2023 Annual Meeting Clinical Content Committee

Brian Kaluf, BSE, CP, FAAOP, Chair
Sally Kenworthy, MPO, CPO, Co-Chair
Kristin Carnahan, MSPO, CPO, FAAOP
Stefania Fatone, PhD, BPO(Hons)
Katie Johnson, MS, CPO, LPO
Taavy Miller, PhD, MS, CPO
Eric Weber, CPO, LPO, FAAOP(D)

Journal of Prosthetics and Orthotics Editorial Board

Steven A. Gard, PhD, JPO Editor-in-Chief
Miki Fairley, Managing Editor
Kristie Bjornson, PT, PhD, MS
Goeran Fielder, PhD
John R. Fisk, MD
Mark Geil, PhD
Brian J. Hafner, PhD
Michelle J. Hall, MS, CPO, FAAOP(D)
Daniel Heitzmann, Dipl. Ing. (FH)
M. Jason Highsmith, PT, DPT, PhD, CP, FAAOP
Peter Kyberd, PhD, MSc, BSc
Matthew Major, PhD
Sara Morgan, PhD, L/CPO
David Morgenroth, MD
Elaine Owen, MSc, SRP, MCSP
Phillip M. Stevens, MEd, CPO, FAAOP

Academy Board of Directors

OFFICERS

JoAnne L. Kanas, DPT, CPO
President

Mark Holowka, MSPO, CPO, FAAOP(D)
President-Elect

Susan Kapp, MEd, CPO, LPO, FAAOP(D)
Vice President

Gerald Stark Jr., PhD, MSEM, CPO/L, FAAOP(D)
Treasurer

Sarah Thomas, CPO, FAAOP(D)
Immediate Past President

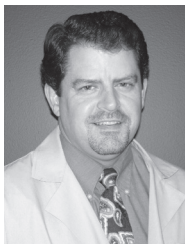
Vacant
Executive Director

DIRECTORS

Greg Armstrong, BSPO, CPO/L, FAAOP
Duffy Felmlee, MSPO, CPO, FAAOP
Tiffany Graham, MSPO, CPO, LPO, FAAOP(D)
Brian Kaluf, BSE, CP, FAAOP
Sara Morgan, CPO, PhD
Seth O'Brien, CP, FAAOP(D)

49th Academy Annual Meeting & Scientific Symposium
Journal of Proceedings

Greetings, friends and colleagues!



I am pleased to help welcome you to the 49th Academy Annual Meeting & Scientific Symposium, where I look forward to renewing old friendships and making new acquaintances in the O&P profession.

I regard this *Journal of Proceedings* as the official documentation for the 49th Academy Annual Meeting & Scientific Symposium. This document is invaluable whether you are planning to attend the conference or not. If you participated in the conference, you can review some of your favorite presentations, read about the content in greater detail, or even learn about presentations you might have missed attending. If you were unable to participate in the meeting, then you can access information that was delivered during the presentations and stay abreast of the latest developments in O&P research, education, and clinical practice.

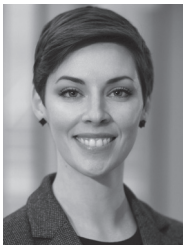
For presenters at the conference, a primary benefit of this *Journal of Proceedings* is that others can formally cite the content as a justification for clinical decision-making and for furthering lines of research in the field. Therefore, authors can receive appropriate recognition for new ideas and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

We hope you enjoy this *Journal of Proceedings!*

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

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

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



It is our great pleasure to introduce the *Journal of the Proceedings* on behalf of the 49th Academy Annual Meeting & Scientific Symposium. We would like to congratulate the *Journal of Prosthetics and Orthotics* for continuing to deliver the research evidence that drives the profession forward. At the Annual Meeting this year, a whole new slate of topics and presenters will highlight the latest advancements in orthotic and prosthetic (O&P) technology, evidence, and clinical approaches. More than ever before, the planning of the Annual Meeting has engaged members of the profession to curate the content to suit the needs of practicing clinicians. We would like to thank the Clinical Content Committee and Academy staff for leading the meeting planning and ensuring that all attendees fulfill their educational and professional development goals.

The topics and material Annual Meeting attendees will experience mirror the acceleration, innovative technology, and evidence-based research seen within the O&P field. From Organized Sessions delivering clinical guidance on complex craniofacial orthoses, ossoeointegrated prostheses, 3D printing, and delivery of O&P care, to Free Paper and Thranhardt Award-winning presentations summarizing the latest in outcome measures and clinical trials, this Annual Meeting is an educational event not to be missed.

We would like to again thank the *Journal of Prosthetics and Orthotics,* as we look forward to meeting in Nashville, Tennessee, for the networking and highest level of educational experiences for the O&P profession.

Sincerely,

Brian Kaluf, BSE, CP, FAAOP

Sally Kenworthy, MPO, CPO
49th Academy Annual Meeting & Scientific Symposium Co-Chairs

Clinical Assessment versus Computer Analysis in Classification of the Severity of Deformational Plagiocephaly Brachycephaly

Timothy R. Littlefield, MS;[1] Sacha C. Hauc, MPH;[2] Aaron S. Long, BS;[2] Jeff A. Riggs, MS;[1]
Mary Kay McGuire OTR/L;[1] Michael Alperovich, MD, MSc[2]

[1]Cranial Technologies, Inc., Chandler, Arizona; [2]Yale School of Medicine, New Haven, Connecticut

INTRODUCTION

Determination of the severity of deformational plagiocephaly-brachycephaly (DPB) is an important consideration when attempting to make treatment decisions or assess treatment outcomes. Severity determination is often made by clinical visual assessment or direct measurement of the skull. The purpose of this study was to determine the relative agreement or disagreement between *clinical assessment* and *computer analysis* in ascertaining the severity of DPB. Furthermore, this study also attempted to determine if a particular type of deformation [isolated deformational plagiocephaly (DP), isolated deformational brachycephaly (DB), or brachycephaly with asymmetry (BWA)] would show the least agreement, with the initial hypothesis that combinational head shapes (i.e., BWA) would be the most difficult to establish agreement on.

METHOD

For the period from July 1, 2014, to June 30, 2019, two separate SQL databases from a single, national cranial remolding orthosis (CRO) provider were exported for comparison. The first database contained the initial clinical evaluation and severity determination made during consultation (clinical assessment), and the second contained the measurement data and severity calculation from 3D images taken at the time of consultation (computer analysis). The databases were cleaned, filtered, patient matched, and merged resulting in a final sample size of 127,269 cases. The percentage of cases that had been classified as mild, moderate, and severe by each methodology were initially compared as a group, and then an additional direct case-by-case match comparison was performed. To evaluate the impact of head shape on the results, the data set was then subdivided into three groups: isolated plagiocephaly, isolated brachycephaly, and brachycephaly with asymmetry, and the process was repeated.

RESULTS

The results of this investigation confirmed an unexpected, yet remarkable agreement between the two methodologies, with a slight tendency for clinicians to rank the deformity more frequently as a moderate deformity (6.5%) and less often as a severe deformity (-2.9%) than the computer analysis did. Under direct-match comparison, the clinical assessment and computer assessment matched 47% of the time, with the greatest match in cases of isolated deformational plagiocephaly (50.8%), followed by brachycephaly with asymmetry (47.9%), and isolated deformational brachycephaly (45.9%). These results confirmed our earlier hypothesis that clinicians may be more likely to downplay the severity to mitigate parental anxiety. By contrast, our second hypothesis that there would be less agreement between the clinical assessment and computer analysis for combinational head shapes (BWA) was disproven. The best overall agreement was seen in brachycephaly with asymmetry (BWA), with less agreement for isolated deformational plagiocephaly (DP) and isolated deformational brachycephaly (DB), respectively.

DISCUSSION AND CONCLUSION

This study suggests that both visual clinical assessment and analytical computer analysis provide both a comparable rating and distribution of severity in DPB. This confirms that for experienced practitioners, clinical assessment is sufficient to determine severity and will generally match results provided by computer analysis. In those situations where analytical results are required (e.g., third-party payors, clinical research, etc.), it may be confirmed that the severity classification will mirror what would have been determined through direct clinical evaluation. In support of our original hypothesis, the results did demonstrate the tendency for clinical assessment to rank the deformity as slightly less severe; in contrast to our second hypothesis, the two methods showed improved agreement on combinational head shapes (BWA) and the least amount of agreement in cases of isolated deformational brachycephaly (DB)

CLINICAL APPLICATIONS

The results of this study provide confidence that qualitative clinical evaluation by experienced clinicians provides severity level assessments comparable to those achieved with quantitative measurement of the skull.

Significant Factors Influencing Cranial Remolding Orthosis Treatment Outcomes and Rates of Correction in Infants with Deformational Plagiocephaly

CJ Richards, AM Petz, M Yosef, SH Khalatbari, CJ Frank, JA Richards

University of Michigan Orthotics & Prosthetics Center, Ann Arbor, MI

INTRODUCTION

There is consensus that the age at which cranial remolding orthosis (CRO) treatment is initiated and the severity of the deformity affect CRO treatment outcomes. However, there is limited quantitative information on treatment success rates based on an infant's specific initial presentation. Further, it is known that preterm birth and the presence of torticollis are risk factors for plagiocephaly,[1,2] but how these factors affect rates of correction is not well understood. This study aimed to quantify the chances of reaching a successful outcome when treated with a CRO, based on an infant's age at the initiation of treatment and the severity of their deformity and determine if the presence of torticollis affected the chances of a successful outcome or treatment duration. It also aimed to determine whether preterm infants' chronological age or corrected age should be used when predicting the chance for success and treatment duration.

METHOD

Participants: This retrospective study included 300 infants with deformational plagiocephaly who were fit with the Michigan Cranial Reshaping Orthosis (Danmar Products) 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 upon corrected age at initiation of helmet therapy (<22 weeks, 22–25 weeks, 26–30 weeks, and >30 weeks) and into four groups based upon severity of deformity [initial cranial vault asymmetry (CVA) of 6–9 mm, 10–12 mm, 13–16 mm, and 17+ mm]. Success rates and rates of correction in CVA were calculated and compared.

Data Analysis: SPSS was used to perform statistical analysis.

RESULTS

A successful outcome was defined as achieving a final CVA of 5mm or less. Infants with an initial CVA of 6–12 mm were 12 times and 56 times more likely to achieve a successful outcome than those who started with 13–16 mm CVA and 17+ mm CVA, respectively. Infants whose corrected age at initiation of CRO treatment was less than 26 weeks (6 months) were 3–4 times more likely to achieve a successful outcome than those whose corrected age at initiation was 26 weeks or greater, but further categorization of age at initiation was insignificant.

Table 1. Percent of infants reaching a successful outcome, categorized by corrected age at initiation of helmet therapy and initial CVA.

	<22 weeks	22–25 weeks	26–30 weeks	>30 weeks
6–9 mm	95.24% N=21	100% N=28	82.61% N=23	88.89% N=27
10–12 mm	95.00% N=20	89.66% N=29	71.43% N=28	83.33% N=30
13–16 mm	80.95% N=21	60% N=20	28.57% N=17	50% N=6
17+ mm	33.33% N=9	50% N=8	11.11% N=9	0% N=8

Infants with torticollis had similar rates of correction to infants without torticollis. The rates of correction in early term infants behaved more similarly to term infants of a similar age when the early term infants' corrected ages were used than when their chronological ages were used.

DISCUSSION

The chance of reaching a successful outcome in CRO treatment depends much more on the starting severity of the deformity than on the corrected age at the initiation of treatment.

CONCLUSION

When predicting the likelihood of achieving a successful outcome in CRO treatment, orthotists should focus more on the severity of the deformity than the infant's age at initiation. Additionally, when determining age at initiation for early term infants, the corrected age, rather than the chronological age, should be used.

CLINICAL APPLICATIONS

This study provides quantitative data to share with parents regarding success rates of CRO treatment based on an infant's initial CVA and the infant's corrected age at initiation (Table 1).

REFERENCES

1. Kane AA. *Pediatrics.* 1996;97(6 Pt 1):877–885.
2. Stellwagen L. *Arch Dis Child.* 2008;93(10):827–831.

Funded by the University of Michigan Orthotics and Prosthetics Center.

Cranial Remolding Orthosis Study on the Use of a Temperature Sensor to Measure Compliance

JL Corso, SD Thach, CL Davis

Children's Healthcare of Atlanta

INTRODUCTION

Nonsynostotic deformational plagiocephaly (DP) is defined as an asymmetry of an infant's skull due to extrinsic forces acting on the skull that may cause abnormal molding.[1] Patients diagnosed with DP are treated with cranial remolding orthoses. Research has evaluated the efficacy of cranial remolding orthosis (CRO) treatment, but evidence is lacking regarding the necessary hours per day for positive outcome. The general guideline is a 23-hour per day wear schedule. This schedule is prescribed regardless of presentation. The study aims to measure each subject's average daily wear with a temperature sensor and compare the measured wear time to each subject's treatment outcome.

METHOD

This was a Children's Healthcare of Atlanta IRB-approved prospective study on subjects treated with a CRO.

Participants: Infants aged three to 18 months diagnosed with DP and prescribed a CRO by a physician. The subjects must have an initial cranial vault asymmetry (CVA) ≥6 mm or a cephalic ratio (CR) ≥0.90. Subjects were treated with an Orthomerica STARband CRO. A total of 106 subjects were enrolled in the study, and 69 subjects were available at the endpoint for analysis. Of the 69 subjects, 50 were male and 19 were female. The adjusted age at the start of CRO treatment was 27±5.3 weeks. Twenty-three also presented with torticollis as a comorbidity. Twenty-eight of the 69 subjects were diagnosed with plagiocephaly (CVA ≥6 mm and CR <0.90), 13 were diagnosed with brachycephaly (CVA <6 mm & CR ≥ 0.90), and 28 were diagnosed with asymmetric brachycephaly (CVA ≥6 mm & CR ≥0.90).

Apparatus: A questionnaire was utilized throughout the study to measure and document the caregiver's reported compliance with the CRO. Objective compliance measurements were obtained utilizing Maximum Integrated's iButton temperature loggers (iButtons) that sample and record temperature data every 15 minutes.

Procedures: Every 6 to 8 weeks, head shape measurements are taken using the Orthomerica STARscanner, caregivers answer the questionnaire, and data from the iButton is retrieved and processed.

Data Analysis: Temperature data was processed to determine average daily wear time. Descriptive statistics were obtained with data reported as mean±SD or median [25th, 75th percentiles]. Non-parametric sign tests were used to test for differences from initial measurement (scan to fabricate CRO) to each subsequent follow-up including discharge visit. Spearman's rank correlations and corresponding 95% confidence intervals and p-values between average wear time and change of measurements between follow-up appointments were obtained. P-values <.05 were considered statistically significant, while p-values between .05 and .2 were considered insignificant trends.

RESULTS

Table1. Reported versus recorded wear time in hours per day.

	Subjects	Reported	Recorded
Initial to 1st	69	22 [22, 23]	18 [14, 19]
1st to 2nd	69	22 [22, 23]	18 [14, 20]
2nd to 3rd	11	22 [21, 23]	17 [12, 20]

Table 2. Correlations between average wear time and change in measurements (initial to discharge).

Diagnosis	Measurement	N	Measurement Median [25th, 75th]	Change in Measurement Median [25th, 75th]	Spearman's Rank Correlation (95% CI)	P
Plagiocephaly						
	CVA	28	18.8 [13.7,20.6]	-6.6 [-8.0,-4.1]	-0.50 (-0.74,-0.16)	***.0054***
	CR	28	18.8 [13.7,20.6]	-0.013 [-0.023,-0.0030]	-0.49 (-0.73,-0.14)	***.0080***
	CVAI	28	18.8 [13.7,20.6]	-4.4 [-5.2,-2.7]	-0.50 (-0.74,-0.16)	***.0059***
	Circumference	28	18.8 [13.7,20.6]	15.4 [12.5,19.2]	-0.0089 (-0.38,0.37)	.96
Brachycephaly						
	CVA	13	17.4 [14.4,20.7]	-1.8 [-3.3,-0.50]	-0.017 (-0.56,0.54)	.96
	CR	13	17.4 [14.4,20.7]	-0.058 [-0.068,-0.045]	-0.17 (-0.66,0.42)	.59
	CVAI	13	17.4 [14.4,20.7]	-1.3 [-2.3,-0.30]	0.039 (-0.52,0.58)	.90
	Circumference	13	17.4 [14.4,20.7]	18.5 [14.2,19.2]	-0.26 (-0.71,0.34)	.39
Asymmetrical Brachycephaly						
	CVA	28	16.5 [13.8,19.8]	-5.6 [-7.3,-4.1]	-0.24 (-0.57,0.14)	.21
	CR	28	16.5 [13.8,19.8]	-0.037 [-0.050,-0.024]	-0.0082 (-0.38,0.37)	.97
	CVAI	28	16.5 [13.8,19.8]	-3.9 [-5.1,-2.7]	-0.24 (-0.56,0.15)	.22
	Circumference	28	16.5 [13.8,19.8]	16.2 [12.1,21.8]	-0.47 (-0.71,-0.11)	***.012***

DISCUSSION

Wear time reported by the caregiver was higher than actual measured wear time. Only the plagiocephaly group showed statistical significance in average wear time and change in measurements. COVID-19 presented limitations, with subjects not showing for required appointments. This resulted in numerous exclusions and contributed to the number of subject data that was not viable. The study is ongoing and expects to increase statistical significance with a larger subject pool.

CONCLUSION

The results show increased effectiveness in treatment of plagiocephaly with a CRO with longer average wear schedules. Increased sample sizing is required to determine if it is the same for brachycephalic and asymmetric brachycephalic head shapes.

CLINICAL APPLICATIONS

CRO wear schedules of 23 hours a day is recommended.

REFERENCE

1. Looman W, Flannery A. *J Pediatr Health Care*. 2012;26(4): 242–250.

Funded by the Dudley Moore Grant.

Effect of Crutch and Walking Boot Use on Whole-Body Angular Momentum during Gait

Robert C. Wiederien,[1] Wesley J. Gari,[1] Jason M. Wilken[1]

[1]Department of Physical Therapy and Rehabilitation Science, University of Iowa, Iowa City, Iowa

INTRODUCTION

Crutches are commonly used for limb offloading after injury or while waiting for prosthetic or orthotic devices. Disadvantages of standard axillary crutches (SACs) include risk of overuse injuries, falls, and restricted use of the upper extremities while standing or walking.[1] The hands-free crutch (Figure 1) is an alternative to SACs. The hands-free crutch (HFC) allows for free use of the hands and arms.[2]

Range of whole-body angular momentum (RAM) during the gait cycle can be used to objectively quantify balance control. Angular momentum characterizes the rotary inertia of the body segments about the body center of mass. Angular momentum is tightly regulated during walking, with reciprocal arm and leg swing negating the effect of the contralateral side, resulting in a RAM of nearly zero during normal gait.[3] A larger RAM is associated with decreased balance control and increased risk of falls.[4]

The purpose of this study was to examine patient preference regarding SACs and HFCs and the effects of crutch and walking boot use on RAM during gait.

Figure 1. Hands-free crutch, iWalk-Free, Inc.

METHOD

Study activities were approved by the Institutional Review Board. Healthy, able-bodied participants were recruited, and written informed consent was obtained.

Participants: Seventeen participants (7M/10F; ages 27 (7.8) years; height 1.72 (0.07) m; mass 74.0 (13.1) kg).

Procedures: Participants reported their device preference and completed the Activity-Specific Balance Confidence scale (ABC). Kinematic (Vicon Ltd., 120Hz) and kinetic (AMTI Inc., 1200Hz) data were collected as participants walked in six randomized conditions.

Apparatus: Participants walked without a crutch (NONE), with a walking boot (BOOT), using SACs with and without a walking boot (SAC and SACBOOT), and using a HFC with and without a walking boot (HFC and HFCBOOT). Preference was recorded and sagittal plane whole-body angular momentum and normalized RAM during the gait cycle were calculated using V3D software (C-Motion, Inc.)

Data Analysis: Mean (SD) normalized sagittal plane RAM was calculated. A two-way repeated measures ANOVA with post-hoc paired t-tests were performed to evaluate RAM. A one-way repeated measures ANOVA with post-hoc paired t-tests evaluated balance confidence. All statistical analyses were performed using SPSS v28 (IBM Corp.) using P=0.05.

RESULTS

Participants preferred the HFC (71.1%) over the SAC. Although there was a significant main effect of device use on balance confidence (P<0.001), there was no difference between SACs and the HFC (P=0.679). There were significant main effects of crutch (P<0.001) and boot (P<0.001) use on RAM and a significant crutch by boot interaction (P=0.01). All pairwise comparisons were statistically significant (P<0.001).

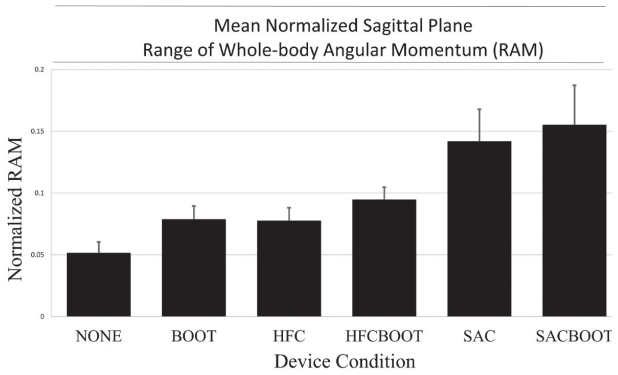


Figure 2. Mean (SD bars) normalized sagittal plane range of whole-body angular momentum through the gait cycle across conditions.

DISCUSSION

Participants demonstrated a strong preference for the HFC. Although balance confidence did not differ between HFC and SAC, the lack of reciprocal motion of the arms and legs while using SACs contributed to significantly greater RAM in the SAC and SACBOOT conditions than with the HFC.

CONCLUSION

Individuals preferred the HFC and had significantly lower RAM, potentially making them less susceptible to falls compared to walking with SACs.

CLINICAL APPLICATIONS

This information can be used to inform the selection or recommendations of assistive devices for individuals who require limb unloading.

REFERENCES

1. Manocha R, et al. *PMR*. 2021;13(10):1176–1192.
2. Martin K, et al. *Foot Ankle Int*. 2019;40(10):1203–1208.
3. Silverman A, et al. *J Biomech*. 2012;45(6):965–971.
4. Vistamehr, A., et al. *J Biomech*. 2015;49(3):396–400.

Funded by iWalkFree, Inc. and National Institutes of Health under award number UL1TR002537.

Orthotist Use of Outcome Measures in Clinic

Eric Weber,[1] Kirsten M. Anderson,[2] Brittany Pousett,[3] Andreas Kannenberg,[4] Jason M. Wilken[2]

[1]Hanger Institute for Clinical Research and Education; [2]The University of Iowa, Iowa City, Iowa; [3]Barber Prosthetic Clinic, Vancouver, British Columbia; [4]Otto Bock Healthcare LP, Austin, Texas

INTRODUCTION

Outcome measures can serve many purposes when used in clinical practice, including evaluation and health status and progress tracking. They can also help to inform decision-making.[1] Patient-reported outcome measures allow patients to self-report health status and function based on activities and experiences over extended periods of time, while performance-based outcome measures evaluate mobility and function in a single controlled setting. There are hundreds of patient-reported and performance-based outcome measures available. However, little is known about which measures are used and how often they are implemented.[2] Further, there is a limited understanding of the barriers to implementation.

The purpose of this study was to survey a cohort of certified orthotists to determine what outcome measures they use, how often they implement them, and the barriers to using them in clinical practice.

METHOD

This study was reviewed and approved by The University of Iowa Institutional Review Board.

Participants: Fifty-four certified orthotists between the ages of 18 and 85 who are currently practicing or who have practiced in the last 5 years participated in this study.

Apparatus: Participants completed a survey examining their knowledge, use, and barriers to use of outcome measures. The survey was administered and responses recorded using the Research Electronic Data Capture secure data management system.

Procedures: An introductory email with a summary of the study and link to the survey was sent to potential participants. Participants were informed they could end their participation at any point and agreed to participate prior to opening the survey.

Data Analysis: Percent populations of those who responded were calculated for each question.

RESULTS

54 individuals participated; most were located in the United States (98.1%) and work in private practice clinics (53.7%). More than half the participants worked with patients who use foot orthoses (70.4%), ankle-foot orthoses (98.1%), knee-ankle foot orthoses (70.4%), knee orthoses (68.5), spine orthoses (70.4%), or wrist-hand orthoses (59.3%).

Participants indicated using outcome measures in clinical practice improves communication (54.0%), evaluation of treatment (74.0%), identification of deficits (66.0%), provision of objective information (70.0%), goal-setting (70.0%), supporting reimbursement (82.0%), tracking patient progress (92.0%), and planning treatment (68.0%). Participants identified activities of daily living (70.3%), balance/coordination (83.8%), general mobility (75.7%), and safety / fall risk (91.9%) as the most important domains to evaluate.

Patient-reported outcome measures have been used by 77.8% of participants, and 67.9% have reported using lower-extremity, performance-based outcome measures. However, only 51.9% and 46.3% currently use patient-reported or performance-based outcomes in practice, respectively. Of the participants currently using performance-based measures, most (43.2%) can allocate 3–5 minutes of the appointment for assessments, with most clinicians using them at intake (41.7%), before an orthosis is made (33.3%), and after the orthosis is delivered (75.0%)

Participants identified multiple barriers to implementing performance-based measures including time available (92.5%), knowledge of what test to use (34.0%), and lack of space (30.2%).

DISCUSSION

Most certified orthotists indicate that outcome measures provide value to their clinical care and have identified common areas of benefit and limitations to implementation in clinical practice. These data can be used to design educational and informational content and address barriers to implementing outcomes assessment in clinical practice. Data can also be used to focus future research and identify a minimal set of outcome measures that can be implemented in a way to avoid many common limitations.

CONCLUSION

Participants identified many commonly recognized benefits of outcomes assessment, but only half of the participants regularly used patient-reported or performance-based outcomes in their practice. Available time, space in the clinic, and knowledge of which measures to use are common barriers preventing widespread use of outcome measures.

CLINICAL APPLICATIONS

These data highlight the benefits associated with outcomes assessment, and common limitations to implementation in clinical practice. Results can serve as a baseline to identify a minimal set of outcomes measures to be used in the future.

REFERENCES

1. Morgan SJ, et al. *Arch Phys Med Rehabil.* 2022;S0003-9993(22)00292-1:1–12.
2. Figueiredo J, et al. *Disabil Rehabil Assist Technol.* 2021;16(6):674–683.

Funded by NIH under award number UL1TR002537.

Factors Influencing Orthotist Decision-Making When Providing Carbon Fiber Ankle-Foot Orthoses

Kirsten M. Anderson,[1] Elisabeth A. Giles,[1] Taavy A. Miller,[2] Shane R. Wurdeman,[2] Jason M. Wilken[1]

[1]Department of Physical Therapy and Rehabilitation Science, The University of Iowa, Iowa City, IA;
[2]Hanger Institute for Clinical Research and Education, Austin, TX

INTRODUCTION

Carbon fiber ankle-foot orthoses (CFOs) are used to improve function for conditions ranging from dorsiflexor weakness to severe limb trauma.[1] Accordingly, clinically available devices vary widely in design and use. Prior studies have evaluated the effect of mechanical characteristics like alignment and heel wedge characteristics on limb mechanics with CFOs.[2,3] However, limited information is available to inform which CFO design is most appropriate for a given patient, or to identify which patient factors influence outcomes.

Figure 1. Examples of available carbon fiber orthoses.

This study investigated the factors clinicians consider when providing CFOs (Figure 1). Insight into the factors orthotists consider when providing care can be used to help standardize patient assessment and CFO provision to optimize patient outcomes.

METHOD

Study activities were approved by the local Institutional Review Board.

Participants: Forty-six certified orthotists between the ages of 18 and 85 who have provided a CFO in the last 5 years participated in this study.

Apparatus: Survey questions, created and administered via the Research Electronic Data Capture data management system, examined factors that influence decision-making when providing CFOs.

Procedures: An email was sent to potential participants with a description of the study and a link to the survey. Participants were informed that they could stop participating at any time and agreed to participate before starting the survey.

Data Analysis: Descriptive statistics, mean (standard deviation [SD]) and percent populations, were used to analyze the results.

RESULTS

Participants had an average 19.6 (10.0) years of clinical experience, and most practiced at free-standing clinics (91.3%). On average, participants provide 37 (44) dorsiflexion assist CFOs and 22 (24) plantarflexion assist CFOs annually. 84.4% indicate that CFOs have a similar or greater potential for adverse effects as traditional thermoplastic AFOs if improperly fit.

Participants most commonly used observational gait assessment (100%), manual muscle testing (97.8%) and visual assessment of ROM (76.1%) to guide their care plan, with limited use of quantitative measures.

Alignment (69.6%), stiffness (45.7%), and comfort (37.0%) were identified as the most important CFO design factors. The primary reason for considering a CFO was unique to each patient population. Pain (trauma with pain primary), strength (progressive peripheral neuropathy; trauma with weakness; central nervous system injury with weakness), and spasticity (central nervous system injury with increased tone) were the primary considerations. Most participants agreed the secondary and tertiary reasons for considering a CFO for all populations were available range of motion and alignment.

Most participants identified patient motivation (45.5%) and donning and doffing ability (45.5%) as two factors that are most predictive of patient success with CFO use.

DISCUSSION

CFOs have been shown to improve patient function, but there is limited information available concerning the decision-making process during CFO provision or patient-related factors affecting successful outcomes with CFO use. Study results indicate consistency in the CFO provision process, with many clinicians considering the same factors for all patient populations. Many participants use the same measures to assess patients but rely on subjective measures that may differ between clinicians. Participant's opinions varied regarding the patient-related factors they feel are most important for achieving successful outcomes with a CFO. These data provide valuable insight from experienced clinicians and can be used to inform educational content for students and patients and guide future scientific study.

CONCLUSION

Many clinicians consider the same factors when providing CFOs, rely on subjective measures during patient assessments, and have varying opinions regarding which patient factors are most likely to result in successful outcomes with CFO use.

CLINICAL APPLICATIONS

The results provide valuable insight into CFO provision and will help to guide future study design and development of clinical practice guidelines.

REFERENCES

1. Potter BK, et al., *JBJS Am.* 2018;100(20):1781–1789.
2. Brown SE, et al., *J Biomech.* 2017;61:51¬–57.
3. Ikeda AJ, et al., *Prosthet Orthot Int.* 2018;42(3): 265–74.

Funded by NIH under award number UL1TR002537.

An Approach For Guiding Orthotic and Prosthetic Education Program Transition to Client-Centric Training

CF Hovorka

Midwestern University, College of Health Sciences, Orthotic and Prosthetic Program, Glendale, AZ

INTRODUCTION

Accredited orthotic and prosthetic (O&P) practitioner education programs in the United States utilize the NCOPE *Master's Curriculum Guide* as the standard to inform their curriculum.[1] The curriculum guide contains limited content on practitioner-oriented knowledge and skills competencies but substantial content on device-oriented knowledge and skills competencies. However, advances in technology and changes in healthcare suggest a need to expand curricular content and training in key areas such as client diagnostic assessment, formulation of a treatment plan, and systematic evidence-based practice competencies. Expanding training in these areas may enable future O&P clinicians to cope with the evolving demands in healthcare.[2] Hence, a shift toward client-centric education is suggested as a potential solution in preparing O&P graduates for the future.

METHOD

A literature review was conducted on clinical education (focusing on client-centered training) and on project-based learning. Thirty-five articles were identified of which 16 articles on clinical education and 5 articles on project-based learning were reviewed. Article content was examined for relevance and application to training O&P clinicians within a scope of practice.

RESULTS

Results revealed three conceptual frameworks that have the potential to be adapted to O&P clinician education and training.

The International Classification of Functioning, Disability and Health (ICF) provides a unifying biopsychosocial framework for classifying the consequences of disease[3,4] viewing function and disability as an interaction between the health condition of the individual, contextual and environmental factors, and personal factors, describe "the person in his or her world." The ICF can help students understand the interaction between function and disability, and the development of treatment plans using the whole-person perspective.[5,6]

The Prosthetic and Orthotic Process (POP) model adapts ICF to clinical O&P processes[7] whereby aspects of the ICF are conceived as different levels of functioning, which are rated and merged to form a holistic view of the person's health status. The client's goals related to activities are realized by achieving goals related to body functions and structures.

The Canadian Medical Education Directives for Specialists (CanMEDS), a framework for practitioner training, adds the provider dimension to ICF by characterizing the core competencies healthcare providers must exhibit, thereby establishing a template for training O&P students in the knowledge, skills, and behaviors they need to cultivate (Figure 1).[8]

Figure 1. The modified CanMEDS framework, illustrating seven core areas of competency of a clinician. The unifying competency, "O&P Expert" and the "Crafter" competency were adapted to translate the model to the O&P professional.

DISCUSSION

Collectively, the CanMEDS practitioner training model, in conjunction with the ICF and POP models present a comprehensive framework in which students in O&P can learn how to use the ICF for O&P client-centered practice.9 This approach provides a wider "lens" through which to view the client, formulate goals, and translate the plan of care to address the client's needs and to produce evidence for clinical outcomes.

CONCLUSION

The 3 frameworks have been incorporated into a new entry-level master's degree curriculum at Midwestern University. The curricular model is slated for assessment as part of a new education program self-study accreditation review by NCOPE.

CLINICAL APPLICATIONS

The new curricular model provides a call to action for O&P schools, accrediting organizations, and other stakeholders in the O&P profession to consider a new client-centric model and examine strategies to inform the master's standards that enable future O&P professionals to cope with the demands for rapid changes in technology and healthcare.

REFERENCES

1. NCOPE *Master's Curriculum Guide;* 2017.
2. Kogler GF, et al. *Can J Prosthet Orthot.* 2021;4(2):21.
3. WHO ICF, Geneva; 2001.
4. WHO ICF-CY, Geneva; 2007.
5. Allan CM, et al. *J Interprof Care.* 2006;20(3):235–245.
6. Geertzen JHB, et al. *Prosthet Orthot Int.* 2011;35(3):318–22.
7. Jarl G, et al. *Prosthet Orthot Int.* 2018;42(5):248–275.
8. Frank J. R., et al., eds. 2015). *CanMeds Physician Competency Framework.* Ottawa: Royal College of Physicians and Surgeons of Canada; 2015.
9. Hovorka CF. *The O&P EDGE.* 2022;March:1–3.

Effectiveness of the Amputee Coalition Peer Visitation Program: Randomized Clinical Trial

Jason T. Kahle,[1] Rebecca M. Miro[2]

[1]OP Solutions, Tampa, FL; [2]University of South Florida, Tampa, FL

INTRODUCTION

The emotional adjustment to amputation can be a challenging aspect of reintegration. Peer visitation allows the patient going through rehabilitation and reintegration to speak directly with another amputee who has shared that similar experience, enabling the patient to relate feelings and concerns about the loss of a limb. There is increasing national interest in this type of patient-centric education. A wide variety of organizations, including hospitals and community-based facilities, are offering patient education and peer visitation programs. The outcome for individuals attending these programs is improvement in quality of life, patient empowerment, self-efficacy, and self-management. Peer support and navigation was introduced as an intervention to reduce patient barriers to reintegration and achieve optimal healthcare outcomes. The mission of the Amputee Coalition (AC) is to reach and empower people affected by limb loss. The AC has the only formally recognized peer visitation program (PVP). The US Department of Veterans Affairs (VA) has partnered with the AC to establish peer support programs as part of the Amputee System of Care. While the AC PVP program is the only nationally recognized PVP program for amputees, it has not been tested for effectiveness. There are no known clinical trials regarding PVPs for people living with limb loss. Therefore, the purpose of this study is to demonstrate that a peer visitation program (PVP) may improve functional outcomes in people with lower-extremity amputations during amputation rehabilitation. The hypothesis was that the AC PVP would improve all outcomes.

METHOD

Subjects: Fifteen females, 21 males (n=36), 59 years mean age; 29 below-knee and 7 above-knee amputations. Etiologies: 18 diabetes, 12 PVD, 3 trauma, 2 blood clots and 1 infection. Intervention: The AC PVP. Outcome Measures: The SF-36 quality of life survey, the PHQ-9 depression survey, and the patient activation measure were chosen for their psychometric properties and an emphasis on clinical translation of patient-reported outcome measures.

