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TITLE: Smart Adaptive Socket to Improve Fit and Relieve Pain in Wounded Warriors

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6. AUTHOR(S)

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

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14. ABSTRACT

Enter a brief (approximately 200 words) unclassified summary of the most significant finding during the research period.

A clinical trial of the Smart Adaptive Socket System (SASS) was initiated during the research period, following IRB approval. While clinical data collection is ongoing using other funding, to date seven eligible male veteran subjects with unilateral transtibial amputations were recruited from James A. Haley VA Hospital. The SASS prostheses were fabricated from duplicated models of the subject's current prostheses socket system (STD). Subjects wore the SASS system and the STD system for three days each. Activity data was collected for each subject using the Step Watch Activity Monitor (SWAM) and Prosthesis Evaluation Questionnaires (PEQ) were completed for each condition. Preliminary results from five completed clinical trials demonstrate that for the majority of users, SASS improved mobility and satisfaction over their STD device in terms of daily step count and step rate and PEQ data, although these preliminary results were statistically insignificant. One subject experienced a technical issue with his SASS system resulting in outlying data that should be excluded from the analysis to improve significance and increase the correlations observed. The development and enhancement of the SASS is clinically applicable to enable patients to easily adapt their socket fit to accommodate volume fluctuation. This will likely improve socket fit, prevent skin breakdown, and improve patient outcomes. Further investigation of this technology is needed to determine treatment efficacy.

15. SUBJECT TERMS Volume compensation, Viscoelastic, Vacuum pump, Liner, Prosthetic socket interface, Dynamic segmental volume control, Wireless connection, Pressure control system.					
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INTRODUCTION:
A prosthetic socket is the physical connection between the user's body and the prosthesis. The functionality and comfort of the prosthesis is to a great degree determined by the intimacy of this connection. Fluctuations in body volume lead to changes in socket fit that negatively influence limb health. These volume changes can be due to the long-term effects of pharmaceuticals, weight gain, or weight loss. Limb volume can also decrease quite noticeably (as much as 11%) throughout the day due to the venous return of fluid out of the tissue caused by the forces of ambulation. This project directly addresses the prevalent and unmet need of prosthetic users for a socket that accommodates a changing residual limb volume while maintaining comfort and fit. We developed and completed preliminary real-world human wear test validation for a smart adaptive socket system (SASS) that controls limb loading and socket fit through dynamic segmental volume control. The system includes a flexible socket inner liner with two viscoelastic foam volume elements and a silent vacuum suspension system, which is also used to control the volume of the socket by evacuating and compressing the foam elements. This system aims to provide improved stability, proprioception, and reduced abrasion by eliminating voids and excess pressure in the socket.

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

SASS – *Smart Adaptive Socket System including a flexible socket liner and a vacuum pump.*
Volume Element – *A viscoelastic foam element built into the liner that can be expanded or compressed to compensate for volume changes in the limb.*
Viscoelastic Foam – *Foam that has both viscous and elastic properties, which vary with strain, strain rate, and frequency.*
Distal – *At the far end, distant from the center of the body.*

ACCOMPLISHMENTS:

What were the major goals of the project?

Aim 1: Design SASS Systems
1.1 Optimal adaptive element layout
1.2 Refine material selection
1.2.a Optimize for: thermal dependence
1.2.b Maximum patient comfort
1.2.c Improve response times for changes in volume
1.2.d Maximize range of compression region 2 the elastic buckling plateau
1.3 Refine and implement adaptive control algorithm
1.3.a Large posterior element maintains an even mean pressure (snugness)
1.3.b stabilizing element to reduce coronal plane moments
1.3.c Distal element: Maintain tolerable contact - indicate insufficient support of other 2 elements
1.3.d Manual mode
1.3.e On board pressure transducer for each element
1.3.f Smart Pyr sensor
1.3.g 'Sport' vs 'Comfort' mode

Aim 2: Clinical feedback development trial
2.1 Recruit 15 individuals with war-related limb loss
2.2 Build prototype liners with 3 VE elements with discrete volume control
2.3 Long term use testing

What was accomplished under these goals?

1. Major Activities: The design of the liner was finalized, and the manufacturing process was refined. An interface between the volume elements and the vacuum pump was iteratively redesigned. Modifications to the vacuum pump and control algorithm was further refined. 5 prototype SASS vacuum units and

socket systems were built and tested using human subjects. A protocol for the clinical trial was designed, approved, and implemented. Results from the clinical trial were analyzed and are summarized below.

