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TITLE: A Novel Prosthetic Foot Designed to Maximize Functional Abilities, Health Outcomes, and Quality of Life in People with Transtibial Amputation

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14. ABSTRACT
Evidence is needed to guide prosthetic component selection for Service members, Veterans, and civilians with lower limb amputation. A randomized crossover study is conducted to compare outcomes associated with use of modified running-specific foot (mRSF) compared to a traditional, energy-storing foot (ESF). Key outcomes include walking endurance, metabolic energy expenditure, step activity, and self-reported mobility, fatigue, activity restrictions, balance confidence, and satisfaction. Results to-date (n=6 of 24 from this study, n=17 of 30 total) indicate users exhibit modest functional benefits in walking when using a mRSF compared to a ESF. Endurance and metabolic energy are slightly improved, gait is largely unaffected, and step activity is reduced. However, particpiants generally report significant improvements in all health outcomes when using the mRSF. Future efforts will target collecting data from additional participants, and exploring other activities or situations that may be affected by use of different contemporary prosthetic feet.

15. SUBJECT TERMS
prosthesis, transtibial amputation, energy expenditure, endurance, functional ability, patient-centered health outcomes, quality of life, randomized crossover trial

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TABLE OF CONTENTS

Page

1. **INTRODUCTION:**

The long-term goals of this project are to evaluate and compare the effectiveness of prosthetic technologies designed to enhance physical function, health, and quality of life in people with lower amputation. At present, limited evidence is available to guide prosthetic component selection or justify the provision of one type of device over another. High-quality research is needed to facilitate evidence-based prescription and justification of contemporary prosthetic technologies. In this randomized crossover study, we compare use of prostheses with a novel, modified running-specific foot (mRSF) to use of prostheses with a traditional, energy-storing foot (ESF). Participants with transtibial amputation are first fit with comparable, definitive prostheses (one with a mRSF, one with a ESF). Participants are randomized to wear one of the fabricated prosthesis for a minimum of four weeks to acclimate to the device. During acclimation, activity is measured with a step monitor. After four weeks, participants attend a laboratory session where endurance, walking performance, gait quality, energy expenditure, and perceived function and satisfaction are assessed. Participants are then provided the other prosthesis and again acclimated for four weeks while activity is monitored. Participants return for testing in the second prosthesis after four weeks. Study outcomes (walking activity, endurance, walking performance, gait quality, energy expenditure, and perceived function and satisfaction) are compared between prosthetic conditions to assess the effectiveness of the mRSF and ESF.

2. **KEYWORDS:**

prosthesis, transtibial amputation, energy expenditure, endurance, functional ability, patient-centered health outcomes, quality of life, randomized crossover trial

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**

  - The specific aims of the project are to (1) Evaluate functional activity outcomes (i.e., energetics, gait quality, and community mobility) in 18 unilateral transtibial prosthesis users and 6 bilateral transtibial prosthesis users walking with a conventional ESF and the mRSF and (2) Assess patient-centered health outcomes (i.e., self-reported mobility, fatigue, balance confidence, activity restrictions, and satisfaction) in transtibial prosthesis users walking with a conventional ESF and the mRSF.

Period	Activity	% Complete
Y1Q1	Obtain human subjects approval	100
Y1Q1	Study preparation	100
Y1Q2-Y2Q2	Participant recruitment	63
Y1Q2-Y2Q2	Data collection	27
Y1Q2-Y2Q4	Data analysis	27
Y1Q3-Y2Q4	Dissemination	10

- **What was accomplished under these goals?**

  - Major activities: Primary activities conducted during the Y1Q1-Y1Q4 reporting period included obtaining human subjects approval to conduct the proposed research; preparing materials, equipment, and staff for participant recruitment and data collection; recruiting and enrolling 24 study participants (i.e., n=18 with unilateral amputation; n=6 with bilateral amputation); collecting outcomes data from human subjects; analyzing interim data, and disseminating preliminary results.
  - Specific objectives: Specific objectives for the Y1Q1-Y1Q4 reporting period included:

- Obtain human subjects approval from the University of Washington institutional review board (IRB) and the USAMRMC Human Research Protections Office (HRPO). *Status*: Approvals for all study procedures were obtained from IRB and HRPO. Local IRB approvals have been obtained for all study modifications; HRPO has been consulted on any modifications that may be deemed substantive (upon review, none were deemed substantive).
- Revise and finalize recruitment, consent, and data collection materials. *Status*: Recruitment scripts and forms were finalized. Study flyers were created and printed. Participant folders with data collection forms were assembled. All relevant materials were reviewed and approved by local IRB and HRPO.
- Develop data management and storage procedures. *Status*: Electronic, password-protected databases with double-entry verification were created. A dedicated study computer was purchased and synchronized with an automated backup server and cloud-based backup service.
- Prepare all equipment for data collection. Status: All equipment (i.e., Cosmed portable metabolic system, GAITRite electronic walkways) was successfully calibrated (as needed) and tested. Study staff were trained in appropriate use.
- Enroll 18 of 24 targeted participants. *Status*: We successfully enrolled 15 of the targeted 18 participants during the Y1Q1-Y1Q4 reporting period (2 additional participants have been recruited as of this report). 11 of 15 participants enrolled to-date have received study prostheses and have started (or completed) longitudinal study procedures; 4 participants are awaiting fabrication of the duplicate study prosthesis. 3 of 15 participants enrolled to-date have completed study procedures (3 additional participants have completed study procedures as of this report).
- Prepare abstracts based on preliminary results and present at scientific and/or clinical conferences. *Status*: Five abstracts describing pilot and/or preliminary results were authored during the reporting period. Four were accepted (one is pending review) and presented as podium talks or posters at national and international conferences during the Y1Q1-Y1Q4 reporting period (see details in Section 6, below).

- Significant results or key outcomes: Data from all participants (with unilateral amputation) who have completed the study (i.e., data has been collected in both ESF and mRSF conditions) have been processed and are presented below. For this report, results from study participants are combined with results from pilot study participants (n=11 people with unilateral amputation) who completed the same protocol. Key outcomes are presented by outcome area (i.e., metabolic energy, temporalspatial parameters, endurance and perceived exertion, and patient-reported outcomes.

Functional activity outcomes
Functional activity outcomes are those that characterize participants' capabilities when they use the studied interventions. Investigators measure participants directly while they perform specified activities (e.g., walking overground or on a treadmill). Functional activities outcomes are sub-divided into outcomes related to energetics, gait quality, and community mobility.

Energetics:

Endurance and perceived exertion: Walking endurance was evaluated using the six-minute walk test (6MWT), a standardized walking test. Following the 6MWT, participants were administered the Borg Rating of Perceived Exertion (RPE), a self-report measure of RPE. RPE is presented with 6MWT results, as the two instruments were co-administered to study participants and results are inter-related. Results to-date varied by participant (Figure 1 and 2). In the mRSF (relative to the ESF), 8 of 17 participants showed increased distance and reduced or no change in RPE; 8

participant showed mixed results (ie, reduced distance and reduced RPE or increased distance and increased RPE); and 1 participant showed reduced distance and increased RPE. Thus, most participants appear to exhibit increased walking distance, reduced effort, or both increased distance and reduced effort when walking in the mRSF, compared to the ESF.

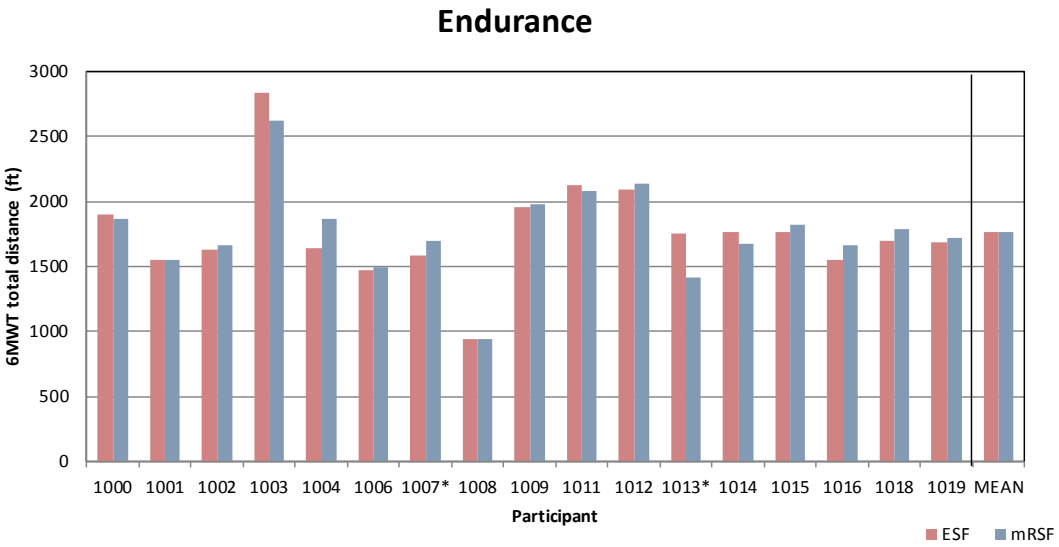


Figure 1 – Six-minute walk test (distance) for participants (n=17) with transtibial amputation. (* = will be analyzed separately due to challenges with data collection).

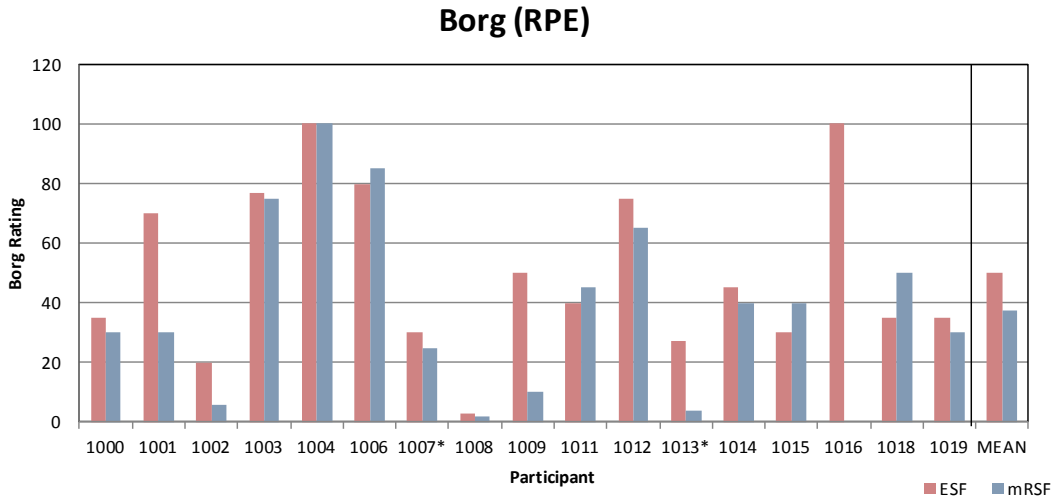


Figure 2 – Borg Rating of Perceived Exertion (RPE) for participants (n=17) with transtibial amputation. (* = will be analyzed separately due to challenges with data collection).

Metabolic energy expenditure: Metabolic energy expenditure was assessed with a portable gas analysis system (Cosmed k4b2) while participants walked at comfortable, fast, and slow walking speed on a treadmill (Landice L7 RTM). Gross metabolic rate (ml O2/min) was calculated as 30-second intervals over the final 3 minutes of testing (6 minute protocol). Results to-date have varied across participants (n=17 total participants).

- At comfortable walking speed (CWS), 9 of 13 participants showed reduced gross metabolic rate, and 8 showed increased gross metabolic rate in the mRSF compared to the ESF condition (Figure 3).
- At fast walking speed (FWS), 9 of 13 participants showed reduced gross metabolic rate and 8 showed increased gross metabolic rate in the mRSF (Figure 4).
- At slow walking speed (SWS), 8 of 13 participants showed reduced gross metabolic rate and 9 showed increased gross metabolic rate in the mRSF (Figure 5).

