AWARD NUMBER: W81XWH-10-1-0744

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

PRINCIPAL INVESTIGATOR:
Stefania Fatone, PhD

CONTRACTING ORGANIZATION: Northwestern University
Evanston IL 60208-0001

REPORT DATE: December 2016

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
December 2016	Final	15 Sep 2010 - 14 Sep 2016

4. TITLE AND SUBTITLE

Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations

5a. CONTRACT NUMBER
W81XWH-10-1-0744

5b. GRANT NUMBER
OR090122

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Stefania Fatone, Ryan Caldwell, Lilly Tran, Matthew Major, Jason Wilken, Oluseeni Komolafe, Sean Wood, Steven Gard, Wei Chen, Cheng Sun, Andrew Hansen, Kerice Tucker, Brian Robillard

E-Mail: s-fatone@northwestern.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Northwestern University
633 Clark St
Evanston IL 60208-0001

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
The purpose of this project was to develop a highly flexible sub-ischial prosthetic socket with assisted-vacuum suspension for highly active persons with transfemoral amputation. The Specific Aims were 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. We completed all tasks, including supplemental tasks related to building and testing the hybrid vacuum pump, year 6 observational study to assess effect of interface components on weight bearing, and dissemination of the technique to certified prosthetists via hands-on workshops.

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

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	480	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

INTRODUCTION **4**

BODY: PROJECT PROGRESS **4**

Task 1 Initial preparatory activities *4*

AIMS 1 & 2 DEVELOP A HIGHLY FLEXIBLE SOCKET WITH SUB-ISCHIAL TRIM LINES AND A DURABLE LINER FOR HIGHLY ACTIVE USERS 5

Task 2 Design and simulation of sub-ischial socket *5*

Task 3 Advanced manufacturing of sub-ischial sockets *9*

Task 4 Mechanical bench testing of sockets and liners *11*

Task 5 Solicit feedback from human subjects *13*

AIM 3 DEVELOP/IDENTIFY AN APPROPRIATE MECHANICAL PUMP TO CREATE SUITABLE VACUUM FOR SUSPENSION OF THE PROSTHESIS 14

Task 6 Determine range of volumes to be evacuated from transfemoral sockets of highly active prosthesis users *14*

Task 7 Characterization of mechanical and electrical pumps *16*

Task 8 Finalize vacuum pump design *18*

AIM 3: SUPPLEMENTAL TASKS 18

Supplemental Task 1 Build three hybrid vacuum pumps *18*

Supplemental Task 2: Performance testing of three hybrid vacuum pumps *20*

Supplemental Task 3: Finalize vacuum pump design. *23*

AIM 4 EVALUATE SYSTEM PERFORMANCE WITH TRANSFEMORAL PROSTHESIS USERS 24

Task 9 Conduct performance evaluation with human subjects *24*

AIM 5 DEVELOP EDUCATION MATERIALS FOR SUB-ISCHIAL SOCKET DESIGN 28

Task 10 Develop a quantification tool for socket rectifications *28*

Task 11 Quantify rectifications for multiple amputees *31*

Task 12 Create education materials *33*

TASK 13 FINAL PROJECT MEETING 35

KEY RESEARCH ACCOMPLISHMENTS **36**

REPORTABLE OUTCOMES **36**

CONCLUSIONS **42**

REFERENCES **42**

BIBLIOGRAPHY OF ALL PUBLICATIONS AND MEETING ABSTRACTS **42**

LIST OF PERSONNEL RECEIVING PAY FROM THE RESEARCH EFFORT **42**

APPENDICES **43**

APPENDIX A – MTS TESTING PROTOCOLS 44

APPENDIX B – SOCKET TESTING PROTOCOLS 45

APPENDIX C - ABSTRACTS AND POSTERS SUMMARIZING TASK 2 46

APPENDIX D - ACCEPTED MANUSCRIPT: PROSTHETICS AND ORTHOTICS INTERNATIONAL, PART 1 DESCRIPTION OF TECHNIQUE 47

APPENDIX E – ROBILLARD MASTER'S THESIS 48

APPENDIX F – ROBILLARD POSTERS AND ABSTRACTS 49

APPENDIX G – WILLOWWOOD SOCKET EVALUATION REPORT 50

APPENDIX H – COPYRIGHT REGISTRATION FOR MULTI-MEDIA INSTRUCTIONAL MANUAL FOR NU-FLEXSIV SOCKET 51

APPENDIX I – AAOP 2013 POSTER AND ABSTRACT....52
APPENDIX J – ACCEPTED MANUSCRIPT: PROSTHETICS AND ORTHOTICS INTERNATIONAL, PART 2 PRELIMINARY EVALUATION....53
APPENDIX K – ACCEPTED MANUSCRIPT: JOURNAL OF PROSTHETICS AND ORTHOTICS TECHNICAL NOTE....54
APPENDIX L – WOOD MASTER'S THESIS....55
APPENDIX M – VACUUM PUMP EVALUATIONS POSTERS AND ABSTRACTS....56
APPENDIX N – MANUSCRIPT PUBLISHED IN JOURNAL OF REHABILITATION RESEARCH AND DEVELOPMENT....57
APPENDIX O – INTERFACE VOLUME ABSTRACTS....58
APPENDIX P – MANUSCRIPT PUBLISHED IN THE JOURNAL OF PROSTHETICS AND ORTHOTICS 59
APPENDIX Q – ME 398 REPORT....60
APPENDIX R – HYBRID VACUUM PUMP PATENT....61
APPENDIX T – MANUSCRIPT PUBLISHED IN JOURNAL OF MEDICAL DEVICES....62
APPENDIX U – HYBRID PUMP TECH ALERT 2016....63
APPENDIX V – SUMMARY OF RESULTS FROM 3 SUBJECTS TESTED AT CFI/BAMC....64
APPENDIX W – CFI/BAMC ABSTRACTS AND POSTERS....65
APPENDIX X – SUBMITTED ABSTRACT ISPO 2017....66
APPENDIX S - ACCEPTED ABSTRACTS AAOP 2017....67
APPENDIX Y - ACCEPTED MANUSCRIPT: PROSTHETICS AND ORTHOTICS INTERNATIONAL....68
APPENDIX Z – EDUCATION MATERIAL PRESENTED AT CONFERENCES AND MEETINGS....69
APPENDIX AA – NU-FLEXSIV SOCKET COURSE AGENDA....70
APPENDIX BB – HIPCHAT ONLINE FORUM....71
APPENDIX CC – 2016 KEYNOTE PRESENTATIONS....72

INTRODUCTION

The objective of this project was to develop a highly flexible sub-ischial prosthetic socket with assisted-vacuum suspension for highly active persons with transfemoral amputation. We focused on developing prosthetic socket technology that enhances user activity by improving active range of motion of the hip; improving coupling between the limb and socket; and increasing comfort during activity. The Specific Aims of this project were 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 and deliver courses for the sub-ischial socket design. For A4, human performance was evaluated at the Center for the Intrepid, Brooke Army Medical Center (CFI/BAMC). Supplemental funding allowed us to construct a working prototype of the hybrid pump for further testing in Aim 3. For Aim 5 we developed education materials based on quantification of the socket rectification and fabrication process. We also disseminated the sub-ischial socket technique to certified prosthetists via a series of hands-on workshops and conducted a clinical observational study to evaluate the contribution of interface components to weight bearing.

BODY: PROJECT PROGRESS

The following is a description of the work conducted over the past 6 years on our project. Our project's progression 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). We have completed all tasks with the exception of Tasks 9b and 9c, which are partially complete.

Task 1 Initial preparatory activities

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
Task 1 Initial preparatory activities.												
1a Convene initial project meeting.												
1b Prepare and submit IRB application.												

1a Convene initial project meeting: *This task was completed in year 1.*

An initial project meeting was convened on September 20, 2010. A meeting with collaborators from the CFI/BAMC was held on March 18, 2011.

1b Prepare and submit IRB application: *This task was completed in year 1.*

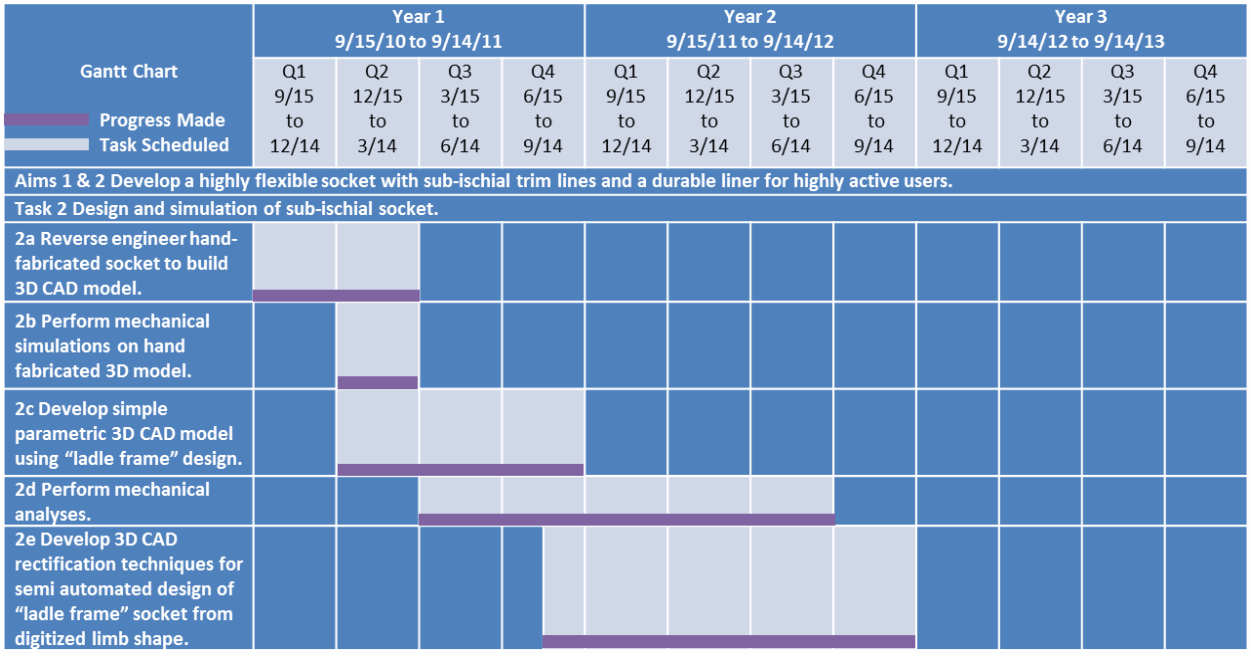
All components for this project received Institutional Review Board (IRB) approval as summarized in **Table 1**.

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 NU Closed 5/17/16 HRPO Closed 6/17/16
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 1/13/12 HRPO Closed 12/4/16
STU00033448	Quantification of Residual Limb Model Rectifications for Sub-Ischial Sockets (Aim 5)	NU IRB 7/2/10 HRPO 7/28/10
STU00202302	Effect of NU-FlexSIV Interface Components on Residual Limb Weight-Bearing Tolerance	NU IRB 3/1/16 HRPO 4/1/16

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 was completed in year 1.*

We used computational and engineering analyses as design tools to create a digital simulation of the current socket as made by our collaborating prosthetist, Ryan Caldwell, CP. This simulation, functionally equivalent to the physical system, established a baseline description of the socket. First, the prosthetist fabricated a physical example of the socket, during which we identified the most critical fabrication stages, as well as the critical load bearing and comfort elements of the socket. The socket was created to highlight these stages/elements. In its final form, the simulated socket was simplified to a flexible inner Polytol (OttoBock, Duderstadt, Germany) layer, a rigid polypropylene frame, and an outer layer of Polytol. By simplifying the simulated socket to fundamental components, we facilitated our understanding of the relative contribution of the different components of the socket to the overall system behavior.

We digitized the geometry of the test socket. For this, we used a commercially available 3D scanner to create a 3D digital representation of physical models by combining planar images of the test socket, acquired while axially rotating the socket incrementally for 360 degrees. The scanned data was then exported to a graphics package (SolidWorks, Dassault Systémes, France) and processed to a 3D Computer Aided Design (CAD) model. This step was important because the CAD model formed the base format for a Finite Element (FE) engineering simulation. We also explored methods to accurately extract the geometry of the frame 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.

The final step of Task 2a was to create the FE model. The FE method was used to numerically analyze the mechanical response of structures to applied loads. The FE model was successfully created in commercially available FE software (Abaqus™, Dassault Systémes, France).

Task 2b Perform mechanical simulations on hand-fabricated 3D model: *This task was completed in year 2.*

The goal of this task was to establish baseline values for the mechanical and material properties of the rigid frame component of the hand-fabricated socket system. In conjunction with Task 4b (socket strength and deflection tests) and Task 4c (indentor tests of elastomers), this test contributed to characterization of the mechanical behavior of the socket and its components in response to load. Material properties of many polymers are known to depend on fabrication parameters, therefore, in addition to reviewing the published literature for values, determining the material properties of the components included preparing standard protocols for the mechanical tensile tests (**Appendix A**). Manufacture of the different test samples was completed and a program was 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. We also completed the design and machining of the necessary fixtures to attach the hand fabricated socket to the testing rig. In anticipation of the high failure loads of the rigid socket frame, a three-point flexural test was performed in accordance with the testing standard ASTM D790-10. Samples were installed in the testing fixtures and compressive loads applied until failure of the material. The flexural modulus values for the different carbon fiber

reinforced samples are shown in **Table 2**.

Sample	1	2	3	4	5	6	7	8	9	10	11	12
Modulus (MPa)	3149.98	3685.03	5993.92	2477.64	4936.90	4977.88	6473.74	6254.13	4242.26	6589.19	5877.43	3571.13
										Mean		4852.43
										Standard Deviation		1350.96

Table 2 Flexural modulus values for carbon fiber reinforced socket material.

Task 2c Develop a simple, parametric 3D CAD model using "ladle-frame" design: *This task was completed in year 1.*

A review of prior FE models of prosthetic sockets was undertaken to refine our understanding of the problem and the variables to be included in our model. For this task we needed to analyze the socket loading response and perform static/dynamic experiments for FE model validation. We defined experimental protocols (**Appendix B**) and designed and built fixtures for attaching the socket prototype and limb phantom to our testing machine. Software for the *pliance* pressure sensors (Novel, Germany), as well as the IPECs 3 dimensional loads and moments sensing load cell (College Park Industries, Warren, MI) were installed and verified to be operational. We then conducted the bench top experiments.

Our initial rigid polypropylene frame, dubbed the '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. Since we hypothesized that the lateral wall requires relatively little support, the window was used to allow flexibility. This design worked 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 frame design, dubbed the 'H' frame. 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.

The parameters identified as most critical to the performance of the socket were the socket frame design and thickness.

Task 2d Perform mechanical analyses: *This task was completed in year 2.*

The models used for simulation were based on direct scans of the flexible lamination and rigid frame components of physical sockets taken as part of Task 2a. Three models with different rigid frame designs (completely rigid, ladle frame, H-frame) were analyzed computationally to quantify the effect of rigid frame type and thickness on the mechanical functioning of the socket. The output of the simulation was the prosthetic socket deflection computed as an average of the deformation along the three principle axes (X,Y,Z). A similar analysis was performed with the stress distribution calculated as the simulation output. A simple template was developed to partition the different socket geometries into discrete regions for which the simulation results were compared. Results consisted of the average displacement of the socket analysis regions for the three different frame designs.

Task 2e Develop 3D CAD rectification techniques for semi-automated design of "ladle-frame" socket from digitized limb shape: *This task was completed in year 4.*

Work on Task 2e is summarized with Task 11e.

The results of our early work on Task 2 were presented at a number of conferences, including the 2012 meeting of the Military Health Research Symposium, 2012 and 2013 annual meetings of the American Academy of Orthotists and Prosthetists (AAOP), the 2012 and 2013 meetings of the Midwest Chapter of the AAOP, the 2013 meeting of the Texas Chapter of the AAOP, and the 14th World Congress of the International Society for Prosthetists and Orthotists (ISPO) in 2013 (see **Appendix C** for abstracts and posters summarizing this work).

Unfortunately, in February 2013 OttoBock discontinued sales of Polytol, which was the material that formed the flexible component of our original single wall socket design (**Figure 1**). This necessitated a search for a replacement material. During our search for a new flexible material we explored EVA foam from Orthomerica, Polytek urethane rubber, Fiberglast, and FlexEVA from medi (Bayreuth, Germany) as replacements for Polytol. The various polyurethane and silicone resins we tested in fabrication to try to re-create the somewhat unique properties of Polytol had their own challenges such as being very sensitive to moisture and the type of barriers used in fabrication (e.g. polyvinyl acetate (PVA) bags) or having a thicker consistency that made it difficult to impregnate fibers during lamination. However, the FlexEVA material provided adequate rigidity to support the residual limb in the axial plane, yet maintain flexibility to conform to the residual limb in the seated position and reduce edge pressures. Using blister forming FlexEVA can be fabricated with a thinner and lighter profile than the other laminated flexible materials we tried. With FlexEVA as the flexible socket, we were able to construct a rigid carbon fiber outer socket with lower proximal trim lines than is typical with other thermoplastics while allowing the liner to reflect over the flexible socket edge and seal with a sleeve that is mounted between the rigid and flexible components (**Figure 1**). This resulted in a two wall socket.

Fabrication of the final definitive socket using FlexEVA has a number of advantages over the previous Polytol socket. For example, the FlexEVA socket can be fabricated using conventional fabrication techniques, is less labor intensive, and far less hazardous. Another advantage is that, after initial fitting with a rigid PETG check socket to ensure correct volumes and total contact at the distal end has been achieved, a second check socket can be fabricated using the FlexEVA as the flexible inner socket and PETG for the outer socket. This allows the check socket to be worn home for a period of days, weeks or months, until the prosthetist and patient are confident that the socket fits well. Sending the patient home in a flexible check socket substantially decreases the risk of

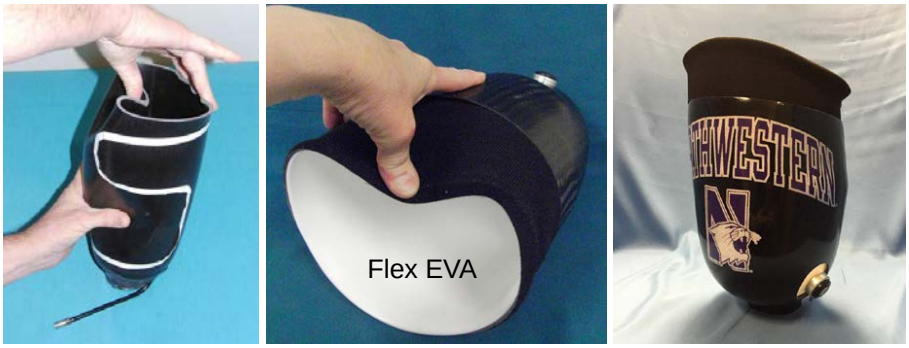


Figure 1 Single wall Polytol socket (left), medi FlexEVA definitive socket (middle and right) showing different lengths of the rigid outer socket.

liner breakdown. If the flexible inner socket is deemed to fit well, it can be re-used as part of the final definitive socket wherein the PETG outer socket is replaced by a carbon fiber reinforced laminated socket.

Our final socket technique was described in a manuscript accepted for publication in *Prosthetics and Orthotics International* (**Appendix D**).

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.												

Training with our Stratasys (Eden Prairie, MN) rapid prototyping system took place on October 4, 2011. Engineering graduate student Brian Robillard was recruited to work on Tasks 3a, 3b and 3d during Year 3 of the grant. This formed the basis for his Master's thesis (**Appendix E**)**,** which provides greater detail than the summary descriptions below. Task 11e provides the basis upon which to proceed with automated fabrication as it forms the input data needed to create frames or molds for frames to be fabricated using fused deposition modeling (FDM) or other automated techniques.

Task 3a Establish criteria and techniques for multi-shot cavity molds: *This task was completed in year 3.*

The workflow for generating the digital residual limb geometry input files for advanced manufacturing of sockets is depicted in **Figure 2**. We explored two general approaches for a two-shot molding process: horizontal and vertical cavity molds. While both approaches evinced similar accuracies, time savings were evident with the horizontal approach due to a faster demolding process, however the vertical approach had minimal leaking. This minimal leaking was what led us to commit to a vertical approach. With additional trials, direct manufacture of the frame and injecting the resin into the frame-layup simplified the process to a single-shot mold providing additional time and cost savings.

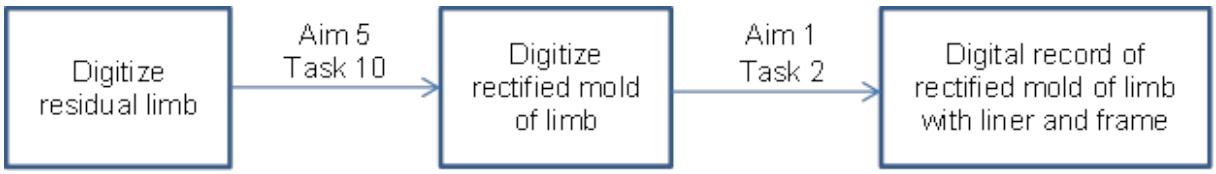


Figure 2 Work flow for input to advanced fabrication process.

The final fabrication technique, developed using an iterative design process, used a handheld scanner to scan a positive mold of the residual limb, SolidWorks to process the digital model, a Stratasys FDM 400mc to build the mold components, and a single-shot molding technique to fabricate the socket using additive manufacturing.

Posters describing this process were presented in 2013 at the Annual Lewis Landsberg Research Day, the Northwestern University InNUvations Applied Research Day (awarded 3rd prize for best poster), the Northwestern University 3rd Annual Research Day, and the Biomedical Engineering Society (BMES) Annual Meeting (**Appendix F**).

Task 3b Develop degassing techniques for liquid resin molding: *This task was completed in year 3.*

With the process described in Task 3a, we encountered two gas related issues: air bubbles (introduced during the filling process) and air spaces (areas of low/failed resin flow). The use of vacuum during the pour process was found to reduce air bubbles, while the introduction of "over-flow" ports maximized the amount of resin introduced into the cavity molds and reduced air spaces.

Task 3c Develop proximal brim vacuum seal: *This task was completed in year 2.*

Our trials with internal sealing rings all led to a tourniquet effect on the residual limb, suggesting that the compression needed for our socket design to be stable on the residual limb may not permit an internal sealing ring to be used safely and comfortably. The internal sealing ring was originally proposed as a way to address issues of liner wear observed due to reflection of the liner over the proximal brim of the socket. However, changes over the course of the project in both socket material and liner type diminished the problem of liner durability. Using Polytol and then FlexEVA as the flexible socket material, liners last longer as these compliant materials do not cut into the reflected liner as quickly or to the same extent as did previous, more conventional, lamination materials. The results of Tasks 4d and 4e provide some support for this observation. 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.

We also changed over time from using the Evolution liner to the medi Relax 3C liner. Our prosthetist Ryan Caldwell, CP, used the medi Relax 3C liner with Polytol sockets in clinical practice for over a year and confirmed that liner durability was improved compared to past experience with other liners and laminations. Previously patients using Evolution liners would replace the liner every 3-4 months, whereas the medi liner can last up to two years when used with FlexEVA. In addition to the flexible socket material, durability may in part be improved due to the presence of fabric laminated onto the outer surface of the liner.

Task 3d Develop mechanical interlock molding techniques: *This task was completed in year 3.*

We used holes in the printed frame to facilitate resin flow to both sides of the frame and create a mechanical interlock between the two flexible laminations.

The single-shot molding process designed to fabricate a three-layer prosthetic socket demonstrated fabrication feasibility, but in order to assess the clinical utility we compared failure loads and modes to two other sockets: first, to a manually fabricated socket to assess how the two approaches compare overall and, second, to a manually fabricated socket fabricated using the same materials as the advanced manufacturing approach. We compared the sockets using the same failure, tensile, flexural, and peel tests used in Task 4.

One advantage of advanced manufacturing is the ability to create a prosthetic socket with precise dimension parameters. Hence, we employed our FE model to explore the effect of prosthetic socket frame thickness variations on stress distribution in the socket. We compared different prosthetist-recommended frame thickness profiles at the transition regions between the rigid and flexible portions of the socket.

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 was completed in year 2.*

The ASTM D 1876-08 (Standard Test Method for Peel Resistance of Adhesives 'T-Peel test') was used to assess the bond strength between layers of the polyurethane socket. In accordance with the standard, 10 samples of two bonded polyurethane layers were prepared and each sample was loaded into a universal testing system. Tensile forces were applied to separate the different layers. The applied forces were monitored and plotted versus time. The most occurring force value (mode) was used as representative of the required force to peel the adjacent polyurethane layers. An average force of 14.65 N (3.30 lbs) was required to separate the bonded materials.

Task 4b Perform socket strength and deflection tests: *This task was completed in year 3.*

Three sockets were fabricated and sent to WillowWood (Mt Sterling, OH) for strength testing according to their published protocol, which is based on a modified ISO 10328 Configuration II A125 test set-up (Gerschutz et al., 2012). All three sockets failed at the distal adapter location similar to sockets fabricated in the general prosthetic community and tested using this protocol (**Appendix G**).

Task 4c Perform indentor tests of elastomers: *This task was completed in year 2.*

An indentor test of the socket elastomer material was originally proposed to establish values of material properties to use in full socket simulation. However, with a better understanding of the socket technology, it became clear that a tensile test would provide a better simulation of the actual loading condition of the socket during use. Specimens of the elastomer material were prepared and tested in tension according to ASTM D638-10 (**Figure 3**). The modulus of each specimen was calculated.

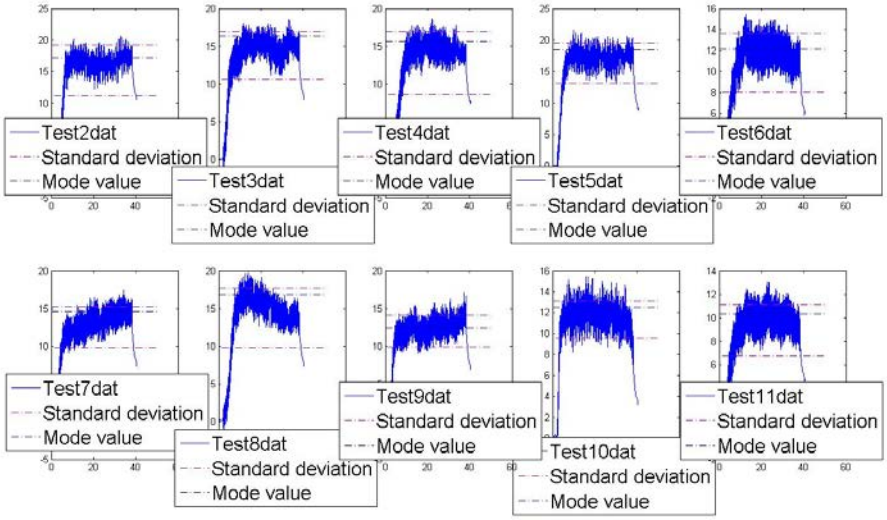


Figure 3 Applied forces on bonded polyurethane samples.

Task 4d Perform sitting durability tests: *This task was completed in year 2.*

This task involved the use of a standard protocol for performing indentor tests to determine material properties. Results are summarized below with Task 4e.

Task 4e Perform cyclic evacuation tests: *This task was completed in year 2.*

This test investigated 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 were fabricated. Initially we believed the conditions responsible for liner failure were repeated pinching and shear of the liner between the hard socket and a sitting socket (Task 4d), as well as stressing of the liner that occurs on the socket brim when vacuum is applied (Task 4e). However, further interactions with users of prosthetic liners suggested the

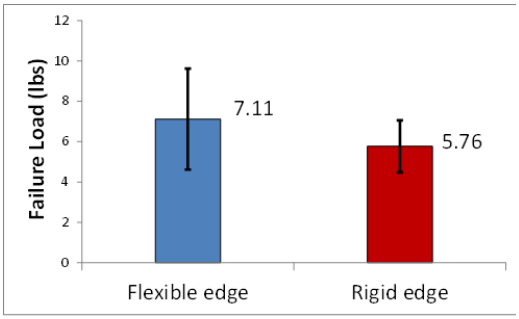
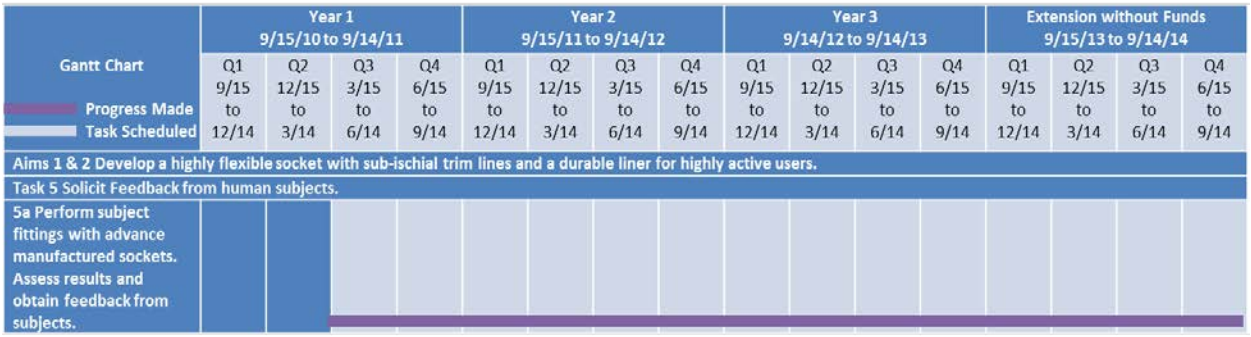


Figure 4 Mean and standard deviation of the load at failure of liners when stretched over flexible and rigid socket brims.

primary mode of failure to be a knife edge action of the brim of the rigid socket through the side of the liner. To reflect this new information, we revised the testing approach for this task. Here, the liner was stretched over two different socket edge types. The first, a flexible edge was representative of the prosthetic socket developed in this study where a flexible Polytol lamination is fabricated over the rigid material of the structural frame. The second, a rigid edge was typical of non-flexible prosthetic sockets typically used clinically. The test results (**Figure 4**) showed the liner failure loads with the knife edge action is about 23% higher for a flexible frame compared to a rigid frame. The higher variability of the failure loads of the flexible edge confirmed the ductile liner failure observed during testing.

Task 5 Solicit feedback from human subjects



Task 5a Perform subject fittings with advance manufactured sockets. Assess results and obtain feedback from subjects: *This task was completed in year 4.*

We recruited two highly active subjects with unilateral transfemoral amputation. For both subjects we completed gait analyses in the sub-ischial and ischial containment sockets. Gait analyses of level walking at both normal and fast speeds suggest that the sub-ischial socket performed as well as conventional ischial containment sockets. We also assessed comfort using the socket comfort scale and time to perform functional tests such as the Four Square Step Test, Rapid-Sit-to-Stand, and T-Test of Agility. Gait analysis results were summarized and included in the copyrighted multi-media instructional manual that we created to support dissemination of the socket (**Appendix H**). They were also presented at the 2013 meeting of the American Academy of Orthotists and Prosthetists (**Appendix I**). Finally, we have an article accepted for publication in the journal *Prosthetics and Orthotics International* describing this preliminary evaluation of socket performance (**Appendix J**). Subject 1 also assisted with clinical assessment of different liners and sealing techniques as well as assisting with videos and photos for the multi-media instructional manual.

During the course of the study, our subjects wore the Polytol sub-ischial socket with different commercially available liners (e.g. Evolution Industries Origin liner, OttoBock Custom Urethane liner, Össur Comfort Cushion liner, Össur Synergy liner, Össur Iceross Seal-In X TF, medi Relax 3C liner) and provided feedback. We found that the medi Relax 3C liner worked well for our socket and in order to better understand the properties of this liner as compared to other liners, we shared a liner with Dr. Joan Sanders at University of Washington to include in the Prosthetic Liner Assistant library that she created (see http://www.linerassist.org/). While the medi liner works well, it has an umbrella on the distal end that means it will not conform well to all residual limbs;

hence, an alternative liner was needed to deal with such cases. As a result of conversations with Össur (Reykjavik, Iceland), they provided us with prototypes of a new liner that combines the properties of two commercially available liners: the dual durometer silicone of the Össur Synergy and the textile covering of the Össur Sport liner. These have been combined to create a single liner (the Össur Iceross Synergy Sport Cushion, not yet commercially available) with properties we think valuable for successful use of our sub-ischial socket. Until this become available we recommend the Össur Synergy liner as an alternative to the medi Relax 3C liner. Regardless of liner type, durability has been good when used in conjunction with the flexible socket materials but remains an issue when checking liner fit with rigid test sockets.

An additional issue that came up is that sweat accumulation in our socket is problematic just as it is in other prosthetic sockets. To address this issue, we developed a simple technique to perforate the liner which is describe in an article that has been accepted for publication as a technical note in the *Journal of Prosthetics and Orthotics* (**Appendix K**). Subjects have reported fewer problems with sweating during activity when the liner is perforated.

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				Extension without Funds 9/15/13 to 9/14/14			
	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	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.																

Engineering graduate student Sean Wood was recruited to work on Task 6. This formed the basis for his Master's thesis (**Appendix L**), which provides greater detail than the summary descriptions below. Sean received the Northwestern University Mechanical Engineering Undergraduate Innovation and Research Award in June 2011 for his Master's research.

Task 6a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test): *This task was completed in year 2.*

We initially characterized five vacuum pumps (2 electric, 3 mechanical) by constructing five test chambers of known volume and measuring the rate of evacuation for each chamber with each pump. It was determined that the Ohio WillowWood LimbLogic® VS was 47% more powerful than the OttoBock Harmony® e-pulse, and that the OttoBock Harmony® P3 was the most powerful mechanical pump. This work was described in Sean Wood's Master's thesis as well as being

presented at the 2012 meeting of the American Academy of Orthotists and Prosthetists, the 2013 International Society for Prosthetics and Orthotics World Congress, and the 9th Annual Lewis Landsberg Research Day at Northwestern University in 2013. (**Appendix M**) and published in the *Journal of Rehabilitation Research and Development* (**Appendix N**).

Task 6b Evaluate time needed to evacuate sockets of transfemoral prosthesis users: *This task was completed in year 4.*

We collected and analyzed data from 18 subjects with unilateral transfemoral amputation. Each subject was asked to don their prosthesis and stand quietly while the space between socket and liner were evacuated to a vacuum pressure of ~17 inHg (5 evacuation trials with each of the electrical pumps: OttoBock Harmony® e-pulse and the WillowWood LimbLogic® VS). Vacuum pressure data and time were recorded during evacuation using a DigiVac (Matawan, NJ) digital vacuum pressure gauge and National Instruments LabVIEW (Austin, TX). We found that across participants, the LimbLogic® pulled vacuum at a faster rate than the e-pulse and required less time to achieve the desired pressure. Additionally, 9 subjects walked for 10 minutes with each pump at a comfortable pace on a treadmill while the vacuum pressure in their socket was monitored.

Details of the method and results of this testing can be found in Sean Wood's Master's thesis (**Appendix L**) as well as being presented at the 2012 meeting of the American Academy of Orthotists and Prosthetists and the 2013 International Society for Prosthetics and Orthotics World Congress (**Appendix O**). This work was also published in the *Journal of Prosthetics and Orthotics* (**Appendix P**). A synopsis of this article was featured on oandp.com, "Study Examines Comparative Effectiveness of Electric Vacuum Suspension Pumps" in September, 2015.

Task 6c Compare results of 6a and 6b: *This task was completed in year 4.*
Key observations from Tasks 6a and 6b are summarized in **Table 3**. Bench top testing showed that the OttoBock Harmony® e-Pulse required 56% more time to evacuate chambers of known volume to 17inHg compared to the WillowWood LimbLogic® VS (Komolafe et al. 2013). *In vivo* results in Task 6b are comparable to results from Task 6a.

Task 6a Observations	Electrical Pumps	The LimbLogic® is 47% more powerful than the e-pulse.
		Unlike the Harmony® 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 Harmony® P3 mechanical pump performs significantly better on average than both the Harmony® P2 and HD pumps.
		The various functional rings of the Harmony® P3 varied in performance.
		The average performance of the Harmony® P3 pump was equal to that of the Harmony® 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 Harmony® e-pulse.
Task 6c Observations		The average volume of the socket/liner interface for persons with transfemoral amputations is 6.14 in^3.

Table 3 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 in year 1.

Our survey identified two electric pumps and three mechanical pumps that are commonly used in lower limb prostheses. These were the Ohio WillowWood LimbLogic® VS (electric), the OttoBock Harmony® e-Pulse (electric), the OttoBock Harmony® P2 (mechanical), the OttoBock Harmony® P3 (mechanical), and the OttoBock Harmony® HD (mechanical).

We thought 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 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 (described in Sean Wood's Master's thesis, **Appendix L**).

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 Q**) and then design modifications and construction of the prototype were undertaken by Sean Wood as part of his Master's thesis (**Appendix L**).

Task 7b Characterize pumps based on cycles and time to pull specific vacuum levels: *This task was completed in year 2.*

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 = 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 72°F.

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) (**Figure 5**). 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.

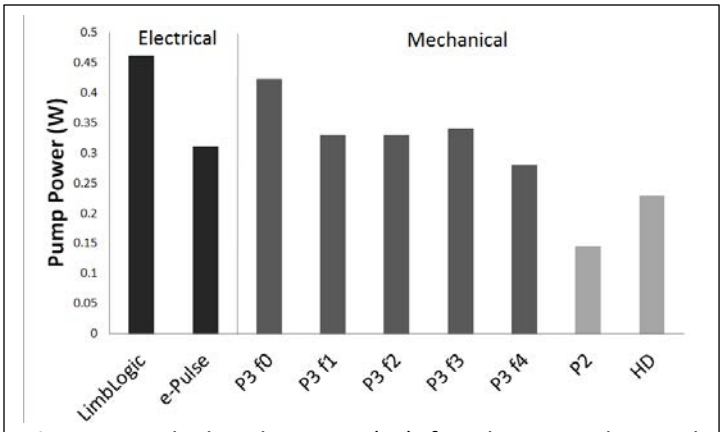


Figure 5 Calculated power (W) for the two electrical pumps and the three mechanical pumps.

Task 7c Publish a journal article on the characterization of the mechanical pumps: *This task was completed in year 2.*

Characterization of the mechanical pumps was included in an article published in the *Journal of Rehabilitation Research and Development* (**Appendix N**).

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.												

This task was completed in year 2.

A patent (#9,066,822) was issued for the hybrid pump we designed on June 30, 2015 (**Appendix R**). Additional actions related to the hybrid pump have been filed with the patent office by Northwestern University (provisional application 62/214,560 (NU2013-184); pending applications 14/730,806 & 14/730,816 (NU2011-089)).

Aim 3: Supplemental Tasks

Supplemental funding was received in December 2012 for additional work to prototype and test the hybrid vacuum pump's ability to create suitable vacuum for suspension of the prosthesis in highly active persons with transfemoral amputation.

Supplemental Task 1 Build three hybrid vacuum pumps

Gantt Chart Progress Made Task Scheduled	1/01/13 to 12/31/13			
	Q1 1/01 to 3/31	Q2 4/01 to 6/30	Q3 7/01 to 9/30	Q4 10/01 to 12/31
Extended Aim 3: Prototype and test hybrid vacuum pumps to create suitable vacuum for suspension of the prosthesis.				
Task 1: Build three hybrid vacuum pumps.				
1a Create detailed 3D CAD drawings for all constituent parts and molds.				
1b Prototype and machine all constituent pump parts and bladder molds.				
1c Injection mold bladders.				
1d Assemble electrical pumps.				
1e Assemble prototype hybrid pumps.				

Supplemental Task 1a Create detailed 3D CAD drawings for all constituent parts and molds**:** *This task was completed in year 4.*

Detailed 3D CAD drawings were created for each of the four proposed hybrid pump designs and a mold for the bladder, which is common to all designs (**Figure 6**). Additionally, CAD drawings of the WillowWood LimbLogic® pump electronics were provided to us by WillowWood. This allowed us to determine if the compartment space designed as part of the hybrid pump was sufficient to house the components required by an electric pump system.

Supplemental Task 1b Prototype and machine all constituent pump parts and molds: *This task was completed in year 4.*

Summarized below with Supplemental Task 1c.

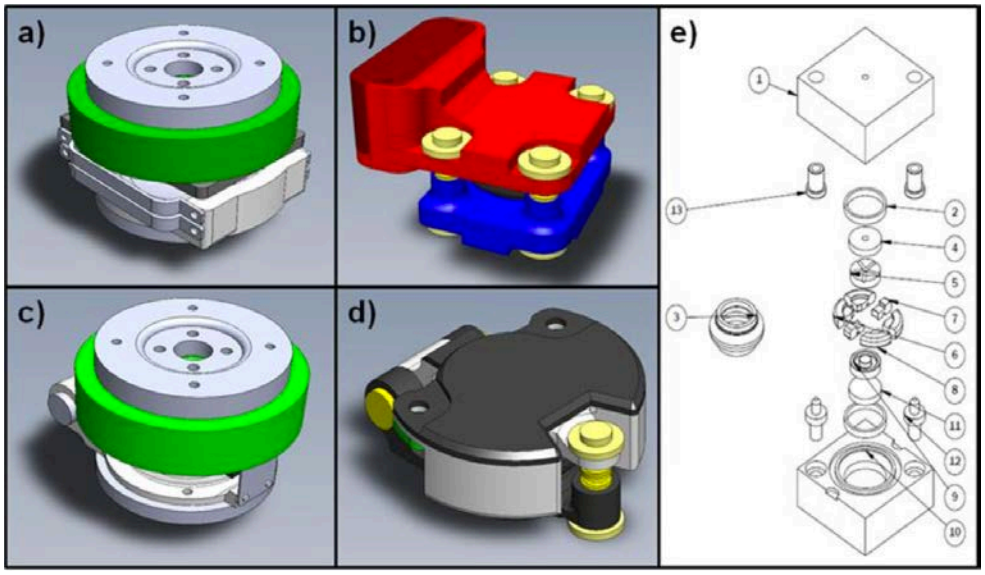


Figure 6 CAD drawings for each hybrid pump design and the bladder mold.

<u>Supplemental Task 1c Injection mold bladders:</u> *This task was completed in year 4.*

Making the bladder required access to injection molding services and as such we worked initially with Weiler Rubber Technologies LLC (Chicago, IL) to manufacture the first prototype bladder. We used our Stratasys FDM system to rapid prototype one of the four designs, the four post design, to assess function of the bladder. Through a series of experiments, we determined that the bladder was unable to generate sufficient vacuum due to leakage and a lack of rebound that did not allow the pump to continue pulling air after several cycles. This rebound issue was most likely the result of too low a stiffness of the bladder material, such that it did not return to its neutral position following compression. Discussion with Weiler led to bladder design changes. The redesign was intended to address leakage by securing the proximal and distal bladder walls within a 'sandwich' plate; an improvement over the original method of securing the bladder to standard pipe fittings.

Unfortunately, prior to fabrication of the redesigned bladder, Weiler withdrew from working on this project due to other commitments. Attempts to identify another injection molding service to work with us were unsuccessful. Hence, an alternative approach to addressing bladder design issues was sought. In order to demonstrate that the hybrid pump was feasible (i.e., could demonstrate concurrent function between the mechanical and electrical pumps) we decided to modify the CAD models of the pump designs such that the OttoBock Harmony® P3 bladder (referred to as the 4X147 Functional Ring by OttoBock) could be retrofitted into the assembly for bench testing. We modified three of the proposed hybrid pump designs (hinge, four-post, and four-bar) for retrofitting with the P3 bladder, which was also modeled. The primary design modification was inclusion of a ring indentation in the housing for intimate fitting of the P3 ring and the overall build height was increased to accommodate the height of the ring. With this approach, it was unnecessary to build the fourth iteration of the hinge design with the external spring as the P3 bladder demonstrated sufficient rebound in previous mechanical testing.

Upon preliminary analysis of each design's mechanical function with the P3 ring, issues were encountered with the hinge and four-bar designs: given the height of the P3 ring it was not possible to derive suitable linear displacement from angular displacement. The angular motion

of these two designs places the P3 ring under asymmetric loads and, furthermore, the moments produced when under load act in such a way that the housing pulls itself apart. Consequently, we tested only the four-post design with integration of both the P3 ring and LimbLogic® system.

Supplemental Task 1d Assemble electrical pumps: *This task was completed in year 4.*

Summarized below with Supplemental Task 1e.

Supplemental Task 1e Assemble prototype hybrid pumps: *This task was completed in year 4.*

Preliminary evaluation of the hybrid system involved setting up the housing in a drill press for creating linear compression and pulling 17 inHg using only the P3 ring, then creating an artificial leak in vacuum, and allowing the LimbLogic® electrical system to activate in order to return vacuum to 17 inHg. Using the four-post design, the hybrid system functioned well with the mechanical and electrical components operating in tandem. For additional testing, further modifications were made to the housing of the four-post design in order to attach male/female pyramid adaptors to the distal and proximal surfaces. This required aligning the center of the (proximal and distal) pyramid attachments with the central axis of the P3 ring to ensure symmetric loading of the ring under uniaxial compression. These changes required that the posterior carriage be extended to house the LimbLogic® electrical components. A hose protruded through this carriage on the distal side that attached to the volume for which vacuum was to be created. Holes were tapped on the top and bottom plate to attach the pyramid adapters and the bolts screwed into these holes were secured with an epoxy resin. An image of the final hybrid pump prototype is shown in **Figure 7**.

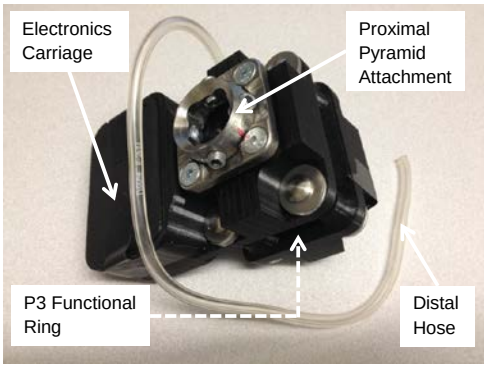


Figure 7 Assembled hybrid pump (four-post design).

Supplemental Task 2: Performance testing of three hybrid vacuum pumps

Gantt Chart Progress Made Task Scheduled	Year 1 1/01/13 to 12/31/13			
	Q1 1/01 to 3/31	Q2 4/01 to 6/30	Q3 7/01 to 9/30	Q4 10/01 to 12/31
Extended Aim 3: Prototype and test hybrid vacuum pumps to create suitable vacuum for suspension of the prosthesis.				
Task 2: Performance testing of three hybrid vacuum pumps.				
2a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test).				
2b Evaluate time needed to evacuate sockets of transfemoral prosthesis users.				
2c Compare results of 2a and 2b to previous results from 6a and 6b.				

Supplemental Task 2a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test): *This task was completed in year 3.*



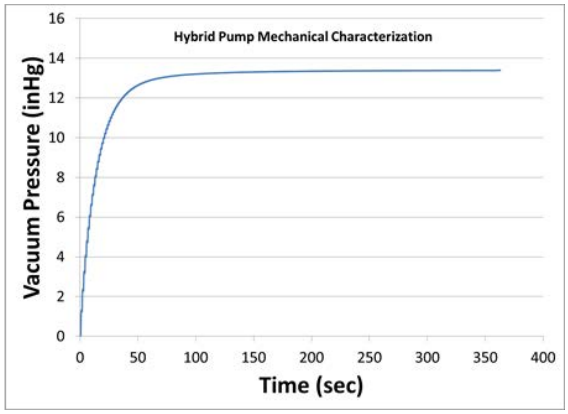


Figure 8 Mechanical test set up (left) and results for 6.46 in^3 canister (right).

The four-post pump design underwent mechanical characterization using the Instron (Norwood, MA) materials testing machine (**Figure 8, left**). This characterization involved cyclical compression of the pump through a displacement of 7 mm (about 1 mm before bottoming out occurred) over 300 cycles and with a frequency equivalent to average walking cadence (100 steps/min). Canister 'C' was used as the test volume (6.46 in^3) for this assessment. The maximum axial force and vacuum pressure achieved during this characterization was 140 lbs and 13.4 inHg, respectively (**Figure 8, right**).

Supplemental Task 2b Evaluate time needed to evacuate sockets of transfemoral prosthesis users: *This task was completed in year 4.*

The pump underwent a form of preliminary *in vivo* characterization, in which it was attached between the distal end of walking boots and prosthetic feet. These simulators were used to subject the pump to the type and magnitude of loads experienced when installed distal to a prosthetic socket. The pump sustained the loads applied without failure or damage, but displayed asymmetric compression during walking (i.e., sequential posterior and anterior compression corresponding to heel-toe gait). There is concern that this asymmetric compression pattern may be a source of discomfort when used in operation with a transfemoral prosthesis. Vacuum level was also compromised by the asymmetric compression: when the pump was compressed symmetrically it was able to pull a higher level of vacuum (~12 inHg) than when it was compressed asymmetrically (~6 inHg).

Modifications to the hybrid pump to address asymmetrical compression were completed and the modified pumps tested with simulators during walking. The results indicated that although these modifications reduced off-axis motion and asymmetric loading of the bladder, vertical motion was also restricted and some asymmetric loading remained. Upon further inspection when applying vertical compression to different sections of the upper pump housing with a drill press, it was revealed that the extension sleeves were flexing. This flexing is due to the compliance of the prototyping plastic, and acted to restrict overall motion while still allowing asymmetric motion.

The third iteration involved stiffening the upper housing plate by filling the gaps between the sleeves, essentially making the upper housing solid and stiffer to restrict off-axis motion of the posts and limit piston binding. This iteration was tested with the simulators during walking and in bench testing. For this third iteration, it was apparent that off-axis motion was limited and

binding reduced. Results from the first walking test revealed that vacuum reached 11 inHg, which was almost a two-fold improvement from the pull of 6 inHg for the previous iteration. There still remained some binding during this test and so the passages for the bolts were widened slightly. Further bench testing revealed that this helped reduce binding while still restricting off-axis motion. Bench testing demonstrated a pull of 18 inHg despite off-axis loading. The second walking test, however, succeeded in pulling out the two anterior bolts connecting the pyramid adapter to the housing and stripping the threaded holes (even with the use of a polymer adhesive). This illustrates the torque magnitude that is being applied to the pump during walking and also the possibility that the 3D printed material may not be strong enough to withstand such torque. However, further inspection showed that alignment of the four posts were not parallel due to slight errors in the alignment of the top and bottom housing plates. Alignment of the posts is critical due to the tight tolerances of the design. The misalignment was addressed by widening the holes in the bottom housing plate. This modification appears to have addressed binding, while previous modifications addressed asymmetric loading. Subsequent bench testing (uniaxial load application at various points on the top housing to mimic asymmetric loading scenarios) produced 20 inHg of vacuum, while *in vivo* testing with the simulator boots plateaued at 15 inHg.

Data was collected from 4 people with transfemoral amputation using the hybrid pump. During testing with the first subject, the hybrid pump functioned adequately, maintaining the appropriate levels of vacuum through use of the electronics. The mechanical function provided some vacuum creation, which was observable in the temporal plot of vacuum pressure, but this was not sufficient to limit use of the electronics. The insufficient pull of air from the mechanical pump was due to limited compression of the internal bladder. As no asymmetric compression was observed during operation, we suspect that the bladder stiffness was too high for the tested subject and this restricted full compression when full body weight was applied. Despite this issue, the hybrid pump housing sustained the loads and moments during walking, displayed symmetric bladder compression, and maintained 17 inHg of vacuum pressure during both walking and standing.

To address the issue of ring compression, our second subject with transfemoral amputation was tested with a more compliant bladder. The subject's own commercial pump appeared to suffer from some form of malfunction, reflected by an inability to maintain an adequate level of vacuum and constant reactivation of the electronics. The hybrid pump functioned flawlessly, quickly arriving (~12 seconds) at 17 inHg with activation of the electronic system, and achieving a maximum of 22 inHg when the mechanical system was engaged. Throughout the 10 minutes of walking, the vacuum level decreased in a linear manner (~0.4 inHg/min), but never dropped below 18 inHg and the electronic system never reactivated. If extrapolated, the hybrid pump would arrive at 13 inHg (the pre-determined lowest acceptable vacuum level before reactivation of the electronic system) after an additional 12.5 minutes of walking (23 minutes of total walking).

Two additional subjects were tested with the hybrid pump. However, for these subjects the four posts tended to migrate away from parallel during walking if the two bolts fixing the posts to the bottom plate were firmly secured. This caused excessive friction in the system and did not allow full compression of the bladder. As such, the bladder only pulled limited vacuum. Although some pull through of the bladder is beneficial, a complete compression is required for the pump to

satisfy its purpose. In order to test if slightly loosening the bolts would resolve this issue while still allowing the pump to remain intact, we subsequently tested the pump in this manner using the simulator boots while walking on the treadmill at 0.53 m/s. The bladder achieved full compression and vacuum pressure plateaued after about 8 minutes of walking. This experiment represents an ideal scenario, in which a canister (Canister 'C' - test volume of 6.36 in^3) that experiences minimal leakage was used to mimic the socket volume. Overall, it is clear that the electronic system will rapidly create vacuum initially, and the mechanical system continues to create vacuum during walking.

Supplemental Task 2c Compare results of Supplemental Tasks 2a and 2b to previous results from Tasks 6a and 6b: *This task was completed in year 4.*

Supplemental Task 3: Finalize vacuum pump design.

Gantt Chart Progress Made Task Scheduled	Year 1 1/01/13 to 12/31/13			
	Q1 1/01 to 3/31	Q2 4/01 to 6/30	Q3 7/01 to 9/30	Q4 10/01 to 12/31
Extended Aim 3: Prototype and test hybrid vacuum pumps to create suitable vacuum for suspension of the prosthesis.				
Task 3: Finalize vacuum pump design.				
3a Iterate/refine final pump design based on performance testing.				
3b Prepare and submit presentations/publication on hybrid pump design and performance results				

Supplemental Task 3a Iterate/refine final pump design based on performance testing: *This task was completed in year 4.*

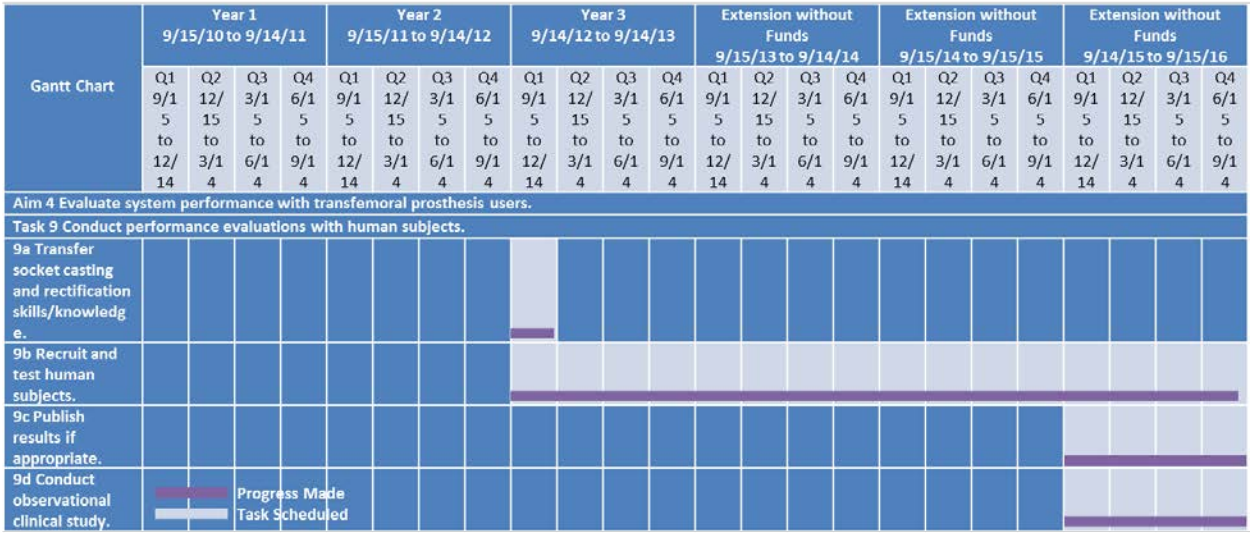
An additional invention disclosure for an alternative diaphragm design approach was submitted to the Northwestern University Innovations and New Ventures Office (INVO). This new design uses a diaphragm in place of the bladder that is installed in series with the electric pump system. A diaphragm will be less susceptible to both asymmetric loading given its function and geometry, and leakage given its construction. The diaphragm prototype was built and bench tested (use link to see video: https://northwestern.box.com/s/mop86jlalak6w89oua7sso34okh1dajs)

Supplemental Task 3b Prepare and submit presentations/publication on hybrid pump design and performance results: *This task was completed in year 5.*

A presentation regarding our hybrid pump development and evaluation was accepted for presentation at the 2017 American Academy of Orthotists and Prosthetists annual meeting (**Appendix S**) and a technical note describing the pump design and operational feasibility was published in the *Journal of Medical Devices* (**Appendix T**). To facilitate discussions about licensing of the pump with potential commercial entities we created a tech alert summarizing our hybrid pump IP in conjunction with the Northwestern University Innovations and New Ventures Office (**Appendix U**).

Aim 4 Evaluate system performance with transfemoral prosthesis users

Task 9 Conduct performance evaluation with human subjects



Task 9a Transfer socket casting and rectification skills/knowledge: *This task was completed in year 3.*

We had the opportunity to share our preliminary education documents (which later became the copyrighted multi-media instructional manual (**Appendix H**) with our collaborators at CFI/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 from 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, John Fergason, CP, reported that initial fittings with two of the three patients were successful but neither patient continued to wear the sub-ischial socket after an initial trial phase. We believe that this was due to (1) choice of liner which we had not finalized at the time of BAMC's initial request, or (2) the sockets having been fabricated using conventional rigid laminations since we were not ready to share with them the more flexible Polytol frame design at the time of BAMC's initial request. However, this initial sharing of our ideas allowed us to incorporate feedback provided by John Fergason, CP, into a second version of our instructional manual.

Three visits to the CFI/BAMC took place (October 2012, August 2013 and February 2015) to transition the socket fabrication and fitting technique to BAMC prosthetists (first, John Fergason, CP, and then Andrea Ikeda, CPO).

Task 9b Recruit and test human subjects: *This task is partially complete.*

Recruitment and retention of military amputees was slower than anticipated due to unanticipated complications scheduling subjects over the duration of the study protocol. We also had staff changes both with the prosthetist working on the study and staff in the lab collecting and processing the data. In 2014, and again in 2016, the research staff at the CFI/BAMC received IRB approval to add additional subjects to the protocol to allow recruitment of additional subjects (from 6 initially to "we will recruit and enroll subjects until we have 10 completers"). Ultimately,

11 male subjects were enrolled in the study before the grant ended, with three completed, six lost to follow up/withdrawn, and 2 still enrolled and partially complete at the time of writing this report (**Table 4**). **Appendix V** provides a summary of the data from the three subjects who completed testing. We are hoping that the two remaining subjects will complete the study soon.

Task 9c Publish results if appropriate: *This task is partially complete.*

Data for one subject was presented at the 2015 American Academy of Orthotists and Prosthetists Annual Meeting and data for the three subjects who completed the study were presented at the Omer Research and Alumni Lectureship at BAMC in 2016 and the American Society for Biomechanics 2016 meeting (**Appendix W**).

Task 9d Conduct Observational Clinical Study: *This task was completed in year 6.*

An observational clinical study was conducted wherein a bathroom scale mounted on a hard stand was used to assess how much weight transfemoral amputees can place on the residual limb when it is bare, when they wear only the liner, and when they wear both the socket and liner. In each of these conditions the amputee also reported the amount of discomfort/pain they experienced. This allowed us to discern the relative contribution each component (liner and socket) made to the ability of the amputee to bear weight on the prosthesis and provided some support for the proposed role of tissue stiffening in creating a weight bearing interface between the amputee and the prosthesis, alleviating weight bearing entirely on the distal end.

We presented this work at the 2016 meeting of the Midwest Chapter of the American Academy of Orthotists and Prosthetists and have submitted an abstract describing this work for presentation at the 2017 International Society for Prosthetics and Orthotics World Congress (**Appendix X**). A manuscript is being drafted for publication.

Table 4 Subject Characteristics and Testing Timeline (gray shading indicates subjects who completed study)

Subject	Date enrolled	Age	Etiology of Amputation	Time since Amputation	Reason for with-drawal	Baseline Socket/Prosthesis			Sub-ischial Socket/Prosthesis		
						Prosthesis Description	Date biomechanics testing	Date fluoroscopy testing	Accomm-odation time	Date biomechanics testing	Date fluoroscopy testing
1	2012/10/29	28	Motorcycle accident	298 weeks	Back in school	IC socket with flexible brim, X3 knee, reflex rotate with Unity foot	2014/12/09	2015/07/21	None to date	N/A	N/A
2	2012/10/29	35	Motorcycle accident	70 weeks	N/A	IC socket with flexible brim, X3 knee, Triton Harmony® foot	2012/12/19	2012/12/18	8 weeks	2013/02/20	2013/02/20
3	2012/10/29	40	IED	Unknown	Still enrolled	IC socket with flexible brim, X3 knee, Triton Harmony® foot	*	*	18 weeks	2013/05/15	2013/06/17
4	2013/02/22	31	Motorcycle accident	Unknown	Moved out of area	IC socket with flexible brim, X2 knee, Renegade foot	2013/08/05	2013/08/08	N/A	N/A	N/A
5	2014/01/31	24	Motorcycle accident	63 weeks	Left the army and did not have time to complete the study	IC socket with flexible brim, gel seal-in liner with passive suction suspension, X3 knee, College Park Trustep foot, push button rotator proximal to the knee	2014/07/01	2014/07/02	3.5 weeks (but then had 2 surgeries and needs to be recast to continue in study)	N/A	N/A
6	2014/10/30	33	IED	107 weeks	Patient moved out of the area and then forgot his sub-ischial socket when he came back	IC socket with a flexible brim, gel seal-in liner with passive suction suspension, X3 knee, Triton Harmony® foot	2015/01/23	2015/01/30	N/A	N/A	N/A

Subject	Date enrolled	Age	Etiology of Amputation	Time since Amputation	Reason for with-drawal	Baseline Socket/Prosthesis			Sub-ischial Socket/Prosthesis		
						Prosthesis Description	Date biomechanics testing	Date fluoroscopy testing	Accomm-odation time	Date biomechanics testing	Date fluoroscopy testing
					for appointments at the CFI						
7	2014/11/21	32	IED	Unknown	Could not be fit with sub-ischial socket	IC socket with a flexible brim, gel seal-in liner with passive suction suspension, X3 knee, Triton foot	N/A	N/A	N/A	N/A	N/A
8	2015/04/30	33	Gunshot wound	23 weeks	N/A	IC socket with flexible brim, X3 knee and XC with Unity pump foot	2015/07/01	2015/06/24	3 days	2015/08/17 & 2015/08/19	2015/08/14
9	2015/05/04	30	Gunshot wound	40 weeks	N/A	IC socket with flexible brim, X3 knee and Triton Shock foot	2015/07/29	2015/08/26	9 weeks	2015/11/13	2015/11/12
10	2015/06/29	36	IED	528 weeks	Did not like the sub-ischial socket after 1 day and didn't want to continue	IC socket with flexible brim, X3 knee and Triton Shock foot	2015/06/30	2015/06/29	None to date	N/A	N/A
11	2016/5/4	31	Humvee roll over	37 weeks	Still enrolled	IC socket, ÖSSUR Iceross seal-in TFX liner, X3 knee and ÖSSUR Proflex XC with Unity foot	2016/7/21	2016/7/07	9 weeks	**	2016/11/3

IED: improvised explosive device; CFI: Center for the Intrepid; IC: ischial containment socket.

Shading indicates subjects who have completed the study.

*Subject 3 was tested in reverse order: sub-ischial biomechanics and fluoroscopy testing have been completed and subject is now being recast for a new baseline socket because patient cannot find his original baseline socket.

**Subject 11 is still enrolled and the biomechanics testing session in the SI socket is still outstanding. The subject is in a wheel chair due to pain in his back and unaffected limb. The subject indicates the pain is not related to the study. The subject and/or his case manager will let us know when the subject is back to walking normally.

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: *This task was completed in year 2.*

MATLAB (MathWorks Inc., Natick, MA) 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 unmodified and modified positive models, reads in the three registration marks on the 3D computer models, aligns the two shapes, calculates the transformation or amount of modification at each point on the modified model, and assigns color coding to the unmodified model to indicate the degree of modification.

To obtain a meaningful color-coded 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 was based on three proximal registration marks. ShapeMaker (S&S ShapeMaker, Hickory Hills, IL) was 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 final 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. A multi-colored scale indicates the amount of rectification. The scale's units are in millimeters: negative numbers represent the amount of material removed during rectification and positive numbers represent the amount of material added. However, since no material is added during rectification, the positive coloring indicates areas where the modified shape is outside the unmodified shape. Positive coloring implies a misalignment when this occurs in the distal portion of the shape.

Task 10b Develop shape registration scheme: *This task was completed in year 2.*

The alignment of modified and unmodified shapes is the first step in quantifying the amount of rectification. We used an iterative closest point (ICP) algorithm to align the shapes. This algorithm seeks to minimize the difference between similar regions. So, we defined four regions that were not modified during rectification. Three regions were defined in the proximal portion of the positive model, and the fourth was placed along the medial wall.

Initially, a jig was constructed to hold casts during scanning with the Inspeck scanner (Jodason Technology Ltd., China). Preliminary scans showed that the scanner was capable of capturing the cast shape and registration marks well. Unlike the Omega T-Ring (WillowWood, Mt Sterling, OH) and Provel d1 (Cle Elum, WA) digitizers we have available, the Inspeck scanner allows the distal end of the positive model to be better captured. Nine scans taken every 45° and at the distal end were required to capture the whole model. The 9 individual scans were 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 that caused problems with processing of the files. Also, the acquisition and registration process were very time consuming, and with a many casts to scan, the Inspeck digitizer was no longer a viable option.

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, adequately fill the hole using the surrounding geometry. Using the Provel digitizer significantly reduced the acquisition time. We modified our code to integrate the new data file structure.

Task 10c Test program accuracy: *This task was completed in year 6.*

After alignment, the differences between the two shapes were calculated and color-coded to indicate the location and degree of rectification. The prosthetist who performed the rectifications confirmed the accuracy of the resulting models.

Based on the digitization of 30 cast pairs, an average template for use in CAD rectification was created using ShapeMaker software. This template was shared with Advanced Orthotic and Prosthetic Solutions (AOPS, Hickory Hills, IL), the current owners of ShapeMaker for further evaluation. Results of that evaluation were accepted for presentation at the 2017 American Academy of Orthotists and Prosthetists annual meeting (**Appendix S**) and are described as part of a manuscript on quantification of rectifications for our sub-ischial socket, which was accepted for publication in the journal *Prosthetics and Orthotics International* (**Appendix Y**).

While the initial template worked well we wanted to both validate it as well as expand the dataset upon which it was based, especially given that the initial 30 cast pairs were collected while the template was still developing (Years 1 to 3). Hence, we collected and digitized an additional 12 cast pairs (Year 6).

In addition to the contour loop method described in Task 11e, we developed a second method for averaging the rectification maps to see if it would give us a similar result and thus validate the contour loop approach. For the second averaging method, we input cylindrical coordinates of

unrectified and rectified cast scans and values for the depth of material removed at each cylindrical coordinate. The output was an average of the rectifications at every degree angular position and % lateral trim line height across all cases rather than a set of contour loops with an arbitrary 1 mm material removal. The distribution of plaster removal using this model was compared to the contour loop approach for both sets of cast pairs by clustering the data points by magnitude of plaster removed from ≥ 1 mm material removed to ≥ 9 mm material removed (**Figure 9**). This new method of averaging plaster removal demonstrated a similar concentration of plaster removal in the lateral and posterior quadrants, biased proximally, and almost no plaster removed in the medial quadrant. It can be seen in **Figure 9** that the deeper the magnitude of plaster removal the more concentrated the location becomes to the proximal lateral area. This was consistent with the original contour loop approach. While this new averaging method allowed us to validate the contour loop approach it cannot be applied to an unmodified cast scan as can the contour map.

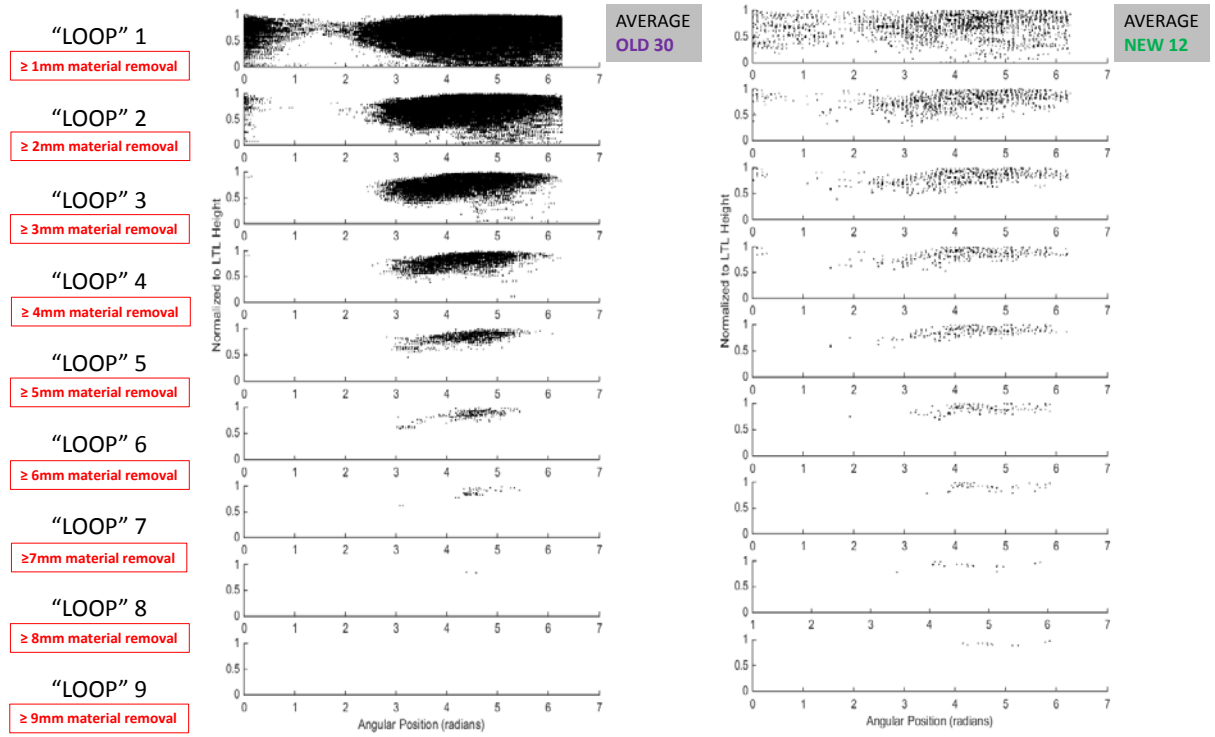


Figure 9 Plots depicting location and magnitude of plaster removal averaged across two sets of cast pairs and clustered by magnitude for comparison to the contour loop approach, such that all of the data points with ≥ 1 mm material removed are shown in the top graph, all of the data points with ≥ 2 mm material removed are shown in the graph immediately below, and so on. It can be seen that the deeper the magnitude of plaster removal the more concentrated the location becomes to the proximal lateral area.

The two methods agreed quite well with regards to the location of material removal but the template seems to have changed over time, with rectifications more localized to the proximal lateral region (**Figure 10**). While the need for more aggressive proximal-lateral rectification was consistent with the findings of the pilot application of the original template by AOPS, more data was needed to confirm that this new template was not just unique to the new set of casts. Hence, we averaged all available data (42 cast pairs) to create a second generation of the template,

which should improve the functionality of the original template by increasing the magnitude of plaster removed proximal-laterally without biasing it entirely in that area based on only 12 cast pairs.

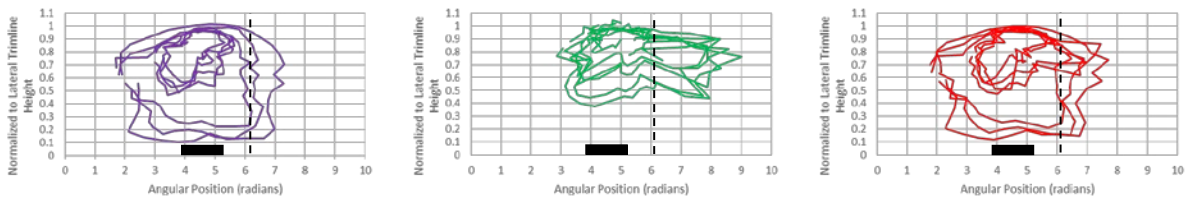


Figure 10 Contour loops based on data from (left) 30 cast pairs collected over years 1-3, (middle) 12 cast pairs collected during year 6, and (right) all 42 cast pairs combined. 0 radians indicates anterior midline. Approximate location of lateral quadrant is indicated by the black bar. Black vertical dashed line indicates where the contour map wraps back round over the anterior midline but for clarity, we chose to depict the contour loops as continuous loops.

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: *This task was completed in year 2.*

Algorithms for clinical decision-making were drafted for transfemoral as well as knee disarticulation patients. Feedback was obtained from prosthetic colleagues to ensure that our algorithm was understandable and revised as necessary. The final algorithm for transfemoral amputation, along with a socket work form, was included in our multi-media instructional manual (**Appendix H**) and used in the hands-on workshops held in Years 5 and 6 to teach prosthetists our socket technique (see Task 12d).

Task 11b Obtain range of negative casts: *This task was completed in year 6.*

We collected 52 pairs of casts: 30 cast pairs were collected initially but since our prosthetist's

rectification technique matured over the years, 12 additional cast pairs were collected later.

Task 11c Digitize casts: *This task was completed in year 6.*

Forty-two pairs of casts were digitized (casts were excluded if they were from patients with knee disarticulation, had warped during transit, or could not be scanned well) using the process described in Tasks 10a and 10b. Initially, we included casts from persons with knee disarticulation, but based on further discussion we decided to exclude those casts as considerations regarding casting and rectification are different and may confuse initial adopters of the socket technique.

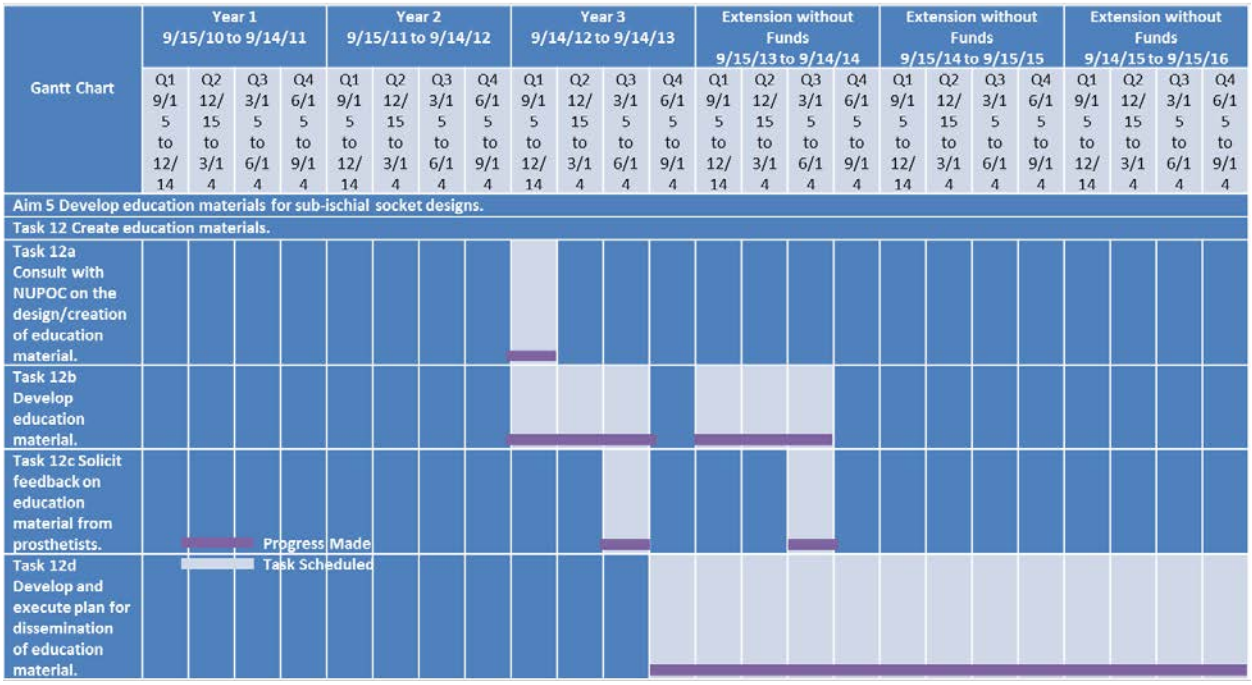
Task 11d Assess digitized shapes: *This task was completed in year 6.*

Color-coded rectification maps for the first 30 casts were included in the copyrighted multi-media instructional manual (**Appendix H**). From these initial templates, it was clear that rectifications were consistently confined to the proximal posterior and lateral portions of the mold and that they were more aggressive for limbs considered to have relatively "soft" tissue compared to limbs considered to have relatively "firm" tissue. Variations in rectifications across these cast pairs led us to wonder how limb characteristics affected the shape and magnitude of rectification. Hence, we recorded limb characteristics (e.g. % gradation used during rectification, residual limb type, tissue type, residual limb symmetry, and liner type) for the second set of cast pairs collected. Unfortunately no relationship was found.

