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TITLE: A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations

PRINCIPAL INVESTIGATOR: David C. Morgenroth, M.D.

CONTRACTING ORGANIZATION: Seattle Institute for Biomedical and Clinical Research
Seattle WA 98108

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David C. Morgenroth, M.D.

E-Mail: dmorgen@uw.edu

**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**

Seattle Institute for Biomedical and Clinical Research
1660 S. Columbian Way, S-151F
Seattle, WA 98108

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**14. ABSTRACT**

The objective of this study is to evaluate a "test-drive" strategy for prosthetic foot prescription using a prosthetic foot emulator (PFE) to accurately reproduce the experience of wearing several commercially available prosthetic feet. The aims of this research are to: (1) determine whether a PFE can be used to predict foot preference and mobility outcomes with corresponding commercial prosthetic feet, and (2) determine whether a brief trial of commercial prosthetic feet would be able to similarly predict longer-term foot preference and mobility outcomes with those feet.

During the current reporting period, we have developed and finalized the project protocol manual of operations, study questionnaires and all IRB documents. We have fabricated and delivered the PFE to VA Puget Sound including training of local staff in PFE use. Mechanical testing of commercial study prosthetic feet for input to the PFE is ongoing. Once we receive all necessary IRB approvals, we will begin human subject testing.

**15. SUBJECT TERMS**

Lower extremity amputee, transtibial, prosthesis, artificial limb, prosthetic foot, mobility

| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON |
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## 1. Introduction

Selecting an optimal prosthetic foot is an important aspect of maximizing mobility and the achievement of functional goals for people with lower limb amputation (LLA), however there is limited evidence to guide this process. The current prosthetic prescription process relies on clinician experience and typically does not allow people with leg amputations to easily try out different prosthetic feet. The purpose of this research is to optimize mobility outcomes and user satisfaction for Service members and Veterans with LLA using an evidence-based, patient-centered approach to prosthetic foot prescription. In order to accomplish this goal, we will use a prosthetic foot emulator (PFE), a prosthetic device that can mimic the performance of a variety of prosthetic feet. The PFE allows individuals with LLA to quickly 'test-drive' candidate prosthetic feet. The scope of this research includes: (1) determining whether a PFE can be used to accurately predict foot preference and mobility outcomes with corresponding commercial prosthetic feet, and (2) determining whether a brief trial of commercial prosthetic feet would be able to predict longer-term foot preference and mobility outcomes with those feet. We hypothesize that participants' preference for each emulated foot (relative to other feet) will correlate strongly with their preference for the corresponding commercial foot. Similarly, participants' preference for each emulated foot will correlate with their satisfaction and perceived and functional mobility in the corresponding commercial foot. Secondarily, we hypothesize that participants' mobility in the emulated foot will correlate strongly with their mobility in the commercial foot.

## 2. Keywords

Lower extremity amputee, transtibial, artificial limb, prosthesis, prosthetic foot, mobility

## 3. Accomplishments

### What were the major goals of the project?

The statement of work (SOW) for this project is divided into major tasks which are listed below:

Major Task 1. Obtain and Maintain Human Subjects Approval:
In order to achieve Major Task 1, we have prepared a manual of operations, all study questionnaires, consent forms, and recruitment materials for all data collection sites. These documents were necessary for submission to the IRB. Applying for local IRB approval consisted of the following:

1. Submission of Principal Investigator Study Chair (PI-SC) and Local Site Investigator (LSI) applications (for both VA Puget Sound Health Care System (VAPSHCS) and Minneapolis VA Health Care System (MVAHCS) sites) to VA Central IRB (CIRB). LSI applications were only able to be submitted after approval of PI-SC application
2. Submission of Center for the Intrepid (CFI) application to local DoD IRB

We currently have approval from VA CIRB for PI-SC and have submitted both LSI applications and are awaiting approvals. We also have received local DoD IRB approval for the CFI site.

We have submitted initial documents to HRPO to begin the process of second level review, and will forward final local IRB approvals (i.e., LSI applications) once approved by VA CIRB.

The SOW for this major task identified four sub-tasks and corresponding target dates shown in Table 1.

**Table 1**: Major task 1 milestones

| Major Task 1 Activities | Target Timeline (months) | Actual Timeline (months) |
|---|---|---|
| Sub-task 1.1: Submit application to VA IRB | Pre-study | 6 |
| Sub-task 1.2: Modify consent forms per VA IRB feedback | Pre-study | 7 |
| Sub-task 1.3: Submit VA IRB approval and forms for Military IRB review (ORP/HRPO) | 1-2 | 11 |
| Sub-task 1.4: Modify consent forms per ORP/HRPO feedback | 3-4 | TBD |
| Milestone 1: IRB approvals obtained from VA and ORP/HRPO | 5 | Ongoing (80-90% completed) |

TBD: to be done.

Major Task 2. Study Preparation

The SOW for this task identified the six sub-tasks and corresponding target dates shown in Table 2. All recruitment materials, data collection forms, study surveys, and databases were created according to schedule. A key component of Milestone 2 is "equipment ready for data collection". One important component of this milestone is to perform mechanical testing of prosthetic feet to develop prosthetic foot profiles for input to the PFE (which is necessary to achieve the stated aims for the overall project).

**Table 2**: Major task 2.

| Major Task 2 Activities | Target Timeline (months) | Actual Timeline (months) |
|---|---|---|
| Sub-task 2.1: Finalize study protocol and consent materials (e.g., recruitment materials, consent forms) | Pre-study | 1-5 |
| Sub-task 2.2: Prepare data collection files (e.g., forms, surveys) | 1-5 | 1-3 |
| Sub-task 2.3: Create recruitment and data collection databases | 1-5 | 2-4 |
| Sub-task 2.4: Purchase research supplies and equipment (e.g., prosthetic feet, treadmill, stairmill, laptops) | 1-3 | 1-12 |
| Sub-task 2.5: Delivery of emulator and training investigators and staff for use | 4-5 | 6-9 |
| Sub-task 2.6: Train research staff | 1-5 | 1-8 |
| Milestone 2: Recruitment, consent, and data collection materials; databases; and equipment ready for data collection (e.g., mechanical testing of prosthetic feet completed) | 5 | Ongoing (80-90% completed) |

Major Task 3. Ongoing Study Coordination

The approved SOW for this task includes monthly teleconference meetings and once per year in-person meeting of the investigative team. Regular calls with co-investigators are ongoing. Our collaborators at Human Motion Technologies, LLC (HuMoTech) participated in an on-site meeting in month 8 at VAPSHCS. We are planning another on-site meeting with the entire investigative team in the near future.

Major Task 4. Participant Recruitment
Major Task 5. Data Collection
Major Task 6. Data Analysis
Major Task 7. Dissemination

These tasks have not begun yet since we do not yet have all the necessary IRB approvals. We plan to begin recruitment efforts immediately after receiving all IRB approvals, with data collection and analysis to follow.

**What was accomplished under these goals?**

An overview of the major activities during this reporting period (first year of the project) includes:

- Hiring project personnel
- Developing and finalizing self-report questionnaire packets for each data collection session (initial assessment, initial testing, and follow up testing sessions), study visit forms, data entry forms, recruitment materials for all three sites, consent forms, and the project manual of operations
- Fabrication and delivery of the PFE to the VAPSHCS site, as well as HuMoTech personnel visit to VAPSHCS site to train staff in use of the PFE
- Completion, submission and approval of PI-SC VA CIRB application
- Completion and submission of LSI applications to VA CIRB for VAPSHCS and MVAHCS sites
- Completion, submission and approval of CFI local IRB application
- Purchase and delivery of key equipment and supplies (e.g., commercial prosthetic feet, stairmill)
- Applying for and receiving local R&D committee approval for the portion of the project not involving human participants (i.e., mechanical testing of prosthetic feet for input to the PFE)
- Mechanical testing of prosthetic feet in robotic gait simulator (RGS) for input to PFE

Major Task 1. The work during this reporting period included creating and submitting IRB applications for human subjects testing for all three sites. The lead site (PI-SC) application was submitted to VA CIRB on 28-February-2017, reviewed by VA CIRB, and approval was granted on 05-May-2017. Approval for local DOD Brooks Army Medical Center (BAMC) IRB review at CFI was received on 5-July-2017. A modification to the VA CIRB application was submitted to VA CIRB on 26-July-2017 to modify prosthetic foot models and make small amendments to study documents. This modification was approved on 28-Septmeber-2017. LSI applications for VAPSHCS and MVAHCS were submitted on 29-Septmeber-2017 to VA CIRB (we had to wait for approval of the modification prior to submission of LSI applications). Preliminary documents were submitted to Military IRB review (ORP/HRPO) on 25-August-2017. The CFI/BAMC site was approved by HRPO ORP on 8-September 2017.

Although we have received PI-SC approval from VA CIRB and CFI local site IRB approval, we have not yet achieved our stated goal of “approvals obtained from VA and ORP/HRPO” (Milestone 1). We have submitted LSI applications to VA CIRB and initial documents to HRPO for second level review. As soon as we receive

LSI approval from VA CIRB, we will forward those with any necessary remaining documentation to HRPO. This process took longer than we had originally anticipated because:

1. Comprehensive discussion amongst the investigative team to ensure that all nuances of the study protocol were optimal led to a prolonged development and finalization of key documents necessary for IRB submission (e.g. Manual of Operations, consent, study questionnaires). These documents have been included in the appendices.
2. It came to our attention after submitting the PI-SC application that a new version of one of the commercial prosthetic feet that we had planned to use in the study became available on the marketplace and has now become more clinically applicable than the original prosthetic foot. This required a modification application which substantially delayed VA CIRB approval and our ability to submit the LSI applications (which were necessary to submit after full PI-SC approvals).

Major Task 2. The work during this reporting period included creating and finalizing the study protocol, consent forms, study surveys, recruitment materials, and de-identified data spreadsheets. Work toward major task 2 during this study period also included mechanical testing of prosthetic feet using the robotic gait simulator (RGS) for input to PFE (Major Task 2, Milestone 2 "equipment ready for data collection"). This is an important component of the ongoing project work, and a necessary precursor for the multi-site human subjects trial (Major Tasks 4-6), which will require emulated foot conditions. The mechanical testing involves the characterization of the ankle torque vs. angle profiles of each commercial prosthetic foot used in the study, and programming these data into the PFE to enable the respective emulated conditions. Activities associated with this goal have included: collecting torque vs. angle data using benchtop testing methodologies, purchasing supplies, creating hardware for benchtop testing set up, refining and optimizing data collection and analysis techniques, analyzing data for all sizes and manufacturer stiffness categories of study commercial feet, constructing torque vs. angle profiles for commercial feet, and using torque vs. angle profiles as input to prosthetic foot emulator.

This work is described in more detail below:

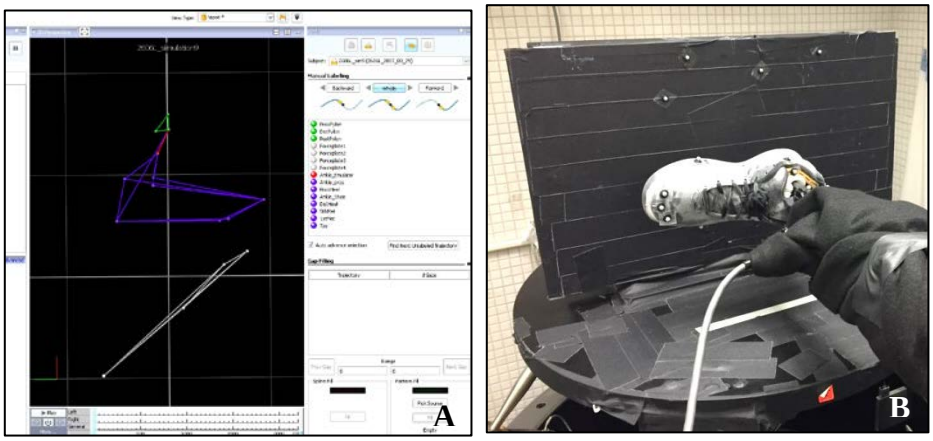



**Figure 1:** Mechanical testing of prosthetic feet with RGS: A) Vicon Nexus data processing model for output for ankle angle generated from testing; B) Prosthetic foot in Vicon motion capture space, connected to an in-line AMTI 6-axis load cell and secured to the RGS with a Kistler forceplate adjusted to pylon progression angles for loading. Note that image B) depicts a shoe on a prosthetic foot, not a human leg.

Benchtop tests are being performed using a robotic gait simulator (RGS) which comprises a force platform (Kistler; Amherst, NY) mounted to a six degree-of-freedom parallel robot (R2000; Mikrolar; Hampton NH) in the collection volume of an 8-camera motion capture system (Vicon; Centennial, CO). The RGS is controlled using custom software to apply quasi-static loads, representative of body weight, during prosthetic foot testing.

Each commercial test foot is attached to a pylon and aligned with zero plantarflexion, internal-external rotation, and inversion-eversion. Feet are tested in a foot shell and shod with standardized, heel-height appropriate footwear to mimic clinical use.

In the first test, the pylon is vertical and the force plate surface is horizontal. The pylon is rigidly attached to a base mount while the RGS moves the force platform vertically towards the foot. Load is developed up to the weight limit threshold representative of body weight. Force, center of pressure and motion capture data are collected throughout loading. In subsequent tests, the force plate yaw orientation is adjusted in 10-degree increments from -10 of dorsiflexion to +30 degrees that represent a range of pylon progression angles

In an effort to optimize data collection procedures and the accuracy of prosthetic feet emulation in the PFE for Aim 1 of this project, several modifications have been made to this data collection protocol during months 7-11. For example, a 6-axis load cell (AMTI; Watertown, MA) was added in-line with the prosthetic foot pylon to improve ankle torque data acquisition (Figure 2). This sensor enhances the quality of torque signal acquisition. Additionally, multiple loading cycles are now conducted at each pylon progression angle to improve the reliability of collected data by taking an average of at least four cycles to create a torque vs ankle angle profile (Figure 3).

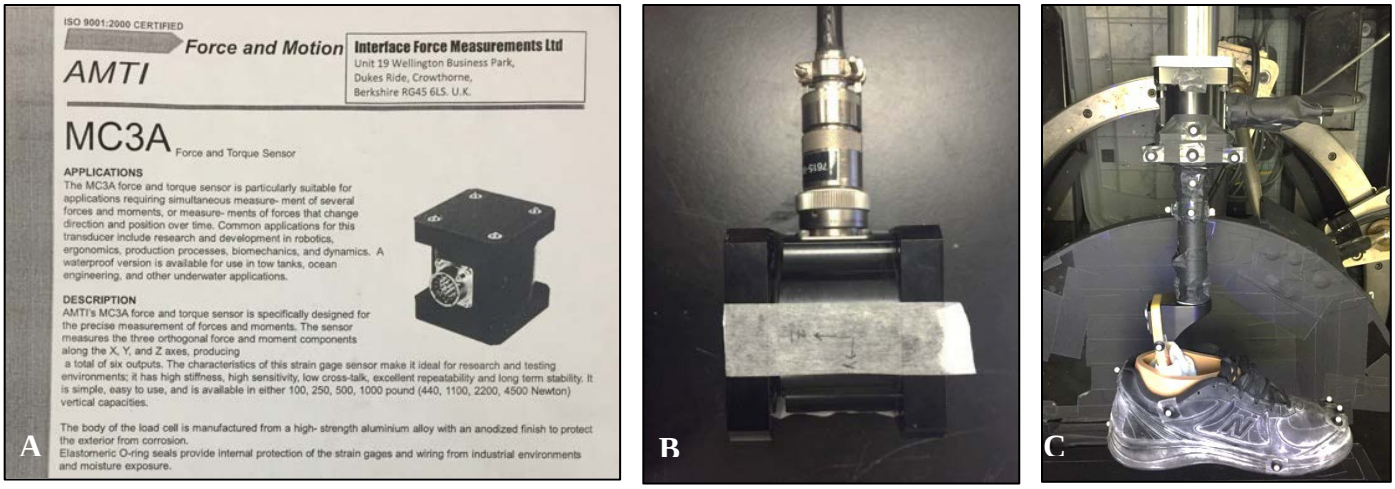



**Figure 2:** (A) AMTI 6-axis load cell added to RGS set-up for mechanical testing of prosthetic feet for improved accuracy of ankle torque data collection; (B) load cell unit separate from RGS mount; (C) load cell configured in-line with prosthetic pylon during data collection (aerial view of RGS).

Data collected with each foot is being used to calculate the nonlinear torque vs. angle profile for input to the prosthetic foot emulator. Testing has commenced with several prosthetic feet (Figure 3). All remaining commercial prosthetic feet have been purchased for the VAPSHCS site to conduct mechanical testing and data collection is ongoing.

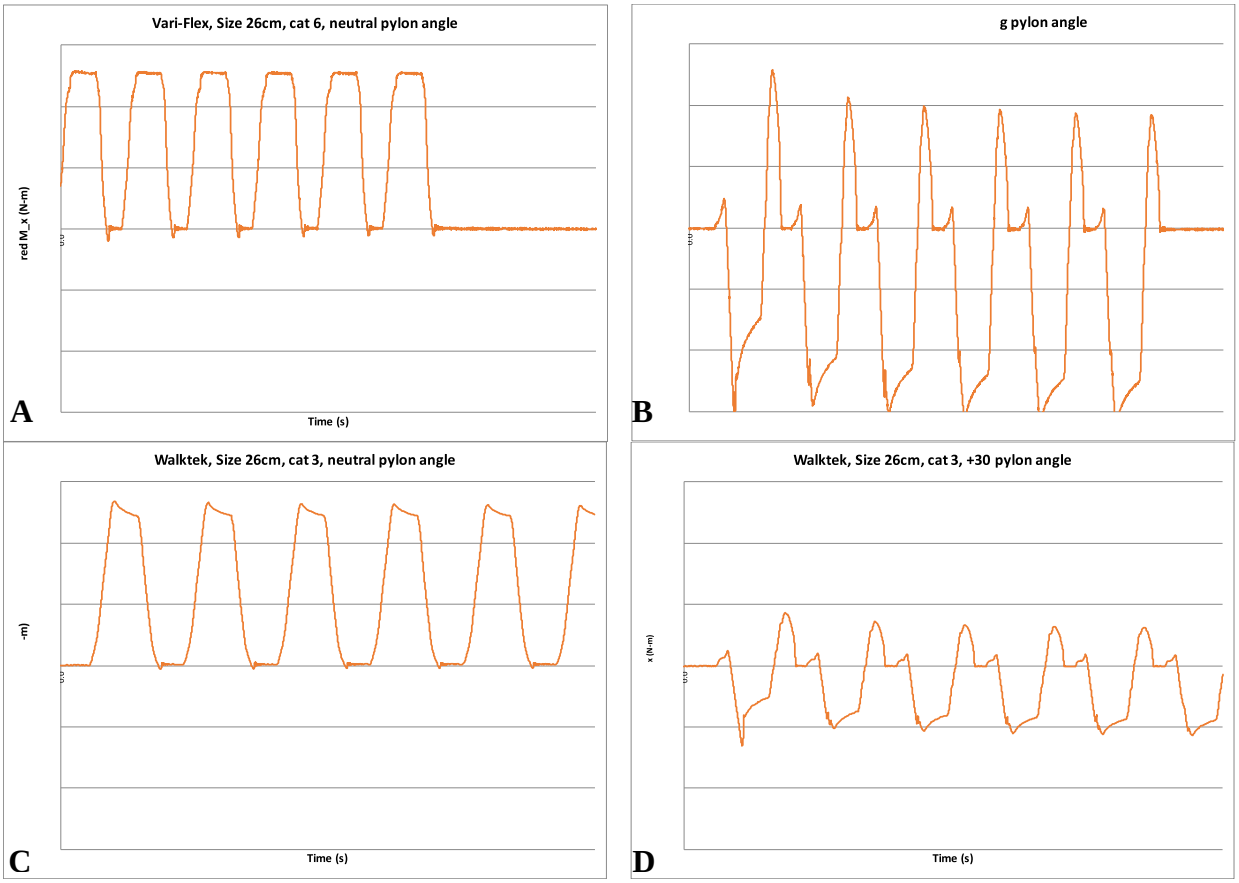



**Figure 3:** Example plots displaying data from multiple loading cycles using the AMTI 6-axis load cell (ankle torque vs time); A) Ossur Variflex with Evo foot, size 26cm at neutral pylon progression angle; B) Ossur Variflex with Evo foot, size 26cm at +30$^{o}$ pylon progression angle; C) Freedom Innovations Walk-tek foot, size 26cm at neutral pylon progression angle; D) Freedom Innovations Walk-tek foot, size 26cm at +30$^{o}$ pylon progression angle

