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CONTRACTING ORGANIZATION: University of Washington, Seattle, WA

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
The focus in Year 2 was on solving minor issues in the study procedures including scanning sockets, executing bioimpedance analysis (residual limb fluid volume monitoring), operating the microprocessor socket in all modes (auto, manual, locked) and executing the CAREN and FCE-M protocols. Three CFI researchers are now certified in socket scanning. The phone app was updated to better meet the project needs. Testing at CFI demonstrated that the system performed properly during study test sessions. All procedures and equipment are finalized, and the full study has begun. Data collection was completed on the first participant in all three modes. Results demonstrated fluid volume gains during the protocol conducted in the CAREN. During the CAREN test in manual mode, the participant slightly over-compensated his panel adjustment when the socket felt tight, creating a looser socket at the end of the protocol than at the outset. When in auto mode in the FCE-M, the socket made frequent automatic adjustments in an effort to maintain a consistent sensed distance.

15. SUBJECT TERMS
None listed.

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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 (termed "auto mode" in this report), user-adjusting (termed "manual mode"), and static (termed "locked mode") 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 in Year 2 were to debug the study procedures including scanning sockets, executing bioimpedance analysis (residual limb fluid volume monitoring), operating the automated control socket, and executing the CAREN and FCE-M protocols; complete data collection on the first participant; and complete data collection and analysis on an additional six participants. 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	100%	Apr 2021
Prepare logistics for upcoming study	7-9	100%	May 2021
Major Task 2: Participant Recruitment and Data Collection	Months		
Recruit and consent initial participant (n=1)	10-12	100%	Nov 2020
Fabricate adjustable sockets for participant	10-39	100%	Feb 2021
Milestone Achieved: 1st participant data collection successful	13-15	100%	Aug 2021
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	17%	
Milestone Achieved: ¾ of participant data collected and analyzed	34-36	9%	
Milestone Achieved: All participants tested	43-48	7%	
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 and execute 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. Data collection was completed on the first participant, and partially completed on an additional two participants. Participant testing delays as a result of COVID-19 restrictions during most of Year 2 as well as equipment damage at CFI from the Texas storms in 2021 limited our capability to complete the third goal (data collection and analysis on an additional six participants). Most of the COVID-19 restrictions were lifted at the end of Year 2 so this issue is expected to improve in Year 3.

Logistics

Additional management materials were generated by UW to facilitate execution of the study at CFI. These included an assembly checklist for automatic mode test sessions, training material on how to assemble the socket frames and panels should repair or replacement be necessary, and instructions to include the trimlines and the shape of the distal end when scanning participant sockets. UW prepared and sent to CFI a "harness tester," an apparatus to test electrode harnesses for proper conductivity before they are used in bioimpedance data collection sessions. A list of tools was prepared for CFI to acquire so as to conduct simple repairs or adjustments during session preparation and operation.

Socket Scanning and Fabrication

The selected three test socket shapes that operators must successfully scan for scanner certification are shown in Fig. 1. The sockets are representative of transtibial residual limbs with shapes described as conical, bulbous, and cylindrical. Conical limbs have less tissue over the more prominent bony structures and are tapered distally. Bulbous limbs have more soft tissue and are rounded distally. Cylindrical limbs have more soft tissue covering the skeletal anatomy, and the end on the limb does not taper like the conical limb. The sockets are representative of the range of socket shapes likely to be encountered during participant testing in this project.

Fig. 1. Test socket shapes. Operators must scan each socket within defined ranges of error to become certified.

Operators are considered certified once they achieve at least 98% radii within ±1.00 mm with an absolute value radial error less than 5.00 mm. If the location of high absolute value radial error is only at the brim or the distal edge, identified by the evaluator visually inspecting images of the shape difference between the scan and the digital shape file, then the 98% cutoff is relaxed and an absolute value radial error greater than or equal to 5.00 mm is acceptable. Error at the brim and distal edge are not considered relevant because the socket is made with a different brim line location and distal edge location than that of the digital file. Three CFI operators are certified, and one other is near completion (Table 1).

