Development of a Wearable System to Optimize Performance and Mitigate Falls in Warfighters with Lower Limb Trauma and/or Loss

Introduction or Purpose

Loss of balance and associated falls are a significant problem for those with lower limb trauma and those who have undergone lower-limb (LL) amputations, with over 50% of lower limb amputees reporting falls in the previous year [1]. Falls in amputees can result in serious injury to the residual limb or other parts of the body, damage to the prosthesis, and the lack of confidence in (and often discontinued use of) the prosthesis [1,2]. Individuals with lower limb trauma may be at high risk of injury-causing falls even after rehabilitation and receiving state-of-the-art prosthetic devices. There is currently a lack of tools for clinicians to use within the clinic for advanced balance and gait training/assessment for the lower limb neuromusculoskeletal injury population. To address this need, LTI and RxFunction partnered to develop the ReLEARN (Return-to-duty with Lower Extremity Augmented RehabilitatioN) System.

Methods

The ReLEARN system is comprised of the Walkasins® sensory prosthesis insole technology commercialized by RxFunction and an instrumented balance monitoring system (the Dynamic Corrective Force Device, or DCFD) developed by LTI and Censeon. The DCFD is comprised of inertial measurement units (IMUs) integrated with a real-time human biomechanical model. This non- invasive, wearable system provides real-time, visual, audio and/or haptic sensory stimuli based on parameters from the wearable sensors and the biomechanical model.

3 male subjects (unilateral transtibial prosthesis users, Age: 46 ± 29 yrs) were tested. Each subject consented to an IRB-approved protocol and had insoles of the proper size placed into their shoes as well as 5 IMU sensors attached to their lower legs, upper legs, and lumbar spine. The protocol tested several aspect of both standing and dynamic balance during gait.

Results

Data collected during the in-lab testing demonstrated improvements in balance with static load symmetry as well as the ability of the system's sensory stimuli to alter the subject's gait to reach target joint angle thresholds.

Discussion/Conclusion

Figure 1A shows that before receiving visual/audible stimuli, Subject 03 favored their right (prosthetic) leg (i.e., body weight is not evenly distributed). When stimuli were provided, their body weight was closer to the center line (1B). When the non-stimuli trial was repeated after stimuli, the participant appeared to retain some of the training and were more equally distributed (1C) than their first trial. Figure 1D shows Subject 01 successfully adjusting their gait based on real-time audible stimuli to reach the target hip angle (i.e., peaks start below yellow threshold but then increase to meet the threshold).

We have shown the feasibility of the ReLEARN system as a tool to aid clinicians in the rehabilitation process to improve balance in individuals with limb loss. Next steps include system validation and longer-term clinical studies to bring the ReLEARN system to market for clinical use

Significance

With further development, the ReLEARN technology may provide clinics with a quantitative, low-cost, user-friendly tool to enhance fall-mitigation training implemented as a part of rehabilitation care.

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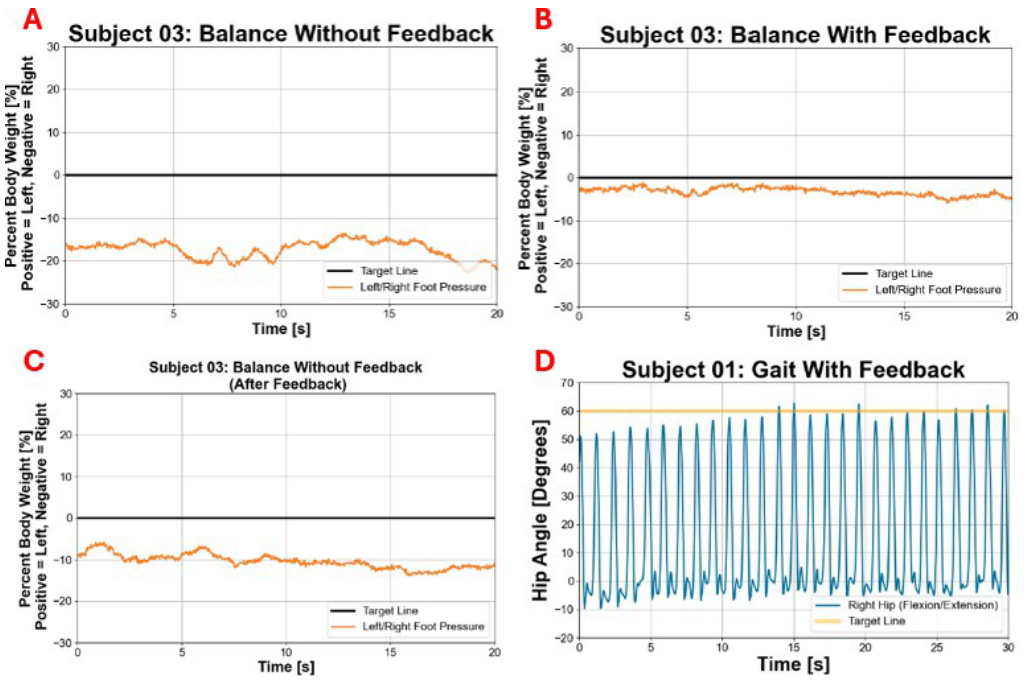

Figure 1
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Abstract PDF - DEVELOPMENT OF A WEARABLE SYSTEM TO OPTIMIZE PERFORMANCE AND MITIGATE FALLS IN WARFIGHTERS WITH LOWER LIMB TRAUMA AND/OR LOSS
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Hydraulic Ankle-Feet Are Associated with Increased Mobility for Individuals Classified as K2

Introduction or Purpose

Hydraulic ankle-feet can aid individuals with smoother gait and balance1,2, reducing socket pressure3, reducing energy2, increasing walking speed4; however, these feet are most commonly prescribed for individuals classified as K3 or K4 ambulators. These ankle-feet provide ankle articulation during stance and swing phases of gait to increase absorb forces at heel strike and improve minimum toe clearance during swing compared to non-articulating ankles.

There has been some preliminary evidence that these feet, when wore by individuals classified as K2 ambulators, can also observe benefits in increasing ambulation, specifically distance walked and walking speed5 as well as increased satisfaction6. Therefore, the aim of this study is to further explore mobility and quality of life of individuals prescribed a hydraulic ankle-foot classified as K2 ambulators.

Methods

A retrospective analysis of outcomes collected between May 2017 and October 2024 was conducted. Individuals were included if they were adults with unilateral transfemoral or transtibial limb loss/limb difference due to dysvascular disease and had two outcomes collected: one prior to receipt of a new prosthesis (baseline) and one post receipt of their new prosthesis (follow- up). Individuals were split into two groups based on prosthesis type: individuals with L5968 & L-5972 were categorized into Hydraulic and individuals with a L- 5972 only were categorized into Non-hydraulic. Each category was further stratified into groups based on mobility as measured by the PLUS-M™ patient- reported outcome of mobility. Individuals with a PLUS-M™ T-score of < 40 were classified as Low, 40-50 were classified as Middle, and >50 were classified as High.

To assess changes from baseline to the follow-up appointment, dependent samples t-test were used. R v4.4.1 statistical software was used to compute all statistical analyses. The alpha level for all analyses was set to 0.05.

Results

A total of 218 individuals met the inclusion criteria (N=78 Hydraulic and N=140 Non-hydraulic). The Hydraulic (H) and Non-hydraulic (NH) groups were similar with respect to age (H: 63.5±11.7 years, NH: 64.5±11.7 years) and sex (H: 66.7% male, NH: 65.0% male); however, differed slightly in level of amputation (H: 83.3% below-knee, NH: 76.4% below-knee).

Comparing outcomes from baseline to follow-up, individuals in the Low mobility group had significantly improved PLUS-M™ T-scores with those in the Hydraulic group experiencing greater improvement (H: 29.95 $p < 0.001$, NH: 30.00 $p < 0.001$). Additionally, those in the Low mobility group with a Hydraulic ankle-foot had significantly greater quality of life at follow-up compared to baseline (H: 6.17 $p=0.023$). Individuals in the High mobility group had a slight decrease in mobility (H: 54.40

Discussion/Conclusion

Hydraulic ankle-feet can be beneficial for improving mobility and quality of life particularly for individuals that are Low K2 ambulators (PLUS-M™ T-score < 40). These individuals had the greatest improvement in their mobility with a hydraulic

ankle-foot and a significant improvement in their overall quality of life.

For individuals in the High mobility group (PLUS-M™ T-score >50) with K2 componentry, a K2 foot may not be the most appropriate device for this patient cohort. Patients in this group may benefit from K3 feet and future research is needed to further explore how K3 feet may benefit individuals with higher mobility that are currently classified as K2.

Significance

Results of this study demonstrate the benefits of providing hydraulic ankle-feet for K2 ambulators. Especially for individuals with lower mobility (PLUS-M™ T- score < 40), hydraulic ankle-feet can significantly improve both mobility and quality of life. These results support continued utilization and prescription of hydraulic ankle-feet for K2 ambulators in the future.

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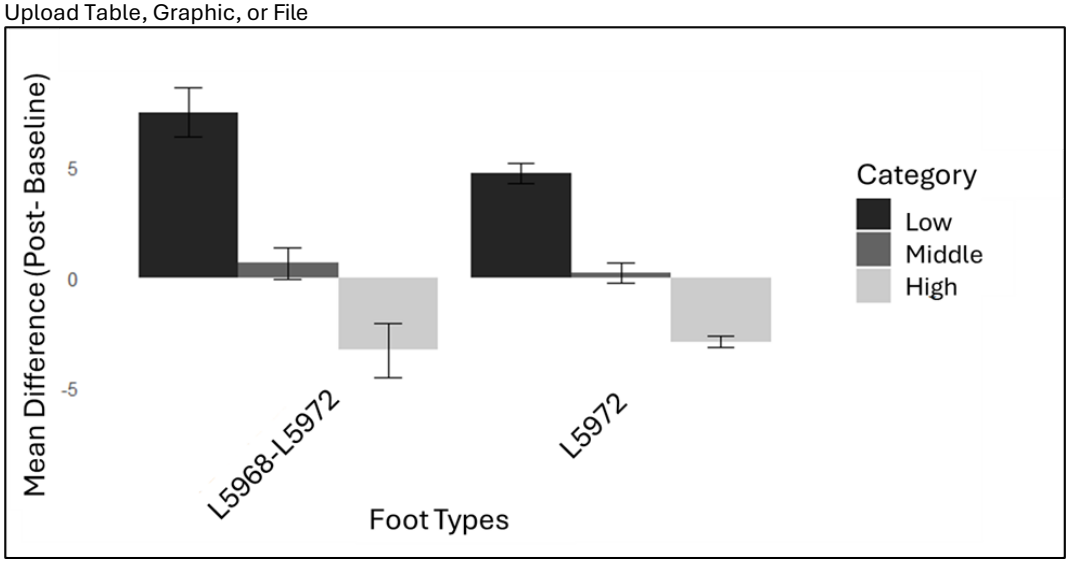

Figure 1: Mean Difference (Post-Baseline) in PLUS-M™ T- scores. Individuals fit with Hydraulic ankle-feet (L5968-L5972) that were in the Low mobility group had greater improvement (mean difference) compared to individuals in the Middle and High mobility groups and greater improvement relative to individuals in the Low mobility group that received a Non-hydraulic ankle-foot.

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<u>The Impact Of Microprocessor-Controlled Knees On Falls And Injuries Is Meanwhile Visible</u>

Introduction or Purpose

Numerous clinical studies have shown that individuals with transfemoral amputation (TFA) experience significantly fewer falls and fall-related injuries when using microprocessor-controlled prosthetic knees (MPKs) compared to non-microprocessor controlled prosthetic knees (NMPKs) (e.g., 1-3). Based on Medicare utilization (4) and commercial health insurance claims data, the rate of MPK users among TFA with K3/K4 mobility in the U.S. can be estimated at about 65%. That raises the question whether the impact of MPKs can be seen in recent epidemiologic studies on falls in the amputee population.

Methods

A literature search with search terms pertaining to lower limb amputation and epidemiology of falls and/or and fall-related injuries was conducted in Pubmed and Google Scholar. Identified publications were screened for pertinence. Findings of publications with sufficient quality were extracted and are presented descriptively.

Results

Three epidemiologic studies on falls or fall-related injuries in amputees were identified, one from the pre-MPK era with 435 patients (5) and two from the MPK era with 268 and 257 patients, respectively (6,7). In the pre-MPK era, 66% of all TFA had fallen at least once in the previous 12 months as compared to only 47% of transtibial amputees (TTA). Patients with TFA were 2.78-times more likely to have fallen than those with TTA (confidence interval [CI]: 1.71- 4.51) (5). However, more important risk factors were multiple residual limb and prosthetic problems (odds ratio [OR] 3.09, CI: 1.58-6.04) and need to concentrate on every step (OR: 4.06, CI: 2.46-7.01). Across all amputation levels, 40% of the fallers had sustained injuries, and about half of them had sought medical attention for these injuries (5).

In the epidemiologic studies conducted in the MPK era, the rate of fallers in 12 months among TFA (76%) was still higher than among TTA (60%), but vascular comorbidities (OR: 3.46, CI: 1.4-8.5) andbetter balance (OR: 23, CI: 3.2-170) turned out to be much more important risk factors than amputation level. In fact, TFA alone was associated with a significantly lower fall risk (OR: 0.08, CI: 0.01-0.82) than TTA (6). Patients with TFA sustained fewer fall-related injuries (11%) than those with TTA (23.5%) over a 12-month period (7).
Patients with TTA were 2.3-times more likely to experience a fall-related injury than those with TFA (CI: 1.01-4.89). Injury risk was significantly increased by female sex (OR: 2.9, CI: 1.35-6.24), non-White race (OR: 4.79, CI: 1.06-21.7), and dysvascular etiology (OR: 2.22, CI: 1.04-4.73) (7).

Discussion/Conclusion

Epidemiologic studies from the pre-MPK era (2001) and MPK era (2018/2019) showed a dramatic shift in risk factors for falling and fall-related injuries in patients with TFA. In the MPK era, patients with TFA are no longer more but even less likely to fall and sustain an injury than those with TTA. Based on the prevalence of MPKs in the U.S. (4), this shift can likely be attributed to the effect of MPKs.

Significance

The reduction of falls and fall-related injuries by MPKs can meanwhile be seen in epidemiologic studies with patients with lower limb amputations.

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Evaluation of the Relative Utility of Custom and Prefabricated Ankle-Foot Orthoses: A Case Series

Introduction or Purpose

Orthotic practice involves designing, fitting, and adjusting devices to manage neuromuscular or musculoskeletal deficiencies, with the goal of enhancing function while minimizing disruption to the patient's activities of daily living. Orthotic intervention aimed at improving gait mechanics and ambulation safety is implemented first by optimizing the fit of the device to comfortably provide postural support and correction based on the patient's needs. The orthosis can then be adjusted to enhance mobility and improve gait mechanics while remediating any iatrogenic consequences of the orthotic treatment. Many factors are considered when determining the most appropriate orthosis design. Prefabricated ankle-foot orthoses (AFOs) offer cost-effectiveness and immediate availability but may lack the precision needed to optimize outcomes in complex cases. Conversely, though they are costlier and more time intensive, custom AFOs provide tailored support that is necessary for patients with more complex postural abnormalities and unique anatomies.

This series of case studies highlights the relative benefits of custom and prefabricated AFOs and compares their ability to comfortably provide a variety of patients with improved ambulatory function. A set of criteria was used to evaluate the fit and function of custom and prefabricated multi-function AFOs across diverse patients. These evaluation criteria are used as a guide for selecting the most appropriate orthotic intervention based on patient-specific factors.

Methods

Participants: This case series includes three patients with distinct pathologic conditions: Charcot-Marie-Tooth disease (CMT), spinal cord injury, and chronic stroke. The patients presented with different body types, foot and ankle postural abnormalities, biomechanical deficits, and ambulatory patterns. None of the patients could safely ambulate without an assistive device.
Procedures: Each patient underwent a comprehensive evaluation, including measurements of height, weight, calf circumference, and fibular neck height, as well as an assessment of tri-planar alignment of the foot, ankle, and knee. Observational gait analysis was performed and augmented with slow-motion video, which may improve the reliability of observations [Brodke 2023].
Following evaluation, patients were molded for the fabrication of custom carbon composite, multi-function AFOs. The molding process aimed to position the foot and ankle optimally for the design of AFOs to reduce any postural abnormalities while ensuring comfort and stability. The resulting molds were optically scanned to create 3D virtual models, which were then aligned and modified using Vorum Canfit and Autodesk Fusion software. Foam anatomic models were produced from the modified virtual models for the fabrication of custom, carbon prepreg, single-upright, multi-function AFOs. Patients were subsequently fit with both their custom AFO and a prefabricated, carbon prepreg, single-upright, multi-function AFO. Both types of AFOs have similar structural stiffness and offer a high degree of

adjustability to the sagittal plane mechanical characteristics via a single multi-function ankle joint. During the fitting process, each AFO was adjusted for comfort and postural control.
Kinematic optimization was then performed by adjusting the multi-function ankle joints according to an evidence-guided adjustment algorithm [LeCursi 2024].

Data Analysis

After all adjustments were completed, each patient's prefabricated and custom AFOs were evaluated for fit and function. Objective measures included AFO height relative to the fibular neck; tri-planar mechanical ankle axis alignment relative to anatomical ankle; tibial cuff fit; shank-to-vertical angle of the AFO; congruence of the tibial crest with the tibial cuff angle in the sagittal plane; and level of pressure or clearance between the limb and the supramalleolar pad. Lower extremity sagittal plane joint alignment and coronal plane posture in quiet standing were observed, and the reduction of pathologic gait deviations were quantified. Subjective feedback on comfort and stability was collected during static weightbearing and while performing ambulatory tasks.