2. Specific Objectives: Aim 1: Final revisions to the SASS System, including the volume element fabrication and location, mechanical pump-liner connection, and firmware adaptive control algorithm were completed. Aim 2: Completion of the Clinical Trial Aim: 2.1 Five of 15 subjects were recruited for the study. Aim 2.2: Five prototypes were built for use in the clinical trial.
3. Results: Daily step count for participants increased from an average of 2,117 (SD 1261.4) with their pre-existing standard socket system to 2,515 (SD 1520.2) with the SASS system; an increase of 397 steps per day on average. The use of the SASS system has a positive correlation with increased activity, although this result is statistically insignificant. Step rate for our participants also increased from 10.85 steps per minute (SD 2.71) using the standard socket to 11.83 (SD 2.10) steps per minute using the SASS system. Use of the SASS system was also shown to have a positive correlation for average step rate, although this result is statistically insignificant. The data from the PEQ supported the qualitative findings as well as our hypothesis that the SASS system would have a positive effect on users' residual limb health (mean +14.8 points) and reduced pain (mean +15.3 points). This was true across all of the study participants, despite some users experiencing technical difficulty with the SASS system.

3.1 Overview:

a. *System Design and Fabrication:* Volume element shape, fabrication, and socket location were finalized. Fabrication instructions were finalized and tested. Prototype socket fabrication was also finalized and tested in the clinical trial.
b. *Socket Insert Interface:* The interface between the liner and vacuum pump was iteratively re-designed and tested to achieve an easy-to-use, simple, airtight connection. This was implemented in the clinical testing.
c. *Vacuum Pump Design:* Five vacuum pumps were assembled and tested for use in the clinical trial.
d. *Control Algorithm Design:* The control algorithm was further refined and implemented. The functionality of the firmware was tested.
e. *IRB approval:* We received IRB approval by both the University of South Florida and HRPO to conduct the clinical trial for this SASS project.
f. *Clinical Trial:* A clinical trial consisting of 5 subjects was conducted in September 2019 at the James A. Haley VA Hospital in Tampa, FL. Results are presented here.

3.2 Discussion of Results:

a. *System Design and Fabrication:*
During the process of fabricating and testing liner fabrication, it was determined that the foam volume elements should not be laminated into the gel liner due to the difficulty it caused reflecting them inside out for donning. Additionally, the air-tightness of the distal components was improved when the volume compensation elements were moved to the walls of the socket rather than within the gel liner. These modifications have made it possible to dramatically shorten the doffing stage of the control algorithm as well as improve the system simplicity and reliability with fewer leak instances. Other benefits from this change include: improved accessibility for maintenance of the volume elements, improved protection of the volume elements against wear,

Figure 1 (left) – SASS system components *Figure 2 (right) – Completed SASS Assembly*

b. *Socket Insert Interface:*

Figure 3 – A sectioned view of the previous custom socket interface. Figure 2 – Final design using non-custom prosthetic shuttle lock (Coyote Air Lock – modified). Figure – 3 Modified vacuum pin.

The liner socket interface was re-designed to make the connection between the volume elements and the vacuum pump robust and non-removable. This decreases the burden and frustration on the user if a vacuum tight seal is not achieved. The design resolved the loss in vacuum by the natural pistoning of the residual limb in the socket during use. Finally, it resolved the need for the liner to automatically seal upon removal from the socket. These changes dramatically improved the simplicity of the system as well as the reliability.

To achieve these requirements, the distal pin and its complementary socket interface were re-designed from last year. Using currently available prosthetic componentry (Coyote Air Lock) and shuttle locking pin, the new design was achieved through simple modification. A Coyote Air Lock is an airtight shuttle lock commonly used in prosthetic fabrication to achieve suspension of a prosthesis on a user's limb. The mechanism requires a pin-locking gel liner to adhere to the users' residual limb and lock into the distal attachment within the base of the socket. Using the airtight lock housing, a vacuum barb was integrated into the release button to create an interface between the vacuum pin and the vacuum unit located external to the prosthetic socket.

Figure 4 – Coyote Air Lock housing unmodified (left) and modified (right)

A Coyote Air Lock uses a shuttle lock pin (pictured below) to create a secure mechanical connection between the liner “umbrella” and the lock housing. A vacuum barb was integrated into the shuttle lock pin and liner “umbrella” to create a vacuum connection between the lock housing (pictured above) and the volume elements within the socket.

Figure 5 – Coyote shuttle pin unmodified (left) and modified (right)and exploded view (bottom).

c. *Vacuum Pump Design:*

Modifications to the vacuum pump housing were designed and fabricated for the 5 pumps built for the clinical trial. The simple design of the housing modifications allowed for in-house printing of the parts and provides a secure and minimal protective cover for the vacuum pumps to be used in the trial.

