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TITLE: Do Adaptable Sockets Improve Military Performance?

PRINCIPAL INVESTIGATOR: Joan E Sanders PhD

CONTRACTING ORGANIZATION: University of Washington, Seattle, WA

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13. SUPPLEMENTARY NOTES					
14. ABSTRACT The focus in Year 4 was on data collection and recruitment. All remaining participants have been recruited and all socket fabrication has been completed. Analysis plots and tables are up to date for all participants who have finished the study protocol. The remaining tasks are to complete data collection and analysis on four remaining participants, approximately 10 data collection sessions. Statistical analysis to address the study hypotheses will then be conducted and a manuscript prepared on the study results.					
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 improves fit, and users 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, adaptable socket, CAREN, FCE-M

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The major goal of the project in Year 4 was to collect data on additional participants, executing the CAREN and FCE-M protocols. 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%	Jul 2020
<i>Milestone Achieved: IRB and HRPO approval received</i>	7-9	100%	Jul 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
<i>Milestone Achieved: 1st participant data collection successful</i>	13-15	100%	Aug 2021
Recruit and consent remaining participants (n=15)	13-39	100%	Sep 2023
Collect data in three socket configurations	10-42	73%	
<i>Milestone Achieved: ½ of participant data collected and analyzed</i>	22-24	100%	Jun 2023
<i>Milestone Achieved: ¾ of participant data collected and analyzed</i>	34-36	100%	Aug 2023
<i>Milestone Achieved: All participants tested</i>	43-48	73%	
Major Task 3: Data Analysis	Months		
Analyze data and prepare results for discussion	13-48	73%	
Zoom discussion of data for ¼ of participants	13-15,	100%	Aug 2022
Zoom discussion of data for ½ of participants	22-24,	100%	Jun 2023
Zoom discussion of data for ¾ of participants	34-36,	100%	Sep 2023
Zoom discussion of data for all participants	43-48	73%	
Discuss results for manuscript prep	43-48		
Major Task 4: Dissemination	Months		
Write manuscript	43-48		
<i>Milestone Achieved: Manuscript submitted for publication</i>	43-48		
Write final report	43-48		
<i>Milestone Achieved: Final report submitted</i>	43-48		

What was accomplished under these goals?

The specific objective in Year 4 was to continue to fabricate sockets and execute data collection on participants. The major activities included: completion of testing of 11 participants total (includes 3 dropouts); and recruitment of the rest of the participants. Four participants are still completing testing.

Logistics

There were still some socket fabrication issues at CFI, so the last 4 sockets for the study were made at UW instead. All socket fabrication is completed.

Study Protocol

Minor modifications were made to the study protocol, based on analysis of test results to date. The algorithm to calculate plant gain was adjusted to be consistent with that currently used in other auto-adjusting sockets in Sanders’ lab, reducing performance error.

Study Execution

Testing was completed on a total of 11 participants (including 3 dropouts). Socket design and fabrication are now complete for all participants. An updated list of study progress is provided in Table 1, and the status of the analysis plots are summarized in Table 2. Issues that occurred during testing in Year 4 and how they were managed are summarized in Table 3.

Table 1. Procedures Completed on Study Participants to Date. Yellow boxes indicate remaining sessions.

Procedure	T01	T02	T03	T04	T05	T06	T07	T08
Signed consent form	X	X	X	X	X	X	X	X
Pre-monitoring*	X	X	X	X	X	X	X	X
Check fitting of socket from UW**	X	X	X	X	X	X	NA ^a	X
Automatic socket fitting***	X	X	X	X	X	X	X	X
Locked/RedOp/CAREN/FCE-M test	X	X	X	X	X		X	X
Manual/RedOp/CAREN/FCE-M test	X	X	X	X	Done		X	X
Auto/RedOp/CAREN/FCE-M test	X	X	X	X			X	x

T09	T10	T11	T12	T13	T14	T15
X	X	X	X	X	X	X
X	X	X	X	X	X	X
X	X	X	X	X	X	X
Done	X	X	X	X		X
	X	X ⁺	X			
	X	Done	X	X		
	x		X	X		

*Includes socket scan; and questionnaire surveys of participants’ normal socket

**Includes clinical assessment of the test socket shape

***Includes plant gain test; and optional in lab walking on final test socket to become familiar with socket operation

⁺ Only the plant gain test part of the protocol was completed

Table 2. Analysis Completed on Study Participants to Date. Yellow boxes indicate remaining analyses.