Results

The first patient is an adult female with CMT, a history of frequent falls, and midfoot pain. She has fixed cavovarus posture, limited dorsiflexion range, flail ankles, and quadriceps weakness bilaterally. Calf circumference was 41 cm; height and weight were 165 cm and 85 kg. Without AFOs, the patient exhibited a slow unstable gait with lateral trunk flexion, anterior lean, plantarflexion throughout swing phase, lateral forefoot initial contact, and knee instability after midstance. The custom prepreg multi-function AFOs with pretibial shell and total contact footplate fit well and provided comfortable and stability. After kinematic optimization, the patient exhibited an increased walking velocity, and all gait deviations were improved or eliminated. Prefabricated carbon composite multi-function AFOs were also fitted and assessed; though their fit was acceptable, they provided suboptimal support to the patient's fixed varus ankle posture and decreased comfort compared to the custom AFOs. The impact on gait deviations was comparable between the two pairs of devices.
Second is a high activity adult male patient with a history of spinal cord injury. He has poor lower extremity muscle control with profound quadriceps weakness but preserved ankle muscle strength and minimal postural abnormalities, bilaterally. Calf circumference was 39 cm; height and weight were 170 cm and 95 kg. Without AFOs, he exhibited anterior trunk lean, slow unstable gait, with intermittent knee buckling and hyperextension throughout stance. The custom prepreg multi-function AFOs with pretibial shell fit well and were comfortable. After kinematic optimization, his knee stability was greatly improved with a smooth loading response and tibial progression throughout stance. Prefabricated carbon composite multi-function AFOs were fitted and assessed; the prefabricated AFOs fit well. They provided adequate and comfortable support similar to the custom AFOs as well as appropriate alignment of the ankle joint. The impact of the prefabricated AFOs on gait deviations was comparable to the custom AFOs.

Last is an adult female patient with hemiparesis secondary to CVA, a history of falls, and popliteus pain. She has severe weakness and mild spasticity in her ankle and knee with mild ankle pronation. Calf circumference was 32 cm; height and weight were 175 cm and 52 kg. Without an AFO, she exhibited
intermittent toe drag, variable initial contact foot position, hyperextension in midstance, limited weight shifting to the affected limb, and shortened contralateral step length. A custom prepreg multi-function AFO with pretibial shell and flat footplate fit well and was comfortable. After kinematic optimization, her gait velocity increased with consistent swing clearance and heel strike, appropriate knee flexion angle during midstance, improved weightbearing on the affected limb, and more symmetrical step length. The prefabricated multi-function AFO with pretibial shell was fitted. This design was not optimal due to a significant mismatch between the tibial cuff size and the patient's small calf circumference and narrow ankle. However, the impact of the prefabricated AFO on gait deviations after kinematic optimization was comparable to the custom AFO.

Discussion/Conclusion

This case series demonstrated that for these patients, custom and prefabricated carbon composite multi-function AFOs provided similar improvement in ambulatory function. The evidence-guided adjustment procedure for multi-function ankle-foot orthoses [LeCursi 2024] was effective at systematically reducing pathologic gait deviations in all cases with both the prefabricated and custom devices. Two of the three patients required custom AFOs to provide the most optimal fit and postural support. A custom-fabricated version of the prefabricated AFO design improved the fit, while preserving the functional benefits for these two patients. For the third patient, the prefabricated AFO provided satisfactory comfort and support, nearly equivalent to that of the custom AFO, but with a faster time to delivery, at a lower cost and with less time investment.

Significance

Both prefabricated and custom fabricated AFOs have relative benefits and shortcomings. If a prefabricated device can provide adequate support, comfort, and functional benefit, it is possible to reduce turnaround time and device cost in these cases by fitting a prefabricated rather than a custom AFO. However, for patients who have more unique anatomies or an increased need for tailored postural support, custom devices are necessary to achieve optimal outcomes. It is advantageous to have prefabricated and custom devices that can provide equivalent functional benefits to aid in the evaluation process and in determining an orthotic intervention recommendation.

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Collaborative Rehabilitation: Co-Treatment Approaches for Vision and Mobility Challenges in a Patient with Limb Loss

Introduction or Purpose

This case study explores the benefits of interprofessional practice between certified orientation and mobility specialists (COMS) and certified prosthetist- orthotists (CPOs) in addressing the needs of individuals with both vision impairment and limb loss.

Methods

The client, a 32-year-old woman with vision impairment and limb loss resulting from a traumatic event, participated in co-treatment sessions with COMS and CPOs. Data were gathered through observational assessments during mobility training, and progress was evaluated based on her ability to navigate environments safely and independently.

Results

Collaborative interventions led to notable improvements in the client's mobility, orientation, and overall functional independence. The integration of prosthetic support and orientation training allowed the patient to adapt effectively to her environment, enhancing her quality of life

Discussion/Conclusion

This case highlights the importance of interprofessional approaches in intervention. The collaborative work between COMS and CPOs allowed for tailored strategies that addressed both visual and physical impairments, demonstrating the value of combining specialized expertise.

Significance

Practitioners working with clients who have additional disabilities should consider collaborative treatment models that involve specialized professionals. By working together, COMS and CPOs can develop individualized plans that support greater client autonomy, safety, and well-being in diverse settings.

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Results Of An Observational Study On Early Rehabilitation After Transfemoral Amputation With Microprocessor-Controlled Knees

Introduction or Purpose

The primary objective of this prospective study is to evaluate specialized early functional rehabilitation for K1-2 transfemoral amputees using a microprocessor-controlled knee (MPK; Kenevo). The protocol will adhere strictly to the German guideline after major amputations and Enhanced- Recovery-After-Surgery criteria [1].

Methods

Subjects from the study group are fitted with MPKs right from the beginning of rehabilitation after direct transfer from the hospital. The study group will be compared to a control group (n = 63 anticipated for each group) from seven German rehabilitation clinics. Inclusion criteria are transfemoral amputation and mobility level K1-2. The measurement outcomes include quality of life, mobility, falls, fear of falling, reintegration to normal living and functional aspects.
Results are reported at 24 weeks after rehabilitation start [2].

Results
The study group indicates a superior quality of life (EQ5D-5L score study group: 0.811 ± 0,182 (CI 95% [0,738 – 0,885]); control group: 0.653 ± 0,339 (CI
95% [0,340 – 0,966]). Furthermore, the study group shows a 10% higher reintegration into normal living (RNLI study group: 70,4% ± 17,3 CI 95% [63,4 – 77,4]; RNLI control group: 60,4% ± 24,7 CI 95% [37,6 – 83,3]. Statistical analysis will follow study completion (June 2025).
10% of falls with an MPK (Kenevo, Ottobock) had severe fall consequences (strong pain, swelling, hematoma), whereas 25% of falls with a non-MPK (NPMK) had severe fall consequences. 20% of all falls with an NMPK led to hospitalization of the patient, whereas 0% of falls with an MPK (Kenevo, Ottobock) led to hospitalization.
Discussion/Conclusion
The intermediate results of this study support the use of MPKs for K1-2 ambulators in an early specialized rehabilitation after transfemoral amputation as quality of life and reintegration into normal living clearly improved.
Furthermore, fall severity and fall related consequences using an NMPK is higher compared when using a MPK. These findings are similar to those found in the independent ASCENDT K2 trial [3]. Rehabilitation with MPKs can lower long-term costs by increasing patient independence and reducing fall-related injuries.
Significance
This highlights the potential benefits of early rehabilitation with microprocessor- controlled knees for transfemoral amputees and low mobility levels, improving quality of life, mobility, and reducing fall-related injuries, which could lead to better long-term patient outcomes and cost savings.
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Course of reintegration into normal living (RNLI) UUILVLHB-2078448-2-IMG.pdf
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Comprehensive Craniometry for Sagittal Synostosis

Introduction or Purpose
Sagittal synostosis is the most common type of craniosynostosis, resulting in a small range of deformities with several possible distinctive morphological characteristics. These include occipital narrowing, parietal narrowing, an anteriorly shifted vertex with parietal depression, and exaggerated frontal bossing. The traditional assessment measure of cephalic index affords limited reliability in quantifying initial severity and correction. The purpose of this study was to conceptualize and evaluate a set of novel metrics based on optical surface scanning (OSS) technology used for cranial remolding orthosis (CRO) treatment. These new indices will enhance the ability of clinicians to assess deformity and monitor improvement in the orthotics management of these children.
Methods
The 25 most recent infants to receive CRO treatment for sagittal synostosis at a single center were reviewed retrospectively. All treated patients underwent the endoscope-assisted craniectomy technique without barrel staving. OSS representations of each patient's head were acquired perioperatively and at cessation of CRO treatment. A novel set of metrics were developed, comprising 1) the occipital contour angle to assess severity of occipital narrowing; 2) the vertex proportionality index to assess the anterior vertex relative to the depressed posterior anatomy; 3) the parietal temporal index to assess proximal cranial narrowing; and 4) the sellion-frontal index as a measure of frontal bossing. The pre- and posttreatment results for all indices were compared against each other and against a control group of 33 nonsynostotic infants with grossly normal head shapes.
Results
The initial treatment group means for all 4 indices demonstrated significant variance against both the final treatment group means and the control group means. However, no statistically significant differences were observed in the group means for occipital contour angle, parietal-temporal index, and sellion- frontal index between the posttreatment and

control cohorts, which was suggestive of mean correction to normative levels for these morphological considerations. Despite an appreciable mean correction of parietal depression in the final treatment group, the mean vertex proportionality index values remained statistically different from the control group.

Discussion/Conclusion

Sagittal synostosis is characterized by several characteristic deviations from normocephaly. These are effectively improved by endoscope-assisted craniectomy with CRO intervention. Importantly, head shape abnormalities differ between patients, and the individual subject can present normatively for some deformational categories. Therefore, a multimetric approach is essential to quantify initial presentation and subsequent outcome. The introduction of novel OSS-enabled craniometry may facilitate more patient-centric management of this complex deformity. Specifically, features with the greatest deviation from normative standards can be identified, enabling creation of discrete treatment plans with respect to the focus and length of postoperative helmeting.

Significance

The previous standard for the diagnosis and management of sagittal synostosis was cephalic index. However, this measure is unable to consistently diagnosis the presence of synostosis and provides limited documentation of its improvement throughout treatment. The newly validated cranial indices in this paper provide a comprehensive set of metrics to identify and track the corrective progress made in infants with sagittal synostosis through their course of post-operative orthotics care.

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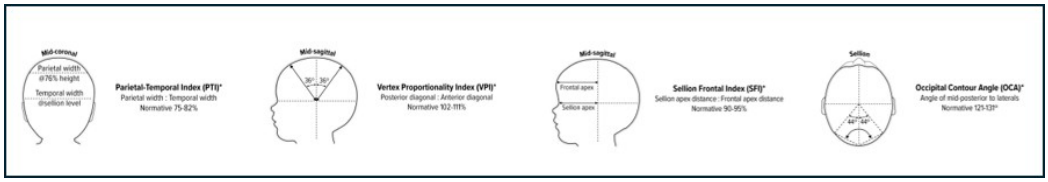

Cranial Indices for the Management of Sagittal Assessment

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Influence of Surgical and Postoperative Factors on Time to Prosthetic Fit: A SwedeAmp Database Study

Introduction or Purpose

This study aimed to evaluate prosthetic fitting outcomes from the SwedeAmp database (the world's largest database on prosthetic outcomes), focusing on amputation levels, gender distribution, and the relationship between incision techniques, postoperative treatments, manufacturing methods, and time to prosthetic fitting in transtibial amputation (TTA) cases. The registry data from 2018 to 2023 included 859 initial prosthetic fittings for 826 patients, with a mean age of 71.6 years (. The majority were men (67.5%), representing a male-to-female ratio of approximately 2:1. Among these patients, 33 (4.0%) were bilateral amputees.

Methods

This study expands on our previous research by further analyzing SwedeAmp data to assess the accuracy of its coverage rate. We examined prosthetic fitting rates for the most common lower limb amputation (LLA) levels performed above the ankle joint, including transfemoral (TFA; n = 137), knee disarticulation (KD; n = 32), and transtibial amputation (TTA; n =

690).
Specifically, we evaluated the surgical techniques used in TTAs and the postoperative treatments applied. The analysis examined whether timely treatment influences both the time to prosthetic fitting and the selection of prosthetic fabrication methods.
In Sweden, prosthetic fitting is recommended by a multidisciplinary team and is fully covered by the public healthcare system. Patients are not required to have private insurance to receive a prosthesis.

Results

Compression therapy using postoperative silicone liners was utilized in 60.9% of all cases. When focusing specifically on cases with documented compression data (n = 450), liner compression was applied in 93.3% of instances.
When compression therapy was initiated within one week of amputation regardless of incision technique, a subgroup of 213 patients had a median prosthetic fitting time of 41 days (IQR: 41 days).
In contrast, 207 patients who began compression therapy more than one week after amputation had a median fitting time of 70 days (IQR: 74.5 days), also irrespective of incision technique.
The optimal outcomes were observed when the sagittal incision technique was used, compression therapy was initiated within one week, and the direct lamination technique was applied during prosthetic fitting (n = 108), resulting in a median fitting time of 37 days (IQR: 26.3 days), (see Figure 1 and Table 1). In contrast, delaying compression therapy beyond one week (n = 104) and fitting to other types of sockets resulted in a considerably longer median time to prosthetic fitting of 76 days (IQR: 75.0 days). Compared with the Long posterior (n = 14) and the same treatment process, the median time for prosthetic fitting was extended by 4 weeks to 66 days (IQR: 82.8 days), compared to the optimal treatment process.
For the 24 cases using other compression methods, starting after a week, the median fitting time was 119 days (IQR: 126 days).
Overall, starting compression within the first week after amputation, as opposed to later initiation or the use of other compression methods, was associated with a significantly shorter time to prosthetic fitting ($p = 0.00013$).

Discussion/Conclusion

The outcomes presented in this study are in line with the findings presented in recent years in the SwedeAmp reports, which currently include approximately 17,000 amputations. The SwedeAmp registry offers a robust dataset for analyzing lower limb amputation outcomes and prosthetic fitting trends. This study identifies key factors influencing the time to prosthetic fitting, particularly in TTAs, where the sagittal incision technique acts as a catalyst for early postoperative treatment, silicone liner compression, and directly laminated sockets, which are all associated with a significant reduction in fitting time.
These results underscore the importance of standardized postoperative care in improving prosthetic rehabilitation, minimizing delays in prosthetic fitting, and enhancing functional recovery for amputees. The findings also highlight gender disparities in prosthetic provision.

Significance

The findings suggest that the sagittal incision technique, when paired with early postoperative silicone liner compression therapy and the direct lamination manufacturing method, can significantly reduce the time to prosthetic fitting in TTA patients. This approach holds promise for improving rehabilitation outcomes and enhancing the quality of care for individuals undergoing transtibial amputation.

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Surgical Technique	Compression Type	Compression Initiation	Socket Manufacturing Type	Mean Days to Fit	Standard Deviation	Median Days to Fit	IQR	N
Sagittal flaps	**Silicone**	Within 1 week	**Direct fit**	50.9	37.3	**37**	26.3	**108**
	Silicone		Other socket‡	77.1	65.8	45	85.0	89
	Other†		Other socket‡	125.6	81.3	159	134.0	5
	Other†		Direct fit	89.0	NA	89	-	1
	Silicone	After more than a week	**Other socket‡**	100.0	73.8	76	75.0	**104**
	Silicone		Direct fit	99.7	82.7	68	80.5	75
	Other†		Other socket‡	163.3	78.0	119	124.5	15
	Other†		Direct fit	87.6	51.5	74	36.5	6
Long Posterior flab	Silicone	Within 1 week	Other socket‡	103.4	88.1	66	82.8	14
	Silicone		Direct fit	54.0	2.8	54	2.0	2
	Silicone	After more than a week	Other socket‡	76.1	38.7	62	41.3	14
	Silicone		Direct fit	68.4	45.3	46	45.8	14
	Other†		Other socket‡	244.7	202.9	184	196.0	3

† Refers to bandages, compression, or other kind of compression

‡ Refers to traditionally laminated or thermoplastic socket made from hand casting or scanning

Table 1 Correlation Between Incision Technique, Compression Therapy, Socket manufacturing type, and Time to Prosthetic Delivery:
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Figure 1: Sagittal incision, rigid dressing, compression with silicone liner and direct fit
UUILVLHB-2071851-2-IMG.png

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Injurious Falls Among Individuals Prescribed Lower Limb Orthoses: Relationships with Mobility, Pain Interference, Lower Limb Strengh, Sex and Age

Introduction or Purpose
The broader population of individuals requiring lower limb orthoses has only recently been investigated, establishing a health profile of reduced physical function and increased pain interference. While populations frequently managed with lower limb orthoses, including those with stroke, multiple sclerosis and spinal cord injury, have reports of elevated rates of injurious falls, the rate of injurious falls has not been reported for the broader population of those prescribed lower limb orthoses. Potential correlates to higher fall rates may include reduced mobility, increased pain interference, reduced lower limb strength, sex and age. The purpose of this analysis was to establish the rate of injurious falls among individuals who have been prescribed lower limb orthoses and to establish the relationship between the rates of such falls and mobility, pain interference, lower limb weakness, sex and age.
Methods
This was a retrospective analysis of data obtained within a national network of orthotic and prosthetic clinics as part of a standardized outcomes collection and physical assessment during routine orthotic care. Participants were those individuals presenting over the age of 18 who had been prescribed a new lower limb orthosis and had a complete data set.

