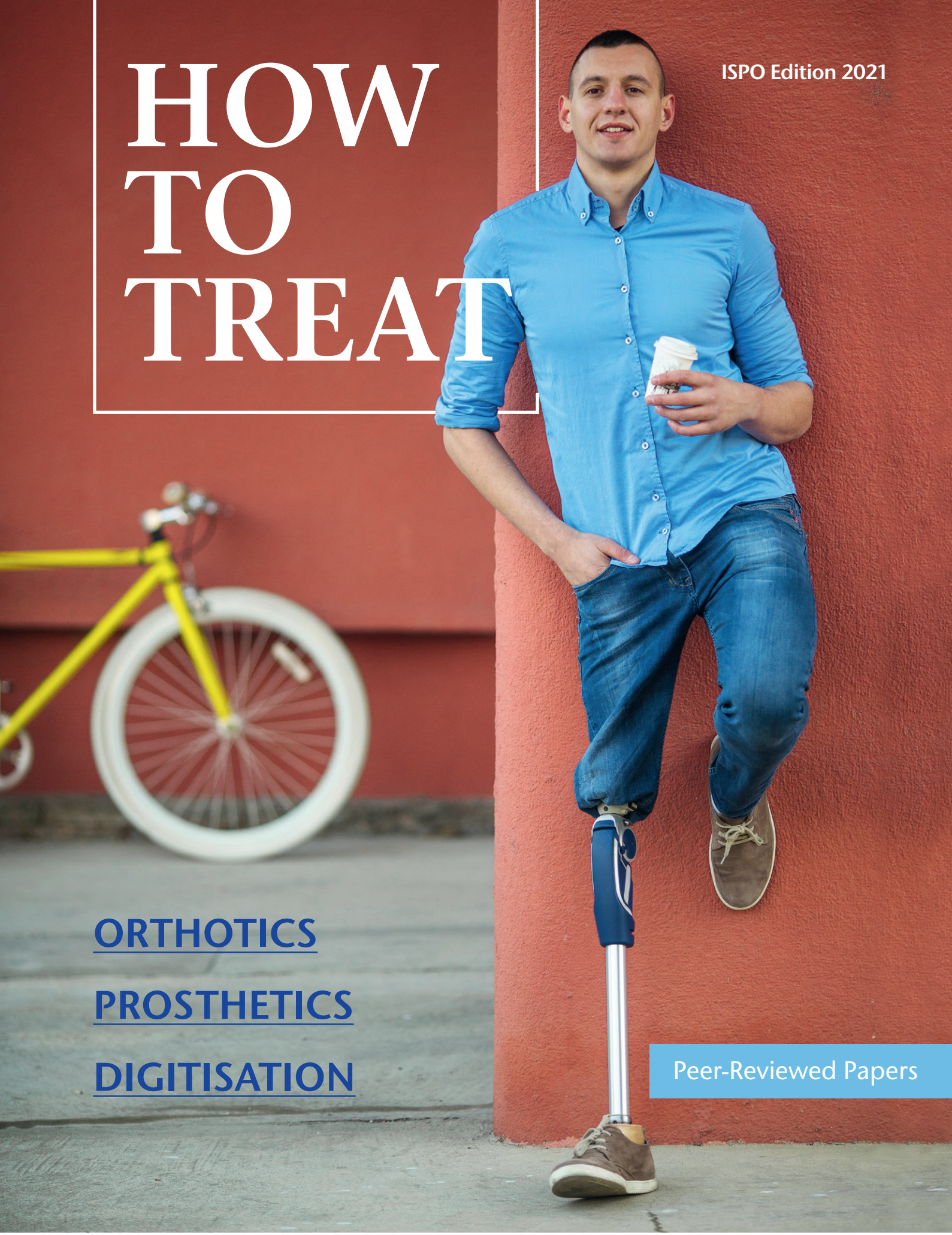
HOW TO TREAT

ISPO Edition 2021



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Digital Transformation for Assistive Technology Devices Services

Prosthetics, orthotics, and the assistive technology sector has been experiencing a digital transformation, evolving from computer aided design systems in the 1990's and initial telehealth use in the early 2000's. The COVID global pandemic has pushed the pace of digital innovation and adoption, and this evolution in services and assistive technology is reflected in ISPO activities and the World Congress theme.

If we consider a person's path through the care process, capturing appropriate patient data and outcome measures leads to improved care. The "LEAD and COMPASS: Defining Outcome Measures and Core Data Set for the lower limb prosthetics sector" report as just been released by ISPO and encompasses global expert consensus on core data sets that can be used to benchmark global needs and assistive device outcomes and outcome measures that can lead to more consistent reporting of results-based information that can be used across countries.

Digital assessment and followup, by using desktop conferencing, smartphones, and other communication technologies, has become more common as clinicians endeavour to work beyond barriers presented by distance or pandemic related restrictions. ISPO uses this technology to support education accreditation, provide continuing education opportunities, and transferring knowledge related to telehealth use with assistive devices. Communication technology remains underused globally and has the potential to ensure the most appropriate devices are prescribed and, by followup, that these devices are used appropriately.

Digital manufacturing, including 3Dprinting, receives most of the attention since the idea of printing a prosthesis directly at the point of patient contact is enticing. The reality is that other manufacturing approaches may produce the most appropriate device for the person. For example, manufacturing a metal component, that meet ISO standards, in volume and shipping globally may be more effective than 3Dprinting an individual component since procurement of appropriate materials and equipment to create a component of equivalent quality is more expensive in the end. ISPO is supporting this transition period to digital manufacturing by working with global partners to assemble and assess the current state-of-the-art, combine research evidence with practical experience to generate global perspectives that can guide practice, and identify and fill gaps in device standards to enable quality validation in this new era where device component manufacturing is not performed by industry. The battle with misinformation is an important part of this path to ensure the most appropriate and high quality assistive device for the end-user.

As part of global digital manufacturing, the "manufacturing ecosystem" needs to keep evolving in order to provide components and tools to the clinician in the most efficient manner. Central fabrication thrives in a digital environment and may be necessary to address the unmet global needs of millions of people with disabilities. We need to look beyond current approaches and engage with other industries, distribution centres, and governments to enable appropriate flow of the required resources and end-products to bring the best device to the person at the appropriate cost.

While many of these factors seem to relate to technology, nothing works without the people providing healthcare services being engaged, knowledgeable, and continually trained. Prosthetics and orthotics has been considered a craft, which is defined as "an activity involving skill in making things by hand". Working digitally is just another step in the evolution of the prosthetics and orthotics craft, and will result in new approaches that bring a better quality of life for people with mobility related disabilities.

Photo: ISPO

Professor Edward Lemaire, PhD,
World Congress Chair and President of ISPO

There's no Working from Home when Providing Treatment with Devices

I can feel a sense of solidarity in our profession that hasn't been there for a long time. And not just in Germany, but throughout Europe and the world as well. Each of us has our own opinion, of course, our specific challenges and our own interests, too – that's how it should be. But the situation surrounding the pandemic has made it clear to us that we have to stand together strong and united all around the world. We're united by our interest in continuing to provide devices to patients across the world during a pandemic.

We know that collaboration between a multitude of different professional associations has to take not just an interdisciplinary but also an international approach. German Association of Orthopaedic Technology (BIV-OT) has launched international projects at many different levels during the pandemic. And while it's true that we have always thought in terms of cross-border concepts, this international outlook has now been given a very practical boost – and the positive effects of our newly discovered transnational solidarity can be seen in the implementation of the Medical Device Regulation (MDR), for example. This has seen allies coming together throughout Germany and Europe to identify common cross-border solutions for implementing the MDR in the device sector. Shared standards to ensure the protection of patients have been established in Europe in particular. The fact that we are defining common treatment standards and sharing our knowledge together and across international borders represents a huge win for everyone receiving treatment with devices.

We have to work to maintain this sense of solidarity when new challenges arise! Germany is planning to set up e-health competence centres throughout Europe with the goal of creating a digital, networked healthcare sector in Europe. The aim is to simplify the exchange of patient data across borders to give patients the security they need in emergencies and facilitate successful treatment. Our European network gives us a great starting point for taking this vision to the international level and developing potential solutions for the device sector as well as recognising and highlighting potential risks.

We are living in the "new normal", and this also means having to maintain a balancing act between being globally interconnected while remaining safely isolated. The functions our sector has to fulfil due to the pandemic are similar at the national level. In this sense, it's worth looking beyond our immediate horizons and asking ourselves: How are my colleagues dealing with this unique and exceptional situation? How can I safely treat my patients? We love discussions just as much as before, there's an even greater need to converse with others, and we have even more to talk about. People require treatment with devices every day. We need to seek out a professional and interdisciplinary debate to help these people. There's no such thing as working from home in our trade.

Transferring trade shows and conferences to the digital space and hosting hybrid events demonstrates that we know how to come together using virtual tools. The upcoming ISPO Congress is further proof of this, and I'm particularly excited that this event is providing an occasion for a new edition of "HowToTreat" (HTT). Like the ISPO Congress, this magazine is an opportunity for us to share ideas with one another. And it demonstrates that the cooperation between ISPO and the BIV-OT is working. The next issue of HTT will be published to coincide with OTWorld 2022, when the global sector comes together once again.

Looking to the future, I hope that we can maintain and expand on our strong sense of solidarity – across international borders. And that we'll be able to see each other in person again soon.

All the best,

Photo: Marcus Zumbansen

Alf Reuter,
President Bundesinnungsverband für Orthopädie-Technik
(German Association of Orthopaedic Technology)

Contents

ISPO 2021:
Digital Transformation in an Evolving World

The 18th World Congress of the International Society for Prosthetics and Orthotics (ISPO) is taking place as a digital event from 1 to 4 November 2021. 320 presenters from 36 countries deliver an interdisciplinary and global programme covering both scientific and clinical progress – sharing new findings in prosthetics & orthotics.

Digital meet-up on treatment with devices

The motto for the virtual edition is "Digital Transformation in an Evolving World". The congress, which has been moved to the digital space in its entirety due to the global coronavirus pandemic, will also look at the question of how treatment with devices can benefit from the use of digital technologies. This reflects the fact that digitalisation is playing an increasingly prominent role in the fabrication and adjustment processes, in patient management and in training.

The agenda therefore features items including digital data capture and analysis, for example, as well as the digital transformation of prosthetic treatment and training with myoelectric prostheses with the assistance of virtual systems. In this sense, the ISPO World Congress also reflects the digital transformation we've seen in every segment of the economy – and which accelerated rapidly last year. But "traditional" topics – such as providing devices to people with disabilities in the various international markets – will also figure prominently at the congress.

Congress to open with inspiration

One special highlight is certain to be the popular IC2A Inspirational Lecture to kick off the virtual 18th ISPO World Congress. This year, Christopher Hutchison, co-founder and Chief Technical Officer (CTO) of ProsFit, will speak on the topic of "Prosthetics for All – Changing Lives through Digital Technologies". Hutchison had an accident resulting in the amputation of both his legs in 2009. Working closely with certified prosthetists/orthotists (CPOs) from every corner of the world, he acquired knowledge about prosthetic treatment, and particularly regarding custom socket design. This gave him the opportunity to push forwards with user-generated innovation and gain a reputation as a positive disruptor in the field of prosthetics. ProsFit was founded in Bulgaria (2013), offering digital end-to-end solutions for prosthetic treatment with a focus on the design and delivery of 3D printed sockets. Patient treatment units called Pando Points, which can be either stationary or mobile, are suitable even in remote and challenging environments.

Keynotes take centre stage

Further highlights on the agenda will definitely include the three keynote presentations by Dr Alarcos Cieza, Dr Matthew Major and Dr Alex Dickinson.

Dr Cieza supervises the work at the World Health Organisation (WHO) in the fields of vision, hearing, disability, and rehabilitation in her role as Unit Head of Sensory Functions, Disability and Rehabilitation. Prior to joining the WHO in 2014, she was Chair and Professor of Medical Psychology in the Faculty for Social and Human Sciences at the University of Southampton in the UK. Dr Cieza also served as head of the research unit at the Department of Physical Medicine and Rehabilitation for over ten years and then at the Pettenkofer School of Public Health at Ludwig Maximilian University of Munich in Germany.

Dr Matthew Major will discuss a selection of novel experimental techniques being implemented to populate digital maps defining the relationships between select parameters in his keynote "Personalized Rehabilitation: Mapping the Links Between Prosthesis Parameters, Motor Capacity, and Clinical Outcomes for Optimizing Interventions". Further, he will discuss how an iterative optimisation approach can deliver personalised lower-limb loss rehabilita-

Keynote-Speakers

Dr Alarcos Cieza

Dr Alex Dickinson

Credits [3]: ISPO

tion interventions when integrating targeted physical therapies that encourage self-organisation with the prosthesis. Dr Major, PhD, is an associate professor at Northwestern University and a Research Health Scientist at Jesse Brown VA Medical Center in Chicago in the US. His research focuses on designing and optimising rehabilitation measures to help people with musculoskeletal or neurological disorders become more mobile and independent.