Procedures: Subjects were randomized by the investigator. The AC PVP was administered to group A immediately (day 1) and to group B 15 days after being admitted to the rehab center. The data collections were administered upon informed consent (baseline), at 15 days, and then again at 30 days. This protocol allowed both groups the opportunity to experience the PVP but at different times in the rehab course. It allowed a true intervention to no intervention (SoC) comparison, while addressing equipoise. Two rehab sites were chosen, in Philadelphia, PA, and Washington DC. WCG Institutional Review Board (IRB), The Army Human Research Protection Office (HRPO), and the local IRB oversaw the study.

Data Analysis: T-tests were used for data comparisons. Data was compared at the end of group A's PVP (15 days) compared to group B's non-exposure to PVP, and then again at 30 days once group B had completed the PVP, which allowed an a priori aim of comparing a timing effect. Significance was set at $p<0.05$.

RESULTS

At 15 days, when group A had completed its PVP and group B had not yet started its PVP, depression was significantly better for group A compared to group B ($p<0.05$). At 15 days, group A experienced a significant improvement in patient activation ($p<0.05$). Quality of life compromise was reported in most subjects from both groups at baseline. All other outcome measure comparisons trended in favor of the administration of the PVP but failed to meet statistical significance.

DISCUSSION

Patient activation, education, and empowerment has become emphasized in healthcare and as a directive of HHS. A person who has recently experienced limb loss and subsequent rehabilitation often experiences depression and a compromised quality of life. Patient activation can be a significant step in a patient's journey and mitigate depression and loss of quality of life. Improvement in a patient's activation level has been shown to reduce overall healthcare costs as much as 15%. While not all study endpoints showed a significant difference, the trends were toward improvement with PVP. A larger study needs to be conducted.

CONCLUSION

The Amputee Coalition's Peer Visitation Program showed or trended toward improving quality of life, depression, and patient activation. Rehabilitation from amputation can be overwhelming and psychologically traumatic. The AC PVP can ameliorate these effects while guiding a person new to living with limb loss through rehabilitation.

SIGNIFICANCE

Effective peer navigation/visitation programs can reduce negative effects of a disease, conditions, or procedures. They have been shown to improve quality of life and patient activation while decreasing depression and overall health expenditure. The Amputee Coalition's peer visitation program has promising positive effects, evidenced by this randomized clinical trial. Prosthetic clinicians should implement and encourage these programs into clinical protocols when possible.

REFERENCES

1. Clancy CM, et al. *Health Serv Res.* 2011;46(2):389–393.

2. Heisler M, et al. P*eer Support Programs to Manage Chronic Disease: Seven Models for Success.* California HealthCare Foundation; 2006.

3. Hibbard JH, et al. *Patient Educ Couns.* 2010;78(3):377–381.

DISCLOSURE

This study was funded by the US Department of Defense, CDMRP, OP160035, W81XWH-17-1-0478.

Effects of Carbon Fiber Bracing and Medial or Lateral Wedges on Frontal Plane Knee Biomechanics

Kirsten M. Anderson, Jason M. Wilken

Department of Physical Therapy and Rehabilitation Science, The University of Iowa, Iowa City, IA

INTRODUCTION

Osteoarthritis negatively impacts the quality of life of more than 20 million Americans and results in more than $60 billion dollars in annual costs.[1] Orthotic interventions for knee OA can include medial/lateral wedging under the foot, knee orthoses, or ankle-foot orthoses. One goal of orthotic treatment of knee OA is to reduce frontal plane knee moments and alter joint loading.[2]

Carbon fiber custom dynamic orthoses (CDOs) improve function and reduce pain for individuals with ankle arthritis, and wedges in CDOs have been shown to alter sagittal plane knee and ankle mechanics.[3,4] CDOs may accentuate the effects of distal medial/lateral wedging on frontal plane knee moments and reduce the risk of knee OA development or progression. This study investigated the combined effects of medial/lateral wedges used with CDOs on frontal plane knee moments.

METHOD

This study was approved by the local Institutional Review Board, and all participants provided written informed consent prior to testing.

Participants: Five healthy able-bodied individuals (5F/0M, 22.2(2.3) years, 1.7(0.1) m, 61.5(12.7) kg) participated.

Apparatus: Participants completed testing without a CDO (NoCDO), with the CDO only (Figure 1), with the CDO+medial wedge (medial), and with the CDO+lateral wedge (lateral). The wedges were the length of the CDO footplate and were 1 cm tall on the medial (medial) or lateral (lateral) edge with a 10° slope.

Procedures: Gait analysis was conducted using optoelectronic motion capture (120Hz, Vicon Ltd.) and force measurement (1200Hz, AMTI Inc.) systems while participants walked at a controlled speed.

Data Analysis: Kinematic and kinetic data were analyzed in Visual 3D (C-Motion Inc.). The percent change relative to the NoCDO condition was calculated for peak loading response internal varus moment and peak stance phase internal valgus moment.

Figure 1. Study CDO.

RESULTS

The loading response internal varus moment (Figure 2, left) decreased in all conditions compared to NoCDO (39.9% CDO, 46.8% medial, 27.1% lateral). Peak internal valgus moment in stance (Figure 2, right) decreased in both CDO (0.4%) and lateral (22.3%) conditions and increased in the medial (15.9%) condition.

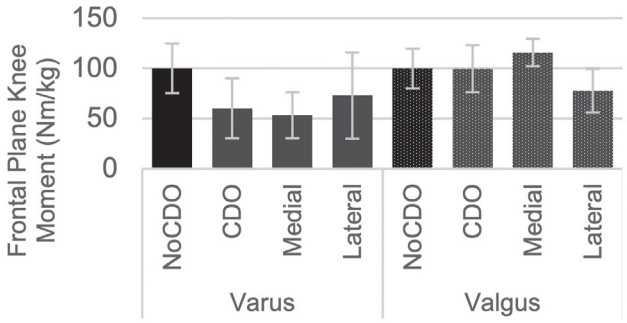


Figure 2. Ensemble average peak loading response internal varus moment (left) and peak stance phase internal valgus moment (right) as a percent of the mean for the NoCDO condition.

DISCUSSION

Medial/lateral wedging and CDO use was found to affect frontal plane knee moments. Peak frontal plane knee moment has been associated with unilateral knee compartment loading.[5] Reduced internal varus moments were observed in all conditions, with the largest reduction seen in the medial condition, as expected. Internal valgus moments were also affected by wedging, with increased moments observed in the medial condition and decreased moments observed in the lateral condition, as expected. Altered frontal plane knee moments may change joint loading, making CDOs with medial wedging an option for lateral knee OA interventions, and CDOs with lateral wedging an option for medial knee OA interventions, indicating they warrant further study. One limitation of this study is the small sample size. Data collection is ongoing to determine if changes in frontal plane knee moments are statistically significant.

CONCLUSION

CDOs with medial/lateral wedging alter frontal plane knee moments and may provide a viable intervention for the treatment of unilateral knee OA.

CLINICAL APPLICATIONS

Knee OA is a costly condition affecting millions of people. Knee OA cannot be cured; it can only be treated. CDOs and medial/lateral wedges provide a non-invasive option for orthotic intervention to treat knee OA.

REFERENCES

1. Buckwalter JA, et al. *CORR.* 2004;427(Suppl):S6–15.
2. Petersen W, et al. *Arch Orthop Trauma Surg.* 2016;136(5): 649–656.
3. Bedigrew KM, et al. *CORR.* 2014;472(10): 3017–3025.
4. Ikeda AJ, et al. *Prosthet Orthot Int.* 2018;42(3):265–274.
5. Butler RJ, et al. *Phys Ther.* 2011;91(8):1235–1243.

Funded in part by a Department of Defense grant (W81XWH-18-1-0658).

Reliability and Responsiveness of a Novel Method for Assessing Passive Ankle Joint Stiffness

Kirsten M. Anderson, Jason M. Wilken

Department of Physical Therapy and Rehabilitation Science, The University of Iowa, Iowa City, IA

INTRODUCTION

Ankle-foot orthoses (AFOs) support the foot and ankle, and AFO stiffness affects overall stiffness of the ankle joint as well as range of motion and loading of the ankle and knee.[1,2] Compliance between the AFO and the limb may change the overall stiffness about the ankle during gait. These interactions between the AFO and the limb are not well understood and are not typically considered when measuring mechanical characteristics of AFOs. AFO stiffness is generally measured using mechanical testing systems that fail to account for the passive limb, the impact of lower-limb muscles, and potential interactions between the AFO, shoes, and limb.[3] Further, despite the importance of reporting AFO mechanical characteristics, this data is commonly omitted in studies evaluating AFOs.[3]

This study investigated the reliability and responsiveness of a novel method for evaluating passive ankle joint stiffness with and without an orthosis (Figure 1).

Figure 1. Malleo-Lok orthosis.

METHOD

This study was reviewed and approved by The University of Iowa Institutional Review Board; all participants provided written informed consent prior to testing.

Participants: Twenty healthy, able-bodied individuals (11F/9M, 26.9 (6.5) years, 1.7(0.1) m, 70.8 (21.9) kg) completed testing with and without an orthosis.

Procedures: Motion capture (Vicon Ltd.) and force measurement (AMTI Inc.) systems were used to measure ankle moment and angle as participants sat with their foot on a force plate and brought their knee forward, dorsiflexing the ankle (Figure 2). Participants were instructed to relax the limb being tested and limit muscle activation. In total, ten trials were collected with (AFO) and without (NoAFO) the orthosis at two different time points; five were collected before (pre) and five after (post) walking.

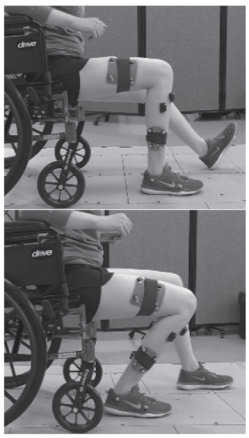


Figure 2. Ankle stiffness testing procedure.

Data Analysis: Mean (SD) stiffnesses were calculated for all condition (AFO, NoAFO) and time point (pre, post) combinations. Paired t-tests were completed using a cut-off of P=0.05. Intraclass dorrelation coefficients (ICC) were calculated in SPSS v.27 (SPSS Inc.) using a (2,k) model, and minimal detectable change (MDC) values were calculated.

RESULTS

Pre and post stiffness was not significantly different for either condition, but AFO stiffness was significantly greater than NoAFO stiffness at both times (Table 1).

Table 1. Average passive ankle joint stiffness for each condition and time.

	AFO		NoAFO	
	Pre	Post	Pre	Post
Stiffness (Nm/deg)	0.96 (0.31)	0.97 (0.37)	0.65 (0.32)	0.59 (0.33)

ICC values were greater than 0.9 for both conditions. MDC values were less than 16% and 46% of the average stiffness for AFO and NoAFO conditions, respectively (Table 2).

DISCUSSION

The lack of significant differences between Pre and Post walking stiffness demonstrates a single bout of testing is adequate for future studies. Additionally, increased stiffness in the AFO condition at both time points indicates the novel testing method is responsive to changes in stiffness associated with orthosis use.

Table 2. ICC and MDC values for each condition.

	AFO	NoAFO
ICC (2,k)	0.97	0.91
MDC (Nm/deg)	0.15	0.27

ICC values for both conditions indicate excellent reliability of the novel testing method. The higher MDC values in the NoAFO condition may be due to greater difficulty reducing leg muscle activation during testing.

CONCLUSION

The novel testing method reported here can be used to reliably assess passive ankle joint stiffness and is responsive to changes in ankle stiffness associated with orthosis use.

CLINICAL APPLICATIONS

This novel testing method is a reliable and responsive way of assessing joint stiffness and is representative of overall stiffness associated with AFO use.

REFERENCES

1. Russell Esposito E, et al. *Clin Orthop Relat Res.* 2014;472(10): 3026–3035.
2. Totah D, et al. *Gait Posture.* 2019;69:101–111.
3. Shuman BR, et al. *J Biomech Eng.* 2022;144(1).
4. Wilken JM, et al. *J Orthop Sports Phys Ther.* 2011;41(4):274–280.

Funded in part by a US Department of Defense grant (W81XWH-18-1-0658). Bio-Mechanical Composites donated the Malleo-Lok devices for testing.

Effects of Carbon Fiber Custom Dynamic Orthoses to Prevent Post-Traumatic Osteoarthritis in the Ankle

Kirsten M. Anderson,[1] Molly S. Pacha,[1] Sara Magdziarz,[1] Donald D. Anderson,[2] Jason M. Wilken[1]

[1]Department of Physical Therapy and Rehabilitation Science; [2]Department of Orthopedics and Rehabilitation, The University of Iowa, Iowa City, IA

INTRODUCTION

Post-traumatic osteoarthritis (PTOA), which occurs after joint injury, affects millions of Americans and costs billions of dollars in healthcare expenditures each year.[1] Development of ankle PTOA following intra-articular fracture (IAF) has been associated with elevated contact stress.[2] Carbon fiber custom dynamic orthoses (CDOs, Figure 1) reduce pain and improve function after traumatic lower-limb injury,[3] but there is little information concerning the effects of CDOs on lower-limb muscle function, joint reaction forces (JRFs), or tibio-talar contact stress. This study was conducted to investigate the effects of different CDO designs on these variables and the potential for CDOs to reduce the risk of PTOA development following IAF.

Figure 1. CDO

METHOD

Study activities were reviewed and approved by the local Institutional Review Board. All participants provided written informed consent prior to testing.

Participants: Four males (41.3 (7.6) years, 1.8 (0.01) m, 95.5 (5.0) kg) who experienced IAF in the prior five years completed testing.

Apparatus: Three CDOs of differing designs and stiffnesses were tested in a randomized order. The moderate stiffness device was designated CDOA (6.0 (0.4) Nm/deg), the stiffest device was designated CDOB (7.7 (0.2) Nm/deg), and the most compliant device was designated CDOC (4.1 (1.7) Nm/deg).

Procedures: CT images were taken and tibo-talar contact stress was calculated using discrete element analysis (DEA). A certified orthotist cast and fit each participant for the CDOs. Motion capture (Vicon Inc.) and force measurement (AMTI Inc.) systems were used to complete biomechanical gait analysis in each condition (NoCDO, CDOA/B/C) while walking at self-selected and controlled speeds.

Data Analysis: Kinematic and kinetic data were processed using Visual 3D (C-Motion Inc). The generic Gait2392 model from OpenSim (SimTK.org) was used to simulate walking. Virtual CDOs, representing the stiffness of each device tested, were added to the model using sagittal plane coordinate limit forces about the ankle. OpenSim v4.0 was used to estimate the muscle forces required to replicate gait kinematics and kinetics and the associated JRFs. DEA was then used to estimate tibio-talar contact stress during stance phase in each condition.[4]

RESULTS

Relative to walking with NoCDO, model estimated soleus muscle forces decreased with each CDO (CDOA, 33 (14)%; CDOB, 38 (16)%; CDOC 17 (15)%). JRFs (CDOA, 28 (7)%; CDOB, 31 (5)%; CDOC, 18 (8)%) and tibo-talar contact stress (CDOA, 21 (7)%; CDOB, 17 (8)%; CDOC, 15 (6)%) also decreased with all CDOs compared to NoCDO (Figure 2).

DISCUSSION

Musculoskeletal modeling and DEA results indicate that CDOs successfully reduce soleus muscle forces, JRFs, and tibio-talar contact stress.

CONCLUSION

Results show stiffer CDOs (A/B) result in greater reductions in muscle force, JRF, and contact stress. CDO stiffness may influence offloading at the ankle.

CLINICAL APPLICATIONS

Reducing in tibio-talar contact stress may prevent or reduce the development of PTOA. CDOs can be used to reduce muscle forces, JRFs, and tibio-talar contact stress following IAF.

REFERENCES

Brown, et al. *J Orthop Trauma.* 2006;20:739–744.
Anderson, et al. *J Orthop Res.* 2011;29L33–39.
Bedigrew, et al. *CORR.* 2014;472:3017–3025.
Anderson, et al. *J Appl Biomech.* 2010;26:215–223.

Funded by a Department of Defense grant (W81XWH-18-1-0658).

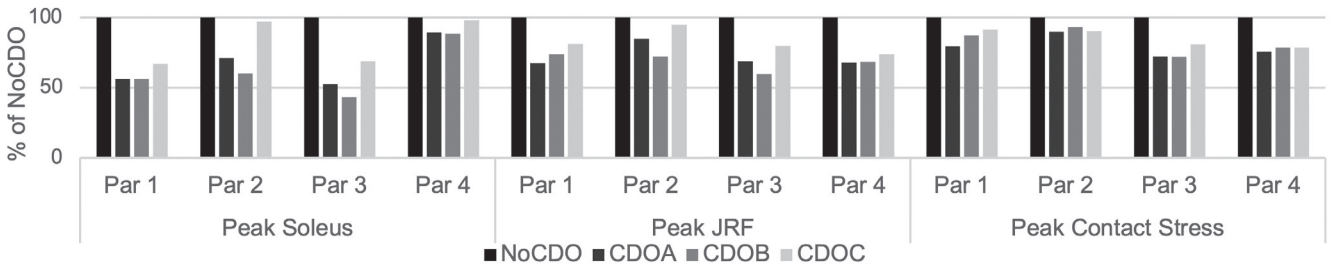


Figure 2. Reductions in peak soleus muscle force, joint reaction force, and contact stress for each participant compared to walking without a CDO.

Initial Construct Validity of the Orthotic Patient-Reported Outcomes-Mobility (OPRO-M™) Item Bank for Assessing Mobility of Lower-Limb Orthosis Users

G Balkman,[1] A Bamer,[1] P Stevens,[2] E Weber,[2] R Salem,[1] S Morgan,[1,3] B Hafner[1]

[1]University of Washington, Seattle, WA; [2]Hanger Clinic, Austin, TX; [3]Gillette Children's Specialty Healthcare

INTRODUCTION

Self-report instruments can be used to assess the effects of orthotic interventions on patients' mobility at home and in the community. However, few instruments with evidence of validity are available for measuring the mobility of lower-limb orthosis users. We recently developed a new survey instrument, the Orthotic Patient-Reported Outcomes-Mobility (OPRO-M) item bank, which includes questions about activities and situations relevant to using lower-limb orthoses.[1] The goal of this study was to establish initial construct validity of OPRO-M.

METHOD

Participants: Participants included adults with at least six months of experience using an orthosis (i.e., AFO, KAFO, HKAFO, or FES device) for one or both legs. Participants were recruited through emails sent to orthosis users, flyers displayed in orthotics clinics, and notices posted to social media.

Apparatus: The OPRO-M item bank includes 39 items that ask respondents to rate how difficult it is for them to perform various activities. Other instruments, including the Orthotic and Prosthetic Users' Survey (OPUS-LEFS),[2] Lower Extremity Functional Scale (LEFS),[3] and Patient-Reported Outcomes Measurement Information System - Physical Function 20-item short form (PROMIS-PF),[4] were co-administered to establish convergent validity.

Procedures: Participants completed an online or paper survey that included the OPRO-M item bank, standardized instruments, and questions about demographics, health, and use of devices.

Data Analysis: We hypothesized that OPRO-M scores would correlate strongly ($r \geq 0.7$) with scores on other co-administered instruments and that lower scores would be observed for participants who present with paresis, have a higher number of comorbidities, use orthoses bilaterally or for multiple joints, and rely on assistive devices (ADs). Convergent construct validity was tested by calculating correlations using Pearson's correlation coefficient. Known groups construct validity was tested using a one-way analysis of variance (ANOVA) and Tukey post-hoc tests to assess differences in scores between groups.

RESULTS

Data were collected from 1036 participants. About 50% of participants were women, and the mean age reported was 60 years. Response data for OPRO-M and the other standardized instruments were normally distributed. OPRO-M scores were strongly correlated with scores from OPUS-LEFS (r=.91, p<0.001), LEFS (r=.86, p<0.001), and PROMIS-PF (r=.86, p<0.001). Results of the ANOVA revealed significant differences in OPRO-M scores between at least two levels for all four groups, including those defined by orthosis level (F(2, 2)=[25.08], p<0.001), paresis type (F(2, 2)=[27.59], p<0.001), AD use (F(2, 2)=[286.45], p<0.001), and number of comorbidities (F(2, 2)=[7.08], p<0.001). Post-hoc comparisons identified significant differences between most groups (Figure 1).

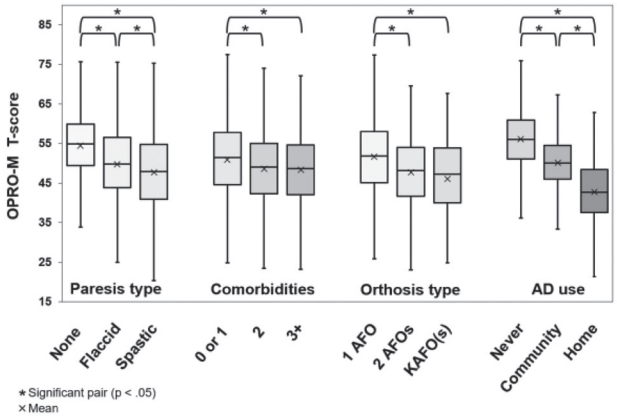


Figure 1. Box and whiskers plot showing OPRO-M T-score means, medians, quartiles, and ranges for groups of respondents expected to have different levels of mobility based on clinical presentation.

DISCUSSION

The strong correlations between OPRO-M scores and those obtained from other instruments demonstrates evidence of convergent construct validity and suggests that OPRO-M measures mobility in a similar manner as established assessment tools. The significant differences in mean T-scores between groups that are expected to differ in mobility level shows evidence of known groups construct validity and indicates that OPRO-M can differentiate between distinct groups of lower-limb orthosis users.

CONCLUSION

Results of this study provide initial evidence of validity of OPRO-M, indicating that the new instrument is capable of measuring mobility and differentiating groups of lower-limb orthosis users. Future efforts will establish additional evidence of validity and reliability.

CLINICAL APPLICATIONS

OPRO-M can be used by clinicians and researchers to evaluate mobility among a wide range of lower-limb orthosis users.

REFERENCES

1. Balkman G. AOPA National Assembly abstract, 2022.
2. Heinemann, AW. *Prosthet Orthot Int.* 2003;27:191–206.
3. Binkley JM. *Phys Ther.* 1999;79:371–393.
4. Fries JF. *Rheumatol.* 2014;41:153–158.

Funded by the Department of Defense, Orthotics and Prosthetics Outcomes Research Program (W81XWH-20-1-0258), and the American Orthotics and Prosthetics Association Research Award (EBP-053119).

Optimized Efficiency of KAFOs: What Is the Effect of Different Orthotic Ankle Joint Principles?

Thomas Schmalz, PhD;[1] Malte Bellmann, PhD, CPO;[1,3] Andreas Kannenberg, MD (GER), PhD[2]

[1]Research Biomechanics, Ottobock SE&Co. KGaA, Göttingen, Germany; [2]Otto Bock Healthcare LP, Austin, TX;
[3]Private University, Göttingen, Germany

INTRODUCTION

A new generation of orthotic ankle joints (triple-action joints) allow for improved functionality by increased range of motion (ROM) and defined, individually adjustable resistances to dorsiflexion and plantar flexion. The patient benefit of the new ankle joint principle has been verified for AFOs.[1,2] The purpose of the present study was to investigate the yet-unknown effect of the new principle in KAFOs based on biomechanical tests of different motion patterns.

METHODS

Five patients (48±16 years, 81±20 kg, 171±9 cm) fitted with a microprocessor-controlled KAFO (C-Brace, Ottobock, Germany) were enrolled in the study. All patients had previous experience with a stance control orthosis (SCO, EMAG Active, Ottobock, Germany).

Both KAFOs were equipped with the new Nexgear Tango (NGT). By using various modules, NGT can be adjusted to function as a conventional ankle joint (CAJ, reduced, uncontrolled ROM limited by a dorsi- and plantarflexion stop).

In the lab session, the ADLs of level walking, walking with predefined short steps (0.4m), ascending ramps, and standing on inclined surfaces (10deg) were biomechanically analyzed for 4 KAFO configurations: C-Brace with NGT or CAJ, and SCO with NGT or CAJ, respectively. Kinematic and kinetic parameters were recorded with an optoelectronic system (Vicon, Oxford, GB) and two force plates (Kistler, Wintherthur, CH).

In the SCO, the reliability of correct switching from locked into unlocked knee was increased with NGT from 66% to 91% for all steps measured during ascending ramps, and from 63% to 76% for all steps investigated during short-step walking. In the C-Brace, the reliability of correct switching from stance to swing was nearly 100% for all motion patterns investigated.

During level walking, the mean maximal dorsiflexion was significantly ($p<0.05$) increased with NGT by 7.1 degrees (C-Brace) and by 7.6 degrees (SCO). That was connected with reduced mean peak external knee extension moments measured with both KAFOs (appr. -0.12 Nm/kg, $p<0.05$). For ascending ramps, the mean maximal dorsiflexion was significantly increased with NGT by 8.7 degrees (C-Brace) and 11.4 degrees (SCO), again leading to reduced peak external knee extension moments (-0.16 Nm/kg [C-Brace]; 0.24 Nm/kg [SCO]). For uphill standing, with both KAFOs the mean dorsiflexion with NGT was increased by 4 degrees, leading to more relaxed standing with an increased uniformity of lower-extremity loading.

DISCUSSION

For both KAFOs, the increased and controlled dorsiflexion with NGT led to an improved roll-over behavior that was connected with an easier swing-phase initiation, especially in more difficult ADLs, such as uphill walking and walking on uneven terrain. In SCOs, a generally increased reliability of the main functionality, switching from locked into unlocked state, can be expected.

CONCLUSION

The new orthotic ankle joint principle enables a new option for a further optimization of custom KAFOs that is especially meaningful for patients with high functional demands.

REFERENCES

1. Kerkum YL, et al. *PLOS ONE.* November 2015.
2. Kobayashi T, et al. *Clin Biomech.* 2018;59:47–55.

DISCLOSURE

Thomas Schmalz, Malte Bellmann, and Andreas Kannenberg are full-time employee of Ottobock SE & Co. KGaA, Duderstadt, Germany or Otto Bock Healthcare LP, Austin, TX.

Impacts of AFO and FES Devices During Multimodal Walking: A Case Study on a pwMS with Foot Drop

Laura Byrnes-Blanco, PhD candidate; Stephanie L. Carey, PhD; Rajiv Dubey, PhD; Kyle Reed, PhD

University of South Florida, College of Engineering

INTRODUCTION

Persons with multiple sclerosis (pwMS) can develop a symptom called foot drop, which limits the individuals' ability to dorsiflex their foot. This impedes a person's ability to ambulate safely and independently. The severity of foot drop can vary from a minor nuisance to complete inability to lift the toes upwards.

Clinicians commonly prescribe ankle-foot orthoses (AFO) and functional electrical stimulation (FES) devices to treat foot drop. These orthotic devices have been extensively studied in highly controlled clinical settings, but little is known about how they impact gait within realistic environments. Additionally, most literature has focused on foot drop resulting from stroke, but stroke and multiple sclerosis (MS) have distinct differences in their disease courses and demographics. The purpose of this research is to provide the MS community with insights into how these common orthoses benefit pwMS in their daily lives.

METHODS

An interventional case study was conducted to explore how AFOs and FES devices impact spatiotemporal gait parameters for pwMS ambulating under realistic environmental conditions. To accomplish this aim, an immersive virtual reality system was used: the Computer Assisted Rehabilitative ENvironment, CAREN (Motek Medical B.V., Netherlands). A CAREN program was customized to present a realistic nature pathway and record data from a full-body motion capture marker set of 46 markers. It operated in a completely self-paced mode where treadmill speeds responded to the participant's location on the system, which allowed natural speeds and gait patterns to be observed. The participant completed three walking trials (no device, AFO, and FES) over two separate sessions to avoid fatigue influencing results. Data was analyzed using Motek's Gait Offline Analysis Toolkit for calculating walking speed, step width, step length, stride length, and cadence. The University of South Florida's Institutional Review Board approved the testing protocol, and informed consent was acquired.

CASE PRESENTATION

The participant was a 58-year-old female with clinically diagnosed relapsing-remitting multiple sclerosis. She presented unilateral foot drop in her right leg. She walked without using an aid, but she did have a patient-determined disease step score of 4 (early cane user). She owned and used both an Ottobock carbon fiber AFO (Otto Bock HealthCare LP, Austin, TX) and a WalkAide FES device (Innovative Neurotronics, Austin, TX). She had used the AFO for 10 years and the FES for 3 years. She was free of physical injuries and other health conditions. Participating in this study was her first time using a CAREN system.

MANAGEMENT AND OUTCOMES

No changes or adaptations to the participant's devices were performed. She donned/doffed her personal AFO and FES devices herself. She completed three separate walking trials (no device, AFO, and FES) over two sessions to avoid fatigue influencing results. She wore a full-body motion capture marker set consisting of 46 markers and a safety harness while completing her trials. The spatiotemporal parameters evaluated were walking speed, step width, step length, stride length, and cadence.

Table 1. Mean and standard deviations of gait parameters calculated over the entire walking trial.

	No Device	AFO	FES
Walking Speed (m/s)	0.93±0.16	0.97±0.13	1.07±0.13
Step			
Width (m)	0.13± 0.03	0.12± 0.02	0.09± 0.04
Left Step Length (m)	0.45± 0.06	0.47± 0.05	0.56±0.04
Right Step Length (m)	0.43± 0.06	0.45± 0.04	0.51±0.04
Stride Length (m)	0.87± 0.10	0.91± 0.08	1.06±0.07
Cadence (steps/min)	129.50±14.69	127.70±11.74	122.40±14.92

DISCUSSION

Both AFO and FES devices impacted gait parameters in a similar fashion, but the magnitudes of those changes were larger for FES. Step width, step length, and cadence were the most interesting and notable differences. As the step width narrows, the base of support shrinks and decreases the margins of stability for stable walking. This implies that FES generated more stability than the AFO. Using FES also allowed her to take longer and fewer steps (as shown by increased step lengths and decreased cadence). This was seen as a decrease in the amount of short, shuffling steps taken while walking. These results indicate that FES generates more stability and allows for more natural step lengths and cadence during multimodal walking than the AFO. These changes are responsible for the faster overall walking speeds and longer stride lengths seen in Table 1.

CONCLUSION

Both AFO and FES devices positively influenced all evaluated gait parameters in a similar way, but the FES device generated larger changes than the AFO. A larger study should be conducted to see if these trends hold true. If they do, FES would be shown as more capable of producing normal gait patterns than AFOs in real-world environments for pwMS.

Sensitivity to Change of Patient-Reported and Performance Measures for Custom AFO Users

AW Heinemann,[1,2] S Fatone,[2,3] SL LaVela,[1,4] M Peterson,[5] BCS Slater,[5] A Deutsch,[1,2] NT Soltys,[1] V McPherson,[1] N McCombs,[1] M Kwasny,[2] I Kale[4]

[1]Shirley Ryan AbilityLab, [2]Northwestern University, [3]University of Washington, [4]Edward Hines, Jr. VA Hospital, [5]Minneapolis VA Health Care System

INTRODUCTION

Patient-reported outcome measures (PROMs) are not used widely to evaluate the benefits of lower-limb orthoses, in part, because there is no consensus on what to measure and little psychometric evidence for PROMs in orthoses users. This study builds on our efforts to assess patient and clinician perspectives on quality-of-care topics that are important to measure for custom ankle-foot orthosis (AFOs) users;[1] identify instruments to assess care quality for individuals using custom AFOs,[2] and assess orthotists' and physical therapists' perspectives on quality-of-care indicators.[3] Aims of this report are to assess sensitivity to change of instruments measuring quality-of-care indicators valued by patients and clinicians.

METHOD

Subjects: We recruited a convenience sample of adults receiving a new or a major new component of a custom AFO from 2 VAs and a rehabilitation hospital's orthotic clinics.

Apparatus: Based on our previous work, we selected the EQ-5D; PROMIS Pain Interference, Physical Function, Participation in Social Roles and Activities, and Satisfaction with Social Roles and Activities short forms; Rivermead Mobility Index; and OPUS Quality-of-Life and Lower Extremity Functional Status.

Procedures: Staff recruited participants and administered survey instruments and recorded PROMs before device delivery, about 1 month after device delivery, and 1 month later. Participants provided consent according to an IRB-approved protocol.

Data Analysis: We calculated descriptive statistics and used generalized linear mixed models to test if measures changed over time. All models assumed an autoregressive (1) covariance structure.

RESULTS

The sample of 31 adults (52% male) had a mean age of 57+14 years and body mass index of 28+6. Patient impairments necessitating a custom AFO resulted from strokes (35%), neurological conditions (26%), traumatic conditions (13%), and various other conditions (26%).

Table 1 shows estimated means and standard errors for the measures. We observed statistically significant improvement for the EQ-5D total score, PROMIS Physical Function, Rivermead, and OPUS Quality of Life. Gains in PROMIS Participation in Social Roles and Activities, and OPUS Lower Extremity Function approached statistically significant improvements.

DISCUSSION

Results provide evidence of sensitivity to change in 4 of the 9 measures. Had the sample size been larger, we likely would have detected significant improvement in 2 additional measures (PROMIS Participation in Social Roles and Activities and OPUS Lower Extremity Function). Clinicians may consider these PROMs for evaluating patients' experiences with orthotic services. Findings are specific to custom AFO users; future studies should evaluate measurement properties in other orthotic and prosthetic populations.

Table 1.

Measure	Pre-Delivery	Post-Delivery	Follow-Up	p
EQ 5D Total	0.54 (0.04)	0.65 (0.05)	0.70 (0.05)	*.008*
EQ 5D Visual Analog Scale	66.2 (3.0)	64.3 (3.4)	72.1 (3.6)	.098
PROMIS Pain	55.5 (1.7)	53.0 (1.8)	51.6 (1.9)	.176
PROMIS Participation in Social Roles & Activities	42.6 (1.7)	45.5 (1.8)	47.1 (1.9)	.057
PROMIS Satisfaction with Social Roles & Activities	42.0 (1.7)	44.5 (1.8)	46.0 (1.9)	.176
PROMIS Physical Function	36.1 (1.1)	38.3 (1.2)	38.7 (1.3)	*.036*
Rivermead Mobility Index	10.3 (0.4)	11.4 (0.5)	11.7 (0.5)	*.016*
OPUS Quality of Life	53.8 (1.6)	56.7 (1.7)	57.7 (1.7)	*.021*
OPUS Lower Extremity Function	46.9 (2.2)	48.2 (2.2)	52.2 (2.2)	.062

CONCLUSION

Findings fill a knowledge gap regarding the sensitivity to change of PROMs that are suitable for use with custom AFOs users.

CLINICAL APPLICATIONS

Orthotists and physical therapists may consider using select PROMs that demonstrate good sensitivity to change to document patient experiences with custom AFOs.

REFERENCES

1. Heinemann AW, et al. *Am J Phys Med Rehabil.* 2020;99(6): 540–549.
2. Fatone S, et al. *Arch Phys Med Rehabil.* 2021;102(4):709–734.
3. Heinemann AW, et al. *Assist Technol.* 2021;33(4):206–216.

Enabling Meaningful Community Ambulation in Stroke Survivors through Use of a Smart Hip Exoskeleton

Kinsey Herrin,[1] Emily Upton,[2] Dean Molinaro,[1] Chase Ruarks,[3] Adesua Ojeifoh,[3] Aaron Young[1]

[1]Georgia Institute of Technology Woodruff School of Mechanical Engineering & Institute for Robotics and Intelligent Machines; [2]Dynocardia; [3]Kennesaw State University MSPO

INTRODUCTION

Stroke is the leading cause of disability in the United States, with the Global Burden of Disease citing 1 in 4 individuals will have a stroke in their lifetime.[1] Inability to walk independently especially outdoors has been cited as one of the most devastating consequences following a stroke, while independent community ambulation is associated with improved quality of life.[2] Powered exoskeletons (exos) have shown promise for assisting stroke survivors with walking,[3] but research on exoskeletons typically occurs in lab settings and therefore lacks adequate translation to real-world community environments where higher attentional demands are required and variable terrain is often encountered. In this proposal, we test the hypothesis that a smart hip exo that assists users at the hip in flexion and extension during gait can improve community ambulation in meaningful ways.