Results
Full data sets were identified for 1296 individuals with a 19% incidence of injurious falls over the preceding 6 months. Low and Modest Mobility levels were associated with an adjusted OR of 1.97 and 1.73 for injurious falls compared to above average mobility. Very high, high, and moderate levels of pain interference were associated with an adjusted OR of 2.45, 2.01 and 1.89 compared to below average pain interference levels. Reduced lower limb strength was associated with an adjusted OR of 1.49 relative to higher lower limb strength. Women had an adjusted OR 0f 1.44 relative to Men. Those over 65 had a non-significant adjusted OR of 1.17 relative to younger ages.
Discussion/Conclusion
The present study is the first to report injurious fall rates among individuals prescribed lower limb orthoses. The rate was concerningly high at 19% over the preceding 6 months. Reduced mobility, elevated pain interference, lower limb weakness and female sex were all associated with increased rates of injurious falls.
Significance
This is the first effort to establish the prevalence of injurious falls among individual prescribed lower limb orthoses. By establishing the odds ratios associated with mobility, pain interference, weakness, sex and age and injurious fall rates, clinicians are now better able to appreciate the relative propensity towards an injurious fall by an individual presenting for orthotic rehabilitation and develop an appropriate treatment plan.
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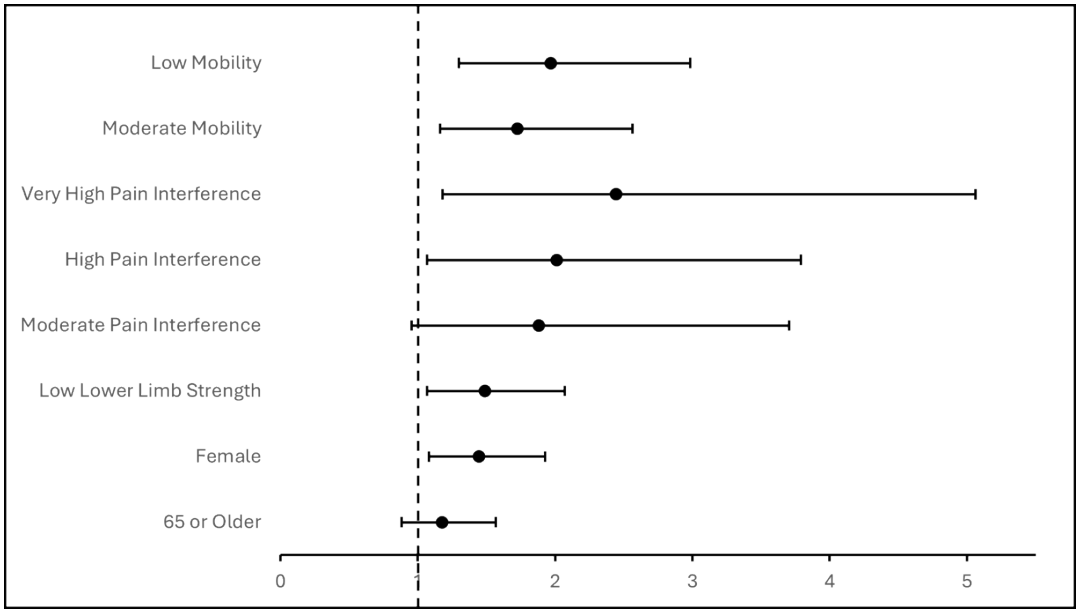

Odds Ratios for the Impact of Mobility, Pain Interference, Lower Limb Weakness, Sex and Age on Rates of Injurious Falls Among Individuals Prescribed Lower Limb Orthoses
UUILVLHB-2069189-1-IMG.png

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Clinical Evaluation of Scoliosis Braces Designed Automatically Using a Generative Algorithm: A Randomized Controlled Crossover Trial

Introduction or Purpose

The effectiveness of brace treatment for idiopathic scoliosis (IS) varies across centers and is often influenced by the expertise of the orthotist. To mitigate this variability, we developed a fully automated generative design algorithm that utilizes patient-specific finite-element modeling (FEM) to optimize brace geometry. This study aimed to clinically assess the effectiveness of nighttime braces generated by our algorithm by comparing their performance to standard Providence-type braces.

Methods

A single-center, double-blinded, prospective randomized controlled crossover trial was conducted. Fifty-eight skeletally immature patients, aged 10-16 years and diagnosed with IS, were enrolled. Each participant received both a nighttime brace designed by our algorithm (Test) and a Providence-type brace crafted by an expert orthotist (Control). Immediate in-brace correction was assessed using radiographs, with both braces tested in a randomized crossover manner.

Results

The immediate Cobb angle correction for the main thoracic curve was 57% ± 19 (Test) versus 58% ± 21 (Control); for the thoracolumbar/lumbar curve, it was 89% ± 25 (Test) versus 87% ± 28 (Control). Test braces were noninferior to Control braces ($p < 0.001$). Additionally, the Test group required significantly fewer fit adjustment iterations at delivery compared to the Control group (1.0 ± 0.8 vs 1.4 ± 1.2, $p = 0.01$).

Discussion/Conclusion

The fully automated generative brace design algorithm demonstrated clinical efficacy, providing immediate in-brace correction equivalent to that of expert- designed braces. The continued two-year patient follow-up will provide additional insights into long-term efficacy. Integrating this algorithm into clinical practice may enhance and standardize brace design for IS treatment.

Introduction or Purpose

This study highlights the potential of generative design algorithms to automate and standardize brace design for IS, reducing reliance on empirical expertise and improving efficiency while maintaining clinical efficacy.

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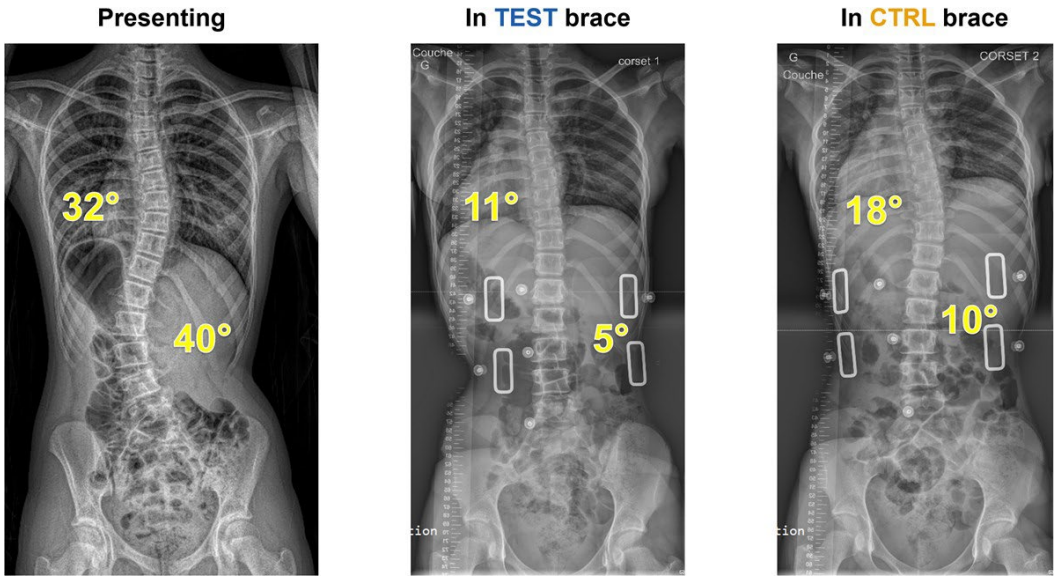

Example of immediate in-brace correction for a single patient wearing both Test (TEST) and Control (CTRL) braces

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Factors That Influence Mobility In Individuals With Lower Extremity Amputations

Introduction or Purpose

Lower-limb amputation (LLA) reduces physical abilities that affect balance, maneuverability, power, strength, and symmetry. Regaining physical function after LLA is challenging because of chronic illnesses that may have led to amputation, arthritis, reliance on specialized prosthetics or equipment, and dermatological issues. Increasing physical activity in people with LLA is critical to assist with weight loss and prevent long-term health issues and risk for secondary disability. The underlying factors that contribute to overall physical function must be identified to enable more appropriate prosthetic design and rehabilitation.

Methods

The data in the Limb Loss and Preservation Registry (LLPR) was analyzed for this study. The LLPR integrates data from the electronic health records (EHRs) of hospitals and orthotic and prosthetic (O&P) providers. The LLPR uses a web-based user-interface which allows a diverse stakeholder community to access role-based standard reports, use embedded analytical business intelligence tools to analyze the data, and respond to research questions efficiently and effectively. There are 1122 diagnosis and procedure codes (CPT, ICD-10, HCSPCS codes) to identify individuals with limb preservation procedures, limb loss, and limb difference. The trigger codes include both upper and lower extremities for patients of all ages. The data comes from both inpatient and outpatient facilities. Once a trigger code is activated for an individual patient, all subsequent episodes of care are collected. The LLPR collects demographic and comorbidity data, social determinants of health, provider information, and payer, as well as outcomes data. The LLPR received Authority to Operate on February 26, 2022. Currently, it has accumulated data on >454,000 patients from all 50 US states and >14 M episodes of care. The data collected is a convenience sample and, as the volume of patients and participating sites continues to grow, can be analyzed to make national estimates. The current data contains patients with limb preservation
procedures (70%) and patients with limb loss (30%). The patients with limb loss are composed of patients with lower limb loss (80%), upper limb loss (17%), both upper and lower limb loss (< 2%), and unknown limb loss (< 2%). The goal of this was to determine significant factors that contributed to the mobility of patients with lower extremity amputation, as reported by the PROMIS physical function (PPF) scale. A linear mixed effects model was used to study the effect of amputation level, comorbidity (using the Functional Comorbidity Index (FCI)), age, years as an amputee, and years since last amputation on mobility. Significance level (α) was set to 0.05.

Results

Data from 699 unique patients with lower extremity amputations were used in this analysis (mean age = 67 + 14, min=4, max=101 years). In this cohort, 209 had a toe amputation, 191 had a partial or complete foot amputation, 188 were below knee, and 111 were above knee amputations. The mean PPF score is 34, which indicates that their mobility is in the bottom 20% of the general US population. Notably, 95% of the patients have a PPF score less than 50 which is the mean score for the general US population. Most importantly, the patient's mobility is affected by level of amputation, age, and FCI (Figure 1). Level of amputation and age had the highest effect on mobility ($p < 0.001$) followed by FCI ($p=0.047$). Patients with a toe or foot amputation had significantly better mobility than those with a below or above knee amputation. The number of years as an amputee or years since the most recent prosthetic fitting were not significant factors in predicting mobility.

Discussion/Conclusion

Beyond the prosthetic design, the major factors affecting the ability of persons with a LLA to participate in physical activities are age, level of amputation, and comorbidities. The mobility of persons with lower limb amputations is slightly less than individuals with severe knee arthritis who are schedule to receive a knee replacement (1) or individuals with cardiac disease who are scheduled for a heart transplant (2). A large body of research has indicated that a patient's outcome depends on their comorbidity status. The types of comorbidities identified in the LLPR are like those previously identified to influence healing and functional outcomes following an amputation (3, 4). While some authors have documented that comorbidities explain a portion of function following amputation (5, 6) other authors have demonstrated that there is no association with physical activity (7). This data demonstrates that comorbidities affect the mobility of patients with lower limb amputations.

Introduction or Purpose

The low physical function scores reported by patients with LLA demonstrate that they cannot do many of the physical activities done by the general US population.

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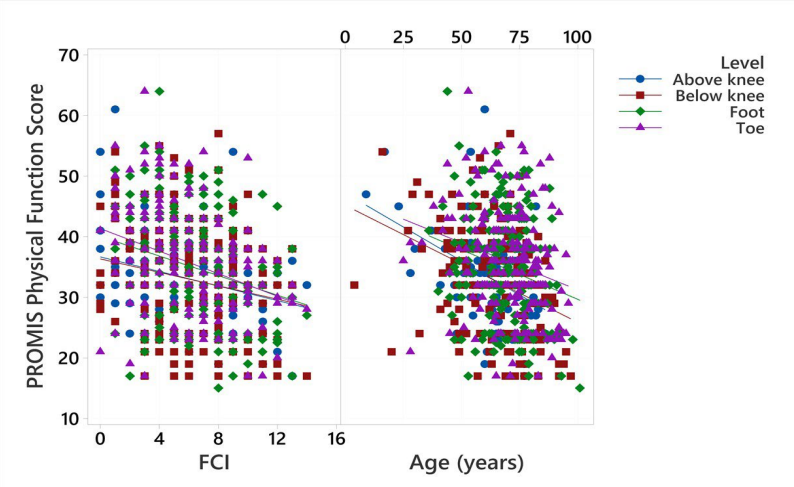

Figure 1. Age, comorbidities, and level of amputation affect mobility of lower extremity amputees.
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Clinical Outcomes of Powered-Ankle Feet: A Systematic Review of Commercially-Available and Predicate Products

Introduction or Purpose

Adding external power to prosthetic components to compensate for lost muscle function appears to be a logical step in prosthetics. However, clinical research with commercially available powered prosthetic ankle-foot (PwrAF) and powered knee (PK) mechanisms has shown inconsistent and conflicting results.(1,2,3) However, the evidence regarding PwrAFs has not yet been aggregated or synthesized. Therefore, the purpose of this work was to perform a systematic literature review, critically appraise identified articles, extract clinical data, and synthesize included data.

Methods

A literature search with terms related to prosthetic powered, active, robotic, or bionic ankle-feet was performed across 4 electronic databases: PubMed, Google Scholar, The Cochrane Library, and O&P IQ. Titles and abstracts were screened for relevance and inclusion/exclusion criteria according to the PRISMA statement. Articles were critically appraised according to the Cochrane critical literature appraisal tool. Data was extracted into spreadsheets and synthesized into Empirical Evidence Statements (EES) by an expert multi- disciplinary panel of prosthetists and research scientists.

Results

Ultimately, 31 articles were included in the systematic review. Of these articles, quality scores were as follows: A-0, B-11, C-17, and 3 were too low to meet scoring criteria. Regarding demographics, 29 articles had unilateral transtibial subjects, 2 had unilateral transfemoral subjects, 15 articles included traumatic etiology and 15 did not report etiology, and 16 included subjects in K3-K4 MFCL level while 15 did not report MFCL level. All subjects included were 882 of which 324 were amputees in the experimental group wearing a PwrAF. These subjects had an average age of 39.5, median age was 41.25, average height 180.6 cm, average weight 91.5kg, and were 6.5% female.

There were 13 EESs synthesized. Of these the most commonly-supported themes included that PwrAFs provide net positive work to users-similar net work to biological ankles in some cases, PwrAFs have shown lack of consistent benefits between subjects, PwrAFs provide metabolic benefit to passive-elastic ankles, PwrAFs provide relief to the sound side of unilateral lower extremity amputees, PwrAFs may be limited by their uniarticular nature in TT users, and that device specific-training would improve patient outcomes. Further PwrAFs have show an ability to reduce musculoskeletal pain,

improve walking speed, improve whole-body angular momentum, but have also shown conflicting results regarding metabolic benefit, sound side relief, and benefits going up and down stairs.

Discussion/Conclusion

While benefits of PwrAFs have been demonstrated in several studies, the integration of power delivered by PwrAF components into the neuromuscular control of walking and the effective transfer and utilization of that power in the kinetic chain of the prosthetic leg does not appear to be intuitive for many transtibial patients. Patients would likely benefit from development of device- specific training including biofeedback to cue stiffening of the knee joint for more effective power transfer to the center of mass.

Introduction or Purpose

A synthesize of commercially-available PwrAF has been completed to guide prosthetists in their prescription and selection. Optimization of patient selection, prosthetic device tuning, and patient training is necessary to ensure PwrAFs deliver clinical benefits.

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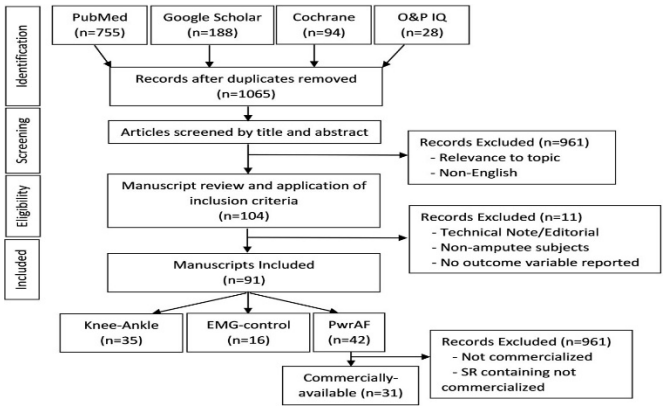

PRISMA Diagram
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Lower-Limb Socket Fit Sensing System: In-Lab Evaluation

Introduction or Purpose

Dudek reported 41% of people who use lower-limb prosthetic sockets experience skin problems such as pressure injuries, irritation, inclusion cysts, calluses, and verrucous hyperplasia [1]. Poor prosthetic socket fit is a main contributor to these types of skin problems [1], and both users and clinicians identify poor socket fit as one of the most significant problems and unmet needs [2]. This problem is exacerbated by residual limbs changing shape and volume over time [3], which can cause problems in even well-made sockets. Clinicians recommend compensating for limb volume fluctuations with prosthetic sock management, the act of adding or removing prosthetic socks [3]. Many prosthetic users struggle to manage sock use properly and prosthetists often report multi-ply discrepancies from ideal fit during clinic visits.

