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

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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 maintained approval from the VA Central IRB and HRPO for the human subjects portion of the project as well as received additional approvals for IRB amendments to optimized study methodology. We have also performed extensive mechanical testing of commercial prosthetic feet, which is ongoing, but has already informed the development of a multiaxial prosthetic foot emulator that will mimic the sagittal and coronal plane mechanical properties of commercial prosthetic feet without physically changing feet. The multiaxial prosthetic foot emulator hardware is now designed in place at the Seattle site; software is awaiting completion of mechanical testing.

15. SUBJECT TERMS

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

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1. INTRODUCTION:

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:

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

3. ACCOMPLISHMENTS:

What were the major goals of the project?

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 the Minneapolis site local (LSI) application. We also submitted and received approval for two PISC amendments to the VA Central IRB and one amendment to each LSI.	This task has been completed. During this reporting year – LSI: 14-Sep-2021 (Minneapolis, approval) Amendments: PISC Amendment 1 13-April-2022 (approval)

			LSI Amendment 1 (Seattle) 13-April-2022 (approval) LSI Amendment 1 (Minn) 13-April-2022 (approval) PISC Amendment 2 30-June-2022 (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. During this reporting year, we received local approval for the human subjects portion of the work at the Minneapolis site. We also received continuing review approval for the non-human subjects portion of the project at the Seattle site.	This task has been completed. During this reporting year – Non-human subjects: 20-May-2022 (Continuing Review Approval) Human subjects LSI (Minneapolis): 08-Oct-2021 (approval)
Prepare and submit HRPO Protocol for Human Subjects Research		We have received all necessary HRPO approvals. During this reporting year, we received secondary level review approval for the PISC (multisite) application and Seattle site from HRPO. We also submitted and received approval for the Minneapolis site application from HRPO.	This task has been completed. During this reporting year – HRPO multisite: 08-Aug-2021 (approval) HRPO Seattle site: 08-Aug-2021 (approval) HRPO Minneapolis site: 14-Sept-2021 (approval)
Study Preparation	Months		
Prepare and finalize study protocol and consent materials (e.g., recruitment materials, consent forms)	pre-study	No updates this reporting year.	Completed 29-Jan-2021
Prepare data collection files (e.g., forms, surveys)	1-5	No updates this reporting year.	Completed 30-Nov-2020
Create recruitment and data collection databases	1-5	No updates this reporting year.	Completed 29-Jan-2021
Purchase research supplies and equipment (e.g., prosthetic feet, treadmill, laptops, software)	1-3	During this reporting year, the Minneapolis site has purchased study materials including a computer system for motion capture (Margins of Stability as part of the study aims) and the uneven ground (Woodway) treadmill. Both sites have also purchased materials to create the cross-slope	Ongoing

		walking condition for human subjects testing.	
Mechanical testing of commercial prosthetic feet and input of mechanical testing data to multiaxial	1-9	During this reporting year, we have been working on mechanically testing commercial prosthetic feet to characterize their sagittal and coronal plane angular stiffness properties. Please see details below. We hold biweekly meetings with Humotech to discuss mechanical testing protocol for prosthetic feet.	45%
In-person kick-off meeting	8-9	This 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.	Completed 30-Oct-2020 (virtual) Completed 24-25 April 2022 (in-person)
Train research staff	1-9	Elizabeth Halsne and Talia Ruxin ongoing training including biomechanical data collection, human subjects research, and mechanical testing of prosthetic feet training. The entire staff completed significant training at the in person full investigative meeting in April 2022.	Ongoing weekly
Registration of clinical trial on ClinicalTrials.gov	8	The study was registered on clinicaltrials.gov during this reporting year, including details about the study protocol, study sites, contact information, objectives, procedures, and outcome measures.	Completed 21-July-2022
Ongoing Study Coordination	Months		
Once per month teleconference meetings of investigative team	1-36	Recurrent meetings (e.g., to discuss mechanical testing, biomechanical data collection protocol).	Ongoing
Participant Recruitment	9-45	Mechanical testing of prosthetic feet for input into the multiaxial prosthetic foot emulator has not yet been completed, but is in progress. Thus, the multiaxial prosthetic foot emulator software foot profiles have also not yet been completed (they depend on the mechanical testing data completion. We are 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).	Not yet begun
Data Collection	9-45	See above.	Not yet begun
Data Analysis	9-45	See above.	Not yet begun
Dissemination	9-48	See above.	Not yet begun

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.

During this reporting period, we received the final approvals for the Institutional Review Boards (VA Central IRB and HRPO) human subjects testing application. We also modified several study materials (i.e., self-report questionnaire packets, consent forms, and the study protocol), and we received approval for those changes. Specifically, the Local Site Investigator (LSI) application for the Minneapolis VA site was approved by the VA Central IRB. Approval for the Seattle application had already been received prior to this reporting period. Additionally, we received approval for the VA Central IRB Continuing Review Applications for the Principal Investigator Study Chair (PISC), and the two LSI applications. Once approval was received, we submitted the Continuing Review approval memorandums to HRPO as part of the HRPO continuing review packages. The HRPO Continuing Reviews for both study sites were also approved.

Additionally, we submitted two amendments to the VA Central IRB. The first amendment included changes to the protocol such as adding details about gait biomechanical data collection. We also added study staff and modified recruitment materials (i.e., talking points and phone scripts). In the protocol and recruitment materials, we updated the participant weight limit from 250lb to 263lb. This weight limit was originally set because testing for the prosthetic foot emulator did not exceed loads of 250lb. However, the prosthetic foot emulator has a new weight limit of 263lb, and we updated the VA CIRB-approved materials accordingly. This PISC amendment has been approved by the VA Central IRB. We also submitted and received approval for VA Central IRB LSI amendments at each site that added study staff.

In the second amendment to the VA Central IRB, we included changes to the study protocol and to the self-report questionnaire packets for each visit. In the protocol, we replaced the Timed Up and Go test for functional mobility with the L Test for functional mobility. The L test is a modification of the Timed Up and Go test that has been shown to overcome the ceiling effect of the Timed Up and Go test in high mobility participants. We also elaborated on how we would calculate Margins of Stability by determining when participants hands are in contact with the handrail during walking. The changes to the self-report questionnaire packets included adding questions about hand dominance, revising questions about comorbidities to reflect the functional comorbidity index, and revising questions about history of falls to align with updated research. We also added questions about the relative importance of certain activities when using a prosthetic foot and the frequency of certain activities. These questions will enable our research team to assess the differences in how participants' place different value on certain activities as they consider their preference for prosthetic feet. Finally, we added questions about participants' satisfaction with their community participation to better understand how their amputation influences their health and whether or not a different prosthetic foot may change their participation. This amendment was also approved by the VA Central IRB.