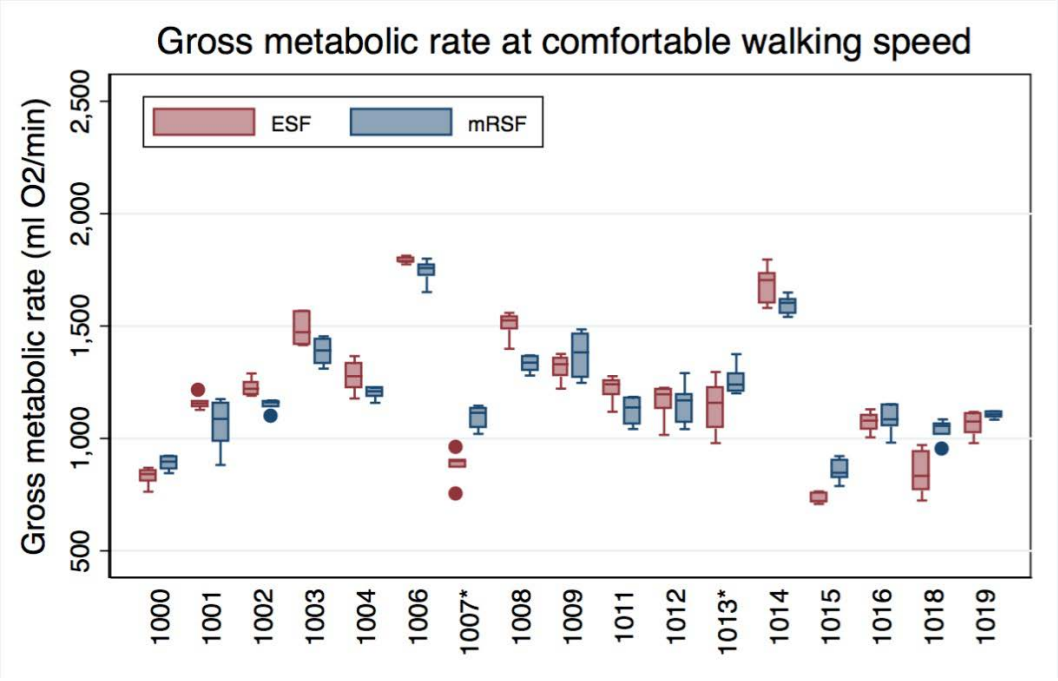


Figure 3 – Gross metabolic rate (ml O2/min) at comfortable speed for participants (n=17) with transtibial amputation. (* = as described in Y1Q3 progress report, particpants 1007 and 1013 will be analyzed separately due to challenges with data collection).

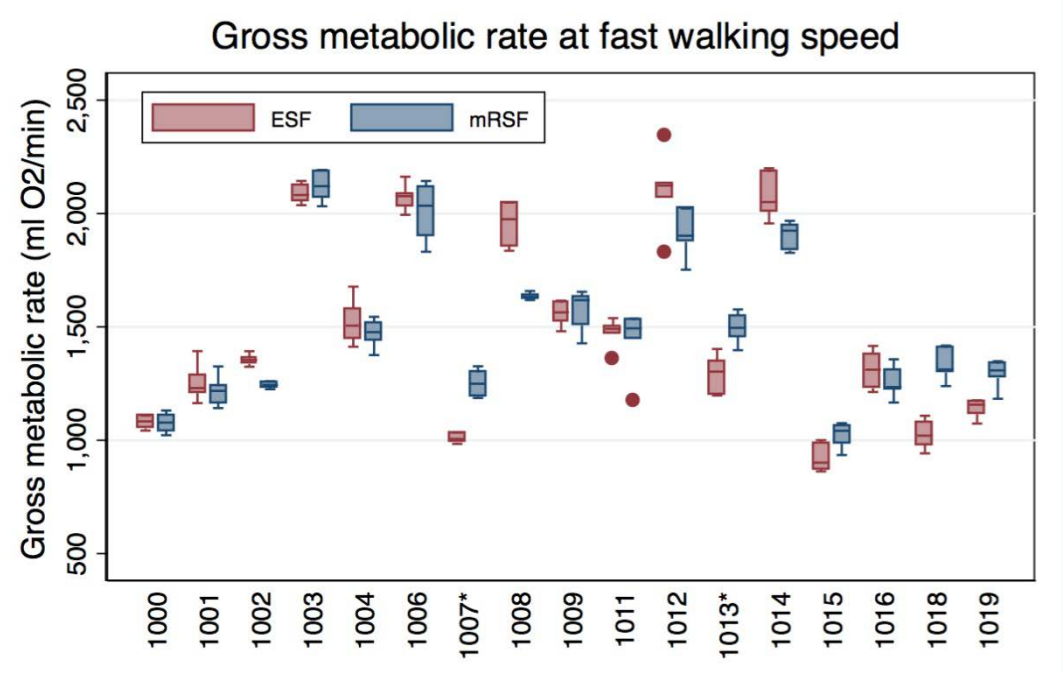


Figure 4 – Gross metabolic rate (ml O2/min) at fast speed for participants (n=17) with transtibial amputation. (* = will be analyzed separately due to challenges with data collection).

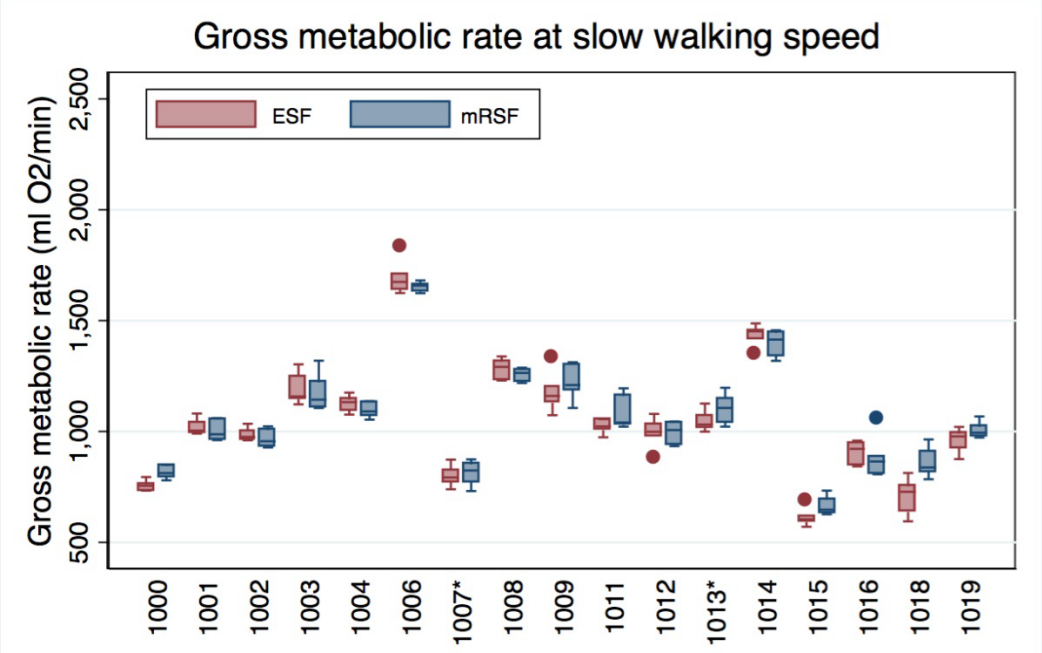


Figure 5 – Gross metabolic rate (ml O2/min) at slow speed for participants (n=17) with transtibial amputation (* = will be analyzed separately due to challenges with data collection).

To compare metabolic rates across participants (i.e., to account for variations in individual mass that may affect metabolic performance), we also calculated mass-adjusted gross metabolic rate (ml O2/min*kg) for each participant. Across particpants, results show that, on average, the mRSF reduces mass-adjusted metabolic rate relative to the ESF at comfortable and fast speeds (Figure 6). At slow speeds, use of the mRSF is associated with slightly increased mass-adjusted metabolic rate relative to the ESF.

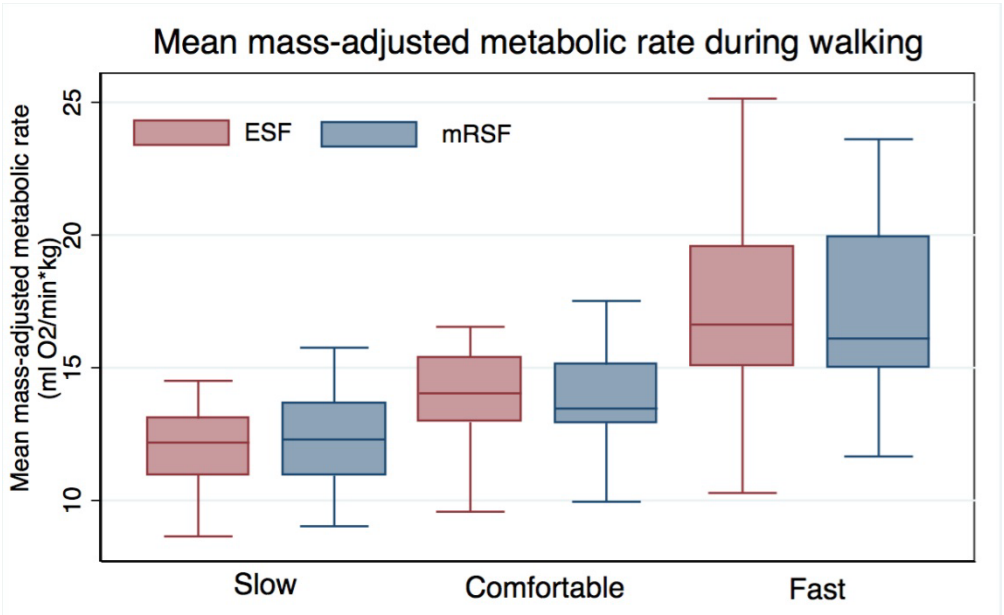


Figure 6 – Mean mass-adjusted metabolic rate (ml O2/min) for participants (n=17) with transtibial amputation

Results of metabolic testing suggest the mRSF may reduce metabolic rate in some participants at some speeds, but additional data is needed to confirm this assessment. In Y2 of this project, we will collect the data required to complete the proposed group-level analyses to examine the overall effectiveness of the mRSF and ESF (n=30 total people with transtibial amputation across our pilot study and the present study). With this data, we will also conduct regression analyses to determine individual characteristics (e.g., body mass, time since amputation) that may be potential predictors of outcome. Results would help to inform prescription criteria for the studied prosthetic foot technologies.

Gait quality:

Temporospatial gait parameters: Temporospatial gait parameters were collected using a GAITRite electronic walkway while participants performed the six-minute walk test (6MWT). Walking speed (m/s), step lengths (m), step time differential (sec) and step width (cm) were measured. Across participants, there appears to be no significant effect of foot condition on any temporospatial gait parameters (Table 1). 5 participants showed 5% or more increases in walking speed in the mRSF relative to the ESF, 3 showed 5% or more decreases in walking speed in the mRSF relative to the ESF, and 9 exhibited no substantial change in walking speed.

Table 1 – Temporospatial gait parameters (mean and SD) collected during 6MWT for participants (n=17) with transtibial amputation. (* = will be analyzed separately due to challenges with data collection).

