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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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5f. WORK UNIT NUMBER

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

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14. ABSTRACT

A modular attachment to the vacuum pump was developed to allow the system to control both the volume elements and the socket vacuum. The design and fabrication of the liner were refined as was the design of the liner to socket connection interface. The control algorithm was also improved and expanded. IRB approval for the clinical trial has been achieved.

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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Unclassified	Unclassified	Unclassified	Unclassified	16	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

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 will develop and complete 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 liner with three distinct viscoelastic foam volume elements and a silent relatively mild vacuum suspension system, which is also used to control the volume in the liner by evacuating and compressing the foam elements. This system provides 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 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 were developed to increase functionality. The control algorithm was further refined. A protocol for the clinical trial was designed.

2. Specific Objectives: Aim 1: Additions to the mechanical and electrical design of the pump and the mechanical design of the pump liner connection. The creation of a new prototype. Aim 1.1: Refining the liner fabrication method and finalizing the foam element thickness through the creation of prototype liners. Aim 1.3: The adaptive control algorithm was refined. Aim 2: A protocol for clinical trials was developed, and IRB approval attained.
3. Results:

3.1 Overview:

a. *Liner Design and Fabrication:* Volume element shape was modified slightly to allow for easy donning. Fabrication steps and instructions were tested and refined. Socket fabrication was also tested, refined, and documented.
b. *Liner to Socket Interface Design:* The interface between the liner and vacuum pump was iteratively re-designed and tested to achieve an easy-to-use, simple, airtight connection.
c. *Vacuum Pump Design:* Housing for the vacuum pump was designed and fabricated using previous pump housings. 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. *Continued Improvement on Liner and Distal Components:* While waiting for IRB approval, we continue to improve the design of the liner and distal components for easier donning and more consistent vacuum pressure.
f. *IRB approval:* We received IRB approval by both the University of South Florida and HRPO to conduct the clinical trial for this SASS project.

3.2 Discussion of Results:

a. *Liner Design and Fabrication:*
During the process of fabricating and testing liners, it was found that the angle of the foam at the top and bottom of the volume elements can interfere with the ease of donning and doffing the socket. To resolve this issue, volume elements are now being shaped with a maximum angle of 30 degrees along the top and bottom edges in the style of a thin wedge (Figure 1). Furthermore, tubes connecting the volume elements have been replaced with a small shaped rectangular piece of foam to further increase the smoothness of the liner. With this design, the two non-distal volume elements can be encased together during the fabrication process. These modifications were added to the design developed in previous years featuring curved elements with a thickness of approximately 11.5cm. As will be discussed later, these modifications have made it possible to dramatically shorten the doffing stage of the control algorithm.

