

ORTHOPÄDIE TECHNIK

PROSTHETICS **ORTHOTICS**

CHEST PROTHETICS

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International Issue

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Official journal of ISPO Germany

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 **OTWORLD** Visit us in Hall 1, Stand A46. 15-18 May 2018.

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Dear readers,

at the ISPO congress in 2015 in Lyon and the OTWorld in 2016, there was a huge demand for the special print of ORTHOPÄDIE TECHNIK in English presented there.

Since then, we have continued to receive inquiries from all over the world about a journal in English for O&P and rehabilitation – which, like OT, is at the interface of science, clinic and practice, but focuses even more on specialised articles and in the global digital era is not printed, but published in ePub or PDF format with two to four issues a year. We take these requests seriously: Verlag Orthopädie-Technik can also be international.

You now have an initial prototype in your hands – sorry, still as hard copy. We printed it because we still need your help in setting up the network required for digital distribution. To accomplish this, we are looking for distribution partners and sponsors all around the world – associations or organisations in the industry, industrial partners or well-networked individuals who would like to promote and support this journal project.

We therefore have this request: Network with us via LinkedIn under “Verlag Orthopädie-Technik (Bundesinventionsverband für Orthopädie-Technik)”, email us, call us or visit us at the OTWorld at our booth in Hall 3, D04. We would like to discuss an international OT with you and hear your suggestions and criticism.

We believe that people trust our small publishing company to engage on an international level because the German journal ORTHOPÄDIE TECHNIK has an excellent reputation outside the German-speaking region. OT has pursued the same goal for nearly 70 years of keeping our readers informed of the latest, state-of-the-art orthopaedic devices. We present the latest treatment concepts that set global standards for technical orthopaedics. Renowned authors from science and research, medicine, trade and therapy publish in our journal. Since 2013, their articles are reviewed by our scientific advisory committee. This allows us to ensure the high professional quality of the articles.

In addition, we cover the entire range of orthopaedic devices like no other journal in the industry, as can be seen in the selection of the three articles from OT published in this issue, which include such different fields as prosthetics, orthotics, sports orthopaedics and insoles. The article written by Jona Sigrun Sigurdardottir of Iceland, winner of the OTWorld prize for young scientists in 2016, and her colleagues shows that we are already an important publishing medium for international authors (p. 10–14).

In addition to specialised articles, an international OT should also report on important activities of global associations and companies and international congresses in this field. We have prepared some interesting information about this on pages 4 to 9. First, we present three new international treatment standards in the field of O&P that were compiled by the WHO, the ISPO and the German Association for Interprofessional Treatment with Orthopaedic Devices (DGIHV). The DGIHV compendium “Qualitätsstandard im Bereich Prothetik der unteren Extremität” [Quality Standard for Lower Limb Prosthetics] published by us will be presented at OTWorld.

Verlag Orthopädie-Technik is the exclusive media partner of the OTWorld, the world’s leading industry gathering. This is why this issue includes a special preview of two keynote addresses in this year’s congress programme (p. 6/7): In an interview, Robert Riener, professor of sensorimotor systems at ETH Zürich, describes the opportunities, but also the risks of “High-tech rehabilitation 4.0”; Ronald Triolo, professor of orthopaedics and biomedical technology at Case Western Reserve University in Cleveland, Ohio, gives a brief description of the current level of technology and the potential for using neurostimulation in patients with paralysis or amputation. On pages 8 and 9, we present selected highlights of the world congress and leading international trade fair and statements from representatives of global exhibitors at OTWorld.

We hope this issue has aroused your interest in an English issue of OT and are eagerly awaiting feedback, hopefully from many of you. Let’s keep in contact!



Dr. Dorothea Becker,
Chief Editor



Foto: BIV-OT

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.

OTWorld offers an overview of the current standards and the latest discussions. The brand new German quality standard in the prosthetic lower-extremity treatment is thus presented, published by the Deutsche Gesellschaft für interprofessionelle Hilfsmittelversorgung (DGIHV). What's more, there are symposiums dedicated to the international consensus report by the International Society for Prosthetics and Orthotics (ISPO), which concerns itself with the treatment of the lower extremities, as well as the guideline published by the World Health Organisation (WHO) last year – the “WHO Standards for Prosthetics and Orthotics”. The ISPO Netherlands is also called upon.

The symposium “International standards for prosthetics and orthotics” is held in English on 15th May 2018 (11:00 a.m., Open Forum at CCO/room 7).

Premiere for new German quality standard

The compendium “Quality standard in the field of lower-extremity prosthetics” is being published by the DGIHV at OTWorld 2018. Qualified O&P professional master craftsman Michael Schäfer is among the lead authors. Exclusively for OT, the CEO of Pohlig GmbH and one of the chairs of the Bundesinnungsverband für Orthopädie-Technik (BIV-OT) introduces the background to the new quality standard in advance:



Michael Schäfer.

Photo: Carolin Ebber

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.

The comprehensive treatment approach comprised 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.

Michael Schäfer, together with PD Dr. med. habil. Lutz Brückner, holds the chair for the symposium “Quality standards in prosthetic lower-extremity treatment” at the OTWorld congress (17th May 2018, 10.30, room 1, in German, English and Spanish).

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

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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 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. ■

Keynote speaker

Robert Riener

Robotic exoskeletons, brain-computer interfaces for overcoming neurological impairment, "smart" devices, 3D-printed prostheses – "High-tech rehabilitation 4.0" with comprehensive connectivity, digital communication and new production techniques are already being adopted in the healthcare system.

Dr.-Ing. Robert Riener, professor for sensorimotor systems at the Swiss Technical University (ETH) in Zürich will speak about the huge opportunities, but also the current deficits and future risks of "Rehabilitation 4.0" in his keynote address at the OTWorld in Leipzig on 16 May 2018. In an interview, he gave a preview of what the audience can expect.

OT: Professor Riener, what high-tech trends in rehabilitation technology will you be focusing on in your presentation?

Prof. Dr.-Ing. Robert Riener: I will report on new portable and implantable technologies for persons with impaired mobility. The media and film industry often describe these individuals as "cyborgs". This can provoke fear because cyborgs are usually the "bad guys" in films. The functionality of this technology is usually still not even satisfactory for users. This means that we are still a long way away from natural human performance. Other fears are fuelled by the media – for example the loss of jobs to intelligent machines or the loss of control. I would like to show that only a small part of these fears are justified – and that we would do better to utilise the excellent potential of these technologies.

Personal Facts

Prof. Dr.-Ing. Robert Riener heads the Department of Health Sciences and Technology at ETH Zürich, develops robots and interaction technology that support motor learning in rehabilitation and sports, and holds 22 patents. He also works at the research centre for paraplegiology at Balgrist University Hospital and is the founder and organiser of the Cybathlon. This international competition will be held for the second time in 2020. Persons with disabilities compete in various disciplines, supported by high-tech assistance systems such as exoskeletons or brain-computer interfaces.



Photo: private

Prof. Dr.-Ing. Robert Riener is the initiator of the Cybathlon among other things.

OT: What does the merger of "Industry 4.0" and rehabilitation mean?

Riener: "Industry 4.0" means a huge gain in performance and efficiency. New technologies in automation, robotics, artificial intelligence and in data collection and processing affect the entire value-added chain. If we apply "Industry 4.0" to rehabilitation, it affects the areas of prevention, diagnosis, therapy and rehabilitation, health economics and accessibility – up to social integration and the acceptance of patients and individuals with disabilities.

OT: Where are the risks?

Riener: In technical safety and data security and in the possible limiting of the right to self-determination of patients or individuals with disabilities and the equitable availability across different social classes – at the national and international level.

OT: Will "Rehabilitation 4.0" mean the loss of conventional jobs in the healthcare sector?

Riener: Conventional jobs will change, some jobs will disappear entirely. This does not necessarily apply to individuals at the microeconomic level, but to the overall job profile at the macroeconomic level. This means that the individual does not need to fear for his specific job, but that positions will likely not be filled again and there will be changes in the broad structures in the healthcare sector. Some sectors have always been subject to constant change – more than half of the jobs that existed in the 1960s are no longer around today. Instead, there are many new jobs, in IT and the internet, for example. Two thirds of today's primary school children will have jobs that do not even exist today. The important thing is to be prepared for change and continue learning. Companies have to stay creative and dare to explore new niches and markets.

OT: High hopes are pinned on robotic prostheses, brain-computer interfaces and exoskeletons – what is your assessment of the current situation?

Riener: The current situation of these technologies is rather sobering – not the technical, robotic aspect, but in view of the human possibilities. There are no devices at this time

that can satisfactorily replace musculoskeletal body function over a wide range of everyday activities. They are still much too heavy and bulky, too slow and need too much power – with very short battery lives. There are also deficits in operation: For a device to be operated with little effort, it has to detect the movement intentions of the user automatically – run by itself, in other words.

OT: Do you anticipate that high-tech prostheses and exoskeletons will become affordable for everyone?

Riener: Every widely accepted technology becomes affordable at some point. In the beginning, there were also very few people who could afford cars, computers and mobile phones. This is why technical advances and commercialisation have

to be encouraged so that technology that is expensive today will be cheaper in the future. Insurance companies and governments can help increase availability and make it more equitable.

OT: Will you report on your own developments at the OTWorld – on exoskeletons, for example?

Riener: We have developed an exoskeleton – the Exosuit MAXX – and are now testing it on patients. I will present the results in May. The exoskeleton will be available as a small series of 15 devices during the course of this year.

Cathrin Günzel asked the questions.



Photo: Prof. Ronald Triolo

Keynote speaker

Ronald Triolo

Prof. Ronald Triolo will speak at the OTWorld on 18 May about neurostimulation for improved standing and walking after paralysis or the loss of a limb.

High-tech for more independent mobility for individuals with a disability: Ronald Triolo of the US Department of Veterans Affairs gives an insight into ongoing research projects in his keynote address "Neurostimulation to Improve Standing and Walking After Paralysis or the Loss of a Limb" on 18 May 2018 at the OTWorld.

The professor for orthopaedics and biomedical technology at Case Western Reserve University in Cleveland, Ohio uses case reports to illustrate the use of technologies that are based on a thorough understanding of the human neuromuscular skeletal system and biomechanics. Professor Triolo reports how this technology is developed and the extent to which it can be translated into concrete treatment concepts based on clinical feasibility studies. One approach to this is walking using external muscle stimulation: Using functional electrical stimulation (FES) of the muscles, patients with severe spinal cord injuries, for example, can walk or ride a bicycle again. Professor Triolo is substantially involved in the "Advanced Exoskeletons for Independent Mobility" project that explores options for improving exoskeletons. For example, a prototype of the first generation of a neuromechanical walking assistance system combines electrical sti-

mulation of the paralysed muscles of the lower limbs with a hydraulic exoskeleton that can be controlled for standing, walking and climbing stairs. This system has shown that it has the potential to improve the stability and posture of persons with paraplegia – in comparison with walking using only electrical stimulation.