Task 11e Generate representative 3D models: *This task was completed in year 6.*

We investigated various 3D unwrapping techniques and how to implement them. The resulting code was used to generate 2D rectification maps. These maps were averaged to create a template for automated socket rectification using all the scanned data from Tasks 11b and 11c. We eventually created a template for use in ShapeMaker since this software was available to us and used locally by a prosthetic central fabrication facility (AOPS) who could assist in assessing it's feasibility in clinical use. Using this method, we input cylindrical coordinates of the unrectified and rectified cast scans and depth of material removed at each cylindrical coordinate. We then output an average of the rectifications in the form of contour loops across all cases (with each contour representing an additional 1 mm of material removed from the cast). The contour loops were implemented into coordinates for use in ShapeMaker software and can be applied to an unmodified cast scan. A manuscript describing this quantification of rectifications for our sub-ischial socket was accepted for publication in the journal *Prosthetics and Orthotics International* (**Appendix Y**).

Task 12 Create education materials



Task 12a Consult with NUPOC on the design/creation of education material: *This task was completed in year 3.*

This task was accomplished in multiple ways. Vacuum assisted technology was 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. Student and faculty feedback on content was received.

With the assistance of the Northwestern University Prosthetics-Orthotics Center's (NUPOC) Audio/Visual Production Specialist, Piper Kruse, we filmed and edited the casting, rectification, and fitting procedures for our sub-ischial socket. These videos formed the basis of the copyrighted multi-media instructional manual intended to support dissemination of the socket to other prosthetists (**Appendix H)**.

Drafts of the manual underwent revisions after feedback from our collaborators at BAMC and NUPOC education faculty.

Task 12b Develop education material: *This task was completed in year 4.*

A multi-media instructional manual was created and the copyright registered in 2015 (**Appendix H**). It has since been provided to all course participants on a thumb drive.

Task 12c Solicit feedback on education material from prosthetists: *This task was completed in year 5.*

Education material was piloted as part of courses/presentations taught at various conferences,

including the 2012 meeting of the Midwest Chapter of the American Academy of Orthotists and Prosthetists, the 2013 medi International Symposium, the 2013 World Congress of the International Society for Prosthetics and Orthotics, the 2013 International Society for Prosthetics and Orthotics Norway Seminar, the 2014 meeting of the Canadian Association of Prosthetists and Orthotists, and the 2014 American Academy of Orthotists and Prosthetists Annual Meeting. (**Appendix Z**). The 2014 instructional course at the American Academy of Orthotists and Prosthetists was so well attended that we were invited to present a live webinar that was recorded and archived on the Academy's online learning center (http://www.oandp.org/olc/course.asp?course_id=8E117078-AC6F-446C-BE3B-62E1560FCE5D) and is freely-available for viewing. Feedback and questions received at all these events helped us improve our education material.

Task 12d Develop plan for dissemination of education material: *This task was completed in year 6.*

In the summers of Years 5 and 6 we held five, 2-day hands-on continuing education courses for Certified Prosthetists from across the US to learn how to make our sub-ischial socket (**Figure 11**). Courses were held at the Northwestern University Prosthetics-Orthotics Center in Chicago on July 31-August 1, August 21-22, and September 11-12, 2015, and June 8-9 and July 22-23, 2016. Courses were open to Certified Prosthetists who were required to register both themselves and a transfemoral amputee patient model. Prosthetists earned 15.5 continuing education credits from either the American Board for Certification in Prosthetics, Orthotics and Pedorthics (ABC) or the Board of Certification (BOC). Over the course of two days, participants engaged in didactic lectures, demonstrations and hands-on activities designed to teach attendees how to cast, rectify, fit and align a sub-ischial check socket (see course agenda in **Appendix AA**). Patient models responded positively to the comfort, range of motion and stability of the sub-ischial socket while prosthetists described the technique as *"straight forward, reproducible."* Our courses were highlighted in the September issue of the Northwestern Research News ("Researchers Showcase Prosthetic Socket Design") and the October issue of The O&P Edge ("Industry Review: NUPOC Launches the NU-FlexSIV Socket"). Feedback from course participants was also included in the manuscript describing our socket technique that was accepted for publication in the journal *Prosthetics and Orthotics International* (**Appendix D**).

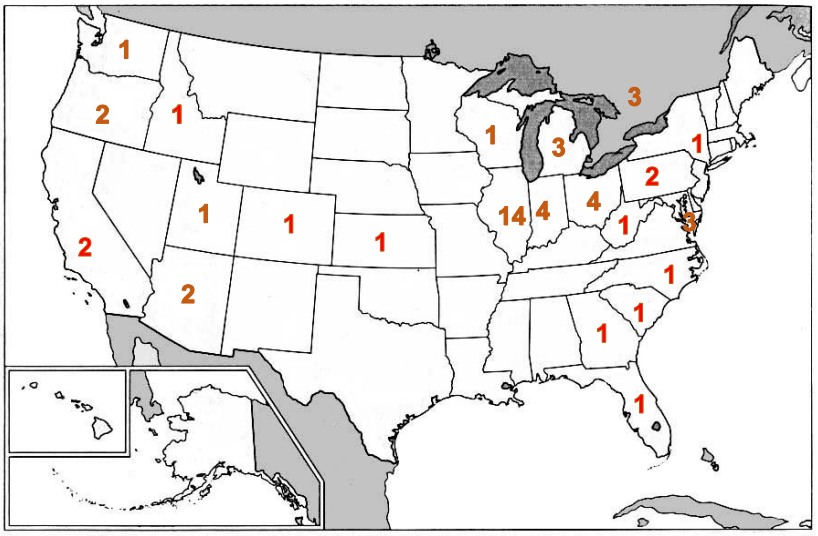
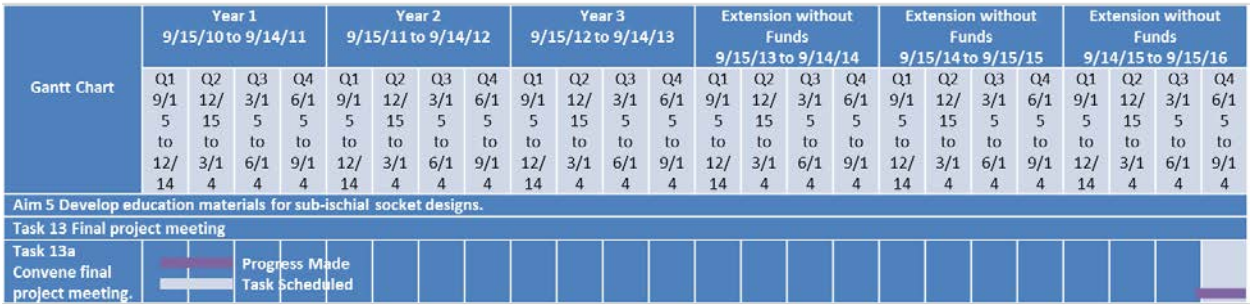


Figure 11 Location of prosthetists (n=52) who participated in our sub-ischial socket courses.

Having the prosthetists participate in the sub-ischial socket course with their own patient and being able to take home the socket and liner was intended to incentivize ongoing implementation of the sub-ischial socket technique in their clinical practice. However, we anticipated that as prosthetists did this, they would encounter additional questions or issues with which they needed help. To efficiently facilitate ongoing learning and troubleshooting for all course participants we have created a private online forum for early adopters of the sub-ischial socket using HipChat.com. The forum is a collaborative platform where early adopters can ask questions, share information about their experiences fabricating and using the socket, and exchange advice and troubleshooting tips with each other and the research team. **Appendix BB** shows a screenshot of the forum used by participants from our five courses. We continue to moderate and support this ongoing educational activity as we believe this will ensure that our dissemination activities gain long-term traction with these early adopters of our sub-ischial socket technique.

Due to additional requests we have taught the sub-ischial socket course for prosthetists at companies such as medi in Bayreuth, Germany (7 prosthetists); Ortos in Brøndby, Denmark (n=11 prosthetists); and Össur Americas in Orlando, FL (n=4 prosthetists). We plan to keep offering and holding courses as long as there is interest, including short interactive overview courses scheduled to be held at the 2017 American Academy of Orthotists and Prosthetists meeting in Chicago, IL, on March 1-4 and a half day course overview to be held at the 2017 Northwest Chapter meeting of the American Academy of Orthotists and Prosthetists in Bellevue, WA, on April 20-22.

Task 13 Final project meeting



Task 13a Convene final project meeting: *This task was completed in Year 6*.

A wrap-up meeting was held with CFI/BAMC PI Jason Wilken, PhD, on August 18, 2016, and at NUPOC on September 6, 2016, with the Chicago based team. These meetings allowed the team to discuss accomplishments and final wrap-up tasks to be completed in preparation for the submission of the final report.

Due to high interest in our new sub-ischial socket technique, three keynote presentations were given on this work during 2016 (**Appendix CC**). A presentation on project accomplishments was also provided at the Clinical and Rehabilitative Medicine Research Program, Joint Program Committee-8 Socket Technology and Related Limb Health In-Progress Review, September 27, 2016, and at the quarterly faculty meeting of the Northwestern University Department of Physical Medicine and Rehabilitation on November 15, 2016.

KEY RESEARCH ACCOMPLISHMENTS

- Developed and taught a socket technique that is straight forward and reproducible when taught to other prosthetists and has been adopted in clinical practice for the benefit of persons with transfemoral amputation who are looking for a more comfortable socket.
- Taught 74 prosthetists from around the world our sub-ischial socket technique, including prosthetists from Walter Reed Army Medical Center, Center for the Intrepid, and some VA facilities.
- Published seven papers and gave more than 40 presentations, including keynotes on this project at three international meetings in 2016.
- Patent issued and additional actions filed for a hybrid vacuum pump.
- Secured additional funding for a clinical trial to more formally assess our sub-ischial socket's comfort and performance (W81XWH-15-1-0708).
- Created a CAD template that can be used in the central fabrication of our sub-ischial socket technique.
- Ryan Caldwell was awarded the 2016 Clinical Creativity Award by the American Academy of Orthotists and Prosthetists for his contribution to development of the sub-ischial socket.
- Trained two engineering Master's students (Brian Robillard and Sean Wood) and a post-doctoral fellow (Seeni Komolafe).

REPORTABLE OUTCOMES

OUTCOMES	APPENDIX
Manuscripts	
Fatone S, Caldwell R (in press) Northwestern University Flexible Sub-Ischial Vacuum Socket for Persons with Transfemoral Amputation: Part 1 Description of Technique. Prosthetics and Orthotics International.	Appendix D
Fatone S, Caldwell R (in press) Northwestern University Flexible Sub-Ischial Vacuum Socket for Persons with Transfemoral Amputation: Part 2 Preliminary Evaluation. Prosthetics and Orthotics International.	Appendix J
Fatone S, Johnson WB, Tran L, Tucker K, Mower C, Caldwell R (in press) Quantification of Rectifications for Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket. Prosthetics and Orthotics International.	Appendix Y
Caldwell R, Fatone S (in press) Technique for Perforating a Prosthetic Liner to Expel Sweat. Journal of Prosthetics and Orthotics.	Appendix K
Major M, Caldwell R, Fatone S (2015) Comparative Effectiveness of Electric Vacuum Pumps for Creating Suspension in Transfemoral Sockets. Journal of Prosthetics and Orthotics, 27(4):149–153.	Appendix P
Major M, Caldwell R, Fatone S (2015) Evaluations of a Hybrid Vacuum Pump to Provide Vacuum-assisted Suspension for Above-knee Prostheses. American Society of Mechanical Engineers, Journal of Medical Devices, 9(4):0445041-445044. PMID: 27462383; PMCID: PMC 4940611.	Appendix T

Komolafe O, Wood S, Caldwell R, Hansen A, Fatone S (2013) Methods for Characterization of Mechanical and Electrical Prosthetic Vacuum Pumps. Journal of Rehabilitation Research and Development, 50(8):1069–78. PMID: 24458892.	Appendix N
Abstracts	
Fatone S, Caldwell R, Major M (submitted) Effect of interface components on residual limb weight-bearing tolerance in the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket. World Congress of the International Society for Prosthetics and Orthotics, May 8-11, 2017, Cape Town, South Africa.	Appendix X
Fatone S, Tran L, Tucker K, Johnson WB, Mowrer C, Caldwell R, (accepted) Quantification of rectifications for the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket. American Academy of Orthotists and Prosthetists, March 1-4, 2017, Chicago, IL.	Appendix S
Major MJ, Caldwell R, Hansen A, Fatone S (accepted) Hybrid vacuum pump for vacuum-assisted suspension in transfemoral prostheses. American Academy of Orthotists and Prosthetists, March 1-4, 2017, Chicago, IL.	Appendix S
Fatone S, Caldwell R (2016) Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation. American Orthotic and Prosthetic Association National Assembly, September 8-11, Boston, MA.	Appendix Z
Fatone S, Caldwell R (2016) Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation. Military Health System Research Symposium (MHSRS), August 15-18, Kissimmee, FL.	Appendix Z
Brown SE, Russell Esposito E, Fatone S, Caldwell R, Wilken J (2016) Effect of socket design and suspension on walking mechanics. 40th Annual Meeting of the American Society of Biomechanics, August 2-5, Raleigh, NC.	Appendix W
Caldwell R, Fatone S (2016) Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation. OTWorld Congress, May 3-6, Leipzig, Germany.	Appendix Z
Fatone S, Caldwell R (2015) Northwestern University Flexible Sub-Ischial Vacuum Socket (NU-FlexSIV). World Congress of the International Society for Prosthetics and Orthotics, June 22-25, 2015, Lyon, France.	Appendix Z
Esposito ER, Fatone S, Wilken J, Caldwell R, Fergason J (2015) Sub-ischial prosthetic sockets improve hip range of motion and performance for individuals with transfemoral amputations. 41st American Academy of Orthotists and Prosthetists Annual Meeting & Scientific Symposium, February 18-21, New Orleans, LA.	Appendix W
Caldwell R, Komolafe O, Fatone S (2014) Clinical outcomes using a new sub-ischial socket with vacuum assisted suspension: the NU-FlexSIV. OTWorld Congress, May 13-16, Leipzig, Germany.	Appendix Z
Robillard B, Komolafe O, Caldwell R, Fatone S (2013) Fabricating prosthetic sockets with rapid prototyping technology. Biomedical Engineering Society (BMES) Annual Meeting, September 25-28, Seattle, WA.	Appendix F
Komolafe O, Caldwell R, Fatone S (2013) An analytic approach to assessing transfemoral socket flexibility. 39th American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium, February 20-23, Orlando, FL.	Appendix C

Fatone S, Howell J, Caldwell R, Komolafe O, Stine R. (2013) Role of socket design, flexibility and suspension in transfemoral sockets during walking (poster). 39th American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium, February 20-23, Orlando, FL.	Appendix I
Komolafe O, Caldwell R, Fatone S (2013) Stress analysis of different rigid frame designs with a flexible transfemoral prosthetic socket. 14th World Congress of the International Society for Prosthetics and Orthotics, February 4-7, Hyderabad, India.	Appendix C
Fatone S, Wood S, Komolafe O, Caldwell R, Chen W, Sun C, Hansen A. (2013) Socket/liner interface volume and vacuum pressure decay in persons with transfemoral amputations. 14th World Congress of the International Society for Prosthetics and Orthotics, February 4-7, Hyderabad, India.	Appendix O
Fatone S, Wood S, Caldwell R, Chen W, Sun C, Hansen A, Komolafe O. (2013) Characterization of mechanical and electrical vacuum pumps for use in vacuum-assisted suspension (poster). 14th World Congress of the International Society for Prosthetics and Orthotics, February 4-7, Hyderabad, India.	Appendix M
Fatone S, Caldwell R, Komolafe O, Tucker K (2013) Sub-ischial sockets with vacuum assisted suspension for persons with transfemoral amputation. Instructional Course, World Congress of the International Society for Prosthetics and Orthotics, February 4-7, Hyderabad, India.	Appendix Z
Komolafe O, Tucker K, Caldwell R, Fatone S (2012) Quantification of transfemoral prosthetic socket fabrication (poster). Military Health System Research Symposium, August 13-16, Fort Lauderdale, FL.	Appendix C
Wood S, Caldwell R, Chen W, Sun C, Hansen A, Komolafe O, Fatone S (2012) Characterization of mechanical and electrical vacuum pumps for use in vacuum-assisted suspension. 38th American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium, March 21-24, Atlanta, GA.	Appendix M
Wood S, Caldwell R, Chen W, Sun C, Hansen A, Fatone S (2012) Socket/liner interface volume and vacuum pressure decay in persons with transfemoral amputations. 38th American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium, March 21-24, Atlanta, GA.	Appendix O
Komolafe O, Caldwell R, Tucker K, Sun C, Chen W, Hansen A, Fatone S (2012) Stress analysis of different rigid frame designs of within a flexible transfemoral prosthetic socket. 38th American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium, March 21-24, Atlanta, GA.	Appendix C
Presentations	
Fatone S (2016) Flexible sub-ischial vacuum socket for transfemoral amputees. Korean Orthopedic and Rehabilitation Engineering Center (KOREC) Workshop, November 7, Incheon, South Korea.	Appendix CC
Fatone S (2016) Flexible sub-ischial vacuum socket for transfemoral amputees. Asian Prosthetic and Orthotic Scientific Meeting (APOSM), November 4-6, Seoul, South Korea.	N/A
Caldwell R, Fatone S (2016) Where does the weight go? Effect of interface components on residual limb weight-bearing tolerance in transfemoral prosthesis users. Midwest Chapter of the American Academy of Orthotists and Prosthetists, November 3-5, Rosemont, IL.	N/A

Fatone S (2016) The Final Frontier: Developments in Transfemoral Sockets. ISPO European Congress on Prosthetics and Orthotics 2016, October 6-8, Rotterdam, The Netherlands.	Appendix CC
Fatone S (2016) The Final Frontier: Developments in Transfemoral Sockets. Invited speaker, NUFSM PM&R/RIC Clinical Research Grand Rounds, July 11, Chicago, IL.	N/A
Brown SE, Russell Esposito E, Ikeda A, Fergason J, Caldwell R, Fatone S, Wilken JM (2016) Effect of socket design and suspension on walking mechanics. George E. Omer Jr. Research and Alumni Lectureship. Brooke Army Medical Center, June 16, San Antonio, TX.	Appendix W
Fatone S, Caldwell R (2016) Socket-related research collaborations at Northwestern University. Scheck Fair, April 8-9, Lombard, IL.	N/A
Caldwell R and Fatone S (2016) Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation (poster). 12th Annual Lewis Landsberg Research Day, April 7, Northwestern University, Chicago, IL.	Appendix Z
Fatone S (2016) Sub-ischial socket with vacuum assisted suspension for persons with transfemoral amputation. Danske Bandagister, April 1-2, Nyborg, Denmark.	Appendix CC
Caldwell R (2016) Symposium "Modern Transfemoral Socket Alternatives and Technologies: The Science behind TFAs." 42nd American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium, March 9-11, Orlando, FL.	N/A
Caldwell R, Fatone S (2016) NU-FlexSIV Socket. NUPOC Biennial Symposium for the German-Speaking Travel Fellows of Initiative '93, February 25, Chicago, IL.	N/A
Fatone S, Caldwell R (2015) An introduction to sub ischial sockets with vacuum assisted suspension. Midwest Chapter of the American Academy of Orthotists and Prosthetists, May 27-29, Rosemont, IL.	N/A
Fergason J (2014) Managing combat amputees, prosthetic experience. UK International Society for Prosthetics and Orthotics Annual Scientific Meeting, Royal College of Physicians, October 3-4, London.	N/A
Fatone S, Caldwell R (2014) Sub-ischial socket with vacuum assisted suspension for persons with transfemoral amputation. Instructional Course, Canadian Association for Prosthetics and Orthotics (CAPO) Annual Conference, August 6-9, Halifax, Nova Scotia, Canada.	N/A
Fatone S, Caldwell R (2014) Sub-ischial socket with vacuum assisted suspension for persons with transfemoral amputation. Instructional Course, 40th American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium, February 26-March 1, Chicago, IL.	Appendix Z
Fatone S (2013) Development of sub-ischial sockets for persons with transfemoral amputation. Invited Speaker, ISPO Norge Seminar on "Lower Limb Socket Design and Rehabilitation", October 22-23, Oslo and Åkershus University College, Norway.	Appendix Z
Fatone S (2013) Evaluation of sub-ischial sockets for persons with transfemoral amputation. Invited Speaker, ISPO Norge Seminar on "Lower Limb Socket Design and Rehabilitation", October 22-23, Oslo and Åkershus University College, Norway.	Appendix Z
Robillard B, Komolafe O, Caldwell R, Fatone S (2013) Fabricating prosthetic sockets with rapid prototyping technology (poster). 3rd Annual Musculoskeletal Research Day, Northwestern University, August 27, Chicago, IL.	Appendix F
Caldwell R (2013) Sub-ischial socket technology: transfemoral vacuum concepts and case studies. 4th Annual medi Scientific Symposium, June 6-9, Mallorca, Spain.	N/A

Komolafe O, Caldwell R, Fatone S (2013) An analytic approach to assessing transfemoral socket flexibility. Midwest Chapter of the American Academy of Orthotists and Prosthetists, May 29-June 1, Lake Geneva, WI.	N/A
Robillard B, Komolafe O, Caldwell R, Fatone S (2013) Design of a process for fabricating prosthetic sockets with rapid prototyping technology (poster). InNUvations Applied Research Day, Northwestern University, May 2, Evanston, IL.	Appendix F
Komolafe OA, Caldwell, R, Fatone S (2013) An analytic approach to assessing transfemoral socket flexibility. Texas Association of Orthotists and Prosthetists Annual Meeting, April 19-20, Dallas, TX.	N/A
Fatone S, Wood S, Caldwell R, Chen W, Sun C, Hansen A, Komolafe O (2013) Characterization of mechanical and electrical vacuum pumps for use in vacuum-assisted suspension (poster). 9th Annual Lewis Landsberg Research Day, Northwestern University, April 4, Chicago, IL.	Appendix M
Robillard B, Komolafe O, Caldwell R, Fatone S (2013) Design of a process for fabricating prosthetic sockets with rapid prototyping technology (poster). 9th Annual Lewis Landsberg Research Day, Northwestern University, April 4, Chicago, IL.	Appendix F
Fatone S (2013) A new socket for persons with above knee amputations. Monthly Veterans Research Forum, Jesse Brown VA Medical Center, March 7, Chicago, IL.	N/A
Komolafe O, Fatone S (2012) Stress analysis of different transfemoral prosthetic socket frame designs. Midwest Chapter of the American Academy of Orthotists and Prosthetists, September 27-29, Lake Geneva, WI.	N/A
Caldwell, R (2012) Sub-ischial socket technology: transfemoral vacuum concepts and case studies. Midwest Chapter of the American Academy of Orthotists and Prosthetists, September 27-29, Lake Geneva, WI.	N/A
Fatone S (2012) Sub-ischial prosthetic socket with vacuum-assisted suspension for persons with transfemoral amputation. Design of Medical Devices Conference, April 10-12, Minneapolis, MN.	N/A
Patents	
Caldwell R, Hansen A, Wood S, Chen W, Radcliffe R, Yngve K, Kuhar B, Nelson AJ, Nickel E. Vacuum Pump Systems for Prosthetic Limbs and Methods of Using the Same. United States Patent 9,066,822. Issued on June 30, 2015.	Appendix R
Caldwell RJ, Major MJ Vacuum Pump Systems for Prosthetic Limbs and Methods of Using the Same. Serial No. 62/214,560. Filed September 4, 2015.	N/A
Theses/Dissertations	
Brian Robillard, (2014) MS degree in Biomedical Engineering, Northwestern University, Evanston, IL. Master's Thesis Title: "Design of a Process for fabricating Prosthetic Sockets with Additive Manufacturing Technology"	Appendix E
Sean Wood, (2011) BS/MS degree in Mechanical Engineering, Northwestern University, Evanston IL. Master's Thesis Title: "Characterization and Design of Vacuum Pumps for Persons with Transfemoral Amputations."	Appendix L
Grants Awarded	
Department of Defense (#W81XWH-15-1-0708) titled**, "**Functional Performance Evaluation of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation"	N/A

Sponsored agreements to hold the NU-FlexSIV Socket Course with: • Medi, gmbh (Bayreuth, Germany), April 29-30, 2016. • Ortos A/S (Brøndy, Denmark), October 12-13, 2016. • Ossur Americas (Orlando, FL), November 18-19, 2016.	N/A
Online Webinar	
Caldwell R, Fatone S (2014) "Subischial Socket with Vacuum-Assisted Suspension for Persons with Transfemoral Amputation". Online webinar hosted by the American Academy of Orthotists and Prosthetists.	N/A
Other Related Publications	
2016 OTWorld Congress presentation on "Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation" spotlighted in The O&P Edge "OTWorld Session Sneak Peeks."	N/A
Fairley M (2016) Expanding Clinical Skills and Knowledge: Rehabilitative Care for Wounded Warriors Meets Unique Challenges. The O&P Edge, February, 15(2):26-36.	N/A
Kahle J and Highsmith JM (2016) The Newest Technology in Transfemoral Socket Interfaces. InMotion, March/April, 26(2):38-43.	N/A
NUPOC Launches the NU-FlexSIV Socket. Industry Review in The O&P Edge, October 2016:10.	N/A
NUPOC Launches the NU-FlexSIV Socket. oandp.com, August 25, 2016.	N/A
Advanced O&P Solutions Facebook Page, September 29 2015.	N/A
Researchers Showcase Prosthetic Socket Design. Northwestern Research News, September, 2015;8(1):11.	N/A
"Study Examines Comparative Effectiveness of Electric Vacuum Suspension Pumps" September 20, 2015. oandp.com	N/A
Gissal J (2014) Scheck & Siress Prosthetist Ryan Caldwell, CP/L, FAAOP, Contributes to NUPOC Research. Scheck It Out, February 24, 2014.	N/A
Murphy C (2013) Socket Technology and Design: the Future of an Evolving Practice. O&P Business News, February 2013.	N/A
World Congress Highlight, Subischial sockets for persons with transfemoral amputation. ISPO ANMS eNews, March 2013.	N/A
Multi-Media Instructional Manual	
Fatone S, Caldwell R (2015) Instructional Manual for NU-FlexSIV Socket. Northwestern University Prosthetics-Orthotics Center, Chicago IL. ©2015 Stefania Fatone and Ryan Caldwell. All rights reserved.	N/A
Awards Received	
Sean Wood received the Mechanical Engineering Undergraduate Innovation and Research Award for hybrid vacuum pump design in June 2011.	N/A
Brian Robillard was awarded 3rd Place at the InNUvations Applied Research Day on May 2013 for the poster "Design of a process for fabricating prosthetic sockets with rapid prototyping technology."	N/A
Ryan Caldwell was awarded the 2016 Clinical Creativity Award by the American Academy of Orthotists and Prosthetists for his contribution to development of the sub-ischial socket.	N/A
Undergraduate Course Work	
ME 398 undergraduate design group report: Bennett Kuhar, AJ Nelson, Regan Radcliffe, Kevin Yngve.	Appendix H

CONCLUSIONS

The socket we have developed, which we have dubbed the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket, was successfully taught to 74 Certified Prosthetists and is slowly gaining implementation in clinical practice. Prosthetists are now able to provide their patients with transfemoral amputation a new, more comfortable, socket option for every-day use. Scope of application would be greater with a passive suction socket version of the technique, which we believe can be accomplished with relatively minor modifications to our current vacuum-based technique and should be explored further.

REFERENCES

Gerschutz, M. J., M. L. Haynes, D. Nixon and J. M. Colvin (2012). "Strength evaluation of prosthetic check sockets, copolymer sockets, and definitive laminated sockets." Journal of Rehabilitation Research and Development 49(3): 405-426.

Komolafe, O., S. Wood, R. Caldwell, A. Hansen and S. Fatone (2013). "Methods for Characterization of Mechanical and Electrical Prosthetic Vacuum Pumps" Journal of Rehabilitation Research and Development 50(8): 1069-1078.

BIBLIOGRAPHY OF ALL PUBLICATIONS AND MEETING ABSTRACTS

See “Reportable Outcomes” for bibliography of all publications and meeting abstracts.

LIST OF PERSONNEL RECEIVING PAY FROM THE RESEARCH EFFORT

(in alphabetical order, payroll only, does not include consultants, subcontractors or human research subjects)

John Brinkmann
Ryan Caldwell
Michael Cavanaugh
Wei Chen
Larissa Conner
Stefania Fatone
Steve Gard
William Brett Johnson
Andrew Hansen
Oluseeni Komolafe
Matthew Major
John Michael
Regan Radcliffe
Brian Robillard
Christopher Robinson
Cheng Sun
Dilip Thaker
Lilly Tran
Kerice Tucker
Sean Wood

APPENDICES

A. Material Testing Protocols.
B. Socket Testing Protocols.
C. Abstracts and Posters Summarizing Task 2.
D. Accepted Manuscript: Prosthetics and Orthotics International, Part 1 Description of Technique.
E. Robillard Master's Thesis.
F. Robillard Posters and Abstracts.
G. WillowWood Socket Evaluation Report.
H. Copyright Registration for Multi-Media Instructional Manual for NU-FlexSIV Socket.
I. AAOP 2013 Poster and Abstract.
J. Accepted Manuscript: Prosthetics and Orthotics International, Part 2 Preliminary Evaluation.
K. Accepted Manuscript: Journal of Prosthetics and Orthotics Technical Note.
L. Wood Master's Thesis.
M. Vacuum Pump Evaluations Abstracts and Posters.
N. Manuscript Published in the Journal of Rehabilitation Research and Development.
O. Interface Volume Abstracts.
P. Manuscript Published in the Journal of Prosthetics and Orthotics.
Q. ME 398 Report.
R. Hybrid Vacuum Pump Patent.
S. Accepted Abstracts AAOP 2017.
T. Manuscript Published in Journal of Medical Devices.
U. Hybrid Pump Tech Alert 2016.
V. Summary of Results from 3 Subjects Tested at CFI/BAMC.
W. CFI/BAMC Abstracts and Posters.
X. Abstract Submitted for ISPO 2017 World Congress.
Y. Accepted Manuscript: Prosthetics and Orthotics International.
Z. Education Material Presented at Conferences and Meetings.
AA. NU-FlexSIV Socket Course Agenda.
BB. Online Forum
CC. 2016 Keynote Presentations

APPENDIX A – MTS TESTING PROTOCOLS

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

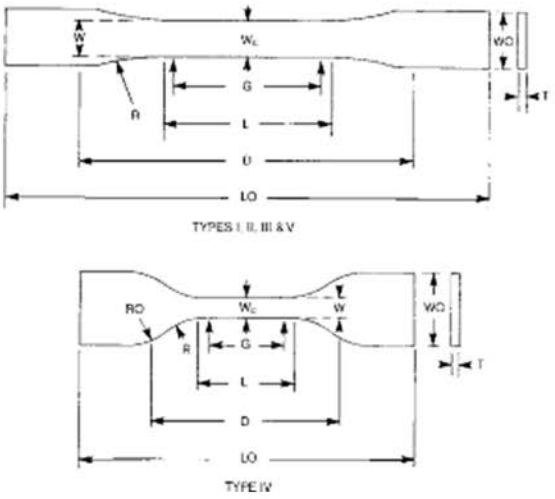
Designations for Recording Atmospheric Conditions:
1. Conditioning: A/B/C (e.g. Condition 96/23/50)
2. Testing: T-B/C (e.g. T-23/50)
   - A – Number in hours of the duration of the conditioning
   - B – Conditioning temperature in degrees Celsius
   - C – Relative humidity

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.

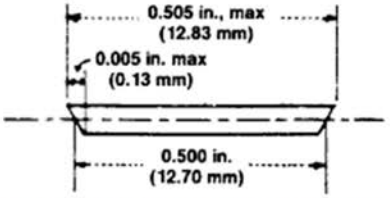


FIG. 1 Tension Test Specimens for Sheet, Plate, and Molded Plastics

APPENDIX B – SOCKET TESTING PROTOCOLS

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 C - ABSTRACTS AND POSTERS SUMMARIZING TASK 2

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:

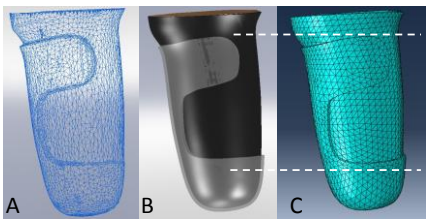


Figure 1: Anterior view of a sub-ischial socket modeled as a simplified two-layered system. A) Scanned 3D vertex data of the socket. B) Solid geometric model. C) FE model is discretized using tetrahedral elements.

Experimental validation:

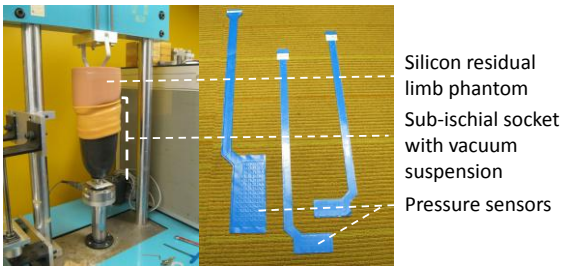


Figure 2: Experimental setup to validate FE model. (Left) Loads are applied to a silicon limb model in a custom made socket. (Right) Sensors are inserted between the liner and socket to estimate the normal stress (interface pressure).

RESULTS

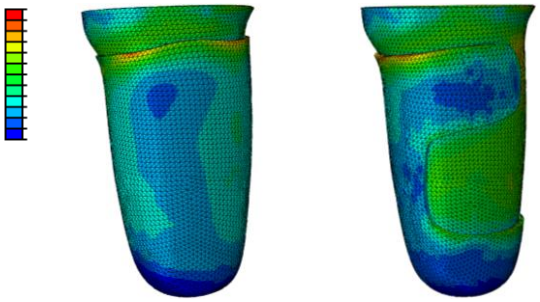


Figure 3: Anterior view of FE analysis stress results: (Left) Totally rigid frame (i.e. no cut-outs) and (Right) a ladle shaped frame with medial strut.

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.

REFERENCES

Radcliffe, CW. Artif Limbs, 2(1), 35-60, 1955.
Ng, P. Rapid Prototyping Journal, 8(1), 53, 2002.
Sanders JE. POI, 33(4), 378 – 390, 2009.
Alley, DA. et al. JRRD, 48(6), 679-696, 2011.

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

MHSRS-12-143

Military Health System Research Symposium, Ft. Lauderdale, August 13-16, 2012

Quantification of Transfemoral Prosthetic Socket Fabrication

Oluseeni Komolafe, PhD, Kerice Tucker, Ryan Caldwell, CP, Stefania Fatone, PhD, BPO(Hons)

Northwestern University Prosthetics-Orthotics Center (NUPOC)

NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE

NORTHWESTERN UNIVERSITY

Background

Prosthetic socket fabrication is typically a specialized process heavily dependent on the craftsmanship skill of the prosthetist. Efficient knowledge dissemination and automation of the fabrication process requires quantification of this process.

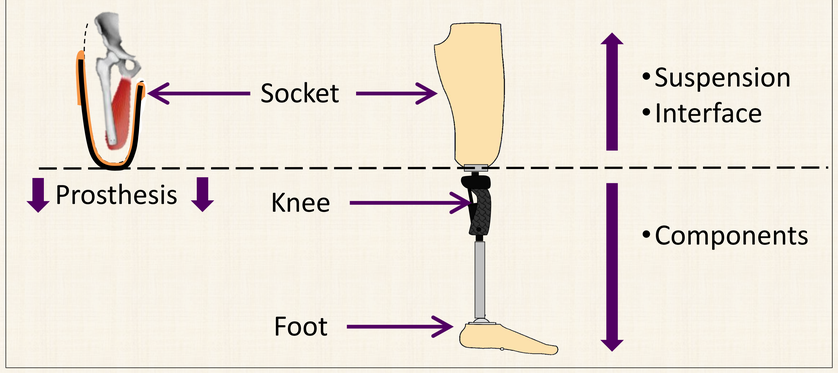
Purpose of the Study

To quantify the specialized process of fabricating sockets for highly active persons with transfemoral amputations (TFA).

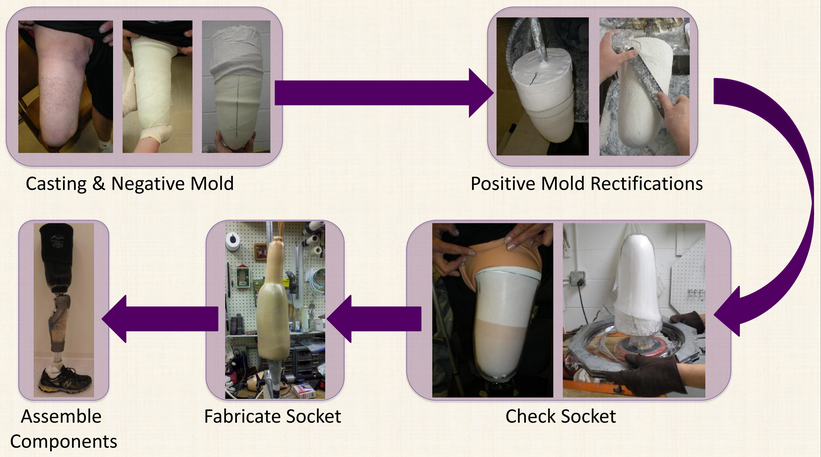
A. Quantify clinical (pre- and post) rectifications
B. Quantify the socket (frame) development process

Introduction

Transfemoral Prosthesis Orientation



Typical Transfemoral Socket Fabrication Process



Observations

- Process is time and resource intensive
- Heavy dependence on clinician experience and craftsmanship
- High variability of quality outcomes
- Process is difficult to quantify and effective instruction typically requires a one-to-one "apprentice" model

Relevance to Military Medical Care

- Prevalence (TFA): General 20% (Owings, 1998); Military 31% (Stansbury, 2008)
- Service persons with amputations
  - Generally young and extensively trained
  - Have high expectations of their function with prostheses

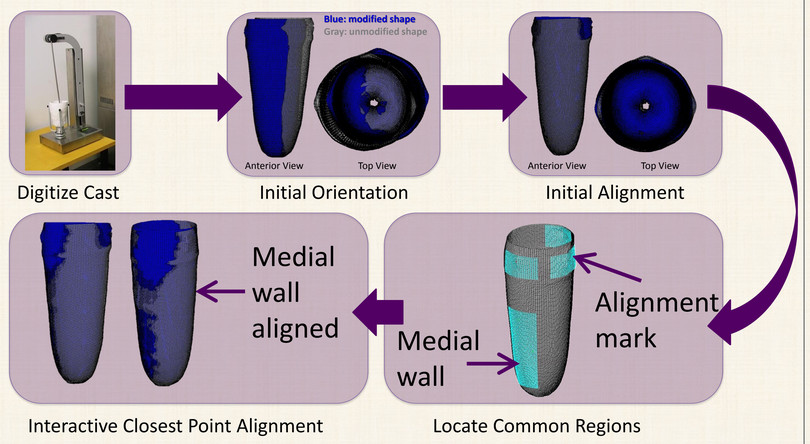
Novel Sub-Ischial Transfemoral Socket



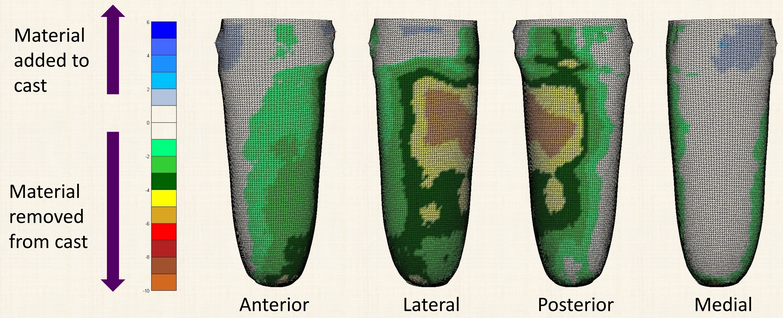
- Vacuum assisted suspension
- Lower sub-ischial proximal trimlines
- 4-Stage lamination procedure
- Optimized frame geometry to increase socket flexibility

Methods/Results

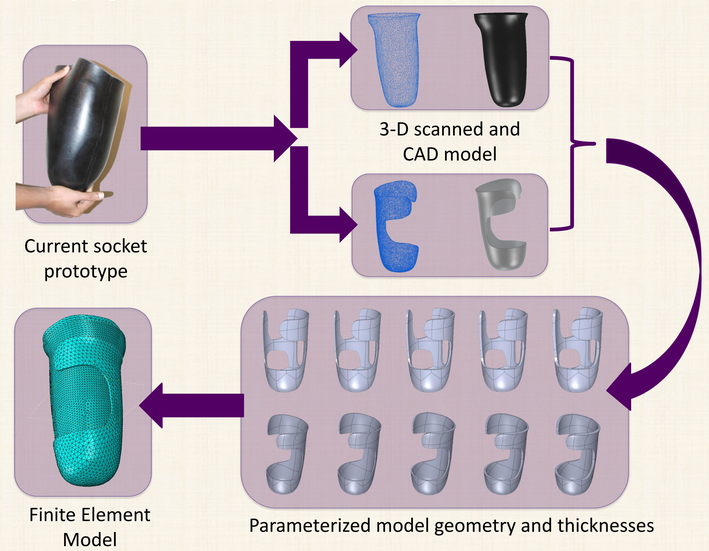
A. Quantifying Clinical (Pre- and Post) Rectifications



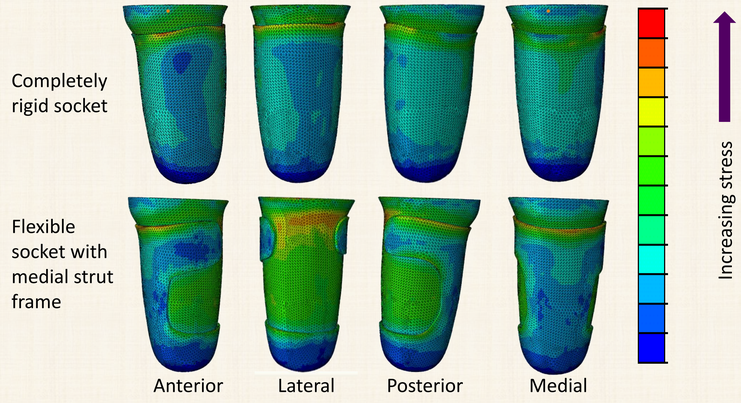
Results: Rectification Patterns



B. Quantifying the Socket (Frame) Development Process



Results: Stress Distribution Patterns



Conclusions

The majority of the rectifications are in the proximal lateral portion of the cast. Preliminary results demonstrate that different frame geometries have different effects on the socket stress distribution.

Implications/Applications

- Technology assisted fabrication (CADCAM, rapid prototyping, etc.)
- Facilitates knowledge dissemination of specialized techniques

Funding Acknowledgement

Award #W81XWH-10-1-0744

The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. The content of this presentation does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred.

AN ANALYTIC APPROACH TO ASSESSING TRANSFEMORAL SOCKET FLEXIBILITY

OA Komolafe, R Caldwell, S Fatone
Northwestern University Chicago IL

INTRODUCTION

Flexible prosthetic socket systems are generally thought to contribute positively to residual limb health and comfort of persons with amputations. Such systems allow greater accommodation of the socket walls to muscular contraction, improving circulation, as well as improving suction suspension due to the clinging nature of the socket walls (Pritham, 1985). Early examples of flexible systems include the use of double wall sockets, with a flexible inner socket joined to an outer rigid socket (McCollough, 1968) and a decade later, fenestrated sockets, with supporting struts formed by windows cut into the rigid socket at medial, posterior and anterior locations (Volkert, 1982). However, despite continued development of such flexible socket systems, there remains a need for formalization of the criteria defining socket flexibility. Existing working definitions, such as that articulated by Ossur Kristinsson as ***"the ability to deform*** [the socket] ***by hand and the resistance to stretching under the loads it will be subject to,"*** although accurate, are not sufficiently nuanced to allow comparison of dissimilar flexible socket designs. The goal of this work was to use an analytic process to provide guidelines for characterization of transfemoral socket flexibility, incorporating the following elements:

(1) Identification of regions of the socket that have distinct functions of clinical significance;
(2) An analytic evaluation of the deformation and internal socket stresses at these functional regions using a computational model.

METHOD

Apparatus: 3-D Creaform Megacapturor digitizer, Abaqus (Dessault Systemes), AMTI forceplates.

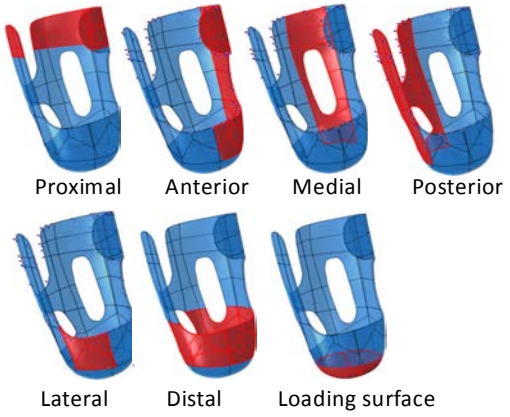


Figure 2: Selected functional regions on the structural frame component of a sub-ischial transfemoral socket.

Procedure: (A) Distinct regions of a transfemoral prosthetic socket with different loading and support functions were identified through discussion with an experienced Certified Prosthetist (Fig 1). (B) The selected regions were evaluated in a previously described finite element model of a sub-ischial prosthetic socket (Komolafe et al. 2012). Evaluation included a global deformation and stress assessment of the selected "functional regions" (from A above).

Data Analysis: The equivalent (von Mises) stress was calculated as an average of all elements in the selected region.

RESULTS

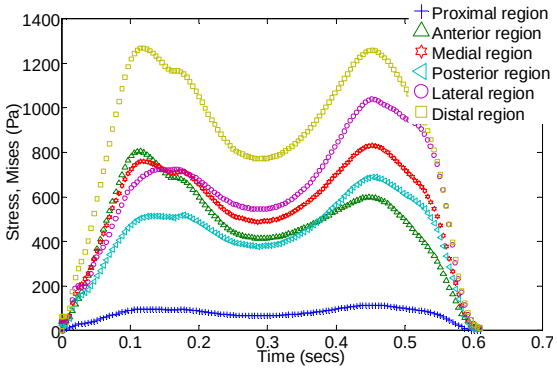


Figure 1: Results from computational model of sub-ischial socket subjected to experimentally measured stance loads.

DISCUSSION/CONCLUSION

Our analysis (Fig 2) confirmed the region of maximum socket flexibility (indicated by minimum stress values) for the duration of the stance phase in this sub-ischial socket design was along the proximal brim. During loading response and early stance, calculations indicated low deformation (and high stresses) along the anterior and medial regions, however, during later stance; low values of deformation were calculated along the posterior and lateral regions of the socket.

CLINICAL APPLICATIONS

Characterization of regional socket flexibility for different loading conditions may benefit the design of activity specific socket systems.

REFERENCES

Pritham CH. Orthot Prosthet, 39:17-32, 1985.
McCollough NC. Artif Limbs, 12:28-35, 1968.
Volkert R. Prosthet Orthot Int, 6:88-92, 1982.
Komolafe et al. 38th AAOP Meeting, Atlanta GA, 2012.

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

American Academy of Orthotists & Prosthetists
39th Academy Annual Meeting and Scientific Symposium
February 20-23, 2013

Title – Stress Analysis of Different Rigid Frame Designs with a Flexible Transfemoral Prosthetic Socket

Introduction

In vacuum suspension sockets, loss of elevated vacuum pressure is often a result of non-conformation of the socket material to changes in residual limb shape and volume. Reduced vacuum suspension may lead to increased relative movements (i.e. pistoning) of the residual limb within the socket. Fabrication of the socket from a flexible material provides a direct solution; however, to be of practical use, minimum socket rigidity for stable load transfer between the residual limb and prosthesis must be maintained. To maximize socket flexibility, we use a fenestrated rigid socket (i.e. frame) embedded within a laminated polyurethane flexible material. We present results of a finite element (FE) analysis evaluating the effect of different frame designs on residual limb/socket interface stress distributions.

Methods

Equipment: Creaform 3-D digitizer, Novel pliance system, Instron mechanical testing system

Procedure: A FE model of a transfemoral sub-ischial prosthetic socket is developed and validated. The model assembly was simplified to the following components: (1) Rigid frame, (2) Flexible polyurethane layer, (3) Silicone liner and (4) Residual limb. A FE analysis was then performed in Abaqus FEA (Dassault Systemes).

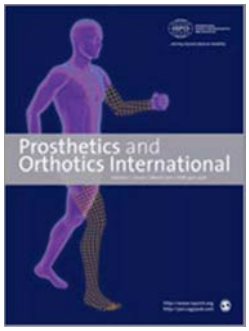
Results

Qualitative results from the FE analysis showed a non-uniform stress distribution that was different for each socket. Preliminary results indicate regions of high normal stresses around the proximal brim and regions of low normal stress values along the lateral wall of the socket. On-going work is focused on quantitative assessment of the effect of different frame geometries of various thicknesses on the stress distribution.

Discussion

The sockets differed only in locations and extent of cut-outs within their rigid frames. Cut-outs in transfemoral sockets have been used to provide release areas that accommodate displaced tissues. The results suggest this approach is useful to optimize flexible sockets capable of conforming to changing residual limbs, while achieving biomechanical load requirements.

APPENDIX D - ACCEPTED MANUSCRIPT: PROSTHETICS AND ORTHOTICS INTERNATIONAL, PART 1 DESCRIPTION OF TECHNIQUE



NORTHWESTERN UNIVERSITY FLEXIBLE SUBISCHIAL VACUUM SOCKET FOR PERSONS WITH TRANSFEMORAL AMPUTATION: PART 1 DESCRIPTION OF TECHNIQUE

Journal:	*Prosthetics & Orthotics International*
Manuscript ID	TPOI-2015-0179.R1
Manuscript Type:	Original Research Reports
Keywords:	prosthetic design < biomechanics, prosthetic interface mechanics < biomechanics, fabriation techniques, gait analysis < gait
Author-supplied Keywords:	artificial limbs, prosthetic socket, transfemoral amputation

SCHOLARONE™
Manuscripts

Abstract

Study Design:

Background: Current transfemoral prosthetic sockets restrict function, lack comfort, and cause residual limb problems. Lower proximal trim lines are an appealing way to address this problem. Development of a more comfortable and possibly functional subischial socket may contribute to improving quality of life of persons with transfemoral amputation.

Objectives: ~~Therefore, the~~The purpose of this study was to (1) describe the design and fabrication of a new subischial socket, (2) describe efforts to teach this technique~~, and (3) illustrate socket use in two subjects. The first two aims are presented in this Part 1 article, while the third aim is presented in the Part 2 article.~~.

Methods: Socket development involved defining: subject and liner selection, residual limb evaluation, casting, positive mold rectification, check socket fitting, definitive socket fabrication, and troubleshooting of socket fit. Three hands-on workshops to teach the socket were piloted and attended by 30 certified prosthetists and their patient models.

Results: Patient models responded positively to the comfort, range of motion and stability of the new socket while prosthetists described the technique as *"straight forward, reproducible."*

Conclusion: To our knowledge, this is the first attempt to create a teachable subischial socket, and, while it appears promising, more definitive evaluation is needed.

Word Count: 197

Clinical Relevance:

Formatted: Font: Not Italic

Introduction

Current transfemoral (TF) prosthetic sockets often restrict function, lack comfort and cause residual limb problems. Although designed to enable load transfer during activities (e.g. walking),[1] sockets interface with soft tissues that are neither accustomed nor well-suited to the high pressure and shear loading that occurs during prosthesis use.[2] Despite high levels of daily use, lack of socket comfort is the most common complaint of prosthesis users.[3-5] Residual limb skin problems (e.g. cysts, calluses, allergic reactions, bacterial or fungal infections) have been reported by 25% to 63% of persons with amputation, negatively influencing ability to perform household tasks, use the prosthesis, function socially, and participate in sports.[3,6-8]

Traditionally there have been two basic designs of TF sockets both of which intentionally interact with the pelvis: the 1950s quadrilateral socket and the 1980s ischial containment socket (ICS).[9] Fundamental to both designs is the proximal "brim" shape: in the quadrilateral socket, a horizontal ischial seat supports the ischial tuberosity,[10,11] whereas in the ICS the ischial tuberosity and ramus are contained within the socket by higher, more rounded proximal trim lines creating more oblique supporting forces. Generally, the ICS is narrower in the mediolateral dimension than the quadrilateral socket, fitting intimately with the ischial ramus and greater trochanter, and purportedly locking onto the pelvis for greater stability.[12-14] Regardless, wearing either socket significantly reduces hip motion compared to motion without a socket.[15,16]

Lowering proximal trim lines of TF sockets is therefore appealing. A recent variant of the ICS, the Marlo Anatomical Socket (MAS), combines greater containment (i.e. contact) of the ischial ramus medially with lower anterior and posterior trim lines. The MAS allows increased hip range of motion compared to either ICS or quadrilateral sockets,[17] providing sufficient control and stability for walking without loss of passive suction suspension.[18-22] Newer vacuum

suspension technology using a pump to maintain subatmospheric socket pressure has spurred additional reductions in proximal trim lines.[23] The resulting sockets have been referred to as "brimless" or subischial since the proximal trim line is located distal to the ischial tuberosity and not intended to interact with the pelvis.[24,25] Subischial sockets with vacuum suspension have the potential to provide not only increased hip range of motion and comfort, but also less pistoning between the socket and limb, and better proprioception and tissue health.[24-32]

The development of a more comfortable and possibly functional subischial socket may improve the quality of life of persons with TF amputation. While early reports suggest subischial sockets are feasible, no one has yet described a teachable subischial socket technique. Therefore, the purpose of this study was to (1) describe the design and fabrication of a new subischial socket, and (2) describe efforts to teach this technique. An accompanying article ~~and (3)~~ illustrates socket use in two subjects~~. The first two aims are presented in this Part 1 article, while the third aim is presented in the Part 2 article~~.[33]

Method

Socket Design/Fabrication

The goal of our subischial socket was to have proximal trim lines that did not impinge on the pelvis; to be flexible so that muscles could move comfortably within the socket as they contract during activity and splay during sitting; and be held securely to the residual limb by compression of an undersized liner and socket as well as vacuum pump suction. An iterative reverse engineering approach was used wherein the technique initially developed in clinical practice by author RC was further developed by defining a clinical decision-making algorithm for socket casting and rectification and quantifying the rectifications.[34-36] Socket development

therefore involved defining: subject and liner selection, residual limb evaluation, casting, positive mold rectification, check socket fitting, definitive socket fabrication, and troubleshooting of socket fit.

Teaching Efforts

A series of three, 2-day, hands-on, continuing education workshops to teach the new socket were piloted. Courses were advertised on the university's website, oandp-l, and by word of mouth. Courses were open to attendance by up to 12 certified prosthetists who were required to register both themselves and a TF amputee patient model. Prosthetists earned 15.5 continuing education credits from either the American Board for Certification in Prosthetics, Orthotics and Pedorthics (ABC) or the Board of Certification (BOC). Participants engaged in lectures, demonstrations and hands-on activities designed to teach how to cast, rectify, fit and align a subischial check socket. Gait was assessed visually by the whole group using split frame coronal and sagittal videos of the patient models walking in their regularly used prosthesis and in the subischial socket. Course feedback was gathered via survey.

Results

Socket Design/Fabrication

Subject and Liner Selection: The Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket is best suited for experienced, compliant amputees with residual limbs that are well-healed with well-regulated volume. Contraindications are primarily linked to use of vacuum suspension (e.g. significant muscle bunching that results in loss of total contact with the liner, deep longitudinal invaginations that trap or allow air between the limb and liner, allergies to silicone liners, and non-compliance with clinical care).

The socket includes a highly compressive, cylindrical, fabric covered silicone liner, a flexible inner socket, a shorter rigid outer socket and a sealing sleeve that creates the seal needed to apply vacuum between liner and inner socket (Figure 1). The liner compresses the limb to create a generic cylindrical shape, stiffening the soft tissues to achieve stability of the socket with respect to the residual limb. While heavily scarred or bulbous residual limbs may require a custom liner to ensure a total contact fit, most limbs can be fit with a transtibial off-the-shelf liner (Figure 2). Transtibial liners are preferred since their non-tapered, cylindrical profile provides relatively high compression of the softer proximal tissues. When measuring for a liner, manufacturer instructions are followed, but a liner one size below the manufacturer's recommendation should be selected. This ensures limb compression and total contact distally. Liners that have worked well to date include the RELAX 3C Cushion Liner (medi gmbh, Bayreuth, Germany) and, when that does not work, the Iceross® Synergy™ Cushion Liner (Össur, Reykjavik, Iceland), both of which incorporate fabric on the exterior surface to wick air from between the liner and socket to maintain suction. If a liner without fabric is used, an air wick (e.g. a nylon sock) must be used. For our socket, we consider a liner to "work well" if it has high compressive stiffness, high shear stiffness, high coefficient of friction, and high thermal conductivity using the definitions provided on the prosthetic liner assistant website (http://www.linerassist.org/).

Residual Limb Evaluation: Before casting, residual limb soft tissue is evaluated with the patient sitting and classified as either soft (i.e., minimal shape change with contraction) or firm (i.e., noticeable shape change with contraction). Liners are donned by inverting and rolling as high on the limb as possible. The excess of the proximal aspect of the liner forms a 50 mm fold that provides additional compression of the softer proximal tissues. To assess the proximal

medio-lateral (ML) width, an ML gauge (i.e., a modified Ritz Stick) is positioned over the folded liner, parallel to the proximal liner edge, which is approximately level with the perineum. The medial arm of the ML gauge is held steady against the proximal edge of the liner approximately at perineal level and the lateral arm moved towards the limb, noting how much compression can be achieved when pushing sub-trochanterically. Limb shape is evaluated by viewing it anteriorly and laterally to determine whether the lateral and posterior edges of the residual limb are parallel to midline of the long axis of the limb or if they angle away from midline of the long axis of the limb proximally (Figure 3). The limb is classified as symmetrical if the angulation away from midline of the long axis of the limb is of similar degree for both the lateral and posterior edges and asymmetrical if one edge angles away from midline of the long axis of the limb more than the other (Figure 3). Once a positive mold of the residual limb is taken and filled with plaster, a goal of mold rectification is to make the posterior and lateral edges nearer to parallel to midline of the long axis of the limb, with amount of plaster removed dependent on symmetrical or asymmetrical classification. Cross-sectional diagrams (Figure 3) show the relative amount of plaster removed posteriorly and laterally based on whether the residual limb is considered symmetrical or asymmetrical.

Casting: The impression is taken with the patient sitting in a chair such that the buttock of the amputated limb is at the edge of the seat and the residual limb is off the chair, flexed 90° and slightly abducted. This allows gravity to pre-modify the limb shape, creating a slight rectus relief, a generous medial flare, and a narrow ML due to posterior soft tissue droop. Slight residual limb abduction allows the impression medially to extend proximally as close to the perineum as possible. The liner clad limb is wrapped in clingfilm with a thin cast sock donned over the top. Fiberglass bandage is wrapped circumferentially without tension over the limb

beginning proximal-laterally and moving medially over the anterior of the limb, overlapping each layer by half the bandage width. The folded proximal edge of the liner should be captured in the impression as it provides the initial, flared proximal socket trim line. The fiberglass over the distal end of the residual limb is contoured to ensure total contact with the liner clad limb. For most limbs, the proximal edge of the mold will be perpendicular to the midline of the residual limb but can be obliquely tapered with a higher lateral trim line for short residual limbs to increase the surface area in contact with the liner. An anterior midline reference is marked and the force required to slide the impression off the residual limb noted: an impression that is difficult to remove from the residual limb requires less reduction of the positive mold than an impression that slides easily.

Positive Mold Rectification: This technique requires only removal of plaster, rather than addition, from the positive mold. Magnitude of plaster removal is graded based on the algorithm shown in Figure 2, with more plaster removed proximally versus distally to ensure the limb seats completely into the socket. Volume reduction, estimated using circumference measures of the positive mold taken in one inch increments along the length of the limb, serves to further compress the soft tissue. The amount of reduction depends on whether the limb soft tissues were classified as soft or firm and removing the impression from the limb was easy or difficult. Using a quadrant system marked on the proximal end of the mold (Figure 4), reductions are concentrated in the lateral and posterior quadrants, with only light smoothing of the medial and anterior quadrants and distal end. The mold rectification map (Figure 4) depicts the target pattern, with plaster removed proximal-laterally to decrease the proximal ML diameter to that which was measured with the ML gauge, and the posterior flattened slightly. Magnitude of plaster removal is based on whether the limb was classified as symmetrical or asymmetrical: if

symmetrical, the same amount of plaster is removed from the posterior and lateral quadrants to achieve target volume reduction; if asymmetrical, more plaster is removed from the quadrant in which the edge of the limb angled more away from midline.

Check Socket Fitting: An initial PETG (polyethylene terephthalate) diagnostic socket is fabricated with a hole drilled into the distal end to expel air when the liner clad residual limb is pushed into the socket. If more than modest resistance is experienced during donning or distal end contact cannot be achieved until vacuum is applied, it is likely that the user will have trouble donning the definitive flexible socket as it has a higher coefficient of friction. Once the socket is donned, the proximal liner is folded over the edge of the socket. A static check fit is conducted to ensure volume reductions are appropriate and total distal end contact achieved. Initially, check socket trim lines may be too high resulting in contact with the ischial ramus or tuberosity. This can be relieved by a combination of trimming and flaring of the socket to gradually lower the trim line until boney contact with the socket no longer occurs. This may be a slow process as it is important to keep as much of the limb within the socket as possible to maximize tissue containment and stiffening, as well as surface area for vacuum suspension.

If initial fit is satisfactory, an attachment plate and barb are adhered to the socket. No specific socket alignment is required other than what is needed for prosthetic knee function. For dynamic fitting, the socket is attached to the prosthetic components, including a vacuum pump (either mechanical or electrical), and donned with the liner folded over the proximal edge of the socket and sealed to the exterior socket wall with a sealing sleeve. While weight bearing with vacuum on, the user should feel a general tightness of the socket without any specific pressure points, especially on the distal end. There should be minimal or no contact with the pelvis during

weight bearing or hip adduction and extension. Note that minor proximal trim line issues may be resolved by transitioning to a flexible inner socket.

Check socket fit is successful if a liner-only fit is achieved; there is only slight resistance seating the limb into the socket upon standing; total contact between the limb and socket is maintained at all times, specifically at the at the distal end, the lateral proximal trim line in standing and the anterior proximal trim line in sitting; there is little or no contact between the socket and pelvis; and there is no excessive flaring of the socket anywhere along the proximal trim line. Rigid check sockets should be used only for short periods to avoid liner breakdown, with a second flexible check socket made for extended wear trials. The flexible check socket is made using Flex EVA (ethyl vinyl acetate, medi gmbh, Bayreuth, Germany) with an outer rigid socket of PETG reinforced with fiberglass (Figure 5). Flex EVA provides sufficient rigidity to support the residual limb axially while maintaining flexibility to reduce edge pressures (i.e., pressure at the proximal socket trim line between the limb and socket as well as the liner and socket) and conform to the residual limb in the seated position. Using blister forming the Flex EVA inner socket can be very thin and light.

Definitive Socket Fabrication: If deemed to fit well, the flexible inner socket used as part of the second check socket can be re-used as part of the definitive socket by replacing the outer rigid PETG socket with a definitive, carbon-fiber laminated version (Figure 1). In the definitive socket, flexible inner socket trim lines are approximately 12 mm distal to the ischial tuberosity and 25 mm distal to the greater trochanter. The height of the rigid outer socket is subject specific but should be at least 75 mm below the proximal trim line of the flexible inner socket, allowing the liner to fold over the proximal trim line of the flexible inner socket and seal with a sleeve that is secured distally by sandwiching between the rigid outer and flexible inner sockets.

Troubleshooting Socket Fit: When distal end contact is not achieved, the proximal trim line should be checked to ensure that it does not contact the pelvis and prevent the limb from seating into the distal end of the socket. Short-term use of padding or gel spots distally in the check socket are permissible to achieve total contact until this issue can be corrected in the next socket iteration. The proximal lateral wall of the socket must remain tightly secure to the residual limb during walking especially at mid-stance as gapping will cause blistering along the proximal lateral trim line over time. If gapping occurs, pad the proximal medial wall of the socket to effectively pull the lateral socket wall tightly into the residual limb. The proximal anterior wall of the socket must remain tightly secure to the residual limb in sitting as gapping will lead to loss of suspension. A small amount of gapping anteriorly may occur with the rigid check socket when sitting: if this gapping is minimal, it will likely resolve when a flexible inner socket material is used, but if gapping is more than minimal, pad the proximal posterior wall of the socket to effectively pull the anterior socket wall tightly into the residual limb.

Teaching Efforts

The three courses were attended collectively by 30 certified prosthetists and their patient models from across North America. For 2/30 sockets a 2nd check socket was made to improve fitting, in one case as a result of switching liner type. Overall, 28/30 patient models were able to walk comfortably in the rigid check socket with little visual change in gait when compared to the patient models' regularly used socket (Figure 6). Course feedback is summarized in Table 2. The participants were generally positive about the quality and value of course content, pre-course planning and communication, and course organization; they indicated that their understanding of subischial socket and vacuum technology improved after taking the course; and most were

confident that they could fabricate the NU-FlexSIV Socket and anticipated using it in their clinical practice.

Discussion

To our knowledge, this is the first attempt to create a teachable subischial socket with the potential to be more comfortable without compromising function. The idea that soft tissue compression can be used to create stability between the residual limb and socket by stiffening the soft tissue and more efficiently transferring force between the underlying skeleton and prosthesis is not new.[45,37] However, the degree to which limbs can be compressed and the socket successfully donned has increased with availability of more compliant socket materials. Most recently, tissue compression and subsequent stiffening has been proposed as the underlying principle for the compression and release socket, which applies three or more localized, longitudinal areas of high compression to the residual limb.[46,38] By contrast, the NU-FlexSIV Socket provides high global compression via an undersized liner and socket and it is believed that tissue stiffness is further enhanced by use of vacuum, which has been reported to increase volume of the residual limb.[25] It may be that the combination of socket/liner compression globally and volume expansion by vacuum, creates better locking of the residual limb within the socket than other forms of suspension.

Some clinicians have expressed concerns regarding the potential for increased fall-related femoral fracture risk while wearing TF sockets with lower trim lines. However, the incidence of post-amputation fall-related fracture is very low (2-3%)[47-50,39-42] and Gailey et al.[51,43] reported that the literature to date does not conclusively support a direct relationship between low bone mineral density and residual limb fractures among people with lower limb amputation.

Additionally, little is known about the circumstances in which fall-related injuries occur in people with lower limb amputation, especially community-dwelling individuals, so it is unclear what effect socket design might have on fracture risk. For inpatients, most falls occur during unassisted transfers[47,49,52,39,41,44]. Gonzalez et al.[47,39] reported that the prosthesis was in use at the time of falling in only 3 of 9 cases studied, while Pauley et al.[49,41] reported that only 3.7% of falls occurred during walking. However, since falls appear to be the leading cause of post-amputation fracture with the femur and hip being the most common site of fracture in both transtibial and TF amputees,[51,43] and since there is a three-fold increase in fall risk for persons with TF amputation[49,41] it would be prudent for future research to assess the relationship between any socket design and fall-related fracture risk in community-dwelling individuals with TF amputation.

Survey feedback from our courses was largely positive. Additionally, patient models who participated in pilot courses responded positively to the comfort, range of motion and stability of the socket while prosthetists described the technique as *"straight forward, reproducible."* Group review of the split screen videos confirmed that gait was comparable in the NU-FlexSIV Socket to the regularly used sockets, consistent with more formal evaluation of two subjects. Initial courses were 2-days long and involved fitting only an initial rigid check socket. Participants suggested that future courses should include fitting of a second flexible check socket to more fully grasp how transition to a flexible socket would resolve minor fitting issues and further improve comfort.

Having prosthetists participate in the course with their own patient and being able to take home the rigid check socket and liner were intended to incentivize implementation of the technique in clinical practice. However, it was anticipated that prosthetists would encounter

additional questions or issues. To facilitate course participants' ongoing learning and troubleshooting, a post-course online forum was created using a free, invitation-only, instant messaging application (hipchat.com). The forum was intended as a collaborative platform where early adopters of the NU-FlexSIV Socket could share information/questions regarding their experiences and exchange advice and troubleshooting tips with each other and the course instructors. It is believed this type of support will help the NU-FlexSIV Socket gain long-term traction with these early adopters.

Given the preliminary nature of the research efforts to date, we have been conservative in suggesting that the NU-FlexSIV Socket is best suited for experienced, compliant amputees with residual limbs that are well-healed with well-regulated volume. However, during 10 years of clinical experience with this socket, author RC has successfully fit more complex limbs with open wounds, scarring, invaginations, heterotrophic ossification, bone spurs, and skin grafts, suggesting that with experience, broader application may be possible. Overall, this preliminary work describes a subischial socket technique that appears to be teachable to prosthetists.

Word Count: ~~4487~~ 3590 words

Acknowledgements

The authors acknowledge the support and contribution of Northwestern University Prosthetics-Orthotics Center (NUPOC) faculty, staff, and students in holding the NU-FlexSIV Socket courses. We also acknowledge the support of Össur and medi in donating liners for patient models who participated in the NU-FlexSIV Socket courses. The authors acknowledge the contribution of Brian Robillard, Wei Chen, Steven Gard, RJ Garrick, Andrew Hansen, Brett

Johnson, Oluseeni Komolafe, Matthew Major, Joshua Rollock, Brian Ruhe, Cheng Sun, Lilly Tran, Kerice Tucker, and Sean Wood to various aspects of this project.

Declaration of Conflicting Interests

The authors declare that there is no conflict of interest.

References

1. Mak AF, Zhang M, Boone DA. State-of-the-art research in lower-limb prosthetic biomechanics-socket interface: a review. *Journal of Rehabilitation Research and Development* 2001;38:161-174.
2. Mak AFT, Zhang M, Tam EWC. Biomechanics of pressure ulcer in body tissues interacting with external forces during locomotion. *Annual Review of Biomedical Engineering* 2010;12:29-53.
3. Dillingham TR, Pezzin LE, MacKenzie EJ, Burgess AR. Use and satisfaction with prosthetic devices among persons with trauma-related amputations: a long-term outcome study. *American Journal of Physical Medicine and Rehabilitation* 2001;80:563-571.
4. Pezzin LE, Dillingham TR, MacKenzie EJ, Ephraim P, Rossbach P. Use and satisfaction with prosthetic limb devices and related services. *Archives of Physical Medicine and Rehabilitation* 2004;85:723-729.
5. Berke GM, Fergason J, Milani JR, Hattingh J, McDowell M, Nguyen V, Reiber GE. Comparison of satisfaction with current prosthetic care in veterans and servicemembers from Vietnam and OIF/OEF conflicts with major traumatic limb loss. *Journal of Rehabilitation Research and Development* 2010;47:361-371.
6. Dudek NL, Marks MB, Marshall SC, Chardon JP. Dermatologic conditions associated with use of a lower-extremity prosthesis. *Archives of Physical Medicine and Rehabilitation* 2005;86:659-663.
7. Meulenbelt HE, Geertzen JH, Jonkman MF, Dijkstra PU. Skin problems of the stump in lower limb amputees: 1. A clinical study. *Acta Dermato-Venereologica* 2011;91:173-177.
8. Meulenbelt HE, Geertzen JH, Jonkman MF, Dijkstra PU. Skin problems of the stump in lower-limb amputees: 2. Influence on functioning in daily life. *Acta Dermato-Venereologica* 2011;91:178-182.
9. Schuch CM, Pritham CH. Current transfemoral sockets. *Clinical Orthopaedics and Related Research* 1999;48-54.
10. Foort J. Socket design for the above-knee amputee. *Prosthetics and Orthotics International* 1979;3:73-81.
11. Radcliffe C. Functional considerations in the fitting of above-knee prostheses. *Artificial Limbs* 1955;2:35-60.
12. Sabolich J. Contoured adducted trochanteric-controlled alignment method (CAT-CAM): Introduction and basic principles. *Clinical Prosthetics and Orthotics* 1985;9:15-26.
13. Hoyt C, Littig D, et al. The Ischial Containment Above-Knee Prosthesis. UCLA Prosthetics Education and Research Program, Los Angeles, CA. 1987.
14. Pritham CH. Biomechanics and shape of the above-knee socket considered in light of the ischial containment concept. *Prosthetics and Orthotics International* 1990;14:9-21.
15. Hagberg K, Haggstrom E, Uden M, Branemark R. Socket versus bone-anchored trans-femoral prostheses: hip range of motion and sitting comfort. *Prosthetics and Orthotics International* 2005;29:153-163.
16. Tranberg R, Zugner R, Karrholm J. Improvements in hip and pelvic motion for patients with osseointegrated trans-femoral prostheses. *Gait and Posture* 2011;33:165-168.
17. Klotz R, Colobert B, Botino M, Permentiers I. Influence of different types of sockets on the range of motion of the hip joint by the transfemoral amputee. *Annals of Physical Rehabilitation and Medicine* 2011;54:399-410.