Table 1. CFI Socket Scan Training

Operator	Test Socket No.	% Volume Difference	% Radii within +/- 1 mm	Min. Radial Error (mm)	Max Radial Error (mm)	St. Dev Radial Error (mm)	Result
1	1	0.03	99.82	-3.30	1.42	0.01	Pass
1	2	0.07	99.45	-4.16	2.65	0.02	Pass
1	3	-0.01	99.43	-2.83	3.86	0.00	Pass
2	1	0.05	99.44	-15.04*	1.68	0.00	Pass
2	2	-0.28	99.37	-12.01*	2.69	-0.08	Pass
2	3						
3	1	2.19	71.72**	-5.25**	2.74	0.68	Pass
3	2	-0.03	98.69	-4.91	3.20	0.00	Pass
3	3	-0.04	98.74	-3.10	3.12	-0.01	Pass
4	1	1.82	75.88**	-4.09	2.57	0.55	Pass
4	2	-0.06	99.38	-1.82	2.77	-0.01	Pass
4	3	-0.01	98.56	-3.24	3.08	-0.00	Pass

*Errors were only at the brim line and very distal edge thus the scan was considered acceptable
** High values a result of an indirect comparison method – the direct method will be implemented shortly

The socket shapes for the first three study participants were successfully scanned. Because one of the participants normally used a suction socket, a procedure needed to be developed to convert his shape to a socket with pin suspension. The height of the distal umbrella needed to be considered as did the location where the umbrella contacted the wall of the socket. Since this issue is likely to happen again in other participants, we developed a computational procedure to make this conversion quickly and accurately. After the socket shape including the distal end is scanned and the dimensions of the umbrella of the liner to be worn are measured, the shapes are merged in the GeoMagic™ software, and the proper socket shape is calculated. This shape is used for fabrication.

Phone App Enhancement

Phone app modifications were deemed necessary during preliminary testing at UW and CFI. The phone app was updated to include the following changes:

- Make auto button toggleable (indicate if on or off)
- Add a counter for the current socket size
- Add some form of color indicator to show that a button push was received
- Make it more difficult for subjects to accidently close the screen of the app
- Ensure that the battery indicator accurately updates to the socket battery level, not the phone battery level
- Change the layout to represent the initial ideation
- Increase the button and display size for easier use in the armband
- Create a separate auto-less version for manual mode testing
- Make the app easier to use

The new phone app is illustrated in Fig. 2, and a flowchart is provided in Fig. 3. To make these changes, the app needed to be updated to a modern API. The following improvements were made:

- Implemented Google's update service in the overall structure of the project (adding in google.android.material to the app level Gradle)
- Ported over to Android using inbuilt refractor function
- Updated the xml files (files that control the appearance of the app) to androidx manually as the refractor did not automatically update them

- Updated butterknife to its most recent version t. Butterknife is a now depreciated 3rd party program that was the gold standard for virewbinding (assigning a button or picture to a program in the code.) This function was added into the androidx libraries but was kept in place as it is a stable library with no known bugs and much of the app's infrastructure was built around it
- Updated the Gradle and Gradle build software to their current versions (first to API 27 version then using the refractor to update to androidx then updating after that). Gradle is a build automation tool that allows one to more easily make the underlying infrastructure for apps and allows communication between different coding languages

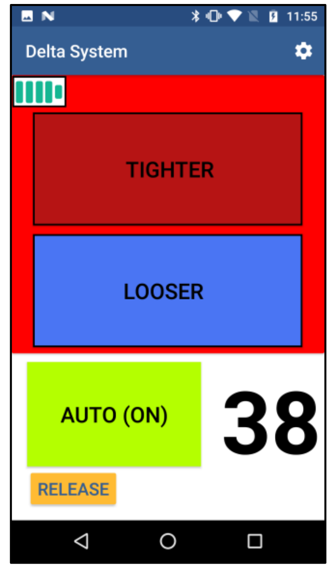


Fig. 2. User interface for the new phone app.