METHOD

Informed consent was obtained from all subjects prior to participation in accordance with the Georgia Institute of Technology IRB.

Participants: Nine stroke survivors (all males, age 52±11 years, 1.69±20.6 m height, 105.4±29 kg, 9±4 years post-stroke) participated in this study.

Procedures: Subjects completed 4 trials of an indoor 10-Meter Walk Test (10MWT) with and without the exo over an instrumented gait mat. Subjects then completed 3 trials of a 60 m outdoor walking course on a level ground sidewalk with and without the exo. During the final trial, the participants also completed a dual task of serial counting while walking. We calculated PCI and Borg RPE following the outdoor walking conditions. The order of exo versus the baseline (no exo) was randomized for outdoor tasks.

Apparatus: Measures included those on self-selected speed (10MWT, single- and dual-task outdoor walking), which is a correlate of overall health; the Gait Variability Index [GVI], which is predictive of falls; energy cost [Physiological Cost Index [PCI]]; and Borg Rating of Perceived Exertion [RPE]), and a modified Prosthesis Evaluation Questionnaire Mobility Scale (PEQ-MS) to assess patient perception of performance.

Data Analysis: In this within-subjects study design, all data were processed in Excel and paired t-tests were completed in Minitab 18 with an alpha set to 0.05.

RESULTS

While trends showed slight improvements in all outcomes inclusive of speed, PCI and Borg RPE with use of the hip exo compared to baseline, no statistical differences were seen between conditions (Figure 1). However, some individuals did show improvements in speed that met the minimal clinically important difference (increase of 0.1 m/s) during exo use. Subjects reported greater ease on the PEQ-MS for walking on level surfaces, sidewalks and in crowded areas when using the exo compared to their baseline.

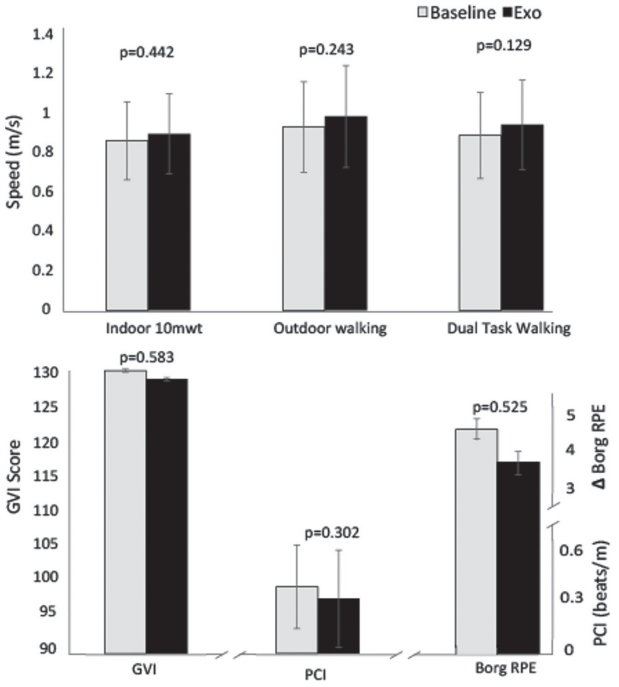


Figure 1. Comparisons of baseline versus exo conditions for n=9 stroke survivors for walking speed (top), and GVI, PCI, and Borg RPE (bottom). Note different y-axes for bottom graph metrics.

DISCUSSION

Our results support and expand upon the work of in-lab studies, which have shown exos hold promise for returning stroke survivors to meaningful community ambulation. Future work will include efforts to reduce exo weight and size, which are critical factors for real-world clinical adoption and may also further influence outcomes positively as our device was heavy (4.5kg).

CONCLUSION

To the authors' knowledge, this is the first study examining the impacts of a hip exoskeleton on outdoor community ambulation in stroke survivors.

CLINICAL APPLICATIONS

While many orthotic interventions for stroke focus on more distal joints (e.g., AFOs), this study indicates that assistance at the hip joint through use of an exo can improve outcomes for some patients.

REFERENCES

1. Ovbiagele B, et al. *Neurother.* 2011;8(3):319.
2. Middleton A, et al. *J Aging Phys Act.* 2002;23(2):314–322.
3. Lee H, et al. *Stroke.* 2019;50(12):3545–3552.

This work was supported through funds from the Orthotic and Prosthetic Education and Research Foundation, Inc. (OPERF).

Instantly Adjustable Dynamic Extension-Assist KAFO

Kevin L. Hines, CPO, LPO, FAAOP; Christine Daire, MSOP, CO

Arise Orthotics & Prosthetics, Inc.

INTRODUCTION

Traditional extension-assist pediatric KAFOs have been limited, as the commonly used dynamic knee joint features an internally wound spring that fails under repeated use with high torque. These joints are custom-contoured stainless-steel uprights over vacuum-formed plastic. These require excess time and skill and provide limited adjustability. Torque adjustments for revising extension assist required the proper wrench. These designs often result in a heavy orthosis that limits patients with weak musculature.1 The aim of this case presentation is to share a collaboration between Arise Orthotics & Prosthetics, Inc. and Icarus Medical that has resulted in a custom, dynamic extension-assist, double-upright KAFO that is instantly and infinitely adjusted without tools. The adjustability of the extension-assist mechanism accommodates changes in speed and cadence and allows for the pursuit of stance flexion in gait for a more normal gait pattern. Patient growth and volume fluctuations can be accommodated. The weight of the KAFO is reduced by approximately 50% compared to a traditional design for the same patient. The device is currently being used for one active pediatric patient. Documented gains have shown the orthosis to be effective for daily use and infer that the unique aspects of the design may be applicable to a wider range of patients in need of extension-assist KAFO alignment and stability.

CASE PRESENTATION

Patient is a male who had right monoparesis secondary to myeloradiculopathy after a viral illness at 5 months old. Presentation is right-side drop foot and knee instability, weakness and genu valgum alignment with a functional leg-length discrepancy (LLD). Patient has trace musculature of the right lower extremity with grade 3 hip musculature. Patient has been managed in KAFO designs since he was 18 months old, but when he was 2.5 years old, he was challenged with the need for flexion to enable transitions to the floor but also stabilized extension when weight bearing. The traditional extension-assist joint was limiting but functional until age 8 when growth required a transition to an adult joint, increasing the bulk and weight of the joint and KAFO. At age 10, the patient had outgrown his current orthosis due to growth and surgery to address the LLD and hip anteversion were expected.

MANAGEMENT AND OUTCOME

Patient was cast and scanned for a right, custom, dynamic KAFO orthosis. Foot/ankle control was achieved with a free-motion AFO with dorsi-assist Tamarack joints to address valgus positioning and drop foot. This allowed toe clearance during swing and plantarflexion control at heel strike. Knee control was accomplished with a custom-fabricated 3D-printed, double-upright knee orthosis from Icarus Medical with integrated growth extensions that vacuum-formed and riveted into the AFO. The patient manages a BOA dial tensioning system for increasing or decreasing extension assist, including locked extension for maximum stability. M-L knee stability is addressed with an intimate fit. Initial hesitancy with the KAFO was attributed to prolonged weight bearing restrictions following rotational osteotomy surgery, which was done between the evaluation appointment and fitting. With daily use and physical therapy, the patient's confidence has increased, as he has been able to navigate an obstacle course and is aiming to run. No fit or function issues have been identified since delivery several months ago.

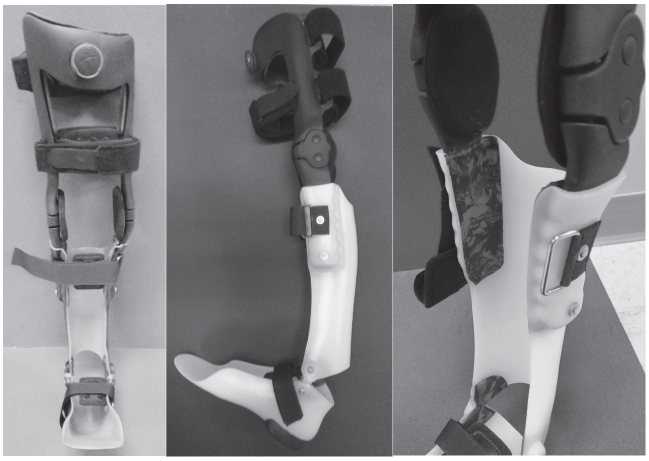


Figure 1. Instantly adjustable dynamic extension-assist KAFO: Anterior view, medial view, and detailed view of vacuum-formed and riveted joints.

DISCUSSION

The instantly adjustable aspect of the dynamic KAFO design allows patient control of the flexion/extension assist based on activity-specific demands. The intimate fit at the knee provides M-L stability. Stance control designs offer more normal gait kinematics but cannot accommodate activity-specific demands. Growth is more easily addressed through the growth extensions and simple proximal strapping system as compared to adjustments of stainless-steel uprights. Limitations currently include a single patient sample and only several months of use. Long-term strength of the BOA system in this application is unknown but has been reliable over several years in the knee orthosis for adults. There is a learning curve with the fabrication techniques for proper alignment and function.

CONCLUSION

This case has demonstrated an ability to combine custom AFO and knee orthosis components to significantly decrease the weight of a KAFO while greatly increasing support and stability. This orthosis allows instant control of extension assist to meet the needs of daily living. Growth extensions will help address the needs of the pediatric population, but the control and abilities offered by this orthosis may offer new opportunities to patients of all ages.

REFERENCE

Tian F, Hefzy MS, Elahinia M. *Ann Biomed Eng.* 2015;43(2): 427–441.

Improved PROMIS Global Health for Individuals Seeking Orthotic Intervention

Emily J. Hurst, MPO, CP;[1] Tom DiBello, CO;[1,2] Taavy A. Miller, PhD;[2,3] Shane R. Wurdeman, PhD[2]

[1]Hanger Clinic; [2]Hanger Institute for Clinical Research & Education; [3]University of Pittsburgh

INTRODUCTION

Patient reported outcomes (PRO) are increasingly utilized across healthcare disciplines.[1,2,3] The Patient-Reported Outcomes Measurement Information System (PROMIS) is a commonly used PRO to address different health domains across various patient populations.[4] The PROMIS Global Health (PROMIS-GH) measure focuses on the physical, mental, and social aspects of health and has been shown to be predictive of future healthcare utilization costs and overall health status for patients across various etiologies.[5,6] While PROs are growing in popularity, limited research has been conducted to assess PROMIS-GH for individuals seeking an ankle-foot orthosis (AFO). As such, the purpose of this study was to characterize PROMIS-GH, and identify factors associated with PROMIS-GH outcomes among individuals seeking an AFO at initial evaluation.

METHOD

This retrospective analysis was approved by WCG Investigational Review Board.

Patients: Observations from 1,626 individuals were extracted from the lower-limb AFO PRO submissions. Subject data included gender, age, reported falls, assistive device use, ability to walk 25 feet, payor source, and etiology.

Procedures: Data was collected in the normal course of providing clinical care from 2018–2020 across a large, multicenter orthotics provider with clinics in different regions across the United States.

Data Analysis: Summary and descriptive statistics were calculated for sample characteristics. Means, standard deviations, counts, and percentages were calculated for continuous and categorical variables, respectively. Multivariate linear regression analyses were applied to evaluate factors associated with global mental health (GMH) and global physical health (GPH) T-scores. Significant factors found during bivariate analysis were retained for final model ($p \leq 0.15$). All analyses were performed with R (version 4.1.2).

RESULTS

The average age was 59.3 (±15.6), 50.7% were male, 39.9% had a legacy AFO, 40.8% were covered by Medicare, 14.6% were covered by Medicaid, 54.4% reported using an assistive device, 37.4% reported having a fall in the past four weeks, 76.3% reported they were able to walk 25 feet on a level surface, 35.8% had a neurologic etiology, 30.1% had an orthopedic etiology, and 34.1% had an etiology defined as "other." The mean T-scores for GMH and GPH at initial evaluation were 47.4 (±10.0) and 39.8 (±7.97), respectively, and were significantly lower ($p<0.001$) than the US general population.

The final model for GPH showed that reported falls, assistive device use, Medicaid as payor, and females were significantly associated with lower GPH T-scores, while the ability to walk 25 feet was associated with higher GPH T-scores (Table 1). The final model for GMH showed that reported falls, assistive device use, and Medicaid as payor were significantly associated with lower GMH T-scores, while the ability to walk 25 feet and age were associated with higher GMH T-scores (Table 1).

Table 1. Multivariate regression model.
*indicates statistical significance $p \leq 0.05$

Variable	GPH p-value	GMH p-value
Falls (Yes)	**<0.001***	**<0.001***
Assistive Device (Yes)	**<0.001***	**<0.001***
Walk 25 Feet (Yes)	**<0.001***	**<0.001***
Payor (Medicaid, Other)	**<0.001***	**0.004***
	0.345	0.754
Gender (Female)	**0.005***	-
Etiology (Ortho, Other)	-	0.524
	-	0.304
Age	-	**<0.001***

DISCUSSION

As might be expected, study results revealed lower values for GMH and GPH among individuals seeking an AFO, with GPH scores being more than one standard deviation lower than the US population mean. Results suggest that mobility-related factors such as falls, assistive device use, and walking confidence may be important modifiable clinical rehabilitation considerations that impact health outcomes when providing AFO interventions for individuals with foot and ankle injuries or physical impairments.

CONCLUSION

These results provide an understanding of factors associated with improved holistic patient outcomes for individuals seeking an AFO.

CLINICAL APPLICATIONS

Clinicians seeking to meet orthotic needs should consider patient history related to falls, assistive device use, and walking confidence to ensure optimal quality of life outcomes.

REFERENCES

Reeve BB. Med *Care*. 2019;57(5 SUPPL. 1).
Seneviratne MG, et al. *Cancer.* 2019;125(6):943–951.
Guyatt GH, et al. *Mayo Clin Proc.* 2007;82(10):1229–1239.
Cella D, et al. *Med Care*. 2007;45(5 SUPPL 1):S3–S11.
Hays RD, Schalet BD, Spritzer KL, Cella D. *J Patient Rep Outcomes.* 2017;1(1):2.
Katzan IL, Lapin B. *Stroke*. 2018;49(1):147–154.

Classifying Prosthesis Use Using Limb Motion Sensing

NS DeGrasse, JC Mertens, JT Brzostowski, KJ Allyn, JE Sanders

Department of Bioengineering, University of Washington, Seattle WA

INTRODUCTION

Step activity monitors used to investigate the effect of clinical interventions on prosthesis users' physical activity provide clinicians and researchers with step count and cadence data.[1] The purpose of the present research is to implement a new technology that monitors residual limb motion within the socket to characterize prosthesis use rather than just activity. The system detects patients' sits, seated shifts, stands, walks, standing weight shifts, partial doffs, and non-use. The limb motion sensing system was worn by a group of people using transtibial prostheses in at-home environments.

METHOD

Participants: Participants were included if they were at least 18 years old, had a transtibial amputation at least 6 months prior, regularly used a definitive prosthesis without walking aides, and were capable of wearing an elastomeric liner. IRB approval was obtained.

Apparatus: Thin, flexible inductive sensing antennae were adhered inside users' sockets, and special liners with a trace amount of iron powder in the elastomer were worn.[2] The sensor detected the distance between the antennae and the ferrous material in the liner and stored the data to a data logger attached to the pylon.

Procedures: After informed consent was obtained, the sensing system was placed in the user's socket, and the special liner was donned. A 20-minute calibration procedure testing different actions and bodily positions was conducted. Users left the lab and wore the system in their at-home setting for up to 8 days. Participants returned to the lab, and the sensed distance data were downloaded and processed.

Data Analysis: Using amplitude and frequency content information within the sensed distance data, we created algorithms to distinguish types of walking and stationary activities. The time between the beginning-of-day prosthesis don and end-of-day prosthesis doff was characterized as bouts of walking, low commotion, weight shifting, stationary, and non-use (prosthesis doffed). All data for each participant were binned by day and by hour of the day.

RESULTS

Twelve participants, 11 males and 1 female; median age 54 years (range 34 to 73); median body mass index 28.6 (range 20.8 to 35.8); 5 smokers; 1 diabetic; 1 congestive heart failure.

Participants spent 61% to 87% of their prosthesis day stationary or doffed (Figure 1). Of the active conditions (bouts of walking, low commotion, weight shifting), 10 of the 12 participants spent more time weight shifting and in low commotion than in bouts of walking.

Two different prosthesis day profiles are shown in Figure 2. The participant on the right concentrated his activity during the morning hours and executed walking bouts about 1.6x more often than low commotion. The participant on the left increased his prosthesis use over the day and executed walking bouts about 14.5x more often than low commotion.

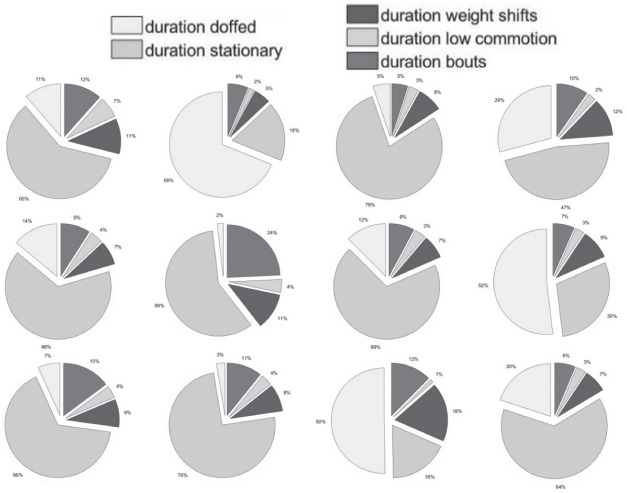


Figure 1. Distribution of activities and bodily positions for all participants.

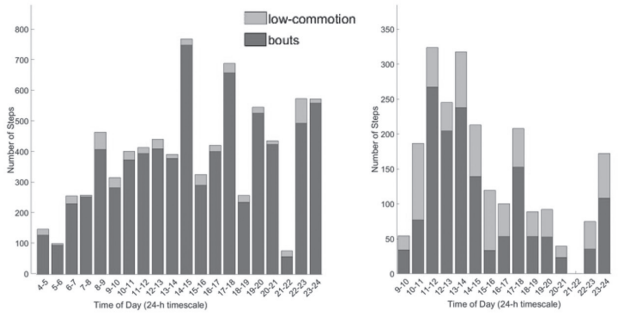


Figure 2. Distribution of steps during low commotion and during bouts of walking for two example participants.

DISCUSSION

The greater time spent weight shifting and in low commotion compared with bouts of walking illustrate how important short motions like standing at the kitchen sink, at the bathroom vanity, or moving within a confined space are to quality of life.

CONCLUSION

Patient monitor data of weight shifting and low commotion, not just walking bouts, should be considered in patient outcome assessment.

CLINICAL APPLICATIONS

Limb motion data provide new insight that may facilitate diagnosis and treatment in clinical care.

REFERENCES

1. Chadwell A. *J Neuroeng Rehabil.* 2020;17:93.
2. Mertens JC. *Clin Biomech.* 2022;99:105741.

Funded by NIHNICHD R01HD060585.

Changes in Mobility and Gait Quality for Veterans with Lower-Limb Loss Who Completed the DoD/VA Mobile Device Outcomes Based Rehabilitation Program: Pilot Study

Yasir Alsamdani,[1,2] Ignacio Gaunaurd,[1,3] Allison Symsack,[4,5,6] Sheila Clemens,[7] Jennifer Lucarevic,[8] Christopher Bennett,[9] Brad Isaacson,[5,6] Paul Pasquina,[4,5,6] Robert Gailey[1,5]

[1]Departments of Physical Therapy, University of Miami, Coral Gables, FL; [2]Faculty of Medical Rehabilitation Sciences, King Abdulaziz University, Jeddah, Saudi Arabia; [3]Bruce W. Carter VA Medical Center (Miami VA), Miami, FL; [4]Walter Reed National Military Medical Center (WRNMMC), Bethesda, MD; [5]Uniformed Services University, Bethesda, MD; [6]Geneva Foundation, Seattle, WA; [7]Department of Physical Therapy, Florida International University, Miami, FL; [8]Orthotics and Prosthetics Program, California State University Dominguez Hills, Carson, CA; [9]Department of Music Engineering, University of Miami, Coral Gables, FL

INTRODUCTION

Veterans with lower-limb loss (LLL) who live in rural areas face many difficulties (time and cost) to receive appropriate prosthetic gait training and exercises that could improve their mobility, gait quality, and strength. The VA and DoD supported the development of a program called the Mobile Device Outcomes Based Rehabilitation Program (MDORP). MDORP is a comprehensive mobile rehabilitation program that includes a mobile sensor system called the Rehabilitative Lower Limb Orthopedic Assistive Device (ReLOAD).[1] The ReLOAD system can assess gait and provide real-time audio feedback during home walking to correct specific gait deviations and subsequently recommend targeted exercises. The purpose of this study was to examine the changes in mobility, gait quality, and strength for lower functioning Veterans with LLL after completing the 8-week MDORP program.

METHOD

Participants: Seventeen Veterans (males=12; females=5) with unilateral LLL (mean age=54.3 years) functioning at the MFCL K2 (n=11) and K3 levels (n=6) completed the program. IRB approval was given to the study sites (WRNMMC and Miami VA).

Apparatus: ReLOAD system consists of a mobile application, mobile device, and wearable sensors.

Procedures: Outcome measures were collected at baseline and 8-weeks post MDORP. Participants received the following training after baseline: standardized functional prosthetic gait training, home ReLOAD use, and proper exercise performance. Participants received home visits every 2 weeks. Participant were asked to walk and perform exercises at least 3 times per week.

Data Analysis: Repeated-measures ANOVA model was used to test whether changes occurred, and Cohen's d was computed to assess effect size.

RESULTS

The mean number of weekly home walks were 3 (SD=2). The mean home walk duration was 16 minutes (SD=13 min). The mean number of weekly exercises was 8 (SD=5). Significant changes in Amputee Mobility Predictor (AMP) and gait goodness were found after the 8-week program with a moderate effect size. The significant changes were not found with the other outcome measures, yet small effect sizes were found with hip extensor strength and speed (Table 1).

Table 1. Changes in outcome measures post-MDORP.

Outcome Measures	p-value	Effect size (Cohen's d)
AMPPro Score	<0.001	0.61
Gait Goodness Metric	.030	0.52
Hip extensor strength (amputated limb)	.190	0.36
Gait Speed	.059	0.33
TUG time	.082	0.20
6MWT distance	.070	0.22
PLUS-M T-score	.425	0.18
ABC Score	.480	0.17

DISCUSSION

Results showed that there was a significant improvement in prosthetic mobility and gait quality following completion of the MDORP program. These findings are consistent with published results on higher functioning Veterans with LLL who completed MDORP as well as including a targeted exercise prescription.1,2 Although not statistically significant, small effect sizes were found with showing clinical improvements in amputated side hip extensors strength, gait speed, and TUG time.

CONCLUSION

The MDORP program was able to improve gait quality and prosthetic mobility for home and community ambulating Veterans with LLL.

CLINICAL APPLICATIONS

Prosthetists can use ReLOAD to observe and track common gait deviations during patient home and community walking. Based on this information, they can provide a targeted prosthetic intervention (i.e., adjustments, new componentry) to maximize current mobility.

REFERENCES

Gaunaurd I, et al. *Mil Med.* 2020;185(Suppl. 1):480–489.
Gailey R, et al. *Phys Ther.* 2020;100(5):773–787.

The Effects of a Modified Passive Socket System on Short-Term Changes in Residuum Volume: A Preliminary Study in Transtibial Amputees

Huthaifa Atallah,[1] Laurence Kenney,[1] David Howard,[2] Anmin Liu,[1] John Head[1]

[1]School of Health Sciences, University of Salford, Salford, UK; [2]School of Computing, Science and Engineering, University of Salford, Salford, UK

INTRODUCTION

Changes in residuum volume are a common problem in lower-limb amputees during prosthesis use and can lead to poor suspension, impaired gait, and tissue damage.[1] Residuum volume can be affected by the in-socket air pressure, which will influence fluid flow in the residuum.[2] The use of "active" pumps to reduce air pressure has been shown to conserve the residuum volume,[3] but these are expensive and unlikely to be widely available. An alternative, passive approach, based on Boyles' Law, is to introduce a larger distal void volume at the end of the socket to reduce the in-socket air pressure.

The aim of this study was to assess the residuum volume changes (RVCs) across 3 test-conditions.

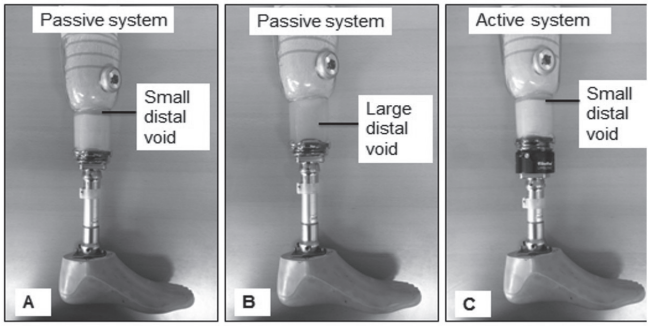


Figure1. Test-conditions: (A) Passive (conventional, with standard distal void), (B) Passive (with increased distal void), and (C) Active system.

METHOD

A repeated measures experiment was designed. Ethical approvals from the University of Salford (UoS) and the National Health Service (NHS) were obtained. The experimental procedure was explained to the potential participants before signing the consent form.

Participants: Five amputee participants took part in this study (3 males and 2 females), aged 49.2±16.6 years, height 1.73±0.07 m, mass 85.8±8.2 kg, 25.8±12.6 years since amputation, and K2/K3 of mobility grade.

Apparatus: Participants were fitted with a bespoke test prosthesis that was adapted to include the 3 test conditions.

Procedures: Participants were asked to be seated for 20 minutes prior to testing to reach a relatively steady-state residuum volume ($V_{baseline}$). $V_{baseline}$ was measured using the OMEGA Tracer system. The participants were then donned the test prosthesis and walked for approximately 5 minutes to allow RVCs to occur. Finally, participants sat down and the volume of their residuum was measured (V_{doff}). However, V_{doff} scanning may affect by the sequences of the test-conditions and keeping the liner donned.

Data Analysis: $RVCs=(V_{doff} - V_{baseline}) / V_{baseline} *100\%$

RESULTS

The residuum volume decreased by 4.2%±2.8%, 1.4%±1.4%, and 1.6%±1.1%, relative to the baseline volume ($V_{baseline}$) under test-conditions A, B, and C respectively.

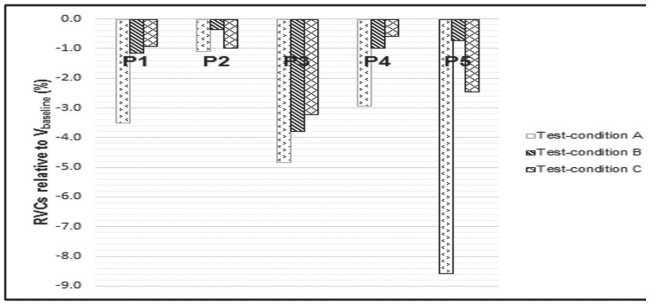


Figure 2. RVCs relative to $V_{baseline}$ (%) across the 3 test-conditions for each participant.

DISCUSSION

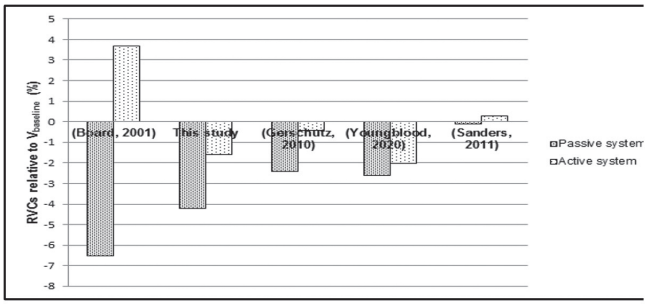


Figure 3. A comparison of RVCs relative to $V_{baseline}$ (%) from this study and associated literature gives some confidence in the findings.

The main limitation of this study was the low number of participants; thus, no inferential statistical analysis is reported.

CONCLUSION

Using a passive suspension system with an increased distal void within the socket may help to stabilize the residuum volume during prosthesis use.

CLINICAL APPLICATIONS

The performance of the passive system in maintaining the residuum volume may be improved by fabricating the prosthetic socket with a larger distal void volume (additional ~100 ml).

REFERENCES

1. Sanders JE. *J Rehabil Res Dev.* 2014;51(2):201–212.
2. Board WJ, Street GM, Caspers C. *Prosthet Orthot Int.* 2001;25(3):202–209.
3. Youngblood RT, et al. *Prosthet Orthot Int.* 2020;44:155–163.
4. Sanders JE, Harrison DS, Myers TR, Allyn KJ. *J Rehabil Res Dev.* 2011;48(10):1231–1248.
5. Gerschutz MJ. *Prosthet Orthot Int.* 2010;22:252–256.

The FootRopter: A Simple Clinical Tool for Prosthetic Foot Prescription

HL Bartlett,[1] MK Shepherd,[2] BE Lawson[1]

[1]Little Room Innovations, LLC; [2]Northeastern University Departments of Mechanical Engineering and Physical Therapy

INTRODUCTION

The clinical standard of care prosthetic foot is a spring-like device constructed from carbon fiber or fiberglass. These designs account for 72% of the feet prescribed to patients.1 Although these feet are so common, current prescription methods are limited in their ability to match patients to the prosthetic foot that is most appropriate for their needs. The current process matches a patient to a foot stiffness using manufacturer-published tables that take the patient's weight and activity level as input and outputs the recommended foot. This methodology groups large sets of patients during the prescription process, disregarding any heterogeneity within these groups. This system significantly limits the degree to which a prosthetist can exercise his or her clinical expertise during the foot selection process. One approach to providing more individualized care is through an emulation-based paradigm in which a single device emulates various mechanical behaviors (similar to the phoropter tool used in eyeglass prescription). A clinician could then tune the emulator device to meet the needs of the patient. This work presents the design of a passive prosthetic foot emulator (the FootRopter), which features independently adjustable forefoot stiffness, hindfoot stiffness, and alignment.

METHOD

Our prosthetic foot emulator (Figure 1) is mechanically passive to minimize complexity, cost, and maintenance. It uses a standard pyramid connector to achieve continuously variable alignment. The variable stiffness forefoot and hindfoot capabilities are enabled by two independently adjustable mechanisms. The hindfoot stiffness is adjusted via a propped cantilevered beam mechanism in which a heel spring support can be repositioned through a linear positioning mechanism. The forefoot component is composed of stacked beam elements and uses a movable clamp to modify its stiffness. When the clamp is tightened, the region of the foot between the clamp and the base of the beam acts like a single, thick beam with high stiffness. The region of the forefoot that is distal to the clamp acts like a compliant structure composed of multiple layered beams.

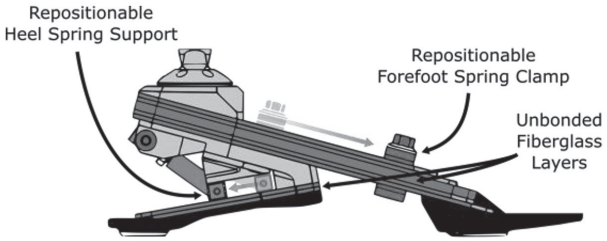


Figure 1. Prosthetic foot emulator device with independently adjustable forefoot stiffness, hindfoot stiffness, and alignment.

By modifying the clamp location, the proportion of the forefoot that is stiff versus compliant can be varied, and the total effective forefoot stiffness can be modulated. The forefoot stiffness and hindfoot stiffnesses can be continuously varied by moving the heel prop and the forefoot clamp, respectively. This can be accomplished with simple hand tools commonly found in clinics. This emulator device was designed, built, and tested in a series of linear compression tests to characterize the device's stiffness variation capabilities.

RESULTS

The range of achievable forefoot and hindfoot stiffnesses in our device are shown in Figure 2. The forefoot and hindfoot components can vary their stiffnesses by factors of 5 and 3, respectively.

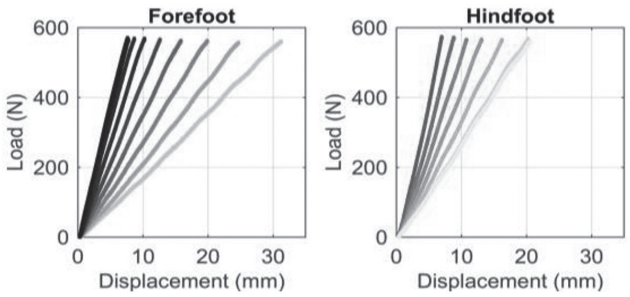


Figure 2. Load versus displacement of the forefoot (left) and hindfoot (right) components of the emulator device. The slopes of these trajectories represent the component stiffness with darker lines indicating stiffer settings.

DISCUSSION

Stiffness characterization of the forefoot and hindfoot components show a linear stiffness behavior of both foot components across the range of achievable stiffnesses.

CONCLUSION

The emulator device can continuously adjust its forefoot stiffness, hindfoot stiffness, and alignment. The stiffness values exhibited by the forefoot and hindfoot components of the emulator device span the stiffnesses seen across feet in the commercial marketplace, making this device capable of emulating a large class of prosthetic feet.

CLINICAL APPLICATIONS

The goal of this work is to design a clinical tool to emulate the behaviors of prosthetic feet in a clinical setting, allowing clinicians to tune the behavior of the foot to the needs of a patient. The emulator device presented here achieves a large range of behaviors, allowing clinicians to select foot properties from a large design space during the fitting process. Note that this device is developed by Little Room Innovations, LLC, which is a for-profit translational research and development company.

REFERENCES

Whiteside SR. *Practice Analysis.* ABC in O&P, 2015.

Benefits of a Microprocessor Foot on Steeper Slopes

Malte Bellmann, PhD, CPO;[1,3] Andreas Kannenberg, MD (GER), PhD;[2] Michael Ernst, PhD,[1] Björn Altenburg, Dipl.-Ing., CPO;[1] Thomas Schmalz, PhD[1]

[1]Research Biomechanics, Ottobock SE&Co. KGaA, Göttingen, Germany; [2]Otto Bock Healthcare LP, Austin, TX
[3]Private University, Göttingen, Germany

INTRODUCTION

Energy storage and return (ESR) feet are prescribed for persons with a lower-limb amputation to restore lost mobility. However, due to the limited adaptability of their rigid ankles and springs, situations like walking on slopes or uneven ground remain challenging tasks. Previous studies reported benefits of a microprocessor-controlled foot (MPF) with very limited range of motion (ROM) on shallow slopes of 5° only.[1,2] This study investigated the effect of an MPF with a larger ROM on the gait on steeper slopes.

METHODS

Seven persons each with a unilateral transtibial amputation (TTA) and unilateral transfemoral amputation (TFA) as well as 10 able-bodied subjects participated. Participants were studied while using a Meridium® MPF (Ottobock, Duderstadt, Germany) and their prescribed standard ESR feet with fixed ankle attachments. The Meridium has a polycentric design (4 axis), generates hydraulic plantar flexion and dorsiflexion resistances, offers instant terrain adaptation and a ROM of 14° dorsiflexion and 22° plantar flexion. The study investigated participants ascending and descending a 10° slope. Kinematic and kinetic data were recorded with a motion-capture system. Biomechanical parameters, in particular leg joint angles, shank orientation, and external joint moments of the prosthetics side were calculated.

Prosthetic foot- and subject group-dependent joint angle and moment characteristics were found for both situations. The MPF showed a larger and situation-dependent ankle range of motion compared to the standard feet. Furthermore, it remained in a dorsiflexed position during swing. While ascending, the MPF adapted the dorsiflexion moment and reduced the knee extension moment. At vertical shank orientation, it reduced the knee extension moment by 26% for TFA and 49% for TTA compared to the standard feet. For descending, differences between feet in the biomechanical knee characteristics were found for the TTA group, but not for the TFA group. At the vertical shank angle during slope descent, TTA demonstrated a behavior of the ankle moment similar as able-bodied controls when using the MPF.