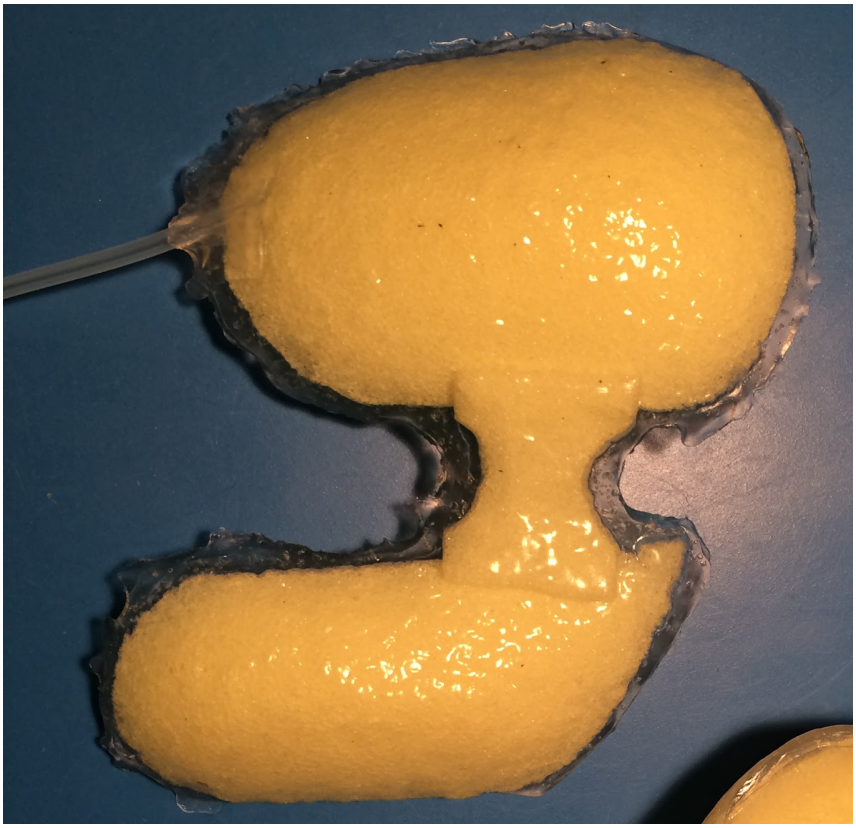

Figure 1 – Medial and posterior volume elements shaped for a small liner and encased in moldable silicone, showing the new connecting element and thin wedge edges.

The liner fabrication procedure was tested by a prosthetist, who used the procedure to fabricate a smaller liner than the previous test liners and refined the documentation of the process.

The socket fabrication procedure was refined and documented in a similar fashion. For use in the trial, check sockets will be fabricated by the usual method and formed over partially evacuated liners. The amount of evacuation in the liner during socket fabrication is important as it will determine the functional range of the liner. It is expected that limb volume will decrease throughout the day so if the socket is cast in the morning the volume elements should only be evacuated enough to be compressed about 10 percent whereas if the socket is fabricated in the evening the volume elements should be near their maximum compression. It was also found that the dummy distal element could be eliminated by filling the barb port with an appropriately sized screw and casting directly over that. The screw head can then be cut away along with the socket material in that area and the remaining screw body unscrewed and replaced with the distal connection barb. This speeds up the socket fabrication process and ensures the alignment and fit of the final distal connection element in the socket.

b. *Liner to Socket Interface Design:*

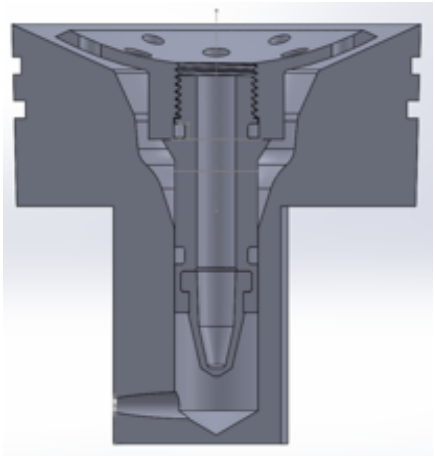

Figure 2 – A sectioned view of the solid model of both halves of the liner to socket interface.

The components of the liner socket interface were designed to allow the user to easily connect the volume elements in the liner to the vacuum pump system while donning their socket. The design was complicated by the natural pistoning of the residual limb in the socket during use and the need to maintain a secure connection without fixing the liner to the socket, which would cause localized forces on the residual limb. Finally, it was necessary that the liner side of the connection automatically seal upon removing the liner from the socket, so that a vacuum can be maintained in the volume elements after they are disconnected from the vacuum pump system. This allows the user to evacuate their liner before putting it on. Having the liner hold its evacuated and compressed state will make the donning process significantly easier.

To achieve these requirements, a distal pin and its complementary socket interface were designed last year. After further testing this year, some improvements were made to the design (Figure 2). As before, the pin screws into the distal umbrella on the liner and connects to the tube coming from the volume elements. On the end of the pin there is a normally-closed valve, which seals the connection to the volume elements when the liner is removed from the socket, and around the outside of the pin there are O-rings, which provide the seal. Placing the O-rings around the base of the pin allows the pin to move up and down in the cylindrical hole of the socket interface without breaking the seal. The second O-ring was moved to the space between the pin and the umbrella to maintain a secure airtight seal between the pin and the liner as it was found that this area created a possible leak in the system.