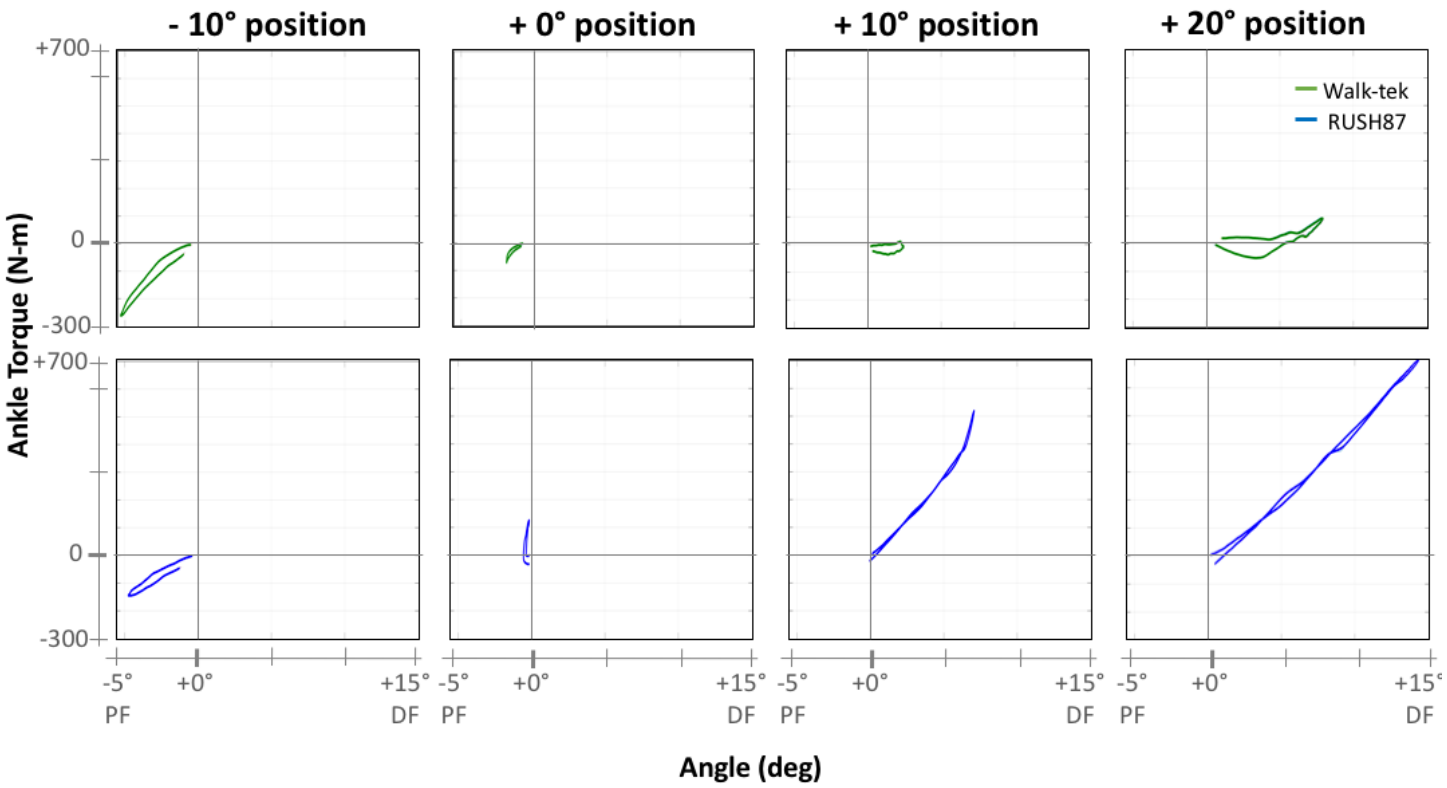



**Figure 4:** Torque vs ankle angle profiles of prosthetic feet collected during mechanical testing with RGS. Data displayed were collected on size 26cm Freedom Innovations Walk-tek and Ability Dynamics RUSH87 feet across a range of four stance phase pylon progression angles.

In addition to the data collection occurring to program the prosthetic foot emulator (PFE) with prosthetic foot profiles, the PFE design was improved with mechanical hardware changes during this reporting period. The actuator unit system and end effector were constructed and delivered to the VAPSHCS site along with all accompanying control hardware (Figures 5, 6).

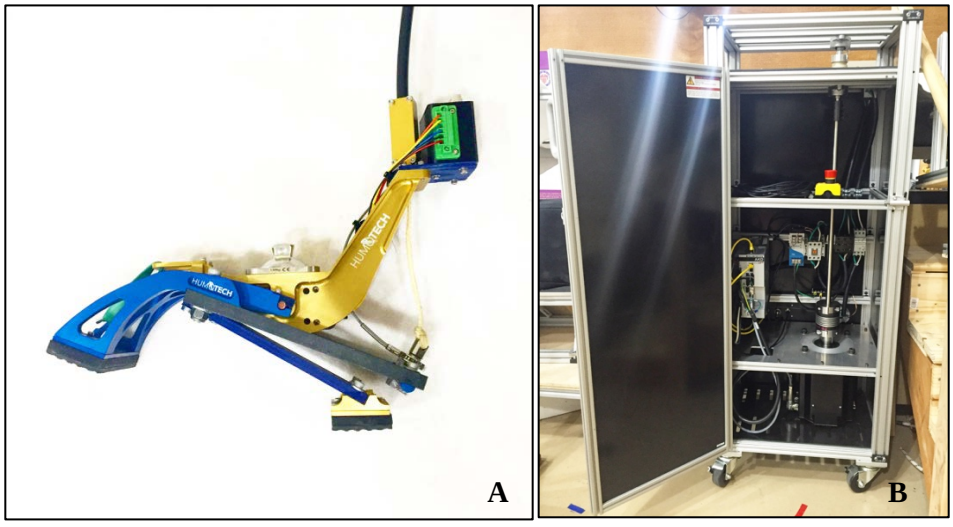



**Figure 5:** The prosthetic foot emulator (PFE) was delivered to VAPSHCS: A) PFE end effector and Bowden cable, B) actuator unit with transmission, controller, emergency stop, and pulley to actuate PFE unit.

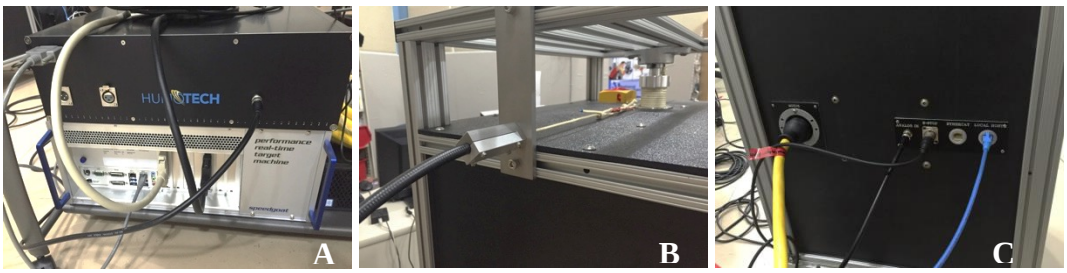



**Figure 6:** All electronics for prosthetic foot emulator (PFE) control system installed, connected, and confirmed to be working during benchtop testing of the PFE end effector. Successfully confirmed motor activation at 60rpm and actuation of Bowden cable at terminal end: A) HuMoTech PFE electronic hardware control units; B) Bowden cable transmission connection to PFE end effector; C) Electronic connections between control hardware and actuator unit of PFE

A system for adjusting the mass of the end-effector of the PFE has been designed, which entails swappable brass weights. This will allow for controlling for weight of the commercially available prosthetic feet. The emulator is now also length-adjustable, to better match the length of the device with the length of each subject's intact foot. In addition to these two new features, this latest version of the emulator end-effector is lighter, more robust, and easier to maintain than previous versions. Investigators and staff at VAPSHCS completed training and installation of the PFE. A Stairmaster Gauntlet was purchased and delivered to the VAPSHCS site in preparation for Phase 2 human subjects testing (Figure 7) during use with the PFE.


**Figure 7**: Stairmaster Gauntlet installed in gait laboratory at Seattle VA site for data collection with Prosthetic Foot Emulator.

Although we have completed a majority of Milestone 2, we have not yet achieved our stated goal of "equipment ready for data collection". Specifically, we have not finished the mechanical testing of commercial prosthetic

feet for input to the PFE yet. We have been working diligently on this aspect of the project, however, we have had to troubleshoot a number of obstacles along the way which has delayed our mechanical testing completion. This is described in more detail below (see “Actual or anticipated problems or delays and actions or plans to resolve them”).

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

Nothing to report.

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

Nothing to report.

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

During the next year, we plan to initiate participant recruitment, enrollment, and data collection at all three sites, once all necessary IRB approvals are received. We will continue to execute the proposal as approved in the grant application.

**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**

There have been no significant changes in the project approach or its direction.

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

The delay in receiving all necessary IRB approvals is described in detail above (see “What was accomplished under these goals?”). At this point we are awaiting final LSI application approvals from VA CIRB. As soon as we receive those, we will send them to HRPO for finalization of HRPO second level review.

The RGS that we are using for Phase 1 mechanical testing of prosthetic feet underwent maintenance to address a hardware issue with the computer controller that prevented successful operation in month 4 (December 2016). The manufacturer sent replacement hardware for the controller board and mechanical foot testing resumed in month 5 (January 2017) once all equipment was installed and the RGS was restored to functioning condition. The hardware frame of the RGS also underwent modification after significant frame motion was noticed during testing; this necessitated a redesign of the mounting support beams in month 11 (July 2017). The new mounting hardware was designed, fabricated, and installed by month 12 (August 2017).

The AMTI 6-axis load cell that we are using for Phase 1 mechanical testing of prosthetic feet required recalibration maintenance. It was shipped to the manufacturer in August 2017 and was received back from the manufacturer after recalibration on 28-September-2017.

These technical issues are now successfully resolved and will no longer delay the mechanical testing of prosthetic feet.

In addition, this study had some administrative actions in year 1 that required resolution:

- Jason Wilken, PhD (site PI) left his position at CFI in spring 2017. Elizabeth Russell Esposito, PhD replaced him as the CFI site lead on this project and PI for the subaward to the Henry M. Jackson Foundation for the Advancement of Military Medicine (HMJF). Prior approval was not required for this change, but Dr. Russell Esposito's CV was provided to our Grants Specialist on March 27, 2017, and Mr. Meinberg noted the new arrangement in our project file (April 19, 2017). While there was an initial delay while this change occurred, Dr. Russell Esposito has overseen an increased effort on the IRB approval that has made up the time. This issue is now resolved.

- Steven Collins, PhD left his position at Carnegie Mellon University as of August 31, 2017 and moved to Stanford University starting in September 2017. SIBCR has informed Carnegie Mellon University that their subaward will not be renewed and submitted a request to Mr. Meinberg for prior approval to change the subawardee for this portion of the work to Stanford Univeristy (July 25, 2017). SIBCR has also submitted an updated Statement of Work (August 9, 2017) reflecting these changes. This issue will be resolved by issuing a subaward to Stanford University when the prior approval is granted.

- For much of the year, HMJF and CFI/ BAMC were unable to reach an agreement with HuMoTech on the purchase terms of the PFE for the CFI site. HMJF was unwilling to accept liability for CFI's use of the equipment onsite at BAMC, which HuMoTech required in the Purchase Agreement to cover their own liability for use. BAMC was willing to have a second User Agreement executed to address these concerns, but could not find a local signatory empowered to execute such an agreement. After significant discussion, Dr. Russell Esposito was able to find a local process that could be used for the User Agreement. It is now being reviewed as a Cooperative Research and Development Agreement (CRADA) between HMJF, BAMC, and HuMoTech. HMJF, BAMC, and HuMoTech have negotiated and agreed on a CRADA draft. It is currently undergoing final legal review with the Federal Laboratory's Clinical and Translational Research Program Office (CTRPO); that process is expected to take another two to four weeks. We believe this issue is close to being resolved, but are still awaiting the results of the CTRPO review. The Seattle and Minneapolis non-profits have already concluded these Purchase Agreements directly with HuMoTech, and Seattle has installed and is performing mechanical testing on its unit. HuMoTech's fabrication of the PFEs for the CFI and MVAHCS sites has been delayed because of this issue; the offered pricing was based on the economy of scale in building both at

the same time. HuMoTech is prepared to move forward quickly with the fabrication for both sites once the CRADA is executed.

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

The negotiation about purchase terms and mechanism between HMJF, BAMC, and HuMoTech have delayed the major Year 1 expenses (personnel and equipment) at HMJF and the MVAHCS site until year 2. As a result, expenditures are below the proposed year 1 budget. These funds are expected to be expended in year 2 for the same purposes as they were originally budgeted in year 1.

The human subjects testing sites have delayed allocating major Research Assistant effort to this project until human subjects approvals are in place. This has also reduced year 1 expenditures but, again, we expect these funds to be expended in years 2-3 for the same purposes as they were originally budgeted in year 1.

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

Nothing to report.

**6. Products**

**Publications, conference papers, and presentations**

Nothing to report.

**Journal publications**

Nothing to report.

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

Nothing to report.

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

Presentation: Elizabeth Halsne presented this project at the VA Rehabilitation Research and Development's Center for Limb Loss and MoBility's 2017 Young Investigator Symposium on 17-Aug-2017 (Appendix H).

**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: | *David C. Morgenroth, MD* |
| Project Role: | *PI* |
| Researcher Identifier (e.g. ORCID ID): | 0000-0002-0226-7775 |
| Nearest person month worked: | 6 |
| Contribution to Project: | *No change.* |
| Funding Support: | No change |

| | |
|---|---|
| Name: | *Andrew Hansen, PhD* |
| Project Role: | *Site PI (Minneapolis VA Health Care System)* |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | 1 |
| Contribution to Project: | No change |
| Funding Support: | No change |

| | |
|---|---|
| Name: | *Jason Wilken, PhD* |
| Project Role: | *Former Site PI (Center for the Intrepid)* |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | 0 (departed mid-year) |
| Contribution to Project: | Served as site PI at the outset, no change from application plan. |
| Funding Support: | N/A |

| | |
|---|---|
| Name: | *Elizabeth Russell Esposito, PhD* |

| | |
|---|---|
| Project Role: | *New Site PI (Center for the Intrepid)* |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | 0 (began mid-year) |
| Contribution to Project: | Replaced Dr. Wilken as site PI mid-year, duties are not changed from application plan. |
| Funding Support: | No change. |

| | |
|---|---|
| Name: | *Brian Hafner, PhD* |
| Project Role: | *Investigator* |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | 2 |
| Contribution to Project: | No change |
| Funding Support: | No change |

| | |
|---|---|
| Name: | *Steve Collins, PhD* |
| Project Role: | *Investigator* |
| Researcher Identifier (e.g. ORCID ID): | 0000-0002-3997-3374 |
| Nearest person month worked: | 1 |
| Contribution to Project: | No change |
| Funding Support: | No change |

| | |
|---|---|
| Name: | *Elizabeth Halsne, CPO* |
| Project Role: | Graduate Research Assistant |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month | 7 |

| | |
|---|---|
| worked: | |
| Contribution to Project: | Implemented mechanical testing of emulator and prosthetic feet onsite at VAPSHCS. Assisted in preparing and submitting VA CIRB and HRPO applications, as well as recruitment-related surveys and study documentation plans. |
| Funding Support: | Supported by this award |

| | |
|---|---|
| Name: | Alana Cataldo |
| Project Role: | Study Coordinator |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | 5 |
| Contribution to Project: | Ms. Cataldo has assisted with CIRB paperwork at the MVAHCS site, as well as purchasing equipment for the project (e.g., stairmill), acquiring and setting up space for the emulator within the Minneapolis VA, and communication with the emulator company to facilitate quick installation and start-up of the study when CIRB is approved and the machine is installed. |
| Funding Support: | Supported by this award |

| | |
|---|---|
| Name: | Vincent Chiu |
| Project Role: | Graduate Student Researcher |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | 5 |
| Contribution to Project: | Assisting with development of control techniques, and debugging and revision of pre-deployment emulator systems under the direction of Steven Collins at Carnegie Mellon University. |
| Funding Support: | Supported by this award |

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

There have been no changes in active support for Dr. Morgenroth over the last funding period.

Dr. Russell Esposito did not submit other support as part of the grant application. Her Previous/Current/ Pending Support document is included in this report as Appendix G.

There have been changes in active support for Dr. Hansen over the last funding period.

**Three projects are no longer active for Dr. Hansen:**
Title: Characterizing Ankle Function During Sloped Locomotion for Prosthetic Development
Role in Project: Secondary Mentor
Time Commitment: Up to 4%
Performance Period: July 1, 2012 – June 30, 2017
Level of Funding: $769,291 (total)
Supporting Agency: United States Department of Veterans Affairs, Rehabilitation Research and Development Service
Name and address of funding agency's Contracting/Grants Officer: Jay Freedman, PhD, Scientific Review Officer, Phone: (202) 443-5760, Email: jay.freedman@va.gov
Brief Description of Project's Goals: The purpose of this Career Development Award 2 application is to determine biomechanical properties of able-bodied persons walking and running at a series of fixed speeds on a variety of fixed slopes and to use this information to develop a control algorithm for active ankle-foot prostheses.
Overlap: None

Title: Microclimate evaluation of custom seating systems during wheelchair activities
Role in Project: Co-Investigator
Time Commitment: As needed
Performance Period: June 1, 2015 – January 31, 2016
Level of Funding: $41,859 (total)
Supporting Agency: Tamarack Habilitation Technologies Administered through Minnesota Veterans Medical Research and Education Foundation
Name and address of funding agency's Contracting/Grants Officer: JoAnn Tallman, Acting Executive Director Minnesota Veterans Medical Research and Education Foundation, Phone: (612) 467-5279, Email: tallm002@umn.edu
Brief Description of Project's Goals: The purpose of this project is to test the microclimate (temperature and humidity) characteristics of strap-based and composite-foam-based custom wheelchair seating systems.
Overlap: None

Title: Bimodal Prosthetic Ankle-Foot System for Improved Balance and Mobility
PI: Andrew Hansen
Role in Project: PI
Time Commitment: 10%
Performance Period: April 1, 2014 – March 31, 2017
Level of Funding: $490,588 (total)
Supporting Agency: United States Department of Veterans Affairs, Rehabilitation Research and Development Service
Name and address of funding agency's Contracting/Grants Officer: Timothy J. Brindle, PhD, Scientific Program Manager, Phone: (202) 443-5829, Email: timothy.brindle@va.gov
Brief Description of Project's Goals: The primary objective of this project is to determine if the standing mode

of a bimodal ankle-foot system, which provides a flat effective rocker shape, can improve the standing balance of veterans with lower-limb amputations compared with the curved (walking) mode of the same system.
Overlap: None

**Five projects have started during the last year for Dr. Hansen:**
Title: Development of an Arm Cycle Ergometer for Supine Use
Role in Project: Co-Investigator
Time Commitment: 1%
Performance Period: October 3, 2016 – October 2, 2017
Level of Funding: $50,000
Supporting Agency: University of Minnesota Office of Discovery and Translation
Name and address of funding agency's Contracting/Grants Officer: Jodi Fenlon Rebuffoni, Project Manager, Office of Discovery and Translation, Clinical and Translational Science Institute, 717 Delaware Street SE, 2nd Floor, Minneapolis, MN 55414, Email: fenl0003@umn.edu, Office: 612-626-6945
Brief Description of Project's Goals: The primary goal of this project is to develop a viable supine arm cycle ergometer prototype. Specific Aims: Objective A – Develop a structure with a stable but mobile base that can raise and lower the cycling mechanism over a bed. Objective B – Develop a cycling mechanism to provide a wide range of resistance levels for exercise of the upper limbs. Objective C – Integrate cycling mechanism with the structural components. Objective D – Develop a system that provides feedback of exercise intensity and duration
Overlap: None

Title: Active Cooling Socket for Improving Residual Limb Skin Comfort and Skin Care
Role in Project: Co-Investigator
Time Commitment: 5%
Performance Period: October 1, 2016 – September 30, 2019
Level of Funding: $167,220 (subcontract total)
Supporting Agency: Department of Defense
Name and address of funding agency's Contracting/Grants Officer: TBD
Brief Description of Project's Goals: This project will create an active cooling system for residual limb sockets. The Minneapolis VA will perform temperature and moisture measurements.
Overlap: None

Title: Sensor system for self-management of prosthetic socket fit
Role in Project: Co-Investigator
Time Commitment: 5%
Performance Period: June 1, 2017 – May 31, 2019
Level of Funding: $200,000
Supporting Agency: United States Department of Veterans Affairs, Rehabilitation Research and Development Service
Name and address of funding agency's Contracting/Grants Officer: Brian Schulz, PhD, Scientific Review Officer, 202-443-5769, brian.schulz@va.gov
Brief Description of Project's Goals: The goal of this project is to develop and test a socket fit sensing system that can adapt to patient-specific changes in limb volume and can help Veterans self-manage their socket fit during post-amputation rehabilitation care.
Specific Aims: Aim 1: Refine the socket-fit sensing system. Aim 2: Test socket-fit-detection algorithms.
Overlap: None

Title: Medical 3D Printing, System and Process for 3D Printing Prosthetic Components
Role in Project: Subcontract Principal Investigator
Time Commitment: 5%
Performance Period: June 10, 2017 – June 9, 2019
Level of Funding: $109,093 (subcontract total)
Supporting Agency: Defense Logistics Agency
Name and address of funding agency's Contracting/Grants Officer: Heather Houtz, DCSO-P, 700 Robbins Ave., Philadelphia, PA 19111
Brief Description of Project's Goals: This project aims to create a commercially viable 3D printed prosthetic product line which is superior, cost effective and more efficiently utilizes clinician time. The Phase II project builds on the results of Phase I in collaboration with the Veterans Administration, a state sponsored university and commercial small businesses. It focuses on creating a scanning system and developing an expanded array of prosthetic and orthotic solutions. These designs will be tested to the full extent of the ISO standard, comprehensive human studies for safety and efficacy will be performed, and the developed process will be integrated into an effective prosthetic manufacturing system.
Specific Aims: Aim 1: Develop designs for specific existing socket types; Aim 2: Develop additional 3D-printed prosthesis and orthosis products.
Overlap: None

Title: Biomimetic Slope Adaptive Foot-Ankle Prosthesis
Role in Project: Subcontract Principal Investigator
Time Commitment: 2.5%
Performance Period: 07/10/2017 – 01/09/2018
Level of Funding: $150,000
Supporting Agency: Department of Defense STTR
Name and address of funding agency's Contracting/Grants Officer: TBD
Brief Description of Project's Goals: The goal of this study is to develop an innovative, passively-controlled prosthetic foot/ankle system that will help individuals with lower limb loss to perform a wider variety of tasks with closer-to-normal walking biomechanics.
Specific Aims: 1. Finalize specifications for the phase I foot-ankle system; 2. Fabricate and assemble phase I foot-ankle system; 3. Test and Demonstrate phase I foot-ankle system.
Overlap: None

There has been a change in active support for Dr. Collins over the last funding period.