Participant	Walking speed (m/s)		Prosthetic step length (m)		Non-prosthetic step length (m)		Step time difference (s)		Step width (cm)	
	ESF	mRSF	ESF	mRSF	ESF	mRSF	ESF	mRSF	ESF	mRSF
1000	**1.71** **0.05**	**1.70** **0.04**	**0.73** 0.02	**0.72** 0.01	**0.67** 0.02	**0.68** 0.02	**0.01** 0.01	**0.01** 0.01	**7.06** 0.36	**7.08** 0.26
1001	**1.42** 0.05	**1.43** 0.05	**0.66** 0.01	**0.66** 0.02	**0.73** 0.02	**0.77** 0.02	**0.04** 0.02	**0.04** 0.01	**7.03** 0.40	**7.31** 0.58
1002	**1.47** 0.03	**1.50** 0.03	**0.72** 0.02	**0.74** 0.01	**0.75** 0.02	**0.75** 0.01	**0.01** 0.01	**0.02** 0.01	**7.57** 0.26	**7.61** 0.19
1003	**2.62** 0.29	**2.48** 0.11	**1.06** 0.04	**0.99** 0.05	**0.94** 0.06	**0.96** 0.05	**0.02** 0.03	**0.02** 0.01	**10.07** 0.87	**9.83** 0.56
1004	**1.55** 0.03	**1.73** 0.03	**0.87** 0.01	**0.88** 0.01	**0.88** 0.01	**0.94** 0.02	**0.01** 0.01	**0.01** 0.01	**8.93** 0.17	**9.28** 0.35
1006	**1.32** 0.06	**1.37** 0.05	**0.73** 0.02	**0.74** 0.01	**0.65** 0.02	**0.69** 0.02	**0.08** 0.03	**0.08** 0.03	**7.22** 0.46	**7.47** 0.33
1007*	**1.49** 0.04	**1.56** 0.04	**0.72** 0.03	**0.75** 0.02	**0.69** 0.03	**0.75** 0.03	**0.02** 0.01	**0.02** 0.01	**7.44** 0.35	**7.80** 0.26
1008	**0.89** 0.05	**0.86** 0.05	**0.60** 0.02	**0.55** 0.02	**0.43** 0.04	**0.45** 0.03	**0.02** 0.02	**0.08** 0.07	**5.87** 0.72	**5.75** 0.44
1009	**1.91** 0.05	**1.80** 0.03	**0.88** 0.03	**0.85** 0.01	**0.85** 0.02	**0.89** 0.02	**0.01** 0.01	**0.03** 0.01	**8.76** 0.28	**8.81** 0.28
1011	**1.90** 0.04	**1.87** 0.03	**0.87** 0.01	**0.85** 0.01	**0.78** 0.01	**0.79** 0.01	**0.01** 0.00	**0.01** 0.01	**8.37** 0.46	**8.37** 0.28
1012	**1.91** 0.11	**1.92** 0.07	**0.84** 0.02	**0.87** 0.02	**0.79** 0.02	**0.83** 0.03	**0.03** 0.02	**0.02** 0.01	**8.39** 0.36	**8.66** 0.36
1013*	**1.63** 0.05	**1.31** 0.07	**0.81** 0.02	**0.73** 0.02	**0.81** 0.02	**0.72** 0.02	**0.06** 0.08	**0.06** 0.01	**8.30** 0.22	**7.40** 0.26
1014	**1.62** 0.06	**1.55** 0.05	**0.82** 0.02	**0.81** 0.03	**0.88** 0.02	**0.90** 0.03	**0.01** 0.01	**0.01** 0.01	**8.69** 0.37	**8.76** 0.56
1015	**1.59** 0.05	**1.68** 0.04	**0.79** 0.02	**0.79** 0.02	**0.79** 0.01	**0.82** 0.02	**0.02** 0.01	**0.02** 0.01	**8.04** 0.20	**8.16** 0.25
1016	**1.39** 0.03	**1.48** 0.02	**0.75** 0.01	**0.75** 0.01	**0.73** 0.01	**0.77** 0.01	**0.02** 0.01	**0.01** 0.01	**7.48** 0.15	**7.75** 0.15
1018	**1.53** 0.04	**1.61** 0.06	**0.74** 0.02	**0.72** 0.02	**0.73** 0.02	**0.76** 0.01	**0.02** 0.01	**0.03** 0.01	**7.40** 0.19	**7.48** 0.26
1019	**1.52** 0.06	**1.55** 0.05	**0.73** 0.03	**0.74** 0.02	**0.83** 0.02	**0.86** 0.02	**0.04** 0.01	**0.03** 0.01	**7.99** 0.57	**8.17** 0.62
Mean	**1.61** 0.06	**1.61** 0.05	**0.78** 0.02	**0.77** 0.02	**0.76** 0.02	**0.78** 0.02	**0.02** 0.02	**0.03** 0.01	**7.92** 0.38	**7.98** 0.35

Community mobility:

Daily step activity: Participants' step activity was measured with Stepwatch activity monitors affixed to the ankle of each participant's prosthesis. Activity was measured continuously over the four-week period prior to in-lab assessment. Mean daily step counts (steps per day, Figure 7) and step count variability (coefficient of variation (CoV), Figure 8) from participants-to-date were deteremined. Interim results suggest participants were less active (and varied their activity slightly less) in the mRSF prosthesis, relative to the ESF prosthesis. 11 of 17 participants showed 5% or more decreased step activity in the mRSF, relative to the ESF; only 4 of 17 showed increased activity with the mRSF. Similarly, 9 of 17 participants showed reduced variation in activity levels (i.e., lower CoV) in the mRSF over the 4-week period.

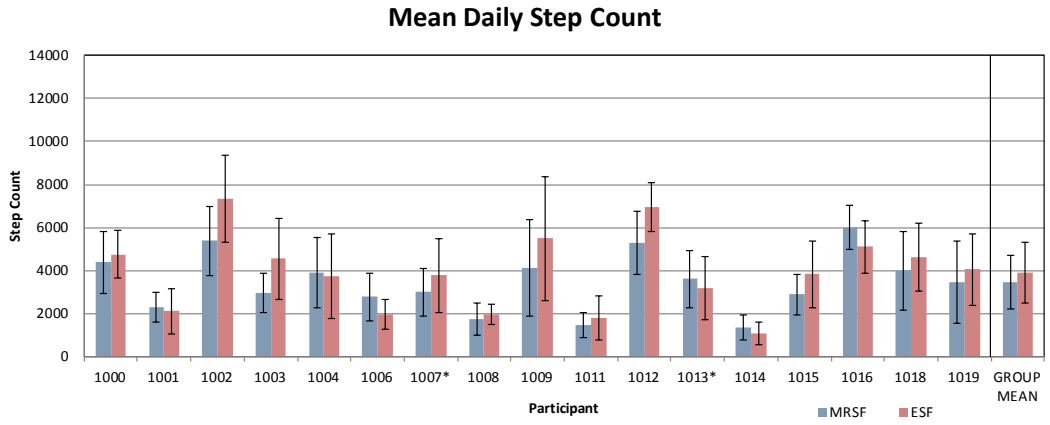


Figure 7 – Mean (±SD) daily step count (step/day) for participants (n=17) with transtibial amputation. (* = will be analyzed separately due to challenges with data collection).

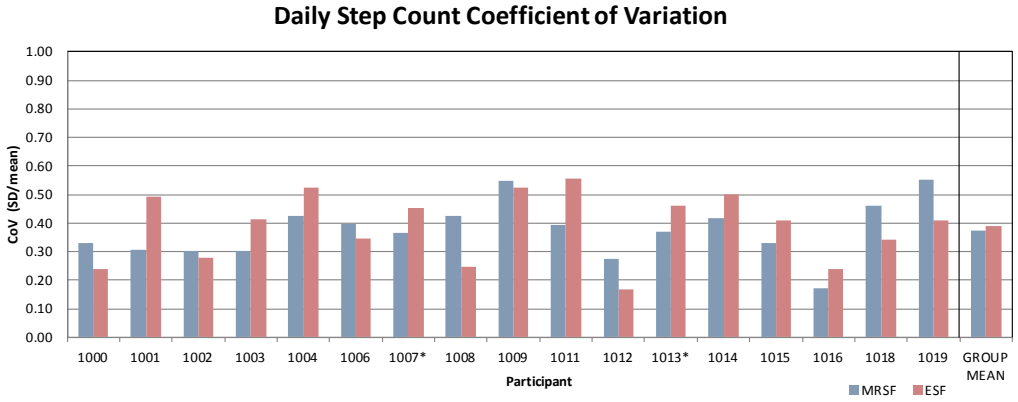


Figure 8 – Coefficient of variation (CoV) in daily step count for participants (n=17) with transtibial amputation. (* = will be analyzed separately due to challenges with data collection).

Patient-centered outcomes

Patient-centered outcomes are those that characterize participants' perceptions of or experiences with with studied interventions. Investigators solicit report of participants' experiences using self-report instruments. All self-report instruments were administered via a tablet computer. Because PLUS-M and PROMIS-Fatigue are calibrated item banks, they were administered using computerized adaptive testing (CAT) methods to improve precision of scoring. Other instruments (ABC, TAPES-R) were administered as fixed-length instruments.

Mobility: Participants' mobility (ability to move from one place to another) was measured with the Prosthetic Limb Users Survey of Mobility (PLUS-M, Figure 7). As PLUS-M was developed specifically for people with lower limb amputation, a T-score of 50 represents the mean mobility of people with lower limb amputation (and 55.9 represents the mean mobility score for people with transtibial amputation from non-vascular causes). 16 of 17 participants reported improved mobility in the mRSF; 12 of 17 reported a change which exceeded the estimated minimum detectable change (4.5 points) of the PLUS-M instrument.

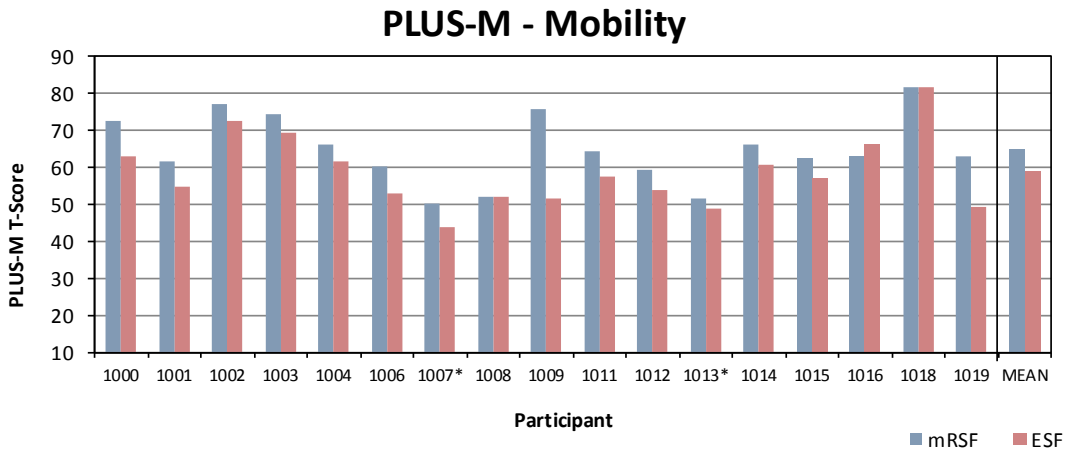


Figure 7 – Self-reported mobility of participants with transtibial amputation. Higher scores reflect improved mobility. (* = will be analyzed separately due to challenges with data collection).

Fatigue: Participants' overall perceptions of fatigue were measured the Patient Reported Outcomes Measurement Information System Fatigue (PROMIS-Fatigue, Figure 8). A PROMIS-Fatigue T-score of 50 represents the mean of the US general population. 13 of 17 participants reported reduced fatigue in the mRSF condition; 8 of 17 reported differences between feet that exceeded the threshold for a clinically meaningful difference for PROMIS instruments (about ½ standard deviation or 5.0 points).

