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TITLE: Development of Sub-Ischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations

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14. ABSTRACT

The purpose of this project is to develop a highly flexible sub-ischial prosthetic socket with assisted-vacuum suspension for highly active persons with transfemoral amputation. The Specific Aims are to: A1. Develop a highly flexible socket with sub-ischial trim lines; A2. Develop durable liners and sealing sleeves; A3. Develop/identify an appropriate vacuum pump; A4. Evaluate system performance with military amputees; and A5. Develop education materials. For Aims 1 and 2, we have created a finite element model to assess our system and investigated different liners and sealing solutions. For Aim 3, we have identified options for vacuum pumps, characterized currently available pumps, and developed a hybrid mechanical-electrical pump design for persons with transfemoral amputation. We have IRB approval in place for Aim 4 which is scheduled to begin in Year 3. For Aim 5, we have developed a computer program to quantify socket rectifications and begun development of education materials to facilitate dissemination of this technique.

15. SUBJECT TERMS
Transfemoral amputation, sub-ischial socket, prosthesis, vacuum-assisted suspension

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INTRODUCTION

The objective of this project is to develop a highly flexible sub-ischial prosthetic socket with assisted-vacuum suspension for highly active persons with transfemoral amputation. We are focused on developing prosthetic socket technology that will enhance user activity by maintaining residual limb volume; improving active range of motion of the hip; improving coupling between the limb and socket; and increasing comfort during sitting, standing, walking, and running in highly active transfemoral prosthesis users. The Specific Aims of this project are to: A1. Develop a highly flexible socket with sub-ischial trim lines; A2. Develop liners and sealing sleeves that are durable for highly active users; A3. Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis; A4. Evaluate system performance with transfemoral prosthesis users; and A5. Develop education material for sub-ischial socket design. Human performance will be evaluated at the Center for the Intrepid in the third year of funding. For Aims 1 and 2, we are using engineering analysis and an advanced manufacturing approach to improve the socket and liner. For Aim 3, we have identified options for vacuum pumps, characterized commercially available vacuum pumps, and designed a hybrid mechanical/electrical pump for persons with transfemoral amputation. For Aim 4, highly active persons with unilateral transfemoral amputation will be recruited to evaluate system performance and will provide important feedback on the design. For Aim 5 we are developing education materials based on quantification of the socket rectification process. This project provides an improved prosthetic socket technology for the clinical care of highly active military service persons with transfemoral amputation. Increased comfort, hip range of motion and coupling between the residual limb and prosthesis will result in increased functional performance of individuals with combat-related transfemoral amputations. Furthermore, improvements in socket comfort and coupling would benefit all persons with transfemoral amputation, regardless of their activity level.

BODY: PROJECT PROGRESS

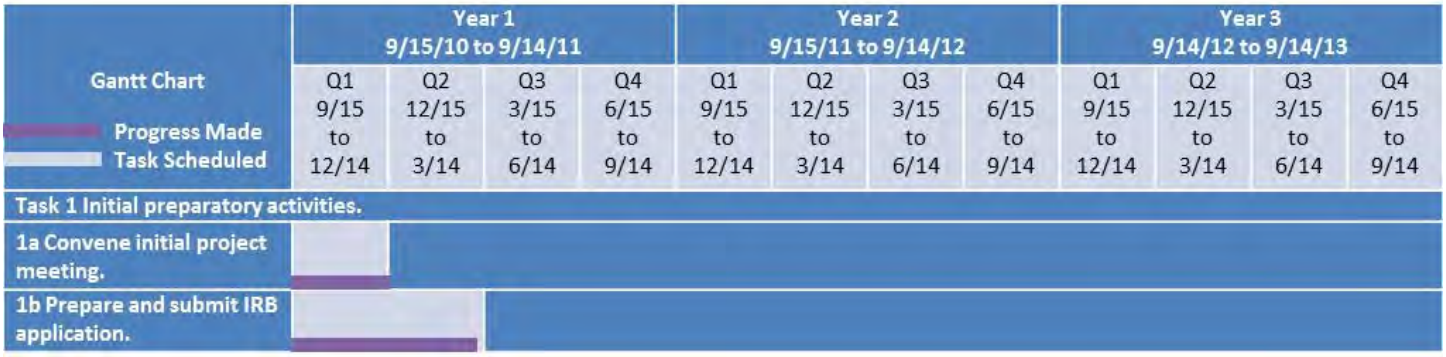
What follows is a description of the work conducted during Year 1 of our project. Our progress is presented with respect to the Aims and Tasks described in our grant application, with progress on each task indicated on the corresponding section of the approved statement of work (Gantt chart). Overall, we have made some progress on the tasks in Aims 1 and 2, completed most of the tasks in Aim 3, begun one of the tasks in Aim 4 ahead of schedule, and made progress on the tasks in Aim 5. We experienced some delays during the year due to recruitment of new personnel and the move to new facilities. While these issues affected tasks in Aims 1, 2 and 5, we forged ahead of schedule on other tasks in Aims 3, 4 and 5.

In executing the different tasks, we have had two main sources of delays. When this project was proposed, Dr. Joshua Rollock was going to lead work on Aims 1 and 2 given his experience with both modeling and rapid prototyping with application to prosthetics. However, he left Northwestern in April 2010 which necessitated finding new co-investigators with experience in these domains. Drs. Wei Chen and Cheng Sun from the Northwestern University Department of Mechanical Engineering joined our team in August 2010. Additionally, in February 2011 we recruited a post-doctoral fellow, Dr. Oluseeni Komolafe, who could contribute

substantially to this work. Although these individuals have extensive experience with modeling and rapid prototyping, they did not initially have experience with application of these techniques to prosthetics. While they have since come up to speed, progress on some tasks has been slower than originally planned.

The other issue that slowed down work in the tasks related to Aims 1 and 2 was function of the MTS and Stratasys machines. In September 2010 our lab moved into new premises, coinciding with the start date of our project. As a result of the move, it took some time to restore all of our equipment to working order, including obtaining approval from the City of Chicago's Electrical Inspector to install various systems, including the MTS machine and the Stratasys rapid prototyping system. Additionally, our MTS machine required upgrading but the process was derailed when MTS Systems Corporation fell under a federal ban and could not be engaged to upgrade our equipment. Unfortunately, we do not have access to a substitute system, so it was difficult to make alternate arrangements. However, after a lengthy search for an alternate company who could provide these upgrades, we negotiated a quote from Instron. The required upgrade of our MTS system is currently being scheduled. In the meantime, we have attempted to use the MTS in its current state for some of our testing but with mixed results. Our research engineer Kerice Tucker has been instrumental in the process of getting these machines operational. This took a substantial amount of his time and effort, which slowed down work on some of the tasks in Aim 5 for which Kerice is responsible.

Task 1 Initial preparatory activities



1a Convene initial project meeting: *This task is complete.* An initial project meeting was convened on September 20, 2010. A meeting with collaborators from Brooke Army Medical Center (BAMC)/Center for the Intrepid (CFI) was held on March 18, 2011.

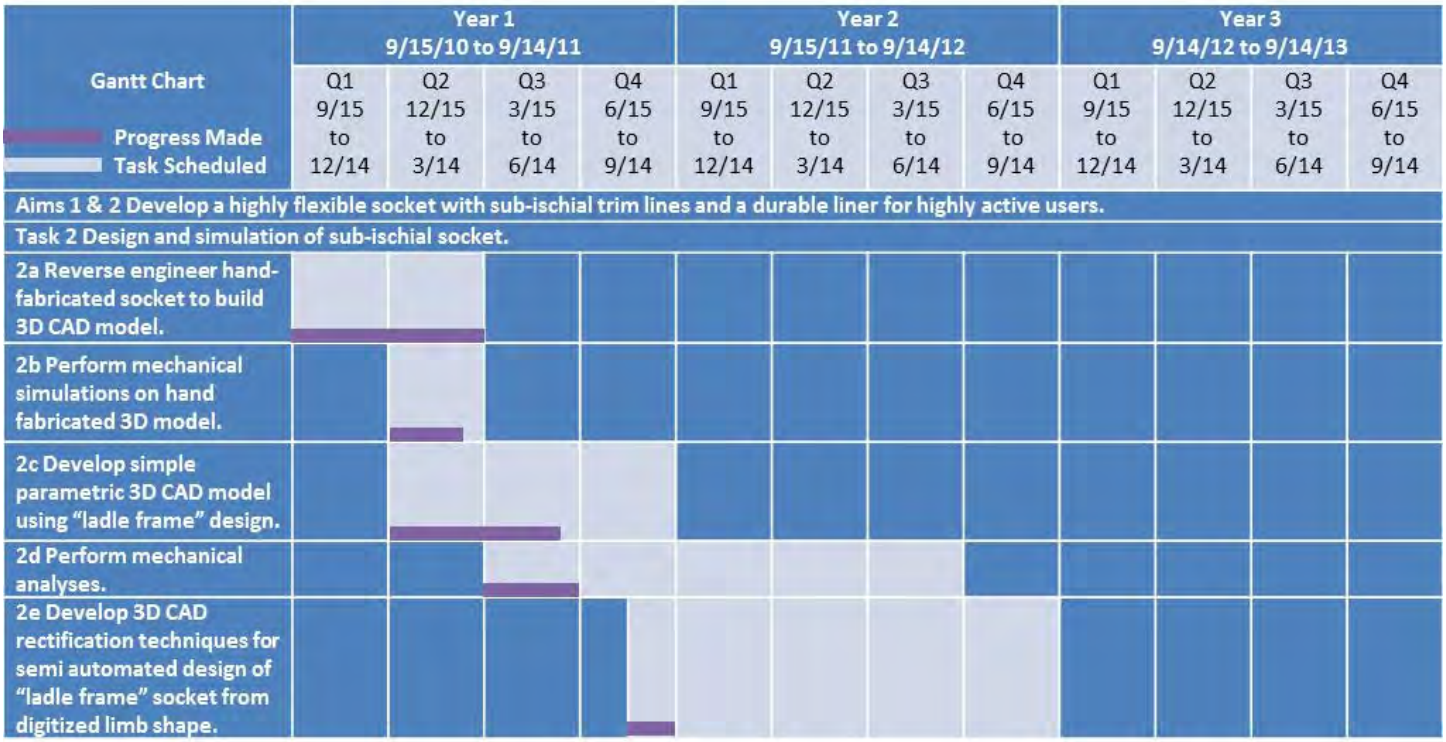
1b Prepare and submit IRB application: *This task is still underway.* All components for this project have received IRB approval with the exception of approval by the Northwestern University IRB for Aim 4 which is currently under review. IRB approvals are summarized in **Table 1**.

NU Project No.	Title	Date Approved
STU00032753 (Umbrella)	Development of Sub-Ischial Prosthetic Sockets with Assisted-Vacuum Suspension for Highly Active Persons with Transfemoral Amputations	NU IRB 6/23/10 HRPO 10/26/10
STU00033437	Development of highly flexible sub-ischial socket and durable liner for highly active transfemoral prosthesis users (Aims 1 & 2)	NU IRB 8/6/10 HRPO 8/18/10
STU00033443	Characterize vacuum pump requirements for persons with transfemoral amputation (Aim 3)	NU IRB 7/26/10 HRPO 8/10/10
STU00033446	Performance Evaluation of Sub-Ischial Socket for Highly Active Persons with Transfemoral Amputation (Aim 4)	BAMC IRB 7/31/11 HRPO 9/22/11 NU IRB submitted
STU00033448	Quantification of Residual Limb Model Rectifications for Sub-Ischial Sockets (Aim 5)	NU IRB 7/2/10 HRPO 7/28/10

Table 1 Summary of IRB protocols.

Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users

Task 2 Design and simulation of sub-ischial socket



Task 2a Reverse engineer hand-fabricated socket to build 3D CAD model and FE model: *This task is complete.* Our decision to use computational and engineering analyses as additional design tools to achieve greater comfort and increased durability of the socket and liner, necessitated a digital simulation of the current standard of care as practiced by our collaborating prosthetist, Ryan Caldwell. This simulation, functionally equivalent to the physical system, would establish the baseline against which developments would be compared throughout the project. The first step of this process was the fabrication of a physical socket system by the prosthetist. We identified the most critical fabrication stages, as well as the critical load bearing and comfort elements of a conventional socket (**Appendix A**). Our experimental test socket was then fabricated to highlight these stages/elements. In its final form, the test socket was simplified to a flexible inner Polytol layer,

a rigid polypropylene frame and an outer layer of Polytol. By simplifying the socket to fundamental components, we facilitated our understanding of the relative contribution of the different components of the socket to the overall system behavior.

The next step was to digitize the geometry of the test socket. For this, we used a commercially available 3D scanner. The scanner creates a 3D digital representation of physical models by combining planar images of the model, acquired while axially rotating the model incrementally for 360 degrees (**Figure 1**). The scanned data was then exported to a graphics package (SolidWorks) and processed to a 3D Computer Aided Design (CAD) model. This step was important because the CAD model formed the base format to be simulated in a Finite Element (FE) engineering simulation. A significant portion of time was spent on this step because it was necessary to develop a work-around for a software glitch that caused the graphics package to crash as we attempted to convert the raw scanned data (*.obj format) to the CAD model. We also explored methods to accurately extract the geometry of the frame (**Figure 2**) from the combined image files and ensure total contact between the frame geometry, ultimately modeled independently as a solid, and the other solid model of the inner sleeve. **Appendix B** provides details of this procedure.

Figure 1 Geometry Acquisition, Digitizing.

Figure 2 Geometry Acquisition, Extracting the Frame.

The final step of Task 2a was to create the FE model. The FE method is an engineering technique used to simulate and numerically analyze the mechanical response of structures to applied loads. The FE model was successfully created in commercially available FE software (Abaqus^{TM}).

Results of the different steps of Task 2a; the scanned model, the solid CAD model and the final FE model, are presented in **Figure 3**. We have submitted an abstract describing our model for presentation at the 2012 annual meeting of the American Academy of Orthotists and Prosthetists (**Appendix C**).

Task 2b Perform mechanical simulations on hand-fabricated 3D model: *We are behind schedule on this task.* The goal of this task was to establish baseline values for the mechanical and material properties of the hand fabricated socket system. Material properties of many polymers are known to depend on the fabrication parameters, therefore, in addition to reviewing the published literature for values, determining the material properties of the components has included preparing standard protocols for the mechanical tensile tests (**Appendix D**). However, as described earlier, we have encountered some problems with our mechanical testing equipment (MTS) that has delayed progress on this task. In anticipation of a break-through with the repairs, we have proceeded with other aspects of this task.

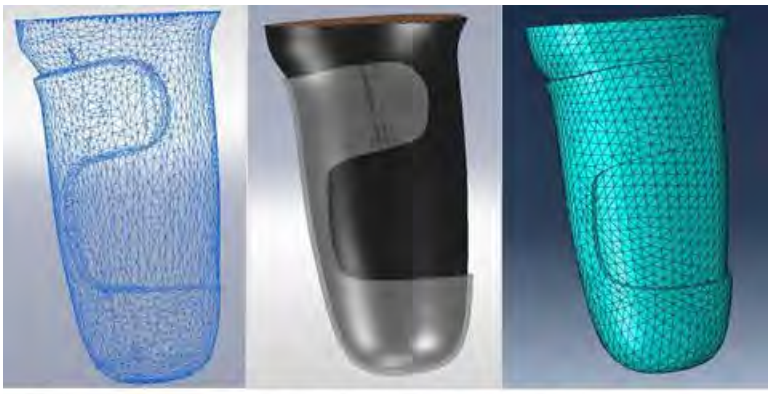


Figure 3 Resampled and cleaned point-cloud triangular mesh (left). Solid 3D CAD model (middle). FE mesh with each socket component independently meshed and linked at nodes (left).

Lamination 1 (Recommended by Otto Bock)	Lamination 2
½ oz Dacron	½ oz Dacron
2 Elastic Stockinettes	2 Spectralon
½ oz Dacron	½ oz Dacron
Lamination 3	**Lamination 4**
½ oz Dacron	½ oz Dacron
2 Aralon 1/2oz Dacron	2 Spectracarb-aralon ½ oz Dacron
Lamination 5	**Lamination 6**
3 Feather Stretch	3 Feather Stretch
6 Spectracarb-aralon	6 Spectralon
3 Feather Stretch	3 Feather Stretch
Lamination 7	**Lamination 8**
3 Feather Stretch	3 Feather Stretch
6 Aralon	6 Spectracarb
3 Feather Stretch	3 Feather Stretch

Table 2 Lamination specimens (see Figure 4).

Figure 4 Square molds fabricated to create samples of Polytol laminations for mechanical testing (top left and right). Bottom image shows laminations 1 to 4 from left to right.

Manufacture of the different test samples is complete (**Table 2, Figure 4**), and a program has been written to allow our CNC milling machine to cut tensile specimens out of the samples. Fabrication of the test samples involved making square molds around which laminations could be hand fabricated. The square molds allowed us to create flat strips of different laminations for testing. Repairs of our screw action grips, required to hold the test specimen securely in the MTS machine, have been completed. We have also completed the design and

machining of the necessary fixtures to attach the hand fabricated socket to the testing rig (**Figure 5**). We anticipate all repairs and upgrades of the MTS to be accomplished in time to complete this task by 12/14/2011.

Figure 5 Experimental setup for simulated static loading of the limb phantom/socket system.

Task 2c Develop a simple, parametric 3D CAD model using "ladle-frame" design: *We are behind schedule on this task.* A review of prior finite element models of prosthetic sockets was undertaken to refine our understanding of the problem and the variables to be included in our model (**Appendix E**). For this task we need to analyze the socket loading response and perform static/dynamic experiments for FE model validation. We have defined experimental protocols (**Appendix F**) and designed and built fixtures for attaching the socket prototype and limb phantom to our testing machine (**Figure 5**). Software for the *pliance* pressure sensors (Novel, Germany), as well as the IPECs 3 dimensional loads and moments sensing load cell (College Park Industries) have been installed and verified to be operational. We are currently conducting the bench top experiments. It is anticipated that this task will be completed by 12/14/11.

We currently have two frame designs (**Figure 6**). Our initial 'ladle frame' was designed to strengthen the medial wall, with arms that extended along both the anterior and posterior walls to provide support for flexion and extension of the prosthesis. The lateral wall requires almost no support, so the window is used to allow flexibility. This design works well but comments from one of our test subjects indicated he could feel the socket deform slightly when he carried heavy loads. This led us to our second 'H' frame design. This frame was designed to increase range of motion in extension, and to allow the wearer to sit on a soft portion of the socket whether seated deep or shallow in a chair. An extension of the frame on the posterior lateral wall was used to improve strength, especially under heavy loads. The subject commented that this frame felt sturdier when carrying heavy loads and while kneeling and leaning back on the socket.

Figure 6a 'Ladle' frame from left to right: anterior, medial, posterior, lateral.

Figure 6b 'H' frame from left to right: anterior, medial, posterior, lateral.

Task 2d Perform mechanical analyses: *This task is scheduled to continue into Year 2.* Performing load simulation analyses on our 3D finite element model requires completion of Tasks 2a, 2b and 2c. It is anticipated that this task will be completed on schedule.

Task 2e Develop 3D CAD rectification techniques for semi-automated design of "ladle-frame" socket from digitized limb shape: *This task is scheduled to continue into Year 2.* This task requires the integration of design tools with the CAD and FE models. Optimization and validation of the FE model requires completion of Tasks 2a, 2b, 2c and 2d. It is anticipated that this task will be completed on schedule.

Task 3 Advanced manufacturing of sub-ischial sockets

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users.												
Task 3 Advanced manufacturing of sub-ischial sockets.												
3a Establish criteria and techniques for multi-shot cavity molds.												
3b Develop degassing techniques for liquid resin molding.												
3c Develop proximal brim vacuum seal.												
3d Develop mechanical interlocking molding techniques.												

The overall objective of Task 3 is to develop new manufacturing techniques that allow for intricate control of material thicknesses. We plan to take advantage of rapid prototyping techniques including fused deposition modeling (FDM) to prepare cavity molds. Training with our Stratasys rapid prototyping system begins 10/4/11 and component tasks are on schedule for completion in the early quarters of Year 2.

Task 3a Establish criteria and techniques for multi-shot cavity molds: *We are behind schedule on this task.* We expect to begin work on this task after training with the Stratasys rapid prototyping system takes place on 10/4/11.

Task 3b Develop degassing techniques for liquid resin molding: *We are behind schedule on this task.* We expect to begin work on this task after training with the Stratasys rapid prototyping system takes place on 10/4/11.

Task 3c Develop proximal brim vacuum seal: *We are ahead of schedule on this task.* We have undertaken clinical testing of commercially available vacuum sealing options with Subject 1. These include the Aura

Sealing Sheath from Evolution Industries, the ESP secure ring, and the Proseal Ring from Otto Bock. Subject feedback is described in **Appendix G**. Our initial trials with internal sealing rings all led to a tornique effect on the residual limb, suggesting that the tension needed for our socket design may not permit a ring to be used safely and comfortably. We have also noted since switching to using Polytol for the sub-ischial sockets that liners are lasting longer. The more compliant Polytol material does not abrade the reflected liner as quickly or to the same extent as other laminations did. Also, when sitting, the posterior portion of the liner does not breakdown as quickly as it is no longer sandwiched between a hard socket and a hard seat.

Figure 7 Medi liner filled with green water.

When testing the Medi Relax Liner on Subject 1, he commented that he perspired less. This led us to non-destructively test the permeability of the Medi Relax liner to see if the textile on the inner surface of the liner would wick moisture to the textile on the outer surface of the liner. The liner was placed in a socket and sealed on the socket wall with the silicone surface of the liner reflected over the PETG socket (the same way it would be donned by a patient). The liner was filled with green colored water and vacuum turned on to see if the subatmospheric pressure would pull the fluid through the liner (**Figure 7**). After four hours under vacuum, there were no signs of moisture or dye on the textile. To further explore the potential for the Medi liner to be permeable to moisture we obtained from Medi liners that had failed quality inspection due to poor saturation of the silicone material through the textile matrix. We repeated our bench test with the green water, but after 10 hours under vacuum, no staining was visible in the filter. We dissected one of these 'reject' liners and confirmed that there were two textile layers with a very thin layer of silicone between the two textiles rather than a single textile layer passing through the silicone that may have acted as a wick.

Task 3d Develop mechanical interlock molding techniques: *Not scheduled to begin until Year 2 of the project.*

Task 4 Mechanical bench testing of sockets and liners

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users.												
Task 4 Mechanical bench testing of sockets and liners.												
4a Perform peel tests of bond strength.												
4b Perform socket strength and deflection tests.												
4c Perform indentor tests of elastomers.												
4d Perform sitting durability tests.												
4e Perform cyclic evacuation tests.												

Task 4a Perform peel tests of bond strength: *This task is currently underway.* Manufacture of the different test samples is complete (**Figure 4**). Additional progress has been hampered by delays with the previously described repairs and upgrade of our mechanical testing system (MTS). However, we anticipate complete mechanical testing of the samples by 12/14/11.

Task 4b Perform socket strength and deflection tests: *We are behind schedule on this task.* We have defined experimental protocols and built fixtures for attaching the socket prototype to our testing machine. We are currently working on calibrating our pressure sensors and conducting the bench top experiments. It is anticipated that this task will be completed by 12/14/11.

Task 4c Perform indentor tests of elastomers: *This task is currently underway.* This task involves the use of a standard protocol for performing indentor tests to determine material properties. This task is also dependent on repair of the MTS system, but we anticipate completion of the task on schedule by the end of Year 2 of the project.

Task 4d Perform sitting durability tests: *We are behind schedule on this task.* This test simulates the repeated pinching and shear of the liner between a socket and the sitting surface. It requires an extensive design of fixtures and we are currently considering the feasibility of this current approach to testing.

Task 4e Perform cyclic evacuation tests: *We are behind schedule on this task.* This test directly investigates the effect of the cyclic application and release of vacuum on the liner material at the socket brim. Different socket designs specific to the limb phantom being used have been fabricated. We anticipate completion of this task by the end of the first quarter of Year 2.

Task 5 Solicit feedback from human subjects

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users.												
Task 5 Solicit Feedback from human subjects.												
5a Perform subject fittings with advance manufactured sockets. Assess results and obtain feedback from subjects.												

Task 5a Perform subject fittings with advance manufactured sockets. Assess results and obtain feedback from subjects: *This task continues into Year 2 of the project.* We have recruited two highly active subjects with unilateral transfemoral amputation. For Subject 1 we have completed baseline gait analysis in the sub-ischial socket with ladle frame (**Figure 8, Appendix H**), undertaken clinical assessment of different liners and sealing techniques (**Appendix G**), scheduled gait analysis to test the sub-ischial socket with H frame, and planning fitting and testing with an ischial containment socket. For Subject 2, we have completed gait analysis in the ischial containment socket (data being processed) and are currently fitting the subject with a sub-ischial socket.

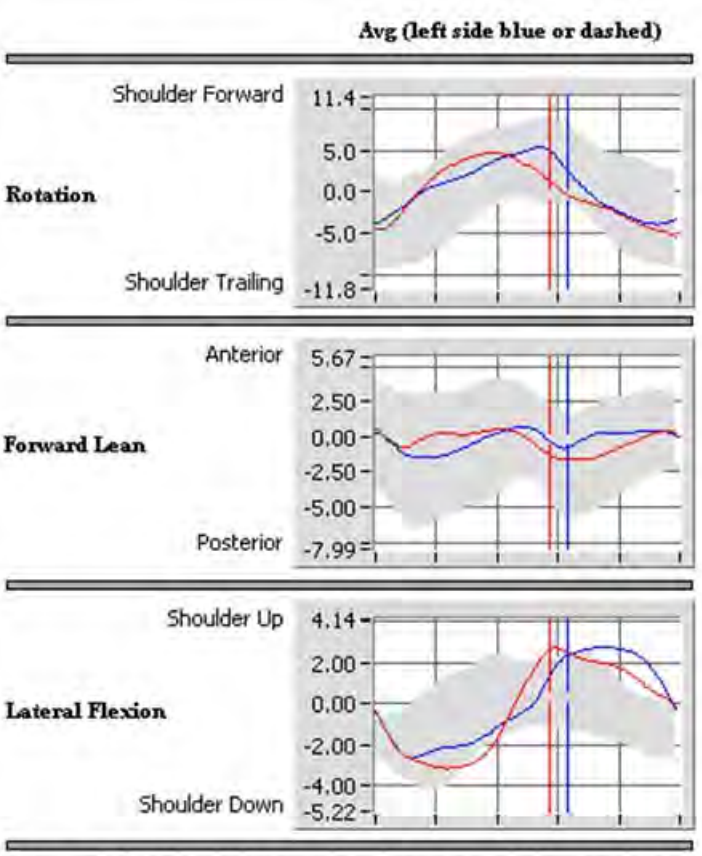


Figure 8 3D trunk kinematics for Subject 1 ambulating with the sub-ischial Polytol socket with ladle frame. Lateral trunk flexion over the amputated (right) limb in stance is within normal limits suggesting no substantial problems with coronal plane stability.

Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis

Task 6 Determine range of volumes to be evacuated from transfemoral sockets of highly active prosthesis users

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis.												
Task 6 Determine range of volumes to be evacuated from transfemoral sockets of highly active prosthesis users.												
6a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test).												
6b Evaluate time needed to evacuate sockets of transfemoral prosthesis users.												
6c Compare results of 6a and 6b.												

Task 6a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test): *The originally planned portion of this task is complete.* We characterized five vacuum pumps (2 electric, 3 mechanical) by constructing five test chambers of known volume (**Figure 9**) and measuring the rate of evacuation for each chamber with each pump. It was determined that the Ohio Willow Wood LimbLogic® VS is 47% more powerful than the Otto Bock Harmony® e-pulse and that the Otto Bock Harmony®P3 was the most powerful mechanical pump. Details of the method and results of this testing can be found in **Appendix I** (Sean Wood's Master's Thesis, Chapter 2). Additionally, we have submitted an abstract for presentation at the 2012 annual meeting of the American Academy of Orthotists and Prosthetists (**Appendix C**).

Figure 9 The test setup used for bench-top testing with the five test canisters in the back, digital vacuum gauge at front left and e-pulse vacuum pump at front right.

Two issues arose during testing. Mechanical vacuum pump activation was performed using a simple lever device (**Figure 10**) that allowed the mounting of mechanical pumps of various heights and a lever 12 inches in length to assist in manual activation. Despite precautions taken to limit the effect of the human tester on the results, testing of the mechanical pumps was still subject to tester bias and stroke power variations. We are currently addressing this limitation by repeating the test using the MTS machine to actuate the mechanical pumps. The fixtures for the limb phantom/socket system were customized to fit the mechanical pumps and the pumps were setup (**Figure 11**) to be characterized in the MTS. After an extensive trial and error, it was determined that the system, in a load controlled configuration, was accurate up to a cyclic loading of 0.2Hz. Vacuum evacuation data was collected for the Harmony®P2 pump at three different load settings.

Our results of testing each of the functional rings (f0 to f4) of the Harmony®P3 mechanical vacuum pump suggested that the f0 ring outperformed the average evacuation time by 24% and the f4 ring underperformed by 18%. It is possible that varying amounts of pre-compression of the functional rings may be responsible for these results. It is recommended by the manufacturer that each ring be pre-compressed, in a specially provided mechanism for 5 minutes prior to use. The f0 ring was the one installed in the pump upon delivery from the manufacturer, while the other rings were provided separately. It may be that the f0 ring received more 'pre-compression' than the other functional rings. This may have served to relax the material more, providing less resistance to energy input into the system,

Figure 10 Simple lever device for testing of mechanical vacuum pumps.

Figure 11 Experimental setup for loading test of mechanical pumps.

and subsequently showing more energy output. However, this does not explain the fact that the f4 ring under-performed. We are currently addressing this issue by repeating testing with a new set of uncompressed functional rings using the MTS machine.

Task 6b Evaluate time needed to evacuate sockets of transfemoral prosthesis users: *The originally planned portion of this task is complete.* We have collected and analyzed data from 13 subjects with unilateral transfemoral amputation, although the data from one subject was excluded due to a minor discrepancy in the testing procedure which affected the results. Details of the method and results of this testing can be found in **Appendix I** (Sean Wood's Master's Thesis, Chapter 3). Additionally, we have submitted an abstract for presentation at the 2012 annual meeting of the American Academy of Orthotists and Prosthetists (**Appendix C**).

For this study, each subject was asked to don their prosthesis and stand quietly while the space between socket and liner was evacuated to a vacuum pressure of ~17 inHg (5 evacuation trials with each of the electrical pumps: Otto Bock Harmony® e-pulse and the Ohio WillowWood LimbLogic® VS). Vacuum pressure data and time were recorded during evacuation using a DigiVac digital vacuum pressure gauge and National Instruments LabVIEW. Calculated average interface volumes for the e-pulse and LimbLogic® are reported in **Table 3** in cubic centimeters.

Interface Volume (cm^3)	e-pulse	LimbLogic®
Average	97.8	103.4
SD	47.4	49.2
Maximum	176.0	189.9
Minimum	21.1	24.3

Table 3 Calculated average interface volumes for the e-pulse and LimbLogic®. SD = standard deviation. (n=12).

We noted that the shapes of several of the evacuation curves for the human subjects differed from those of fixed volume canisters, resembling s-shaped curves (**Figure 12**). These "S" shaped curves observed in 5 of the 12 subjects may represent a change in the initial volume for those people who are pulled into the socket with "soft" tissue (i.e. having a small distal gap between liner and socket before vacuum is generated). We are currently exploring additional bench top testing to help us better understand this phenomenon.

Additionally, 5 of the 12 subjects walked for 10 minutes with each pump at a comfortable pace on a treadmill while the vacuum pressure in their socket was monitored. Data from one subject was excluded as an outlier. Using the remaining data, we determined that the average (± standard deviation) rate of vacuum decay was 0.0061 ± 0.0047 and 0.0045 ± 0.0021 inHg/sec for the LimbLogic® and e-pulse, respectively. We are currently collecting data from an additional 12 subjects to confirm these results.

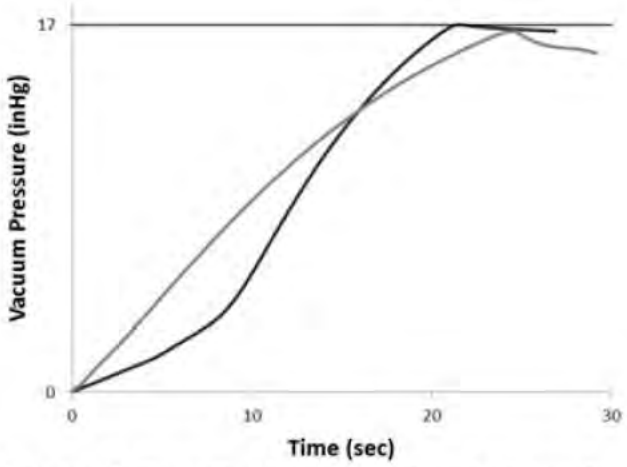


Figure 12 Example of 's' curve: Time to evacuate the socket/liner interface for a representative subject (black line) compared to time to evacuate a 99.3 cm^3 canister (gray line).

Task 6c Compare results of 6a and 6b: *This task was completed on time.* Key observations from Tasks 6a and 6b are summarized in **Table 4**. Combining information from Tasks 6a and 6b, the average socket/liner interface volume was determined to be 6.14 in^3.

Task 6a Observations	Electrical Pumps	The LimbLogic® is 47% more powerful than the e-pulse.
		Unlike the e-pulse, the performance of the LimbLogic® appears to be independent of the charge of its Li-ion battery.
		The LimbLogic® is potentially capable of more than two times as many evacuations as the e-pulse even with a similarly sized Li-ion battery.
	Mechanical Pumps	The P3 mechanical pump performs significantly better on average than both the P2 and HD pumps.
		The various functional rings of the P3 varied in performance.
		The average performance of the P3 pump was equal to that of the e-pulse.
Task 6b Observations	Electrical Pumps	Vacuum pressure variation during ambulation is pump independent.
		The rate of vacuum decay was found to be 36% faster in the LimbLogic® than in the e-pulse.
Task 6c Observations		The average volume of the socket/liner interface for persons with transfemoral amputations is 6.14 in^3.

Table 4 Key Observations from Tasks 6a and 6b.

Task 7 Characterization of mechanical and electrical pumps

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis.												
Task 7 Characterization of mechanical and electrical pumps.												
7a Survey and collect all mechanical and electric pumps for use in lower limb prostheses.												
7b Characterize pumps based on cycles and time to pull specific vacuum levels.												
7c Publish a journal article on the characterization of the mechanical pumps.												

Task 7a Survey and collect all mechanical and electric pumps for use in lower limb prostheses: *This task was completed ahead of schedule.* Our survey identified two electric pumps and three mechanical pumps that are commonly used in lower limb prostheses. These were the Ohio Willow Wood LimbLogic® VS (electric), the Otto Bock Harmony® e-Pulse (electric), the Otto Bock P2 (mechanical), the Otto Bock P3 (mechanical), and the Otto Bock HD (mechanical) (**Figure 13**).

It was desirable to design a vacuum pump system with the military's advanced needs in mind. Aside from the reliability and durability required of military equipment, one need stood out more than any other: the ability to function when common sources of electricity were not available. This need highly encouraged the use of a mechanical pump over an electric one. Even so, an electric pump was still desired for a quick evacuation in the case of an emergency, for users incapable of walking without any vacuum assisted suspension, or any time in which there is a sudden loss of vacuum pressure. Based on what we learned in Tasks 6 and 7, we explored two design solutions. The first was a hybrid electric/mechanical pump and the second a biomechanical energy harvesting design which converts the energy lost during swing phase into electrical energy for use in an electric vacuum pump.

Figure 13 The five vacuum pumps used in bench-top testing A) Ohio Willow Wood LimbLogic® VS, B) Otto Bock Harmony® e-pulse, C) Otto Bock Harmony®P3, and D) Otto Bock Harmony®P2 and HD.

A hybrid pump has the advantage of being capable of quickly evacuating the socket using the electrical system, then maintaining that vacuum through mechanical activation while walking. Without the need to maintain vacuum pressure the electrical system can go into a sleep mode, greatly conserving battery life. The results of Tasks 6 and 7 led to the conclusion that electrical pumps are more desirable than mechanical pumps in terms of their evacuation speed and user independence. We undertook two rounds of design, first with the assistance of an undergraduate team working on this problem for their senior design project (**Appendix J** includes the students' report) and then design modifications and reconstruction of the prototype were undertaken by a graduate student as part of his Master's thesis in mechanical engineering (**Appendix I** Sean Wood's Master's Thesis, Chapter 4). These efforts are detailed in full in **Appendix I** and **Appendix J**, and a provisional patent based on this design has been filed by Northwestern University (**Appendix J**). While we believe that the LimbLogic® electronics can be used successfully within our hybrid pump, a custom made bladder is needed to fully realize a functioning prototype that can be tested both on the bench and with a human user to assess feasibility. With the assistance of another mechanical engineering graduate student, our current work focuses on designing and manufacturing a custom bladder.

As stated previously, the biggest problem with electric pumps is there dependence on a source of electricity. Since the target solution is directed at use by military personnel, it is not possible to assume that the user of our pump would always have access to this. With the increased use of portable electronic devices this problem has become common place. As such, many researchers have explored methods of harvesting human energy,

which might otherwise be wasted, to charge portable electronic devices. Since an electric vacuum pump is nothing more than a portable electric device, we investigated the possibility of using one of these emerging energy harvesting methods to power the pump, negating the need for regular access to a wall outlet. We assessed the feasibility of using an energy harvesting unit designed by Professor Max Donelan [1] with persons with transfemoral amputation. Dr Donelan's device is designed to convert the negative work performed on the human knee joint during swing phase with minimal additional energy provided by the user. We hypothesized that if damping in the C-Leg was made minimal through its control circuitry, it would be possible to slow the movement of the lower leg during swing phase with an energy harvesting unit similar to that designed by Dr Donelan. This unit would then convert the mechanical energy exerted in slowing the prosthetic shank into electrical energy through a brushless DC motor. Details of our analysis can be found in **Appendix I** (Sean Wood's Master's Thesis, Chapter 4).

While our analysis demonstrated that the typical C-Leg users exert enough energy while walking in an average day to charge a Li-ion battery, there remain a number of issues to be addressed before this design can be implemented. For one thing, the conversion efficiency was found to be only 16%. It should be possible to improve this to reach nearly 50% by using a higher quality gear box than was available for testing. This would greatly increase the usefulness of the system. Additionally, the advantage of micro-processor controlled knees such as the C-Leg is their ability to dynamically alter the torque in the knee during swing phase to match the gait of the user. It is theoretically possible to do this with our energy harvester by rapidly activating and deactivating the energy harvester to provide intermediate torque values, but this remains untested.

Task 7b Characterize pumps based on cycles and time to pull specific vacuum levels: *This task was completed ahead of schedule.* For this task, it was useful to determine an arbitrary measurement of each pump's efficiency for means of comparison. With the averages of the evacuation times from each pump (averaged over twenty evacuations for the electric pumps and over five for the mechanical pumps), the vacuum pressure to which they were evacuated, and the precise volumes of each chamber, we were able to calculate a value for the power of each pump. This value was calculated by:

$$Power = \frac{PV}{T}$$

where P is the vacuum pressure, V is the volume of the chamber, and T is the time needed to evacuate the chamber to the vacuum pressure level. This was changed to a more conventional metric of Watts by converting inHg to Pa and in^3 to m^3 using a total conversion factor of 0.05544. All tests were performed at 72ºF.

Our data indicated that the LimbLogic® was 47% more powerful on average than the e-pulse (**Figure 14**). While we expected the electrical pumps to outperform the mechanical pumps the P3 was, on average, as powerful as the e-pulse (i.e. it evacuated each canister to 17 inHg as quickly). However, there were large discrepancies among the calculated powers of the P3 functional rings, possibly due to variation in pre-compression of each ring before testing. While the P3 may be the most "powerful" pump, clinical experience indicates the other mechanical pumps are capable of higher vacuum levels. It remains unknown what level of vacuum is most beneficial for persons with amputation. The power outputs of the mechanical pumps were dependent upon the tester for actuation which may have affected the consistency of results. While this study provides some insight into pump performance it may not be directly indicative of in-vivo performance given other prosthetic and human subject variables that may affect development and maintenance of vacuum.

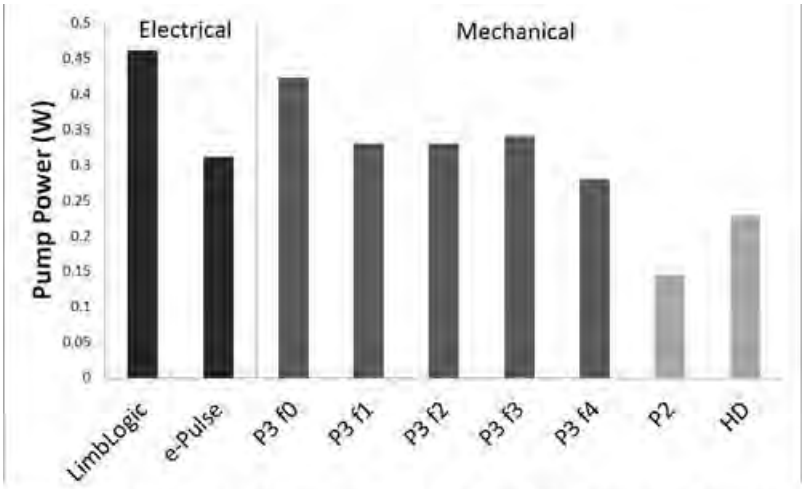


Figure 14 Calculated power (W) for the two electrical pumps and the three mechanical pumps.

Task 7c Publish a journal article on the characterization of the mechanical pumps: *This task is not scheduled to start until Year 2 of the project.* However, we have submitted abstracts based on our work with vacuum pumps for presentation at the 2012 annual meeting of the American Academy of Orthotists and Prosthetists (**Appendix C**).

Task 8 Finalize vacuum pump design

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis.												
Task 8 Finalize vacuum pump design.												

We are ahead of schedule on this task. A provisional patent for a hybrid vacuum pump has been filed by Northwestern University (**Appendix J**).

Aim 4 Evaluate system performance with transfemoral prosthesis users

Task 9 Conduct performance evaluation with human subjects

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 4 Evaluate system performance with transfemoral prosthesis users.												
Task 9 Conduct performance evaluations with human subjects.												
9a Transfer socket casting and rectification skills/knowledge.												
9b Recruit and test human subjects.												
9c Publish results if appropriate.												

Task 9a Transfer socket casting and rectification skills/knowledge: *We have begun work on this task ahead of schedule.* Although this task was not scheduled to begin until Year 3 of the project, we had the opportunity to share our preliminary education documents (**Appendix K**) with our prosthetic collaborators at BAMC. Due to an overwhelming number of military service personnel with bilateral transfemoral amputations who were dissatisfied with their current prosthesis, we received a request form our BAMC collaborator in March 2011 to provide them with any information we had that may allow them to try our current prototype socket system with these individuals. Our BAMC collaborator indicated that they have tried our system on their patients and have feedback regarding our preliminary education documents.

Task 9b Recruit and test human subjects: *Not scheduled to start until Year 3 of the project.*

Task 9c Publish results if appropriate: *Not scheduled to start until Year 3 of the project.*

Aim 5 Develop education materials for sub-ischial socket design

Task 10 Develop a quantification tool for socket rectifications

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 5 Develop education materials for sub-ischial socket designs												
Task 10 Develop quantification tool for socket rectifications.												
10a Develop computer program to quantify socket rectifications.												
10b Develop shape registration scheme.												
10c Test program accuracy.												

Task 10a Develop computer program to quantify socket rectifications: *We are behind schedule on this task.* MATLAB programs were written to import the 3D scans created by our digitizer and calculate the difference between the modified and unmodified positive models. The program calculates and visualizes the modifications made by a prosthetist to the positive model of a patient's residual limb. The program imports the scanned data from both the pre-modified and modified positive models, allows the user to select the three registration marks on the 3D computer models, calculates the transformation and aligns the two shapes, calculates the amount of modification at each point on the modified model, and assigns color coding to the modified model to indicate the degree of modification.

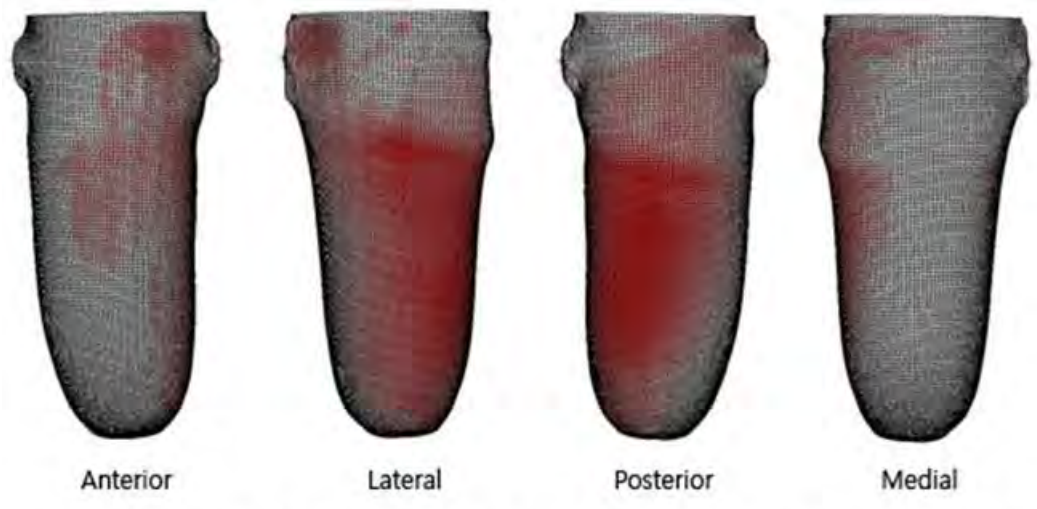


Figure 15 Results of fully implemented alignment algorithm. The intensity of the color red indicates the degree of modification between an unrectified and rectified model.

To obtain a meaningful colored image, the alignment between the unmodified and modified shapes must be as good as possible. Our first alignment algorithm used points in the proximal unmodified region to fine tune the initial alignment, which is based on three proximal registration marks. Shapemaker is used to identify the registration marks on both the modified and unmodified shapes. However, this approach did not produce the best results. So, a new optimization scheme was implemented. The current approach combines points from the proximal registration marks with a collection of points from an unmodified region on the distal, medial wall. For each pair of casts, our prosthetist identified the regions that he did not modify. These regions were captured during the digitization process, and used to improve the alignment of the modified and unmodified shapes. We altered the program to identify these regions. At present, the algorithm uses only red to indicate the amount of rectification (**Figure 15**), but a multi-colored scale would allow easier interpretation of the images. Fine tuning of the color algorithm is currently underway. It is anticipated that this task will be completed by 12/14/11.

Task 10b Develop shape registration scheme: *We are behind schedule on this task.* Initially, a jig was constructed to hold casts during scanning with the Inspeck scanner (**Figure 16**). Preliminary scans showed that the scanner was capable of capturing the cast shape and registration marks well. Unlike the Omega T-ring and Provel d1 digitizers we have available, the Inspeck scanner allows the distal end of the positive model to be captured. Nine scans taken every 45º and at the distal end are required to capture the whole model. The nine individual scans are stitched together using Inspeck's EM Software to create the final 3D model and

export the model in a variety of formats (e.g. *.obj,* .stl, *.dxf). Unfortunately testing showed that the resulting data files contained many orphan points which caused problems with processing of the files. Also, the acquisition and registration process were very time consuming, and with a possible 80 casts to scan, the Inspeck digitizer was no longer a viable option.

Figure 16 Adjustable scanning jig.

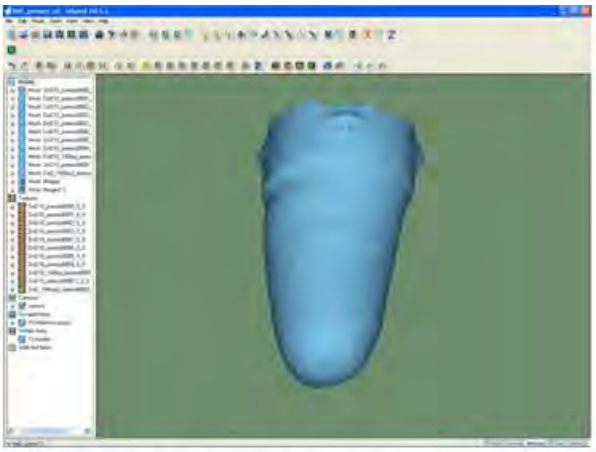


Figure 17 Anterior-distal view of the 3D model after all scans have been stitched together. This image shows how the entire distal end of the positive model has been captured.

We returned to using the Provel digitizer to identify a method of obtaining better capture of the distal end. We adjusted several of Provel's parameters and found that we could reduce the size of the hole in the distal end, and by using Shapemaker CAD software, fill the hole using the surrounding geometry as a guide (**Figure 17**). Using the Provel digitizer significantly reduces the acquisition time from hours to minutes. We modified our code to integrate the new data file structure. It is anticipated that this task will be completed by 12/14/11.

Task 10c Test program accuracy: *We are behind schedule on this task.* Now that the alignment algorithm has been fully implemented, testing of the program will begin. It is anticipated that this task will be completed by 12/14/11.

Task 11 Quantify rectifications for multiple amputees

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 5 Develop education materials for sub-ischial socket designs.												
Task 11 Quantify rectifications for simple amputees.												
Task 11a Develop limb type categorization scheme and inclusion criteria.												
Task 11b Obtain range of negative casts.												
Task 11c Digitize casts.												
Task 11d Assess digitized shapes.												
Task 11e Generate representative 3D models.												

Task 11a Develop limb type categorization scheme and inclusion criteria: *We are behind schedule on this task.* Algorithms for clinical decision making have been drafted for transfemoral as well as knee disarticulation patients (**Appendix L**). Our next step is to obtain feedback from prosthetic colleagues to ensure that our algorithm is understandable and revise as necessary.

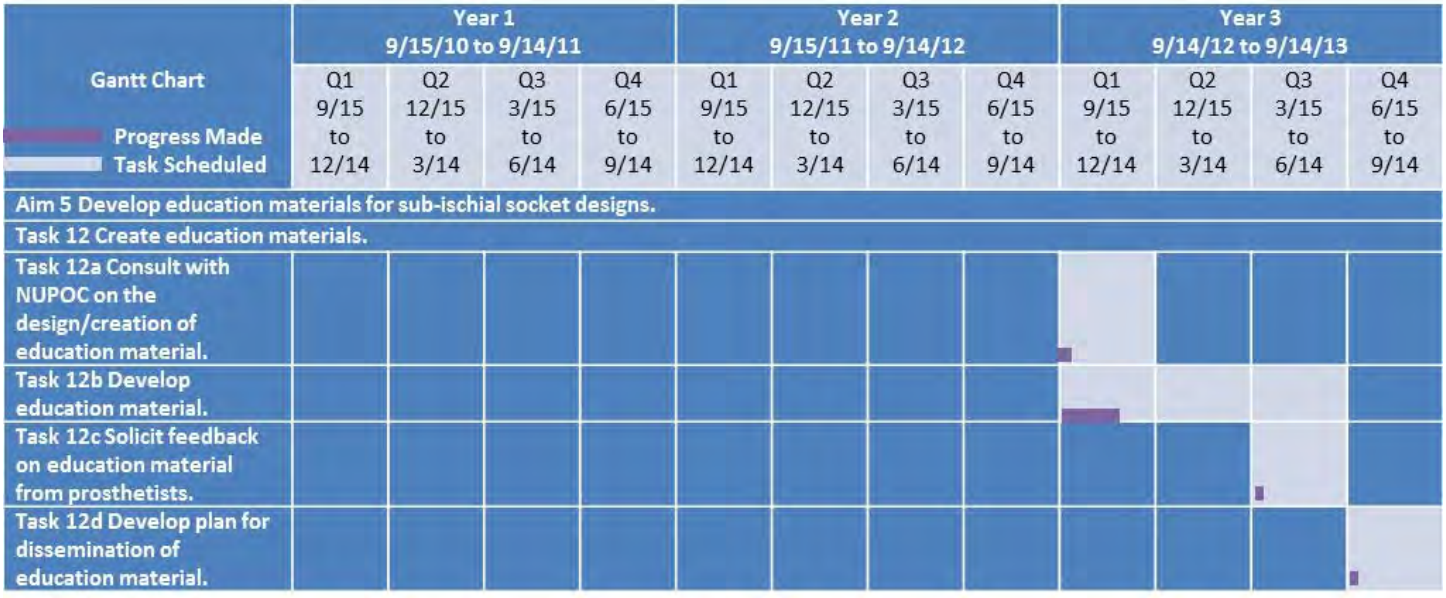
Task 11b Obtain range of negative casts: *The originally planned portion of this task is complete.* Initially we planned to collect 20 pairs of casts but soon realized that this number would be insufficient to capture the heterogeneity in residual limb types, so we increased our target number of casts. To date we have collected 22 of the planned 40 pairs of casts.

Task 11c Digitize casts: *We are behind schedule on this task.* 15 pairs of casts have been digitized to date using the process described in Tasks 10a and 10b.

Task 11d Assess digitized shapes: *This task is scheduled to continue into Year 2 of the project.* Preliminary assessment is underway. Final assessment requires completion of Tasks 10a, 10b and 10c.

Task 11e Generate representative 3D models: *Not scheduled to start until Year 2 of the project.*

Task 12 Create education materials



Task 12a Consult with NUPOC on the design/creation of education material: *We are ahead of schedule with this task.* Although not scheduled to start until Year 3, we have made some progress on this task. Vacuum-assisted technology has been presented to the prosthetics students at Northwestern University through a series of lectures, video modules, and hands-on experience working with patient models. Modules including the history of vacuum-assisted technology, physics of subatmospheric pressure, impression and modification

techniques, fabrication and system troubleshooting are taught. At present, this course focuses application on persons with transtibial amputation but the content is also applicable for persons with transfemoral amputation. An introduction to elevated vacuum systems for persons with transfermoral amputation has been presented and more complete modules are currently being written to be coupled with the previously recorded transtibial modules. A first generation manual specific to our sub-ischial socket has been drafted (**Appendix K**) and will undergo revisions pending feedback from our collaborators at BAMC and NUPOC education faculty.

Task 12b Develop education material: *We are ahead of schedule with this task.* Educational material has been developed and shared with our colleagues at BAMC (see Task 9a) and education modules were developed and taught to the Northwestern University prosthetics students (see Task 12a).

Task 12c Solicit feedback on education material from prosthetists: *We are ahead of schedule with this task.* We are awaiting feedback from our colleagues at BAMC (see Task 9a).

Task 12d Develop plan for dissemination of education material: *We are ahead of schedule with this task.* Although this task is not yet scheduled to start until Year 3 of the project, we are planning ahead and have submitted an application for an instructional course at the 2013 World Congress of the International Society for Prosthetics and Orthotics (**Appendix M**). Additionally, Ryan Caldwell has been invited to speak about vacuum-assisted technology at the 2012 meeting of the Canadian Association of Prosthetists and Orthotists.

Task 13 Final project meeting

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 5 Develop education materials for sub-ischial socket designs.												
Task 13 Final project meeting												
Task 13a Convene final project meeting.												

KEY RESEARCH ACCOMPLISHMENTS

- Developed a finite element model of a transfemoral sub-ischial prosthetic socket that can be used to analytically evaluate the performance of different frame designs using the socket-residual limb interface stress magnitude and distribution.
- Characterized performance and efficiency of available mechanical and electrical vacuum pumps.
- Designed a hybrid vacuum pump for persons with transfemoral amputations and filed a provisional patent application.
- Drafted clinical decision making algorithms for the sub-ischial socket.
- Developed a computer program to quantify socket rectifications.

REPORTABLE OUTCOMES

Abstracts	**Submitted to the 38th American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium to be held March 21-24, 2012, Atlanta, GA:** (1) Characterizing the performance of prosthetic vacuum pumps: bench top testing. (2) Characterizing the performance of prosthetic vacuum pumps: in vivo testing. (3) Stress Analysis of Different Rigid Frame Designs of within a Flexible Transfemoral Prosthetic Socket.	**Appendix H**
	Submitted to the World Congress of the International Society for Prosthetics and Orthotics to be held February 4-7, 2013, Hyderabad, India: Subischial Sockets with Vacuum Assisted Suspension for Persons with Transfemoral Amputation.	**Appendix G**
Presentations	Northwestern University Department of Physical Medicine and Rehabilitation Quarterly Faculty Meeting (February 15, 2011).	**Appendix N**
	Invited to present at 2012 meeting of the Canadian Association of Prosthetists and Orthotists to be held in Victoria BC, August 1-5.	N/A
Provisional Patent	Title: Hybrid Prosthetic Vacuum Pump for Transfemoral Amputees.	**Appendix I**
Degrees Obtained	Sean Wood BS/MS degree in Mechanical Engineering Title: Characterization and Design of Vacuum Pumps for Persons with Transfemoral Amputations.	N/A
Other	Sean Wood received the Mechanical Engineering Undergraduate Innovation and Research Award for hybrid vacuum pump design.	N/A
	BME 398 undergraduate design group: Bennett Kuhar, AJ Nelson, Regan Radcliffe, Kevin Yngve.	**Appendix I**

CONCLUSIONS

Aims 1 & 2: Preliminary results from our finite element model showed a non-uniform interface stress (pressure) distribution that was different for each frame design tested suggesting that this approach can be useful to optimize responsive (i.e. flexible) sockets simultaneously capable of conforming to a changing residual limb and achieving biomechanical load requirements. Work is ongoing to refine the computational model and to perform more extensive experimental validation. Future work will focus on directly extracting optimal frame designs from the FE analysis and using advanced manufacturing methods to fabricate them.

We wanted to find a method to improve the durability of the liner. Our initial trials with internal sealing rings suggest that this may not be a feasible approach with our sub-ischial socket. However, we have noted that durability has increased with use of Polytol. We are continuing to explore methods of increasing liner durability.

Aim 3: The results of our characterization of vacuum pumps showed that the LimbLogic® outperformed the e-pulse in total evacuations on a single battery charge, consistency in evacuations over time, and time to evacuation, while the Harmony® P3, was the most “powerful” of the mechanical pumps (i.e., it pulled vacuum to the required level with the least amount of actuations). While the P3 may be the most "powerful" pump, clinical experience indicates the other mechanical pumps are capable of higher vacuum levels. It remains unknown what level of vacuum is most beneficial for persons with amputation.

While our bench-top evaluation of vacuum pumps provides some insight into pump performance it may not be directly indicative of in-vivo performance given other prosthetic and human subject variables that may affect development and maintenance of vacuum. For example, in our human subjects testing, we observed “S” shaped curves in some of our subjects that are likely the result of soft tissue properties. Testing on a greater number of subjects is underway to better understand vacuum pump performance in human subjects.

Our testing of vacuum pumps confirmed that electrical pumps are more desirable than mechanical pumps in terms of their evacuation speed and user independence but battery life may be a problem. We designed a hybrid vacuum pump that is capable of quickly evacuating the socket using the electrical system, then maintaining that vacuum through mechanical activation while walking. A provisional patent has been filed and work is ongoing to build a testable prototype of our hybrid pump.

Aim 5: Our computer program to quantify socket rectifications is promising for two reasons (1) it can improve our ability to teach other prosthetists how to make this socket and (2) it can potentially be used in conjunction with our finite element model to automate fabrication of the socket in conjunction with advanced manufacturing techniques that we are exploring.

REFERENCES

1. Q. Li, V. Naing, J. A. Hoffer, D. J. Weber, A. D. Kuo, J. M. Donelan, Biomechanical Energy Harvesting: Apparatus and Method. *IEEE International Conference on Robotics and Automation*, Pasadena CA, USA, May 19-23, 2008, p 3672-3677.

APPENDICES

A Socket Breakdown for Scanning Procedure

B Verified instructions for converting scanned data to solid model

C Abstracts Submitted to 2012 Meeting of the American Academy of Orthotists and Prosthetists

D MTS Testing Protocols

E Finite Element Modeling of Lower Limb Prosthetic Sockets

F Experimental protocol for bench-top simulations of sub-ischial prosthetic socket loading

G Subject 1 Feedback Summary

H Subject 1 Gait Data

I Master of Science Thesis – Sean Wood

J Provisional Patent for Hybrid Prosthetic Vacuum Pump for Transfemoral Amputees

K Preliminary Education Materials

L Clinical Algorithms for the Sub-Ischial Socket

M Abstracts Submitted to 2013 World Congress of the International Society for Prosthetics and Orthotics

N Presentation Given at Northwestern University Department of Physical Medicine and Rehabilitation Quarterly Faculty Meeting (February 15, 2011)

Appendix A

Socket Breakdown for Scanning Procedure

Sealed Mold

A mold from Subject #1 was used in the fabrication of scanning models of Polytol lamination lay-up and two different frame designs.

Pictured Above (L to: R) Anterior, Medial, Lateral, Posterior

Removable Inner Polytol Lamination

Removable inner polytol lamination for scanning with Polytol layup of 2 Flexistretch and 2 Spectracarb Aralon. Reference marks are used to ensure proper orientation of the socket on the mold.

Ladle Frame - Initial Design

The initial ladle frame was designed to strengthen the integral medial wall, with arms that extend both along the anterior and posterior walls to provide support for flexion and extension of the prosthesis. The lateral wall requires almost no support and the window is used to allow flexibility.

Pictured above: (L to R) Anterior, Medial, Posterior, Lateral

“H” Frame Design

The new frame was designed to increase range of motion in extension, and to allow the wearer to sit on a soft portion of the socket whether seated deep or shallow in a chair. An extension of the frame on the posterior lateral wall is used increase strength and reduce buckling of the medial strut under heavy loading or torque.

Pictured above: (L to R) Anterior, Medial, Posterior, Lateral

Appendix B

Verified instructions for converting scanned data to solid model

1. Acquisition – Pointcloud (x,y,z,normal)
    a. Clean using Mesh prep wizard in SW
    b. Decimate (use Quadric edge collapse decimation in Meshlab)
2. Convert to surface in SW
    a. Automatic creation
    b. Adjust feature lines to populate geometry with regular faces
3. Extract ROI (cut out frame geometry on flexible socket) and convert to solid
    a. First prepare rough cutout of the frame using the mesh prep wizard
    b. Overlay the frame cutout on the flexible socket surface
    c. Select 'Spline on surface' and trace out frame boundary onto flexible socket surface
    d. After curve is drawn, 'check' in left panel
        i. Insert -> Surfaces -> trim
        ii. Insert -> Boss/Base -> thicken
        iii. Insert -> Surfaces -> Knit
            1. Use mouse to select all faces
            2. Toggle 'Try to form solid'
    e. In feature tree, look in solids list and delete any extraneous solids
4. Convert flexible socket surface to solid
    a. Insert -> Surface -> fill
        i. Select edge around hole
    b. Insert -> Surface -> Knit
        i. Select surfaces (2)
        ii. Toggle 'Try to form solid'
    c. Insert -> features ->Shell
        i. Select face (proximal end)
5. Export for Abaqus
    a. Save As
        i. Type: ACIS (*.sat)
        ii. Options: Output as – solid/suface
        iii. CHANGE version to 1.6
    b. Export -> All bodies

Appendix C

Stress Analysis of Different Rigid Frame Designs within a Flexible Transfemoral Prosthetic Socket

OA Komolafe[1], R Caldwell[1], K Tucker[1], C Sun[2], W Chen[2], AH Hansen[1, 3], S Fatone[1]

[1]Prosthetics-Orthotics Center and [2]Mechanical Engineering, Northwestern University; [3]Minneapolis VA Health Care System.

INTRODUCTION

Transfemoral sockets were originally constructed from wood or hard plastic laminates (Radcliffe, 1955). More recently, thermoplastics and acrylic resins with carbon fiber or other woven materials have been used (Ng, 2002). Although these materials achieve suitable load transmission between the residual limb and the prosthesis, their rigidity prevent the sockets from dynamically conforming to changes in residual limb shape and volume during gait (Sanders, 2009).

The ensuing separation (i.e. loss of contact) between the socket and residual limb leads to a loss of negative pressure in suction and vacuum sockets and increase in relative movements (e.g. pistoning) of the residual limb within the socket. A direct, easily achievable solution can be obtained by constructing the socket from a flexible material. However, this solution is constrained by the minimum socket rigidity necessary for effective and stable biomechanical load transfer between the residual limb and the prosthesis.

Our approach to maximizing socket flexibility and maintaining effective load transfer is to construct a single walled, flexible socket, reinforced with a rigid carbon fiber frame (Figure 1). We present results of a finite element (FE) stress analysis evaluating different frame designs.

METHOD

Equipment: Creaform 3-D MegaCapturor digitizer, Novel Pliance system, MTS load system, iPecs unit.

Procedure: A FE model (Figure 1) of a transfemoral sub-ischial prosthetic socket is developed by digital scanning and validated using experimental data (Figure 2). The FE model is formulated to analytically evaluate the performance of three unique frame designs identified with clinical input. The designs are assessed based on the socket-residual limb interface stress magnitude and distribution.

Developing the FE model

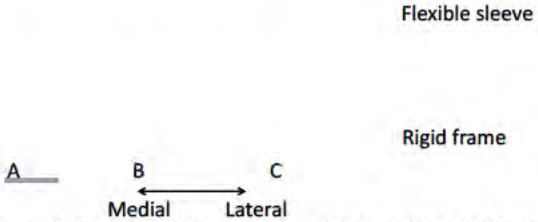


Figure 1: A sub-ischial socket modeled as a simplified two-layered system. A) Scanned 3D vertex data of the socket. B) Solid geometric model. C) FE model is discretized using tetrahedral elements.

Experimental validation

Figure 2: Experimental setup to validate FE model. (Left) Loads are applied to a silicon limb model in a custom made socket. (Right) Sensors are inserted between the liner and socket to estimate the normal stress (interface pressure).

RESULTS

Figure 3: FE analysis stress results: (Left) Totally rigid frame (i.e. no cut-outs) and (Right) a ladle shaped frame with medial strut

DISCUSSION & CONCLUSIONS

The FE results showed a non-uniform interface stress (pressure) distribution that was different for each socket (Figure 3). The sockets differed in the location and extent of cut-outs in the rigid frame. Cut-outs in transfemoral sockets have been used to provide release areas that accommodate displaced tissues (Alley, 2011). The results suggest this approach can be useful to optimize responsive (i.e. flexible) sockets, capable of conforming to a changing residual limb while achieving biomechanical load requirements. Work is ongoing to refine the computational model and to perform more extensive experimental validation. Future work will focus on directly extracting optimal frame designs from the FE analysis.

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Ng, P. Rapid Prototyping Journal, 8(1), 53, 2002.
Sanders JE. POI, 33(4), 378 – 390, 2009.
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American Academy of Orthotists & Prosthetists
38th Academy Annual Meeting and Scientific Symposium
March 21-24, 2012

Characterization of Mechanical and Electrical Vacuum Pumps for Use in Vacuum-Assisted Suspension

S Wood[1], R Caldwell[2], W Chen[1], C Sun[1], A Hansen[3], O Komolafe[2], S Fatone[2]
[1]Mechanical Engineering and [2]Prosthetics-Orthotics Center, Northwestern University; [3]Minneapolis VA Health Care System.

INTRODUCTION

Vacuum-assisted suspension is becoming a popular system for use in lower-limb prostheses[1]. However, the performance of current prosthetic vacuum pumps responsible for creating and maintaining negative pressure between the socket and liner, have not been studied. Knowledge of the time to evacuation and overall efficiency for the most commonly used vacuum pumps could assist the prosthetist's decision-making when providing lower-limb prostheses with vacuum-assisted suspension to patients. In this study, several widely used prosthetic vacuum pumps, both mechanical and electrical, were tested and compared to gain insight into their overall performance and efficiency.

METHOD

Apparatus: The pumps compared in this study included 2 electrical pumps (Otto Bock Harmony® e-pulse and Ohio WillowWood LimbLogic® VS) as well as 3 mechanical pumps (Otto Bock Harmony® P3, P2, and HD). Five sealed canisters were used to simulate the estimated volumes of a range of socket/liner interfaces (37.5, 68.6, 99.3, 133.1, 198.9 cm^3). Data were captured using a DigiVac digital vacuum pressure gauge. Actuation of the mechanical pumps was provided by the tester with the use of a lever activated fixture.