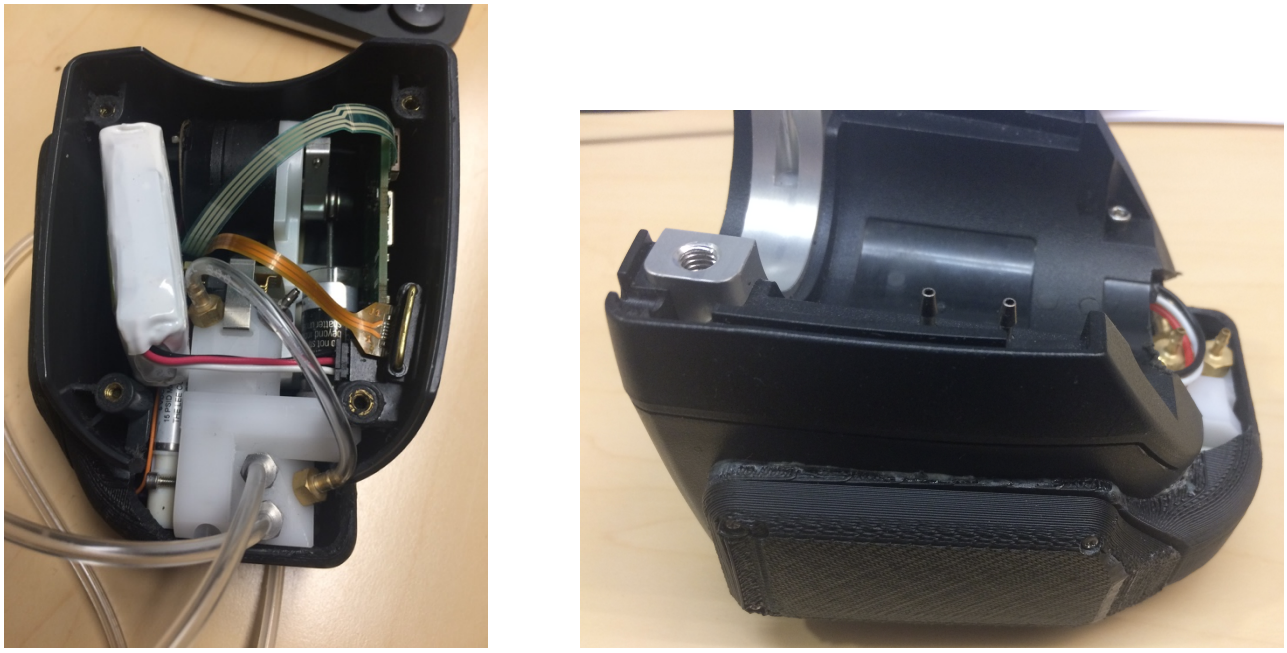

Figure 6 – The vacuum pump with SASS backpack in the new modified housing.

d. *Control Algorithm Design:*

The adaptive control algorithm for controlling the vacuum level and step detection functions of the pump was finalized and implemented in clinical testing. The pre-donning stage occurs immediately after turning on the pump. The volume elements which are fabricated into the walls of the socket are evacuated to 12 inHg. This pre-evacuation of the volume elements allows the patient to more easily don the liner and insert their limb into the socket. When the patient has completed their donning process (of the liner, any prosthetic socks (if applicable) and the prosthetic socket, the mobile application or the button on the pump is used to trigger the pump to continue to the next stage where the socket pressure is pumped to its donning target pressure. When that pressure is achieved, the pump automatically transitions to the final stage of donning where the volume elements are adjusted to an adjustable operational target pressure. At this point, the pump enters operational mode. If at any point during the donning process the pump fails to achieve a target pressure in either the volume elements or socket in the allotted time, the user is given an option to restart that stage of donning.

During normal operation, the pump now periodically switches between the volume elements and socket volumes to check their current pressure averages against the target values and adjusting as needed. The majority of the time is spent on the socket volume as that is expected to need more constant adjusting. It is important that an appropriately averaged pressure be used to compare to the target as the pressure in both volumes fluctuates during stepping.

Figure 7 – Data streamed to the mobile app showing the vacuum pressure in the volume element during the pre-donning phase. Pressure rises from 0 inHg to 12 inHg to fully deflate the volume elements prior to donning.

Figure 8 – Data streamed to the mobile app showing the vacuum pressure in the socket during the donning phase. The vacuum level target for the low activity mode is 4 mmHg as seen by the horizontal red line.

