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# 51st Academy Annual Meeting & Scientific Symposium
## *Journal of Proceedings*

### Greetings, friends and colleagues!

I am pleased to help welcome you to Atlanta for the Academy's 51st Annual Meeting & Scientific Symposium! Many long-time Academy members are well aware of the high-quality, stimulating offerings that can be expected at this meeting. For some of you, this may be your first time attending the Academy's Annual Meeting, and I can confidently predict that you are in for an exciting and memorable time! The Academy's Clinical Content Committee has put together an outstanding program again this year that will serve to educate and challenge you in your thinking while providing you with knowledge and information that can be applied in clinical, research, and educational settings.

I regard this *Journal of Proceedings* as a guidebook to the presentations and activities taking place at this conference. Specifically, you can review the numerous sessions in advance, plan your schedule for the week accordingly, read about presentation content in greater detail, and even learn about presentations you might have missed attending. If you are unable to participate in the meeting, then you can access information that was delivered during the presentations and stay abreast of the latest developments in O&P research, education, and clinical practice.

For presenters at the conference, a primary benefit of this *Journal of Proceedings* is that others can formally cite the content as a justification for clinical decision-making and for furthering lines of research in the field. Therefore, authors can receive appropriate recognition for new ideas and original concepts mentioned in their presentations prior to the publication of an article. Finally, this *Journal of Proceedings* is searchable online, so it will be easy to find presentations on specific topics from one year to the next.

I sincerely hope that you enjoy the Academy's Annual Meeting and this *Journal of Proceedings!*

Steven A. Gard, PhD
Editor-in-Chief
*Journal of Prosthetics and Orthotics*

While the American Academy of Orthotists and Prosthetists has made every reasonable effort to ensure the accuracy and validity of the references provided in this *Journal of Proceedings,* we are not responsible for any errors or omissions.

# 51st Academy Annual Meeting & Scientific Symposium
## *Journal of Proceedings*

### Greetings Academy Members and *Journal of Prosthetics and Orthotics* readers!

This year marks the 51st Annual Meeting & Scientific Symposium of the American Academy of Orthotists and Prosthetists. It is an honor for me to introduce the *Journal of the Proceedings* for this year's meeting. This edition exemplifies how we as a profession are continuing to expand the collection and dissemination of evidence in the *Journal of Prosthetics and Orthotics* and through other avenues throughout the year. After celebrating the 50th year of the Academy Annual Meeting & Scientific Symposium in 2024, we are forging ahead to build on our professional foundation, tapping into emerging technologies, and continuing to put our patients and clients first in every aspect of clinical practice, research, and education.

This year, we will see multiple topics presented in more than one session format, allowing attendees to be exposed to variable perspectives and applications for each of those topic areas. Additionally, for the first time, we are offering free paper sessions that include outcomes related to both prosthetic and orthotic interventions as we embrace the professional trajectory of dual discipline education and certification.

In this first year serving as the Chair of the Clinical Content Committee, I have been encouraged and impressed by the support of the Academy staff, the dedicated efforts of the Clinical Content Committee volunteers, and the robust slate of abstract submissions to support another engaging and informative meeting. I would like to thank each one of these colleagues for their passion and contributions to bring this Academy Annual Meeting to life.

Sincerely,

Kristin Carnahan

Kristin Carnahan, MSPO, CPO, FAAOP
51st Academy Annual Meeting & Scientific Symposium
Chair, Clinical Content Committee

# A 10-Year Review of Cranial Remolding Orthosis Treatment for Infants with Isolated Deformational Plagiocephaly

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## INTRODUCTION

Cranial remolding orthoses (CROs) are used in the treatment of deformational plagiocephaly to help correct asymmetry in infants with skull deformations. Previous studies have demonstrated the efficacy and reliability of CROs,[1-3] and it is widely accepted that an earlier entry age into treatment will have better outcomes.[4-5] However, previous studies have been limited by small sample sizes, and few provide a comprehensive assessment of multiple factors that influence treatment outcomes.

The purpose of this study was to examine the overall efficacy of CROs, treatment outcomes, and variables that influence CRO treatment of infants with isolated deformational plagiocephaly (IDP). IDP is defined as a deformational head shape of nonsynostotic origin, a cranial index (CI) less than 90 and more than 75, and a cranial vault asymmetry index (CVAI) greater than 3.5.

## METHOD

The Argus Institutional Review Board approved this study, and a waiver of informed consent was granted.

***Participants:*** 27,990 patients with IDP were included. There were 18,412 males and 9,578 females. The sample was comprised of N=1,358 patients in the 3–4 months category, N=13,249 patients in the 4–5 months category, N=8,617 patients in the 6–7 months category, N=3,866 patients in the 8–10 months category, and N=900 patients in the more than 11 months category. The age at entry into treatment ranged from 3–18 months, with a mean of 6.4 months. Treatment duration ranged from 25 days to 7.7 months, with a mean of 3 months.

***Apparatus:*** This was a retrospective chart review of CROs (DOC Band®) in the treatment of IDP.

***Procedures:*** Patient data was queried from Cranial Technologies' internal electronic health record (EHR) system for infants that were treated for IDP between July 1, 2014, and March 25, 2024.

***Data Analysis:*** Paired t-tests were used to evaluate whether there was significant change in infants' CVAIs. Multiple regression was used to examine change in CVAI as a function of various factors. All tests were two-tailed and a p-value of <0.05 was set to indicate statistical significance.

## RESULTS

There was a significant overall mean change in CVAIs across all age groups of -3.42±.011 (p<0.001). There was significant improvement in CVAIs in all age groups, even in older babies (11–18 months of age) with very severe plagiocephaly. Between 93.66%–96.57% of infants with an entry age of 3–5 months achieved a "good" or "great" outcome rating, regardless of their initial severity rating. For infants who started CRO treatment after 11 months of age, 48%–77.6% achieved a "good" or "great" outcome.

Multiple regression analysis identified the following factors as significant predictors of change in CVAI: (1) younger age at initiation of treatment (p<0.001, β=0.01); (2) initial severity rating as measured by CVAI (p<0.001, β=-0.43); (3) left plagiocephaly (p<0.001, β=-0.36); and (4) and the presence of torticollis (p<.001, β=0.17). Younger babies also had significantly shorter treatment durations (p<.001).

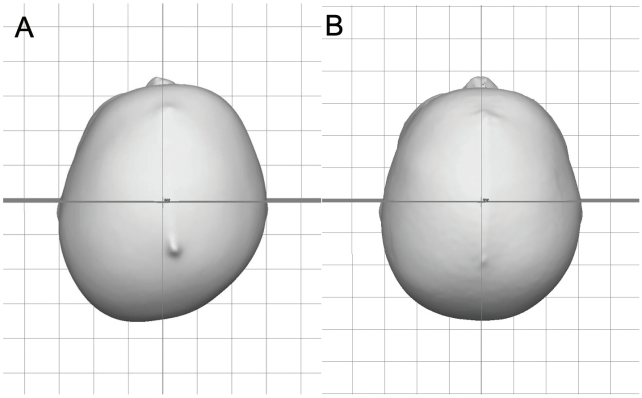


**Figure 1.** Vertex view of a 3.5-month-old after 1.7 months of treatment. A. Entry CVAI of 12.7. B. Exit CVAI of 1.5.

## DISCUSSION AND CONCLUSION

This study is the largest retrospective examination of CRO treatment for patients with IDP to date. Our study results demonstrate that CRO treatment for isolated deformational plagiocephaly led to significant improvements in CVAI across all age groups. These findings are consistent with the results of previous studies and highlight the importance of prompt referral.

## CLINICAL APPLICATIONS

Study findings help to inform pediatric healthcare providers of the efficacy of CRO therapy, the risk factors for plagiocephaly, and the need for referral at an earlier age.

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# Preceptor Feedback on the Integrated Residency Model

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## INTRODUCTION

The first orthotic and prosthetic integrated residency model will soon graduate its 10th class of students. Having offered an alternative to the traditional residency model, it is important to evaluate the outcomes and perceptions of this model to determine whether it should continue to be an accredited program structure. While a few publications have described graduate and student outcomes related to the integrated model,[1,2] no data related to preceptor (or clinical mentor) experience has been evaluated and published.

The purpose of this study was to evaluate the experiences and perceptions of clinical preceptors who work with integrated model residents from at least one integrated program.

## METHODS

***Participants:*** Preceptors who had worked with an integrated resident within the last three years.

***Apparatus:*** Online survey containing items pertaining to demographics of the respondent, frequency of working with residents, satisfaction with the residents, satisfaction with the program, perceptions of the benefit of integrated and traditional residency models, desire for additional training and benefits for being a preceptor, and open-ended items for feedback on resident and program performance.

***Procedures:*** The survey was disseminated via email, and respondents were provided with one reminder email regarding completion.

***Data Analysis:*** Descriptive statistics of each survey item were generated. The responses to the open- ended item were analyzed for themes.

## RESULTS

Forty-four preceptors (21% response rate) submitted complete responses to the survey, representing 21 states of residence and an age range of 25 to 65+ years of age. Men made up 70.5% of the respondents, and 84.1% of the respondents were White. In terms of educational attainment, 54.5% of the respondents had obtained a post-baccalaureate certificate, and 29.5% had obtained a master's degree in orthotics and prosthetics. The majority of survey respondents (61.4%) had been practicing for at least 11 years and were located in an urban setting. A majority of respondents (70.5%) had been a preceptor with the integrated program for at least two years, with 63.6% having worked with five or fewer residents. Most respondents (93.2%) were satisfied or very satisfied as an integrated model preceptor. Most of the respondents (95.5%) were satisfied or very satisfied with the quality of the integrated residents. Most respondents (86.4%) agreed or strongly agreed that an integrated residency model is an effective model for residency. Nearly the same percentage of respondents (84.1%) agreed or strongly agreed that a traditional model is an effective model for residency. The majority of respondents rated residents at the level of "good / sometimes exceeds expectations" or "excellent / always exceeds expectations" with respect to entry-level competencies. When asked what additional resources or support they would like from the program, 52.3% indicated a desire to improve the awareness of their clinic, 43.2% wanted to be featured on the program's website, and 40.9% requested continuing professional development related to teaching skills. Open-ended items indicated praise for resident performance and program communication, with some indicating a desire for longer residency rotations.

## DISCUSSION

This study evaluated the perceptions of preceptors who work with integrated residents. The responses indicated a positive perception of both the integrated model and the performance of the residents. Preceptors were generally satisfied with program communication and the frequency with which they receive residents. While providing support for the integrated model, preceptors also indicated that benefit for the traditional model remains. Given the relatively small population of students being trained in orthotics and prosthetics each year, it is important to collect and disseminate feedback related to educational approaches.

## CONCLUSION

The results of this survey indicate strong satisfaction with integrated residents and an integrated program. Respondents were supportive of both integrative and traditional approaches. Additional support for clinical preceptors needs to include training in teaching methods and representation as valuable and active members of the integrated program.

## CLINICAL APPLICATIONS

Educational models impact the preparedness of new clinicians and, as a result, the outcomes of the patients they treat. Evaluating educational models and experiences of clinical preceptors is important to sustaining orthotic and prosthetic education.

## REFERENCES

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# Viability of a Horizontal Ladder Task as a Functional Test of Somatosensation in Lower-Limb Prosthesis Users

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## INTRODUCTION

Sensory loss impacts human stability and movement.[1] Following lower-limb amputation, there is a lack of sensory information normally attained from direct foot–ground interaction. Attempts to restore sensation have been shown to improve balance and motor control.[2,3] However, it is difficult to isolate and investigate the impact of sensory loss on locomotor function.

In animal studies, ladder tasks have been used to demonstrate the impact of impaired cutaneous sensory input on sensorimotor function.[4] A version of this task has been proposed for human participants, evaluating an individual's ability to quickly and accurately traverse a horizontal ladder with unequally spaced rungs.[3] The task aims to isolate somatosensation through the elimination of visual feedback.

The purpose of this study was to determine whether a Horizontal Ladder Task (HLT) is a viable assessment of functional somatosensation to be used for clinical and rehabilitation research in lower-limb prosthesis users (LLPU). Inter-rater reliability was assessed, and convergent validity against measures of sensation, balance confidence, and motor function. To establish known groups validity, performance across cohorts of LLPU, young adults (YA), and older adults (OA) were compared.

## METHOD

***Participants:*** Eight LLPU (8 male; 44.8±7.6 years; 1.8±.10 m, 102.2±22.5 kg, 12 YA (8 male, 4 female; 27.6±7.6 years; 1.8±.13 m; 82±17.7 kg), 10 OA (3 male, 7 female; 72.4±5.2 years; 1.7±.13 m; 74.8±19.0 kg) attended two laboratory sessions. Written informed consent was obtained. This study was approved by the Biomedical Institutional Review Board of the University of Nevada, Las Vegas (ID: UNLV-2023-35).

***Apparatus:*** The HLT utilized a ladder placed on the ground with adjustable inter-rung spacing.

***Procedures:*** Participants traversed the rungs of the ladder while blindfolded using bilateral handrails. Rung spacing was changed between trials to minimize learning effects. Ten trials were completed per session. Two assessors measured trial completion time with handheld stopwatches. Trial completion time was adjusted for skipped rungs.

***Data Analysis:*** Trial completion times were plotted for each participant. Based on an observable learning curve, the times were averaged across trials 6–10 from the first session. Inter-rater reliability was assessed with an Intraclass Correlation. For known groups validity, trial completion time was compared across groups using a Kruskal-Wallis test. All statistics were performed in SPSS v26.

## RESULTS

The HLT was performed successfully by individuals with unilateral (N=7) and bilateral (N=1) amputation. Amputation levels included transtibial (N=3), transfemoral (N=4), and hip disarticulation (N=1). Different movement strategies were observed across participants due to individual movement deficits. Excellent inter-rater reliability was observed (ICC=.998). Significant differences were observed in average trial completion time between the LLPU and YA groups (p=.001) but not between the LLPU and OA groups (p=.271) and YA and OA groups (p=.104) (Figure 1).

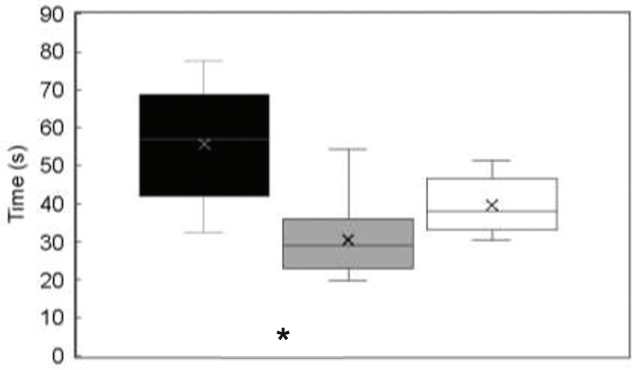


***Figure 1.*** Trial completion time. Average of session 1 trials 6–10. LLPU (black), YA (gray), OA (white).
• - significant p<0.05.

## DISCUSSION

The success of the heterogeneous cohort of LLPUs in performing the task suggests the HLT may be a viable test for the population. High inter-rater reliability indicates the test is simple to administer. Slower LLPU times compared to YA, with OA showing intermediate values, align with expected functional and sensory losses. It is not possible to attribute differences across participants or groups to somatosensation directly with this test due to variations in movement strategies. A within-subject design may be appropriate when evaluating interventions to restore sensation.

## CONCLUSION

The HLT may be a viable tool to assess functional somatosensation in LLPU.

## CLINICAL APPLICATIONS

Reliable and valid tests of functional somatosensation are currently lacking. Such tests are needed to establish the effect of somatosensory loss on functional mobility and the efficacy of interventions designed to restore sensation following amputation.

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# Mismatched Balance Confidence and Objective Balance Capacity: Impact on Fall Frequency from C-Brace Crossover Trial

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## INTRODUCTION

Two factors contributing to mobility are objective balance and subjective balance confidence, which can be measured by the Berg Balance Scale (BBS) and Activity-Specific Balance Confidence Scale (ABC), respectively. Wong and Chihuri[1] compared these measures in people with lower-limb amputations and paradoxically found that higher objective balance ability increased the likelihood of falling. They also found that, for people with amputations, a mismatch with high balance confidence and poor balance based on items ten and 11 in the BBS greatly increased the chances for a fall. This relationship has not been explored in other populations, however. During the C-Brace Crossover international trial,[2] 69 subjects with impaired balance completed the study with BBS, ABC, and fall history. We explored the relationship between the BBS-ABC mismatch and fall risk in this sample.

## METHOD

During the C-Brace Crossover international trial, subjects reported falls at baseline and after three-month home-use periods with their KAFO (locked, posterior offset, or SCO) and the C-Brace in randomized order. Subjects also completed a falls diary. In cases where subjects reported more falls in the diary, the number of falls from the diary was used. The analysis was carried out in subjects with a mismatch between the average of BBS items number ten and 11 being rated less than 3 out of 4 and the ABC score higher than 67%. A mismatch between fall-risk cut-off scores of <45 (out of 56) for the total BBS and 67% for the ABC was also compared to reported falls.

## RESULTS

Sixty-nine subjects completed the study and were included in the analysis. Subjects included 30 females and 39 males with a mean age of 55.5 years and with mean BBS score of 34.2±10.1 (5–45). Six subjects were bilateral users. The most common diagnoses were polio (35), incomplete spinal cord injury (9), lumbar disk herniation (6), and multiple sclerosis (2). Table 1 shows the percentage of subjects with a mismatch for each arm of the study. At baseline, subjects were more likely to have a mismatch between balance confidence and overall balance ability.

**Table 1.** Percentage of subjects with a balance-confidence mismatch by device type.

| **Mismatch Type** (low balance ability with high balance confidence) | **Baseline** (n=68) | **KAFO** (n=66) | **C- Brace** (n=69) |
|---|---|---|---|
| **BBS Items 10 & 11 Avg <3 ABC >67%** | 13% | 15% | 8% |
| **BBS Total score <45 ABC >67%** | 22% | 19% | 14% |

**Table 2.** Percentage of subjects falling more than once

| **Category** | **Baseline** | **KAFO** | **C-Brace** |
|---|---|---|---|
| **BBS items 10 & 11 Avg <3 ABC >67% (mismatch)** | 11% | 80% | 0% |
| **BBS items 10 & 11 Avg No high-confidence mismatch** | 39% | 37% | 20% |
| **BBS Total score <45 ABC >67% (mismatch)** | 13% | 56% | 8% |
| **BBS Total score No high-confidence mismatch** | 42% | 38% | 20% |

As shown in Table 2, subjects with a confidence mismatch between the two items from the BBS chosen by Wong and Chihuri were slightly more than twice as likely to be multiple fallers than those with no mismatch in the KAFO arm. The C-Brace arm had approximately the same proportion of multiple fallers regardless of mismatch status. Baseline confidence mismatch indicated multiple fallers at a lower rate than no mismatch. Differences between overall BBS and ABC had smaller influence on mismatch compared to the two BBS items chosen by Wong and Chihuri in the KAFO arm.

## DISCUSSION

The C-Brace appears to protect orthotic subjects from the dangers of a confidence mismatch. The proportion of multiple fallers in the KAFO arm were likely much higher than baseline due to the nature of the crossover design. Approximately half of the orthotic users returned to their baseline device after experiencing the relative safety of the C-Brace and therefore had an increased risk for experiencing multiple falls.

## CONCLUSION

In clinical practice, it is sometimes necessary to downgrade an orthosis due to age-related reduction in physical ability or a change in dwelling status. Special care should be taken to ensure that these orthotic users do not underestimate the impact of the downgrade, especially in elderly and frail populations where multiple falls can cause significant complications.

## CLINICAL APPLICATIONS

This analysis points to a potential problem when switching from high-performance MP-SSCO to a conventional KAFO or SCO.

## REFERENCES

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# Burden and Outcomes of Microprocessor SSCO and Conventional KAFO from Experts' and Patients' Perspectives

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## INTRODUCTION

The burden of disease (BoD) and individual needs of people requiring knee-ankle-foot orthoses (KAFOs) have so far received little consideration. Neuromuscular knee instability can cause a variety of problems including pain, falls, mobility problems, and limited participation in daily activities. All of these can be managed with advanced orthopedic equipment.[1,2] The purpose of this analysis was to understand the disease burden from the perspective of professionals[1] and individual patients[3] and to understand the benefits of using a microprocessor-based stance-and-swing-phase-controlled KAFO (MP-SSCO).

## METHOD

The results of a semi-structured expert interview regarding patients' BoD were evaluated descriptively and compared to those of an observational patient survey. Both research projects were conducted in Germany.[1,3] In Table 1, a comparison to a UK patient survey was done.

## RESULTS

From an expert point of view, mobility restriction was the leading observed patient burden, and impaired stair climbing of had the highest expert-observed frequency of impairments. Quality of life, improved gait pattern, and high reliability of the orthosis were the most relevant observed potential patients benefits as perceived by the experts. Gait analysis was reported as the most relevant patient outcome criteria, followed by number of falls, participation, and walking distance.

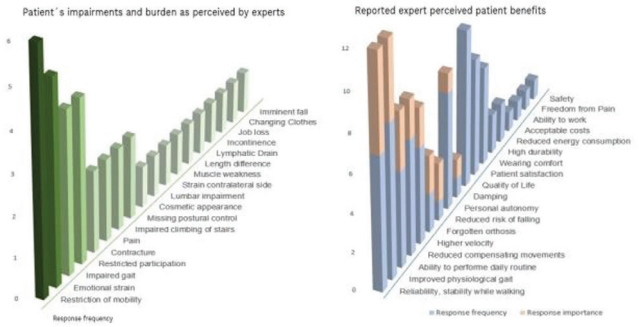


**Figure 1.** Impairment, burden and benefits perceived by the experts.

Mobility and functionality with the MP-SSCO were well perceived by the patients. The average usability of the MP-SSCO was ranked 2.1 (good), compared to an average 3.9 (poor) with the previous KAFO (p=0.01). When evaluating gait pattern, over 90% of the participants stated that they achieved poor or very poor gait symmetry with the previous orthosis compared to only 9% when using the MP-SSCO. When rating the ability to descend stairs with the previous KAFO, 14.3% of the patients rated it as good compared to 81% who rated it as good or very with the MP-SSCO. Among patients with prior KAFO (n=14), 78.6% recalled experiencing falls, with a combined annual fall frequency (AF) of 67.9. After excluding two outliers, a mean of 12.1 falls per patient per year was reported. With the MP-SSCO, only 42.7% reported falls with an AF of 5.3. After excluding the outliers, the average number of falls with the MP-SSCO was 0.5 per year (p=0.01). Whereas painful conditions were reported by the experts as further impairment whose frequency was rated as "sometimes" or "rarely," every second patient using the previous KAFO reported pain compared to 38.1% with the MP-SSCO. Previous orthosis use resulted in higher pain intensity (3.8) than MP-SSCO use (2.8) on a 1–5 scale (p=006).

**Table 1.** BoD key characteristics (patients' and experts' perspectives).

| | Current Patient Survey[3] | Historical Patient Survey[2] | Expert Survey[1] |
|---|---|---|---|
| **Patients desired outcomes** | Safety | Reduction in falls or trips<br>Improved balance and stability | Reliability<br>Stability while walking |
| | Independence | | Ability to perform daily routine* |
| | Quality of life | | |
| | Improved gait | | |
| | Meeting fellow people at eye level | | |
| | | Reduction in pain | |
| **Most valued features** | Safety | Reliability | High dependability of the orthosis |
| | Effectiveness | Effectiveness | Improved gait patterns |
| | Weight | | |
| | | | Improved quality of life |
| | | Comfort and durability | |

The MP-SSCO was considered better compared to the former orthosis by 94% of participating patients.

## DISCUSSION

Mobility and participation were rated as the most frequent problems of KAFO users by both experts and patients and were significantly improved by the MP- SSCO.

## CONCLUSION

Patients' outcome and experts' opinions demonstrate the potential of the MP-SSCO to reduce the BoD.

## CLINICAL APPLICATIONS

Participation should be considered for individual MP- SSCO rehabilitation targets.

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# Individual Responder Analysis of the International Randomized C-Brace Crossover Study

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## INTRODUCTION

An international, randomized crossover study with the C-Brace found significant improvements in balance, falls, fall risk, function, mobility, and quality of life compared to the use of traditional locked (LKAFO) and posterior-offset (PO-) KAFOs and stance control orthoses (SCOs).[1] The purpose of this secondary data analysis was to evaluate whether certain subgroups of the study sample benefit at greater magnitudes or in higher numbers than others, namely polio survivors versus individuals with non-polio conditions, and previous users of LKAFOs versus free-swing KAFOs (PO-KAFOs/SCOs).

## METHODS

The data of the 69 subjects who had completed the protocol of the original study was subjected to a secondary analysis for rates of responders defined as participants who experienced individual clinically meaningful benefits by the C-Brace in the outcome measures Berg Balance Scale (BBS), Activities-Specific Balance Confidence Scale (ABC), Dynamic Gait Index (DGI), or self-reported falls. Thresholds for clinical meaningfulness were defined as follows: BBS: improvement by 5 points, score >40, score >45 (2); ABC: improvement by 11 points, score ≥67 (3); DGI: improvement by 1.9 points (4); falls: reduction in self-reported falls.

Compared to baseline with their existing traditional KAFO or SCO, polio survivors improved in the BBS by 4.5±5.5 points, while participants with non-polio conditions improved by 9.8±8.8 points when using the C-Brace. Forty-three percent of polio survivors but 76% of participants with non-polio conditions were responders who improved ≥5 points in the BBS with the C-Brace. At baseline, only 14% of polio survivors presented BBS scores >45 and 60% scores ≥40. These rates improved to 54% and 80% with the C-Brace, respectively. Baseline rates of individuals with non-polio conditions were 15% for scores >45 and 32% for scores ≥40, which improved to 50% and 73% with the C-Brace, respectively. Responder rates with individual improvements ≥11 points in the ABC were 34% among polio survivors but 59% among individuals with non-polio conditions. At baseline, only 23% of both polio survivors and patients with non-polio conditions presented ABC scores ≥67. These rates improved to 43% for polio survivors and 56% for non-polio patients with the C-Brace. In the DGI, 46% of polio survivors and 59% of patients with non-polio conditions were classified as responders who improved by ≥1.9 points with the C-Brace. Regarding falls, 80% of both polio survivors and individuals with non-polio conditions reported reductions in falls when using the C-Brace. Considerably higher responder rates with individual clinically meaningful improvements were also obvious among previous free-swing KAFO (posterior-offset KAFO and SCO) users as compared to locked KAFO users in the BBS, ABC, DGI, and reported falls.

## DISCUSSION

Participants with non-polio underlying conditions were more likely to experience individual clinically meaningful improvements in balance, risk of falling, falls, and mobility with the C-Brace than polio survivors. Similarly, previous users of free-swing KAFOs were more like to benefit from the C-Brace individually than previous users of locked KAFOs.

## CONCLUSION

Patients with non-polio conditions and users of free-swing KAFOs are promising C-Brace candidates. Polio survivors and locked KAFO users require more clinical effort to identify C-Brace candidates.

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## DISCLOSURE

*Andreas Kannenberg is a full-time employee of Otto Bock Healthcare LP. Barbara Pobatschnig is a full-time employee of Ottobock SE & Co. KG.*

# Repeatability of a Novel In-Vivo Strain Measurement Approach in Carbon Fiber Custom Dynamic Orthoses

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## INTRODUCTION

Assessments of ankle-foot orthosis (AFO) mechanical properties are primarily performed using mechanical testing or computational modeling. These approaches, however, largely ignore the potential effects of the limb-orthosis interactions. The purpose of this study is to evaluate the reliability of a novel, standardized, in-vivo approach to measure AFO strain.

