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TITLE: Prosthetic Smart Socket Technology to Improve Patient Interaction, Usability, Comfort, Fit and Function

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6. AUTHOR(S)
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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
The interface between the body and the prosthetic socket is critical to comfort, function and safety. When the socket is not fitting well, it is very likely that the user's residual limb volume has changed. When this happens, the weight bearing forces are increased in pressure intolerant areas of the limb which can cause skin breakdown, pain and other problems. The typical feedback to prevent these problems is the patient's perception whereby discomfort hopefully triggers the patient to investigate the skin and fit. If a skin problem or compromised fit is noted, the user would likely add or remove socks to restore a proper fit and continue about their routine. . This is a problematic methodology for many reasons. To begin with, a person with a newly acquired amputation lacks the historical experience to understand what they are feeling in terms of what is normal or abnormal specifically in a time when they are experiencing the most volume fluctuation and are most at risk of problems. The goal of this study is to determine if a prosthetic socket that notifies its user that the fit is compromised can actually train a user to adjust the sock ply of their prosthesis thereby reducing skin problems and functional compromise more than persons reliant upon the usual feedback based solely upon their discomfort.

15. SUBJECT TERMS

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		19b. TELEPHONE NUMBER *(include area code)*

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1. INTRODUCTION:

The interface between the body and the prosthetic socket is critical to comfort, function and safety. When the socket is not fitting well, it is very likely that the user's residual limb volume has changed. When this happens, the weight bearing forces are increased in pressure intolerant areas of the limb which can cause skin breakdown, pain and other problems. The typical feedback to prevent these problems is the patient's perception whereby discomfort hopefully triggers the patient to investigate the skin and fit. If a skin problem or compromised fit is noted, the user would likely add or remove socks to restore a proper fit and continue about their routine. . This is a problematic methodology for many reasons. To begin with, a person with a newly acquired amputation lacks the historical experience to understand what they are feeling in terms of what is normal or abnormal specifically in a time when they are experiencing the most volume fluctuation and are most at risk of problems. Consider that many persons with amputation have compromised sensation due to nerve injury related to their traumatic amputation or a lack of sensation due to sequela from vascular disease. For these numerous reasons, the ability for many persons with lower limb amputation to "feel" and "perceive" a poor fitting socket is unreliable.

The goal of this study is to determine if a prosthetic socket that notifies its user that the fit is compromised can actually train a user to adjust the sock ply of their prosthesis thereby reducing skin problems and functional compromise more than persons reliant upon the usual feedback based solely upon their discomfort.

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

Prosthesis, prosthesis fit, technology, skin problems, amputee, amputation, socket

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Primary Aim: To determine if military, veteran and civilian transtibial amputees in the intermediate recovery stage will experience improved residual limb health following use with SST+P compared to more common SOC protocols. In order to address the primary aim, research question (RQ) #1 was posed:
RQ #1. Compared to more commonly practiced SOC protocols, does SST+P decrease:

a. intermediate recovery stage complications?
b. limb volume activity of the RL?

Secondary Aim #1: To determine if military, veteran and civilian transtibial amputees in the intermediate recovery stage will experience improved functional performance following use with SST+P compared to more common SOC protocols. In order to address Secondary Aim #1, RQ #2 was posed:
RQ #2. Compared to more commonly prescribed SOC protocols, does SST+P improve:

a. balance and stability?
b. mobility?
c. step activity?

Secondary Aim #2: To determine if military, veteran and civilian transtibial amputees in the intermediate recovery stage will experience increased comfort and decreased pain following use with SST+P compared to more common SOC protocols. In order to address Secondary Aim #2, RQ #3 was posed:
RQ #3. Compared to more commonly prescribed SOC protocols, does SST+P improve:

a. more comfortable?
b. less painful?
c. residual limb skin and body temperature?

Secondary Aim #3: To determine if military, veteran and civilian transtibial amputees in the intermediate recovery stage will experience improved healthcare outcomes following use with SST+P compared to more common SOC protocols. In order to address secondary aim #3, research question (RQ) #4 was posed:
RQ # 4. In a 120-day rehabilitation period, does SST+P:

a. reduce overall healthcare costs?
b. reduce healthcare dependence, re-hospitalization and rehabilitation time?
c. improve quality of life?
d. improve patient interaction and activation?

What was accomplished under these goals?
Data collection for the study is underway. Twelve (12) subjects have been enrolled in the study.

What opportunities for training and professional development has the project provided?
Many Prosthetists have been exposed to the benefits of this technology and have actively and successfully participated in the data collections.

How were the results disseminated to communities of interest?
We do not plan on disseminating findings until the study is complete.

