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50th Academy Annual Meeting & Scientific Symposium
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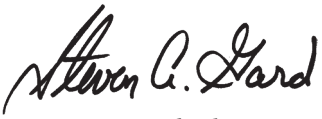
Greetings, friends and colleagues!

I am pleased to help welcome you to Chicago for the 50th Academy Annual Meeting & Scientific Symposium! Please note that special congratulations and recognition are in order for the Academy this year, which is celebrating its 50th annual conference on clinical practice, education, and research for the O&P profession. What a fantastic achievement! Many of you are long-time members who are well aware of the high-quality, stimulating offerings that you can anticipate at this meeting. For some of you, this may be your first time attending the Academy Annual Meeting, and I can confidently predict that you are in for a treat! The Clinical Content Committee is to be commended once again for putting together an outstanding program that will serve to educate and challenge you in your thinking while providing you with knowledge and information that can be applied in your practice.

This *Journal of Proceedings* is invaluable whether you are planning to attend the conference or not. If you participate in the conference, then you can review some of your favorite presentations, read about the presentation content in greater detail, or even learn about presentations you might have missed attending. If you are unable to participate in the meeting, 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 a clinical or research article. Finally, this *Journal of Proceedings* will be searchable online, so it will be easy to find presentations on specific topics from one year to the next.

I sincerely hope you enjoy the Academy Annual Meeting, this *Journal of Proceedings,* and your time in Chicago!



Steven A. Gard, PhD
Editor-in-Chief
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50th Academy Annual Meeting & Scientific Symposium
Journal of Proceedings

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

As we celebrate the 50th Annual Meeting & Scientific Symposium of the American Academy of Orthotists and Prosthetists, it is a time to reflect on the success and growth of the event and a time to look forward to the future of both the Annual Meeting and the O&P profession.

It is my great pleasure to introduce the *Journal of the Proceedings.* This edition exemplifies how the *Journal of Prosthetics and Orthotics* continues to deliver timely and useful evidence to clinicians and researchers. As evidenced by the increasing number of submissions for presentations and posters, the Academy Annual Meeting & Scientific Symposium continues to grow and evolve along with clinical consensus and the state of the science.

Reflecting upon the five years of Academy Annual Meetings for which I've had the pleasure to serve as Chair of the Clinical Content Committee, the content and format of the meeting have become much more approachable, interactive, and centered on delivering insights to apply in daily practice. This point is underscored by the record number of clinical case studies accepted as Free Paper Presentations and the Hands-On and Organized Sessions that address contemporary clinical topics.In welcoming new members to the Clinical Content Committee, I also look forward to seeing how the Academy Annual Meeting will advance into the future. While it is difficult to predict how the O&P profession will look 50 years from now, I am confident that the Academy Annual Meeting will continue to play a pivotal role in shaping that future.

I would like to thank the dedicated Academy staff, Clinical Content Committee volunteers, and attendee contributors. The continual impact of the Annual Meeting is due to your passion and efforts.

Sincerely,

Brian Kaluf

Brian Kaluf, BSE, CP, FAAOP
50th Academy Annual Meeting & Scientific Symposium
Chair, Clinical Content Committee

Time to Successful Outcome versus Treatment Duration in Cranial Remolding Orthosis Treatment

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INTRODUCTION

Families looking to initiate cranial remolding orthosis (CRO) treatment for their infant's plagiocephaly often ask how long treatment will take. Typical CRO treatment durations are well-documented.[1-3] Treatment duration is defined as the time between fitting of the CRO and the last follow-up appointment.[1–3] However, treatment duration is not a direct measurement of the time necessary to achieve a successful outcome; it is often influenced by factors unrelated to clinical presentation. The time necessary to achieve a successful outcome has not been reported previously. Thus, there is limited evidence available to predict the treatment time necessary to reach a success outcome. This study aimed to determine the time it took to achieve a successful outcome, based on an infant's initial presentation, and compare it to the treatment duration in infants with deformational plagiocephaly.

METHOD

Participants: This retrospective study included 300 infants with deformational plagiocephaly who were fit with the Michigan Cranial Reshaping Orthosis by Danmar, at the University of Michigan Orthotics & Prosthetics Center. This study was approved by the Institutional Review Board of the University of Michigan.

Apparatus: Medical records were reviewed, and data were extracted.

Procedures: Infants were categorized into four groups based on corrected age at initiation of CRO treatment (<22 weeks, 22–25 weeks, 26–30 weeks, and >30 weeks) and into four groups based on severity of deformity (initial cranial vault asymmetry (CVA) of 6–9 mm, 10–12 mm, 13–16 mm, and 17+ mm). A successful outcome was defined as achieving a final cranial vault asymmetry of 5 mm or less. Time to successful outcome was defined as the time between CRO fitting and the first CVA measurement of 5 mm or less. Time to successful outcome and treatment duration were compared within and between the groups.

Data Analysis: SAS 9.4 was used to perform statistical analysis.

RESULTS

Both the time to successful outcome and the treatment duration depended on severity of the deformity but not on age at initiation of treatment. The median time to successful outcome ranged from 6 weeks to 17.5 weeks, depending on the severity of the deformity. Time to successful outcome was significantly shorter than treatment duration for infants in all severity groups except for the most severe group (initial CVA of 17+ mm) (Figure 1).

DISCUSSION

Treatment durations are likely longer than time to successful outcome partially because discharge decisions consider a variety of factors in addition to the achievement of a CVA of ≤5 mm. Even so, this study calls into question the length of current treatment durations for infants with moderate plagiocephaly, as they were significantly longer than the time necessary to achieve a successful outcome. Future studies measuring CVA on a weekly basis would provide a more precise time to successful outcome than the present study, which only measured every 6 weeks, and may find even shorter times to successful outcome.

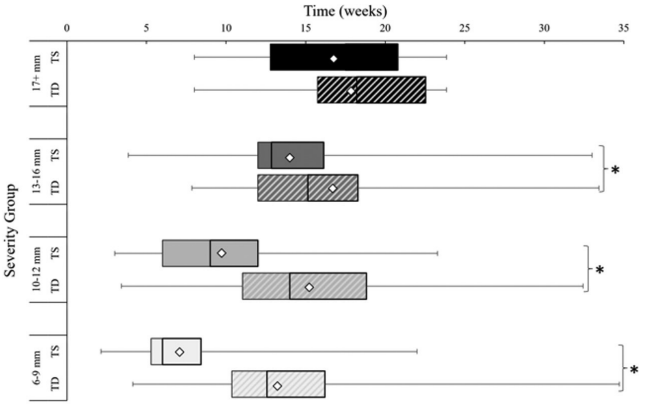

Figure 1. Time to successful outcome (TS) (final CVA ≤ 5 mm) versus treatment duration (TD) for initial severity groups. * Statistically significant difference ($p < .05$).

CONCLUSION

The time to successful outcome for CRO treatment varies significantly depending on severity of the deformity but not corrected age at initiation of treatment. Estimated treatment timelines should be formulated based on an infant's initial severity.

CLINICAL APPLICATIONS

This study provides orthotists with quantitative data on the time necessary to achieve a successful outcome depending on an infant's initial presentation to aid in setting appropriate expectations for treatment duration.

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Funded by the University of Michigan Orthotics and Prosthetics Center.

Setting Expectations for Cranial Remolding Orthosis Treatment Based on Changing Rates of Cranial Vault Asymmetry

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INTRODUCTION

Cranial remolding orthoses (CRO) are an effective treatment for deformational plagiocephaly in infants. Orthotists know from experience that cranial asymmetry corrects most rapidly during the early weeks of cranial remolding orthosis treatment. However, the decrease cranial asymmetry correction over time in treatment has not been well studied. Previous studies have compared overall rates of correction during treatment based on the initial severity of the deformity or age at initiation of CRO treatment.[1–3] However, few have considered the variation in the rate of correction during the course of treatment.[1] Thus, there is limited understanding of the period of time in which the CRO is causing meaningful correction to the cranial asymmetry. This study aimed to determine if there is a time during CRO treatment at which the rate of cranial vault asymmetry (CVA) correction slows enough that it becomes insignificant.

METHOD

Participants: This retrospective study included 300 infants with deformational plagiocephaly who were fit at the University of Michigan Orthotics & Prosthetics Center with the Michigan Cranial Reshaping Orthosis by Danmar. This study was approved by the Institutional Review Board of the University of Michigan.

Apparatus: Medical records were reviewed, and data were extracted.

Procedures: Infants were categorized into four groups based on corrected age at initiation of CRO treatment (<22 weeks, 22–25 weeks, 26–30 weeks, and >30 weeks) and into four groups based on the severity of deformity (initial cranial vault asymmetry (CVA) of 6–9 mm, 10–12 mm, 13–16 mm, and 17+ mm). A piecewise linear mixed model was used to access changes in rates of correction during treatment for the entire cohort and for each of the groups.

Data Analysis: SAS 9.4 was used to perform statistical analysis.

RESULTS

Rates of correction decreased with time in the CRO. The rate of correction of cranial vault asymmetry was most rapid in the first 11.8 weeks of treatment. After 11.8 weeks, the rate of correction slowed enough that it was no longer statistically significant (Figure 1). The variation in the rate of correction was dependent on the initial severity, but not on corrected age at initiation.

DISCUSSION

Our study differs from previous studies in that it analyzed how the rate of correction varied as treatment progressed, identifying a clear change in rates of correction at 11.8 weeks. CVA correction still occurred after 11.8 weeks of treatment but at a rate that was statistically insignificant. This supports Dorage et al.'s finding that the amount of asymmetry correction was significant in the first 75 days (approximately 11 weeks) but insignificant in the following 75–150 days of treatment.[1]

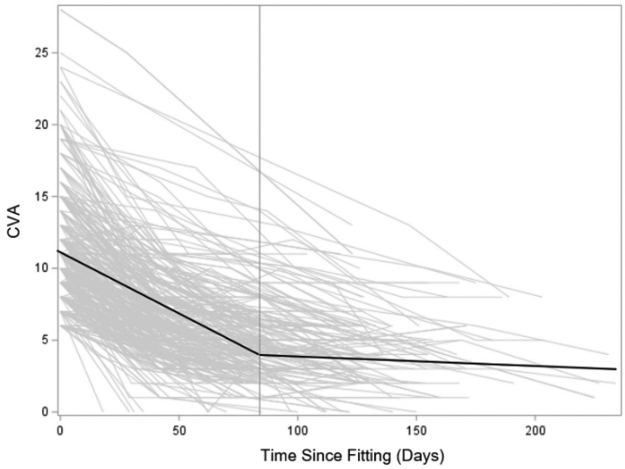

Figure 1. Piecewise mixed model of CVA correction throughout CRO treatment. Knot at 84 days since fitting indicates two distinct periods of correction.

CONCLUSION

The period of greatest CVA correction is in the first 12 weeks of treatment. After this time, the asymmetry continues to correct, but at a significantly slower rate.

CLINICAL APPLICATIONS

This study provides orthotists with quantitative data on the decreasing rates of CVA correction during CRO treatment that can aid in setting families' expectations about the significant greater time investment that may be required to achieve continued correction when extending treatment beyond 12 weeks.

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Funded by the University of Michigan Orthotics and Prosthetics Center.

A Pilot Examination of 3-Dimesional Changes While Repositioning Infants from 2–4 Months of Age

T. Graham, V. Moses, J. Wang, S. Briggs, O. Sheffer, A. Payne, L. Pauline, T. Lam, A. Blasingim, C. Holley, T. Marlow, R. Hallac

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INTRODUCTION

Repositioning therapy (RT) is often recommended for infants with deformational head shapes.[1] Most methods used to track cranial shape involve 2D measurements; however, very few studies have examined 3D changes.[2] This pilot study examines 3D morphometric changes in infants in RT from 2–4 months of age.

METHOD

This pilot study was approved by the UT Southwestern Institutional Review Board, and caregivers consented to subject participation.

Participants: Ten infants (7 male, 3 female) from 2 to 4 months of age who underwent RT.

Apparatus: Caregivers were instructed on RT, and infants received physical therapy if torticollis was noted.

Procedures: Infants were photographed with the 3dMD system at 2 and 4 months of age. Caregivers were asked if their infant's head was in the recommended position when laid down for sleep. Those who answered "often" or "always" were considered compliant. Custom MATLAB software was used to analyze growth using a symmetric 3D model, defined by 65 landmarks. Through a two-step deformation process involving thin-plate-splines and closest-point deformation, the model was tailored to each subject's head, facilitating exact point correspondence. Color maps were generated to illustrate the spatial variations in asymmetry or growth (Figure 1).

Data Analysis (asymmetry): 3D images were divided into left and right anterior and posterior quadrants. The net percent change in asymmetry = 100*[(net growth in bossed quadrants) – (net growth in flattened quadrants)] ÷ (net growth in the bossed quadrants).

Data Analysis (proportion): The anterior, posterior, left, and right quadrants were segmented by vertical planes drawn 45 degrees from the midsagittal line. The net percent change in length growth = 100*[(net growth in anterior + posterior quadrants) – (net growth in left + right quadrants)] ÷ (net anterior + posterior growth).

RESULTS

Individual results of RT varied as shown in Figure 2. The mean net percent improvement in asymmetry was 12.8% (n = 5) and worsening was -17.7% (n = 4). The mean net proportional improvement was 15.9% (n = 4) and worsening was -13.9% (n = 2).

Figure 1. Example of overlaid scans (a) and morphometric growth heat map (b) during RT efforts.

DISCUSSION

RT has had variable reported results[3,4] based on 2D measurements and is most effective before 4 months of age.[1,4] Risk factors for failed RT include poor compliance, torticollis, and higher initial deformation.[3] Of the 5 who failed RT in this study, these factors were present in n = 0, 4, and 3 infants, respectively. All caregivers were given written and verbal RT instructions based on the infant's head shape. RT results did not correlate to the examined definition of compliance in this pilot study. A larger study should examine this and compare 3D to 2D analyses.

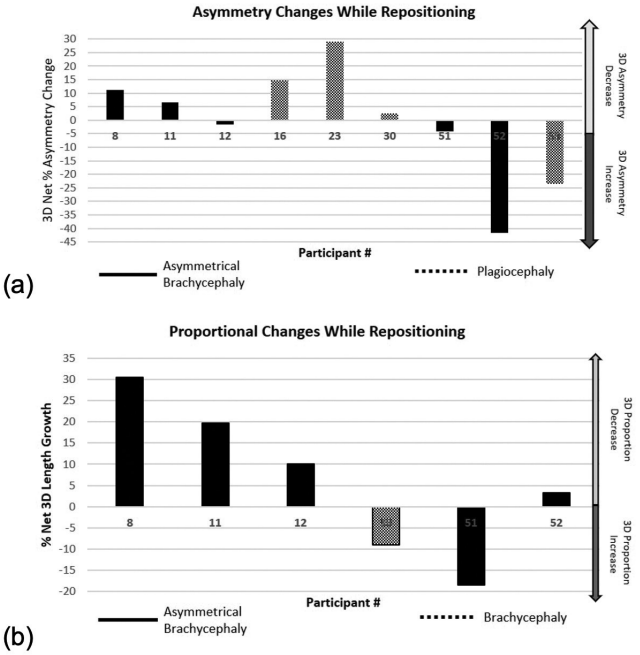

Figure 2. 3-dimensional net changes in asymmetry (a) and proportion (b) during RT for each participant.

CONCLUSION

RT reduced cranial deformation in the majority of participants; however, a few worsened.

CLINICAL APPLICATIONS

3D analysis may be useful for assessing RT outcomes when paired with clinical assessments.

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Funded by an American Orthotic and Prosthetic Association research award administered by the Center for Orthotics and Prosthetics Learning and Outcomes/Evidence-Based Practice.

Three Dimensional Changes in Deformational Head Shapes

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INTRODUCTION

Some evidence exists that cranial remolding orthoses (CROs) correct cranial deformation faster than repositioning therapy (RT),[1] but few studies have compared treatments in three dimensions.[2] This study compares 3D cranial growth during consecutive RT, CRO use, and natural growth post-correction (NPC).

METHOD

This study was approved by the UT Southwestern Institutional Review Board, and caregivers consented to subject participation.

Participants: Sixteen infants with deformational head shapes. Five (2M/3F) had plagiocephaly (DP), 9 (5M/4F) had asymmetrical brachycephaly (DAB), and 2 (M) had brachycephaly (DB).

Apparatus: Infants began RT at 2 months of age, switched to CRO between 4–6 months of age, and were treated a with CRO until the head shape normalized.

Procedures: The 3dMD system was used to measure infants at 2 and 12 months of age, when they switched to a CRO, and at the time of cranial correction. Custom MATLAB software was used to analyze growth using a symmetric 3D model, defined by 65 landmarks. Through a two-step deformation process involving thin-plate-splines and closest-point deformation, the model was tailored to each subject's head, facilitating exact point correspondence.

Data Analysis: For asymmetry change, 3D images were divided into left and right anterior and posterior quadrants. The net percent change in asymmetry = 100*[(net growth in bossed quadrants) – (net growth in flattened quadrants)] ÷ (net growth in the bossed quadrants).

For proportional change, the anterior, posterior, left, and right quadrants were segmented by vertical planes drawn 45 degrees from the midsagittal line. The net percent change in length growth = 100*[(net growth in anterior + posterior quadrants) – (net growth in left + right quadrants)] ÷ (net anterior + posterior growth).

Monthly 3D change was the net change divided by the months in that type of treatment. Groups were compared using a non-parametric mixed model with Tukey's method for multiple comparison.

RESULTS

When examining mean monthly rate of change (Table 1, Figure 1), overall treatment methods' asymmetry changes were significantly different for DP and DAB ($p = 0.035$, $p = 0.041$). Pairwise significance was nearly found for asymmetry change for CRO versus NPC and CRO versus RT; significance was found for DAB in CRO versus NPC.

DISCUSSION

Participants were being actively treated for asymmetry or proportion showed greater mean monthly improvement with a CRO than with RT despite circumferential growth rate decreasing. Proportional improvement seems to occur in NPC. Further analysis should be done to determine clinically significant 3D changes, as clinical differences between groups may exist.

CONCLUSION

In this pilot 3D analysis, CROs generally resulted in a faster monthly active correction rate than RT during consecutive treatment. In NPC, asymmetry minimally changed or worsened while proportion improved.

Table 1. Mean monthly 3D net percent growth changes.

		Mean Monthly Changes in Cranial Shape					
Deformation Type	**Type of 3D Change**	**RT**		**CRO**		**NPC**	
		%	**n**	**%**	**n**	**%**	**n**
Plagiocephaly	Asymmetry	1.94	5	6.31	5	0.90	4
	Proportion	2.32		4.00		7.87	
Asymmetrical Brachycephaly	Asymmetry	2.55	12	5.90	8	-3.83	7
	Proportion	5.38		9.19		11.45	
Brachycephaly	Asymmetry	2.64	2	2.55	2	-3.39	1
	Proportion	-10.02		4.82		18.12	

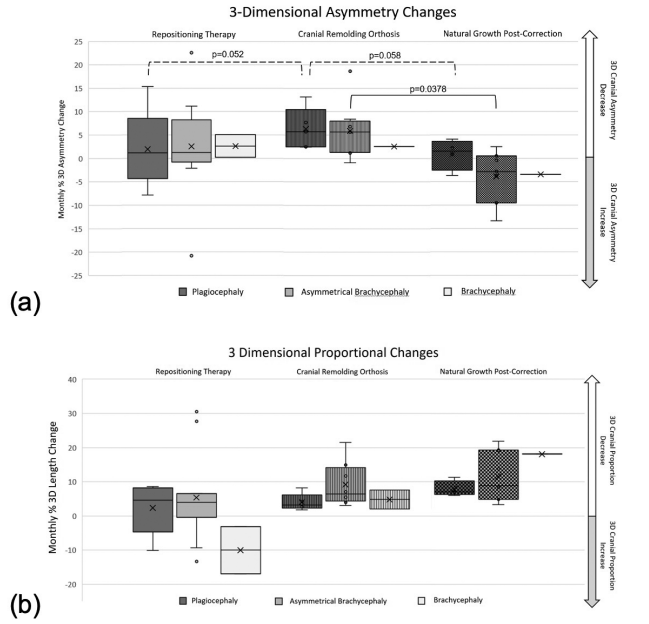

Figure 1. Three-dimensional monthly net percent changes in (a) asymmetry and (b) proportion for each treatment group.

CLINICAL APPLICATIONS

CROs may more effectively change cranial shape than RT. Proportion will likely improve post CRO treatment.

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Funded by an American Orthotic and Prosthetic Association research award administered by the Center for Orthotics and Prosthetics Learning and Outcomes/Evidence-Based Practice.

Health Screenings and Prosthetist Impact on Care-Seeking Behaviors

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INTRODUCTION

Adults in the general population do not routinely receive clinical screens for life-limiting comorbidities, which leads to under-diagnosis and under-treatment.[1] The prosthetist may be an underutilized member of the health care team, as ~85% of adults receive prosthetic care after amputation.[2] Sound-limb assessment by the prosthetist, coupled with communication of screening findings to the patient and the patient's care provider, may reduce undesirable outcomes post amputation; for example, wounds or subsequent amputation. In the general population, comorbidity screening coupled with patient education positively influence care-seeking behaviors.[3] This study sought to explore health-seeking behaviors following prosthetist screening and referral for peripheral arterial disease (PAD) and peripheral neuropathy (PN).

METHOD

As part of this clinical trial of 70 adults seeking prosthetic follow-up care at least 1-year post-amputation, 35 individuals were randomized to receive prosthetist screening for PAD and PN in addition to standard care. All participants provided written informed consent, and the project received ethical approval (Institutional Review Board #1865677).

Participants: The 35 participants randomized to this study arm were, on average, 61.5±12.2 years-old; 74.3% were male, 77.1% were white, 71.4% had a transtibial amputation, and 60.0% had experienced an amputation due to dysvascularity.

Apparatus: Participants completed a standardized medical history checklist and underwent pedal pulse palpation to evaluate for PAD and Semmes-Weinstein monofilament testing to evaluate for PN.

Procedures: The participant's prosthetist discussed the results of the screenings for PAD and PN with each patient, and a letter communicating results was faxed to the patient's primary care physician. A standardized checklist regarding health professionals seen since the onsite prosthetic visit was completed 3 months later.

Data Analysis: Descriptive statistics were used to assess prevalence of self-reported PAD and PN compared to clinical assessment and to explore care-seeking behaviors between the visit and the remote follow-up.

RESULTS

Twelve participants (34%) lacked ≥1 palpable pulse. Of these, only 3 (25%) reported a history of PAD, but 6 (50%) reported being told they had "poor blood flow to their feet." Fourteen participants (40%) lacked protective sensation at ≥1 test site, of whom only 1 (7%) reported a history of PN and 5 (36%) reported being told they had "nerve damage to their feet" (Figure 1).

In the 3 months following prosthetist assessment, 9 of 12 individuals with suspected PAD (75%) followed recommendations for follow-up care (Figure 2a). Of the 14 individuals with suspected PN, 9 participants (64%) sought care from a specialist (Figure 2b).

DISCUSSION

Accuracy of self-reported medical history for both PAD and PN improved when non-medical terms were used (e.g., "poor blood flow" versus PAD), suggesting that the use of common vernacular is crucial for improved accuracy of self-reporting of PAD and PN.

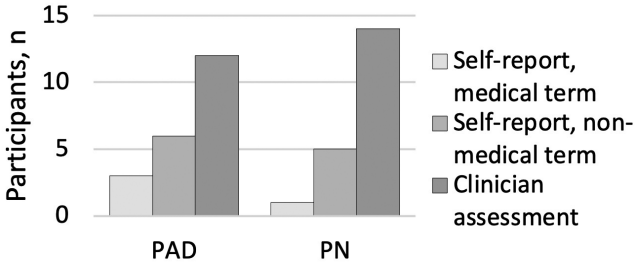

Figure 1. Accuracy of self-report medical history versus clinician assessment.

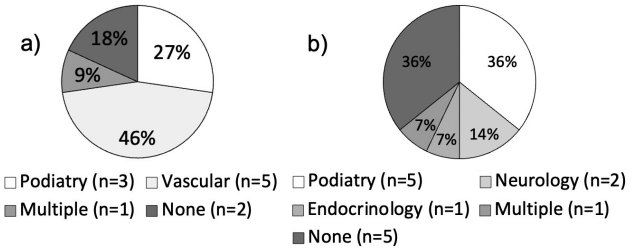

Figure 2. Care received during the 3 months following prosthetist assessment for (a) PAD and (b) PN.

However, even with non-medical terminology, 50% of cases of suspected PAD and 65% of cases of suspected PN would have been missed without sound-limb assessment. Thus, assessment of sound-limb health is critical; self-report is inaccurate. Prosthetists may assume this screening role during routine follow-up care.

Most participants who had positive screens for suspected PAD and/or PN went on to receive care from a specialist in the 3 months following their prosthetic visit. Data suggest that prosthetist screening and referral for PAD and PN may positively influence care-seeking behavior among adults post amputation. With increased screening, perhaps subsequent "sound-limb" amputation rates would be reduced.

CONCLUSION

When collecting medical history from adults with lower-limb loss, use of common vernacular is recommended. Self-reported history of PAD and PN cannot be obtained in lieu of sound-limb assessment. Comorbidity screening and referral may positively influence care-seeking.

CLINICAL APPLICATIONS

Routine screening and referral for under-reported PAD and PN should be considered during prosthetic visits.

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Coy T, et al. *BMC Public Health.* 2023;23(46).

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Preferred Terminology of People with Limb Difference Compared to Health Care and Research Professionals

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INTRODUCTION

A wide variety of terms exist to refer to people with limb difference (PwLD) in media, health care, and research. Debate exists over which terms are the most appropriate in each setting, and terms are often decided by people who do not have a limb difference. Research on preferred terminology has been conducted in several populations, including people with autism.[1,2] However, this topic has not yet been examined among PwLD. We sought to elicit preferred terminology in PwLD, as well as with health care and research professionals (PRO) who work with this population, to help inform terminology considerations. Specifically, we examined (1) the importance of terminology, (2) person-first (e.g., individual with limb loss) versus disability-first (e.g., amputee) terminology preference, and (3) perceptions of terminology via an open-ended question.

METHOD

Participants: One hundred twenty-two people completed the survey (n = 65 PwLD; n = 57 PRO, n = 42 health care, n = 15 research).

Apparatus: Anonymous cross-sectional survey.

Procedures: This protocol was approved by the North Texas Regional Institutional Review Board. Preferred population terms (e.g., amputee, person with limb difference) and limb terms (e.g., residual limb, stump) during writing and speaking were collected through a list of terms (i.e., Which one term would you prefer?) and an open-ended question (i.e., What else do you want us to know regarding your terminology preferences?). A pilot study including both PwLD and PRO participants aided in defining a full list of terms. All participant data was collected using REDCap (Vanderbilt University, USA).

Data Analysis: Chi-squared tests and descriptive statistics were used to determine differences between PwLD and PRO groups. Two authors (MGF, CM) conducted a content analysis of open-ended responses. Significance was considered $p < 0.05$.

RESULTS

Participants primarily identified as white. Age significantly differed between groups (PwLD = 49.9 ± 15.4; PRO = 41.0 ± 14.3; $p = 0.001$).

Table 1. Raw counts of participants who responded: Not Important (NI), Somewhat Important (SI), Moderately Important (MI), Very Important (VI), or Extremely Important (EI). Significant values are bold.

	PwLD (n = 65)	**PRO** (n = 57)	χ^2	*p*-value
	NI/SI/MI/VI/EI	NI/SI/MI/VI/EI		
How important is the terminology you use?	10/12/11/20/12	0/3/15/26/13	16.6	**0.002**

Table 2. Person-first versus disability-first population terms. Raw counts of participants who selected person-first or disability-first for the one term they preferred. Significant values in bold.

	PwLD (n = 65) **Person/Disab.**	**PRO** (n = 57) **Person/Disab.**	χ^2	*p*-value
Writing	27/38	35/22	4.8	**0.029**
Speaking	33/32	42/15	6.7	**0.009**

Table 3. Preferred terms. Most frequently chosen terms when participants were asked to select which one term they preferred.

	PwLD (n = 65)	**PRO** (n = 57)
Population-Writing	Tie (n = 13): Ind./PwLD and Specific level [i.e. below knee or transtibial] amputee	Ind./PwLD (n = 12)
Population-Speaking	Amputee (n = 18)	Ind./PwLD (n = 11)
Limb-Writing	Residual limb (n = 32)	Residual limb (n = 31)
Limb-Speaking	Residual limb (n = 30)	Residual limb (n = 32)

Content analysis themes included the following: context matters, just ask (PwLD), follow their (PwLD) lead, and language has power.

DISCUSSION

Compared to PRO, PwLD were more likely to report terminology was not important and select disability-first terms, in alignment with research in communities with autism.[1,2] Both PwLD and PRO tended to select the same terms, "residual limb" and "individual/person with limb difference." However, PwLD preferred a different term for population-speaking, "amputee." Perhaps because the majority of PwLD (n = 56 of 65) underwent an amputation, while most of the 9 participants born without a limb selected a person-first term. Future research could examine if findings are generalizable to people who do not identify as white, or if these terminology preferences are held in other countries and languages.[2]

CONCLUSION

Findings suggest that PwLD might be less likely to state terminology is important to them and more likely to prefer disability-first terms, compared to PRO.

CLINICAL APPLICATIONS

This study does not intend to recommend terminology, but rather help inform terminology choices that are PwLD-centered. As participants noted, individuality and context should be considered.

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Case Studies of the Use of Outcome Measures to Demonstrate Medical Necessity of Prosthetic and Orthotic Devices for Individual Patients

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INTRODUCTION

In many health care systems, demonstration of the medical necessity of interventions for individual patients is a key requirement of insurance coverage policies. By experience, many prosthetists and orthotists struggle understanding the concept of medical necessity and meeting its requirements for health care payor approval. This paper will present three case studies from the United States of how medical necessity was established and insurance approval obtained using outcome measure assessments.

Prosthetists and orthotists who received denials of their applications for prosthetic or orthotic devices from their patients' health care insurance providers contacted the reimbursement department of a manufacturer in the United States. After review of the medical and prosthetic/orthotic records and a telephone interview of the patients, the reimbursement specialists gave advice on what unmet patient needs to document and what outcome measures to assess to demonstrate medical necessity of the prosthetic/orthotic devices requested. The individual cases were followed until payor approval was obtained.

CASE PRESENTATION

Three case studies whose claims were originally denied by the patients' insurances will be presented: (1) a patient with an above-knee amputation using a mechanical prosthetic knee but requesting a microprocessor knee; (2) a patient with a paresis of leg muscles after spinal surgery using a locked KAFO but requesting a C-Brace; and (3) a patient with a transtibial amputation requesting a replacement of his powered prosthetic foot. The phone interviews found that the records of all three patients were missing important unmet needs that helped establish medical necessity of the requested devices, such as falls and fall-related injuries, pain, and restrictions to the daily routine and work. Assessments of suitable patient-reported outcomes over the phone and performance-based outcomes in the clinics helped establish medical necessity that ultimately resulted in approvals of the requested devices by the patients' insurances.

DISCUSSION

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

CONCLUSION

The use of a targeted patient history and outcome measures to identify unmet safety and/or mobility needs of patients is a successful method to achieve pre-authorizations and final approval of advanced prostheses and orthoses.

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Measuring Patient Outcomes Using Multi-Lingual Mobile App Technology

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INTRODUCTION

According to the U.S. Census Bureau, the number of persons aged 5 years and older who speak a language other than English is greater than 66 million, and the number of persons who also reported speaking English "less than very well" is greater than 25 million.[1] Individuals with limited English proficiency report lower satisfaction with clinician communication, lower satisfaction with their overall health care, and more difficulty understanding medical situations.[2,3,4] Further, language barriers are a contributing factor in the increasing health disparities experienced by minority populations.[5]

Patient-reported outcome measures (PROMs) can be challenging to complete with individuals who prefer to speak a language other than English. Comprehension of the questions in the PROMs can be challenging when health literacy or reading skills are low, resulting in inaccurate responses or inability to complete the measures, leaving gaps in clinical data.

METHOD

This presentation reports on the engineering development undertaken and the resulting mobile app called *Miasano* ("My Health" in the Esperanto Universal Language) to effectively integrate innovative approaches to overcome the language and literacy barriers in prosthetic and orthotic patient care. Miasano builds upon prior work called Clinical Outcome Measures Electronic Toolkit (COMET), which implemented outcome measures in a mobile application to enable practitioners to easily select and administer the tests with their patients.

Throughout development, Miasano underwent continual unit and system integration testing. Once it is fully tested and verified, the software will be tested with users who speak Spanish and evaluated for clinical feedback and user experience. Any feedback or issues discovered during usability testing will be addressed through the iterative engineering process prior to the deployment of the finished version for clinical evaluation in 2024–2025.

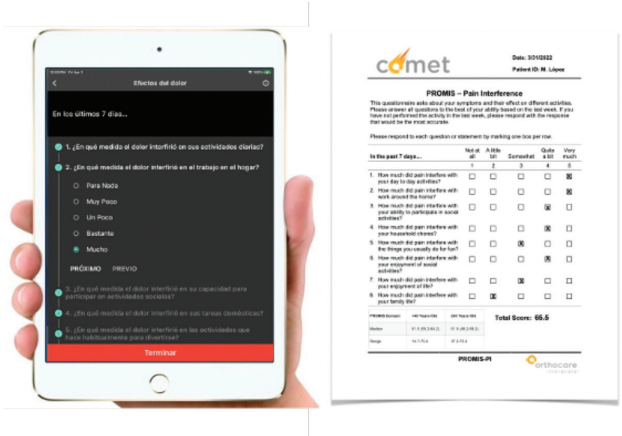

Figure 1. The Miasano app demonstrates PROM answered in Spanish (left) and Results provided to clinician in English (right).

RESULTS

The Miasano mobile app has been completed. The following key features have been implemented:

- Most outcome measures available in COMET have been implemented in Miasano.
- On-the-fly selection of alternate languages for completing PROMs with automatic scoring and reporting in both the selected language and English (Figure 1).
- Multi-lingual text to speech that "reads" PROMs aloud to the patient to overcome illiteracy.
- Dictionary that defines selected words within the outcome measure to aid comprehension.
- Direct translation of patient communication (spoken or typed) in the provider's language.

DISCUSSION

Previous research has clearly identified the clinical need for being able to communicate with patients whose preferred language is not English. A clinical trial of the completed system to establish clinical efficacy of our technical approach is planned for 2024–2025.

CONCLUSION

Miasano can be used by P&O clinicians to bridge language gaps both in real-time clinical communication and in the collection and interpretation of patient-reported outcomes using multiple languages.

CLINICAL APPLICATIONS

Communication is a key element to effective, personalized patient care management. Miasano provides clinicians a way to maintain a high level of communication with their patients even when patients may not speak or understand English.

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Limb Loss and Mental Health

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INTRODUCTION

Physical disability, including limb loss, often represents a life-altering event. In an ACA survey, individuals with limb loss reported that physical and mental health affect one another.[1] Care for individuals facing limb loss is often managed by orthopedic physicians, prosthetists, and physical therapists—disciplines that often lack training in mental and behavioral health—-and patients lack the tools to navigate the mental changes that accompany the physical changes.

Czeisler et al. found that individuals with disabilities disproportionately experienced anxiety and depression, and new or increased substance abuse, and that they were less able to access care and medication related to their conditions.[2]

The purpose of this study was to examine issues associated with mental and behavioral health, access to and utilization of mental health services, and social determinants of health in individuals with limb loss or other limb difference or impairment compared to a broader sample of individuals self-reporting with a different physical disability.

METHOD

Participants: A custom survey was administered to U.S. adults aged 18 and older with a self-identified physical disability in a study approved by our university Institutional Review Board.

Apparatus: The survey was developed using validated instruments related to disability, mental and behavioral health, and quality of life, including the NIH Common Data Elements for Lower Limb Loss Research, which aggregates instruments such as the PROMIS, Disability Rating Scale, WHO Quality of Life, Social Support Questionnaire, and Center for Epidemiological Studies Depression Scale.

Procedures: The 15-minute survey, with branching for specific physical conditions, was administered using Qualtrics (Seattle, WA).

Data Analysis: Aggregate results were analyzed to determine prevalence, type, and degree of mental health issues. Subpopulations related to prosthetics and orthotics were analyzed using multivariate logistic regression models with a stepwise approach to further assess access to mental health care and resources.

RESULTS

Verified responses were received from 4,890 individuals, 66% female and 34% male.

In the broad sample, the most common physical disability was related to back or spine (N = 1,428). The most common age of onset of disability was 19–39 years (N = 2,015). A total of 2,348 respondents reported that "my mental health became worse as a result of my physical disability," and 60.3% reported a diagnosis of a depressive disorder. This is substantially higher than the 9.5% of general adults in the United States who report major depression, bipolar disorder, dysthymia per the NIH National Institute of Mental Health Disorders.