**Two projects are no longer active for Dr. Collins:**
Title: Ankle exoskeletons that make recreational runners faster
Role: PI (Collins)
Time commitment: 2 months
Supporting Agency: An undisclosed company.
Grants Officer: Not disclosed.
Performance period: 01/01/2016–4/30/2017
Level of funding: $319,829
Project goals: This project will identify the ankle exoskeleton properties that augment human running performance and develop the key enabling technology for implementation in efficient, lightweight exoskeletons.
Overlap: There is no overlap with the proposed work.

Title: User-optimal robotic prosthesis design

Role: PI (Collins)
Time commitment: 1 month
Supporting Agency: NSF CMMI ESD
Award number: CMMI-1300804
Grants Officer: Christian Paredis | cparedis@nsf.gov | 703-292-2241
Performance period: 08/15/2013–07/31/2016
Level of funding: $216,740
Project goals: The objective of this research is to develop computational models of human-prosthesis interaction, use them to predict optimal device designs, and refine predictions in experimental work with a versatile robotic ankle-foot prosthesis testbed.
Overlap: There is no overlap with the proposed work.

**One project has started during the last year for Dr. Collins:**
Title: Optimizing hip, knee and ankle exoskeleton assistance during walking and running at various speeds, grades and loads
Role: PI (Collins)
Time commitment: 2 months
Supporting Agency: U.S. Army NSRDEC
Grants Officer: Karen Gregorczyk | karen.n.gregorczyk.civ@mail.mil | 508-233-4157
Performance period: 09/01/2016–08/31/2019
Level of funding: $2,225,718
Project goals: This project will build a systematic understanding of the exoskeleton properties that are needed to augment human walking and running performance at various speeds and loads. We will develop a high-performance exoskeleton emulator system, refine methods for optimizing exoskeleton assistance, and perform experiments identifying optimal assistance parameters under a variety of conditions.
Overlap: There is no overlap with the proposed work.

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

We are working closely with Josh Caputo, PhD at HuMoTech to ensure optimal use of the prosthetic foot emulator.

## 8. Special Reporting Requirements

Please see Department of Defense Quad Chart in Appendix A.

## 9. Appendices

This annual report includes the following appendices:

A. Department of Defense Quad Chart (updated September 30, 2017).
B. Manual of Operations for Human Subjects Trial
C. Consent Form for Human Subjects Trial
D. Study Survey for Visit 1 for Human Subjects Trial
E. Study Survey for Visits 2-3 for Human Subjects Trial
F. Study Survey for Visits 4-6 for Human Subjects Trial
G. Previous/Current/Pending Research Support for Dr. Elizabeth Russell Esposito
H. Abstract for VA Rehabilitation Research and Development's Center for Limb Loss and MoBility's 2017 Young Investigator Symposium presentation

# A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations

Log Number OP150005; W81XWH-15-OPORP-PORA (Funding level 2)
Award Number: W81XWH-16-1-0569

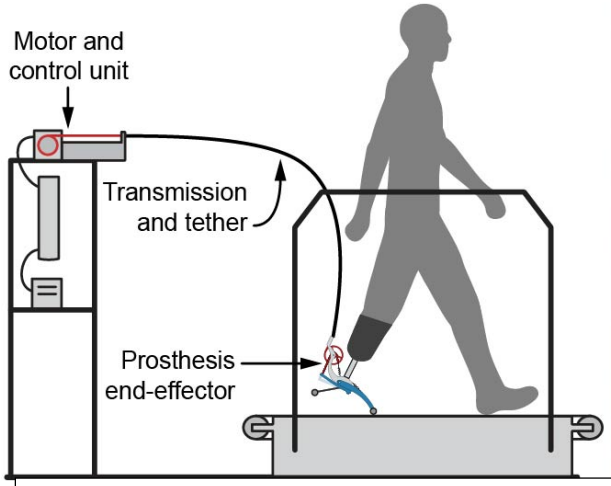
**PI:** David Morgenroth, MD **Org:** Seattle Institute for Biomedical and Clinical Research **Award Amount:** $2.5 Million

## Study Aims

- Determine whether a prosthetic foot emulator can be used to predict foot preference and mobility outcomes with corresponding, commercial prosthetic feet in Service members and Veterans with transtibial amputation (TTA)
- Determine whether a brief trial of commercial prosthetic feet can predict longer-term preference and mobility outcomes with prosthetic feet in Service members and Veterans with TTA
- Determine potential barriers and facilitators to the inclusion of a patient-centered 'test-drive' component to clinical prosthetic foot prescription

## Approach

We will conduct a repeated measures study with cross sectional and longitudinal components to study foot preference and mobility outcomes for a variety of commercially available prosthetic feet compared with emulated versions of those feet In 75 Veterans and Service members with lower limb amputation.




Accomplishment: We have fabricated the Prosthetic Foot Emulator that is able to mimic a diverse range of prosthetic feet (for VA Seattle site so far).

## Timeline and Cost

| Activities | CY | 16-17 | 17-18 | 18-19 |
|---|---|---|---|---|
| Obtain all institutional and regulatory approvals | | | | |
| Develop/finalize manual of operations | | | | |
| Mechanical testing of prosthetic feet | | | | |
| Recruit participants and conduct data collection | | | | |
| Analyze data and disseminate results | | | | |
| **Estimated Budget ($K)** | **$2493** | **$1467** | **$437** | **$522** |

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**Updated:** 9/29/2017

**Goals/Milestones**

**CY16-17 Goals** – Study preparation and participant recruitment
☑ Obtain R&D Committee approval for non-human subjects work
☑ Develop and finalize self-report questionnaire packets and data spreadsheet
☑ Continued mechanical testing of prosthetic feet for input to emulator
☑ Received PI-SC approval from VA Central IRB, and IRB approval for CFI site
☑ Submitted LSI to VA Central IRB and initial documents to HRPO
☐ Recruit first 21 participants
☐ Conduct data collection procedures

**CY17-18 Goals** – Ongoing recruitment and data collection
☐ Recruit additional 30 participants
☐ Conduct data collection procedures
☐ Disseminate initial results at national conference

**CY18-19 Goal** – Analysis and dissemination
☐ Recruit and collect data from final 24 participants
☐ Analyze final data set
☐ Disseminate final study results

**Comments/Challenges/Issues/Concerns**
- Hardware delays in mechanical testing of prosthetic feet

**Budget Expenditure to Date:** Projected Expenditure: $2.493M/3years
Actual Expenditure to date: $427,314

A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations

CIRB # 17-08

Funding Agency: Department of Defense

Principal Investigator/Study Chair: David Morgenroth, MD

Version 1; 4/5/2017

## Abstract

*Objectives and Rationale:* Severe injury to a foot or leg may necessitate amputation of the limb. Using a prosthesis allows many who experience lower leg amputation to regain functional abilities, but walking may be more difficult, and a sub-optimal prosthesis can substantially restrict participation in desired activities. Selecting an optimal prosthetic foot is an important aspect of maximizing mobility and the achievement of functional goals for people with lower leg amputation, however there is limited evidence to guide this process. The current prosthetic prescription process relies on clinician experience and typically does not allow people with a leg amputation to easily try out different prosthetic feet. We have developed a customizable robotic prosthetic foot that mimics the mechanical properties of commercially available prosthetic feet without physically changing feet. This 'prosthetic foot emulator' (PFE) can be attached to the prescribed prosthetic socket and worn like a regular prosthetic foot within the laboratory or clinic, providing people with leg amputations the opportunity to quickly 'test-drive' many prosthetic foot designs within a single test session. Trial and error with actual commercial prosthetic feet can be inefficient given the time and expense required for the purchasing and fitting of prosthetic feet. The PFE could provide a means to explore a range of feet in a very short period of time. This study will evaluate the ability of the emulator to accurately reproduce the experience of wearing several commercially available (*actual*) prosthetic feet. We will test whether brief in-laboratory experiences with *emulated* or *actual* feet can accurately predict longer-term foot preference, satisfaction, and walking ability in the community. Results from this study may provide evidence to support a new approach to prosthesis prescription and could resolve longstanding uncertainty in the prescription process for prosthetic feet.

*Objective/Hypotheses and Specific Aims*: The primary aim of this proposal is to determine whether a PFE can be used to predict foot preference and mobility outcomes with corresponding commercial prosthetic feet in Service members and Veterans with a unilateral transtibial amputation (TTA). Secondarily, we aim to determine whether a brief trial of commercial prosthetic feet would be able to similarly predict longer-term foot preference and mobility outcomes with those feet.

*Study Design*: We will use a participant blinded cross-over study with repeated measurements in Veterans and Service members with TTA. Up to 50 participants will be enrolled at each of the three study sites: two VA sites (Puget Sound and Minneapolis), and one DoD site (Center for the Intrepid). Participants will complete up to 6 visits. After an initial assessment visit, participants will be assigned to the high or low mobility group, and then during visit 2 they will be randomized to use the PFE in three foot modes or the three corresponding actual (commercially available) feet during walking tests in the laboratory. During visit 3 participants will repeat the procedures in the other condition (e.g., PFE if Day 2 included actual feet testing). At the end of visit 3 participants will be fit with one of the actual feet and wear it at home and in the community for at least two weeks. At visit 4 participants will be fit with the next actual foot and repeat the 2 week use window. The same process will be followed for the final foot at visit 5, and the study foot will be returned at visit 6. Participants' preference, satisfaction and perceived mobility, and functional mobility will be measured and compared across all foot conditions (*emulated* and *actual*). Please see **Figure 2** in section 5.5 below for schematic of study design.

## List of Abbreviations

Provide a list of all abbreviations used in the protocol and their associated meanings.

2MWT – Two Minute Walk Test
ABC – Activity Balance Confidence
AE – adverse event
CCTV – closed-circuit television
CFI – Center for the Intrepid
CPRS – Computerized Patient Record System
CRQ – Continuing Review Questionnaire
DoD – Department of Defense
HM – high mobility
HRPO – Human Research Protection Office
ISO – information security officer
LLA – lower limb amputation
LM – low mobility
MVAHCS – Minneapolis Veterans Administration Health Care System
NSR – non-significant risk
PFE – prosthetic foot emulator
PHI – protected health information
PLUS-M – Prosthetic Limb Users Survey of Mobility
RAC – Regional Amputation Center
SACH – solid ankle cushion heel
SAE – serious adverse event
TAPES-R – Trinity Amputation and Prosthesis Experience (revised scales)
TTA – transtibial amputation (below-knee)
USAE – unanticipated serious adverse event
USAMRMC ORP - US Army Medical Research and Materiel Command Office of Research Protections
VAPSHCS – Veterans Administration Puget Sound Health Care System

## List of Attachments

| | |
|---|---|
| Attachment 01c | Non-Significant Risk Device Determination |
| Attachments 04a-b | HIPAA Authorization Form; model and Seattle site |
| Attachment 05 | VHA form 10-3203, Image use and release form; all sites |
| Attachments 06a-b | Informed Consent form; model and Seattle site |
| Attachments 07a-b | Study approach letter; model and Seattle site |
| Attachments 07c-j | Recruitment Flyers, CCTV slides; model and Seattle site |
| Attachments 08a-d | Telephone screening script, In-person Talking Points screening; model and Seattle site |
| Attachments 09a-b | Visit reminder; model and Seattle site |
| Attachments 10a-b | Seattle Privacy Officer data sheet review, De-identified data template; all sites |
| Attachment 11a | Regional Amputation Center database; Seattle site permission |
| Attachments 12a-c | Study Surveys; all sites |

# Contents

## Protocol Title: A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations

## 1.0 Study Personnel

**Project Staff at VA Puget Sound Health Care System (Seattle, WA)**

**Principal Investigator/Study Chair:** David Morgenroth, MD, Staff Physician, Investigator, VA RR&D Center for Limb Loss and Mobility, david.morgenroth@va.gov, 206-277-1982

**Medical Monitor/Research Physician:** Jeff Heckman, DO, Jeffrey.t.heckman@va.gov, 206-277-5719

**Research Prosthetist/Coordinator:** Elizabeth Halsne, CPO, JPA, WOC, elizabeth.halsne@va.gov, 206-277-1217

**IRB Program Coordinator:** Tasha Mikko, MSW, tasha.mikko@va.gov , 206-277-1155

**Research Coordinator:** TBD

**Project Staff at Minneapolis VA Health Care System (Minneapolis, MN)**

**Local Site Principal Investigator:** Andrew Hansen, PhD, Director, Rehabilitation Engineering Research Program, Minneapolis VAHCS, andrew.hansen2@va.gov, (612) 725-2000 x2910

**Research Coordinator:** Alana Cataldo, alana.cataldo@va.gov, (612) 725-2000

**Study Staff:** Billie Slater, billie.slater@va.gov, (612) 629-7830

**Research Prosthetist:** Kyle Barrons, kyle.barrons@va.gov, (612) 467-2001

## 2.0 Introduction

Approximately one million people in the United States are living with lower limb amputation (LLA), and this number is projected to more than double by 2050.[1] LLA results in a wide range of mobility limitations,[2,3] primarily due to the loss of the biologic foot-ankle in those with transtibial amputation (TTA). The human foot-ankle mechanism plays a key role during gait in shock absorption, weight-bearing stability, energy conservation, and propulsion.[4,5] Although commercial prosthetic feet cannot fully replicate physiologic foot-ankle function, selection of an optimal foot is an important aspect of prosthetic prescription and vital to maximizing mobility and the achievement of functional goals after LLA.[6]

There is a great need for strategies to enhance prosthetic foot prescription in order to improve satisfaction and functional outcomes for Service members and Veterans with

LLA. At present, there is relatively little empirical evidence to guide clinical prosthetic foot prescription practices.[7-12] Although numerous comparative studies of prosthetic feet exist, they are typically limited by an exclusive focus on biomechanical and metabolic outcomes that have uncertain clinical significance.[6,9,13,14] Further, the vast majority of studies compare a very small number of feet without sufficiently addressing implications for the clinical selection of prosthetic feet in the current marketplace where there are hundreds of feet available, and new products are commercialized regularly.[6,9,13,14] Since commercial prosthetic foot designs and features have important functional trade-offs (e.g. increased ankle motion often comes at a cost of decreased stability), the selection of an appropriate foot is highly dependent on the unique needs, goals, and abilities of each individual patient.

Current Prosthetic Foot Prescription Process: Limited User-Input:

A Cochrane review of prosthetic foot prescription reported limited evidence and no clear consensus on criteria that should be used to best match patients with an appropriate foot.[7] In the absence of convincing empirical evidence from the scientific literature, prosthetic prescription is instead determined by prescribing clinicians' expertise, familiarity with specific commercial prosthetic feet, and other factors such as advertisements from foot manufacturers. This can result in selection of a foot that is not ideally matched to the patient, or a potentially expensive and lengthy provision process based on trial and error. Evidence-based strategies to better match individual patients with an optimal prosthetic foot in a timely and cost-effective manner are therefore needed.

In contemporary practice, prescribing clinicians typically choose a prosthetic foot based on a patient's medical and functional history, physical examination, and functional goals. There are generally limited opportunities for patients to try out different prosthetic feet and provide input to their prescription (as an analogy, imagine going to a car dealership and being told what car you were going to take home without test driving and comparing different vehicles). This process is particularly problematic since a successful prosthetic prescription is primarily defined by a patient's satisfaction and perceived achievement of mobility goals with their prosthesis. Further, as service providers' perspectives on treatment success are known to differ from that of their patients,[8] involvement of patients in this prescription process may be an ideal means to maximize clinical outcomes. Previous studies have shown that including patient perspectives in the prescription of prostheses (and other assistive devices) improves both user satisfaction and use of these devices.[18,19] Perhaps more importantly, involving patients in medical decision-making has been shown to improve functional outcomes.[20] Thus, we believe the ability to 'test-drive' different prosthetic feet will facilitate patients' participation in the prescription process, increase patient satisfaction, and ultimately improve health outcomes.

Measuring Success in Clinical Prosthetic Foot Prescription Using Patient-Centered Outcomes:

Although there is no consensus on what defines successful prosthetic rehabilitation,[16] it has been suggested that there is often excessive focus on clinical indicators (e.g. observational gait analysis) and insufficient regard for what is important to prosthetic

users.[21] Although some studies have examined self-reported outcomes of satisfaction and perceived mobility associated with different prosthetic feet, participants in these studies typically are not blinded. Blinding is vital in studies of this type to eliminate expectation bias, and to isolate differences in perception and performance.[7,13,14,27] Although occasional studies have blinded participants to prosthetic foot condition,[17,28] sample sizes in these studies were small and there was variability in foot preference across subjects. Other studies have also demonstrated variations in foot preference by activity level, amputation etiology, age, and/or weight,[29-32] suggesting that further research is needed to support evidence for individualized prescription optimization.

Satisfaction is a clinically important construct since satisfied patients have been shown to be more likely to seek and continue using medical services and comply with medical treatments.[23,34] In order to promote a patient-centered approach to prosthetic foot prescription, we will target key self-report outcomes, including prosthetic foot preference, satisfaction, and perceived mobility in this project.

Prosthetic Foot Emulator (PFE)

To enhance the prosthetic foot prescription process, we have developed a customizable robotic prosthetic foot that mimics commercial feet to predict how individual patients will respond to candidate feet (**Figure 1 below**). The behavior of the PFE is controlled by the experimenter through a software interface without requiring mechanical changes to the foot hardware, providing people with TTA the opportunity to quickly 'test-drive' many prosthetic foot designs within a single test session.