This development is one of the ambitious projects at the Advanced Platform Technology Center in Cleveland, Ohio. The Department of Veterans Affairs competence centre focuses on the practical medical needs of persons who are impaired by sensorimotor dysfunction, cognitive deficits or the loss of a limb. The researchers and engineers at the centre are working "among other things" on dynamic exoskeletons, neural implants to restore natural sensation or muscle function, innovative materials for prosthetic liners and reconfigurable walking aids for uneven surfaces or for climbing stairs.

"Assistive technologies that communicate directly with the peripheral nervous system can facilitate or restore the independence of many functions that have been impaired by a disease of the central nervous system or trauma," wrote Professor Triolo in the abstract of his keynote address. In a similar manner, selectively activating the sensory nerves can provide natural and valuable information about the interaction of lower limb prostheses with the environment in order to improve balance when standing and gait stability in amputees.

Triolo announced that he would address the following aspects in particular in his presentation: biomimetic control systems for stable, two-legged balance and gait, new methods of selectively activating and maximising muscle contractions, systems for improving sitting posture and function and the design of hybrid systems that link exoskeletons with the user's muscle activity to enable them to walk after complete paralysis. Last but not least, Professor Triolo presents preliminary results on the extent to which natural sensory perception can be restored after amputation using neurostimulation. ■

OTWorld: Internationality is a given fact

Working on behalf of patients worldwide: OTWorld will once again become more international this year. The improvement in patient care is reflected in the world congress as well as in the trade fair, the reach of which extends from Leipzig across the entire globe. Half of the exhibitors thus travel from abroad (2016: 48 percent). The top countries are the USA, Italy, France, Spain, United Kingdom, Netherlands, Turkey, and China.

OTWorld also cooperates with renowned specialist companies and associations. The trade fair, for instance, brings together national and international associations such as the International Society for Prosthetics and Orthotics (ISPO), the Italian Associazione Nazionale Aziende Ortopediche – Assortopedia, the Spanish Federation of Healthcare Technology Companies (Fenin), and the Union Française des Orthoprothésistes (UFOP).

Two years ago, OTWorld attracted a total of 21,300 visitors from 86 countries and 542 exhibitors from 43 nations.

Global Networking Area: A focus on international networking

The Global Networking Area at OTWorld is once again all about multinational collaborations and a transnational transfer of knowledge. International specialist associations, scientific societies, and educational institutions within the orthopaedics and rehabilitation technology industry traditionally meet here at the invitation of the German Association of Orthopaedic Technology (BIV-OT). They discuss the best and latest possibilities within device fitting and the treatment of patients worldwide. What's more, they display their concepts, new approaches and experience, and present conferences and further training opportunities.

O&P professionals and shoemakers, engineers, physicians and therapists can make new contacts, network across continents, and exchange information at this interdisciplinary, global P&O "meeting point". Around 40 associations, organisations and societies are expected at the shared stand this year. Those represented include: American Orthotic & Prosthetic Association (AOPA), Arab United Society for Prosthetics and Orthotics, IC2A – International Confederation of Amputee Associations, ISPO Canada/Germany/Slovenia/UK NMS/Netherlands, Kilimanjaro Christian Medical University College (KCMU-Co), The National Syrian Project for Prosthetic Limbs, Polish Society for Prosthetics and Orthotics, Tanzania Training Centre for Orthopaedic Technologists (TATCOT), and WCPT Network for Amputee Rehabilitation (AR). Renowned organisations and associations from 24 countries were involved in 2016.

OTWorld congress programme: Improving the quality of treatment worldwide

The OTWorld congress takes a global and interdisciplinary look at the quality of modern patient care. The central topic of the world congress is the interaction between medicine and technology. With around 320 speakers from 32 countries (at the previous event in 2016: 29 countries), its programme is very wide-ranging. The congress languages are German and English, simultaneous interpreting is provided for many speakers. For the first time, there is also Spanish simultaneous interpreting for all talks given in room 1 at the OTWorld Congress Center (CCO).

The over 100-hour lecture programme looks at various aspects of modern device fitting in an inter-professional team. The programme committee chaired by Prof. Dr. Volker Bühren has worked with 15 leading specialist societies for this, including the Association of Diabetic Foot Surgeons (A-DFS) and the Gesellschaft für Orthopädisch-Traumatologische Sportmedizin (GOTS).

For instance, the English-language satellite symposium "Surgical treatment of complex diabetic foot deformities. An international perspective by A-DFS" is held in cooperation with the A-DFS (16th May 2018, 4:45 p. m., room 5). The topics include stump function following a partial foot amputation and rehabilitation following reconstructive surgery.

Two satellite symposiums are held in collaboration with GOTS: current concepts on avoiding sports injuries and the importance of preventative training and orthopaedic technology are presented under the title "Prevention of damage caused by excessive stress" (German/English, 16th May, 3:15 p. m., room 3). The second symposium, «Instabilities of the athlete's knee», is dedicated to contemporary treatment concepts (German/English/Spanish, 17th May, 3:15 p. m., room 1).

The symposium "How a Charcot foot should not be amputated: the necessity of interdisciplinary collaboration" is on the agenda with the involvement of the ISPO Netherlands (English/German, 17th May, 4:45 p. m., room 3). Among other things, this is about the latest technology for early identification and early treatment of a Charcot foot. ■

Otto Bock HealthCare GmbH

Global marketplace and shop window for our industry!



Photos: Ottobock

*Dr. Oliver Scheel,
CEO of Otto Bock Health-
Care GmbH.*

*Norbert Aumann,
CEO of Otto Bock HealthCare
Deutschland GmbH.*

For four whole days, Leipzig is the centre of the universe for all those involved in the care process, O&P professionals, physicians, therapists, cost bearers, teachers, students, and many others. OTWorld is firmly established as a pioneering entity for science and technology.

The focus lies on the digital transformation, which is proceeding at an unstoppable pace both for our customers and for us. Communication is becoming faster, more precise,

more dynamic, and more flexible. CAD/CAM and alternative production methods, such as 3D printing, are no longer a pipe dream. We look forward to personal meetings and opportunities to discuss with each other, listen to each other, and learn from each other. We want to know: what moves our customers? This is incredibly important. At the same time, OTWorld enables us to show what we can do.

One highlight in the “Ottobock Arena” is pattern recognition – it will make it possible to use myoelectric arm prostheses even more intuitively. Using the example of the bebionic hand, we show for the first time what benefits this learning control system offers to the user.

Other areas of focus: the second generation of the C-Brace® – now smaller, lighter, and possible to use virtually intuitively – as well as individual care solutions in prosthetics with a focus on the various user groups. In neurorehabilitation, we offer a wide range of highly functional orthoses through to products with functional electrostimulation – all of which are embedded in modern treatment concepts and networks.

Our trade fair team is getting ready with great enthusiasm. Years ago, we coined the slogan “Shaping the future together”. Although we no longer write this on the wall of our stand, we live by it. It remains the guiding principle for our customer relationships. ■

Blatchford/Endolite

Great window on P & O

OTWorld is the largest and most influential tradeshow in our industry, attracting visitors from Europe and the rest of the world. At Blatchford, we see OTWorld as an opportunity to re-connect with customers, partners and colleagues, renew old friendships and make new ones. It is also a time to catch up on the latest thinking in prosthetic and orthotic science and practice, and on the most up-to-date technology.

There are so many reasons to visit OTWorld! Endolite is a Blatchford group company and a leading supplier to our industry. With recent innovations such as the award-winning Linx, Orion3, Echelon Vac and Silcare Breathe, it’s a chance to hear more about the benefits that integrated microprocessor technology, hydraulic ankles and perforated liners can bring to amputees. There is a fantastic team of demonstrators who will gladly answer any questions about their own experiences with the technology and the products they are wearing. At Endolite, we believe long term musculoskeletal health depends on the replication of natural limb movement, so we will also have a science area where visitors can find out more about the evidence behind our product designs. Finally, and most importantly, OTWorld is also an opportunity for us to meet visitors and find out how we might be able to help them or their patients better achieve their mobility

goals – perhaps in greater comfort, with greater ease or stability, or in being able to do something new for the first time.

Also ourselves can see in Leipzig what is going on in the field – as the OTWorld congress is a great window on the world of prosthetics and orthotics. ■



*Stephen Blatchford,
Blatchford Executive
Chairman, Directors.*

Photo: Blatchford/Endolite

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 adaptation 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 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



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



Fig. 2 A photograph of the implanted myoelectric sensor.

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 biceps 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 bioamplifier 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 level ground walking to mimic the control signal for dorsi- and plantarflexion. The muscle activity pattern was then recorded

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

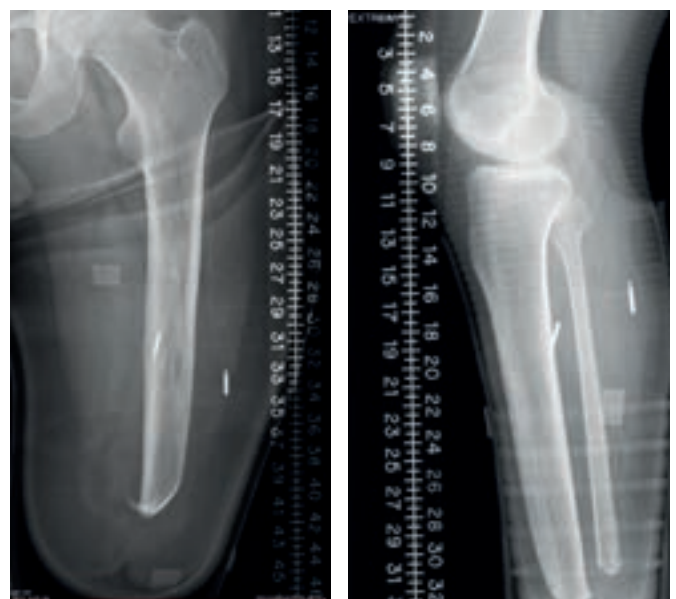




Fig. 4 Shows the IMES system for a TT user. The coil is laminated within the socket and wirelessly communicates with the IMES. The IMES control interface is used to control the coil and send muscle signals to the BSMB which then communicates with the prosthesis.

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 therefore 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.

