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

PRINCIPAL INVESTIGATOR: M. Jason Highsmith

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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.					
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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?

No data collection has begun. Regulatory approvals for the New York VA, Bay Pines, VA, University of South Florida and DOD HRPO are pending. Subcontractor OP Solutions received Western IRB approval.

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 at this time.

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

Once regulatory approvals are in place, study recruitment will begin.

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.

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 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: \$81,600 (yr 1 subcontract amount)
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: Prosthetic Design & Research
Location: Tampa, FL
Financial Support: \$338,800 (yr 1 subcontract amount)
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: Bay Pines, VA
Location: Bay Pines, FL
Financial Support: \$104,683 (yr 1 subcontract amount)
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: New York HHS VA
Location: New York, NY
Financial Support: \$44,464 (yr 1 subcontract amount)

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