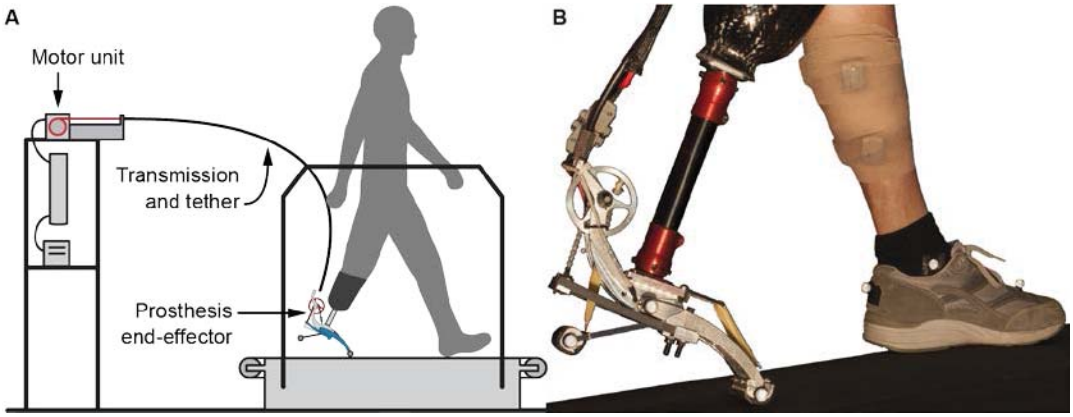


**Figure 1: A)** The prosthetic foot emulator (PFE) consists of a lightweight prosthetic foot actuated through a flexible tether by a powerful off-board motor and control system, enabling emulation of an exceptional variety of prosthetic feet. **B)** Photograph of the PFE end-effector as worn by an individual with transtibial amputation.

Our benchtop experiments have demonstrated the PFE's exceptionally high torque control performance, power output, and low end-effector worn mass,[45] and the PFE has been used in human subject experiments to assess the effects of ankle push-off work on gait.[46-48] Our initial experiments in participants with TTA (N=6) have demonstrated the PFE's ability to accurately mimic commercial prosthetic foot mechanics, with subjective reports that emulations convincingly represented commercial feet. Thus, use

of the PFE enables assessment of users' perceptions of different feet, while measuring mobility outcomes across walking conditions.[49]

One major limitation to the clinical translatability of prior research comparing commercial prosthetic feet is the limited number and diversity of feet included in studies relative to those available on the market. Given that there are hundreds of feet available, it is simply impractical to evaluate all feet in research studies. Development of a PFE, like that proposed here, could address this critical limitation and allow for a large number of feet to be examined, without the burden and cost of including many commercial feet. Once the predictive validity of the PFE has been established through the proposed research, the mechanical properties of additional prosthetic feet (including emerging designs) can be easily measured with benchtop testing and then integrated into the PFE 'library.'

This project aims to enhance clinical practice by providing an evidence-based means for patients to trial and compare different commercial prosthetic feet thus providing input to prosthetic prescription using patient-centered outcomes.

## 3.0 Specific Aims and Hypotheses

***Primary Aim:*** **Determine whether a prosthetic foot emulator can be used to predict foot preference and mobility outcomes with corresponding commercial prosthetic feet in Service members and Veterans with TTA.** Participants will be evaluated after walking in the laboratory with three distinct emulated prosthetic feet (*initial testing*: *emulated* feet) and after using each corresponding, commercial foot for at least two weeks (*follow up testing*: *actual* feet). Participants' preference, satisfaction and perceived mobility, and functional mobility will be measured and compared across foot conditions (*emulated* and *actual*). Preference, satisfaction and perceived mobility will be measured and compared across foot conditions with a Foot Preference Survey using an 11-point scale (0 – 10). Additionally, at follow-up evaluations, perceived mobility and satisfaction will be measured using the Prosthetic Limb Users Survey of Mobility (PLUS-M), Activity Balance Confidence (ABC) scale, and Trinity Amputation and Prosthesis Experience Scales (TAPES-R) Activity Restriction and Satisfaction scales, and functional mobility will be measured with the Two Minute Walk Test (2MWT).

*H1.1:* Participants' preference for each *emulated* foot (relative to other feet) will correlate strongly with their preference for the corresponding *actual* foot. Similarly, participants' preference for each *emulated* foot will correlate with their satisfaction and perceived and functional mobility in the corresponding *actual* foot.

*H1.2:* Participants' mobility in the *emulated* foot will correlate strongly with their mobility in the *actual* foot.

***Secondary Aim:*** **Determine whether a brief trial of commercial prosthetic feet can predict longer-term preference and mobility outcomes with prosthetic feet in Service members and Veterans with TTA.** Participants will be assessed in the lab

after briefly walking with three distinct prosthetic feet (*initial* testing: *actual* feet) and again after using each foot for two weeks (*follow-up* testing: *actual* feet). Participants' preference, satisfaction and perceived mobility, and functional mobility at each evaluation will be compared.

> *H2.1:* Participants' *initial* preference for each foot will correlate strongly with their preference at *follow-up*. Participants' *initial* preferences will also correlate strongly with their satisfaction and perceived and functional mobility at *follow-up*.

***A modification will be submitted at a later date to address the Exploratory Aim:***

**Determine potential barriers and facilitators to the inclusion of a patient-centered 'test-drive' component to clinical prosthetic foot prescription.** *Emulated* and *actual* trials will be pilot tested in VA and DoD amputee clinics during the prosthetic prescription process. Participating patients, prescribing physicians, and prosthetists will be interviewed regarding barriers and facilitators to implementation. The procedures for the exploratory aim will be submitted at a later date because they will be informed by the work and results of the primary and secondary aims.

## 4.0 Resources and Personnel

Data collection procedures for this study will be conducted at three sites: (1) VA Puget Sound Health Care System (VAPSHCS), (2) Minneapolis VA Health Care System (MVAHCS) and (3) The Center for the Intrepid (CFI). Please note, CFI is a Department of Defense site and therefore they will obtain IRB approval through their local process; a copy of their approval will be submitted to CIRB once it is obtained if requested. VAPSHCS and MVAHCS are both part of the VA CIRB application.

| **VA Puget Sound, Seattle WA** | | | | |
|---|---|---|---|---|
| **Study Team Member** | **Degree** | **Study Role** | **Access to PHI at site** | **Obtaining Consent** |
| David Morgenroth | MD | Principal Investigator/Study Chair | Yes | Yes |
| Jeff Heckman | DO | Medical Monitor/Research Physician | Yes | No |
| Elizabeth Halsne | CPO | Research Prosthetist/Lead Coordinator | Yes | Yes |
| Tasha Mikko | MSW | IRB Program Coordinator | Yes | No |
| Jane Shofer | MS | Biostatistician | No | No |
| TBD | | Research Coordinator | Yes | Yes |

| Minneapolis VA, Minneapolis MN | | | | |
|---|---|---|---|---|
| **Study Team Member** | **Degree** | **Study Role** | **Access to PHI at site** | **Obtaining Consent** |
| Andrew Hansen | PhD | Local Site Investigator | Yes | Yes |
| Alana Cataldo | BS | Research Coordinator | Yes | Yes |
| Billie Slater | BS | Study Staff | Yes | Yes |
| Kyle Barrons | BS | Research Prosthetist | Yes | Yes |

Under the supervision of the overall project PI (Morgenroth) at VAPSHCS and the local supervision of each site PI, the Research Coordinators will be primarily responsible for conducting recruitment, consent and scheduling study procedures. The PI, Investigators, and/or Research Coordinators/Prosthetist will conduct study procedures with participants. The PI, Investigators, and the Biostatistician will be primarily responsible for data analysis and interpretation; Research Coordinators may also assist with this. Under the supervision of the PI, the Program Coordinator is responsible for IRB related matters. The Medical Monitor named above is responsible for overseeing the safety of the research and report observations/findings to the IRB or a designated institutional official. The Medical Monitor will review all unanticipated problems involving risks to subjects or others associated with the protocol and provide an independent report of the event to the IRB. The Medical Monitor may discuss the research protocol with the investigators; shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report; and shall have the responsibility to promptly report their observations and findings to the IRB or other designated official and the HRPO.

# 5.0 Study Procedures

## 5.1 Study Design Overview

Participants will be men and women, age 18 or over, with a unilateral TTA that have been fit with a prosthesis and use it on a regular basis (full inclusion/exclusion criteria are listed below. Participants will be recruited at three sites, VA Puget Sound, Minneapolis VA, and the Center for the Intrepid (DoD; this site will obtain local DoD IRB approval). We will conduct a participant blinded cross-over study with repeated measurements. Data collection methods will be

identical at all sites. Participants will walk in the laboratory with the PFE and with corresponding/matched, commercial prosthetic feet under various walking conditions (e.g. level ground, incline, and stairs). Participants will then wear each of the commercial feet at home and in the community for two-week periods. We will assess participant preference, satisfaction, perceived mobility and walking ability in order to determine whether the PFE and/or a brief trial of commercial feet in the laboratory are able to predict mobility, prosthetic foot preference and walking ability after two weeks of use in the home and community setting.

No exclusions based on sex, race, or ethnic status will be applied.

| **Study Groups and sites** | |
|---|---|
| Seattle VA: Participants with transtibial amputation | up to 50 |
| Minneapolis VA: Participants with transtibial amputation | up to 50 |
| **Total VA sites** | **up to 100** |
| For reference:<br><br>Center for the Intrepid (DoD site) | up to 50 |
| **Total all sites** | **Up to 150** |

See section 5.5 below for data collection procedures and risk management.

All participating sites will use the most current version of this study protocol. If these procedures are revised, the PI/SC will notify the site-specific Principal Investigator at each participating site and provide the revised version. All necessary local facility approvals will be obtained, if required, before the amendment or modification is implemented at each participating site.

## 5.2 Inclusion/Exclusion Criteria

Inclusion criteria

- has a unilateral (one leg) transtibial (below-knee) amputation
- has used a prosthetic limb for walking for at least six months
- has a comfortably fitting prosthetic socket
- be able to walk with a prosthetic limb sufficiently to participate in the experiment walking trials
- be age 18 years or older

Exclusion criteria

- contralateral limb or upper limb amputation
- are unable to use test feet for any reason (e.g., excessively long residual limb that is not compatible with wearing study prosthetic feet)

- unable to walk under the minimal necessary study walking conditions in order to complete the study procedures without undo stress
- currently pregnant (determined via self-report during screening)
- current surgical, neurological, rheumatologic, or lower limb musculoskeletal problem that significantly impairs ambulation (e.g., current ulcer, terminal illness, lower extremity joint replacement)
- weight greater than 300lbs.
- inadequate cognitive or language function to consent to participate
- currently incarcerated

## 5.3 Recruitment Methods and Initial Screening

Please note that all references in this section to in-person contact/initial-screening will follow the *Talking Points (*attachment 08c/08d), all phone calls for contact/initial-screening will follow the *Phone Script* (attachment 08a/08b), and all references to approach letters and flyers refer to the *Recruitment Letter (07a/07b)* and *Flyers/CCTV (*attachments 07c-07j).

Participants will be recruited at each of the three data collection sites: (1) VA Puget Sound Health Care System (VAPSHCS), (2) Minneapolis VA Health Care System (MVAHCS), and (3) The Center for the Intrepid (CFI) (this DoD site will obtain its own IRB approval). Potential participants may learn about the study from several sources: 1) targeted mailing from medical record/database/registry, 2) study recruitment materials (e.g., flyers and brochures) posted throughout each data collection site, 3) clinician referral and study representative attending clinic.

Medical Record/Database: Letter/Phone/In-person

Designated research staff will screen relevant clinic lists in CPRS (amputee rehabilitation, prosthetics, amputee support groups), and the Regional Amputation Center (RAC) databases at each site (these are clinical databases that include a list of patients with an amputation who receive care at each site; see attachment 11a for the local approval for use) to identify potential participants. After review of relevant clinic lists in CPRS, designated staff will go to the clinic or contact providers on the phone to ask if the patient might be a good fit for the study. If the clinician agrees that the patient may be an appropriate study participant, during an appointment the clinician will ask the patient if she/he is interested in speaking with designated study staff; patients will be given a chance to opt out. For patients who are interested, designated study staff will speak to potential participants directly after a clinic visit and/or use CPRS to obtain potential participants' contact information (i.e., name, address, telephone number). For potential participants who learned about the study in person, designated study staff may make a follow-up approach phone call and/or send an approach letter to potential participants asking whether they are interested in participating in the study. If potential participants are unable to meet with designated study staff in-person then we will send an approach letter to them asking whether they are interested in participating. We may also search

CPRS, and the RAC databases, to identify individuals with a qualifying lower limb amputation and mail them the approach letter. If potential participants have not spoken with us within 14 days of the first call and/or mailing the approach letter, designated study staff will contact them by phone up to two more times (three times total) about this study. The approach letter will also include an “opt out” postcard. The opt-out postcard will have a unique study recruitment identification code. If an individual returns the postcard to opt out they will not be approached about this study again. Each site will maintain a link between the study recruitment identification code and the contact information; these will be kept in a separate password protected documents at each site. Interested individuals will be screened for eligibility.

Clinician Referral

Designated staff will inform providers working in relevant clinics about the study and inclusion/exclusion criteria so that they can refer potential participants to contact the study team.

Flyers

Flyers will be posted in designated areas at each site, on the CCTV system and in publically accessible locations in the community (e.g., public libraries, community centers, coffee shops).

VA Puget Sound Center Registry: Letter/Phone

At the VA Puget Sound, designated study staff may also identify potential participants using the VA Center for Limb Loss Prevention and Prosthetic Engineering Subject Registry (PI: Klute, #00433). The Registry contains contact information for participants who were screened for and/or participated in previous studies with our research group and agreed to be contacted for future studies. Designated study staff may make an approach phone call and/or send an approach letter to potential participants asking whether they are interested in the study. If potential participants have not spoken with us within 14 days of the first call and/or of the mailing the approach letter, designated study staff will contact them by phone up to two more times. The approach letter will also include an “opt out” postcard. The opt-out postcard will have a unique study recruitment identification code. If an individual returns the postcard to opt out they will not be approached about this study again. The link between the study recruitment identification code and their contact information will be kept in a separate password protected document on site at the VA Puget Sound (Seattle). Interested individuals will be screened for eligibility.

Minneapolis VA registry: Letter/Phone

Designated staff may also identify potential participants using a list of individuals that previously consented (when participating in a prior study) to be contacted for

study recruitment purposes. Designated study staff may make an approach phone call and/or send an approach letter to potential participants asking whether they are interested in the study. If potential participants have not spoken with us within 14 days of the first call and/or of the mailing the approach letter, designated study staff will contact them by phone up to two more times. The approach letter will also include an “opt out” postcard. The opt-out postcard will have a unique study recruitment identification code. If an individual returns the postcard to opt out they will not be approached about this study again. The link between the study recruitment identification code and their contact information will be kept in a separate password protected document on site at the Minneapolis VA. Interested individuals will be screened for eligibility.

Please see participant payment information below in section 5.5

## 5.4 Informed Consent Procedures

A waiver of informed consent and HIPAA authorization will be used for the recruitment and screening processes described above. A waiver of documentation of consent and HIPAA authorization will be used in order to retain the preliminary eligibility screening information *(see Talking Points and Phone Script and eligibility criteria listed above)*. Informed consent will be obtained prior to enrollment in the study.

Consent form

All participating sites will use the most current version of the informed consent form. If the informed consent form is revised, the PI/SC will notify the PI’s at each participating site and provide the revised draft of the consent form. All necessary approvals will be obtained before the amendment or modification is implemented at each participating site.

Consent process

Following initial screening, designated study staff and the participant will set-up a time to meet for the first visit; this will include going through the informed consent process and obtaining the necessary signatures. The informed consent process will take place in a private area or in a discreet manner to protect the participant’s privacy. Participants will be reminded that their participation is voluntary. Staff will go over the consent form with the participant and then give them time to read the form. Potential participants will also be asked if they need some time to consider their involvement before providing consent, and they will be given the opportunity to ask any questions related to the study before consenting. No attempt will be made to persuade individuals who decline participation.

Designated staff at each site (as noted above) will conduct the informed consent process. We will avoid having the study PI/LSI conduct consent in order minimize the risk that individuals might feel obligated to participate. However, in the event the PI/LSI is the only team member available to conduct consent then she/he

may do so. Finally, we will tell all potential participates that their decision about participation will not affect their clinical care in any way.

All study staff will complete the necessary human subjects protections training per VA policy. Additionally, the PI/SC and LSIs are responsible for training all applicable study staff at participating sites how to conduct the informed consent process. The PI/SC will also hold pre-study training conference calls, which will cover the informed consent process. LSIs are responsible for ensuring that their site study staff receive any additional training as necessary.

## 5.5 Study Visits, Data Collection, and Risk Management

**Visits and length of participation**

The same data collection procedures will take place at each study site. Participants will be asked to participate in up to six study visits at the VA over approximately two to three months (See **Figure 2**). Visits 1-3 may take up to four hours each, and visits 4-6 may take up to two hours each. These time estimates are high, and we anticipate that the visits will take less time but we also expect there will be variability between participants. We also wish to ensure that participants have adequate time to rest between walking sessions. If for any reason we find that data are missing or corrupted we may ask participants to return for another visit to recapture the data. We will make every effort to keep "on time" with the two-week follow up visit windows, however flexibility for participants' schedules will be allowed and any variations in time will be noted as part of the data set.

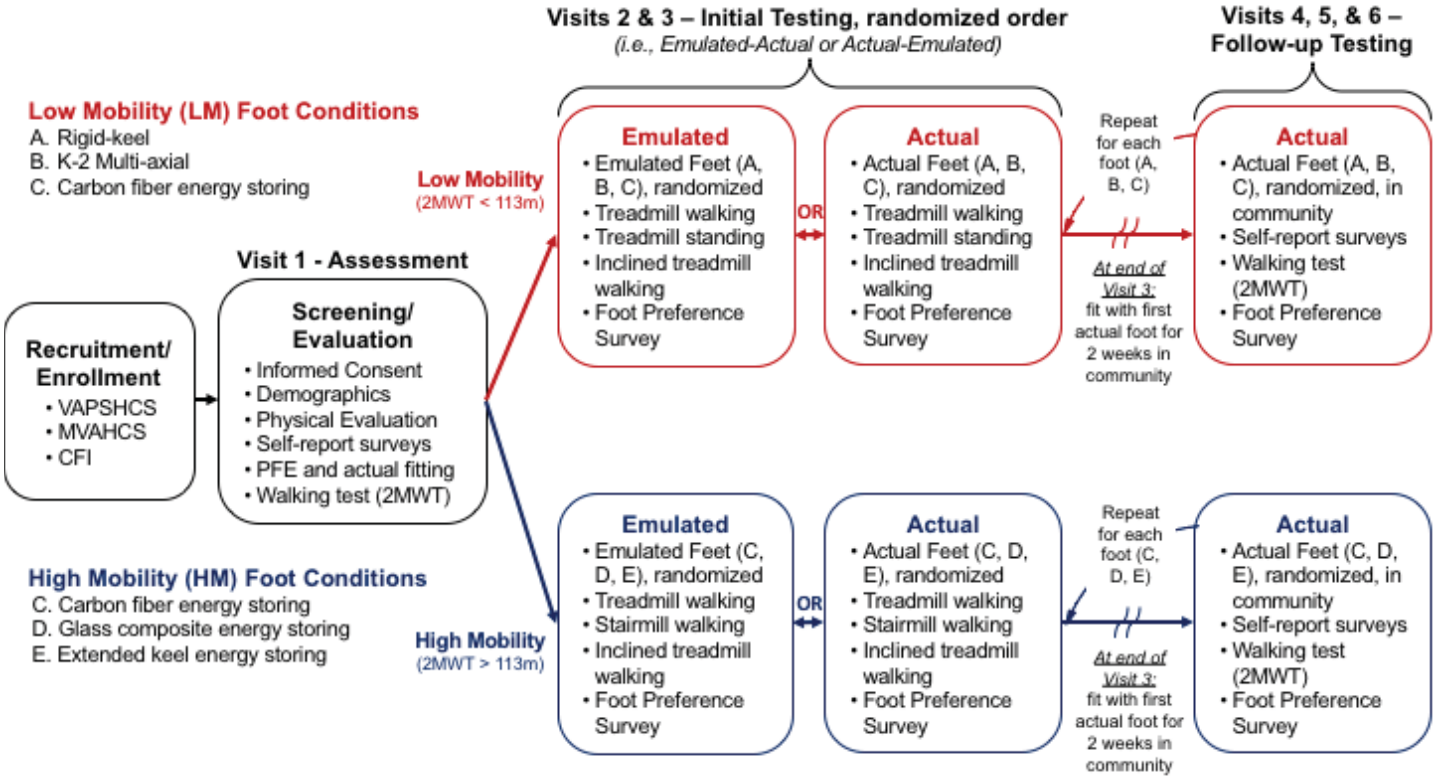

**Figure 2**. Schematic diagram of data collection study visits and outcome measures.

## Data collection

Photos and video recording

With the participant's explicit consent, we may take video and photos during portions of this study, for documentation and use in research publications. All videos and photos will exclue the participant's face and identifying marks will be covered. If any identifiable features or marks are mistakenly captured they will be anonymized during data processing; the participant's face or other unique marks would be blurred prior to any use outside of the research team that captured the images. Videos will be recorded without sound so that we do not capture any voice prints. If a participant's voice is accidently recorded that section of video would be altered prior to any use outside of the VA study team.