To add the functionality items, the following updates were made:

- **Auto**
  - Toggle Button imported `(Line 25,82,102)`
    - Allows the auto toggle button to change what it displays when it gets pressed so that the user knows whether the auto is currently on or off
  - Edited the Auto Message Dialog so it works with the toggle
  - Removed the automatic disabling of the auto button when the loosest position of the socket is reached. This was an odd use case that was caused by an error in how the original app makers set up the auto toggle in `BleCommander`. The stop function does not stop the device, it simply toggles whether it is on or off
  - Created a separate version without the auto button for manual mode. This basically means that as opposed to reading in the values from the board the entire time, the phone instead keeps track of the position on its own and only reads in the position when opening the app to ensure it starts at the right place `(counterMethod)`
- **Battery**
  - Ensured it was updating. There was a firmware problem on the board causing miscommunication to the app
- **Counter**
  - Implemented a counter. Previously, the state was not tracked on the app `(socketSize)`
  - Updated every 0.5 seconds based on the current device state `(keepChecking)`
  - Created a color changing method built off the counter for further indication of size at a glance `(changeBackground)`
  - Allowed for a more efficient auto-less version without a need for constant checking operations `(counterMethod)`
- **Crash Save**
  - Auto state now saved `(stopOrResume.onClickListener)`
  - Current position now saved `(socketSize)`
  - Current battery now saved `(batteryPercent)`
  - If app is disconnected and changes are made elsewhere, the app will still find the correct values `(deviceConnected->connectHandler)`
- **Exterior Buttons**
  - Key Event Imported `(Line 17)`
    - Removed ability to volume up or down which allowed users to get out of the app `(dispatchKeyEvent)`
    - Attempted to remove power button but there were issues with the current implementation that prevented users from being able to power down or make emergency calls `(OnKeyDown)`
- **Looser**
  - Minor changes. Addition made to Autoless version `(counterMethod)`

- **Release**
    - Minor changes. Addition made to Autoless version `(counterMethod)`
- **Tighter**
    - Minor changes. Addition made to Autoless version `(counterMethod)`

