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TITLE: The Effect of Prosthetic Socket Interface Design on Socket Comfort, Residual Limb Health, and Function for the Transfemoral Amputee

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Residual limb health and comfort of any person with limb loss of all levels is crucial to achieving maximum prosthetic use and function. There is currently inadequate data substantiating the impact of interface design on socket comfort, residual limb health and function. There are two alternative interface designs for the military and veteran above knee amputee that could provide answers to issues germane to above knee amputees such as moisture control, skin temperature and condition. The Dynamic Socket (DS) design is comprised of a flexible interface and minimal laminated rigid frame to reduce thermal layers, increase flexibility and comfort while retaining ischial containment. In contrast, a Sub-I design has significantly lower trim lines, without ischial containment compared with a traditional interface. However, these alternative designs could compromise overall function compared to the standard of care interface design. Therefore the focus of this clinical trial is to determine if the DS and Sub-I alternative interface designs will improve socket comfort, residual limb health and function compared to the standard of care IRC interface design.

15. SUBJECT TERMS
prosthetic socket, interface, perspiration, residual limb, comfort, health, vacuum-assisted suspension, brimless

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	9	19b. TELEPHONE NUMBER *(include area code)*

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1. INTRODUCTION:

Residual limb health and comfort of any person with limb loss of all levels is crucial to achieving maximum prosthetic use and function. There is currently inadequate data substantiating the impact of interface design on socket comfort, residual limb health and function. There are two alternative interface designs for the military and veteran above knee amputee that could provide answers to issues germane to above knee amputees such as moisture control, skin temperature and condition. The Dynamic Socket (DS) design is comprised of a flexible interface and minimal laminated rigid frame to reduce thermal layers, increase flexibility and comfort while retaining ischial containment. In contrast, a Sub-I design has significantly lower trim lines, without ischial containment compared with a traditional interface. However, these alternative designs could compromise overall function compared to the standard of care interface design. Therefore the focus of this clinical trial is to determine if the DS and Sub-I alternative interface designs will improve socket comfort, residual limb health and function compared to the standard of care IRC interface design.

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

prosthetic socket, interface, perspiration, residual limb, comfort, health, vacuum-assisted suspension, brimless

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Primary Aim: To determine if military and veteran transfemoral amputees of non-dysvascular etiology will experience improved residual limb health following accommodation with DS and Sub-I interfaces compared to the standard of care IRC interface. In order to address the primary aim, research question (RQ) #1 was posed:

RQ #1. Compared to the standard of care IRC interface, do DS and Sub-I interfaces decrease:

a. skin temperature?
b. perspiration?
c. vertical interface movement (pistoning)?

Secondary Aim #1: To determine if military and veteran transfemoral amputees of non-dysvascular etiology will demonstrate increased function following accommodation with DS and Sub-I interfaces compared to the standard of care IRC interface. In order to address Secondary Aim #1, RQ #2 was posed:

RQ #2. Compared to the standard of care IRC interface, do DS and Sub-I interfaces improve:

a. balance and stability?
b. mobility?

Secondary Aim #2: To determine if military and veteran transfemoral amputees of non-dysvascular etiology will prefer DS or Sub-I interfaces compared to the standard of care IRC interface, following accommodation. In order to address Secondary Aim #2, RQ #3 was posed:

RQ #3. In the short and long term, compared to the standard of care IRC interface, are DS and Sub-I
interfaces:

a. more comfortable?
b. preferred?

What was accomplished under these goals?
The current reporting period included 6 months of obtaining IRB approval from the University of South Florida and the Department of Defense. During the waiting period, the research team focused on accomplishing non-human subjects related tasks, with the goal of expediting activities once IRB approval was received.

Scientifically, the PI collaborated with the Florida Gulf Coast University PI to build and test the thermistor. Administratively, all subcontracts were executed and the study was registered at ClinicalTrials.gov.

DOD HRPO IRB was received 06-005-2016. Subsequently, subject recruitment was initiated. Three subjects have been recruited, cast, and fitted for the study sockets. They are accommodating to the sockets in preparation for testing and data collection.

Additionally, the PI presented a status update at the September 2016 review and analysis meeting for the DOD prosthetic socket portfolio at Fort Detrick, MD.

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?
We plan to continue subject recruitment and work toward recruiting toward the 15 subject recruitment goal. Additionally, testing will begin during the next reporting period.

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
Nothing to Report

Changes that had a significant impact on expenditures
Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, 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.
The PI presented a status update at the September 2016 review and analysis meeting for the DOD prosthetic socket portfolio at Fort Detrick, MD..

