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TITLE: Do Adaptable Sockets Improve Military Performance?

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CONTRACTING ORGANIZATION: University of Washington

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14. ABSTRACT
The focus in Year 1 was on preparation for the randomized control trial to be conducted at CFI during Years 2 to 4 of the research. BAMC IRB and HRPO approval for the study were achieved by the 4th quarter. Because travel between UW and CFI was not allowed (COVID-19 restrictions), UW prepared instructional videos to train CFI personnel on socket scanning using the CFI purchased industrial coordinate measurement machine and electrode preparation and placement for limb fluid volume monitoring (bioimpedance analysis). These materials were supplemented with training via video teleconferencing and with biweekly meetings of all project personnel. CFI staff have completed about 80% of the training and have begun subject recruitment. CFI provided UW with video files of the FCE-M and data files of tests run in the CAREN system so that UW could make minor adjustments to the microprocessor-adjusting sockets and control system algorithms to meet the study needs. The first participant is expected to complete the protocol during the 1st quarter of Year 2.

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NONE LISTED

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Unclassified	Unclassified	Unclassified			

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1. INTRODUCTION:

The subject of the research is to make prosthetic limbs more comfortable for Service Members who seek to return to active duty or engage in an active lifestyle. The purpose is to evaluate a currently available automatic-adjusting socket technology. Findings will inform whether automatic-adjusting sockets affect user outcomes compared with user-adjusting and traditional sockets and establish best practices of how Service Members and Veterans should incorporate adjustable socket technologies to achieve optimal outcomes in their daily lives. There are two aims. The first aim is to fabricate microprocessor-adjusting sockets for Service Members and Veteran participants that can be easily modified into two alternative configurations – user-adjusting and static (traditional). The second aim is to test performance of all three socket configurations (microprocessor-adjusting, user-adjusting, static) in a return to duty assessment simulator reflecting Military relevant environments and duties. The hypothesis is tested that the microprocessor-adjusting socket will improve fit, and users will experience less pain and perform Military specific tests nearer to pre-injured levels of performance.

2. KEYWORDS:

Microprocessor-adjusting socket, residual limb volume, socket fit sensor, amputee, transtibial, biompedance analysis, FCE-M

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The major goals of the project were to set up the study, including hiring of personnel, purchasing of major equipment, obtaining IRB and HRPO approval, and training of personnel to scan sockets, execute bioimpedance analysis (residual limb fluid volume monitoring), operate the automated control socket, and execute the study protocol.

Targeted and actual completion dates for important phases of the project are listed below:

	Timeline	**Progress**	**Completion Date**
Major Task 1: Study Set Up	Months		
Hire research assistant and research prosthetist	1-6	100%	Apr 2020
Place order for precision socket digitizer	1-6	100%	Mar 2020
Obtain IRB and HRPO approval	7-9	100%	July 2020
Milestone Achieved: IRB and HRPO approval received	7-9	100%	July 2020
Train personnel to monitor limb fluid volume and use microprocessor-adjusting socket	7-9	80%	
Prepare logistics for upcoming study	7-9	80%	
Major Task 2: Participant Recruitment and Data Collection	Months		
Recruit and consent initial participant (n=1)	10-12	50%	
Fabricate adjustable sockets for participant	10-39		
Milestone Achieved: 1st participant data collection successful	13-15		
Recruit and consent remaining participants (n=15)	13-39	20%	
Collect data in three socket configurations	10-42		
Milestone Achieved: ½ of participant data collected and analyzed	22-24		
Milestone Achieved: ¾ of participant data collected and analyzed	34-36		
Milestone Achieved: All participants tested	43-48		
Major Task 3: Data Analysis	Months		
Analyze data and prepare results for discussion	13-48		
Travel to UW for discussion of data	13-15, 22-24, 34-36, 43-48		
Discuss results	43-48		
Major Task 4: Dissemination	Months		
Write manuscript	43-48		
Milestone Achieved: Manuscript submitted for publication	43-48		
Write final report	43-48		
Milestone Achieved: Final report submitted	43-48		

What was accomplished under these goals?

The specific objective was to prepare for study data collection. The major activities included completion of logistics and preparation and implementation of socket scanning and fabrication procedures, bioimpedance analysis measurement, and automated control operation. Minor modifications were made to the study protocol. Each of these activities is described in more detail below.

Logistics

The subaward from the University of Washington (UW) to the Brooke Army Medical Center (BAMC) was finalized and approved on 6 Mar 2020.