Procedures: Each canister was evacuated to a vacuum pressure of ~17 inHg at least 5 times with each pump. Vacuum pressure data and time were recorded during evacuation using National Instruments LabVIEW software. Additionally, the electrical pumps were tested repeatedly on the 99.3 cm^3 canister to complete battery depletion. All five functional rings (f0 to f4) were tested for the P3, while the P2 and HD pumps were set for a patient weighing 55 kg, which is equivalent to the weight resistance provided by the f0 ring of the P3.

Data Analysis: Evacuation data (negative pressure versus time) were plotted using Microsoft® Excel and times to evacuation calculated graphically. Average power was calculated by multiplying the achieved vacuum pressure by the canister volume and dividing by the time taken to achieve that pressure.

RESULTS

There was a large difference in number of evacuations to complete battery depletion between electrical pumps (e-pulse < 180 trials; LimbLogic® > 225 trials). Additionally, time to evacuation for the e-pulse increased by 7.5% over the course of battery depletion, while the LimbLogic® demonstrated no change. Figure 1 depicts average power calculated for each of the vacuum pumps, averaged for each trial on each canister.

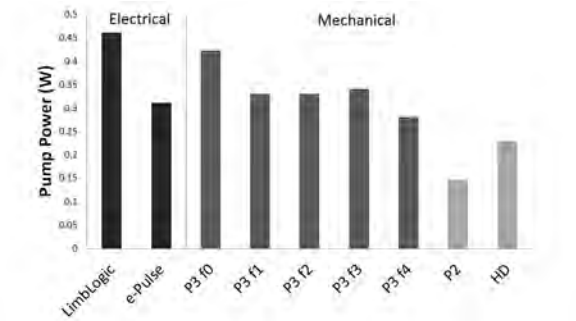

Figure 1. Calculated power (W) for the two electrical pumps and the three mechanical pumps.

DISCUSSION & CONCLUSION

Our data indicated that the LimbLogic® was 47% more powerful on average than the e-pulse. While we expected the electrical pumps to outperform the mechanical pumps the P3 was, on average, as powerful as the e-pulse (i.e. it evacuated each canister to 17 inHg as quickly). However, there were large discrepancies among the calculated powers of the P3 functional rings, possibly due to variation in pre-compression of each ring before testing (f0 came from the manufacturer mounted in the device while the other rings were purchased separately). While the P3 may be the most "powerful" pump, clinical experience indicates the other mechanical pumps are capable of higher vacuum levels. It remains unknown what level of vacuum is most beneficial for persons with amputation. The power outputs of the mechanical pumps were dependent upon the tester for actuation which may have affected the consistency of results. While this study provides some insight into pump performance it may not be directly indicative of in-vivo performance given other prosthetic and human subject variables that may affect development and maintenance of vacuum.

CONCLUSIONS

In bench testing the LimbLogic® outperformed the e-Pulse in total evacuations on a single battery charge, consistency in evacuations over time, and time to evacuation, while the Harmony® P3, was the most "powerful" of the mechanical pumps.

REFERENCES

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This work was funded by Department of Defense Award #W81XWH-10-1-0744.

American Academy of Orthotists & Prosthetists
38th Academy Annual Meeting and Scientific Symposium
March 21-24, 2012

Socket/Liner Interface Volume and Vacuum Pressure Decay in Persons with Transfemoral Amputations

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[1]Mechanical Engineering and [2]Prosthetics-Orthotics Center, Northwestern University; [3]Minneapolis VA Health Care System.

INTRODUCTION

Vacuum-assisted suspension is becoming a popular system for use in lower-limb prostheses. However, we know very little about socket/liner interface volume in persons with transfemoral amputations (TFA) or the rate at which vacuum pressure decays during regular activity. What research has been performed in this area pertains to persons with transtibial amputations.[1] Understanding these two characteristics of vacuum-assisted suspension could lead to improvements in vacuum pump designs and assist in provision of improved lower-limb prostheses with vacuum-assisted suspension. In this study, an empirical approach was used to obtain evacuation curves on human subjects by measuring change in vacuum pump pressure, and therefore to gain insight into socket/liner interface volume and pressure decay.

METHOD

Subjects: Persons with unilateral TFA who regularly used vacuum-assisted suspension with sub-ischial sockets and silicone liners were recruited to participate in this study. The Northwestern University Institutional Review Board approved this study and informed consent was obtained from subjects prior to participation.

Apparatus: The pumps used in this study were the Otto Bock Harmony® e-pulse and the Ohio WillowWood LimbLogic® VS. Data were captured using a DigiVac digital vacuum pressure gauge. Subjects walked on a Cosmed Sport Treadmill.

Procedures: Each subject was asked to don their prosthesis and stand quietly while the space between socket and liner was evacuated to a vacuum pressure of ~17 inHg (5 evacuation trials with each pump). Between evacuation trials air was allowed to return into the system by disconnecting the tubing attaching pump to socket. Vacuum pressure data and time were recorded during evacuation using National Instruments LabVIEW. Additionally, subjects were asked to walk for 10 minutes with each pump at a comfortable pace on the treadmill while the vacuum pressure in their socket was monitored.

Data Analysis: Vacuum pressure versus time were plotted using Microsoft® Excel and times to evacuation were calculated graphically. Interface volume was then calculated from the relationship between time to evacuation in the human subjects and time to evacuate sealed canisters of known volume which were assessed for the same pumps in a related study performed by the same authors.[2]

RESULTS

Twelve subjects were involved in the study (age = 56±14 years; height = 174±7cm; and mass = 82±25kg). Table 1 shows the calculated interface volumes for both pumps.

Only 5 of the 12 subjects participated in treadmill testing. From 4 of these subjects (one outlier) we determined that the average (± standard deviation) rate of vacuum decay was 0.0061 ± 0.0047 and 0.0045 ± 0.0021 inHg/sec for the LimbLogic® and e-pulse, respectively.

	Interface Volume (cm^3)	
	e-pulse	LimbLogic®
Average	97.8	103.4
SD	47.4	49.2
Maximum	176.0	189.9
Minimum	21.1	24.3

Table 1. Calculated average interface volumes for the e-pulse and LimbLogic® reported in cubic centimeters.

The shapes of several of the evacuation curves for the human subjects differed from those of fixed volume canisters, resembling s-shaped curves (Figure 1).

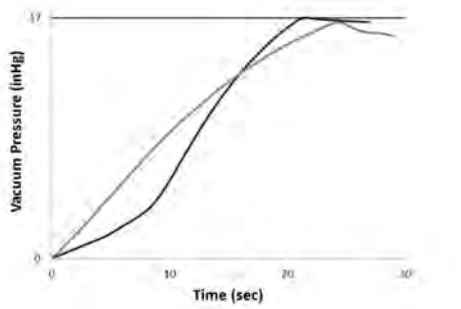

Figure 1. Time to evacuate the socket/liner interface for a representative subject (black line) compared to time to evacuate a 99.3 cm^3 canister (gray line).

DISCUSSION & CONCLUSIONS

Estimated average volume for the transfemoral sockets tested was about 100 cm^3. The "S" shaped curves observed in 5 of the 12 subjects may represent a change in the initial volume for those people who are pulled into the socket with "soft" tissue (i.e. having a small distal gap between liner and socket before vacuum is generated). Testing on a greater number of subjects is needed to better understand the rate of vacuum depletion in these systems.

REFERENCES
1 Gershutz *et al.* J Prosthet Orthot 2010, 22(3):172-6.
2 Wood S. MS Thesis, Northwestern University, 2011.

This work was funded by Department of Defense Award #W81XWH-10-1-0744.

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Appendix D

PROTOCOL FOR MTS TESTING

1. Power up system on 413 Master Control Panel – Allow system to idle for 30 mins
2. Connect multimeter leads to 442 controller
    a. (**Black**)o---"meter output"---o(**Red**)
    b. Switch "meter" knob to "DC Error"
    c. Zero-out multi-meter reading using "set point" knob
    d. Push "interlock reset"
3. On 413 Master Control Panel
    a. Push "reset"
    b. Push "hydraulic pressure" to turn on hydraulics. Indicator will light on "low"
4. On 442 Controller
    a. Adjust "set point" to 5.0, then lock position
    b. Select loading option
        i. **Strain** – this toggles for a **load controlled** test
        ii. **Stroke** – this toggles for a **displacement controlled** test
    c. Open front panel on 442 controller. On back panel, adjust only "Zero" and "Range" knobs corresponding to selected loading option
        i. Set zero load reading and position of cross head
        ii. *****Set system "range" knob from 100% to 10% of Fullscale – indicator is on front of 442 controller.
            1. maximum voltage out for 100% FS – 10 V
            2. maximum system stroke – 5.0"
    d. Set "span 1" as % of maximum load or displacement

$$\frac{desired\ travel}{max.travel} \times 1000$$

    e. Do not adjust "span 2"
5. On 410 Digital Function Generator
    a. "Rate 1" – loading/Ramp time/frequency
    b. "Rate 2" – Unloading time
    c. Set functions on the right of panel
        i. Set loading function – "ramp", "sine", etc.
        ii. **Invert – Moves cross head up first or down first
6. Press "hydraulic pressure." Indicator will light on "high"
7. Start test
   (Light on 410 DFG indicates a return of the system to zero)

Notes:

*****"Range" adjusts the voltage scaling of the system. The maximum voltage reading possible from the system controller is 10 V. Depending on expected maximum loads, or maximum displacements of a particular test, the user can rescale the system so that 10 V corresponds to the new maximum value.

** Particular to this system, the crosshead is fixed and stroke is controlled through movement of the load cell. Therefore, for tensile tests, the load cell moved downwards. It is important to remember this in the setup.

EXPERIMENT TO DETERMINE THE TENSILE MATERIAL PROPERTIES OF POLYPROPYLENE PROSTHETIC SOCKET FRAME

Oluseeni Komolafe, PhD.
Northwestern University Prosthetic-Orthotics Center
May 23, 2011

Purpose:
To perform a tensile test on samples of the polypropylene socket frame material and calculate the Modulus of elasticity, Poisson's ratio, Yield strength and the Tensile strength. ***(Satisfies task 2 and 4b of DoD grant W81XWH-10-1-0744.)***

Applicable Testing Standards:
ASTM D638-10: Standard Test Method for Tensile Properties of Plastics
**ASTM D618: Standard Practice for Conditioning Plastics for Testing

Equipment and Materials:
Loading system: Servo-hydraulic loading system (MTS™, Eden Prairie, MN)
Extensometer: Bi-axial extensometer @ >= 20Hertz
Micrometer – Apparatus for measuring width and thickness of test specimen

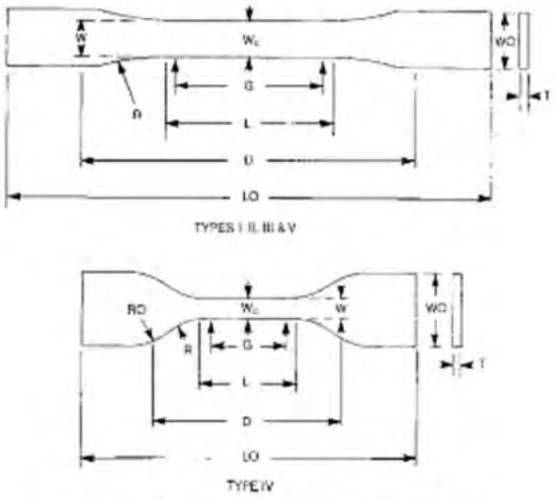
Designations for Recording Atmospheric Conditions:
1. Conditioning: A/B/C (e.g. Condition 96/23/50)
2. Testing: T-B/C (e.g. T-23/50)
   - A – Number in hours of the duration of the conditioning
   - B – Conditioning temperature in degrees Celsius
   - C – Relative humidity

No. of Specimens: 8

Specimen Exclusion Criteria:
1. Surface gouged / scratched specimen
2. Obvious material inconsistencies upon visual inspection
3. Specimen that fractures outside of gage region

Testing Procedure:
1. Allow specimen to equilibrate in testing environment for 40 hours**
2. Measure and record temperature and relative humidity of the test area
3. Measure and record the width and thickness of specimen middle zone ***(to the nearest 0.025 mm)***
4. Mark gage length on specimen surface using India ink/permanent marker
5. Place the specimen in the grips of the testing machine
   a. Take care to align the long axis of the specimen and the grips
   b. Tighten the grips evenly and firmly to prevent slippage of the specimen during the test
   c. Apply a small preload (less than 5 N at 0.1 mm/min) to eliminate any bending in the specimen
6. Attach the extensometer to the specimen and balance all readings to zero
7. Set strain rate to 5 mm/min
8. Start the test
9. Record the load-extension curve of the specimen
10. Extend specimen to failure (i.e. breakage)

Appendix A: Specimen dimensions



Specimen Dimensions for Thickness, *T*, mm (in.)[A]

Dimensions (see drawings)	7 (0.28) or under		Over 7 to 14 (0.28 to 0.55), incl	4 (0.16) or under		Tolerances
	Type I	Type II	Type III	Type IV[B]	Type V[C,D]	
W—Width of narrow section[E,F]	13 (0.50)	6 (0.25)	19 (0.75)	6 (0.25)	3.18 (0.125)	±0.5 (±0.02)[B,C]
L—Length of narrow section	57 (2.25)	57 (2.25)	57 (2.25)	33 (1.30)	9.53 (0.375)	±0.5 (±0.02)[C]
WO—Width overall, min[G]	19 (0.75)	19 (0.75)	29 (1.13)	19 (0.75)	...	+ 6.4 (+ 0.25)
WO—Width overall, min[G]	...	...	...	...	9.53 (0.375)	+ 3.18 (+ 0.125)
LO—Length overall, min[H]	165 (6.5)	183 (7.2)	246 (9.7)	115 (4.5)	63.5 (2.5)	no max (no max)
G—Gage length[I]	50 (2.00)	50 (2.00)	50 (2.00)	...	7.62 (0.300)	±0.25 (±0.010)[C]
G—Gage length[I]	...	...	...	25 (1.00)	...	±0.13 (±0.005)
D—Distance between grips	115 (4.5)	135 (5.3)	115 (4.5)	65 (2.5)[J]	25.4 (1.0)	±5 (±0.2)
R—Radius of fillet	76 (3.00)	76 (3.00)	76 (3.00)	14 (0.56)	12.7 (0.5)	±1 (±0.04)[C]
RO—Outer radius (Type IV)	...	...	...	25 (1.00)	...	±1 (±0.04)

[A] Thickness, *T*, shall be 3.2± 0.4 mm (0.13 ± 0.02 in.) for all types of molded specimens, and for other Types I and II specimens where possible. If specimens are machined from sheets or plates, thickness, *T*, may be the thickness of the sheet or plate provided this does not exceed the range stated for the intended specimen type. For sheets of nominal thickness greater than 14 mm (0.55 in.) the specimens shall be machined to 14 ± 0.4 mm (0.55 ± 0.02 in.) in thickness, for use with the Type III specimen. For sheets of nominal thickness between 14 and 51 mm (0.55 and 2 in.) approximately equal amounts shall be machined from each surface. For thicker sheets both surfaces of the specimen shall be machined, and the location of the specimen with reference to the original thickness of the sheet shall be noted. Tolerances on thickness less than 14 mm (0.55 in.) shall be those standard for the grade of material tested.

[B] For the Type IV specimen, the internal width of the narrow section of the die shall be 6.00 ± 0.05 mm (0.250 ± 0.002 in.). The dimensions are essentially those of Die C in Test Methods D412.

[C] The Type V specimen shall be machined or die cut to the dimensions shown, or molded in a mold whose cavity has these dimensions. The dimensions shall be:
W = 3.18 ± 0.03 mm (0.125 ± 0.001 in.),
L = 9.53 ± 0.08 mm (0.375 ± 0.003 in.),
G = 7.62 ± 0.02 mm (0.300 ± 0.001 in.), and
R = 12.7 ± 0.08 mm (0.500 ± 0.003 in.).
The other tolerances are those in the table.

[D] Supporting data on the introduction of the L specimen of Test Method D1822 as the Type V specimen are available from ASTM Headquarters. Request RR:D20-1038.

[E] The width at the center W_c shall be +0.00 mm, −0.10 mm (+0.000 in., −0.004 in.) compared with width *W* at other parts of the reduced section. Any reduction in *W* at the center shall be gradual, equally on each side so that no abrupt changes in dimension result.

[F] For molded specimens, a draft of not over 0.13 mm (0.005 in.) may be allowed for either Type I or II specimens 3.2 mm (0.13 in.) in thickness, and this should be taken into account when calculating width of the specimen. Thus a typical section of a molded Type I specimen, having the maximum allowable draft, could be as follows:

[G] Overall widths greater than the minimum indicated may be desirable for some materials in order to avoid breaking in the grips.

[H] Overall lengths greater than the minimum indicated may be desirable either to avoid breaking in the grips or to satisfy special test requirements.

[I] Test marks or initial extensometer span.

[J] When self-tightening grips are used, for highly extensible polymers, the distance between grips will depend upon the types of grips used and may not be critical if maintained uniform once chosen.

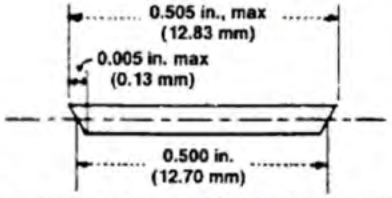


FIG. 1 Tension Test Specimens for Sheet, Plate, and Molded Plastics

Appendix E

Northwestern University Feinberg School of Medicine

FINITE ELEMENT MODELING OF LOWER LIMB PROSTHETIC SOCKETS

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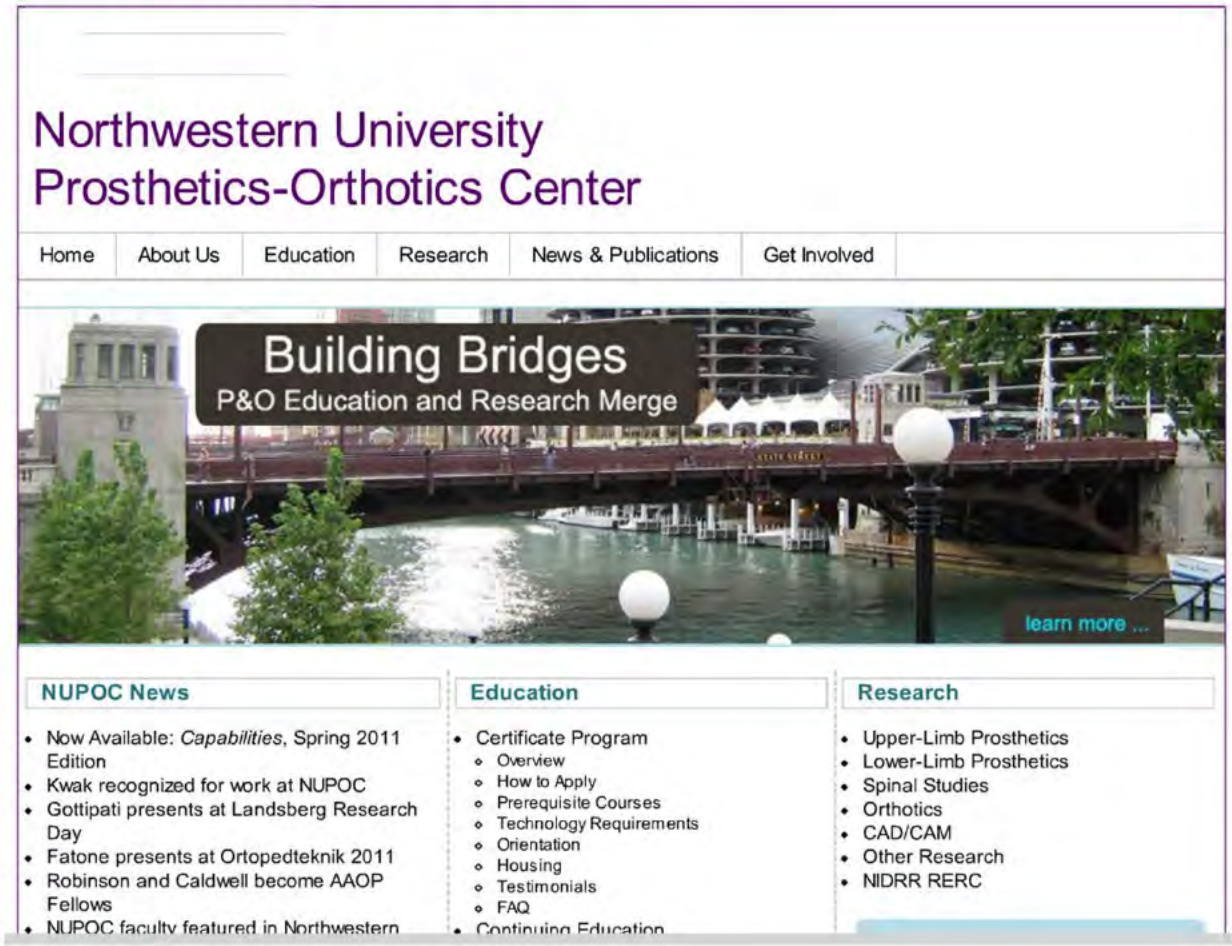
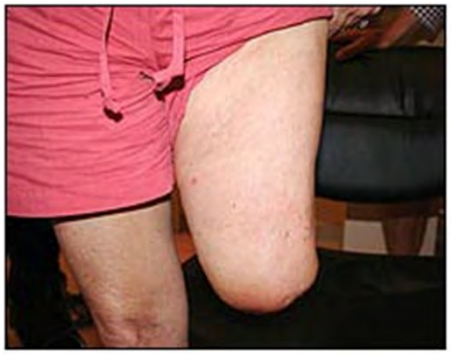
Postdoctoral fellow
Northwestern University Prosthetics-Orthotics center (NUPOC)

NORTHWESTERN UNIVERSITY
FEINBERG
SCHOOL OF MEDICINE

INTRODUCTION: NUPOC

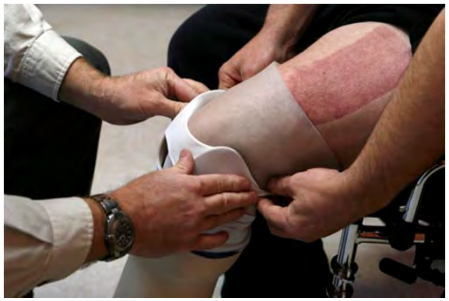


INTRODUCTION: PROSTHETICS SOCKETS



- Residual limb

- Socket modifications



- Comfort

GOAL

Current socket design

- Clinician's subjective experience
- Patient's subjective report
  - Difficult to quantify
  - Trial and error approach to fit

Numerical approach

- Analyze proposed designs for interface stress distributions
- Design socket shapes that achieve specified distributions

GOAL

Introduce the different aspects of developing FE models for prosthetic socket development and analysis by highlighting 3 independent FE studies that use the clinical problem of socket interface pressure as a primary design parameter.

OVERVIEW

Normal and shear stresses on a residual limb in a prosthetic socket during ambulation: Comparison of finite element results with experimental measurements

Joan E. Sanders, PhD and Colin H. Daly, PhD
Center for Bioengineering and Department of Mechanical Engineering, University of Washington, Seattle, WA 98195; Prosthetics Research Study, Seattle, WA 98122

Abstract—Interface stresses on a below-knee
residual limb during the stance phase of gait c

Parametric analysis using the finite element method to investigate prosthetic interface stresses for persons with trans-tibial amputation

M. Barbara Silver-Thorn, PhD and Dudley S. Childress, PhD
Marquette University, Department of Biomedical Engineering, Milwaukee, WI 53201-1881; Northwestern University, Prosthetics Research Laboratory, Chicago, IL 60611-4496

Abstract—A finite element (FE) model of the
residual limb and prosthetic socket was created to
the effects of parameter variations on the inte
distribution during static stance. This model was
geometric approximations of anthropometric re
geometry. The model was not specific to an indi
amputation, but could be scaled to approximate t
particular subject. Parametric analyses were co
investigate the effects of prosthetic socket design
limb geometry on the residual limb/prosthetic sock
stresses. Behavioral trends were illustrated vi

Development of a non-linear finite element modelling of the below-knee prosthetic socket interface

M. Zhang, M. Lord, A. R. Turner-Smith and V. C. Roberts

Centre of Rehabilitation Engineering, Department of Medical Engineering & Physics, King's College School of Medicine & Dentistry, Denmark Hill, London SE5 9RS, UK

Received 2 June 1994, accepted 7 December 1994

ABSTRACT

A non-linear finite element model has been established to predict the pressure and shear stress distribution at limb–socket interface in below-knee amputees with consideration of the skin–liner interface friction and slip. In model, the limb tissue and socket liner were respectively meshed into 954 and 450 three-dimensional eight-n isoparametric brick elements, based on measurements of an individual's amputated limb surface; the bone was mes

COMPLETELY GLUED INTERFACE: BACKGROUND

J.E. Sanders, C.H. Daly, "Normal and shear stresses on a residual limb in a prosthetic socket during ambulation: Comparison of finite element results with experimental measurement," J.Rehab. Res. Develop., vol. 30, no. 2, pp. 191-204, 199

Background

- **Goal:** Predict interface stresses *during ambulation*
- **Previous work:** Investigated "standing support."
- **Rationale:** "Ambulation induced interface stresses are of primary clinical interest because tissue breakdown and the subsequent functional impairment occur more often as a result of ambulation than from standing."
- Trans-tibial (below knee) PTB socket
- Simplifying model assumptions
  - Quasi-static
  - Linear superposition of model results to different load vectors
- Model results are compared to experimental results

COMPLETELY GLUED INTERFACE: METHODS

EXPERIMENT

- 3 shank-socket alignment settings
  - Plantar-flexion (12°)
  - Zero
  - Dorsi-flexion (4°)
- Patient Details
  - Unilateral BK amputee (4 years)
  - 23years, 178cm, 65.9kg
  - Amputation due to trauma
  - PTB (Patellar tendon bearing)
  - Latex sleeve suspension
- Subjects walked to a metronome cadence
- Boundary conditions
  - Instrumented pylon (20 strain-gages)
    - Shank forces (axial and shear)
    - Moments (bending and torsional)
  - 4 X,Y,Z transducers (diaphragm strain gages)
    - A-M proximal, A-L proximal, A-L distal, ***P- proximal***.
    - A-M proximal, A-L proximal, A-L distal, ***P-distal***

COMPLETELY GLUED INTERFACE: METHODS

FE MODEL

- Geometry acquisition
  - MRI acquisition resolution
    - Axial (10mm)
    - Coronal plane (12mm)
    - In plane (1mm)
- Mesh elements (795 nodes, 840 elements)
  - Skin, fat, muscle, liner(8 node iso-parametric block)
  - Socket (Quad. shell)
  - Shank (Beam)
- Material properties
  - Literature values
  - Linear, homogeneous, isotropic
- Loading/B.C.'s
  - Model extended beyond proximal end of socket (avoid end effects)
  - Proximal end is fixed
  - Loading applied to distal end
  - Unit loads for 6 shank forces and moment directions
- Contact
  - Totally glued interface

COMPLETELY GLUED INTERFACE: SELECT RESULTS

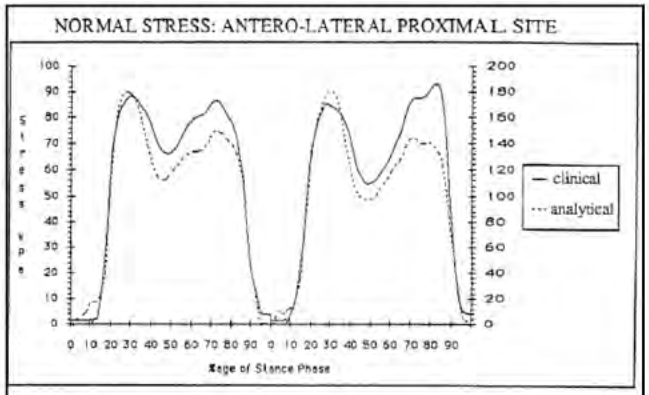


Figure 6.
Normal stress at an antero-lateral proximal site during stance phase of two consecutive steps at a plantarflexion alignment setting are shown. Stance phase between the steps has been removed for clarity. The left scale is for clinical data (solid line) and the right scale is for analytical data (dashed line).

Table 2.
Comparison of analytical results with experimental data: 'under X%' = underestimated by X%; 'over Y%' = overestimated by Y%.

NORMAL STRESS

	site				
alignment	**postero-proximal**	**antero-medial proximal**	**antero-lateral proximal**	**antero-lateral distal**	**postero-distal**
plantarflexion	under 90%	over 49%	over 95%	over 550%	under 16%
zero	under 89%	under 29%	over 63%	over 221%	under 25%
dorsiflexion	under 86%	under 83%	over 52%	over 197%	under 19%

RESULTANT SHEAR STRESS

	site				
alignment	**postero-proximal**	**antero-medial proximal**	**antero-lateral proximal**	**antero-lateral distal**	**postero-distal**
plantarflexion	under 82%	under 19%	under 49%	under 51%	under 44%
zero	under 87%	under 11%	under 53%	under 74%	under 51%
dorsiflexion	under 88%	under 1%	under 57%	under 75%	under 54%

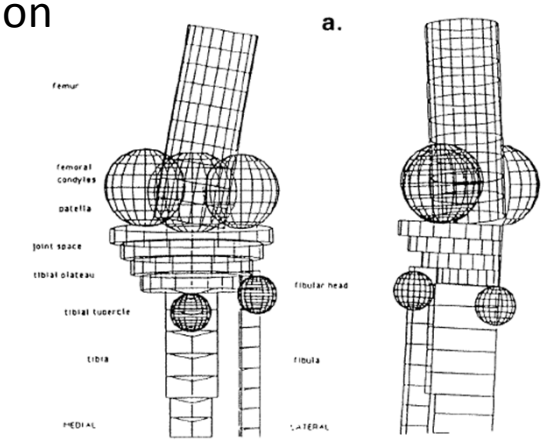
Sources of error

- Slip/Loss of contact
  - Elements in tension reduced resultant shear stresses across interface
- Pre-stress error
  - Assumption of total contact and zero pre-stress

PARTIALLY GLUED INTERFACE

M.B. Silver-Thorn and D.S. Childress, "Parametric analysis using the finite element method to investigate prosthetic interface stresses for persons with trans-tibial amputation," J. Rehab. Res. Develop., vol. 33, no. 3, pp. 227-238, 1996

- **Goal:** Investigate the influence of prosthetic design parameters and residual limb geometry on the interface stress distribution
- Geometry
  - Geometric shapes
    - Femur (cylindrical shapes)
    - Condyles (spheres)
    - Tibial shaft (tapered prism)



- Parameters
  - Socket stiffness, liner stiffness, socket rectification (rectified and un-rectified)
  - Limb surface shape/taper, limb length, bulk tissue stiffness
- Contact (i.e. Loss of contact)
  - Iterative "release" of elements in tension normal to interface
  - Repeat analysis with new B.C.

SLIP MODELED AT INTERFACE: INTRODUCTION

M. Zhang, M. Lord, A. R. Turner-Smith, and V.C. Roberts, "Development of a nonlinear finite element modeling of the below-knee prosthetic socket interface," Med. Eng. Phys., vol. 17, no. 8, pp. 559-566, 1995

Background

- **Goal:** Analyze the stress distribution and the *relative slip* of the limb-socket interface
  - Incorporate frictional effects at the interface
  - Nonlinearities due to large deformations
- Trans-tibial (below knee) PTB socket
- Numerical analysis. No experimental validation

Methods

- Geometry
  - Generated radii of points (CASD software)
    - Points at axial intervals of 6.35 mm
    - Angular intervals of 10°
- Material Properties
  - Tissues/liner – linear, isotropic, homogeneous
  - Pelite liner (380kPa)
  - Bone (10MPa)
  - Non-uniform distribution of soft tissue moduli
    - Patellar tendon (260kPa)
    - Popliteal depression, anteromedial tibia(160kPa)

SLIP MODELED AT INTERFACE: METHODS

- Mesh (2421 nodes, 1854 elements)
  - Limb tissues/liner – 8-node brick elements
  - Bone – 6-node triangular prism elements
- Contact
  - Internal friction/slip – 450 interface elements
    - Skin/liner contact – No slip
    - Shear stress > friction limit – Slip
- Loading/B.C
  - Socket – Rigid boundary
  - Distal end of the socket/liner – Free
  - Proximal end – Free
  - Loading analysis
    - Pre-stress: Free limb state to donned (radial displacements to nodes on external surface of liner)
    - Purely axial load to proximal end of bone
      (μ = 0, 0.25, 0.5, 0.75)

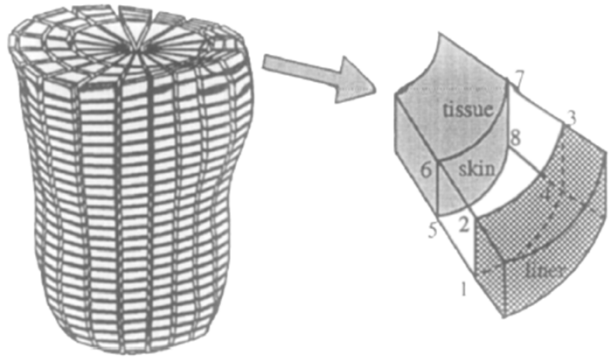
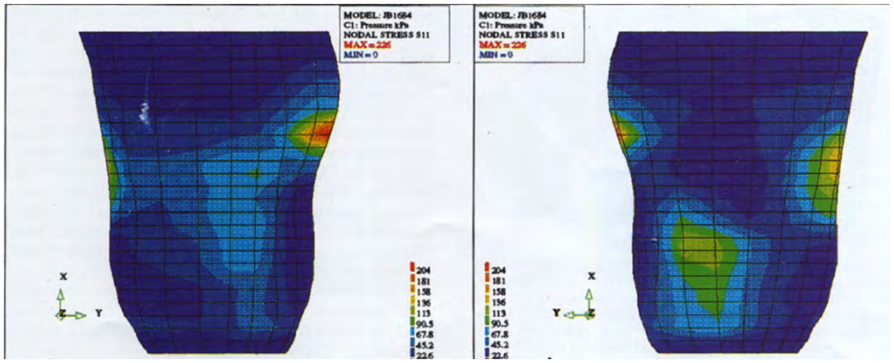


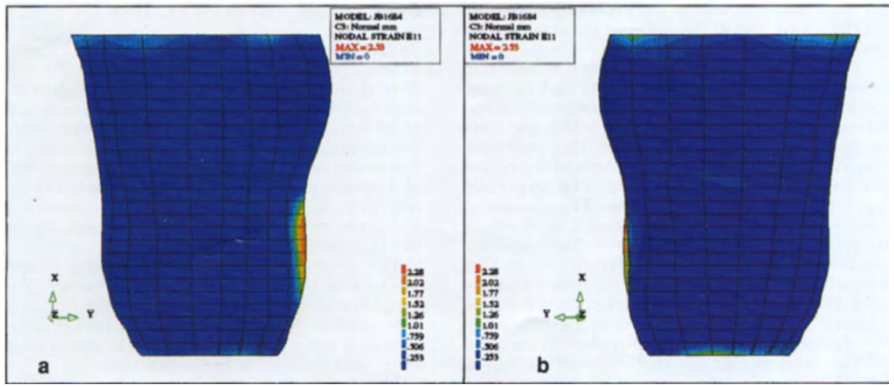
Figure 2 (a) Mesh structure. The 6-node triangular prism elements in the centre represent the bone; the middle two layers of 8-node brick elements are the soft tissue and outer layer of elements is the liner; (b) Interface element consisted of node 1–8. Node 1–4 is on the inner surface of the liner and node 5–8 is on the limb skin. When the skin contacts with liner, the thickness of interface element is zero

$$F_{\max} = \quad \cdot N$$

SLIP MODELED AT INTERFACE: RESULTS



Top: Medial and lateral views of the interface pressures



Bottom: The medial and lateral views of separation amount between skin and liner

- No experimental measures to validate slip
- Does not consider slip at socket wall-liner interface
- Larger slip occurs in lower pressure region
- Non-slip model overestimates the shear stress and underestimates pressures
- Non friction model ignores shear stresses and overestimates pressure

SUMMARY

- Important/variable components of a FE model
  - Geometry – Digitization
  - Mesh
    - Mesh quality
    - Choice of elements
    - Number of elements
  - Material properties – Linearity
  - Boundary Conditions
  - Contact
  - Loading
  - Validation

<u>THE NUPOC SOCKET</u>

- Trans-femoral socket
- Multi-layered socket
- Liner/socket is under vacuum
- Subject to significantly higher loads

Geometry

NUPOC

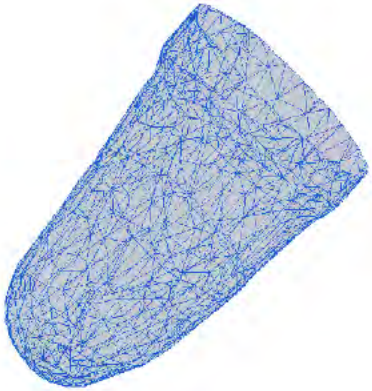
NORTHWESTERN UNIVERSITY
FEINBERG
SCHOOL OF MEDICINE

GEOMETRY ACQUISITION: DIGITIZING

GEOMETRY ACQUISITION: EXTRACTING FRAME

GEOMETRY: PROCESSING (SOLID-WORKS)

Raw



Decimated/cleaned

Surface

Thickened

THANK YOU!

??

Appendix F

EXPERIMENTAL PROTOCOL FOR BENCH-TOP SIMULATIONS OF TRANSFEMORAL SUB-ISCHIAL PROSTHETIC SOCKET LOADING

Oluseeni Komolafe, PhD.
Northwestern University Prosthetic-Orthotics Center
May 23, 2011

Purpose:
To measure the interface stresses between a silicon transfemoral residual limb phantom and a sub-ischial prosthetic transfemoral socket in a simulated single stance load state. The experimental stress values are to be used for validation of a finite element model of the transfemoral sub-ischial prosthetic socket. (*Satisfies* **task 2c** *of DoD grant W81XWH-10-1-0744)*

Equipment and Materials:
- Intelligent Prosthetic Endoskeletal Component System (IPECS)
- Novel Pliance system
- trublu® calibration device
- Loading system: Servo-hydraulic loading system (MTS™)
- Silicon femoral residual limb
- Stopwatch (HR:MM:SS)

Protocol:

Part A: Obtain human subject loading data

1. Calibrate sensors (trublu® calibration device)
2. Attach sensors to the subject's residual limb (see figure 1)
   Placement
   A – Distal lateral
   B – Proximal medial
   C – Distal anterior
   D – Straight distal
   E – Posterior/medial/proximal (in range of IT)
3. Outfit subject with liner, socket and IPECS device
4. Perform the following tests while recording loading data from IPECS device

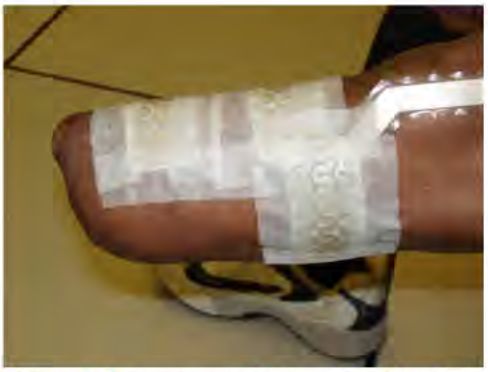


Figure 1: Sensors attached to a residual limb using Tegaderm

	Duration	Number of Trials
a. Quiet standing (double limb support)	10 seconds (@ I kHz acquisition)	2
b. Walking at self-selected pace	2 passes on force-plate array	2

Part B: Correlate MTS load cell measurements to IPECS load readings

5. Attach sensors to limb phantom using placements from Part A, step 2
6. Setup the instrumented phantom system and IPECS in the MTS (see figure 2)
7. Configure the MTS for a 'load controlled,' ramp loading option (i.e. "strain" mode)
8. Apply loads in 10 load unit increments (IPECS weight limit – 275lbs)
   - Monitor IPECS loads. Terminate test at maximum reading from Part A

Figure 2: The limb phantom and socket system setup in the mechanical testing device

- Visually inspect limb phantom and socket for damage or excessive slippage. Terminate immediately
- Confirm sensor pressures (recommended range: 20 – 600 kPa). Terminate protocol if maximum pressure exceeds 550 kPa
- Record data in table 2
    i. Use linear regression to relate MTS load to IPECS load
    ii. Use linear regression to relate MTS displacement to IPECS load (provides the option for displacement control testing)

	MTS		IPECS	PLIANCE
Time	Displacement	Load	Load	Pressure

Part C: Testing

9. Setup MTS for 'displacement controlled' loading option (i.e. "stroke" mode)
10. Activate Pliance system
11. Apply a 'ramp and hold' load. Ramp from a 'zero' baseline load to maximum IPECS load.
    - RAMP – 3 seconds
    - HOLD – 8 seconds
    - Repeat 3x
12. Unload system

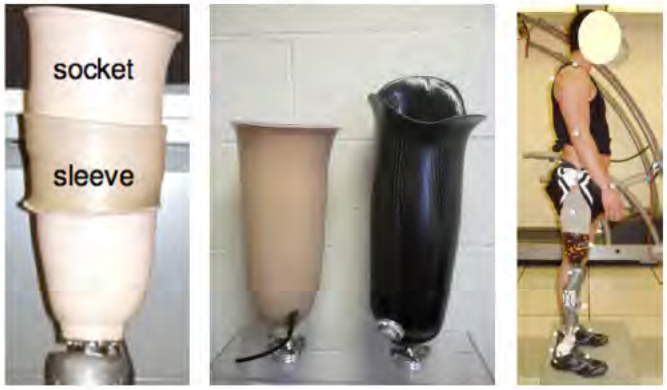
Appendix G

Test Subject #1

Profile: 29 y/o male, K4, construction worker, snow boarder, runner, weight lifter

Sockets

Rigid Single Wall Socket



Prior to participation in this project, the subject had worn a variety of subischial socket systems during the previous 4 years, including a rigid single wall socket system and more flexible double wall socket systems (see next slide) with some success. The success of the system was limited by the durability of the seal with silicone liner life limited to 4-6 months with minor adjustments or temporary patches to increase liner life. The socket on the left was one of several versions of a rigid socket worn by this subject. The subject was evaluated in the gait lab with this socket system. Black ischial containment socket shown for comparison.

Rigid Double Wall Socket

The double wall socket improved upon the single wall system by utilizing a silicone inner socket that increased friction through texturing. This design improved comfort by removing portions of the rigid lamination to allow the user to sit on a soft surface. Sleeve/liner wear did not increase, and the point of breakdown moved from the socket brim to the transition point between the rigid lamination and the inner socket.

Polytol Socket with 'ladle frame'

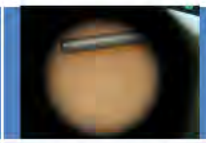
During preparation of the application for this grant, an initial polytol socket was fabricated with the assistance of Otto Bock (manufacturers of the polytol material). Socket included a carbon fiber "ladle frame". The subject wore an off-the-shelf silicone liner (Origin Liner by Evolution Industries, Orlando FL) and used an above-knee sealing sleeve (Ohio Willow Wood, Mt. Sterling OH). The subject wore this version of the socket almost exclusively for a year and a half prior to failure of the socket in a snowboarding incident that torqued the socket close to 180 degrees on the subject's limb and broke the pylon torsion adapter. The subject was not injured. Using this system, the subject commented that when he carried extreme loads like bags of concrete on his shoulder, he could feel the socket wobble and deform under heavy weight.

Polytol Socket with 'H' frame

A second polytol socket was fabricated with a different frame design ("H" frame). The frame was constructed out of polypropylene which reduced the fabrication time by 3 hours and costs significantly less due to elimination of expensive carbon fiber and Kevlar. The subject commented that this frame felt more sturdy when carrying concrete bags and while kneeling and leaning back on the socket.

Liners and Seals

Current and New Transfemoral Liners

Liner Viewed under Microscope			
Name/ Manufacturer	Origin Cushion Liner/ Evolution Industries, Orlando FL	Proseal Liner/ Otto Bock, Minneapolis MN	Relax Cushion/ Medi USA, Whitsett NC
Liner Profile	13mm - Distal End, gradual taper to 6mm - Mid level 3mm – Proximal Round shape of distal end	10mm – Distal end, abrupt taper to 3mm mid and proximal levels Round shape of distal end	14mm – distal end, gradual taper to 7mm – mid level 2.4mm – Proximal Umbrella shape of distal end
Special Feature	Tackiness through uncured silicone, custom available, uncovered	Textured inner surface, custom not available, uncovered	Textured distal half with textile, custom not available, covered

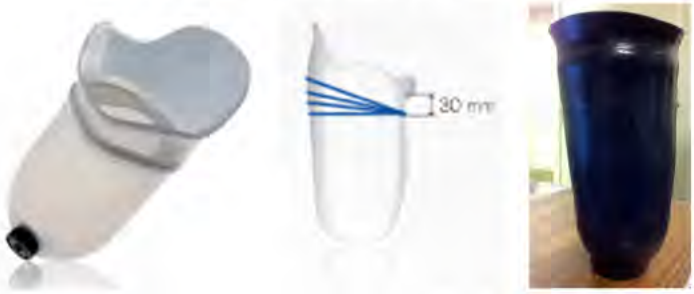
Aura Sealing Sheath

Breakdown of the liner can be an issue when it is reflected over the brim of the socket. Additionally, reflecting the liner over the edge of the socket can in some cases introduce air between the liner and the skin causing a loss of coupling. Sealing the liner to the inner wall of the socket would eliminate both of these issues. The Aura sealing sheath (Evolution Industries, Orlando FL) is a nylon that is injected with silicone on both sides of the sheath creating a seal with a flange that extends outwards from the sheath. Our subject tested the Aura sheath for a week with a socket built to accommodate it. The subject experienced a line of water blisters along the sealing ring and described a strangling sensation of his limb. He indicated that he preferred when more of his limb was under vacuum than just the distal half as is the case with this sheath.

Symmetry-Sealing Liner

Our subject was fit with a Symmetry Liner (Symmetry Prosthetics, Dothan AL) which has a silicone skirt on the distal 1/2 of the liner that seals on the internal wall of the socket with the use of a short air-wick sock. During fitting, the subject commented that he could feel the excessive silicone buildup on the distal end and had difficulty donning the liner. The subject described the liner as being very bouncy and less supportive than the liners previously used. The subject commented that it didn't feel as though the vacuum was spread over the entire limb. The silicone used in this liner is very soft and does not provide sufficient compression for use with our system.

Pro-Seal System

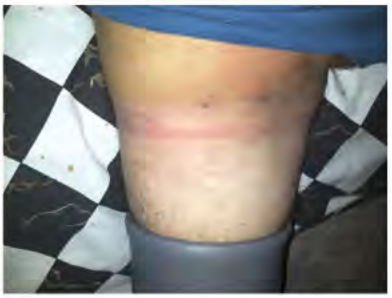


Subject was fit with a ProSeal system (Otto Bock, Minneapolis MN) with the silicone liner and sealing ring in a check socket. The transition in thickness of the ProSeal liner is very abrupt from 12mm distally to 3mm proximally. The subject immediately reported an inability to tolerate the socket pressure due to lack of silicone where the liner thinned out. The subject was then fit with an Origin silicone liner (Evolution Industries, Orlando FL) with the ProSeal ring in a check socket. This system was was initially better tolerated and so a definitive polytol socket was made. While wearing the this system, the subject observed that there was too much tension on the tissue and a ring mark was visible on the subject's limb when the system was doffed. The subject described having to push past the ring the entire length of the limb before it seated into the socket. This caused the tissue to stretch proximally as the patient stood into the socket even with use of a donning aid like water and alcohol. This tension caused bunching of tissue proximally that wasn't able to enter the socket causing problems with the socket trimlines. Over time this led to significant discomfort to the point where the patient tore the ring out of the socket and terminated the nylon air wick distal to the ring groove to continue wearing the prosthesis over the weekend before the socket could be replaced.

Medi Relax Liner

The subject was fit with a Medi Relax Cushion Liner (Medi USA, Whitsett NC). This liner is unique in that it has textile on the interior distal half of the liner which may improve suspension through increased friction from the additional texturing. However, custom versions of these liners are not available. While wearing this liner, the subject noted that the proximal portion of the liner was very snug and secure on the limb. The subject stated that this liner "grabbed" more securely on the distal half of the residual limb. The subject also noted a reduction in perspiration between the liner and residual limb. This liner has an umbrella shape which requires the wearer to don the liner the same way every time. To date, the subject prefers this liner to all previous liners.

Secure Ring on Relax Liner



The Secure Rings (Engineered Silicone Products, Newton NJ) are glued to the outer surface of any liner and come in different sizes and thicknesses to accommodate any size residual limb. They offer flexibility with regards location and orientation of the seal. Our subject was fit with a 2mm thick secure ring to seal the covered Relax Liner on the inside of the socket. The subject wore this liner for a week and each day a ring mark was left on the skin where the secure ring terminated distally on the limb. The subject noted that the pump ran more frequently with the secure ring than when he wore a reflected exterior sleeve.

Appendix H

Subject 1

Gait analysis in sub-ischial polytol socket with ladle frame

MotionAnalysis

Aggregate Temporal/Spatial Data

Patient Name:		Measure:	Spatial_Temporal
I.D. #		File Name:	LL_WN9.XLS
Test Date:	2/16/11	Norm File:	21.nrm

Comment:

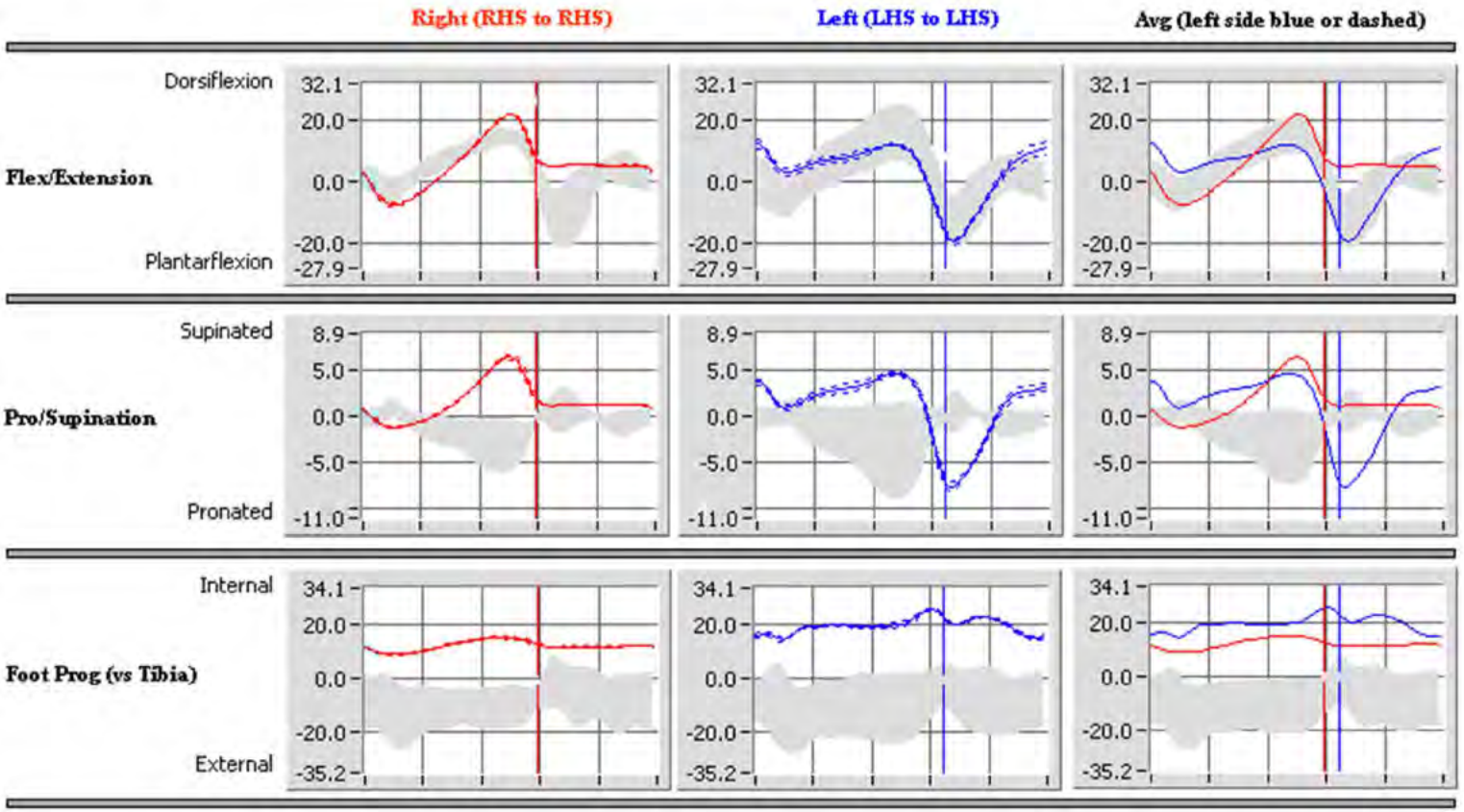
	Right Side Measures				Left Side Measures		
				Normal			
Step Length Avg (cm)	83.64			64.88	72.47		
Standard Deviation	1.45			7.60	1.62		
Number of Steps	6.00			10.00	5.00		
Stride Length Avg (cm)	155.75			129.82	155.33		
Standard Deviation	1.19			15.05	2.16		
Number of Strides	5.00			10.00	3.00		
Forward Velocity Avg (cm/s)	152.63			118.34	155.98		
Standard Deviation	2.97			17.83	6.02		
Number of Strides	5.00			10.00	3.00		
Cadence Avg (steps/min)	118.06			109.46	120.09		
Standard Deviation	1.75			8.52	3.27		
Number of Steps	5.00			10.00	3.00		
Total Support Time (%)	59.01			60.56	64.16		
Standard Deviation	0.76			0.87	0.30		
Number of Strides	5.00			10.00	3.00		
Swing Phase (%)	40.99			39.44	35.84		
Standard Deviation	0.76			0.87	0.30		
Number of Strides	5.00			10.00	3.00		
Initial Double Support Time (%)	11.64			10.53	10.54		
Standard Deviation	0.53			0.83	0.77		
Number of Strides	5.00			10.00	3.00		
Single Support Time (%)	35.84			39.44	40.99		
Standard Deviation	0.30			0.87	0.76		
Number of Strides	3.00			10.00	5.00		
Step Width (cm)	18.12			11.97			
Standard Deviation	0.71			3.31			
Number of Trials	3.00			10.00			

Patient Name:	
I.D. #	
Test Date:	2/16/11
Age:	28

Measure:	Ankle Joint Angles (deg)
Comment:	
File Name:	LL_WN9.XLS
Norm File:	21.nrm (+/- 2 SD)

MotionAnalysis

# of Rt Cycles:	5
# of Lt Cycles:	3

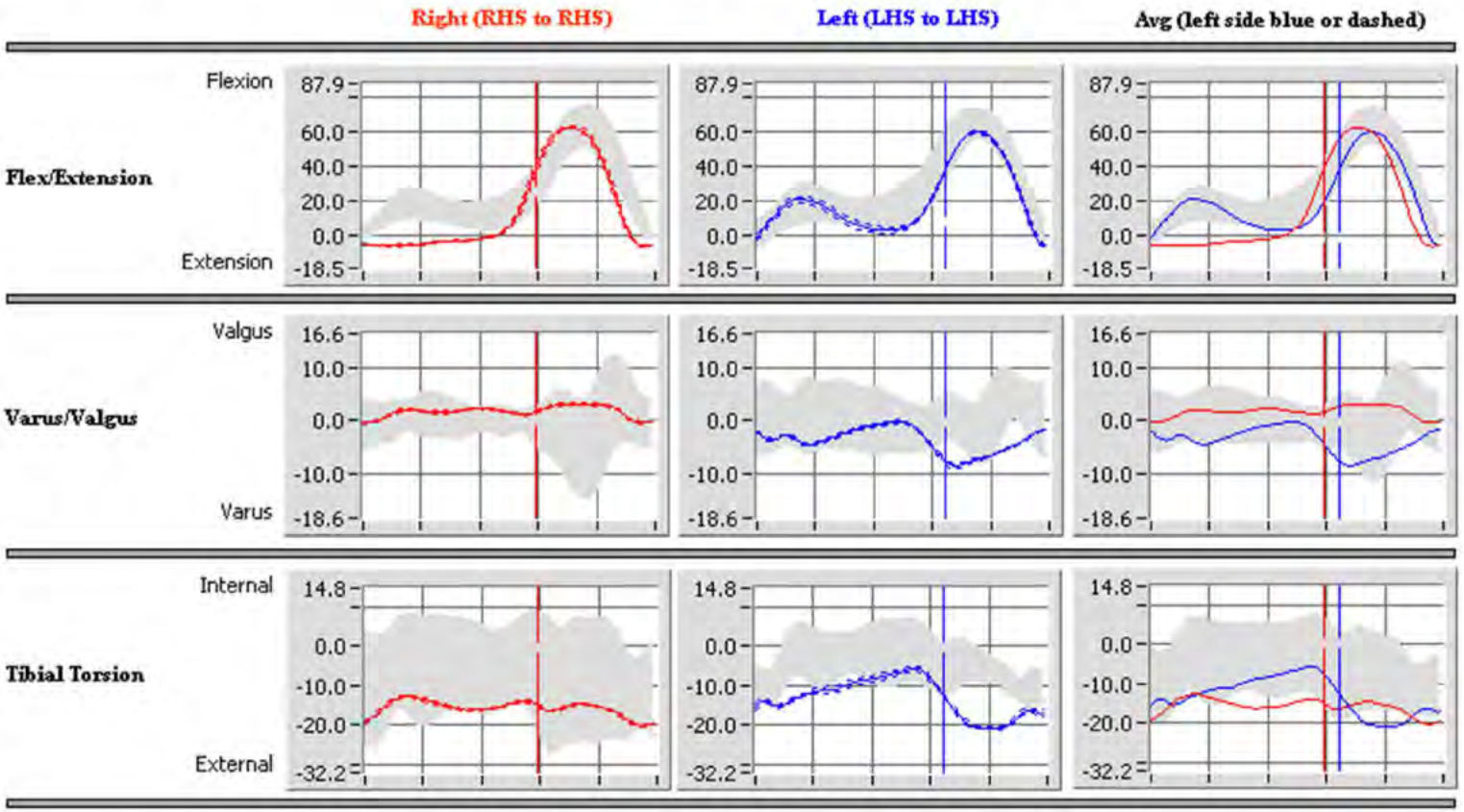


Patient Name:	
I.D. #	
Test Date:	2/16/11
Age:	28

Measure:	Knee Joint Angles (deg)
Comment:	
File Name:	LL_WN9.XLS
Norm File:	21.nrm (+/- 2 SD)

MotionAnalysis

# of Rt Cycles:	5
# of Lt Cycles:	3

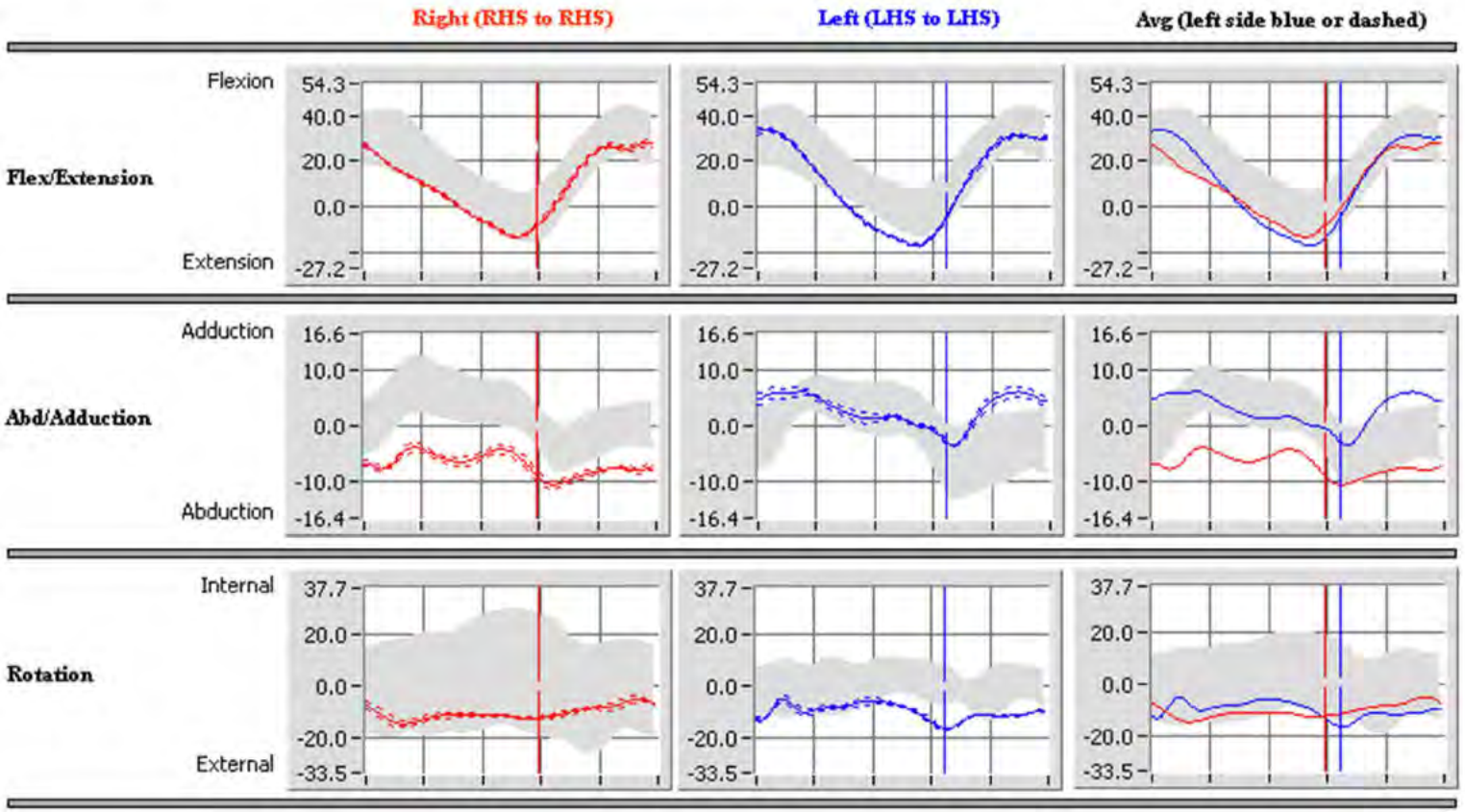


Patient Name:	
I.D. #	
Test Date:	2/16/11
Age:	28

Measure:	Hip Joint Angles (deg)
Comment:	
File Name:	LL_WN9.XLS
Norm File:	21.nrm (+/- 2 SD)

MotionAnalysis

# of Rt Cycles:	5
# of Lt Cycles:	3

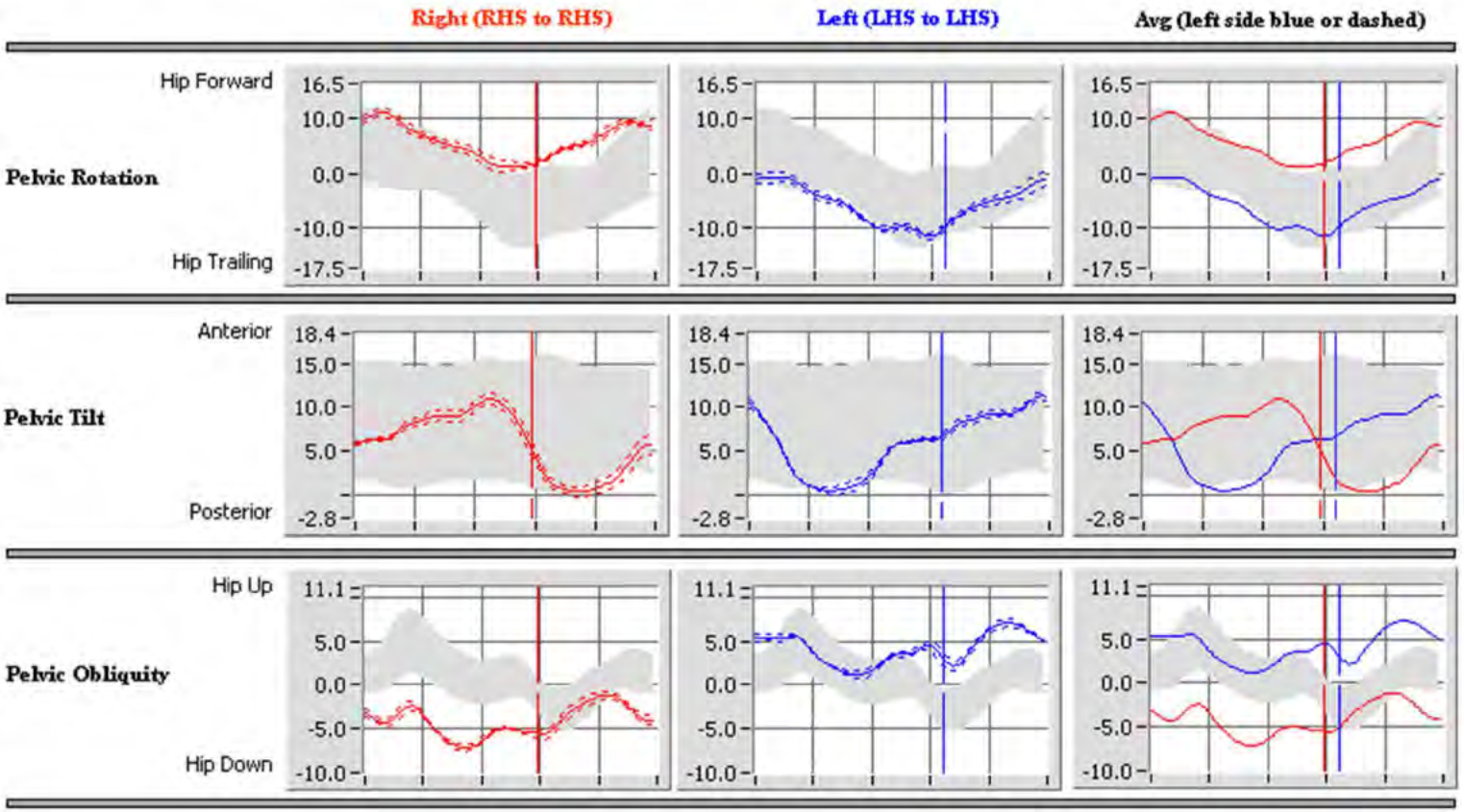


Patient Name:	
I.D. #	
Test Date:	2/16/11
Age:	28

Measure:	Pelvis Orientation Relative to Room
Comment:	
File Name:	LL_WN9.XLS
Norm File:	21.nrm (+/- 2 SD)