What do you plan to do during the next reporting period to accomplish the goals?
During the next study period, we are prioritizing the success and validation of the IForce. Once resolved we will resume recruitment, enrollment, and data collection.

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
Paused recruitment during the iForce issues resolution (below).

Actual or anticipated problems or delays and actions or plans to resolve them
Some issues with the ALPs iForce device not reporting accurately and consistently were identified. ALPs worked and continues to work on these problems daily to quickly resolve these issues. We are closely monitoring the progress with weekly meetings with ALPs to ensure resolution. Additionally, recruitment is paused until we are confident of the resolutions. We are internally testing the changes before we re-open recruitment.

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 at this time.

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

Other publications, conference papers, and presentations.
Nothing to report at this time.

• 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.

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. Submitted USF IRB applications and ClinicalTrials.gov registry.

Name: Jason Kahle
Project Role: Subcontract PI (OP Solutions)
Researcher Identifier: N/A
Nearest person month worked: 0.5 calendar month
Contribution to Project: Submitted and received approval from Western IRB.

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: OP Solutions
Location: Tampa, FL
Financial Support: $86,181 (subcontract total)
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: Prosthetic Design & Research
Location: Tampa, FL
Financial Support: $616,000 (subcontract total)
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: Bay Pines, VA
Location: Bay Pines, FL
Financial Support: $104,683 (subcontract total)
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: New York HHS VA
Location: New York, NY
Financial Support: $134,302 (subcontract total)
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

Prosthetic smart socket technology to improve patient interaction, usability, comfort, fit and function.

W81XWH-16-1-0785

PI: M. Jason Highsmith, PhD, DPT, CP, FAAOP **Org:** The University of South Florida (Tampa) **Award Amount:$1,446,392**

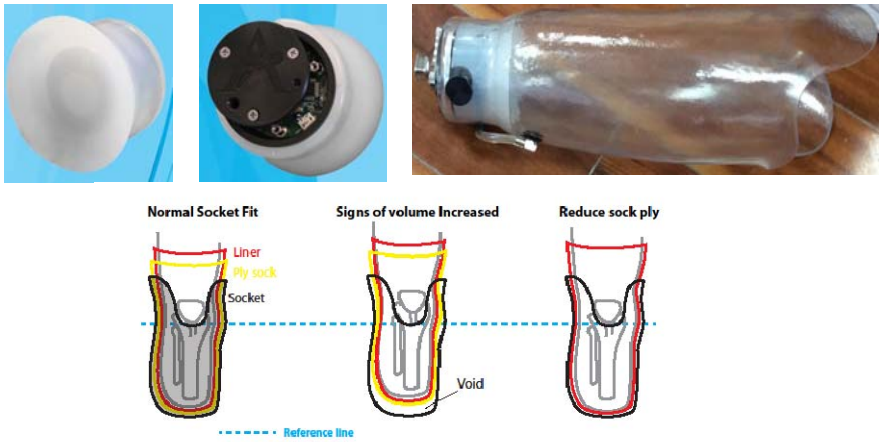
Study/Product Aim(s)

Assess whether the iForce smart socket technology will:

- supplement proprioceptive and other sensory inputs that inhibit functional use and safety for the prosthetic user.
- Improve intuitive user intent control for functional use of a prosthesis associated with appropriate prosthetic interface fit.
- Improve interoperability between user and prosthesis interface interface and positively effect limb health, comfort, and function.

Approach

3 year, 2-arm parallel design preclinical study of transtibial amputees will assess the validity and reliability of the iForce smart prosthetic interface against accepted measures (i.e. tech scan, x-ray) as well as a traditional course of volume management (i.e. clinical outcomes) to maintain limb health, comfort and function.



Figures. Circular iForce fit into a prosthetic socket (top row). The app also provides text-based warnings/indications. Additionally, the app provides audible indications and suggestions to add/remove socks (bottom row).

Timeline and Cost

Activities CY:	16-17	17-18	18-19
Regulatory approvals, begin recruitment			
Ongoing recruitment & data collection. Begin data analysis			
Complete data collection & analysis. Dissemination			
Estimated Budget ($1.44M)	**$739**	**$519**	**$188**

***Direct Costs**

Updated: Tampa, FL 10/29/2018

Goals/Milestones (Example)

CY16 – Award received; regulatory process begun.

CY17 Goal –. Two (2) sites obtained full regulatory approval by the end of CY 2017 and are ready to initiate study activities. One (1) site still in regulatory process.

CY18 Goal – Initiate data collection.

CY19 Goal – Complete data collection and initiate data analysis.

Comments/Challenges/Issues/Concerns

• None

Budget Expenditure to Date

Expenditures to Date: $457,226.96

Projected Expenditure: $1.44M