DISCUSSION

The studied MPF facilitated walking on slopes by adapting instantaneously to inclinations and, thus, easing the forward rotation of the leg over the prosthetic foot compared to standard feet with a fixed ankle attachment with amputation-level dependent effect sizes. It assumed a dorsiflexed ankle angle during swing, enabled a larger ankle range of motion and reduced the moments acting on the residual knee of TTA compared to the prescribed prosthetic standard feet. For individuals with TFA, the prosthetic knee joint seems to play a more crucial role for walking on ramps than the foot.

CONCLUSION

On steeper slopes, an MPF with instant terrain adaptation and large ROM facilitates ascent in both TTA and TFA but descent in TTA only. For TFA, the prosthetic knee seems to be more important for slope descent than the foot.

REFERENCES

1. McGrath M, Piotr Laszczak P, Zahedi S, Moser D. *J Rehabil Assist Technol Eng.* 2018;5:1–10.
2. Struchkov V, Buckley JG. *Clin Biomech* (Bristol, Avon). 2016;32:164–170.

DISCLOSURE

All authors are full-time employees of Otto Bock Healthcare LP, Austin, TX, or Ottobock SE & Co. KGaA, Duderstadt, Germany.

Impact of a Powered Prosthetic Ankle-Foot Component on Musculoskeletal Pain and Function in Individuals with Transtibial Amputation: A Real-World Cross-Sectional Study with Concurrent and Recalled Outcome Measures

Cory Cacciola, MS, CPO;[1] Andreas Kannenberg, MD (GER), PhD;[2] Karl D. Hibler;[3] Jared Howell, MS, CPO, FAAOP[4]

[1]Ability Prosthetics and Orthotics, King of Prussia, PA; [2]Otto Bock Healthcare LP, Austin, TX; [3]Statistician, Bradenton, FL; [4]Baylor College of Medicine, Houston, TX

INTRODUCTION

Traditionally, lower-limb prostheses are composed of passive components that provide a fraction of the push-off power of the natural ankle-foot complex.[1] In individuals with transtibial amputation (TTA), this leads to deviations and compensatory mechanisms.[2] Studies have reported significant unloading of the sound limb and knee joint with a powered prosthetic ankle-foot.[3] Therefore, this study aimed to determine if a powered ankle-foot system decreases knee and back pain when compared to a passive prosthetic foot.

METHOD

Procedures: Two-hundred-fifty Empower/BiOM foot owners were invited via email to participate in an IRB-approved online survey. Fifty-seven surveys were subjected to data analysis (response rate 22.8%), and 6 responses were excluded.

Subjects: Forty-one unilateral transtibial amputees currently wearing a powered ankle-foot and 16 unilateral transtibial amputees who had been fitted with a powered ankle-foot in the past but were currently wearing a passive foot were included in the data analysis.

Apparatus: A survey included typical prosthetic history information as well as numerical pain rating scales across different body regions, the Socket Comfort Score (SCS), the activity of daily living domain of the Knee Injury and Osteoarthritis Outcome Score (KOOS-ADL) and the Oswestry Disability Index (ODI) for both their current and past prosthetic ankle-foot.

Data Analysis: Medians and interquartile ranges were compared across foot type. An adjustment of the retrospective ratings was conducted to account for recall bias in a secondary analysis.

RESULTS

Table 1. Numbers and percentages of patients who reported moderate or severe pain (>3 NPRS), and clinically meaningful improvement ≥2 NPRS in pain (original, unadjusted scores) per prosthetic foot type.

Body Region	Powered Ankle-Foot	Passive Foot	p-value
Patient's with NPRS >3			
Sound knee	18 (32%)	30 (53%)	0.004
Amputated side knee	14 (25%)	25 (44%)	0.007
Low back	25 (44%)	35 (61%)	0.013
All 3 body regions	7 (12%)	16 (28%)	0.012
Patient's with NPRS >3 who improved ≥2 NPRS using the other foot			
Sound knee	19/30 (63%)	3/18 (17%)	n/a
Amputated side knee	18/25 (72%)	5/14 (36%)	n/a
Low back	19/35 (54%)	4/25 (16%)	n/a
All 3 body regions	12/16 (75%)	2/7 (29%)	n/a

DISCUSSION

Unilateral transtibial patients were less likely to report moderate or severe knee and/or low-back pain when using their powered ankle-foot compared to their passive prosthetic foot. Of the patients with moderate or severe pain, a larger percentage of the patients saw a "much better" (≥2 NPRS) improvement when using their powered ankle-foot. One limitation of the study was that subjects had to rate pain with the previous foot retrospectively.

CONCLUSION

The data suggests that use of a powered ankle-foot may reduce knee and low-back pain in unilateral transtibial amputees. Future research should address a possible correlation with improved gait symmetry and investigate musculoskeletal pain prospectively.

CLINICAL APPLICATIONS

Understanding the link between gait asymmetry and pain can lead to improvement in patient outcomes, alignment practices, and component selection.

REFERENCES

1. Adamczyk PG, Kuo AD. *IEEE Trans Neural Syst Rehabil Eng.* 2015;23(5):776–785.
2. Hak L, van Dieën JH, van der Wurff P, Houdijk H. *Physical Ther.* 2014;94(10):1480–1488.
3. Russell Esposito E, Wilken JM. *Clin Biomech* (Bristol, Avon). 2014;29(10):1186–1192.

DISCLOSURE

Survey recipients were identified through Ottobock Healthcare's powered ankle patient registry database.

Recent Amputee Functional Level Determination

Cory Cacciola, MS, CPO;[1] Brian Kaluf, CP, FAAOP;[2] Russel Lundstrom[2]

[1]Ability Prosthetics and Orthotics, King of Prussia, PA; [2]Otto Bock Healthcare LP, Austin, TX

INTRODUCTION

Determining mobility potential for a recent amputee is important to their care. Access to technology is dependent upon Medicare Functional Classification Level (MFCL K-Level) assignment made by the treating prosthetist and/or physician at the time of initial evaluation. Multiple factors are considered when determine MFCL K-Level, including comorbidities, prior functional capability, motivation, and goals. However, little objective or standardized information is available about mobility prior to amputation to inform MFCL recent amputees.

The Functional Comorbidity Index (FCI) is a tool that helps to quantify the number of comorbidities that may affect mobility.[1] The Amputee Single Item Mobility Measure (AMPSIMM) is a validated self-reported outcome measure that consist of a singular multiple choice question regarding mobility capabilities.[2] Medicare published a Consensus Document with guidance of particular mobility activities of daily living (ADL) tasks associated with certain K-Levels.[3] These ADL examples extend beyond the MFCL definitions and provide useful examples of mobility tasks relevant to each K-Level.

For patient care documentation, a HIPAA-compliant digital survey was created for routine collection of FCI, prior AMPSIMM, and prior MFCL ADLs, among other self-reported factors. The aim of this study is to evaluate self-rated comorbidities health, prior mobility and participation in mobility related ADLs among patients in different MFCL K-Levels groups.

METHOD

Procedures: IRB-approved retrospective chart review of recent unilateral amputees receiving their first prosthesis.

Subjects: K2 subjects (N = 35) had mean age 67.8 (10.1) years and amputation level (TT = 25, TF = 11). K3 subjects (N = 39) had mean age 58.3.8 (13.6) and amputation level (TT = 23, TF = 16).

Apparatus: Microsoft Forms digital survey and Electronic Health Record (EHR) reports were generated by a private prosthetic and orthotic practice to create a limited dataset including FCI, prior AMPSIMM, MFCL ADLs, and other factors.

Data Analysis: Mean and standard deviations for the FCI, prior AMPSIMM, and prior MFCL ADLs per K-Level were calculated in Microsoft Excel with unpaired t-test to determine statistical significance ($\alpha = 0.05$).

RESULTS

The difference in mean FCI score was statistically significant ($p < 0.05$), with the K3 having 1.26 fewer comorbidities than K2. The difference in mean prior AMPSIMM scores was statistically significant ($p < 0.05$), with K3 having 0.68 greater self-reported mobility. The difference in mean prior MFCL ADLs approached statistical significance ($p < .05$), with K3 having 1.92 more self-reported participation in MFCL relevant ADLs.

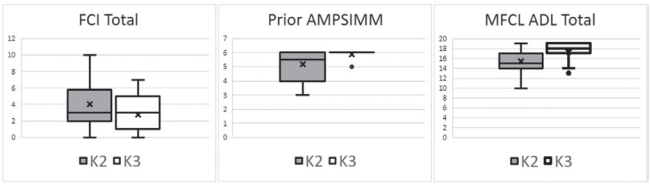


Figure 1. Box and whisker plots for FCI, Prior AMPSIMM, and Total MFCL ADLs data across the K2 and K3 groups.

Table 1. Means and SD for FCI, Prior AMPSIMM, and Total MFCL ADLs for both the K2 and K3 groups.

K-Level	N	FCI Total		Prior AMPSIMM		Total MFCL ADLs	
		Mean	SD	Mean	SD	Mean	SD
2	36	4.03*	2.78	5.19*	0.92	15.39*	5.56
3	39	2.77*	1.95	5.87*	0.34	17.31*	3.38
*designates statistical signficance at (α=0.05)							

DISCUSSION

No patients with K1 or K4 MFCL K-Level were observed. Increased age and more self-reported comorbidities of the K2 group correspond with clinical experience. Standardized assessment of mobility prior to amputation poses a temporal difficulty for the amputee treatment team, and significant differences in AMPSIMM prior to amputation self-reported participation in MFCL relevant ADLs prior to amputation present a useful result for differentiating K2 and K3. Limitations to this study pertain to the retrospective review of available records, possible confounding between survey responses and MFCL assignment by the clinician, and the subjective nature of clinician assigned MFCL K-Level.

CONCLUSION

This study found significantly fewer self-rated comorbidities (FCI), significantly greater self-rated mobility (AMPSIMM) prior to amputation and significantly greater self-reported participation in MFCL relevant ADLs in recent amputees assigned as K3 for their first prosthesis. Future work may improve the clarity of the digital survey and consider additional ADL tasks relevant to higher mobility to improve the survey item.

CLINICAL APPLICATIONS

Collecting standardized surveys of prior mobility and comorbidities may improve MFCL K-Level assignment for recent amputees receiving their first prosthesis.

REFERENCES

1. Kabboord A, et. al. *BMC Geriatr.* 2020;20(114).
2. Norvell D, Williams RM, Turner AP, Czerniecki JM. *Clin Rehabil.* 2016;30(9):878–889.
3. *Lower Limb Prosthetic Consensus Document.* (2017) Medicare.

Disparities in Functional Recovery After Lower-Limb Amputation Are Associated with Full-Time Employment and Self-Efficacy

SM Clemens,[1,2] KN Kershaw,[3] CL McDonald,[4] BJ Darter,[5] Z Bursac,[1] SJ Garcia,[1] MD Rossi,[1] SP Lee[6]

[1]Florida International University, [2]University of Kentucky, [3]Northwestern University, [4]University of Washington, [5]Virginia Commonwealth University, [6]University of Nevada, Las Vegas

INTRODUCTION

Initiatives by the World Health Organization and the NIH recognize employment as a social determinant of health. Persons with lower-limb amputation (LLA) experience extended periods of unemployment or underemployment post-surgery and often face barriers to returning to full-time work.[1] This may particularly affect younger individuals with LLA, who likely have personal and family obligations that necessitate employment. With dysvascular LLA rates increasing in an ever-younger demographic,[2] it is imperative that work-related research becomes a priority to address quality of life in persons with LLA. With previous work-related research focused on return to work as the outcome of interest, no evidence exists about how employment status could serve as an independent variable influencing prosthetic mobility performance. The purpose of this study was to explore both performance-based and self-reported outcome measures and assess how employment status serves as a determinant of health in its association to functioning after LLA.

METHOD

A cross-sectional study of 49 people with dysvascular LLA was conducted. The study was approved by the IRB at Florida International University with informed consent signed by all participants. Participants: Mean age of 62.1±9.7 years, 39% female. Apparatus and Procedures: Participants completed the PLUS-M™, PROMIS self-efficacy and PROMIS Ability to Participate surveys. Finally, research personnel administered the Component Timed-Up-and-Go test (cTUG) and 2-Minute Walk Test (2-MWT) to physically assess prosthetic mobility. Data Analysis: T-test or Mann Whitney U tests were administered to examine group differences based on full-time (FT) or no full-time (NFT) employment. Hedges' g effect size calculations accompany the p values. Regression analyses were utilized to investigate contributions of age, amputation level, work status, and self-efficacy to mobility.

RESULTS

Eighty percent (n=39) of study participants were not employed FT. There were no differences in age, number of comorbidities, or level of amputation based on employment status. Furthermore, there were no differences in reported availability of insurance or access to rehabilitation services. Measures of prosthetic mobility and self-efficacy were significantly lower in participants who were categorized as NFT employment (Table 1).

Table 1. Comparisons of FT and NFT employment status. *Indicates significant difference at p≤.05.

Variable	FT employment (n=10) Mean (SD)	NFT employment (n=39) Mean (SD)	p value	Hedges' Effect size g
Age (years)	61.7 (8.5)	62.2 (10.1)	0.87	-----
cTUG (sec)	14.6 (8.0)	20.3 (9.5)	0.02*	0.62
2-MWT distance (m)	92.6 (29.2)	68.7 (31.4)	0.03*	0.77
PLUS-M	58.0 (9.4)	44.7 (9.7)	< 0.01*	1.38
PROMIS Ability to participate	53.7 (6.8)	43.5 (10.8)	< 0.01*	1.00
PROMIS Self-efficacy	54.3 (6.0)	42.6 (8.6)	< 0.01*	1.43

Separate regression models were created to examine the unique contributions of employment status (Table 2) and self-efficacy to 2-MWT, cTUG, and PLUS-M scores. Primary contributors to better prosthetic mobility were working FT (R^2 ranging from 0.06 to 0.24) and greater self-efficacy (R^2 ranging from 0.32 to 0.75).

Table 2. Multiple linear regression modeling of prosthetic mobility measures with *amputation level, age, and FT employment.*

2-MWT Model: (F (1, 47) = 4.72, p = 0.03)					
Independent Variable	Parameter estimate	SE	R^2	F	p value
Amputation level	0.65	5.76	0.09	0.01	0.91
Age	0.01	0.03	0.09	0.14	0.71
FT employment status	23.89	11.0	0.09	4.72	0.03*
cTUG Model: (F (1, 47) = 3.11, p = 0.08)					
Amputation level	0.63	1.70	0.08	0.14	0.71
Age	-0.01	0.01	0.08	0.70	0.40
FT employment status	-5.78	3.30	0.06	3.11	0.08*
PLUS-M Model: (F (1, 47) = 15.21, p < 0.01)					
Amputation level	-2.12	1.71	0.31	1.55	0.21
Age	0.02	0.01	0.29	2.81	0.10*
FT employment status	13.3	3.41	0.24	15.21	< 0.01*

*Statistical significance at p = 0.10. FT=full-time; 2-MWT=2-minute walk test; cTUG=Component Timed-Up-and-Go; PLUS-M™=Prosthetic Limb Users Survey of Mobility.

DISCUSSION

This is the first study to expose the positive influence of FT employment on the functional recovery of people with LLA. Despite sample size limitations, differences in prosthetic functioning based on employment were exposed, with moderate/large effect sizes. Non-traditional variables of employment and self-efficacy had greater influence on prosthetic mobility outcomes than typical factors of age and amputation level.

CONCLUSION

It is imperative to understand by what mechanisms FT employment contributes to better mobility. One possible mechanism may be the mediating effect of self-efficacy. Further research is needed to determine causation or temporal relationships.

CLINICAL APPLICATIONS

Prosthetic practitioners should consider socioenvironmental variables and their potential effect on prosthetic mobility.

REFERENCES

Darter BJ, et al. *J Occup Rehabil.* 2018;28(4):656–665.
Geiss LS, et al. *Diabetes Care.* 2019;42(1):50–54.

Funded in part by the NIMHD and the RCMI at FIU.

Examining the Influence of Clinical Characteristics of New Transtibial Amputees on the Clinical Workflow for Prosthesis Delivery

B Collins[1,2]

[1]Hanger Clinic, [2]National Commission on Orthotics and Prosthetics Education (NCOPE) Research & Development Prosthetic Residency

INTRODUCTION

Early prosthesis fitting and delivery help to improve physical and psychological health outcomes during recovery after a lower-limb amputation.[1,2] While many benefits of early prosthesis fitting are known, some patients still experience delayed care when receiving their first lower-limb prosthesis. It takes a multidisciplinary care team to successfully provide a new amputee with a lower-limb prosthesis. As a consequence, some internal factors that influence the care workflow for prosthesis delivery may exist.[3]

The purpose of this study is to determine clinical sources of care delay for prosthesis delivery for new unilateral transtibial amputees.

METHOD

Procedures: Electronic health records of new unilateral, transtibial amputees who received prosthetic care from April 2017 to December 2021 (n=58) were included in the study. A single reviewer performed chart audits and entered de-identified patient data for predetermined clinical characteristics in a locked Microsoft Excel spreadsheet for quantitative analysis.

Data Analysis: The elapsed time for prosthesis delivery was calculated from dates in patient charts and compared for the following clinical characteristics: amputation etiology, K-Level, referral source, and payor source. Nonparametric statistical analysis between these clinical characteristics and prosthesis delivery times were performed using the Chi-Squared test of Association, the Kruskal-Wallis test, and Dunn's test to determine significant differences.

RESULTS

The average time elapsed from time of initial evaluation to prosthesis delivery was 37 business days (std=24 days). The average number of administrative requests for prosthetic paperwork was four, with a negative correlation between number of requests and the number of cases that received a prosthesis sooner.

K-Level classification did not impact prosthesis delivery times. Amputation etiology, specifically vascular-related etiologies, was significantly associated with longer prosthesis delivery times. The medical speciality of the physician providing prosthetic-related paperwork and the payor source billed for care had statically significant differences in prosthesis delivery times. Prosthetic-related paperwork provided by internal medicine physicians and orthopaedic surgeons had statistically significant longer and shorter prosthesis delivery times, respectively. Commercial insurance plans had the shortest statistically significant prosthesis delivery times.

Table 1. Nonparametric statistical analysis p-values. Triple asterisks (***) indicates a significant finding among comparative delivery times (alpha [0.05]).

	Kruskal-Wallis	Chi-Squared
Etiology	0.2382	2.2745E-07***
K-Level	0.2844	0.2656
Referral Source	1.6841E-05***	0.7134
Payor Source	0.03684***	0.04616***

DISCUSSION

The time for prosthesis delivery following new transtibial amputations was found to be comparable with findings from other studies.[4] Contrary to current findings, Miller, et. al., found diabetic and vascular etiologies to receive a prosthesis sooner than non dysvascular amputees.[4] The present study pulled data from a single clinic, used different inclusion criteria, and focused on different parameters for analysis, specifically clinical workflow points of contact with the payor source and the physician providing prosthetic paperwork, which had not been previously examined in other works.[4,5] The current reimbursement structure for durable medical equipment creates additional responsibilities for clinical documentation that must be coordinated within the care team, specifically between the prosthetist, referral source, and payor source.

CONCLUSION

The referral and payor sources of a new amputee can contribute to delays, leading to longer times between the initial evaluation delivery of the lower-limb prosthesis.

CLINICAL APPLICATIONS

Improved efficacy of practice and communication of care needs to referral sources and payor sources are needed to prevent delayed prosthetic care.

REFERENCES

1. Miller T. *Am J Phys Med Rehabil.* 99(11),1026-1031, 2020.
2. Mackenzie E, Wegener S. *Atlas of Amputations and Limb Deficiencies,* 4th ed. Vol. 2, 720–722; 2016.
3. Bowker J. *Atlas of Limb Prosthetics,* 2nd ed. 1992.
4. Miller TA, Rajib P, Forthofer M, Wurdeman S. *PM&R.* 2022;1–8.
5. Fletcher D, et al. *Arch Phys Med Rehabil.* 2001;82(6):776–779.

Comparative Observational Pilot Study: Blind Test Hydrostatic Casting versus Other Residual Limb Impression Methods

Jeffrey A. Denune, CP/L

Motus Research LLC

INTRODUCTION

To maximize socket performance and comfort without adversely affecting residual limb health, a prosthetist custom fits a socket for every patient using plaster wraps or computer aided design (CAD). Although the use of the socket is to ambulate in a full weight bearing environment, currently almost all of fittings and plaster casting takes place in a seated or standing *non-weight bearing environment.* Hydrostatic casting while bearing weight is an alternative to traditional casting impression methods in providing lower-limb amputees with a prosthetic socket. Previous research related to the new method have shown positive results in regard to the patient's acceptance, the limited number of necessary modifications, and the high amount of successfully produced sockets. For this study, the application and fit of the sockets in relation to proprioception, the mastering of a distance and the length of distance, as well as the patient's subjective perception were examined, and the results were compared to other shape capture methods.

METHOD

In a pilot study, three different transtibial residual limb shape-capture methods for producing prosthetic sockets were compared: (1) traditional plaster hand casting **(reference group 1);** (2) optical scanning / CAD tracer **(reference group 2)**; (3) hydrostatic cast impression using the Symphonie Aqua System, which enables shape capture under load (weight bearing, **test group 3)** of the residual limb. A plaster impression is taken of the residual limb in a standing position. Simulation of a prosthetic socket under actual loading conditions and to produce a plaster impression while bearing full weight. Due to the hydrostatic pressure, the sensitive areas, bony structures, pressure and pain points, and residual limb tissue are recognized. The plaster impression is smoothed only with minimal modifications. The resulting socket is fit to the anatomy of the residual limb. All three shape capture techniques currently require a diagnostic / test socket made of a thermoplastic material to confirm fit and patient comfort. After trying the test socket on the patient in a static and dynamic environment, the socket is commonly modified until an acceptable wearing comfort level is reached, and the fit is considered correct from the prosthetist and patient's feedback, and considerations of biomechanical points of view.

Participants: Seven transtibial amputee patients were recruited (2 females, 5 males), aged 20 to 70 years, in varying states of physical condition. Three of the study participants were amputated on the left side; four were amputated on the right side. K2 and K3 subjects were chosen depending on level of ambulation with or without assistive devices.

Apparatus: The following equipment/apparatus were used for the study: scanning / CAD tracer and hydrostatic cast impression using the Symphonie Aqua System.

Procedures: For the Omega CAD, subjects Omega CAD files were all modified by the author, reducing the scan by -5% globally. The aqua system was performed by trained prosthetist from Romedis GmbH, who smoothed the plaster model. The hand cast was the SoC socket, and they were modified in the conventional manner by each subject's prosthetist.

Statistical Analysis: Because of limited number of subjects in this pilot study, no statistical analysis could be performed. The results from this study will, however, be critical to determine sample size for a larger controlled randomized study.

RESULTS

The comparison of the volume demonstrated that the hydrostatically produced sockets had a larger volume than those produced by either the plaster hand cast method or the 3D optical scanning method.

TUG: the hydrostatic socket, the mean time for performing TUG was 9.12 sec (n=7), whereas hand cast socket mean time required to perform TUG was 14.06 seconds and the 3D scanned socket mean time for TUG was 11.55 seconds.

2MWT: This test revealed that the subjects using the hydrostatic socket were able to walk a longer distance (91.0 meters) in two minutes than with the other sockets (mean for hand cast=85.5 meters) for the and 88.3 meters for the 3D scanned socket.

CONCLUSION

All 7 patient's shape captured under a weight bearing environment comment that the Aqua socket was more comfortable even though the socket was obviously larger than the traditional hand cast or CAD sockets. The Aqua sockets presented a very different shape than traditional sockets, with the distal end being more bulbous. All 7 patients felt that the suspension was equal to or better than the comparator sockets. A better understanding of how this can play a roll in improved limb health and circulation is needed in future research.

Funded by Romedis GmbH.

Veteran Experience and Perceived Effectiveness with Phantom Limb Pain Treatments

KJ Falbo,[1,2] H Phelan,[3] AH Hansen,[1,2] ME Matsumoto,[1,2] TL Rich[1,2]

[1]Minneapolis VA Health Care System, [2]University of Minnesota, [3]Medical College of Wisconsin

INTRODUCTION

Several intervention options are available to treat phantom limb pain (PLP).[1] Best clinical practices for choosing the appropriate treatment for an individual patient remain unclear; however, patient engagement and willingness to participate in the intervention are critical considerations.[2] To inform clinical decisions, it is important to understand patient perception of pain treatments. The purpose of this study was to explore Veteran experience with PLP treatments and perceived treatment effectiveness.

METHOD

This study was determined to be Institutional Review Board exempt.

Participants: Veterans with lower-limb amputations who received care at the Minneapolis VA's Regional Amputation Center were recruited via mail to participate.

Apparatus: Phone interviews.

Procedures: Data regarding Veteran experience and perceived effectiveness with PLP treatments were collected using semi-structured questionnaires.

Data Analysis: Descriptive statistics (i.e., frequency counts of techniques, reported benefit or no benefit), and a review of qualitative interview data were used to explore experiences with and perceived effectiveness of PLP treatments.

RESULTS

Fifty Veterans with lower-limb amputations were interviewed (48 male; average age: 66; 41 (82%) with unilateral below-knee amputation, 9 (18%) with bilateral amputations). Forty reported experiencing PLP (80%). Of those, 21 reported currently taking pain medications for general pain and/or PLP (53%), and 31 reported attempting at least one non-drug treatment for PLP (78%). Of the 24 non-drug treatments reported, the most common are shown in Table 1. Non-drug treatments that some Veterans reported were effective included massaging the residual limb, walking or wearing the prosthesis, engaging in mirror therapy, using cannabis, and applying compression garments, among others. Effectiveness of treatment was reported on various levels, from "helps a little" to "completely alleviates PLP," with most reporting moderate or temporary pain reduction. Some Veterans experienced unexpected success with treatment; for example, when discussing mirror therapy, one stated, "That really helped me. I was surprised." A few reported that treatment effectiveness varied over time, with one stating treatment "helped a little at the beginning" and another stating, "This helps, but not all the time." Veterans occasionally noted effectiveness on specific characteristics of pain (e.g., "[Walking] makes the pain not as intense…but doesn't shorten the duration," and "The compression helps decrease the frequency").

Table 1. Most common reported non-drug treatments by Veterans for phantom limb pain (n=40). *Note: Not all Veterans specifically reported treatment effectiveness.*

Non-Drug Treatment	Number of Veterans	Number of Veterans Reporting Positive Effect	Number of Veterans Reporting No Effect
Mirror therapy	14	4	4
Walking, wearing prosthesis, exercise	12	4	1
Tapping/massaging residual limb	11	4	1
Compression or shrinker	5	2	0
Meditation, breathing, or relaxation	4	1	0
Applying heat to residual limb	4	0	0

DISCUSSION

Experience with the use and effectiveness of PLP treatment varies across Veterans. Treatment effects were highly individualized. The mechanisms underlying PLP remain unknown, contributing to unclear treatment protocols. To improve patient-specific treatment selection, a better understanding of factors that contribute to PLP is needed. Future qualitative work to explore contributing factors and patients' understanding of PLP and its treatment will inform recommendations of effective interventions. Results may have been influenced by recall bias, and future work could involve real-time data collection to avoid such bias.

CONCLUSION

Veterans reported familiarity with several non-drug treatments for PLP. The response to treatment varies across individuals without a clear understanding of person-specific factors that influence this response.

CLINICAL APPLICATIONS

Understanding patient interpretation of PLP and perceived effectiveness of treatments can inform clinicians in prescribing effective interventions. Better informed treatment recommendations may improve patient engagement and trust in clinical care and reduce the time and cost burden on healthcare providers.

REFERENCES

1. Collins KL, et al. *J Clin Invest.* 2018;128(6):2168–2176.
2. Richardson C, Kulkarni J. *J Pain Res.* 2017;10(Aug):1861–1870.

DISCLAIMER

The views expressed herein are those of the authors and do not reflect the official policy or position of the US Department of Veterans Affairs or the US Government.

FUNDING

This work was supported in part by the US Department of Veterans Affairs Award 1IK1RX003216-01A2.

Rethinking Hip Strength in Lower-Limb Prosthesis Users

A Sawers,[1] S Fatone,[2] R Caldwel[3,4]

[1]University of Illinois at Chicago, [2]University of Washington, [3]Northwestern University, [4]Hanger Inc.

INTRODUCTION

Strength deficits may play a key role in the severity of balance and mobility impairments in lower-limb prosthesis (LLP) users. A recent review of muscle strength in LLP users noted that strength deficits are consequential, yet there was considerable variation in methods used to assess muscle strength.[1] Only a quarter of studies normalized strength data to basic anthropometric variables (e.g., body mass), limiting the validity of comparisons between people or legs that vary in size.[1] We recently demonstrated that hip strength in LLP users is dependent on body-mass (BM) x thigh length (TL),[2] and failure to adjust for this association masks between limb differences in hip strength and their relationship to balance ability. The objective of this study was to test if hip strength, estimated by peak isometric torque normalized to BMxTL, differed between residual and intact limbs of LLP users, as well as age and gender-matched controls.

METHOD

Cross-sectional study approved by an Institutional Review Board. All subjects provided informed consent.

Participants: Twenty-eight unilateral LLP users (mean age: 55 years, mean body mass: 82.2 kg, mean height: 1.75 m, 14 male, 14 transtibial, 7 dysvascular, 10 K2/17 K3/1 K4, median: 13.5 years since amputation). Twenty-eight age- and gender-matched control subjects.

Apparatus: Maximum voluntary isometric hip flexion, extension, and abduction/adduction torques were measured with a motorized dynamometer (Biodex 4 Pro, NY).

Procedures: The order of testing leg and muscle group was randomized, and the prosthesis removed when testing the residual limb. After 3 submaximal practice trials, participants completed 15 five-second maximum voluntary effort trials with 10 seconds of rest between trials.

Data Analysis: Peak isometric hip torques were normalized to BMxTL. Initial assessment of a 3-way interaction between amputation level, leg, and muscle group indicated that the effects of leg and muscle group on peak torque were not dependent on amputation level. Similarly, 2-way interactions between amputation level and muscle group, as well as amputation level and leg were not significant. LLP users were therefore combined into one group for comparison to controls. A 2-way mixed ANOVA with a between-subject factor of leg (3-levels: intact, residual, control) and a within-subject factor of muscle group (4-levels: extensors, flexors, abductors/adductors) was run to test for differences in hip strength among combinations of leg and muscle group. Significance for all tests was set at α=0.05. Multiple comparisons during post-hoc tests were adjusted using Tukey's Honest Difference (SPSS; IBM).

RESULTS

Normalized peak torques were log-transformed so that values approximated a normal distribution for any combination of amputation level, leg, and muscle group. A significant 2-way interaction between leg and muscle group indicated that normalized peak torque differed according to combinations of muscle group and leg. Here we focus on the between-leg results. A significant simple main effect of leg (p=.001) indicated that peak torque differed between two or more legs for each muscle group. Post-hoc comparisons revealed that for hip extensors, flexors, and abductors, peak torques were not significantly different between the residual and control legs (p≥.067), but both were significantly greater than the intact leg (p<.001) (Figure 1). For hip adductors, peak torque was significantly greater in the control and residual legs compared to the intact leg (p<.001), yet unlike other hip muscles, peak adduction torque was significantly greater in the residual than control leg (p<.001).

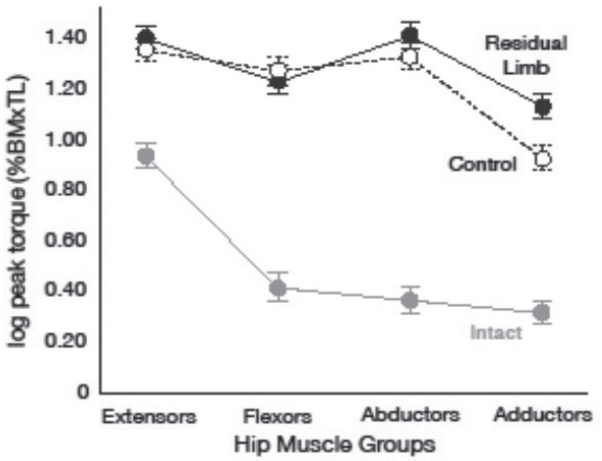


Figure 1. Peak hip torque across muscle group for each limb.

DISCUSSION AND CONCLUSION

In contrast to prior research, our results suggest that hip strength does not differ as a function of amputation level, and that it is the intact, rather than the residual limb, that is weaker. These novel findings may be due to methodological choices (e.g., normalization, age- and gender-matching), or biomechanical demands placed on residual limb hip muscles. Specifically, intact limb hip strength may be reduced due to lower overall activity (i.e., fewer steps), while residual limb hip muscles do not suffer the same fate as they are "always on," performing more work per step to compensate for lost ankle and knee muscles. Further research to test these hypotheses is required.

CLINICAL APPLICATIONS

Historical patterns of hip muscle weakness and their implications in LLP users should be reconsidered.

REFERENCES

1. Hewson A, Dent S, Sawyers A. *Prosthet Orthot Int.* 2020; 44(5):323–340.
2. Sawers A, Fatone S. *Clin Biomech* (Bristol Avon). 2022;105702.

Funded by the US Department of Defense under award No. W81XWH1910507.

Lifetime Mobility Values Following Lower-Limb Loss

Bretta L. Fylstra, PhD; Dwiesha L. England, MS; Phillip M. Stevens, MEd; James H. Campbell, PhD; Shane R. Wurdeman, PhD

Hanger Institute for Clinical Research and Education

INTRODUCTION

Previous work has generated normative values of mobility across age and etiology for individuals with below-knee (BKA) and above-knee amputations (AKA); however, age groupings were reported in 7 groups that spanned approximately 10 years each based on limitations in sample size for cancer and congenital etiologies.[1]

The purpose of this study was to stratify mobility outcomes for individual years of patient age for the primary causes of lower-limb amputation: trauma and diabetes/dysvascular (DV). This analysis will enable more individualized mobility goal-setting for patients specific to their age, etiology, and amputation level. Secondarily, an initial analysis to investigate how these mobility goals may change dependent on type of prosthesis was performed for patients with microprocessor knees integrated into their care.

METHOD

Participants: Individuals were included if they were ≥18 years old, had their amputation due to either trauma or DV, and were either AKA (i.e., transfemoral and knee disarticulation) or BKA (i.e., transtibial and Symes). AKA were further stratified into microprocessor (MPK) or non-microprocessor (nMPK) based on their prosthesis type for secondary analysis.

Apparatus: A retrospective, cross-sectional analysis was performed on mobility outcomes (PLUS-M t-scores) collected in private prosthetic clinics across the United States between April 2016 and December 2021.[2]

Procedures: Data were analyzed across 61 years of age (25–85). Individuals <25 and >85 were grouped accordingly due to limited sampling at the extremes. Averages for each age group were excluded if the age group had less than 15 individuals.

Data Analysis: The mean PLUS-M score was calculated for each age group and a cubic fit was applied to the mean data across age ranges. A 95% confidence interval was also calculated around the fitted line.

RESULTS

A total of 29,522 individuals (6,437 AKA and 23,085 BKA) met the inclusion criteria and were included in the final sample. For AKAs, the average number of individuals in each age group was 47.3±17.0 for trauma and 77.3±40.4 for DV. For BKAs, the average number in each age group was 108.2±49.6 for trauma and 288.9±188.8 for DV. In the secondary analysis, further subdividing based on MPK status, the average number of individuals in each age group was 29.4±9.7, 58.3±27.7, 22.6±5.7, and 31.6±9.6 for MPK-DV, nMPK-DV, MPK-trauma, and nMPK-trauma, respectively.

Trend models were built for AKA-trauma (y=-1.45e^-04 x^3+0.020x^2-0.955x+65.76 R=0.79 p<0.001), AKA-DV (y=-6.16e^{-05} x^3+0.0058 x^2-0.117x+40.39 R=0.86 p<0.001), BKA-trauma (y=-1.71e^{-04} x^3+0.0265x2-1.38x+78.48 R=0.90 p<0.001), BKA-DV (y=-2.36e^{-04} x^3+0.0402x^2-2.36x+95.08 R=0.96 p<0.001). Patients with MPK had on average, higher PLUS-M scores compared to nMPKs (Figure 1).