MotionAnalysis

# of Rt Cycles:	5
# of Lt Cycles:	3



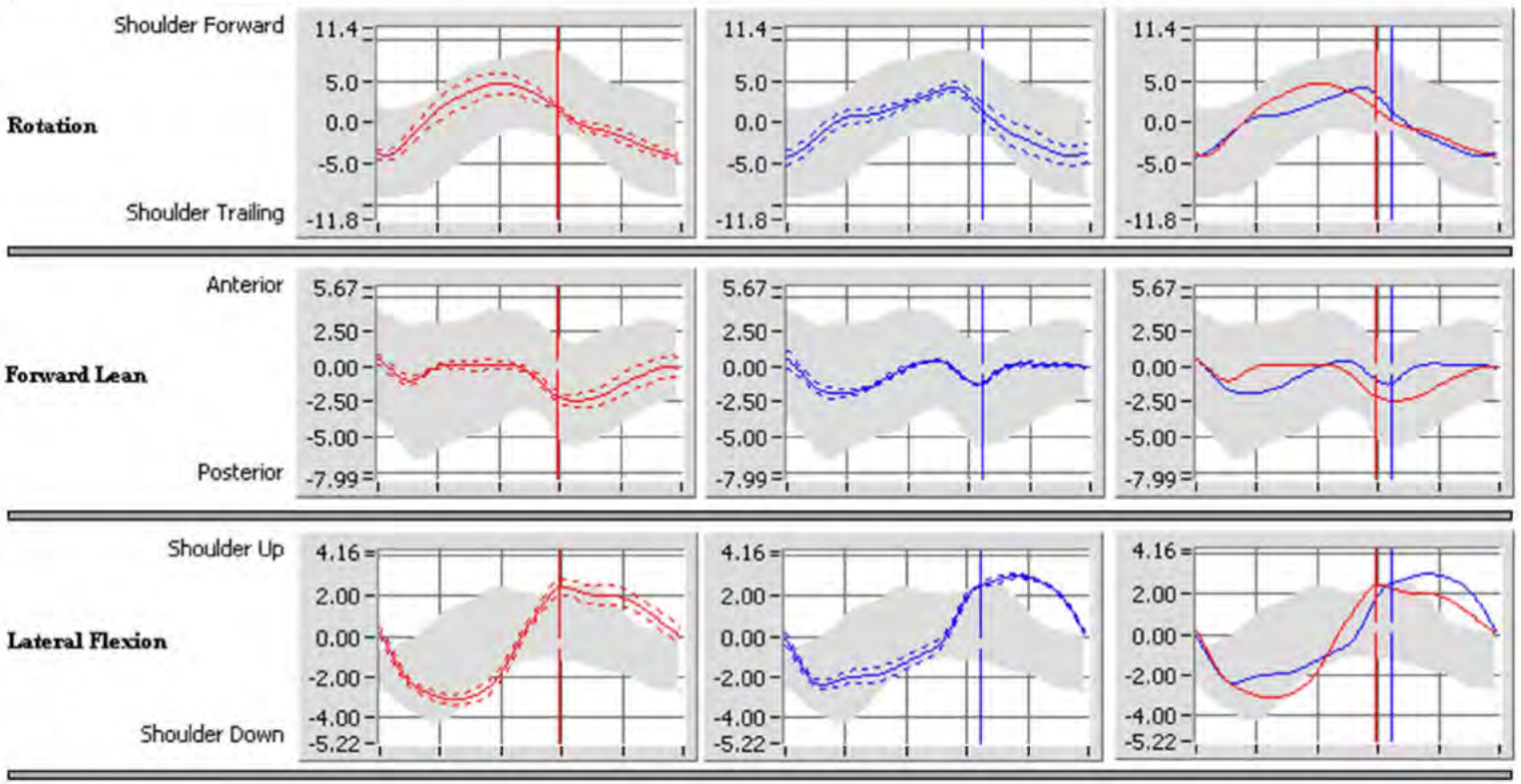
Patient Name:	
I.D. #	
Test Date:	2/16/11
Age:	28

Measure:	Trunk Orientation Relative to Room
Comment:	
File Name:	LL_WN9.XLS
Norm File:	21.nrm (+/- 2 SD)

MotionAnalysis

# of Rt Cycles:	5
# of Lt Cycles:	3

Right (RHS to RHS) **Left (LHS to LHS)** **Avg (left side blue or dashed)**

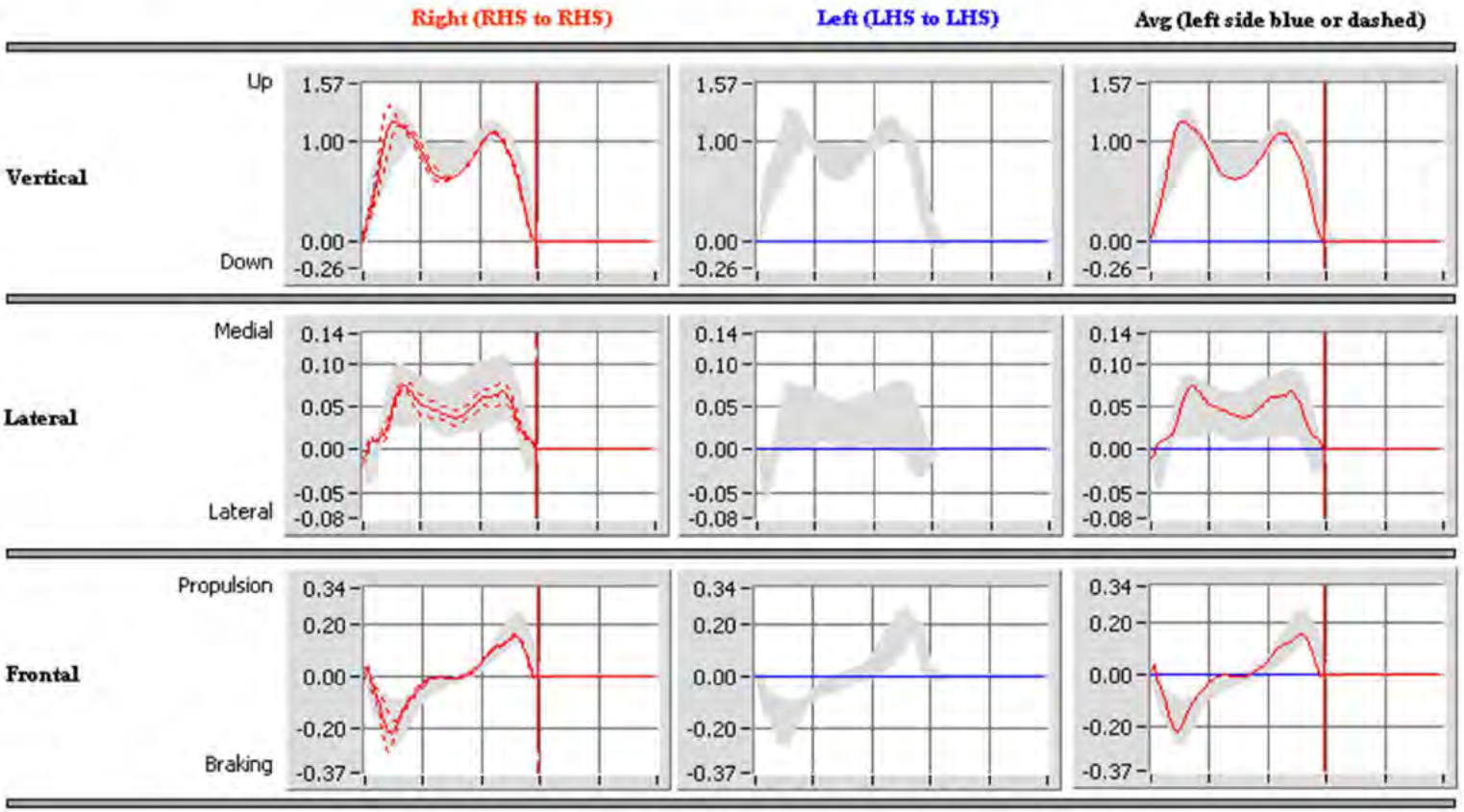


Patient Name:	
I.D. #	
Test Date:	2/16/11
Age:	28

Measure:	Ground Reaction Forces (N/kg)
Comment:	
File Name:	LL_WN9.XLS
Norm File:	21.nrm (+/- 2 SD)

MotionAnalysis

# of Rt Cycles:	4
# of Lt Cycles:	0

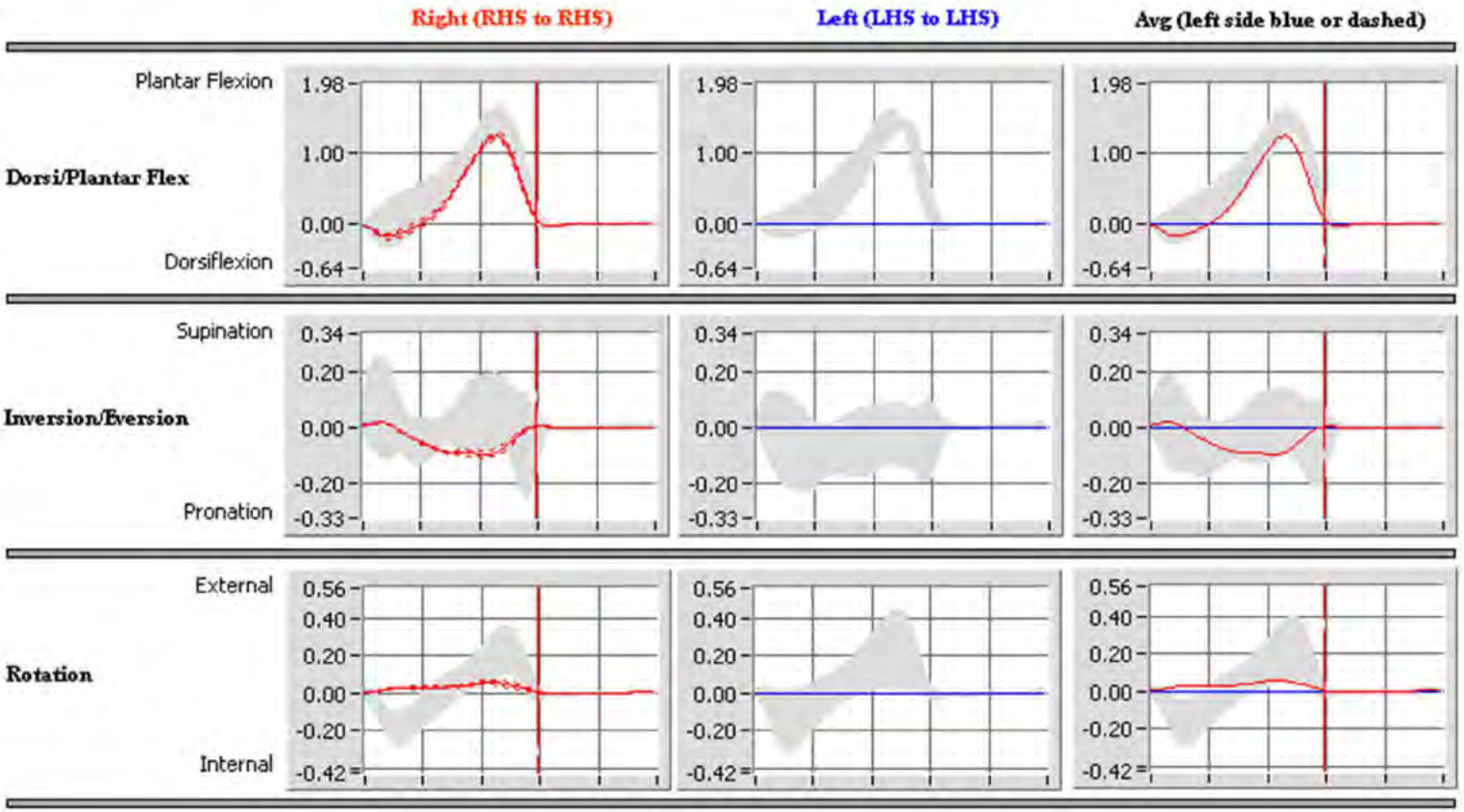


Patient Name:	
I.D. #	
Test Date:	2/16/11
Age:	28

Measure:	Ankle Joint Moments (Nm/kg)
Comment:	
File Name:	LL_WN9.XLS
Norm File:	21.nrm (+/- 2 SD)

MotionAnalysis

# of Rt Cycles:	4
# of Lt Cycles:	0

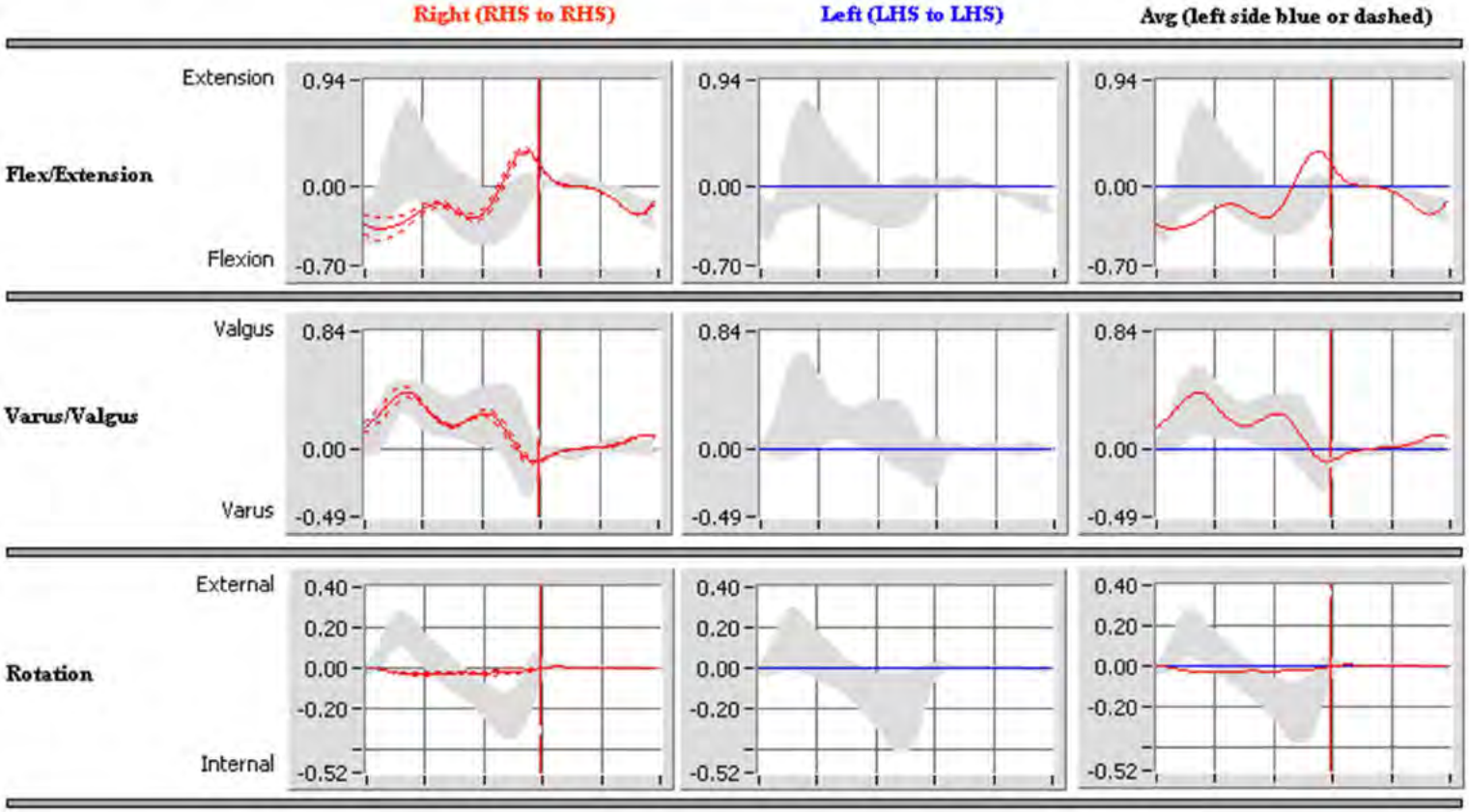


Patient Name:	
I.D. #	
Test Date:	2/16/11
Age:	28

Measure:	Knee Joint Moments (Nm/kg)
Comment:	
File Name:	LL_WN9.XLS
Norm File:	21.nm (+/- 2 SD)

MotionAnalysis

# of Rt Cycles:	4
# of Lt Cycles:	0



Patient Name:	
I.D. #	
Test Date:	2/16/11
Age:	28

Measure:	Hip Joint Moments (Nm/kg)
Comment:	
File Name:	LL_WN9.XLS
Norm File:	21.nrm (+/- 2 SD)

MotionAnalysis

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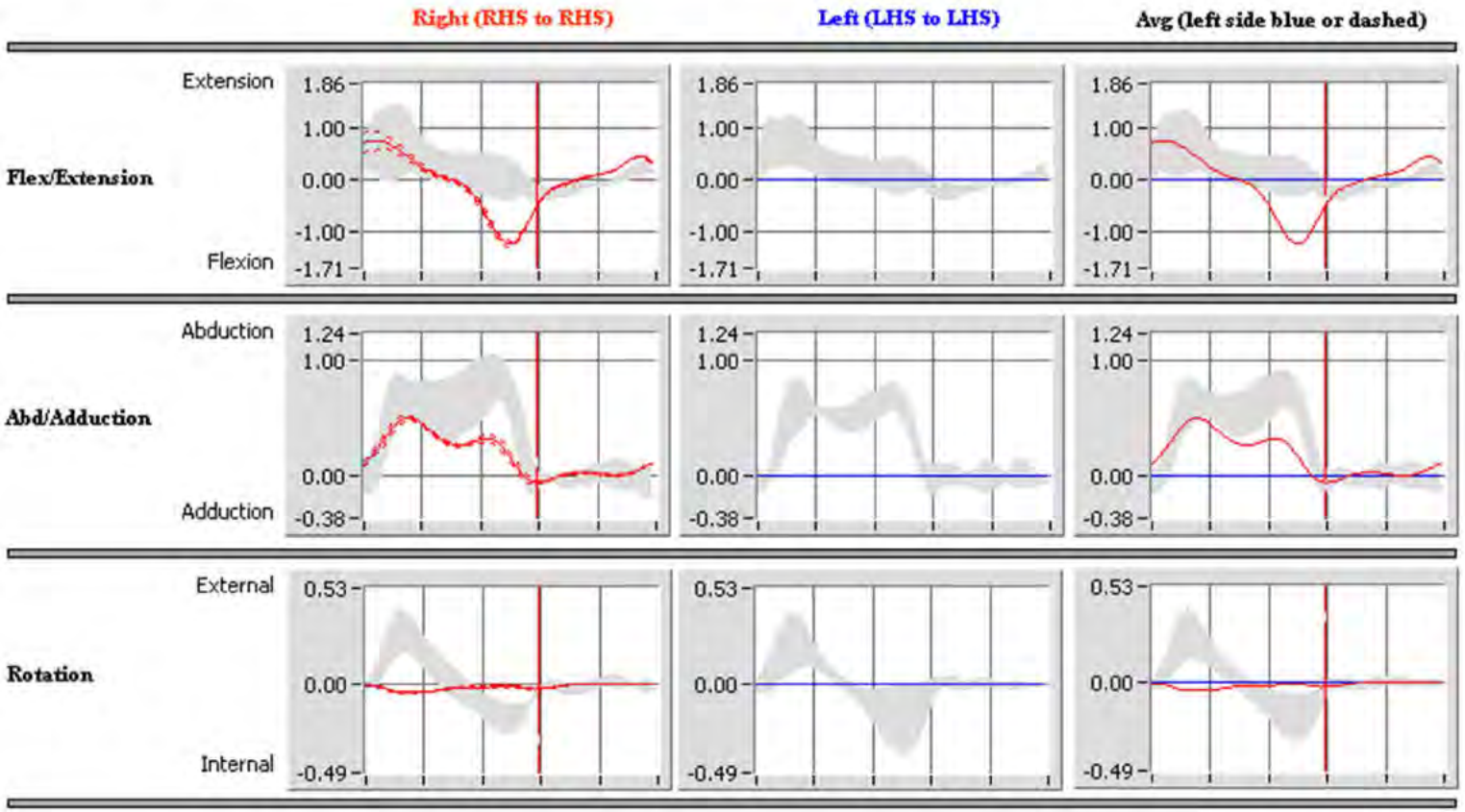
# of Lt Cycles:	0



Patient Name:	
I.D. #	
Test Date:	2/16/11
Age:	28

Measure:	Sagittal Joint Powers (Watts/kg)
Comment:	
File Name:	LL_WN9.XLS
Norm File:	21.nrm (+/- 2 SD)

MotionAnalysis

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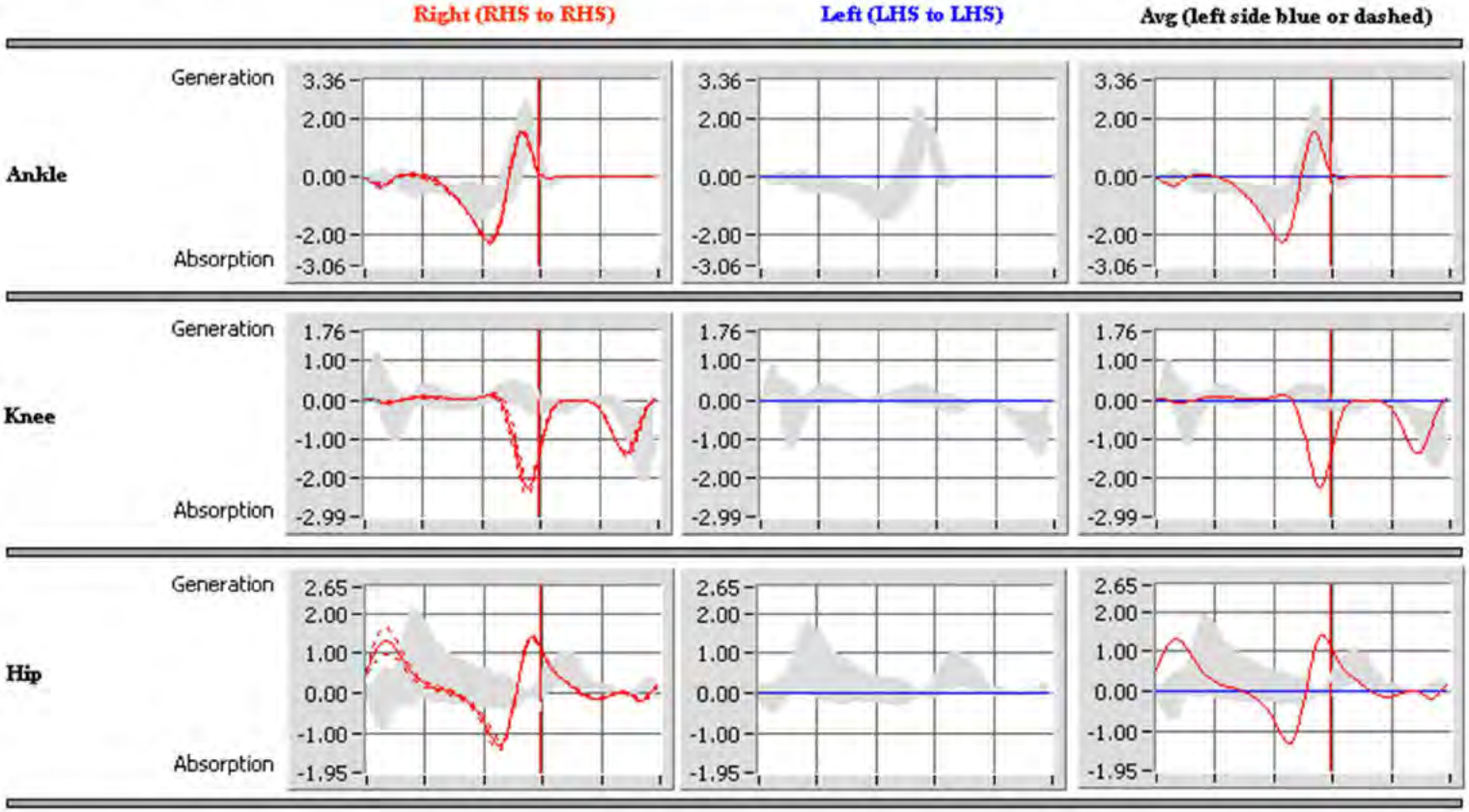
# of Lt Cycles:	0



Appendix I

NORTHWESTERN UNIVERSITY

Characterization and Design of Vacuum Pumps for Persons with Transfemoral Amputations

A DISSERTATION

SUBMITTED TO THE GRADUATE SCHOOL IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

for the degree

MASTER OF SCIENCE

Field of Mechanical Engineering

By

Sean Michael Wood

EVANSTON. ILLINOIS

August 2011

ABSTRACT

CHARACTERIZATION AND DESIGN OF VACUUM PUMPS FOR PERSONS WITH TRANSFEMORAL AMPUTATIONS

SEAN MICHAEL WOOD

Vacuum assisted suspension has become a widely accepted means of socket suspension in prosthetics. To improve this relatively new means of suspension more must be known about the pumps which create and maintain the vacuum and about the socket/liner interface in which the vacuum is created. The goal of this study is three-fold: to characterize the various vacuum pumps used for vacuum assisted suspension in lower-limb prosthetics, to use the information from characterization to determine the average volume to be evacuated for VAS as well as study the vacuum pressure within the socket/liner interface during activity, and then to use the knowledge gained in these first two studies to assist in designing a superior vacuum pump. We characterized 5 vacuum pumps (2 electric, 3 mechanical) by constructing 5 test chambers of known volume and measuring the rate of evacuation for each chamber with each pump. Through these studies it is determined that the Ohio Willow Wood LimbLogic VS is 47% more powerful than the Otto Bock Harmony e-Pulse and that the Otto Bock Harmony P3 was the most powerful mechanical pump. Using the knowledge gained from the first study the average socket/liner interface volume was determined to be 6.14 in^3. It is also discovered that the rate of vacuum pressure decay may be dependent upon the vacuum pump used, with the LimbLogic showing a decay rate 36% faster on average than the e-Pulse. With this knowledge we propose two different vacuum pump designs. The first of which is a hybrid electric/mechanical pump and the second is a biomechanical energy harvesting design which converts the energy lost during swing phase into electrical energy for use in an electric vacuum pump.

ACKNOWLEDGEMENTS

First of all I would like to thank Stefania Fatone for teaching me more than I could have thought existed about prosthetics. More importantly though she provided a ton of guidance when it came to both designing experiments properly as well as writing of my actual thesis. Her help has helped turn me into a much more competent researcher than I was before beginning this project. Another big thanks has to go to Ryan Caldwell for the unbelievable amount of help he provided during the project and helping Stef in teaching me everything I know about Prosthetics. Thanks to Steven Gard and Andrew Hansen for all of their help on the project as well.

On the McCormick side of things I owe a big thanks to Cheng Sun and Wei Chen for bringing me into this project, and just being generally extremely helpful both as advisors on my thesis as well as professors over the course of the last 5 years. No acknowledgements page would be complete without thanking Robert Taglia and Scott Simpson. The two of them have taught me more in my 5 years at Northwestern than I learned in any classroom. I literally would have gotten nothing done (or done right at least) on any project I ever worked on if it weren't for their guidance and expertise.

Last but not least I need to thank the Department of Defense (DOD) Peer Reviewed Orthopaedic Research Program Technology Development Award #W81XWH-10-1-0744 for providing the funding for all the research I performed this last year.

LIST OF ABREVIATIONS

BPM	Beats Per Minute
CP	Certified Prosthetist
DAQ	Data Acquisition
DOD	Department of Defense
IED	Improvised Explosive Device
OB	Otto Bock
OWW	Ohio Willow Wood
PWA	Persons With Amputation
PWLLA	Persons With Lower-Limb Amputation
PWTA	Persons With Transfemoral Amputation
VAS	Vacuum Assisted Suspension
VI	Virtual Interface

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CHAPTER 1: PROBLEM DESCRIPTION AND RESEARCH OBJECTIVES

The research in this dissertation is motivated by the need to better understand the workings of vacuum assisted suspension (VAS) systems which have recently become a popular form of suspension for persons with lower limb amputation. Anecdotal evidence suggests that VAS is currently the best suspension for use by highly active individuals. The Department of Defense provided funding for this project in the hope that VAS may allow soldiers with transfemoral amputations to return to the field at activity levels similar to those before their amputation. However, much still remains to be learned about the interactions between limb, liner, socket, and the vacuum pump which creates and maintains the vacuum between socket and liner. Specifically, there has been little research performed into the functioning of the currently available pumps on the market or how the vacuum they create between the users socket and liner is maintained over time and during regular activity. The objective of this research is to:

- Show which currently available pumps are most efficient in evacuating the socket/liner interface
- Provide an estimate to the vacuum/liner interface volume
- Provide an estimate as to the rate at which vacuum pressure decays over time
- Design a pump capable of meeting the needs of military personnel

1.1 TECHNICAL BACKGROUND

Transfemoral amputation is an amputation of the lower limb through the femur, the bone which connects the knee and hip joints. This results in the loss of the two major lower limb joints: the knee and ankle. The loss of the knee joint in particular is a major factor which challenges the mobility of persons with transfemoral amputations. The current sockets on the market for amputations of this type encompass the pelvis and hip joint, therefore limiting the range of motion at the hip joint, compromising comfort. While current prosthetic technologies are reasonably serviceable for persons with amputation levels distal to the knee and for those persons with low to moderate functional levels, they provide limited functional restoration for those with more proximal amputations, especially more highly active individuals (Fatone et al., 2010).

1.1.1 RESEARCH IMPACT

There were a projected 623,000 persons living with major lower limb amputations (both transtibial and transfemoral) in the United States alone as of 2006 (Ziegler-Graham et al., 2008). Vascular disease (such as diabetes) was the cause for a majority of these amputations (54%) (Ziegler-Graham et al., 2008). As diabetes continues to grow as a problem in the US and globally, the rates of amputations from vascular disease will also continue to grow, particularly among the elderly and minority populations (Dillingham et al., 2002). This has led researchers to project that the number of persons living with major lower-limb amputations will increase to 879,000 by 2020 (Ziegler-Graham et al., 2008). This is relevant to this research since, while the research was funded by the Department of Defense for the purpose of getting soldiers with transfemoral amputations back into the field, the results will hopefully be applicable to all persons with lower limb amputations.

Military conflicts in Iraq and Afghanistan have resulted in a large number of military personnel undergoing lower-limb amputations as well. As of 2006, 132 service persons had undergone transfemoral amputations alone, largely due to Improvised Explosive Device (IED) related injuries (Stansbury et al., 2008). Based on the continued rate of casualties and IED related injuries, this number very likely increased to over 200 by 2011. These service persons with amputation present challenges that are different from the more typical older amputee with vascular problems. Individuals who enter the military are generally young and in excellent health prior to their combat-related injury. Many wounded soldiers wish to return to the level of activity they enjoyed before their injuries, including active duty. Therefore, they have much higher expectations of their function after amputation.

1.1.2 A Brief History of Lower Limb Sockets and Suspensions

There have been precious few changes in socket and suspension technology over the past 50 years. The two most common socket designs are the quadrilateral socket and the ischial

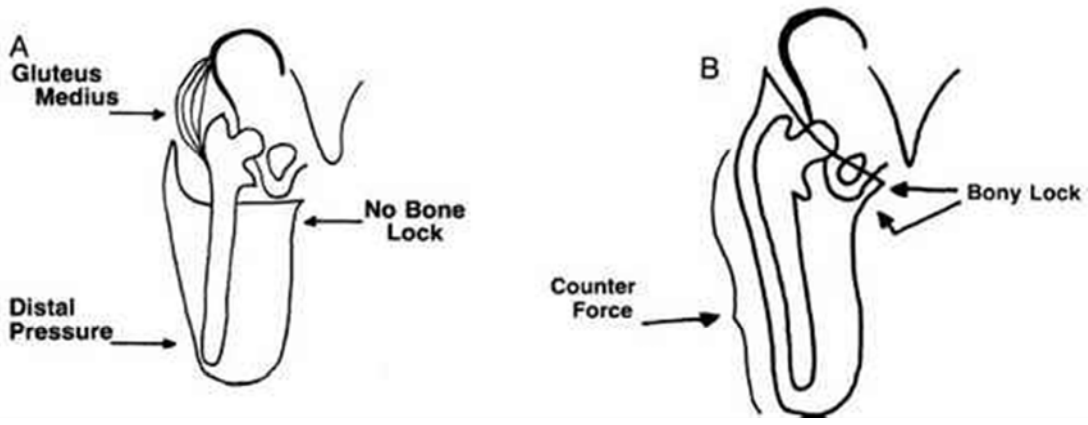

Figure 1: Drawings of the cross-section of A) a quadrilateral socket and B) an ischial containment socket. Taken from: Michael JW: Instr Course Lect 1990; 39:375.

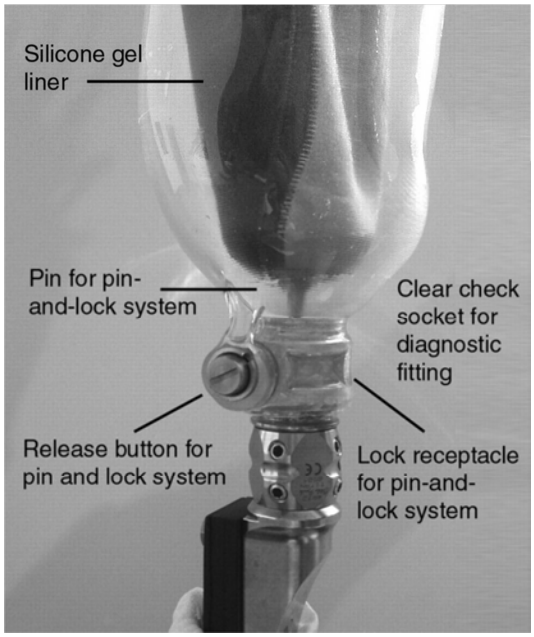

Figure 2: Shuttle lock suspension system.

containment socket (graphically pictured in Figures 1a and 1b), introduced in the 1950s and 1980s respectively (Schuch et al., 1999). While both methods have their respective advantages, the main weight bearing surface in both is the lower part of the hip bone known as the ischial tuberosity. As anyone who has sat for extended periods of time on any hard, flat surface knows, the ischial tuberosity quickly becomes uncomfortable when forced to bear weight for any length of time. This can make both the quadrilateral and ischial containment sockets slightly uncomfortable (Stewart and Spiers, 1983; Neumann et al., 2005).

One of the more dated methods of suspension is known as a Silesian belt. This method is composed of a strap or sleeve that attaches to the proximal end of the prosthesis and ascends to encircle the patient's waist. Two more recently developed methods of suspension are suction suspension and the shuttle lock system (also known as the pin-and-lock system, figure 2). The suction suspension system works by creating a negative pressure between the residual limb and the socket during swing phase, which when combined with surface tension, acts to hold the socket firmly in place (Friel, 2005). The shuttle lock system uses a gel or silicon liner with a locking pin at the bottom. The liner is rolled over the residual limb and the locking pin slides into a shuttle lock inside the socket. This method provides a total contact fit and the liner acts as an interface between the skin and socket, increasing comfort. While both of these methods provide more secure connections than the Silesian belt, there are still unwanted changes in pressure on the residual limb, which can compromise skin health. Ulcers,

epidermoid cysts, and verrucous hyperplasia are all skin conditions that are attributed to external pressures applied to the residual limb (Lyon et al., 2000).

1.1.3 Vacuum Assisted Suspension and Sub-Ischial Sockets

A relatively new form of suspension known as vacuum assisted suspension (a cross section of this suspension used on a transtibial amputation can be viewed in figure 3) was introduced in the 1990s (Patterson, 2007). Both vacuum-assisted suspension and suction suspension use a difference in atmospheric pressure to achieve suspension. However, where suction systems use the passive force of the user's weight to expel air from the system, vacuum-assisted suspension uses an active pump to create negative pressure (relative to atmospheric pressure) between a liner and socket (Fatone et al., 2010). These pumps may be mechanical, or electronic. In both systems, as air is expelled from the socket, the limb and liner are pulled toward the socket wall and held in place by the force of the negative air pressure as the vacuum is created. With suction suspension some movement of the residual limb within the socket remains, but with vacuum-assisted suspension pistoning is supposedly eliminated (Gerschutz, 2010). The socket is held securely to the leg by suction from a vacuum pump, which makes for a more secure connection between the residual limb and prosthesis.

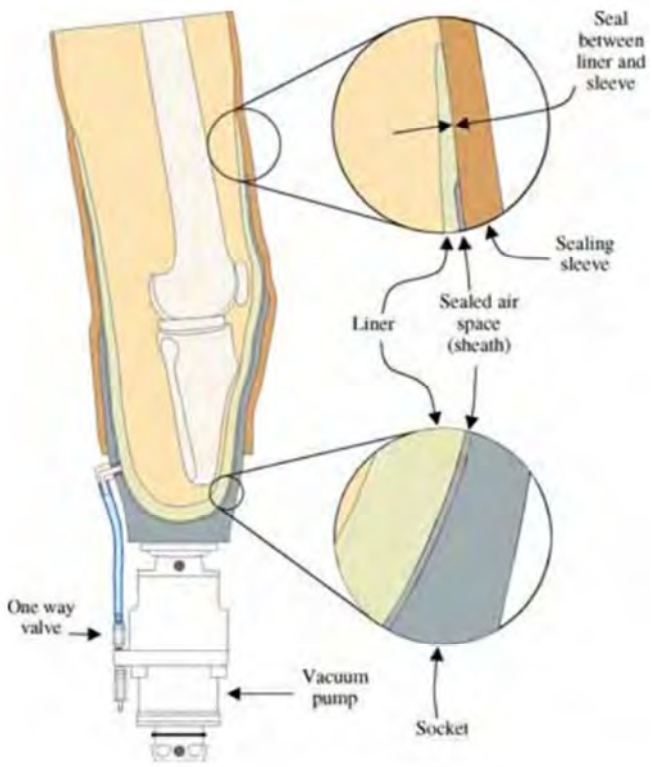

Figure 3: Cross section of vacuum suspension system. Note that the sealed air space does not extend to the thigh. The seal between the top of the liner and sealing sleeve isolates the limb from the vacuum.

The proposed advantages of vacuum assisted suspension are numerous. Researchers have reported that loss of residual limb volume typically observed after a bout of activity was reduced with the use of vacuum in trans-tibial amputees (Board et al., 2001). They also reported that there was significantly more stance phase and step length symmetry, and significantly less pistoning of the tibia and liner with use of vacuum (Board et al., 2001). A follow-up study showed that application of vacuum reduced the interface pressure differences between the stance and swing phases of walking (Beil et al., 2002). The authors suggested that this lower pressure difference was the mechanism by which limb volume was maintained with vacuum-assisted suspension. Hence, it appears that vacuum-assisted suspension may improve tissue health by minimizing the motion between the socket and residual limb that causes tissue trauma, as well as stabilizing residual limb volume by minimizing the changes in pressure that drive fluid in and out of the limb. It is thought that these effects promote increased circulation and hydration of the residual limb, creating an environment that leads to positive changes in tissue health (Brunelli et al., 2009). That being said, these studies were all performed with regards to persons with trans-tibial amputations. However, it is believed that these studies remain more or less valid when discussing persons with transfemoral amputations, which there have been far fewer studies of this type conducted.

The use of vacuum assisted suspension has allowed prosthetists to lower the trim lines of the transfemoral socket (Fairley, 2008). This lowering of the trim line below the ischial tuberosity means that the socket no longer interferes with the hip during movement, and has become known as a sub-ischial socket. Anecdotal evidence suggests that this can increase comfort, both while walking and sitting, as well as allow increased range of comfortable motion of the hip joint.

A lower trim line means that there is less total contact area between the socket and the residual limb, limiting the degree to which surface tension can securely hold the prosthesis on firmly. Additionally, while suction works passively and the socket is held on more or less securely immediately after being donned, the requirement of an active vacuum pump means that the users' mobility may be limited until that vacuum is generated. Little research has been performed with regards to the speed at which this vacuum is generated or which pumps evacuate to which levels of vacuum fastest. Additionally, there has been almost no research performed on the vacuum suspension of highly active individuals. Important questions such as:

- How is the vacuum maintained during activity?
- How does the vacuum pressure vary during activity?

Have not been studied at all. It is for these reasons that there is special interest regarding interaction between the vacuum pump and the socket/liner interface.

1.2 TASKS AND ORGANIZATION

Research Task 1 – Characterization of the Vacuum Pumps Currently Available: As mentioned previously, the vacuum can be provided by either a mechanical or electrical pump. Prosthetic companies such as Otto Bock (OB, Duderstadt Germany) and Ohio Willow Wood (OWW, Mt. Sterling, Ohio) provide several pumps specifically designed for use in prostheses. In order to characterize these pumps, this research focuses on evacuating air from chambers with known volumes in a series of bench-top tests. These volumes are representative of the air that needs to be removed from transfemoral sockets just after donning the prosthesis.

Research Task 2 – Study the Socket/Liner Interface and Pump Interaction of Users: The specific questions this task aims to answer are: What is the volume of the socket/liner interface,

and, what is the rate at which the vacuum pressure decreases during regular activity? To explore these questions a number of human subjects are recruited for testing. The first of these questions is explored by comparing the time required for evacuation in the human subjects to those obtained from the chambers of known volumes in the bench-top tests. This comparison should provide an accurate estimate of the average volume evacuated. The second question is examined by monitoring the vacuum pressure in the system while the user walks on a treadmill.

Research Task 3 – Suggest Designs for a Vacuum Pump Capable of Meeting the Military's Needs: Finally, the knowledge gained from tasks 1 and 2 are used to aid in designing a superior vacuum pump. While the use of either a mechanical or electrical pump may not matter much for the average user, this research is focused specifically on the needs of military personnel. Ideally, a pump used by the military would be purely mechanical, removing the need to charge or replace batteries, reducing noise, and improving the likelihood of the pump being serviceable in the field (Fatone et al., 2010). Although there are a number of commercially-available mechanical pumps, they are infrequently used in transfemoral prostheses as their flow rate is considered insufficient to quickly evacuate the relatively large air space present in a transfemoral socket compared to a transtibial socket. For example, the new Harmony® P3 (Otto Bock) mechanical vacuum pump specifies that up to 50 steps with the prosthesis may be needed to reach the recommended vacuum of -15 inHg (Otto Bock, Minneapolis MN, P3 User's Manual 2009). While the user's manual does not specify a level of amputation, the P3 is typically used by persons with trans-tibial amputations. The need for multiple cycles to draw sufficient vacuum delays the achievement of optimal suspension and coupling. Additionally, the large amount of vertical space required for commercially available mechanical pumps makes their use in transfemoral amputations difficult. This is because the amount of space available between the bottom of the socket and top of the knee is typically quite small. Hopefully, the

knowledge gained in our previous tests will lead us to either choose one of the commercially available pumps as adequate to fulfill the military's needs, or to guide us in the design of a hybrid electric/mechanical pump.

CHAPTER 2: ELECTRICAL AND MECHANICAL VACUUM PUMP CHARACTERIZATION

2.1 VACUUM PUMP SYSTEM BACKGROUND

As mentioned in Chapter 1, vacuum assisted suspension has the potential to increase user comfort. However, this vacuum can be achieved with a variety of different pumps. There are currently several different electric and mechanical pumps, specifically designed for use in prosthetics, available for consumers. There are a variety of reasons why one might choose one pump over another. One consideration is price: typically the mechanical pumps are a bit more expensive than the electric pumps. Another is build height: mechanical pumps (and some electric pumps) must be mounted “in-line” and therefore require there must be enough space between the residual limb and the knee (in the case of transfemoral amputees) for the pump to be placed.

The prosthetist may also be motivated by the functionality of the pump. Most mechanical pumps operate as the user walks. The weight of the user during stance phase compresses a chamber, expelling air from it. Then, as the user transfers their weight onto the other leg, the expansion of the chamber pulls air from the socket via a one-way valve. This method of evacuation requires the user be walking, and they therefore must endure a limited vacuum assisted suspension for at least some period of time after doffing. The P3 user manual suggests that a vacuum pressure of 15 inHg should be reached within 50 steps with the prosthetic leg (Otto Bock, Minneapolis MN, P3 User’s Manual 2009). The electric pumps operate with only the press of a button. A small Li-ion battery powers a DC motor which rapidly runs a very tiny

pump. Most electric pumps have control circuitry that monitors the vacuum pressure in the system and will reactivate the pump when the pressure crosses some threshold value. While this method allows for evacuation while sitting and does not require walking to maintain the vacuum, it does require that the user plug the pump into a wall outlet for several hours a day to recharge the Li-ion battery.

While it is assumed that the electric pumps are capable of evacuating the socket/liner interface at a faster rate than the mechanical pumps, there has not been any research performed to explore this. In this chapter we will study the rate of evacuation of several mechanical and electric vacuum pumps to determine the specific characteristics of each. The characteristics we determine will then be used in future chapters to both determine the average volume of the socket/liner interface of users as well as to assist in the development of a new vacuum pump. *We hypothesized that the electric pumps would outperform the mechanical pumps* based on anecdotal information provided by users.

2.2 TEST METHODS

2.2.1 EQUIPMENT, MATERIALS, AND SOFTWARE USED DURING TESTING

Under the guidance of Certified Prosthetist Ryan Caldwell 2 electric pumps and 3 mechanical pumps were purchased based on their common use in the field. These were the:

- Ohio Willow Wood LimbLogic VS (electric)
- Otto Bock Harmony e-Pulse (electric)
- Otto Bock P2 (mechanical)
- Otto Bock P3 (mechanical)
- Otto Bock HD (mechanical)

These are all pictured in Figure 4. In order to characterize these pumps a set of consistent tests was designed to compare them to one another.

Previous work performed led us to believe that the typical volume evacuated between the liner and socket in transfemoral amputees was approximately 6 in^3 (Fatone et al., 2010). With this in mind 5 chambers were manufactured with PVC tubing and end-caps (Figure 5). Volumes ranged from roughly 2 to 12 in^3, initially determined geometrically. Exact volumes were later calculated by weighing the empty chambers, then filling each with water and weighing again. The volume was then calculated based on the known density of the water.

In order to determine both the vacuum pressure and the times required to evacuation, the team purchased the DigiVac Model 2L760 digital pressure transducer (with sampling frequency of 1Hz), which was interfaced with a computer via RS232 connection. A Virtual Interface was created in National Instruments' Labview to record the evacuation profile and export it to Microsoft Excel for additional data processing.

Figure 4: The five vacuum pumps used in bench-top testing A) Ohio Willow Wood LimbLogic VS, B) Otto Bock Harmony e-Pulse, C) Otto Bock Harmony P3, and D) Otto Bock Harmony P2 and HD.

With all of our equipment set up (Figure 5) evacuations were performed with both electric pumps 5 times on each of the 5 chambers, to over 17 inHg in each test (this was the pressure threshold at which time measurements were calculated). The electrical pumps

were later tested an additional 20 times on each chamber to get a more accurate data set and to ensure that the method of averaging was accurate. Once accuracy was ensured for the electrical pumps it was deemed unnecessary to do more than the 5 tests with each mechanical pump based on an insignificant difference ($p > .05$) between the results of 20 trials vs. those of 5 trials.

2.2.2 Vacuum Pump Test Procedure

After the initial data collection it was discovered that some early assumptions that were made were false, requiring minor adjustments to the data collection process and analysis.

The first assumption to be disproven was that the electric pumps would have the same performance independent of the charge level of their Li-ion batteries. This was discovered after inconsistent times were achieved on two consecutive days with the e-Pulse. An easy solution to this problem would have been to perform all evacuations with the pump plugged in to an AC power supply to ensure consistency between tests. Unfortunately, the Otto Bock e-Pulse does not allow the pump to activate while charging (although the OWW LimbLogic does).

In order to characterize the rate at which performance decreases as the battery discharges, exhaustive testing was performed on each pump. This testing involved evacuating the 6 in^3 chamber (as this was thought to be the size typical of the socket/liner interface in a person with transfemoral amputation) repeatedly, allowing minimal time between each evacuation until the Li-ion battery was depleted. This test was performed with both pumps.

Figure 5: The test setup used for bench-top testing with the 5 test canisters in the back, digital vacuum gauge at front left and e-Pulse vacuum pump at front right.

While only 3 individual pumps were tested in the mechanical testing, the Otto Bock P3 came equipped with 5 different 'functional rings', each for a different user weight range. The P2 and HD pumps overcome the issue of user weight variation by providing an adjustable screw within the pump. For both pumps testing was performed at 4.5 turns out, intended for a patient weighing 120 lbs. This is equivalent to the weight resistance provided by the f0 functional ring of the P3.

The mechanical pumps were tested using the same canisters, digital pressure gauge, Labview Virtual Interface and evacuated to above the same pressure threshold (17 inHg) as the electric pumps. The only significant difference was the method of activation. Pump activation was performed using a fixture provided by Ryan Caldwell**.** This fixture was a simple lever action device allowing the mounting of mechanical pumps of various heights and utilizing a lever 12 inches in length to assist in manual activation (Figure 6). Activation was timed using an online metronome located at http://www.metronomeonline.com/. Timing was set at 50 beats per minute (bpm), which was determined by informal experimentation to be roughly equivalent to the number of single leg activations in a quick walk by an able-bodied male of average height.

All tests were performed with an attempt at equivalent force and always over a full stroke length for the mechanical pumps. To further limit the influence of human actuation of the lever

on our results, the tester was blinded to the specific pump being tested as well as the number of strokes elapsed until after each test was performed. Short breaks were allowed after each test to ensure that the testing arm remained 'fresh'.

Figure 6: Mechanical Pump Test Fixture

It was useful to determine an arbitrary measurement of each pump's efficiency for means of comparison. With the averages of the evacuation times from each pump (averaged over twenty evacuations for the electric pumps and over five for the mechanical pumps), the vacuum pressure to which they were evacuated, and the precise volumes of each chamber, we were able to calculate a value for the power of each pump. This value was calculated by:

$$P = Pressure * Volume \frac{Volume *}{Time\ to\ E} \quad (1) \quad \frac{ire}{tion}$$

This was converted to a more conventional metric of Watts by converting inHg to Pa and in^3 to m^3 using a total conversion factor of .05544. All tests were performed at 72°F.

2.3 Results of Vacuum Pump Characterization

2.3.1 Electric Vacuum Pump Battery Depletion Test Results

We found that while the e-Pulse's performance decreased considerably (a time increase of over 7.5%) there was no difference in the times to evacuate for the LimbLogic over the measured period of battery depletion. We discovered a variation of only 1.5% over all sets of trials and

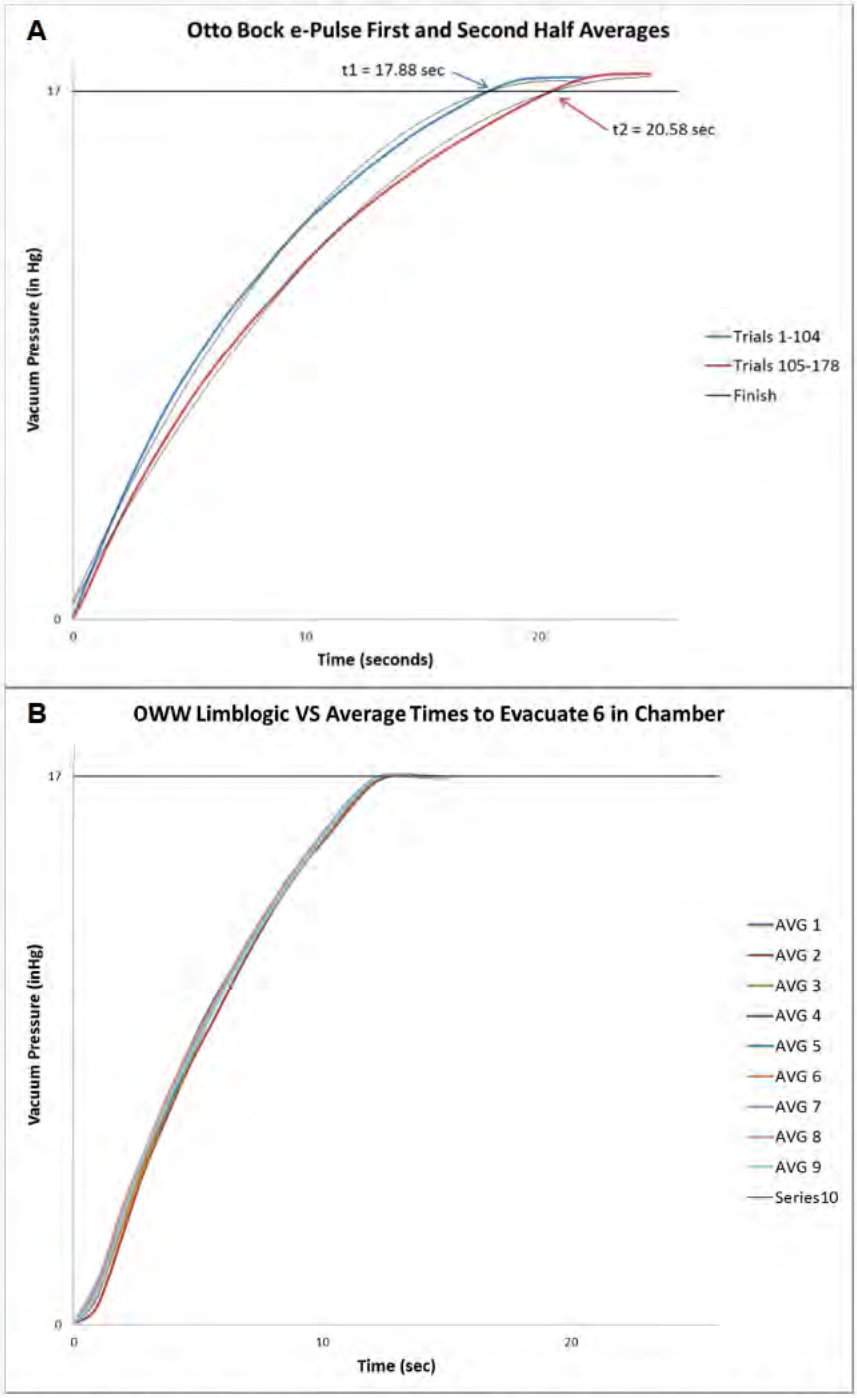

Figure 7: Plots of Vacuum Pressure vs. Time for the A) e-Pulse and the B) LimbLogic

only 0.8% between the first and last sets.

While analyzing the data collected it was noticed that the evacuation times for the e-Pulse were broken into two distinct groups: the first 104 trials and the subsequent 75 trials to complete battery depletion. Trials had nearly the same times to evacuation in their respective groups ($p > .05$). It was for this reason that the data was graphed in just two groups. Each series in **Figure 7b** represents the average of 25 trials. Simple algebra will show that this means that 225 trials were performed with the LimbLogic while only 178 were performed with the e-Pulse. This was because, while the e-Pulse battery was completely depleted after 179 evacuations (the last of which was not included in the averages because its evacuation was significantly slower), the LimbLogic had just dropped to 2 of 4 bars on the battery meter after 225 trials. While the incompleteness of the LimbLogic data means that there may still be a breaking point for evacuation time at the lower battery levels, any change in performance would be insignificant for the number of trials we had planned to perform.

2.3.2 Electrical and Mechanical Pump Test Results

Table 1a and Figure 8 display summaries of the results from the electric pump testing. Our results show that the LimbLogic consistently outperformed the e-Pulse with an average power output 47% greater. Figure 8 is a bit misleading as the slope of the LimbLogic is smaller than that of the e-Pulse. This is due to the fact that the dependent variable is time to evacuation which should ideally be as small as possible.

Table 1b and Figures 9 and 10 similarly display summaries of the data obtained from testing of the mechanical pumps. These figures and tables show that the P3 consistently outperformed the P2 and HD pumps. However, the P3 pump did not perform consistently with different functional rings attached.

Table 1a: Electrical Pump Evacuation Time and Power Results

Volume	Evac Press	Time to Evac (sec)		Power (W)	
(in^3)	(inHg)	LimbLogic	e-Pulse	LimbLogic	e-Pulse
2.69	17	6.62	9.09	0.38	0.28
4.59	17	9.29	13.83	0.47	0.31
6.46	17	13.48	19.70	0.45	0.31
8.52	17	16.45	24.56	0.49	0.33
12.54	17	23.43	35.09	0.50	0.34
		Average		**0.46**	**0.31**
		Power Difference		**47%**	

Table 1b: Mechanical Pump Power Results

Volume	Evac Press	Power (W)						
(in^3)	(inHg)	P3 f0	P3 f1	P3 f2	P3 f3	P3 f4	P2	HD
2.69	17.00	0.34	0.30	0.28	0.29	0.24	0.13	0.21
4.59	17.00	0.42	0.34	0.34	0.35	0.29	0.15	0.22
6.46	17.00	0.40	0.31	0.33	0.32	0.27	0.14	0.21
8.52	17.00	0.46	0.35	0.34	0.36	0.30	0.15	0.24
12.54	17.00	0.49	0.35	0.37	0.38	0.31	0.15	0.26
	Average	**0.42**	**0.33**	**0.33**	**0.34**	**0.28**	**0.15**	**0.23**

Evac - Evacuation, Press - Pressure

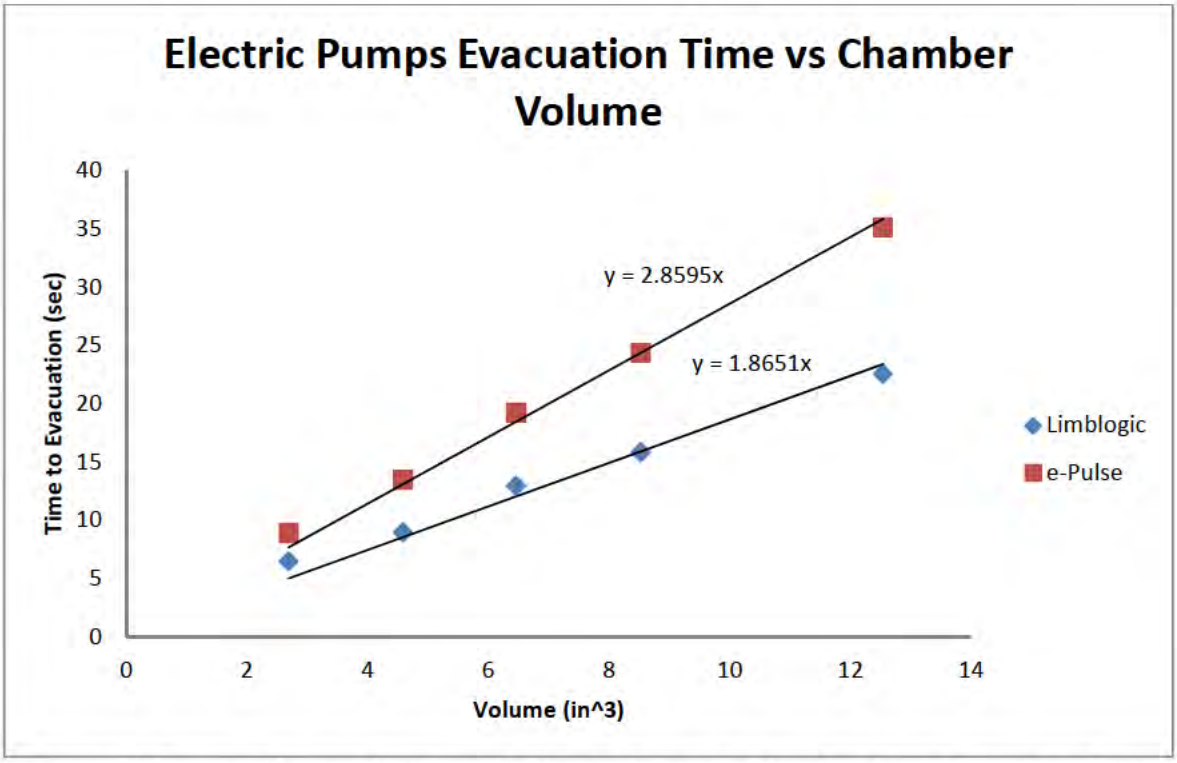

Figure 8: Summary of evacuation times for electrical pumps as dependent upon the volume they evacuated.

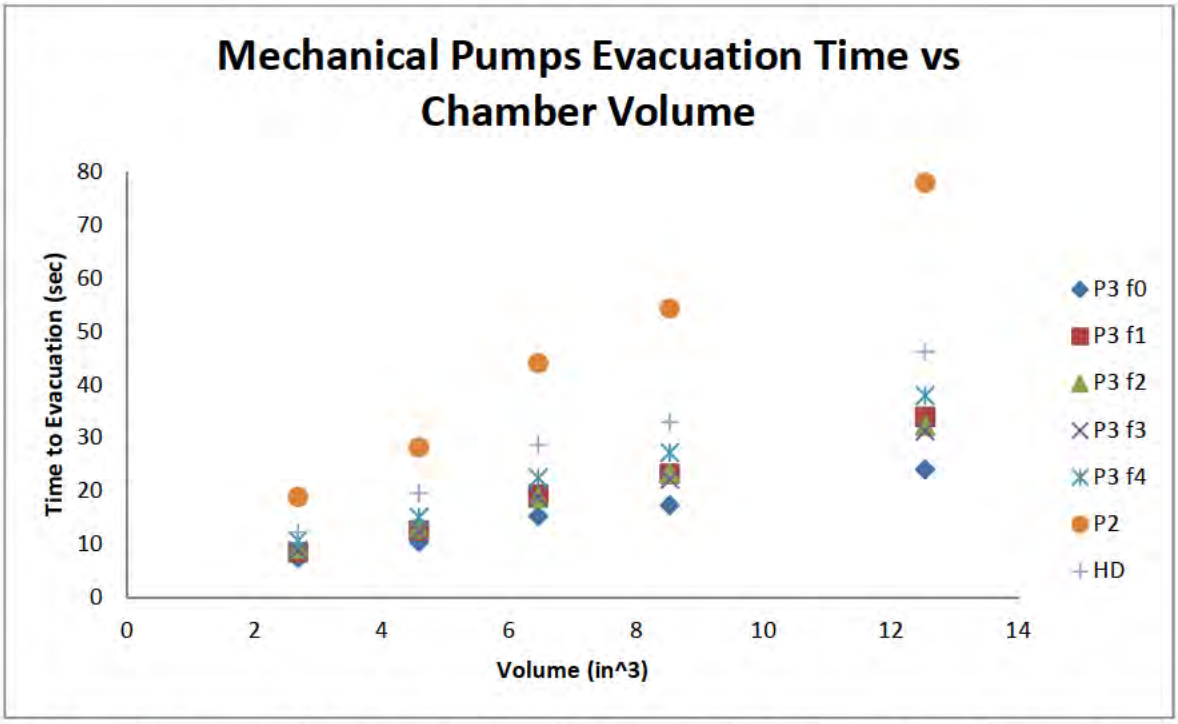

Figure 9: Summary of the evacuation times for the mechanical pumps as dependent upon the volume they evacuated.

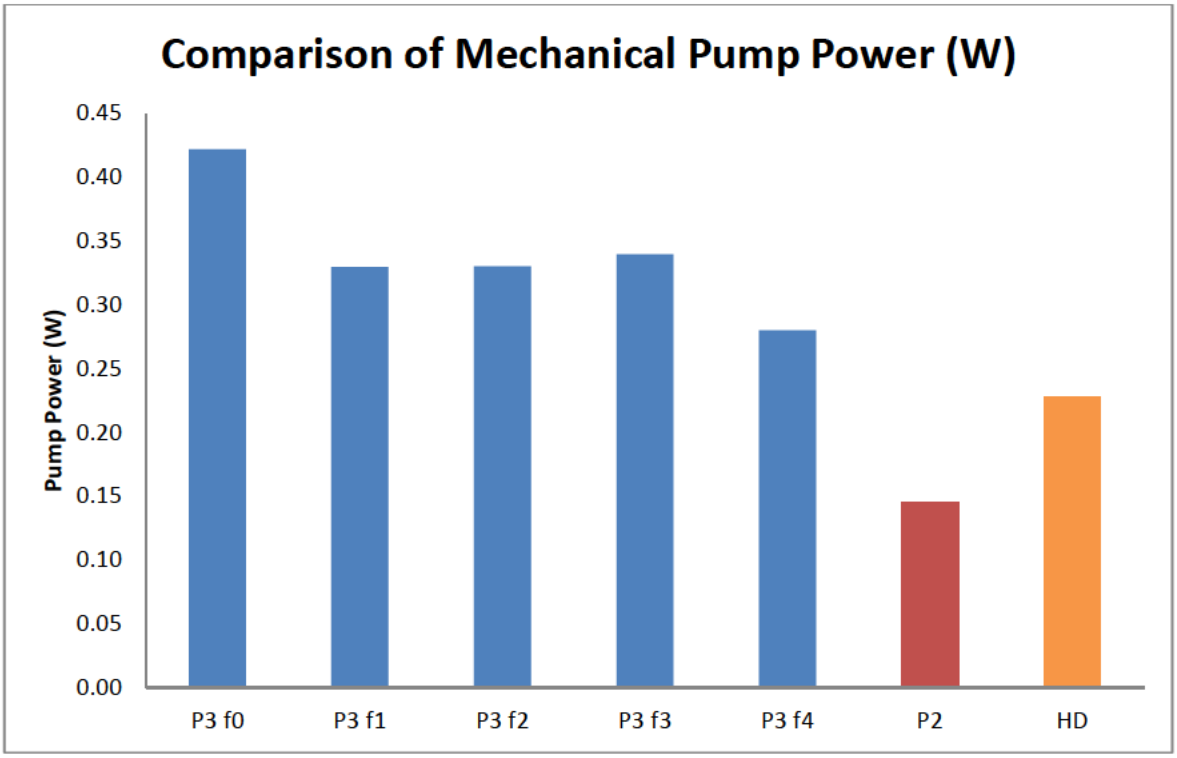

Figure 10: Summary of the pump powers calculated for the mechanical pumps.

2.4 Discussion of Results and Testing Procedure

2.4.1 Discussion Regarding Testing Procedure and Data Analysis

One interesting realization from the endurance testing is with regards to the overall efficiency of the two electric pumps. The LimbLogic pump contains a 2.04 Wh battery while the e-Pulse contains a 2.2 Wh pump. Both pumps were brand new when we first began to test them. This means that less than 10 hours of testing had been performed with each before the endurance trials occurred. With this knowledge we can assume that both batteries were still true to their technical specifications. *This implies that the LimbLogic is a much more efficient pump than the e-Pulse as it was able to perform many more (potentially twice as many) evacuations before depleting its slightly smaller battery.* Additional testing in which the current flow and voltage drop

across the motor is measured would need to be performed in order to determine the efficiencies of both pumps exactly but our data suggests that the LimbLogic is the more efficient of the two pumps. These tests also showed that the performance for both pumps was self-consistent over the first ~100 trials on a chamber volume of 6 in^3. From this information we decided that charging pumps between canisters or subjects would provide enough consistency for our tests.

Another issue we were forced to address during testing was that of pressure inconsistency stemming from slight variations in atmospheric pressure from day to day and hour to hour. These were typically quite small (less than 10 torr) but we thought it important to take them into account in order to get the most accurate information. This was handled by normalizing the evacuation time by the total change in pressure as opposed to just measuring the time from start to finish for both the mechanical and electrical trials.

The final procedural adjustment involved the point in time at which evacuation started versus the intervals at which data was acquired. Due to the way in which the system was set up, the DAQ system was constantly capturing data, so the point in time at which the pump started evacuating could fall anywhere between two data capture points. Since the rate of data capture was nearly 1Hz, there was a large variability in how long after the pump was started that the first point was captured. We saw evidence of this by a shallower slope at the very start of our curves, as shown in Figure 11. This issue was resolved by subtracting half of one time step from the data, time shifting all of the data slightly to the left, and effectively straightening the slope from the first to second acquisition. This is also shown in Figure 11**.** The accuracy of this method was confirmed by increasing the number of trials averaged from 5 to 20 for the electric pumps. It was found that there was no significant difference ($p > .05$) between 5 and 20 trials and so only the 5 were performed with the mechanical pumps.

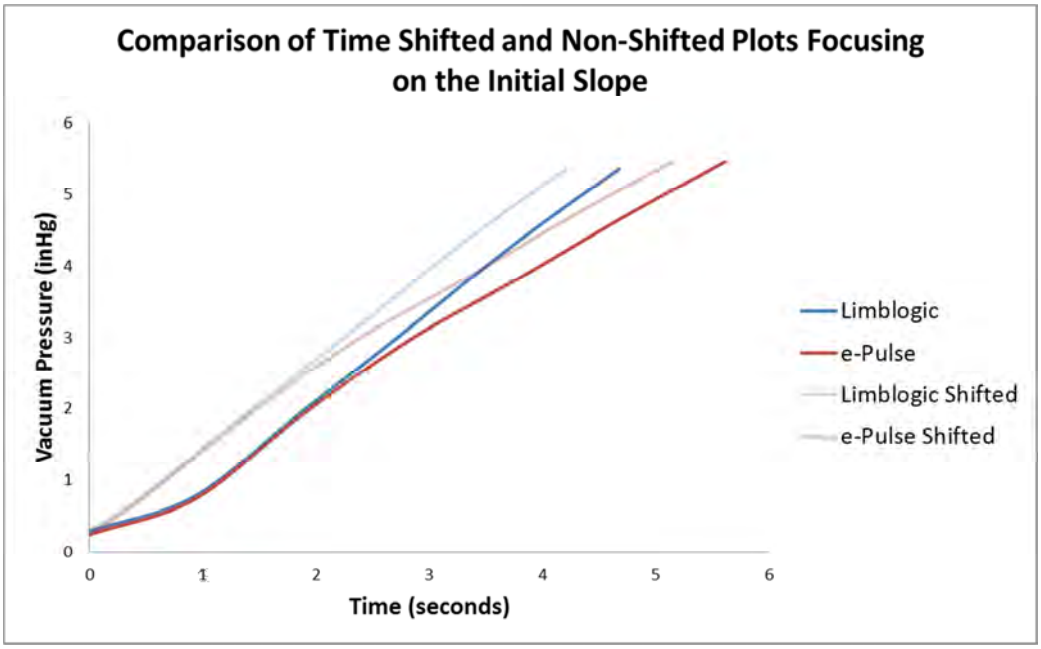

Figure 11: Comparisons of the original plots of evacuation time for the electrical pumps vs. their time shifted plots.