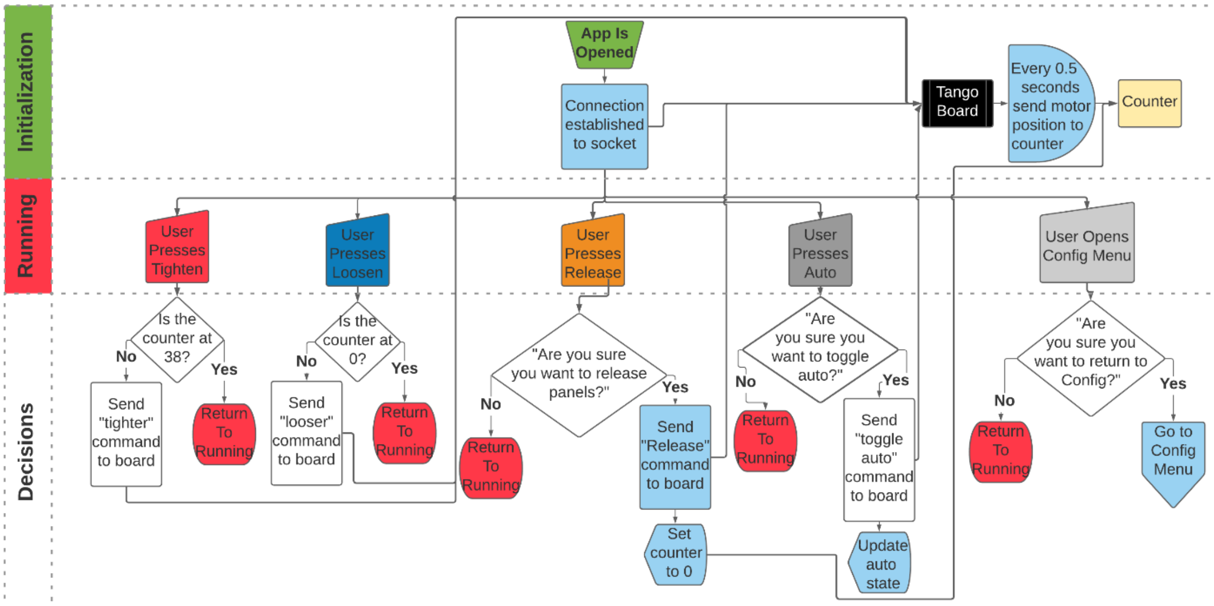


Fig. 3. App Flowchart. Diagram illustrating operation of the phone app that communicates user instructions to the microprocessor socket.

The phone application is fully functional and has successfully been utilized during bioimpedance data collection of the user-adjusting socket configuration.

Study Protocol

Preliminary testing of the microprocessor socket in study procedures at CFI showed that it functioned properly when participants wore their regular military knee pads. The knee pads did not interfere with the actuator or its performance, and the pads effectively protected the actuator and frame that supported the socket panels from mechanical damage. Thus, no additional modifications were made to the frame or actuator design to enhance durability.

Two minor amendments were made to the study protocol. The first amendment (Ref #9306398) changed the squat task from the FCE-M to an ammunition carry task out of the Marine Combat Fitness Test. This change was made since it was considered a more relevant test of the microprocessor socket. The amendment was approved on 12 Nov 2020. The second amendment (Ref #932613) added an additional data collection form (Subject Session Data v1.0 20201102) to improve organization and ensure consistency between visits. The second amendment was approved on 16 Nov 2020.

Study Execution

To date, three participants have been recruited and signed the consent form. Test sockets were made for two of the study participants. One participant has completed testing in all three modes.

Table 2. Procedures Completed on Study Participants to Date

Procedure	T01	T02	T03
Signed consent form	X	X	X

Pre-monitoring*	X	X	X
Check fitting of socket from UW**	X	X	
Automatic socket fitting***	X	X	
Locked/RedOp/CAREN/FCE-M test	X		
Manual/RedOp/CAREN/FCE-M test	X		
Auto/RedOp/CAREN/FCE-M test	X		

*Includes bioimpedance 5-cycle test; socket scan; and questionnaire surveys of participants' normal socket
**Includes bioimpedance 5-cycle test on check socket of the test socket shape
***Includes biompedance 5-cycle test; plant gain test; and optional in lab walking on final test socket to become familiar with socket operation

Table 3. List of Issues and Corrections

Issue	Correction