DISCUSSION

In general, mobility decreases with respect to age and individuals with amputation due to trauma had higher mobility compared to those with DV (Figure 1). Individuals with MPKs had increased mobility compared to nMPKs (Figure 1). These equations can predict expected mobility for patients specific to their presentation.

CONCLUSION

The models generated can be used to create adjusted mobility scores for patients to better qualify good patient outcomes. Future efforts will consider additional factors (e.g., comorbidities, time since amputation) to further enhance rehabilitation goal setting.

CLINICAL APPLICATIONS

The results of this study provide clinicians and patients tools for improved goal setting based on age and amputation level for traumatic and DV etiologies.

REFERENCES

1. England DL, et al. *Am J Phys Med Rehabil.* 2021;100(2):130–137.
2. Hafner BJ, et al. *Arch Phys Med Rehabil.* 2018;98(2):277–285.

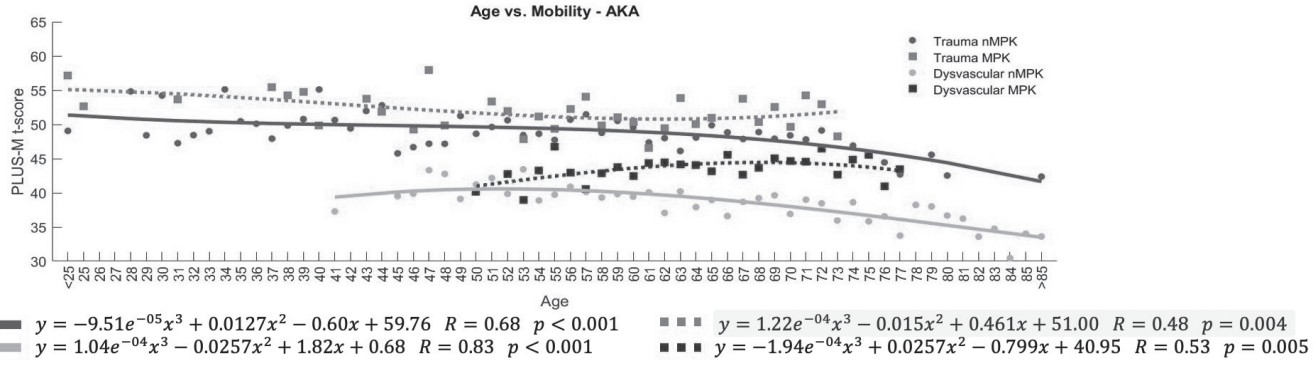


Figure 1. Those with an MPK (square markers and dotted line) have a higher PLUS-M t-score compared to those with a nMPK (circle markers and solid line) for both etiologies.

Preliminary Findings from a Clinical Trial of Adjustable Volume Transfemoral Sockets

DH Gates,[1] L Nolasco,[1] J Wensman,[1] T Gutierrez,[2] M Avalos,[3] NJ Rosenblatt[3]

[1]University of Michigan, Ann Arbor, MI; [2]Bionic Prosthetics and Orthotics, Chicago, IL; [3]Rosalind Franklin University of Medicine and Science, North Chicago, IL

INTRODUCTION

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

METHOD

Participants with a unilateral transfemoral amputation (TFA) were randomly allocated to complete testing with a laminated socket and each of 3 adjustable prosthetic sockets: CJ Sail (CJ Socket Technologies, Inc., Beverly, MA), Quatro (Quorum, Windsor, CO), and Infinite (LiM Innovations, San Francisco, CA). Participants acclimated to each socket for a minimum of 4 weeks.

Participants: Twenty-one participants (4 female) with TFA have enrolled in the study. At the time of enrollment, 18 used a laminated sockets and 3 used a CJ Sail.

Apparatus: Three weeks after final fitting, participants completed surveys to assess their socket comfort score (SCS), self-reported mobility (PLUS-M), falls, and activities-specific balance confidence. After 4 weeks, they completed various tests of functional mobility including the 10-Meter Walk Test (10MWT), 2-Minute Walk Test, L-Test, Timed Up and Go (TUG), and Five Times Sit-to-Stand. At the conclusion of the study, participants could choose to keep one experimental socket.

RESULTS

To date, 4 participants have completed testing with all socket designs, and 4 participants have dropped out of the study. All participants were able to complete testing with a traditional laminated socket (19/19). In contrast, only 36% (4/11), 56% (5/9), and 83% (5/6) of participants were able to complete testing with the CJ Sail, LiM, and Quatro sockets, respectively. Of the 12 failures, 4 participants were not able to leave the clinic with the socket, while the remaining participants asked to have the socket removed during the acclimation period due to instability or discomfort. Of the sockets that participants were able to wear for the full trial, all were deemed "comfortable" (average socket comfort score>7/10). While very preliminary, there are no obvious trends for any socket type to improve either self-reported mobility or functional measures. Three participants chose to keep the socket they entered the study with (2 laminated, 1 CJ Sail); they also kept the Quatro (n=2) and laminated (n=1) sockets as "back-up" sockets. The fourth chose to switch from laminated to CJ Sail.

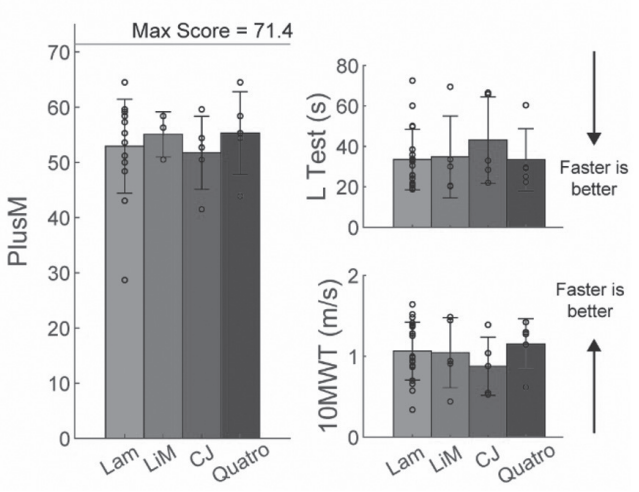


Figure 1. Average PLUS-M score, L-Test time, and 10MWT speed for each socket.

DISCUSSION

Preliminary findings suggest that adjustable sockets have a lower success rate than laminated sockets. This finding is supported by prosthetist self-reported success rates with adjustable sockets [3]. However, our findings may be biased by the fact that a majority of participants already had a well-fitting laminated socket at the start of the study. Nonetheless, we found that certain socket designs can be successful in some participants. Our future work will determine if there are specific patient characteristics that predict success with a particular socket design.

CONCLUSION

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

CLINICAL APPLICATIONS

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

REFERENCES

1. Paterno L. *IEEE Trans Biomed Eng.* 2018;65(9):1996–2010.
2. Barr EA, et al. *J Prosthet Orthot.* 2021;34(4):233–240.

Funded by DoD Award #W81XWH1810656

The Effect of Microprocessor-Controlled Exo-Prosthetic Knees on Limited Community Ambulators: Systematic Review and Meta-Analysis

Andreas Hahn, PhD, MSc;[1] Simon Büschges, MSc;[2] Andreas Kannenberg, MD, PhD[1]

[1]Ottobock HealthCare, [2]STAT-UP GmbH

INTRODUCTION

The clinical benefits of microprocessor-controlled prosthetic knees (MPK) in unlimited community ambulators are well-established. A systematic review in limited community ambulators published in 2014 found benefits in safety, function, and perception in a limited number of studies.[1] In the meantime, the topic received continued scientific attention, and the body of evidence increased significantly in quality and quantity. This work provides an updated of systematic review and a meta-analysis of all published data.[2]

METHOD

A literature search was conducted in 10 scientific databases, including Medline, the Cochlear Library, and Google Scholar. Search terms related to MPK, transfemoral amputation, MFCL-2, and low mobility. The review was conducted by AH and AK. Rating followed the recommendations of the American Academy of Orthotists and Prosthetists. Inclusion required the studies to comprise quantitative and analyzable information on low-mobility subjects, allowing a direct comparison to non-MPKs. Outcomes were categorized by whether they favor the use of MPK, non-MPK or were inconclusive. Mean differences (MD) or standardized mean differences (SMD) were calculated with 95% CIs. Selected effect sizes for SDMs were calculated using Heges `g.

RESULTS

Thirteen research projects presented in 15 publications were identified. Overall validity was "high" in 9 studies, "moderate" in 3, and "low" in 1. The literature described a total of 2,366 patients, with 704 classified as limited community ambulators. The use of MPKs in limited community ambulators led to a reduction in falls (SMD *g*: -0.59; 95% confidence interval (CI) [-0.85, -0.32; I^2=0%]); fear of falling (SMD *g*: 1.2; 95%CI [0.55, 1.85; I^2=80%]); risk of falling as indicated by the Timed Up and Go (SMD *g*: -0.45, 95%CI [-0.87, -0.02; I^2=0%]); improvement in mobility grade (0.51; 95%CI [0.47,0.55]); self-selected walking speed (SMD *g*: 0.47; 95%CI [0.14,0.81; I^2=0%]); and patient-reported ambulation (MD 9.32; 95%CI [3.61, 15.02; I^2=7%]), and utility (MD 7.76; 95%CI [2.05-13.47; I^2=0%]). Other outcomes exhibited trends in favor of MPK use or remained insensitive. No outcome was identified favoring non-MPKs.

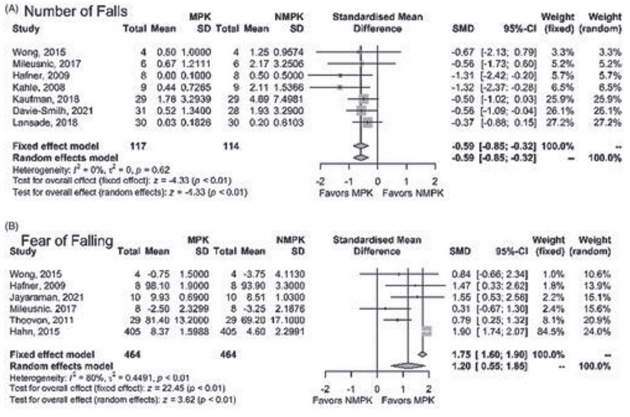


Figure 1. The use of MPKs in low-mobility ambulators leads to a significant decrease in the number of falls and fear of falling.

DISCUSSION

The number of studies addressing the effectiveness of MPKs in limited community ambulators has increased notably. We identified publications relating to a total of 13 research projects. Designs and outcomes utilized in these studies varied widely and covered a broad range of research approaches. The meta-analysis helps to overcome ambiguities.

CONCLUSION

Effects of MPKs in low-mobility ambulators are similar as in unlimited community ambulators.

CLINICAL APPLICATIONS

MPKs should be considered a valuable therapeutic option in limited community ambulators with an above-knee amputation.

REFERENCES

1. Kannenberg A, Zacharias B, Pröbsting E. *J Rehabil Res Dev.* 2014;51(10):1469–1496.
2. Hahn A, Bueschges S, Prager M, Kannenberg A. *Disabil Rehabil.* 2021;Oct 25:1–19.

Self-Reported Annual Falls in Lower-Limb Prosthesis Users and Estimating Falls from Shorter Recall Periods

EG Halsne,[1,2] AB Sawers,[3] A Humbert,[1] R Salem,[1] BJ Hafner[1]

[1]University of Washington, [2]VA Puget Sound Health Care System, [3]University of Illinois at Chicago

INTRODUCTION

Falls are a serious problem facing lower-limb prosthesis (LLP) users.[1] Falls are most often measured retrospectively by self-report over a recalled period of time. However, studies of people with lower-limb loss have used a range of recall periods to collect information about fall events. Variations in methods for measuring falls and in defining "fallers" versus "non-fallers" complicates the interpretation of the findings across studies. Therefore, the goals of this study were to determine self-reported fall rates in a large, national sample of LLP users and then compare estimates of falls over 12-months based on data from shorter periods. A secondary objective was to assess the accuracy of categorizing participants as fallers or non-fallers based on extrapolations of data from shorter recall periods compared to their status at 12 months.

METHOD

Participants: All participants provided informed consent, and an IRB determined procedures qualified for exempt status. Two-hundred thirty-seven participants completed the study (141 men / 96 women; 58.6±13.4 years of age, n=140 below-knee and n=97 above-knee).

Apparatus: Numbers of self-reported falls during the specified recall periods were collected. Surveys also included questions about users' overall health, fall-related health, and mobility.

Procedures: The cross-sectional online survey was administered using REDCap. Participants were asked about their fall history over a 12-month recall period and were then randomized to answer the same questions over a shorter recall period (i.e., 1-, 3-, 6-, or 9-months).

Data Analysis: Data were analyzed using R. Linear regression models of falls/month with an indicator for no fall events were created for each period to estimate annual falls by scaling data from the shorter periods.

RESULTS

75.5% of participants reported falling within 12-month recall period. Of those who reported ≥1 fall, the mean number of annual falls was 4.7±6.2 (median=3).

Predicted falls at 12 months based on data from shorter recall periods resulted in overestimates of falls, on average (Figure 1). Corrective scaling formulas for estimating annual falls based on falls/month data from shorter recall periods are displayed in Table 1.

Faller status defined from shorter intervals also had poorer accuracy based on faller status at 12 months. For example, 69% of participants (n=31) categorized as non-fallers based on 1-month data were fallers at 12 months. By contrast, only 20% of participants (n=3) were miscategorized as non-fallers based on 9-month data.

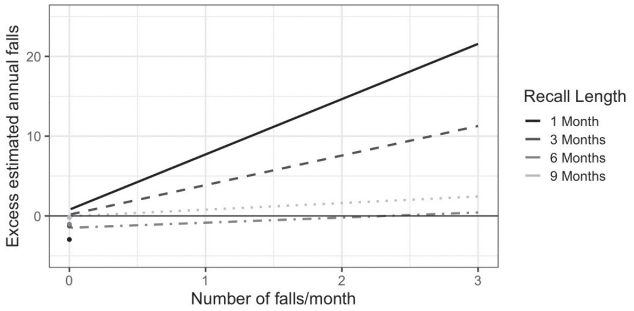


Figure 1. Predicted number of falls at 12 months based on falls from shorter recall periods, depending on the number of falls per month reported within the shorter period.

Table 1. Corrective scaling to estimate falls at 12 months. based on data from shorter recall periods.

Recall Period	Scaling to Estimate 12-Month Falls	R^2
1 month	3.8*(falls/month) - 0.8	0.16
3 month	8.3*(falls/month) - 0.2	0.52
6 month	11.4*(falls/month) + 1.5	0.43
9 month	11.2*(falls/month) + 0.0	0.88

DISCUSSION

On average, annual numbers of falls predicted from data obtained over shorter recall periods, overestimated the reported number of falls over a 12-month period, with increasing error for shorter recall periods (e.g., 1 month versus 6 months) or for participants with higher numbers of falls per month in the shorter periods. These findings are consistent with estimation errors observed across recall periods for self-reported falls in other populations (e.g., older adults).[2]

CONCLUSION

Estimating annual numbers of falls based on self-reported falls from shorter recall periods is not as straightforward as multiplying the number of falls within the period by a simple factor (e.g., 4x the number of falls reported in 3 months). Similarly, defining faller status based on shorter recall periods results in misidentified non-fallers. The equations developed in this study may help to facilitate interpretation of data from studies with different recall periods, but additional validation is needed.

CLINICAL APPLICATIONS

Falls remain a major issue for lower-limb prosthesis users. Improved synthesis of data across studies may help to inform efforts to address this problem.

REFERENCES

1. Miller WC. *Arch Phys Med Rehabil.* 2001;82:1031–1037.
2. Ganz DA. *J Am Geriatr Soc.* 2005;53(12):2190–2194.

Funded by the Office of the Assistant Secretary of Defense for Health Affairs through the OPORP under Award Nos. W81XWH-17-1-0551 and W81XWH-20-1-0197.

3D Scanning of Lower-Limb Sockets: Technologies Comparison

S Assis, MBE;[1] M Castro, MBE;[1] V Carvalho, BSPO, CPO;[1] L RUBIO, PhDSc[2]

[1]Adapttech Inc.; [2]RUNAVISION LTD

INTRODUCTION

At present, modern prosthetic and orthotic clinical practice workflows may involve the use of 3D scanning. One of the uses of these systems in the field is the scanning of the inner surface of lower-limb prosthetic sockets. Scanning systems use different technologies to obtain the three-dimensional shape of the surface of an object, which is made up of vertices and faces. Scanners can be split according to several criteria, such as construction and method of scanning.[1,2] The main goal of these systems is the creation of accurate models of real-world objects. The aim of this abstract is to describe a methodology to compare the performance of different 3D scanning technologies (quality of reconstruction and time) when digitizing the inner surface of a prosthetic socket and to provide a preliminary comparison of different devices on that task.

METHOD

Six lower-limb prosthetic sockets (3 below-knee and 3 above-knee) were used as target objects to assess the performance of different digitizing solutions. A digital shape representing the true shape of each of the sockets was available for reference. Four different technologies were tested to obtain digital representations of the internal surfaces of these sockets: the ECHO Digitizer (Rodin4D); INSIGHT™ Digitizer (Adapttech); D1 Digitizer (Provel); and Structure™ ST01 (Occipital). The technologies were compared in terms of repeatability, accuracy, and procedure duration (preparation and shape capture). The digital models were not modified after they were built by the devices in study. However, they were aligned with their respective reference model for comparison.

To compare 2 aligned models, the average point-to-plane distance is computed (distance between a vertex in model A and its projection on the closest face in model B). The system's repeatability error was calculated through the difference between models of the same socket and technology. When evaluating accuracy error, the average distance error is computed between the model and its reference. Additionally, a novel error metric is introduced where the difference among height-correspondent transverse section perimeters is evaluated between the models and their references. Per technology, we determined the median (pointwise) repeatability and accuracy (pointwise and section perimeter) errors, and the average procedure duration.

RESULTS

Not all the scanning attempts were successful. Only the valid ones were considered for evaluation.

Table 1. Number of trials and valid models obtained per technology. The total number of valid models is shown, both for all experiments and for each socket, in parentheses.

Device	Total Attempts (Valid)	Below Knee	Above Knee
ECHO	4 (4)	2 (1, 0, 1)	2 (1, 1, 0)
INSIGHT™	21 (20)	10 (4, 3, 3)	10 (3, 3, 4)
D1	13 (7)	6 (6, 0, 0)	1 (1, 0, 0)
Structure™	36 (12)	6 (3, 3, 0)	6 (3, 0, 3)

Table 2. Success rate (%), median error (mm), and average time (minues). P stands for preparation and C for capture. Worst and best performances by metric are bolded and underlined, respectively.

Device	Success Rate	Repeat. Error	Acc. Error	Perimeter Error	Total (P, C) Time
ECHO	100	-	**0.37**	4.58	12.5 (3.0, 9.5)
INSIGHT™	95	0.67	0.70	3.69	11.9 (0.3, 10.6)
D1	56	**0.40**	0.50	**3.17**	16.4 (7.2, 9.2)
Structure™	33	0.89	0.93	6.84	**2.8 (0.2, 2.6)**

DISCUSSION

The ECHO never failed to obtain a digital model of the socket (out of the 4 attempts). INSIGHT failed once in 21 experiments. D1 and Structure had the lowest success rates.

The most repeatable system was D1 (INSIGHT and Structure had, respectively, 68% and 123% higher error).

Concerning pointwise accuracy, ECHO had a median error under 0.4 mm (D1's, INSIGHT's and Structure's errors were 35%, 89%, and 151% greater, respectively). Regarding the perimeter error, D1 presented the best result of 3.17 mm (INSIGHTs, ECHO's, and Structures errors were 16%, 44%, and 116% higher, respectively).

The most time-consuming device was D1, where 44% of the 16 total minutes were spent preparing the socket to be digitized. The fastest was Structure, although its low success rate implies that many trials are required to get a valid scan. Within the remaining devices, INSIGHT required less preparation time (<1 minute). It should be highlighted that the shape capture in ECHO, INSIGHT, and D1 does not require the supervision or participation of an operator, meaning that this process can be done in parallel with other tasks in the O&P daily practice.

CONCLUSION

An equitable representation of experiments with different sockets for the technologies would be required for a fairer comparison. Moreover, new product releases have been done by both Occipital and Provel, whose reconstruction abilities and setup requirements might have changed. Also, ECHO is no longer publicly marketed. Nevertheless, the obtained results provide a reference for procedure duration and reconstruction metrics to drive the improvements of technologies in this field.

CLINICAL APPLICATIONS

3D scanning of lower-limb prosthetic sockets' inner surfaces allows the clinicians to quickly obtain their 3D model and integrate it in the digital workflow.

REFERENCES

1. Barrios-Muriel J, Romero-Sánchez F, Alonso-Sánchez FJ, Salgado DR. *Materials.* 2020;13(2):295.
2. Tóth T, Živcák J. *Procedia Engineering.* 2014;69:393–401.

Funded by Adapttech (INSIGHT Digitizer) for data processing.

Does Wearable Technology Improve Patient Outcomes? Multi-Site, Randomized Clinical Trial

Jason T. Kahle,[1] Rebecca M Miro,[2] M. Jason Highsmith[2,3]

[1]OP Solutions. Tampa, FL; [2]University of South Florida, Tampa, FL; [3]US Department of Veterans Affairs, Washington, DC

INTRODUCTION

Amputee rehabilitation may be enhanced by strategies for edema control, accelerated wound healing, increased blood flow, limb protection, fall reduction, and the psychological benefit of being able to stand and walk shortly following amputation. These factors would collectively reduce healthcare costs. Utilizing the latest science is paramount in preventing unnecessary delays in rehabilitation and represents the best use of limited healthcare resources. A common problem for the intermediate preparatory stage of prosthetic rehabilitation is distal residual limb (RL) pressure, due to commonly compromised sensation and patients' lack of understanding of how to address it in a newly fitted prosthesis. Excess pressure can lead to skin breakdown, infection, surgical revision, re-hospitalization, and delayed rehabilitation. To prevent this common problem among rehabilitating amputees, smart socket technology has been developed to better identify problems that may occur. Smart socket technology including prompting (SST+P) in this randomized clinical trial senses distal pressure. When excess RL pressure is detected, the user's smart phone is signaled, which cues the patient to make a volume adjustment. This prompting may improve patient interaction and prevent problems as a result of common volume fluctuation and compromised sensation. The primary objective of this clinical trial is to determine if this SST+P will improve patient interaction, usability, comfort, fit, function, and health economy outcomes compared with the standard of care (SOC) clinical practice protocols of fitting prosthetic socket interfaces for preparatory prostheses users during the intermediate recovery stage of amputation rehabilitation. The hypothesis for this randomized clinical trial is that SST+P will improve rehabilitation outcomes.

METHOD

Subjects: n=60 unilateral TTA subjects were enrolled and consented; 13 females, 47 males, mean age of 53 years, mean weight 190 lbs; etiology: n=40 diabetes/PVD, n=20 trauma, cancer, or other etiologies.

Intervention: SST+P technology.

Outcome Measures: Pressure Ulcer Scale for Healing (PUSH); AMP; Socket Comfort Score (SCS); Pain, Quality of Life surveys (SF-36, EQ-5D); Patient Activation Measure (PAM); and PEQ. These outcome measures were chosen for their psychometric properties and emphasis on clinical translation of patient-reported outcome measures.

Procedures: Multiple O&P clinics through the United States chose to participate when they had eligible subjects. WCG IRB and Army's HRPO provided study oversight. All subjects provided informed consent.

Data Analysis: Parametric tests (i.e., repeated measures ANOVA, t-tests, etc.) were used for all data comparisons with continuous scaled, normally distributed data. Otherwise, non-parametric alternatives were used. Data were compared over a 90-day period of intermediate prosthetic use. Significance was set at $p<0.05$.

RESULTS

There were no significant differences in distal RL pressure (mean or peak) between time periods (30 to 60, 60 to 90, 30 to 90 days) regardless of whether the group was prompted. Over 90 days, all clinical outcomes and PROMs were not different between groups (Figure 1).

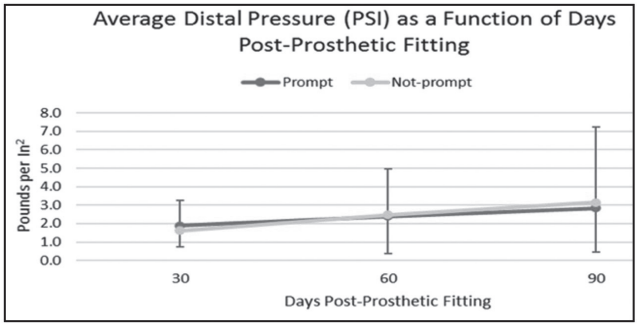


Figure 1

DISCUSSION

There was a trend of increasing mean pressure over the measurement period while ambulation increased. This suggests that some combination of improved limb healing, resilience, and pressure tolerance took place over the time periods measured. However, the difference was not significant. Trends observed in peak pressures were divergent between the prompted and non-prompted groups. The non-prompted group experienced less peak pressure where oppositely, the tendency was for the prompted group to experience higher peak pressures, perhaps suggesting reliance on prompting cues to indicate the need for volume adjustments. Differences did not reach statistical significance.

CONCLUSION

Compared with self-management, prompting for distal socket pressure did not yield RL pressure changes or other rehabilitation outcomes at 30, 60, or 90 days. SST+P may be a comparably effective option relative to the SOC.

CLINICAL APPLICTION

This study provides objective outcome measures of how intermediate prosthetic users with SST+P technology may enhance functional human performance through improved comfort and residual limb health in the below-knee amputee who uses a prosthesis. Remote patient monitoring (RPM) and wearable technology allow clinicians to monitor their patients and automate monitoring 24/7/365. Physicians have implemented RPM into their clinical practices of chronic care patients. Understanding the indications and advantages of RPM in healthcare could help prosthesis and orthosis users improve outcomes in the future.

REFERENCES

1. Sanders JE, Cagle JE, Harrison DS, Karchin A. *Prosthet Orthot Int.* 2012;36(1):77–86.
2. Sanders JE, Harrison DS, Allyn KA, Myers TR. *Prosthet Orthot Int.* 2009;33:378–390.
3. Hibbard JH, Mahoney E. *Patient Educ Couns.* 2010;78(3): 377–381.

DISCLOSURE

This study was funded by the US Department of Defense, W81XWH-15-JPC-8/CRMRP-NMSIRA.

Use of Outcomes to Achieve the Impossible: Approval of MPK in K2 Patients

Andreas Kannenberg, MD (GER), PhD;[1] Seth O'Brien, CP, FAAOP(D);[2] Pete Freigang, CPO[3]

[1]Otto Bock Healthcare LP, Austin, TX; [2]Artificial Limb Specialists, Phoenix, AZ; [3]Wright&Filippis, Saginaw, MI

INTRODUCTION

The concept of evidence-based medicine and practice combines the clinical expertise of the clinician with the consideration of the best-available published scientific evidence and patient values for clinical decision-making. Using outcome measures to identify and demonstrate unmet patient needs, assess the effects of an intervention, and convince a healthcare payor to cover an intervention is part of evidence-based practice. Many CPOs believe that it is impossible to get an MPK approved by Medicare for a K2 patient. We present two case studies that have demonstrated that it is possible to achieve such approval with proper documentation of outcome measures.

METHODS

We performed a retrospective chart review of 2 patients with transfemoral amputation and K2 mobility using non-microprocessor knees (NMPK) and health insurance through Medicare who underwent trial fittings with the MPK Kenevo for 3 months. For both trials, Kenevo loaners had been made available by Ottobock.

Patient #1 was a 70-year-old male using a 3R62 (multiaxial knee with friction swing control) and a walker. In the 4 weeks prior to the trial fitting, he had experienced 8 stumbles. With the 3R62 knee, he performed the Timed Up and Go (TUG) test in 26.7 seconds and had an ABC score of 29, both indicating an increased risk of falling. After 3 months of Kenevo use, he had not experienced any stumbles, performed the TUG in 12.2 seconds and had an ABC score of 70, both no longer indicating an increased risk of falling. In addition, the PLUS-M T-score had improved from 37.9 with the 3R62 to 49.8 with the Kenevo, clearly exceeding the minimal detectable change (MDC) and indicating a clinically meaningful improvement in patient-reported mobility. With these documented results, Medicare issued a pre-authorization for a Kenevo and paid the claim.

Patient #2 was an 81-year-old male using a 3R92 (single axis friction knee with manual lock). He had adopted a very secure forward leaning gait pattern with strong reliance on the walker and extensive use of a wheelchair indoors and outdoors as well as a powered scooter outdoors. After 2 months of Kenevo use, he mostly walked with the walker indoors and considerably reduced his use of the wheelchair. His ABC score had improved from 8.5 to 38, his PLUS-M T-score from 39.0 to 42.9, and his Patient-Specific Functional Scale (PSFS) had considerably improved for 3/5 activities of daily living that were important to him. With these results, Medicare issued a preauthorization for a Kenevo. The claim was being processed by Medicare at the time of submission of this paper.

DISCUSSION

In the prosthetic foot and knee sections, the Medicare Local Coverage Determination (LCD) for Lower Limb Prostheses (L33787) contains the provisions that *"Coverage* [beyond K-level restrictions listed in the respective paragraphs] *is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of foot/knee. This information must be retained in the treating practitioner's or prosthetist's files."* The presented case studies demonstrate that the knowledgeable use of outcome measures and clinical observation satisfy the requirement for additional documentation of functional need for prosthetic technology that K2 patients typically have no access to.

CONCLUSION

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

DISCLOSURE

Andreas Kannenberg is a full-time employee of Otto Bock Healthcare LP. Artificial Limb Specialists and Wright & Filippis are both part of the Ottobock Patient Care network.

Comparing the Ultimate Strength of 3D-Printed and Laminated Sockets

Sunjung Kim,[1] Sai V. Yalla,[1] Sagar Shetty,[2] Anthony Gutierrez,[2] Noah J. Rosenblatt[1]

[1]Dr. William M Scholls College of Podiatric Medicine's Center for Lower Extremity Ambulatory Research (CLEAR), North Chicago, IL; [2]Bionic Prosthetics & Orthotics, Merrillville, IN

INTRODUCTION

3D printing is a robust tool for fabricating complicated objects in a cost-effective and timely manner. Limited information on strength of 3D printed sockets (3DS) may curtail their adoption as definitive sockets in the United States. Systematic review results conducted by our group found that failure forces of 3DS trended toward those observed in laminated sockets. We performed ultimate failure testing of 3DS using some of the latest filaments available and compared results to those of a standard laminated composite socket.

METHODS

Three standard check sockets (CS) were fabricated with 16-inch diameter and 13 mm thickness thermoforming plastic (Ringmaster® T-FLEXTM). The definitive laminated composite socket (LCS) was made with epoxy acrylic resin (Nano Resin, PAMS) and braided carbon fiber (carbon braid, ST&G USA Corp). For 3DS, three different material filaments were used: Polyethylene terephthalate glycol (PETG), polycarbonate (PC) and polypropylene (PP). All sockets were assembled with a pin lock (3rd Generation Genesis A), 2 four-hole pyramids, and a short pylon. Reinforcement was provided via struts that were angled, starting narrow distally and wide proximally (Short struts), mostly for aesthetic reasons.

A second batch of 3D-printed sockets were manufactured with additional reinforcement struts that remained wide from the base up to the point where it blended into the socket (long struts). PC sockets with ling struts also underwent an annealing process to strengthen the bonds between layers. The mechanical strength was tested in accordance with ISO 10328 standards. Sockets were aligned in Condition II for P5 load level. Testing was performed using an Interlaken test frame equipped with 5000 lbf of load cell. All sockets were subject to the settling test (920 N), proof test (2013N), and then ultimate test at a rate of 100N/s.

RESULTS

The ultimate force of PP with the short struts, which was the highest in the first batch, was 34.9% lower than the LS and 9.12% lower than CS. Ultimate force of PETG was 101.8 % lower than that of LCS and 63.1% lower than that of CS. With the long strut, the ultimate force of PC showed the smallest difference (22.6% and 0.88%) when compared to LCS or CS. Failure mainly occurred in the distal end of the socket or the pyramid attachment. The failure of 3DS, whether short or long strut, was observed near the distal end where the entire distal end plate tore apart from the body of the socket.

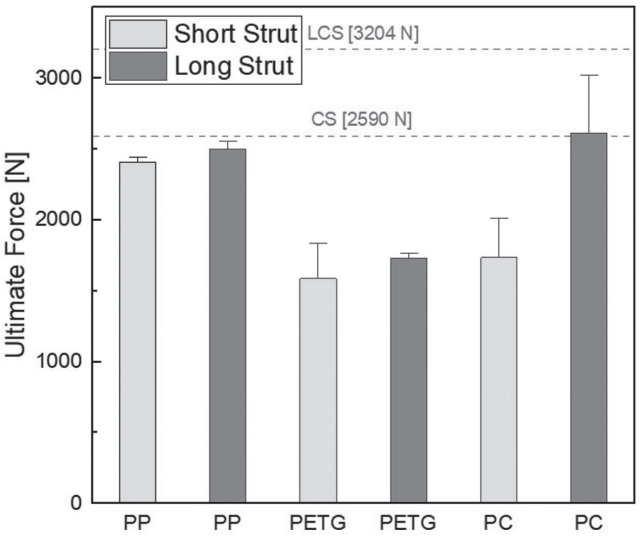


Figure 1. Bar plots for the ultimate failure forces for 3 different materials under Condition II and P5 loading. Horizontal dotted lines represent failure force of LCS and CS sockets. 3DS materials include polypropylene (PP), polyethylene terephthalate glycol (PETG), and polycarbonate (PC).

DISCUSSION

Longer struts in combination with the annealing process in PC sockets gave the best improvements in strength for 3DS, resulting in ultimate failure within 22% of the ultimate failure of LCS. The pyramid socket interface continues to be the weakest area for all sockets. Annealing seems to improve the bonds between 3DS layers, improving ultimate failure loads. Results show 3DS can sustain twice the amount loads they are designed for, and design and filament improvements can bring the gap between failure loads of LCS and 3DS closer, making 3DS safe to use for their prescribed loading levels.

CONCLUSION

Improving the pylon socket interface and inclined layer printing might help improve the strength of 3DS to match that of laminated composite sockets.

CLINICAL APPLICATIONS

This paper was designed to assess the strength of various types of 3D-printed sockets compared to their traditionally fabricated counterparts. The results can help in understanding the potential clinical value of 3D-printed sockets.

This study was funded by the US Department of Defense under award W81XWH2010175.

Adjustable-Volume Prosthetic Interfaces: A Systematic Review and Meta-Analysis of Existing Literature

Tyler D. Klenow, MSPO, MBA, CPO, FAAOP

Ottobock HealthCare LP, Austin, TX, USA

INTRODUCTION

The human-device interface, referred to clinically as the socket, is commonly considered to be the most important part of a prosthesis.[1] It is also the most problematic, however, as lack of socket fit is a commonly reported issue among end users.[2] Lack of socket fit can lead to pain, discomfort, skin irritation and breakdown, subsequent prosthetic abandonment, and deleterious health effects due to inactivity. Adjustability has been stated as a desire for patients and as a potential solution to socket fit issues for several years, but adjustable-volume (AV) interfaces are commonly omitted from literature reviews on socket design categorically. Therefore, the purpose of this article is to review and synthesize the available evidence pertaining to AV prosthetic interfaces.

METHOD

A multidisciplinary team conducted a systematic review of literature published since January 2000 in accordance with the PRISMA statement. Databases included PubMed, Google Scholar, Cochrane Library, and O&P IQ. Search terms included analogous inputs and MeSH terms relating to use of a prosthesis or presence of an amputation and a socket or interface and adjustable or modular design. Articles were included if they utilized at least one individual with limb loss as a subject(s), made use of an AV or modular interface feature, and reported some corresponding outcome variable. Systematic reviews (SR) reporting these criteria were also included. Data was extracted, aggregated, and statistics of central tendency calculated. Articles were then critically appraised using the United Kingdom National Service Framework for Long-Term Conditions tool. Research grades were assigned according to the framework and were used to develop empirical evidence statements (EES). A meta-analysis was performed on variables with common elements reported in at least two articles.