18. Pike A. A new concept in above-knee socket design. *The O&P Edge* November, 2002.
19. Ortiz Vazquez del Mercado M. Evolution of ischial containment socket. Paper presented at the American Academy of Orthotists and Prosthetists, San Diego, CA, March 19-22, 2003.
20. Fairley M. M.A.S. Socket: A transfemoral revolution. *The O&P Edge* June, 2004.
21. Fatone S, Dillon M, Stine R, Tillges R. Coronal plane socket stability during gait in persons with unilateral transfemoral amputation: pilot study. *Journal of Rehabilitation Research and Development* 2015;51:1217-1228.
22. Traballesi M, Delussu AS, Averna T, Pellegrini R, Paradisi F, Brunelli S. Energy cost of walking in transfemoral amputees: Comparison between Marlo Anatomical Socket and Ischial Containment Socket. *Gait and Posture* 2011;34:270-274.
23. Fairley M. 'Hanging Tight': Elevated Vacuum Suspension Systems Step Forward. *O&P Edge* Mar, 2008.
24. Kahle JT, Highsmith MJ. Transfemoral interfaces with vacuum assisted suspension comparison of gait, balance, and subjective analysis: Ischial Containment versus brimless. *Gait and Posture* 2014;40:315-320.
25. Kahle JT, Orriola JJ, Johnston W, Highsmith MJ. The effects of vacuum-assisted suspension on residual limb physiology, wound healing, and function: A systematic review. *Technology and Innovation* 2014;15:333-341.
26. Arndt B, Caldwell R, Fatone S. Use of a partial foot prosthesis with vacuum-assisted suspension: A case study. *Journal of Prosthetics and Orthotics* 2011;23:82-88.
27. Street G. Vacuum suspension and its effects on the limb. *Orthopadie Technik* Apr, 2006.
28. Beil TL, Street GM, Covey SJ. Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets. *Journal of Rehabilitation Research and Development* 2002;39:693-700.
29. Board WJ, Street GM, Caspers C. A comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthetics and Orthotics International* 2001;25:202-209.
30. Hoskins R, Sutton E, Kinor D, Schaeffer J, Fatone S. Using vacuum assisted suspension to manage limb wounds in persons with transtibial amputation: A case series. *Prosthetics and Orthotics International* 2014;38:68-74.
31. Klute GK, Berge JS, Biggs W, Pongnumkul S, Popovic Z, Curless B. Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: Effect on fit, activity, and limb volume. *Archives of Physical Medicine and Rehabilitation* 2011;92:1570-1575.
32. Traballesi M, Delussu AS, Fusco A, Iosa M, Averna T, Pellegrini R, Brunelli S. Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study. *European Journal of Physical Rehabilitation Medicine* 2012;48:613-623.
33. Fatone S, Caldwell R. Northwestern University Flexible Subischial Vacuum Socket for Persons with Transfemoral Amputation: ~~Part 2~~ Preliminary Evaluation. *Prosthetics Orthotics International*. In press.
~~33. Dillon M. Insights into socket geometry and coronal plane alignment. Paper presented at the 12th World Congress of the International Society for Prosthetics and Orthotics, Vancouver, Canada, July 29-August 3, 2007.~~
34. Sidles J, Boone DH, JS, Burgess E. Rectification maps: A new method of describing residual limb and socket shapes. *Journal of Prosthetics and Orthotics* 1989;1:149-153.

35. Zachariah SG, Sorenson E, Sanders JE. A method for aligning trans-tibial residual limb shapes so as to identify regions of shape change. *IEEE Transactions on Neural Systems and Rehabilitation Engineering* 2005;13:551-557.

36. Sanders J, Severance M. Assessment technique for computer-aided manufactured sockets. *Journal of Rehabilitation Research and Development* 2011;48:763-774.

~~37. Kadaba MP, Ramakrishnan HK, Wooten ME, Gainey J, Gorton G, Cochran GV. Repeatability of kinematic, kinetic and electromyographic data in normal adult gait. *Journal of Orthopaedic Research* 1989;7:849-860.~~

~~38. Winter D. *Biomechanics and Motor Control of Human Movement*. 2nd ed. New York: John Wiley and Sons, Inc.; 1990.~~

~~39. Hanspal RS, Fisher K, Nieveen R. Prosthetic socket fit comfort score. *Disability and Rehabilitation* 2003;25:1278-1280.~~

~~40. Whitney SL, Wrisley DM, Marchetti GF, Gee MA, Redfern MS, Furman JM. Clinical measurement of sit-to-stand performance in people with balance disorders: Validity of data for the Five-Times-Sit-to-Stand Test. *Physical Therapy* 2005;85:1034-1045.~~

~~41. Lusardi M, Pellecchia G, Schulman M. Functional performance in community living older adults. *Journal of Geriatric Physical Therapy* 2003;26:14-22.~~

~~42. Dite W, Temple VA. A clinical test of stepping and change of direction to identify multiple falling older adults. *Archives of Physical Medicine and Rehabilitation* 2002;83:1566-1571.~~

~~43. Gailey RS, Gaunaurd IA, Raya MA, Roach KE, Linberg AA, Campbell SM, Jayne DM, Scoville C. Development and reliability testing of the Comprehensive High-Level Activity Mobility Predictor (CHAMP) in male servicemembers with traumatic lower-limb loss. *Journal of Rehabilitation Research and Development* 2013;50:905-918.~~

~~44. Gailey RS, Scoville C, Gaunaurd IA, Raya MA, Linberg AA, Stoneman PD, Campbell SM, Roach KE. Construct validity of Comprehensive High-Level Activity Mobility Predictor (CHAMP) for male servicemembers with traumatic lower-limb loss. *Journal of Rehabilitation Research and Development* 2013;50:919-930.~~

3745. Redhead R. Total surface bearing self suspending above-knee sockets. *Prosthetics and Orthotics International* 1979;3:126-136.

3846. Alley R, Williams T, Albuquerque M, Altobelli D. Prosthetic sockets stabilized by alternating areas of tissue compression and release. *Journal of Rehabilitation Research and Development* 2011;48:679-696.

3947. Gonzalez E, Matthews M. Femoral fractures in patients with lower extremity amputation. *Archives of Physical and Medical Rehabilitation* 1980;61:276-280.

4048. Denton J, McClelland S. Stump fractures in lower extremity amputees. *Journal of Trauma* 1985;25:1074-1078.

4149. Pauley T, Devlin M, Heslin K. Falls sustained during inpatient rehabilitation after lower limb amputation: Prevalence and predictors. *American Journal of Physical Medicine and Rehabilitation* 2006;85:521-532.

4250. Gooday H, Hunter J. Preventing falls and stump injuries in lower limb amputees during inpatient rehabilitation: completion of the audit cycle. *Clinical Rehabilitation* 2004;18:379-390.

4351. Gailey RS, Allen K, Castles J, Kucharik J, Roeder M. Review of secondary physical conditions associated with lower-limb amputation and long-term prosthesis use. *Journal of Rehabilitation Research and Development* 2008;45:15-30.

4452. Dyer D, Bouman B, Davey M, Ismond K. An intervention program to reduce falls for adult in-patients following major lower-limb amputation. *Healthcare Quarterly* 2008;11:117-121.

~~53. Kahle JT, Highsmith MJ. Transfemoral sockets with vacuum assisted suspension comparison of hip kinematics, socket position, contact pressure, and preference: Ischial Containment versus brimless. *Journal of Rehabilitation Research and Development* 2013;50:1241-1252.~~

~~54. Highsmith MJ, Schulz BW, Hart-Hughes S, Latlief GA, Phillips SL. Differences in the spatiotemporal parameters of transtibial and transfemoral amputee gait. *Journal of Prosthetics and Orthotics* 2010;22:26-30.~~

~~55. Esposito E, Fatone S, Wilken J, Caldwell R, Fergason J. Sub-ischial prosthetic sockets improve hip range of motion and performance for individuals with transfemoral amputations. Paper presented at the 41st American Academy of Orthotists and Prosthetists Annual Meeting & Scientific Symposium, New Orleans, Louisiana, February 18-21, 2015.~~

4556. Fatone S, Caldwell R. *Instructional Manual for NU-FlexSIV Socket.* Northwestern University Prosthetics-Orthotics Center, Chicago IL. 2015.

~~57. Wilken JM, Darter BJ, Goffar SL, Ellwein JC, Snell RM, Tomalis EA, Shaffer SW. Physical performance assessment in military service members. *Journal of the American Academy of Orthopedic Surgeons* 2012;20 Suppl 1:S42-47.~~

Figure Captions

Figure 1 Left: NU-FlexSIV Socket on limb showing sealing sleeve. Right: Definitive version of the NU-FlexSIV Socket fabricated by Advanced O&P Solutions (Hickory Hills IL). Photo courtesy of Michael Angelico.

Figure 2 Clinical algorithm for NU-FlexSIV Socket. Regarding liner selection, almost all transfemoral limb shapes can be made more cylindrical by fitting an off-the-shelf transtibial liner; custom liners are only required when the limb is heavily scarred or bulbous. The manner in which the liner is customized should ensure that the liner clad limb shape is cylindrical. "Gradated reductions" refer to the reduction of circumferences more proximally than distally. For example, for 6-4% reductions, the circumferences in the proximal third of the limb are reduced by 6%, the circumferences in the middle third of the limb are reduced by 5%, and the circumferences in the lower third of the limb are reduced by 4%. Reprinted with permission of the authors.[~~56~~45]

Figure 3 Example of a symmetrical residual limb shape wherein the area of the residual limb bounded by the reference line and posterior or lateral edges of the limb are approximately the same: this area represents the material to be removed during rectification of the positive model. Cross-sectional diagrams show the plaster removed based on whether the residual limb is considered symmetrical or asymmetrical.

Figure 4 Quadrant system and exemplar mold rectification map for NU-FlexSIV Socket. M: medial; P: posterior; L: lateral; A: anterior. Color coding on the rectification map indicates depth of plaster removed.

Figure 5 Flexible check socket fabrication: (a) flexible inner socket with Velcro and sealing ring to hold rigid PETG (polyethylene terephthalate) outer socket in place (distal port hole for air not

shown); (b) outer socket sprayed with alcohol to allow it to be pushed onto inner socket; (c) lateral and (d) anterior view of flexible inner socket inserted into outer socket and reinforced with fiberglass tape, black line indicates top of rigid socket; (e) donned socket showing attachment of barb to distal end of outer socket (vacuum is drawn from between liner and inner socket through port hole and between inner and outer socket via barb); and (f) mid-stance of gait with flexible check socket.

Figure 6 Still frame from one of the split-screen videos used to visually assess gait in both sockets during the courses.

Table 1 Prosthetist Feedback on NU-FlexSIV Socket Courses

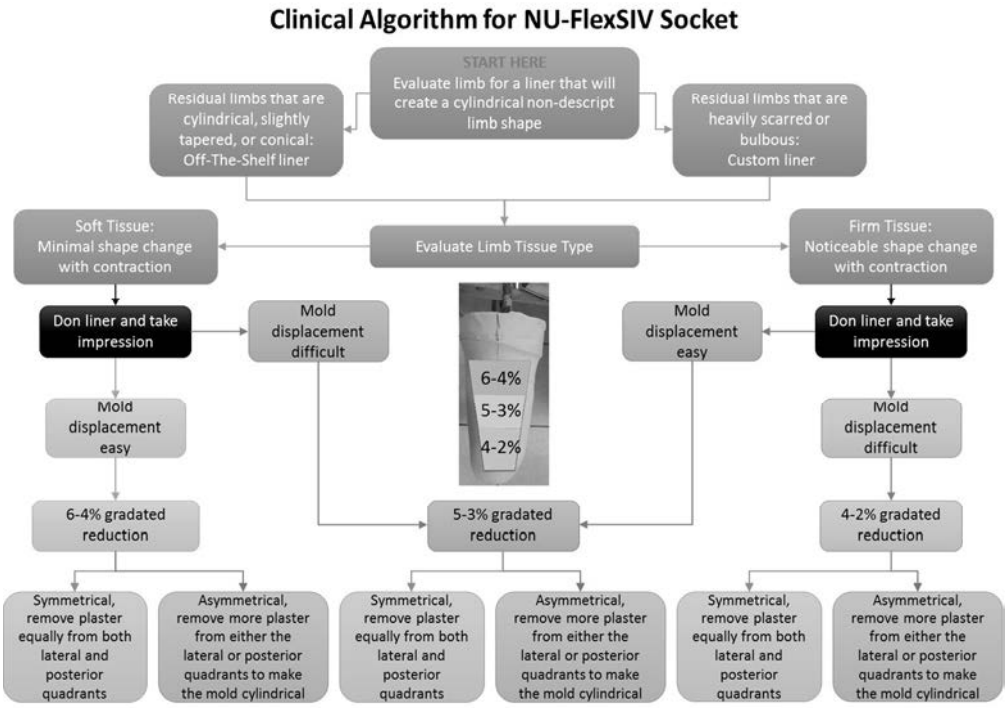
	Course 1 (n=6)					Course 2 (n=12)					Course 3 (n=12)				
Instruction	*With 5 being the best and 1 being the worst, please indicate rank of content, quality, and value on the scale provided.*														
Scale	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
Content	0	0	0	0	100	0	0	0	17	83	0	0	0	0	100
Quality of presentation	0	0	0	0	100	0	0	0	25	75	0	0	0	10	90
Value of hands-on casting	0	0	0	0	100	0	8	0	8	84	0	0	0	0	100
Value of hands-on rectification	0	0	0	0	100	0	0	0	25	75	0	0	0	10	90
Value of hands-on check socket fitting	0	0	0	0	100	0	0	0	17	83	0	0	0	10	90
Pre-course understanding of subischial socket and vacuum technology	0	50	25	0	25	8	8	25	50	0	0	10	40	10	40
Post-course understanding of subischial socket and vacuum technology	0	0	0	75	25	0	0	8	25	67	0	0	0	0	100
Post-course ability to fabricate NU-FlexSIV Socket	0	0	0	75	25	0	8	17	25	50	0	10	0	10	80
Anticipated clinical use	0	0	0	0	100	0	0	17	8	75	0	10	10	30	50
Pre-course planning	0	0	0	25	75	0	0	0	17	83	0	0	0	0	100
Pre-course communications	0	0	0	0	100	0	0	0	8	92	0	0	0	10	90
On-site organization	0	0	0	10	90	0	0	0	0	100	0	0	0	10	90

Note: Responses indicated as % of participants who selected that number on the scale. Not all responses sum to 100% due to unanswered items.



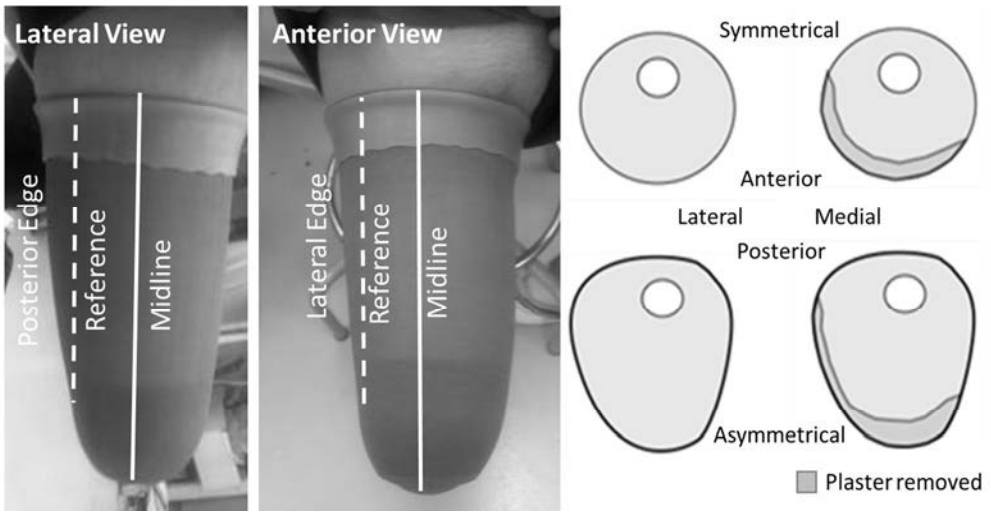
Left: NU-FlexSIV Socket on limb showing sealing sleeve. Right: Definitive version of the NU-FlexSIV Socket fabricated by Advanced O&P Solutions (Hickory Hills IL). Photo courtesy of Michael Angelico.

144x95mm (300 x 300 DPI)



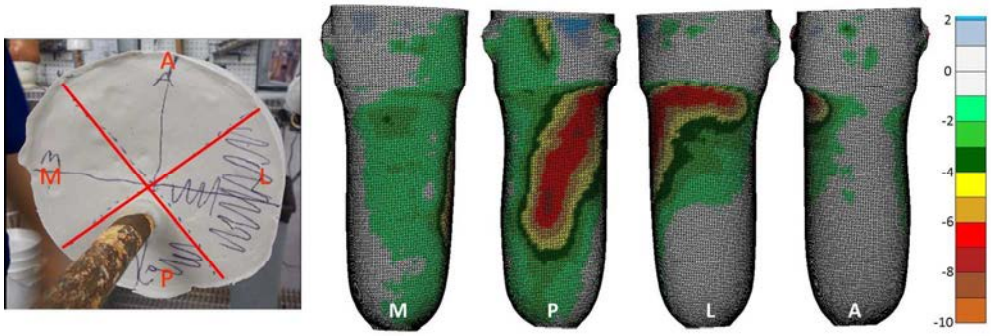
Clinical algorithm for NU-FlexSIV Socket. Regarding liner selection, almost all transfemoral limb shapes can be made more cylindrical by fitting an off-the-shelf transtibial liner; custom liners are only required when the limb is heavily scarred or bulbous. The manner in which the liner is customized should ensure that the liner clad limb shape is cylindrical. "Gradated reductions" refer to the reduction of circumferences more proximally than distally. For example, for 6-4% reductions, the circumferences in the proximal third of the limb are reduced by 6%, the circumferences in the middle third of the limb are reduced by 5%, and the circumferences in the lower third of the limb are reduced by 4%. Reprinted with permission of the authors.[56]

124x89mm (300 x 300 DPI)



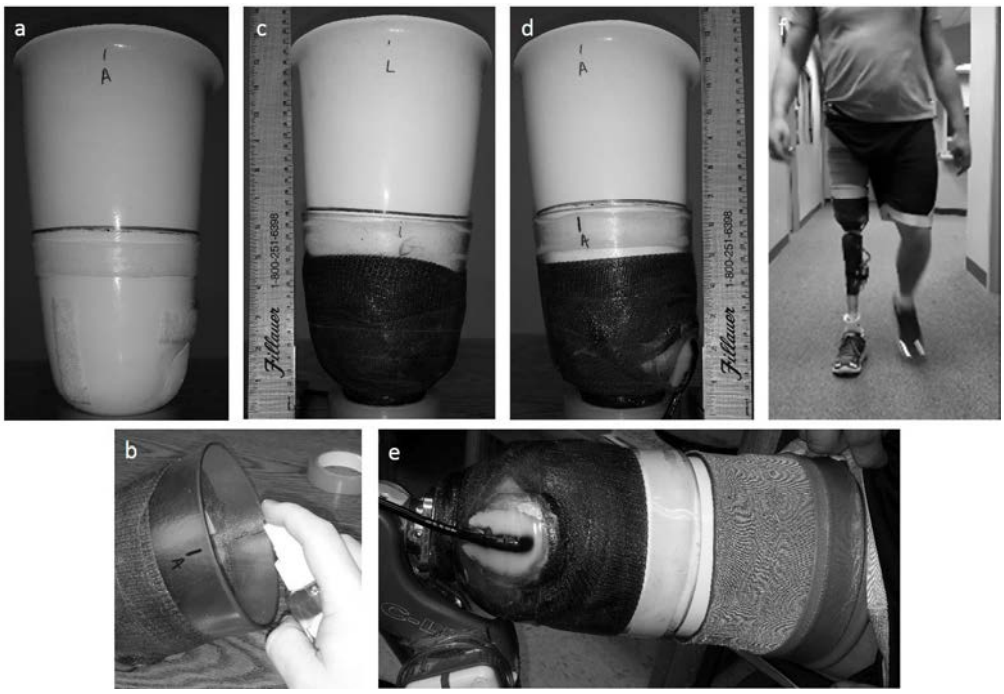
Example of a symmetrical residual limb shape wherein the area of the residual limb bounded by the reference line and posterior or lateral edges of the limb are approximately the same: this area represents the material to be removed during rectification of the positive model. Cross-sectional diagrams show the plaster removed based on whether the residual limb is considered symmetrical or asymmetrical.

107x54mm (300 x 300 DPI)



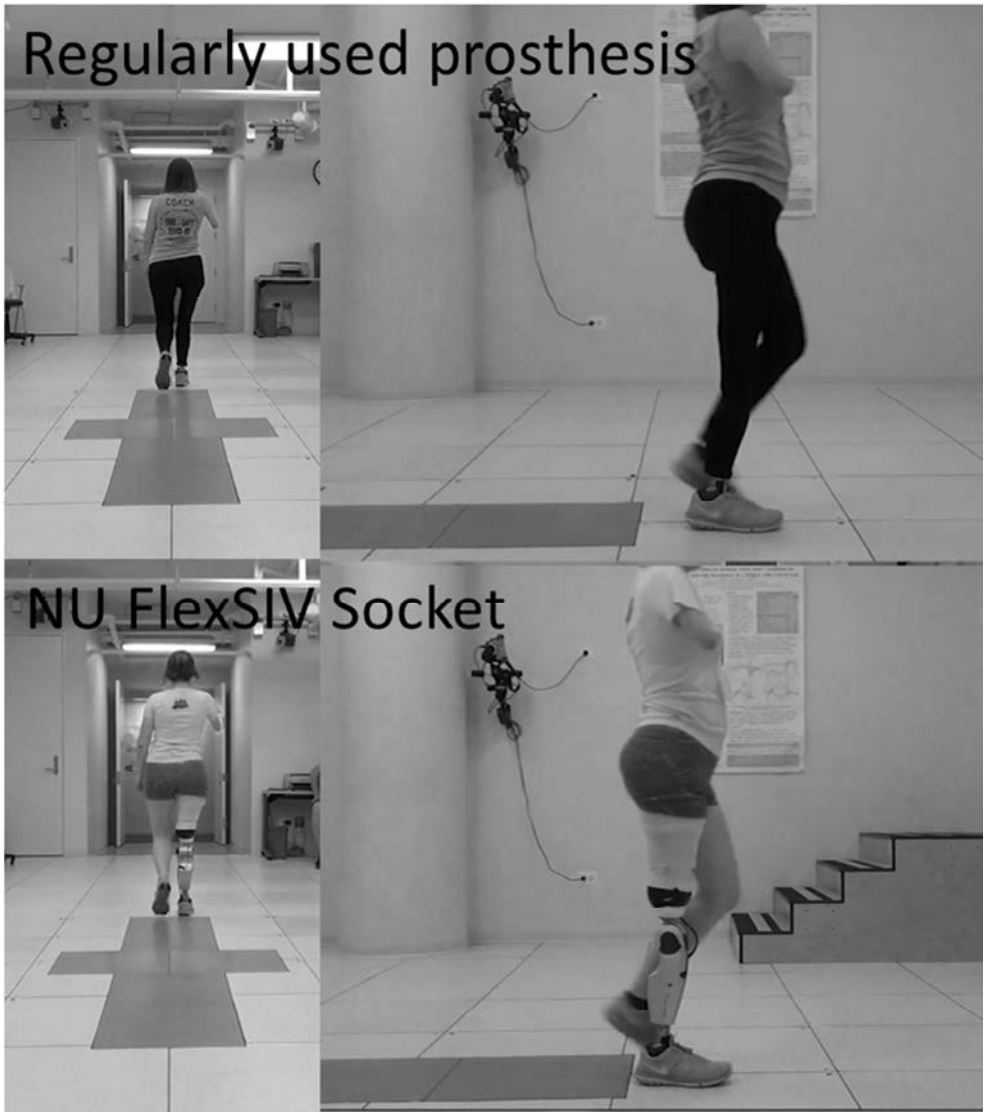
Quadrant system and exemplar mold rectification map for NU-FlexSIV Socket. M: medial; P: posterior; L: lateral; A: anterior. Color coding on the rectification map indicates depth of plaster removed.

146x51mm (300 x 300 DPI)



Flexible check socket fabrication: (a) flexible inner socket with Velcro and sealing ring to hold rigid PETG (polyethylene terephthalate) outer socket in place (distal port hole for air not shown); (b) outer socket sprayed with alcohol to allow it to be pushed onto inner socket; (c) lateral and (d) anterior view of flexible inner socket inserted into outer socket and reinforced with fiberglass tape, black line indicates top of rigid socket; (e) donned socket showing attachment of barb to distal end of outer socket (vacuum is drawn from between liner and inner socket through port hole and between inner and outer socket via barb); and (f) mid-stance of gait with flexible check socket.

127x87mm (300 x 300 DPI)



75x83mm (300 x 300 DPI)

APPENDIX E – ROBILLARD MASTER'S THESIS

NORTHWESTERN UNIVERSITY

Design of a Process for Fabricating Prosthetic Sockets with Additive Manufacturing Technology

A THESIS

SUBMITTED TO THE GRADUATE SCHOOL

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

for the degree

MASTER OF SCIENCE

Field of Biomedical Engineering

By

Brian Joseph Robillard

EVANSTON, ILLINOIS

March 2014

ABSTRACT

Design of a Process for Fabricating Prosthetic Sockets with Additive Manufacturing Technology

Brian Joseph Robillard

The conventional process used in prosthetic socket fabrication is a time intensive, manual technique that depends on the craftsmanship of highly skilled prosthetists and does not allow for precise control of the resulting socket's dimension parameters. The ability to control dimension parameters would allow for gradated transitions between rigid and flexible regions of the socket, preventing stress concentrations at transition points and enhancing socket comfort. Additive manufacturing (AM) technology is the process of building a part by adding material in successive layers. The development of AM technology as a reliable fabrication technique presents an opportunity to create a socket with precise dimension parameters. The purpose of this thesis project was to utilize AM technology to fabricate transfemoral sub-ischial prosthetic sockets with rigid frames encapsulated by flexible layers while exploring socket designs that gradate the transitions from rigid to flexible materials.

A fabrication technique was developed that used a Stratasys Fused Deposition Modeler to fabricate flexible transfemoral sockets with a molding approach. The AM sockets were subjected to structural testing using a modified International Organization for Standardization (ISO) standard for performance testing of lower limb prosthetic components. Northwestern University Flexible Sub-ischial Vacuum – NU-FlexSIV – Sockets – flexible transfemoral sockets developed by Northwestern University – and hybrid sockets – sockets fabricated with the conventional technique but using AM materials – were also tested, and the yield strengths and compression points of the three socket types were compared. It was hypothesized that the NU-FlexSIV Socket would outperform the hybrid and AM sockets. All tested sockets failed at the distal adapter, with the average yield strength and compression point greater for the NU-FlexSIV Socket than those of the hybrid and

AM sockets. The AM socket had the lowest yield strength and compression point of the sockets tested.

Finite element analysis (FEA) of a flexible transfemoral prosthetic socket was used to explore the effect of a frame with a gradated thickness edge on frame stress levels. It was hypothesized that a socket with a gradated thickness frame would reduce stress levels on the frame when compared to a socket with a uniform thickness frame. Von Mises stress indicated that the gradated thickness frame experienced a greater amount of stress than the uniform thickness frame. Stress was determined to be a unsubstantial metric by which to examine comfort and other potential avenues to explore this topic were discussed.

Acknowledgements

I would like to thank my advisor, Dr. Stefania Fatone, for her guidance and encouragement. Additionally, I would like to thank Dr. Steven Gard and Dr. Cheng Sun for serving on my thesis committee and providing valuable feedback on my work. I would like to thank Dr. Oluseeni Komolafe for helping design the process described in this thesis and ensuring that I developed as an engineer, writer, and thinker. I would also like to thank Ryan Caldwell for fabricating many of the sockets used in this study and sharing his expertise with me in innumerable ways.

Further, I would like to thank Erin Boutwell and Dr. Matty Major for their daily friendship, advice, and support. I would also like to thank Dr. Kiki Zissimopoulos and José Luis Zavaleta for their friendship and support. I have been very fortunate to work at NUPOC and would like to thank all members of the lab. I would also like to to express my gratitude to Dr. Suzanne Olds for supporting me through my masters program.

The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. The content of this thesis does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred.

Table of Contents

ABSTRACT 2

Acknowledgements 4

List of Tables 7

List of Figures 8

Chapter 1. Introduction 10

1.1. Overview 10

1.2. Specific Aims 12

1.3. Outline 14

Chapter 2. Fabricating Prosthetic Sockets with Additive Manufacturing Technology 15

2.1. Introduction 15

2.2. Methods 18

2.3. Results 28

2.4. Discussion 31

2.5. Conclusion 36

Chapter 3. Finite Element Analysis of Prosthetic Socket Models with Varying Frame Thickness 37

3.1. Introduction 37

3.2. Methods 39

3.3. Results 44

3.4. Discussion and Conclusions 50

Chapter 4. Discussion 53

4.1. Overview 53

4.2. Significance 53

4.3. Limitations 54

4.4. Future Work 55

References 58

Appendix A. WillowWood Socket Testing Reports 60

A.1. Socket Testing 2012 60

A.2. Socket Testing 2014 67

A.3. Combined Socket Testing Results 73

Appendix B. FEA Submitted Manuscript 76

Appendix C. Mold Design Process 104

Appendix D. FEA Analysis: Results at Residual Limbs at Sections of Frames 117

Appendix E. Posters Presented 121

List of Tables

2.1	Material layup of fabricated sockets.	25
2.2	Thickness measurements of sockets	28
2.3	Static testing measurements for tested sockets	30
3.1	Location of FEA on socket models	43
4.1	Flexural moduli of frame and potential frame materials	55

List of Figures

2.1	CAD models of mold components	19
2.2	Fabricated components	21
2.3	Partial cross-sectional schematic of pour setup showing the insertion of material	22
2.4	Anterior views of fabricated sockets	26
2.5	Locations of thickness measurements from anterior, medial, posterior, and lateral views	26
2.6	Socket test setup	27
2.7	Force-displacement curves generated during static testings	29
2.8	Failed distal adapter on tested AM socket	30
3.1	Rotated views of the uniform thickness frame	40
3.2	Rotated views of the gradated thickness frame	41
3.3	Anterior view of Abaqus model	43
3.4	Global VM stress on frames	
3.5	Local VM stress on edge of frames	45
3.6	Local VM stress on frames without edgess	46
3.7	Stress on the residual limb	47

3.8	Local VM stress on residual limbs at edge of frames	47
3.9	Local VM stress on residual limb at lateral extension	48
3.10	Local VM stress on residual limbs at posterior buttress	49
3.11	Rotated view of VM stress distributions on uniform thickness socket model	49
3.12	Rotated view of VM stress distributions on gradated thickness socket model	50
D.1	VM stress on residual limb below proximal brim	118
D.2	VM stress on residual limb below proximal brim and anterior cutout	118
D.3	VM stress on residual limb below distal cup	119
D.4	VM stress on residual limb below lateral fenestration	119
D.5	VM stress on residual limb below posterior fenestration	120

CHAPTER 1

Introduction

1.1. Overview

The prosthetic socket is the component of a prosthesis that interfaces with the residual limb and is responsible for the transfer of force from the residual limb to the prosthesis. Load transfer is most efficient via a rigid interface, thus most prosthetic sockets are composed of only rigid material. However, a rigid prosthetic socket is uncomfortable for the user to wear, as it does not conform to fluctuations in shape and volume of the residual limb (Sanders et al., 2009). Further, transfemoral residual limbs tend to be larger and more pliant than transtibial residual limbs, making the pathway for load transfer less direct. The transfemoral prosthetic socket designed by Northwestern University (referred to as the Northwestern University Flexible Sub-ischial Vacuum – NU-FlexSIV – Socket) attempted to address these design challenges (Komolafe et al., 2014).

The NU-FlexSIV Socket was conceived by prosthetist Ryan Caldwell and was the basis for a Department of Defense funded project titled, "Development of Sub-Ischial Prosthetic Sockets with Assisted-Vacuum Suspension for Highly Active Persons with Transfemoral Amputations" (Fatone, 2010). The NU-FlexSIV Socket emphasized flexibility by sandwiching a rigid frame between layers of flexible material – creating alternating rigid and flexible regions. The socket design attempted to minimize the amount of rigid material required to effectively transfer load while maintaining socket durability.

Though the NU-FlexSIV Socket has proved to be both flexible (Fatone et al., 2013) and durable (WillowWood, 2012), the conventional process employed to fabricate the NU-FlexSIV Socket was unable to precisely control the thicknesses of the different layers of the socket wall. The grant application described this drawback, stating that with the conventional fabrication process "it is 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" (Fatone, 2010).

Further, the conventional process used in prosthetic socket fabrication is a time intensive, manual technique that depends on the craftsmanship of highly skilled prosthetists. The ability to control dimension parameters, such as socket thickness, might allow greater ability to minimize the amount of rigid material used and maximize flexibility, with the overall goal of improving user comfort.

Additive manufacturing (AM) technology is the process of building a part by adding material in successive layers. The development of AM technology as a reliable fabrication technique presented an opportunity to create a socket with precise dimension parameters. Task 3 of the grant application, titled "Advanced Manufacturing of Sub-ischial Sockets" proposed new fabrication approaches utilizing AM technology to fabricate the NU-FlexSIV Socket (Fatone, 2010). Specifically, fabrication using multi-shot cavity molding was proposed. This thesis project includes work focused on Task 3 of the grant, including Subtask 3a, "Establish criteria and techniques for multi-shot cavity molding;" Subtask 3b, "Develop degassing techniques for liquid resin molding;" and Subtask 3d "Develop mechanical interlock molding techniques" (Fatone, 2010).

Hence, the purpose of this thesis was to utilize AM technology to fabricate transfemoral sub-ischial prosthetic sockets with rigid frames encapsulated by flexible layers and explore socket designs that gradate the transitions from rigid to flexible materials. The approach consisted of the following specific aims:

1.2. Specific Aims

Aim 1: To develop a process for fabricating sub-ischial prosthetic sockets using AM technology.

A design process was undertaken that iterated through several mold approaches and resin pouring processes until a technique was reached that repeatedly produced a socket with minimal air pockets and bubbles. Further, the mold did not leak and was easily demolded. The fabrication technique developed used a handheld scanner to scan a positive mold of the residual limb, SolidWorks 2011 (Dassault Systemes SolidWorks Corp., Waltham, MA) to processes the digital model, a Stratasys Fused Deposition Modeler 400mc (Stratasys, Ltd., Edina, MN) to build the mold components, and a molding technique to fabricate the AM socket.

Aim 2: To compare the mechanical properties of an AM socket, a NU-FlexSIV Socket, and a hybrid socket.

To gain insight into the mechanical properties of the AM socket, it was compared to a NU-FlexSIV Socket. The AM socket was also compared to a hybrid socket (a socket fabricated by a manual technique using AM

socket materials), eliminating material choice as a confounding variable and allowing a focused examination of the effect of the AM technique on the socket fabrication process. Sockets were compared using a modified International Organization for Standardization (ISO) standard for structural testing of lower limb socket components (Gerschutz et al., 2012). Further, the thickness of each socket was measured to examine the level of control each process had over thickness during the fabrication process.

We expected the average yield strength and compression point of the AM sockets to be lower than those of the currently available NU-FlexSIV Sockets due to the tendency of the AM socket materials to fail when flexed.

Aim 3: To study the effect of prosthetic sockets with gradated frame thicknesses on stress distributions at the frame.

To assess the clinical applicability of the AM socket, we employed finite element analysis (FEA) to study the effect of prosthetic socket frame thickness variations on the stress at the frame. Specifically, we calculated stress distributions on the frames and residual limbs of transfemoral socket models with frames with uniform thicknesses and frames with gradated edge thicknesses. Frames with gradated edges were defined by their area and percent gradation as recommended by a Certified Prosthetist.

We expected the frames with gradated transition regions to experience stresses lower in magnitude than the frames of uniform thickness.

1.3. Outline

This thesis is comprised of four chapters: Chapter 1, this introduction; Chapter 2, a description of the AM process developed and comparison of the static strength and thickness of the AM socket to that of manually fabricated sockets; Chapter 3, a finite element analysis of the effect of gradated frame thicknesses on stress distributions on a transfemoral socket model; and Chapter 4, overall discussion and conclusions.

Included in the Appendices are the following: Appendix A, two reports by Willow-Wood (Mt. Sterling, OH) – a company that designs, manufactures, and tests prosthetic products – documenting static testing of the fabricated sockets, and one report by WillowWood combining results from two separate tests; Appendix B, a submitted manuscript by Komolafe et al. (2014) that describes the FEA used in Chapter 3; Appendix C, documentation of the iterative design approach used to establish the AM fabrication technique described in Chapter 2; Appendix D, a collection of more in-depth results from the FEA; and Appendix E, two posters presented at national conferences on portions of this thesis project.

CHAPTER 2

Fabricating Prosthetic Sockets with Additive Manufacturing Technology

2.1. Introduction

Note: This chapter is a modified version of a manuscript intended for submission to the Rapid Prototyping Journal.

The prosthetic socket is the component of a prosthesis that interfaces with the residual limb and facilitates transfer of forces from the residual limb to the prosthesis. Prosthetic sockets are generally manually fabricated by a trained prosthetist. This manual technique is time-intensive, wasteful of material, and does not allow for direct control of the resulting socket's dimension parameters such as thickness.

Though sockets made of rigid materials are effective at transferring loads at the residual limb-socket interface, they cannot adapt to changes in the volume and shape of the residual limb during gait (Sanders et al., 2009). A desirable socket design would emphasize flexibility while maintaining the necessary rigidity to transfer loads (Lehneis et al., 1984).

The transfemoral prosthetic socket designed by Northwestern University (referred to as the Northwestern University Flexible Sub-Ischial Vacuum – NU-FlexSIV – Socket) emphasizes flexibility (Komolafe et al., 2014). Flexibility is achieved during the manual fabrication process by sandwiching a rigid frame within layers of flexible resin – creating

selective flexible and rigid regions. Although clinical testing of the NU-FlexSIV Socket suggested that it was durable (WillowWood, 2012) and comfortable (Fatone et al., 2013) for the user to wear, the fabrication process remains laborious and reliant on artisan methods. Further, the flexibility of the socket might be improved by having greater control of the resulting socket's dimension parameters. Specifically, control of the thickness of the rigid frame would present the opportunity to further decrease the amount of rigid material necessary to fabricate a socket.

In recent years, sporadic efforts have been made to improve upon the manual process of prosthetic socket fabrication using additive manufacturing (AM) (Faustini et al., 2005; Herbert et al., 2005; Hsu et al., 2008, 2010; Rogers et al., 2000, 2001, 2008; Sengeh and Herr, 2013; Tay et al., 2002). AM is a type of automated fabrication process that builds parts by adding material in successive layers. Previous approaches to fabricating prosthetic sockets with AM have employed a three-step process wherein a positive mold of a residual limb is scanned, the scanned image is modified with computer-aided design (CAD) software, and the socket is fabricated with an AM system (Faustini et al., 2005; Herbert et al., 2005; Hsu et al., 2008, 2010; Rogers et al., 2000, 2001, 2008; Sengeh and Herr, 2013; Tay et al., 2002).

While these approaches have focused on fabricating transtibial sockets (Faustini et al., 2005; Herbert et al., 2005; Hsu et al., 2008, 2010; Rogers et al., 2000, 2001, 2008; Sengeh and Herr, 2013; Tay et al., 2002), transfemoral sockets present a greater fabrication challenge due to differences in residual limb geometry. Transfemoral residual limbs tend to be larger in volume and more pliant than transtibial residual limbs, making force transfer from the transfemoral residual limb to the socket less direct. Thus, greater attention

to the placement of rigid regions during transfemoral socket fabrication is necessary to ensure a successful transfer of force from the socket to the residual limb.

These previous approaches to fabricating transtibial sockets had demonstrated varied success. Many fabricated sockets were post-processed with conventional fabrication materials to ensure user safety (Herbert et al., 2005; Hsu et al., 2010), while some were described as either too heavy or too brittle for clinical applications (Hsu et al., 2008; Sengeh and Herr, 2013). Furthermore, testing of fabricated sockets has involved measuring residual limb-socket interface pressure (Faustini et al., 2005; Hsu et al., 2010; Rogers et al., 2008, 2001; Sengeh and Herr, 2013), gait analysis (Rogers et al., 2008, 2001, 2000; Sengeh and Herr, 2013; Tay et al., 2002), and finite element analysis (FEA) (Rogers et al., 2001; Sengeh and Herr, 2013), preventing similar AM fabrication approaches from being compared using a common metric.

The purpose of this project was to develop a technique for fabricating flexible transfemoral sockets utilizing AM technology. A molding process was introduced to the fabrication process, because it allowed the sockets to be fabricated with a combination of AM and manual fabrication materials. The rigid frame of the socket was fabricated with AM, and flexible material was inserted into the mold. The direct fabrication of the rigid frame allowed for the potential fabrication of a variable thickness rigid frame encapsulated by a uniform thickness flexible resin. We anticipated the material choices available to AM systems to be a limiting factor in the study but focused on developing a technique that could be adapted if more durable materials became available. As a common metric, the static strength of the sockets was tested using a modified International Organization for Standardization (ISO) test set-up (Gerschutz et al., 2012).

The prosthetic sockets manufactured with our AM process (referred to as AM sockets) were compared to sockets made for the same residual limb using (1) standard clinical methods and materials (referred to as NU-FlexSIV Sockets) and (2) standard clinical methods but the same materials as used in the AM process (referred to as hybrid sockets). Testing of the hybrid sockets allowed for comparison between the manual and AM fabrication techniques, eliminating material choice as a confounding variable.

2.2. Methods

2.2.1. Design Overview

The AM fabrication technique described below was developed using an iterative design process. Appendix C provides a more thorough documentation of this process. The final fabrication approach involved mold design with CAD software, mold construction with a fused deposition modeling (FDM) system, and socket fabrication with a mold pouring process. FDM involves extruding plastic through a liquefying nozzle to build a party layer by layer. A total of three AM sockets were fabricated for testing.

2.2.2. Mold Design

Sockets were designed using a scan of a positive mold of a transfemoral residual limb wearing a silicone liner. The scan was imported into SolidWorks 2011 (Dassault Systemes SolidWorks Corp., Waltham, MA) and used to generate the ensuing mold components (Figure 2.1).

The imported model was processed in SolidWorks to design the core and cavity seen in Figures 2.1A and 2.1C. A 3D MegaCapturor white light digitizer (Creaform, Levis,

Quebec) was used to scan a manually fabricated frame for the same residual limb geometry. This scan was processed in SolidWorks to design the frame seen in Figure 2.1B. The frame was designed to have a uniform thickness of 3.5 mm.

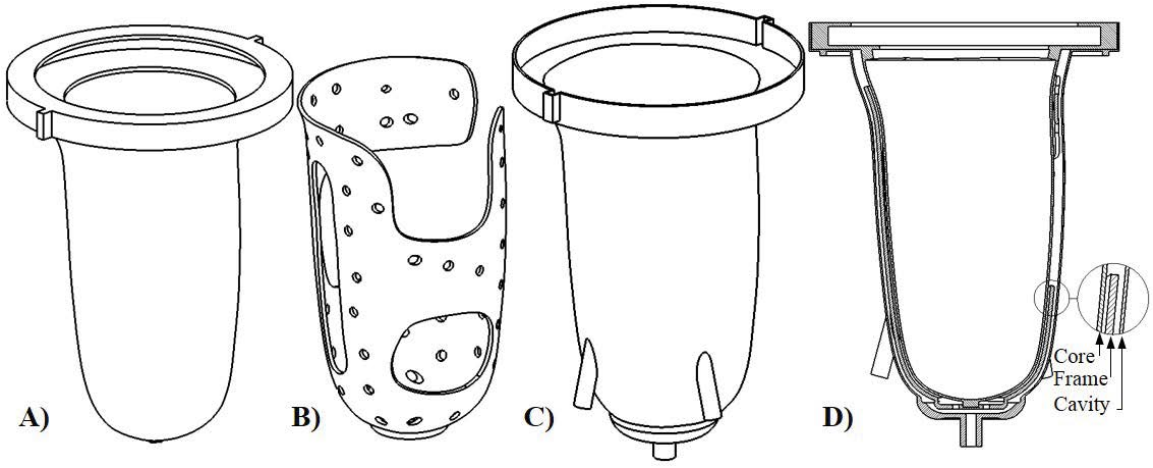


Figure 2.1. CAD models of mold components: (A) Core, (B) Frame, (C) Cavity, and (D) cross section of assembled mold

Mold components were designed to minimize movement during the pouring process and encourage saturation of the socket. As seen in Figure 2.1A, a proximal base was added to the core with extruded flanges to prevent rotation of the core inside the cavity. A hexagonal extrusion was added to the distal end of the cavity as seen in Figure 2.1D. The extrusion cut into the distal end of the frame prevented rotation of the frame while maintaining a fixed distance between the core and frame.

The cavity was designed with three material nozzles. The multiple entry ports allowed for thorough saturation during the pouring process. An overfill port was placed at the distal end of the cavity to allow air to escape from the mold system and a deliberate oversaturation of the mold.

The cavity was designed to fabricate a socket with a uniform wall thickness of 8.5 mm. The uniform socket wall thickness allowed for a simpler pouring technique than a variable wall thickness would have, while still allowing a variable thickness frame to be incorporated if desired.

2.2.3. Mold Construction

The SolidWorks models were converted to *.STL files and opened with Insight 8.1 (Stratasys, Ltd., Edina, MN). The parts were sliced at a layer height of 0.254 mm, packaged as a single *.CMB file, and sent to a Stratasys FDM 400mc large bay system (Stratasys, Ltd., Edina, MN).

The components were printed using a size T16 tip with PC-ABS material for the core and frame and ABS-M30 material for the cavity. A size T12 tip with SR-20 support material was used for all components. All materials were native to the Stratasys system. Each frame was fabricated in 33 hours, while the core and the cavity were fabricated in 33 and 31 hours, respectively. The support material for all components was dissolved overnight in a NaOH solution (Stratasys, Ltd., Edina, MN). The fabricated parts can be seen in Figure 2.2. One core and two cavities were used to fabricate all three AM sockets.

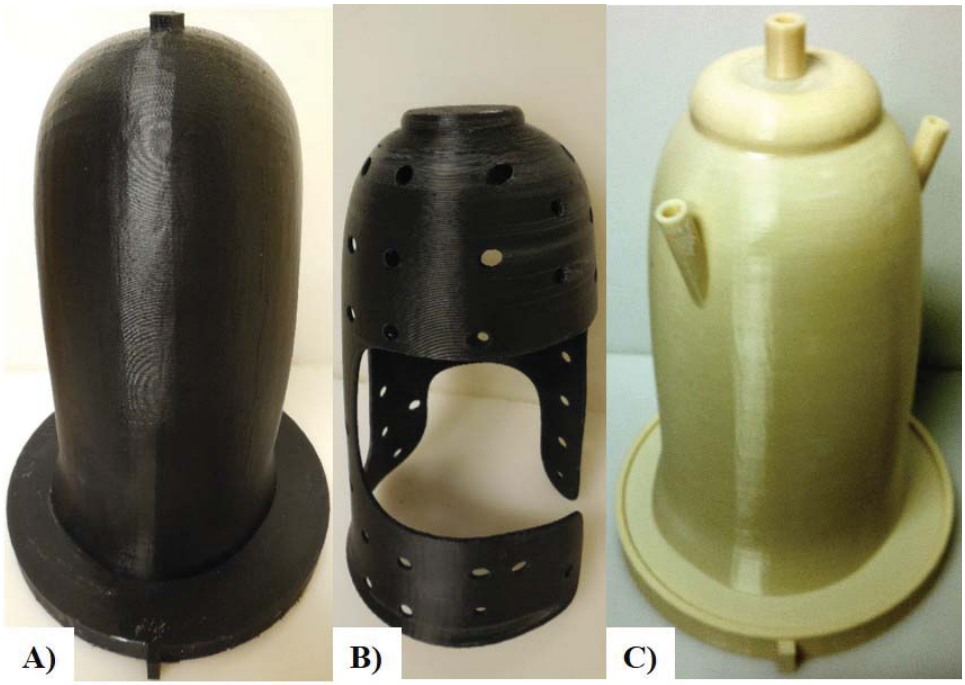


Figure 2.2. Fabricated components: (A) core, (B) frame, and (C) cavity

2.2.4. Mold Pouring Process

The core and cavity were sprayed with Smooth-On Universal Mold Release (Smooth-On, Inc., Easton, PA) to ease the demolding process. Two layers of 4-inch Nylon Stockinette (Comfort Products, Inc., Croydon, PA) were fitted over the core. The distal end of the frame was fitted with a titanium 4-hole laminating plate (American Prosthetic Components, Green Bay, WI) – referred to as the distal adapter – and adhered with +PLUSeries 60 Second Adhesive (Fabtech Systems, Everett, WA). The frame was placed over the hexagonal extrusion of the core, two layers of Nylon Stockinette were draped

over the frame, and the core was placed inside the cavity. The cross section of this mold setup can be seen in Figures 2.1 and 2.3.

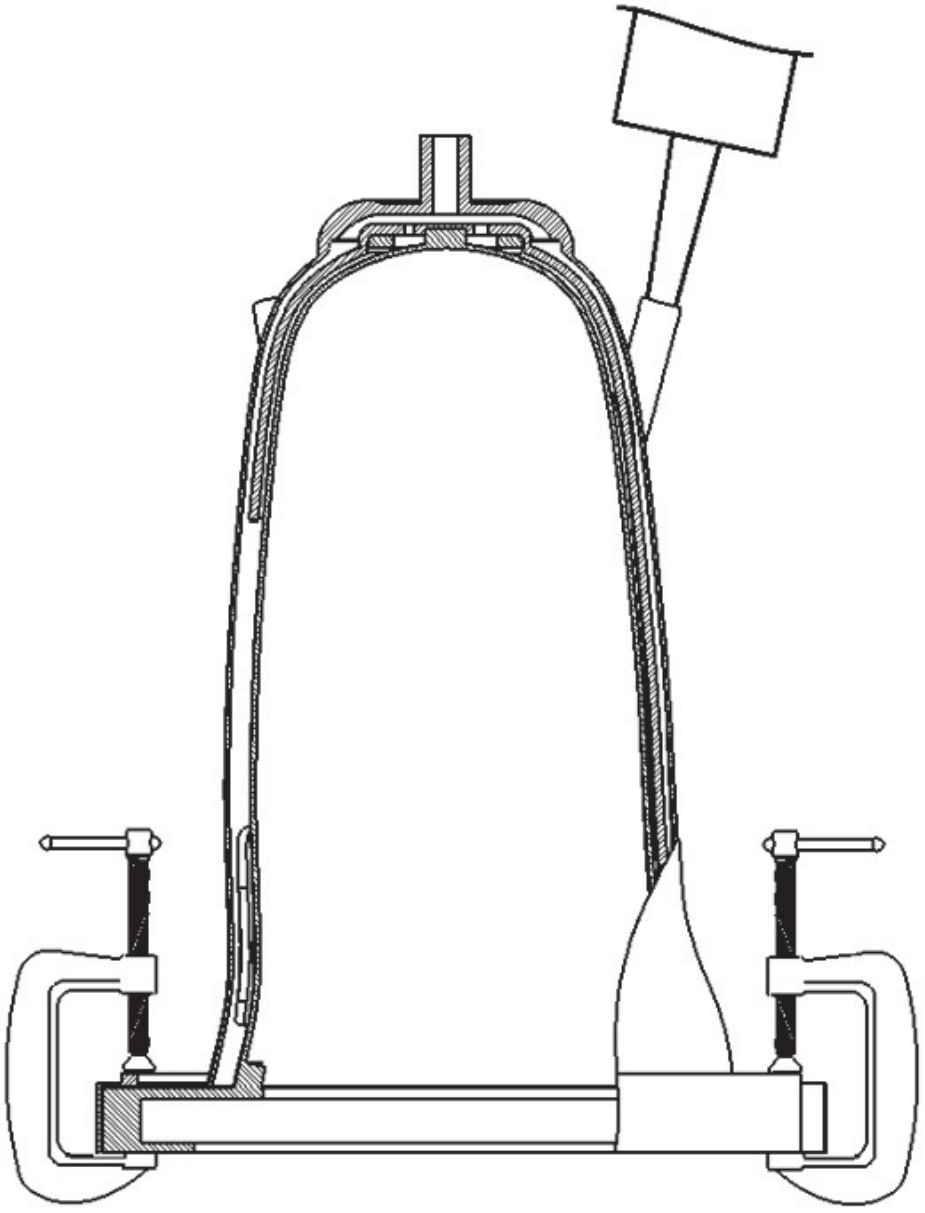


Figure 2.3. Partial cross-sectional schematic of pour setup showing the insertion of material

Movement of the core in the vertical direction was minimized by placing four c-clamps on the base of the mold, two of which can be seen in Figure 2.3. As mentioned, rotation of the core was prevented by the interlocking flanges on the proximal base. A plastic tube was placed over the overfill port at the distal end of the inner core to allow a pathway for trapped air to escape the mold and a deliberate overfilling of the mold.

Urethane Casting Resin 60 Shore A (Fibre Glast Developments Corporation, Brookville, OH) was prepared by mixing its two components together. The resin was transferred to three empty caulk gun canisters. With the mold oriented so that the distal end pointed up, a caulk gun was used to insert material into the mold through the three material nozzles.

The force created by the caulk gun facilitated insertion of material, while the overfill port served to minimize the formation of small air bubbles and pockets in the resulting socket. Material was poured until the caulk guns were empty. The mold cured overnight and was demolded by hand with the help of a screwdriver. This process was repeated twice to fabricate a total of three AM sockets for testing. An anterior view of one of the fabricated AM sockets can be seen in Figure 2.4A.

2.2.5. Fabrication of Sockets for Testing

The AM sockets were tested to failure and the results compared against NU-FlexSIV Sockets and hybrid sockets, which were fabricated by a Certified Prosthetist. All socket material lay-ups are summarized in Table 2.1. Three sockets were fabricated using each fabrication approach, resulting in a total of nine sockets fabricated for testing.

The NU-FlexSIV Sockets were fabricated with three layers. All stockinettes were supplied by Comfort Products, Inc. (Croydon, PA) unless otherwise noted. The inner layer consisted of one layer of Dacron Stockinette and two layers of Spectralon Stockinette that were hand laminated together with Polytol Polyurethane Resin (Otto Bock, Duderstadt, Germany). The second layer was the rigid frame, which was comprised of one layer of Carbon Braid (SPT Technology, Inc., Monroe, NC), one layer of Spectralon Stockinette, one layer of Carbon Braid, a VMP-002-B Standard Mounting Plate (Evolution Industries, Inc., Orlando, FL) – referred to as a distal adapter – mounted at the distal portion of the fabric layup, two layers of SpectraCarb Aralon Stockinette, and two layers of Spectralon Stockinette, all adhered together with Epox-Acryl resin (Foresee Orthopedic Products, Oakdale, CA). The third and outer layer of the socket was comprised of two layers of Spectralon Stockinette and one layer of Dacron Stockinette. The third layer was hand laminated with Polytol Polyurethane resin over the two inner layers. An anterior view of one of the fabricated NU-FlexSIV Sockets can be seen in Figure 2.4B. The distal adapter used in the NU-FlexSIV Socket fabrication was different than the distal adapter used in both the AM and hybrid sockets.

The hybrid sockets were fabricated with the same materials as the AM socket: two layers of Nylon Stockinette were draped over a positive mold of the residual limb and liner, a PC-ABS frame – fabricated using the Stratasys system, fitted with a laminating plate, and adhered in place with +PLUSeries 60 Second Adhesive – was placed over the Nylon Stockinette, two more layers of Nylon Stockinette were draped over the frame, and Fibre Glast 60 Shore A resin was hand laminated over the materials. An anterior view of one of the fabricated hybrid sockets can be seen in Figure 2.4C.

Table 2.1. Material layup of fabricated sockets.

Socket Type	**AM Socket**	**NU-FlexSIV Socket**	**Hybrid Socket**
Number of sockets fabricated for testing	3	3	3
Material layup (from deep to superficial)	2 layers Nylon PC-ABS frame 2 layers Nylon	1 layer Dacron 2 layers Spectralon 1 layer Carbon 1 layer Spectralon 1 layer Carbon 1 mounting plate 2 layers SpectraCarb Aralon 2 layers Spectralon 2 layers Spectralon 1 layer Dacron	2 layers Nylon PC-ABS frame 2 layers Nylon
Resin lamination	Fibre Glast	Polytol Resin	Fibre Glast

2.2.6. Testing Procedures

Socket testing was conducted by WillowWood (Mt Sterling, OH) and involved thickness measurements and static strength testing. The NU-FlexSIV Sockets were tested in November of 2012, and the hybrid and AM sockets were tested in January of 2014. The thicknesses of the nine sockets were measured at eight different locations on each socket as seen in Figure 2.5.

Static strength testing was conducted using an ISO 10328 Condition II A125 level test set-up shown in Figure 2.6. Though this ISO standard is intended for testing the performance of lower limb prosthetic components, the standard does not include prosthetic sockets. However, WillowWood has experience adapting this standard for testing prosthetic sockets (Gerschutz et al., 2012). Sockets tested by Gerschutz et al. (2012) using the ISO standard placed the anterior portions of the sockets in compression and the

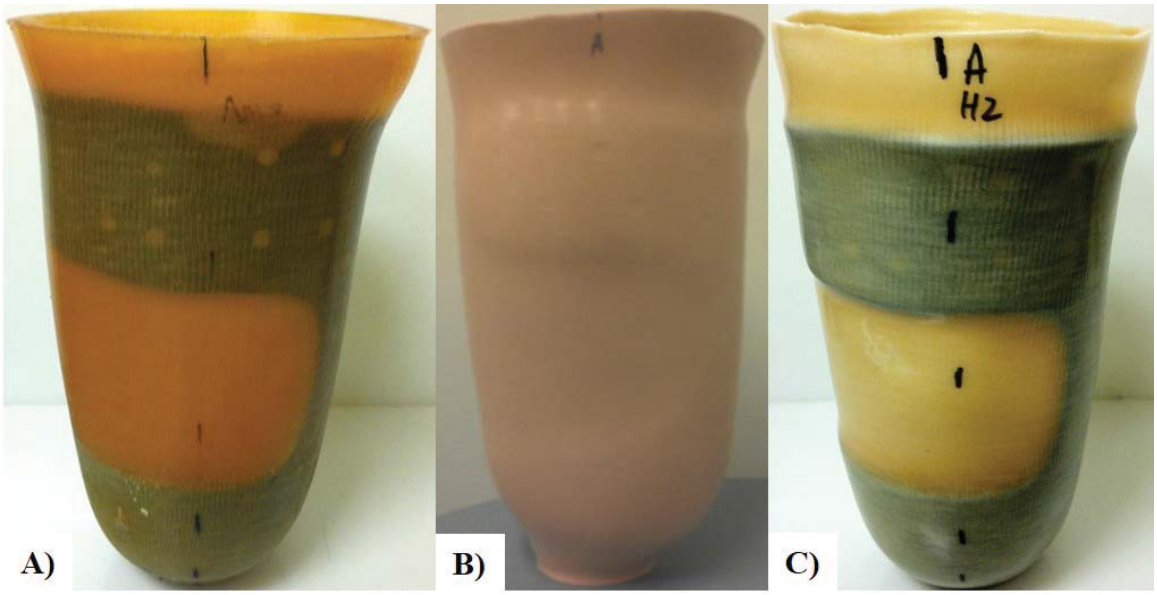


Figure 2.4. Anterior views of (A) AM socket , (B)NU-FlexSIV Socket, and (C) hybrid socket

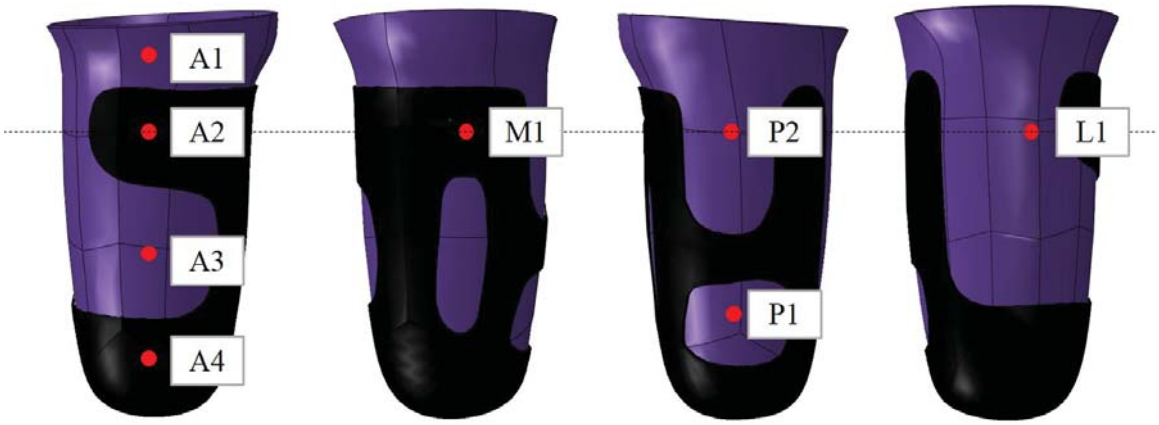


Figure 2.5. Locations of thickness measurements from anterior, medial, posterior, and lateral views

posterior portion of the sockets in tension. We chose to have the anterior portions of the sockets placed in tension and the posterior portions of the sockets placed in compression.

This was due clinical observations of NU-FlexSIV Sockets failing when a user overloaded the posterior portions of the sockets.



Figure 2.6. Socket test setup (WillowWood, 2012)

The sockets were tested with an Interlaken 3300 series test frame with a series 3200 controller (Interlaken Technology Corporation, Chaska, MN). The sockets were attached to a standard four-hole distal attachment plate and fit with a residual limb model wearing a liner. A 4.5 kg preload was applied to the sockets then loading was increased at a rate of 250 N/s until failure (Gerschutz et al., 2012).

Force-deflection curves were generated. Using the curves, the yield strengths were determined using the 0.2% elongation offset method, and the compression points were

determined using either a “deformation peak or a plateau change after the initial linear portion of the curve"(WillowWood, 2012, 2014a). Sockets were compared based on the thickness measurements, yield strengths, and compression points.

2.3. Results

The test report from WillowWood indicated that all the sockets fit the test model well with “no visual presence of gapping or non-distal contact” (WillowWood, 2012, 2014a). This indicated that all of the sockets maintained the original shape of the residual limb test model during fabrication. Specifically, the AM fabrication technique was able to maintain the shape of a scanned residual limb test model during processing in SolidWorks, processing in Insight, fabrication with the Stratasys system, and pouring. The thickness averages and standard deviations of each socket can be seen in Table 2.2 (WillowWood, 2012, 2014a). “AM" referred to an AM socket, “H" referred to a hybrid socket, and “NU" referred to a NU-FlexSIV Socket. Measurement locations can be seen in Figure 2.5.

Table 2.2. Thickness measurements of sockets

	AM1	**AM2**	**AM3**	**H1**	**H2**	**H3**	**NU-1**	**NU-2**	**NU-3**
A1	9.1	7.8	8.7	4.0	3.2	2.7	7.85	8.20	7.60
A2	8.0	6.9	7.6	7.1	6.4	7.8	4.40	3.65	4.30
A3	8.0	7.3	7.5	4.1	3.3	2.8	7.85	7.25	6.90
A4	8.5	7.7	8.0	11	10.8	10.5	4.50	3.70	4.30
M1	8.2	8.8	7.9	8.6	7.5	7.7	7.30	6.70	7.90
P1	7.9	8.2	8.5	3.8	3.5	4.0	3.50	4.35	3.70
P2	8.0	8.5	7.6	3.3	3.0	2.8	3.30	4.30	3.20
L1	8.0	6.9	8.0	5.0	4.0	3.9	4.45	5.00	4.35
AVG	**8.2**	**7.8**	**8.0**	**5.9**	**5.2**	**5.3**	**5.39**	**5.39**	**5.28**
STDEV	**0.41**	**0.71**	**0.43**	**2.8**	**2.8**	**3.0**	**1.94**	**1.74**	**1.87**

During static testing of the sockets, all nine of the sockets failed at the distal adapter. Two of the three AM sockets failed prematurely at the distal adapter when inserting the model of the residual limb into the sockets. Hence, only seven of the nine sockets were tested to failure. The yield strengths and compression points of the sockets were determined from force displacement curves (WillowWood, 2012, 2014b). The curves can be seen in Figure 2.7, and the summarized results can be seen in Table 2.3.

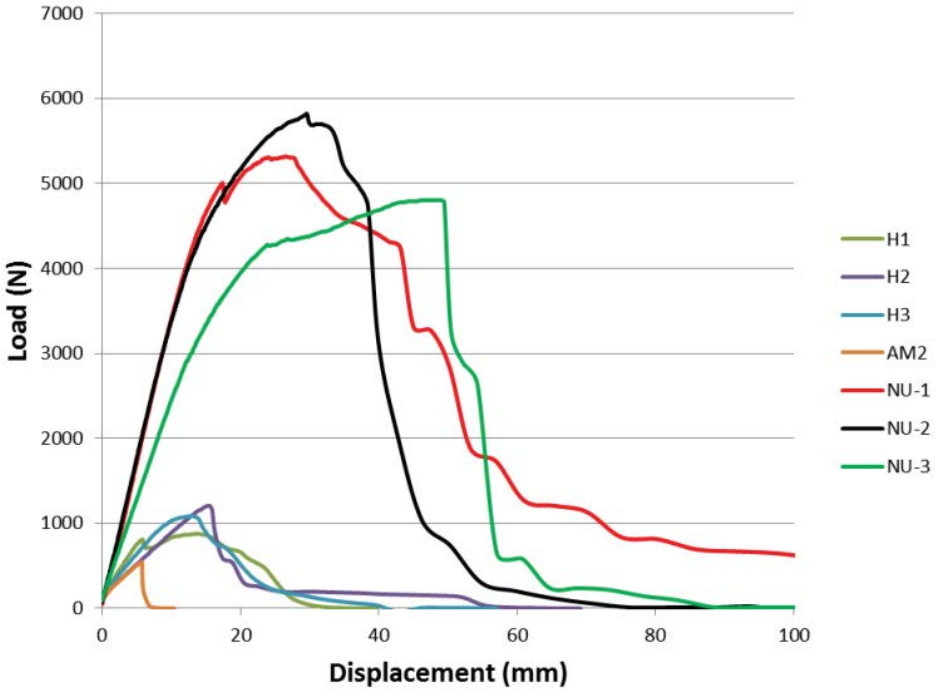


Figure 2.7. Force-displacement curves generated during static testing (WillowWood, 2014b)

The NU-FlexSIV Sockets had an average yield strength that was more than four times that of the hybrid sockets and nearly ten times greater than the AM socket. Likewise, the average compression point of the NU-FlexSIV Socket was nearly five times that of the hybrid socket and nearly ten times greater than the AM socket. Further, the NU-FlexSIV

Table 2.3. Static testing measurements for tested sockets

Socket		Yield Strength		Compression Point	
		N	mm	N	mm
NU-FlexSIV	Average	3787.0	13.00	5033.4	23.61
	Stdev	573.92	0.7053	770.9	6.110
Hybrid	Average	896.0	11.13	1029.3	11.05
	Stdev	167.2	5.140	196.30	4.700
AM	Socket 2	388.3	3.350	507.70	5.020

Sockets were able to withstand greater loads and undergo greater displacements before failure. The AM socket that failed at the distal adapter during loading can be seen in Figure 2.8.



Figure 2.8. Failed distal adapter on tested AM socket

2.4. Discussion

In this study, flexible transfemoral prosthetic sockets were fabricated with a novel fabrication technique using AM technology and compared using a static strength test to sockets fabricated with standard clinical methods and materials, and sockets fabricated with standard clinical methods using the same materials as in the AM process.

2.4.1. Socket Thickness

A major proposed advantage of fabricating prosthetic sockets with AM technology was the ability to precisely control dimension parameters, namely thickness of the socket walls. Our AM technique printed the rigid frame with the Stratasys system, allowing for exact control of the frame's geometry. Though a uniform thickness frame was designed for this study, the AM technique has the potential to fabricate a frame with variable thickness.

Thickness of the socket wall was dictated by the space between the core and cavity mold. A uniform wall thickness of 8.5 mm was assigned using SolidWorks, and all three of the fabricated AM sockets achieved an average thickness within 0.7 mm of this intended thickness. The low standard deviations of the AM socket thicknesses indicated a low variability in socket wall thickness, suggesting good control of this dimension parameter.

The standard deviations of the hybrid and NU-FlexSIV Socket thicknesses were greater than those of the AM sockets. However, this is an unfair comparison, as the manual fabrication technique deliberately manufactured sockets with uniform frame thickness but variable flexible wall thickness. In contrast, the AM technique fabricated sockets with uniform frame thickness and uniform flexible wall thickness. The AM technique was

designed such that it may be adapted to allow for a variable frame thickness in future iterations of the technique.

It is unclear if the variable wall thickness of the manually fabricated sockets contributed to the better performance of these sockets in static testing compared to the AM socket. As mentioned, the AM approach was designed to fabricate a socket with a uniform frame thickness and a uniform socket wall thickness, while allowing the incorporation of a variable frame thickness if desired. It may be worth exploring an AM approach that allows for the fabrication of a frame with both s variable frame thickness and variable wall thickness. This may require the development of a horizontal molding approach, as the current vertical mold setup may be unable to be demolded due to interlocking between the cavity and the variable thickness socket.

2.4.2. Static Testing

While all sockets tested failed at the distal adapter, two of the three AM sockets failed while being attached to the loading mechanism, before loads were applied. Visual inspection of these failed sockets indicated that the distal portion of the frame that encapsulated the adapters of both sockets separated from the rest of the frame. The reasons why the distal portion of the frame separated are unclear. Although for the AM socket frame design attachment of the distal adapter was discussed with a Certified Prosthetist, the attachment of the distal adapter on the frame was not overseen by the prosthetist. This may have led to poor adherence between the distal portion of the frame and the distal adapter and could have contributed to the decreased strength of the distal portion of the socket.

The ability of one of the AM sockets to withstand testing indicated that the technique is capable of fabricating sockets that can withstand load, but the premature failure of two of the sockets indicated that the technique is not currently reliable. Future iterations of the AM technique should strengthen the distal portion of the frame by thickening the frame in that region and ensure that a Certified Prosthetist is involved in the attachment of the adapter.

These large differences in performance between the NU-FlexSIV and other sockets were likely due to material choice, namely the strength of the NU-FlexSIV Socket's carbon frame compared to the AM socket's PC-ABS frame. The carbon frame had a flexural modulus of 4852 MPa (Komolafe et al., 2014). The reported flexural modulus for the PC-ABS is 1900 MPa (Stratasys, 2014). The greater flexural modulus of the NU-FlexSIV carbon frame allowed the NU-FlexSIV Socket to withstand a greater load. This was illustrated in Figure 2.7, where the NU-FlexSIV Sockets displaced significantly more before failure than the hybrid and AM sockets. Further, the different distal adapters used in the NU-FlexSIV Sockets may have contributed to its improved performance.

Gerschutz et al. (2012) tested definitive laminated (DL) transtibial sockets – sockets defined as being laminated by saturating carbon fiber or fiber glass reinforcement materials with resin – to failure with the ISO 10328 standard. DL sockets were fabricated by nine facilities and were tested with the anterior portions of the sockets in compression and the posterior portions in tension. Sockets were evaluated by their compression points. The average compression points for the sockets, grouped by the facilities in which they were fabricated ranged from 2791 – 5713 N; the average compression point of the NU-FlexSIV Socket was 5033.4 N, outperforming the average of six of the nine facilities (Gerschutz

et al., 2012). The average compression points of the hybrid and AM sockets were 1029.3 N and 507.7 N, respectively, both falling below the range reported for DL sockets.

The passing criteria for ISO 10328 condition II A125 level was 4426 N for brittle failure and 3421 N for ductile failure, evaluated by compression point and yield strength, respectively. Gerschutz et al. (2012) classified sockets that deformed before breaking as ductile failures and sockets that exhibited none or minuscule deformation before breaking as brittle failures. Four of the nine facilities fabricated sockets that passed the A125 value for brittle failure. The NU-FlexSIV Sockets were reported to deform before breaking, indicating a ductile failure. The NU-FlexSIV Socket passed the ISO 10328 standard for both brittle and ductile failure, while the hybrid sockets and AM sockets failed to meet either standard. The above average performance of the NU-FlexSIV Sockets compared to the DL sockets and the ability of the NU-FlexSIV Sockets to pass the ISO standard indicated that these sockets were the only ones we fabricated that would be durable for clinical use.

2.4.3. AM Socket Performance

Comparison of the AM and hybrid sockets was intended to allow an assessment of the two fabrication techniques. While the hybrid sockets outperformed the single AM socket that was tested to failure, premature failure of two of the AM sockets made it difficult to determine how the different fabrication techniques contributed to durability of the sockets.

The attachment of the distal adapter and the hand lamination technique were the two major differing variables. The distal adapter issue may stem from how the resin

interacts with the distal portion of the frame. The hand lamination technique used in the manual fabrication process may have been more successful than the AM approach in saturating the rigid frame and fabric layups with resin. A pour technique that focuses on full saturation of the distal portion of the socket – possibly by applying pressure to the curing resin – may prevent premature failure of the distal adapter.

Variably compliant transtibial sockets fabricated directly from AM material by Rogers et al. (2008) may be considered the most well developed approach to socket fabrication currently described in the literature based on FEA rigor, positive feedback from users, and reduced socket-residual limb interface pressures in sensitive areas (Rogers et al., 2008). The AM technique described above has the potential to be iterated to achieve similar benchmarks if a more suitable frame material can be found and user testing can be conducted to better understand the comfort and performance of the sockets during gait.

2.4.4. Limitations

Our proposed AM technique was limited by the materials available for use with the Stratasys system. The greater average yield and compression points of the NU-FlexSIV Sockets compared to the hybrid and AM sockets suggested that the strength of the NU-FlexSIV carbon frame was unmatched by the strength of the PC-ABS frame.

The decision to create a core and cavity mold allowed for the use of conventional fabrication materials and AM materials. However, the rigid nature of the core and cavity limited the space available for the fabric layup and viscous resin.

ISO 10328 was designed for structural testing of lower-limb prosthetic components. However, ISO 10328 does not include prosthetic sockets, so it was modified by Willow-Wood for testing prosthetic sockets. Previously, sockets fabricated with AM technology have been tested by gait analysis, measuring residual limb-socket interface pressure, FEA, and subjective user feedback. The lack of formal strength testing has made it difficult to discern the clinical applicability of sockets fabricated with AM technology. Adoption of the modified ISO 10328 standard as a metric for testing sockets fabricated with AM technology would allow for a better understanding of the strength of these sockets and would allow for sockets fabricated with different techniques to be compared using a common metric.

2.5. Conclusion

The proposed AM technique demonstrated the feasibility of using FDM technology to fabricate a transfemoral prosthetic socket. The novel process introduced a molding technique that was capable of producing a socket with good fit and controlled thickness. Improved attachment of the distal adapter is needed to improve socket durability.

Testing of the sockets by a modified ISO standard allowed for a common metric to be used to evaluate the sockets. Though this metric demonstrated the performance gap between a socket fabricated with AM technology and manually fabricated sockets, the metric allowed for a fair and quantitative evaluation of socket performance.

CHAPTER 3

Finite Element Analysis of Prosthetic Socket Models with Varying Frame Thickness

3.1. Introduction

As discussed in both Chapter 1 and Chapter 2, a desirable prosthetic socket emphasizes flexibility (Lehneis et al., 1984). This is achieved by minimizing the amount of rigid material necessary to transfer load from the residual limb to the prosthesis while maintaining socket durability.

The conventional manual fabrication process for a transfemoral prosthetic socket does not allow for precise control of the resulting socket's dimension parameters. Specifically, the process by which the NU-FlexSIV Socket is fabricated does not grant the prosthetist control over the resulting socket's thickness. This lack of control is two-fold; the prosthetist is unable to (1) dictate the thickness of the rigid frame when it is formed over a mold and (2) manage the thickness of the socket when the resin is hand-laminated over socket components.

Additive manufacturing (AM) technology offers the ability to precisely control a part's dimension parameters and has been used to address shortcomings in the manual prosthetic socket fabrication process. Rogers et al. (2008) developed variably compliant transtibial prosthetic sockets using selective laser sintering (SLS). SLS is a process by which a part is built in successive layers by selectively sintering a thermoplastic powder together with a

high-powered laser. The group sought to increase the compliance of transtibial socket walls at areas of high contact pressure with the residual limb. They fabricated a socket with concentric spiral slots at sensitive sites on the socket wall. The spiral slots were reinforced with a stiffening membrane to control compliance. Contact pressure measurements at the residual limb-socket interface of users demonstrated a reduction in average and peak pressures at areas previously defined as having high residual limb-socket contact pressure in conventionally fabricated sockets.

