

AWARD NUMBER: W81XWH-20-1-0291

TITLE: A Prosthetic Foot Test-Drive Strategy for Improving Stability and Falls-Related Outcomes in Veterans with Leg Amputations

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REPORT DATE: August 2023

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE AUGUST 2023		2. REPORT TYPE Annual		3. DATES COVERED 1AUG2022 - 31JULY2023	
4. TITLE AND SUBTITLE A Prosthetic Foot Test-Drive Strategy for Improving Stability and Falls-Related Outcomes in Veterans with Leg Amputations				5a. CONTRACT NUMBER W81XWH-20-1-0291	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Dr. David Morgenroth, MD 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 South Columbian Way Mailstop: SIBCR-116-MIRECC Seattle WA 98108				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The objective of this project is to assess the effects of prosthetic feet of varying stiffness on dynamic stability and falls-related outcomes in people with transtibial amputation and to determine whether a test-drive strategy using a multiaxial prosthetic foot emulator can be used to predict stability and balance-confidence outcomes. During this reporting period, we have performed extensive mechanical testing of commercial prosthetic feet, which is nearing completion. We are using that data to program the multiaxial prosthetic foot emulator that will mimic the sagittal and coronal plane mechanical properties of the study commercial prosthetic feet without physically changing feet. The multiaxial prosthetic foot emulator hardware is now designed in place at both data collection sites. We have also set up data collection sites and run through the protocol in anticipation of human subjects testing to begin soon.					
15. SUBJECT TERMS Lower extremity amputee, transtibial, prosthesis, artificial limb, prosthetic foot, mobility, balance, stability, biomechanics, stiffness, falls, mechanical testing, robotics					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
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1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The objective of this project is to assess the effects of prosthetic feet of varying stiffness on dynamic stability and falls-related outcomes in people with transtibial amputation and to determine whether a test-drive strategy using a multiaxial prosthetic foot emulator (PFE) can be used to predict stability and balance-confidence outcomes. We have developed a customizable robotic prosthetic foot that mimics the mechanical properties of commercial prosthetic feet without physically changing feet. We will test the ability of the multiaxial emulator to reproduce the experience of wearing the corresponding commercial (actual) prosthetic feet by testing whether brief in-laboratory experiences with feet accurately predict longer-term dynamic stability and balance-confidence outcomes.

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

Lower extremity amputee, transtibial, prosthesis, artificial limb, prosthetic foot, mobility, balance, stability, biomechanics, stiffness, falls, mechanical testing, multiaxial, robotic

3. ACCOMPLISHMENTS: *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Primary and Secondary and Exploratory Aims (specified in proposal)	Timeline	Description of Tasks Completed	Completion Date or Percent Completion
Obtain and Maintain Human Subjects Approval	Months		
Prepare and submit application to VA Central IRB	pre-study	We have received all necessary VA Central IRB approvals. During this reporting year, we received approval for Continuing Review documents for the VA CIRB PISC and both LSI applications at the Seattle and Minneapolis data collection sites. We also recently submitted PISC Amendment 3 to the VA CIRB PISC to update the protocol and surveys to align with the consent forms and correct small wording issues and formatting errors that were discovered during research personnel training sessions to prepare for human subject recruitment and data	Completed. During this reporting year, the following was accomplished: Continuing Reviews: PISC Continuing Review: 07-Mar-2023 (approval) LSI Continuing Review (Seattle): 07-Mar-2023 (approval) LSI Continuing Review (Minn):

		collection. We will submit the corresponding LSI amendments once the changes to the PISC are approved.	07-Mar-2023 (approval)
Prepare and submit VA Puget Sound Research and Development (R&D) Application for Human Subjects Research		We have received all necessary VA R&D approvals. We previously submitted and received approval for the non-human subjects portion of the project that occurs at the Seattle site only (i.e., prosthetic foot mechanical testing to program the multi-axial prosthetic foot emulator (PFE)) from the VA Puget Sound R&D. For the human subjects portion of the work, we submitted and have received approval for the PISC, local LSI Seattle R&D, and local LSI Minneapolis R&D. During this reporting year, we submitted and received updated continuing review approval from R&D.	Completed. During this reporting year, the following was accomplished: <u>Seattle Site</u> - Non-human subjects (mechanical testing): 11-Apr-2023 (Continuing Review Approval) - Human subjects PISC: 11-Apr-2023 (approval) - Human subjects LSI 11-Apr-2023 (Continuing Review Approval) <u>Minneapolis Site</u> - Human subjects LSI 11-Apr-2023 (Continuing Review Approval)
Prepare and submit OHRO Protocol for Human Subjects Research		We have received all necessary HRPO approvals. We previously submitted and received approval for the human subjects protocol from HRPO (now OHRO). During this reporting year, we submitted and received continuing review approval from OHRO.	Continuing Review: OHRO Seattle site: 8-Apr-2023 (Continuing Review Approval) OHRO Minneapolis site: 2-Apr-2023 (Continuing Review Approval)
Study Preparation	Months		
Prepare and finalize study protocol and consent materials (e.g., recruitment materials, consent forms)	pre-study	This task has been completed. No updates this reporting year.	Completed 29-Jan-2021
Prepare data collection files (e.g., forms, surveys)	1-5	This task has been completed. No updates this reporting year.	Completed 30-Nov-2020
Create recruitment and data collection databases	1-5	This task has been completed. No updates this reporting year.	Completed 29-Jan-2021
Purchase research supplies and equipment (e.g., prosthetic feet, treadmill, laptops, software)	1-3	During the reporting year, the Minneapolis VA purchased marker clusters and equipment for motion capture system calibration in preparation for human subjects data collection. The Minneapolis VA site also purchased several materials to build a set of custom touch sensor devices that could be easily attached and detached from the	Ongoing

		handrails of each treadmill. These materials included plastic piping and conductive foil tape. These sensors will be used to determine biomechanical Margin of Stability (MoS) data that should be excluded when participants contact the safety handrails during walking trials (rendering MoS inaccurate).	
Mechanical testing of commercial prosthetic feet and input of mechanical testing data to multiaxial emulator	1-9	We have made tremendous progress towards completion of mechanical testing commercial prosthetic feet to characterize sagittal and coronal plane angular stiffness properties and are nearly finished mechanical testing and importing the data into emulated foot profiles for use in the multiaxial PFE. During this reporting year, we increased our frequency of meetings to a weekly basis with Humotech to expedite software development for analysis of mechanical testing data and the multiaxial PFE controller. During this reporting year, the Humotech team also visited on-site at VAPSHCS twice to continue this work in person using the updated hardware and software (described below). In addition to collecting mechanical property data for commercial prosthetic feet, we also refined our data collection procedures based on the results from validation testing conducted at the beginning of this reporting year. For example, during this reporting year, we installed a new in-line load cell to achieve the target loading forces and moments for physiologic testing of the prosthetic feet. We also built and began using an adjustable tibial mount as part of the mechanical testing setup to precisely position the prosthetic feet for consistent data collection across foot types in accordance with testing standards. In addition, the software that we use for mechanical testing to control the RGS (i.e., simVITRO) was updated during an on-site visit from the manufacturer and our staff were trained on the updated features to improve our testing procedures and quality of data collection. We also added new sets of markers to accurately track the force	95%

		plate kinematic motion during mechanical testing in order to precisely reconstruct the Center of Pressure (CoP) for the calculation of ankle torque vs angle data. Using these new equipment and methods, we have been able to recollect data and transform the raw data into torque vs angle curves in both the sagittal and coronal planes for input into the multiaxial PFE. With all of the progress we have made in validating our methods, we have made exponential progress in mechanical testing, particularly during the last few months. At the time of writing this report, we have collected data for over 75 commercial prosthetic feet, which includes all but 1-2 foot sizes of two types of low mobility feet (i.e., K2 Sensation in size 28cm and Seattle Lightfoot2 in sizes 26 and 28). We have also been able to use our updated software code to analyze and transform these mechanical testing data for the completed feet into ankle torque vs. angle in both the sagittal and coronal planes for input into the multiaxial PFE.	
In-person kick-off meeting	8-9	This task has been completed. No updates this reporting year. During the previous reporting year, we held an in-person full team meeting in April 2022 to train research staff, deliver and install the multiaxial prosthetic foot emulator, and discuss study methods. We previously held a virtual (due to the COVID-19 pandemic) kick-off meeting with entire investigative team in October 2020.	Completed
Train research staff	1-9	Research staff ongoing training including biomechanical data collection, human subjects research, and mechanical testing of prosthetic feet training. In this reporting year, a new research coordinator was hired at each site (Seattle—Tyler Ho, Minneapolis—Rachel Steiner).	Ongoing weekly
Registration of clinical trial on ClinicalTrials.gov	8	This task has been completed (NCT05473065). No updates during this reporting year.	Completed 21-July-2022

Ongoing Study Coordination	Months		
Once per month teleconference meetings of investigative team	1-36	We continue to hold monthly meetings with the entire team (e.g., to discuss mechanical testing, biomechanical data collection protocol).	Ongoing
Participant Recruitment	Months		
Post recruitment materials at recruitment site	9-44	Mechanical testing of prosthetic feet for input into the multiaxial prosthetic foot emulator has not yet been completed but is nearly complete. Thus, the multiaxial prosthetic foot emulator software foot profiles have also not yet been finished for all commercial prosthetic feet. We are therefore not yet able to initiate human subjects recruitment and testing until mechanical testing is complete (since human subjects testing requires the use of the multiaxial prosthetic foot emulator programmed with the mechanical properties of the commercial study feet). However, we anticipate completing mechanical testing and property characterization for all prosthetic feet within the next reporting period and initiating human subjects recruitment and enrollment.	
Screen candidate participants by telephone	9-44	See above	
Screen eligible candidate participants in-person and enroll if eligible and interested	9-44	See above	
Enroll n=30 participants per site into the study	9-44	See above	
Enhance recruitment efforts if needed	18-44	See above	
Data Collection	Months		
Collect data for Specific Aims 1,2 and 3 for n=30 participants per site	9-45	See above	
Data Analysis	Months		
Enter raw data into database for analysis	9-45	See above	
Score outcomes data	9-45	See above	
Analyze outcomes data combined from all sites to confirm appropriate statistical approach	22-24	See above	
Conduct statistical analysis for hypotheses 1.1, 1.2, and 2.1, and 3.1 on overall	43-47	See above	
Dissemination	Months		
Attend required DoD conference	As requested		

Prepare abstracts and manuscripts for publication	7-12, 19-24, 31-36, 43-48		
Attend national scientific conferences to present preliminary/final data	9-12, 21-24, 33-36, 45-48		

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

We recently submitted an amendment to our IRB-approved PISC protocol and surveys to align with our IRB-approved informed consent form and correct several small wording and formatting issues that were discovered during research personnel training sessions to prepare for human subject recruitment and data collection. This amendment does not introduce any new risk to participants and is currently pending approval from the VA Central IRB. After the PISC amendment has been approved, we will submit the corresponding LSI amendments, as needed, and submit the updated documents to OHRO. During this reporting year, we received IRB approval for study staff changes to add Tyler Ho (Seattle Research Coordinator) and Rachel Steiner (Minneapolis Research Coordinator) to this study, and to remove several departed members of the research teams.

Before human subjects testing can begin, the multiaxial PFE must be programmed with the sagittal and coronal plane mechanical properties of the study commercial prosthetic feet. These prosthetic foot properties are being collected as part of the Study Preparation major goal. During this reporting year, we made substantial progress in mechanical testing commercial prosthetic feet and characterizing their sagittal and coronal plane angular stiffness properties for input into the multiaxial PFE for upcoming human subjects testing. At the time of writing this report, we have collected mechanical testing data for 93 commercial prosthetic feet, out of 95 feet planned for use in this study. The only two feet that we have not collected at the time of writing this report are ones that we waiting to be delivered. We have also been able to use our updated software code to analyze and transform these mechanical testing data for the completed feet into ankle torque vs. angle in both the sagittal and coronal planes for input into the multiaxial PFE. During this year, we continued to refine our methods for the mechanical testing of prosthetic feet to ensure accurate and consistent mechanical properties data. The validation process for our mechanical testing protocol took longer than expected because of a litany of challenges we encountered while using the robotic gait simulator (RGS), which we have detailed in previous quarterly reports and have summarized below.

We discovered the most significant error during the first quarter of this reporting year: a deviation of the measured center of pressure (CoP) and the expected CoP during each trial. We deduced that this deviation was due to the force plate (the “ground” which we test these feet against) deflecting both vertically and in the coronal direction during the body weight loading conditions used during physiological testing of the commercial prosthetic feet. To address this issue, we replaced the existing RGS force plate mounting bracket with a newly-designed, more robust version that we expected would prevent the force plate from deflecting and thus resolve this issue. Unfortunately, while the deviation of the CoP is significantly reduced when using the new mounting bracket, this error has not been completely eliminated in the medial-lateral direction. The CoP error was particularly exacerbated when we tilted the force plate in the coronal plane, which is necessary to accurately characterize the coronal angular stiffness properties of these prosthetic feet for walking on cross-slopes and uneven terrain. Because of our inability to correct for the CoP error (since the error magnitude was dependent on load and orientation), we opted to collect forces and moments data through an in-line 6-axis load cell (AMTI MC3A-500) which was mounted just proximal to the prosthetic foot during each trial.

During the second quarter of this reporting period, we discovered additional challenges with mechanical testing hardware. While the existing in-line load cell had been robust enough for collecting forces for previous testing orientations, our study procedures require us to place these prosthetic feet under higher loads and at more severe coronal angles than anything that has been previously attempted using the RGS. Because of the increased coronal ankle torque placed on these prosthetic feet—and thus on the in-line load cell itself—we found that our load cell was not capable measuring the highest forces and moments experienced during testing because the moment signals were saturating. After some deliberation about several possible solutions to this saturation issue, we elected to purchase the same model of load cell rated for forces and moments that are twice as high (i.e., AMTI MC3A-1000). This purchase allowed us to maintain all of the same testing procedures because it has an identical form factor as the existing load cell and interfaced with the exact same hardware and software procedures, so as to not create any further delays. We were able to pay for the new load cell with funds from VA Center support so that it did not affect funding for the current study.

During the third quarter of this reporting year, after integrating the new in-line load cell to our testing protocol, some representatives from simVITRO—which develops the software we use to control the RGS and program trajectories for use during testing—visited the Seattle site to update our software and train our staff on several new features. One of the major improvements in this update was a new automatic coordinate system optimization program that allows us to create new RGS force plate kinematic trajectories based on trials that have failed. This coordinate system optimization enables us to quickly rerun a trajectory without needing to manually find an optimal starting position to complete the mechanical testing within the working envelope of the RGS. With these improvements to both the hardware and software used in our testing protocol, we have been able to make substantially more progress in collecting mechanical testing data during the third and fourth quarters of this reporting period.

Along with these improved features, we made additional improvements to our testing protocol during the fourth quarter of this reporting year, and have been able to increase the loading rate of physiological testing by two-fold. Because of this increased loading rate, the commercial prosthetic feet are undergoing viscoelastic conditioning at rates closer to typical stepping than we were able to achieve previously (Figure 1). Using these techniques, we have been able to collect a full mechanical testing dataset of physiological loading (at neutral, +10, and -10 deg coronal inclination angles) and all quasistatic data (at -15 and +20deg sagittal pylon progression angle and multiple coronal angles to characterizing the linear stiffness properties for use in Aim 1) for 93 feet and the three interchangeable heel PFE heel springs (Figures 2,3).

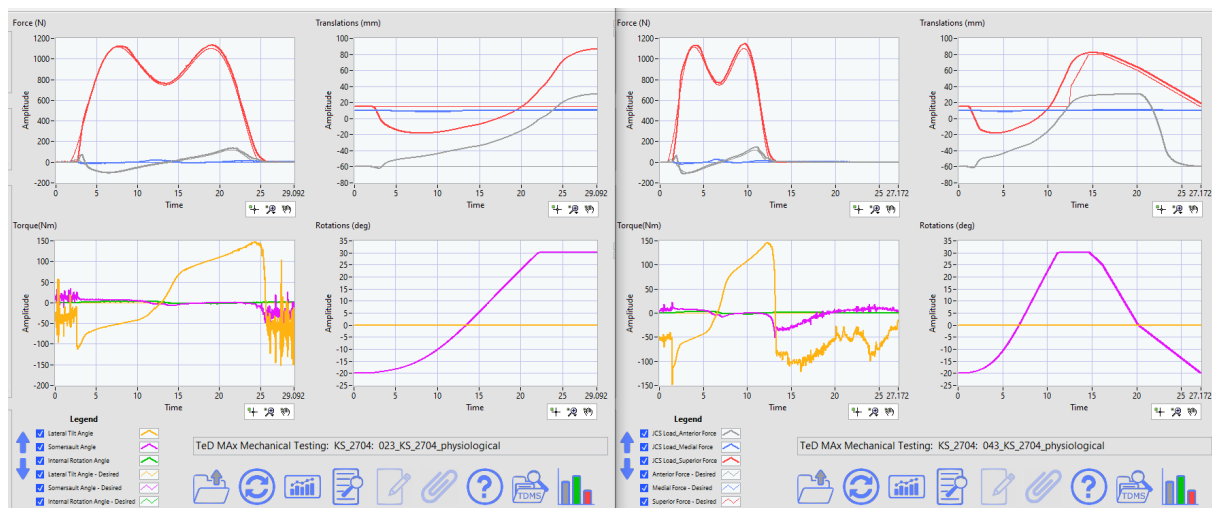


Figure 1. Mechanical testing data collected with the same commercial prosthetic foot before (left) and after (right) increasing the rate of loading with hardware and software improvements in simVITRO for RGS forceplate kinematic control. These changes allow for loading that is twice as fast (i.e., closer to physiological loading rates). *Note*: the sped-up trajectory on the right includes a ~15 second “return trajectory” automatically programmed into the physiological loading cycle, so that the RGS ends each cycle back at its starting position for the next cycle. This return trajectory was not included in the original slower cycles, so the RGS would need ~45-60 seconds between each cycle to return to the starting position. By programming the return trajectory, we shaved off an additional 30-45 seconds during each cycle.

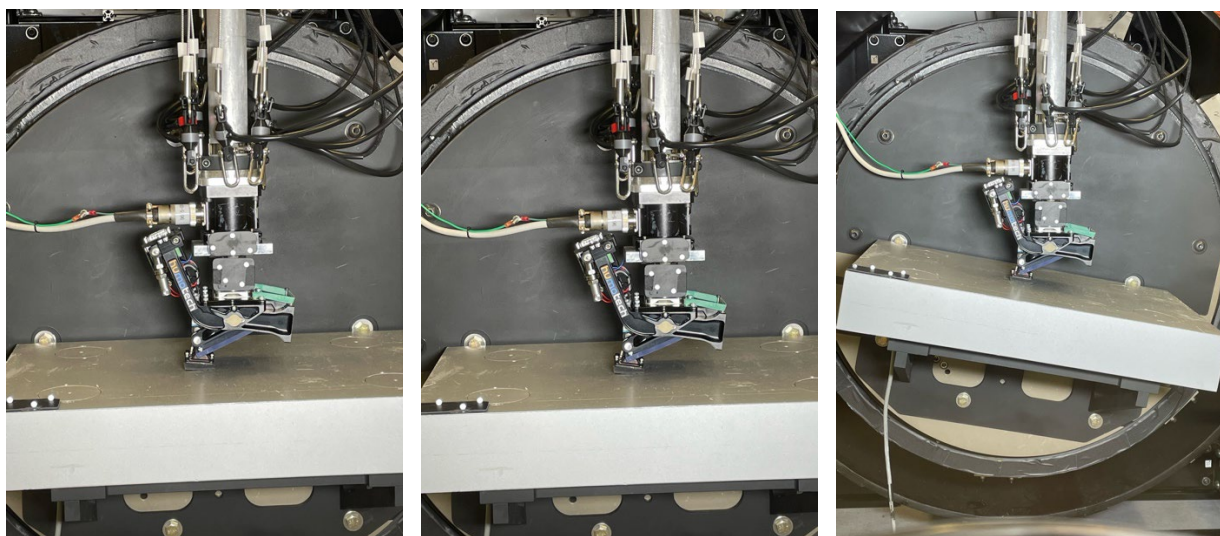


Figure 2. Mechanical testing of the PFE heel springs to characterize their properties.