For both the electric and mechanical pumps the “power” values, are the vacuum power outputs of the pump. In reality what should be measured are the conversion efficiencies of the pumps, or in other words, their ability to convert electrical/mechanical power into vacuum power. Unfortunately, there was no ready means of measuring the power input into either pump. For the electric pumps this would have required measuring the current input and the voltage drop across the DC motor of the pump as previously mentioned. For the mechanical pumps this could have been done in a few ways. In the test method used, the power source was a human being. To measure this power input would require determining the metabolic output of the pumper and multiplying by the lever (neglecting the frictional losses in the lever system). Alternatively, if the mechanical pumps were mounted in a pneumatic or motor driven test structure the mechanical power input could be measured by more conventional means. To

measure exact efficiency in the electrical pumps a test involving the current through and voltage drop across the electric pump (as mentioned previously) would need to be performed.

2.4.2 Discussion of Evacuation Times and Powers

The results indicated that the power values for the smaller chamber sizes were notably smaller than those of the larger sizes. We originally hypothesized that this was due to an acceleration factor involved in the pumps that became less significant as the size of the chamber increased. However, the same results were noticed in the mechanical pumps which do not require an electric motor to speed up. Further experimentation would be needed to prove or dis-prove this hypothesis or to determine the true cause of this phenomenon. One possible approach would be to perform the same experiment on both smaller and larger chamber sizes and checking whether the same pattern continued.

The secondary purpose of the electrical characterization was to be able to determine the volumes of human subjects' socket/liner interface with only the knowledge of the pump used and the evacuation time. As such a relationship between volume evacuated and time to evacuation for each of the pumps was needed. This was done by plotting these two variables (time being the dependent variable in this case) and fitting a linear trend line to the data as shown in Figure 9**.** The equations of the trend lines can then be used to calculate the exact volume of a human subjects' socket/liner interface given the type of pump and the time to evacuation. These same results were also plotted for the mechanical pumps for comparison.

The one major surprise from mechanical pump testing was the discrepancy in time to evacuation with the various functional rings. While the f1, f2 and f3 rings performed similarly, the f0 ring and f4 ring were definite outliers, with the f0 outperforming the average by 24% and the f4 underperforming by 18%. One potential explanation for this result may lie in the

recommended use of the functional rings. It is recommended by the manufacturer that each ring be pre-compressed, in a specially provided mechanism for 5 minutes prior to use. The f0 ring was the one installed in the device upon delivery from the manufacturer, while the other rings were provided separately. It may be that the f0 ring received more 'pre-compression' than the other functional rings. This may have served to relax the material more, providing less resistance to energy input into the system, and subsequently showing more energy output. However, this does not explain the fact that the f4 ring *under*-performed. More likely, the f4 ring had the highest tensile strength as it is intended for persons weighing 190-220 lbs compared to 100-190 lbs for the other 4 functional rings. During testing with the lever device, the f4 ring would have required a higher energy input from the tester to reach full compression and, hence, performed more poorly than the other pumps. However, if this was the case it would seem logical to have seen a consistent downward trend in power from the f0 ring to the f4 ring, which was not observed. Finally, it may be possible that the energy required to compress the f4 ring was above some threshold energy that the tester could comfortably exert, in which case it would have a lower energy output than the other pumps.

Despite the precautions taken to limit the effect of the human tester on the results, testing of the mechanical pumps was still subject to tester bias and stroke power variations. In future tests this limitation could be addressed by constructing a motorized or pneumatic test fixture to ensure consistency between tests and between individual strokes. This would eliminate some of the possible sources of error mentioned in the previous paragraph. Additionally, purchasing 5 brand new functional rings and pre-compressing each for some arbitrarily large period of time (an hour perhaps) would help negate any differences between the pre-loading they received prior to delivery.

Results showed that the P3 mechanical pump was similar in power to both the e-Pulse and LimbLogic electric pumps. However, this was true only for the method in which it was tested, i.e. the power output of the user multiplied by the lever system used (ignoring frictional losses). It would be possible for the mechanical pumps to perform better or worse depending on the user. This is another major advantage which the electric pumps have over the mechanical pumps, they are user independent.

2.5 CONCLUSIONS

The results obtained from the bench-top testing of the mechanical and electrical pumps led to several conclusions. The first is that the electric pumps' performance appears to be dependent upon the total charge available in their Li-ion battery. The e-Pulse pump in particular showed a clear drop in performance once its battery reached a charge slightly less than half of its total charged (judged based on the number of evacuations it managed after this point). Another finding was that while, on average, the electrical pumps outperformed the mechanical ones, one of the mechanical pumps performed slightly better than one of the electrical pumps. Specifically, the Otto Bock Harmony P3 pump had a power output 3% greater than that of the e-Pulse, evacuating the 6 in^3 canister to 17 inHg in just under 16 steps. This was of course, partially due to the power input provided to activate the mechanical pumps, implying that the mechanical pumps could either perform better or worse than was found experimentally. Even so, this served to partially disprove our hypothesis that the electric pumps would consistently outperform the mechanical ones. Even among the electric pumps there were large discrepancies. The Ohio Willow Wood LimbLogic VS outperformed the Otto Bock Harmony e-Pulse by nearly 50% on average. This result, combined with the evidence that it is capable of evacuating the same chamber significantly more times on a single battery charge, makes it a superior pump. In

conclusion, we found that the Ohio Willow Wood LimbLogic was the strongest performing pump but the P3 had the potential to perform nearly as well.

CHAPTER 3: DETERMINATION OF KEY CHARACTERISTICS IN THE SOCKET/LINER INTERFACE

3.1 INTRODUCTION

While VAS has been around for over a decade, little is known about the characteristics of the socket/liner interface in which the vacuum is created. In vacuum assisted suspension, a vacuum is created between the inner socket wall and the liner worn on the residual limb of the user. However, the volume of this chamber is unknown. Additionally, the rate at which vacuum leaks from this chamber has remained largely unexplored. Without information on these user needs, it is difficult to properly design a vacuum pump capable of meeting them.

This chapter will explore these questions. Specifically, tests have been performed in order to answer the questions:

- What is the volume of the socket/liner interface for transfemoral amputees?
- What is the rate at which vacuum pressure decays while a subject is active?
- How does walking affect vacuum pressure over time?

The primary goal in answering each of these questions was to further understand the daily and hourly vacuum pump requirements of active prosthesis users.

3.2 HUMAN SUBJECT TEST METHODS

3.2.1 PARTICIPANTS

Participants were recruited by Certified Prosthetist Ryan Caldwell from among his patients with unilateral transfemoral amputation at Suburban Prosthetics & Orthotics, Des Plaines, IL. Mr. Caldwell identified subjects on the basis of their experience with use of the Otto Bock C-Leg (a popular microprocessor controlled prosthetic knee) and vacuum assisted suspension. The significance of user experience with the C-Leg was to not introduce additional variables into the rate of vacuum decay during activity.

The protocol was approved by the Northwestern University Institutional Review Board (NU IRB) and the DOD HRPO, and written informed consent was obtained from each person before participation.

3.2.2 TEST PROCEDURE

Testing was performed in much the same way as bench-top testing in order to determine the volumes of participants' socket/liner interface. Human subjects were brought in and asked to stand comfortably while their prosthesis was evacuated ten times, five times with both the Otto Bock e-Pulse and the Ohio Willow Wood LimbLogic VS (the order in which the pumps were tested was randomized). During each evacuation the socket/liner interface was evacuated to just over -17 inHg. The pressure was measured using the same digital vacuum gauge (the DigiVac Model 2L760) and recorded using the same NI Labview Virtual Interface as were used during bench-top testing described in Chapter 2. The exact procedure for the first test was modified slightly after the second participant. This modification involved where exactly atmospheric pressure was allowed back into the system. The first two subjects broke the

vacuum seal directly at the socket/liner interface near the socket trim-line. For subjects 3 through 13, air was allowed back into the system by separating the “T” joint from the digital pressure gauge.

Questions regarding variations in vacuum pressure due to walking were addressed with a treadmill test. Participants were asked to walk for 10 minutes at a comfortable speed on a treadmill (Cosmed Sport Treadmill T170). This test was performed with both the electric pumps (the order in which they were tested was again randomized) and monitored with the same interface as previously mentioned. After allowing 5 minutes of rest between each test users were asked if they were willing to perform the same test at a higher walking speed for an additional 5 minutes with each pump. This test was designed to compare the rates of vacuum pressure decay at various activity levels for each user.

The treadmill test could only be performed at the facilities available at the Northwestern University Prosthetics-Orthotics Center, Chicago, IL. As such, only the first 5 participants performed the treadmill test as they were the only ones willing to make the commute into Chicago. Participants 6-13 (and the additional test of the first participant) were tested at Suburban Orthotics & Prosthetics, Des Plaines, IL. All tests were facilitated by Certified Prosthetist Ryan Caldwell.

One additional test was performed on subject 1. Using the exact same comfortable standing protocol we tested 4 different socket conditions. Two of the sockets were made from Polytol, with one slightly larger volume than the other. The other two sockets were 'check' sockets, formed from the same mold as their respective Polytol sockets. A ‘check' socket is a socket made from Polyethylene Terephthalate

(PETG) used by prosthetists to evaluate the fit of a socket before making a more permanent one.

3.3 Socket Evacuation and Treadmill Test Results

Thirteen participants with unilateral transfemoral amputation participated in the study. However, due to discrepancies in the testing procedure (a change in the location which air was allowed back into the system) the data from only 12 subjects was used. Information for the subjects tested can be viewed in Table 2.

Table 2: Test Subject Data

Characteristic	Transfemoral (n = 12)
Age	55.6 (14.3)
Sex (M/F)	8/4
Height (cm)	174 (7)
Weight (kg)	82 (25)

Note: Values are Mean ± (Standard Deviation)

The change in procedure regarding the location at which air was allowed back into the system after evacuation was changed primarily out of convenience. Both the tester and the subjects found it faster and more effective if the vacuum was released from the “T” joint than forcing the test subject to pull away the tight seal between socket and liner. However, it is believed that this change in procedure may have affected the results slightly and so the data from the first two participants was discarded. Fortunately we were able to re-test the first participant with the modified procedure, leaving us with data from 12 total subjects. There was also an issue with the socket of the third subject, making the data inconsistent with that of the

other participants so that data was disregarded when calculating the socket/liner interface volume.

Figure 12 displays the evacuation curves for the human subject trials using the Otto Bock Harmony e-Pulse. The times to reach full evacuation and the shapes of the curves varied widely between users. The summary data for both pumps can be seen in Table 3.

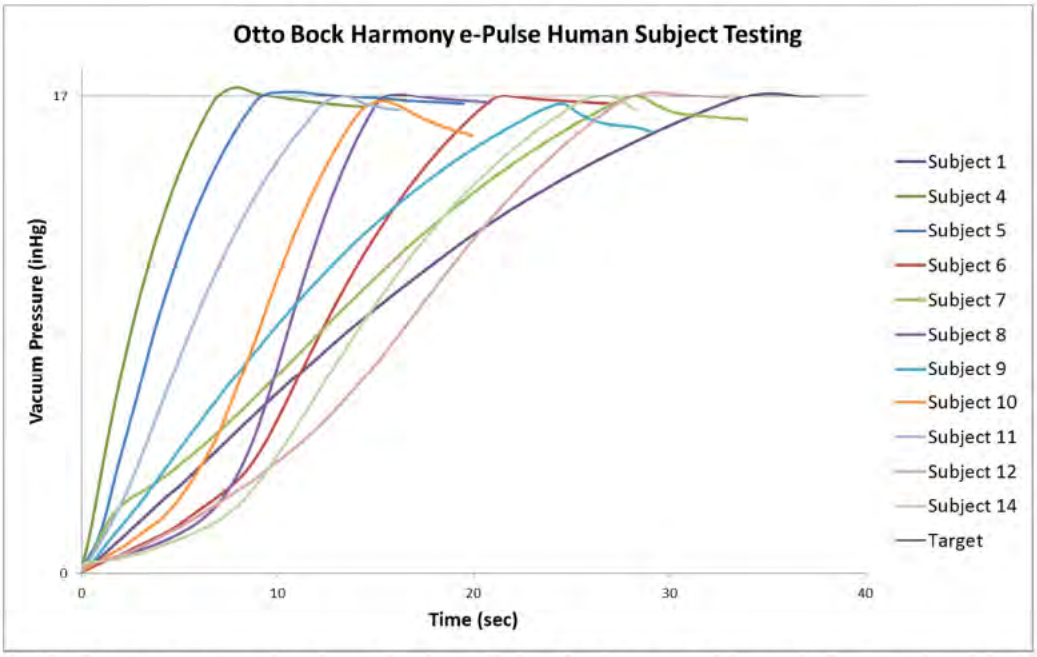

Figure 12: Average evacuation times for the e-Pulse the human subjects during comfortable standing (n=11).

Table 3: Summary of Interface Volumes

	Socket Volume Statistics (in^3)	
	e-Pulse	LimbLogic
Avg	5.97	6.31
Stdev	2.89	3.00
Max	10.74	11.59
Min	1.29	1.48

Vacuum pressure was monitored over time for each user while walking on the treadmill. Results for the first 5 users are shown in Figure 13**.** Variation in vacuum pressure during the gait cycle as well as the rate at which the vacuum pressure decayed was determined graphically and is shown in Table 4.

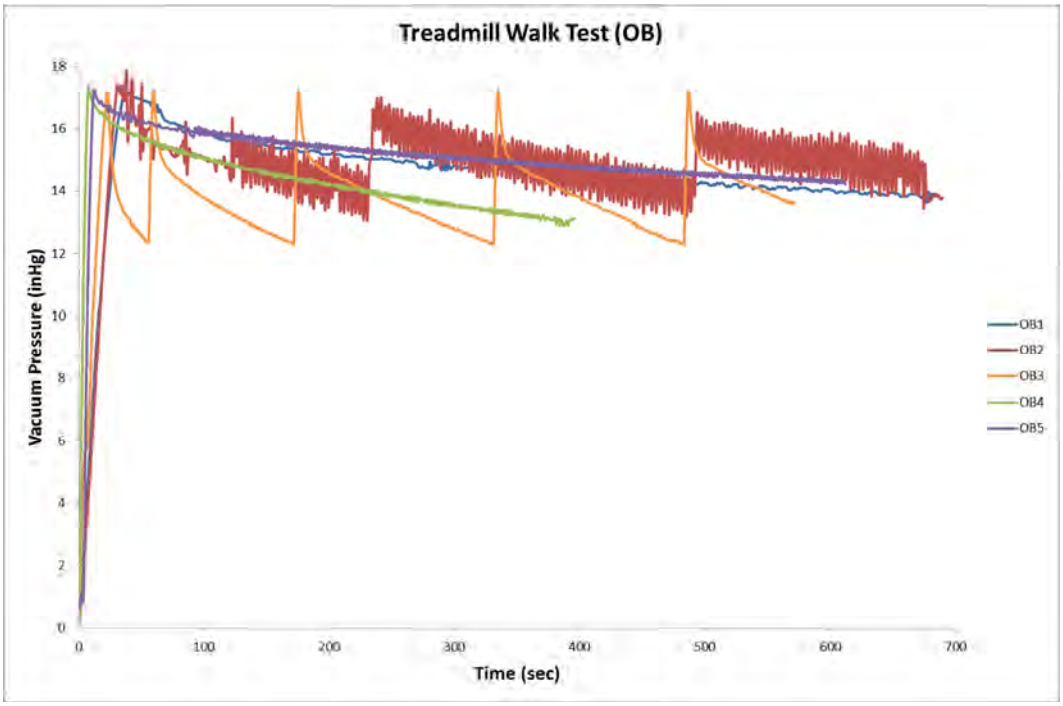

Figure 13: Vacuum pressure over time recorded during treadmill testing using the e-Pulse

Table 4: Treadmill Test Analysis

	Gait Cycle Variation (inHg)		Rate of Vacuum Decay (inHg/sec)	
Trial	OWW	OB	OWW	OB
1	0.04	0.04	-0.0019	-0.0028
2	1.1*	1.2*	-0.0112	-0.0068
3	0.05	0.05	-0.0595*	-0.0190*
4	0.08	0.12	-0.0089	-0.0058
5	0.11	0.12	-0.0022	-0.0026
AVG	**0.07**	**0.08**	**-0.0061**	**-0.0045**

*Indicates values that were omitted from calculation of the average.

3.4 Discussion of Evacuation and Treadmill Results

One important thing to notice in Figure 12 is the differences in shape between the various user evacuation curves. Several of the human subjects demonstrated a shallower slope initially, followed by a rapid increase in vacuum pressure. It was initially hypothesized that this was due to the rigidity of the chamber being evacuated. The socket material used for a majority of the subjects tested was fiber reinforced Polytol, a polyurethane-based three-component lamination resin manufactured by Otto Bock. This is a very flexible material and, as such, is likely to deform when placed under vacuum pressure. Therefore, the initially shallow plots could have been due to the socket pulling inward toward the users' residual limb and liner during evacuation, causing a change in volume and a minimal change in pressure. Then, with a smaller volume to evacuate, the vacuum pressure would shoot up at a faster rate than in a rigid chamber. This effect would be more noticeable in a socket with a larger volume than in a small one due to the increased radial distance between socket and liner.

This phonemena was explored further with the additional test performed on subject 1 mentioned at the end of section 3.2.2. As PETG is a much more rigid material, it should have allowed minimal deformation and held an approximately constant volume throughout evacuation. The check socket is then acting like a control group to determine whether the less rigid polytol socket is deforming under vacuum pressure. The results of this comparison can be seen in Figure 14.

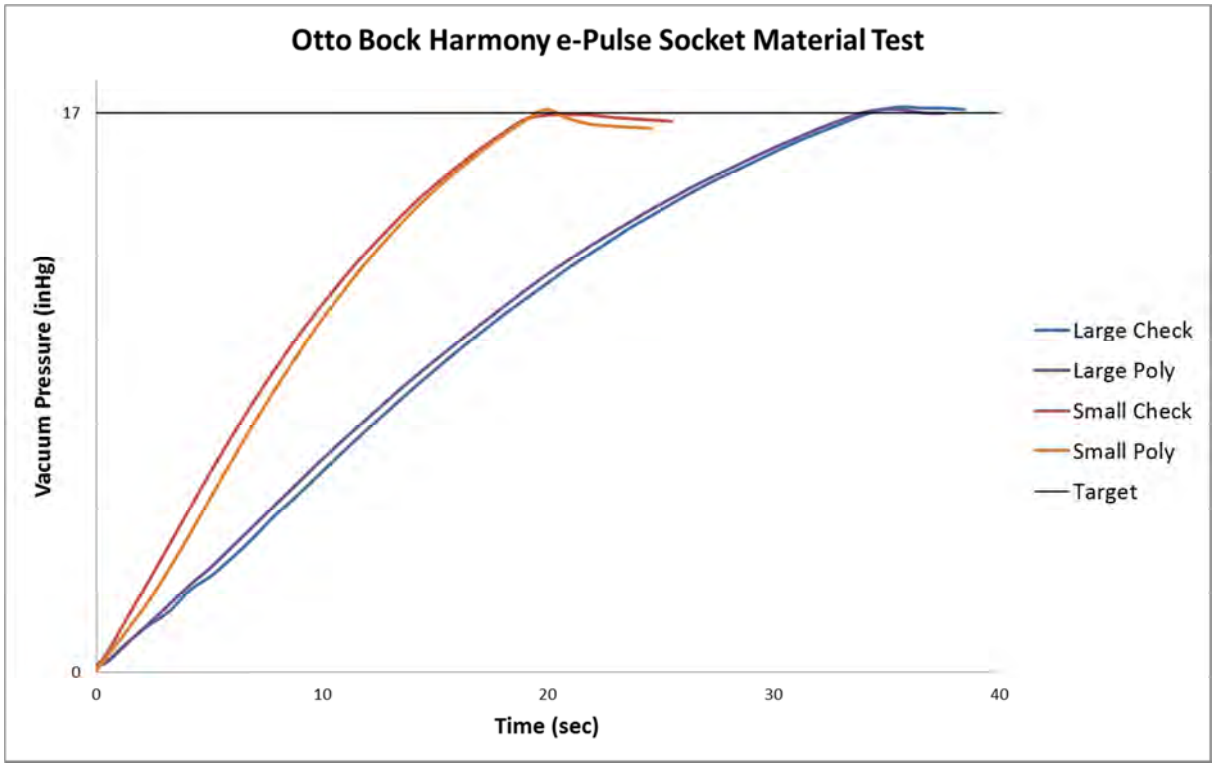

Figure 14: Comparison of vacuum pressure during in the Polytol and Check sockets on Subject 1 while standing.

Figure 14 shows a minimal difference between the check and Polytol sockets, demonstrating that socket material was not the contributing factor. None-the-less, it is clear from the shape of the "S" curves that, for some of the participants, the energy of the vacuum pump is temporarily being exerted on something other than decreasing the pressure of the socket/liner interface. It is

possible that this phenomenon may be due to a change in volume of the socket/liner interface as the result of the disappearance of air pockets. These air pockets could be the result of the subject coming slightly unseated from the distal end of the socket when they lose vacuum pressure. Another potential explanation could be the type of sock or nylon worn by the user. Different quantities or materials of socks/nylons might affect the rate at which air can escape the interface and alter the shape of the curve. Additional testing is needed to further explore these ideas. Such testing would not necessarily need to involve human subjects and could potentially be done using a silicon residual limb and matching socket. Then, the degree to which the limb was seated in the socket, as well as the number of sock/nylons, could be altered freely without the risk of discomfort to a human participant.

We noticed from the first 5 subjects that there was a large discrepancy between them in terms of the rate at which the vacuum pressure decreased within their sockets. Note that subject 2 had a large vacuum pressure variation during the gait cycle. For this reason the averaged results of the gait cycle variation column in Table 4 omit the values from subject 2. Similarly, subject 3 had a leaky socket, leading to an abnormally high rate of vacuum decay over time. Subject 3's data was therefore omitted from the averages in the vacuum decay column of Table 4. Both are considered outliers since they lie greater than 3 standard deviations from the mean of the other trials.

As only 5 participants performed the treadmill test, the data obtained was limited. Even so, we can still draw some conclusions. The first two columns of Table 4 show a slight variation between the two pumps (.08 vs .07 inHg) in terms of average variation in vacuum pressure during the gait cycle. However, the vacuum gauge used was only accurate to +/- .04 inHg, which is not high enough to show a clear difference between the pumps. Even with this limited

accuracy we can assume that there is no difference between the pumps in terms of vacuum variation during the gait cycle, as we would have expected. Previous work regarding variations in vacuum pressure during ambulation suggests that the change in pressure may be as high as ±.25 inHg at a vacuum pressure of 20 inHg (Gerschutz et al., 2010). These measurements were taken using the LimbLogic Communicator System which transmits data wireless from the users prosthesis. This direct connection to the socket as opposed to the 6 feet of vacuum tubing connecting the digital vacuum pressure gauge used in this study may account for the discrepancy in data.

The rate of vacuum decay was determined only over the period near the end of the trial when the slope was approximately linear. Vacuum decay immediately after evacuation was not taken into account due to inconsistencies in procedure. In our procedure, each subject's socket was evacuated off the treadmill, and then they were asked to make their way onto the treadmill. The treadmill was then accelerated until it reached a comfortable level. Because of this, there was no standardized procedure for the users' actions immediately after evacuation. The user may have taken more or less time or steps to make their way comfortably onto the treadmill, and the rate of acceleration of the treadmill may not have been consistent between tests. This would have introduced unknowns into the equation and so the slope was only determined near the end of the test when the slope was approximately linear and assumedly independent from the subjects early movements.

The rate of vacuum decay, however, showed a clear difference between the two pumps. Even with the data from subject 3 excluded, the rate of decay for the LimbLogic pump was 36% higher than that of the e-Pulse. However, the data from subjects 1 and 5 suggested that the rates were very similar, and even slightly in favor of the LimbLogic. One important factor not

shown in either Figure 9 or Table 4 is the average pressure difference between the two pumps at the start of the period over which it was averaged. This value was 0.86 inHg higher for the LimbLogic VS on average. This higher vacuum pressure in the case of the LimbLogic may have very well contributed to the greater rate of vacuum decay since the greater differential between the internal pressure and atmospheric would have created a greater potential for air to leak into the system. In any case, more subjects need to be tested to come to any firm conclusions over the dependency of vacuum decay on the vacuum pump equipped. The higher rate walking test was completed by only two subjects so this data was omitted from the report.

3.5 CONCLUSIONS

The human subject testing performed led to several conclusions. We found that the volume between the socket and liner (neglecting any tubing or connecting apparatus) was **6.14 in^3**. This is, in fact, slightly smaller than the true volume of the 6 in^3 chamber which was actually 6.46 in^3.

One unexpected result was the difference in the evacuation curve shape for various users. The cause of this discrepancy remains unclear but it is believed that it has something to do with a slight change in volume within the socket during evacuation. This could possibly be caused by the user coming slightly unseated from the socket when they lose vacuum pressure or potentially from some other source of air pockets within the socket. Alternatively, the difference in slope may be caused by the number or material of the sock/nylon worn by the user in between the liner and socket.

While the treadmill test was limited in participants, some insights into the functioning of the vacuum over time were realized. The first realization was that the *slight variations in vacuum pressure during the gait cycle are independent of the vacuum pump used*. The second was that *the rate of vacuum decay while walking, may be pump dependent*. We found that, when wearing

the Ohio Willow Wood LimbLogic, the users vacuum depleted 36% faster. Seeing as this result was determined from only 1 trial on each of the 4 users, this result will need to be confirmed. The results obtained from this testing can be used to aid in designing a better vacuum pump.

CHAPTER 4: VACUUM PUMP DESIGN

4.1 CONNECTION BETWEEN DESIGN AND PREVIOUS RESEARCH

The knowledge gained from bench-top testing, human subject testing, and informal surveying of the users of prostheses with vacuum assisted suspension (Appendix B) provided the groundwork for an improved vacuum pump design.

Table 5: Key Observations from Chapters 2 and 3

Chapter 2 Observations	Electrical Pumps	The OWW LimbLogic is 47% more powerful than the OB e-Pulse
		Unlike the OB e-Pulse the performance of the OWW LimbLogic appears to be independent of the charge of its Li-ion battery
		The OWW LimbLogic is potentially capable of more than 2x as many evacuations as the OB e-Pulse even with a similarly sized Li-ion battery
	Mechanical Pumps	The OB P3 mechanical pump performs significantly better on average than both the OB P2 and HD pumps
		The various functional rings of the P3 varied in performance
		The average performance of the OB P3 pump was equal to that of the OB e-Pulse
Chapter 3 Observations		The average volume of the socket/liner interface for persons with transfemoral amputations is 6.14 in3
		Vacuum pressure variation during ambulation is pump independent
		The rate of vacuum decay was found to be 36% faster in the OWW LimbLogic than in the OB e-Pulse

The results obtained from the bench-top testing of the mechanical and electrical pumps led to several conclusions, summarized in Table 5. On average the electric pumps outperformed the mechanical ones. However, the Ohio Willow Wood LimbLogic VS outperformed the Otto Bock Harmony e-Pulse by nearly 50% on average. Additionally, one of the mechanical pumps

performed particularly well during bench-top testing. The results obtained for the time to evacuation for the Otto Bock Harmony P3 pump were, on average, 3% faster than that of the e-Pulse, evacuating the 6 in^3 canister to 17 inHg in just under 16 steps. This was of course, partially due to the power input provided to activate the mechanical pumps, implying that the mechanical pumps could perform better or worse than was found experimentally. The electrical pump performances, on the other hand, were independent of the user (in terms of its power output) which is a desirable characteristic. In general, we found that the LimbLogic was the strongest performing pump but the P3 had the potential to perform nearly as well.

Our human subject testing suggested that the average volume to be evacuated between the socket and liner (neglecting any tubing or connecting apparatus) is 6.14 in^3. It is important to note that this is slightly smaller than the true volume of the 6 in^3 chamber which was actually 6.46 in^3. These tests also gave us reason to believe that the rate of vacuum decay in the prosthesis is higher for the LimbLogic than the e-Pulse. However, this last conclusion is far from certain and was considered insubstantial when the power outputs and the battery lifetime of the pumps were taken into consideration.

As this project was funded by the Department of Defense it was desirable to design a vacuum pump system with the military's advanced needs in mind. Aside from the reliability and durability required of military equipment, one need stood out more than any other: the ability to function when common sources of electricity were not available. This need highly encouraged the use of a mechanical pump over an electric one. Even so, an electric pump was still desired for a quick evacuation in the case of an emergency, for users incapable of walking without any vacuum assisted suspension, or any time in which there is a sudden loss of vacuum pressure. With the results from our previous research as well as the military's advanced needs in mind,

two different design approaches were pursued: a mechanical/electric hybrid pump, and an energy harvesting electric pump.

4.2 Design of a Hybrid Vacuum Pump

A hybrid pump has the advantage of being capable of quickly evacuating the socket using the electrical system, then maintaining that vacuum through mechanical activation while walking. Without the need to maintain vacuum pressure the electrical system can go into a sleep mode, greatly conserving battery life. Our DOD project team recruited the assistance of undergraduates working on a senior design project to pursue the design problem with fresh eyes.

4.2.1 Undergraduate Design Work

The structure of the undergraduate team's course was such that the team was required to bring the challenge through a rigorous design process. This process began by defining a problem statement which read:

> *"Our goal is to design a quiet, compact, and unobtrusive vacuum pump with adjustable pressure and minimal recharging needs that will evacuate the cavity between a residual limb and socket for military personnel who have suffered transfemoral amputations."*

The most important step in solving any problem is properly outlining all of the requirements of the solution. So in addition to the problem statement, exact design specifications were laid out. As the final product was meant for use by military personnel, many of the design considerations were directed to fulfilling the needs of the average soldier. The full specifications can be viewed

in Appendix A but they addressed such issues as performance, power requirements, safety, ergonomics, geometry, durability, cost, weight, and manufacturing. One of the biggest issues for this particular problem was geometry. Due to the nature of transfemoral amputations, build height between the bottom of the socket and the top of the prosthetic knee being used is often limited. It is this small envelope which restricts the use of currently available mechanical pumps such as the Otto Bock P3 pump, which require nearly 5 inches of vertical space between the top of the knee and bottom of the prosthesis.

With these considerations in mind, the team and I visited Certified Prosthetist Ryan Caldwell at Suburban Prosthetics & Orthotics, Des Plaines, IL to perform user observations. A full summary of these observations can be viewed in Appendix B. One important realization from the user interviews performed was that some users are incapable of using purely mechanical pumps. Conditions such as heterotropic ossification exist which cause the user extreme pain when walking without vacuum assisted suspension. This makes it impossible for them to slowly build up vacuum using a mechanical pump and necessitates an electrical one, which does not require putting pressure on the residual limb before the VAS is fully formed.

These user observations greatly influenced the evaluation of conceptual designs which was performed using a design decision matrix. After modifying the weights of the various design specifications to reflect what was learned from the user interviews the team came to the same solution we had anticipated initially: that a hybrid pump would best solve the problem. The teams' final design is pictured in Figure 15a.

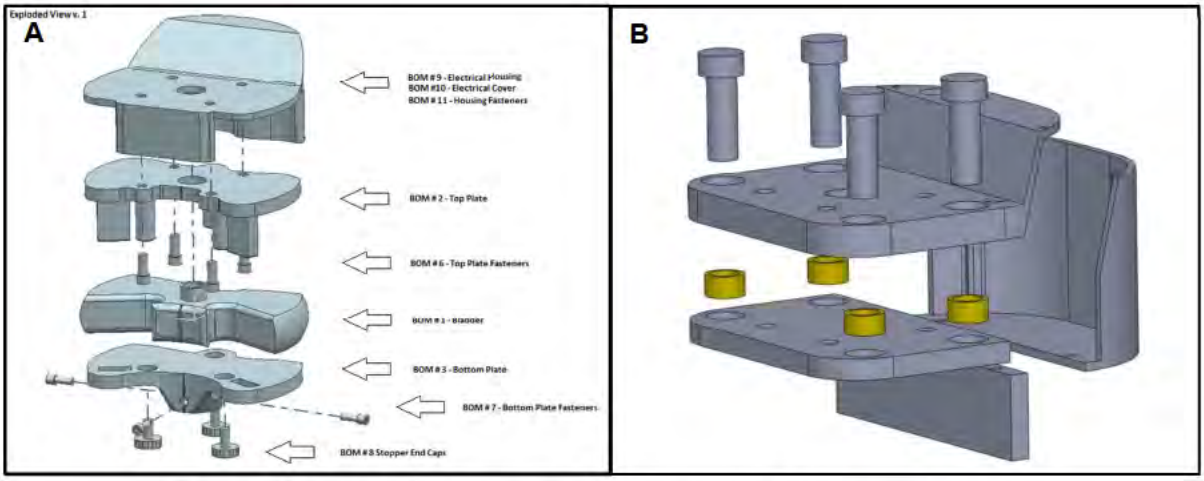

Figure 15: Images of the A) original and B) modified hybrid pump designs.

The specifics of the design were determined through additional engineering analysis. The geometric envelope was limited to the vertical space taken up by the Ohio Willow Wood LimbLogic VS, and the diameter of a typical prosthetic socket. It was determined that the space in front of and above the knee was the least obtrusive to the user so this is where the electrical components of the design were located. Additionally, the design space was limited towards to back of the knee to prohibit impedance of knee flexion. An artistic rendering of the final prototype in place between a prosthetic socket and a C-Leg is shown in Figure 16.

Figure 16: An artists' rendering of the hybrid pump mounted between a socket and C-Leg.

The results from the bench-top testing described in Chapter 2 were provided to the team for determination of the exact components to be used in the

system. These results led the team to propose a combination of the electrical system of the Ohio Willow Wood Limblogic VS and a functional ring similar to that of the Otto Bock Harmony P3. Due to the geometric differences between their prototype and the P3, a butterfly shaped functional ring was proposed. In addition to this, the team performed engineering analysis to determine the materials to be used and the structural requirements of the design. Based on these structural and mass considerations it was determined that the best material for the final design would be Aluminum.

4.2.2 Design Modification and Reconstruction

After the team passed their prototype to me it was determined that some changes needed to be made in order for the prototype to function as intended.

1. The method of compression for the mechanical system was not stable in the original formation and with the materials it was designed with. Specifically, the team's design used 3 circular and two rectangular guide rails made from aluminum. The triangular configuration chosen is particularly unstable when dealing with machines similar to dies (as this one is).
2. Both rails and plates were designed with aluminum, which tends to stick and bind to itself.
3. The total volume available for the electrical system was not adequate to house the components of the Ohio Willow Wood LimbLogic VS.
4. There was no means to connect the electrical system and mechanical systems internally, forcing the team to use external hosing, which was deemed undesirable for the final design.

To address these issues we redesigned the prototype as shown in Figure 15b**.** This redesign incorporates 4 guide pins as opposed to the 3 used in the original design and places the pins further apart to increase stability and the total area available for the bladder. The pins are also precision machined steel, and slide into specially made oillite bushings to insure smooth movement in only one direction. By making some minor changes to the geometry the total volume to the electrical system was increased. SolidWorks 3D CAD Software (Concord, MA) was used to confirm that all components fit properly with. Finally, by combining the top two plates room was made to run a channel from the electric system, through the top plate, and directly into the interface between the mechanical system and socket, eliminating the need for external tubing.

4.3 Biomechanical Energy Harvester Design

Previous testing, both bench-top and human subject, has led to the conclusion that electrical pumps are more desirable than mechanical pumps in terms of their evacuation speed and user independence. As stated previously, the biggest problem with the electric pumps is there dependence on a source of electricity. Since the target solution is directed at use by military personnel, it is not possible to assume that the user of our pump would always have access to this. With the increased use of portable electronic devices this problem has become common place. As such, many researchers have looked into methods of harvesting human energy, which might otherwise be wasted, to charge portable electronic devices. Since an electric vacuum pump is nothing more than a portable electric device, we investigated the possibility of using one of these emerging energy harvesting methods to power the pump, negating the need for regular access to a wall outlet.

Several means of harvesting biomechanical energy was looked at initially (Yang et al., 2009; Niu et al., 2004; Niu et al., 2008; Starner and Paradiso, 2005; Paradiso and Starner, 2005; Kuo, 2005; Rome et al., 2005). These included: magnetic, piezoelectric, electrostatic, and electrical polymers. These possibilities were also considered with several biomechanical motions, such as foot impact, arm and leg movement, and the up and down motion of the body during the gait cycle. However, the C-Leg already dissipates considerable energy in its hydraulically damped knee during flexion and extension, energy that could be converted to electricity instead of being lost. The advantage to this approach is that by tapping into this source of energy, the body would not be taxed for additional metabolic energy. Many energy harvesting methods which use "spent" energy, are actually absorbing energy that would otherwise be stored in muscles and tendons, forcing the body to consume more metabolic energy in the long run.

While researching the prior-art, Professor Max Donelan's research at Simon Frasier University was discovered (Li et al., 2008). Professor Donelan's lab has spent the last couple of years designing an energy harvesting unit to convert the negative work performed on the human knee joint during swing phase with minimal additional energy provided by the user. A CAD model of his solution, which uses a clutch, gearbox, and DC motor is pictured in Figure 17**.** This appeared to be the perfect solution for our particular problem.

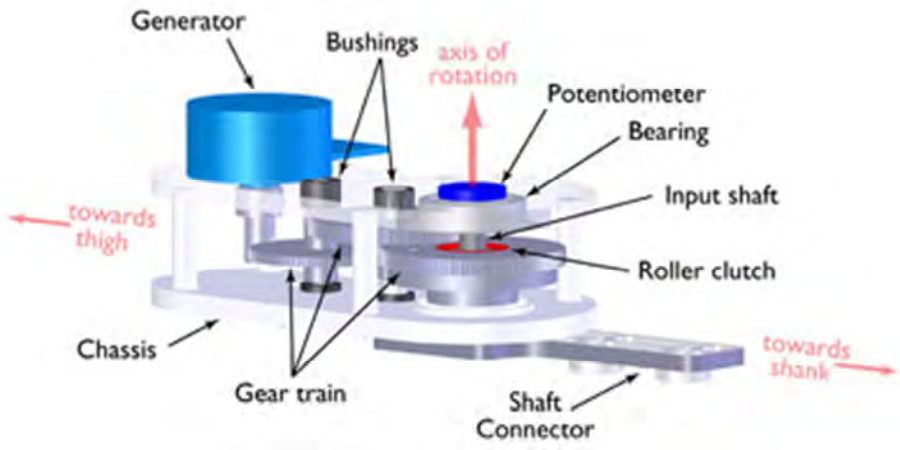

Figure 17: CAD model of a mechanical to electrical energy harvesting system (Li et al., 2008).

4.3.1 Determination of Feasibility for Use by PWTA

We hypothesize that if the damping in the C-Leg was made minimal through its control circuitry, it would be possible to slow the movement of the lower leg during swing phase with an energy harvesting unit similar to that designed by Donelan and his team. This unit would then convert the mechanical energy exerted in slowing the prosthetic lower leg into electrical energy through a brushless DC motor.

Special note should be made that the C-Leg and similar microprocessor-controlled prosthetic knees are capable of variable damping in order to adjust and control the gait cycle depending on the desired step frequency of the user (Johansson et al., 2005). This solution would be capable of adjusting the damping during swing phase by controlling the quantity and frequency of energy harvesting. The methods by which this could be done are addressed later in this chapter.

In order to determine the practicality of harvesting energy from lower-limb prostheses, the amount of energy expended during swing phase by the average C-Leg user as well as the total number of steps taken per day by the average person with a unilateral transfemoral amputation had to be determined. Fortunately, researchers at the Northwestern University Prosthetics-Orthotics Center had recently performed a study on a C-Leg user in their Motion Analysis Laboratory. While the original purpose of this research was not to study the energy profile of the knee, the de-identified data was available. The results of this data are shown in Table 6**.**

This data led to the belief that even with only 25% of the mechanical energy being converted to electrical energy it would take less than 2200 total steps each day to fully charge the Li-ion battery used in the Ohio Willow Wood LimbLogic VS (at 50 steps/minute). Additionally, anecdotal reports have led to the belief that only half of this battery would need charging daily, decreasing the necessary walking time to fewer than 1100 steps/day with the prosthesis.

Table 6: Gait Analysis Results of Energy Expended in C-Leg During Swing Phase

Knee Flexion in C-Leg		Battery Characteristics	
Peak Torque (Nm)	20.31	Voltage	3.7
Max Velocity (rpm)	-84.48	Amperage (mAh)	550
Energy (mWh/step)	3.74	Energy (Wh)	2.04
25% Harvest	0.93	Time To Charge (min)	43.55
Wattage at 50 steps/min	2.80	**Steps to Charge**	**2177**

These data were compared to research previously published with regards to the total energy expenditure during swing phase in a C-Leg (Johansson et al., 2005). After making additional calculations with the published data a result of 1.4 mWh/step was obtained, averaged from four

C-leg users. Even with this reduced energy exertion a user would be able to achieve the necessary charge with less than 2900 steps/day.

Additional research was performed with regard to the number of steps taken per day by persons with transfemoral amputations. Data presented in multiple papers (Parker et al., 2010; Stepien et al., 2007; Hafner et al., 2007) suggests that anywhere from 1763 to 3145 steps are taken each day with the prosthetic leg alone (10,000 total steps/day are recommended for the healthy adult population (Schuch et al., 1999)). At the low range estimate of 1.4 mWh/step and an energy harvester with a mechanical to electrical efficiency of only 25%, 2850 steps are required each day to charge the Li-ion battery to the necessary level. Considering these conservative estimates (Donelan's energy harvester had an efficiency of 56%), this energy harvesting approach is feasible, particularly in the highly active population.

4.3.2 Principles of Design

The prototype which was constructed (Figure 18) was based upon Professor Donelan's design. The design included a one-way clutch, an encoder, a gear box, and a brushless DC motor. The purpose of the clutch and potentiometer was to ensure the harvester only activates during knee extension and for angular position and velocity measurement, respectively. The kinematics of the knee are naturally low velocity and high torque, while maximum efficiency of DC motors are at high velocity and low torque. The gear box was incorporated to perform this conversion in order to achieve the highest possible efficiency of the DC motor.

The knee joint provides a large amount of power during swing phase. This mechanical power can be calculated from the product of the knee's angular velocity and torque:

$$P_k = \omega_k \times M_k \qquad (2)$$

The energy harvester then amplifies the angular velocity by putting it through a gear box, producing a lower torque and higher velocity output. This new angular velocity is then the speed at which the generator spins. The generated voltage is then calculated by the equation:

$$V = K_g \times \omega_g \qquad (3)$$

Here, K_g is the back electromotive force (EMF) constant of the generator. This value gives the voltage per unit of rotational velocity and is the inverse of the speed constant of the motor. The power produced by the generator and the torque it provides in response is then a function of the generator resistance (R_g) and the external load resistance (R_l), in addition to the gearing ratio (r_t) and the speed constant. Equations 4-8 show how these values relate to the energy dissipation, current, torque output, generator efficiency, and total efficiency, respectively.

$$E = IR_g + IR_l \qquad (4)$$

$$I = \frac{K_g r_t}{R_g + R_l} \omega_k \qquad (5)$$

$$\tau_r = \frac{{r_t}^2}{n_t} \frac{{K_g}^2}{R_g + R_l} \omega_k \qquad (6)$$

$$n_g = \frac{R_l}{R_g + R_l} \qquad (7)$$

$$n = n_t n_g \qquad (8)$$

4.3.3 Mechanical Design of the Biomechanical Energy Harvester

The ideal design of the harvester would maximize the power output and total efficiency, and minimize the mass, all while dynamically controlling the torque output of the system. The key components responsible for achieving these goals were the gear box and the generator. Here, losses to friction, the speed constant, and the resistance of the motor were the primary concerns. The final mechanical design of the harvester can be seen in Figure 18**.**

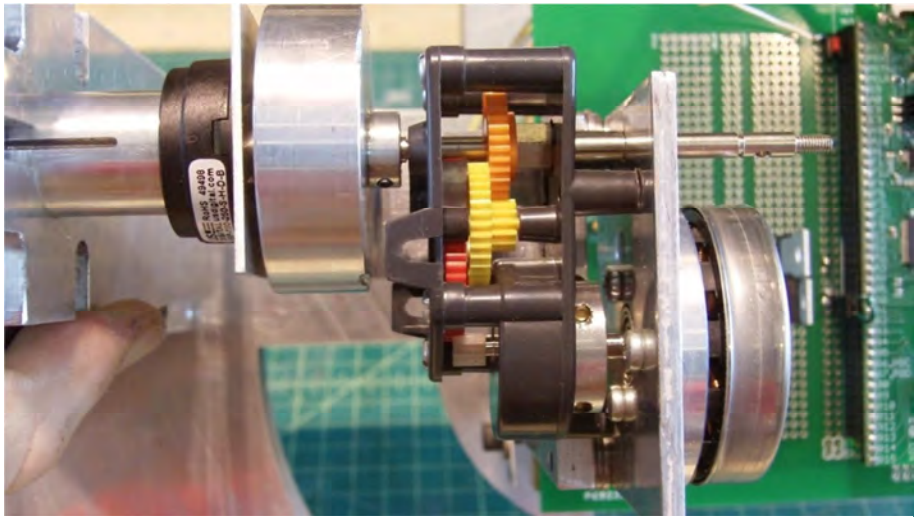

Figure 18: Final prototype of the energy harvester, from left to right: encoder, clutch housing, gearbox, and DC motor.

Arguably the most important component of the harvester was the DC motor, which would act as a generator. After performing research on small motor efficiencies and consulting with Professor Donelan, a motor manufactured by Maxon Motors (Fall River, MA) was selected. This decision was made primarily on the basis of its light weight, low speed constant, and low terminal resistance. There is a trade-off between these factors as the speed constant of a motor typically goes down with increasing weight. The motor selected had a speed constant of 285rpm/V, a terminal resistance of R_g = 1.03Ω, and a mass of 110g.

Gear boxes usually have high energy losses due to friction between gear teeth. Typically, the higher the gearing ratio of the gear box, the higher the frictional losses, which presented another tradeoff in our design. Unfortunately, the limited budget available for this research prohibited the purchase of a custom gear box or a high efficiency gear box. As such, an inexpensive plastic gear box was selected in order to perform a general proof-of-concept. The materials and mechanical construction of this gear box prevented achieving as high a gear ratio as desired due to the high torques present at the input to the gear box. This was because the combination of weak mounting of the gears and the plastic material they were made of caused the teeth to skip at these high torques. A gearing ratio of 47.1:1 was eventually selected.

The clutch was another potential source of mechanical energy loss. A large one-way bearing manufactured by Boca Bearing (Delray Beach, FL) was chosen. While the weight and size of this bearing were prohibitive, it was the only bearing found capable of the high torques produced at the knee joint. While there are small electric clutches on the market which would allow for higher torque inputs and variable clutching (allowing us to completely disengage the energy harvester when desired), these clutches require significant energy inputs. Due to the minimal amount of energy available for harvesting in the first place, it seemed impractical to waste energy on an electric clutch.

Joining all of these components together without allowing any slipping due to high torques as well as minimizing misalignment which may cause additional friction proved to be one of the biggest challenges. **Figure 19** shows an image of the final prototype with circuit board. However, this image shows more than just the energy harvester. Also included in this image are the test bed in which the energy harvester was mounted as well as the control circuitry responsible for manipulating both the harvester and test bed.

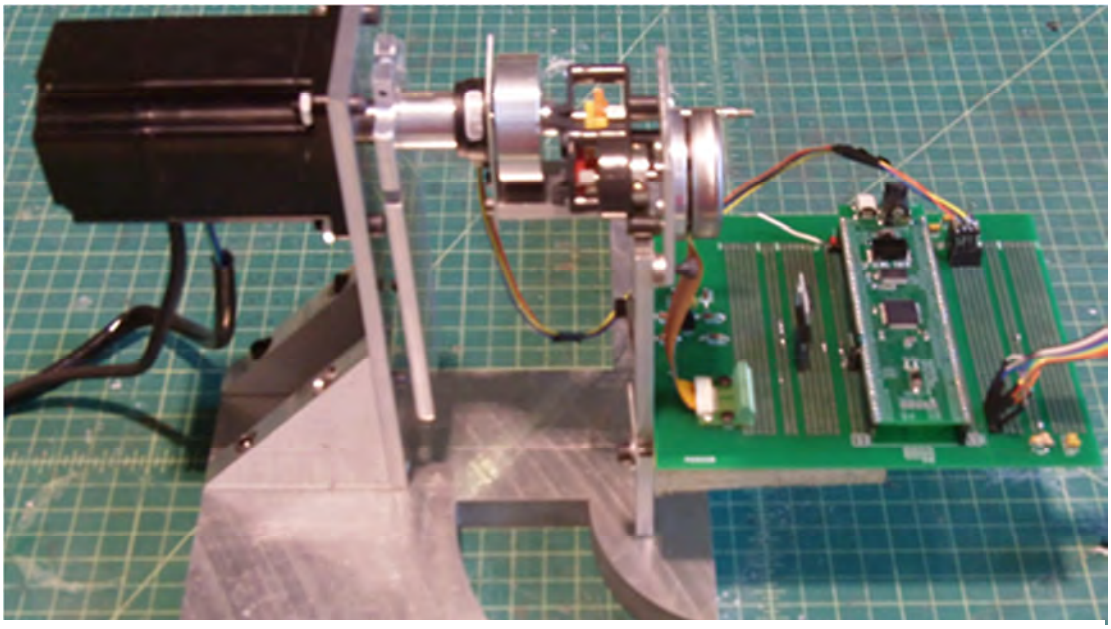

Figure 19: Full view of the final energy harvester prototype, from left to right: Yaskawa motor, pendulum, energy harvesting unit, and control circuitry.

4.3.4 Test Bed Construction and Electrical Design

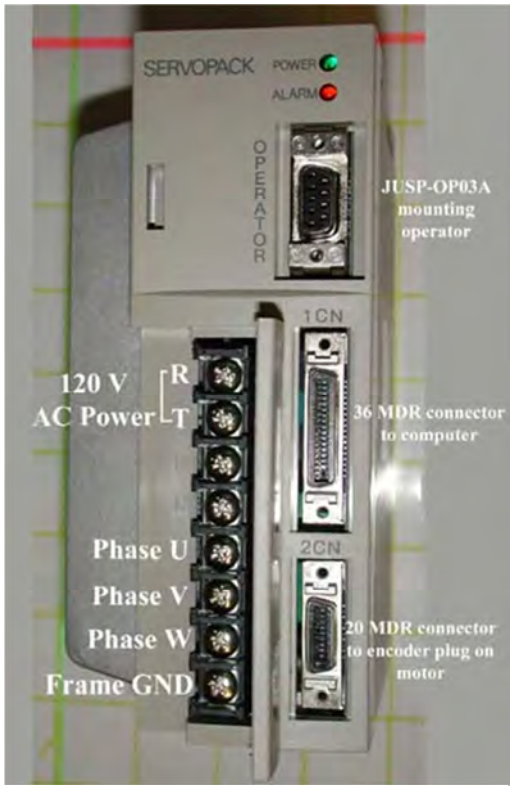

Figure 20: The Yaskawa SGD-02BS Servopack.

The test bed consisted of a drive motor (separate from the harvesting motor mentioned previously) and a swinging pendulum to simulate the knee joint and lower leg, respectively. The motor used to drive the system was the Yaskawa SGM-02B312 motor (100V, 200W) and works together with the Yaskawa Servopack (pictured in Figure 20) which acts as a controller/amplifier. The SGD-02BS works in either velocity or torque control modes. The value of the desired velocity or torque can be set by providing a reference voltage to two pins on the servopack (one acts as the 0V reference, the other as the velocity reference). The servopack then multiplies this voltage by a value set with a detachable operator to obtain the targeted velocity. This analog voltage reference was provided via two of the pulse width modulation (PWM) pins available on the NU32v2 (the microprocessor and related circuitry used on the project pictured in the center of Figure 21). This PWM signal was then run through a low pass filter to produce a smooth analog voltage. The reason for the two analog voltage references as opposed to one was to provide multi-directional velocities to the servopack. This was accomplished by alternating the positive analog voltage output between the 0V reference and the velocity reference. This gave the motor the impression that it was receiving a negative voltage reference even though the NU32v2 is not capable of producing a negative analog voltage output via PWM.

The voltage values sent to the servopack were designed to simulate the gait cycle of the lower leg. This was accomplished by continuously measuring the position of the "leg" with an encoder. The PWM controller then used this information to drive the "leg" within certain angular bounds, specifically from 60 degrees (the approximate value of full flexion with the C-Leg during gait (Hafner et al., 2007)) to 0 degrees (full extension).

The energy harvested was drawn from each of the 3 motor windings of the Maxon motor. DC motors operate by running a current through multiple windings surrounding a magnetic core. Rotation occurs as this current is sequentially alternated between the different windings. When driven mechanically, DC motors produce a current which alternates between the windings. The Maxon motor used for our energy harvester had 3 separate windings, similar to the motor internals illustrated in **Figure 22**. In order to harness the current flowing between the windings in either direction we designed a circuit consisting of a system of diodes, including a capacitor for storing energy, and a resistor to dissipate the energy (to simulate the Li-ion battery). This circuit ensured that no matter which windings current flowed between, the current had to flow through the capacitor, thus charging it.

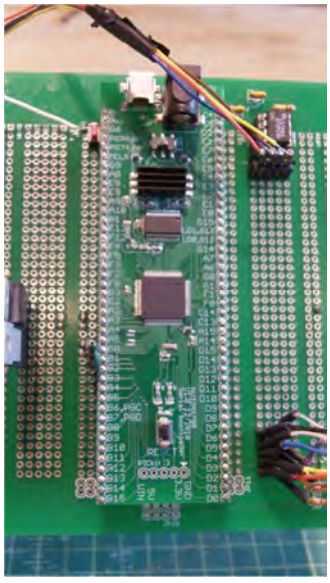

Figure 21: The control circuitry with NU32v2 at center and encoder circuit in the upper right.

Two vital components for controlling the charging and discharging of the capacitor were the MOSFET transistors. A MOSFET is an electrically controlled switch, which allows current to flow through it or not based on a digital signal. One MOSFET was placed between one set of diodes and the capacitor, allowing the generator to either charge the capacitor, or isolate it from the harvesting circuit. The second was placed between the capacitor

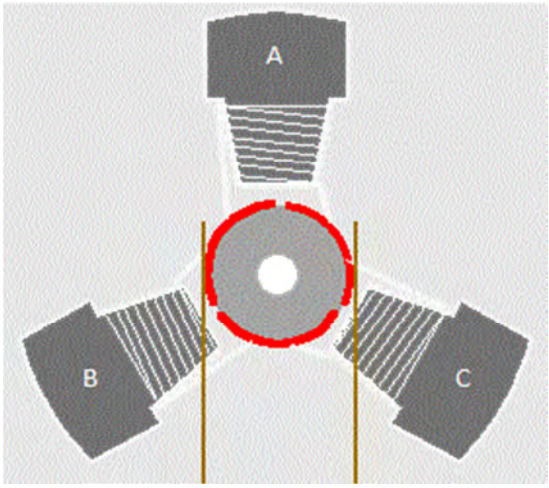

Figure 22: An illustration of the inner workings of a DC motor.

and the resistor, controlling when the energy from the capacitor was “dumped” across the resistor.

The MOSFETs were controlled by two digital outputs from the NU32v2, allowing the controller to open and close the circuits rapidly. This made it possible to dynamically control the energy harvested as well as alter the output torque of the system. The lowest torque is provided when both MOSFETs are open, allowing no current to go through the harvesting circuitry. The highest torque occurred when both were closed, and all the electrical energy provided by the motor was immediately dissipated in the resistor. It may also be possible to achieve intermittent torque values by rapidly opening and closing the MOSFET circuits, similar to how motors are controlled with pulse width modulation (PWM).

4.3.5 Methods of Measuring the Energy Harvested and Related Results

The angular position and voltage across the capacitor (measured using one of the analog to digital conversion pins on the NU32v2) were viewed using a Processing program written by Nick Marchuk. This allowed for the visualization of the rise in voltage as the knee moved from fully flexed to fully extended. While this enabled the viewing and calculation of the voltage (and therefore the energy) produced by the harvester, there were no means available to measure the torque input provided by the Yaskawa motor. Without this information it was not possible to calculate the mechanical energy input. To calculate this, the driving motor was detached from the system, and a small mass was attached to the end of the pendulum. Then, with the control

circuitry still operating regularly, the mass and pendulum were dropped from a position near full flexion, and recorded the output voltage. This test was performed 5 times.

The mechanical energy was calculated by simple geometry and physics. The potential energy of the mass (including the mass of the pendulum) at initial position relative to its potential energy at its final position were equivalent to the mechanical energy input. This value was calculated with the initial and final angles of the pendulum, also recorded with the Processing program. We omitted air resistance and assumed the acceleration due to gravity to be that at sea level. The electrical energy was calculated by the voltage across the capacitor and its capacitance. With these two values we were able to approximate the conversion efficiency of our energy harvesting unit. *We calculated this value to be 16.25%.*

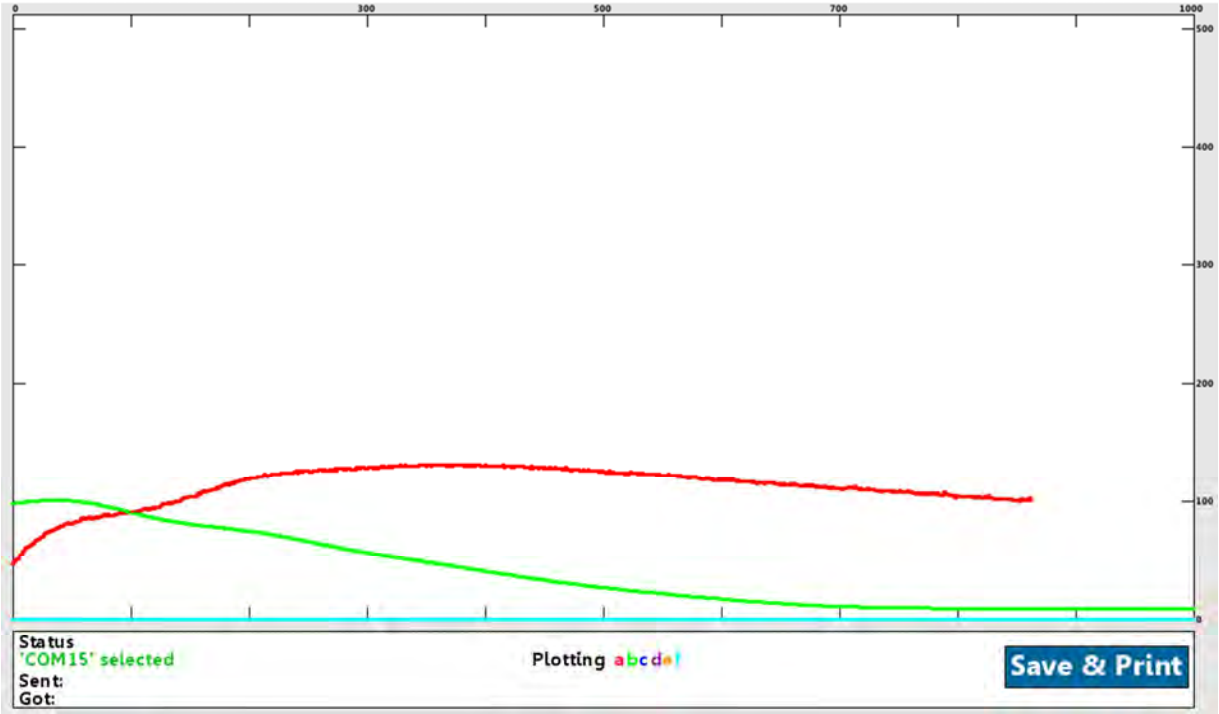

Figure 23: A plot of the angular “leg position” and voltage across the capacitor. The angle is in green with its value multiplied by 2 for viewing and the voltage is in red and measured in hundredths of a Volt

4.3.6 Discussion of the Results and Potential Applicability

The efficiency of the system is considerably less than the targeted efficiency of 25%. One major reason for this is the quality of the gear box. With a higher quality gearbox there would be smaller losses due to friction and it would be possible to achieve a higher gearing ratio without the gear teeth slipping. Additionally, a lot of energy was needlessly lost due to the control circuitry. As shown in Figure 23, the voltage (the red line) begins to dissipate before it is dumped (which occurs so rapidly that no data was captured during this period). This could be remedied in multiple ways. One possible solution is to perform multiple “dumps” during each step, so that when the capacitor reached some threshold voltage, the energy would quickly be dumped and the capacitor charging would resume. Another solution would be to use a larger capacitor. This would increase the storage capacity of the system and likely minimize losses.

In order for an energy harvesting unit to replace the swing phase damping of a microprocessor controlled knee it must be capable of providing dynamic torque to the knee joint. This may be possible through rapid adjustment of the MOSFETs. By doing this it is possible to switch rapidly between the largest possible torque when the motor is fully shorted, to the lowest possible torque when the circuit is open. Intermediate values would then be achieved much as an analog voltage is from a PWM signal. At a high enough frequency the changes in mechanical resistance should be indistinguishable from a constant value.

The total energy harvested would be dependent upon the amount of torque provided by the knee, to the harvester. So, the more the circuit was opened to allow freer motion, the less energy would be harvested. This could pose issues if the user is dissipating a small amount of energy in the knee joint during ambulation as the harvester may not be able to meet the energy requirements of the battery.

The energy conversion efficiency of the motor will also limit its real world applicability. The changes mentioned in the results section should be implemented to attempt to get this efficiency to about 25%. The higher the conversion efficiency achieved the fewer steps will be required by the user to provide adequate charge to their battery. The fewer steps that are required by the user the larger the population base which can benefit from this technology, although it is likely that military users would dissipate enough energy in a given day to fully charge the battery.

4.4 Pump Design Conclusions

The conclusions reached from chapters 2 and 3 and listed in Table 5, along with user observations helped to guide the design process and led to 2 desings. The first design examined was that of a hybrid electric/mechanical pump. This design has the advantages of both its electrical and mechanical components, with few of their disadvantages. It is capable of quickly evacuating the socket with no user movement required, meaning that the user never has to experience walking without vacuum assisted suspension. Then, after evacuation, vacuum can be maintained with the mechanical system. This allows for the electrical system to retain its charge for cases of emergency use. The one disadvantage to this design is that it still requires a fairly significant vertical envelop, effectively limiting its users.

The other design that was looked at was an energy harvester for use on the prosthetic knee. This energy harvester would convert the mechanical energy dissipated during swing phase of the prosthetic leg into electrical energy for the use of a commercially available electric vacuum pump. It was proven that there is enough energy naturally dissipated by the C-Leg to be converted into enough energy to charge the Li-ion battery used in the LimbLogic pump. A simple energy harvester was then constructed and its basic functionality was proven. While the targeted energy efficiency of 25% was not reached, it is believe that several modifications to the

design such as a higher efficiency gear box and better control algorithms would enable this threshold to be surpassed. The advantage to this design is that it eliminates the one major disadvantage to using electric vacuum pumps, the need for external sources of electric power. The key challenge to this design is the need to dynamically regulate the mechanical resistance of the knee during swing phase in the same way that the C-Leg already does.

Both designs have their advantages and disadvantages and will require much more work before either can be tested by human users. However, we have suggested two potential designs which show promise in enabling soldiers with transfemoral amputations to return to active duty.

CHAPTER 5: CONCLUSIONS

In the previous chapters the functioning of several commercially available vacuum pumps was explored through bench-top testing. We then applied what we learned about the electric vacuum pumps to enable us to determine users average socket/liner interface volume and to study the variance in vacuum pressure as well as the rate of vacuum decay during ambulation. Finally, we applied the knowledge gained from both the bench-top and human subject testing towards designing an adequate vacuum pump for use by military personnel. Table 7 summarizes the objectives, contributions and future work of the project.

Table 7: Objectives, Contributions and Future Work

Objective	Contribution	Future Work
Characterize the Mechanical and Electrical Vacuum Pumps Currently Available	Calculated the vacuum powers of the 5 most commonly used vacuum pumps and determined a relation for each pump between time to evacuation and volume evacuated	Construction of an automated test for the mechanical pumps in order to eliminate the uncertainty present in human actuated testing
Study the Interaction Between the Socket/Liner Interface and Vacuum Pump, Specifically the Volume and Rate of Vacuum Decay	Discovered the average volume of the socket/liner interface, showed that the rate of vacuum decay may be dependent upon the vacuum pump used	Perform additional treadmill testing to confirm or disprove the hypothesis that the rate of vacuum decay is pump dependent and to determine the cause of the "S" shaped curves present in human subject testing
Design a Vacuum Pump System Capable of Meeting the Needs of an Active Duty Soldier	Suggested and created prototypes for two separate designs, both of which meet the desired requirments	Further pursue the testing and development of both vacuum pump systems

Through bench-top testing we improved our understanding of the functioning of electric and mechanical vacuum pump systems. *We were able to determine the power level of each in Watts in order to more easily compare them to one another*. While this value for power output is dependent on the power input of the pumps, if we assume that the power inputs of the pumps are the same (as was the approximate case for both the electrical and mechanical pumps, respectively), these results still tell us a lot about the efficiencies of each pump. Of the electric pumps *the Ohio Willow Wood LimbLogic VS was found to be nearly 50% more powerful than the Otto Bock Harmony e-Pulse*. Among the mechanical pumps the Otto Bock P3 had by far the fastest rate of evacuation, although there were some inconsistencies among the different functional rings used. We concluded by determining a method with which to accurately judge the volume of the socket/liner interface worn by persons with transfemoral amputation by evacuating with the electric pumps and comparing to the results obtained on chambers of known volume. While the electrical pump tests were made as accurate as possible, the mechanical pump tests may have been limited by human error. Correcting this, as well as the discrepancies between the P3 functional rings, will require an automated test bed. This will eliminate the possibility of significant variance between strokes and ensure that each pump was tested in exactly the same way.

We found the volume of the socket/liner interface to vary widely between users with a range of nearly 10 in^3. Additionally, two distinct shapes were noticed in the vacuum pressure versus time curves among users. Specifically, several of the users had distinct “S” shaped curves in which the rate of evacuation started slow and then rapidly accelerated. It is believed that this discrepancy is due to a change in volume which occurs in some users sockets after the socket has been brought to atmospheric pressure. The exact cause of this still remains to be proven and will require additional testing. Even with this issue, *we confirmed our hypothesis that*

the average user volume was approximately 6 in^3, determining that the average volume was in fact 6.14 in^3. We also took a look at vacuum pressure variation over time and from step to step during ambulation. While only 5 users participated in this testing we saw large variability from user to user. One interesting realization was that the rate of vacuum pressure decay during ambulation may be dependent on the vacuum pump used. Specifically the Ohio Willow Wood LimbLogic pump lost vacuum at a rate 36% greater than the Otto Bock Harmony e-Pulse. However, several of the individuals tested showed roughly equal vacuum decay with both pumps, so additional testing should be performed before these results can be confirmed.

The information gathered with the first two studies led us to pursue two different vacuum pump designs: a mechanical/electric hybrid pump and a biomechanical energy harvester for use with a purely electrical system. The hybrid pump utilizes components from the most successful mechanical and electric pumps, the P3 and the LimbLogic. *So far two prototypes (an original and an improved version) have been manufactured.* However, the mechanical and electrical components still remain to be integrated into the system. Most importantly, this involves the design of a new functional ring, based on the same principals of the P3 functional ring, but designed to fit our pump. Once both systems have been integrated into the design we will be able to pursue testing.