We also submitted and received continuing review approval from the local Seattle VA R&D Committee for the non-human subjects portion of work to characterize the mechanical properties of commercial prosthetic feet in the sagittal and coronal planes for input to the multiaxial prosthetic foot emulator during this reporting year. At the Minneapolis site, local approval of the human subjects portion of the work was received. Approval at the Seattle site was already approved prior to this reporting year.

Additionally, once the Minneapolis site LSI application and local site applications were approved, we submitted and received approval from HRPO for secondary level review. Approval for the PISC (multisite) application and Seattle site application were also approved by HRPO.

Finally, we also registered this research study on clinicaltrials.gov. This process included adding details about the study protocol, location and contact information for the two study sites, and detailing the outcome measures (Figure 1). The ClinicalTrials.gov Identifier is NCT05473065.


Record Summary Preview Edit All Help Definitions

Edit **Study Identification**
Unique Protocol ID: W81XWH-20-1-0291
Brief Title: A Prosthetic Foot Test-Drive Strategy for Improving Stability in Veterans With Leg Amputations
Official Title: A Prosthetic Foot Test-Drive Strategy for Improving Stability and Falls-Related Outcomes in Veterans With Leg Amputations
Secondary IDs:

Edit **Study Status**
Record Verification: June 2022
Overall Status: Not yet recruiting
Study Start: January 1, 2023 [Anticipated]
Primary Completion: July 31, 2024 [Anticipated]
Study Completion: July 31, 2024 [Anticipated]

Edit **Sponsor/Collaborators**
Sponsor: Seattle Institute for Biomedical and Clinical Research
Responsible Party: Sponsor
Collaborators: VA Puget Sound Health Care System
Minneapolis Veterans Affairs Medical Center
University of Chicago

Edit **Oversight**
U.S. FDA-regulated Drug: No

Figure 1. Clinicaltrials.gov registration process was completed during this reporting year.

In addition to the regulatory progress and study preparation progress we made during this reporting period, we also purchased research supplies and equipment. The largest purchase, the hardware for the first multiaxial prosthetic foot emulator has been completed and is described starting on page 15 of this report. In addition, both testing sites purchased supplies to create custom jacks to achieve cross slopes on the treadmills required for human subjects testing (Figure 2). The Minneapolis site also purchased the Woodway Pro Slat rocky treadmill (for uneven ground testing in the study aims) as well as the Qualsys computer system for biomechanical data collection within the study aims.

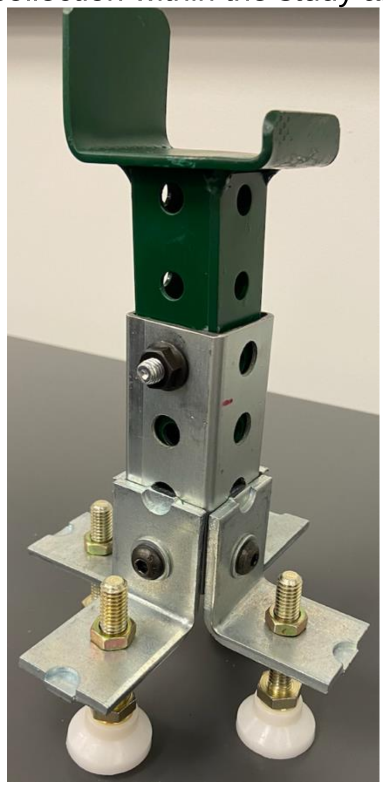

Figure 2. Custom jack that will be used to support the SciFit treadmill during cross-slope walking conditions for human subjects data collection.

Before human subjects testing can begin, the multiaxial PFE must be programmed with the sagittal and coronal plane mechanical properties of commercial prosthetic feet. These prosthetic foot properties are being collected as part of the Study Preparation major goal. During this reporting period, we experienced delays in commencing with mechanical testing (*see Actual Problems section below*). However, we were still able to make considerable progress in collecting data and establishing and iterating on study methods. Below we detail that progress by quarter.

During the first quarter of this reporting period, we conducted quasistatic testing of commercial prosthetic feet using the Robotic Gait Simulator (RGS). This type of testing helped us mitigate delays as we waited for the simVITRO software architecture to control the RGS to be installed and functional. Furthermore, ongoing weekly meetings with BioRobotics simVITRO software engineers were conducted to continue remote installation to use simVITRO software architecture to control the RGS and collect prosthetic foot mechanical testing data using physiological loads. Four virtual training sessions with simVITRO were completed during the first quarter to prepare for using the software for mechanical testing. Subsequent installation and training sessions were completed in the winter and spring to complete the installation. In advance of these subsequent trainings, quasi-static testing of commercial prosthetic feet continued using the RGS, the in-line load cell, and the OptiTrack camera system at three fixed sagittal and coronal plane angles. These data informed hardware design for the multiaxial PFE to ensure that the passive composite heels used with the PFE have sagittal and coronal plane properties that reflect the properties of the range of commercial prosthetic feet. We mechanically tested feet of all five types that will be used in future human subjects testing in a range of foot sizes. The force-displacement curves yielding sagittal and coronal plane linear stiffness results for commercial prosthetic feet sizes 25cm and 29cm of multiple models were analyzed. Furthermore, we also tested and analyzed the force-displacement curves for the PFE heels (e.g., HLC 55Nmm). This testing was important to making progress on addressing specific aim 1, where we seek to study the effects of commercial prosthetic feet with a variety of sagittal and coronal plane stiffness characteristics, especially given the limited studies on coronal plane stiffness.

In the second quarter of this reporting year, we tested multiple PFE heels and heel pads (intended to replicate the stiffness properties of the commercial prosthetic feet heels) using the RGS. These data directly contributed to the hardware design of the multiaxial PFE. In addition, we prepared for the final installation and training of the simVITRO software by continuing to participate in weekly meetings with the BioRobtics simVITRO software engineers. These meetings helped us continue the remote installation aspects of the simVITRO software architecture which is necessary to control the RGS and collect prosthetic foot mechanical testing data using physiological loading profiles. The study team built on the previous four initial, virtual training sessions led by the BioRobotics simVITRO engineers by completing two additional in-person training sessions with the simVITRO team onsite at the VAPSHCS. This training coincided with equipment installation and RGS motor tuning by the simVITRO engineers. During these sessions, study staff gained experience positioning the RGS, digitizing the force plate and test prosthetic foot specimen, and preparing the RGS for data collection. Finally, we also prepared for physiological-loading mechanical testing of commercial prosthetic feet using simVITRO software by developing trajectories that can be used with the simVITRO software to load the feet in the coronal, sagittal, and transverse planes. To develop these trajectories, the study team investigated previous standards and methods used to collect mechanical testing data on prosthetic feet using physiological loading profiles and coronal plane orientations. We designed sagittal plane kinematic trajectories for ground-to-tibia motion and vertical ground reaction force profiles, met with representatives from the relevant International Organization of Standards (ISO) sub-committees for testing of lower limb prosthetic devices, and met with our co-investigators with expertise in this area to discuss best practice methods for writing trajectories for mechanical testing.