To further reduce leaks between the socket and liner systems, the fabrication method and materials used for the distal parts were modified. Previously, the parts were fabricated out of injection molded ABS plastic. However, to maintain a good seal between the O-ring and the walls of the distal connection piece, especially while the pin is in motion, a high tolerance and smooth surface finish is required on the pieces. To achieve this, the distal connection piece is now being machined out if a hard nylon with a required surface finish of 32 on the inside of the cylindrical hole (Figure 3). Additionally, the pin and distal umbrella are machined out of aluminum. In addition to ensuring a good fit between the pin and the distal connection piece, this allows the pin to be screwed directly into the distal umbrella, eliminating the need for an additional connection piece.

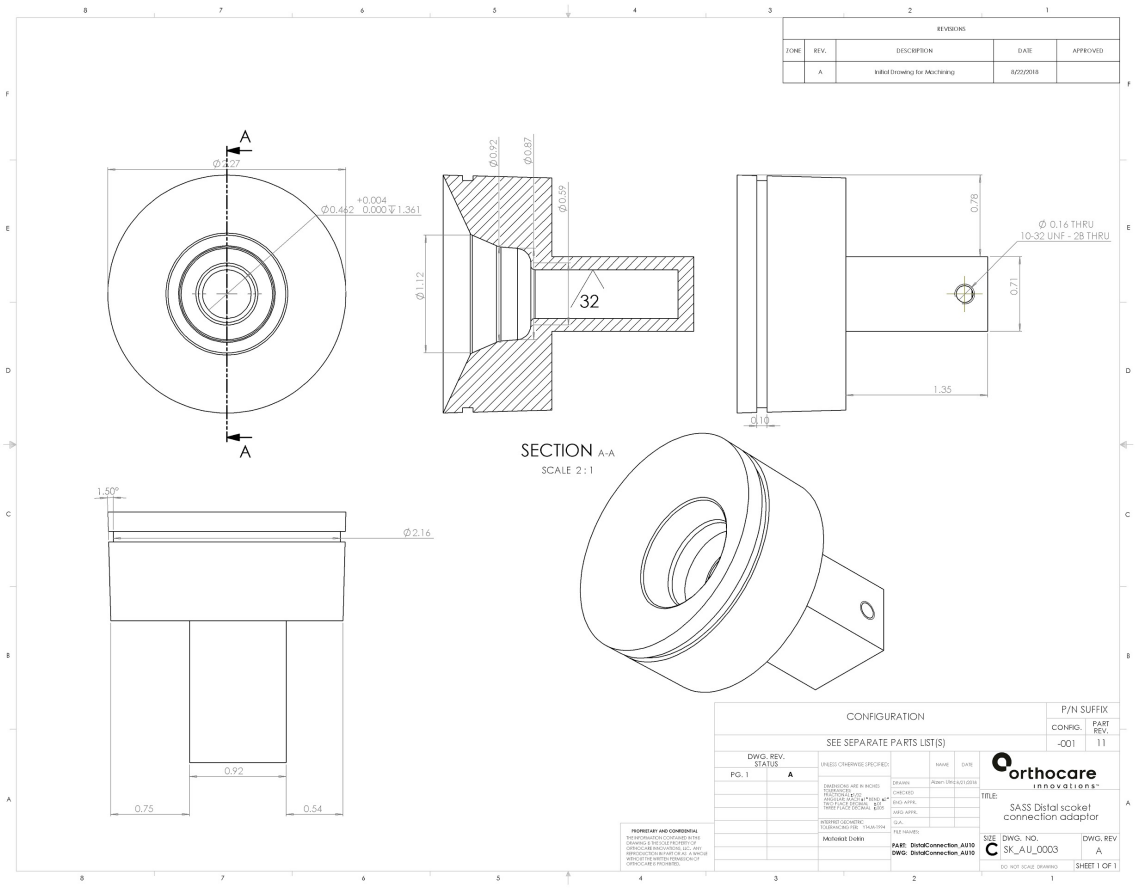

Figure 3 – A drawing, used for machining, showing multiple views of the new distal connection design.

Further improvements to the distal connection piece included pre-tapping the barb port during machining to ensure a good seal around the distal barb and moving the barb port from the bottom to the side of the base. Moving the port decreased the build height and allows for easier access when installing the barb during socket fabrication. During socket fabrication, the area around the barb is also coated with silicon glue to further guard against leaks in this area.