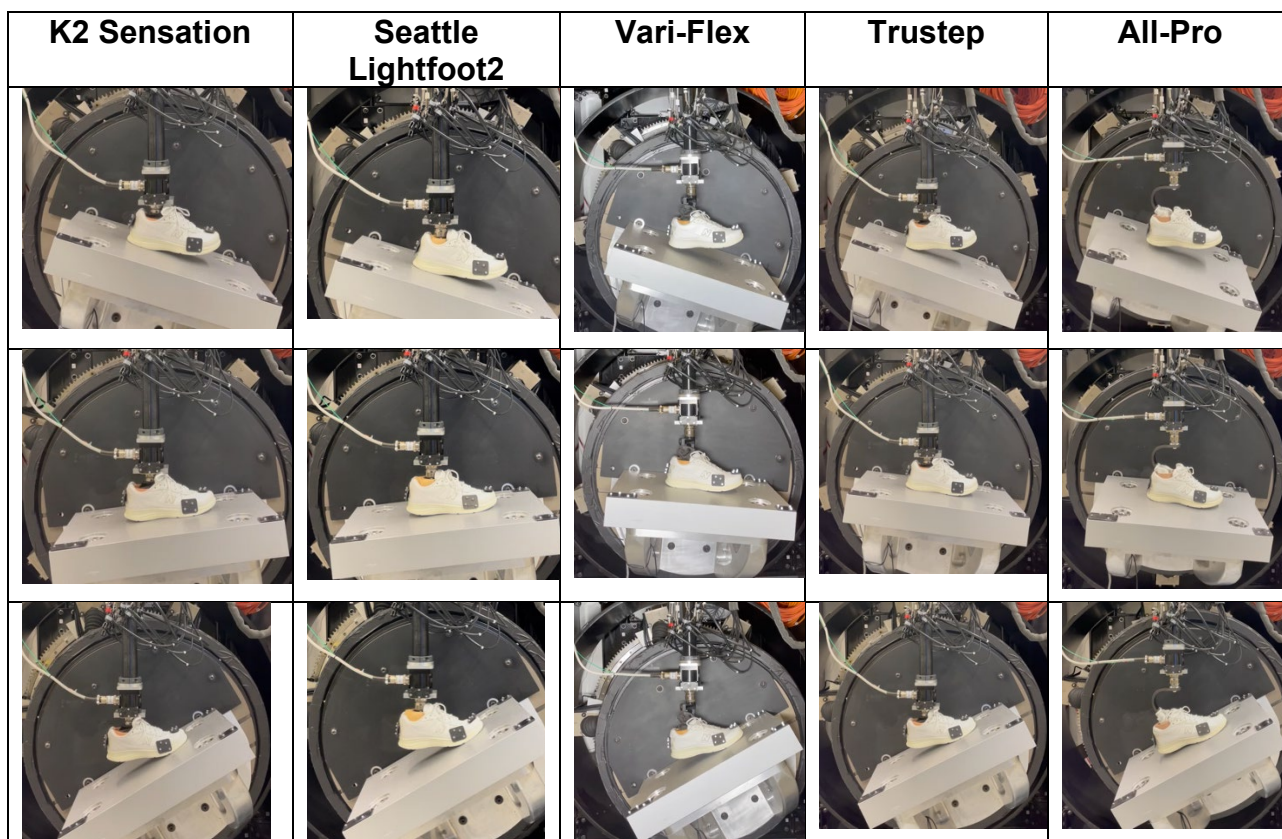


Figure 3. Different types of commercial study prosthetic foot being mechanically tested through a physiological loading cycle as part of data collection for Aim 1 and for use as input to PFE in future human subjects testing.

In addition to collecting mechanical testing data during this reporting year, we have made significant advances in our software code to analyze these data and calculate the stiffness properties of the feet for Aim 1 and transform these data into angular stiffness curves in

multiple planes that can be used in the multiaxial PFE controller to emulate their properties. See additional details below.

During the first quarter of this reporting year, the lead software engineer at HumoTech left the company. In his absence, our team has had the opportunity to completely review the codes we use to analyze mechanical testing data and program it into the PFE. In the second quarter of this reporting year, we held biweekly meetings with Humotech (e.g., Josh Caputo) to re-familiarize ourselves with these codes and begin updating/debugging them. We changed to weekly meetings during the third quarter, and we quickly made significant progress in modifying these codes to calculate center of pressure and re-create ankle torque vs angle curves in both the sagittal and coronal planes from the mechanical testing data collected with prosthetic feet.

During the fourth quarter of this reporting year, we have been able to use these updates to the software analysis code to analyze the mechanical testing data from commercial prosthetic feet toward achieving Aim 1 stiffness property measurements and make progress towards being prepared for human subjects data collection by characterizing the sagittal and coronal plane angular stiffness properties. Specifically, we can use the in-line load cell forces and moments and motion capture marker data on the load cell, prosthetic feet, and RGS force plate to solve for the CoP during testing in multiple coronal planes (Figures 4-5).

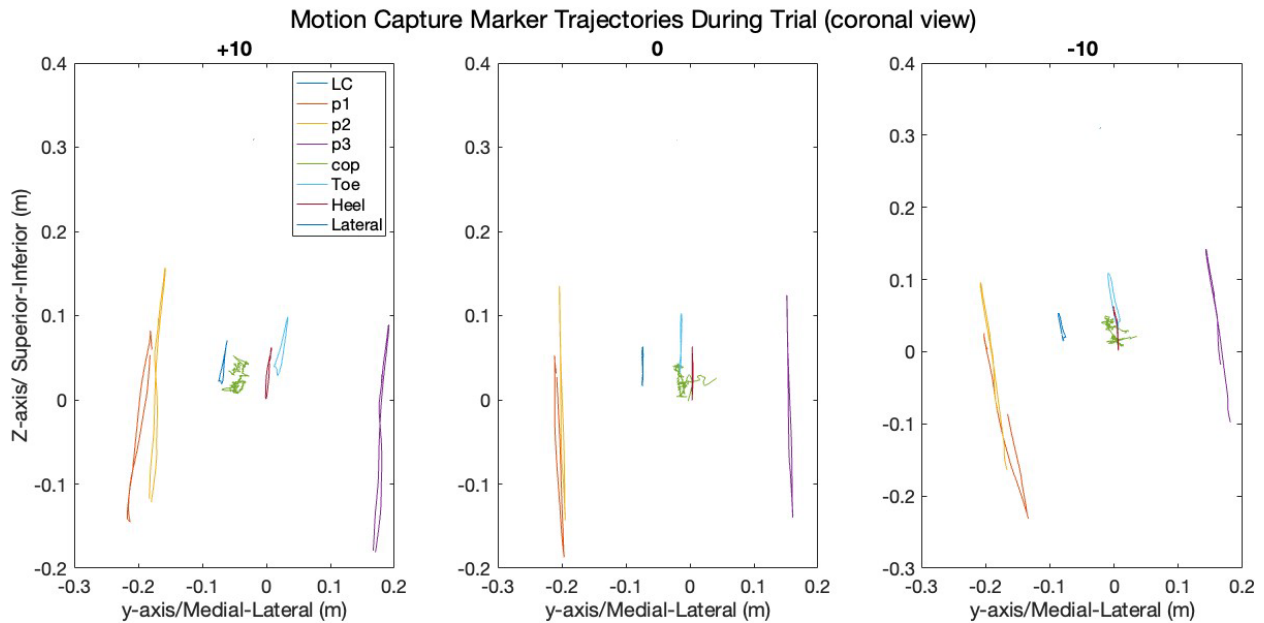


Figure 4. Traces of motion capture markers on the force plate, commercial prosthetic foot, and load cell during mechanical testing, as viewed from the front (i.e., coronal plane). Images show coronal orientation differences across physiological loading trials. Data are used to calculate CoP for angular stiffness curves.

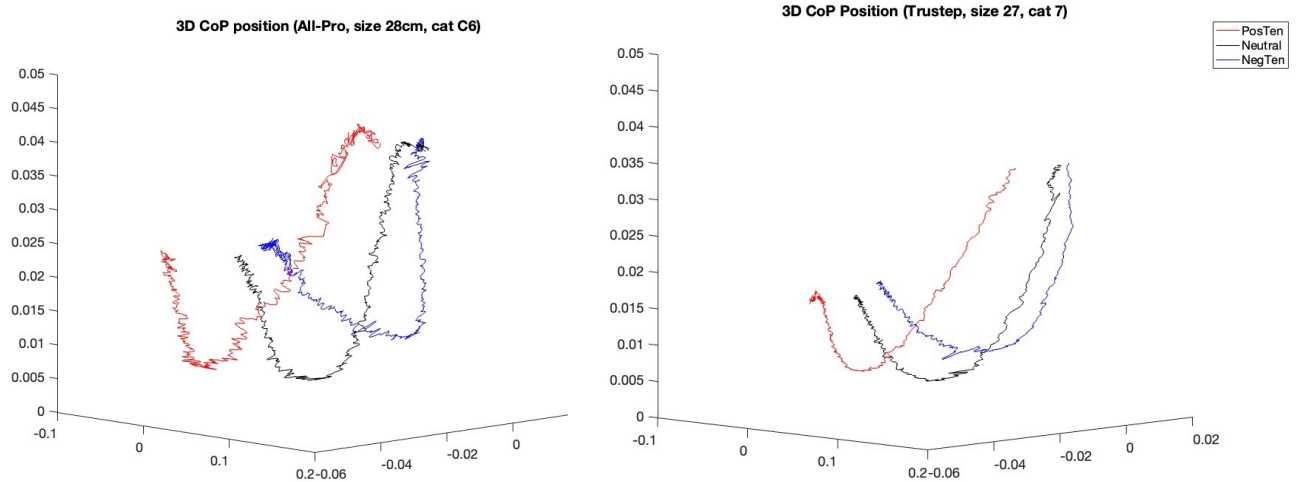


Figure 5. Center of Pressure (CoP) data in 3D from three trials of physiological loading (i.e., three different coronal plane orientations) during mechanical testing for two example commercial prosthetic feet: All-Pro (left) and Truststep (right).

Using the CoP data, we have been able to characterize the angular stiffness properties of the commercial feet in the sagittal and coronal planes (Figure 6-9). These are the values that are then used in the software controller for the multi-axial PFE to emulate the commercial prosthetic feet during human subjects data collection.

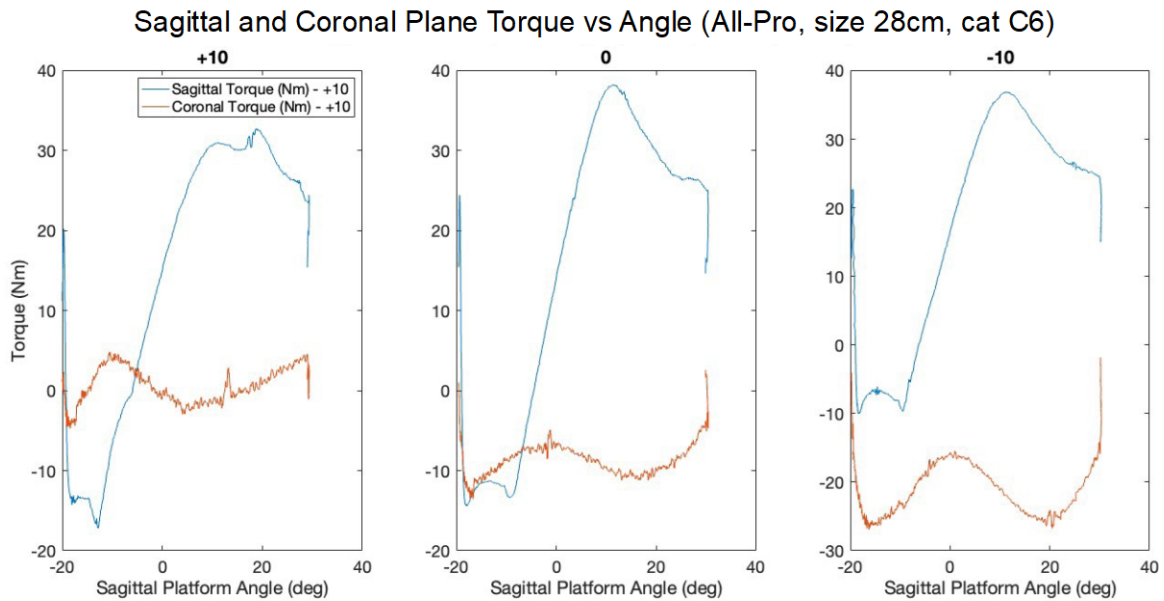


Figure 6. Sagittal and coronal plane angular stiffness for an example commercial prosthetic foot across three mechanical testing coronal orientations.

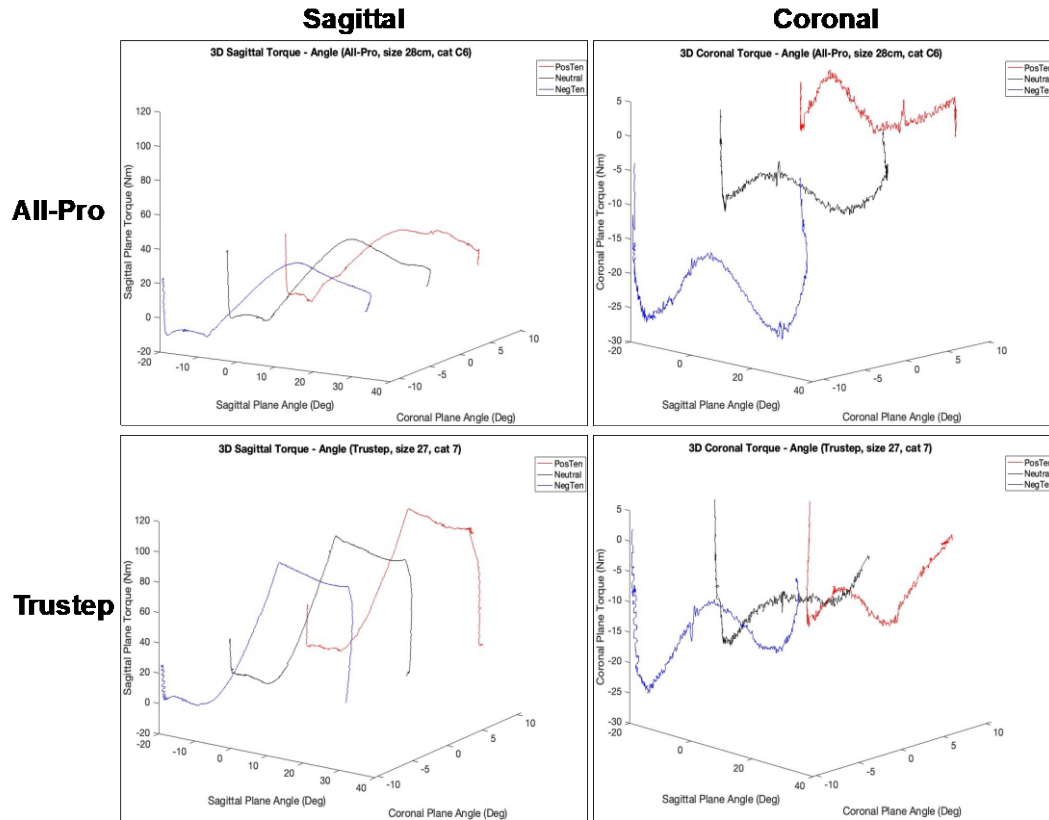


Figure 7. 3D sagittal and coronal plane angular stiffness properties for two example types of prosthetic feet.

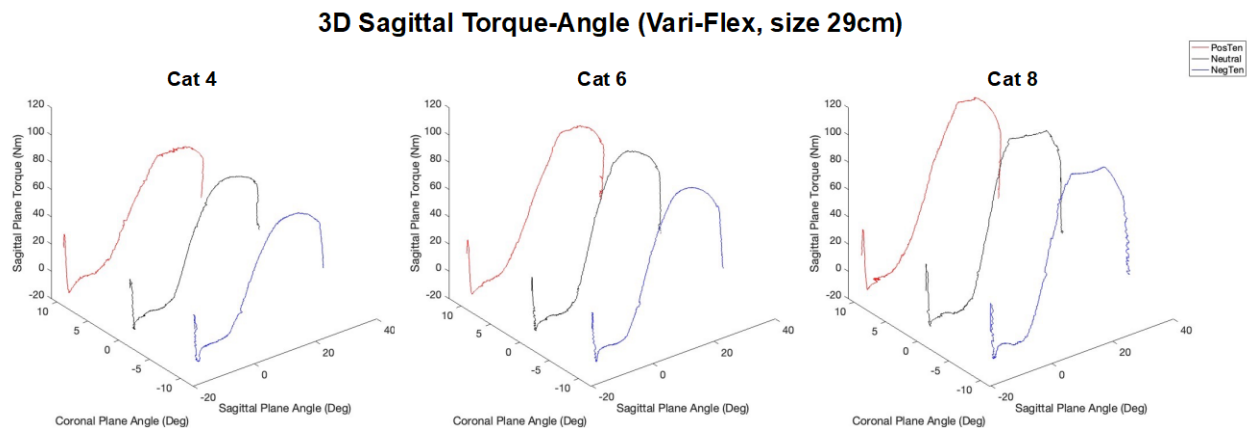


Figure 8. 3D sagittal plane angular stiffness properties across three stiffness categories of an example type of prosthetic foot.

3D Coronal Torque-Angle (Vari-Flex, size 29cm)

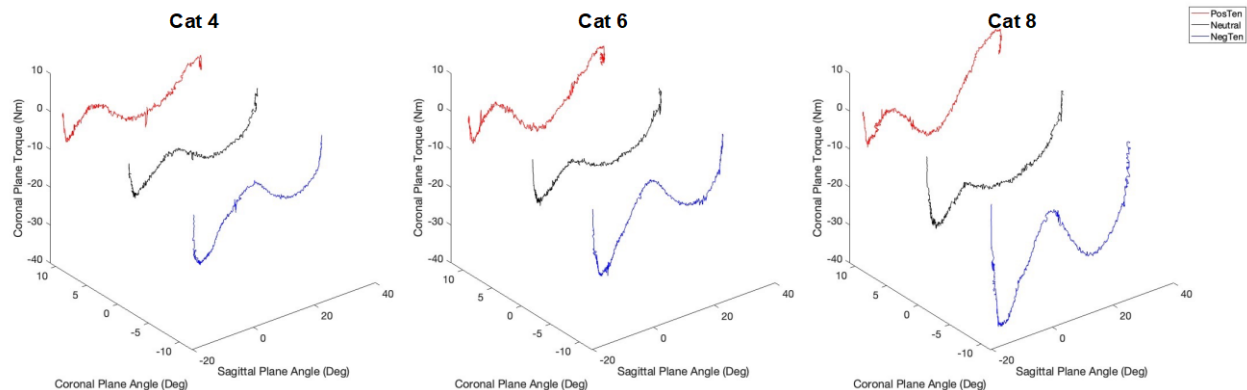


Figure 9. 3D coronal plane angular stiffness properties across three stiffness categories of an example type of prosthetic foot.