RESULTS

The review identified 2,104 potentially relevant articles of which 26 were ultimately included. Of these, 12 were low, 11 were medium, and 3 were high quality. Overall, 8 case studies or series, 7 pilots, 5 technical notes, 6 experimental trials, 2 RCTs, and 1 SR were included. Twenty-one of the 26 included articles related to lower extremity with 16 of those relating to transtibial amputation (TTA). Of the 5 upper-extremity articles, 4 were regarding the transhumeral (TH) level. The articles included 351 total subjects of which 199 were TTA, 114 were transfemoral (TFA), 28 were TH, and 10 were transradial level. Regarding interface type 5 articles included prefabricated sockets, 5 modular, 5 custom with an adjustable-volume component, and 11 custom with an adjustable-volume feature.

Meta-analysis was possible on 2 variables related to socket comfort and satisfaction. Analysis of 129 subjects in 3 manuscripts showed an improvement in socket comfort score from 4.53 with their existing standard of care (SoC) socket to 7.66 with an adjustable-volume socket. This difference of 3.13. Analysis of 46 TTA subjects in 2 manuscripts showed an improvement in overall Prosthetic Evaluation Questionnaire score from 24.63 with SoC to 29.25 with the iFit system. In total, 10 EESs were able to be synthesized. One was of grade A, 5 of grade B, and 2 of grade C. The grade A EES is: "Manipulating the volume of adjustable-volume prosthetic interfaces can influence residual limb fluid volumes in prosthesis users with history of TTA."

DISCUSSION

A systematic review and literature synthesis was completed regarding AV prosthetic interfaces. The literature varies greatly in substance and quality, but meta-analysis regarding socket comfort and patient satisfaction were possible and showed beneficial outcomes with AV interfaces for individuals with lower extremity amputations. Improvement in intra-socket pressures were also shown. These figures along with the Grade A EES regarding residual limb fluid volume has clinical impact and will facilitate future research on this disruptive technology.

CONCLUSION

AV interfaces showed improved outcomes for socket comfort, user satisfaction, residual limb fluid dynamics, and intra-socket pressures compared to legacy interfaces in lower extremity amputees.

CLINICAL APPLICATIONS

The results of this work show the viability of AV sockets, especially for individuals with frequent volume fluctuations. This should provide alternatives to vacuum suspension for indicated patients and add AV sockets to many prosthetists' clinical toolbox.

REFERENCES

1. Collins DM, et al. *Crit Rev Biomed Eng.* 2006;34:379–438.
2. Paterno L, et al. *IEEE Trans Biomed Eng.* 2018;65:1996–2010.
3. Stevens PM, et al. *J Prosthet Orthot.* 2019;31:72–78.

Clinical Outcomes Measurement in Pediatric Lower-Limb Prosthetics: A Scoping Review

K Koenig,[1] M Hall,[1] C Gormley,[2] J Laine,[1,2] S Morgan[1,2,3]

[1]Gillette Children's Specialty Healthcare, St. Paul, MN; [2]University of Minnesota, Minneapolis, MN; [3]University of Washington, Seattle, WA

INTRODUCTION

There are roughly 25,000 children with limb amputation or difference in the United States.[1] Often, this population's unique characteristics and needs are overlooked when creating and evaluating outcome measures to assess function and health-related quality of life (HRQoL) in people who use lower-limb prostheses (LLP). Valid and reliable outcome measures are needed to document change in health outcomes and to assess the effectiveness of prosthetic interventions for children using LLP.

Clinicians and researchers specializing in pediatric prosthetics are tasked with selecting measures best suited to evaluate children who use LLP. Outcome measure selection can be informed by evidence of a measure's clinical utility and psychometric properties (e.g., validity, reliability) in the population of interest. There is a growing collection of outcome measures that have evidence of sufficient validity and reliability for use with adult LLP users.[2] However, the available evidence to support the use of similar outcome measures in children who use LLP has not been examined. The purpose of this review was to (1) identify outcome measures in published literature that have been used to evaluate function and HRQoL of children who use LLP, and (2) to review the psychometric evidence available for each measure to assess their suitability for use with children who use LLP.

METHODS

A systematic search of PubMed, CINAHL, and Web of Science databases was performed to identify articles that used standardized outcome measures to examine function or HRQoL outcomes in children who use LLP. A list of outcome measures was extracted from eligible articles. An additional search was performed in the same databases to obtain articles that describe measure development or psychometric testing of the identified measures with pediatric LLP users. For standardized outcome measures that had been developed for or evaluated with children who use LLP, psychometric findings were extracted. For outcome measures that had not been psychometrically evaluated in children who use LLP, we indicated if development or psychometric testing had been conducted with similar populations (i.e., adult LLP users, children without LLP).

RESULTS

We identified 36 outcome measures from 37 articles that assessed function or HRQoL in children who use LLP. Of these measures, only 4 had published evidence of psychometric properties to guide their clinical use with children who use LLP (Table 1). Twenty-five measures had evidence in children who do not use LLP, and 16 measures had evidence in adult LLP users.

Table 1. Measurement properties for standardized outcome measures evaluated with children who use LLP.

Measure	Validity Data	Reliability Data
Gait Outcomes Assessment List for Lower Limb Differences questionnaire (GOAL-LD)[3]	Content adaption and sensibility analysis performed	N/A
Functional Mobility Assessment (FMA)[4]	Good discriminant validity (p<.01)	N/A
Child Amputee Prosthetics Project - Prosthesis Satisfaction Inventory (CAPP-PSI)[5]	Positive correlations between each scale with wear, use, and appearance (r=.16-.56)	High internal consistency (Alpha=.8-.9) Acceptable Item-Total Correlations (.52-.8)
Lower Limb Function Questionnaire (LLFQ)[6]	Correlated with gait kinematics and distance travelled on obstacle course	Good test-retest reliability (ICC=.79)

DISCUSSION

There is limited evidence about the psychometric properties of standardized outcome measures that assess physical function and HRQoL in children who use LLP. Many other measures are either being used based on psychometric evidence in similar populations or expert opinion. Some of these measures may not be optimal for use with pediatric LLP users.

CONCLUSION

Results of this review suggest that few outcome measures have been evaluated with children who use LLP. Additional research is needed to develop and/or evaluate a suite of standardized outcome measures that are well-suited to clinical and research-related outcomes measurement in children who use LLP.

CLINICAL APPLICATIONS

Few standardized outcome measures have been evaluated with children who use LLP, and most focus on gait and function. Clinicians may need to rely on psychometric evidence from similar patient populations (e.g., adult LLP users, children without LLP) to inform holistic outcome measure selection for pediatric LLP users.

REFERENCES

1. Ziegler-Graham K, et al. *Arch Phys Med Rehabil.* 2008;89(3): 422–429.
2. Condie E, Scott H, Treweek S. *J Prosthet Orthot.* 2006;18(6): 13–45.
3. Dermott J, Wright FV, Salbach NM, Narayanan UG. *Health Qual Life Outcomes.* 2021;19:139.
4. Pierce S, Fergus A, Brooks B, Wolff-Burke M. *J Pediatr Phys Ther.* 2011;23(2):171–177.
5. Pruitt SD, Varni JW, Seid M, Setoguchi Y. *Arch Phys Med Rehabil.* 1997;78(7):750–754.
6. Funk L, et al. *Disabil Rehabil: Assist Technol.* 2017;12(3):262–271.

Differences in the Use of the Amputee Mobility Predictor in the Assignment of K-Level across Four Prosthetic Clinics

Russell Lundstrom, MS;[1] Brian Kaluf CP, FAAOP;[1,2] Scott Sabolich, CP, LP;[3] Chris Kort, CPO;[4] Cyle Gates, CPO[5]

[1]Otto Bock Healthcare LP, Austin, TX; [2]Ability Prosthetics and Orthotics, King of Prussia, PA; [3]Scott Sabolich Prosthetics & Research, Oklahoma City, OK; [4]Prosthetics in Motion, New York, NY; [5]JP&O, Jonesboro, AR

INTRODUCTION

The Amputee Mobility Predictor (AMP) was developed as a performance-based outcome measure to assess functional capabilities and mobility and to assist in Medicare Functional Level (K-Level) assignment.[1] Available reference data assists in AMP score interpretation, but no clear cutoff scores between K-Levels exist,1 and applying unverified cutoff scores is cautioned against.[2,3] For recent amputees being fit with their first prosthesis, several studies have found limitations to relying on unverified cutoff scores for interpreting AMPnoPRO results.[2,4,5] A retrospective chart review was conducted to examine AMP scores obtained during routine lower-limb fittings to assess the relationship between the AMP scores and the assignment of K-Levels.

METHOD

Procedures: IRB-approved retrospective chart review of lower-limb amputees fitted at 4 clinics (all locations) between January 2010 and October 2020.

Subjects: 6,953 subjects screened yielded 2,064 TF/KD amputees with 727 (35%) having valid AMPPRO or AMPnoPRO scores and 4,527 TT/Symes amputees with 1,637 (36%) having valid AMP scores. Overall, 5% were assigned K1, 28% K2, and 58% K3.

Apparatus: Data were obtained from an export from the Electronic Health Record (OPIE) from each site to compare AMP scores with the assigned K-Level. Bilateral amputees were excluded from the analysis along with partial foot toe amputations.

Data Analysis: Mean and standard deviations for the AMP Scores were calculated in Microsoft Excel.

RESULTS

Table 1 shows the percentage of subjects with AMP scores by amputation level and site.

Table 1. % Patients with AMP Scores.

Number, % of Patients	Site 1	Site 2	Site 3	Site 4
TF/KD	1236	308	215	305
AMP Scores	340	104	22	261
% Patients	28%	34%	10%	86%
TT/Symes	2406	1081	370	670
AMP Scores	716	363	38	520
% Patients	30%	34%	10%	78%

Table 2 shows the average AMPPRO scores by K-Level and amputation level. Figure 1 illustrates differences in the distribution of AMP scores by K-Level and site.

Table 2. Mean and standard deviation for AMP scores.

Mean AMPPRO Score					
Amputation Level	K1	K2	K3	K4	Overall
TF/KD	18.79 ± 7.17 n=19	29.78 ± 6.19 n=117	39.18 ± 4.31 n=502	43.39 ± 1.99 n=116	**37.86 ± 6.73 n=754**
TT/Symes	22.65 ± 7.11 n=49	31.05 ± 5.78 n=388	40.33 ± 3.82 n=1288	44.50 ± 1.53 n=391	**38.94 ± 6.49 n=2099**
Overall	**21.57 ± 7.28 n=68**	**30.75 ± 5.89 n=505**	**40.01 ± 4.00 n=1770**	**44.24 ± 1.71 n=507**	**38.65 ± 6.57 n=2853**

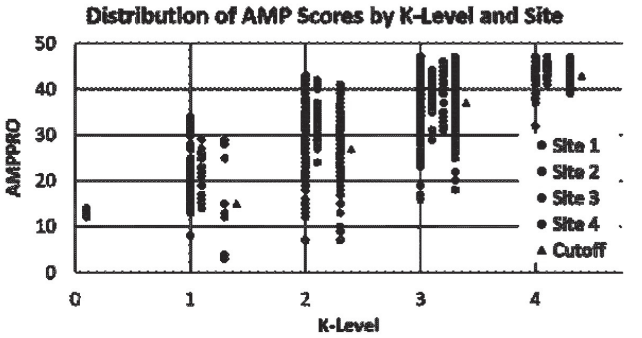


Figure 1. Distribution of AMP scores by K-Level and site and "cutoff" for minimum AMPPRO score for K-Level.

DISCUSSION

Differences in the administration of the AMP were apparent between sites, with some sites limiting the AMP assessments to K3 patients. Most sites assessed the AMP in 45%–60% of K3 subjects.

There were clear differences in the distribution of AMP scores by K-Level for each site, with a significant proportion of subjects assigned to K-Levels above the unverified AMP score "cutoffs." Differences in these distributions may reflect beliefs by practitioners regarding the role of the AMP in assigning K-Level to a patient.

CONCLUSION

The use of the AMP in routine clinical practice is feasible for supporting justification of K-level in lower-limb prosthetics but varies from clinic to clinic.

CLINICAL APPLICATIONS

Results from this study may reflect differences in the way the AMP is used to support K-Level assignment. More research is warranted to investigate how the AMP scores are being used by clinicians and the application of AMP score "cutoffs."

REFERENCES

1. Gailey R, et al. *Arch Phys Med Rehabil.* 2002;83(5):613–627.
2. Spaan MH, et al. *Prosthet Orthot Int.* 2017;41(2):171–177.
3. Dillon MP, et al. *Prosthet Orthot Int.* 2018;42(2):191–197.
4. Kaluf B, Major M. Amputee Mobility Predictor in Persons with Recent Lower Limb Amputation. Abstract presented at: 45th Academy Annual Meeting & Scientific Symposium, March 6–9, 2019; Orlando, Florida.
5. Andrews K, Nanos KN, Hoskin TL. *Int J Phys Med Rehabil.* 2017;5(2).

Secondary Prosthesis Use among Lower-Limb Prosthesis Users

CL McDonald,[1] A Kahn,[1] BJ Hafner,[1] SJ Morgan[1,2,3]

[1]University of Washington, Seattle, WA; [2]Gillette Children's, St. Paul, MN; [3]University of Minnesota, Minneapolis, MN

INTRODUCTION

People with lower-limb amputation who are deemed eligible typically receive only a single, daily-use prosthesis as part of their prosthetic prescription. This prosthesis is intended to restore an individual's function, mobility, and participation in vocational and avocational activities. While prosthetic components generally restore some aspects of balance, function, and mobility, there is no perfect prosthesis. Every prosthetic design has its limitations.1 To compensate for functional limitations in their daily-use prosthesis, lower-limb prosthesis users may seek to obtain an additional prosthesis (e.g., running prostheses or prostheses designed for water use). However, it is unknown how many prosthesis users successfully obtain a secondary prosthesis or what factors contribute to obtaining these devices. Therefore, the goal of this study was to estimate the prevalence of secondary prostheses in a large, national sample of lower-limb prosthesis users and to determine which demographic and clinical factors are associated with use and non-use of secondary prostheses.

METHOD

Sample: Lower-limb prosthesis users (n=1907 unique participants) who participated in prior survey studies2,3 related to prosthetic mobility.

Study Design: Secondary analysis of cross-sectional survey data collected between December 2011 and January 2020. An Institutional Review Board approved all study procedures.

Eligibility Criteria: Eighteen years of age or older, unilateral or bilateral lower-limb amputation, regular use of a prosthesis, and proficiency in English.

Procedures: Participants completed surveys that included demographic information, clinical characteristics, and questions about use of secondary prostheses (e.g., back-up, sport and recreation, showering and bathing).

Analysis: We combined datasets from 4 studies for this analysis. Participants were grouped by those who did and did not report use of at least 1 secondary prosthesis. Descriptive statistics were used to characterize the numbers and the types of secondary prostheses used by study participants. Sample demographic and clinical characteristics were compared between groups using independent t-tests or Chi-squared tests, as appropriate (α=0.05).

RESULTS

The mean (SD) age of our sample was 53.0 (14.3) years. The majority of participants identified as men (68.0%), reported amputation from non-dysvascular causes (68.0%), unilateral amputation (87.9%), and below-knee amputation (52.0%). Most participants (62.6%) did not use a secondary prosthesis (Table 1). The most common secondary prostheses used by participants were back-up (20.7%) and sport/recreation (17.5%) devices. People who did and did not use secondary prostheses significantly differed with respect to demographic and clinical characteristics, including age, gender, race, education, and amputation etiology (p<0.05).

Table 1. Prevalence of secondary prosthesis use and type of devices used among lower-limb prosthesis users (n=1907).

Secondary prosthesis use	n	%
Did not use a secondary prosthesis	1193	62.6%
Used ≥1 secondary prosthesis	714	37.4%
Type of secondary prosthesis used*		
Backup	395	20.7%
Sport and recreation	334	17.5%
Showering/bathing	137	7.2%
Other	147	7.7%

*Some participants used multiple secondary prostheses. Thus, the sum total of people reporting use of each device type may exceed the total number of people who reported using one or more devices.

DISCUSSION

Our results indicate that most lower-limb prosthesis users do not use a secondary prosthesis. Disparities in secondary prosthesis use exist by gender, age, race, education level, and amputation cause and level. Without secondary prostheses, individuals may experience restricted mobility and participation. Future research is needed to examine potential causal relationships between access to, use of, and outcomes associated with secondary prostheses.

CONCLUSION

Most lower-limb prosthesis users do not use secondary prostheses, and those who do tend to be men, more educated, younger, and have more distal, non-dysvascular amputations.

CLINICAL APPLICATIONS

Secondary prostheses can optimize lower-limb prosthesis users' mobility. However, observed disparities in use of secondary prostheses in this large sample of users suggest that critical clinical reflection is needed to examine prescription practices and policies that influence access to these devices.

REFERENCES

1. Keszler MS, Heckman JT, Kaufman GE, Morgenroth GC. *Phys Med Rehabil Clin N Am.* 2019;30(2):423–437.
2. Hafner BJ, et al. *Arch Phys Med Rehabil.* 2017;98(2):277-285.
3. Prosthetic Limb Users Survey of Mobility (PLUS-M) Version 1.2 Short Forms Users Guide. 2015.

Funded by NIH Award R01HD065340 and DOD OPORP Award W81XWH-17-1-0551.

Defining Success in Lower-Limb Prosthetics: Which Outcomes Matter Most?

CL McDonald CL, G Balkman, S Shrivastav, BJ Hafner

University of Washington, Seattle, WA

INTRODUCTION

Standardized measurement of patient outcomes is essential to making informed prosthetic rehabilitation decisions. The first step in measurement is identifying which outcome(s) should be measured. Historically, clinicians, researchers, and providers have selected which outcomes to assess based on their experience. This approach, however, often neglects to consider the perspectives and values of lower-limb prosthesis (LLP) users. Consideration of LLP users' needs, goals, and priorities may offer an alternative means to select which outcomes to measure.[1] This study was conducted using a phenomenological approach to explore which outcomes matter most to LLP users. Through focus group discussions, we examined how LLP users define and prioritize success.

METHOD

Sample: LLP users were purposively sampled (based on gender, race, etiology, and amputation level).

Study Design: Qualitative focus groups.

Eligibility Criteria: Eighteen years of age or older, prior lower-limb prosthesis use, and proficient in English.

Procedures: Each participant attended a 2-hour focus group with 3–8 other LLP users. A trained facilitator used a standardized guide to lead group discussions. All procedures were determined to qualify for exempt status by a local Institutional Review Board.

Analysis: Researchers first read each focus group transcript and applied open coding. Subsequent coding was used to identify relationships between codes and common themes. Two investigators independently coded all transcripts; a third mediated disagreements. Researchers documented positionality prior to coding and used reflexive practice throughout the analysis.

RESULTS

Thirty-one LLP users participated in this study. Five themes emerged from the qualitative analysis (Table 1). A conceptual model (Figure 1) for success with an LLP was developed based on participant descriptions.

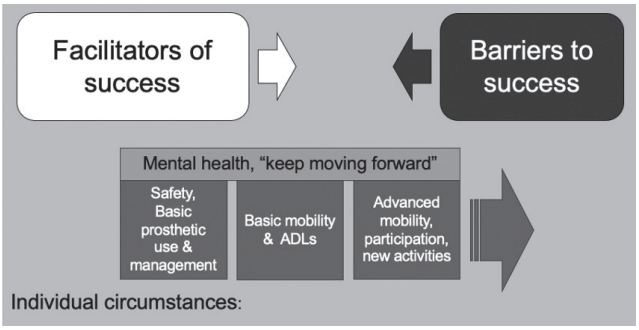


Figure 1. Conceptual model for success with a lower-limb prosthesis.

Table 1. Themes and example quotes.

Keep moving forward, despite ups and downs "I don't think there is an end to [rehabilitation]. You just kind of have to roll with it, figure out what the next day is going to be like, and then that is your success for that day. You survived it, you go to sleep, you wake up, and you do it." *- Lorena, 37 y.o. W, TT, cancer*
Being able to live MY normal life and do the things I want to do "…what is my ability to just get through my day or any activity like I would any other time? I mean…there may be a different way I have to approach something, but I'm still able to reach the same conclusion." *–Manuel, 53 y.o. M, TT, infection*
Learning what works for me and how to manage my prosthesis "…I think success is being knowledgeable about what's out there and being able to make the right choices that are going to benefit you and help you be comfortable for as long of the day as possible." *– George, 35 y.o. M, TT, trauma*
Only I can define my success "They [providers] probably all have their ideas. But we're human beings, and we're individually unique….So everybody's idea of success is going to be different….the only person that can truly, realistically define success is the individual. There's just no two ways about it." *– Max, 63 y.o. M, TT, dysvascular*
What about my mental health? "…the key, number one thing that is a health issue for all of us I think is mental health...it impacts me on levels that I never anticipated or expected…So I would say mental health is not a part of it, I think it's key to the whole thing [success]." *–Lucas, 53 y.o. M, TT, infection*

DISCUSSION

Participants in our study described success with an LLP in terms of resiliency and individuality. Our findings on success also align with existing literature that describes the importance of function, participation, and individual needs.[2,3] Participants also described a desire for patient-driven care, in which LLP users are empowered to define what "success" means to them.

CONCLUSION

Emergent themes provide insight into LLP users' perceptions of success after amputation. These themes should be compared with perceptions of related stakeholder groups (e.g., prosthetists, therapists, doctors, and manufacturers) to assess areas of agreement and discord between groups.[1]

CLINICAL APPLICATIONS

Defining success is critical to effectively assessing outcomes that matter most to LLP users. This process must be directed by the user. However, stakeholders should be aware that success also changes over time and must be revisited periodically through explicit provider/user conversations.

REFERENCES

1. Van der Linde H, et al. *Disabil Rehabil.* 2007;29(13):1049–1055.
2. Schaffalitzky E, Gallagher P, Maclachlan M, Ryall N. *Disabil Rehabil.* 2011;33(15-16):1314–1323.
3. Schaffalitzky E, Gallagher P, Maclachlan M, Wegener ST. *Disabil Rehabil.* 2012;34:2085-2094.

Funded by the Orthotic and Prosthetic Education and Research Foundation (OPERF).

Influences of Low Back Pain on Trunk Momentum during Sit-to-Stand in Lower-Limb Prosthesis Users

TE Parr,[1,2,4] S Farrokhi,[1,2] BD Hendershot,[1,3] A Bunn,[1,2] CM Butowicz[1,3]

[1]DoD-VA Extremity Trauma & Amputation Center of Excellence; [2]Naval Medical Center, San Diego, CA; [3]Walter Reed National Military Medical Center, Bethesda, MD; [4]Oak Ridge Institute for Science and Education, Oak Ridge, TN

INTRODUCTION

Sit-to-stand (STS) tasks are an important activity of daily living requiring trunk momentum to assist the transition from sitting to standing, particularly among injured populations. During STS, persons with versus without lower-limb amputation (LLA) increase trunk flexion and velocity.[1,2] While large and asymmetric trunk motion may contribute to the development or progression of low back pain (LBP) among persons with LLA,[3] it is unclear how LBP affects trunk momentum generation for completion of STS or overall task performance. Thus, this study aimed to determine the differences in trunk rotational angular momentum (RAM) among persons with LLA, with and without LBP.

METHOD

Subjects: Sixty-three prosthesis users with unilateral LLA [49 with transtibial amputation (TTA) and 14 with transfemoral amputation (TFA)] were recruited from community events and for this analysis were grouped based on presence of LBP (LBP: 25TTA/9TFA, 25 males / 9 females, age = 34.9±7.7 years, mass = 86.0±19 kg, height=175.9±7.7 cm; no LBP: 24TTA/5TFA, 20 males / 9 females, age = 32.7±8.4 years, mass = 84.2±17 kg, height = 176.1±7.7 cm). Informed consent was obtained prior to testing.

Apparatus: Eight triaxial Inertial Measurement Units (IMUs; Opal, Generation 2, APDM, Inc, Portland, OR) were placed bilaterally on the feet, shanks, and thighs, as well as the sacrum and sternum.

Procedures: Subjects performed 5 STS with their arms crossed in front of their chest. Subjects were encouraged to perform the task quickly and were timed until completion.

Data Analysis: Angular velocity was filtered through a 4th order Butterworth filter with a 10 Hz cut-off frequency. Trunk moment of inertia about the hip joint was found using anthropometric principles for mass and radius of gyration. Peak trunk RAM during the transition (40–50% STS), defined as the time point trunk forward flexion ends (~45% STS, T*),[4] was compared between persons with versus without LBP using ANCOVA with level of amputation as a covariate. Significance was set at $p<0.05$.

RESULTS

Task completion time (LBP=11.8s, no LBP=11.35s; p=0.40) and trunk RAM (LBP=20.3 kg.m2/s, no LBP=16.2kg.m2/s; F (1,60)=0.435, p=0.51) was marginally larger in persons with versus without LBP.

DISCUSSION

Greater peak trunk RAM at transition (T*) in persons with LBP supports previous research that excessive trunk motions are correlated to LBP in persons with LLA. Increased trunk RAM (and velocity) in late trunk flexion may be due to trunk strength impairments from LBP or a compensation for lack of confidence or strength in the lower limbs for subsequent knee extension and critical RAM needed for STS.[5]

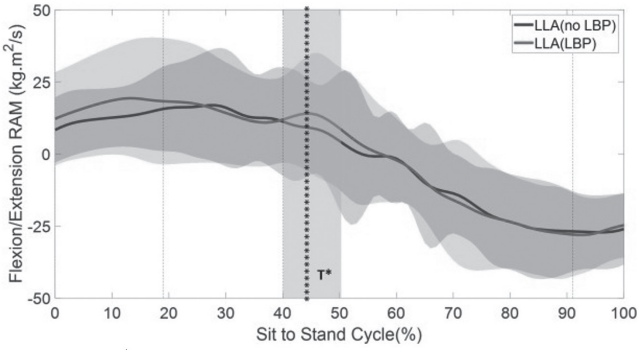


Figure 1. Sagittal trunk RAM of persons with LLA with vs. without LBP during STS. [T*=transition point (range considered- gray)]

CONCLUSION

Increases in peak trunk flexion RAM to achieve STS, especially during the transition point, may be linked to presence of LBP in persons with LLA.

CLINICAL APPLICATIONS

Better understanding the relationship between trunk momentum development and LBP may assist in movement retraining and assistive device prescriptions to reduce excessive pelvis and trunk movement associated with LBP.

REFERENCES

1. Agrawal V. *Ergonomics.* 2011;54(7):656–664.
2. Devan H, et al. *Disabil Rehabil.* 2015;37(10):873–883.
3. Highsmith MJ, et al. *Gait Posture.* 2011;34(1):86–91.
4. Li J, et al. *Medicine.* 2021;100(22):e26208.
5. Riley PO, Schenkman, ML, Mann RW, Hodge WA. *J Biomech.* 1991;24(1):77–85.

ACKNOWLEDGEMENTS

This work was supported, in part, by an appointment to the DoD Research Participation Program administered by ORISE (contract number DE-SC0014664). The views expressed herein are those of the authors and do not reflect the official policy of USU, US Departments of the Army/Navy/Air Force, DoD, or the US Government.

Ground Reaction Forces during Running and Walking with a Bimodal Run/Walk Ankle Prosthesis

KA Perrin,[1] LA Nolasco,[1] C Nwokeabia,[1] JL Johansson,[2] B Bokser,[2] K Keough,[2] S Park,[2] K Lawrence,[2] TR Farrell,[2] DH Gates[1]

[1]University of Michigan, Ann Arbor, MI; [2]Liberating Technologies, Inc. Holliston, MA

INTRODUCTION

High-activity, daily-use prostheses (DUPs) offer flexibility for use in running activities and can eliminate the need to switch into running-specific prostheses (RSPs). However, RSPs were designed to provide greater energy storage and return[1] and thus provide greater propulsive ground reaction forces (GRFs) compared to running with a DUP.[2] This is significant as the amputated side hip muscles compensate for the lack of ankle propulsion by generating greater hip work during running with DUPs compared to RSPs.[2] As an alternative, Liberating Technologies Inc. developed a bimodal foot, the CAESAR, which switches foot geometries for running and walking. The purpose of this study was to compare GRFs with the CAESAR foot to a DUP during walking and running. We expected that the CAESAR foot would have similar characteristics to an RSP during running and to a DUP during walking.

METHOD

Participants: Four males with unilateral transtibial amputation consented to participate in this IRB-approved study (Table 1).

Procedures: Participants ran on a treadmill and walked overground with the bimodal CAESAR foot, a commercial high-activity DUP (Fillauer AllPro, Chattanooga, TN), and their prescribed DUP and RSP, if they had one. We collected GRFs from 7 force plates as participants walked across 10 meters at a fixed speed based on leg length (~1.2 m/s). Participants ran on an instrumented treadmill at a comfortable speed for 5 minutes. Only the first 2 participants are included for running as the other 2 participants were not comfortable running without significant hand support.

Table 1. Participant details.

ID	Age (years)	K-Level	Prescribed Feet (Walk; Run)
P01	41	4	Freedom Renegade AT; Össur Flex-Run
P02	31	4	Össur Proflex XC; none
P03	67	3	College Park Soleus; none
P04	57	4	Ottobock Empower; none

Data Analysis: We determined peak GRF in all 3 directions during specific phases of the movement. Given the small sample size, we calculated the effect size for each comparison during walking using Cohen's d. We did not perform statistics on running data. Instead, we compared differences between feet in peak GRFs to the between-session minimal detectable change (MDC) of horizontal (4% BW) and vertical (9% BW) forces during sprinting.[3]

RESULTS

Walking: Participants had a larger peak anterior GRF on their amputated side (d=0.89) and smaller first peak vertical GRF on their intact side (d=1.17) with the CAESAR compared to AllPro (Figure 1A).

Running: The two participants who ran had greater amputated side peak anterior and vertical GRFs with the CAESAR foot compared to AllPro and prescribed (Figure 1B). P01 also had greater intact side posterior peak GRFs with the CAESAR compared to the AllPro. P02 had greater intact side peak vertical GRF with the CAESAR foot compared to AllPro or prescribed.

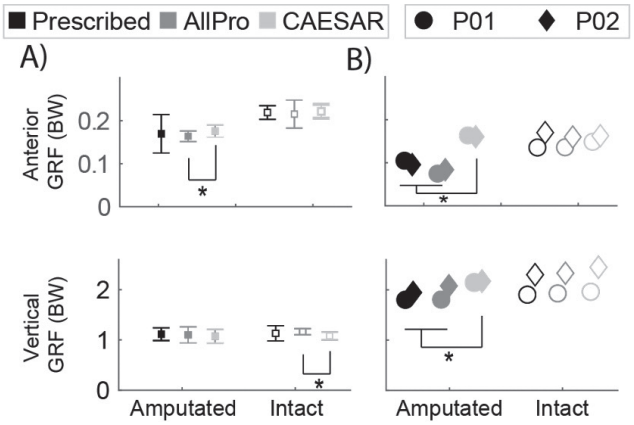


Figure 1. (A) Average GRF during walking. (B) Individual data for running. P01 (o) ran on a blade, while P02 (◊) ran on his DUP.

DISCUSSION

Participants had greater anterior and vertical GRF with the bimodal CAESAR foot in walking and running compared to their DUPs. While promising, this study is limited by the small sample. Future work will include a larger sample, with recreational runners.

CONCLUSION

The bimodal CAESAR foot may be beneficial for increasing propulsion during running and walking.

CLINICAL APPLICATIONS

The bimodal CAESAR can allow individuals to use a single foot for running and walking without compromising push-off mechanics.

REFERENCES

1. McGowan CP, et al. *J R Soc Interface.* 2012;9(73):1975–1982.
2. Sepp LA, Baum BS, Nelson-Wong E, Silverman AK. *J Biomech.* 2020;101(Mar):109629.
3. Girard O, Brocherie F, Morin JB, Millet GP. *Int J Sport Phys Perf.* 2015;11(4):432–439.

Funded by DoD Award # W81XWH-19-C-0031.

Associations Between Psychiatric Symptoms and Prosthetic Use in US Combat Veterans with Above-Knee Amputations

LMG Richer,[1] MR Manley,[1] JD Mack[1,2,3]

[1]Veterans Affairs Portland Health Care System, [2]Oregon Health & Science University, [3]Legacy Good Samaritan Medical Center

INTRODUCTION

Paraphrasing Heidi Squier Kraft, war has two rules: it damages people, and doctors cannot change this.[1] Half of the troops returning to the United Stated between 2001 and 2018 screening positive for mental health needs demonstrates part of this damage.[2] Those working with amputees seek to restore part of what was lost. Little research looks at associations between physical and psychological damage related to amputation, including wartime. This study aims to expand existing research by increasing the knowledge regarding prosthetic use and psychiatric symptoms of veterans with combat-related above-knee amputations in the post 9/11 era.

METHOD

Veterans Affairs (VA) Portland Health Care System Internal Review Board gave approval 9/17/2021. Participation required the completion and return of a questionnaire packet, implying consent. An information sheet acted in lieu of an informed consent.

Participants: 1,526 charts were reviewed, 529 patients were contacted, and 54 patients participated. Included were 48 males and 1 female, ages 29 to 67 years, with amputations at levels above the knee either unilaterally (33) or bilaterally (16), and 87.8% identified as White/Caucasian.

Apparatus: A modified VA Survey for Prosthetic Use (SPS), the Questionnaire for Persons with Trans- Femoral Amputation (Q-TFA), Hospital Anxiety and Depression Score (HADS), and the Post-Traumatic Stress Disorder (PTSD) Checklist for the Diagnostic and Statistical manual of Mental Disorders V (PCL-5).

Procedures: Manual chart review identified potential participants who were contacted. In January and March of 2022, participants who did not opt out were mailed questionnaires. Participants completed and returned questionnaires by mail. Phone support was provided to participant with HADS scores of 15 or greater and/or PCL-5 scores of 33 or greater.

Data Analysis: Analysis was done with PSPP software. Pearson R correlations were run between 4 prosthetic use Q-TFA scores and 3 psychiatric symptom measures. T-test and Wilcoxon tests found significant demographics in relation to prosthetic use scores and compared psychiatric symptom scores (split for clinical intervention) with prosthetic use scores (split at mean). Demographic/prosthetic use pairings related to psychiatric scores with linear regression.

RESULTS

Correlations between Q-TFA scores and psychiatric symptoms scores are in Table 1. The most significant finding was the high positive correlation between problem scores (PS) and both anxiety and PTSD, correlation to depression was moderate. Anxiety and PTSD found statistically significant by T-test when comparing split psychiatric symptom scores and split prosthetic use scores. Significantly more problems were reported by enlisted than officers when PS scores were compared by highest military grade. Significant differences were found with Prosthetic Mobility Scores (PMS) and Global Scores (GS) when comparing scores by time to amputation (≤1 year/more).

Table 1. Pearson R Correlations between Q-TFA and Psychiatric Symptoms Scores.

	Prosthetic Use Score	Prosthetic Mobility Score	Problem Score	Global Score
Anxiety	-.225	-.584	.790	-.657
Depression	-.220	-.481	.572	-.624
PTSD	-.228	-.620	.768	-.690

DISCUSSION

Significant associations between psychiatric symptom burden and aspects of prosthetic use were shown in this cross-sectional study of veterans with amputation. Directionality of correlations highlight the trend that increased prosthetic problems are associated with greater psychiatric symptom burden. Psychiatric scores for PTSD and anxiety had the highest levels of significance. Other factors were found to impact the initial correlation between prosthetic use and psychiatric measures. Further longitudinal research with a wider lens is warranted given the small sub-population sample of this cross-sectional pilot. The narrow population and geopolitical changes at the time of the study were additional limitations.

CONCLUSION

Results support the hypothesis that there is a measurable association between psychiatric symptom burden and prosthetic use. The increased burden of psychiatric symptoms' association with prosthetic problems was highlighted. Further research is necessary.