Rates were similar or higher for individuals who reported that their primary physical disability was limb loss, difference, or impairment (LL/D/I) (Table 1).

Compared to the full sample, the LL/D/I reported significantly higher incidence of a host of mental health issues including mood disorders, eating disorders, and mental disorders caused by substance abuse. Per the logistic regression, the odds of someone receiving mental or behavioral healthcare related to their physical disability were approximately 1.57 times higher for LL/D/I than individuals with other types of physical disability ($p = 0.041$).

Table 1. Percentages of entire sample (N = 4,890) and individuals reporting a primary disability of limb loss/difference/impairment (N = 147).

	FULL SAMPLE	LIMB LOSS/DIFF/IMP
Diagnosis of depressive disorder	60.3%	60.3%
Mental health became worse	48.5%	60.8%

DISCUSSION

The results showed that there are very high mental health needs, currently and in the past, among adults with physical disabilities, and that these needs are even higher for individuals with LL/D/I. Important factors such as abuse, social isolation and food insecurity among others seem to exacerbate mental health needs and highlight key intervention and prevention points for improving the health and well-being among those with a limb loss.

CONCLUSION

Individuals with limb loss and impairment face serious, multifaceted mental health issues. On the positive side, they are more likely to receive professional mental healthcare services than the broader population of individuals with physical disabilities.

CLINICAL APPLICATIONS

The O&P profession should consider improved ways to infuse mental health resources into patient care.

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Development and Pilot Testing of the Amputation-Related Pain and Experiences Assessment Tool

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INTRODUCTION

Patients and clinicians often have difficulty differentiating between amputation-related pain and experiences such as residual limb pain (RLP), phantom limb pain (PLP), and phantom limb sensation (PLS).[1] Without clearly identifying the underlying experience, it is challenging for clinicians to recommend effective treatments. The purpose of this project was to develop and pilot test an assessment tool for aiding patient-clinician conversations regarding amputation-related pain and experiences.

METHOD

This study was determined to qualify for exempt status by the Minneapolis VA Institutional Review Board.

Participants: Veterans with amputation who received care at the Minneapolis VA Regional Amputation Center were recruited through collaboration with clinicians. Recruitment is ongoing to reach our desired sample of 50 Veterans.

Apparatus: The Amputation-related Pain and Experiences assessment tool was designed based on input from clinicians and collaboration with a medical illustrator. The tool includes images depicting RLP, PLP, and PLS, paired with definitions of the three experiences. The tool also includes questions about intensity, frequency, and interference of the pain and sensation, modeled after those in the Expanded Socket Comfort Score and the Pain, Enjoyment of Life, and General Activity scale.[2,3]

Procedures: Participants were presented with this tool by study staff during or after their clinic appointment and asked to engage in discussion about these amputation-related experiences. Participants were asked to describe in their own words each experience and to provide numeric ratings of the characteristics of their pain and sensation. Data collection sessions lasted <10 minutes.

Data Analysis: Descriptive words used by participants were analyzed to identify phrases (and frequency of phases) that were unique and common to each experience. Numeric ratings of intensity and interference were analyzed using descriptive statistics.

RESULTS

In 36 Veterans assessed to date (94% male; average age: 64; 97% with lower-limb amputation), RLP was experienced by 69% in the past month, PLP by 72%, and PLS by 61%. Some participant descriptions were unique to one of these experiences, while other phrases were used to describe two or more experiences. "Tingling" was used in discussions of all three experiences. The experience with the most varied description was PLP, with few participants describing PLP using the same phrases. PLP descriptions were vivid; for example, "It feels like my hand is forced into a grip and each fingernail is pulled out…by a knife." Another Veteran described PLP as "my friend 'Spike.'" RLP was frequently described as soreness, pressure, and rubbing, and PLS was frequently described as a general awareness of the limb and itching. Numeric ratings of intensity and interference of RLP, PLP, and PLS are summarized in Table 1.

Table 1. Numeric ratings on 0–10 scale of single-question items for average intensity, interference with enjoyment of life, and interference with daily activities for 36 Veterans. Data shown as mean (SD, range reported).

	Residual Limb Pain	Phantom Limb Pain	Phantom Limb Sensation
Average intensity	3.04 (2.41,0-8)	3.5 2.49,0-7)	3.41 (2.26,0-8)
Interference with enjoyment	3.24 (3.74,0-10)	3.08 (3.44,0-10)	1.36 (2.34,0-10)
Interference with activities	3.64 (4.07,0-10)	3.12 (3.67,0-10)	1.41 (2.50,0-10)

DISCUSSION

Preliminary results from this ongoing study suggest that our tool is a simple but potentially useful way to help patients and clinicians differentiate between RLP, PLP, and PLS. Participants' descriptions of pain and sensation improved our understanding of their experiences. The variation and vividness in descriptions of PLP supported the results from previous qualitative work.[4] Limitations of this project include a lack of diversity in the sample as well as recall bias in participants' reports. Future development of this tool will involve versions with increased diversity of images and a stakeholder-created word bank of descriptions.

CONCLUSION

A tool that uses images, definitions, and descriptions can facilitate useful discussions about different types of patient experiences after amputation. Accurate and efficient identification of the specific type of experience can assist clinicians in recommending appropriate referrals or interventions.

CLINICAL APPLICATIONS

The Amputation-related Pain and Experiences assessment tool can help clinicians identify the nature of a patient's pain or sensation to guide effective treatment recommendations.

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Skin Assessment on Darker Skin Tones in Orthotics and Prosthetics

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INTRODUCTION

Darker skin tones are not well represented in orthotics and prosthetics (O&P) clinical education. Available teaching resources on skin problems focus primarily on lighter skin tones.[1,2] Yet, evaluation of all skin tones is an important aspect of O&P care including socket fit assessment, orthosis fit, residual limbs, and wound healing. An unpublished pilot study conducted among O&P students at the University of Washington found greater accuracy in identifying O&P-related skin conditions on light skin tones compared to dark skin tones. If students and clinicians are not trained to identify common skin problems on darker skin tones, many treatable issues may go unidentified and untreated, contributing to outcome disparities for patients with darker skin. Materials to teach evaluation of patients with darker skin tones do not currently exist in O&P education.

METHOD

We are developing an evidence-based digital handbook that includes images and descriptions of various skin problems related to O&P as they appear on darker skin tones.

We are using a stepwise approach to create the handbook. First, we finalized a prioritized list of clinical assessment areas and common skin problems seen among O&P users. This list was compiled using current resources in O&P clinical education, a literature review of available evidence in dermatology and O&P, and clinical expertise from prosthetists, physiatrists, and dermatologists.

Next, we created a website and survey (using REDCap) to facilitate the submission of images by O&P users and their providers. The website and survey include guidelines on best practices for image capture and a required color correction swatch for standardization across images. With an established mechanism for image submission, we are now soliciting images from the O&P community.

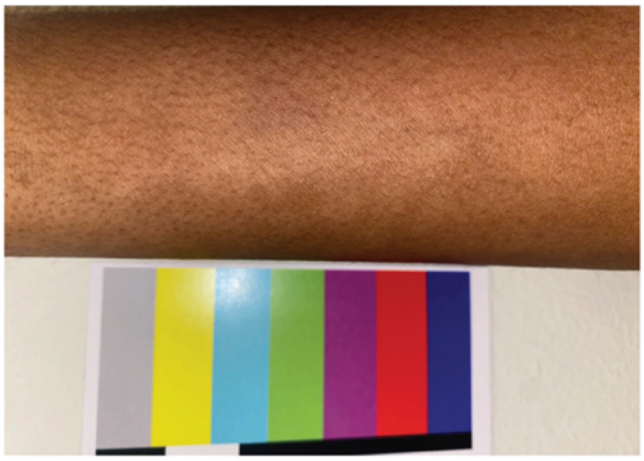

Figure 1. Example patient photo using color card for post processing standardization.

RESULTS

To date, we have established a website and standardized processes for the collection of images and permissions for image use. Five individuals piloted processes to improve clarity of instructions and usability of interface.

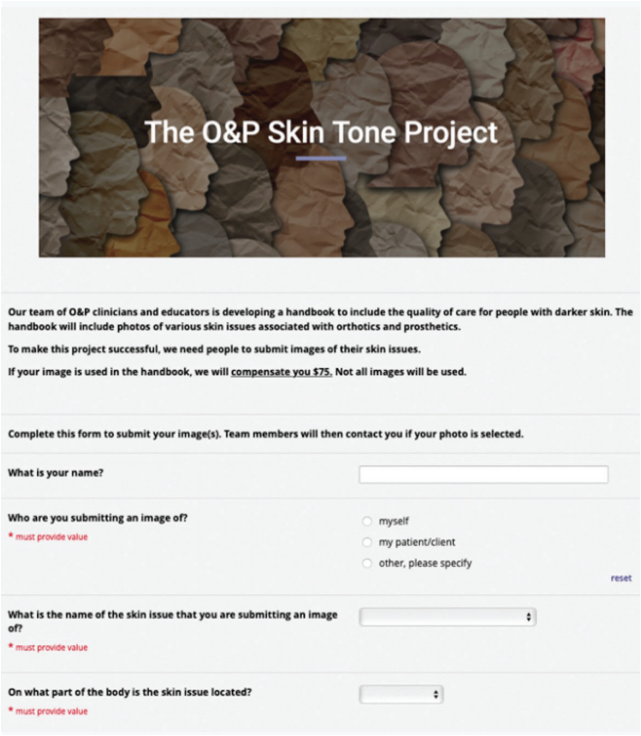

Figure 2. The O&P Skin Tone Project image submission survey.

Next steps for the project include engagement with the O&P community to recruit individuals willing to share their images. Additionally, an advisory board of clinicians, O&P users, and related persons will be established to guide project progress, development, dissemination, and maintenance.

DISCUSSION

The O&P community must work together to improve equity for O&P users. Skin assessment is an area in need of improvement to provide equitable care to all patients. Development of a digital handbook requires support from the O&P community and will also serve as a free resource to improve care provided to individuals with darker skin tones.

CONCLUSIONS

Once finalized, the digital handbook will be available free of charge for all O&P educational institutions and clinical practices. The advisory board will guide subsequent dissemination of the resource.

CLINICAL APPLICATIONS

A handbook to increase awareness and skill of skin assessment related to O&P on darker skin tones is needed to improve equity in patient care and outcomes for patients with darker skin.

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Racial Bias in Orthotics and Prosthetics

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INTRODUCTION

Racial disparities in orthotics and prosthetics (O&P) access and outcomes have been identified in the literature.[1] To reduce racial health disparities, the underlying causes of inequity must be identified and addressed. Causes may include structural, institutional, and/or interpersonal racism, all of which have been associated with disparate outcomes across healthcare.[2] Interpersonal racism occurs when an individual's racial beliefs, such as implicit and/or explicit bias, affects his or her interactions. Racial biases in many health professions have been found to influence diagnosis and treatment.[3] To assess the current state of racial bias in O&P, we conducted a cross-sectional survey of implicit and explicit biases among O&P clinicians, residents, educators, and students.

METHOD

Sample: All current U.S. O&P educators, students, and BOC-certified clinicians were invited via email to participate. A random sample of 2,000 ABC-certified clinicians were invited via mailed postcard.

Study Design: A cross-sectional online survey was conducted. An institutional review board reviewed and deemed all study procedures to be exempt.

Eligibility: ≥18 years of age, English proficiency, and a self-reported role in O&P education or clinical practice.

Procedures: Participants were self-screened for study eligibility. If eligible, the participant was assigned a survey based on his or her reported role in O&P. Surveys included demographic, work or education questions, explicit racial preference questions, and the Race Implicit Association Test (IAT).

Data Analysis: Participants were grouped by O&P role. Descriptive statistics were used to characterize demographic and work/education-related information and racial preferences for each group. The IAT effect was calculated as the standardized difference in mean response time on two conditions of the IAT, presented as the IAT D score.[4] Effect size for implicit bias was calculated by role, race/ethnicity, and gender groups. Spearman's rank-order correlation was used to assess correlation between implicit and explicit bias. Group level comparisons of IAT scores were made using independent t-tests and analysis of variance.

RESULTS

The survey was completed by 454 individuals (136 students, 24 educators, 294 clinicians/residents). Many participants (255) were screened out due to ineligibility or the survey being closed. Some individuals (87) began but did not complete the survey. Overall, study participants were young (36% were between 25–34 years old), identified as women (52%), identified as White (80%), and had completed a master's degree (46%).

The O&P sample in this study had a similar distribution of implicit racial preferences as the general population (Figure 1). However, most participants did not report explicit racial preference.

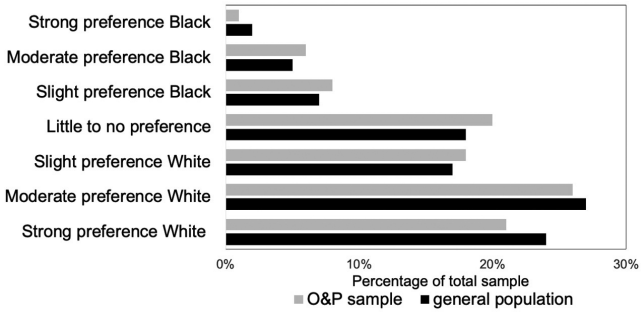

Figure 1. Implicit racial bias of the O&P sample and the general U.S. population.

No significant difference in implicit bias was found between role groups. However, statistically significant differences in implicit bias were found by gender (men versus women), and race (Black/non-Black, and non-Hispanic White/not non-Hispanic White). Women, Black individuals, and those who did not identify as non-Hispanic White had significantly less implicit racial bias.

DISCUSSION

Members of the O&P community have similar levels of implicit bias as other health care providers.[5] Black individuals in the O&P community were found to have less implicit bias, which is similar to findings among Black physicians.[5] Gender differences in implicit bias were also found in our O&P sample, but findings in this area are inconsistent among other providers.[5]

CONCLUSION

O&P providers, educators, and students have similar implicit racial bias as the general U.S. population, but most individuals do not report explicit racial preference. Further research is needed to examine the complex relationships between implicit and explicit bias, clinician actions, and O&P patient outcomes for Black individuals.

CLINICAL APPLICATIONS

O&P professionals may address unconscious bias through implicit bias training such as self-reflection and active learning exercises. Study data also support the need for active recruitment of individuals with diverse backgrounds (specifically Black individuals) into O&P.

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Loading Rate Across a Range of Walking Speeds in Individuals with Transfemoral Amputation Using Mechanical and Microprocessor-Controlled Knees

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INTRODUCTION

Individuals with unilateral transfemoral amputation commonly suffer from disabilities such as knee osteoarthritis or back pain that are secondary to the repetitive loading on the intact limb. The loading rate, defined as the initial slope of the vertical ground reaction force development, is associated with these secondary intact limb musculoskeletal injuries in individuals with lower-limb amputation.[1,2] A recent study demonstrated that the use of the microprocessor-controlled prosthetic knees (MPKs) with active variable damping control may help to compensate for exclusive reliance on the intact limb. The MPKs users demonstrated a reduced intact limb collision work across walking speeds compared to non-microprocessor-controlled prosthetic knees (NMPKs), which is thought to reduce the peak vertical ground reaction force and loading rate in the intact limb.[3] However, little is known about the loading rate between NMPK and MPK users across a range of walking speeds. Therefore, the aim of this study is to investigate the relationship between walking speeds and loading rate in NMPK and MPK users.

METHOD

This study was approved by the local ethics committee, and all procedures followed the Declaration of Helsinki (1983). Participants were informed of the test content, and their consent was obtained.

Participants: Thirteen NMPK (3 females, 31.8±9.2 years, 1.65±0.1m, 64.2±17.5kg) and 12 MPK users (3 females, 30.5±11.5 years, 1.67±0.1m, 66.5±10.4kg) with unilateral transfemoral amputation were recruited.

Apparatus and Procedures: All participants walked on the force plate-instrumented treadmill (FTMH-1244WA, Tec Gihan, Kyoto, Japan) at eight speeds (2.0–5.5 km/h with increments of 0.5 km/h) for 30 seconds per speed.

Data Analysis: The loading rate was calculated as the average slope from initial contact to the first peak of vertical ground reaction force with the normalized units of BW/s in their intact limb. For each group, we used best-fit linear regression analyses, where coefficients of determination (R2) were calculated ($p < 0.05$).

RESULTS

There were significant linear relationships between walking speeds and loading rate in both NMPKs ($R2 = 0.973$, $p < 0.01$) and MPKs ($R2 = 0.990$, $p < 0.01$), respectively (Figure 1). The slope of the linear regression line of the MPK group tended to be gentler than that of the NMPK group.

DISCUSSION

Both groups displayed statistical significance in linear regression analyses and exhibited a positive linear association with walking speeds. These results indicate that intact limbs of both NMPK and MPK groups would be exposed to a higher risk of degenerative disease with increasing walking speeds. Further, the gentle slope of the regression lines suggests that the use of MPKs may be more beneficial to reduce the intact limb's loading than NMPKs at faster walking speeds.

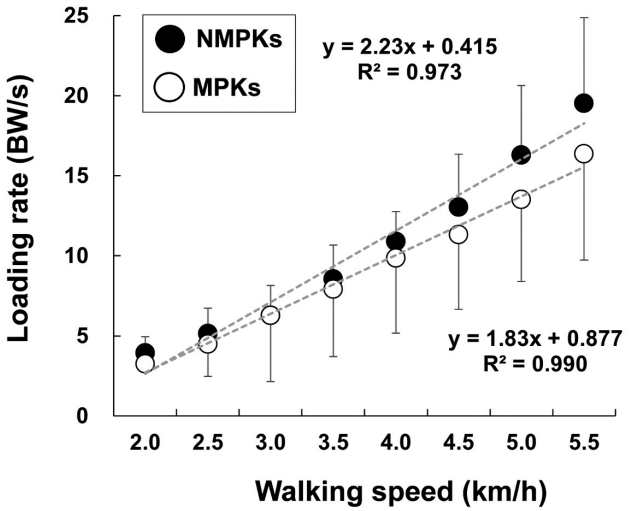

Figure 1. Relationship between the walking speeds and loading rate in NMPK (black) and MPK (white) groups, respectively. Grey dotted lines indicate a significant positive linear relationship between two variables over a wide range of walking speeds.

CONCLUSION

The loading rate across a range of walking speeds in individuals with unilateral transfemoral amputation could be reduced by using MPKs compared to NMPKs.

CLINICAL APPLICATIONS

Since reduced loading rate with MPKs can lead to prevention or decrease of pain and secondary musculoskeletal injuries in the intact limb, current results could provide valuable insights for decision-making on whether to choose an MPK in clinical practice.

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Benefits and Barriers to Clinical Mentorship

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INTRODUCTION

Multiple measures have indicated that approximately one quarter of the orthotics and prosthetics practitioner population will be of retirement age within the next decade.[1] As the profession seeks to educate the next generation of prosthetist-orthotists, it is critical to determine the benefits and barriers to clinical mentorship during residency training. Researchers have identified factors such as time, funding, lack of training, and a lack of clinical sites as potential barriers to clinical education in the health professions.[2] There is currently no research evaluating the experience of clinical residency from the clinical mentor's perspective. The primary aim of this study was to evaluate the benefits and barriers to clinical mentorship. The secondary aim was to determine if there were differences in responses based on the demographic factors of the respondents.

METHODS

This study involved a cross-sectional survey distributed over a 6-month period in 2021. The survey was sent via email to a contact list via the National Commission on Orthotic and Prosthetic Education (NCOPE).

Participants: One hundred forty-three (12% response rate) individuals responded to the survey. One hundred Twenty-one responses met the inclusion criteria (eligibility to be an NCOPE mentor) and were completed in full and included for data analysis.

Apparatus: Respondents completed 7 items related to demographics, 6 items related to working with a clinical resident, and 17 matrix-style items related to benefits and barriers of clinical mentorship identified in the literature. Respondents were asked to use a 7-point scale to agree or disagree with statements regarding clinical mentorship and working with residents. There were open-ended questions at the end of the survey allowing for respondents to share additional thoughts or feedback.

Data Analysis: Descriptive statistics of sample demographics and responses were generated via SPSS v.26. Responses were analyzed across demographic factors to determine statistical differences.

RESULTS

Respondents represented 34 states from all regions of the country. Most respondents were male (71.1%), certified prosthetist-orthotists (72.7%), 45 years of age or older (61.1%), White (95%), and had more than 11 years of experience in the profession (76%). The highest level of education obtained by 55.4% of respondents was a bachelor's degree; 38.8% of respondents indicated that they had completed a master's degree. The majority of respondents participated in a single-discipline residency program (57.6%).

Ninety-three percent of respondents had worked with a resident in the past, but only 77% of those respondents indicated "yes" when asked if they planned to continue to work with residents. Respondents indicated they "somewhat agreed" (Mdn = 5, IQR = 2) with the following statements: hiring a resident is a smart financial decision, residency offers time to train a new clinician at a reduced cost, residency allows for improved patient care experiences, having a resident allows them to be a more productive clinician, and residents are prepared for clinical practice. Respondents "agreed" (Mdn = 6, IQR = 1) that they were excited to work with residents, had an obligation to work with residents, had access to educational resources, had enough time to support a resident, and that working with residents was beneficial to their education. Differences in responses based on demographic characteristics were observed but were minimal.

Open-ended responses were evaluated for themes. Barriers mentioned included time, financial constraints, and varied preparedness of residents. Benefits to clinical mentorship included keeping up to date with clinical practices, bringing energy and assistance to the clinic, and sharing years of clinical practice and knowledge.

DISCUSSION

This study evaluated views of clinicians related to clinical residency. The overwhelming majority of respondents were supportive of clinical mentorship and indicated a desire to continue working with residents, despite the barriers. Limitations to the study include a low response rate and a bias toward those inclined to work with residents. Additional research should examine ways to support clinicians as clinical mentors to ensure sufficient sites for training.

CONCLUSION

While clinicians in orthotics and prosthetics are engaged in working with residents, data regarding the considerations of those who chose not to work with resident are lacking. Additional exploration of clinical mentorship in orthotics and prosthetics will aid in the development of clinical education training and support.

CLINICAL APPLICATIONS

Optimizing clinical education and supporting clinical mentors is paramount to the preparation of new clinicians.

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Microprocessor Stance and Swing Control Orthosis for Patients Dependent on a Knee-Ankle-Foot Orthosis for Walking: A Randomized, Controlled Crossover Trial

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INTRODUCTION

For patients with paresis or paralysis of the quadriceps and other knee-stabilizing muscles, locked knee-ankle-foot orthoses (KAFOs) have been the standard of care for a long time. Improvements in KAFO technology, such as posterior offset KAFOs and stance control orthoses (SCO), have improved functionality for patients with free swing but work reliably and safely on level ground only. The C-Brace is the first microprocessor stance and swing control orthosis (MP-SSCO) that makes the benefits of microprocessor-controlled prosthetic knees, including stumble recovery, available to patients who are dependent on a KAFO to restore walking capability. The purpose of this study was to test the hypothesis that patients experience improved balance, fewer falls, and improved mobility and quality of life when using the C-Brace compared to standard KAFOs and SCOs.

METHODS

In this randomized, controlled crossover trial, legacy KAFO users with Berg Balance scores <45 were enrolled in 13 clinics in four countries (Germany, Austria, Netherlands, USA) and randomized to KAFO/C-Brace or C-Brace/KAFO home use for 3 months with each orthosis. The primary outcome measure was the Berg Balance Scale (BBS).[1] Secondary outcome measures assessed were: Dynamic Gait Index (DGI),[1] falls, Activity-Specific Balance Confidence (ABC) scale,[2] fear of falling, Reintegration into Normal Living Index (RNLI),[3] Orthotic and Prosthetic Users' Survey–Lower Extremity Functional Profile (OPUS-LEFS),[4] SF-36v2,[5] and EQ-5D-5L.[6]

Intention-to-treat analysis (ITT, including dropouts) with 102 participants and per-protocol analysis (PP, without dropouts) with 69 participants. With the C-Brace in the PP analysis, the BBS improved by 3.6±6.1 points ($p<0.00006$) versus KAFO and 7.4±7.7 ($p<0.00001$) versus baseline. Significantly fewer participants presented BBS scores <40 indicative of almost 100% fall risk (12 versus 25, $p=0.00361$). Mean falls reduced from 5.0±18.9 with KAFO to 1.1±3.3 with C-Brace ($p=0.002$). The ABC score improved by 11.3±22.7 ($p=0.00011$), and significantly fewer patients presented ABC scores <67 indicating increased fall risk with the C-Brace than with KAFO (31 versus 48, $p=0.0008$). Also, the fear of falling indoors ($p=0.0023$) and outdoors ($p=0.0065$) reduced significantly with the C-Brace. The DGI improved by 1.0±3.7 ($p=0.005$), and the OPUS-LEFS improved by 2.0±5.2 ($p=0.00019$). The SF-36 improved significantly in the domains of physical functioning ($p<0.00001$), emotional well-being ($p=0.0011$), general health ($p=0.0038$), health change ($p=0.0045$), and energy/fatigue ($p=0.022$). Significant improvements were also found in the RNLI ($p=0.042$) and EQ-5D-5L utility score ($p=0.037$).

DISCUSSION

The improvements in balance, falls, fall risk, function, and mobility can be attributed to the stumble recovery and controlled knee flexion during weight bearing of the C-Brace. These device features and functions have a positive impact on the quality of life of users who have increased fall risk compared to the use of standard KAFOs and SCOs.

CONCLUSION

The C-Brace represents a viable orthotic option for KAFO and SCO users who have increased fall risk and reduced mobility.

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DISCLOSURE

Andreas Kannenberg is a full-time employee of Otto Bock Healthcare LP.

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Determining AFO Footwear Combination Heel Wedge Height Using a Web-Based Electronic Calculator

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INTRODUCTION

The pathologic gaits of patients with neuromuscular disorders are often treated with ankle- foot orthoses (AFOs).[1] AFOs provide tri-planar control of the foot and ankle complex as the limb travels through the gait cycle.[1] Previous studies have shown that inclining the shank to an optimal degree at temporal mid-stance is the prime determinant of a positive gait outcome.[2] Shank inclination is determined by both the ankle angle of the AFO (AA-AFO) and the pitch of the sole of the shoe (or the heel-sole differential; HSD). Depending on the AA-AFO and the HSD, it may be necessary to add a heel wedge to either the AFO or the shoe sole to achieve the desired shank inclination. Previously, the amount of heel wedging has largely been selected based on clinician expertise or experimentation. This paper presents the use of a web-based electronic heel wedge calculator that uses trigonometric equations to mathematically determine initial heel wedge height, based on the goal shank inclination, the ankle angle of the AFO, and the pitch of the shoe sole.

METHOD

To determine the amount of heel wedge necessary to achieve the desired shank inclination, the calculator requires four inputs: the foot length (L), the shoe sole pitch (HSD), the fixed ankle angle of the AFO (θ), and the goal shank inclination (SVA) (Figure 1).

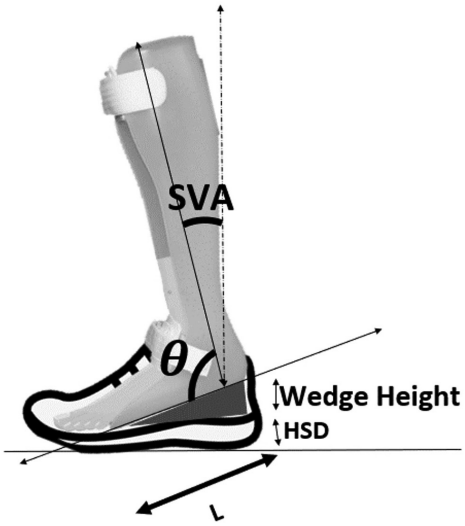

Figure 1. Diagram of measured values used to calculate heel wedge height.

The foot length, (L), is measured from the back of the heel to the apex of the 5th metatarsal phalangeal joint. The shoe sole pitch, or (HSD), is the difference between the height of the sole at the heel and the height of the sole at the metatarsal heads. The fixed ankle angle of the AFO (θ), is the angle at which the ankle is held within the orthosis (AA-AFO). The goal shank inclination, commonly referred to as the shank to vertical angle (SVA), is the angle between the long axis of the calf and a line perpendicular to the walking surface. The optimal starting SVA has been determined by previous studies and depends on the patient's stance phase shank kinematics.[2] The initial total heel wedge height is calculated according to equation 1 using a pre-programmed spreadsheet on a website.

Equation 1

$$\text{Wedge Height} = (\cos(180 - \theta - \text{SVA})L) - \text{HSD}$$

Case Study: Patient with a solid ankle AFO set at 10 degrees of plantarflexion.

$\theta = 90° + 10°$ of plantarflexion $= 100°$
Goal SVA = 7 degrees
L = 17 cm
HSD = 0.9525 cm

RESULTS

Case Study: For a patient with a solid ankle AFO set at 10 degrees of plantarflexion and an HSD of ⅜ inch, the heel wedge calculator determines that a 1.5-inch heel wedge is necessary to achieve a SVA of 7 degrees.

DISCUSSION

The electronic heel wedge calculator produces the necessary heel wedge height instantly, making it easy to use during the impression-taking appointment or afterward when filling out the work order.

CONCLUSION

The electronic heel wedge calculator reduces reliance on empirical evidence to determine amount of wedging necessary to achieve the desired shank inclination.

CLINICAL APPLICATIONS

This web-based calculator enables clinicians to design an AFO-footwear combination (AFOFC) in the precise alignment required to achieve the goal SVA for normalizing gait kinematics. This may reduce the number of adjustments necessary when aligning the AFOFC for optimal gait during the fitting process.

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3D-Printed Accommodative Insoles: A Pilot Study and Integrating Clinician Perspectives

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INTRODUCTION

Complications due to diabetes are a leading cause of amputation in the United States.[1] To redistribute plantar pressures and decrease ulceration risk, standard of care (SoC) accommodative insoles are commonly prescribed to this population.[2] Advances in 3D printing, materials, and software allowed our team to design accommodative patient-specific insoles (3DP) using 3D-printed metamaterials. Production incorporates an in-shoe pressure assessment to identify regions of high pressure and reliefs to offload those areas. The purpose of this study is to evaluate the effectiveness of novel 3DP insoles at reducing plantar pressures and obtain clinician perspective on the feasibility of translating the insoles and fabrication workflow into a clinical setting (Figure 1).

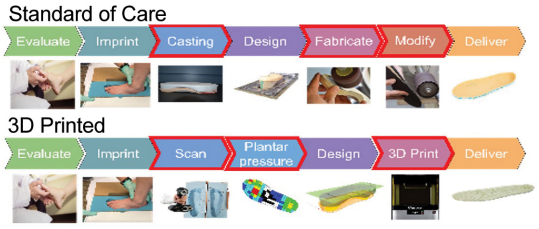

Figure 1. SoC and 3DP workflows.[3]

METHODS

Pilot Study[2] *Participants:* Twelve individuals (3 with diabetes).

Procedures: Walking plantar pressure in the research shoe (RS) were recorded at baseline. Sensels with pressure over 200 kPa were used to define an offloading region. Three pairs of custom insoles (SoC, hybrid, full) were fabricated (Figure 2). At a second visit, plantar pressure during walking was recorded and compared across RS and insoles.

Data Analysis: Peak plantar pressure was evaluated in the offloading region and the adjacent region (the sensels around the offloading region).

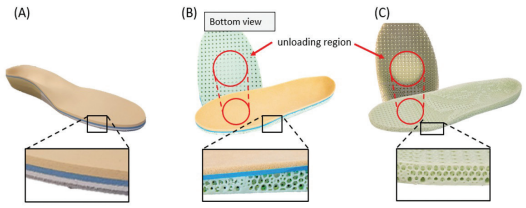

Figure 2. Insoles (A)SoC, (B)3DP with bilaminate top layer, (C) full 3DP. Offloading regions indicated in red.

Clinician Focus Group Participants: Five (3 male, 2 female) Veteran's Affairs (VA) O&P clinicians (years of practice: 13.8 ± 11).

Procedures: During the focus groups, clinicians were shown 3 orthotics (Figure 2) and prompted to discuss potential advantages and disadvantages.

Data Analysis: Focus group sessions were audio-recorded and transcribed, and main themes pertaining to each category were extracted (Table 1).

RESULTS

Maximum peak plantar pressure in the offloading region was reduced in the Hybrid and Full, but not in the SoC compared to the RS. Plantar pressure in the adjacent regions was not increased. Several advantages and disadvantages of the SoC and 3DP were identified (Table 1).

Table 1. Key themes from focus groups, sorted by category.

Category	Theme
SoC Disadvantages	• Poor durability • Edge pressure around reliefs • Poor customization
SoC Advantages	• Quick manufacturing time • Easily modifiable by clinicians
3DP Disadvantages	• Perforated top surface • Limited ability to make adjustments and modify
3DP Advantages	• Support in the arch
3DP Workflow Application in the Clinic	• Insurance guidelines • Addition of walking pressures to appointment • Bandwidth of software

DISCUSSION

The findings of our study demonstrate the capabilities of 3DP insoles to reduce plantar pressures, even in individuals without elevated pressures. The feedback from clinicians revealed that recording in-shoe pressure during clinic visits would be feasible and valuable if the 3DP insoles provide improved durability, ultimately reducing the frequency of device replacement and clinic visits. Next steps include evaluating plantar pressures with the 3DP insoles in a diabetic population with elevated pressures and comparing to the SoC in both short-term and long-term use.

CONCLUSION

The pilot study was successful in showing the 3DP insoles can reduce plantar pressure and be modified to offload peak pressures. Clinician feedback is essential to inform the design of the 3DP insoles and continue improving clinical care and patient outcomes.

CLINICAL APPLICATIONS

Understanding clinician perspective on current SoC disadvantages and shortcomings, areas for improvement in 3DP insole fabrication, and what is feasible in clinic appointments will help inform insole design and translate the new 3D-printing technology to clinical care.

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Reliability and Validity of the Orthotic Patient-Reported Outcomes – Mobility (OPRO-M™) Short Forms in Lower-Limb Orthosis Users

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INTRODUCTION

The Orthotic Patient-Reported Outcomes – Mobility (OPRO-M) is a self-report item bank developed to measure mobility of lower-limb orthosis users.[1] Previous research provided support for the initial construct validity of the OPRO-M item bank.[2] Two fixed-length short forms were developed for use in clinical practice and research. The goals of this study were to assess the convergent construct validity of the OPRO-M short forms by comparing OPRO-M scores to scores from clinician-administered tests of mobility and to assess the test-retest reliability of the OPRO-M short forms by comparing scores obtained from administrations spaced 1 to 2 weeks apart.

METHOD

Participants: Adults with at least one month of experience using an orthosis (i.e., AFO, KAFO, HKAFO, or FES device) for one or both legs were recruited for the study by clinicians at P&O clinics across the United States. All study procedures were approved by a University of Washington Institutional Review Board, and informed consent was obtained for all participants.

Apparatus: The OPRO-M 12- and 20-item short forms are fixed-length versions of the OPRO-M item bank intended for use in clinical practice and research. OPRO-M items ask respondents to rate how difficult it is for them to perform various activities. The Timed Up and Go (TUG),[3] 10-Meter Walk Test (10MWT),[4] and Two-Minute Walk Test (2MWT)5 are performance tests commonly used in clinical practice to assess patients' physical function, including mobility, walking speed, and endurance, respectively.

Procedures: Participants first completed the OPRO-M short forms on a tablet computer. They were then administered the three performance tests by a trained clinician. OPRO-M was re-administered 7–14 days later as an online survey.

Data Analysis: Convergent construct validity was examined by calculating Spearman correlations between OPRO-M and the performance tests. Specifically, we hypothesized that OPRO-M scores would correlate moderately ($0.3 \leq |r| \leq 0.7$) with TUG, 10MWT, and 2MWT scores. Test-retest reliability was examined by calculating the intraclass correlation coefficient (ICC, 2-way mixed-effects, absolute). We hypothesized that OPRO-M ICCs would exceed 0.9, which would be indicative of excellent reliability.

RESULTS

A total of 89 participants completed all study procedures. The mean age of the sample was 53 years, 49% were men, and 73% reported being non-Hispanic and White. OPRO-M scores correlated more strongly with performance tests than hypothesized (Table 1). The ICCs between OPRO-M test and retest scores exceeded 0.9 for both short forms (Figure 1).

Table 1. High correlations between OPRO-M short forms and performance test scores provided evidence of convergent construct validity. All correlations were significant ($p < .001$).

	TUG	10mWT	2MWT
OPRO-M-12	-0.73	0.75	0.82
OPRO-M-20	-0.74	0.76	0.84

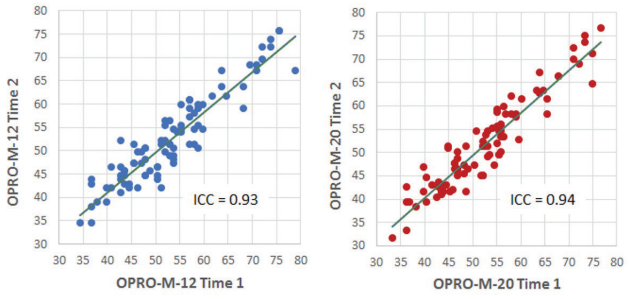

Figure 1. High correlations between OPRO-M scores at time 1 and time 2 indicate both short forms have excellent reliability.