Visit 1: Screening, Prosthetic Foot Emulator Fitting, and Assessment Visit (up to 4 hours)

After consent, participants will be assessed to determine if they can safely and successfully use all of the standard prosthetic feet and the prosthetic foot emulator. For example, if a participant's residual limb length is too long to accommodate one of the prosthetic feet or if any other residual limb condition that precludes use of a prosthesis, e.g., ulcer, is present, she/he will be withdrawn from the study. Individuals who are determined to be not eligible will be compensated $50 for their effort.

Eligible participants will be asked to fill out the baseline self-report surveys (**see attachment 12a**); we will explain that they do not have to answer any questions they do not want to.

Participants will then be asked to complete a walking test called the Two-Minute Walk Test using their own prosthesis. They will be asked to walk continuously back and forth between two cones on level ground for 2 minutes; however, they may stop or take a seated rest break at any point during the test. Participants will be instructed to walk as quickly and safely as they can during this test. Study staff will walk alongside the participants to ensure safety during the test. Participants may use an assistive device, such as a cane or walker, when performing this test. We will record the total distance participants walked during the test.

**Please note**: All prosthetic fittings for this study will be completed by a certified prosthetist, and they will be performed to meet normal clinical care standards. The treadmill and stairmill described in the procedures below are equipped with safety rails and emergency stop features; participants will be given the option to wear a gait belt or safety harness during the walking tests on this equipment.

The study research prosthetist will fit participants with a robotic ankle-foot prosthesis (the prosthetic foot emulator, PFE). The PFE will be attached to

participants' current prosthetic socket in the same way that a regular prosthetic foot would be attached. The PFE can be programmed to operate in different modes that mimic the mechanical properties of different commercially available prosthetic feet. For this study the PFE will be programmed with 5 foot modes – 3 high mobility feet and 3 low mobility feet (one foot mode is shared between high and low mobility groups). Designated research staff will use the computer software interface to switch the PFE between different foot modes. Changing out the physical foot is not necessary. After participants are fitted with the PFE, we will give them time to walk on the treadmill while using the PFE in up to 3 different modes (3 high mobility vs. 3 low mobility modes depending on their 2 Minute Walk Test distance; see details below). This will allow the participants to practice walking with the PFE and we will assess their walking ability to confirm whether the participant is a good fit for the study. Adjustments may be made to the PFE hardware or software settings in order to optimize the walking performance for each participant. If participants are not able to feel confident and stable on one or more of the modes, we will stop the session. We will also give participants time to rest at any point, and each time we switch foot modes.

After the practice and optimization of the PFE, participants will be asked to walk on the treadmill again and choose three walking speeds: comfortable, slow, and fast. Participants will choose these speeds by increasing and/or decreasing the speed on the treadmill. They will be asked to walk for up to a minute at each of the self-selected speeds in order to confirm that they are comfortable using the PFE in each of the three modes on the treadmill for a short period of time. Participants will also be given the opportunity to practice walking with the commercially available (actual) prosthetic study feet. Participants will be able to take rest breaks at any time they would to like during the testing procedures.

At the end of the study visit, the prosthetist will refit the participants' prescribed prosthetic foot. The next study visit will be scheduled.

<u>Visit 2: Randomization & First Initial Testing Visit – Emulator or Actual Feet (up to 4 hours)</u>

Based on the result of the Two Minute Walk Test completed during Visit 1, participants will be assigned to the low mobility group (LM) or the high mobility group (HM). LM vs. HM grouping will determine which 3 prosthetic foot conditions each participant will wear during the testing protocol. At this visit, within each group (LM and HM) participants will be randomized to test either the PFE in the 3 foot modes for their group (LM vs. HM) or the 3 actual corresponding feet for their group. Once randomized to PFE or actual feet, the order in which the different modes and actual feet will be tested will also be randomized; participants will be blinded to all PFE modes and actual foot conditions. At visit 3 they will be tested under the other condition (e.g., if randomized to PFE testing during Visit 2, the participant would undergo testing with the corresponding actual feet during Visit 3).

The research prosthetist will fit participants with the assigned prosthetic feet (PFE or actual feet); participants will use their own prosthetic socket, interface and prosthetic suspension system. Participants will be asked to walk at their chosen comfortable speed while using the assigned PFE mode or actual foot until they feel comfortable. Adjustments may be made to the hardware or software settings in order to optimize the walking performance for each participant, if needed. If participants are not able to feel confident and stable on one or more of the PFE modes or on one of the actual feet, we will stop the session. We will also give participants time to rest at any point, and at every instance between switching modes or switching between actual feet. Participants will be able to take rest breaks at any time during the testing procedures and may choose to opt out of any of the tests at any time.

When ready, all participants will be asked to walk on the treadmill for up to a minute at each of their previously-selected walking speeds: slow, comfortable, and fast.

**Group 'LM'** (low mobility), participants will then be asked to walk again for up to a minute at each of their selected walking speeds (comfortable, slow, and fast), this time with the treadmill inclined to 3 degrees (similar to going up a slight hill). After completing all of these walking trials, they will be asked to stand still for up to a minute; they will be allowed to hold onto the safety bars on the treadmill if needed in order to keep their balance. Participants will be offered breaks between speeds.

**Group 'HM'** (high mobility), participants will then be asked to walk again for up to a minute at each of at their selected walking speeds (comfortable, slow, and fast), this time with the treadmill inclined to 6 degrees (similar to going up a moderate to steep hill). Next they will be asked to walk, at a comfortable walking speed, up stairs on a stairmill for up to a minute. Participants will be offered breaks between speeds on the treadmill and prior to walking on the stairmill.

All participants will then be given at least 10 minutes to rest. During this time, they will be asked to complete a survey **(see attachment 12b)** that includes questions about their preference, satisfaction and perceived mobility with the PFE mode or actual foot that they just walked with.

Based on the randomized order, designated staff will set the PFE to one of the remaining two foot modes, or the prosthetist will fit the next of the two remaining actual feet. When ready, participants will be asked to repeat the activities (i.e., walking, standing, stairclimbing), and survey activities described above.

When ready, participants will be asked to repeat the same process with the third PFE mode or actual foot.

Once the data collection is completed, the prosthetist will refit participants' prescribed prosthetic foot. The next study visit will be scheduled.

Visit 3: Second Initial Testing Visit – Emulator or Actual Feet (up to 4 hours)

At this visit participants will be asked to repeat the study procedures described above in Visit 2; they will complete the procedures using the equipment (PFE or actual feet) that they did not use during Visit 2.

At the end of this visit, the prosthetist will fit participants with one of the three actual feet that they used earlier; foot order will be randomized again and participants will remain blinded to foot condition (lightweight fabric will be secured around any potentially identifying features of the prosthetic foot using zip ties). Participants will wear the assigned prosthetic foot (connected to their prescribed socket) for the next two weeks at home and in the community environment. Participants will be scheduled to return for a follow-up visit after 2 weeks. Designated study staff will store the participants' prescribed prosthetic foot until they have completed the study or choose to stop their participation. Participants will be instructed to contact us if they have any concerns or discomfort associated with their prosthetic limb. If needed, participants can come in for prosthetic alignment adjustments during the 2 week in home/community test window.

Note that prosthetic alignment will be optimized under all foot conditions.

Visits 4, 5 and 6: Follow-up Testing Visits (up to 2 hours each)

During each of these visits participants will be asked to complete a survey **(see attachment 12c)** that includes questions about their preference, satisfaction, balance and mobility while using the study assigned prosthetic foot that they wore for the past two weeks. During each of these visits, the Two Minute Walk Test (as described under Visit 1) will be repeated.

At the end of Visits 4 and 5, the prosthetist will fit participants with one of the other remaining prosthetic feet (based on their randomized foot order and participants will remain blinded to foot condition). Participants will wear the assigned prosthetic foot (connected to their prescribed socket) for the next two weeks at home and in the community environment. Again, participants will be scheduled to return for a follow-up visit after 2 weeks. Participants will be reminded to contact us if they have any concerns or discomfort associated with their prosthetic limb. If needed, participants can come in for prosthetic alignment adjustments during the 2 week in home/community test window.

These procedures will be repeated again at Visit 6. At the end of Visit 6, the prosthetist will re-fit the participants' prescribed prosthetic foot, which will conclude the testing sessions.

Visit reminders

Designated study staff may call and/or send a visit reminder email (see attachment 09a/09b) to participants prior to each study visit.

Payment

Participants will receive payment after each completed visit based on the schedule below. Payments will be dispersed by check by each site; checks will

be mailed out as soon as possible after each visit, it may take up to 8 weeks for checks to be processed and mailed. The Seattle Institute for Biomedical and Clinical Research will process study payments for the Seattle VA. The Minnesota Veterans Medical Research and Education Foundation will process study payments for the Minneapolis VA.

Visit 1 – In-person evaluation and assessment: $100
Visits 2-3 – Testing: $100 each
Visits 4-6 – Follow-up: $50 each

As noted above, individuals who are determined to be not eligible during the first visit will be compensated $50 for their effort.

VA Puget Sound only: Repository (optional)

We will ask participants if they want to add their data (without identifiers) from this study to our data repository. Interested participants will be asked to sign a separate Consent Form for the repository.

## Risks and Risk Management

**Potential physical risks:** Please note, the increase in physical risks associated with participation in this study only represent a small increase from those encountered in daily life of the participant population.

- Trip and/or fall resulting from movement during study procedures and/or study provided prosthetic component failure or malfunction, leading to minor soft tissue injury (e.g., soreness, bruising, scrape) or other minor mechanical injury (e.g., knee or ankle joint soreness)

- Fatigue, minor muscle ache, or other soft tissue irritation from walking with an unfamiliar prosthetic foot

Note that all of the commercially available prosthetic feet used in this study are commonly prescribed. The prosthetic foot emulator also mimics the mechanical properties of these commonly prescribed feet.

**Physical risk management:** These risks will be minimized by providing frequent rest breaks during study sessions, providing brief prosthetic foot acclimation periods during study sessions, fitting participants with commercially available prosthetic feet that are specific to their mobility level (low or high), conducting walking tests at participants' self-selected speeds, and having experienced certified prosthetists conduct all prosthetic fittings. Since participants will have a chance to wear each of the commercially available feet for at least an hour in the laboratory setting, we do not expect any problems to arise during the 2 week at home portion of the study. However, if a participant becomes uncomfortable with the study foot for any reason during the course of the study, they will be asked to meet with our study prosthetist who will assess the study foot and alignment. If a participant chooses, their originally prescribed prosthetic foot will be replaced and

study participation can be terminated as per participant request. To minimize the risks of falls or injury, the treadmill and starimill are equipped with safety handrails, and emergency stop capabilities. Participants will also be offered the option to be fit with a safety harness that is attached to the ceiling of the lab or a gait belt, while performing walking tests on the stairmill or treadmill while using the prosthetic foot emulator or the commercially available study feet. If a participant declines to be fitted with the extra safety equipment but appears unsteady or experiences a fall, we will request that they wear it if they wish to continue in the study.

Additional information regarding the prosthetic foot emulator: A Non-Significant Risk Device Determination has been provided by the Carnegie Mellon University IRB regarding a very similar protocol conducted by members of the investigative team; this is detailed further in the NSR determination (attachment 01c) of this application. We do not anticipate safety problems associated with the emulator, however we will follow precautions to protect participants and have taken several design measures to prevent problems from arising:

(a) Standard Socket Emulator Interface: All loads delivered by the prosthesis emulator will be similar in magnitude and direction to those generated by off-the-shelf prosthetic devices. These loads will be transmitted through subjects' standard prescribed socket interface.

(b) Limited Load Direction: The platform cannot produce unusual loads on, e.g., ankle or knee joints, and cannot produce loads on the body when the foot is off of the ground, e.g. during swing.

(c) Mechanical Limits: To prevent emulator forces from becoming too large under any circumstances, we have implemented force-limiting break-away points along the transmission from the motor to the end-effector. Before the emulator could apply forces large enough to cause injury, one of these force-limiting break-away points would break and the device would become passive.

(d) Electrical Hardware Stop: During all trials, both participant and lead experimenter will have an emergency switch that, when pushed, disconnects all power from the device. These switches allow participants or experimenters to stop the experiment in cases where co-robot behavior seems to present a potential risk, even though no negative events have occurred in prior studies with the emulator.

(e) Software Limits: Software limits have also been included, so as to prevent commanded torques and powers from becoming too large, and also to prevent the emulator from behaving in ways that might lead to mechanical failure.

(f) Extensive Pre-Trial Tests: To ensure proper mechanical function of the device and safety measures, we always perform pre-trial and benchtop testing prior to implementation of any modifications or upgrades to the emulator. When changes are made to the emulator structure or controller, we test each safety feature and perform both passive (motors unpowered) and powered (motors on) software checks on all commanded torques and velocities.

**Potential psychological risks:** Please note, the psychological risks are minimal, the information collected is similar to that encountered in daily life or during the conduct of routine medical care.

- Participants may find some of the survey questions uncomfortable or embarrassing.
- Participants may experience mild stress when acclimating to an unfamiliar prosthetic foot.
- Participants may find it inconvenient or frustrating to schedule and attend multiple study visits every 2 weeks during their participation (6 total visits).

**Psychological risk management:** Participants do not have to answer any questions that they do not want to and they may withdraw from the study at any time.

### Privacy and Confidentiality

See section 7.0 below for Information Security, Privacy and Confidentiality related procedures.

All engaged participating sites will safeguard data as required by VA information security policies.

## 5.6 Data Analysis

Statistical Analysis

Linear mixed effects regression will be used to test for correlation between preference score for the emulated foot (the independent fixed effect) and preference score for the corresponding actual foot (the dependent variable) with study participant as a random effect. Linear mixed effects regression provides a more flexible approach to analyze repeated measures data compared to the traditional repeated measures models, with fewer model assumptions and the ability to incorporate data from participants who do not complete the study. These models account for non-independent data due to within-participant repeated measures by estimating separate between- and within-participant errors. The model described above will estimate a slope of change in actual foot preference score per increase of one unit in the emulated preference score. A similar set of models will be used to test for the correlation between preference score for the emulated foot (the independent fixed effect) and satisfaction and

perceived or functional mobility scores for the corresponding actual foot (the dependent variables) with study participant as a random effect. analyzed with a similar set of models, substituting emulated mobility scores for emulated preference scores as the independent fixed effects in the models described in H1.1. Testing of H1.1 and H1.2 will enable us to determine which self-reported measure (preference or perceived mobility) is a better predictor of mobility outcomes with the actual foot at follow-up. For H2.1, linear mixed effects regression will be used to test if initial preference scores from actual feet (the independent fixed effect) correlate with preference and mobility outcome scores obtained at follow-up (the dependent variable) with study participant as a random effect.

Power Analysis

Sample size for this study was based on pilot data collected in support of our Primary Aim (see "Prosthetic Foot Emulator" section). Power analysis was carried out for two of the primary study variables: prosthetic foot preference score and perceived mobility score, using pilot data collected for three participants, who each tested two prosthetic feet (SACH and Vari-Flex). Due to the small sample size of the pilot study, slope of change in actual score per increase in emulated score was estimated using linear regression (instead of linear mixed effects regression) with actual score as the dependent variable. For the preference score average, the slope was 1.1, with a model residual error of 31. For the perceived mobility score average the slope was 0.3 and residual error of 15. Based on these estimates of slope and residual error, 10,000 datasets of emulated and actual preference and perceived mobility scores were simulated each with a sample size of 50 (assuming each participant tests only one foot). Linear regression on each data set was carried out to test the null hypothesis that the slope equaled zero, with significance set at 0.05. Power, estimated as the proportion of datasets that rejected the null hypothesis, was 97% for the preference score average and 98% for the perceived mobility score average. Given that participants will test multiple feet, power may be even higher. Considering the potential for attrition during the longitudinal component of the study, if we enroll/consent at least 75 participants (total across sites), and even if 33% of the consented participants drop out, we will still have enough participants for adequate statistical power.

Our intent is to have 50 or more participants (total across sites) complete the study. It is possible that we may be able to get more than 50 total participants to complete the study, which could strengthen the statistical power. Therefore we will allow each site to consent/enroll up to 50 participants (150 total across sites). This will also allow us to accommodate a higher drop out rate and those who are deemed ineligible after signing consent during physical examination screening without a modification.

## 5.7 Withdrawal of Subjects

This is not a medication or treatment study therefore a strict process is not necessary because withdrawing or being terminated from this study will not have

an impact on participant safety. A study clinician or the PI may withdraw a participant without their consent if he or she feels that it is not in a participant's best interest to continue in the study or if they are unable to complete the study procedures. All data previously collected from participants who withdraw or are withdrawn will be kept and may be used in the study data analysis. Participants may withdraw at any time by informing the Research Coordinator and/or the PI at their site.

There is a possibility that some participants may decide to stop their participation, or be lost to follow up, while in possession of one of the commercial feet belonging to the study. If this circumstance arises, we will make a concerted effort to recover the prosthetic foot from the participant. Since the study feet are commercially available and prosthetic foot alignment will be optimized, there is no concern that a retained study foot would cause a safety risk beyond standard prosthetic care. The participant's prescribed prosthetic foot will be stored by the researchers at each site while the participant is wearing the study provided foot in the community.

## 6.0 Reporting and Safety Monitoring

All safety information on Adverse Events (AE's), Serious Adverse Events (SAEs), unanticipated events or problems involving risks to subjects, and protocol deviations will be collected. This information will be collected at study visits and whenever participants call to report a problem. This data will be collected for each participant throughout their invovlement in the study. All reporting requirements as noted in VHA Handbook 1508.01 will be followed.

The Local Site PI at each site will conduct timely reviews of all AEs (including anticipated AEs, SAEs, and Unanticipated AEs, U-SAEs, and other problems) and protocol deviations that occur at their site. These will be reported to the PI/SC and designated study staff as they occur/when the reporting site becomes aware of the events; this will allow the PI/SC and the medical monitor to track issues from all sites in a timely manner and take corrective action as needed. In addition, SAEs that have the potential to affect implementation of the study will be communicated to all engaged participating sites and the Medical Monitor by the PI/SC. The Local Site PIs will report to the VA Central IRB and the PI/SC (Dr. Morgenroth) all problems involving previously unknown risks to participants or others and all local AEs and SAEs related to the research. Anticipated AEs related to the research will be reported to CIRB annually with the continuing review; if anticipated AEs occur at a higher than expected rate the PI/SC, Medical Monitor and other investigators will reevaluate the study procedures and modifications will be prepared as needed. Unanticipated SAEs, protocol deviations and/or serious problems that are related to the research will be reported to the Central IRB within 5 business days of becoming aware of the event, per VA reporting requirements. Additionally, the local site PIs will also report to the VA Central IRB and PI/SC any issues of serious or continuing non-compliance within 5 days of becoming aware of the issue. If study data is improperly used or disclosed we will notify the ISO and Privacy Officer within one hour of becoming aware of the issue.

Lastly, the PI/SC will ensure that the main study site (Seattle) keeps sites informed of any items that might be relevant to participant protection through regular teleconference meetings and/or email communications. The study coordinators and site PIs will meet (typically by telephone since site PIs are geographically disparate) at least once per month while data collection is ongoing).

The occurrence of 5 or more study-related AEs per site, or 2 or more study-related SAEs across all sites will trigger a review to compare frequency of AE's and/or SAEs to rates reported in the literature and in the experience of the Medical Monitor. In the case of an SAE, an immediate review of the protocols by the LSI may be warranted at the time of occurrence. Although it is unlikely, if the review determines that the rate of AEs and SAEs is more prevalent in the study than reported in the typical clinical setting in this patient population (per literature review and experience of the Medical Monitor) the research would be immediately suspended.