• 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
Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Name: Jason Highsmith
Project Role: Principal Investigator
Researcher Identifier: N/A
Nearest person month worked: 1 calendar month
Contribution to Project: Coordinated and planned project with the members of the research team. Submitted institutional and DOD IRBs and ClinicalTrials.gov registry. Tested study thermistor with Dr. Lura (see below). Presented a status update at the September 2016 review and analysis meeting for the DOD prosthetic socket portfolio at Fort Detrick, MD

Name: Rebecca Miro
Project Role: Research Coordinator

Researcher Identifier: N/A
Nearest person month worked: 1 calendar month
Contribution to Project: Managed set-up and execution of 4 study subcontracts. Worked with Dr. Highsmith to submit IRB applications and ClinicalTrials.gov registry. Assisted Dr. Highsmith

Name: Derek Lura
Project Role: Subcontract PI (Florida Gulf Coast University)
Researcher Identifier: N/A
Nearest person month worked: 0.5 calendar month
Contribution to Project: Designed, built, and tested the thermistor that will be used to record temperature during treadmill walking.

Name: Loi Ho
Project Role: Study Prosthetist
Researcher Identifier: N/A
Nearest person month worked: 2 person months
Contribution to Project: As the study prosthetist, Ms. Ho measured, cast, fabricated and fit sockets for enrolled subjects.

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. Highsmith was awarded 2 Department of Defense grants that were previously pending:

W81SWH-16-1-0738
The IM ABLE Study: A Cross-Sector, Multi-Site Initiative to Advance Care for Warriors and Veterans Following Neuromusculoskeletal Injury of the Lower Limb
Effort: 1.2 calendar months

W81XWH-16-1-0785
Prosthetic Smart Socket Technology to Improve Patient Interaction, Usability, Comfort, Fit and Function
Effort: 1.2 calendar months

Dr. Miro will serve as Research Coordinator (0.5 cal months) on the following study (previously pending):
W81SWH-16-1-0738
The IM ABLE Study: A Cross-Sector, Multi-Site Initiative to Advance Care for Warriors and Veterans Following Neuromusculoskeletal Injury of the Lower Limb

What other organizations were involved as partners?

Organization Name: Florida Gulf Coast University
Location: Fort Myers, FL
Financial Support: None

In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: Prosthetic Design & Research
Location: Tampa, FL
Financial Support: None
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: Tampa VA Research & Education Foundation
Location: Tampa, FL
Financial Support: None
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

8. SPECIAL REPORTING REQUIREMENTS: None

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

The effect of prosthetic socket interface design on socket comfort, residual limb health, and function for the transfemoral amputee

Award: W81XWH-15-1-0410

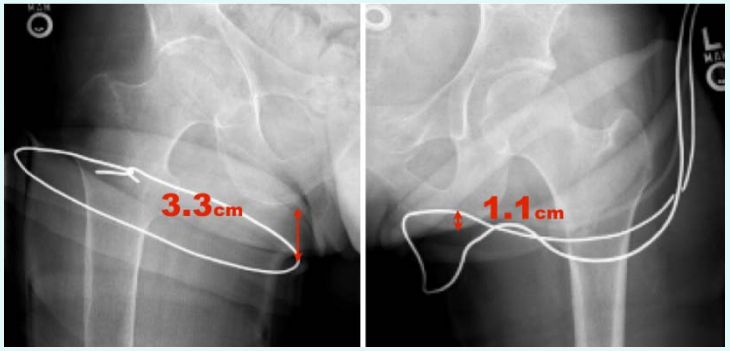
PI: M. Jason Highsmith, PhD, DPT, CP, FAAOP **Org:** University of South Florida **Award Amount:$912K**

Study/Product Aim(s)

The objective of this clinical trial is to determine if the new technologies of DS and Sub-I alternative interface designs will improve the interface environment, socket comfort, residual limb health and function compared to the standard of care IRC interface design.

Approach

Active, separated and retired military TFAs will be recruited for this study. The study will involve 15 TFA human subjects. Three different interface designs will be tested: IRC suction sockets, IRC sockets with roll on silicone suspension and windows created in the frame, and VAS brimless. Subjects will serve as their own controls in this A-B-C crossover clinical trial. Subjects will be randomized regarding the crossover sequence through the 3 interface designs.



Brimless VAS (Left), vs. IRC (Right), relative to the IT, the brimless interfaces were an average of 4.4 cm lower than IRC.

Timeline and Cost

Activities CY	15	16	17	
Obtain regulatory approvals, begin recruitment				
Ongoing recruitment & data collection. Begin data analysis				
Complete data collection & analysis. Dissemination				
Estimated Budget ($912K)	**$ 197**	**$530**	**$185**	

Updated: Tampa, FL 10/7/2016

Goals/Milestones (Example)

CY14 Goals – Complete regulatory approvals, begin recruitment

CY15 Goal – Continue recruitment, data collection, and begin data analysis.

CY16 Goal – Complete data collection and data analysis. Disseminate study findings.

Comments/Challenges/Issues/Concerns

- None

Budget Expenditure to Date

Projected Expenditure: $180,181