours per week
- The prosthesis restricts walking distance: less than 2 km (with or without walking aids)
- The prosthesis is very unreliably attached during daily activities
- The prosthesis is quite uncomfortable when sitting down
- The prosthesis causes sores, chafing, or skin irritation
- The prosthesis causes considerable discomfort due to heat/sweating during hot weather
- The problems experienced with the current prosthesis are considerable

Tab. 2 Exclusion Criteria:

- Severe diabetes (including a medical history of multi-organ failure)
- Systemic/local infection
- Age <18 (immature bone)
- Bone deformity, dysplasia, metabolic bone disease
- Radiotherapy on residual limb within 3 months before OI surgery
- Chemotherapy within 3 months before OI surgery
- Immunosuppressive drugs use
- Peripheral arterial disease and no femoral artery pulsations present (palpable) at the unilateral groin area and/or percutaneous oxygen pressure < 40 mmHg at the tip of the residual limb
- Unclear stump pain
- Amputees that probably might not comply with medical instructions
- Amputees with unrealistic expectations of OI outcome
- Smoking
- BMI more than 30

Tab. 1, 2

vere diabetes did not met the inclusion criteria but was, nevertheless, implanted with a tibia osseointegration implant. This patient was not able to walk with a socket prosthesis because of recurrent skin ulcerations and was referred to our clinic for a transfemoral amputation. Instead of a transfemoral amputation, a custom made tibia osseointegration implant was attempted and this unfortunately failed because of septic loosening. Seventeen of the cohort of 116 patients (14.7 %) had vascular pathology as cause of their amputation and met the in- and exclusion criteria as indicated in Tables 1 and 2. Four out of these 17 patients had acute arterial ischaemia because of a vascular injury or ruptured popliteal/femoral aneurysm. Thirteen out of 17 patients had chronic peripheral artery occlusive disease. The follow-up range was 1 to 5 years and 37 patients had at least 3 years follow-up.

Of those 17 patients (17 implants, average age 62 years, age range 44–75 years, 4 females, 5 tibia implants, median follow-up 3 years, follow-up range 1–5 years) with a vascular cause of amputation, one patient with a tibia implant had a progressive course of his chronic arterial occlusive disease resulting in soft tissue infection of his residual limb. This male patient (age 55) had prior to osseointegration surgery palpable femoral pulsations but in the first months after osseointegration surgery, he developed a complete femoral artery occlusion. Finally, this resulted in progressive untreatable soft tissue infection and transfemoral amputation 6 months after his single-stage surgery. There were no (a)septic implant loosening or untreatable soft tissue infections in the group of 99 patients without a vascular cause of the lower limb amputation (Fig. 5).

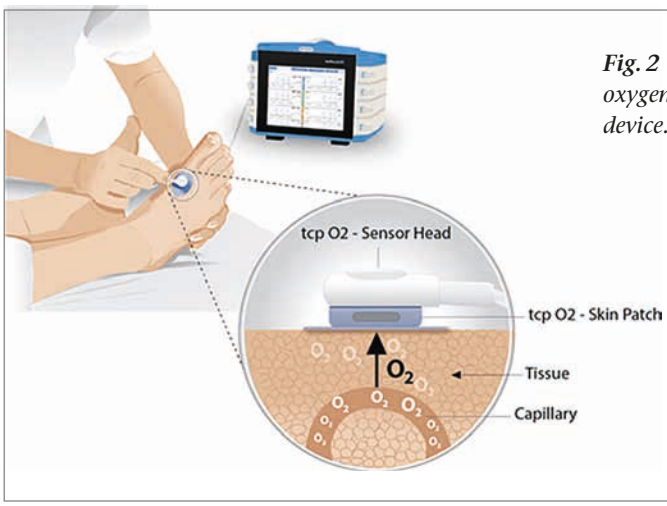


Fig. 2 Transcutaneous oxygen measurement device.

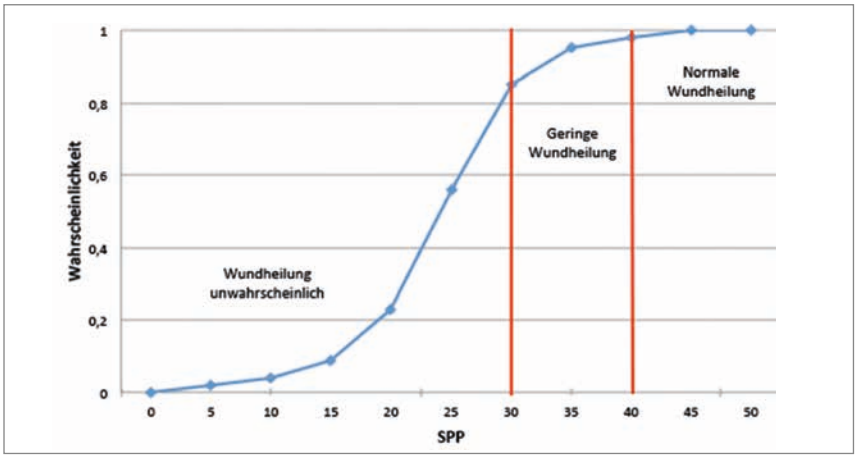


Fig. 3 *Graphic presentation of wound-healing probability measured with oxygen skin perfusion pressure (SPP).*

Discussion

In this paper the referral and indication process of the Dutch Osseointegration group is presented. Our previous study [3] and the follow-up results of the present cohort of 99 patients indicate that osseointegration implant surgery is safe if the candidates are selected according to strict criteria. Additionally, we presented the application of osseointegration implant surgery in a selected group of patients with a vascular cause of lower limb amputation. Preliminary results show that this application is relatively safe taken into account the study limitations of a small group with relatively short follow-up. Long term follow-up evaluation in a larger group with a vascular cause of lower limb amputation is required to elucidate the exact risk-benefit ratio. Nevertheless, the preliminary results are very promising given the fact that this vascular group suffers from a progressive disease with high morbidity and mortality even without osseointegration. Subjects with a vascular cause of amputation are possibly an interesting target population for osseointegration implant surgery. This specific group of vascular amputees is very large and the beneficial effects of osseointegration surgery in this group are to be expected very high. Previous studies have shown that prosthetic use, walking distances, and quality of life increased with respectively 45%, 27% and 68% with bone-anchored prostheses compared to socket prostheses [2, 7]. Bone-anchored prosthesis might specially benefit amputees with peripheral artery occlusive disease since it has been shown that enhanced mobility in this group is associated with much higher life expectancy [8]. In the Netherlands and probably also in the rest of Europe, 90–95% of the lower limb amputations are a result of peripheral artery occlusive disease [9]. Prosthetic use in this group is often very low. A community-based study in Finland showed that in 175 transfemoral amputees, 50% did not use or used their prosthesis less than 7 hours per day [10]. Socket prosthesis fitting problems, constant stump pain and sores were identified as significantly limiting factors related to disuse [11]. The application of bone-anchored prostheses might bring the desired mobility and quality of life in these vascular amputees. On the other hand, peripheral artery occlusive disease is a progressive disorder. The vascular status may easily deteriorate after osseointegration implant surgery and may lead to osseointegration implant failures or untreatable soft tissue infection of the residual limb. A certain calculated risk is to be expected and should be accepted in this group as long as the osseointegration technique brings secure prosthetic attachment, easy donning and doffing, sitting comfort, and quality of life, especially in this older age group. The exact risk-benefit ratio has to be determined, discussed, and finally accepted. Larger prospective studies in vascular amputees are now highly desirable.

For the authors:
Dr Hendrik Van de Meent, MD, PhD
Radboud University Medical Centre
Department of Rehabilitation
Nijmegen, Netherlands
Henk.vandemeent@radboudumc.nl

Reviewed paper

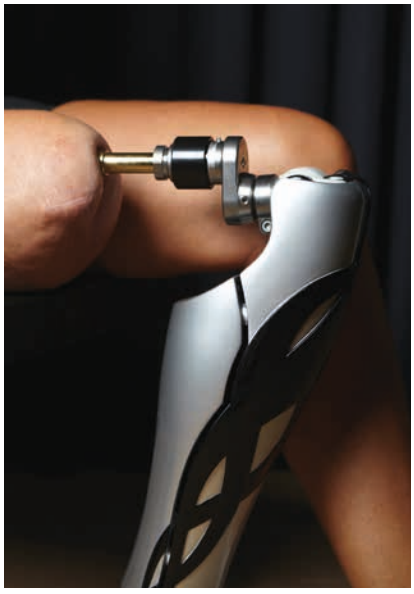


Fig. 4 *Stoma detail of bone-anchored osseointegration prosthesis.*

Fig. 5 *Freedom in daily life with bone-anchored osseointegration prosthesis.*

References:

[1] Hagberg K, Brånemark R, Hägg O. Questionnaire for Persons with a Transfemoral Amputation (Q-TFA): initial validity and reliability of a new outcome measure. J Rehabil Res Dev, 2004; 41 (5): 695–706

[2] Van de Meent H, Hopman MT, Frölke JP. Walking ability and quality of life in subjects with transfemoral amputation: a comparison of osseointegration with socket prostheses. Arch Phys Med Rehabil, 2013; 94 (11): 2174–2178

[3] Al Muderis M, Khemka A, Lord SJ, Van de Meent H, Frölke JP. Safety of Osseointegrated Implants for Transfemoral Amputees: A Two-Center Prospective Cohort Study. J Bone Joint Surg Am, 2016; 98 (11): 900–909

[4] Dwars BJ, van den Broek TA, Rauwerda JA, Bakker FC. Criteria for reliable selection of the lowest level of amputation in peripheral vascular disease. J Vasc Surg. 1992; 15 (3): 536–542

[5] Adera HM, James K, Castronuovo JJ Jr, Byrne M, Deshmukh R, Lohr J. Prediction of amputation wound healing with skin perfusion pressure. J Vasc Surg, 1995; 21 (5): 823–828

[6] Leijendekkers RA, van Hinte G, Nijhuis-van der Sanden MW, Staal JB. Gait rehabilitation for a patient with an osseointegrated prosthesis following transfemoral amputation. Physiother Theory Pract, 2017; 33 (2): 147–161

[7] Leijendekkers RA, van Hinte G, Frölke JP, van de Meent H, Atsma F, Nijhuis-van der Sanden MW, Hoogeboom TJ. Functional performance and safety of bone-anchored prostheses in persons with a transfemoral or transtibial amputation: a prospective one-year follow-up cohort study. Clin Rehabil, 2019;33 (3): 450–464

[8] Dillingham TR, Pezzin LE. Rehabilitation setting and associated mortality and medical stability among persons with amputations. Arch Phys Med Rehabil, 2008; 89 (6): 1038–1045

[9] Fortington LV, Rommers GM, Postema K, van Netten JJ, Geertzen JH, Dijkstra PU. Lower limb amputation in Northern Netherlands: unchanged incidence from 1991–1992 to 2003–2004. Prosthet Orthot Int, 2013; 37 (4): 305–310

[10] Pohjolainen T, Alaranta H, Kärkkäinen M. Prosthetic use and functional and social outcome following major lower limb amputation. Prosthet Orthot Int, 1990; 14 (2): 75–79

[11] Gauthier-Gagnon C, Grisé MC, Potvin D. Predisposing factors related to prosthetic use by people with a transtibial and transfemoral amputation. J Prosthet Orthot, 1998; 10: 99–109

Foto: AdobeStock: dimdimich

#otworld20

JOIN WORLDWIDE O&P PROFESSIONALS AT OTWORLD IN LEIPZIG!

THE SECTOR'S LEADING EVENT IN 2020

WHAT TO EXPECT:

- a comprehensive overview of the market and its trends
- a professional and interdisciplinary dialogue in the World Congress
- simultaneous translation of lectures

WATCH NOW

Oustanding papers
of the World Congress for free
www.ot-world.com/congress-webcast

Videos powered by
con.fair.med
Gesellschaft für Congressmanagement mbH

OTWORLD

International Trade Show and World Congress

12 – 15 May 2020
Leipzig, Germany

Join the progress.

www.ot-world.com

Treatment Standards: Improved Quality for Patients

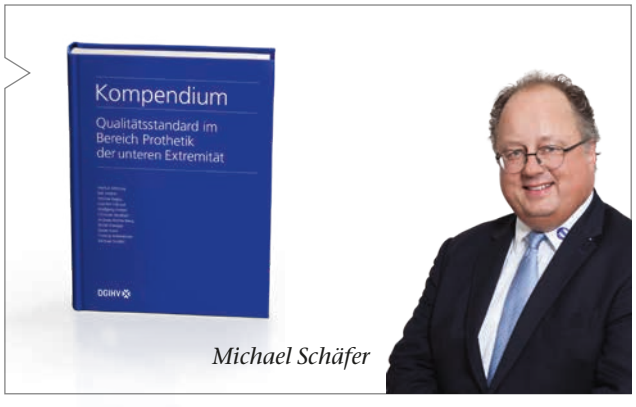
Quality of treatment continues to be a matter of definition, with various treatment concepts existing in different parts of the world. A look at the different healthcare systems of individual countries shows how wide the spectrum is. Especially in developing countries – but not only there – standardised and generally applicable guidelines for treatment must be developed, improved or adapted to current conditions.

This article offers an overview of the current standards and the latest discussions. The German quality standard for lower limb prosthetics is published by the Deutsche Gesellschaft für interprofessionelle Hilfsmittelversorgung e.V. (DGIHV; engl.: German Association for the Interprofessional Supply of Medical Aids). In addition the article presents the international consensus report by the International Society for Prosthetics and Orthotics (ISPO), which concerns the treatment of the lower extremities, as well as the guideline published by the World Health Organization (WHO) in 2017 – the "WHO Standards for Prosthetics and Orthotics". The ISPO Netherlands is also called upon.

German Quality Standard

The compendium "Quality Standard for Lower Limb Prosthetics" was published by the Deutsche Gesellschaft für interprofessionelle Hilfsmittelversorgung e.V. (DGIHV; engl.: German Association for the Interprofessional Supply of Medical Aids) at OTWorld 2018. Qualified O&P professional master craftsman Michael Schäfer is among the lead authors. He introduces the background to the quality standard:

"Over many years, a German expert committee, comprised of physicians and O&P professionals, drafted a quality standard reference for prosthetic treatment following lower-extremity amputations. While avoiding a technology-focused presentation, the aim was to place prosthetic treatment – based on the levels in the respective sections of treatment – in the context of a systematic treatment path for the first time.



Michael Schäfer

The two symposia concerning quality standards held at the OTWorld – World Congress 2018 in Leipzig are available as webcast:

- *"Quality standards in prosthetic fittings for lower limbs" Chair PD Dr. med. habil. Lutz Brückner and Michael Schäfer, Pohlig GmbH*
- *"Quality standards in prosthetic fittings for upper limbs", Chair Dipl.-Ing. Merkur Alimusaj Universitätsklinikum Heidelberg Technische Orthopädie and Michael Schäfer, Pohlig GmbH*

www.ot-world.com/congress-webcast

The comprehensive treatment approach consisting of 17 stages presents the chronologically necessary steps and framework conditions for successful prosthesis treatment. At the same time, it conveys practical measures, recommendations and approaches for the respective amputation situation, which ultimately enable quality-oriented and sustainable prosthesis treatment.

Expert knowledge of amputation surgery among experienced physicians with regard to the respective types of amputation was incorporated into the study along with qualified experience from level-related day-to-day prosthetic treatment. Treatment recommendations and relative and absolute exclusion criteria within treatment are shown very clearly using a traffic light system. This reference offers valuable information about successful prosthetic lower-extremity treatment for both interested physicians and committed O&P professionals."

WHO: Strengthening Healthcare Systems with Service Standards

The WHO Standards for Prosthetics and Orthotics (P&O) published in 2017 are intended to strengthen healthcare systems so that they can provide improved services. They aim to make care available, effective and efficient. With their recommendations, the standards cover four areas: (political) guidelines (governance, financing and information), products (prostheses and orthoses), personnel (workers), and the provision of services. After all, the challenge is to integrate interdisciplinary P&O treatment into every level of healthcare – from acute and long-term to primary, secondary and tertiary care.

The WHO standards created in an international collaboration represent a milestone, particularly for prosthetic and orthotic treatment in developing countries, where a close link exists between the frequency of physical disabilities

and the lack of resources. The promise behind this: everyone everywhere should have access to prostheses and orthoses in line with their needs, no one should be left behind.

In addition to the standards, there is a handbook for implementation. This helps the countries to develop or expand high-quality and affordable P&O services. The demand by the WHO on governments: The service standards should be viewed as part of healthcare and be the basis for comprehensive collaboration. Governments play a leading role when it comes to providing high-quality P&O services, identifying corresponding national priorities, and creating and coordinating guidelines, plans and programmes.

WHO: Standards for Prosthetics and Orthotics
Part 1 – Standards: http://apps.who.int/medicinedocs/documents/s23363en/s23363en.pdf
Part 2 – Implementation Manual: http://apps.who.int/medicinedocs/documents/s23364en/s23364en.pdf

ISPO Report: Amputations Resulting from Vascular Diseases

The ISPO has placed the "Consensus Report on Major Lower Limb Amputations" online for discussion and commenting by the P&O community until May 2018, before it publishes the final version. The report on lower limb amputations was created as part of an intensive consensus-finding process. The members of the ISPO International Consensus Group included orthopaedic surgeons, rehabilitation physicians, O&P professionals and therapists. The consensus report is intended to provide an updated version of previous guidelines. It is oriented towards service providers worldwide, who are involved in treating people with lower limb amputations due to vascular diseases. Both the availability of resources and expert knowledge differ widely in many parts of the world. For OT, co-author and coordinator Karen L. Andrews, MD, summarises the updates on the management of prosthetic treatment from the ISPO report:

An ISPO report was recently created thanks to ISPO International, Ottobock, Proteor, Ossur, and Blatchford. The first draft was presented in 2017 at the ISPO World Congress. This international report is intended to help countries to implement their own care guidelines. A brief summary of the updates on prosthetic treatment outlined in the report is provided below.