As a part of our preparation for human subjects testing, we have installed/developed, and conducted trainings for the use of, several important devices for collection of accurate and reliable data to address the aims of this study. During the first quarter of this reporting year, HumoTech installed the prosthetic foot emulator at the Minneapolis data collection site and trained the staff on its use. Shortly after, the Woodway uneven terrain treadmill at the VA Minneapolis site had its rock features set up to be identical to those of the Seattle site treadmill, to ensure identical data collection at both sites. Motion analysis cameras were also installed for biomechanical data collection at the Minneapolis VA site during this same quarter. At both sites, we completed modifications to the custom jacks to enable treadmill cross-slopes at each data collection site.

An important feature necessary to ensure participant safety during study sessions is a reliable harness system, particularly when they are walking on the uneven treadmill, which is designed to perturb users' balance during walking (as per the original study protocol and approved by VA CIRB and OHRO). The Seattle site has a built-in harness system that they are able to use for this study, but the Minneapolis site does not yet. During the first quarter of the reporting year, the Minneapolis team identified the need for a custom harness system because of the constraints of the motion capture room, which does not allow for a full-sized system that might have otherwise worked. This issue has been particularly difficult to resolve, and has taken until the fourth quarter of this year to find two options that are viable. The Minneapolis team is currently exploring the option of using two LiteGait harnesses (Figure 10). We have identified one of these LiteGait harnesses, which could be retrofitted for the SciFit treadmill, but the uneven walkway treadmill would require a custom-built one. Fortunately, clinical staff at the Minneapolis VA have expressed interest in using the uneven treadmill, and are exploring the option of using clinical funds to purchase a LiteGait harness system both for this study and for future clinical use (clinical use would be entirely separate from this study and the investigative team). If these harnesses don't prove feasible for this study, the Minneapolis team plans to build custom harnesses so that they can be ready for human subjects testing once mechanical testing is wrapped up. They have the know-how to enable this option.



Figure 10. A LiteGait harness set up over a SciFit treadmill.

We have completed several practice sessions of the human subjects testing protocol at VAPSHCS to train research personnel and resolve any challenges that arise during practice. For the study visits that use the multiaxial PFE, we have fit a staff team member with the PFE attached to a walking boot with an adapter (Figures 11-13). We have been able to test the updates to the PFE controller while walking with the PFE in different prosthetic foot conditions across different walking activities (i.e., level treadmill, uneven treadmill) (Figures 11-13). We also made modifications to our hardware for creating the cross-slope conditions to improve stability and safety after the practice runs.



Figure 11. A team member wearing the PFE and a lift shoe while walking on the SciFit treadmill during a protocol practice run.

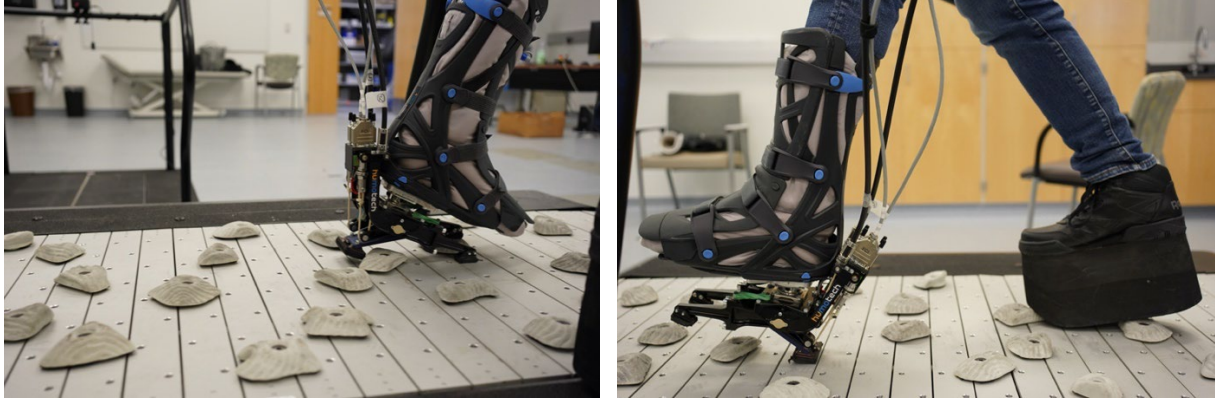


Figure 12. A team member wearing the PFE and a lift shoe while walking on the Woodway uneven treadmill.

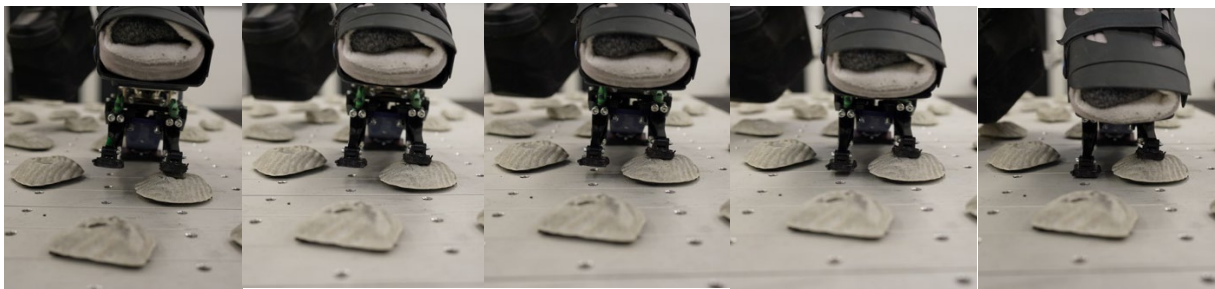


Figure 13. The PFE toe pads successfully deflecting as the wearer steps on one of the rocks on the Woodway uneven treadmill.

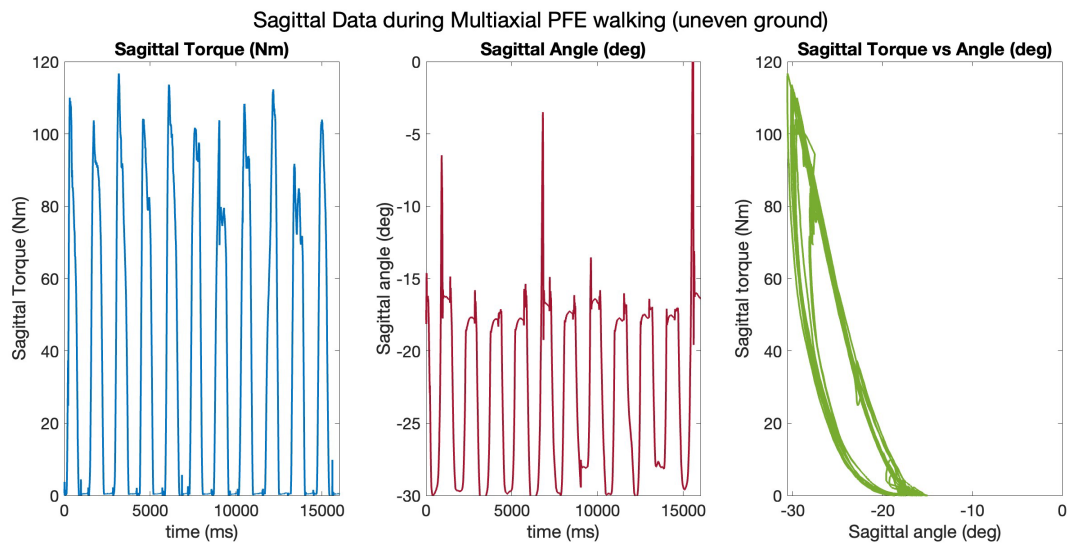


Figure 14. Data collected with Humotech GUI during walking on uneven treadmill (above), showing sagittal torque vs angle behavior of the multi-axial PFE during walking.

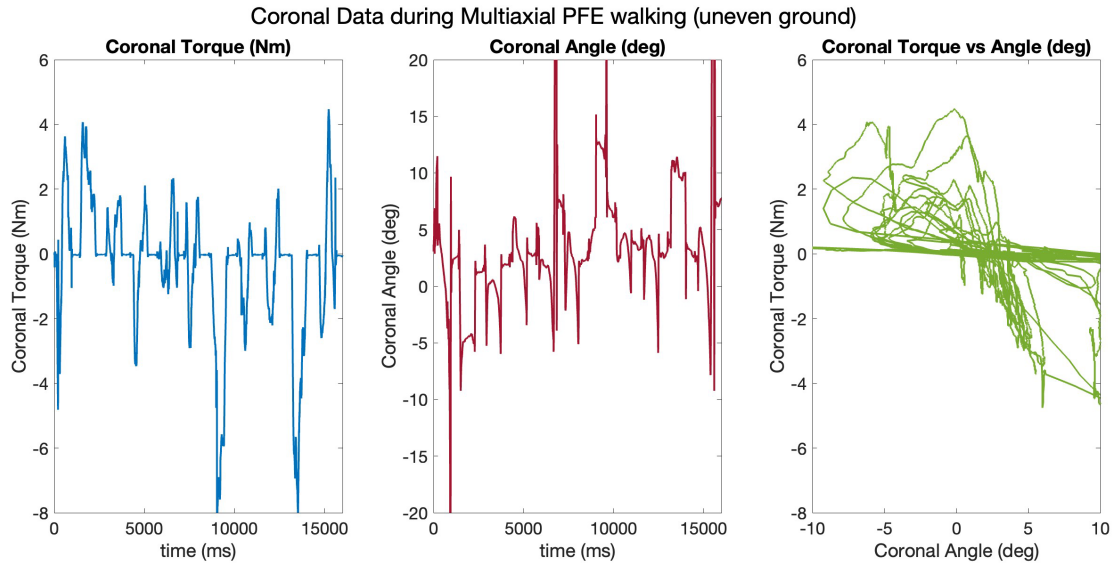


Figure 15. Data collected with Humotech GUI during walking on uneven treadmill (above), showing coronal torque vs angle behavior of the multiaxial PFE during walking.

Following the practice runs, we also confirmed the motion capture marker set that we will be using during study visits to collect human subjects' kinetics and kinematics (Figure 16). In addition, we confirmed that the cross-slope jack stands (which were fabricated during the previous reporting year) will safely and accurately allow us to change the coronal angle of the treadmill for the "cross-slope" walking conditions. We also discovered several places in our IRB-approved documents (i.e., protocol and surveys) that needed to be modified for consistency after going through the practice runs of the human subjects protocol. For example, there were discrepancies between the protocol and informed consent documents and formatting issues that would make it challenging for participants to read. Therefore, we have made edits to the VA CIRB PISC application documents accordingly (as described above). Based on the results from these practice runs, we will be able to efficiently and safely run participants through the protocol with both the multiaxial PFE and the commercial prosthetic feet.

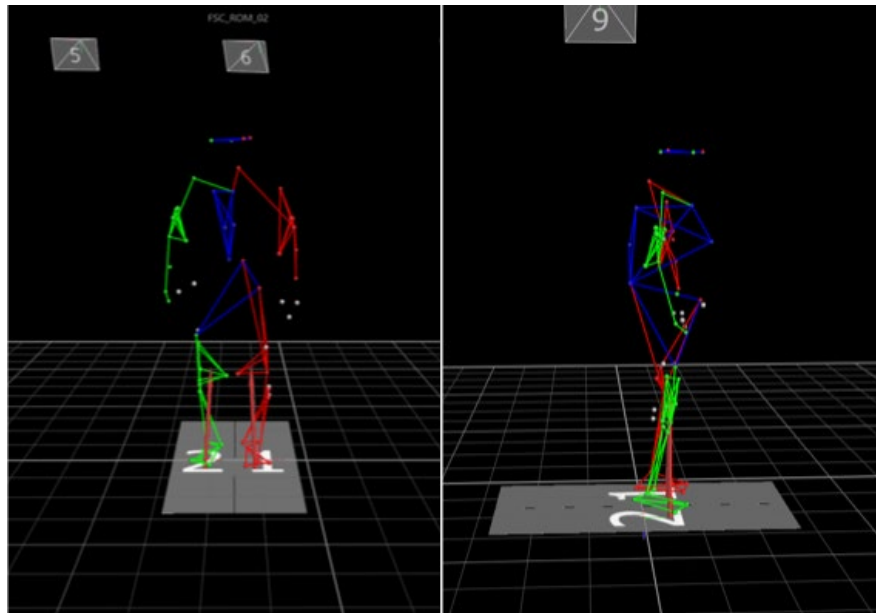


Figure 16. Final motion capture retroreflective marker set to be used for human subjects data collection protocol.

With all of the accomplishments detailed above, we are preparing to start human subjects testing in the coming months (projecting October) at the Seattle study site. We expect that we will be able to enroll initial human participants that wear the sizes of prosthetic feet on which we have already collected and validated mechanical testing data (which are more commonly used sizes) and begin collecting human subjects data as we finish collecting and validating mechanical testing of the remaining sizes in parallel (noting that we are almost finished with mechanical testing). Working on both of these tasks in tandem will give us the opportunity to resolve any problems that arise early in human subjects testing before we move into exclusively focusing on the human subjects phase of this study. We also expect that the lessons we learned from the first few human subjects trials will be very beneficial for the efficiency of testing at the Minneapolis study site when they begin enrolling participants.

During the first quarter of this reporting year, we designed and fabricated a set of capacitive touch sensor devices that can directly record a signal in our motion capture software when participants contact the handrails of the treadmills. This data is important because it will help us to identify any steps taken during the time that participants are in contact with the safety bars because one of the main outcomes of interest in this study is the margin of stability. The margin of stability is affected by the body center of mass trajectory, so any time that participants are touching the safety bars, it will render their margin of stability data inaccurate. During this same period, we identified several important challenges to the use of these touch sensors. Primarily, we required an interface that can attach to the handrails and to which a touch sensor can connect. As such, these interface devices need to be conductive, safe (i.e. no sharp edges but also secure), and easily moveable, since these treadmills are shared amongst several different research groups. We shipped a set of the touch sensor devices to the Minneapolis site during the third quarter of this year and discussed options for interface devices in our meetings. During the third and fourth quarters of this year, we have developed plans for these interface devices that will be cost-effective

and customized for each treadmill. Also, importantly, these devices were designed to secure to the rails, so that they would not move, which maintains the stability of the safety bars, while still allowing us to collect the information necessary. At the time of writing this report, these devices are currently being fabricated in Minneapolis, where they will be shipped to Seattle before the start of human subjects testing.

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

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report (we have not yet disseminated results).

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

If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

1. Complete mechanical testing of prosthetic feet to characterize the torque vs. angle profiles in the coronal and sagittal plane for input to the multiaxial prosthetic foot emulator
 - (a) All high mobility feet have been collected, as well as most low mobility feet. We expect to have all mechanical testing done within the upcoming reporting period.
2. Continued purchase of necessary research equipment and supplies

3. Obtain approval for IRB documents modification prior to initiating data collection from human participants at both Seattle and Minneapolis sites
4. Begin recruitment and enrollment of human subjects and human subjects data collection

4. IMPACT: *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

- 5. CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:*

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to report.

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

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Actual:

The study team has encountered and resolved repeated COVID-19 related problems during prior reporting periods which have delayed progress but not changed the overall project plan. During this reporting year, we faced several new problems and delays, and the study team worked to resolve them and/or mitigate the impact on our progress. In July 2022, Talia Ruxin (the Seattle site Research Coordinator) left the study in order to begin medical school (at UCSF, one of the top medical schools in the country where she maintains an interest in limb loss rehabilitation inspired by her work on this and the previously funded OPORP projects) and Tyler Ho was hired to fill the vacancy. The hiring process and subsequent training of Mr. Ho took significant time as expected with any new hire. Because Elizabeth Halsne (the Seattle site Research Prosthetist) was on parental leave for the latter part of 2022, Tyler Ho was not hired until January 2023. This was done to preserve research funds as he would not have been able to get up to speed on mechanical testing protocols without guidance from Dr. Halsne. As such, the Seattle site made substantially less progress between September 2022 and January 2023. During this time the Seattle site PI worked with

the Minneapolis VA closely to get their infrastructure in place for human subjects testing. However, in the months since January 2023, exponential progress has been made in developing mechanical testing protocols and collecting data from prosthetic feet.

Similarly, we experienced some slow-down at the Minneapolis study site when Sara Koehler-McNicholas (site PI) and Alexandria Lloyd (Research Coordinator) both went on parental leave in the spring and early summer of 2023.

An unexpected problem that slowed down mechanical testing at the Seattle site this year was an error in measuring the CoP by the RGS (described in more detail above). This added a few weeks of work in the spring, as we attempted to resolve this error. Since then, we have been able to work around this error and begun collecting mechanical data with an improved in-line load cell. Though this error delayed progress in mechanical testing for several weeks, we now have a greater confidence in our data moving forward because of the extra validation this process required.

Another unexpected and significant delay we experienced this reporting year was due to the unexpected departure of Humotech's lead software engineer. In his absence, Humotech and the Seattle site research team have increased the frequency of our meetings (now weekly) to continue refining code for the PFE controller and mechanical testing analysis software.

Anticipated:

The Minneapolis site may experience some slowdown this upcoming quarter, as Dr. Koehler-McNicholas will be periodically taking some parental leave (she did not use all of her parental leave during this past reporting year).

The Seattle site also anticipates that some learning opportunities are likely to present themselves as we begin human subjects testing. We have planned to start with one participant, so that we can make note of and solve any problems that arise before we bring in additional participants. Though this choice is likely to slow down the early phases of human subjects testing, a cautious approach will pay off later, as we will have time to solve these problems before we get to the bulk of testing (to ensure accuracy of results as well as safety of our participants).

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

The approved budget for Year 1+Year 2+Year 3 of this project is \$1,623,452 total costs. Expenditures at the close of the current budget period are estimated at \$1,172,219 total costs. This is an estimate because the July invoicing period ends after August so some July expenses are still outstanding. The \$451,233 difference between the budget and expenses at the end of Year 3 reflects the delays in completing mechanical testing and beginning

human participant data collection. \$239,832 of this balance is obligated to subawards but not yet invoiced. Most of the remaining funds are earmarked for increased staff support in Year 4 to make rapid progress against the project's approved goals once mechanical testing is complete. We anticipate substantial portions of both the prime and subaward budgets will be available to devote to the remaining human subjects testing activities as all major equipment has now been purchased. Expenditures at the Seattle and Minneapolis sites are delayed but there is no significant change to the overall spending plan for the project. We were able to address the RGS mechanical challenges faced this year with VA-based infrastructure funds, so the solution did not detract from the available support for this project.

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

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

Nothing to report.

Significant changes in use of biohazards and/or select agents

Nothing to report.

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report.

- **Website(s) or other Internet site(s)**
List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report.

- **Technologies or techniques**
Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to report.

- **Inventions, patent applications, and/or licenses**
Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products**
Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the

understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Name: David Morgenroth, MD

Project Role: PI

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 4.8 calendar months

Contribution to Project: As PI, Dr. Morgenroth has led study team meetings, coordinated with Humotech on PFE design and delivery discussions, worked with study staff on local mechanical testing approvals in place, had primary responsibility for all DoD reporting, and documentation, overseen work on protocol finalization and submissions of continuing reviews and other relevant documents to the VA Central IRB, overseen mechanical testing, overseen preparations for human subjects testing, and led team meetings.

Funding Support: Partial VA contributed effort and partial University of Washington IBS support (grant-paid)

Name: Tyler Ho

Project Role: Study Coordinator

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 6.9 calendar months

Contribution to Project: Drafted and revised all documents relevant to the submission of continuing reviews to the VA Central IRB, to the VA R&D Committees, and to OHRO, coordinated submission of any other relevant documents or amendments, scheduled

multisite team meetings and ongoing meetings with Humotech. Assisted in equipment preparation and mechanical testing of commercial prosthetic feet.

Name: Elizabeth Halsne, PhD

Project Role: Research Prosthetist / Co-Investigator

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 5.4 calendar months

Contribution to Project: Dr. Halsne went on parental leave from late August 2022 until the beginning of January 2023. After returning, she led equipment preparation and mechanical testing of commercial prosthetic feet to inform design of prosthetic foot emulator heels for future use in human subjects data collection. Assisted with submission of the human subjects protocols and modifications to the VA Central IRB and OHRO. Participated in meetings with investigators regarding human subject testing protocol, and participated in ongoing meetings with Humotech to inform procedures for inputting mechanical testing of prosthetic feet data to the PFE. Dr. Halsne's expanded role in this project is reflected in a revised Statement of Work (April 2023) approved by the DOD including her as a Co-Investigator with proposed 2.4 calendar months effort commitment to those duties.