CLINICAL APPLICATIONS

By filling the knowledge gap surrounding psychiatric symptoms and prosthesis use, clinicians will be able to improve care. This research will better support providers in overcoming barriers to care, improving the support of those living with amputation.

REFERENCES

1. Kraft HS. *Rule Number Two: Lessons I Learned in a Combat Hospital.* Back Bay Books; 2007.
2. Thomas JL, et al. *Arch Gen Psychiatry.* 2010;67(6):614-623.

Factors Associated with Participation Following Lower-Limb Amputation

JM Sions,[1] M Seth,[1] SJ Stauffer,[1,2] RT Pohlig,[3] JR Horne,[2] S Smith1, FB Sarlo[4]

[1]University of Delaware, Department of Physical Therapy; [2]Independence Prosthetics-Orthotics, Inc.;
[3]University of Delaware, Biostatistics Core; [4]Christiana Spine Center

INTRODUCTION

Participation in social, professional, and leisure activities is essential to maintaining a high quality of life.[1] Adults with a lower-limb amputation (LLA), however, experience difficulties in attaining pre-amputation participation levels, including challenges in re-integrating socially, maintaining pre-amputation employment status,[2] and participating in leisure and sports-related activities.[3] To facilitate participation post-LLA, it may be vital to mitigate the influence of factors that negatively impact post-amputation outcomes.4 Currently, however, evidence is lacking on risk factors that are likely to predict poor participation post-LLA. Once identified, risk factors could be addressed to enhance participation post-LLA. Hence, the purpose of this cross-sectional study was to determine factors that may be predictors of community participation post-LLA.

METHOD

Participants: Data was acquired from a limb loss clinic (2014–2022). Adults were included if they were aged≥18 years and had undergone a unilateral transtibial (TTA) or transfemoral (TFA) amputation ≥1-year prior.

Procedures: Community participation was assessed with Community Integration Questionnaire (CIQ). Factors: i.e., demographics, comorbidities, prosthesis-use (per Houghton Scale), Socket Comfort Score, assistive device use, falls history, and activity level [per General Practitioner Physical Activity Questionnaire (GPPAQ)] were evaluated. Additional factors including balance confidence [per the Activities-Specific Balance Confidence Scale (ABC)], mobility [per Locomotor Capabilities Index (LCI)], fast and self-selected gait speed [per 10-Meter Walk Test (10mWT)] and functional mobility [per Timed Up and Go (TUG)], were also included in this study seeking to identify potential risk factors for future longitudinal research.

Data Analysis: To identify the strongest predictors, we used a 2-step process. First, for all potential predictor variables, correlation analyses with CIQ were conducted. Then, variables correlated with CIQ were entered into a stepwise regression model (entry $\alpha \leq 0.50$; removal $\alpha \leq 0.10$).

RESULTS

Table 1. Participant characteristics.

	Sex*	Age (y)	Time since LLA (y)	CIQ
TTA (n=82)	F=27; M=55	59±14	13±15	16±5
TFA (n=44)	F=12; M=32	59±14	19±19	18±5

Abbreviations: LLA: Lower-limb amputation; CIQ: Community Integration Questionnaire (0-29); TTA=Transtibial amputation; TFA=Transfemoral amputation; F=Females; M=Males; y=years.

*Data presented as n rather than mean (standard deviation).

According to the analyses, participation (CIQ) was significantly (p<0.050) correlated with demographics (i.e., age, amputation level, etiology, time since amputation); comorbidities (heart disease, peripheral neuropathy, diabetes, phantom sensation, and phantom pain); Houghton Scale; GPPAQ; and physical function (per ABC, LCI, 10MWT, and TUG). The final model yielded GPPAQ, ABC, peripheral neuropathy, and Houghton Scale as the strongest potential predictors, explaining 50% of the variance in CIQ.

Table 2. Stepwise regression results for participation.

		B[λ]	Sig.
GPPAQ[Σ]			
	Inactive	-3.990	<0.001
	Moderately Inactive	-0.044	0.578
	Moderately Active	0.045	0.613
ABC		0.063	0.003
Peripheral Neuropathy		-2.327	0.038
Houghton Scale		0.510	0.044
R^2		**50.1%***	

[λ]Values presented are unstandardized beta coefficients.

[Σ]Reference group is GPPAQ Active.

R^2 refers to total variance explained by final model.

*p< .050 for final model.

DISCUSSION

Community participation post-LLA may be influenced by several modifiable and non-modifiable factors identified in this study. Specifically, adults with LLA who have higher self-reported physical activity, greater balance-confidence, greater prosthesis use, and lack peripheral neuropathy are likely to have greater community participation.

CONCLUSION

While environmental and psychosocial factors are common barriers to participation post-LLA, addressing identified modifiable factors may be critical during rehabilitation to enhance participation. Results support future longitudinal studies evaluating identified factors.

CLINICAL APPLICATIONS

Physical activity, balance confidence, prosthesis use, and peripheral neuropathy may be factors that significantly impact community participation post-LLA.

REFERENCES

1. Dijkers MP, et al. *Arch Phys Med Rehabil.* 2010;91:5–16.
2. Roepke AM, et al. *Am J Phys Med Rehabil.* 2017;96(1):741–747.
3. Gallagher P, Donovan MA, Doyle A, Desmond D. *Prosthet Orthot Int.* 2011;35(3):278–284.
4. Kahle JT, et al. *Technol Innov.* 2016;18(2-3):125–137.

Effect of Commercial Prosthetic Foot Stiffness on Intact Knee Loading, Foot-Ankle Biomechanics, and User Perception

C Slater,[1] EG Halsne,[2,3] DC Morgenroth[2,3]

[1]Hanger Clinic, [2]VA RR&D Center for Limb Loss and Mobility (CLiMB), [3]University of Washington

INTRODUCTION

When prescribing a prosthetic foot, clinicians choose a stiffness category to match the user's body weight and activities. Previous studies have demonstrated effects of foot stiffness on a range of user gait biomechanics. For example, increased prosthetic forefoot stiffness has been associated with decreased prosthesis push-off power but increased intact limb loading.[1,2] However, these studies used experimental feet, which may not be representative of commercial foot properties, and the effects of commercial foot stiffness remain unclear.[3] The purpose of this study was to assess if changing foot stiffness +/- 1 category from manufacturer recommendation, while maintaining prosthetic alignment, would impact prosthetic foot biomechanics and intact limb knee loading. A secondary goal was to assess if users could accurately perceive changes in foot stiffness.

METHOD

Participants: Seventeen males with unilateral transtibial amputation were enrolled (age: 49.2±15.3 years; height: 69.3±4.1 inches; weight: 196.2±36.0 lbs.; time since amputation: 9.6±12.7 years). Most amputations were due to trauma (N=12), followed by dysvascular disease (N=3). Informed consent was obtained from all participants and all procedures were IRB approved.

Apparatus: A motion-capture system and in-ground force plates were used to collect biomechanical data while participants walked at a fixed speed. Outcomes included prosthetic foot rollover radius, peak push-off power, and peak intact knee external adduction moment (EAM) and loading rate. Participants were also queried regarding perceived foot stiffness.

Procedures: Participants trialed 3 Össur Variflex feet with varied stiffness categories (medium=manufacturer-recommended based on participant weight and medium activity, stiff = +1 category, soft = -1 category). Participants were fit with the medium condition first with alignment optimized, followed by the other two conditions in randomized order without changing alignment. Participants were blinded to foot condition throughout testing.

Data Analysis: Biomechanical data were processed in Vicon Nexus and outcomes were calculated in Matlab. Linear mixed-effects regression was performed in R.

RESULTS

For each increase in foot stiffness category, there was an estimated 0.028 Nm/kg mean decrease in intact knee EAM (p<.001) and 0.795 Nm/s kg decrease in EAM loading rate (p=.016). With each increase in stiffness category, there was an estimated 1.6 cm mean increase in foot rollover radius (p<.001) and 0.165 W/kg decrease in prosthetic peak push-off power (p<.001) (Figure 1). When asked to rate the foot stiffness, 15/17 participants identified the soft foot as having the lowest stiffness, and all 17 participants identified the stiff foot as having the highest stiffness.

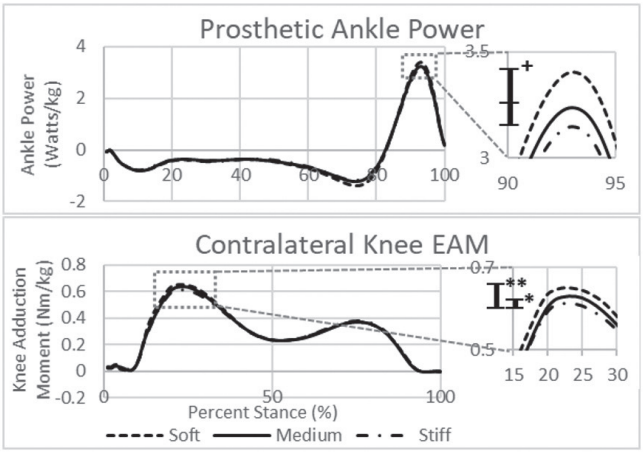


Figure 1. Ensemble averages for prosthetic ankle power and intact knee EAM. *= significant difference between medium & stiff; **= significant difference between soft & stiff; + = significant difference between all conditions.

DISCUSSION AND CONCLUSION

Increasing prosthetic foot stiffness while maintaining alignment resulted in decreased prosthetic foot push-off power and decreased intact knee EAM. While prior studies have demonstrated a correlation between increased energy return and decreased intact limb loading in experimental prosthetic feet, the present study evaluated commercial foot stiffness and controlled for prosthetic alignment between conditions. By not mediating the effect of stiffness with alignment changes across foot conditions, a "drop-off" effect was observed when using a softer versus stiffer foot. In addition, participants were able to accurately discern respective differences between prosthetic feet.

CLINICAL APPLICATIONS

Increased intact loading is associated with the development of knee osteoarthritis, with knee EAM being a predictor.[4] Optimizing prosthetic foot stiffness may be a strategy to mitigate the increased risk of intact limb knee OA.

REFERENCES

1. Fey NP, Klute GK, Neptune RR. *Clin Biomech*. 2011;26: 1025–1032.
2. Adamczyk PG, Roland M, Hahn ME. *Hum Mov Sci*. 2017;54(Aug):154–171.
3. Halsne EG, Czerniecki JM, Shofer JB, Morgenroth JC. *Clin Biomech* (Bristol, Avon). 2020;80(Dec):105141.
4. Morgenroth DC, Medverd JR, Seyedali M, Czerniecki JM. *Clin. Biomech* (Bristol, Avon). 2014;29(6):664–670.

Funded by VA RR&D Career Development Award-2 No. A7489W.

Hip Check: Active Range of Motion Is Related to Physical Function among Adults with Transtibial Amputation

SJ Stauffer,[1,2] M Seth,[1] SC Smith,[1] JR Horne,[2] JM Sions[1]

[1]University of Delaware, Department of Physical Therapy, Delaware Limb Loss Studies, Newark, DE;
[1]Independence Prosthetics-Orthotics, Newark, DE

INTRODUCTION

Maintenance of hip range of motion (ROM), which is vital after transfemoral amputation given contracture risk,[1] may be just as important for adults with transtibial amputations (TTA). Among older adults without TTA, reduced hip extension and abduction ROM is associated with increased risk of falls and poorer balance.[2]

Loss of active ROM may be a contributor to reduced functional mobility as this is the range available for use when transferring, ambulating, and regaining balance. Active ROM is determined by joint capsule tightness and passive muscle tension, as well as agonist muscle strength.[3] However, taking hip ROM in multiple planes (e.g., flexion, abduction) may not be feasible in prosthetic practice given appointment time constraints. Therefore, the purpose of this study was to assess relationships between active hip ROM and physical function among adults with TTA to aid in the prioritization of hip active ROM in clinical assessments.

METHOD

We conducted a secondary analysis of data obtained from adults with unilateral TTA during outpatient interdisciplinary limb loss clinics held from September 2013 to December 2021 (IRB #531197).

Participants: Individuals (n=74) were 58.6±14.7 years old; 69% were male, and 57% experienced TTA due to dysvascularity. Median time since amputation was 6.5 (25th, 75th percentile: 2, 19.5) years.

Outcome Measures: Bilateral active (sound- and residual-side) hip flexion, extension, adduction, and abduction ROM; Amputee Mobility Predictor (AMP); Timed Up and Go (TUG); 10-Meter Walk Test performed at "self-selected" gait speed (SSGS).

Table 1. Outcome measures.

	Total Sample (n=74)
Hip Active ROM Measurement (°)	
Sound Flexion	95.0±15.2
Residual Flexion	99.2±12.2
Sound Extension	5.6±5.7
Residual Extension	5.8±6.6
Sound Abduction	27.3±10.0
Residual Abduction	27.5±9.9
Sound Adduction	17.6±7.7
Residual Adduction	15.8±7.9
Performance-based Measures	
Amputee Mobility Predictor, 0-47*	42 (39, 45)
Timed Up and Go, sec*	11.27 (8.17, 15.49)
10-meter Walk Test, m/sec	0.96±0.30

*Data presented as median (25th, 75th percentile) rather than mean ± standard deviation.

Abbreviations: ROM=range-of-motion; °=degrees; sec=seconds; m=meters.

Data Analysis: The 8 ROM measures were reduced using principal component analyses, which combined sound- and residual-side measurements to yield 4 principal components. Multivariate regression was used to examine the relationships ($p \leq 0.05$) between the principal components and performance outcomes.

RESULTS

Participants on average showed globally reduced active hip ROM bilaterally (Table 1). Resultant principal components 1–4 were loaded by extension, adduction, flexion, and abduction, respectively. Extension ROM was associated with AMP score ($p=0.001$), TUG time ($p=0.040$), and SSGS ($p<0.001$). Flexion ROM was associated with AMP score ($p=0.010$), TUG time ($p=0.001$), and SSGS ($p<0.001$). Abduction ROM was associated with AMP score ($p=0.018$), and TUG time ($p=0.033$). Adduction was not associated with performance measures ($p>0.05$).

DISCUSSION

Results suggest greater hip active ROM is associated with better physical function post-TTA, which aligns with findings in older adults with intact limbs, where reduced ROM predicts functional decline.[4]

Sagittal plane active ROM was related to all 3 performance measures evaluating functional mobility. Results may be explained by the need for greater flexion and extension (compared to other hip ranges) necessary for foundational activities.[5]

Active abduction ROM was significantly related to AMP and TUG, but not gait speed. Results might be due to required active abduction ROM for balance-related tasks,[5] as balance is assessed with AMP items and transfers and turning required by the TUG.

With respect to physical function, adduction ROM may be the least important to evaluate. Further research is needed to identify the functional impact of sound-side versus residual-side active ROM limitations over time.

CONCLUSION

This study indicates reduced active hip ROM in flexion, extension, and abduction may help explain reduced physical function among adults with unilateral TTA.

CLINICAL APPLICATIONS

Clinicians may prioritize hip flexion, extension, and abduction ROM measurements over adduction, when seeking to identify deficits that, if addressed, might improve physical function among adults with TTA.

REFERENCES

1. Jaegers SM, Arendzen JH, de Jongh HJ. *Clin Orthop Relat Res.* 1995;319(Oct.):276–284.
2. Chiacchiero M, et al. *Top Geriatr Rehabil.* 2010;26(2): 148–155.
3. Bohannon RW, et al. *Clin Rehabil.* 1991;5(3):219–224.
4. Coyle PC, et al. *ACR Open Rheumatol.* 2021:3(12):850–859.

OASIS 2: Mobility Differences with Specific Prosthetic Feet Across Procedure Codes

TA Miller, DL England, PM Stevens, JH Campbell, SR Wurdeman

Hanger Institute for Clinical Research and Education, Austin, TX

INTRODUCTION

In 2020, many prosthetic devices were subjected to reimbursement coding review by PDAC. Several prosthetic feet that were historically coded L-5987 with the shock-attenuating function were recoded to L-5981. The purpose of this analysis was to compare patient-reported functional mobility across a range of prosthetic feet using real-world clinical outcomes data to assess whether differences based on mechanical features aligns with functional benefits.

METHOD

Participants: Final sample of 526 individuals were included for analysis (Table 1). Analysis was limited to adults age ≥18 years confirmed to receive 1 of the specific prosthetic feet in the 4–12 weeks prior to the completion of outcomes.

Apparatus: Mobility was measured using the Prosthesis Limb Users Survey of Mobility (PLUS-M).[1]

Procedures: Patient outcomes were analyzed 4–12 weeks after patient began wearing the specific prosthetic foot type. There were 4 categories of feet: Sustained-87 (i.e., historically L-5987), Modified (i.e., L-5987 code changed to L-5981), Not-Reviewed (i.e., historically L-5987 but not yet reviewed by PDAC), and Original-81 (i.e., historical L-5981 for comparison). These encompassed 10 specific manufacturer make/models (Figure 1). The current analysis was approved through WCG Investigation Review Board.

Data Analysis: ANOVA and generalized linear models were used to assess mobility across foot categories.

RESULTS

The comparison of prosthetic foot categories were significantly different from the control category (i.e., historically L-5981). There were no differences across the different L-5987 categories.

Across specific prosthetic feet, notably within the Modified group, the All-Pro was associated with outcomes similar to those that sustained their L-5987 code (Triton VS and Rogue).

DISCUSSION

The current study represents an analysis of real-world evidence generated during routine clinical practice. The finding that L-5987 feet are associated with increased mobility is consistent with previous work in a purely diabetic/dysvascular population.[2] The finding of similar function across feet that sustained their coding and those that were reclassified from L-5987 to L-5981 underscores the value of clinical outcomes to inform new processes by which coding decisions can be made based on the functional benefit for patients rather than mechanical features.

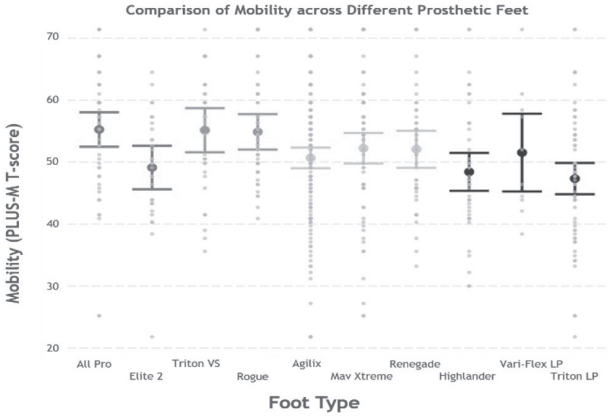


Figure 1. Mean mobility across specific prosthetic feet.

CONCLUSION

The current data suggest prosthetic foot designs using advanced materials and geometric designs can provide comparable functional benefits as those with distinct shock-absorbing mechanical features. Decision makers should be determining coding alignment based on functional benefit and not mechanical features.

CLINICAL APPLICATIONS

The ability to understand differences related to specific prosthetic feet with clinical outcomes is novel and represents an opportunity to improve patient care.

REFERENCES

1. Hafner BJ, et al. *Arch Phys Med Rehabil.* 2017;98(2):277–285, 2017.
2. Wurdeman SR, et al. *J Rehabil Assist Tech Eng.* 2019;13(6): 2055668318820784.

Table 1. Sample characteristics, means, and counts by foot category grouping.

Total n=526	Sustained-87 n=79	Modified n=83	Not-Reviewed n=250	Original-81 n=114
Mobility T-score, mean(SD)	55.0 (8.66)	52.9 (9.94)	51.3 (10.6)	48.1 (10.3)
Age, mean (SD)	49.7 (14.4)	49.6 (15.8)	52.4 (12.9)	56.5 (13.6)
Cause of amputation (n/%)				
Vascular disease/Diabetes	19 (24.1)	26 (31.3)	109 (43.6)	43 (37.7)
Trauma	27 (34.2)	25 (30.1)	64 (25.6)	26 (22.8)
Other/Unknown	33 (41.8)	32 (38.6)	77 (30.8)	45 (39.5)
Amputation level				
Transtibial/Below the knee	61 (77.2)	75 (90.4)	211 (84.4)	65 (57.0)
Transfemoral/Above the knee	18 (22.8)	8 (9.6)	39 (15.6)	49 (43.0)
Gender				
Male	71 (89.9)	68 (81.9)	213 (85.2)	86 (75.4)

Short-Term Outcomes of the Boston Brace 3D Program Based on SRS and SOSORT Criteria: A Retrospective Study

JH Wynne, LR Houle

Boston Orthotics & Prosthetics, Avon MA

INTRODUCTION

Adolescent idiopathic scoliosis (AIS) is characterized by a lateral curvature of the spine, with a Cobb angle greater than 10°, accompanied by rotation of the vertebral body. Bracing has been shown to be effective in halting the progression of at-risk curves, and, in some cases, even improving the Cobb angle by 6° or more.[1,2] The Boston Brace 3D is part of the Boston Orthotics and Prosthetics standardized scoliosis program. The orthosis is a custom-fabricated from scan, computer-aided design CAD/CAM thoracolumbosacral orthosis used in the non-operative management of AIS. The aim of this retrospective study was to evaluate the outcomes of a scoliosis program utilizing the Boston Brace 3D orthosis for patients with AIS, based on SRS and SOSORT criteria.[3]

METHOD

Participants: After filtering those who met inclusion criteria, the sample consisted of 178 patients (150 female and 28 male) with AIS, with a primary Cobb angle between 25°–40°, Risser 0–2, fit with a Boston Brace 3D within the established timeline.

Apparatus: Internal chart review of included participants with Institutional Review Board (IRB) exemption (exemption obtained by WCG IRB).

Procedures: An electronic medical records search was conducted to identify first-time brace wearers fitted between January 1, 2018, and June 30, 2019, at Boston Orthotics and Prosthetics Boston area clinics who met the SRS/SOSORT research guidelines. The initial out-of-brace, in-brace, and last follow-up X-rays (taken at least 12 months after fitting) were compared.

Data Analysis: Full sample separated into curve type, magnitude, Risser, and one-way ANOVA to compare heterogeneity between means of age, gender, and average break in wear time. Mean and standard deviation change in Cobb angle, in-brace correction, and average wear time were reported during the study period.

RESULTS

Eighty-four percent of patients presenting with a single curve and 69% of patients with a double curve saw their curves improve (reduced 6° or more) or remain unchanged (±5°). Eight of the 178 patients (4%) have progressed to surgery to date. In general, the patients who wore their brace for more hours per day saw improved results.

DISCUSSION

Our study adds to the body of evidence that orthotic management is effective in stopping scoliotic curve progression and can show reduction of Cobb angle over the course of treatment. It also indicates that wear time is an important factor in the outcome of a bracing program.

Limitations include patients lost to follow up, thus not completing the bracing program. Additionally, not all patients had complete objective average hours of wear time data.

Future studies should have all included patients with objective wear time data, be prospective, and include quality of life questionnaires at beginning and end of treatment.

CONCLUSION

The Boston Brace 3D program is effective in controlling (and in some cases improving) curve progression in the non-operative management of adolescent idiopathic scoliosis. The approach is a repeatable system, as shown in this cohort of thirteen clinicians across six area clinics following the Boston Brace 3D clinical guidelines.

CLINICAL APPLICATIONS

This study furthers our knowledge of effective orthotic management of AIS and identifies further areas of development in clinical programs and multidisciplinary programmatic approaches that are aimed at non-operative management of scoliosis.

REFERENCES

1. Weinstein SL, Dolan LA, Wright JG, Dobbs MB. *N Engl J Med.* 2013;369(16):1512–1521.
2. Katz DE, Herring A, Browne RH. *J Bone Joint Surg Am.* 2010;92(6):1343–1352.
3. Negrini S, Boards S, Hresko TM, O'Brien JP, Price N. *Scoliosis.* 2015;10(1):1–12.

Table 1. Cobb angle changes and dose double curves.

Cobb Angle Change	N (%)	Break-In Average Wear Time Hours/Day	Number of Break-In Reads (%)	2nd Average Wear Time	Number of Second Reads	Third Average Wear Time	Number of Third Reads
Improved (6° or more)	32 (25%)	10.2 ± 3.29	28 (88%)	14.91 ± 3.79	20 (63%)	15.6 ± 3.07	17 (53%)
Unchanged (±5°)	56 (44%)	10.98 ± 3.76	41 (73%)	12.72 ± 5.02	35 (63%)	13.29 ± 4.61	29 (52%)
Progressed (6° or more)	39 (31%)	7.6 ± 3.64	33 (85%)	7.84 ± 4.45	23 (59%)	7.67 ± 4.59	17 (44%)

Table 2. Cobb angle changes and dose single curves.

Cobb Angle Change	N (%)	Break-In Average Wear Time Hours/Day	Number of Break-In Reads (%)	2nd Average Wear Time	Number of Second Reads	Third Average Wear Time	Number of Third Reads
Improved (6° or more)	14 (27%)	11.02 ± 3.63	13 (93%)	15.6 ± 3.42	13 (93%)	15.5 ± 3.62	10 (71%)
Unchanged (±5°)	29 (57%)	10.47 ± 3.79	23 (79%)	13.97 ± 4.14	27 (93%)	14.1 ± 4.13	16 (55%)
Progressed (6° or more)	8 (16%)	6.94 ± 3.07	7(88%)	10.66 ± 3.58	5 (63%)	8.2 ± 3.87	5 (63%)

Treatment of Proximal Junctional Kyphosis Following Lumbar Fusion: A Case Study

Emily A. Steffensen, MS, CPO[1,2]

[1]University of Nebraska at Omaha, Department of Biomechanics, [2]Hanger Clinic

INTRODUCTION

Proximal junctional kyphosis (PJK) is a common complication in operative treatment of spinal deformity.[1] PJK is symptomatic kyphosis occurring superior to the fused segments.[2] Severe kyphosis significantly affects aerobic capacity and respiratory efficiency,[3] requiring treatment to prevent these negative outcomes. Lack of compliance with bracing inhibits treatment success.[4] Therefore, it is imperative to adopt a holistic approach during orthotic treatment plan development for effective control and compliance. This case study aims to demonstrate how clinical decision-making that integrates the patient, caregivers, medical providers, and orthotist results in positive orthotic outcomes. This case study demonstrates the use of this holistic approach to effectively treat PJK.

CASE PRESENTATION

The patient, a 15-year-old male, was assessed for orthotic treatment of PJK. He had history of lumbar scoliosis and underwent a spinal fusion (T11–L4). Four months following surgical fusion, there was an observed loss in patient height (1.5 inches) and excessive thoracic kyphosis. The patient could not identify any acute injury associated with these changes but reported having previous broken bones from mild injuries and a family history of excessive kyphosis with mild-type osteogenesis imperfecta (OI). Radiographs showed stable fusion hardware with T7 vertebra subacute fracture and T7, T10, and T11 compression deformities, and diagnosed with PJK measured as 55 degrees with T7–T8 apex. He was prescribed a Milwaukee CTLSO while awaiting genetic testing for OI. The patient reported midback pain increasing with long periods of sitting or standing. He could actively correct his sagittal alignment slightly, and manual correction could be achieved.

MANAGEMENT AND OUTCOME

Due to psychosocial implications of Milwaukee CTLSO use, the patient and parents rejected this treatment plan, and alternatives were discussed. A custom hyperkyphosis TLSO design was agreed upon. The patient was photographed, measured, and 3D-scanned (Structure Scanner, iPad) for orthosis fabrication. TLSO design included anterior opening, anterior superior trim lines just inferior to the clavicles, and corrective force at the level of the kyphotic apex to neutral sagittal alignment.

At initial fitting, immediate sagittal postural improvement was achieved during standing. The patient tolerated the TLSO, well and both patient and parent were pleased with postural correction. A gradual break-in schedule was implemented for 1 week. At follow up, the patient reported that the orthosis has been well-tolerated and is worn full-time when the patient is vertical. Additional corrective pad and stabilizing force pads were added, and in-brace radiographs were obtained. Radiographic findings indicated a reduction in kyphosis from 55 to 38 degrees in-brace.

At the four-month follow-up appointment, the patient and parent report the orthosis is well-tolerated, and the compliance monitor indicates 16–18 hours of wear time per day. Genetic testing revealed an underlying X-linked osteoporosis for which the patient had begun infusion treatments. Orthotist and medical provider continue to follow up in tandem at 4-month increments.

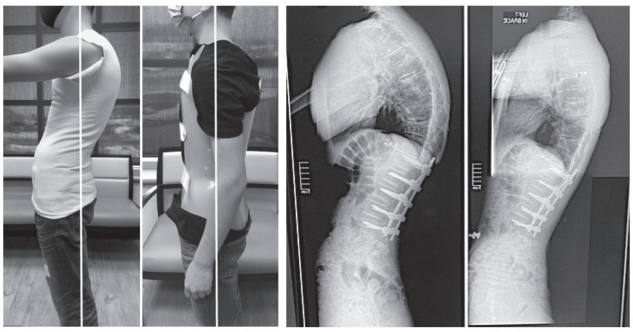


Figure 1. Photographic (Panel A) and radiographic (Panel B) representation of patient pre- and post-orthotic treatment.

DISCUSSION

This case study demonstrates the successful orthotic treatment of PJK with unique underlying pathology. The clinical decisions made to treat this patient were done in consideration of biomechanical principles, medical status, psychosocial impacts of orthosis use, and patient and parent goals, resulting in reduction of kyphosis in-brace and high patient compliance. This case study is limited, as one individual with a unique presentation may not be representative of a larger population and what might constitute successful treatment.

CONCLUSION

Collaboration between patient, caregivers, medical providers, and orthotist can result in positive orthotic outcomes despite unique and challenging circumstances. Orthotists should prioritize patient input in addition to biomechanical goals, and advocate for them accordingly.

REFERENCES

1. Huq S. *J Neurosurg Spine.* 2019;32(2):235–247.
2. Sinagra Z. *ANZ J Surg.* 2020;90(4):597–601.
3. Lorente A. *Spine J.* 2019;19(2):330–338.
4. Piazzolla A. *Spine Deform.* 2021;9(2):549–557.

A Wearable Ultrasound System for Controlling an Upper-Limb Prosthesis

SA Acuña, A Bashatah, RF Sutherland, RR Kaliki, S Sikdar

George Mason University, Fairfax, VA

INTRODUCTION

Surface electromyography (EMG) has become the primary means for sensing residual muscle activity to actuate a prosthetic hand. However, EMG has a low signal-to-noise ratio and is subject to crosstalk from adjacent muscles, which makes it difficult to derive a large set of control signals. Sonomyography (SMG) is a promising alternative to EMG that uses ultrasound imaging to non-invasively record superficial and deep muscle activity, making it possible to differentiate the independent contributions of individual muscles during functional movements.[1] From these ultrasound signals, prosthesis control signals can easily be extracted in real time using machine learning models trained to recognize patterns of muscle deformation corresponding to a user's intentions.[2] Recent advances in ultrasound signal processing now permit miniaturization of ultrasound systems using low-voltage commodity hardware that can be embedded into an upper-limb prosthesis.[3] To demonstrate the feasibility of SMG to control an upper-limb prosthesis, we present a 4-channel wearable ultrasound system capable of extracting a large set of independent prosthesis control signals from forearm muscle activity.

METHOD

Participants: Five able-bodied subjects (age: 21–30) with no history of neuromuscular impairment participated in the feasibility study.

Apparatus: Our ultrasound system (Figure 1) consists of four single element ultrasound transducers, a power regulation subsystem, hardware for four-channel signal processing, and a processor capable of executing machine learning classification algorithms in real-time.

Procedures: Subjects repeatedly performed 5 unique hand grasps (rest, key, tripod, power, point) to collect training and testing data for the machine learning algorithm. Four wearable ultrasound transducers placed over the forearm muscles collected m-mode ultrasound data that was then input to the processor. Our human testing protocol was approved by the George Mason University Institutional Review Board, and all human subjects provided written informed consent before participating in this research.

Data Analysis: We trained a linear discriminant analysis algorithm to predict the 5 grasps. A separate set of collected data was then used to test the classification accuracy in offline settings.

RESULTS

Our wearable ultrasound system could predict a user's intended hand grasp with remarkable accuracy during offline testing (Global Median = 89.1%, Global Std Error = 4.9%). Participants also reported that the system could reliably detect their hand grasp during real-time testing (as confirmed by a computer monitor).

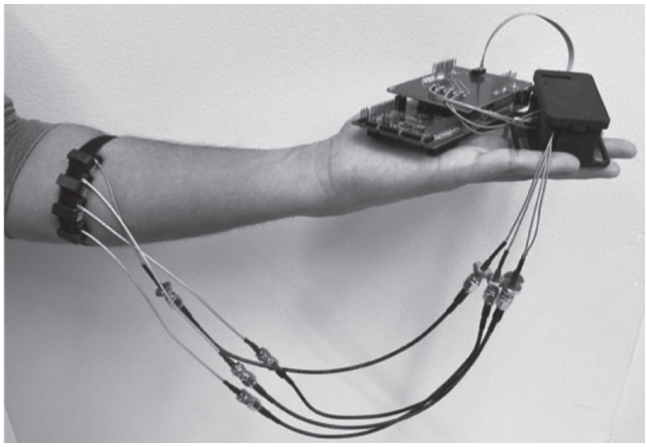


Figure 1. Our wearable ultrasound system can be embedded into an upper-limb prosthesis to extract prosthesis control signals from forearm muscle activity.

DISCUSSION

Our wearable SMG system can reliably record m-mode ultrasound imaging signals, which can be used to classify hand grasps. We believe SMG is a promising modality for restoring dexterous movement to individuals using upper-limb prostheses. One of the primary benefits of SMG is that muscle activity can be sensed with high spatial specificity, even in deep-seated muscle compartments. It is also noteworthy that full-resolution ultrasound imaging is not required to achieve robust classification, as only 4 ultrasound scanlines are required. We are currently working on packaging all the hardware components to fit within a socket alongside the hardware to drive a multiarticulate prosthetic hand.

CONCLUSION

Because our approach enables miniaturization of ultrasound instrumentation using low-voltage commodity hardware, we envision a future with SMG as a viable option for upper-limb prosthesis control.

CLINICAL APPLICATIONS

We previously showed that a tethered SMG-controlled prosthesis can perform functional tasks in real-time.[1] We now present a miniature, wearable SMG control system that can be embedded into an upper-limb prosthesis as feasible alternative to EMG control.

REFERENCES

1. Engdahl SM, et al. *Front Bioeng Biotechnol.* 2022(May).
2. Dhawan AS et al. *Sci Rep.* 2019;9(1):9499.
3. Bashatah A, et al. *Acoustical Soc Am.* 2021;150(4):A289.

Funded by NIH Award No. 5U01EB02760, DoD Award No. W81XWH-16-1-0722, and Virginia CCF Award No. MF19-108-LS.

Preliminary Results from Task-Based Calibration of Pattern Recognition Control in a Virtual Reality Environment

GT Baer,[1] LA Miller,[1,2] KL Turner,[1] AM Simon,[1,2] LJ Hargrove[1,2]

[1]Shirley Ryan AbilityLab, Chicago, IL; [2]Northwestern University, Chicago, IL

INTRODUCTION

Pattern recognition (PR) control of myoelectric upper-limb prostheses is clinically available and growing in popularity. PR systems require calibration to create a mapping between electromyographic (EMG) signals and control outputs. Standard calibration (SC) builds a PR classifier from EMG data collected and labelled while a user attempts to perform the movement displayed on a computer screen or demonstrated by pre-programmed prosthesis movement.[1] While convenient and effective to quickly calibrate a controller, SC may not elicit the same motor response as when performing a functional task.[2] A new method of calibrating, called "task-based calibration" (TBC) is proposed, in which a user mimics the movement of a hand performing a functional task. This study assessed whether TBC may facilitate improved pattern recognition control compared to SC in a virtual reality (VR) environment.

METHOD

Participants: Six individuals with unilateral transradial limb difference participated.

Apparatus: A VR application was developed in Unity 3D for the Oculus Quest 2. Data from 8 EMG channels were collected using custom electronics.

Procedures: With their residual limb, participants calibrated 5 motion classes (no motion, hand open/close, wrist pronation/supination). Both SC and TBC were performed in a randomized order by each person. For TBC, participants mimicked a VR hand that picked up a cup off a shelf, turned it over, and placed it on a table. SC mimicked clinical practice techniques, with display in the VR headset.