The precise details of a prosthetic prescription include socket design, suspension, interface, pylon, knee, and foot components. Prosthetic training should be arranged when the initial prosthesis is prescribed. A well-fitting prosthesis with appropriate components, supervised training, and ongoing follow-up optimises the use and function of the device.

The socket interface connects the prosthesis with the body. This is a critical element in socket design. Thorough research is needed to inform decisions about socket/liner prescriptions.

Research findings suggest that hydraulic microprocessor knees (MPKs) improve patient satisfaction, safety, and energy consumption. They benefit those with limited mobility, improve confidence, and decrease cognitive demands. Additional studies suggest the benefits of MPKs are not reduced by age, mobility grade, BMI, and other clinical variables.

A review of ankle foot components concluded that, at the transtibial level, stride length is greater with a dynamic response foot, than a conventional fixed prosthetic foot. At high activity levels, better gait efficiency was noted. Hydraulic and microprocessor controlled feet (MPF) have recently also become available. They reduce stress on the amputated limb, optimise residual limb pressure distribution, increase toe clearance, and feel safer during ramp ascent. It is, however, challenging to predict an individual's response to a specific prosthetic device/component on clinical variables alone. Empirical knowledge and individual judgement remain indispensable to determine appropriate prosthetic management. The opinion of the working group was that prosthetic management is best accomplished with a multidisciplinary, specialised treatment team.

Authors

Karen L. Andrews; Malte Bellmann; Helena Burger; Joseph Czerniecki; Bernard Greitemann; Jan H. B. Geertzen; Andreas Hahn; Matthew Houdek; Anton Johannesson; Gert-Uno Larsson; Magnus Lilja; Saffran Moeller; Carolina Schiappacasse; Ernst Schrier; Harmen van der Linde; Harry Voesten; Saeed Zahedi.

The complete report can be read at:
www.ispoint.org/?page=lowerlimbconsult

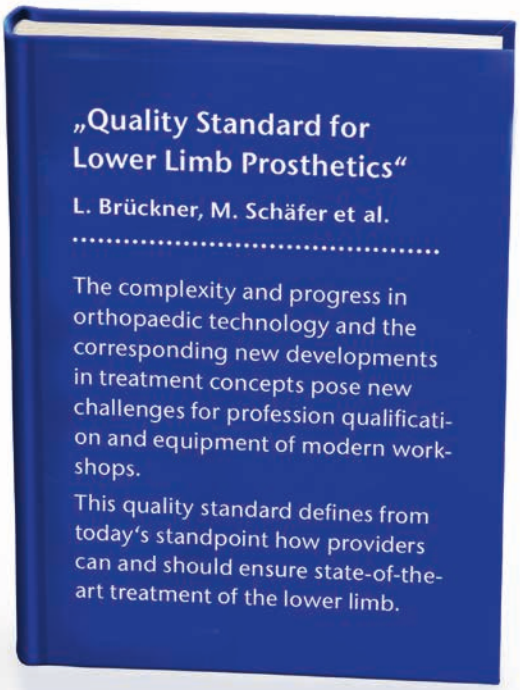
Conclusion

Bringing more knowledge, standardised approaches and a verifiable quality level into prosthetic treatment – this unites all three standards. The international reports and standards from the ISPO and WHO aim to largely set national implementation processes in motion. The WHO has published a special implementation handbook that can ultimately lead to guidelines in individual countries and, in particular, introduce developing countries to the latest standards in medicine.

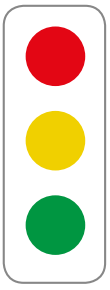
The ISPO Consensus Group drafted the report in conjunction with the updating of a Dutch guideline from 2012 on amputations and prosthetic rehabilitation due to vascular diseases. The consensus report summarises current expert knowledge and formulates updated recommendations of key points for daily practice, which are based on available evidence and and expert opinion.

The new standard on prosthetic lower-extremity treatment published by the DGIHV shows: until now, even in Germany, there was a lack of a standardised understanding of treatment and a definition that could withstand the requirements of a comprehensive, binding quality standard. In the compendium, systematic treatment paths were developed for the first time so that treatment is now more understandable and verifiable, not only for physicians, O&P professionals and therapists but also for cost bearers. ■

Quality Standard for Lower Limb Prosthetics



The German compendium “Quality Standard for Lower Limb Prosthetics” was published in 2018. Following the “Quality Standard for Upper Limb Prosthetics” published in 2014, this is the second of five treatment pathways that are currently being developed by working groups of the DGIHV e.V. (German Association for the Interprofessional Supply of Medical Aids), the former advisory board for technical orthopaedics. To give our readers an idea of the amount of expertise and depth of the treatment standard, you will find a complete sample chapter on pages 34 to 39. We selected Section 3.3 “Amputation at knee level, high activity level” from Chapter 3 “Knee disarticulation” as our sample, which is a useful supplement to this issue's focus: knee prostheses. In the following we also include some quotations from the compendium. We furthermore provide information on the experts who contributed to this German standard work and on the special colour system that allows readers to see at a glance which measures are recommended (green) or possible (amber) and which no longer comply with state-of-the-art treatment procedures (red).



Treatment recommendation

Strong recommendation: green ●

Can be implemented functionally based on the characteristics of the residual limb, general biomechanical properties and effects and mode of action

Recommended under certain circumstances: amber ●

Limited functional implementation based on the characteristics of the residual limb criteria, general biomechanical properties and effects and mode of action

Not recommended: red ●

Based on the characteristics of the residual limb, general biomechanical properties and effects and mode of action

From the preface:

"Different amputation levels of the segment of the limb and their special features in prosthetic treatment of the lower limb can be described using the same system.

For the respective segments of the limbs, treatment pathways were developed and applied to different amputation levels in correlation with the actual treatment situation:

1. Residual limb length
2. Activity level
3. Requirements of the residual limb
4. Rehabilitation goal
5. Prosthesis recommendation
6. Socket design
7. Components
8. Aesthetics
9. Add-ons
10. Instructions for use of the device
11. General information
12. Approval criteria
13. Service and maintenance
14. Training in the use of the prosthesis
15. Framework conditions
16. Trial fitting
17. Quality assurance

They guide readers systematically through requirements of and measures for prosthetic fitting of individual amputation levels of the lower limb. It is practical information like this that distinguishes this document from the rigid system of the catalogue of devices. (...)

We examined established methods such as classification of amputees in mobility grades 1 to 4 and discussed their value for assessment. To satisfy the requirements of the dynamic device provision process, a conscious decision was made to place less importance on this method of classifying mobility. Instead, indications were distinguished according to activity requirements of prosthesis users who were classified as patients with 'low activity requirement' and 'high activity requirement'. If desired, patients with low activity requirement could be assigned to mobility grades 1 and 2 and patients with high activity requirement to mobility grades 3 and 4.

Experts state that this method of differentiation according to activity requirement describes dynamic processes and aims of individual prosthetic fitting with respect to the actual situation more accurately.

Following the system used in literature for this field, we classified amputation of thigh and lower leg in three different length categories: short, medium, and long. Separate chapters were devoted to special lengths with specific treatment requirements such as an extremely short residual limb of the lower leg.

This method also contributes to a more objective, dynamic assessment, as treatment differs depending on amputation level, thus also affecting the rehabilitation goal. The team of experts took a clear position on this. In order to introduce a visual guideline to this reference work, a 'traffic light' rating system was invented that clearly indicates which measures are recommended according to the quality standard (green), which are possible under certain circumstances (amber), and which should be avoided (red).

This method should not only facilitate the work of orthopaedic technicians, but also assist physicians in prescribing a prosthesis, help physiotherapists understand the prosthesis, and support experts and insurance employees in evaluating the necessary treatment.

If an orthopaedic technician provides a device that complies with the recommendation of the quality standard (green), it can potentially accelerate the assessment of the service by the responsible employee in charge of the case and support an evaluation. Other options (amber or red) would require justification and, if necessary, the specific treatment situation would need to be discussed with the health insurance."

The authors:

Chairpersons:

PD Dr. med. habil. Lutz Brückner
Senior Consultant

Michael Schäfer
Certified Orthopaedic Technician
CEO of Pohlig GmbH
Board Member of the German Association of Orthopaedic Technology
Board Member of the Bavarian Association of Orthopaedic Technology

Other authors:

Olaf Gawron
Certified Orthopaedic Technician, Pohlig GmbH
Director of the Prosthetics Business Unit

Christian Hartz
Certified Orthopaedic Technician, CEO of EproTec Orthopädietechnik GmbH, Berlin
Board Member of Innung-Nordost and Fachverband Nordost

Lars Jäger
Certified Orthopaedic Technician
CEO of ORTHOVITAL GmbH

Dr. med. Armin Koller
Specialist in Orthopaedics
Senior Consultant for Technical Orthopaedics
Mathias-Spital Rheine

Daniel Merbold
Master of Business Administration
Certified Orthopaedic Technician
Owner of D Med Tech Consulting

Ingo Pfefferkorn
Engineer, Certified Orthopaedic Technician, Director of Orthopaedic Technology
OTB GmbH, Rostock, President of FOT, e. V.

Bernd Sibbel
Certified Orthopaedic Technician, Instructor for Prosthetics at the Federal Academy of Orthopaedic Technology, Dortmund

L. Brückner, M. Schäfer et al.

Extract from the compendium "Quality Standard for Lower Limb Prosthetics"

Section 3.3:

Amputation at Knee Level; High Activity Level

Residual Limb Length – Type of Amputation, Requirements, and Treatment Recommendation

- Knee disarticulation
- Transcondylar amputation

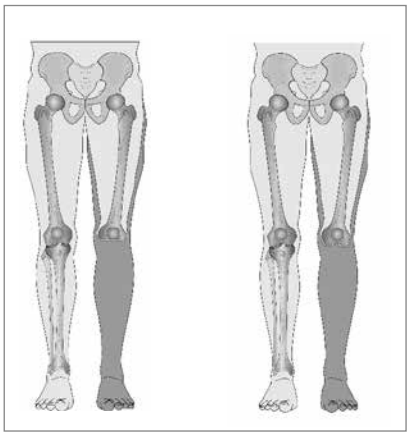


Fig. 1a *Transcondylar amputation.*

Fig. 1b *Knee disarticulation.*

Unlike the descriptions of other amputation levels, these two different amputation levels (Fig. 1a and b) are described together, since their prosthesis design is very much alike.

Activity level

Normal activity level: active user, no limitation of walking distances:

The amputee is able or has the potential to use the device in everyday routine to move on nearly any terrain with even and alternating speeds. Walking duration and distance are unlimited.

High activity level: active user, no limitation of walking distances:

Functional requirements such as high impact loads, tension, etc. and athletic activity result in special prosthesis requirements. Devices for children and adolescents are included in this category. A well-conditioned residual limb would be optimal.

Requirements of the residual limb

See Chapter "Knee disarticulation General information"

Rehabilitation goal

- As much equality with unimpaired individuals as possible
- Social integration; conduct activities of daily living (ADL)
- Fit amputee who is able to achieve the predicted higher activity level
- Independent donning, doffing, and handling of the prosthesis

Fitting recommendation

- Knee disarticulation prosthesis produced using custom measurements and/or impression technique with movable knee joint and foot component

Further differentiation is made by remarks in the general information section: types of prostheses, socket technology, knee and ankle joint function

Special criteria regarding residual limb length, requirements of the socket:

- Accommodation of residual limb volume
- Full-contact containment of the residual limb when standing and sitting
- Transfer of movement
- Load transfer
- Full-surface adhesion between residual limb and prosthesis for fixation
- Minimisation of pressure, tension, rotation, torsion, and shear forces
- Full contact and end loading
- Accommodation of sensitive bone protrusions

Requirement:

- Functional knee disarticulation prosthesis

Justification:

- Participation and greatest possible independence in everyday life
- Enabling ADL
- Restoration of body integrity
- Restoration of the support area
- Restoration of a physiological gait pattern
- Stabilisation

Socket technology

Requirement:

- Full-contact containment of the residual limb when standing and sitting
- Transfer of movement
- Load transfer
- Securely fixed to the residual limb

Justification:

- Preservation and protection of remaining muscle, skin and bone
- Preservation and support of blood flow
- Prevention of secondary damage
- Preservation and support of maximum possible joint and movement functions

Remarks:

Trial fitting required:

1. Manufacture of at least one analysis socket
2. Trial prosthesis for use in the manufacturing workshop (fittings, use training)
3. Trial device with the components to be tested or selected including a customised, load-bearing design. We recommend testing the device twice: first with the support of the therapist and orthopaedic technician and then in the amputee's daily routine.

Socket types
see Fig. 2

Commentary on restricted recommendations:

Containment socket with soft inner socket ●
Since this socket type is usually equipped with a tensioning adhesion mechanism, it may result in reduced lift stability in high activity levels (sport) due to high inertia.

Special type: Load transfer via the pelvis ●
This socket type should only be used if there is no or only a minute possibility of end loading via femoral condyles. The major functional advantages of a distal force transfer in conjunction with a socket rim that ends below the ischial level are nearly eliminated. The same generally applies to the more physiological gait pattern compared to higher amputation levels. If this socket system has proven to be the only usable socket type, fabrication is obligatory.

Which socket type is chosen depends not only on the individual requirements of an amputee but also on the quality criteria applied by the orthopaedics manufacturer (equipment in the workshop and level of training/expertise of the orthopaedic technician).

Adhesion and support mechanisms (Fig. 3)

Due to slight supracondylar tapering, the special shape of the residual limb resulting from wide femoral condyles allows for the use of a shape tensioning adhesion mechanism, regardless of the choice of socket material. Various materials are suitable for fitting a prosthesis after knee disarticulation.

Due to an individually adjustable shape of the rim, flexible and semi-flexible inner sockets made of PE foam, polyethylene, or silicone offer enhanced comfort.

Note: The criteria for selecting suitable materials for higher activity levels are determined after identifying the patient's specific condition.

Note: Criteria for selecting the materials to be used

Commentary on restricted recommendations:

Rigid hard socket – Outer containment ●
This type of socket system does not fulfil the requirements regarding function, handling, and comfort for this activity level. It limits the patient's possibilities and is not recommended.

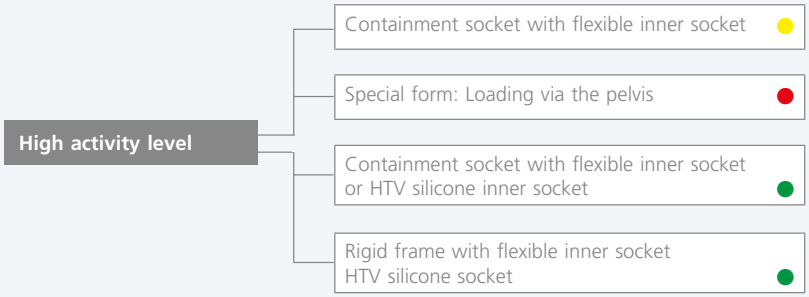


Fig. 2 *Recommended socket systems for knee-level amputation, higher activity level.*

Adhesion and support mechanisms

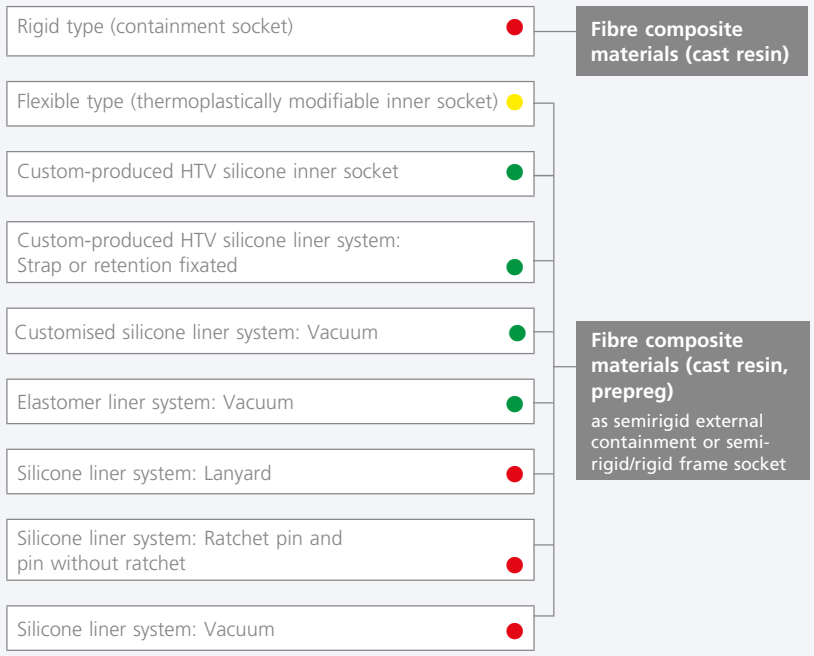


Fig. 3 *Recommended adhesion principles in socket technology for knee-level amputations, higher activity level.*

Flexible type: PE foam ●
This adhesion mechanism does not offer sufficient longitudinal stroke stability for high activity levels.