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 promptly dorsiflexed due to the invo-

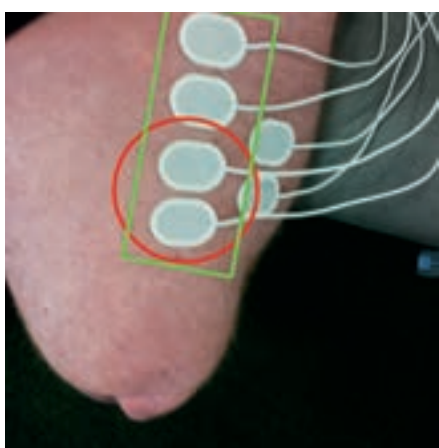


Fig. 5 Determining the region of greatest interest (green box) and the area of strongest myoelectric signal (red circle) was done with iterative measurements. Electrodes were then placed on and around the area of interest taking in account the possible movement of the strongest myoelectric signal location.

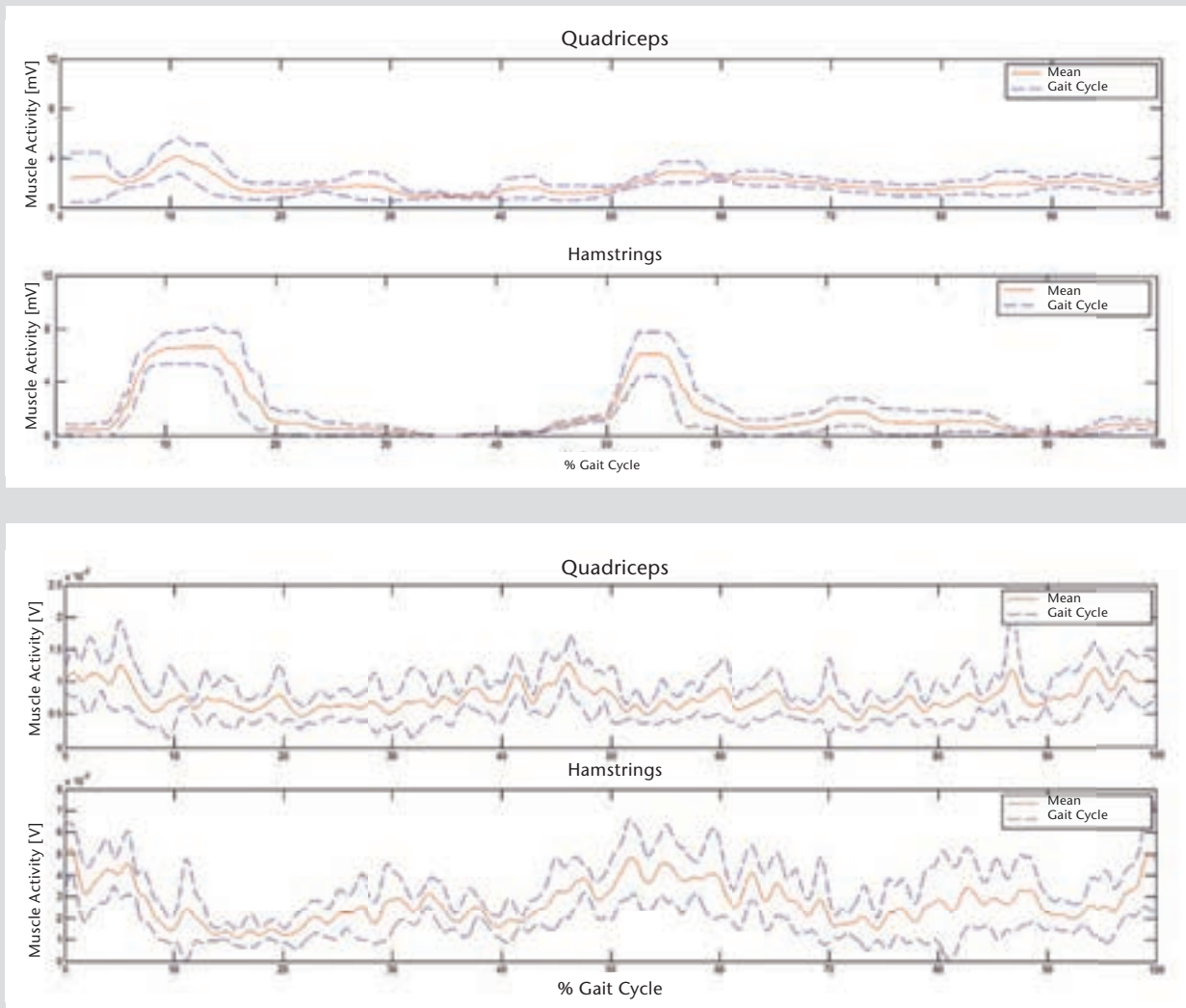


Fig. 6 Mean value and standard deviation of 8 gait cycles during stair descent. IMES measurements can be seen in the top two graphs and the surface EMG measurements in the two lower graphs. These figures show that the IMES muscle activity pattern is more distinct than the sEMG signal.

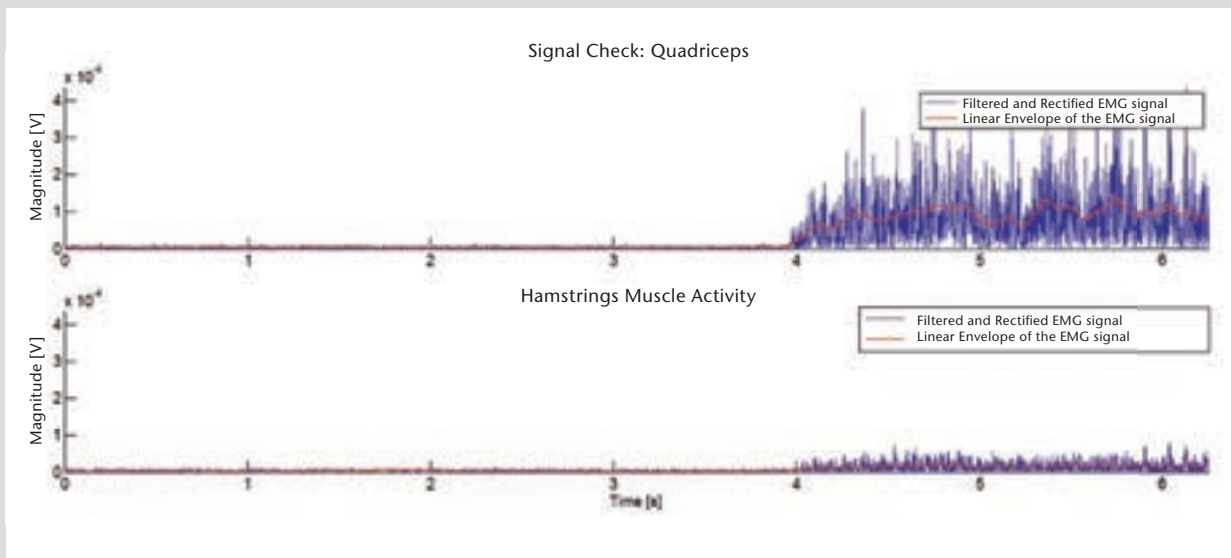


Fig. 7 Signal check of the Quadriceps muscles where the subject was asked to relax and then contract his muscle. Muscle contraction of the Quadriceps resulted in muscle activity of the Hamstring muscles as well.

luntary 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 therefore 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 bioamplifier 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.

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Reviewed paper

Reference

- [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



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Superiority of a Knee Relief Orthosis in the Treatment of Knee Osteoarthritis

A Prospective Randomised Controlled Trial

The results of this randomised controlled trial on patient-related clinical endpoints show a high medical benefit of wearing the „Genu OA“ orthosis compared with standard treatment in patients with osteoarthritis of the knee. In addition to the considerably longer pain-free walking distance, the high degree of comfort and ease of use contribute to acceptance of the orthosis and thus to the success of treatment. This study shows the need for further high-quality clinical studies on the long-term clinical benefit of knee orthoses that apply a valgus/varus torque.

Key words: osteoarthritis of the knee, osteoarthritis, knee, randomised controlled trial, knee orthosis

Introduction

Osteoarthritis of the knee is one of the most common diseases among the elderly. It affects around 34% of women and 24% of men over age 60 around the world [1]. According to data from the Federal Statistical Office, osteoarthritis of the knee is the main reason for the indication for knee replacement surgery [2]. In 2015, total knee replacements were number 18 of the 50 most common operations in hospitals [3]. Elderly patients in particular are affected by increased risks due to total knee replacement surgery such as complications during anaesthesia, revision surgery or bacterial infections of the knee prosthesis that can lead to sepsis and heart attack [2, 4, 5].

The medial knee compartment is affected by osteoarthritic changes more often than the lateral knee compartment [6]. This is due to axis deviation [7]. An important treatment approach thus involves shifting the load to the intact compartment [8, 9]. The use of

an unloader knee brace that encompasses the knee has proven to be a safe, cost-efficient treatment option for reducing pain and improving function. It can even delay the need for surgery [10]. Both clinical and biomechanical studies have confirmed the effectiveness of knee orthoses, however they were only rarely based on randomised comparative study designs. In addition, the long-term benefit of valgus/varus orthoses must be proven in additional clinical studies. The evidence of a benefit also depends on patient acceptance with respect to wearing the orthosis and on the progression of osteoarthritis [10, 11]. The objective of this prospective randomised study with a parallel group design on the use of the „Genu OA“ knee orthosis was thus to document the following aspects:

- The medical benefit in the sense of effect on pain, walking distance and range of movement and these results from the patient's perspective
- The suitability of the orthosis in outpatient care
- Handling and acceptance by patients with osteoarthritis of the knee.

Methods

Study design

The study is a post-market clinical follow-up study according to the European MEDDEV 2.12/2 rev.2 [2012-01] guideline. In this randomised, prospective, interventional, single-centre study with a dual-arm parallel group design, a group of patients with osteoarthritis of the knee was treated with the „Genu OA“ knee orthosis for a period of two months and compared with a control group that received a standard inter-

Patients

Patients were recruited from an orthopaedic centre for the study. The patients were assigned to one of the two groups based on a randomisation list prepared in advance. The study included patients with medial or lateral femorotibial osteoarthritis grade 2 or 3 according to the Kellgren-Lawrence system. The exclusion criteria included inability to walk or dependence on a wheelchair and diseases that did not allow participation in the study for a period of two months. Additional exclusion criteria were concomitant ipsilateral patellofemoral osteoarthritis grade 3 or 4, ipsilateral osteoarthritis of the hip grade 2 to 4, each according to the Kellgren-Lawrence system, a body-mass index over 30, cortisone injections within the last four weeks before the start of the study and inability to communicate in German.