Participant 1 experienced an adverse event related to skin breakdown	A certified prosthetist will now be responsible for assessing fit not only during normal level ground walking, but also during dynamic activities involving knee flexion greater than 80 degrees. The prosthetist will also perform routine skin inspections prior to data collection and between tasks, specifically the RedOp and FCE-M
Bioimpedance system crashed at the outset of a test session. Researchers did not know this until the session was over	UW provided a portable tablet computer to CFI with appropriate software so that the researchers can see the bioimpedance data in real time during the test session. The tablet allows a crash to be identified, and the unit is reset
Inconsistent electrode placement and wire routing from session to session due to different procedures executed by new staff members	UW provided CFI with an updated illustrated document describing the procedures, a video showing how to place electrodes and wires on a participant, verbal comments during data collection sessions via Zoom, and written comments from photographs CFI collected during sessions where UW personnel were not Zoom connected
CFI needed to learn how to calibrate the locking pin since on one participant the pin was changed after the socket was sent to CFI	UW provided CFI the calibration testing materials and a written document describing the pin calibration procedure. A Zoom conference was conducted to ensure the process was done correctly the first time CFI executed it
Panels did not move during CAREN testing on a participant	A safety feature previously put in the code for at-home testing turned off the controller in automatic mode if the panels were more than +1.50 mm outward from the flush position. This constraint has been eliminated from the firmware since it is not necessary for the CFI protocol

Data Analysis

Participant plant gain results have shown values ranging from 3146 to 3497 (Table 4), within the range of plant gains collected during at-home testing in prior studies on participants at UW. The plant gain is the slope of the LCD counts from the socket fit sensor plotted against the panel distance. The plant gain is programmed into the microprocessor socket for each individual user so that the socket size is appropriately adjusted based on sensed distance data. The consistency of plant gain results for the first test participant in multiple sessions indicates that the limb microprocessor socket system is performing well.