FIGURES & TABLES	T01	T02	T03	T04	T05⁺⁺	T06	T07	T08
<u>CAREN</u>								
Socket fit over time	X	X	X	X	X		X	X
Integral of absolute error over time (IAE)	X	X	X	X	X		X	X
Integral of error over time (IE)	X	X	X	X	X		X	X
Socket fit metric stability by cycle number (variance)	X	X	X	X	X		X	X
Socket fit distribution by cycle number	X	X	X	X	X		X	X
<u>FCE-M</u>								
Socket fit metric over time	X	X	X	X	X		X	X
Distal tibia motion over time	X	X	X	X	X		X	X
Locking pin motion over time	X	X	X	X	X		X	X
<u>ALL DATA</u>								
Data organization table	X	X	X	X	X		X	X

	T09	T10	T11	T12	T13	T14	T15
<u>CAREN</u>							
Socket fit over time	NA	X	NA	X			
Integral of absolute error over time (IAE)	NA	X	NA	X			
Integral of error over time (IE)	NA	X	NA	X			
Socket fit metric stability by cycle number (variance)	NA	X	NA	X			
Socket fit distribution by cycle number	NA	X	NA	X			
<u>FCE-M</u>							
Socket fit metric over time	NA	X	NA	X			
Distal tibia motion over time	NA	X	NA	X			
Locking pin motion over time	NA	X	NA	X			
<u>ALL DATA</u>							
Data organization table	NA	X	NA	X			

⁺⁺Only data for Locked mode were collected and analyzed for this participant

Table 3. New Issues and Corrections.

Issue / Participant	Description
T05 dropped	Participant stopped responding to researchers queries – unable to be scheduled
T07 protocol modification	Traveled to San Antonio for 1 week to participate in the study. Because of limited time available, a check fitting was not conducted. This did not cause problems because the instrumented socket fit properly during testing
T09 dropped	Due to an eligibility issue – participant weight is now too high to meet CAREN requirements
T11 plant gain test correction	Participant preferred the panels far from the surrounding socket. Since the plant gain test procedure extends the panels outward from the preferred setting, for much of the range there was minimal contact with the liner. The plant gain test was repeated using a range that included inward panel positions
T11 dropped	Due to an eligibility issue – participant weight is now too high to meet CAREN requirements
T12 fabrication issues	Socket fabrication was transitioned over to CFI technicians. However, they have had issues with sensor damage during fabrication. The SOP has been amended to correct the problem
T13 pin length adjustment	T13 exhibited difficulty successfully donning the socket with the pin liner. A longer pin eased donning but did not allow for successful pin calibration. The longer pin was modified to an intermediate length that was sufficient for donning and allowed for successful pin calibration

Data Analysis

An updated list of plant gain results is show in Table 4.

Table 4. Participant Plant Gain Results.

Participant	Plant Gain				Mean [range]
	Fitting	1 nd test session	2 rd test session	3 rd test session	
T01	3497	3000	3146	4858	3625 [3000-4858]
T02	3481	4422	4263	3622	3947 [3481-4422]
T03	3049	4499	3347	4105	3750 [3049-4499]
T04	4836	4813	3842	3528	4255 [3528-4836]
T05	2995	2827/4201*	NA	NA	NA
T06	1367	1642			
T07	NA ^b	3242	2382	2285	2636 [2285-3242]
T08	2390	1753	3569	4397	3027 [1753-4397]
T09	NA	NA	NA	NA	NA
T10	2150	1957	3074	1980	2290 [1957- 3074]
T11	1759/1479**	1643	NA	NA	NA
T12	921	2022	4045	2046	2259 [921-4045]
T13	3290	2618	1580		
T14					
T15	1252				

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

Nothing to Report.

How were the results disseminated to communities of interest?

Conference presentations during Year 4 are listed below:

Price CA, Baumann ME, Allyn KJ, DeGrasse N, Guerrero NA, Lanahan CR, Childers L, Sanders JE. Effects of an Adaptable Socket on Comfort During Military Specific Tasks. Poster presented at: American Academy of Orthotists & Prosthetists Annual Meeting & Scientific Symposium; 2022 Mar 2-5; Atlanta, GA

Price CA, Baumann ME, Allyn KJ, DeGrasse NS, Guerrero NA, Lanahan CR, Ramesh BJ, Garbini JL, Childers L, Sanders JE. Impact of Microprocessor-Adjusting Socket on Prosthetic Fit During Military Specific Tasks. Podium presentation at: George E. Omer Jr. Research Symposium; 2022 Jun 23; San Antonio, TX. Received the Milton S Thompson, MD Award for Most Outstanding Research in the Field of Neuromuscular Rehabilitation

Baumann ME, Price CA, Allyn KJ, DeGrasse NS, Guerrero NA, Lanahan CR, Ramesh BJ, Garbini JL, Childers L, Sanders JE. Effects of an Adaptable Socket on Socket Fit during Military Specific Task. Poster presented at: Military Health System Research Symposium; 2022 Sep 12-15; Kissimmee, FL

Price CA, Baumann ME, Allyn KJ, DeGrasse NS, Guerrero NA, Lanahan CR, Ramesh BJ, Garbini JL, Childers WL, Sanders JE. Impact of Microprocessor-Adjusting Socket on Prosthetic Fit During Military Specific Tasks. Podium presentation at: American Orthotic & Prosthetic Association National Assembly; 2022 Sep 28 – Oct 1; San Antonio, TX

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

We expect to complete data collection during the next quarter.