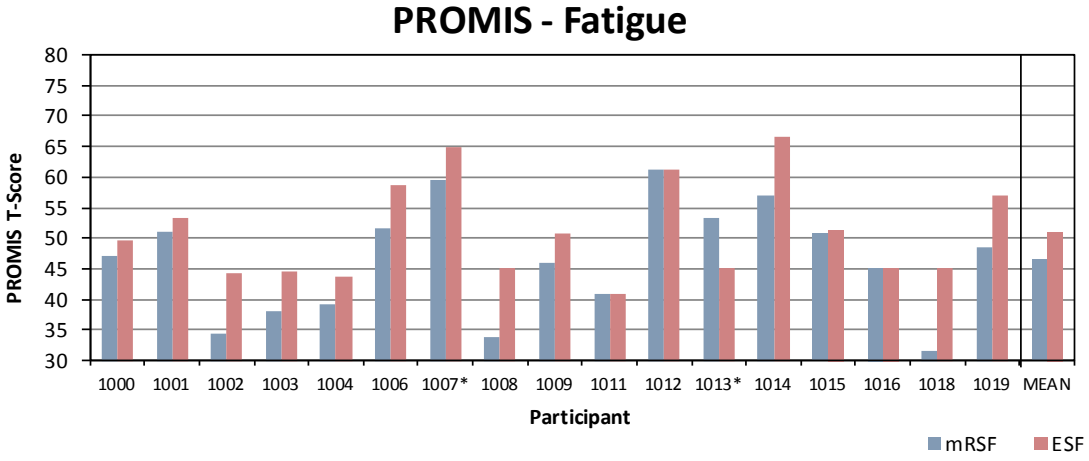


Figure 8 – Self-reported fatigue of participants with transtibial amputation. Lower scores reflect reduced fatigue. (* = will be analyzed separately due to challenges with data collection).

Balance Confidence: Participants' balance confidence was evaluated using the Activities Specific Balance Confidence Scale (ABC, Figure 9). 13 of 17 participants reported greater balance confidence in the mRSF foot condition. 11 of 17 participants also reported a change of 5% or more, relative to the ESF condition (10 increased; 1 decreased). We consider 5% a threshold for clinically significant difference or change, in absence of evidence of meaningful change (e.g., MDC or MID) in the population of interest.

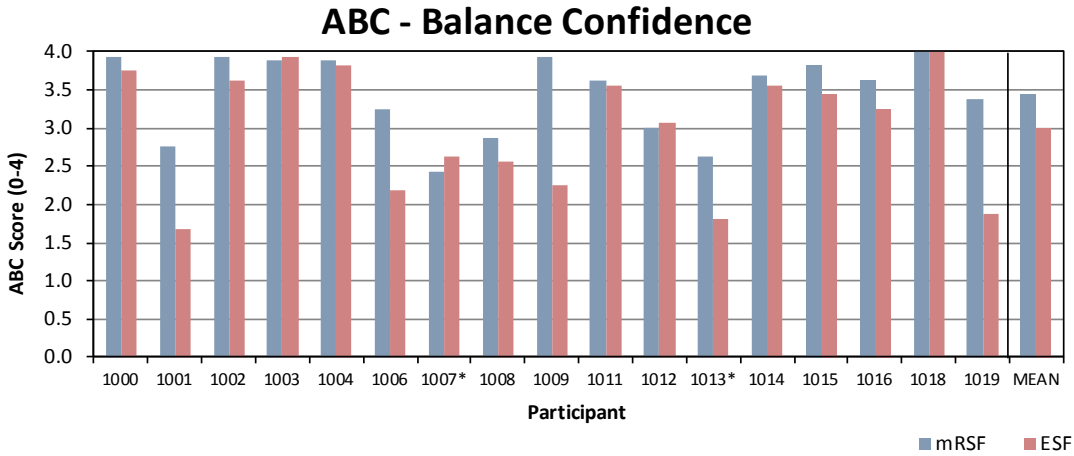


Figure 9 – Self-reported balance confidence of participants with transtibial amputation. Higher scores reflect greater balance confidence. (* = will be analyzed separately due to challenges with data collection).

Activity Restrictions: Participants' perceptions of activity restrictions in both prosthetic foot conditions were evaluated using the revised Trinity Amputation Prosthesis Experience Scales (TAPES-R) instrument (Figure 10). The activity restriction scale asks the user about how much their prosthesis limits them in performing daily activities, from going to work to engaging in vigorous activities (e.g., running, lifting heavy objects). 12 participants experienced more restrictions in the ESF, 3 others reported the feet restricted them equally and 2 reported greater restriction with the mRSF.

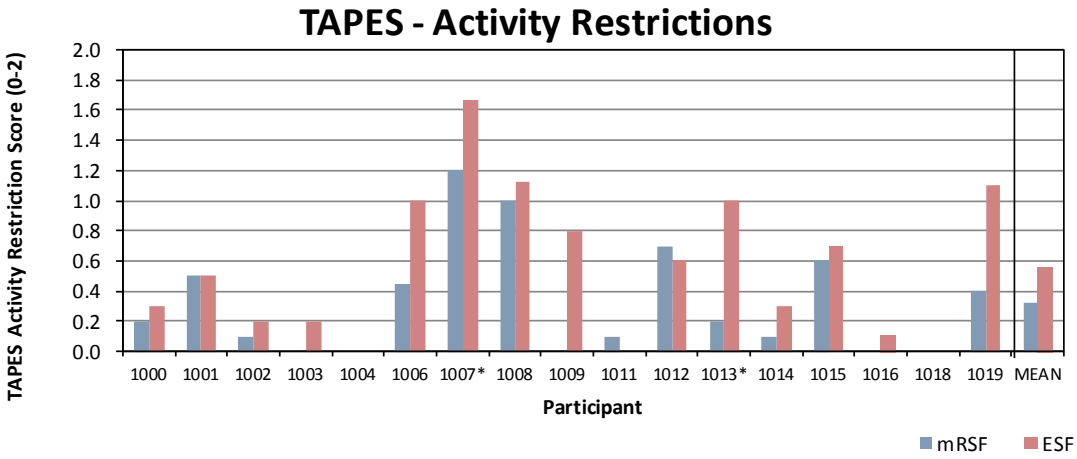


Figure 10 – Self-reported activity restrictions of participants with transtibial amputation. Lower scores represent fewer activity restrictions. (* = will be analyzed separately due to challenges with data collection).

Satisfaction: Satisfaction was measured using subscales of the TAPES-R, the Aesthetic satisfaction subscale (which relates to the user's perception of the shape, color, and appearance of the device), and the functional satisfaction subscale (which relates to the user's perception of weight, usefulness, reliability, fit, and comfort). 5 participants found the mRSF more aesthetically pleasing, 5 found the ESF more pleasing, and 7 found them equivalent. 14 participants found the mRSF more functional, while 3 reported the mRSF and ESF were equally functional. Satisfaction results are presented in Figures 11 and 12, below.

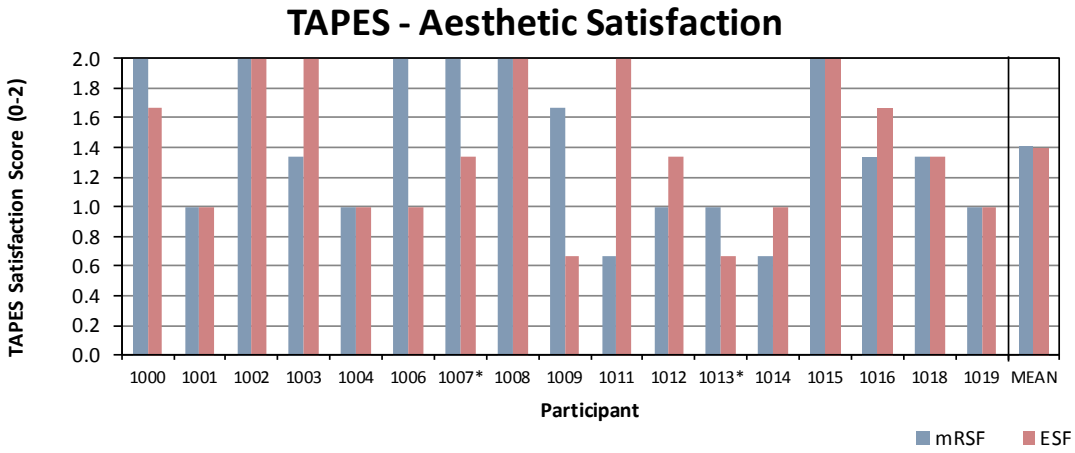


Figure 11 – Self-reported aesthetic satisfaction of participants with transtibial amputation. Higher scores reflect improved satisfaction. (* = will be analyzed separately due to challenges with data collection).

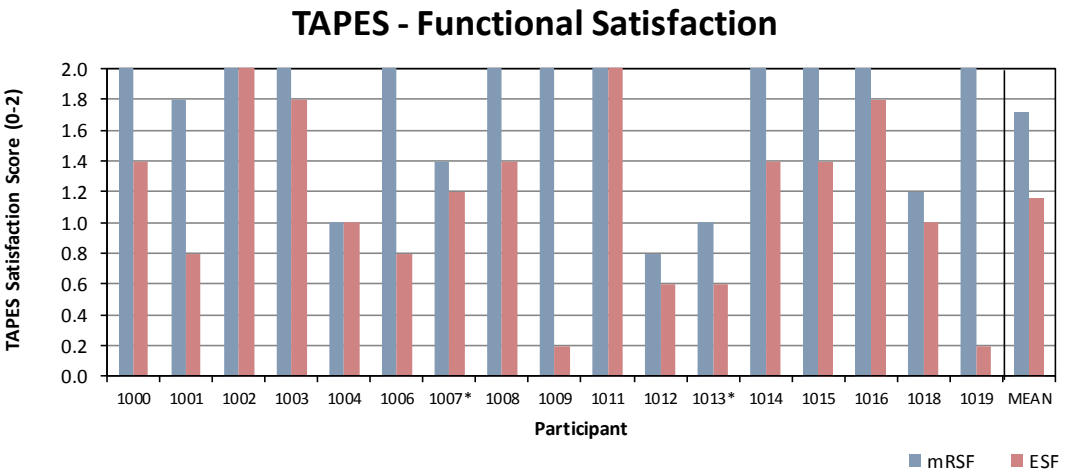


Figure 12 – Self-reported functional satisfaction of participants with transtibial amputation. Higher scores reflect improved satisfaction. (* = will be analyzed separately due to challenges with data collection).

Results summary (to-date): *Functional activity outcomes* for the study sample to-date are mixed. Trends suggest that metabolic energy may be reduced in the mRSF foot (relative to the ESF foot) at comfortable and fast walking speeds, but not slow speeds. However, individual participant results are quite variable, and additional data will be required to deteremine overall effectiveness of these feet. A regression analysis of metabolic data (obtained from a larger sample of people

with transtibial amputation) may reveal influential, individual characteristics that may guide prescription criteria and identify those most likely to benefit from mRSF. Endurance, perceived exertion, or both are often improved when participants are using the mRSF, but additional data and analysis will be required to determine which outcomes (i.e., increased endurance, decreased perceived exertion, both, or neither) are most associated with the mRSF. Temporospatial outcomes were largely unaffected by foot condition. It is likely that the mRSF has little effect on gait quality when users walk rapidly on level terrain. Step activity, overall, was reduced when participants wore the mRSF, suggesting use of the mRSF may inhibit overall daily activity. In contrast to modest benefits in functional outcomes, the large majority of participants showed improvements in all *patient-centered outcomes* in the mRSF compared to those obtained in the ESF condition. Mean (and individual) scores on self-report measures showed that participants perceived significantly better mobility, lower fatigue, better balance confidence, fewer activity restrictions, and increased satisfaction (both aesthetic and functional) with the mRSF relative to the ESF. Spontaneous comments from participants upon conclusion of the study suggest that they much preferred the mRSF and expected to use it on a daily basis after the study concluded.