Methods

A prototype socket fit sensor system (SFSS) was developed to install in the distal end of a prosthetic socket and measure relative intra-socket pressures. IRB and OHRO approvals were obtained for an in-lab study. Data collection has been

completed on the first five participants (5 male transtibial prosthesis users, 55 +/- 14 years).

Participants performed several different gait tasks (variable walking speeds, stairs, etc.) while wearing a custom-made socket fitted with the SFSS. The socket was fabricated to be an ideal fit with a minimum of a 3-ply sock. Each gait task was repeated 3 times for 4 fit conditions: (Good 1) baseline ply, (Tight) too many (plus 3-ply) socks, (Loose) too few (minus 3-ply) socks, and (Good 2) a repeat of the baseline.
A peak detection algorithm identified the peak pressure during each step taken.

Results

Peak pressure analysis from participants revealed clearly distinct pressure regions between different fit conditions that were repeatable even after doffing the socket. Different gait tasks had minimal changes in peak pressure compared to different fit conditions.

Discussion/Conclusion

Results suggest that measuring peak pressures during gait show clear distinctions between good and poor (+/- 3-ply) socket fit conditions Gait task type caused minimal change in pressure compared to different fit conditions.
Initial results are encouraging and suggest that the SFSS, when calibrated to an individual, could meaningfully be deployed in real-world conditions to help users manage socket fit. Take-home pre-clinical trials are currently in the recruitment stage

Significance

The SFSS could reduce skin problems by detecting socket fit issues early and alerting the user to add or remove prosthetic socks. This technology may prove especially helpful for new users or users struggling with prosthetic sock management.

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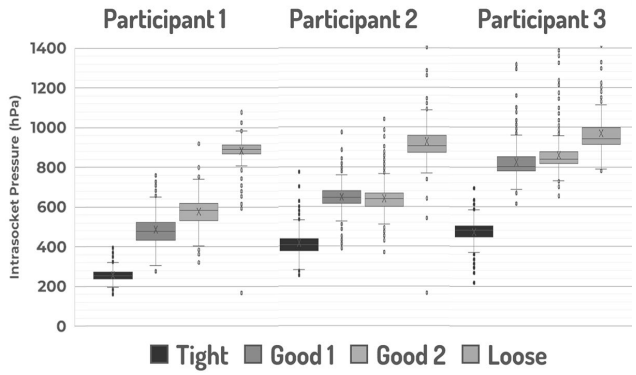

Figure 1. A box and whisker chart including peak pressure [hPa] of every step recorded in all gait tasks for 3 participants in each condition showing a distinction between fit conditions.
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	Average Peak Step Pressure (hPa) in Gait Tasks															
	Tight				Good 1				Good 2				Loose			
	AVG		CI	N	AVG		CI	N	AVG		CI	N	AVG		CI	N
L-Test	401	±	11	54	792	±	16	62	789	±	12	62	931	±	15	62
Self-Selected	470	±	6	38	823	±	13	39	823	±	11	38	940	±	20	36
Fast	546	±	17	32	968	±	30	31	910	±	25	33	1091	±	35	34
Slow	505	±	4	40	799	±	5	40	836	±	3	42	939	±	4	42
Stairs	337	±	50	13	795	±	26	15	937	±	84	17	1149	±	##	17
Slopes	474	±	12	57	807	±	11	57	887	±	16	65	964	±	20	57
Random Walk	490	±	5	139	825	±	14	136	876	±	18	158	961	±	13	147
All Gait	**465**	**±**	**7**	**373**	**824**	**±**	**8**	**380**	**855**	**±**	**9**	**415**	**960**	**±**	**11**	**395**

Table 1. Participant 3 average peak step pressure [hPa] (AVG), 95% confidence interval (CI), and number of steps (N) in each gait task during each fit condition.
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Lower-Limb Socket Fit Sensing System: In-Lab Evaluation UUILVLHB-2085667-3-PDF(2).pdf

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ENHANCED FORCE PRODUCTION IN SIT-TO-STAND TASK: THE ADVANTAGE OF MOTORIZED KNEE PROSTHESIS IN INDIVIDUALS WITH UNILATERAL TRANSFEMORAL AMPUTATION

Introduction or Purpose

The sit-to-stand (STS) movement is one of the most physically demanding tasks for individuals with unilateral transfemoral amputation (uTFA). Previous studies have reported that peak vertical ground reaction force (vGRF) is significantly greater in the intact limb compared to the prosthetic limb during the STS task in individuals with uTFA [1,2], indicating excessive loading on the intact limb. A motorized knee prosthesis (MKP) has the capability to actively generate knee extension torque, thereby assisting in the initiation and execution of the upward movement. While MKPs have demonstrated potential in improving loading symmetry compared to daily-use prostheses (DUPs), the extent to which vGRF differences manifest throughout the entire STS task remains unclear. Therefore, this study aimed to investigate the differences in vGRF development between MKPs and DUPs during the STS task in individuals with uTFA.

Methods

Seven individuals with uTFA were recruited for this study. All participants were instructed to perform the STS task three times as naturally as possible, without executing a countermovement. The STS task was performed under two conditions: first, using their DUPs and subsequently with a MKP (BioLeg, BionicM Inc., Tokyo, Japan). Among the participants, four individuals used a microprocessor-controlled knee, while three used a non-microprocessor- controlled knee as their DUP. Using two force plates (Tec Gihan, Kyoto, Japan), vGRF during the STS task was measured. Then, a statistical parametric map (SPM{t}) was constructed by computing the conventional t- statistic at each time point throughout the ascending phase [3]. Random Field Theory (RFT) was then applied to determine the critical threshold, ensuring that only 5% ($\alpha = 0.05$) of equally smooth random data would be expected to exceed this threshold. This approach allows for independent control of Type I errors when analyzing correlated field data. A significant difference in the prosthetic limb's vGRF between the two conditions was identified if the temporal SPM value at any node exceeded the critical threshold.

Results

The MKP generated significantly greater vGRF than that of DUPs during the early phase (~45%) of the STS task (Figure 1). Although the peak vGRF observed with the MKP was higher than that of the DUP, this difference did not reach statistical significance.

Discussion/Conclusion

As expected, vGRF development in the prosthetic limb was greater in MKP than in DUPs. In particular, MKP consistently generated greater vGRF during the early phase (~45%) of the STS task, suggesting that the current MKP offers an advantage in initial loading. Since the initial phase of STS (seat-off or liftoff phase) requires overcoming inertia to transition from a seated to a standing position, the increased force production by MKP at this stage may facilitate smoother movement initiation, thereby reducing the effort required from the intact limb and upper body.

Significance

Given that the sit-to-stand (STS) task is performed approximately 60 times per day in daily life [4], the use of a motorized knee prosthesis (MKP) may help reduce the physical demands of this repetitive movement and enhance functional independence in individuals with uTFA.

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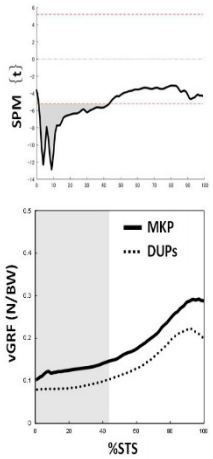

Figure 1. SPM t-value (upper panel) and time-course vGRF profiles in DUPs (dotted line) and MKP (solid line) conditions (lower panel), respectively. Shaded area indicates statistical significance between two conditions determined by SPM.
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Outcomes from the Clinical Application of an Externally Powered Pediatric KAFO

Introduction or Purpose
Flexed-knee gait is a common movement disorder in children with neuromuscular and orthopedic conditions, such as cerebral palsy and spina bifida. Traditional orthotic interventions for this population, including locked knee-ankle-foot orthoses (KAFOs) and ground reaction ankle-foot orthoses (GRAFOs), have limitations. The application of a microprocessor-controlled knee-ankle-foot orthosis with powered knee flexion and extension assist (MPKAFO-P), has shown promise in improving gait. However, its long-term impact on mobility and gait in home and community settings remains unclear. This clinical study evaluates the effectiveness and benefits of an MPKAFO-P in children with flexed-knee gait.
Methods
This ongoing prospective, multi-site, open-label, pragmatic clinical study aims to enroll up to twenty children aged 8-16 years with neuromuscular and orthopedic disorders causing flexed-knee gait. Following informed consent, participants are screened for the MPKAFO-P (Agilik, Bionic Power) using the test orthosis (Agilik Test Drive) to assess knee flexion improvement with the addition of a powered actuator. Baseline mobility and quality-of-life data are collected. Participants receive a custom MPKAFO-P and complete a five-hour in-clinic training period over two weeks before taking the orthosis home for daily use. Follow-up assessments occur monthly for three months. Outcome measures include the Neuro-QoL Pediatric Lower Extremity Function-Mobility, EQ-5D-Y-3L, Timed Up and Go (TUG), and 2-Minute Walk Test (2MWT).
Results
Preliminary analysis among four subjects indicates improvements (mean ±SD) in Neuro-QoL (Baseline: 61.3±13.5 and 1-month follow-up: 67.1±17.5) and EQ- 5D-Y-3L index values (Baseline:.847±.093 and 1-month follow-up: .869± .145) with MPKAFO-P use. Changes in TUG (Baseline:12.2 ± 3.9 and 1-month follow-up: 11.7 ± 4.9), and 2MWT (Baseline:130.6 ± 37.1 and 1-month follow- up:123.5 ± 37.4) vary based on the patient's pre-existing mobility level and diagnosis.
Discussion/Conclusion
The MPKAFO-P shows potential in enhancing mobility and gait in children with flexed-knee gait. The current study findings provide insights into potential long- term benefits in real-world settings, possibly informing clinical practice and improving quality of life for children with neuromuscular and orthopedic disorders.
Significance
Current orthotic interventions rarely improve flexed-knee gait for children with neuromuscular and orthopedic conditions, such as cerebral palsy and spina bifida. An MPKAFO-P offers a potential advancement by enhancing both gait mechanics and functional mobility. This multi-site clinical study assesses its long-term impact, with preliminary findings suggesting not only improved mobility but also enhanced quality of life, highlighting an opportunity to refine clinical practice and expand treatment options for this population.
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COSMETIC ONLY? ASSESSING THE LONG TERM NON-COSMETIC OUTCOMES OF POSITIONAL CRANIAL DEFORMITIES

Introduction or Purpose

Deformational Plagiocephaly (DP) is typically considered cosmetic due to a lack of a causal relationship with cognitive or physical developmental milestone delays. However, several studies compared children with craniofacial abnormalities to control groups found a higher incidence of social, academic, and attention issues, internalizing problems, less peer acceptance, and increased anxiety. Facial asymmetry caused by DP often **Results** in jaw malalignment and dental occlusion which have been shown to persist throughout life. The purpose of this survey is to assess the long term effects of positional head shape deformities on quality of life, psychosocial aspects and other costs.

Methods

A questionnaire was sent via text message and email to parents of patients previously seen and diagnosed with DP at the Texas Children's Hospital Plagiocephaly Clinic from 2007 to 2018. The chart review included 2,000 elgibile subjects after screening out synostotic or hydrocephalus diagnoses and ages outside of 5 to 15 years. This questionnaire includes validated outcomes to assess quality of life, anxiety, social distress, life satisfaction, and positive affect via the CBCL and the pedsql. Our medical questionnaire includes history of dental work, speech therapy, corrective lenses, craniofacial surgery, and CRO treatment. The survey was sent out between August and December of 2024. $25 gift cards were awarded for completion through TangoRewards.com. Funding for this study was awarded through the COPL Pilot Grant.

Results

The survey was succusfully sent out to 1,500 subjects via text and email. After several rounds of email reminders, a total of 227 responses were collected.

The majority of the respondents children are now between the ages of 7 and 9 years (62%) and were between 5 and 7 months of age at the TCH plagiocephaly clinic appointment. 68% of patients are male, 32% female with the races white (81%), unable to obtain 7%, asian 5.7%, black or african american 4.8%, and american indian or alaska native .4%. Ethnicities report non hispanic 53% and hispanic or latino 41%. The control group did not complete CRO treatment 52.6% of subjects. A slight trend was noted for CRO treatment completion and the need for dental work, corrective glasses, and speech therapy.

Discussion/Conclusion

These are the preliminary **Results**, the mann whitney U test will be run for the CBCL and PedsQL as well as the Cochran-Mentel Haenszel test to look medical history, an ANOVA, and finally a logistic regression to assess if severity of cranial head shape is predictive of psychosocial outcomes and other medical effects. We suspect the trend seen in the need for dental work, glasses, and speech therapy with be more strongly associated with intiial cranial asymmetry severity than CRO treatment completion.

Significance

The current climate surrounding cranial remolding orthoses is at a critical moment. Skepticism surrounding clinical benefits of cranial remolding orthoses is rapidly outpacing generation of new research to demonstrate clinical benefits. There is very little evidence regarding long term outcomes of plagiocephaly which are not deemed cosmetic. We defined non cosmetic outcomes as psychosocial effects, qualitfy of life, corrective lenses needed, dental work needed, and speech therapy needed.

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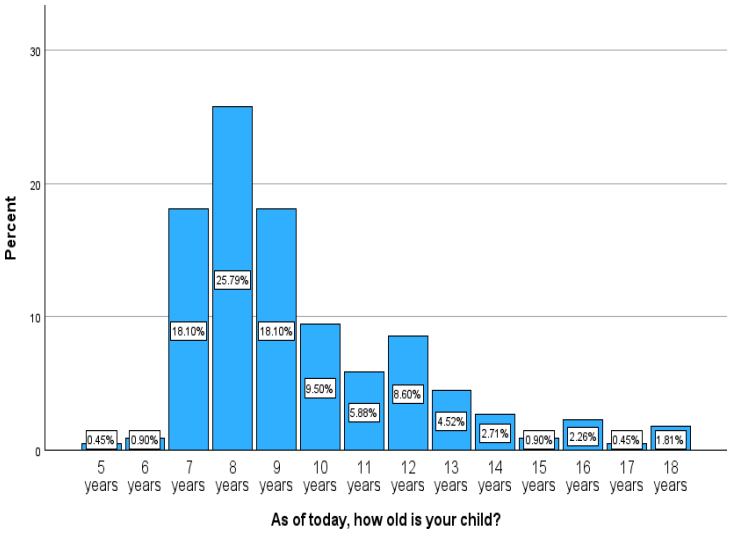

Age of Subjects
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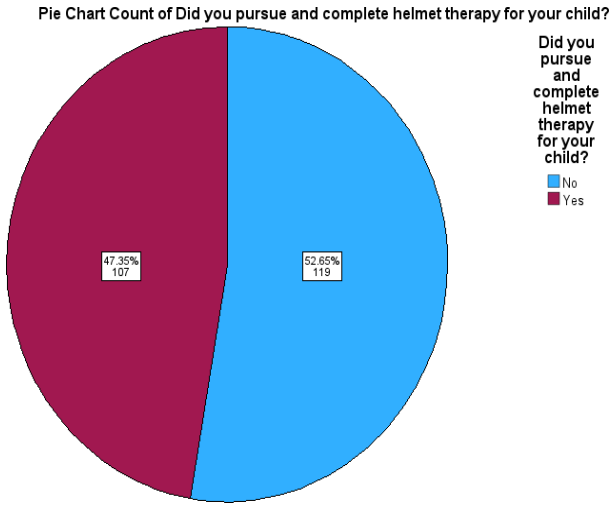

CRO Treament vs No CRO Treatment
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Effect of Orthosis Daily Wear Time on Pectus Carinatum Treatment Outcomes

Introduction or Purpose

Adolescents with pectus carinatum (PC) deformity often seek orthotic treatment for cosmetic reasons, but once treatment starts, many find it difficult to follow the recommended treatment protocol. Treatment of PC with a pectus carinatum orthosis (PCO) is effective with good adherence to wear-time recommendations but adherence to these protocols is relatively poor [1-3].

Less than optimal wear time is common, but there is limited information regarding the impact of various levels of

adherence on treatment outcomes. This can make it difficult to advise patients and families on the minimum daily wear time necessary to achieve improvement in PC deformity. The purpose of this study was to assess the impact of PCO daily wear time on treatment outcomes.

Methods

Participants: This is a retrospective cohort study of 67 patients treated for pectus carinatum with a pectus carinatum orthosis. This study was approved by the Institutional Review Board of the University of Michigan.

Procedures: At each follow up visit, we assessed patient-reported wear time and categorized each treatment interval between visits into one of four categories: full-time wear (16+ hours), partial wear (8-15 hours), minimal wear (2-7 hours), and not wearing (0-1 hours). The change in chest anterior- posterior (AP) dimension during each visit interval was calculated by subtracting the measurement at the previous visit from the measurement at the current visit. A negative change in AP dimension represents a reduction in the PC deformity.

Data Analysis: We used a multivariable linear mixed effects model, adjusted for days in treatment, to evaluate changes in chest AP dimension during visit intervals by wear-time categories.

Results

The 67 participants had a total of 255 visits, producing 188 visit intervals. Average improvement in PC deformity was greatest during the full-time wear visit intervals (-0.88 cm) (Table 1). Full-time wear visit intervals produced significantly greater improvement in deformity than all other categories (partial wear: $P = .036$; minimal wear: $P < .0001$; not wearing: $P = .0003$) (Table 2).