The process of iteratively redesigning the valve at the end of the pin was completed this year. As mentioned in the previous report, initial 3D printed prototypes were used to narrow down the shape of the valve, but the material of these initial valves was unresponsive and flimsy. In the next stage of development, valves were molded out of a more durable plastic. Multiple hardnesses of this were tested, but all of them were found to be insufficiently resilient. After being deformed into the open position for one minute, the valve would take nearly half a minute to fully close. This was a significant problem as it prevented the valve from maintaining vacuum in the liner after it was removed from its connection to the pump during the donning process. Valve materials were investigated, and a soft silicone material was found to possess suitable resilience for this application.

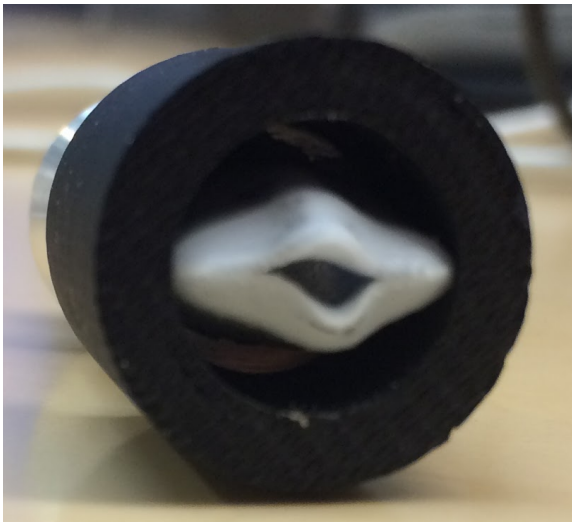

Figure 4 – A silicon valve being held open by a test hole (left) and a benchtop setup for testing the distal connection pieces and valve function (right).

Valves were tested with a benchtop setup (Figure 4). The pump and distal pieces were connected normally to a test volume element enclosed in an air volume representing the socket. A second pressure sensor was then connected to the volume element in order to measure the vacuum maintained after disconnecting the pin. Multiple tests at different vacuum levels were conducted. The results of one such test are summarized in Table 1.

Table 1 – One set of results from the benchtop test

Pressure	Start	After Detach	After re-attach
t1	12.7	9.4	6.8
t2	12.2	9.7	6.4
t3	10.9	8.8	6
t4	12.3	9.5	6.3
t5	12.3	9.1	6.3
	12.08	9.3	6.36
Ave Pressure Difference:		2.78	2.94

It was found that there was no significant correlation between the amount of pressure change and the initial vacuum in the volume element, which may be partially attributed to the slow constant expansion rate of the foam. However, more importantly it was impossible to distinguish a significant difference because the variation in the speed with which the valve was disconnected, which was done by hand, had a much more significant effect on the amount of vacuum lost. At a fast but reasonable disconnection speed, the silicone valve would allow a drop of 2-3 inHg. From the correlation with disconnection speed, it was determined that the valve was performing optimally, and the loss was occurring during the time between when the O-ring leaves the distal connection tube and the seal is lost and when the valve leaves the tube and can close. This pressure loss is acceptable and will be mitigated by evacuating the liner to a slightly higher vacuum level than necessary prior to donning.

The final distal machined components (distal connection and distal pin) are illustrated in Figure 5.