In his talk "Digital Workflows for Predictive Prosthetic Socket Design", Dr Alex Dickinson will describe how he and his team have tried to reframe prosthetic socket design in the paradigm of formal engineering design, whilst aiming to make simulation-based design tools usable and accessible to clinicians. Dr Dickinson is an Associate Professor in the Mechanical Engineering Department at the University of Southampton (UK).

Dr Dickinson was the recipient of a personal research grant at the Royal Academy of Engineering from 2015 to 2020. He used his grant to set up a team that works with data technologies to improve the design of prosthetic limbs, among other aspects. His research aims to expand the understanding of the design of the prosthetic socket. It includes, for example, computer-assisted modelling of the interface between the residual limb and socket as well as the capture of medical imaging and biophysical data to assess the impact of mechanical strain caused by the prosthesis on soft tissue in the residual limb.

Regional Panels Provide a Global Perspective

At the virtual edition of the ISPO 18th World Congress, a series of regional panels will offer the opportunity to discuss aspects of the congress theme "Digital Transformation in an Evolving World". Each day will feature one panel with regional experts who will explore how digital transformation is affecting practice in different parts of the world, providing a global perspective on digital applications for assistive technology.

Virtual exhibition and exhibitor workshops enhance the exchange of knowledge

The industrial exhibition at this special edition of the ISPO World Congress has also made the move to the virtual space. In the digital exhibition area, companies be showcasing their latest products in assistive technology. Most of the exhibitors will also host a workshop for attendees to get hands-on information.

Long-term knowledge

But the exchange of knowledge won't end when the four days of the 18th ISPO World Congress come to a close – the recordings of all scientific sessions and exhibitor workshops as well as the scientific posters will remain available in the virtual platform until 31 October 2022. The virtual exhibition area and international community area will be accessible during the live event as well as around the clock on demand until 30 November 2021.

See you in Mexico!

The ISPO initially planned to hold its global meeting this year in Mexico. They'll get there eventually, as the 19th edition of the ISPO World Congress will be hosted in Guadalajara in 2023.

Dr Matthew Major

M. Raslan, U. Thiel, H. P. Neunzig

The Effect of Dynamic Functional Shoulder Orthoses on the Development of a Shoulder-Hand Syndrome (SHS) Following a Stroke

Review of Evidence-based Studies

Stroke is a common disease and a significant cause of permanent impairment. Due to paralysis of the arm, many stroke patients develop a shoulder subluxation, a painful shoulder, or a shoulder-hand syndrome (SHS). This review provides answers to the key question of whether the use of shoulder orthoses can significantly prevent or reduce subluxation and shoulder-hand syndrome after a stroke. A selective literature search was conducted in PubMed. The results show that improving SHS was addressed only in a clinical study by Hartwig et al. Significant clinical improvement was found for the Neuro-Lux® (Sporlastic GmbH, Nürtingen) functional shoulder orthosis. The studies discussed came to contradictory results regarding improvement of subluxation and pain perception, which can be explained by the different study designs and different design and function of the orthoses used.

Key words: functional shoulder orthoses, shoulder-arm syndrome, shoulder-hand syndrome, shoulder subluxation, stroke

Introduction

Cardiovascular diseases are among the most common causes of death around the world. According to estimates of the World Health Organization, approx. 17.5 million people died as a result of cardiovascular diseases in 2012, around 6.7 million of them due to a stroke [1]. In Germany, around 1 million individuals are currently living with the consequences of a stroke, with around 270,000 more added each year. Around 50% of those who survive suffer permanent impairment and are dependent on support, assistance, and devices. Because stroke is primarily a disease of the elderly (> 65 years) and due to demographic developments, a considerable increase in those affected can be expected in the decades to come [2-5].

In addition to impaired speech, vision, and perception, hemiparesis is one of the most common results of a stroke [4]. To restore or improve the ability to walk, the focus has long been on neuroorthopaedic care of foot and leg paresis. A wide range of different devices are available for this indication. However, patients with a subluxated and painful shoulder, which can be a secondary result of a central arm paresis, often do not receive adequate care [6-9]. This is despite the fact that a painful shoulder occurs in 15%-40% of all those affected and is thus quite a common symptom. The cause is insufficient muscular stability in the shoulder joint due to weakened muscles. As a result, a change in the the position of the scapula and caudal movement of the humerus (subluxation) often occur, causing tension in the capsular ligament complex [10, 11].

Because of the resulting shoulder-hand syndrome (SHS) rate after shoulder subluxation – approx. 18% of those suffering from hemiparesis [12] – Koike et al. studied the underlying changes in skin temperature between patients with a shoulder-hand syndrome and an unimpaired control group [13, 14].

Davis et al. report that painful shoulders and oedematous wrists are often seen in combination with paresis-related limitation of mobility, while the elbow is not affected [13]. In view of these limitations of mobility, patients are predestined to develop flexion contractures of the hand and fingers in the long term without specific treatment [15].

Key question

Are functional orthoses for the shoulder joint available that can significantly prevent shoulder subluxation and the potentially resulting shoulder-hand syndrome (SHS) after a stroke?

Material and methods

A selective literature search was made using the search terms “shoulder-hand syndrome stroke orthosis”, “shoulder subluxation stroke orthosis”, “shoulder-hand syndrome stroke orthoses”, “shoulder subluxation stroke orthoses”, “shoulder-hand syndrome stroke brace”, “shoulder subluxation stroke brace”. All articles up to 10 February 2017 were included.

Results

A total of 21 articles about “shoulder subluxation and specific treatment options” were identified. Of these, 20 articles dealt only with the treatment of shoulder subluxation without the shoulder-hand syndrome and were therefore not included in addressing the key question.

Only the clinical study by Hartwig et al. examined the use of a special shoulder subluxation orthosis in connection with SHS. The study includ-

ed patients who had had a fresh ischaemic stroke (0-21 days) confirmed by CT scan who were mobilised at least four hours per day. Twenty patients were randomised and assigned to the intervention group classified according to the dominant hand. The control group included 21 patients. Patients in the intervention group were given a functional shoulder orthosis (Neuro-Lux®, Sporlastic GmbH, Nürtingen) in addition to standard treatment (physiotherapy and occupational therapy) (Fig. 1) [16, 17].

Pain and hyperalgesia, distal oedema, pain-free passive abduction, and external rotation in the shoulder were assessed using the shoulder-hand syndrome score by Braus et al. [18] at the start of the study and on days 7, 14, 21, and 28. In addition, anthropometric measurements of subluxation (without orthosis) and measurements of muscle strength (Medical Research Council [19]) were made. The patients in the intervention group were also asked to assess the wearing comfort of the orthosis and report the average daily wearing time. The averaged SHS score on days 14, 21, and 28 was significantly lower in the intervention group than in the control group (2.7 ± 1.5 vs. 4.8 ± 2.1; $p < 0.0001$) (Fig. 2) [17].

Muscle strength was comparable in the two groups, as was anthropometric measurement of subluxation after taking off the functional shoulder orthosis [17]. In summary, significant clinical effectiveness of the functional shoulder orthosis with respect to reducing SHS was found.

Discussion

Stroke is a common disease that causes a variety of limitations and impairments. One common complication of flaccid paralysis of the upper limb is the development of SHS, which is associated with a poor outcome. The relevance of this secondary disease is also reflected in scientific studies [13, 14].

The first systematic studies of the painful shoulder after a stroke or traumatic brain injury were conducted back in the 1970s. Krempen et al. emphasise that there are many causes of a painful shoulder in neurological diseases. In the cases where the painful shoulder occurred in conjunction with a subluxation, effective pain relief was achieved using a conventional neck sling [20]. Static systems of this type are still used today for immobilisation, e.g. after anterior or posterior shoulder dislocation (Fig. 3). [21].

However, during rehabilitation for arm paresis, immobilisation of the affected arm with a neck sling is problematic because it prevents effective therapy, fixates the arm to the body, and encourages learned non-use. Taking this criticism into account, Rajaram et al. developed a custom-made two-part shoulder orthosis that allowed movement of the affected arm while stabilising the shoulder [22]. Radiologic evidence of the reduction of subluxation was found when this shoulder sling was used. The authors also report a reduction of pain. However, no information was provided on the effect on the development or reduction of SHS.

Zorowitz et al. also studied the effect of different orthoses ("single-strap hemisling", "Bobath roll", "Rolyan humeral cuff sling", "Cavalier support") for a shoulder subluxation [23]. For the study, 20 stroke patients were provided with 4 different orthoses and the change in horizontal, vertical, and absolute asymmetry compared with the unaffected side was determined by radiologic analysis. Ultimately, an improvement of subluxation was found for all orthoses, although different orthoses had the best result for different patients. The

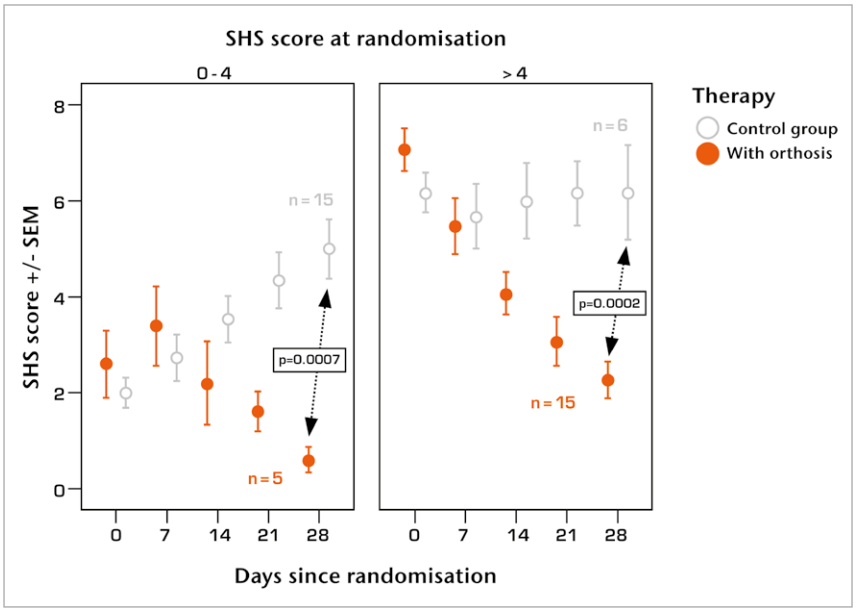

Fig. 1 *Neuro-Lux® II functional orthosis for stabilising the shoulder joint [16] (image shows the successor model of the tested orthosis).*

Fig. 2 *Change in the SHS score during treatment with and without a functional orthosis for stabilising the shoulder joint [17].*

authors concluded that fitting with an orthosis for shoulder subluxation must be customised for the individual patient. This study did not investigate other effects of the orthosis such as relieving pain or reducing SHS.

In 2002, Turner-Stokes and Jackson published a review which, among other things, studied the causes of developing a painful shoulder in patients with hemiplegia and the effectiveness of different treatment approaches [24]. In flaccid paralysis, subluxation due to the absence of muscular stability was identified as the cause of pain. In addition to cautious use of the affected arm and systematic interdisciplinary care, continuous support of the arm was considered to be essential. Functional electrical stimulation (FES) to activate muscles could also be important. It was not specified how continuous support of the arm should be implemented in practice. However, continuous support of the arm must be ensured not only when sitting, but also when the patient is mobilised when standing, walking, or during therapy. Consequently, merely positioning on a therapy table or immobilising the arm in a neck sling is neither sufficient nor useful.

Ayoyagi and Tsubahara also ascribe only a limited level of evidence to the use of shoulder slings and splints to reduce subluxation and call for additional randomised studies [25].

Fig. 3 *Conventional neck sling for relief of the shoulder [21].*

Ada et al. come to a similar conclusion. In a review, four studies were identified that investigated the effect of an orthosis on preventing subluxation, repositioning the humeral head, reducing pain, and improving the motor function of the shoulder after a stroke [26]. In summary, no clear evidence was found for the use of a shoulder sling. Taping the subluxated shoulder was the only method that appeared to delay the onset of pain. However, it did not reduce pain. The same working group reported in another study that the conventional neck sling was the orthosis most often used in practice, but that there was insufficient evidence regarding an improvement of subluxation [27]. Dajpratham et al. reach the same conclusion. They also found no significant reduction of shoulder subluxation when using two different neck slings [28]. By contrast, Hesse et al. found positive effects of a subluxation orthosis on gait and mobility. However, no reduction of pain was achieved with the subluxation orthosis used [29]. The study by Nadler et al. yielded similar data. It was shown that modern orthoses can effectively reduce subluxation. There is still insufficient evidence regarding a reduction of pain; no statement is made regarding the development of an SHS [30].