DISCUSSION

Results of this study provide promising evidence of OPRO-M's construct validity and reliability. While correlations between OPRO-M and performance-tests were slightly higher than expected, they were not perfect, suggesting that OPRO-M measures a different aspect of mobility. OPRO-M may therefore provide clinicians and researchers with information that is distinct and complementary. Test-retest reliability for both OPRO-M short forms exceeded 0.9, indicating that they can be used for individual-level assessment. OPRO-M appears to be well-suited to prospective applications like selecting and evaluating the effectiveness of orthotic devices.

CONCLUSION

Results of this study add to a growing body of evidence in support of the reliability and validity of the OPRO-M measure. OPRO-M short forms are now available for use in clinical care, research, and education (https://opro-m.org).

CLINICAL APPLICATIONS

OPRO-M 12- and 20-item short forms are valid and reliable tools for evaluating mobility across a wide range of lower-limb orthosis users.

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Can Confirmation Bias Toward Advanced Orthopedic Devices Affect Self-Report and Functional Outcomes?

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INTRODUCTION

Within orthotics and prosthetics, many technologically advanced devices and components promise increased functionality, which must be balanced against increased cost and complexity. Research has shown that patients prefer these products over their less advanced, more affordable counterparts.[1] The natural assumption is that advanced devices are preferred because they function better; however, it is possible that patient perception, and even patient performance, is influenced by cognitive biases.

One such cognitive bias, called "confirmation bias," is defined as an altered perception due to prior expectations of a stimulus. Within this context, users might alter their perception of or performance with an advanced prosthesis or orthosis because they expect it to perform better, simply based on its complexity or cost.

Balsamo et al. found that healthy young adults who were led to believe that a standard knee orthosis was advanced and computerized preferred it in self-reported outcomes but walked with no differences while using it.[2] Walking performance was unlikely to change in that population.

The current study assessed cognitive biases in relation to orthotic use in an older patient population performing a functional task with a higher likelihood of reflecting bias in performance, not just perception.

METHOD

The deception study presented users with two functionally identical off-the-shelf bilateral knee orthoses (Ovation Medical Compact Pro), but one was modified with wires, motors, circuits, and a USB port to appear computerized. Participants were provided a flyer describing the "advanced features," and were told the study was a test of a prototype for an anonymous company.

Participants: Five healthy older adults (aged 70.0±8.15 years), 4 males and 1 female.

Apparatus: Participants were asked to complete a survey of brace preference in five domains both before using any orthosis and after using both orthoses. The Likert survey measured comfort, performance, cost, appearance, and overall preference.

Procedures: Following consent, introduction, and pre-survey, 8 reflective markers were attached, and subjects completed a Five Times Sit to Stand (5XSTS) test while their motion was recorded using a Vicon system, and with one foot on each of two force platforms. After both orthoses were tested twice in randomized order, the survey was repeated.

Data Analysis: Pairwise comparison of 5XSTS time, loading impulse, knee angles, and survey results.

RESULTS

On average, users increased preference for the "advanced" orthosis after use, even though both orthoses were functionally identical (Figure 1).

Four were faster in the "advanced" orthosis (Table 1). Only 2 showed clinically meaningful differences, and both were faster in the "advanced" condition. An inverse correlation was observed between time and peak force, as well as time and impulse.

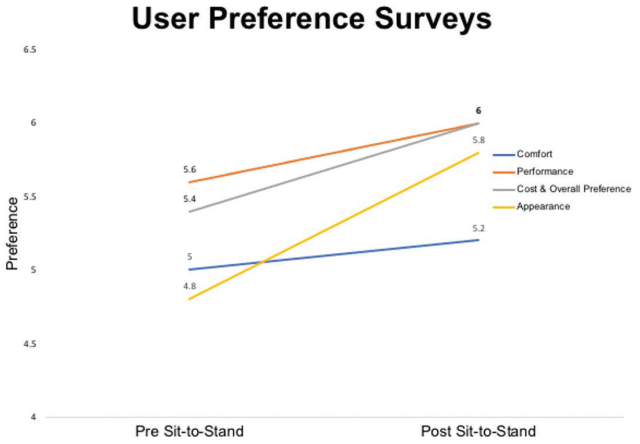

Figure 1. Average user preference results before and after orthosis use.

Table 1. 5XSTS times (seconds) in both conditions. Difference values are + if "advanced" was faster.

Subject	Standard Orthosis	"Advanced" Orthosis	Difference
1	17.17	17.06	0.115
2	17.89	17.18	0.71
3	11.62	11.64	-0.015
4	21.35	21.31	0.04
5	13.58	13.16	0.42

DISCUSSION

Three of the 5 subjects were slower than age-based norms for the 5XSTS in both conditions. Implications are unclear. Survey results were more consistent across subjects than functional outcomes.

CONCLUSION

Results show evidence of confirmation bias in self-reported outcomes and some evidence in functional outcomes.

CLINICAL APPLICATIONS

This study can help establish the need for blinding when using self-reported outcomes to influence orthotic and prosthetic treatment plans.

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Gait Study of a Novel Fast Cast Ankle Foot Orthosis

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INTRODUCTION

In the event of an acute injury to the ankle-foot complex, it is standard practice to immobilize and partially unload the foot with an ankle-foot orthosis (AFO) to prevent further musculoskeletal injury.[1] However, there are situations when the injury must be treated, but an individual might need to independently ambulate (without aids or assistance) and bear weight on the injured limb, such as in field military care. For those cases, it is crucial for the AFO intervention to support walking following acute injury by offloading and immobilizing the ankle-foot complex. We have developed an AFO system to achieve both aims by immobilizing the ankle-joint complex with a spray-on, fast-setting cast and exoskeletal frame that offloads the limb and supports ambulation with a carbon-fiber footplate. The aim of this study was to assess the effects of wearing this experimental AFO system on: (1) ankle joint motion during walking to confirm joint immobilization, and (2) endurance and walking speed.

METHOD

Institutional Review Board approval was granted by the Jesse Brown Veterans Affairs Medical Center. Written informed consent was obtained from each participant.

Participants: Ten male, able-bodied individuals participated (26.6 ± 6.6 years; 1.8 ± 0.1 m; 84.3 ± 14.7 kg).

Apparatus: The AFO consisted of a patellar tendon brace and a cuff strapped around the tibia to lift and offload the limb from the footplate, both attached to 2 upright carbon fiber struts. The ankle-foot complex was immobilized with fast-setting foam sprayed into a donned fabric sleeve to form a cast that was tethered to the AFO to reduce motion. Kinematic and kinetic data were collected using a 12-camera motion capture system at 120 Hz (Motion Analysis Corporation, Rohnert Park, CA). A full-body marker set consisting of 37 markers was used to create a 6 degree-of-freedom, 13-segment kinematic model that included the anatomical foot separate to the AFO footplate to estimate kinematics of the ankle joint.

Procedures: Participants walked back and forth along a level 10-meter walkway at their self-selected normal under two conditions: with and without the AFO. Walking trials were conducted until five clean force plate strikes were recorded for each foot, not presented in the current work. All participants wore military-style boots, and the AFO was worn without a boot. Participants also completed a 6-Minute Walk Test (6MWT) with and without the AFO to record distance walked.

Data Analysis: From the gait laboratory, kinematic data were processed using Visual3D (C-motion, Inc., Germantown, MD), filtered with a frequency cutoff of 6 Hz, and analyzed in Visual3D and custom Matlab Code (Mathworks, Natick, MA) to estimate sagittal plane ankle range-of-motion (ROM) for both limbs. Average ROM was estimated across all analyzed walking trials. Average walking speed was estimated from the 6MWT distance. A 2-way repeated measures analysis of variance (ANOVA) was used to assess the effect of AFO and limb side (affected and unaffected) on sagittal plane ankle ROM. A paired t-test was used to assess the main effect of AFO on distance and speed from the 6MWT.

RESULTS

Ankle ROM, 6MWT distance and speed are displayed in Table 1. There was a significant interaction between AFO and limb ($p < 0.001$) for ankle ROM. Simple main effects revealed significant differences between limbs in the AFO condition ($p < 0.001$) and between AFO conditions for the affected limb ($p < 0.001$). Participants walked significantly less and slower when wearing the AFO.

Table 1. Ankle ROM and 6MWT distance and speed for walking with and without the AFO.

	With AFO	Without AFO
Affected Ankle ROM (Degrees)	3.23 ± 1.8	18.65 ± 2.4
Unaffected Ankle ROM (Degrees)	22.61 ± 5.4	19.53 ± 2.3
6MWT Distance (m)	510.87 ± 104.7	632.94 ± 118.9
6MWT Speed (m/s)	1.42 ± 0.1	1.76 ± 0.3

DISCUSSION

Results suggest that our fast-cast, offloading AFO achieved its design goal as reflected by a significant reduction in the affected ankle sagittal-plane ROM, nearly eliminating all motion during walking, thereby providing evidence that we can immobilize the foot-ankle complex. Walking unaided with the AFO was possible, but with increased effort as indicated through reductions in walking speed and distance over 6 minutes. This performance decrement was due to compensations to overcome restrictions to the affected limb motion and potential limb length discrepancies.[2]

CONCLUSION

We have demonstrated the effectiveness of a fast-cast, offloading AFO to immobilize an ankle joint but allow continued unaided walking over an extended bout.

CLINICAL APPLICATIONS

In the event if an acute injury to the ankle-foot complex, this device may be used to assist the injured individual to ambulate under his or her own power.

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Development of an Online Pediatric AFO Evaluation and Decision-Making Tool

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INTRODUCTION

Although there are published algorithms for pediatric ankle-foot orthosis (AFO) decision-making, few practitioners are applying these tools in practice.[1,2] There is a need for AFO guidelines that can be applied in multiple contexts and with practitioners of varying experience in order to improve consistency in orthotic care.[3] The primary purpose of this study was to develop an online tool to aid in the evaluation, decision-making, and design process of pediatric AFOs. The secondary purpose was to determine which of the evaluation procedures included in the tool were utilized by clinicians in practice.

METHOD

This 2-phased study involved a consensus technique to develop the tool followed by trial implementation.

Participants: Five experienced clinicians from multiple professions were recruited to participate in a modified Delphi approach to consensus on the AFO tool. Following tool development, certified prosthetist- orthotists, residents, and students were recruited as a trial group (TG) through convenience sampling.

Apparatus: A repeated measures survey approach was used with the consensus group (CG). A post-use survey assessed the following dimensions on a 5-point scale (1 = strongly disagree, 5 = strongly agree): whether decision-making tool was clear and easy to follow; whether the language and descriptions were appropriate for clinicians at all stages of education and experience; whether the tool reflected applicable knowledge and recommendations; and whether they would recommend the tool to others.

Procedures: The CG was asked to provide feedback and answer a survey after multiple iterations of a tool created by the research team. The TG was asked to use the tool, offer feedback on its agreement with the recommended design, and rate the utility of the tool according to the dimensions outlined above. TG participants were asked to report whether they performed each aspect of the evaluation as indicated by the tool.

Data Analysis: Responses were evaluated for rates of agreement, descriptive statistics, trends across groups, and which portions of the evaluation process were completed in clinic.

RESULTS

After 3 rounds of tool development, all 5 members (100%) of the CG agreed or strongly agreed that the steps in the decision-making tool were clear and easy to follow and that the language and descriptions in the decision-making tool were appropriate for clinicians at all stages of education and experience. Four out of 5 (80%) agreed or strongly agreed that the tool reflected applicable knowledge and recommendations and that they would recommend the tool to others.

Sixteen TG participants of varying clinical experience utilized the tool and answered the post-use survey. Sixty-nine percent of the TG indicated that they would recommend the same AFO design as generated by the tool. Ninety percent agreed or strongly agreed that the tool was clear and easy to follow, and the language was appropriate for clinicians at all stages. Seventy-three percent agreed or strongly agreed that the tool reflected applicable knowledge and recommendations. Forty-five percent of respondents indicated they would recommend the tool to others. Almost half of the TG respondents did not assess their patient's foot length or height in relation to making AFO design decisions.

DISCUSSION

This study presents a methodological and developmental approach to designing a pediatric AFO evaluation, decision-making, and design tool. Early results indicate the tool aligns with clinician-decision making and may be useful for practitioners with less experience. Feedback indicated a need to incorporate additional factors, such as patient or parent preference, into the decision-making process.

CONCLUSION

CG and TG participants indicated alignment with the recommendations generated by the tool and offered both positive and constructive feedback. The current iteration may be useful in educational settings and in contexts.

CLINICAL APPLICATIONS

Instructive and informative clinical decision-making tools may improve consistency and standards in orthotic care.

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Improvement in Walking Speed and Reduction in Falls and Risk of Falling: Results from the C-Brace® Registry

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INTRODUCTION

Orthosis users with neuromuscular disease and central nervous system disorders fall frequently, and reducing falls is an important goal for health care professionals in treating these patients.[1] The C-Brace is a microprocessor-controlled stance and swing controlled orthosis (MP-SSCO) that provides stumble recovery. Previous studies have shown that C-Brace reduces the potential for falls after a stumble, may reduce fall frequency, and improves patient-perceived safety.[2–4] A prospective, multicenter registry was designed to gather real-world safety and effectiveness data from patients who have been fitted with a C-Brace. Results for walking speed, falls, and outcomes measuring fall risk are presented.

METHOD

Thirty-nine O&P clinics were in the United States and Europe agreed to participate in an observational registry targeting a minimum enrollment of 65 patients fitted with a C-Brace. Institutional Review Board or ethics committee approval was obtained, and all subjects provided informed consent.

Participants: Forty-two subjects had both baseline and follow-up data for the analysis: 14 female/28 male, mean age of 52.5 (22–83) years and mean weight of 178 (58–270) lbs. Nine subjects were bilateral users. Most common diagnoses were incomplete spinal cord injury (11), polio (8), trauma (7), iatrogenic (3), and multiple sclerosis (2), but many other causes (10) also led to paralysis of the knee stabilization muscles and a KAFO indication; 1 primary diagnosis was unknown.

Apparatus: Outcome measures included a timed walking test (25 feet or 10 meters) at a fast walking speed (FWS), the Timed Up and Go (TUG) and the Activity-Specific Balance Confidence Scale (ABC). In addition, the number of falls in the previous 6 months was collected.

Procedures: Assessments were done by the orthotists at baseline with the existing orthosis and at 6 and 12 months with the C Brace.

Data Analysis: Means and standard deviations were calculated at baseline and follow-up. For patients who dropped out of the study or missed their 12-month follow-up, 6-month data were used for data analysis. Changes of +0.1 meters/second, -3.6 seconds, +13%, and -25% compared to baseline were considered clinically meaningful for FWS, TUG, ABC, and fall frequency respectively. Multiple fallers were defined as those falling twice or more in 6 months. Paired t tests were used if data were normally distributed and Wilcoxon Signed-Rank Test if not.

RESULTS

The mean scores and changes versus baseline by outcome are summarized in Table 1. The subjects showing improvement, no change, or decline for each outcome measures are shown in Table 2.

DISCUSSION

Most subjects increased in FWS, with the average change twice what is considered clinically meaningful. The majority also showed clinically meaningful average improvements in TUG, ABC, and fall frequency. Subjects falling daily or weekly at baseline skewed the fall results, but the median number of falls dropped from 3 at baseline to 1 at follow-up. Furthermore, 86% of subjects who were classified as "multiple fallers" at baseline or follow-up demonstrated a clinically meaningful reduction in falls. Overall, 67% of subjects were responders with a meaningful improvement in at least one outcome without declining in any other. These results suggest a reduced risk of falling confirmed by a reduction in reported fall frequency for most subjects.

Table 1. Mean ± SD for outcome scores at baseline and follow up after C-Brace fitting. Falls reported as means in the upper row and medians in the bottom. *Denotes Wilcoxon Signed-Rank Test.

Outcome	Baseline	Follow-Up	Change	p
FWS (m/s) n=38	0.72±0.34	0.95±0.43	+0.23±0.33	<0.001
TUG (s) n=38	24±18	16±10s	-8.2±10.3s	<0.001*
ABC (%) n=40	46±22	71±18	+25±26	<0.001
Falls (n=36)	26±70	2.8±5.6	-24±65	<0.05*
	median: 3	median: 1	median: -2	

Table 2. Number of subjects showing clinically meaningful improvement or decline compared to baseline.

	Improved	No Change	Declined
FWS	24 (62%)	9 (24%)	5 (13%)
TUG	21 (53%)	15 (39%)	2 (5%)
ABC	21 (53%)	18 (45%)	1 (3%)
Falls in			
multiple fallers (n=22)	19 (86%)	1 (5%)	2 (9%)

CONCLUSION

Interim results from this prospective registry revealed that most C-Brace subjects demonstrated clinically meaningful improvements in walking speed and in both objective and subjective measures of the risk of falling and fall frequency.

CLINICAL APPLICATIONS

A registry in the context of routine clinical practice characterizes real-world benefits of the C-Brace for reducing falls and improving walking speed.

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Burden and Outcome of Microprocessor-Stance-and-Swing-Phase-Controlled-Knee-Ankle-Foot Orthoses and Conventional Knee-Ankle-Foot Orthosis from Two Perspectives: Experts and Patients

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INTRODUCTION

The burden of disease (BoD) and the individual needs of people requiring knee-ankle-foot orthoses (KAFOs) have so far received little consideration. Knee instability can cause a variety of problems, including pain, falls, mobility problems, and limited participation in daily activities. All of such 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 and individual patients and to understand the benefits of using a microprocessor-based stance-and-swing-phase-controlled KAFO (MP-SSCO).

METHOD

The results of a published semi-structured expert interview were evaluated together with an observational patient survey sponsored by Ottobock. Both research projects have been conducted in Germany.

Participants: Twenty-two individuals who had used an MP-SSCO (C-Brace) for at least 6 months and had used a conventional KAFO prior, or were fitted with a MP-SSCO as their first orthosis, >18 years of age, were invited by their orthopedic technician to take part in an online survey.

Apparatus: LimeSurvey using Likert-Scale-based questionnaires directed to inform on perceived burden of disease.

Procedures: After giving informed consent, participants received a survey link and filed out the questionnaire digital at home.

Data Analysis: Statistical analysis was conducted using IBM SPSS Statistics Version 29.0.0.0; the Mann-Whitney U test was used for comparisons for the observational study. The comparison of both projects is descriptive.

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

RESULTS

From an expert point of view, the restriction in mobility was the leading observed patient burden, and impaired climbing of stairs obtained the highest expert-observed frequency of impairments. Quality of life, improved gait pattern followed by 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.

Mobility and functionality with the MP-SSCO were well perceived by the patients. The average usability of the MP-SSCO was ranked 2 (good) compared to an average of 4 with the previous SCO. When evaluating the gait pattern, over 90% of the participants stated that they achieved poor or very poor harmonization with the previous orthosis compared to only 9% using the MP-SSCO. When rating the ability to descend stairs with the SCO, 11% of the patients rated it to be good compared to 95% MP-SSCO who said they were able to descend stairs well or very well. In total, falls were reported by 59.1% of patients at a combined annual frequency of 77.3 fall events per year when using conventional KAFOs. Only 45.5% of MP-SSCO users reported to have fallen with a combined annual frequency of 11.5 falls. The MP-SSCO is considered better compared to the former orthosis used in opinion of the majority (94%) of participating patients.

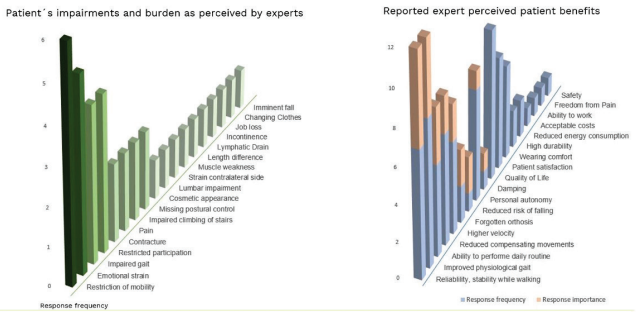

Figure 1. Impairment, burden, and benefits perceived by the experts.

DISCUSSION

Mobility and participation (daily routine, personal autonomy, ability to work) were the most frequently and most important topics mentioned by the experts and demonstrated by patient outcomes.

CONCLUSION

Patients' outcome and expert's opinion 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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Race and Ethnicity Reporting in Contemporary Limb-Loss Literature: A Scoping Review

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INTRODUCTION

Accurate and consistent reporting of demographic data, including race and ethnicity, is essential for identifying, studying, and addressing health disparities. Race and ethnicity, widely accepted as social constructs, are often used as proxy variables to measure bias and discrimination (i.e., racism) experienced by racial and ethnic minorities.[1] Racism, as a social determinant of health, contributes to health disparities and resultant inequities.[2]

Significant racial and ethnic disparities exist in the prevalence and incidence of lower-limb amputation in the United States, which cannot be explained by biological or genetic factors.[3] Rather, disparities in amputation prevalence and incidence among people of color are most likely due to social causes such as racism.[3,4] Understanding these disparities can inform the development of equitable health care strategies for people with limb loss.

Incomplete or inconsistent reporting of demographic data impedes the identification, study, and mitigation of health disparities.[5] Detailed reporting of demographic data is crucial for assessing the generalizability of study results and facilitating synthesis of data across studies.[6] The purpose of this scoping review was to assess the frequency and variability with which race and ethnicity are reported in recent articles that present results of limb-loss research conducted in the United States.

METHOD

A comprehensive search of CINAHL, PubMed, and Web of Science was used to identify original, peer-reviewed articles that described the results of research conducted in the United States involving individuals with limb loss published between January 2015 and December 2020.

Procedures: The search strategy included controlled vocabulary and free-text terms related to "amputation" and "artificial limb." Journals that regularly publish limb-loss articles (defined as ≥30 from 2015 to 2020) were selected for inclusion. After removing duplicates, eligible articles underwent sequential title, abstract, and full-text reviews by two independent researchers. Data from eligible articles were extracted using a Microsoft Excel template. One reviewer extracted the data and another verified its accuracy. A third reviewer resolved discrepancies. Extracted data included study design, publication year, number of participants, race and ethnicity categories used, number of participants per race/ethnicity category, levels and etiologies of limb loss, and study focus.

Data Analysis: Articles were grouped based on the reporting or non-reporting of race and ethnicity data and stratified by limb-loss level (upper/lower), etiology (dysvascular/non-dysvascular), study focus (prosthetic technology/other), study design (observational/experimental/mixed), and publication year. Descriptive analyses were conducted to evaluate the quality and consistency of racial and ethnic reporting relative to established governmental reporting standards.

RESULTS

Across 420 eligible research articles included in this scoping review, only 16% (n = 67 articles) reported race or ethnicity data. Classification of race and ethnicity was inconsistent; 40 variations of racial and ethnic categories were used to classify participants across the 67 articles. Additionally, 10 of the reviewed articles reported race as only a binary variable (e.g., White and non-White). A disparity was observed in the race reporting across articles. The racial categories most frequently reported across articles were White (n = 56 articles), followed by Black (n = 40 articles), while other racial categories such as American Indian/Alaskan Native, Asian, and Native Hawaiian/Other Pacific Islander were reported at substantially lower frequencies (n = 21, n = 19, and n = 16 articles, respectively).

DISCUSSION

These findings suggest three deficiencies with how race and ethnicity are reported in contemporary limb-loss literature: (1) low frequency of reporting participant race or ethnicity, (2) lack of specificity in race reporting, and (3) limited adherence to existing standards for reporting race and ethnicity categories.

CONCLUSION

This review details the current state of reporting practices for race and ethnicity variables in limb-loss research and highlights the need for improved adherence to reporting standards. Race and ethnicity reporting is essential to reduce health information disparities and improve care and outcomes for minority groups in the limb-loss community.

CLINICAL APPLICATIONS

The limb loss research community should commit to consistent and reliable race and ethnicity reporting to promote accurate assessment of generalizability of research findings and to reduce health information disparities experienced by racial and ethnic minorities.

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Validity of the Fitbit Inspire 3 to Predict Daily Step Count in Adults with Transtibial Amputation

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INTRODUCTION

Accelerometers can be used to assess the physical activity (PA) of individuals with amputation. The activPAL and Fitbit represent two devices utilized in research, clinical, and commercial settings to collect PA information. While the activPAL has been used in various studies featuring individuals with amputation, the validity of the commercially available Fitbit Inspire 3 has not been extensively tested in this group.[1,2]

Determining the Fitbit's validity among individuals with amputation is important because Fitbits are a more feasible, cost-effective option for assessing rehabilitative outcomes compared to research-grade devices. Fitbits may also serve as a motivational tool for those interested in enhancing their daily PA. Thus, the purpose of this study was to investigate the validity of the Fitbit for assessing steps in individuals with transtibial amputation (TTA).

METHOD

The Syracuse University Institutional Review Board approved this study, and informed consent was obtained from volunteers prior to participation.

Participants: Participants were between the ages of 18 and 80 and had a unilateral TTA. Participants had used a prosthesis for ≥ 3 months prior to beginning the protocol and had no other movement disorders.

Apparatus: The activPAL 3 is triaxial accelerometer that estimates sitting, standing, walking, and step count using proprietary algorithms based on measurements of acceleration. The Fitbit Inspire 3 is a microelectromechanical accelerometer that collects data in 60-second epochs and converts raw acceleration data to step counts using proprietary algorithms.

Procedures: Participants completed a health survey and were provided with activPAL and Fitbit accelerometers to wear concurrently for 7 days. The activPAL was worn on the non-amputated thigh and the Fitbit was worn on the non-dominate wrist.

Data Analysis: The relationship between devices was examined using Pearson Correlation. Equivalence testing, Bland-Altman analysis, paired samples t-test, mean difference and mean absolute difference (MAD) were calculated to assess difference between devices.

RESULTS

A total of 79 adults (58.1 ± 14.8 years; 22 women) provided valid Fitbit Inspire 3 and activPAL 3 data. A high correlation was found between the two devices ($r = 0.93$). However, paired samples t-test revealed significant mean differences between the devices ($t_{78} = -6.83$, $p < 0.001$). The activPAL predicted an average of 4,674 ± 3,081 steps per day while the Fitbit predicted 5,768 ± 3,750 steps per day. The mean difference and MAD between the activPAL and Fitbit Inspire 3 was 1,094 ± 1,423, and 1,347 ± 1,184 steps, respectively.

The results were outside of the 95% confidence interval for equivalency, indicating that equivalency could not be claimed (lower 95% confidence interval: $t_{78} = 9.75$, $p < 0.00$; upper 95% confidence interval: $t_{78} = 3.91$, $p > 0.99$). Bland-Altman plots yielded 4 participant data points outside the 95% limit of agreement (±1.96 SD) (Figure 1).

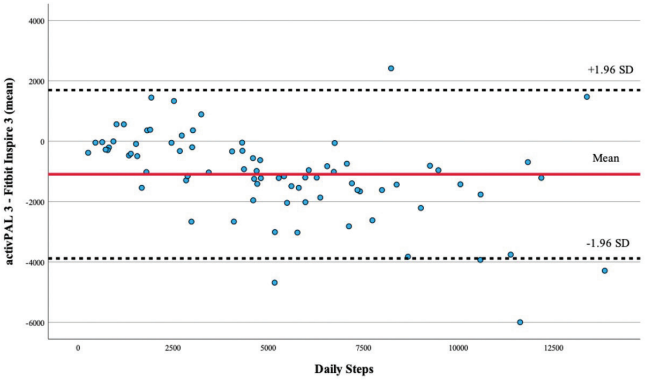

Figure 1. Bland-Altman plot of activPAL and Fitbit predicted daily steps. Bland-Altman plots comparing devices yielded four data points outside the 95% limit of agreement (±1.96 SD).

DISCUSSION

This study provides insight into the validity of Fitbit for estimating steps for individuals with TTA. While a strong relationship was noted between the devices, they may not be equivalent or interchangeable. These limitations should be considered before selecting the most appropriate option this population. This study highlights the importance of noting the incongruities between commercially available and research-grade accelerometers when estimating steps in this group.

CONCLUSION

The Fitbit overestimated PA by predicting higher steps compared to the activPAL. Because of the significant mean differences and large MAD between the devices, the activPAL and Fitbit are not interchangeable for estimating PA in individuals with TTA.

CLINICAL APPLICATIONS

Individuals with TTA should be cautious when selecting and interpreting data from commercially available accelerometers. Although these devices can be valuable for monitoring PA, inter-device comparisons may be nuanced and not always provide accurate and/or interchangeable data.

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Comorbidity Screening and Referral by Prosthetists

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INTRODUCTION

As compared to the general population, life-altering and life-limiting comorbidity rates are higher among adults with lower-limb amputation (LLA). Peripheral neuropathy and peripheral vascular disease (PVD) affect >50% of adults with LLA and are risk factors for subsequent amputation.[1] Low back pain (LBP) and depression are associated with reduced quality of life.[2] Prosthetists may play a role in comorbidity screening to mitigate potential negative sequelae, as assessment of protective sensation, circulation, mental function, and pain is within a prosthetist's scope of practice. Given that screening is part of a holistic approach to patient care, it is possible that satisfaction might be enhanced. Further, referral for life-limiting conditions may reduce unnecessary care visits for prosthetic modifications that fail to overtly address psychological and/or pain-related factors impacting prognosis. Thus, the purpose of this study was to establish feasibility and explore potential benefits of comorbidity screening by prosthetists during routine follow-up appointments. We hypothesized that the addition of comorbidity screening would result in greater patient satisfaction at 3 months and less prosthetic care minutes over 3 months.

METHOD

This pilot, randomized clinical trial, approved by our Institutional Review Board for Human Subjects Research, recruited 70 adults with unilateral LLA (≥1-year of prosthesis use), from June–November 2022.

Participants: Participants included 70 adults (68.6% male; mean age ± standard deviation: 59.6 ± 12.5 years; 71.4% transtibial-level amputation; 22.9% African American/Black)

Apparatus: Peripheral neuropathy was evaluated via monofilament testing on the non-amputated plantar foot using a 10g filament. PVD was evaluated via dorsalis pedis and posterior tibial pulse palpation for presence or absence. Moderate to high risk for persistent, disabling LBP was assessed using the 6-item, STarT Back Screening Tool.[3] The 9-item Patient Health Questionnaire (PHQ) was used to screen for major depression and suicidal ideation.[4] The Orthotic-Prosthetic Users Survey (OPUS)[5] and the Client Satisfaction Inventory (CSI)[6] were used to evaluate patient satisfaction at 3 months. Prosthetic service utilization over 3 months was evaluated as the number of prosthetic care minutes following the baseline visit.

Procedures: Participants were randomized into 1 of 2 study arms: standard of care (SOC; n = 35) or SOC + screening (n = 35), where patients received comorbidity screening by a certified prosthetist and education on screening findings. Screening results were communicated to the patient's primary care provider. At 3-months, satisfaction surveys were administered, and data were extracted from medical chart reviews. The 4 participating prosthetists logged interactions with primary care providers and their medical staff.

Data Analysis: With n = 35 per group (and 17% attrition), we were powered to detect a medium-to-large effect; i.e., .66. Mann Whitney U tests were used to evaluate between-group differences in non-parametric data ($p \leq .050$) using IBM SPSS Statistics 28.

RESULTS

Based on prosthetic check-in and check-out times, the average appointment time was 70 ± 20 minutes for SOC and 73 ± 20 minutes for SOC+ ($p = .425$). There were no significant differences between study arms in 3-month satisfaction, per OPUS or CSI, nor number of care minutes ($p > .050$; Table 1). Of note, at baseline, 47.8% and 77.1% of participants had maximum scores for the OPUS services and CSI, respectively. Prosthetists had no negative interactions with primary care teams.

Table 1. Primary Outcomes Between Study Arms

	SOC	SOC+	p
OPUS devices, 11-55	40 (33, 46)	42.5 (38, 49)	.178
OPUS services,10-50	47 (40, 50)	49 (44, 50)	.135
CSI, 0-100%	100 (73.8,100)	100 (96.3, 100)	.829
Care minutes over 3 months	77 (35, 168)	51 (32, 119)	.352

Data presented as median (25th, 75th percentile).

DISCUSSION

Alternate outcome measures for evaluating prosthetic service satisfaction are recommended due to ceiling effects of the OPUS and CSI. The time necessary to incorporate comorbidity screening in prosthetic clinical care may be negligible. Primary care appears receptive to prosthetist screening, reporting, and referring.

CONCLUSION

Short-term and long-term benefits of prosthetist comorbidity screening remain theoretical, despite some evidence of potential clinical feasibility.

CLINICAL APPLICATIONS

As the field advances, prosthetists might align their clinical practice with other allied health professionals who routinely screen and refer for comorbidities.

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Fidelity and Prosthetists' Perspectives from a Clinical Trial

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INTRODUCTION

Adults following lower-limb amputation (LLA) are known for their medical complexity, including multiple comorbidities, which can contribute to mediocre outcomes. Comorbidity screening in prosthetic clinical practice is not routine. Clinical trials among patients with LLA are lacking, particularly those conducted during outpatient visits to prosthetic practices. Thus, the objectives of this clinical trial were to evaluate (a) prosthetist acceptability of comorbidity screening post-LLA, and (b) the feasibility of conducting comorbidity assessment and education during routine prosthetic care visits. We sought to understand prosthetists' perspectives as they relate to comorbidity screening during routine prosthetic visits. We hypothesized that intervention fidelity would be >90% and that few protocol deviations and adverse events would occur.

METHOD

Prosthetists participated in a randomized clinical trial, approved by our Institutional Review Board for Human Subjects Research, which recruited 70 adults with unilateral LLA, from June to November 2022.

Participants: The 4 prosthetists (1 male; 3 females) had approximately 38 years of collective experience as certified prosthetists-orthotists (range: 1.3–17.7 years).

Procedures: Board-certified prosthetists completed Human Subjects and Good Clinical Practice Training, read the manual of operating procedures for the study, and underwent 4 hours of pre-trial training, including skills checks and role-playing using case-based scenarios. Consecutive, eligible patients were randomized into 1 of 2 study arms: standard of care (SOC; n = 35) or SOC + screening (n = 35). All participants underwent self-report and performance-based tests; e.g., Prosthetic Limb User's Survey of Mobility,[1] Timed Up and Go,[2] and 10-Meter Walk Test.[2] SOC+ participants also received comorbidity screening for peripheral vascular disease (pulse assessment); peripheral neuropathy (monofilament assessment); elevated risk for persistent, disabling low back pain (STarT Back Screening Tool);[3] and major depression and suicidal ideation [9-item, Patient Health Questionnaire (PHQ-9)].[4] Prosthetists shared screening findings with their patients using a template form/letter, and results were communicated to the patient's primary care provider via the letter and a follow-up phone call when indicated (e.g., major depression, suicidal ideation). Prosthetists logged interactions with primary care teams, protocol deviations, and adverse events.

Data Analysis: Fidelity was evaluated using standardized checklists by the principal investigator and consisted of 1 onsite observation per prosthetist and medical chart reviews of all evaluations. A 2-hour prosthetist focus group was held in December 2022.

RESULTS

Onsite fidelity was >99%. Fidelity per 70 chart reviews was 95.7% for SOC and 95.9% for SOC+. Eight protocol deviations were reported, 5 of which were justified modifications of performance-based testing procedures. Prosthetists followed-up via telephone with primary care teams regarding 8 participants and deemed the 13 interactions overall as "neutral" (other options were "positive" and "negative"). Two adverse events were reported, 1 of which related to study testing.

Prior to the start of the study, prosthetists had not used pulse palpation, the PHQ-9, or the STarT Back Tool in clinical practice. Prosthetists acknowledged learning monofilament testing in their prosthetics-orthotics education programs, but most did not routinely use this screen in clinical practice. After study participation, prosthetists agreed that monofilament testing was valuable as it reminded them to look at the non-amputated side and facilitated a conversation about the patient's general limb health. Pulse assessment was found to be challenging; concerns included potential bias given the patient's medical history (e.g., vascular disease) and lack of confidence with interpretation of pulse presence/absence. Prosthetists agreed that screening helped to "show they were part of the health care team and that they care." Prosthetists offered the following screens for consideration at routine prosthetic follow-ups: blood pressure using automated cuff, heart rate using pulse oximeter, and skin/wound assessment. Prosthetists commented that the template form/letter helped facilitate explanation of the findings with the patient and communication with the primary care provider. Standardized follow-up examinations "made it easier to see other prosthetists' patients."

DISCUSSION

Consideration of focus group feedback may inform future clinical trials. Trained prosthetists can carry out a trial in everyday practice with excellent fidelity and few unjustified protocol deviations and adverse events.