Silicone liner system: Lanyard ●
This liner system is usually equipped with a distal cup in standard shape and does not accommodate anatomical requirements of knee disarticulations. In addition, there is considerable lengthening of the socket system due to the deflector mechanism of the lanyard that counteracts the biomechanical requirements for a balanced lower leg length. This type of device is not recommended.

Silicone liner system: Ratchet closure ●
This liner system is usually equipped with a distal cup in standard shape and does not accommodate anatomical requirements of knee disarticulations. In addition, there is considerable lengthening of the socket system due to the closure mechanism that counteracts the biomechanical requirements for a balanced length of the lower leg. This type of device is not recommended.

Silicone liner system: Passive vacuum ●
This liner system usually has a standard shape that does not accommodate the anatomical requirements of a knee disarticulation and is not recommended due to fitting issues.

Components
Knee components

see Fig. 4

Commentary on restricted recommendations:

Knee joint systems 1.0 ●
Joints in this category do not comply with the manufacturer's recommendations for this activity level and do not fulfil the user's functional requirements. They limit the patient's possibilities and are therefore not recommended.

Knee joint systems 4.0 ●

Can be used under certain circumstances, as the generally limited structural height might not allow combination. In addition, the weight of the knee/foot of this combination may have a negative impact on the wearer's comfort.

Knee components

Mechanically controlled resistance mechanism:
– Bouncing
– Yielding

Electronically controlled resistance mechanism:
– Yielding
– Fixing
– Freezing

Foot components

The prosthetic foot is the basis of every prosthesis and makes safe standing and walking possible. Currently, classifications are made according to the following function-related selection criteria:

– Heel strike
– Foot roll-over
– Push-off

Tabular overview of foot systems
see Fig. 5

Knee components

Knee joint systems 1.0 ●
- Locking knee
- Mono- or polycentric axis geometry

Knee joint system 2.0 ●
- Mechanical: Weight or situation-dependent SP + SW
- Hybrid knee: Mechanical and hydraulic SP + fluid SW
- Hydraulic knee: Hydraulic SP + fluid SW

Knee joint system 3.0 ●
- Microprocessor: Hydraulic or magnetorheological SP + SW
- Electromechanical SP + SW

Knee joint system 4.0 ●
- Linked function control of knee & foot, control of SP + SW

Fig. 4 *Knee joint systems for knee-level amputations, higher activity level.*

Commentary on restricted recommendations:

Foot systems 1.0 ●
Due to limited planes of movement no physiological stance phase can be achieved with a locked knee.

Foot systems 4.0 ●
Functional benefits must be weighed against available structural height and increased component weight (possibly negative effect).

Foot systems 5.0 ●
Functional benefits must be weighed against available structural height and increased component weight (possibly negative effect).

Foot systems 6.0 ●
No current entries

Tabular overview of foot systems
see Fig. 6

Commentary on restricted recommendations:

Rotation adapter ●

Due to functional lengthening and a

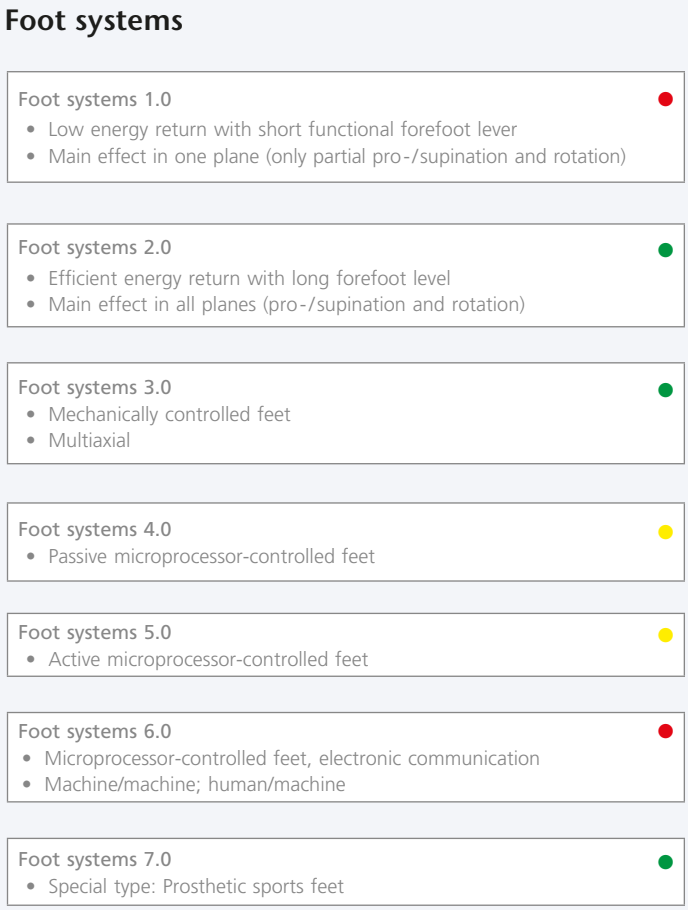


Fig. 5 *Foot systems for knee-level amputations, higher activity level.*

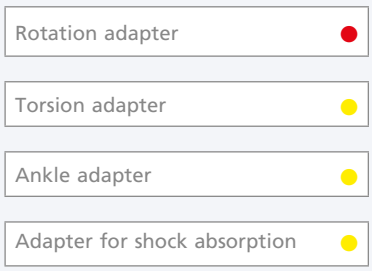


Fig. 6 *Functional add-ons for prostheses for knee-level amputations, high activity level.*

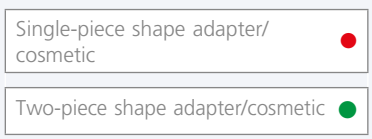


Fig. 7 *Shape adapter/cosmetic for knee disarticulation prostheses, high activity level.*

not generally limited hip rotation in a knee disarticulation socket, rotation adapters should not be used.

Torsion adapter ●

Test whether torsion adapters offer functional benefits and weigh these benefits against weight and structural height.

Ankle adapter ●

When used, check whether negative effects of adapter's own weight is proportional to the functional benefit.

Adapter for shock absorption ●

When used, check whether negative effects of adapter's own weight is proportional to the functional benefit.

Shape adjustment

Anatomical and optical shape adjustment of the amputated side, if applicable in two parts for thigh and lower leg. Also as protection of prosthesis components and coating (Fig. 7).

Commentary on restricted recommendations:

Red ●

A single-piece continuous cosmetic cover limits mobility/functionality of the prosthetic knee joint and has functional disadvantages. A single-piece cosmetic cover should be produced only at the express request of the user.

Add-ons

- Care sets
- Donning aids
- Shoes suitable for prostheses

Instructions for use of the device by orthopaedic technicians

- Explain and practice donning and doffing
- Explain and practice operating functions
- Explain and practice care instructions
- Personal hygiene/residual limb care:
  - Daily cleaning with water and pH-neutral soap; care of the residual limb with suitable products
  - Cleaning of components: clean according to manufacturer's instructions
  - Cleaning the socket: suitable cleaning of the inner and outer surface
  - Cleaning the liner: daily cleaning according to manufacturer's instructions

General information/ Hazard information

- Explain uses and limitations (e.g. water, temperatures, mechanical/chemical influences, etc.)
- Daily inspection (safety and function)

Approval criteria

Structural check

Prosthesis components must be used according to the respective manufacturer's guidelines.

Note: Observe manufacturer's structural recommendation and Medical Devices Act. Always conduct a static structural check showing vertical ground reaction forces.

Trial fitting

We distinguish between two phases of a trial fitting of a prosthesis
- Static fitting (trial fitting only when sitting or standing)
- Kinematic/dynamic fitting or walking trial.

Note: During static fitting, only fit and socket position are checked and any changes/adjustments needed are made. These trial fittings can first be conducted with a static device, followed by a fully assembled prosthesis. During dynamic fitting, the behaviour of the prosthesis during movement is the main point of concern, so any required changes/adjustments of the structure and the socket can be made. Always conduct a static structural check showing vertical ground reaction forces at the end of a trial fitting.

Phases of a trial fitting

Static fitting:
Check of
- Socket form/functional containment of the correct volume
- Length
- Foot position
- Proportions
- Flexion/extension
- Abduction/adduction
- Contact of shoe and ground

Dynamic fitting:

Implementation of the values determined during static fitting with respect to the patient's dynamics through gait analysis, e.g.:
- Step and stride length
- Rollover behaviour of the prosthesis shoe
- Socket system behaviour in stance and swing phases
- Knee joint movement
- Upper body movement
- Use of upper limb
- Compensation movements

Check of socket fit:

Only a well-fitting socket that completely contains the residual limb volume, correct load bearing, and fixation result in a patient-friendly functional prosthesis that is acceptable for the patient.
The following are especially important:
- Changes in skin structure/ colour (redness)
- Pressure points
- Skin temperature

Note: For patients with arterial occlusive disease, excessive compression or pressure points must be avoided at all costs. The fit of the prosthesis socket must be checked repeatedly at short intervals.

Check of fit
- Volume
- Skin redness
- Skin temperature (contralateral comparison)
- Check of residual limb containment (especially the distal surface of the femoral condyle)
- Socket brim
- For patients with arterial occlusive disease, check blood flow very carefully
- The prosthesis must remain in position (stance and swing phases)
- Consider comorbidities and restrictions of motion, especially of the preserved joints

Check of overall appearance
- Dimension
- Workmanship
- Body symmetry
- Aesthetics
- Colouration
- Equivalent to dimensions and alignment of the contralateral side

Check of support mechanisms
- Functional test of all support mechanisms

Static and dynamic check
- Stance stability
- Check structural criteria
- Prosthesis length
- Clinical gait check
- Stance/swing phase times

Wearing period
- Comparison of the individually required wearing time with the patient's actual wearing time
- Check indication for an alternative prosthesis

Functional benefit
- Range of movement/function and ability to carry out activities of daily living (ADL)
- Check (questionnaire/demo) activities that enable the amputee to lead an independent life according to their possibilities

Service and maintenance

Initial prosthesis (interim prosthesis)
- Check fit every 2 to 4 weeks, more frequently if necessary
- Check at least once a week during rehab
- Recommended period of use: 3 to 6 months

Definitive prosthesis
- Check fit semi-annually
- Carry out service and maintenance according to the manufacturer's directions
- Period of use max. 3 to 5 years if the conditions and requirements remain the same

Justification:
- Preservation of functionality and fit
- Comply with warranty rights/ claims

Note: Have the amputee's mobility, morbidity, and/or weight changed?

Prosthesis training

Requirements
Interim prosthesis:
- Conditioning the residual limb
- Ensure full end loading and weight transfer
- Restoration of body balance
- Symmetrical, harmonious gait
- Adaptable to changing residual limb situations

Definitive prosthesis:
- Improvement and fine adjustment of ability to walk and stand
- Increase load capacity; coping with different situations and walking speeds
- Use of varying walking speeds
- Adaptation of physiological roll-over
- Stability of shape and function

Goals
Interim prosthesis:
- Support of consolidation measures
- Gait training
- Transfer
- Ramps, stairs, etc.
- Check of potential/anticipated mobility

Definitive prosthesis:
- Permanent, stable prosthesis with biomechanical compensation of the amputation loss
- For use in ADL

Repeated prosthesis and gait training

Due to primary movement patterns that are subconsciously controlled by the central nervous system, the functional implementation of compensating for a missing lower limb is – despite a prosthesis – an extremely complex task for amputees. The follow-up of the changed biomechanics and post-amputation proprioceptive coordination of the gait is essential for further care and depends on several factors:
- Amputee's age
- Underlying disease and amputation level
- Condition of soft tissues
- Mental and physical condition
- Accompanying diseases
- Loss of proprioception of the foot and its afferent effect on movement coordination of the central nervous system

Only continuous and systematic training with the goal of achieving coordinated interaction of the factors listed above enable individuals with a disability to achieve self-determination and participation in social life, guaranteed in Art. 3 (3) of Germany's Basic Law. This implies that after every fitting with a new prosthesis or component, a combination of prosthesis training and special gait training under competent supervision (rehabilitation clinic, outpatient rehabilitation facility, certified medical supplier) will be necessary. Amputees will therefore be able to practise coping with the new prosthesis, care and maintenance, donning technique, and in gait training rhythm, speed, step length optimisation, stairs climbing, walking on slopes, terrain training, fall training, and fitness training.

Framework conditions

Requirement:

- Pre-qualification
- Certified orthopaedic technology mechanic and/or professional instructor
- Certification of the provider

Justification:

- Assuring the required quality of provider expertise
- Assuring qualification and quality of care

Note: For complex prostheses, specific in-depth expertise is necessary; trial prostheses are available for complex residual limb situations.

(Analysis socket) Trial prosthesis

Requirement:

1. Production of trial socket (analysis socket)
2. Trial prosthesis for use in the production workshop (trial fittings, training in prosthesis use)
3. Trial device with the components to be tested or selected including a customised, load-bearing design. We recommend testing the device twice: first with the support of the therapist and orthopaedic technician and then in the amputee's daily routine.

Note: Analysis sockets are thermoformed, rigid, stable, transparent sockets made of plastic, (e.g. PETG), produced directly on the moulded model, used for checking the exact static fit. These sockets may also be used for conducting dynamic walking trials with the amputee. If the prosthesis has a containment socket with a flexible inner socket, the analysis socket is to be produced using the definitive design.

Quality assurance

- Technical and process-oriented control and quality assurance for the production of lower limb prostheses
- Internal and external further training required
- Dimension sheet/assessment sheet/ mobility evaluation
- Documentation (video/photo)

J. S. Sigurdardottir, S. P. Sigurthorsson, G. Halldorsdottir, G. K. Ludviksdottir, Th. Helgason, K. Lechler, M. Oddsson, Th. Ingvarsson, K. Kristjansson

Surface vs. Implanted Electrodes for the Control of Lower Limb Prosthetics

Current lower limb prosthetics are limited when compared with the human leg. These prosthetics have a limited range of motion, lack power support and have no direct measure of what the user wants their prosthesis to do. Myoelectric signals have been utilized to achieve a direct link to the users nervous system. They can allow the user to control their prosthesis in a way that conventional devices simply cannot offer. For example volitional control over the ankle flexion whilst walking is not possible but would be very beneficial to the user. In this study we compared two myoelectric signals, recorded with surface vs. implanted electrodes, for the control of lower limb prosthesis. The applicability and practicality of a myoelectric control system was examined. We found that the implanted electrodes provided a more robust signal and currently offer a more practical myoelectric control than systems using surface electrodes.

Key words: myoelectric, sensors, implantable, control, prosthesis

Introduction

The Pros and Cons of Adaptable Prostheses

Of commercially available lower limb prostheses, the most advanced control is provided in microprocessor controlled prostheses. These use information from kinetic and kinematic sensors to adapt to the user's locomotion and have no direct measure of the user intent. A microprocessor controlled prosthesis can adapt to the user to certain extent e.g. by adjusting to different walking speeds. The main benefits have been shown to be e.g. decrease in stumbles and falls leading to increased safety [1], more natural gait during stair and ramp descent and ascent [2–3], reduced metabolic cost [4] and improved ambulation [5].

Current shortcomings of microprocessor controlled prosthesis is a long adaption time and they are not always intuitive for the users. They also have a limited range of motion across multiple planes, offer limited or no power support and offer no direct volitional control. Simply put, current devices are quite limited when compared with their normal lower limb. A human-machine interface, taking use of the brain, can address some of these limitations by tapping into the world's greatest control center capable of controlling complex movements while also thinking about what's for dinner. Advance human-machine interfaces use bioelectric signals to directly connect to the nervous system and thus utilize the world's greatest control center, that is, the brain [6].

Using Electric Muscle Signals

Using the electric activity of muscles, Electromyographic (EMG) signals have been used to provide prosthetic users with both volitional and non-volitional control and myoelectric upper limb prosthesis are commercially available. Research using surface electrodes suggest that EMG controlled prosthesis can provide improved function and prosthesis embodiment while also reducing muscle atrophy and phantom limb pain [6–9]. By allowing the amputee to directly control his prosthesis in an intuitive way he becomes more aware of his prosthesis and feels more like the prosthesis is a part of him. This should also allow the user to react faster and more appropriately in situations that the programs are unable to predict.

Surface vs. Implanted Electrodes

Despite their promising results in a lab environment there are no EMG controlled lower limb prosthesis commercially available. This is largely due to the limitations linked to the use of surface electrodes and the challenge of creating a practical and comfortable surface EMG recording setup. Surface electrodes are sensitive to environmental changes such as high forces within the amputee's socket, disturbances because of sweat, movement of electrode position when donning and doffing, power hum and movement artifacts [10–11]. These limitations have resulted in the need of extensive training and the systems are often only applicable during sitting or non-ambulation [7].