Sengeh et al. (2013) designed a technique for fabricating variable impedance prosthetic (VIPr) sockets using magnetic resonance imaging (MRI) and a three-dimensional (3D) printer. A 3D printer builds a part by binding powdered material with a liquid adhesive in successive layers. The group used MRI data to "approximate the stiffness of each location on the residual limb from the distances between the bone and the outside surface of the skin" (Sengeh and Herr, 2013). Using an inverse linear relationship, the group was able "to map bone tissue depth to socket material stiffness properties"(Sengeh and Herr, 2013). They used an Object Connex 3D printer (Billerica, MA) that was capable of printing two materials simultaneously in order to fabricate a socket with a "smoothly varying socket wall impedance"(Sengeh and Herr, 2013). The VIPr socket demonstrated reduced contact interface pressures in sensitive areas of the socket compared to a manually fabricated socket.

The previously mentioned Department of Defense funded projected titled "Development of Sub-Ischial Prosthetic Sockets with Assisted-Vacuum Suspension for Highly Active Persons with Transfemoral Amputations" recognized the role AM technology could play in fabricating prosthetic sockets (Fatone, 2010). The third specific task of the grant

was focused on advanced manufacturing of sub-ischial sockets. The ability of AM to precisely control thickness was discussed in the grant, and the feasibility of using the Northwestern University Prosthetics-Orthotics Center (NUPOC) in-house FDM system for prosthetic socket fabrication was discussed in Chapter 2.

This chapter is concerned with the use of AM fabrication techniques to increase the flexibility of the NU-FlexSIV Socket. Specifically, the challenge of obtaining a smooth transition between the rigid and flexible areas of the socket, which may increase flexibility of the socket. The purpose of this project was to study the effect of prosthetic sockets with gradated thicknesses on stress distributions on the frame. This problem was initially intended for testing in a motion analysis lab where socket-residual limb interface pressures could be measured. However, the low sensitivity of the Pliance pressure sensors (Novel, Munich, Germany) was not suitable for measuring minute pressure differences and led to the finite element analysis (FEA) approach.

We employed FEA to study the effect of prosthetic socket frame thickness variations on the stress at the frame. We hypothesized that frames with gradated transition regions would experience stresses lower in magnitude than frames of uniform thickness.

3.2. Methods

Socket frame designs were processed in SolidWorks 2011 (Dassault Systemes SolidWorks Corp., Waltham, MA). The FEA was completed with Abaqus 6.10-2 (Dassault Systemes SolidWorks Corp., Waltham, MA) and was an extension of previous work related to the same grant investigating the effect of different rigid frame designs on overall prosthetic socket flexibility (Komolafe et al., 2014). The model setup by Komolafe is

summarized below, and the entire manuscript can be found in Appendix B. Modifications made to the model for this project are described in the following.

3.2.1. CAD Work

Scans of a residual limb, a liner, and a manually fabricated rigid frame were taken using a 3D MegaCapturor white light digitizer (Creaform, Levis, Quebec). This scan was imported into SolidWorks and modified by Komolafe et al. (2014). The resulting frame had a thickness of 6 mm and can be seen in Figure 3.1.

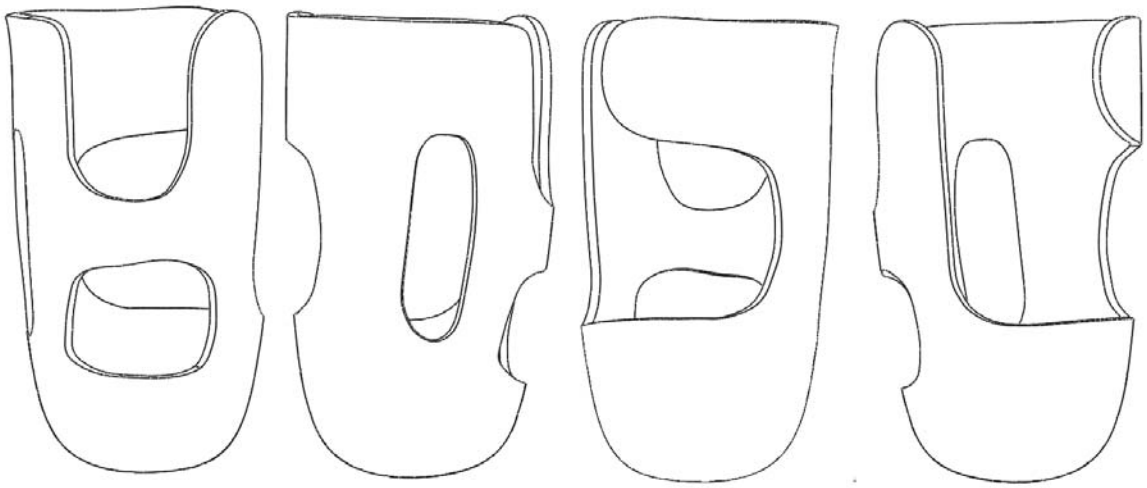


Figure 3.1. A uniform thickness frame from posterior, medial, anterior, and lateral views

The uniform thickness frame shown in Figure 3.1 was modified using the chamfer tool in SolidWorks. A Certified Prosthetist familiar with the project recommended reducing the edge thickness of the frame from 6 mm to 0.3 mm over a distance of 20 mm from the edge. However, due to limitations in SolidWorks, the edge of the outer surface of the frame was reduced from a thickness of 6 mm to approximately 1 mm. The gradation

occurred over a distance of 11.5 mm from the edge. The socket with gradated edges can be seen in Figure 3.2.

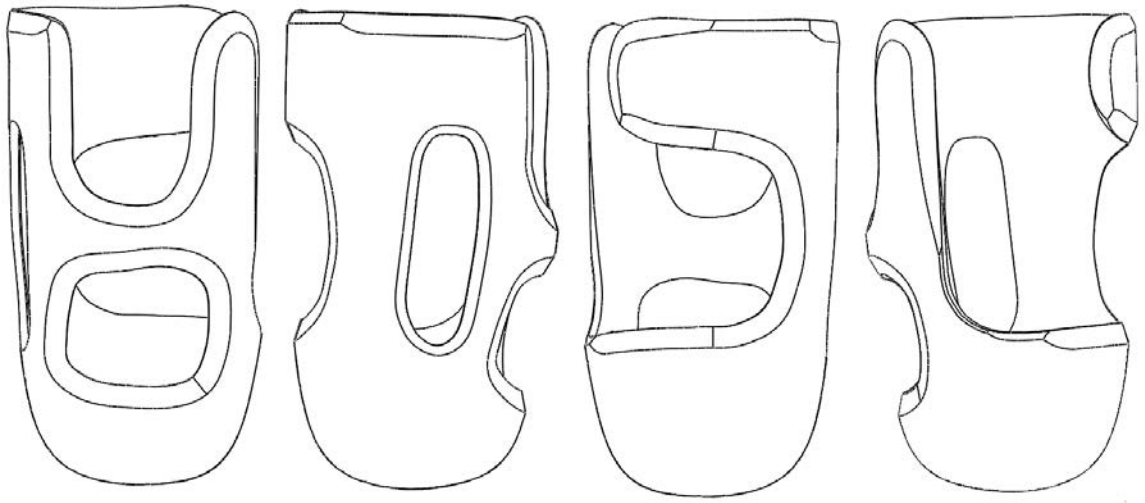


Figure 3.2. A gradated thickness frame from posterior, medial, anterior, and lateral views

3.2.2. Abaqus Work

3.2.3. Overview

FEA models of a uniform thickness prosthetic socket and a gradated thickness prosthetic socket were analyzed. Both models were based on work completed by Komolafe et al. (2014) and are summarized below. The models were loaded at the distal end with the ground reaction forces recorded during the stance phase of gait from a single subject. The simulation was ran and von Mises (VM) stresses were calculated for both models. The stresses were plotted against the percent of gait, and the levels of VM stress on the frame and residual limb were compared between the two models.

3.2.4. Model Setup

The socket modeled in Abaqus was an NU-FlexSIV Socket. This socket was fabricated with a rigid frame laminated between two layers of flexible material, but it was modeled as a single flexible layer and a rigid frame. It was assumed that the simplification of the model to a single flexible layer would have a negligible difference on the results. The full model consisted of the socket, a residual limb created to fill the inner surface of the flexible layer of the socket, and a femur inserted into the residual limb. The model was oriented to "simulate the clinical bench alignment of 5° flexion and 5° adduction"(Komolafe et al., 2014). The contacting surfaces of the model were mated with tie constraints that ensured the motions of different model surfaces were equal.

The loads applied to the socket were recorded from gait analysis of a single human subject. The ground reactions forces in the force-aft (F_x), medial-lateral (F_y), and vertical (F_z) direction were measured and applied at the distal end of the socket. A boundary condition was placed at the proximal end of the femur. This served to constrain vertical translation of the model.

Material properties of the socket were determined from material testing and literature values and can be found in Appendix B.

First order, 4-node linear tetrahedral elements were used. A more refined mesh was used on the residual limbs to account for the larger deformations expected within the residual limb. An anterior view of the models can be seen in Figure 3.3.

VM stresses were output for both of the models. The areas of the models analyzed are summarized in Table 3.1. The stresses on the gradated and uniform frames were plotted for the stance phase of gait and compared to assess the hypothesis that gradating the

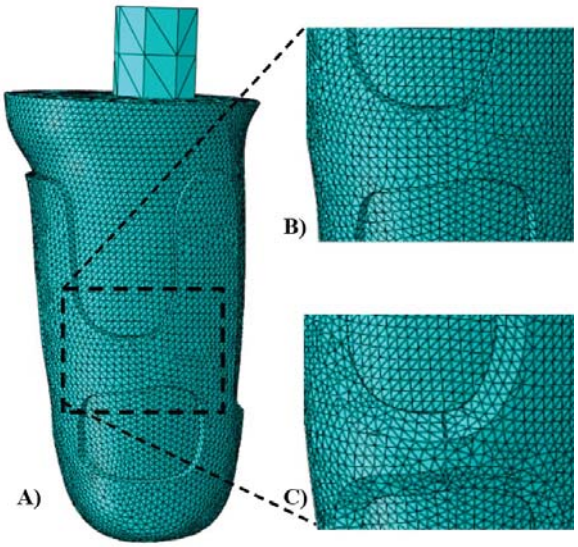


Figure 3.3. Anterior view in Abaqus of (A) NU-FlexSIV model, (B) uniform frame, and (C) gradated frame

thickness would result in lower stresses on the frames. The stresses at the residual limb were explored to better understand the effects of the gradated thicknesses at different levels of the model by dividing the residual limb into seven distinct regions. Data were processed in MATLAB (MathWorks, Natick, MA).

Table 3.1. Location of FEA on socket models

Socket Components Analyzed	**Results Analyzed (location)**
Frames	Global stresses
Frames	Local stresses (edge)
Frames and liners	Global stresses
Residual limbs	Global stresses
Residual limbs	Local Stresses (residual limb area covered by frame edge)
Residual limbs	Stress distributions

3.3. Results

The chamfer tool was unable to evenly gradate the edges, resulting in an inconsistent reduction of material. Further, the 1 mm reduction of material over a distance of 11.5 mm was the maximum limit of the chamfer tool, preventing the frame from being modified to the prosthetist recommended level.

The global VM stresses on the frames can be seen in Figure 3.4.

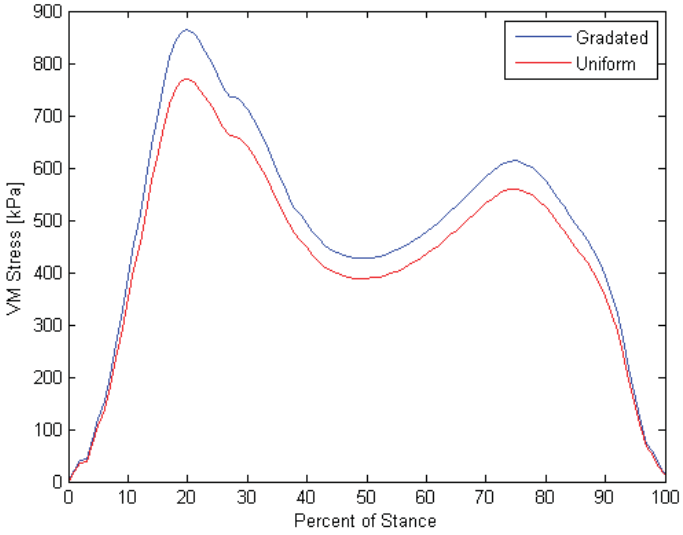


Figure 3.4. Global VM stress on gradated and uniform frames

As seen in Figure 3.4, for the entire stance phase, the VM stress on the gradated frame was greater than the stress on the uniform frame.

The local VM stress on the gradated portion of the gradated frame and the corresponding nodes on the uniform frame can be seen in Figure 3.5.

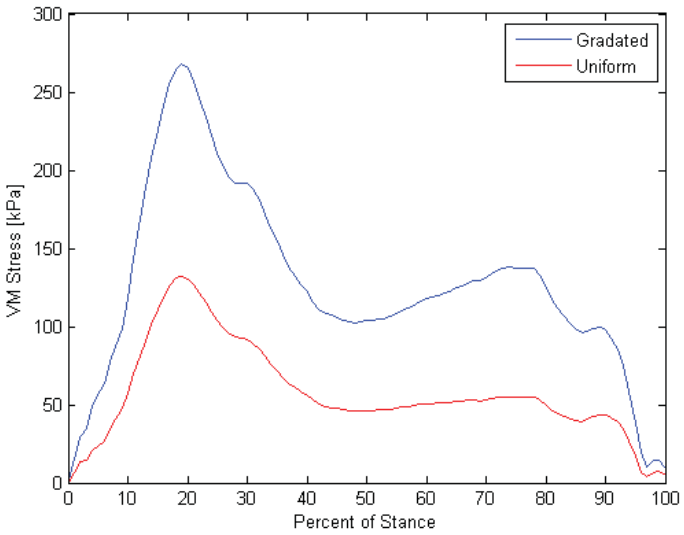


Figure 3.5. Local VM stress on edge of gradated and uniform frames

The VM stress on the edge of the gradated frame was greater than the VM stress on the edge of the uniform frame during all of stance. This indicated that the gradated edge played a role in increasing stress levels on the entire frame. The VM stresses on the areas of the frames not including the 11.5 mm edge portion can be seen in Figure 3.6.

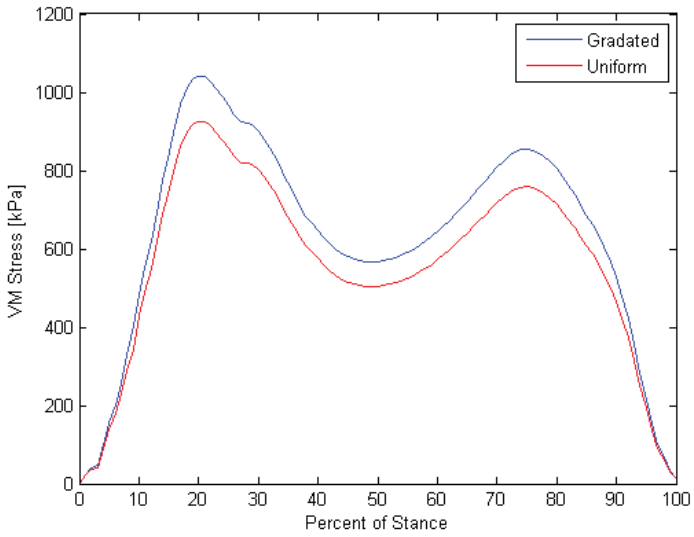
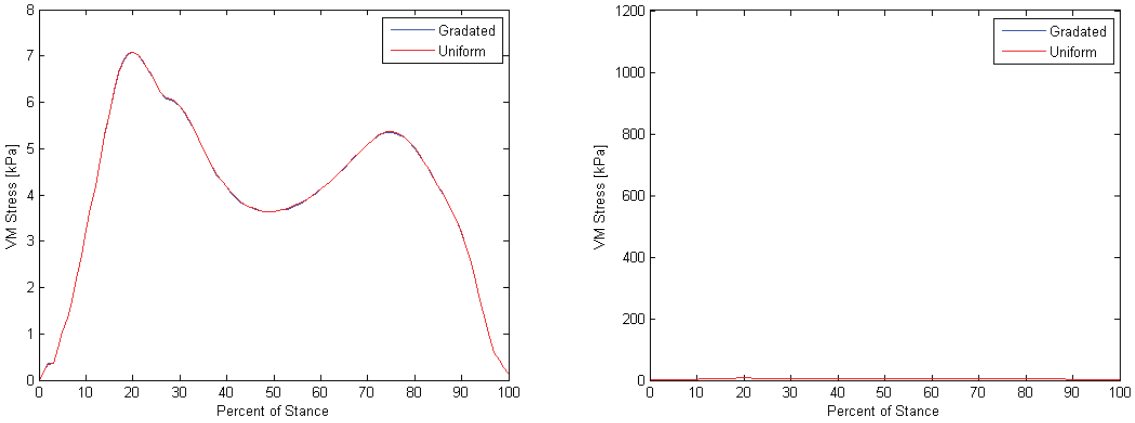


Figure 3.6. Local VM stress on gradated and uniform frames without edges

The greater stress on the gradated frame than the uniform frame in non-edge areas indicated that the reduction of material at the edge served to increase stress on the entire gradated frame design.

The global stress on the residual limbs can be seen in Figure 3.7a. There was no discernible difference between the VM stresses on the residual limb or the gradated and uniform socket models. The stress was two orders of magnitude less than seen on the frame. The global stress on the residual limbs is plotted again in Figure 3.7b with the scale of stress seen on the frame.

The barely visible results in Figure 3.7b indicated that substantially lower levels of stress were being calculated on the residual limb than the frame. The VM stresses on the residual limbs at the portions of the limbs that were covered by the edges of the frames can be seen in Figure 3.8.



(a) Global VM stress on residual limb (outer surface)

(b) Global VM Stress on residual limb (outer surface) with alternate scale

Figure 3.7. Stress on the residual limb

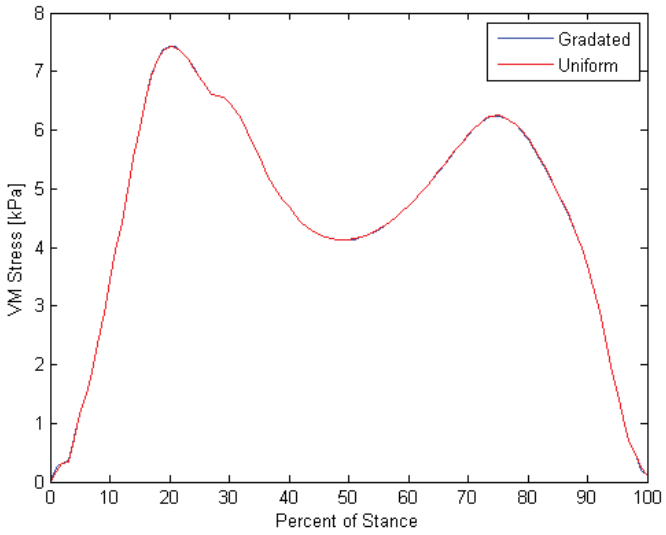


Figure 3.8. Local VM stress on residual limbs at edge of frames

As with the global stresses on the residual limbs, the local stresses on the residual limbs are nearly identical.

The frame was then divided into seven distinct regions, and the stresses at the residual limbs that interfaced with the edges of those regions were examined. These seven regions all displayed similar results, namely the stresses were nearly identical with sporadic instances of negligible difference between the gradated and uniform thickness frames. The results for the lateral extension and posterior buttress regions are shown below in Figures 3.9 and 3.10. Results for the proximal brim, anterior cutout, distal cup, lateral fenestration, and posterior fenestration can be found in Appendix D.

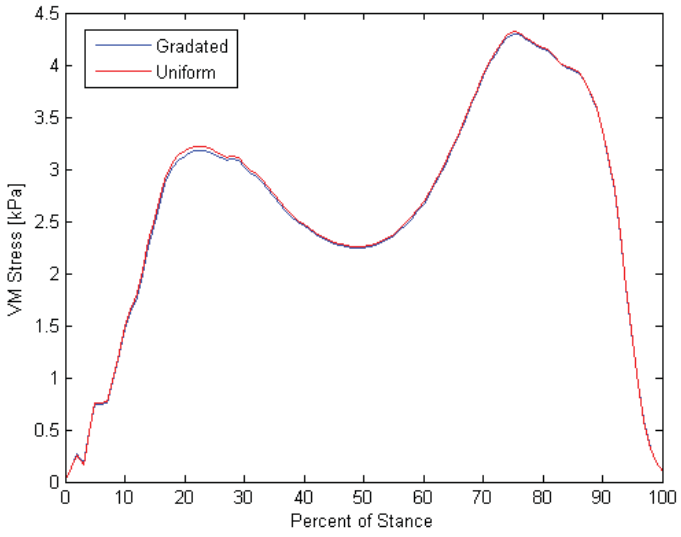


Figure 3.9. Local VM stress on residual limb at lateral extension

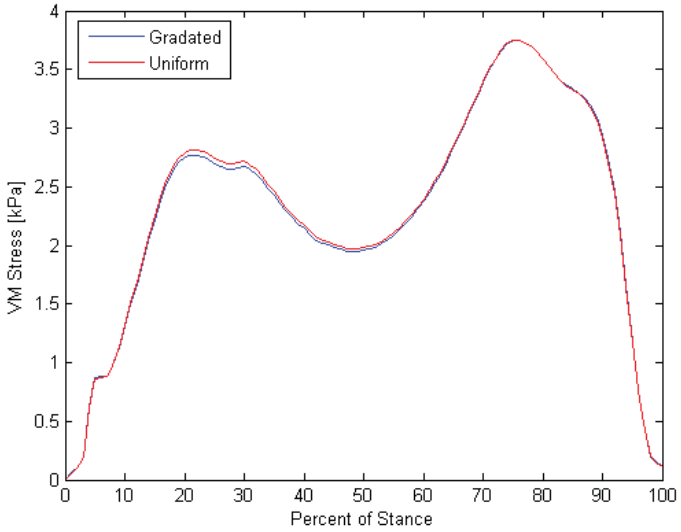


Figure 3.10. Local VM stress on residual limbs at posterior buttress

The results for the lateral extension and the posterior buttress demonstrate that there was no discernable difference between the stresses on the residual limb, either global or local, between the two socket designs. Figures 3.11 and 3.12 show the stress distributions on the residual limbs of the two socket designs.

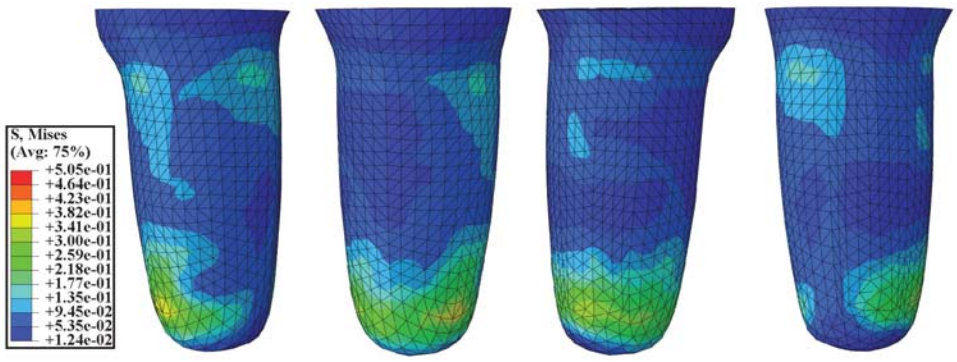


Figure 3.11. VM stress distributions on uniform thickness socket model from posterior, medial, anterior, and lateral views

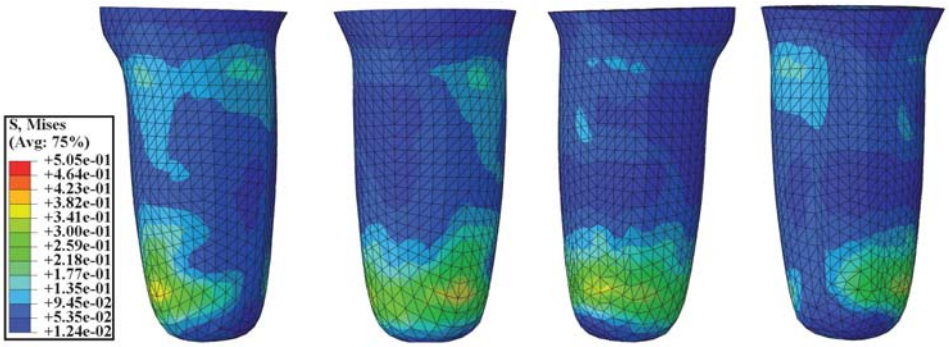


Figure 3.12. VM stress distributions on gradated thickness socket model from posterior, medial, anterior, and lateral views

3.4. Discussion and Conclusions

The increased stress on the gradated frame was surprising but explainable. The removal of material from the gradated frame functioned to weaken the frame and caused the stress to increase in the frame.

The stress results for the global and local frame data indicated that stress on the gradated frame was greater than the stress on the uniform frame and rejected the hypothesis. Since the gradated frame visibly impacted the model, it was necessary to examine the stress at the residual limb.

Results at the residual limb indicated that the gradated socket design had a negligible difference. This may be due to the fact that the residual limb of the uniform frame design seen in Figure 3.11 has no discernible stress concentrations. However, the VM stresses calculated at the residual limbs were two orders of magnitude less than on the frames. This was highlighted by Figure 3.7b, and indicated that the residual limb stress values may not be significant enough to draw any conclusions. It appeared that a majority of the

load applied to the socket was dispersed through the rigid frame, resulting in calculated stress values on the residual limb that had no credibility. Thus the only clear result from the analysis was that the gradated frames demonstrated increased stress when compared to uniform frames, leading us to reject our hypothesis.

The question thus shifted from whether or not the gradated frame socket design affected the model to whether or not stress was the best criterion to examine our problem. In this project, the benefit of reducing rigid socket material is twofold. First, it should help to increase the flexibility of the socket, and second, it should increase the comfort of the socket for the user. Stress measurements in this model were not able to indicate an increase or decrease in socket flexibility or comfort, and the model proved inadequate to answer this question.

Though VM stress is a valuable criterion when exploring the failure of a system, it may not have been the best metric to determine the effect of gradated thicknesses on comfort. The FEA was not designed to test to failure, preventing the models from determining the maximum VM stresses that the sockets could withstand.

Stress was an ineffective criterion for exploring the impact of the gradated frame designs. Different approaches for testing the hypothesis that gradated edges improve socket design (either comfort or flexibility) could be (1) measuring the pressure distributions at the residual limb-socket interface of users wearing gradated and non-gradated sockets, (2) eliciting socket fit comfort scores from users, (3) or redesigning the FEA approach. A measurement of pressure distributions in a clinical setting with more robust sensors would indicate whether the gradated edges relieve pressure at the residual limb-socket interface. A survey of socket comfort scores would allow for subjective user feedback.

A redesign of the FEA approach would involve redefining the surface interaction between the residual limb and socket components, which may improve the validity of the results at those surfaces. Previous approaches to surface interaction between the residual limb and the socket have used automated contacts and gap elements. Gap elements are interface elements introduced between the socket and the residual limb that help to simulate the friction and slip that occurs at the interaction (Zhang et al., 1995; Zachariah and Sanders, 2000). Automated contact is similar to what was used in this study and involves modeling the interface as two deformable, non-penetrating surfaces (Zachariah and Sanders, 2000; Lee et al., 2004; Jia et al., 2004). However, our approach tied the surfaces together and ensured equal motion at the contacting surfaces, whereas previous groups who used automated contact incorporated defined coefficients of friction for the residual limbs and sockets(Zachariah and Sanders, 2000; Lee et al., 2004; Jia et al., 2004). This allowed for slipping to be modeled between the surfaces. This model could be redesigned to account for slipping, which may prevent the attenuation of loads at the residual limb-socket interface and provide better insight on the effect of the gradated frame on the residual limb.

The results from the FEA of the NU-FlexSIV Socket model led to rejecting our hypothesis that gradated frame thicknesses would experience less stress than uniform frame thicknesses. The greater stress on the gradated frame was due to the reduction of material. The results examined at the residual limb were so low in magnitude that the results were negligible. Alternate approaches to explore the hypothesis that gradated frames may improve socket flexibility and comfort have been recommended.

CHAPTER 4

Discussion

4.1. Overview

This thesis examined the role additive manufacturing (AM) could play in the fabrication of flexible transfemoral prosthetic sockets. The work conducted involved (1) an iterative design process to develop a process for using a Stratasys Fused Deposition Modeling (FDM) system to fabricate a flexible transfemoral prosthetic socket, and (2) finite element analysis (FEA) of flexible transfemoral socket models to understand the effect of gradating socket frame edge thickness on stress distributions on the frame and residual limb.

4.2. Significance

The technique designed for fabricating AM sockets was the first developed for the fabrication of transfemoral prosthetic sockets. Further, the AM socket fabrication technique was the first process to deliberately combine AM and manual fabrication materials while still maintaining control over dimension parameters of both materials.

A modified International Organization for Standardization (ISO) standard for the structural testing of lower-limb prosthetic components was recommended as a common metric to test the performance of sockets fabricated with AM technology (Gerschutz et al., 2012). This common metric would allow for sockets fabricated by different approaches – either manually or with AM – to be compared by structural testing. Gait analyses, FEA,

and pressure measurements at the residual limb-socket interface – techniques commonly used by previous groups – do not allow for objective comparison between techniques.

The FEA of the socket models with uniform and gradated frames calculated VM stresses on the socket. The stress calculations indicated that stress increased on the gradated frame geometry and led to speculation of different ways to approach the problem and better understand how a socket would be affected by a gradated thickness frame.

4.3. Limitations

The major limiting factor of the proposed AM fabrication technique was the materials available for use with the AM system. The flexural modulus of the NU-FlexSIV carbon frame was 4852 N, more than 2.5 times greater than the PC-ABS frame (Stratasys, 2014). The greater flexural modulus of the NU-FlexSIV carbon frame contributed to the better performance of the socket in static strength testing.

The introduction of a molding technique using AM fabrication allowed for the combination of AM and manual fabrication materials. However, the molding setup resulted in viscous polyurethane resin being poured into a thin gap between the core and the cavity. Unlike the manual fabrication technique in which resin is laminated between a positive mold of the transfemoral limb and a flexible plastic, the AM technique inserts material into a space constrained by rigid boundaries. This limited the fabric layup that could be used with the molding technique. This could be improved by developing a more powerful technique for material into the mold, allowing for the minimal space in the rigid space to be overcome.

Limitations and issues with the FEA approach were discussed in depth in Chapter 3. The hypothesis that was tested was that flexible transfemoral sockets with gradated rigid frames would increase flexibility and reduce stress on the residual limb when compared to sockets with uniform frames. This gradated rigid frame would hopefully lead to an increase in comfort for the user. Initially, this problem was thought to be best suited for the gait laboratory where pressure could be measured at the residual limb-socket interface. However, previous work at the Northwestern University Prosthetics-Orthotics Center (NUPOC) had dealt with Pliance pressure sensors (Novel, Munich, Germany) and had found the sensitivity of the sensors to be too low to measure the minute differences in pressure that would occur at the limb due to the gradated framed thickness. This shortcoming led to the FEA approach.

4.4. Future Work

The fabrication of NU-FlexSIV or similar sockets with the NUPOC Stratasys FDM system is limited until Stratasys updates its material choices. The mechanical properties of four plastics available to the Stratasys system can be seen below in Table 4.1 (Stratasys, 2014; Komolafe et al., 2014).

Table 4.1. Flexural moduli of frame and potential frame materials

Material	**Flexural Modulus**
NU-FlexSIV carbon frame	4852 MPa
PC-ABS	1900 MPa
ULTEM 9085	2500 MPa
ABS-M30	2300 MPa
PPSF	2200 MPa

Though PC-ABS was a good material to help display feasiblity, it may be worth fabricating a frame with ULTEM 9085. The flexural modulus of ULTEM 9085 is more than 30% great than that of the PC-ABS, but is still just 51% of the flexural modulus of the NU-FlexSIV carbon frame. An upgrade to the current Stratasys FDM 400 is necessary to fabricate parts with ULTEM 9085 and should be considered if the AM technique is to be iterated.

There is potential to pursue the fabrication of NU-FlexSIV Sockets with the use of other AM systems. A very similar approach to what was designed could be developed using a selective laser sintering (SLS) machine, much like Rogers et al. (2008) used. Rogers et al. (2008) used a Sinterstation Vanguard (3D Systems, Rock Hill, SC) with DuraForm Polyamide. DuraForm Polyamide has a reported flexural modulus of 1387 MPa. Though this is similar to the flexural modulus of the PC-ABS, the demonstrated success of the transtibial sockets fabricated by Rogers et al. (2008) – the sockets were designed by FEA analysis, worn by users, and analyzed in a gait laboratory – indicates potential for the material. Although the success they demonstrated with SLS may be due to the fact that a transtibial socket doesn't require as much flexibility as a transfemoral socket.

Sengeh and Herr (2013) demonstrated the feasibility of fabricating transtibial sockets with an Objet Connex (Stratasys, Ltd., Edina, MN) 3D printer. The Northwestern University Rapid Prototyping Lab houses an Object Connex 350 but was not used due to lack of accessibility and higher costs associated with outsourcing the fabrication of the sockets. The system is capable of printing two materials at once and blending the two materials together. The Objet Connex 350 offers the possibility of (1) directly printing

the socket or (2) directly printing the frame. Sengeh and Herr (2013) noted the heavy weight of their resulting transtibial sockets, indicating that the Objet Connex 350 may best be suited for printing the rigid frame of the NU-FlexSIV Socket. Future research on this topic should focus on using new materials to fabricate prosthetic flexible sockets in order to improve the performance of the sockets during structural testing.

References

Fatone, S. (2010). Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations. Funded by: Department of Defense, #W81XWH-10-0744.

Fatone, S., Caldwell, R., Komolafe, O., and Tucker, K. (2013). Subischial Sockets with Vacuum Assisted Suspension for Persons with Transfemoral Amputation. Instructional Course. In *14th World Congress of the International Society for Prosthetics and Orthotics*, February 4-7, Hyderabad, India.

Faustini, M. C., Crawford, R. H., Neptune, R. R., Rogers, W. E., and Bosker, G. (2005). Design and Analysis of Orthogonally Compliant Features for Local Contact Pressure Relief in Transtibial Prostheses. *Journal of Biomechanical Engineering*, 127(6):946.

Gerschutz, M. J., Haynes, M. L., Nixon, D., and Colvin, J. M. (2012). Strength Evaluation of Prosthetic Check Sockets, Copolymer Cockets, and Definitive Laminated Sockets. *Journal of Rehabilitation Research and Development*, 49(3):405–26.

Herbert, N., Simpson, D., Spence, W. D., and Ion, W. (2005). A Preliminary Investigation into the Development of 3-D Printing of Prosthetic Sockets. *Journal of Rehabilitation Research and Development*, 42(2):141–6.

Hsu, L., Huang, G., Lu, C., Lai, C., Chen, Y., Yu, I., and Shih, H. (2008). The Application of Rapid Prototyping for the Design and Manufacturing of Transtibial Prosthetic Socket. *Materials Science Forum*, 594:273–280.

Hsu, L. H., Huang, G. F., Lu, C. T., Hong, D. Y., and Liu, S. H. (2010). The Development of a Rapid Prototyping Prosthetic Socket Coated with aResin Layer for Transtibial Amputees. *Prosthetics and Orthotics International*, 34(1):37–45.

Jia, X., Zhang, M., and Lee, W. C. C. (2004). Load Transfer Mechanics bBetween Transtibial Prosthetic Socket and Residual Limb–Dynamic Effects. *Journal of Biomechanics*, 37(9):1371–7.

Komolafe, O., Caldwell, R., Hansen, A., and Fatone, S. (2014). A Finite Element Analysis of Rigid Frame Designs for Transfemoral Prosthetic Sockets. Manuscript submitted for publication. *Journal of Rehabilitation Research and Development*.

Lee, W. C. C., Zhang, M., Jia, X., and Cheung, J. T. M. (2004). Finite Element Modeling of the Contact Interface Between Trans-tibial Residual Limb and Prosthetic Socket. *Medical Engineering and Physics*, 26(8):655–62.

Lehneis, H. R., Chu, D. S., and Adelglass, H. (1984). Flexible Prosthetic Socket Techniques. *Clinical Prosthetics and Orthotics*, 8(1):6–8.

Rogers, B., Bosker, G., Faustini, M., Walden, G., Neptune, R. R., and Crawford, R. (2008). Case Report: Variably Compliant Transtibial Prosthetic Socket Fabricated Using Solid Freeform Fabrication. *JPO: Journal of Prosthetics and Orthotics*, 20(1):1–7.

Rogers, B., Gitter, A., Bosker, G., Faustini, M., Lokhande, M., and Crawford, R. (2001). Clinical Evaluation of Prosthetic Sockets Manufactured by Selective Laser Sintering. In *2001 Solid Freeform Fabrication Symposium Proceedings*, Austin, TX.

Rogers, B., Stephens, S., Gitter, A., Bosker, G., and Crawford, R. (2000). Double-wall, Transtibial Prosthetic Socket Fabricated Using Selective Laser Sintering: A Case Study. *JPO: Journal of Prosthetics and Orthotics*, 12(3):97–103.

Sanders, J. E., Harrison, D. S., Allyn, K. J., and Myers, T. R. (2009). Clinical Utility of In-socket Residual Limb Volume Change Measurement: Case Study Results.

Sengeh, D. M. and Herr, H. (2013). A Variable-Impedance Prosthetic Socket for a Transtibial Amputee Designed from Magnetic Resonance Imaging Data. *JPO: Journal of Prosthetics and Orthotics*, 25(3):129–137.

Stratasys. (2014) PC-ABS. Retrieved February 22, 2014 from http://www.stratasys.com/ /media/Main/Secure/Material Specs MS/Fortus-Material-Specs/Fortus-MS-PC-ABS-01-13-web.pdf.

Stratasys. (2014) ABS-M30. Retrieved February 22, 2014 from http://www.stratasys.com/ /media/Main/Secure/Material%20Specs%20MS/Fortus-Material-Specs/Fortus-MS-ABS-M30-01-13-web.pdf.

Stratasys. (2014) ULTEM. Retrieved February 22, 2014 from http://www.stratasys.com/ /media/Main/Secure/Material%20Specs%20MS/Fortus-Material-Specs/FortusUltem9085MaterialSpecSheet-US-ENG-1-14%20Web.pdf.

Tay, F. E., Manna, M., and Liu, L. (2002). A CASD/CASM Method for Prosthetic Socket Fabrication Using the FDM Technology. *Rapid Prototyping Journal*, 8(4):258–262.

WillowWood (2012). Evaluate the Static Strength of AK Prosthetic Sockets Using a Modified ISO 10328 Configuration II A125 Test Set-up. Report.

WillowWood (2014b). Combined Charts and Tables of AK Socket Testing Conducted at Ohio Willow Wood on 11/5/2012 (NU-1, NU-2, NU-3) & 1/27-28/2014 (H1, H2, H3, AM2).

WillowWood (2014a). Evaluate the Static Strength of AK Prosthetic Sockets Using a Modified ISO 10328 Configuration II A125 Test Set-up. Report.

Zachariah, S. G. and Sanders, J. E. (2000). Finite Element Estimates of Interface Stress in the Trans-tibial Prosthesis Using Gap Elements are Different from those Using Automated Contact. *Journal of Biomechanics*, 33:895–899.

Zhang, M., Lord, M., Turner-Smith, A. R., and Roberts, V. C. (1995). Development of a Non-linear Finite Element Modelling of the Below-knee Prosthetic Socket Interface. *Medical Engineering and Physics*, 17:559–566.

APPENDIX F – ROBILLARD POSTERS AND ABSTRACTS

Presenting Author: Brian J Robillard, BS
Position: Student
Principal Investigator: Stefania Fatone, PhD, BPO (Hons)
Department: Physical Medicine and Rehabilitation
Clinical, or Basic Science, or Public Health and Social Sciences: Basic Science
Email:

Title: Design of a Process for Fabricating Prosthetic Sockets with Rapid Prototyping Technology

Summary: The conventional process used in prosthetic socket fabrication is a time intensive, manual technique that involves saturating reinforced fabric layups (e.g. Aralon™, SpectraCarb™, cotton, nylon stockinettes and Dacron felt) with resins. The resulting prostheses have a demonstrated utility for users, but they may be improved by incorporating advanced manufacturing techniques into the fabrication process. Specifically, in the fabrication of flexible sockets using strategically designed rigid frames, conventional processes do not allow for precise control of thickness, nor for a smooth transition between the flexible and rigid layers. The development of rapid prototyping technology as an efficient fabrication technique has presented the opportunity to address the limitations of the manual process. With improved control of the socket dimension parameters (e.g. socket thickness), rapid prototyping has the ability to create a more comfortable and durable prosthetic socket

Objective: The purpose of this study was to explore feasible processes of fabricating transfemoral sub-ischial prosthetic sockets with flexible inner sleeves and rigid outer frames using rapid prototyping technology.

Methods: Computer aided design software (SolidWorks 2011) was used to process a scan of a transfemoral residual limb clad with a silicone liner. The scan was scaled to 50 percent of its original size to speed-up fabrication. The liner surface was modified by surface offsetting, thickening, deleting, and shelling to create a series of molds with inner cores and outer cavities. The computer models were processed by the rapid prototyping software (Insight 8.1) in .STL format and sent to a Stratasys 400mc fused deposition modeling system. The slice heights of the models were either 0.178 mm or 0.254 mm. The molds were filled with Poly PT Flex 60 for the flexible layer and Smooth-Cast 385 for the rigid frame.

Results: A total of six molds have been fabricated to-date in the Stratasys 400mc system. Three of the molds are designed so that the cavity will be separated from the core in the horizontal direction (horizontal approach), and the remaining three of the molds are designed so that the cavity will be separated from the core in the vertical direction (vertical approach).

Conclusions: The Stratasys 400mc system is capable of producing molds that resemble the geometry of conventionally fabricated prosthetic sockets. The rapid prototyping mold fabrication process is easily repeatable, as all models are stored digitally. The pouring of the molds is ongoing. Future work will include finish the pouring the molds, determining the mechanical properties of the fabricated sockets, and demonstrating the process on a full-sized socket.

Fabricating Prosthetic Sockets with Rapid Prototyping Technology

Brian Robillard, BS, Oluseeni Komolafe, PhD, Ryan Caldwell, CP,
Stefania Fatone, PhD, BPO(Hons)

Research Need and Aims

The conventional process used in prosthetic socket fabrication is a time intensive, manual technique that does not allow for precise control of the resulting socket's dimension parameters. Control of dimension parameters allows for gradated transitions between the rigid and flexible regions of sockets, which may prevent stress concentrations at transition points and improve the health of the residual limb of persons with lower limb amputation. The development of rapid prototyping technology (RPT) as an efficient fabrication technique presents the opportunity to create a more comfortable and durable prosthetic socket through improved control of socket dimension parameters. The purpose of this study was to utilize RPT to fabricate transfemoral sub-ischial prosthetic sockets with flexible inner sleeves and rigid outer frames. Our approach comprised of the following specific aims: (1) exploring the feasibility of different approaches to automated fabrication of prosthetic sockets; (2) developing an efficient automated fabrication technique for socket fabrication utilizing our in-house Stratasys fused deposition modeler; and (3) evaluating the sockets fabricated using the Stratasys system to examine the effect of precisely controlled dimension parameters on socket comfort and residual limb stress distributions. This presentation focuses on results to date of specific aims 1 and 2.

Preliminary Results and Commercialization

To date, two prosthetic sockets have been fabricated. The approach to fabricating these molds includes the following steps:

1. Acquire geometry of transfemoral residual limb clad with a silicon liner via Creaform 3D MegaCapturor
2. Process the geometry in SolidWorks to create models of molds; send to Stratasys using Insight 8.1
3. Fabricate the molds in Stratasys; for iterative purposes, molds are scaled to 50 percent
4. Pour the molds under vacuum pressure
    a. First pour: flexible sleeve; Second pour: rigid frame

Though the resulting sockets mimic the appearance of manually fabricated prosthetic sockets, the design process needs to be further developed in order to fabricate wearable sockets that can be introduced to the marketplace. The path to commercialization involves the following steps: improve mold closure, standardize the pouring process, select more appropriate materials, automate the computer aided design (CAD) process, fabricate full-scale sockets, and potentially revise socket design based on results of clinical testing. Once these steps have been completed, the efficient fabrication of a prosthetic socket will be possible with access to a scanner, CAD software, rapid prototyping system, and off-the-shelf materials.

Fabricating Prosthetic Sockets with Rapid Prototyping Technology

Brian Robillard, BS, Oluseeni Komolafe, PhD, Ryan Caldwell, CP, Stefania Fatone, PhD, BPO(Hons)

Northwestern University Prosthetics-Orthotics Center (NUPOC)

NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE

NORTHWESTERN UNIVERSITY

Background

Prosthetic socket fabrication is a time intensive process heavily dependent on the craftsmanship skill of the prosthetist. The novel subischial prosthetic socket requires an improved control over socket dimensions parameters to maximize flexibility and comfort.

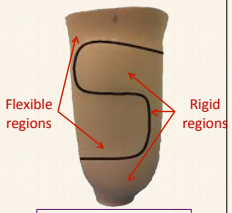
Purpose of the Study

To explore two mold orientation processes for fabricating a subischial transfemoral prosthetic socket with a flexible inner sleeve and a rigid outer frame using rapid prototyping technology.

Introduction

Manual Fabrication of Transfemoral Prosthesis

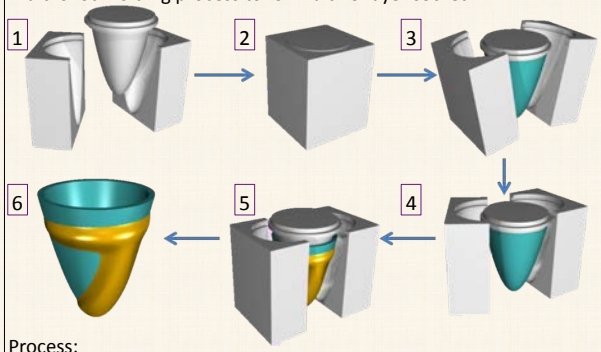
- Drawbacks:
  - Time and resource intensive
  - Requires expert prosthetist
  - Little control of socket dimension parameters (e.g. thickness)
- Fabricated socket:
  - Rigid frame sandwiched between two flexible layers



Subischial prosthetic socket

Proposed Solution (Highlighted for Horizontal Approach)

Multi-shot molding process to form a two-layer socket



Process:

1. Inner core and inner cavity form the flexible sleeve
2. Mold is poured
3. Inner cavity is removed; inner core and sleeve remain
4. Inner core and outer cavity form the rigid frame
5. Mold is poured
6. Inner core and outer cavity are removed; socket remains

Methods/Results

1. Model design with CAD software (SolidWorks 2011)

Horizontal Approach



Separate cavity horizontally | Inner core | Inner cavity | Outer cavity

Vertical Approach



Separate cavity vertically | Inner core | Inner cavity | Outer cavity

2. Fabrication in Stratasys Fortus 400mc fused deposition modeler

Horizontal Approach



Inner core | Inner cavity | Outer cavity

Vertical Approach



Inner core | Inner cavity | Outer cavity

3. Pour Process

Fabrication of flexible sleeve



Prepare molds by spraying with demolder



Clamp core and cavity; attach plastic bag to pour hole



Introduce vacuum pressure to the system

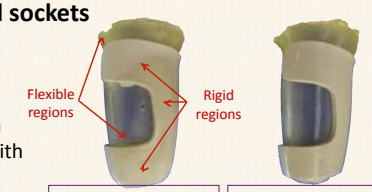


Mix material* and insert into mold

*Poly PT Flex 60 for flexible layer; Smooth-Cast 385 for rigid layer

Results: Fabricated sockets

- Rigid material is heavy and brittle
- Leaking issues with horizontal approach
- Demolding issues with vertical approach



Horizontal approach | Vertical approach

Conclusions

The multi-shot molding process designed to fabricate a two-layer prosthetic socket has a demonstrated feasibility, but the process needs to be further developed in order to fabricate wearable sockets. The next steps in the design process include the following: improve mold closure, standardize pouring process, fabricate full scale socket, select new materials, and automate CAD process.

Funding Acknowledgement

Award #W81XWH-10-1-0744

The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. The content of this presentation does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred.

Biomedical Engineering Society Annual Meeting, 2013

Fabricating Prosthetic Sockets with Rapid Prototyping Technology

Brian Robillard, BS, Oluseeni Komolafe, PhD, Ryan Caldwell, CP, Stefania Fatone, PhD, BPO(Hons)

Northwestern University Prosthetics-Orthotics Center (NUPOC)

NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE

McCormick Northwestern Engineering

Biomedical Engineering

Background

The conventional process used in prosthetic socket fabrication is a time intensive, manual technique that does not allow for precise control of the resulting socket's dimension parameters and depends on the craftsmanship of highly skilled prosthetists.

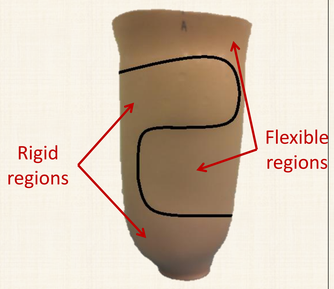
Purpose of the Study

To develop a process for fabricating a subischial transfemoral prosthetic socket with a flexible sleeve and a rigid frame using rapid prototyping technology.

Introduction

Manual Fabrication of a Transfemoral Prosthetic Socket

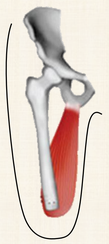
- Drawbacks:
  - Time and resource intensive
  - Requires expert prosthetist
  - Little control of socket dimension parameters (e.g. thickness)
- Socket Design
  - Rigid frame sandwiched between two flexible layers



Subischial prosthetic socket

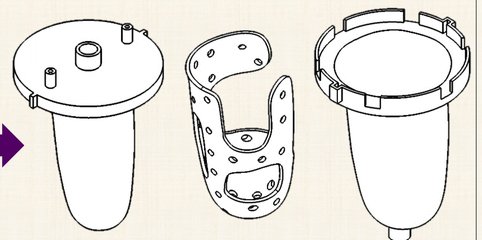
Approach Overview

1. Scan of residual limb



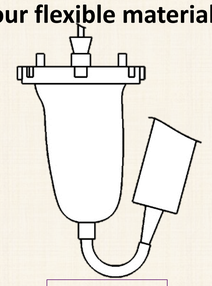
Transfemoral residual limb

2. Design with SolidWorks



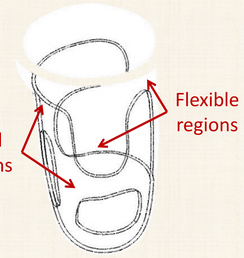
Core | Frame | Cavity

3. Build components with Stratasys and pour flexible material



Pour setup

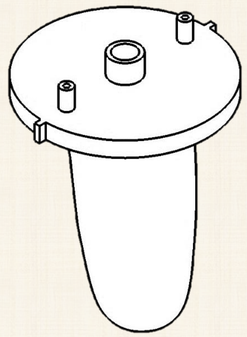
4. Fabricated Socket



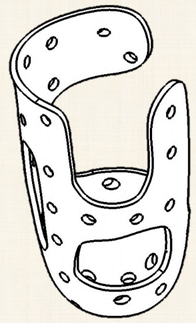
Flexible transfemoral socket

Methods/Results

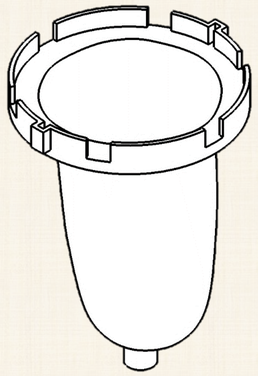
Mold design with CAD software (SolidWorks 2011)



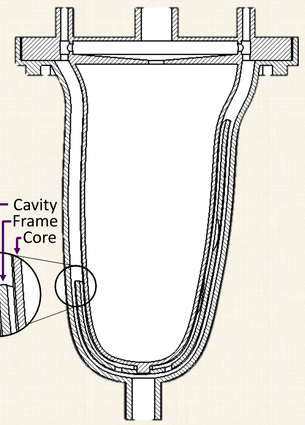
Core



Frame



Cavity



Cross section of mold setup

Fabrication in Stratasys Fortus 400mc Fused Deposition Modeler

Slice height: 0.25 mm; Build material: PC-ABS

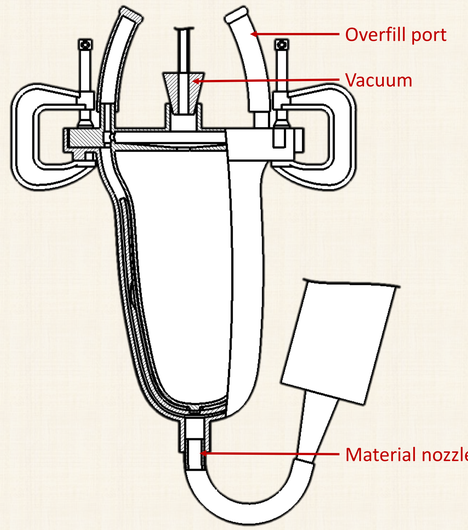


Core | Frame | Cavity

Pour Process

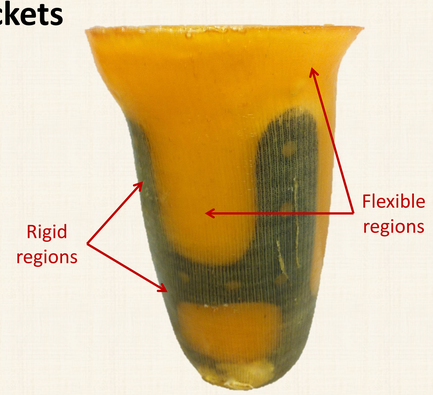
Fabrication of socket with single-shot molding technique

- Flexible material:
  - Fibre Glast Urethane Casting Resin
- Vacuum pressure:
  - Prevents air bubbles and air pockets
- Overfill ports:
  - Ensure complete saturation
- Pour time:
  - 5 minutes to pour
  - Overnight cure



Results: Fabricated sockets

- Minimal air bubbles
- Minimal air sockets
- No issues with demolding



Conclusions

The single-shot molding process designed to fabricate a two-layer prosthetic socket has demonstrated feasibility, but the socket's clinical applicability remains to be determined. The next steps in the project include the following: material and failure testing on the rapid prototyped socket with results compared to a manually fabricated socket.

Funding Acknowledgement

Award #W81XWH-10-1-0744

The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. The content of this presentation does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred.

APPENDIX G – WILLOWWOOD SOCKET EVALUATION REPORT

WillowWood
15441 Scioto Darby Road
P.O. Box 130
Mt. Sterling, OH 43143

TEST: AK SOCKET EVALUATION
DATE: 11/5/2012

SUBJECT: Evaluate the static strength of AK prosthetic sockets using a modified ISO 10328 Configuration II A125 test set-up

TESTING NOTES:

(1) The sockets were arbitrarily labeled NU-1, NU-2 and NU-3.

(2) All three sockets fitted the test model well. No visual presence of gapping or non-distal contact.

(3) Socket measurements were collected prior to testing. Measurements were taken in relatively the same location on each socket.

	Socket ID		
	NU-1	NU-2	NU-3
A1	7.85	8.20	7.60
A2	4.40	3.65	4.30
A3	7.85	7.25	6.90
A4	4.50	3.70	4.30
M1	7.30	6.70	7.90
P1	3.50	4.35	3.70
P2	3.30	4.30	3.20
L1	4.45	5.00	4.35

General Notes
Measurements were take in the same relative area.

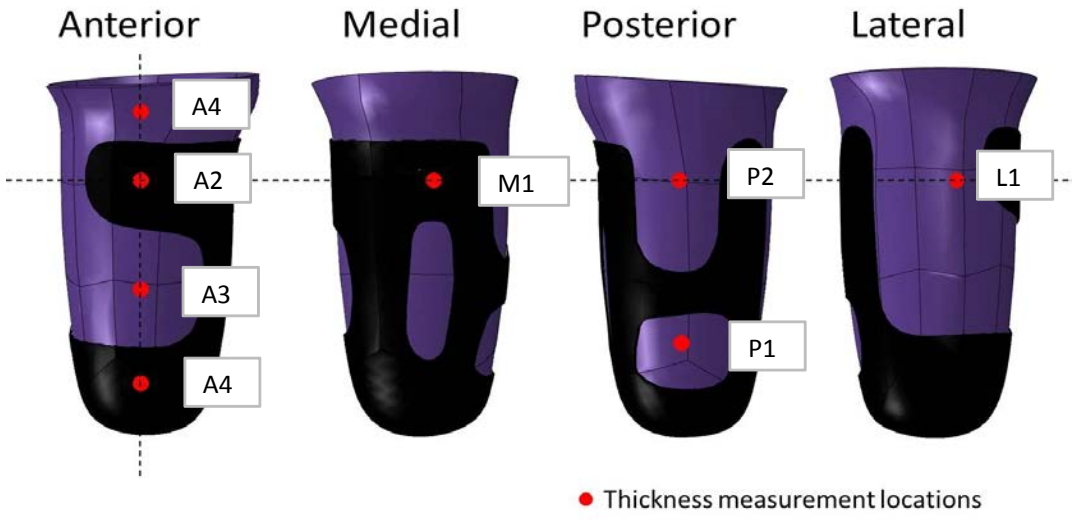


Figure 1: Thickness Measurements

WillowWood
15441 Scioto Darby Road
P.O. Box 130
Mt. Sterling, OH 43143

TEST: AK SOCKET EVALUATION
DATE: 11/5/2012

TEST PARAMETERS: The static test was conducted in accordance with ISO 10328 Configuration II A125 with the anterior in tension and posterior in compression. The sockets were tested to failure.



Figure 2: Socket set-up

RESULTS: All three sockets failed at the distal adapter location. The distal adapter was pulled out of the socket. For two of the sockets (NU-2 and NU-3), the distal adapter pulled completely out of the socket.



Figure 3: NU-1 distal adapter failure



Figure 4: NU-2 distal adapter failure



Figure 5: NU-3 distal adapter failure

Even though it is not visible in the video, one of the test technicians commented that the distal posterior area (close to P1 on the thickness measurements) exhibited a buckling effort. The soft structural material in this area flexed upon itself. Pictures below indicate the effects upon this area. A slight crease was visible on the exterior and interior of the socket.

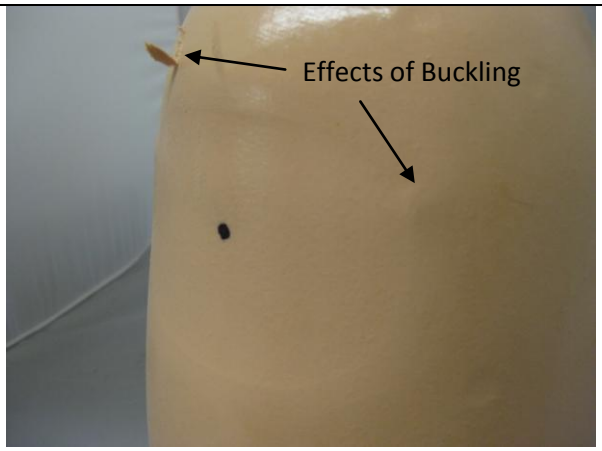


Figure 6: NU-2 Posterior portion after testing

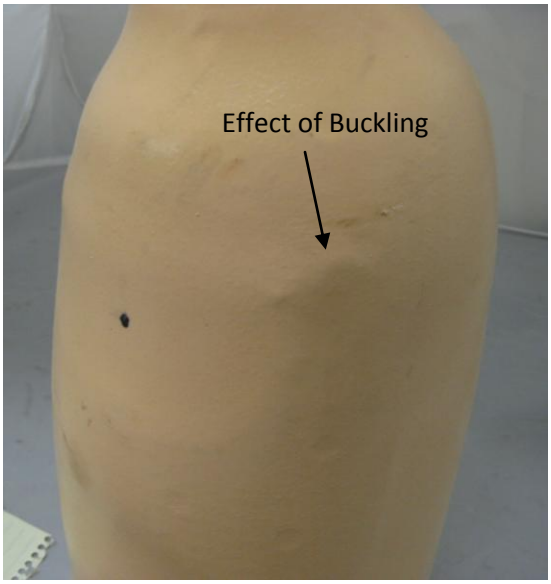
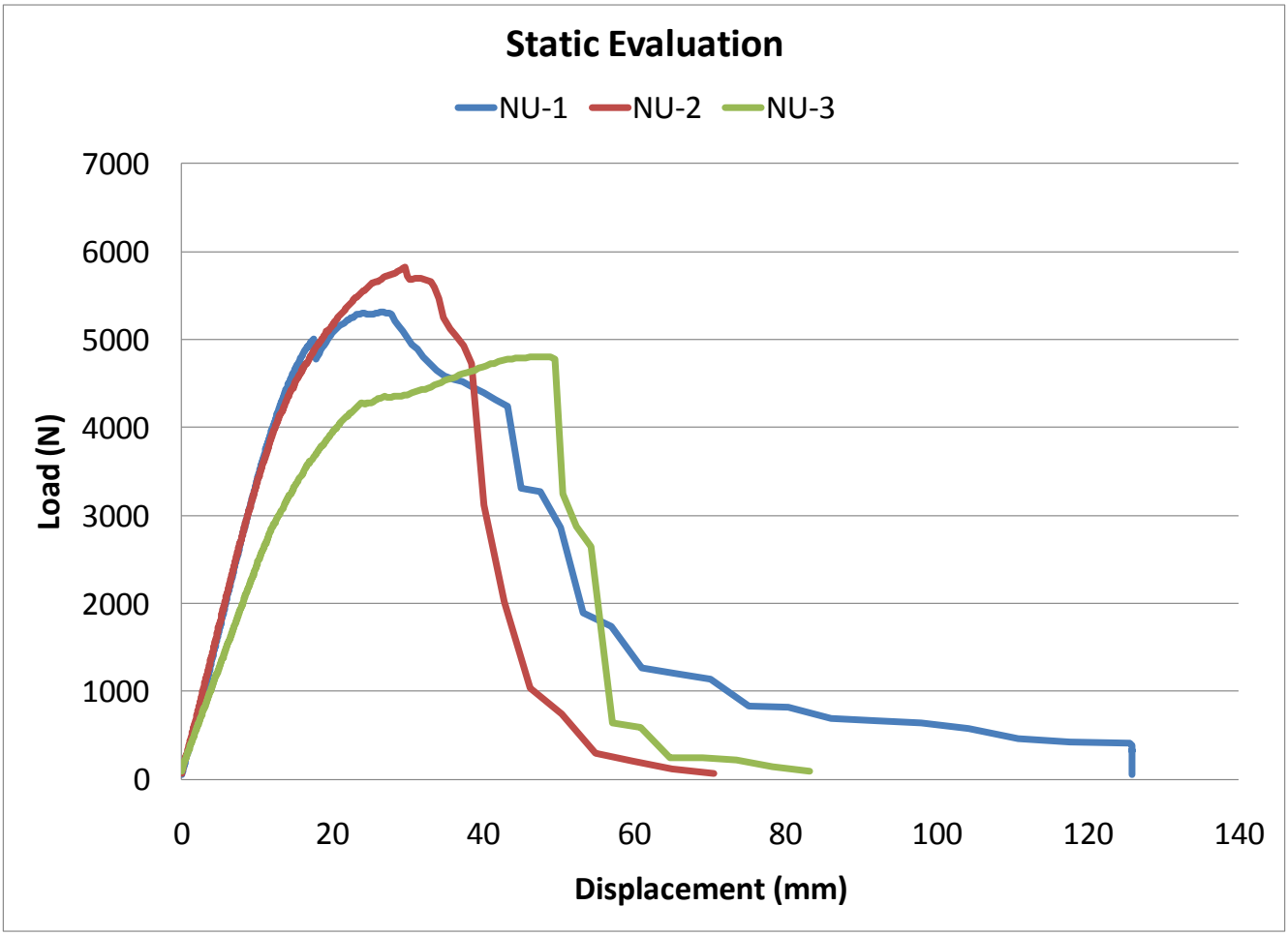


Figure 7: NU-3 Posterior portion after testing

The force deflection curve for all three sockets is provided below. The yield strength and compression point were determined from the force deflection curves. Yield strength was defined as the location where plastic deformation occurs (location where the initial linear characteristic portion of the curve deviates). The yield strength was used in a previous study to evaluate sockets that failed in a ductile mode. The compression point is either a deformation peak or plateau change after the initial linear portion of the curve. The compression point was used in a previous study to evaluate sockets that failed in brittle mode. The ISO 10328 Configuration II A125 passing criteria for brittle failure is 4426 N and for ductile failure is 3421N. Prosthetic sockets are not subjected to any standard including ISO 10328. ISO 10328 is intended for structural components that would normally be attached to a socket. Visually, the sockets exhibited some ductile characteristics by deforming prior to breaking. The force deflection curves for the tested sockets also displayed this slight tendency towards a ductile failure. The curves illustrated a small deformation after the linear portion of the curve prior to a peak or plateau change. NU-1 exhibited more of a distinct peak than the other two sockets. The displacement range for all three sockets were similar to the carbon transtibial sockets tested in another study. Previously tested transtibial carbon sockets were classified as having brittle failures.

WillowWood
15441 Scioto Darby Road
P.O. Box 130
Mt. Sterling, OH 43143

TEST: AK SOCKET EVALUATION
DATE: 11/5/2012



	Yield Strength (Inflection Point)		Compression Point (Deformation Peak or Plateau Change)	
	mm	N	mm	N
NU-1	13.02	4240.93	17.41	5005.49
NU-2	12.28	3978.11	29.62	5817.83
NU-3	13.69	3141.87	23.81	4276.77
	Ave	*3786.97*	*Ave*	*5033.36*
	Stdev	*573.92*	*Stdev*	*770.908*

Supplementary Information:

Video: Socket 1 video; Socket 2 video; Socket 3 video

Pictures: Socket 1_1 to Socket 1_3; Socket 2_1 to Socket 2_8; Socket 3_1 to Socket 3_8

WillowWood
15441 Scioto Darby Road
P.O. Box 130
Mt. Sterling, OH 43143

TEST: AK SOCKET EVALUATION
DATE: 11/5/2012

APPENDIX H – COPYRIGHT REGISTRATION FOR MULTI-MEDIA INSTRUCTIONAL MANUAL FOR NU-FLEXSIV SOCKET

Certificate of Registration

This Certificate issued under the seal of the Copyright Office in accordance with title 17, *United States Code*, attests that registration has been made for the work identified below. The information on this certificate has been made a part of the Copyright Office records.

Maria A. Pallante

United States Register of Copyrights and Director

Registration Number
TX 8-250-832
Effective Date of Registration:
July 23, 2015

Title

Title of Work: Instruction Manual for NU-FlexSIV Socket

Completion/Publication

Year of Completion: 2015
Date of 1st Publication: April 27, 2015
Nation of 1st Publication: United States

Author

- **Author:** Stefania Fatone
  Author Created: text, photograph(s), artwork, video
  Citizen of: Australia

- **Author:** Ryan Caldwell
  Author Created: text, photograph(s), artwork, video
  Citizen of: United States

Copyright Claimant

Copyright Claimant: Stefania Fatone
680 North Lake Shore Drive, Suite 1100, Chicago, IL, 60611, United States

Copyright Claimant: Ryan Caldwell
680 North Lake Shore Drive, Suite 1100, Chicago, IL, 60611, United States

Limitation of copyright claim

Material excluded from this claim: artwork

New material included in claim: text, photograph(s), artwork, video

Rights and Permissions

Name: Stefania Fatone
Email: s-fatone@northwestern.edu
Telephone: (312)503-5720
Address: Northwestern University Prosthetic-Orthotics Center

680 North Lake Shore Drive, Suite 1100
Chicago, IL 60611

Certification

Name: Stefania Fatone
Date: July 17, 2015
Applicant's Tracking Number: 1-2562517061

Correspondence: Yes



APPENDIX I – AAOP 2013 POSTER AND ABSTRACT

Role of Socket Design, Flexibility and Suspension in Transfemoral Sockets during Walking

S. Fatone, PhD, BPO(Hons), J. Howell, CPO, R. Caldwell, CPO, O. Komolafe, PhD, R. Stine, MS

NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE

NORTHWESTERN UNIVERSITY

Background

Socket Design



Ischial Containment (IC) sockets encompass the pelvis and hip joint limiting hip range of motion and compromising comfort (Tranberg et al. 2011). With the advent of vacuum-assisted suspension (VAS) there has been an increasing interest in brimless sockets (Kahle 2002; Fairley 2008; Strachan et al. 2011; Kahle & Highsmith 2011, 2012).

Purpose of the Study

By systematically altering an IC socket, the purpose of this case study was to assess the role socket brim and flexibility have on stability, comfort, suspension and gait parameters during walking.

Methods

Subject

- 29 year old male with a unilateral transfemoral amputation due to trauma (height 182cm; weight 83.3kg).
- Relatively long residual limb (48% of leg length) with firm skin tissue.

Apparatus

- 8 camera motion analysis system (Motion Analysis Corporation)
- 6 force plates (AMTI) embedded in the middle of a 12m walkway.

Intervention

- An IC socket (modified NU/RIC design) with silicone seal-in suction suspension and one-way valve.
- Constructed of a rigid carbon frame with posterior U-shaped fenestration and 1.5" Dacron strap over gluteal region; and flexible thermoplastic inner socket with ½" flexible brim extending proximal to the carbon frame.
- Subject was assessed by a Certified Prosthetist as having total contact and appropriate containment in the socket.
- Prosthetic alignment was unchanged for conditions 1 to 6.
- Prosthetic components for all test conditions included a C-leg with torsion pylon (Otto Bock) and Highlander foot (Freedom Innovations).

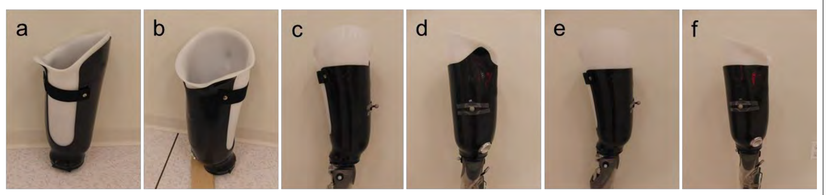
Funding Acknowledgement

Award #W81XWH-10-1-0744. The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. The content of this presentation does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred.

Procedures

- Gait analysis was conducted on a single day.
- Helen Hayes marker set was used (Kadaba et al. 1989).
- Subject walked at comfortable self-selected speed in 7 socket conditions:

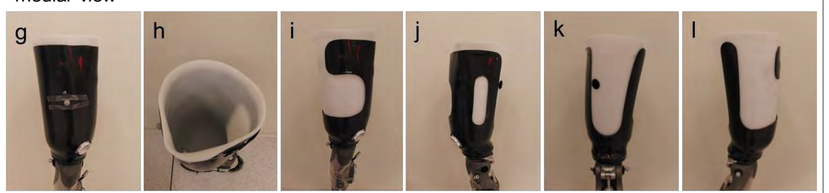
1. Intact IC socket (a,b);	
2. IC socket with lateral proximal frame removed (c,d);	5. Brimless socket with more flexible frame (i, j, k, l);
3. IC socket with anterior medial frame removed (e,f);	6. Condition 5 with VAS (e-pulse, Otto Bock);
4. Brimless socket with rigid frame (g,h);	7. Condition 6 with alignment adjustment.



Condition 1: (a) posterior lateral view (b) posterior medial view

Condition 2: (c) lateral view (d) anterior view

Condition 3: (e) lateral view (f) anterior view



Condition 4: (g) anterior view (h) superior view

Condition 5: (i) anterior view (j) medial view (k) posterior view (l) lateral view

Data Analysis

For each socket condition we recorded:

- Subjective comments
- Socket Comfort Score (Hanspal et al. 2003)
- Walking speed - assessed as an indicator of overall function
- Step width - assessed as an indicator of coronal socket stability
- Maximum lateral trunk lean during prosthetic limb stance - assessed indicator of coronal plane socket stability
- Swing phase foot rotation range of motion - assessed as an indicator of socket suspension

Results

Relationship Between Variables

- Socket comfort score and step width (r = 0.6)
- Socket comfort score and maximum lateral trunk lean during prosthetic side stance (r = 0.7)
- Socket comfort score and walking speed (r = -0.35)
- All other correlations were poor.

Socket	SCS	Comments	Speed (m/s)	Step Width (cm)	Max Lateral Trunk Lean (degrees)	Swing Foot Rotation ROM (degrees)
1	2	Lots of pressure on IT	1.7	15.4	**2.6**	12.0
2	2	Still pressure on IT	1.6	15.6	3.4	12.0
3	5	Still pressure on IT but not as bad, alignment is off – toes are too in	1.7	**14.2**	4.3	**10.7**
4	4	Socket more comfortable but foot feels too far back	1.7	15.1	4.0	15.5
5	2	Socket feels like it wants to come off	1.6	17.9	3.2	12.7
6	4	Way better, rotational wobble gone	1.7	15.0	3.3	15.7
7	**6**	That's more like it!	**1.8**	16.3	3.7	10.9

Results for socket conditions #1 to #7. Bold indicates "best" result for each variable, red indicates the "worst" result. IT = ischial tuberosity. SCS = socket comfort score (0 = least comfortable; 10 = most comfortable).

Discussion

- Removing the brim of an IC socket alters gait.
- Although socket comfort score seemed to relate well to the biomechanical data, other subjective comments did not.
- For this subject no one condition clearly provided the greatest comfort, fastest speed, smallest step width, least coronal plane trunk motion in prosthetic stance and least transverse plane foot motion in swing.

References

Fairley M. The O&P Edge, March 2008.
Hanspal et al., Disabil Rehabil 25(22):1278-80, 2003.
Kadaba et al. J Orthop Res 7:849-860, 1989.
Kahle & Highsmith, 37th AAOP Meeting, 2011.
Kahle & Highsmith, 38th AAOP Meeting, 2012.
Kahle J. Prosthet Orthot 14(3):121-6, 2002.
Strachan et al., 37th AAOP Meeting, 2011.
Tranberg et al., Gait Posture 33(2):165-8, 2011.

Role of Socket Design, Flexibility and Suspension in Transfemoral Sockets during Walking

Fatone S[1], Howell J[2], Caldwell R[1], Komolafe O[1], Stine R[1,3]

[1]Northwestern University, Chicago IL; [2]Baylor College of Medicine, Houston TX; [3]Jesse Brown VA Medical Center, Chicago, IL

INTRODUCTION

Ischial Containment (IC) sockets encompass the pelvis and hip joint limiting hip range of motion and compromising comfort (Tranberg et al. 2011). With the advent of vacuum-assisted suspension (VAS) there has been an increasing interest in brimless sockets (Kahle 2002; Fairley 2008; Strachan et al. 2011; Kahle & Highsmith 2011, 2012). The purpose of this case study was to assess the role the brim and flexibility of the socket have on stability, comfort, suspension and gait parameters during walking.

METHOD

Subject: 29 year old male with a unilateral transfemoral amputation due to trauma (height 182cm; weight 83.3kg). Relatively long residual limb (48% of leg length) with average to firm skin tissue.

Apparatus: 8 camera motion analysis system (Motion Analysis Corporation) with 6 force plates (AMTI) embedded in the middle of a 12m walkway.

An IC socket with modified NU/RIC design, silicone seal-in suction suspension and one-way valve was used as the starting point (Fig 1). Socket was constructed of (1) a rigid carbon frame with posterior U-shaped fenestration and 1.5" Dacron strap over gluteal region; and (2) flexible thermoplastic inner socket with ½" flexible brim extending proximal to the carbon frame. Subject was assessed by a Certified Prosthetist as having total contact and appropriate containment in the socket. Prosthetic alignment was unchanged for conditions 1 to 6. Prosthetic components for all test conditions included a C-leg with torsion pylon (Otto Bock) and Highlander foot (Freedom Innovations).