Intervention

In the study, the treatment of patients with the „Genu OA“ knee orthosis (Fig. 1) from Thuasne was compared with the standard intervention for a period of two months. The orthosis consists of an elastic textile material. One side of the orthosis has a removable joint bar that supports physiological joint alignment. Extension and flexion limitation can be set using stops. The unloader system consisting of non-elastic tension elements acts on the contralateral side. The tension system is based on a 3-point unloading system and ensures the necessary relief for the affected knee compartment. It consists of two cross-over straps. To make it easier for the patient to open and close the orthosis, the straps have an automatic magnet closure on the front. The orthosis design allows it to be used for either medial or lateral unloading.

All patients in the orthosis group were trained in the handling of the orthosis and the risks of a circulatory disorder and swelling of the lower leg due to too tight straps were explained. Two groups of patients, one with and one without an orthosis, were observed for a pre-defined period of two months. The standard treatment given up to then (oral and local analgesics, physiotherapy, buffer heel, lateral wedge or use of a walking cane) was continued. The two groups were then compared with respect to previously determined parameters.

Parameters

All parameters for the results of the study were determined in advance. The main parameter was extension of the pain-free walking distance after using the orthosis for two months. The following secondary parameters were recorded:

- The Lequesne index was used to register changes in: pain, walking distance and physical functions as a useful complement to the clinical findings. It allows the patient's individual health status to be measured and the results from the patient's perspective to be assessed [12].
- Pain on loading was measured on the numerical rating scale (NRS) after a thirty-minute walk.
- Pain at rest was also recorded based on the NRS.
- The use of analgesics at the end of the study was compared with the baseline amount at the start of the study. Discontinuing the pain medication was equivalent to a reduction of 100%. The medication itself was not changed. Data from patients who did not take any analgesics at the start of the study were not included in the reduction.
- The subjective range of movement was assessed qualitatively by having patients rate it as „clearly improved“, „improved“, „unchanged“, „deteriorated“ or „clearly deteriorated“.
- The objective improvement of range of movement was measured in degrees.
- Pressure and unpleasant sweating in the orthosis were also assessed qualitatively as reported by patients. The patients indicated whether wearing the orthosis was bothersome and whether the pressure was perceived to

be „annoying“, „unpleasant“, „painful“ or „tolerable“ and whether any permanent pressure points or unpleasant sweating occurred.

- Handling of the orthosis was measured qualitatively by asking both the patient and the medical specialists about problems with care or use (fitting, adjusting, adapting) as well as how easy the user information was to understand. Wearing comfort was also assessed by asking qualitative questions about the following aspects: presence of pressure points, individual adjustability, constrictions, skin irritation, unpleasant sweating and heat build-up.

Statistics

With a statistical power of 80%, a sample size of 16 patients per group was calculated to be necessary for the study to prove a change in the walking distance from 1.0 (± 0.8) to 0.3 (± 0.4) in an independent two-sample t-test with a level of significance of 0.05. A drop-out rate of 5% was assumed when calculating the number of cases. The randomisation list was generated with the „randomizR“ program. Mean values and standard deviations, absolute frequencies and percentages are used to describe the data. T-tests were used to calculate the differences between the groups with respect to „pain at rest“ and „objective range of movement“. The group differences in analgesic use were examined using F tests, subjective range of movement using Cochran-Armitage tests. A linear mixed-effects model with the variable of influence „Treatment“ and the covariable „Previous value“ was adapted to fit the data on change of the Lequesne index, the walking distance and pain on loading. The statistical analyses were conducted using the „SAS 9.4“ program (SAS Institute Inc., Cary, NC, USA; Windows 10, 64 bit).

Results

The follow-up period was two months long, from 12 December 2016 to 28 February 2017. A total of 32 suitable patients were randomised to the two groups: 15 patients were assigned to the control group and 17 to the orthosis group (see the flowchart in Fig. 2). All 32 patients were available to follow-up after the study.

There were no statistically significant differences in the characteristics between the two groups at the start of the study (Tab. 1). Nine patients in the orthosis group (52.9%) and nine patients in the control group (60%) had grade 3 osteoarthritis of the knee; eight patients (47.1%) in the orthosis group and six patients (40.0%) in the control group had grade 2 osteoarthritis of the knee. The pain-free walking distance in the orthosis group was 2.71 (± 1.39) km and in the control group 2.87 (± 1.55) km at the start of the study. The average level of pain at the end of a 30-minute walk was indicated to be 4.71 (± 0.99) on the NRS in the orthosis group at the start of the study; in the control group, this value was 4.20 (± 0.56). At the start of the study, the average Lequesne index was reported to be 7.62 (± 3.24) in the orthosis group and 8.43 (± 3.58) in the control group. Some 13 patients in the orthosis group and 11 in the control group took analgesics at the start of the study. The objective range of movement was between 104 degrees in the control group and 105 degrees in the orthosis group.

Table 2 presents the primary and secondary endpoints of the study. The change in the pain-free walking distance was significantly increased in the orthosis group compared with the control group (F = 20.23, ndf 1, ddf 29, p = 0.0001). While the increase in the pain-free walking distance was 1.29 in the orthosis group after treatment, the difference on the control group was barely measurable. Figure 3 shows the changes in the pain-free walking distance over the two months of treatment.



Fig. 1 „Genu OA“ orthosis.

Characteristic	Orthosis group	Control group
Female (%)	12 (70.6)	10 (66.7)
Age, mean (\pm)	69.53 (9.91)	70.07 (12.26)
BMI, mean (\pm)	26.82 (1.83)	26.48 (2.01)
Left knee affected (%)	7 (41.25)	9 (66.0)
Lateral osteoarthritis of the left knee grade 3 (%)	2 (11.8)	0
Lateral osteoarthritis of the right knee grade 3 (%)	0	1 (6.7)
Lateral osteoarthritis of the left knee grade 2 (%)	0	1 (6.7)
Lateral osteoarthritis of the right knee grade 2 (%)	2 (11.8)	2 (13.3)
Medial osteoarthritis of the left knee grade 3 (%)	3 (17.6)	7 (46.7)
Medial osteoarthritis of the right knee grade 3 (%)	4 (23.5)	1 (6.7)
Medial osteoarthritis of the left knee grade 2 (%)	2 (11.8)	1 (6.7)
Medial osteoarthritis of the right knee grade 2 (%)	4 (23.5)	2 (13.3)
Pain-free walking distance, mean (\pm)	2.71 (1.39)	2.87 (1.55)
Pain on loading (30-min. walk, NRS), mean (\pm)	4.71 (0.99)	4.20 (0.56)
Pain at rest (NRS), mean (\pm)	1.59 (1.0)	2.0 (0.93)
Lequesne index, mean (\pm)	7.62 (3.24)	8.43 (3.58)
Use of analgesics, N (%)	13 (76.47)	11 (73.34)
Objective range of movement, degree (\pm)	105.29 (11.25)	104.0 (11.83)

Tab. 1 Basic characteristics.

Result	Orthosis group	Control group
Change in the pain-free walking distance, mean (\pm)	1.29 (0.90)*	0.20 (0.37)
Change in pain on loading (30-min. walk, NRS), mean (\pm)	-1.06 (0.66)*	-0.13 (0.35)
Change in pain at rest (NRS), mean (\pm)	-0.06 (0,24)	0 (0)
Change in the Lequesne index, mean (\pm)	-0.68 (0.71)*	-0.17 (0.36)
Change in use of analgesics, mean (\pm)	-17.31 (23,68)	-3.09 (10.25)
Improvement in subjective range of movement, N (%)	6 (35.3)	2 (13.3)
Improvement in objective range of movement, degree (%)	2.35 (4.37)	0.67 (2.58)

Tab. 2 Primary and secondary endpoints.

*p=0.0001

The average intensity of pain at the end of a maximum 30-minute walk was reduced in the orthosis group by 1.06 (± 0.66) points on the numerical rating scale; this value was hardly changed in the control group during the study (-0.1 ± 0.35). The change in pain under loading was significantly increased in the orthosis group compared with the control group ($F = 22.13$, $ndf 1$, $ddf 29$, $p < 0.0001$). Figure 4 shows this change in the groups over a period of two months.

With respect to pain at rest, no changes were observed over the course of the study. Only one study participant reported a value lower by one unit on the NRS after two months. The resting pain was reduced only in the orthosis group from 1.59 (± 1.00) to 1.53 (± 0.94) and did not change in the control group. There was no difference between the groups at the end of the two-month treatment period with respect to the average values of resting pain ($t = 1.42$, $df 29.64$, $p = 0.1654$).

The Lequesne index dropped in the control group by an average of 0.17 (± 0.36) to 8.27 (± 3.48), while in the orthosis group, it was reduced by 0.68 (± 0.71) to 6.94 (± 2.86). The change in the Lequesne index was significantly higher in the orthosis group compared with the control group ($F = 10.08$, $ndf 1$, $ddf 29$, $p = 0.0035$). Figure 5 shows this change during the study period of two months.

A reduction of 17.3% in the use of analgesics was observed in the orthosis group; the reduction in the control group was 3.1%. However, this difference was not statistically significant ($F = 3.40$, $ndf 1$, $ddf 22$, $p = 0.0785$).

Despite wearing the orthosis, 35% of the patients reported that their range of movement was „improved“ and 65% said it was „unchanged“. In the comparison group, two patients rated their range of movement as „improved“ and the remaining patients „unchanged“. There was no significant difference in the change in subjective range of movement between the treatment groups (Cochran-Armitage test, $p = 0.1522$).

The objective range of movement was improved in the orthosis group by 2.35 (± 4.37) degrees and in the comparison group by 0.67 (± 2.58) degrees. The difference between the groups was not significant ($F = 1.61$, $ndf 1$, $ddf 21$, $p = 0.2142$).