During the third and fourth quarter of this reporting period, study staff completed the final training sessions with the BioRobotics simVITRO software representatives and conducted physiologic testing of commercial prosthetic feet using the RGS. Mechanical testing commenced with commercial prosthetic feet and emulator heels, to characterize the angular stiffness properties for input to the multiaxial emulator. In addition, hardware and software configurations were iterated to improve the quality of collected data. For example, the motion capture marker clusters and local coordinate system definitions were modified to improve the calculation of rigid body kinematics during testing and optimize calculation of the relative motions between bodies for coordinate transformation (Figure 3).

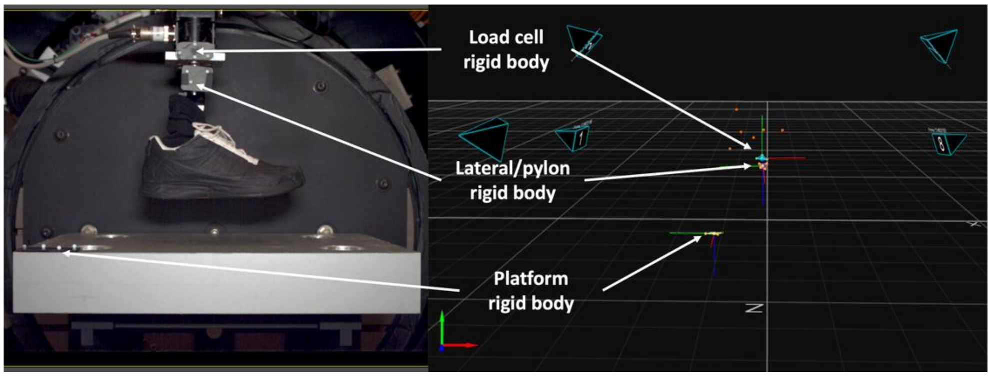

Figure 3. Optimized motion capture marker coordinate systems as defined during mechanical testing in the RGS (left) and represented within the Optitrack Motive software (right)

Loading profiles during mechanical testing included physiological target loads and sagittal plane tibia-to-ground kinematics to mimic prosthetic foot loading during walking based on the ground reaction force profile from ISO standard 22675. Testing was conducted in multiple coronal plane orientations to measure coronal plane angular stiffness properties, in addition to measuring sagittal plane properties (Figures 4 and 5).

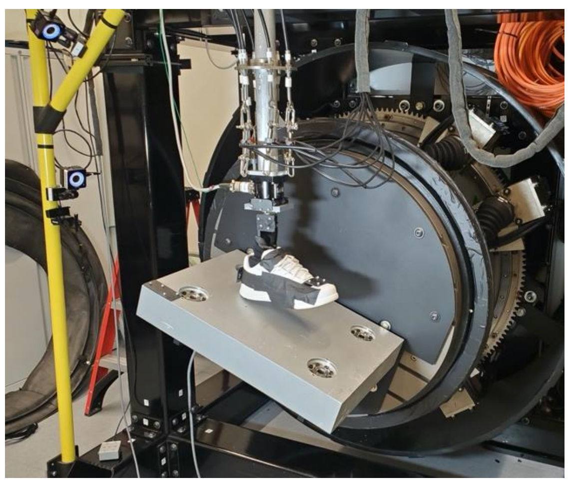

Figure 4. Prosthetic foot being tested under physiological loading conditions using the Robotic Gait Simulator.

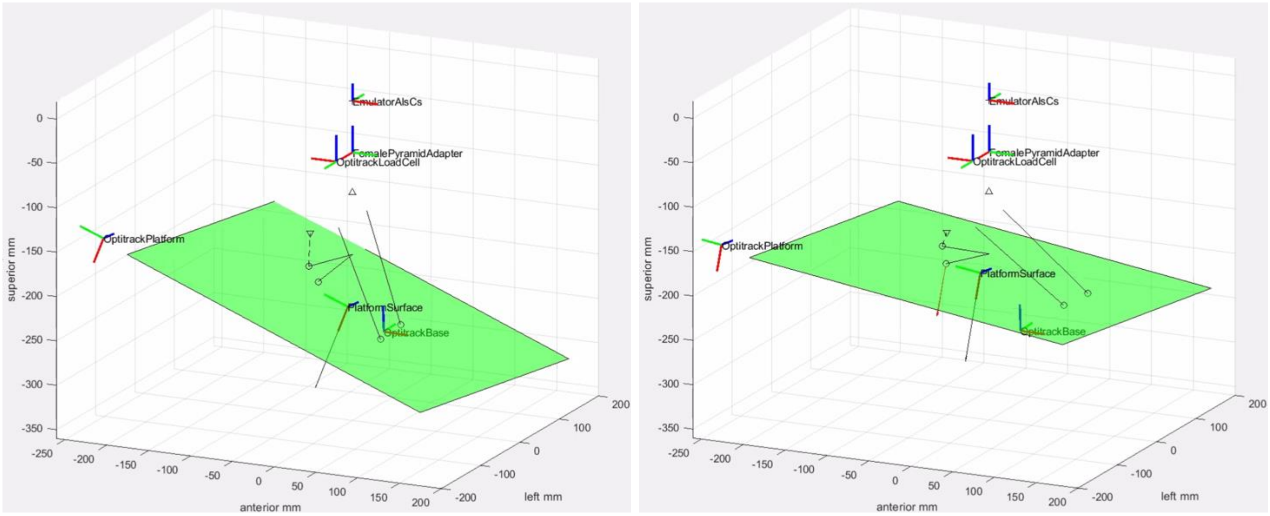

Figure 5. Demonstrating our calculation of prosthetic foot properties from physiological loading of an example commercial prosthetic foot (i.e., Vari-Flex, size 27cm, category 6) shown in two different pylon progression angles in the sagittal plane. The multiaxial emulator toes are represented in black lines, the force plate is represented as a green surface, and the Optitrack rigid bodies and coordinate systems are represented in three-dimensional space.