UW approved to defer decision-making of internal review board (IRB) review and approval to BAMC on 9 Oct 2019. IRB approval from BAMC was received on 2 Apr 2020. A HRPO application was submitted on 9 Apr 2020, and HRPO approval was received on 15 July 2020.

Support staff were hired at the Center for the Intrepid (CFI) at BAMC in Apr 2020 at a total FTE of approximately 83%, consistent with the original grant application. Support staff at UW were hired at a total FTE of approximately 50%, consistent with the original grant application.

Socket Scanning and Fabrication

A high-resolution coordinate measurement machine, equivalent to that currently used at UW to scan participants' current socket shape, was purchased and assembled at CFI on 14 May 2020. A socket support apparatus was designed and constructed jointly by CFI and UW. Because of intermittent closure issues at CFI from COVID-19 regulations, the socket scanning system was not able to be used regularly until July 2020. UW created a training video (Figure 1) to teach CFI staff how to use the digitizer and prepare a socket shape file for socket fabrication. UW sent four test sockets of varying shape to CFI. Comparisons of CFI-scanned sockets and UW-scanned sockets were made so as to help determine when a CFI researcher was sufficiently proficient using the coordinate measurement machine so as to scan sockets for the study. Scan results were than compared to the 3d surface files previously created by UW for each socket using a 3d surface alignment and comparison algorithm (Zachariah 2005, Sanders 2012). The "traditional" weighting algorithm (i.e. 0.8:0.2 ratio minimizing radial error and maximizing shape similarity) served as the optimization criteria when the alignment was performed. Before alignment, the socket brim line was digitally traced to serve as the proximal boundary of the surface considered for alignment and comparison. For all comparisons, the original shape file created by UW served as the reference for the shape file created by CFI staff. For example, when considering percent volume difference, the negative value indicates when the CFI shape is smaller than the UW shape while a positive value indicates shows where the CFI shape is larger. Once each individual operator was able to complete each socket scan with accuracy acceptable for socket fabrication, the scans were repeated in order to verify consistent performance and sufficient operator speed. Results for the final socket scan are listed below in Table 1. The 1st operator at CFI is performing very well and is ready to begin scanning sockets of study participants. Example surface comparison results for Operator 1 Socket 2 are shown in Figure 2a-c and Figure 3a,b. The 2nd operator has completed training and is ready to complete the final scans to characterize performance.

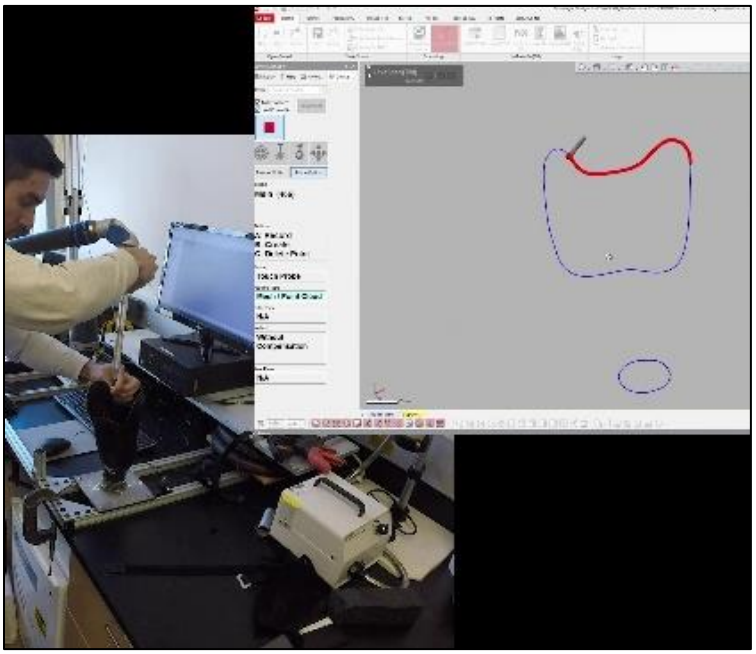


Figure 1. Training video illustrating technique for socket scanning using the industrial coordinate measurement machine.