CONCLUSION

Stakeholder engagement has provided valuable insight and pilot data for a larger-scale, multisite, clinical trial evaluating comorbidity screening by certified prosthetists during routine post-LLA care.

CLINICAL APPLICATIONS

Monofilament testing may facilitate patient education on limb health. Template forms/letters for facilitating communication of comorbidity findings appear helpful.

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Metabolic Cost of Walking during Steady and Non-Steady State Tests in Persons with Lower-Limb Amputations

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INTRODUCTION

Metabolic outcome measures are useful when comparing different prosthetic devices or therapy interventions. The most accepted steady state metabolic test is a 6-minute treadmill walk. Unfortunately, for a large portion of the population with amputations, specifically those with low mobility levels and dysvascular amputations, continuously walking on a treadmill is often not achievable or representative of typical ambulation. However, shorter tests which may be more applicable to this population do not achieve the steady state criteria.[1] This limits participation in research for those who would greatly benefit from the development of prosthetic components that reduce energy cost. Our study looks to investigate whether metabolics of a shorter treadmill walk that is not considered steady state correlates with the steady state metabolics of a 6-minute treadmill walk.

METHOD

Institutional Review Board approval was obtained (STU00209522), and participants were recruited from a research registry and clinical referrals.

Participants: Thirty individuals participated: 10 persons without amputations (5 male / 5 female, 29.6 ± 10.1 years), 10 persons with transtibial amputations (8 male / 2 female, 52.9 ± 11.8 years, 6 traumatic, 2 sarcoma, 2 infection/other), and 10 persons with transfemoral amputations (7 male / 3 female, 46.2 ± 15.5 years, 5 traumatic, 4 sarcoma, 1 other).

Procedures: Participants selected their preferred walking speed on a treadmill during an acclimation period. A Cosmed K5 portable metabolic unit was donned. Participants were given at least 7 minutes of seated rest prior to any testing. They then walked on a treadmill at a constant pace (their pre-determined preferred walking speed) for 6 minutes.

Data Analysis: Metabolic data were exported from the Cosmed system, and O_2 cost (ml/kg/m) was calculated. Data averaged over minute 2 represented a 2-minute non-steady state walk, and data averaged over minutes 4 to 6 represented steady state. Paired Pearson correlations were performed to compare minute 2 results with steady state results. Significance level was set to $p < 0.05$.

RESULTS

Strong correlations were found in O_2 cost between minute 2 and steady state in all 3 populations (control: $r = 0.92$, $p < 0.01$; transtibial: $r = 0.98$, $p < 0.01$; transfemoral: $r = 0.99$, $p < 0.01$; all populations combined: $r = 0.99$, $p < 0.01$) (Figure 1).

DISCUSSION

These results reveal a very strong positive correlation between steady state O_2 cost from 6 minutes of walking compared to only 2 minutes. This indicates that only 2 minutes of walking may be required to obtain valid results for assessing relative metabolic differences.

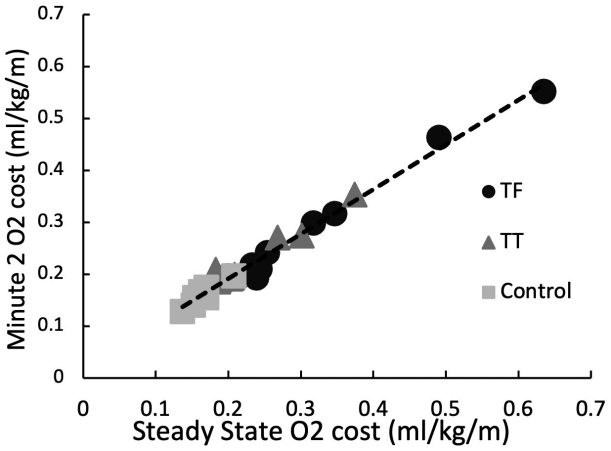

Figure 1. O_2 Cost for minute 2 compared to steady state.

Previous studies with individuals with amputations have investigated shorter tests but did not compare with steady state results. The shorter time requirement has the potential to increase the population that can participate in metabolic testing. This test also better represents a more typical walking duration than the 6-minute test. Study limitations include a relatively small number of participants (10 in each group) and participants with generally high activity levels.

CONCLUSION

To obtain meaningful metabolic results, a 6-minute steady state treadmill walk may not always be necessary. Instead, a shorter 2-minute constant speed treadmill walk may provide results that are both strongly correlated with steady state and more representative of real-world activity.

CLINICAL APPLICATIONS

These results may be applicable to increasing the population that can participate in metabolic testing. This has potential to be used for assessing efficiency of prosthetic components and tracking of aerobic fitness levels of persons with amputations, specifically those with lower activity levels.

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Comparing Clinical and Real-Word Outcome Measures: Assessing Activity Levels in Lower-Limb Prosthesis Users

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INTRODUCTION

Traditional in-clinic self-reported and performance-based outcome measures have been commonly employed in the evaluation of lower-limb prosthetic users' functional levels.[1] In this study, wearable pedometers were utilized to monitor users' overall activity levels in a real-world environment. The goal of this study is to present a comparative analysis between the 2 assessment methods and highlight the advantages of incorporating daily-life activity monitoring. With this approach, we aim to overcome certain constraints associated with relying solely on clinical assessments.

METHOD

Participants: Four patients were included in the study.

Apparatus: AMPPRO questionnaires; wearable pedometers, and informed consent.

Procedures: Initial assessment: Participants completed AMPPRO questionnaires, and in-clinic K-levels were obtained. Pedometer application: Participants were given pedometers to wear for 8 consecutive days.

Data Analysis: Step data was collected to calculate metrics such as the Blind 2-Minute Walk Test (B2MWT), which represents the number of strides taken during continuous walking for 2 minutes without the patient knowledge. The average B2MWT and the proportion of days with detected B2MWTs during the evaluation period were determined. Additionally, the frequency of different stepping rates (cadences) was assessed for each patient. By combining the clinician assessments with the derived step data,[2] a "calculated K-level" was obtained. This calculation incorporated metrics such as energy expenditure (kcal burned), peak cadence, daily steps, and cadence variability observed during the data acquisition days.

RESULTS

Table 1. Patient Data Collected during the Study.

Patient ID	BK1	BK2	AK1	AK2
AMPPRO	35	42	37	38
In-clinic K-level	2	3	3	3
Average B2MWT (strides)	91	117	124	105
% of days with ≥1 detected B2MWT	100	50	75	25
Average Daily steps	9,539	6,071	5,989	4,064
Calculated K-level2	3.7	3.7	3.8	3.4

DISCUSSION

Table 1 presents the collected AMPPRO scores, resulting K-levels, B2MWTs, and step counts for all patients. The distribution of different cadences' occurrences is shown in Figure 1. A comparative analysis was conducted between the 2 participants with below-knee amputations (BK1 and BK2) and the 2 participants with above-knee amputations (AK1 and AK2).

BK1 was rated as K2 at the clinic, while BK2 received a K-3 rating (Table 1). Table 1 reveals that BK2 had 50% of the observed days with continuous 2-minute bouts of walking, while BK1 performed

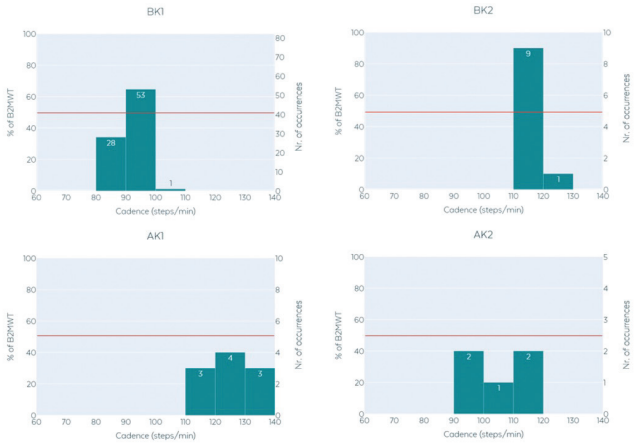

Figure 1. Cadence histograms for the 4 evaluated patients.

B2MWTs daily. Both achieved daily step counts typical of K-4 prosthesis users, with BK1 recording a significantly higher value (averaging 3,468 more daily steps than BK2). Figure 1 illustrates that BK1 walked at lower cadences than BK2 but showed higher levels of daily activity, with 53 B2MWTs detected at a pace of 90–100 steps per minute. Both patients had a "calculated K-level" of 3.7, which is supported by established reference cadence values2 that place both patients in high gait intensity ranks (cadence above 80 steps/minute) and surpass the defined thresholds of typical K4 profiles.[3]

Despite both AK1 and AK2 being clinically evaluated as K3, there were significant differences in their remote evaluations. AK1 demonstrated a higher mobility level, performing B2MWTs on 75% of the observed day, while AK2 only managed to walk continuously for 2 minutes in 25% of the observed days. Figure 1 demonstrates that AK1 maintained higher cadences for a greater portion of time (70% of the time at 120–140 steps/minute) and had more occurrences of 2-minute gait bouts. By combining the activity monitoring parameters with the initial in-clinic evaluation, AK1 achieved a "calculated K-level" of 3.8. This calculation aligns with typical K4 profile metrics,[3] such as a daily step count of 5,000 or more and a registered cadence of 100 steps/minute or higher. On the other hand, AK2 exhibited a lower level of activity with a daily step count consistent with K3 profiles[3] (2,500 or more daily steps). The "calculated K-level" for AK2 was determined to be 3.4.

CONCLUSION

This study highlights the effectiveness of remote monitoring as a valuable tool in patient evaluation. It complements clinic assessments and enables more informed decisions regarding K-level attribution.

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Response Probabilities of PLUS-M Scores for Individuals with Lower-Limb Amputation

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INTRODUCTION

Improving mobility is a primary goal of rehabilitation after lower-limb amputation. Increased mobility is associated with many aspects of well-being, including quality of life and satisfaction.[1] Measuring mobility also facilitates goal setting during rehabilitation.[2]

The Prosthetic Limb Users Survey of Mobility (PLUS-M) is a self-report survey created to measure prosthetic mobility.[3] PLUS-M was developed using item response theory (IRT), similar to instruments from the Patient-Reported Outcomes Measurement Information System (PROMIS). PLUS-M asks respondents to rate their difficulty in performing various activities using a 5-point ordinal scale that ranges from "unable to do" to "without any difficulty." The resultant score is a T-score. Previous research has expanded interpretation of T-scores for various PROMIS measures through response probabilities.[4] The goal of this study is to determine response probabilities of PLUS-M using a similar approach.

Results from this study will help clinicians and patients contextualize the meaning behind changes in PLUS-M T-scores and establish expectations for individual item responses relative to a given T-score.

METHOD

Data: The training dataset included 28,719 outcomes, and the test dataset included 26,535 outcomes.

Instrument: PLUS-M 12-item short form (v1.2).3

Procedures: The PLUS-M probability maps were built using the training dataset. IRT-generated item characteristic curves (ICCs) were used to calculate the most likely response. These responses were then "mapped" to a T-score. Four cohorts were compared: individuals with below-knee amputation due to dysvascular disease (BK_DV), above-knee amputation due to dysvascular disease (AK_DV), below-knee amputation due to trauma (BK_T), and above-knee amputation due to trauma (AK_T).

Data Analysis: T-scores from the test dataset were used to predict responses to each item (based on T-score). The predicted responses were compared to the actual responses. Accuracy was defined as the percentage of outcomes with a difference of ± 1 point.

RESULTS

The resulting probability maps (Figure 1) indicate an estimate of the expected responses for each T-score for each cohort. For example, an individual with BK_DV and a T-score of 49 would be expected to answer "without any difficulty" to PLUS-M item 1 ("are you able to walk a short distance in your home?"), "with a little difficulty" to items 2 and 3, and "with some difficulty" to item 4, and so forth. Accuracy and mean T-scores for each cohort are displayed in Table 1.

DISCUSSION

On average, maps for the 4 cohorts had relatively high accuracy (~90%). However, the AK_DV cohort had lower accuracy. This may be due to the lower overall T-score (39.4) and increased number of patients reporting "unable to do" for most items. Thus, the PLUS-M map underpredicted responses for this cohort. Future work should focus on different modeling techniques to generate the PLUS-M maps to account for different distributions in responses.

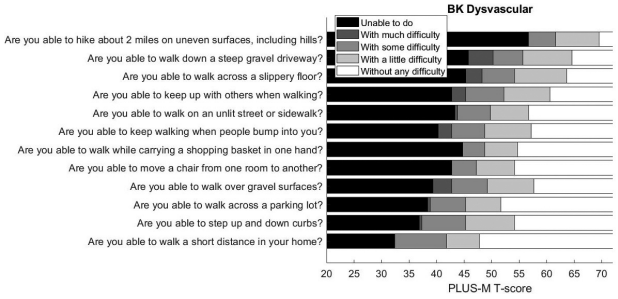

Figure 1. Expected responses to items on the PLUS-M 12-item short form for individuals with below-knee amputation due to dysvascular disease.

Table 1. Average accuracy of the IRT predicted versus actual item responses. Accuracy was defined as the percentage of outcomes with a predicted response ±1 point from the actual response. Mean T-scores are from the test dataset.

	BK_T	AK_T	BK_DV	AK_DV
Accuracy (%)	92.7	95.6	89.0	67.1
Mean T-Score	52.3	48.3	46.0	39.4

CONCLUSION

The maps generated from this study offer further interpretation of the PLUS-M T-score. Clinicians can use this information to manage expectations with their patients and provide targeted areas of improvement to focus on during rehabilitation and physical therapy.

CLINICAL APPLICATIONS

In addition to the above, clinicians can also use this information to contextualize what T-score changes mean for their patients. For example, a change from a 45 to 55 could be conveyed as the difference between "*with some* difficulty" to "*without any* difficulty" when stepping up and down curbs.

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A Pilot Study to Evaluate the Effects of Hydraulic Ankle-Foot Prostheses in K2-Level Ambulators

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INTRODUCTION

Prosthesis users perform many basic indoor and outdoor walking activities where traversing uneven terrain and slopes or ascending and descending stairs may be necessary in addition to level-ground walking. Increased prosthetic ankle range of motion (ROM) may lead to improved kinematics and kinetics on slopes and stairs in K2-level transtibial prosthesis users. Hydraulic ankle-foot (HAF) components can adapt to uneven ground and have an increased ankle joint ROM that may be beneficial for transtibial prosthesis users when performing daily mobility tasks.[1,2] The purpose of this pilot study was to evaluate the effects of a HAF component on the walking and standing abilities of K2-level transtibial prosthesis users.

METHOD

Participants: The following inclusion criteria were used to identify prospective participants for our pilot study: age 18–80 years, unilateral transtibial amputation, residual limb length classified as medium, prosthesis user for at least one year prior to enrolling in the study, K2-level ambulator, good sensation on residual limb, good skin integrity upon visual inspection, does not require the use of assistive devices to walk, clinically presents with good standing balance and recovery, and not currently taking medications that are known to affect gait and balance.

Study Design: In a crossover study design, subjects were randomly fitted with either the College Park Industries OdysseyK2 HAF prosthesis or Celsus prosthetic foot, and permitted 2 weeks to accommodate before returning for the data acquisition session of walking and standing analyses.

Procedures: Quantitative gait analyses were conducted as the subjects ambulated along the level and sloped walkways and ascended/descended stairs. Standing analyses were completed as subjects stood statically on level and sloped surfaces. After the data acquisition session, subjects' perceptions with the different prosthetic configurations were recorded using the Locomotor Capabilities Index, Hill Assessment Index, and Stair Assessment Index to document the research participants' abilities to perform different tasks with the HAF prosthesis compared to a non-hydraulic prosthesis. We also administered a customized questionnaire that we developed to record the subjects' perceptions of walking with the 2 different prosthetic feet.

RESULTS

Three subjects meeting the inclusion criteria were enrolled and tested for this study. Contrary to expectations, the HAF component had little effect during level and upslope walking. However, the ankle motion when descending a slope demonstrated reasonably good accommodation with the HAF component, with the foot in relatively more plantarflexion throughout stance phase compared with the control foot (Figure 1).

The most compelling data that we obtained differentiating function between the HAF and control feet was during quiet standing on different sloped surfaces. The HAF component automatically adjusted to the slope of the surface, requiring less accommodation by the subject at their knee and hip joints. At the conclusion of the study, subjects 1 and 2 indicated a general preference for the control foot, while subject 3 indicated a preference for the HAF component.

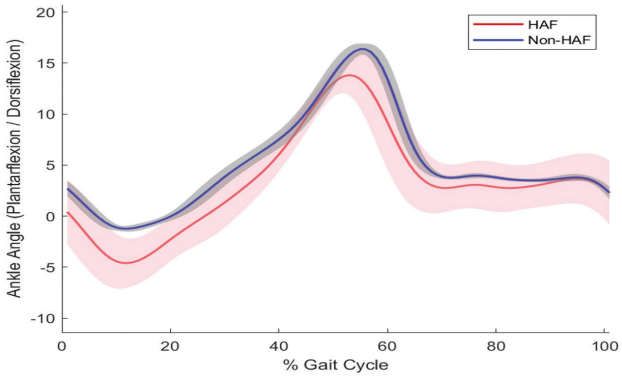

Figure 1. The HAF appeared to accommodate reasonably well when subjects walked down a slope.

DISCUSSION

More research into the effects of hydraulic ankle-foot components on K2-level ambulators is encouraged, particularly as commercially available designs undergo further refinement.

CONCLUSION

HAF components do not appear to offer much benefit to K2-level ambulators at this time.

CLINICAL APPLICATIONS

The main advantage of a HAF component appears to be in reducing compensatory joint actions while transtibial prosthesis users stand on sloped surfaces, which is not the primary consideration when fitting these types of components.

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AMPDECIDE: Point of Care Clinical Decision-Making Tools That Facilitate Patient Engagement in Amputation Level Decision-Making

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INTRODUCTION

Patients facing lower-extremity amputation (LEA) due to advanced peripheral artery disease (PAD) or diabetes may receive amputations at varying levels. Each amputation level profoundly affects the risks of re-hospitalization, reamputation, functional mobility, and therefore quality of life (QoL).[1] One of the most important factors influencing the amputation level decision is the preservation of mobility.[2] While more distal amputations may preserve patient mobility, the potential mobility benefits may not be realized because of an increased risk of compromised healing that can occur with more distal amputations, which may result in an additional amputation surgery.[3] Therefore, patients requiring amputation face the competing risks of mobility loss versus the risks of non-healing and reamputation.

To facilitate patient engagement in surgical decision-making, we developed and evaluated two novel amputation-level patient decision aids (PtDAs) for patients who require amputation secondary to dysvascular disease to facilitate shared decision-making around these competing risks and benefits.

METHOD

Participants: Particpants included 11 male patients (9 post-amputation, 2 pre-amputation) across a VA and university medical center. All participants provided informed consent, and all study procedures were approved by the local Institutional Review Board.

Apparatus: Think aloud, acceptability and usability measures, and open-ended survey.

Procedures: Participants were encouraged to think aloud as they interacted with the decision aid. At completion, participants completed several surveys about the tools and their preferences.

Data Analysis: Descriptive statistics were computed. Qualitative data collected by study coordinators were consolidated, organized, and summarized.

RESULTS

Participants generally had favorable responses to the PtDAs. All found the aids easy or very easy to navigate. When asked about their own specific risks, nearly all participants wanted to know their individual risk of mortality, reamputation, and chance of achieving independent mobility. Based on a summary of the "think aloud" notes, many patients were surprised that there was a decision to be made about amputation level. Many post-amputation patients indicated that they weren't exposed to this information prior to their amputation and said the information would help them clarify their values (Figure 1).

DISCUSSION

We successfully developed and evaluated 2 patient decision aids. The data from this study will inform a future efficacy trial. This study will examine the efficacy of personalized amputation-level decision aids (linking the aids to the personalized risk data produced by the AMPREDICT decision support tool). With personalized data, patients will be better able to balance the risks of available options to ensure that the amputation level decision is congruent with their preferences and priorities.

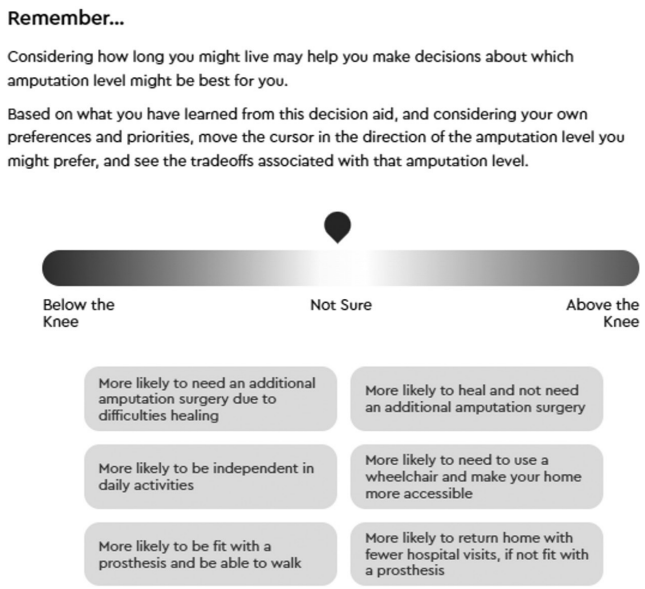

Figure 1. Values clarification exercise from one of the AMPDECIDE amputation-level patient decision aids.

CONCLUSION

The AMPDECIDE PtDAs allow patients to participate in amputation level decision-making, ensuring this decision is consistent with their values and priorities.

CLINICAL APPLICATIONS

The AMPDECIDE PtDAs are available now (www.ampredict.org) to assist providers and patients in amputation level shared decision-making and increase decisional satisfaction among patients.

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Biomechanical Evaluation of a Knee-Ankle Synergetic Device for Individuals with Transfemoral Limb Loss

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INTRODUCTION

Uneven ground, slopes, stairs, and sidewalks are walking situations that require increased ankle mobility compared to level walking. These walking situations are more difficult to overcome for persons with transfemoral amputation (TFA) due to the typical limitation of the ankle mobility. If the flexibility of energy storing and return feet is suitable on level ground, it does not allow a complete adaptation to daily walking situations, like slopes (ascent and descent) or downstairs. Increased fall risk can be partly attributed to this misadaptation. This risk is increased by the muscle atrophy related to the amputation and to the absence of mobility of the prosthetic ankle during the swing phase.[1] The aim of this study was to perform a biomechanical analysis of persons with transfemoral amputation wearing a microprocessor-controlled knee-ankle system (MPKA_NEW) specifically designed to address these issues.

METHOD

Participants: Twelve active (upper than ICF d4602) adults (46±15 years old, 178±9 cm and 75±9 kg,) gave their informed consent to participate in this prospective, multicenter, and randomized crossover study approved by a national ethics committee (CPP Sud Est III n° 2018-045B).

Apparatus: Quantified gait analysis was conducted with a VICON® optoelectronic system (Vicon Motion Systems, Oxford Metrics, UK, sampling at 100Hz).

Procedures: Participants randomly wore their usual (more than 3 months) microprocessor knee (MPK_HAB) and MPKA_NEW for 4 weeks before the analysis on level ground, 12% slopes ascent and descent, and stairs descent.

Data Analysis: Flat foot motion time (FFMT, period of the gait cycle where the foot angle in the sagittal plane was within ± 1.25 degrees of its orientation at 20% of the gait cycle) and minimum toe clearance (MTC, minimum distance in cm between the foot and the ground during the swing phase) were calculated for both prostheses and averaged over trials and compared through student or Wilcoxon test (p=0.05).

RESULTS

Figure 1 shows a significant increase in FFMT with MPKA_NEW, coming closer to able bodies (AB) values. Table 1 shows a significant increase in MTC when walking in level ground and slope ascent with the MPKA_NEW prosthesis.

DISCUSSION

Ankle plantar flexion during stance and dorsal flexion during swing respectively increases FFT (stance stability) and MTC (swing security) bringing to TFA advanced functions as already proposed to TTA.[2,3]

CONCLUSION

This biomechanical study supports the functional advantages targeted by the knee-ankle device.

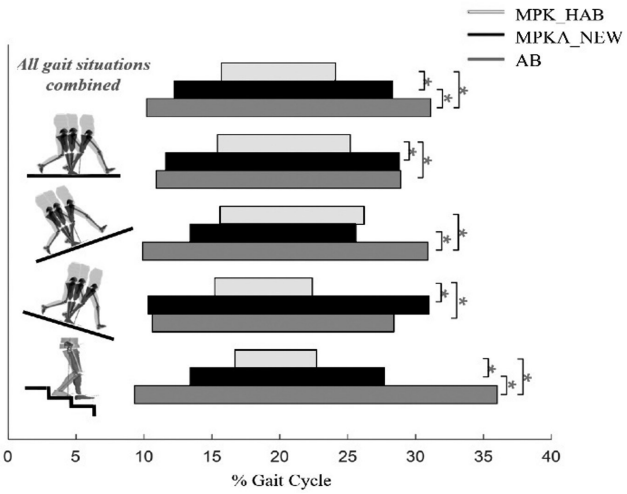

Figure 1. Flat foot motion time during the gait cycle (*significant difference AB data taken from literature).[4]

Table 1. Minimum Toe Clearance (MTC), with Each Prosthesis (*significant difference).

	Level Ground		Slope Ascent	
	MPK_HAB	MPKA_NEW	MPK_HAB	MPKA_NEW
MTC (cm)	2±1*	5±2*	2±1*	4±2*

CLINICAL APPLICATIONS

This new prosthetic system may improve stability and security for TFA on uneven terrain, slopes, and stairs.

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User Experience with a Passive Slope Adaptive Foot-Ankle Prosthesis

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INTRODUCTION

Few commercially available passive prosthetic feet adapt to sloped or uneven terrain. Motion Control, Inc. has partnered with the Minneapolis VA to develop a passive slope-adaptive foot-ankle prosthesis (SAF). The SAF uses a hydraulic mechanism to automatically adapt ankle alignment on varied terrain, allowing energy storage to begin early in stance phase.[1]

The purpose of this pilot study was to test a prototype SAF with veterans with unilateral transtibial amputations in their home and community environments.

METHOD

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

Participants: Six veterans with unilateral transtibial amputation completed the study (age: 57.7 ± 13.5 years; time using a prosthesis: 17.5 ± 17.9 years; male: 4; female: 2; K2: 1, K3: 3, K4: 1). Each participant used a prescribed energy storage and return (ESAR) foot.

Apparatus and Procedures: Participants completed the Prosthetic Limb Users Survey of Mobility (PLUS-M), Activity-Specific Balance Confidence Scale (ABC), and Prosthesis Evaluation Questionnaire (PEQ) regarding use of their prescribed prosthetic foot. The SAF was fit by a certified prosthetist, and participants completed a take home trial of at least one week. Participants then completed the PLUS-M, ABC, PEQ, a custom questionnaire regarding comfort and stability, and an unstructured interview focusing on user perceived advantages and disadvantages of the SAF.

Data Analysis: Scores from the PLUS-M, ABC, and PEQ were analyzed using descriptive statistics. Ratings of comfort and stability were reviewed for trends.

RESULTS

Average self-reported outcome measure scores when using the SAF were better than those reported with the prescribed foot (Figure 1) and the minimal detectable change was exceeded for the PLUS-M using the SAF.[2] On the custom questionnaire, participants rated the SAF the same or better as the prescribed foot for 11 of 12 stability questions and 8 of 8 comfort questions from the custom questionnaire. When asked about their overall rating of the SAF compared to their prescribed foot, all participants rated it "better" or "much better."

Within the unstructured interviews, veterans reported decreased residual limb and knee pain, decreased phantom pain, improved navigation of slopes and stairs, fewer tripping incidents, increased participation in the home and community, and improved dressing ability using the SAF. One veteran voiced concerns regarding inconsistent operation of the SAF on the first step and for small steps.

DISCUSSION

Data collected strongly supported the development of the SAF for improved mobility on slopes and uneven terrain along with unanticipated aspects of daily living. Features of the SAF may improve prosthesis-related quality of life, balance confidence, and mobility, allowing users to traverse various terrains more easily. Additionally, the SAF may improve and promote participation and reintegration after amputation.

This was a small pilot study with a prototype SAF and was limited by a small sample size and short take-home period. Further studies are needed to understand the user experience with the commercially available version of the foot. A longer take-home trial with a larger sample size would help elucidate the impact of the SAF on patient-reported outcomes of quality of life, balance, mobility, and participation across K-levels.

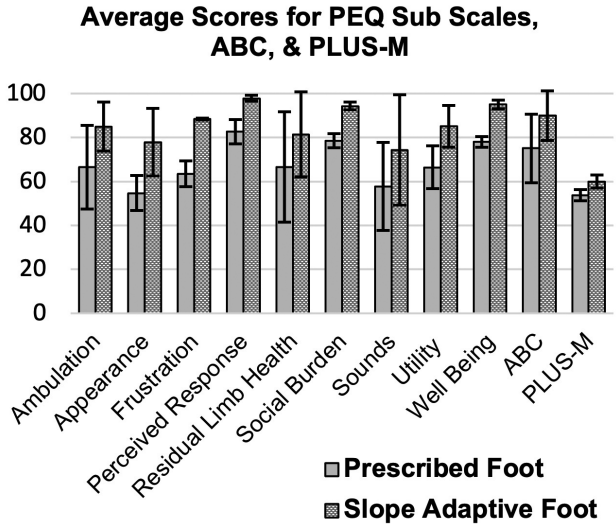

Figure 1. Mean scores for PEQ sub scores, ABC, and PLUS-M. PEQ and ABC are scored out of 100. PLUS-M is scored out of 76.6. Higher scores indicate a more positive response.

CONCLUSION

Features of the SAF may improve the user experience in the home and community environments when compared to use of the prescribed ESAR foot.

CLINICAL APPLICATIONS

Many prosthesis users find walking on sloped or uneven terrain difficult. The novel SAF may offer a prosthetic foot option that improves balance and mobility on challenging terrains.

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AMPREDICT PROsthetics: The Development of a Prediction Model and Decision Tool to Aid in Prosthesis Prescription and Rehabilitation Planning

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INTRODUCTION

The ability to ambulate after lower-limb amputation is associated with higher levels of function and independence via improved self-care and mobility, quality of life, and employment success.[1] The current paradigm for prescription of a lower-limb prosthesis (LLP) is largely driven by K-levels, which rely on clinicians to estimate future mobility based on their clinical experience. Clinicians have expressed a significant lack of confidence in this system.[2]

The purpose of this study was to develop and validate a multivariable prediction model (aka, AMPREDICT PROsthetics) that utilizes readily available patient-specific factors to predict 12-month mobility at the time of prosthesis prescription. This prediction model is being converted into a risk calculator to translate to the point of care as a clinical decision support tool.

METHOD

Participants: Participants included 357 veterans (98% male) who underwent an incident transtibial (TT; n = 266) or transfemoral (TF, n = 91) amputation for diabetes or peripheral artery disease and received a qualifying lower-limb prosthesis (LLP) between March 2018 and November 2020.

Apparatus: The patient reported Amputee Single Item Mobility Measure (AMPSIMM), which was divided into 4 categories: wheelchair, household, basic community, or advanced community mobility.[3]

Procedures: Participants and their predictors were identified retrospectively through the Veteran's Affairs (VA) Corporate Data Warehouse and prospectively contacted to obtain their patient-reported mobility through a combination of mailed and phone AMPSIMM surveys. The study was approved by the local Institutional Review Board.

Data Analysis: A machine learning methodology was used for variable selection to predict the four-category mobility outcome. The final model was validated internally with bootstrap sampling. As a sensitivity analysis, 10-fold cross validation was also performed.

RESULTS

Seventy-two individuals (20.2%) reported AMPSIMM scores indicating wheelchair mobility, 63 (17.6%) reported household mobility, 110 (30.8%) reported basic community, and 112 (31.4%) reported advanced community mobility. The final model included 23 predictors: amputation level, time to prescription, age, body mass index, marital status, several comorbidities and mental health diagnoses, and prior revascularization. The model effectively discriminated household from basic community and advanced community ambulation levels of key clinical importance (Figure 1).

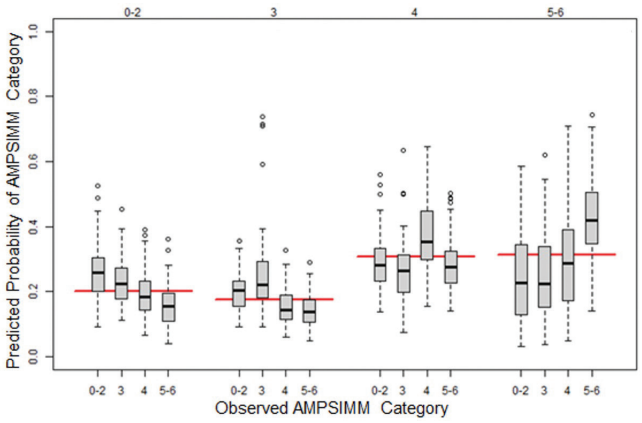

Figure 1. Distributions of predicted probabilities for each AMPSIMM category stratified by the actual observed category. (Red lines = prevalence of each category).

DISCUSSION

We have successfully developed and validated the AMPREDICT PROsthetics prediction model to be applied at the time of prosthesis prescription using predictors available in the medical record. The absence of evidence to help guide optimum prosthetic prescription has been identified as a concern by rehabilitation clinicians and the Agency for Health Care and Research Quality.[2,4] The model is limited by a small number of female participants due to the nature of the veteran population. It is currently being converted into an online clinical decision support tool that will provide an interactive user-friendly visual display of an individual patient's predicted probabilities for achieving each of the 4 levels of mobility.

CONCLUSION

The AMPREDICT PROsthetics model will meet the perceived clinical need for assistance in determining future prosthetic mobility, setting expectations and goals, and choosing an LLP to accomplish these goals.

CLINICAL APPLICATIONS

The AMPREDICT PROsthetics model and decision support tool will assist providers at the point of clinical care in estimating an individual patient's future mobility at the time of prosthesis prescription.

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The Effect of Passive-Mechanical Prosthetic Knee and Ankle-Foot Components on Gait Safety in Transfemoral Prosthesis Users

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INTRODUCTION

Studies report that the majority of falls in transfemoral prosthesis users (TFPUs) occur during walking.[1] To facilitate gait safety during walking, motor control of the legs must achieve certain objectives during the two phases of gait: (1) prevent buckling while weight-bearing during stance[2] and (2) avoid limb collision with the ground during swing.[3] TFPUs must rely on their intact hip and leg prosthesis, comprised of a prosthetic knee and ankle-foot mechanism, to achieve these objectives. The purpose of this study was to examine the interaction effects of prosthetic knees and feet on transfemoral prosthetic gait safety.

METHOD

This study was approved by the Jesse Brown VA Medical Center Institutional Review Board, and participants provided written informed consent prior to data collection.

Participants: Six TFPUs (1 female / 5 males, 43 ± 13 years, 82.35 ± 16.75 kg; 1.70 ± .12 meters).

Apparatus: Participants were randomly fitted with one of 4 different combinations of prosthetic knee and ankle-foot components (Figure 1). Kinematic and kinetic data were collected at 960 Hz using a digital motion-capture system (Motion Analysis Corp, CA) and 6 floor-embedded force plates (AMTI, Watertown, MA).

Procedures: Participants performed 3 tasks: (1) walking on level ground along a 10-meter walkway; (2) walking on an inclined surface with 5-degree slope; (3) walking on a declined surface with 5-degree slope.

Data Analysis: Two variables were analyzed to determine changes in gait safety during stance phase: knee moment angular impulse (PKAI) and pre-swing knee moment (PSKM). Three variables were analyzed during swing phase: timing of terminal knee swing extension (TKS); toe clearance (TC), and heel clearance (HC). Gait data were analyzed using Visual 3D (C-Motion, Germantown, MD) and custom software in MATLAB (Mathworks, Natick, MA). Linear mixed models were used to analyze data with 2 repeated factors (prosthetic knee and foot). Only level walking data are presented here.

RESULTS

Results suggest that gait safety was improved, reflected by more negative KMAI, smaller PSKM, later TKSE, and increased TC for the prosthetic setups including the PC knee ($p < .001$ for the 5 variables of interest) (Figure 2). Across outcomes, the results suggest some ($p < .05$ for TKSE, TC and HC) interaction effect between the prosthetic knee and foot. However, effects of adding the hydraulic foot to the polycentric knee were not consistently additive for improving gait safety (e.g., TC appears to have no differences when using both feet and the PC, but there was an increase when using HY and SA compared to NA and SA) despite the design intention of that foot to improve stance progression and swing toe clearance. Data collection on additional participants is ongoing.