Improvement in deformity decreased as wear time decreased. PC deformity improved during intervals in which the participants reported wearing the PCO full time or part time. PC deformity worsened during visit intervals in which the PCO was worn minimally (0.15 cm) or not at all (0.93 cm) (Table 1).

Discussion/Conclusion

Few studies have reported outcomes based on various levels of wear-time adherence [4]. Wong et al. assessed the effect of two levels of protocol adherence on final treatment outcomes and the effect of daily wear time on outcomes within visit intervals. Patients who reported more than 12 hours a day of wear time had significantly greater improvement in final adjusted Haller Index (HI) than those who wore is less than 12 hours a day and those who wore it less than 12 hours a day had similar outcomes as those who did not wear an orthosis at all. Increased daily wear time produced significantly greater improvement in adjusted HI within visit intervals [4]. Our study's findings are complementary, but our study uses a more detailed categorization of wear time and shows that improvement can occur with less than full-time wear.

This study demonstrates that improvement in PC deformity requires a substantial daily time commitment, but that improvement can occur even with less than strict adherence to the full-time wear protocol.

Significance

This study helps clinicians provide patients and families with detailed information regarding the effects of daily wear time on successful orthotic management of pectus carinatum. This aids patients and families in understanding the daily time commitment necessary to see improvement and may help motivate patients who are struggling to fully adhere to the wear-time protocol.

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	Change in Chest AP Dimension at Maximum Protrusion				
Visit Intervals by Wear Time	N	Mean (cm)	SD (cm)	Max (cm)	Min (cm)
Full Time Wear (16+ hours)	91	-0.88	1.05	-3.60	1.20
Partial Wear (8-15 hours)	65	-0.08	0.86	-2.00	2.10
Minimal Wear (2-7 hours)	13	0.15	0.88	-1.50	2.00
Not Wearing (0-1 hours)	19	0.93	0.97	-0.60	2.80

Table 1: Change in chest AP dimension within visit intervals for each wear time category.

Change in chest AP dimension within visit intervals for each wear time category
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Visit Interval Wear-Time Category	Multivariable Estimate [95% CI]
Days In Treatment Adjustment	-0.0002 [-0.0011, 0.0007]
Full Time Wear vs. Partial Wear (8-15 hours)	0.28 [0.02, 0.54] *
Full Time Wear vs. Minimal Wear (2-7 hours)	1.16 [0.66, 1.66] ***
Full Time Wear vs. Not Wearing (0-1 hours)	0.92 [0.44, 1.40] ***

*$P < .05$, **$P < .01$, ***$P < .001$
CI, 95% confidence interval

Table 2: Multivariable linear mixed effects model of change in chest AP dimension, adjusted for days in treatment, during visit intervals by wear-time categories

Multivariable linear mixed effects model of change in chest AP dimension, adjusted for days in treatment, during visit intervals by wear-time categories
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References

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What the kids want: OPUS Results from 30 children wearing AFOs

Introduction or Purpose

Foot drop is one of the most common gait deviations in the pediatric clinical population and is characterized by persistent plantarflexion during the swing phase of the gait cycle. It places a child at risk for trips and falls and limits their ability to maintain activity levels commensurate with peers. In clinical orthotic practice these children are traditionally treated with ankle foot orthoses (AFOs). There is a growing body of literature that emphasizes the voice of the end user in technology prescription, assessment, and future technology development.

However, there is scant literature on what pediatric patients want from their own devices. Therefore, in this work, we aim to understand satisfaction levels with existing lower extremity orthoses as well as capture the special desires of children and their families for future lower extremity orthoses.

Methods

Following informed consent, 30 pediatric participants who use lower extremity ankle foot orthoses (AFOs) were asked to complete the OPUS Satisfaction questionnaire. Patient's caregivers were allowed to complete the survey on behalf of their child. Data was analyzed to determine differences in patient reported outcomes between users of articulated AFOs and users of posterior leaf spring AFOs.

Participants were also asked for freeform feedback on any features that they would like to see implemented into their devices. Freeform feedback was analyzed and categorized into broader themes for improved analysis and understanding.

Results

N=30 patients (age 10.2 ± 3 years) who were users of AFOs participated. All 30 participants completed the OPUS Satisfaction questionnaire. We observed no differences on any OPUS Satisfaction item between the articulated AFO (N=8) and posterior leaf spring AFO (N=22) group. Key items of greater concern for families on the Satisfaction with Device included: "My orthosis is comfortable to wear throughout the day", "My skin is free of abrasions and irritations" and "My orthosis is pain-free to wear". Key items of greater concern for families on the Satisfaction with Services included: "I can afford the out-of-pocket expenses to purchase and maintain my orthosis" and "I can afford to repair or replace my orthosis as soon as needed".

N= 24 participants gave freeform feedback on the features they would like to see implemented into their device(s). Broader themes which emerged from the freeform feedback included requests under three themes including: aesthetics, comfort and user friendliness. 14 comments were related to aesthetics including six comments related to shoes. Six comments were about comfort and five comments were about features related to user-friendliness.

Discussion/Conclusion

Our data reveals that pediatric patients and their caregivers are generally satisfied with multiple aspects of their lower

extremity AFO care with comfort being an area of slight concern for existing devices. Participants also reported comfort as well as user friendliness as high priorities in the features they would like to see implemented into future devices. However, aesthetics emerged as a primary feature that should be implemented into devices indicating that increased attention should be given to this area during the design and development, treatment, and prescription of these devices.

Significance

This work emphasizes the importance of comfort, aesthetics and user- friendliness in pediatric lower extremity orthotic clinical care. Aesthetics was a key feature of importance for a majority of users and likely plays a role in the acceptance and successful use of an orthosis for pediatric patients. Clinicians and engineers may want to consider incorporating more creative ways to enhance aesthetics in pediatric lower extremity care as they design newer orthoses for improved patient outcomes.

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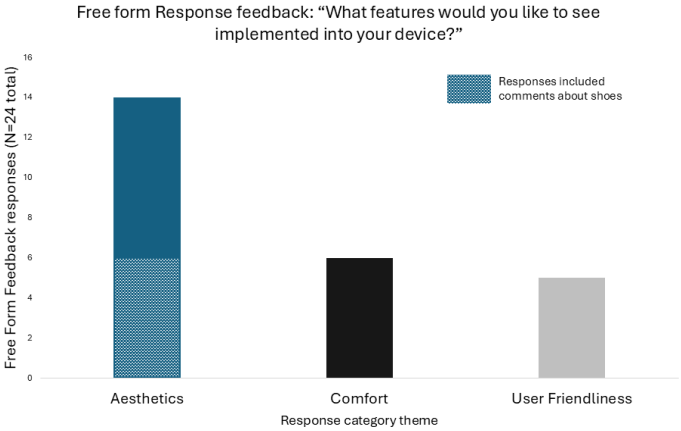

Figure 1. Themes emerging from pediatric freeform feedback survey question, "What features would you like to see implemented into your device?"

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Validating Clinical Anthropometry in the Assessment of Pediatric Pectus Carinatum

Introduction or Purpose

The severity of pectus carinatum deformity is assessed by computed tomography, x-ray, three-dimensional (3D) scans, or clinical anthropometry. During orthotic treatment, pectus carinatum deformity progression or improvement is often assessed with clinical anthropometry. A strong correlation has been established between deformity severity assessed by 3D scans and radiographic imaging [1-3]. However, correlation between measurements from 3D scans and clinical anthropometry has not yet been determined. This study aimed to assess the correlation between clinical anthropometry and 3D scan- derived measurements of pectus carinatum.

Methods

Participants: This is a retrospective cohort study of patients evaluated for pectus carinatum orthotic treatment. This study was approved by the Institutional Review Board of the University of Michigan.
Procedures: We reviewed the medical records of 86 patients who were treated with a pectus carinatum orthosis. The anterior-posterior and medial-lateral chest dimensions and chest circumference at maximum protrusion of the deformity were taken using two measurement Methods: manually by the treating clinician and from a 3D scanned model of the chest, assessed separately by a different clinician and a researcher.
Data Analysis: The Pearson's correlation coefficients were calculated to assess the strength of the relationship between the clinical anthropometry and the 3D scan-derived measurements. The intraclass correlation coefficient was used to measure the reliability of measurements among the three raters.

Results

There is a strong linear relationship between clinical anthropometry and 3D scan-derived measurements for all three chest measurements. Pearson's correlation coefficients for chest circumference (r = .90 - .93), medial-lateral dimension (r = .83 - .84), and anterior-posterior dimension (r = .81 - .88) all showed a strong positive correlation (Figure 1). Intraclass correlation coefficients showed excellent reliability of measurements among the raters (ICC = .81 - .98) (Table 1).

Discussion/Conclusion

Previous studies have demonstrated strong correlations between 3D scan- derived measurements and radiographic imaging, confirming the validity of the use of 3D scans as a non-invasive, radiation-free technique to assess pectus carinatum [1-3]. The present study compared clinical anthropometry with 3D scan-derived measurements and found that assessment of pectus carinatum deformity using clinical anthropometric measurements, performed by the treating clinician, demonstrates a strong correlation with and is highly consistent with measurements obtained from 3D scans. The strong correlation between clinical anthropometry and 3D scan-derived measurements, in combination with the correlation between 3D scans and radiographic imaging, helps to validate the use of clinical anthropometry and suggests that it is an effective method of monitoring treatment progress.

Significance

This finding holds significant value for both clinicians and researchers, as clinical anthropometry is a widely used and trusted method for evaluating changes in, or the progression of, pectus carinatum deformity during treatment. Clinical anthropometry offers several advantages over other Methods: it is cost- effective, time-efficient, easily accessible, and poses minimal risk to patients. The confirmation of its reliability and effectiveness in assessing the magnitude of pectus carinatum deformity provides reassurance for its continued use in clinical practice.

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Figure 1: Scatter plot correlation of clinical anthropometry versus measurements from 3D Scan, assessed by both clinician and researcher
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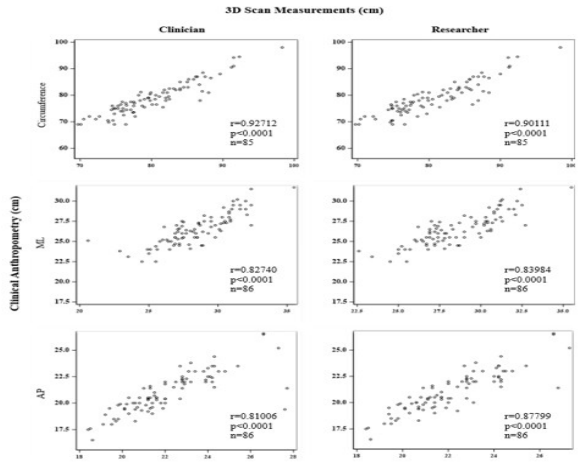

Figure 1: Scatter plot correlation of clinical anthropometry versus measurements from 3D Scan, assessed by both clinician and researcher

	Rater Groupings															
	Clinical anthropometry Clinician 3D scanned measurements Researcher 3D scanned measurements				Clinician 3D scanned measurements Researcher 3D scanned measurements				Clinical anthropometry Clinician 3D scanned measurements				Clinical anthropometry Researcher 3D scanned measurements			
	n	ICC	Lower	Upper	n	ICC	Lower	Upper	n	ICC	Lower	Upper	n	ICC	Lower	Upper
Circumference at max protrusion	85	.93	.91	.95	86	.98	.97	.99	85	.92	.89	.95	85	.90	.85	.93
ML at max protrusion	86	.86	.81	.90	86	.94	.90	.96	86	.81	.72	.87	86	.82	.74	.88
AP at max protrusion	86	.87	.82	.91	86	.92	.88	.95	86	.81	.72	.87	86	.88	.82	.92

Table 1: Intraclass correlation coefficient (ICC) of maximum protrusion variables between assigned rater groupings

Table 1: Intraclass correlation coefficient (ICC) of maximum protrusion variables between assigned rater groupings
UUILVLHB-2074582-2-IMG(2).png

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Developing New Low-Cost Sensing Platforms For Patient-Specific Orthotic Applications

Introduction or Purpose
Diabetic foot ulcers (DFUs) are a leading cause of hospitalization and amputation among individuals with diabetes, underscoring the urgent need for effective early detection and monitoring solutions. While various diagnostic Methods exist—such as thermography and plantar pressure systems—many lack integration into wearable, reimbursable platforms. This work presents the development of a novel, flexible insole system embedded with carbon nanotube (CNT)-based capacitive sensors, designed for real-time plantar pressure monitoring within orthotic footwear. The system aims to enable early identification of high-risk pressure zones that can lead to DFU formation. By leveraging CNT/Ecoflex composites, our insole prototype offers high sensitivity, stability under cyclic loading, and repeatable performance across varied weight and pressure profiles. This research introduces a scalable, patient-friendly solution aligned with current orthotic manufacturing workflows, with the potential to enhance clinician decision-making and reduce long-term healthcare burdens related to DFUs.

Methods
A capacitive pressure sensor was developed using carbon nanotube (CNT) composites embedded within elastomeric matrices of PDMS and Ecoflex.
CNTs were dispersed in isopropyl alcohol and incorporated into the polymer base to form a 3 wt% composite, which was cured using laser-micromachined acrylic molds. The composite materials were characterized for morphology and dispersion using TEM, SEM, and laser confocal microscopy. Mechanical performance was evaluated through tensile and cyclic loading tests, while electrical response was assessed via capacitance measurements across multiple pressure levels. Based on superior performance, CNT/Ecoflex was selected for integration into a custom orthotic insole prototype. Sensors were embedded in key foot regions (metatarsal, mid-arch, heel) and connected to capacitance meters. The prototype was tested with human volunteers of varying foot sizes and weights, and pressure distribution data was processed using Python-based heat mapping to assess sensor responsiveness and repeatability under physiological conditions.

Results
he CNT/Ecoflex composite demonstrated superior performance in terms of sensitivity, mechanical flexibility, and stability compared to CNT/PDMS. The selected 3 wt% CNT/Ecoflex sensors showed high pressure sensitivity (2.38– 3.40 kPa^{-1}) across a sensing range of 0–68.95 kPa, with consistent capacitance responses under repeated cyclic loading.

Tensile testing confirmed the material's suitability for wearable applications, with elongation over 120% and stable stress-strain behavior. A 12-sensor insole prototype was successfully fabricated and integrated into an orthotic boot, capturing real-time pressure data during volunteer testing. Capacitance outputs correlated with body weight and foot contact regions, with heat maps revealing distinct pressure patterns across metatarsal, mid-arch, and heel zones. The sensors demonstrated reliable performance with low variability across multiple cycles and users, validating their potential for continuous DFU risk monitoring in clinical and at-home settings.

Discussion/Conclusion

This study introduces a custom-built pressure sensing insole using a flexible carbon nanotube and Ecoflex composite, designed to monitor high-risk pressure zones in the feet of individuals with diabetes. Unlike rigid, off-the-shelf sensors, our approach prioritizes comfort, stretchability, and reliability— essential features for integration into everyday orthotic use. The CNT/Ecoflex sensors demonstrated strong sensitivity (2.38–3.40 kPa^{-1}), excellent durability under repeated loading, and consistent readings across different pressure levels and sensor batches. Mechanical testing confirmed that the material could withstand foot movement without degrading, and user trials showed the system could accurately detect variations in pressure related to body weight and foot anatomy. Heat maps created from volunteer data highlighted specific pressure patterns across the metatarsal, arch, and heel regions, supporting the sensor's real-world applicability. Importantly, the insole fits seamlessly into existing orthotic boots, making it a practical solution for future clinical use. By enabling early detection of pressure buildup—before wounds form—this system has the potential to significantly reduce the burden of diabetic foot ulcers, offering a smarter, more proactive approach to patient care than current commercial technologies can provide.

Significance

Diabetic foot ulcers are a major driver of hospitalizations and amputations, yet effective, accessible tools for prevention remain limited. Many current technologies—while clinically valuable—are cost-prohibitive and constrained by reimbursement challenges, limiting their widespread adoption. This work addresses that barrier by developing a low-cost, flexible sensor platform designed for integration into orthotic footwear. By leveraging affordable materials and scalable fabrication methods, this system offers a practical alternative to expensive, off-the-shelf sensor platforms. Its custom design enables accurate, real-time pressure monitoring in high-risk foot regions while remaining compatible with existing orthotic workflows. The result is a wearable solution with the potential to extend ulcer prevention to more patients, reduce long-term healthcare costs, and sidestep traditional reimbursement bottlenecks—ultimately improving outcomes through earlier intervention and smarter, more proactive care.

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BKA Pre-surgical, OR Techniques, and Post-op Protocols to Advance Patients' Independence and Increased K-level

Introduction or Purpose

This presentation represents several medical teams of clinical care for "new" BKA protocols/procedures, with a prosthetist and physical therapist being integral practitioners in all teams while "creating" techniques to help/advance BKA patient recovery and independence.

Methods
Pre-operative consults with patients, family members and primary care providers and/or surgeons. Pre-operative Physical therapy with strengthening exercises, range of motion and learning to ambulate with a "bent-knee" product, as is possible OR viewing of amputation surgery with input/suggestions, observations of vascularity/coloration of remaining limb and specific dressings following closure Close attention to post-op recovery of residual limb, amount and color of exudate from suture line and observing patient's recovery from anesthesia Excercise, range of motion and partial weight-bearing as possible, as determined by team. Physical and occupational therapy in in-patient rehab hospitals, nursing homes, home health care.