Table 1. CFI Socket Scan Training Results: Error in CFI Scan Data Compared with UW Scan Data

Operator	Socket	% Volume Difference	% Radii within +/- 1 mm	Min. Radial Error (mm)	Max Radial Error (mm)	St. Dev Radial Error (mm)
1	1	0.03	99.82	-3.30	1.42	0.01
1	2	0.07	99.45	-4.16	2.65	0.02
1	3	-0.01	99.43	-2.83	3.86	0.00
1	4	-0.40	98.80	-1.42	3.99	-0.11
2	1					
2	2					
2	3					
2	4					

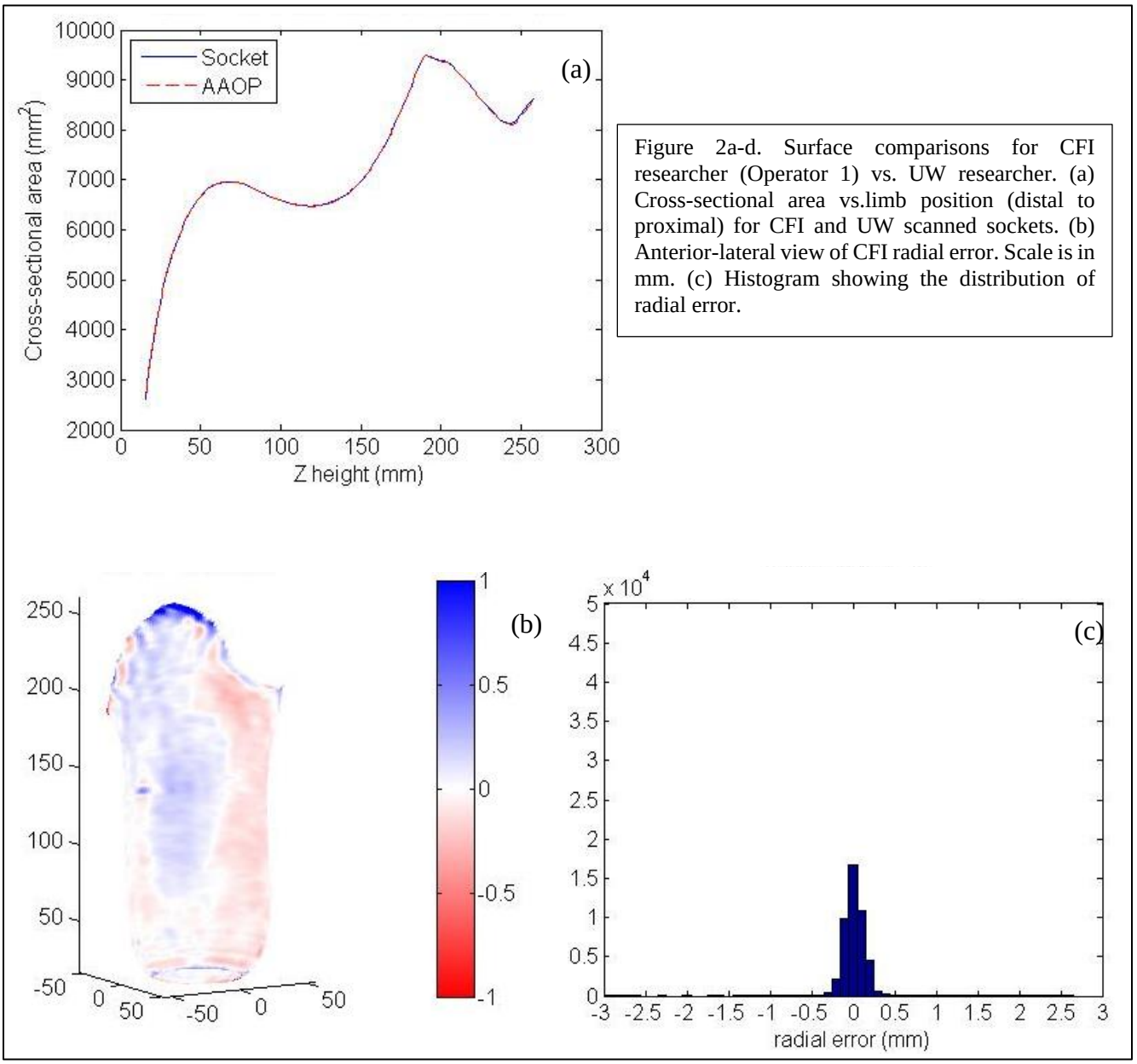


Figure 2a-d. Surface comparisons for CFI researcher (Operator 1) vs. UW researcher. (a) Cross-sectional area vs.limb position (distal to proximal) for CFI and UW scanned sockets. (b) Anterior-lateral view of CFI radial error. Scale is in mm. (c) Histogram showing the distribution of radial error.