If we become aware of relevant findings or information that may affect participants' health or welfare we will contact them by phone and/or a letter to provide the information.

**Additional Safety Monitoring**

Dr. Jeff Heckman (VA Puget Sound), will act as the Medical Monitor for this study. After each report of a U-SAE or problem, and/or SAE, the Medical Monitor will evaluate study procedures for previously-assessed risks, and will determine whether any changes must be made to minimize risks. The Medical Monitor has the authority to stop the research protocol in progress, remove individual participants from the research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB assesses SAEs or other reports. As noted above, cumulative safety data will be reviewed yearly by the PI-SC and the Medical Monitor, and will be reported to the CIRB in the Continuing Review Questionnaire (CRQ). The Medical Monitor will periodically (quarterly) have discussions with the PI-SC about the research progress to date. The Medical Monitor will periodically (quarterly) review study enrollment, data, and procedures. The PI and the Medical Monitor will ensure security, privacy, and confidentiality by following all IRB-approved procedures. The Medical Monitor will review all unanticipated problems involving risk to subjects or others, serious adverse events and all subject deaths associated with the protocol and provide an unbiased written report of the event to the IRB. The Medical Monitor will comment on the outcomes of SAE events or problems and in the case of a serious adverse event or death, he will comment on the relationship to participation in the study. The Medical Monitor must also indicate whether he concurs with the details of the report provided by the principal investigator. Reports for events determined by either the investigator or Medical Monitor to be possibly or definitely related to participation and reports of events resulting in death will be promptly forwarded to the USAMRMC ORP HRPO.

# 7.0 Information Security, Privacy, and Confidentiality

As with any study, there is a risk of breach of confidentiality. Given the largely impersonal nature of the data collected (e.g., Participants' preference, satisfaction and perceived mobility, and functional mobility), the risk of invasion of privacy is minimal. All engaged participating sites will safeguard VA data as required by VA information security policies.

At each site, electronic data with PHI or other sensitive information/data that are labeled with the study assigned codes will be stored on VA secured servers in restricted access study folders at each site. These data will only be accessed by authorized study personnel at each site. Hardcopies of coded sensitive data and documents with PHI will be stored in locked file cabinets in locked offices at each site. Each site will maintain its own documentation that contains PHI, and this information from the different sites will not be shared or consolidated into a master list. A unique study code instead of identifying information will be used to code (label) study data. The key to the code will be stored separately from the data, in a protected electronic file on a secure server at each data collection site. We will securely store the key to the code and any other identifiable study data until the end of the study and it will be destroyed in accordance with VA policy and the federal records control schedule.

At each site de-identified, non-sensitive electronic data labeled with the study assigned codes, and with all 18 HIPAA identifiers removed or converted to a de-identified format, may be stored on non-networked equipment (computers/laptops/sd cards/optical discs). These devices are stored in locked areas at each site. The key to the study codes cannot be accessed via non-networked equipment.

Identifiable and sensitive study data will not be transmitted or shipped between study sites.

A copy of each site's de-identified data set (as described above) will be emailed to the PI/SC site as needed, and will be consolidated into a complete data set. De-identified electronic data will not be encrypted. De-identified data files will also be sent off-site to our biostatistician (VA research staff) Jane Shofer, MS. The VA Puget Sound Privacy Officer reviewed the format of the data files (see included data file template, attachment 10b) that will be emailed and concurred that the data was sufficiently de-identified to be sent without encryption (see attachment 10a for correspondence).

A digital camera may be used to take photos and videos in a de-identified format; no identifying features will be captured and video will be recorded on mute. If any features, voice, or marks are mistakenly captured the images will be altered prior to any use outside of the research team. At each data collection site, the storage card will be stored in a locked cabinet in a locked office and will not be encrypted.

Only de-identified data will be disclosed outside of the VA. A copy of the de-identified data set will be sent off-site to our biostatistician, Jane Shofer, MS, (VA study staff) so that she may assist with data analyses, Ms. Shofer will not have access to the key to the study codes/crosswalk or to any PHI. Our offsite collaborators (Drs. Andrew Hansen, Brian Hafner, Steve Collins, Josh Caputo, Riley Sheehan, and Jason Wilken)

may receive copies of data analyses summary reports so that they may assist with data interpretation and manuscript preparation. These summary reports will not contain study assigned id codes.

Data and other study documents with PHI or other sensitive information will be stored for at least 6 years per the VHA records control schedule for research. A copy of the de-identified electronic data will be kept indefinitely.

Hard copy data with identifiable and/or sensitive information will be shredded per VA approved policies. Electronic data containing identifiable information will be wiped using VA approved software.

Only authorized study staff at each data collection site will have access to data that contains PHI or VA sensitive information and this type of data will not be transferred between sites. Study staff will only have access to the minimum necessary identifiable information needed to perform their role. Study staff that depart the VA or are removed from the research team will be promptly removed from the research application and will no longer have access to sensitive study data. If study data is improperly used or disclosed we will notify the ISO and Privacy Officer within one hour of becoming aware of the issue.

**At the VA Puget Sound**:

Electronic data with PHI, including the key to the study assigned id codes will be stored on the VA network in R:\Morgenroth\00949; this is a permissions restricted folder to which only designated study staff will have access. Hard copies of data and research documents containing PHI or sensitive data will be stored in locked cabinets in locked offices in Building 1/Rooms 516, 513, 501B and in Building 100/Room 1D-104.

A copy of the de-identified data set (compiled from all sites) will be stored on the VA network in R:\Morgenroth\00949 and on non-networked laptops at the VA and with staff working offsite. De-identified data may also be stored on non-networked equipment in the gait lab (bldg. 100/rm 1D-118). The digital camera and the recording media (e.g., SD cards, optical disks) will be stored in a locked area (bldg. 100/rm 1D-118). Photos and videos that do not contain identifiable information may also be stored on non-networked password-protected computers for future use in scientific presentations and publications.

**At the VA Minneapolis:**

Electronic data with PHI, including the key to the study assigned id codes, will be stored on the VA network in (XX-XX = study number that is TBD):
S:\Services\ResearchHansen\Shared\SecureStudyData\XX-XX FEmu\SensitiveData;
S:\Services\ResearchHansen\Shared\IRB\XX-XX CIRB Morgenroth- FEmu; and

S:\Services\ResearchHansen\Shared\Projects\XX-XX CIRB Morgenroth- FEmu

Hard copies of data and research documents will be stored in a locked cabinet in Room 4P-121, Building 70, Minneapolis VA Health Care System. The 4P Research wing has PIV-card controlled access.

## 8.0 Communication Plan

The PI/SC and LSIs are responsible for training all applicable staff at participating sites. The PI/SC will hold a series of pre-study training conference calls to establish regular communication among the site study coordinators and site PIs. The protocol will be reviewed during these meetings, including a plan for keeping in regular communication. All participating sites will use the most current version of the protocol, the informed consent form, and the HIPAA authorization. If any of these documents is revised, the PI/SC will notify the PI's at each participating site through written documentation and provide the revised draft of the form(s). All necessary local facility approvals will be obtained, if required, before the amendment or modification is implemented at each participating site. Study events and interim results will be communicated regularly to engaged participating sites.

The site PIs and coordinators will also participate in regular monthly conference calls. The purpose of the monthly meetings is to discuss study progress, issues with recruitment, enrollment, and retention, and to share strategies to ensure the success of the study at each site. The meeting frequency may adjust throughout the course of the study as necessary and appropriate. Additionally, the site PIs will be in contact by phone and email to discuss any issues related to randomization, intervention delivery or fidelity, AEs, SAEs and UAPs, and other necessary topics (see section 6.0 Reporting, for the communications and reporting plan for AEs, SAEs, Unanticipated problems etc.).

In order to ensure adherence to the protocol and Central IRB reporting requirements, the PI/SC and VAPSHCS study personnel will do the following:

- Collect and track site* IRB approval letters prior to study initiation.
- Collect and track site* R&D approval letters, including ACOS letters, prior to study initiation.
- Collect and track all site protocol modifications and continuing review approvals for IRB and R&D.
- Distribute amendments and the most current version of the protocol, consent form, and HIPAA authorization form to all sites. Staff will also track the receipt of these documents by all sites, including the approval of any required protocol modifications.
- VAPSHCS will track all written and verbal communication with all sites.

- Discuss any AEs and SAEs, Unanticipated problems, and protocol deviations as needed and review reporting requirements as necessary.

*Site IRB approval letters will be issued by the governing IRB at each respective site. VA Central IRB is the IRB of record for all VA participating study sites. Sites will submit the study to their local R&D Committee for review and approval.

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Participant Name: _____ Date:_____

Title of Study: A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: David Morgenroth, MD

**INTRODUCTION**

You are being invited to take part in a research study that is being supported by the Department of Veterans Affairs and funded by the United States Department of Defense. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. **This consent form may contain words you do not understand. Please ask the study staff to explain any words or information that are unclear to you.** Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

**BACKGROUND AND PURPOSE**

Choosing the best prosthetic foot is an important part of helping people with a leg amputation walk better and reach their functional goals. The current process for choosing a prosthetic foot depends mostly on clinician experience and does not usually allow people with a leg amputation to easily try out different feet. Trying out different commercially available prosthetic feet can take a lot of time and be expensive.

We have developed an adjustable robotic prosthetic foot, called a prosthetic foot emulator (PFE). The PFE can be programmed to feel like different commercially available prosthetic feet. The PFE can be fitted to any prosthetic socket. It allows the user to feel what it would be like to walk with different feet, without actually having to take the time to change feet.

The purpose of this research study is to see if using the PFE to “test-drive” different feet improves the process for choosing a foot. We also want to see how the “test-drive” experience affects satisfaction with prosthetic feet. We will do this by studying how well the PFE imitates the experience of wearing a few different commercially available (*actual*) prosthetic feet. We will also compare the experience of walking with actual prosthetic feet in the laboratory to the experience of walking with the same actual feet at home and in the community.

SUBJECT’S IDENTIFICATION

**FOR VA CENTRAL IRB USE ONLY**

**PI/SC Approval Date: 05/08/17**

**LSI Approval Date: N/A**

**LSI Verification Date: N/A**

Participant Name: _____ Date:_____

Title of Study: A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: David Morgenroth, MD

This is a multi-site study being conducted at the VA Puget Sound Health Care System, the Minneapolis VA Health Care System, and the Center for the Intrepid at Brooke Army Medical Center. You have been asked to participate in this study because you have a below-knee amputation on one side of your body. Up to 150 participants may be enrolled in this study. There may be up to 50 participants enrolled locally at your site.

**DURATION OF THE RESEARCH**

You will be asked to do up to 6 study visits at [insert study site] over 2-3 months. Visits 1-3 may take up to 4 hours each, and visits 4-6 may take up to 2 hours each. These time estimates are high and we think that the visits may be shorter, but we want to make sure that you have enough time to rest between the walking sessions (described below). If we find that data are missing or corrupted we may ask you to come back for another visit so we can collect the data again. This research study is expected to take about 3 years, but you will only be asked to be involved in the study for about 2-3 months.

**STUDY PROCEDURES**

This part of the consent form describes what you will be asked to do if you choose to participate in this study.

**Visit 1: Screening, Prosthetic Foot Emulator Fitting, and Assessment (up to 4 hours)**

You will have a short physical exam to make sure that your stump does not have any broken skin or other conditions that would stop you from wearing your prosthesis. We will also make sure that you do not have any other conditions that would get in the way of the data collection. We will check if your stump length can fit the PFE and all of the actual prosthetic feet that will be used in this study.

You will be asked to do a questionnaire about your medical history, demographics, and mobility. You can skip any questions that make you feel uncomfortable.

You will be asked to do a walking test where you will walk as fast as you comfortably can on flat ground for 2 minutes using your own prosthesis. We will record how far you walked. You may rest at any point during the test. If you normally walk with a cane or other device you can use it during this test. Based on this test, you will be put into one of the two study groups, A or B.

All of the prosthetic fittings during this study will be done by a certified prosthetist. They will follow clinical care standards. Your prosthetic alignment will be adjusted for you in the same



**FOR VA CENTRAL IRB USE ONLY**

**PI/SC Approval Date: 05/08/17**

**LSI Approval Date: N/A**

**LSI Verification Date: N/A**

way that it would be in normal clinic appointments. Also, the treadmill and stairmill described in the procedures below have safety rails and emergency stop features. During the study visits you will be given the option to wear a gait belt or safety harness during the walking tests on this equipment.

Our prosthetist will attach the PFE to your socket in the same way that a regular prosthetic foot attaches to your socket. The PFE has a cable that connects it to a motor, which is controlled by a computer. The computer controls the foot settings through the cable.. In other words, the computer sends the settings to the PFE to tell it which type of actual foot to imitate. The cable will not be in the way while you walk. During this study, each group (A and B) will do the walking tests using the PFE in three foot modes and with three actual prosthetic feet. The PFE is programmed to imitate 5 different actual feet. Each group (A and B) will use two foot modes and two actual feet that are different from the other group, and one foot mode and one actual foot that is the same in both groups. For example, Group A will use foot modes and feet 1, 2, and 3, and Group B will use foot modes and feet 3, 4, and 5.

The PFE will be set to one of the foot modes for your group (A or B). We will give you some time to stand and walk on the treadmill to get used to how it feels. If you do not feel comfortable on the PFE please let us know. If needed, we will make some adjustments to the PFE to try to make you more comfortable during standing and walking. After you feel comfortable with the PFE mode, one of the study staff will use the computer to switch the PFE into a different foot mode. You will be asked to repeat the practice standing and walking with the PFE in up to 3 different foot modes. The PFE mode willbe changed while you are sitting down. You will have an opportunity to take rest breaks while the PFE mode is changed and if you would like to take a break at any other time please let us know. You will also be offered an opportunity to practice walking with the three different commercially available (actual) prosthetic study feet for your group (A or B). During this fitting and practice session, if we determine that the study is not a good fit for you, you will be compensated $50 for your time and you will not be able to continue in the study.

After you have practiced on the different foot modes you will be asked to walk on the treadmill again. You will be asked to choose three different walking speeds, comfortable, slow, and fast. You will be asked to walk at each of these speeds for up to one minute, with each of the three PFE foot modes. You will have a chance to take rest breaks while the PFE mode is changed. If you would like to take a break at any other time, please let us know.

At the end of this visit the prosthetist will re-fit your prosthetic foot and schedule your next visit.

SUBJECT'S IDENTIFICATION

**FOR VA CENTRAL IRB USE ONLY**

**PI/SC Approval Date: 05/08/17**

**LSI Approval Date: N/A**

**LSI Verification Date: N/A**

If you provide us with your email address, we will send you appointment reminders before each of your study visits. We may also call you to remind you about upcoming study appointments.

**Visit 2: Randomization & Initial Testing Visit 1 – Emulator or Actual Feet (up to 4 hours)**

At this visit, you will be randomized, like flipping a coin, to test either the PFE in the 3 foot modes for your group, or the 3 actual feet for your group. If you are randomized to the PFE testing during this visit, you will test the actual feet during Visit 3, or vice versa. The order in which you use the 3 PFE modes or the 3 actual feet will also be randomized. We will not tell you the name of the actual feet or the corresponding PFE modes while you are in the study. The actual feet may be covered with a lightweight fabric that is attached to cover any brand names or other identifying features.

The prosthetist will fit your socket with the assigned prosthetic (PFE or actual foot). You will be asked to walk at a comfortable speed while you get used to the PFE mode or actual foot. If you do not feel comfortable please let us know. If needed we will make some adjustments to try to make you more comfortable. During this visit, you will have a chance to take rest breaks while the PFE mode or actual foot is changed, and if you would like to take a break at any other time please let us know.

When you are ready, you will be asked to walk on the treadmill for up to a minute at a time, at each of your walking speeds: slow, comfortable, and fast. Next:

***If you are in Group A****,* we will set the treadmill to a 3 degree incline, similar to a going up a slight hill. You will be asked to walk on the treadmill for up to one minute at each of your self-selected speeds: comfortable, slow, and fast. After you have finished each walking speed, you will also be asked to stand still for up to one minute. The treadmill has handrails that you can use to help you keep your balance. You can take rest breaks between each walking speed.

***If you are in Group B****,* we will set the treadmill to a 6 degree incline, similar to going up a moderate to steep hill. You will be asked to walk on the treadmill for up to one minute at each of your self-selected speeds: comfortable, slow, and fast. After you have finished each walking speed, you will also be asked to walk on a stairmill, at a comfortable speed, for up to a minute. The treadmill and stairmill have handrails that you can use to help you keep your balance. You can take rest breaks between each walking speed and before walking on the stairmill.

At the end of the first foot condition test, you will be given at least 10 minutes to rest. You will also be asked to fill out a survey that asks questions about how you liked the foot and how well you think you walked with the PFE mode or actual foot that you just used.

When you are ready, study staff will set the PFE to one of the two remaining foot modes, or the prosthetist will fit the next of the two remaining actual feet. When you are ready, you will be asked to repeat the activities (i.e., walking, standing, stairclimbing), and surveys described above.

Then, after another rest break, you will be asked to repeat the same process with the third PFE mode or actual foot.

After you have finished testing each of the PFE modes or actual feet, the prosthetist will re-fit your prosthetic foot and schedule your next visit.

**Visit 3: Initial Testing Visit 2– Emulator or Actual Feet (up to 4 hours)**

At this visit you will be asked to repeat the study procedures described above in Visit 2. This time, you will complete the procedures using the prosthetic (PFE or actual feet) that you did not use during Visit 2.

At the end of this visit, we will randomly select one of the actual feet you used earlier in the study and the prosthetist will fit you with that foot. You will be asked to wear the foot at home and in the community for the next 2 weeks. Like in the laboratory, a lightweight fabric will be placed around any identifying parts of the prosthetic foot. Please do not remove the fabric from the foot. Please contact us if you have any concerns or discomfort associated with your prosthetic limb. If needed, you can come in for prosthetic alignment adjustments during the 2 week test window. We will store your prescribed prosthetic foot until you have finished the study or if you choose to stop participating in the study.

You will be asked to return for a follow-up visit after 2 weeks.

**Visits 4, 5 and 6: Follow-up Testing Visit(s) (up to 2 hours each)**

At each of these visits you will be asked to fill out a survey that asks you questions about how you liked the foot and how well you think you walked during the last 2 weeks while you were using the study foot. You will also be asked to do the Two Minute Walk Test (as described under Visit 1) using the study assigned foot.

At the end of Visits 4 and 5, the prosthetist will fit you with one of the other remaining prosthetic feet. You will be asked again to wear the foot for the next 2 weeks at home and in the community. You will be scheduled to return again in 2 weeks for the next follow up visit.

During Visit 6, you will be asked to repeat the survey and walking test once more. At the end of Visit 6, the prosthetist will re-fit your prescribed prosthetic foot.

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**FOR VA CENTRAL IRB USE ONLY**

**PI/SC Approval Date: 05/08/17**

**LSI Approval Date: N/A**

**LSI Verification Date: N/A**

Participant Name: _____ Date:_____

Title of Study: A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: David Morgenroth, MD

| Visit | Time | Description of Activities | Prosthetic Foot You Leave With |
|---|---|---|---|
| 1 | Up to 4 hours | Consent, physical exam, questionnaire, walking test, assignment to Group A or B, PFE and actual foot fitting, practice with study equipment, select walking speeds. | Your own |
| 2 | Up to 4 hours | Randomized to PFE or Actual Feet and fill out questionnaires about these feet<br><br>**Group A:** walk at self-selected walking speeds on treadmill and stand test in 3 PFE modes or 3 actual feet<br><br>**Group B:** walk at self-selected walking speeds on treadmill and walk on stairmill at comfortable speed in 3 PFE modes or 3 actual feet | Your own |
| 3 | Up to 4 hours | Repeat visit 2 tests using opposite condition equipment (PFE if used actual feet, or actual feet if used PFE)<br><br>Take home randomly selected actual prosthetic foot to wear for two weeks | actual prosthetic foot |
| 4 | 1-2 hours | Complete questionnaire about prosthetic foot you wore for two weeks<br><br>Take home next actual prosthetic foot to wear for two weeks | actual prosthetic foot |
| 5 | 1-2 hours | Complete questionnaire about prosthetic foot you wore for two weeks<br><br>Take home actual prosthetic foot to wear for two weeks | actual prosthetic foot |
| 6 | 1-2 hours | Complete questionnaire about prosthetic foot you wore for two weeks | Your own |

**Photos and video recording**

We may take video and photos of you during portions of this study, for documentation and use

in research publications. All videos and photos will exclude your face and any identifying marks will be covered (for instance, tattoos). If any identifiable features or marks are mistakenly captured they will be blurred out prior to any use outside of the research team that captured the images. Videos will be recorded without sound so that we do not record your voice print. If your voice is accidently recorded that section of video would be altered prior to any use outside of the VA study team. We will also ask you to sign a separate release form that describes how we will use photos and videos.