## METHODS

***Participants:*** Study activities were approved by the local Institutional Review Board. Thirty healthy individuals (10 males; 20 females, 26.4(8.5) years, 1.7(0.1) m, 75.3(16.7) kg) without a history of lower-limb injury provided written informed consent prior to testing. Participants wore a carbon fiber dynamic orthosis[1] (CDO; moderate stiffness, Bio-Mechanical Composites, Des Moines, IA). Testing was completed after a brief accommodation (T1), after repositioning the limb in the camera volume (T2), and after doffing and re-donning the device (T3).

***Apparatus:*** The posterior strut of the CDO was sprayed with a speckle pattern to enable an ARAMIS digital image correlation (DIC) system (GOM, Inc., Braunschweig, Germany) to measure displacement and surface strain in the proximal, middle, and distal third of the strut.

***Procedures:*** Participants deflected the CDO into ankle dorsiflexion in a manner consistent with terminal stance of gait. The knee was brought forward and the heel of the CDO limb was kept in contact with the floor while participants stepped forward with the opposite limb.

***Data Analysis:*** Video data, captured at 245 Hz, were analyzed using GOM Correlate Pro 2020 (GOM, Inc., Braunschweig, Germany). Sagittal plane displacement and maximum tensile (major) strain were assessed on the posterior face of the CDO strut. Strain was calculated at 4, 6, and 8 degrees of ankle dorsiflexion. Intraclass correlation coefficients (ICCs) and minimum detectable change (MDC) values between T1–T2 and T2–T3 were calculated using a two-way mixed, absolute agreement model.

## RESULTS

Major strain increased with ankle dorsiflexion and more distal location (Table 1).

**Table 1.** Ensemble mean (SD) major strain at all three angles of ankle dorsiflexion and analysis locations.

| | Distal | Middle | Proximal |
|---|---|---|---|
| **4 deg** | 0.13 (0.02) | 0.08 (0.01) | 0.04 (0.01) |
| **6 deg** | 0.18 (0.02) | 0.11 (0.02) | 0.06 (0.01) |
| **8 deg** | 0.24 (0.03) | 0.14 (0.02) | 0.07 (0.02) |

ICC and MDC values are presented in Table 2. MDC values were between 0.005–0.010 major strain for all comparisons, with generally higher values at greater dorsiflexion. The MDC values as a percentage of mean values (MDC%) were generally lower at more distal locations and greater ankle dorsiflexion (Table 2).

**Table 2.** ICC, MDC, and MDC% at distal (D), middle (M), and proximal (P) analysis locations for 4, 6, and 8 degrees of ankle dorsiflexion. ICC values >0.5 are **bolded.**

| | | ICC | | MDC | | MDC% | |
|---|---|---|---|---|---|---|---|
| | | *T1-T2* | *T2-T3* | *T1-T2* | *T2-T3* | *T1* | *T2* |
| **D** | 4 | 0.43 | **0.67** | 0.007 | 0.006 | 0.05 | 0.05 |
| | 6 | **0.62** | **0.73** | 0.008 | 0.008 | 0.04 | 0.04 |
| | 8 | **0.69** | **0.75** | 0.010 | 0.010 | 0.04 | 0.04 |
| **M** | 4 | 0.31 | **0.70** | 0.007 | 0.005 | 0.08 | 0.06 |
| | 6 | 0.38 | **0.75** | 0.008 | 0.006 | 0.07 | 0.05 |
| | 8 | 0.42 | **0.76** | 0.010 | 0.007 | 0.07 | 0.05 |
| **P** | 4 | 0.14 | **0.56** | 0.006 | 0.005 | 0.14 | 0.12 |
| | 6 | 0.29 | **0.62** | 0.007 | 0.006 | 0.13 | 0.11 |
| | 8 | 0.37 | **0.64** | 0.009 | 0.008 | 0.12 | 0.11 |

## DISCUSSION

ICC values were generally better with more ankle dorsiflexion or a more distal strut location, both of which were conditions with greater strain. MDC values with doffing and donning were less than 0.15% of the measured strain for all locations and ≤0.06% for the middle and distal locations, with good to excellent reliability. Improved reliability for the T2–T3 comparison may be due to a learning effect with the participant applying force more gradually in later trials. Measured strain was more than three times higher at the distal strut than the proximal strut, and strain values are comparable to previously published orthotic research.[2,3] MDC values for this novel in-vivo testing approach indicate the approach is relevant for cases where expected differences in major strain exceed 0.01.

## CONCLUSION

Digital optical strain assessment allows reliable evaluation of major strain in CDOs while accounting for potential limb-device interactions.

## CLINICAL APPLICATION

This method may provide a more holistic and functionally relevant approach to quantifying ankle-foot orthosis mechanical characteristics, ultimately improving future AFO design.

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# An Adjustable Dynamic AFO: Dorsiflexion Angle at Different Strut Stiffness Settings during Running

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## INTRODUCTION

Though selecting strut stiffness is an important part of fitting a dynamic AFO to a patient, different stiffnesses have not been shown to significantly affect ankle angle in laboratory investigations on participants with ankle disability.[1] The angle changes may be smaller than the resolution of traditional gait analysis lab equipment. In this research, a novel onboard sensing system was created to quantify dorsiflexion/plantarflexion angle during running. Participants were tested with different strut stiffnesses while running on a treadmill.

## METHOD

***Apparatus:*** The sensors detected sagittal plane ankle torque and axial force using strain-sensing elements affixed to the footplate. Onboard electronics sampled the sensors at a rate of 200 Hz, conditioned the signals, and stored the data to an SD card.

***Procedures:*** Three able-bodied participants between the ages of 26 and 61 (two female, one male) took part in this study. A custom dynamic AFO was designed by a certified orthotist, fabricated by a professional clinic (FabTech), and instrumented. During a fitting session, the orthotist selected an optimal strut stiffness as well as a lowest acceptable and highest acceptable stiffness. During test sessions, participants were asked to run on a treadmill (Clubtrack, Quinton) at their preferred running speed for approximately one minute at each stiffness setting with the ordering of settings randomized. An additional set of trials were conducted at a 27%–37% faster running speed. Participants also walked on the treadmill with their ankle relaxed and their ankle actively plantarflexed during stance phase.

***Data Analysis:*** Collected data were converted to AFO ankle torque and angle using calibration data and a computational model. Data were plotted over time, and the maximum dorsiflexion AFO ankle angle in each step was determined. A mean and standard deviation for each setting was calculated for each participant.

## RESULTS

Maximum dorsiflexion angle during running decreased with increased strut stiffness for each participant (Figure 1). Differences between stiffness settings (low versus medium, medium versus high, and low versus high) were statistically significant ($P<0.05$) for all participants.

Maximum dorsiflexion angle increased with a faster running speed over a nominal speed by a mean (SD) of 1.4 degrees (±1.1), 1.3 degrees (±3.1), and 3.4 degrees (±1.7) for participants 1, 2, and 3, respectively.

All four walking participants significantly ($P<0.05$) reduced their ankle torque when they actively plantarflexed their ankle compared with relaxing their ankle (Figure 2). Mean reductions were 3.1 N•m (12.3), 21.1 N•m (24.4), 46.2 N•m (19.8), and 61.7 N•m (13.7), respectively.

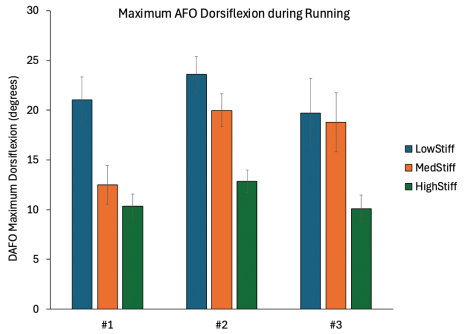


**Figure 1.** Results from strut stiffness testing.

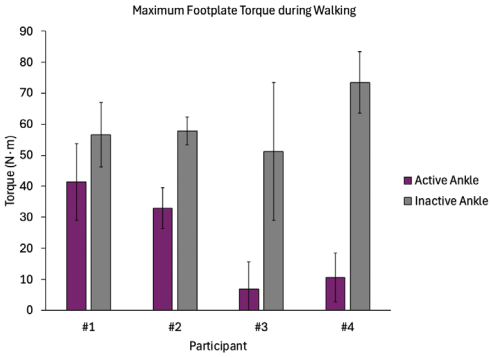


**Figure 2.** Torque results with and without ankle activation.

## DISCUSSION

A sensor angle detection resolution of 0.1 degree and torque detection resolution of 0.5 N provided meaningful data in the context of lower-limb orthotics. The innovative sensors were capable of observing small stance phase dorsiflexion and ankle torque changes during clinical use.

## CONCLUSION

Future studies should investigate how AFO design settings affect torque and dorsiflexion on people with ankle disability.

## CLINICAL APPLICATIONS

The system has use as a clinical monitor to present kinetic and kinematic variables during fitting and summary data from take-home use. It may serve as a control system feedback sensor for an auto-adjusting dynamic AFO.

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# Effect of Carbon Fiber Custom Dynamic Orthosis on Limb Mechanics Following Traumatic Lower-Limb Injury

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## INTRODUCTION

Carbon fiber custom dynamic orthoses (CDOs) are used to support and protect the foot and ankle after traumatic injury. They consist of a rigid or semi-rigid proximal cuff, a carbon fiber posterior strut, and a full-length custom footplate. CDO design characteristics can vary widely and are known to influence gait mechanics.[1] However, data for commercially available CDOs is limited, and it is unknown if these CDOs alter ankle mechanics in a manner consistent with very stiff CDOs previously studied.[1–4] The purpose of this study was to investigate the effect of two commercially available CDOs on gait mechanics relative to walking with no CDO and each other.

## METHOD

***Participants:*** Twenty-three individuals (7 female / 16 male, 42.1(11.4) years, 1.8(0.2) m, 101.5(18.9) kg) who had experienced a traumatic lower-limb injury more than two years prior participated. Study activities were approved by the Institutional Review Board at each site, and participants provided written informed consent.

***Apparatus:*** A minimum of 12 motion capture cameras (Vicon Motion Systems or Qualisys AB), three force plates (AMTI Inc.), and 57 retro-reflective markers were used to calculate joint angles, moments, and powers.

***Procedures:*** After three months of accommodation, testing was completed without an orthosis (NoCDO); with a modular CDO (MOD, Reaktiv, FabTech Systems) that uses a patellar-tendon-bearing proximal cuff and rigid footplate; and with a more compliant, monolithic CDO (MONO, PhatBrace, Biomechanical Composites) that has a flexible, padded proximal cuff and semi-rigid footplate (Figure 1). Device order was randomized.

***Data Analysis:*** Data were processed in Visual 3D (C-motion Inc.) and MATLAB (The MathWorks Inc.). One-way repeated measures ANOVAs were used to determine main effects of condition. Post-hoc testing included paired sample t-tests with a Bonferroni Holm correction.

## RESULTS

The MOD CDO (8.7(2.7) Nm/deg) was significantly stiffer than the MONO CDO (4.6(2.4) Nm/deg), and alignment did not differ significantly between CDOs. Both CDOs significantly reduced ankle range of motion by 51%–55%, increased peak ankle dorsiflexor moment by 35%, and decreased push-off power by 38-40% compared to NoCDO (Figure 2). The MOD CDO also significantly increased peak plantarflexion moment by 19% compared to NoCDO. The only differences in kinematics or kinetics between CDOs were in loading response and initial swing peak plantarflexion.

**Figure 1.** MOD (left) and MONO (right) CDOs.

## DISCUSSION

The MONO and MOD CDOs altered ankle motion, moments, and power generation, with biomechanical data closely resembling prior publications with very stiff CDOs.[2] While ankle push-off power with both study CDOs was decreased relative to NoCDO, it was more than 25% greater than in prior publications.[2]

## CONCLUSION

Despite multiple differences between MONO and MOD CDOs, including stiffness and overall design, significant differences in mechanics were limited.

## CLINICAL APPLICATIONS

The study CDOs had a similar effect on ankle joint mechanics despite their apparent differences.

## REFERENCES

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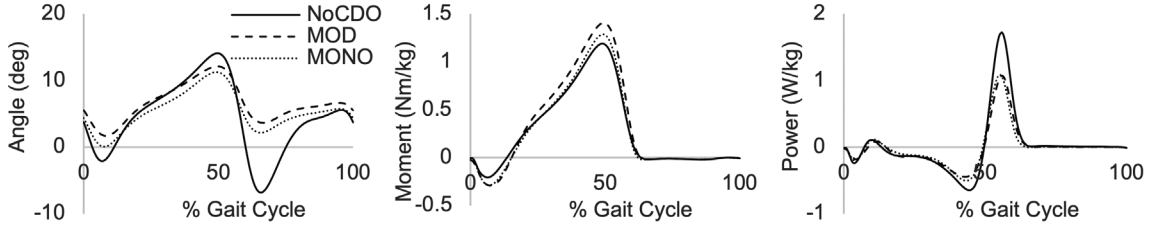


**Figure 2.** Ensemble average ankle joint angles, moments, and powers in each of the study conditions (NoCDO, MOD, MONO).

# The Effect of Carbon Fiber Custom Dynamic Orthosis Use on Outcomes After Traumatic Lower-Limb Injury

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## INTRODUCTION

Carbon fiber custom dynamic orthoses (CDOs) are used to improve function following traumatic lower-limb injury.[1-2] CDOs consist of a semi-rigid foot plate, a carbon fiber posterior strut, and a proximal cuff that transfers force to the limb. CDOs improve patient-reported and performance-based outcomes when paired with a specialized rehabilitation program.[1-3] However, access to specialized care programs is limited, and the effect of commercially available CDOs, without specialized training, is unknown. The purpose of this study was to determine the effect of two commercially available CDOs on patient-reported (PRO) and performance-based (PBM) outcomes in individual with impairment following lower-limb trauma.

## METHOD

***Participants:*** Individuals greater than two years post-traumatic lower-limb injury provided informed consent and completed testing without a CDO (NoCDO) and with a modular (MOD; Reaktiv, Fabtech Systems LLC, Everett, WA) or monolithic (MONO; posterior spring orthosis, Bio-mechanical Composites, Inc., Des Moines, IA) CDO. MOD: Thirty-one individuals (22 male / 9 female, 41(11) years, 1.8(0.1) m, 101.3(18.5) kg). MONO: Twenty-eight individuals (19 male / 9 female, 42(11) years, 1.8(0.1) m, 103.8(18.9) kg). This study was approved by the Institutional Review Board at each study site.

***Apparatus:*** PROs: PROMIS physical function (PF), pain interference (PI), pain behavior (PB), depression (D), and ability to participate (APS) and satisfaction with (SSR) social roles and activities scales, Numerical Pain Rating Scale (NPRS), and Global Rating of Change (GROC). PBMs: Four Square Step Test (FSST), Five Times Sit to Stand (5xSTS), self-selected walking velocity (SSWV), shuttle run (SR), and timed stairs ascent (TSA).

***Procedures:*** Patients were cast and fit by a certified orthotist using standardized procedures. CDOs were centrally fabricated for consistency. Participants completed a three-month accommodation period prior to testing and did not complete a device-specific rehabilitation program.

***Data Analysis:*** Data were analyzed using R statistical software v4.3.3. Paired sample t-tests were used to compare outcomes ($p<0.05$).

## RESULTS

Mean change scores, the difference between each CDO condition and the NoCDO condition, for all outcome measures are presented in Tables 1 and 2.

**Table 1.** Change scores for PROMIS PROs. Statistically significant improvements relative to NoCDO are identified with an asterisk.

| | PF | PI | PB | D | APS | SSR |
|---|---|---|---|---|---|---|
| MOD | 3.0* | -4.1* | -2.3* | -3.8* | 4.0* | 7.1* |
| MONO | 3.6* | -5.0* | -2.7* | -3.3* | 3.0* | 5.3* |

**Table 2.** Mean change scores for all PBMs. Statistically significant improvements relative to NoCDO are identified with an asterisk.

| | FSST | STS | SSWV | SR | TSA |
|---|---|---|---|---|---|
| MOD | -0.5 | -0.6 | -0.1 | -1.2 | -0.1 |
| MONO | -0.7* | -0.5 | -0.1 | -1.2 | -0.5 |

The MOD and MONO CDOs significantly improved all PROMIS PROs and self-reported pain (NPRS). Participants indicated that the CDOs improved their ability to complete daily activities (GROC). All mean PBM times improved with CDO use, but only the FSST significantly improved with the MONO CDO.

## DISCUSSION

Both CDOs significantly reduced pain and improved physical function and daily activities similar to studies with specialized training programs.[1] CDO use reduced self-reported depression, which has not been reported in previous studies.[1] Most PBMs did not significantly improve in the absence of specialized training. The largest changes in PROs were observed for pain interference and participation in social roles, suggesting an improved ability to participate in important life activities, a common goal for orthotic intervention.

## CONCLUSION

The MOD and MONO CDOs improved patient-reported physical and psychological outcomes after lower-extremity trauma. The lack of large improvements in PBMs, as compared to prior studies, may be due to the lack of device-specific specialized training in this study.

## CLINICAL APPLICATIONS

This study provides compelling data demonstrating wide-ranging positive effects of using two commercially available CDOs. Further study is needed to determine if device-specific training further improves outcomes with CDO use after limb trauma.

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# Effect of Carbon Fiber Custom Dynamic Orthosis Stiffness on Limb Mechanics During Gait

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## INTRODUCTION

Carbon fiber custom dynamic orthoses (CDOs) can improve function, reduce pain, and alter foot loading.[1–4] CDOs include a rigid or semi-rigid proximal cuff, a carbon fiber posterior strut, and a full-length, custom-molded footplate. CDO stiffness can be selected to meet patients' needs. However, the effect of CDO stiffness on foot loading has not been previously studied. The purpose of this study was to investigate the effect of CDO stiffness on limb mechanics and foot loading during gait in individuals who have experienced an intra-articular ankle fracture.

## METHOD

***Participants:*** Seven participants (1 female / 6 male, 35.9(10.1) years old, height 1.8(0.1) m, weight 92.2(19.4) kg) who had sustained an intra-articular ankle fracture within five years. Activities were approved by the local Institutional Review Board, participants provided informed consent.

***Apparatus:*** Participants completed testing without an orthosis (NoCDO) and with three CDOs of different stiffnesses (compliant: 3.9(1.2) Nm/deg; moderate: 5.4(1.4) Nm/deg; stiff: 7.0(2.1) Nm/deg) in a randomized order.

***Procedures:*** Ankle kinematic and kinetic data and ground reaction forces (GRFs) were collected using 12 infrared cameras (Vicon Motion Systems Ltd.), 3 force plates (AMTI Inc.), and 57 retro-reflective markers. Wireless force-measuring insoles (Novel Electronics Inc.) were used to collect peak force and force impulse data for the forefoot, midfoot, hindfoot, and total foot. Force impulse was calculated using the indefinite integral of forces acting on the foot during stance.

***Data Analysis:*** Data were processed using Visual 3D (C-motion Inc.) and MATLAB (The MathWorks Inc.). One-way repeated measures ANOVAs were used to test for main effects of condition. Post-hoc testing was performed using paired sample t-tests with a Bonferroni Holm correction.

## RESULTS

All CDOs significantly reduced ankle range of motion ($p \leq 0.003$), peak power absorption ($p \leq 0.002$) and peak power generation ($p < 0.001$) compared to the NoCDO condition (Figure 1). Additionally, all CDOs significantly reduced medial ($p \leq 0.009$) and braking ($p \leq 0.021$) GRF, while the stiff CDO significantly reduced propulsive GRF ($p = 0.007$) relative to NoCDO. Peak forefoot force ($p \leq 0.019$) and forefoot force impulse ($p \leq 0.021$) were 20%–21% and 15%–18% lower in the CDOs compared to NoCDO, respectively. Peak hindfoot forces ($p \leq 0.010$) were reduced 12%–18% in the compliant and stiff CDOs relative to NoCDO (Figure 2). There were no significant differences between CDO stiffness conditions.

## DISCUSSION

The CDOs in this study reduced ankle motion and power in a manner consistent with prior CDO-related literature.[4] Foot loading was significantly reduced by the study CDOs, but CDO stiffness did not influence the level of force reduction. The reductions in foot loading align with those reported using similar CDOs in a healthy population[1] but are smaller than those previously reported with very stiff CDOs.[2,3]

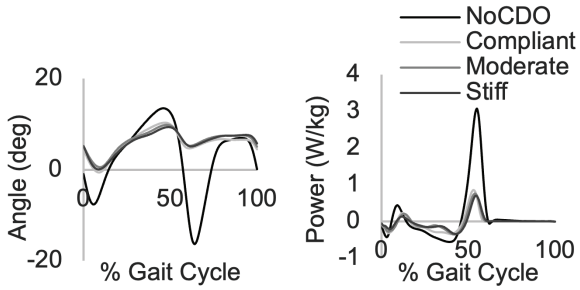


**Figure 1.** Ankle motion and power in each of the study conditions (NoCDO, compliant, moderate, and stiff CDOs).

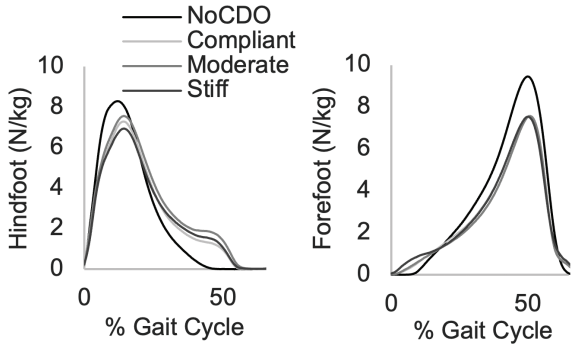


**Figure 2.** Hindfoot and forefoot forces in each of the study conditions (NoCDO, compliant, moderate, and stiff CDOs).

## CONCLUSION

Only minor differences in mechanics and foot loading were seen across CDO stiffnesses, despite the stiff CDO being nearly 80% stiffer than the compliant CDO.

## CLINICAL APPLICATIONS

CDOs of a range of stiffness, like those studied here, can be used to reduce ankle motion and foot loading to benefit individuals who experience pain with motion and loading after ankle fracture.

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# The Effects of Carbon Fiber Custom Dynamic Orthosis Proximal Cuff Design on Foot Loading During Gait

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## INTRODUCTION

Traumatic foot and ankle injuries often cause pain with loading during gait. Carbon fiber custom dynamic orthoses (CDOs) have been shown to decrease pain and improve patient-reported outcomes by controlling motion and offloading the foot.[1–4] CDOs consist of a proximal cuff below the knee, a posterior carbon fiber strut, and a semi-rigid footplate. The proximal cuff is the primary interface for offloading the foot. Despite the potentially important role of cuff design in offloading the foot, studies comparing cuff designs are lacking. The purpose of this pilot study is to determine the effects of common CDO cuff designs on foot loading.

## METHOD

***Participants:*** Five healthy, able-bodied individuals (2 female and 3 male, 45.6(16.5) years, 1.8(0.1) m, 73.1(3.1) kg) and one individual who had experienced an intra-articular ankle fracture in the prior five years (female, 59 years, 1.7 m, 80.8 kg) participated after providing informed consent. Study activities were approved by the local Institutional Review Board.

***Apparatus:*** Loadsol force measuring insoles (Novel Electronics, Inc.) were used to assess plantar forces for the total foot, hindfoot (proximal 30%), midfoot (middle 30%), and forefoot (distal 40%).

***Procedures:*** Participants walked at a controlled pace without a CDO (NoCDO), and with a CDO using three different cuff designs in randomized order (Figure 1).

***Data Analysis:*** Peak force, force-time integral (impulse), and Cohens ***d*** effect sizes were calculated. One-way repeated measures ANOVAs ($p<0.05$) were used to test for main effects, with post hoc paired t-tests with Bonferroni Holm correction.

## RESULTS

There were no appreciable differences in data for post-fracture and able-bodied participants, so their data were combined for analysis. No statistically significant differences were found for between-condition peak forces and force impulse pair-wise comparisons. However, average peak forefoot and hindfoot forces decreased by 22%–29% and 11%–16% with CDO use, respectively, resulting in large effect sizes (Table 1.) Cuff B had the greatest reduction in peak hindfoot force with large to moderate effect sizes (Figure 2.)

## DISCUSSION

Similar to previous literature,[1–3] CDO use reduced peak hindfoot and forefoot forces, with moderate to large effects sizes. The lack of significant difference is likely due to the small sample size in this pilot study. The effect sizes for between cuff comparisons, particularly in hindfoot loading, indicate that proximal cuff design may impact foot loading, but further study with a larger cohort is required.

**Table 1.** Effect sizes for all peak force comparisons.[2] **Large** >0.8, moderate 0.8–0.5, small <0.5.

| | NoCDO /A | NoCDO /B | NoCDO /C | A/B | A/C | B/C |
|---|---|---|---|---|---|---|
| Hindfoot | **1.53** | **1.97** | **1.81** | **2.99** | **1.69** | 0.61 |
| Midfoot | **1.01** | 0.80 | 0.56 | 0.57 | **0.81** | 0.50 |
| Forefoot | **1.00** | **1.19** | **1.36** | **0.81** | 0.24 | 0.39 |


**Figure 1.** Three cuff designs assed in this study: (A) anterior shell with Chicago screw attachment; (B) patellar tendon bearing anterior shell with BOA ratcheting dial; and (C) anterior shell with Velcro.

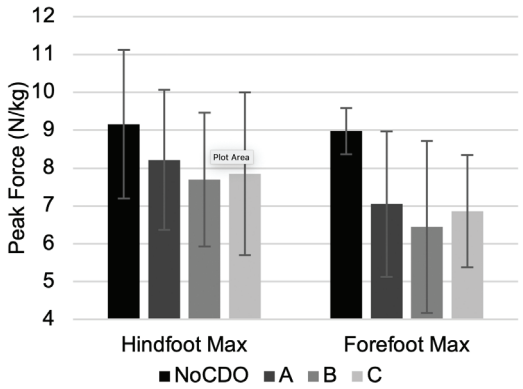


**Figure 2.** Mean peak hindfoot and forefoot forces.

## CONCLUSION

In this pilot study, the moderate-to-large effect sizes for most pair-wise comparisons indicate that CDO cuff design may influence peak foot loading, and that a fully powered study with a larger cohort of post-fracture and able-bodied participants is required to fully understand the effect of cuff design on foot loading.

## CLINICAL APPLICATIONS

For patients with CDOs, proximal cuff design may play an important role in offloading painful areas of the foot. A fully powered study is warranted to further investigate these effects.

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# Goal Attainment and Reduction in Walking Aids: Interim Results from the C-Brace® Registry

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## INTRODUCTION

Goal achievement is an important treatment outcome for patients treated with a KAFO.[1] Previous studies have shown that C-Brace microprocessor-controlled Stance and Swing Controlled Orthosis (MP-SSCO®) improves users' perceived ease and safety of activities of daily living (ADLs) and quality of life.[2,3] However, C-Brace users' ability achieve their personal goals and reduce the use of walking aids has yet to be disseminated.

A prospective, multicenter registry was designed to gather real-world safety and effectiveness data from patients who have been fitted with a CBrace. The purpose of this interim analysis of registry data was to examine goal achievement after 12 months of wear. A secondary purpose was to assess reduced dependence on walking aids.

## METHOD

Institutional Review Board approval was obtained, and all subjects signed informed consent prior to participation.

***Participants:*** Forty-six subjects from 29 sites had both baseline and follow-up data available for analysis; 17 female / 29 male, mean age of 51.8 years and mean weight of 174.8 (58–270) lbs. Nine subjects were bilateral users. Most common diagnoses were incomplete spinal cord injury (13), trauma (9), polio (7), iatrogenic (3), and multiple sclerosis (2).