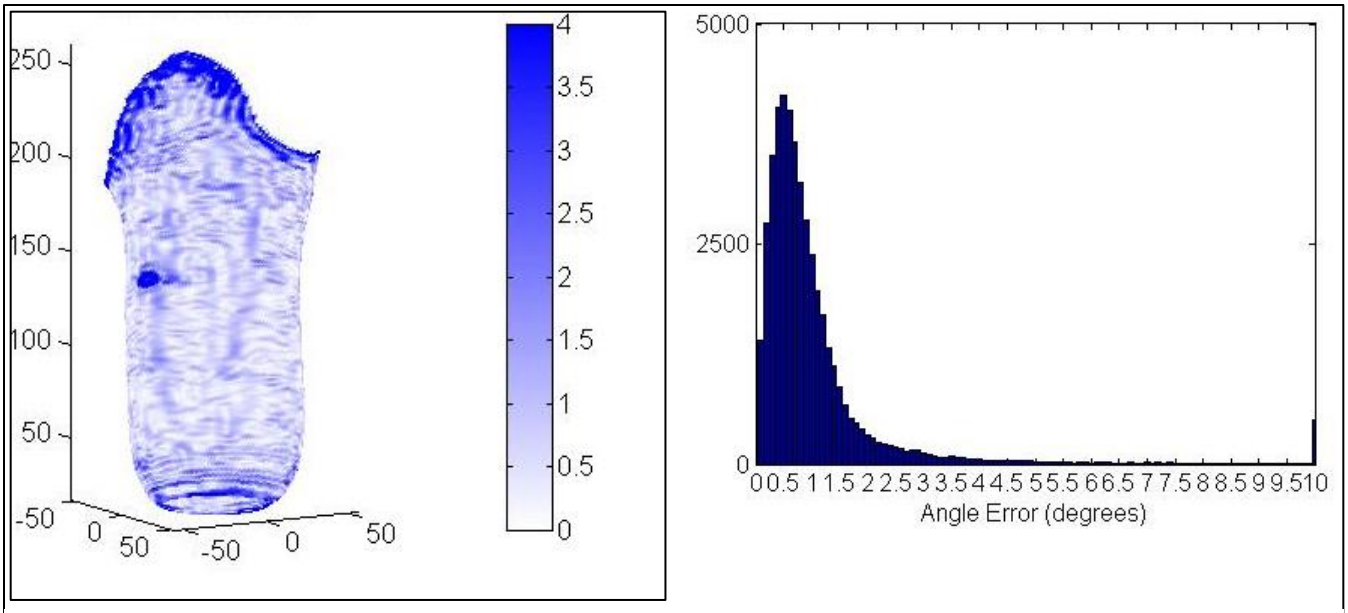


Figure 3a,b. Comparison of socket surface contours using surface angle error. (a) Anterior lateral view of surface angle error for CFI vs. UW scanned sockets. (b) Histogram showing the distribution of surface angle error.

From the sizes and shapes of residual limbs of candidate participants identified during initial recruitment efforts, elastomeric liners with embedded ferrous polymer in a range of sizes were purchased. The ferrous material serves as a target for sensors in the auto-adjusting sockets. UW previously worked with this vendor to develop a means to make these "ferrous" liners, and they are now regularly used in UW's lab. Other materials including antennas to be embedded in the sockets, panel-adjustment parts, batteries and chargers were purchased. Current protective coverings over the motors, gears, electronics, and other parts are expected adequate for testing to be conducted at CFI. However, it will be necessary to determine if panel locations need to be adjusted so as not to interfere with user activities.