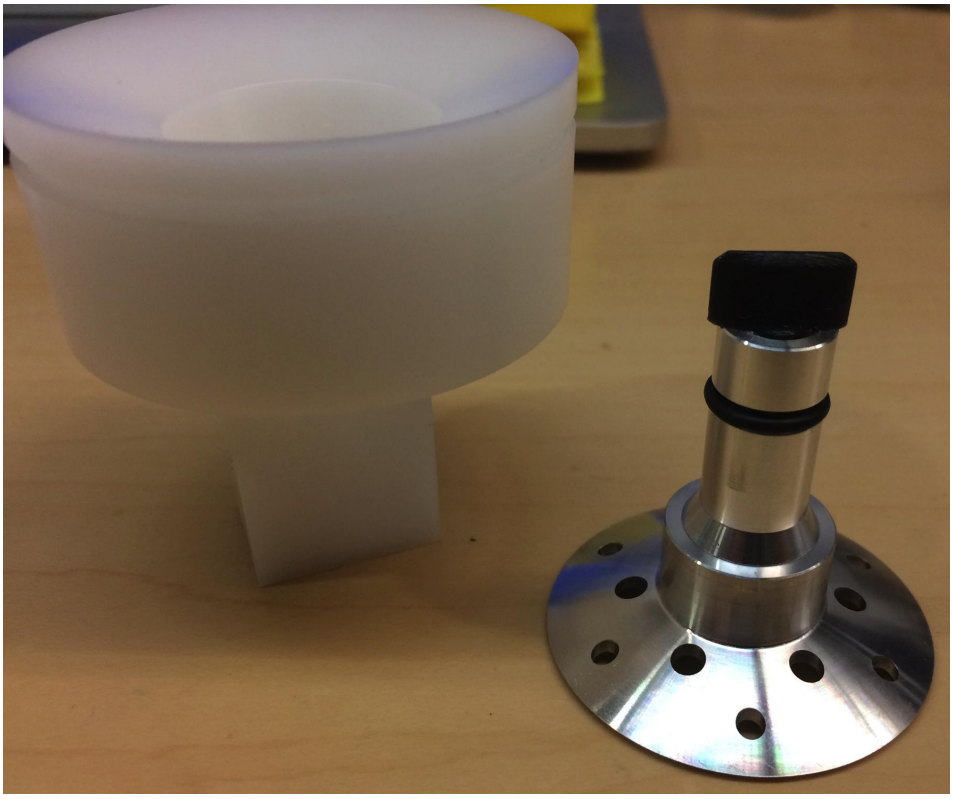

Figure 5 – The final machined distal pieces with an overmolded valve on the pin.

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 implemented, tested, and further refined.

A benchtop test was setup to mimic a stationary liner and socket system and explore the relationship between volume element pressure and socket pressure. Using the modified test pump with a second pressure sensor attached to the volume element enabled the recording of socket and liner pressures simultaneously.

This setup was also used to test the functionality of the control algorithm implemented in the firmware. There are three main parts to the volume element control algorithm: the donning stage, the operational stage, and the doffing stage. The final control algorithm for the liner volume elements as implemented in the firmware for the clinical trial adds two new stages to the donning process. The pre-donning stage occurs immediately after turning on the pump. The liner, which is inserted into the socket without a limb and connected to the pump is evacuated to 12 inHg. This pre-evacuation of the liner allows the patient to more easily don the liner and insert their limb into the socket. When the patient has completed their donning process, 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 liner is 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 liner 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 liner 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.

With the previously mentioned smoothing of the liner, it was found that additional evacuation of the liner was not necessary to facilitate doffing. The residual evacuation of the liner from normal operation coupled with the release of vacuum in the socket, which further compresses the volume elements was found to be sufficient for the patient to easily remove the limb from the socket. Therefore, there will be no delays added to the doffing process by the liner. When the pump is shut down for doffing, it quickly releases vacuum in the socket. As the liner is pulled out of the socket, the valve closes to maintain its current compression and allows the liner to exit the socket with a small amount of force.