In addition to testing the properties of commercial feet for input into the multiaxial PFE, we also completed testing to finalize a re-design of the force plate bracket used in the RGS for testing prosthetic feet to optimize testing accuracy (important to ensure accurate emulation of commercial feet to accomplish the study aims). Previously, one challenge with our testing methods was the presence of noise in the force plate's signal during trials where we applied full physiological loads from the prosthetic foot, which reduced the precision and accuracy of the data we were collecting. When examining the design of the force plate bracket, we discovered that there was significant deflection of the bracket, which caused load cell signals to cross-talk (Figure 6). The three-axis forces being applied at the four mounting points on the bracket caused deflection of the bracket through its geometry with the lowest stiffness. The deflection observed in the simulation below indicated that the four mounting points, which are directly attached to four three-axis load cells in the load cell assembly, were seeing differential displacement which produced reaction forces from the bracket that interfered with readings of externally applied loads.

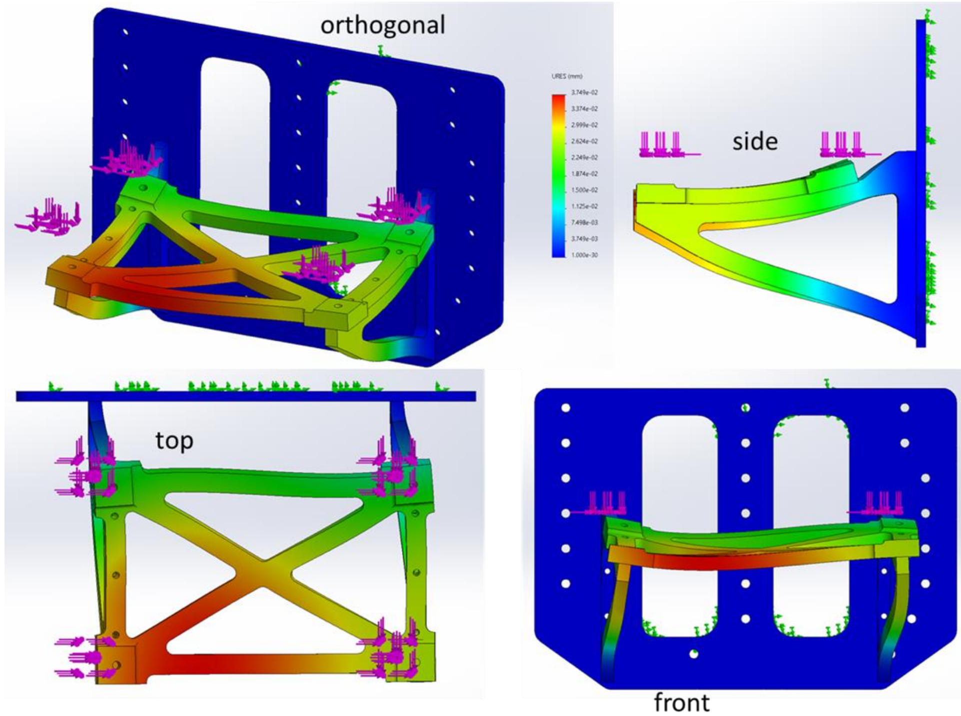

Figure 6. Mechanical deformation of the RGS force plate bracket under normal loading conditions. Relative displacement of the four load cell mounting points causes inaccurate readings due to sensor cross-talk.

To overcome this challenge, we designed a new force plate bracket and conducted testing to ensure that the design was sound. The goal of the redesign was to increase the stiffness of the bracket for scenarios with higher loading conditions (e.g., physiological loading during heel strike and push-off on the highest stiffness category prosthetic foot in the study) While the stiffest bracket would be a solid block attached between the robot's output to the load cell, the additional mass would overload the maximum payload for the robot, which is limited at 500 lbs. Therefore, we needed to redesign the bracket with the highest three-axis stiffness-to-weight ratio load path between the load cell's four mounting points and the robot's output plate. To this end, we used Solidworks Topology Study simulations to find the optimal solution for a mass target bracket that minimized the displacement of the four load cell mounting points. We applied two loading cases to the four mounting points (one for heel-strike, one for push-off), fixed the back of the bracket to the ground reference (such that this would be the load path from the load cell to the robot's output plate), and used a symmetry constraint to accommodate loading from either direction (Figure 7). Regarding material choice, we selected T6-7075 aluminum for its high stiffness-to-mass and strength-to-mass ratios. Although carbon steel has approximately the same values as this aluminum alloy, the structural stiffness of the bracket depends both on the material stiffness and the geometric stiffness. Using a lower-mass material increases the volume of that material for the same mass quantity, which can as much as double the total stiffness of aluminum relative to carbon steel. The results of the Solidworks Topology Study are shown below, which illustrates the optimal use of material to reduce bracket deflection given the mass constraint on the design.

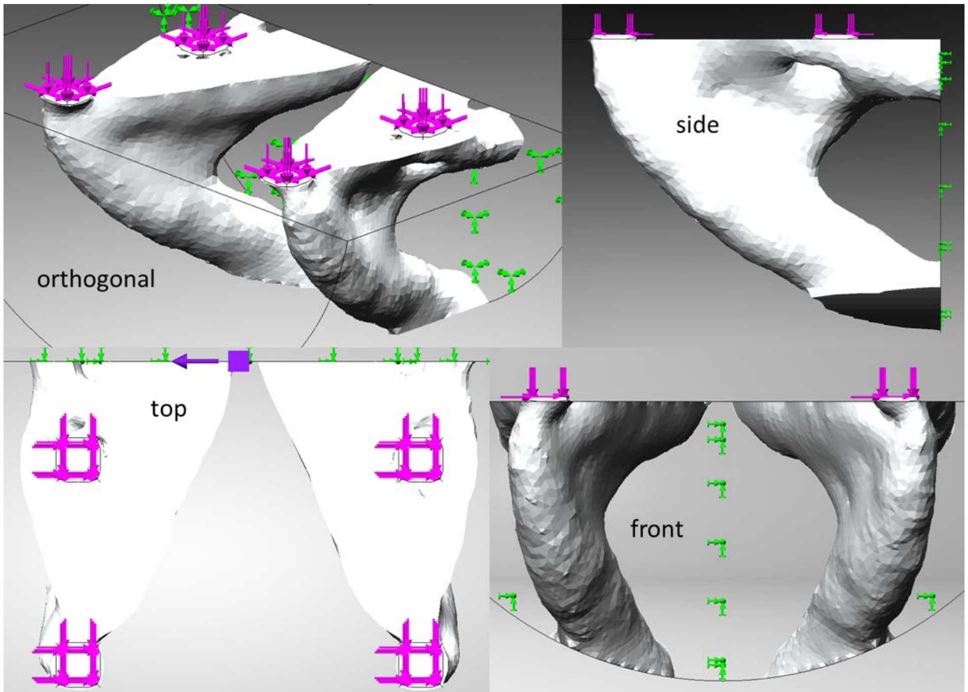

Figure 7. Results of Solidworks Topology Study for the RGS force plate bracket redesign. The loading conditions for heel strike and push off were applied to the model, which optimizes the mass distribution to minimize displacement of the load cell mounting points.