**Research participant responsibilities:**

Throughout the study, please keep your study appointments. If you need to reschedule an appointment, please contact us as soon as possible to do so. If you miss an appointment we will call you to reschedule.

During the follow-up parts of the study, please use the prosthetic foot that we give you as instructed. If you have any issues with comfort, prosthetic fit, or alignment, you may contact the investigators or study team prosthetist to try to solve the issues. You can choose to end your participation in this study at any time. Your own prosthetic foot will be returned to you and properly fit and aligned by the study prosthetist.

You may ask questions as you think of them, at any time during the study.

**POSSIBLE RISKS OR DISCOMFORTS**

The procedures in this study may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk. You may be asked to sign an updated Consent Form to document that this new information has been explained to you. Below are the potential study-related risks that are known at this time:

**Physical Risks:** It is possible that you might trip and/or fall, and hurt yourself, during the walking procedures. We will make every effort to watch you closely to reduce this risk. The treadmill and stairmill have safety handrails that you can use to help you keep your balance. You will also be offered the option of using a gait belt or a safety harness to prevent you from falling while you are walking in the laboratory. Please tell us immediately if you feel unbalanced during any of the procedures. It is possible, although unlikely, that the study provided prosthetic components could fail or stop working. This could cause you a minor soft tissue injury (such as soreness, bruising, scrape) or other minor injury (such as knee or ankle joint soreness). The actual prosthetic feet you will wear during the study are commonly prescribed commercially

available feet. The risks of using these actual feet are the same as they would be if your prosthetist prescribed them to you.

It is possible that you will experience mild to moderate muscle soreness, pain, or other soft tissue irritation from walking with the study provided equipment (prosthetic feet, and walking on the treadmill and stairmill). This might happen during or after the study visits. You may feel tired from walking during the study visits. You will be allowed to take as many breaks as you want and you can stop walking at any time if you need to.

**Risks to Privacy/Confidentiality:** Although we will make every effort to keep your information secret, no system for protecting information can be completely safe. It is still possible that someone could find out that you were in this study and could find out information about you. The Confidentiality section below describes how we will protect your privacy to the best of our ability.

**Other Risks:** You may experience some stress or inconvenience by coming to the [study site] for multiple visits. If it feels too inconvenient, you can withdraw from the study at any time. You may find some of the survey questions uncomfortable or embarrassing. You may feel some emotional or physical stress while getting used to wearing an unfamiliar prosthesis. You do not have to answer any questions that you do not want to and you can withdraw from the study at any time.

**POTENTIAL BENEFITS**

There are no expected direct benefits to you for participating in this study. It is possible that you could find that you like one of the study's actual prosthetic feet more than your currently prescribed foot. If this happens, at the end of the study you may ask us for the name/model of the foot you liked so you can request a new foot from your regular prosthetist. People who have had a lower-limb amputation may benefit in the future from the results of this study.

**CONFIDENTIALITY**

Taking part in this study will involve collecting private information about you. Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study. We will include information about your study participation in your medical record and therefore study investigators and your medical care team may be able to confirm your participation in this study. If you do not have a VA medical record one may be created for you and information about your participation in this study may be included in the record.

Participant Name: _____ Date:_____

Title of Study: A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: David Morgenroth, MD

The following list of people or groups may know that you are in this study. They may have access to your research records, which may include your medical records:

- Approved members of this research team
- The Medical Monitor – Dr. Jeff Heckman
- Department of Veterans Affairs and the Department of Defense (study sponsors)
- Other federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research
- [Non-Profit agency issuing award or sub-award] will be provided with your full name, address, phone number, and social security number in order to allow payment for your participation in this study

The access to your records, including your medical records, could be either for study-related purposes or to make sure your study record meets all legal, compliance, and administrative requirements. The reviewers will protect your privacy.

Electronic data with information that could be used to identify you will be stored on VA secured servers at each study site. These data will only be accessed by authorized study personnel at each site. Hardcopies of documents with information that could identify you will be stored in locked file cabinets in locked offices at each site. Each study site will maintain its own documentation that contains information that could identify you, and identifiable information from the different sites will not be combined.

A unique study code instead of identifying information will be used to code (label) your study data. The key to the code will be stored separately from the data, in a protected electronic file on a secure server at each study site. We will securely store the key to the code and any other identifiable study data until the end of the study. The key to the study code, data and any other study documents with information that could identify you will be stored for at least 6 years after the end of the study per the VHA records control schedule for research.

Data that cannot be used to identify you will be labeled with the study assigned code. This de-identified data will be combined with the de-identified data collected from the other people taking part in the study. The research team at the VA Puget Sound will receive and store a copy of all of the de-identified data collected by this study. A copy of the de-identified data set will be sent off-site to our biostatistician and other offsite collaborators so that they may assist with data

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analysis, interpretation and writing publications. These collaborators will not have access to any data that could identify you. A copy of the de-identified electronic data will be kept indefinitely at the VA Puget Sound.

In the future, researchers may write publications using the information collected from this research study. Any publications will not include any identifying information about you without your approval in writing. As previously noted, video and photos that do not identify you may be used in academic publications and presentations.

**No financial gain:** We will use the information that we collect for this study only for research purposes, not for profit. Neither you nor your family will gain financially from discoveries made using the data you provide.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

## COSTS TO PARTICIPANTS AND PAYMENT

**Costs to Participants***:* The VA requires some Veterans to pay co-payments for medical care and services. You will still have to pay these co-payments as long as they are not related to this research study. There will be no additional medical costs to you for taking part in this study. However, frequent clinic visits may result in transportation costs and possible wages lost due to time missed from work.

**Payment Offered for Participation:** You will receive up to $450 by the end of the study. We will submit a payment request for you after each completed visit, based on the schedule below. Payments will be made by check. Checks will be mailed out as soon as possible after each visit, but it may take up to 8 weeks for *each check* to be processed and mailed. *[The non-profit organization processing DoD funds]* will process study payments.

Visit 1 – In-person evaluation and assessment: $100
Visits 2-3 – Testing: $100 each
Visits 4-6 – Follow-up: $50 each

As noted above in Visit 1, if we determine that the study is not a good fit for you, you will be compensated $50 for your effort.

## MEDICAL TREATMENT AND COMPENSATION FOR INJURY

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Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

If you should have a medical concern or get hurt as a result of taking part in this study, call:

DURING THE DAY: Dr./Mr./Ms. _____ at _____.
and
AFTER HOURS: Dr. /Mr./Ms._____ at _____.

**PARTICIPATION IS VOLUNTARY**

It is up to you to decide whether or not to take part in this study. If you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

If you choose to withdraw, data already collected, including pictures and videos of you will be kept. If we publish the results of this study, we will not use your name or any other health information that identifies you.

**RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION**

The Investigator or a study clinician may terminate your participation in this study if you cannot safely perform the tasks described as part of the study or if she or he feels it is not in your best interest to continue in the study. This termination will not require your consent. If you decide to withdraw, or if you are terminated from the study, a person from the study team may need to meet with you to discuss the steps that are necessary to end your participation in the study.

**PERSONS TO CONTACT ABOUT THIS STUDY**

SUBJECT'S IDENTIFICATION

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**LSI Approval Date: N/A**

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Participant Name: _____ Date:_____

Title of Study: A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: David Morgenroth, MD

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

_____ *(Name of person obtaining consent and role)* has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent form after you sign it.

| **I agree to participate in this research study as has been explained in this document.** | | |
|---|---|---|
| _____ Participant's Name | _____ Participant's Signature | _____ Date |
| _____ Name of person obtaining consent | _____ Signature of person obtaining consent | _____ Date |

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**PI/SC Approval Date: 05/08/17**

**LSI Approval Date: N/A**

**LSI Verification Date: N/A**

Participant ID: _____

# Participant Information – ASSESSMENT

**Please provide the following information:**

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Preferred phone number: _____ May we leave a message?: Yes No

Email address: _____

Contact Preference (if we have follow-up questions): ☐ Phone ☐ Email

Date of Birth: _____

The contact information here will be used to provide you with payment for your participation in this study or if we have questions related to your participation in this study.

**Please Note:** this is the only page that includes personal information that can be used to identify you. It will be separated from the survey and stored in a secure place. All other pages will only use your participant identification number.

# This page is intentionally blank

# Information About Your Amputation – ASSESSMENT

**Please answer these questions about your amputation:**

1. **When did your amputation occur?**

   _____month _____ year
   (*if unsure, please make your best guess)*

2. **What was the cause of your amputation?** (please choose the best answer)

   ☐ My amputation was related to diabetes, problems with blood flow, or dysvascular disease.
   ☐ My amputation was related to trauma, injury, or an accident
   ☐ My amputation was related to an infection (*non-diabetes related*).
   ☐ My amputation was related to a tumor or cancer.
   ☐ My amputation was related to another cause (please describe): _____
   _____

3. **On a typical day, how many hours do you wear your prosthetic leg?**

   _____ hours *(if unsure, please make your best guess)*

Participant ID: _____

# Information About You – ASSESSMENT

1. **Please indicate your gender:**
   - ☐ Male
   - ☐ Female

2. **Please indicate your ethnicity:**
   - ☐ Hispanic or Latino
   - ☐ Not Hispanic or Latino

3. **Please indicate your race:** *(please check all that apply)*
   - ☐ White
   - ☐ Black or African-American
   - ☐ American Indian or Alaskan Native
   - ☐ Asian
   - ☐ Native Hawaiian or other Pacific Islander

4. **Please describe your present job status:** *(please choose the best answer)*
   - ☐ Employed (or self-employed)
   - ☐ Homemaker
   - ☐ Retired
   - ☐ On disability
   - ☐ Unemployed (or seeking employment)
   - ☐ Student

5. **Please indicate your approximate household income:** *(please choose one)*
   - ☐ less than $24,999
   - ☐ $25,000 - $39,999
   - ☐ $40,000 - $54,999
   - ☐ $55,000 - $69,999
   - ☐ $70,000 - $84,999
   - ☐ $85,000 - $99,999
   - ☐ $100,000 or more

6. **Please indicate your status in the US Armed Forces (Army, Navy, Air Force, Marine Corps, Coast Guard, or National Guard) or Reserves:** *(please check all that apply)*
   - ☐ I am not active in or a veteran of the US Armed Forces or Reserves
   - ☐ I am active in the US Armed Forces or Reserves
   - ☐ I am a veteran of the US Armed Forces or Reserves

7. **What is the highest grade in school that you completed?** *(please choose one)*
   - ☐ Some high school
   - ☐ High school grad/GED
   - ☐ Some college/Technical degree/AA
   - ☐ College degree (BA/BS)
   - ☐ Advanced degree (MA, PhD, MD)

# Information About You – ASSESSMENT

**8. Please indicate your approximate height with your prosthesis on (in feet/inches):**

_____feet _____inches

**9. Please indicate your approximate weight (in pounds) with your prosthesis on:**

_____ pounds

# Assistive Device Use – ASSESSMENT

**Please mark one box per row.**

| How often do you use… | Never | On occasion | Daily (less than 2 hours per day) | Daily (more than 2 hours per day) |
|---|---|---|---|---|
| 1. One cane | ☐ | ☐ | ☐ | ☐ |
| 2. Two canes | ☐ | ☐ | ☐ | ☐ |
| 3. One crutch | ☐ | ☐ | ☐ | ☐ |
| 4. Two crutches with your prosthesis on | ☐ | ☐ | ☐ | ☐ |
| 5. A walker with your prosthesis on | ☐ | ☐ | ☐ | ☐ |
| 6. A manual wheelchair | ☐ | ☐ | ☐ | ☐ |
| 7. A scooter or powered wheelchair | ☐ | ☐ | ☐ | ☐ |

Participant ID: _____

# Questions about Your General Health – ASSESSMENT

**As far as you know, do you have any of the following health conditions at the present time?**

| | | |
|---|---|---|
| a. Asthma, emphysema, or chronic bronchitis | ☐ No | ☐ Yes |
| b. Arthritis or rheumatism | ☐ No | ☐ Yes |
| c. Cancer, diagnosed in the past 3 years | ☐ No | ☐ Yes |
| d. Diabetes | ☐ No | ☐ Yes |
| e. Digestive problems (such as ulcer, colitis, or gallbladder disease) | ☐ No | ☐ Yes |
| f. Heart trouble (such as angina, congestive heart failure, or coronary artery disease) | ☐ No | ☐ Yes |
| g. Kidney disease | ☐ No | ☐ Yes |
| h. Liver problems (such as cirrhosis) | ☐ No | ☐ Yes |
| i. Stroke | ☐ No | ☐ Yes |

Participant ID: _____

# Mobility – ASSESSMENT

**How would you rate your current level of mobility?** (pick one of the following that most closely describes you).

- ☐ I am able to walk in the community, with no ambulation aids, unlimited distances (e.g., shopping mall).
- ☐ I am able to walk in the community, with no ambulation aids, limited distances (e.g., one block or equivalent).
- ☐ I am able to walk in the community with ambulation aids (e.g., cane, crutches, walker).
- ☐ I am able to walk inside my house with ambulation aids and use a wheelchair for community ambulation.
- ☐ I am not able to walk but could get around my house and the community with a wheelchair.
- ☐ I am not able to walk but could get around my house with a wheelchair but not get out into the community.
- ☐ I am housebound and mostly bedridden and require help for all household transfers and mobility.

Participant ID: _____

# Mobility – ASSESSMENT

**Please respond to all questions as if you were wearing the prosthetic leg(s) you use most days. If you would normally use a cane, crutch, or walker to perform the task, please answer the questions as if you were using that device.**

**Please choose "unable to do" if you:**

- **Would need help from another person to complete the task,**
- **Would need a wheelchair or scooter to complete the task, or**
- **Feel the task may be unsafe for you**

**Please mark one box per row.**

| Question | Without any difficulty | With a little difficulty | With some difficulty | With much difficulty | Unable to do |
|---|---|---|---|---|---|
| 1. Are you able to walk a short distance in your home? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2. Are you able to step up and down curbs? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3. Are you able to walk across a parking lot? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 4. Are you able to walk a block on flat ground? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 5. Are you able to walk over gravel surfaces? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 6. Are you able to move a chair from one room to another? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 7. Are you able to walk while carrying a shopping basket in one hand? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 8. Are you able to keep walking when people bump into you? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 9. Are you able to walk up a gently sloping ramp without a handrail? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 10. Are you able to walk on an unlit street or sidewalk? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 11. Are you able to walk on a surface that slants sideways where one side is higher than the other? | ☐ | ☐ | ☐ | ☐ | ☐ |

Participant ID: _____

# Mobility – ASSESSMENT

| Question | Without any difficulty | With a little difficulty | With some difficulty | With much difficulty | Unable to do |
|---|---|---|---|---|---|
| 12. Are you able to keep up with others when walking? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 13. Are you able to climb up 2-3 steps without a handrail? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 14. Are you able to walk across a slippery floor? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 15. Are you able to walk down a steep gravel driveway? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 16. Are you able to carry a laundry basket up a flight of stairs? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 17. Are you able to walk up and down steep stairs in a crowded stadium? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 18. Are you able to hike about 2 miles on uneven surfaces, including hills? | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0 | 1 | 2 | 3 | 4 |

Participant ID: _____

# Balance – ASSESSMENT

**For each of the following, please indicate your level of confidence in doing the following activities without losing your balance or becoming unsteady. If you do not currently do the activity in question, try and imagine how confident you would be if you had to do the activity. If you normally use walking aids to do the activity or hold onto someone, rate your confidence as if you were using these supports.**

| **How confident are you that you will <u>not</u> lose your balance or become unsteady when you…** | **No confidence** | **Low confidence** | **Moderate confidence** | **High confidence** | **Complete confidence** |
|---|---|---|---|---|---|
| 1. Walk around the house? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2. Walk up and down stairs? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3. Pick up something off the floor? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 4. Reach at eye level? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 5. Stand on your tiptoes? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 6. Stand on a chair to reach? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 7. Sweep the floor? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 8. Walk outside to a nearby car? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 9. Get in and out of a car? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 10. Walk across a parking lot? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 11. Walk up and down a ramp? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 12. Walk in a crowded mall? | ☐ | ☐ | ☐ | ☐ | ☐ |

Participant ID: _____

# Balance – ASSESSMENT

| **How confident are you that you will <u>not</u> lose your balance or become unsteady when you…** | **No confidence** | **Low confidence** | **Moderate confidence** | **High confidence** | **Complete confidence** |
|---|---|---|---|---|---|
| 13. Get bumped? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 14. Ride an escalator holding the rail? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 15. Ride an escalator <u>not</u> holding the rail? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 16. Walk on icy sidewalks? | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0 | 1 | 2 | 3 | 4 |

Participant ID: _____

# Activity Restrictions – ASSESSMENT

**The following questions are about activities you might do during a typical day. Does limb loss limit you in these activities? If so, how much?**

**Please tick the appropriate box.**

| | Yes, limited a lot | Limited a little | No, not limited at all |
|---|---|---|---|
| 1. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports | ☐ | ☐ | ☐ |
| 2. Climbing several flights of stairs? | ☐ | ☐ | ☐ |
| 3. Running for a bus? | ☐ | ☐ | ☐ |
| 4. Sport and recreation | ☐ | ☐ | ☐ |
| 5. Climbing one flight of stairs | ☐ | ☐ | ☐ |
| 6. Walking more than a mile | ☐ | ☐ | ☐ |
| 7. Walking half a mile | ☐ | ☐ | ☐ |
| 8. Walking 100 metres (about 1 block) | ☐ | ☐ | ☐ |
| 9. Working on hobbies | ☐ | ☐ | ☐ |
| 10. Going to work | ☐ | ☐ | ☐ |
| | 2 | 1 | 0 |

# Satisfaction – ASSESSMENT

**Please tick the box that represents the extent to which you are satisfied or dissatisfied with each of the different aspects of your prosthesis mentioned below:**

| | Not satisfied | Satisfied | Very satisfied |
|---|---|---|---|
| 1. Weight | ☐ | ☐ | ☐ |
| 2. Usefulness | ☐ | ☐ | ☐ |
| 3. Reliability | ☐ | ☐ | ☐ |
| 4. Fit | ☐ | ☐ | ☐ |
| 5. Comfort | ☐ | ☐ | ☐ |
| | 1 | 2 | 3 |

□ Actual □ Emulated Participant ID: _____

□ Foot A □ Foot B □ Foot C □ Foot D □ Foot E Date: _____

**For each of the following questions, please indicate the number that best describes your response to the question. Please answer the questions based on your experience with the <u>prosthetic foot that you just wore</u>.**

**1. Rate your willingness to regularly use this prosthetic foot:**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Would NOT use on a daily basis WOULD use on a daily basis

**2. Rate your balance while standing when using this prosthetic foot:**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Completely unstable Completely stable

**3. Rate how much energy it took to walk when using this prosthetic foot:**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Completely exhausting Not exhausting at all

**4. Rate your ability to walk at a comfortable speed when using this prosthetic foot:**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Unable to do Without any difficulty

□ Actual □ Emulated Participant ID: _____
□ Foot A □ Foot B □ Foot C □ Foot D □ Foot E

# Preference – INITIAL TESTING

**5. Rate your ability to walk at a slow speed when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Unable to do Without any difficulty

**6. Rate your ability to walk at a fast speed when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Unable to do Without any difficulty

**7. Rate your ability to walk up stairs when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Unable to do Without any difficulty

**8. Rate your ability to walk down stairs when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Unable to do Without any difficulty

□ Actual □ Emulated Participant ID: _____
□ Foot A □ Foot B □ Foot C □ Foot D □ Foot E

## Preference – INITIAL TESTING

**9. Rate your ability to walk uphill when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Unable to do Without any difficulty

**10. Rate your ability to walk downhill when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Unable to do Without any difficulty

**11. Rate your overall satisfaction when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Completely dissatisfied Completely satisfied

Date: _____ Participant ID: _____

□ Foot A □ Foot B □ Foot C □ Foot D □ Foot E

**For each of the following questions, please indicate the number that best describes your response to the question. Please answer the questions based on your experience with the prosthetic foot that you are wearing now.**

**1. Rate your willingness to regularly use this prosthetic foot:**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Would not use on a daily basis — Would use on a daily basis