Table 4. Participant Plant Gain Results

Participant	Plant Gain			
	1st test session	2nd test session	3rd test session	Mean (range)
T01	3497	3146	3428	3357 (3146 to 3497)

T02	3481			
T03	Not started			

Results from data collection during manual mode operation for participant T01 are shown in Figs. 4 and 5 below.

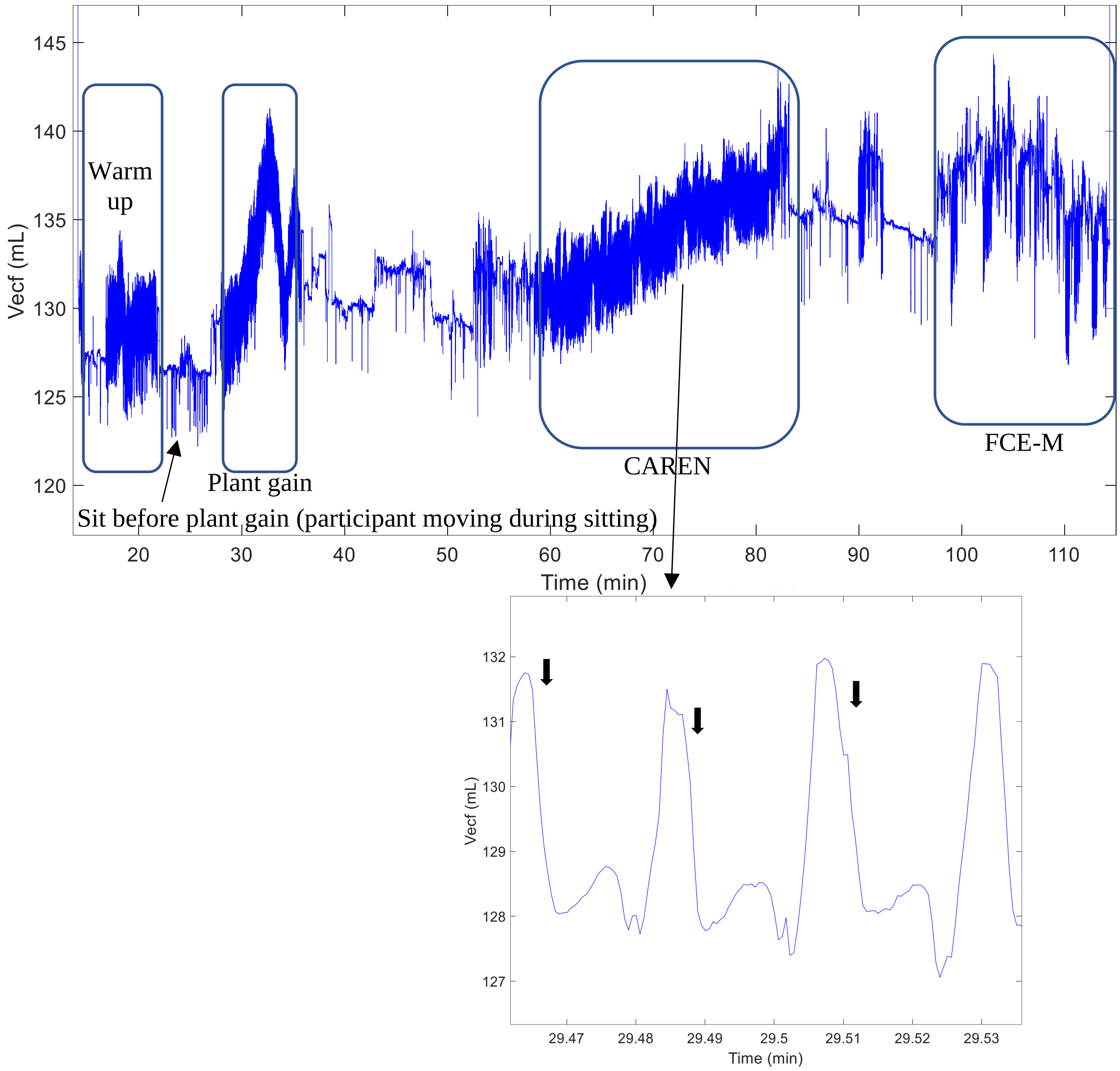


Fig. 4. Limb fluid volume (bioimpedance) data from CAREN and FCE-M testing. In the inset, 3 steps in the CAREN are shown. The start of stance phase is indicated with arrows.

In Fig. 4, limb fluid volume data from the posterior region is shown over the course of the 2-h test session. After a warm-up walk getting used to the test socket and establishing his preferred socket size, the participant sits in preparation for start of the plant gain test. The signal changes during sitting because the participant is fidgety, continually moving. The plant gain test starts, and the participant walks on the treadmill at a constant speed. Limb fluid volume increases over time because the socket panels are slowly being pulled outward. The increased space available to the residual limb combined with the greater vascular drive generated by the participant while walking causes this increase. When the participant indicates that the socket is of a size that he would normally add a sock (i.e., it feels loose), the researchers move the socket panels inward at a rate about twice as fast as earlier when they were pulled outward. During the plant gain test, the signal looks thick because the fluid volume is decreasing and increasing within each step. After the plant gain test, the participant sits and stands for 15 min while preparing for the protocol in the CAREN. While in the CAREN performing the test, the participant gains limb fluid volume over time. No panel position changes are executed for the first half of the CAREN test and limb fluid volume continues to increase over time. The limb fluid volume signal demonstrates a double-peak curve during stance phase, as shown by the insert in Fig. 4.

After the CAREN test is completed, the participant and researchers prepare for the FCE-M test. During the FCE-M test, the participant sometimes shows increases and sometimes shows decreases in his limb fluid volume.

Data from the microprocessor socket for the CAREN part of the same manual mode test are shown in Fig. 5. The upper plot shows socket fit metric (SFM) data. This is the sensed distance data (liner-to-socket distance) from the sensors within the socket wall. There are cycles of maneuvers conducted during this test, explaining part of the change in signal. The lower plot shows panel position (socket size) which are adjustments made by the participant