The optimal solution creates two major load paths from the most cantilevered mounting points to the lowest part of the robot's output plate, which provides stiffness to the major superior/inferior forces. The plane of the mounting points forms two triangles that provide stiffness for the anterior/posterior and medial/lateral forces. These results were used to inform a manufacturable design. The interpretation of these results includes a top mounting plate and two support brackets. A manufacturable version of this interpretation was modeled and tested using the same Topology Study to optimize the distribution of mass throughout the model. The final design of the support bracket is depicted below (Figure 8).

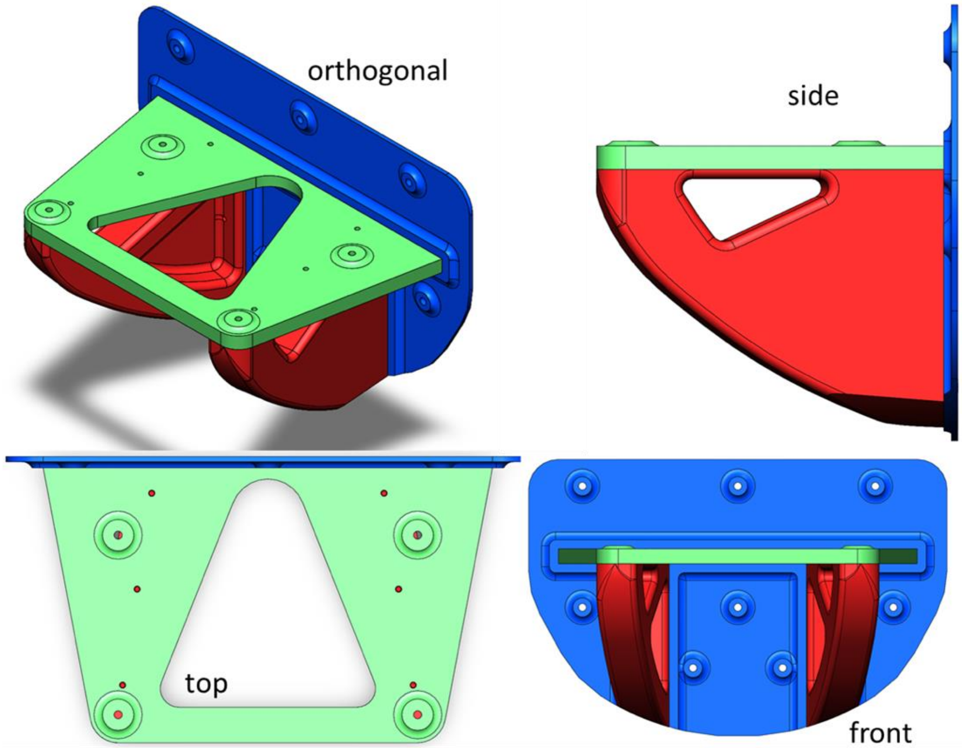

Figure 8. A manufacturable version of the optimal topology was designed and tested. The resulting design is capable of being machined from aluminum plates and has 15 times the stiffness of the current RGS load cell bracket.

The decided method of fastening is to use precision shoulder screws to mate components in parallel with an epoxy appropriate for structural bonding of aluminum. The bond is a stiffer and stronger interface than friction from fasteners alone, increasing the bracket's ability to effectively transfer loads from the load cell to the top plate to the brace supports to the robot's output plate.

Static loading analysis of the redesigned force plate bracket shows that, for the maximum loading conditions of heel strike and push off, that the redesigned bracket decreases relative displacement of the four load cell mounting points by a factor of 15 (i.e., the redesigned bracket is 15 times stiffer than the current bracket). Although the mass of the redesigned bracket is three-times that of the current bracket, the total payload which includes load cell mass, bracket mass, and maximum force from loading of prosthetic feet is below the maximum payload of 500 lbs.

Another important project development this reporting period was the completion of the hardware for the multiaxial prosthetic foot emulator, which is a major equipment purchase. Weekly written communications and biweekly meetings with the Humotech engineering team for discussion of hardware design decisions continued to be held throughout the reporting period. During the first quarter of this reporting period, the hardware design for the PFE end effector was completed and production began. Prior to production, the Humotech team identified hardware design challenges and conducted testing to solve these challenges. For example, to address the issue of accessing the prosthetic male pyramid adaptor set screw, a cut-out on the modular weight was added to create room for use of the pyramid adaptor. Furthermore, input from the mechanical testing of the emulator heels and heel pads informed the design of the 2.5 inch heel pad present on the final version. During the second quarter of this reporting period, all custom machined parts for the PFE end effector were ordered and assembled at Humotech. The team at Humotech produced a 3D-printed version of the final end effector design to allow for production testing by operating at lower loads while the machined pieces were undergoing fabrication from external vendors. The production parts were machined and received from the external vendors during this reporting period for the PFE end effector. Assembly and hardware testing were conducted on the finished end effector assembled with all components. In March, the multiaxial PFE was delivered to the Seattle site. This delivery included the second actuator unit, terminal device, and other hardware components necessary to control the device (Figure 9).

Figure 9. Multiaxial prosthetic foot emulator end effector shown connected to a simulator boot.