Name: Andrew Sawers

Project Role: co-I

Researcher Identifier (e.g. ORCID ID): 0000-0002-3493-304X

Nearest person month worked: 1

Contribution to Project: Dr. Sawers participated in meetings as scheduled. Based on his expertise and previous research in balance and falls, he has contributed to the project by providing recommendations for the assessment and measurement of balance and falls in the lab and community among lower limb amputees via:

- Providing feedback and expertise on the design, implementation, and use of the "touch sensor" to instrument the handrails of the treadmill and infer stability/balance control.
- Providing feedback and expertise on the proposed reduced marker sets for kinematic data collection.
- Reviewing and summarizing the literature on the perception of stability, and the role of the upper extremities in balance recovery.
- Presenting alternative motion capture solutions (e.g., OpenCap).

Name: Sara Koehler-McNicholas, PhD

Project Role: Subaward PI

Researcher Identifier (e.g. ORCID ID): 0000-0002-7201-3607

Nearest person month worked: 1

Contribution to Project: Dr. Koehler-McNicholas has overseen all activities performed at the Minneapolis VA site. Most of the work performed during this project year has involved regulatory approvals and changes, attending monthly planning meetings, ordering equipment and supplies, installing/training with Humotech, and setting up the laboratory space that will be used for data collection. During this reporting year, Dr. Koehler-McNicholas went on parental leave from March 2023 until July 2023. Her role as site PI was

covered by Dr. Andrew Hansen, Co-Investigator, at levels of effort below the reporting threshold.

Name: Alexandria Lloyd

Project Role: Study Coordinator

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 4

Contribution to Project: Ms. Lloyd has performed work in the area of study initiation and set-up, including drafting and submitting regulatory documents to the IRB and OHRO committees, generating study documents, ordering supplies, and assisting with the delivery and set-up of equipment for data collection (e.g., installing motion analysis cameras, delivery and set-up of treadmills, software installation, etc.). Ms. Lloyd has also participated in monthly project meetings and helped train new staff on the. Ms. Lloyd also went on parental leave during this reporting year starting in June 2023.

Name: Rachel Steiner

Project Role: Study Coordinator

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 3

Contribution to Project: Ms. Steiner has assisted with regulatory documents to the IRB and OHRO committees, generating study documents, ordering supplies, and has helped with building/procuring a harnessing system for the treadmill equipment to be used in the study. Ms. Steiner has also participated in monthly project meetings.

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

If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Dr. Morgenroth has two new "Current" projects this year, highlighted in yellow on the Previous Current Pending Support page attached in the Appendix. "The AMPREDICT PROsthetics Decision Support Tool: using evidence to guide appropriate prosthetic prescription and rehabilitation plan" and "Impact of Improving Footwear Options for Women Veterans with Amputations" are new.

Dr. Halsne has not had changes in her Current support since submitting her Previous Current Pending Support document for the first time in April 2023 as part of her addition as a Co-Investigator.

Dr. Sawers has submitted a new Previous Current Pending Support document with changes highlighted in yellow in the attached Appendix. There are two new Current projects, “ASCENT K2: Assessing outcomes with microprocessor knee utilization in a K2 population”, and “Fall-related health outcomes in lower limb prosthesis users: a pragmatic clinical trial to assess effectiveness of microprocessor-controlled prosthetic knees.”

Dr. Koehler-McNicholas has submitted a new Previous Current Pending Support document with changes highlighted in yellow highlighted in yellow in the attached Appendix. There is one new Current project, “Impact of Improving Footwear Options for Women Veterans with Amputations”, and an extension of the end date of “Improving Footwear Options for Women and Men Veterans with Amputations”.

Dr. Andrew Hansen has submitted a new Previous Current Pending Support document. He has not indicated any changes.

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner’s contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner’s facilities for project activities);*
- *Collaboration (e.g., partner’s staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and*
- *Other.*

Minneapolis VA Health Care System (MVAHCS)

Center for Veterans Research and Education

One Veterans Drive

Minneapolis, MN 55417-2309

Site PI: Sara Koehler-McNicholas (SKM)

Investigator: Andrew Hansen (AH)
Staff: MVAHCS Study Staff (SS) includes Research Coordinator and Research Prosthetist
Contribution: in-kind support, facilities, collaboration
Role: Subawardee as per proposal

University of Illinois at Chicago (UIC)

Department of Kinesiology 502A
1919 W. Taylor Street (AHSB)
Chicago, IL 60612

Investigator: Andrew Sawers (AS)

*Note that UIC is not a human subjects data collection site.

Contribution: Collaboration. Aids in study methodology and survey development.

Role: Subawardee as per proposal

Human Motion Technologies LLC

U-PARC Building A2
630 William Pitt Way
Pittsburgh, PA 15238

Consultants: Joshua Caputo

Role: Vendor as per proposal, designing and manufacturing the multi-axial prosthetic foot emulator.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ebrap.org/eBRAP/public/index.htm> for each unique award.*

There are no Partnering PIs involved in this project.

QUAD CHARTS: *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil/Pages/Resources.aspx>) should be updated and submitted with attachments.*

Quad chart is attached as an appendix on page 32.

- 9. APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

A Prosthetic Foot Test-Drive Strategy for Improving Stability and Falls-Related Outcomes in Veterans with Leg Amputations

OP190048 / W81XWH-20-1-0291



PI: David Morgenroth, MD **Org:** Seattle Institute for Biomedical and Clinical Research

Award Amount: \$2,000,000

Study/Product Aim(s)

- Determine the effects of commercial prosthetic feet of varying stiffness on stability and falls-related outcomes in Service members and Veterans with transtibial amputation (TTA)
- Determine whether a multi-axial prosthetic foot emulator can be used to predict stability and balance-confidence outcomes with corresponding commercial prosthetic feet in Veterans with TTA
- Determine whether a brief trial of commercial prosthetic feet can predict longer-term stability and balance-confidence outcomes in Veterans with TTA

Approach

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



Accomplishment: We 95% completed with mechanical testing and have been readying the study for beginning human subjects testing including running through the study protocol (as shown here – team member walking with PFE and simulator boot).

Timeline and Cost

Activities	Budget Year	20-21	21-22	22-23	23-24
Obtain Human Subjects approvals					
Mechanical testing of prosthetic feet					
Human subjects data collection					
Data analysis and results dissemination					
Estimated Budget (\$2M)		\$859K	\$397K	\$367K	\$377K

Goals/Milestones (Example)

CY20-21 Goal – Study preparation and Institutional approvals

- ☒ Obtain R&D Committee approval for non-human subjects work
- ☒ Develop and finalize self-report questionnaire packets and data spreadsheet
- ☒ Obtain human subjects approval Initiate mechanical testing of prosthetic feet and emulator fabrication

CY21-22 Goals – Completion of mechanical testing, emulator delivery, and initiation of human subjects testing

- ☐ Complete mechanical testing of prosthetic feet and emulator fabrication
- ☐ Recruit participants and conduct human subjects data collection

CY22-23 Goal – continued human subjects testing and preliminary analyses

- ☐ Continue human subjects data collection
- ☐ Analyze preliminary data set for dissemination at scientific meetings

CY23-24 Goal – Completion of testing, analysis and dissemination

- ☐ Finalize human subjects data collection
- ☐ Analyze final data set and disseminate findings

Comments/Challenges/Issues/Concerns: There have been COVID-related delays in the custom hardware and software development work which have delayed project progress.

Budget Expenditure to Date

Budget: \$2,000,000. Actual Expenditure: \$1,172,219

Updated: 08/31/2023

CURRENT/PENDING/PREVIOUS SUPPORT

MORGENROTH, DAVID

ACTIVE/CURRENT:

Title: A Prosthetic Foot Strategy for Improving Stability and Falls-Related Outcomes in Veterans with Lower Limb Loss (W81XWH-20-1-0291/OP190048)

Role in Project: Principal Investigator

Time Commitment: 40%

Performance Period: 8/1/2020 – 7/31/2024

Level of funding:

Supporting Agency: Department of Defense Congressionally Directed Medical Research Programs, Orthotics and Prosthetics Outcomes Research Program, Prosthetics Outcomes Research Award, Clinical Trial Award, Level 2

Name and address of funding agency's Contracting/Grants Officer:

Grants Specialist: Ebony S. Simmons

Assistance Agreement Branch Email: usarmy.detrick.medcom-usamraa.mbx.aa1@mail.mil

U.S. Army Medical Research Acquisition Activity

820 Chandler Street

Fort Detrick, MD 21702

Brief Description of Project's Goals: The purpose of this project is to assess the effects of commercially available prosthetic feet of varying stiffness on stability and balance-related outcomes in Veterans with TTA, and to assess a test-drive strategy for predicting stability and balance-confidence outcomes with corresponding commercial prosthetic feet.

Specific Aims:

Specific Aim 1: Determine the effects of commercially available prosthetic feet of varying stiffness on stability and balance-related outcomes in Veterans with TTA. *Specific Aim 2:* Determine whether a multi-axial prosthetic foot emulator can be used to predict stability and balance-confidence outcomes with corresponding commercial prosthetic feet in Veterans with TTA. *Specific Aim 3:* Determine whether a brief trial of commercial prosthetic feet can predict longer-term stability and balance-confidence outcomes in Veterans with TTA.

Overlap: None

Title: Optimizing Ankle-Foot Orthotic Prescription Using an Emulation Test-Drive Strategy

Role in Project: Site Principal Investigator

Time Commitment: 10% (project years 1 and 5), 15% (project years 2-4)

Proposed Project Period: 9/30/2021 – 9/29/2025

Level of funding: project total costs (anticipated local subaward total costs) **Supporting Agency:** Department of Defense Congressionally Directed Medical Research Programs, Orthotics and Prosthetics Outcomes Research Program, Clinical Trial Award, Level 2

Name and address of funding agency's Contracting/Grants Officer:

Assistance Agreement Group

Department of the Army

US Army Medical Research Acquisition Activity

820 Chandler Street

Fort Detrick, MD 21702

Brief Description of Project: *Specific Aim 1:* Test the ability of the exoskeleton emulator to reproduce the user experience of wearing commercially-available AFOs during different activities in individuals with lower limb

musculoskeletal injury. *Specific Aim 2:* Test the ability of a short-term, in-laboratory evaluation of function, mobility, and preference to predict those same outcomes longer-term in AFO users with lower limb musculoskeletal injury. *Specific Aim 3:* Allow the user to self-tune emulator settings while walking (patient-optimized) and compare function, mobility, preference, and walking economy to the clinically prescribed AFO (clinician-optimized).

Overlap: None

Title: Impact of Improving Footwear Options for Women Veterans with Amputations

Role in Project: Investigator

Time Commitment: 5%

Performance Period: 04/01/2023 – 03/31/2026

Level of Funding:

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

Brief Description of Project's Goals: This project will assess the impact of a new prosthesis system including a modular prosthetic ankle that can be used interchangeably with several 3D-printed feet. The prosthetic feet are customized to fit a wide range of footwear, including shoes of different heel heights and widths. To change footwear, the user simply removes the prosthetic ankle from one foot-shoe combination and connects it to another, without the need for tools or modifications to the prosthetic alignment. This new prosthesis system dramatically improves footwear options for persons using leg prostheses, enabling potential to increase body image and community participation for women Veterans with leg amputations.

Overlap: None

Title: VA RR&D Center for Limb Loss and Mobility (1I50 RX002357)

Role in Project: Investigator

Time Commitment: No specific effort committed

Performance Period: 10/1/2012 - 9/30/2027

Level of Funding:

Supporting Agency: VA Puget Sound Health Care System Center Grant

Name and address of funding agency's Contracting/Grants Officer:

Shirley Groer, PhD

Scientific Program Manager

Brief Description of Project's Goals: The primary mission of our VA RR&D Center for Limb Loss and MoBility (CLiMB) is to improve the quality of life and functional status of veterans who are at risk for lower extremity amputation, and veterans and service members who have undergone lower extremity amputation.

Overlap: None

Title: The AMPREDICT PROsthetics Decision Support Tool: using evidence to guide appropriate prosthetic prescription and rehabilitation plan

Role in Project: Investigator

Time Commitment: No specific effort committed

Performance Period: 10/1/2022 – 9/30/2023

Level of Funding:

Supporting Agency: VA Puget Sound Health Care System Seed Grant

Name and address of funding agency's Contracting/Grants Officer:

William A. Banks, MD

ACOS for Research, VA Puget Sound Health Care System

1660 S. Columbian Way

Seattle, WA 98108

Brief Description of Project's Goals: The purpose of this study is to 1) Determine prescribing providers' informational needs; 2) Develop a beta web-based decision support tool using the prediction model coefficients, results of the qualitative interviews, and iterative expert panel input; and 3) Evaluation the content, structure and usability, and potential implementation obstacles of the beta web-based decision support tool using a mixed methods approach using a qualitative approach.

Overlap: None

PREVIOUS (WITHIN PAST 5 YEARS):

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

Role in Project: Principal Investigator

Time Commitment: 50% to August 31, 2020

15% from September 1, 2020 to August 31, 2021

Performance Period: September 1, 2016 – August 31, 2021

Level of Funding:

Supporting Agency: Department of Defense CDMRP/Orthotics and Prosthetics Outcomes Research Program

Name and address of funding agency's Contracting/Grants Officer:

Chris Meinberg MBA, OPM LEAD (Leadership Education & Development)

Grants Specialist

Assistance Agreements, Branch 1

U.S. Army Medical Research Acquisition Activity

820 Chandler Street

Fort Detrick, MD 21702

Brief Description of Project's Goals: The overall goal 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.

Specific Aims: 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. 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. Exploratory Aim: Determine potential barriers and facilitators to the inclusion of a patient-centered 'test-drive' component to clinical prosthetic foot prescription.

Overlap: None.

Title: Improving Footwear Options for Veterans with Amputations

Role in Project: Investigator

Time Commitment: 5%

Performance Period: 07/01/2018 – 06/30/2022

Level of Funding:

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

Brief Description of Project's Goals: 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.

Specific Aims: Develop a prosthetic ankle-foot system that improves footwear options for female and male Veterans with amputations.

Overlap: None

Title: The Evaluation and Redesign of Transmetatarsal Prosthetics to Reduce Peak Plantar Pressures (R21HD095516)

Role in Project: Investigator

Time Commitment: 2.5%

Performance Period: 8/30/2018 – 7/31/2022

Level of Funding:

Supporting Agency: National Institutes of Health, R21HD095516

Name and address of funding agency's Contracting/Grants Officer:

Louis Quatrano, PhD

National Center for Medical Rehabilitation Research

NICHHD/NIH

6710B Rockledge Drive, Room 2114 MSC 7002

Bethesda, MD 20892

Brief Description of Project's Goals: This project's goal is to evaluate the plantar pressures and stiffness of current prosthetic componentry for transmetatarsal amputees, and to develop a new design approach to reduce those pressures.

Specific Aims:

Primary Aim: Evaluate and optimize the design of TMA prosthetic components (forefoot stiffness and toe-flex) to reduce peak plantar pressures in diabetic dysvascular participants with TMA.

Secondary Aim: Improve participant functional measures and reported outcomes by optimizing toe-flex design.

Overlap: None.

Title: VA RR&D Center for Limb Loss and Mobility (1I50 RX002357)

Role in Project: Investigator

Time Commitment: No specific effort committed

Performance Period: 10/1/2017 - 9/30/2022

Level of Funding:

Supporting Agency: VA Puget Sound Health Care System Center Grant

Name and address of funding agency's Contracting/Grants Officer:

Shirley Groer, PhD

Scientific Program Manager

Brief Description of Project's Goals: The primary mission of our VA RR&D Center for Limb Loss and MoBility (CLiMB) is to improve the quality of life and functional status of veterans who are at risk for lower extremity amputation, and veterans and service members who have undergone lower extremity amputation.

Overlap: None

Title: Patient-centered prosthesis prescription for Veterans with leg amputation

Role in Project: Co-Principal Investigator

Time Commitment: No specific effort committed

Performance Period: 10/1/2021 – 9/30/2022

Level of Funding:

Supporting Agency: VA Puget Sound Health Care System Seed Grant

Name and address of funding agency's Contracting/Grants Officer:

William A. Banks, MD

ACOS for Research, VA Puget Sound Health Care System

1660 S. Columbian Way

Seattle, WA 98108

Brief Description of Project's Goals: The Specific Aims of this study are 1. To determine how prosthetic foot stiffness affects experiential foot preference for Veterans with lower limb amputation across a range of mobility activities, and 2. To assess how stiffness affects foot-ankle biomechanics.

Overlap: None

PENDING:

Title: The AMPREDICT PROsthetics Decision Support Tool: using evidence to guide personalized prosthetic prescription and rehabilitation planning

Role in Project: Investigator

Time Commitment: 5%

Performance Period: 10/01/2023– 09/30/2026

Level of Funding:

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

Brief Description of Project's Goals: Specific Aim 1: Determine LEA patients' and rehabilitation clinicians' informational needs at the time of LLP prescription and associated clinical implementation barriers/facilitators through a qualitative assessment, including the timing and preferred mode (e.g., electronic health record, external website, app) of receiving a future prosthesis user's predicted mobility level to best aid in LLP decision-making, rehabilitation planning, and expectation setting.

Specific Aim 2: Develop a beta web-based DST (*AMPREDICT PRO DST*), with a printable handout feature, using the *AMPREDICT PRO* prediction model coefficients and results of the qualitative interviews with iterative expert panel input.

Specific Aim 3: Evaluate the content, structure, and usability of the beta web based *AMPREDICT PRO DST*, and complimentary printable output, using a mixed methods approach that will combine a qualitative "think aloud" approach and a quantitative assessment.

Specific Aim 4: Modify and finalize the web based *AMPREDICT PRO DST* through expert panel input utilizing the results of the qualitative and quantitative results from the usability testing.

Overlap: None

Title: A Prospective, Pivotal Study to Characterize the Efficacy and Safety of a Percutaneous Osseointegrated Prosthesis

Role in Project: Investigator

Time Commitment: 12.5%

Performance Period: 10/01/2023– 09/30/2029

Level of Funding:

Supporting Agency: United States Department of Veterans Affairs, Cooperative Studies Program

Name and address of funding agency's Contracting/Grants Officer:

Grant Huang, MPH, PhD

Director, Cooperative Studies Program

Brief Description of Project's Goals: Primary Objectives:

The first co-primary objective is to compare the 12-month success rate based on the Q-TFA Problem Score in participants randomized to a control optimized socket (SOCKOPT) arm to participants randomized to the POP intervention. The second co-primary objective is to evaluate the safety and efficacy at 24 months of the POP device as compared to an a priori determined performance goal.

Overlap: None

IN-KIND:

None

CURRENT POSITIONS AND APPOINTMENTS:

See Biosketch for Details

- Staff Physician, Veteran Affairs Puget Sound Health Care System (VAPSHCS)
- Core Investigator, VA RR&D Center for Limb Loss and Mobility (CLiMB), Seattle, WA
- Professor, Dept of Rehab Medicine, Univ of Washington, Seattle, WA
- Vice Chair for Research, Dept of Rehab Medicine, Univ of Washington, Seattle, WA
- Associate Program Director, Amputee Rehabilitation Fellowship, VAPSHCS, Seattle, WA
- Member, Seattle Institute for Biomedical and Clinical Research

The following statements assure:

- I certify that the current and pending support provided here is current, accurate, and complete;
- I agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award;
- I have been made aware of these disclosure requirements as required under Section 223(a)(1) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (<https://www.govinfo.gov/content/pkg/PLAW-116publ283/pdf/PLAW-116publ283.pdf>).
- I am aware that false, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (218 USC 1001).