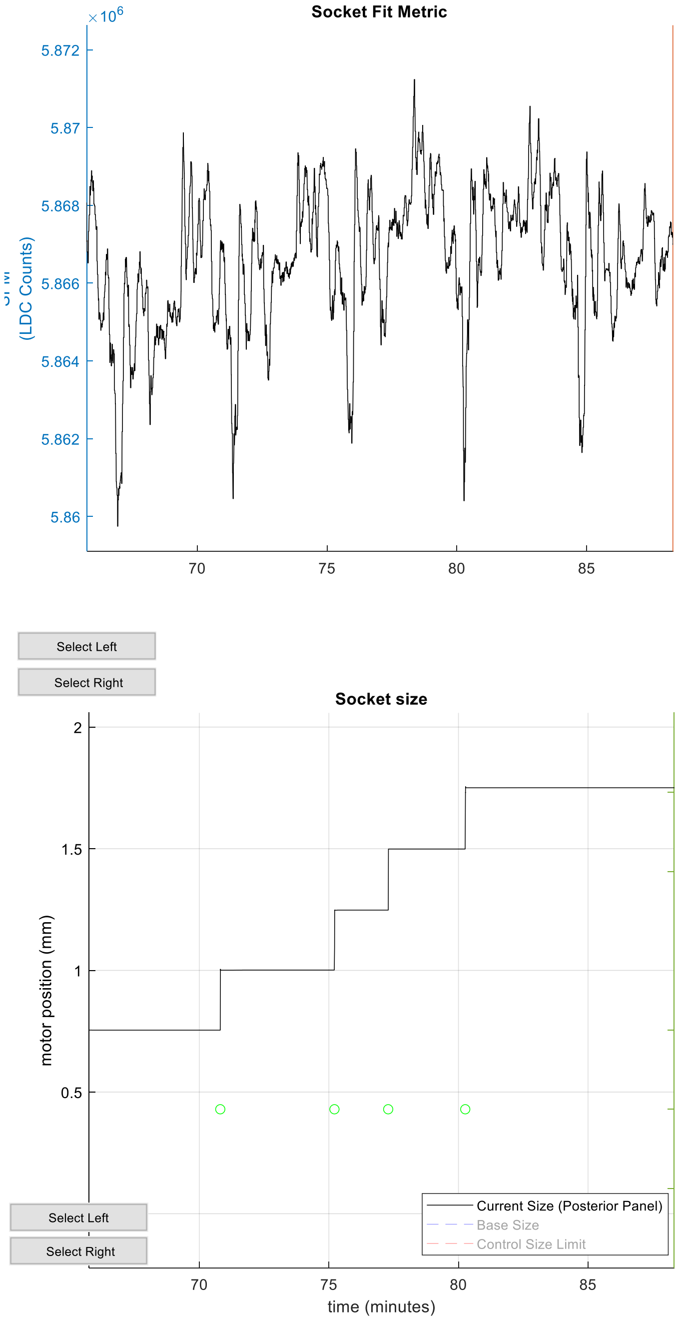


Fig. 5. Socket fit metric (SFM) data (upper plot) and socket size change data made by the participant (lower plot) during the CAREN part of the test (same session as Fig. 4). The subject is using the test socket in manual mode.

while in the CAREN in manual mode. The participant senses that the socket is too tight, consistent with the limb fluid volume data shown in Fig. 4 up to the 71 min mark. At about the 71 min mark, he enlarges the socket one step (0.250 mm). He conducts three more panel size increases, during the next 10 min, each of 0.250 mm. Because the participant is increasing socket size, his limb fluid volume (Fig. 4) continues to increase. Because the SFM data (upper plot, Fig. 5) is slightly increasing during this time, we conclude that the participant is overcompensating, moving the panels outward at a faster rate than is appropriate to maintain a consistent sensed distance. If the socket were in auto mode receiving this sensed distance signal, it would not have increased socket size so rapidly. Instead, a lower gradual size change would have been executed.

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

Nothing to Report.

How were the results disseminated to communities of interest?

Nothing to Report.

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

During the next quarter, we expect to continue with recruitment and data collections at CFI. Participant 2 will begin data collection for each socket condition. UW will fabricate participant 3's microprocessor-adjusting socket. Participant 3 will then begin data collection for each socket condition.

4. IMPACT:

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

Completion of data collection in the first participant is an important milestone that enables addressing the study questions.

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

The CAREN at CFI was shut down from March 2021 to June 2021, slowing data collection. Subject recruitment will be stepped up in Year 3. Staff turnover at CFI required time be devoted to training new personnel, slowing down data collection.

Participant 1 experienced an adverse event related to skin breakdown. A certified prosthetist will now be responsible for assessing fit not only during normal level ground walking, but also during dynamic activities involving knee flexion greater than 80 degrees. The prosthetist will also perform routine skin inspections prior to data collection and between tasks, specifically the RedOp and FCE-M.

Participant 1 had 2 protocol deviations due to taking longer than six weeks to complete all socket conditions. This was due to a combination of factors. The research team needed a tablet and WiFi bioimpedance board to ensure that bioimpedance data was collected uninterrupted. The participant also had unexpected commitments occur at work, forcing cancellations.