Figure 9 – Data streamed to the mobile app showing the vacuum pressure in the socket and sampling of the vacuum pressure in the volume elements during normal operation. The target pressure in the socket for the low activity phase is 4 inHg, while in the volume elements the target is set to 10 inHg.

e. *IRB approval:* We received IRB approval by both the University of South Florida and HRPO to conduct the clinical trial for this SASS project. This IRB was extended through September 2020. No further progress to report.

f. *Clinical Trial:* A clinical trial consisting of 5 subjects was conducted in September 2019 at the James A. Haley VA Hospital in Tampa, FL. Results are presented here:

Daily step count for participants increased from an average of 2,117 (SD 1261.4) with their pre-existing standard socket system to 2,515 (SD 1520.2) with the SASS system; an increase of 397 steps per day on average. The use of the SASS system has a positive correlation with increased activity, although this result is statistically insignificant. Step rate for our participants also increased from 10.85 steps per minute (SD 2.71) using the standard socket to 11.83 (SD 2.10) steps per minute using the SASS system. Use of the SASS system was also shown to have a positive correlation for average step rate, although this result is statistically insignificant. The data from the PEQ supported the qualitative findings as well as our hypothesis that the SASS system would have a positive effect on users' residual limb health (mean +14.8 points) and reduced pain (mean +15.3 points). This was true across all of the study participants, despite some users experiencing technical difficulty with the SASS system. Further testing is required to determine if the SASS system is beneficial for the veteran amputee population and leads to improved outcomes in function and increased socket comfort.

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

This project has provided ample opportunity for members of our team to interact with amputee end users of this technology. Experience gained will benefit the development for other technologies or further development of this technology. Additionally, the clinical trial provided training to the research prosthetists and other partners in Tampa Florida in the fabrication and implementation of the technology. Professional development opportunities at O&P organization annual national conferences may be available pending the selection of submitted project abstracts.

How were the results disseminated to communities of interest?

Following the clinical trial, preliminary data was disseminated among an interdisciplinary team of researchers, and rehabilitation clinicians at the James Haley VA Hospital in Tampa, FL. Following further analysis, the results were disseminated to engineers and other team members within Orthocare Innovations. Abstracts have been submitted to numerous organization meetings for Prosthetics, including the American Academy of Orthotists and Prosthetists (AAOP) and the International Society of Prosthetics and Orthotics (ISPO). Future publications resulting from this work are probable.

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

Project is complete. No further progress, beyond dissemination of results is anticipated.

4. **IMPACT:**

What was the impact on the development of the principal discipline(s) of the project?

Knowledge about limb volume fluctuation and accommodation as it relates to prosthetic socket fit was gained by the completion of this project. A novel approach for volume accommodation and prosthetic suspension was created and tested. Refinement of this technology will be beneficial for veteran amputees and VA prosthetists.

What was the impact on other disciplines?

Nothing to Report.

What was the impact on technology transfer?

This project has enabled completion and testing of technology has had a patent US9345590B2 granted (applied for previous to this contract) and the patented technology has drawn commercial interest from two companies, Ottobock and Freedom Innovations.

What was the impact on society beyond science and technology?

The project will improve living conditions for transtibial amputees.

5. **CHANGES/PROBLEMS:**

Changes in approach and reasons for change

As previously described, the volume element to pump connection circuit has been updated from the original design. The volume elements were removed from the liner worn by the amputee user. The volume elements were instead moved to the socket where the volume adjustments could happen in real time. These design changes were necessary to maintain the simplicity and usability of the system while improving reliability.

Actual or anticipated problems or delays and actions or plans to resolve them

There were delays in the approval process for the clinical trials. We were initially planning to work with two VA hospitals in Florida which both had their own internal review boards with site-specific documentation and applications. However, the one of the sites was under review and was not able to be included in the trial so the application process was restarted with a single VA hospital, which is overseen by the IRB board at the University of South Florida. This problem has been resolved and there are no other anticipated delays. We were recently given HRPO approval for the clinical trial which is ongoing.

Changes that had a significant impact on expenditures

Delays in IRB approval postponed the clinical trial significantly. During this period, progress continued thus depleting team member salary budget prior to the clinical trial. Additional expenses were necessary to conduct the clinical trial after a no-cost extension of the project was granted.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report.

6. **PRODUCTS:**

Preliminary discussions of potential future partnership and product development have taken place with a prosthetic manufacturing company. Nothing else to report.

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

What individuals have worked on the project?