Results
Most patients start partial weight-bearing, in parallel bars, within 5-10 days following surgery
Most patients attain full weight-bearing within 10-15 days post-op Most patients attain K3-K4 within a year, post-op

Discussion/Conclusion
After 2-3 months of creating/working together with several specialists, our teams created opportunities for patients to heal their BKA and start using a prosthesis 3 to 6 months earlier than previous outcomes.
Procedures in the OR nearly eliminated the complications of short tibias (short lever arms and residual muscle tissue), minimal to non-existing "dog ears" and reduction of post-operative pain/discomfort while aiding internal "bleeding" pressures that typically causes dehiscence of suture lines.

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Case Studies of the Use of Outcome Measures as Clinical Diagnostics to Demonstrate Medical Necessity.

Introduction or Purpose
Demonstration of the medical necessity of interventions for individual patients is a key requirement of insurance coverage policies. By experience, many prosthetists and orthotists struggle with the understanding of the concept of medical necessity and meeting its requirements for healthcare payor approval. This paper will present three case studies of how outcome measures were used as clinical diagnostics to establish medical necessity and obtain insurance approval of the respective claims.

Methods
CPOs who received denials of their claims for prosthetic or orthotic devices from healthcare insurances sought support of the Reimbursement Department of Ottobock. After review of the medical and prosthetic/orthotic records and a phone interview of the patients, the reimbursement specialists gave advice on what unmet patient needs to document and what clinical tests and questionnaires to assess to demonstrate medical necessity of the prosthetic/orthotic devices requested. The individual cases were followed until a final decision of the payor was obtained.

Results
Three case studies whose claims were originally denied by the patients´ insurances will be presented:
a patient with a transtibial amputation using a suction socket but requesting a socket with elevated vacuum,
a patient with a paresis of leg muscles after spinal surgery using a locked KAFO but requesting a C-Brace, and
a patient with a transtibial amputation requesting a replacement of his powered prosthetic foot.
The phone interviews found that the records of all three patients were missing important unmet needs that helped establish medical necessity of the requested devices, such as falls and fall-related injuries, pain, and restrictions to the daily routine and work. Assessments of suitable patient-reported instruments over the phone, such as the Activity-specific Balance Confidence (ABC) scale, numerical pain rating scales (NPRS), and the Patient-specific Functional Scale

(PSFS) for activities of daily living important to the individual patients´ lives as well as performance-based tests in the clinics, such as the Timed-up-and-go test (TUG) or the 10m walk test helped establish medical necessity that ultimately resulted in approvals of the requested devices by the patients´ insurances.

Discussion/Conclusion

Medical necessity means to weigh unmet patient needs and potential benefits of an intervention against its potential risks to protect patients from unnecessary adverse effects. Healthcare payors have adopted this concept to control access to interventions they consider "too expensive". Proper understanding and leveraging the components of medical necessity and clinical diagnostics help overcome that barrier and increase approval rates of prosthetic and orthotic technology for the benefit of patients.

Significance

Knowledgeable use of evidence-based practice and clinical diagnostics yields a great potential to improve the quality of clinical care and business Results in O&P.

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Testing in Tight Quarters: Feasibility of the 2-Minute Step Test in Prosthetic Practice

Introduction or Purpose

Among adults with lower-limb amputation (LLA), assessment of cardiorespiratory fitness is a key component of determining functional mobility classification, for which the 6-Minute Walk Test (6MWT) is often used.(1) Though the 6MWT is a valid, reliable measure, its space requirements limit clinical utility.(2) An alternative may be the 2-Minute Step Test (2MST), which has minimal space and equipment requirements.(3) This study aimed to investigate the clinical utility of the 2MST among adults with unilateral transtibial LLA.

Methods

A total of 24 adults with unilateral transtibial LLA (aged 57.5 [25th, 75th percentile: 50.3, 64.5] years; 54.2% male; 8.5 [25th, 75th: 4.2, 32.8] years since amputation) completed the 2MST. Heart rate was monitored continuously using 3-lead electrocardiography, and immediate pre-and post-test vitals were taken using an automatic sphygmomanometer and a pulse oximeter.

Results

Of the 24 participants, 22 (91.7%) were able to complete the 2MST. Two female participants stopped the test early: 1 due to hip pain and 1 due to shortness of breath. Of the 22 participants (77.2%), 17 required touch stability on the wall. The median number of steps taken was 100.5 (25th, 75th: 88.3, 111.0), and participants reached 84.3% (25th, 75th: 74.6%, 101%) of their age- predicted maximum heart rates. Vital sign response to submaximal testing was within normal limits for most participants (Table 1). Two individuals had exaggerated but asymptomatic blood pressure responses, i.e., post-test diastolic blood pressure >120mmHg.

Discussion/Conclusion

The majority of participants were able to complete the 2MST, indicating the test may have clinical utility in prosthetic practice. Due to balance-related concerns, the majority of participants required modification to the testing protocol to allow touch stabilization on the wall.

The peak heart rate was higher than that observed during 6MWTs,(4) indicating moderate-to-high degree of exercise intensity. While heart rate and blood pressure increased significantly from pre-test values, diastolic blood pressure and oxygen saturation remained stable in most participants. Two individuals had post-test diastolic blood pressures consistent with a hypertensive crisis, despite being asymptomatic. These individuals remained seated, at rest, until blood pressure returned to normative ranges. These asymptomatic but concerning responses indicate the need for monitoring of vital signs when performing cardiorespiratory testing after LLA.

Adults with LLA performed well below the normative average for adults aged 60-64 without LLA,(3) i.e., 182 steps for females and 202 steps for males. This is consistent with findings that adults with traumatic LLA perform worse on the

6MWT than matched peers.(5) Reduced performance on the 2MST may indicate reduced cardiorespiratory fitness after LLA,(6) or may be a product of hip flexor weakness and/or prosthesis-induced limitations in knee range of motion. Further research is needed to determine validity and reliability of the 2MST among adults with LLA, and to establish normative values for each functional level classification.

Significance

The 2MST is relatively safe and well-tolerated among adults with LLA and may be a viable alternative to the 6MWT. Monitoring of vital signs and allowance of touch for stability is recommended in this population.

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Table 1. *Vital sign response to the 2-Minute Walk Test among adults with unilateral transtibial amputation (n=22)*

Vital Sign	Pretest	Posttest	p
Heart Rate, bpm	76 (69, 83)	94 (95.75)	<0.001*
SBP, mmHg	126 (115, 154)	154 (142, 169)	<0.001*
DBP, mmHg	75 (69, 84)	75 (67, 83)	0.398
SpO_2, %	97 (96, 98)	97 (96, 98)	0.942

Data presented as median (25^{th}, 75^{th} percentile).
Abbreviations: bpm=beat/minute; SBP=systolic blood pressure; DBP=diastolic blood pressure; mmHg= millimeters of mercury; SpO_2=oxygen saturation
**p<0.050*

Table 1. Vital sign response to the 2-Minute Walk Test among adults with unilateral transtibial amputation (n=22)
UUILVLHB-2065016-1-IMG(1).png

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Performance of Bilateral Transtibial Prosthesis Patients on Clinical Outcome Tests

Introduction or Purpose

Several clinical outcomes tests exist to help clinicians evaluate the performance of patients who use lower extremity prostheses. Often, a patient's performance during these clinical outcome measures can be compared to normative data and relate to the likelihood of falls or K-level, which can help their rehabilitation and device selection and justification. To date, little data exists showing how patients with bilateral amputation or limb differences perform on clinical outcome tests.

Methods

To date, 13 persons with bilateral transtibial amputation or limb difference have completed the research protocol. Data is collected across four data collection visits occurring in two-week intervals. At each visit, the tests are performed with different foot conditions. A sequential study design (A-B-A) was completed by all participants, where A is their usual prosthetic foot, and B is an investigation foot. The investigational foot has an ankle mechanism with frontal plane motion, and participants complete two two-week phases with the B condition in randomized order: one where the ankle is unlocked and one where the ankle is locked. At each data collection visit, the 10-meter walk test, the three times figure of eight, the four square step test, and the Timed Up and Go Test (TUG; once turning right and once turning left) were completed. The AMP-Pro was also collected during the first study visit to quantify K-Level.

Results

The average completion time for these 13 participants on the 10-meter walk test was 9.6 +/- 2.2 seconds or 1.04 m/s. The average completion for the 3 Times Figure of Eight Test was 25.8 +/- 6.6 seconds. The average completion time for the

Four Square Step Test was 15.6 +/-4 seconds. The average completion for the turning left and right TUG was 11.2 +/- 3.8 seconds and 10.7
+/- 3.5 seconds, respectively. There was no meaningful difference in the time to complete these tests with any of the foot conditions. While the averages over the sequential visits slightly decreased from visit 1 to visit 4, there does not appear to be a significant learning effect.

Discussion/Conclusion

The bilateral transtibial patient population in the study could complete the tests in times that compared well against the reported literature of non-bilateral populations. The predicted K-level calculated by the AMP-Pro matched the K- level thresholds predicted by the 10-meter walk test. Further, only one trial of the Four Square Step Test for all subjects was over the 24-second mark, the established threshold for predicting an increased risk of falls. While the times did not show a difference between foot conditions, other data collected, such as gait mat data during each of these tests, a daily log book with rating and open response questions during each 2-week at-home period, and classification of exit interview data should be analyzed before conclusions can be drawn between feet.

Significance

This work is the largest study population of bilateral transtibial prosthesis patients known to the authors. The data suggests that the K-level thresholds for the 10-meter walk test can be applied to a bilateral transtibial population Providing this data will help clinicians by providing a data set that can be referenced when evaluating their patients in the clinic.

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Walking On Different Inclines: How Do Transfemoral Amputees Adapt Their Gait? – A Biomechanical Study

Introduction or Purpose

Compared to walking on level ground, walking on ramps requires an adaptation of the gait pattern, which is associated with increased muscle strength and an increased range of motion (ROM) in the lower extremity [1,2]. In addition, walking on slopes requires greater balance and increases the risk of slipping [3]. These factors can pose a particular challenge for transfemoral amputees (TFAs) due to the lack of sensitive feedback as well as unfavourable lever ratios and functional limitations of the prosthetic components [4].
The purpose of this study was to identify inclination-dependant gait adaptations for transfemoral amputees when walking up and down slopes with state-of the- art prosthetic components.

Methods

Eight unilateral TFAs and a reference group of 12 non-amputated persons participated in this study. All TFAs used the prosthetic knee joint Genium or Genium X3 (Ottobock) and a conventional energy-storing and returning foot. Walking on level ground, 2.5°, 5°, 7.5°, and 10° (up and down) with self- selected gait speed was analysed. Kinematic and kinetic parameters were recorded with an optoelectronic camera system and piezoelectric force plates.

Results

Functional limitations of the prosthetic fittings lead to altered gait patterns and compensation strategies that showed inclination-dependent systematics. The lack of adaptation of the prosthetic knee joint at prosthetic side initial contact and the limited ROM of the prosthetic foot led to various compensation mechanisms when walking upslope, such as a decreasing stride length, an increasing contralateral plantar flexion in late stance and an increasing vaulting movement of the contralateral leg. These compensations are accompanied by overloading of the contralateral side. When walking downslope, the yielding gait strategy is more frequently used as the inclination increases. The inclination from which

yielding is used varies between the subjects. The knee and hip dynamics are significantly altered by this strategy compared to the reference group.

Discussion/Conclusion

The study shows that there is still room for improvement in the functionality of prosthesis fittings in order to further reduce compensatory movements and overloading of the contralateral side when walking on inclines. Future studies with adaptable and active prosthetic components could provide interesting insights into the extent to which prosthesis users could benefit from these systems.

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Effects of Pin-Lock and Vacuum Suspension Systems on Gait Biomechanics in a Unilateral Transtibial Amputee

Introduction or Purpose

Prosthetic suspension methods significantly impact gait biomechanics, influencing movement efficiency and load distribution. This study investigates how different suspension systems, specifically the Pin-Lock (PIN) and Vacuum Suspension (VIP, ALPS south) systems, affect gait characteristics in a unilateral transtibial amputee.

Methods

A single transtibial amputee with left-side limb loss participated in this case study. Walking trials were conducted under two conditions: wearing a prosthesis with a PIN suspension system and with a VIP suspension system. Gait data were collected using an optical 3D motion capture system and force plates. Temporal-spatial parameters and ground reaction forces (GRFs) were analyzed. Time-series data were normalized to one gait cycle, and Statistical Parametric Mapping (SPM) was applied to detect significant differences between the two conditions.

Results

The VIP system led to a significantly higher walking speed and longer stride length compared to the PIN system. Additionally, knee flexion angles during both the stance and swing phases were greater with the VIP system. Analysis of GRFs revealed that the VIP system reduced asymmetry in both vertical and anterior-posterior force components.

Discussion/Conclusion

The VIP suspension system enhanced gait performance, likely due to improved socket-limb adhesion, reducing movement lag and increasing responsiveness. Furthermore, the reduction in GRF asymmetry suggests a decreased load on the sound limb, potentially minimizing long-term musculoskeletal strain. These findings provide valuable insights into optimizing prosthetic suspension for improved gait efficiency and comfort in transtibial amputees.

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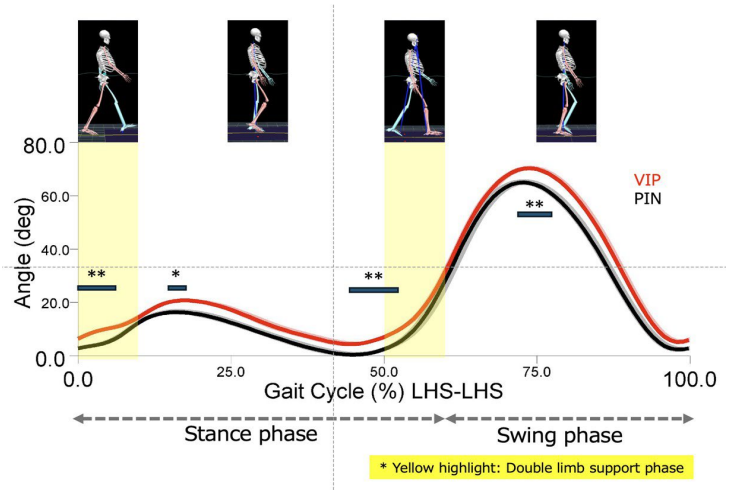

Comparison of knee joint flexion angles on the prosthetic side (leg in blue, *p<0.05, **p<0.001)
UUILVLHB-2077525-1-IMG(1).png

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Is The Improvement In Comfort For Transfemoral Sub-Ischial Sockets Maintained In The Long Term?

Introduction or Purpose
The prosthetic socket is key element for patient comfort. Various designs are available for above-knee amputees (AKA). Subischial sockets are one of the most recent designs for AKA [1]. Comfort is paramount to socket design but is mostly studied on short term, from instantaneous feedback [2] to after a 7-week acclimation period [3]. Subischial sockets have been studied for about 10 years, but no literature reports long term feedback.
The aim of this study is to provide an answer to the research question: How does the comfort of AKA evolve after more than a year of daily use of a subischial socket? How does it compare to short-term comfort assessment?
Methods
A previous clinical investigation, randomised cross-over trial, comparing comfort of AKA using ischial containment (IC) vs subischial (ISUB) sockets, was run in 2021-2022 [4]. Subjects participating in this previous study and having kept ISUB as their everyday prosthesis were contacted by the investigator. After giving their informed consent, they were asked which socket type they currently wore. In a single visit consisting of a phone call, they answered the same questions as in the previous study regarding Socket Comfort Scores (SCS) [5] in various situations.
The difference between SCS (current long-term ISUB – previous study short- term ISUB), was processed: after checking data distribution, Student or Wilcoxon tests are used. Significance is set for a $p < 0.05$.
Long-term ISUB SCS was also compared to long-term IC SCS (rated at the initial visit of previous investigation).
Results
Among the 23 potential subjects having finished the previous clinical investigation, 16 were successfully reached. 4 could not be included or did not wish to participate. 12 subjects were included: 10 males and 2 females, age

62.67 ± 13.92 y.o, mass: 77.68 ± 15.15kg, height: 1.76 ± 0.06m, wearing their prosthesis 11.6 ±3.04h/day. At the time of the assessment, patients were wearing ISUB for 22.08 ± 9.51months.
After more than a year of use, socket comfort score with ISUB decreased but not significantly, compared to SCS with ISUB after 2 weeks of use: -0.50±1.00 (p=0.1) (Figure 1).
The long-term ISUB SCS was significantly improved compared to long-term IC SCS: +1.58 ±1.78 (p=0.005) (Figure 1).

Discussion/Conclusion

Socket Comfort Scores were not significantly different after 2 weeks or more than a year using subischial sockets. Comfort provided by subischial socket is still significantly improved in the long-term compared to ischial containment: originally, short-term comfort assessment was significantly improved with ISUB compared to IC +1.78(±2.54). Despite a slight decrease over time, average comfort score with ISUB, in all evaluated daily situations, is above 7.5/10. In the long-term, there is no more wow effect, the difference between sockets scores is attenuated, but ISUB is still significantly more comfortable than IC.

Significance

Short-term Socket Comfort Scores may be a good predictor for long-term comfort for above-knee prosthesis socket users.