The Alfred Mann Foundation developed the first fully Implantable

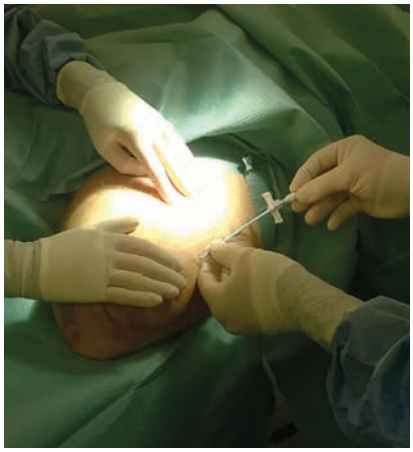


***Fig.1** Photograph taken in the surgery during the insertion of the IMES.*

Fig. 2 *A photograph of the implanted myoelectric sensor.*

Myoelectric Sensors (IMES) to overcome the inherent problems of surface electrodes. The sensors can be injected into a residual muscle through a small (5–10 mm) incision and used to record muscle activity [12]. They are powered through a magnetic link which is also used to wirelessly transmit data to and from the IMES. The sensors can be easily turned off by the user by turning off the magnetic link or by removing the prosthetic socket. These sensors provide a robust recording setup and the environmental factors that cause discomfort and signal disturbance with surface EMG are completely bypassed by implanting the electrodes.

The aim of this study was to compare myoelectric signals recorded with surface electrodes vs. IMES and the feasibility of their use for control of lower limb prosthetics.

Equipment & Method

Subjects & Surgery

Two lower limb amputees were recruited for an IMES study, one transfemoral (TF) and one transtibial (TT). Both amputees were experienced users at a K3 activity level. Fine wire electrodes were used to verify that an adequate myoelectric signal could be recorded from each muscle during a volitional contraction. Two IMES sensors were subsequently implanted into each user, into the bicep femoris and the rectus lateralis of the TF subject and into the tibialis anterior and the gastrocnemius of the TT subject. Each procedure took about 30 minutes and was performed under local anesthesia and mild sedation (figure 1). Both subjects were asked to use crutches instead of their prosthesis for two weeks after the operation and allowed a 4-week recovery period before testing with the IMES began.

The IMES System

Each sensor is about 2.5 mm in diameter and 16 mm long with custom electronics housed within a ceramic cylinder. Each end of the cylinder is made from conductive metal that serve as electrodes (figure 2). X-rays were taken after the implantation to confirm the correct implant location relative to the intended placement of the socket (figure 3). After the sensors had been implanted into the residual muscles the coil, which is housed by the prosthetic socket, can be used to wirelessly transmit power and data to and from the IMES through a magnetic field. The coil is controlled by a coil drive module which modulates the magnetic field. The IMES controller interface powers, programs and receives data from the IMES and is connected to the bionic signal message broker (BSMB) which connects the IMES system and Össur's prosthetic devices (figure 4). The IMES are only capable of sending a filtered, rectified and integrated signal due to stability issues and the sampling rate of the sensors was 236 samples per second.

Surface Electrode Setup

Preliminary testing was done to identify the appropriate surface electrode setup. A bioamplifer and recording system from Kine ehf. was used to record the surface EMG signal. These amplifiers have a sampling frequency of 1600 Hz and can wirelessly transmit the EMG data to a computer. Socket fit has been shown to effect the muscle activity of the residual limb and it was therefore crucial to use the same socket for both the IMES and the surface EMG recording. The amplifiers were too bulky to be utilized within the IMES socket and therefore soft hydrogel electrodes were placed on the skin and the connecting wires passed proximally over the socket rim to the bioamplifiers located on the subjects back. In order to determine the optimal position of the electrodes the subjects' residual limb was palpated during contractions and the area of greatest interest was identified and marked. Iterative measurements were then done to identify the strongest signal location. Finally electrodes were placed on the strongest signal location as well as around that area taking in account the anticipated displacement by the liner and socket i.e. in the proximal direction (figure 5).

Testing

Muscle activity patterns vary more between prosthetic users than between non-amputees largely because of anatomical differences between residual limbs and due to different walking strategies [7]. Therefore the natural muscle activity patterns and volitional contractions were initially recorded with the Rheo knee and Proprio foot without EMG control to establish when and how the controls should be implemented.

Surface EMG signals were recorded during sitting with and without the liner and during standing on a prosthesis to evaluate the effect of the prosthetic interface on the signal. Additionally the TT user was asked to volitionally contract his muscles during

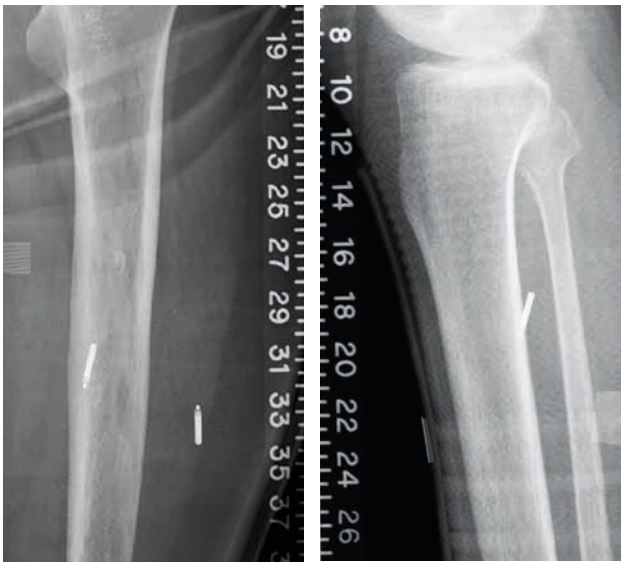


Fig. 3 *X-rays of the TF user to the left and TT user to the right showing the location of the IMES sensors.*

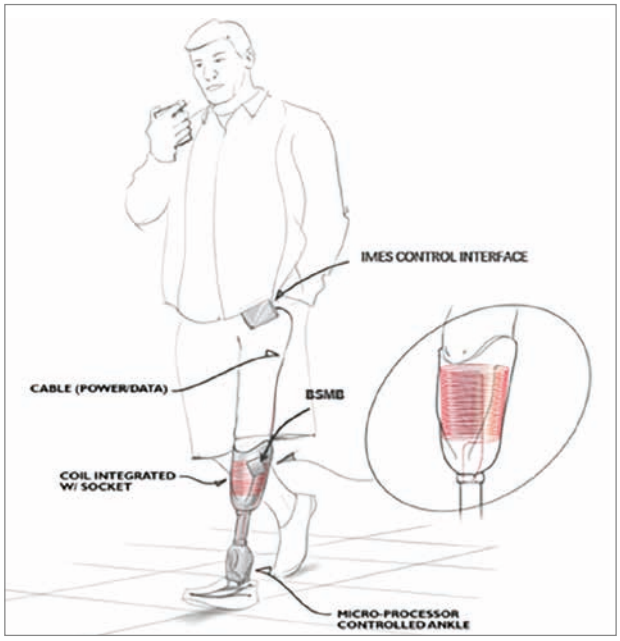


Fig. 4 *Shows the IMES system for a TT user. The coil is laminated within the socket and wirelessly communicates with the IMES. The IMES control interface is used to control the coil and send muscle signals to the BSMB which then communicates with the prosthesis.*

level ground walking to mimic the control signal for dorsi- and plantarflexion. The muscle activity pattern was then recorded with the IMES and surface electrodes during walking, stair descent, and sit-to-stand and stand-to-sit movements. The surface EMG could not be recorded while the IMES system was turned on due to the magnetic field produced by the system and therefor these measurements were not done simultaneously.

The difference between the IMES and surface EMG signals were compared, focusing on long term use and reliability. Signal qualities were examined using EMG profiles, comparing the mean amplitudes and standard deviation of the signal during multiple cycles. Practicalities of the two recording methods were assessed in light of connection failures and user comfort.

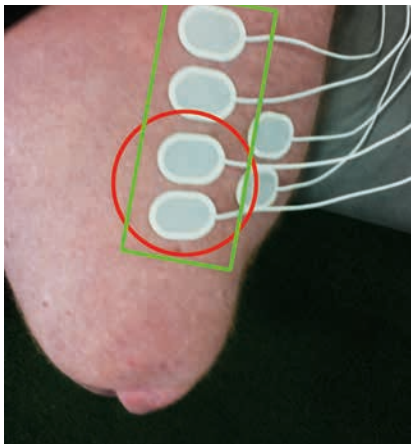


Fig. 5 *Determining the region of greatest interest (green box) and the area of strongest myoelectric signal (red circle) was done with iterative measurements. Electrodes were then placed on and around the area of interest taking in account the possible movement of the strongest myoelectric signal location.*

Results

No adverse events occurred during the procedures and the implants are fully functional three years post implant. The subjects have not experienced any discomfort due to the sensors and they have not had to limit their prosthetic use.

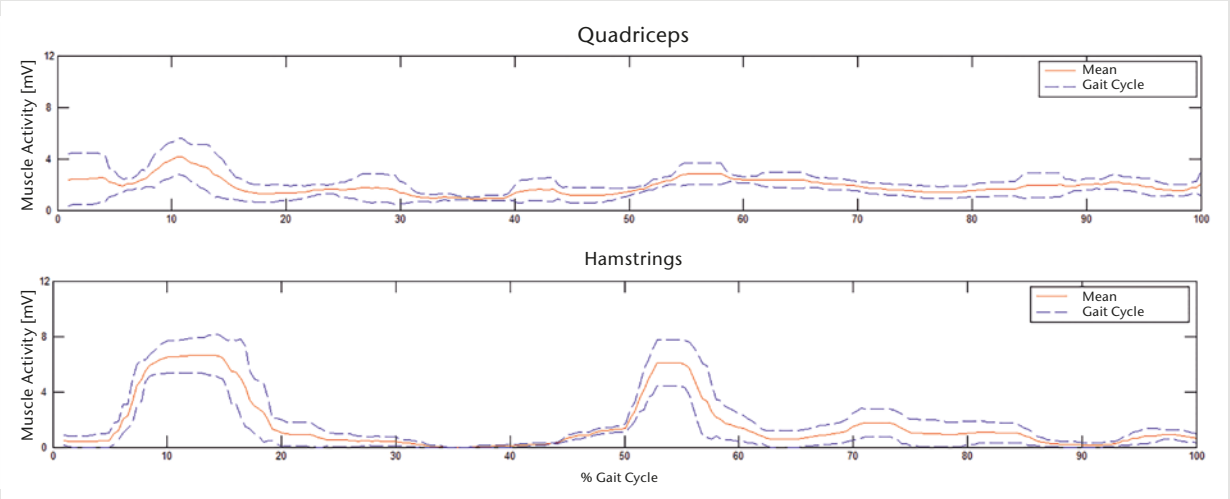
The surface EMG recordings of volitional contractions during sitting showed improved signal-to-noise ratio after donning the liner. The signal was the strongest during the volitional contraction of the subjects while they were standing on their prosthesis. This might be because the added pressure from the socket held the electrodes close to the signal source and/or subjects were able to produce a stronger contraction while standing. Both subjects' volitional contractions could be detected with the surface electrodes and IMES, during non-weight bearing and weight bearing situations. However, the signal quality of the sEMG was inferior to the IMES signals based on the EMG profiles.

The signals' mean amplitude for both muscles in all weight bearing exercises (i.e. walking, stair descent and sit-to-stand and stand-to-sit) was higher and showed less variability for the IMES signal when compared with the surface EMG signal. This is illustrated in figure 6 which shows the mean and standard deviation of the IMES and surface EMG signals recorded during stair descent. In this figure it can be seen that the hamstrings are activated when the knee starts flexing and also prior to the subsequent swing extension. During ambulation a distinct muscle activity pattern could be recorded from the TF subject. However, during volitional contractions the TF user had difficulties with contracting individual muscles as indicated by both the surface EMG and IMES measurements. An example of the sEMG signal check can be seen in figure 7 where the subject was asked to relax for 5 seconds and then contract his quadriceps. The contraction signal of the muscle under investigation was always stronger than the signals of co-contracting muscles which could therefore be ignored in a control scheme with a simple threshold. The TT subject did not have any distinct muscle activity patterns that could be recorded with either setup during level ground walking. However, when the subject was asked to think about lifting his toe during gait a very distinct activity could be seen.

The surface EMG recording session lasted for 6 hours while the IMES recording session lasted for 3 hours. The difference was because of connection failures of the surface electrodes due to sweat and motion artifacts which resulted in more frequent recordings. The subjects experienced little or no discomfort during the recording session but the electrodes and wires left visible marks on the subjects' skin in both cases. Both subjects reported that these marks remained for the rest of the day.

Discussion

Both the surface EMG and the IMES signals recorded could potentially be used for volitional control of lower limb prosthesis given the right control scheme. The distinct involuntary muscle activity pattern of the TF user seen with the IMES measurements during all exercises could also be used for control, however it also need to be taken into account when implementing volitional control. When the TF user was provided with direct control over his ankle was prompt-



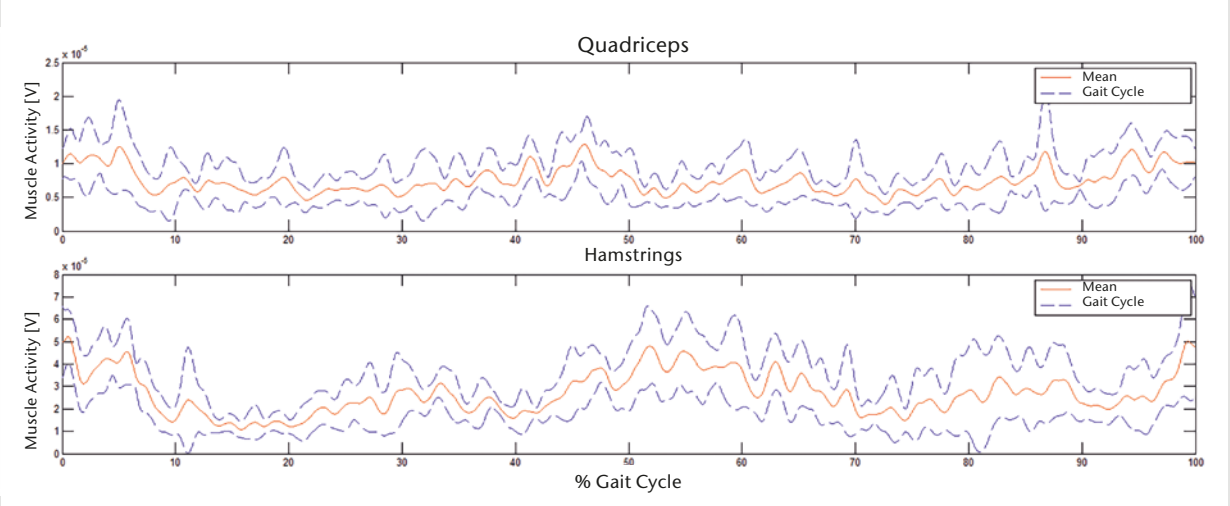


Fig. 6 *Mean value and standard deviation of 8 gait cycles during stair descent. IMES measurements can be seen in the top two graphs and the surface EMG measurements in the two lower graphs. These figures show that the IMES muscle activity pattern is more distinct then the sEMG signal.*

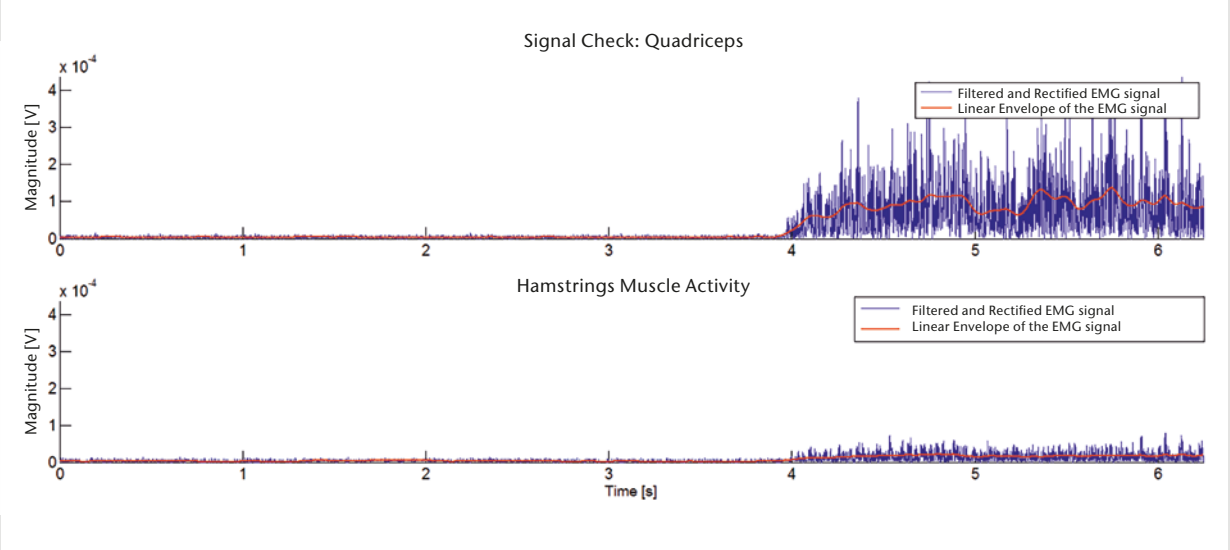


Fig. 7 *Signal check of the Quadriceps muscles where the subject was asked to relax and then contract his muscle. Muscle contraction of the Quadriceps resulted in muscle activity of the Hamstring muscles as well.*

ly dorsiflexed due to the involuntary muscle activity occurring during the forward movement of the foot.

Standard filtering methods did not always remove the noise from the surface EMG signal but the characteristics of the artifacts and muscle signal differed and therefor useful information and viable control signals could always be extracted from the surface EMG signal. These results suggest that the main problem of using myoelectric signals for lower limb prosthetic control is not the signal quality but rather the designing a commercially acceptable prosthetic interface that is robust enough and comfortable for the user.

