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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: NONE LISTED

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	7	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?

Both aims above have been completed at this time with most data analysis complete and two (2) publications submitted. Findings included that medial socket wall height was significantly different between the 3 experimental sockets ($p<.05$). There were no differences in femoral adduction angle, ischial containment or other imaging findings between interventions. Preliminary analysis of balance/Neurocom data reveal that amputees had more falls while using the brimless socket. Statistical analyses ongoing.

Study tasks 1, 2a, 2b, and 2c as presented in the Statement of Work are complete. Task 3b (dissemination) is ongoing, as one more publication will be submitted shortly. Task 3d, translating plans back to stakeholders, is ongoing. DOD representatives (Jason Ghannadian) approved use of study funds to host a consensus conference focusing on transfemoral socket designs and considerations. The consensus conference was held August 26 and 27, 2019. Author team manuscripts and the final manuscript by the study co-chairs will be completed and submitted in November 2019.

What opportunities for training and professional development has the project provided?
A Mechanical Engineering undergraduate student was hired to assist with lab setup, equipment calibration, data collection, and data management and analysis. As part of these duties, the student learned to interact with human subjects as well as how to manage data and prepare it for analysis. He continues to be instrumental in the preparation, analysis, and dissemination of the study data. Additionally, the study PI, co-PI, and research coordinator attended the American Academy of Orthotists & Prosthetists (AAOP) annual meeting, March 6-9, 2019, Orlando, FL. The study team disseminated study results took part in professional development by attending sessions discussing latest scientific developments regarding transfemoral prosthetics.

How were the results disseminated to communities of interest?
The PI and co-PI presented study results at AOPA National Assembly, September 26-29, 2018, Vancouver, British Columbia, Canada and at the American Academy of Orthotists & Prosthetists (AAOP) annual meeting, March 6-9, 2019, Orlando, FL.

What do you plan to do during the next reporting period to accomplish the goals?
At this point, final data analysis and knowledge dissemination continue. Currently, we are analyzing dermatology, perspiration, and subjective (surveys) portions of the data.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?
Nothing to report at this time.

What was the impact on other disciplines?
Nothing to report at this time.

What was the impact on technology transfer?
Nothing to report at this time.

What was the impact on society beyond science and technology?
Nothing to report at this time.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change
Nothing to report at this time.

Actual or anticipated problems or delays and actions or plans to resolve them
Nothing to report at this time

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

Highsmith MJ(chair/moderator), Klenow TD, Kahle JT, Wernke M. Prosthetic Socket Design Impact on the Amputee User in the Laboratory and Clinic. Symposium (C15). Sept 2018. American Orthotics & Prosthetics Association (AOPA) National Assembly. Vancouver, B.C. Canada

Kahle JT, Miro RM, Ho LT, Porter M, Lura DJ, Carey SL, Lunseth P, Swanson A, Highsmith MJ. The effect of above the knee prosthetic socket interface design on gait, balance, mobility, and preference: randomized clinical trial. Pros Orth Int, Submitted, July 2019

Publications in process include: (1) Physical functional performance measures, and (2) Temperature responses.

Books or other non-periodical, one-time publications.
Nothing to report at this time.

Other publications, conference papers, and presentations.

Publications resulting from the Multi-Sector State of the Science Conference: Transfemoral Socket Design and Considerations will include the following topics (full titles to be determined):

- Critical Design Features/Socket Variations
- Heat Retention/Perspiration/Dermatologic Concerns
- Surgical Variations and Prescription Recommendations
- Suspension/Interface Issues
- Alignment, Movement Constraints, and Compensatory Strategies
- Considerations for the Female using a Transfemoral Prosthesis
- Clinical, Regulatory, Ethical and Other Considerations with Osseointegration

• 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). Data analysis and knowledge dissemination (publication and presentations).

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 with data collection.

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.

Name: Stephanie Carey
Project Role: Collaborator, Mechanical Engineering
Researcher Identifier: N/A
Nearest person months worked: 0.6 cal months

Contribution to project: Collaboration with research team regarding preliminary data analysis. Mentoring undergraduate student.

Name: Michael Porter
Project Role: Undergraduate student, Mechanical Engineering
Research Identifier: N/A
Nearest person months worked: 0.6 calendar months
Contribution to project: De-identifying and processing data from various outcome measures. Preparing all study data for processing and preliminary data analysis. Literature searches.

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

No.

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

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

Log No. MR140125; Award Number: W81XWH-15-1-0410

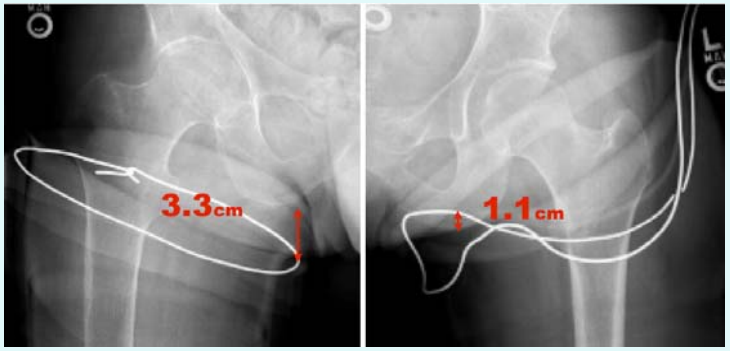
PI: M. Jason Highsmith, PhD, DPT, CP, FAAOP **Org:** University of South Florida **Award Amount:$912,628**

Study/Product Aim(s)

1. To determine if TFAs will demonstrate decreased RL skin temperature and perspiration following accommodation with a brimless VAS and flexible interface/ rigid frame design with windows interface compared to the current standard of care IRC. 2. To determine if TFAs will demonstrate increased *stability, mobility, gait, comfort, function and quality of life* following accommodation with a brimless VAS and flexible interface/ rigid frame design with windows interface compared to the current standard of care IRC.

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.



(Left) Windows created in a TFA interface design (Middle), Brimless VAS, vs. (Right) IRC, 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 ($912.6K)	**$100**	**$500**	**$300**	

Updated: Tampa, FL 09/09/2019

Goals/Milestones (Example)

CY15 Goals – Complete regulatory approvals, begin recruitment

CY16 Goal – Continue recruitment, data collection, and begin data analysis.

CY17 Goal – Complete data collection and data analysis. Disseminate study findings.

Comments/Challenges/Issues/Concerns

- Due to the delayed start as the result of regulatory approvals, a no cost extension may be needed.

Budget Expenditure to Date

Expenditures to date: $752,901.68