***Apparatus:*** Outcome measures included the Patient-Specific Functional Scale (PSFS) and use of assistive devices at baseline and during performance measures (PM), Timed Up and Go and 10-Meter Walk Test. The PSFS is a goal-attainment scale in which subjects identify three to five activities and rate them on zero-to-ten scale, with zero being unable to perform and ten being able to perform at the same level as before the injury.

***Procedures:*** Questionnaires were completed by the subjects and PMs performed by the investigators at baseline with the existing orthosis and at six and 12 months with the C-Brace.

***Data Analysis:*** Changes of two points on the PSFS were considered clinically meaningful. The Wilcoxon signed-rank test was used to test the difference in the PSFS scores between baseline and follow up.

## RESULTS

The PSFS scores at baseline and follow up are displayed in Figure 1 and the scores for the top activity categories in Table 1. The assistive devices used at baseline and for performance measures at follow-up are shown in Table 2.

## DISCUSSION

Subjects significantly increased PSFS scores after CBrace fitting with clinically meaningful changes in the top categories. Eighty-seven percent reported using walking aids at baseline, and 70% used them during baseline PMs. After the C-Brace fitting, only 48% still needed them.

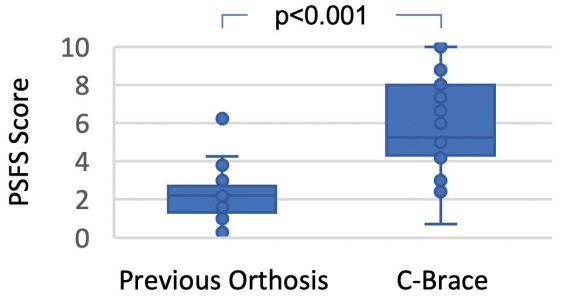


**Figure 1.** PSFS scores at baseline and six or 12 months after C-Brace fitting.

**Table 1.** Top activity categories, PSFS scores at BL and after C-Brace fitting.

| Activity Category | Goals/ Subjects | Avg PSFS | |
|---|---|---|---|
| | | BL | C-Brace |
| Sports/exercise | 59/27 | 1.5 | 4.0 |
| Slope/stairs/uneven ground | 31/19 | 2.0 | 6.2 |
| Shopping/concerts/crowds | 13/10 | 2.5 | 5.6 |
| Household chores/repairs | 10/10 | 3 | 7.8 |
| Walking better/faster/farther | 7/7 | 3.3 | 7.6 |

**Table 2.** Use of walking aids at baseline and during PMs.

| | Baseline Reported (n=46) | Use during PMs | |
|---|---|---|---|
| | | Baseline (n=40) | C-Brace (n=46) |
| None | 6 (13%) | 12 (30%) | 21 (52%) |
| Cane/quad cane | 15 (32%) | 14 (35%) | 12 (26%) |
| Multiple | 13 (28%) | -- | -- |
| Crutches | 7 (15%) | 9 (23%) | 4 (9%) |
| Walker | 3 (6%) | 4 (10%) | 4 (9%) |
| Wheelchair | 1 (2%) | -- | -- |
| Other | 1 (2%) | 1 (3%) | 2 (4%) |

## CONCLUSION

The majority of CBrace subjects progressed toward achieving their goals as measured by the PSFS, and many reduced their dependence on walking aids.

## CLINICAL APPLICATIONS

A device registry in routine clinical practice characterizes real-world benefits of the C-Brace. The PSFS can demonstrate goal achievement after orthotic fittings.

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# Dynamic Balance Responses to Somatosensory Foot Orthoses in Older Adults: A Posturographic Assessment

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## INTRODUCTION

Foot orthoses (FOs), including insoles or shoe inserts, have been recommended for their potential to improve gait, balance, and stability. More recently, FOs with textured surfaces or protruded knobs that aim to provide somatosensory stimulation of the mechanoreceptors on the glabrous foot skin have been suggested to enhance proprioceptive inputs and consequent postural balance and stability.[1]

Although FOs with protruded knobs offer a passive intervention for enhancing proprioceptive responses, the evidence for their effectiveness is still emerging, and the mechanisms that influence balance are not fully understood. Moreover, most previous studies have only relied on force plates and motion captures systems to investigate the sway variability or functional clinical tools for the assessment of balance and stability.[2] However, these measurements do not quantify the functional scores related to visual, vestibular and somatosensory systems. There is a need for comprehensive assessments on how FOs with protruded stimulating knobs influence postural balance in the elderly.

The sensory organization test (SOT) in computerized dynamic posturography (CDP) method provides a sophisticated way of quantifying balance performance under various sensory conditions including visual, vestibular, and somatosensory inputs.[3] Thus, the aim of this study was to investigate the immediate effects of FOs with stimulating knobs on the postural balance among the elderly using CDP.[3]

## METHOD

***Participants:*** Twenty-three elderly participants (female: 16; age=71.58±3.44; male: 7; age=71.85±3.80) were recruited through convenience sampling technique in the study. All participants were healthy older adults aged 65 or above who had the ability to walk for 30 minutes continuously without any breaks or external assistance. The Human Subject Ethics Sub-Committee of The Hong Kong Polytechnic University approved the study protocol, which followed the guidelines outlined by the Declaration of Helsinki.

***Apparatus:*** The Bertec Balance System (Bertec Corporation, Columbus, OH, USA), integrated with a built-in dynamic force plates was employed to collect comprehensive data sets on SOT.

***Procedures:*** The postural balance of all the participants was examined under two FO conditions in a randomized order: (i) flat FOs and (ii) prefabricated stimulating FOs. The surface of the stimulating FOs (Copper Fit Zen Step Comfort, China) was entirely covered with protruded rounded knobs distributed evenly throughout the bottom surface. The study protocol for SOT included six experimental conditions under both static and dynamic support surfaces, which are used to generate balance scores related to composite equilibrium (ComEQM), somatosensory (SOM), visual (VIS), vestibular (VEST), and preference (PREF) functions.

***Data Analysis:*** A paired sample t-test was performed between FO conditions for each outcome measure using the IBM SPSS software (v.22, SPSS Inc., Chicago, IL).

## RESULTS

A significant improvement in ComEQM score was noted with the stimulating FOs when compared to flat FOs ($P<0.05$). Moreover, an increasing trend of score was observed for SOM, VIS, and VEST systems.

| Parameters | Flat FO | | Stimulating FO | | P |
|---|---|---|---|---|---|
| | Mean | ± SD | Mean | ± SD | |
| ComEQM | 68.17 | 3.54 | 69.61 | 3.92 | **0.048** |
| SOM | 99.04 | 1.71 | 100.13 | 1.20 | 0.188 |
| VIS | 67.26 | 5.94 | 69.13 | 7.31 | 0.337 |
| VEST | 65.57 | 5.74 | 67.00 | 6.02 | 0.401 |
| PREF | 96.09 | 2.61 | 97.04 | 1.98 | 0.481 |

ComEQM: composite equilibrium; SOM: somatosensory; VIS: visual; VEST: vestibular; PREF: preference.

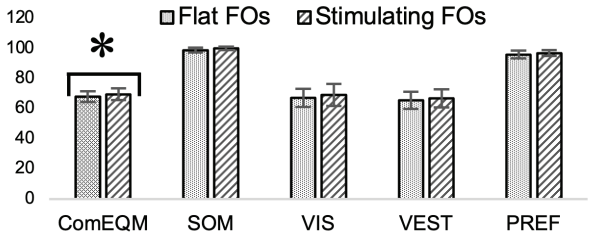


**Figure 1.** Comparisons between the FOs conditions.*Indicates significant differences (p<0.05).

## DISCUSSION AND CONCLUSION

The improvement in the ComEQM highlights the potential of stimulating FOs to provide enhanced proprioceptive feedback, which could lead to better postural control and coordination. The increasing trend in scores for the SOM, VIS, and VEST systems indicates that FOs with stimulating knobs may facilitate better integration and function of these sensory systems. These findings underscore the importance of considering such FOs with protruded knobs in clinical application to improve balance and sensory integration. To explore site-specific and long-term effects, as well as the underlying mechanisms, longitudinal research is warranted.

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# Systematic Review and Meta-Analysis of Foot Orthosis Biomechanics in Runners with Asymptomatic Flatfeet

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## INTRODUCTION

Asymptomatic flatfeet are recently regarded as anatomical variants and non-pathomechanical, similar to normally arched feet. A recent systematic review has demonstrated no significant correlation with running-related injuries.[1] However, this condition is typically associated with pronation, which may alter multiple joint motions of the foot, including dorsiflexion, eversion, and abduction.[2]

In clinical trials, it has been demonstrated that foot orthoses (FOs) with a variety of designs, including wedges and arch-supports, can prevent or manage running-related conditions, such as ankle sprains, tibial stress syndromes, runner's knee, Achilles tendinopathy, plantar fasciitis, etc.[3]

However, our understanding of the specific clinical benefits that FOs can offer to runners with asymptomatic flatfeet is limited. Therefore, a systematic evaluation and meta-analysis of relevant studies are needed to summarize collective evidence the biomechanical effects of FOs on lower-extremity running in individuals with asymptomatic flatfeet and to implement guidelines for clinicians and orthotists.

Therefore, the aim of this systematic review and meta-analysis was to evaluate the effectiveness of FOs interventions on the midfoot/arch, ankle, tibial, and knee kinematics and kinetics of runners with asymptomatic flatfeet. We hypothesized that the insertion of FOs can modify lower-extremity mechanics, reduce pronation-related motion, and improve performance during running.

## METHOD

A comprehensive database search of PubMed, Scopus, Web of Science, Cochrane, and CINAHL from inception to April 2024 was employed to identify original articles with orthotic interventions, including FOs made of either arch-support-only or arch-support with posts on the medial side.

***Apparatus:*** The methodological quality was evaluated using a modified Downs and Black index.

***Procedures:*** The PICO framework was utilized to develop a systematic search strategy, incorporating three categories of keywords (flatfoot-related terms, foot orthoses-related terms, and biomechanics-related terms) connected by Boolean operators ("OR," "AND," and "NOT"). Two reviewers (AJ and NL) independently searched the databases and screened the titles and abstracts of the non-duplicated articles to assess their eligibility for inclusion in this review. The outcomes of interest included the frontal plane joint angles and internal moments of the knee, ankle, and midfoot/arch, which are primarily associated with flatfeet.

***Data Analysis:*** The main outcomes of respective FO conditions reported in each study were systematically input into data tables (mean, standard deviation, and sample size for both intervention and control groups). Due to the small sample size and methodological differences among the studies, a random effects model was employed in the meta-analysis. Since all outcome measurements were continuous, the standardized mean difference (SMD) and 95% confidence interval (95% CI) were used to determine effect sizes. Statistical analyses were performed using the Comprehensive Meta-Analysis v.4 software (Biostat Inc., Englewood, NJ, USA), with a statistical significance set at $p<0.05$.

## RESULTS

This review included 240 participants (122 male and 118 female) in 12 single-group quasi-experimental studies with 18 different orthotic trials (orthotic trial to indicate different orthotic conditions). Our meta-analysis indicated that arch-support-only FOs did not result in any significant changes on frontal plane joint angles and moments. However, a random effects analysis demonstrated that arch-support FOs with rearfoot and forefoot medial posts significantly reduced peak forefoot to rearfoot eversion (SMD=-0.68, 95% CI [-1.54, 0.18]), peak ankle eversion (SMD=-0.41, 95% CI [-0.78, -0.04]), peak ankle invertor moments (SMD=-0.51, 95% CI [-0.97, -0.05]), and Achilles tendon loading rates (SMD=-0.94, 95% CI [-1.78, -.09]) during running.

## DISCUSSION AND CONCLUSION

Our findings revealed that modifying lower-extremity kinematics and kinetics using FOs is strongly associated with its design modifications, particularly with the positioning of the medial posts. The medial post at the rearfoot and forefoot of the arch-support FOs could be clinically beneficial, although this was evident in a few available studies. This review underscores the necessity for further research and highlights that arch-support FOs with rearfoot and forefoot medial posts may have a greater impact on modifying the lower-extremity biomechanical function in individuals with asymptomatic flatfeet.

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# Toward Improved Mechanical Characterization of Prosthetic Feet

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## INTRODUCTION

Prosthetic feet are elastic structures that provide compliance predominantly within the sagittal plane. This sagittal plane compliance can be divided into two primary components: (1) vertical stiffness (stiffness along the axis of the shank) and (2) rotational stiffness (stiffness about the "ankle joint").

Prosthetic componentry exists that provides each of these stiffness independently or in combination. For example, an axial shock-absorbing pylon provides a pure vertical stiffness with no rotational stiffness while a single axis prosthetic foot provides a pure rotational stiffness with no vertical stiffness. Other feet, however, provide a combination of rotational stiffness and vertical stiffness. Rotational stiffness and vertical stiffness serve different biomechanical functions and are not interchangeable. For example, a vertical stiffness allows for impact shock. Consequently, vertical shock pylons are typically used to mitigate heel strike impact forces. Rotational stiffness, on the other hand, accommodates various ground slopes, allowing compliant ankles to work well across various terrains.

Unfortunately, the most prevalent method for characterizing the behavior of prosthetic feet conflates these two stiffnesses. The most common method of assessing the stiffness of a prosthetic foot is based on the protocol described in the ISO 10328 testing standard in which the prosthetic forefoot is loaded at a 20-degree angle, and the force and displacement of the actuator is used to compute a stiffness. However, this computed stiffness captures axial and rotational deflections, thereby conflating both the rotational and vertical stiffnesses into a single number.

## METHOD

To better understand the implications of the ISO 10328-based assessment protocol, a mathematical model was investigated in which a system with series rotational stiffness and vertical stiffness was loaded at a 20-degree angle. The model was then used to demonstrate that for a given stiffness measured by the ISO 10328-based test, there are an infinite number of combinations of vertical and rotational stiffnesses that can achieve this equivalent output stiffness.

In this model, a target output stiffness of 31.4 N/mm was selected and is equal to the softest stiff category of the Össur VariFlex prosthetic foot.[1] The set of rotational and vertical stiffnesses that can achieve this output stiffness was then computed.

## RESULTS

Figure 1 shows the combinations of rotational and vertical stiffnesses that can achieve an output stiffness of 31.4 N/mm (as measured by the ISO 10328-based test). Figure 1 also highlights that the stiffest category of the Össur VariFlex foot, if paired with a vertical shock pylon, will exhibit identical stiffness to that of the softest category.

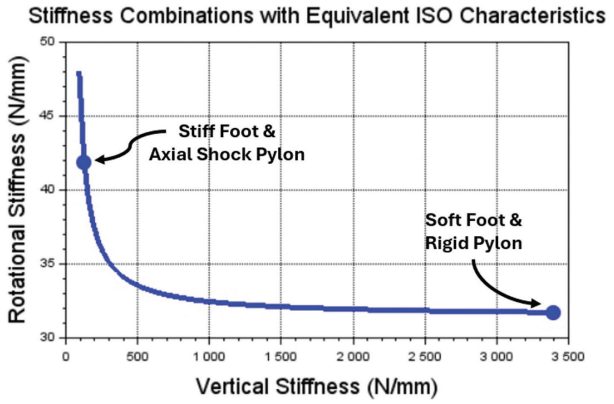


**Figure 1.** Combinations of rotational and vertical stiffnesses that achieve equivalent stiffnesses when assessed using the ISO 10328-based test. Solid dots show that the softest category of a prosthetic foot can exhibit identical measured behavior as the stiffest category of the same foot when paired with a vertical shock pylon.

## DISCUSSION

Although the two systems highlighted in Figure 1 exhibit the same behavior when tested using the ISO- based test, they exhibit different biomechanical behavior and are appropriate for different patients. This highlights one of the major deficiencies of the ISO-based foot characterization method: It does not independently measure rotational and vertical stiffness. Consequently, we advocate for characterization methods that independently measure the rotational and vertical stiffnesses of the prosthetic foot such as those proposed by Adamczyk.[2]

## CONCLUSION

We hope to highlight the deficiencies of current foot characterization methods in the hopes that new methods will be adopted that better reflect important clinical differences between prosthetic components.

## CLINICAL APPLICATIONS

This work aims to develop a better mechanistic understanding of how the physical properties of prosthetic componentry impact patient outcomes. The first step in this process is to develop characterization methods that capture the salient features of the components themselves.

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# Gait Classification in Individuals with Unilateral Transfemoral Amputation Using K-Means Clustering

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## INTRODUCTION

Individuals with unilateral transfemoral amputation (uTFA) demonstrate asymmetrical gait patterns due to the partial loss the lower limb and associated muscles on the amputated side.[1] The gait asymmetry is influenced by various factors, including the type of prosthesis, level of amputation, muscle strength, compensatory strategies, amputation surgery, and individual gait deviations. Due to the complexity and interplay of these factors, it is challenging to categorize the gait pattern in individuals with uTFA holistically.

Unsupervised learning clustering algorithms can effectively classify similar gait patterns from gait data by leveraging the inherent data structure, bypassing the need to account for factors influencing gait patterns. This study aims to assess the effectiveness of using clustering algorithms in classifying the gait patterns of individuals with uTFA and to analyze and compare the distinctive characteristics of these gait patterns.

## METHOD

***Participants:*** Twelve individuals with uTFA (age: 53.92±6.81 years; height: 1.74±0.07 m; body mass: 74.42±15.38 kg) participated in this study. This study was approved by the Human Subject Ethics Sub-Committee of The Hong Kong Polytechnic University.

***Apparatus:*** Spatiotemporal data and vertical ground reaction forces (vGRF) were collected using an instrumented treadmill Zebris FDM-T (Zebris Medical GmbH, Germany).

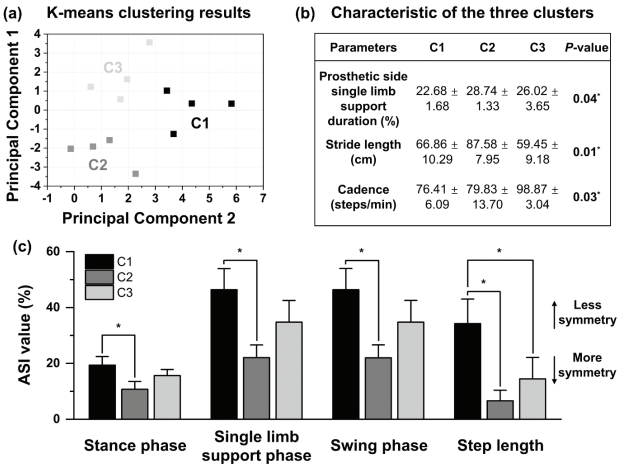
***Data Analysis:*** The Absolute Symmetry Index (ASI) was calculated for both spatiotemporal parameters and ground reaction forces. All collected and computed parameters were normalized and used as input features for the k-means clustering model. The optimal number of clusters was determined using the silhouette score and elbow method. One-way analysis of variance (ANOVA) and independent sample Kruskal-Wallis tests were employed to evaluate differences in spatiotemporal, vGRF, and ASI parameters among the different clusters, with the significance level set at P=0.05.

## RESULTS

K-means clustering revealed three distinct clusters (figure 1a). Cluster 1 (C1) exhibited the lowest symmetry with the shortest duration of single limb support on the prosthetic-side phase; cluster 2 (C2) demonstrated the highest symmetry, characterized by the longest duration of single limb support on the prosthetic side and the longest step length on the intact side; and cluster 3 (C3) showed moderate symmetry, marked by the highest cadence (figure 1b and 1c).

## DISCUSSION

The three clusters of individuals with uTFA exhibited significant differences in spatiotemporal and symmetry parameters, revealing distinct gait patterns. Targeted training to enhance gait symmetry could focus on increasing step length and extending the duration of single limb support phase on the prosthetic side (C1 versus C2). However, the influence of cadence on gait symmetry remains inconclusive (C2 versus C3). It appears that increasing step length may have a more positive effect on walking speed for individuals with uTFA than increasing cadence.[2]




| Parameters | C1 | C2 | C3 | *P*-value |
|---|---|---|---|---|
| Prosthetic side single limb support duration (%) | 22.68 ± 1.68 | 28.74 ± 1.33 | 26.02 ± 3.65 | 0.04* |
| Stride length (cm) | 66.86 ± 10.29 | 87.58 ± 7.95 | 59.45 ± 9.18 | 0.01* |
| Cadence (steps/min) | 76.41 ± 6.09 | 79.83 ± 13.70 | 98.87 ± 3.04 | 0.03* |

**Figure 1.** (a) K-means clustering results; (b) characteristics of the three clusters; (c) absolute symmetry index results.

## CONCLUSION

This study identified the primary gait patterns of individuals with uTFA using k-means clustering, categorizing them as follows: C1, characterized by the worst symmetry and the shortest single-limb support duration on the prosthetic side; C2, demonstrating the best symmetry and the longest step length; and C3, exhibiting better symmetry and the highest cadence.

## CLINICAL APPLICATIONS

The three distinct gait patterns can serve as a classification standard for individuals with uTFA, paving the way for tailored rehabilitation programs that target specific gait characteristics to improve walking ability and overall mobility.

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# Reactive Balance in Older Transfemoral Amputees

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## INTRODUCTION

Although transfemoral amputees (TFAs) have balance difficulties,[1,2] few studies have examined reactive balance control in this population.[3] Our aim was to characterize the reactive balance system in TFAs using rigorous external surface perturbations to capture detailed segmental balance responses. We compared people with transfemoral amputations to age-matched controls and compared two different types of knees.

## METHOD

***Participants.*** Eleven TFAs and 10 controls provided written informed consent and were tested under an approved Institutional Review Board protocol. TFAs were on average 57 years old (17 SD), 175 cm tall (7 SD), and weighed 87 kgs (21 SD). Controls were 56 years (14 SD), 173 cm (12 SD), and 78 kg (18 SD). Females: Two TFAs and five controls. We typically tested one microprocessor knee (often prescribed) and one mechanical knee (3R90).

***Procedures.*** Subjects' balance was tested during one stable surface test (no perturbation) and four pseudorandom surface tilt tests (two medial-lateral, ML, and two anterior-posterior, AP). Figure 1 (upper left) shows a ML test with surface tilts, which was unpredictable to subjects.

***Data Analysis:*** 3D segmental and center of mass (COM) kinematics were recorded and used to calculate sway metrics. In the time domain, root-mean-square (RMS) quantified the in-plane sway (same direction as perturbation) and out-of-plane sway (sway in a perpendicular plane that is considered extraneous). In-plane sway was also analyzed across frequencies: (1) sway divided by surface tilt to quantify the relative sway magnitude at each frequency; (2) coherence to quantify the linear correlation between sway and surface tilt; and (3) sway at non-stimulated frequencies to quantify the non-linear noise, or "remnant sway." We used a linear statistical model with model effects: perturbation amplitude (0, 2, 5 deg); direction (ML, AP); knee type; and group (control, amputee).

## RESULTS

For both ML and AP tests, amputees' in-plane sway was similar to controls in overall magnitude (RMS) and in sway / surface tilt across frequencies (Figure 1, upper right and bottom left). There were no significant differences in COM sway across groups in these two metrics. The main group differences were found in metrics related to out-of-plane sway, noise, and non-linearity. Amputees' out-of-plane sway was larger for each segment ($p<0.05$) and COM ($p=0.054$) (Figure 1, middle right). Coherence was significantly lower for amputees' COM (Figure 1, bottom middle) and segmental sway across most frequencies ($p<0.05$). These coherence results mean that amputee sway was less correlated with the stimulus. Remnant sway ("noise") was larger on average for amputees (Figure 1, bottom right) and was significantly larger at high frequencies for upper-body sway and at low frequencies for lower-body sway. Knee type was not a significant main model effect for any metric.

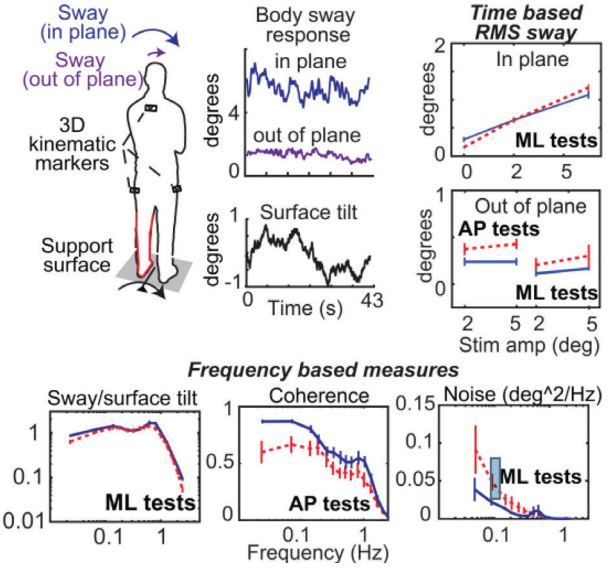


**Figure 1.** Balance responses were evoked with surface tilts, and sway was measure in the same direction as the surface tilt (in plane) and in the opposite direction (out of plane). Dotted red lines are mean amputee data, solid blue are controls, and error bars are 1 SE. All responses shown are COM sway with eyes closed.

## DISCUSSION

Adding a mechanical device to a human could make balance responses more linear and stereotyped compared to controls. But we found TFAs had heightened non-linear extraneous sway and were less correlated with the surface. Possible contributors include the non-linear socket limb interface and observable instances of knee buckling, transient loss of balance, and amputees' reported high effort on tests.

## CONCLUSION

TFAs differed from age-matched controls with excessive non-linear and noisy sway that were less correlated with the perturbation, and there were minimal differences in reactive standing balance between the two knees tested.

## CLINICAL APPLICATIONS

Perturbations provide a window to detect one's state of balance. Clinicians should examine nonlinear extraneous movements in TFAs.

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# Participation in Work–Life of Individuals Living with Transfemoral Amputation Using a Microprocessor-Controlled Prosthetic Knee Joint: Results of a Digital Patient Survey

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## INTRODUCTION

One important aspect of the burden of disease (BoD) is participation in work–life (PW) and return to work (RtW), which affects patients as well as their families, the healthcare/social system, and society at a large. This is of 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] Characteristics of PW/RtW in patients with transfemoral amputation prior to the introduction of MPKs favor traumatic etiology and younger age. Indicators analyzed so far include amputation level, time since amputation, time to definitive fitting, mobility, Reintegration to Normal Living Index (RNLI), quality of life (QoL), and occupational rehabilitation.[3,4,5] The purpose of this observational study was to gain a deeper understanding of PW and the potential benefits of using MPKs.

## METHOD

***Participants:*** Individuals using an MPK (C-Leg/Genium, Ottobock) for at least three months, >18 years, with or without prior prosthesis in Germany.

***Apparatus/Procedure:*** A digital survey was sent via e-mail to participants; it included Likert scales, self-designed items, RNLI, Amputee Body Image Scale (ABIS), and EQ-5D-5L. The observational investigation was conducted in accordance with all ethical and legal requirements.

***Data Analysis:*** Minitab/Matlab; Chi2-/Fisher-Exact Test; Bonferroni correction; Kruskal-Wallis / MannWhitney-U Test.