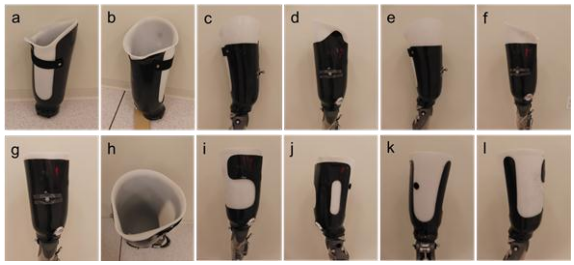


Figure 1. Viewing angle: Condition 1: (a) posterior lateral (b) posterior medial. Condition 2: (c) lateral (d) anterior. Condition 3: (e) lateral (f) anterior. Condition 4: (g) anterior (h) superior. Condition 5: (i) anterior (j) medial (k) posterior (l) lateral.

Procedures: Gait analysis was conducted on a single day. Subject walked at a comfortable self-selected speed in 7 socket conditions: (1) intact IC socket; (2) IC socket with lateral proximal frame removed; (3) IC socket with anterior medial frame removed; (4) brimless socket with rigid frame; (5) brimless socket with more flexible frame; (6) condition 5 with VAS (e-pulse, Otto Bock); (7) condition 6 with alignment adjustment.

Data Analysis: We recorded subjective comments, Socket Comfort Score (0 represents the most uncomfortable socket fit imaginable and 10 represents the most comfortable socket fit) (Hanspal et al. 2003), walking speed, stride width, and maximum lateral trunk lean in prosthetic stance for each socket condition.

RESULTS

Socket	SCS	Comment	Speed (m/s)	Step Width (cm)	Max Lateral Trunk Lean (degrees)
#1	2	Lots of pressure on IT	1.71	15.44	**2.6**
#2	2	Still pressure on IT	1.64	15.57	3.4
#3	5	Still pressure on IT but not as bad, alignment is off – toes are too in	1.65	**14.23**	4.3
#4	4	Socket more comfortable but foot feels too far back	1.69	15.13	4.0
#5	2	Socket feels like it wants to come off	1.63	17.94	3.2
#6	4	Way better, rotational wobble gone	1.71	14.98	3.3
#7	**6**	That's more like it!	**1.84**	16.3	3.7

Table 1. Results for conditions #1 to #7. Bold indicates "best" result for each variable, underline indicates the "worst" result. IT = ischial tuberosity. SCS = socket comfort score.

DISCUSSION/CONCLUSION

Subjective comments and data did not match exactly. No one condition clearly provided the greatest comfort, fastest speed, smallest step width and least coronal plane trunk motion for this subject. However, removing the lateral and medial walls affected stability as suggested by increased lateral trunk lean.

CLINICAL APPLICATIONS

Removing the brim of an IC socket appears to affect gait if VAS is not used.

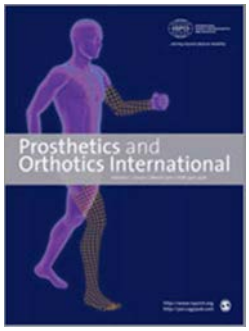
REFERENCES

Tranberg et al., Gait Posture 33(2):165-8, 2011.
Kahle & Highsmith, 37th AAOP Meeting, 2011.
Strachan et al., 37th AAOP Meeting, 2011.
Kahle & Highsmith, 38th AAOP Meeting, 2012.
Kahle J. Prosthet Orthot 14(3):121-6, 2002.
Fairley M. The O&P Edge, March 2008.
Hanspal et al., Disabil Rehabil 25(22):1278-80, 2003.

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

American Academy of Orthotists & Prosthetists
39th Academy Annual Meeting and Scientific Symposium
February 20-23, 2013

APPENDIX J – ACCEPTED MANUSCRIPT: PROSTHETICS AND ORTHOTICS INTERNATIONAL, PART 2 PRELIMINARY EVALUATION



NORTHWESTERN UNIVERSITY FLEXIBLE SUBISCHIAL VACUUM SOCKET FOR PERSONS WITH TRANSFEMORAL AMPUTATION: PART 2 PRELIMINARY EVALUATION

Journal:	*Prosthetics & Orthotics International*
Manuscript ID	TPOI-2016-0082
Manuscript Type:	Technical Note
Keywords:	prosthetic design < prosthetics, biomechanics of prosthetic/orthotic devices < biomechanics
Author-supplied Keywords:	artificial limb, prosthetic socket, gait, transfemoral amputation

SCHOLARONE™
Manuscripts

Abstract

Current transfemoral prosthetic sockets are problematic as they restrict function, lack comfort, and cause residual limb problems. Development of a subischial socket with lower proximal trim lines is an appealing way to address this problem and may contribute to improving quality of life of persons with transfemoral amputation. Therefore, the purpose of this study was to (1) describe the design and fabrication of a new subischial socket, (2) describe efforts to teach this technique, and (3) illustrate socket use in two subjects. The third aim is presented in this Part 2 article, while the first two aims are presented in the Part 1 article. Two unilateral transfemoral prosthesis users participated in preliminary socket evaluations comparing functional performance of the new subischial socket to ischial containment sockets. Testing included gait analysis, socket comfort score and performance-based clinical outcome measures (Rapid-Sit-To-Stand, Four-Square-Step-Test and Agility T-Test). For both subjects, comfort was better in the subischial socket, while gait and clinical outcomes were generally comparable between sockets. While ~~it~~ these evaluations ~~appears~~ are promising regarding the ability to function in this new socket design, more definitive evaluation is needed.

Word Count: ~~209~~183

Introduction

Current transfemoral (TF) prosthetic sockets are problematic as they ~~often~~ restrict function, lack comfort and cause residual limb problems. Lack of socket comfort is the most common complaint of prosthesis users.[~~3-5~~1-3] Traditionally, there have been two basic designs of TF sockets both of which intentionally interact with the pelvis: the 1950s quadrilateral socket and the 1980s ischial containment socket (ICS).[~~9~~4] Because of the pelvic interaction, wearing either socket significantly reduces hip motion compared to motion without a socket.[~~15,16~~5,6] A recent variant of the ICS, the Marlo Anatomical Socket (MAS), combines greater containment (i.e. contact) of the ischial ramus medially with lower anterior and posterior trim lines. While the MAS allows increased hip range of motion compared to either ICS or quadrilateral sockets,[~~17~~7] it still requires interaction with the pelvis. Development of a subischial socket with lower proximal trim lines is an appealing way to address ~~this~~ these problems and may contribute to improving quality of life of persons with TF amputation.

Subischial sockets with vacuum suspension have the potential to provide not only increased hip range of motion and comfort, but also less pistoning between the socket and limb, and better proprioception and tissue health.[~~24-32~~8-16] However, the lower trim lines of subischial sockets challenge conventional understanding of the biomechanics of TF sockets wherein 'locking onto the pelvis' is believed to stabilize the socket in the coronal plane. When coronal plane stability of the socket is poor, the proximal-medial brim impinges on the soft tissues of the groin and the distal femoral end abducts inside the socket uncomfortably contacting the lateral wall.[~~11~~17] To minimize this discomfort and reduce the coronal plane hip joint moment, TF prosthesis users often increase trunk lateral displacement and step width.

Dillon[3318] argued that the ability of any TF socket to provide coronal plane stability may come from *either* ischial ramal containment or compression of the proximal medial soft tissue to increase stiffness. Preliminary research supports the idea that TF sockets without IC rely on soft tissue compression for coronal plane stability, socket comfort, and functional gait.[21,248,19,] A recent study using the MAS showed that both ischial ramal containment and tissue loading contribute to socket comfort: with containment tissue loading did not influence socket comfort, but with no containment the socket was comfortable only when tissue loading was high.[2119] Kahle et al.[248] reported that gait and balance in a brimless socket were equivalent to an ICS, without any of the gait adaptations typically associated with coronal plane instability.

The development of a more comfortable and possibly functional subischial socket may improve the quality of life of persons with TF amputation. While early reports suggest subischial sockets are feasible, no one has yet ~~described~~ illustrated functional performance of a teachable subischial socket technique. Therefore, the purpose of this study was to (1) describe the design and fabrication of a new subischial socket, (2) describe efforts to teach this technique, and (3) illustrate socket use in two subjects. The third aim is presented in this article, while the first two aims are presented in the Part 1 article. In the Part 1 article we described development of a teachable subischial socket technique, the Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket.[20]

Method

With approval from the Northwestern University Institutional Review Board two unilateral TF prosthesis users provided informed consent to participate in preliminary socket evaluation comparing functional performance of the subischial socket and ICS. All data were

acquired in our motion analysis laboratory equipped with eight cameras (Motion Analysis Corporation, MAC, Santa Rosa, CA) and six force-plates (Advanced Mechanical Technology, Inc., Watertown, MA).

Reflective markers were taped to the skin over palpable boney landmarks or prosthetic equivalents using a modified Helen Hayes marker set.[37,21] Specifically, markers were located on the shoe over the dorsum of the foot (between the 2nd and 3rd metatarsals immediately proximal to the metatarsal heads) and the heel counter at the same height as the toe marker; on the lateral malleolus and lateral femoral condyle; on the left and right anterior superior iliac spines (ASIS); and the L5/sacral interface. An additional marker was placed anteriorly on each thigh and shank. For consistency, the same experienced person placed all markers. Static trials were also collected with additional markers placed on the medial malleoli and medial femoral condyles. Medial markers were removed for dynamic trials.

Data were collected as each subject ambulated in each socket at self-selected normal, slow and fast walking speeds over level ground until at least three force-plate strikes were recorded for each foot. EVa RealTime software (MAC, Santa Rosa, CA) was used to determine the three-dimensional position of each marker relative to the laboratory coordinate system during each frame of each trial. The raw coordinate data were filtered using a 2nd order Butterworth bi-directional low pass filter with an effective cutoff frequency of 6 Hz.[38,22] Temporospatial data and gait events were calculated using OrthoTrak software (MAC, Santa Rosa, CA).

Additional standardized clinical outcome measures included the Socket Comfort Score (SCS),[39,23] Rapid-Sit-To-Stand (RSTS) test,[40,41,24,25] Four-Square-Step-Test (FSST),[42,26] and Agility T-Test.[43,44,27,28] For the Socket Comfort Score (SCS)[39,23], subjects were asked, *"On a 0-10 scale, if 0 represents the most uncomfortable socket fit you can imagine, and 10 represents the*

most comfortable socket fit, how would you score the comfort of the socket fit of your prosthesis at the moment?"

The Rapid Sit-to-Stance (RSTS) test provides a standardized measure of active hip range of motion, lower limb muscle strength, and balance.[~~40~~24] Subjects were asked to rise from a chair without arm rests five times as fast as possible with their arms folded across their chest.[~~40~~24] Subjects performed two trials, with a three minute rest period between trials.[~~41~~25]

The Four Square Step Test (FSST) is a timed measure of dynamic standing stability involving rapid stepping in different directions and obstacle avoidance. A square cross was formed using four sticks laid flat on the floor. The stepping sequence was demonstrated and then one practice trial allowed. Subjects were instructed to *"Try to complete the stepping sequence as fast as possible without touching the sticks. Both feet must make contact with the floor in each square. If possible, face forward during the entire sequence."* [~~42~~26] The test was timed twice and the best time taken as the score. A trial was repeated if the subject failed to complete the sequence successfully, lost balance, or made contact with a stick.

The Agility T-Test is typically used by athletes and includes forward, sideway and backward running.[~~43,44~~27,28] Four markers were set out on the floor in the shape of a T. The subject started at the base of the T, sprinted forward to the top of the T and touched the marker, shuffled sideway and touched the marker, shuffled sideway in the opposite direction and touched the marker at the other end, shuffled back to touch the middle marker, before running backward to the initial marker. The trial was not counted if the subject crossed one foot in front of the other while shuffling sideway, failed to touch any markers, or failed to face forward throughout the test. The best time of three successful trials was used, with a three minute rest period between trials.

Results

Two subjects participated in preliminary evaluation of socket use (Table 1). For both subjects the NU-FlexSIV Socket was fabricated by author RC, while the ICS was made for Subject 1 by a prosthetics instructor and Subject 2 wore his clinically prescribed ICS. For both subjects, socket comfort was better with the NU-FlexSIV Socket and gait and clinical outcomes data were generally comparable between sockets. Figure 1 illustrates the gait variables commonly thought to be affected by coronal plane socket stability[2,19] and proximal trim lines[1,7]. While walking speed was slightly faster at self-selected normal and fast speeds for both subjects with the NU-FlexSIV Socket, step width results were inconsistent, with Subject 1 unchanged but Subject 2 wider with the NU-FlexSIV Socket. NU-FlexSIV Socket coronal plane stability during walking was confirmed by lack of change in lateral trunk flexion when compared to ICS. No consistent changes in sagittal plane hip motion or coronal plane hip moments were observed for these two subjects.

Discussion

To our knowledge, this is the first attempt to create a teachable subischial socket with the potential to be more comfortable without compromising function. Gait and clinical outcomes data suggest improved comfort and comparable function to IC sockets, confirming previous reports.[24,5,8,29] NU-FlexSIV Socket coronal plane stability during walking was confirmed by both lack of change in lateral trunk flexion (assessed with gait analysis) and lateral socket gapping at mid-stance (assessed visually). For self-selected normal walking speed, step width was slightly less for Subject 1 and within normal limits for Subject 2 for both sockets when compared to

other unilateral TF amputees (20.7 ± 4.4 cm), while self-selected normal walking speed was substantially faster than other unilateral TF amputees (0.96 ± 0.01 m/s) in both sockets.[~~54~~30] Report of initial evaluation of the NU-FlexSIV Socket with a military TF amputee is similarly promising.[~~55~~31]

An obvious limitation of this work is the preliminary nature of socket evaluation. Subject 1 was not as accustomed to an ICS as Subject 2 and Subject 2 wore different knees with each socket. Lack of standardization of socket accommodation may have influenced the results. More definitive evaluation in the form of randomized cross-over trials comparing comfort and functional performance with the NU-FlexSIV Socket to the ICS in persons with unilateral TF amputation are needed, and fortunately underway (https://clinicaltrials.gov/ct2/show/NCT02678247). Overall, this preliminary work describes a subischial socket technique that appears to be more comfortable for users and results in gait that is at least comparable to that of conventional TF sockets with a proximal brim.

Word Count: ~~4487~~ 1607 words

Acknowledgements

The authors acknowledge Jared Howell, CPO, MS, for ICS fabrication, the assistance of Rebecca Stine, MS, in acquiring data for the study, and the use of the Jesse Brown VA Chicago Motion Analysis Research Laboratory for data collection The authors acknowledge the contribution of Brian Robillard, Wei Chen, Steven Gard, RJ Garrick, Andrew Hansen, Brett Johnson, Oluseeni Komolafe, Matthew Major, Joshua Rollock, Brian Ruhe, Cheng Sun, Lilly Tran, Kerice Tucker, and Sean Wood to various aspects of this project.

Declaration of Conflicting Interests

The authors declare that there is no conflict of interest.

References

~~1. Mak AF, Zhang M, Boone DA. State-of-the-art research in lower-limb prosthetic biomechanics-socket interface: a review. *Journal of Rehabilitation Research and Development* 2001;38:161-174.~~

~~2. Mak AFT, Zhang M, Tam EWC. Biomechanics of pressure ulcer in body tissues interacting with external forces during locomotion. *Annual Review of Biomedical Engineering* 2010;12:29-53.~~

1~~3~~. Dillingham TR, Pezzin LE, MacKenzie EJ, Burgess AR. Use and satisfaction with prosthetic devices among persons with trauma-related amputations: a long-term outcome study. *American Journal of Physical Medicine and Rehabilitation* 2001;80:563-571.

2~~4~~. Pezzin LE, Dillingham TR, MacKenzie EJ, Ephraim P, Rossbach P. Use and satisfaction with prosthetic limb devices and related services. *Archives of Physical Medicine and Rehabilitation* 2004;85:723-729.

3~~5~~. Berke GM, Fergason J, Milani JR, Hattingh J, McDowell M, Nguyen V, Reiber GE. Comparison of satisfaction with current prosthetic care in veterans and servicemembers from Vietnam and OIF/OEF conflicts with major traumatic limb loss. *Journal of Rehabilitation Research and Development* 2010;47:361-371.

~~6. Dudek NL, Marks MB, Marshall SC, Chardon JP. Dermatologic conditions associated with use of a lower-extremity prosthesis. *Archives of Physical Medicine and Rehabilitation* 2005;86:659-663.~~

~~7. Meulenbelt HE, Geertzen JH, Jonkman MF, Dijkstra PU. Skin problems of the stump in lower limb amputees: 1. A clinical study. *Acta Dermato-Venereologica* 2011;91:173-177.~~

~~8. Meulenbelt HE, Geertzen JH, Jonkman MF, Dijkstra PU. Skin problems of the stump in lower-limb amputees: 2. Influence on functioning in daily life. *Acta Dermato-Venereologica* 2011;91:178-182.~~

4~~9~~. Schuch CM, Pritham CH. Current transfemoral sockets. *Clinical Orthopaedics and Related Research* 1999;48-54.

~~10. Foort J. Socket design for the above-knee amputee. *Prosthetics and Orthotics International* 1979;3:73-81.~~

~~11. Radcliffe C. Functional considerations in the fitting of above-knee prostheses. *Artificial Limbs* 1955;2:35-60.~~

~~12. Sabolich J. Contoured adducted trochanteric-controlled alignment method (CAT-CAM): Introduction and basic principles. *Clinical Prosthetics and Orthotics* 1985;9:15-26.~~

~~13. Hoyt C, Littig D, et al. The Ischial Containment Above-Knee Prosthesis. UCLA Prosthetics Education and Research Program, Los Angeles, CA. 1987.~~

~~14. Pritham CH. Biomechanics and shape of the above-knee socket considered in light of the ischial containment concept. *Prosthetics and Orthotics International* 1990;14:9-21.~~

~~1~~5. Hagberg K, Haggstrom E, Uden M, Branemark R. Socket versus bone-anchored trans-femoral prostheses: hip range of motion and sitting comfort. *Prosthetics and Orthotics International* 2005;29:153-163.

~~1~~6. Tranberg R, Zugner R, Karrholm J. Improvements in hip and pelvic motion for patients with osseointegrated trans-femoral prostheses. *Gait and Posture* 2011;33:165-168.

~~1~~7. Klotz R, Colobert B, Botino M, Permentiers I. Influence of different types of sockets on the range of motion of the hip joint by the transfemoral amputee. *Annals of Physical Rehabilitation and Medicine* 2011;54:399-410.

~~18. Pike A. A new concept in above-knee socket design. *The O&P Edge* November, 2002.~~
~~19. Ortiz Vazquez del Mercado M. Evolution of ischial containment socket. Paper presented at the American Academy of Orthotists and Prosthetists, San Diego, CA, March 19-22, 2003.~~
~~20. Fairley M. M.A.S. Socket: A transfemoral revolution. *The O&P Edge* June, 2004.~~
~~21. Fatone S, Dillon M, Stine R, Tillges R. Coronal plane socket stability during gait in persons with unilateral transfemoral amputation: pilot study. *Journal of Rehabilitation Research and Development* 2015;51:1217-1228.~~
~~22. Traballesi M, Delussu AS, Averna T, Pellegrini R, Paradisi F, Brunelli S. Energy cost of walking in transfemoral amputees: Comparison between Marlo Anatomical Socket and Ischial Containment Socket. *Gait and Posture* 2011;34:270-274.~~
~~23. Fairley M. 'Hanging Tight': Elevated Vacuum Suspension Systems Step Forward. *O&P Edge* Mar, 2008.~~
8~~24~~. Kahle JT, Highsmith MJ. Transfemoral interfaces with vacuum assisted suspension comparison of gait, balance, and subjective analysis: Ischial Containment versus brimless. *Gait and Posture* 2014;40:315-320.
9~~25~~. Kahle JT, Orriola JJ, Johnston W, Highsmith MJ. The effects of vacuum-assisted suspension on residual limb physiology, wound healing, and function: A systematic review. *Technology and Innovation* 2014;15:333-341.
10~~26~~. Arndt B, Caldwell R, Fatone S. Use of a partial foot prosthesis with vacuum-assisted suspension: A case study. *Journal of Prosthetics and Orthotics* 2011;23:82-88.
11~~27~~. Street G. Vacuum suspension and its effects on the limb. *Orthopadie Technik* Apr, 2006.
12~~28~~. Beil TL, Street GM, Covey SJ. Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets. *Journal of Rehabilitation Research and Development* 2002;39:693-700.
13~~29~~. Board WJ, Street GM, Caspers C. A comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthetics and Orthotics International* 2001;25:202-209.
14~~30~~. Hoskins R, Sutton E, Kinor D, Schaeffer J, Fatone S. Using vacuum assisted suspension to manage limb wounds in persons with transtibial amputation: A case series. *Prosthetics and Orthotics International* 2014;38:68-74.
15~~31~~. Klute GK, Berge JS, Biggs W, Pongnumkul S, Popovic Z, Curless B. Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: Effect on fit, activity, and limb volume. *Archives of Physical Medicine and Rehabilitation* 2011;92:1570-1575.
16~~32~~. Traballesi M, Delussu AS, Fusco A, Iosa M, Averna T, Pellegrini R, Brunelli S. Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study. *European Journal of Physical Rehabilitation Medicine* 2012;48:613-623.
17. Radcliffe C. Functional considerations in the fitting of above-knee prostheses. *Artificial Limbs* 1955;2:35-60.
18~~33~~. Dillon M. Insights into socket geometry and coronal plane alignment. Paper presented at the 12th World Congress of the International Society for Prosthetics and Orthotics, Vancouver, Canada, July 29-August 3, 2007.
19. Fatone S, Dillon M, Stine R, Tillges R. Coronal plane socket stability during gait in persons with unilateral transfemoral amputation: pilot study. *Journal of Rehabilitation Research and Development* 2015;51:1217-1228.

Review Copy

~~34. Sidles J, Boone DH, JS, Burgess E. Rectification maps: A new method of describing residual limb and socket shapes. *Journal of Prosthetics and Orthotics* 1989;1:149-153.~~
~~35. Zachariah SG, Sorenson E, Sanders JE. A method for aligning trans-tibial residual limb shapes so as to identify regions of shape change. *IEEE Transactions on Neural Systems and Rehabilitation Engineering* 2005;13:551-557.~~
~~36. Sanders J, Severance M. Assessment technique for computer-aided manufactured sockets. *Journal of Rehabilitation Research and Development* 2011;48:763-774.~~
20. Fatone S, Caldwell R. Northwestern University Flexible Subischial Vacuum Socket for Persons with Transfemoral Amputation: Part 1 Description of Technique. *Prosthetics Orthotics International*. in press.
~~37~~21. Kadaba MP, Ramakrishnan HK, Wooten ME, Gainey J, Gorton G, Cochran GV. Repeatability of kinematic, kinetic and electromyographic data in normal adult gait. *Journal of Orthopaedic Research* 1989;7:849-860.
~~38~~22. Winter D. *Biomechanics and Motor Control of Human Movement*. 2nd ed. New York: John Wiley and Sons, Inc.; 1990.
~~39~~23. Hanspal RS, Fisher K, Nieveen R. Prosthetic socket fit comfort score. *Disability and Rehabilitation* 2003;25:1278-1280.
~~40~~24. Whitney SL, Wrisley DM, Marchetti GF, Gee MA, Redfern MS, Furman JM. Clinical measurement of sit-to-stand performance in people with balance disorders: Validity of data for the Five-Times-Sit-to-Stand Test. *Physical Therapy* 2005;85:1034-1045.
~~41~~25. Lusardi M, Pellecchia G, Schulman M. Functional performance in community living older adults. *Journal of Geriatric Physical Therapy* 2003;26:14-22.
~~42~~26. Dite W, Temple VA. A clinical test of stepping and change of direction to identify multiple falling older adults. *Archives of Physical Medicine and Rehabilitation* 2002;83:1566-1571.
27~~43~~. Gailey RS, Gaunaurd IA, Raya MA, Roach KE, Linberg AA, Campbell SM, Jayne DM, Scoville C. Development and reliability testing of the Comprehensive High-Level Activity Mobility Predictor (CHAMP) in male servicemembers with traumatic lower-limb loss. *Journal of Rehabilitation Research and Development* 2013;50:905-918.
28~~44~~. Gailey RS, Scoville C, Gaunaurd IA, Raya MA, Linberg AA, Stoneman PD, Campbell SM, Roach KE. Construct validity of Comprehensive High-Level Activity Mobility Predictor (CHAMP) for male servicemembers with traumatic lower-limb loss. *Journal of Rehabilitation Research and Development* 2013;50:919-930.
~~45. Redhead R. Total surface bearing self suspending above-knee sockets. *Prosthetics and Orthotics International* 1979;3:126-136.~~
~~46. Alley R, Williams T, Albuquerque M, Altobelli D. Prosthetic sockets stabilized by alternating areas of tissue compression and release. *Journal of Rehabilitation Research and Development* 2011;48:679-696.~~
~~47. Gonzalez E, Matthews M. Femoral fractures in patients with lower extremity amputation. *Archives of Physical and Medical Rehabilitation* 1980;61:276-280.~~
~~48. Denton J, McClelland S. Stump fractures in lower extremity amputees. *Journal of Trauma* 1985;25:1074-1078.~~
~~49. Pauley T, Devlin M, Heslin K. Falls sustained during inpatient rehabilitation after lower limb amputation: Prevalence and predictors. *American Journal of Physical Medicine and Rehabilitation* 2006;85:521-532.~~

~~50. Gooday H, Hunter J. Preventing falls and stump injuries in lower limb amputees during inpatient rehabilitation: completion of the audit cycle. *Clinical Rehabilitation* 2004;18:379-390.~~

~~51. Gailey RS, Allen K, Castles J, Kucharik J, Roeder M. Review of secondary physical conditions associated with lower-limb amputation and long-term prosthesis use. *Journal of Rehabilitation Research and Development* 2008;45:15-30.~~

~~52. Dyer D, Bouman B, Davey M, Ismond K. An intervention program to reduce falls for adult in-patients following major lower-limb amputation. *Healthcare Quarterly* 2008;11:117-121.~~

29~~53~~. Kahle JT, Highsmith MJ. Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure, and preference: Ischial Containment versus brimless. *Journal of Rehabilitation Research and Development* 2013;50:1241-1252.

30~~54~~. Highsmith MJ, Schulz BW, Hart-Hughes S, Latlief GA, Phillips SL. Differences in the spatiotemporal parameters of transtibial and transfemoral amputee gait. *Journal of Prosthetics and Orthotics* 2010;22:26-30.

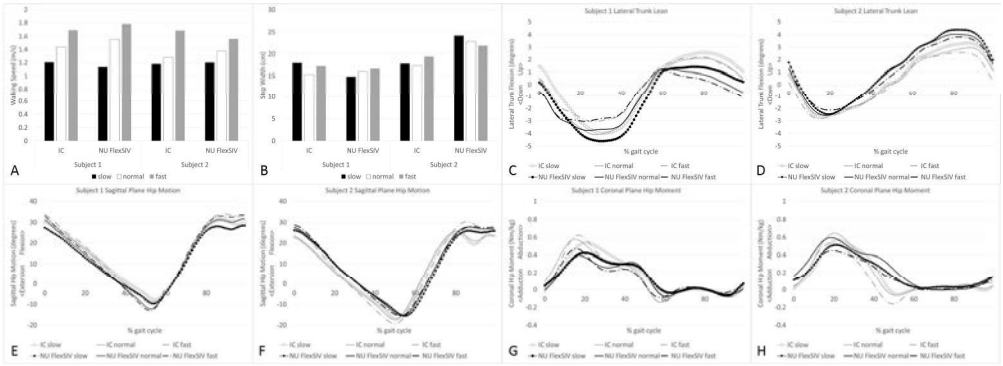
31~~55~~. Esposito E, Fatone S, Wilken J, Caldwell R, Fergason J. Sub-ischial prosthetic sockets improve hip range of motion and performance for individuals with transfemoral amputations. Paper presented at the 41st American Academy of Orthotists and Prosthetists Annual Meeting & Scientific Symposium, New Orleans, Louisiana, February 18-21, 2015.

~~56. Fatone S, Caldwell R. *Instructional Manual for NU-FlexSIV Socket.* Northwestern University Prosthetics-Orthotics Center, Chicago IL. 2015.~~

32~~57~~. Wilken JM, Darter BJ, Goffar SL, Ellwein JC, Snell RM, Tomalis EA, Shaffer SW. Physical performance assessment in military service members. *Journal of the American Academy of Orthopedic Surgeons* 2012;20 Suppl 1:S42-47.

Figure Captions

Figure 1 Selected gait data for Subjects 1 and 2 walking at three self-selected speeds (slow, normal and fast) in an ischial containment and NU-FlexSIV Socket.



211x77mm (300 x 300 DPI)

Table 1 Subject and Prosthesis Characteristics and Temporospatial Data

	Subject 1		Subject 2	
Age (years)	29		26	
Sex	Male		Male	
Height (cm)	181		188	
Weight (kg)	88.4		89.6	
Amputation	Right Transfemoral		Left Knee Disarticulation	
Cause of Amputation	Trauma		Tumor	
Time Since Amputation (years)	9		15	
Activity Level	Very active (construction worker)		Very active (athletic trainer)	
	ICS	**NU-FlexSIV**	**ICS**	**NU-FlexSIV**
Suspension	Suction one-way valve	Origin liner Ottobock ePulse	Suction one-way valve	Custom polyurethane liner Ottobock ePulse
Knee	Ottobock C-leg	Ottobock C-leg	Ottobock 3R45	Ottobock C-leg
Foot	Ottobock Highlander	Ottobock Highlander	Össur Ceterus	Ottobock Highlander
Socket Comfort Score (SCS)	2	10	8	9
Rapid Sit-to-Stand (RSST)*	11.81	11.66	9.41	10.46
Four-Square-Step-Test (FSST)*	9.52	10.6	5.47	6.95
Agility T-Test**	26.6	26.81	15.75	13.1

*Able-bodied US service member's Minimal Detectable Change (MDC): RSTS= 0.27; FSST=0.30[32,57]
**US service members with transfemoral amputation: 27.7 ± 6 s (MDC = 3.74)[43,44,27,28]
NU-FlexSIV: Northwestern University Sub-Ischial Vacuum Socket; ICS: Ischial Containment Socket.

APPENDIX K – ACCEPTED MANUSCRIPT: JOURNAL OF PROSTHETICS AND ORTHOTICS TECHNICAL NOTE

JPO: Journal of Prosthetics and Orthotics

Technique for Perforating a Prosthetic Liner to Expel Sweat

--Manuscript Draft--

Manuscript Number:	JPO14-409R1
Full Title:	Technique for Perforating a Prosthetic Liner to Expel Sweat
Short Title:	Perforating a Prosthetic Liner
Article Type:	Technical Note
Keywords:	artificial limb prosthetic socket prosthetic liner sweating amputation
Corresponding Author:	Stefania Fatone, PhD Northwestern University Chicago, IL UNITED STATES
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	Northwestern University
Corresponding Author's Secondary Institution:	
First Author:	Stefania Fatone, PhD
First Author Secondary Information:	
Order of Authors:	Stefania Fatone, PhD
	Ryan Caldwell, CP
Order of Authors Secondary Information:	
Manuscript Region of Origin:	UNITED STATES
Abstract:	Introduction: Sweating and moisture build up are caused by the insulative nature of prosthetic interface materials increasing the temperature of the residual limb. Hence, heat and sweating in the socket are among the most frequently reported problems that reduce quality of life for persons with amputation. The purpose of this technical note was to describe a simple, inexpensive technique for perforating a silicone prosthetic liner to expel sweat and enhance use of a lower limb prosthesis. Materials and Methods: A liner holder consisting of a towel and socks layered over a mandrel to mimic the distal liner shape was made to stabilize the liner during the perforation process. With the liner placed over the holder such that the exterior surface was exposed, a perforating roller was used to perforate the distal third of the liner. When the liner was inverted the holes were visible all the way through to the inner surface of the liner. Results: Expulsion of sweat through the perforations was demonstrated by pouring water into the liner, folding the proximal, open end of the liner to create a seal, and forcing water droplets to escape the perforations with some resistance. Additional evidence that water escaped was seen by the wet patches that formed on the exterior fabric of the liner after active wear. One amputee user described sweat being pumped out of the liner into the socket and in some cases out of the socket through the air relief valve of the vacuum pump. Another amputee indicated that the perforations did not damage the skin and reduced slippage of the liner with respect to the limb. Conclusions: Initial clinical experience with this technique suggested that expulsion of sweat occurred and user feedback indicated improved prosthesis use as a result. Current experience using this technique in clinical practice has been limited to silicone liners. The long term effect of perforations on liner durability or limb health are not yet known.
Response to Reviewers:	See included file.

Powered by Editorial Manager® and ProduXion Manager® from Aries Systems Corporation

Technique for Perforating a Prosthetic Liner to Expel Sweat

Short title: Perforating a Prosthetic Liner

[1,2]Ryan Caldwell, CP, and [1]Stefania Fatone, PhD, BPO(Hons)

[1,2]Northwestern University, Chicago, IL

[2]Scheck and Siress, Schaumburg, IL

Submitted as a Technical Note.

Corresponding Author:

Stefania Fatone, PhD, BPO(Hons)

680 N Lake Shore Dr, Suite 1100

Chicago IL 60660

7

Conflicts of Interest and Source of Funding: The U.S. Army Medical Research and Materiel Command Acquisition Activity, 820 Chandler 10 Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office (Award #W81XWH-10-1-0744). The content of this presentation does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred. No conflicts of interest declared.

Technique for Perforating a Prosthetic Liner to Expel Sweat

Abstract

Introduction: Sweating and moisture build up are caused by the insulative nature of prosthetic interface materials increasing the temperature of the residual limb. Hence, heat and sweating in the socket are among the most frequently reported problems that reduce quality of life for persons with amputation. The purpose of this technical note was to describe a simple, inexpensive technique for perforating a silicone prosthetic liner to expel sweat and enhance use of a lower limb prosthesis.

Materials and Methods: A liner holder consisting of a towel and socks layered over a mandrel to mimic the distal liner shape was made to stabilize the liner during the perforation process. With the liner placed over the holder such that the exterior surface was exposed, a perforating roller was used to perforate the distal third of the liner. When the liner was inverted the holes were visible all the way through to the inner surface of the liner.

Results: Expulsion of sweat through the perforations was demonstrated by pouring water into the liner, folding the proximal, open end of the liner to create a seal, and forcing water droplets to escape the perforations with some resistance. Additional evidence that water escaped was seen by the wet patches that formed on the exterior fabric of the liner after active wear. One amputee user described sweat being pumped out of the liner into the socket and in some cases out of the socket through the air relief valve of the vacuum pump. Another amputee indicated that the perforations did not damage the skin and reduced slippage of the liner with respect to the limb.

Conclusions: Initial clinical experience with this technique suggested that expulsion of sweat occurred and user feedback indicated improved prosthesis use as a result. Current experience

using this technique in clinical practice has been limited to silicone liners. The long term effect of perforations on liner durability or limb health are not yet known.

Key Words: artificial limb, prosthetic socket, prosthetic liner, sweating, amputation

Introduction

Prosthetic sockets form the interface between the residual limb and the prosthesis and are important for the transmission of forces and distribution of pressure in persons with amputation[1]. Combinations of prosthetic liners, socks, and/or the socket are worn over the residual limb. However, the insulative nature of prosthetic interface materials[2,3] increases temperature of the residual limb causing sweating and moisture buildup[1,2,4]. Socket wear, activity and a hot climate increase residual limb temperature[5-7], with a 1-2^{0}C increase in residual limb skin temperature potentially causing discomfort[5]. Increased humidity leads to dermatitis and infections[8]. It also disrupts suspension forces[9] and skin with slight moisture is more susceptible to blisters than wet or dry skin[10]. The most frequently reported problems that reduce quality of life for persons with amputation are heat and sweating in the socket (72%) and sores and skin irritation from the socket (62%)[11]. These type of residual limb skin problems impede daily prosthesis use, reduce mobility, and jeopardize the vocational activities of persons with amputation[8].

When sweating becomes disruptive of socket suspension and/or causes discomfort, persons with amputation must stop their activity, remove the socket and wipe down the residual limb and interface. Options available to persons with amputation to manage issues with sweating inside the liner or socket include anti-perspirant sprays, Botulinum toxin injections, medication, electrical stimulation, and surgery. However, these treatments are often not entirely successful. While a number of temperature regulation and sweat management methods have been explored[12-14], only recently have technologies such as the SmartTemp® Liner from WillowWood (Mt Sterling, OH) and the Silcare Breathe Liner from Endolite (Basingstoke, Hampshire, UK) become commercially available. The SmartTemp® Liner is said to regulate heat by incorporating phase change material that responds to fluctuations in residual limb skin temperature, absorbing

and storing heat as it builds up and delaying the onset of sweat. Furthermore, by releasing stored heat as the body cools, the liner is said to stabilize skin temperature to keep the person with amputation comfortable all day. A recent clinical trial indicated that the SmartTemp® Liner resulted in significantly reduced mean skin temperature and perspiration during and after stationary cycling in persons with transtibial amputation compared with a placebo liner[14]. The Silcare Breathe Liner features laser drilled perforations to allow moisture to escape, presumably resulting in drier skin and a healthier environment for the residual limb (http://www.silcareliners.com/us/). The purpose of this technical note was to describe a simple, inexpensive technique for perforating any silicone prosthetic liner to expel sweat and enhance use of a lower limb prosthesis.

Materials and Methods

A liner holder was made to hold the liner during the perforation process (Figure 1A). The liner holder was made from a mandrel that was covered by a rolled towel and then a series of socks sufficient in number to form a cylindrical/cone shape, mimicking the distal shape of the liner to be perforated. The mandrel was approximately 2 cm in diameter and long enough to accommodate the liner to be perforated. The liner holder ensured that the liner did not move during the perforation process allowing the perforation tool to be positioned reliably against the soft surface of the liner. The liners were simply held in place by the liner holder: the aim was to have total contact between the liner holder and liner without tension on the liner.

A silicone liner was placed over the liner holder with the external surface of the liner exposed (Figure 1B). A perforating roller typically used to perforate foam padding was then rolled over the distal end of the liner (e.g. PEL® Perforating Tool, http://cascade-

usadev.com/pelr-perforating-tool.html Figure 1C, 1D). The perforating tool was rolled over the distal third of the liner in the pattern shown in Figure 1E. This particular perforating tool created consistently sized holes distributed approximately 1cm apart. The distal portion of the liner was covered with holes but without interrupting the sealing mechanism incorporated into the liner.

When the liner was inverted the holes were visible all the way through to the inner surface of the liner (Figure 1F). Liner perforations were tested to determine permeability by pouring water into the liner. The proximal, open end of the liner was sealed by folding it upon itself, and forcing air/water through the perforations. Water droplets and air escaped through the small perforations with some resistance (Figure 1G, 1H).

Results and Discussion

Initial clinical experience with this technique suggested that expulsion of sweat occurred and user feedback indicated improved prosthesis use as a result. Figure 2 demonstrates that sweat does indeed seep out of the perforations and can be seen as wet patches on the exterior fabric of the liner after active wear. One amputee user described that liner perforations resulted *"in whatever fluid exists to be pumped out* [of the liner] *into the socket and in some cases pumped out of the socket through the air relief valve* [of] *a dual chamber* [vacuum] *pump."* Another amputee user stated, *"I have had no damage to my leg from the holes or any marks either. I would NOT go back to wearing the liner without them* [holes]*; before the sweating was so bad I had to remove the liner and dry it out numerous times a day. Now I wear it all day with minimal slip, if any."* This technique appears to result in similar expulsion of sweat as is claimed of the Endolite Silcare Breathe Liner (http://www.silcareliners.com/us/).

An additional potential advantage of liner perforations is that they may help to reduce air pockets between the liner and skin when used with active vacuum pump systems. For example, in residual limbs that are oddly shaped and/or hairy, air might be trapped between the limb and liner when the liner is initially donned and the perforations may allow for that air to escape, improving the seal between liner and limb. The perforations may also help maintain contact between the limb and liner when the limb loses volume during the course of a day.

While this technique has been used in clinical practice by the author (RC), experience is limited to an estimated 40 initial cases, approximately half transfemoral and the rest transtibial, wherein active vacuum pumps or suction were used. The long term effect of perforations on liner durability or limb health are not yet known. Caution is required to ensure that one does not make too many holes and that the holes are not too large. If the holes are too large, use with active vacuum will likely result in water blisters. Using the perforating tool described will control the size and distribution of the holes and ensure that they are not too large. If there are too many holes liner durability may be compromised leading to premature wear of the liner.

While this technique has been successful with silicone liners, it is unclear if it would be equally successful with thermoplastic elastomer (TPE) or polyurethane liners given that they are generally less durable materials. Similarly, this technique has not been used with pin-locking liners, so it is unknown whether it would work well with that system. It is not typically recommended that patients wash the exterior textile of liners since it is not in contact with the skin. However, when the liner is perforated, washing both internal and external liner surfaces should be recommended given that any sweat expelled through the liner may lead to bacterial buildup on the external, textile covered surface. When cleaning the liner, patients should routinely push alcohol through the perforations to avoid bacteria build-up. This can be

accomplished by pouring rubbing alcohol into the liner, folding the proximal edge to create a seal with the liner, and forcing air/alcohol out of the perforations.

Conclusion

This technical note describes a simple, inexpensive technique for perforating a silicone prosthetic liner to expel sweat and enhance use of a lower limb prosthesis. Initial clinical experience with this technique suggested that expulsion of sweat occurred and user feedback indicated improved prosthesis use as a result.

References

1. Mak AF, Zhang M, Boone DA. State-of-the-art research in lower-limb prosthetic biomechanics-socket interface: a review. *Journal of Rehabilitation Research and Development* 2001;38:161-174.
2. Klute GK, Rowe GI, Mamishev AV, Ledoux WR. The thermal conductivity of prosthetic sockets and liners. *Prosthetics and Orthotics International* 2007;31:292-299.
3. Webber CM, Klittich MR, Dhinojwala A, Davis BL. Thermal Conductivities of Commercially Available Prosthetic Materials. *Journal of Prosthetics and Orthotics* 2014;26:212-215.
4. Ghoseiri K, Bahramian H. User satisfaction with orthotic and prosthetic devices and services of a single clinic. *Disability and Rehabilitation* 2012;34:1328-1332.
5. Peery J, Ledoux W, Klute G. Residual-limb skin temperature in transtibial sockets. *Journal of Rehabilitation Research and Development* 2005;42:147-154.

6. Huff E, Ledoux W, Berge J, Klute G. Measuring Residual Limb Skin Temperatures at the Skin-Prosthesis Interface. *Journal of Prosthetics and Orthotics* 2008;20:170-173.

7. Klute GK, Huff E, Ledoux WR. Does activity affect residual limb skin temperatures? *Clinical Orthopedics and Related Research* 2014;472:3062-3067.

8. Meulenbelt HEJ, Dijkstra PU, Jonkman MF, Geertzen JHB. Skin problems in lower limb amputees: A systematic review. *Disability and Rehabilitation* 2006;28:603-608.

9. Legro MW, Reiber G, del Aguila M, Ajax MJ, Boone DA, Larsen JA, Smith DG, Sangeorzan B. Issues of importance reported by persons with lower limb amputations and prostheses. *Journal of Rehabilitation Research and Development* 1999;36:155-163.

10. Naylor P. Experimental friction blisters. *British Journal of Dermatology* 1955;67:327-342.

11. Hagberg K, Branemark R. Consequences of non-vascular trans-femoral amputation: a survey of quality of life, prosthetic use and problems. *Prosthetics and Orthotics International* 2001;25:186-194.

12. McCarthy J, Ross J, Mcdougall A, Ritchie L, Ward A, Zahedi S. Moisture management within a prosthetic socket. Paper presented at the International Society for Prosthetics and Orthotics World Congress, Hyderabad, India, February 4-7, 2013.

13. McCarthy J, Zaheedi S, Ross J, Ward A, Ritchie L. Sweat Management in Prosthetic Sockets. Paper presented at the 13th ISPO World Congress, Leipzig, Germany, May 10-15, 2010.

14. Wernke MM, Schroeder RM, Kelley CT, Denune JA, Colvin JM. SmartTemp Prosthetic Liner Significantly Reduces Residual Limb Temperature and Perspiration. *Journal of Prosthetics and Orthotics* 2015;27:134-139.

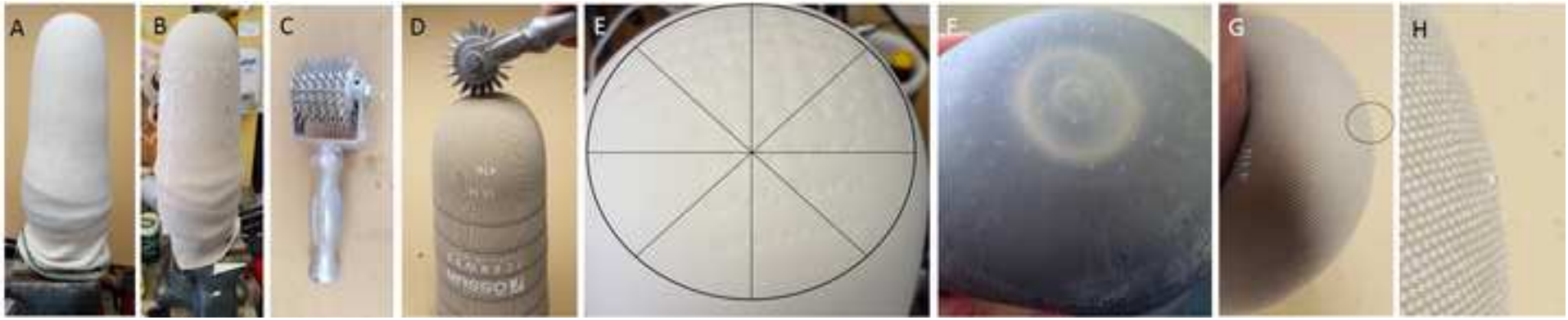
Figure Captions

Figure 1 (A) Liner holder consisting of a rolled towel and socks layered over a mandrel to mimic the distal liner shape. (B) Liner was placed over the liner holder with the exterior surface visible, ensuring total contact of the liner with the liner holder. (C) Perforating tool. (D) The perforating tool was rolled over the distal end of the liner. (E) Pattern of perforations overlaid on actual perforations on the interior surface of the liner. (F) Close up view of perforations on the interior surface of the liner. (G) To test perforations, liner was filled with water and squeezed. Circle indicates where a droplet of water can be seen emerging through a perforation. (H) Close up view of water droplet circled in figure G.

Figure 2 (A) Interior of liner showing perforations. (B) Exterior of fabric covered liner showing wet patches where sweat was absorbed during active wear. These sweat patches appeared after approximately five minutes of light jogging indoors in a patient that has reported sweating as a problem.

Figure

Click here to download Figure Figure 1.jpg



Figure

Click here to download Figure Figure 2.jpg



APPENDIX L – WOOD MASTER'S THESIS

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

© Copyright by Sean Michael Wood 2011

All Rights Reserved

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

CONTENTS

ABSTRACT 3
Acknowledgements 4
List of Abreviations 5
List of Figures 8
List of Tables 10
Chapter 1: Problem Description and Research Objectives 11
1.1 Technical Background 12
1.1.1 Research Impact 12
1.1.2 A Brief History of Lower Limb Sockets and Suspensions 13
1.1.3 Vacuum Assisted Suspension and Sub-Ischial Sockets 15
1.2 Tasks and Organization 17
Chapter 2: Electrical and Mechanical Vacuum Pump Characterization 20
2.1 Vacuum Pump System Background 20
2.2 Test Methods 21
2.2.1 Equipment, Materials, and Software Used During Testing 21
2.2.2 Vacuum Pump Test Procedure 23
2.3 Results of Vacuum Pump Characterization 25
2.3.1 Electric Vacuum Pump Battery Depletion Test Results 25
2.3.2 Electrical and Mechanical Pump Test Results 27
2.4 Discussion of Results and Testing Procedure 30
2.4.1 Discussion Regarding Testing Procedure and Data Analysis 30
2.4.2 Discussion of Evacuation Times and Powers 33
2.5 Conclusions 35
Chapter 3: Determination of Key Characteristics in the Socket/Liner Interface 37
3.1 Introduction 37
3.2 Human Subject Test Methods 38
3.2.1 Participants 38
3.2.2 Test Procedure 38
3.3 Socket Evacuation and Treadmill Test 40

Results 40
3.4 43
Discussion of Evacuation and Treadmill Results 43
3.5 Conclusions 47
Chapter 4: Vacuum Pump Design 49
4.1 Connection Between Design and Previous Research 49
4.2 Design of a Hybrid Vacuum Pump 51
4.2.1 51
Undergraduate Design Work 51
4.2.2 54
Design Modification and Reconstruction 54
4.3 55
Biomechanical Energy Harvester Design 55
4.3.1 Determination of Feasibility for Use by PWTA 57
4.3.2 59
Principles of Design 59
4.3.3 Mechanical Design of the Biomechanical Energy Harvester 61
4.3.4 Test Bed Construction and Electrical Design 64
4.3.5 Methods of Measuring the Energy Harvested and Related Results 66
4.3.6 Discussion of the Results and Potential Applicability 68
4.4 Pump Design 69
Conclusions 69
Chapter 5: Conclusions 71
References 75
Appendix A: Product Design Specifications 78
Appendix B: User Interview Summary 80
Appendix C: Labview DAQ Procedure 84
Equipment 84
Procedure 84

LIST OF FIGURES

Figure 1: Drawings of the cross-section of A) a quadrilateral socket and B) an ischial containment socket. 13

Figure 2: Shuttle lock suspension system. 14

Figure 3: Cross section of vacuum suspension system 15

Figure 4: The five vacuum pumps used in bench-top testing 22

Figure 5: The test setup used for bench-top testing 24

Figure 6: Mechanical Pump Test Fixture 25

Figure 7: Plots of Vacuum Pressure vs. Time for the A) e-Pulse and the B) LimbLogic 27

Figure 9: Summary of the evacuation times for the mechanical pumps 29

Figure 8: Summary of evacuation times for electrical pumps 29

Figure 10: Summary of the pump powers calculated for the mechanical pumps. 30

Figure 11: Comparisons of the original plots of evacuation time for the electrical pumps 32

Figure 12: Average evacuation times for the e-Pulse the human subjects 41

Figure 13: Vacuum pressure over time recorded during treadmill testing 42

Figure 14: Comparison of vacuum pressure during in the Polytol and Check sockets 44

Figure 15: Images of the A) original and B) modified hybrid pump designs. 53

Figure 16: An artists' rendering of the hybrid pump 53

Figure 17: CAD model of a mechanical to electrical energy harvesting system 57

Figure 18: Final prototype of the energy harvester 61

Figure 19: Full view of the final energy harvester prototype 63

Figure 20: The Yaskawa SGD-02BS Servopack. 64

Figure 21: The control circuitry with NU32v2 at center and encoder circuit in the upper right. 65

Figure 22: An illustration of the inner workings of a DC motor. 66

Figure 23: A plot of the angular "leg position" and voltage across the capacitor 67

Figure C.1: The DigiVac Reader Labview Virtual Interface.....85

Figure C.2: The Back-End of the DigiVac Reader Labview Virtual Interface.....86

LIST OF TABLES

Table 1a: Electrical Pump Evacuation Time and Power Results 28

Table 1b: Mechanical Pump Power Results 28

Table 2: Test Subject Data.....40

Table 3: Summary of Interface Volumes 41

Table 4: Treadmill Test Analysis 43

Table 5: Key Observations from Chapters 2 and 3.....49

Table 6: Gait Analysis Results of Energy Expended in C-Leg During Swing Phase 58

Table 7: Objectives, Contributions and Future Work 71

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

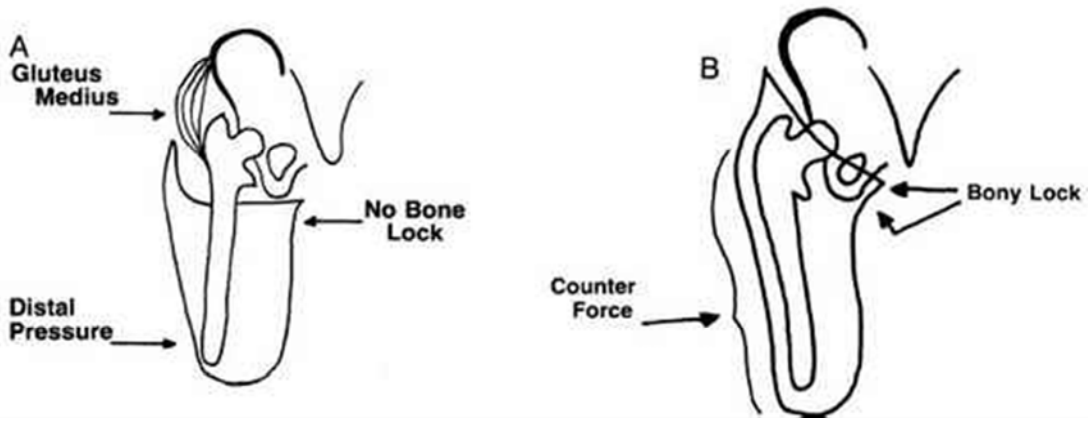


Figure 1: Drawings of the cross-section of A) a quadrilateral socket and B) an ischial containment socket. Taken from: Michael JW: Instr Course Lect 1990; 39:375.

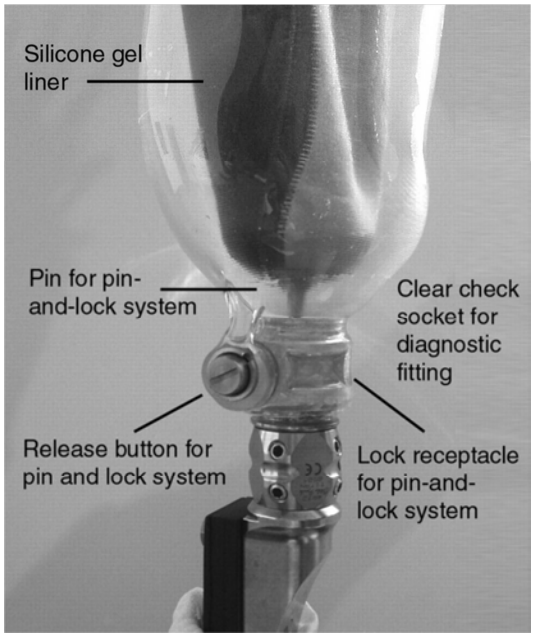


Figure 2: Shuttle lock suspension system.

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.

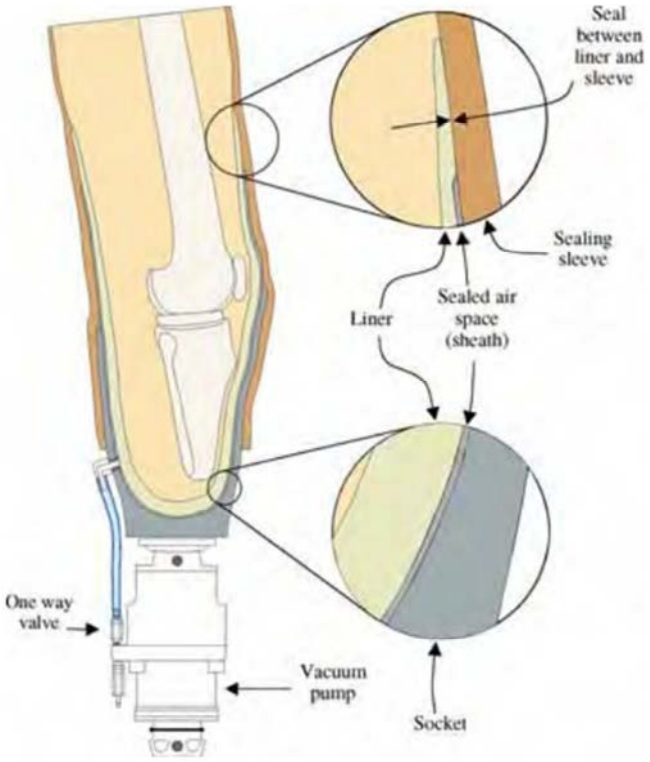


Figure 3: Cross section of vacuum suspension system. Note that the sealed air space does not extend to the thigh. The seal between the top of the liner and sealing sleeve isolates the limb from the vacuum.

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:

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

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

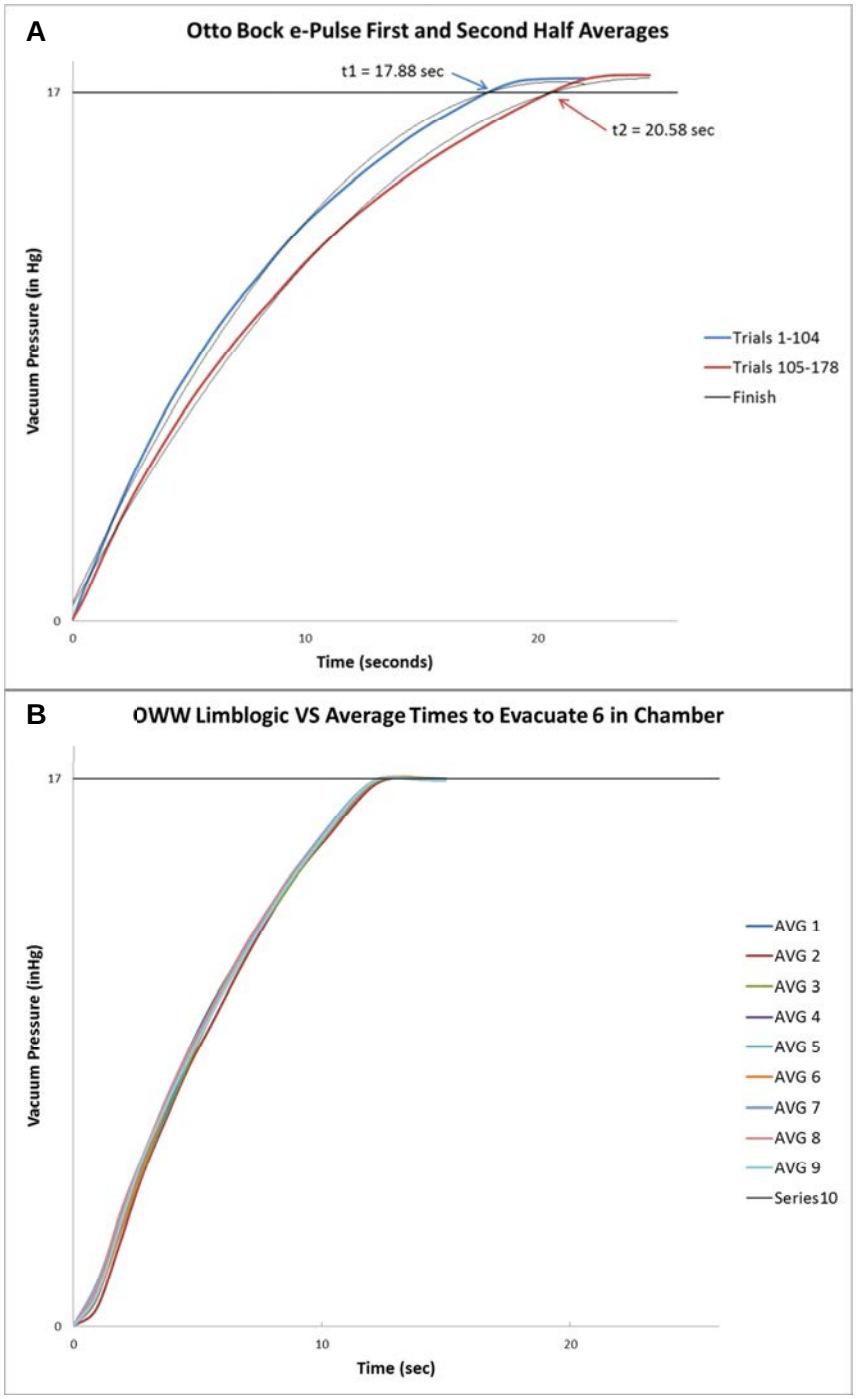


Figure 7: Plots of Vacuum Pressure vs. Time for the A) e-Pulse and the B) LimbLogic

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

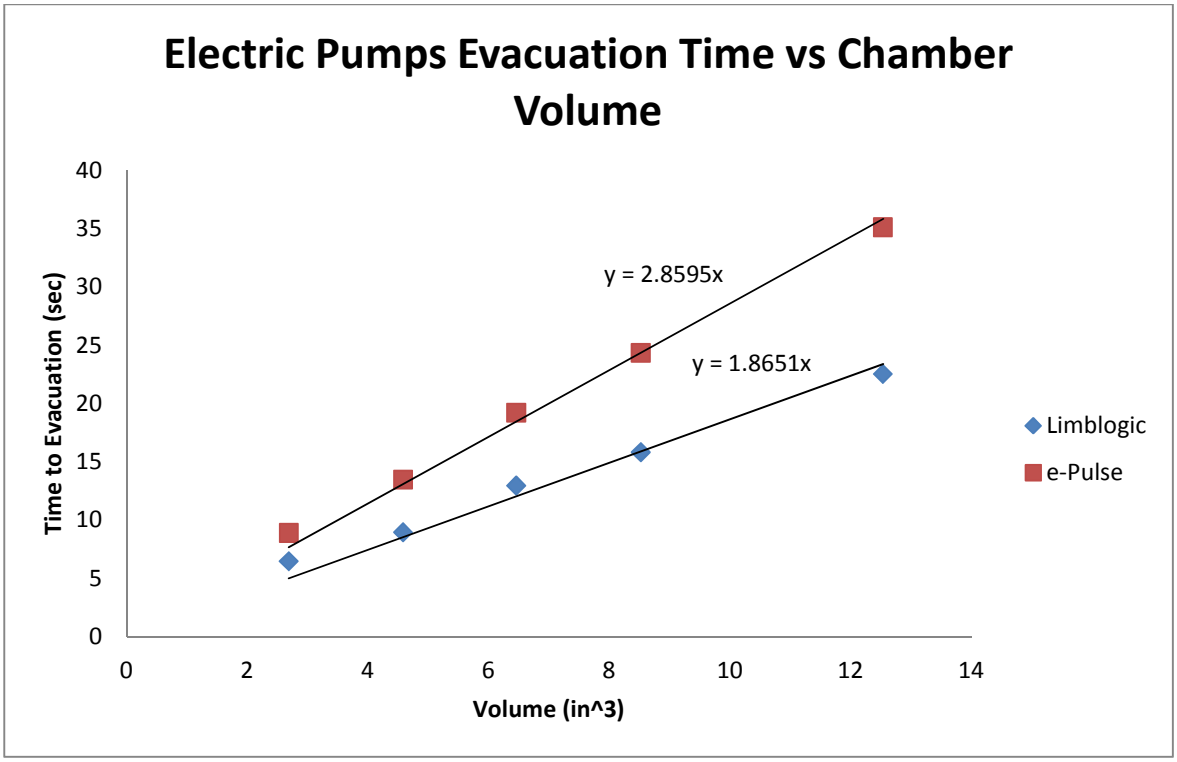


Figure 8: Summary of evacuation times for electrical pumps as dependent upon the volume they evacuated.

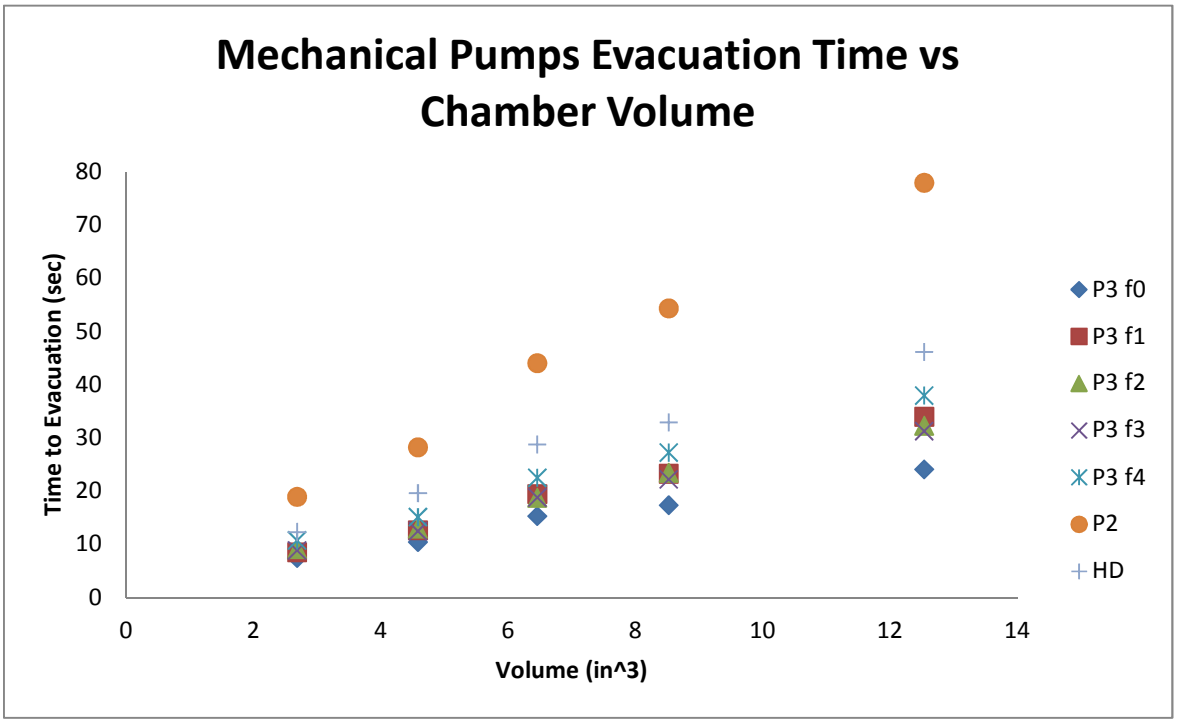


Figure 9: Summary of the evacuation times for the mechanical pumps as dependent upon the volume they evacuated.

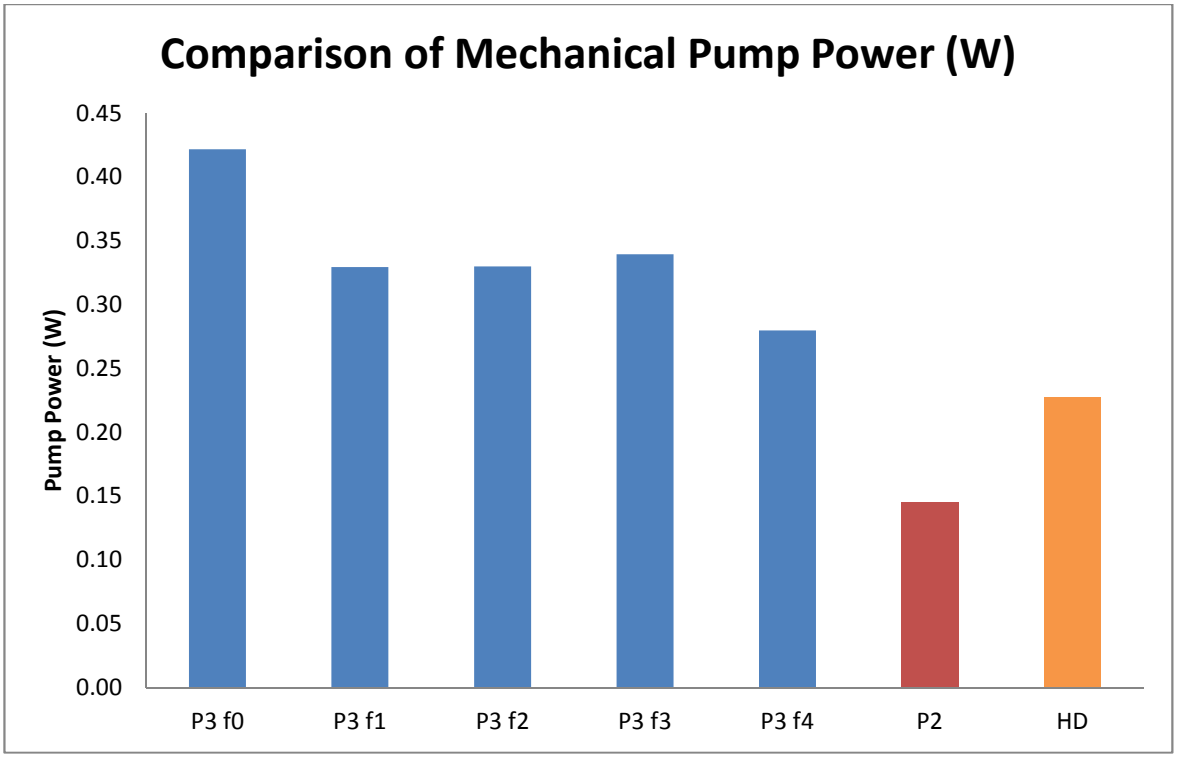


Figure 10: Summary of the pump powers calculated for the mechanical pumps.

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.

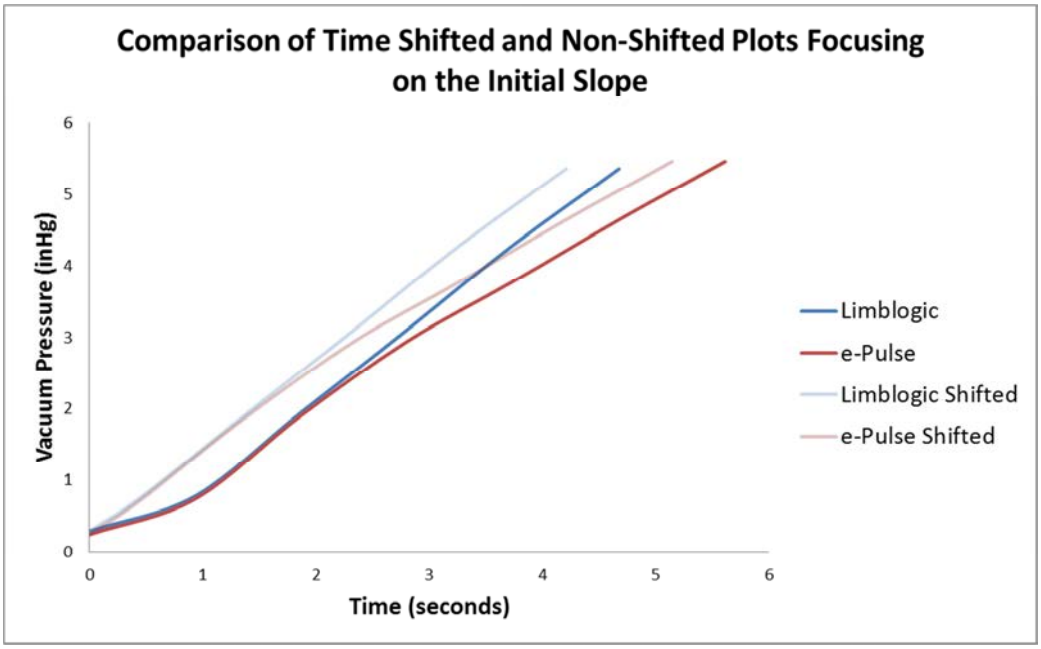


Figure 11: Comparisons of the original plots of evacuation time for the electrical pumps vs. their time shifted plots.

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.

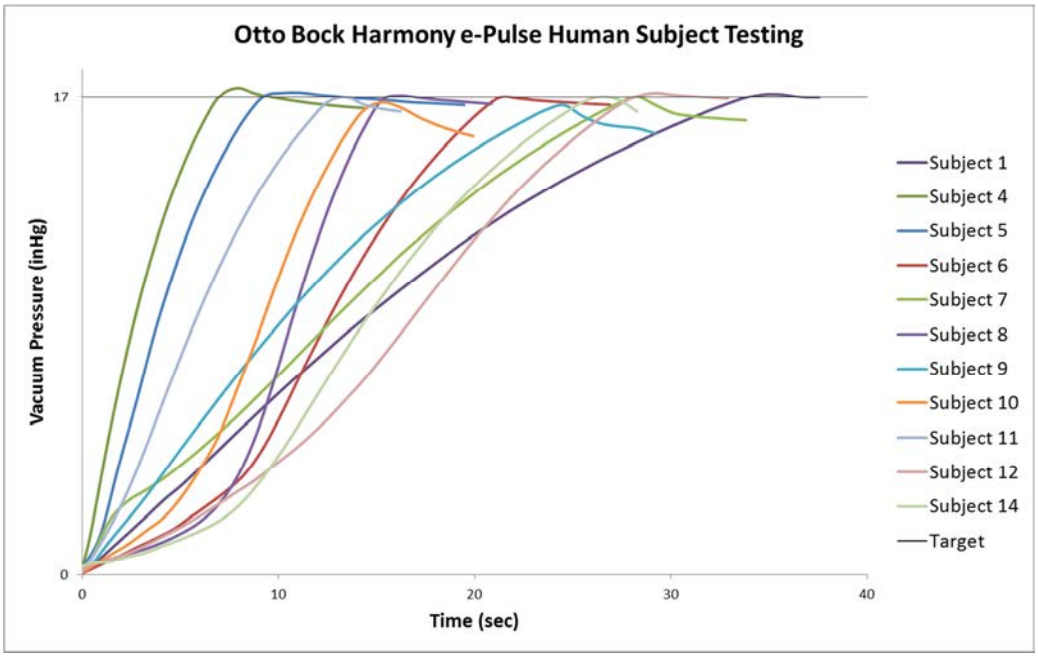


Figure 12: Average evacuation times for the e-Pulse the human subjects during comfortable standing (n=11).

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.

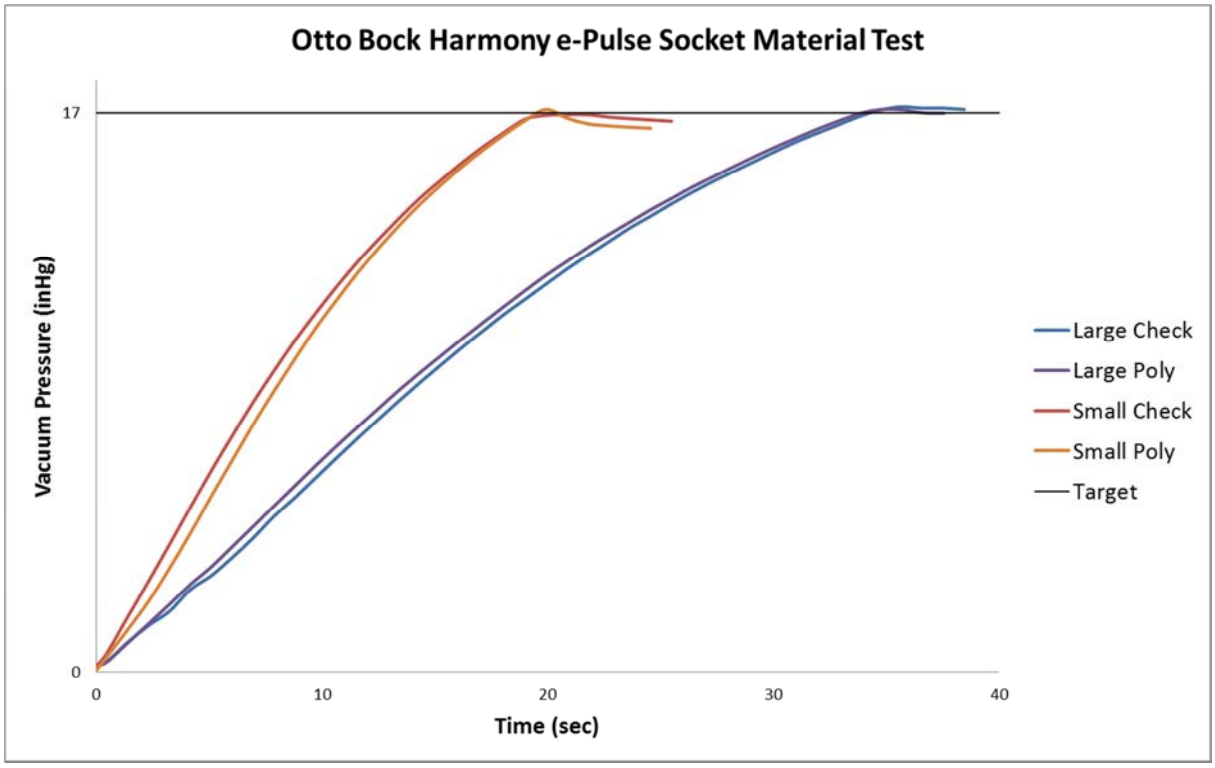


Figure 14: Comparison of vacuum pressure during in the Polytol and Check sockets on Subject 1 while standing.