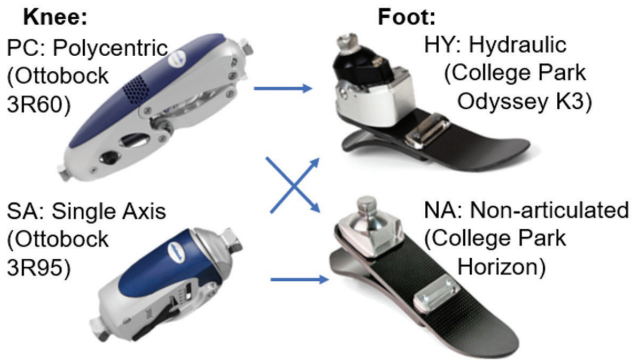

Figure 1. Knee-foot combinations tested.

CONCLUSION

These results suggest an effect of prosthetic knee on gait safety and an interaction effect between the prosthetic knee and foot. The inconsistent interaction effect of adding a hydraulic foot to a polycentric knee on gait safety outcomes may be indicative of gait compensations, which will be analyzed in future work.

CLINICAL APPLICATIONS

The results from this study indicate that the PC knee provides substantial benefits over the SA knee, regardless of foot type, for most outcome measures during both stance and swing phases of gait. However, the results are less clear when comparing the two feet.

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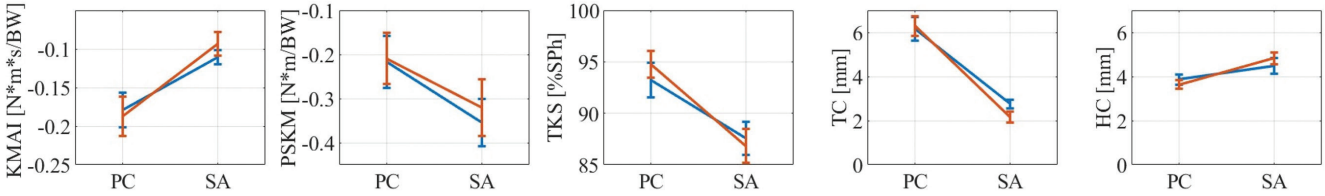

Figure 2. Results for level walking at each prosthetic knee (x-axis) and prosthetic foot (each line represent a different foot: HY-blue, NA-orange). Error bars denote 95% confidence intervals.

Comparative Effectiveness of Casting Approaches for Transtibial and Transfemoral Prostheses: Interim Results of a Clinical Trial

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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, positive plaster mold rectification, and, as needed, check socket modifications. An alternative approach using a standing hydrostatic pressure cast is proposed to be simpler, relying less on manual manipulation of the cast, less rectification, and possibly less time to achieve a comfortable check socket fit.[1] The aim of this clinical trial was to compare the time required to cast, rectify, and modify a check socket, as well as the initial socket comfort of check sockets made by hand casting and standing hydrostatic pressure casting in persons with lower-limb amputation.

METHOD

A 3-site randomized crossover trial is underway with Institutional Review Board approval (total recruitment goal N = 90).

Participants: Seventy-four adults to date (52 transtibial + 18 transfemoral amputations, 4 withdrawn).

Procedures: A single prosthetist per site took each cast in random order by hand and using the Symphonie Aqua System (Romedis GmbH, Germany), rectified each mold, and fabricated a check socket. The time required to cast the participant, rectify the positive model, and modify each check socket was recorded in minutes. Check sockets were randomly presented to each participant: they donned each socket, sat for 2 minutes, and then stood for 5minutes. After re-donning socket 1, the socket comfort score (SCS, 0 = least comfortable to 10 = most comfortable)[2] was administered by a masked-assessor and repeated for socket 2. Prosthetists used a socket-fit checklist to evaluate fit and make modifications to improve comfort of the check socket. SCS was administered again to each socket.

Data Analysis: Paired t-tests ($\alpha = 0.05$) were used to assess (1) differences in time (total, casting, rectifying, modifying) for each casting approach and (2) differences in comfort between sockets before and after modification.

RESULTS

In terms of time, results were the same for all participants as well as by amputation level (Table 1). Total time and socket modification time were no different between casting approaches. Casting time was significantly longer for Symphonie casting, but rectification time was significantly shorter.

In terms of comfort, there was no difference before and after modification for all groups except for TF participants, where the hand cast check socket was more comfortable before modifications (Table 2).

DISCUSSION/CONCLUSION

Initial results suggest that there are no differences between casting approaches in terms of total time and comfort. Additional analysis by site is warranted to assess whether there were differences given different levels of experience across sites with the Symphonie system prior to study commencement.

Table 1. Time in minutes. *Significant at $p < 0.05$.

Group		Hand Cast	Symphonie Cast	p-value
Total	All	45.1 ± 17.5	48.4 ± 10.8	0.0608
	TT	46.3 ± 19.0	48.7 ± 10.9	0.2528
	TF	41.6 ± 12.1	47.6 ± 10.8	0.0803
Cast	All	11.0 ± 5.5	23.7 ± 6.3	<0.001*
	TT	10.9 ± 5.6	24.3 ± 6.0	<0.001*
	TF	11.3 ± 5.3	21.9 ± 6.9	<0.001*
Rectify	All	26.0 ± 12.7	17.1 ± 7.2	<0.001*
	TT	27.0 ± 13.8	16.5 ± 7.4	<0.001*
	TF	23.1 ± 8.2	18.8 ± 6.3	0.0025*
Model	All	8.0 ± 7.7	7.6 ± 6.2	0.5859
	TT	8.4 ± 6.8	7.9 ± 6.1	0.5560
	TF	7.1 ± 10.0	6.9 ± 6.7	0.9048

Table 2. Socket comfort score before and after modification. *Significant at $p < 0.05$.

Group		Hand Cast	Symphonie Cast	p-value
After	All	6.6 ± 2.4	6.9 ± 1.9	0.3354
	TT	6.3 ± 2.6	7.0 ± 1.9	0.0761
	TF	7.4 ± 1.8	6.6 ± 2.2	0.0358*
Before	All	7.6 ± 2.0	7.9 ± 1.5	0.1639
	TT	7.5 ± 2.1	8.0 ± 1.5	0.0613
	TF	8.0 ± 1.8	7.7 ± 1.4	0.3621

CLINICAL APPLICATIONS

Our current data do not support claims that hydrostatic casting takes less time to achieve a more comfortable socket than hand casting.

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Bilateral Asymmetry in Unilateral Use of Running-Specific Prostheses: Implications on Paralympic Competition

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INTRODUCTION

Advances in material science and prosthetic technology have enabled individuals with limb loss to sprint at elite levels, fostering global competitions such as the Paralympic Games, which has origins dating back to 1948.

To promote equity across competitions, the International Paralympic Committee utilizes a complex classification scheme to group athletes for different events. Para Athletics (track and field) has 10 eligible impairment types, one of which is limb deficiency.

From the 1988 Paralympics in Seoul to the 2020 Paralympics in Tokyo, unilateral (left and right) and bilateral athletes competed and were scored together in the 100-meter and 200-meter events, despite the difference in classes. A key difference between the two distances is that the 100 meter uses only a straightaway, while the 200 meter involves running around a curved section of the track, always in the same direction.

Taboga et al. studied the biomechanics of running around a curve with a unilateral prosthesis and found that athletes were 3.9% slower on curves when the affected leg was on the inside compared to the affected leg on the outside.[1] This result has implications on equity when athletes with left, right, and bilateral limb loss are grouped in a race that involves a curve.

The purpose of this study was to review Paralympic and world championship results to assess the implications of affected limb in 100-meter versus 200-meter events.

METHOD

Results from 100-meter and 200-meter events were obtained from the Paralympic Games and World Championships between 1988 and 2021 using an archive at paralympic.org. The archive does not include affected side, so videos of these races were reviewed, and side was hand coded for each athlete.

Type 3 generalized estimating equations analysis was used to assess the effect of gender, event distance, and affected side on race times.

RESULTS

Three hundred twenty-two results were included. Males were significantly faster than females, but the interaction with side was not significant, meaning the impact of side was the same regardless of gender.

In the 100 meter, there was no impact of side on time for athletes with unilateral limb loss, but bilateral athletes were, on average, 0.92 seconds faster than unilateral athletes. In the 200 meter, bilateral athletes were 2.08 seconds faster than unilateral athletes, and athletes with right side limb loss were 0.28 seconds faster than athletes with left side limb loss (Figures 1 and 2).

DISCUSSION AND CONCLUSION

These results reveal important average time differences based on involved side. In general, bilateral athletes appear to have an a priori advantage over unilateral athletes. For events involving curves, unilateral side is important as well. For context, in the 2020 Athens Paralympics, the difference between a gold medal and no medal was 0.3 second, and the average side difference found here was 0.28 second.

Solutions to these potential inequities are complex. Simply adding additional events can become impractical. However, the results indicate that certain athletes are immediately disadvantaged in the current system.

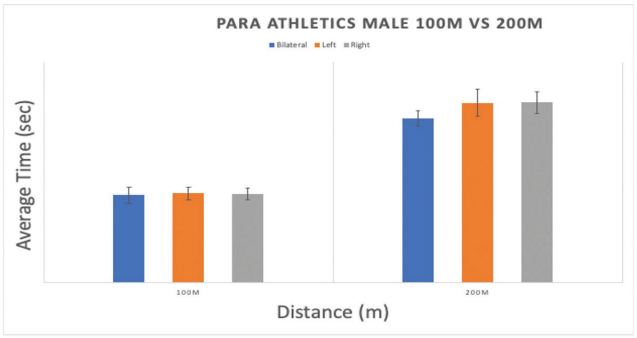

Figure 1. Average results and standard deviations for males in 100-meter and 200-meter events by involved limb.

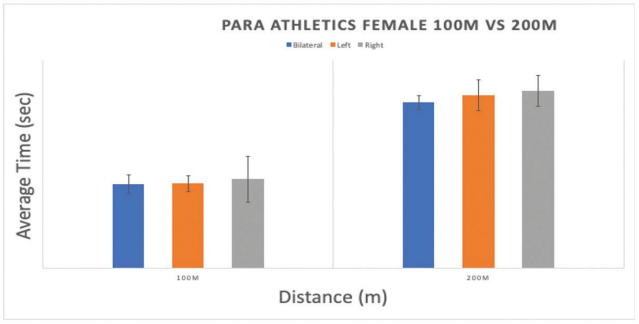

Figure 2. Average results and standard deviations for females in 100-meter and 200-meter events by involved limb.

CLINICAL APPLICATIONS

The International Paralympic Committee should explore options to improve equity in athletics events, including the potential for fewer combined events, running in different directions, or factored timing similar to Nordic events.

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Metabolic Assessment of Traversing a Mixed Terrain Course with a Transfemoral or Transtibial Prosthesis

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INTRODUCTION

Realistic outcome measures that are representative of activities of daily living are necessary to determine how a particular device or intervention may affect an individual in their day-to-day life. Unfortunately, typical steady-state metabolic assessments are *not* representative of day-to-day activity and therefore lack ecological validity.[1] A novel, recent study used a course of level walking and stairs to assess metabolic outcomes in a more realistic setting.[2] Similarly, utilization of a course that also incorporates inclined surfaces may be beneficial in evaluating metabolic outcomes for persons with amputation. Such a course would be more representative of real-life scenarios for household and community ambulators.

The aim of this study was to assess the metabolic cost of traversing a mixed terrain course of level walking, ramps, and stairs for individuals with transfemoral (TF), transtibial (TT), or without (NoAmp) amputation.

METHOD

This protocol was approved by the Northwestern University Institutional Review Board (STU00209522), and all participants provided their written informed consent.

Participants: There were a total of 29 participants: 9 in the TF group (3 female, 6 male; 44 ± 16 years; 4 trauma, 5 sarcoma; 1 K4, 8 K3); 10 in the TT group (2 female, 8 male; 53 ± 12 years; 6 trauma, 2 sarcoma, 2 other; 2 K4, 8 K3); and 10 in the NoAmp group (5 female, 5 male; 30 ± 11 years).

Procedures: Participants completed a mixed-terrain course (238 meters total) consisting of a circuit of stairs and a ramp, walking down a hallway, descent of a stairwell, brief walking and turning on a landing, ascent of a stairwell, walking down a hallway, another repetition of the circuit of stairs and a ramp. Metabolic data were collected with a COSMED K5 portable metabolic unit.

Data Analysis: O_2 cost was calculated as the average volume of O_2 consumed (ml) per body mass (kg) per distance traveled (m) for the entire course. A one-way ANOVA and unpaired t-tests were used to compare O_2 cost between groups with significance set to $p < 0.05$.

RESULTS

All groups completed the course with similar timing proportions (Figure 1). O_2 cost was significantly different between all groups for the full course (Figure 2).

DISCUSSION

Results followed similar trends as previous literature on steady-state O_2 cost of gait,[3] even though subjects did not reach steady-state on the mixed-terrain course. The TF group had the greatest O_2 cost and the slowest completion time for the course; the NoAmp group had the least O_2 cost and fastest completion time. Compared to the NoAmp group, O_2 cost was 54% greater for those in the TF group and 11% greater for those in the TT group, indicating that individuals with a prosthesis had to use more energy to complete the course than those without amputation. Limitations of the study include the lack of matching groups by age and by gender, and a relatively small sample size.

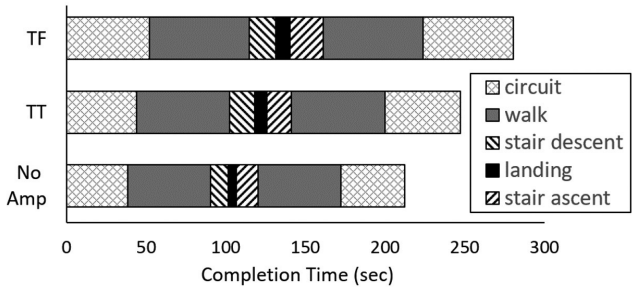

Figure 1. Time to complete each portion of the mixed-terrain course.

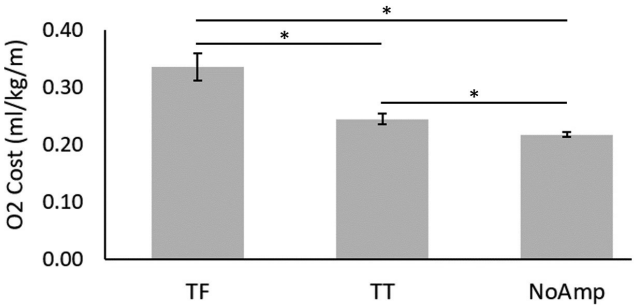

Figure 2. O_2 cost (mean ± SE) averaged over the full course. Higher O_2 cost = more energy required; lower O_2 cost = less energy required. *significant difference $p < 0.05$.

CONCLUSION

A varied course that includes level-ground walking, stairs, and ramps can be a useful tool for metabolic assessments. The course has greater ecological validity, being more representative of day-to-day ambulation activities than standard steady-state tests, and may be more tolerable for those who are adverse to treadmill walking.

CLINICAL APPLICATIONS

As outcome measures are further developed to better assess real-world situations, practitioners will gain a better understanding of how a prosthetic device or therapeutic intervention may affect patients in their home and community environments.

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Clinical Solution for Prominent Distal Tibia and Bone Spurs on Left Transtibial Residuum

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Ability Ottobock.care

INTRODUCTION

For individuals with lower-limb amputation, socket fit was identified as the most important aspect of a prosthesis.[1,2] As a mechanical coupling between the patient's residuum and the prosthesis, an intimate and stable fit is crucial to optimize useability/comfort of a prosthesis and decrease the risk of skin breakdown.[1,3] In the United States, a "long posterior flap surgical technique" is used for transtibial amputations to protect/pad the distal end of the residuum when wearing a prosthesis.[4] In some cases, the gastrocnemius atrophies and no longer protects the distal end of the tibia. In these situations, the patient's distal tibia becomes prominent and sensitive, rendering prosthetic socket fit difficult.

This case presentation highlights a unique socket design to address a painful and prominent transtibial residual limb.

CASE PRESENTATION

This case involves a 61-year-old Caucasian male (height: 165.1 cm, weight: 74.5 kg) with a left transtibial amputation (vascular in origin) performed in July 2020. He meets the criteria of a K2 ambulator but historically used a manual wheelchair due pain experienced when using a prosthesis. The patient presented with a prominent distal tibia, bone spurs, and inadequate distal end padding (Figure 1). Bone spurs are located on the posterior distal tibia, in the concavity produced from inadequate posterior flap coverage. The patient has considered a surgical revision, but he is a poor surgical candidate due to a pre-existing heart condition.

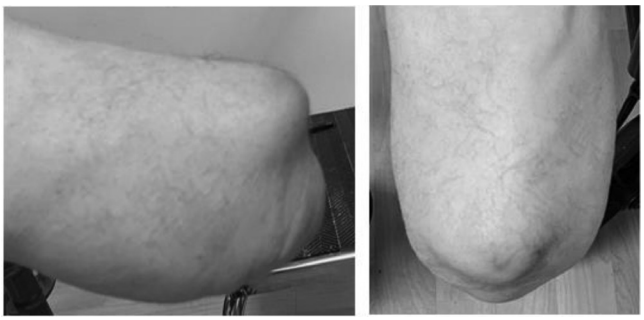

Figure 1. Coronal and sagittal views of the distal end of the left transtibial residuum, respectively.

The patient presented with an endoskeletal carbon fiber laminate prosthesis (1 year prior) including modified patellar tendon bearing socket style, passive suction suspension, Ottobock Proflex sleeve, and a prefabricated Alpha Cushion Progressive Hybrid liner. Patient wore five to eight ply prosthetic socks for volume management. Socket comfort score (SCS) is rated as 2/10. Objectively, his lower-extremity strength and range of motion were within normal limits bilaterally. After a thorough assessment by the prosthetist, it was decided that a new replacement socket was needed based on physiological changes to the residual limb and low SCS.

MANAGEMENT AND OUTCOME

A gel distal end cap (Proteor USA, 1S390-3) with a 3-millimeter distal end was applied directly to the patient's residuum. An Alpha Classic Cushion liner of 6-millimeter uniform thickness (WillowWood, ALC-5064-E) was applied over the patient's residuum. The carbon fiber laminate socket utilized a total surface bearing socket design with a flexible inner socket and passive suction suspension. In the fabrication process, a 1-inch Plastazote distal end pad was applied to a positive model of his residuum. A flexible TPU inner socket was pulled over the distal end pad. A ½-inch Plastazote distal end pad was pulled over the flexible inner as well as a ¼-inch Plastazote anterior panel (to allow the flexible inner socket to be removed if necessary). The carbon fiber laminate socket was formed over this layer of padding. At the patient's socket fitting, he noted no pain in his residuum and was able to walk in the parallel bars with one hand free. Volumetric fit was 0-ply of prosthetic socks over the liner. SCS was an 8/10 at final fitting.

DISCUSSION

The placement of a distal gel cup, 6mm liner, and additional 1¼" of Plastazote dispersed distal end pressures while maintaining distal contact. This case study aligns with recent results of custom silicone distal caps for irregular transfemoral distal end morphology,[5] and these solutions should be explored further.

CONCLUSION

This case study highlights a unique prosthetic socket design for patients presenting with a prominent distal tibia. Clinicians may consider additional padding deep to the liner and superficial to the flexible inner socket for addressing challenging prominent distal tibia in transtibial residual limbs. The role of the liner and padding thickness and location may be evaluated in future clinical research.

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Joint Strength Reduces Whole-Body Angular Momentum during Perturbations in Prosthesis Users and Controls

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INTRODUCTION

People with lower-limb amputation have a greater risk of falling compared to aged-matched controls,[1] likely due to a combination of factors that include reduced muscle strength,[2] different sensory feedback, and reduced proprioception. Reacting to a loss of balance caused by a slip or a trip requires a rapid and coordinated acceleration or deceleration of body segments (i.e., torso, thigh, foot) to maintain balance and prevent a fall. However, partially due to differences in anthropometrics, the strategy for preventing falls for individuals with unilateral transtibial amputations may differ from able-bodied controls.

One paradigm for quantifying balance control is to deliver perturbations by rapidly accelerating and decelerating the treadmill belt while an individual is walking, which simulates a trip. During gait, whole body angular momentum (WAM) has been hypothesized to correlate with dynamic balance, where greater peak-to-peak WAM magnitudes indicates increased fall risk.[3] Muscle groups at the hip and ankle (gluteus maximus, hamstrings, gastrocnemius, soleus) are important for controlling WAM during gait.[4] In response to a trip, the swing limb plays an important role in preventing a fall, either via an "elevating strategy" for trips during early swing or a "lowering strategy" for trips during late swing.[5] We performed an exploratory analysis to assess the relationship between swing limb joint strength and peak-to-peak WAM during a perturbation in unilateral transtibial prosthesis users and controls. We hypothesized that individuals with greater hip and ankle strength will have less sagittal plane peak-to-peak WAM during perturbations on the contralateral limb.

METHODS

Participants: We collected data on 5 healthy older adults (74 ± 4 years, 82 ± 6 kg, 1.72 ± 0.05 meter) and 5 prosthesis users (71 ± 3 years, 87 ± 5 kg, 1.77 ± 0.07 meter), who each provided informed consent for this study. The protocol was approved by the Jesse Brown VA Medical Center.

Apparatus: Torque at the hips, knees, and ankles were measured with a handheld dynamometer (Lafayette Manual Muscle Test System; Lafayette, IN). Participants walked on an instrumented treadmill (Motekforce; Link, Netherlands) while 3D kinematics were measured with a 12-camera motion capture system (Motion Analysis Corporation; Santa Rosa, CA).

Procedures: Participants walked on the treadmill at 0.8 meter/second for 5 minutes to accommodate to the environment. Then, 12 individual trials of perturbations (6 per limb) occurred at an unexpected time during single limb stance, with rest breaks between each perturbation.

Data Analysis: We computed the sagittal plane peak-to-peak WAM following perturbation onset for each limb, which we averaged across the last 5 trials per side. We normalized joint torque and WAM such that the units were dimensionless to compare across individuals. We compared the peak-to-peak WAM with the joint strength of the contralateral limb hip flexion, hip extension, and ankle plantar flexion strength using separate linear regressions analyses for each variable.

RESULTS

For healthy, older adults, WAM during non-dominant limb perturbations were negatively correlated with dominant limb hip extension ($p = 0.04$; $r = -0.87$), hip flexion ($p = 0.02$; $r = -0.93$), and ankle plantar flexion ($p = 0.04$; $r = -0.88$) strength. No relationships were significant between WAM and strength for perturbations on the non-dominant limb. For prosthesis users, there were no statistically significant relationships between WAM and contralateral joint strength for either side. However, there were negative relationships between WAM and contralateral hip extension ($p = 0.63$; $r = -0.29$) and hip flexion ($p = 0.34$; $r = -0.54$) strength for impaired-side gait perturbations.

DISCUSSION

Our hypothesis that greater joint strength would result in lesser peak-to-peak WAM was supported for our control group for dominant limb perturbations, but there was not a statistical relationship for prosthesis users although our statistics may be limited by a small sample size. Additional work to investigate the strategy that prosthesis users utilize in response to a gait perturbation is warranted, including an analysis of muscle activation patterns in reaction to a perturbation.

CONCLUSION

Regulating WAM during gait perturbations may be related to contralateral limb muscle strength. However, because ankle plantar flexion strength correlated with reduced WAM during perturbations for the control group, transtibial prosthesis users will need to rely on other joints to prevent falling.

CLINICAL RELEVANCE

Interventions targeting the strength of specific muscle groups (i.e., hip and ankle strength) may help older adults prevent falls from a gait perturbation.

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Perceptions of Prosthetic Attention among Lower-Limb Prosthesis Users: A Focus Group Study

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INTRODUCTION

Using a lower-limb prosthesis (LLP) generally requires greater cognitive effort than walking with 2 intact limbs. However, the experience of prosthetic attention among LLP users has not been explored. This study sought to examine how LLP users perceive paying attention to their prostheses in daily life.

METHOD

Participants: LLP users were purposively sampled (based on age, gender, race, etiology, amputation level, laterality, and time using an LLP).

Study Design: Qualitative focus groups.

Eligibility Criteria: Age ≥18 years, limb loss at or above the ankle, use of an LLP most days, LLP use for ≥3 months, and English proficiency.

Procedures: Each participant attended a 2-hour focus group with 4–8 other LLP users. Trained facilitators used a standardized discussion guide to lead focus groups. Discussions were recorded and transcribed for subsequent analysis. All procedures were reviewed and given exempt status by two local Institutional Review Boards.

Data Analysis: Verbatim transcripts were analyzed using inductive coding and thematic analysis. Two researchers independently excerpted and coded each transcript. A third mediated disagreements during reconciliation. All researchers involved in the analysis documented positionality prior to analysis and used reflective journaling throughout coding. Triangulation among researchers and member checking of emergent themes were used to improve credibility.

RESULTS

Thirty LLP users participated in one of 5 focus groups. Participants included women (60%) and men (40%) ranging from 21 to 84 years (mean: 52.6) with limb loss due to trauma (33%), infection (30%), dysvascular (20%), or congenital causes (17%). Many had transfemoral or higher levels of amputation (37%).

Five themes emerged from the analysis. Themes and supporting quotes are noted in Table 1. Prosthetic attention was described as a ubiquitous experience that involved both foreground (focused and infrequent) and background (low and constant) attention. Attention was needed to prevent falls, learn tasks with an LLP, and prevent problems related to socket fit.

DISCUSSION

Reasons for prosthetic attention described by LLP users in our study, including fall prevention[1] and maintaining socket fit,[2] are consistent with existing literature. Participants also described how specific prosthetic technologies (e.g., microprocessor-controlled knees) can lessen prosthetic attention and increase trust in the prosthesis as previously noted.[3]

Table 1. Emergent themes and example quotes.

Paying attention to my prosthesis is just what I have to do. "Sometimes [the prosthesis is] just something…in the background… And other times you're really focusing on it because you know that you're going to get in trouble if you don't." —Tyler, 84-year-old man, TF due to infection
I pay attention to how my prosthetic socket fits and feels every day. "You sort of monitor the fit, the condition, regular maintenance, how does it feel each day, what needs to be done. Have sort of a backup plan if something breaks, goes wrong." —Matthew, 82-year-old man, congenital PF/TT
I pay attention because I don't want to fall. "I need to be aware that this can give out on me at any time. I could fall at any time." —Samantha, 34-year-old woman, congenital HD
I pay attention because I have to learn to do things in a new way. "I want to go walk on a jetty, well, that's going to be my first time. I better be aware." —Joshua, 58-year-old man, TT due to infection
If I can trust that my prosthesis will do what I want it to do, I can pay less attention to it. "If I move my femur, I know that my leg is going to be there when I take a step, and so I've built a lot more trust with my leg, which makes it so I use it more efficiently." —Emily, 25-year-old woman, KD due to trauma

Note: All names are pseudonyms to maintain confidentiality.

CONCLUSION

Prosthetic attention is a shared experience among LLP users. The amount and frequency of prosthetic attention fluctuate depending on the task and/or situation, and often diminish over time. Measuring attention could inform prescription and evaluation of technologies intended to reduce cognitive effort.

CLINICAL APPLICATIONS

Clinicians should inform new LLP users to expect elevated prosthetic attention but anticipate it may decrease with time. Clinicians should inquire about prosthetic attention during follow-up visits, as it is a meaningful outcome that can potentially be influenced by changes in prosthetic technology.

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Comparison of Gait Biomechanics in Transtibial Prosthesis Users Walking with Prosthetic Feet and Corresponding Emulated Feet

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INTRODUCTION

Selection of an optimal prosthetic foot is an important aspect of maximizing mobility for people using lower-limb prostheses (LLP).[1] However, people using LLP typically do not have an opportunity to compare different types of prosthetic feet or contribute their preferences to foot selection, despite evidence that patient preference is an important component of a successful prosthesis prescription.[2] Offering LLP users brief trials of walking with a range of prosthetic feet could be useful to inform patient preference. To facilitate this "test-drive" approach, a robotic prosthetic foot emulator (PFE) was programmed to mimic the mechanical behavior of actual prosthetic feet. While previous mechanical testing results demonstrated strong agreement between the emulated and actual foot properties,[3] comparisons during walking have not yet been investigated. Thus, this study aimed to compare the gait biomechanics of LLP users walking with emulated feet versus the respective actual feet. We hypothesized that no significant differences in gait biomechanical outcomes would exist between pairs of actual and emulated prosthetic feet.

METHOD

This study was approved by a local Institutional Review Board, and participants provided informed consent. Participants: Ten males (50.6 ± 13.9 years, 102.3 ± 9.7kg, 1.80 ± 0.50 meter) with unilateral transtibial amputation.

Apparatus: Three prosthetic foot types: Vari-Flex, Rush HiPro, All-Pro, and the corresponding PFE versions.

Procedures: After brief accommodation, participants walked with actual and emulated feet (with optimized alignment) in a randomized order. Walking trials were at least 30 seconds each on a level, instrumented treadmill while a motion capture system recorded marker data. Participants were blinded to foot type throughout the study. After walking with all feet, participants were asked to match each emulated foot with each actual foot.

Data Analysis: Kinematic and kinetic data were imported to Visual3D, where they were filtered (4th-order Butterworth at 6Hz). Ankle joint peak power and positive work were calculated for intact and prosthetic limbs. Asymmetry in step length and step time were calculated. Linear mixed-effects regression was used to evaluate gait outcomes by foot condition with participant as a random effect. An alpha of 0.05 with correction for multiple comparisons was used.

RESULTS

Most differences in outcomes between emulated and actual feet were non-significant, except for prosthetic foot-ankle work ($p = 0.0014$). Post-hoc tests revealed differences when comparing the Vari-Flex and Rush ($p < 0.01$) feet to their emulated versions, with ankle work being greater in emulated feet. Eight out of 10 participants correctly identified all emulated feet, while two confused the Vari-Flex and Rush feet.

Table 1. Gait biomechanical outcome differences between pairs of emulated-actual feet by foot type. Bold indicates significant differences, $p < .05$.

	Vari-Flex	**Rush HiPro**	**All-Pro**	**Mean [95% CI]**
Pros. Ankle Power (W/kg)	0.15 ± 0.09	0.21 ± 0.09	-0.08 ± 0.09	0.09 ± 0.06, [-0.02,0.21]
Pros. Ankle Work (J/kg)	0.04 ± 0.01	0.03 ± 0.01	-0.02 ± 0.01	0.018 ± 0.007, [0.003,0.032]
Step Length Symm. (%)	4.3 ± 1.4	1.2 ± 1.4	3.2 ± 1.4	2.9 ± 0.8, [-1.3,4.5]
Step Time Symm. (%)	0.9 ± 0.8	1.2 ± 0.8	0.2 ± 0.8	0.8 ± 0.4, [-0.1, 1.7]

DISCUSSION

Our results demonstrated no significant differences in most key gait biomechanical outcomes between the actual prosthetic feet and the emulated versions using the PFE. The differences in prosthetic foot-ankle work, without corresponding differences observed in peak ankle power, may be explained by limitations in how the PFE was programmed. To create emulated feet in the PFE, we mechanically tested each foot at a fixed angle representative of late stance (i.e., +20 degrees) to collect angular stiffness properties,3 so the prosthetic feet may have incidentally flexed more under load during testing than is typically seen during use. Consequently, emulated feet may have exhibited greater ankle ROM during midstance than the actual feet, which could account for differences in ankle work despite similar peak ankle power. Future work should collect angular stiffness properties from using heel-to-toe rollover testing to emulate actual feet better. It is important to acknowledge that non-significance is not the same as statistical equivalence. Future work should also quantify the extent of gait biomechanical outcome agreement between emulated and actual prosthetic feet during walking and across a range of speeds and activities (e.g., inclines).

CONCLUSION AND CLINICAL APPLICATIONS

Emulated feet using a robotic PFE enabled similar gait biomechanical outcomes compared to corresponding actual feet during walking. Further, most participants correctly matched PFE feet to actual feet. These results agree with previous findings demonstrating the use of a PFE to facilitate rapid trials of prosthetic feet and can enable LLP users to contribute their preferences to prosthetic foot selection.

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Individuals in Warmer Climate Regions Do Not Report Worse Socket Comfort

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INTRODUCTION

For individuals with a lower-limb amputation, climate has been identified as the biggest environmental barrier to participation.[1] Recent work reported individuals in the Northeast have increased mobility [measured by the Prosthetic Limb Users Survey of Mobility (PLUS-M)] compared to individuals living in the South.[2] The climate differences in these regions would support the role of climate on patient outcomes. However, the analysis covered the four U.S. census regions, which consequently have high within-region climate variance.

Therefore, the purpose of this study was to evaluate differences in outcomes across multiple regions with differing climates. The primary focus was socket comfort based on believed impact of climate and mobility due to its role in participation. Nine regions of the United States were outlined based on climate from the National Oceanic and Atmospheric Administration. It was hypothesized that warmer climates would have lower socket comfort scores (SCS) as individuals likely cope with increased sweating and volume loss and reduced mobility from impacted fit.

METHOD

Data: This retrospective analysis on outcomes collected in the U.S. between 2017 and 2023 included 50,883 participants (males = 37,476; age = 59.19 ± 13.97 years, height = 1.75 ± 0.10 meter, weight = 89.94 ± 23.82 kg).

Outcomes: SCS, PLUS-M T-score.

Procedures: Patients were grouped into 9 climatic regions. For patients with more than one outcome during the time frame, the date with the highest PLUS-M T-score was chosen to reflect the highest functional mobility level the patient was able to achieve during their care.

Data Analysis: ANOVAs for SCS and PLUS-M T-score were conducted to test differences across regions. Season was entered as an interaction variable, defined as summer (June, July, August), winter (December, January, February), fall (September, October, November), and spring (March, April, May).

RESULTS

The main findings for SCS demonstrated a significant difference between regions ($F_{1,8} = 3.505$, $p = 0.0004$). After adjusting for the 4 seasons, the interaction effect between climatic regions and SCS and PLUS-M T-score was not significant.

DISCUSSION

Unexpectedly, the Northwest had decreased SCS, while both the Southwest and Upper Midwest had increased mobility. The data appears to suggest factors other than climate may cause regional differences in SCS and mobility. Limitations to this study include the inability to account for known differences in social determinants of health, which could have an impact on patient outcomes.

CONCLUSION

Individuals with a lower-limb prosthesis may experience lower SCS in the Northwest compared to other regions in the United States.

	n	Socket Comfort Score	PLUS-M T-score
Northeast	9539	6.85 ± 2.58*	47.76 ± 11.74†
Northwest	1360	6.54 ± 2.58	46.91 ± 11.82†
Northern Rockies	1130	6.91 ± 2.60*	48.99 ± 11.36
Ohio Valley	7989	6.81 ± 2.64*	47.22 ± 11.40†∞^
South	7059	6.79 ± 2.66	47.26 ± 11.52†∞
Southeast	9271	6.90 ± 2.64*	47.28 ± 11.56†∞^
Southwest	4444	6.91 ± 2.59*	48.02 ± 11.70
Upper Midwest	3974	6.78 ± 2.54	47.97 ± 11.58
West	6117	6.83 ± 2.62*	47.78 ± 11.85†

** Statistically significant versus Northwest. † Statistically significant versus Northern Rockies. ∞ Statistically significant versus Southwest. ^ Statistically significant versus Upper Midwest.*

CLINICAL APPLICATIONS

Prosthetic practices everywhere should be diligent in following up with patients to ensure their socket fit is acceptable, recognizing climate conditions may not be a precursor to socket fit issues.

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Straight-Line Walking on Cross-Slope in Lower-Limb Prosthesis Users

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INTRODUCTION

Outdoor walking for lower-limb prosthesis users (LLPUs) is challenged by uneven terrain, including cross-slope.1,2 To achieve stable straight-line walking on the cross-slope, LLPUs are required to generate an equal amount of upward mediolateral ground reaction force (ML GRF) impulse to counteract the downward gravitational impulse pulling the individual toward the bottom of the slope. A previous study demonstrates an asymmetric ML GRF control strategies between prosthetic and intact limbs in LLPUs during level-ground walking.3 Moreover, unilateral LLPUs have 2 different conditions: the bottom side is the prosthesis or an intact limb. Thus, compared to able-bodied controls, they would have more difficulty achieving the similar amount of ML GRF impulse as gravitational impulse for both conditions. Therefore, the aim of this study was to investigate the difference between ML GRF impulse and the gravitational impulse during cross-slope walking in unilateral LLPUs.

METHOD

This study was ethically approved by the Paris Ile-de-France VI committee. Participants were informed of the test content, and their consent was obtained.

Participants: Twelve unilateral transtibial prosthesis users (TTPUs: 11 males, 51.3±12.5 years, 1.75±0.05 meter, 81.8±13.7kg), 12 unilateral transfemoral prosthesis users (TFPUs: 12 males, 40.3±9.6 years, 1.75±0.08 meter, 75.6±10.5kg), and 14 able-bodied controls.

Apparatus and Procedures: All participants wore their own shoes and prosthesis, and their alignment was checked by the expert prosthetist on-site. They performed straight-line walking on a 6-degree inclined cross-slope surface at their self-selected walking speeds.