The results of the literature review thus identified only one clinical study that examined the effect of a functional shoulder orthosis in connection with SHS. According to the manufacturer's information, the Neuro-Lux® orthosis is indicated for shoulder subluxation and to reduce SHS [16, 17]. Hartwig et al. found sig-nificant clinical effectiveness of the Neuro-Lux® functional shoulder orthosis for reducing existing SHS. This means that the Neuro-Lux® is currently the only orthosis that can effectively reduce a shoulder subluxation (Fig. 4) [17] while allowing free movement of the arm and thus facilitating effective therapy.

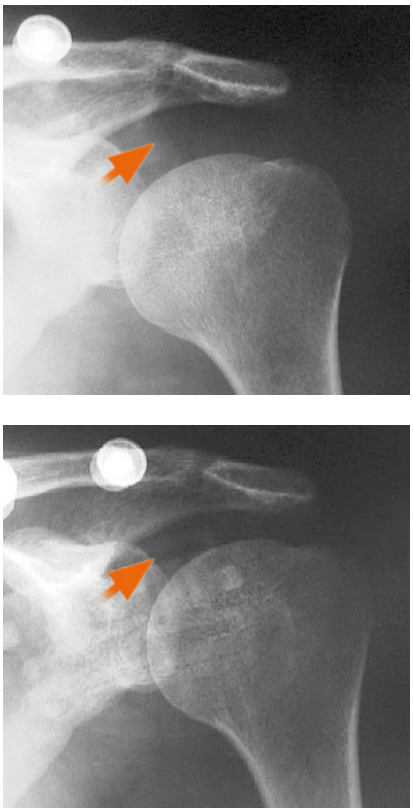

Fig. 4 *X-ray of the shoulder, without orthosis on the left, with the Neuro-Lux® on the right [16].*

Conclusion

Further studies are needed to verify the effect of dynamic functional shoulder orthoses on shoulder subluxation and the development of shoulder-hand syndrome. The at times contradictory results of the available studies that were discussed do not yet allow a conclusive evaluation to be made, which is certainly also a result of the different designs and mode of action of the orthoses. However, the tendency is that more recent studies show evidence of positive results with modern orthoses. The aim should be the effective and evident prevention of SHS through the use of contemporary materials and specific dynamic product details in the orthosis design.

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Reviewed paper

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M. Benning, R. Schneider-Nieskens

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 ortheses 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:

a) The medical benefit in the sense of effect on pain, walking distance and range of movement and these results from the patient's perspective
b) The suitability of the orthosis in outpatient care
c) 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 intervention.

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

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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 crossover 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 ad-justability, 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 con-

***Fig. 1** „Genu OA" orthosis.*

trol 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.

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, $p = 0.0785$).

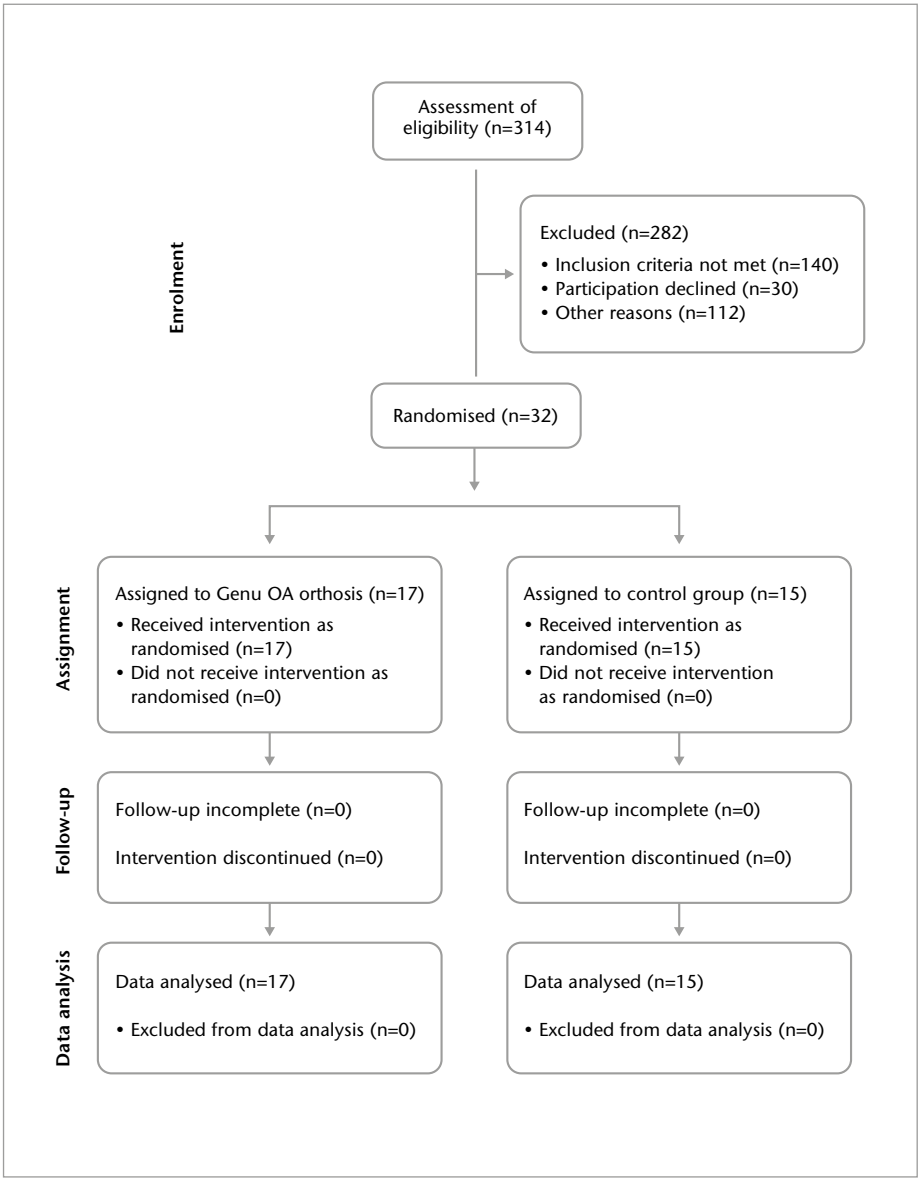

Fig. 2 *Flowchart of patient inclusion and follow-up examinations.*

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, $p = 0.2142$).

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 fit-

ted with the orthosis had difficulty handling or caring for the orthosis.

Discussion

In this prospective randomised comparative study, the pain-free walking dis-tances 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 pos-itive 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

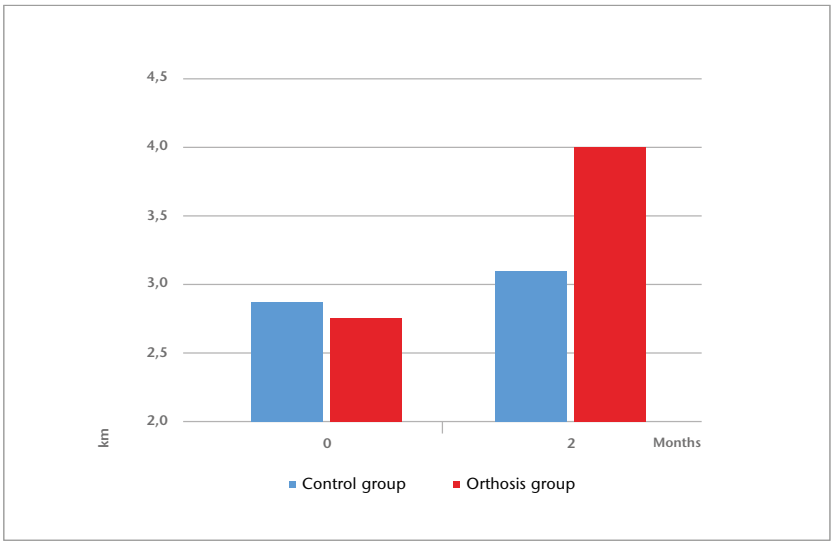

Fig. 3 *Change in the pain-free walking distance.*

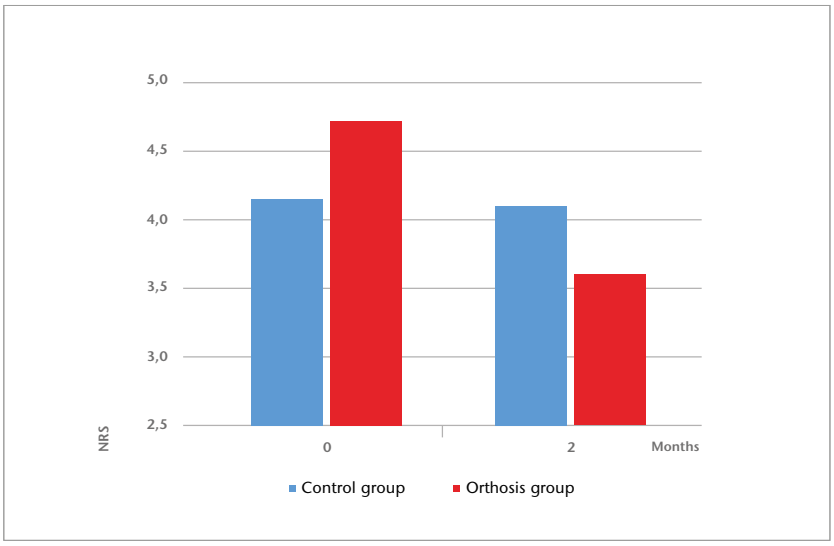

Fig. 4 *Change in loading pain.*

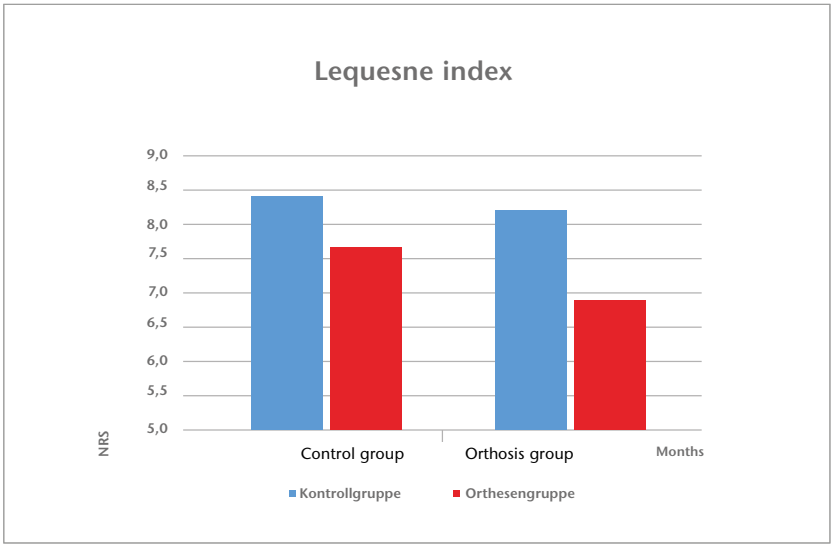

Fig. 5 *Change in the Lequesne index.*

Characteristic	Orthosis group	Control group
Female (%)	12 (70.6)	10 (66.7)
Age, mean (±)	69.53 (9.91)	70.07 (12.26)
BMI, mean (±)	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 (±)	2.71 (1.39)	2.87 (1.55)
Pain on loading (30-min. walk, NRS), mean (±)	4.71 (0.99)	4.20 (0.56)
Pain at rest (NRS), mean (±)	1.59 (1.0)	2.0 (0.93)
Lequesne index, mean (±)	7.62 (3.24)	8.43 (3.58)
Use of analgesics, N (%)	13 (76.47)	11 (73.34)
Objective range of movement, degree (±)	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 (±)	1.29 (0.90)*	0.20 (0.37)
Change in pain on loading (30-min. walk, NRS), mean (±)	-1.06 (0.66)*	-0.13 (0.35)
Change in pain at rest (NRS), mean (±)	-0.06 (0,24)	0 (0)
Change in the Lequesne index, mean (±)	-0.68 (0.71)*	-0.17 (0.36)
Change in use of analgesics, mean (±)	-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

(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 mobility appeared at least subjectively to improve the range of movement as well. Due to the gradual in-crease 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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A. Hahn, A. Kannenberg

Benefits of Microprocessor-Controlled Prosthetic Knees for Limited Community Ambulators – Update of a Systematic Literature Review

The benefits of microprocessor-controlled prosthetic knees (MPK) for unlimited community ambulators (MFCL-3) with an above-knee amputation (AKA) have been well established in scientific literature. In a frequently cited publication, Kannenberg et al. analysed the state of scientific research for limited community ambulators (MFCL-2) in 2014/2015 in the areas of safety of prosthesis usage, performance-based function and mobility, and patient-reported function and satisfaction. This work is an update of that analysis using the same methodological approach. A systematic literature search identified seven additional studies whose methodological quality was rated "moderate" using the criteria of a Cochrane review of prosthetic components. These studies describe a total of 2,249 patients, 677 of which are classified as MFCL-2 and 432 with an above-knee amputation due to vascular disease. The level of evidence which has now been significantly improved in qualitative and quantitative terms makes it possible to determine the potential offered by MPKs with linear hydraulics in particular in terms of helping to improve safety, mobility and quality of life – even and especially in such vulnerable patient groups. Furthermore, these systems have also been shown to be cost-effective for this patient group. In conclusion, the results of this systematic literature review suggest that MPKs may be considered the current standard of care in limited community ambulators with an above-knee amputation.