## RESULTS

Five hundred twenty participants who responded to the productivity chapter of the survey were analyzed. More than half (55.96%) were employed (82% full and 18% part time, which is almost comparable to the national cohort, 71% full-time and 29% part-time), 11.54% were not employed, and 32.5% retired with a mean age of 63.63, 45.98 and 49.91 years, respectively. Of those who worked, 21.3% were retrained after the amputation. Nearly half of the participants (44.3%) reported that their job changed due to amputation: 60% changed the type of professional activity. Almost three quarters (73%) reported spending most of their work time sitting, and 20% indicated they usually stand or walk for long periods of time do moderately hard professional activities. Individuals with traumatic amputation had a 1.85 times higher probability of RtW than those with other etiologies; compared to vascular amputation, RtW was 81% higher. The likelihood of maintaining PW increased by 1.31 for every additional five years after amputation. Age at amputation was identified as a negative RtW factor, with the likelihood of working decreasing by 10% for every five-year increase. Time to definitive fitting indicates likelihood of RtW, indicating the importance of sufficient and completed rehabilitation: 2–3 months: 4.53 times compared to less than three months (.001), with individuals using Genium having 2.88 times higher chances than those with C-Leg (.007). After 12 months, chances for RtW decreased 4.47 times (.003), Higher mobility was associated with higher odds of RtW (mobility grade 4: 4.06/MG 3: 2.85). The use of assistive devices had a negative impact on RtW(OR: 0.26). Participation in all-day activities as indicated by the RNL (mean score 86.8) was positively associated with RtW, with each seven-point increase resulting in 1.42 times higher probability. Good body image (BI) (ABIS mean score 45.9; the higher the score, the worse BI) indicated a positive association with PW. Each 10-point decrease on the ABIS score increased the odds of RtW by 28%. Improving QoL was strongly associated with RtW; each 0.1 improvement in utility led to 1.38 times greater chances for RtW. 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).

**Table 1.** PW limitation ratings (n=289).

| PW limitation of professional duties | mean |
|---|---|
| Mastering a regular workday | 2.35 |
| Work without additional breaks | 2.84 |
| Change location at any time | 2.43 |
| Carrying, picking up moving objects | 3.30 |
| Same posture over a longer period | 3.62 |
| All necessary movements for work | 2.90 |
| Concentrate on work throughout | 2.83 |
| Take part at social activities at work | 2.57 |

## DISCUSSION

PW/RtW of individuals using a MPK in Germany was high.

## CONCLUSION

Patients' participation in work–life is limited to some extent and can be improved utilizing an MPK.

## CLINICAL APPLICATIONS

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

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# Health-Related Quality of Life in Amputees with a Microprocessor-Controlled Prosthetic Knee Measured by the EQ-5D-5L

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## INTRODUCTION

The EQ-5D-5L is commonly used to evaluate the Quality of Life (QoL) of individuals using a MPK (iMPK), but little is known about how well the questionnaire matches this specific cohort. The aim of this observational study was to gain a better understanding of iMPK QoL and if German normative EQ-5D data[1,2,3] adequately represent them.

## METHOD

***Participants:*** Individuals using an MPK (C-Leg or Genium, Ottobock) for at least three months, age 18–80-plus years, with or without prior prosthesis.

***Apparatus:*** A digital survey provided by a third party (www.rogator.de) was used; EQ-5D-5L (European QoL questionnaire in five dimensions and five levels).

***Procedures:*** MPK users in Germany were invited per e-mail to participate in the online survey.

***Data Analysis:*** All data analyses were conducted with SPSS (Version 29). The first evaluation part was to compare the EQ-5D-5L data of different subgroups to normative data,[1] and the second part was to determine how individuals with amputation value health conditions associated with their own situation to other health conditions in seven hypothetical health states (HS) (amputation, leg fracture, inguinal hernia, diabetes mellitus, colon cancer, myocardial infarction, single eye blindness), with the goal of establishing anchoring benchmarks.

The observational investigation was conducted in accordance with the European Medical Device Regulations (Art. 82 MDR), and its respective implementation in the German Medical Device Law (§47(3) MPDG). It complied with all applicable data protection legislation.

## RESULTS

In total 512 participants completed the survey and provided data on EQ-5D-5L. Among the five EQ-5D dimensions, self-care (SC) had the least problems (11.9%), whereas pain/discomfort (PD) (75.0%) had the highest, followed by mobility (Mo) (46.7%). Severe problems were extremely uncommon (2.1%). Of the participants, 18.2% reported being problem-free. The majority of respondents (58%) had responses not exceeding minor problems. When the dimensions were analyzed by age group, the dimensions SC and usual activities (UA) showed the greatest significant variance across age groups among individuals who reported issues (0.08 Mo; 0.04 SC; 0.04 UA; 0.63 P/D; 0.53 A/D). A similar pattern was observed for gender and employment status. A comparison of German value set-derived EQ-5D-5L index data to average generated index values (gender and age, range (0.82-0.86) indicated no significant differences.

The results of the participants' own assessment of their health state with the EQ-Visual Analogue Scale showed a mean VAS of 89.6 for participants with a problem-free health state; 14.9 points higher (74.7) than for those with at least one problem (81.8%). With regard to age, the mean VAS score of the oldest participant group was 9.2 points lower than the mean VAS score of the youngest group (p<0.01).

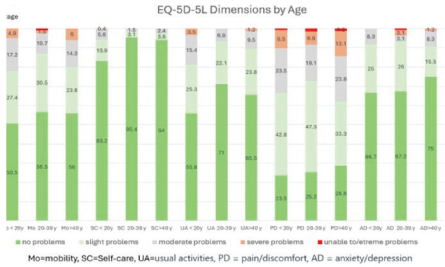


**Figure 1.** EQ-5D-5L dimensions by age.

The results of participants' perception of hypothetical disease states showed that inguinal hernia was attributed the lowest decline in QoL, followed by above- knee amputation. Females tend to place a higher value on blindness and myocardial infarction, whereas males place a higher value on amputation and diabetes. With the exception of colon cancer, higher age groups had slightly lower values. Employed participants had higher valuations except for hernia. Participants valued their health today 20.1 points higher compared to the HS patients with amputation.

## DISCUSSION

Future research should start prior to fitting non-MPK users, or a longitudinal study would contribute to a better understanding of the beneficial impact of an MPK on QoL measured by the EQ5D.

## CONCLUSION

The results suggest a substantial beneficial impact of MPKs. Individuals utilizing MPKs had a comparable quality of life as the general German population with one medical condition.

## CLINICAL APPLICATIONS

Prior to the provision of a prosthesis, a baseline EQ-5D assessment should be performed to demonstrate the potential of an MPK to improve QoL.

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# Markerless Motion Capture for Clinical Gait Analysis: Feasibility Study

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## INTRODUCTION

Prosthetic gait is complex, can be affected by many factors, and has been studied for many years.[1,2] Previous gait analysis techniques have limited the ability to analyze prosthetic gait in real-world settings.

Markerless motion capture (MMC) is an emerging technique that uses computer vision to measure human movements from video.[3,4] The use of these systems could greatly expand access to movement analysis in rehabilitation, research, and clinical practice. However, the use of these systems in prosthesis users has not been widely studied. We previously developed and validated an MMC-based gait analysis pipeline on a heterogeneous clinical population.[5,6] Recent advancements in our modeling methods have lead to improved accuracy of spatiotemporal gait parameter outputs among many clinical populations, including lower limb prosthesis users (LLPUs), compared to able-bodied controls.[7] While these results are promising, our data collection has been performed in controlled settings in our laboratory or rehabilitation hospital.

Our long-term goal is to create a gait analysis tool that can be used by healthcare providers in real-world settings. To test the real-world application of our MMC system, we collected data at the 2024 Academy Annual Meeting to determine the feasibility of performing gait analysis on a large scale in a real-world setting.

## METHODS

***Participants and Apparatus:*** Thirty able-bodied individuals and 14 LLPUs were included. Subjects were recruited by word-of-mouth at the 2024 Academy Annual Meeting over a two-day period. Subject demographics were as follows: LLPUs: gender (11 male, 3 female); age (average: 41.8, range: 25-53); amputation level (5 TT, 3 B/L TT, 6 TF); K-level (11 K4, 3 K3). Prosthetic components and suspension varied. Able-bodied individuals: gender (9 male, 21 female); age (average: 32.1, range: 23–59). Apparatus: MMC system.

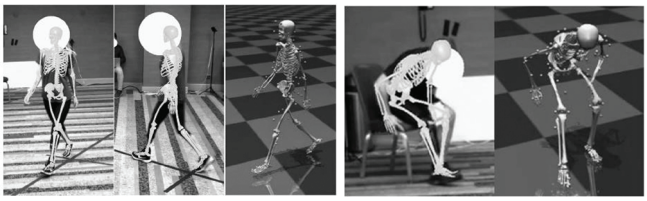
***Procedures:*** Subjects were asked to complete several self-report surveys (fall questionnaire, ABC, PLUS-M) and several performance-based outcomes (10MWT at three speeds, TUG, TUG with dual task, L-Test, FSST, Postural Sway Test) as able. Data was collected with the MMC system during all performance-based outcome measure tasks.

***Data Analysis:*** Processing of the videos was performed using our custom gait analysis pipeline.[6]

Northwestern University Institutional Review Board approved all methods, and all participants provided written informed consent.

## RESULTS

In total, we recruited and collected data on 44 individuals, including 14 LLPUs, with 440 total trials over a two-day period. No trials were discarded due to technical difficulties during data collection or processing. Data collection required four full-time research personnel. Our sample included a diverse set of LLPUs including six unilateral transfemoral, five unilateral transtibial, and tree bilateral transtibial prosthesis users. Among the transfemoral users, two individuals used MPKs, three individuals used powered knees, and one individual used a microprocessor knee/ankle system. All 44 subjects were able to complete all performance-based outcome measures. Self-report surveys were only completed by LLPUs and response rate was 86%.



**Figures 1 and 2 (from left).** (1) 3D MMC analysis from a left TT during 10mWT; (2) 3D MMC from a right TF during TUG, showing decreased loading of prosthetic limb during stand-sit.

## DISCUSSION/CONCLUSION

Here we demonstrate that it is feasible to perform gait analysis with our MMC system on a large scale in a real-world setting. We were able to recruit and collect data on 44 individuals over a two-day period with minimal complications and had a good survey response rate, showing ease of use. While results from the MMC system are promising, the ability to measure gait parameters from a single camera would improve the capacity to analyze gait in real-world settings. Therefore, we are currently developing methods to improve accuracy from a single camera.[8] Future directions will look to determine the ability to use video-based biomechanical gait analysis to predict fall risk and quantify changes in gait in LLPUs.

## CLINICAL APPLICATIONS

Our long-term goal is to develop a gait analysis tool that can be integrated into clinical practice with results immediately available to the clinician. Potential applications include outcome assessment, dynamic alignment and fall risk assessment.

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# Innovative Technology: A Sensor for 3D Limb-to-Socket Interface Motion Measurements

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## INTRODUCTION

The fit between a user's prosthesis and his or her residual limb is fundamental to socket comfort. Socket interface mechanics have been studied rigorously over the past half-century in various forms.[1] In this research, inductive sensor technology was created to provide 3D limb-to-socket motion data from locations within the socket.

## METHOD

***Apparatus:*** An innovative sensor-array was developed to interact with a 32-mm diameter ferromagnetic-polymer target. Benchtop validation studies were conducted with a three-axis linear slide rail (Zaber Technologies Inc.) and software (LabVIEW) that allowed position control of the target in relation to the sensor-array. Investigational prostheses with the innovative sensor-arrays in the anterior distal and posterior midlimb aspects of the socket were fabricated. Practitioner-prescribed socket shapes and suspension types were maintained (FARO Arm). The 32-mm ferromagnetic-polymer target was affixed to the outside of the prosthetic liner with adhesive (Sil-Poxy). The sensor-array recorded at 32Hz.

***Procedures:*** A target was moved above the sensor-array in a predetermined flightpath that contained 1000 known positions to validate sensitivity. Participants provided informed consent and completed a series of uniform-speed walks on a flat treadmill. Various experimental conditions were created by altering the rotation, sock ply, and slippage (introduced with Vaseline application as a surrogate for sweat) between the residual limb and the prosthesis.

***Data Analysis:*** Raw data acquired from the sensors were processed by custom algorithms that output a 3D position of the target (MATLAB). Euclidian scaler distances between known positions and output positions were used to calculate sensitivity. Participant data were processed at the individual step level, and limb-socket position metrics were calculated and aggregated for both socket sites.

## RESULTS

The sensor detection region was 1.8cm^3. We averaged 175,000 Euclidean scaler measurements, yielding a 0.5-mm movement-sensitivity-error.

Nine participants completed all protocol instructions (n=5 used suction and n=4 used pin suspension). We analyzed 9526 steps across all participants.

The mean neutral position of the anterior site relative to the socket's circumferential axis was 0.16±1.3mm. When the limb was rotated clockwise and counterclockwise within the socket, it was 3.6±3.2 and -3.9±2.8mm, respectively (posterior: 0.19±1.3, 3.3±3.1, and -4.2 ±3.6mm, respectively) (Figure 1A).

The mean perpendicular distance of the anterior site from the socket wall was -0.025 ±0.20mm. When 1-ply was added, 2-ply was added, and 1-ply was removed from neutral, it was 0.11±0.18, 0.39±0.23, and -0.21±0.20mm respectively. [Posterior: -0.031 ±0.16, 0.19±0.24, 0.40±0.23, and -0.18±0.26mm] (Figure 1B).

The mean neutral pistoning of the anterior site relative to the socket's longitudinal axis was 2.4±0.90mm. When Vaseline was applied to the residual limb, and then cleaned with soap and water, it was 3.2±1.5, and 1.8±1.4mm, respectively. Posterior results reflected less pistoning and less change across conditions, 1.6±1.0, 1.6±1.2, and 1.5±1.1mm, respectively (Figure 1C).

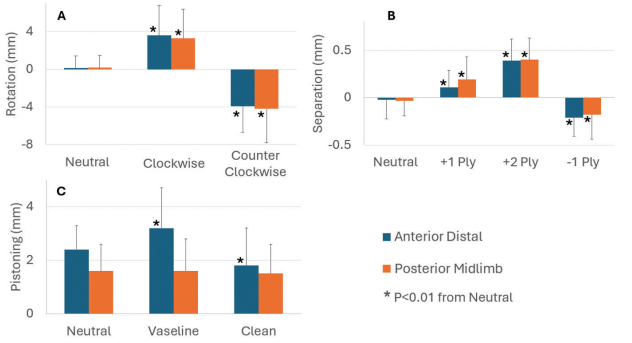


**Figure 1.** (A) Limb-socket circumferential position for neutral, clockwise, and counter-clockwise rotation of the limb in the socket; (B) limb-socket separation for sock ply changes; (C) limb-socket pistoning for Vaseline application and cleaning.

## DISCUSSION

Movement sensitivity of 0.5mm provided efficacious 3D data in the context of lower limb prosthetics. Statistically meaningful global and localized changes in limb-socket mechanics were detected.

## CONCLUSION

Our innovative sensor-array can observe movements between the residual limb and socket in all anatomical planes simultaneously and is sensitive enough to detect changes in socket fit relevant to clinical care.

## CLINICAL APPLICATIONS

Clinical scalability for individualized patient fit data is imminent because our sensored-socket fabrication and data processing is largely automated.

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# Prosthetic Attention Among People with Lower-Limb Bone-Anchored Prostheses: A Pilot Study

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## INTRODUCTION

Direct attachment of a prosthetic limb to the residual bone via an osseointegrated implant is a promising alternative to a socket-suspended prosthesis. This direct skeletal connection between the body and prosthesis has been suggested to improve sensory feedback, proprioception, and embodiment; however, it is unknown how or if this connection alters the need to pay attention to one's prosthesis in daily activities.[1]

Individuals who have transitioned from a lower-limb (LL) socket-suspended prosthesis to a bone-anchored prosthesis (BAP) have a unique perspective to be able to describe how prosthetic attention differs between these suspension methods. The purpose of this pilot study was, therefore, to explore how BAP users perceive and experience prosthetic attention.

## METHOD

***Sampling:*** Participants were recruited through O&P clinics known to treat individuals with osseointegrated implants. Study design: Qualitative focus group.

***Eligibility Criteria:*** Participants were ≥18 years of age, LL amputation, >3 months of BAP use, and proficient in English.

***Procedures:*** Participants attended a 90-minute focus group conducted via web conference. A trained facilitator used semi-structured questions to facilitate discussion. The discussion was recorded and transcribed verbatim. All procedures were reviewed and given exempt status by two local Institutional Review Boards.

***Analysis:*** Reflexive thematic analysis was used to analyze the discussion transcript. Three researchers read, familiarized themselves with, and independently excerpted and coded the transcript inductively. Excerpts and codes were reconciled with a fourth researcher. Themes were identified through a similar process, then discussed with the full research team. To improve credibility, member checks of themes were conducted with all participants.

## RESULTS

Four lower-limb BAP users (three transfemoral and one transtibial) participated in this study. All participants were white men with recent unilateral amputations (two to six years) who had undergone osseointegration (OI) within the past two years. Four themes were generated through thematic analysis (Table 1). Participants compared attention with their BAP to prior experiences (i.e., before OI and/or amputation) and described how their prosthetic attention had changed. BAP use was stated to reduce prosthetic attention. Individuals no longer needed to plan for tasks such as limb volume management or monitor the fit of their sockets. They also were better able to sense and trust their limbs. Conversely, BAP users described the need for heightened attention to prevent falls due to a perceived increase in risk for severe fall consequences with an osseointegrated implant.

**Table 1.** Themes and example quotes.

| |
|---|
| **I don't have to guess where my leg is because I can feel things now.** |
| "In my old socket, I could hear leaves crunching under my feet, but after [OI] you can actually feel the sensations."<br>—Austin, 27 year old male, traumatic transfemoral |
| **My daily routine is less complicated with my bone-anchored prosthesis.** |
| [With my prosthetic socket]…I was constantly adjusting layers and it was absolutely horrible. I carried around a little lunch bag, that had sleeves and all that stuff in it, because throughout the day I had to change it constantly, and it was miserable."<br>—Ryan, 49 year old male, transtibial due to infection |
| **The consequences of a fall could be worse now that I have OI.** |
| "It's a little more scary now. Before, I could just drop down that knee and do whatever. But now, in the back of my mind, that bolt is in my bone. It could snap, or anything like that, just by my sheer body weight."<br>—Ethan, 35 year old, male, traumatic transfemoral |
| **I still have to pay attention to my surroundings.** |
| "You think you're walking straight, but if you step on a twig on your heel, all of a sudden your knee thinks you're walking downhill and will like kind of buckle. You do have to pay attention to the surfaces you're walking on, to anticipate how your leg is going to think."<br>—James, 40 year old, male, traumatic transfemoral |

*Note: All names are pseudonyms to maintain confidentiality.*

## DISCUSSION

Prosthetic attention among BAP users in this study was similar to that described by socket-suspended prosthesis users,2 with a few notable exceptions. Both groups described the importance of attention to their surroundings to prevent falls and avoid injury.[2] Both BAP and socket-suspended prosthesis users noted the importance of trusting their prosthesis and the inverse relationship between trust and the need to pay attention. BAP users emphasized how OI improved trust in their prosthesis and reduced attention.

## CONCLUSION

Prosthetic attention changes with OI and use of a BAP. Attention to the prosthetic socket and daily tasks related to the prosthesis are reduced, however, attention to the environment and concerns about falling remain.

## CLINICAL APPLICATIONS

Given the invasive nature of lower-limb OI, it is important for prosthetists and researchers to carefully examine all benefits and potential consequences, including changes in prosthetic attention.

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# Pain Cognitions and Self-Reported Mobility Among Adults with Lower-Limb Amputation

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## INTRODUCTION

Chronic low-back pain (cLBP) is a leading cause of secondary disability among patients with lower-limb amputation (LLA).[1] The relationship between pain intensity and function is inconsistently reported among other clinical populations,[2,3] possibly due to confounding effects of pain cognitions (e.g., pain self-efficacy, pain catastrophizing, and pain interference). The influence of pain cognitions on mobility among adults with LLA remains relatively unknown. The aim of this study was to determine which pain cognitions are most related to self-reported mobility among adults with LLA and comorbid cLBP. We hypothesized that pain cognitions would have stronger associations with mobility than pain intensity.

## METHOD

Participants provided written informed consent for this cross-sectional survey-based study, and data were collected between 2019 and 2022 (Institutional Review Board 1434428).

***Participants:*** N=85 participants with unilateral LLA ≥1year prior (53% male; 55±11 years-old; 76% non-dysvascular; 70% transtibial) who used a prosthesis for mobility. All participants reported cLBP (pain ≥3 months on ≥half the days in the past six months).[4]

***Outcome Measures:*** Demographic and amputation-related information; Prosthetic Limb Users Survey of Mobility (PLUS-M); Patient-Reported Outcomes Measurement Information System, 29-item (PROMIS29); Pain Catastrophizing Scale (PCS); Pain Self-Efficacy Questionnaire (PSEQ).

***Data Analysis:*** Descriptive statistics were calculated using SPSS Statistics. Linear regression modeling was used to identify relationships between pain intensity, cognitions, (i.e., pain self-efficacy, catastrophizing, and interference), and self-reported mobility; i.e., PLUS-M, while considering covariates (i.e., sex, age, amputation level, and etiology).

## RESULTS

Mean PLUS-M T-score was 54.21±9.22. After considering non-modifiable covariates, when pain cognitions were added to the model, they explained an additional 34.8% of the variance in PLUS-M score. Sex, pain, self-efficacy, and interference significantly predicted self-reported mobility (model-adjusted $R^2$=.459, p<.001). In the final model, neither pain intensity nor PCS significantly contributed to mobility (Table 1).

**Table 1.** Relationships between pain cognitions and mobility (n=85).

| Predictors | Unstandardized β (95%CI) | p-value |
|---|---|---|
| Sex, ***female*** | -4.63 (-7.81, -1.45) | .005 |
| PSEQ, ***0-60*** | 0.22 (0.01, 0.43) | .042 |
| Pain Interference, ***t-score*** | -0.54 (-0.87, -0.21) | .002 |

## DISCUSSION

Sex, pain interference, and pain self-efficacy significantly predict self-reported mobility. Female sex is associated with a 4.6-point reduction in PLUS-M T-score, which is consistent with prior findings that females have poorer prosthesis-related outcomes, including mobility, than males.[5] Sex differences in pain experience may contribute to limited mobility among females, as females with LLA report higher prevalence of multisite pain.[6] Greater pain interference was associated with poorer self-reported mobility, while pain intensity was not significant. Previous studies in populations with LLA show a correlation between pain intensity and interference.[7] Our findings suggest pain interference may influence self-reported mobility more than pain intensity. This is consistent with findings among adults with cLBP without LLA, where pain self-efficacy mediates the relationship between negative pain cognitions, such as fear, and self-reported disability, independent of pain intensity.[8] Beyond sex differences in prosthetic-enabled mobility, psychological pain cognitions, specifically pain interference and pain self-efficacy, may be primary factors in determining mobility and more relevant than pain intensity.

## CONCLUSION

Pain cognitions, especially pain interference and pain self-efficacy, may significantly influence self-reported mobility among adults with LLA and comorbid cLBP. Sex-specific differences in PLUS-M scores were noted.

## CLINICAL APPLICATIONS

Care should be taken to ensure that maladaptive pain cognitions are addressed to reduce barriers to successful prosthetic functional outcomes.

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# Impact of Transfemoral Adjustable-Volume Sockets on Functional Outcomes

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## INTRODUCTION

Several adjustable-volume prosthetics sockets have become commercially available in the last 15 years.[1] With these systems, prosthesis users are instructed to adjust the size of the socket using rachets, dials, or Velcro straps. While each socket system claims fit and function, there is little outcomes-research to support these claims. Only two studies of the LiM Innovations Infinite Socket quantified functional outcomes.[2,3] In a case study, a young male had improved L-Test and Four Square Step Test (FSST) but similar 2-Minute Walk Test (2MWT) when wearing the LiM socket compared to a laminated socket.[2] In a 30-site trial, participants showed significant improvements in the 2MWT and FSST, but no change in L-Test when using the LiM compared to a laminated socket.[3] No studies have compared other socket styles, and no studies have looked at differences between different types of adjustable sockets. Therefore, the purpose of this work was to compare functional outcomes between three commercially available adjustable-volume sockets and a conventional laminated socket.

## METHOD

Participants with a unilateral transfemoral amputation (TFA) were randomly selected to complete testing with a laminated socket and each of three adjustable prosthetic sockets: CJ Sail (CJ Socket Technologies, Inc., Beverly, MA), Quatro (Quorum, Windsor, CO), and Infinite Socket (LiM Innovations, San Francisco, CA). Participants acclimated to each socket for a minimum of four weeks.

***Participants:*** Twenty-nine (four female) people with TFA consented to participate in this study. A total of 19 completed all four conditions and are included in analyses. All participants used a laminated socket at enrollment, except three, who had a CJ Sail.

***Apparatus:*** One month after final fitting, participants completed various tests of functional mobility including the 10-Meter Walk Test (10MWT), 2MWT, L-Test, Timed Up and Go (TUG), and Five Times Sit-to-Stand (FTSTS). At the conclusion of the study, participants could choose to keep one experimental socket.

***Statistical Analysis:*** We compared functional measures across all socket styles using a generalized linear model with the socket as a fixed factor and subjects as a random factor. To assess individual benefits, we compared each individual's change in outcome to published minimal detectable changes (MDC).

## RESULTS

All 19 participants were able to complete testing with the laminated socket. Due to discomfort or instability, only 14 (74%) completed testing with the CJ Sail, and 16 (84%) each with the LiM and Quatro.

There were no significant main effects of socket for any functional outcome ($p \geq 0.242$). Eight participants had changes that exceeded the MDC for the TUG, nine for the L-Test, 11 for the 10MWT, three for the 2MWT, and 12 for the FTSTS. Three participants had no change in any functional test. At the end of the study, four participants chose the laminated socket, eight chose the CJ, two chose the LiM, and five chose the Quatro. Participants generally chose the socket that they performed the best with in at least one functional test, though which test that was differed between participants.

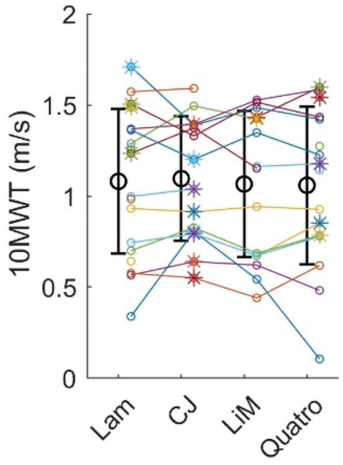


**Figure 1.** 10MWT speed with each socket type. Error bars are standard deviations. Lines represent individual participants.
* indicates the socket they selected.

## DISCUSSION

This study suggest that adjustable sockets do not offer any absolute advantage over traditional laminated sockets in terms of function. Nonetheless, we found that certain socket designs are successful in some participants, leading to measurable improvements in functional outcomes. Future work will determine if there are specific patient characteristics that predict success with a particular socket design.

## CONCLUSION

Adjustable-volume prosthetic sockets can improve functional outcomes in some, but not all transfemoral prosthesis users.

## CLINICAL APPLICATIONS

Those patients who are difficult to fit in traditional sockets may find functional benefits with adjustable-volume sockets.

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# Analysis of Residency Experience in Transfemoral Prosthetics

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## INTRODUCTION

Currently, there is limited published data on the residency experience. Analyzing this data and evaluating the residency experience may lead to guidelines for clinical training. Transfemoral prosthetic design and patient management are particularly complex and may require increased exposure and experience for residents to achieve competence.[1] This study aimed to quantify resident experiences in transfemoral prosthetics and to assess whether the timing of competency attainment had an association with volume of case exposure and resident engagement.

## METHOD

***Participants***: The study was a retrospective review of transfemoral patient data collected from three cohorts of residents from July 2018 to December 2021 in an integrated residency program.

***Apparatus:*** Data collected in National Commission on Orthotic and Prosthetic Education (NCOPE) Tracker were utilized for statistical analysis.

***Procedures:*** Appointment types were aggregated into three main categories: patient evaluation and formation of treatment, implementation of treatment, and continuation of treatment, based on the American Board for Certification in Prosthetics, Orthotics, and Pedorthics (ABC) practice domains and the data available from NCOPE Tracker.