This study was limited to only two prosthetic interfaces, one for each subject, but research and experience has shown that integrating a bioamplifer within the prosthetic interface results in a more comfortable setup with reduced artifacts [13]. Further research on the development of a comfortable and robust surface EMG prosthetic interface are ongoing and show the promise of EMG controlled lower limb prosthetics [6–7, 14–16]. However, these studies also highlight the main limitations of the use of surface electrodes as previously discussed and lack practicality.

Both myoelectric signals, IMES and surface, can be used for control provided if a practical myoelectric recording system is developed for the surface recording. Surface signals might be used complimentary to current microprocessor control of bionic prosthesis.

The IMES provide a robust myoelectric recording system allowing for continued IMES testing. Preliminary results from these tests are promising providing the subject with a reliable direct and spontaneous control over his prosthesis in different terrains and circumstances.

Some human activities and motions can't be expressed by algorithms and mechanical data alone. By connecting with the nervous system the user can take the prosthetic control beyond existing possibilities. The nervous system can provide bi-directional information for both sensing and control, providing information to the prosthesis from the user and feedback about the prosthesis to the user. That is the future, but in the meantime the focus needs to be on the creation of a practical, robust and intuitive control system with a comfortable interface.

For the authors:
Jona Sigrun Sigurdardottir
Ossur Iceland
Grjothals 1–5, Reykjavik, Island
jssigurdardottir@ossur.com

Reviewed paper

References:

[1] Kahle JT. Comparison of nonmicroprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference. J Rehabil Res Dev, 2008; 45 (1): 1–14

[2] Alimusaj M, Fradet L, Braatz F, Gerner HJ, Wolf SI. Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of transtibial amputees. Gait & Posture, 2009; 30 (3): 356–363

[3] Fradet L, Alimusaj M, Braatz F, Wolf SI. Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system. Gait & Posture, 2010; 32 (2): 191–198

[4] Delussu AS et al. Assessment of the effects of carbon fiber and bionic foot during overground and treadmill walking in transtibial amputees. Gait & Posture, 2013; 38 (4): 876–882

[5] Gailey RS et al. Application of self-report and performance-based outcome measures to determine functional differences between four categories of prosthetic feet. J Rehabil Res Dev, 2012; 49 (4): 597–612

[6] Zhang X, Liu Y, Zhang F, Ren J, Sun YL, Yang Q, Huang H. On Design and Implementation of Neural-Machine Interface for Artificial Legs. IEEE Trans Ind Inform, 2012; 8 (2): 418–429

[7] Wentink EC. Feasibility of Enhanced User Control and Feedback in Upper Leg Prostheses. Diss. University of Twente, Enschede, 2013

[8] Hargrove LJ et al. Robotic Leg Control with EMG Decoding in an Amputee with Nerve Transfers. New Engl J Med, 2013; 369 (13): 1237–1242

[9] Ortiz-Catalan M, Sander N, Kristoffersen MB, Håkansson B, Brånemark R. Treatment of phantom limb pain (PLP) based on augmented reality and gaming controlled by myoelectric pattern recognition: a case study of a chronic PLP patient. Front Neurosci, 2014; 8: 24

[10] Ortiz-Catalan M, Brånemark R, Håkansson B, Delbeke J. On the viability of implantable electrodes for the natural control of artificial limbs: Review and discussion. Biomed Eng Online, 2012; 11 (1): 33

[11] Oskoei MA, Hu H. Myoelectric control systems – A survey. Biomed Signal Process Control, 2007; 2 (4): 275–294

[12] Weir RF, Troyk PR, DeMichele GA, Kerns DA, Schorsch JF, Maas H. Implantable Myoelectric Sensors (IMESs) for Intramuscular Electromyogram Recording. IEEE Trans Biomed Eng, 2009; 56 (1): 159–171

[13] Hefferman GM, Zhang F, Nunnery MJ, Huang H. Integration of surface electromyographic sensors with the transfemoral amputee socket: A comparison of four differing configurations. Prosthet Orthot Int, 2014; 39 (2): 166–173

[14] Zhou P, Lowery MM, Englehart KB, Huang H, Li G, Hargrove L, Dewald JPA, Kuiken TA. Decoding a New Neural-Machine Interface for Control of Artificial Limbs. J Neurophysiol, 2007; 98 (5): 2974–2982

[15] Ha KH, Varol HA, Goldfarb M. Volitional control of a prosthetic knee using surface electromyography. IEEE Trans Biomed Eng, 2011; 58 (1): 144–151

[16] Lipschutz RD, Lock BA. A Novel Research And Clinical Approach To Using Gel Liners For Collection Of Surface Myoelectric Signals For Prosthetic Control. In: Proceedings of the MyoElectric Controls/Powered Prosthetics Symposium 2011, New Brunswick, Canada, 2011

D. Hochmann

3D Printing in Technical Orthopaedics – Current Status and Outlook

The article describes the current status and prospects for development of additive manufacturing processes in technical orthopaedics. In addition to describing the special advantages, it discusses the existing technological, material-based and regulatory risks and presents a vision of a completely digital process chain.

Key words: 3D printing, additive manufacturing, technical orthopaedics, prosthetics, orthotics

Introduction

Additive manufacturing (AM), often also called "3D printing", is now considered to be the next industrial revolution. The vision of being able to produce highly-complex, customised orthopaedic devices with a high level of precision practically at the touch of a button has gained more and more fans. At the same time, many orthopaedic technicians who use conventional methods are concerned and fear being left behind by the rapid pace of technological development. Others describe 3D printing as the next "hype" and point to recent developments that were hailed as revolutionary but failed to meet the high expectations – such as osseointegration – or were only partially successful – such as industrial service fabrication.

The objective of this article is to describe the specific advantages of AM for technical orthopaedics as well as the technical, material, and regulatory risks that could ultimately jeopardise the success of 3D printing. An attempt is also made to show what a complete digital supply chain of the future would look like. This should not address the use of AM as one potential fabrication technique among many, but instead its role as an essential component of a largely digital supply chain. When an OT workshop scans plaster casts and "3D prints" them when needed, this may solve the workshop's storage problems, but does not fundamentally change patient care. In orthopaedic footwear technology, it is ultimately irrelevant whether the lasts are produced conventionally or using AM if the shoes are still produced using conventional methods.

The changes brought on by AM methods can come sooner than expected. This has already been seen in other areas of medical technology. For example, 3D printing for hearing aids has already led to a revolution – today, over 90% of all hearing aids are adapted to the shape of the patient's ear. This shows that the mass generative fabrication of medical devices can already be profitable today and will push companies that use conventional methods out of the market.

Additive manufacturing

The term "3D printing" is often used for all fabrication methods in which three-dimensional objects are generated from a CAD model by adding layers of material. However, this generalisation is not quite accurate, as the various additive methods differ greatly with respect to the physical principles, the existing technological challenges and possible defects of the finished product. AM methods can be classified based on the following characteristics:

- Type (metal, polymer) and form (wire, powder, paste, fluid, etc.) of the starting material,
- Solidification mechanism (polymerisation, separation, adhesion, chemical reaction, etc.),
- Kind of energy (heat, laser, electron beam, etc.).

Selective laser sintering (SLS) is mentioned here as an example as it has been used especially frequently in technical orthopaedics up to now. This is a thermal method in which a plastic powder is melted locally and partially with a laser beam in order to ensure a bond between the particles. The process is repeated layer by layer until the desired 3D object has been made. Thermoplastic materials – both crystalline (nylon, polyamide PA11 and PA12) and amorphous (polystyrene, polycarbonate) – are primarily used. Other methods that are now used are fused deposition modelling (FDM) and multi jet fusion (MJF).

Because of the fabrication in layers, AM differs greatly from subtractive methods that involve removing material and from formative fabrication methods in which a formative container defines the desired shape. AM does not require product-specific tools, so there are no restrictions due to certain tools. The components can also be fabricated in any spatial orientation. The decisive advantage for medical technology, however, is that the cost of items is not connected to their complexity or degree of customisation. This makes it possible to produce medical devices adapted to the individual anatomical situation of a specific customer within a short time – on the spot and as needed. Simultaneously, the designer has the unprecedented freedom to produce complex shapes integrating a high degree of functionality and with a highly efficient use of material in a single manufacturing step. Some disadvantages of AM such as the limited construction size and the relatively long time needed per piece are less important in medical technology. Other disadvantages, however, such as the (still) limited number of additive materials available with modest mechanical properties and the difficulty of ensuring quality and process control are more problematic in the heavily regulated medical devices market. It is therefore expected that AM pro-

cesses will become established mainly in those areas of medical technology in which their advantages give them a crucial edge over the current situation and where their disadvantages are negligible or can be overcome.

3D printing is not an end in itself

Orthopaedic and medical supply companies are very interested in additive manufacturing. As was apparent at OTWorld 2018 in Leipzig, many companies have already had their first experience with the new technology. But many disappointments are also reported. This is due in part to the very high expectations, but also to an incorrect approach.

If we look at the products presented at trade fairs, congresses and on the internet, there are two extremes: on the one hand, there are attractive futuristic devices by industrial designers, which are, however, frequently deficient in biomechanical aspects regarding force transmission, axis incongruence, pressure points, etc. On the other hand, orthopaedic technicians copy the old product designs intended for conventional fabrication and they are subsequently criticised because the functional characteristics are worse. Neither approach leads to success. The most attractive design is useless if the requirements of functionality, precise fit and wearing comfort are not met. Since the (currently) available additive materials cannot yet compete with the mechanical properties of conventional materials, merely copying an old design is not very useful, as it entails foregoing the opportunity to compensate for this disadvantage using suitable – i.e. numerically optimised or bionically inspired – structures. This also shows that there is often too little understanding of how shape and functional properties correlate with the biomechanical effect of the orthoses.

This makes it clear that devices made using additive methods must be redesigned from scratch. The possibilities of producing complex structures that additive manufacturing opens up must be taken into consideration when designing the devices. The designer must have a fundamental understanding of the biomechanical mechanisms of action and the functional parameters of the devices. Orthopaedic devices are not necessarily better, less expensive, and available more quickly simply because they are made using additive manufacturing.

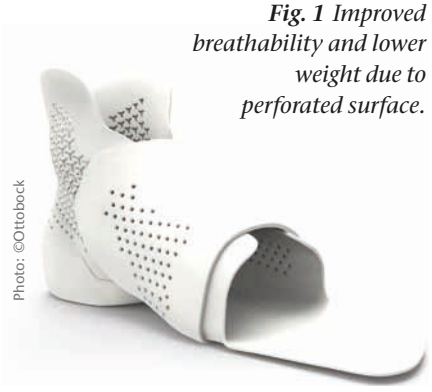


Photo: ©Ottobock

***Fig. 1** Improved breathability and lower weight due to perforated surface.*

Additive manufacturing in technical orthopaedics

Nevertheless, AM has already had initial success in technical orthopaedics. Selective design can already lead to optimised properties, e.g. improved breathability using perforated surfaces that are also associated with a lower weight (Fig. 1).

Another very valuable aspect is the option of adapting the appearance to suit the patient's taste. For idiopathic scoliosis, which, for female patients, usually has to be corrected before adulthood, the success of treatment is directly related to acceptance of the device. There have been initial scientific studies that show that giving the orthosis a modern shape and involving the patient in its design can have a lasting effect on acceptance [1]. These results can also be transferred to other kinds of orthoses. An example of this is the "WHO-Spiral-Printorthese®" from Pohlig (Fig. 2), for which a wide range of different patterns and colours are offered that can also be combined individually [2].

Three areas of use can be defined in technical orthopaedics that can benefit from the potential advantages of additive manufacturing:

- Additive manufacturing of previously custom-made devices (AFO, KAFO, socket, liner, etc.),
- Customised additive manufacturing as a substitute for standardised fabrication, i.e. devices that are prefabricated according to a size system (positioning splints, cervical orthoses, etc.),
- Customised additive manufacturing of previously industrially produced system components (prosthetic feet, prosthetic hands, orthosis joints, etc.).

These uses vary widely with respect to the persons involved, the previously used production techniques and the applicable regulatory and clinical requirements.

The first group does not benefit from the possibilities for customisation offered by AM as these devices are already custom made. At the same time, these products must meet the strictest requirements for fit and functionality, so the advantages of AM currently lie more in saving money and reducing production time. In their review of the studies conducted up to now, Bagaria et al. conclude that 3D printed devices in this group are usually already comparable with conventionally produced devices [3]. However, this assessment contradicts the practical experience in Germany up to now. The reason for this lies in the devices tested and in the comparison parameters of the studies: Primarily thermoformed drop-foot orthoses made of polypropylene were used in the comparisons and only rough time-distance parameters such as step length and gait speed were compared. However, there are initial studies that show that devices made using additive manufacturing can be biomechanically equivalent if their functional parameters are comparable with conventional orthoses. In a study by Harper et al., additive manufactured AFOs were just as good as conventional dynamic AFOs made of carbon prepreg in the gait analysis when they had the same joint stiffness [4]. Due to the differences in materials, additive manufactured AFOs are still heavier, bulkier and more conspicuous than conventional devices.

A major challenge when using AM in prosthetics is the fact that, despite the huge improvements made in recent years, optical 3D scanning techniques are still not an adequate substitute for conventional plaster casts, in which the technician can put targeted pressure on the tissue and thus estimate the tissue properties and compress the tissue if re-

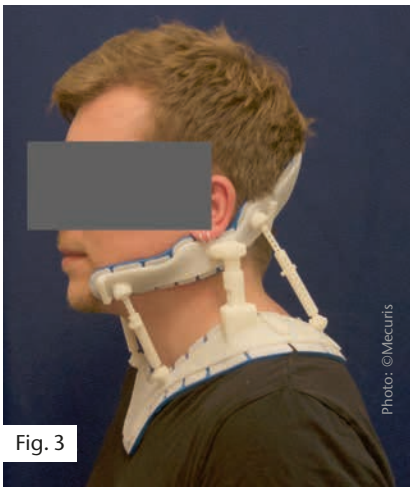


Fig. 2 *WHO-Spiral-Printorthese®.*

Fig. 3 *3D-printed postoperative cervical orthosis.*

quired to achieve the optimal shape for the transfer of force. In the liner area, the lower precision when measuring the shape can be partially offset by elastic properties of the liner. The first routine uses of this have been reported [5]. Additive manufacturing of prosthesis sockets still requires more research despite some promising approaches such as the possibility of specific thermal regulation [6] and improvements in fit using CT and MRI data [7].

As a replacement for standardised orthopaedic devices, additive manufactured devices, with their customisation possibilities, have the advantage of a better fit to the individual patient anatomy and thus the possibility of optimising the transfer of loads, reducing pressure points and improving wearer comfort. An example of this is a 3D-printed postoperative cervical orthosis (Fig. 3), with which good patient compliance and improved immobilisation can be expected. The disadvantages are the higher cost and the longer time required. Clinical studies are needed to be able to quantify the extent of the anticipated positive effects – without a convincing cost-benefit analysis, it will be difficult to obtain reimbursement from insurers. However, clinical studies are also associated with costs and time and due to the pending introduction of the EU Medical Device Regulation (MDR), there are few people available with the necessary qualifications. But it can still be profitable for manufacturers to take this path. Recently, the first randomised controlled study was published that proves the advantages of a custom-made device for plantar fasciitis compared with prefabricated devices [8].

The customised additive manufacture of system components such as prosthetic feet has the advantage of targeted continuous adaptation of the functional properties to the needs and activities of patients. At the same time, the use of highly complex load and weight optimised structures that cannot be produced in this form using conventional methods reduces the weight of the device. These advantages are especially important for paediatric devices. However, here again, the currently available materials are still not sufficient to realise the biomechanical functions of adequate energy storage or damping based on the shape and structure alone, so additional elements such as springs or dampers must be used. Another area for the preferred use of AM are waterproof prostheses. The first 3D-printed prosthetic feet are already available on the market and have passed the required certification for ISO 10328 [9] (Fig. 4).

In Germany, there is currently no major interest in the additive manufacturing of prosthetic hands. However, internationally, there are many reports of promising approaches where the focus is not on improving the functional properties but primarily on lowering costs and ensuring that more patients can be supplied. The story of the then-17-year-old American gymnast Easton LaChappelle, who developed a 3D-printed, EEG-controlled prosthesis in 2012 that he made available under an open source licence, went through the international media. Several start-ups are working on developing inexpensive 3D-printed prostheses for victims of land mines in Asia and Africa [10].

Up to now, no usable products are known for orthotic components such as joints or splints. It is true that design studies for KAFOs for which the joints can also be "printed" are presented occasionally. But there is some doubt as to whether these devices can meet the extreme requirements with respect to breaking strength and wear resistance. Due to the high variability among patients and the small numbers produced, this approach is only

Fig. 4 *3D-printed prosthetic foot.*

economically feasible to a limited extent, so no development is expected in the near future. The area of orthoses for use in water is not economically attractive because waterproof carbon-fibre reinforced joints have been available for several years.

This overview makes it clear that AM methods are currently used primarily when the customisation leads to verifiable advantages for the patient or it makes it possible to reduce costs, shorten the production time or improve fabrication processes.

Additive manufacturing in orthopaedic footwear technology

Compared with orthopaedic technology in general, orthopaedic footwear technology has a smaller range of products. Despite the high level of anatomical and functional complexity of the human foot, there are fewer indications to be treated and some of the general conditions are better known. In addition, the use of measuring technology such as plantar foot pressure measurement has had a firm place in the sector for years. These are possible explanations for the fact that additive manufacturing has advanced more quickly in orthopaedic footwear technology.