Key words: clinical benefits, microprocessor-controlled prosthetic knee joints, limited community ambulators, mobility, satisfaction, systematic literature review

Introduction

A missing or amputated lower limb can be the life-changing result of congenital deformities, trauma, cancer, peripheral arterial occlusive disease (PAOD), diabetic neuropathy or other diseases. For transfemoral amputees, the prosthetic knee joint is an extremely important component that must restore the functional biomechanics of the knee as well as ensure the greatest possible stability and safety of the prosthesis [1]. In the last 25 years, the technology of prosthetic knee joints has progressed considerably due to the use of microprocessors in stance and/or swing phase control. This enabled the technology to overcome the contradiction in conventional prosthetic knee joints between safety and functional support – "the safer, the less functional; the more functional, the less safe". The vast majority of clinical studies were conducted with unlimited community ambulators (activity level [AL] 3 or the US equivalent Medicare Functional Classification Level (MFCL-] 3). They demonstrate that microprocessor-controlled prosthetic knee joints (MPKs) [2–4] offer greater safety with simultaneously improved functionality when walking on level [5–9] and uneven ground [5, 6, 8, 9], slopes [5, 6, 10–12], stairs [3, 8, 13–15] and coping with critical everyday situations [3, 4]. A number of studies found a significant reduction of falls and improved balance compared with the use of non-microprocessor-controlled knee joints (NMPKs) [3, 5, 8, 11, 12, 16, 17]. The cost-effectiveness of MPKs in this group of users has now been proven as well [18, 19].

Younger, healthier and more active patients are frequently given preference for treatment with modern prosthetic systems. Lower limb prosthetics has thus taken a different direction than other areas of healthcare – normally, the most modern medical technology is used for the oldest and sickest patients with the most severe health problems. This also explains why 80 per cent of lifelong healthcare costs come in the second half of life [20], whereby a large portion are incurred in the last year of life alone [21, 22]. Today, most transfemoral amputees are over age 65 [23] and do not achieve the mobility grade of an unlimited community ambulator [24]. Another potential

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contributing factor is the fact that the most commonly used prosthetic knee joints have considerably limited functionality and were often developed decades ago.

This raises the question as to whether limited community ambulators (activity level 2 or the US equivalent MFCL-2) can derive a benefit from the use of MPKs similar to that of unlimited community ambulators (AL/MFCL-3). Kannenberg et al. [25, 26] found a significant reduction in falls of up to 80 per cent and a significant improvement of indicators for the risk of falls when using an MPK in their systematic analysis of clinical studies comparing the benefit of NMPKs and MPKs in limited community ambulators (AL/MFCL-2). The performance-based test parameters showed that an MPK can enable patients with mobility grade 2 to walk approx. 14–25 per cent faster on level ground, around 20 per cent faster on uneven ground and up to 30 per cent faster when walking down slopes. Furthermore, the patients were also more capable of managing activities that are actually typical for mobility grade 3. However, one interesting result of the analysis was also that the clinically relevant objective improvements in terms of safety, functionality and mobility were primarily only reflected in a clear preference of 90 per cent for the MPK in subjective terms. By contrast, the results of validated measuring instruments on the subjective perception of the safety and functionality of the prosthesis were less convincing.

The purpose of this updated literature analysis is to clarify the following questions:

1. Have any new, possibly larger studies with MPKs for limited community ambulators been published in the last five years that support or refute the results of the literature review in 2014/2015 [25, 26]?
2. Have recent studies potentially investigated additional benefits of MPKs for limited community ambulators that were not yet included in the literature analysis in 2014/2015?
3. Are there any studies assessing the healthcare cost factors of MPKs for limited community ambulators?

Methods

Search strategy

The systematic literature search was conducted on 13 January 2020 in the scientific literature databases Medline and Cochrane Library as well as in Google Scholar. For the database research, search terms relating to MPK and unilateral transfemoral amputees with mobility grade 2 or MFCL-2 were used along with an extension to vascular aetiologies. Following database search logic, specific additional searches were conducted in DARE, Cirrie (now NARIC Rehab Database), PEDRO and OT Seeker. The literature search was limited to English and German language publications in the period from 2014 to 2020. In addition, the references of the analysed articles were searched for additional potentially relevant publications.

Selection procedure

First, the titles and abstracts of the identified articles were independently reviewed by the two authors to check for inclusion and exclusion criteria and classified as (I) relevant, (II) not relevant or (III) possibly relevant.

Inclusion criteria

The following criteria had to be met for inclusion in the analysis:

1. The article had to be a randomised or non-randomised comparison study comparing the treatment and the results or aspects of healthcare costs of one or more MPKs with those of one or more NMPKs or – in the case of studies on healthcare costs – modelling them.
2. The study had to report on patients with unilateral above-knee amputation or knee disarticulation and mobility grade 2 (or MFCL-2) and/or the "vascular disease" aetiology. The limited community ambulators thus had to be either the study target group or the study had to present their results as an independent subgroup analysis or as raw data that allowed a subsequent (post hoc) statistical analysis.
3. The study used and reported on results of validated clinical test procedures that can be independently reproduced in quantitative terms and validated questionnaires in the areas of safety, functionality and mobility as well as on reported functionality and satisfaction with the prosthesis.

Exclusion criteria

The following criteria led to exclusion from the analysis:

1. Studies with implantable knee joints (total knee prosthesis/total knee replacement)
2. Studies with bilateral amputees or patients with a higher or lower amputation level than transfemoral or knee disarticulation
3. Studies that contained only opinions or qualitative evaluations of the authors but no concrete quantitative data for an independent evaluation
4. Studies that were already included in Kannenberg et al. 2014/2015
5. Duplicates.

Assessment of methodological quality

After reviewing the publications with respect to their relevance for this analysis, the methodological quality and the risk of bias were assessed separately by both authors using the checklist of a systematic Cochrane review of prosthetic ankle-foot mechanisms published by Hofstad et al. [27]. The Hofstad et al. checklist includes 13 methodological quality criteria related to patient selection, the quality and reproducibility of the study design and the statistical validity of the data. The identified healthcare feasibility study (see below) is discussed without a separate assessment of the methodology.

Results

Literature search

The literature search in the databases yielded 3,220 articles. After excluding duplicates and checking for relevance, a full-text review was made of 31 articles. Seven articles met the inclusion criteria. One other article described a healthcare feasibility model for assessing the cost effectiveness and effect on the budget from the standpoint of insurers in Germany. The identified articles are described briefly below:

Criterion	Comment	Hahn 2015	Wong 2015	Hahn 2016	Hasenöhrl 2017	Mileusnic 2017	Kaufman 2018	Lansade 2018
A1	Inclusion/exclusion criteria	0	1	0	1	1	1	1
A2	Homogeneity of the study group	1	1	1	1	1	1	1
A3	Prognostic comparability of the study group	1	1	1	1	1	1	1
A4	Randomisation	0	0	0	0	0	0	2
B5	Reproducibility of the study	1	1	1	1	1	1	1
B6	Check for co-interventions	0	1	0	1	0	1	1
B7	Blinding	0	0	0	0	0	0	0
B8	Familiarisation time	1	1	1	1	1	1	1
B9	Measuring instruments	1	1	1	1	1	1	1
C10	Dropout rate < 20 per cent	1	1	1	0	0	0	1
C11	Case number analysis	0	0	0	0	0	1	1
C12	Intention-to-treat analysis (including dropouts)	0	0	0	0	0	0	1
C13	Data presentation quantitatively reproducible	1	1	1	1	1	1	1
A+B		5	7	5	7	6	7	9
C		2	2	2	1	1	2	4
Total		7	9	7	8	7	9	13
Classification		B	B	B	B	B	B	B

Tab. 1 *Evaluation of the methodological quality of the identified studies based on the Cochrane criteria described by Hofstad et al. [29]. Class: A = very good, B = moderate, C = acceptable.*

1. **Lansade et al.** [28] described a randomised cross-over study in the relevant target group of above-knee amputees with low mobility and a "Kenevo" knee using validated functional and patient-based measuring instruments.
2. **Kaufman et al.** [29] reported on a prospective cross-over study conducted with four different MPKs ("C-Leg Compact", "Rheo Knee 3", "Plie 3", "Orion 2"). No distinction was made between the different MPKs. In addition to validated instruments, activity sensors were also used.
3. **Wong et al.** [30] investigated the influence of the "C-Leg" on subjects with a vascular aetiology in a prospective cohort study using standardised clinical measuring instruments.
4. **Mileusnic et al.** [31] described the first use of the "Kenevo" in the treatment of limited community ambulators in a prospective cohort study. In addition to validated instruments, this study used specifically adapted comparative Likert scales.
5. **Hasenöhrl et al.** [32] described a prospective A-B-A design to test an MPK prototype based on the "Genium" in a pilot study with limited community ambulators and used an instrumented gait analysis in addition to clinically standardised instruments.
6. **Hahn et al.** [33 (with 34), 35] described the results of over 1,223 and 899 trial fittings, respectively, with the "C-Leg"/"C-Leg Compact" and "Genium" in two independent retrospective analyses. Comparative Likert scales were used as recommended by the former clinical study site in Münster [36, 37]. The influence on the "low

MFCL/mobility grade" and "vascular aetiology" subgroups was assessed using regression analyses.

7. **Kuhlmann et al.** [38] designed a decision-analytic model (Markov State Transition Model) for the cost effectiveness and budget impact analysis from the standpoint of the insurers. The assumptions of the model with respect to the frequency of falls with NMPKs and avoiding falls with MPKs were based on the results of the studies cited in this article. To determine the demographic data of the model population and the consequential costs of falls, data from the institute for the payment system in hospitals (InEK), the Federal Statistics Agency and the German pension insurance system were used. The model population included amputees with an MPK or NMPK with and without vascular aetiology in the age range of 40 years and above.

Assessment of the methodological quality of the identified studies

The results of the assessment of the methodological quality are presented in Table 1. Despite significant variations in the total points, a moderate quality level was determined for all the included tests. This was surprising, especially in the case of the randomised study by Lansade et al. [28], whose methodological quality was assessed to be only "moderate" despite achieving 13 of 14 possible points, due to the absence of blinding. The demographic data of the 2,249 patients in the articles used for the analysis and information on the study design and the interventions or control joints used are presented in Table 2. In this study group, 692 patients had mobility grade 2; for 436 patients, a vascular disease was the reason for the amputation.

In the cost effectiveness and cost impact analysis by Kuhlmann et al. [38], a probabilistic sensitivity analysis (PSA) was conducted that allowed the error probability of the model and the influence of different baseline parameters to be estimated. The model observed 125 cohorts derived from DRG data over a period of 25 years. The results were referenced per 1,000 subject years.

Results on the objective and subjective safety perceived by the patient, functionality and mobility are summarised in Table 3.

Results on safety

All clinical studies reported results on safety when using the prosthesis.

Wong et al. [30] and Kaufman et al. [29] reported a significant ($p < 0.05$) reduction in the number of falls during the respective observation periods.

Lansade et al. [28] reported a non-significant reduction in the number of falls within the four-week observation period.

Wong et al. and Mileusnic et al. [31] reported a reduction in the fear of falling measured on a numerical analogue scale. The results of Wong et al. were significant ($p= 0.042$); the results of Mileusnic et al. indicated a statistical trend ($0.05 \leq p [=0.075] < 0.1$).

In [35], Hahn et al. reported a clear reduction in the number of subjects who were afraid of falling (87 per cent in MG2, 95 per cent CI [0.871;0.849]).

Wong et al., Hasenöhrl et al. [32] and Lansade et al. reported on the Timed Up and Go test (TUG) associated with the risk of falls.