Signature:



David Morgenroth, MD

June 9, 2023

Date

KOEHLER-McNICHOLAS, SARA

PREVIOUS (last 5 years):

I01-RX002267 (Koehler-McNicholas & Hansen) 12/01/2017-12/31/2021 (NCE) 4.8 calendar months Y1
U.S. Department of Veterans Affairs, VA RR&D 3.6 calendar months Y2
Total direct cost: 1.2 calendar months Y3-4

Role: Co-Principal Investigator

Brian Schultz, PhD, VA Rehabilitation Research & Development Service, Bethesda, MD

Development of a Foot-Ankle Prosthesis to Improve Physical Therapy Outcomes

The primary aim of this proposal is to develop a prosthetic foot-ankle system that can be adjusted by a physical therapist to gradually increase ankle ROM as the patient learns to stand and walk with the prosthesis. To achieve the primary aim of this study, we will address the following subtasks:

- *Subtask 1:* Implement design improvements that optimize the standing and walking performance of the foot-ankle system, allow for easy ROM adjustments (i.e., minimal extra training or tools), and offer a method of tracking ROM adjustments so that therapists can document the patient's progress.
- *Subtask 2:* Conduct ISO 10328 mechanical testing to establish structural stability for human subject testing.
- *Subtask 3:* Perform human subject testing to assess the standing and walking performance of the device and obtain feedback to guide design modifications.
- *Subtask 4:* Design a standardized physical therapy protocol, based on patient and clinical feedback, which can be used in a future multi-site clinical trial of the fully developed foot-ankle system.
- *Subtask 5:* Implement an appropriately scoped quality management system to document design criteria, reduce overall development costs, and increase the likelihood of technology transfer.

No overlap with the current project exists.

90BISB0010-01-00 (Wernke) 09/30/2018-09/29/2021 (NCE) 0.6 calendar months Y1
NIDILRR, SBIR Phase II 3.0 calendar months Y2

Total direct cost (Minneapolis VA):

Role: Site Principal Investigator

Thomas Corfman, NIDILRR, Washington, DC

The Bimodal Ankle for Mobility and Stability of Prosthesis Users

The overall objective of the proposed project is to develop a novel Bimodal Ankle Prosthesis (BAP) that can modulate between the appropriate roll-over shapes for walking and standing.

- *Aim 1:* Develop the Bimodal Ankle Prosthesis incorporating the hydraulic cylinder that allows a curved rocker shape during gait and a flat rocker shape during standing.
- *Aim 2:* Ensure the safety of the Bimodal Ankle Prosthesis using industry standard mechanical testing procedures.
- *Aim 3:* Collect objective and subjective data from lower-extremity prosthesis users wearing the Bimodal Ankle Prosthesis.

No overlap with the current project exists.

Industry-sponsored (Koehler-McNicholas) 07/01/2018-12/31/2020 2.4 calendar months Y1
RxFunction, Inc. 1.2 calendar months Y2-3

Total direct cost:

Role: Site Principal Investigator

Lars Oddsson, CTO, RxFunction, Inc, Eden Prairie, MN

walk2Wellness: Long-term Use Effects of walkasins® Wearable Sensory Prosthesis on Gait Function, Balance-Confidence, and Social Participation

The purpose of this study is to investigate the long-term effects of walkasins® use on clinical and subject-reported outcomes of balance and gait function, quality of life, physical activity/participation, pain, and medication use in persons with peripheral neuropathy who experience balance problems.

- *Aim:* Pool data from five sites for use in submission to CMS for walkasins® HCPCS code application. No overlap with the current project exists.

W81XWH-17-C-0005 (Myers) 11/04/2016-11/03/2020 (NCE) 1.8 calendar months Y2
U.S. Department of Defense, CDMRP 1.2 calendar months Y3
Total direct cost (Minneapolis VA): 3.0 calendar months Y4

Role: Site Principal Investigator

Jason Ghannadian, MS, Congressionally Directed Medical Research Programs, Fort Detrick, MD

Development of Moisture Management Liner and Active Cooling System for Improving Residual Limb Skin Care

This project will create an active cooling system for residual limb sockets.

- *Aim 1:* Refine system conceptual design, including: (a) refine and optimize the intrasocket cooling element and (b) improve socket integration procedures and expand the indicated population.
- *Aim 2:* Finalize design under quality system and produce devices for clinical validation.
- *Aim 3:* Perform validation testing via laboratory and take-home trials.
- *Aim 4:* Prepare for commercialization.

No overlap with the current project exists.

W81XWH-11-2-0222 (Schnall) 04/01/2015-09/30/2018 (NCE) 1.8 calendar months Y1
U.S. Department of Defense, BADER Consortium, CDMRP through University of Delaware
Total cost (Minneapolis VA):

Role: Co-Investigator

Steven Stanhope, PhD, BADER Consortium, Newark, DE

Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower-Limb Amputations

The goal of this project is to gain a better understanding of K4 prosthetic feet and their effects on K4-level transtibial prosthesis users.

- *Aim 1:* Determine mechanical characteristics and durability of current prosthetic feet intended for highly functional transtibial prosthesis users.
- *Aim 2:* Compare the biomechanical and functional outcomes between prosthetic feet with linear and non-linear mechanical properties during weighted walking and high-intensity activities.

No overlap with the current project exists.

I01-RX001514 (Hansen) 10/01/2014-09/30/2018 (NCE) 4.8 calendar months Y1
U.S. Department of Veterans Affairs, VA RR&D 2.4 calendar months Y2-3

Total direct cost:

Role: Co-Investigator

Brian Schulz, PhD, VA Rehabilitation Research & Development Service, Bethesda, MD

Development of Adaptive Prosthetic Ankle-Foot Systems

This project will examine the advantages of a new adaptable ankle-foot prosthesis that can adapt to different terrain on every step of walking using only passive mechanical parts (i.e., without the need for motors or batteries). This new system also provides plantarflexion in the late stance phase of walking, which should increase the efficiency of walking.

- *Development Aim:* Perform mechanical tests of the adaptable ankle-foot system and refine the design to improve durability.
- *Aim 1:* Test the adaptable ankle-foot system in Veterans to assess slope adaptation.
- *Aim 2:* Test the adaptable ankle-foot system in Veterans to determine its ability to reduce submaximal oxygen uptake during walking.

No overlap with the current project exists.

CDMRP #OR130393 (Hansen) 09/30/2014-09/29/2018 (NCE) 1.8 calendar months Y1-2
U.S. Department of Defense 0.6 calendar months Y3

Total direct cost:

Role: Co-Investigator

Miriam Darnell, PhD, Congressionally Directed Medical Research Programs, Fort Detrick, MD

Improving Energy Return and Residual-Limb Climate in Prostheses for High-Functioning Amputees

The objective of this work is to establish the feasibility for prosthetic sockets with passive ventilation properties, allowing for improved socket climate for high functioning military amputees.

- *Aim 1:* Develop and test a new socket connection system to open up the distal end of the socket for passive ventilation.
- *Aim 2:* Develop and test sockets with passive ventilation properties.

No overlap with the current project exists.

P2CHD086841 (Hauck)

04/01/2017-03/31/2018

1.2 calendar months

NIH/TREAT

Total cost:

Role: Site Principal Investigator

Ralph Nitkin, PhD, National Institute of Child Health and Human Development, Bethesda, MD

Evaluation of a Novel Gait Training Device Using a Pressurized Lower Body Suit to Support Body Weight

The purpose of the present study is to investigate the ability of the Lite Run device to provide more efficient rehabilitation and improve therapy for MVAHCS patients with gait disorders.

- *Aim 1:* To compare the efficiency and labor requirements of Lite Run with the standard harness lifts used for gait training at the MVAHCS (e.g., ceiling lift, Lite Gait).
- *Aim 2:* To compare the effectiveness of treatment using Lite Run to the standard harness lifts used for gait training at the MVAHCS.

No overlap with the current project exists.

W81XWH-17-C-0086 (Sears)

10/01/2017-03/30/2018

0.4 calendar months

U.S. Department of Defense, STTR Phase I

Total cost:

Role: Co-Investigator

CAPT Joseph Cohn, Defense Health Agency, Falls Church, VA

Biomimetic Slope Adaptive Foot-Ankle Prosthesis

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.

- *Aim 1:* Finalize specifications for the Phase I foot-ankle system.
- *Aim 2:* Fabricate and assemble the Phase I foot-ankle system.
- *Aim 3:* Test and demonstrate the Phase I foot-ankle system.

No overlap with the current project exists.

University-sponsored (Silver-Thorn)

01/01/2017-12/31/2017

0.8 calendar months

Marquette University College of Engineering Legacy Initiative Grant

Total cost:

Role: Consultant

Brian Schmit, Marquette University, Milwaukee, WI

Dynamic EMG Control of Powered Below Knee Prostheses

The purpose of this study is to confirm preliminary findings that indicate that myoelectric control of transtibial and transfemoral prostheses is possible for lower limb amputees.

- *Aim 1:* Refine prosthetic socket designs to incorporate surface EMG electrodes (e.g., discs, foil and conductive fabric electrodes). While many surface EMG electrode options exist, comfortable within-socket EMG sensing requires thin, low profile electrodes.

No overlap with the current project exists.

5R44AG040865 (Leach)	04/01/2016-09/30/2017	2.8 calendar months
NIH/NIA		
Total cost (Minneapolis VA):		
Role: Site Principal Investigator		
Lyndon Joseph, PhD, National Institute on Aging, Bethesda, MD		
A Wearable “Balance Booster” – Stepping Closer to the Market: Peripheral Neuropathy and Balance Function in the Veteran Population		
The purpose of this study is to investigate the impact of Walkasins, an external lower limb sensory prosthesis, on the balance and gait of people with sensory peripheral neuropathy who also experience balance problems.		
• <i>Aim 1:</i> Revise and finalize design of Walkasins based on accomplishments, user input, as well as reviewer criticism from our Phase 1 grant and manufacture 200 units of the device for clinical testing. • <i>Aim 2:</i> In a double-blind randomized control trial, investigate effects of using Walkasins on clinical outcomes related to gait, balance function and associated fall risk in a hospital-based outpatient rehabilitation program.		
No overlap with the current project exists.		
I01-RX001531 (Hansen)	04/01/2014-03/31/2017	4.8 calendar months Y1-2
U.S. Department of Veterans Affairs, VA RR&D		3.6 calendar months
Y3 Total direct cost:		
Role: Co-Investigator		
Timothy J. Brindle, PhD, VA Rehabilitation Research & Development Service, Bethesda, MD		
Bimodal Prosthetic Ankle-Foot System for Improved Balance and Mobility		
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.		
• <i>Aim 1:</i> Determine if static postural stability can be improved with the use of a flat effective rocker shape compared with a curved effective rocker shape. • <i>Aim 2:</i> Determine if dynamic postural stability can be improved with the use of a flat effective rocker shape compared with a curved effective rocker shape. • <i>Aim 3:</i> Determine if functional postural stability can be improved with the use of a flat effective rocker shape compared with a curved effective rocker shape.		
No overlap with the current project exists.		
MVMREF 2014 (Koehler-McNicholas)	02/01/2015-01/31/2017	0.0 calendar months
Minnesota Veterans Medical Research and Education Foundation		
Total direct cost:		
Role: Principal Investigator		
JoAnn Tallman, Acting Executive Director,		
Development of a Prosthetic Ankle to Improve Physical Therapy Outcomes for Veterans with Lower-Limb Amputations		
The purpose of this research study is to design and test a novel prosthetic ankle-foot system that can be adjusted by a physical therapist to gradually increase the range of motion of the ankle as the patient learns to stand and walk with the prosthesis.		
• <i>Aim 1:</i> Design an adjustable ankle-foot system that offers different ranges of ankle motion. • <i>Aim 2:</i> Develop a mobile app that can control the range of motion of the new ankle-foot system. • <i>Aim 3:</i> Characterize the mechanical properties of the new ankle-foot system during level walking.		
No overlap with the current project exists.		

CURRENT:

D4256-R (Hansen) 01/01/2023-12/31/2025 2.4 calendar months Y1-3

U.S. Department of Veterans Affairs, VA RR&D

Total cost:

Role: Co-Investigator

TBD Program Officer

Impact of Improving Footwear Options for Women Veterans with Amputations

The goal of this study is to assess the impact of a new prosthesis system including a modular prosthetic ankle that can be used interchangeably with several 3D-printed feet. The study will test the hypotheses that improving footwear options with the new prosthesis system will improve body image and participation in women Veterans with amputations.

- *Aim 1:* Assess the impact of improving footwear options on amputee-specific body image.
- *Aim 2:* Assess the impact of improving footwear options on participation.
- *Aim 3:* Explore the benefits and barriers to use of the UNYQ ankle-feet system.

No overlap with the current project exists.

W81XWH-22-10362 (Fatone) 09/01/2022-08/31/2025 2.4 calendar months Y1-3

University of Washington (U.S. Department of Defense, CDMRP OPORP-CTA)

Total direct cost (Minneapolis VA):

Role: Site Principal Investigator

Jason D. Kuhns, Grants Officer, 820 Chandler Street, Fort Detrick, MD 21702-5014

Evaluation of the Northwestern University Sub-Ischial Socket for Persons with Transfemoral Amputation and Lower Mobility Levels

The objective of this project is to assess use and benefits of the sub-ischial socket for persons with transfemoral amputation and lower mobility levels.

- *Aim 1:* To evaluate whether the NU Sub-Ischial Socket is more comfortable than the standard-of-care ischial containment (IC) socket in persons with transfemoral amputation and lower mobility levels.
- *Aim 2:* To evaluate whether the NU Sub-Ischial Socket improves wear time, mobility and participation compared to the IC socket.
- *Aim 3:* To evaluate whether the NU Sub-Ischial Socket improves health-related quality of life (HRQL), skin-related HRQL, and satisfaction with device (i.e., the prosthetic socket) compared to the IC socket.

No overlap with the current project exists.

W81XWH-20-0197 (Hafner) 09/30/2020-09/29/2024 1.2 calendar months

University of Washington (U.S. Department of Defense, CDMRP OPORP)

Total direct cost (Minneapolis VA):

Role: Site Principal Investigator

Tracy Behrsing, PhD, 1053 Patchel St, Fort Detrick, MD 21702

Fall-Related Health Outcomes in Lower Limb Prosthesis Users: A Pragmatic Clinical Trial to Assess Effectiveness of Microprocessor-Controlled Prosthetic Knees

The purpose of this study is to determine if and how microprocessor- and non-microprocessor-controlled prosthetic knee technologies influence fall-related health outcomes in limited community ambulators.

- *Aim 1:* Develop self-report item banks, short forms, and computerized adaptive tests to measure fall-related self-efficacy and fall-related interference in life activities in lower limb prosthesis users.
- *Aim 2:* Assess the construct validity and test-retest reliability of fall-related instruments in lower limb prosthesis users relative to similar surveys, performance-based tests, and sensors.
- *Aim3:* Apply fall-related instruments in a pragmatic clinical trial to assess whether provision of a microprocessor-controlled prosthetic knee (MPK) improves fall-related health outcomes relative to a standard-of-care NMPK in limited community ambulators

No overlap with the current project exists.

W81XWH-20-0783 (Myers) 09/01/2020-08/31/2024 0.6 calendar months Y1
Vivonics, Inc. (U.S. Department of Defense, CDMRP OPORP) 3.6 calendar months Y2-3
Total direct cost (Minneapolis VA): 1.2 calendar months Y4

Role: Site Principal Investigator

Jason Ghannadian, PhD, U.S. Army Medical Research & Material Command, Fort Detrick, MD

Clinical Effectiveness of Intrasocket Cooling on Incidence and Severity of Dermatological Conditions in Lower Limb Amputees

The objective of the proposed program is to investigate the hypothesis that the clinically relevant intra-socket cooling delivered by the ICE system can reduce the incidence rate of skin conditions that occur on the residual limb of lower limb amputees and improve the dermatological quality of life by a clinically and statistically significant degree as measured by the Dermatology Life Quality Index (DLQI) via a 2x2 crossover clinical trial.

- *Aim 1:* Finalize the trial requirements and manufacture clinical trial systems.
- *Aim 2:* Execute 2x2 crossover clinical trial (N=44).
- *Aim 3:* Analyze and report results of clinical trial.

No overlap with the current project exists.

W81XWH-20-0291 (Morgenroth) 08/01/2020-07/31/2024 0.6 calendar months Y1
SIBCR (U.S. Department of Defense, CDMRP OPORP) 1.2 calendar months

Y2-4 Total direct cost (Minneapolis VA):

Role: Site Principal Investigator

Tracy Behrsing, PhD, 820 Chandler St, Fort Detrick, MD 21702

A Prosthetic Foot Test-Drive Strategy for Improving Stability and Falls-Related Outcomes in Veterans with Leg Amputations

The proposed work will assess the relationship between prosthetic foot mechanical properties and stability and balance-related outcomes. This will include testing the ability of a multiaxial prosthetic foot emulator to accurately reproduce the experience of wearing actual prosthetic feet. We will test whether trying different emulated or actual feet for a brief period in the laboratory can accurately predict longer-term dynamic balance and perceived stability after wearing each foot in the community for two weeks.

- *Aim 1:* Determine the effects of commercial prosthetic feet of varying stiffness on stability and falls-related outcomes in Veterans with transtibial amputation (TTA).
- *Aim 2:* Determine whether a multiaxial prosthetic foot emulator can be used to predict stability and balance-confidence outcomes with corresponding commercial prosthetic feet in Veterans with TTA.
- *Aim 3:* Determine whether a brief trial of commercial prosthetic feet can predict longer-term stability and balance-confidence outcomes in Veterans with TTA.

Current project.

W81XWH-18-C-0314 (Iversen) 07/27/2018-05/04/2024 0.6 calendar months Y1-2
Fillauer Motion Control (U.S. Department of Defense, STTR Phase II/TRL Booster) 2.4 calendar months
Y4-5 Total direct cost (Minneapolis VA):

Role: Co-Investigator

CAPT Joseph Cohn, Defense Health Agency, Falls Church, VA

Biomimetic Slope Adaptive Foot-Ankle Prosthesis

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.

- *Aim 1:* Slope adaptive prosthesis design update.
- *Aim 2:* Structural and durability testing of the slope adaptive prosthesis.
- *Aim 3:* Human subjects testing of the slope adaptive prosthesis.
- *Aim 4:* Design changes in response to structural, durability and human subjects testing.

No overlap with the current project exists.

I01-RX002634 (Hansen) 07/01/2018-09/30/2023 2.4 calendar months Y1
U.S. Department of Veterans Affairs, VA RR&D 1.8 calendar months Y2
Total direct cost: 2.4 calendar months Y3

Role: Co-Investigator

Brian Schultz, PhD, VA Rehabilitation Research & Development Service, Bethesda, MD

Improving Footwear Options for Women and Men Veterans with Amputations

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.

- *Aim 1:* Develop a prosthetic ankle with a distal attachment system for connection to custom prosthetic feet.
- *Aim 2:* Develop a digital foot model that can be adapted for different footwear.
- *Aim 3:* Develop a process for fabricating custom prosthetic feet from the digital foot model.
- *Aim 4:* Use mechanical testing (ISO 10328) to identify structural weaknesses and iteratively improve system.
- *Aim 5:* Iteratively improve the design of the system with feedback from Veterans.

No overlap with the current project exists.

PENDING:

TBD (Hansen and Krebs) 10/01/2023-09/30/2028 3.0 calendar months Y1-5

U.S. Department of Veterans Affairs, VA RR&D

Total direct cost:

Role: Associate Director

Rehabilitation & Engineering Center for Optimizing Veteran Engagement & Reintegration (RECOVER)

The mission of RECOVER is to maximize Veteran participation in important lifelong roles and activities through development, evaluation, and clinical translation of practical rehabilitation interventions and technologies. Since barriers to participation may change as Veterans with disabilities age or experience other life events, RECOVER aims to identify and help Veterans adapt to these changes. RECOVER's work focuses on the needs of Veterans with amputations and Veterans with spinal cord injuries and disorders (SCID), with cross-cutting emphases on (1) pain, discomfort, and secondary complications, and (2) aging with a disability.