While the hardware for the multiaxial PFE was in production and being delivered, the study team also made considerable progress during this reporting period on the controller and software development including the following: 1) Varying the behaviors with heel deflection and pylon angle after heel-off; 2) Target features for the controller were also determined and testing was initiated; 3) Testing included emulation of example 3-dimensional torque-angle surfaces drafted in the sagittal and coronal planes. The software analysis for mechanical testing data from commercial prosthetic feet was also drafted. This analysis software optimizes the fit of ankle torque-angle functions to the data for each foot, which will then be used to be program the PFE. In addition, the analysis software outputs determinations for candidate swappable heel and forefoot options that will best emulate the corresponding commercial prosthetic foot were created. In the second quarter, further testing of a learning heel timer feature was conducted as well as integration of the system with standard controller features, and packaging for deployment to the Speedgoat target machine. Furthermore, the controller draft was restructured into a full product and verified using unit tests and integration tests. A final simulation test was conducted prior to input/output and walking tests on the PFE end effector hardware, which was carried out during the full investigative team meeting this year.

Study coordination with all investigative sites continued throughout this reporting year discuss and provide updates on commercial prosthetic foot mechanical testing, multiaxial PFE hardware and software development progress, refining human subjects testing study methods, and preparing for human subjects testing through monthly virtual meetings with the full study team. Some discussion topics included creating a mechanism to achieve the cross-slope walking condition for participants during human subjects data collection to address specific aims 1 and 2. We have also discussed additions to the surveys querying participant preference for the study feet and weighing the relative importance of various activities in determining preference which were incorporated into the amendment approved by the VA Central IRB during this reporting period. The Seattle site (VAPSHCS) also hosted a full in-person investigative team meeting (with investigators from all study sites and Humotech personnel) that also served as an installation of and training for the multiaxial PFE. In advance of this meeting, the Seattle site prepared the motion analysis lab for human subjects testing by readying the space for data collection and training.

The Minneapolis site (MVAHCS) also prepared their motion analysis lab for the delivery and installation of the PFE and equipment preparation for human subjects testing (which will occur in the next reporting quarter). Their site purchased the custom uneven Woodway Pro Slat Belt treadmill and 3D motion capture system equipment and supplies necessary for this project. The MVAHCS team also worked with facility electricians to install 3-phase, 208V power outlets for the PFE. In addition, the space was modified to make room for the new testing equipment (e.g., the uneven treadmill).

We also designed custom jacks to safely and consistently achieve 3 and 5 deg cross-slope treadmill angles which will be used during human subjects testing (Figure 10). Materials were ordered and fabricated at the MVAHCS and transported to the Seattle site for testing during the in person full investigative team meeting.

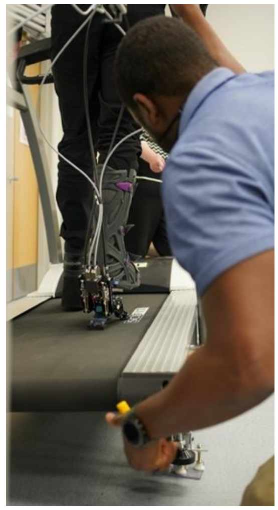

Figure 10. Research prosthetist adjusting the treadmill belt to prevent belt slippage when the treadmill is pitched at a cross sloped angle.

Before all investigators arrived at the Seattle site for the team meeting, engineers from Humotech trained the Seattle team on the multiaxial PFE (Figure 11). Subsequently, the full investigative team arrived and team members were trained on using the PFE for data collection, and several team members trialed the PFE by walking on it using a simulator boot on both on level ground and on the uneven, rocky treadmill (Figure 12).

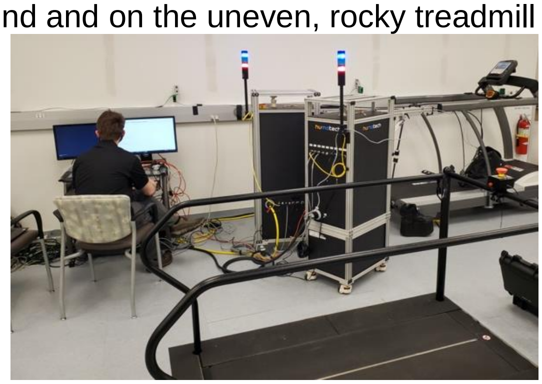

Figure 11. Humotech engineer representative prepares the multiaxial prosthetic foot emulator for testing in advance of the in-person meeting.

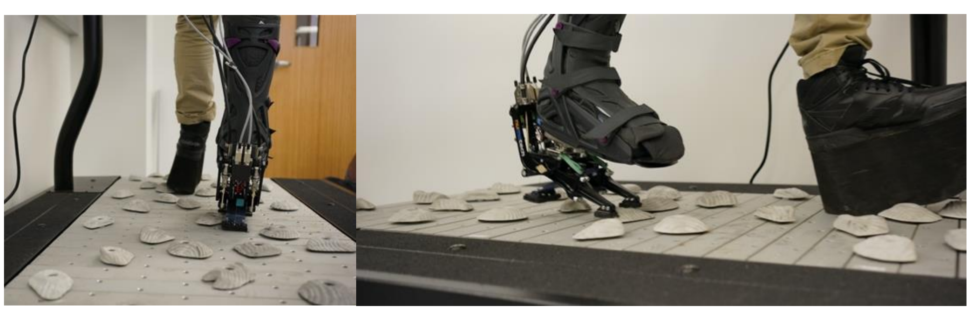

Figure 12. Study team members test out the prosthetic foot emulator on the uneven, rocky treadmill.

In addition to training for use of the PFE, all team members discussed and scrutinized the study protocol by reviewing all study procedures, study visit forms, and surveys (Figure 13). Out of these discussions, several modifications to the surveys and protocols were prepared to optimize the protocol, and these changes were captured in an amendment submitted to the VA Central IRB, which has since been approved. Furthermore, we also discussed methods for improving the accuracy of the margins of stability calculation as a means to measure changes in stability during each walking condition. We discussed and designed a mechanism to count instances in which participants touch the treadmill handrails due to reduced stability, consisting of conductive electrodes for the handrails and a circuit board to measure capacitance.

Figure 13. Study team members engage in discussion at the in-person full investigative team meeting.

Finally, this full investigative team tested out the custom jacks (built at the MVAHCS site) to safely and consistently achieve the cross slope treadmill angles (Figure 14). During the in-person meeting, the custom stands and system to prevent belt slippage were tested. The Minneapolis designed and constructed minor modifications to the stands after the meeting and sent a set of the final version to Seattle. Ongoing communication continues via monthly virtual meetings and email.