**2. Rate your balance while standing when using this prosthetic foot:**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Completely unstable — Completely stable

**3. Rate how much energy it took to walk when using this prosthetic foot:**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Completely exhausting — Not exhausting at all

**4. Rate your ability to walk at a comfortable speed when using this prosthetic foot:**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Unable to do — Without any difficulty

□ Foot A □ Foot B □ Foot C □ Foot D □ Foot E Participant ID: _____

## Preference – FOLLOW-UP TESTING

**5. Rate your ability to walk at a slow speed when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Unable to do Without any difficulty

**6. Rate your ability to walk at a fast speed when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Unable to do Without any difficulty

**7. Rate your ability to walk up stairs when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Unable to do Without any difficulty

**8. Rate your ability to walk down stairs when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Unable to do Without any difficulty

**9. Rate your ability to walk uphill when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Unable to do Without any difficulty

# Preference – FOLLOW-UP TESTING

**10. Rate your ability to walk downhill when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Unable to do Without any difficulty

**11. Rate your overall satisfaction when using this prosthetic foot:**

| ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Completely dissatisfied Completely satisfied

# Mobility – FOLLOW-UP TESTING

**Please respond to all questions as if you were wearing the prosthetic leg(s) you use most days. If you would normally use a cane, crutch, or walker to perform the task, please answer the questions as if you were using that device.**

**Please choose "unable to do" if you:**

- **Would need help from another person to complete the task,**
- **Would need a wheelchair or scooter to complete the task, or**
- **Feel the task may be unsafe for you**

**Please mark one box per row.**

| Question | Without any difficulty | With a little difficulty | With some difficulty | With much difficulty | Unable to do |
|---|---|---|---|---|---|
| 1. Are you able to walk a short distance in your home? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2. Are you able to step up and down curbs? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3. Are you able to walk across a parking lot? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 4. Are you able to walk a block on flat ground? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 5. Are you able to walk over gravel surfaces? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 6. Are you able to move a chair from one room to another? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 7. Are you able to walk while carrying a shopping basket in one hand? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 8. Are you able to keep walking when people bump into you? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 9. Are you able to walk up a gently sloping ramp without a handrail? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 10. Are you able to walk on an unlit street or sidewalk? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 11. Are you able to walk on a surface that slants sideways where one side is higher than the other? | ☐ | ☐ | ☐ | ☐ | ☐ |

□ Foot A □ Foot B □ Foot C □ Foot D □ Foot E Participant ID: _____

## Mobility – FOLLOW-UP TESTING

| Question | Without any difficulty | With a little difficulty | With some difficulty | With much difficulty | Unable to do |
|---|---|---|---|---|---|
| 12. Are you able to keep up with others when walking? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 13. Are you able to climb up 2-3 steps without a handrail? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 14. Are you able to walk across a slippery floor? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 15. Are you able to walk down a steep gravel driveway? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 16. Are you able to carry a laundry basket up a flight of stairs? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 17. Are you able to walk up and down steep stairs in a crowded stadium? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 18. Are you able to hike about 2 miles on uneven surfaces, including hills? | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0 | 1 | 2 | 3 | 4 |

# Balance – FOLLOW-UP TESTING

**For each of the following, please indicate your level of confidence in doing the following activities without losing your balance or becoming unsteady. If you do not currently do the activity in question, try and imagine how confident you would be if you had to do the activity. If you normally use walking aids to do the activity or hold onto someone, rate your confidence as if you were using these supports.**

| **How confident are you that you will <u>not</u> lose your balance or become unsteady when you ….** | **No confidence** | **Low confidence** | **Moderate confidence** | **High confidence** | **Complete confidence** |
|---|---|---|---|---|---|
| 1. Walk around the house? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 2. Walk up and down stairs? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 3. Pick up something off the floor? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 4. Reach at eye level? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 5. Stand on your tiptoes? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 6. Stand on a chair to reach? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 7. Sweep the floor? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 8. Walk outside to a nearby car? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 9. Get in and out of a car? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 10. Walk across a parking lot? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 11. Walk up and down a ramp? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 12. Walk in a crowded mall? | ☐ | ☐ | ☐ | ☐ | ☐ |

□ Foot A □ Foot B □ Foot C □ Foot D □ Foot E Participant ID: _____

## Balance – FOLLOW-UP TESTING

| **How confident are you that you will <u>not</u> lose your balance or become unsteady when you ….** | **No confidence** | **Low confidence** | **Moderate confidence** | **High confidence** | **Complete confidence** |
|---|---|---|---|---|---|
| 13. Get bumped? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 14. Ride an escalator holding the rail? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 15. Ride an escalator <u>not</u> holding the rail? | ☐ | ☐ | ☐ | ☐ | ☐ |
| 16. Walk on icy sidewalks? | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0 | 1 | 2 | 3 | 4 |

## Activity Restrictions – FOLLOW-UP TESTING

**The following questions are about activities you might do during a typical day. Does limb loss limit you in these activities? If so, how much?**

| | Yes, limited a lot | Limited a little | No, not limited at all |
|---|---|---|---|
| 1. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports | ☐ | ☐ | ☐ |
| 2. Climbing several flights of stairs? | ☐ | ☐ | ☐ |
| 3. Running for a bus? | ☐ | ☐ | ☐ |
| 4. Sport and recreation | ☐ | ☐ | ☐ |
| 5. Climbing one flight of stairs | ☐ | ☐ | ☐ |
| 6. Walking more than a mile | ☐ | ☐ | ☐ |
| 7. Walking half a mile | ☐ | ☐ | ☐ |
| 8. Walking 100 metres (about 1 block) | ☐ | ☐ | ☐ |
| 9. Working on hobbies | ☐ | ☐ | ☐ |
| 10. Going to work | ☐ | ☐ | ☐ |
| | 0 | 1 | 2 |

## Satisfaction – FOLLOW-UP TESTING

**Please tick the box that represents the extent to which you are satisfied or dissatisfied with each of the different aspects of your prosthesis mentioned below:**

| | Not satisfied | Satisfied | Very satisfied |
|---|---|---|---|
| 1. Weight | ☐ | ☐ | ☐ |
| 2. Usefulness | ☐ | ☐ | ☐ |
| 3. Reliability | ☐ | ☐ | ☐ |
| 4. Fit | ☐ | ☐ | ☐ |
| 5. Comfort | ☐ | ☐ | ☐ |
| | 0 | 1 | 2 |

## PREVIOUS/CURRENT/PENDING RESEARCH SUPPORT

**RUSSELL ESPOSITO, ELIZABETH**

**CURRENT SUPPORT**

Congressionally Directed Medical Research Programs (CDMRP) Prosthetics (PORA) 09/2016-08/2019
Outcomes Research Award

Title A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations
Role Site Principal Investigator (D Morgenroth, PI) (5% effort)
Funding $2,499,545
Purpose To determine the predictive validity of a prosthetic foot emulator and/or a brief trial of commercial prosthetic feet in order to predict of foot preference, satisfaction, and mobility outcomes with specific prosthetic feet in Veterans and Service members with lower limb loss.
Overlap No scientific or budgetary overlap
Contracting/Grants Officer:
Danielle Belisle, MPA
Seattle Institute for Biomedical and Clinical Research
1660 S. Columbian Way, S-151F
Seattle, WA 98108-1532

Center for Rehabilitation Sciences Research II (CRSR) 03/2015-03/2019

Title Identification of Factors that Influence Return to
Duty Role Principal Investigator (20% effort)
Funding $299,939
Purpose To use focus group efforts to identify clinician-reported and patient-reported factors that influence the desire and ability to return to active duty after lower extremity injury. This prospective study will then use patient-centered questionnaires at multiple points in the recovery process to determine barriers that hinder return to duty.
Overlap: No scientific or budgetary overlap
Contracting/Grants Officer:
Aaron Wade
USAMRAA
820 Chandler St.
Fort Detrick, MD 21702

Congressionally Directed Medical Research Programs (CDMRP) 09/2015-09/2017
Orthotics and Prosthetics Outcomes Research Award (OPORA)

Title Impact of Powered Knee-Ankle Prosthesis Leg on Everyday Community Mobility and Social Interaction
Role Site Principal Investigator (A Jayaraman, PI) (5% effort)
Funding $2.5 M
Purpose To evaluate new prosthesis that has powered controls at both the knee and ankle joints and a new way of controlling this device.
Overlap No scientific or budgetary overlap

Contracting/Grants Officer:
Aaron Wade
USAMRAA
820 Chandler St.
Fort Detrick, MD 21702

Telemedicine and Advanced Technology Research Center (TATRC) 09/2015-09/2017
AMEDD Advanced Medical Technologies Initiative (AAMTI)

Title Real Time Bio-Feedback during Running Rehabilitation
Role Principal Investigator (15% effort)
Funding $248,202
Purpose To provide real time feedback on running mechanics for service members recovering from lower extremity injuries who wish to return to running. We will develop and test a real-time feedback training tool to address the asymmetries and high loading rates currently found in a subset of our patient population.
Overlap No scientific or budgetary overlap

Contracting/Grants Officer:
Caitlin E Buchheit
Telemedicine and Advanced Technology Research Center (TATRC)
1054 Patchel Street
Fort Detrick, MD 21702-5012

Center for Rehabilitation Sciences Research II (CRSR) 03/2015-03/2019

Title Initial Validation of a Virtual Reality-Based, Military-Specific Treatment Tool for Combat Injured Service Members
Role Associate Investigator (CA Rábago, PI) (10% effort)
Funding $393,861
Purpose To evaluate the efficacy of current virtual reality-based, military-specific treatment applications in the rehabilitation of injured service members with severe lower extremity trauma.
Overlap No scientific or budgetary overlap

Contracting/Grants Officer:
Aaron Wade
USAMRAA
820 Chandler St.
Fort Detrick, MD 21702

Army Phase II SBIR 09/2012-06/2017

Title Advanced Military Footwear System with Composite Orthotic - Phase II Role
Site PI (T Hurley, PI) (5% effort)
Funding $997,025.00
Purpose To incorporate up-to-date biomechanical knowledge and state-of-the-art materials in the development of a novel boot and in-shoe foot orthoses to allow improved performance and decreased injury risk in service members.
Overlap No scientific or budgetary overlap
Contracting/Grants Officer:

Aaron Wade
USAMRAA
820 Chandler St.
Fort Detrick, MD 21702

**PENDING SUPPORT**

Telemedicine and Advanced Technology Research Center (TATRC)

AMEDD Advanced Medical Technologies Initiative (AAMTI)

| | |
|---|---|
| Title | Blood Flow Restricted Training during Rehabilitation for Lateral Epicondylitis |
| Role | Co-Investigator (J Cancio, PI) (2% effort) |
| Funding | $183,288 |
| Purpose | To examine how augmenting rehabilitative care with BFR training affects outcomes in patients with LE in a randomized controlled trial. We propose to compare standard of care rehabilitation methods with standard of care + BFR training in patients who are undergoing occupational therapy for lateral epicondylitis. |
| Overlap | No scientific or budgetary overlap |

NIH-DoD-VA Pain Management Collaboratory - Pragmatic Clinical Trials Demonstration Projects (UG3/UH3)

| | |
|---|---|
| Title | Resolving the Burden of Low Back Pain in Military Service Members and Veterans: A multi-Site Pragmatic Randomized Clinical Trial |
| Role | Site Principal Investigator (S Farrokhi, PI) (5% effort) |
| Funding | $6M |
| Purpose | To determine if psychologically informed physical therapy approach can reduce healthcare utilization, opioid use, and the costs associated with the treatment of low back pain in Service Members and Veterans |
| Overlap | No scientific or budgetary overlap |

United States Department of Veterans Affairs Rehabilitation Research and Development Service 11/01/2017-09/30/2020

| | |
|---|---|
| Title | Improving Footwear Options for Veterans with Amputations |
| Role | AI (5% effort) |
| Funding | $781,901 |
| Purpose | The purpose of this project is to develop a new ankle-foot prosthesis system that will allow Veterans with amputations to choose any footwear with heel heights between 0-100mm (0-4 inches), and to be able to easily switch between these footwear without needing to change the alignment of their prosthesis. |
| Overlap | None |

Contracting/Grants Officer:
Brian Schulz, PhD
Scientific Review Officer
202-443-5769
brian.schulz@va.gov

Congressionally Directed Medical Research Programs (CDMRP) 10/1/2017-9/30/2019
Prosthetics Outcomes Research Award (PORA)

Title Women's–Specific Footwear with Prosthetic
Feet Role Principal Investigator (15% effort)
Funding $146,969
Purpose To characterize perceived limitations in footwear among female prosthesis users and compare how women's-specific footwear affects the mechanical properties of prosthetic feet
Overlap Scientific overlap complements, but does not replicate, objectives of current study. No budgetary overlap
Contracting/Grants
Officer: Jessica Clement
Congressionally Directed Medical Research Programs (CDMRP)
1053 Patchel Street
Fort Detrick, MD 21702

**PAST SUPPORT (5 YEARS)**

Center for Rehabilitation Sciences Research I (CRSR) 04/2011-03/2015
Title Optimization of Dynamic Ankle Foot Orthosis Design for High Level Activity Performance Following Limb Salvage for Severe Lower Extremity Trauma.
Role Associate Investigator (JM Wilken, PI)
Funding $1.7 M
Purpose To systematically vary mechanical parameters of custom carbon fiber orthoses to determine their effect on gait biomechanics. The study will help identify which mechanical parameters have the greatest effect on walking with clinically prescribed AFOs.
Overlap No scientific or budgetary overlap
Contracting/Grants Officer:
Aaron Wade
USAMRAA
820 Chandler St.
Fort Detrick, MD 21702

Telemedicine and Advanced Technology Research Center (TATRC) 09/2011-03/2015
United States Army Medical Research Acquisition Activity (USAMRAA)
Title PowerFoot Orthosis: Treatment for Traumatic Lower Extremity Injury
Role Associate Investigator (R Casler, PI, JM Wilken, Site PI)
Funding $299,642
Purpose To build, test and clinically evaluate a wearable robotic knee orthosis on soldiers with quadriceps weakness. We tested the hypothesis that a biomimetic orthosis will improve metabolic economy and gait mechanics on sloping ground and stairs.
Overlap No scientific or budgetary overlap
Contracting/Grants Officer:
Aaron Wade
USAMRAA
820 Chandler St.
Fort Detrick, MD 21702

Telemedicine and Advanced Technology Research Center (TATRC) 09/2011-09/2014
AMEDD Advanced Medical Technologies Initiative (AAMTI)

Title Supplementing Gait Training with Real-Time Feedback to Optimize Walking Energetics
Role Associate Investigator (JM Wilken, PI)
Funding $234,002
Purpose To determine if feedback provided while walking can change performance and reduce energy cost to a more normal level. Specifically, we will determine in persons with a below knee (transtibial) amputation whether providing real-time feedback on muscle activity is better than providing feedback based on body motion.
Overlap No scientific or budgetary overlap
Contracting/Grants Officer:
Caitlin E Buchheit
Telemedicine and Advanced Technology Research Center (TATRC)
1054 Patchel Street
Fort Detrick, MD 21702-5012

American Orthopaedic Foot and Ankle Society (AOFAS) 06/2012-06/2013

Title Clinical and biomechanics outcomes following gastrocnemius recession vs. plantar fasciotomy for plantar fasciitis: A prospective, randomized controlled clinical trial
Role Principal Investigator (E Nilssen, Co-PI)
Funding $20,000
Purpose Compare clinical, biomechanical, and patient-reported outcomes following surgical treatment for plantar fasciitis. These outcomes data will determine the efficacy and effectiveness of each treatment and provide best clinical practice guidelines for clinicians.
Overlap: No scientific or budgetary overlap
Contracting/Grants Officer: None

# Ankle Torque vs. Angle Characterization of Prosthetic Feet for Input to a Prosthetic Foot Emulator

Elizabeth Halsne, CPO[1,3,4]; Josh Caputo, PhD[2]; Stina Stender, MS[1]; David Morgenroth, M.D.[1, 4]
[1]RR&D Center for Limb Loss and MoBility (CLiMB), VA Puget Sound, Seattle, WA; [2]HuMoTech, Pittsburgh, PA
Departments of [3]Mechanical Engineering, [4]Rehabilitation Medicine,
University of Washington, Seattle, WA
email: bhalsne@uw.edu, dmorgen@uw.edu

## INTRODUCTION

Prosthetic feet are designed to replace the biological foot and ankle for people with lower limb amputation (LLA). Although there have been many studies comparing the effect of different prosthetic feet on gait, these mostly compare a few different feet in a small number of participants. There remains insufficient evidence to inform clinical decision-making [1]; consequently, prosthetic foot prescription typically depends on prescribing clinician experience, manufacturer advertising, and other factors. Our collaborators recently developed a prosthetic foot emulator (PFE) which has the potential to offer a novel approach to foot prescription [2]. Using the PFE, individuals could make an informed decision by "test-driving" a range of foot modes that emulate commercially available feet. In order to program the PFE, we are currently characterizing the mechanical performance of corresponding prosthetic feet.

A number of studies have collected data on the mechanical performance of prosthetic feet, such as linear stiffness, damping, and roll-over shape properties [3,4]. The PFE uses angular stiffness information to simulate the behavior of prosthetic feet. Current approaches for collecting angular stiffness information rely on data collected while an amputee walks in a laboratory, potentially confounding the mechanical behavior results with individual gait variations.

Therefore, the purpose of this study was to use a novel, user-independent technique to determine angular stiffness profiles (ankle torque vs angle) of a variety of prosthetic feet across a range of pylon progression angles for input to a PFE.

## METHODS

Mechanical testing will be performed on a range of size and stiffness categories of five different commonly prescribed prosthetic feet. To date, data has been collected on three size 26cm, medium stiffness category feet: Variflex (Össur, Reykjavik, Iceland), Walk-tek (Freedom Innovations, Irvine, CA) and RUSH87 (Ability Dynamics, Tempe, AZ).

Apparatus: The Mikrolar R2000 robot and an 8-camera Vicon motion capture system were used to perform mechanical testing of prosthetic feet. A 6-axis AMTI load cell was used to collect torque data in parallel with the prosthetic foot.

Procedures: A novel technique was developed to evaluate torque vs. angle behavior. Each foot was attached in line with the load cell, shod with standardized walking shoes, and fixed to the RGS in neutral alignment. Procedures included quasi-static testing across a range of pylon progression angles that represent the stance phase of the gait cycle, at 10 degree intervals. Each foot was compressed for five cycles of loading/unloading to 800N at each progression angle. Ankle torque (N-m) in the sagittal plane was collected about the origin of the load cell transducer. Ankle angle (deg) was defined based on motion capture data of the prosthetic foot base relative to a vertical pylon position.

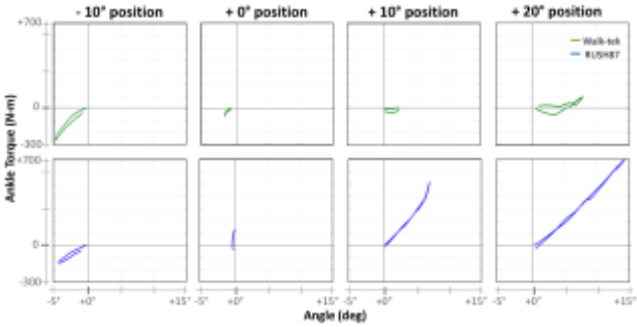


**Figure 1**: Ankle torque versus angle - 26cm Walk-tek and RUSH87 feet across four pylon phase progression angles.

## RESULTS AND DISCUSSION

An average ankle torque vs. angle profile was created at each progression angle (Figure 1) for the following two feet: Walk-tek (low-activity foot) and RUSH 87 (flexible, energy storing foot). The difference in torque vs ankle behavior between these two feet is most apparent during mid to late stance (10° and 20° progression angles). The RUSH87 exhibits substantially more dorsiflexion under the same amount of load than the same size and similarly-rated stiffness category Walk-tek. Data collection is ongoing and will include a range of sizes and stiffness categories for five prosthetic foot types. Ongoing project development includes defining ankle angle using COP data for a variety of prosthetic foot geometries, and creating composite foot profiles from a range of progression angles.

## CONCLUSIONS

The ankle torque vs angle profiles produced using this novel technique will quantify angular stiffness performance of prosthetic feet, independent from the user. The profiles will be used as an input to a PFE to offer people with LLA the experience of wearing different prosthetic feet. Use of a PFE could inform prosthetic foot prescription by making a "test-drive" strategy feasible through simple software mode changes.

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