The energy harvester works by converting the energy naturally lost in the knee joint to slow down the lower leg at the end of swing phase into electrical energy. During the design process *we proved that typical C-Leg users exert enough energy while walking in an average day to charge a Li-ion battery, as well as proved the design concept.* However, there still remains a large amount of work before the design can be implemented. For one thing, the conversion efficiency was found to be only 16%. It should be possible to improve this to reach

nearly 50%, greatly increasing the usefulness of the system. Additionally, the advantage of micro-processor controlled knees such as the C-Leg is their ability to dynamically alter the torque in the knee during swing phase to match the gait of the user. It is theoretically possible to do this with our energy harvester by rapidly activating and deactivating the energy harvester to provide intermediate torque values. This still remains to be tested.

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APPENDIX A: PRODUCT DESIGN SPECIFICATIONS

The military transfemoral amputee has several important requirements for the vacuum system. Referenced in Chapter 4.

PERFORMANCE

- Will allow user to set a preferred amount of suction between 15 -20 inches mercury for a comfortable and secure prosthetic fit
- Will allow users to readjust pressure when necessary
- Device will reach desired pressure in considerably less than 50 steps
- Device will operate below 40 decibels (ambient noise level) while in the field
- Device will maintain stability in use

POWER REQUIREMENTS

- Like current electrical pumps, the device will be designed to operate for over two days without the use of a wall outlet or battery replacement
- An electric device will operate with a 12 Volt battery or smaller

SIZE

- For inline above-knee pumps, the vertical height of the device will be less than 1.5 inches
- For other pumps, the device will remain inside the profile of a typical leg

SAFETY

- Device will be designed to avoid loose cords or wires that could catch, disabling prosthetic pressure or use
- Device will maintain pressure at acceptable level, even if out of power

ERGONOMICS

- Device should be easy to access and use and therefore will not cause the user any physical discomfort or stress
- Device will be easy to install by the user
- Device will minimize user maintenance and cleaning

DURABILITY/LIFESPAN

- Device will be used for military application and thus will be waterproof, sand-proof, and generally weather and corrosion resistant
- At least 2 years for non-replaceable components
- At least 6-12 months for replaceable components

PATENTS

- Device cannot infringe on any existing American or European patents

COST

- Will be less than $3,000

WEIGHT

- The mass of the prosthetic leg with device included will not exceed the mass of the matching limb. The device will not exceed 5 pounds.

CUSTOMERS

- Trans-femoral amputees

MANUFACTURING

- Prototype will be produced at Ford Design Shop
- Looks-like prototype will be produced in Ford Rapid Prototyping Lab

APPENDIX B: USER INTERVIEW SUMMARY

ME 398: User Observation Visit and Interview Summary referenced in Chapter 4.

Users

Subject (sb) 1: *Trans-femoral amputee. Professional contractor with excellent insurance. Athletic and has a physically demanding job. Has tried everything and is Ryan's main test subject for new prosthetic technologies.*

Subject 2: *Retired. Trans-tibial amputee. Body is not in great shape: missing the toes on his right foot. Walks a mile a day inside his apartment building. Has used a Harmony P2 in the past and now uses a LimbLogic electric pump. Was part of beta testing for the LimbLogic.*

Subject 3: *Polish Olympic skier. Bilateral trans-tibial amputee. Traumatic injury caused his amputations and he has severe heterotropic ossification on his left residual limb. Currently uses two LimbLogics. Irritation to his left residual limb causes dramatic injury and bleeding.*

Question & Answers

User Questions:

- How long have you been using a vacuum pump?
    - What kinds of pumps have you used? Which do you prefer? Why?

  Users preferred the electric vacuum pump in most cases. Either e-pulse or LimbLogic. (sb1/ sb2) because it works. They don't have to charge it more than once a day and it does what it's supposed to. LimbLogic can last up to four days with constant use (sb3). sb2 has used the LimbLogic pump for several years and in one day he sees one of four battery indicators turn off. It takes about two hours to recharge that one battery indicator. sb2 used to use the Harmony P2 mechanical pump and he found that to be as functional as the LimbLogic he's using now. However, the poor battery life on his previous electric pump caused him a great deal of discomfort. sb2 has other issues besides the pump that he thinks need to be addressed.

- Do they want hybrid, or is that too much effort?

  They weren't against it, but for some people, mechanical is not an option. For soldiers that's debatable, but we have to consider times when they might lose pressure and not be moving around (sb1). For sb3, mechanical is not an option, but according to Ryan, a mechanical solution would still help a very large number of people. Situations where a mechanical pump won't maintain pressure that is notable: extended sitting or kneeling, lying down or crawling.

- Is a hand pump better than a step activated pump?

  sb1 said he could get used to it, but he really likes just having to push a button. sb1 says that amputees will do whatever they have to do, but it's better if it's easier.

- How often do you exercise?

  sb1: Exercises regularly (runs) several times a week, is active in his job as a building contractor.

  sb3: Olympic athlete, exercises 6-8 hours a day while in training.

- Is there ever a noticeable change in vacuum pressure while exercising/has your prosthesis ever fallen off?

  Usually pressure is all the way up for sb1 (18-20mmHg), and with the electrical pumps this isn't necessarily an issue because they maintain the vacuum pressure, but yes some pressure is lost. Sitting the vacuum re-pumps about once or twice an hour for 10-15 seconds (sb1). That being said, if anything does go wrong, it's immediately noticeable and can have a big effect quickly.

- If vacuum was lost, would the prosthesis still function? How long would it be able to function?

  It will stay on but it is almost immediately uncomfortable. Function goes out the window as soon as comfort is lost and that is right after the pressure is lost. Ability to function also varies based on the user. A user with heterotropic ossification will risk damaging the residual limb and pain/damage can occur immediately after device fails.

- Would this kind of pump (above-knee mechanical) affect your range of motion for your prosthetic?

  Yes, when the knee is completely bent, there is not space behind it to have anything or else motion will be impeded. A redesign that considers this was taken positively.

Questions for Ryan:

- How big can a prosthetic mold be to accompany an electrical device?

  There's enough space to bring out the mold to accommodate an electric pump above the knee. However, this may make knee placement awkward if the residual limb is very long. Ryan seemed to believe a solution like this can still help a large number of people.

- When making prosthetic molds how much do you have to consider the motion of the leg? Is this something we'd need to consider for an above-knee device?

  Must allow it to bend back to less than a right angle (think kneeling). Yes, it became clear that we might need to alter our design to a D or crescent shape. Sitting on a chair is also a constraint that the shape of the pump faces.

- Is there a standard connection between the prosthetic socket and the knee joint? Could this connection be modified to include a one-way valve?

  There are different connections (e-pulse/P3 tubing versus LimbLogic), but mostly this is just a hole or a tube in a hole. Yes, it seems like this connection point could incorporate a 1 way valve.

- Would a hand pump above or below knee be too much human interaction?

  It's something that could be learned or something someone could get used to, but it was pretty clear that the interaction with the user should be minimal. It seemed like sb1 really liked that he didn't have to do more than touch a button.

- What do the tubing connections for current pumps look like? How are they connected to the socket of the prosthesis?

  It's basically just a tube going into the socket, pretty simple, just need to make sure it is sealed. There is a plastic protective cover on the "tibial" area of the C-leg. The tubing was stuffed inside this empty space and was almost completely out of the way.

- What did you have in mind with the in-mold pump?

  Ryan explained that there is some space that we can play with at the bottom of the mold where the plate that connects to the knee joint is located. Ryan also indicated that mounting a pump in the wall of the mold could be a feasible option. He noted that only the inside of the leg has structural support for mounting a pump. Something to consider is that an embedded pump may be more difficult to service--we would need to remain detachable.

- Because of the cost requirements and added gear, is energy harvesting something we are really interested in pursuing?

  Energy harvesting is still on the table but we are still concerned about impeding the motion of the knee or having a heel that harvests, but that is not comfortable when walking.

<u>Important notes/ Personal Reflections:</u>

Some people cannot use mechanical solutions; they need immediate pressure before walking. This means we have to drastically revamp our design decision matrix. In the team's opinion, this might mean developing more than one solution to the problem or at least mandating an electrical component.

We found it interesting that sb1 said he adapted to whatever system he needed as long as it worked. This gives us some leeway in terms of how much user interaction we can require.

We have a half inch or an inch of space to work with at the bottom of the prosthetic mold.

We should investigate how the LimbLogic is able to produce so much more battery life. The direct pump connection of the LimbLogic was a great benefit, since there is not any tubing there.

We learned that different people have different needs and that it may be impossible to find a solution that is perfect for every case. We should not consider extreme users part of our scope. Any person with overly intense conditions will not be sent back into the field (we should remember the intended user is military). That being said, we need to consider the function of our design in every way it will be used by a soldier.

APPENDIX C: LABVIEW DAQ PROCEDURE

A general research for those wishing to continue or reproduce aforementioned research using the same or similar equipment.

EQUIPMENT

- Computer with Labview 7.1 or newer installed
    - DigiVac Reader.vi, Labview Virtual Interface Program
- DigiVac Digital Vacuum Pressure Guage model 2L760
    - Power Cord
    - Serial-to-USB Cord
    - Serial-to-Vacuum Tubing Cord
    - Vacuum Tubing with “T” joint

PROCEDURE

1 Obtain and lay out all equipment
2 Plug in power cords for both the laptop and vacuum gauge
3 Laptop Set-up
    a. Turn on the laptop
    b. Log in as the “NUPRL” user
    c. The password is “nuprl”
4 Opening Labview
    a. Once logged in open the “Test Data” folder in the upper right hand cordern of the desktop
    b. Double-click the DigiVac Reader.vi program
    c. Image C.1 should appear
5 Setting up Other Equipment
    a. Plug both serial cables into their respective ports in the back of the DigiVac Digital Pressure Gauge
    b. Plug the USB end of the one cable into the upper USB slot in the back of the laptop, this corresponds to COM Port 5
    c. Attach the other end of the pressure gauge line to the shorter of the vacuum tubes attached to the “T” joint
6 Setting up Labview
    a. Now, in the Labivew VI, type the location and name of your output file in the available box the upper right
    b. On the left, change the “VISA resource name” from “COM1” to “COM5”
    c. Also on the left, change the “delay before read (ms)” value from 500 to 915
    d. Toggle the “Write” switch from “On” to “Off”

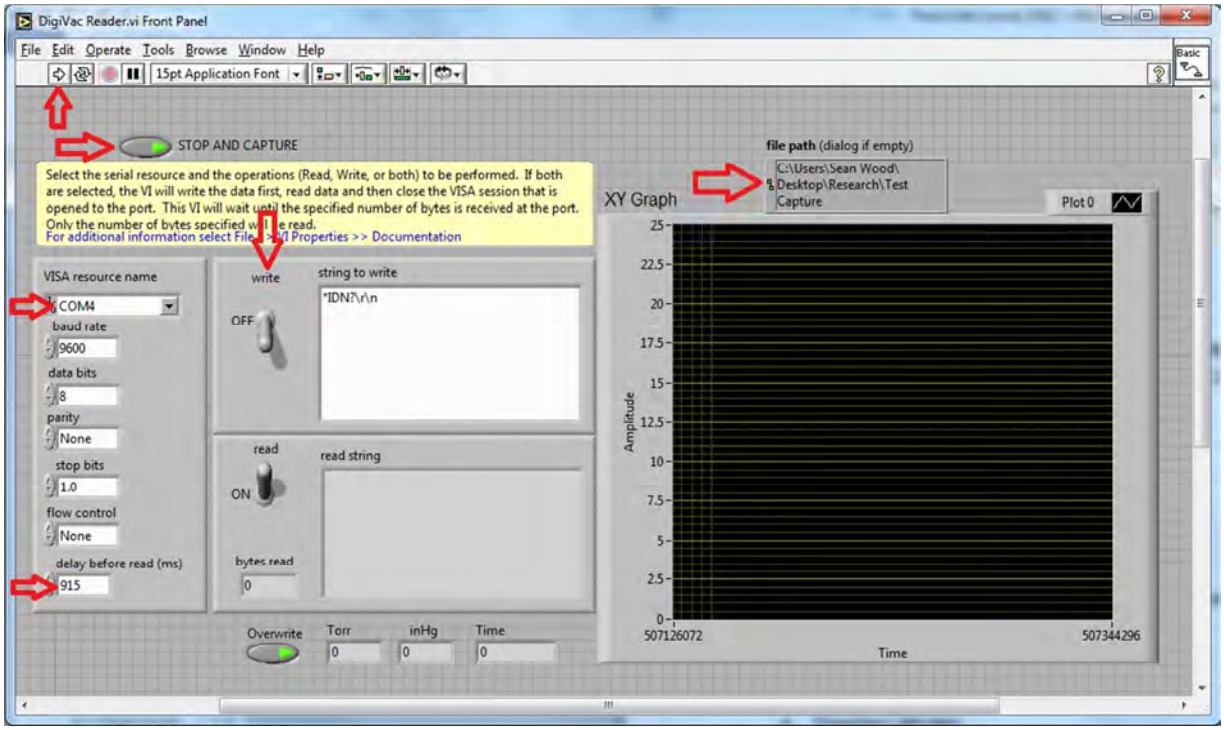

Figure C.1: The DigiVac Reader Labview Virtual Interface

e. Click the “STOP AND CAPTURE” button so the green light on it is not illuminated

7 Capturing Data

a. To capture data just click on the “Run” button located directly under the “Edit” drop down menu and the pressure in inHg will begin to plot on the graph to the right

b. To output this data to the file you listed in the “file path” box, click the “STOP AND CAPTURE” button

8 Clearing the Memory Array and Plot

a. After several captures you may wish to clear the plot and reset the array which holds the captured data

b. To do this you must go into the back end of the VI by double-clicking on the plot

c. This will open a new window containing the components of the VI (Figure C.2)

d. To reset the data you must right click on the Shift Register shown in figure C.2 and select “Replace with Tunnels”

e. After this is done, press CTRL+Z on your keyboard to undo this action

f. Your plot and data should now be reset

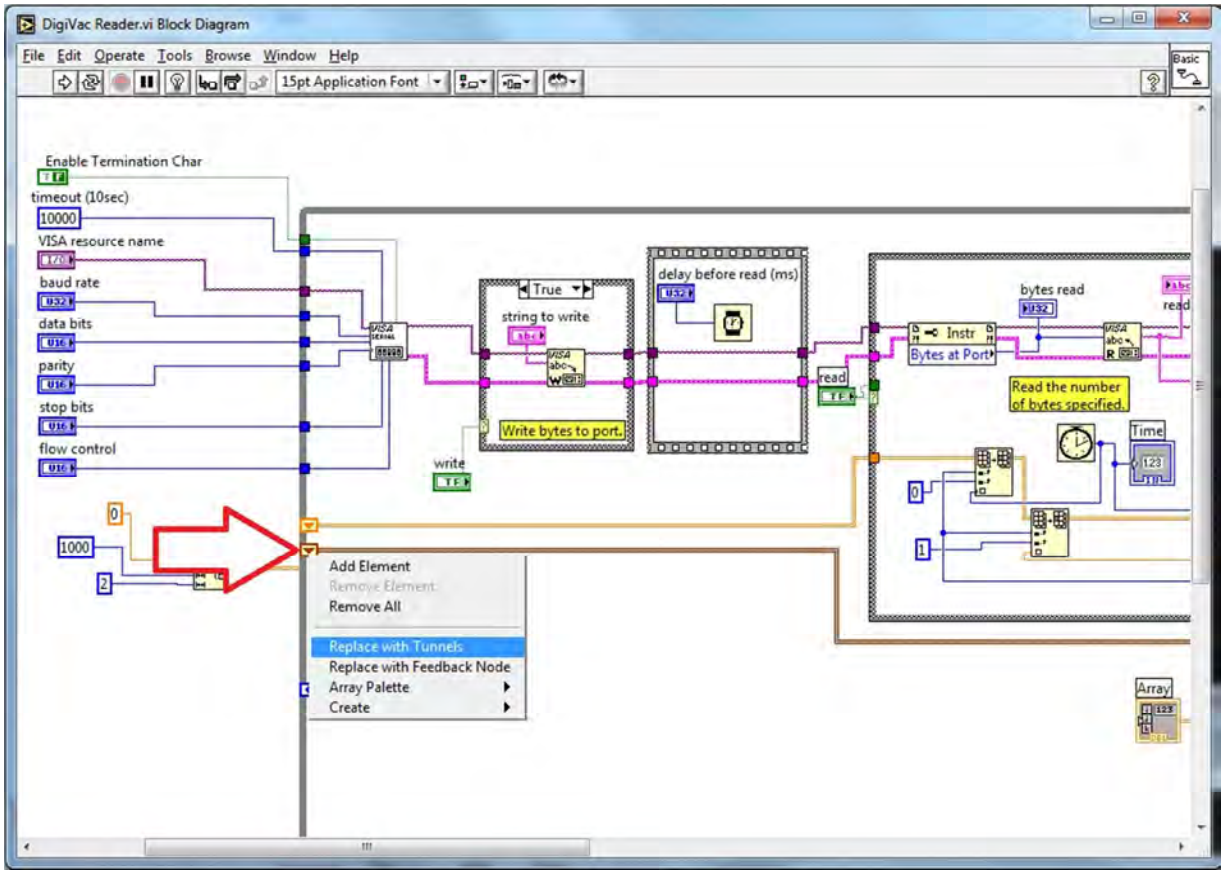

Figure C.2: The Back-End of the DigiVac Reader Labview Virtual Interface

Appendix J

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
61/571,233	06/23/2011		110	2011089		

CONFIRMATION NO. 8762

FILING RECEIPT

Edward J. Timmer
Suite 205
121 East Front Street
Traverse City, MI 49684

Date Mailed: 07/15/2011

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

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If Required, Foreign Filing License Granted: 07/13/2011

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 61/571,233**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****

Title

Hybrid prosthetic vacuum pump

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

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For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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INVENTION TITLE

Hybrid Prosthetic Vacuum Pump for Transfemoral Amputees

INVENTOR(S) INFORMATION

Please place an asterisk next to the primary investigator's name

Please insert your first name, middle initial and last name as it will appear on any patent applications and related documentation.

NAME	SCHOOL	DEPARTMENT	POSITION
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NB PI on the grant funding this work is Stefania Fatone, PhD.

SOURCES OF SUPPORT, RESEARCH SPONSOR AND GRANT NUMBERS All Funding Sources and Grant Numbers must be correct. Please list all digits including zero.		
SOURCE OF FUNDS		**NAME AND GRANT NO.** (if applicable)
Federal Agencies:	* Department of Defense US Army Medical Research and Materiel Command	*W81XWH-10-1-0744 Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations
Foundation:		
Corporate:		
Northwestern University Funds, Facilities:		
Other:		
***SUBCONTRACTOR INFORMATION**	Government agencies require subcontractor information when reporting Federal funding.	
Grant Number:	**Subcontractor Institution:** Henry Jackson Foundation	**Subcontractor DUN or other number:**

DESCRIPTION OF INVENTION: Please provide as attachments
Brief summary stating its novelty and utility (Please attach separately)
Background information: How it works and improvements over existing technologies (Please attach separately)
Detailed description with photographs, drawings, graphs, and relevant manuscripts (Please attach separately)
Expected commercial applications (Please attach separately)

PUBLIC DISCLOSURE		
	WHERE	**DATE**
Journal Article		
Conference Abstract		
Oral Presentation	ME398 class presentation, ITW auditorium, Ford Building, Northwestern University*	3/15/11
Poster Presentation		
Disclosure to Industry		
Grant Proposal	OR090122 Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations	Date contract signed 8/20/10
Other	ME 398 Final Report*	ME 398 Final Report

* Since these two activities were part of a class taken by undergraduate students at Northwestern University we do not believe that they constitute a public disclosure.

DATE AND PLACE WHERE DISCOVERY WAS MADE	
When was the idea conceived?	During proposal writing at Northwestern University 9/25/09 to 11/17/09.
Where and how was it documented?	In the DOD grant proposal and in the students final report.
When was the idea reduced to practice?	

PRIOR ART

Have you done a literature search? ☒ **YES** ☐ **NO**

If yes, include references:

•Beil, T. L. and G. M. Street (2004). "Comparison of interface pressures with pin and suction suspension systems." Journal of Rehabilitation Research and Development 41(6A): 821-828.
•Board, W. J., G. M. Street, et al. (2001). "A comparison of trans-tibial amputee suction and vacuum socket conditions." Prosthetics and Orthotics International 25(3): 202-209.
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•Traballesi, M., T. Averna, et al. (2009). "Trans-tibial prosthesization in large area of residual limb wound: is it possible? A case report." Disability and Rehabilitation. Assistive Technology 4(5):373-5.
•Certificate Program Sub-Atmospheric Suspension Systems: Clinical Applications, Evidence and Reimbursement.
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•Gerschutz, M., J. Denune, et al. (2010). "Elevated Vacuum Suspension Influence on Lower Limb Amputee's Residual Limb Volume at Different Vacuum Pressure Settings." Journal of Prosthetics and Orthotics 22(4):252-256.
•Brunelli, S, Delussu, A, Averna, T and Pellegrini, R (2010). "First Statistical Evidences about the Differences between the Use of an Assisted or Passive Vacuum Socket System in Unhealed Stumps of TT Amputees." 13th ISPO World Congress, Leipzig, Germany, May 10-15, 2010.
•Arndt, B, Caldwell, R, Fatone, S (2011). "Use of a Partial Foot Prosthesis With Vacuum-Assisted Suspension: A Case Study." Journal of Prosthetics and Orthotics, 23(2):82-88.
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With Pin Suspension." Journal of Prosthetics and Orthotics, 23(2):78-81.

What related work in this area by others do you know? These are the relevant findings from a search of the USPTO:

http://appft1.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PG01&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.html&r=1&f=G&l=50&s1=%2220030191539%22.PGNR.&OS=DN/20030191539&RS=DN/20030191539

http://patft.uspto.gov/netacgi/nph-Parser?Sect2=PTO1&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&d=PALL&RefSrch=yes&Query=PN%2F6554868

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COMMERCIALIZATION

Are you aware of potential licensees for this invention?	☒ **YES**	☐ **NO**
If yes, give names of companies and contact persons known to you on a separate sheet		
If no, what industry might have interest in this invention? List on a separate sheet.		
Would you like to develop this invention further with corporate research support?	☒ **YES**	☐ **NO**
Are you willing to participate in the marketing of this invention?	☒ **YES**	☐ **NO**

MATERIALS ASSOCIATED WITH INVENTION	
Did this invention use any Materials which were obtained with a Materials Transfer Agreement from a company or another institution?	☐ YES ☒ NO
If yes, please list the name of the company or institution	
Did you transfer to any researcher outside Northwestern any new Materials (DNA, peptides, cell lines, vectors, catalysts, polymers, alloys, etc.) of this invention?	☐ YES ☒ NO

This disclosure is submitted pursuant to the Northwestern University Patent and Invention Policy and is subject to all the terms of that Policy.
http://www.northwestern.edu/invo/policies/policy_patentafter1999.html
If this invention is accepted by the Innovation and New Venture Office at Northwestern University, I/We hereby agree to execute all necessary documents, assigning to Northwestern our rights in any patent application filed on this invention.

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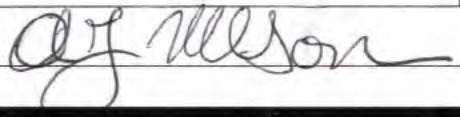
SIGNATURE: 	

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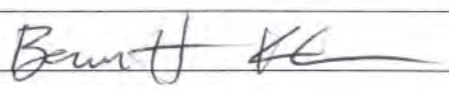
SIGNATURE: 	

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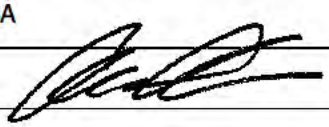
SIGNATURE: 	

DESCRIPTION OF INVENTION: Please provide as attachments

Brief summary stating its novelty and utility:

Pumps currently on the market are either mechanical or electrical. No hybrid pump (combining electrical and mechanical) is available. With the exception of the OWW LimbLogic pump, no other in-line electrical pump is available for use with transfemoral amputees. Our hybrid pump will provide greater function for active amputees who require long-lasting and effective performance from their vacuum-assisted suspension.

Background information: How it works and improvements over existing technologies

Refer to ME398 Final Report.

Detailed description with photographs, drawings, graphs, and relevant manuscripts

Refer to ME398 Final Report.

Expected commercial applications

Pumps currently on the market are either mechanical or electrical:

- Tss II Vaculink mechanical pump http://www.micacorp.com/solutions.php?prod=vaculink
- All Otto Bock Pumps http://www.ottobockus.com/cps/rde/xchg/ob_us_en/hs.xsl/3331.html
- Ohio Willow Wood electric pump http://www.owwco.com/limblogic.php
- Edison electric pump from Orthocare Innovations http://orthocareinnovations.com/pages/edison_trade
- Hand brake bleeding pump http://www.denlorstools.com/home/dt1/page_19431_741/mityvac_mitmv8500_silverline_elite_automotive_hand.html

No hybrid pump (combining electrical and mechanical) is available. We believe that our hybrid pump would make a nice addition to the product lines currently available from either Ohio Willow Wood or Otto Bock.

Potential Licensees

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Appendices

1. ME398 Final Report
2. DOD grant application

SPONSORED BY NORTHWESTERN UNIVERSITY PROSTHETICS AND ORTHOTICS LAB

Prosthetic Vacuum Pump

ME 398 Final Report

Submitted by: Bennett Kuhar, AJ Nelson, Regan Radcliffe, Kevin Yngve
Faculty Supervisor: Wei Chen

3/17/2011

Table of Contents

1. Executive Summary

There are many military amputees that would be willing to serve again if they were able to maintain acceptable physical performance. In the past, prosthetics have been uncomfortable and unreliable, making military service almost impossible. Currently, vacuum pump technology is used to increase comfort by relieving pressure points on the residual limb. By creating a vacuum between the residual limb and the socket of the prosthetic, force will be distributed across the limb and the comfort of the user will be increased.

Current vacuum technology consists of mechanical and electrical pumps. Depending on the length of the residual limb, different users may have different preferences and needs when choosing a pump. There are several advantages and disadvantages to both mechanical and electrical pumps. The electrical pump evacuates quickly, but requires a wall outlet to charge its battery. The mechanical pump uses the walking motion of the user, which allows it to operate without access to electricity. The mechanical pump takes longer than the electric pump to evacuate, and is uncomfortable for some users. Our goal is to design a quiet, compact, and unobtrusive vacuum pump with minimal recharging needs for use in the field by military personnel who have suffered transfemoral amputations.

After research and brainstorming, several conceptual designs were introduced. These designs included electrical, mechanical, and hybrid electromechanical solutions in various locations on the prosthetic leg. From further review and a user interview, the final design was developed. A hybrid design was chosen for its optimal performance and adaptability. This design incorporates both electrical and mechanical pumps, utilizing the strengths of each type of pump and creating a redundant system to avoid many of the individual pump disadvantages. The design consists of a mechanical pump bladder located just below the residual limb and above the knee. This bladder is supplemented by an electrical pump which is stored inside housing located around the mechanical bladder. Both the electrical and mechanical pumps are inline with the leg, and do not require any external tubing. By placing the pump above the knee, many of the hindrances associated with below knee solutions were avoided. In order to prove the effectiveness of our design, several forms of engineering analysis were completed. These include electrical benchmarking, mechanical forecasting, material selection, illustrative FEA, and geometrical analysis. The outcomes of these processes led to important design decisions, such as choosing aluminum and rubber for the pump materials. Through our analysis and industrial design prototype, we proved that our design meets the requirements of the military user.

2. Problem Background

2.1 Client

The Northwestern University Prosthetics Lab is currently working on a Department of Defense sponsored project to improve the use of prosthetic legs for transfemoral amputees. Transfemoral amputees are those who have had a leg amputated above the knee. The prosthetic lab project is specifically designed to help U.S. soldiers with transfemoral amputations return to active duty.

2.2 Statement of Need

Currently, many prosthetic limbs are secured to the user through the use of a vacuum pump that creates a vacuum between the residual limb and a custom made mold cavity. Most of our users utilize a prosthetic limb called the C Leg, shown in the figure below.

Figure 1: Military Amputee [1]

Our project focuses on improving current vacuum pumps or proposing a new vacuum pump system that will keep the prosthetic limb securely attached to our user's residual limb as they perform actions necessary in the line of duty. Before vacuum pumps, straps were used to attach prosthetic limbs. This method is extremely irritating to the limb and can cause lesions that are difficult to heal. The vacuum pump has been employed as a solution to the problem, by creating even weight distribution.

2.2.1 Nature of the Vacuum Pump Solution

The viability of vacuum suction as an attachment method has become more feasible as technology has allowed pumps and controllers to be assembled in smaller profiles. The physical

justification for a vacuum suction attachment method is sound and well understood. The vertical extraction holding force is determined by the diameter of the socket at the sealing point on the limb. The limb in the socket behaves much like a syringe plunger when the syringe is blocked. The vertical holding force is equal to the cross sectional surface area of the limb at the sealing point multiplied by the pressure differential. A negative air pressure is created between the outside of the fabric coated liner and the airtight socket when the vacuum pump pulls the air from between the liner gel and socket wall. The negative air pressure pulls the liner towards the wall of the socket. The gel liner creates a similar airtight seal to the limb, so when the liner is pulled towards the socket, the body's internal interstitial outward force in the limb is pushed towards the socket and holds the limb firmly in place. The side force then stabilizes the limb in the socket.

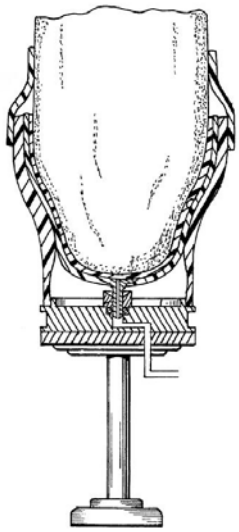


Figure 2: Vacuum between socket and residual limb [2]

2.2.2 Existing Vacuum Suction Solution

Based on our user testing and competitive products research, we found that standard vacuum pressures for this application range from 15mmHg to 25mmHg, with a typical pump supplying a range closer to 18-20mmHg. This level of evacuation provides a comfortable and secure connection, with higher levels of vacuum for activities that are more strenuous and for which a higher strength connection is desired. Due to the nature of activities that we expect our users to engage in, we are targeting the 20mmHg mark, as this will provide users with a confident connection and will allow them to undertake challenging physical activities without fear of their prosthetic leg coming off or chaffing their residual limb due to lost vacuum pressure.

This vacuum evacuation is applied with a small pump system, traditionally either mechanical or electrical in nature.

2.2.2.1 Mechanical Pumps

Mechanical micro pumps utilize the motion of the user to evacuate the pocket between the residual limb and the prosthetic, typically taking up to 50 steps to reach the desired level of evacuation. An important feature of mechanical pumps is the ability to mechanically self-regulate. The inherent stiffnesses of the functional rings are designed to reach a specific vacuum pressure depending on the user's weight. The rings will continue to expel air in a consistent effort to reach that vacuum pressure limit, meaning that as long as a user walks occasionally, a mechanical pump is able to maintain vacuum indefinitely.

Figure 3: Current Otto Bock Pumps : Mechanical Harmony P3 (left),

2.2.2.2 Electrical Pumps

Electrical micro pumps use a battery to power a small DC motor, which powers a small pump to evacuate the volume. Electrical pumps provide the user with quick evacuation and simple user interface, since all that is needed with modern pumps is a single button push. Electrical pumps maintain the vacuum by switching to a standby mode that monitors the pressure in the pocket and turns on for a short time when the pressure drops below a certain threshold. After the initial evacuation, an electrical pump will need to remain powered on in order to maintain pressure. Thus the battery in an electrical micro pump needs to be recharged regularly. For example, the Ohio Willow Wood LimbLogic [3] pump lasts around 4 days on a single charge (depending on the user), but is typically recharged nightly.

Figure 4: Current Ohio Willow Wood LimbLogic Electrical Pump [3] and E-Pulse (right) [4]

2.2.2.3 Advantages and Disadvantages of Pump Types

Based on our project description, client interviews, user interactions and target market, we found a number of advantages and disadvantages with mechanical and electric pumps.

Pump Type	Advantages	Disadvantages
Mechanical	-Utilize human weight and motion, eliminating need for battery power. -Little maintenance required. -Minimal user interaction.	-Pressure in the vacuum chamber is gradually lost when the user is immobile. -Takes up to 50 steps to evacuate the chamber. -Users with uncommon residual limb geometry may not be comfortable with excess time to evacuation.
Electrical	-Vacuum is created immediately. -Pressure is maintained at all times by the pump.	-Requires more extensive user interaction, must be preset. -Requires battery and frequent charging (lasts for 4 days [3]).

Table 1: Summary of Electrical and Mechanical Pump Advantages and Disadvantages

3. Problem Statement

Our goal is to design a quiet, compact, and unobtrusive vacuum pump with adjustable pressure and minimal recharging needs that will evacuate the cavity between a residual limb and socket for military personnel who have suffered transfemoral amputations.

3.1 Product Design Specifications

There are several important requirements for military transfemoral amputees. See Appendix A for the full product design specifications documentation.

One of the most important specifications is the pump performance. The pump must be able to evacuate the chamber to a comfortable, secure fit for the user. The pump must also operate with limited access to electricity, as soldiers might not be able to charge an electric device daily like

typical amputee. In order to be an effective solution for transfemoral amputees, the device must be less than 1.5 inches if located above the knee.

Another important aspect of the design specifications is the safety of the design. The device should not have any loose cords or wires that could get caught. The device should also maintain pressure, even if out of power. To remain a reliable device, the pump will need to be waterproof, sand-proof, and weather and corrosion resistant. The replaceable parts should last at least 6-12 months, and non-replaceable parts should last at least 2 years.

The device should not hinder the natural walking motion and balance of our users, so it must not weigh over 15 pounds. The device should also be easily accessible, and easy to clean and maintain.

Finally, the device should be financially competitive with other products and should not exceed the price of $3000.

4. Design Approach

4.1 Process Flow Diagram

The diagram below gives an overview of the evacuation process that our design performs.

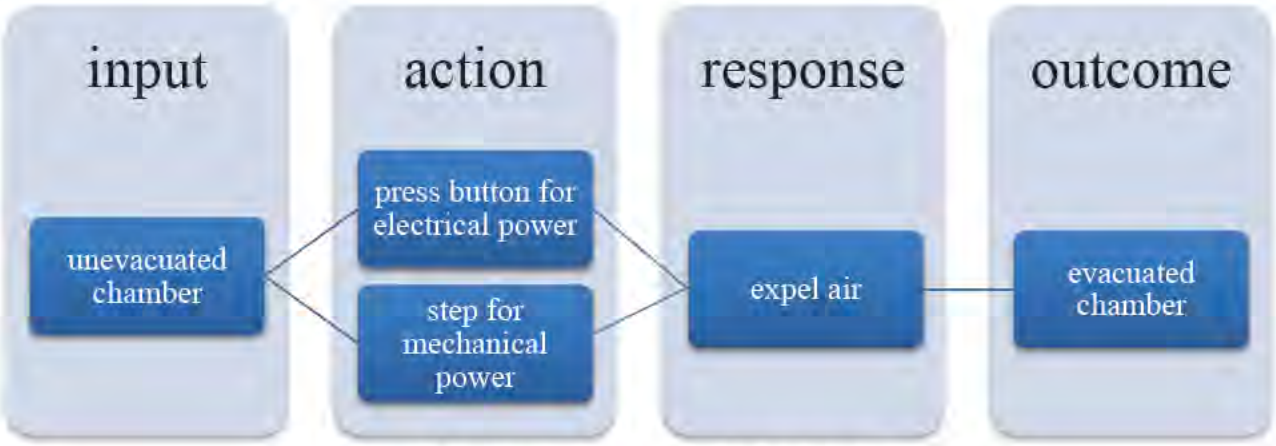


Figure 5: process flow diagram for our design

The functions performed by the device are to evacuate the chamber between the prosthetic and the residual limb, and to provide structural support to enable the walking motion. When the user wants to achieve these functions, the prosthetic leg with the hybrid pump attached is placed onto the residual limb. Then, the user presses a button that activates the electric pump, causing the chamber to evacuate. While the prosthetic is in use, the mechanical portion of the pump will maintain the pressure in the chamber. If the user is still for an extended period of time, the electric pump will maintain the pressure in the absence of mechanical power. A remote may be used to adjust the level of evacuation. The user is responsible for recharging the electric portion

of the device as needed. Routine maintenance, such as replacing the battery or the bladder occasionally, will also need to be performed by the user.

4.2 Technical Challenges

The geometry of our design is limited by a few factors. The biggest factor is the length of the residual limb, which varies for every user. This has large implications because our design is located above the artificial knee joint between the joint and the custom mold cavity. Thus, we need to make sure the height of our pump is minimized so users with the longest residual limbs will still be able to use our vacuum pump comfortably. Another factor is that our final design should not impede the motion of the artificial knee joint in any way. The application of our design above the knee joint removes any impedance from tubing that would be present with a below knee design. In addition, the shape of our mechanical pump has been specially designed so that in the pump will not interfere with flexion of the knee.

5. State-of-the-Art Survey

In order to gather more information about the project, we turned to a few different sources. We began by looking into competitive products and dissecting them. We first acquired the Harmony P3 pump. When dissecting the mechanical pump, we were curious to discover how the vacuum process worked and why the pump was so large. The pump was made of several components including a clamp ring, shaft, base, functional ring, and intake and expulsion valves. It is through this dissection that we initially conceptualized the information from the vacuum background section above. We realized during the dissection process, that the seemingly excessive length of the pump was likely due to structural support and stability requirements and the availability of space on the lower limb region. We were also able to obtain a Harmony E-Pulse and Ohio Willow Wood LimbLogic, taking note of the parts inside including the pump, circuit board, and battery.

Aside from these competitive products currently used by the patients at the prosthetics lab, we also completed a patent search on the internet. Through this we were able to gain useful inspiration for our group brainstorm. The patents we viewed provided useful background about how the pump is connected to the socket in different designs. Some were direct, inline solutions and some utilized tubing to achieve the vacuum.

6. Conceptual Design

6.1 Initial Design Ideas

At the beginning of our project, we completed a research phase which uncovered several design requirements for our system. Having learned about the currently available and soon to be released prosthetic models on the market, we decided to analyze not only the components we

needed to incorporate in our design, but the location in which we would be able to incorporate these functions. This immediately led us to identifying available space location of the prosthetic as our largest constraint. In the figure below, the two major pump locations are shown.

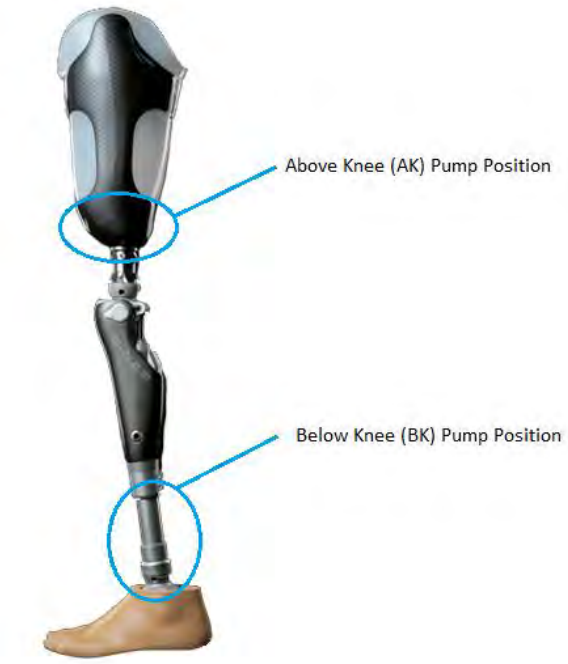


Figure 6: Potential Pump Positions on C Leg Prosthetic [6]

Balancing pump size and location were our primary concerns for our first round of prototyping. In our initial brainstorming, we came up with three major designs. These designs were the above knee mechanical design (AK mechanical), above knee hybrid design (AK hybrid), and below knee mechanical with hand pump. Each design had several benefits and shortcomings, but the highlight of all three was that they utilized the available space of their intended location.

6.1.1 The mechanical above knee pump

The mechanical above knee pump is a design that originated from the functional ring of the Otto Bock Harmony P3 Pump. This design is located in the above knee pump position as indicated in Figure 6 above. The goal of this design was to create a mechanical pump that was small enough to fit between the prosthetic mold and the top of the artificial knee, while still requiring fewer steps to reach optimum pressure. The resulting design concept, on the left below, is a 1.5in thick, 4in wide mechanical pump consisting of a large bladder, top and bottom plates, an intake valve and 2 expulsion valves.

6.1.2 The hybrid above knee pump

The electrical above knee pump is a design which would include the mechanical AK solution mentioned above, but also has an electrical component for fast evacuation. This device would be located in the above knee pump position as indicated in Figure 6 above, along with the mechanical solution mentioned previously. The electrical pump would be located above the knee imbedded in the mold that is custom made for every user. This application of the electrical pump would protect the pump and would increase comfort of the user as it would not be protruding from the prosthetic at all.

6.1.3 The mechanical below knee pump

The mechanical below knee pump is a design that originated from the original Harmony P3. The pump would be used inline, below the knee just like the current P3. Please refer to the below knee pump position in Figure 6, above, for this relative positioning. We added a hand pump feature that would allow for faster evacuation by moving the hand pump up and down until a comfortable evacuation level is reached.

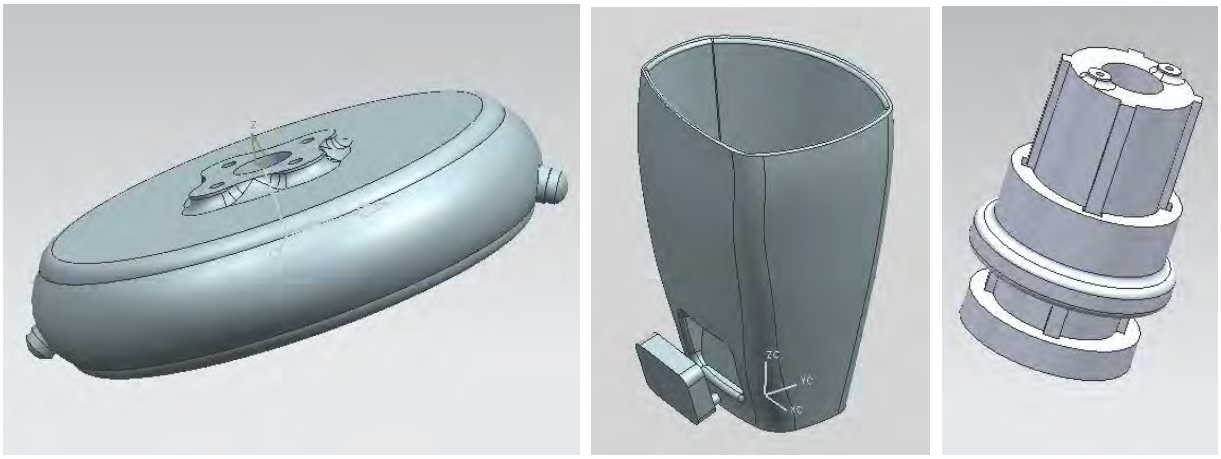


Figure 7: Initial designs: Mech. AK pump (left), Hybrid AK pump (center), Mech. BK pump (right)

These designs were taken to the client for evaluation during the user observation session.

6.2 User Observation Summary

Information gathered from our first user observation revealed that we needed to reconsider our design direction from our conceptual design. For a detailed summary of our interview, see Appendix D. On our visit to Ryan Caldwell's prosthetics clinic, we met three users of different variations of amputations:

- Luke, a transfemoral amputee
- Barry, a transtibial amputee
- Tom, a bilateral transtibial amputee with a complication known as heterotopic ossification

While Barry and Tom are transtibial amputees, they still provided valuable information. For instance, Barry has used both mechanical and electrical pumps, and was able to provide insight about both options. Tom is an example of a person who absolutely needs an electrical vacuum pump due to the discomfort caused by his complication, heterotopic ossification (irregular bone growth).

Major findings from our user testing include the fact that users are immediately affected by the discomfort caused by lack of vacuum pressure. While it is not the case with every user, complications can lead to serious discomfort that make the longer evacuation time of a purely mechanical solution unacceptable. However, Ryan believes that a redesigned mechanical pump applied above the artificial knee joint can be very beneficial to many potential users considering its robustness, simplicity, and ability to maintain vacuum pressure while walking. Ryan was also able to show us approximately how much space we would have to work with if we decided to approach an above knee design, about 1.5 inches.

6.2.1 Lessons Learned: New design decisions matrix

After discussing our ideas in detail with users and with Ryan, we found that we needed to reevaluate our designs and adjust some of our specification weights in our original design decision matrix. Below is our original design decision matrix, as well as our new matrix directly beneath. The categories that show different specification weights are highlighted in yellow in our new matrix. In addition to changing our design decision matrix, we learned at our meeting that it would be very difficult for an entirely mechanical solution to fulfill all of our design requirements outlined in our PDS. Therefore, even though our current design decisions matrix may indicate that mechanical solutions are the best option, we see that these types of solutions are not complete solutions.

6.2.2 Reevaluated categories

See Appendix A for category definitions from the PDS.

- **Pump Efficiency**: We found that pump efficiency was extremely important because the user becomes uncomfortable immediately if vacuum is lost.
- **Relative Size**: We determined that the size was less important than originally planned because the device could be located in many positions and simply had to be formed to fit with the shape of the leg, rather than minimized to the smallest possible shape.
- **Ergonomics/Ease of Use**: During user testing, we learned that users will adapt to the procedure required to use the leg. Users are willing to have a high level of interaction if the device works much better. The users do not mind increasing their interaction with the device if the improvement in functionality is substantial.

- **Noise**: We observed the use of several different electrical pumps during our user observations, and we found that while we still want to minimize sound, the noise was not extreme enough to eliminate electric pumps from our design.

	Categories	Safety	Pump Efficiency	Power Requirement	Relative Size	Ergo/Ease of Use	Durability	Cost	Weight	Manufacturability	Joint Impedance	Noise	Score
	Weights	5	4	3	4.5	3.5	4	1	1	2	4	4	
	Designs												
5th	Hybrid: Mech (BK), Elec (inline AK)	2	3	1	1	2	2	1	1	1	2	2	64.5
6th	Hybrid: Mech (BK), Elec (extern)	1	3	1	2	2	2	1	1	1	2	2	64
1st	Mech (AK)	3	2	3	1	3	3	3	3	3	3	3	95
4th	Hand Pump/ Mech (BK) (Sean)	2	3	2	2	1	2	2	2	2	2	1	68.5
2nd	Mech (BK)	2	2	3	3	2	2	3	3	3	2	3	87.5
3rd	Hybrid: Mech (AK), Elec attached	3	3	1	1	2	2	1	1	1	3	2	73.5

	Categories	Safety	Pump Efficiency	Power Requirement	Relative Size	Ergo/Ease of Use	Durability	Cost	Weight	Manufacturability	Joint Impedance	Noise	Score
	Weights	5	5	3	3	3	4	1	1	2	4	2	
	Designs												
4th	LimbLogic	3	2	1	2	3	3	2	3	2	2	2	76
3rd	Hybrid AK mount	3	3	2	2	3	2	2	2	1	2	2	77
2nd	**Doughnut**	**3**	**3**	**2**	**2**	**3**	**2**	**2**	**2**	**2**	**2**	**2**	**79**
5th	hand pump Mech BK	2	2	3	2	1	2	3	2	1	3	2	69
1st	Mech AK	3	1	3	2	3	3	3	3	3	2	3	82

Table 2: Design Decision Matrices (Top: Pre-User Interview, Bottom: Post-User Interview)

6.2.3 Design Evaluation

In our second design decisions matrix we found that our highest ranking solutions were the AK mechanical and a hybrid solution that involves rearranging the parts in a doughnut shape to save space. After our client and user interviews, we found that a solution that is solely mechanical in nature is not an optimal solution for initial evacuation. This led to our choice the "Doughnut" hybrid solution for further development.

7. Prototype Design

7.1 Scope of Prototype

We elected to build a full-scale prototype that showcases the highlights of our hybrid electrical and mechanical design. We used aluminum as the material for our prototype to make it similar to our final design in order to give a more accurate representation of our ideal production device. In the end, we developed an industrial design prototype that demonstrates how electrical and mechanical pumps can be reengineered to fit in a compact design and how this compact design

can integrate with current prosthetic devices like the C leg. Further functionality of our design was tested through computer modeling and simulation. Material and structural analysis were conducted to ensure appropriate performance for our design. The most important part of our prototype was to show how it interfaced with the prosthetic limb and the custom molded socket. Without this geometry, our design is unusable and therefore is irrelevant. With our prototype we are able to clearly demonstrate this interface and the client is able to imagine how the pump would perform based on our detailed engineering analysis. We have built two prototypes to demonstrate our geometry, one with a Rapid Prototyping manufacturing method and the other using CAM. As a result of this, we have the benefit of demonstrating how the interface would work and also how we would expect the final industrial design of our final design to look. These two prototypes are full size and describe our geometry, and clearly demonstrate the functionality of our design.

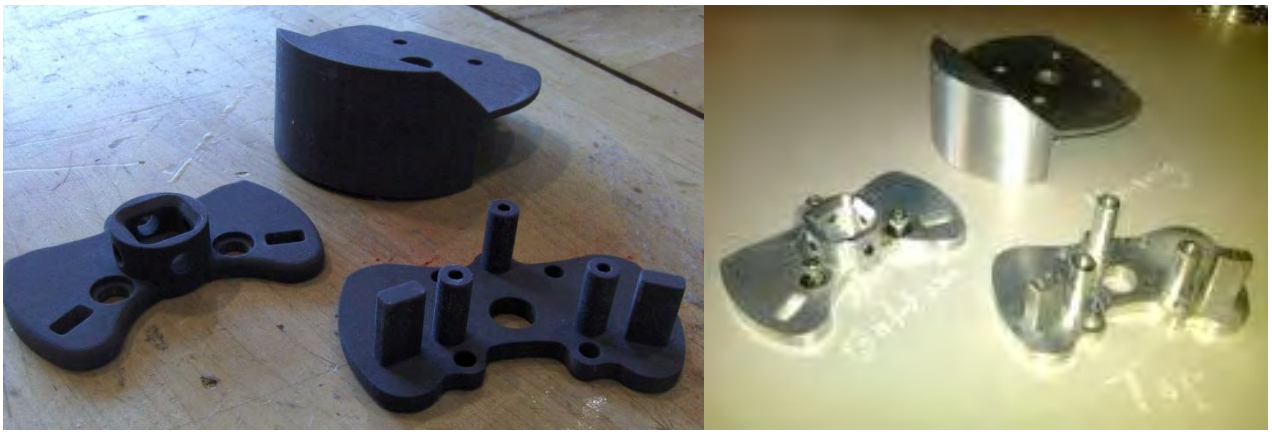


Figure 8: Rapid Prototyped Model (left); CAM Model (right)

7.2 Design Considerations

7.2.1 Geometry

One of the key requirements outlined by our PDS was a custom geometry that allows transfemoral amputees to gain greater benefit from our pump. We will be able to demonstrate how much better our design is when compared to currently available prosthetic vacuum pump technologies.

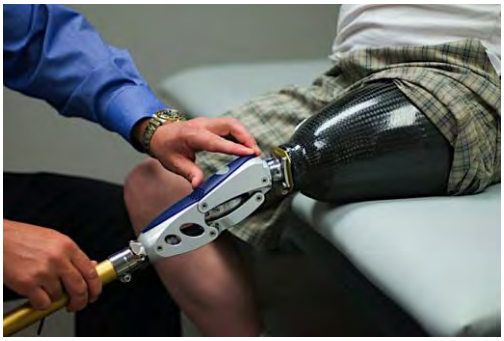


Figure 9: C-Leg Prosthetic Knee [7]

7.2.2 Interfacing with Prosthetic

While this is fundamentally tied to the geometry of our prototype, this part of our prototype is important enough to warrant special mention. Interfacing with the rest of the prosthetic limb is an inflexible requirement outlined in our PDS. Please refer to Figure 10 for how our device interfaces with a prosthetic limb. Without proper connection methods, the design of the remainder of our device is irrelevant, since it will be unusable. Additionally, because we are retrofitting our device to existing prosthetic limbs, we have deemed any limitation of user movement as a result of our geometry as strictly unacceptable. Therefore, our prototype will demonstrate the ability to interface with the prosthetic, helping to demonstrate its validity as a design solution.

Figure 10: Device will interface with C-Leg Geometry

7.2.3 Modularity

A significant part of our design is that both the mechanical and electrical devices can be used separately but also fit together when used it tandem. This design feature is valuable to us because it adds to the safety of our device as well as the value of our modules. Modularity plays into the safety of our device in that our pump has a direct seal to the cavity to be evacuated, allowing us to forgo the use of tubing that runs the risk of getting caught on protrusions. Modularity also makes our design more valuable because each component is capable of being used individually. In other words, when used together, a higher level of performance is expected, but should one component ever fail, the entire pump can rely on either of the pumping methods to preserve functionality. Additionally, this means that repairs are easier, as the entire device does not need to be replaced if one of the modules breaks.

7.2.4 Estimated Performance

In order to provide performance specifications without a functional prototype, we have chosen to provide this information through geometry-based calculations. With our electrical vacuum pump module, we have chosen components fundamentally similar to the Ohio Willow Wood LimbLogic vacuum pump, and we expect to reach similar performance figures in terms of

evacuation times and pressures. With the addition of a larger battery and the tandem use of our mechanical module, we expect to see dramatically better battery duration performance. To provide us with initial test data we have the research currently being done by Sean Wood, giving us a powerful resource and base of information. We will provide theoretical performance figures for our mechanical pump by using a two-part approach that includes benchmarking of the current mechanical pump available on the market, the Otto Bock Harmony P3, and calculations involving the pressure generated by the step of an average user and the size of our bladder. The combination of this competitive benchmarking data and our empirically derived estimates for performance based on our geometry will provide us a strong foundation on which to continue development of this design.

7.3 Final Design Overview

Our design is a modular hybrid electromechanical system. Both mechanical and electrical pumps have valuable features. Most notably, these include a mechanical pump's ability to maintain pressure solely with the motion of the user and an electrical pump's ability to quickly and efficiently evacuate the pocket and secure the connection between the residual limb and the prosthetic. In order to harness both advantages, we propose a modular hybrid solution that combines the features of both of these types of pumps. Our design is specifically built for transfemoral amputees, combining a custom mechanical pump along with a modified electrical micro pump in a package that is ideal for the unique requirements of military transfemoral amputees.

Figure 11: Design Rendering

The features of this concept will be further explored in this document, but some of the key design features that led to our choosing this concept are as follows:

7.3.1 Final Design Key Features

- **Modularity**: The doughnut design involves two components which can be used individually or in conjunction, based on the user needs.
    - **Electrical Component**: The electrical pump module of the doughnut is designed to have performance similar to that of the Ohio Willow Wood LimbLogic electrical pump, currently the best performing electrical prosthetic vacuum pump available on the market.
    - **Mechanical Component**: The mechanical module of the doughnut is similar in design to the functional ring of the Otto Bock Harmony P3, which uses a flexible bladder that deforms to evacuate air with the walking motion of the user.
- **High Pump Efficiency**: With mechanical components and electrical components, we expect this hybrid solution to have excellent performance figures, as our electrical pump module can provide initial evacuation quickly and our mechanical pump module can maintain this pressure while the user is active. This means we can expect a higher level of vacuum maintenance and a lower electrical power requirement.
- **Ergonomics/Ease of Use**: With the hands-off nature of the mechanical pump module that means the user does not need to interact to maintain pressure and the one touch evacuation ability of our electrical pump module, this hybrid solution is able to reach and unparalleled level of usability.

7.4 Prototype Description

The custom shape of our design utilizes the empty space at the bottom of the user's custom prosthetic mold in addition to space in between the artificial knee joint and the custom mold. The profile of our pump was designed so that the flexion of the knee would not be impeded and so that structural stability would be maintained.

Figure 9 shows how the components of our design fit together. In all, the design consists of four main bodies that incorporate both the electrical and mechanical solutions: the electrical housing, the top plate, the bladder, and the bottom plate. These components which are held together by a number of fasteners are described in further detail below.

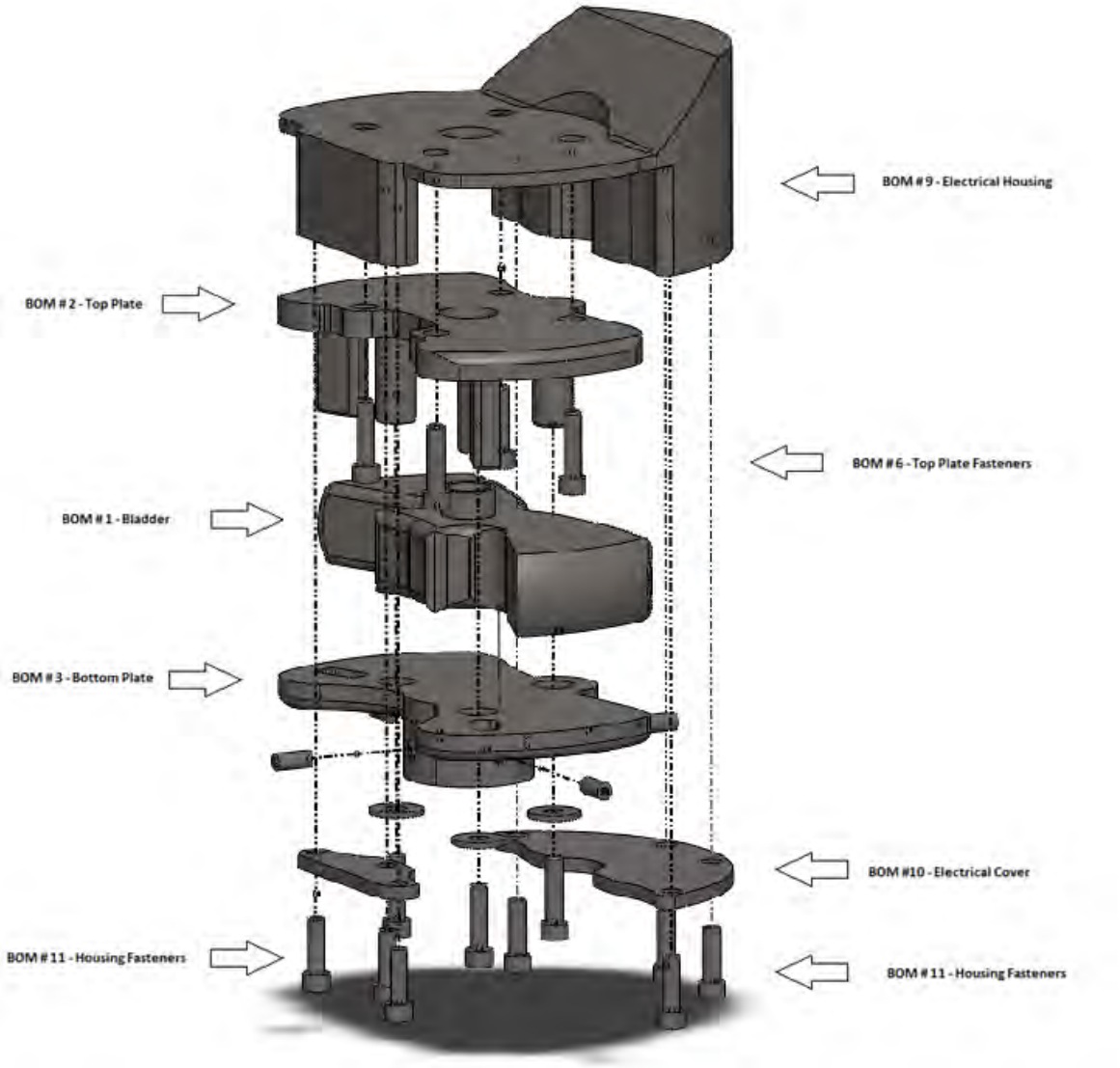


Figure 12: Exploded View of Prototype Assembly

7.4.1 Electrical Housing

The electrical housing for this device was designed specifically to accommodate the components of the Ohio Willow Wood LimbLogic. The geometry was made large enough to house these components, but was designed so that it would not be obtrusive for the user. To protect these components from environmental hazards, endplates secure to the bottom of the housing through the use of 10-24 fasteners. As a modular component, this housing fits around the mechanical aspect of this pump and fits neatly over the top plate. The 10-24 fasteners that are also used to secure the top plate may also be used to secure the electrical housing to the prosthetic mold as is seen Figure 12 above.

7.4.1.1 Internal Electrical Geometry

We've provided a wireframe view of our electrical housing, showing the layout of the interior components. For a symbolic representation of connections between different components within our device please refer our schematic below.

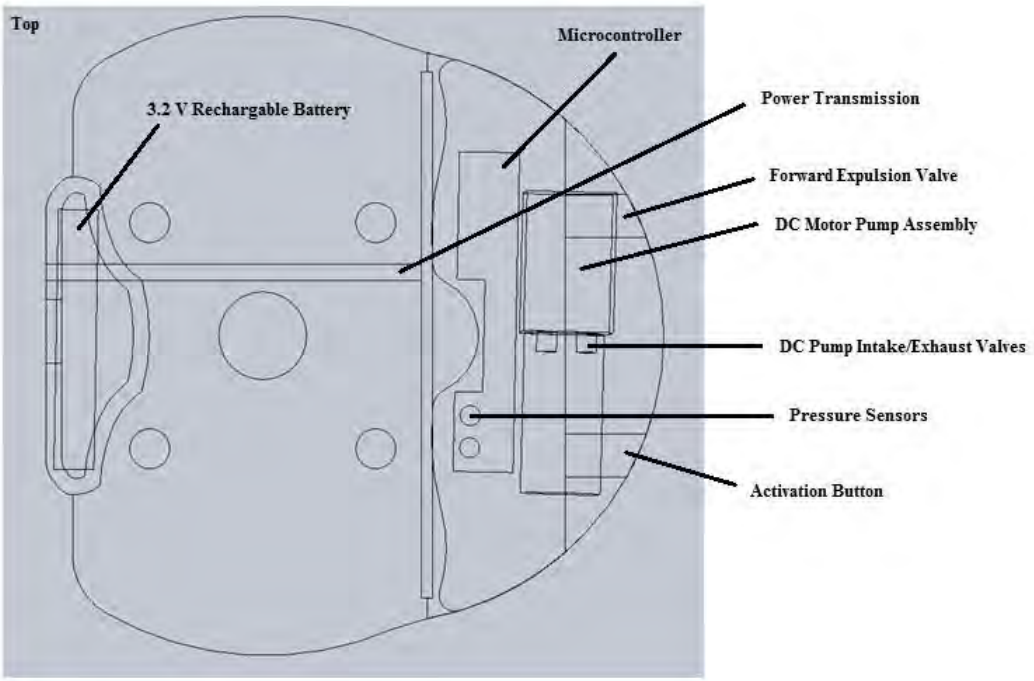


Figure 13: Top View of Wireframe Electrical Schematic with Tags

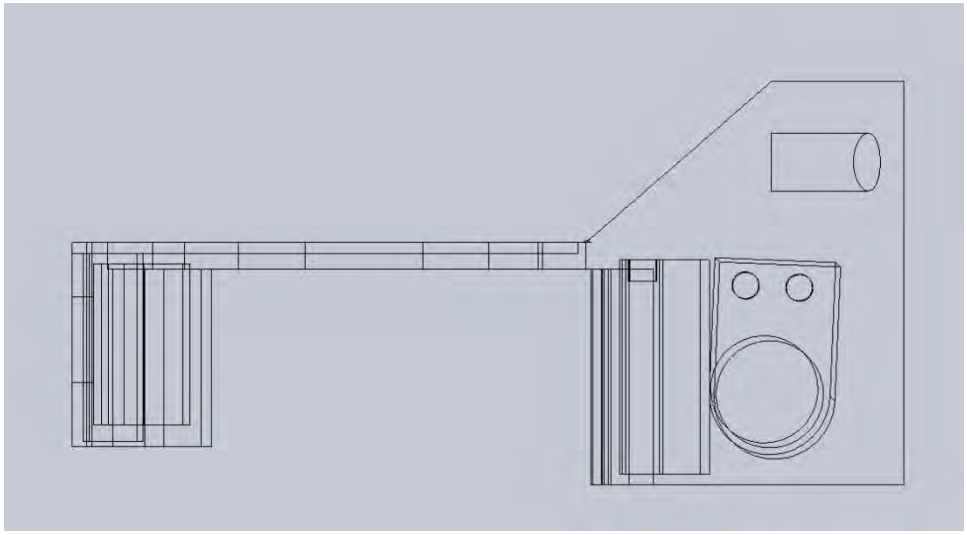


Figure 14: Side View of Wireframe Electrical Schematic

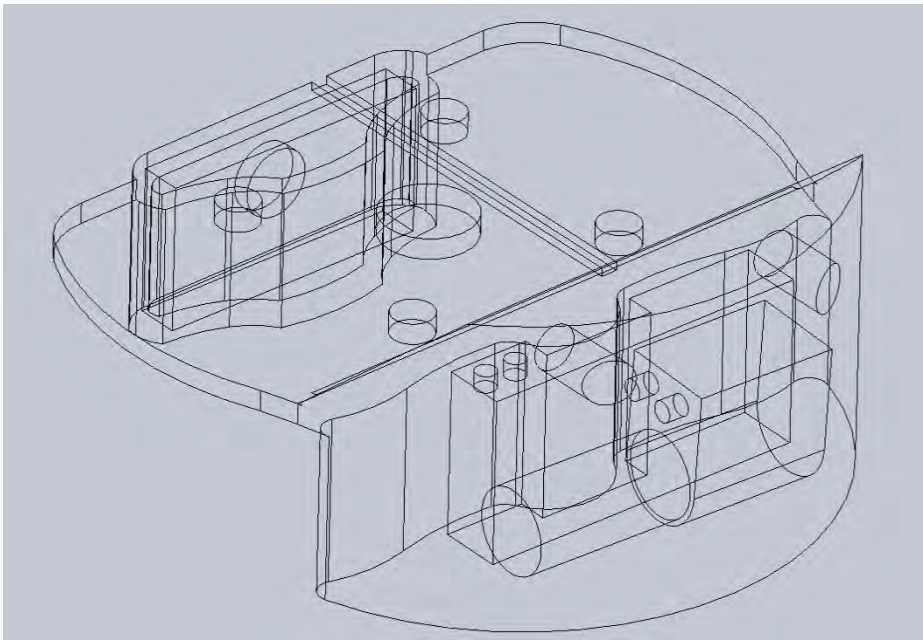


Figure 15: Isometric View of Wireframe Electrical Schematic

7.4.1.2 Electrical Schematic and Components

An electric micro pump has several key components. Below is an illustration of the standard components included in our design. This is a functional schematic describing how each of our parts will connect with one another in order to function, and aspects that are critical to the development of our custom housing.

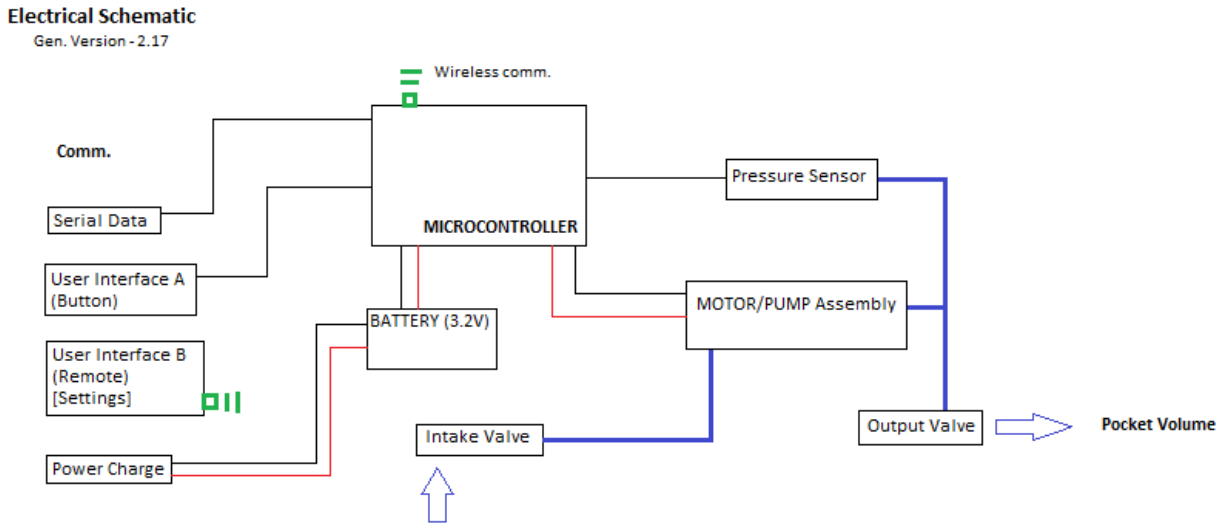


Figure 16: Design Schematic Diagram

The purpose of this diagram is to show the basic function and connection configuration for our electrical design. Key components and are outlined below along with their function.