Data Analysis: GRFs were recorded using 2 force platforms for the prosthetic and intact limbs (the left and right limbs in the controls). Four successful trials were selected in both conditions (bottom side: prosthetic/left or intact/right limbs). Upward ML GRF impulse was calculated as summation of upward GRF impulse of both limbs. Downward gravitational impulse during the gait cycle was calculated as the product of body weight, sin 6 degree, and stride time. All variables were normalized by body weight of each participant. Finally, paired t-tests were performed to test the statistical differences in upward ML GRF impulse and downward gravitational impulse. Statistical significance was set at $p < 0.05$.

RESULTS

Figure 1A shows the averaged ML GRF for unilateral TTPUs, unilateral TFPUs, and able-bodied controls during the stance phase of cross-slope walking. In the unilateral TTPUs and TFPUs, the upward ML GRF impulse was significantly greater than the downward gravitational impulse for both conditions (Figure 1B). However, in the able-bodied controls, no significant differences were observed between two impulses for either condition (Figure 1B).

DISCUSSION

The results suggest that the LLPUs in both conditions move upward rather than in a completely straight direction. This extra upward impulse could provide a margin of safety if the LLPUs encounter a perturbation that pushes them downward and causes them to fall.

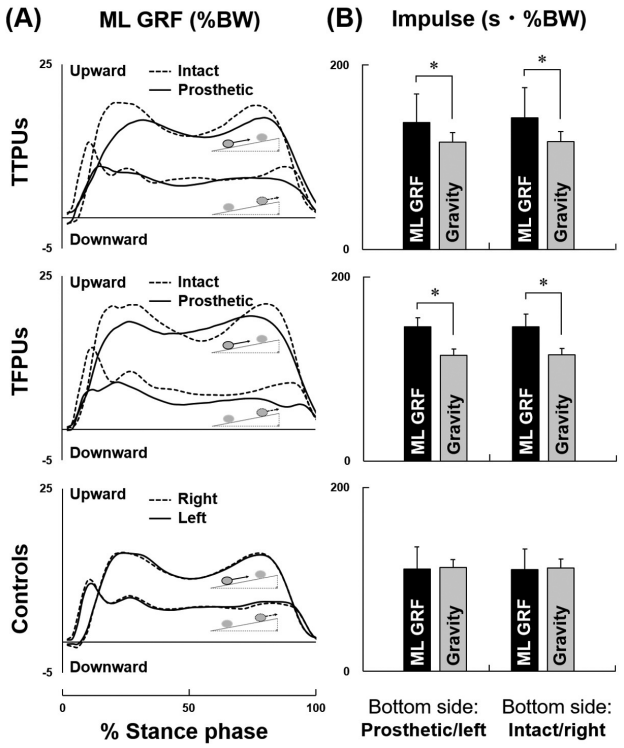

Figure 1. (A) Averaged waveform of mediolateral (ML) GRF for TTPUs (transtibial), TFPUs (transfemoral), and able-bodied controls during the stance phase of cross-slope walking. (B) Comparison between upward ML GRF impulse and downward gravitational impulse in both conditions (bottom side: prosthetic/left or intact/right limbs). An asterisk indicates a significant difference between 2 impulses.

CONCLUSION

Unilateral LLPUs have the specific ML GRF control strategies during straight-line walking on cross-slope.

CLINICAL APPLICATIONS

Further insights on this mechanics may serve as guidelines on prosthetic design to improve frontal plane stability during cross-slope walking in LLPUs.

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Fall-Related Health Outcomes in Lower-Limb Prosthesis Users: A Focus Group Study

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INTRODUCTION

More than half of lower-limb prosthesis (LLP) users experience at least one fall a year.[1] In addition to physical injuries, falls can lead to adverse emotional, behavioral, and/or fall-related self-efficacy outcomes. While described somewhat in the literature,[2,3,4] the relationships among these fall-related health outcomes are not well understood. The purpose of this study was to explore how LLP users experience fall-related self-efficacy, emotions, behavior changes, and life interference using the established tripartite affective, behavioral, and cognition (ABC) model of attitudinal structure.[5]

METHOD

Participants: LLP users were purposively sampled based on the following characteristics: woman, aged 65 years or older, active in or U.S. Armed Forces veteran, bilateral lower-limb amputation, transfemoral amputation, use of a prosthesis for ≤ 18 months, use of a prosthesis for 20+ years, fall in the last 12 months, and injurious fall in the last 12 months. At least 2 participants who met these criteria were included across the focus groups.

Study Design: Qualitative focus groups.

Procedures: Each focus group included 5–7 LLP users and lasted 2 hours. Group discussions were led by a trained facilitator using a standardized discussion guide. Each discussion was recorded and transcribed verbatim. All study procedures were reviewed and given exempt status by a local Institutional Review Board.

Data Analysis: A phenomenological framework was used to guide data analysis. Two researchers independently excerpted and coded each transcript. Codes were then organized into themes and mapped to the affective, behavioral, and cognitive components of the tripartite (ABC) model[5] to assess the model's application for describing LLP users' fall-related health outcomes. Triangulation among researchers was used to improve the credibility of the study findings.

RESULTS

Thirty-seven LLP users participated in 1 of 6 focus groups. Participants were men (17) and women (20) ranging in age from 27 to 86 years (median: 61). Level of amputation included transtibial (25), transfemoral (11), and hip disarticulation (1). Six participants reported no falls (16%), 5 reported one fall (14%), and 26 reported 2+ falls (37%) in the past year. Three themes emerged (Table 1).

DISCUSSION

The study findings are consistent with existing literature that describes fall-related anxiety, embarrassment, and shame among LLP users, in addition to a fear of falling.[6] Prior qualitative studies among LLP users have described behavior modification to improve participation and prevent future falls, such as planning ahead or using an assistive device.[2,7] Study findings also suggest the need for comprehensive interventions to reduce fall risk and increase LLP users' participation. Our study also supports the utility of the tripartite model of attitude for characterizing the effects of falls on LLP users' health and quality of life.

CONCLUSION

LLP users describe a range of emotional responses, behavioral changes, and beliefs about ability when thinking about falls. These outcomes are interrelated and can change over time. Measuring constructs pertaining to any of the tripartite model components, like affect (emotions), cognition (self-efficacy), or behavior (activity avoidance), in isolation may not fully capture the overall consequences of falls in LLP users. Future research should consider studying these constructs together to fully understand the effects of falls on the lives of LLP users.

Table 1. Emergent themes and example quotes.

My relationship with falls has changed with time. "Thirty years ago, the embarrassment was probably the biggest factor..., out in public or especially like if it was at work. Now...it is constantly...in my mind that I don't want to fall, because I'm afraid of the other damage it could do, either the knees or shoulders or whatever." —Pt 14, 81-year-old man, bilateral TT amputation
Navigating the world safely with my prosthesis requires attention and planning. "I think being an amputee, you have to be a lot more aware of your surroundings and pay more attention of where you are walking, where you are going, more so than what people do that have both of their limbs." —Pt 1, 69-year-old woman, TT amputation
I must make a tradeoff between my risk tolerance and what I want or need to do. "I don't think I've ever been in a situation where I wasn't worried about the fall, but whatever the activity was or the people I was doing it with, the desire to do that thing or be with that person, or whatever, outweighs that." —Pt 36, 28-year-old woman, TF amputation

CLINICAL APPLICATIONS

Clinical interventions that improve fall-related self-efficacy, reduce fall-related avoidance behaviors, and/or reduce fall-related emotions (e.g., anxiety) may have a positive effect on LLP users' health outcomes.

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A Biomechanical Explanation of Bone Loss in Transfemoral Prosthesis Users: How Our Everyday Decisions Can Influence Bone Behavior

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INTRODUCTION

There is a 50-year recorded history suggesting bone loss in persons with transfemoral amputation (TFA) at levels seen in bedridden and post-menopausal individuals, irrespective of age and mobility levels. These reports suggest that gait deviations, time from post-amputation to prosthetic fitting, muscle atrophy, and chemical imbalance may be factors predicting surviving femur bone loss, but the evidence to support their contributions is inconsistent.[1,2]

Despite the function of a prosthesis (and prosthetic socket) to transfer ground forces to the residual limb and the role of mechanotransduction in bone health,[3] prosthesis design is rarely described in prior studies, and its relationship to bone loss has not been studied. To our knowledge, studies have not yet quantified the effects of prosthetic socket design on the mechanical environment of the residual femur during loading. This study aimed to quantify those relationships, namely effects of ischial containment sockets (ICS) and sub-ischial sockets on bone strain, through finite element (FE) simulation of load bearing during gait.

METHOD

Participants: Data of computerized tomography (CT) scans from 5 females (10 scans total), and kinetic and kinematic level ground gait data from 10 age-matched (26.4 ± 5.5 years), height-matched (174 ± 6.5cm), and weight-matched (70 ± 9.4) persons with unilateral TFA.[3]

Procedures: FE models were assembled recreating pelvic and femur position as recorded by gait analysis markers. Prosthetic socket geometry was defined to resemble an ICS and sub-ischial socket design, and loads were applied to simulate instances of peak load during heel strike (HS) and push-off (PO).

Data Analysis: CT and prosthetic socket geometries were reconstructed in ABAQUS (Aachen, Germany) for FE analysis. Strain applied to the residual femur was estimated following simulated load.

RESULTS

Figure 1 displays percentage of trabeculae bone under certain ranges of strain for each socket and gait instance. Results suggest that for the ICS condition, all of the trabecular bone is mechanically stimulated below -300 μstrains (less compressive strain) for both HS and PO. However, the sub-ischial design elevates compressive strain (more negative), stimulating more bone tissue above the -300 μstrains, especially during HS, which is the threshold for rescuing the bone from atrophy according to the mechanostat theory.[4]

DISCUSSION

Our simulation suggests that all strain experienced by a residual femur under walking is shifted below the threshold needed for retaining bone mass in an IC socket compared to a sub-ischial socket.[4] This finding may partially explain the bone loss observed in transfemoral prosthesis users.

CONCLUSION

Socket designs that rely on ischial support may produce a mechanical isolation effect of the femur (a "floating femur") by minimizing axial forces as it is redirected to the pelvis.

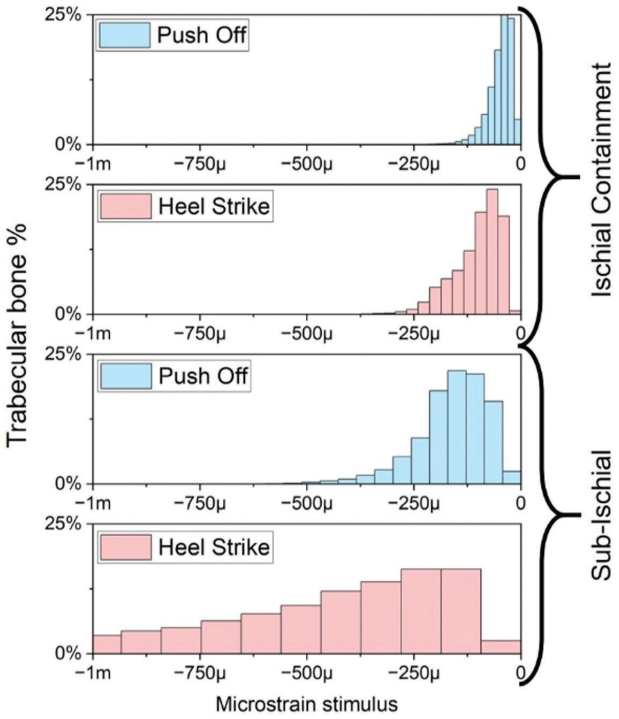

Figure 1. Minimum compressive strain during heel strike and push-off under effect of two different socket designs (ischial containment and sub-ischial).

CLINICAL APPLICATIONS

Clinical design of a prosthetic socket may impact bone health in transfemoral prosthesis users, emphasizing the importance of prosthetic component selection and design when considering patient health from a holistic perspective.

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Real-World Evidence Burden of Disease of Transfemoral Amputees Using a C-Leg or Genium: First Results of a Patient Survey

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INTRODUCTION

Typically, an account of the burden of disease (BoD) experienced by afflicted individuals proves to be highly advantageous in evaluating the individual additional benefits of a therapy for the patient, their family, the health care system, and society at a large. Despite this, individuals who could effectively describe the BoD, including participating in occupational, social, and everyday activities, and coping with disability and self-perception have seldom been expounded upon in relation to microprocessor-controlled knee-joints (MPKs). The purpose of this observational study was to gain further understanding of the BoD and the potential benefits of using MPKs.

METHOD

Participants: Participants were between the ages of 18 and 80+ years with transfemoral amputation or knee disarticulation who had used a microprocessor-controlled knee joint (C-Leg or Genium, Ottobock) for at least 3 months, with or without pre-fitting.

Apparatus: Rogator survey was used; Likert scales, Reintegration into Normal Living (RNL), Amputee Body Image Scale (ABIS), EQ-5D-5L, as well as self-designed questions.

Procedures: Users of the Cockpit app (Ottobock) who consented were invited via e-mail to participate in the survey in Germany. After Informed consent (IC) was given, participants filed in a digital survey that contained 115 question points with a maximum number of 184 questions.

Data Analysis: Minitab/Metlab; non-parametric methods; Chi2-/Fisher-Exact test; Bonferroni correction; Person's correlation.

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

RESULTS

Five hundred sixty-four individuals participated in the survey (32%); 531 participants had an average age of 53.7 (+12.5) years have been analyzed (80.09% males and 19.91% females). Genium was the actual knee joint in slightly above 70% of the participants. It was shown that the participation of the responders is generally good. Just over half (55.5%) of the participants were employed full or part-time; compared to the German population, part-time is 50% less common. Just over 21% (21.3%) of those who worked have been retrained. Participation in social activities in the workplace is seen as significant less of a constraint compared to physical demands: carrying, picking up or moving objects ($p = 0.01$), or maintaining the same posture for an extended period of time ($p = 0.001$). Overall, the RNL achieved a mean score of 86.8, indicating a very high level of participation in activities of daily living in the community. Participants using Genium had an average total RNL score of 93.93. This value was 5.08% higher than the mean total RNL score for the C-Leg ($p = 0.001$). For self-perception, the median ABIS score was 44, indicating some form of body image disorder. Differences were shown for age, gender, and employment status. For quality of life (QoL), a median of 0.9 was shown, which was even 5.81% higher in Genium users (0.91). Just over half of the participants (51.1%) stated that their QoL is much better with their actual MPK.

Regarding differences between the genders, it was shown that females and males perceive the BoD differently. Self-perception was significantly worse for women.

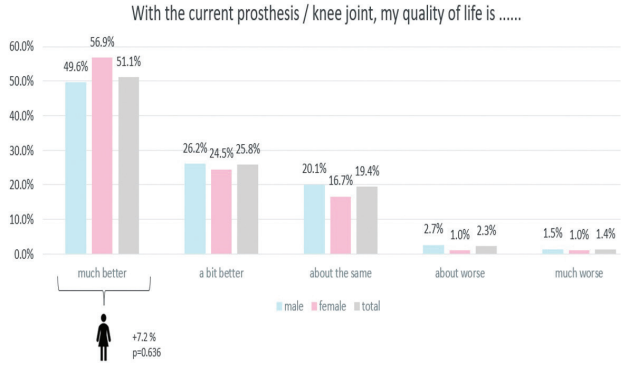

Figure 1. Quality of life: Actual MPK compared to previous knee joint.

DISCUSSION

Compared to the German DRG amputee cohort with a nearly balanced gender distribution, only 20% of females who used an MPK participated. This might have influenced the gender results. In general, more research is needed to raise awareness about the BoD among transfemoral amputees.

CONCLUSION

Participation in daily and occupational life of patients is restricted to some degree and can be improved using a microprocessor-controlled knee joint.

CLINICAL APPLICATIONS

Individual participation aspects should be considered when selecting an MPK to reduce the individual's burden of disease.

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Evaluation of Damping Componentry on Prosthesis Work during Gait

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INTRODUCTION

Damping componentry includes but is not limited to hydraulic ankle units and shock-absorbing pylons (SAPs). Hydraulic ankles are a passive damped articulation between the prosthetic foot and the shank/pylon, and they have been linked to an increase in walking speed.[1] SAPs comprise a shank with viscoelastic properties that can compress about the longitudinal axis and/or twist about the transverse axis. They have been shown to increase the magnitude of negative work during stance.[2] An increase in damping of the prosthesis system could reduce the energy transmitted from the prosthesis to the proximal anatomy during a load-bearing activity such as walking and minimize trauma to the tissue of the residuum. The purpose of this study was to assess the interaction effects of SAPs and hydraulic ankles on prosthesis power and work during level-ground walking.

METHOD

Institutional Review Board approval was obtained from the Jesse Brown VA Medical Center. Prior to data collection, informed consent was obtained from participants.

Participants: Three unilateral transtibial prosthesis users (1 female/2 male; 44 ± 8 years; 1.70 ± 0.15 meters; 76.8 ± 15 kg).

Apparatus: Kinematic and kinetic data were collected using a 12-camera motion capture system at 120 Hz (Motion Analysis Corporation, Rohnert Park, CA), and 6 floor-embedded force plates at 1200 Hz (AMTI, Waterton, MA), respectively. A full-body marker set consisting of 37 markers was used to create a 6 degree-of-freedom 12-segment kinematic model.

Procedures: Participants walked overground along a 10 meter level walkway at a self-selected comfortable speed under 4 passive prosthesis conditions: dynamic prosthetic foot (Horizon, College Park, MI) (Foot), hydraulic ankle foot (Odyssey K3, College Park) (Foot+Ankle), and both feet with a SAP (DuraShock Short, Fillauer, TN) (+Pylon) based on body weight according to manufacturer guidelines. Participants walked with their customary socket, suspension system, and standardized minimal-sole shoes.

Data Analysis: Kinematic and kinetic data were processed using Visual3D (C-motion, MD) and were filtered with a frequency cutoff of 6 Hz and 25 Hz, respectively. Instantaneous mechanical power (W/kg) from the prosthesis (i.e., foot and pylon) and anatomical ankle-foot complex during stance were calculated using the unified deformable power analysis.[3] Positive, negative, and net mechanical work (J/kg) of the ankle-foot complex were calculated by integrating power with respect to time using custom Matlab code (Mathworks, Natick, MA). Net work is the sum of the positive work (energy generated) and negative work (energy absorbed) by the prosthesis.

RESULTS

Between the sound limb and the prosthetic limb, there was mechanical work differences as demonstrated by a deficit in positive work throughout stance phase (Figure 1).[2] The inclusion of shock-absorbing prosthetic componentry decreased net work, or increased the energy dissipated from the system compared to the foot-only condition.

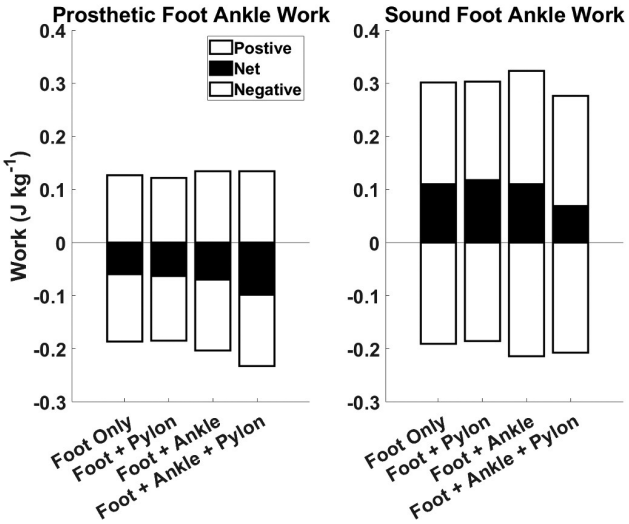

Figure 1. Group average prosthetic positive, negative, and net mechanical work. Error bars omitted for clarity.

DISCUSSION

Results suggest a compounding effect of added componentry, with the greatest prosthetic energy dissipated (most negative net work) from the hydraulic ankle and SAP condition. Despite increased energy absorption (negative work), addition of damping componentry had minimal effect on prosthetic energy generation (positive work). The sound limb demonstrated minimal changes in work in all conditions except for the hydraulic ankle and pylon condition, where less energy was generated by the prosthetic limb (decreased positive work). Data collection and analysis is ongoing.

CONCLUSION

The addition of damping componentry (hydraulic ankle and SAP) may increase transtibial prosthetic energy absorption and dissipation during walking. Future analyses will investigate proximal joint work.

CLINICAL APPLICATIONS

The increase in energy dissipated from the prosthetic system may increase patient comfort and potentially reduce injury to the proximal anatomy.

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Prosthetic Feet and the Carriage of Infants, Toddlers, and Other Loads

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INTRODUCTION

When weight bearing loads borne by a prosthesis change suddenly, such as when an individual carries an infant, toddler, or other load, an increase in prosthesis stiffness may be needed to maintain important biomechanical functions such as body weight support and forward propulsion.[1,2] While many occupations (including parenthood) require load carriage, there is little evidence to guide the prescription practice to improve mobility. The purpose of this research is to provide evidence to support prosthesis prescription for individuals with a lower-limb amputation who frequently carry infants, toddlers, or other loads.

METHOD

Subjects: Twelve individuals with unilateral transtibial amputations provided informed consent to participate in this Institutional Review Board-approved protocol (2 female, mass: 96.1 ± 15.9 kg, height: 1.76 ± 0.09 meters, age: 46 ± 15 years, post-amputation: 13 ± 14 years, etiology: 8 trauma, 2 congenital, 1 infection, 1 diabetic). All participants considered themselves moderately active community ambulators.

Interventions: Each participant wore a standard-of-care prosthetic foot (PR), this same prosthetic foot with a heel-stiffening wedge (HW), this same prosthetic foot but one category stiffer (SF), a dual keel prosthetic foot intended for load carriage applications (DK), and a powered foot (PF).

Apparatus: Five embedded force plates (AMTI) and a motion capture system (Vicon) were used to record the ground reaction force data at 1,200 Hz.

Procedures: Following an acclimation period and overnight rest, each subject walked overground at their self-selected speed with no added load (NL) and 4 added load conditions using a 13.6 kg weighted pack (approximately 30 pounds) to simulate an infant, toddler, or other load. The 4 load conditions included the pack strapped to their front (LF), the pack strapped to their back (LB), the pack carried with arm assistance on their intact limb side (IS), and the pack carried with arm assistance on their prosthetic limb side (PS).

Data Analysis: Ground reaction impulse in the vertical direction, a measure of body support, and anterior direction, a measure of body forward propulsion, were calculated as the integral of ground reaction forces during stance using MATLAB software. Linear mixed effects regression was used to assess differences by foot type for each load. Conditional F-tests were used to detect overall associations, and Tukey's method was used to identify pairwise differences with significance at $p < 0.05$.

RESULTS

The powered foot (PF) provided greater body support compared to the standard of care (PR, $p = 0.024^{a}$) and the dual keel foot (DK, $p = 0.046^{b}$) when the load was carried on the back (LB) (Table 1). No differences in body support between feet were observed for no load or other load carriage conditions.

The foot with the heel-stiffening wedge (HW) provided greater forward propulsion compared to the foot one category stiffer (SF, $p = 0.009^{f}$) when the load was carried on the front (LF) (Table 2).

Table 1. Vertical ground reaction impulse (N-s/kg). Superscript letters indicate pairwise differences.

	LF	LB	IS	PS	NL
PR	5.24	5.37[a]	5.25	5.29	5.24
HW	5.26	5.40	5.24	5.29	5.30
SF	5.29	5.42	5.14	5.24	5.27
DK	5.28	5.39[b]	5.21	5.34	5.33
PF	5.44	5.63[a,b]	5.35	5.51	5.46

When there was no load (NL), the powered foot (PF) provided more forward propulsion than the foot one category stiffer (SF, $p = 0.027^{d}$) and the dual keel foot (DK, $p = 0.036^{e}$). The standard-of-care foot (PR) also provided more forward propulsion than the foot one category stiffer (SF, $p = 0.048^{c}$) when there was no load (NL). No differences in forward propulsion between feet were observed for other load carriage conditions.

Table 2. Anterior ground reaction impulse (N-s/kg). Superscript letters indicate pairwise differences.

	LF	LB	IS	PS	NL
PR	0.225	0.236	0.224	0.219	0.232[c]
HW	0.235[f]	0.236	0.219	0.223	0.228
SF	0.212[f]	0.219	0.21	0.213	0.213[e,d]
DK	0.217	0.225	0.208	0.214	0.214e
PF	0.248	0.257	0.247	0.256	0.257[d,e]

DISCUSSION AND CONCLUSIONS

For individuals who need additional body support, a powered foot appears to offer advantages when a load is carried on the back. For those who need additional forward propulsion, a heel wedge is better than a one category stiffer foot when a load is carried on the front. When no load is carried, there were no differences between study feet in providing body support, but the powered foot and the standard-of-care appeared to provide more forward propulsion than other study feet.

CLINICAL APPLICATIONS

For individuals who carry loads, consideration of their preferred load carrying method may help guide the most appropriate foot prescription for these biomechanical measures.

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Initial Investigation on Portable Measurement Systems for Ground Reaction Forces Utilizing Powered Prosthetic Knees

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INTRODUCTION

Ground reaction forces (GRFs) have been widely used to evaluate biomechanics of lower-limb amputees.[1,2] Most of the studies were conducted in the laboratories with stationary force plates to measure the GRFs. These devices are limited to indoor use, making it difficult to measure GRFs during daily activities in outdoor environments such as rough terrains, slopes, and stairs. These limitations can be solved by utilizing sensors mounted on microprocessor-controlled prosthetic knees (MPKs). As an initial investigation, one of the MPKs with a force sensor was used to confirm differences between the GRFs measured by the prosthetic knee and by stationary force plates.

METHOD

This study was approved by the local ethics committee, and all procedures followed the Declaration of Helsinki (1983). Participants were informed of the test content, and their consent was obtained.

Participants: A 35-year-old male (170 cm, 60 kg) with a right transfemoral amputation (amputated in 1996) was recruited for this study. The participant wore a motor-powered MPK (Bio Leg, BionicM Inc., Japan) and his prosthetic foot (Assure, Össur, Iceland) during experimental trials.

Apparatus and Procedures: As shown in Figure 1, the participant walked on the force plate-embedded instrumented treadmill (FTMH-1244WA, Tec Gihan, Japan) for 30 seconds at 4.0 km/h, which was the most comfortable walking speed for the participant. During the trial, we collected the force data measured by a force sensor equipped on the prosthetic knee. Both of the data, measured by the treadmill (1000 Hz) and by the prosthesis (200 Hz), were collected simultaneously.

Data Analysis: The data of the prosthetic knee was resampled from 200 Hz to 1000 Hz to align the data lengths. All the data were trimmed until the data on the vertical axis became smaller than 40 N for the first time to synchronize the data. The mean value of each axis was removed. We used the Pearson's correlation coefficient to compare similarities of the time-series data.

RESULTS

Pearson's correlation coefficients of these data in each axis are shown in Table 1. Figure 2 shows time-series post-processed data on 2 axes in the sagittal plane. Black solid and gray dotted lines indicate the data measured by the treadmill and by the prosthetic knee, respectively.

DISCUSSION AND CONCLUSION

The experimental results shown in Table 1 indicate that data of the prosthetic knee show a high degree of similarity with those of the treadmill. The vertical GRF of the prosthetic knee was able to capture the characteristic two peaks in the gait cycle (Figure 2B). It was confirmed that the data of the prosthetic knee in the transverse plane showed the general trend as those of the treadmill; however, some of the peak values may not be measured as shown in Figure 2A. Further studies may be required to investigate how the differences of prosthetic foot and shoes may affect on the GRFs.

Figure 1. Experimental setups.

Table 1. Pearson's correlation coefficients of the processed data on each axis.

Axes	Medio-lateral	Antero-posterior	Vertical
Correlation	0.621	0.809	0.986

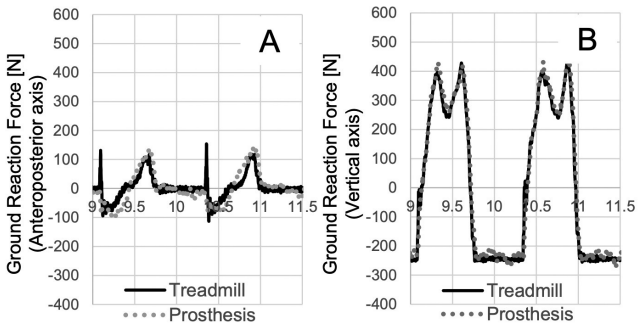

Figure 2. Time-series processed data in the sagittal plane.

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Unveiling the Hidden Harm: Examining the Impact of Microagressions in Health Care and the Efficacy of a Microagressions Education Workshop in Orthotics and Prosthetics

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INTRODUCTION

Workplace environments and patient adherence are both negatively impacted when there is an increase of microaggressions present.[1] Microaggressions (MA) are defined as an everyday nonverbal or environmental slight, snub, or insult, whether intentional or unintentional, that communicates hostile, derogatory, or negative messages to target persons based solely upon a marginalized group membership.[2] The aim of this study is to evaluate the effectiveness of a microaggressions education workshop.

METHOD

An investigation of current research was conducted to determine the prevalence, effect, and current approaches to decrease microaggressions in different workplace environments. Information was adapted for the formulation of a training presentation that included definitions, short and long-term effects, written and clinical vignettes, and tools to address microaggressions within the orthotics and prosthetics (O&P) workplace.

Participants: This interactive virtual presentation was presented through the Baylor College of Medicine Continuing Education platform to O&P practitioners.

Apparatus: An evaluation was distributed to all participants after the presentation to assess their self-reported improvement of knowledge related to concepts presented in the educational workshop.

Procedures: Participants answered a total of the same 8 questions on an agreeance scale: 8 questions for pre-session knowledge and the same 8 questions for post-session knowledge.

Data Analysis: A comparative analysis on participant responses was conducted to evaluate the effectiveness of the training on perceived knowledge.

RESULTS

There were 22 participants that attended the workshop, and 16 participants completed the post survey. There was an increase of responses toward agreeance with some statistically significant differences. The greatest changes were noted in how participants felt they were prepared to respond if they witnessed an MA toward a patient or themselves and then their ability to properly identify MAs in the workplace. There was not a statistically significant difference in responses where the participant witnessed a co-worker the recipient of an MA, with most agree or strongly agree both pre and post survey.

DISCUSSION

Participants tended to agree in all areas that the information provided in the workshop increased their awareness of MAs in the workplace. The ability to define the term MA and properly identify instances in the workplace increased post presentation. Notably there was one participant who answered "strongly agree" to the statement "I feel I can properly identify MAs in the workplace" but then answered "agree" in the post survey. This participant may have thought they were aware of what is considered an MA but after the presentation provided knowledge of concepts and examples, is no longer sure of certain behaviors. We still see these results as a positive finding as awareness leads to self-introspection and behavioral changes.

Table 1. Summary of statistically significant responses.

Participants were asked level of agreeance of the following statements: (abbreviated)	Median Differences[a]	Wilcoxon Signed Rank Test[b]	IQR[c]
MA Definition	1	0.004	1.75
Identify MA	1	0.003	1.5
Self Recipient of MA	1	0.014	1
Co-worker recipient of MA	0.5	0.050	1
Patient Recipient of MA	0	0.025	1
Self aggressor of MA	1	0.002	1
Prepared to Respond Self Aggressed	1	0.001	1
Prepared to Respond Patient Aggressed	1	<0.001	1
Is MA Training Beneficial	0	0.011	1

a. Not the difference between the medians
b. The significane level is $p<0.05$
c. Interquartile range

CONCLUSION

Our findings suggest that the average participant had an increase of knowledge and awareness of microaggressions in comparison to the start of the workshop. Most participants agreed that a microaggression training can directly reduce microaggressive behaviors in the workplace environment. Further investigation is necessary to confirm the long-term impacts of the training.

CLINICAL APPLICATIONS

Microaggression training can decrease the instance of MAs in the O&P workplace, therefore increasing positive workplace environments.

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Defense Health Agency Knowledge, Skills, and Abilities for Orthotists

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INTRODUCTION

The purpose of this platform is to present advanced orthotic care specific knowledge, skills, and abilities (KSAs) for orthotists within the Defense Health Agency (DHA). Increased battlefield survivability resulted in Department of Defense (DOD) service members entering rehabilitation with levels of impairment that challenged the orthotists' knowledge and skills. This forced advances in practice. The Defense Health Board provided the report, *Sustainment and Advancement of Amputee Care*.[3] Finding 2 states, "Although DoD is providing excellent amputee care and trauma care, failure to sustain and advance medical readiness in peacetime has limited DoD's capability to deliver high-quality traumatic amputee care in the past and may threaten that capability in the future." Recommendation 2 states, "DoD must ensure sustainment of the highest quality delivery of health care and health research despite post-conflict resource limitations. Core competencies in optimal amputee care and trauma care must be defined, periodically updated, tracked, and regularly reported to the leadership of the Military Health System (MHS)."

METHOD

The DOD Extremity Trauma and Amputation Center of Excellence (EACE) has documented the orthotist KSAs associated with advancement in clinical practice over the past 16 years. A small group of subject matter experts (SMEs) utilized an existing DoD KSA documentation format, an EACE sponsored Rand Corporation study that documented orthotist and prosthetist competencies in amputation care, and existing clinical practice guidelines to create the orthotist KSA document. Two successively broader teams of DOD and non-DOD SMEs then reviewed the developed document for edits and consensus.

RESULTS

The orthotist KSAs contain five domains: (1) Body Segment: The specific segment of the body where there is functional and/or mobility deficit; (2) Practice or Practice Management: advanced orthotist practice within a transdisciplinary team; (3) Health Comorbidities: secondary or concurrent diagnoses that affect the treatment of the body segment that addresses loss of function; (4) Military Specific: advanced orthotist practice within the U.S. military context; and (5) Diseases and Disorders: advanced orthotic care for the complex trauma patient that recognizes the unique prognosis of specific diseases and disorders with focus on the need for the orthosis. Resulting in 20 terminal learning objectives (TLOs) and 90 enabling learning objectives (ELOs).

Table 1. Orthotic KSA domains and number of terminal and enabling learning objectives.

DOMAIN	TLOs #	ELOs #
Body Segment	4	24
Practice or Practice Management	9	27
Diseases & Disorders	2	12
Health Comorbidities	3	17
Military Specific	2	10

DISCUSSION

The primary responsibility of the DOD orthotist is to provide expert orthotic care to injured service members. The goal of this care is to optimize outcomes that result in return to duty or full community reintegration. The current ad hoc approach to training and retention in the DHA is inadequate to maintain this critical wartime combat casualty care skill set. Maintenance of this skill set requires both currency and competency in the treatment of individuals after trauma requiring orthotic intervention.

CONCLUSION

The standardization of KSAs is an essential first step in standardizing advanced education for orthotists as orthotists' roles in DOD/DHA evolves, orthotic care advances with technology, and new paradigms in care emerge.

CLINICAL APPLICATIONS

Standardization of KSAs enhances the quality-of-care beneficiaries receive. This free paper will familiarize attendees with the methodology of the development, the current content, the implications for current practice, and additional resources.

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Design and Evaluation of a Personalized Orthosis Based on Trunk Asymmetry in Adolescents with Idiopathic Scoliosis

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INTRODUCTION

Adolescent idiopathic scoliosis is a three-dimensional, progressive spine deformity that affects mostly girls in their rapidly growing age; i.e., from 10 years old to skeletal maturity. Spinal orthoses combined with exercise are the best-evidenced method to prevent the progression of curves aiming to avoid invasive surgery.[1] There is a dissimilarity between therapists' and the families' aims of therapy. Therapists are interested in achieving a better lateral curvature, measured on the spinal X-ray using the Cobb method, while families are interested in acquiring a symmetrical look of the body's appearance.[2]

The pads in the spinal orthoses are responsible for exerting corrective forces on the curves. The location of the pads is usually determined by the visual assessment of the clinician to correspond with the X-ray evaluation of the spine. Moreover, the shape of pads in many orthoses, such as Milwaukee and Boston, is pre-defined with minimum personalization.[3] We believe that a more personalized orthosis design will improve the efficacy of the treatment in terms of better trunk and spine symmetry. Therefore, this study aimed to design a new orthosis based on trunk asymmetry in adolescents with idiopathic scoliosis and investigate the efficacy of the new design on Cobb angle and trunk morphology in a pilot study.

METHOD

We employed surface 3D scanning and conducted asymmetry analysis to compare the shape of the torso's two left and right halves. The orthosis pads' shape and location were identified based on the asymmetry of the torso.[4] Then in a pilot study, we compared the efficacy of the new design with the conventional orthoses on 3 patients using the new design and 4 patients using the conventional orthosis. The Cobb angle of the lateral curvature, trunk asymmetry, Trunk Appearance Perception Scale (TAPS), and brace satisfaction were employed as outcome measures.