***Data Analysis:*** Descriptive statistics included medians and interquartile ranges due to non-parametric data distribution. Data were evaluated for difference between cohorts using the Kruskal Wallis test, with post-hoc Mann Whitney U tests. The total cases and the percentage of those cases performed independently were compared based upon the quarter in which a resident was deemed competent using Kruskal Wallis tests.

## RESULTS

Data from 67 residents was included in the study. Transfemoral cases comprised just under one tenth of the total cases residents logged, compared to one quarter reported by the ABC Practice Analysis. Residents experienced a median of 112 (IQR=61) transfemoral patient encounters. Engagement level was predominantly assisting (Mdn=64.0%, IQR=21.9) followed by independence (Mdn=17.8%, IQR=17.2) and observing (Mdn=11.8%, IQR=17.4). Results were similar across the three cohorts of residents. Competency was completed during the sixth rotation for 38 (60.3%) residents. There were no statistically significant differences in the total number of cases logged or the percentage of cases a resident performed independently based upon the quarter in which competency was achieved.

## DISCUSSION

Comparison with the ABC Practice Analysis indicated slightly lower volume of transfemoral cases and differences in appointment types experienced during residency as compared to clinical practice.

The implications of the level of resident engagement in patient encounters within the O&P field have not been studied; however, multiple analyses of medical residencies have shown that engagement is essential to resident learning.[2,3] A notable limitation of this study was the self-reported nature of residency experience.

## CONCLUSION

The volume of transfemoral cases in residency appears to be slightly less than what is reported in practice. The timing of transfemoral competency attainment by residents did not affect their subsequent case volume or engagement level in transfemoral care.

## CLINICAL APPLICATIONS

Documentation and comparison of the residency experience may offer a pathway toward developing consistency in residency training and continuation into entry level practice.

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# Prosthetist Feedback on Fitting Adjustable Sockets Based on a Randomized Clinical Trial

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## INTRODUCTION

Adjustable sockets are becoming more common in clinical practice. A recent survey of prosthetists found that a majority of respondents had fit at least one adjustable style above-knee prosthetic socket. Success rates are not as high as standard sockets though,[1] which suggests either the socket style is not working, or prosthetists are not well trained to fit them. To determine which sockets offer the greatest likelihood of success, we completed a two-site clinical trial comparing three commercially available adjustable sockets to conventional laminated sockets.

## METHOD

***Design:*** Twenty-nine participants (four female) with transfemoral amputation (TFA) were randomly allocated to complete testing with a laminated socket and each of three adjustable prosthetic sockets: CJ Sail (CJ Socket Technologies, Inc., Beverly, MA), Quatro (Quorum, Windsor, CO), and Infinite (LiM Innovations, San Francisco, CA). Participants were scanned, etc., per the manufacturers' recommendation and prosthetists preferred shape capture method for the three fittings, and we tried to keep the patient's preferred suspension where possible. The CJ and Quattro socket systems were able to use up to two diagnostic fittings. Sockets were adjusted as needed. Participants then acclimated to each socket for a minimum of four weeks. Sockets were deemed successful if the participant could wear them for the full four weeks and complete functional assessments with them. Patient feedback was attained via pre- and post-fitting surveys.

***Analysis:*** Prosthetists perspectives were collated by reviewing fitting notes captured throughout the study.

## RESULTS

Ten participants dropped out of the study after receiving zero (n=2), one (n=4), or two (n=4) sockets. There were no failures with the laminated, nine with the CJ Sail, six with the LiM, and four with the Quatro (Figure 1). Socket failures typically occurred in the initial definitive fitting stages. Failures were related to a variety of factors. Some were due to socket instability, which could not be overcome with modifications. Some participants had concerns with the alignment that could not be accommodated by the socket system. Additionally, there were limb-length concerns, which required an adjustment to the participant's knee center. Very short limb lengths were difficult to stabilize in certain socket styles, leading participants to feel uncomfortable or unstable. The need to change suspension systems with certain socket systems also contributed to some failures.

## DISCUSSION

Dropouts of study were higher during the beginning of the study due to the learning curve for patient and the prosthetist. Through the process, we found that there were certain styles that tended to be easier to fit on different limb lengths. As noted in the contraindications, the Infinite Socket was challenging to fit on long limbs due to limitations of the premade base plates and strut attachments. The CJ Sail was more difficult to fit on shorter limbs due to socket instability. There were also differences in the manufacturing process that affected the success of different approaches. The Infinite Socket was more difficult to adjust to users' needs than the other designs. The nylon material of the Quatro Socket was challenging to adjust due to its material properties. We found the CJ Socket to be the easiest to work with as it was manufactured with standard prosthetic manufacturing techniques and materials. Another challenge was that the various designs are not fixed. In particular, we noted that the Quatro design, particularly the inner socket, changed several times during the course of the study.

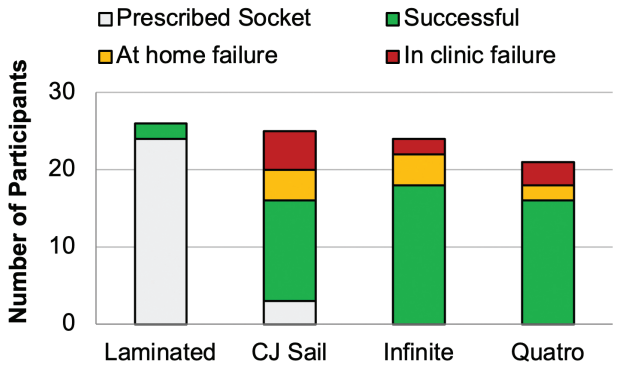


**Figure 1.** Socket successes and failures.

## CONCLUSION

Commercially available adjustable sockets can be challenging to fit and may require a learning process of several fittings for the prosthetist.

## CLINICAL APPLICATIONS

Enhancing understanding of the factors affecting the success of adjustable sockets will inform clinical decision making for better clinical outcomes.

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# Key Predictors of Radicular Pain Among Adults with Low Back Pain and Lower-Limb Loss

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## INTRODUCTION

Low back pain (LBP) is reported by up to 89% of adults with lower-limb loss (LLL).[1] Radicular pain, defined as a radiation of pain distally into the lower extremities, affects 13%–40% of individuals during their lifetime.[2] Presence of LBP with radicular pain is associated with greater disability, poorer quality-of-life, and increased healthcare usage when compared to LBP alone.[3] Nevertheless, despite the impact radicular pain has on adults with LBP, there is little research examining radicular pain among adults with LBP and LLL.

This study seeks to identify factors associated with the presence of radicular pain among individuals with LLL and comorbid LBP. Identifying factors associated with radicular pain is necessary to develop targeted LBP interventions to improve outcomes post-amputation.

## METHOD

We conducted a cross-sectional survey study among adults with unilateral LLL and comorbid LBP; participants provided written informed consent and the project secured ethical approval (Institutional Review Board #1434428).

***Participants:*** Individuals (n=135) had a median age of 56 years (25th, 75th percentile: 47, 64); 56% were male; 83% were Caucasian; 65.9% had transtibial-level LLL; and 46% had a traumatic LLL. Median time since amputation was eight years (25th, 75th: 2, 17). In the sample, 69% had chronic LBP, defined as pain persisting for ≥three months and resulting in pain on at least half the days in the past six months.[4]

***Apparatus:*** Sociodemographics; pain and amputation-specific history; NIH Task Force on Research Standards for Chronic LBP minimal dataset;[4] 29-item, Patient-Reported Outcomes Measurement Information System (PROMIS-29); Socket Comfort Score.

***Data Analysis:*** Chi-Square, Mann-Whitney U, and independent T-tests, as appropriate, were used to assess between-group differences (i.e., with radicular pain versus no radicular pain) in sociodemographics, pain, and other variables. Variables with significant between-group differences were examined via forward stepwise logistic regression models (p≤0.10).

## RESULTS

Radicular pain was reported in 34% (n=46) of the sample. Three variables; i.e., residual limb pain presence, PROMIS-29 depression subscale, and PROMIS 7-day pain intensity, were included in the final model (Table 1). Individuals with greater depressive symptoms, higher pain intensity, and residual limb pain presence were more likely to report radicular pain. These variables collectively explained 25.1% of the variance in presence of radicular pain.

**Table 1.** Logistic Regression Model for Radicular Pain Presence

| Variable | β | Odds Ratio [95% CI] | p-value |
|---|---|---|---|
| PROMIS Depression, *t-score* | 0.063 | 1.07 [1.01,1.12] | 0.012 |
| PROMIS 7-Day Pain Intensity, *0-10* | 0.196 | 1.21 [1.02, 1.46] | 0.034 |
| Residual Limb Pain, yes | 0.855 | 2.35 [0.93, 5.94] | 0.071 |

*Abbreviations: PROMIS=Patient-Reported Outcome Measurement System; CI=Confidence Interval.*

## DISCUSSION

Greater depressive symptoms and pain intensity are associated with increased likelihood of radicular pain, which affected one in three participants with comorbid LBP post-LLL. This is consistent with findings among adults presenting with LBP with intact lower limbs, where depression is noted to be associated with greater LBP intensity and LBP-related disability.[5] Pain intensity among adults with radicular pain with intact limbs has also been linked to changes in central nervous system pain processing.[6] Greater depressive symptoms and higher pain intensity may be indicative of central sensitization, resulting in greater pain sensitivity, which has been associated with depressive symptoms.[7] One study limitation is that data acquired did not allow for determination of side(s) of radicular pain.

## CONCLUSION

With LLL, greater depressive symptoms and higher pain intensity are associated with an increased odds of patients with comorbid LBP presenting with radicular pain into the lower limb(s). Identified factors may signal underlying changes in central nervous system pain processing in this LBP subgroup.

## CLINICAL APPLICATIONS

Psychological factors should be considered alongside physical factors when providing care for adults with LLL and comorbid LBP, particularly those who present with radicular symptoms. Integrating mental health support with traditional pain management strategies may improve outcomes for these patients.

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# Impact of Transfemoral Adjustable-Volume Sockets on Socket Comfort

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## INTRODUCTION

Socket discomfort continues to be a challenge. To accommodate changes in limb volume throughout the day, prosthesis users add or remove prosthetic socks or adjust the size of the socket using an adjustable socket system. There are several adjustable socket systems that have recently become commercially available.[1] These systems allow the user to adjust the fit of the socket manually while it is worn, potentially alleviating the hassle of using prosthetic socks. While each socket system claims to improve socket comfort and fit, there is no outcomes research to support these claims. The purpose of this work was to compare socket comfort between three commercially available adjustable volume sockets and a conventional laminated socket.

## METHOD

***Participants:*** Twenty-nine (four female) people with a unilateral amputation at or above the knee consented to participate in this institutionally approved study.

***Apparatus:*** Participants were randomly allocated to complete testing with a laminated socket and each of three adjustable prosthetic sockets: CJ Sail (CJ Socket Technologies, Inc., Beverly, MA), Quatro (Quorum, Windsor, CO), and Infinite (LiM Innovations, San Francisco, CA). Three weeks after final fitting, participants provided a Socket Comfort Score (SCS) rating.[2] One week later, they completed various functional assessment tests in the lab. During this time, they rated their socket comfort after two minutes of walking, standing, and sitting. Following testing, they had a minimum of one week wash-out in their prescribed prosthesis before starting the next socket condition. At the conclusion of the study, participants could choose to keep one experimental socket.

***Data Analysis:*** We compared SCSs between sockets using univariate analysis of variance (ANOVA), where the subject was a random factor. Significant effects of the socket were explored using paired t-tests for all socket combinations. Individual changes in SCS were compared to the minimal detectable change of 2.7.[3]

## RESULTS

A total of 19 participants completed all four conditions. Two participants dropped out before trialing any adjustable socket, and eight dropped out during the study. Most participants (n=22) were comfortable in their prescribed prosthesis (SCS>7), including all eight who dropped out.

***Group Differences:*** There was a significant main effect of socket for overall SCS (p=0.04) and after standing (p=0.013), but not after sitting or walking. Post-hoc testing indicated that participants had greater overall comfort with the Quatro compared to laminated socket and greater comfort after standing with the LiM socket compared to the laminated socket, and the Quatro socket compared to the CJ socket.

***Individual Differences:*** Seven participants had baseline SCS less than five. Six of these participants chose to change their socket to one that provided a meaningful (>MDC) improvement in comfort, while one chose to remain in his prescribed socket, despite the lack of comfort. Six participants who were initially satisfied with their socket (SCS>7) chose to change to an adjustable socket. Of the 12 participants who chose to change sockets, six chose the CJ socket, four chose the Quatro socket, and two chose the LiM socket.

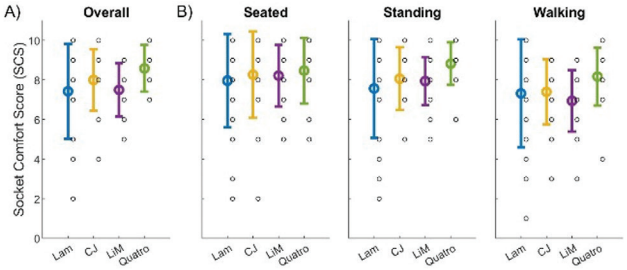


**Figure 1.** (A) Socket comfort score (SCS) after at least three weeks of accommodation. (B) SCS in the lab after two minutes of sitting, standing, and walking.

## DISCUSSION

We found that certain socket designs are successful in some participants, leading to measurable improvements in comfort. The Quatro socket was found to have greater overall comfort compared to traditional non-adjustable laminated sockets. Future work will determine if there are specific patient characteristics that predict success with a particular socket design.

## CONCLUSION

While commercially available adjustable sockets may not be suitable for improving comfort in all patients, they may be preferred by some.

## CLINICAL APPLICATIONS

Enhancing understanding of the factors affecting the success of adjustable sockets will inform clinical decision-making for better clinical outcomes.

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# Perceptions of Phantom Limb Pain After Lower-Limb Amputation: A Focus Group Study

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## INTRODUCTION

Pain is a subjective and multifactorial experience. Phantom limb pain (PLP) adds a layer of complexity, since this type of pain is perceived as originating from a limb that was amputated and no longer remains.[1] Qualitative research methods can allow for exploration of the ways in which PLP specifically affects daily life, revealing valuable insights about how pain influences participation in meaningful activities after an amputation.[2] The purpose of this qualitative study was to explore how individuals perceive PLP, its effects on their daily life, and its contributing factors.

## METHOD

Study procedures were approved by the local Institutional Review Board. All participants provided written informed consent.

*Participants*: Participants were over the age of 18 with lower-limb amputation and at least two episodes of PLP per month. Thirteen individuals participated, including women (54%) and men (46%) ranging in age from 33–79 (mean: 61). Time since amputation ranged from 1–65 years (mean: 15), and causes of amputation were trauma (46%), infection (23%), cancer (15%), vascular disease (8%), and blood clot (8%). Most (85%) used a prosthesis.

*Procedures*: Four virtual focus groups were conducted with individuals from across the United States.

*Data Analysis*: Focus groups were recorded and analyzed using thematic analysis with an inductive approach.[2]

## RESULTS

Six themes were identified from the focus groups: (1) moving target, (2) life disruption, (3) choices and trade-offs, (4) isolated and unsure, (5) waiting out the storm, and (6) pushing forward and holding hope. Example quotes are included in Table 1. Participants described examples of pain interference with life, both in immediate and lasting effects. A multitude of factors were reported that were perceived to contribute to PLP, including activity level, prosthesis use, mood, and others. Participants commonly experienced self-doubt, since PLP is perceived from a limb they no longer have and since many individuals did not remember receiving education about PLP following their amputation.

## DISCUSSION

The unpredictability of PLP discussed in these sessions gives insight as to why effective treatment can be so difficult. Self-doubt regarding PLP may lead to patients being reluctant to introduce the topic with providers.[3] A sense of community and shared wisdom was evident during the focus group sessions, illustrating the power of connecting with others with amputation. Future research may systematically examine factors hypothesized to contribute to PLP to guide treatments. Limitations of this study include exclusion of individuals with upper-limb amputation and those who did not have the ability to be involved virtually.

**Table 1.** Focus group themes and example quotes.

| Theme | Example Quotes |
|---|---|
| Moving target | "It can hit just like that for no rhyme or reason. I can have my leg on, I can have my leg off, I can be doing something, not doing anything." Participant 11, Group 4 |
| Life disruption | "Yesterday we had appointments…. I couldn't go because I was just hurting so bad you know? And like I said I had tears running down my face, so it interferes lots of times life comes to a halt." Participant 07, Group 2 |
| Choices and trade-offs | "They tried oxy [oxycodone] on me, and I took it for a few weeks, and it was just too hard to think clearly. I'd rather deal with the pain than deal with the fuzz, so I don't use any narcotics." Participant 13, Group 4 |
| Isolated and unsure | "It's not there. I look, you know, I wake up and I go like but it's not there what am I doing? And it makes me think I'm crazy half the time." Participant 10, Group 3 |
| Waiting out the storm | "There's nothing you can do to stop it…. It's more or less an endurance contest to see how long you can take it." Participant 10, Group 3 |
| Pushing forward and holding hope | "I struggled a lot, but after a while it just gets better. Just don't give up, keep pushing forward, and ignore everybody else. Do it for you; don't do it for anybody else—just do it for yourself." Participant 03, Group 1 |

## CONCLUSION

PLP is an experience that can affect individuals after lower-limb amputation physically, mentally, and emotionally. Individuals can exhibit a sense of desperation regarding their pain or a sense of hope despite their pain. Connecting with other individuals with amputation can be powerful.

## CLINICAL APPLICATIONS

These findings expand our understanding of PLP perceptions. The uncertainty expressed by participants highlights the importance of clinician-initiated discussions and assessment of amputation-related pain. Clinicians may consider initiating more conversations with patients about PLP, providing additional educational materials, and facilitating connections with others with amputation.

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## FUNDING

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## DISCLAIMER

*The materials presented here do not represent the views of the U.S. Department of Veterans Affairs, the U.S. Government, or the National Institutes of Health.*

# Community Falls in Transfemoral Amputation: A Sign of Poor Balance or Enhanced Mobility?

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## INTRODUCTION

Fall rates are still unacceptably high in users of microprocessor prosthetic knees (MPKs). Individuals with transfemoral amputation (TFA) have a particularly high risk for falls compared to the general population and those with transtibial amputation. More than half of individuals with TFA report at least one fall within the last year. Fall surveys are often used as the gold standard for understanding stability in clinical populations in community environments, with higher numbers of reported falls associated with lower stability.

The Narrowing Beam Walking Test (NBWT) is used as a performance measure of balance ability with lower scores correlated with higher fall risk.[1] Therefore, in this project, we sought to understand if the NBWT was related to measures of community ambulation and anthropomorphic characteristics in a cohort of individuals with TFA.

## METHOD

The Georgia Institute of Technology Institutional Review Board approved this study under H21008, and participants provided written informed consent prior to participating.

***Participants:*** Twelve individuals with TFA participated (three females, nine males, age 46.6±11.5 years, height 1.72±0.11 m, mass 80.9±16.1 kg, residual limb proportion of sound-side limb length 0.45±0.26, AMPnoPro score 38.9±4.0).

***Procedures:*** Participants completed the NBWT, 10-Meter Walk Test (10MWT), and stair ascent and ramp descent speeds were averaged across three microprocessor prosthetic knees. Participants were administered the Lower Limb Prosthesis (LLP) User Fall Event Survey[2] in which they reported falls or near-falls over the past one year. Based on the LLP User Fall Event Survey, participants were categorized as: fallers, near fallers, or non-fallers.

***Data Analysis:*** A linear-mixed effects model was used to determine the effect of fall group on each outcome measure, while Pearson's correlations were used to understand the relationship of the NBWT performance to each outcome measure.

## RESULTS

Fallers (N=4) and near fallers (N=3) traveled farther distances on the NBWT than non-fallers (N=5), but no statistically significant differences were seen between groups(p=0.40) (Figure 1). However, fallers traveled farther distances beyond the minimal detectable change (MDC90) than non-fallers. Five out of the seven reported falls or near falls were on a hill or stairs. Greater beam walking scores (e.g., walking farther on the beam), were significantly correlated with higher AMPnoPro scores (R2=0.43; p=0.030), longer limb residual limb lengths (R2=0.41; p=0.034), faster ramp decline speed (R2=0.38; p=0.030), and faster stair ascent speed (R2=0.39; p=0.030), and approached significance with younger age (R2=0.33; p=0.053). No correlation was observed between the NBWT and 10MWT (R2=0.13; p=0.27).

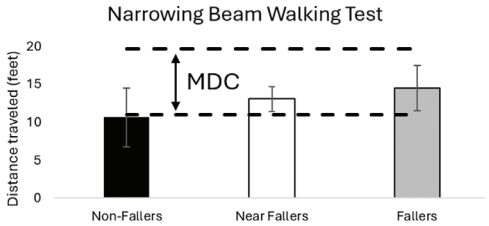


**Figure 1.** Distance travelled down the NBWT in non-faller, near faller, and faller groups. MDC=minimal detectable change.

## DISCUSSION

Our data contrasts previous studies in which lower NBWT performance is seen in individuals with a history of falls. In this study, we observe the opposite: individuals with better NBWT performance fell more in their communities. These individuals were younger, had higher mobility, and moved more quickly across community terrains (i.e., ramps and stairs). Interestingly, but perhaps not surprisingly, individuals with longer residual limbs, and thus improved voluntary control over their prosthesis, were able to traverse greater distances on the beam. Our findings suggest that individuals willing to accept higher community risk secondary to enhanced mobility, as indicated by improved NBWT scores and other measures of mobility, may be more likely to experience falls in the community. This implies that fall surveys may capture a broader spectrum of stability than previously understood. Low sample size is a limitation, and further study in a larger cohort of individuals with TFA would provide validation of the results presented herein.

## CONCLUSION

Performance on the NBWT should be weighed carefully in assessing or predicting patient fall risk. Our data indicate improved NBWT performance does not necessarily equate to reduced community fall risk.

## CLINICAL APPLICATIONS

Improved balance ability in younger, high-mobility individuals with TFA does not eliminate community fall risk. Therefore, rehabilitative fall training safety should be prioritized regardless of a patient's mobility level. Further, fall surveys may capture a broader range of stability levels than previously understood.

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# Impact of Transfemoral Adjustable-Volume Sockets on Prosthetic Use in Daily Life

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## INTRODUCTION

Adjustable sockets allow users to modify socket volume to suit their needs. This enables users to tighten or loosen manually to maintain fit while donned. In contrast, conventional, non-adjustable sockets require users to doff the prosthesis to add or remove socks. Several adjustable socket systems have been introduced commercially,[1,2] but there is no research on how each system impacts prosthetic use in daily life. Daily-life measures from wearable sensors can provide a more holistic view of an individual's prosthetic use.[3] Therefore, the purpose of this work was to record how many times users don and doff the prosthesis during the day and monitor their daily activity level with adjustable sockets compared to a laminated socket.

## METHOD

***Participants:*** Twenty-nine (four female) participants with a unilateral transfemoral amputation (TFA) were randomly allocated to complete Institutional Review Board-approved testing after consent with a laminated socket and each of three adjustable prosthetic sockets: CJ Sail (CJ Socket Technologies, Inc., Beverly, MA), Quatro (Quorum, Windsor, CO), and Infinite (LiM Innovations, San Francisco, CA). Participants acclimated to each socket for a minimum of four weeks.

***Apparatus/Procedures:*** Donning and doffing frequency was monitored through surveys sent through Research Electronic Data Capture (REDCap) to the participant's phone. Some participants who had issues completing these surveys were sent both electronic surveys and paper surveys, which improved patient compliance. During the fourth week of accommodation, participants wore two activity monitors: one on their prosthetic ankle and one with IMU enabled on the top of their foot.

***Data Analysis:*** Activity measures such as average acceleration, step counts, number of bouts, and steps per bout were calculated from the accelerometer data for each day. Daily activity levels were averaged across all days for the week. Dependent measures were compared across adjustable sockets using a generalized linear model with socket as a fixed factor and subjects as a random factor.

## RESULTS

Thirteen participants were able to complete donning and doffing surveys with multiple socket systems. There was no significant main effect of socket for average donning and doffing frequency per day (p=0.249). Twenty-one participants were able to complete activity monitoring with multiple socket systems. There was no significant main effect of socket for daily step count (p=0.257).

## DISCUSSION

This study suggests that adjustable sockets do not impact prosthetic use in daily life via donning and doffing frequency or change user activity level. This indicates that the added function of adjustability may not limit users' overall prosthetic use in daily life. Future work will determine if there are other benefits such as increased wear time or changes in walking speed.

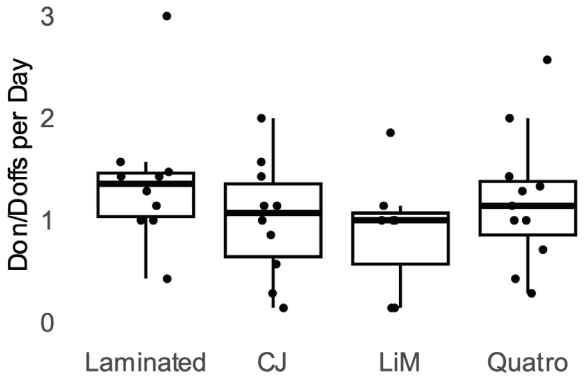


**Figure 1.** Daily donning and doffing frequency during at-home trials with each socket style.

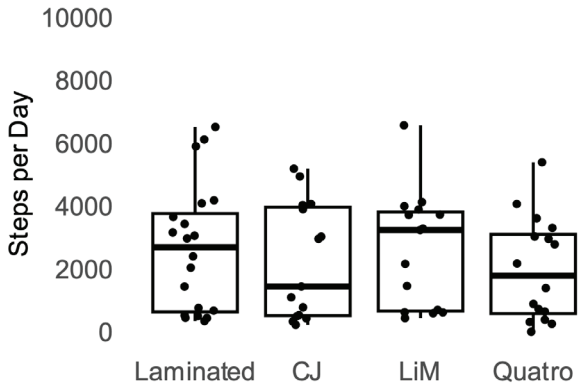


**Figure 2.** Daily step count during at-home trials with each socket style.

## CONCLUSION

Adjustable sockets can offer manual adjustability for users when wearing their prosthesis without hindering prosthetic activity levels in daily life.

## CLINICAL APPLICATIONS

Utilizing daily-life measures to quantify prosthetic use with adjustable sockets can inform clinical decisions.

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# The Role of Walking Speed and Leg Proprioception in Foot Clearance for Older Transtibial Prosthesis Users

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## INTRODUCTION

Falling is a relevant concern for both older persons and transtibial prosthesis user (TPUs). Considering 44.7% of the limb loss population is 65 or older,[1] a sizable cohort may potentially face compounded risks to falls. As tripping is a leading cause of falling in both groups, adequate foot clearance (FC) during the swing phase is important to minimize risk of foot collision that could lead to a trip and fall. Evidence suggests that older adults and TPUs generally display FC behavior that may contribute to increased tripping risk.[2,3] Moreover, knowledge of leg orientation and foot position relative to the body (i.e., proprioception) plays a role in managing FC, which may be challenged for TPUs given their limited ability to sense position of the prosthesis. Age-related decline in proprioception may increase fall risk, but older TPUs demonstrate better proprioception than age-matched controls to suggest studying the relationship between proprioception and FC in this group. This study aimed to compare FC between older persons with and without transtibial limb loss, assess the effect of increased walking speed on FC in both groups, and assess the relationship between FC and leg proprioception in both groups.

## METHOD

Institutional Review Board-approval granted by the Jesse Brown VA Medical Center. All participants provided informed consent.