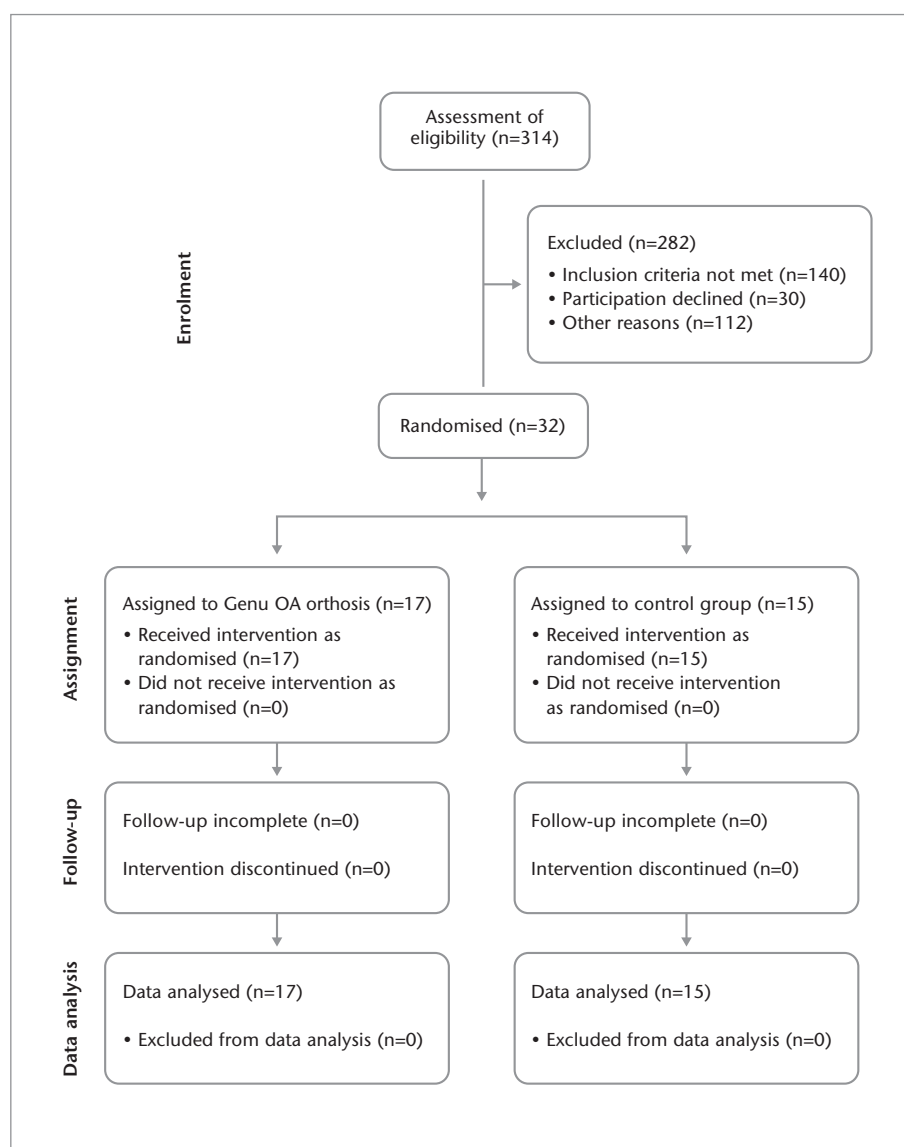


Fig. 2 Flowchart of patient inclusion and follow-up examinations.

The patients in the orthosis group reported that they perceived wearing the orthosis to be unpleasant: The pressure of the corrective straps was described as „annoying“ and „uncomfortable“ but not „painful“ or „intolerable“. No persistent pressure points developed, also no unpleasant sweating. Five patients came outside of the scheduled follow-up appointments to have the orthosis readjusted.

During the entire application and observation period, no adverse side effects occurred that might have been related to the use of the orthosis. In five patients, the metal bar of the orthosis had to be readjusted due to insufficient unloading of the osteoarthritic compartment. No patients fitted with the orthosis had difficulty handling or caring for the orthosis.

Discussion

In this prospective randomised comparative study, the pain-free walking distances were extended significantly in patients with osteoarthritis of the knee by wearing the „Genu OA“ orthosis; the pain on loading was also reduced considerably compared with standard treatment. The significant reduction of the Lequesne index confirmed the positive effect on pain, walking distance, and physical functions in the orthosis group from the patients' perspective as well. Handling was found to be easy and wearing comfort was good. The orthosis thus meets the technical and medical requirements for products of the type „Knee orthoses for unloading and alignment“ and according to the results of this study, is suitable for use in

patients with osteoarthritis of the knee, both in outpatient care and at home.

This study contributes to the requirement for evidence of efficacy for clinical trials with a randomised comparative study design [11]. The power of the study was appropriate for detecting differences between the groups. All patients included were available to follow-up and their results could be analysed at the end of the study. In addition, the selection criteria were based on radiological criteria for the classification of osteoarthritis of the knee as used in clinical practice [13], which allows the results of the study to be transferred to practice. The relevance of the results for fitting practice was increased by including the patient perspective. This is important with respect to acceptance of the orthosis and thus of the treatment success. Overall, no change in resting pain was observed, which could be due to the short treatment period of just two months. The results suggest a need for further high-quality clinical trials on the sustained benefit of valgus/varus orthoses.

Although no change in the treatment regimen took place in the control group, the pain-free walking distance was increased. What is called a response bias may be responsible for this. A bias of this kind may be attributed to the study participants, to changed (response) behaviour in a study situation, to the design of the questions or of the questionnaire, or to an interviewer effect.

Based on the Lequesne index, wearing the orthosis had a greater positive effect on pain, walking distance and physical functions than the standard treatment from the patient perspective as well. The Lequesne index allowed the individual health status and the patient's view of the treatment results to be assessed [12]. This index is widely used around the world and is recommended by the World Health Organization (WHO) to measure outcomes of knee diseases [14]. Since the Lequesne index measures the duration, but not the intensity of pain, and measures walking distances only up to one kilometre, pain was assessed in this study using the numerical rating scale and the walking distance was measured separately.

Although the improvement in the range of movement was not the primary goal of the orthosis, the increase in mo-

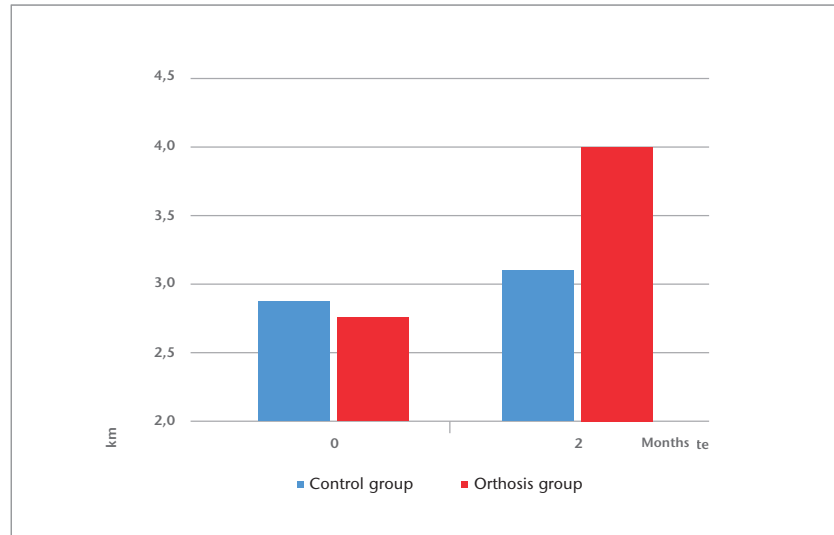


Fig. 3 Change in the pain-free walking distance.

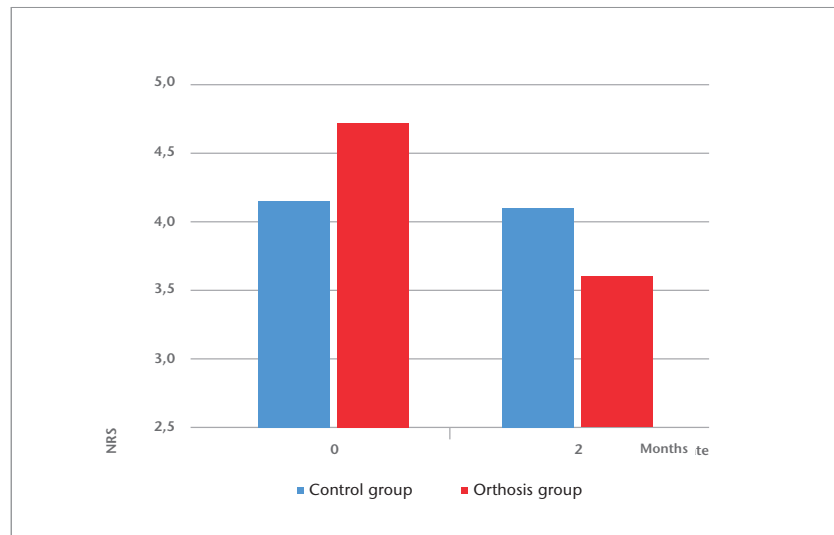


Fig. 4 Change in loading pain.

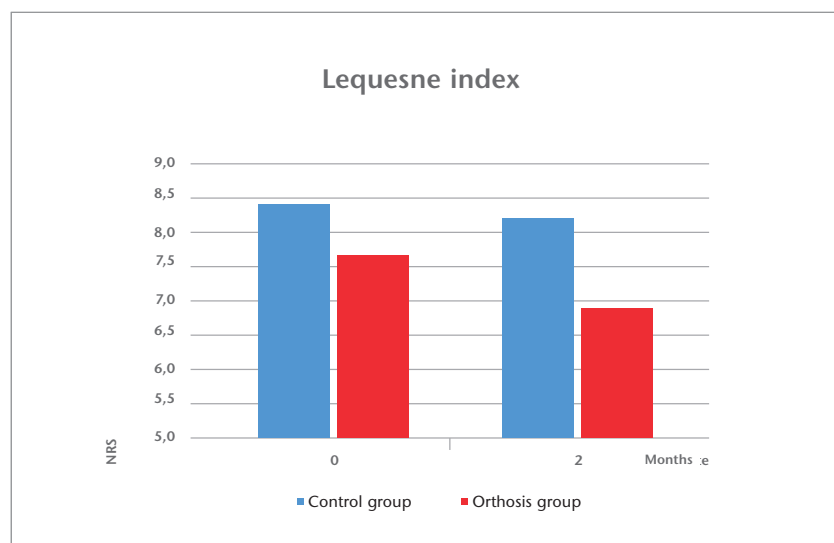


Fig. 5 Change in the Lequesne index.

bility appeared at least subjectively to improve the range of movement as well. Due to the gradual increase in unloading of the osteoarthritic compartment during follow-up, the patients learned to estimate the correlation between pain relief, the pain-free walking distance and corrective compression of the tension straps. Providing comprehensive information to the patient and readjusting the orthosis were basic requirements for acceptance of the orthosis.

The results of this method were that it ensured easy, correct and safe use of the orthosis. No intolerable pressure from the metal bar occurred in any of the patients that they could not correct

themselves immediately. There was no constriction at the back of the knee or skin irritation where the orthosis came into contact with the patient's skin.

Conclusion

Wearing the „Genu OA“ orthosis had a significantly superior effect on pain, walking distance and physical functions compared with standard treatment and thus on aspects that ultimately have a positive effect on the quality of life and independence of patients. In addition to a good corrective effect, the orthosis is also comfortable to wear, is easy to handle, can be applied quickly and can be worn under clothing or for sports.

In addition, it can be individually adjusted. The orthosis is thus suitable for independent use by the intended users in a domestic setting.