Bioimpedance Analysis

In the original grant proposal, CFI was to travel to UW during Year 1 so as to learn how to make and place electrodes on a residual limb and use the bioimpedance analysis system in testing sessions. The bioimpedance analysis system monitors participant limb fluid volume. Travel was not possible because of COVID-19 regulations so this effort was accomplished via remote communication. UW prepared a bioimpedance electrode fabrication and placement training video (Figure 4) and communicated with CFI staff via Zoom conferencing to provide feedback on performance and refinement of their technique if

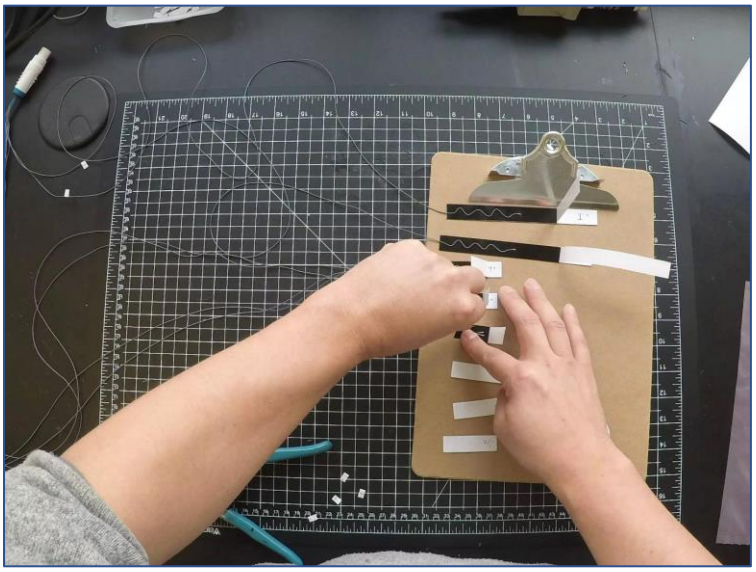


Figure 4. Training video illustrating technique for electrode fabrication.

necessary. CFI personnel have become proficient at electrode fabrication and assembly and are ready to begin bioimpedance data collection on human subjects.

Harnesses are the sets of wires and connectors between the electrodes and the bioimpedance electronic unit. UW ordered numerous harnesses from our regular vendor to send to CFI for use in this study. A duplicate of UW's testing system to test each harness before use will be sent to CFI. This evaluation helps to ensure data from all channels are properly collected during a session. The impedance should be less than 0.75 Ω on each channel. Additional bioimpedance electronic boards were purchased, the units assembled and tested at UW and one unit sent to CFI for training. A remaining issue is to bring CFI up to speed on execution of data processing algorithms. There appears to be a Python code difference between UW and CFI computers. Old functions that are not supported are being updated to new functions that work with currently available libraries and support packages. CFI will send collection data to UW for processing in the interim until this issue is resolved.

Automated Control

Enhancements to the automated control system are needed for the FCE-M protocol because participants do not walk for at least 5 s in each subsection of the test, thus they may not activate the auto-control. UW created a "high-activity" control setting algorithm instead, which is activated by the user via a mobile phone interface. The mobile phone is mounted to the upper arm of the participant (Figure 5). This interface may need to be modified for tactile sensitivity as well if the user needs to operate it without seeing the screen. The high-activity setting sets a smaller liner-to-socket distance, thus a more secure socket fit. The control system returns to the normal activity state when certain low activity conditions are met.