***Subjects:*** Data was collected on 10 able-bodied controls (72±4 years, 168±2 cm, 76.8±3.7 kg) and 13 unilateral TPUs (72±4 years, 176±2 cm, 86.3±3.2 kg).

***Apparatus:*** A digital goniometer measured knee joint position to quantify proprioception. A motion capture system (Motion Analysis Corp, CA) recorded reflective marker positions from a modified Helen Hayes model.

***Procedures:*** Bilateral leg proprioception was assessed by testing the ability to replicate knee joint angle to a previously guided position while blindfolded, wearing their prosthesis as applicable, and seated with legs suspended. Participants then walked at self-selected normal and fast speeds across a 10-m level walkway.

***Data Analysis:*** Proprioception was estimated as the average absolute error of angle reposition across five trials. FC was estimated as the first metatarsal joint marker position at mid-swing. The main effect of group (prosthetic versus control non-dominant limb) on FC was assessed with an independent t-test. The main and interaction effects of speed and limb on FC were assessed using a two-way R-M analysis of variance for each group separately. Significant interaction effects were followed with simple main effect analyses. Linear regressions controlling for speed assessed association between FC and proprioception. The α was 0.05 for all analyses.

## RESULTS

FC was significantly greater for the prosthetic limb compared to the control non-dominant limb during fast (p=.041) but not normal walking (p=.360). For both groups, FC decreased with faster walking for both limbs (p<.001). The limb×speed interaction effect was significant for TPUs (p=.041), with greater prosthetic limb FC compared to the sound limb for fast walking (p=.192) and generally similar FC at normal walking (p=1.0). Only TPUs exhibited significant associations between proprioception and FC, with worse prosthetic limb side proprioception associated with smaller sound limb FC at both speeds (normal: p=.048; fast: p=.016).

## DISCUSSION

Older TPUs appear to walk with greater FC of their prosthetic limb compared to the non-dominant limb of their age-matched able-bodied counterparts, likely reflective of a desire to increase ground clearance and minimize risk of prosthetic foot collision. However, that difference was only observed during faster walking, suggesting no such protective strategy when walking at a self-selected normal speed. Both TPUs and controls did exhibit smaller FC when walking faster, but TPUs maintained greater elevation of the prosthetic limb compared to their sound limb which may again reflect a protective measure given the faster speed, increased body momentum, and greater perceived risk. Notably, worse proprioception of the prosthetic side limb was associated with smaller sound limb FC. A possible explanation may be that TPUs prioritize keeping their sound limb close to the ground when they are less able to sense position of their prosthetic limb.

## CONCLUSION

Older TPUs walk with greater FC of their prosthetic limb compared to the non-dominant limbs of able-bodied controls while walking fast that may help avoid foot collision during swing. Less sound limb FC was associated with worse proprioception of the prosthetic limb side, suggesting a nuanced relationship.

## CLINICAL APPLICATIONS

Better understanding of the relationship between leg proprioception and FC in older TPUs may inform ways to help mitigate fall risk across walking speeds.

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# A Human-in-Loop Optimization Approach for Personalized Ankle-Foot Prosthesis Stiffness to Maximize Comfort

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## INTRODUCTION

Parameter optimization is required to tailor prosthesis to satisfy individual user needs and maximize functional outcomes. A previous study suggested that ankle-foot prostheses (AFP) stiffness may affect residuum-socket interface pressures,[1] which directly influences perceived socket comfort, and ultimately, user performance and satisfaction.[2] Due to the heterogeneity in anthropometry, biomechanics, and socket design across prosthesis users, the interaction between the user and AFP will vary and uniquely affect personal socket comfort. Therefore, AFP stiffness should be optimized on an individual basis. This pilot study implemented a data-driven human-in-loop Bayesian optimization (HILBO) approach to optimize AFP stiffness for maximizing comfort of unilateral transtibial prosthesis users. After design of an appropriate objective function modeling the residuum-socket interaction pressure profile, the study examined that function in a real-time HILBO algorithm that tuned stiffness of a robotic AFP as individuals walked.

## METHOD

Institutional Review Board approval was granted by the University of Illinois, and all participants provided informed consent.

***Subjects:*** Three persons with unilateral transtibial amputation (two male and one female, 47.7±8.9 years, 80.5±17.7 kg) without known medical conditions other than amputation.

***Apparatus:*** Pressure sensors (Tekscan, US) were attached to the lateral and anterior walls of the customary socket to measure instantaneous interface pressure. The objective function estimated pressure cost defined as the sum of the pressure over the entire trial divided by the peak pressure. Given a set of the observed data over time while walking with the AFP, the HILBO algorithm optimizes a function (Gaussian process) to select new parameter values. A maximum value of the pressure cost is then selected as the optimal parameter (AFP keel stiffness).

***Procedures:*** Participants walked at a self-selected speed on a treadmill with a robotic AFP (Figure 1A),[3] which permits rapid changes in AFP keel stiffness, attached to their customary socket. On Visit one, they walked with five discrete AFP keel stiffness values for twp minutes. After each trial, they scored their socket comfort (0–10 via a visual analogue scale) and rate of perceived effort (RPE).[4] The pressure cost was calculated and its association with comfort and RPE were assessed with estimates of Pearson's Correlation coefficient. On visit two, HILBO was performed during four minutes of walking using the pressure objective function to identify the optimized AFP stiffness which maximized the pressure cost outcome. Cost and socket comfort were recorded while participants walked with the HIL optimized robotic AFP stiffness, a fixed robotic AFP stiffness reflecting a typical dynamic response AFP, and their customary (prescribed) AFP.

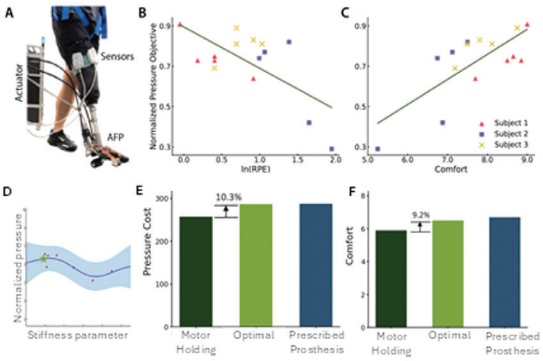


**Figure 1.** (A) Experimental setup. (B-C) correlations between interface pressure and RPE (B) and comfort (C). (D-F) HILBO outcomes from AFP settings. (D) Gaussian process landscape shows AFP stiffness parameters and associated pressure costs. (E-F) Comparing optimal stiffness to fixed "motor holding" stiffness and customary AFP; higher cost and comfort indicates better outcomes.

## RESULTS

The pressure cost was strongly correlated (Figure 1B–C) with socket comfort (r=0.75) and log-transformed RPE (r=-0.67). The HILBO algorithm successfully converged onto an optimized AFP stiffness for each participant (Figure 1D), increasing the pressure cost and user comfort by 10% and 9%, respectively, compared to the fixed stiffness setting and approached levels similar to the participants' customary AFP (Figure 1E–F).

## DISCUSSION AND CONCLUSION

These results suggest that residuum-socket interface pressures share a direct relationship with socket comfort and effort during walking. These pressures can be input into an objective function that through a HILBO algorithm can effectively identify a personalized AFP stiffness to maximize perceived socket comfort. Residuum-socket interface pressure may offer a useful measurement to optimize AFP mechanical function to maximize perceived socket comfort and hence patient user mobility and satisfaction.

## CLINICAL APPLICATIONS

Socket pressure can optimize AFP stiffness for personalized prostheses, enabling future patient-centric, data-driven robotic assistance.

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# The Effect of Sensory Feedback in Improving Gait Stability and Decreasing Phantom Limb Pain Illustrated in a Case Study

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## INTRODUCTION

Despite many functional improvements in the last decades in lower-limb prostheses, currently available devices still lack sensory feedback. Previous research has shown the positive effect of sensory feedback on gait stability and safety and in the elimination of phantom limb pain.[1,2] Several attempts have been made to eliminate phantom limb pain, including invasive methods. This case study presents the effect of vibrotactile feedback on increasing prosthesis function and eliminating phantom limb pain.

## CASE PRESENTATION

The individual is a 53 year old man who underwent a transfemoral amputation at the age of 20. Since then, he suffered daily from severe phantom limb pain. He is using a lower-limb prosthesis daily for work as well as leisure and household activities.

## MANAGEMENT AND OUTCOME

The prosthesis user was offered a trial of the vibrotactile feedback system SURALIS developed by the manufacturer Saphenus Medical Technology. The sensory feedback system consists of a prosthetic sensor cover and a thigh cuff with vibration motors. When one of the sensors on the sole detects ground contact, one of the actuators vibrates on the skin. This vibrotactile signal allows the user to feel the prosthetic foot roll over. As the residual limb was short, the cuff was placed on the non-affected leg.

The feedback system was applied to the leg prosthesis without modifying its function. The user could then use the prosthesis with the feedback system in his daily life for 41 days.

Gait analysis was carried out both on day zero of application of the feedback system and after using the system for 41 days. On both days, three runs of the Timed Up and Go test (TUG), Four Square Step Test (FSST) and 10 Meter Walk Test (10MWT) were performed. Table 1 shows the best results on both days and the difference between them.

The individual was able to walk much more confidently and stably with the feedback system. This is demonstrated by the improved results of the gait assessments. The feedback system increased gait stability, safety, and walking speed.

Furthermore, the patient was asked to assess his pain level on a scale from 0 to 10 (0=no pain, 10=unbearable pain) regularly during use of the sensory feedback system. Before the trial of the feedback system his pain level was around 6–7 daily.

During the use of the device, his pain level decreased significantly to 2–3. Furthermore, he reported that he had no more short pain attacks. Overall, his pain changed from a permanent and obtrusive distraction to a non-intrusive background sensation.

**Table 1.** Results of the gait assessments on baseline day 0 and after using the sensory feedback system for 41 days.

| | Day 0 | Day 41 | Difference |
|---|---|---|---|
| TUG | 7.9 seconds | 6.29 seconds | **-1.61 seconds** |
| FSST | 10.10 seconds | 8.39 seconds | **-1.71 seconds** |
| 10MWT | 6.89 seconds | 5.63 seconds | **- 1.26 seconds** |

## DISCUSSION

The cortical reorganisation in the brain following an amputation causes phantom limb pain, which can be reduced by sensory feedback.[3] This case study illustrates the non-invasive treatment of phantom limb pain by applying a vibrotactile feedback system to prostheses. The vibrations over the skin representing the prosthetic foot rollover while walking were processed intuitively by the brain. The use of vibrotactile feedback for several consecutive days almost completely eliminated the subject's phantom pain and increased his gait stability. The positive effect on both factors enhanced satisfaction with his prosthesis and quality of life.

## CONCLUSION

Individuals with lower-limb loss may no longer require additional surgery to reduce or eliminate their phantom limb pain. This non-invasive device demonstrates significant promise in the elimination of phantom limb pain and provides increased gait stability.

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# Safety and Efficacy of Vibrotactile Feedback for Adults with Transtibial Amputation: A Randomized Controlled Crossover Trial

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## INTRODUCTION

Sensory feedback systems aim to improve proprioception and rehabilitation by facilitating prosthesis utility and embodiment.[1] Pain, social integration, and walking safely with divided attention challenge people with lower-limb amputation. The non-invasive vibrotactile feedback device Suralis® (Saphenus Medical Technology, Vienna, Austria) aims to improve gait, postural control, and pain treatment. This randomized controlled crossover trial investigated 60-day effects of vibrotactile ground-contact feedback on gait performance and quality of life in adults with unilateral transtibial amputation.

## METHOD

We conducted assessments before and after the intervention period and compared within-period changes to the control period without intervention, separated by a one-week washout. The trial, funded by the Austrian workers' compensation board AUVA, and supported by Saphenus Medical Technology, is registered on clinicaltrials.gov (no. NCT05895253).

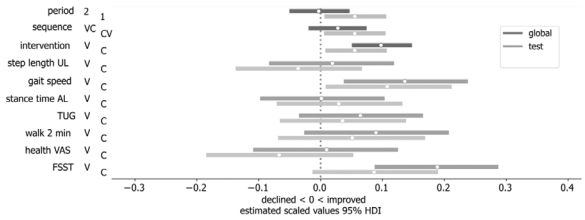
***Participants/Apparatus:*** We recruited participants via referral and advertising by the sponsor through medical supply stores. The trial enrolled 13 participants (four female) aged 26–81 years (median 57.91 years) who had undergone unilateral transtibial amputation (seven left, six right) at least 18 months before signing the informed consent form and could walk without walking aids. The primary outcome substitute was affected-leg stance time. Secondary outcome measures included instrumented-walkway gait speed and four-square-step-test.

***Procedures/Data Analysis:*** Participants were assigned randomly to receive the sensory feedback first and then no intervention or vice versa. Each period lasted 60 days. The feedback system was a modular add-on to their normal leg prosthesis and transmitted the ground contact of the prosthetic foot using vibrations to the residual limb. We used a Bayesian generalized linear mixed model intention-to-treat analysis.

## RESULTS

Analyzing groups of six and seven participants showed that participants walking slower than 1.41 $ms^{-1}$ [1.34 $ms^{-1}$, 1.49 $ms^{-1}$] [95% highest-density interval] with affected-leg stance times above 0.64 second [0.58 second, 0.69 second] responded most positively. Four Square Step Test (FSST) times had the largest within-period effect size (mean 0.89; [0.44, 1.34] for 0.5 second [0 seconds, 1 second] improvement), followed by period-one (−0.37; [−0.56, −0.18]), and treatment (0.28; [0.095, 0.46]) (Figure 1).

**Figure 1.** Estimated scaled within-period (post/pre) changes in global and test as 95% highest density intervals (HDI). The lighter colors represent C, and the darker colors V. UL=unaffected-leg, AL=affected-leg, TUG=Timed Up and Go, VAS=health-related visual analog scale, and FSST=Four Square Step Test.




## DISCUSSION

Our findings showed that the vibrotactile feedback had a positive effect enhancing gait performance. Our results are consistent with an earlier case series[2] demonstrating that the benefits of vibrotactile feedback were most evident for the FSST. The FSST involves taking steps backward and over small obstacles while disrupting visual control, thereby emphasizing motor planning and somatosensory inputs. This is substantiated by the relationship between vibration perception threshold and FSST time.

## CONCLUSION

Walking with the vibrotactile feedback system consistently yielded more beneficial outcomes than without, resulting in an improvement in gait performance primarily driven by improvements in functional balance. The vibrotactile feedback system particularly benefited participants with unilateral transtibial amputation walking at slower gait velocities. This indicates that slower-walking people with amputation could regain walking confidence through increased somatosensory input while walking.

## CLINICAL APPLICATIONS

Faster FSST times imply improvements in walking safely with divided attention and clearing small obstacles, such as in congested situations. Using vibrotactile feedback to improve functional balance may have clinical significance in aiding the social integration of individuals with unilateral transtibial amputation or lower-limb deficits related to somatosensory issues.

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# Physiological Cost Index in Lower-Limb Amputees: Insights From a Prosthetic Foot Feasibility Study

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## INTRODUCTION

The energy cost of walking is higher for people with amputations compared to individuals with sound lower limbs and higher for transfemoral (TF) compared to transtibial (TT) amputees.[1] The 6-Minute Walk Test (6MWT) is commonly used to measure walking endurance in people with lower-limb amputations. However, cardiopulmonary exercise testing to measure energy expenditure requires special equipment and is not feasible in most clinics. The Physiological Cost Index (PCI) has been used as an index of energy expenditure in people with amputations.[2] A randomized, crossover, feasibility study was conducted in subjects with TT and TF amputations to compare a prototype energy storage and return foot with the their currently worn feet and with comparator feet. Results for the 6MWT and PCI are presented.

## METHOD

Institutional Review Board approval was obtained, and all subject signed informed consent prior to participation. Four P&O clinics in the United States participated in the study.

***Participants:*** Twenty-seven unilateral amputees were enrolled, and 16 subjects from three sites had 6MWT and PCI data for this analysis. Subjects were 14 male and two female, mean age of 59.0 years and mean weight of 201±28.5 lbs. Eight TT and eight TF. TF users wore C-Leg (5), Genium (1) or X3 (2) knees, all with passive vacuum suspension. The causes for amputation were trauma (9), cancer (9), infection (2), dysvascular (1), and other (1).

***Apparatus:*** Heart rate was obtained with a Polar heart rate monitor strap during the 6MWT, and the Borg CR100 rating of perceived exertion (RPE) was obtained immediately after the test.

***Procedures:*** After enrollment, patients were assigned one of two study feet (ESR prototype or comparative feet) in randomized order completing home-use periods eight weeks. Investigators had subjects perform 6MWTs at baseline, after each home-use period, and after a final home-use period after returning to the original prosthetic foot.

***Data Analysis:*** PCI was calculated with the formula, PCI=(working HR-rest HR) / walking speed, where average HR during the 30 seconds prior to the test was used as rest HR and the average of the last minute for working HR. The heart rate reserve (HRR) was estimated as the age-predicted max HR-rest HR and the %HRR calculated based on the (working HR)/HRR. P-values were computed using non-paired t-tests.

## RESULTS

There were no significant differences for any of the 6MWT outcome measures between the feet. Table 1 shows the mean 6MWT distance, RPE, %HRR and PCI by amputation level.

TF subjects had statistically significantly higher PCI and consumed a higher percentage of their HRR compared with TT subjects, while there were no differences in distance walked or RPE between feet. PCI was also moderately correlated with BMI (r=0.54, p=0.03).

**Table 1.** Average and SD for 6MWT distance, Borg RPE, %HRR and PCI.

| Group | 6MWT (m) | Borg RPE | %HRR | PCI (beats/m) |
|---|---|---|---|---|
| **TF** | 346 ± 77 | 56 ± 23 | 59 ± 11 | 0.87 ± 0.34 |
| **TT** | 403 ± 72 | 34 ± 29 | 37 ± 15 | 0.42 ± 0.13 |
| **p-value** | 0.15 | 0.11 | 0.005 | 0.003 |

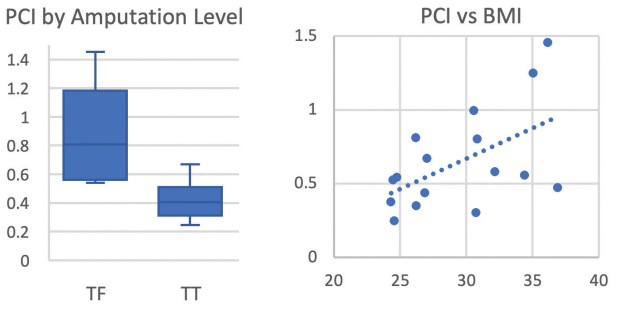


**Figure 1.** Box and whisker plots for Physiological Cost Index and scatter plot of Physiological Cost Index versus BMI.

## DISCUSSION

In this feasibility study, there were no differences in any 6MWT outcomes between prosthetic feet studied. This is consistent with a recent systematic review on the subject.[3] However, both PCI and %HRR show clear differences between TT and TF subjects. The PCI results are similar, but slightly higher for TF subjects than those previously published, most likely due to the higher BMI and age of the subjects in this study.[2]

## CONCLUSION

PCI was not sensitive to differences in prosthetic feet, but was able to differentiate between amputation level and showed a correlation with BMI. %HRR may be an alternative to PCI and easier to interpret.

## CLINICAL APPLICATIONS

The collection of heart rate data in non-research sites is feasible using commercially available HR monitors and facilitates measuring PCI as a surrogate for the energy cost of walking.

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# Characterizing the Prevalence of Pelvic Floor Disorders in People with Lower-Limb Amputation

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## INTRODUCTION

Pelvic floor disorders (PFDs) are major health burdens affecting millions of people. A broad term used to describe several impairments, PFDs manifest in a variety of ways, including urinary and fecal incontinence, and urinary frequency or urgency. Understudied in males compared to females, PFDs are even more poorly understood in people with physical disabilities like lower-limb amputation (LLA). In the non-LLA population, associations exist between spinal pain and urinary incontinence and fall risk.[1] Incidentally, individuals with LLA experience increased rates of low back pain[2] and falls,[3] provoking interest of a possible association to undiagnosed PFDs. Currently, no evidence exists regarding the prevalence of PFDs in people with LLA or any effect they may have on functioning and quality of life. The purpose of this study is to provide novel data on the prevalence and severity of PFDs in males and females with unilateral LLA who use a prosthetic limb.

## METHOD

***Participants:*** One hundred thirty-five individuals (97.8% Veterans; 39% females) with unilateral LLA who utilize a prosthesis for daily mobility. Mean age 49.3±12.6 years, 73% with transtibial amputation and 62% due to trauma.

***Apparatus:*** Surveys administered, nationwide, through a VA-approved, secure, study-specific website. The primary outcome measure was the Pelvic Floor Disability Index-20 (PFDI-20) to determine the perceived distress and severity of urinary (UDI-6), colorectal (CRADI-8), and prolapse (POPDI-6) symptoms using traditional (distress) and new (severity classification) scoring methods. Secondary outcomes included the Prosthetic Limb Users Survey of Mobility (PLUS-M) and Activities-Specific Balance Confidence Scale (ABC), to determine relationships of PFDs to perceived functioning, as well as reports of previous low back pain (LBP) and falls.

***Procedures:*** Veteran participants were identified through the VA's Computer Data Warehouse and were mailed and emailed study flyers. Approval was provided to recruit female non-Veterans due to a low percentage of Veterans with LLA identifying as female. Inclusion criteria: 18–80 years old, unilateral LLA above the ankle, and daily prosthetic use. Participants accessed the study website from their personal computer or phone. The study was deemed Institutional Review Board exempt by the Lexington VA Healthcare System.

***Data Analysis:*** Mann Whitney U tests were used to compare groups based on sex, and low back pain and fall history. Spearman correlations tested associations of PFDs to perceived mobility and balance.

## RESULTS

Preliminary results indicate that 98% of participants are experiencing some level of distress from pelvic floor disorder symptoms: 2% of participants reported no distress caused by symptoms, 52% reported mild distress, 29% reported moderate distress, and 2% reported severe distress. Additionally, 72% of participants reported previous medical treatment for LBP, and 59% reported a fall in the past year. Significant differences existed between males and females ($p<0.01$), with females reporting higher distress related to PFD symptoms. Additionally, participants with a history of LBP or falls scored significantly worse. Moderate correlations existed between PFDI-20, PLUS-M and ABC scores ($rs=-0.50$ and $rs=-0.60$, respectively).

## DISCUSSION

This is the first study to examine PFD in people with LLA, indicating that females and those with a history of LBP or falls are reporting significantly more distress from their symptoms.

**Table 1.** Comparison of previouos low back pain and falls.

| Type of score | **Previous LBP treatment** (n=97) Median (IQR) | **No previous LBP treatment** (n=38) Median (IQR) | **P value** |
|---|---|---|---|
| **PFDI-20 traditional** Summary score | 62.5 (34.4, 114.6) | 28.6 (3.1, 72.9) | <0.01 |
| UDI-6 | 29.2 (8.3, 50.0) | 10.4 (0.0, 33.3) | 0.01 |
| CRADI-8 | 18.8 (0.0, 40.6) | 6.3 (0.0, 18.8) | 0.02 |
| POPDI-6 | 16.7 (0.0, 37.5) | 0 (0.0, 25.0) | 0.02 |
| **PFDI-20 new** Total score | 11.0 (7.0, 19.0) | 8.0 (4.0, 13.0) | 0.03 |
| | **Previous fall** (n=80) | **No fall** (n=55) | |
| **PFDI-20 traditional** Summary score | 68.2 (34.4, 115.6) | 39.6 (0.0, 94.8) | <0.01 |
| UDI-6 | 33.3 (8.3, 50.0) | 16.7 (0.0, 41.7) | 0.03 |
| CRADI-8 | 20.0 (3.1, 40.6) | 6.3 (0.0, 25.0) | <0.01 |
| POPDI-6 | 16.7 (0.0, 37.5) | 12.5 (0.0, 25.0) | 0.09 |
| **PFDI-20 new** Total score | 11.5 (7.0, 19.9) | 9.0 (4.0, 16.0) | 0.02 |

Moderate association of PFDs to perceived functioning warrants additional study. Future research with a broader sample into biomechanical relationships with prosthetic gait could provide further insights.

## CONCLUSION

Study results address a previously unchartered area in amputation research, highlighting the potential impact undetected PFDs may have on functioning.

## CLINICAL APPLICATIONS

The PFDI-20 can serve as a tool for practitioners to screen patients with LLA for previously unidentified PFDs that may be affecting function and quality of life.

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# Algorithm Development for Accelerometery-Based Step and Wear Time Measurement in Lower-Limb Prosthesis Users

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## INTRODUCTION

There is a growing trend in the use of wearable sensors to evaluate physical activity for individuals with lower-limb amputation[1] because understanding how prostheses are used in daily life is important to the evaluation of prostheses in research and clinical care. We aimed to develop algorithms to measure step count and prosthesis wear time in persons with transfemoral amputation using data from a single accelerometer.

## METHOD

***Participants:*** With Institutional Review Board approval, our algorithms for assessing step count and wear time were validated in two participants with unilateral transfemoral amputation.

***Apparatus:*** An FDA compliant, GENEActiv triaxial accelerometer (Activinsights Ltd, UK) was strapped to the lower limb, laterally at ankle height. An open data format provides a platform for algorithm development, to create new techniques and measures from raw data.

***Procedures:*** Algorithms were written in Matlab (Mathworks Inc., Natick, MA). The following steps were implemented for **step counting:** (1) Resultant acceleration magnitude was calculated to minimize the effect of possible sensor tilt. (2) The signal was demeaned to eliminate the effect of constant gravitational acceleration. (3) The signal was filtered using a 4th order double-pass Butterworth low-pass filter at 2 Hz cut-off frequency to eliminate high frequency noise while still keeping the effective natural frequency of the human body for walking.[2] (4) Counting peaks greater than 0.05 g threshold (baseline noise standard deviation is 0.02 g) as indication of heel strike and toe off occurrences. (5) Excluded steps with durations <0.3 second and >1.2 second, as they are metabolically costly and not expected in typical over ground walking.

The following steps were implemented for **prosthesis wear time:** (1) Resultant acceleration magnitude was calculated. (2) The signal was demeaned. (3) Signal peaks >0.03 g were detected as they can be associated with gait or non-gait-related minute leg movements (e.g., sitting quietly). (4) Donning onsets were defined as the trailing edge of a five-minute moving window if at least two peaks were detected within that window. (5) Doffing onsets were defined as the trailing edge of a 30-minute moving window if the peaks within that window were ≤2. (6) Wear periods lasting <10 minutes were considered non-wear incidents and eliminated. Participants wore an accelerometer on each limb. First, they sat for 30 minutes, shifting normally as needed (e.g., to reach for a water bottle). Movements of the lower limbs were noted. Then, they walked laps up and down a hallway while steps were counted manually using a clicker.

## RESULTS

A high rate of agreement was observed between step counts on the sound and prosthetic limbs, as well as between accelerometer and manual step counts (Table 1). Figure 1 illustrates accelerations recorded from the prosthetic limb during 30 minutes of sitting for one participant. Our results suggest that even when sitting quietly, sporadic bursts of acceleration at magnitudes of 0.03 g threshold or greater at time intervals of four minutes or shorter were evident (i.e., the prosthetic limb is not completely silent). Our proposed algorithm was able to detect wear time with five-minute resolution.