This randomised comparative study suggests a need for further high-quality clinical trials over a longer observation period to prove evidence of the long-term benefit of valgus/varus orthoses.

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References:

- [1] Pereira D, Peleteiro B, Araujo J, et al. The effect of osteoarthritis definition on prevalence and incidence estimates: a systematic review. *Osteoarthritis Cartilage*, 19 (11): 1270–1285
- [2] RKI – Robert Koch-Institut (Hrsg.) *Arthrose. Gesundheitsberichterstattung des Bundes, Heft 54*. Berlin: RKI, 2013
- [3] Statistisches Bundesamt. Fallpauschalenbezogene Krankenhausstatistik (DRG-Statistik). Diagnosen, Prozeduren, Fallpauschalen und Case Mix der vollstationären Patientinnen und Patienten in Krankenhäusern, 2015. https://www.destatis.de/DE/Publikationen/Thematisch/Gesundheit/Krankenhaeuser/FallpauschalenKrankenhaus2120640157004.pdf?__blob=publicationFile (Zugriff am 23.05.2017)
- [4] Deutsche Gesellschaft für Unfallchirurgie (DGU) in Zusammenarbeit mit der Österreichischen Gesellschaft für Unfallchirurgie (ÖGU) (Hrsg.). *S1-Leitlinie Endoprothese bei Gonarthrose (AWMF-Leitlinienregister Nr. 012-008)*. Stand: 01.06.2009 (in Überarbeitung), gültig bis 30.06.2014. http://www.awmf.org/uploads/tx_szleitlinien/012-008_S1_Endoprothese_bei_Gonarthrose_2009_abgelaufen.pdf (Zugriff am 23.05.2017)
- [5] Lalmohamed A, Vestergaard P, Klop C, Lerkevang Grove E, de Boer A, Leufkens HGM, van Staa TP, de Vries F. Timing of Acute Myocardial Infarction in Patients Undergoing Total Hip or Knee Replacement. *Arch Intern Med*, 2012; 172 (16): 1229–1235
- [6] Hernborg JS, Nilsson BE. The natural course of untreated osteoarthritis of the knee. *Clin Orthop Relat Res*, 1977; (123): 130–137
- [7] Cerejo R, Dunlop DD, et al. The influence of alignment on risk of knee osteoarthritis progression according to baseline stage of disease. *Arthritis Rheum*, 2002; 46 (10): 2632–2636
- [8] Greitemann B. *Konservative Therapie der Arthrose – Hilfsmittelversorgung*. *Arthroskop*, 2009; 22: 176–182
- [9] Waller C, Hayes D, et al. Unload it: the key to the treatment of knee osteoarthritis. *Knee Surg Sports Traumatol Arthroscop*, 2011; 19 (11): 1823–1829
- [10] Lorbach O, Mosser P, et al. Sense or nonsense of unloader braces. *Orthopäde*, 2014; 43 (11): 984–987
- [11] Moyer R, Birmingham T, et al. A systematic review and meta-analysis of biomechanical and clinical effects of valgus knee bracing. *Osteoarthritis Cartilage*, 2014; 22: 457
- [12] Grimmig H, Melzer C et al. Der routinemäßige Einsatz des Lequesne-Index zur Ergebnismessung in der orthopädischen Rehabilitation bei Hüft- und Knieerkrankungen. Using the Lequesne questionnaires for patients with hip and knee disabilities in daily routine to reflect the quality of outcome in rehabilitation. *Z Orthop Unfall*, 2002; 140 (4): 452–459
- [13] Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie und Berufsverband der Ärzte für Orthopädie (Hrsg.). *Leitlinien der Orthopädie. 2. Auflage*. Köln: Deutscher Ärzte-Verlag, 2002
- [14] Ludwig FJ, Melzer C et al. Kulturelle Adaptation des Lequesne-Index für Hüft- und Kniegelenkerkrankungen im deutschen Sprachraum. *Cross Cultural Adaptation of the Lequesne Algofunctional Indices for German Speaking Patients with Osteoarthritis of the Hip and the Knee*. *Rehabilitation*, 2002; 41 (4): 249–257

The Effect of Dynamic Carbon Insoles in Running Sports

Background: This study was carried out to examine the benefits of dynamic carbon insoles for runners suffering from Achilles tendon pain or knee pain. **Materials and Methods:** A treadmill analysis was performed in 26 subjects. The effects of carbon insoles on hip rotation and foot stresses in the shoe were then determined. The data were recorded by the MyoMotion (Noraxon) inertial sensor system and the vebitoSCIENCE (Vebito) insole measurement system. **Results:** The results showed that hip internal rotation and ankle eversion were reduced in male and female subjects by the insole. The bending and torsional moments at the heel and the metatarsophalangeal joint (MTP) 5 were also reduced. No significant effect on foot stress at MTP 1 was detected. **Conclusion:** A treadmill analysis is highly recommended for athletes with specific symptoms. Carbon insoles can optimise the runner's gait pattern regarding bending and torsional stress at the foot, ankle motion, and hip rotation.

Key words: carbon insole, treadmill analysis, running, Achilles tendon pain, patellofemoral pain syndrome

Introduction

Running is great. People of all ages, at all levels of training and from all segments of the population run. It is the natural form of movement and many have discovered this sport in recent years. Although many individuals take up running, only a few of them keep at it. Athletes often complain of orthopaedic problems that make running difficult.

Comprehensive running and movement analyses are the basis for optimal

care. Many athletes decide to have a running analysis because of recurring pain at or around the knee joint or Achilles tendon. The most common diagnosis for pain located in the patella, the patellar groove and connective tissue is the patellofemoral pain syndrome (PFPS). Achilles tendon pain frequently stems from the severe stress to the Achilles tendon caused by running.

Previous studies have examined the causes of pain and found a relation to increased internal rotation of the hips and instability of the subtalar joint [1, 2, 3]. This gives rise to the question of how these factors can be positively affected by fast, practical care.

Additionally, Kraus showed back in 1973 that statics and load bearing capacity of the arch of the foot depend, among other things, on the arch rise. "Flat feet with a low arch put more strain on plantar tension than feet with high arches, i.e. they have a greater tendency to deformation," said Kraus [4]. The height of the arch also depends on the position of the rearfoot. The position of the rearfoot in turn is affected by the size and vector of forces arising from the different individual and also pathological static and kinetic properties of the entire lower limb. Every analysis of the statics of the foot must therefore include the entire pelvis-leg statics.

Hohmann et al. described in 2004 that all movements in the ankle joints are possible only as combination movements due to the oblique movement axes of the joints: "An inward rotation of the lower leg under loading causes compensatory movement of the talus in plantar-medial direction, the plantar surface moves to relative abduction, the heel to pronation, and the medial longitudinal arch of the foot flattens considerably under supination of the forefoot.

The outward rotation of the lower leg reverses this process." said Hohmann [5]. When walking, the lower leg is rotated outward at the time of heel strike. Under full loading in the stance phase, the lower leg rotates inward. In the toe-off phase, the lower leg rotates outward again as knee extension increases and the foot can straighten again.

It is already known that both hobby and professional runners saw a positive change in their conditions after being fitted with a dynamic carbon insole from Medi. Hence, the objective of this study was to examine the effect of the shell insole with a carbon clip on the internal rotation of the hips, ankle eversion and thus on the inward rotation of the lower leg. It examines the hypothesis that the insole can reduce these parameters to have a positive effect on the causes of pain in individuals with knee and ankle pain [1, 2, 3].

Material and methods

Subjects

To compile the measurement data, running analyses were conducted in 26 subjects (male: $n = 12$, female: $n = 14$). The arithmetic mean age was 29.5 ± 9.5 years, weight 69.5 ± 15.5 kg and height 1.77 ± 0.12 m. The subjects reported different levels of fitness. Exclusion criteria were injuries within the last six months, impaired joint mobility and a pathologically conspicuous gait. Some 21 of 26 subjects reported having experienced pain in the patellar region at least once during running training.

Carbon insole

The carbon insole is a shoe insole in the form of a shell (Fig. 1). The underside of the insole has a 0.8 mm thick carbon clip (model "Igli Allround

light C+” from Medi). The carbon clip has torsion sections at the level of the sustentaculum tali and in the forefoot area to facilitate physiological rollover. Due to the sections and the resilience of the material, the insole does not have the effect of a rigid object that immobilises the joints in the foot. Instead, the effect should be to activate the muscles of the lower limbs. The top of the insole is a 4 mm layer of EVA 35° Shore A with a velour cover. Below the carbon clip, a 2 mm thickness of EVA 50° Shore A was used.

The insole was tested in a “Makai” neutral shoe from Zoot. Zoot produces the midsole of the women’s shoe with a drop of 11.5 mm, the midsole of the men’s shoe with a drop of 13.1 mm.

Inertial sensor system “MyoMotion”

“MyoMotion” (Noraxon) is a camera-free, transportable, 3D kinematic system able to capture human movement in three degrees of freedom. It consists of a combination of hardware (inertial sensors) and the MyoResearch MR3 software. By positioning the inertial sensors at adjacent segments of the body, their spatial orientation is registered and the range of movement of the

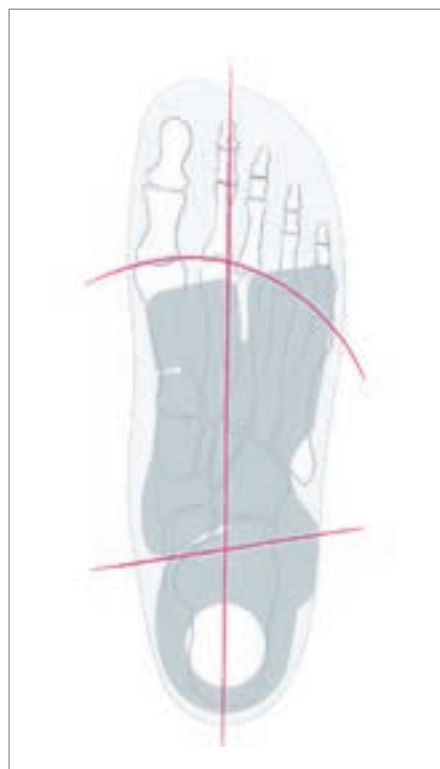


Fig. 1 Technical illustration of the Igli carbon clip with torsion sections.

joint between them is determined. The data measured are transmitted wirelessly to a receiver and analysed by the MR3 software.

Inner sole measurement system (ISM) “vebitoSCIENCE”

The “vebitoSCIENCE” measuring system developed in the biomechanics laboratory at the Münster University of Applied Sciences is a combination of hardware (measuring soles) and software for the purpose of determining multidimensional stresses acting on the foot in shoes. Kerkhoff et al. published initial studies in 2014 that showed that “the (...) inner sole system allows the fast, easy, and reliable testing of orthopaedic devices using mobile bending and torsional load measurements” [6].