The apparent discrepancy between functional and self-report outcomes may be indicative of limitations in test conditions (e.g., walking may be largely unaffected and differences between feet are more apparent in other activities), assessment methods (e.g., testing equipment may not be sensitive enough to detect user experiences), or user bias (e.g., preference unrelated to true performance). Research pertaining to user performance in other activities (e.g., jogging, sporting activities) and/or qualititative studies to solicit experiences from users (e.g., focus groups) may help to reveal other activities or life situations that may explain participants' strong preference for the mRSF in light of modest measured benefits to-date.

Interim analyses also suggest the need to collect more data from a larger sample, as results are markedly affected by the relatively small number of participants included in the analysis. For example, a recent interim analysis of metabolic data from n=14 participants showed a statistically significant benefit to use of the mRSF at comfortable and fast walking speeds (see Appendix E - AAOP 2017 abstract). However, with the addition of the n=3 participants added to this report, the results show no significant effect. This illustrates the large effect that each participant can have on the interim results of the study and reinforces the need for collecting data from the remainder of the participants targeted in the original proposal.

- Other achievements: Nothing to report.

➢ **What opportunities for training and professional development has the project provided?**

- Several individuals received research training from Drs. Hafner and Kramer during the Y1Q1-Y1Q4 reporting period.
    - Ms. McDonald is a third-year student in the University of Washington's Rehabilitation Science Doctoral Program. She served as a research prosthetist on this project during the Y1Q1-Y1Q4 reporting period. Ms. McDonald received training specific to research design, ethical protection of human subjects, data collection, statistical analysis, and dissemination during the course of her involvement in this project.
        - Ms. McDonald's initial involvement in this project was designated as a Research and Scientific Inquiry (RSI), a period of research experience and training required of predoctoral students in the UW Rehabilitation Sciences PhD Program. Ms. McDonald presented the results of her RSI, titled "Energy Expenditure in People with Transtibial Limb Loss Walking with Crossover and Energy Storing Prosthetic Feet," on 25-04-2016.
        - Ms. McDonald received also training specific to review of scientific literature from Dr. Hafner. Ms. McDonald and Ms. Halsne conducted a mentored

scoping review of scientific literature pertaining to metabolic energy expenditure in people with transtibial amputation. They received training specific to searching bibliographic databases and critically appraising scientific studies.

- Ms. McDonald participated in an independent study with Dr. Hafner to develop a focus group study proposal to evaluate prosthesis users' experiences as they transitioned between different types of prosthetics technology (i.e., from ESF to mRSF). She received training specific to conduct of qualitative interviews and focus groups, research proposal design, and budget planning. Ms. McDonald applied for and received supplementary funding for the focus group study via a Walter C. and Anita C. Stolov Research Award (a small pilot grant made available to students in our Department).

- Ms. Halsne is a second-year student in the University of Washington's Rehabilitation Science Doctoral Program. She served as research prosthetist on this project during periods when Dr. Morgan and Ms. McDonald experienced increased teaching commitments. Like Ms. McDonald, Ms. Halsne received training specific to research design, ethical protection of human subjects, data collection, statistical analysis, and dissemination during the course of her involvement in this project.

  - Ms. Halsne participated in an independent study course with Dr. Kramer. She received training specific to measurement and analysis of metabolic energy expenditure. She was trained in use of the Cosmed k4b2 portable metabolic measurement system (the equipment used in this study), as well as analysis and interpretation of resultant data.

  - As noted above, Ms. Halsne and Ms. McDonald conducted a mentored scoping review of scientific literature pertaining to metabolic energy expenditure in people with transtibial amputation.

- Dr. DiGirolamo is a third-year Physical Medicine & Rehabilitation resident at Harborview Medical Center, a level-1 trauma center managed by the University of Washington. Dr. DiGirolamo served as a clinical consultant on the project and received training specific to self-report outcome measures. He received one-on-one training from Dr. Hafner on issues related to instrument development, administration, scoring, and interpretation.

  - Dr. DiGirolamo analyzed preliminary self-report data collected from study participants and presented results at a physicians' conference during the reporting period.

- Ms. Cheever is a part-time staff member. She received training specific to research design, ethical protection of human subjects, prosthetic device design, and data collection from Dr. Hafner, Ms. McDonald, and Ms. Halsne.

  - Exposure to the field of prosthetics during this project inspired Ms. Cheever to pursue a career in orthotics and prosthetics. In Y1Q2, she applied to the University of Washington's Master in Prosthetics and Orthotics (MPO) Program. She was accepted into the program in Y1Q3, and will begin her training in Y2Q1 of this project (fall term, 2016).

➢ **How were the results disseminated to communities of interest?**

- Preliminary results from this research were disseminated as podium and poster presentations during the Y1Q1-Y1Q4 reporting period. Presentations were delivered to:

  - University of Washington Department of Rehabilitation Medicine students and faculty (presentation at Ms. McDonald's Research and Scientific Inquiry)

- Local clinical providers, faculty, students, and others (presentation at the Northwest Chapter of the American Academy of Orthotists and Prosthetists Meeting)
- National clinical providers, researchers, students, and others (presentations at the American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium and the American Orthotic and Prosthetic Association National Assembly; poster at the American Osteopathic College of Physical Medicine & Rehabilitation Meeting)
- International clinical providers, researchers, students, and others (presentation at the OTWorld World Congress)

➢ **What do you plan to do during the next reporting period to accomplish the goals?**

- We will continue to collect data from 9 participants with unilateral amputation who have been enrolled in the study (but have not yet completed the study).
- We will continue to recruit additional participants with unilateral amputation. Recruitment of 3 additional participants with unilateral amputation are required to achieve the study goals of 18 people with unilateral amputation. We anticipate no challenges with recruitment of participants with unilateral amputation.
- We will begin recruitment of participants with bilateral amputation. Recruitment of participants with bilateral amputation has been more challenging than expected, and we are working closely with our clinical partner(s) to identify candidates. Given the expected small sample of participants with bilateral amputation, results will be analyzed separately from participants with unilateral amputation and a manuscript describing the results will be authored and submitted for publication.
- We will combine data collected from all participants with unilateral amputation with data collected in our prior pilot study (of 12 participants with unilateral amputation). The combined sample of 30 people with unilateral amputation will be used to address study hypotheses. Results will be analyzed and one or more manuscripts describing the results will be authored and submitted for publication.
- We will conduct pilot studies to explore differences in metabolic energy and mobility performance between mRSF and ESF in high-performance activities (i.e., jogging and agility drills). These data will provide valuable insight into activities other than walking where mRSF and ESF may have an effect on user outcomes. Results of the pilot studies will be analyzed and manuscripts describing the results will be authored and submitted for publication.
- We will conduct a qualitative focus group study with mRSF users to identify experiences and outcomes associated with transitions between ESF and mRSF technologies. Results of the focus group study will be analyzed using best practice methods and a manuscript describing the results will be authored and submitted for publication.

4. **IMPACT:**

➢ **What was the impact on the development of the principal discipline(s) of the project?**

- Nothing to Report

➢ **What was the impact on other disciplines?**

- Nothing to Report

➢ **What was the impact on technology transfer?**

- Nothing to Report

➢ **What was the impact on society beyond science and technology?**

- Nothing to Report

5. **CHANGES/PROBLEMS:**

➢ **Changes in approach and reasons for change**

- No significant changes in approach were made to the study during the Y1Q1-Y1Q4 reporting period.
- Two minor protocol revisions (termed "substudies") were added to explore effects of ESF and mRSF on activities that require increased energy and movement. Substudies were added to the protocol because of spontaneous participant feedback that indicated the prosthetic feet under study performed quite differently in these situations. The pilot data we collect with the substudies will be valuable towards determining future study directions. Protocols for the substudies were submitted and approved by our local IRB (see details pertaining to Modifications 7 and 8, below). They were submitted to HRPO for review, and deemed to be non-substantive protocol changes.
    - Jogging substudy – upon conclusion in the primary study, participants will be invited to attend a jogging session. We will measure participants' metabolic energy while they jog on a treadmill using procedures identical to those used to evaluate walking in the primary study. Participants will jog using both prostheses and data will be compared to evaluate the relative effectiveness of ESF and mRSF during jogging.
    - Agility substudy – upon conclusion in the primary study, participants will be invited to attend an agility testing session. We will measure participants' performance on several standardized performance-based tests, including the Timed Up and Go, the Four Square Step Test, and the Comprehensive High-Activity Mobility Predictor. Scores or times on these tests will be compared to evaluate the relative effectiveness of ESF and mRSF during activities that required running, jogging, turning, and pivoting.

➢ **Actual or anticipated problems or delays and actions or plans to resolve them**

- Recruitment of study participants has been slightly lower than anticipated. We originally targeted recruitment of 6 participants per quarter, but we have successfully recruited between 1 and 6 participants per quarter over the Y1Q1-Y1Q2 reporting period (average 3.5 per quarter). A principal reason for recruitment challenges is that many individuals being fit with the mRSF prosthesis live remote to Seattle and travel to visit our clinical partner (Davidson Prosthetics). Thus, they are not able to commit to a study protocol that requires multiple visits to our laboratory. To address recruitment delays, we have implemented a variety of actions (noted below). These strategies have improved recruitment and we have averaged 5.5 participants per quarter since their implementation.
    - We work more closely with our primary clinical partner to identify candidate participants. We have scheduled weekly phone calls to review candidate participants. We regularly review study inclusion/exclusion criteria with clinic providers and staff, and provide the clinic with study flyers that can be used to inform interested individuals about the study.
    - We have recruited participants from additional clinical facilities in the local area (American Artificial Limb and Hanger Clinic). Practitioners at these facilities have

helped us to identify 2 study participants (both have successfully completed the study). We will use this strategy to supplement participant recruitment as needed.

- Several participants experienced unexpected minor issues that affected their ability to engage in study activities. For example, one participant experienced a back injury that significantly affected their mobility. Another participant experienced a death in the family that greatly affected self-reported activity. To minimize the effect of these confounding injuries or life situations, we have provided individuals the opportunity to delay participation in the study. Both participants have agreed to return to the study and will be re-scheduled for participation at a later time (when the issues they experienced are less likely to affect study outcomes).
- One participant was temporarily incarcerated during the course of his participation in the study. We suspended his participation in the study upon notice of incarceration. We plan to re-contact the individual following his release to determine if he is interested in continuing his participation in the study. We informed our local IRB and HRPO of this event and our plan (see details of Modification 6, below). We received approval to re-contact the participant following his release in Y2Q1.

➢ **Changes that had a significant impact on expenditures**

- Delays in participant recruitment during the Y1Q1-Y1Q4 period have reduced projected expenditures related to participant visits (e.g., socket fabrication costs, participant payments, parking cost, personnel time). These funds will be required in Y2 when an increased number of participants (relative to Y1) will receive test prostheses and attend study data collection sessions.

➢ **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

- No significant changes in use or care of human subjects have been required during the reporting period. Small revisions to study population (e.g., inclusion of participants with bilateral amputation) and protocols (e.g., addition of pilot trials to assess metabolic energy during jogging and performance in agility tests) have been reviewed with the Human Research Protections Office (HRPO). All revisions were deemed non-substantive.
- A brief summary of non-substantive modifications, local institutional review board approvals, and HRPO communications that have occurred since the original HRPO approval of the study protocol (01-09-2015) is included below:
    - Modification 3 (local IRB approval 15-08-2015): Added collection of social security number (SSN) to data collection forms and consent materials. SSN is required by our University for reporting payment of study subjects. Deemed a non-substantive change to study protocol; not submitted to HRPO.
    - Modification 4 (local IRB approval 19-01-2016): Added the Montreal Cognitive Assessment (MoCA) and Neuro-Qol Applied Cognition General Concerns instruments to initial testing. Instruments were added to inform results of self-report and performance-based tests. Deemed a non-substantive change to study protocol; not submitted to HRPO.
    - Modification 5 (local IRB approval 29-02-2016): Inclusion and exclusion criteria revised slightly to include participants with bilateral amputation, in accordance with the approved scope-of-work (SOW). Deemed a non-substantive change to study protocol; not submitted to HRPO.
    - Modification 6 (local IRB approval 07-07-2016): Notification of incidental incarceration of one study participant. Proposed plan to suspend all contact while participant was incarcerated, and re-contact once released to determine interest in continuing study

participation. Both local IRB and HRPO were notified. HRPO approved the proposed participant management plan on 21-07-2016.