Lansade et al. reported a highly significant ($p \leq 0.001$) and clinically relevant improvement with the "Kenevo". The significant results ($p = 0.043$) of Wong et al. clearly exceeded the minimal detectable change (MDC, measurement error) of 3.6 s. The results of Hasenöhrl et al. were below the MDC and were not significant.

Mileusnic et al. reported a significant reduction in the number of subjects who were observed with stumbling events ($p = 0.044$).

Hasenöhrl et al., Mileusnic et al. and Lansade et al. each reported a non-significant increase in the number of persons who no longer experienced falls after using an MPK.

In both [33] and [35], Hahn et al. reported a significantly higher number of subjects who reported a comparative improvement in their perceived safety (85 per cent in MG2, 95 per cent CI [0.81;0.88] for [35]).

While there were subjects who reported no improvement in their perceived safety, none of the safety-relevant parameters showed a statistically significant effect or trend in favour of an NMPK.

Results on functionality and mobility

Statistically significant results on the objective evaluation of functionality and mobility were reported in six studies. The results of the TUG were not counted again.

Mileusnic et al. [31] reported a significant reduction in the number of subjects who continued to use a wheelchair ($p = 0.0046$).

Kaufman et al. [29] reported significant reductions in the time spent sitting ($p = 0.01$), which were identified via activity measurements, and, similarly, significantly increased movement activity during the day ($p = 0.02$). Hahn et al. [33, 35] reported on the utilisation of the benefits of use of the MPKs documented by the evaluating O&P professionals. Furthermore, Hahn et al. identified a significantly improved ability to carry out complex movement sequences (for example, walking backwards, overcoming unseen obstacles, changing direction in the middle of a movement, etc.), a significant reduction in the use of additional walking aids and a significant increase in the mobility grade.

While all studies also reported a number of parameters for which no significant differences between MPKs and NMPKs were found, it should be noted again that an advantage in favour of an NMPK was not identified for any of the parameters of use that were investigated.

Perceived functionality and satisfaction with the prosthesis

Lansade et al. [28] reported highly significant improvements in satisfaction with the "Kenevo" in the validated QUEST 2.0 questionnaire ($p = 0.001$). Lansade et al. also reported significant improvements with respect to subjectively perceived mobility with the "Kenevo" in the Locomotor Capability Index 5 (LCI-5: $p = 0.02$) and in the SF-36 Mental Component Score (MCS: $p = 0.03$).

Kaufman et al. [29] found significant improvements in satisfaction with prosthesis functionality in the

		Hahn 2015	Wong 2015	Hahn 2016	Hasenöhrl 2017	Mileusnic 2017	Kaufman 2018	Lansade 2018
Design		Cross section, retrospective	Cohorts, prospective	Cross section, retrospective	Pilot A-B-A, prospective	Cohorts, prospective	Prospective, x-over	RCT, x-over
Patients (n)	2,249	1,223	8	899	5	29	50	35
MG-2/MCFL-2 (n)	677	470	4	99	5	19	48	32
Dropouts > 20%		No	No	No	Yes	Yes	Yes	No
Aetiology	Vascular (n = 432)	318	8	50	1	6	25	24
	Trauma (n = 1,161)	526		620	1	1	5	8
	Other (n = 634)	379		229	3		20	3
Gender	Male	1,052		746	4	18	28	27
	Female	171			1	11	22	8
Age (SD) [years]		55.6 (15.2)	60.8 (11.3)	49 (12.9)	68.2 (7.6)	63.2 (9.5)	69 (9)	65.6 (10.1)
MPK used	C-Leg	1,030	5					
	C-Leg Compact	128	3				x	
	Kenevo					x		x
	Genium			899				
	Other				Prototype		x	
Control	Locked knee joint	40	1	2	1	4		12
	Braking knee joint	306		9	3	6		6
	Polycentric	648	4	34	1	8		2
	Hydraulic	219	3	38				11
	MPK	9		689		4		
	Other	1		127				4
Familiarisation time		1 day	48 weeks	1 week	4–6 weeks	7.8 days	3 months	3 months

Tab. 2 *Demographics of the patients and description of the MPK and control knee joints in the studies. MG: mobility grade; MFCL: Medicare Functional Classification Level; SD: standard deviation.*

Prosthesis Evaluation Questionnaire (PEQ: p = 0.01), while Wong et al. [30] found significant improvement in the sense of balance with the MPK measured using the Activity-specific Balance Confidence (ABC) scale.

Hahn et al. [33, 35] saw significant improvements in a number of perception categories; the perception of using the toilet was determined as especially significant.

Patient-reported improvements with the MPK with the statistical character of a trend were found by Lansade et al. for the SF-36 Physical Component Score and by Mileusnic et al. [31] for the Houghton scale (prosthesis use), the LCI-5 (performing activities of daily living), the comparative assessment of different gait situations and the prosthesis preference.

No improvements in patient perception were reported by Wong et al. for the Houghton scale, by Hasenöhrl et al. [32] for the Houghton scale, the ABC scale, the OPUS questionnaire (activities of daily living) and the two SF-36 sum scores and by Mileusnic et al. for pain and comfort.

Likewise, no parameters or categories were identified in the area of subjective patient-perceived functionality and satisfaction with the prosthesis that showed an advantage in favour of an NMPK.

Cost effectiveness

Kuhlmann et al. [38] found a reduction from 134 to 20 in fall-related hospital-

isations in patients with non-vascular causes of amputation and from 146 to 23 for vascular-related amputations per 1,000 patient years. The prevention of 15 and 14 falls leading to death, respectively, was found with the use of an MPK in the same reference period. The base values for the costs per additional QALY (quality-adjusted life year) are EUR 16,123 for patients without and EUR 20,332 for patients with diabetes. These figures are considerably lower than the comparative value proposed by the WHO for cost effectiveness of a per capita GDP (gross domestic product per capita; in Germany, approx. EUR 40,000 in 2018). The PSA determined a moderate uncertainty of the model and allows the cost effectiveness to be determined with a probability of 97–99 per cent. If all new above-knee amputees were switched to hydraulic MPKs and 50 per cent of the prevalent population were also switched, the impact on the budget of German insurers (budget impact analysis) over a period of four years would be EUR 93 million, i.e. less than EUR 25 million per year. In its simulation logic, the model assumes that there are not yet any patients with an MPK; i.e., the actual impact would be lower.

Discussion

This update of a systematic analysis of the literature looked at the question of whether unilateral above-knee amputees who are members of a vulnerable patient group – i.e. with mobility grade MG/MFCL-2 or, in particular, those with a vascular aetiology – can benefit from using a microprocessor-controlled prosthetic knee joint as has already long been established for more active patients with mobility grade MG/MFCL-3 [3–17].

In this context, seven additional peer-reviewed published articles were identified that investigated the benefit of MPKs in this patient group. All have a moderate methodological quality. It should be noted that there are considerable obstacles in prosthesis research compared with other areas of medical devices. For example, as in this case, blinding is practically impossible. As a result, even the excellent methodological quality of the article by Lansade et al. [28] was classified as only "moderate" due to the absence of blinding.

Safety

The objectively and subjectively perceived safety is the basis for the extensive use of the prosthesis in everyday life and for improved functionality and mobility [36, 39, 40]. The significant 80 per cent reduction found by Kannenberg et al. [25, 26] in the number and frequency of uncontrolled falls compared with NMPKs [8, 41] with the "C-Leg" was again confirmed by Wong et al. [30] and Kaufman et al. [29].

Lansade et al. [28] also found a lower number of falls, but this did not reach statistical significance. This can be attributed to the comparatively short observation period (four weeks).

Hahn et al. [33, 35], Wong et al. and Mileusnic et al. [31] reported a significant reduction in the fear of falling. Kaufman et al. reported that, due to a fear of falling, 30 per cent of patients refused to be switched back to their original NMPK after being fitted with an MPK and dropped out of the study. The fear of falling has a significant impact on lifestyle, as those affected generally avoid active situations that present a risk of falls. This frequently results in withdrawal from social activities and represents a considerable impairment in quality of life.

In their study, Burnfield et al. [42] found a significant reduction of the time required for the Timed Up and Go test (TUG) that was nearly twice the minimal detectable change (MDC) reported by Resnik et al. [43]. The TUG with the MPKs was even lower than the threshold of 19 seconds that, according to Dite et al. [44], indicates a risk of repeated falls in above-knee amputees. Lansade et al. confirmed this result in a highly significant manner – both in the intention-to-treat analysis (including dropouts) and in the per-protocol analysis (without dropouts). Wong et al. also confirmed this result in their investigations.

Hasenöhrl et al. [32] did not find any changes, but they were limited to a descriptive analysis due to the very small group size and high heterogeneity.

Hahn et al. reported a significant improvement in patient-perceived safety for both the "C-Leg"/"C-Leg Compact" [33] and the "Genium" [35]. In [35], perceived safety is reported separately with respect to different gait situations. The regression analyses in both studies also confirm these effects for lower mobility grades and the vascular disease aetiology.

In their respective studies, Hasenöhrl et al., Mileusnic et al. and Lansade et al. each reported a non-significant increase in the number of persons who no longer experienced falls after using an MPK. Mileusnic et al. also reported a significant increase in the number of persons who no longer stumble with the "Kenevo".

In summary, all studies showed a considerable gain in safety with an MPK, both in terms of the validated performance-based safety parameters and in terms of the scales for subjective patient-perceived safety relating to the use of the prosthesis. Based on this, it can be concluded that the investigated hydraulic MPKs improved the safety of prosthesis use in unilateral above-knee amputees with mobility grade MG/MFCL-2 and/or a vascular aetiology to the same extent as in patients with a higher mobility grade. The design differences in the safety profile of various knee components that are the main reason for this were described in detail by Blumentritt [4] and Kannenberg [25, 26]. It should also be pointed out that MPKs vary significantly with respect to their design, safety and functionality [45-49] to some extent. The overwhelming majority of study results presented here were attained with MPKs with linear hydraulics for stance and swing phase control, i.e. the "C-Leg", "Genium" and "Kenevo".

The manifested gain in safety and, in particular, the reduced number of falls and thus reduction of the subsequent costs relating to falls, combined with the significant improvement in quality of life, was the decisive factor for the proven cost effectiveness of MPKs in this especially vulnerable patient group [38]. As a result, the percentage of falls with a fatal outcome in this patient group was also considerably reduced by the use of suitable MPKs. The new evidence published since 2014 is a striking confirmation in a much larger population of the results of earlier studies.

Hahn 2015		Wong 2015		Hahn 2016		Hasenöhrl 2017		Mileusnic 2017		Kaufman 2018		Lansade 2018	
		Number of falls	Reduced by 60% ↓↓							Number of falls	(median) 2→0 ↓↓	Number of falls	NMPK 6 MPK 1 o
Fear of falling	Reduced in 86% (all MG), 87% in MG2 ↓↓	Fear of falling 11-point NAS	-2.4 ± 3.2 ↓↓					Fear of falling 10-point NAS	3.5→2.2 reduced in 50% ↓				
		Risk of falls TUG	-12.3 ±25.6 s ↓↓			Risk of falls TUG	o					Risk of falls TUG	NMPK 23.1 s MPK 19.4 s ↓↓↓
Perceived safety	Improved in 83% overall, 85% in MG2, 88% with vascular aetiology ↑↑			Perceived safety	67% to 96%, regardless of MG and vascular aetiology ↑↑	Number of patients without falls	o	Patients without falls	NMPK 42% MPK 72% o			Patients without falls	NMPK 87% MPK 97% o
								Patients without stumbles	NMPK 8% MPK 50% ↓↓				

Tab. 3a *Results of safety of prosthesis use. MG: Mobility grade; NAS: Numerical analogue scale; TUG: Timed Up and Go test.*

Hahn 2015		Wong 2015		Hahn 2016		Hasenöhrl 2017		Mileusnic 2017		Kaufman 2018	
Functional benefits	83–95% overall, 84–95% in MG2, 87–94% with vascular aetiology ↑↑	BBS	o	Functional benefits	42–59% very conclusive, regardless of MG and vascular aetiology ↑↑	Walking distance in the 2-min walking test	o	Wheelchair use	NMPK 87%, MPK 37% ↓↓	Time spent sitting	NMPK 61% MPK 52% ↓↓
				Complex movement sequences	32%–91%, regardless of MG and vascular aetiology ↑↑	Walking speed (10-min walking test)	o			Active time	NMPK 16% MPK 20% ↑↑
Reduction of walking aids	23% overall, 34% in MG2, 39% with vascular aetiology ↑↑					AMPRO	o			Gait complexity	o
Improvement of mobility grade	50% MG2 → MG3; 22% MG3 → MG4 ↑↑					BBS	o				
						Reduction 2 of 5 walking aids	o				

Tab. 3b *Results on objective functionality and mobility with the prosthesis. MG: Mobility grade; AMPPRO: Amputee Mobility Predictor Test with prosthesis; BBS: Berg Balance Scale.*