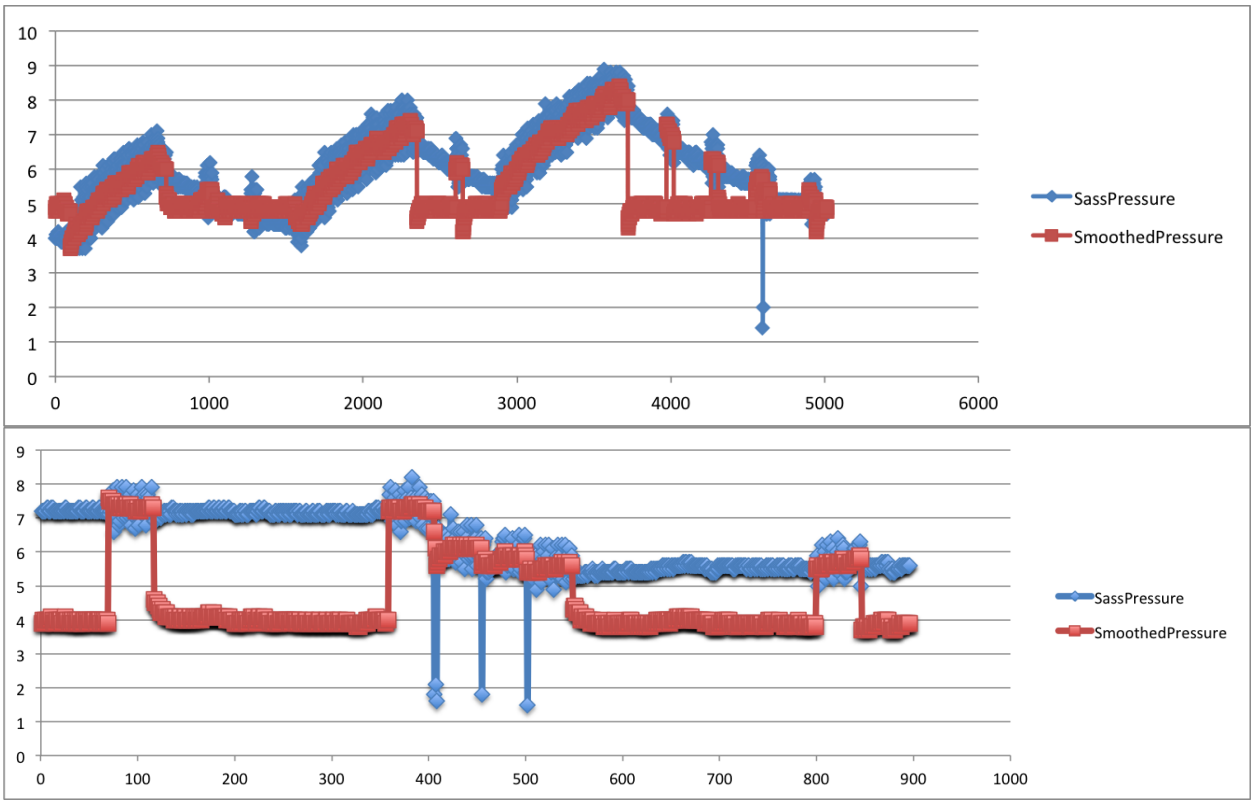

Figure 7 – Data recorded by the mobile app connected to the modified vacuum pump showing the vacuum pressure in the volume element (blue) and the pressure measured by the pump as it switched between systems (red).

The results of firmware testing showed that the control algorithm was working correctly to maintain target pressures in both the liner and the socket (Figure 7). More specifically, when the target vacuum pressure was more than 2 inHg different from the measured value, the control algorithm consistently triggered the pressure level adjustment. A vacuum pressure difference of more than 0.77 inHg and 2.3 or less inHg triggered a valve adjustment. The adjustment continued until the pressure difference was less than 0.53 inHg. A difference of 0.798 inHg was sufficient to continue the valve adjustment.

The relationship between the liner pressure and socket pressure was also clarified by the test results (Figure 8). Pumping up the socket pressure to 4 inHg causes a similar increase in the liner pressure of about 2.3 inHg. This gives a socket to liner ratio of approximately 0.6. This is because the liner volume elements are enclosed in the socket volume. An increase in the socket vacuum pressure allows the volume elements to expand slightly without gaining any more air which causes a corresponding increase in their vacuum pressure.