Name:	David Boone, PhD
Project Role:	Principal Investigator
Research Identifier:	0000-0002-9479-8396
Nearest person month worked:	1
Contribution to Project:	No Change

Name:	Lucas Lincoln
Project Role:	Technical Supervisor
Research Identifier:	0000-0002-7139-0267
Nearest person month worked:	0
Contribution to Project:	No Change

Name:	Aaron Griswold
Project Role:	Project manager
Research Identifier:	0000-0002-5154-2315
Nearest person month worked:	0
Contribution to Project:	No Change

Name:	Courtney Fisher
Project Role:	Mechanical Engineer
Research Identifier:	0000-0003-4315-3835
Nearest person month worked:	0
Contribution to Project:	No Change

Name:	Ray Austin
Project Role:	Electrical Engineer
Research Identifier:	0000-0002-0586-9966
Nearest person month worked:	1
Contribution to Project:	No Change

Name:	Jonathan Maier
Project Role:	Software/Firmware
Research Identifier:	0000-0002-2895-6632
Nearest person month worked:	1
Contribution to Project:	No Change

Name:	Jung Kim
Project Role:	Software/Firmware
Research Identifier:	0000-0001-7887-6879
Nearest person month worked:	0
Contribution to Project:	No Change

Name:	Aizen Ulric
Project Role:	Materials Engineer
Research Identifier:	0000-0002-8133-4541
Nearest person month worked:	2
Contribution to Project:	No Change

Name:	Sara Chang
Project Role:	Co-Primary Investigator
Research Identifier:	0000-0002-2870-0055
Nearest person month worked:	1
Contribution to Project:	No Change

Name:	Natalie Harold
Project Role:	Research Prosthetist-Orthotist

Research Identifier:	0000-0002-7963-756X
Nearest person month worked:	5
Contribution to Project:	No Change

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

Nothing to Report.

What other organizations were involved as partners?

Organization Name: Cadence Biomedical
Location of Organization: Seattle, WA
Partner's contribution to the project *(identify one or more)*
Collaboration Staff exchanged knowledge and tools for liner manufacturing.

Organization Name: Dept. of Veteran Affairs Tampa
Location of Organization: Tampa, FL
Partner's contribution to the project *(identify one or more)*
Collaboration Subject recruitment, facility operation and completion of clinical trials.

8. **SPECIAL REPORTING REQUIREMENTS**

QUAD CHARTS:

Smart Adaptive Socket for lower extremity prosthetic users

Log Number: OR140328
Award Number: W81XWH-15-1-0712

PI: Boone, David **Org:** Orthocare Innovations **Award Amount:** $747,345

Product Development Aims

- Refine viscoelastic interface liner for manufacturability
- Integrate modular viscoelastic vacuum elements
- Validate control algorithm integrating force data for optimal fit
- Develop mobile device App to enable user control of parameters

Approach

We propose to develop a Smart Adaptive Socket System (SASS) that will dynamically adapt contact pressure on the residual limb to ensure a superior fit with high performance when needed, and will modulate pressure for periods of comfort during rest. The pressure within the viscoelastic vacuum elements will be modulated using a silent pump with force-sensing input and a dynamic control algorithm. User control with mobile App.

Total volume and volume distribution adjusting viscoelastic interface liner

Modular, integrated viscoelastic vacuum elements

Mechanical efficiency of interface loading monitored in real-time

Silent HVLP Smart Pump

We have developed a silent, high volume low pressure (HVLP) pump to modulate interface shape. We have developed, marketed and published 9 peer-reviewed publications validating our load sensing element

Timeline and Cost

Activities / CY	15	16	17	18	19
Refine viscoelastic interface					
Define vacuum element locations					
Validate hardware and controls					
User testing of SASS					
Estimated Budget ($K)	**$80**	**$211**	**$249**	**$207**	**$0**

Updated: 12/17/19

Goals/Milestones
CY15 Goal – Complete system specifications
☑Refine material engineering of interface
☑Bench test functionality
☑Initiate prototyping of smart pump and control system
CY16 Goals – Systems Integration
☑Design and Produce prototype adaptive viscoelastic liners
☑Design and Produce prototype smart pump control system
CY17 and CY18 Goals – Continued system improvement and IRB
☑Making improvements on design
☑Attain IRB approval
NCE CY19 Goal – Clinical testing
☑Field test on amputee subjects
Comments/Challenges/Issues/Concerns
- To enhance future manufacturability of the technology, we engaged an existing prosthetic liner manufacturer for prototype fabrication.

Budget Expenditure to Date
Projected Expenditure: $747,345
Actual Expenditure: $747,345