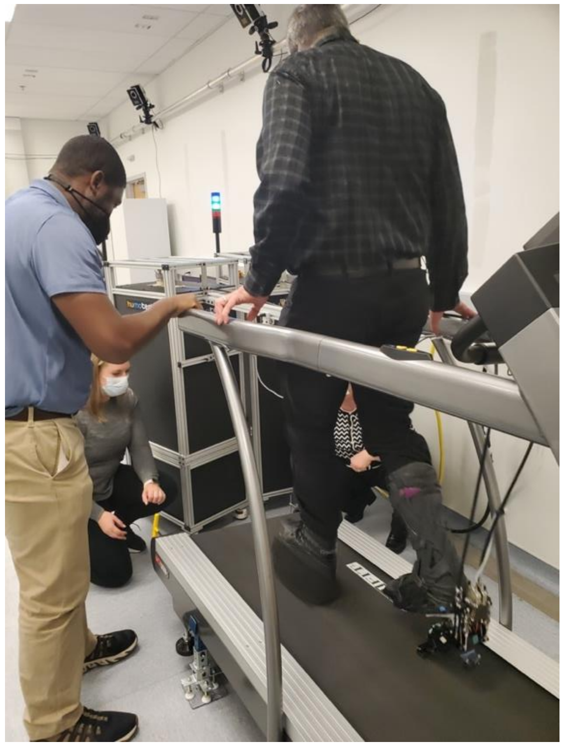

Figure 14. Study team members trial the cross-slope walking condition using the multiaxial prosthetic foot emulator, custom jack stands, and mechanism to prevent belt slippage.

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

Nothing to Report.

How were the results disseminated to communities of interest?

Nothing to report.

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

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
2. Continued purchase of necessary research equipment and supplies including study prosthetic feet at the Minneapolis site
3. Delivery and installation of the prosthetic foot emulator at the Minneapolis site
4. Initiate data collection from human participants at both Seattle and Minneapolis sites

4. IMPACT:

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

Nothing to Report.

What was the impact on other disciplines?

Nothing to Report.

What was the impact on technology transfer?

Nothing to Report.

What was the impact on society beyond science and technology?

Nothing to Report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to report.

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

Anticipated:

The Seattle site is anticipating a temporary slow down of local progress in the next quarter since Talia Ruxin, our project Study Coordinator, recently moved on from the Research Coordinator position (end of June) to attend medical school and Elizabeth Halsne, Seattle's Research Prosthetist (who is also leading our mechanical testing efforts), will begin parental leave at the end of August. We plan to hire another Study Coordinator/Research Assistant (we have interviewed candidates and recently selected the top candidate) to begin in tandem with Dr. Halsne's return from leave in early January, 2023. This will leave the Seattle site short-staffed for the first quarter but it will also conserve project funds for when full staffing can resume. The junior staff member would be difficult to train and have be productive without Dr. Halsne. We believe delaying the expense of hiring the Research Assistant until we know they can be productive will be a better use of funds than paying for a period of slow progress. In the interim, the study team will focus on readying the Minneapolis site for data collection and inputting the emulated angular stiffness profiles for the commercial prosthetic feet into the multiaxial PFE software controller.

Actual:
During this reporting year, we faced several problems and delays, and the study team worked to resolve them and/or mitigate the impact on our progress. The COVID-19 pandemic caused unavoidable delays in the delivery of hardware and software infrastructure (VA resources) that are necessary for mechanical testing of prosthetic feet, which were resolved during the first quarter of this year. Additionally, there were VA facilities-related delays in installation of mechanical testing hardware. We resolved several of these delays related to installation of mechanical testing hardware within the reporting period (i.e., installing and receiving training for using simVITRO software to control the RGS).

We are still waiting for a necessary electrical modification for equipment power requirements. Specifically, in order to use the prosthetic foot emulator within the RGS to perform validation mechanical testing of the emulated foot conditions prior to human subjects data collection, there needs to be additional 3-phase power receptacles installed in the biomechanical testing laboratory. A work order has now been submitted to our facility to make this change and is pending. In the meantime, we have been able to continue with quasi-static mechanical testing of prosthetic feet during the first quarter and physiological loading testing during the third and fourth quarters to determine their stiffness properties to achieve Aim 1 and progress towards human subjects data collection.

Furthermore, we resolved several ongoing delays related to using the prosthetic foot mechanical testing hardware within this reporting period (i.e., troubleshooting simVITRO software communication with the RGS hardware). There remain ongoing challenges (e.g., software control bugs) that are being worked through via weekly meetings with the simVITRO software engineers and consulting with RGS hardware (Mikrolar) representatives as needed to troubleshoot and address new errors as they arise. For example, we encountered an issue while establishing the physiological loading trajectories for testing feet where the RGS trucks became too near to one another and the RGS would generate a fatal error in which the test would fail while the prosthetic foot was loaded. We worked together to solve this issue through iterative software debugging sessions during the reporting period. Similarly, we were troubleshooting noisy motion during testing that interfered with the quality of the collected data. Working with the software engineers, we discovered that the control gain parameter values (PID controller) needed to be adjusted such that smoother motions were created for testing than initially. Despite these challenges, we have been able to proceed with testing the commercial prosthetic feet and optimizing our data collection methods to collect physiological loading trajectories in the sagittal and coronal planes. We anticipate being able to continue collecting prosthetic foot mechanical properties during the next reporting period and characterizing their properties for Aim 1, as well as using sagittal and coronal angular stiffness profiles as input to the multiaxial PFE for human subjects testing.

Finally, due to global supply chain issues, the shipment of some key components of the PFE (e.g., string potentiometer) to Humotech necessary for the completion and assembly of the PFE was delayed. However, we have been in regular communication with Humotech to develop work work-arounds, leading to successful recent finalized production of the multiaxial PFE hardware, and the device arrived in Seattle during this reporting year.

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 of this project is total costs. Expenditures at the close of the current budget period are estimated at total costs. This is an estimate because the July invoicing period ends after August so some July expenses are still outstanding. The difference between the budget and expenses at the end of Year 2 reflects the delays in completing mechanical testing and beginning human participant data collection. is obligated to subawards but not yet invoiced, including the large purchase of the second PFE from Humotech by the Minneapolis site that will occur in the coming year. Most of the remaining funds are earmarked for increased staff support in Years 3-4 to make rapid progress against the project's approved goals once mechanical testing is complete. Expenditures at the Seattle and Minneapolis sites are delayed but there is no significant change to the overall spending plan for the project.

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

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:

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

  Journal publications.

  Nothing to report.

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

  Nothing to report.

  Other publications, conference papers and presentations.

  Nothing to report.

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

Nothing to report.

- **Technologies or techniques**

Nothing to report.

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

Nothing to report.