The “vebitoSCIENCE” hardware consists of a data transfer unit for the wireless transfer of measurement data to the software and insoles, each with five integrated measuring sites for measuring loads. The carrier layer of the measurement soles consists of a specially formed elastic material onto which strain gauge sensors (Vishay) are attached. The measuring sites are located proximal to the distal interphalangeal joints 1 and 5 (DIP 1, DIP 5), proximal to the meta-tarsophalangeal joints 1 and 5 (MTP 1, MTP 5) and distal to the calcaneal process (heel).

The multidimensional foot stresses include bending strains such as the strain of the forefoot to the rearfoot at the transition from the mid to the terminal stance phase caused by bending moments. Physically, bending moments are defined as the product of the force acting and the length of the lever arm. Torsion describes the twisting of a body, for example twisting of the foot around its longitudinal axis.

Test procedure

Prior to measurement, the age, height, weight, fitness level, and injury history are taken for every subject and documented in a short form. To determine limitation of movement in the ankles and conspicuities in the gait, the neutral-null method was used and an initial barefoot measurement was conducted on a slat belt treadmill (Woodway).

Every subject warmed up for 3 minutes without sensors to become familiar with the treadmill. The subjects selec-

ted different speeds between 8 km/h and 10 km/h. In the barefoot measurement that followed, the inertial sensors were used to record the angles. For the following measurements, the subjects wore the neutral shoe including the inner sole measuring system (ISM). The measurements were made with and without the insole and in random order. For the measurement with the carbon insole, the original sole of the shoe was removed to make space and replaced with the trimmed-to-size insole. The ISM was placed on the insoles. All sensors and the ISM were placed by the same person for the measurements and the position was checked after every measurement (Fig. 2).

Analysis

For the analysis, the mean was formed from 20 strides extracted from every measurement. The statistical analysis of the data collected was made using the SPSS software from IBM. The software was used in the study to check the maximum and minimum values measured for statistical significance. The significance level was specified as $p = 0.05$.

The measurement data of women and men were analysed separately, as Kerkhoff et al. found gender-specific differences in running style and foot loads in previous studies [7] and also because the drop of the shoes differed.

Results

The diagrams in Figures 3 to 8 show the analyses of the angle and load measurements. The calculated mean values and the maximum and minimum value of a subject are presented for barefoot measurement (B), measurement without insole (w/oI) and measurement with insole (wI). The greatest variance resulted from the different speed selected by each subject. The term “range” below describes the range of movement or the difference between the external rotation and internal rotation moments.

The running shoe alone had no statistically significant effect ($sm = 0.211$, $sf = 0.421$) for male and female subjects Eversion (Fig. 3, 4) was reduced significantly with the insole by about 1.5° in both groups of subjects ($sm = 0.001$, $sf = 0.017$). The reduction of the range of movement was statistically significant only for the male subjects ($sm = 0.002$, $sf = 3.309$).



Fig. 2 Fixation of the measuring systems and calibration.

The comparison of the hip rotation angle (Fig. 5, 6) shows that the neutral shoe had no significant effect on the internal rotation of the hip ($sm = 0.289$, $sf = 0.758$). The hip external rotation was also unchanged by the carbon insole ($sm = 0.502$, $sf = 0.755$). However, internal rotation was reduced by the insole from 7.03° to 5.83° in male subjects ($sm = 0.005$). The combination of shoe and insole compared with barefoot resulted in a reduction of the internal rotation angle by 2.48° ($sm = 0.001$). Hip internal rotation is reduced by the insole from 3.26° to 1.55° in the female subjects ($sf = 0.045$). The increased internal rotation with the shoe was not statistically significant for the female subjects ($sf = 0.758$). The range of movement was also not significantly affected by any of the conditions. In measurements with the insole, the comparisons of the torsion moment measurements at the heel measuring site (Fig. 7, 8) were statistically significant only for the internal rotation-moment and range. The mean internal rotation moment was reduced with the insole by 15.00 Nmm to 5.56 Nmm in male subjects ($sm = 0.031$). The range between the external and internal rotation moment was reduced by 6.6 Nmm ($sm = 0.047$). For the female subjects, the internal rotation moment was reduced with the insole from 22.75 Nmm to 10.42 Nmm ($sf=0.001$). As a result, the range was 21.17 Nmm smaller ($sf = 0.000$).

Discussion

Ankle joint

The limitation of eversion by the insole was proven by the angle measurements (Fig. 3, 4). The eversion angle was significantly reduced by the insole, while there was no significant change to the inversion angle. Merely moving without changing the angle would result in putting the rearfoot in supina-

tion deformation. These results show that the insole does not force the foot to overcorrect, but only compensates for hyperpronation with specific support.

The values of the torsion moment measurements at the heel (Fig. 7, 8) serve to clarify these results. The fewer torsion moments acting at the heel, the less change in the axis and position of the rearfoot to the forefoot there is and the lower the tensile and

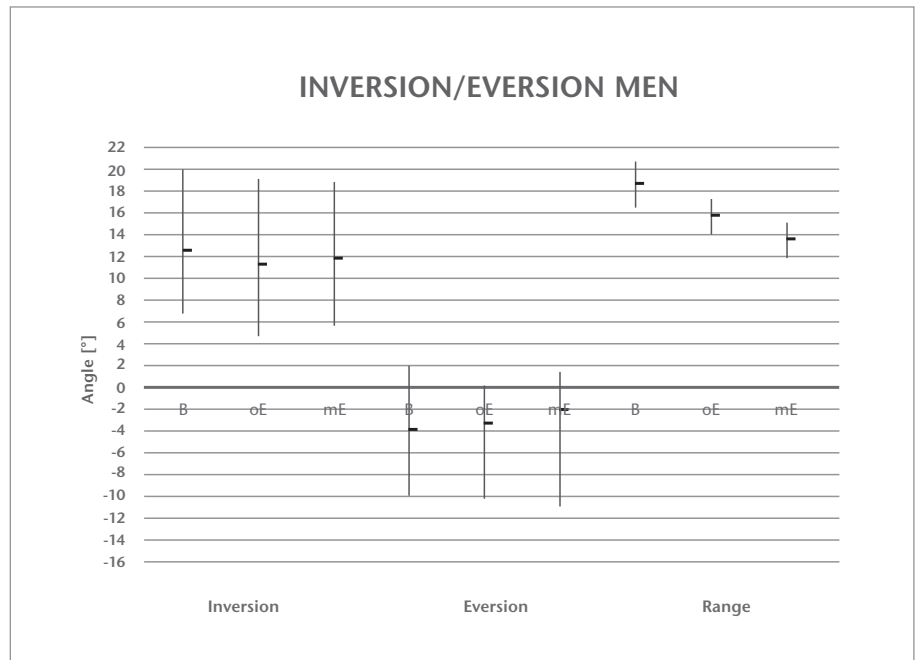


Fig. 3 Inversion/eversion men.

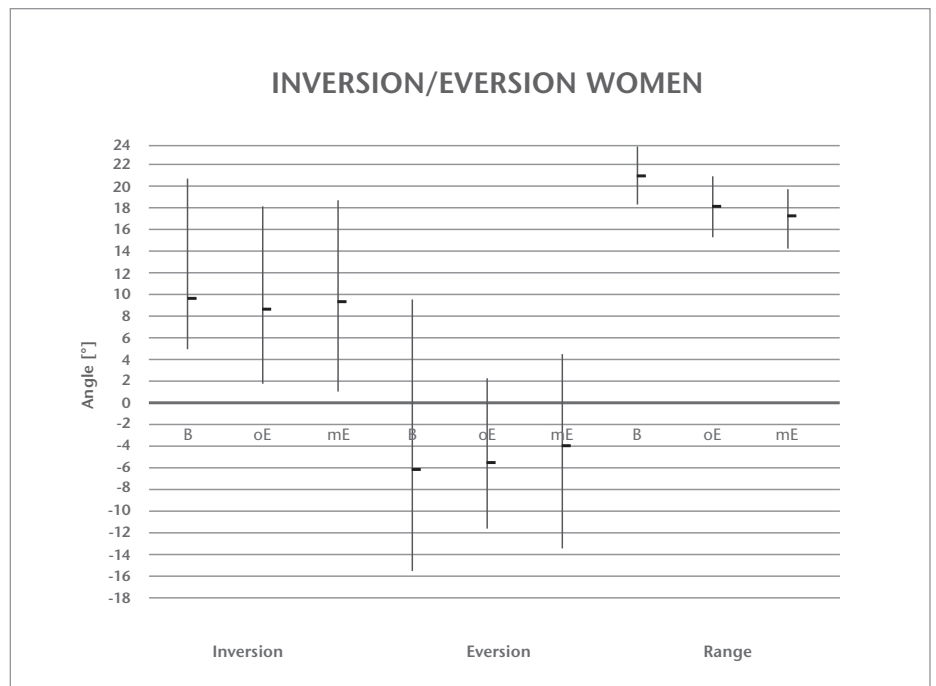


Fig. 4 Inversion/eversion women.

friction forces acting on the Achilles tendon are. With vebitosolution, a significant reduction of more than 50% of the load at the heel due to internal rotation moments was found for both groups of subjects. Overall, the difference between external and internal rotation moments was smaller when the subjects wore carbon insoles. Smaller dorsal extension moments were also found at the same measuring site. This indicates lower loads on the short muscles of the foot, the tendons of the long muscles of the foot and especially on the plantar aponeurosis, which support the longitudinal arch.

The carbon slip integrated into the shell insole has a torsion section medial between the calcaneus and the tarsal bones that extends approximately up to the longitudinal axis of the foot. On the lateral side, the insole is stable due to the full-length carbon. The purpose of the torsion sections is to support natural rollover and prevent compensatory movement toward genu varum. As both the dorsal extension moments and the external rotation moments at MTP 5 are reduced by the insole, compensatory movement can be prevented. No statistically significant changes due to wearing the insole were found at MTP 1, which leads to the conclusion that it continues to allow physiological rollover over the first ray.

These results proved the positive effect of the dynamic carbon insole on the factors identified as possible causes for Achilles tendon pain or injuries and the patellofemoral pain syndrome in the studies by Lorimer et al. [1], Reule et al. [2] and Souza et al. [3].

Hip

The second parameter to be studied was the reduction of hip internal rotation when running. The results show only little variation, but this variation was constant and found in almost all subjects (Fig. 5, 6).

The running shoe alone had no significant effect on hip rotation movement in either group of subjects. For this reason, an effect of the cables attached to the legs can also be ruled out.