No overlap with the current project exists.

OVERLAP:

There is no scientific or budgetary overlap between these projects.

Previous/Current/Pending Support
Halsne, Elizabeth

Employment

Research Prosthetist, Seattle Institute for Biomedical Clinical Research, Seattle, WA

Scientific appointments

Investigator, Center for Limb Loss and Mobility, VA Puget Sound Health Care System, Seattle, WA

Affiliate Assistant Professor, Department of Rehabilitation Medicine, University of Washington, Seattle, WA

CURRENT

W81XWH-20-1-0291 (Morgenroth)

Performance Period: 08/01/2020-07/31/2024

Time Commitments: Proposed 2.4 calendar months effort commitment under review

Total Award Amount:

Role: Co-Investigator and Research Prosthetist

Supporting Agency: Department of Defense

Name and Address of the Funding Agency's Procuring Contracting/Grants Officer: Ebony S. Simmons,
820 Chandler Street, Fort Detrick MD 21702

Title of the Project: A prosthetic foot test-drive strategy for improving stability and falls-related outcomes in Veterans with leg amputations

Major Goals: The purpose of this project is to assess the effects of commercially available prosthetic feet of varying stiffness on stability and balance-related outcomes in Veterans with transtibial amputation (TTA), and to assess a test-drive strategy for predicting stability and balance-confidence outcomes with corresponding commercial prosthetic feet.

Specific Aims:

- *Aim 1:* Determine the effects of commercially available prosthetic feet of varying stiffness on stability and balance-related outcomes in Veterans with TTA.
- *Aim 2:* Determine whether a multiaxial prosthetic foot emulator can be used to predict stability and balance-confidence outcomes with corresponding commercial prosthetic feet in Veterans with TTA.
- *Aim 3:* Determine whether a brief trial of commercial prosthetic feet can predict longer-term stability and balance-confidence outcomes in Veterans with TTA.

Overlap: No overlap with the current project.

W81XWH-21-10169 (Darter)

Performance Period: 07/01/2021-06/30/2025

Time Commitments: 2.40 calendar months

Total Award Amount:

Role: Research Scientist

Supporting Agency: Department of Defense

Name and Address of the Funding Agency's Procuring Contracting/Grants Officer: Amanda Coldren,
CPO, 1053 Patchel St, Fort Detrick MD 21702

Title of the Project: Exploring the impact of microprocessor-controlled knees on prosthesis awareness and overall health

Major Goals: The purpose of this study is to develop a new patient report measure of prosthesis awareness to complement the existing Prosthetic Limb Users Survey of Mobility (PLUS-M) and facilitate a more comprehensive and holistic assessment of prosthesis user functioning.

Specific Aims:

- *Aim 1:* Develop an item bank to measure prosthesis awareness (PLUS-A).
- *Aim 2:* Examine the psychometric properties (i.e., reliability and validity) of the PLUS-A instruments.

- *Aim3*: Track the impact of knee prosthesis technology on prosthesis awareness and health trajectories.

Overlap: No overlap with the current project.

PENDING

OP220020 (Darter)

Performance Period: 09/25/2023-09/24/2027

Time Commitments: 1.80 calendar months

Total Award Amount:

Role: Co-Investigator

Supporting Agency: Department of Defense

Name and Address of the Funding Agency's Procuring Contracting/Grants Officer: TBD Scientific Officer, 1053 Patchel St, Fort Detrick MD 21702

Title of the Project: Comparing the attentional demands and functional outcomes of pattern recognition and direct myoelectric control in people with transradial amputation

Major Goals: The goal of the proposed research is to evaluate the impact of pattern recognition control of an upper limb prosthetic relative to one with direct control.

Specific Aims:

- *Aim 1*: Perform a randomized crossover clinical trial to evaluate the effect of using an upper limb prosthesis with a PRC on attentional demand, and function relative to 2-site DC.
- *Aim 2*: Identify potential clinical or demographic predictors of response to the myoelectric control strategies to determine which patients will be appropriate and will benefit most from a PRC device.
- *Aim 3*: Validate measures of prosthesis attention and function in upper limb users.

Overlap: No overlap with the current project.

PREVIOUS

W81XWH-15-1-0458 (Hafner)

Performance Period: 09/01/2015-08/31/2018

Time Commitments: 1.20 calendar months

Total Award Amount:

Role: Graduate research assistant

Supporting Agency: Department of Defense

Name and Address of the Funding Agency's Procuring Contracting/Grants Officer: Jessica Clement, MS, 1053 Patchel St, Fort Detrick MD 21702

Title of the Project: A novel prosthetic foot designed to maximize functional abilities, health outcomes, and quality of life in people with transtibial amputation

Major Goals: The purpose of this study is to evaluate endurance, energy expenditure, gait quality, perceived function, satisfaction, and walking activity of transtibial users walking with a modified running-specific prosthetic foot (mRSF) and a conventional energy-storing prosthetic foot (ESF). A randomized crossover study, will be conducted to compare the walking performance and efficiency of a prosthesis with a novel mRSF to a prosthesis with a traditional ESF.

Specific Aims:

- *Aim 1*: Evaluate functional activity outcomes (i.e., energetics, gait quality, and community mobility) in transtibial prosthesis users walking with a conventional ESF and the mRSF.
- *Aim 2*: Assess patient-centered health outcomes (i.e., self-reported mobility, fatigue, balance confidence, activity restrictions, and satisfaction) in transtibial prosthesis users walking with a conventional ESF and the mRSF.

Overlap: No overlap with the current project.

R01HD079428 (Hargrove)

Performance Period: 09/06/2014-09/19/2018

Time Commitments: 2.40 calendar months

Total Award Amount:

Role: Research Prosthetist

Supporting Agency: NIH/NICHD

Name and Address of the Funding Agency's Procuring Contracting/Grants Officer: Louis A. Quatrano, PhD, 10 Center Dr, Bethesda, MD 20814

Title of the Project: Adaptive recalibration of a prosthetic leg neural control system

Major Goals: The purpose of this study is for transfemoral amputees to walk with an experimental robotic prosthesis. Electric signals will be measured from their muscles and used to help control an artificial leg. The investigators will record from sensors placed on a prosthesis and electric signals measured from muscles in the participants leg to see if the investigators can develop better computer programs to help predict subject actions and prostheses function.

Specific Aims:

- *Aim 1:* Develop a gait-pattern estimator to robustly label prior ambulation modes following correct or incorrect control system predictions.
- *Aim 2:* Identify an effective method to update the pattern recognition control system for prediction of ambulation modes.
- *Aim 3:* Evaluate a real-time adaptive neural control system using pattern recognition in 12 transfemoral amputees.

Overlap: No overlap with the current project.

5R01HD081525 (Kuiken)

Performance Period: 09/20/2014-12/31/2019

Time Commitments: 2.40 calendar months

Total Award Amount:

Role: Research Prosthetist

Supporting Agency: NIH/NICHD

Name and Address of the Funding Agency's Procuring Contracting/Grants Officer: Louis A. Quatrano, PhD, 10 Center Dr, Bethesda, MD 20814

Title of the Project: Application of targeted reinnervation for people with transradial amputation

Major Goals: The goal of this multicenter study is to develop surgical techniques for transradial targeted muscle reinnervation (TMR) and to evaluate the benefits of TMR in transradial amputees by performing clinical trials to compare pattern recognition control, before and after TMR, with a conventional control strategy (before TMR).

Specific Aims:

- *Aim 1:* Perform targeted muscle reinnervation surgery (TMR) for transradial amputees by transferring median nerve to flexor digitorum superficialis muscle and ulnar nerve to flexor carpi ulnaris muscle.
- *Aim 2:* Evaluate prosthesis control of multifunction myoelectric prosthesis for transradial amputees combining targeted muscle reinnervation surgery and pattern recognition control compared to the standard of care, direct control prosthesis.

Overlap: No overlap with the current project.

W81XWH-16-1-0569 (Morgenroth)

Performance Period: 08/15/2016-08/14/2021

Time Commitments: 6.00 calendar months

Total Award Amount:

Role: Research Prosthetist

Supporting Agency: Department of Defense

Name and Address of the Funding Agency's Procuring Contracting/Grants Officer: Tracy Behrsing, PhD, 1053 Patchel St, Fort Detrick MD 21702

Title of the Project: A prosthetic foot emulator to optimize prescription of prosthetic feet in veterans and service members with leg amputations

Major Goals: The objective of this research is to enhance the prosthetic foot prescription process through use of a prosthetic foot emulator that mimics the behavior of a range of commercial prosthetic feet. A participant-blinded study will be conducted to determine if we can successfully assess and predict users' preferences and mobility outcomes using the emulator.

Specific Aims:

- *Aim 1:* 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.
- *Aim 2:* 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 transtibial amputation.
- *Aim 3:* Determine potential barriers and facilitators to the inclusion of a patient-centered 'test-drive' component to clinical prosthetic foot prescription.

Overlap: No overlap with the current project.

Seed Grant (Morgenroth/Halsne)

Performance Period: 10/1/2021-09/30/2022

Time Commitments: 2.40 calendar months

Total Award Amount:

Role: Co-Principal Investigator

Supporting Agency: VA Puget Sound Health Care System Research & Development

Name and Address of the Funding Agency's Procuring Contracting/Grants Officer: William Banks, MD, 1660 S. Columbian Way Seattle, WA 98108

Title of the Project: Patient-centered prosthesis prescription for Veterans with leg amputations

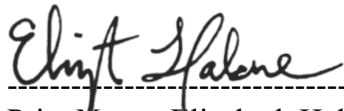
Major Goals: The purpose of this project is to assess how prosthetic foot stiffness affects experiential foot preference for Veterans with lower limb amputation across a range of in-laboratory mobility activities.

Overlap: No overlap with the current project.

The following statements assure:

- I certify that the current and pending support provided here is current, accurate, and complete;
- I agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award;
- I have been made aware of these disclosure requirements as required under Section 223(a)(1) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (<https://www.govinfo.gov/content/pkg/PLAW-116publ283/pdf/PLAW-116publ283.pdf>).
- I am aware that false, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (218 USC 1001).

Signature:



Print Name: Elizabeth Halsne

6/15/23

Date:

CURRENT/PENDING/PREVIOUS SUPPORT

HANSEN, ANDREW

CURRENT

Title: Impact of Mobile Manual Standing Wheelchair on Standing Dosage and Utility

PI: Andrew H. Hansen, PhD and B. Jenny Kiratli, PhD

Role in Project: Co-Principal Investigator

Time Commitment: 20%

Performance Period: 10/01/2021 – 09/30/2025

Level of Funding:

Supporting Agency: United States Department of Veterans Affairs, Rehabilitation Research and Development Service

Name and address of funding agency's Contracting/Grants Officer:

Timothy Brindle, PhD

Scientific Review Officer

Brief Description of Project's Goals: This study compares the mobile manual standing wheelchair to a non-mobile manual standing wheelchair in a randomized controlled trial. The purpose of this project is to determine if the feature of mobility-in-standing will increase utility and self-selected standing doses in Veterans with SCI.

Specific Aims: Aim 1 – Assess the utility of the mobile manual standing wheelchair (MMSW) compared with a non-mobile manual standing wheelchair (NMMSW) during home/community use. Aim 2 – Assess the daily self-selected standing dose (duration and frequency) of Veterans with SCI when using the MMSW compared with a NMMSW and their baseline standing activity. Aim 3 – Explore associations between standing dose (duration and frequency) and various health outcomes.

Overlap: None.

Title: Impact of Improving Footwear Options for Women Veterans with Amputations

PI: Andrew H. Hansen, PhD

Role in Project: Principal Investigator

Time Commitment: 10%

Performance Period: April 1, 2023 – March 31, 2026

Level of Funding:

Supporting Agency: United States Department of Veterans Affairs, Rehabilitation Research and Development Service

Name and address of funding agency's Contracting/Grants Officer: TBD

Brief Description of Project's Goals: This project will assess the impact of a new prosthesis system including a modular prosthetic ankle that can be used interchangeably with several 3D-printed feet. The prosthetic feet are customized to fit a wide range of footwear, including shoes of different heel heights and widths. To change footwear, the user simply removes the prosthetic ankle from one foot-shoe combination and connects it to another, without the need for tools or modifications to the prosthetic alignment. This new prosthesis system dramatically improves footwear options for persons using leg prostheses, enabling potential to increase body image and community participation for women Veterans with leg amputations.

Specific Aims: Aim 1 – Assess the impact of improving footwear options on amputee-specific body image. Aim 2 – Assess the impact of improving footwear options on participation. Aim 3 – Explore the benefits and barriers to use of the UNYQ ankle-feet system.

Overlap: None.

Title: Comparative Effect of Commercially Available Custom Dynamic Orthoses

PI: Jason Wilken, PhD PT

Role in Project: Site Principal Investigator

Time Commitment: 10%

Performance Period: 09/21/2018 – 09/20/2023

Level of Funding: (Minneapolis VA total costs)

Supporting Agency: Department of Defense, CDMRP

Name and address of funding agency's Contracting/Grants Officer: Jason Kuhns, 820 Chandler Street, Fort Detrick, MD 21702-5014

Brief Description of Project's Goals: The objective of this research is to provide first of its kind comparative effectiveness data for commercially and clinically available CDOs, and identify factors most strongly associated with device preference and function. Our efforts primarily focus on outcomes associated with the form, fit and resulting function with the devices.

Specific Aims: Aim 1: Determine the comparative effect of custom dynamic orthosis type in individuals with limb impairment resulting from traumatic limb injury. Aim 2: Determine if study-provided custom dynamic orthoses improve function relative to no device and standard clinical care conditions, in individuals with impairment resulting from traumatic limb injury. Aim 3: Identify factors that are associated with device preference and function.

Overlap: None

Title: Multi-Speed Ergonomic Wheelchair

PI: John M. Looft, PhD and Andrew H. Hansen, PhD

Role in Project: Co-Principal Investigator

Time Commitment: 5%

Performance Period: April 1, 2023 – March 31, 2026

Level of Funding:

Supporting Agency: United States Department of Veterans Affairs, Rehabilitation Research and Development Service

Name and address of funding agency's Contracting/Grants Officer: TBD

Brief Description of Project's Goals: The objectives of this proposed work are to (1) explore the effect of different gearing options on Veteran wheelchair user steady-state propulsion efficiency, and (2) develop a multi-speed ergonomic wheelchair allowing for lower gears during difficult situations (initiating movements, moving over carpeting) and higher gears for steady-state movements on flat surfaces.

Specific Aims: Aim 1: Explore the effect of different gearing options on Veteran wheelchair user steady-state propulsion efficiency. Aim 2: Develop, test, and refine a multi-speed ergonomic wheelchair with input from Veteran wheelchair users.

Overlap: None.

Title: Improving Footwear Options for Women and Men Veterans with Amputations

PI: Andrew H. Hansen, PhD

Role in Project: Principal Investigator

Time Commitment: 5%

Performance Period: 07/01/2018 – 09/30/2022

Level of Funding:

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

Brief Description of Project's Goals: 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.

Specific Aims: Develop a prosthetic ankle-foot system that improves footwear options for female and male Veterans with amputations.

Overlap: None.

Title: Biomimetic Slope Adaptive Foot-Ankle Prosthesis – TRL Booster

PI: Edward Iversen, MEME and Andrew H. Hansen, PhD

Role in Project: Subcontract Principal Investigator

Time Commitment: 5%

Performance Period: 01/05/2022 – 01/04/2024

Level of Funding: (subcontract Y1)

Supporting Agency: Department of Defense

Name and address of funding agency's Contracting/Grants Officer: TBD

Brief Description of Project's Goals: The goal of this study is to continue the development of 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. This project will allow advancement of a TRL level to more advanced and commercially viable prototypes, as well as data collection from take-home trials to support the commercialization efforts.

Specific Aims: The aims of this project include further development by Motion Control and take-home testing by the Minneapolis VA Health Care System.

Overlap: None.

Title: Comparative Effectiveness of Socket Casting Methods: Improving Form and Fit

PI: Stefania Fatone, PhD BPO (Hons)

Role in Project: Site Principal Investigator

Time Commitment: 5%

Performance Period: 09/30/2019-09/29/2022

Level of Funding: (Minneapolis VA total costs)

Supporting Agency: Department of Defense, CDMRP

Name and address of funding agency's Contracting/Grants Officer: TBD

Brief Description of Project's Goals: The overall objective of this project is to compare hand casting to standing hydrostatic pressure casting with regards to consistency and efficiency of residual limb shape capture, socket fit and comfort in persons with lower limb amputation.

Specific Aims: Aim 1: To compare the consistency of two residual limb shape capture techniques in persons with transtibial and transfemoral amputation. Aim 2: To compare the efficiency of two residual limb shape capture techniques in persons with transtibial and transfemoral amputation. Aim 3: To compare the outcomes of two residual limb shape capture techniques and the preferred socket in persons with transtibial and transfemoral amputation.

Overlap: None

Title: Hybrid Electrical-Mechanical pump for Vacuum Suspension of Prosthetic Sockets

PI: Matthew Major, PhD

Role in Project: Co-Investigator

Time Commitment: 5%

Performance Period: 04/01/2020 – 09/30/2024

Level of Funding: (RRD) +

Supporting Agency: United States Department of Veterans Affairs, Rehabilitation Research and Development Service with supplement from VA Technology Transfer Program (BRAVE funding)

Name and address of funding agency's Contracting/Grants Officer:

Brian Schulz, PhD

Scientific Review Officer

Brief Description of Project's Goals: The purpose of this research and development project is to further design and evaluate a hybrid vacuum pump device that integrates electrical and mechanical systems to produce vacuum-assisted suspension of lower limb prosthetic sockets.

Specific Aims: N/A

Overlap: None.

Title: Socket Fit Sensing and Management System

PI: Benjamin McDonald

Role in Project: Site Principal Investigator

Time Commitment: 5%

Performance Period: 10/01/2020-09/30/2024

Level of Funding: (site total)

Supporting Agency: Department of Defense - RESTORE

Name and address of funding agency's Contracting/Grants Officer: TBD

Brief Description of Project's Goals: This project will advance a socket fit sensing system originally developed at the Minneapolis VA. This project will advance the system to include other suspension types (e.g., pin suspension) and will include larger subject testing in the laboratory and in the home/community.

Specific Aims: 1) Refine and optimize the SFSS prototype to be applicable to a robust and durable system in preparation for take-home pre-clinical testing. 2) Enhance and confirm robustness of the socket fit detection algorithms on a larger population of subjects with a range of socket/suspension types (e.g. suction suspension, pin-lock, etc.) and user characteristics (e.g. age, activity level, limb shape/length, etc.) over a variety of different ambulatory tasks (e.g. ramps, stairs, different speeds, etc.). 3) Evaluate effectiveness of the SFSS system to assist amputees in the self-management of prosthetic socket fit through the use of prosthetic socks and generate pilot data to power a future clinical trial. 4) Iterate and prepare the SFSS for regulatory approvals and commercialization tasks.

Overlap: None.

Title: Caregiver Assist Folding Ergonomic Wheelchair

PI: Andrew H. Hansen, PhD

Role in Project: Principal Investigator

Time Commitment: 5%

Performance Period: September 1, 2021 – August 31, 2023

Level of Funding:

Supporting Agency: Clinical and Translational Science Institute, University of Minnesota

Name and address of funding agency's Contracting/Grants Officer:

Sandra M. Wells, Ph.D.