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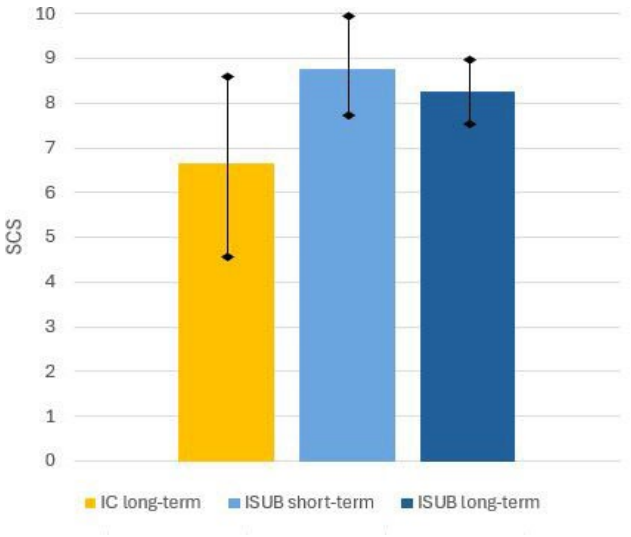

Socket Comfort Score with ischial containment (IC) (yellow) and subischial (ISUB) sockets, short-term (light blue) and long- term (dark blue)
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Gait Variations Among Adults with Lower Limb Amputation and Chronic Low Back Pain

Introduction or Purpose

Chronic low back pain (cLBP) is a major cause of secondary disability for adults with unilateral lower-limb amputation

(LLA), occurring in >50% post- LLA.(1,2) Adults with unilateral transtibial amputation (TTA) may be at higher risk for cLBP when compared to peers with transfemoral amputation (TFA).(3) While previous work evaluating post-amputation cLBP has focused on spinal kinematics and changes in low back musculature,(3,4) less is known about cLBP and its impact on gait, including whether differences exist by amputation level. This study explores spatiotemporal gait parameters during the 6 Minute Walk Test (6MWT) among adults with and without cLBP, while considering LLA level.

Methods

Adults ≥1-year post-unilateral TTA or TFA (n=41, 61.0 [25th, 75th percentile: 41.0, 69.0] years-old, 78% male, 54% TFA, 7.7 [25th, 75th: 3.0, 21.0] years post-LLA, 41.5% traumatic cause) consented to participation, reported on cLBP, and underwent instrumented gait analysis (Mobility Lab, APDM) during the 6MWT, a reliable and valid measure of walking endurance. The average value of spatiotemporal gait parameters was taken across all test strides.

Between-group differences, i.e., TTA versus TFA, in gait parameters and distance walked were assessed, and between-group differences, i.e., cLBP presence or absence, in gait were also evaluated using Mann-Whitney U-tests ($p \leq 0.050$).

Results

Adults with TTA reported cLBP more frequently than peers with TFA, i.e., 84% versus 45%, respectively, but had more symmetrical gait (p=0.001). There were no significant differences in 6MWT distance between amputation levels (p=0.565). Among adults with TTA, those with cLBP walked shorter distances ($p < 0.001$). Adults with TTA and cLBP had slower cadence, shorter stride lengths and longer gait cycles bilaterally, and shorter amputated-side single- limb support (Table 1), compared to level-matched peers without cLBP. With TFA, gait did not significantly differ (p=.346-1.000) between adults with (n=10) and without cLBP (n=12).

Discussion/Conclusion

Though adults with TTA presented with more gait symmetry than peers with TFA, adults with TTA were twice as likely to report cLBP. Adults with TTA have altered trunk dynamics and hip adductor weakness,(5) as well as increased spinal loads compared to individuals without LLA,(6) which may lead to cLBP. Among adults with TTA, cLBP presence is associated with worse walking endurance and slower gait, achieved via a combination of reduced cadence and stride length. This may be due to a need to reduce trunk range of motion for enhanced stability, as is seen among adults with cLBP in the general population.(7) Early focus on spinal stability during TFA rehabilitation may improve trunk muscle recruitment and stabilization, thereby reducing the functional impact of cLBP.(3, 7) Surprisingly, with TFA, our preliminary data suggest cLBP presence is not associated with walking endurance or gait parameters.

Significance

Results suggest the potential for addressing cLBP among adults post-TTA to enhance gait and walking endurance.

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Table 1. Gait Parameters during the 6MWT in Adults with TTA (n=19).

	cLBP	No cLBP	p-value
6MWT Distance, m	376.5 (285.6, 407.6)	565.2 (528.0, 701.5)	0.002*
Cadence, steps/min	105.8 (92.5, 108.6)	121.1 (111.7, 138.4)	0.008*
GC, sec			
Amputated-side	1.14 (1.12, 1.30)	0.99 (0.87, 1.07)	0.004*
Contralateral-side	1.14 (1.12, 1.30)	0.99 (0.87, 1.07)	0.004*
Single-limb Support, % GC			
Amputated-side	36.49 (33.93, 38.06)	40.61 (38.77, 42.19)	0.004*
Contralateral-side	37.47 (35.41, 38.30)	40.03 (37.75, 40.83)	0.064
Stride Length, m			
Amputated-side	1.17 (1.01, 1.27)	1.38 (1.32, 1.84)	0.008*
Contralateral-side	1.17 (1.05, 1.25)	1.44 (1.31, 1.77)	0.008*

*Data presented as median (25^{th}, 75^{th} percentile). GC=gait cycle. *$p \leq 0.050$.*

Gait Parameters during the 6MWT in Adults with TTA (n=19).

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Effects of Different Prosthetic Knee Joints on Gait Biomechanics

Introduction or Purpose
Prosthetic knee joints play a crucial role in determining gait biomechanics, affecting walking efficiency, stability, and overall mobility. This study investigates the biomechanical differences in gait performance when using three different knee joint systems—C-Leg, Kenebo (ottobock.), and ProStride (Alps south)—in a unilateral transfemoral amputee. The aim is to extract the unique characteristics of each knee joint and assess their influence on gait parameters.
Methods
A single case study was conducted with a transfemoral amputee (left-side limb loss). The participant performed five walking trials using three different prosthetic knee joints: C-Leg, Kenebo, and ProStride. Gait data were collected using an optical 3D motion capture system and force plates. Temporal-spatial parameters and knee joint flexion-extension angles were analyzed to compare the three conditions.
Results
Walking speed was highest with ProStride (1.26 m/s), followed by C-Leg (1.15 m/s) and Kenebo (1.14 m/s). Similarly, stride length was longest with ProStride (1.46 m), compared to C-Leg (1.37 m) and Kenebo (1.37 m). Regarding knee flexion-extension angles, mild knee flexion during the stance phase was observed with both C-Leg and Kenebo, but not with ProStride. Additionally, knee extension velocity during the swing phase was highest with ProStride compared to the other two knee joints.
Discussion/Conclusion
The results suggest that the ProStride knee joint may facilitate a more dynamic and extended gait pattern, leading to increased walking speed and stride length. However, the absence of stance-phase knee flexion in ProStride could indicate reduced shock absorption upon heel contact, potentially affecting user comfort and joint loading. In contrast, C-Leg and Kenebo allowed for mild stance-phase knee flexion, which may provide greater shock absorption and stability during weight acceptance. Additionally, the higher knee extension velocity in ProStride during the swing phase may contribute to a more energy- efficient gait cycle but could also impact gait smoothness.
These findings highlight the trade-offs among different prosthetic knee designs. While ProStride may enhance forward propulsion and efficiency, C-Leg and Kenebo might offer superior stability and impact absorption. The selection of a prosthetic knee joint should consider both the user's mobility goals and biomechanical factors to optimize gait performance and comfort.

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Improvements In Gait Stability After Using Sensory Feedback For Prosthetic Legs

Introduction or Purpose

In the last decades, sensory feedback has been a focus of research and development for prosthetic limbs [1,2,3]. However, it is still not widely used and there is only rare clinical evidence showing the practical benefit for the prosthesis user.

Methods

In this summary of 98 case studies, the changes in gait stability and safety through the use of a sensory feedback system were observed in people with leg amputations. Three different functional gait tests, the Four Square Step Test (FSST), the Timed "Up & Go" Test (TUG), and the Vienna Traffic Light Test (VTLT), were performed before and after the use of the sensory feedback system for at least 30 days in their daily life. The statistical effect size was calculated using a Bayesian general linear mixed model.

Results

Figure 1 shows the changes observed in people after 30 days of using the sensory feedback system. 81% of users (79 people) improved in the FSST, 86% (84 people) in the TUG test and 74% (72 people) in the VTLT. Of these, 39%, 15% and 18% were certain improvements. Taking individual fluctuations into account, Figure 3 shows that 41% of users (40 people) benefited safely from the use, while only 1% of users (1 person) experienced disadvantages. Overall, 72% of users (71 people) improved across all three gait tests.

Discussion/Conclusion

The improved test times with and after using the sensory feedback system show that gait stability, safety and speed of movement increased significantly within just one month. For people with a lower limb amputation, these improvements are directly associated with an improved quality of life and increased participation in public and social life.

Significance

This talk shows clinical data highlighting the benefits of using sensory feedback for prosthetic legs.

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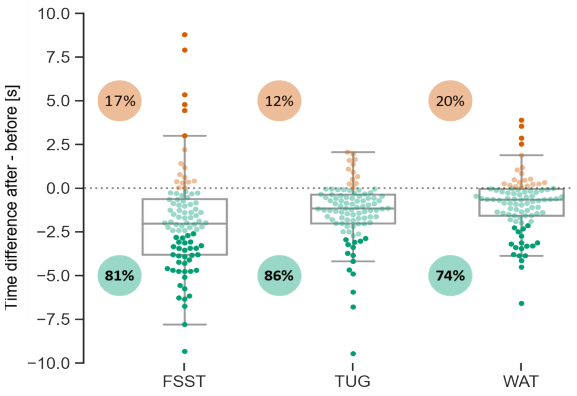

Change in individual best times for various tests of functional gait performance. The dark green dots represent definite improvements and the dark red dots definite deteriorations . The light green and light red dots indicate medium to small improvements or deteriorations.

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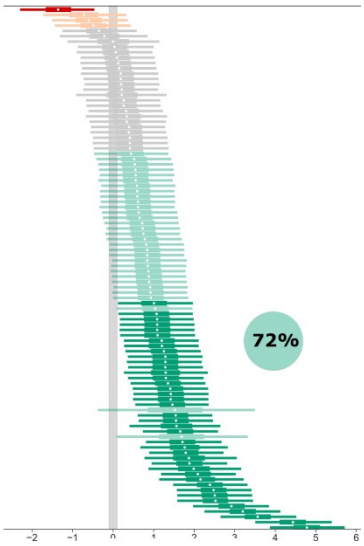

deteriorated< -0.1 < 0.1 < improved Effect size
Illustration of the effect size of the before/after change in individual users for all three tests. Dark-colored 95% highest density intervals that lie outside ± 0.1 indicate a change.
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Microprocessor Knee Receipt Within 12 Months Post-Amputation is Associated with Greater Odds of Employment for Individuals Living in Distressed Communities

Introduction or Purpose
Individuals post-amputation have low rates of returning to work, possibly due to limited recovery of functional mobility. Return to employment may improve overall wellbeing of the individual, increase financial independence, and reduce reliance on publicly sponsored disability and health care programs. These benefits may be more critical to individuals living in distressed communities coping with high unemployment and poverty rates. Therefore, prosthetic rehabilitation that facilitates return to work is an important goal post- amputation. This study sought to investigate the impact of microprocessor knee provision in the first 12 months post-amputation on employment status in distressed communities.
Methods
A retrospective chart analysis of 357 individuals with transfemoral amputations living in distressed communities across the United States was performed. The regression model included age, sex, mobility, insurance type, and prosthetic knee type as independent variables and employment status as the dependent variable. Community distress was determined by patient ZIP code and the Distressed Communities Index (DCI).
Results
Individuals living in distressed communities who received a microprocessor knee in the first year post-amputation had 2.75 times greater odds of being employed than those who received a non-microprocessor knee. Younger age, higher mobility, and commercial insurance further contributed to greater odds of being employed.
Discussion/Conclusion
Receipt of a microprocessor knee is associated with increased odds of employment, even when controlling for age, mobility, and insurance type. Increased provision of microprocessor knees may facilitate improved rates of returning to work for individuals post-amputation living in distressed communities.
Significance

These findings should be considered by clinicians when creating rehabilitation plans for individuals with transfemoral amputation. Specifically, understanding how the living environment for the patient can contribute to or hinder the patient's goals, and how certain devices such as MPKs can help to overcome hurdles in achieving noted goals.

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What Are The Functional Expectations Of Above-Knee Amputee Prosthesis Users With High Activity In Their Daily Life? A Randomized Crossover Trial Comparing Microprocessor-Controlled Knees.

Introduction or Purpose

Microprocessor-controlled knee (MPK) systems have been used by active people with above-knee amputations (AKA) for decades, offering technical benefits like stumble recovery and clinical benefits such as being able to walk at variable speeds. MPK users report higher mobility and quality of life compared to those using mechanical alternatives [1], and biomechanical studies generally confirm MPK's advantages [2]. However, when comparing MPK systems to one another, it is difficult to identify differences in functional mobility or satisfaction [3]. This raises the question of how patients select their prosthesis and what is guiding their final choice.

The aim of this study is to assess patient's functional mobility in their chosen daily life situations with different MPK systems. We hypothesize that users will rate their achievement of daily life personal objectives differently depending on the MPK system used.

Methods

A randomized controlled trial was conducted in five rehabilitation centers in France to assess the QUATTRO MPK compared to other MPK solutions.

Patients with K3-K4 activity levels using an MPK were recruited to participate in this crossover trial. Subjects wore each MPK (current and QUATTRO) for a minimum of four weeks of daily use to allow for adaptation. At the first visit, they were asked to determine their specific functional objectives, using the patient-specific functional scale (PSFS) [4] [5]. At each evaluation session, they were asked to rate their ability to achieve each goal on a scale from 0 = "unable to perform" to 10 = "able to perform activity without any restriction". All objectives across the entire cohort were then combined according to the type of activity or situation (e.g. ground type) to extract main benefits or limitations.

Results

18 subjects were recruited and 1 was dismissed before any assessment. Data of n=17 subjects is presented: 15 males and 2 females, age 49.6 ± 10.8 yo, weight 77.3 ± 16.9 kg, height 1.76 ± 0.08 m, time since amputation of 18 ± 15.8 years, currently wearing Ottobock C-Leg (n=11), Össur Rheo Knee (n=5) or Blatchford Orion (n=1). Sixteen subjects defined 3 personal objectives; one subject defined 2. In the end, 50 objectives were combined into eleven categories. Average score for each category was calculated for "Current" and "QUATTRO" assessments. **Results** are presented in Figure 1. Overall, all functional activities were improved with QUATTRO.

Discussion/Conclusion

All tested MPK systems are high-end products enabling more and more daily activities. Nevertheless, it seems there is a gap between claimed functions and the ability to use some of those functions: all MPKs enable walking backwards or downhill, but their scores are variable, not reaching a 10/10. Rather than a given, it should be seen as a potential feature / activity.

Rating the achievement of a function interestingly highlights that functional features are not always fulfilled as intended. Using this patient related outcome measurement (PROM) for functional mobility enabled differentiating MPK systems that can give insight into a patient's final choice.

Significance

AKA MPK users can feel and rate a difference between MPK systems in achieving some daily activities. Despite technical claims, all functions are not always easily achieved. QUATTRO seems to improve daily life activities.

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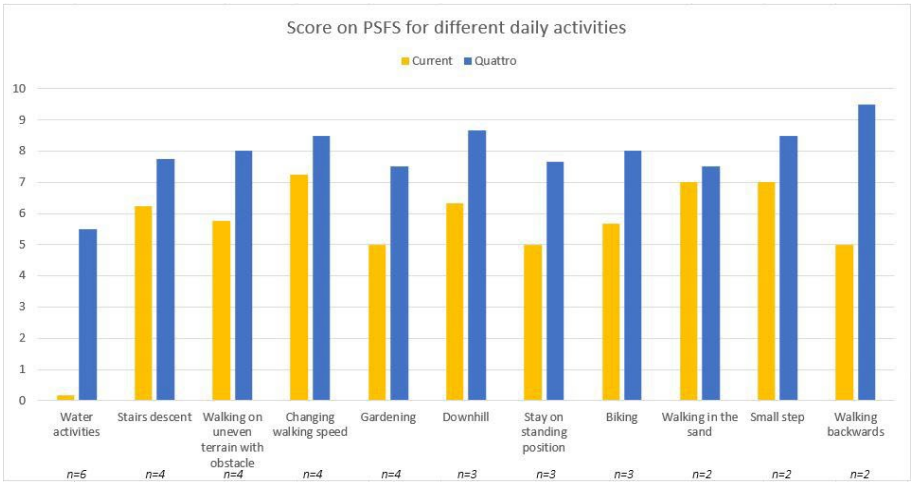

Figure 1. Average scores (from 0 to 10) on PSFS for different activity types. Current MPK (Yellow) vs QUATTRO (blue)
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Return To and Participation In Work Life Of TF Amputees Using A Microprocessor- Controlled Prosthetic Knee Joint

Introduction or Purpose

Return to work (RtW) and participation in work life (PW) are important aspects of the burden inflicted upon amputees. These effects their families, the health care/social system, and society at a large. Hence, RtW and PW are amongst the most important rehabilitation goals[1]. In Germany, this materializes in a legal entitlement to PW including the provision of the essential rehabilitation and medical aids[2]. Current research investigated characteristics favouring RtW and PW in mixed populations primarily prior to the introduction of microprocessor controlled knee components [3,4,5]. The purpose of this study was to gain a deeper understanding of PW and the potential benefits of using MPKs.