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.

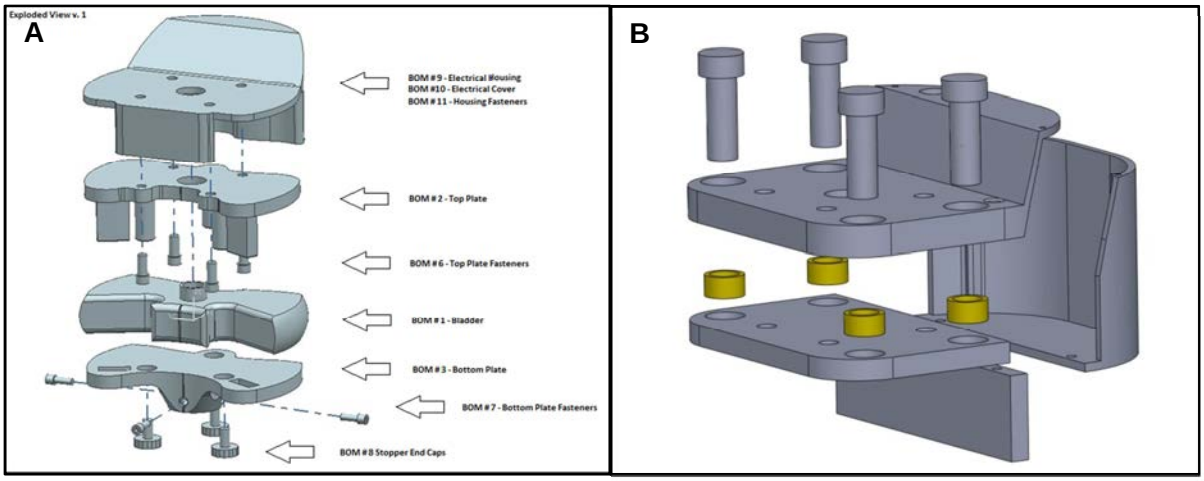


Figure 15: Images of the A) original and B) modified hybrid pump designs.

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.

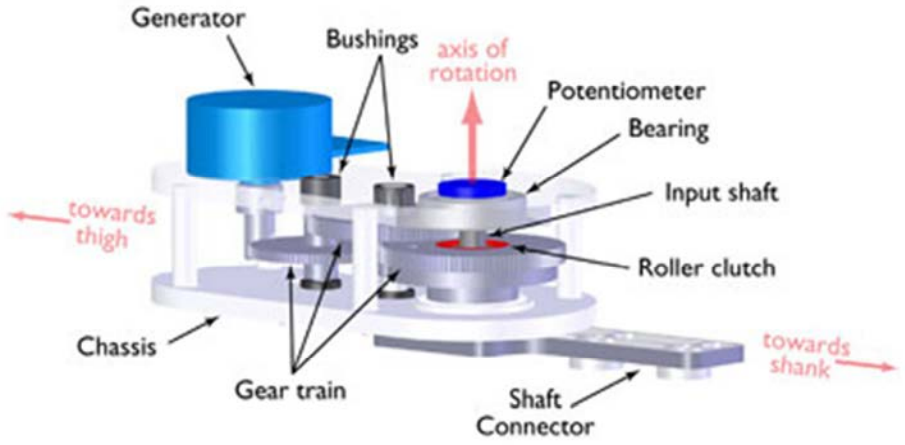


Figure 17: CAD model of a mechanical to electrical energy harvesting system (Li et al., 2008).

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**.**

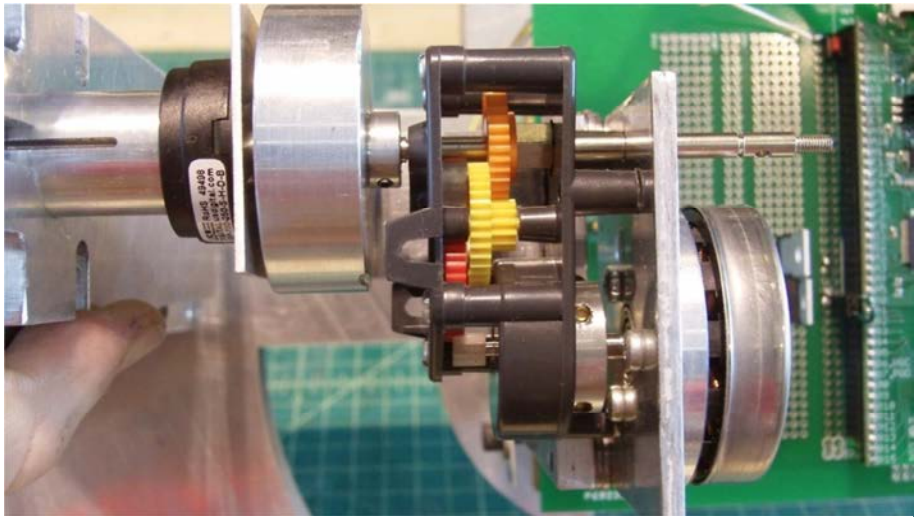


Figure 18: Final prototype of the energy harvester, from left to right: encoder, clutch housing, gearbox, and DC motor.

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.

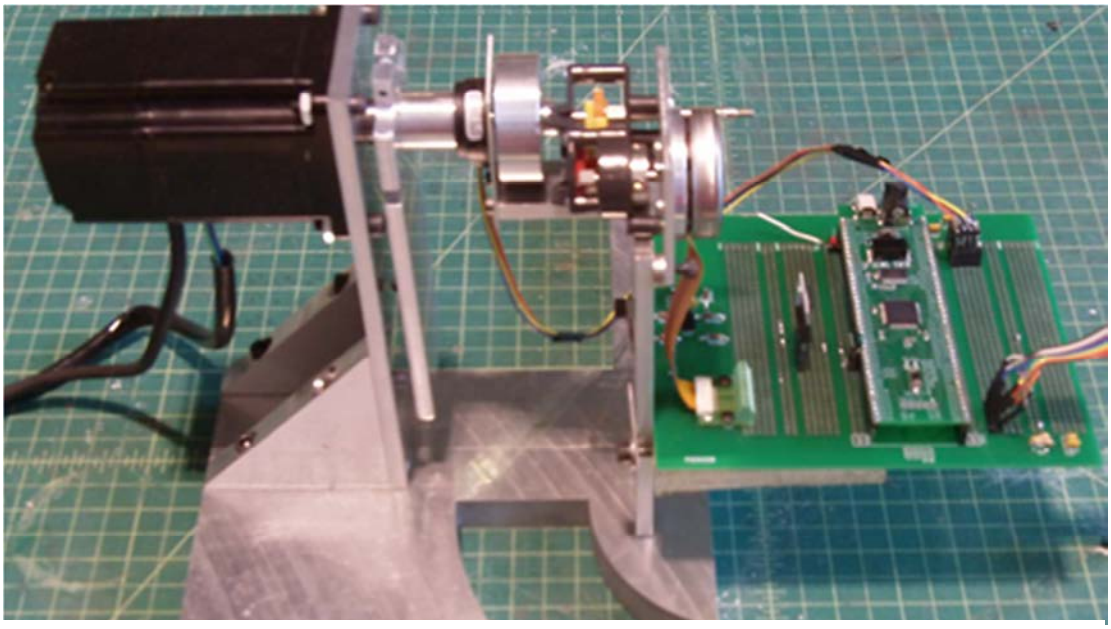


Figure 19: Full view of the final energy harvester prototype, from left to right: Yaskawa motor, pendulum, energy harvesting unit, and control circuitry.

4.3.4 Test Bed Construction and Electrical Design

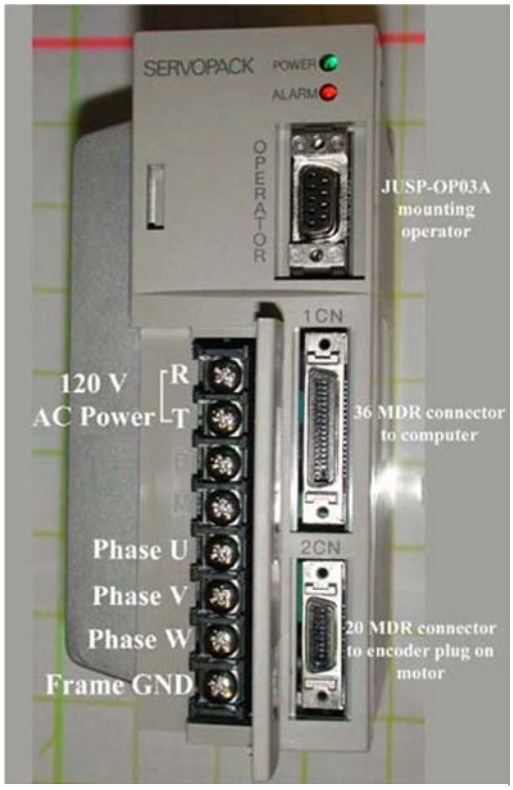


Figure 20: The Yaskawa SGD-02BS Servopack.

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.

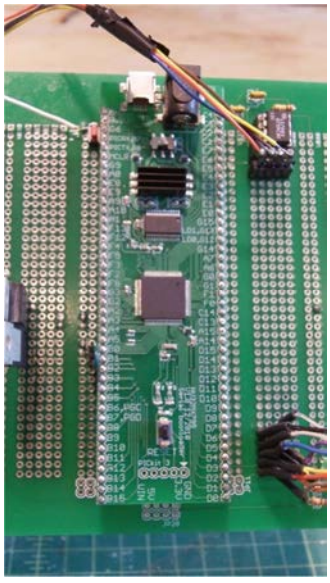


Figure 21: The control circuitry with NU32v2 at center and encoder circuit in the upper right.

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

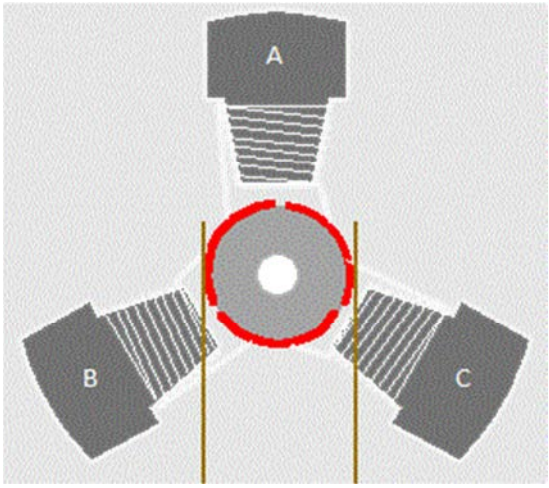


Figure 22: An illustration of the inner workings of a DC motor.

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%.*

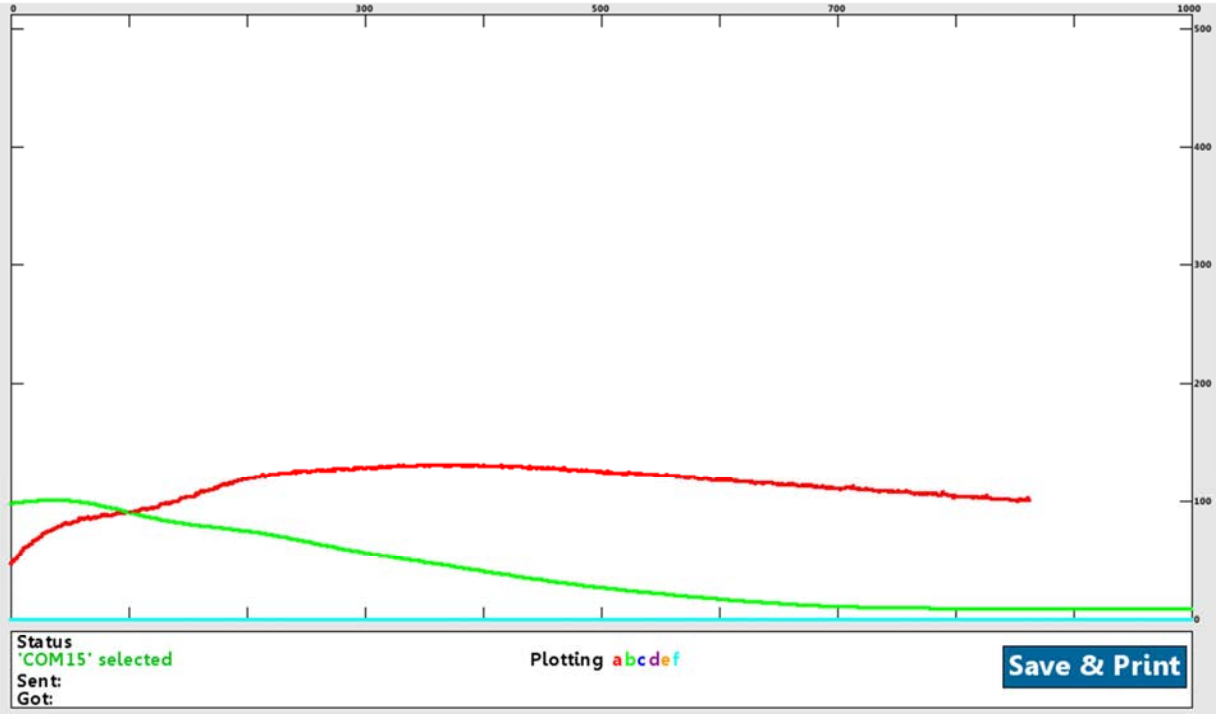


Figure 23: A plot of the angular “leg position” and voltage across the capacitor. The angle is in green with its value multiplied by 2 for viewing and the voltage is in red and measured in hundredths of a Volt

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.

REFERENCES

Beil, T. L., Street, G. M., Covey, S. J. Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets. Journal of Rehabilitation Research and Development, 2002. 39(6): p. 693-700.

Board, W. J., Street, G. M., Caspers, C. A comparison of trans-tibial amputee suction and vacuum socket conditions. Prosthetics and Orthotics International, 2001. 25(3): p. 202-209

Brunelli, S., Averna, T., Delusso, S., Traballesi, M. Vacuum assisted socket system in transtibial amputees: clinical report, in Orthopadie Technik. 2009: Germany. 2-8.

Dillingham, T. R., Pezzin, L. E., Mackenzie, E. J. Limb Amputation and Limb Deficiency: Epidemiology and Recent Trends in the United States. Southern Medical Journal; Aug 2002, 9(8): 875-883.

Fairley, M. 'Hanging Tight': Elevated Vacuum Suspension Systems Step Forward, in O&P Edge. 2008.

Fatone, S., Caldwell, R., Gard, S., Hansen, A. Development of Sub-Ischial Prosthetic Sockets with Assisted-Vacuum Suspension for Highly Active Persons with Transfemoral Amputations. 2010.

Friel, K. Componentry for Lower Extremity Prostheses. 2005 13(5): 326-335.

Gerschutz, M. J. Elevated Vacuum Suspension: Evaluation of Residual Limb Movement in a Prosthetic Socket. Journal of Prosthetics and Orthotics, 2010.

Gershutz, M. J., Haynes, M. L., Calvin, J. M., Nixon, D., Denune, J. A., Schober, G. A Vacuum Suspension Measurement Tool for Use in Prosthetic Research and Clinical Outcomes: Validation and Analysis of Vacuum Pressure in a Prosthetic Socket. Journal of Prosthetics and Orthotics, 2010. 22(3): p. 172-176.

Hafner, B. J., Willingham, L. L., Buell, N. C., Allyn, K. J., Smith, D. G. Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition From Mechanical to Microprocessor Control of the Prosthetic Knee. Arch Phys Med Rehabil. 2007 Apr; 88(4): 544.

Johansson, J. L., Sherrill, D. M., Riley, P. O., Bonato, P., Herr H. A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. Am J Phys Med Rehabil 2005;84:563–575.

Johansson, J. L., Sherrill, D. M., Riley, P. O. Bonato, P., Herr, H. A Clinical Comparison of Variable-Damping and Mechanically Passive Knee Devices. American Journal of Physical Medicine & Rehabilitation, 2005. 84(8): p. 563-575.

Kuo, A. D. Harvesting Energy by Improving the Economy of Human Walking. Science, 2005. 309(5741): p. 1686-7.

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

Lyon, C. C., Kulkarni, J., Zimerson, E., Ross, E. V., Beck, M. H. Skin Disorders in Amputees. Journal of the American Academy of Dermatology, 2000. 42(3): p. 501-507.

Neumann, E. S., Wong, J. S., Drollinger, R. L. Concepts of Pressure in an Ischial Containment Socket: Perception. Journal of Prosthetics and Orthotics, 2005. 17(1): p. 12-20.

Niu, P., Chapman, P., DiBerardina, L., Hsiao-Wecksler, E. Design and Optimization of a Biomechanical Energy Harvesting Device. Power electronics Specialists Conference. 15-19 June, 2008; 4062-4069.

Niu, P., Chapman, P., Riemer, R., Zhang, X. Evaluation of Motions and Actuation Methods for Biomechanical Energy Harvesting. IEEE Power Electronics Specialists Conference, Aachen, Germany, 2004.

Paradiso, J. A., T. Starner,. Energy Scavenging for Mobile and Wireless Electronics. IEEE Pervasive Computing, 2005. 4(1): p. 18-27.

Parker, K., Kirby, R. L., Adderson, J., Thompson, K. Ambulation of People With Lower-Limb Amputations: Relationship Between Capacity and Performance Measures. Archives of Physical Medicine and Rehabilitation, 2010. 91: 543-549.

Patterson, S. Experiences with Negative-Pressure Socket Design, in Academy Today. 2007: A7-9.

Rome, L. C., Flynn, L., Goldman, E. M., Yoo, T. D. Generating Electricity While Walking With Loads. Science, 2005. 309(5741): p. 1725-8.

Schuch, C. M., Pritham, C. H. Current Transfemoral Sockets. Clinical Orthopaedics and Related Research, 1999(361): 48-54.

Stansbury, L., Lalliss, S. J., Branstetter, J. G., Bagg, M. R., Holcomb, J. B. Amputations in U.S. Military Personnel in the Current Conflicts in Afghanistan and Iraq. Journal of Orthopaedic Trauma, 2008. 22(1): 43-46.

Starner, T., Paradiso, J. A. Human Generated Power for Mobile Electronics, in Low-Power Electronics Design, C. Piguet, Editor. 2005, CRC Press: Boca Raton.

Stepien, J. M., Cavenett, S., Taylor, L., Crotty, M. Activity Levels Among Lower-Limb Amputees: Self-Report Versus Step Activity Monitor. Archives of Physical Medicine and Rehabilitation 2007. 88:896-900.

Stewart, C. P. U., Spiers, R. Technical note—modified above-knee socket to relieve anterior pressure caused by abdominal hernia. Prosthetics and Orthotics International, 1983. 7: p. 48-49.

Street, G. Vacuum Suspension and its Effects on the Limb, in Orthopadie Technik. 2006: Germany. 1- 4.

Yang, R., Qin, Y., Li, C., Zhu, G., Wang, Z. L. Converting Biomechanical Energy into electricity by a Muscle-Movement-Driven Biogenerator. Nano Letters 2009; 9-3: 1201-1205.

Ziegler-Graham, K., MacKenzie, E. J., Ephraim, P. L, Travison TG, Brookmeyer R. Estimating the prevalence of limb loss in the United States: 2005 to 2050. Arch Phys Med Rehabil 2008;89:422-9.

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”

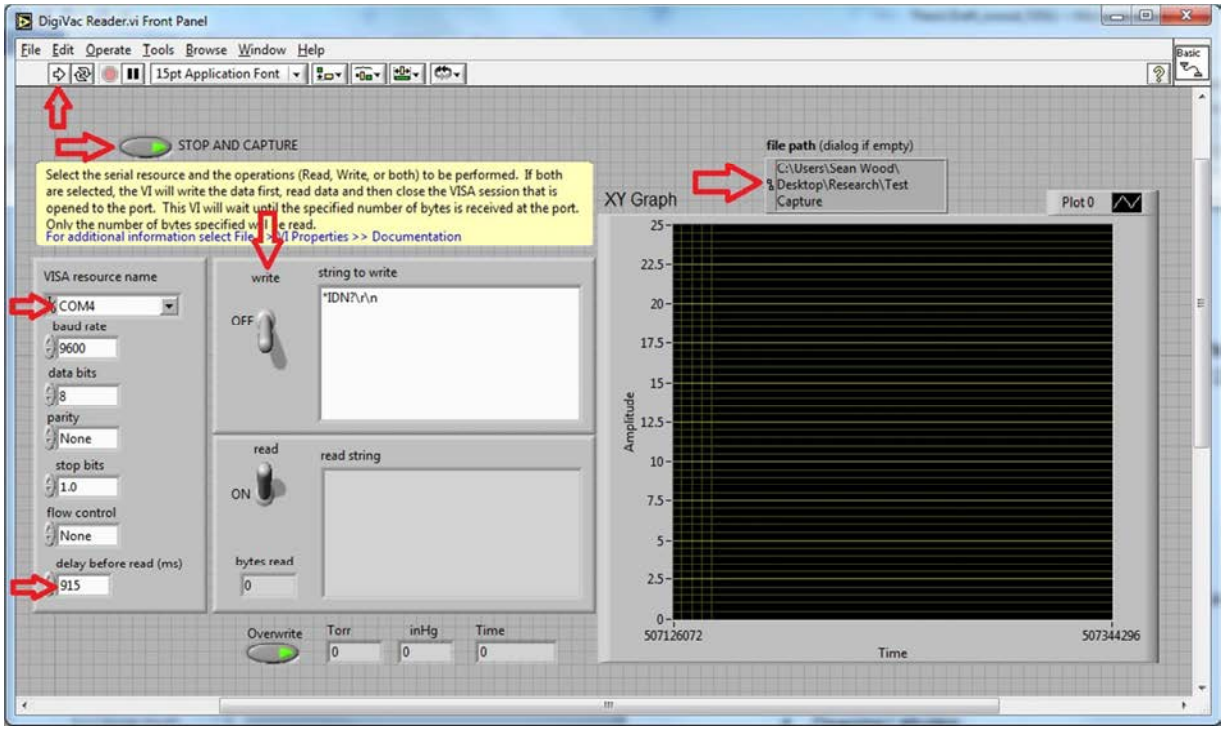


Figure C.1: The DigiVac Reader Labview Virtual Interface

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

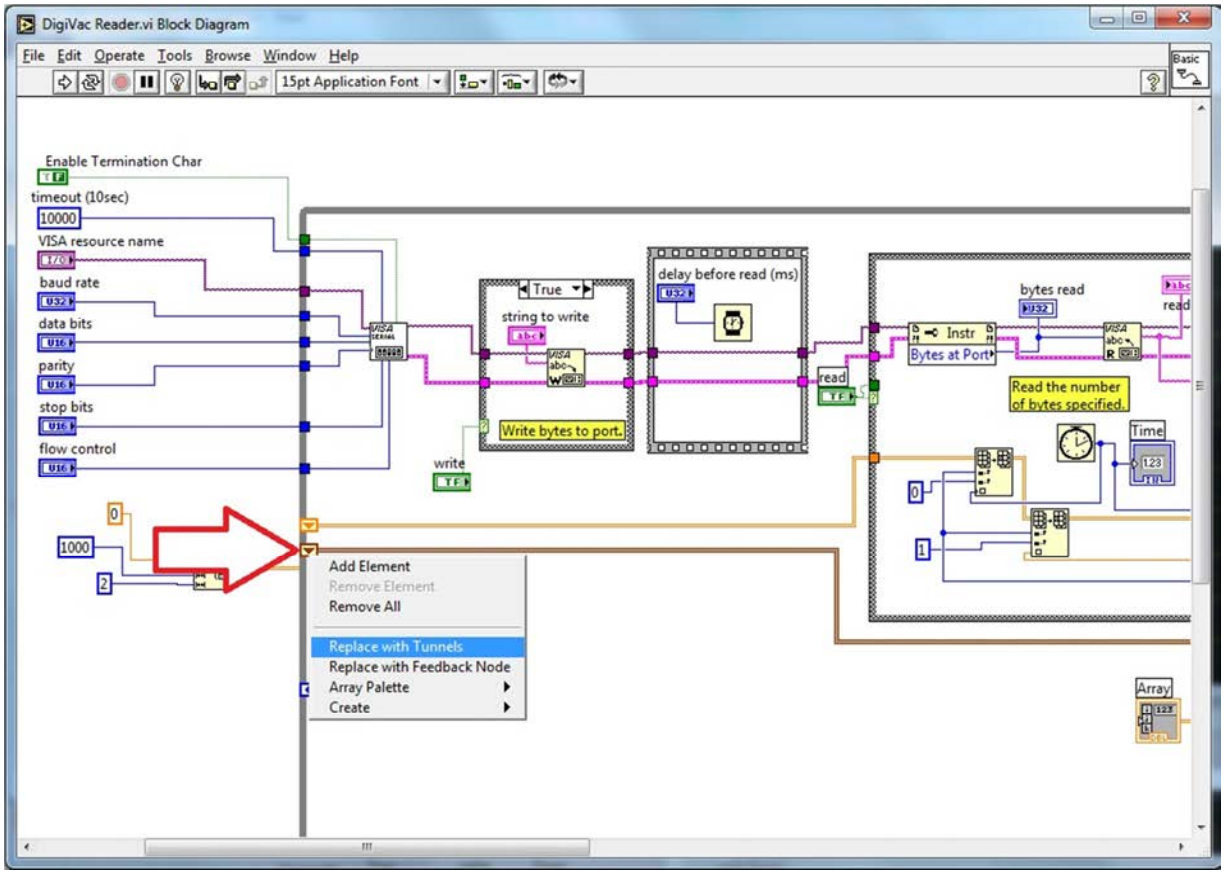


Figure C.2: The Back-End of the DigiVac Reader Labview Virtual Interface

APPENDIX M – VACUUM PUMP EVALUATIONS POSTERS AND ABSTRACTS

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.

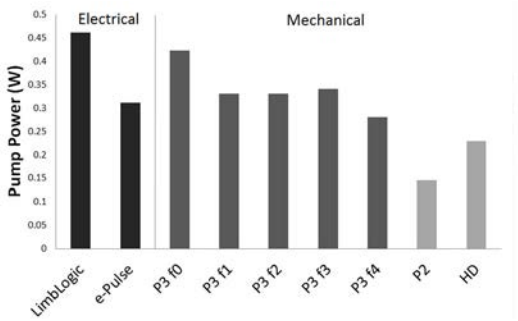


Figure 1. Calculated power (W) for the two electrical pumps and the three mechanical pumps.

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

1. Fairley, M., 'Hanging Tight': Elevated Vacuum Suspension Systems Step Forward. The O&P Edge, March 2008.

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

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

S. Fatone, PhD, BPO(Hons), S. Wood, MS, R. Caldwell, CP, W. Chen, PhD, C. Sun, PhD, A. Hansen, PhD, O. Komolafe, PhD

NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE

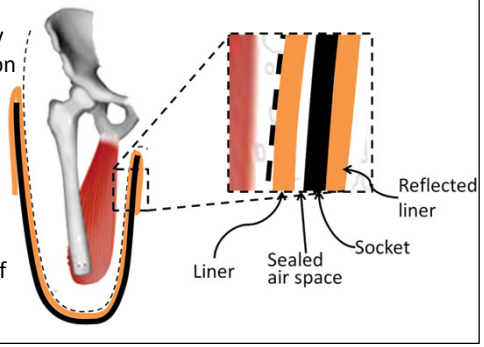
NORTHWESTERN UNIVERSITY

Background

Vacuum-Assisted Suspension

Vacuum assisted suspension (VAS) of prosthetic sockets uses electrical or mechanical pumps to create a negative pressure differential (i.e. vacuum) between the interior of a prosthetic socket and the surface of a liner clad residual limb.

Despite increasingly widespread adoption of VAS systems in prosthetic clinical practice, there remain gaps in the body of scientific knowledge guiding clinicians' choices of existing products.

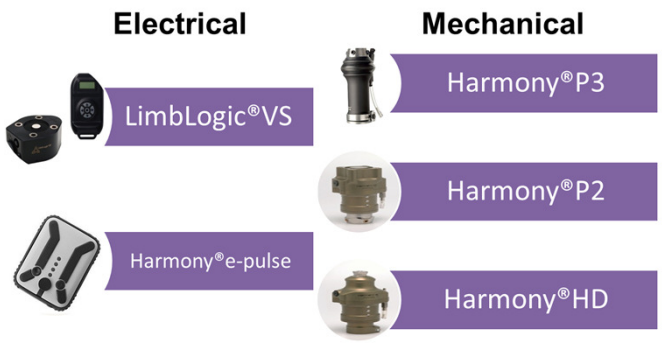


Purpose of the Study

To identify pump performance metrics and develop techniques to objectively characterize the evacuation performance of prosthetic vacuum pumps.

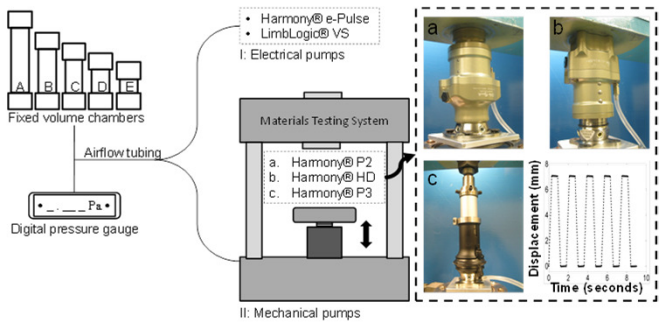
Methods

Prosthetic Vacuum Pumps Tested



- P2 and HD pumps are configured for different user weights using tension adjustments of an elastomer rod (3 weight settings).
- P3 was configured for different user weights using bladders of varying resistance to compression (functional rings "0" to "4").

Experimental Setup for Electrical and Mechanical Pumps



- Inserts show the fixture attachment within the materials testing machine for (a) Harmony® P2, (b) Harmony® HD, and (c) Harmony® P3. The bottom right insert is the displacement loading profile for the mechanical pump tests.

Volumes of PVC chambers				
A	B	C	D	E
2.05E-4 m^3 [12.54 in^3]	1.40E-4 m^3 [8.52 in^3]	1.06E-4 m^3 [6.46 in^3]	7.52E-5 m^3 [4.59 in^3]	4.41E-5 m^3 [2.69 in^3]

- For each chamber, "evacuation time" was defined as the total time from initial pump activation (start-time) to achieving a vacuum pressure of 5.76E4 Pa [17 inHg] (end-time).

A Electrical Pumps (n=2)

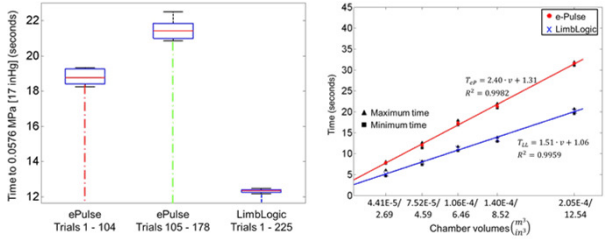
- Inconsistent evacuation times suggested pump performance was dependent on level of battery charge.
- Dependence was assessed by repeatedly evacuating chamber "C" to 5.76E4 Pa [17 inHg] until Li-Ion battery was depleted.

B Mechanical Pumps (n=3 pumps, 8 settings)

- Each functional ring was "pre-compressed" for 15 minutes prior to testing and allowed to equilibrate to testing temperature and humidity for 24 hours before testing.
- Piston ram configured to compress piston-actuated pumps by manufacturer's recommended displacement and cadence of 100 steps/min with a 50:50 of single and double limb stance.
- For all settings and chambers, 3 trials of 200 loading-unloading cycles were applied to the piston actuated pumps and 3 trials of 300 loading-unloading cycles were applied to the compressible bladder pump.

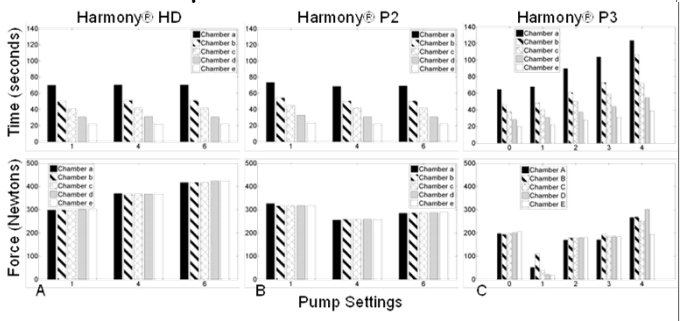
Results

A. Electrical Pump Battery Depletion Test



Left: Boxplot indicating substantially lower median activation time for LimbLogic compared to both groups of data from the e-Pulse. **Right:** Plot showing average evacuation time vs exact chamber volumes. Evacuation times of the e-Pulse (T_{eP}) are consistently higher than evacuation times of the LimbLogic (T_{LL}).

B Mechanical Pump Results



Top: Time to evacuate chambers to 5.76E4 Pa [17 inHg] for pump settings (x-axis). **Bottom:** Maximum force exerted by testing system for each chamber: (a) P2, (b) HD and (c) P3.

Conclusions

- The proposed techniques demonstrated sensitivity to the different electrical and mechanical pumps and to a lesser degree, the different setting adjustments of each pump.
- The sensitivity was less pronounced for the mechanical pumps and future improvements for testing of mechanical vacuum pumps were proposed.
- Overall, this study developed techniques feasible as standards for assessing the evacuation performance of prosthetic vacuum pump devices.

Funding Acknowledgement

Award #W81XWH-10-1-0744. The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. The content of this presentation does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred.

ABSTRACT SUBMITTED AND ACCEPTED FOR ISPO WORLD CONGRESS 2013

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

Introduction

Vacuum-assisted suspension is becoming a popular system for use in lower-limb prostheses. However, the performance of current prosthetic vacuum pumps has not been studied. In this study, prosthetic vacuum pumps, both mechanical and electrical, were tested and compared to gain insight into their overall performance and efficiency.

Methods

We compared 2 electrical (Otto Bock Harmony® epulse and Ohio WillowWood LimbLogic® VS) and 3 mechanical pumps (Otto Bock Harmony® P3, P2, and HD). Sealed canisters simulated estimated volumes of a range of socket/liner interfaces (37.5, 68.6, 99.3, 133.1, 198.9 cm3). A lever activated fixture was used to actuate the mechanical pumps. Each canister was evacuated to ~17 inHg at least 5 times with each pump. Vacuum pressure and time were recorded during evacuations using a digital gauge. Electrical pumps were also tested repeatedly on the 99.3 cm3 canister to complete battery depletion. All P3 functional rings (f0 to f4) were tested, while the P2 and HD pumps were set for a 55 kg patient (equivalent to the P3 f0 ring). 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

The LimbLogic® was 47% more powerful on average than the e-pulse. 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 epulse increased by 7.5% over the course of battery depletion, while the LimbLogic® demonstrated no change. The P3 was the most “powerful” of the mechanical pumps.

Discussion/Conclusion

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.

APPENDIX N – MANUSCRIPT PUBLISHED IN JOURNAL OF REHABILITATION RESEARCH AND DEVELOPMENT

JRRD Volume 50, Number 8, 2013
Pages 1069–1078

Methods for characterization of mechanical and electrical prosthetic vacuum pumps

Oluseeni Komolafe, PhD;[1] Sean Wood, MS;[1] Ryan Caldwell, CP;[1] Andrew Hansen, PhD;[2–3] Stefania Fatone, PhD, BPO(Hons)[1*]

[1]Northwestern University Prosthetics-Orthotics Center, Chicago, IL; [2]Minneapolis Department of Veterans Affairs Health Care System, Minneapolis, MN; [3]University of Minnesota, Minneapolis, MN

Abstract—Despite increasingly widespread adoption of vacuum-assisted suspension systems in prosthetic clinical practices, there remain gaps in the body of scientific knowledge guiding clinicians' choices of existing products. In this study, we identified important pump-performance metrics and developed techniques to objectively characterize the evacuation performance of prosthetic vacuum pumps. The sensitivity of the proposed techniques was assessed by characterizing the evacuation performance of two electrical (Harmony e-Pulse [Ottobock; Duderstadt, Germany] and LimbLogic VS [Ohio Willow Wood; Mt. Sterling, Ohio]) and three mechanical (Harmony P2, Harmony HD, and Harmony P3 [Ottobock]) prosthetic pumps in bench-top testing. Five fixed volume chambers ranging from 33 cm^3 (2 $in.^3$) to 197 cm^3 (12 $in.^3$) were used to represent different air volume spaces between a prosthetic socket and a liner-clad residual limb. All measurements were obtained at a vacuum gauge pressure of 57.6 kPa (17 inHg). The proposed techniques demonstrated sensitivity to the different electrical and mechanical pumps and, to a lesser degree, to the different setting adjustments of each pump. The sensitivity was less pronounced for the mechanical pumps, and future improvements for testing of mechanical vacuum pumps were proposed. Overall, this study successfully offers techniques feasible as standards for assessing the evacuation performance of prosthetic vacuum pump devices.

Key words: electrical prosthetic pump, elevated vacuum, mechanical prosthetic pump, negative pressure, prosthetic pump, prosthetic pump performance, prosthetic vacuum, socket evacuation, vacuum assisted suspension, vacuum pump.

INTRODUCTION

Prosthetic suspension refers to the mechanism by which the prosthetic socket is secured onto the residual limb of a person with an amputation, with poor suspension resulting in relative motion between the prosthetic socket and residual limb [1]. Vacuum-assisted suspension (VAS) of prosthetic sockets uses electrical or mechanical pumps to create a negative pressure differential, relative to the atmospheric pressure, between the interior of a prosthetic socket and the surface of a liner-clad residual limb. Since VAS was introduced and adopted in the late 1990s, investigations of VAS have focused on lower-limb prosthetic applications and the effects of vacuum on residual-limb volume [2–5], socket suspension [2], socket fit and interface pressures [6–7], gait kinematics, and residual-limb health [8–9]. These studies suggested VAS improves the

Abbreviations: ISO = International Organization for Standardization, Li-Ion = lithium-ion, VAS = vacuum-assisted suspension.

[*]**Address all correspondence to Stefania Fatone, PhD, BPO (Hons); Northwestern University Prosthetics-Orthotics Center, 680 N Lake Shore Dr, Suite 1100, Chicago, IL 60611; 312-503-5717; fax: 312-503-5760. Email: s-fatone@northwestern.edu**

http://dx.doi.org/10.1682/JRRD.2012.11.0204

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

limb health of prosthesis users by minimizing trauma-inducing relative motion between the socket and residual limb, as well as by promoting tissue hydration, evidenced by reduction in fluctuations in residual-limb volume.

The high numbers of reports in related professional journals [10–11], as well as in prosthetic trade magazines [12–13], suggest an increasingly widespread use of VAS in prosthetic clinical practice, as well as a concomitant increase in the number of commercially available pumps for achieving VAS in prosthetic socket systems. However, other than manufacturer specifications, we have no knowledge of any guidelines in the way of standardized pump performance characterization that may assist clinicians' decision-making. This is in contrast to the large number of characterization studies on other commercially available prosthetic devices and components, such as prosthetic feet [14–15], shock absorbing pylons [16–17], prosthetic knees [18–19], liners, and interface materials [20–22].

Hence, the purpose of this study was to develop techniques to characterize the performance of prosthetic vacuum pumps. Important performance metrics considered included the pumps' evacuation rates to specific vacuum levels and maximum evacuation capabilities based on repeated evacuation of leakage-free containers. The approach described in this article represents a first step toward understanding vacuum pump characteristics in chambers with known leakage (a more clinically relevant scenario). The sensitivity of the proposed techniques was assessed by characterizing the evacuation performance of several commercially available electrical and mechanical pumps.

METHODS

Equipment

Based on input from a certified prosthetist (author RC) regarding the level of use in prosthetic practice, two electrical (Harmony e-Pulse [Ottobock; Duderstadt, Germany] and LimbLogic VS [Ohio WillowWood; Mt. Sterling, Ohio]) and three mechanical (Harmony P2, Harmony HD, and Harmony P3 [Ottobock]) prosthetic pumps (**Table 1**) were purchased and their evacuation performance evaluated. In both electrical pumps, a lithium-ion (Li-Ion) battery powered a direct current motor, which ran a small capacity pump. Microprocessor circuitry within the pump monitored the vacuum pressure in the prosthetic socket system and reactivated the pump if the vacuum pressure level decreased below a prescribed threshold.

The three mechanical pumps were designed to be installed in-line with the prostheses and engaged the weight of the user to generate vacuum pressure through two distinctly different activation mechanisms. The two "piston-actuated" mechanical pumps (Harmony P2 and Harmony HD) pulled air from the socket to the pump chamber during stance phase on the prosthetic limb while walking (i.e., when the prosthesis was loaded). The pumps could be configured for different user weights through adjustments of the tension of an elastomer rod within the pumps (**Table 2**). Conversely, the "compressible bladder" mechanical pump (Harmony P3) pulled air from the socket to the pump bladder during swing phase of the prosthetic limb while walking (i.e., when the prosthesis was

Table 1.
Description of vacuum pumps tested.

Pump	Description
Electrical	
Harmony e-Pulse (Ottobock)	• 2.20 Wh nominal battery energy. • 61 kPa (18 inHg) maximum negative pressure level.
LimbLogic VS (Ohio WillowWood)	• 2.04 Wh nominal battery energy. • 68 kPa (20 inHg) maximum negative pressure level.
Mechanical	
Harmony P2 (Ottobock)	• Patient weights of 50–100 kg (110–220 lb). • Vacuum capability of 51–85 kPa (15–25 inHg).
Harmony HD (Ottobock)	• Patient weights of 100–150 kg (220–330 lb). • Vacuum capability of 51–85 kPa (15–25 inHg).
Harmony P3 (Ottobock)	• Patient weights of 45–100 kg (100–220 lb). • Functional rings denoted 0–4 in order of increasing resistance to compression. • Vacuum capability of 51–85 kPa (15–25 inHg).

Table 2.
Weight settings for mechanical pumps.

Setting	Number of Turns out (counterclockwise) from Fully Inserted Position*	Harmony P2 / Harmony HD Corresponding Patient Weight (lb/kg)		Harmony P3		
				Functional Ring (*n*)	Body Weight (kg)	Load (lb)
1†	4.5	120/50	220/100	0	45–50	100–110
2	4.0	140/60	240/110	1	50–60	110–130
3	3.5	160/70	260/120	2	60–73	130–160
4†	3.0	180/80	280/130	3	73–86	160–190
5	2.5	200/90	300/140	4	86–100	190–200
6†	2.0	220/100	320/150	—	—	—

*Manufacturer instructions: To adjust settings, locate blue cup inside pump shaft, screw in completely using 3/8" Allen wrench. Set elastomer rod by backing out blue cup completely to release pressure on rod, then turning clockwise by suggested number of turns.
†Settings used for benchtop testing. Settings 1, 4, and 6 were weight settings assessed in study.

unloaded). In this case, the pump was configured for different user weights using bladders of varying resistance to compression (i.e., functional rings denoted "0" to "4" in order of increasing resistance in **Table 2**). In both mechanisms, air was pushed out from the pump chamber during the alternate phase of walking, i.e., during swing phase for the piston-actuated pumps and during stance phase for the compressible bladder pump.

For the purpose of this study, a well-fitted subischial prosthetic check socket was fabricated for an average-sized male subject with a transfemoral amputation. The air volume space between the inner surface of the doffed check socket and an appropriately sized liner was estimated at 98 cm^3 (6 $in.^3$) based on a linear interpolation of the relationship from a previous characterization of the evacuation time of the LimbLogic VS pump using known volumes. Scaling about this reference, five fixed-volume chambers were manufactured from PVC (polyvinyl chloride) tubing and end-caps (ranging from 33 cm^3 [2 $in.^3$] to 197 cm^3 [12 $in.^3$]). These chambers were used during evacuation testing of the prosthetic pumps to simulate varying air volume spaces of transfemoral sockets, although the range of volumes, in particular the smaller volumes, may also be relevant to transtibial sockets. Exact volumes of the chambers were calculated by dividing the weight of the mass of water required to fill the chambers by the density of water.

A servo-hydraulic materials testing system (8800 Controller, Instron; Norwood, Massachusetts) was used to apply periodic vertical loads, representative of a prosthesis user's weight during walking, to the mechanical pumps. For both electrical and mechanical pump systems, vacuum pressure measurements were acquired using a digital vacuum pressure gauge (model 2L760, DigiVac; Matawan, New Jersey) with a detection resolution of 0.27 kPa (0.08 inHg). The gauge was customized to a full scale output of 5 V at atmospheric pressure of the testing environment. Prior to each testing session, the gauge was calibrated for a maximum vacuum gauge measurement of –84.7 kPa (25 inHg) relative to the atmospheric pressure. For simplicity, the negative sign on the vacuum pressure levels will be omitted in the remainder of this report.

Experimental Procedures

Electrical Pump Testing

The setup for the performance testing of the two electrical pumps consisted of connecting each pump to one of the five fixed-volume chambers using airflow tubing (**Figure 1**). The pump was activated and the vacuum pressure within the connected chamber was monitored and recorded. After evacuation to a specified vacuum level, the airflow tubing was disconnected to return the chamber to the baseline pressure. This process was repeated for five trials of each electrical pump and chamber combination.

Preliminary assessment of the out-of-box capabilities of the two electrical pumps in this study indicated the maximum vacuum pressure level common to both pumps was 57.6 kPa (17 inHg). Consequently, for each chamber, the "evacuation time" of both electrical pumps was defined as the total time from initial pump activation (start-time) to achieving a vacuum pressure of 57.6 kPa (17 inHg) in that chamber (end-time).

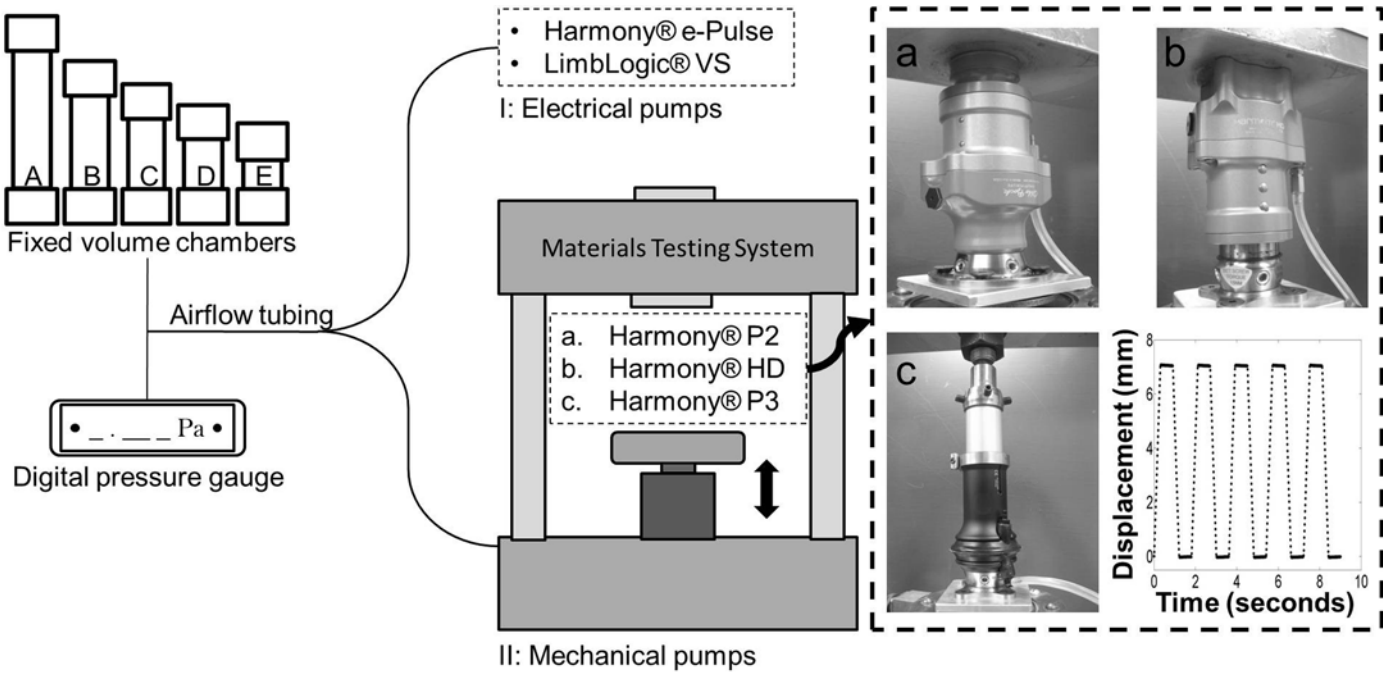


Figure 1.
Schematic of experimental test setup for electrical and mechanical pumps showing fixed volume chambers, digital pressure gauge, and servo-hydraulic materials testing system. Volumes of five PVC chambers used for testing from left to right are (A) 205 cm^3 (12.54 $in.^3$), (B) 140 cm^3 (8.52 $in.^3$), (C) 106 cm^3 (6.46 $in.^3$), (D) 75 cm^3 (4.59 $in.^3$), and (E) 44 cm^3 (2.69 $in.^3$). Inserts show fixture attachment within materials testing machine for **(a)** Harmony P2, **(b)** Harmony HD, and **(c)** Harmony P3. Bottom right insert is displacement loading profile for mechanical pump tests.

The discovery of inconsistent evacuation times for the electrical pumps over consecutive days suggested the performance of the pumps was dependent on level of battery charge. Accounting for this dependency by performing all evacuations with the pumps connected to an alternating current power supply was not possible because the Harmony e-Pulse pump was unable to be simultaneously activated and charged. Instead, a series of exhaustive tests (i.e., testing each pump to complete battery charge depletion) was performed to quantify the dependence of both pumps' evacuation performance on battery discharge. The exhaustive testing for each pump involved evacuating the 106 cm^3 (6.46 $in.^3$) chamber repeatedly to 57.6 kPa (17 inHg), allowing only time to return the chamber to the baseline atmospheric pressure between each evacuation trial, until the Li-Ion battery of the pump was depleted.

Mechanical Pump Testing

The performance of the two piston-actuated mechanical pumps (Harmony P2 and Harmony HD) was assessed at three different settings of manufacturer-prescribed elastomer rod tension adjustments, while the performance of the compressible bladder mechanical pump (Harmony P3) was assessed for the five weight-rated functional rings (**Table 2**). Prior to testing, each functional ring was "precompressed" for 15 min using a compression tool provided by the manufacturer and was allowed to equilibrate to the testing temperature and humidity environment for a minimum of 24 h before testing. To simulate the in vivo compressive cyclic loads exerted on the pumps during walking, the pumps were loaded using the hydraulic piston ram of the material testing system. Airflow tubing was used to connect the installed pumps to the fixed volume chambers and the digital vacuum pressure gauge (**Figure 1**).

The piston ram was configured to compress the two piston-actuated pumps by 7 mm, at a cyclic loading rate of 23 mm/s and the compressible bladder pump by 5 mm at the same cyclic loading rate. These values represent the manufacturer's displacement recommendations for optimal pump performance [23] and an approximate

prosthetic-limb cadence of 100 steps/min, with a 50:50 proportion of single- and double-limb stance support. The numbers of loading-unloading cycles applied to each mechanical pump were determined from pilot data and identified as the number of cycles at which continued activation of the pumps created a negligible increase in vacuum pressure. Consistently for all pump weight settings and chamber combinations, three trials of 200 loading-unloading cycles were applied to the piston actuated pumps and three trials of 300 loading-unloading cycles applied to the compressible bladder pump.

Data Analysis and Calculations

The vacuum pressure data generated by the mechanical pumps exhibited a step-like profile, increasing as the pumps were loaded and staying approximately constant upon removal of load. The data were resampled to isolate the vacuum pressure value at the start of the loading-unloading cycle, effectively reducing the data to a single data point per cycle. Unlike the electrical pumps, where the maximum vacuum pressures were controlled by microprocessor circuitry, the maximum vacuum pressures generated by the mechanical pumps were potentially dependent on the number of cyclic activations of the pumps. In an attempt to address this dependence, a theoretical maximum vacuum capacity was calculated and reported for each mechanical pump. This calculation involved a linear extrapolation of the terminal region of the asymptotic trending vacuum pressure data to three times the total testing duration of that trial. For all electrical and mechanical pump trials, the evacuation times to a vacuum pressure of 57.6 kPa (17 inHg) were measured and averaged over the number of repeated trials for all pump, setting, and chamber combinations.

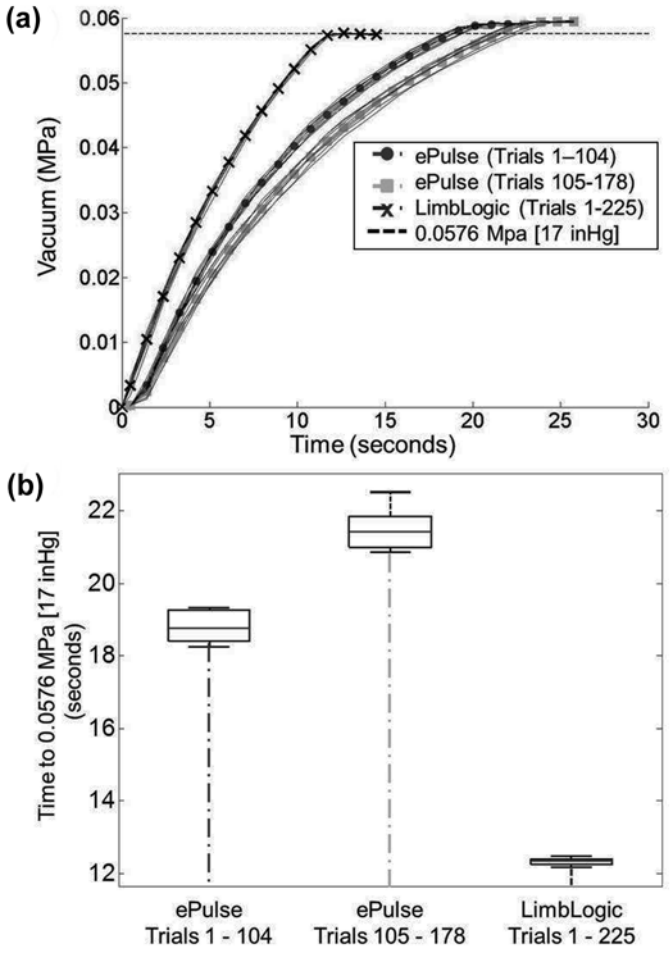


Figure 2.
Electrical pump battery depletion test results. **(a)** Plot of vacuum pressure vs time for two grouped evacuation trials of Harmony e-Pulse and single group evacuation trial of LimbLogic VS. **(b)** Boxplot indicating substantially lower median activation time for LimbLogic VS compared with both groups of data from Harmony e-Pulse.

RESULTS

Electrical Pump Testing

Exhaustive testing of the electrical pumps demonstrated the Harmony e-Pulse had a total of 178 evacuations before complete battery depletion, with a 14 percent increase in time to evacuate to 57.6 kPa (17 inHg) over the entire course of the test (**Figure 2(a)**). We noted a distinct change in the time to evacuate between the first 104 trials and the subsequent 74 trials (**Figure 2(b)**), with consistent evacuation times within each group of trials (standard deviation of 0.40 and 0.54, respectively). By comparison, the LimbLogic VS achieved a total of 225 evacuations using only half a full battery charge (as indicated by the pump battery meter) before exhaustive testing was terminated. There was a 2.4 percent total increase in evacuation time to 57.6 kPa (17 inHg) over the course of the test.

The average time to evacuate all five chambers to 57.6 kPa (17 inHg) for the LimbLogic VS was 11.57 s, while the Harmony e-Pulse required 18.04 s (56% more time) to evacuate the same chambers (**Table 3**). For both electrical pumps, linear equations were able to describe

Table 3.
Electrical pump results. Standard evacuation pressure level was set at 57.6 kPa (17 inHg).

Chamber Volume (cm^3/$in.^3$)	Time to Evacuate (s)	
	LimbLogic VS	Harmony e-Pulse
205/12.54	20.16	31.56
140/8.52	13.38	21.32
106/6.46	11.28	17.37
75/4.59	7.95	12.06
44/2.69	5.10	7.86
Mean ± Standard Deviation	11.57 ± 5.74	18.04 ± 9.13

most of the variability in the evacuation times as a function of the five chamber volumes ($R^2 > 0.99$) (**Figure 3**). The best-fit lines of evacuation times plotted against chamber volume showed the LimbLogic VS had a smaller slope compared to the Harmony e-Pulse despite having a similar *y*-intercept.

Mechanical Pump Testing

Across the three manufacturer-prescribed elastomer rod tension settings and for the same chamber volumes at those settings, neither the Harmony P2 nor the Harmony HD pumps showed substantial differences in their evacuation times to 57.6 kPa (17 inHg), the number of activation cycles required, or their theoretical maximum vacuum capacity (**Table 4**). The Harmony P3 pump showed a consistent trend of increasing evacuation times to 57.6 kPa (17 inHg), increasing number of activations required, and a decreasing theoretical maximum vacuum capacity with increasing resistance to compression (i.e., functional rings denoted "0" to "4").

A comparison of the maximum forces exerted by the hydraulic piston ram during application of the programmed compressive displacement to the Harmony P2 and Harmony HD pumps showed no sensitivity to the chamber volume within the three elastomer rod settings. However, across the three settings, there were clear differences, generally trending, with the exception of results of setting 1 of the Harmony P2 pump, to increasing maximum force with increasing resistance to compression of the elastomer rod (**Figure 4**). The Harmony P3 pump performed with less consistency within and across the different resistances to compression.

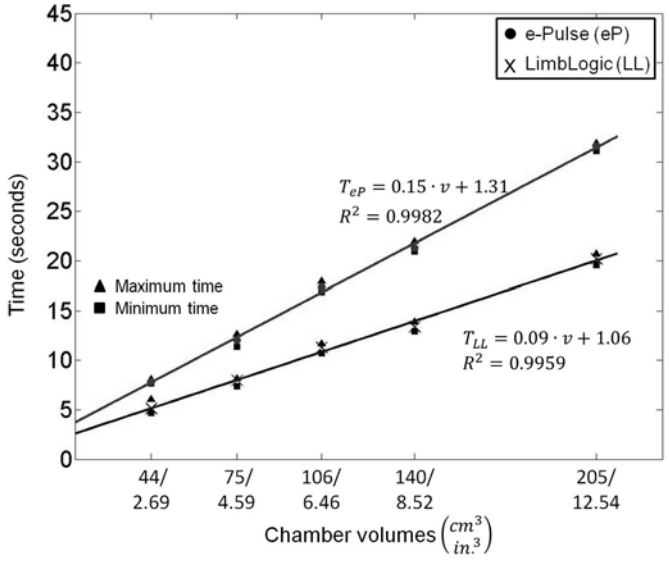


Figure 3.
Electrical pump results showing average evacuation time vs exact chamber volumes. Evacuation times of Harmony e-Pulse (superior line, T_{eP}) are consistently higher than evacuation times of LimbLogic VS (inferior line, T_{LL}).

DISCUSSION

The purpose of this study was to develop techniques to characterize the performance of vacuum pumps intended for clinical application within prostheses. Such characterizations offer insights to guide clinician selection of devices and components. To assess the sensitivity of the proposed techniques, several commercially available vacuum pumps were characterized in a series of benchtop tests.

Electrical Pump Battery Depletion Testing

Results of the exhaustive battery testing indicated a slight increase in evacuation time of sequential trials, suggesting a dependence of pump performance on total battery charge. The substantially higher number of total evacuations of the LimbLogic VS pump than the Harmony e-Pulse was likely because of the quality of the battery and other components of the pumps. In spite of this dependence, both pumps performed consistently for the first 100 evacuation trials of the 106 cm^3 (6.46 $in.^3$) chamber volume.

Electrical Pump Testing

Selection of 57.6 kPa (17 inHg) as a standard vacuum pressure level for measuring evacuation time was based on a preliminary assessment that determined the maximum

Table 4.
Mechanical pump results.

Measure	Harmony P2 (Settings)			Harmony HD (Settings)			Harmony P3 (Functional Rings)				
	1	4	6	1	4	6	0	1	2	3	4
Time to Evacuate to 57.6 kPa (17 inHg) (s)	42.72	42.59	42.71	42.47	43.31	43.06	39.50	41.78	53.31	62.12	79.17
Number of Cycles to 57.6 kPa (17 inHg) (units)	26	25	25	26	25	25	25	27	34	39	50
Maximum Vacuum Gauge Pressure (kPa/inHg)	80.39/ 23.74	89.43/ 26.41	89.43/ 26.41	88.93/ 26.26	88.38/ 26.10	88.69/ 26.19	75.11/ 22.18	70.40/ 20.79	67.90/ 20.05	65.15/ 19.24	63.16/ 18.65

vacuum pressure level common to both electrical pumps. The LimbLogic VS consistently outperformed the Harmony e-Pulse in time to evacuate each chamber, averaging 56 percent less time to achieve a vacuum level of 57.6 kPa (17 inHg) (**Figure 3**). For both pumps, linear equations were able to describe most of the variability in evacuation times as a function of the different chamber volumes. Despite having similar *y*-intercepts, the LimbLogic VS had a smaller slope than the Harmony e-Pulse pump, suggesting a higher base functional performance because increases in volumes resulted in smaller increases in evacuation time.

Mechanical Pump Testing

Our decision to adopt a benchtop approach to characterize the performance of the mechanical pumps allowed precise control of the loading variables. The pumps were actuated by the servo-hydraulic materials testing system using a displacement control paradigm. The amount of compression of the pumps, the cyclic loading rate, and the total number of loading-unloading cycles were determined prior to initiation of the test.

At the three weight settings tested for the Harmony P2 and Harmony HD pumps, there were no differences in pump performance within, as well as across, both pumps (**Table 4**, **Figure 4**). This misleading finding suggested the different elastomer rod tension adjustments had no effect on pump performance. Correct interpretation required consideration of the control paradigm used for loading of the mechanical pumps. Under a displacement control paradigm, the testing system adjusted the force applied at each weight setting to achieve prescribed displacements. We expected the applied force to increase with increasing resistance (i.e., setting $1 < 4 < 6$) for both pumps. The results (**Figure 4**), with the inexplicable exception of the Harmony P2 pump at setting 1, followed these trends and demonstrated sensitivity of the pump performance to the different settings.

As previously described, the Harmony P3 pump used compressible bladders (functional rings) to pull air from the socket and generate vacuum pressure. With increasing resistance of the functional rings (from ring 0 to 4), the time and number of cyclic activations required to achieve 57.6 kPa (17 inHg) for each chamber also increased. Conversely, the theoretical maximum vacuum capacity was reduced. These results suggested the mechanism used to increase resistance was increased wall thickness of the bladders, effectively reducing the total volume of the bladders. Hence, with the stiffer bladders, the amount of air moved by the pump per activation cycle was reduced.

The testing of the mechanical pumps could be improved by use of machines for International Organization for Standardization (ISO) 22675 testing (ISO; Geneva, Switzerland) [24]. ISO 22675 testing machines are designed to test prosthetic feet in a heel-to-toe loading fashion that simulates walking. These machines also use force control to mimic the ground reaction forces during walking. Mechanical pumps could be placed in line with pylons and feet within these testing machines to obtain more realistic results. Manufacturers of mechanical vacuum pumps for use in prostheses could use similar metrics as described in this article, but with improved loading from ISO 22675 machines.

There were several practical limitations that curtailed the scope and generalizability of our findings. First, a single pump of each type was used to assess the techniques presented in this report. Findings from such a sample are not generalizable to all pumps of the same type, and a number of precautions were taken to mitigate potential errors introduced by the use of single samples. Both electrical pumps had less than 10 h of use, primarily usage for preliminary evaluation at commencement of our testing. Similarly, the three mechanical pumps were exposed to very limited use at the start of data collection. Brand new functional rings were purchased for the Harmony P3

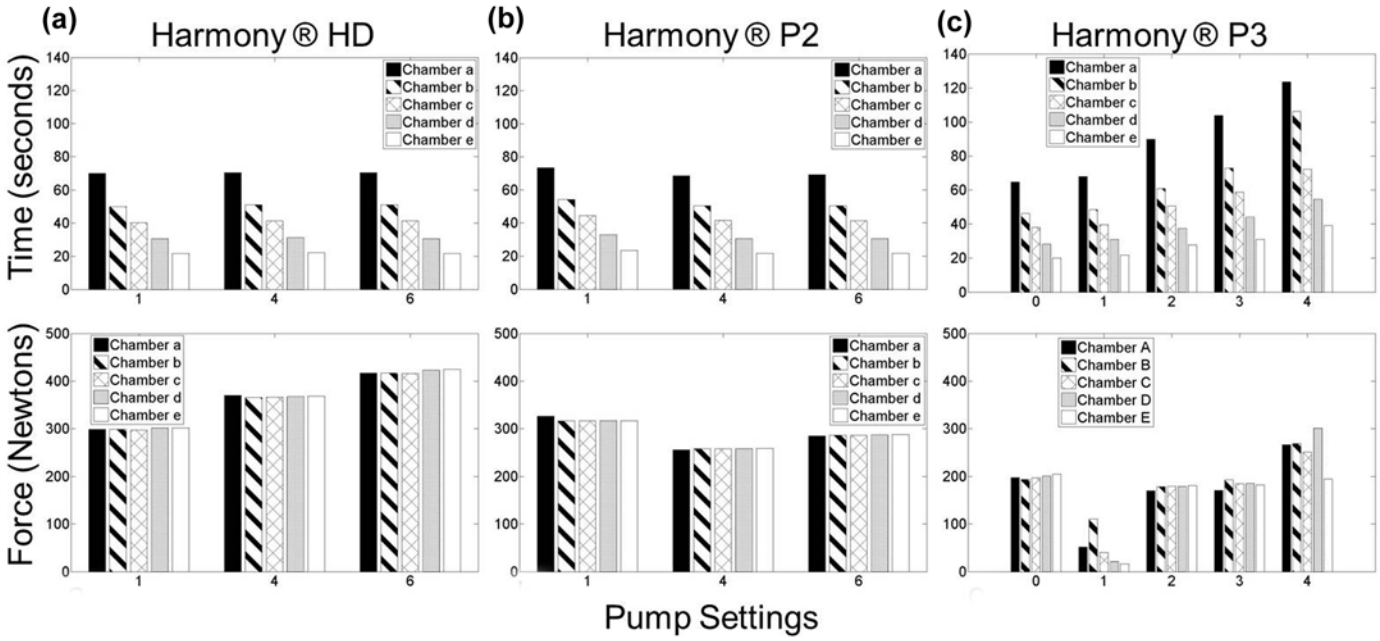


Figure 4.
Mechanical pump results showing (top plots) time to evacuate chambers to 57.6 kPa (17 inHg) for pump settings (*x*-axis) and (bottom plots) maximum force exerted by testing system for each chamber evacuated: **(a)** Harmony HD, **(b)** Harmony P2, and **(c)** Harmony P3.

pump and were precompressed according to manufacturer recommendations. These precautions allowed the reasonable assumption that all pumps, batteries, and components remained true to their original technical specifications.

Second, the estimate of air volume space between the prosthetic socket's inner surface and the outer surface of the liner-clad residual limb was calculated from an average-sized male with a transfemoral amputation. To include a range of air volume spaces in our analysis, we used this estimate as a scaling reference for several fixed volume canisters, including smaller volumes that are likely relevant to air volume spaces found in transtibial prosthetic sockets.

Third, the ideal setup for the electrical and mechanical prosthetic vacuum pumps characterization would have simulated a gradual loss of vacuum gauge pressure (i.e., leakage), providing a more realistic representation of the everyday usage of prosthetic vacuum pumps. This would be of particular significance for the electrical pump battery depletion testing since the primary power mode of electrical pumps within minimally leaking socket systems would conceivably be a "stand-by" monitoring mode. In this mode, the electrical motor is deactivated and battery power supply is limited to essential pump tasks for monitoring the vacuum gauge pressure within the socket system. An electrical pump with more efficient battery consumption in the stand-by monitoring mode may be capable of a higher number of overall evacuations for the same air space volumes and socket leakage rates. Our decision to assess pump performance based on repeated, complete loss of vacuum gauge pressure (i.e., full depletion) was due to the difficulty of developing a standard characterization of typical leakage. Repeated full depletion represents an unlikely worst case scenario and should be considered in the interpretation of performance findings determined using the proposed techniques.

Finally, although only one end of the two piston-actuated pumps was directly attached to the testing system (**Figure 1(a)** and **(b)**), both ends of the compressible bladder pump were directly attached to the testing system for the entire actuation cycle (**Figure 1(c)**). The difference in setup was due to the inability of the Harmony P3 pump to return to its original, uncompressed height after the loading (i.e., pump compression) phase of the actuation cycle. With increasing number of actuation cycles, the pump height gradually decreased until all evacuation functioning ceased

because of a fully compressed bladder, i.e., a "bottoming out" of the bladder. Attaching both ends to the testing system introduced a forcible, as opposed to a passive, restoration to the original bladder pump height during the unloading phase of the actuation cycle. Care was taken to ensure the compressible bladder pump was returned only to its uncompressed height, with negligible off-axial forces applied to the bladder while unloading. For these reasons, we expect the Harmony P3 pump to experience a bottoming out effect in clinical use and the actual performance, particularly regarding the maximum vacuum capacity, to be worse than our results suggest.

The proposed techniques offer objective assessments necessary for potential performance characterization guidelines of prosthetic vacuum pumps. They demonstrated sensitivity to the different commercially available electrical and mechanical pumps characterized in this study, and to a lesser degree, the pump settings. Overall, this study offers techniques feasible for general adoption as standards for assessing the evacuation performance of electrically controlled and mechanical prosthetic vacuum pumps.

CONCLUSIONS

There are presently no performance guidelines to assist clinicians when selecting from among existing prosthetic vacuum pumps. If adopted by the prosthetics community, the proposed techniques will provide testing guidelines and standard performance metrics for prosthetic pumps that can enhance clinicians' ability to make informed choices for patients using VAS.

ACKNOWLEDGMENTS

Author Contributions:
Study concept and design: O. Komolafe, S. Wood, R. Caldwell, A. Hansen, S. Fatone.
Acquisition of data: O. Komolafe, S. Wood, R. Caldwell.
Analysis and interpretation of data: O. Komolafe, S. Wood, R. Caldwell, A. Hansen, S. Fatone.
Drafting of manuscript: O. Komolafe.
Critical revision of manuscript for important intellectual content: O. Komolafe, S. Wood, R. Caldwell, A. Hansen, S. Fatone.
*Obtained funding:*S. Fatone, R. Caldwell, A. Hansen.
Financial Disclosures: The authors have declared that no competing interests exist.
Funding/Support: This material was based on work supported by the U.S. Army Medical Research and Materiel Command Acquisition Activity, Fort Detrick, Maryland (Award #W81XWH-10–1-0744).
Additional Contributions: We thank James Schweitzer for acquisition of mechanical pump data and Kerice Tucker for mechanical pump testing setup and training. Mr. Wood is now with Space Exploration Technologies, Hawthorne, California.
Disclaimer: The contents of this article do not necessarily reflect the position or the policy of the government, and no official endorsement should be inferred.

REFERENCES

1. Kapp S. Suspension systems for prostheses. Clin Orthop Relat Res. 1999;(361):55–62. [PMID:10212596] http://dx.doi.org/10.1097/00003086-199904000-00008
2. Board WJ, Street GM, Caspers C. A comparison of trans-tibial amputee suction and vacuum socket conditions. Prosthet Orthot Int. 2001;25(3):202–9. [PMID:11860094] http://dx.doi.org/10.1080/03093640108726603
3. Goswami J, Lynn R, Street G, Harlander M. Walking in a vacuum-assisted socket shifts the stump fluid balance. Prosthet Orthot Int. 2003;27(2):107–13. [PMID:14571940] http://dx.doi.org/10.1080/03093640308726666
4. Gerschutz M, Denune JA, Colvin JM, Schober G. Elevated vacuum suspension influence on lower limb amputee's residual limb volume at different vacuum pressure settings. J Prosthet Orthot. 2010;22(4):252–56. http://dx.doi.org/10.1097/JPO.0b013e3181f903df
5. Sanders JE, Harrison DS, Myers TR, Allyn KJ. Effects of elevated vacuum on in-socket residual limb fluid volume: Case study results using bioimpedance analysis. J Rehabil Res Dev. 2011;48(10):1231–48. [PMID:22234667] http://dx.doi.org/10.1682/JRRD.2010.11.0219
6. Beil TL, Street GM, Covey SJ. Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets. J Rehabil Res Dev. 2002;39(6):693–700. [PMID:17943671]
7. Gerschutz M. Elevated vacuum suspension: Evaluation of residual limb movement in a prosthetic socket. Proceedings of the 36th Annual Meeting and Scientific Symposium of the American Academy of Orthotists and Prosthetists; 2010 Mar 24–27; Chicago, IL.
8. Traballesi M, Averna T, Delussu AS, Brunelli S. Trans-tibial prosthesization in large area of residual limb wound: Is it possible? A case report. Disabil Rehabil Assist Technol. 2009; 4(5):373–75. [PMID:19565372] http://dx.doi.org/10.1080/17483100903038568
9. Traballesi M, Delussu AS, Fusco A, Iosa M, Averna T, Pellegrini R, Brunelli S. Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study. Eur J Phys Rehabil Med. 2012;48(4):613–23.
10. Street G. Vacuum Suspension and its effects on the limb. Orthopädie Technik. 2006;English Edition IV:1–6.