While until just a few years ago, AM was just being established as a better alternative for the production of lasts and insoles, today there are several providers who offer a complete digital production process for orthopaedic footwear technology – from digital measurement with a 3D scan to CAD last design and position correction up to additive production. The number of patent applications for digital processes in orthopaedic footwear technology is also skyrocketing.

Development is even faster in the market for conventional shoes: Several shoe manufacturers have now integrated 3D-printed soles and shoelaces to their product range. For 2019, several companies have announced serial products that will be produced entirely using 3D printing. Complex hardware and software platforms based on measuring technology have been developed that make the customised production of made-to-measure shoes possible [11]. An example of this is the mobile measuring system from Ecco that uses a combination of inertial and microclimate sensors to analyse the individual patient needs. The biomechanical measurement data are converted by the software into shapes for 3D printing; the resulting designs are then validated by FEM simulations. The "Fit-Station" is even better known – a foot measuring station from Hewlett-Packard that was introduced in 2018 and given the ISPO "Product of the Year" award. The system uses sensor technology with a combination of 3D scan and dynamic foot pressure measurements. After measuring and optimising, a customised 3D model is made; the product is then produced in a multi jet fusion process. When the US Food and Drug Administration (FDA) approval as a medical device was obtained, it became clear that this would not be limited to athletic shoes. Hewlett-Packard has now entered into various strategic partnerships, including with Superfeet for shoe insoles and Go 4-D for orthopaedic shoes and foot orthoses.

These and other examples show that large companies have now also discovered digital fabrication in orthopaedic footwear technology and are actively promoting the technology. It cannot be ruled out entirely that there will soon be major changes in the orthopaedic footwear technology sector, which is currently dominated by small companies.

Regulatory challenges

Currently, the major obstacles to the success of AM in medical technology are not the technological challenges mentioned, but the regulatory aspects. Strictly speaking, every individual adaptation is a design change, the safety of which has to be confirmed with the appropriate risk management steps and even new product testing. There is no doubt that this process is not feasible due to the high costs and ensuing delays. But there are currently no regulations that allow a practical way of ensuring the safety of custom-made 3D-printed medical devices [12].

The concept of custom fabrication plays a key role in the regulatory considerations for 3D-printed medical devices at this time because custom fabrication makes it possible to have a simplified conformity assessment procedure without the involvement of a designated site and without CE marking. However, it is debatable whether the modified definition of custom fabrication in the MDR even applies to additive manufactured medical devices – in the USA, the FDA assumes industrial production with all the regulatory consequences this entails if more than five custom fabrications of one type per year are produced. For the future, suitable methods for the safety assessment of customised 3D-printed devices will be needed that take all the innovative aspects of 3D printing and existing relevant requirements such as the FDA regulations into account, while still being feasible – especially for smaller and mid-sized orthopaedic companies. Solutions are being studied intensely, for example at Münster University of Applied Sciences [12]. Additive manufacturing methods are leading to new business models, especially in the medical field, which, compared with the previous models, show changes in the roles and responsibilities of the various persons involved and lead to new unanswered questions and uncertainties.

An additional challenge is the separation between development and production: especially smaller start-ups that are searching for new applications for 3D printing have to depend on collaboration with external service providers because of the still very high costs for equipment. But these providers are rarely willing to agree to comprehensive process validation because of the small quantities produced. Another challenge is the software for controlling the additive manufacturing processes. Since this software has more tasks than in conventional production processes, depending on the purpose and functionality, it may in some cases have features that can mean that the software is classified as a medical device with the corresponding regulatory requirements.

Digital process chain

AM is only one component of a complete digital process chain that can make full use of its advantages only in combination with a digital shape capture, design, and simulation process. Some companies are already using digital solutions for various process steps – especially for shape capture and the designing of the devices – but a completely digitalised process does not yet exist.

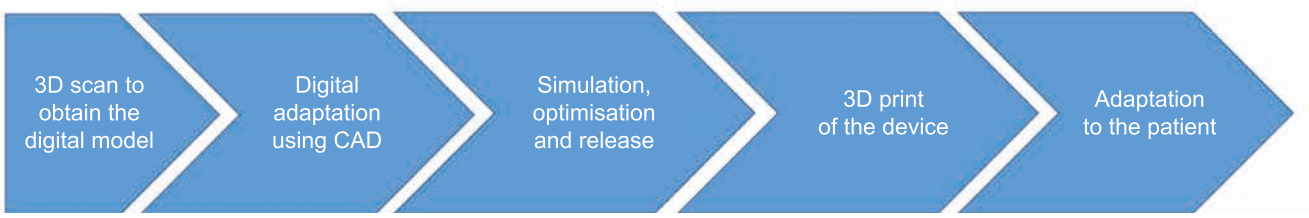


Fig. 5 *Possible digital process chain in technical orthopaedics.*

A digital process chain as shown in Figure 5 must take all the new aspects of 3D printing and existing relevant regulations such as the FDA guideline [13] into account, but also makes it possible to integrate complex regulatory process steps within a software platform that would be challenging for individual medical supply companies to implement. They include the automatic parametric optimisation of the product design based on the patient data and the background simulation and load testing of the designed devices in the form of a "virtual crash test".

The key element of the "virtual crash test" is a numerical simulation integrated into the software that is validated using measurement technology methods for compliance with the required conformity test. In a comparison of the simulation results, e.g. with the specifications of an existing standard, the admissibility of the modification is assessed in order to ensure the structural strength of the customised device. This makes it possible to minimise the number of time-consuming and expensive physical tests. A conformity test is then conducted only on one "worst case" test piece, which is defined based on the critical dimensions, design features and 3D-printing parameters such as component alignment. Since the platform operator assumes the responsibility for these steps, the individual user of the platform does not need to deal with them. The feasibility of this approach has already been demonstrated in small projects. A large research project with the aim of describing the complete digital supply chain is slated to begin soon.

Conclusion

There are many different future milestones on the road towards the mass use of additive technologies in technical orthopaedics. They include increasing the number of available materials, clarifying and adapting regulatory requirements, specifying uniform production conditions and setting up digital process chains. However, considering the advantages described, it is hardly conceivable that additive methods will not have an established place in technical orthopaedics in the future.

Author:
Prof. Dr.-Ing. David Hochmann
Fachhochschule Münster
Fachgebiet Biomechatronik
und medizinische Messtechnik
Stegerwaldstraße 39, Steinfurt, Germany,
david.hochmann@fh-muenster.de

Reviewed paper

References:

[1] Papagelopoulos PJ et al. Three-dimensional Technologies in Orthopedics. Orthopedics, 2018, 41 (1): 12–20

[2] Kienzle C, Schäfer M. Integration additiver Fertigungsverfahren (3D-Druck) in den orthopädietechnischen Versorgungsalltag. Orthopädie Technik, 2018; 59 (5): 48–57

[3] Bagaria V, Chaudhary K, Shah S. Technical note: 3D printing and developing patient optimized rehabilitation tools (PORT): a technological leap. Int J Neurorehabil, 2015; 2: 175

[4] Harper NG, Russell EM, Wilken JM, Neptune R. Selective laser sintered versus carbon fiber passive-dynamic ankle-foot orthoses: a comparison of patient walking performance. Journal of Biomechanical Engineering, 2014; 136 (9): 91001

[5] Poziembo B. 3D Printing: Custom Liners. Vortragsmanuskript OTWorld, Leipzig, 18.05.2018

[6] Webber CM, Davis BL. Design of a novel prosthetic socket: Assessment of the thermal performance. Journal of Biomechanics, 2015; 48 (7): 1294–1299

[7] Sengeh DM, Herr H. A variable-impedance prosthetic socket for a transtibial amputee designed from magnetic resonance imaging data. Journal of Prosthetics and Orthotics, 2013; 25 (3): 129–137

[8] Xu R et al. Effect of 3D Printing Individualized Ankle-Foot Orthosis on Plantar Biomechanics and Pain in Patients with Plantar Fasciitis: A Randomized Controlled Trial. Medical Science Monitor, 2019; 25: 1392–1400

[9] Dodziuk H. Applications of 3D printing in healthcare. Kardiochir Torakochirurgia Pol, 2016; 13 (3): 283–293

[10] Opitz M, Taubmann C, Gundlack F, Breuninger J. Stabilität von additiv gefertigten Prothesen. In: Richard H, Schramm B, Zipsner T (Hrsg.). Additive Fertigung von Bauteilen und Strukturen. Wiesbaden: Springer Vieweg, 2017

[11] Issolio A. Digital citizens. High technology process innovation in footwear design. Master Thesis, Politecnico Milano, 2018. https://www.politesi.polimi.it/bitstream/10589/142173/1/Thesis_Agostina_Issolio_2018_final.pdf (Zugriff am 28.03.2019)

[12] Hochmann D. Produktprüfung von individualisierten additiv hergestellten Medizinprodukten. MT Medizintechnik, 2017; 3: 32–35

[13] U.S. Food & Drug Administration (FDA). Technical Considerations for Additive Manufactured Devices. Draft Guidance for Industry and Food and Drug Administration Staff. 10.05.2016 (draft issued). https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM499809.pdf (Zugriff am 28.03.2019)

H. Trentmann, O. Baasch

Diabetes-Adapted Footbeds

A diabetes-adapted footbed (DAF) is a footbed especially customised for the foot of a diabetes patient that takes the many different changes in the anatomy, the biomechanics and in particular the neuropathy-related sensitivity to pressure points into account. Its purpose is to allow the patient to be mobile while protecting the foot that is prone to injuries. Many design details have to be considered to meet these requirements.

Key words: diabetes-adapted foot bed, shaping, material, pressure measurement

Introduction

Because of the complexity of the condition, treatment of diabetic foot syndrome (DFS) requires an interdisciplinary treatment approach with close cooperation between the primary care doctor, diabetologist, vascular surgeon, general surgeon, orthopaedist, podiatrist, orthopaedic technician, and orthopaedic footwear technician. The treatment principles are based on the guidelines for diabetic foot from the diabetic foot working group [1]. Before making a DAF, the orthopaedic technician or footwear technician must record the exact status of the foot and its changes due to diabetes. The focus is on relieving pressure in the areas of the foot that are at risk. It is important to distribute pressure to the entire foot. The interaction of the DAF with a suitable protective shoe or custom-made orthopaedic shoe must be observed. Effective pressure relief also depends on other factors. They include the patient's life situation and accompanying circumstances, activity level, acceptance of the shoe (appearance), patient compliance and biomechanics.

Foot status

Fitting a patient with a DAF first requires a thorough examination of the foot. In addition to the orthopaedic aspects that are relevant for every foot treatment, the neuropathy status, in particular, must be assessed. The examination of the mobility of the foot must include all joints in the foot, as limited movement is always associated with an increased biomechanical load when walking. If limitations of movement are found, the treatment team (doctor, therapist) should first determine whether they can be permanently eliminated by a surgical or therapeutic intervention. If that is not the case, the orthopaedic (footwear) device must compensate for the functional impact of the limitation of movement. For example, limited dorsal extension of the metatarsophalangeal joints (especially the first ray) always requires sole reinforcement with an appropriate roll in order to regain physiological loading by normalising the rollover pattern and lever lengths. There is a similar situation if there are limitations of movement in the upper ankle joint. If limited dorsal extension is overlooked, this often leads to compensatory eversion movement in the lower ankle with the corresponding three-dimensional deformation of the foot contour, which in turn leads to abnormal pressures – especially on a footbed adapted to the normal position. A pes equinus must be identified and, if it cannot be treated otherwise, the footbed must be appropriately adapted. The absent dorsal extension must be compensated for by the sole design. For severely deformed or already ulcerated feet, a decision must be made at this time as to how much load can be put on which regions of the foot in order to relieve areas especially at risk.

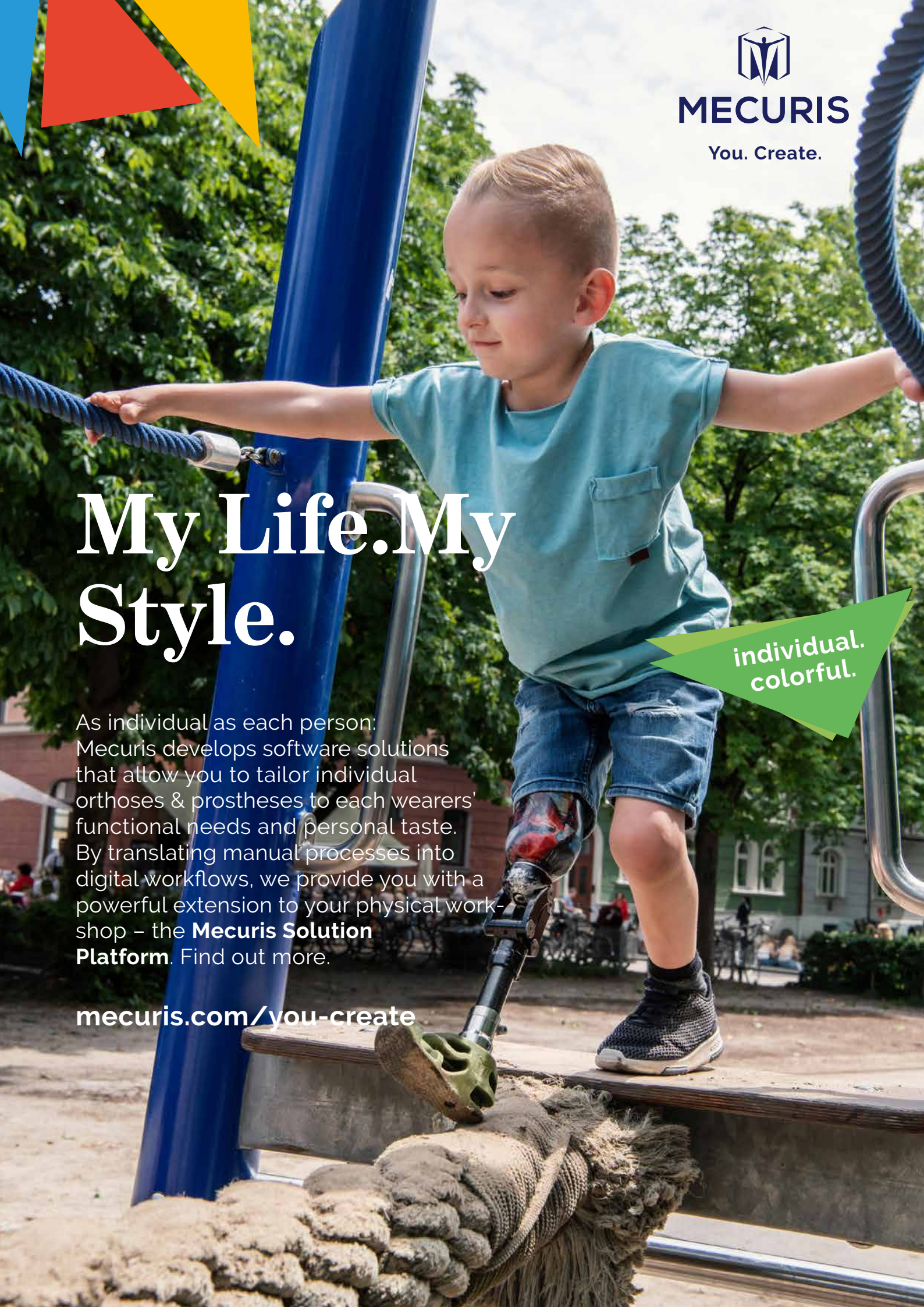
The neuropathy status is tested using a tuning fork and a monofilament (Fig. 1). In addition, sensitivity to heat or cold and the surface temperature of the foot can be measured. In the diabetic foot guidelines from the foot working group, the failure to detect a 10 g monofilament is the crucial criterion. The monofilament is applied to the plantar side of the pad of the big toe and the metatarsophalangeal joints of the big and little toes in random order three times each for around two seconds. A mock application must also always be conducted. The patient must correctly identify at least two of three applications in each region. It is important that the monofilament is not applied to calluses or the like [2].

The test also includes recording body weight and shoe size. The patient should also be asked about their mobility. If the circulation situation is unclear, the orthopaedic technician or footwear technician should ask the patient's doctor or diabetologist. All examination results must be clearly documented.

After the foot status is assessed, the treatment guideline for footwear and risk classes for the diabetic foot syndrome and analogous neuro-angio-arthropathies from the foot working group can be used to assess the risk potential and determine the necessary treatment. A DAF is considered the standard treatment for risk class III ("status post plantar ulcer") or higher. If there are defined criteria for a higher grade of treatment, a DAF can even be used for risk class II ("diabetes with loss of sensitivity due to polyneuropathy/relevant peripheral arterial occlusive disease"). It must be noted that the treatment recommendations of the foot working group are currently the generally recognised basis for the treatment of the diabetic foot syndrome – not the older list of indications from the catalogue of therapeutic devices (HMV) [3].