Due to medial support, the insole ensures that the talus is straightened in the stance phase. The stabilisation of the talus minimised eversion movement. As already explained in the introduction, any movement in the

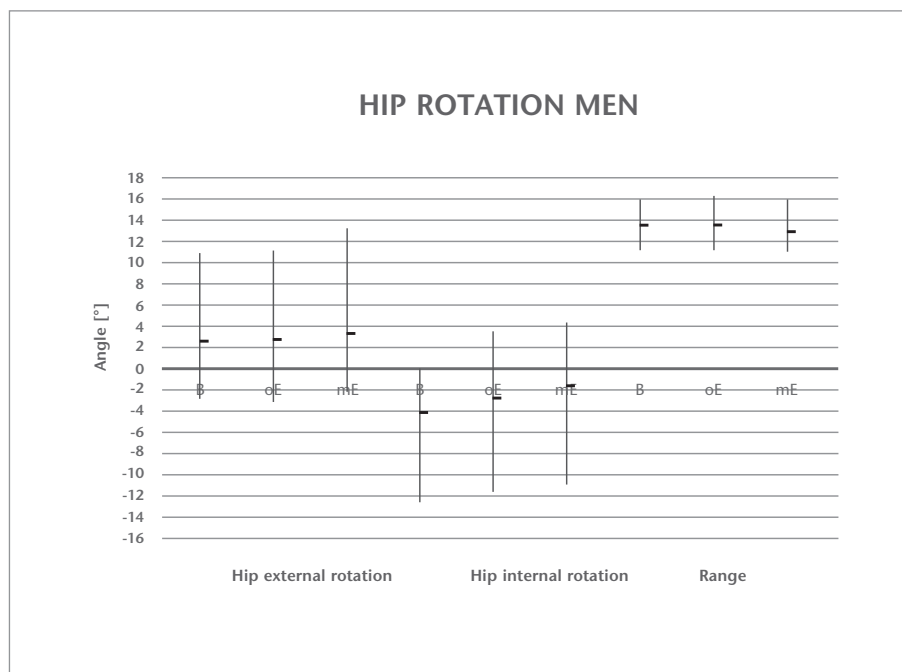


Fig. 5 Hip rotation men.

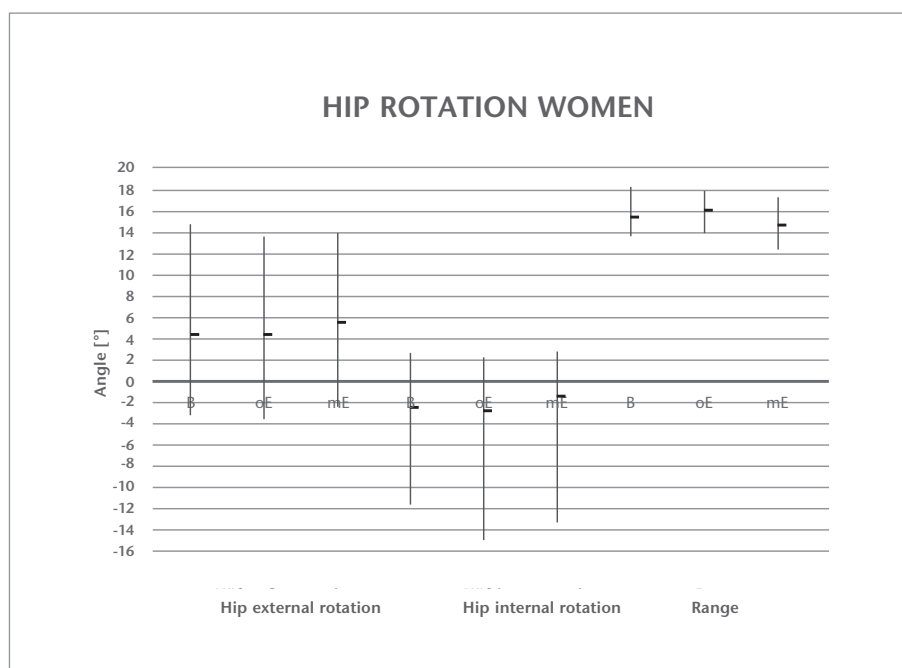


Fig. 6 Hip rotation women.

joints can only be a combination of movements. Loading with an upright talus leads to outward rotation of the lower leg. Due to anatomical and muscular conditions, this effect also reduces hip internal rotation.

Both measuring systems showed a gender-specific difference. The reason for a separate analysis of the results was due to already documented differences in previous studies [7]. The results of this study confirm that it makes sense

to view each gender separately. However, the results were compared with one another to a limited extent only, as the different drops of the running shoes may have affected the values.

Conclusion and perspective

The insole does not replace specific muscle training to compensate for muscular imbalance. This training also takes time.

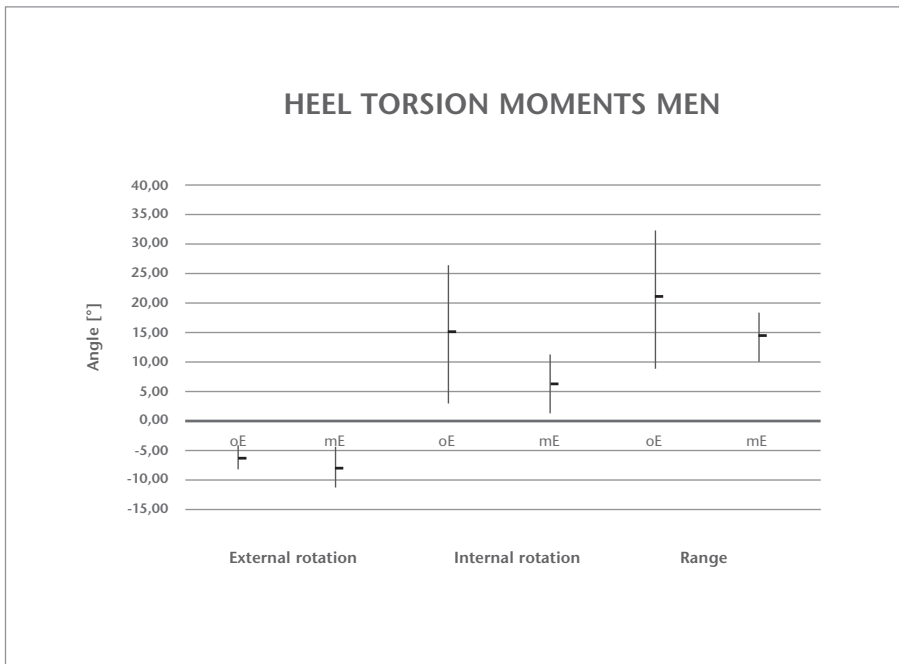


Fig. 7 Heel torsion moments men.

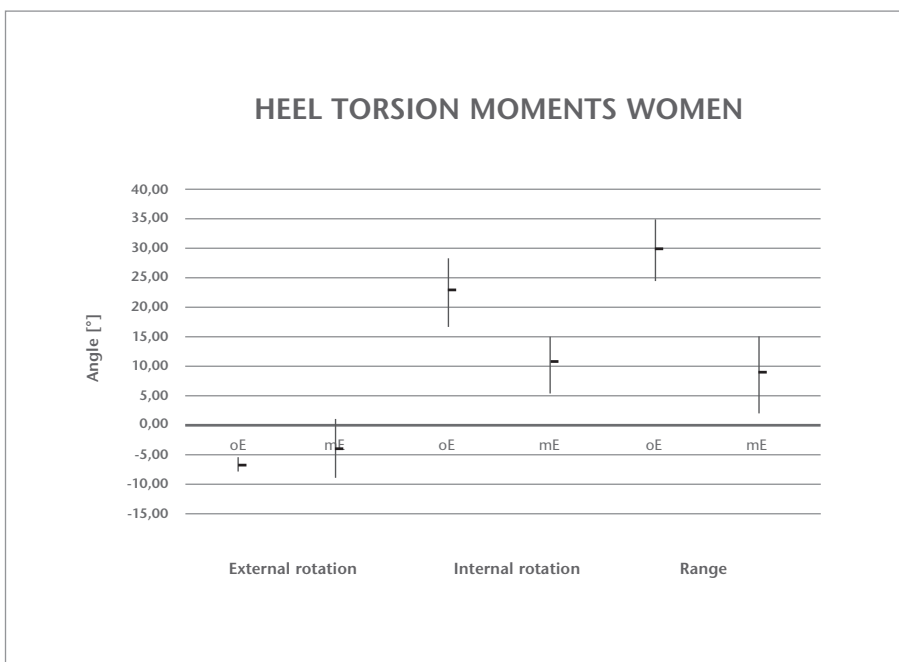


Fig. 8 Heel torsion moments women.

However, in running sport especially, there is an interest in at least a temporary quick treatment. A gait analysis and exact observation of movement sequences are therefore absolutely recommended for athletes with one of the syndromes described here. The advantage of the carbon insole is that a small effect can be measured immediately. The carbon insole can optimise the runner's gait, at least with respect to faulty foot loading, ankle movement and hip rotation.

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References:

[1] Lorimer AV, Hume PA. Achilles tendon injury risk factors associated with running. *Sports Med*, 2014; 44 (10): 1459–1472

[2] Reule C, Alt W. Individual Risk Factors Contributing to Achilles Tendon Disorders in Running Related Sports. *Deutsche Zeitschrift für Sportmedizin*, 2011; 62 (6): 448–456

[3] Souza RB, Powers CM. Predictors of hip internal rotation during running: an evaluation of hip strength and femoral structure in women with and without patellofemoral pain. *Am J Sports Med*, 2009; 37 (3): 579–587

[4] Kraus E. Biomechanik und Orthopädiesschuhtechnik. Geislingen an der Steige: Maurer Verlag, 1973

[5] Hohmann D, Uhlig R. Biomechanik und funktionelle Fußhilfen. In: Hohmann D, Uhlig R (Hrsg.). *Orthopädische Technik*. 9., überarbeitete u. neu gestaltete Auflage. Stuttgart: Thieme Verlag, 2004: 509–522

[6] Kerkhoff A, Dawin N, Stief T, Seeßle M, Peikenkamp K. Innovatives Messsystem bietet neue Möglichkeiten der Bewegungsanalyse in der Prothetik. *Orthopädie Technik*, 2014; 65 (12): 30–34

[7] Kerkhoff A, Peikenkamp K. Norm data for bending and torsional loads of the foot in shoes including the effect of gender. Präsentation AS-0233 auf dem Kongress der International Society of Biomechanics ISB 2015 in Glasgow. <https://isbweb.org/activitiescongresses> (Zugriff am 26.07.2017)

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