- Modification 7 (local IRB approval 26-07-2016): Addition of a test session to assess metabolic energy at jogging speeds in select participants. Submitted to HRPO on 29-07-2016; HRPO deemed changes non-substantive on 16-08-2016.
- Modification 8 (local IRB approval 27-07-2016): Addition of a test session to assess agility performance in select participants. Submitted to HRPO on 29-07-2016; HRPO deemed changes non-substantive on 16-08-2016.
- Focus Group Study (local IRB approval 08-01-2016): Added a qualitative focus group study to examine mRSF users' shared experiences and outcomes after transition from ESF to mRSF. Submitted to HRPO on 17-08-2016; HRPO deemed study non-substantive change to parent study on 02-09-2016.

- No vertebrate animals, biohazards, and/or select agents are included in this study.

6. **PRODUCTS:**

➢ **Publications, conference papers, and presentations**

- **Journal publications**

  Nothing to report.

- **Books or other non-periodical, one-time publications**

  Nothing to report.

- **Other publications, conference papers, and presentations**

  Five presentations resulting from this work were presented during the Y1Q1-Y1Q4 reporting period:

  - Hafner BJ, Morgan SJ, McDonald CM, Kramer PA, Davidson GE. Effects of a modified running foot prosthesis on users' endurance and perceived exertion. American Academy of Orthotists & Prosthetists (AAOP) 42nd Annual Meeting and Scientific Symposium, Orlando, FL, March 9-12, 2016 (podium presentation) [Appendix A]
  - DiGirolamo A, McDonald C, Halsne B, Morgan S, Cheever S, Hafner B. Self-report health outcomes in people with transtibial amputation using a modified running foot (poster). American Osteopathic College of Physical Medicine & Rehabilitation (AOCPMR) 61st Mid Year Meeting & Scientific Seminar, Philadelphia PA, March 17-20, 2016. (poster presentation) [Appendix B]
  - McDonald C, Kramer P, Hafner B. Energy expenditure in people with transtibial limb loss walking with crossover and energy storing prosthetic feet. Northwest Chapter of the American Academy of Orthotists and Prosthetists (NWAAOP), Bellevue, WA, April 8-9, 2016.
  - Hafner BJ, Morgan SJ, McDonald CM, Kramer PA, Davidson GE. Walking performance, endurance, and perceived exertion in people with transitibal amputation: effects of a modified running-specific foot. OTWorld 2016 Congress, Leipzig, Germany, May 3-6, 2016 (podium presentation). [Appendix C]
  - McDonald CL, Kramer PA, Hafner BJ. Energy expenditure in people with transtibial limb loss walking with crossover and energy-storing feet. American Orthotic and Prosthetic

Association (AOPA) National Assembly. Boston, MA, September 8-11, 2016 (podium presentation).[Appendix D]

One additional abstract resulting from this work was submitted for presentation (review pending) during the Y1Q1-Y1Q4 reporting period:

- Hafner BJ, Halsne EG, McDonald CL, Morgan SJ, Kramer PA. Crossover and energy storing prosthetic feet in adults with transtibial amputation: a comparative effectiveness study. American Academy of Orthotists and Prosthetists (AAOP) 43rd Annual Meeting and Scientific Symposium, Chicago IL, March 1-4, 2017 (submitted for podium presentation). [Appendix E]

- **Website(s) or other Internet site(s)**

  Nothing to report.

- **Technologies or techniques**

  Nothing to report.

- **Inventions, patent applications, and/or licenses**

  Nothing to report.

- **Other products**

  Nothing to report.

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

- **What individuals have worked on the project?**

Name:	Brian Hafner, PhD
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3
Contribution to Project:	Dr. Hafner has performed work to finalize study protocols and materials; prepare and submit human subjects materials to UW IRB and USAMRMC HRPO; hire and train research staff; purchase research supplies; review study progress and coordinate study activities, review and revise study materials, conduct and review data analyses, mentor students, and prepare materials for dissemination.
Funding Support:	N/A

Name:	Patricia Kramer, PhD
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Dr. Kramer has performed work to conduct and review data analyses, mentor students, and prepare materials for dissemination
Funding Support:	N/A

Name:	Cody McDonald, CPO
Project Role:	Graduate Student
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Ms. McDonald has performed work to recruit and screen participants, collect data from participants, process and analyze collected data, and disseminate preliminary results.
Funding Support:	N/A

Name:	Elizabeth Halsne, CPO
Project Role:	Graduate Student
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Ms. Halsne has performed work to screen participants, collect data from participants, process and analyze collected data, and prepare materials for dissemination.
Funding Support:	N/A

Name:	Sarah Cheever
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Ms. Cheever has performed work to collect and process data from participants.
Funding Support:	N/A

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

  - Effort for Dr. Morgan (co-investigator) was reduced (from 2.4 to 0.6 calendar months during the Y1Q1-Y1Q4 reporting period) to accommodate a personal leave and increased teaching commitments required by an unexpected faculty transition. Ms. Halsne (also a certified prosthetist-orthotist) was temporarily added to the study team (1.2 calendar months) to fulfill Dr. Morgan's roles and responsibilities (i.e., participant recruitment and scheduling, data collection, assisting with data analyses, and preparing materials for dissemination). Dr. Morgan will return to the study in October, 2016, when her teaching commitments are reduced.
  - All other effort remains as planned.

- **What other organizations were involved as partners?**

  - **Organization Name:** Davidson Prosthetics, LLC
  - **Location of Organization:** Puyallup, WA
  - **Partner's contribution to the projec**t
    - **In-kind support** Davidson Prosthetics practitioners, Greg and Nathan Davidson, donated time to fabricate prostheses for 13 participants in this study during the Y1Q1-Y1Q4 reporting period.
    - **Collaboration** *(e.g., partner's staff work with project staff on the project)*;

  - **Organization Name:** American Artificial Limb Company
  - **Location of Organization:** Seattle, WA
  - **Partner's contribution to the projec**t
    - **In-kind support** AAL practitioner, John Shaffer, donated time to fabricate prostheses for one participant in this study during the Y1Q1-Y1Q4 reporting period.

  - **Organization Name:** Hanger Clinic
  - **Location of Organization:** Gig Harbor, WA
  - **Partner's contribution to the projec**t
    - **In-kind support** Hanger Clinic practitioner, Ryan Blanck, donated time to fabricate prostheses for one participant in this study during the Y1Q1-Y1Q4 reporting period.

  - **Organization Name:** Össur ehf
  - **Location of Organization:** Reykjavik, Iceland
  - **Partner's contribution to the projec**t
    - **In-kind support** Össur donated components to fabricate 15 control (ESF) prostheses in this study during the Y1Q1-Y1Q4 reporting period.

8. **SPECIAL REPORTING REQUIREMENTS**

- **Collaborative awards**

  Not applicable.

- **Quad chart**

  Updated quad chart attached.

9. **APPENDICES**

- **Appendix A -** AAOP 2016 abstract.

- **Appendix B –** AOCPMR 2016 abstract.
- **Appendix C –** OTWorld 2016 abstract.
- **Appendix D -** AOPA 2016 abstract.
- **Appendix E -** AAOP 2017 abstract.

A Novel Modification of a Running-Specific Foot

OP140079

W81XWH-14-OPORP-OPORA (Funding Level 1)

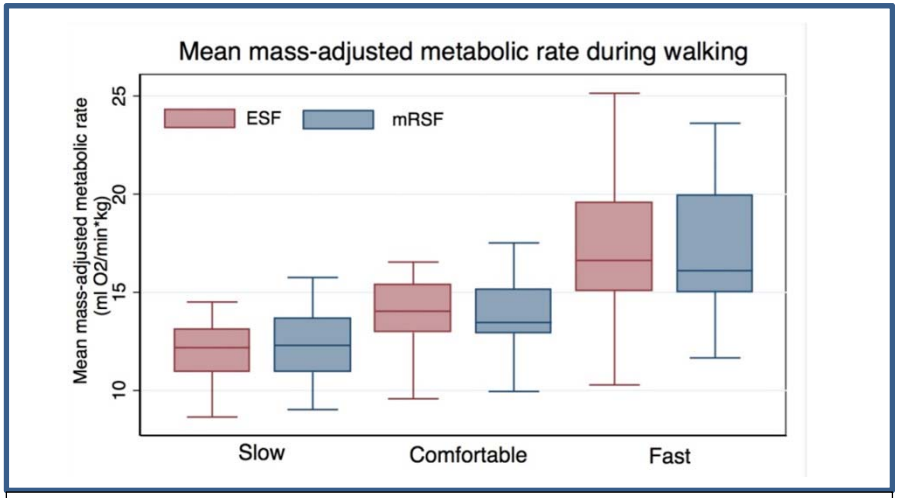
PI: Brian Hafner, PhD **Org:** University of Washington **Award Amount:** $500,000

Study Aim(s)

- Evaluate functional activity outcomes (i.e., energetics, gait quality, and community mobility) in transtibial prosthesis users walking with a conventional energy storing foot (ESF) and a modified running-specific foot (mRSF).
- Assess patient-centered health outcomes (i.e., self-reported mobility, fatigue, balance confidence, activity restrictions, and satisfaction) in transtibial prosthesis users walking with a conventional ESF and the mRSF.

Approach

We will conduct a rigorous randomized crossover study to compare functional and self-reported health outcomes in 18 participants with unilateral and 6 participants with bilateral amputation under two test conditions: (1) use of a conventional ESF and (2) use of a novel mRSF. Functional performance and self-report outcomes data will be collected after participants use each prosthesis for 1 month.



Accomplishment: Results to-date indicate that use of a mRSF may reduce metabolic rate in walking at comfortable and fast speeds in participants with lower limb amputation, however results are highly variable due to the small sample (n=17).

Timeline and Cost

Activities	CY	15	16	17
Obtain human subjects approval				
Participant recruitment				
Conduct data collection procedures				
Analyze data and disseminate results				
Estimated Budget ($K)	**$500**	**$25**	**$275**	**$200**

Updated: 08/31/2016

Goals/Milestones

CY15 Goals – Study preparation and participant recruitment

- ☑ Obtain human subjects approval

CY16 Goals – Ongoing recruitment and data collection

- ☑ Recruit and collect data from first 21 participants (15 to-date)
- ☑ Collect data from first 15 participants (3 to-date)
- ☑ Analyze interim results from study participants
- ☑ Disseminate initial results at national conference

CY17 Goal – Analysis and dissemination

- ☐ Recruit final 3 participants; collect data from final 9 participants
- ☐ Analyze final results from all 24 participants
- ☐ Disseminate final study results

Comments/Challenges/Issues/Concerns

- Initial recruitment slow, but targets met last 2 quarters; no other significant challenges to-date.

Budget Expenditure to Date

$163,976.99

EFFECTS OF A MODIFIED RUNNING FOOT PROSTHESIS ON USERS' ENDURANCE AND PERCEIVED EXERTION

Hafner, B.J., Morgan, S.J., McDonald, C.M., Kramer, P.A., Davidson, G.E.
University of Washington, Davidson Prosthetics

INTRODUCTION

For people with transtibial amputations (TTA), use of a prosthesis can facilitate return to a basic level of functional mobility. However, absence of an anatomical foot and ankle still greatly impairs physical performance, resulting in decreased walking speeds, diminished endurance, and restricted ability to participate in life situations. Contemporary energy storing feet (ESF), which use advanced materials and geometric designs, have been developed to address these deficits. Yet even the most advanced ESF do not significantly mitigate the increased energy demands required for walking compared to conventional, rigid prosthetic feet (Hsu, 2006). Running-specific feet (RSF), however, enable runners with TTA to achieve endurance similar to people without limb loss (Brown, 2009) by increasing the length, curvature, and the stiffness of the keel. These features facilitate vertical and forward propulsion in running, but lack of a heel component restricts the ability to walk with a RSF.