Measuring/impression technique

In addition to the correct planning of the device, taking measurements and the precise impression technique of the foot are the basis for a satisfactory footbed. The challenge here is that a static impression method is used to produce a footbed that must accommodate the changed peak loads in the dynamic situation. This means


MECURIS
You. Create.
My Life.My Style.
individual. colorful.
As individual as each person: Mecuris develops software solutions that allow you to tailor individual orthoses & prostheses to each wearers' functional needs and personal taste. By translating manual processes into digital workflows, we provide you with a powerful extension to your physical workshop – the **Mecuris Solution Platform**. Find out more.
mecuris.com/you-create

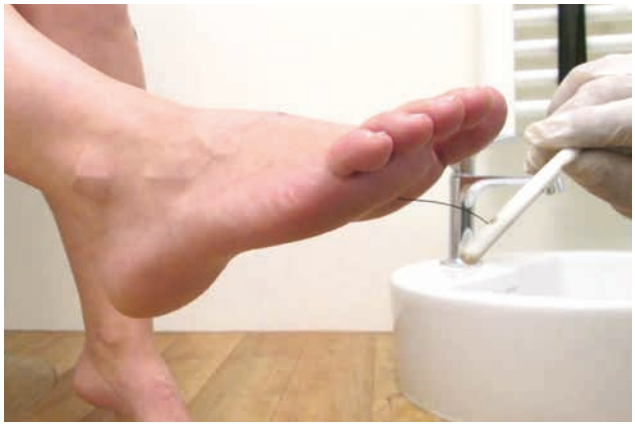


Fig. 1 Sensory test with the Semmes-Weinstein monofilament.

Fig. 2 Foam impression for a DAF. The foot is pressed manually into the foam while the patient is sitting.

that the pressure distribution during movement must also be measured. For this, what is known as a neutral measurement is conducted using electronic pedobarography. This should be done in a neutral shoe. The advantage of the internal shoe measurement over a pressure measuring plate is that realistic loading is measured over several steps, not in a single step that has to meet the measuring plate exactly, which influences the rollover behaviour. Alternatively, the measurement can be conducted in a standard protective shoe for diabetics in which the footbed will later be worn. This allows the pressure influence from the later shoe to be recorded.

In addition to the analysis of dynamic loading, when producing the footbed it is essential to be able to reproduce the exact position of the pressure points on the model. A blueprint of the foot is made while standing to identify the pressure peaks under full loading. The evaluations of the blueprint and pressure measurement are the basis for the further processing of the later model and for integrating the relief elements in the footbed.

The actual impression is generally made as a foam impression while sitting. This technique of making the impression in a situation without loading or with partial loading has become established because it gives a very accurate image of the soles. When making a foam impression while sitting, the lower leg should be at a 90° angle to the thigh. One of the orthopaedic or footwear technician's hands is placed on the patient's knee while the other hand holds the heel. The knee is pressed down and the heel is guided. Then pressure is placed on the top of the foot to press down the outer side of the foot, followed by the ball of the large toe and the other toes (Fig. 2). The heel pitch of the later shoe and the relative position of the forefoot to the rearfoot can also be set individually. This impression method requires some practice, as it is relatively easy to press the heel into the foam from the knee, but considerably more strength is required to then adjust the forefoot evenly. This can easily lead to excessive height of the longitudinal arch support.

Prior to pouring the foams, the extension at the tip of the foot and moderate lowering at the main pressure points can be integrated. This saves the need for later application at these areas.

If the preliminary work is adequate, only the areas where a greater load should occur need to be removed on the positive model. This must generally be done at the transverse arch because the soft tissues cannot be compressed sufficiently when the foam impression is made. Following the bony transverse arch with the aim of even pressure distribution should not be confused with a corrective pad for a splayfoot – pads and steps on the surface are obsolete in a DAF according to the provisions of the HMV [4]. Following the bony shape at the junction from the metatarsal heads to the metatarsal shafts – which may look like a retrocapital support – is not considered to be a step, but an enlargement of the load-bearing surface for even pressure distribution. This reworking must always be done with great care as incorrectly positioned or shaped loading elements can easily lead to overloading.

Fabrication of the diabetes-adapted footbed/ selection of materials

In addition to the shape and design of the shoe, the choice of the material is crucial for the load-distribution effect of the DAF. Only materials that allow effective pressure distribution for a sufficiently long period should

Fig. 3 Deep drawing the heated material over the processed model.

***Fig. 4** Handover of the finished diabetes-adapted footbed.*

be used. The manufacturer's test certificates must be checked. Selection criteria include Shore hardness, rebound elasticity, continuous load capacity and hygienic properties. Only with an indication-based combination of materials of at least three different hardnesses [4], in which the patient's weight and activity level must be accommodated, can optimal pressure distribution in the footbed be achieved. However, are not enough data are available on this topic, especially considering the importance for successful treatment. While there are studies [5, 6, 7] that confirm the suitability or non-suitability of certain materials for the different layers, no concrete recommendations can be derived from them for certain weight classes, mobility levels or kinds of damage. However, the studies agree that the different layers have different tasks and that different requirements for the material can be derived from them: The layer facing the body is designated the "embedding layer". Its purpose is to accommodate the mobility of the foot and adapt to the varying foot contour in different load situations, but also to follow up on long-term changes in the foot. The middle layer has mainly a damping function and the third layer is for stabilisation. Pressure-specific points (such as pressure peaks or ulcerations) can be bedded additionally with extra soft material. According to these requirements, the layer with the lowest Shore hardness is adjacent to the foot and the layers moving away from the foot are increasingly hard. It is also important that a washable and disinfectable layer or appropriate cover is selected to face the foot in order to meet hygienic requirements. With respect to hygiene, it must be noted that open-cell materials have good damping properties, but can also absorb moisture like a sponge and should not be used in direct contact with the foot.

The manufacturers of padding material for diabetic footbeds have many different layering panels in different Shore hardnesses. These layers are heated and drawn over the model using a thermoforming technique. The processing temperatures and holding times must be adhered to precisely as overheating results in considerable changes to the padding properties. In addition, what are called sandwich or combination panels are available in different combinations that are vulcanised with each other in the manufacturing process. They have the advantage of eliminating the need for the adhesive that could have a negative effect on the material properties. Faulí et al. showed that the adhesive does not initially have an effect [6], but no long-term tests after the adhesive was cured were conducted in this study. Very soft materials cannot be processed under the rubber mat, so a harder material must first be used as a placeholder which is then replaced manually with the softer material. The thermoforming process itself is specified as a quality requirement in the HMV regulations (Fig. 3) [8]. Newer methods such as milling or 3D printing of footbeds are not yet included in the HMV.

The DAF should ideally be worn in protective shoes for diabetics made for this purpose (HMV 31.03.08.xxxx) or in custom-made orthopaedic shoes. The thickness of the footbed varies and depends on the size of the foot and the available space in the shoe. The HMV requires a minimum thickness of 8 mm [4], but this can frequently be achieved only with special shoes with an enlarged inner volume. For custom-made orthopaedic shoes, the thickness can be determined individ-

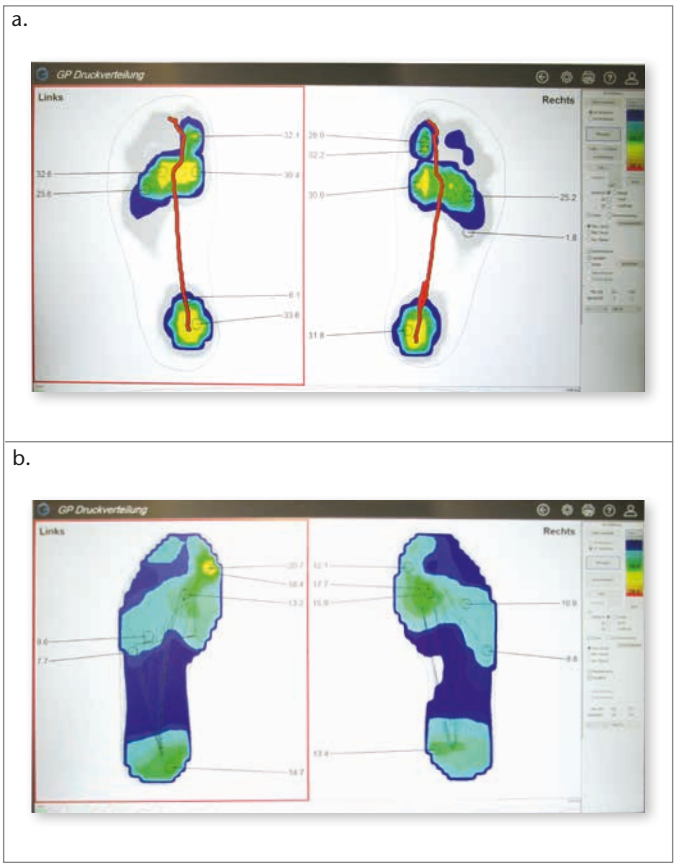


***Fig. 5a & b** Comparison of pressure distribution without a footbed **(a)** and with the DAF **(b)**.*

ually in advance depending on the indication.

Handover

When the DAF is given to the patient (Fig. 4), it must first be fitted exactly into the intended shoe. The DAF is considered to be an integral part of the shoe and is not intended to be a replacement footbed for other shoes – even if they are the same basic model. A new shoe always requires a footbed made specifically for it. This is also why the DAF is listed in product group 31 (shoes), not 08 (insoles).

After fitting in the shoe, the footbed should be held against the foot and checked for correct positions of the loading and relief zones. However, this does not provide any information about concrete loading in a dynamic situation, so a control measurement between the foot and footbed must also be carried out. This pressure measurement with the footbed can be compared with the neutral measurement to document the success of the device (Fig. 5a and b.). There is no scientifically proven limit for the maximum tolerable load at a point, but a study by Owings et al. is often cited, in which in a follow-up examination of patients who remained free from relapse for a long period after a healed ulceration, a mean pressure of 207 kPa was measured at the former ulcerated site [9]. This value is also selected by Bus et al. as the target parameter for a successfully tested algorithm for the footbed. The second, alternative target parameter consisted of relief of at least 25 % compared with the untreated situation [10]. Because foot loading can change over the period the DAF is used – whether due to material fatigue or changes in the shape of the foot – the footbed should be rechecked at regular intervals.

Even if the pressures measured in a new footbed appear to be unremarkable, a new footbed should never be worn immediately for a whole day. In the beginning, a visual check of the feet by the patient himself or by an assistant is urgently recommended after a specified period of use.

Conclusion

The provision of diabetes-adapted footbeds is quite challenging for the orthopaedic technician or footwear technician. Faulty footbeds can have more serious consequences than for other indications due to the neuropathy. This is why only licensed providers with the corresponding certification are allowed to provide a DAF. Complete documentation with pressure distribution measurement is urgently recommended as proof of the functionality of the footbed when it is given to the patient. The recommendations of the foot working group and the requirements of the HMV must be taken into consideration.

For the authors:
Hermann Trentmann
Trentmann-Gromotka Orthopädie-Schuhtechnik GmbH
Weidenallee 48
Hamburg, Germany
info@trentmann-gromotka.de

Reviewed paper

References:

[1] Interdisziplinäre Arbeitsgruppe Schuhversorgung beim diabetischen Fußsyndrom. Schuhversorgung und Risikoklassen beim Diabetischen Fußsyndrom – und analogen Neuro-Angio-Arthropathien. Stand: 25.02.2006. http://www.ag-fuss-ddg.de/download/Schuhversorgung_Risikoklassen_Regelversorgung.pdf (Zugriff am 13.08.2018)

[2] Arbeitsgemeinschaft Diabetischer Fuß in der Deutschen DiabetesGesellschaft. Fuß-Dokumentationsbogen der AG-Fuß in der DDG. http://www.ag-fuss-ddg.de/download/Fussdokumentationsbogen_DDG.pdf (Zugriff am 13.08.2018)

[3] Hilfsmittelverzeichnis des GKV-Spitzenverbandes. Diabetes adaptierte Fußbettungen für orthopädische Schuhe nach Maß oder konfektionierte Schuhe (31.03.07.0). Beschreibung/Indikation. https://hilfsmittel.gkv-spitzenverband.de/produktlisteZurArt_input.action?paramArtId=2016 (Zugriff am 13.08.2018)

[4] Hilfsmittelverzeichnis des GKV-Spitzenverbanden. Diabetes adaptierte Fußbettungen (31.03.07). Medizinische Anforderungen. https://hilfsmittel.gkv-spitzenverband.de/untergruppe Anzeigen_input.action?untergruppeId=708 (Zugriff am 13.08.2018)

[5] Paton J, Jones RB, Stenhouse E, Bruce G. The physical characteristics of materials used in the manufacture of orthoses for patients with diabetes. Foot Ankle Int, 2007; 28 (10): 1057–1063

[6] Faulí AC, Andrés CL, Rosas NP, Fernández MJ, Parreño EM, Barceló CO. Physical evaluation of insole materials used to treat the diabetic foot. J Am Podiatr Med Assoc, 2008; 98 (3): 229–238

[7] Healy A, Dunning DN, Chockalingam N. Effect of insole material on lower limb kinematics and plantar pressures during treadmill walking. Prosthet Orthot Int, 2012; 36 (1): 53–62

[8] Hilfsmittelverzeichnis des GKV-Spitzenverbandes. Diabetes adaptierte Fußbettungen für konfektionierte Schuhe (31.03.07.0002). Merkmale. https://hilfsmittel.gkv-spitzenverband.de/produktAnzeigen_input.action?produktId=26435 (Zugriff am 13.08.2018)

[9] Owings TM, Apelqvist J, Stenström A, Becker M, Bus SA, Kalpen A, Ulbrecht JS, Cavanagh PR. Plantar pressures in diabetic patients with foot ulcers which have remained healed. Diabet Med, 2009; 26 (11): 1141–1146

[10] Bus SA, Haspels R, Busch-Westbroek TE. Evaluation and optimization of therapeutic footwear for neuropathic diabetic foot patients using in-shoe plantar pressure analysis. Diabetes Care, 2011; 34 (7): 1595–1600

Education (BUFA):

Orthopädietechniker-Meister:
Certified prosthetist/orthotist

Postgraduate courses:
Diabetic foot, upper limb prosthetics, wheelchair and assistive devices, soft braces and compressive stockings

Short courses:
Transfemoral prosthetics, transtibial prosthetics, upper limb prosthetics, trunk orthosis, AFO/KAFO, insoles, soft orthotics, functional aids

Bachelor and Master programme (IMB):

B. Eng./M. Eng. Orthopädieingenieur

B. Eng. OI: 3-year programme, 180 ECTS
M. Eng. OI: 2-year programme, 120 ECTS

In cooperation with Dortmund University of Applied Sciences and Arts, Department Mechatronics and Embedded Systems

Entry requirements: OT-Geselle (successfully passed journeyman's examination as prosthetist/orthotist), ISPO Cat II, language certificate German DSD II or equivalent

Bundesfachschule
für Orthopädie-Technik
Schliepstraße 6-8
44135 Dortmund
Germany

Phone: + 49 (0)231-5591-0
Fax: + 49 (0)231-5591-333

zentrale@ot-bufa.de

Evaluation of further education (IQZ):

Evaluation and recognising of training programmes

Postgraduate qualifying

Registration based on health and care professional council (SGB V)

Partners:

Bundesinnungsverband für Orthopädie-Technik (BIV-OT)

German Association of Orthopaedic Technology

Federal Ministry for Economic Affairs and Energy

Dortmund University of Applied Sciences and Arts

Münster University of Applied Sciences

Further Training Association for Orthopaedic Technology

Ministry of Economic Affairs, Energy and Industry of the State of North Rhine-Westphalia

325 Members of BUFA e. V. (registered association)

Applied research (IMB):

Gait and motion analysis

Functional design in prosthetics and orthotics

Quantitative assessment of function

Cooperation with different research groups

3 questions to **Deirdre Desmond**

What does holding a keynote lecture at the ISPO World Congress mean to you?

Deirdre Desmond: It is a great privilege to have the opportunity to address the ISPO delegates as a keynote speaker in Kobe. The interdisciplinary nature of the Society and World Congress always makes for a really interesting and inspiring mix of presentations, workshops and exhibitions – I look forward to a diverse and dynamic programme showcasing the best research and practice developments of ISPO members internationally. It is my favourite event in the conference calendar and so I am very honoured and excited to contribute as a keynote speaker in 2019.

What can participants expect from your keynote lecture?

Deirdre Desmond: My hope is that delegates will be engaged in a thoughtful way to consider the interface between people and technology and the transformative potentials of technology at individual and societal levels. My background in psychology makes me curious about people and behaviour, and strategies for people to live and thrive in a complex world. I hope that my lecture will help nurture curiosity about the psychological and social aspects of assistive technology use.

What were the reasons that made you specialise in your field of practice?

Deirdre Desmond: Irish playwright and activist Bernard Shaw said: "First love is only a little foolishness and a lot of curiosity"; from early days, I have been curious about and interested in understanding the evolving challenges and benefits of assistive technology use and its implications for individual users, their circles of support and wider society. I have been incredibly fortunate to have the mentorship, guidance, inspiration and friendship of the Dublin Psychoprosthetics Group members (past and present) in my research career. Working collaboratively with engaged, thoughtful, inspired and inspiring colleagues and service users is a huge privilege; one that sustains the endeavour. I am hugely privileged to work with a great team and proud to represent some of our research endeavours at ISPO's World Congress in Kobe 2019.

Photo: Deirdre Desmond

Deirdre Desmond PhD

Deirdre Desmond PhD is a Senior Lecturer in the Department of Psychology and member of the Assisting Living and Learning (ALL) Institute at Maynooth University, Maynooth, Ireland. She is also co-director of the Dublin Psychoprosthetics Group. Her research focusses on psychological adjustment to illness, injury and disability, rehabilitation, self-management and psychosocial aspects of assistive technology.

At ISPO World Congress 2019 she will give the keynote "Complex Entanglements: People and Assistive Technologies".