Changes that had a significant impact on expenditures
Nothing to Report.

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:	2
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
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:	3
Contribution to Project:	Video preparation, study execution, materials prep
Name:	Ciera Price, CPO
Project Role:	Research Prosthetist
Researcher Identifier (ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Recruitment, materials prep, study execution
Name:	Molly Baumann, PhD
Project Role:	Research Prosthetist
Researcher Identifier (ORCID ID):	0000-0002-5462-405x
Nearest person month worked:	1
Contribution to Project:	Recruitment, prosthetic support, 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: 2
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

Name: Gabriel Lake
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Electronics design and debugging

Name: Nicholas DeGrasse
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Study execution management, data processing, and analysis

Name: Daniel Ballesteros
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Data presentation

Name: Brian Larsen
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Data analysis

Name: Bailey Ramesh
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Control system debugging

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 that has closed:

W81XWH-16-C-0020 (Sanders)
JWMRP
"Automatic control of volume management systems for people with limb loss"

New grant that has started:

W81XWH-21-2-0003 (Childers)
OPORP
"Clinical translatability of reactive hyperemia measurements that can monitor adaptation of residual limb skin to socket wear"
Level of effort: 0.6 mo

Childers

Previously active grant that has closed:

NRI 2.0 1734416
NSF
"NRI:INT:COLLAB: Accelerating large-scale adoption of robotic lower-limb prostheses through personalized prosthesis controller adaptation"

W81XWH-15-2-0035
USAMRAA (site-PI)
"Development of an engaging training tool to provide superior muscle computer interfaces for rehabilitation of neuromusculoskeletal injuries"

W911QY-16-A-0013
Telemedicine and Advanced Technology (site PI)
"Automated assessment of rehabilitation outcomes"

CDMRP (site PI)
"A prosthetic foot emulator to optimize prescription of prosthetic feet in Veterans and Service Members with leg amputations"

New grants that have started:

W81XWH-21-CCCRP-AD (Childers)
CCCRP
"Development of ambulatory external fixation device for lower extremity combat injuries"
Level of effort: 0.9 month

W81XWH18SBAA1 (Childers)
CRMRP
"Rapidly deployable exoskeletons for prolonged field care scenarios in austere environments"
Level of effort: 1.2 months

W81XWH-21-2-0003 (Childers)
OPORP
"Clinical translatability of reactive hyperemia measurements that can monitor adaptation of residual limb skin to socket wear"
Level of effort: 01.2 months

PRORP
CDMRP (Childers)
"Exoskeletons for rapid return to duty after tibial stress fracture"
Level of effort: 1.2 months

OPORP
CDMRP
"Validation of military-relevant assessments to predict successful return to duty following lower limb injury"
Level of effort: 0.6 month

OPORP
CDMRP
"Personalizing MPK prescription for individuals with transfemoral amputation"
Level of effort: 0.3 month

What other organizations were involved as partners?

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHART:

Do Adaptable Sockets Improve Military Performance?

OP180051

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

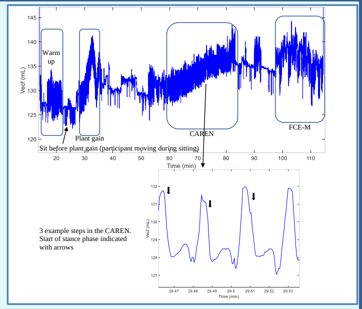
Study Aims

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.

Limb fluid volume data collected while the participant wears the socket in the manual mode.



Accomplishments: Data collection on the first participant completed.

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, 2021

Goals/Milestones

CY19 Goals – Prepare for data collection
☒ IRB/HRPO approval
☒ Training
CY20 Goals – 1st group data collection
☒ Socket fab at UW, testing at CFI (25%)
☒ Analysis of collected data (25%)
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: $ 767k
Actual Expenditure: $ 519k

9. APPENDICES

Nothing to Report.