**Table 1.** Agreement across step count measures (mean and SD per lap walked).

| ID | Manual | Prosthetic Limb | Sound Limb |
|---|---|---|---|
| 1 | 75.1±1.5 | 75.0±1.7 | 74.8±1.3 |
| 2 | 81.5±3.1 | 82.4±2.9 | 82.6±3.0 |

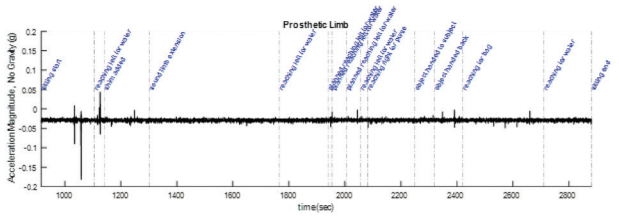


**Figure 1.** Example wear time data for prosthetic limb of one participant. Blue text notes manual observations.

## DISCUSSION

Initial validation suggests step count algorithm works well for straight line over ground walking. To the best of our knowledge, this is the first study to assess prosthesis wear time using accelerometry.

## CONCLUSION

Our proposed algorithm can detect steps and measure wear time during sitting, standing and walking; however, more extensive validation is required.

## CLINICAL APPLICATIONS

The ability to use a single monitor to record multiple types of clinically relevant data is efficient for both clinical care and research.

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# Reproducibility of Residual Lower-Limb Shape Captured Using Two Casting Methods

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## INTRODUCTION

The conventional lower-limb prosthetic socket fabrication process consists of residual limb shape capture via a non-weight bearing negative wrap. An alternative approach using a standing hydrostatic pressure cast is proposed to be simpler, relying less on manual manipulation of the cast.[1] The aim of this clinical trial was to compare the shape of casts made by hand casting and standing hydrostatic pressure casting in persons with lower-limb amputation. We compared casts taken by pairs of prosthetists from the same participant. We hypothesized that casts taken with hydrostatic pressure casting would be more reproducible than casts taken by hand.

## METHOD

Data were collected with Institutional Review Board approval as part of a three-site randomized crossover trial.

***Participants:*** Seventy-nine participants (55 with unilateral transtibial (TT) amputation and 24 with unilateral transfemoral (TF) amputation).

***Procedures:*** Two prosthetists per site took a cast by hand and using the Symphonie Aqua System (Romedis GmbH, Germany). The order of prosthetists and of casts taken by each prosthetist was randomized. For each participant, all casts were taken over the same brand, model, and size silicone liner. After casting, physical landmarks were applied to the inner surface of the negative plaster molds over the landmark locations identified by palpation of the residual limb by the prosthetists. Casts were then filled with liquid plaster, and the resulting unrectified positive mold was scanned using the EINScan Pro 2X Plus structured light scanner with High Definition Prime Pack (SHINING 3D Tech. Co, Ltd, China).[2]

***Data Analysis:*** Custom SocketFactory software[3] was used to calculate volume and six equidistant cross-sectional perimeters of each mold. Level of agreement between mold pairs for volume and perimeters were assessed using Bland-Altman plots.[4]

## RESULTS

Figure 1 illustrates the results for volume: limits of agreement (LOA) were wider for hydrostatic casting for both TT and TF. The same was observed for perimeters. This suggests that hydrostatic casting was slightly less reproducible than hand casting, particularly distally.

## DISCUSSION

One possible explanation for why hydrostatic casting was less reproducible than hand casting could be due to the fact that the prosthetists set up the Symphonie cylinder differently (e.g., choosing distal cups with different dimensions or setting the tower height differently). Furthermore, the speed and pressure with which the individual shifts his or her weight onto the residual limb during casting may alter the pressures applied to the distal end of the residuum.

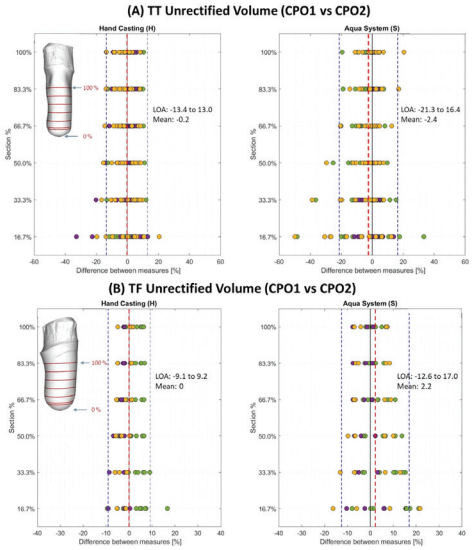


**Figure 1.** Bland-Altman plot for volume (A) transtibial (TT) casts and (B) transfemoral (TF) casts. Blue vertical lines indicate limits of agreement. Red vertical line is the mean.

## CONCLUSION

Our results suggest that hydrostatic casting was slightly less reproducible between prosthetists than hand casting in terms of cast shape. This was likely the result of variations in cylinder set up and procedure. Future research should control these variables.

## CLINICAL APPLICATIONS

These results do not support the use of hydrostatic casting where consistency of residual limb shape capture between prosthetists is a goal.

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# Pain and Performance: Important Considerations for Outcome Measure Assessment

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## INTRODUCTION

Pain is known to negatively affect prosthesis use and physical function.[1] Of potentially greater concern is multisite pain, which is defined as pain in two or more locations. Multisite pain affects up to 60% of adults with lower-limb loss (LLL).[2] Among the general population, multisite pain is associated with slower gait speed and worse physical function.[3] However, associations between multisite pain and functional mobility among adults with LLL remains less studied. This purpose of this study was to examine the relationship between multisite pain and functional mobility per standardized performance-based outcome measures.

## METHOD

A secondary analysis of a cross-sectional dataset collected from 2013 to 2023 during an interdisciplinary, outpatient limb loss clinic (Institutional Review Board #531197).

***Sample:*** Ninety-nine community-dwelling adults ≥6 months after LLL (74.7% male; 54.9±13.8 years; 34.3% dysvascular; 61.6% below-knee; 19.2% bilateral).

***Outcomes:*** Demographic, pain, and amputation history; 10-Meter Walk Test at self-selected speed (SSWS); Timed Up and Go (TUG); 6-Minute Walk Test (6MWT).

***Procedures:*** Pain in the past week was classified by regional presence in five sites: bilateral upper and lower extremities and axial pain. Participants were grouped by presence or absence of multisite pain (≥2 regions). Extent of amputation was classified as unilateral below-knee, unilateral above-knee, or bilateral LLL.

***Data Analysis:*** Descriptive statistics were calculated using SPSS Statistics. Between-group differences in functional test performance were evaluated using Mann Whitney U-tests ($p<0.05$). Linear regression was used to identify the strength of the relationships between multisite pain presence and functional tests (i.e., SSWS, TUG, 6MWT), with an adjusted $p\leq0.0167$.

## RESULTS

Multisite pain was reported by 59.6% of participants. Individuals with multisite pain had significantly slower SSWS (0.95±0.30 m/s versus 1.11±0.24 m/s; p=0.005], longer TUG times [11.19s (25th, 75th percentile: 8.95, 11.27) versus 8.99s (7.07, 12.37); p=0.034], and shorter 6MWT distances (358.0±139.5m versus 435.3±139.5; p=0.006; Figure 1). After controlling for covariates (i.e., age, sex, extent of amputation), multisite pain presence explained 6.1% (p=0.007), 4.8% (p=0.019), and 5.5% (p=0.010) of the variance in SSWS, TUG, and 6MWT performance, respectively. Multisite pain presence was associated with a 0.15 m/s slower gait speed and a 70.1 m shorter 6MWT distance.

## DISCUSSION

Adults with LLL who have multisite pain exhibit significantly worse ambulatory function than peers without multisite pain.

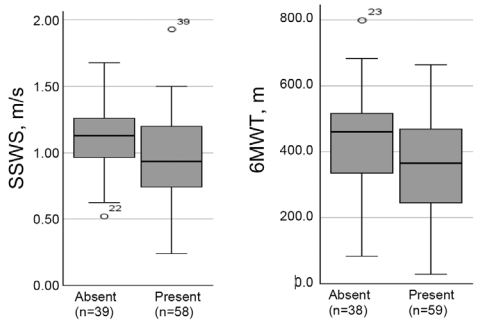


**Figure 1.** Between-group differences in performance on functional outcome measures based on presence of multisite pain.

These findings expand our prior work in LLL, which found multisite pain is associated with post-amputation adjustment,[4] recurrent falls, and activity restrictions,[4] suggesting pain extent may be a more important metric than non-specific pain presence or absence. The relationship to multisite pain was strongest for SSWS and 6MWT, indicating individuals with multisite pain walk more slowly and have reduced walking endurance, which is consistent with findings among adults with chronic multisite pain in the general population.[6] The relationship with TUG performance was not significant, perhaps due to one-third of participants completing the test in less than ten seconds. Nonetheless, findings support the need for enhanced pain management after LLL. Specifically, future research is needed to determine if addressing multisite pain improves outcomes among adults following LLL.

## CONCLUSION

Multisite pain presence is associated with reduced walking speed and endurance among adults with LLL. Successful post-amputation pain management may improve mobility outcomes in this clinical population.

## CLINICAL APPLICATIONS

Presence of multisite pain should be considered when interpreting performance on standardized outcome measures among adults with LLL.

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# Patient Reported Outcomes Following Lower-Limb Socket and Prosthesis Replacement

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## INTRODUCTION

Prosthetic sockets are fundamental in stabilizing the residual limb and providing a secure attachment for the prosthesis, which in turn aids in achieving a more natural and efficient walking motion. Measuring success for both sockets and prostheses is commonly completed through the collection of outcomes.

Patients who experience a lower-limb amputation also experience a decrease in mobility that correlates with a decrease in quality of life and satisfaction.[1] While timely receipt of an initial prosthesis following amputation improves patient outcomes, the impact of a replacement socket or prosthesis is less documented.

The purpose of this study was to assess the average change in outcomes resulting from socket and prosthesis replacements.

## METHOD

This study included patients from a national database from a private prosthetic clinic. Inclusion criteria consisted of adults with a unilateral lower-limb amputation who received either a replacement socket or prosthesis.

***Participants:*** Four groups were separately analyzed based on socket or prosthesis replacement status (above-knee socket replacement n=2,725, below-knee socket replacement n=9,099, above-knee prosthesis n=1,962, and below-knee prosthesis n=8,195).

***Outcomes:*** Data were collected during routine clinical care with questionnaires about quality of life and satisfaction (Prosthesis Evaluation Questionnaire (PEQ), Well Being), and mobility from the Prosthetic Limb Users Survey of Mobility (PLUS-M).[2,3]

***Procedures:*** Groups were identified based on L-Codes for replacement sockets (L5701, L5700), and replacement prosthesis base codes (L5200, 5321, 5100, 5105, or 5301). Participants without a pre and post delivery were excluded.

***Data Analysis:*** Student's t-tests were performed to test for significant differences from pre to post timepoints (α=0.05).

## RESULTS

Patients receiving a replacement socket or prosthesis experience an increase in satisfaction, quality of life, and mobility (Table 1).

## DISCUSSION

Prosthetic rehabilitation provides benefits to patients following an amputation. However, the rehabilitation journey for patients does not end with receipt of the initial prosthesis. Rather, patients face a lifetime of changes to their residual limb and functional needs that may necessitate the replacement of a socket or prosthesis. The current study findings demonstrate that a replacement socket or prosthesis on average will improve patient outcomes. These improvements were demonstrated while only accounting for difference in intervention (i.e., socket or prosthesis) and functional level (i.e., above-knee or below-knee). Future work should account for additionally factors that have demonstrated impact on patient outcomes such as age and comorbidities.

**Table 1.** Patient reported outcomes following replacement socket or prosthesis delivery.

| | n | Δ Sat | Δ QoL | Δ Mobility |
|---|---|---|---|---|
| AK socket | 2,725 | +0.73* | +0.35* | +2.50* |
| BK socket | 9,099 | +0.54* | +0.40* | +1.51* |
| AK prosthesis | 1,962 | +0.63* | +0.63* | +2.05* |
| BK Prosthesis | 8,195 | +0.73* | +0.56* | +2.50* |

Δ Change from pre to post. * Significant differences from pre and post. Sat: Satisfaction, QoL: Quality of life.

## CONCLUSION

On average, patients with lower-limb amputation receiving an above-knee or below-knee replacement socket or prosthesis can expect an improvement in their outcomes. The magnitude of improvement will depend on individual factors.

## CLINICAL APPLICATIONS

Socket or prosthesis replacements can provide improved patient outcomes. However, the magnitude of potential improved outcome should be considered based on individual patient presentation.

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# Effects Of Low-Profile Prosthetic Foot Compliance on Gait

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## INTRODUCTION

Availability of prosthetic feet is limited for individuals with long residual limbs or long proximal components. These individuals require low-profile prosthetic feet (LPF), which have a reduced build height.

Due to geometric constraints and loading demands in the cantilever beam design, LPFs are mechanically stiffer than standard feet and poorly replicate anatomical foot function. Despite the increased stiffness, individuals who use LPFs report higher incidences of mechanical failure.[1] A foot that is too stiff can result in reduced push-off propulsion, increased knee moment, altered rollover shape, increased metabolic cost, and decreased energy storage density.[2–4]

This study tested the effects of a novel layered LPF prototype[5] designed to increase compliance without sacrificing strength. As an example of the reduced stiffness, the conventional foot used for two subjects in this study was a 28 cm Horizon HD with stiffness category 3. We independently measured its forefoot stiffness according to the ISO 10328 standard loading test and measured a stiffness of 72.4 N/mm. The prototype foot built for the same two subjects was designed to have a stiffness of 32 N/mm, a 56% reduction.

## METHOD

***Participants:*** Five adults with unilateral lower-limb loss who were current or previous users of an LPF participated in this Institutional Review Board-approved study. The prototype was compared to each subject's conventional LPF, which included Ossur Pro-Flex LP Torsion, Rush 86LoPro, and Ottobock Taleo LP. Two subjects who used a conventional-height foot with a posterior mount were fitted with College Park Horizon HD feet for comparison.

***Apparatus:*** Three-dimensional instrumented gait analysis, portions of OPUS, and subjective feedback interview. A stiffness category selection table was generated for the prototype based on patient weight and activity level. The categories were designed to achieve stiffnesses two categories lower than an equivalent LP Vari-Flex (as reported in footnote 6), while still achieving a sufficient factor of safety against material failure.

***Procedures:*** Following informed consent, each subject was fitted with the prototype foot by the study prosthetist. Foot testing order was determined by block randomization. Subjects were blinded to foot condition via placement of a black sock over each foot by the prosthetist. The researcher collecting feedback was also blinded. Using Vicon's Plug-in-Gait lower-body model, kinematics (100 Hz) and kinetics (1000 Hz) were recorded during at least ten trials per condition of level overground walking at self-selected speed. Surveys and interviews followed each condition.

***Data Analysis:*** Multivariate analysis of variance with factors for subject and condition was used to compare spatiotemporal parameters, gait deviation index, limp index, and peak prosthetic side ankle dorsiflexion angle in stance.

## RESULTS

While walking speed and cadence were not significantly different, prosthetic side step length was longer with the prototype ($p=0.047$). Subject 4, who took much longer steps with both limbs while using the prototype, showed similar speed between conditions but a much lower cadence with the prototype. Peak dorsiflexion was significantly greater with the prototype ($p<0.001$). The overall difference in means was 5.0 degrees, ranging from 1 to 19.6 degrees. Subjects indicated a preference for the prototype in subjective feedback, with a mean improvement of one point for the prototype on a ten-point Likert-scale overall rating. There were no significant differences for OPUS results.

**Table 1.** Outcome measure means by foot condition.

| | COND | N | Mean | Std. Dev. |
|---|---|---|---|---|
| Peak dorsiflexion (deg) | conv | 18 | 14.74 | 5.56 |
| | pronto | 18 | 19.71 | 10.18 |
| Prosthetic side Gait Deviation Index | conv | 14 | 85.20 | 11.13 |
| | pronto | 11 | 84.25 | 5.72 |
| Cadence (step/minute) | conv | 21 | 103.82 | 6.50 |
| | pronto | 22 | 102.41 | 4.74 |
| Speed (m/second) | conv | 21 | 1.23 | 0.14 |
| | pronto | 22 | 1.24 | 0.16 |
| Prosthetic side step length (m) | conv | 21 | 0.74 | 0.10 |
| | pronto | 22 | 0.80 | 0.16 |
| Prosthetic side Limp Index | conv | 21 | 0.98 | 0.03 |
| | pronto | 22 | 0.98 | 0.05 |

## DISCUSSION

Increased dorsiflexion is a gross measure of the real-world application of mechanical compliance in the prototype and suggests that a more appropriately compliant foot offers less resistance to rollover in gait. Even with blinding, subjects noticed a difference between the feet and expressed preference for the prototype.

## CLINICAL APPLICATIONS

Clinicians should consider the importance of stiffness when prescribing low-profile prosthetic feet.

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# Mixed Methods Pilot Study of a Slope Adaptive Foot

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## INTRODUCTION

Motion Control, Inc. and the Minneapolis VA have developed a novel slope adaptive foot (SAF) that adapts the ankle alignment for each step of walking. The primary aim of this pilot study was to evaluate how the SAF impacts users' perceived mobility on slopes and uneven terrain. Secondarily, we evaluated how the SAF impacts their balance confidence and participation in social roles and activities.

## METHOD

This study was approved by the Minneapolis VA Institutional Review Board, and participants provided written informed consent.

***Participants:*** Nine male Veterans with unilateral, transtibial amputation; average age: 66.1±7.4 years; average time using a prosthesis: 13±17.1 years; functional level: K3 (n=8) and K4 (n=1); prescribed foot: dynamic response (n=7), hydraulic (n=2).

***Apparatus:*** A custom Prosthetic Limb Users Survey of Mobility short form (PLUS-M*) focused on varied terrain, the Activities-Specific Balance Confidence (ABC) scale, and the Patient-Reported Outcomes Measurement Information System (PROMIS) Ability to Participate and Satisfaction with Participation in Social Roles and Activities (PROMIS-APSRA and PROMIS-SSRA, respectively).

***Procedures:*** Participants completed surveys before and after a four-week take-home trial of the SAF. During the take-home trial of the SAF, participants submitted photos of activities or environments where they noticed a meaningful difference in function of the SAF compared with their prescribed foot. At the end of the four weeks, a semi-structured interview was conducted to gather feedback about the SAF.

***Data Analysis:*** Survey data were tested for normality using a Shapiro-Wilk test. A one-sided paired t-test and one-sided Wilcoxon Signed Rank test were used for normally and non-normally distributed data, respectively. Participant feedback was organized into descriptive categories generated from data content.

## RESULTS

There was a significant improvement in PLUS-M* and PROMIS-APSRA scores when using the SAF (Table 1). No significant differences were found for ABC or PROMIS-SSRA scores.

**Table 1.** Self-report outcomes (mean and SD).

| Survey | Prescribed | SAF | SAF-Prescribed | p-value |
|---|---|---|---|---|
| PLUS-M* | 56.7 (6.0) | 58.2 (5.7) | 1.5 (2.4) | <.05 |
| ABC | 86.0 (10.8) | 83.5 (15.0) | -2.6 (6.7) | .86 |
| PROMIS-APSRA | 46.9 (6.9) | 50.4 (9.8) | 3.4 (5.4) | <.05 |
| PROMIS-SSRA | 52.3 (6.8) | 51.1 (9.2) | -1.1 (7.1) | .90 |

Photographs collected during the study included pictures of stairs, sloping landscapes, hiking trails, cracked sidewalks, cluttered floors (Figure 1). Overall, participants reported improved ability to navigate these environments with the SAF. Comments about the SAF included improved mobility on slopes and uneven terrain, improved participation in meaningful activities, feeling more like a "normal" foot, and reduced need to view the ground to avoid tripping.

## DISCUSSION

Pilot results indicate the SAF may improve mobility and participation. Quantitative results aligned with participants' qualitative data, but feedback gathered from participants provided rich information about the user experience that was not captured by the self-report surveys. Further research is needed to explore how the experience of using a SAF differs from other commercially available feet and to inform prescription.

## CONCLUSION

Quantitative data and participant feedback suggest the SAF may provide improved mobility and ability to participate. Future prosthesis user experience studies should consider a mixed methods approach to improve the ecological validity of the results.

## CLINICAL APPLICATIONS

Prostheses that adapt their alignment to uneven terrain may provide improved mobility, allowing users to more easily participate in social roles.

## ACKNOWLEDGEMENTS

*This project was funded by the Department of Defense under contract W81XWH18C0314.*

**Figure 1.** Pictures provided by Veterans showing uneven terrain more easily navigated during use of the SAF.

# Home Exercise and Telehealth: Adherence to Home Walking and Prescription-Based Exercise Program for Lower-Limb Loss

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## INTRODUCTION

The home-based exercise program (HEP) for individuals in rehabilitation following lower-limb loss (LLL) is an integral part of rehabilitation outside of the clinic for the maintenance and improvement of strength, mobility, and functional goals.[1] Moreover, reducing physical limitations and improving movement patterns can accelerate prosthetic use and quality of performance.[2] However, clinical evidence shows that patients have varying degrees of exercise adherence to HEPs.[3] Evidence-based exercise prescription to improve HEP adherence has suggested dosing of 20 minutes per day for a minimum of three times per week or that a patient completes two-thirds the prescribed exercise routine. The purpose of this study is to determine patient adherence to home walks and prescription-based exercise programs among servicemembers (SMs) and Veterans with lower-limb loss (LLL) using the Rehabilitative Lower Limb Orthopaedic Assistive Device (ReLOAD).[4]

## METHOD

Patients were medically stable men and women between the ages of 18–80 with a major unilateral lower-limb amputation, at least one month post initial prosthetic fitting, and cleared for home use. The patient's physical therapist (PT) utilized a mobile application (app) called ReLOAD as part of the standard of care, collecting initial evaluation data in the clinic, administering outcomes through the app, conducting follow-up visits every 30 days, tracking patient progress, and prescribing HEP. The system consists of wearable sensors over the knee and a Bluetooth app on a mobile device (Apple iTouch). Based on functional outcome assessment performance and an algorithm that suggests exercises based on functional limitations, PTs prescribed HEP to patients. A maximum of four exercises can be prescribed at one time. Patients can view and report on their adherence through the app, check on their prescription dosage (sets, repetitions, and times per week). Moreover, patients can view with text, illustration, or video-specific exercises. The PTs can track patient adherence and modify the HEP remotely through the clinician app and communicate electronically with the patient. Home walks are performed based on walking capacity, and real-time audio-feedback using a patient's preferred music choices lets the patient know how well they are walking and provides cues designed to maintain or improve prosthetic walking patterns.

## RESULTS

A total of 427 exercises have been prescribed to patients. Patients performed 65% of their home exercises and a total of 2,728 exercises have been performed to date. The five most prescribed exercises (systems addressed) were stool stepping (single limb balance and hip extensor/abductors strength and endurance), ball rolls with arm support (single limb postural stability and balance), partial squats (lower-limb strength), chair squats (postural extensor strength), and braiding (balance and prosthetic gait control). In addition, 72% have performed home walks for a total of 1,040 home walks performed with a mean walk time of 15 minutes to date. Patients reported that the real-time verbal cueing provided helpful hints to improve prosthetic use, and music distortion helped maintain walking symmetry.

## DISCUSSION

The ability to exercise and walk at home is important to people learning how to use a prosthesis. Providing targeted exercise programs based on objective outcome measures, modifying the HEP over time, and monitoring walks with the prosthesis while providing real-time audio feedback can improve prosthetic function and mobility. Assisting people with mobile health technology to improve adherence to their HEP can help people reach their mobility goals.

## CONCLUSION

Preliminary results demonstrates that people with LLL using the ReLOAD system have improved HEP adherence for their prescription-based exercise program and home walks with auditory feedback.

## CLINICAL APPLICATIONS

Mobile health technology, such as ReLOAD can be prescribed for home use by SMs and Veterans with LLL to improve HEP adherence, reducing many of the barriers to access care at a military treatment facility or VA hospital. ReLOAD provides continuity of care by facilitating remote monitoring and communication between clinicians and patients.

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# Assessing Need for Intervention in Limb Loss: Comparing Clinical Consensus and Outcome Measures

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## INTRODUCTION

Identifying individuals with lower-limb amputation who fall short of their mobility goals and providing effective interventions is critical for enhancing their overall well-being.[1] The aim of this study was to address the gap between prescribed and actual functional level among prosthesis users by evaluating how effectively clinical outcome measures identify those in need of intervention compared to a multidisciplinary expert panel.

## METHOD

***Design/Participants:*** All data were collected under Institutional Review Board approval across a three-site multicenter, nine-month longitudinal study, with three, 3-month phases: (1) baseline, (2) intervention, and (3) carry-over. Performance and patient-reported outcome measures were collected at the conclusion of each phase. Fifty-eight (51 male, 7 female; ages 24–77) participants with lower-limb amputations across three sites were enrolled. Nineteen (17 male, 2 female; ages 29–76) participants were identified for targeted interventions during Phase 2. Eleven of the Phase 2 participants (9 male, 2 female; ages 29–77) completed Phase 3.

***Procedures/Data Analysis:*** A multidisciplinary team of amputation allied healthcare professionals reviewed outcome measures, community measures of mobility, and structured interviews after each phase to determine whether participants met their prescribed K-level and personal mobility goals. After Phase 1, only participants who were not meeting their goals and/or performing at their K-level moved on to Phase 2, where interventions were assigned according to each participant's outcome measure performance and/or goals. Interventions included any combination of physical therapy, prosthetic intervention, and motivational interviewing. Phase 3 assessed the carryover effects of the intervention on participants who progressed toward their K-level. Outcome scores were compared at baseline for the non-intervention group versus the intervention group, using a one-sided Wilcoxon Rank Sum test. Post-intervention groups deemed improved versus not improved by the expert panel were also assessed. Lastly, equivalence was tested using two one-sided t-tests (TOST), comparing all Phase 2 participants, Phase 2 improvers, and all Phase 3 participants to those meeting their prescribed K-levels and goals. The significance thresholds were set to $p \leq 0.05$ without adjustments for multiple comparisons.

## RESULTS

Most participants were performing at their prescribed K-level according to the expert panel. Participants needing intervention (n=19) had significantly worse scores at baseline than those not needing intervention ($n$=39) as measured by physical outcome measures (all $p \leq 0.005$) and a subset of the patient-reported outcome measures (p $p \leq 0.05$). Post-intervention, 11 of the participants were deemed improved by the expert panel, scoring significantly better on depression, gait velocity, endurance, dynamic balance, and prosthetic-related survey measures than those who were not deemed improved. Additionally, all participants post intervention ($n$=19) and those who completed the carryover phase ($n$=11) were statistically equivalent ($p \leq 0.05$) in the Amputee Mobility Predictor with prosthesis (AMP) but not other measures compared to those who met their prescribed K-level and/or goals at baseline. Prior to the carryover phase, those who were deemed improved ($n$=11) were borderline equivalent ($p$=0.053) when compared to the baseline group meeting their prescribed K-level.

## DISCUSSION

The multidisciplinary team identified two groups that were significantly different with respect to outcome variables at baseline: those meeting K-level and/or goals and those who were not. The team also identified a small majority of participants who responded to intervention supported by a subset of outcome measures. AMP equivalence over two comparisons and near equivalence in a third suggests the strongest agreement with clinical consensus out of all outcome measures used. When choosing clinical tools for assessing interventional need, the AMP may be the optimal tool when a multidisciplinary consensus is not available. Although there were positive findings, some participants did not improve with interventions, indicating that additional factors such as psychological issues or socioeconomic barriers may limit intervention effectiveness. Future research should address these barriers.

## CONCLUSION

Predicting K-levels and responses to interventions in clinical care is complex, but most patients responded positively to targeted interventions. The AMP had the strongest agreement with clinical consensus.

## CLINICAL APPLICATIONS

A multidisciplinary team, if available, is a very powerful tool when assessing need for intervention; however, if a team is unavailable, the AMP is a useful tool to aid in that determination across the continuum of care.