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?

Results to date suggest that microprocessor auto adjusting sockets improves socket fit during Military relevant tasks, providing evidence to stimulate incorporation of adaptive socket technology into clinical care.

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

These are summarized in Table 3.

Changes that had a significant impact on expenditures

Nothing to Report.

6. PRODUCTS:

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Name: Joan Sanders, PhD
Project Role: PI
Researcher Identifier (ORCID ID): [0000-0002-8850-243X](https://orcid.org/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](https://orcid.org/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: Noel Guerrero
Project Role: Research Assistant
Researcher Identifier (ORCID ID): 0000-0002-5129-1763
Nearest person month worked: 4
Contribution to Project: Study preparation and execution, materials prep

Name: Ciera Price, CPO/L
Project Role: Research Prosthetist
Researcher Identifier (ORCID ID): N/A
Nearest person month worked: 9
Contribution to Project: Recruitment, materials prep, prosthetic support, study execution

Name: Alyssa Salazar
Project Role: Researcher
Researcher Identifier (ORCID ID): N/A
Nearest person month worked: 3
Contribution to Project: Recruitment, materials prep, study execution, analysis

Name: Molly Baumann, PhD
Project Role: Research Prosthetist
Researcher Identifier (ORCID ID): [0000-0002-5462-405x](https://orcid.org/0000-0002-5462-405x)
Nearest person month worked: 4
Contribution to Project: Recruitment, materials prep, study execution, analysis

Name: John Ferguson, 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: Salary is covered 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: 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: Nicholas McCarthy
Project Role: Research Engineer
Researcher Identifier (ORCID ID):
Nearest person month worked: 1
Contribution to Project: Data analysis

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-18-1-0595 (Sanders)
US Army Medical Research Acquisition Activity
“A release/relock socket to enhance volume management an facilitate patient self-care”
Level of effort: 1.8 months

Childers

Previously active grants that has closed:
Title: Assessing Rehabilitation Outcomes after Severe Neuromusculoskeletal Injury
Dr. Childers was site-PI at 7.5% effort from 8/1/2017-7/31/2022

New grants that have started:
Title: Validation of military-relevant assessments to predict successful return to duty following lower limb injury
Dr. Childers is Co-I at 3.75% effort from 8/1/2021-7/31/2023

Title: Exoskeletons for rapid return to duty after tibial stress fracture

Dr. Childers is PI at 10% effort from 8/1/2021-8/1/2025

Title: Personalizing MPK Prescription for Individuals with Transfemoral Amputation

Dr. Childers is a consultant at 2.5% effort from 10/1/2022-9/30/2026

Title: Development of the Intrepid Battlefield Exoskeleton to enable continued battlefield lethality during prolonged field care scenarios

Dr. Childers is Site PI at 7.5% effort from 10/1/2022-9/30/2024

Title: Impact of Technologies that Personalize Robotic Leg Prostheses for Individuals with Transfemoral Amputation of Varying Mobility

Dr. Childers is Co-I at 5% effort from 8/1/2023-7/31/2027

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.

Procedures Completed on Study Participants to Date. Yellow boxes indicate remaining sessions.

Procedure	T01	T02	T03	T04	T05	T06	T07	T08
Signed consent form	X	X	X	X	X	X	X	X
Pre-monitoring*	X	X	X	X	X	X	X	X
Check fitting of socket from UW**	X	X	X	X	X	X	NA*	X
Automatic socket fitting***	X	X	X	X	X	X	X	X
Locked/RedOp/CAREN/FCE-M test	X	X	X	X	X		X	X
Manual/RedOp/CAREN/FCE-M test	X	X	X	X	Done		X	X
Auto/RedOp/CAREN/FCE-M test	X	X	X	X			X	x

T09	T10	T11	T12	T13	T14	T15
X	X	X	X	X	X	X
X	X	X	X	X	X	X
X	X	X	X	X	X	X
Done	X	X	X	X		X
X	X	X	X			
X	Done	X	X			
x		X	X			

Updated participant completion table

Accomplishment: The four remaining participants are near study completion.

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: 15 Sep 2023

Goals/Milestones

CY19 Goals – Prepare for data collection

- IRB/HRPO approval
- Training (completed)

CY20 Goals – 1st group data collection

- Socket fab at UW, testing at CFI (100% completed)
- Analysis of collected data (100% completed)

CY21 Goals – 2nd group data collection

- Socket fab at UW, testing at CFI (100% completed)
- Analysis of collected data

CY22 Goal – 3rd group data collection

- Socket fab at UW and CFI, testing at CFI (33% completed)
- Analysis and interpretation of all data

Comments/Challenges/Issues/Concerns

- NA

Budget Expenditure to Date

Projected Expenditure: \$ 1.48 M
Actual Expenditure: \$ 1.4 M

9. APPENDICES

None.