11. Brunelli S. Vacuum assisted socket system in transtibial amputees: Clinical report. Orthopädie Technik. 2009;2:2–8.
12. Patterson S. Experiences with negative-pressure socket design. The Academy Today. 2007;3(3):A7–9.
13. Fairley M. “Hanging tight”: Elevated vacuum suspension systems step forward. O&P Edge. March 2008.
14. Lehmann JF, Price R, Boswell-Bessette S, Dralle A, Questad K. Comprehensive analysis of dynamic elastic response feet: Seattle Ankle/Lite Foot versus SACH foot. Arch Phys Med Rehabil. 1993;74(8):853–61. [PMID:8347071] http://dx.doi.org/10.1016/0003-9993(93)90013-Z
15. Sam M, Hansen AH, Childress DS. Mechanical characterization of prosthetic feet using a prosthetic foot loading apparatus. Proceedings of the 22nd Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Vols 1–4. 2000;22:1968–71.
16. Berge JS, Klute GK, Czerniecki JM. Mechanical properties of shock-absorbing pylons used in transtibial prostheses. J Biomech Eng. 2004;126(1):120–22. [PMID:15171138] http://dx.doi.org/10.1115/1.1645865
17. Gard SA, Konz RJ. The effect of a shock-absorbing pylon on the gait of persons with unilateral transtibial amputation. J Rehabil Res Dev. 2003;40(2):109–24. [PMID:15077637] http://dx.doi.org/10.1682/JRRD.2003.03.0109
18. Theeven PJ, Hemmen B, Geers RP, Smeets RJ, Brink PR, Seelen HA. Influence of advanced prosthetic knee joints on perceived performance and everyday life activity level of low-functional persons with a transfemoral amputation or knee disarticulation. J Rehabil Med. 2012;44(5):454–61. [PMID:22549656] http://dx.doi.org/10.2340/16501977-0969
19. Bellmann M, Schmalz T, Ludwigs E, Blumentritt S. Immediate effects of a new microprocessor-controlled prosthetic knee joint: A comparative biomechanical evaluation. Arch Phys Med Rehabil. 2012;93(3):541–49. [PMID:22373937] http://dx.doi.org/10.1016/j.apmr.2011.10.017
20. Gholizadeh H, Osman NA, Kamyab M, Eshraghi A, Abas WA, Azam MN. Transtibial prosthetic socket pistoning: Static evaluation of Seal-In(®) X5 and Dermo(®) Liner using motion analysis system. Clin Biomech (Bristol, Avon). 2012;27(1):34–39. [PMID:21794965] http://dx.doi.org/10.1016/j.clinbiomech.2011.07.004
21. Sanders JE, Nicholson BS, Zachariah SG, Cassisi DV, Karchin A, Fergason JR. Testing of elastomeric liners used in limb prosthetics: Classification of 15 products by mechanical performance. J Rehabil Res Dev. 2004;41(2):175–86. [PMID:15558371] http://dx.doi.org/10.1682/JRRD.2004.02.0175
22. Sanders JE, Greve JM, Mitchell SB, Zachariah SG. Material properties of commonly-used interface materials and their static coefficients of friction with skin and socks. J Rehabil Res Dev. 1998;35(2):161–76. [PMID:9651888]
23. Otto-Bock-HealtCare-LP. Harmony P2 and Harmony HD instructions for use. Duderstadt (Germany): Ottobock; 2004.
24. ISO. ISO 22675:2006 Prosthetics—Testing of ankle foot devices and foot units—Requirements and test methods. [Internet]. Geneva (Switzerland): ISO; 2006. Available from: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=36413

Submitted for publication November 9, 2012. Accepted in revised form March 11, 2013.

This article and any supplementary material should be cited as follows:
Komolafe O, Wood S, Caldwell R, Hansen A, Fatone S. Methods for characterization of mechanical and electrical prosthetic vacuum pumps. J Rehabil Res Dev. 2013;50(8):1069–78.
http://dx.doi.org/10.1682/JRRD.2012.11.0204

ALL SUBMISSIONS SCREENED BY: iThenticate Professional Plagiarism Prevention
WANT TO PRE-CHECK YOUR WORK? »
crossref MEMBER
CROSSREF.ORG THE CITATION LINKING BACKBONE

APPENDIX O – INTERFACE VOLUME ABSTRACTS

ABSTRACT SUBMITTED AND ACCEPTED FOR ISPO WORLD CONGRESS 2013

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

Introduction

Vacuum-assisted suspension (VAS) is becoming a popular system for use in lower-limb prostheses. However, little is known about socket/liner interface volume in persons with transfemoral amputations (TFA) or the rate of vacuum pressure decay during regular activity. We measured changes in vacuum pump pressures on human subjects, empirically obtaining evacuation curves and gaining insights into volume and pressure decay.

Methods

Persons with unilateral TFA using VAS, sub-ischial sockets and silicone liners participated. Otto Bock Harmony® e-pulse and Ohio WillowWood LimbLogic® VS pumps were tested. Each subject donned their prosthesis and stood quietly while the space between socket and liner was evacuated to ~17 inHg (5 evacuation trials per pump). Between trials, air was allowed into the system by disconnecting the tubing attaching pump to socket. Vacuum pressure data and time were recorded during evacuation using a digital gauge. Some subjects also walked for 10 minutes with each pump at a comfortable pace on a treadmill while vacuum pressure was monitored. Interface volume was 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.

Results

Twelve subjects (age = 56±14 years; height = 174±7cm; mass = 82±25kg) were tested. Calculated average interface volume was 97.8±47.4cm3 and 103.3±49.2cm3 for the e-pulse and LimbLogic, respectively. During treadmill walking (4 subjects) the average rate of vacuum decay was 0.0045 ± 0.0021 and 0.0061 ± 0.0047 inHg/sec for the e-pulse and LimbLogic, respectively. Evacuation curves for some human subjects differed in shape from those of fixed volume canisters, resembling s-shaped curves.

Discussion/Conclusion

S-shaped curves may represent a change in the initial volume for those people with “soft” tissue who are pulled into the socket by vacuum. Testing on a greater number of subjects is needed.

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

S Wood[1], R Caldwell[2], W Chen[1], C Sun[1], A Hansen[3], 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. 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).

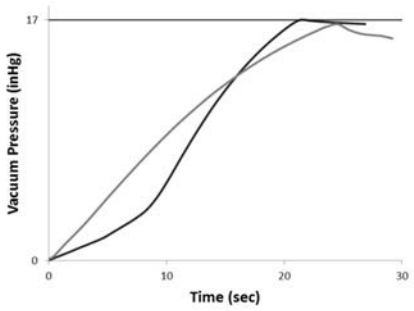


Figure 1. Time to evacuate the socket/liner interface for a representative subject (black line) compared to time to evacuate a 99.3 cm^3 canister (gray line).

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.

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

APPENDIX P – MANUSCRIPT PUBLISHED IN THE JOURNAL OF PROSTHETICS AND ORTHOTICS

Comparative Effectiveness of Electric Vacuum Pumps for Creating Suspension in Transfemoral Sockets

Matthew J. Major, PhD, Ryan Caldwell, CP, Stefania Fatone, PhD, BPO(Hons)

ABSTRACT

Introduction: There is increasing evidence to support the benefits of vacuum-assisted suspension (VAS) as a means of securing lower-limb prosthetic sockets to the residual limb. As use of VAS increases, there is need to assess comparative effectiveness of different vacuum pumps. This study conducted in vivo tests to evaluate the effectiveness of two commercial electric pumps, the Ohio Willow Wood LimbLogic and Otto Bock Harmony e-pulse, in transfemoral sockets.

Materials and Methods: Tests evaluated (1) the rate and time of evacuation for each pump to achieve a clinically recommended socket-liner interface pressure of 17 in-Hg below atmospheric pressure while 18 subjects stood quietly and (2) the number of times each pump reactivated during 10 minutes of treadmill walking by 9 subjects to reestablish 17 in-Hg below atmospheric pressure after initial evacuation.

Results: During quiet standing, each pump displayed an S-shape temporal profile of vacuum pressure until 17 in-Hg below atmospheric pressure was achieved. Across participants, the LimbLogic pulled vacuum at a faster rate than the e-pulse (62 vs. 39 in-Hg/min) and required less time to achieve the desired pressure (22 vs. 27 seconds). However, the LimbLogic reactivated once during walking to account for vacuum leakage, whereas the e-pulse did not reactivate.

Conclusions: The small differences in outcome metrics between pumps suggests that they were comparable in terms of effectiveness for creating and maintaining VAS of transfemoral sockets. This study describes simple methods that can be used in future studies when comparing electric vacuum pump performance. (*J Prosthet Orthot*. 2015;27:149–153.)

KEY INDEXING TERMS: prosthesis, vacuum, suspension, socket

Prosthetic sockets form the interface between the residual limb and prosthesis, acting to support the body and transfer forces.[1] To do this comfortably and efficiently, the socket must be both well conformed and well coupled to the residual limb. Coupling has been achieved using various types of suspension mechanisms, including belts, lanyards, passive suction, locking liners, and most recently active suction using vacuum pumps.[2,3] Poor suspension leads to problems such as "pistoning" (i.e., relative vertical motion between the socket and residual limb). It has been proposed that vacuum-assisted suspension (VAS) results in the least pistoning of current suspension systems.[2,4,5]

MATTHEW J. MAJOR, PhD; RYAN CALDWELL, CP; and STEFANIA FATONE, PhD, BPO(Hons), are affiliated with Northwestern University Prosthetics-Orthotics Center, Northwestern University, Chicago, Illinois.

MATTHEW J. MAJOR, PhD, is affiliated with Jesse Brown VA Medical Center, Chicago, Illinois.

RYAN CALDWELL, CP, is affiliated with Scheck and Siress Prosthetics & Orthotics, Schaumburg, Illinois.

Funding: The US Army Medical Research and Materiel Command Acquisition Activity (Fort Detrick, MD) is the awarding and administering acquisition office (award number W81XWH-10-1-0744). The content of this presentation does not necessarily reflect the position or the policy of the government, and no official endorsement should be inferred.

Disclosure: The authors declare no conflict of interest.

Copyright © 2015 American Academy of Orthotists and Prosthetists.

Correspondence to: Matthew J. Major, PhD, Prosthetics-Orthotics Center, Northwestern University, 680 N Lake Shore Dr, Suite 1100, Chicago IL 60611; email: matthew-major@northwestern.edu

Use of vacuum pumps has increased dramatically since their introduction in the late 1990s, with a reported increase in VAS device-specific Medicare billing codes from $1.1 million in 2003 to $7.1 million in 2013.[6] Although initially used primarily by persons with transtibial amputation,[7–13] vacuum pumps are now also being used by persons with transfemoral amputation.[14–16] As more pumps become commercially available, there is need for better understanding of pump function including comparative effectiveness using standardized methods for both bench and in vivo evaluation.[16–18] Previous work by Komolafe et al.[17] described a method for bench-top performance evaluation of commercially available mechanical and electrical pumps. Gerschutz et al.[18] proposed that real-time vacuum pressure monitoring was necessary to understand how vacuum varies with time and usage by patients and illustrated use of a tool for doing so in persons with transtibial amputation. Major et al.[16] used both bench-top and in vivo methods to evaluate a newly designed hybrid mechanical-electrical vacuum pump in a single subject with transfemoral amputation. The purpose of this study was to conduct in vivo tests to evaluate the effectiveness of two commonly used commercially available electric pumps, the Ohio Willow Wood LimbLogic (Sterling, OH, USA) and Otto Bock Harmony e-pulse (Duderstadt, Germany), on participants with transfemoral amputation.

METHODS

This study was approved by the university's institutional review board, and participants provided written informed consent before data collection. A convenience sample of individuals with a unilateral transfemoral amputation who routinely used VAS was recruited to participate. Participants were tested at two sites,

Copyright © 2015 by the American Academy of Orthotists and Prosthetists. Unauthorized reproduction of this article is prohibited.

a research laboratory and a prosthesis clinical facility, using each pump during two testing protocols:

1. Quiet standing—participants were instructed to stand quietly as the pressure within the socket-liner interface was brought to baseline atmospheric pressure, and a pump was then used to decrease pressure until 17 in-Hg below atmospheric pressure was achieved. This test was repeated five times.
2. Walking—participants were instructed to first stand quietly until the socket-liner interface pressure was brought to 17 in-Hg below atmospheric pressure using a pump, and then to walk at a comfortable, self-selected speed on a level treadmill (T170; Cosmed, Rome, Italy) for 10 minutes. Both pumps were programmed to allow a minimum vacuum pressure of 13 in-Hg below atmospheric pressure before reactivating to reestablish 17 in-Hg below atmospheric pressure.

The order of pump testing was randomized for each participant, and socket-liner conditions remained the same for both pumps. To ensure the same socket attachment for both pump systems, the LimbLogic pump was connected to the socket volume via a barbed fitting similar to how the e-pulse is typically connected (Figure 1).

For both test protocols, instantaneous pressure in the socket-liner interface was measured with a digital vacuum pressure gauge (model 2 L760, DigiVac, Matawan, NJ, USA) and recorded using custom Labview software (National Instruments Corporation, Austin, TX, USA). For each test protocol, the following outcome metrics were estimated:

1. Quiet standing—the rate of evacuation, estimated as the slope of a best-fit linear approximation applied to the linear portion of the pressure temporal profile, and the total evacuation time from pump activation until pressure of 17 in-Hg below atmospheric pressure was achieved. These data were analyzed using Excel (Microsoft Corporation, Redmond, WA, USA) and averaged across the five standing trials for each participant.
2. Walking—the number of times the pump reactivated to reestablish a pressure of 17 in-Hg below atmospheric pressure.



Figure 1. Image of the LimbLogic pump and barbed fitting used to connect the pump to the socket-liner volume.

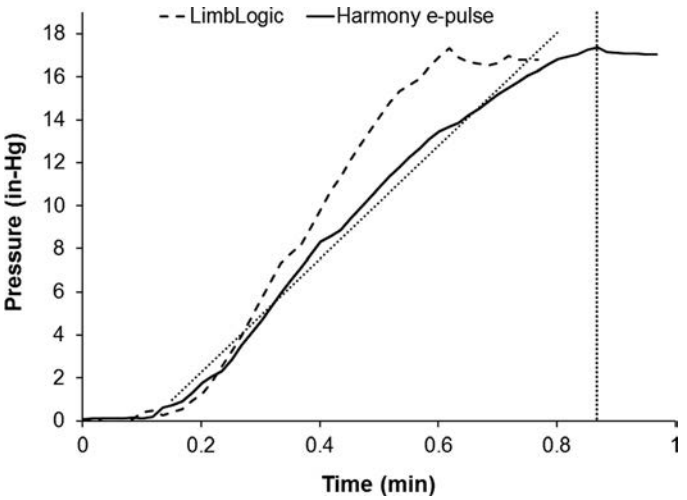


Figure 2. Representative plots of instantaneous pressure below atmospheric pressure collected during standing trials for both pumps. To illustrate the methods used for analysis, the vertical dotted line represents the estimated evacuation time of the Harmony e-pulse, and the diagonal dotted line represents the best-fit linear approximation applied to the linear portion to estimate evacuation rate. Similar analysis was applied to the LimbLogic but for the sake of clarity is not shown here.

These outcome metrics were selected as they represent clinical information that may assist with device recommendations. For example, a clinician must consider if the time required for a pump to achieve a desired level of pressure is important for a given patient based on their activity demands and need for rapidly generated suspension. In addition, as pump reactivation for reestablishing pressure levels would consume additional battery power beyond that of pressure monitoring, the number of reactivations over a specific time would suggest relative frequency of battery recharging during operation. Although pump reactivations are a necessary response due to leakage resulting from features across the entire prosthetic system, some portion of leakage may be due to pump interfacing with the prosthesis and socket-liner interface.

The Shapiro-Wilk test was used to assess data normality with the results suggesting that the data sets were of a nonnormal distribution. Consequently, the Wilcoxon signed-rank test for paired samples was used to statistically assess differences in evacuation rate, evacuation time, and number of reactivations between each pump. The critical alpha was set at 0.05, but applying a Bonferroni correction to account for the familywise type I error rate lowered this threshold to 0.02.

RESULTS

Data for the quiet standing analysis were collected on 18 individuals (13 male, 5 female, 53 ± 14 years, 177 ± 7 cm, 82 ± 8 kg), 9 of whom participated in the walking analysis (8 male, 1 female, 51 ± 13 years, 179 ± 6 cm, 84 ± 10 kg). Fewer subjects participated in the walking analysis because data were collected at two sites, and only one site was equipped with a treadmill.

A representative set of data for the temporal profile of instantaneous pressure for both pumps during the standing

Copyright © 2015 by the American Academy of Orthotists and Prosthetists. Unauthorized reproduction of this article is prohibited.

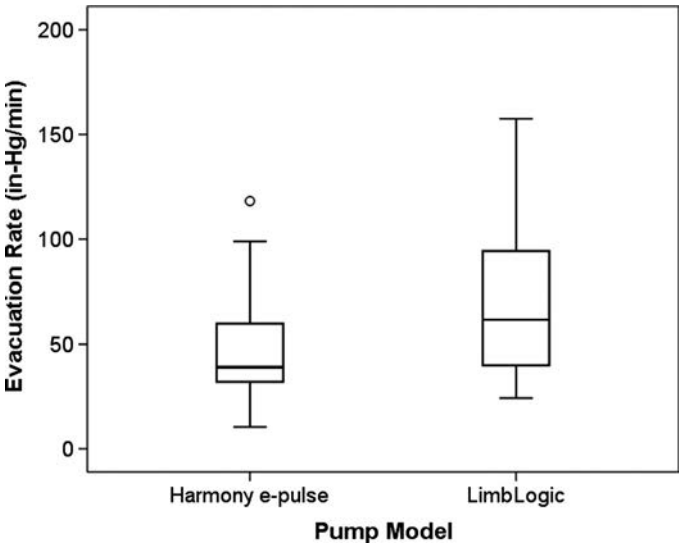


Figure 3. Box plots of evacuation rate for each pump (n = 18) during quiet standing. Median is denoted by the center line, quartiles are denoted by the box ends, maximum and minimum values are denoted by the tail ends, and circles denote outliers beyond 1.5 × box height.

protocol is presented in Figure 2, and this behavior was observed for all subjects. Each pump demonstrated a characteristic S-shape profile during evacuation, with three distinct periods of 1) accelerated, 2) constant, and 3) decelerated vacuum pressure rate. The estimated evacuation rate and time across participants are displayed in Figures 3 and 4. These indicated that the LimbLogic required less time to achieve the desired pressure level of 17 in-Hg below atmospheric pressure, and this difference was significant (Table 1). A representative set of data for the temporal profile of instantaneous pressure for both pumps during the walking protocol is presented in Figure 5, and this behavior was observed for all subjects. Both

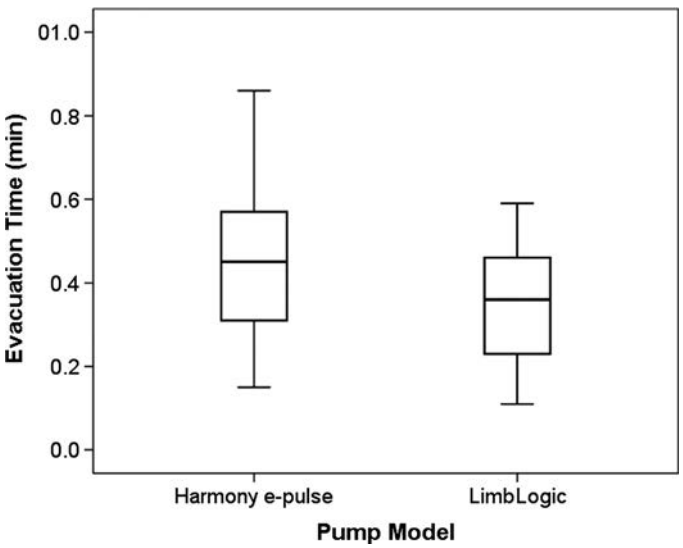


Figure 4. Box plots of evacuation time for each pump (n = 18) during quiet standing. Median is denoted by the center line, quartiles are denoted by the box ends, maximum and minimum values are denoted by the tail ends, and circles denote outliers beyond 1.5 × box height.

Table 1. Statistical results from pairwise comparisons between pump models

Outcome	*P*	*Z*	Order Effect
Evacuation rate	<0.001	153.0	OWW > OB
Evacuation time	<0.001	2.5	OWW < OB
No. pump reactivations	0.024	21.0	OWW > OB

OWW, Ohio Willow Wood LimbLogic; OB, Otto Bock Harmony e-pulse.

pumps exhibited similar profiles of pressure leakage, but the rate of leakage for the prosthetic system when using the LimbLogic was more rapid, resulting in a significantly greater median reactivation number of one, whereas the e-pulse required no reactivations (Figure 6, Table 1).

DISCUSSION

Overall, the differences in evacuation rate (23 in-Hg/min) and time (5 seconds) between both pump systems were statistically significant. Although these differences were small, they are likely clinically important. The reduced time needed by the LimbLogic system to achieve full evacuation shortens the period of noise emission and may improve patient compliance and satisfaction with pump use. In addition, less time to achieve the desired pressure level may facilitate longer periods of ideal socket fit during use.

The number of reactivations during walking is interesting as this activity increases the rate of battery power drainage compared with periods of pressure monitoring. A more rapid depletion of battery power would require more frequent charging to maintain socket suspension during operation. The pump-specific reasons for this difference in leakage rate despite no change in the socket is unknown and warrants further investigation as minimizing leakage would maximize battery life. Using

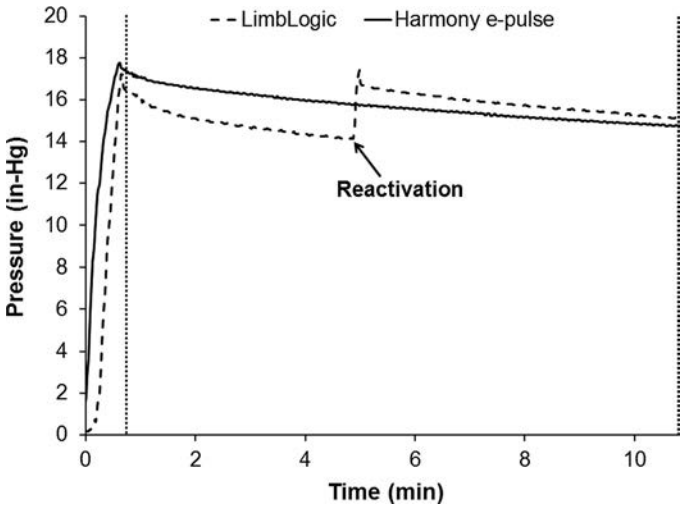


Figure 5. Representative plots of instantaneous pressure below atmospheric pressure collected during walking trials for both pumps. The first and second vertical dashed lines denote the start and finish time, respectively, of the 10 minutes of treadmill walking.

Copyright © 2015 by the American Academy of Orthotists and Prosthetists. Unauthorized reproduction of this article is prohibited.

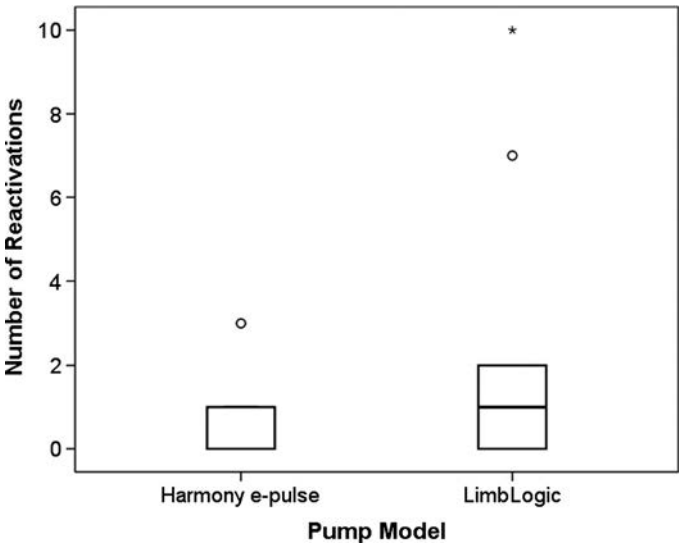


Figure 6. Box plots of number of pump reactivations during walking (n = 9). Median is denoted by the solid center line, quartiles are denoted by the box ends, maximum and minimum values are denoted by the tail ends, circles and asterisks denote outliers beyond 1.5 and 3 × box height, respectively.

a connection (i.e., the barbed fitting) that is not commonly implemented clinically with the LimbLogic may have partially contributed to this increased rate in vacuum leakage.

In addition to these types of installation issues, future research may consider patient-specific factors that likely affect pump evacuation time and vacuum leakage (e.g., residuum dimensions, residuum tissue properties, and liner type) to develop a more nuanced understanding of pump function. Regardless, both pumps were successful in identifying a loss in pressure that necessitated pump reactivation for maintaining appropriate pressure levels for suspension. In this study, pumps were evaluated for the walking trials immediately after evacuation during standing. Clinical experience suggests that pump reactivations occur less frequently with increasing wear time, potentially due to a continuous reduction in air pockets and better seating in the socket. Future studies could explore such issues by monitoring vacuum activity outside the laboratory during prolonged usage.

Although outcome differences between pumps were statistically significant and may be clinically relevant, results from these in vivo tests suggest that both electric pump systems are equally effective in creating and maintaining socket-liner interface pressure for VAS in transfemoral sockets. Importantly, this study demonstrates the use of a simple set of experiments and limited equipment to capture clinically relevant outcome metrics for assessing the effectiveness of pumps for VAS. As use of this suspension method increases, this study addresses the need for standard methods to assess comparative effectiveness of commercial pumps. A combination of in vivo and bench testing methods are required to fully characterize the properties of these devices and their relationship with overall prosthesis function to inform clinical recommendations of appropriate prosthetic technology and development of future designs.[16,17,19] Clinical selection of electric pump designs is likely a function of patient activity demands, device evacuation rate, and device-related vacuum leakage.

CONCLUSIONS

Based on the time required for achieving clinically recommended levels of pressure for VAS and the number of pump reactivations to maintain that level during walking, the results from this study suggest that the LimbLogic and Harmony e-pulse are equally effective electric pumps despite the observed differences in outcome metrics. Importantly, this study aids in developing standard evaluation methods of commercial pump systems for generating clinically relevant information. Future research should consider investigations on patient- and device-specific factors related to vacuum leakage rate and methods for minimizing this leakage to maximize battery life.

ACKNOWLEDGMENTS

The authors would like to thank Sean Wood for writing the program used for data collection, as well as Oluseeni Komolafe and William Johnson for their assistance with data collection. The authors acknowledge the Jesse Brown VA Medical Center Motion Analysis Research Laboratory for use of their facilities for data collection.

REFERENCES

1. Kapp SL. Transfemoral socket design and suspension options. *Phys Med Rehabil Clin N Am* 2000;11:569–583 vi.
2. Kahle JT, Orriola JJ, Johnston W, et al. The effects of vacuum-assisted suspension on residual limb physiology, wound healing, and function: a systematic review. *Technology & Innovation* 2014;15:333–341.
3. Gholizadeh H, Abu Osman NA, Eshraghi A, et al. Transfemoral prosthesis suspension systems: a systematic review of the literature. *Am J Phys Med Rehabil* 2014;93:809–823.
4. Darter BJ, Sinitski K, Wilken JM. The effect of elevated vacuum suspension on axial bone-socket displacement in persons with a traumatic transtibial amputation. *35th Annual Meeting of the American Society of Biomechanics*. Long Beach, CA; 2011.
5. Papaioannou G, Mitrogiannis C, Nianios G, et al. Assessment of amputee socket-stump-residual bone kinematics during strenuous activities using Dynamic Roentgen Stereogrammetric Analysis. *J Biomech* 2010;43:871–878.
6. Centers for Medicare & Medicaid Services. The Part B national summary data file: prosthetic procedures (L5000-L9999). In: United States Department of Health and Human Services (ed.). 2013.
7. Beil TL, Street GM, Covey SJ. Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets. *J Rehabil Res Dev* 2002;39:693–700.
8. Board WJ, Street GM, Caspers C. A comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthet Orthot Int* 2001;25:202–209.
9. Gerschutz MJ, Denune JA, Colvin JM, et al. Elevated vacuum suspension influence on lower limb amputee's residual limb volume at different vacuum pressure settings. *J Prosthet Orthot* 2010;22:252–256.

Copyright © 2015 by the American Academy of Orthotists and Prosthetists. Unauthorized reproduction of this article is prohibited.

10. Goswami J, Lynn R, Street G, et al. Walking in a vacuum-assisted socket shifts the stump fluid balance. *Prosthet Orthot Int* 2003; 27:107–113.
11. Klute GK, Berge JS, Biggs W, et al. Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: effect on fit, activity, and limb volume. *Arch Phys Med Rehabil* 2011;92:1570–1575.
12. Ferraro C. Outcomes study of transtibial amputees using elevated vacuum suspension in comparison with pin suspension. *J Prosthet Orthot* 2011;23:78–81.
13. Brunelli S, Averna T, Delusso S, et al. Vacuum assisted socket system in transtibial amputees: clinical report. *The Orthopadie Technik* 2009;II:2–8.
14. Kahle JT, Highsmith MJ. Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure, and preference: ischial containment versus brimless. *J Rehabil Res Dev* 2013;50:1241–1252.
15. Kahle JT, Highsmith MJ. Transfemoral interfaces with vacuum assisted suspension comparison of gait, balance, and subjective analysis: ischial containment versus brimless. *Gait Posture* 2014; 40:315–320.
16. Major MJ, Caldwell R, Fatone S. Evaluation of a hybrid vacuum pump to provide vacuum-assisted suspension for above-knee prostheses. *J Med Devices* 2015.
17. Komolafe O, Wood S, Caldwell R, et al. Methods for characterization of mechanical and electrical prosthetic vacuum pumps. *J Rehabil Res Dev* 2013;50:1069–1078.
18. Gerschutz M, Haynes M, Colvin J, et al. A vacuum suspension measurement tool for use in prosthetic research and clinical outcomes: validation and analysis of vacuum pressure in a prosthetic socket. *J Prosthet Orthot* 2010;22:172–176.
19. Major MJ, Kenney LP, Twiste M, et al. Stance phase mechanical characterization of transtibial prostheses distal to the socket: a review. *J Rehabil Res Dev* 2012;49:815–829.

Academy Book Reviews

THE LATEST PUBLICATIONS REVIEWED BY O&P EXPERTS

Available in the "Recommended Reading" section of the Academy's website.

www.oandp.org/reading.asp

Academy book reviews keep clinicians informed about the latest publications related to the O&P profession.

The Academy Publications Committee has teamed up with a group of experienced O&P practitioners to assess the usefulness of texts for students, clinicians, and researchers.



Enhance your reference library!

Visit www.oandp.org/reading.asp today.

THE AMERICAN ACADEMY OF ORTHOTISTS & PROSTHETISTS

1331 H Street, NW, Suite 501, Washington, DC 20005 • phone (202) 380-3663 • fax (202) 380-3447 • www.oandp.org

Copyright © 2015 by the American Academy of Orthotists and Prosthetists. Unauthorized reproduction of this article is prohibited.

APPENDIX Q – ME 398 REPORT

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 3
2. Problem Background 4
2.1 Client 4
2.2 Statement of Need 4
3. Problem Statement 7
3.1 Product Design Specifications 7
4. Design Approach 8
4.1 Process Flow Diagram 8
4.2 Technical Challenges 9
5. State-of-the-Art Survey 9
6. Conceptual Design 9
6.1 Initial Design Ideas 9
6.2 User Observation Summary 11
7. Prototype Design 13
7.1 Final Design 13
7.2 Scope of Prototype 13
7.3 Design Considerations 14
7.4 Prototype Description 17
8. Engineering Analysis 17
8.1 Material Selection 22
8.2 Geometric Considerations 26
8.3 Competitor Benchmarking 28
8.4 Evacuation Analysis 29
8.5 Structural Analysis 30
9. Contextual Analysis 34
9.1 Global Considerations 34
9.2 Social Considerations 34
9.3 Environmental Considerations 34
9.4 Economic Considerations 34
10. Test Results and Evaluation 35
11. Next Steps 36

11.1 Design Changes 36
11.2 Future Enhancements 36
11.3 Cost Estimation 36
12. Summary 37
13. Acknowledgements 39
14. References 40
15. Appendix A: PDS 41
16. Appendix B: Drawings 43
17. Appendix C: Prototype Bill of Materials 48
18. Appendix D: User Interview Summary 49
19. Appendix E: Estimated Mechanical Performance 52

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.

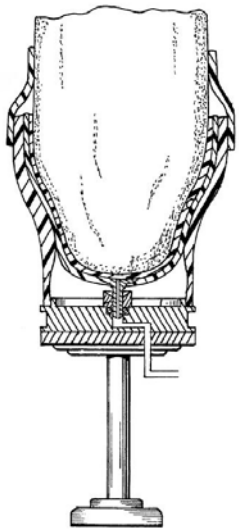


Figure 2: Vacuum between socket and residual limb [2]

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.

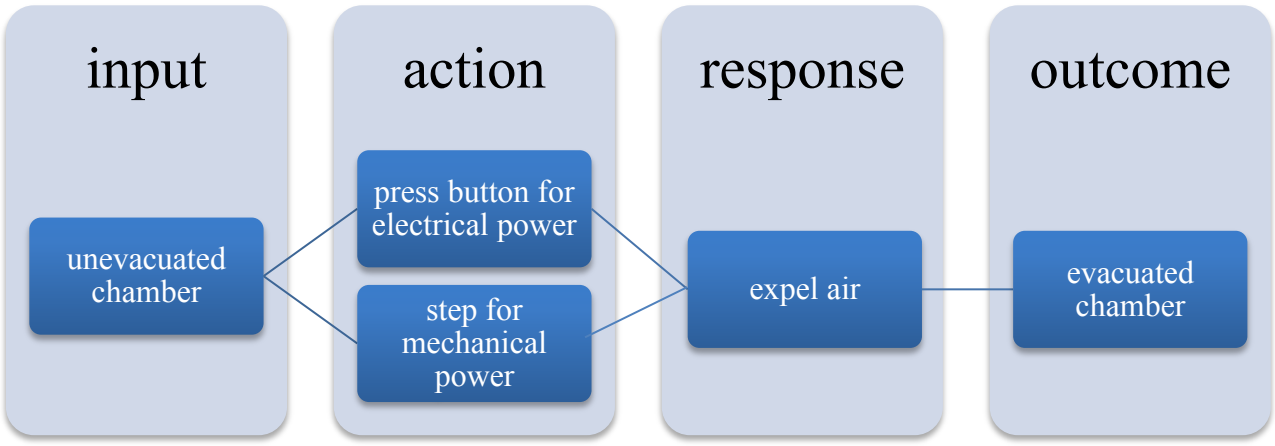


Figure 5: process flow diagram for our design

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.

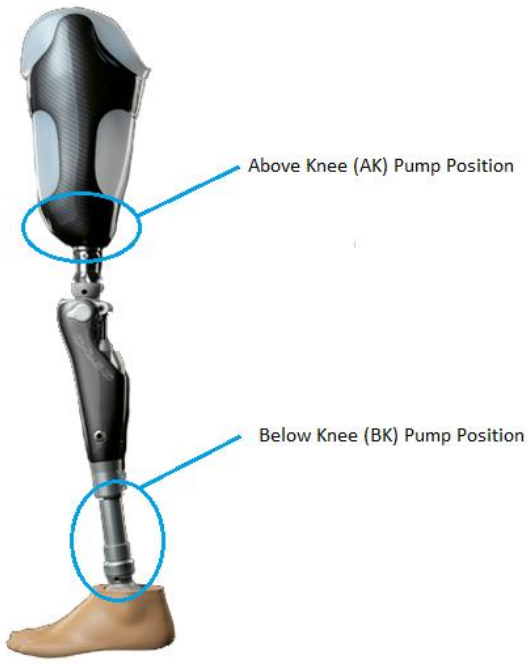


Figure 6: Potential Pump Positions on C Leg Prosthetic [6]

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.

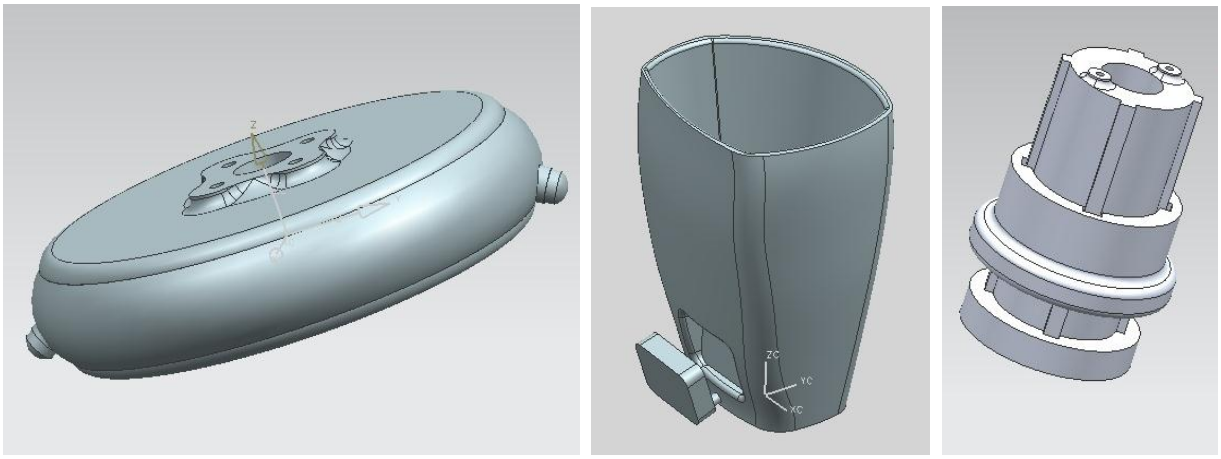


Figure 7: Initial designs: Mech. AK pump (left), Hybrid AK pump (center), Mech. BK pump (right)

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.

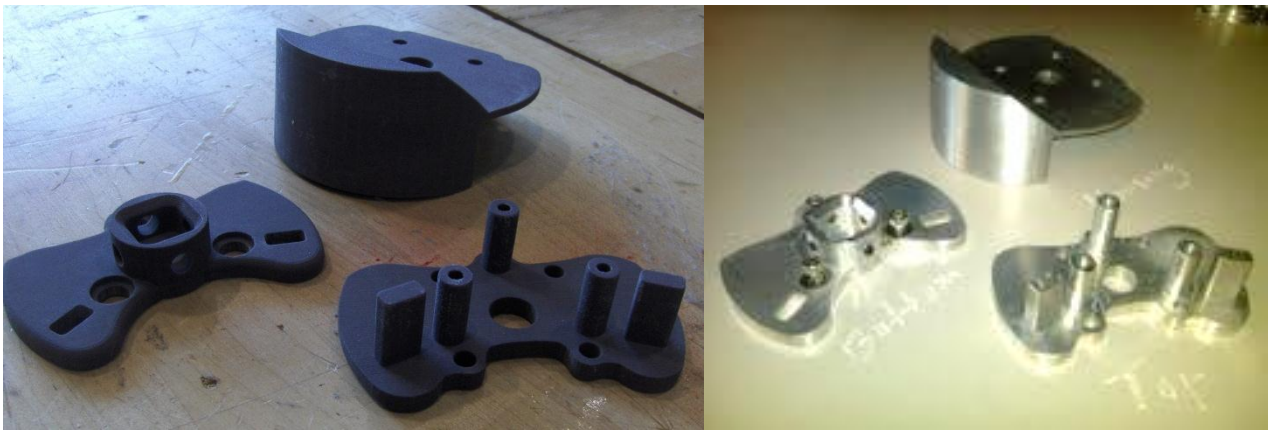


Figure 8: Rapid Prototyped Model (left); CAM Model (right)

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.

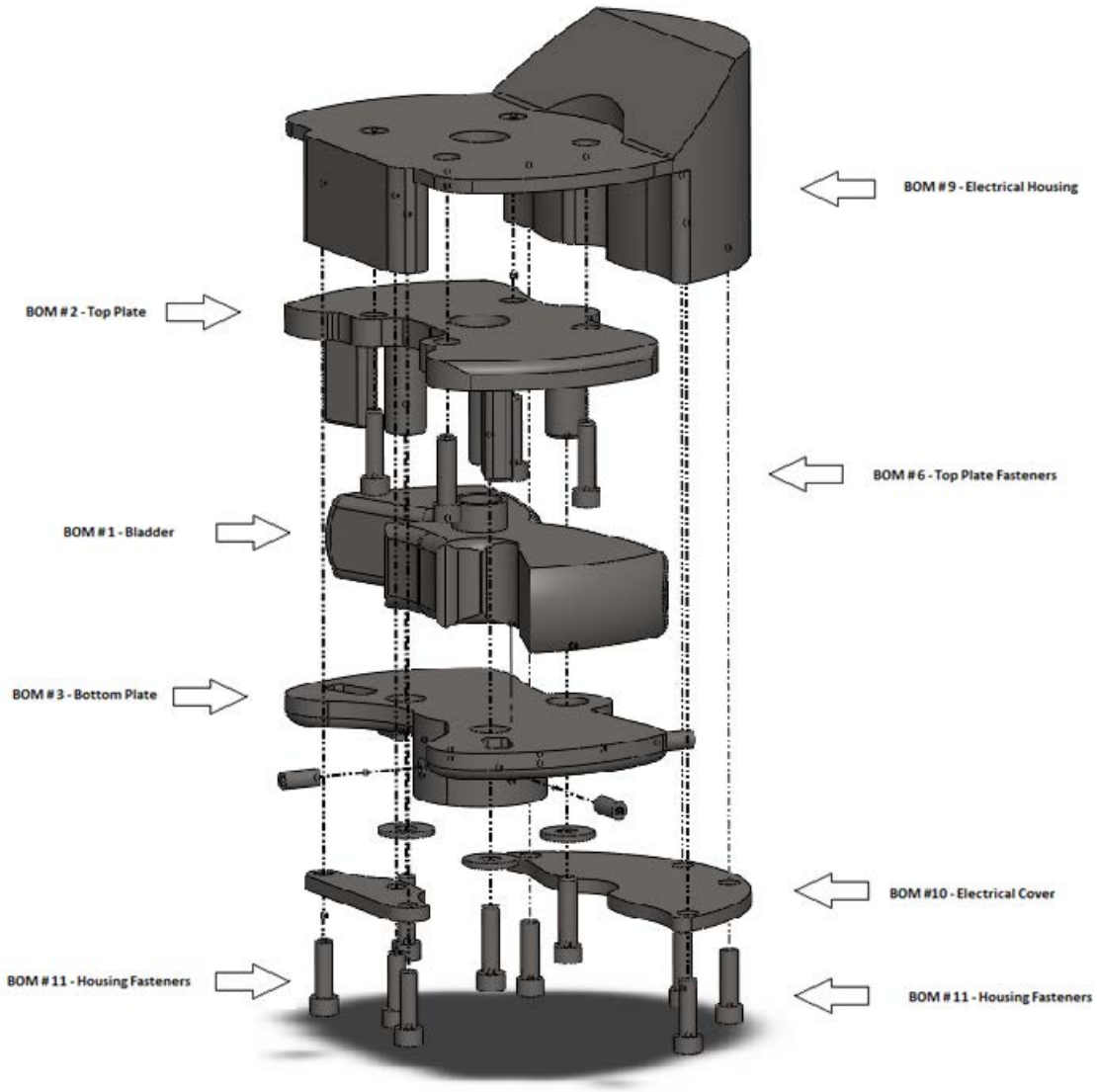


Figure 12: Exploded View of Prototype Assembly

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.

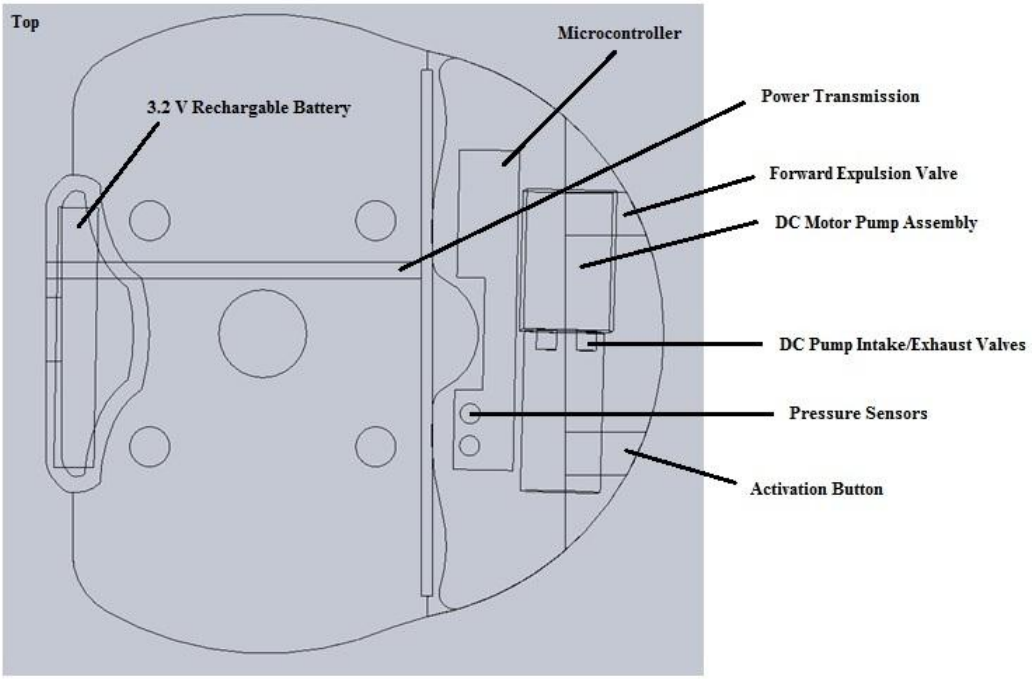


Figure 13: Top View of Wireframe Electrical Schematic with Tags

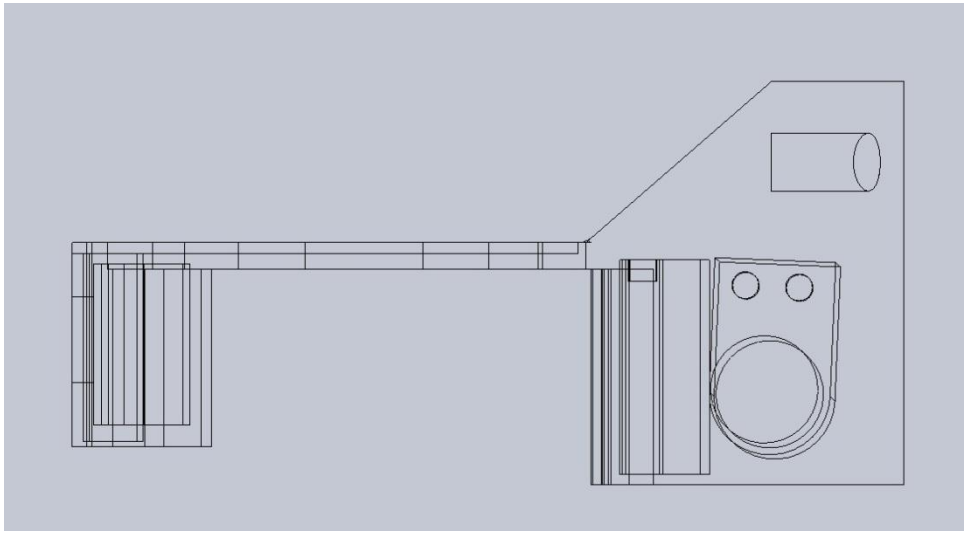


Figure 14: Side View of Wireframe Electrical Schematic

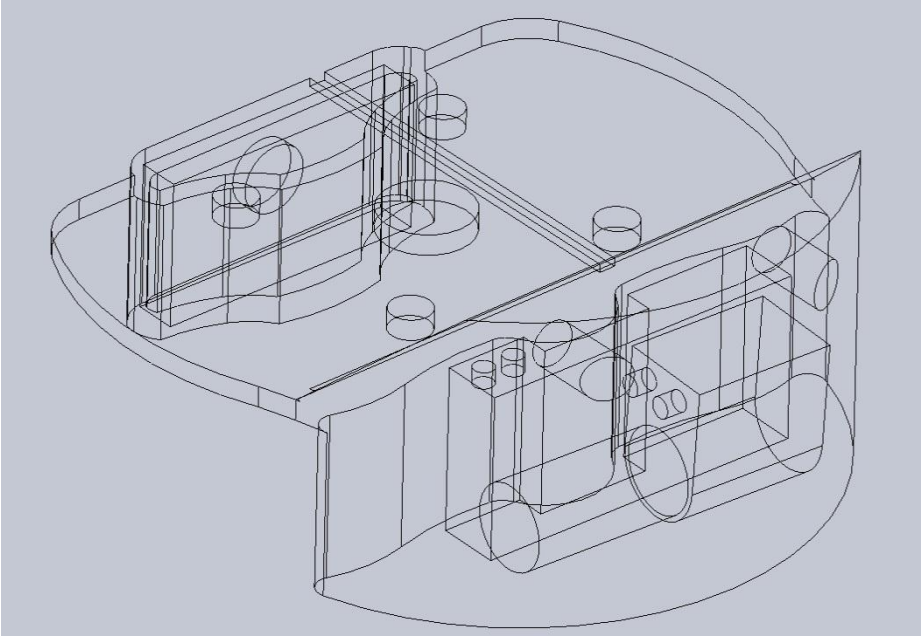


Figure 15: Isometric View of Wireframe Electrical Schematic

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.

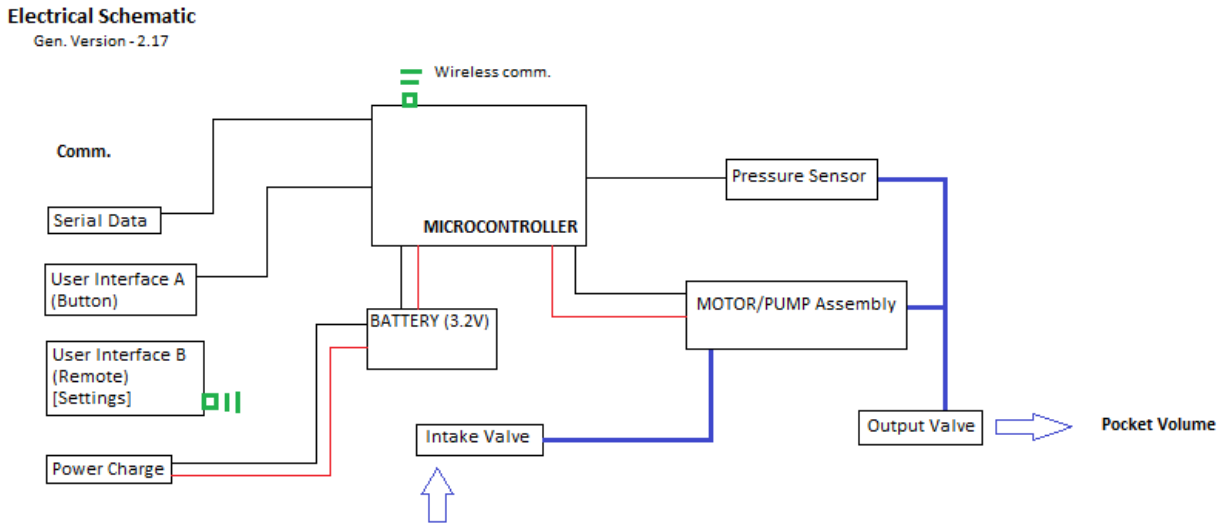


Figure 16: Design Schematic Diagram

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.

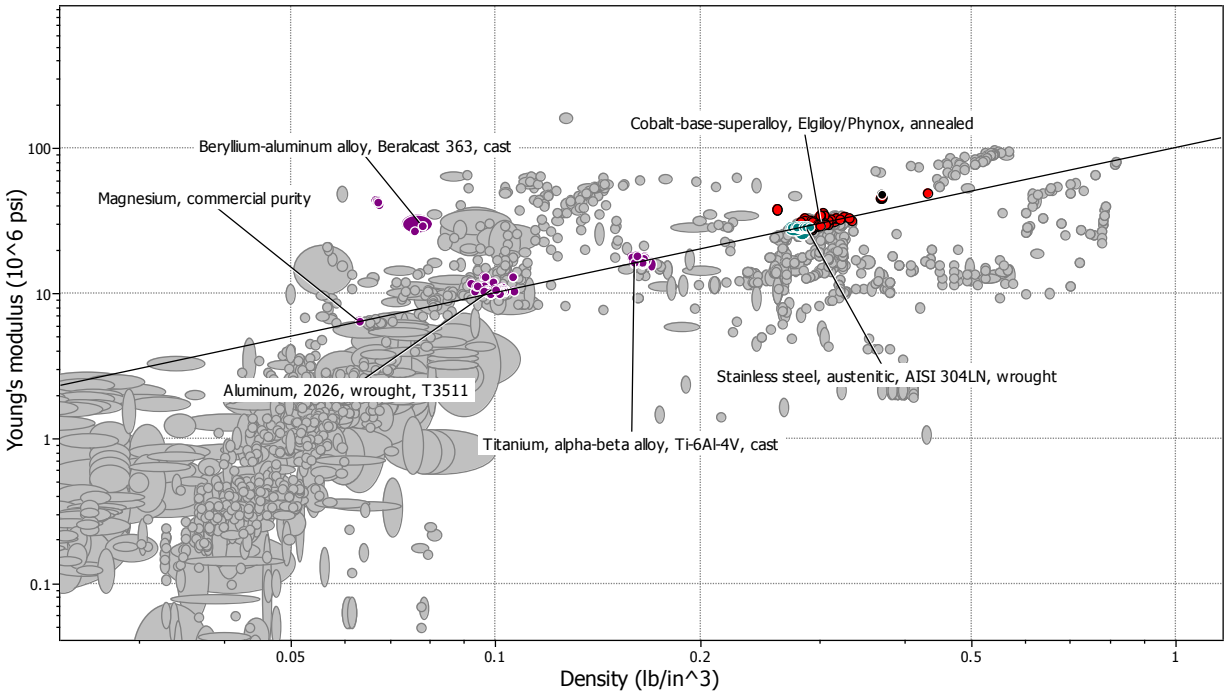


Figure 17: Young's Modulus (colors represent different materials, as called out on the image)

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.

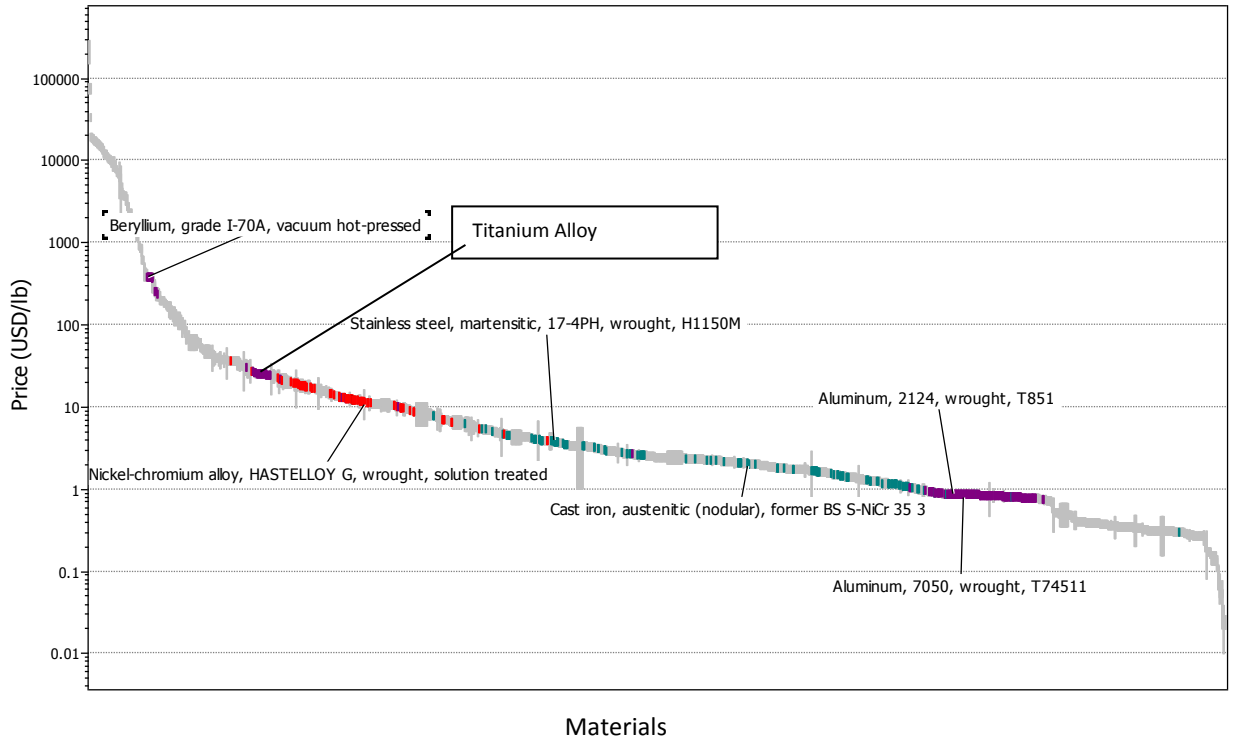


Figure 18: Price of various materials (colors represent different materials)

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.

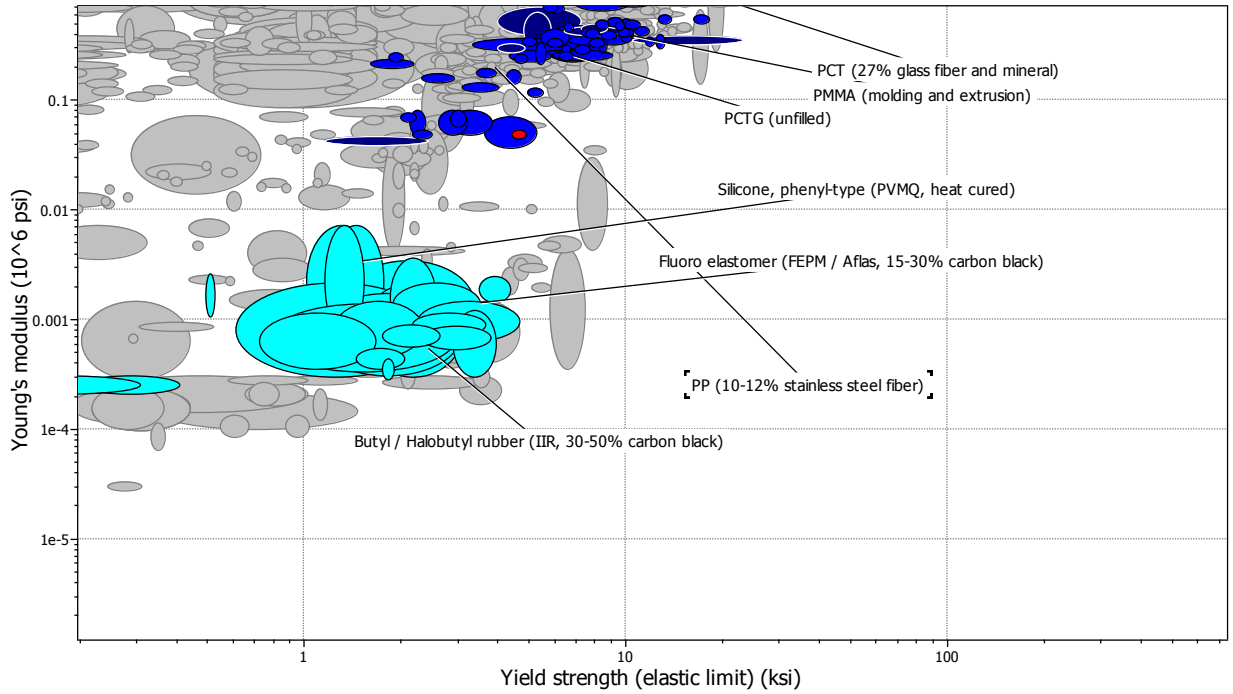


Figure 19: Young's Modulus vs. Yield Strength (colors represent different materials)

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.

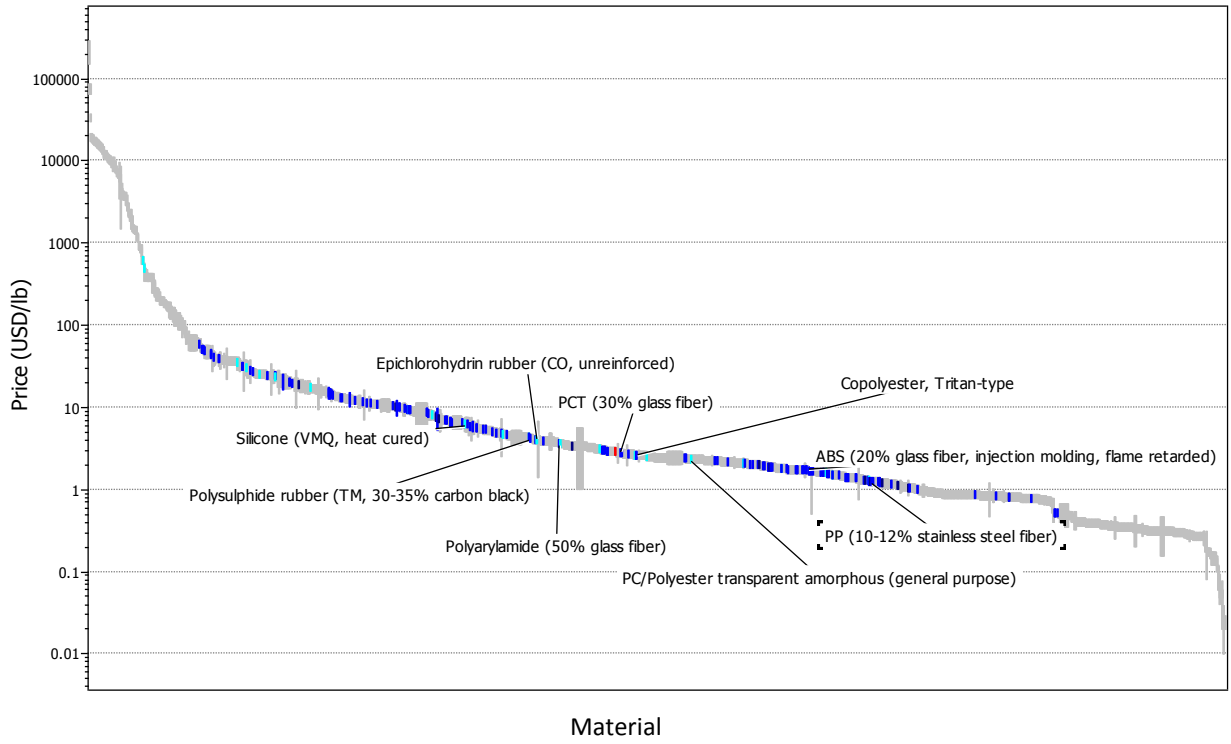


Figure 20: Material Prices (colors represent different materials)

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.

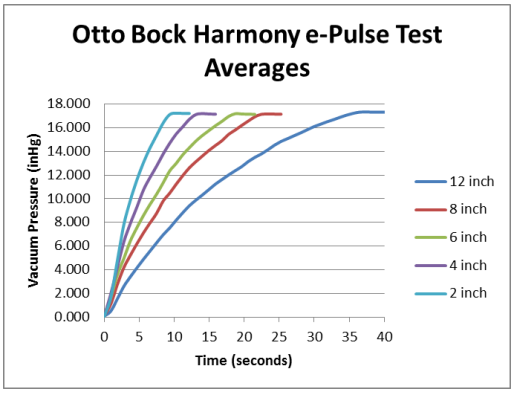
8.2.3 Space above the knee cap

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.

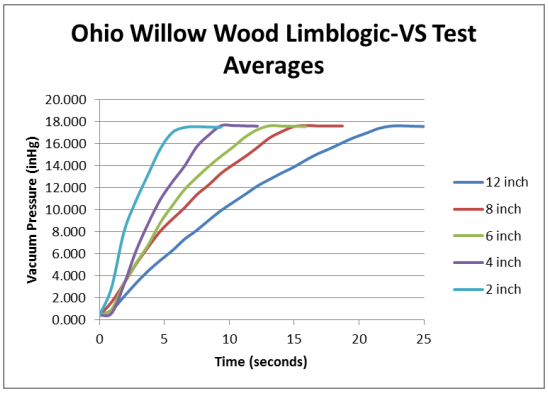
8.3 Competitor Benchmarking

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.



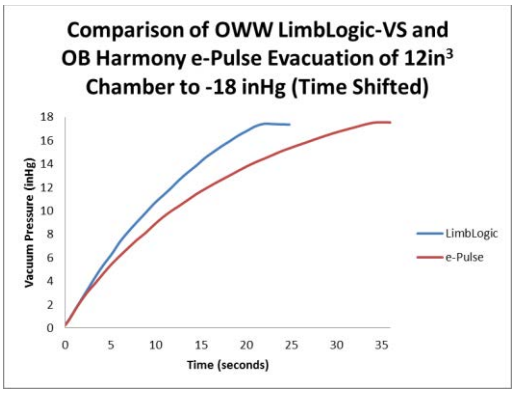
Plot 1 – Otto Bock Avg. Test data: Evacuating various volumes



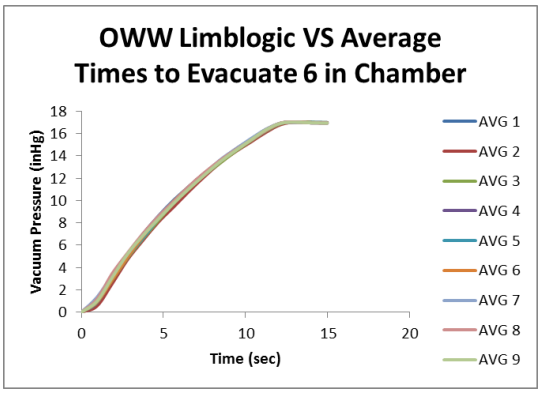
Plot 2 – Ohio Willow Wood Test Data: Evacuating volumes

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 $12in^3$



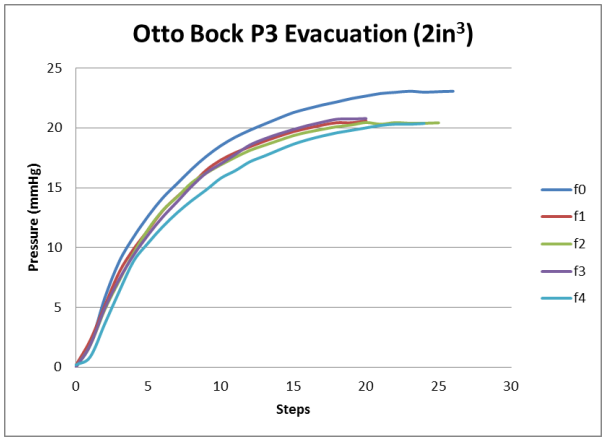
Plot 4 – Performance decrease over 10 tests for $6in^3$

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.



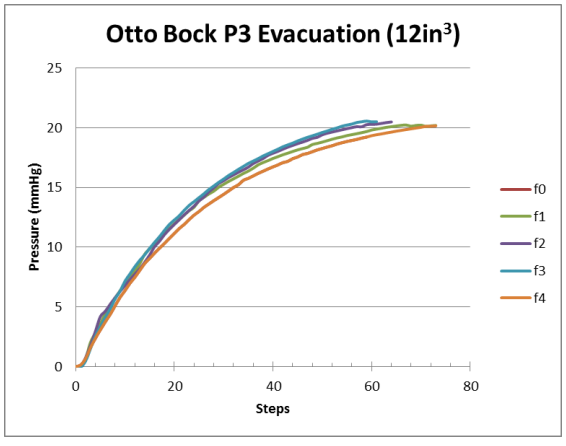


Figure 24: Average Evacuation Times for Otto Bock P3

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.

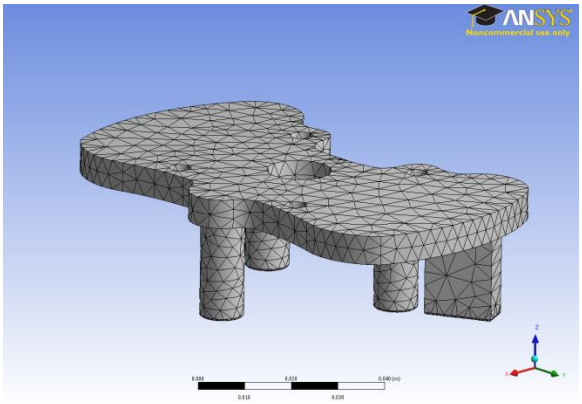
From our calculations we characterize both the spring stiffness and the maximum deflection as determined by the volumetric pressure analysis of the Harmony P3. These results dictate the performance of our pump, in that we design our pump system stiffness to match this deflection as to not increase user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

8.5 Structural Analysis

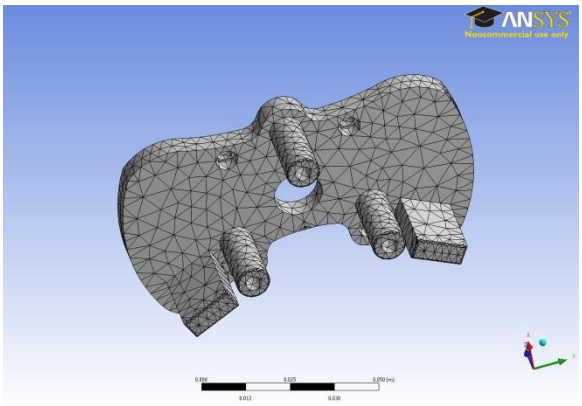
In order to develop a foundation of data from which we can characterize the performance of our design under different loading scenarios, we used the finite element analysis tool ANSYS to run various simulations on the load-bearing top plate of our design. Our simulations fell into four different categories, 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.

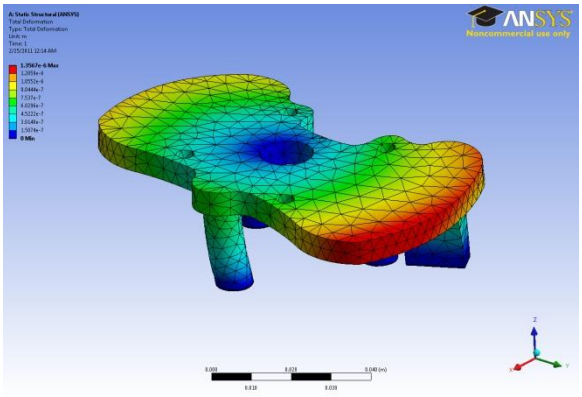


Figure C: Deformation with pillar torque (Top)

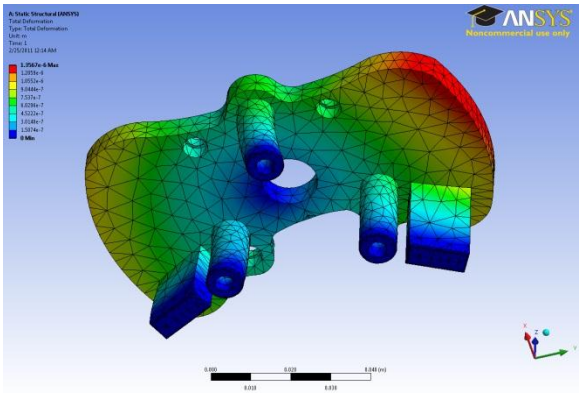


Figure D: Deformation with Pillar Torque (Bottom)

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.

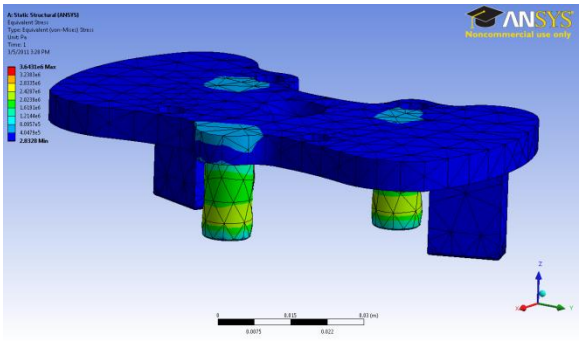


Figure E: Stress analysis vertical loading (Top)

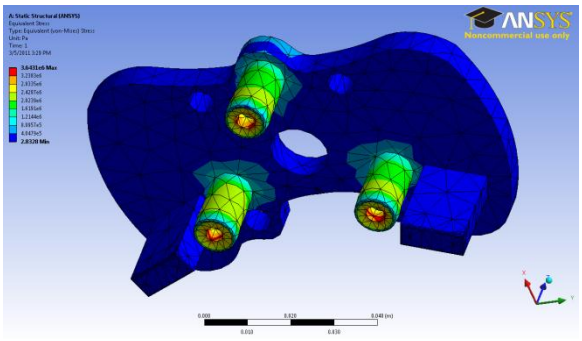


Figure F: Stress analysis vertical loading (Bottom)

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.

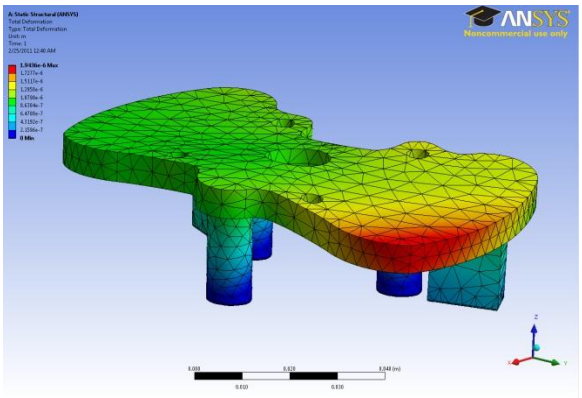


Figure G: Deformation connection loading (Top)

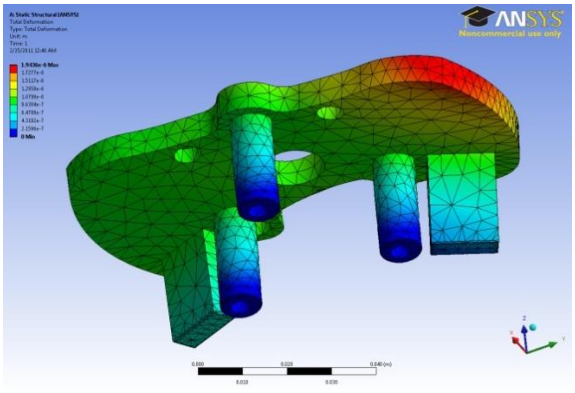


Figure H: Deformation connection loading (Bottom)

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.

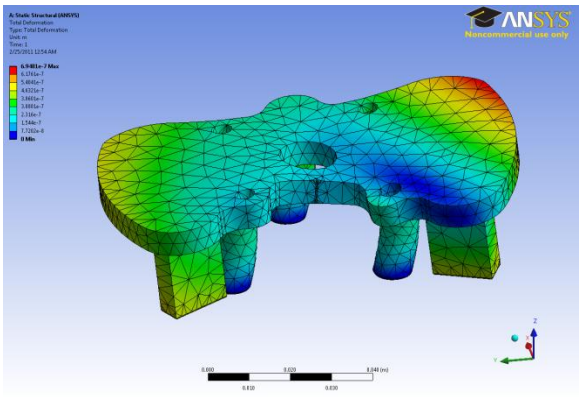


Figure I: Worst-case deformation loading (Back)

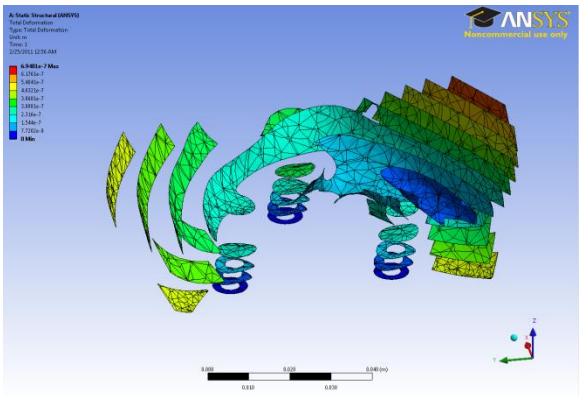


Figure J: Worst-case deformation loading (Isosurfaces)

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.