Assistant Director

Office of Discovery and Translation

Clinical and Translational Science Institute

University of Minnesota

717 Delaware Street SE, Room 214

Minneapolis, MN 55414

Brief Description of Project's Goals: The goal of this project is to further develop the caregiver assist folding ergonomic wheelchair, including creating a more modular system that can be easily attached when needed and detached when not needed for weight reduction. We will also create a new folding ergonomic wheelchair frame that is optimized for our chain-drive design and that accepts the modular caregiver assist system.

Specific Aims: Aim 1 – Stakeholder interviews with senior wheelchair users and their caregivers. Aim 2 – Develop next generation Caregiver Assist Folding Ergonomic Wheelchair.

Overlap: None.

Title: Technology Transfer Assistance Program (TTAP)
PIs: Rory Cooper, PhD, Ron Triolo, PhD, and Andrew Hansen, PhD
Role in Project: Site Principal Investigator
Time Commitment: 5%
Performance Period: Ongoing
Level of Funding: Varies annually
Supporting Agency: United States Department of Veterans Affairs, Technology Transfer Program
Name and address of funding agency's Contracting/Grants Officer:
Dr. John Kaplan
Director of Technology Transfer Program

Brief Description of Project's Goals: TTAP sites develop prototypes for VA inventors throughout the nation in close collaboration with Technology Transfer Specialists. Pittsburgh, Cleveland, and Minneapolis have existing engineering and design teams that can be accessed by other VA investigators and sites through this program. Prototypes developed in this program are then marketed by TechLink Center to potential industry partners for licensing.
Specific Aims: Not Applicable
Overlap: None

Title: Personalized Mobility Interventions using Smart Sensor Resources for Lower-limb Prostheses Users **PI:** Arun Jayaraman, PT, PhD
Role in Project: Co-Investigator
Time Commitment: 2%
Performance Period: 09/30/2018 – 09/29/2022
Level of Funding: (Minneapolis VA total costs)
Supporting Agency: Department of Defense, CDMRP
Name and address of funding agency's Contracting/Grants Officer: Jason Kuhns, 820 Chandler Street, Fort Detrick, MD 21702-5014
Brief Description of Project's Goals: The primary goals of the proposed work are to implement a smartphone system, together with a comprehensive toolbox of standard outcome measures and participant-reported measures to obtain a quantitative assessment of the physical and psychological factors contributing to reduced use of a prosthesis—compared to ability predicted by K-level and/or participant-stated goals.
Specific Aims: Aim: 1 Develop a strategy to determine whether a participant's prosthesis use matches assigned K-level and/or self-reported goals and, if not, determine the reason(s) using expert panels to evaluate data from performance-related measures, participant-reported measures, and data from smartphone and wearable sensors. Aim 2: Quantify effects of targeted physical intervention (prosthesis repair/refit, physical rehabilitation) or psychological intervention (motivational interviewing) on activity levels and patient goals using smartphone sensor data, outcome measures, and participant-reported measures. Aim 3: Identify best/most sensitive measures for community mobility/optimal prosthesis use as a clinical toolbox to accurately predict prosthesis use and identify problems over the long term.
Overlap: None

Title: A Prosthetic Foot Test-Drive Strategy for Improving Stability and Falls-Related Outcomes in Veterans with Leg Amputations
PI: David Morgenroth, MD
Role in Project: Co-Investigator
Time Commitment: 2%
Projected performance Period: February 1, 2020 – January 31, 2024
Level of Funding:
Supporting Agency: DoD/CDMPR/W81XWH-19-OPORP-CTA

Brief Description of Project's Goals: The proposed work will assess the relationship between prosthetic foot mechanical properties and stability and balance-related outcomes. This will include testing the ability of a multiaxial prosthetic foot emulator to accurately reproduce the experience of wearing actual prosthetic feet. We will test whether trying different emulated or actual feet for a brief period in the laboratory can accurately predict longer-term dynamic balance and perceived stability after wearing each foot in the community for two weeks.

Specific Aims:

Aim 1: Determine the effects of commercial prosthetic feet of varying stiffness on stability and falls-related outcomes in Veterans with transtibial amputation (TTA).

Aim 2: Determine whether a multiaxial prosthetic foot emulator can be used to predict stability and balance-confidence outcomes with corresponding commercial prosthetic feet in Veterans with TTA.

Aim 3: Determine whether a brief trial of commercial prosthetic feet can predict longer-term stability and balance-confidence outcomes in Veterans with TTA.

Overlap: None.

Title: Acoustic measurement of preradiographic OA using a wearable orthosis

PI: Ewart, David, MD

Role in Project: Consultant, unpaid

Time Commitment: 2%

Performance Period: 10/01/2020 – 10/31/2022

Level of Funding:

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

Brief Description of Project's Goals: The purpose of this project is to develop a knee orthosis with an integrated microphone system to use acoustic emissions from the knee to diagnose preradiographic osteoarthritis of the knee in common clinical settings.

Specific Aims: 1. Prototype and iteratively design a portable knee orthosis with an embedded microphone to measure acoustic emissions from the knee at the point of care. 2. Conduct a pilot study to use acoustic emissions to identify knees with pre-radiographic OA.

Overlap: None.

Title: Refinement of the CMAP System for Prevention of Pressure Injuries in Wheelchair Users

PI: Christine Olney, PhD RN

Role in Project: Co-Investigator

Time Commitment: 1%

Performance Period: 04/01/2020 – 03/31/2024

Level of Funding:

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

Brief Description of Project's Goals: The goal of this project is to enhance and refine the Comprehensive Mobile Assessment of Pressure (CMAP) system. We will build a docking station for, and add a smart watch to, the CMAP system. Further we will be asking therapist for feedback to develop the app to provide key

educational components when teaching persons with SCI how to use the app for optimization of pressure relieving behaviors. We will conduct in-home testing.

Specific Aims: Aim 1: Expand functionality of CMAP app system. (Years 1-2). Aim 2: Determine usability of refined CMAP system for clinician and patient use within the hospital setting. (Years 2-3). Aim 3: Determine usability and efficacy of refined CMAP system for clinician and patient use in the outpatient and home settings.

Overlap: None.

Title: Fall-Related Health Outcomes in Lower Limb Prosthesis Users: A Pragmatic Clinical Trial to Assess Effectiveness of Microprocessor-Controlled Prosthetic Knees

PI: Brian Hafner, PhD

Role in Project: Co-Investigator

Time Commitment: 1%

Projected performance Period: February 1, 2020 – January 31, 2024

Level of Funding:

Supporting Agency: DoD/CDMPR/W81XWH-19-OPORP-CTA

Brief Description of Project's Goals: The long-term goals of this project are to determine how different prosthetic technologies affect users' safety, mobility, and quality-of-life. The goal of this study is to determine whether prosthetic knee technology affects fall-related self-efficacy and fall-related interference in life activities.

Specific Aims: Aim 1: Develop self-report item banks, short forms, and computerized adaptive tests to measure fall-related self-efficacy and fall-related interference in life activities in lower limb prosthesis users. Aim 2: Assess the construct validity and test-retest reliability of fall-related instruments in lower limb prosthesis users relative to similar surveys, performance-based tests, and sensors. Aim3: Apply fall-related instruments in a pragmatic clinical trial to assess whether provision of a microprocessor-controlled prosthetic knee (MPK) improves fall-related health outcomes relative to a standard-of-care NMPK in limited community ambulators.

Overlap: None.

Title: From opinion to evidence: Multi-site evaluation of custom dynamic orthosis best practices.

PI: Jason Wilken, PhD PT

Role in Project: Site Principal Investigator

Time Commitment: 1% (Y1), 5% (Y2-Y4)

Performance Period: 09/30/2022 – 09/29/2026

Level of Funding: (subcontract total)

Supporting Agency: Department of Defense

Name and address of funding agency's Contracting/Grants Officer: TBD

Brief Description of Project's Goals: The objective of this multi-site, double-blind, randomized, crossover-controlled clinical trial is to provide data-driven guidance for CDO clinical fittings for two types of CDOs. This study leverages best available evidence, decades of combined experience, and multiple complementary measures to evaluate recommended CDO benchmark configurations relative to alternate configurations.

Specific Aims: Specific Aim 1: Determine the comparative effect of CDO configuration on patient-reported preference, perceived comfort, and smoothness in individuals with limb impairment following severe lower extremity trauma. Specific Aim 2: Determine the comparative effect of CDO configuration on biomechanical measures of limb function in individuals with limb impairment following severe lower extremity trauma. Specific Aim 3: Determine the comparative effect of CDO configuration on physical performance in individuals with limb impairment following severe lower extremity trauma.

Overlap: None.

PENDING

Title: Rehabilitation & Engineering Center for Optimizing Veteran Engagement & Reintegration (RECOVER)

PI: Andrew H. Hansen, PhD and Erin Krebs, MD, MPH

Role in Project: Director of RECOVER (Principal Investigator)

Time Commitment: 40%

Performance Period: 10/01/2023 – 09/30/2028

Level of Funding:

Supporting Agency: United States Department of Veterans Affairs, Rehabilitation Research and Development Service

Name and address of funding agency's Contracting/Grants Officer: TBD

Brief Description of Project's Goals: The mission of RECOVER is to maximize Veteran participation in important lifelong roles and activities through development, evaluation, and clinical translation of practical rehabilitation interventions and technologies. Since barriers to participation may change as Veterans with disabilities age or experience other life events, RECOVER aims to identify and help Veterans adapt to these changes. RECOVER's work focuses on the needs of Veterans with amputations and Veterans with spinal cord injuries and disorders (SCID), with cross-cutting emphases on (1) pain, discomfort, and secondary complications, and (2) aging with a disability.

Specific Aims: There are three primary research areas for RECOVER: R1 – Expanding Understanding of Participation Barriers and Facilitators, R2 – Improving Participation through Management of Pain, Discomfort, and Secondary Complications, and R3 – Maintaining Participation of Veterans as they Age and Promoting Aging-in-Place.

Overlap: None.

Title: Home-based rehabilitation intervention for phantom limb pain in Veterans with lower limb amputations

PI: Tonya Rich, PhD, OTR/L

Role in Project: Primary Mentor

Time Commitment: 5%

Performance Period: January 1, 2024 – December 31, 2028

Level of Funding:

Supporting Agency: United States Department of Veterans Affairs, Rehabilitation Research and Development Service

Name and address of funding agency's Contracting/Grants Officer: TBD

Brief Description of Project's Goals: This VA Career Development Award-2 proposal focuses on refining a mobile app for GMI (VA-GMI) and then testing serial sessions of mobile app use in a sample of Veterans with lower limb amputation and moderate to severe PLP in their home setting.

Specific Aims: Aim 1 – Conduct iterative testing of prototypes to refine the VA-GMI mobile app. Aim 2 – Assess the feasibility and acceptability of a telehealth GMI intervention using the VAGMI mobile app. Aim 3 – Explore effects of the telehealth + VA-GMI mobile app intervention on health outcomes.

Overlap: None.

PREVIOUS (last 5 years)

Title: Pediatric Mobile Standing Wheelchair for Children with Disabilities

PI: Andrew H. Hansen, PhD

Role in Project: Principal Investigator

Time Commitment: 2%

Projected performance Period: July 1, 2021 – December 31, 2022

Level of Funding:

Supporting Agency: The Pediatric Device Innovation Consortium

Name and address of funding agency's Contracting/Grants Officer:

Jodi Fenlon Rebuffoni

Sr. Program Manager

Office of Discovery and Translation and

The Pediatric Device Innovation Consortium

Clinical and Translational Science Institute

University of Minnesota

717 Delaware Street SE, 2nd Floor

Minneapolis, MN 55414

Brief Description of Project's Goals: The goals of this project are to develop a rough CAD drawing of a new pediatric mobile manual standing wheelchair, and to conduct 10 stakeholder interviews to get feedback on the drawing and this new wheelchair concept.

Specific Aims: N/A

Overlap: None.

Title: Improving Shoulder Health For Persons with SCI Through an Ergonomic Wheelchair

PI: John Looft, PhD

Role on Project: Co-Investigator

Time Commitment: 2%

Supporting Agency: Maslowski Charitable Trust

Name and Address of the Funding Agency's Procuring Contracting/Grants Officer: Frank J Maslowski and Eleanor A Maslowski Charitable Trust, 9121 Baltimore St NE, Blaine, MN 55449-4338

Performance Period: 04/01/2019 – 03/31/2022

Level of Funding:

Brief Description of Project's Goals: The purpose of the proposed project is to use bi-plane fluoroscopy and 2D/3D shape matching to directly determine the rotator cuff compression during both hand-rim positions. This information will ultimately provide direct quantitative measures of rotator cuff compression. Additionally, this project will also get direct user feedback for both hand rim positions to help with better wheelchair design for persons with SCI.

Specific Aims: Aim 1: Determine whether manual wheelchair users with spinal cord injury have reduced subacromial rotator cuff compression using the theorized optimal push rim position compared to the standard wheelchair push rim position. Aim 2: Determine if there is a reduction in shoulder muscle peak activation and co-contraction when the push rims are placed in the theoretical optimal position as part of an ergonomic wheelchair.

Overlap: None

Title: Camera System Development for Pressure Injury Screening in Veterans with SCI

PI: Christine Olney, PhD RN

Role in Project: Co-Investigator

Time Commitment: 2%

Performance Period: January 1, 2018 – June 30, 2022

Level of Funding:

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

Brief Description of Project's Goals: The long term goal is to help Veterans prevent the progression and severity of an early detected pressure injury. The short term goals are to 1) provide Veterans with SCI a more efficient and efficacious tool [camera system] to examine their at-risk skin areas; and to 2) provide a secure and efficient communication process with their health care provider or skin specialist regarding skin areas of concern.

Specific Aims: 1: Refine camera system to meet the expressed needs of the consumer, the Veteran with SCI. 2: Test and refine usability and communication between the Veteran with SCI in their home environment and our VA SCI certified wound care nurse.

Overlap: None

Title: Developing Assessments and Interventions for Phantom Limb Pain in Veterans with Amputations

PI: Tonya Rich, PhD OTR/L

Role in Project: Primary Mentor

Time Commitment: 5%

Performance Period: 05/01/2020 – 04/30/2022

Level of Funding:

Supporting Agency: United States Department of Veterans Affairs, Rehabilitation Research and Development Service

Name and address of funding agency's Contracting/Grants Officer:

Shirley Groer, PhD

Scientific Review Officer

Brief Description of Project's Goals: The goal of this career development award project is to collect fMRI in both a resting-state and during a sensory task for Veterans with and without phantom limb pain to compare functional connectivity and to lay the groundwork for development of interventions in the next phase. Patient-reported outcomes will also be compared between groups.

Specific Aim: Compare the effects of PLP on brain activation for Veterans with lower limb amputation (LLA) who do (n = 8) and do not (n = 8) experience PLP.

Overlap: None.

Title: Sensor System for Self-Management of Prosthetic Socket Fit

PI: John Ferguson (until 2020); Andrew H. Hansen, PhD (since 2020)

Role in Project: Co-Investigator (until 2020); PI (since 2020)

Time Commitment: 5%

Performance Period: August 15, 2018 – August 14, 2022

Level of Funding: (total)

Supporting Agency: Department of the Army - USAMRAA

Name and address of funding agency's Contracting/Grants Officer: Jason Kuhns, 820 Chandler Street, Fort Detrick, MD 21702-5014

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 and Service members self-manage their socket fit during post-amputation rehabilitation care. We have built and tested a prototype that can distinguish good sock fit from too many and too few socks. Our innovative device design is low cost, easy for prosthetists to build into a socket, and easy for Service members and Veterans to use on their own. This system can be used as a training and education tool during post-amputation rehabilitation care in the clinic and as a self-management tool at home.

Specific Aims: Aim 1: Refine the socket-fit sensing system; Aim 2: Test socket-fit-detection algorithms; Aim 3: Assess the system during post-amputation rehabilitation care and education

Overlap: None.

Title: Mounted Display Virtual Reality in the Treatment of Upper Extremity Function in Acute TBI Rehabilitation: A comparison study to convention OT treatment alone.

PI: Brian Fay, PhD (until 2019); Gary Goldish, MD (2019-2020); Andrew H. Hansen, PhD (since 2020)

Role on Project: Principal Investigator (since 2020)

Time Commitment: 1%

Supporting Agency: Minnesota Office of Higher Education – SCI and TBI Grant Program

Name and Address of the Funding Agency's Procuring Contracting/Grants Officer: Alaina DeSalvo
Competitive Grants Administrator, Grants Division

Minnesota Office of Higher Education

1450 Energy Park Drive, Suite 350

St. Paul, MN 55108

Performance Period: 07/01/2018 – 06/30/2022 (with no-cost extension)

Level of Funding:

Brief Description of Project's Goals: This project seeks to examine the effectiveness of the addition of head-mounted virtual reality (VR) as a treatment intervention for upper extremity function in patients being seen by occupational therapists in an inpatient Polytrauma/TBI setting, and to apply various 2-D models used in previous VR studies to more immersive head-mounted technology to explore applicability and tolerance. **Specific Aims:** AIM 1: To examine the effectiveness of the addition of HMD VR as a treatment intervention for UE function in patients being seen by OT in an inpatient Polytrauma/TBI setting. AIM 2: To apply various 2-D models used in previous VR studies to more immersive HMD technology to explore applicability and tolerance in an inpatient Polytrauma/ TBI setting.

Overlap: None

Title: Development of a Foot-Ankle Prosthesis to Improve Physical Therapy Outcomes

PI: Sara Koehler-McNicholas, PhD and Andrew H. Hansen, PhD

Role in Project: Co-Principal Investigator

Time Commitment: 5%

Performance Period: 12/01/2017 – 12/31/2021

Level of Funding:

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

Brief Description of Project's Goals: The goal of this work is to develop a new device that will enable physical therapists to maximize stability at the beginning of physical therapy, thereby allowing patients to weight shift with a highly stable system. As the patient's confidence increases, therapists will be able to gradually decrease the stability of the device.

Specific Aims: The primary aim of this proposal is to develop a prosthetic foot-ankle system that can be adjusted by a physical therapist to gradually increase ankle ROM as the patient learns to stand and walk with the prosthesis.

Overlap: None.

Title: The Bimodal Ankle for Mobility and Stability of Prosthesis Users

PI: Matthew Wernke, PhD and Sara Koehler-McNicholas, PhD

Role on Project: Co-Investigator

Time Commitment: 2%

Supporting Agency: National Institute on Disability Independent Living & Rehabilitation SBIR

Name and Address of the Funding Agency's Procuring Contracting/Grants Officer:

Performance Period: 9/30/2018 – 09/29/2021

Level of Funding: (subcontract)

Brief Description of Project's Goals: The overall objective of the proposed project is to develop a novel Bimodal Ankle Prosthesis (BAP) that can modulate between the appropriate roll-over shapes for walking and standing.

Specific Aims: Aim 1: Develop the Bimodal Ankle Prosthesis incorporating the hydraulic cylinder that allows a curved rocker shape during gait and a flat rocker shape during standing. Aim 2: Ensure the safety of the Bimodal Ankle Prosthesis using industry standard mechanical testing procedures. Aim 3: Collect objective and subjective data from lower-extremity prosthesis users wearing the Bimodal Ankle Prosthesis.

Overlap: None

Title: Women's-Specific Footwear with Prosthetic Feet

PI: Elizabeth Russell Esposito, PhD

Role in Project: Site Principal Investigator

Time Commitment: 2%

Supporting Agency: Congressionally Directed Medical Research Program

Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:

Lisa Straker, The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. 6720-A Rockledge Drive, Suite 100, Bethesda, MD 20817-1891, 240-694-4016

Performance Period: 09/29/2017-9/28/2021

Level of Funding (Direct):

Brief Description of Project's Goals: The purpose of this study is to address footwear challenges unique to female prosthesis users.

Specific Aims: The specific aims of this investigation are to determine 1) the types of footwear worn and desired to be worn by female prosthesis users, as well as perceived limitations when wearing and using different footwear and 2) how women's-specific footwear alters the stiffness and energy return of prosthetic feet.