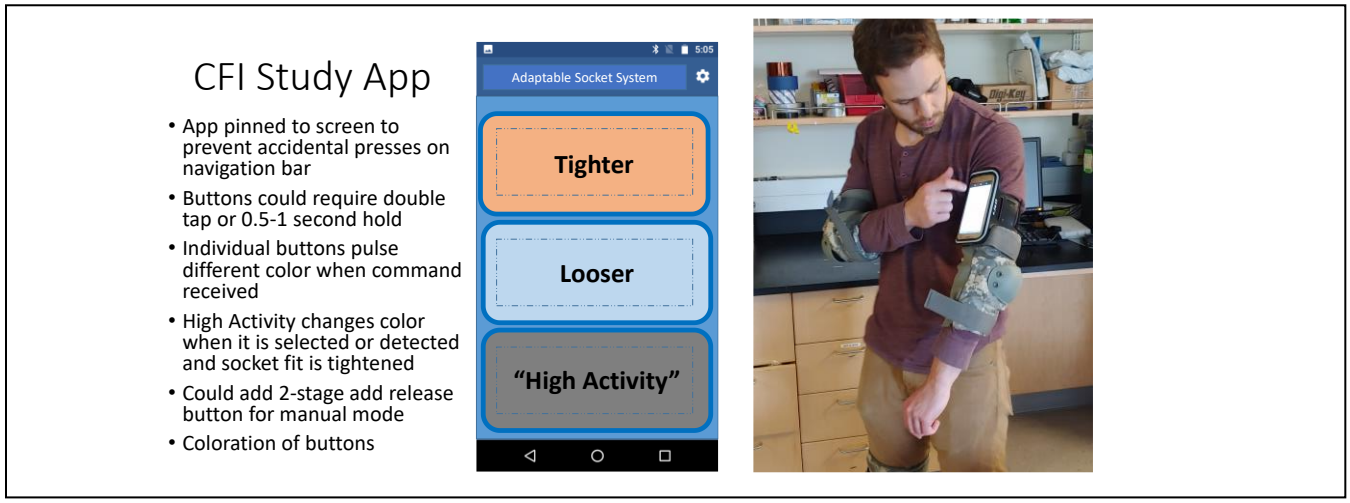


Figure 5. Phone on upper arm and the user interface.

Study Protocol

COVID-19 restrictions required us to modify our preparations to execute the study protocol since UW travel to CFI was not possible from Mar to Sept 2020. UW prepared to run simple bench tests using the biompedance monitoring system in FCE-M-like activities. A drag dummy and flak jacket were acquired in Sep 2020 to facilitate this effort.

CFI reopened for in-person data collection on 1 Sep 2020. As per memo on 19 May 2020 the hold on on-site human subject research from BAMC HRPO was removed. This left the decision to support on-site human subject research to the Department Chiefs or their designees. A request to support data collection for this protocol was sent to the Director of the CFI on 27 Jul 2020. The CFI Director tentatively approved support for on-site data collection after a downgrade of the Joint Base San Antonio Health Protection Condition status, which occurred in Sep 2020.

In recruitment efforts to date, all potential participants considered were from interaction with current patients who met our inclusion criteria – full-time ambulatory transtibial endoskeletal prosthesis users over 18 years of age. Our list of candidates was reduced by prosthesis inclusion criteria – laminated sockets without a flexible inner liner and use of WillowWood elastomeric liners. Our list of candidates was further reduced by availability for a 4 h protocol during the months of data collection and the distance candidates lived from CFI. Despite these issues, we do not expect difficulty recruiting the necessary participants for this study, and we expect at least 4 participants to be immediately available early during Year 2.

For the CAREN part of the study, CFI sent UW a sample CAREN data file so that changes in surface angle of the treadmill are clear, and UW can simulate controller performance in Seattle under these conditions. CFI staff demonstrated on themselves in the CAREN that they could follow COVID-19 protection procedures during this test.

For the FCE-M part of the study, CFI provided UW with videos to teach them the protocol. The protocol will be implemented

similar to prior FCE-M studies executed at CFI, thus prior insight will be used to ensure a successful test. We decided to change the squat task for the FCE-M to an ammunition can carry task out of the Marine Combat Fitness Test as that would be more like what someone would need to do in a deployed environment. That amendment was submitted to the IRB for approval.

While most of the Year 1 goals were met, those involving amputee participants were not completed. This was a result of COVID-19 restrictions that were in place from Mar to Sep 2020. We expect to complete those goals, i.e. finish training CFI personnel how to use the microprocessor-adjusting socket and consent the first participant during the fall of 2020.

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?

Our plan is to complete fabrication and data collection on the first test participant during the first quarter of Year 2. During the remaining three quarters, we expect to collect data on an additional five participants. Data will be prepared for analysis and discussed among the investigators.

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

COVID-19 restrictions caused delays related to human subject testing between Mar and Sep 2020. Our plan to resolve the delay is to enhance recruitment and testing during Year 2 to get the project back on the original timeline. Additional staff will be hired to accomplish this objective.

Changes that had a significant impact on expenditures

There were delays in hiring staff because of the time it took to work out the subcontract between UW and CFI. The primary issue had to do with submission of IRB documents.

Travel was not conducted in the second half of Year 1 because of COVID-19 restrictions.

Human subject studies were not started because of IRB restrictions on human subject testing due to COVID-19 restrictions.