RESULTS

The new design decreases spine deviation (31%), improves trunk asymmetry (mean back surface rotation: 49.6% / mean trunk rotation: 30%) and appearance perception (38%), and promotes brace satisfaction (79% compared to 55% in conventional brace).

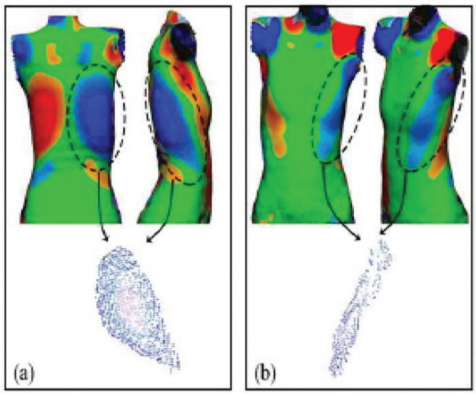

Figure 1. Three-dimensional deviation contour map.

Table 1. Comparing the improvement of the parameters between the new and conventional brace groups after follow-up.

	Parameter in Detail	N.B.: Mean (SD) [%]	C.B.: Mean (SD) [%]	P
ΔCobb Angle (°)	Mean	+11.50 (3.69) [31%]	+11.50 (3.12) [20%]	1.00
Trunk Rotation (°)	Max	+8.00 (5.89) [+41%]	-0.14 (10.41) [-17%]	0.40
	Mean	+2.63 (3.78) [+30%]	-2.31 (7.46) [-2%]	0.63
Back Surface Rotation (°)	Max	+5.00 (6.87) [+27%]	+4.00 (3.54) [+27%]	1.00
	Mean	+3.36 (2.83) [+50%]	-1.19 (3.20) [-7%]	0.63
TAPS (score)	Mean	+0.88 (0.83) [38%]	-0.11 (0.19) [-3%]	0.20
Brace Satisfaction	Mean	79% (0.16)	55% (0.04)	0.10

N.B: New Brace group, C.B: Conventional Brace group, [%]: Percentage of improvement, TAPS: trunk appearance perception scale.

CONCLUSION

The current study's findings suggest that the brace with a personalized padding system enhanced the aesthetic aspect of the trunk while maintaining the positive effects on correcting the Cobb angle.

CLINICAL APPLICATIONS

The findings of the present study might affect the brace treatment approaches by emphasizing the importance of considering trunk symmetry when estimating treatment goals.

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Orthotic Management of a Hypermobile Transgender Patient with Ehlers Danlos Syndrome: A Case Study

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INTRODUCTION

Ehlers-Danlos Syndrome (EDS) is a connective tissue disorder characterized by joint hypermobility, fragile skin, and hypersensitivity. Gender dysphoria is an incongruence between a person's gender assigned at birth and their affirmed gender, which may result in psychological factors such as anxiety, depression, and body dysmorphia.[1] Though there has been little research done to date on transgender adolescents diagnosed with EDS, there are indications in the adult EDS population that the incidence of transgender and gender non-conforming (GNC) individuals is twice as high than in the general population.[1] This case study seeks to identify and highlight some of the multidimensional challenges experienced by a 13-year-old transgender patient diagnosed with EDS and provide a successful wholistic approach to orthotic care, addressing the confluence of these complex conditions.

CASE PRESENTATION

The patient is a 13-year-old transgender boy who was referred to the orthotic outpatient clinic by a pediatric physiatrist who specializes in EDS, joint hypermobility syndrome, and chronic pain. Prior to the evaluation appointment, we were informed of the patient's gender identity and preferred name which were noted in the chart. The patient reports symptoms starting about 2 years prior with an increase in frequency and pain level, specifically in the knees, cervical spine, and lumbar spine. The patient presented with global weakness secondary to fatigue with scores of 4/5 in manual muscle testing in all gross muscle groups and hypermobility in hips, shoulders, and thoracic spine. Due to chest dysphoria, the patient has a volitional postural kyphosis and practices chest binding (compression of breast tissue to achieve a more masculine appearance) 75% of the time. He reports a severe drop in physical and social activities since the onset of pain, fatigue, and instability secondary to EDS.

MANAGEMENT AND OUTCOME

The primary orthotic treatments selected for this patient were a dynamic elastomeric fabric orthosis (DEFO) and bilateral custom foot orthoses. Somatosensory orthoses have been shown to improve postural control impairment[2] and reduce pain for patients with EDS. The DEFO was designed to provide increase stability and provide compression to the hips, thoracic spine, and shoulders, helping to control excessive mobility and reduce the risk of subluxations. It accommodated the patient's use of a chest binder, ensuring comfort, freedom of movement, and expected body profile to increase patient acceptance and compliance. The orthosis was designed to fit appropriately with or without the binder due to a supportive stretch fabric being integrated into the chest area of the orthosis. The DEFO's corrections influencing shoulder retraction and thoracic extension were reduced due to volitional kyphosis. Outcomes were collected using the 11-point Numeric Pain Rating Scale (NPRS) and the Fatigue Severity Scale (FSS) at the evaluation, 6-week follow-up and 6-month follow-up. The patient was also treated with custom foot orthoses (FOs), contributing to scores.

Table 1. Patient's self-reported pain and fatigue levels.

	EVAL	6 WK. F/U	6 MO. F/U
NPRS	3	2	2
NPRS Max	10	7	7
FSS	60	50	53

DISCUSSION

Orthotic management with a DEFO and FOs to improve the patient's mobility, stability, and function resulted in the patient's self-reported decrease in pain and fatigue levels (Table 1) which were the primary barriers to the patient's ability participate in physical and social activities. Importantly, wholistic treatment of the patient required some additional considerations. An open discussion was initiated with the patient about what types of orthoses he would consent to wearing and what the benefits and drawbacks of different treatment modalities may entail. In consideration of the patient's psychosocial factors, his preference was to have the DEFO accommodate his body shape both with the chest binder and without. The orthotic treatment choices made as part of an interdisciplinary collaboration between the physiatrist, patient, patient's family, and orthotist enhanced the patient's acceptance and compliance, resulting in a decrease in pain and fatigue, which facilitated improved participation in physical and social activities.

CONCLUSION

This case study highlights the successful orthotic management of a 13-year-old transgender boy with EDS. The orthotic interventions facilitated improved joint stability, enhanced functional mobility, reduced pain, and reduced fatigue. The outcomes of this case study underscore the importance of individualized care, wholistic treatment, and evidence-based orthotic treatments to optimize the quality of life for patients with complex musculoskeletal and psychosocial factors. The correlation between transgender pediatric and adolescent patients with an EDS diagnosis is still being studied, but indications are this may be a growing patient population necessitating further study.

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Orthotists Perspectives on Physiotherapy Scoliosis Specific Exercises to Treat Idiopathic Scoliosis

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INTRODUCTION

Physiotherapy scoliosis specific exercises (PSSE) is a specific physical therapy regimen to treat idiopathic scoliosis (IS). It must consist of auto correction in 3 dimensions: training in activities of daily living, stabilizing the correct posture, and patient education.1 There are 7 schools of PSSE that are currently accepted and named based on the region where they were founded.[1] When comparing surgical rates of brace treatment and brace treatment combined with PSSE, the surgical rate dropped from an average of 23% to 14%.1 Brace treatment is effective at preventing curve progression, while PSSE in combination with bracing has shown to reduce Cobb angles.[1] No studies were found regarding orthotist's attitudes regarding PSSE to treat IS. The purpose of this research study is to investigate orthotists' perspectives on PSSE to understand whether orthotists in the United States are discussing and educating patients about PSSE as an option for treating IS.

METHOD

This research study was approved by Eastern Michigan University Human Subject Review Committee. Informed consent was obtained prior to participation.

Participants: Twenty-one people (14 CPOs, 5 COs, and 2 orthotic/prosthetic residents) completed the survey.

Apparatus: A 25-question Google Form survey, which was written based on surveys from published papers.[2,3] The wording of the survey was reworked to target the orthotist's perspective instead of the doctor's opinions regarding PSSE. This survey was validated by 3 orthotists in the field who were not affiliated with the research project.

Procedures: Subjects were recruited via email, LinkedIn, the OANDP-L email discussion list, and O&P-related websites. Subjects completed an anonymous survey to answer questions regarding their perspectives of PSSE to treat IS.

Data Analysis: Descriptive analysis was conducted to summarize survey results.

RESULTS

Seventy-eight percent of respondents reported recommending PSSE, with the Schroth method being the most recommended school. Preventing curve progression and improving posture were the most common reported reasons for recommending PSSE. See Figure 1 for a summary of reasons for recommending. Respondents reported not recommending PSSE due to a lack of evidence, a lack of access to a physical therapist, a lack of personal knowledge, or because they leave it up to the referring doctor to discuss with the patient. The majority of respondents (83.3%) reported that the physicians they work directly with prescribe PSSE. When the patient or family asks about PSSE, 44.4% of respondents reported giving background information, 33.3% reported that they would help the patient and family find a physical therapist that specializes in PSSE, and 22% advised the patient to discuss the option with their doctor.

Figure 1. Summary of PSSE methods that respondents recommend to their patients.

DISCUSSION

Orthotists reported that the referring doctors they work directly with are prescribing PSSE at a higher rate than previous research.[2,3] Limitations of this study include the small sample size, recruitment style, lack of knowledge of settings subject's work, and the title of the survey.

CONCLUSION

Orthotists in the United States are familiar with PSSE, and the various methods. The majority of the time, orthotists are recommending PSSE to their patients. With 21 responses, generalizations cannot be made regarding orthotists' attitudes and current practices of treating IS with PSSE.

CLINICAL APPLICATIONS

Research has shown that PSSE is effective when used with brace treatment; however, little research has been conducted regarding orthotists' perspectives. It is important for the orthotist to know the benefits of PSSE and discuss it with their patients.

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The Role of Postural Bias in Pediatric Kyphus Brace Correction

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INTRODUCTION

This clinical case study has played a crucial role in enhancing our understanding of the metrics employed in designing orthosis modules for pediatric Department of Orthopaedics correction. It also highlights the significance of quantifiable metrics in consistently achieving reproducible outcomes for our patients. Our ongoing efforts to standardize brace modifications stem from the recognition of the pivotal role that postural bias plays in both ensuring successful kyphus correction and enhancing patient brace tolerance.

CASE PRESENTATION

Our female patient presented with a 62-degree kyphus (T2–T12). She is a healthy, moderately flexible, 12.5-year-old, and participates in sports. She was referred by her pediatrician to the spinal specialist.

MANAGEMENT AND OUTCOME

The patient was prescribed a brace to treat her thoracic hyperkyphosis and mild scoliosis. This brace was digitally designed using accepted standards of practice for the reduction of kyphosis, with additional modifications that addressed her pelvic tilt and postural bias.

The accepted normal angle of pelvic tilt is 13 degrees +/- 6degrees. When pelvic tilt is greater, the center of gravity shifts further posterior to the femoral heads, resulting in an increased lordotic angle. This increased lordotic angle can potentially lead to pain and the development of spondylolysis/spondylolisthesis. To mitigate these risks, we have established a standard of 15-degree to 18-degree lumbar lordosis to help prevent such complications.

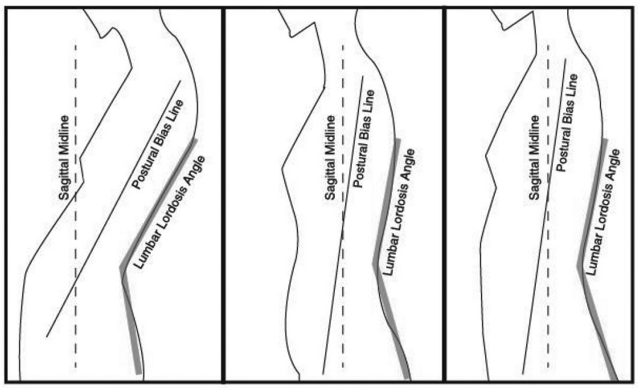
In the thoracic spine, apart from employing accepted standards of practice guidelines to reduce kyphosis, we also consider the sagittal midline—specifically, a perpendicular line drawn through the humeral head to the femoral head. Our goal is for that line to align with or be positioned ahead of the vertical midline.

The patient has adhered to the prescribed daily hours of brace wear and exercise regimen. She has been wearing the brace successfully for 8 months and is currently undergoing a gradual 6-month weaning process. The patient has demonstrated compliance with both wear hours and exercise routines, resulting in a correction rate of 41.4%. She is continuing with her exercises as instructed and is scheduled for her next appointment in September, which is anticipated to be the final appointment for her treatment.

DISCUSSION

Our observations revealed that even when the brace was designed according to the standard practice guidelines for reducing kyphosis, the patient still exhibited a postural bias characterized by a backward lean. This postural bias persisted despite the reduction in kyphosis. As a result, additional manual modifications were necessary during the fitting of the brace to realign the patient closer to the sagittal midline and effectively address the postural bias.

By incorporating initial modifications that targeted both the patient's pelvic tilt and overall postural alignment with the sagittal midline, in addition to the standard kyphosis reductions, we observed significant improvements in both the fit of the brace and the patient's posture while wearing it. Furthermore, this approach resulted in continued success in reducing kyphosis and correcting the postural bias.



	Initial X-Ray	In-Brace X-Ray (1 mo)	OOB X-Ray (6 mo)
Scoliosis	11°	13°	12°
Kyphosis	62°	42°	37°
Risser	3	3	4
Hrs/day	16	16–22	Begin to wean
Treatment Plan	Brace + exercise	Brace + exercise	Exercise

Figure 1. Relevant angles and baseline metrics at treatment onset, in-brace at 1 month and out-of-brace at 6 months.

CONCLUSION

As a result of our findings, we have implemented the standard of using the sagittal midline in the design of over 50 kyphus modules to date. This approach has provided us with a consistent and measurable metric, allowing us to establish a reproducible template for successful kyphus correction among our adolescent patients.

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Concurrent Treatment of Adolescent Idiopathic Scoliosis and Pectus Carinatum: A Case Study Reviewing Design and Outcomes

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INTRODUCTION

Quite often, patients are diagnosed with scoliosis and pectus carinatum concurrently, with treatment options focusing on the more medically impactful scoliosis diagnosis. However, pectus carinatum is very often the more concerning diagnosis for the patient, as it is much more visible to the patient. It is possible to treat both conditions with the same orthosis, depending on the location of both the scoliosis and pectus carinatum; however, this is not standard practice.

There is minimal research on instances of scoliosis and pectus carinatum being comorbidities[2,3] (typically associated with syndromic conditions such as Loeys-Dietz and Marfan Syndromes). Existing related literature has been done on the effects of pectus excavatum surgery on the scoliotic spine,[1] but this author could not find any specific published research on orthotic intervention treating scoliosis and pectus carinatum concurrently.

The design and outcome of the treatment of a patient with both scoliosis and pectus carinatum will be described.

CASE PRESENTATION

At the time of initial evaluation, the patient was a 13-year-old male with a 27-degree right thoracic curve and a 25-degree left lumbar curve, referred for a scoliosis TLSO by his orthopedic physician, but the patient's primary concern was treating the present pectus carinatum. The chest wall prominence was atypical, located along the left side of the sternum, extending from the axillary level inferior to the xyphoid level of the torso along the medial costal margin. Upon evaluating the severity and location of both the scoliosis and pectus carinatum, it was determined that a single TLSO could treat both conditions concurrently, satisfying the patient's primary concern.

MANAGEMENT AND OUTCOME

The CAD modifications for the design of the TLSO were performed by the evaluating clinician, with compression for the pectus carinatum being incorporated into the design, along with corrective forces for the scoliosis. Throughout the course of treatment (2 years, 2 months), the patient has been fit with 3 TLSOs and has been consistent with adhering to the physician's recommendation of 18 hours of daily wear, as self-reported. The prominence of the anterior aspect of the chest wall reduced gradually over the course of treatment, ultimately resolving to near symmetry, as illustrated in figures 2 and 3.

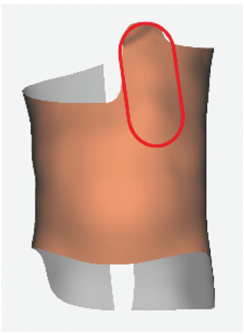

Figure 1. Image of the trimlines of the TLSO incorporating the pectus carinatum extension, with the pectus carinatum highlighted.

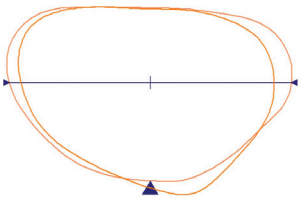

Figure 2. Comparative transverse view of chest wall at the level of the xyphoid.

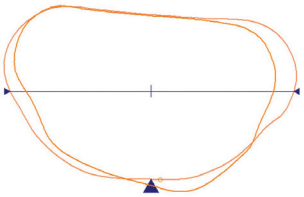

Figure 3. Comparative transverse view of the chest wall at the level of nipple line.

DISCUSSION

The patient's Pectus Carinatum has been reduced to the point where the patient is no longer concerned about it, so his most recent (third) TLSO was designed to manage his scoliosis only. Cobb angles have remained relatively stable, with the most recent X-ray showing a 26-degree right thoracic curve and a 28-degree left lumbar curve.

CONCLUSION

There is a need for a standard of care to be established for treating scoliosis and pectus carinatum concurrently, as (in most cases), a single TLSO can be designed to address both effectively.

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Stakeholder Engagement in Scoliosis Research Planning

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INTRODUCTION

Adolescents with idiopathic scoliosis (IS) are often prescribed an orthosis to prevent curve progression and avoid surgery.[1] Most scoliosis orthoses are prescribed for full-time wear and have been shown to be effective[2] but often cause stress on patients and families. Nighttime hypercorrective orthoses are worn while sleeping and thus have minimal impact on daily life. Currently, there is little evidence to guide prescription of nighttime orthoses.[3]

A high-quality, prospective clinical trial is needed to compare the effectiveness of nighttime and full-time scoliosis orthoses in adolescents with IS. To inform the development of this trial, preliminary research with relevant stakeholders (i.e., patients with IS, parents, and the clinicians who provide scoliosis care) is needed to ensure that the trial is well designed, feasible, and results can inform clinical decision-making.

The aims of this study were to (1) describe stakeholder opinions about nighttime and full-time orthoses, (2) assess stakeholder willingness to accept random assignment to orthosis type, and (3) identify outcomes important to patients with IS and their parents.

METHOD

Cross-sectional survey studies were conducted to assess opinions about orthosis type and randomization (Aims 1 and 2). Qualitative focus groups were conducted to identify outcomes important to patients and parents (Aim 3). All activities were approved by an Institutional Review Board.

Participants:

- *Surveys:* Adolescents with IS who have never used an orthosis and their parents (n = 104 dyads across 3 U.S. metro areas); clinicians (n = 214) engaged in non-operative management of IS.
- *Focus groups:* Adolescents (n = 27) with IS who used an orthosis for ≥3 months and their parents (n = 26).

Apparatus: Separate surveys were designed for adolescents, parents, and clinicians. Adolescent and parent surveys solicited opinions about orthosis type and randomization. Clinician surveys included 12 clinical cases. For each case, clinicians were asked about orthosis preference and willingness to randomize. Discussion guides were designed for focus groups.

Procedures: Adolescents with IS and parents completed online surveys during a clinic visit. Clinicians were invited to complete an online survey through emails from professional organizations. Adolescents and parents participated in separate virtual focus groups (14 total) to encourage open discussion among peers.

Data Analysis: Descriptive statistics were used to summarize survey data. Focus group discussions were transcribed and de-identified for thematic analysis.

RESULTS

Orthosis Preference: Most adolescents (77%) and their parents (82%) preferred *nighttime orthoses* for treatment of IS. In contrast, most clinicians (70%–92%) preferred *full-time orthoses* across case scenarios. Clinicians were more likely to prefer nighttime bracing for cases with small, thoracolumbar/ lumbar curves and more skeletally mature cases.

Randomization: About one-third of adolescents (32%) and parents (30%) were willing to have orthoses "chosen by chance", with another 35%–38% stating that they were "not sure." For clinicians, between 28%–57% were willing to randomize cases to orthosis type in a hypothetical trial, depending on patient characteristics.

Patient-Centered Outcomes: Adolescents and their parents noted the importance of traditional clinical outcomes of treatment (e.g., curve progression). They also stressed the importance of holistic outcomes, including mental health, self-image, social experiences, discomfort, and participation.

DISCUSSION

Adolescents with IS and parents preferred nighttime, while clinicians would prescribe full-time braces in a majority of cases. Adolescents and parents may more strongly consider the effects of orthoses on their daily life, while clinicians weigh the lack of evidence in support of nighttime orthoses. While these contrasting opinions support the need for high-quality trials comparing scoliosis orthoses, trial feasibility will be impacted by the willingness of patients, parents, and clinicians to randomize treatment. Holistic outcomes identified in this study can be mapped to existing patient-reported outcomes for use in future orthosis studies.

CONCLUSION

High-quality evidence is needed to inform the use of nighttime orthoses for IS. Research with stakeholders suggests (1) adolescents with IS and parents prefer nighttime orthoses due to less burden on daily life, (2) clinicians prefer full-time orthoses due to the quality of existing evidence,[3] (3) stakeholder willingness to randomize to orthosis is acceptable for study feasibility, and (4) adolescents with IS and parents want researchers to use holistic outcomes.

CLINICAL APPLICATIONS

Stakeholder surveys and focus groups can provide guidance in the design of trials to ensure that research findings are clinically meaningful.

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Prospective Cohort Study on Treatment Parameters for the UCSF Pectus Carinatum Orthosis

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INTRODUCTION

Pectus carinatum (PC) is a chest wall deformity created by an overgrowth of the cartilage between the ribs and sternum. PC is most common in adolescent males[1] and tends to progress during growth spurts. Prior to 2000, surgical intervention[2] was the standard of care. Over the last 2 decades, PC orthoses (PCOs) which apply a compressive force along the PC have become common. In 2006, the Calgary protocol outlined 2 phases of orthotic treatment; a corrective phase (approximately 23 hours/day PCO wear) and a maintenance phase (8 hours/day PCO wear).[3] There is a lack of objective data to validate this protocol. This pilot study is the first to use i-Button data to measure wear time for PCOs. Multiple factors such as age at treatment onset, pressure of initial correction (PIC), in-PCO pressures, wear time, quality of life, and distance traveled to clinic are considered.

METHOD

A cohort of 99 participants were enrolled as part of an Institutional Review Board-approved prospective study (IRB # 15-17899).

Inclusion Criteria: Study participants were 7–17 years old, prescribed a UCSFPCO, skeletally immature, and English speaking.

Subjects were evaluated and fit with a custom UCSFPCO fabricated with a Thermochron iButton Sensor (iButtonLink, LLC, Whitewater, WI) to track wear time. At the delivery appointment and multiple follow-ups, a Tekscan FlexiForce force sensitive resistor (Tekscan, Inc, Boston, MA) was used to assess in and out of PCO pressure, i-Button data was downloaded, PC dimensions were taken, and Redcap was used to administer the PCEQ and PedsQOL surveys. Of the ongoing study cohort, 50 subjects currently have sufficient data for statistical analysis. SAS v9.4 was used to perform a survival analysis, Cox proportional hazards regression and Kaplan Meier analysis, of treatment completion, looking at variables influencing treatment outcomes.

RESULTS

Of the 50 subjects analyzed (47 male, 3 female), median treatment lengths were 7.2 months in the corrective phase, and 13.7 months in the maintenance phase. To assess age effects on treatment, data was looked at for 2 groups: ages 7–13 and ages 14–17. The older cohort demonstrated a higher PIC (6%) and lower reduction in in-PCO pressure over the course of treatment (15%). Recorded wear time for the 2 groups was comparable, with a median of 14.6 hours/day in the corrective phase and 9.4 hours/day in the maintenance phase. There was no meaningful change in reported quality of life pre- and post-PCO treatment, and subjects infrequently reported any side effects of treatment.

Subjects who withdrew prior to transitioning to the maintenance phase of treatment lived on average 2 times farther from clinic than those who reached that phase.

Multiple variables were assessed to determine which was most predictive of a subject reaching treatment completion. One notable variable was PCO wear time at 1 month. If wear time was 12.4–19.4 hours/day in the corrective phase, the subject was significantly more likely to complete treatment compared to those who wore it less than 12.4 hours per day (Table 1). Kaplan Meier plots with log-ranked p values also demonstrated an observable increase in median time to complete treatment if the PCO was worn for < 12.4 hours per day.

Table 1. Univariate Cox Proportional Hazards Models of Time to Complete Treatment with Firth Option.

Time Variable	PCO Wear Time @ 1 month follow-up	PCO Wear Hours/day	# Events/ # subgroup (% Events)	Hazard Ratio	Lower 95% CI	Upper 95% CI	P-Value
Time to Complete Treatment	Quartile 1	<12.4	4/12 (33.3%)	1.000			
	Quartile 2	12.4-15.4	3/10 (30.0%)	8.9	1.240	64	0.030
	Quartile 3	15.5-19.4	3/12 (25.0%)	40	3.0	548	0.0054
	Quartile 4	>19.4	6/11 (54.5%)	1.078	0.272	4.3	0.92
	Events, censored (%Events)	16, 29 (35.6%)					

Pink cells indicate effects with p<0.05
Red cells indicate evidence for violations of linearity assumptions.
Orange cells indicate evidence for violations of proportional hazards assumption.

DISCUSSION

The preliminary results of this pilot study suggest that the only statistically significant factor influencing the overall treatment completion is average wear time at 1 month. Younger subjects have greater flexibility in their chest wall which is why they experienced lower corrective pressures and treatment duration. Treatment did not meaningfully impact quality of life. Overall treatment ranged from 11–32 months with follow-ups every 3 to 6 months, and one barrier to completion was travel distance to the clinic. This factor is worth discussing with families during onset of treatment. Major sources of error include subjects lost to follow-up, small sample size, and sensor error.

CONCLUSION

The Calgary protocol recommendations are higher than necessary based on the objective measure of wear time. Factors influencing treatment the most include wear time at 1 month, age, and distance from clinic.

CLINICAL APPLICATIONS

Evidence-based treatment for PC will enable practitioners to better inform patients.

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The Effect of Thoracolumbosacral Orthosis Wear on Curve Progresion for Individuals with Adolescent Idiopathic Scoliosis

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INTRODUCTION

The effectiveness of bracing with a thoracolumbosacral orthosis (TLSO) for adolescent idiopathic scoliosis (AIS) has been studied extensively, with a growing body of evidence supporting TLSO use. In this study, we will confirm or refute existing treatment efficacy estimates, understand the causal factors affecting curve progression, and develop a risk model that can be applied to individual patients and is based on important casual factors.

METHOD

Design: Prospective, multi-center, cohort study, Institutional Review Board (University of Minnesota 0912M75512; Allina 860911-5).

Participants: Diagnosis of AIS, age of 10–16 years, primary Cobb angle of 20 degrees–45 degrees, Risser 0–2, <1 year post menarche if female, to be treated with a TLSO.

Apparatus: Wear time was monitored with iButtons.

Procedures: Participants were followed until the end of growth. Cobb angle of the primary curve at the start of TLSO treatment was compared to primary Cobb angle at TLSO discontinuation. We examined the causal effects of wear time and baseline skeletal maturity as measured by triradiate cartilage (TRC) status, Cobb angle, and age.

Data Analysis: We fit an outcome prediction model based on important casual factors.

RESULTS

Final cohort consisted of 145 individuals (baseline age 12.1–13.4 years). We found that efficacy of treatment matched previous studies, with an odds ratio around 2.0.[1] Wear time was an important cause of response to treatment, including an interaction with TRC status. Baseline Cobb angle and age were also meaningful causes of response. The prediction model was accurate (79%) and had good specificity (81%) and moderate sensitivity (68%).

DISCUSSION

There is a clear causal effect of TLSO treatment on curve progression in AIS. The rate of progression and risk of treatment failure can be reduced significantly for individuals with certain characteristics. In addition to wear time, there are clear causal effects of baseline TRC status and Cobb angle and a small effect of baseline age.

CONCLUSION

Our study confirms the efficacy of treatment with a TLSO. We show the explicit causal effects of wear time, baseline skeletal maturity, Cobb angle, and age.

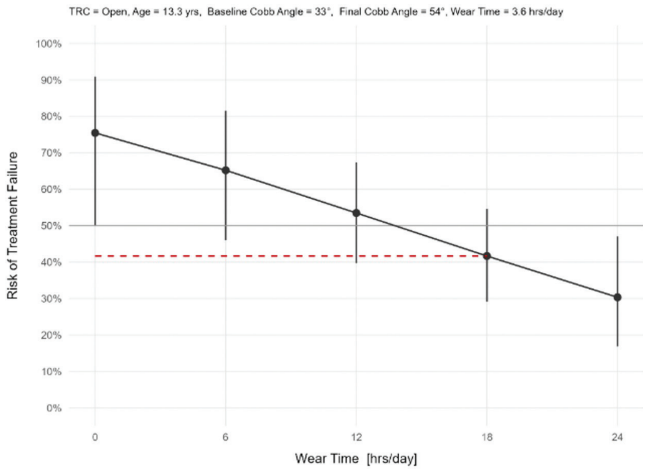

Figure 1. Predicted risk for an individual. We have chosen an ideal example to demonstrate the potential effect of bracing. The individual has open TRC and a moderate baseline Cobb angle of 33 degrees. Individuals like this are likely to benefit from TLSO wear. In this case, the individual wore their TLSO 3.6 hours/day and progressed to 54 degrees. The model predicts that had the patient worn their TLSO 18 hours per day, they would have reduced the risk of treatment failure from ~75% to ~40%. Vertical bars indicate the 90% confidence interval.

CLINICAL APPLICATIONS

We developed a risk model that can be used for counseling patients and their families regarding TLSO wear and expectations for outcome.

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Sources of Support in Scoliosis Orthotic Treatment

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INTRODUCTION

The diagnosis of scoliosis and corresponding treatment intensify stress levels as patients are often simultaneously navigating adolescence—an inherently stressful period of life. While bracing is effective, it has been linked to feelings of anger, shame, and diminished body image; the psychological impact of bracing helps to explain the challenge of adherence. Peer support has been suggested to increase adherence in braced scoliosis patients. Therefore, the purpose of this study was to investigate the sources of emotional support for scoliosis patients and to analyze a program designed to encourage social support, the Scolios-us Mentor Program.

METHOD

Participants: Fifty-five subjects with scoliosis (53 female, 1 male, 1 nonbinary) with a median age of 13 (IQR: 3). More than half of subjects (31) participated in the Scolios-us Mentor Program. Treatment modalities included scoliosis bracing (n = 52), physical therapy (n = 33), and surgery (n = 8).

Apparatus: This cross-sectional survey was approved by the Baylor College of Medicine Institutional Review Board and developed using Qualtrics©.

Procedures: The survey consisted of the SRS-22r, BSSQ-Brace, questions about demographics, mental health, counseling, sources of support, and the Scolios-us Mentor Program. It was distributed via email to Scolios-us Mentor Program participants and to clinicians to share with their patients.

Data Analysis: Descriptive statistics were calculated to summarize demographic characteristics, sources of emotional support, and Scolios-us Mentor Program responses the Mann-Whitney U two-sample rank sum test was used to analyze the impact of numerous factors on SRS-22r and BSSQ-Brace scores. The Cochran-Armitage test of trend, Somers' D test, and Spearman's rho test were also used to assess correlations. For all statistical tests, the alpha was set to .05.

RESULTS

Our results indicated that scoliosis subjects receive emotional support from several sources: family (83.6% of subjects), friends (52.7%), support groups (52.7%), and healthcare providers (21.8%). More than half (72.7%) of subjects received support from at least 2 sources. Mental health scores were higher for those receiving emotional support from their friends ($p = .013$). Subjects who participate in the Scolios-us Mentor Program reported social support as more important ($p < .001$). No significant differences were noted in BSSQ-Brace or SRS-22r scores between participants and non-participants. As program satisfaction increased, BSSQ-brace scores decreased ($p = .012$) (Figure 1).

DISCUSSION

Scoliosis patients receive emotional support from different sources, but each patient's support system is unique. When considering that not all patients receive support from their family and friends, the need for social support and support groups, like the Scolios-us Mentor Program, becomes apparent. Those with greater brace-related stress were more satisfied with the Mentor Program, indicating that those who need the program the most also value the program the most.

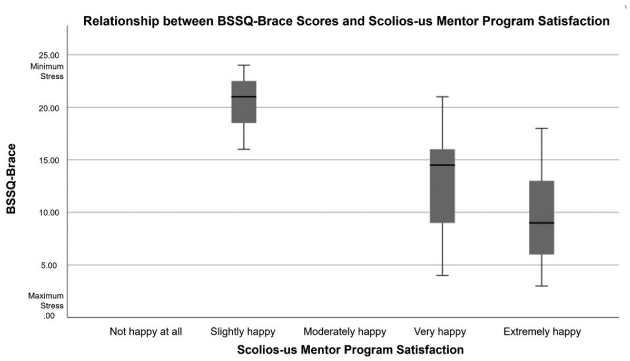

Figure 1. Subjects responded to the question: "Overall, how happy are you with the Scolios-us Mentor Program?" Subjects with increased brace-related stress reported greater satisfaction with the Scolios-us Mentor Program.

CONCLUSION

Having a strong support system is important for patients as they undergo scoliosis treatment. Receiving emotional support from friends may be important for improving mental health. The Scolios-us Mentor Program may be a good option for scoliosis patients who value social support and struggle with brace-related stress. Limitations of this study include the predominately female population and small sample size. The survey distribution method may also introduce bias, with more than half of subjects participating in the Scolios-us Mentor Program.

CLINICAL APPLICATIONS

Clinicians should help scoliosis patients feel emotionally supported as they undergo treatment by talking with them about their support system and using the available resources.

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Clinician-Led Mental Health Conversations Are Significantly Associated with Clinical Outcomes for Scoliosis Patients and Emphasize the Need for Counseling

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INTRODUCTION

The psychological impact of idiopathic scoliosis has been well established in the literature. Adolescents with scoliosis are at a greater risk for developing suicidal ideations,[1] and anxiety levels in the AIS population are comparable to children with obesity and pediatric heart transplant recipients.[2] While the diagnosis of scoliosis is concerning, bracing often compounds patients' stress levels. While it has not been studied in this population, counseling can be an effective coping strategy for adolescent patients with chronic illness.[3] Therefore, the purpose of this study was to assess the current mental health landscape in the scoliosis community and to assess the need for counseling.

METHOD

This cross-sectional study was approved by the Baylor College of Medicine Institutional Review Board (H-50560), and informed consent was obtained.

Participants: Fifty-three female, 1 male, 1 nonbinary; median current age: 13; median diagnosis age: 10; 38 were currently braced at the time of participation.

Apparatus: Cross-sectional survey; SRS-22r, BSSQ-Brace survey, questions about demographics, counseling, and general scoliosis experience.

Procedures: The survey was distributed to Scolios-us Mentor Program participants and to scoliosis clinicians to provide to their patients.

Data Analysis: Data was exported from Qualtrics into SPSS for data cleaning and analysis. Mann-Whitney U two-sample rank sum test was used to analyze the relationship between clinician-led mental health discussions and counseling on SRS-22r and BSSQ-Brace scores. A Spearman's rho test was used to determine associations between current age various factors. For all statistical tests, the alpha was set to .05.

RESULTS

Results show that 19 subjects discussed mental health with at least one scoliosis healthcare provider, while 27 subjects desired these conversations. A desire to discuss mental health was significantly associated with lower function ($p = .005$), mental health ($p < .001$), SRS-22r total scores ($p = .002$), and BSSQ-Brace scores ($p = .015$). Subjects who engaged in a mental health discussion with their provider exhibited higher management scores ($U = 172.0$, $p = .002$). Only 9 subjects sought counseling, and most of these subjects found counseling to be very or extremely helpful.

DISCUSSION

Our results demonstrated that a discussion of mental health is desired more often than it occurs, and a desire to have these conversations is negatively associated with several clinical outcomes. Although health care providers are not initiating conversations about mental health on a regular basis, these discussions were found to improve patients' satisfaction with their treatment. Those that participated in counseling found it to be helpful.

Limitations include the small sample size and high percentage of female subjects. Survey distribution may also introduce bias, as 56.4% of subjects participate in the Scolios-us Mentor Program. Future studies should further investigate the role of psychologists and identify best practices for discussing mental health in clinic.

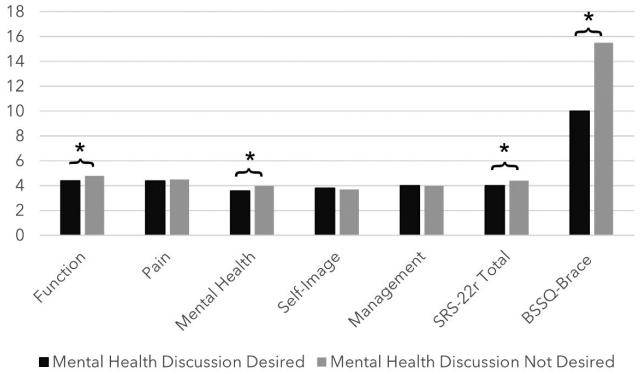

Figure 1. The desire to discuss mental health is negatively significantly associated with several outcomes, denoted with an asterisk in this graph.