A novel modified running-specific foot (mRSF, Figure 1), which combines features of both ESF and RSF, has been developed for use in walking, running, and other daily activities. The mRSF includes an extended carbon keel that is directly connected to the socket, heel springs to facilitate heel-toe walking, and a shell to enable the foot to fit in a typical shoe. Although users' opinions of the mRSF have been positive, evidence is needed to support clinical prescription. The goal of this pilot study was to assess endurance and perceived exertion of people with TTA walking with the developed mRSF and an ESF.

Figure 1 - mRSF

METHOD

Subjects: People with TTA (n=7, mean age=43 yrs) who own comfortable ESF and mRSF prostheses.

Apparatus: Six-Minute Walk Test (6MWT) and Borg Rating of Perceived Exertion (RPE) CR100 scale.

Procedures: Subjects attended a cross-sectional data collection session where they performed the 6MWT in both prosthetic conditions. Immediately following the 6MWT, they were asked to rate their perceived exertion with the Borg RPE. The order of conditions was randomized to reduce order effects.

Data Analysis: Participants' individual and sample mean 6MWT times and RPEs were plotted for visual inspection and comparison. Group-level statistical testing was not performed, due to the small sample.

RESULTS

6MWT: 5 of 7 subjects increased their distance (in feet) when using the mRSF compared to the ESF (mean difference +65, range: -18 to +230). Two subjects increased their distance by more than 131ft.

Borg: 6 of 7 subjects reported reduced exertion when using the mRSF compared to the ESF (mean difference -13, range: -38 to 0).

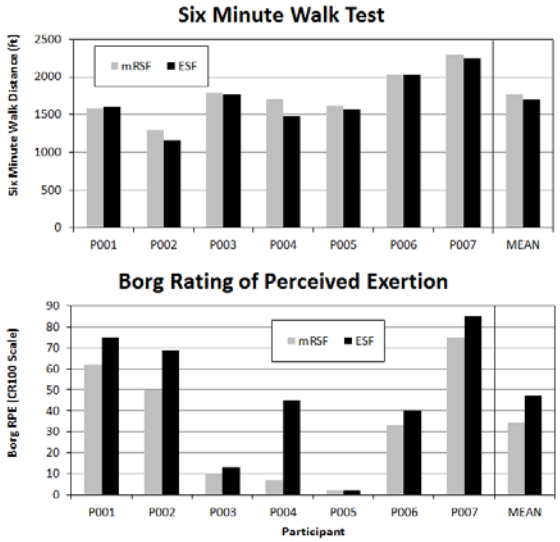


Figure 2 and 3. Individual and mean results for the 6MWT and RPE for the mRSF and the ESF prosthetic conditions.

DISCUSSION

Results of this study suggest that the mRSF may improve endurance while simultaneously decreasing perceived exertion for people with TTA. However, differences were substantial for only 2 of 7 participants for the 6MWT and 4 of 7 subjects for the Borg, indicating that improvements may not be clinically significant for all users.

CONCLUSION

Initial results suggest that the mRSF may facilitate improvements in mobility by increasing endurance while mitigating exertion when compared to traditional ESF in people with TTA. Prospective research is needed to assess mobility and other health outcomes.

CLINICAL APPLICATIONS

The mRSF is a novel prosthetic foot design that may enhance mobility outcomes in people with TTA.

REFERENCES

Hsu, M-J. Arch Phys Med Rehabil. 87,123-9, 2006.
Brown, M.B. Med Sci Sports Exerc. 41, 1080-7, 2009.

American Academy of Orthotists & Prosthetists
42nd Academy Annual Meeting &
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Self-report health outcomes in people with transtibial amputation using a modified running foot

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Objectives:
Transtibial amputation (TTA) is associated with impaired mobility and balance, fatigue and activity restriction. Energy storing feet (ESF) are considered standard-of-care for most active prosthesis users with TTA but do not significantly reduce energy demand required for walking. Runners with TTA using running-specific feet (RSF), however, have similar energy expenditure to non-amputee runners. While adequate for running, RSF lack a heel, limiting the stability required for walking. A modified running specific foot (mRSF) is a combination of the ESF (heel springs and foot shell) and RSF (extended carbon keel attached to the socket) that has been developed to decrease energy expenditure while providing stability during daily activities including walking and running. The goal of this study was to determine if the mRSF improves transtibial prosthesis users' self-reported outcomes, compared to the standard-of-care (traditional ESF).

Design:
A randomized crossover study was conducted to compare patient-centered health outcomes through self-report. Participants with unilateral TTA were recruited from a community-based prosthetics clinic. Studied outcomes included mobility (Prosthetic Limb Users Survey of Mobility), balance confidence (Activities Specific Balance Confidence Scale), fatigue (Patient-Reported Outcomes Measurement Information System-Fatigue), activity restrictions and satisfaction (Trinity Amputation and Prosthesis Experience Scales, Revised). Self-reported health outcomes were assessed using a standardized self-report survey, which was administered on a tablet computer. Participants were fit with two prostheses with identical sockets; one prosthesis included a traditional ESF and one included a mRSF. Participants were then randomized to use one of the prostheses as their daily prosthesis for one month. At the end of one month, the participants returned to complete the survey, and then returned home to use the second prosthesis for one month. Outcomes were assessed again at the end of the second one-month period. IRB approval was obtained prior to the start of the study. All participants provided informed consent prior to beginning the study.

Results:
Six people with TTA participated in the study to-date. All participants reported significantly improved mobility ($p<0.04$) and less fatigue ($p<0.04$) while using the mRSF compared to the ESF. Five out of six participants reported improved balance confidence and fewer activity restrictions. Four participants reported higher functional satisfaction (two participants reported equal values). Aesthetic satisfaction was comparable across study participants.

Conclusion:
This study suggests that patient-centered health outcomes such as self-reported mobility, balance, fatigue, and activity restriction are generally improved in people with TTA while using a mRSF compared to a traditional ESF.

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TITLE (137/150 CHARACTERS)

Walking performance, endurance, and perceived exertion in people with transitibal amputation: effects of a modified running-specific foot

SUMMARY (300/300 CHARACTERS)

A modified running-specific foot (mRSF) was compared to an energy storing foot (ESF) in a cross-sectional study of participants with unilateral, transtibial amputation. Walking performance, endurance, and perceived exertion were generally improved with the mRSF, but not all users benefitted equally.

INTRODUCTION (1000/1000 CHARACTERS)

Transtibial amputation (TTA) is associated with decreased walking speeds, diminished endurance, and increased metabolic demands [1-2]. Energy storing feet (ESF) are often prescribed to address these deficits, but may not mitigate the increased energy required for walking [3-4]. Running-specific feet (RSF), however, enable runners with TTA to achieve endurance similar to non-amputees [5]. The length, curvature, and stiffness of a RSF keel promotes running, but lack of a heel prevents heel-toe walking. A mRSF, which combines features of ESF and RSF, was developed for walking, running, and other daily activities. It includes an extended carbon keel attached directly to the socket, heel springs to facilitate heel-toe walking, and a shell that fits typical shoes. Initial mRSF user feedback has been positive, but evidence is needed to support prescription. The goal of this pilot study was to compare walking performance, endurance, and perceived exertion between the mRSF and conventional ESF.

METHODS (998/1000 CHARACTERS)

A cross-sectional study was conducted to compare walking performance, endurance, and perceived exertion of people with TTA using a mRSF and an ESF. Inclusion criteria were 18+ years of age, transtibial amputation, prosthesis user for 1+ years, own and use two comfortable prostheses (one with an ESF and one with a mRSF), and can walk continuously for at least 6 minutes. Exclusion criteria were any health conditions that limit prosthesis use or ability to walk safely for 6 minutes. Outcome measures included the Six-Minute Walk Test (6MWT) [6], GaitRITE electronic walkway [9], Timed Up and Go (TUG) [7], and Borg Rating of Perceived Exertion CR100 scale (RPE) [8]. The order of foot conditions was randomized to reduce order effects, but measures were administered in order for all participants. Participants' individual times, distances, and scores (and sample means) were computed and compared across conditions. Group-level statistical testing was not performed due to the small sample size.

RESULTS (1413/1500 CHARACTERS)

Seven participants with TTA (mean age = 43 yrs, mean weight = 200lbs, mean height = 1.8m, mean time since amputation = 11.5 years) participated in the study. Participants were predominantly male (n=5),

white (n=6), and civilian (n=5). Participants' etiology of amputation varied (trauma=4, infection=1, dysvascular=1, congenital=1). All participants used their prostheses daily (mean = 16.6 hrs/day).

Five of seven participants increased their walking distance in the mRSF compared to the ESF (mean difference 20m, range: -1m to +70m). Four increased distances by more than 2% and two by more than 10%. Six participants' Borg RPE was lower in the mRSF (mean difference -13, range: -38 to 0). All six of these participants reported exertion was 10% or more reduced, while three reported an RPE reduction of 30% or more in the mRSF. Change in 6MWT distance and associated RPE are shown in Figure 1. TUG times were reduced in the mRSF compared the ESF for five of seven participants (mean difference = -0.82s, range: -2.22s to +1.35s). Four of seven participants decreased TUG time by 20% or more in the mRSF. Walking speed improved for six participants in the mRSF (mean difference = 5.6cm/s, range: -0.9cm/s to +17.8cm/s). Four participants increased speed by more than 2%, and two by more than 8.5%. Sound step length increased for in all participants in the mRSF (mean difference = 3.3cm, range: 1.4cm to 4.8cm).

CONCLUSION (1477/1500 CHARACTERS)

Results of this study suggest that a mRSF can improve walking performance and endurance while simultaneously decreasing perceived exertion for people with TTA. As a group, study participants showed improvements in all primary outcomes (i.e., 6MWT distance, Borg RPE, TUG time, and walking speed) when using a prosthesis with the mRSF, as compared to one with an ESF. However, not all participants experienced improvements in all domains. Further, differences were large in only select participants. For example, only one participant improved in 6MWT distance by more than 45m, the minimum detectable change (MDC) reported for people with amputation [10]. Subjects in that study, however, were of generally lower ability (as evidenced by 6MWT distances of 332-334m, compared to the 517-537m observed here). Thus, MDC may be lower for active individuals. Some participants improved by 10% or more across multiple domains in the mRSF, which suggests that outcomes may be clinically significant for these individuals. As with any study, limitations are present. Participants in this study wore their own prostheses, thus ESF were not standardized. Further, although participants reported both sockets as comfortable, differences in socket design, suspension, or alignment may have affected the results. A prospective, controlled trial is needed to more effectively control confounding variables and further evaluate the effectiveness of the mRSF, compared to other prosthetic feet.