Wong 2015		Hahn 2016		Hasenöhrl 2017		Mileusnic 2017			Kaufman 2018		Lansade 2018	
ABC	+27.5 26.7 ↑↑	Using the toilet	↑↑	ABC	o							
Houghton (prosthesis use)	o	Tasks while walking with the prosthesis	↑↑	Houghton	o	Houghton	NMPK 7 MPK 8	↑				
		Walking up, down stairs	↑↑			LCI-5	NMPK 37.7 MPK 40.4	↑			LCI	NMPK 40.4 MPK 42.8 ↑↑
		Standing on ramps	↑↑	OPUS	o	PLUS-M	NMPK 45.5 MPK 48.3, d=0.31	o			QUEST 2.0	NMPK 3.9, MPK 4.6 ↑↑↑
		Variability of walking speed	↑↑	SF-36 PCS	o		Preference for MPK 89%	↑			SF-36 PCS	NMPK 44.1, MPK 46.3 ↑
		Stepping on small obstacles	↑↑	SF-36 MCS	o	Mobility/ADLs	Walking (level ground) 79%	↑			SF-36 MCS	NMPK 53.3, MPK 60.2 ↑↑
		Overcoming unseen obstacle	↑↑				Uneven ground 64%	↑				
							Stairs 37%	↑				
							Exhaustion 84%	↑				
							Concentration 79%	↑				
							Pain	o	PEQ	↑		
							Comfort 66%	o				

Tab. 3c *Results of self-perception of the study patients. ABC: Activity-specific Balance Confidence scale; OPUS: Orthotics and Prosthetic Users' Survey; SF-36 PCS: Quality of life – physical component score; SF-36 MCS: Quality of life – mental component score; LCI-5: Locomotor Capability Index (activities of daily living); PLUS-M: Prosthetic Limb Users' Survey of Mobility (activities of daily living); PEQ: Prosthesis Evaluation Questionnaire (perception of prosthesis function); QUEST: Quebec User Evaluation of Satisfaction with Assistive Technology.*

Legend for Tab. 3a–c: ***↓↓↓,↑↑↑*** *= statistically highly significant ($p < 0.01$) increase/reduction;* ***↑↑, ↓↓*** *= statistically significant ($p < 0.05$) increase/reduction;* ***↑,↓*** *= statistical trend ($0.05 < p < 0.1$) for increase/reduction;* ***o*** *= no change.*

Performance-based functionality and mobility

The results identified by Kannenberg et al. [25, 26] were also confirmed in the area of performance-based functionality and mobility.

For example, Hahn et al. [33, 35] reported similar improvements in the assignment of mobility grades as Kahle et al. [8] and Hafner and Smith [41]. In the respective studies, some 50 per cent of the patients assigned to mobility grade 2 were able to be reassigned to mobility grade 3 with an MPK.

Kaufman et al. [29] reported higher daily activity levels and less time spent sitting, while Mileusnic et al. [31] even reported a significantly lower number of subjects who still used a wheelchair in addition to the prosthesis. These improvements can certainly be interpreted to mean that the previously mentioned loss of gait safety was compensated for or mitigated so that the patients were generally able to improve their activity level.

Hahn et al. [33, 35] reported a higher number of patients with the ability to demonstrate the benefits of using the MPK. This basic skill is independent of the mobility grade. The absence of an influence of the mobility grade is described by Hahn et al. [35] in a correlation and regression analysis as well as using a graphic presentation of the summarised measurements of the functional benefits. This makes it apparent that the general level in mobility grade 2 is lower, but many patients can still meet the criteria for a functional benefit.

However, the observations of more complex movement patterns (going up and down stairs, walking backwards, overcoming obstacles, etc.) show that the mobility grade has the greatest effect. Depending on the task, there is a difference of between 0.32 und 2.29 points per mobility grade on a 5-point Likert scale ($p < 1E-24$). In concrete terms, this means that some of the especially complex manoeuvres such as climbing stairs step-over-step can be carried out only by patients with higher mobility grades.

While Hasenöhrl et al. [32] found no differences between the MPKs and mechanical knee joints due to the characteristics of their specific cohorts despite a comparatively high number of measured parameters, they also – like Hahn et al. [33] – reported a reduction in the walking aids used. This reduction in walking aids in particular can also be assessed as an indicator of increased safety, which, however, can simultaneously be associated with a reduction of the walking speed measured in the tests.

Subjectively perceived functionality and satisfaction

While Kannenberg et al. [25, 26] still found a discrepancy between the performance-based and parameters reported subjectively by the patients in the studies analysed at that time, this was no longer found in the updated analysis:

Lansade et al. [28] reported highly significant improvements in the QUEST 2.0 (satisfaction with the prosthesis) and significant improvements in the LCI-5 (activities of daily living) and the SF-36 (quality of life, mental health) mental summary score.

Kaufman et al. [29] reported significant improvements in satisfaction with the prosthesis in the PEQ, especially in the categories locomotion, appearance and usefulness.

Wong et al. [30] reported significant improvements in the sense of balance (ABC scale), and Hahn et al. presented an improvement in the perception of various activity categories independent of the mobility grade, whereby the difficulty of using the toilet was identified as a particularly sensitive parameter.

Mileusnic et al. [31] reported trends in favour of MPKs in the Houghton scale (prosthesis use), the LCI-5 and the assessment of patients' execution of a few specific movement patterns.

It is worth noting that the improvements in the LCI-5 were mainly observed in the basic activities. The safety-relevant aspects of the gait pattern with the prosthesis also appear to become evident here. At the same time, not even a hydraulic MPK such as the "Kenevo" designed specifically for the needs of patients with a lower mobility grade can be expected to completely compensate for the fundamental limitations of mobility resulting from the aetiology or morbidity.

Using the toilet and the perceived gain in safety when doing so were found to be an especially sensitive parameter in the regression analysis; i.e., the impact of comorbidities and the effect of MPKs are very pronounced here. Patients who are more severely affected perceive the gains from the MPK in this situation to be especially beneficial. It is easy to imagine that the supportive effect of an MPK is especially important in this specific, highly vulnerable situation in which the person sometimes has to walk backwards in a confined space. It is also evident that the dimensions in which the usual measuring instruments record the general advantages of mobility might not always cover all the important areas of life. There are only a few study results for prosthesis users on the aspects of self-sufficiency and preserving independence in personal hygiene and care in particular.

The high preference for MPKs appears to reflect the extent to which they meet the personal needs of patients in the class of limited community ambulators and patients with a vascular aetiology. The information from Kaufman et al. regarding the large number of patients who refused the planned (for methodological reasons) return to an NMPK clearly underlines this aspect.

Cost effectiveness

The determination of cost effectiveness was conducted in a cohort of patients starting at age 40 identified in a DRG report of amputation numbers in Germany. The utility values stratified by age groups by Cutti et al. [19] was assumed. Cutti et al. identified a reduction of cost effectiveness and an ICER (incremental cost-effectiveness ratio) of EUR 51,000 per QALY in this particular age group due to the increasing influence of depression and anxiety. However, this particular age group exhibits the effects of preventing the consequences of falls described by Kuhlmann et al. [38] especially clearly, leading to a considerable increase in cost effectiveness. It should be noted that this was the case even taking the high mortality rate of vascular patients in particular into consideration. The disproportionately high risk of injuries in this population is compensated here.

Methodological aspects

In summary, it can be stated that evidence of the benefit offered by an MPK with linear hydraulics for limited community ambulators and amputees with a vascular aetiology has been expanded considerably, both in quantitative and qualitative terms. It should be noted that even a study such as the one by Lansade et al. [28] was classified as having only "moderate" methodological quality due to the absence of blinding. The further development of adequate classification methods and a solution to the blinding problem will be the priority when designing clinical studies to evaluate exoprosthetic components.

Five of the additional studies evaluated, just like the six articles evaluated by Kannenberg et al. [25, 26], are about four independent prospective studies.

The studies by Hahn et al. [33, 35] conducted retrospective analyses of the results of trial devices whose results were used for applying for the assumption of costs. This requires a separate observation that takes the influence of bias factors into account.

Both cohorts consisted of subjects for whom, in the estimation of the examining O&P professionals, a clinical benefit of the MPK could very likely be demonstrated in a trial fitting. However, this is actually a result rather than a selection bias – contrary to the occasional objections, which likely have not been considered sufficiently. While the detailed preselection criteria of the O&P professional may not be known, the cohort, which has a demographic variety oriented to the potential for fulfilling these functional benefits of use, represents the result of this precise selection. Even if the extent to which the results can be generalised cannot be directly derived, the fact remains that the remaining parameters in the cohort (for example mobility grade or aetiology, etc.) have not lost their qualification as a contraindication. In other words, the potential that subjects in lower mobility grades or, for example, with a vascular aetiology can benefit from joints such as "C-Leg" or "Genium" results merely from their representation in the cohort itself.

Wurdemann et al. [50] identified the influence of the functional comorbidity index on the mobility of subjects with an MPK in a similar analysis and came to the same conclusion: While an influence can be identified, a predictive power, as would be required for an exclusion criterion, for example, cannot be derived. Wurdemann et al. also verified that factors such as the body mass index (BMI) cannot be considered even a potential exclusion criterion due to the lack of any degree of sensitivity.

Kannenberg et al. [25, 26] pointed out in their study that there were insufficient study results for subjects with walking speeds less than 0.5 m/s. Kaufman et al. [29] addressed this and stated that this evidence gap had now been closed with their study.

To summarise, it can be stated in view of the current literature available that the hypothesis that a limited mobility grade or the "vascular disease" aetiology would rule out treatment with an MPK due to the lack of a clinical benefit is not supported by research. The authors find that withholding a technology that is useful from a medical perspective and in terms of healthcare costs based on individual parameters that are difficult to prove scientifically is extremely problematic in view of the potentially serious consequences for the individual.

Limitations

The available literature and thus the number of subjects studied have increased considerably. Moreover, no parameters were identified that would systematically allow a statement to be made in favour of NMPKs. The new studies identified include a number of perspectives and cover different study scenarios and aspects of the functional gain offered by an MPK.

Nevertheless, the problem of effective blinding prevents clinical studies with a high formal methodological quality that meets the general standard of medical technology from being conducted. Some studies also suffer from a high rate of dropouts, and as they are mainly in the vascular population, the influence of the progression of the underlying disease must be taken into consideration, especially for longer observation periods. All studies reported individual situations in which the gain in clinical effectiveness was not as great as desired. The patient groups studied have a high level of comorbid disorders, and cognitive abilities also play a role.

The question of the extent to which the results can be universally generalised therefore remains unanswered in these studies. At the same time, it is also true that there is no scientific basis for excluding these patients from treatment with an MPK with linear hydraulics. In cases of doubt, the recommendation of a customised trial fitting to determine the individual potential is the method of choice. Further research will have to deal more intensively with the specific circumstances and needs of this patient group.

Conclusions

The results of this updated systematic review of the literature suggest that limited community ambulators and prosthesis users with a vascular aetiology for the amputation can significantly reduce the risk of falls, their fear of falling and the number of falls by using microprocessor-controlled prosthetic joints. Outdoor activities that are actually typical for the mobility grade MG/MFCL-3 can be performed significantly better. This is also reflected in the way patients perceive themselves. The components, which are specifically designed for the needs of this patient group, increase the likelihood of a successful and safe prosthesis. Overall, the results of this work support the position that the use of MPKs by limited community ambulators with a unilateral above-knee amputation should be considered standard treatment today. Trial fittings can help identify patients who would not benefit from an MPK.

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Increasing Efficiency in Orthopaedic Technology with Additive Manufacturing

By implementing additive manufacturing within the production processes of orthopaedic technology, various efficiency-enhancing potentials for a company can be achieved. These can be easily measurable economic benefits, but also less readily measurable effects such as increasing customer satisfaction or patient compliance. The respective additive manufacturing process influences the applicability within production and thus also the efficiency-enhancing effects for the company. This article presents the three most important additive methods and their implications for the changing work processes and discusses the importance of a completely digital production chain in orthopaedic technology.

Key words: additive manufacturing, increase efficiency, digital manufacturing

Introduction

Digitisation is still a major topic in Germany, and its expansion does not stop with orthopaedic manufacturing. What this means in the context of orthopaedic manufacturing is that those who have to deal with digitisation will be unable to avoid additive manufacturing. It therefore seems necessary to deal with the implementation of additive manufacturing and the resulting consequences and potentials for one's own company in order to best utilise any opportunities and potential for improvement that may arise. But what are the options and opportunities offered by additive manufacturing? Which printing processes are particularly suitable for the production of orthopaedic appliances? Will additive manufacturing replace orthopaedic technology as a skilled trade in the long run? These and many other questions must be clarified before and during the implementation of an additive manufacturing method used in orthopaedic technology work processes in order to enable step-by-step development towards a digital production chain. This article answers these questions and reveals essential options and opportunities for additive manufacturing. The article also discusses its limits.