- *Microcontroller*
  The microcontroller portion of the circuit contains the electronics that dictate the user interfaces and drive the motor/pump assembly. The microcontroller uses the voltage of the battery to drive this assembly, and also controls the pressure sensor that monitors the volume between the prosthetic and the residual limb.

- *Motor/Pump Assembly*
  As with the Ohio Willow Wood LimbLogic vacuum pump, there is a combined DC motor/pump assembly that drives the pressure difference. This assembly includes an input valve from the outside and an output valve that drives the evacuation.

7.4.2 Top and Bottom Plates

The top and bottom plates of our prototype were designed as a pair so that they would integrate flawlessly. Because the stability of our entire design hinders on the precision of these two components, the integration of their designs are critical. For this reason, the profiles of these plates were designed with three intentions:

- *Lateral Stability*
  In order to ensure stability of our design, we had to make the profiles of the top and bottom plates nearly identical. Because the top plate passes through the guides in the bottom plate, the space between the bores and the columns must be minimal to prevent any wobbling.

- *Non-Interference*
  We decided very early in the project that any inhibition of user movement as a result of our design would be unacceptable. For this reason, the profiles of the top and bottom plates were "cut out" in the back to allow the artificial limb to bend normally without any interference.

- *Flawless Integration*
  The usefulness of our prototype is inherently dependent on whether the design can be attached to current prosthetic devices. For this reason, the top and bottom plates were modified in order to attach flawlessly at their specific connection points. For the top plate, this meant adding four holes so it could be attached to the circular plate that is

embedded in the prosthetic mold. For the bottom plate, this meant adding an extension to hold and secure the knob found at the top of the C leg.

7.4.3 Functional Bladder

While we were not able to create the functional bladder for our prototype with the resources available to us, the requirements for the functional bladder had a large impact on our design because the mechanical functionality of our prototype is dependent on the bladder capability. For one, the bladder itself must be of appropriate stiffness to allow compression and expulsion of air, but resistant enough to decompress and draw in air from the prosthetic socket. This required us to maintain a design that would allow for vertical motion. Secondly, the size of the bladder inherently determines its efficiency. As a result, we made every effort with the design of the top and bottle plates to maximize the space available for the bladder. In our engineering analysis section, we will show how this benefitted our design.

8. Engineering Analysis

An integral part of our prototype development was a multi-disciplinary engineering analysis approach that allowed us to characterize our design and compare it to competitively set benchmarks. The primary components of our engineering analysis are materials selection, a group of finite-element analysis simulations describing structural stability, a fluids-based estimation of evacuation performance and a detailed description of the anatomical interfacing with a typically used prosthetic leg. These different analysis methods are meant to show that our prototype fulfills some of the key requirements outlined in our Product Design Specification, providing us with a foundation of data that supports the legitimacy of our device.

8.1 Material Selection

In order to choose materials for our prototype we utilized the Granta CES Material Selection software's material database. Using this database we were able to approach the material selection process with our projects needs and specifications in minds. We did this process for the end plates, structural elements and housings, as well as the mechanical pump bladder.

8.1.1 End Plates, Structural Elements, and Housing Materials

The materials we needed for these elements of our design needed to meet specific criteria. We wanted our design to have a high stiffness, or Young's Modulus, but still be relatively light. Also, from a durability standpoint these pieces must be both fresh and salt water resistant, as oxidation/rusting of our parts would be unacceptable. Finally, we further limited our material search by how we plan to process and manufacture our design, which could include machining or casting. Using these criteria and a graph of Young's Modulus vs. density we yielded the following results.

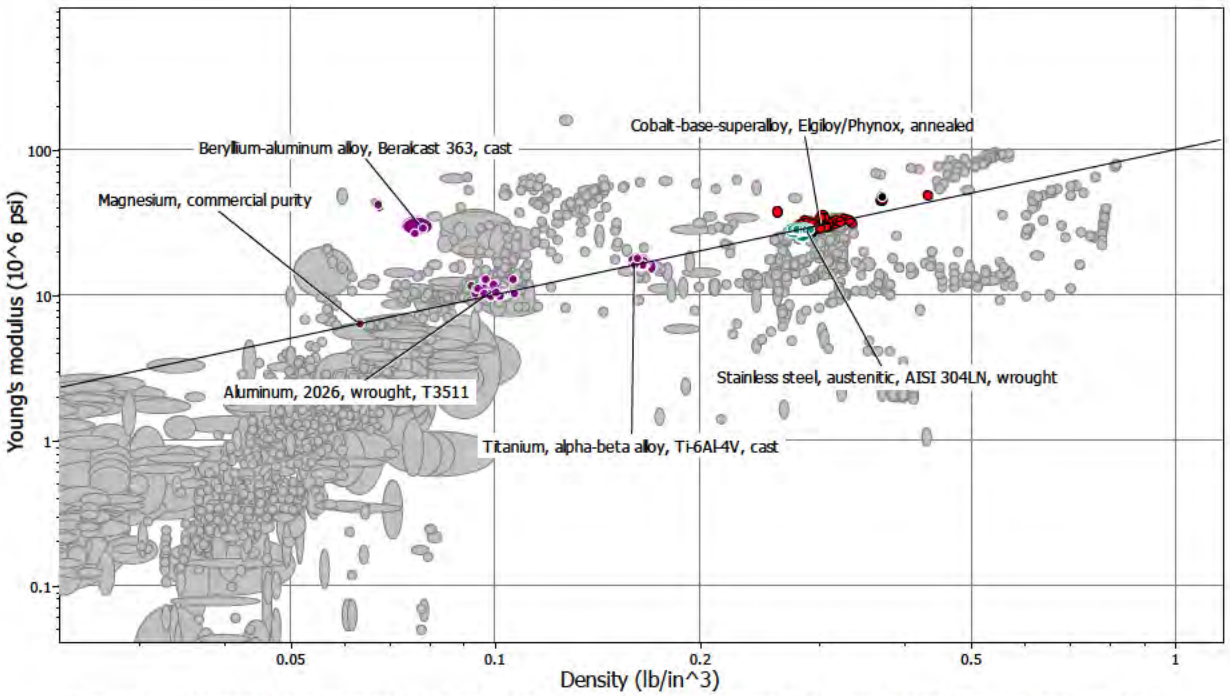


Figure 17: Young's Modulus (colors represent different materials, as called out on the image)

Notable features of this graph is the selection line with a slope of 1, which is the slope of selection lines used for maximizing Young's Modulus divided by density for materials in compression or tension. While maximizing Young's Modulus divided by density usually yields a variety of composites like carbon fibers, we decided to limit our material selection to metals for a couple of reasons. Firstly, the benefit of high stiffness and low density seen in composite materials is not usually observed when the material is in compression, which is the type of loading our design will experience the most. Also, composites are usually very expensive. Some notable materials that are highlighted on the graph include aluminum alloys, titanium allows, stainless steels, and also some superalloys.

To help choose what materials would be best for our application we decided to look at the prices of the previous results.

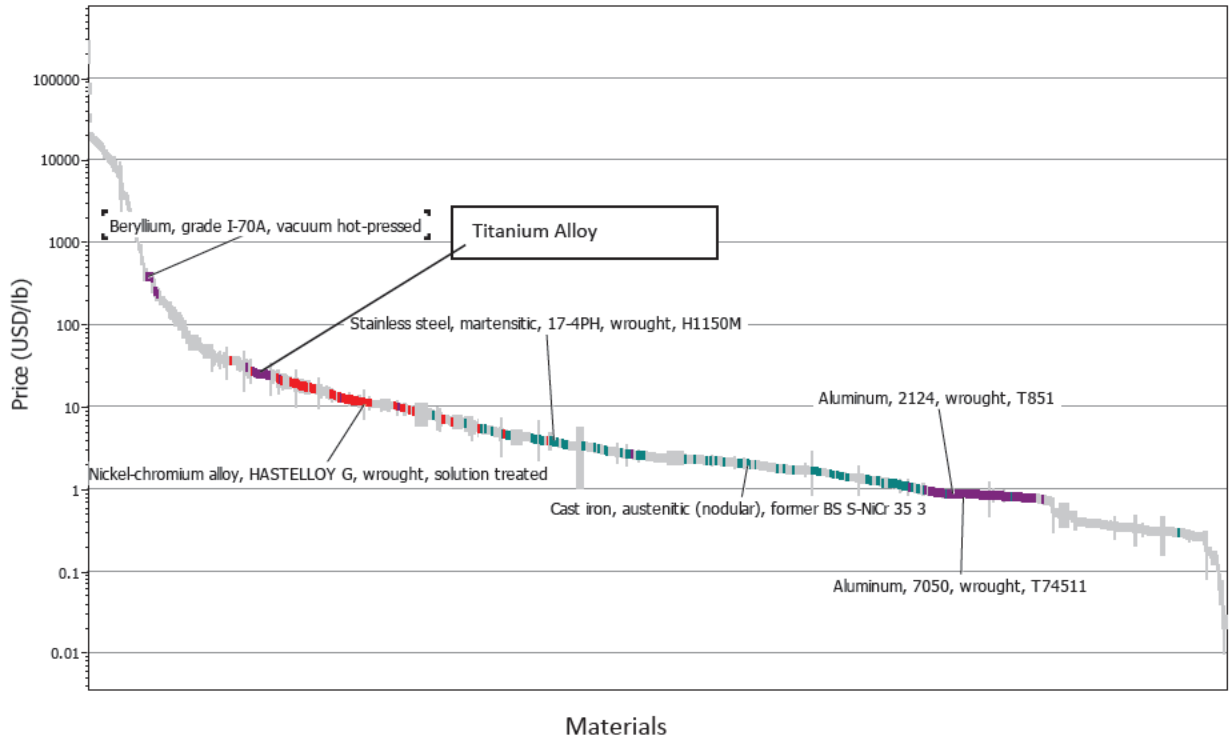


Figure 18: Price of various materials (colors represent different materials)

After looking of the prices our results from the CES material database it easy to see that the most appropriate choice of material would be an aluminum alloy. While metals like titanium and beryllium would give similar if not better results, they are drastically more expensive than aluminum alloys, which range from approximately 0.70-0.80 USD/lb.

8.1.2 Mechanical Pump Bladder

Our mechanical pump bladder design also has to meet a certain set of criteria. The current Harmony P3 pump has a functional ring made of Nylon. This part has a life cycle of six months to one year.[3] We need to design a bladder that is at least as functional as this current design. Considering the bladder's primary function is air evacuation, the bladder has to be airtight. It also has to be elastic, while still relatively stiff so it will return to its original shape after it is compressed. The bladder must also be resistant to degradation that could occur from exposure to salt and fresh water, as well as UV radiation. Finally, in terms of processing and manufacturing, we needed materials that can be injection or blow molded. Graphing Young's Modulus vs. yield strength (elastic limit) in the CES database yielded the following group of materials.

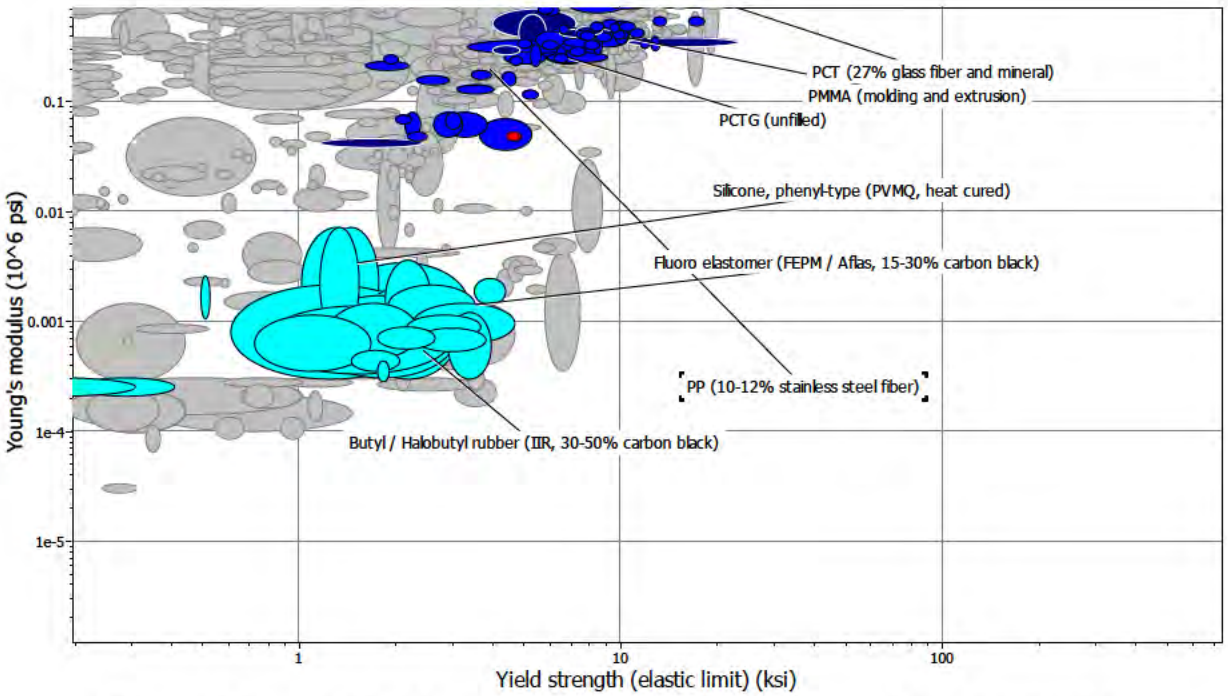


Figure 19: Young's Modulus vs. Yield Strength (colors represent different materials)

A few of the highlight materials that the database provided for us is Halobutyl rubber and polysulphide rubber which are materials that are commonly used in tires. These materials are interesting because the functions of both a tire and our bladder are somewhat similar in the sense that they are both elastic but still somewhat rigid. Both applications also need to be air tight. A few other notable materials are ABS (which was actually created as a rubber alternative), PEEK and many other polymers.

The bladder will be used in a range of temperatures that is in the acceptable range for Halobutyl rubber and polysulphide rubber.

A graph of the pricing of the materials yielded by CES is provided below.

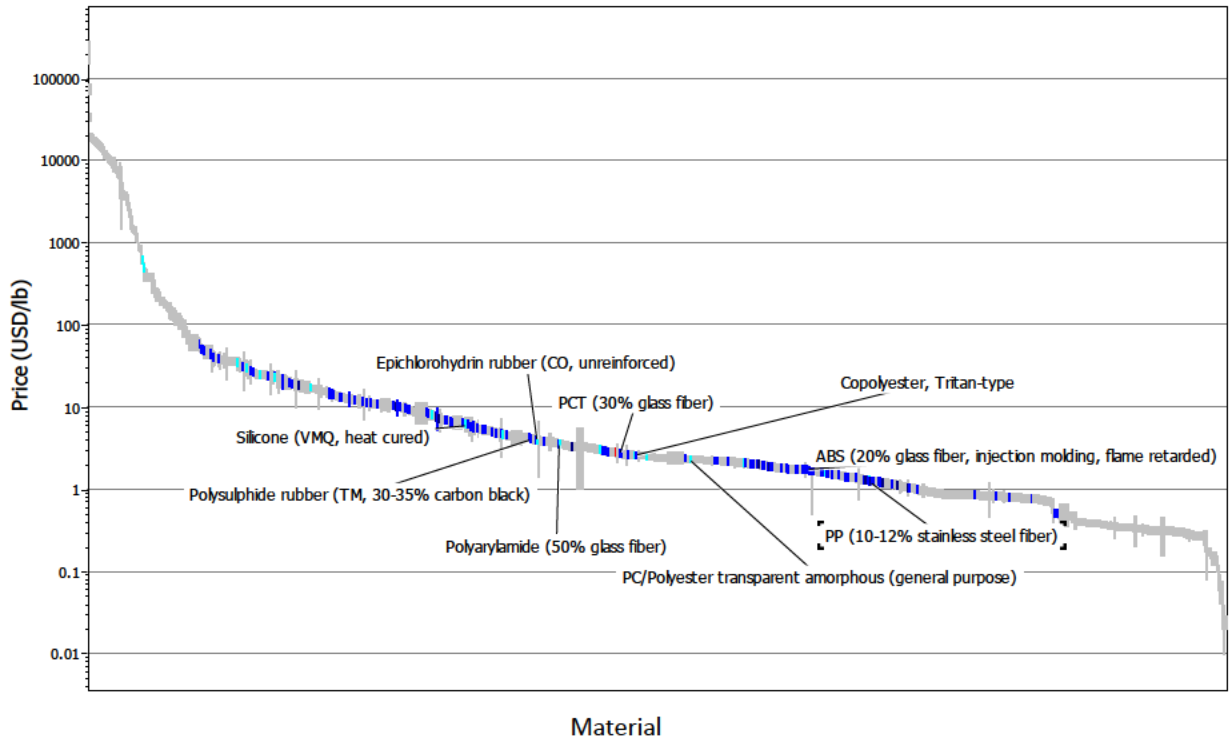


Figure 20: Material Prices (colors represent different materials)

The light blue materials are rubbers while the dark blue materials are all polymers. Generally speaking polymers are cheaper than rubbers. However, the similarities between the functions of our bladder and that of tires make us think that polysulphide and halobutyl rubbers would be worth pursuing for our bladder. Rubber generally costs 1.19- ~8.00 USD/lb ranging from pure rubber to a bunch of different forms of plasticized rubbers and post processed rubbers.

Our choice of bladder material will most likely be a plasticized rubber or a polysulphide rubber with carbon black additive to increase the stiffness of the material. The best parameters to examine for our final design will be the lowest density but highest stiffness of these elastomer materials.

8.2 Geometric Considerations

Our design problem is fundamentally focused on the lack of proper geometry for pumps intended for transfemoral amputees. To this end, we understand that the geometric design and prosthetic interface are the most important constraints we are challenged with the task of meeting. If our design does not use space intelligently and does not address the geometric issues of current vacuum pump technology, our design does not serve any purpose.

8.2.1 Space below the residual limb, above the knee joint

Transfemoral amputees have wildly differently shaped residual limbs, so we need to accommodate as many of them as we can. The average space between the knee joint and the base of the residual limb is 8.48 cm (with a standard deviation of 5.27cm), or 3.34 inches, according to a study published by Elsevier Ltd. On average, patients retain about 81% of their above knee limb. The implications this has for us is that we need to use as little space above the knee joint as possible, in case a user has a comparatively long residual limb. See Figure 20 below for an image of our pump location. Currently available pumps are too long to mount inline above the knee, which makes our design a major advancement. In response to this design constraint, we have developed a solution that occupies only 1.375 inches of inline, vertical space , taking off nearly half an inch from the nearest competition, all while improving functionality. We expect that with further analysis and testing, a thinner solution would emerge.

Figure 21: Location of Our Design

8.2.2 Space behind the knee

It is important that transfemoral amputees have space behind the knee in order to allow users to kneel without interference from the components that we add. This means that the back portion of our design needs to be less obtrusive in order to somewhat model the part of the space behind an everyday knee joint.

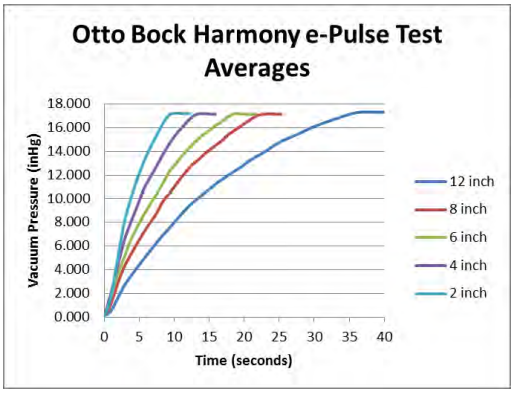
8.2.3 Space above the knee cap

In order to find space for the electrical components of our micro vacuum pump module, we have designed a housing that fits modularly with our mechanical pump, allowing us to save space and create a more elegant design. One of the places where we have space to work with is the kneecap region, as modern prosthetic limbs do not use this space.

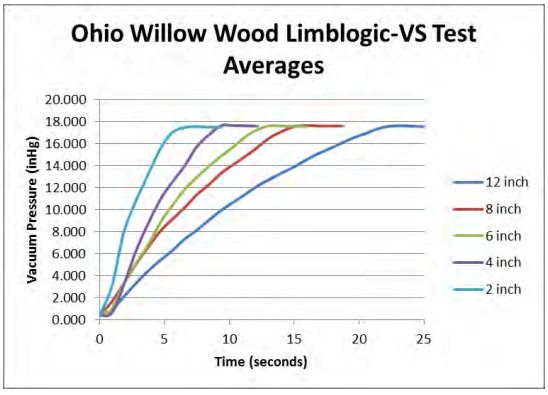
8.3 Competitor Benchmarking

The value of our design will be evaluated with respect to pumps currently available in the prosthetics market. This means it's vital that our expected performance is superior to state-of-the-art technologies. In order to ensure that this is the case, our client has provided us with characterization testing on many of the currently available cutting-edge pumps. Pumps that were competitively benchmarked include the mechanical Otto Bock Harmony P3, and the electrical Otto Bock e-pulse and Ohio Willow Wood LimbLogic pumps. Features that were characterized includesteps to ideal pressure and time to this pressure for the P3 and time to ideal pressure and power expenditure in establishing pressure for the electrical pumps. With the data provided we were able to establish mechanical pump baseline performance figures, as well as electrical pump performance figures, allowing us to better understand how our pump will perform as a combined unit.

In order to establish required specifications for our electrical pump module, we referred to testing done by Sean Wood on several of the better available electrical vacuum pumps available on the market. The two pumps tested were the Otto Bock Harmony e-Pulse and the Ohio Willow Wood LimbLogic electrical pump. The two plots below show the average times and evacuation pressures for various volumes.



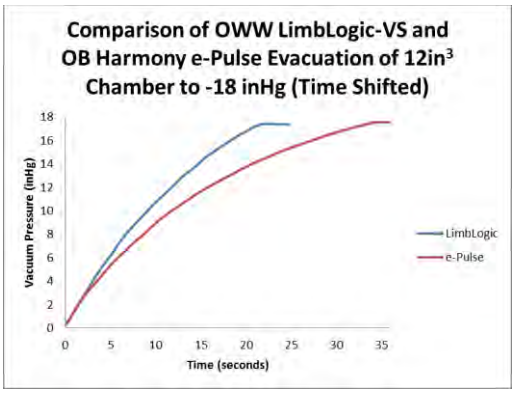
Plot 1 – Otto Bock Avg. Test data: Evacuating various volumes



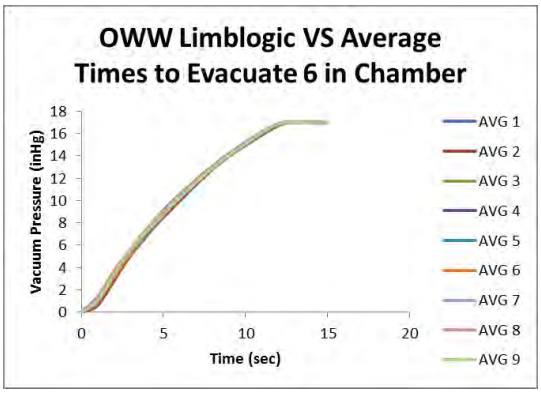
Plot 2 – Ohio Willow Wood Test Data: Evacuating volumes

Figure 22: Average Evacuation Times for e-Pulse and Ohio Willow Wood LimbLogic

Additional comparisons done for these two pumps include a comparison of the time to evacuate a $12in^3$ chamber to -18 inHg. This data is valuable because it shows that there can be a significant difference between competing products even at the higher end level of vacuum pumps on the market. In the plot below we see that the Ohio Willow Wood LimbLogic pump performs significantly better than the Otto Bock Harmony e-Pulse.



Plot 3 – Competitive Test data for evacuating $12in^3$



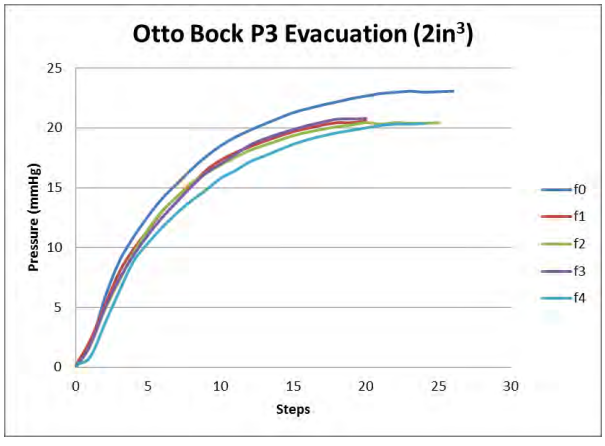
Plot 4 – Performance decrease over 10 tests for $6in^3$

Figure 23: Evacuation Times for $12in^3$ chamber

We have included this analysis because similar, if not the same, pumps will be used in our design. We have designed our housing to accommodate the geometric contraints of pump and electric components. The electric pump is approximately 1 and 2/3 inches long and about and inch wide. The circuit board is the largest component we had to house. It is about 2 ¼ inches long by 1 inch wide.

8.4 Evacuation Analysis

Our evacuation analysis demonstrates the performance of our mechanical pump and provides information about the system characteristics that are required for this style of pump. We see that the performance of our pump is estimated to be around three times better at low pressures and equivalent at high vacuum pressures, exceeding our specified requirements by a good margin. The key design constraints that we note from this section is that the stiffness of our internal spring system needs to be very high, as there is significant user discomfort if the deflection while stepping is too great. This deflection can create an unnatural gait for the user until the leg gets up to pressure, potentially causing irritation and less control over the prosthetic limb. For our specific calculations, please refer to Appendix E. Below we've detailed some of the fundamentals or our work.



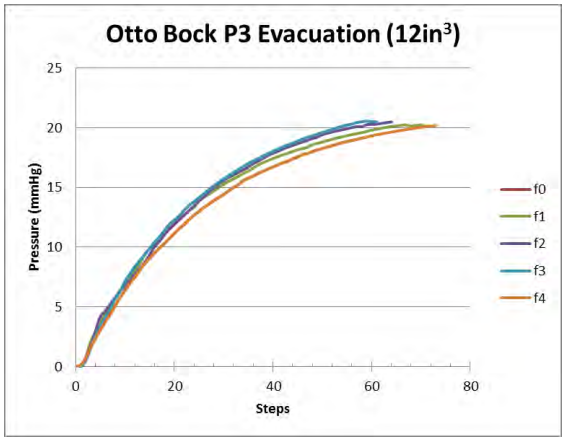


Figure 24: Average Evacuation Times for Otto Bock P3

Our characterization work is based on the Otto Bock Harmony P3, our main competitor in the market of mechanical prosthetic vacuum technology, and a benchmark against which we developed our final prototype. Based on the research done by Sean Wood for the Northwestern University Orthotics and Prosthetics lab, we are able to establish a foundation for our benchmarking.

To relate evacuation rate to functional ring volume, we calculate the amount of deflection and accompanying performance figures for the P3 while using a $12in^3$ evacuation volume and a $2in^3$ volume. We know that the two most interesting cases for each volume are the cases where the pressure is zero inHg and when the pressure is close to 20 inHg, since these cases describe when the mechanical pump is used as a backup to establish initial pressure and when the pump is acting in a pressure maintenance role.

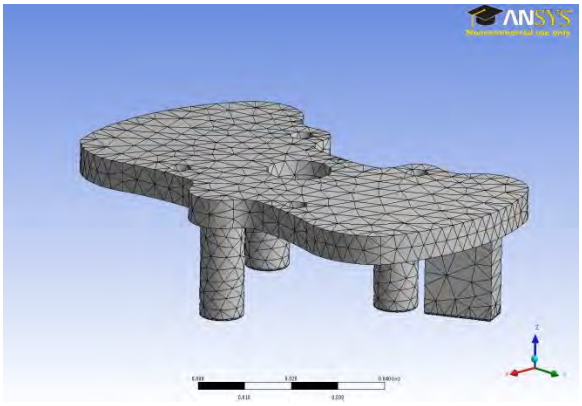
From our calculations we characterize both the spring stiffness and the maximum deflection as determined by the volumetric pressure analysis of the Harmony P3. These results dictate the performance of our pump, in that we design our pump system stiffness to match this deflection as to not increase user discomfort beyond the level caused by the Harmony P3.

8.5 Structural Analysis

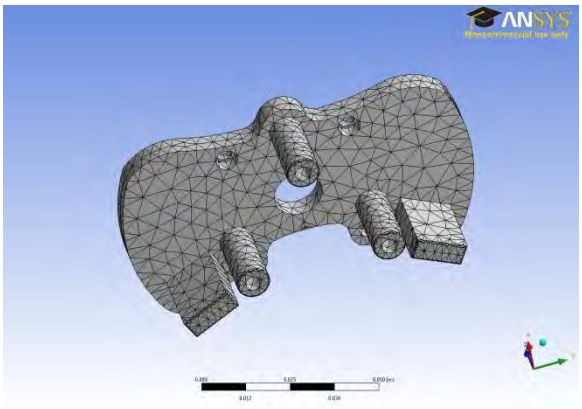
In order to develop a foundation of data from which we can characterize the performance of our design under different loading scenarios, we used the finite element analysis tool ANSYS to run various simulations on the load-bearing top plate of our design. Our simulations fell into four different categories, each with a goal of describing a specific loading method and each with a different failure mode. These four categories are: a torqueing load at each of the support pillars, a vertical loading that focuses stress in the pillars, an extreme loading at the bolt connection points and a worst-case torsion model that combines bolt loading with pillar torsion. For our numeric results to these simulations, please refer to Table 3. Our key findings for this method of structural analysis were that there is no danger of deformation from a typical application of force to our device. Questions that were not addressed in this iteration of structural analysis are lifetime under cyclical loading and response to extreme loading scenarios.

Name	Load	Distribution Description	Result	Conclusions
Pillar Torque (Def)	100 N (ea)	90 deg. Forces on each pillar	0 - 1.367e-6 m	Medium Risk, Generally Low Def
Verical Force at Pillars	400 N (ea)	Vert. Forces on each pillar	2.8328 – 3.6421e6 Pa	High Risk, High Stress
Bolt Loading (Def)	100N (ea)	Loading on bolts (fwd)	0 – 1.9436e-6 m	Bending occurs, Low Risk
Worst Case torsion	100N (ea)	Force on bolts and pillars	0 – 6.9481e-7 m	Warping, Med Risk

Table 3: Top-plate ANSYS results



Simulation Figure A – Bottom view of Top Plate Mesh



Simulation Figure B – Top view of Top Plate Mesh

Figure 25: Simulation Figures of Top Plate

8.5.1 Torsional force applied at pillars

The first deformation modeling we did was with a torqueing force acting on each of the cylindrical pillars that affix the top plate to the bottom plate. Each of the pillars was subjected to a load acting in a clockwise direction in order to model the effects of planting and twisting of the leg while in use and under loading. We used a loading of 100N on each pillar, a load equal to 22.48 lbf on each of them. This loading was chosen because we expect this region to be relatively stable, making 100N well above the maximum force we'd expect to see on these pillars. Please refer to final results table, Table 3, for the values we determined from this analysis. We see that our maximum deformation occurs on the outer edge of the top plate, with a value of 1.367 μm**,** which we conclude is a suitable level of deformation.

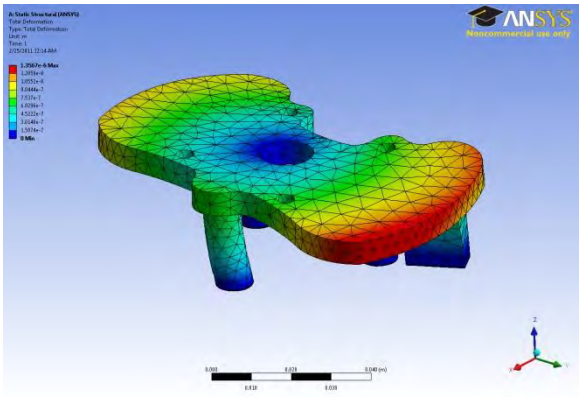


Figure C: Deformation with pillar torque (Top)

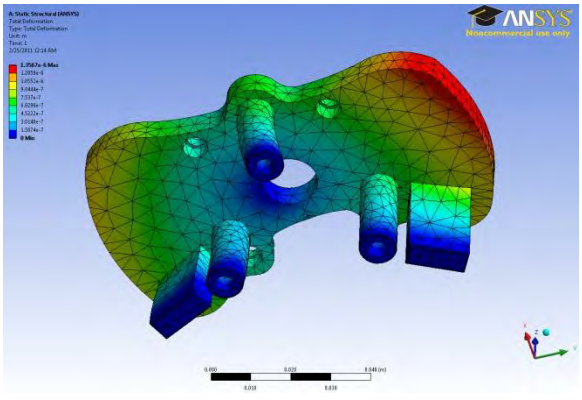


Figure D: Deformation with Pillar Torque (Bottom)

Figure 26: Deformation of Top Plate under Pillar Torque

8.5.2 Vertical force applied at pylons and pillars

This stress analysis was done vertically on the extended members of the model with the top plate fixed. The intent of this modeling was to better understand how having the force concentrated on these points would affect the stress distribution on the plate as a whole. We expect users of our device to weigh between 600N and 1200N (140-280 lbs), meaning we can expect a loading that will vary accordingly. Because of this range, we tested the heaviest load, which would be a 280 lbf loading solely concentrated on this plate, modeling a case where the user is balancing all weight on this one limb. Please refer to our results table, Table 3, for the values we determined using this analysis. We see a maximum stress of 3.6 MPa, located at the bolt connection points on the bottom of the structural pillars.

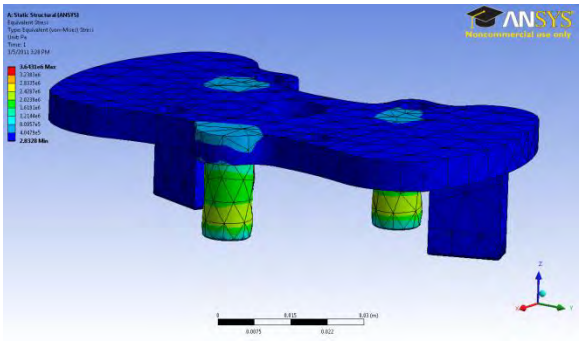


Figure E: Stress analysis vertical loading (Top)

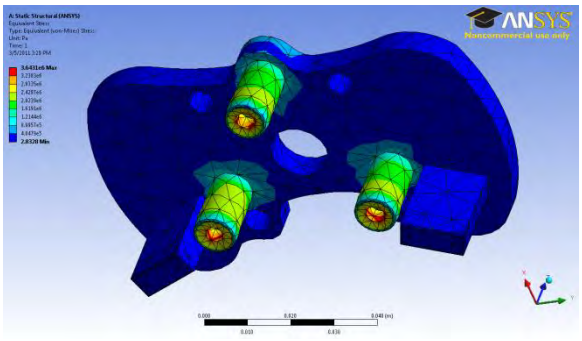


Figure F: Stress analysis vertical loading (Bottom)

Figure 27: Deformation of Top Plate under Compression

8.5.3 Forward force applied at connection points

In order to better understand how our mechanical design might deform in response to an extreme loading on the connection points of our top plate, we ran a simulation that checked the deformation. This type of loading may occur with the user is bending down on one knee in order to pick something off the ground. However, we know that this won't be the only place where force is concentrated, as our device is mounted above the limb, meaning we expect a reasonable amount of force to be shunted through the support pillars with this type of motion. For this reason we have chosen a loading of 100N (22.46 lbf) on each of the connection points. Please refer to our results table, Table 3, for our values for this analysis. With this analysis we see a maximum deformation of 1.97 µm, which is again within our acceptable limits. This occurs at the edge of our top plate in the zone marked in red.

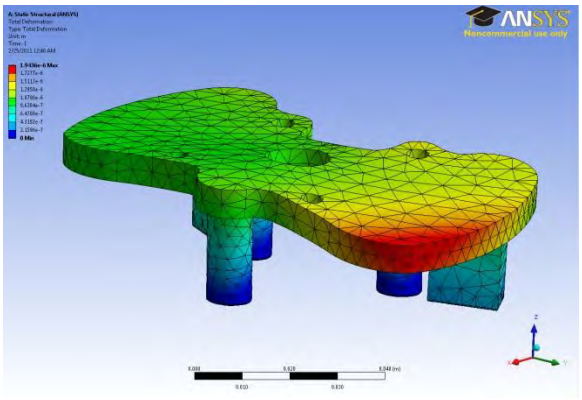


Figure G: Deformation connection loading (Top)

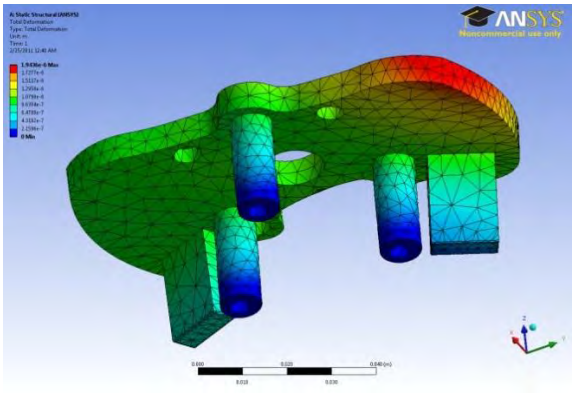


Figure H: Deformation connection loading (Bottom)

Figure 28: Deformation under Connection Loading

8.5.4 Max Torsion for Top Plate Connectors and Bottom Plate Pillars

This analysis demonstrates locations of maximum deformation due to a theoretical worst case scenario loading. This shows that there would be significant geometry alterations under this scenario, but only serves as rough ballpark. While we know the top plate will bear most of the loading, it is more difficult to predict how the components will work when assembled together. This loading is a combination of the torsional analysis that we did as well as the connection loadings, each directed in a different cardinal direction to show how a worst-case loading scenario could affect our design. We've combined our previous loadings of 100N (22.46 lbf) on each member so as to remain consistent with our previous work. Please refer to our results table, Table 3,for our values. With this worst case loading we see a maximum deformation at the far edge of our top plate, showing yet again that this is the torsional failure method of our plate, and that we need to be wary using such a large single plate, as inter-plate forces dominate our stress analysis results.

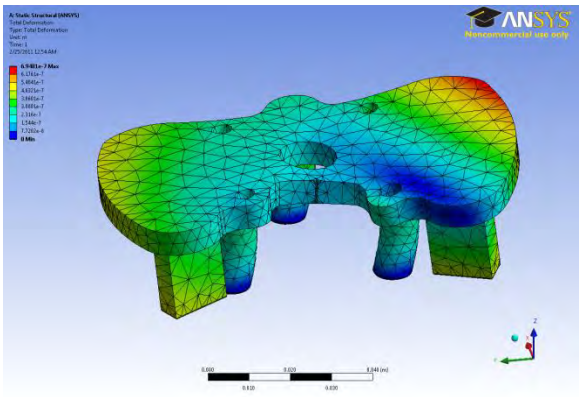


Figure I: Worst-case deformation loading (Back)

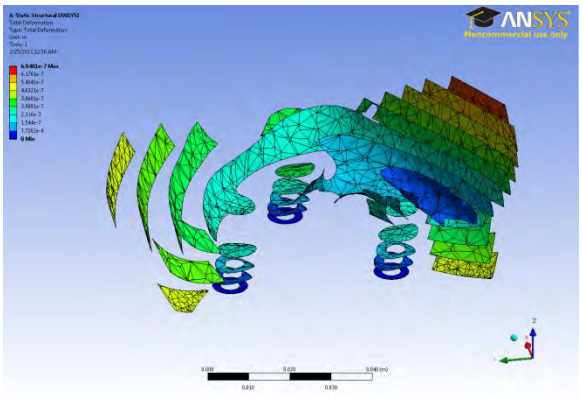


Figure J: Worst-case deformation loading (Isosurfaces)

Figure 29: Deformation under Combination Loading

9. Contextual Analysis

When making design decisions, there were several factors that affected our choices. As a design team, we had to keep in mind the context of our design. This means taking into account the global, economic, environmental, and social factors surrounding our design.

9.1 Global Considerations

As a device for military users, our design will be used all over the world. The device needs to accommodate the varying levels of resources abroad as well as the extreme environments where soldiers may work. We made sure to include a mechanical portion of our design to accommodate those places where electricity and wall outlets are few and far between. We also designed the electrical component of the device to be water tight and free from sand penetration. This will keep the device working well in all situations.

9.2 Social Considerations

Our device has powerful social implications, essentially classified as a health care product. With the success of our product, we expect to see a significant leap forward in transfemoral vacuum pump technology, as we are developing a cutting-edge user centered design. Not only will this device provide a better quality of life for amputees, but we will see the benefits of higher levels of social contribution by new users of our device. By pushing the vacuum pump technology bubble, we expect to help drive further innovation in the relatively young field of vacuum prosthetic technology, yielding further benefits for amputees and others working in this field.

9.3 Environmental Considerations

Designing a device with an eye to environmental sustainability is a key feature of modern design and manufacturing engineering. A micro vacuum pump system is not something that has a heavy environmental impact during use by the user, but a complicated manufacturing process can make or break the sustainability of this type of product. To this end, we are designing our devices with an eye to environmental consciousness, including but not limited to a fundamentally sustainable manufacturing process and a detailed recycling process. In addition, we have minimized the consumption of the device itself, using a rechargeable battery unit instead of lighter but more wasteful disposable batteries. We are also aware that sustainability does not begin with the manufacturing process. The source from which the materials we use in manufacturing is also important to maintaining environmental integrity. In order to fully support our ideal of sustainability, we will consider the entire lifecycle of the device, from the gathering of the raw materials to the disposal of the used product.

9.4 Economic Considerations

The budget for this project is less restrictive because of the vast resources of the military. We know that our product will be used, even if it is a luxury option. Despite this fact, we have kept cost in mind because the design would be beneficial for all users, not just soldiers. There are several other prosthetic vacuum pumps available on the market, providing economic competition

for our device. Ours will be set apart by its unique hybrid qualities. Having both electrical and mechanical pumping power will make the device more attractive than the currently popular P3 mechanical pump, or LimbLogic and E-Pulse electrical pumps.

10. Test Results and Evaluation

Test Results

The testing of our prototype is intended to support our geometric design, while our theoretical characterizations are meant to describe how the pump performs based on benchmarking. The geometric guidelines of our system are defined by the connection points of the standard connection of the c-leg. By developing pump housing with these connections in mind, we are able to demonstrate this interfacing between the prototype and the c-leg, justifying part of our plate geometry. Since our prototype is an industrial design prototype that is designed to show geometry and appearance with a limited degree of motion, this is the extent of our physical testing. The structural stability aspect of our design isn't meant to be proven with our prototype, as our bladder will not have the structural characteristics that are meant to exist in the final design.

Evaluation

The degree to which our design meets the specifications outlined in the PDS give us a framework to evaluate the success of our project. Our most important specifications were that our design fit in the profile of many different leg lengths, has a long recharging cycle, has redundancy to maintain pressure and is durable enough to take the beating it will be subjected to as a device for use in the field. While our prototype was not able to directly address the issues of power requirement and durability, we were able to show how our geometry is valuable and provide some of the analytical data supporting our efficiency argument. Please refer to our mechanical pump analysis for the data we've generated with regards to mechanical efficiency. When we combine this data with electrical benchmarking from Sean Wood's research, we are able to form an estimation for charge cycle longevity. The intended operation of our hybrid solution has the electrical pump taking the role of providing initial pressure, while the mechanical pump provides maintenance pressure while the user walks and acts as a redundancy should the electrical pump fail altogether. With the electrical characterization and the mechanical data we have, we expect a **25%** increase in battery performance over solely using an electrical pump. This is based on the power required for the maintenance mode of the electrical pump and the current battery performance of the Ohio Willow Wood LimbLogic pump.

11. Next Steps

There are several extremely important next steps for our final design if this pump is to be considered for production. An in-depth biomechanically oriented stress analysis is vital to understanding how stress distributions will occur in a product like this. In addition to this, the bladder size and spring stiffness have yet to be optimized. We would recommend further design work and eventually testing to characterize and develop this performance. In addition, more in-depth cost estimation is crucial to determine the costs of manufacturing and assembly.

11.1 Design Changes

Several areas require attention in the next iteration of our design. These areas include the structurally supporting pillars and pylons, as well as the outer diameter of the housing. These things must be evaluated to improve structural stability and seamless integration into the typical prosthetic limbs. Designing and testing a structurally sound solution was not our first priority, and our device is likely not as structurally sound as such a device would need to be to take the rigors of combat, certainly not without some form of additional testing. In particular, we would suggest that this analysis focus on normal biomechanical movement and force distribution for the average user. In terms of the outer diameter of the design, in an effort to safeguard against interference and obtrusion we made our diameter smaller than it would likely need to be. New diameters should be explored and user tested. In addition to these considerations, there isn't a clear description of how the electrical components would optimally fit into the electrical housing, but this positioning could likely be optimized.

11.2 Future Enhancements

The future of our design is founded in the principles we've developed. The fundamental concept of combining a mechanical pump with an electrical pump in an inline modular package is sound and has many clear upsides. This means the hybrid platform we've developed is valuable even if some of the components of our design haven't yet been optimized. If we were to build an alpha prototype of our final design, it would be incorrect to call it anything other than a proof-of-concept for another, more complete design. We feel that in just 10 weeks we weren't able to develop the perfect solution, but we also think we've laid strong groundwork for an excellent one. Specific features of our design that we feel deserve attention are the bladder size and stiffness and our pillar/pylon mechanical pump support structure. We think that the repackaging of the Ohio Willow Wood LimbLogic's electrical and pump components is a strong approach and energy should be developing the mechanical component of our solution.

11.3 Cost Estimation

We've provided a brief costing estimate for the Aluminum raw materials required for a CAD manufacturing approach as well as the costing for sourcing a mechanical pump bladder. In addition, we've provided estimates for labor costs with using CAM to manufacture our top plate, bottom plate, and electrical housing. This gives us a rough estimate for our mechanical pump. We expect Ohio Willow Wood part costing to add approximately $200 in components. We then

use the 3*C rule to estimate that a production cost would be approximately $1500. Since this isn't a commercial product, we're not aware of how it would be sold to the military, so we've opted to omit this analysis. We also expect to achieve a somewhat lower cost through economies of scale.

Tooling: 0.5 hr at $60/hr

Setup: 5 min at $60/hr

Processing: 0.25 hr at $60/hr

Material: 8 lbs 6061 Al at $124

Bladder sourcing: $125 per

Assembly: 0.25 hr at $60/hr

	1	10	100
Tooling	**$30**	**$30**	**$30**
Setup	**$5**	**$50**	**$500**
Processing	**$15**	**$150**	**$1500**
Material	**$124**	**$1240**	**$12400**
Bladder	**$125**	**$1250**	**$1250**
Assembly	**$15**	**$150**	**$1500**
Total (per)	**$314 ($314)**	**$2870 ($287)**	**$17180 ($171.8)**

Table 4: Cost analysis at 1, 10, and 100 unit increments

12. Summary

Current prosthetic vacuum technology is essential for user comfort and mobility. There are drawbacks to the current pump designs that need to be addressed. The electrical pump relies on wall outlet access, which cannot be guaranteed for military users. The mechanical pump takes too long to evacuated, and does not necessarily maintain vacuum if the user is not in motion. Our goal was to design a quiet, compact, and unobtrusive vacuum pump with minimal recharging needs for use in the field by military personnel who have suffered transfemoral amputations.

Through our user interview, we found that users were willing to accept a more complex solution in order to achieve better performance. The desire for top performance led us to the hybrid design. The hybrid is the only way to combine all the strengths of the electrical and mechanical

pumps, while still providing a redundant system to prevent some of the disadvantages each single pump displays. We designed our pump to be modular, so users that need one pump type could have that option. Choosing only one pump type (either electrical or mechanical) will be a way to make the pump less expensive for the customer. With both the electrical and mechanical components, the hybrid design will have high pump efficiency. The electrical pump will be able to evacuate the chamber quickly. The mechanical pump will be able to maintain the vacuum during motion, making the electric pump cycle less frequently thereby extending the battery life.

To analyze the feasibility of our design, we completed a material selection process using Granta CES software. We were able to conclude the materials for the end plates, structural elements and housings, and the mechanical pump bladder. We also performed extensive calculations on the expected performance of the bladder, which resulted in a performance rate three times better than the current Harmony P3 design. In addition to performance, an important aspect of our design was geometry. We needed to make sure that the device would fit in the profile of a normal leg. Through the fabrication of an industrial design prototype, we were able to assemble our design with an actual C Leg prosthetic to prove that the device properly interfaces with the prosthetic.

A major concern about our design was its structural stability. ANSYS modeling was used to determine high risk loadings. While we were able to show that certain loading conditions will be accommodated by our design, further research and testing is needed to prove that the device will be natural and stable during use.

13. Acknowledgements

We would like to thank:

- Our client, Sean Wood, for bringing us the opportunity to work on this project.
- Ryan Caldwell, for arranging user interviews and answering our many questions.
- Our users, Luke, Tom, and Barry, who were open and honest with their feedback.
- Stefania Fatone, for her biomechanical expertise and providing information about prosthetic technology and bio
- Dr. Wei Chen and Paul Arendt for their continuous support and advice.
- Robert Taglia for his help in making our prototype a reality.
- The members of our ME 398 class for their support and feedback.

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7. http://www.ncopi.com/wp-content/gallery/people/NCOPI_Prosthetic_C-Leg_Adjustment_2.jpg
8. http://www.mcmaster.com/#
9. http://ourgivinggarden.org/images/sustainabitlity.jpg
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15. Appendix A: PDS

The military transfemoral amputee has several important requirements for the vacuum system.

Performance

- Will allow user to set a preferred amount of suction between 15 -20 inches mercury for a tight, comfortable, and secure prosthetic fit
- Will allow users to readjust pressure when necessary
- Device will reach desired pressure in less than 50 steps
- Device will operate below 40 decibels (ambient noise level) while in the field
- Device will maintain stability in use

Power Requirements

- Like current electrical pumps, the device will be designed to operate for over two days without the use of a wall outlet or battery replacement
- An electric device will operate with a 12 Volt battery or smaller

Size

- For inline above-knee pumps, the vertical height of the device will be less than 1.5 inches
- For other pumps, the device will remain inside the profile of a typical leg

Safety

- Device will be designed to avoid loose cords or wires that could catch, disabling prosthetic pressure or use
- Device will maintain pressure at acceptable level, even if out of power

Ergonomics

- Device should be easy to access and use and therefore will not cause the user any physical discomfort or stress
- Device will be easy to install by the user
- Device will minimize user maintenance and cleaning

Durability/Lifespan

- Device will be used for military application and thus will be waterproof, sand-proof, and generally weather and corrosion resistant.
- At least 2 years for non-replaceable components
- At least 6-12 months for replaceable components

Patents

- Device cannot infringe on any existing American or European patents

Cost

- Will be less than $3,000

Weight

- The prosthetic leg with device included will balance the natural leg. The device will not exceed 15 pounds.

Customers

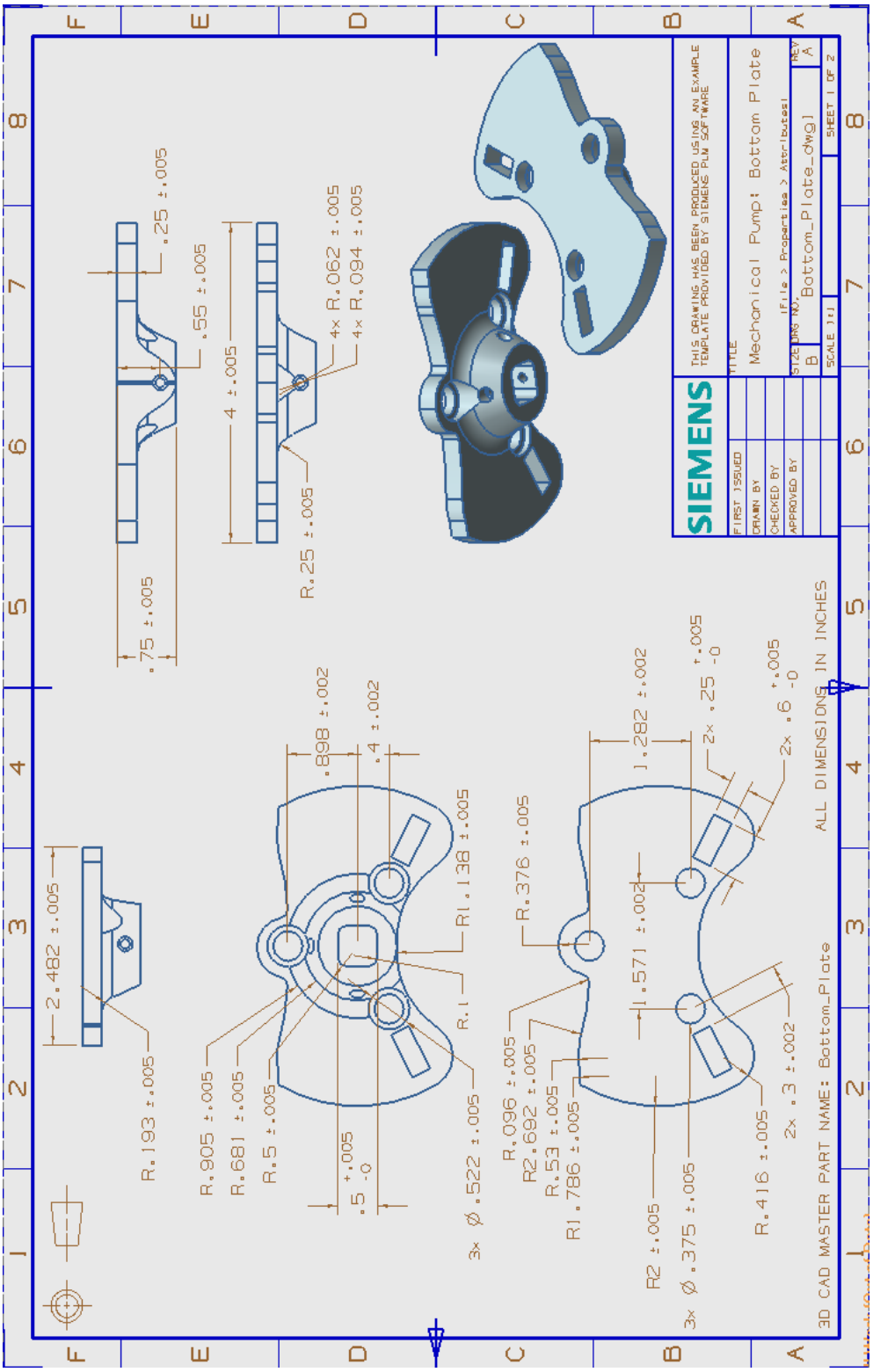
- Trans-femoral amputees

Manufacturing

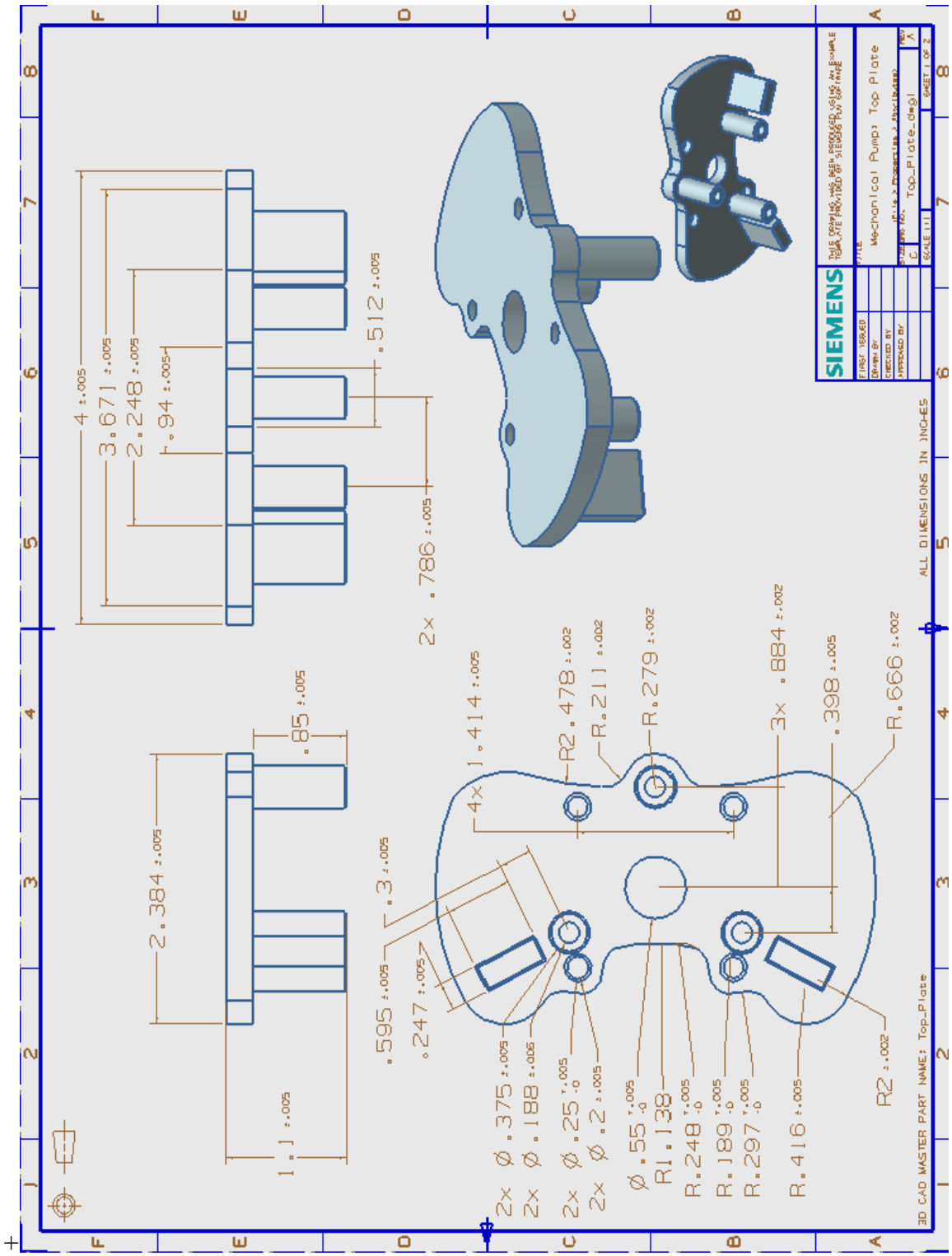
- Prototype will be produced at Ford Design Shop
- Looks-like prototype will be produced in Ford Rapid Prototyping Lab

16. Appendix B: Drawings

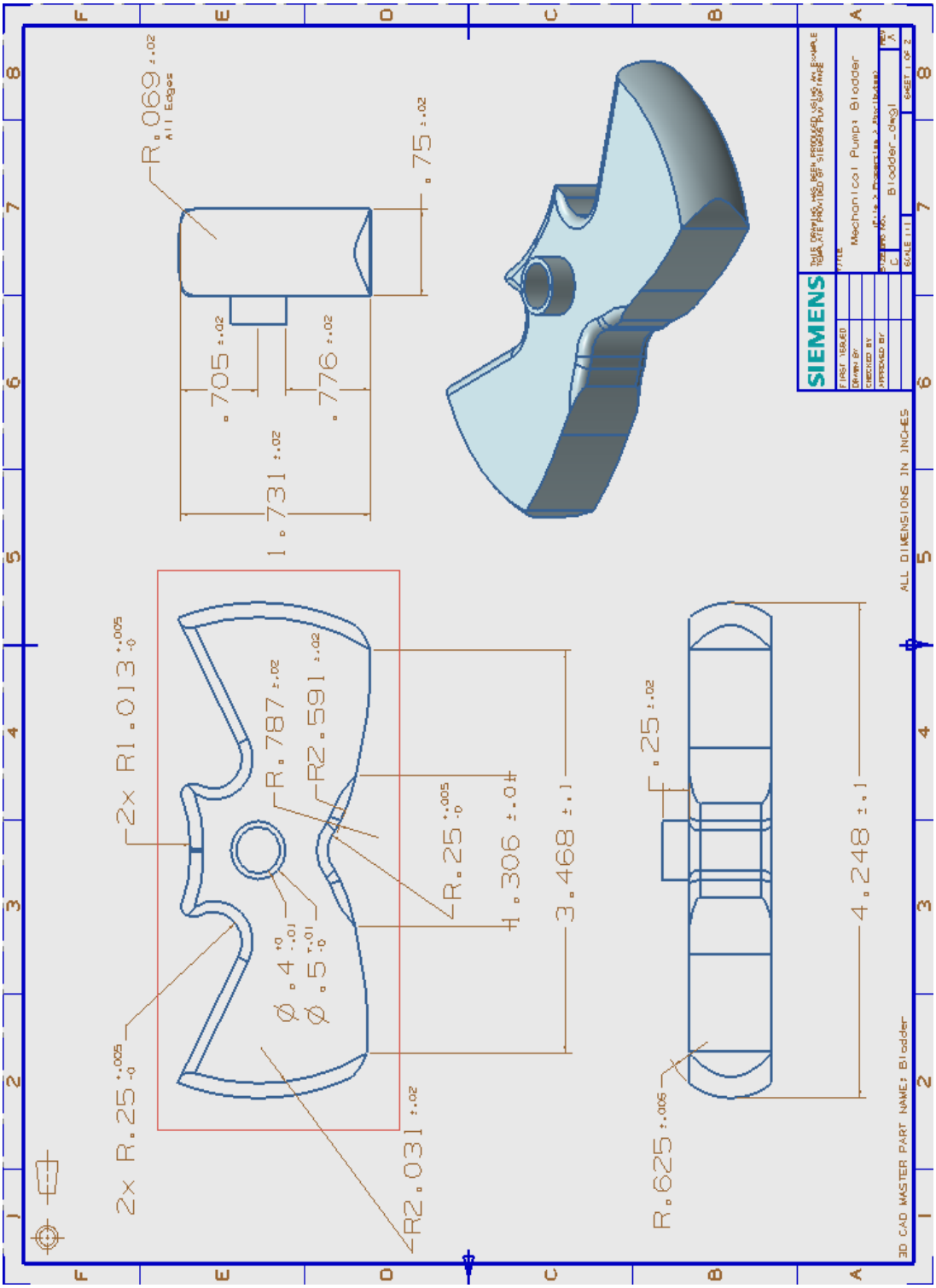
Bottom Plate (BOM 3)



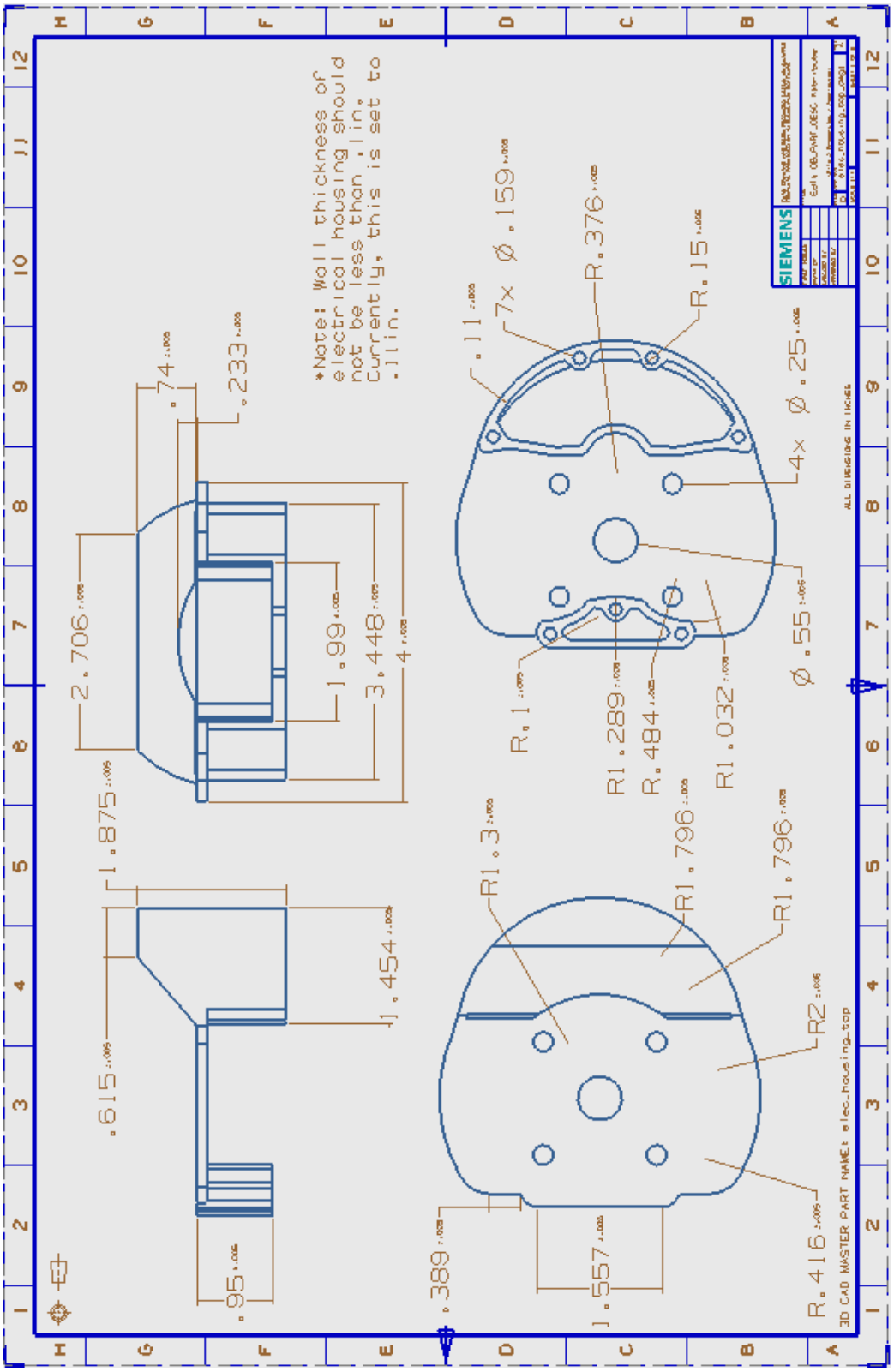
Top Plate (BOM 2)



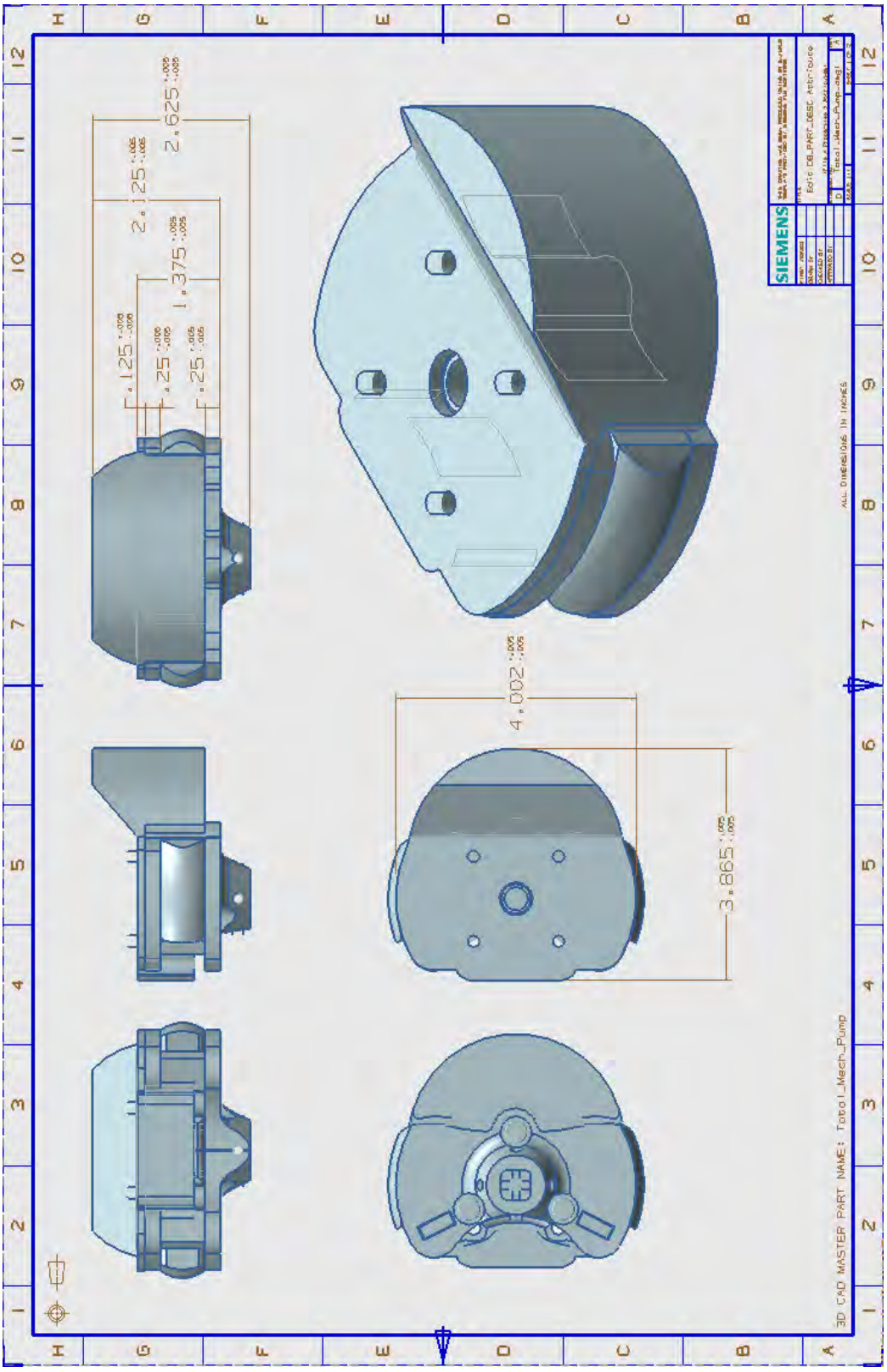
Bladder (BOM 1)



Electrical Housing (BOM Nos. 9,10)



Full Assembly



17. Appendix C: Prototype Bill of Materials

	Part	Quantity	Part number [8]	Supplier	Material	Cost [8]
1	Bladder	1	86085K18	McMaster Carr	Latex Rubber	$88.00
2	Top plate	1	86825K34	McMaster Carr	Aluminum	$172.91
3	Bottom Plate	1	See item 2	See item 2	See item 2	N/A
4	Intake Valve	1	2987K45	McMaster Carr	Nylon	$3.81
5	Expulsion Valve	2	2987K45	McMaster Carr	Nylon	$3.81
6	Top Plate Fasteners	4	92196A264	Ford Machine Shop	Stainless Steel	$0.00
7	Bottom Plate Fasteners	4	92196A264	Ford Machine Shop	Stainless Steel	$0.00
8	Stopper End Caps	3	91746A696	McMaster Carr	Stainless Steel	$2.53
9	Electrical Housing	1	See item 2	See item 2	See item 2	N/A
10	Electrical Cover	1	See item 2	See item 2	See item 2	N/A
11	Housing Fasteners	8	92196A264	Ford Machine Shop	Stainless Steel	$0.00
13	Springs	3	1692K29	McMaster Carr	Stainless Steel	$5.54

Total Prototype Cost: $296.55 [8]

18. Appendix D: User Interview Summary

ME 398: User Observation Visit and Interview Summary

Users

Luke: *Trans-femoral Amputee. Professional contractor with excellent insurance. Athletic and has a physically demanding job. Has tried everything and is Ryan's main test subject for new prosthetic technologies.*

Barry: *Retired. Trans-Tibial Amputee. Body is not in great shape: missing the toes on his right foot. Walks a mile a day inside his apartment building. Has used a Harmony P2 in the past and now uses a LimbLogic electric pump. Was part of the beta testing for the LimbLogic.*

Tom: *Polish Olympic skier. Bilateral Trans-Tibial Amputee. Traumatic injury caused his amputations and he has severe heterotropic osification on his left residual leg. Currently uses two LimbLogics. Irritation to his left residual leg causes dramatic injury and bleeding.*

Question & *Answers*

User Questions:

- How long have you been using a vacuum pump?
    - What kinds of pumps have you used? Which do you prefer? Why?