REFERENCES (1476/1500 CHARACTERS)

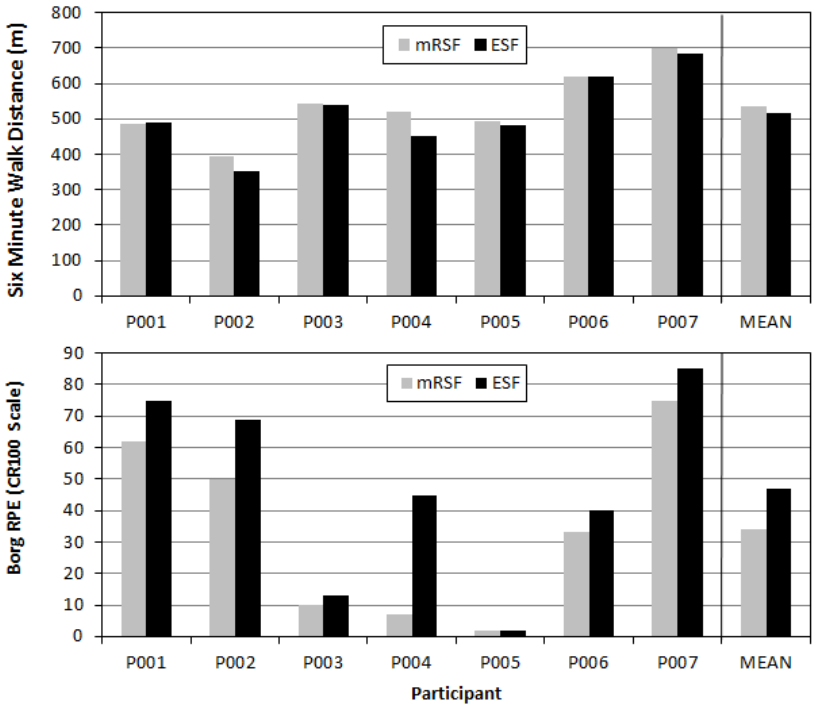
1. Waters R. The energy expenditure of normal and pathologic gait. Gait Posture. 1999;9(3):207-31.
2. Genin J. Effect of speed on the energy cost of walking in unilateral traumatic lower limb amputees. Eur J Appl Physiol. 2008;103(6):655-63.
3. Hsu M. The effects of prosthetic foot design on physiologic measurements, self-selected walking velocity, and physical activity in people with transtibial amputation. Arch Phys Med Rehabil. 2006;87(1):123-9.

4. Schmalz T. Energy expenditure and biomechanical characteristics of lower limb amputee gait: the influence of prosthetic alignment and different prosthetic components. Gait Posture. 2002;16(3):255-63.
5. Brown M. Running-specific prostheses permit energy cost similar to nonamputees. Med Sci Sports Exerc. 2009;41(5):1080-7.
6. Lin S. Six-minute walk test in persons with transtibial amputation. Arch Phys Med Rehabil. 2008;89(12):2354-9.
7. Webster K. Validity of the GAITRite walkway system for the measurement of averaged and individual step parameters of gait. Gait Posture. 2005;22(4):317-21.
8. Schoppen T. The Timed "up and go" test: reliability and validity in persons with unilateral lower limb amputation. Arch Phys Med Rehabil. 1999;80(7):825-8.
9. Borg E. A comparison of AME and CR100 for scaling perceived exertion. Acta Psychol. 2002;109(2):157-75.
10. Resnik L. Reliability of outcome measures for people with lower-limb amputations: distinguishing true change from statistical error. Phys Ther. 2011;91(4):555-65.

MESSAGE/NOTE (289/500 CHARACTERS)

Data collected in this study was used to power a prospective, randomized cross-over study of 30 participants with TTA funded by the US Department of Defense. Data collection is ongoing (n=8 currently enrolled), and available results will be shared along with those results presented above.

FIGURE (1/1)



ENERGY EXPENDITURE IN PEOPLE WITH TRANSTIBIAL LIMB LOSS WALKING WITH CROSSOVER AND ENERGY-STORING FEET

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INTRODUCTION

People with transtibial amputation (TTA) experience increased energy expenditure during normal ambulation compared to people without limb loss.[1-2] Modern energy storing feet (ESF) are unable to reduce the increased metabolic demands for walking.[3] Running-specific feet (RSF), however, allow runners with TTA to achieve speeds and energy requirements comparable to people without limb loss.[4] The extended carbon fiber keel of an RSF promotes energy return for running but lacks a heel to allow stable standing or heel-to-toe gait.

Crossover feet (XF), like the Össur Cheetah Xplore, combine features of ESF and RSF to create a foot suitable for walking, running, and other daily activities. The XF design incorporates the extended keel and direct posterior socket attachment of an RSF with the carbon fiber heel of an ESF. These features maximize energy return, while providing the posterior stability needed for comfortable heel-to-toe walking. The goal of this study was to determine if use of an XF can decrease the metabolic energy required for walking in people with TTA, relative to use of a standard-of-care ESF.

METHODS

Participants: XF prosthesis users with transtibial limb loss due to non-dysvascular causes (n=10) were recruited from a local clinic. Each participant received a second prosthesis that included a duplicate socket and standardized ESF (Össur Vari-Flex).

Apparatus: Portable oxygen analyzer (Cosmed K4b^2)

Procedures: A randomized cross-over study design was used to evaluate and compare participants' metabolic energy while walking in prostheses with an XF and an ESF. Participants served as their own controls. The order of foot conditions (XF and ESF) was randomized and participants used each foot for at least 1 month, prior to data collection. Energy expenditure was measured while participants walked on treadmill for six minutes at three speeds (self-selected fast, comfortable, and slow). Order of speeds was randomized across participants but maintained within participants to mitigate order effects.

Data Analysis: Breath-by-breath data over the final 3.5 minutes of the trial were extracted from the oxygen analyzer to ensure steady-state walking. Gross and mass-adjusted gross metabolic rates were calculated. Rates were compared across subjects using a Wilcoxon Signed-Rank test ($p<.05$).

RESULTS

Metabolic rate: 6 of 10 participants had reduced mean gross metabolic rates at slow, comfortable, and fast walking speeds with the XF compared to the ESF. Notably, the magnitude of reduction was not consistent across speeds or participants. Differences in gross metabolic rate were not found to be statistically significant across participants at slow ($z=-0.524$, $p=.600$), comfortable ($z=0.933$, $p=.351$, Figure 1), or fast ($z=0.670$, $p=.503$) speeds.

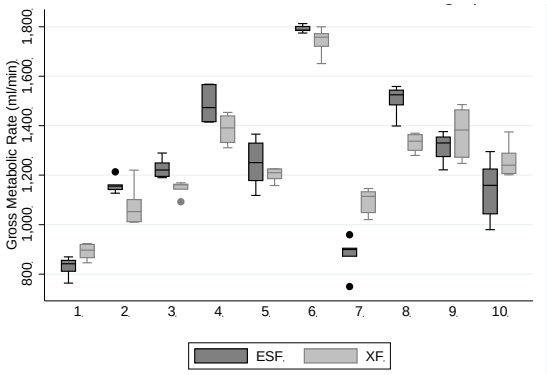

Figure 1. Gross metabolic rate at comfortable walking speeds with the ESF and XF.

CONCLUSION

Interim results suggest that the XF may facilitate reduced energy expenditure for people with TTA at comfortable walking speed. However, not all users appear to benefit equally. Association between user characteristics (e.g., activity level, time since amputation) and reduced energy expenditure with the XF can be examined further through linear regression to identify individuals who may most benefit from use of a prosthesis with an XF foot.

REFERENCES

1.Waters R. *Gait Posture;* 9(3), 207-31, 1999.
2.Genin J. *Eur J Appl Physiol*;103(6), 655-63, 2008.
3.Hsu M. *Arch Phys Med Rehabil*; 87(1),123-9, 2006.
4.Brown M. *Med Sci Sports Exerc.*; 41(5), 1080-7, 2009.

DISCLOSURE

ESF and components for control prostheses were donated by Össur Iceland ehf R&D (Reykjavík, Iceland). Time and materials to fabricate study prostheses were donated by Davidson Prosthetics (Pullayup, WA).

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Crossover and energy storing prosthetic feet in adults with transtibial amputation: a comparative effectiveness study

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INTRODUCTION

People with transtibial amputation (TTA) demonstrate increased energy expenditure, reduced walking speed, compromised balance, and decreased endurance compared to people without amputation (Waters, 1999; Genin, 2008). Contemporary energy storing feet (ESF) promote users' mobility, but do not fully restore their functional capabilities (Hsu 2006). Crossover feet (XF) combine features of ESF (carbon fiber heel, split keel, foot shell) and running-specific prostheses (extended keel, posterior attachment) to facilitate greater energy return and performance across a wide range of functional activities.

The goal of this study was to determine if use of an XF could decrease users' energy required for walking, increase endurance, enhance walking performance, or improve self-report health, relative to using an ESF.

METHOD

Participants: People with TTA due to non-dysvascular causes were recruited from local prosthetics clinics.

Interventions: Participants were tested in a prosthesis with an XF (Össur Cheetah Xplore) and an equivalent prosthesis (duplicate socket and suspension) with an ESF (Össur Vari-flex with EVO foot).

Procedures: A randomized crossover study was conducted to assess changes in energy expenditure, walking performance, endurance and reported health. Participants wore an activity monitor (Orthocare Innovations Stepwatch 3) for 1 month before testing. Energy expenditure was measured with a portable metabolic analyzer (Cosmed K4b2) while participants walked at 3 speeds (self-selected slow, comfortable and fast) on a treadmill (Landice L7). Endurance was measured with the 6-min walk test (6MWT). Walking performance was measured with an electronic walkway (CIR Systems GAITRite) while participants performed the 6MWT. Self-reported mobility, fatigue, balance confidence, activity restrictions, and satisfaction were measured with standardized surveys (PLUS-M, PROMIS-Fatigue, ABC, and TAPES).

Analysis: Mean mass-adjusted metabolic rates were calculated from the last 3 minutes of each 6-minute treadmill trial (slow, comfortable, and fast). Overall 6MWT distance was measured; mean speed, cadence, and step length, width, time were computed using the GAITRite software; mean daily steps were calculated. Surveys were scored according to developers' instructions. All outcomes were compared across conditions using a Wilcoxon Signed-Rank test and a threshold of $\alpha<.05$.

RESULTS

Participants: 14 participants have completed the study to-date; 2 people were dropped due to extrinsic factors that affected data integrity. 12 participants (83% male, age = 41±10 years, time since amputation = 12±12 years) were included in this analysis.

Metabolic energy: Participants showed significantly reduced mean mass-adjusted metabolic rates at comfortable (p=0.0499) and fast (p=0.0499) walking speeds in the XF compared to the ESF (Fig. 1). No significant differences in metabolic rates were seen at slow speed (p=.638).

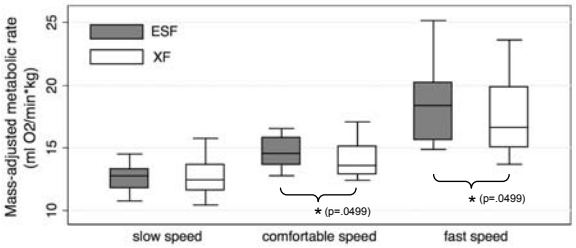

Figure 1. Mean mass-adjusted metabolic rate during walking

Walking performance: No significant differences in walking distance (p=0.730), speed (p=.875), cadence (p=.239), step length (p=.099), step width (p=.0504), or step time (p=.857) were observed between the XF and ESF conditions. Similarly, no significant differences in step activity were seen between conditions (p=.182).

Self-report: Participants reported improved mobility (p=.004), balance confidence (p=.005), and functional satisfaction (p=.007); lower fatigue (p=.008); and fewer activity restrictions (p=.021) in the XF, relative to the ESF. No differences in aesthetic satisfaction were reported (p=.673).

DISCUSSION

Results indicate that XF may reduce users' metabolic energy at comfortable and fast walking speeds. Indoor walking performance and endurance may not reflect performance under real-world conditions, as users perceived significant benefits and were highly satisfied with the XF's function. However, not all participants experienced the same outcomes. Thus, future work is needed to refine prescription criteria.

CONCLUSION

XF are a promising alternative to traditional ESF, as they may reduce energy expenditure during walking and improve users' perceived functional outcomes.

CLINICAL APPLICATIONS

Crossover feet may be an effective solution for people with TTA who wish to engage in a range of activities, particularly those that require walking at fast speeds.

REFERENCES

Waters R. Gait Posture; 9(3), 207-31, 1999.
Genin J. Eur J Appl Physiol;103(6), 655-63, 2008.
Hsu M. Arch Phys Med Rehabil; 87(1),123-9, 2006.

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