Overlap: None.

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

PI: David Morgenroth, MD

Role in Project: Site Principal Investigator

Time Commitment: 10%

Performance Period: September 1, 2016 – August 31, 2021

Level of Funding:

Supporting Agency: Clinical and Rehabilitative Medicine Research Program/ CDMRP/Orthotics and Prosthetics Outcomes Research Program

Name and address of funding agency's Contracting/Grants Officer: Chris Meinberg

Brief Description of Project's Goals: The overall goal 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.

Specific Aims: 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. 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. Exploratory Aim: Determine potential barriers and facilitators to the inclusion of a patient-centered 'test-drive' component to clinical prosthetic foot prescription.

Overlap: None

Title: Biomimetic Slope Adaptive Foot-Ankle Prosthesis

PI: Edwin Iversen, MEME and Andrew H. Hansen, PhD

Role in Project: Subcontract Principal Investigator

Time Commitment: 10%

Performance Period: 07/27/2018 – 07/26/2021

Level of Funding:

Supporting Agency: Department of Defense STTR Phase II

Name and address of funding agency's Contracting/Grants Officer: Capt Joseph Cohn, Defense Health Agency, Falls Church, VA

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. Slope Adaptive Prosthesis Design Update; 2. Structural and Durability Testing of the Slope Adaptive Prosthesis; 3. Human Subjects Testing of the Slope Adaptive Prosthesis; 4. Design Changes in Response to Structural, Durability and Human Subjects Testing.

Overlap: None

Title: Improving Commercial Readiness of the Multi-Purpose Arm Cycle Ergometer (M-PACE)

PI: Christine Olney, PhD, RN and Gary Goldish, MD

Role on Project: Co-Investigator

Time Commitment: 1%

Supporting Agency: Department of Veterans Affairs Technology Transfer Program

Name and Address of the Funding Agency's Procuring Contracting/Grants Officer: John Kaplan, PhD, JD

Performance Period: 04/01/2019 – 09/30/2020

Level of Funding:

Brief Description of Project's Goals: The purpose of the proposed project is to improve the M-PACE hardware and software into a commercial-ready state, list the system with the FDA, and disseminate systems to Milwaukee VA, Hines VA, and Palo Alto VA.

Specific Aims: N/A

Overlap: None

Title: Active Cooling Socket for Improving Residual Limb Skin Comfort and Skin Care

PI: Ryan Myers

Role in Project: Co-Investigator

Time Commitment: 5%

Performance Period: November 4, 2016 – November 3, 2020

Level of Funding: (subcontract total)

Supporting Agency: Department of Defense

Name and address of funding agency's Contracting/Grants Officer: Erica K. Smith, U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD, 21702.

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.

Specific Aims: N/A

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 – December 31, 2019

Level of Funding:

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

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: Mobile Manual Standing Wheelchair

Role in Project: Co-Principal Investigator

Time Commitment: 5%

Performance Period: October 1, 2015 – September 30, 2019

Level of Funding: (total)

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

Brief Description of Project's Goals: The primary goal of this project is to develop a commercially-viable mobile manual standing wheelchair in close collaboration with a standing wheelchair company. The development process will be guided by functional testing of prototypes by Veterans with SCI and by durability testing of wheelchair prototypes at Levo and the Pittsburgh VA Medical Center.

Specific Aims: 1) Develop a commercially-viable mobile manual standing wheelchair, sub-aim 1A) Functional (human subjects) testing with Veterans with SCI to inform the development, sub-aim 1B) Durability testing of mobile manual standing wheelchair prototypes to inform the development.

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 – September 9, 2019

Level of Funding: (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: Upper Body Dynamic Positioning System for Persons with SCI

Role in Project: Co-Principal Investigator

Time Commitment: 10%

Performance Period: 07/01/2017 – 06/30/2019 (no cost extension)

Level of Funding:

Supporting Agency: Minnesota Office of Higher Education

Name and address of funding agency's Contracting/Grants Officer:

Dr. Nancy B. Walters, Program Manager

Minnesota Office of Higher Education

St. Paul, MN

Brief Description of Project's Goals: The goal of this project is to develop and test a first generation trunk control system for persons with SCI with the goal of improving bimanual workspace, improving pressure relief, and shifting the center of mass forward for more stable inclined wheelchair propulsion.

Specific Aims: 1. Gather feedback from Minnesotans with SCI regarding desirable design features; 2. Engineer design concepts into first generation prototypes; 3. Test first generation prototypes to understand benefits of trunk control systems.

Overlap: None

Title: Improving Energy Return and Residual-Limb Climate in Prostheses for High- Functioning Amputees

PI: Andrew Hansen

Role in Project: PI

Time Commitment: 5%

Performance Period: September 30, 2014 – March 29, 2019 (no cost extensions)

Level of Funding: (total)

Supporting Agency: United States Department of Defense Congressionally Directed Medical Research Programs

Name and address of funding agency's Contracting/Grants Officer:

Miriam Darnell, Ph.D. Science Officer, PRORP

Congressionally Directed Medical Research Programs

U. S. Army Medical Research and Materiel Command Fort Detrick, Maryland

Brief Description of Project's Goals: The objective of this work is to establish the feasibility for prosthetic sockets with passive ventilation properties, allowing for improved socket climate for high functioning military amputees.

Specific Aims: 1) Develop and test a new socket connection system to open up the distal end of the socket for passive ventilation; 2) Develop and test sockets with passive ventilation properties.

Overlap: None

Title: Development of a Personal Use Seating Pressure Measurement System

Role in Project: Consultant

Time Commitment: Up to 1%

Performance Period: October 2015-September 2018

Level of Funding: (total costs)

Supporting Agency: Department of Defense, CDMRP, SCIRP

Name and address of funding agency's Contracting/Grants Officer:

Lucinda (Cindy) F. Keeney

USAMRAA, MCMR-AAA-AA, Bldg 843

820 Chandler Street

Fort Detrick, MD 21702-5014

Brief Description of Project's Goals: Complete development of our CMAP app with significant input from Veterans with SCI and test the feasibility of the system during personal use in the free-living environment by Veterans.

Specific Aims: 1) Develop a personal-use pressure mapping mobile app with integrated alters and motivational cues; 2) Test feasibility of the personal-use pressure mapping mobile app

Overlap: None

Title: Muscle Powered Exoskeleton for Standing and Walking by People with Spinal Cord Injury

Role in Project: Co-Investigator

Time Commitment: 1%

Performance Period: August 3, 2016 – June 30, 2018

Level of Funding:

Supporting Agency: Minnesota Office of Higher Education

Name and address of funding agency's Contracting/Grants Officer:

Dr. Nancy B. Walters, Program Manager

Minnesota Office of Higher Education

St. Paul, MN

Brief Description of Project's Goals: The objective of this work is to determine the technical feasibility of a new approach that combines surface FES and a passive exoskeleton to determine whether the new system is technically feasible for limited standing and walking, and to determine the potential of a muscle powered walking system for providing the same benefits as a motor powered system.

Specific Aims: Aim 1: Design, fabricate and bench test the FES-ESE. Aim 2: Perform a pilot study using one volunteer with spinal cord injury to demonstrate the technical feasibility of the FES-ESE in a laboratory environment.

Overlap: None

Title: Development of an Arm Cycle Ergometer for Supine Use

Role in Project: Co-Investigator

Time Commitment: 1%

Performance Period: October 3, 2016 – June 30, 2018 (no cost extension)

Level of Funding:

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

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: Self management to improve functioning following limb loss

Role in Project: Site Principal Investigator

Time Commitment: 5%

Performance Period: July 1, 2014 – June 30, 2018

Level of Funding: (total)

Supporting Agency: United States Department of Veterans Affairs, Rehabilitation Research and Development Service

Name and address of funding agency's Contracting/Grants Officer:

Kristy Benton-Grover, BFA, CAE

Management Analyst

Brief Description of Project's Goals: This is a two-arm RCT to examine the efficacy of a group-based self-management intervention for individuals with limb loss (VETPALS). The goal of the intervention is to provide education, skills, and peer support to promote self-efficacy to engage in self-management and improve physical and psychosocial outcomes following amputation.

Specific Aims: Examine the efficacy of a group based self-management intervention to improve physical and mental health functioning following limb loss.

Overlap: None

Title: The Bimodal Ankle: Development and Engineering Validation of a Hydraulic Actuator

Role in Project: Subcontract Principal Investigator

Time Commitment: 5%

Performance Period: 10/01/2017 – 03/31/2018

Level of Funding: (subcontract total)

Supporting Agency: National Institute on Disability Independent Living & Rehabilitation SBIR

Name and address of funding agency's Contracting/Grants Officer: TBD

Brief Description of Project's Goals: The purpose of this project is to create a locking hydraulic actuator for an ankle-foot prosthesis that will have a stable standing mode and flexible walking mode (i.e., a bimodal ankle-foot prosthesis).

Specific Aims: Aim 1: Develop (design and fabricate) a hydraulic actuator that allows movement. Aim 2: Perform engineering verification of the hydraulic actuator assembly

Overlap: None.

Title: Development of Adaptive Prosthetic Ankle-Foot Systems

PI: Andrew Hansen

Role in Project: PI

Time Commitment: 5%

Performance Period: October 1, 2014 – September 30, 2018 (no cost extension)

Level of Funding: (total)

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

Brief Description of Project's Goals: This project will examine the advantages of a new adaptable ankle-foot prosthesis that can adapt to different terrain on every step of walking using only passive mechanical parts (i.e., without the need for motors or batteries). This new system also provides plantarflexion in the late stance phase of walking, which should increase the efficiency of walking.

Specific Aims: 1) Perform mechanical tests of the adaptable ankle-foot system and refine the design to improve durability; 2) Test the adaptable ankle-foot system in veterans to assess slope adaptation. Research; 3) Test the adaptable ankle-foot system in veterans to determine its ability to reduce submaximal oxygen uptake during walking.

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:

Supporting Agency: Department of Defense STTR

Name and address of funding agency's Contracting/Grants Officer: Capt Joseph Cohn, Defense Health Agency, Falls Church, VA

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

SAWERS, ANDREW

PREVIOUS:

OPERF-SGA-2016-1 (Sawers) 09/15/2016-05/31/2017 0.59 calendar months

Orthotics and Prosthetics Education and Research Foundation

Total Costs:

Role: Principal Investigator

Andrew Hansen, PhD, OPERF, PO Box 34635, Washington, DC 20043-4635

Validation of a novel beam-walking test to assess fall risk in people with lower limb amputation The objective of the proposed research is to establish the construct validity of beam walking as a measure of balance and fall risk among people with unilateral transtibial and transfemoral limb loss. We will quantify the convergent construct validity, known groups construct validity, and discriminant ability of beam walking in people with transtibial and transfemoral limb loss.

- *Aim 1:* Test the hypothesis that beam-walking performance in people with LLL is related to their performance on existing standardized balance tests.
- *Aim 2:* Test the hypothesis that beam walking performance will differ significantly between groups of people with LLL who are expected to exhibit different levels of balance ability.
- *Aim 3:* Test the hypothesis that beam walking can discriminate between multiple and non-multiple fallers more accurately than existing clinical balance tests.

No overlap with the current project exists.

K12HD073945 (Sawers) 01/01/2016-01/01/2018 9.00 calendar months

Interdisciplinary Rehabilitation Engineering Research Career Development Program

Total Costs:

Role: K12 Scholar

Jules Dewald, PT PhD, David Reinkensmeyer, PhD, Eric Perreault, PhD, Rick Segal, PT, PhD

Identifying neuromuscular mechanisms of better walking balance

The objective of the proposed research is to identify neuromuscular determinants of falls. We will use muscle synergy analysis and conventional EMG onset latency analysis to quantify and compare patterns of muscle coordination during successful and failed balance recoveries following a slip while walking.

- *Aim 1:* Test the hypothesis that falls in older adults are associated with a reduction in the complexity of neuromuscular control.
- *Aim 2:* Test the hypothesis that coordination of muscles about the knee in older adults is critical to restoring balance following a slip.

No overlap with the current project exists.

W81XWH-17-1-0547 (Sawers) 09/29/2019 – 09/28/2020 1.35 calendar months

Department of Defense

Total Costs:

Role: Principal Investigator

Tracy Behrsing, PhD, 1053 Patchel St, Fort Detrick MD 21702

Orthotics and Prosthetics Outcomes Research Program, Prosthetics Outcomes Research Award

Can a novel beam-walking test improve fall risk assessment in Service Members, Veterans, and civilians who use lower limb prostheses?

The objective of the proposed research is to establish whether a narrowing beam walking test (NBWT) is a valid and reliable method for predicting fall risk in lower limb prosthesis (LLP) users. This project will develop and test a novel clinical balance test based on a progressively challenging beam-walking task in order to address a central limitation of contemporary clinical balance tests; they are too easy to detect fall risk among Service Members, Veterans, and civilians who are LLP users.

- *Aim 1:* Assess and compare the criterion validity of NBWT to contemporary clinical balance tests.
- *Aim 2:* Assess and compare the reproducibility of NBWT to contemporary clinical balance tests.
- *Aim 3:* Assess and compare the predictive validity of NBWT to contemporary clinical balance tests.

No overlap with the current project exists.

Industry-sponsored grant (Sawers)

03/01/2019-02/29/2020

2.49 calendar months

Otto Bock LP and Össur hf

Total Costs:

Role: Principal Investigator

Andreas Kannenberg, PhD, Otto Bock Healthcare LP, Austin TX 78758

Development and administration of a fall survey to record and report fall frequency, circumstances, and consequences among lower limb prosthesis users.

The objective of the proposed research is to develop and validate a population-specific fall survey capable of characterizing fall circumstances and consequences in lower limb prosthesis users. This will be achieved using best practices in survey development (i.e., focus groups and cognitive interviews), as well as survey evaluation (i.e., psychometric testing).

- *Aim 1:* Identify common vocabulary and experiences related to falls among lower limb prosthesis users.
- *Aim 2:* Evaluate the clarity, comprehension, and applicability of potential fall survey questions, their response options, and instructions.
- *Aim 3:* Assess the validity of the lower limb prosthesis user-specific fall survey.

No overlap with the current project exists.

CURRENT:

W81XWH-19-1-0507 (Sawers)

09/23/2019 – 09/22/2022

1.26 calendar months

Department of Defense

Total Costs:

Role: Principal Investigator

Tracy Behrsing, PhD, 1053 Patchel St, Fort Detrick MD 21702

A pilot clinical trial to assess the effect of transfemoral socket design on hip muscle function

The objective of the proposed pilot clinical trial is to assess the effect of socket design on residual limb hip muscle strength and endurance in Service members, Veterans, and civilian transfemoral prosthesis users transitioning from an ischial-containment to a sub-ischial socket. This project will help to establish preliminary evidence for whether walking in a different socket design alters hip muscle function, characterize strength deficits in transfemoral prosthesis users, and examine whether deficits in hip muscle strength or endurance play a causal role in balance and mobility impairment in transfemoral prosthesis users.

- *Aim 1:* Evaluate hip muscle function and its contribution to balance and mobility among unilateral transfemoral prosthesis users.
- *Aim 2:* Test whether walking with a sub-ischial socket alters hip muscle function among unilateral transfemoral prosthesis users.

No overlap with the current project exists.

OP190025 (Hafner)

07/01/2020-06/30/2024

1.20 calendar months

Department of Defense

Total cost:

Role: Co-Investigator

Tracy Behrsing, PhD, 1053 Patchel St, Fort Detrick MD 21702

Fall-related health outcomes in lower limb prosthesis users: a pragmatic clinical trial to assess effectiveness of microprocessor-controlled prosthetic knees. The purpose of this study is to determine if and how microprocessor- and nonmicroprocessor-controlled prosthetic knee technologies influence fall-related health outcomes in limited community ambulators.

- *Aim 1:* Develop self-report item banks, short forms, and computerized adaptive tests to measure fall-related self-efficacy and fall-related interference in life activities in lower limb prosthesis users.
- *Aim 2:* Assess the construct validity and test-retest reliability of fall-related instruments in lower limb prosthesis users relative to similar surveys, performance-based tests, and sensors.
- *Aim3:* Apply fall-related instruments in a pragmatic clinical trial to assess whether provision of a microprocessor-controlled prosthetic knee (MPK) improves fall-related health outcomes relative to a standard-of-care NMPK in limited community ambulators

No overlap exists with the current project.

OP190048 (Morgenroth)

02/01/2020-01/31/2024

1.20 calendar months

Department of Defense

Total cost:

Role: Co-Investigator

Tracy Behrsing, PhD, 1053 Patchel St, Fort Detrick MD 21702

A Prosthetic Foot Test-Drive Strategy for Improving Stability and Falls-Related Outcomes in Veterans with Leg Amputations

The objective of the proposed research is to determine the effects of coronal and sagittal plane stiffness among commercially-available prosthetic feet on stability and fall-related outcomes in people with transtibial, and whether a test-drive strategy using a multiaxial prosthetic foot emulator can be used to predict stability and balance-confidence outcomes with corresponding commercially-available prosthetic feet in people with transtibial amputation.

- *Aim 1:* Determine the effects of commercially available prosthetic feet of varying stiffness on stability and fall-related outcomes in people with transtibial amputation.
- *Aim 2:* Determine whether a multiaxial prosthetic foot emulator can be used to predict stability and balance-confidence outcomes with corresponding commercial prosthetic feet in people with transtibial amputation.
- *Aim3:* Determine whether a brief trial of commercial prosthetic feet can predict longer-term stability and balance confidence outcomes in people with transtibial amputation

No overlap exists with the current project.

Industry-sponsored project (Wurdeman)

08/01/2022-07/30/2023

1.0 calendar months

Ottobock Healthcare

Total cost: (total costs); (sub-contract)

Role: Co-Investigator

Andreas Kanneberg, 11501 Alterra Parkway, Domain 7, Suite 600, Austin TX 78758

ASCENT K2: Assessing outcomes with microprocessor knee utilization in a K2 population.

The goal of this study is to assess the long-term health benefits to use of a microprocessor-controlled prosthetic knee (MPK) relative to standard-of-care non-microprocessor-controlled knees (NMPKs) in limited community ambulators.

- *Aim 1:* To understand the effect of MPK technology for the limited community ambulator on reducing fear and anxiety of falling, improving health-related quality of life, and participation in society and activities.

No overlap with the current project exists.

PENDING

Restore Center Pilot Project Program

05/01/2024-07/01/2025

1.0 calendar months

Total cost:

Role: Principal Investigator

Assessing the real-world accuracy of the Apple Watch's automatic fall detection in lower limb prosthesis users. The objective of this pilot study is to assess the suitability of a popular, unobtrusive, commercially available wearable, the Apple Watch, for detecting falls by LLP users.

- *Aim 1:* Assess the validity of the Apple Watch as a falls monitor in LLP users.
- *Aim 2:* Assess the acceptability of the Apple Watch as a falls monitor for LLP users.

No overlap exists with the current project.

OP230007 (Sawers)

09/23/2024 – 09/22/2027

3.0 calendar months

Department of Defense

Total Costs:

Role: Principal Investigator

Hip muscle co-contraction: the effect of transfemoral socket design and impact on balance and mobility.

The **objective** of this clinical research award is to assess the effect of socket design on hip muscle co-contraction, a leading cause of movement inefficiency, and its association with balance and mobility in transfemoral prosthesis users. Identifying socket design as a contributor to hip muscle co-contraction could have an immediate impact on transfemoral prosthesis users' health and well-being by decreasing the effort required to walk and improving their balance.

- *Aim 1:* Evaluate the effect of socket design on hip muscle co-contraction in unilateral transfemoral prosthesis users during a non-weightbearing isometric torque-matching task
- *Aim 2:* Evaluate the effect of socket design on hip muscle co-contraction in unilateral transfemoral prosthesis users during balance, mobility, and agility tasks.

No overlap with the current project exists.