  Users preferred the electric vacuum pump in most cases. Either E-pulse or LimbLogic. (Luke/Barry) because it works. They don't have to charge it more than once a day and it does what it's supposed to. LimbLogic can last up to four days with constant use (Tom). Barry has used the LimbLogic pump for several years and in one day he sees one of four battery indicators turn off. It takes about two hours to recharge that one battery indicator. Barry used to use the Harmony P2 mechanical pump and he found that to be as functional as the LimbLogic he's using now. However the poor battery life on his previous electric pump caused him a great deal of discomfort. Barry has other issues besides the pump that he thinks need to be addressed.
- Do they want hybrid, or is that too much effort?

  They weren't against it, but for some people, mechanical is not an option. For soldiers that's debatable, but we have to consider times when the might lose pressure and not be moving around (Luke). For Tom, mechanical is not an option, but according to Ryan, a mechanical solution would still help a very large number of people. Situations where a mechanical pump won't maintain pressure that is notable: extended sitting or kneeling, lying down or crawling.
- Is hand pump better than the design Bennett presented at the presentation?

  Luke said he could get used to it, but he really likes just having to push a button. Luke says that amputees will do whatever they have to do, but it's better if it's easier.
- How often do you exercise?

  Luke: Exercises regularly (runs) several times a week, is active in his job as a building contractor.

  Tom: Olympic athlete, exercises 6-8 hours a day while in training.

- Is there ever a noticeable change in vacuum pressure while exercising/ has your prosthetic ever fallen off?
  Usually pressure is all the way up for Luke (18-20mmHg), and with the electrical pumps this isn't necessarily an issue because they maintain the vacuum pressure, but yes some pressure is lost. Sitting the vacuum re-pumps about once or twice an hour for 10-15 seconds (Luke). That being said if anything does go wrong, it's immediately noticeable and can have a big effect quickly.
- If vacuum was lost, would the prosthetic still function? How long would it be able to function?
  It will stay on but it is almost immediately uncomfortable. Function goes out the window as soon as comfort is lost and that is right after the pressure is lost. Ability to function also varies based on the user. A user with heterotropic osification will risk damaging the residual limb and pain/damage can occur immediately after device fails.
- Would this kind of pump (AK mech) affect your range of motion for your prosthetic?
  Yes, when the knee is completely bent, there is not space behind it to have anything or else motion will be impeded. A redesign that considers this was taken positively.

Questions for Ryan:

- How big can a prosthetic mold be to accompany an electrical device?
  There's enough space to bring out the mold to accommodate an electric pump above the knee. However, this may make knee placement awkward if the residual limb is very long. Ryan seemed to believe a solution like this can still help a large number of people.
- When making prosthetics molds how much do you have to consider the motion of the leg? Is this something we'd need to consider for an AK device?
  Must allow it to bend back to less than a right angle (think kneeling). Yes, it became clear that we might need to alter our design to a D or crescent shape. Sitting on a chair is also a constraint that the shape of the pump faces.
- Is there a standard connection between the prosthetic and the knee joint? Could this connection be modified to include a one-way valve?
  There are different connections (E-pulse/P3 tubing vs. LimbLogic), but mostly this is just a hole of a tube in a hole. Yes, it seems like this connection point could incorporate a 1 way valve.
- Would a hand pump above or below knee be too much human interaction?
  It's something that could be learned or something someone could get used to, but it was pretty clear that the interaction with the user should be minimal. It seemed like Luke really liked that he didn't have to do more than touch a button.
- What do the tubing connections for current pumps look like? How are they connected to the pocket of the prosthetic?

It's basically just a tube going into the socket, pretty simple, just need to make sure its sealed. There is a plastic protective cover on the "tibial" area of the c leg. The tubing was stuffed inside this empty space and was almost completely out of the way.

- What did you have in mind with the in-mold pump?
  Ryan explained that there is some space that we can play with at the bottom of the mold where the plate that connects to the knee joint is. Ryan also indicated that mounting a pump in the wall of the mold could be a feasible option. He noted that only the inside of the leg has structural support for mounting a pump. Something to consider is that an embedded pump may be more difficult to service--we would need to remain detachable.
- Because of the cost requirements and added gear, is energy harvesting something we are really interested in pursuing?
  Energy Harvesting is still on the table but we are still concerned about impeding the motion of the knee or having a heel that harvests, but that is not comfortable when walking.

<u>Important notes/ Personal Reflections:</u>
Some people cannot use mechanical solutions; they need immediate pressure before walking. This means we have to drastically revamp our design decision matrix. In my opinion, this might mean developing more than one solution to the problem or at least mandating a electrical component.

We found it interesting that Luke said he adapted to whatever system he needed as long as it worked. This gives us some leeway in terms of how much user interaction we can require.

We have a half inch or an inch of space to work with at the bottom of the prosthetic mold.

We should investigate how the LimbLogic is able to produce so much more battery life. The direct pump connection of the LimbLogic was a great benefit, since there is not any tubing there.

We learned that different people have different needs and that it may be impossible to find a solution that is perfect for every case. We should not consider extreme users part of our scope. Any person with overly intense conditions will not be sent back into the field (we should remember the intended user is military). That being said, we need to consider the function of our design in every way it will be used by a soldier.

19. Appendix E: Estimated Mechanical Performance

First, we look at the $12in^3$ case:

Evacuation Volume = $12\ in^3$

By linearly modeling the first 5 data points: ΔPressure = 0.75 inHg

We want to find how much air we remove with a pressure change of 0.75 inHg.

pV=nRT, assuming V, R, T are constant: $\frac{1}{2} = \frac{n_1}{n_2}$ (E. 1)

P_1 = atmospheric pressure = 1 atm = 29.92 inHg
P_2 = (29.92 inHg – 0.75 inHg) = 29.17 inHg
$n_1 = (12in^3)(16.39\ cm^3/\ 1\ in^3)(0.001275\ g/cm^3)(1\ mol\ /28.96\ g) = 0.008655559$ mol air (E. 2)

Then if we rearrange our ideal gas equation: $n_2 = \left(\frac{2}{1}\right) n_1$ (E. 3)

n_2 = (29.17 inHg / 29.92 inHg) 0.008655559 mol air = 0.00843862 mol air
$V_0 = (0.00843862\ mol\ air)(28.96\ g/mol)(1/0.001275\ cm^3/g)(1/16.39\ in^3/cm^3) = 11.6945\ in^3$
$\Delta V = 12\ in^3 – 11.6945\ in^3 = 0.3055\ in^3$ (E. 4)

This is the volume removed with one step at low vacuum from a $12in^3$ container.

Modeling the P3 functional ring as a cylindrical doughnut with outside radius r_0 and inner radius r_1, we can calculate how much this ring would have to deflect to accommodate this volume change.
$V = \pi r_0^2 h – \pi r_i^2 h$ (E. 5)

For the P3 functional ring, r_0 = 1in, r_i = 0.5in, h = 0.5in

$V_1 = \pi h (1 – 0.5^2) = \pi (0.5in) (0.75in^2) = 1.178\ in^3$ (E. 6)
$V_2 = V_1 – \Delta V = 1.178in^3 – 0.3055in^3 = 0.8725\ in^3$ (E. 7)

Then if we solve for h for V_2 assuming the same radii, we can find our vertical deflection:

$\pi h (0.75) = 0.8725\ in^3$
h = 0.3703 in, Δh = 0.5 in – 0.3703 in = 0.1297 in (E. 8)

Next, we look at the $2in^3$ case:

Evacuation Volume = $2\ in^3$

By linearly modeling the first 5 data points: ΔPressure = 4.0 inHg

We want to find how much air we remove with a pressure change of 4.0 inHg.

pV=nRT, assuming V, R, T are constant: $\frac{1}{2} = \frac{n_1}{n_2}$

P_1 = atmospheric pressure = 1 atm = 29.92 inHg
P_2 = (29.92 inHg – 4.0 inHg) = 25.92 inHg
n_1 = (2in^3)(16.39 cm^3/ 1 in^3)(0.001275 g/cm^3)(1 mol /28.96 g) = 0.00144318 mol air

Then if we rearrange our ideal gas equation: $n_2 = \left(\frac{2}{1}\right) n_1$

n_2 = (25.92 inHg / 29.92 inHg) 0.00144318 mol air = 0.00125024 mol air
V_0 = (0.00125024 mol air)(28.96 g/mol)(1/0.001275 cm^3/g)(1/16.39 in^3/cm^3) = 1.73262 in^3
ΔV = 2 in^3 – 1.73262 in^3 = 0.26738 in^3

This is the volume removed with one step at low vacuum from a 2in^3 container.

Modeling the P3 functional ring as a cylindrical doughnut with outside radius r_0 and inner radius r_1, we can calculate how much this ring would have to deflect to accommodate this volume change.
$V = \pi r_0^2 h - \pi r_i^2 h$

For the P3 functional ring, r_0 = 1in, r_i = 0.5in, h = 0.5in

$V_1 = \pi h (1 - 0.5^2) = \pi (0.5in) (0.75in^2) = 1.178in^3$
$V_2 = V_1 - \Delta V = 1.178in^3 - 0.26738in^3 = 0.9106 in^3$

Then if we solve for h for V_2 assuming the same radii, we can find our vertical deflection:

$\pi h (0.75) = 0.9106 in^3$
h = 0.3865 in, Δh = 0.5 in – 0.3865 in = 0.1135 in

Now we look at the case where the pump is maintaining vacuum pressure and is providing a much smaller amount of additional vacuum per step. According to Sean Wood's data, we see that regardless of the volume being evacuated, we see a plateau of around 0.075 inHg per step as the desired pressure level is reached. If we take this to be a rigid volume, we can calculate deflection in the same way as before, but in reality we have a volume change and we can't make this assumption. Therefore, to model this volume change we'll make an assumption about the settling volume of the suction pocket, taking into account leakage and the theoretical volume of zero. The theoretical zero volume would describe a perfect vacuum, but since there's leakage, we can expect a volume of approximately 0.1 in^3. This scenario also changes the theoretical deformation of the functional ring, since the ring itself is subject to the vacuum pressure in the system, meaning that the ring will expand much less as the vacuum has risen.

Our evacuation volume is now 0.1in^3

By linearly modeling the last few data points: ΔPressure = 0.075 inHg

We want to find how much air we remove with a pressure change of 0.075 inHg.

pV=nRT, assuming V, R, T are constant: $\frac{1}{2} = \frac{n_1}{n_2}$

P_1 = goal pressure – 0.075 inHg = 29.92 inHg - 20 inHg + 0.075 inHg = 9.995 inHg
P_2 = 9.92 inHg
$n_1 = (0.1in^3)(16.39\ cm^3/\ 1\ in^3)(0.001275\ g/cm^3)(1\ mol\ /28.96\ g) = 0.000072159$ mol air

Then if we rearrange our ideal gas equation: $n_2 = \left(\frac{2}{1}\right) n_1$

n_2 = (9.92 inHg / 9.995 inHg) 0.000072159 mol air = 0.0000716175 mol air
$V_0 = (0.0000716175\ mol\ air)(28.96\ g/mol)(1/0.001275\ cm^3/g)(1/16.39\ in^3/cm^3) = .0992496\ in^3$
$\Delta V = 0.1\ in^3 – 0.0992496\ in^3 = 0.0007504\ in^3$

This is the volume removed with one step at high vacuum.
$V = \pi r_0^2 h – \pi r_i^2 h$

For the P3 functional ring, r_0 = 1in, r_i = 0.5in, h = 0.5in

$V_1 = \pi h (1 – 0.5^2) = \pi (0.5in) (0.75in^2) = 1.178in^3$
$V_2 = V_1 – \Delta V = 1.178in^3 – 0.0007504in^3 = 1.17725\ in^3$

Then if we solve for h for V_2 assuming the same radii, we can find our vertical deflection:

$\pi h (0.75) = 1.17725in^3$
h = 0.49964 in, Δh = 0.5 in – 0.49964 in = 0.00036 in

Now that we better understand how the P3 performs, we can compare its performance to the theoretical performance of our prototype. The performance at high pressure is a key part of our design, as maintaining pressure is the most important role of our mechanical pump. However, this scenario is also significantly less interesting, since we know that the performance once the pump reaches high pressure will be identical as long as our system maintains a similar system spring constant *k*. This means we'll evaluate our pump as if it were being used as the primary device, describing a case where our electrical pump has failed and we need to rely on it for establishing initial pressure.

First, we compare the volume of the P3 functional ring with the volume of our functional ring:

P3 = $1.178in^3$, our design = $3.8368\ in^3$ (E. 9)

Volume Percentage = $(3.8368\ in^3/1.178in^3) = 325.7\%$ (E. 10)

This means we can expect a performance based on volume:

$12in^3$ = 2.442 inHg per step

$2in^3$ = 13.028 inHg per step

Since we are using a similar spring constant *k* in order to maintain comfortable levels of support through the limb, we expect similar deflection to the results we found with the P3. We calculate the approximate value of *k* for the P3 below:

F = kx, where k is the spring constant and x is the deflection of the spring. (E. 11)

If we take a standard value for F of 180lbf = 800N, and the displacement we've calculated from our first calculation (with a $12in^3$ volume) of 0.1297 in = 0.00329, we calculate k:

k = 800N/0.00329 m = 2.43e5 N/m (E. 12)

This high level of stiffness is to ensure that the user is stable and supported by the limb, limiting the deflection to a very small range of motion. In user testing it's clear that if a limb has too much give that the comfort of the user can suffer significantly.

Appendix K

Subischial Prosthetic Socket Technology: Mold Impression and Modification

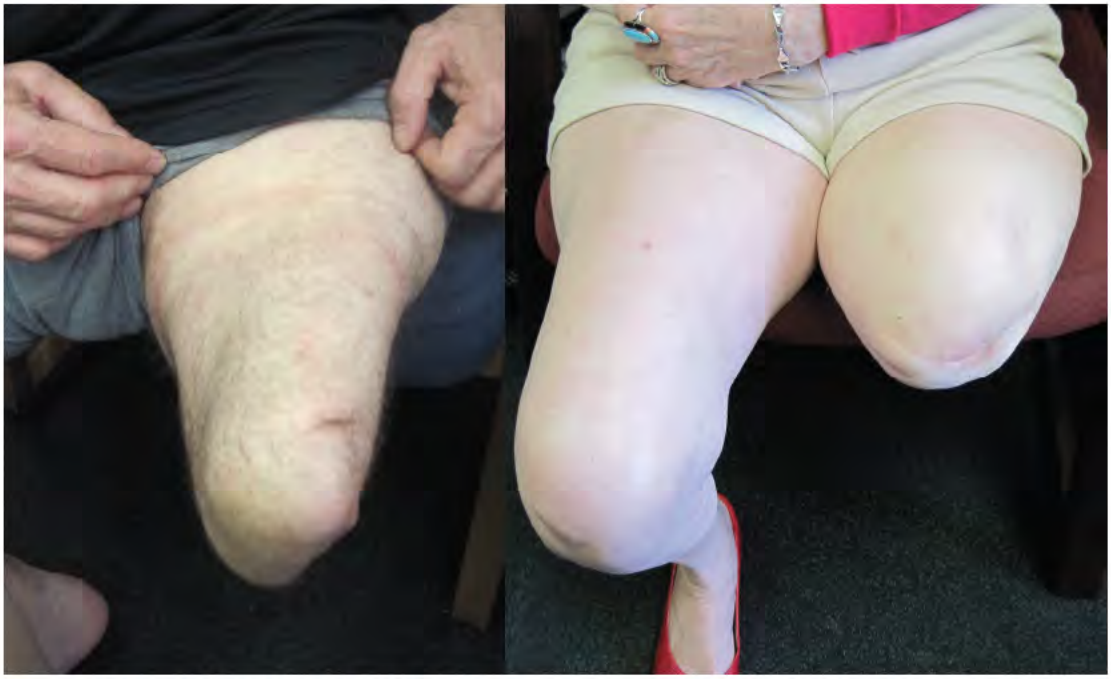
Single Wall Subischial Socket Technology

The system consists of a silicone liner that is rolled on to the residuum, void of any air pockets between the liner and limb. An air wick is pulled over the liner to provide an air space for the negative pressure. The patient stands into the socket and pulls the remaining liner and air wick over the socket edge. A sleeve is used to seal the portion of the liner that is outside the socket to the socket wall. The vacuum pump is activated to seat the liner/limb securely to the interior of the socket to provide suspension and linkage of the prosthesis. The trim lines are such that through range of motion and walking, the ischial tuberosity does not contact the socket.

Sequence of Events

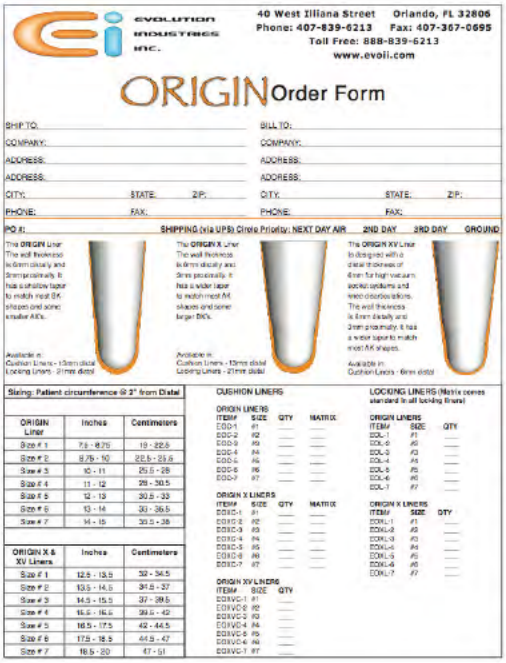
- Evaluate residual limb shape
- Determine liner type
- Don liner
- Evaluate limb shape with liner compression
  - Modifications are based on limb shape with liner
- Mold assessment/modification
- Check socket evaluation

Patient Evaluation for Liner Selection



Residual limbs that have a somewhat cylindrical, non-descript shape utilize an undersized off-the-shelf liner.

OTS Liner Selection



EVOLUTION INDUSTRIES INC.
40 West Illiana Street Orlando, FL 32806
Phone: 407-839-6213 Fax: 407-367-0695
Toll Free: 888-839-6213
www.evoii.com

ORIGIN Order Form

SHIP TO: BILL TO:
COMPANY: COMPANY:
ADDRESS: ADDRESS:
ADDRESS: ADDRESS:
CITY: STATE: ZIP: CITY: STATE: ZIP:
PHONE: FAX: PHONE: FAX:
PO #: SHIPPING (via UPS) Circle Priority: NEXT DAY AIR 2ND DAY 3RD DAY GROUND

The ORIGIN Liner The wall thickness is 6mm distally and 3mm proximally. It has a shallow taper to match most BK shapes and some smaller AKs.
Available in: Cushion Liners - 13mm distal Locking Liners - 21mm distal

The ORIGIN X Liner The wall thickness is 6mm distally and 3mm proximally. It has a wider taper to match most AK shapes and some larger BKs.
Available in: Cushion Liners - 13mm distal Locking Liners - 21mm distal

The ORIGIN XV Liner is designed with a distal thickness of 6mm for high vacuum socket systems and knee disarticulations. The wall thickness is 6mm distally and 3mm proximally. It has a wider taper to match most AK shapes.
Available in: Cushion Liners - 6mm distal

Sizing: Patient circumference @ 2" from Distal

ORIGIN Liner	Inches	Centimeters
Size # 1	7.5 - 8.75	19 - 22.5
Size # 2	8.75 - 10	22.5 - 25.5
Size # 3	10 - 11	25.5 - 28
Size # 4	11 - 12	28 - 30.5
Size # 5	12 - 13	30.5 - 33
Size # 6	13 - 14	33 - 35.5
Size # 7	14 - 15	35.5 - 38

ORIGIN X & XV Liners	Inches	Centimeters
Size # 1	12.5 - 13.5	32 - 34.5
Size # 2	13.5 - 14.5	34.5 - 37
Size # 3	14.5 - 15.5	37 - 39.5
Size # 4	15.5 - 16.5	39.5 - 42
Size # 5	16.5 - 17.5	42 - 44.5
Size # 6	17.5 - 18.5	44.5 - 47
Size # 7	18.5 - 20	47 - 51

CUSHION LINERS
ORIGIN LINERS — ITEM | SIZE | QTY | MATRIX
ORIGIN X LINERS — ITEM | SIZE | QTY | MATRIX
ORIGIN XV LINERS — ITEM | SIZE | QTY

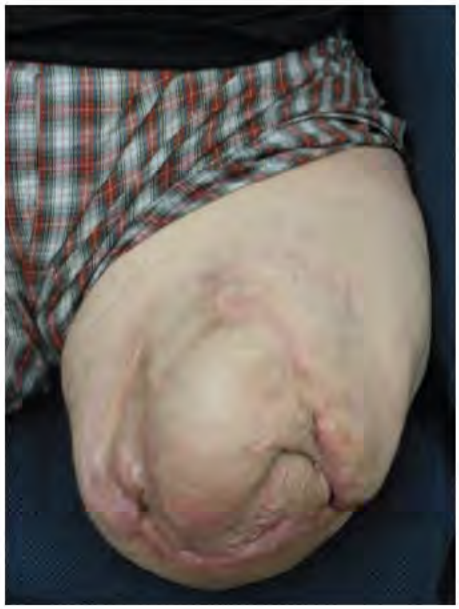
LOCKING LINERS (Matrix comes standard in all locking liners)
ORIGIN LINERS — ITEM | SIZE | QTY
ORIGIN X LINERS — ITEM | SIZE | QTY

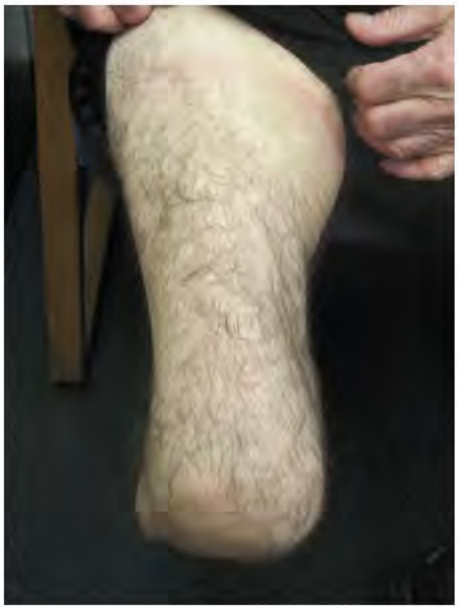
Sizing: Patient circumference @ 2" from Distal

ORIGIN Liner	Inches	Centimeters
Size # 1	7.5 - 8.75	19 - 22.5
Size # 2	8.75 - 10	22.5 - 25.5
Size # 3	10 - 11	25.5 - 28
Size # 4	11 - 12	28 - 30.5
Size # 5	12 - 13	30.5 - 33
Size # 6	13 - 14	33 - 35.5
Size # 7	14 - 15	35.5 - 38

An undersized, tacky silicone liner is utilized to apply compression to the soft tissues of the limb and to pre-define limb shape. A size smaller than the recommended manufacturer selected liner is typically used. For an Origin liner, a patient that measures 36 cm in circumference at 2 inches from distal end in this case would be fit with a size #6.

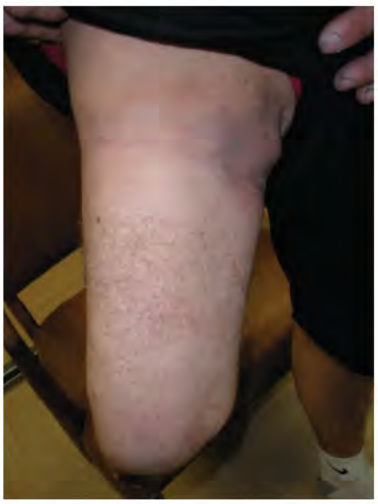
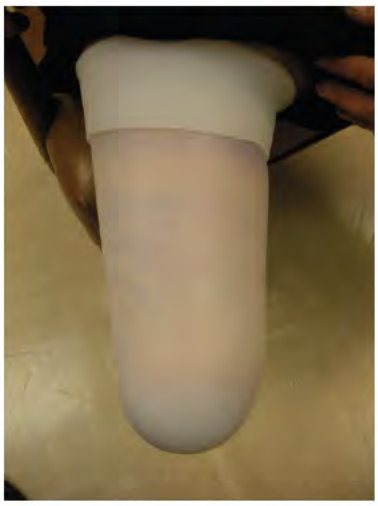
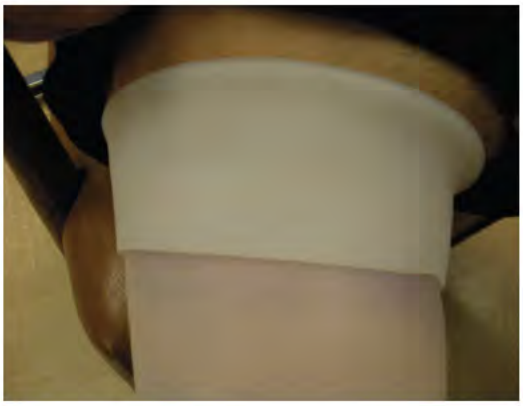
Patient Evaluation for a Custom Liner





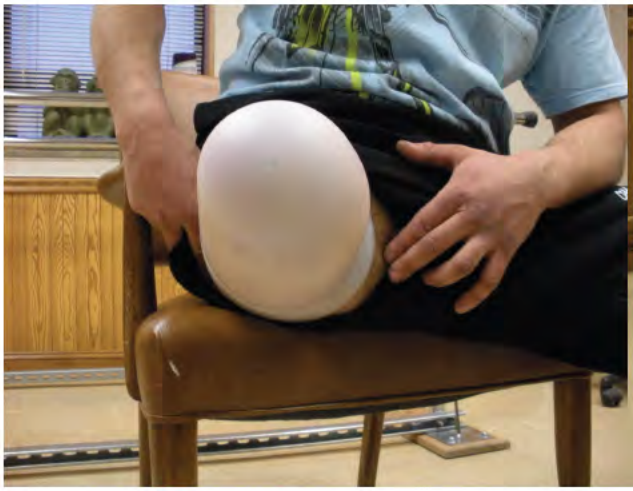
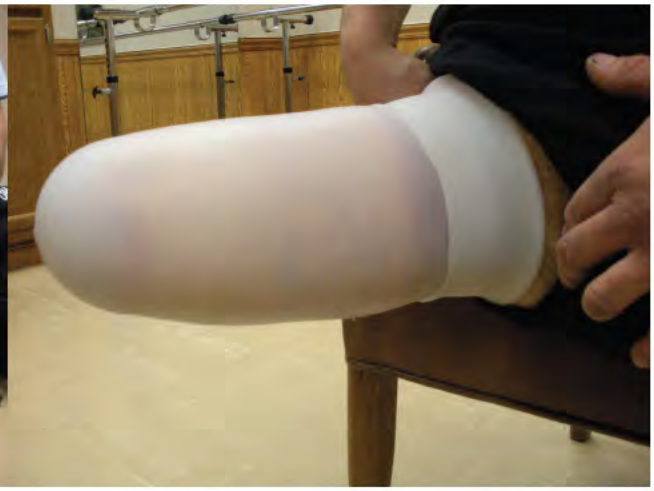
Limbs that are heavily scarred or irregular in shape may require a custom silicone tacky liner to help provide a more cylindrical non-descript shape. Custom liners are also used to eliminate problems associated with air pockets between the liner and limb, or to utilize silicone build-ups to allow the user to don the socket.

Donning the Liner

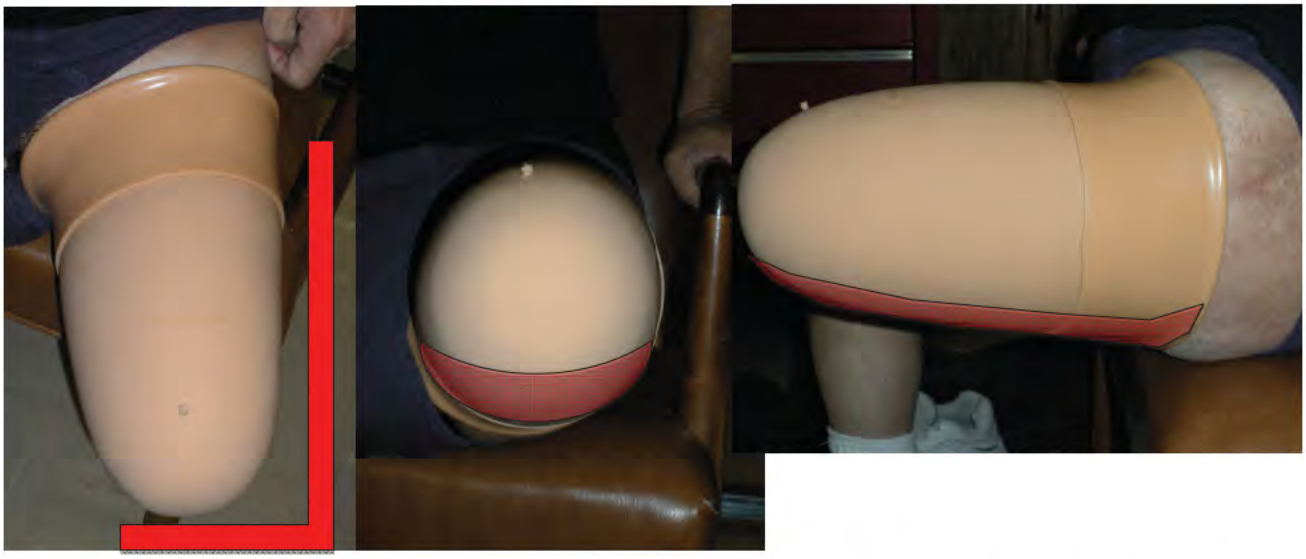
The liner is rolled onto the limb as high as it will go into the inguinal crease void of any air pockets. 1-2 inches of the proximal liner may remain folded over and away from the inguinal crease. This fold provides a generous proximal flare that will help create the socket trim line at the most proximal point of the liner and increase compression the soft proximal tissue. The overlapped liner thickness must be taken into consideration when the mold is modified.

Residual Limb Positioning During Evaluation and Casting

The patient will sit with their limb in flexion and abduction to allow a mold to extend as proximally as possible and to allow gravity to help pre-define the limb/liner shape. Evaluation of the limb under the compression of the liner in this position is important to reassess the uniform or oblong shape. The shape with the liner is what determines your final decision for the modifications.

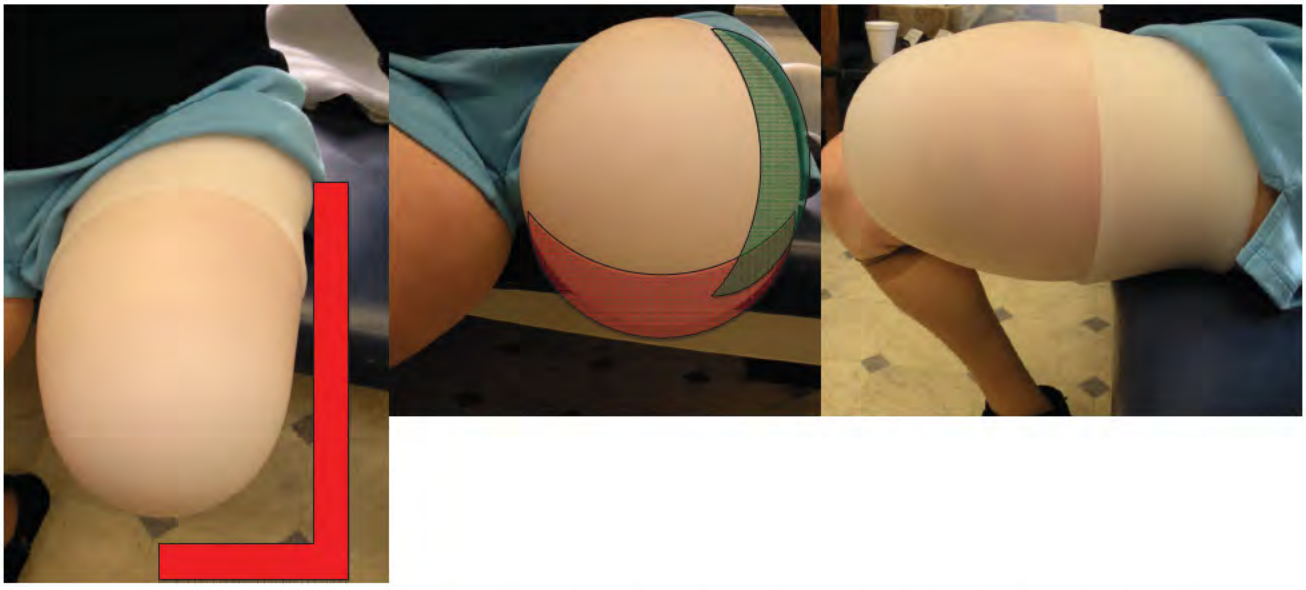
Patient Residual Limb/Liner Evaluation
Limb Shape in Seated Position



Lateral wall of limb does not flare outwards very much (i.e. away from a vertical anterior midline.)

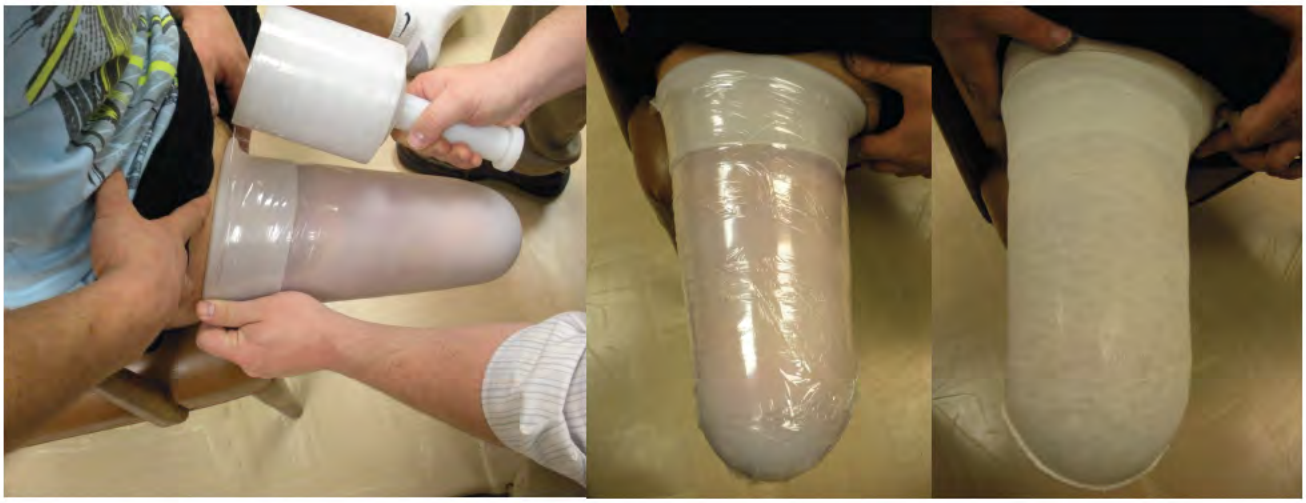
Standard transfemoral shape where the anterior muscle belly is more firm than the posterior tissues. The posterior soft tissue tends to droop in the seated position creating an oblong shape.

Patient Residual Limb/Liner Evaluation
Limb Shape in Seated Position



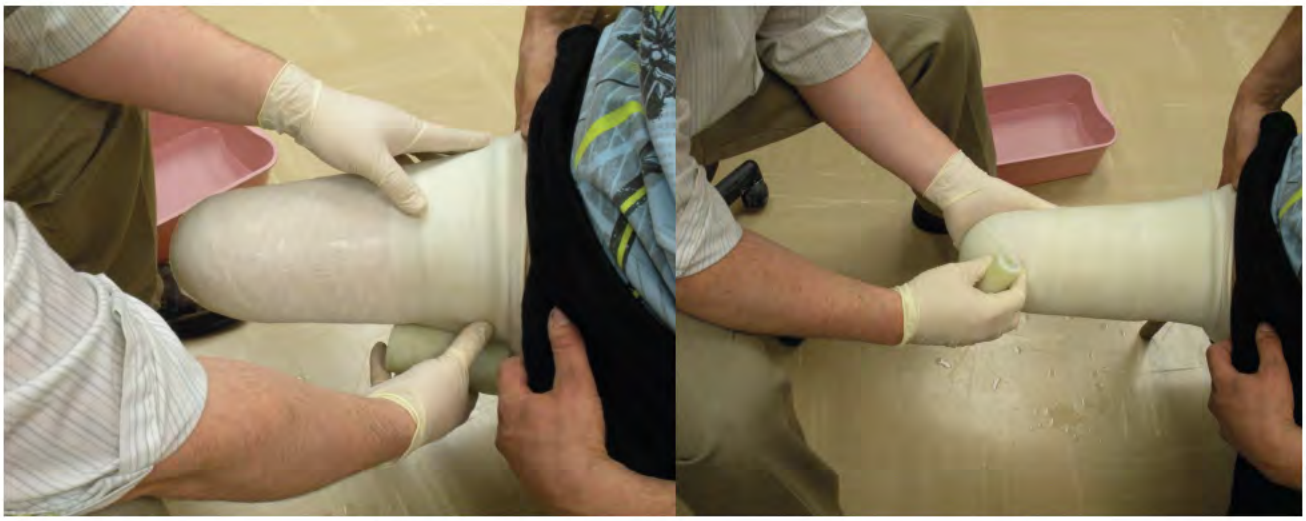
A more uniformly shaped residual limb and liner is presented in these photos. The lateral and posterior silhouettes both flare away from the anterior midline of the limb.

Preparation for the Molding Process



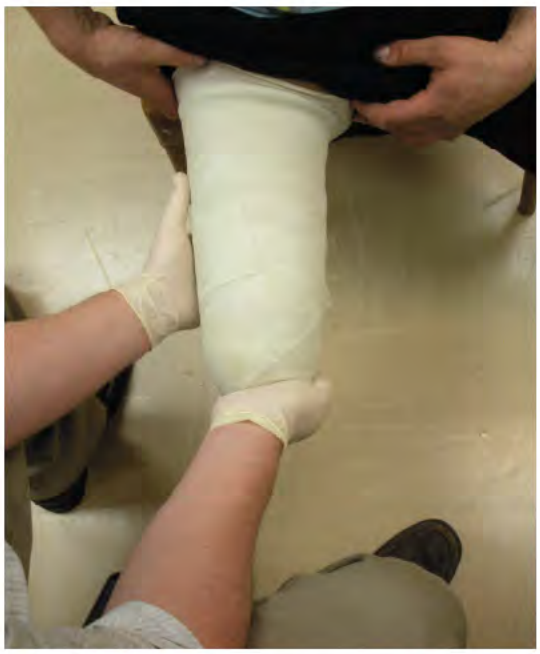
A thin layer of plastic wrap is used to keep the resins within the fiberglass casting tape from altering the silicone surface properties. A thin cast sock is donned making sure to extend past the folded silicone liner.

Mold Impression



Lightly wrap the residual limb with two layers of the fiberglass casting tape from the proximal lateral corner moving medially through the inguinal crease and proceeding distally on the limb.

Distal End Consideration



Finish the distal end with a figure of eight wrap and apply slight compression distally with one hand to ensure a total contact impression. Significant distal end redundant tissue will require more distal end pressure to ensure a total contact fit due to a possible elongation effect when the liner is donned.

Anterior Reference Line

Mark the anterior midline of the mold. This will assist in the modification and alignment of the socket.

Removing the Mold

It is important to gauge the force needed to displace the mold from the residual limb and to utilize this information when making modifications. As you pull the mold off the limb, the degree of resistance encountered may vary. Pay particular attention to these variations as difficult spots with more resistance may affect whether the patient will be able to properly don the socket and impact your modification decisions. Typically, difficulty in removal of the cast occurs when there is a slight increase in volume at a particular point along the limb and this "bulge" should be reduced when modifying the mold, assuming it is due to soft tissue only.

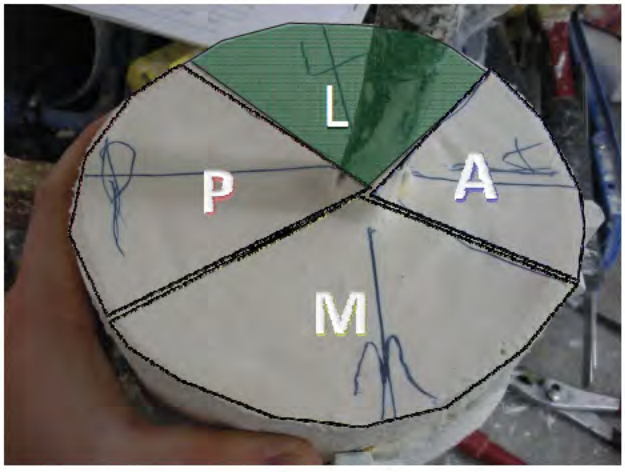
Pouring the Negative Mold

Plaster wrap is used to make the mold longer for easier fabrication making sure to follow the shape of the proximal edge as this is your initial check socket trim line. The negative mold is filled with plaster of Paris to create the positive model. The mold is poured with the anterior midline vertical to the ground. The mandril is an important reference for modifications and should be parallel to the anterior midline and centered in the mold. It helps to identify vertical when modifying.

Preparing the Positive Model

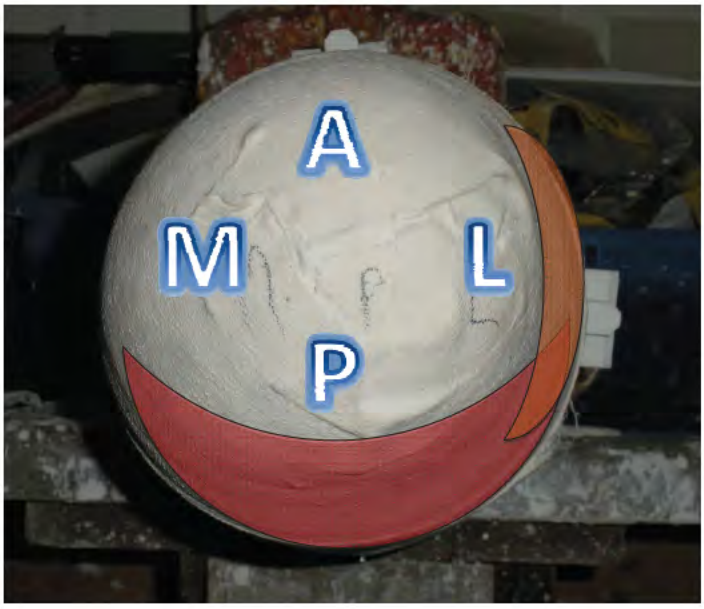
Before stripping the fiberglass casting tape from the mold, transfer the anterior midline reference point to the top of the mold.

Establishing Quadrants for Modifications



The anterior midline mark is used to create a quadrant system on the top of the mold to divide the mold into sections. The anterior midline on the top of the mold continues in a straight line posteriorly to create the posterior midline. Medial and lateral lines are formed perpendicular to these lines. The bisection of these lines form quadrants that will be used in the modification procedure.

Confirmation of Limb Shape



The positive model should have the shape that was seen in the evaluation of the limb with the liner on. If the mold does not present the same shape, a second mold should be made.

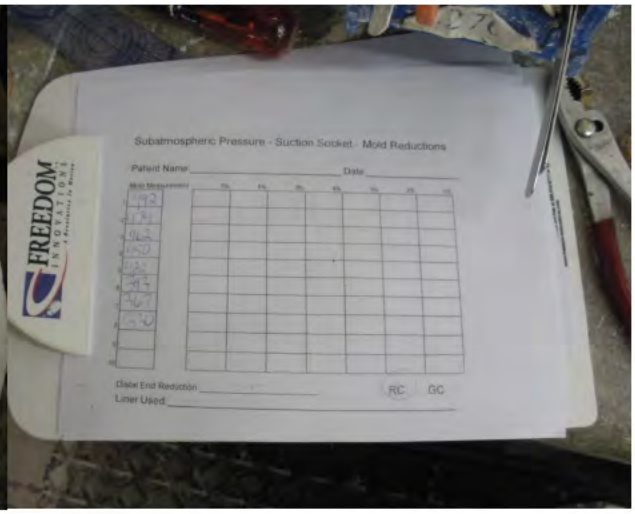
Preparation of the Mold for Percentage Reduction

In order to take accurate measurements, it is recommended to lightly smooth the mold to remove the overlapping liner thickness proximally and any artifacts from the molding procedure.

Mold Preparation

A scratch awl is used to mark one inch increments on the medial wall of the mold from one inch below the initial trim line as a reference for the mold rectification reduction percentages. Refer to algorithm to determine percentage based on shape, tissue type and difficulty to displace the mold from the limb.

Measurements and Calculations for Reduction of the Positive Model



Lateral Quadrant Assessment

Photo: Anterior Aspect of Mold
Blue Line: Anterior Midline
Green Line: Lateral Line of Taper

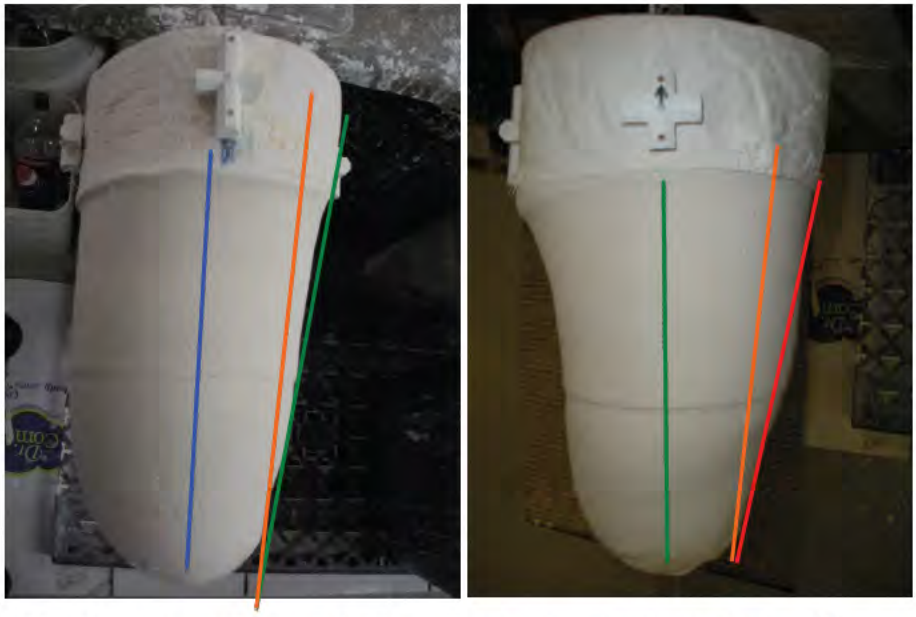
The lateral wall is assessed by using the anterior midline and the lateral line of taper which is a line that extends along the lateral silhouette of the mold. After modification the lateral line of taper should be more vertical to the ground.

Posterior Quadrant Assessment

Photo: Lateral Aspect of Mold
Green Line: Lateral Midline
Red Line: Posterior Line of Taper

The posterior wall is assessed using the lateral midline and the posterior line of taper which follows the silhouette of the posterior wall. After modification, the posterior line of taper should be more vertical to the ground.

Modification Assessment



Left Photo: Anterior Aspect of Mold

Right Photo: Lateral Aspect of Mold

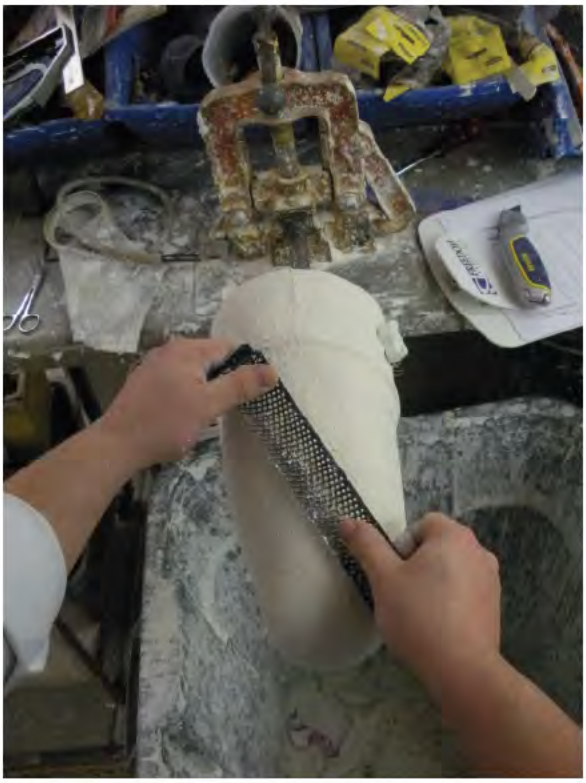
Blue Line: Anterior Midline
Green Line: Lateral Line of Taper/Lateral Midline
Red Line: Posterior Line of Taper
Orange: Ideal Modification Line

Modifications are typically concentrated on the posterior and lateral walls. Of these two walls, the one with the most "taper" will be reduced the most within the limits set by the overall circumferential reductions. This reduction should make the wall more vertical with the ground. The areas that typically need the most reduction are the proximal lateral wall and the posterior soft tissue belly.

Distal End Reduction

The distal end reduction is utilized to ensure a total contact fit with hydrostatic loading of the soft tissue. Distal end reduction is proportional to the amount of redundant soft tissue distally, taking into consideration the initial limb and liner evaluation. 0-20mm reduction. Refer to algorithm.

Mold Rectification



Posterior:

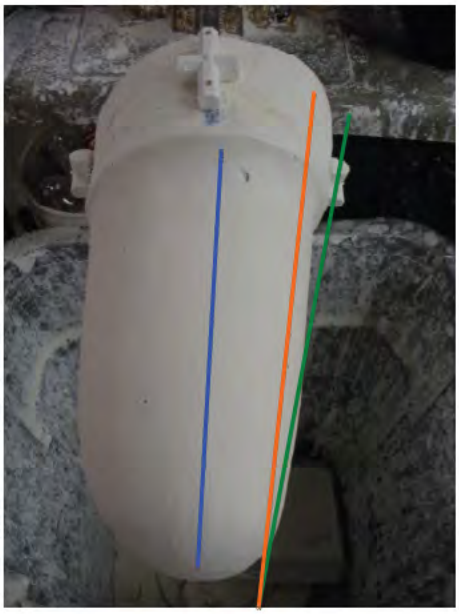
The reduction of the "droop" of the soft tissue belly is flattened to provide pressure and ensure hydrostatic loading of the soft tissues. It is important that this area be relatively flat to provide soft tissue support while standing and sitting. This flattening effect simulates the splaying of posterior tissues that happens when seated and helps eliminate the loss of limb/liner coupling. Refer to algorithm for reduction percentage.

Mold Rectification

Lateral:

The proximal lateral wall is heavily modified to eliminate the toggling effect of the limb/liner that occurs when the M/L of the socket is loose. This tight proximal trim line also creates improved cosmesis by hugging the proximal tissue. Refer to algorithm for reduction percentage. After the reduction is finished, smooth the mold using screen or fabricut.

Anterior View of Mold



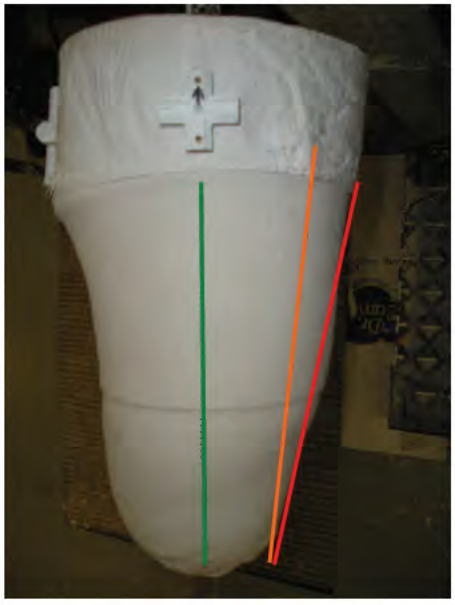
The rectified mold's lateral wall is more perpendicular to the ground. The proximal trim line is cupped in with a slight flare for the soft tissue to exit the socket.

Un-rectified

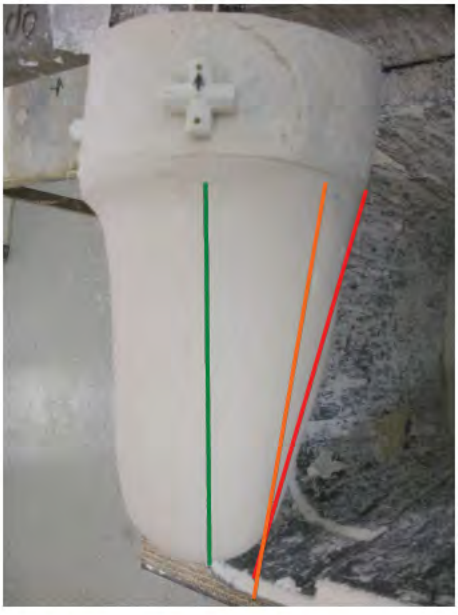
Rectified

Lateral View of Mold

Un-rectified

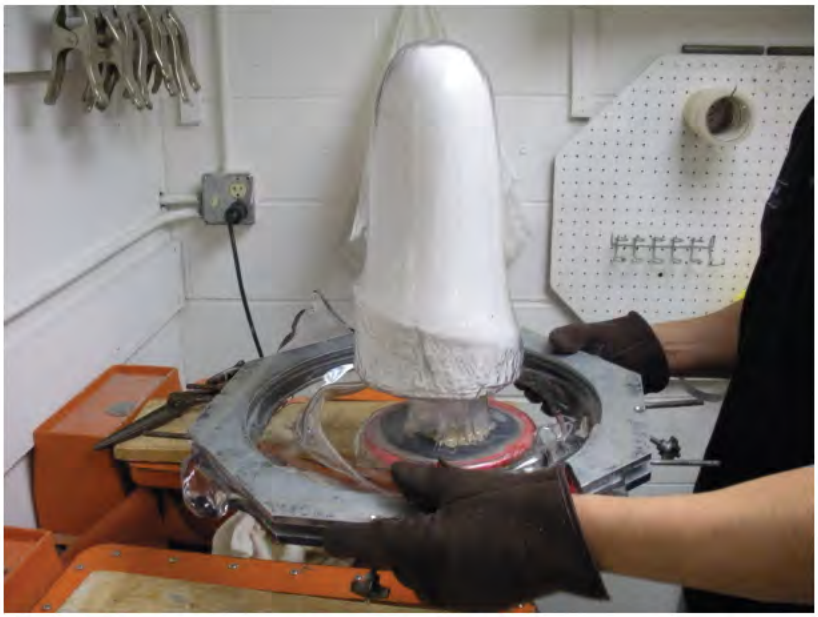


Rectified



The posterior soft tissue belly has been flattened and is almost perpendicular to the ground when the patient is standing. The proximal trim line has been tightened with a slight flare for the soft tissue.

Check Socket

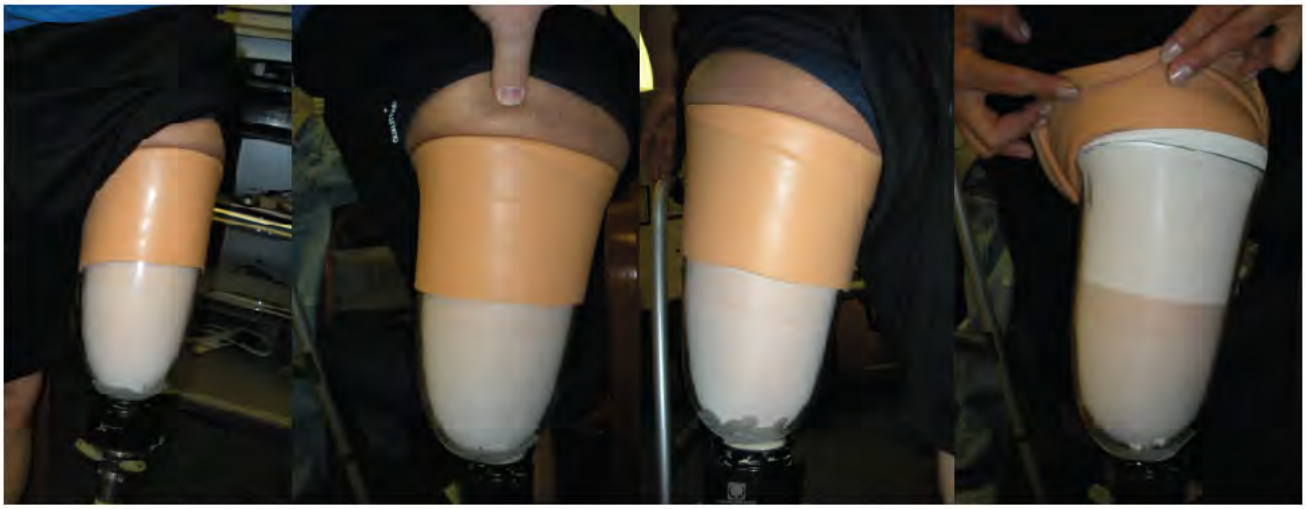


PETG clear thermoplastic is blister formed over the mold to fabricate a dynamic diagnostic tool to evaluate the fit of the socket.

Initial Socket Trim Lines

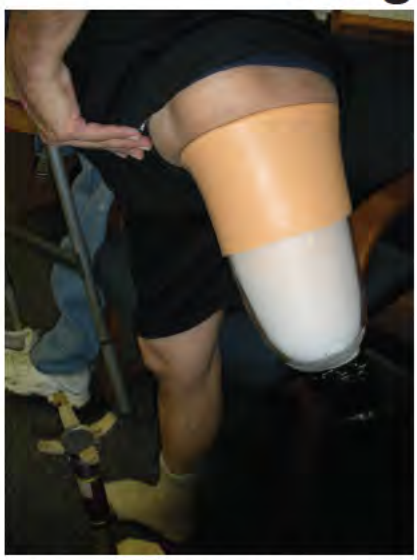
Initial socket trim lines were established in the molding process and are used for the diagnostic check socket. The socket is cut just proximal to the trim line to allow for sanding and buffing. The initial trim line was discussed in slide 7. The shiny surface of the plastic is lightly sanded on the distal end to allow the socket attachment block and epoxy to bond. Pictured above from left to right (anterior, medial, posterior, lateral). The extension of the mold and the trim lines created in the molding process are clearly visible.

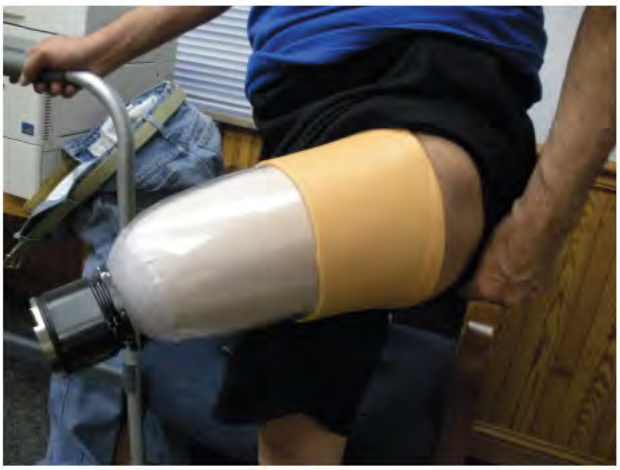
Check Socket Fitting:
Volume



In the check socket fitting, the patient will don the liner and air wick, and stand into the clear socket. The socket is supported on a fitting stand or any hard surface. Initially there is some opposition getting into the distal end of the check socket with uniform pressure throughout. There should be no gapping of the socket along the lateral wall upon weight-bearing and under vacuum. The user should not feel pressure in any one area.

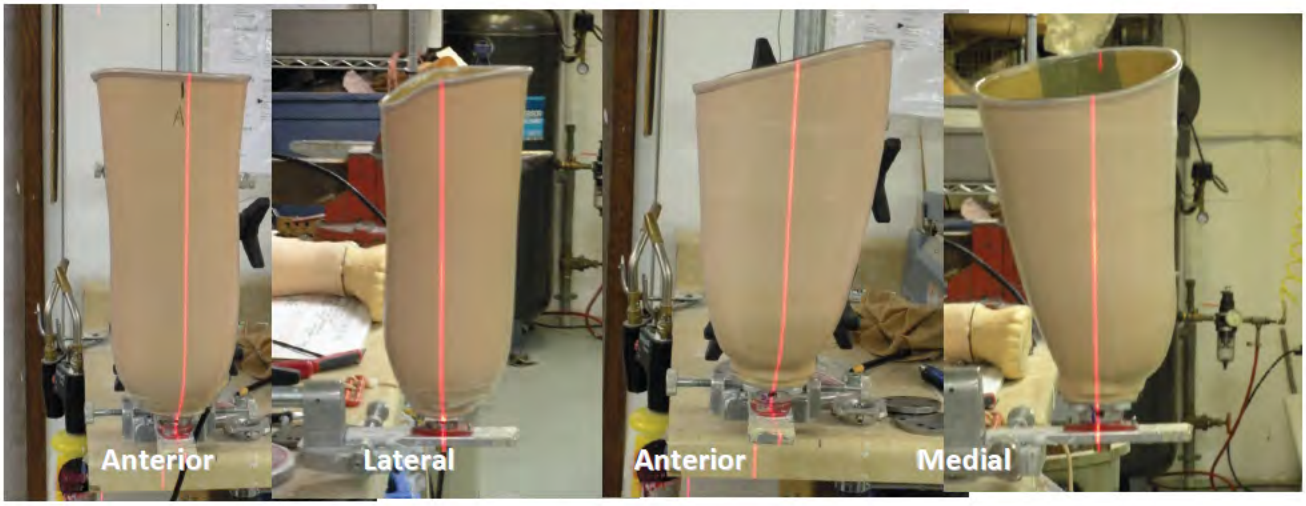
Check Socket Fitting:
Range of Motion





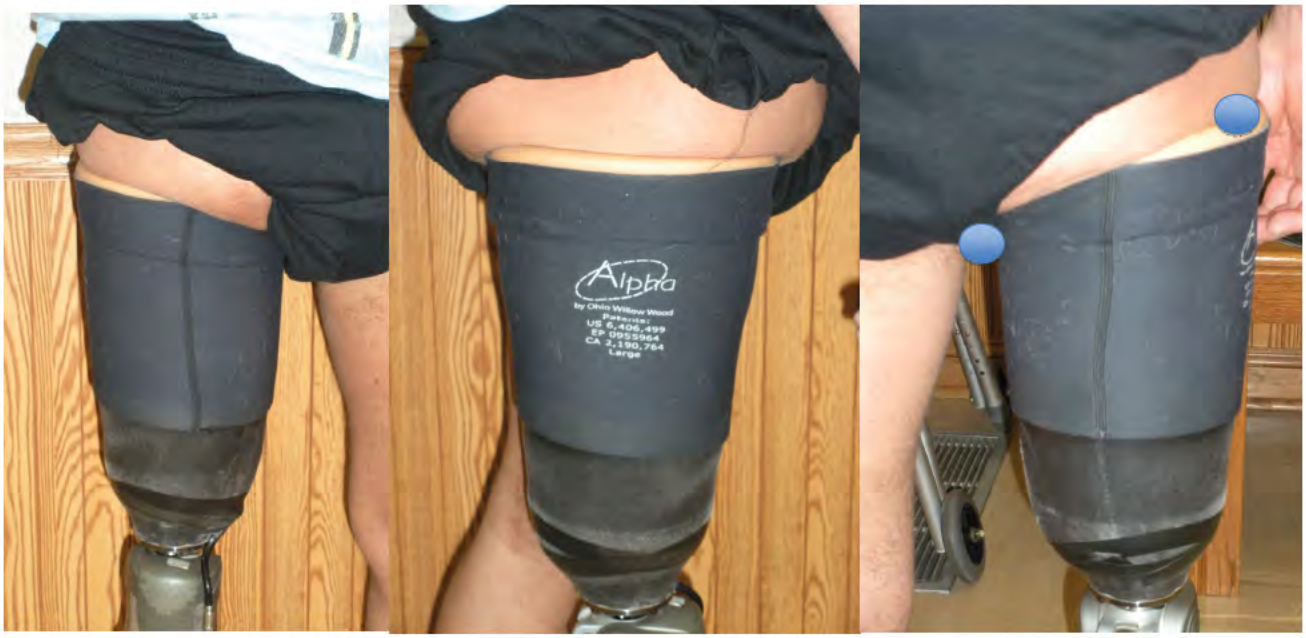
Once the volume evaluation looks satisfactory, the vacuum pump is turned on. The user will go through their range of motion to ensure the ischial tuberosity is not touching or impinging the socket under vacuum. If there is tendon or ischial tuberosity impingement, flaring the posterior/medial trim line is recommended as a first option. If flaring does not resolve the impingement, trimming the proximal edge of the check socket (usually posterior/medial) is the next option.