Suitable additive manufacturing systems for orthopaedic technology

The development process begins with the identification of a suitable additive manufacturing system. Essentially three processes have been identified so far as suitable for orthopaedic technology:

-Fused Deposition Modelling (FDM; limited suitability),
– Selective Laser Sintering (SLS; well suited)
– Multi Jet Fusion (MJF; well suited)

These three processes are described hereafter in more detail. In addition, Table 1 compares all the significant differences for orthopaedic technology.

Fused Deposition Modelling (FDM)

Figure 1 shows the FDM printing process schematically. The raw material on the filament spool is drawn into the extruder by two gear wheels located in the extruder. The filament is guided through a heating spiral and heated. The liquefied filament emerges from the extrusion nozzle and is applied to the build platform. The extruder moves the areas to be printed in a horizontal plane. The build platform moves down one layer thickness after each finished layer.

However, the FDM process is only of limited suitability for the orthopaedic technology sector. This is because the manufactured appliances are only stable in a maximum of two planes – depending on the respective material properties. Since an applied layer of material cools down before the new layer is applied, the layers do not bond homogeneously with the previously applied layer and fractures may occur. Due to the lack of mechanical strength, the FDM process is not suitable for the production of permanent appliances. Nonetheless, this method can be used expediently within the appliance manufacturing process. For example, test versions for checking the fit of the appliance can be printed in advance at low cost, thus ruling out the possibility of an incorrect fit of the appliance (Figures 2 and 3). After successful trial fitting of the temporary appliance, the permanent appliance can be manufactured using a powder-based printing process. The SLS and MJF processes, which are suitable for this purpose, are discussed below.

Selective Laser Sintering (SLS)

As shown schematically in Figure 4, a 3D printer for the SLS process consists of two main chambers (storage chamber and installation space). The raw material in powder form is transported from the storage chamber into the installation space by means of a supply platform in the storage chamber pushing the powder upwards. At the same time, a powder roller ensures that a new thin layer of powder is transported into the installation space for each new layer to be printed. As the build platform in the pressure chamber moves downwards in the opposite direction to the supply platform, volume is created in the installation space for

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	FDM	SLS	MJF
Support structures required	yes	no	no
Print speed	very slow	fast	very fast
Dynamic load capacity of the components	no	yes	yes
Surface finish after printing	only surfaces with grooves possible	slightly rough surface (can be smoothed well)	slightly rough surface (can be smoothed well)
Complex shaping	not possible	possible	possible
Subsequently thermally formable	possible to a limited extent	possible to a limited extent	possible to a limited extent
Acquisition costs	low	high	high

Tab. 1 *Comparison of the 3D printing processes FDM, SLS and MJF.*

each newly applied powder layer. After the application of a new powder layer, a UV laser travels along the respective powder layer to each of the positions of the component to be fused. Where the UV laser scans the plastic powder, the material is sintered; the powder beads are thus joined together and hardened. During the entire printing process, the installation space is additionally heated so that layers that have already been applied do not cool and harden before the printing job is finished. After completion of a layer, the build platform is lowered, a new layer of powder is applied and the process starts all over again. In this way, the component is produced in layers from bottom to top [1].

As the UV laser only cures the necessary areas and the remaining material of the respective layer still remains on the build platform, there is no need to produce special support structures as with the FDM process, since the unprocessed powder encloses the component and thus also supports any overhanging structures. In addition to the advantage of manufacturing without supporting structures, the high mechanical load capacity of the components is another major reason why the SLS process using polyamide (PA) 11 or PA 12 is particularly suitable for the production of appliances [2]. The mechanical load capacity is independent of the orientation of the component in the installation space. Due to the manufacturing process described, the components are largely isotropic and have the same load-bearing capacity – depending on the material properties – independent of the load direction [1].

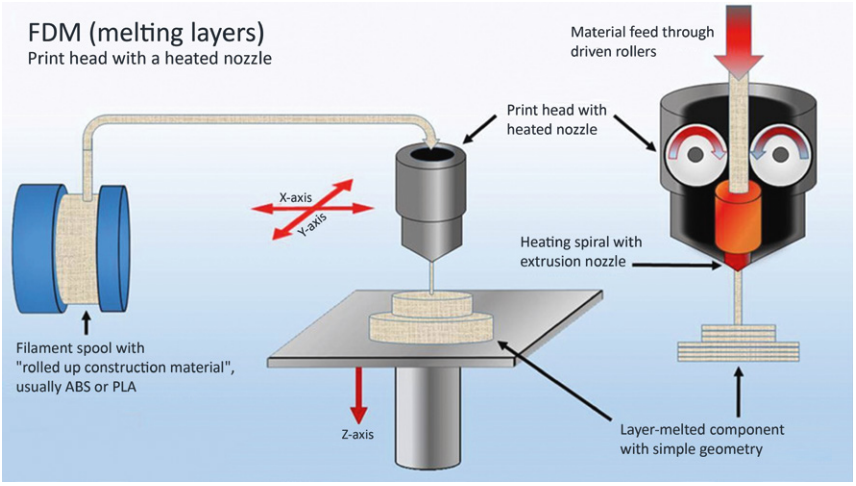

Fig. 1 *Functionality of the FDM-process. Source: ProTec3D.*

Multi Jet Fusion (MJF)

The functionality of the MJF process can be seen in the schematic diagram in Figure 5. The construction of the printer and the transfer of the powder to be processed from the storage chamber into the heated installation space functions in the same way as in the SLS process. The essential difference lies in the way the powder is cured or made to fuse: A print head with thousands of small nozzles distributed across the entire width of the print head sprays the fusing agent, a heat-conducting liquid (shown in dark blue) onto the area of the powder material to be cured. At the same time, the detailing agent, a heat-insulating liquid (shown in yellow), is applied around the areas that are wetted with the fusing agent. The detailing agent is necessary to produce precise

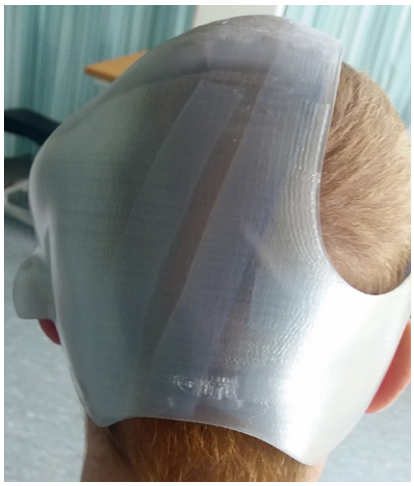

Fig. 2 Trial fitting of an individual head protection helmet, produced with PETG using the FDM process.

Abb. 3 Trial fitting of an ulnar deviation splint, manufactured with PETG using the FDM process.

edges on the components. The detailing agent applied leads to an abrupt temperature difference between the printed and unused powder. To apply both agents, a print carriage moves over the applied powder layer while a print head applies the agents in droplet form. As soon as the print head has applied the agents, another carriage with integrated UV lamps moves over the print table. The entire powder material is irradiated and heated with UV light over its entire width. The areas that have been printed with the fusing agent absorb more heat and are therefore heated more than the powder material that has not been wetted with it. In doing so, the required areas ultimately merge with each other. After the respective layer has been exposed to UV light, the build platform is lowered again by one layer thickness before a new layer of powder is applied and the process begins again [3].

Selective and time-consuming fusion using a laser (SLS process) is not necessary with the MJF process. As a result, 3D printing using the MJF process is on average faster than the FDM and SLS processes for the same package size and number of parts to be printed. The resulting components have an almost 100% component density, which, according to the manufacturer, is about 5 to 10 % higher than for components produced by the SLS process. In addition, the components produced by the MJF process are also largely isotropic. The components produced by the MJF process have a high mechanical load-bearing capacity, just like components produced by the SLS process. Therefore, the use of the MJF process is equally well suited for the production of permanent appliances, especially since PA 11 and 12 can also be processed for the production of appliances [2].

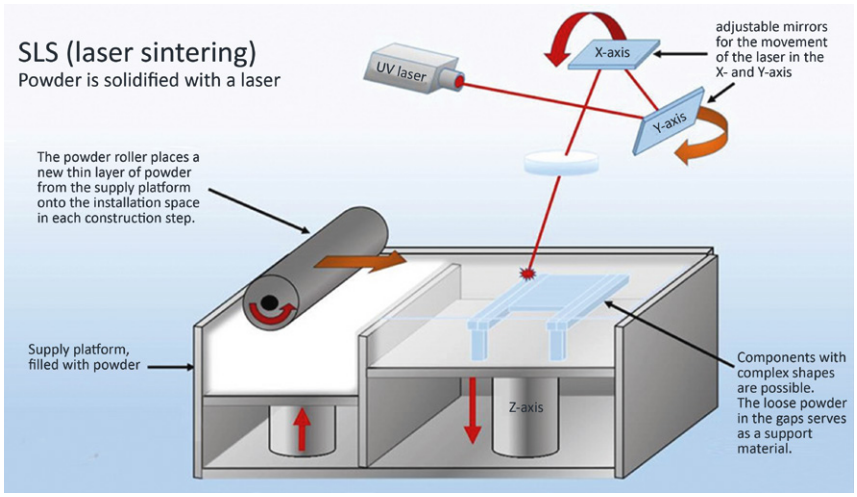

Fig. 4 Functionality of the SLS process. Source: ProTec3D.

Digital production chain

Regardless of the manufacturing process chosen, it should be noted that 3D printing comes at the end of a digital production chain, and that this assumes the upstream activities of 3D scanning and CAD modulation. Specifically:

- The 3D scan always comes at the beginning of a digital production chain. This is a three-dimensional recording of body parts. The accuracy of the scanning model is influenced by the choice of scanning technology. It is therefore recommended to work with a high-resolution scanning system such as the Eva scanner from Artec for scanning projects where high resolution is required (e.g. a scan for a prosthesis cover or a hand orthosis). For scanning projects that do not require millimetre-precise resolution (e.g. the scan of a seat impression for seat shell production), it is also possible to work with a low-resolution scanning system such as the iSense scanner for the iPad.
- Once the scan is complete, further model processing and the design of the actual tool is carried out using one or more CAD programs (Fig. 6).
- At the end of the CAD design comes additive manufacturing or 3D printing. The appliances designed in this way are printed using the favoured additive manufacturing process and then prepared for trial fitting or delivery.

Figure 7 shows the digital production chain presented here schematically as an inverted pyramid. The width of the respective stage symbolises the possible frequency of use of the respective digital production step within the digital production chain. This is because not all appliances can be realised in 3D printing. The experience of the orthopaedic technician is required to decide this. They must know the properties of an additive manufactured appliance and make an appropriate recommen-

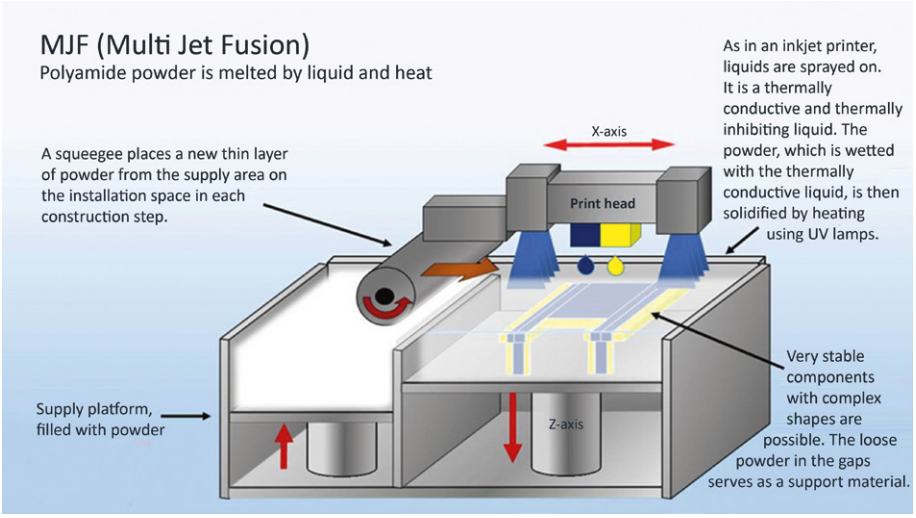

Fig. 5 *Functionality of the MJF process. Source: ProTec3D.*

dation for the appliance. A very large proportion of the appliances can be scanned and then edited on the PC. However, this does not necessarily imply 3D printing: According to today's manufacturing standards in the orthopaedic appliance sector, it is much more common for a classic CAD-CAM appliance model to be milled out of a rigid foam after modification on the PC and for the appliance to be manufactured conventionally in the further process of producing the appliance. Accordingly, sub-processes of appliance production can also be digitised.