- **Other Products**

None to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

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, and overseen work on protocol finalization and modification of the initial application to the VA Central IRB.
Funding Support: Partial VA contributed effort and partial University of Washington IBS support (grant-paid)

Name: Talia Ruxin
Project Role: Study Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 10.5 calendar months
Contribution to Project: Drafted and revised all documents relevant to the submission of the initial application to the VA Central IRB, to the VA R&D Committees, and to HRPO, coordinated submission of the initial application, 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
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 5.6 calendar months
Contribution to Project: 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 HRPO. Participated in meetings with investigators regarding human subject testing protocol, participated in ongoing meetings with Humotech to inform procedures for mechanical testing of prosthetic feet, and participated in ongoing meetings to resolve remaining anticipated issues with obtaining necessary VA electrical work prior to mechanical testing of the prosthetic foot emulator.

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 team meetings. In addition, based on his expertise and previous research in the area, 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 data examining the influence of foot type on balance ability (i.e., NBWT performance) was presented and discussed

- Identifying, reviewing, and presenting single item fear of falling questions, accompanied by appropriate citations, to be used during data collections
- Creating a custom version of Dr. Sawers' LLP User Fall Circumstance and Consequence
- Survey for baseline testing
- Presenting a conceptual model characterizing the continuum of balance and falls in LLP users to guide and inform plans for data collection, analysis, and interpretation
- Providing input in discussion with the team that the biomechanical assessment of gait instability on the uneven treadmill be based on a novel measure of the frequency of "reach and grasp" balance recovery strategies while on the treadmill. It was suggested that this may provide a simple binary measure of the instances of instability that requires less interpretation than more complex measures of gait stability. Current efforts are underway to instrument the handrails of the treadmill
- Developing a comprehensive list of co-morbidities for baseline assessment that may impact stability in lower limb prosthesis users
- Revising a list of medications that may be related to falls in lower limb amputees to be collected at baseline
- Delivering a final version of the lower limb prosthesis user fall circumstance and consequence survey
- Presenting validated fall prediction models to assess baseline fall risk in study participants

Name: Sara Koehler-McNicholas, PhD
Project Role: Subaward PI
Researcher Identifier (e.g. ORCID ID): 0000-0002-7201-3607
Nearest person month worked: 0.5
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, including a multi-site visit hosted by the VA Puget Sound study team in April 2022, ordering equipment and supplies, and setting up the laboratory space that will be used for data collection.

Name: Alexandria Lloyd
Project Role: Study Coordinator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 2.5
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 HRPO 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 attended a multi-site study planning meeting held at VA Puget Sound in April 2022.

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

Dr. Morgenroth has had two "Action" projects end this year.

Title: The Evaluation and Redesign of Transmetatarsal Prosthetics to Reduce Peak Plantar Pressures
Funder: National Institutes of Health, R21HD095516
Performance Period: 8/30/2018 – 7/31/2022
Role in Project: Investigator
Time Commitment: 5%

Title: Improving Footwear Options for Women and Men Veterans with Amputations
Funder: VA
Performance Period: 07/01/2018 – 06/30/2022
Role in Project: Investigator
Time Commitment: 5%

In addition, **Dr. Morgenroth** has had one formerly pending project has become active:

Title: Optimizing Ankle-Foot Orthotic Prescription Using an Emulation Test-Drive Strategy
Role in Project: Co-Investigator
Time Commitment: 10% Years 1 and 4; 15% Years 2-3
Funder: Department of Defense/CDMRP/Orthotics and Prosthetics Outcomes Research Program
Performance Period: 3/1/2022-9/29/2022
Proposed Subaward Budget: subaward total costs
Name and address of funding agency's Contracting/Grants Officer: Mark Wilkison, USAMRAA, 1541 Porter Street, Fort Detrick, MD 21702
Brief Description of Project's Goals: To determine the extent to which a test-drive strategy, using an AFO emulator, can be used to predict device function, mobility and preference outcomes with corresponding commercially available AFOs in Service members and Veterans with lower limb musculoskeletal trauma.
Specific Aims: Specific Aim 1. Test the ability of the AFO emulator to reproduce the user experience of wearing commercially available AFOs during different in-laboratory activities in individuals with lower limb musculoskeletal injury. Specific Aim 2: Test the ability of a short-term, in-laboratory evaluation of function, mobility, 5nd preference with the AFO emulator to predict those same outcomes longer-term in AFO users with lower limb musculoskeletal injury. Specific Aim 3: Allow the user to self-tune AFO emulator stiffness settings while walking (patient-optimized) and compare function, mobility, and preference to the clinically prescribed AFO (clinician-optimized).

Overlap: None

Dr. Koehler-McNicholas has submitted a new Previous Current Pending Support document with changes highlighted in yellow, included as an appendix on page 34.

Dr. Sawers has had one project that was pending last year funded and become Active. Dr. Sawers has 1.2 calendar months support on it.

OP190025 (Hafner) 07/01/2020-06/30/2024
1.20 calendar months
Department of Defense
Total cost:
Role: Co-Investigator
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.
Aim 3: 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

What other organizations were involved as partners?

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 and Tianyao Chen (departed this year)
Role: Vendor as per proposal, designing and manufacturing the multi-axial prosthetic foot emulator.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

There are no Partnering PIs involved in this project.

QUAD CHARTS:

Quad chart is attached as an appendix on page 33.

9. APPENDICES:

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 multiaxial 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 held an in-person full investigative team meeting and training at the Seattle VA to discuss study methods and survey instruments and complete training for the use of the multiaxial prosthetic foot emulator. Shown above is a study team member testing the multiaxial prosthetic foot emulator on the rocky Woodway treadmill.

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**

Updated: 07/31/2022

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 hardware and software which have delayed project progress.

Budget Expenditure to Date

Budget: $2,000,000. Actual Expenditure: $712,693 (est. by 7/31/22: $734,515)

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.

- *Aim 1:* 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.
- *Aim 2:* 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.

- *Aim 1:* Determine if static postural stability can be improved with the use of a flat effective rocker shape compared with a curved effective rocker shape.
- *Aim 2:* Determine if dynamic postural stability can be improved with the use of a flat effective rocker shape compared with a curved effective rocker shape.
- *Aim 3:* 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.

- *Aim 1:* Design an adjustable ankle-foot system that offers different ranges of ankle motion.
- *Aim 2:* Develop a mobile app that can control the range of motion of the new ankle-foot system.
- *Aim 3:* Characterize the mechanical properties of the new ankle-foot system during level walking.

No overlap with the current project exists.

CURRENT:

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) 07/01/2018-09/30/2022 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) 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.

OVERLAP:
There is no scientific or budgetary overlap between these projects.