CONCLUSION

The mental health needs of scoliosis patients are not being met by the current healthcare system.

CLINICAL APPLICATIONS

As practitioners, the ability to acknowledge the desire to discuss mental health and refer patients to a clinical psychologist when necessary may improve our holistic approach to scoliosis care.

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The Effect of EMG Channel Count on Pattern Recognition Control of a Multiarticulate Prosthetic Hand

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INTRODUCTION

Pattern recognition (PR) systems are now clinical options that can be trained to recognize patterns of electromyographic (EMG) activity across the residual limb, classify those patterns in real time, and control a prosthesis. Previous research has shown improvement in PR classifier accuracy (via decreased classification error rates) with an increase in the number of electrode pairs used to capture EMG data. However, research also suggests that this trend begins to plateau between 4 and 6 EMG channels and often disagrees on whether decreased classification error translates to improved functional prosthesis control.[1,2] Notably, the effect of EMG channel count on physical prosthesis control in the limb-loss population has not been investigated. This pilot study addresses that knowledge gap.

METHODS

This study received Institutional Review Board approval (STU00216244), and participants underwent an informed consent process.

Participants: Two individuals (2 males, 35.00 ± 1.41 years) with traumatic, transradial (TR) amputation were recruited.

Apparatus: TR prosthesis with a novel 2 degree-of-freedom (DOF) wrist unit and Psyonic Ability hand.

Procedures: Participants donned a PR-controlled prosthesis equipped with 16 pairs of electrodes. Training and testing data for 3 DOFs were collected as the participant was guided through a calibration using computer-generated prompts. Training data were used to build a classifier with either 4, 8, or 16 EMG channels. In each of the channel count conditions, participants completed a suitcase packing task as part of the Assessment for Capacity of Myoelectric Control (ACMC) and a survey aimed at assessing their perceived prosthesis control. Both participants and researchers were blinded to the condition being tested, except for the researcher manipulating the classifier.

Data Analysis: Classification error (number of incorrect decisions / total number of decisions) was calculated for each condition. The ACMC was scored post-test by a single rater via video playback. A single factor analysis of variance was conducted on ACMC and survey results to assess the difference between conditions ($p < 0.05$).

RESULTS

With an increase from 4 to 8 to 16 EMG channels, the average classification error rate decreased from 25% to 20.5% to 17.5%, respectively. With an increase from 4 to 8 to 16 EMG channels, the average ACMC score increased from 42.1, to 46.7 to 54.6 (Figure 1). Participants also reported that their perceived prosthesis control improved with an increase in EMG channel count.

DISCUSSION

Classification error decreased with an increase in EMG channel count, which is consistent with prior literature1 and suggests that more data input improves a PR system's ability to correctly classify EMG patterns. Increased channel count also improved physical prosthesis control via the ACMC. While virtual testing by Li et al.[1] suggests that improvements in classifier accuracy beyond 4 to 6 EMG channels are negligible for control, our results show that physical prosthesis control improved notably (>3 times the minimal detectable change) from 8 to 16 channels. Perhaps more importantly, our survey results showed that this improved prosthesis control with 16 channels was perceptible to the user, which could be significant for user satisfaction. Clinical disadvantages of using 16 EMG channels in a TR socket should be considered in future research, including the increased surface area requirement for electrodes and the added complexity in socket fabrication. Recruitment efforts for this study were limited by the weight of the experimental prosthesis, resulting in a small sample size (n = 2).

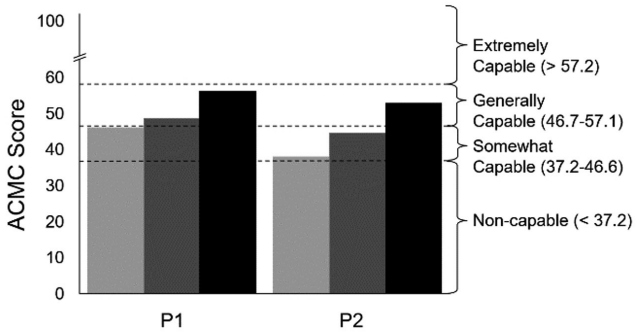

Figure 1. ACMC score for participant one (P1) and two (P2) in 3 conditions: 4, 8, and 16 channels.

CONCLUSION

Eight EMG channels is the current clinical standard for PR-controlled TR prostheses. However, this study demonstrates that increasing channel count beyond 8 channels may result in perceptible, functional improvements in upper-limb prosthesis control.

CLINICAL APPLICATIONS

The integration of more EMG channels into commercial PR systems could improve control, leading to higher user satisfaction when using PR control systems.

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Transhumeral Prosthetic Limb Attachment via Magnetic Attraction

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INTRODUCTION

Poor attachment of upper-extremity prosthetic limbs is the dominant cause of patient problems and device abandonment.[1] These problems, such as pain, discomfort, or the inability to use a socket due to short/conical residua, all stem from suspending the limb from soft tissues. To achieve proper suspension, conventional sockets must snugly fit the limb and enclose large areas of skin, which causes discomfort, sweating, and may not be viable due to limb shape.

To address these problems, we present a new attachment method consisting of a bone-anchored ferromagnetic implant fully enclosed within the limb, and an external magnet housed within a socket. Magnetic attraction between these 2 components transfers suspension loads (acting to "pull" the prosthesis off the limb) directly to the residual bone *across,* rather than through, the soft tissues. Since there is no chronic wound, this system would not have the infection risk of percutaneous osseointegration.

In contrast to lower-limb applications, the lack of a weight bearing phase (e.g., stance) for upper-limb devices means that the attachment system must continually provide suspension forces. This precludes the use of electromagnets to modulate attractive force, since supplying constant power to the electromagnet would generate far too much heat. To address this problem, we developed a permanent magnet array that requires power only to change the magnetic field and not to maintain suspension with a static field. In this abstract, we detail this magnet array and test its viability in transhumeral prosthetic suspension.

METHOD

Apparatus: The musculoskeletal modeling software OpenSim was used to calculate the "pull-off" force on the socket. The electromagnetic simulation software JMAG (JSOL Corp.) was used to simulate the system.

Procedures: We first estimated the pull-off force on the socket during several motions, including drinking (Figure 1B). This was done using a skeletal model in OpenSim and kinematics from non-amputee activities of daily living. To create an adjustable permanent magnet, we nested 2 cylindrical magnet arrays such that the resultant field depends on the relative angle between the 2 rings. With this design, the rings can be rotated via a motor and then locked at the desired magnetic field. This array was modeled within JMAG, and the attractive force on the implant was calculated as a function of ring angle. To inform implant design, we conducted cadaveric simulations of transhumeral amputation. Based on the force-angle relationship of the magnet array, we tested the viability of the magnet array for suspending a prosthesis by calculating the ring angle required to produce the force profile.

Data Analysis: Processing was performed in MATLAB.

RESULTS

Pull-off forces during a drinking motion peak as the forearm raises (Figure 1B). The magnet array produced an adjustable force on between 0–90 degrees ring angle (Figure 2A). The array was 3 inches in diameter and 1-inch tall, with a mass of 0.5kg. Assuming the total socket is 2kg (1kg socket, 1kg magnet), the ring angle required to suspend a prosthesis ranged from 40–90 degrees (Figure 2B).

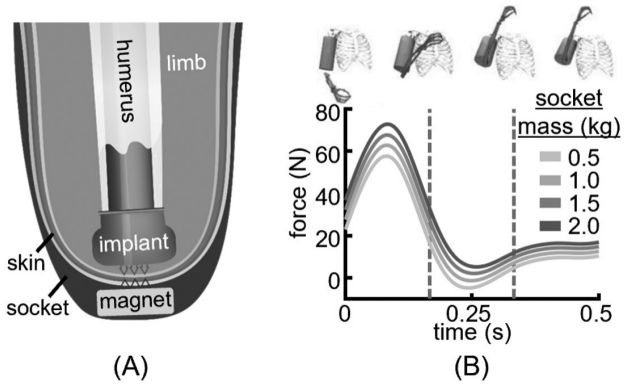

Figure 1. (A) Transhumeral magnetic attachment. (B) Pull-off force during a drinking motion over socket masses.

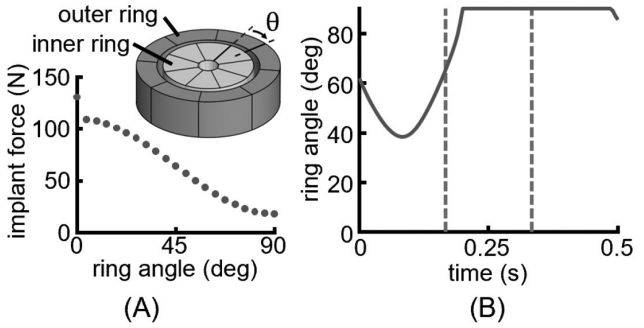

Figure 2. (A) Force on the implant versus magnet ring angle. (B) Ring angle (θ) to suspend a prosthesis while drinking.

DISCUSSION

A permanent magnet array fitting within a prosthetic socket was able to produce the forces required to suspend a transhumeral prosthesis within its range of ring angles. This showed that the design could be viable for this application. Future work will focus on building this magnet and testing the proposed magnetic attachment system using model limbs.

CONCLUSION

Prosthetic attachment via magnetic attraction has the potential to address the major shortcomings of current attachment methods and would be feasible for upper-extremity prostheses using a novel magnet array.

CLINICAL APPLICATIONS

The proposed attachment method may provide prosthetists new options to address patient problems.

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The Role of Elective Amputation and the Role of Prosthetic Fitting in Traumatic Adult Complete Brachial Plexus Injury: A Systematic Review of the Literature

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INTRODUCTION

Traumatic brachial plexus injuries (BPI) represent a spectrum of peripheral nerve pathology where one or more components of the brachial plexus are either reversibly or irreversibly injured following high-energy trauma. Whether complete or incomplete, BPIs create challenges for patients, surgeons, and prosthetists including flail limbs, chronic shoulder subluxation, severe neuropathic pain, and loss of sensation. The purpose of this review is to describe the advances in prostheses, coupled with surgeon and patient enthusiasm for the application of these devices and the changing paradigm in the treatment of BPIs.

METHOD

Following the Preferred Reporting Items for Systematic Reviews and Meta-analyses guideline, a comprehensive search of several databases was conducted from their date of inception through June 2023. The databases included Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, and Daily, Ovid EMBASE, Ovid Cochrane Central Register of Controlled Trials, Ovid Cochrane Database of Systematic Reviews, and Scopus. The search strategy was designed and conducted by an experienced librarian with input from the study's principal investigator. Controlled vocabulary supplemented with keywords was used to search for elective amputation and prosthetic fitting in traumatic adult brachial plexus injury patients.

RESULTS

Among 410 articles identified, 15 studies, comprising 56 total patients, were reviewed. The majority of the studies reviewed were individual case reports with the majority of patients included in this study reported on by 2 major brachial plexus centers.

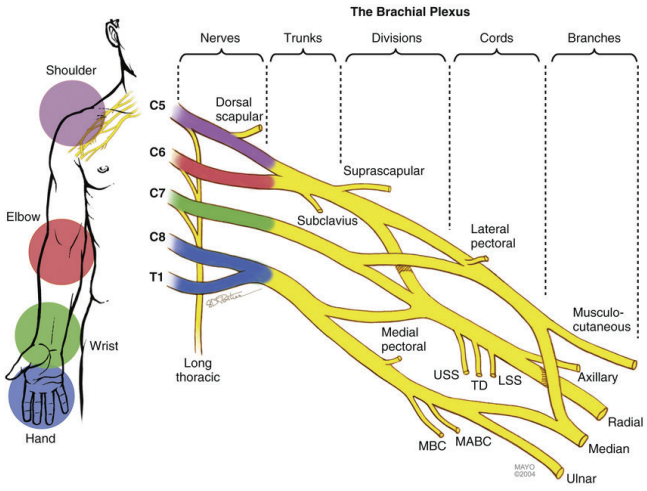

Figure 1. Brachial plexus diagram.[1]

DISCUSSION

Early elective amputation was lessened with the advancement of microsurgical techniques in the late 20th century (intraplexal nerve grafting, intra- and extraplexal nerve transfers, and free functioning muscle transfers). However, rudimentary grasp remains a surgical challenge to reconstruct. Technological advances in prosthetic devices continue to improve the ability of patients to control their prostheses through capturing EMG potentials using single- or dual-site electrodes, pattern recognition, linear transducers, and the application of non-intuitive input signals.

CONCLUSION

The modernized approach/concept of elective amputation following brachial plexus injury has been aided, in part, by 2 key improvements: technological advancement for upper-limb prosthetic options and increased multidisciplinary collaboration between the surgeon and prosthetist.

CLINICAL APPLICATIONS

Findings from this literature review promote knowledge and understanding of the treatment of traumatic complete brachial plexus injuries with elective amputation and prosthetic fitting.

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Restoring Lost Function with RPNIs and Implanted Electrodes

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INTRODUCTION

Advanced prosthetic limbs have the potential to increase functionality for patients with upper-limb amputations. However, this potential is often unrealized due to an inability to record strong and reliable control signals for multiple hand and wrist functions. Regenerative peripheral nerve interface (RPNI) surgery is commonly performed to treat residual-limb pain and also amplifies efferent motor action potentials to produce control signals in lieu of missing muscles.[1,2] Surgically implanting electrodes into RPNIs and residual muscles has been shown to provide highly accurate and reliable finger and grasp control without controller recalibration.[3] This study examines the signal quality of implanted EMG electrodes in RPNIs and residual muscles and its implications for prosthetic finger and thumb control.

METHOD

Surgical Procedures: An RPNI consists of a free muscle graft reinnervated by a transected peripheral nerve.[1,2] Three participants with transradial amputations (P1, P2, P3) had bipolar electrodes surgically implanted into previously created median and ulnar nerve RPNIs and residual innervated muscles. A 4th participant with a transradial amputation (P4) had bipolar electrodes surgically implanted into newly created median, ulnar, and radial RPNIs and residual innervated muscles during the same operation.

SNR Measurements: A virtual hand cued participants to make individual finger and wrist movements with their phantom hand. Signal-to-noise ratios (SNRs) were measured monthly across 267 days for P1, 1645 days for P2, 335 days for P3, and 251 days for P4. P2 and P4 each completed 1 SNR session with simultaneously recorded surface EMG signals using adhesive electrodes with conductive gel.

Movement Prediction: Linear discriminant classifiers were trained to predict multiple grasps (fist, pinch, point, finger abduction) or distinguish thumb and index finger flexion from movements controlled by intrinsic hand muscles (thumb opposition, finger abduction, finger adduction). For each participant and movement set, 1 classifier used signals from RPNIs and residual muscles and 1 classifier used signals from residual muscles only. The impact of RPNI signals on predicting movement intent was determined by comparing the error rate of the 2 classifiers.

RESULTS

Across all 4 participants, the implanted RPNIs produced large amplitude signals with a median SNR of 32.2dB (40.8 gain, n = 13), while electrodes in residual muscles had a median SNR of 40.4dB (104.7 gain, n = 25). Implanted electrodes recorded significantly stronger signals than P2 and P4's surface EMG, which had a median SNR of 20.7dB (10.9 gain, n = 16 channels).

Removing RPNIs as a control input increased grasp prediction errors by 5.7%, while errors distinguishing intrinsic hand movements increased by 13.2% on average. Thumb opposition and finger adduction were the most negatively impacted movements with error increases of 20.5% and 18.9% respectively.

DISCUSSION

Surgically implanted electrodes record stronger control signals from both residual muscles and RPNIs than surface EMG. Electrodes can be implanted into existing RPNIs or at the time of RPNI creation in a single operation. At a transradial level, implanting RPNIs is most beneficial to control fine thumb movements controlled by absent intrinsic thenar muscles. At a transhumeral level, multiple RPNIs can be created on subdivided nerves and may be implanted to restore thumb and finger function.

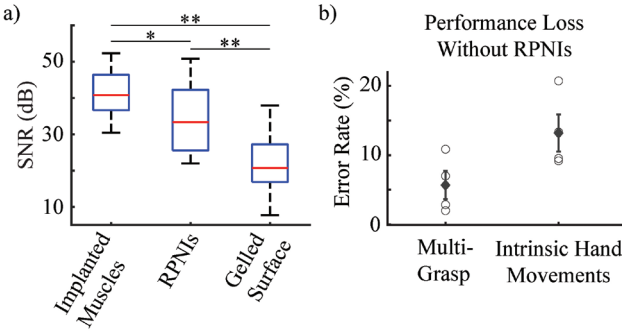

Figure 1. (a) Signal to noise ratio from implanted residual innervated muscles, implanted RPNIs, and gelled adhesive surface electrodes (* $p<0.05$, ** $p<0.01$, Wilcoxon rank sum). (b) Impact of RPNIs when predicting multiple grasps and intrinsic movements, filled diamonds show the average performance loss across all four patients (mean ± s.e.m.).

CONCLUSION

Implanted electrodes in RPNIs produces strong and reliable control signals to restore lost function.

CLINICAL APPLICATIONS

Accurate and reliable control of individual finger and fine thumb movements may enable patients to fully utilize the capabilities of multiarticulating hands. This may reduce the initial device learning curve and increase the effectiveness of occupational therapy. Furthermore, the use of implantable nerve interfaces may provide this benefit to a broad range of patients with varying levels of amputation and anatomy.

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Translating Outcomes That Matter Most to Individuals Living with Orthotics and Prosthetics to Shared Decision-Making in the Practice Setting

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INTRODUCTION

In the United States, 540,000 individuals live with upper-limb loss (ULL).[1] Despite rapid advancements in upper-limb prosthetic technology, up to 60% of individuals discontinue or have low use rates.[2,3]

There is a misalignment between patient expectations and actual experience with prosthetic devices, due to a lack of studies examining the decision-making process for upper-limb prosthetic selection.

The overall purpose of our study is to measure risk and benefit trade-off preferences of ULL when choosing a prosthesis choice and test this aid in Hanger prosthetic clinics. Our specific objective is to report results of our first aim: a systematic literature review to determine the current landscape of prosthetic decision-making and identify the specific factors of risk and benefit important to individuals' choice of upper-limb prosthetic devices for use in a discrete choice measure.

METHODS

A comprehensive systematic search of the literature was conducted using PubMed, Web of Science, Embase, and CINAHL databases. The searches were developed using MeSH terms around 4 main concepts: ULL, prosthetics/artificial limbs, preference, outcomes assessment, and satisfaction.

The inclusion criteria were ULL, ages 18+, English language, and a focus on prosthetic decision-making.

RESULTS

All 1381 abstracts were screened to ensure they met the inclusion criteria. These 176 abstracts were screened again, and all resulting (67) articles were reviewed by 2 independent authors using the PRISMA methodology.[4] Study quality was assessed using the Critical Appraisal Skills Program checklist.[5] The content of each study was recorded on a spreadsheet created as relevant to our study purpose.

Design and Purpose: The studies were predominantly preliminary, with small sample sizes, observational or descriptive designs, biased sample selection, and results that were difficult to implement into clinical decision-making. Eight themes emerged.

Only 3 of 37 satisfaction studies specifically examined patient preferences, 2 used conjoint analysis and another repertory grid techniques, and all showed importance of functionality, appearance, and ease of use in the decision-making process. The strongest studies focused on outcomes assessments (18%) with some consistency in measures used (SHAP, DASH, OPUS, and Tapes) although these were considered as limiting, with measures of embodiment, quality of life, satisfaction and Activities Measure for Upper Limb Amputees (AMULA), expanding the assessment scope. Several articles assessed reasons for abandonment of prosthetic devices (37%); comfort and lack of adequate function were predominant, indicating a useful focus for prosthetist/patient decisions. Many studies (53%) compared technological advances showing more acceptance of newer features of myoelectric control; however, this was balanced by its risks for increased weight, costs, and loss of speed and reliability. Opinion pieces (38%) provided the most relevant information on how to integrate current knowledge into prosthetic selection in practice but without the rigor of research-based evidence. Finally, the factors or attributes important to decision-making in prosthetic choice were identified (Table 1).

Table 1. Attributes of Risk and Benefit Preferences.

Main Factor or Attribute for Decision-Making	
Functionality, Performance, Control, Responsiveness	Health, Mental Health, Symptoms, Well-being
Comfortability, Efficiency, Learning, Adjustment, Satisfaction	Appearance, Esthetics, Visual appeal
Durability, Reliability	Freedom of Movement
Cost, Longevity, Servicing	Sensory Integration, Feedback, Body Integration

DISCUSSION

This systematic literature review explores the research landscape supporting the prosthetic decision-making process of individuals with ULL and their care providers. The findings revealed a complex process influenced by factors such as functionality, financial, aesthetics, and psychological.

CONCLUSION

The review highlights the importance of personalized approaches, valid outcome measures, and tailored solutions based on specific patient populations. More rigorous studies specifically directed to patient/clinician prosthetic decision-making are needed.

CLINICAL APPLICATIONS

This organized collection of insights can guide clinicians in selecting appropriate prosthetic devices and improving interventions to reduce upper-limb prosthetic abandonment rates.

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Transcutaneous Electrical Nerve Stimulation at the Wrist as a Method to Restore Sensory Feedback for Individuals with Partial Hand Amputation

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INTRODUCTION

Partial hand amputation accounts for an estimated 92% of all upper-limb amputations[1] and results in up to a 90% loss of total upper-extremity ability and a 54% decrease in whole-person ability.[2] Sensory feedback is critical for dexterous hand function, yet there are limited methods available to restore sensory function to this population.

Artificial sensory feedback via mechanical or vibrotactile stimulation only evokes sensation locally at the site of the stimulation, which impedes use of the residual hand or prosthesis. Here we explore the use of transcutaneous electrical nerve stimulation (TENS) of the nerves at the wrist to evoke distally referred sensations from the amputated digit(s).

METHODS

Participants: Thirty-eight intact individuals and 1 individual with partial hand amputation participated in this study. Participants were 55% male and between the ages of 18 and 52. Informed consent and experimental protocols were carried out in accordance with the University of Utah Institutional Review Board.

TENS: Stimulation was delivered using a non-invasive neural stimulator,[3] and surface electrodes were placed around the wrist. Pulse frequency (PF) varied between 12.5-225 Hz, pulse width (PW) between 0.170-0.230 ms, and pulse amplitude (PA) between 2.52-4.98 mA.

Experimental Design: Participants reported the location of sensations evoked by different electrode placements around the wrist. Participants also reported the perceived intensity of the sensations on a free-magnitude scale in response to changes in stimulation PF, PW, and PA.

RESULTS

TENS at the wrist elicited localized distally referred sensations on the digits. Isolated sensations were achieved in the palm and 4 of the 5 digits using only changes in electrode positioning (Figure 1A). Consistent with prior work,[4,5] increasing PF, PW, or PA resulted in more intense sensations (Figure 1B). Findings were consistent between the intact participants and the individual with partial hand amputation; sensations were evoked on the phantom digit using similar electrode placements and stimulation parameters as used with intact individuals.

DISCUSSION

TENS can be delivered non-invasively at the wrist to create intuitive, distally referred sensations in the hand. The location of the sensations can be determined by the electrode placement, and the intensity of the sensations can be modulated using PF, PW, or PA. It has been suggested that TENS's greatest barrier to achieving localized sensation is the spillover of the referred sensation into adjacent projected map areas.[6] Here we show TENS at the wrist can produce isolated sensations with no spillover. However, identifying the specific stimulation parameters to achieve these ideal sensations can be time-consuming. We turned away 35% of participants because we could not identify the necessary stimulation parameters within 1 hour. Future work will attempt to create a heatmap of common electrode placements that produce functionally relevant isolated sensations.

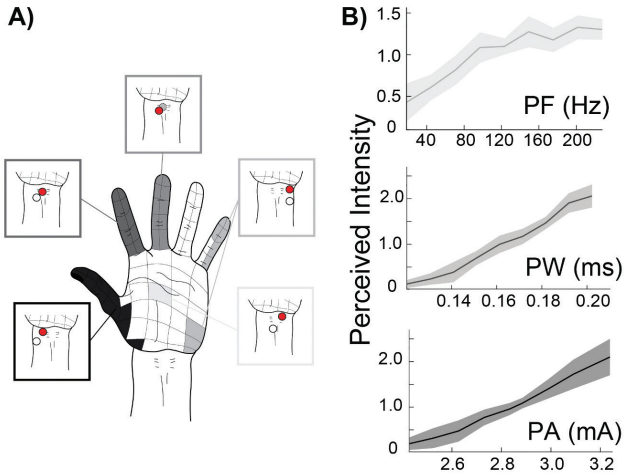

Figure 1. Distally referred sensations were localized on the digits using the electrode placements shown in the boxes (A). Increasing PF, PW, or PA increased sensation intensity (B).

CONCLUSION

TENS of the nerves at the wrist provides a unique opportunity to restore anatomically congruent sensory feedback after a partial hand amputation without interfering with the residual hand or prosthesis.

CLINICAL APPLICATIONS

A bracelet or watchband with integrated TENS could be worn by individuals with partial hand amputation. Forces exerted on a sensorized prosthesis could be wirelessly transmitted to the TENS unit to evoke a sensation on the phantom digit with a corresponding intensity.

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Projection-Based Visual Feedback of Classification Outputs Improves Efficacy of Prosthesis Training for Myoelectric Pattern Recognition

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INTRODUCTION

Myoelectric prostheses are often controlled via pattern recognition (PR) algorithms that translate surface electromyograph (EMG) activity into motor outputs.[1] Prosthesis users often require extensive training to consistently generate distinguishable EMG patterns of activity for prosthesis operation;[2] however, current training paradigms do not provide individuals with enough feedback to modulate EMG activity to accomplish these goals in an informed manner. To aid in the process, we present the results of a real-time feedback visualization method that presents prosthesis users with a projection of their EMG activity into the classification-space defined by a user's PR system.

METHOD

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

Participants: Twelve naïve participants (4 males and 8 females between the ages of 18 and 31) with intact limbs took part in a longitudinal study.

Apparatus: EMG data was collected with an 8-channel surface electrode band that interfaced wirelessly with a host PC. Participants were also required to wear a bypass prosthesis attached to their dominant limb.

Procedures: Each participant underwent an initial 10-session longitudinal protocol over 14 days. Participants were assigned to 1 of 2 groups: the experimental group (EG), which visualized their control by driving the position of a 3D cursor in the classification-space projection; and the control group (CG), which visualized their control by operating a virtual limb.

During each session, participants trained a PR system on several hand and wrist movements. Participants trained 4 movements (Sessions 1–4), 6 movements (Sessions 5–7), and 8 movements (Sessions 8–10). Participants then explored the performance of the PR system in an unstructured manner using their prescribed visualization method for a period of 2 minutes per active movement class (i.e., 4-movement classes has an 8-minute exploration period). If unsatisfied with their performance, participants were allowed to retrain any of the required movements before the assessment.

After the training period, participants were asked to complete a series of Fitts Law tests (FLTs) to assess the efficacy of their control. Each FLT required the participant to modify the aperture and orientation of a virtual cursor to a target configuration within a 15-second time limit using their PR control outputs.[3]

After the completion of the initial 10-session study, participants were asked to return after 30 days for a final session. Eleven of 12 participants returned for this post-washout evaluation.

Data Analysis: Python 3.6.8 (Python Software Foundation, Wilmington, DE) was used to collect and process the EMG data in real time. Statistical significance was calculated using the two-sample two-sided t-test for between-group comparisons.

RESULTS

EG participants demonstrated an increased task completion rate, outperforming CG participants in every session (including post-washout; Session 11). Furthermore, EG participant performance was robust to the addition of novel movements (Sessions 5 and 8).

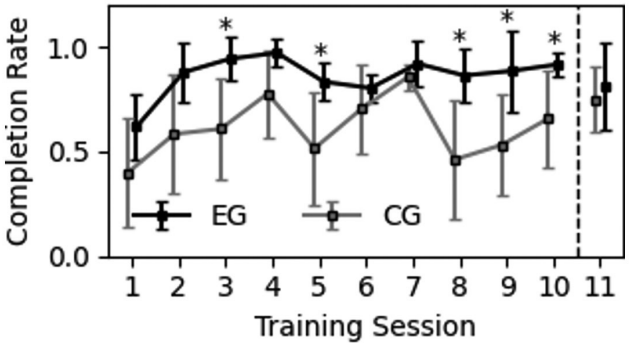

Figure 1. EG participants demonstrated a greater mean task completion rate than CG participants in every session. Statistically significant difference between participant groups is denoted with * ($p < 0.05$).

DISCUSSION

By providing real-time visual feedback on where EMG signals lie in the classification-space of a PR controller, it is possible that users can more efficiently and effectively learn EMG patterns that generate their desired motor output. While the results achieved are promising, future studies including individuals with upper-limb loss are required. Preliminary work in this regard has been encouraging.

CONCLUSION

Projection-based visual feedback of classification outputs is an effective method for increasing the efficacy of PR-based prosthesis training.

CLINICAL APPLICATIONS

This work provides a new paradigm for visual feedback that improves the efficacy of prosthesis training.

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Investigating 3D Printability of Lattice Structures Used to Prevent Soft Tissue Damage in Cushioned Transhumeral Compression-Release Stabilized Sockets

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INTRODUCTION

Pressure, shear, and friction can cause damage to the soft tissue of a residual limb.[1] Current compression-release stabilized (CRS) socket designs place areas of high compression directly beside open release areas.[2] While this strategy can increase socket stability, range of motion, and prosthesis control, the abrupt differences in compression throughout the socket can present risks for tissue damage. Printable density-graded lattice structures show promise for mitigating such tissue damage by allowing more gradual decreases in magnitudes of compression toward release areas.[3]

Numerous lattice geometries can be digitally created. While 3D printing allows a means to fabricate many lattices unable to be produced otherwise, not all shapes are ideal for printing with every additive manufacturing process. The aims of this study are to (1) examine factors that influence the printability of lattice structures using benchtop fused filament fabrication (FFF) 3D printers and (2) to identify a set of lattice structures with the highest potential for functioning within a transhumeral CRS socket to reduce the risk of tissue damage.

METHOD

Twenty-three types of graph lattice and 6 types of walled triply periodic minimal surface (TPMS) lattice structures were examined. Polylactic acid (PLA) filament was used to print samples on Ultimaker 2+ 3D printers. Factors investigated included lattice structure, cell size, beam/wall thickness, relative density, and beam angles and their influence on printability. Three researchers independently assigned printability scores to each sample based on scoring criteria. Scores were then averaged for each sample.

RESULTS

Results of lattice printability analyses revealed that beam/wall thickness had a greater effect on printability than cell size (Figure 1). Printability did not always increase when the beam angles increased. Lattice geometries had highly significant impacts on printability scores ($p = 0.000$). Fifteen lattice structures received the highest average printability scores (above 2.5/3). Of these, 7 had a relative density of 0.5 or less, which implies lighter weight lattices requiring less material to fabricate. Based on previous results,[3] a wider range of firmness levels should be attainable when such structures are printed in TPU; thus, they were chosen as the most appropriate for potential use in lattice cushioned CRS-style sockets.

DISCUSSION

While printability improved as beams/walls became thicker—which works well for compression areas—greater compressibility for release areas of modified CRS cushioned sockets would require thinner walls.

Because many lattice structures contain more than 1 beam angle, angles that printed well could not be separated from those that printed poorly in a single sample. A limitation is that the printability score often reflected printability of the worst performing angle.

Future research could include compression testing of the 7 chosen lattice structures to determine their adequacy to serve as compression and release areas of a modified CRS socket. Ideally, 1 lattice structure would be used, with its density tuned up or down to modify firmness within chosen areas of the socket.

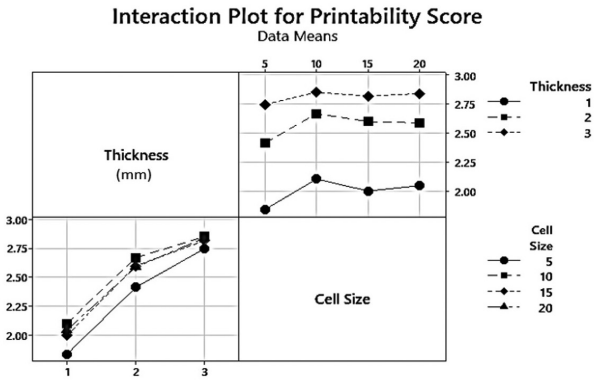

Figure 1. Beam/wall thickness of lattice structures affect printability scores more than cell size. Printability increases as beam/wall thickness increases.

CONCLUSION

For lattice structures to be beneficial in preventing soft tissue damage from CRS sockets, they must first be printable. Seven highly printable lattice structures were identified as a result of this study, offering promise for their use in such sockets.

CLINICAL APPLICATIONS

While this study focuses on a transhumeral socket application, similar principles could be applied to other levels of amputation with some modification.

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Movement Patterns and Prosthesis Use with Transradial Amputation: Pilot Insights of Bilateral Limb Loss and Congenital Limb Deficiency

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INTRODUCTION

Upper-limb movement patterns in acquired unilateral transradial amputees have been reported previously.[1] Prosthesis usage trends have been further informed by patient-reported outcomes.[2] We expand on our earlier work with the preliminary comparative differences seen among those with congenital unilateral and bilateral transradial deficiencies and the impact of prosthesis type and limb dominance.

METHOD

Participants: A total of 45 below-elbow amputees (52.20 ± 17.03 years old, 8 females), including 7 individuals with unilateral congenital deficiencies and 4 individuals with bilateral transradial amputation, and 46 healthy adults (53.48 ± 14.52 years old, 5 females) were included.

Procedures: Subjects participated in a 3-day data collection period using 4-sensor accelerometers (GT9X Link, ActigraphCorp) bilaterally on both distal segments (i.e., wristwatch) and proximal segments (cuffs worn just above the elbow).

Data Analysis: Derivation of wear times, forearm activity times, interlimb reliance ratios for the both the proximal and distal upper-limb segments and intralimb reliance ratios between the proximal and distal limb segments have been described previously.[1]

Differences between amputee groups based on limb dominance, prosthesis type, and amputation etiology, and differences in prosthesis on versus off status were variably examined using paired t-tests, Wilcoxon signed rank tests and Mann-Whitney U tests as appropriate. Nonparametric tests were used to examine populations of small sample size. This work was performed under informed consent and approved by the University of Missouri Institutional Review Board.

RESULTS

Among prosthesis users, individuals with acquired unilateral amputation (n = 26) wore their prosthesis for 11.1 hours/day. This was unaffected by the dominance/non-dominance of their amputation or prosthesis design (myoelectric versus body-powered). Among individuals with unilateral congenital deficiency (n = 7) and bilateral amputation (n = 4), prosthesis wear times were observed at 7.1 and 8.6 hours/day respectively.

While unimanual engagement of the prosthesis was generally uncommon, bimanual task engagement was observed at an average of 4.0 and 1.7 hours per day among those with unilateral acquired amputation and unilateral congenital deficiency, respectively. Bilateral prosthesis users tended to demonstrate a reliance on a "dominant" limb with unilateral prosthesis engagement observed at an average of 1.3 and 0.6 hours/day at the dominant and nondominant limbs in this pilot group.

Interlimb forearm reliance on the prosthesis was far less than that observed in the non-dominant forearms of controls. However, this was unaffected by the dominance status of the amputation. Greater prosthesis reliance was observed among body-powered devices. Among those with bilateral amputations, reliance on the dominant prosthesis was 67.8%, a greater reliance than that observed among the dominant limbs of able-bodied controls.

Relative reliance on the proximal segment of the affected limb for acquired unilateral users was greater when the prosthesis was worn than during hours of non-use of the prosthesis. This was unaffected by dominance or prosthesis type. Upper-arm reliance ratios were unaffected by prosthesis use among bilateral users. Among those with congenital deficiencies, upper-arm reliance was lower with the prosthesis on than it was with the prosthesis off, suggesting reduced limb engagement.

DISCUSSION

Users of transradial prostheses tend to wear their prostheses much of the day. Bimanual prosthesis engagement is more common than unimanual engagement, especially among those with acquired unilateral amputation. Greater upper-arm symmetry was observed with the prosthesis following acquired amputation and without the prosthesis with congenital deficiency. Bilateral prosthesis users demonstrate the tendency toward a dominant extremity.

CONCLUSION

These observations constitute relevant considerations respecting prosthesis design with respect to amputation etiology, limb dominance, and laterality.

CLINICAL APPLICATIONS

Prosthetic design for unilateral acquired amputation should anticipate bimanual activity, while bilateral prostheses may anticipate both unimanual and bimanual engagement. Bilateral prostheses should anticipate a dominant limb.

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