Data Analysis: Offline classification accuracy was calculated via Matlab and Excel by building and testing a classifier model with various types of calibration data.

RESULTS

EMG patterns and contraction strength differed between SC and TBC (Figure 1). Overall, EMG activity during motions is lower in TBC compared to SC (e.g., there is less muscle activity elicited for "open" during the VR task compared to when prompted to open their hand by SC). Compared to SC, TBC captured a greater amount of EMG activity for data labeled as "no motion," when no prosthetic motion is intended.

Building and testing a classifier with similar calibration types resulted in high accuracies (Table 1, diagonal values). Building with data from one calibration type (e.g., SC) and testing with a different type (e.g., TBC) shows notably lower classification accuracy. Building with mixed (SC and TBC) data results in accuracies similar to when building and testing with like data.

DISCUSSION

The data suggest that SC and TBC capture different muscle activation patterns for similar motion classes. The PR system built with TBC data was able to better classify a user's intended motion when performing the same simulated functional task compared to a system trained with only SC data. SC could allow for purposeful movements to be accurately decoded, and TBC could allow for continuous functional activities to be decoded. To make the system more intuitive, using a mixture of TBC and SC might allow for both categories of patterns to be accurately classified during use. These results may help explain why some users initially face difficulty using PR even if they are successful at calibrating and making repeatable movements.

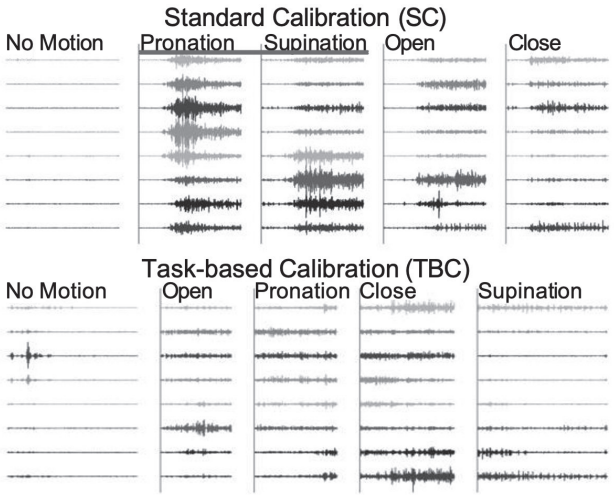


Figure 1. Example of EMG recorded during SC (top) and TBC (bottom) for the same participant.

Table 1. Offline accuracy (mean±SD) when building and testing a PR classifier.

		Building		
		SC	TBC	Mix
Testing	SC	81.7±10.7	46.8±20.1	74.5±13.0
	TBC	40.4±10.8	75.7±12.3	74.8±11.1
	Mix	n/a	n/a	75.6±8.2

CONCLUSION

Calibrating via TBC may facilitate better prosthetic control and improve the clinical experience. Future work should evaluate the impact of TBC when controlling a physical prosthesis, including with PR systems built on mixed calibration types.

CLINICAL APPLICATIONS

The principles of TBC or mixed calibration could be employed even in current clinical practice by asking users to pretend to perform a task while calibrating.

REFERENCES

1. Sensinger JW, Weir RF. *IEEE Trans Biomed Eng.* 2008;55(3): 1043–1055.
2. Simon AM, Lock BA, Stubblefield KA. *J Prosthet Orthot.* 2012;24(2):56–64.

This work is supported by the NIH (5R01HD094861) and the NIDILRR (grant #90REGE0003).

Hand Surgeon Understanding of Partial Hand Prostheses: Results of a National Survey Study

Emily M. Graham,[1] Christopher M. Baschuk,[2] Diane J. Atkins,[3] Lana Hutchinson,[4] Christopher C. Duncan,[5] Shaun D. Mendenhall[1,6]

[1]The Children's Hospital of Philadelphia, Division of Plastic and Reconstructive Surgery, Philadelphia, PA; [2]Handspring Clinical Services, Salt Lake City, UT; [3]Department of Physical Medicine and Rehabilitation, Baylor College of Medicine, Houston, TX; [4]Department of Occupational Hand Therapy, University of Utah, Salt Lake City, UT; [5]Department of Physical Medicine and Rehabilitation, University of Utah School of Medicine, Salt Lake City, UT; [6]Division of Plastic Surgery, University of Utah School of Medicine, Salt Lake City, UT

INTRODUCTION

Partial hand amputations are devastating injuries that often negatively impact individuals and communities. Partial hand prostheses can mitigate the burdens of living with an amputation, especially when reconstruction alone cannot restore form or function. However, hand surgeons may be unfamiliar with these newer devices since the prosthetic field is rapidly progressing and many surgeons work independently without the support of a multidisciplinary team. Assessing surgeon awareness of the modern partial hand prosthetic devices and measuring the degree of collaboration within a multidisciplinary team may help improve amputee care and advocacy.

METHOD

A nationally distributed electronic survey was distributed within the United States to hand surgeon members of the American Association of Hand Surgery with the intent of assessing surgeon familiarity with partial hand prosthetic devices and their clinical applications. Secondary aims explored degree of collaboration with prosthetists, therapists, and physical medicine and rehabilitation physicians. Survey items utilized Likert 5-point scales, rank order, multiple choice, and yes/no question formats. Responses were compared by training background (orthopaedic or plastic surgery) and by years of experience (10 years in practice) using independent t-tests. Demographic and clinical decision-making questions were reported as proportions and/or were reassigned into a binary format for Fisher's exact analyses.

RESULTS

Overall, hand surgeons are unfamiliar with modern partial hand prosthetic devices. Regardless of the level of amputation, activity-specific prostheses were popular answer choices. Body-powered and passive functional devices were underutilized responses for digital and transdigital amputations. Myoelectric devices were frequently listed as options for digital and transdigital amputations. Plastic trained hand surgeons were more likely to list toe-to-hand transfers as treatment options for multilevel digital amputations ($p=0.03$) and transmetacarpal amputations ($p=0.02$). Senior hand surgeons were more likely to suggest no treatment for partial thumb amputations ($p=0.02$). Hand surgeons identified cost and difficulty with insurances as significant barriers to prosthesis utilization. Perceived barriers were not influenced by years of experience ($p=0.95$ and $p=0.83$, respectively) or training background ($p=0.96$ and $p=0.59$, respectively). The majority of the cohort denied working within a multidisciplinary hand team (76.2%) or consulting with a prosthetist prior to revisional surgeries (71.4%). Plastic trained hand surgeons were more likely to highly rank the importance of having a prosthetist present during amputee rehabilitation than orthopaedic trained hand surgeons ($p=0.02$).

DISCUSSION

This survey demonstrates that hand surgeons are not familiar with modern partial hand prostheses. This may reflect a need for educational initiatives on a national level. Most hand surgeons also do not work within multidisciplinary teams or understand the roles of other hand team members. Encouraging participation in such teams may mitigate these findings and improve amputee care.

CONCLUSION

Traumatic partial hand amputations are devastating injuries that frequently impair independence and identity. Through recent engineering advancements, partial hand prosthetic devices are increasingly available and functional, and have the potential to mitigate many of the challenges faced by those living with an amputation. However, this study shows that hand surgeons are not familiar with these newer prostheses. Expanding surgeon knowledge and encouraging multidisciplinary collaboration may enhance amputee care.

CLINICAL APPLICATIONS

Understanding the knowledge gap that exists outside of the prosthetics profession relative to partial hand prosthetic rehabilitation should encourage prosthetists to reach out to their local referral sources to provide additional clinical education. Prosthetists can utilize the findings of this research to coordinate the organization of multidisciplinary prosthetic rehabilitation teams.

REFERENCE

1. Graham E, et al. *Hand Clin.* 2021;37(1):167–187.

A Motorized Prosthetic Elbow for Restoring Arm Swing

MJ Major,[1,2] Y Ben Shalom,[2] ML Elwin[2]

[1]Jesse Brown VA Medical Center, Chicago, IL; [2]Northwestern University, Evanston IL

INTRODUCTION

Asymmetries in arm mass and motion affect the regulation of whole-body angular momentum during walking in individuals with major upper-limb deficiency (ULD).[1] Persons with ULD often demonstrate little to no arm swing of their affected limb,[2] which gives rise to a significant momentum imbalance between sound and affected limb side strides. These asymmetries may contribute to the relatively high prevalence of falls in persons with ULD, where nearly one-third will experience at least one fall per year, and two-thirds of falls occur during walking.[3] Conventional transhumeral prostheses do not swing at the elbow while walking to restore arm swing symmetry as a potential means to balance momentum. This project developed a robotic prosthetic elbow that imitates able-bodied elbow rotations to restore affected limb arm swing during walking.

METHOD

Development and evaluation of the prosthetic elbow involved the following sequence of 4 tasks:

I. Prosthesis measurements: The mass and center-of-mass locations of various body-powered transhumeral prosthesis designs were measured using a scale and reaction board, respectively. These values were used to calculate the segment inertial properties of conventional prostheses to be actuated by the elbow.

II. Arm dynamic modelling: Existing (unpublished) lab data of 13 able-bodied individuals walking at a self-selected speed overground was used to calculate shoulder and elbow angular velocities across a range of walking speeds. Data from a single able-bodied control subject walking on a treadmill at 0.6, 0.8, 1.0, and 1.2 m/s were also analyzed. Combined with the mass measurements of Part I, a numerical simulation of the full arm modelled as a double pendulum was built to characterize relationships between elbow joint torque, segment angular velocities, and walking speed. These results were used to select an electric motor to meet those demands of actuating arm swing.

III. Mechatronic design: A battery-powered motorized elbow joint prototype was designed and fabricated (Figure 1a). The prototype included a microprocessor operating a proportional–integral–derivative controller to regulate joint angular position and motor current according to the defined angle-speed relationship.

IV. Proof-of-concept: The prototype device was tested while attached to the control subject in Part II walking at the same 4 set speeds. These validation tests were performed to verify function of the elbow joint to track the command signal (input position) accurately and increase angular velocity and magnitude (output position) according to increases in walking speed to imitate natural arm dynamics measured in Part II.

RESULTS

A prototype motorized prosthetic elbow was designed and fabricated with capability of generating cyclical elbow flexion-extension during walking (patent US17/705,655). The elbow contained a direct drive electric motor, encoder printed circuit board (PCB), driver, driver adaptor PCB, and rechargeable battery (Figure 1a). Proof-of-concept testing across 4 slow to intermediate walking speeds was successful and observed elbow motion suggested imitation of natural elbow flexion-extension during walking. The prototype elbow was able to track the command elbow cyclical motion with less than 5% angular deviation (Figure 1b).

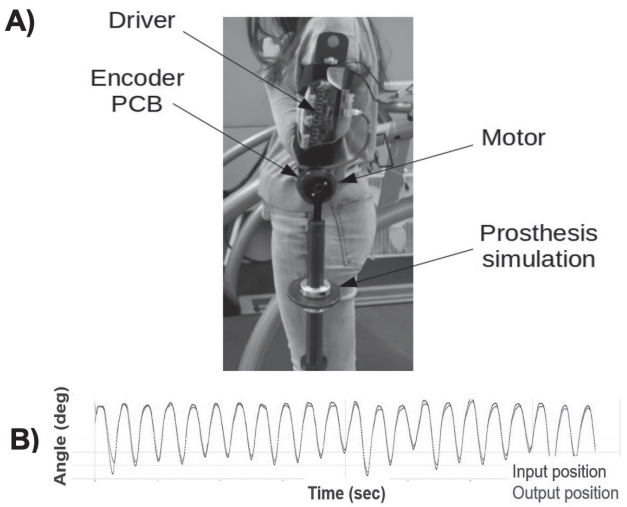


Figure 1. Prototype elbow attached to a weighted adaptor simulating a prosthetic forearm segment (A) and example cyclical elbow flexion-extension (B).

DISCUSSION

This work has generated the first motorized prosthetic elbow joint that produces natural elbow flexion-extension in concert with physiological shoulder motion during walking. Proof-of-concept testing suggests this natural motion can be demonstrated across a range of speeds by increasing elbow angular velocity and magnitude. Future work involves condensing the system and fitting inside an elbow shell with distal attachments for a conventional forearm segment.

CONCLUSION

A battery-operated motorized prosthetic elbow has been designed to generate natural elbow flexion-extension across a range of walking speeds.

CLINICAL APPLICATIONS

A simple motorized prosthetic elbow that automatically flexes could potentially be used to encourage natural arm swing of transhumeral prosthesis users across a range of walking speeds.

REFERENCES

1. Kent JA. *Biomech.* 1999;11:34–67.
2. Major MJ, et al. *J Electromyogr Kinesiol.* 2019;48: 145–151.
3. Major MJ. *Phys Ther.* 2019;99(4):377–387.

Improved Patient Outcomes through the Application of Ratcheting Mechanical Prosthetic Fingers

Ben Pulver, MS;[1] Jacob Segil, PhD;[1,2] Stephen Huddle, MS;[1,3] Richard Weir, PhD;[1,3] Levin Sliker, PhD[1,2]

[1]Point Designs; [2]University of Colorado Boulder; [3]University of Colorado Denver, Anschutz

INTRODUCTION

There is a lack of robust quantitative outcome data for people fit with partial hand prostheses.[1] This is a challenge for both manufacturers and practitioners. For manufacturers, it is challenging to support clinical benefit claims in regulatory submissions and provide robust reimbursement support to practitioners. For practitioners, it can be difficult to receive insurance reimbursement as devices are often seen as experimental, not state-of-the-art, or as having limited functional benefit. All of this results in patients not getting access to devices that could dramatically improve their quality of life.

A study was conducted to collect outcome measures data on subjects fit with ratcheting mechanical prosthetic fingers. The study measured functional and psychological outcomes across 11 subjects before and after treatment with a prosthesis. The goal of this study was to demonstrate the significant functional and psychological improvements resulting from treatment with a partial hand prosthesis.

METHOD

The Western Institutional Review Board (WIRB) approved this study (protocol #20182022), and informed consent was obtained from all subjects.

Participants: Eleven (11) subjects with partial hand amputation were recruited for this study. Eight (8) participants were male, and three (3) were female. The age range of participants was 22–61 years. Inclusion criteria was loss of at least index and/or middle fingers, but an intact thumb.

Apparatus: Each subject was fit with a partial hand prosthesis consisting of a HTV silicone liner, carbon fiber frame, and ratcheting prosthetic fingers.

Procedures: Subjects participated in 4 data collection sessions. The first session occurred prior to prosthesis fitting (pre). The second session occurred immediately after definitive prosthesis fitting (post). The third session occurred approximately 30 days after prosthesis fitting (30-day post). The final session occurred approximately 60 days after prosthesis fitting (60-day post).

During each session, functional and psychological outcome measures were collected using the following tools: EuroQol 5 Dimension 5 Level (EQ-5D-5L) health questionnaire, and Disabilities of the Arm, Shoulder and Hand (DASH).

RESULTS

The average reduction in DASH score was 16.1±11.0 (min: 1.7, max: 41.6). The average increase in EQ-5D- 5L score was 7.8±6.7 (min: 0.0, max: 20.0).

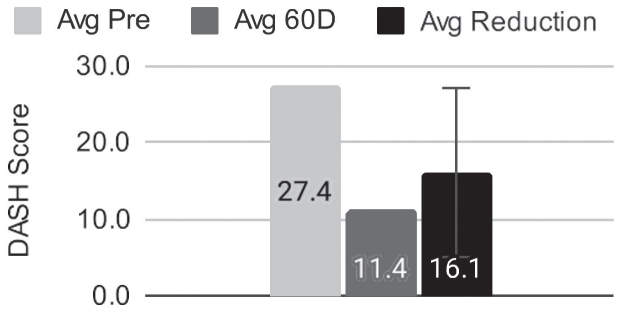


Figure 1. Average pre, post, and reduced DASH scores.

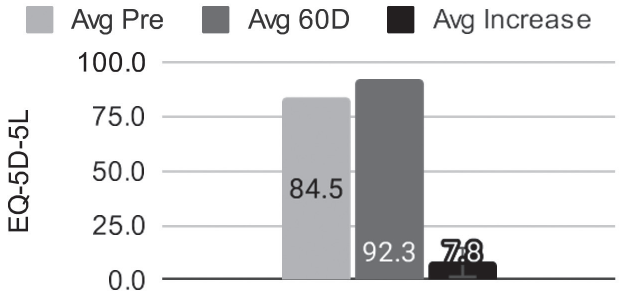


Figure 2. Average pre, post, and increased EQ-5D-5L.

DISCUSSION

The DASH score range is 0–100, with 0 indicating no disability and 100 indicating high disability. The minimal clinically important difference (MCID) for the DASH is 10.8.[2] Eight of the subjects had MCID scores for the DASH outcome measure. The EQ-5D-5L score range is 0–100, with 0 indicating the worst health imaginable and 100 indicating the best health imaginable. All subjects had a reduced DASH score and an increased EQ-5D-5L score after prosthetic treatment showing functional and psychological improvements.

CONCLUSION

This evidence shows that significant functional and psychological gains can be achieved by fitting patients with robust partial hand prostheses.

CLINICAL APPLICATIONS

This data may allow partial hand prosthetic devices to achieve wider acceptance in the field, improve reimbursement outcomes, and provide patients with better access to life-changing prosthetic treatment.

REFERENCES

1. Graham EM, et al. *Hand Clinics.* 2021;37(1):167–187.
2. Franchignoni F, et al. *J Orthop Sports Phys Ther.* 2014;44(1): 30–39.

Research reported in this publication was supported, in part, by the NICHD of the NIH under Award Number R42HD097827.

Self-Reported Prosthetic Use: Implications on Prosthetic Design and Training

PM Stevens,[1] M Borgia,[2] AW Heinemann,[3] P Ni,[4] L Resnik[2]

[1]Hanger Institute; [2]Providence VA Medical Center; [3]Shirley Ryan Ability Lab and Northwestern University; [4]Boston University

INTRODUCTION

Prior research has suggested that persons with unilateral upper-limb (UL) amputation perform the majority of their daily activities with their non-involved side.[1] Data obtained from wearable movement trackers suggests that prostheses are generally used during two-handed activities in concert with the non-amputated limb.[2] Usage patterns in those with bilateral upper-limb loss have not been described.

This paper presents the usage patterns reported by unilateral and bilateral UL amputees during one- and two-handed tasks according to amputation laterality and level.

METHOD

The data for this report are a subset of cases collected in a large telephone survey.

Participants: US military veterans and civilians, largely recruited through VA databases and Hanger Clinic. Subjects had at least 1 amputation at or proximal to the wrist. The study sample included 379 unilateral and 32 bilateral amputees. Participants were primarily male (81%). Transradial (TR) amputation was the most common (66%) followed by transhumeral (TH) (20%) and shoulder level (6%). The mean age was 62 years old.

Apparatus: Survey of 34 everyday tasks taken from the Upper Extremity Functional Scale (n=23) and other sources (n=11). Eleven tasks were categorized as one-handed activities and 23 as two-handed.

Procedures: Respondents reported whether they performed or attempted each of the items with the assistance of their prosthesis in the prior 2 weeks.

Data Analysis: The sample was stratified bilaterality, and the proportion of each subgroup who completed each of the 34 tasks with their prosthesis was calculated and compared using chi-square analysis. The proportion of one- and two-handed tasks completed were compared by laterality and amputation level using t-tests and ANOVAs.

RESULTS

Persons with unilateral UL amputation engaged their prosthesis in an average of 24% of unilateral tasks and 38% of bilateral tasks. Those with bilateral amputation engaged their prostheses in 64% of unilateral and 46% of bilateral tasks.

DISCUSSION

Persons with bilateral amputation engaged their prostheses in more activities than those with unilateral amputation and were more likely to report prosthesis utilization in one-handed tasks than two-handed tasks.

Persons with unilateral amputations were more likely to engage their prosthesis in the performance of two- handed tasks than one-handed tasks. Individuals with TR amputations tended to report higher levels of prosthetic engagement in both one- and two-handed tasks relative to participants with more proximal amputation.

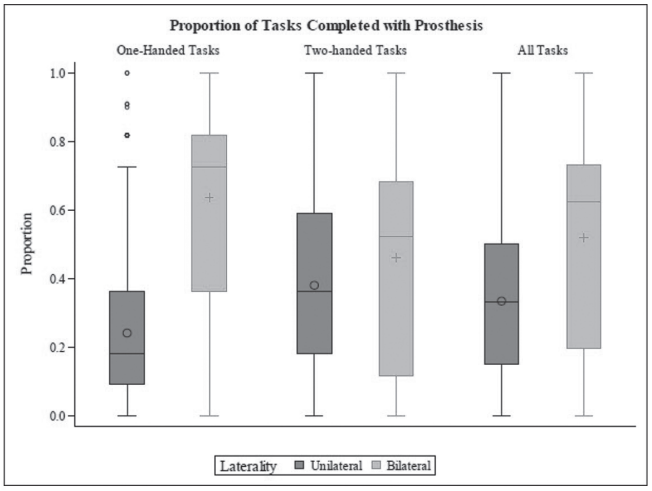


Figure 1. Box plots showing mean, median and distribution of the proportion of tasks completed with prostheses bilaterality.

Our study provides new information about the types of activities performed by prosthesis users that may inform prosthetic design and training. Those with unilateral UL amputation may benefit from prostheses designed to participate in a non-dominant capacity in two-handed tasks. Those with bilateral amputation appear to engage frequently in one-handed tasks and may benefit from prostheses designed to support a wide range of activities. Engagement in one-handed tasks was more common in lifting than in fine motor activities. This finding was especially true with more proximal amputation levels, suggesting the importance of robust prosthetic design for unilateral applications.

Prosthetic training may benefit from an informed characterization of usage patterns.

CONCLUSION

Self-reported usage patterns may inform prosthetic design decisions and training priorities, with different protocols used for bilateral and unilateral amputees.

CLINICAL APPLICATIONS

Prosthesis design and training should reflect anticipated utilization patterns.

REFERENCES

1. McFarland LV, et al. *J Rehabil Res Dev.* 47(4): 299–316.
2. Frey S, et al. *Neurorehabil Neural Rep.* 2022;36(3):227–238.

Funded by the Dept of Veterans Affairs Research and Development Service (A2936-R and A9264-S).

Impact of Unilateral Transradial Prostheses on Upper Limb Utilization Relative to Able-Bodied Controls: Wireless Accelerometer Data

PM Stevens,[1,2] B Motawar,[3] K Buchanen,[3] SH Frey[3,4]

[1]Hanger Institute; [2]Division of PM&R, University of Utah Health; [3]Department of PM&R, University of Missouri; [4]Department of Psychological Sciences, University of Missouri

INTRODUCTION

Upper-limb amputation has a profound impact on both function and quality of life. Prostheses can improve outcomes, but disuse occurs among a minority of patients, and those who use a prosthesis often rely heavily on their intact limbs during everyday life.[1] This tendency toward one-handedness has been associated with greater disability and overuse injury.[2]

Recent efforts have reported the engagement of upper-limb prostheses through wrist-worn accelerometers, observing a preferential use of the intact extremity, a lack of correlation between prosthesis wear and prosthesis use, and a lack of correlation between prosthetic skill and prosthetic engagement.[1] The data shared below is drawn from a recently published paper.[3]

METHOD

We implemented a wireless accelerometry protocol to record upper-extremity movements during 3 days of normal activity in transradial amputees and healthy age-matched controls. In addition to bilateral distal sensors, we placed sensors proximally above the elbows for additional insight.

Participants: Group 1: users of unilateral transradial prostheses (N=22, aged 56.4±17.1 years, 1 female, 30.2±21.6 years after traumatic amputation). Half of the limb-loss group had dominant hand affected; and Group 2: healthy age-matched controls (N=20, aged 53.4±15.8 years, 3 females, 18 right-handed.

Procedures: Four accelerometer sensors were shipped to subjects. Subjects wore these accelerometers for 3 consecutive days on the anatomical or prosthetic forearm and above the elbows of that forearm.

Data Analysis: Reported in detail elsewhere.[3]

RESULTS

Prostheses were used an average of 79% of waking hours with a mean recorded utilization of 11.1±1.8 hours/day. Additional variables of interest are shown in Table 1. Unilateral engagement of the prosthesis was recorded an average of 20 minutes per day. Unilateral engagement of the sound side extremity was recorded for an average of 4.5 hours per day. Among prosthesis users, an average of 4 hours of bimanual activity was recorded.

Relative reliance upon the forearm relative to the upper arm was recorded in on the dominant limb in controls, the non-dominant limb of controls, the sound-side limb of the prosthesis users and the affected extremity of the prosthesis users. Mean forearm reliance ratios are shown in Figure 1.

Table 1. Hours of measures forearm use in amputees and controls as measures on affected, sound, dominant and non-dominant extremities.

	Amputees	Control Dominant	Control Nondominant
Unilat activity	4.80±1.60 (hrs/day)	2.72±.89 (hrs/day)	N/A
Unilat px activity	0.33±0.19 (hrs/day)	N/A	1.06±.46 (hrs/day)
Unilat non-px activity	4.47±1.61 (hrs/day)	1.65±.54 (hrs/day)	N/A
Bilat activity	4.02±1.35 (hrs/day)	5.04±1.33 (hrs/day)	N/A

Reliance upon the prosthetic side relative to the sound side increased from 25% to 31% with the use of the prosthesis.

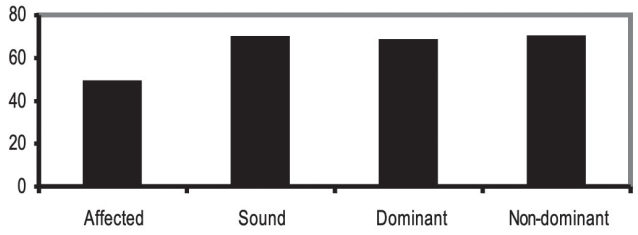


Figure 1. Relative reliance upon the forearm (versus upper-arm segment) for amputees and controls.

DISCUSSION

Prosthesis users engaged in unimanual and bimanual tasks an average of 8.82 hours daily. Prostheses were used for more than 4 hours daily with an emphasis on bimanual activities. They appear to reduce the reliance on the sound-side limb but increase engagement of the upper arm.

CONCLUSION

Transradial prostheses are used throughout the day, especially during bimanual activity. However, limited unimanual prosthetic activity also occurs.

CLINICAL APPLICATIONS

Prosthetic design should primarily anticipate bimanual activity. Proximal joint compensation is common.

REFERENCES

1. Chadwell A, et al. *Sci Rep.* 2018;8(1):11084.
2. Hanley MA, et al. *Am J Phys Med Rehabil.* 2009;88:742–751.
3. Frey S, et al. *Neurorehabil Neural Repair.* 2022;36(3):227–238.

Funded by US Department of Defense Grant #MRI140043 to S.H.F.

Well-Being, Bimanual Upper-Limb Function, Activity and Participation and Prosthesis Satisfaction Are Strongly Correlated among Individuals with Upper-Limb Loss

PM Stevens,[1,2] A Todd,[3] S Mandacina,[3] D England, S Wurdeman[1,2,3,4]

[1]Hanger Institute for Clinical Research and Education; [2]Division of Physical Medicine and Rehabilitation, University of Utah Health; [3]Hanger Inc., Clinical and Scientific Affairs, Upper Limb Program; [4]Department of Biomechanics, University of Nebraska

INTRODUCTION

Upper-limb amputation and congenital upper-limb deficiencies are associated with a number of disabling characteristics. In addition to the obvious functional deficits, these individuals contend with a spectrum of pain experiences and social stigma, and in the case of acquired amputation, a dramatic alteration in self- image and vocation.

Key rehabilitation outcomes in this population appear to include quality of life,[1] life satisfaction,[2] activity and participation levels,[3] and bimanual upper-limb function.[4]

The purpose of this retrospective analysis was to better understand the relationships observed between well- being and upper-limb function during bimanual tasks, activity and participation levels, satisfaction with a prosthesis, and pain interference among a convenience sample of individuals with unilateral limb deficiency.

METHOD

Procedures: A convenience sample of 250 patients from a national prosthetic care provider completed a standardized suite of outcome measures. These included ratings of well-being, defined as a product of their satisfaction with life and quality of life over the past 4 weeks as measured within the Prosthesis Evaluation Questionnaire. To evaluate upper-limb physical function, a previously assessed custom 9-item short form derived from the PROMIS®-UE v2.0 item bank was administered.5 Additional patient-reported outcomes included the 4-item short form of the PROMIS-Ability to Participate in Social Roles and Activities (APSRA). Patients were additionally asked to report prosthesis satisfaction using the Trinity Amputation and Prosthesis Experience Scales- Revised (TAPES-R), a single item of pain interference (PROMIS-Pain Interference), number of months since amputation, hours of daily wear time per, age, and gender.

Data Analysis: To analyze the data, a multivariate linear regression model was run (forward enter method) with patient well-being as the predicted variable. Secondarily, in addition to the multivariate model, each variable was separately analyzed through a univariate linear regression to assess individual effects. This retrospective database review was approved by Western Investigational Review Board (Protocol #20170059).

RESULTS

The majority of the study sample had a transradial or wrist disarticulation amputation (73.2%), and reported amputation due to trauma. Slightly less than half reported having an electronic arm (46.0%).

The overall regression model was statistically significant [R=0.675, $F_{(8,241)}$=25.162, p<0.001; Table 1].

Table 1. Correlates to well-being among upper-limb amputees, where * indicates a significant correlation.

R=0.675	B	P
(Constant)	2.280	0.02*
Activity/Participation (APSRA)	0.077	<0.01*
Prosthesis Satisfaction (TAPES)	0.200	<0.01*
Pain Interference (PROMIS)	-0.328	<0.01*
Physical Function (PROMIS-9 UE)	0.028	0.05*
Daily wear time (hours)	-0.023	0.34
Time since amputation (months)	0.000	0.88
Gender (male)	-0.040	0.90
Age (years)	-0.001	0.94

DISCUSSION

This retrospective analysis provides some insight into those factors that appear to correlate most strongly with improved satisfaction and quality of life among individuals with major upper-limb amputation or deficiency.

CONCLUSION

Our data suggest that greater levels of well-being are correlated with higher levels of functional capacity with bimanual activity, higher levels of activity and participation, higher levels of prosthesis satisfaction, and reduced levels of pain interference. By contrast, daily reported wear times, times since amputation, age and gender failed to correlate strongly with well-being.

CLINICAL APPLICATIONS

Prosthetic capacity in bilateral function, facilitation of activity and participation, satisfaction with prostheses, and managing the complex pain experiences appear to be key considerations in enhancing their well-being.

REFERENCES

1. Resnik L, Eckerholm S, Borgia M, Clark MA. *PloS One.* 2019;14:e0213578.
2. Ostlie K, et al. *Disabil Rehabil.* 2011;33: 1594-1607.
3. Gallagher P, O'Donovan MA, Doyle A, Desmond D. *Prosth Orthot Int.* 2011;35(3):278–284.
4. McFarland LV, et al. *J Rehabil Res Dev.* 2010;47: 299–316.
5. England DL, et al. *Am J Phys Med Rehabil.* 2021;100(2):130–137.

PROMIS-UE Physical Function Demonstrates Good Clinical Utility for Patients Following Upper-Limb Prosthesis Intervention

DL England,[1] PM Stevens,[1,2] A Todd,[3] S Mandacina,[3] SR Wurdeman[1,4]

[1]Hanger Institute for Clinical Research and Education; [2]Division of Physical Medicine and Rehabilitation, University of Utah Health; [3]Hanger Inc, Clinical and Scientific Affairs, Upper Limb Program; [4]Department of Biomechanics, University of Nebraska

INTRODUCTION

The implementation and utilization of outcomes measures in clinical practice can aid in the tracking of changes in patient condition, patient perspectives, and the overall improvement in clinical practice.

For individuals with upper-limb amputation, the provision of a prosthesis is a major intervention in that person's health condition. A previous study reported that individuals who did not use a prosthesis experienced more difficulties performing one-handed tasks than those who did.[1] It would be valuable to understand whether outcomes instruments developed for clinical practice can detect improvements or reduction in functional capacity over time.

One such measure utilized to evaluate bimanual functional capacity is the 9-item custom short form PROMIS®-UE v2.0,[2] but little has been published about the clinical utility for detecting changes in care pre- and post-prosthesis receipt over a specified timeframe.

The purpose of this study was to determine the clinical utility of the 9-item custom PROMIS®-UE v2.0 to discriminate changes in bimanual physical function before and after initiation of first prosthesis intervention.

METHOD

Individuals receiving a first prosthesis who completed the 9-item custom PROMIS-UE v2.0 were included for analysis. Paired t-tests and effect sizes evaluated unadjusted differences before and after first prosthesis receipt. Time from first-prosthesis receipt to follow-up assessment was constrained to 1–12 months. A mixed effect regression model was subsequently used to control for the effect of amputation level and time between assessments. The current study was approved by the WCG Institutional Review Board.

RESULTS

Thirty-four individuals were included. Descriptive statistics revealed that the average (SD) age was 48.3±14.4 years. From the total sample, 74% of the sample were male,14.7% of the sample had an above-elbow (AE) amputation, while 85.3% had a below-elbow (BE) amputation. The mean PROMIS-UE T-score for persons with AE and BE at initial assessment were 15.8±6.0 and 25.0±7.8, respectively, while the follow-up T-scores were 19.2±6.9 and 31.5±10.0, respectively.

Paired t-test model revealed that the average T-score (before: 23.6±8.2 and after: 29.7±10.5) following first prosthesis receipt significantly improved with a strong effect size [t(33)=4.7, p< 0.0001, Cohen's d=0.807]. In the multivariate model, individuals' T-score still remained significantly higher at the follow-up assessment after controlling for amputation level and timing (p<0.0001).

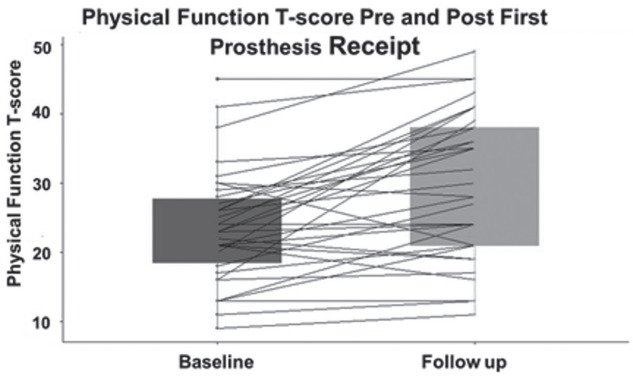


Figure 1. Longitudinal assessment of bimanual physical function after receipt of first prosthesis.

DISCUSSION

The findings of this analysis revealed that there was a significant improvement in bimanual physical function T-scores following first prosthesis receipt among patients compared to pre-prosthesis. While a recent publication failed to observe mean differences between individuals who used or did not use a prosthesis,[3] the findings from this present study effectively demonstrated changes in patient outcomes longitudinally through the receipt of a prosthesis using a 9-item custom PROMIS-UE v2.0 short form.

It is worth noting that individuals in the sample had varying follow-up time points from first prosthesis to follow up. There was an attempt to control for this through the statistical model, but these varying time points may reflect underlying clinical issues, as some follow-up time points may have captured a patient returning with no issues, or alternatively the patient may have deferred any clinical issues until this scheduled appointment. In other words, it is not possible in this analysis to confirm patients were at their optimal function. This may further explain the 15% of the sample that had a decrease in physical function scores. Future studies should consider the optimal timeframe for which to measure patients to capture their optimal performance.

CONCLUSION

Patients with upper-limb amputation had significant improvements in bimanual physical function following receipt of their first prosthesis. The custom PROMIS-UE is clinically acceptable to capture patient progress following prosthesis intervention.

CLINICAL APPLICATIONS

The custom PROMIS-UE physical function instrument can track changes in functional capacity after the initiation of prosthesis intervention.

REFERENCES

1. Resnik L, Borgia M, Clark M. *Arch Phys Med Rehabil.* 2020;101(8):1396–1406.
2. England DL, et al. *Am J Phys Med Rehabil.* 2021;100(2):130–137.
3. Resnik LJ, et al. *Am J Phys Med Rehabil.* 2022;101(6):545–554.