Methods

A digital survey (www.rogator.de) was sent per E-mail to participants who had prior indicated their consent. Participants were invited who used a nMPK (C-Leg/Genium, Ottobock) for at least 3 months, were older than 18 years, with or without prior prosthesis in Germany. Ouitcomes included customised Likert scales and validated instruments such as the Integration into Normal Living Index (RNL), Amputee Body Image Scale (ABIS), and EQ-5D-5L.

Results

520 participants responding to the productivity chapter of the survey were analyzed. Demographics: Mean age of the cohort was 53.75ys (SD12,6), 20% female- Etiology was trauma in 56%, vascular in 11% and in 33%. 55.96% of the respondents were employed, 11.54 % were not employed and 32.5 % retired. Mean age was 63ys, 46ys and 50. ys, respectively. 21.3 % of those who worked were retrained after the amputation. 44.3% reported that their job changed

due to amputation: 60 % changed the type of professional activity,73% reported spending most of their work time sitting. 20% indicated they usually stand and/or walk for long periods of time do moderately hard professional activities. Odds of RtW were 1.85 (p=.046) for individuals with traumatic amputation compared to other etiologies. Amputation due to vascular etiology yielded odds below 0.36 (p<.033). The likelihood of maintaining PW increased by 1.31 (p<.001) for every additional 5 y after amputation. Age at amputation was identified as a negative RtW factor, with odds decreasing by 10% (p< 0.03) for every 5ys increase. Time to definitive fitting indicates likelihood of RtW, indicating the importance of sufficient and completed rehabilitation: 3 -12 months (mo): 4.53 times compared to < 3 mo (p<.001), with individuals using Genium having 2.88 times higher chances than those with C- Leg (p=.007). After 12 mo chances for RtW decreased 4.47 times (p=.003) Higher mobility was associated with higher odds of RtW (MG4: 4.06,p<.001;MG3: 2.85 (p<.01). The use of assistive devices had a negative impact on returning to work (OR: 0.26, p<.001). Participation in all-day activities as indicated by the RNL (mean score 86.8) was positively associated with RtW (OR:1.42, p<.001). Good body image (ABIS) indicated a positive association with PW (OR:0,72, p<.01). QoL was strongly associated with RtW (OR:1,38, p<.010). Satisfaction with the MPK increased the likelihood of RtW by 3.21 times. Overall, the impairment in PW was rated low with a mean of 2.89 (9- point Likert scale, 1=no limitation, 9=full impairment).

Discussion/Conclusion

RtW and PW of individuals using a MPK in Germany was comparable to the healthy norm population. Favorable ODDs are associated with mobility grade, etiology, QoL, Body Image, appropriate fitting window, knee joint type, satisfaction with the joint and wear time. Patients' return to and participation in work life may be improved utilizing an MPK.

Significance

Integration of MPK in occupational rehabilitation should be considered for patients with the potential to participate in work life.

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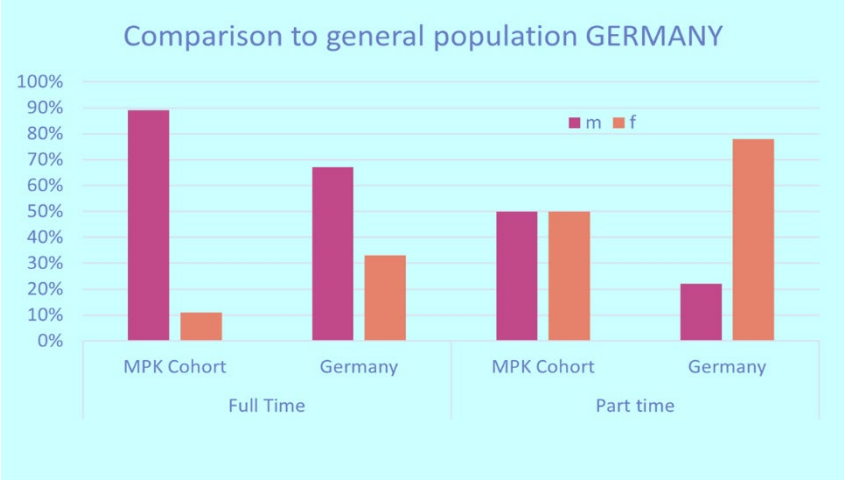

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Optimal AFO Alignment: The Necessity of Dynamic Contracture Management and Prevention to Maintain Range of Motion and Correct Knee Hyperextension

Introduction or Purpose

Soleus contractures severely limit passive ankle dorsiflexion and can lead to a plantar flexion contracture. During walking, that contracture can lead to severe knee hyperextension in stance and gait. This contracture restricts joint

mobility and can be effectively treated with the Low load Prolonged Stretch (LLPS) method, facilitating elongation of muscle chains and connective tissues. After gaining PROM a customized well aligned AFO can limit knee hyperextension, provided there is adequate dorsal flexion PROM and a minimum Quadriceps force (MRC4). The case involves a 51-year-old woman with a 30-year history of Cerebrovascular Accident (CVA) sequelae, resulting in specific deficits in dorsal flexors and a 10° plantar flexion contracture which she compensated since the beginning with high heels. Over the last two years, she developed knee hyperextension by wearing shoes with lower heel height. During stance, her hyperextension measured 18 degrees which increased during gait.

Methods

Manual Measurements of PROM with knee in 90° and 0° were executed with a goniometer before, during and after the treatment period. To treat the soleus contracture, a custom made resting AFO with a dynamic contracture MultiMotion ankle joint has been worn following the LLPS-protocol 5 to 7 hrs a day, combined with exercises, manual therapy (translation) and follow-up from the physical therapist by measuring.

To observe the impact of the plantar flexion contracture in postural control, pictures were made before the dynamic contracture management and afterwards with the tuned Triple Action ankle joint to observe the hyperextension outcome of the knee. Gait was recorded with and without the tuned AFO to evaluate the effect of the alignment and the applied 5° ROM towards dorsal flexion given in resistance on the hyperextension of the knee.During the contracture treatment, an AFO with dynamic contracture ankle joint was prescribed, and worn 5-7 hours daily following Low Load Prolonged Stretch (LLPS) protocol. The patient was able to do this protocol 5 days on 7. This aimed to elongate muscle chain and connective tissue. Active exercises, manual therapy and especially translation in the talocrural joint and a follow-up on regular base by measurements done by the physical therapist were implemented. The tension on the spring was increased by one key turn when gain in ROM stagnated. Initial goniometric measurements assessed the PROM in the ankle. Photos pre and post dynamic contracture management evaluated plantar flexion contracture's impact on postural control. Recorded gait analysis evaluated the AFO's effect. **Results** showed a significant 15° increase in dorsal flexion PROM.. Static alignment in the triple action joint was adjusted to 5° anterior inclination added to 1 cm heel height, combined with 5° of Dorsal flexion ROM (resistance). This corrected knee hyperextension by a total of 27° towards flexion. The AFO provided dynamic correction during gait, aligning the knee neutrally. Walking speed increased by 25.5%, emphasizing the substantial impact of precise AFO tuning during gait.

Results

Results showed a significant 15° increase in dorsal flexion PROM. Static alignment in the Triple Action joint was adjusted to 5° anterior inclination added to 1 cm heel height, combined with 5° of Dorsal flexion ROM (resistance). This corrected knee hyperextension by a total of 27° towards flexion. The AFO provided dynamic correction during gait, aligning the knee neutrally. Walking speed increased by 25.5%, emphasizing the substantial impact of precise AFO tuning during gait.

Discussion/Conclusion

The dynamic contracture management following the LLPS protocol lead to a significant PROM increase towards dorsal flexion. Having a ability to dorsal flexion PROM, gives the opportunity to increase Shank to Vertical Angle (SVA) by adapting the static alignment into the Triple Action joint adding ROM towards dorsal flexion and heel height. This tuning provides a static correction of hyperextension in the knee of 27° towards knee flexion and a dynamic correction during gait to neutral. This increases the walking speed up to 25,5%. These data show the importance of treatment and/or prevention of contractures to obtain PROM in the ankle which will allow a correct alignment in order to correct hyperextension in the knee.

An individual pathway needs to be followed in each new patient. Besides the above-mentioned items, training for proximal stability (strength and coordination) , and more specifically control of the M. Gluteus Medius also plays a major role for an optimal gait.

Significance

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31. The impact of simulated ankle plantarflexion contracture on the knee joint during stance phase of gait: a within-subject study

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A Novel Weight-Bearing Ankle-Foot Orthosis For Adjustable Offloading And Symmetric Walking Dynamics

Introduction or Purpose

There are various conditions that require ankle or foot offloading, including fractures, diabetic foot ulcers, and deformity corrections. While crutches are traditionally prescribed for walking during this offloading period, they can significantly alter natural walking patterns, place excessive strain on the upper body and the intact weight-bearing leg, and lead to muscle atrophy and reduced bone density in the proximal affected leg. As a result, there is a need for alternative devices. Our recent findings suggest that an ankle-foot orthosis (AFO) could help maintain walking dynamics and metabolic costs closer to those of normal gait compared to knee- and forearm- crutches1. However, despite their potential benefits, existing prefabricated AFO designs face limitations in offloading adjustability, comfort, and the ability to preserve a natural gait1. Moreover, specialized custom AFOs tend to be expensive and often inaccessible; they also face limitations in offloading adjustability and facilitation of a symmetric and stable gait.

Therefore, our goal is to develop a novel fully weight-bearing device that allows for precise offload adjustability while preserving natural walking dynamics and maximizing comfort.

Methods

Our AFO features a patient-specific shank brace, medio-lateral foot plates, and an adjustable frame (see Fig. 1). The patient-specific shank brace is computationally designed based on a 3D scan (Fig. 1a), allowing for effective load distribution across the soft tissues of the shank. The foot height can be adjusted in 2 mm increments using locking serrated struts, which facilitates precise load distribution between the shank and the plantar foot (Fig. 1a inset). The customized foot plates provide medial and lateral support for the foot while allowing for minimal elevation. They feature a convex rocker designed according to the natural roll-over shape (ROS) during walking2. The ROS is calculated by transforming the center of pressure (CoP) of the foot into a shank-fixed coordinate system (see Fig. 1c). This design helps maintain a natural and symmetric gait, despite offloading and the lack of ankle flexion in the affected leg.

Preliminary evaluation involved two healthy participants and two patients with severe ankle injuries. Experiments included walking at self-selected speed in a motion capture lab equipped with force plates and pressure-instrumented walkway. In addition, the participants filled out evaluation questionnaires.

Results

A prototype of the AFO (Ankle-Foot Orthosis) worn by one of the participants is illustrated in Fig. 1a. It effectively demonstrates single-support weight-bearing, with the foot remaining off the ground. Fig. 1b displays the normal plantar forces measured during walking for this participant, showing the impact of different levels of offloading adjustments between 0-100%. These **Results** indicate that the device can deliver precise offloading levels while maintaining natural plantar force patterns. Furthermore, the specialized ROS feature of the new AFO produced gait patterns that were more symmetrical and closely aligned with normal gait compared to previously tested devices. Participants also reported feeling comfortable and stable while using the AFO.

Discussion/Conclusion

Our AFO promotes a natural walking pattern while allowing for adjustment of the offloading level. The plantar force measurements show a direct relationship

between the height adjustments and the amount of offloading provided. The participants reported that the brace was comfortable at all offloading levels, indicating an effective stress distribution by the custom shank brace. Future research will focus on refining the design, assessing the impact of ROS designs on gait patterns, and evaluating the AFO's performance through a more comprehensive biomechanical analysis and clinical outcomes assessment.

Significance

The expected benefits of using the new AFO include reducing the negative effects of immobilizing the proximal leg and preventing excessive strain on the weight-bearing leg and upper body. It also encourages a more natural and symmetrical walking pattern and can improve recovery by precisely controlling the level of partial offloading. These advantages can help a diverse range of patients regain their functionality and speed up their recovery periods.

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Figure 1. Design and preliminary **Results** of our new orthosis.
(a) Left: computational design informed by a patient's 3D scan of the lower leg. Right: orthosis prototype worn by a participant, demonstrating 100% offloading (no foot contact) during single support. Inset: the serrated struts used for offloading adjustability. (b) Vertical plantar forces measured during the walking stance phase at six different height levels with 4 mm increments. (c) The ROS rocker shape is computed by transforming the trajectories of the foot CoP from the global coordinate system to the shank-fixed coordinate system.
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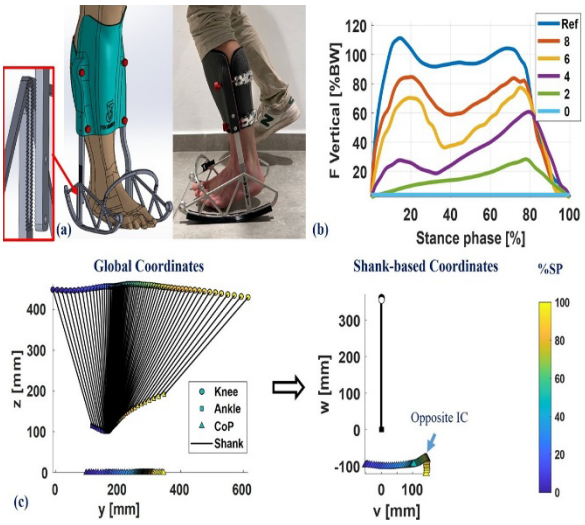

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Greater Pain Interference is Associated with Reduced Mobility in Lower Limb Orthosis Users

Introduction or Purpose
Lower limb orthosis users have a greater incidence of pain interference and lower physical function than the general population. However, the influence of pain interference on their mobility is not well understood. The purpose of this study was to understand the relationship between pain interference and mobility in lower limb orthosis users.
Methods
Demographic factors as well as patient-reported mobility and pain interference were collected at the time of lower limb evaluation appointment as part of routine clinical care. Pearson's correlations and linear mixed effects models were used to understand the relationships between mobility and pain interference, age, and sex.
Results
4974 individuals were included in this analysis. 67.2% of these individuals did not have an existing lower limb orthosis at the time of evaluation. Greater pain interference and female sex were associated with lower mobility; age, however, was not associated with mobility. A linear mixed effects model was then used to understand how pain and sex (independent variables) influence mobility (dependent variable). The relationship between pain interference and mobility was sex-dependent, where males generally had higher mobility, but their mobility was more affected by pain than females.
Discussion/Conclusion
Pain interference may be an important factor contributing to reduced mobility in lower limb orthosis users, and reducing or managing pain may be an important factor in increasing mobility. Further, females may require a greater reduction in pain to achieve similar mobility as males. Age may be a less important factor influencing mobility in this population, likely due to the level of disability resulting in the need to use a lower limb orthosis.

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Lower Limb Orthotic Interventions With A 360° Treatment Concept – A Case Series

Introduction or Purpose

This case series applies a 360° treatment concept that facilitates the optimization of an orthoses for patients with functional deficits of the lower limb. A biomechanical analysis and the calculation of the load on the orthosis is determinant for the stabilization and the application of individually adjusted corrective forces to obtain the best possible control of stance and gait.

Methods

Subjects: Three patients with lower limb mobility impairment due to neurological deficits were selected and orthotic configurations were made with the assistance of an online algorithm.
Methodology: The casting position was biomechanically optimized1 and the orthoses were fabricated with the suggested functional components to dynamically compensate the mobility deficits. The orthoses were aligned on the workbench, statically and dynamically to provide stability in stance and restore a natural gait.
Gait Analysis: Contemplas software with video analyses with markers and a BTS Motion Analysis Lab were used for Kinematic outcome measures.
Functional tests: Timed Up and Go and a 6 Minute Walk Test
Procedure: Two tests were performed in a randomized order one at baseline with standardized shoes and a second with the optimally adjusted orthosis. The kinematic outcome measures and the Results of the functional tests were analyzed.

Results

The Results include a considerable increase in the velocity, step length, cadence and gait symmetry. The functional tests showed a reduction in the time required for the chores and more endurance in general while the stability and trunk balance were noticeably better. A marked improvement of the angles in the sagittal and frontal planes was observed and the kinematic Results show a normalization of the hip, knee and ankle angles while walking with the orthosis.

Discussion/Conclusion

The 360° orthotics treatment concept is a systematic approach that includes not only assessment, configuration, casting, modifications and fabrication of an orthosis but also bench alignment to match the optimal loading posture of each patient. It is followed by control of the static alignment and joint positions in relation to the base of support. Additional adjustments may be necessary to obtain a correct tibial inclination and thus a stable stance. The dynamic alignment consists in adjusting the plantar flexion and dorsiflexion resistance/assistance forces of the spring units and the range of motion at the ankle. The orthosis must be bending and torsion resistant to maximize the function of the components and maintain the desired alignment of the lower limb. All of these aspects contributed to the good Results of the orthotic intervention and it can be concluded that this 360° treatment concept is a repeatable process that Results in an extremely effective orthotic intervention for the patients.

Significance

Orthotic components that are adjusted to the patient's needs and an orthosis that provides the necessary structural stiffness are fundamental to maintaining a biomechanically optimized alignment and enhance the function of the components. An optimal lower limb orthosis stabilizes the patient during stance and supports a physiological gait pattern improving functionality and consequently increasing the participation and quality of life of the subjects with lower limb impairment.

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