6. PRODUCTS:

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Joan Sanders, PhD
Project Role:	PI
Researcher Identifier (ORCID ID):	0000-0002-8850-243X

Nearest person month worked: 1
Contribution to Project: Dr. Sanders coordinates the project, communicating regularly with Dr. Childers on study-related issues

Name: Lee Childers, PhD
Project Role: Co-PI
Researcher Identifier (ORCID ID): 0000-0002-6119-983X
Nearest person month worked: 1
Contribution to Project: Dr. Childers manages IRB and other administrative issues, and study personnel at the CFI
Funding Support: The Extremity Trauma and Amputation Center of Excellence covers my salary for this project as a DoD employee

Name: Lauren Brousseau CPO
Project Role: Research Prosthetist
Researcher Identifier (ORCID ID): 0000-0002-9159-4144
Nearest person month worked: 5
Contribution to Project: Recruitment, video preparation, prosthetic support

Name: Noel Guerrero
Project Role: Research Assistant
Researcher Identifier (ORCID ID): 0000-0002-5129-1763
Nearest person month worked: 1
Contribution to Project: Video preparation, study execution, materials prep

Name: John Fergason, L/CPO
Project Role: Collaborator (formerly Associate Investigator)
Researcher Identifier (ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Recruitment
Funding Support: The Extremity Trauma and Amputation Center of Excellence covers my salary for this project as a DoD employee

Name: Jonathon Wilson DPT
Project Role: Collaborator (formerly Associate Investigator)
Researcher Identifier (ORCID ID): N/A
Nearest person month worked: 1
Contribution to Project: Study execution, subject screening
Funding Support: The Extremity Trauma and Amputation Center of Excellence covers my salary for this project as a DoD employee

Name: Mathew Weissinger
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Mechanical design

Name: Andrew Vamos
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Control system design

Name: Ryan Carter
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Socket preparation

Name:	Katheryn Allyn
Project Role:	Research Prosthetist
Researcher Identifier (ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Clinical advisor, prosthetic support, recruitment

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

Sanders

Previously active grant has closed
W81XWH-16-1-0585. *Preliminary investigation of a diagnostic tool for prosthetics*
Level of effort: 1.6 mo

Previously pending grant is now active
CDMRP DM190651. *An automatically adjusting dynamic orthosis to enhance performance of Warfighters with lower limb injury*
Level of effort: 1.7 mo

Childers

Previously active grant has closed
W81XWH-17-1-0031. *User-independent intent recognition on a powered transfemoral prosthesis*
Level of effort: 0.25 mo

What other organizations were involved as partners?

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHARTS:

Do Adaptable Sockets Improve Military Performance?

OP180051

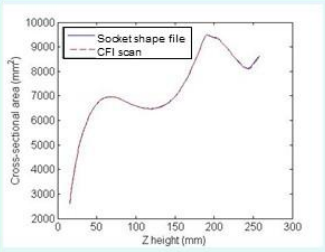
PIs: JE Sanders PhD **Orgs.:** University of Washington **Award Amount:** $1.48M

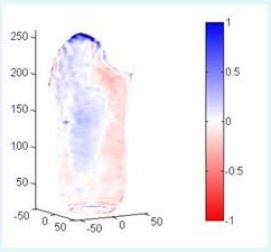
Study Aims

1. Fabricate microprocessor-adjusting sockets specific for Service Members and Veterans with transtibial limb loss who have goals of returning to high-level physical activities
2. Evaluate Military task performance using "Readiness Assessments," testing three different socket configurations – microprocessor-adjusting, user-adjusting, and static:
   * Simulated combat patrol in a Virtual Realty Environment
   * Military version of a Functional Capacity Evaluation
3. Characterize performance, user preference, and usability of different socket configurations

Approach

A novel adaptable socket is tested on Military participants with transtibial limb loss.





Example CFI socket scanning result. Both cross-sectional area and socket shape are well matched between shape file data and CFI scan data.

Accomplishments: CFI able to proficiently execute socket scanning; starting to implement bioimpedance data collection system

Timeline and Cost

Activities / CY	19	20	21	22
Prepare microprocessor-adjusting sockets for Military participants				
Evaluated under simulated combat				
Characterize performance, user preference, and usability				
Estimated Budget ($K)	**$369**	**$398**	**$409**	**$304**

Updated: October 1, 2020

Goals/Milestones

CY19 Goals – Prepare for data collection
☒ IRB/HRPO approval
☐ Training (80% completed)
CY20 Goals – 1st group data collection
☐ Socket fab at UW, testing at CFI
☐ Analysis of collected data
CY21 Goals – 2nd group data collection
☐ Socket fab at UW, testing at CFI
☐ Analysis of collected data
CY22 Goal – 3rd group data collection
☐ Socket fab at UW, testing at CFI
☐ Analysis and interpretation of all data

Comments/Challenges/Issues/Concerns

- NA

Budget Expenditure to Date

Projected Expenditure: $ 369k
Actual Expenditure: $196k

9. APPENDICES

Nothing to Report.