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*Department of Defense Orthotics and Prosthetics Outcomes Research Program (W81XWH-18-2-0057).*

# Efficacy of Wood Cheneau Rigo (WCR) Bracing in the Idiopathic Scoliosis Population

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## INTRODUCTION

Bracing has been the standard of care for the non-operative treatment of idiopathic scoliosis (IS) for decades. In the United States, many scoliosis braces are used, including the Boston, Providence, Charleston Bending, and Rigo Cheneau braces. In recent years, the Rigo Cheneau brace and its variations have gained popularity.[1] One commonly used variation is the Wood Cheneau Rigo (WCR) brace. While the WCR brace follows the Rigo Cheneau concept, the approach differs in three key ways. First, orthotists must complete a fellowship-style training period, often lasting one to two years, before fitting WCR braces independently. Second, all WCR braces are fabricated at Align Clinic headquarters by a small, consistent team of expert orthotists. Third, the WCR brace uses a lower-profile design to encourage adherence. With the increasing popularity of the WCR brace, it is crucial to assess the efficacy of the design in the treatment of IS.

## METHOD

This retrospective chart review was approved by the Baylor College of Medicine Institutional Review Board (H-53917).

***Participants:*** Subjects were included in the review if they had a diagnosis of juvenile or adolescent IS and were receiving a brace for the first time. Any prior brace treatment resulted in exclusion from this study. Forty-two subjects were included in the final analysis (35 females and 7 males).

***Apparatus:*** Retrospective chart review. All subjects in this review were evaluated and fit with a WCR brace by one clinician at Align Clinic in the Woodlands, TX.

***Procedures:*** The initial, in-brace, and six-month out-of-brace x-rays were measured across all subjects. All x-rays were read by an external Schroth-trained physical therapist. Data was collected between June 2021 and February 2024.

***Data Analysis:*** The primary outcome was curve progression (6-degree or more increase), stabilization (±5 degrees), or regression (6 degree or more decrease) based on the six-month out-of-brace (OOB) x-ray.[2] Descriptive statistics, Pearson Chi-Square, and analysis of variance were used to look for associations between primary outcome and patient characteristics.

## RESULTS

Demographic characteristics, including age, diagnosis, gender, and baseline Risser can be found in Table 1. In this retrospective chart review, we found that 11.9% of curves progressed, 45.2% stabilized, and 42.9% regressed (Table 2). There was a significant decrease in the mean of the largest curves from baseline (32.1 dgrees±9.3 degrees) to six-months OOB (27.8 degrees±10.0 degrees, p=<.001). The sum of all curves also significantly decreased from baseline (62.0±21.3) to six-months OOB (57.68±22.5, p=.001). There were no significant relationships found between the primary outcome and other variables, such as age at delivery, Risser, largest Cobb angle at baseline, in-brace correction, and Rigo brace type.

**Table 1.** Demographic characteristics for all subjects.

| | |
|---|---|
| **Number of Subjects** | 42 |
| **Age at Fitting** | 11.9 (SD: 1.8) |
| **Scoliosis Diagnosis** | JIS: 5 / AIS: 37 |
| **Baseline Risser** | 0: 20<br>1: 7<br>2: 3<br>3: 7<br>4: 1<br>Not visible: 4 |

**Table 2.** Primary outcomes across all Rigo brace types.

| | **Brace Type Based on Rigo Clasification** | | | | |
|---|---|---|---|---|---|
| Primary Outcome | A | B | C | E | Across all brace types |
| Progression | 1 | 2 | 1 | 1 | 5 (11.9%) |
| Stabilization | 5 | 2 | 8 | 4 | 19 (45.2%) |
| Regression | 2 | 3 | 10 | 3 | 18 (42.9%) |

## DISCUSSION

We found that WCR bracing effectively controls curve progression in patients with IS. Over 40% of subjects achieved out-of-brace correction at the six-month mark, demonstrating that correction can be achieved with scoliosis bracing. About 12% of subjects progressed, which is consistent with previous literature suggesting that a small portion of IS patients have highly aggressive curves.[3] Interestingly, none of the participant characteristics were significantly associated with the primary outcome, evincing that correction is possible in more mature patients. Limitations of this retrospective chart review include the small sample size, lack of adherence monitors to track wear-time, and the use of short-term x-ray data. Future studies should examine long-term outcomes for WCR bracing.

## CONCLUSION

WCR bracing is an effective treatment method for IS. This study sets the foundational groundwork for future long-term studies on WCR bracing efficacy.

## CLINICAL APPLICATIONS

Curve correction appears to be attainable when orthotists take a tri-planar approach to a three-dimensional deformity.

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# Enhancing Scoliosis Brace Comfort: The Key Role of Orthotists

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## INTRODUCTION

While scoliosis bracing is an effective method for controlling curve progression, adherence is often challenging and multifactorial, with both physical and psychosocial components. Since braces must be worn for many hours each day, brace comfort frequently appears in the literature, and superior brace comfort has been suggested to improve brace acceptance. Despite the importance of comfort, it is unclear what factors are associated with brace comfort. Therefore, the purpose of this study was to identify factors associated with brace comfort to better understand the patient experience and improve care.

## METHOD

This cross-sectional survey study was approved by the Baylor College of Medicine Institutional Review Board (H-50560). Parental consent and participant assent were obtained prior to beginning the survey.

***Participants:*** Participants were eligible for the study if they had a scoliosis diagnosis and were currently wearing a scoliosis brace.

***Apparatus:*** The survey included the BSSQ-Brace and questions about demographics, diagnosis, bracing appointments, comfort, and overall experience.

***Procedures:*** The was survey distributed via the Scolios-us website, social media, and email newsletter from January to August 2023.

***Data Analysis:*** Descriptive statistics, Mann-Whitney U tests, and Kendall's tau-b correlations were used to analyze responses.

## RESULTS

Fifty-one subjects with a median age of 13.5 (IQR: 3) participated in the study. Subjects reported that brace comfort/discomfort (41%) is the biggest barrier to brace adherence, followed by extracurricular activities (29%), peer pressure (10%), brace appearance (6%), and bullying (2%) (Figure 1).

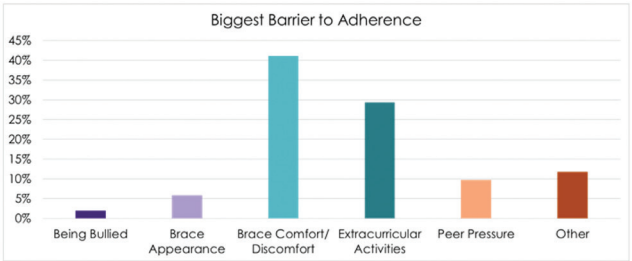


**Figure 1.** Participants selected their biggest barrier to brace adherence.

Orthotist gender emerged as a key factor, with significant positive associations between women orthotists and brace comfort at the fitting appointment (U=159.5, p=.002) (Figure 2), ease of adjusting to the brace (U=192.5, p=.015), and skin integrity (U=190.0, p=.013).

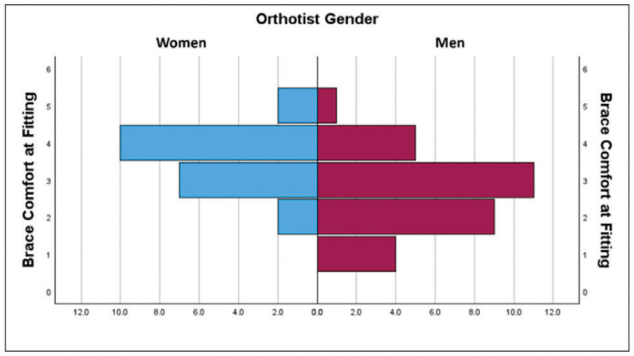


**Figure 2.** Perceived brace comfort at the end of the fitting appointment, with 1 representing "very uncomfortable" and 5 representing "very comfortable."

Brace comfort at fitting was correlated to ease of adjusting to the brace (τb=.420, p<.001). Brace pain at the fitting (U=91.5, p=.014) and current brace pain (U=81.0, p=.046) were negatively associated with BSSQ-Brace scores, while perceived brace appearance and BSSQ-Brace scores were positively correlated (τb=.339, p=.002). The orthotists' understanding of subjects' needs emerged as another key factor, demonstrated by strong correlations with perceived brace fit (τb=.515, p<.001), perceived orthotist skill level (τb=.660, p<.001), and desire to choose the same orthotist again (τb=.571, p<.001). Brace type was not found to be associated with brace comfort, ease of adjusting, or BSSQ-Brace scores.

## DISCUSSION AND CONCLUSION

Brace comfort appears to be linked to the orthotist, not the brace design. Women orthotists are associated with superior brace comfort at the fitting appointment. Since brace pain and poor brace appearance are associated with increased brace-related stress, orthotists should focus on these details during fitting and follow-up appointments. Finally, orthotists should actively listen to and understand patients' needs to improve patients' bracing experience.

## CLINICAL APPLICATIONS

By focusing on brace fit at the fitting appointment, orthotists can improve patients' bracing experience.

# Development of a Psychoeducational Support Group Program for Newly Braced Scoliosis Patients: A Pilot Study

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## INTRODUCTION

Social support and counseling have been suggested to mitigate the psychological impact of scoliosis and bracing and improve treatment adherence. Psychoeducation, a strategic method of providing information, resources, and coping skills, is often used by mental health providers during counseling. A combination of psychoeducation and social support has not been previously studied in the scoliosis population. Therefore, the purpose of this study was to develop a psychoeducational support group program for adolescents receiving a scoliosis brace and to assess the program's feasibility and efficacy.

## METHOD

This pilot study was approved by the Baylor College of Medicine Institutional Review Board (H-51464). Participants were recruited at their initial orthotic evaluation appointment from February to September 2023, at which point informed parental consent and participant assent were obtained.

***Participants:*** Participants were adolescents between the ages of 10 and 17, had an idiopathic scoliosis diagnosis, and were receiving a brace for the first time.

***Apparatus:*** Several outcome measures, including the GAD-7, SRS-22r, BSSQ-Brace, were used to assess participants at brace delivery, before the first psychoeducational session, and after the fourth session. Adherence monitors were used but have been excluded from data analysis due to unreliable readings. The study protocol is outlined in Figure 1.

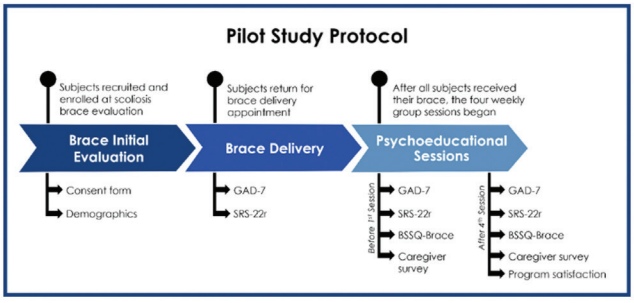


**Figure 1.** Study protocol. Abbreviations: GAD-7=General Anxiety Disorder-7; SRS-22r=Scoliosis Research Society Score-22 revised; BSSQ-Brace=Bad Sobernheim Stress Questionnaire – Brace.

***Procedures:*** A series of four online group-based psycho-educational sessions was conducted with three cohorts of participants. Topics covered included building community, fostering a strong sense of self, managing emotions, and coping with stress. The sessions were led by doctoral clinical psychology students who were supervised by a clinical psychologist.

***Data Analysis:*** Descriptive statistics, Friedman's test, and Wilcoxon signed-rank test were used to analyze responses.

## RESULTS

Ten participants completed the program. One was excluded from data analysis due to incomplete survey responses. Median age of participants was 11 (IQR: 2), and 8 were female. Group size ranged from 3 to 4 participants. Survey responses from all three data collection time points were compared using Friedman's test, and no significant differences were found. Eight participants found the sessions to be helpful or very helpful, and 8 reported that participating in a program like this is important or very important for someone new to bracing. Eight participants reported that they plan to use the strategies they learned to adhere to their prescribed brace treatment, and 8 were confident in their ability to make these changes.

Nine female parents completed the caregiver survey before the first and after the fourth session. One mother also had a scoliosis diagnosis. Although the decrease did not achieve statistical significance, absolute levels of parental perception of child stress were lower following the sessions ($z=-1.77$, $p=.077$), as were perceptions of brace-related emotional outbursts ($z=-1.63$, $p=.102$). Brace-related parental stress also trended downward ($z=-1.41$, $p=.157$). All parents reported that they would recommend a program like this to a parent of a newly braced child.

## DISCUSSION

This innovative psychoeducational support group program was well-received by the participating adolescents and their parents. Participants found the program helpful and reported confidence in their ability to adhere to treatment. Limitations of this pilot study include the small sample size, which led to small cohort sizes, and the lack of adherence data.

## CONCLUSION

Psychoeducational support group programs show potential in helping adolescent scoliosis patients cope with their diagnosis and accept their brace.

## CLINICAL APPLICATIONS

Supporting adolescent scoliosis patients is a challenging but important task for clinicians. Psychoeducational support group programs are another tool clinicians can use to help patients feel emotionally supported.

# Restoration of Sensory Feedback and Proprioception Following Hand Amputation with Targeted Sensory Reinnervation

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## INTRODUCTION

The loss of a hand can dramatically impact one's personal and professional quality of life. Currently, myoelectric prostheses can restore many of the prehensile functions of the hand. Sensory feedback represents the one major challenge of restoring one's true sense of self. Based on our successful experience with targeted sensory reinnervation (TSR) surgery on the lower limb, we have further developed the technique to the upper limb. The application to the lower limb has shown to be successful in reducing phantom limb pain (PLP) by restoring sensory feedback to the residual limb. The indications for TSR are primarily PLP and neuropathic pain that cannot be controlled by conservative therapy or, in the case of elective amputation, its prevention.

## METHOD

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the ethics committees in Austria and Italy (no. M2022-24 and no. 50-2022). Written informed consent was obtained from all subjects involved in the study. Between October 2020 and March 2024, we performed TSR in eight patients with a total of nine TSRs (one patient was bilateral). The TSR technique involves neurorrhaphy of the median and ulnar nerves with the lateral and medial cutaneous antebrachia nerves to reinnervate the skin of the residual limb at the forearm. Follow up was carried out regularly after the operation. Clinical examination included percussion of the forearm and identification of moving Hoffmann Tinel sign. Sensory qualities as pressure and temperature capacity were assessed by touching the forearm skin and with hot (at 38 degrees) and cold (frozen) square packs. After the reinnervation reached the forearm skin and showed a clear somatotopy of the thumb and fingers,[2–4] the patients were fitted with a vibrotactile stimulation system. This was implemented in the existing socket prosthesis. In addition, electroencephalography (EEG) and nerve conduction studies (NCS) were performed. All patients underwent a rigorous rehabilitation program.

## RESULTS

There was no PLP in the electively and acute patients with upper-limb amputation. For the patient who underwent secondary TSR, the pain decreased significantly or disappeared completely. In all patients, a phantom limb map of all five fingers at the level of the residual limb could be regularly visualized. In addition, the patients can distinguish between hot and cold. Somatosensory evoked potentials in EEG and sensory nerve action potentials in NCS could be derived as a clear reinnervation sign.

## DISCUSSION

We describe a new technique for targeted sensory reinnervation to restore genuine sensitivity in people with amputations. With traditional methods such as targeted muscle reinnervation, this genuine restoration is missing or significantly reduced. TSR involves denervating a specific area of the forearm skin and reinnervating it with hand sensory nerves, leading to precise, somatotopic reinnervation. The technique avoids the use of implantable devices, enhancing biosafety and effectiveness. Initial results are promising, with patients reporting significant pain reduction and natural limb sensation.

## CONCLUSION

Targeted end-to-end redirection of sensory palmar nerves of the hand to sensory forearm nerves restores the sensory hand map and preserves the proprioception of each individual finger of the lost hand in people with transradial amputations. This procedure, in combination with an external non-invasive feedback system, which is connected to the tactile sensors of the hand prosthesis, facilitates the transfer of haptic sensations to a spatially separated reinnervated skin area. This mechano-neural interface thus enables the perception of genuine functional sensitivity to restore tactile gnosis, and it can effectively treat PLP.

## CLINICAL APPLICATIONS

When the TSR is performed at the time of trauma or elective amputation, phantom pain is suppressed by this event-triggered feedback. Additionally, the impact of sensory feedback enhances the acceptance of a prosthetic hand due to the embodiment effect.

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# A Preliminary Comparison Between Glide and Dual-Site Control for Proportional Myoelectric Output

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## INTRODUCTION

Proportional control of upper-limb myoelectric prostheses is an important feature required for functional use of the prosthesis.[1] Traditional control allows for precise proportional output but is limited by its inability to easily accommodate multiple degrees-of-freedom (DOFs). In this work, we aim to investigate the proportional output capabilities of Glide, an advanced control algorithm designed for multi-DOF control,[2] compared to traditional dual-site control.

## METHOD

The Johns Hopkins University Institutional Review Board approved this study, and informed consent was obtained from the participant prior to participation.

***Participants:*** A naïve, male participant with intact limbs took part in this preliminary study.

***Apparatus:*** Electromyogram (EMG) data was collected using two systems: Glide and dual-site control.

The Glide system (Infinite Biomedical Technologies, LLC, Baltimore, MD) consisted of an armband of eight surface EMG electrodes placed equidistant around the forearm of the dominant arm along the cross section of greatest muscle mass. The armband interfaced with a Glide controller and configured such activation of the flexors and extensors activated hand close and open, respectively. By exceeding a rate-based threshold, the participant could access wrist pronation and supination. Proportional outputs were accessed wirelessly via the Glide controller's Bluetooth API.

The dual-site control system consisted of two surface EMG electrodes (Ottobock, Duderstadt, Germany) placed over the flexor carpus radialis and extensor carpi ulnaris of the dominant arm. Electrodes were connected to an MC ProWrist Rotator (Fillauer, LLC, Chattanooga, TN), which employed a rate-switching method to alternate between hand and wrist DOFs. Proportional outputs were normalized to match the range of the Glide system.

***Procedures***: The participant was asked to complete a series of Fitts' Law Tests (FLTs) to assess their proportional control with each system.[3] Each FLT required the participant to modify the size and orientation of a virtual cursor to match a target configuration, with hand outputs modifying the cursor size and wrist outputs modifying its orientation. For a FLT to be successful, the participant must achieve the target configuration (within a tolerance, ε) and maintain the target for 0.5 second within the time limit of 15 seconds.

For a single control strategy, the participant was first presented with 28 practice target configurations (ε=0.25). Afterward, the participant was presented with three blocks of 40 target configurations each for evaluation. Blocks progressed in difficulty with the following tolerances: easy (ε=0.20), medium (ε=0.10), and difficult (ε=0.05). The participant completed the proportional control evaluation once with each system.

***Data Analysis:*** Python 3.6.8 (Python Software Foundation, Wilmington, DE) was used to interface with the commercial control systems. Statistical significance was calculated using the two-sample two-sided t-test for between-group comparisons.

## RESULTS

The participant demonstrated nearly identical task completion rates at each difficulty level for both control strategies. While the difference in completion time at both the easy and medium difficulty levels was statistically insignificant, the participant did complete difficult FLTs marginally more quickly using the Glide control system ($p<0.05$).

**Table 1.** Participant performance on the FLTs using Glide (white) and dual-site control (grey).

| | ε=0.20 | ε=0.10 | ε=0.05 |
|---|---|---|---|
| Completion Rate | 100.00% | 97.50% | 95.00% |
| | 100.00% | 95.00% | 95.00% |
| Completion Time | 3.33±1.68 s | 5.14±2.89 s | 6.76± 2.99 s |
| | 3.48±1.91 s | 4.47±2.40 s | 8.41± 3.21 s |

## DISCUSSION

These preliminary results suggest a parity between Glide and traditional dual-site control in terms of proportional output. While the results are promising, future studies including individuals with upper-limb loss are required.

## CONCLUSION

While supporting scalable, multi-DOF control, the Glide system additionally facilitates proportional myoelectric control on par with traditional dual-site alternatives.

## CLINICAL APPLICATIONS

This work provides preliminary data that demonstrates that the Glide system can provide users with industry-equivalent proportional control across multiple DOFs.

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# Interfacing Innovation: The Role of Compatibility in an Upper-Limb Myoelectric Prosthesis

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## INTRODUCTION

Commercial myoelectric prostheses have been available since the 1960s, but the last 15 years have demonstrated large growth in options and functionality available. For an upper-limb myoelectric prosthesis to be successful in meeting the needs of an individual with limb loss or limb difference, there needs to be seamless integration between all the prosthetic parts used. Reviews have been performed on the clinical usability of the vast number of individual terminal device, wrist, and elbow components, but none of them discuss the interoperability requirements when multiple components are used in conjunction in a prosthetic arm. The purpose of this study was to investigate design considerations for compatibility between the various parts of the prosthesis and its impact on clinical decision-making.

## METHOD

A review was performed on commercially available parts for upper-limb myoelectric prostheses. Instruction for use manuals, technical datasheets, and compatibility application programming interfaces (APIs) were studied to determine the specifications of components and their interfacing requirements.

## RESULTS

***Componentry Review:*** There are more than 3,000 permutations of myoelectric prosthetic terminal devices, wrists, and elbows to be reviewed for compatibility.

***Parts of a Prosthesis:*** Components used in an upper-limb myoelectric prosthesis can be broadly categorized into prosthetic control systems, inputs to the control system, power sources, and prosthetic components (terminal devices, wrists, and elbows, including connection points).

***Compatibility Requirements:*** Each successively proximal component is responsible for mechanical and electrical compatibility with distal components. Mechanical compatibility includes component-dependent cabling and connections and mechanical design that fits within the existing fabrication processes. Electrical compatibility comprises of support of various operating voltages and currents for inputs and outputs.

***Control Systems:*** The largest burden for compatibility falls on the prosthetic control system—the most proximal component. Primarily, the control system manages reading, processing, and determining user intent from the inputs; activating and pausing the correct terminal device, wrist, or elbow movement based on the determined user intent; and converting user intent into speed-based proportional control of the prosthesis.

***Integration Design:*** The prosthetic control system typically interfaces with other parts of the prosthesis through wired connections. Through the wired connection, a variety of signals can be sent to the prosthetic components to move them. These control signals are specified within the design of the prosthetic component itself and can take various forms, such as motor control (0 – battery voltage, typically 7.4V), analog control (0–5 V analog signal), analog trigger control (timed patterns of 0–5 V analog signals), and digital control, which uses a communication protocol such as I2C, UART, or CAN. Most components use a unique protocol or combination of the abovementioned input signals. Each component connects to the prosthesis over a variety of connections. There are a minimum of 14 connection combinations needed to accommodate all permutations.

## DISCUSSION

Ensuring compatibility within a myoelectric upper-limb prosthesis requires a multifaceted approach. It presents an extremely complex conundrum for manufacturers of control systems, who must find a way to control any combination of these devices while maintaining the functional, mechanical, and electrical compatibility between all systems. Complexity of compatibility is a challenge, and developing uniformity in specifications during prosthetic component design as well as early-stage collaborations between manufacturers to standardize APIs and testing protocols can significantly reduce the same.

The complexity of compatibility between components also provides a significant barrier to prosthetists fitting patients with myoelectric prostheses, especially those who are less familiar with upper-limb care. The complexity around compatibility can delay fitting or decrease functionality due to mismatched components, non-optimized settings, and incorrect connections. Clinicians may be less likely to try new technologies if they do not understand the intricacies and are unfamiliar with the parts. Additionally, the time required to ensure compatibility between components can increase the time to market of new technologies, slowing down innovation that would provide additional function and options to patients.

## CONCLUSION

Compatibility between prosthetic parts is essential for the optimal function of a prosthesis and improved user experience. Lack of universal specifications in integration design makes interoperability challenging. This is mitigated through extensive testing and increased collaborations within the industry.

## CLINICAL APPLICATIONS

Understanding compatibility between different prosthetic parts can guide practitioners in choosing parts that optimize the functioning of the prosthesis for the patient's needs.

# Setting the Stage for the Elimination of Phantom Limb Pain Following Upper-Limb Amputation: A Case Study

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## INTRODUCTION

The impact of losing one or both arms cannot be overstated. The hand functions in prehensile activities as a sensory organ and as a means of communication. Any loss interferes with an individual's productivity and feeling of completeness, as well as altering that person's interaction with the environment.[1] The hand plays a significant role in the creative life of every known society. It has come to be symbolic of the whole person in art, drama, and dance.[2]

What is the impact of a brachial plexus injury to a young male adult who is a world-class, aspiring snowboarding and skateboarding athlete who chooses amputation of the hand? This case study will capture a new surgical procedure that promises to be a game-changer in the treatment of neuropathic and phantom limb pain for people with upper- and lower-limb amputations. The procedure also offers the opportunity to restore genuine sensitivity for upper-limb amputees. The aim of presenting this case report is to provide an overview of this innovative procedure, targeted sensory reinnervation (TSR). This groundbreaking procedure will be described, and the subsequent impact it has made on a gifted athlete will be demonstrated.

## CASE PRESENTATION

In 2009, at the age of 17, this Italian male was involved in a motorbike accident. This resulted in a brachial plexus lesion on the right side. An attempted reconstruction of C5 and C6 followed with sural nerve interposition. His brachial plexus injury resulted in partial return of his shoulder and elbow musculature, but no active return at his wrist or hand. Prior to his accident, athletics dominated his life, as he actively competed in football, soccer, basketball, motorbiking, snowboarding, skateboarding and BMX biking. Following his brachial plexus injury, and despite his flaccid wrist and hand, he pursued a passion of swimming and trained daily with two of Italy's best competitive swimmers. He competitively swam while simultaneously pursuing his love of snowboarding. Soon he was offered an opportunity to join the Italian national Paralympic Snowboard team. Despite a non-functioning wrist and hand, and ongoing unrelenting pain, he competed in the Paralympics in Beijing.

Although his pain was rated on a scale of 8–10/10, because he was a Paralympic athlete, he was forbidden to use any medications to treat his ongoing pain. Few non-medication interventions were effective, other than his desire to compete and distract himself from the nonstop, "tortuous" "pain.

## MANAGEMENT AND OUTCOME

Following 14 years of living with his partially paralyzed arm and hand, and ongoing pain, in August of 2023, he was offered an opportunity to be the sixth TSR patient of Alexander Gardetto, MD, from Brixen, Italy. At age 31, this gentleman agreed to an elective amputation of his right hand 7 cm proximal to his wrist. The TSR procedure was performed. This involves targeted end-to-end redirection of sensory palmar nerves of the hand to sensory forearm nerves, resulting in the restoration of a "sensory hand map" of the hand. This procedure preserves the proprioception of each individual finger of the amputated hand. He was fit with a transradial myoelectric prosthesis with a multiarticulating hand. He was trained in its use and wears it daily. He is pain free, totally independent, and is very happy with his myoelectric hand. Additionally, and perhaps most impressively, he won first place for the Italian team at the 2024 Paralympics Snowboard Cross event in Canada.

## DISCUSSION

This case study presents a new, innovative and remarkably impressive surgical technique to manage the complex challenge of neuropathic and phantom limb pain. Only ten TSR procedures have been performed to date on the upper limb, and its impact on the complete, or almost complete, elimination of pain is potentially game-changing for this population. The functional and quality of life impact of this procedure will be discussed. Additionally, with a "sensory hand map" and proprioception of each finger being preserved, the opportunities for sensory feedback in an electric hand are currently being explored.

## CONCLUSION

This case study will introduce a surgical and prosthetic team approach in addressing two of the most challenging dilemmas for those with upper-limb amputation. The almost complete elimination of phantom limb pain and the opportunity to restore sensation to the upper limb will be previewed in the remarkable outcome of this uniquely gifted young man.

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