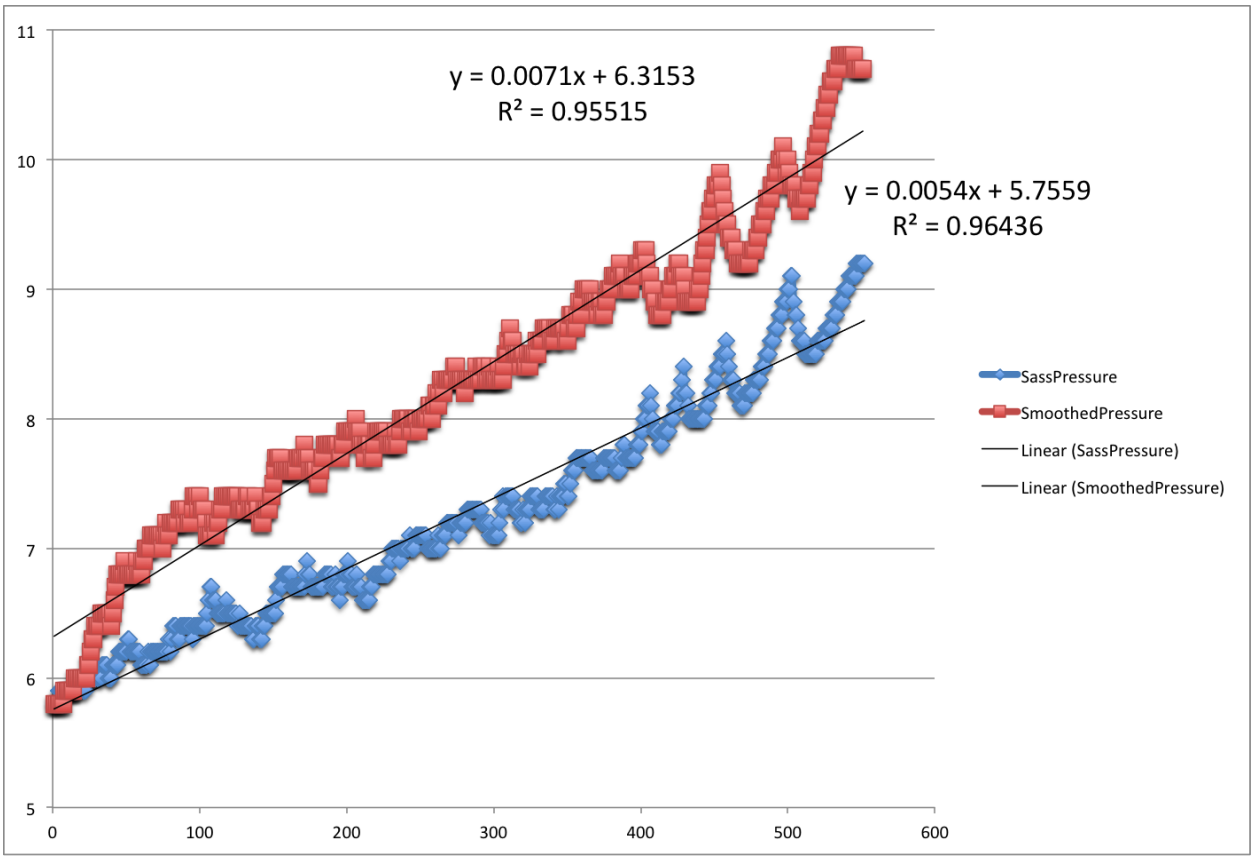

Figure 8 – The SASS (liner) vacuum pressure (blue) is increasing as the socket vacuum pressure (red) is increased by the pump.