I keep myself motivated by wanting to embrace life ... Interview with **David Constantine**

What does it mean to you that you have been selected to present the Knud Jansen Lecture at the ISPO World Congress?

David Constantine: After spending some years working in the provision of mobility devices in low-income countries, we at Motivation came to realise how important it was to have ISPO in the sector of prosthetics and orthotics. ISPO represents the bedrock and jumping-off point for all work in the sector of providing and fitting appropriate mobility devices in challenging environments. It also acts as the umbrella to oversee the education and development of the skills required in the sector. Without ISPO there would be a huge vacuum of knowledge, education, collaboration and progress and disabled people's lives would not be so well served. As a co-founder of Motivation focusing on design and provision of low-cost wheelchairs in low-income countries, I have seen first-hand how important it is to have ISPO in our sector. I am therefore hugely proud and honoured to have been asked to give the lecture.

Photo: David Constantine

David Constantine MBE

What can participants expect from your keynote?

David Constantine: As a disabled person and wheelchair user, I know first-hand how important it is to have the

right product fitted in the right way. Without this life becomes very difficult, if not impossible. I know I am very lucky to live in a country where I have access to the products, the knowledge and the finance that enables me to access the right product and therefore live the life I want to. I will aim to leave the participants of my keynote with the understanding and inspiration of why their work is so important, and, despite all the challenges, that it is worthwhile. My aim will be to bring it back to the focus of the user.

While you are motivating others, how do you keep yourself motivated?

David Constantine: I keep myself motivated by wanting to embrace life and all that it can offer. To do this I need to get up every day and out of my bed. Without my wheelchair, my orthosis, I cannot do this. My part in helping to bring mobility to other people in situations much more challenging than mine motivates me to continue the work alongside the team at Motivation and the rest of the sector.

How did you get the idea of founding a charity for people with mobility impairment?

David Constantine: If I'm really honest the idea found me. While studying design at the Royal College of Art the whole of my course was given a design challenge assignment in our first year. The three-week challenge assignment was to "Design a Wheelchair for Developing Countries". I just happened to be at the College that year when the subject of this assignment was a wheelchair. I teamed up with a fellow student Simon Gue and together we won the competition. The idea for the charity came when we were joined by a third colleague, Richard Frost, and the three of us travelled to Bangladesh and realised the enormity of the problem facing disabled people living in low-income countries.

Within your organisation, which of your projects of are you specifically proud of?

David Constantine: In 2019 it will be 30 years since Simon and I designed the first wheelchair that led to the foundation of Motivation. In those 30 years over numerous projects, design ideas, trainings and collaborations with other organisations, the most important milestone has to be the part Motivation played in the initiation and publication of the World Health Organization 'Guidelines on the provision of manual wheelchairs in less resourced settings'. The publication of these fundamentally change the sector for the better and personally am very proud to have been part of the process. ISPO were fundamental in the development and publication of the Guidelines and I really value working with ISPO.

What are your visions? Which objectives would you like to achieve with your organisation in the future?

David Constantine: I have a vision for the sector where every person who needs some form of assistive device can get the appropriate, affordable, properly fitted device for their needs wherever they live – provided and paid for by their own government and society. Motivation's focus has been on wheelchairs and we would like to continue to use design to help drive the sector forward, enabling people to get the right wheelchair in the right way wherever they live in the world thereby enhancing their quality of life.

David Constantine MBE is the co-founder of Motivation, a charity which works to improve the quality of life of people with mobility impairment.

At ISPO World Congress 2019 he will give the Knud Jansen Lecture ("AT Changed My Life – Practical Solutions and Education Enabling a Lifetime of Human Potential").

3 questions to **Max Ortiz Catalán**

What does holding a keynote lecture at the ISPO World Congress mean to you?

Max Ortiz Catalán: It's a great honor to host a lecture at the ISPO World Congress as the biggest and most important forum on prosthetics and orthotics in the world. I'm excited to talk about our latest achievements on the clinical implementation of highly integrated prosthetic limbs and the future ahead, as well as on a novel treatment for phantom limb pain which has shown positive results in patients for whom available treatments failed.

What can participants expect from your keynote lecture?

Max Ortiz Catalán: I will present the latest prosthetic technologies with particular focus on the clinical implementation of our osseo-neuromuscular prosthetic system. Interfacing the neuromuscular system to provide intuitive prosthetic control and sensory feedback has been long thought as the optimal limb replacement. For the first time, our osseo-neuromuscular interface allowed the use of implanted electrodes on nerves and muscles to control a prosthetic arm while also providing sensory feedback in daily life and outside control environments such as research laboratories. I will talk about how combining the latest surgical techniques with engineering developments can considerable increase prosthetic function. I will also present clinical outcomes on a novel treatment for phantom limb pain which

Photo: Max Ortiz Catalán

Dr. Max Ortiz Catalán, Ph.D.

has shown positive results in patients for whom available treatments failed.

What were the reasons that made you specialise in your field of practice?

Max Ortiz Catalán: I started my career working in automation for the manufacturing industry, but I soon realized that that ultimate purpose of that job wasn't fulfilling enough for me. I then decided to quit and obtained a postgraduate degree in science, from where I continued into research in biomedical engineering. I've been working in prosthetics for almost 10 years, and it has been an amazing journey full of rewarding moments developing technology that help others and matter to people.

Dr. Max Ortiz Catalán, Ph.D., led the development of the first bionic arm directly connected to patient's bone, nerves, and muscles. This technology allows for safe, long-term stable, and intuitive closed-loop control of prosthetic hands in daily life. In addition, he developed a novel treatment for phantom limb pain that has helped chronic sufferers for whom no other treatments were effective. Dr. Ortiz Catalán is an Associate Professor at the Department of Electrical Engineering, Chalmers University of Technology, Sweden, where he founded and currently leads the Biomechatronics and Neurorehabilitation Laboratory (@ChalmersBNL).

At ISPO World Congress 2019 he will give the keynote "Osseo-Neuromuscular Integration of Prosthetic Limbs and Neurorehabilitation from Phantom Limb Pain".

In the very near future, robotics is poised to become one of the most helpful tools for disabled people …

Activity Assistive Robotics from the Viewpoint of Rehabilitation Medicine

Eiichi Saitoh MD, DMSc [1)], Satoshi Hirano MD, DMSc [1)], Shigeo Tanabe RPT, PhD [2)]

1) Department of Rehabilitation Medicine I, School of Medicine, Fujita Health University
2) Faculty of Rehabilitation, School of Health Sciences, Fujita Health University

In the very near future, robotics is poised to become one of the most helpful tools for disabled people in four domains: they will assist exercise, assist independence, assist caregivers, and assist emotional and cognitive activities. We have been engaged in developing assistive robots for 15 years. This presentation will describe our experience in the development of the following robots:

WPAL (Wearable Power Assist Locomotor): To assist walking in paraplegic people, we developed the Wearable Power Assist Locomotor (WPAL) in collaboration since 2005 with Aska Co. (Aichi, Japan). WPAL incorporates a medial hip joint system composed of medially placed bilateral hip-knee-ankle motor joints without a pelvic component. To date, we have used WPAL with more than 20 persons with spinal cord injury (SCI, including cervical SCI). Patients were able to don/doff the device by themselves, stand up/down and from/to their wheelchair, keep standing without arm support, and walk around on a flat floor. These results were observed even in cases who could not perform these activities with orthoses.

Welwalk (Gait exercise assist robot): We developed a gait exercise assist robot (Welwalk) in collaboration with the Toyota Motor Corporation (Aichi, Japan). Welwalk is for gait exercise in hemiplegia. Use of the robot will be discussed in the context of motor learning.

STAR (Side Transfer Assist Robot): For elderly care in the community, we propose a Robotic Smart Home (RSH) that consists of a smart home and care assist robots. In the RSH setting, the STAR has an important role in assisting transfers. STAR consists of an omnidirectional wheel for moving around and a height-adjustable mechanism incorporating a seat, arm rest, and foot rest for lateral transfers. It provides safe and easy lateral transfers even in small spaces such as a standard size toilet within a typical home.

Photo: Eiichi Saitoh

Professor Eiichi Saitoh (MD, DMSc)

Professor Eiichi Saitoh (MD, DMSc) is a certified physiatrist, Executive Vice President of Fujita Health University, and Professor and Chairperson of Department of Rehabilitation Medicine I, School of Medicine, Fujita Health University, Aichi, Japan. Professor Saitoh is specifically interested in dysphagia, robotics, orthosis, motion analysis, locomotion, exercise science, and psychology.

At ISPO World Congress 2019 he will give the keynote "Activity Assistive Robotics from the Viewpoint of Rehabilitation Medicine".

Solve the Problem!

The challenges of patient care and the use of modern measuring techniques require professional prosthetists and orthotists to have knowledge of biomechanics. In order to upgrade and broaden this knowledge, the exercises compiled in this booklet address mechanical topics such as force, pressure, moment, centre of mass, velocity and acceleration, each with examples from the field of orthopaedic technology. The integration of biomechanics in the well-known context aims at reducing the 'fear' of the theory. The problems presented are intended for self-study or as courses for professional prosthetists and orthotists and bachelor students. The mathematical background knowledge required is nominal. Essentially, one has to know how to construct a triangle from three given elements (angles or sides), for example to determine the equilibrium of three forces, how to apply the lever rule, for example when determining an unknown force in the equilibrium of moments, and how to use the trigonometric functions. When adding vectors, for example when adding two forces, the graphical method is used exclusively for reasons of clarity. Freehand sketches suffice in most cases.

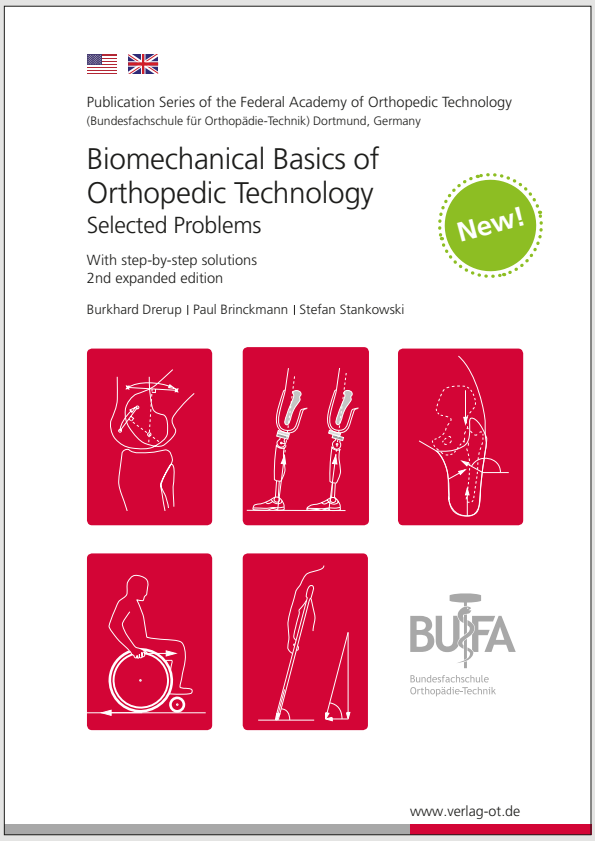
There are specific reasons why solving some problems appears to be difficult at first glance. In the field of biomechanics, one is often confronted with complicated structures and systems. In order to gain insight, it is necessary to rely on model assumptions and simplifications. However, it is sometimes difficult to determine which assumptions are really justified and which simplifications falsify a result. Is it, for example, permissible to pool the forces of all muscles effecting the extension of the back into one single muscle force? Is it permissible to replace the mechanical effect of pressure distribution in the socket of a prosthesis by the effect of a single resultant force?

To meet these difficulties, all problems include detailed instructions for solving them. This approach was selected deliberately. Starting from practical examples should generate interest for scientific problem solving. The solution process thus leads to initial training in the methods and provides an insight in the line of reasoning of biomechanics. Irrespective of their prior knowledge, students can gain new knowledge and broaden their horizons.

The book can be used for study as well as for reference.

Burkhard Drerup, Paul Brinckmann, Stefan Stankowski

Biomechanical Basics of Orthopedic Technology. Selected Problems.



Federal Academy of Orthopedic Technology

2nd expanded edition

160 pages · more than 90 illustrations · paperback € 24,95

Publisher: Verlag Orthopädie-Technik, Germany
www.verlag-ot.de

We have selected for you a problem from the book "Biomechanical Basics of Orthopedic Technology".

Solve the problem and win one edition of the book!

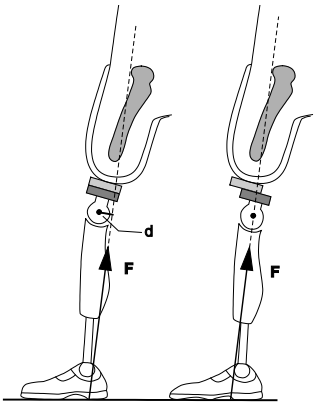
The first ten submissions of the correct solution will receive a book. Simply send the solution under the heading "I solved the problem – HTT No. 1" to

info@ot-medien.de until 30.11.2019.

Solve the Problem

Shifting the axis of a knee prosthesis in posterior direction

If during prosthetic fitting after a transfemoral amputation, the axis of the knee joint is placed at its anatomical position, the ground reaction force exerts (as in the unimpaired state) a flexion moment on the knee (graph at left).



Reference values of the relative ground reaction force F_{rel} (force divided by the body mass m_{body}) and the relative moment M_{rel} (moment divided by the body mass m_{body}) have been determined in the phase of heel-strike from gait analysis:

F_{rel} = 8 N/kg, M_{rel} = 0.1 Nm/kg.

These numbers must be multiplied by the body mass to obtain the numerical values of the force F and the moment M.

Problem

Determine the distance d by which the axis of the knee joint must be shifted in dorsal direction by means of an adapter so that the flexion moment becomes zero (right graph). Disregard the fact that the directions of the moment arm d and the shift effected by the adapter do not agree exactly.

Instructions

In a first step, the moment arm of the ground reaction force in the initial, unimpaired state is to be determined. The magnitude of the shift is then chosen so that the moment arm becomes zero. The moment arm in the unimpaired state is determined from

$$M = d \cdot F \ [Nm]$$

Inserting the reference values for M and F yields

$$0.1 \cdot m_{body} = d \cdot 8 \cdot m_{body} \ Nm$$

The shift d is obtained from this equation.

The first ten persons to submit the correct solution will receive a book. Simply send the solution under the heading "I solved the problem – HTT No. 1" to **info@ot-medien.de until 30.11.2019.**

Illustration: Karlheinz Baumann

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:

Bundesinnungsverband für Orthopädie-Technik (German Association of Orthopaedic Technology)

Orthopädie.Technik Bundesinnungsverband

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.
⇢ www.biv-ot.org

International Society for Prosthetics and Orthotics (ISPO)

ISPO INTERNATIONAL SOCIETY FOR PROSTHETICS AND ORTHOTICS

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.
⇢ www.ispoint.org

The editorial board of the journal is also supported by the following institutions:

Verlag Orthopädie-Technik (Verlag OT)

Verlag Orthopädie.Technik

The publisher Verlag OT, part of the German Association of Orthopaedic Technology, publishes ORTHOPÄDIE TECHNIK, which has been the industry's leading trade journal since 1949. It is the official journal of the German Association of Orthopaedic Technology and the International Society of Prothetics and Orthotics Germany e.V. In addition, Verlag OT, in close cooperation with the German Association for the Interprofessional Supply of Medical Aids e.V. (DGIHV) publishes reference works for technical orthopaedic devices, incl. the compendium "Quality Standard for Lower Limb Prosthetics" in 2018. Verlag OT, the exclusive media partner of OTWorld, the global industry's most important event, reports comprehensively on the congress and trade show. Moreover, in its role as mouthpiece for the industry, it issues publications in English especially for OTWorld.
⇢ www.verlag-ot.de

Human Study e. V.

HUMAN STUDY e.V.

Human Study is a German-based institution offering a unique model of comprehensive education custom-tailored 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

Legal Notice

Publishing House:
OT Medien GmbH
Reinoldistr. 7–9
D-44135 Dortmund, Germany
CEO: Georg Blome

Printing House: Mojoprint Ltd., Osaka

The peer-reviewed papers of this issue of "HowToTreat – Kobe Edition" – were first published in the German magazine ORTHOPÄDIE TECHNIK, the official journal of the German Association of Orthopaedic Technology and the International Society of Prothetics and Orthotics Germany e.V.

The Advisory Bord for "HowToTreat" No 1/19 Kobe Edition:
The peer-review procedure ensures the quality of the technical articles. The reviewers are recognised scientists, doctors, and O&P professionals. All members at:
⇢ www.verlag-ot.de/fachzeitschrift/beirat

Cover photo: iStock / MichaelSvoboda

HowToTreat 1/19 Kobe Edition
October 2019 · 64 pages
circulation: 4,000

Copy price of the print version: € 15.00
including e-paper, available at
⇢ www.howtotreat.world

International Society for Prosthetics and Orthotics
Japanese National Member Society


ottobock.
"My biggest step forward was taking a step back."
Melvin, C-Brace® user, post-polio syndrome
「後ろに歩くことができるのは、素晴らしい進歩です。」
メルヴィン、C-Brace®の装着者、ポリオ後症候群
Mobility for people – for 100 years
The new C-Brace®. Taking you further.
人々にモビリティを – 100年の歴史
新しいC-Brace®が皆さまを未来にお連れします。
YouTube
www.ottobock.com
100 Years
Quality for life