Either way, the question arises as to whether the orthopaedic trade will lose craftsmanship expertise in the long term in view of the digital production options. Sceptics who fear a loss of craftsmanship skills due to the introduction of a digital process chain should be informed in detail about the options and opportunities (Fig. 8). In general, digital manufacturing should only be seen as an additional tool that complements the craftsmanship of the orthopaedic technician in a meaningful way. After all, in "digital manufacturing" there still is the Latin "manus" ("hand").

Options and limits of additive manufacturing in orthopaedic technology

Additive manufacturing in combination with a completely digitalised manufacturing process offers an adequate means of designing processes more efficiently to produce appliances.

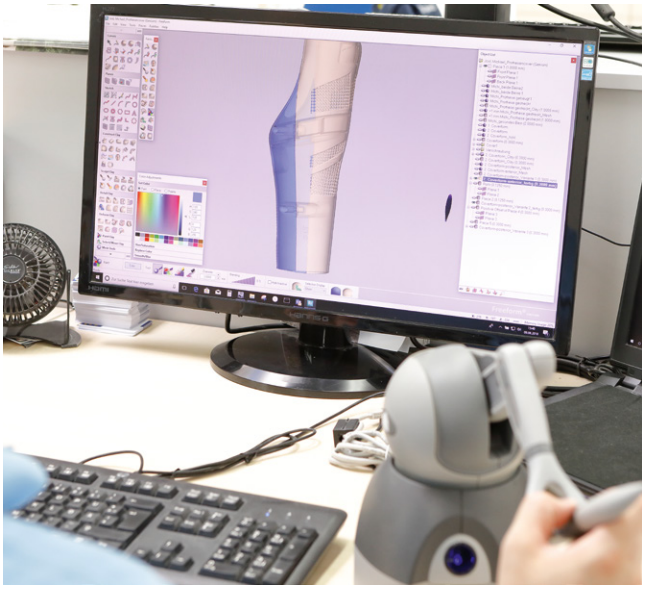

Fig. 6 *CAD modulation of a prosthesis cover at Sanitätshaus o. r. t. GmbH. using Geomagic Freeform.*

But what can such an increase in efficiency look like in real terms? In the following, significant opportunities of additive manufacturing for orthopaedic technology are shown on the basis of relevant examples, but also its limitations are discussed.

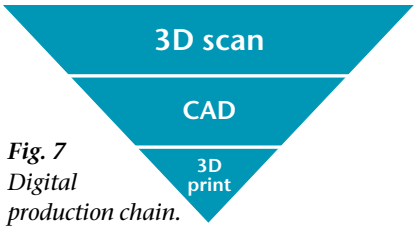

Fig. 7 *Digital production chain.*

Additive manufacturing of a head protection helmet

A suitable example to illustrate the advantages of a digital production chain is the creation of a custom-made head protection helmet. Patients who have undergone a craniectomy often require a custom-made head protection helmet due to the swelling that occurs. In addition, the appliances must be made as quickly as possible in order not to compromise the subsequent rehabilitation process and the success of the therapy.

Within a completely digital production chain, the head of an affected patient can be scanned while still in the hospital. This eliminates the need for a plaster cast in the hospital bed, where care must also be taken to ensure that head wounds do not come into contact with plaster. Accordingly, the 3D scan at the beginning of the

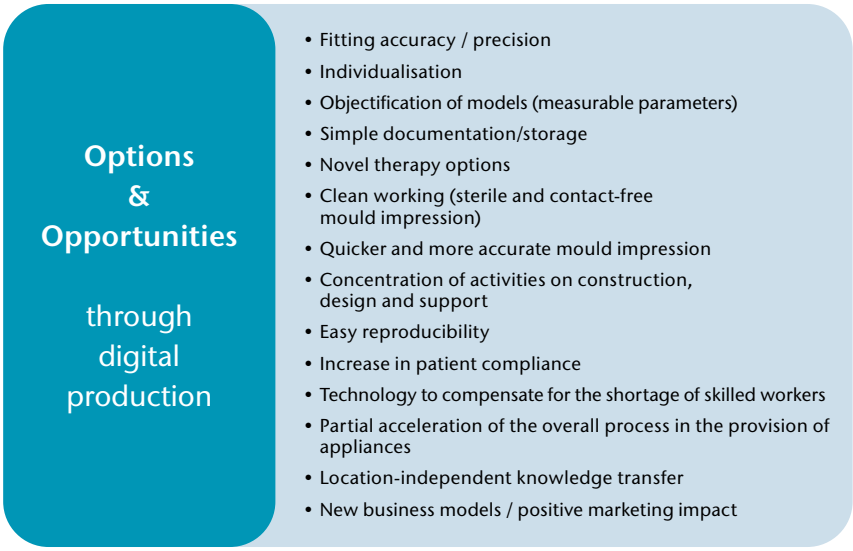

Fig. 8 *Options and opportunities of digital production in orthopaedic technology.*

therapy helps to reduce the time required for model removal to a minimum and also enables a contact-free and therefore sterile impression. The fact that plaster can now be dispensed in this way means that caregivers do not have to move patients to a new bed to change the bedding, etc. This saves the caregivers additional work and is less stressful for the patient.

After the scan, the head protection helmet is designed on the PC within approx. 30 minutes and the finished helmet is then sent to additive manufacturing. During the entire printing process, the technician working on the appliance is able to carry out other activities or devote more time to customer service. Once the helmet has been printed, it can be fitted with padding and straps before delivery.

Experience with additive manufactured head protection helmets has shown that it is possible to forgo an intermediate trial fitting, as the fitting accuracy of the head protection helmet after a 3D scan is very high due to the bony structure of the head. As a result of the digital production process described above, the pure manufacturing time for an individual head protection helmet can be reduced by 50 percent.

The manufacture of a head protection helmet must be distinguished from the manufacture of a helmet to correct cranial deformities, however. With head prostheses for the correction of cranial deformities, correction zones are modelled and incorporated into the virtual head model, which is why a trial helmet is still often required here. Nevertheless, even with a corrective helmet, a reduction in production time is achieved through the use of additive manufacturing.

The effect of reducing manufacturing times within orthopaedic technology achieved through the implementation of additive manufacturing can also be seen in other groups of appliances, such as support splints for the upper and lower extremities, face protection masks and redression splints for the upper ankle and wrist (Fig. 9a-e).

Integration of joint systems

When integrating joint systems in additive manufactured appliances, the question must be asked how the subsequent adaptation of a joint can be carried out. As the appliance was not conventionally manufactured from a plaster cast, there is no fixation to which the joint splints could subsequently be attached. Here, too, additive manufacturing offers a solution: joint attachment device or necessary adjustment

Fig. 9a-e a) *Face mask, manufactured using the MJF process;* ***b)*** *Head protection helmet, manufactured using the MJF process;* ***c)*** *Prosthesis cover, manufactured using the MJF process;* ***d)*** *Spiral orthosis, manufactured using the MJF process with leaf spring for thumb extension;* ***e)*** *Hand support splint, manufactured using the MJF process.*

cores for the positioning and fixation of a joint can be integrated directly into the corresponding appliance and printed out after the appropriate CAD design. After adaptation of the corresponding joint system, the supporting joint attachment device is removed from the appliance. In addition, a medial follower can be integrated directly into the appliance on the opposite side, which was previously created in various sizes and saved in a model library. With the modulation, only the required joint then has to be integrated in the appropriate CAD model with an additional workload of no more than 5 minutes. As a conventional medial follower is no longer absolutely necessary for such therapies, not only are purchasing costs reduced, but time is also saved in the subsequent joint adaptation and completion of the appliance (Fig. 10a and b).

Additives production and shortage of skilled workers

Also with regard to the future, additive manufacturing represents an important and indispensable manufacturing method for orthopaedic technology. In Germany, demographic change is leading to an increase in the older population and at the same time to a decline in the number of people of working age. As a result of this development, the orthopaedic appliance sector in particular will face major challenges in the coming years: On the one hand, the number of people who have to be provided with an appliance is growing due to the increasing number of elderly people, on the other hand there are less and less well-trained specialists on the labour market who are qualified to produce suitable appliances [4-6].

The falling production times per appliance resulting from additive manufacturing can help to at least partially counteract this imbalance between the skilled workers available and the anticipated increase in orders. Furthermore, the attractiveness of additive manufacturing technology can help make the orthopaedic appliance sector more interesting for the next generation of skilled workers.

Impact on increasing patient compliance

However, rising efficiency cannot be solely determined by economic indicators such as the reduction of manufacturing times. It is also important to keep an eye on increasing social efficiency [7]. For instance, the individualisation of additive manufactured appliances offers the chance to enhance patient compliance. An appliance can easily be decorated with patterns or pictures according to the patient's wishes and then printed out. For children especially, but for adults too, this helps enhance patients' compliance with their own appliances. According to experience, this extends the wearing time of the appliance and thus has a direct positive impact on the success of the therapy.

However, therapeutic success does not only result from enhanced patient compliance. A good fit, which, as mentioned above, is usually rated as very good thanks to the 3D scan, also plays an important role. Because only with well-fitting appliances can biomechanical principles of action be optimally achieved and implemented depending on professional CAD modulation. In contrast to CAD plaster modulation, however, care must be taken to ensure that a scanned limb, as a rule, corresponds exactly to the volume of the original limb and that there is no excess at the start of model processing, as is the case with a cast plaster model. Further options and opportunities that can result from digital production are summarised in Figure 8.

Limits of additive manufacturing in orthopaedic technology

There are, however, also limits to additive manufacturing. For example, some appliances cannot yet be realised using additive manufacturing. If, for example, the required appliance has to have functional properties that cannot yet be represented by the printed materials, the conventional production method must be used, at

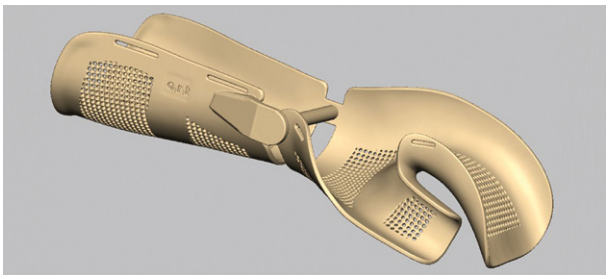

Fig. 10a *CAD model of a hand support with integrated medial follower and adjustment aid for joint assembly.*

Fig. 10b *Arm support with ventral shells, manufactured using the MJF process.*

the latest, after the 3D scan and CAD modulation with subsequent foam milling [2]. This applies, for example, to appliances in which the energy-returning properties of carbon are to be used for the therapy. Additionally, the adaptability of appliances made of PA 11 or PA 12 is more difficult than that of appliances made of conventional thermoplastics used in orthopaedic technology.

Even when considering the economic aspects of additive manufacturing, attention must be paid to ensure that its use remains economical despite all the options and opportunities mentioned above. This is because the pure material and printing costs of SLS and MJF are higher on average than those of conventional thermoformed sheets used in orthopaedic technology and production is therefore more cost-intensive than traditional production.

Therefore, additive manufacturing should not be seen in the future as the only way to produce appliances with an acceptable cost-benefit ratio. Rather, the feasibility of production and the subsequent benefit for the patient should be considered individually for each appliance before the most suitable production process for the appliance manufacture is selected [8].

Conclusion

In the implementation of additive manufacturing, care must be taken to ensure that the selected printing process has an effect on the degree of applicability in orthopaedic technology. This means that the respective printing process determines whether the printed appliances are only suitable for fit checking or also ultimately for patient therapy.

As has been shown, the implementation of additive manufacturing can result in a variety of efficiency-enhancing effects for one's own company and for orthopaedic manufacturing. The reduction in production times is particularly impressive. This effect enables a company to increase its production output with the same number of employees or to give the individual technician more time for tailored customer support, which can result in greater customer satisfaction. It must be ensured, however, that these benefits compensate the higher manufacturing costs resulting from additive manufacturing.

Not only are beneficial economic effects to be expected from the implementation of additive manufacturing, but potential improvements that cannot be directly measured, such as an improvement in patient compliance. The attractiveness of additive manufacturing technology may also help make the orthopaedic appliance sector more interesting for the next generation of skilled workers. So an impending shortage of skilled workers can be countered by a positive marketing effect, thus leading to employee recruitment, but also faster production output.

In conclusion, it should be borne in mind that an increase in efficiency cannot be achieved by implementing additive manufacturing alone. The full benefits and potentials are only possible with an end-to-end digital process chain that includes not only additive manufacturing but also upstream activities - 3D scanning and CAD modulation [9].

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