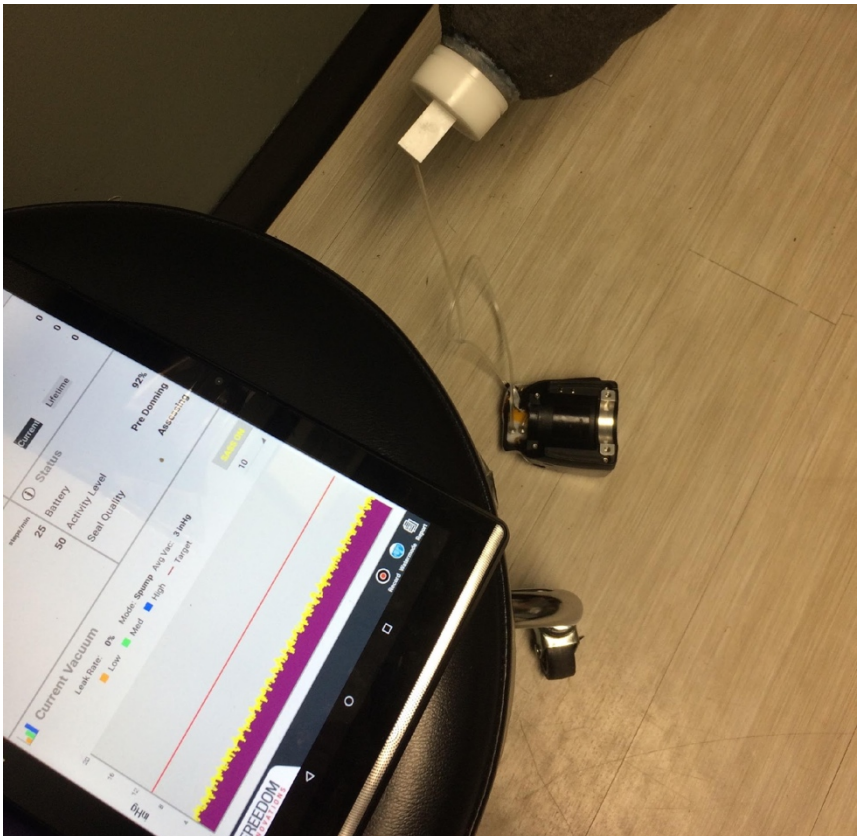

Figure 9 – The modified mobile software application is functioning on a tablet while connected over Bluetooth to the pump which controls the liner and socket vacuum pressures.

The Mobile software was modified to interact with the final implemented firmware (Figure 9). This included the addition of a dropdown menu for selecting the target pressure in the liner, changes to the graph to distinguish between socket and liner pressure readings and the pump switches back and forth, and the addition of a button for manually switching which one the pump is connected to. The SASS firmware and mobile software application will be further improved as needed when the initial subject testing takes place.

e. *Continued Improvement on Liner and Distal Components:* While waiting for IRB approval, we continued to work on the design of the liner and distal components for easier donning and more consistent vacuum pressure. A good seal is important for the functionality of SASS and some leaking issues still occur. We are exploring the options for pre-laminating the volume elements to protect them from the silicone and different liner materials to create a better seal. We are also exploring the options for appropriately sizing the volume elements, since each prosthesis user will have different thickness needs for these elements. Rather than using a single average limb volume, we are calculating a range of limb volumes for which different volume element thicknesses can be sized.

f. *IRB approval*: We have been approved to conduct the clinical trial for this SASS project by both the University of South Florida IRB and HRPO. The approval letters are appended to this report. The clinical trial will provide clinical feedback on SASS and allow us to refine the design and processes.

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?

Since we were recently given IRB approval by HRPO to conduct the clinical trial for the SASS project, the goal for the next reporting period is to begin subject recruitment and fabricating liners for the subjects. We are continuing to practice fabrication and testing of the system in order to further refine the process in preparation for the trial. We will also train the researchers in Florida, who will be conducting the trial, on the use and setup of the SASS system.

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?

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 medial and posterior elements are now connected so that the pump can be used to adjust them simultaneously. Their roles are still distinct and are biased based on their shape and placement in the liner. The larger posterior element provides the majority of the volume adjustment, while the smaller vertical medial element provides stability but their relationship to limb volume is similar enough that it makes sense to link the control of these two elements. The distal element however, primarily provides stability and comfort and has a somewhat inverse relationship with limb volume compared to the other volume elements. It is now linked to the socket volume. These design changes were necessary to maintain the simplicity and usability of the system.

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 to begin the clinical trial.

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:**

Nothing 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:	2
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:	2
Contribution to Project:	No Change

Name:	Jung Kim
Project Role:	Software/Firmware
Research Identifier:	0000-0001-7887-6879
Nearest person month worked:	1
Contribution to Project:	No Change

Name:	Aizen Ulric
Project Role:	Materials Engineer

Research Identifier:	0000-0002-8133-4541
Nearest person month worked:	6
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.

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
- Determine number of elements with user feedback
- Develop smart phone 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 three viscoelastic vacuum elements will be modulated using a silent pump with force-sensing input and a dynamic control algorithm. User control with smart phone 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: 1/31/19

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