Alignment Considerations



- Neutral or slight adduction for longer limbs.
  - Neutral means anterior midline vertical in the coronal plane.
  - For longer limbs, consider the socket placed on the limb and adduct the hip slightly.
- Bench alignment specific to the knee only.
  - Typically these alignments focus on the sagittal plane.

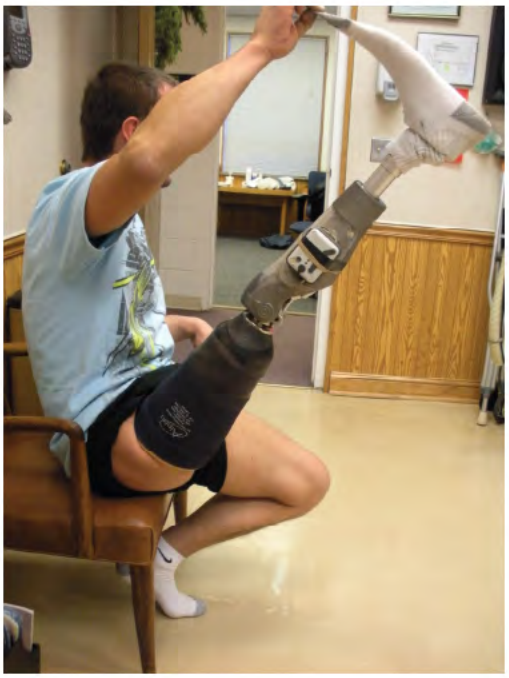
Finished Socket Trim lines



Finished socket trim lines are typically 25 mm distal to the ischial tuberosity, and 30 to 45mm distal to the greater trochanter. In comfortable standing and during midstance the proximal trim line should maintain a total contact fit.

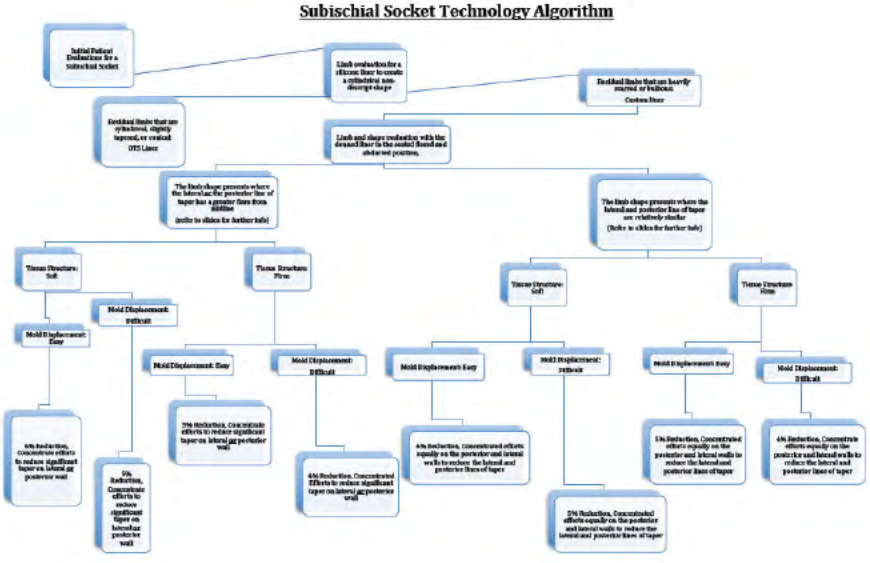
ROM
Hip Flexion

ROM



Hip Extension

Subischial Socket Technology Algorithm



Distal End Considerations:
Distal end reduction based on amount of redundant soft tissue:
No soft tissue=0mm reduction, 12mm of soft tissue=6mm reduction, 25mm of soft tissue=12mm reduction
Significant redundant tissue requires distal pressure during molding procedure to ensure total contact fit

Gait Kinematics and Kinetics in Sub-Ischial Sockets with Assisted-Vacuum Suspension: Case Studies of Persons with Transfemoral Amputation

Stefania Fatone, PhD, BPO (Hons)
Northwestern University Prosthetics Research Laboratory & Rehabilitation Engineering Research Program
Chicago IL

Ryan Caldwell, CP
Suburban Orthotics & Prosthetics
Des Plaines IL

Socket Comparison

Subischial Socket Components

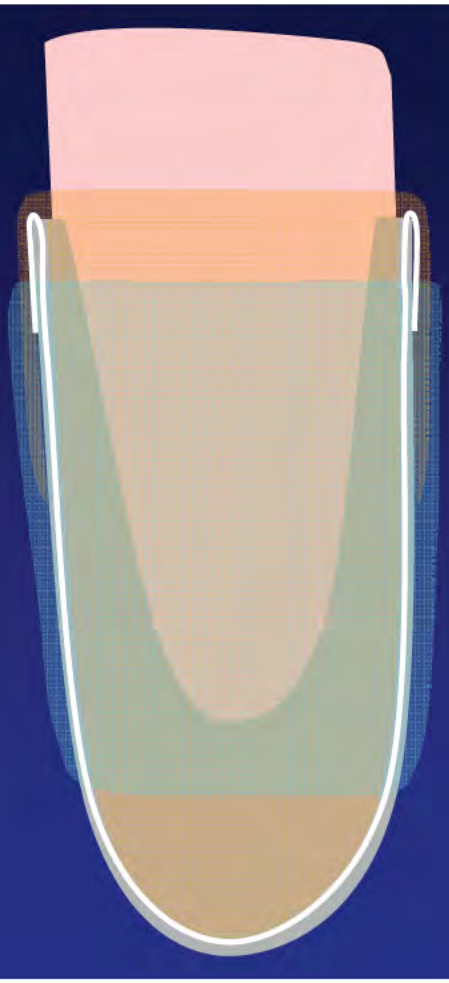
Limb

Liner
10-30% undersized

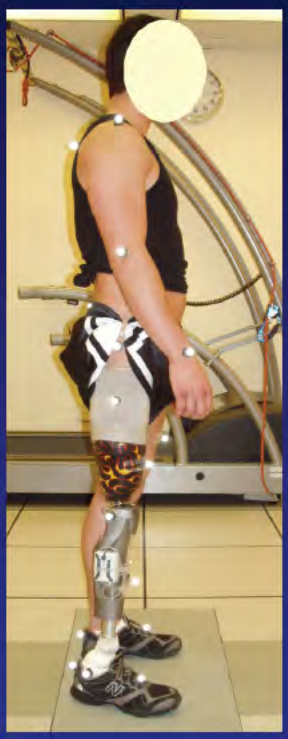
Wick

Socket
4-7% undersized

Sleeve

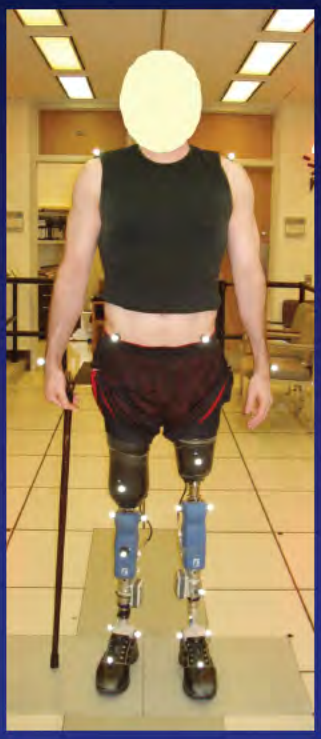


Case 1



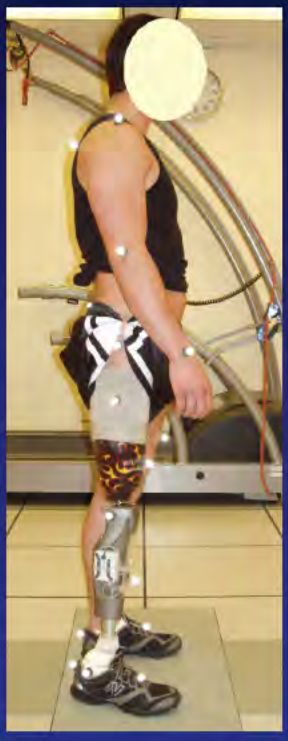
R TFA (trauma)
26 y.o., 179cm, 81.5kg
Sub-ischial socket
E-Pulse (Otto Bock)
C-leg (Otto Bock)
Highlander foot

Case 2



L TFA / R KDA (trauma)
34 y.o., 188.5cm, 76.7kg
Sub-ischial sockets
E-Pulse (Otto Bock)
Rheo Knees (Ossur)
Delta Twist (Otto Bock)
True Step (College Park)
Single point cane

Case 1



Data collected at VACMARL
8 cameras
6 force plates

Modified Helen Hayes marker set

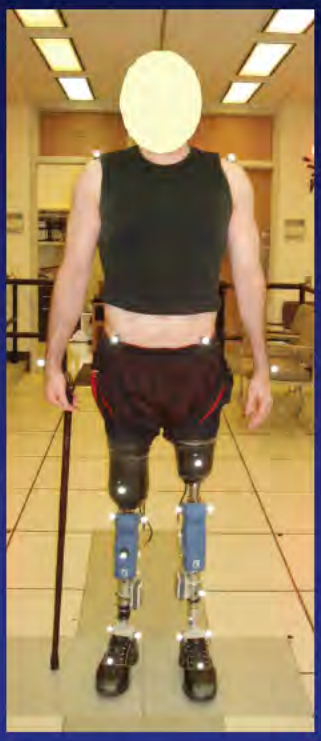
Self-selected walking speed

Level ground

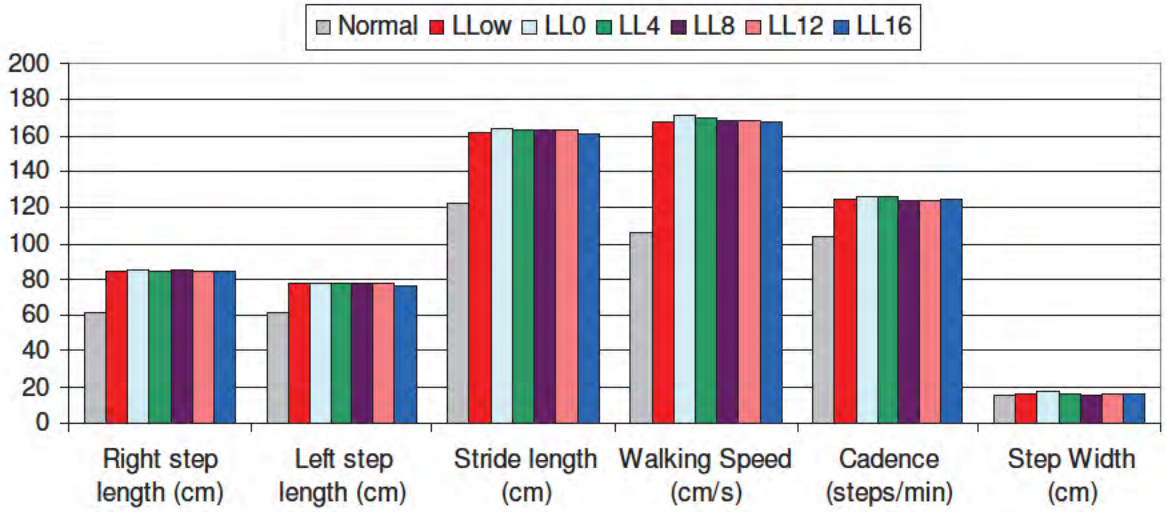
Different Vacuum Levels

16 inHg	Left side only
12 inHg	12-16 inHg
8 inHg	4-8 inHg
4 inHg	
0	0
One way valve	

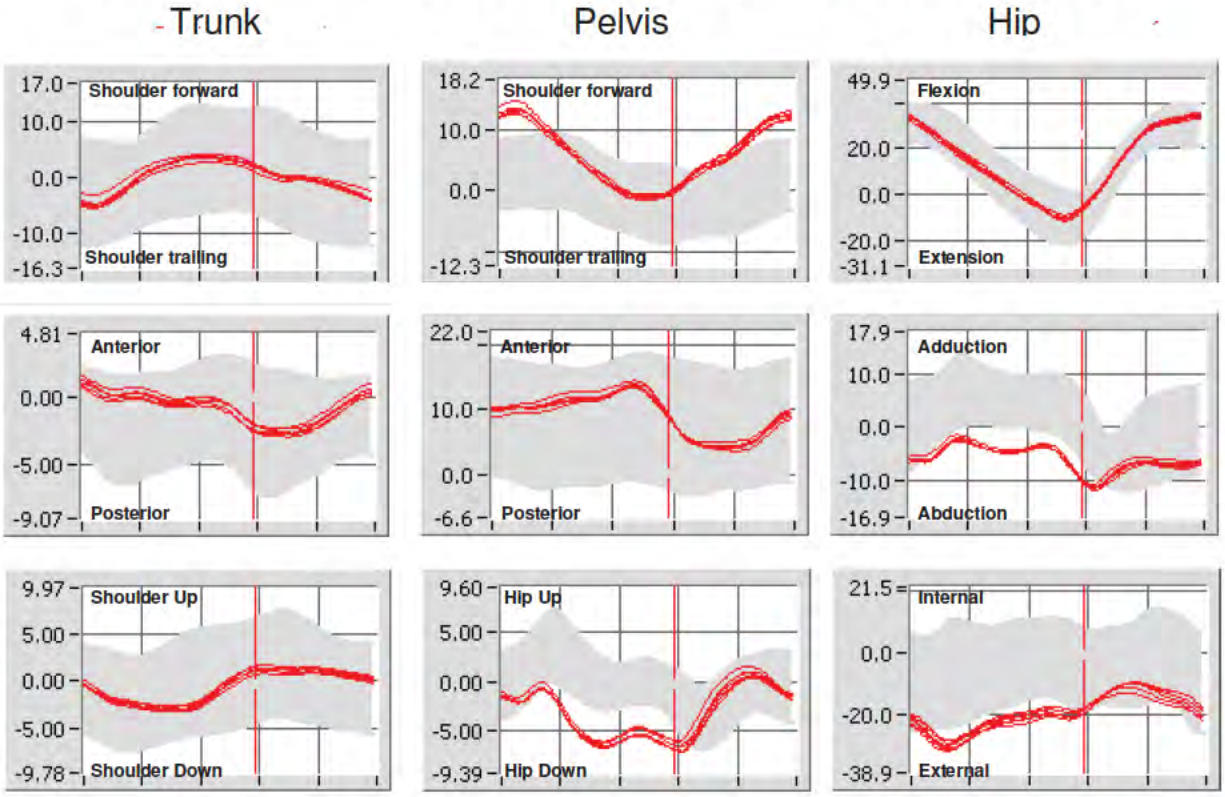
Case 2

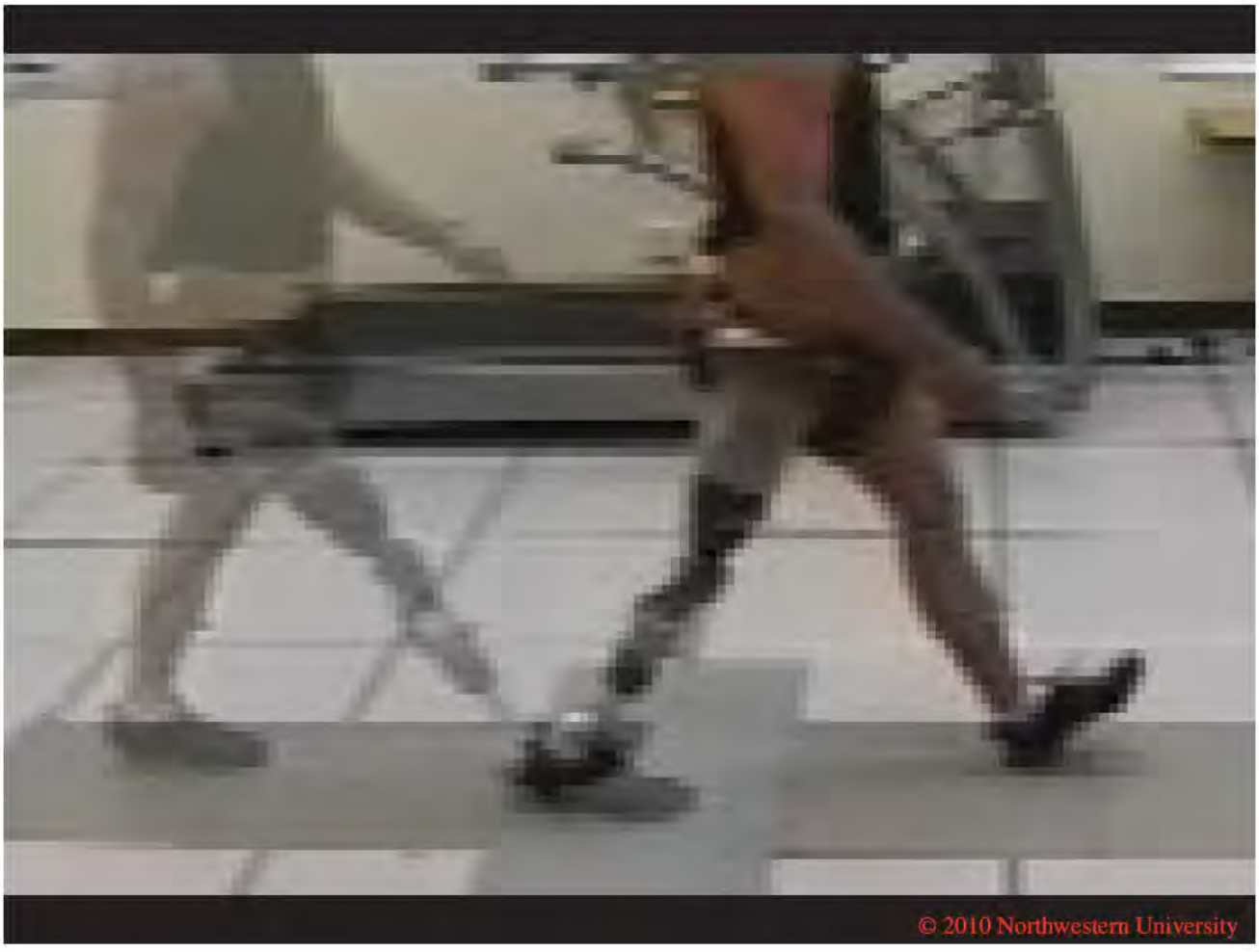


Case 1 (unilateral) Temporospatial (all vacuum levels)

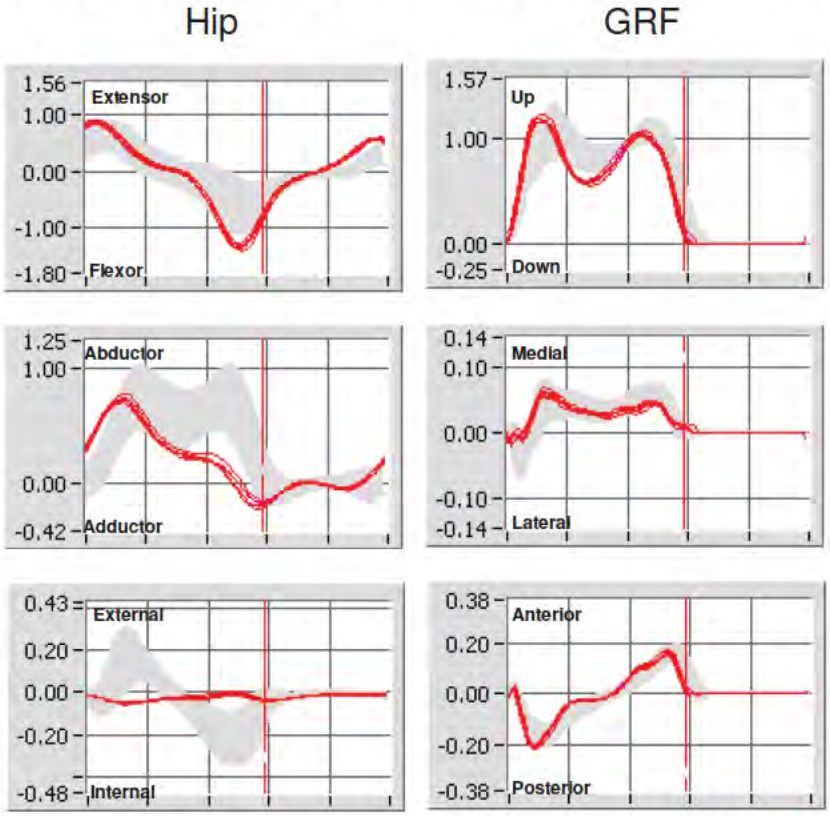


Case 1 (unilateral) Kinematics (all vacuum levels)

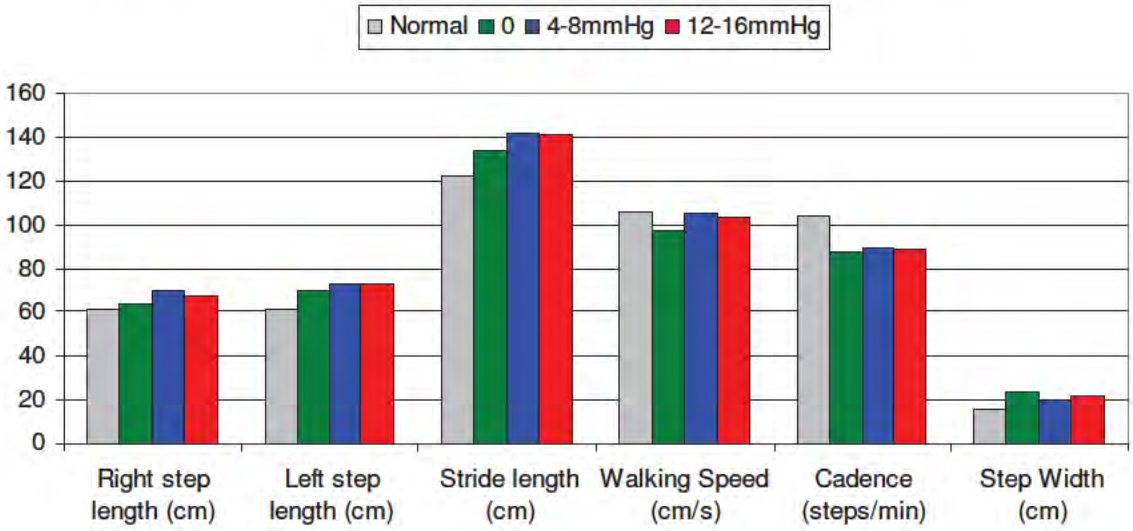




Case 1 (unilateral) Kinetics (all vacuum levels)

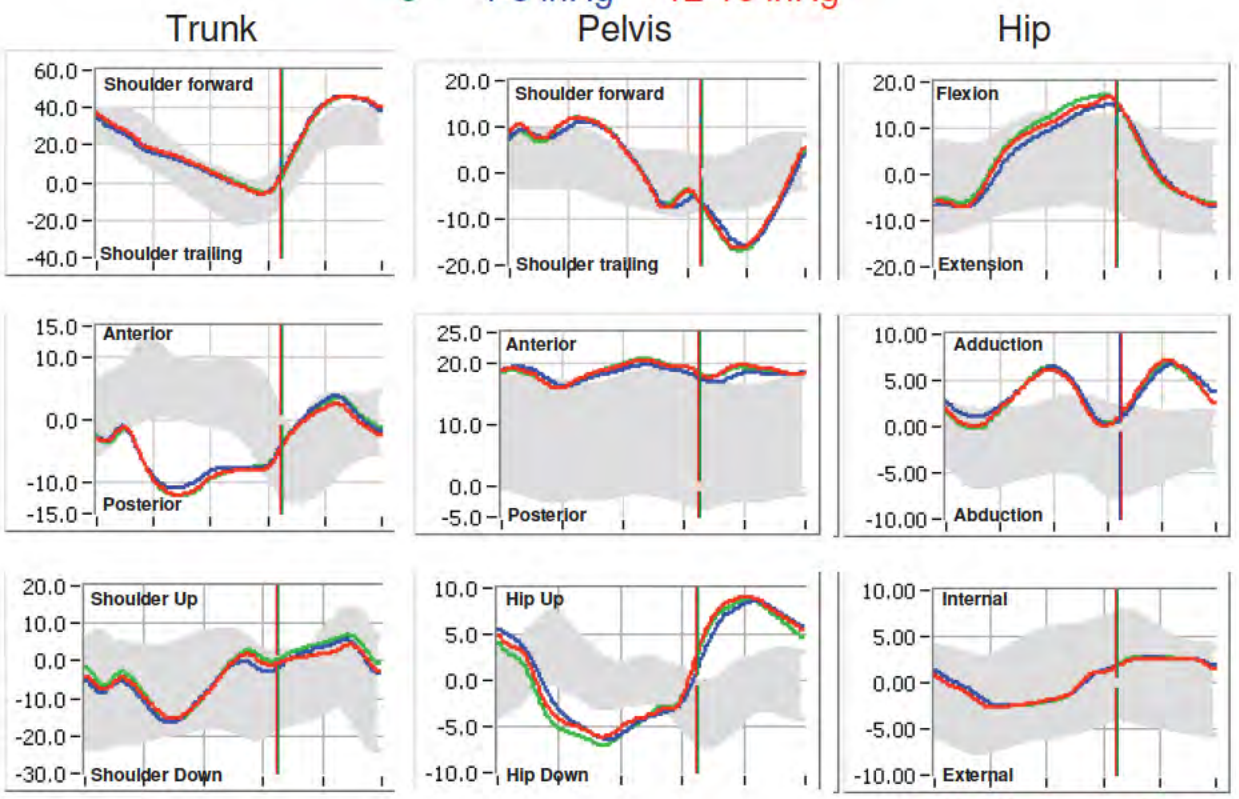


Case 2 (bilateral) Temporospatial (all vacuum levels)



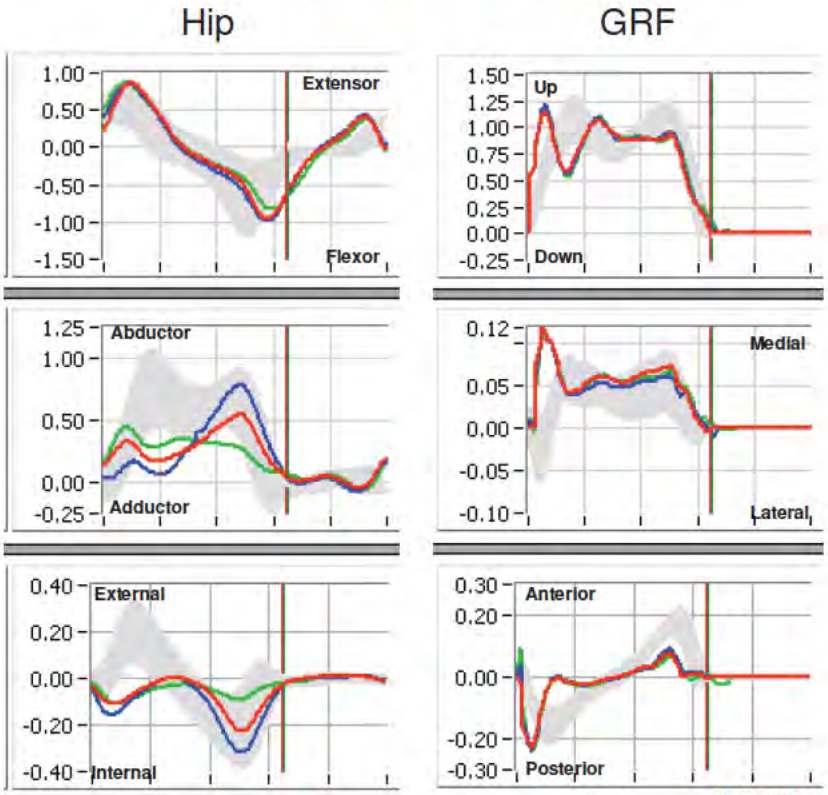
Case 2 (bilateral) Kinematics

0 4-8 inHg 12-16 inHg



Case 2 (unilateral) Kinetics

0 4-8 inHg 12-16 inHg



Socket Comfort Score (SCS)*

0 — Least comfortable

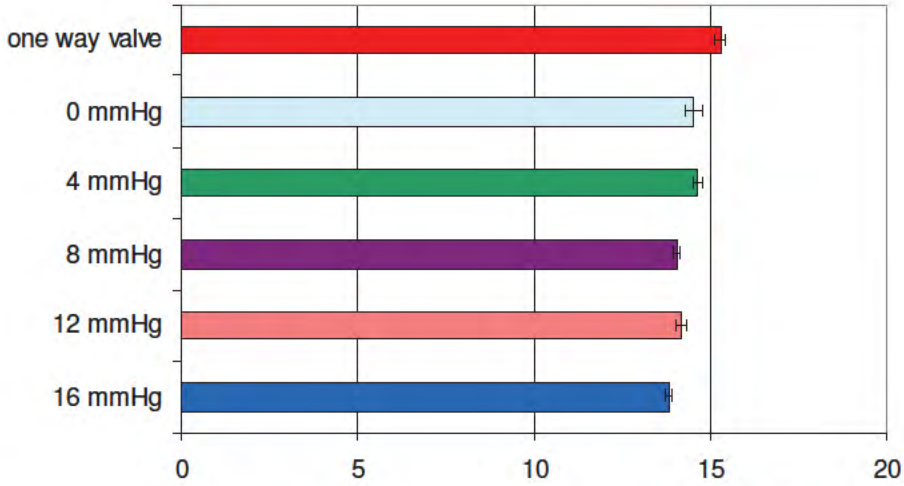
10 — Most comfortable

Case 1 (unilateral)		Case 2 (bilateral-left)	
16 inHg	10	12-16 inHg	6.5
12 inHg	8.5		
8 inHg	6.5	4-8 inHg	8
4 inHg	5		
0	3.5	0	5
One way valve	3.5		

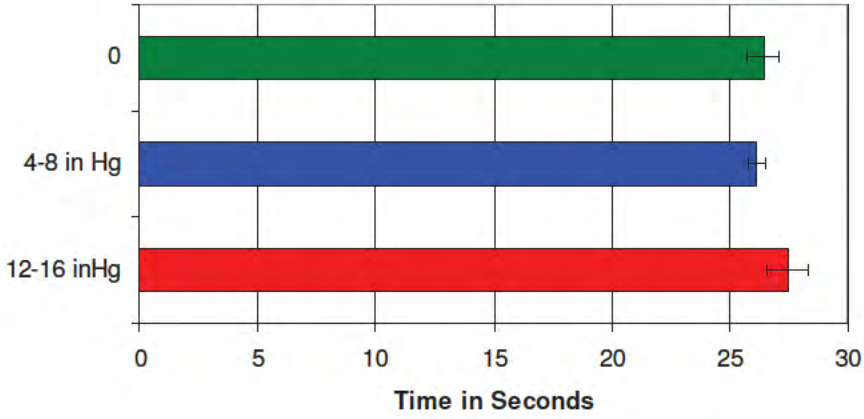
*Hanspal et al. Disability & Rehab, 2003, 25(22):1278-1280.

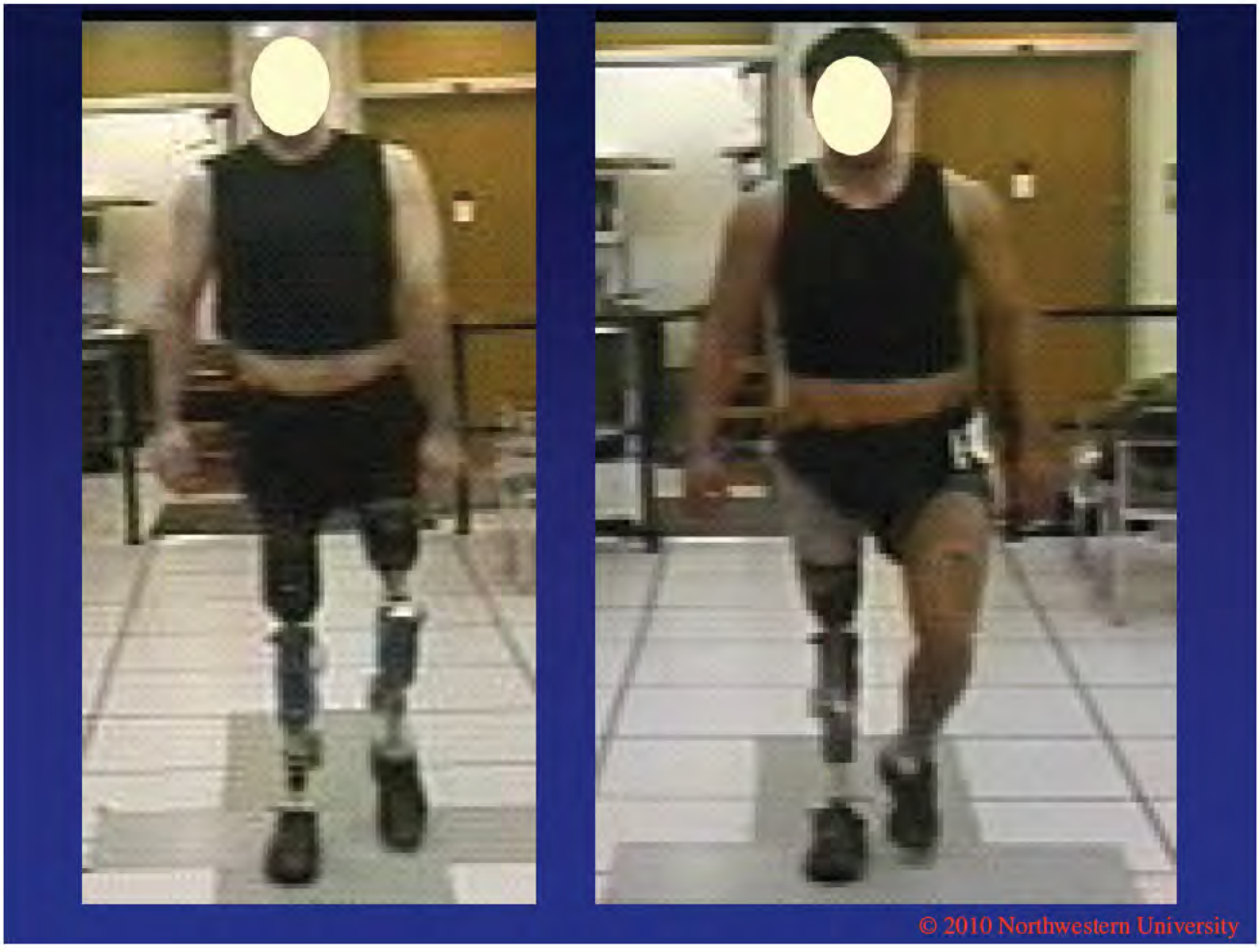
L-Test

Case 1
(unilateral)



Case 2
(bilateral)





Final Thoughts

- Results from these case studies demonstrate that:
  - It is possible to create a sub-ischial socket that provides adequate coronal plane stability
  - Vacuum does not appear to contribute substantially to coronal plane stability

Appendix L

Proposal for Instructional Course / Symposium
ISPO 2013, 4th - 7th February, Hyderabad India

Please copy-paste this page and use as much space to answer as you require.

This proposal is for an Instructional Course: **YES**/NO Symposium: YES/**NO**

1.Title of Proposed Session:
Subischial Sockets with Vacuum Assisted Suspension for Persons with Transfemoral Amputation

2. Name of Proposer and Chair with professional designation:
Stefania Fatone, PhD, BPO(Hons),
Research Associate Professor, Department of Physical Medicine and Rehabilitation
Feinberg School of Medicine, Northwestern University, Chicago IL, USA

3. Contact details of Chair:
Northwestern University Prosthetics-Orthotics Center
680 N Lake Shore Dr, Suite 1100, Chicago IL 60611
ph +1 312 503 5717
fax +1 312.503.5760
s-fatone@northwestern.edu

4. For Instructional Courses Only

Objective: To provide attendees with a description of a newly developed approach to management of persons with transfemoral amputation using a subischial socket with vacuum assisted suspension.

Course Content: (1) Introduction to subischial sockets with vacuum assisted suspension; (2) Overview of patient selection, casting, model rectification and socket fitting; (3) Preliminary results of functional analyses; (4) Q&A with attendees.

Benefits to Attendees: Attendees will gain knowledge of an additional prosthetic option for the management of persons with transfemoral amputation.

Intended Level of Audience: Prosthetists with experience in the management of persons with transfemoral amputation.

5. Why is this topic suitable for a Symposium/Instructional Course?
(in terms of current practices, modern trends etc -max 250 words)

Current transfemoral prosthetic socket designs encase the hip joint and portions of the pelvis, limiting range of motion at the hip and compromising comfort. Subischial socket design does not impinge on the pelvis when the hip is moved because it has intentionally lower trimlines than typical transfemoral sockets. The socket we have developed is flexible, allowing muscles to move comfortably within the socket as they contract during activity and to improve comfort during sitting. The socket is held securely to the leg by suction from a vacuum pump, which makes for a firmer connection between the residual limb and prosthesis. Increased comfort, hip range of motion, and connectivity between the residual limb and prosthesis provides better functional performance for individuals with transfemoral amputations. Modeling of the socket, quantification of the rectification process and evaluation of function using motion analysis and pressure measurement provides insights into the potential benefits of this socket for persons with transfemoral amputation.

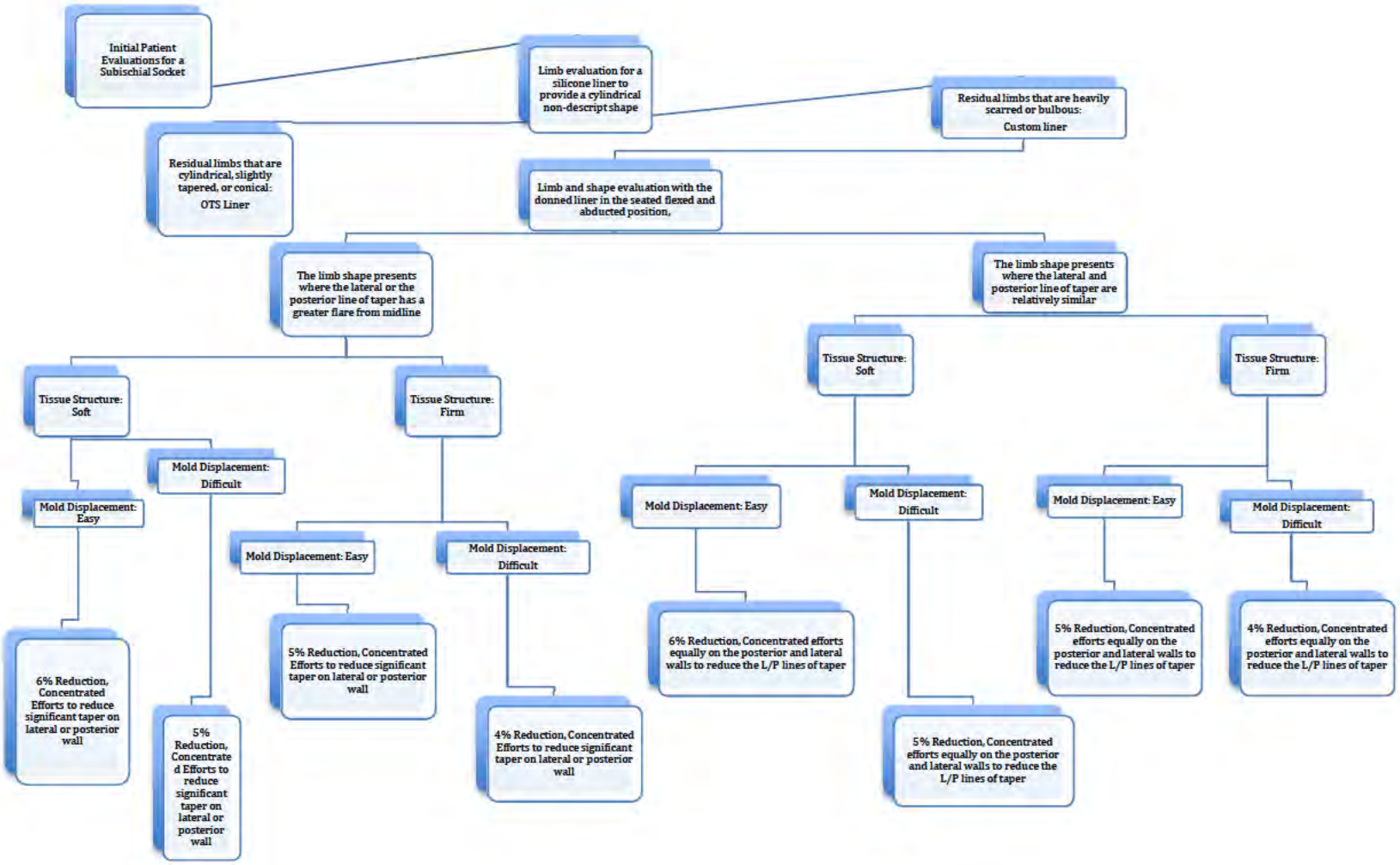
6. Proposed Speakers

Name	Affiliation	Email address	Title of Presentation
Oluseeni Komolafe, PhD	Northwestern University	o-komolafe@northwestern.edu	Introduction to subischial sockets with vacuum assisted suspension
Ryan Caldwell, CP Kerice Tucker	Northwestern University	r-caldwell@northwestern.edu k-tucker@northwestern.edu	Overview of patient selection, casting, model rectification and socket fitting
Stefania Fatone, PhD, BPO(Hons)	Northwestern University	s-fatone@northwestern.edu	Preliminary results of functional analyses

Please email this form to Dr. Ashok Johari, Chair Scientific Committee at scientific@ispo2013.org **by July 1st, 2011 with the email subject titled as "Proposal for Symposium / Instructional Course"**

Appendix M

Transfemoral Amputation Algorithm



<u>Distal End Considerations:</u>

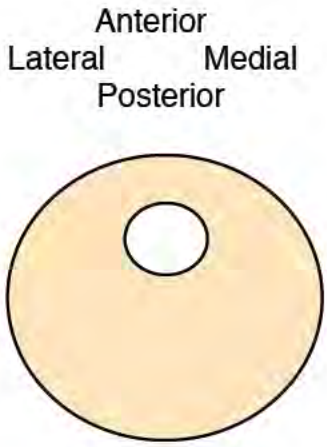
Distal end reduction based on amount of redundant soft tissue:

No soft tissue=0mm reduction, 12mm of soft tissue=6mm reduction, 25mm of soft tissue=12mm reduction

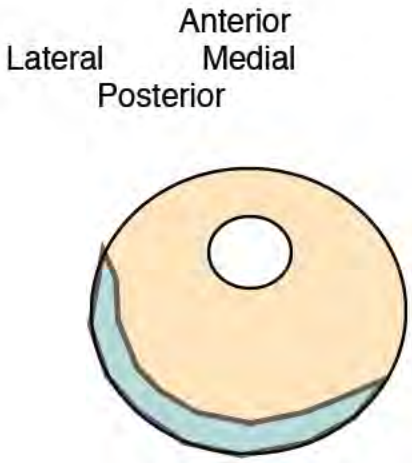
Significant redundant tissue requires distal pressure during molding procedure to ensure total contact fit

Transfemoral Residual Limb in the Transverse plane

Un-rectified Mold

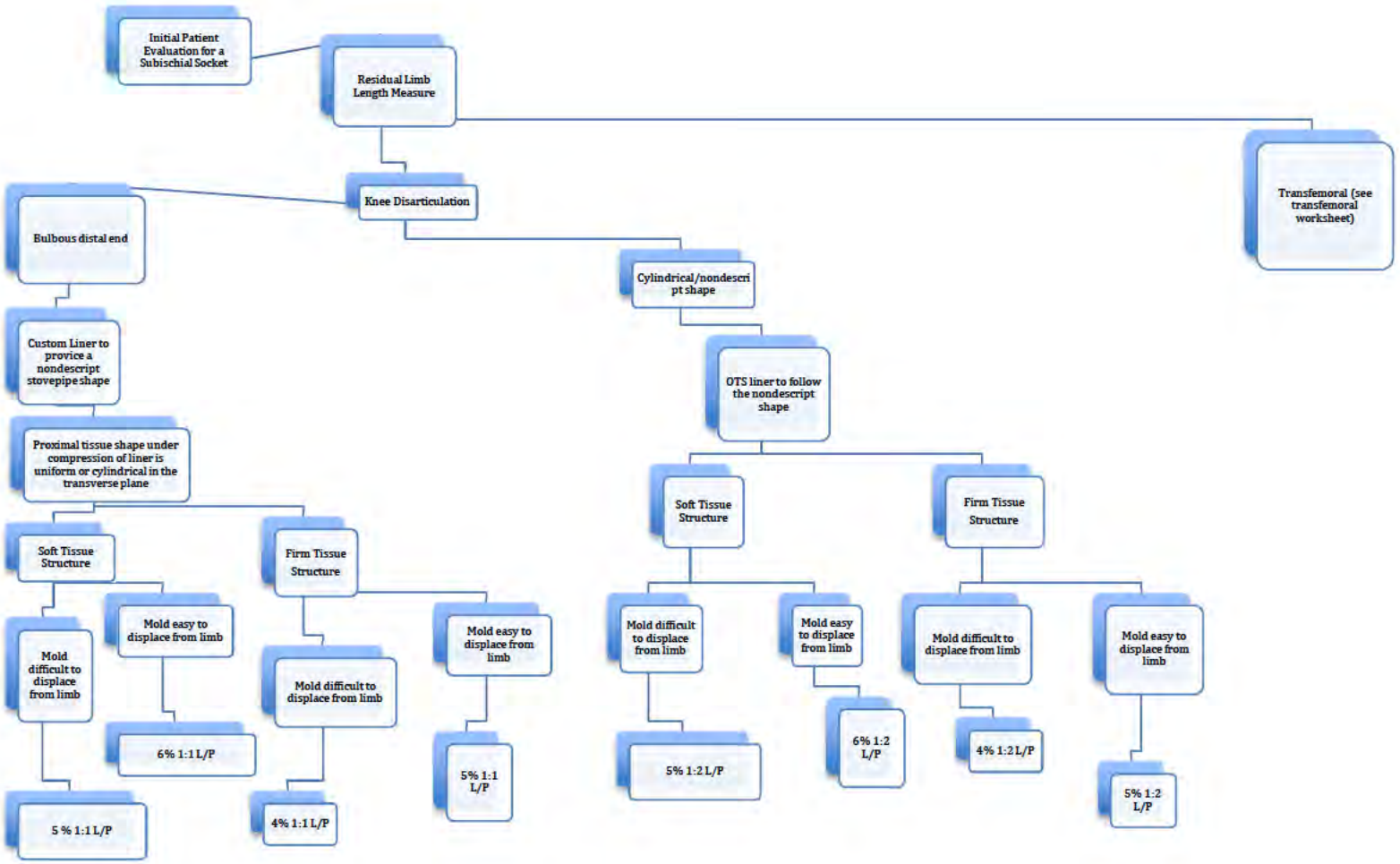


Rectified Mold



=Modified area of the mold when looking from the distal end of the mold upwards

Knee Disarticulation Algorithm



Omm Distal end reduction
Omm Femoral condyle reduction

Appendix N

Northwestern University Feinberg School of Medicine

Development of Sub-Ischial Prosthetic Sockets with Assisted-Vacuum Suspension for Highly Active Persons with Transfemoral Amputations

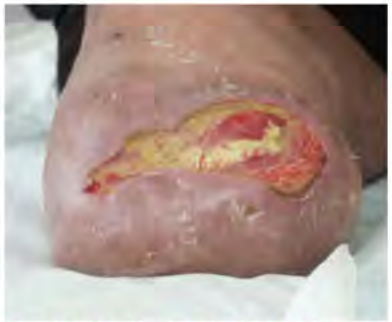
February 15, 2011

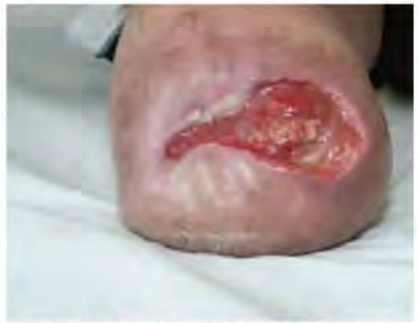
NORTHWESTERN UNIVERSITY
FEINBERG
SCHOOL OF MEDICINE

How we got here…

1990s…Vacuum Assisted Suspension introduced

- Initially used with transtibial amputees
- Superior linkage:
  - ***"It feels like I got my leg back!"***
- Volume management
- Improved limb health





Traballesi et al. (2009): case report of wound healing after 4 months of wearing vacuum-assisted suspension

How we got here…

2000s…Impact on Transfemoral Sockets

- ***"With the elevated vacuum suspension system it has been possible to design transfemoral sockets with lower trimlines, greatly increasing amputees' comfort and range of motion."*** – Fairley (2008)
- With other transfemoral designs, e.g. ischial containment, narrow M-L, etc., the ischium sits in the socket, which creates discomfort for the amputee
- Traditionally, transfemoral sockets have been designed for standing and walking; the socket can dig uncomfortably into the groin and buttocks when the person is seated

How we got here…

Ryan Caldwell, CP, Suburban O&P, Des Plaines, IL

- Developed his own technique for making sub-ischial sockets
- Experimenting with making the sockets more flexible
  - Using standard P&O fabrication techniques

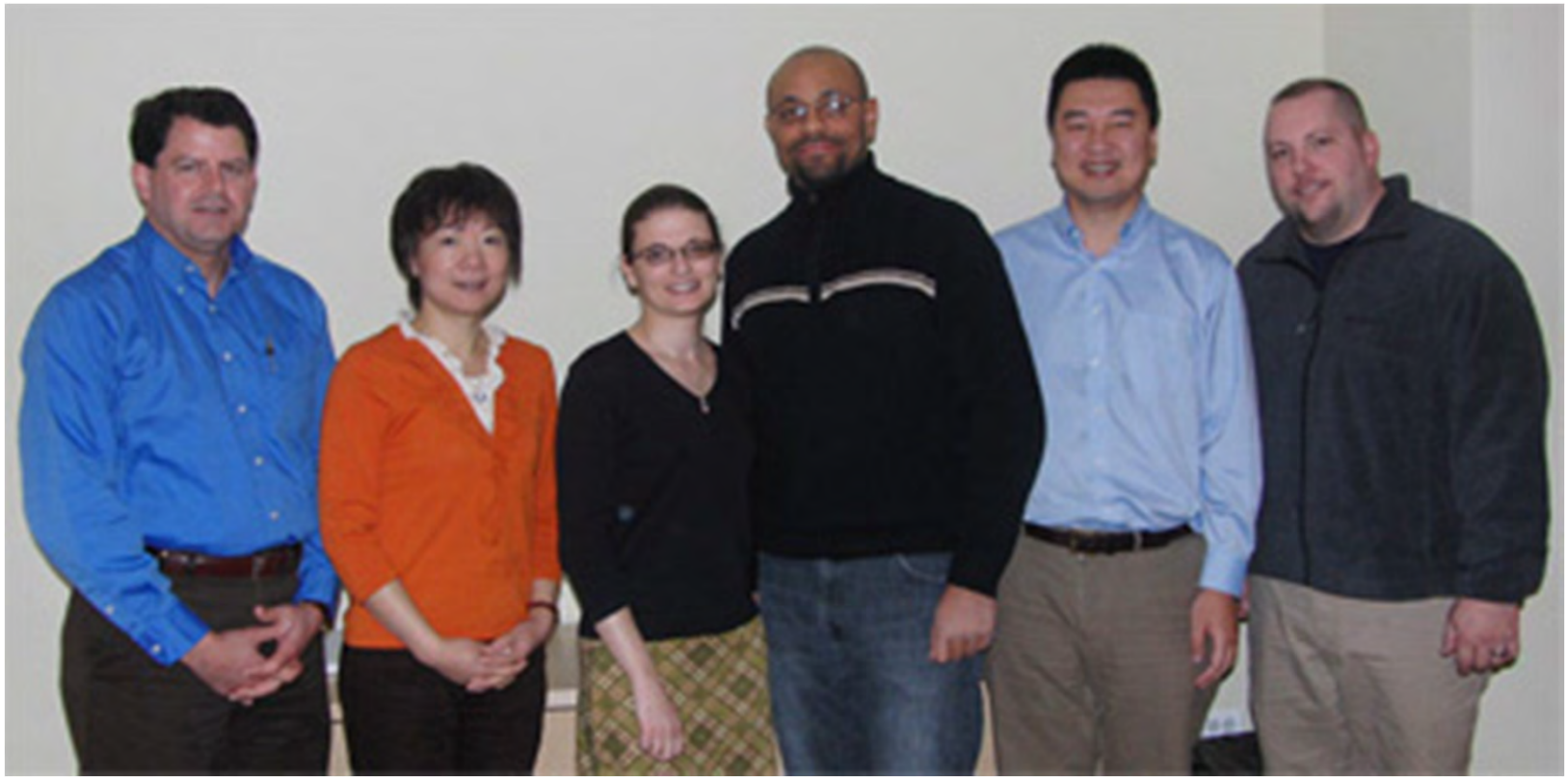
Program Details

Department of Defense (DOD) Congressionally Directed Medical Research Programs

- Peer Reviewed Orthopaedic Research Program (PRORP) (FY09)
- Technology Development Award
- Funding Opportunity Number: W81XWH-09-PRORP-TDA

- **Priority Research Areas:**
- Prosthetics and Orthotics - Maintenance/enhancement of long-term socket performance/fit
    - Design and development of flexible socket suspension systems
    - Evaluation of socket performance
    - Maintenance of limb volume/mass
    - Clinical applications of new technologies

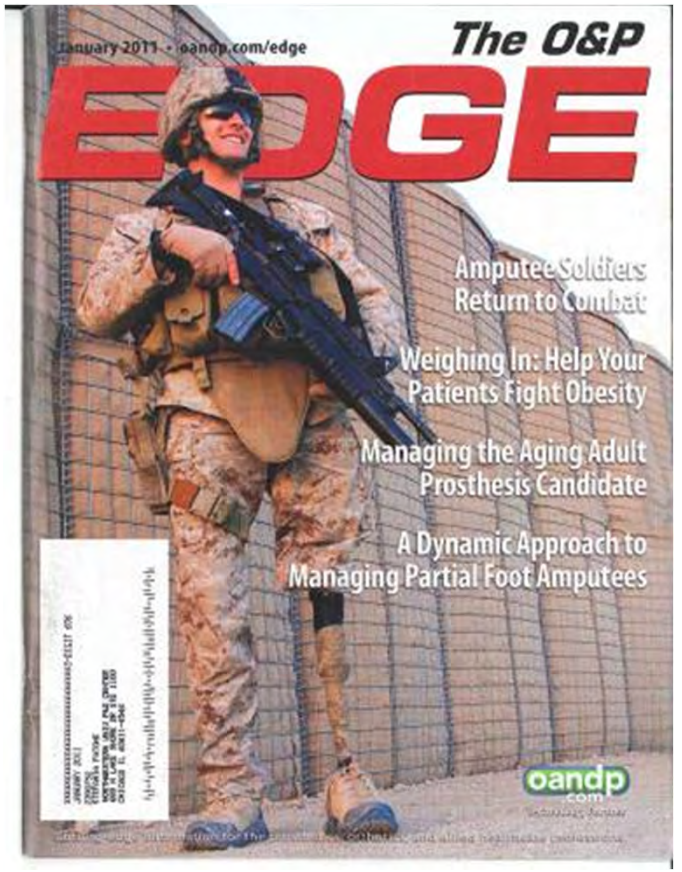
Project Team



Left to Right: Steven Gard, Wei Chen, Stefania Fatone, Kerice Tucker, Cheng Sun, Ryan Caldwell (not pictured - Andrew Hansen, Sean Wood and Oluseeni Komolafe).

Project Motivation

- Current transfemoral prosthetic socket designs:
  - encompass the pelvis and hip joint, limiting range of motion at the hip and compromising comfort
  - provide limited functional restoration, especially for highly active individuals
- Service persons with amputation present challenges that are different from the more typical older amputee with vascular problems.
  - wounded soldiers are generally young and in excellent health prior to combat-related injury
  - many wounded soldiers wish to return to the level of activity they enjoyed before their injuries, including active duty and they have very high expectations of their function after amputation



Project Objectives

To develop prosthetic socket technology that will maintain residual limb volume; improve active range of motion of the hip; and increase comfort during sitting, standing, walking, and running in highly active transfemoral prosthesis users, allowing users to be more active.

Our socket…

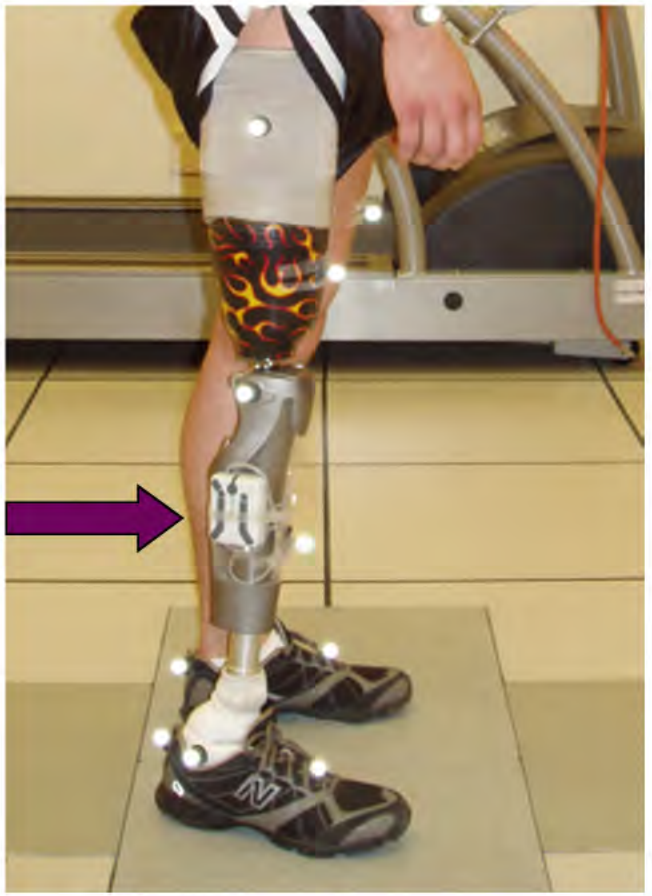
…does not impinge on the pelvis when the hip is moved because it has lower edges than typical transfemoral sockets

Our socket…

…is as flexible as possible, allowing muscles to move comfortably within the socket as they contract during activity and to improve comfort during sitting

Our socket…

…is held securely to the leg by suction from a vacuum pump, which makes for a firmer connection between the residual limb and prosthesis



Applicability of the Research

- Enable clinicians to provide better prosthetic care to highly active military service persons with transfemoral amputation.
    - Increased comfort, hip ROM, and connectivity between the residual limb and prosthesis will result in better functional performance
- Improvements in socket comfort and connectivity can benefit all persons with transfemoral amputation, not just those who are highly active.
- Traditional methods of prosthetic socket construction are not very robust, e.g.
    - it is to possible to craft a socket that is rigid in some areas and flexible in other areas, but it is not possible to smoothly transition between the two
    - it is possible to specify the internal shape of a socket, but it is not possible to precisely control the thickness of the socket wall

Specific Aims

- **Aim 1 & 2.** Develop a highly flexible socket with sub-ischial trimlines and a durable liner for highly active users
  - Ryan Caldwell, Wei Chen, Cheng Sun and Oluseeni Komolafe
- **Aim 3.** Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis
  - Cheng Sun, Andrew Hansen, Sean Wood, Ryan Caldwell
- **Aim 4.** Evaluate system performance with transfemoral prosthesis users
  - Center for the Intrepid at Brooke Army Medical Center
- **Aim 5.** Develop education materials for sub-ischial socket design
  - Kerice Tucker, Ryan Caldwell

Aim 4 Hypotheses

It is hypothesized that, compared to ischial containment sockets with suction suspension, the sub-ischial socket with vacuum-assisted suspension will:

H1. Reduce fluctuations in residual limb volume;

Digital scan of limb; qualitative feedback

H2. Improve socket suspension, reducing relative movements between the liner and the socket;

Digital video fluoroscopy

H3. Improve active hip range of motion;

Goniometer (passive ROM), motion analysis (active ROM, walking/running), Rapid Sit-to-Stand

H4. Improve comfort during sitting, standing, walking, and running;

Prosthetic Socket Comfort Score

H5. In combination, improvements in suspension, hip range of motion, residual limb volume and comfort will lead to improved functional performance of persons with transfemoral amputation.

Four Square Step Test, Agility T-Test, Stair climbing, Obstacle Course

Current Prototype

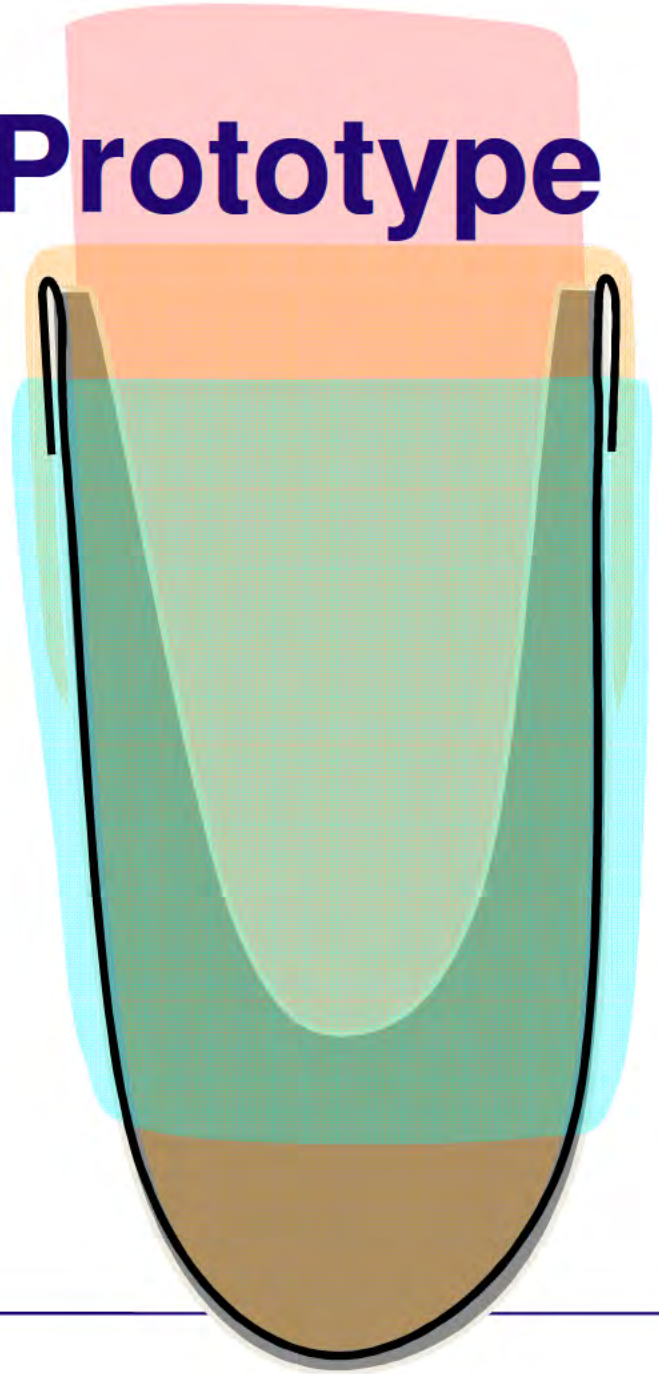
Limb

Liner
10-30% undersized

Wick

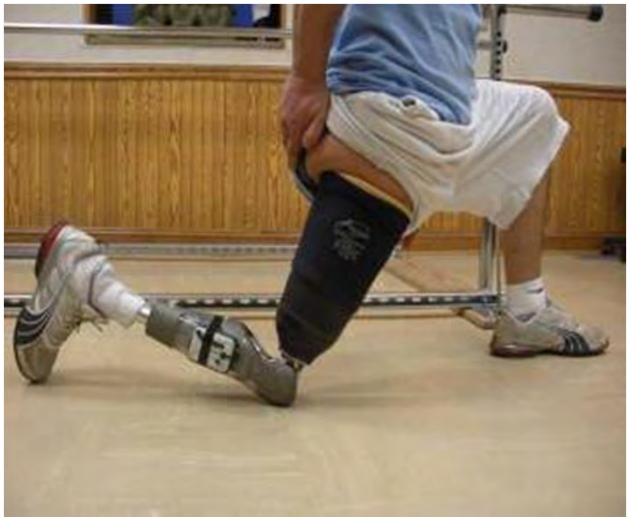
Socket
4-7% undersized

Sleeve



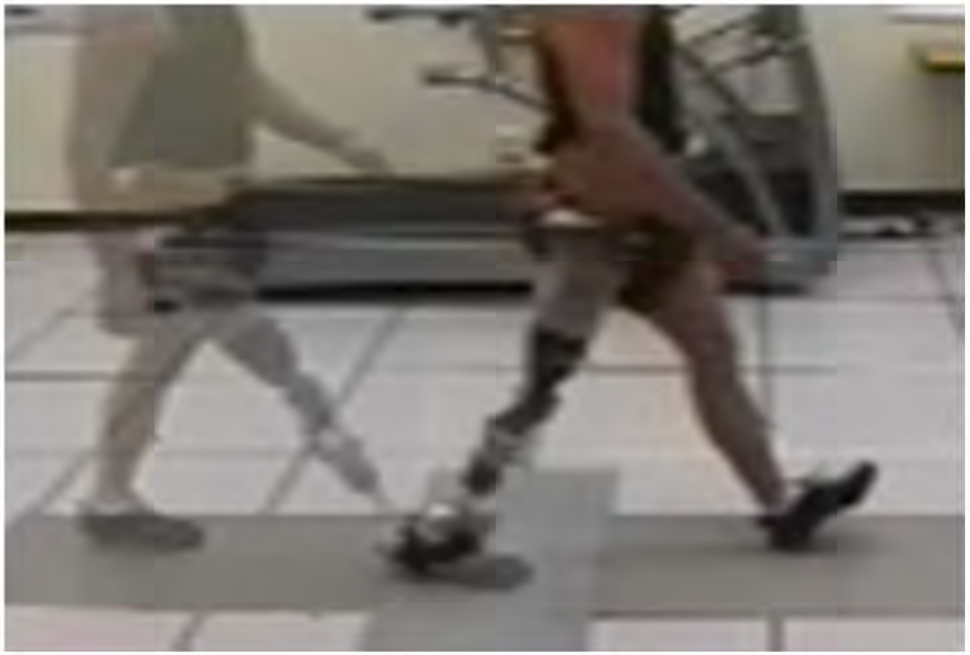
Preliminary Results

Range of Motion

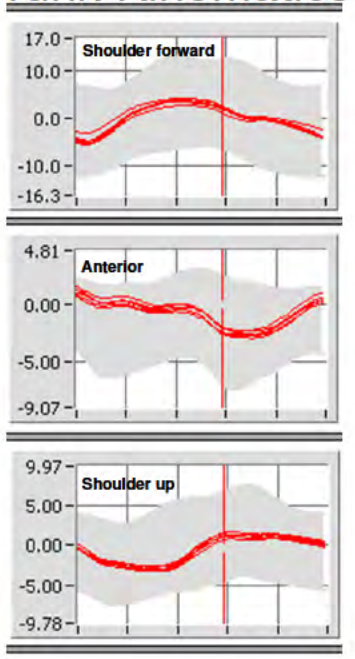



Preliminary Results

Gait



Trunk Kinematics



Project Timeline

Project began Sept 15, 2010

Year 1												Year 2												Year 3											
Q1			Q2			Q3			Q4			Q1			Q2			Q3			Q4			Q1			Q2			Q3			Q4		
1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12

Challenges

- Creating a sufficiently robust and durable system for use by individuals with combat-related transfemoral amputation
- Demonstrating improved performance and comfort
- Transferring socket casting and rectification techniques successfully to other prosthetists
- Why we are confident…