14. References

1. http://bouhammer.com/wordpress/wp-content/uploads/2008/10/080620-m-2322l-017.jpg
2. James M. Colvin et al, “PROSTHETIC DEVICE UTILIZING ELECTRIC VACUUM PUMP”, US 2007/0191965 A1, Mar 20, 2007
3. Ohio Willow Wood site, http://www.owwco.com/pr7908.php
4. LimbLogic site, http://www.ortho-europe.com/products/limb%20logic/limblogic.htm#1
5. LimbLogic product description, http://www.ortho-europe.com/products/limb%20logic/Limblogicqxp.pdf
6. http://www.norellprostheticsorthotics.com/pages/Portals/0/c-leg3.png
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
10. http://www.tececo.com/images/graphics/sustainability/LifeCycleAnalysis.gif
11. James Jay Martin, “Vacuum Attachment System” US 2009/0281637 A1, Sept 11, 2007 http://www.google.com/patents?id=IxDKAAAAEBAJ&printsec=drawing&zoom=4#v=onepage&q&f=false
12. Craig Mackenzie, “Mounting plate system, vacuum reservoir plate and electronic pump system for ...” US 2010/0094432 A1, Sep 25, 2009 http://www.google.com/patents?id=xo7OAAAAEBAJ&printsec=drawing&zoom=4#v=onepage&q&f=false
13. Morris J. Danzig et al, “Prosthetic vacuum system”, US 2008/0147202 A1, Dec 14, 2006 http://www.google.com/patents?id=U4fXAAAAEBAJ&printsec=drawing&zoom=4#v=onepag&q&f=false
14. http://www.google.com/patents/about?id=pCyBAAAAEBAJ

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

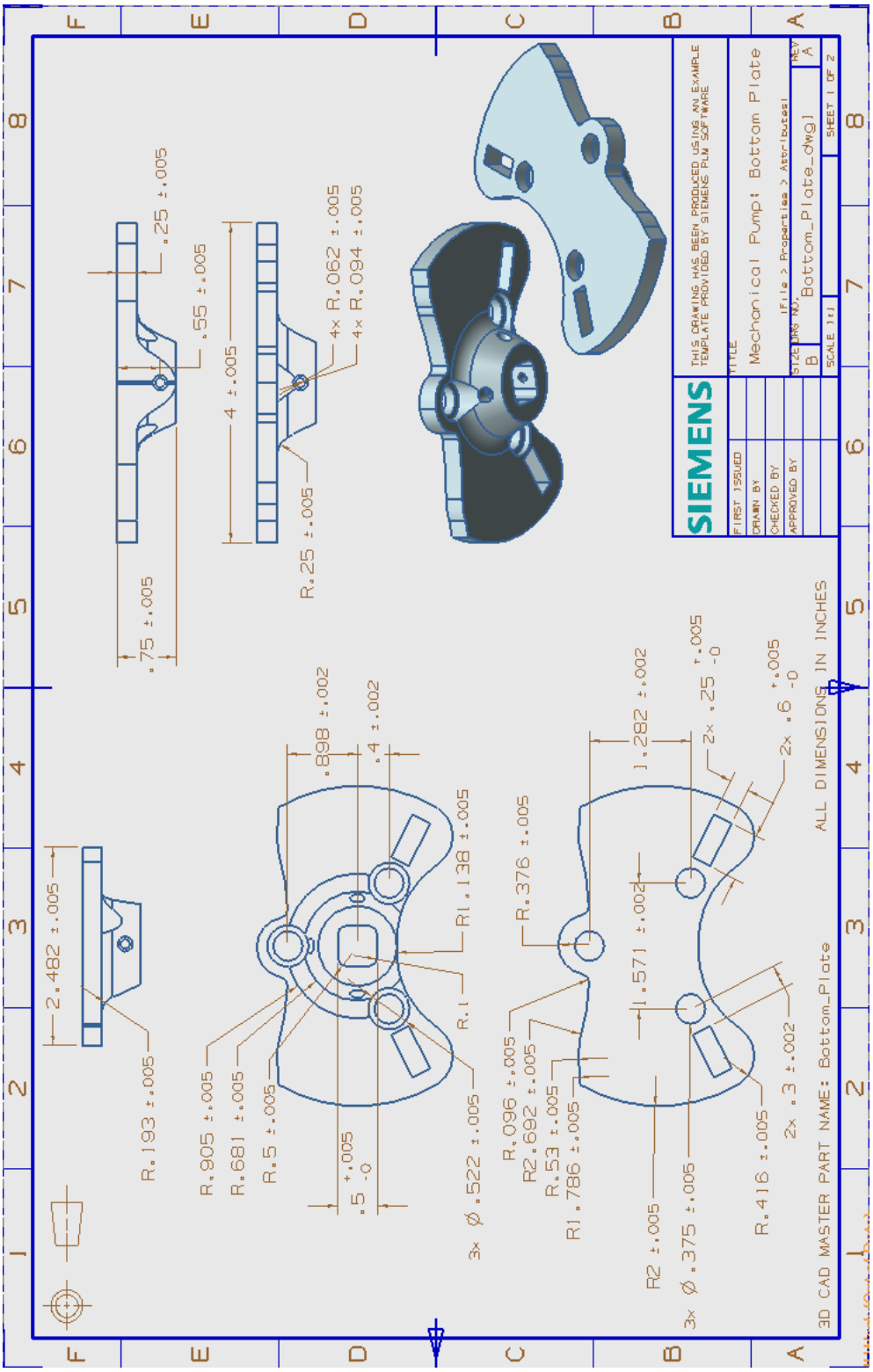
- Trans-femoral amputees

Manufacturing

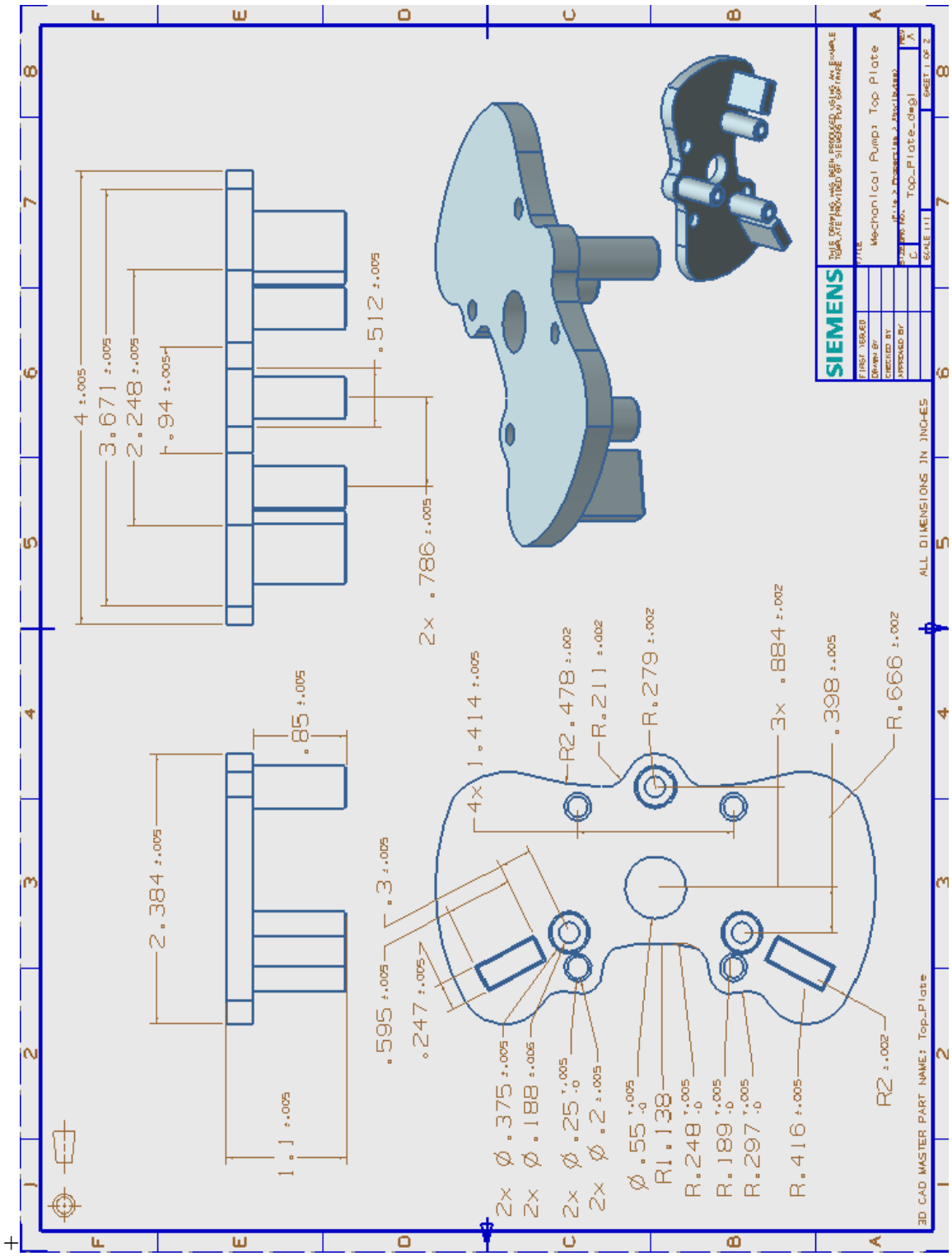
- Prototype will be produced at Ford Design Shop
- Looks-like prototype will be produced in Ford Rapid Prototyping Lab

16. Appendix B: Drawings

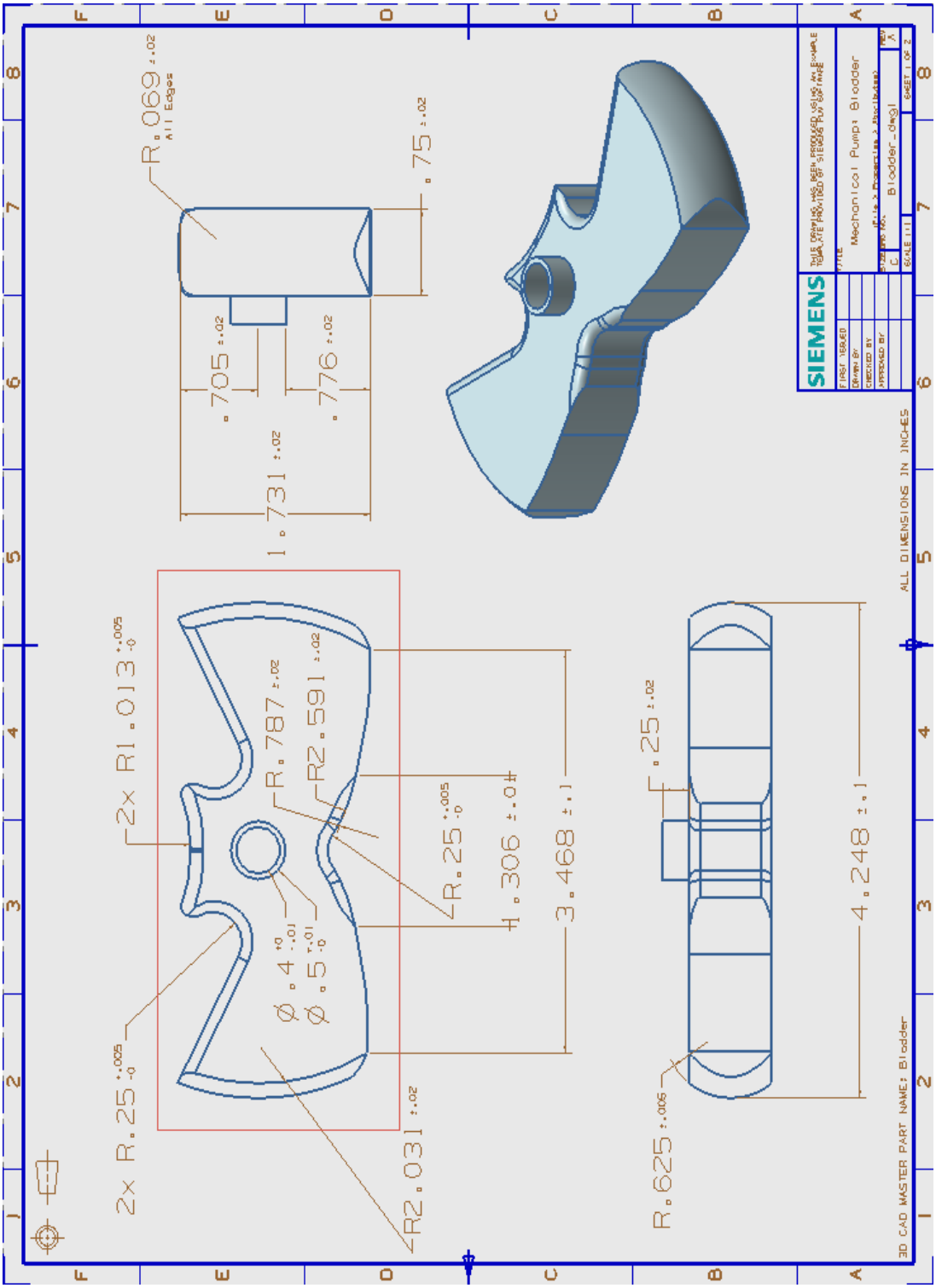
Bottom Plate (BOM 3)



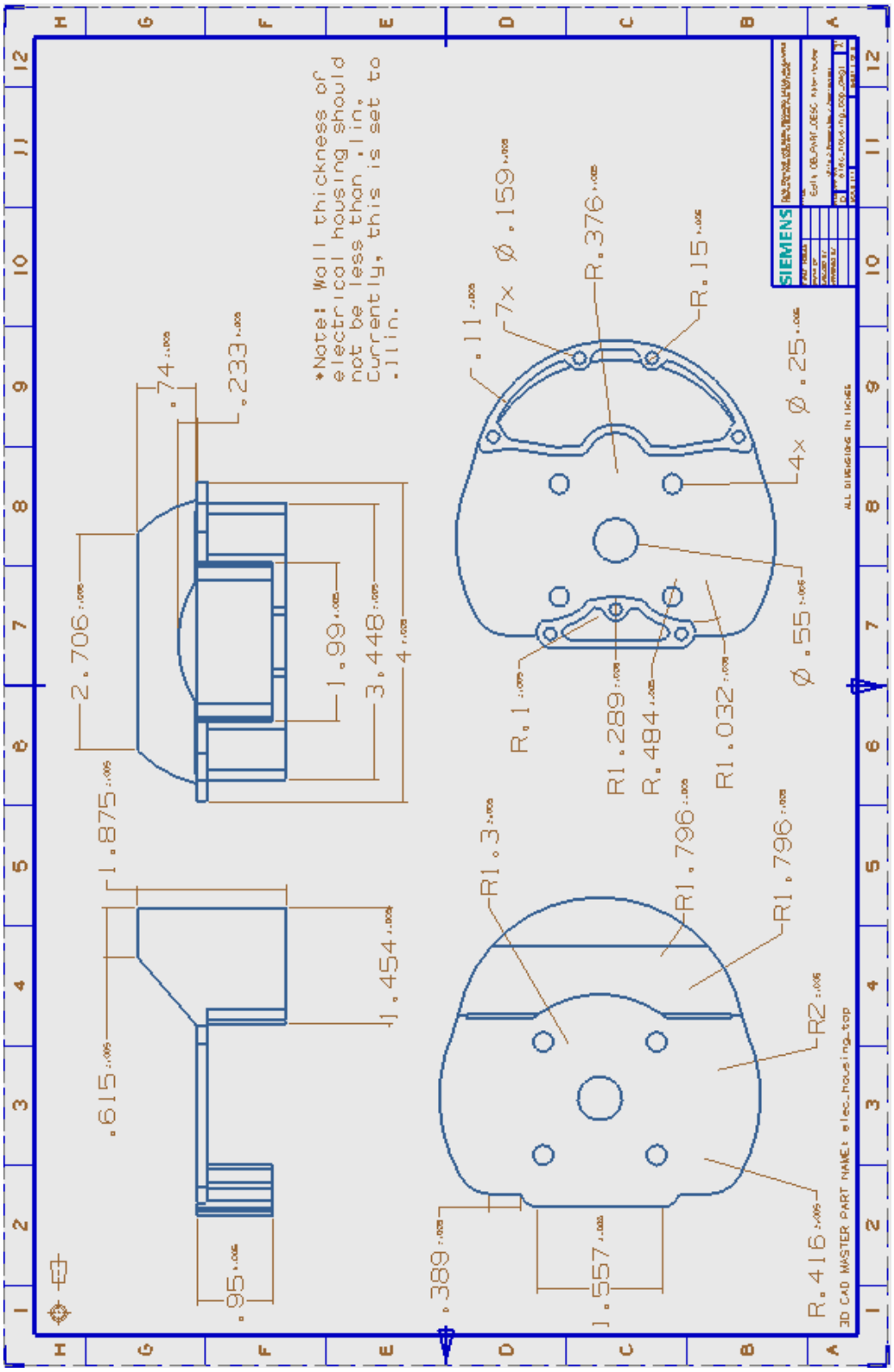
Top Plate (BOM 2)



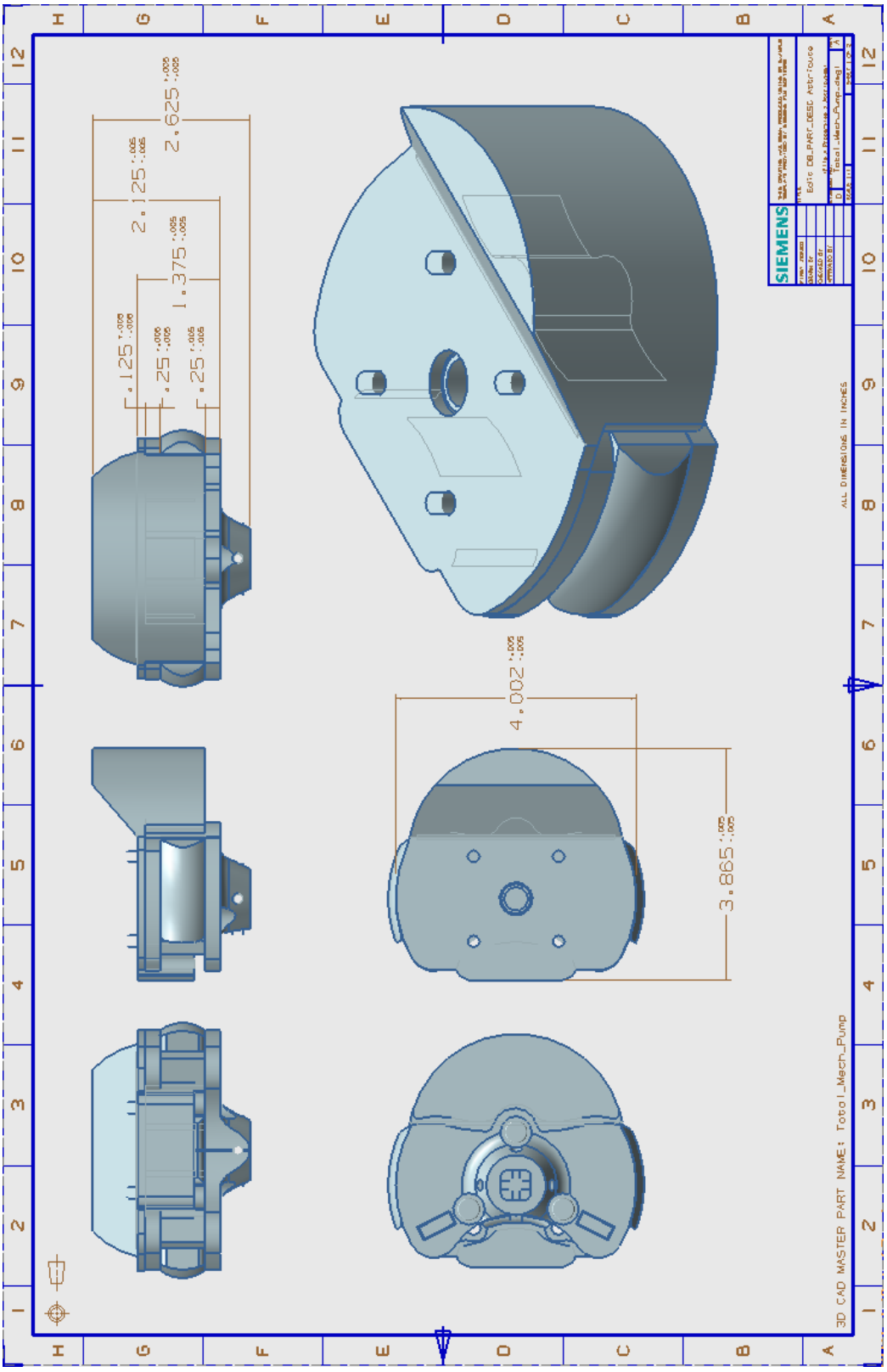
Bladder (BOM 1)



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: $\frac{P_1}{P_2} = \frac{n_1}{n_2}$ (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: $n_2 = \left(\frac{P_2}{P_1}\right) n_1$ (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: $\frac{P_1}{P_2} = \frac{n_1}{n_2}$

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: $n_2 = \left(\frac{P_2}{P_1}\right) n_1$

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: $\frac{P_1}{P_2} = \frac{n_1}{n_2}$

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

Then if we rearrange our ideal gas equation: $n_2 = \left(\frac{P_2}{P_1}\right) n_1$

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 R – HYBRID VACUUM PUMP PATENT

2

Patents Application Grant Find prior art Discuss this patent View PDF Download PDF

Vacuum pump systems for prosthetic limbs and methods of using the same

US 9066822 B2

ABSTRACT

Pump systems for use in suspension of a prosthetic device from a residual limb and methods of suspending a prosthetic device from a residual limb are disclosed. The pump systems include a mechanically activated pump having a first compression member coupled to a second compression member, a compressible bladder disposed between the first and second compression members, and coupling elements that engage and couple together the first and second compression members. The mechanically activated pump may be connected with an electrically activated pump within a fluid circuit of a hybrid pump system to provide vacuum engagement between a prosthetic device and a residual limb.

Publication number	US9066822 B2
Publication type	Grant
Application number	US 13/529,833
Publication date	Jun 30, 2015
Filing date	Jun 21, 2012
Priority date	Jun 23, 2011
Also published as	US20130096694, US20150265435, US20150265436, WO2012177965A1
Inventors	Ryan J. Caldwell, 8 More »
Original Assignee	Northwestern University
Export Citation	BiBTeX, EndNote, RefMan

Patent Citations (25), Non-Patent Citations (2), Referenced by (2), Classifications (24), Legal Events (4)

External Links: USPTO, USPTO Assignment, Espacenet

IMAGES (15)



DESCRIPTION

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Patent Application Ser. No. 61/571,233, filed Jun. 23, 2011, the disclosure of which is hereby incorporated by reference in its entirety.

CONTRACTUAL ORIGIN OF THE INVENTION

This invention was made with government support under Grant No. W81XWH-10-1-0744 awarded by the U.S. Army Medical Research and Material Command. The government has certain rights in the invention.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention generally relates to suspension systems for prosthetic devices, and more particularly to vacuum pump systems for prosthetic limbs that include at least a mechanically activated pump.

2. Discussion of the Prior Art

Various systems have been developed for coupling a prosthetic device or prosthetic limb to a residual limb. The residual limb is connected to the prosthesis via a socket which receives and holds in place an end portion of the residual limb. Suspension is the mechanism that holds the socket to the residual

CLAIMS (15)

What is claimed is:

1. A hybrid pump system that includes a prosthetic device that is adapted for suspension from a transfemoral residual limb comprising:

a prosthetic device having a transfemoral receiving socket and a knee joint;

a mechanically activated pump having pumping action that requires a mechanical input via movement of the prosthetic device;

a separate electrically activated pump having an electrical power source and pumping action that requires an electrical input from the electrical power source;

the mechanically activated pump and electrically activated pump being connected within a fluid circuit that evacuates air from the transfemoral limb receiving socket;

wherein the mechanically activated pump is positioned between the transfemoral limb receiving socket and the knee joint;

wherein the mechanically activated pump further comprises a first compression member coupled to a second compression member and a compressible bladder disposed between the first and second compression members; and

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

limb tissue by providing cushioning and helping distribute the applied negative pressure in a uniform manner.

Vacuum pump technology is used to suspend the socket to the residual limb by creating a vacuum between the liner and the socket. The ability to maintain vacuum at a relatively consistent level can help avoid undesirable movement between the socket and the residual limb which improves comfort and avoids soft tissue damage.

Vacuum pumps fall into two categories, namely, mechanically activated or electrically activated. Electrically activated pumps tend to evacuate air more quickly, are able to monitor and adjust the vacuum pressure, and to automatically initiate pump operation if the vacuum pressure is not at least at a preselected threshold. However, electrically activated pumps include a small DC motor that requires a power source, such as disposable or rechargeable batteries. Electrically activated pumps also may generate undesirable noise.

Mechanically activated pumps use the walking motion of the user to create vacuum. One way pressure valves permit proper maintenance of vacuum pressure, without access to electricity. The necessary vacuum may be maintained indefinitely as long as there are no leaks in the system and/or the user walks occasionally. However, the mechanically activated pumps do not provide initial evacuation of air without effort, take longer to achieve operative vacuum levels, and typically need periodic motion to maintain appropriate vacuum levels. Mechanically activated pumps also tend to require a significant length for operation, as they typically operate by using a telescoping assembly. Depending on the number of parallel alignment elements involved, length can be important within a telescoping assembly, so as to provide adequate surface engagement to avoid binding. Mechanically activated pumps generally are configured for mounting below the knee because the pumps are too long to fit between the socket and the knee joint of the prosthetic limb, and as such, are not as well suited for transfemoral amputees.

Mechanically activated pumps also typically use a piston within a cylinder for pumping, or systems that include a flexible toroidal or ring-shaped reservoir or bladder that has a relatively large cylindrical telescopic tube running through the center, in place of a section of a lower limb pylon. The tube must be relatively large and of length sufficient to avoid binding, while withstanding the significant stresses encountered. In turn, the reservoir must be constructed to account for the large opening through the center.

For some users, such as military personnel with amputation who wish to return to active duty, there is an enhanced need to be able to maintain acceptable physical performance. An active soldier with amputation may be in the field for a prolonged period of time, with a need to maintain proper vacuum levels for suspension, while being without access to a power source for recharging of batteries. Thus, there exists a need for a compact, quiet, unobtrusive vacuum pump system with adjustable pressure and minimal battery recharging needs that will evacuate air from a cavity between a socket of a prosthetic limb and a residual limb.

The present invention addresses shortcomings in prior art vacuum pump systems for prosthetic limbs, while providing enhanced pumping systems that enable more flexible design and enhanced performance.

SUMMARY OF THE INVENTION

The purpose and advantages of the invention will be set forth in and apparent from the description and drawings that follow, as well as will be learned by practice of the claimed subject matter.

The present disclosure generally provides pump systems that include mechanically activated pumps having a lower profile design while still being able

members, and wherein all of the coupling elements are disposed about an outer perimeter of the compressible bladder.

2. The hybrid pump system in accordance with claim 1, wherein the socket is configured to receive and be in direct contact with the transfemoral residual limb or in contact with a liner component that covers the transfemoral residual limb.

3. The hybrid pump system in accordance with claim 1, wherein the electrical power source further comprises a battery.

4. The hybrid pump system in accordance with claim 3, wherein the battery is rechargeable.

5. The hybrid pump system in accordance with claim 1, wherein at least one spring is disposed between the first compression member and the second compression member.

6. The hybrid pump system in accordance with claim 5, wherein the at least one spring biases the first compression member toward a position spaced apart from the second compression member.

7. The hybrid pump system in accordance with claim 1, wherein the first compression member translates relative to the second compression member.

8. The hybrid pump system in accordance with claim 1, wherein the electrically activated pump is disposed above or below the mechanically activated pump.

9. The hybrid pump system in accordance with claim 1, wherein the electrically activated pump is disposed outward from the outer perimeter of the compressible bladder.

10. The hybrid pump system in accordance with claim 1, wherein a preselected level of vacuum within the socket is maintained by operation of the mechanically activated pump.

11. The hybrid pump system in accordance with claim 1, wherein a preselected level of vacuum within the socket is maintained by operation of the electrically activated pump.

12. The hybrid pump system in accordance with claim 1, further comprising a controller and wherein the fluid circuit and controller are configured to evacuate air from the socket by operating the electrically activated pump when the transfemoral residual limb is initially received within the socket.

13. The hybrid pump system in accordance with claim 1, further comprising a controller and wherein the fluid circuit and controller are configured to evacuate air from the socket by operating the electrically activated pump when the prosthetic device is not being used to walk and the air pressure within the socket is outside of a preselected range of values.

14. The hybrid pump system in accordance with claim 1, wherein the fluid circuit is in communication with the socket and the compressible bladder of the mechanically activated pump, and the mechanically activated pump evacuates air from the socket when the prosthetic device is used to walk.

15. A hybrid pump system that includes a prosthetic device that is adapted for suspension from a transfemoral residual limb comprising:

a prosthetic device having a transfemoral receiving socket and a knee joint;

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

opening for a tubular telescopic assembly. By avoiding use of such a central tubular telescopic assembly, the mechanically activated pumps of the present disclosure permit use of a relatively large diameter bladder having a greater volume and which requires less displacement to achieve adequate pumping capacity. Such pumps optionally permit location above or below the knee joint in a transfemoral prosthetic limb, or compact placement within a transtibial prosthetic limb.

The mechanically activated pumps of the present disclosure may utilize first and second compression members, with a compressible bladder disposed therebetween and any of a variety of coupling elements disposed about an outer perimeter of the compressible bladder. Thus, the compression members may be pivotally coupled in a configuration that permits angular displacement of a first compression member relative to a second compression member, or in a configuration that permits the first compression member to translate, maintaining a parallel relationship to the second compression member. Alternatively, the compression members may be coupled in a configuration that does not involve any pivotal connection, and permits the first compression member to translate relative to the second compression member.

To further enhance the performance of pump systems for suspension of a prosthetic limb, the present disclosure also provides pump systems that include an electrically activated pump, such as of the micro pump type utilized in exclusively electrical systems, thereby providing a modular hybrid system. A hybrid pump system may offer significant advantages, such as the desired rapid engagement upon initial donning of the prosthetic device, while not requiring solely battery power to evacuate air and to maintain appropriate vacuum levels. This may permit elongated intervals between charging of rechargeable batteries or battery packs, or between replacement of disposable batteries. A hybrid system also may provide for better optimization of the size and capacities of the components utilized, as the mechanically activated pump portion of a hybrid system need not be as concerned with the ability to rapidly establish initial evacuation solely via the mechanically activated pump, while the electrically activated pump is less likely to be cycled during the course of many activities that now will provide operation of a mechanically activated pump. Accordingly, depending on the length of the residual limb, it may be possible to implement a hybrid pump system of this disclosure within a system having a relatively short length, such that it could be located above the knee joint for a transfemoral amputee.

Thus, a hybrid system may utilize the respective strengths of mechanically and electrically activated pumps to achieve superior overall performance, while essentially also providing a redundant pump system to ensure at least adequate performance for the user. By utilizing a low profile design, the systems also permit placement above the knee for a transfemoral amputee, for direct interaction with a socket of a prosthetic device. The pump systems preferably have a height of about 1.5 inches or less, to permit positioning above the knee. It will be appreciated that the height may be more or less, depending on the configuration of mechanically activated pump, and whether or not the system includes an electrically activated pump, as well as its configuration. This, in turn, helps avoid many of the hindrances associated with below knee systems, while permitting an inline assembly that need not require external tubing.

Accordingly, in a first aspect, disclosed herein is a pump system for use in suspension of a prosthetic device from a residual limb. The pump system includes a mechanically activated pump having a first compression member coupled to a second compression member, a compressible bladder disposed between the first and second compression members, and coupling elements that engage and couple together the first and second compression members, wherein all of the coupling elements are disposed about an outer perimeter of the compressible bladder.

In a second aspect, disclosed herein is a method of suspending a prosthetic device from a residual limb. The method includes providing a prosthetic device having a socket that receives the residual limb. The method further includes providing a mechanically activated pump having a first compression member coupled to a second compression member, a compressible bladder disposed between the first and second compression members, and coupling elements engaging and coupling together the first and second compression members, wherein all of the coupling elements are disposed about an outer perimeter of the compressible bladder. The method also includes providing a fluid circuit in communication with the socket and the compressible bladder, the fluid circuit being configured to evacuate air from the socket when operating the mechanically activated pump, and operating the mechanically activated pump when the prosthetic device is used to walk.

In a third aspect, disclosed herein is hybrid pump system for use in suspension of a prosthetic device from a residual limb. The hybrid pump system includes a mechanically activated pump, an electrically activated pump, and the mechanically activated pump and electrically activated pump are connected within a fluid circuit that provides vacuum engagement between the prosthetic device and the residual limb.

a mechanically activated pump having pumping action that requires a mechanical input via movement of the prosthetic device;

a separate electrically activated pump having an electrical power source and pumping action that requires an electrical input from the electrical power source;

the mechanically activated pump and electrically activated pump being connected within a fluid circuit that evacuates air from the transfemoral limb receiving socket;

wherein the mechanically activated pump further comprises a first compression member coupled to a second compression member and a compressible bladder disposed between the first and second compression members; and

wherein the mechanically activated pump further comprises coupling elements that engage and couple together the first and second compression members, and wherein all of the coupling elements are disposed about an outer perimeter of the compressible bladder.

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

It will be appreciated that the unique mechanically activated pumps disclosed herein provide advantageous configurations that permit low profile arrangements to be utilized in suspending a prosthetic device from a residual limb. It also will be appreciated from this disclosure that a mechanically activated pump may be connected to a fluid circuit that includes an electrically activated pump, so as to create a hybrid system for use in suspension of a prosthetic device from a residual limb. It is contemplated that various configuration may be utilized and the appended claims are not to be limited to the examples illustrated.

Thus, the present disclosure presents alternatives to the prior art mechanically activated pumps, as well as to systems that use only an electrically activated pump, where the prior art systems have proven to be less effective than desired.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and provided for purposes of explanation only, and are not restrictive of the subject matter claimed. Further features and objects of the present disclosure will become more fully apparent in the following description of the preferred embodiments and from the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

In describing the preferred embodiments, reference is made to the accompanying drawing figures wherein like parts have like reference numerals, and wherein:

FIG. 1A is a simplified side view of a prosthetic device in the form of a prosthetic limb for a transfemoral amputee having a first example pump system that includes a mechanically activated pump, with the pump system also including an electrically activated pump, so as to provide a hybrid pump system.

FIG. 1B is a simplified side view of a prosthetic device in the form of a prosthetic limb for a transtibial amputee having the pump system shown in FIG. 1A.

FIG. 1C is a side perspective view of the pump system shown in FIG. 1A.

FIG. 1D is a lower rear perspective view of the pump system shown in FIG. 1A.

FIG. 1E is a side view of the pump system shown in FIG. 1A.

FIG. 1F is an upper front perspective view of the pump system shown in FIG. 1A.

FIG. 1G is simplified top view of a layout of major components within the electrically activated pump of the pump system shown in FIG. 1A.

FIG. 1H is further simplified upper perspective view of a layout of major components within the electrically activated pump of the pump system shown in FIG. 1A.

FIG. 1I is an upper front perspective partially exploded view of the pump system shown in FIG. 1A.

FIG. 1J is an alternative view of that shown in FIG. 1I, showing a portion of the fluid circuit of the pump system shown in FIG. 1A.

FIG. 1K is a side partially exploded view of the pump system shown in FIG. 1A.

FIG. 1L is an alternative view of that shown in FIG. 1K, showing a portion of the fluid circuit of the pump system shown in FIG. 1A.

FIG. 1M is a schematic view of the process involved in using the pump system shown in FIG. 1A.

FIG. 1N is a schematic view of the control system for the pump system shown in FIG. 1A.

FIG. 1O is a schematic view of operation of the pump system shown in FIG. 1A when the electrically activated pump and the mechanically activated pump are in operation.

FIG. 1P is a schematic view of operation of the pump system shown in FIG. 1A when only the mechanically activated pump is in operation.

FIG. 2A is a side perspective view of a second example pump system for a prosthetic device.

FIG. 2B is a side view of the pump system shown in FIG. 2A

FIG. 2C is a lower rear perspective view of the pump system shown in FIG. 2A.

FIG. 2D is an upper front perspective view of the pump system shown in FIG. 2A.

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

FIG. 2F is an alternative view of that shown in FIG. 2E, showing view of a layout of major components within the electrically activated pump of the pump system shown in FIG. 2E.

FIG. 3A is an upper perspective view of a third pump system for a prosthetic device.

FIG. 3B is a front view of the pump system shown in FIG. 3A.

FIG. 3C is a side view of the pump system shown in FIG. 3A.

FIG. 3D is an upper front perspective partially exploded view of the pump system shown in FIG. 3A.

FIG. 3E is a simplified upper perspective view of a layout of major components within the electrically activated pump of the pump system shown in FIG. 3A.

FIG. 4A is a simplified side view of a prosthetic device in the form of a prosthetic limb for a transfemoral amputee having a fourth example pump system that includes a mechanically activated pump.

FIG. 4B is a simplified side view of a prosthetic device in the form of a prosthetic limb for a transtibial amputee having the pump system shown in FIG. 4A.

FIG. 4C is a rear view of the pump system shown in FIG. 4A.

FIG. 4D is a side view of the pump system shown in FIG. 4A.

FIG. 4E is an upper perspective view of the pump system shown in FIG. 4A.

FIG. 4F is a lower perspective view of the pump system shown in FIG. 4A.

FIG. 4G is a lower rear perspective partially exploded view of the pump system shown in FIG. 4A.

FIG. 4H is a simplified upper perspective view of an upper compression member of the pump system shown in FIG. 4A and further including an electrically activated pump that is shown with a layout of the major components.

It should be understood that the drawings are not to scale. While some details of a pump system for a prosthetic device, including details of fastening means and other plan and section views of the particular components, have not been included, such details are considered well within the comprehension of those of skill in the art in light of the present disclosure. It also should be understood that the present invention is not limited to the example embodiments illustrated.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring generally to FIGS. 1A-4H, it will be appreciated that a vacuum pump system for use in suspension of a prosthetic device from a residual limb of the present disclosure generally may be embodied within numerous configurations of pump systems having a mechanically activated pump and/or a hybrid pump system having a mechanically activated pump and an electrically activated pump. Indeed, while acknowledging that all of the example configurations may include at least one of the example mechanically activated pumps, it is contemplated that a pump system may be incorporated into various prosthetic devices, such as transfemoral and transtibial prosthetic limbs.

FIG. 1A shows a simplified side view of a prosthetic device or limb 2 in the form of a prosthetic limb for a transfemoral amputee. The prosthetic device 2 generally includes a socket 4, a first example pump system 6, a knee joint 8, a pylon 10 and a prosthetic foot 12. The socket 4 has an upper end 18 that is open and is adapted to receive a transfemoral residual limb, with a lower end 20 that includes a port (not shown) in fluid communication with the pump system 6.

FIG. 1B incorporates somewhat similar components in showing a simplified side view of a prosthetic device or limb 2′ in the form of a prosthetic limb for a transtibial amputee. The prosthetic device 2′ generally includes a socket 4′, the first example pump system 6, a pylon 10′ and a prosthetic foot 12. The socket 4′ has an upper end 18′ that is open and is adapted to receive a transtibial residual limb, with a lower end 20′ that includes a port (not shown) in fluid communication with the pump system 6.

There are numerous configurations of socket assemblies for suspension systems, some custom molded and constructed for direct contact with the skin of the residual limb, while others are intended to receive a residual limb that is covered with one or more liner components that prevent the skin from direct contact with the socket and exposure to vacuum pressure developed within the socket. It will be appreciated that the pump systems of the present disclosure could be configured for use in prosthetic devices with either type of socket, whether for use with transfemoral or transtibial residual limbs, with the components and specifications being appropriately matched to the desired vacuum pressure. Indeed, the specific construction and shape of the socket are not at issue, and depending on the particular configuration used, the port may be placed at various locations within the socket.

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

pump system 6 or to other intermediary components. Similarly, the upper end of the knee joint 8 or pylon 10′ will be equipped for connection to the pump system 6, such as by having a mounting flange for a standard pyramid four bolt connector. It will be appreciated that the low profile, inline structure of the pump system 6 may be incorporated into a reduced package height, preferably although not necessarily of about 1.5 inches or less, which permits fluid connection of the pump system 6 to the lower end 20, 20′ of the socket 4, 4′, and may eliminate the need for external tubing. Avoiding the use of external tubing can reduce the likelihood of interference or impedance of flexion of the knee, or the risk of getting caught on a protrusion.

A pump system 6 consistent with the first example may be seen in various views within FIGS. 1C-1L and includes at least a mechanically activated pump 30. As shown, the first example also includes an electrically activated pump 70, and the mechanically activated pump 30 and electrically activated pump 70 are connected within a fluid circuit 90 that is connected to and adapted to evacuate air from the socket 4, 4′, thereby forming a particularly advantageous modular, hybrid pump system 6. The evacuation of air from the socket 4, 4′, provides vacuum engagement between the prosthetic device 2, 2′ and a respective transfemoral or transtibial residual limb. It also will be appreciated that with a pump system that includes a mechanically activated pump 30, the pump system alternatively could be configured for periodic use with a separate hand operated pump to establish initial air evacuation.

The hybrid pump system 6 of this first example provides a compact, low profile, inline structure. As may be seen in FIGS. 1C-1F and 1I-1L, the mechanically activated pump 30 of the first example pump system 6 includes a first compression member 32 coupled to a second compression member 34, with a compressible bladder 36 is disposed therebetween. The first and second compression members 32, 34 preferably are constructed of relatively light weight, generally rigid, suitable metals, such as aluminum alloys, titanium alloys, stainless steels or superalloys, or various plastics or composite materials. Depending on the environment to which a prosthetic device may be subjected, it may be desirable for the materials to be waterproof, sand-proof, and weather and corrosion resistant, although an outer pump system cover also may be employed to reduce the likelihood of intrusion of fluids or foreign matter.

The first compression member 32 includes a generally planar central body 38 having a central recess 40, spaced apart mounting apertures 42, and extensions in the form of hinge knuckles 44 that are opposite a flange 46. The mounting apertures 42 are configured to permit fasteners to pass therethrough for mounting to a standard pyramid four bolt connector at the upper end of a knee joint 8 or pylon 10′, but it will be appreciated that alternative connective elements could be integrally formed into the first compression member for this or the other examples. The second compression member 34 includes a generally planar central body 48 having a central aperture 50, spaced apart mounting apertures 52, and an extension in the form of a hinge knuckle 54 that is opposite a flange 56. The first compression member 32 is coupled to the second compression member 34 via coupling elements that include a the hinge knuckles 44, 54 and a hinge pin 58 that pivotally engages the respective knuckles 44, 54, thereby making the first compression member 32 pivotally coupled to the second compression member 34. An optional spring assembly 60 extends between the respective flanges 46, 56 and biases the flanges toward a spaced apart position. Use of the spring assembly 60 may assist in providing consistent operation and feedback to the user.

While the coupling elements may be of a different configuration and size, the mechanically activated pump 30 should provide sufficient structural integrity and stability to maintain a consistent and predictable gait and resistance to torsional inputs, such as a twisting motion after planting a step. Also, it will be appreciated that the hinge or pivotal coupling is shown on the anterior or front side of the pump. While the hinge could be placed anteriorly or posteriorly, depending on the preference of particular prosthetists, placement anteriorly should cause the bladder to compress upon heel contact, providing some shock absorption, and movement of the pivots should mimic a desirable stance phase knee flexion.

The compressible bladder 36 may be particularly effective, while being of relatively short height because it has nearly continuous generally planar upper and lower surfaces 36′, 36″, which are connected to a radially bulging outer sidewall 36‴ that defines an outer perimeter of the compressible bladder 36. This configuration of the compressible bladder 36 permits much greater capacity, and therefore potential efficiency, within a given overall diameter, when compared to a compressible bladder having an enlarged passage through the center to accommodate a tubular pylon-like telescopic structure. Locating the pump system 6 above the knee in a transfemoral configuration may permit a relatively large overall diameter, such as around 4 inches.

The compressible bladder 36 generally is an airtight, elastomeric body, and depending on the extent of the desired inherent rebound within the structure, and the anticipated environmental conditions, may be constructed of various rubbers, such as plasticized Halobutyl or polysulphide rubbers, plastics, such as ABS, PEEK or other polymers, Nylon, composites or other suitable materials. Also, depending on the selected material, the compressible bladder may be constructed by blow molding or other suitable manufacturing techniques.

While the compressible bladder 36 may be constructed of one or more materials and in a manner that will tend to expand or return to its original non-compressed state, thereby separating the first and second compression members 32, 34, the optional spring assembly 60 is intended to ensure rebound and expansion of the compressible bladder 36 during repeated

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

that many configurations of compression members, compressible bladders and coupling elements may be utilized to couple a first compressible member to a second compressible member, and optional spring assemblies may include alternative spring forms, including for example, a leaf spring, or a coiled torsion spring having opposed arms and being incorporated with a hinge pin, or other suitable alternative structures.

The first and second compression members 32, 34 and compressible bladder 36 utilize a fluid circuit 90 to evacuate air from the socket 4, 4′. The compressible bladder 36 includes an intake valve 62 that communicates through the aperture 50 in the second compression member 34, and an output valve 64 that is vented to the atmosphere to expel air that has been evacuated from the socket 4, 4′ by the pump system 6.

In the first example, the electrically activated pump 70 is positioned inline with and connected to the second compression member 34 of the mechanically activated pump 30. As may be seen in a simplified manner in FIGS. 1L and 1J, the electrically activated pump 70 includes a housing 72 having an inlet valve 74 in communication with a central passage 76 therethrough for fluid connection to the socket 4, 4′, and an output valve 78 that is vented to the atmosphere to expel air that has been evacuated from the socket 4, 4′ by the pump system 6. The housing 72 also includes passages 80 therethrough that are aligned with the mounting apertures 52 in the second compression member 34 and together receive fasteners (not shown) that provide mechanical connection of the mechanically activated pump 30 and electrically activated pump 70 to a suitable mounting flange (not shown) at the lower end 20, 20′ of a socket 4, 4′. It will be appreciated that the electrically activated pump may be equipped with alternative valving and operative features, as desired. Also, the housing of the electrically activated pump could be configured to be integrated into the lower end of a socket.

As may be appreciated in FIGS. 1G, 1H and 1N, the electrical components of the electrically activated pump 70 are shown in a simple layout and with a functional schematic to show the basic function and connection configuration. It will be appreciated that the components may be configured and connected in fluid communication by conventional means, such as by suitable tubing, and/or may be configured and connected electrically by conventional means, such as by suitable wires, leads or other circuitry, so as to meet the needs and satisfy the design specifications and constraints within of a particular implementation. In this first example, within the housing 72 of the electrically activated pump 70 is a microcontroller M that includes a circuit board and is connected to a motorized pump MP, a pressure sensor PS, and a battery BAT. A user interface A, in the form of an on/off button, is located in conjunction with the output valve 78 and is connected to the microcontroller M. An optional serial data port D may be utilized to interact with the microcontroller M, such as to track and record the operating conditions of the pump system 6, for diagnostic and historical monitoring purposes.

A further user interface B, such as in the form of a wireless remote control device, a personal data assistant device, a laptop or tablet computer, a cell phone or other wireless apparatus, may be utilized to interact with the microcontroller M to input particular settings that are associated with performance parameters, such as the minimum and maximum vacuum pressures between which the system will operate, the battery charge level at which a warning light or alarm may be emitted, or to adjust other parameters that would be desirable to control. The user interface B also may be used to display information associated with the present status of the system, such as the current vacuum pressure level, battery charge level, or predictive information, such as the battery life remaining or time interval until the next regular maintenance is recommended. The pump system 6 may include warning lights or alarms that may be connected to the housing 72, or embodied within a user interface B, to alert a user to important information.

The battery BAT preferably is rechargeable, such as by direct or indirect connection to a power charge device PC. It further is desirable that the battery BAT be replaceable, so as to permit one or more spare, charged batteries to be utilized during periods of extended use away from a power recharging source. It will be appreciated that the battery BAT may simply be of a disposable type, or that there could be an interface to permit interchangeability between a rechargeable battery and a disposable battery, based on the convenience and circumstances faced by the user.

It will be appreciated that the pump system 6 presents a hybrid, modular system that can be utilized in a number of ways. A high level schematic is provided in FIG. 1M to show that when the residual limb of a user has been received in a socket 4, 4′, the user is faced with an input that essentially could be considered an unevacuated chamber. The user then may take one of two actions, namely, first to press a button, such as user interface button A on the housing 72, or on a user interface B, such as a remote control, to provide electrical power to engage the electrically activated pump 70, or second to step with the prosthetic limb 2, 2′ to provide mechanical power to the mechanically activated pump 30. The two different actions both cause the pump system 6 to provide a response by which air is expelled to the atmosphere, resulting in an outcome by which the chamber between the socket 4, 4′ and the residual limb changes to an evacuated chamber.

Thus, the mechanically activated pump 30 or the electrically activated pump 70 may be used to evacuate air from the socket 4, 4′, with the understanding that either pump may be used exclusively, if need be. However, maximum comfort and convenience can be achieved by first utilizing the electrically activated pump 70 to establish rapid initial evacuation, and thereafter the user may rely on the mechanically activated pump 30, if the user is actively moving, such as walking, running or able to impose at least a bouncing motion on the prosthetic limb 2, 2′, or if the user happens to be inactive at a time when further evacuation of air is needed, the monitoring system within the electrically activated pump 70 may automatically

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

FIG. 1O provides a schematic representation of the pump system 6 when a user is walking and the pump system 6 is within an electrical pump-vacuum control range. Thus, within a swing phase, the first and second compressible members 32, 34 move away from each other, allowing the compressible bladder 36 to expand and draw air from the socket 4, 4′. Meanwhile, the electrically activated pump 70 may draw air from the socket 4, 4′ and expel the air to the atmosphere through the output valve 78. Within the stance phase, the compression member 32 pivots relative to the compression member 34 to compress the compressible bladder 36, expelling the air previously withdrawn from the socket 4, 4′, while the electrically activated pump 70 is able to continue to operate in the same manner as during the swing phase.

FIG. 1P provides a schematic representation of the pump system 6 when a user is walking and the pump system 6 is outside of an electrical pump-vacuum control range. While the schematic represents portions of the fluid circuit 90 as elongated lines, it will be appreciated that the connections between components may be direct, or may be by tubing, and that tubing could be used in a configuration of a prosthetic device having a socket 4 for a transfemoral residual limb, with a pump system 6 positioned below the knee joint. Within the swing phase shown in FIG. 1P, the first and second compressible members 32, 34 again move away from each other, allowing the compressible bladder 36 to expand and draw air from the socket 4, 4′. Meanwhile, the electrically activated pump 70 is not energized, to save battery charge. Within the stance phase, the compression member 32 pivots relative to the compression member 34 to compress the compressible bladder 36, expelling the air previously withdrawn from the socket 4, 4′.

From the foregoing description, it will be appreciated that a method of suspending a prosthetic device 2, 2′ from a residual limb is provided herein. The method includes providing a prosthetic device 2, 2′ having a socket 4, 4′ that receives the residual limb. The method further includes providing a mechanically activated pump 30 having a first compression member 32 coupled to a second compression member 34, a compressible bladder 36 disposed between the first and second compression members 32, 34. The coupling elements include the hinge knuckles 44, 54 and the hinge pin 58 which engages and couples together the first and second compression members 32, 34, wherein all of the coupling elements are disposed about an outer perimeter that is defined by the sidewall 36‴ of the compressible bladder 36, such that the coupling elements are at or beyond the outer perimeter of the compressible bladder 36. The method also includes providing a fluid circuit 90 in communication with the socket 4, 4′ and the compressible bladder 36, the fluid circuit 90 being configured to evacuate air from the socket 4, 4′ when operating the mechanically activated pump 30. Operation of the mechanically activated pump 30 occurs when the prosthetic device 2, 2′ is used to walk.

Turning to FIGS. 2A-2F, a second example pump system 106 is disclosed for use in a prosthetic device, such as the prosthetic devices 2, 2′. The pump system 106 is quite similar to the first example pump system 6, but varies somewhat in the mechanically activated pump 130 that replaces the mechanically activated pump 30. However, the second example pump system 106 also includes at least a mechanically activated pump 130, and is equipped with an electrically activated pump 70. The mechanically activated pump 130 and electrically activated pump 70 are connected within a fluid circuit that is similar to the fluid circuit 90 and is connected to and adapted to evacuate air from the socket 4, 4′, thereby forming a particularly advantageous hybrid pump system 106. The evacuation of air from the socket 4, 4′, provides vacuum engagement between the prosthetic device 2, 2′ and a respective transfemoral or transtibial residual limb.

The hybrid pump system 106 similarly provides a compact, low profile, inline structure, where the mechanically activated pump 130 includes a first compression member 132 coupled to a second compression member 134, which preferably are constructed of materials similar to those mentioned with respect to the first example pump system 6. A compressible bladder 136 is disposed between the first and second compression members 132, 134.

The first compression member 132 includes a generally planar central body 138 having a central recess 140, spaced apart mounting apertures 142, and extensions in the form of hinge knuckles 144 that are opposite a flange 146. The second compression member 134 includes a generally planar central body 148 having a central aperture 150, spaced apart mounting apertures 152, and an extension in the form of a hinge knuckle 154 that is opposite a flange 156. The first compression member 132 is coupled to the second compression member 134 via coupling elements that include a the hinge knuckles 144, 154 and a hinge pin 158 that pivotally engages the respective knuckles 144, 154, thereby making the first compression member 132 pivotally coupled to the second compression member 134. An optional strap 159 is connected, such as by rivets, screws or other fasteners, to the respective flanges 146, 156, extends between them and limits the pivotal travel of the first compression member 132 relative to the second compression member 134. In this second example pump system 106, an optional spring assembly 160 extends through a central opening 176 in the compressible bladder 136 between and biases the respective bodies 138, 148 toward a spaced apart position. It will be appreciated that the optional spring assembly 160 also would not be needed if the strap 159 alternatively incorporated a spring element.

The compressible bladder 136 may be particularly effective, while being of relatively short height because it has nearly continuous generally planar upper and lower surfaces 136′, 136″, which are connected to a radially bulging outer sidewall 136‴ that defines an outer perimeter of the compressible bladder 136. As with the first example pump system 6, the coupling elements of the second pump system 106 are disposed about the outer perimeter of the compressible bladder 136. This configuration of the compressible bladder 136 permits much greater capacity within a given overall diameter, when compared

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

structure. The compressible bladder 136 generally is elastomeric and may be constructed of materials similar to those mentioned above with respect to the first example pump system 6.

While the compressible bladder 136 may be constructed of one or more materials and in a manner that will tend to expand to a non-compressed state, thereby separating the first and second compression members 132, 134, the optional spring assembly 160 is intended to ensure rebound and expansion of the compressible bladder 136 during repeated hinged compression movements that occur during walking or isolated bouncing-type movements. Also, it will be appreciated that many configurations of compression members, compressible bladders and coupling elements may be utilized to couple a first compressible member to a second compressible member, and optional spring assemblies may include alternative spring forms, such as are mentioned above with respect to the first example pump system 6.

The first and second compression members 132, 134 and compressible bladder 136 utilize a fluid circuit 190 to evacuate air from the socket 4, 4′. The fluid circuit 190 is similar to the fluid circuit 90 of the first example pump system 6, but the compressible bladder 136 incorporates an intake valve (not shown) that communicates through the aperture 150 in the second compression member 134, and an output valve (not shown) that is vented to the atmosphere to expel air that has been evacuated from the socket 4, 4′ by the pump system 106.

In the second example, the electrically activated pump 70 is positioned inline with and connected to the second compression member 134 of the mechanically activated pump 130. As shown in a simplified manner, the electrically activated pump 70 is essentially the same as that shown in the first example pump system 6 and operates in the same way. The housing 72 of the electrically activated pump 70 includes passages 80 therethrough that are aligned with the mounting apertures 152 in the second compression member 134 and together receive fasteners (not shown) that provide mechanical connection of the mechanically activated pump 130 and electrically activated pump 70 to a suitable mounting flange (not shown) at the lower end 20, 20′ of a socket 4, 4′.

As may be best appreciated in FIG. 2F, the electrical components of the electrically activated pump 70 are shown in a simple layout, and it will be appreciated that the components may be configured and connected in a manner similar to that discussed above with respect to the first example pump system 6. The pump system 106 also may utilize similar user interfaces, operations and methods of use to those described above with respect to the schematic diagrams provided for the first example pump system 6.

Turning to FIGS. 3A-3E, a third example pump system 206 is disclosed for use in a prosthetic device, such as the prosthetic devices 2, 2′. The pump system 206 is somewhat similar to the second example pump system 106, but varies in the mechanically activated pump 230 that replaces the mechanically activated pump 130. However, the third example pump system 206 also includes at least a mechanically activated pump 230, and is equipped with an electrically activated pump 70 that is similar to that used in the first example pump system 6. The mechanically activated pump 230 and electrically activated pump 70 are connected within a fluid circuit that is similar to the fluid circuit 90 and is connected to and adapted to evacuate air from the socket 4, 4′, thereby forming a particularly advantageous hybrid pump system 206. The evacuation of air from the socket 4, 4′, provides vacuum engagement between the prosthetic device 2, 2′ and a respective transfemoral or transtibial residual limb.

The hybrid pump system 206 similarly provides a compact, low profile, inline structure, where the mechanically activated pump 230 includes a first compression member 232 coupled to a second compression member 234, which preferably are constructed of materials similar to those mentioned with respect to the first example pump system 6. A compressible bladder 236 is disposed between the first and second compression members 232, 234.

The first compression member 232 includes a generally planar central body 238 having a central recess (not shown), spaced apart mounting apertures 242, and an extension 244 that is generally perpendicular to the central body 238 and has a pair of parallel bores 246 extending therethrough. The second compression member 234 includes a generally planar central body 248 having a central aperture 250, spaced apart mounting apertures 252, and an extension 254 that is generally perpendicular to the central body 248 and has a pair of parallel bores 256 extending therethrough. The respective pairs of parallel bores 246, 256 are parallel to each other and each bore is aligned with a further bore 255 through an end of a respective parallel upper or lower link 257. Pairs of pivot pins 258 are received by the respective pairs of bores 246, 256 in the first and second compression members 232, 234, and are pivotally connected to the bores 255 at the ends of the links 257.

The parallel links 257 permit the first and second compression members 232, 234 to be pivotally coupled to each other, but form a four bar linkage that also causes the first compression member 232 to translate toward and away from the second compression member 234, while maintaining a relative parallel orientation of the generally planar central bodies 238, 248. This compact, low profile configuration presents a further alternative that may utilize the same shorter height, yet higher capacity compressible bladder 136 that is used in the second example pump system 106. Accordingly, the compressible bladder 136 is disposed between the first and second compression members 232, 234, and utilizes an optional spring assembly 160 that extends through a central opening 176 in the compressible bladder 136 and assists in biasing the

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

respective central bodies 238, 248 toward a spaced apart position. It will be appreciated that the coupling elements include the extensions 244, 254, the pivot pins 258 and the links 257.

The compressible bladder 136 may be particularly effective, while being of relatively short height because it has nearly continuous generally planar upper and lower surfaces 136′, 136″, which are connected to a radially bulging outer sidewall 136‴ that defines an outer perimeter of the compressible bladder 136. In this configuration, as with the prior examples, the coupling elements are disposed generally outside of or about the outer perimeter of the compressible bladder 136. This permits much greater capacity within a given overall diameter, when compared to a compressible bladder having an enlarged passage through the center to accommodate a tubular pylon-like telescopic structure. The compressible bladder 136 generally is elastomeric and may be constructed of materials similar to those mentioned above with respect to the first example pump system 6. The first and second compression members 232, 234 and compressible bladder 136 utilize a fluid circuit that is the same as the fluid circuit 190 in the second example pump system to evacuate air from the socket 4, 4′.

While the compressible bladder 136 may be constructed of one or more materials and in a manner that will tend to expand to a non-compressed state, thereby separating the first and second compression members 232, 234, the optional spring assembly 160 is intended to ensure rebound and expansion of the compressible bladder 136 during repeated hinged compression movements that occur during walking or isolated bouncing-type movements. Also, it will be appreciated that many configurations of compression members, compressible bladders and coupling elements may be utilized to couple a first compressible member to a second compressible member, and optional spring assemblies may include alternative spring forms, such as are mentioned above with respect to the first example pump system 6.

In the third example, the electrically activated pump 70 is positioned inline with and connected to the second compression member 234 of the mechanically activated pump 230. As shown in a simplified manner, the electrically activated pump 70 is essentially the same as that shown in the first and second example pump systems 6, 106 and operates in the same way. The housing 72 of the electrically activated pump 70 includes passages 80 therethrough that are aligned with the mounting apertures 252 in the second compression member 234 and together receive fasteners (not shown) that provide mechanical connection of the mechanically activated pump 230 and electrically activated pump 70 to a suitable mounting flange (not shown) at the lower end 20, 20′ of a socket 4, 4′.

A simple schematic representation of the layout of the electrical components of the electrically activated pump 70 was previously provided with respect to the first example pump system 6, but is included again for convenience in FIG. 3E. Accordingly, it will be appreciated that the components of the third example pump system 206 may be configured and connected in a manner similar to that discussed above with respect to the first example pump system 6. The pump system 206 also may utilize similar user interfaces, operations and methods of use to those described above with respect to the schematic diagrams provided for the first example pump system 6. It further will be appreciated that the linkage and first and second compression members 232, 234 that provide parallel relative displacement, with a compressible bladder 136 therebetween, may achieve advantages over pumps utilized in other contexts and configurations.

Turning to FIGS. 4A-4H, a fourth example is provided, with the example initially including only a mechanically activated pump in FIGS. 4A-4G, and then in FIG. 4H showing further coupling to and inclusion of an electrically activated pump to form a modular, hybrid pump system.

FIG. 4A shows a simplified side view of a prosthetic device or limb 302 in the form of a prosthetic limb for a transfemoral amputee. The prosthetic device 302 generally includes a socket 4, a fourth example pump system 306, a knee joint 8, a pylon 10 and a prosthetic foot 12. The socket 4 has an upper end 18 that is open and is adapted to receive a transfemoral residual limb, with a lower end 20 that includes a port (not shown) in fluid communication with the pump system 306. It will be appreciated that aside from the pump system 306, the other components of the prosthetic limb 302 are the same as those of the previously described prosthetic limb 2.

FIG. 4B incorporates in a prosthetic device 302′ the same components as shown in the simplified side view of a prosthetic device or limb 2′, in the form of a prosthetic limb for a transtibial amputee. The prosthetic device 302′ generally includes a socket 4′, the fourth example pump system 306, a pylon 10′ and a prosthetic foot 12. The socket 4′ has an upper end 18′ that is open and is adapted to receive a transtibial residual limb, with a lower end 20′ that includes a port (not shown) in fluid communication with the pump system 306.

The disclosure provided previously relating to the sockets 4, 4′ and other components of prosthetic devices apply to and will not be repeated for this fourth example. Thus, though not shown in the simplified drawings, it will be understood that the prosthetic devices 302, 302′ would include mounting flanges or other hardware to accommodate mounting of the pump system 306 to the socket 4, 4′ and to the upper end of the knee joint 8 or pylon 10′. Nevertheless, the fourth example prosthetic devices 302, 302′ also embody low profile, inline structures with a pump system 306 that may be incorporated into a reduced package height, as discussed with the other examples. This would permit fluid connection of the pump system 306 to the lower end 20, 20′ of the socket 4, 4′, and may eliminate the need for external tubing, having the advantages of such previously noted with respect the first example.

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

A fourth example pump system 306 may be seen in various views within FIGS. 4C-4H and includes at least a mechanically activated pump 330. As shown in FIG. 4H, the fourth example also may include an electrically activated pump 370. The mechanically activated pump 330 and electrically activated pump 370 may be connected within a fluid circuit 390, a portion of which is shown, but which is connected to and adapted to evacuate air from the socket 4, 4′ in a similar manner to that shown in the first example, thereby forming a particularly advantageous modular, hybrid pump system. The evacuation of air from the socket 4, 4′, provides vacuum engagement between the prosthetic device 2, 2′ and a respective transfemoral or transtibial residual limb. It also will be appreciated that with a pump system that includes a mechanically activated pump 330, the pump system alternatively could be configured for periodic use with a separate hand operated pump to establish initial air evacuation.

The hybrid pump system of this fourth example provides a compact, low profile, inline structure, and takes advantage of space provided at the front of the knee. As may be seen in FIGS. 4C-4H, the mechanically activated pump 330 of the fourth example pump system 306 includes a first compression member 332 coupled to a second compression member 334, with the compressible bladder 36 of the first example being disposed therebetween. The first and second compression members 332, 334 preferably are constructed of relatively light weight, generally rigid materials, such as discussed with respect to the first example.

The first compression member 332 includes a generally planar central body 338 having a central recess (not shown), spaced apart mounting apertures 342, and extensions 344 having bores 345 therethrough and being generally perpendicular to the central body 338. The second compression member 334 includes a generally planar central body 348 having a central aperture 350, spaced apart mounting apertures 352, and an extension in the form of a flange 354 that extends upward and forward from the central body 348. The first compression member 332 is coupled to the second compression member 334 via coupling elements that include four respective fastener pins 356 that may be connected to the second compressible member 334 at apertures 358, such as by press fit or other suitable means of connection, and that slide within the bores 345 of the extensions 344 of the first compression member 332. This coupling configuration provides for translation of the second compression member 334 relative to the first compression member 332. While the coupling elements may be of a different configuration and size, the mechanically activated pump 330 should provide sufficient structural integrity and stability to maintain a consistent and predictable gait and resistance to torsional inputs, such as a twisting motion after planting a step. Optional springs 360 may be placed around the extensions 344 and extend between and first and second compression members 332, 334, tending to bias them toward a spaced apart position. Use of the springs 360 may assist in providing consistent operation and feedback to the user.

The compressible bladder 36 and its associated valving may be particularly effective in this example, as well, in light of the relatively short height, and nearly continuous generally planar upper and lower surfaces that are connected to the radially bulging outer sidewall 36‴. As with the prior examples, the outer sidewall defines an outer perimeter of the compressible bladder 36 and such a configuration for a compressible bladder 36 may permit greater capacity and potential efficiency, within a given overall diameter, when compared to a compressible bladder having an enlarged passage through the center to accommodate a tubular pylon-like telescopic structure. This fourth example similarly has all of the coupling elements disposed about an outer perimeter that is defined by the sidewall 36‴ of the compressible bladder 36, such that the coupling elements are at or beyond the outer perimeter of the compressible bladder 36. This permits a shorter pump height and location of the pump system 306 above the knee in a transfemoral configuration, which in turn, may permit a relatively large overall diameter and capacity for the compressible bladder.

As noted previously, the compressible bladder 36 may be constructed of one or more materials and in a manner that will tend to expand or return to its original non-compressed state, thereby separating the first and second compression members 332, 334. However, the optional springs 360 are intended to ensure rebound and expansion of the compressible bladder 36 during repeated telescopic compression movements that occur during walking or isolated bouncing-type movements. Also, as previously noted, it will be appreciated that many configurations of compression members, compressible bladders and coupling elements may be utilized to couple a first compressible member to a second compressible member, and optional spring assemblies may include alternative spring forms, including for example, a leaf spring, or coiled torsion springs having opposed arms and being positions to bias the first and second compression members 332, 334 to a spaced apart position. Given the number of coupling elements and their spaced arrangement, it is believed that a central, relatively long and large tubular telescopic assembly need not be required, and that the shorter, thinner fastener pins 356 sliding within the bores 345 of the extensions 344 will provide for proper alignment and smooth translational movement.

The first and second compression members 332, 334 and compressible bladder 36 utilize a fluid circuit that would be comparable to those previously described to evacuate air from the socket 4, 4′ of the prosthetic devices 302, 302′. As noted, the compressible bladder 36 includes an intake valve, and it is able to communicate through an aperture 350 in the second compression member 334, and an output valve is vented to the atmosphere to expel air that has been evacuated from the socket 4, 4′ by the pump system 306.

In the fourth example, the electrically activated pump 370 is positioned essentially above and forward of the knee joint 8 or

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

As may be seen in a simplified manner in FIG. 4H, the electrically activated pump 370 includes a housing 372 having an inlet valve 374 in communication with the central aperture 350 of the second compression member 334 for fluid connection to the socket 4, 4′, and an output valve (not shown) that is vented to the atmosphere to expel air that has been evacuated from the socket 4, 4′ by the pump system 306. The housing 372 also includes mounting bores 378 that receive fasteners (not shown) through passages 380 in the central body 348 of the second compression member 334 to connect the electrically activated pump 370 to the mechanically activated pump 330. It will be appreciated that the electrically activated pump may be equipped with alternative valving and operative features, as desired. Also, the housing of the electrically activated pump could be configured to be connected to the mechanically activated pump in an alternative manner, such as for example, in the stacked arrangement shown in the first three examples, just as any of those examples could have utilized a side mounting of their respective electrically activated pumps, such as in the manner shown with the fourth example or in an alternative configuration that places the electrically activated pump outside of the outer perimeter of the compressible bladder. It also will be appreciated that an additional reduction in height may be achieved if the circuitry is positioned along the outer perimeter of the first and/or second compression member.

As may be appreciated in FIG. 4H, the electrical components of the electrically activated pump 370 are shown in a simple layout and it will be understood that they have similar basic functions and connection configurations those described for the first example pump system 6 and which also would apply to the other examples. It will be appreciated that the components may be configured and connected in fluid communication by conventional means, such as by suitable tubing, and/or may be configured and connected electrically by conventional means, such as by suitable wires, leads or other circuitry, so as to meet the needs and satisfy the design specifications and constraints within of a particular implementation. In this fourth example, within the housing 372 of the electrically activated pump 370 is a microcontroller M′ that includes a circuit board and is connected to a motorized pump MP′, a pressure sensor PS′, and a battery BAT′. A user interface A′, in the form of an on/of button, is located along the top of the flange 354 and is connected to the microcontroller M′. An optional serial data port D′ may be utilized to interact with the microcontroller M′, such as to track and record the operating conditions of the pump system 306, for diagnostic and historical monitoring purposes.

As described with respect to the first example and would apply to the other examples, a further user interface, such as in the form of a wireless remote control device or other devices may be utilized, as previously described. In addition, the battery BAT′ may be similar to that which was described previously for the other examples.

It will be appreciated that, with inclusion of an electrically activated pump 370, the pump system 306 may present a hybrid, modular system that can be utilized in a number of ways to evacuate air from a socket 4, 4′. Schematics provided for the first example, as well as the associated description, may be referred to and similarly apply to the means of operation and methods of use of the fourth example pump system 306 to establish and maintain an evacuated chamber in the socket 4, 4′ of a prosthetic device 302, 302′, whether the mechanically activated pump 330 is used alone, or is paired with the electrically activated pump 370 to provide a hybrid pump system.

It will be appreciated that a pump system for use in suspension of a prosthetic device from a residual limb in accordance with the present disclosure may be provided in various configurations. Any variety of suitable materials of construction, configurations, shapes and sizes for the components and methods of connecting the components may be utilized to meet the particular needs and requirements of an end user. It will be apparent to those skilled in the art that various modifications can be made in the design and construction of such pump systems without departing from the scope or spirit of the claimed subject matter, and that the claims are not limited to the preferred embodiments illustrated herein.

PATENT CITATIONS

Cited Patent	Filing date	Publication date	Applicant	Title
US4161042	Oct 25, 1977	Jul 17, 1979	Bhn, Inc.	Adjustable prosthetic limb
US5724714	May 10, 1994	Mar 10, 1998	Love; Michael G.	Prosthetic socket containing inflatable means
US5931872	Mar 16, 1998	Aug 3, 1999	Lohmann; Klaus H.	Prosthetic sock for reducing movement between residual limb and prosthesis and method for use
US6761742	Jan 29, 2002	Jul 13, 2004	Otto Bock Healthcare Lp	Vacuum pump and shock absorber for artificial limb
US7025792	Oct 25, 2004	Apr 11, 2006	Collier Milo S	Vacuum-assisted prosthetic device
US7744653	Apr 22, 2005	Jun 29, 2010	Otto Bock Healthcare Lp	Vacuum pump with shock absorption and controlled rotation for prosthetic devices
US7947085 *	Jun 12, 2006	May 24, 2011	The Ohio Willow Wood Company	Prosthetic device utilizing electric vacuum pump
US8007543	Sep 11, 2007	Aug 30, 2011	OrthoCare Innovations, Inc.	Vacuum attachment system
US8308816 *	Jul 22, 2010	Nov 13, 2012	Prosthetic Design, Inc.	Sealing liner and lock for prosthetic limb
US20020099450	Apr 24, 2001	Jul 25, 2002	Dean Robert C.	Dynamic variable geometry fitting system for use with a body appliance

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

Cited Patent	Filing date	Publication date	Applicant	Title
US20050278039	Jun 8, 2005	Dec 15, 2005	Nobbe Ralph W	Composite limb guard
US20070055383	Sep 8, 2006	Mar 8, 2007	Charles King	Vacuum assisted heat/perspiration removal system and limb volume management for prosthetic device
US20070112439	Nov 17, 2005	May 17, 2007	Panucialman Peter V	Power evacuation valve for prosthetic limb socket
US20070213839	Mar 20, 2007	Sep 13, 2007	Thure Nachbar	Artificial limb assembly having microprocessor-controlled vacuum pump
US20080221706	Sep 26, 2007	Sep 11, 2008	Scussel S.B.J. Systems, Llc	Vacuum assisted prosthetic sleeve and socket utilizing a double membrane liner
US20080269911	Apr 22, 2008	Oct 30, 2008	Otto Bock Healthcare Lp	Pneumatic connections for prosthetic socket
US20090036998 *	Aug 1, 2008	Feb 5, 2009	Otto Bock Healthcare Lp	Vacuum pump
US20090192619	Nov 21, 2008	Jul 30, 2009	Orthocare Innovations Llc	Passive electro-magnetically damped joint
US20090222105	Mar 23, 2009	Sep 3, 2009	Ossur Hf.	Transfemoral prosthetic systems and methods for operating the same
US20100312360	Sep 21, 2009	Dec 9, 2010	Caspers Carl A	Dynamically-activated variable response socket with hydraulic pump
US20110046748	Nov 1, 2010	Feb 24, 2011	Orthocare Innovations, Llc	Pump system for prosthesis
US20110060421	Nov 10, 2010	Mar 10, 2011	James Jay Martin	Control system for prosthesis
US20110224802	May 18, 2011	Sep 15, 2011	OttoBock HealthCare LP	Shock absorbing apparatus and method
US20120123559 *	Nov 15, 2011	May 17, 2012	Otto Bock Healthcare Gmbh	Pump comprising a moving wall and use of a pump of this type

* Cited by examiner

NON-PATENT CITATIONS

Reference	
1	International Search Report for PCT/US2012/043685 dated Sep. 21, 2012.
2	Written Opinion of the International Searching Authority for PCT/US2012/043685 dated Sep. 21, 2012.

REFERENCED BY

Citing Patent	Filing date	Publication date	Applicant	Title
US9364348	Feb 28, 2014	Jun 14, 2016	Ossur Hf	Vacuum suspension system
US9486335	Apr 30, 2015	Nov 8, 2016	Ossur Hf	Prosthetic device, system and method for increasing vacuum attachment

CLASSIFICATIONS

U.S. Classification	1/1
International Classification	A61F2/70, A61F2/80, A61F2/76, A61F2/50, A61F2/68, A61F2/60, A61F2/74
Cooperative Classification	A61F2/60, A61F2002/747, A61F2002/607, A61F2/70, A61F2002/5073, A61F2/80, A61F2002/608, A61F2002/741, A61F2/68, A61F2002/501, A61F2002/7655, A61F2002/689, A61F2002/704, A61F2002/742, A61F2002/6809, A61F2002/802

LEGAL EVENTS

Date	Code	Event	Description
Jun 26, 2013	AS	Assignment	Owner name: US ARMY, SECRETARY OF THE ARMY, MARYLAND Free format text: CONFIRMATORY LICENSE;ASSIGNOR:NORTHWESTERN UNIVERSITY;REEL/FRAME:030687/0310 Effective date: 20130111
Jun 12, 2015	AS	Assignment	Owner name: U.S. DEPARTMENT OF VETERANS AFFAIRS, DISTRICT OF C Free format text: ASSIGNMENT OF ASSIGNORS INTEREST;ASSIGNORS:HANSEN, ANDREW H.;NICKEL, ERIC A.;REEL/FRAME:035827/0843 Effective date: 20131031 Owner name: NORTHWESTERN UNIVERSITY, ILLINOIS Free format text: ASSIGNMENT OF ASSIGNORS INTEREST;ASSIGNORS:NELSON, ANDREW J.;KUHAR, BENNETT E.;RADCLIFFE, REGAN A.;AND OTHERS;SIGNING DATES FROM 20130702 TO 20130831;REEL/FRAME:035895/0816
Jul 1, 2015	SULP	Surcharge for late payment	
		Certificate	

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

Google Home - Sitemap - USPTO Bulk Downloads - Privacy Policy - Terms of Service - About Google Patents - Send Feedback
Data provided by IFI CLAIMS Patent Services

Try the new Google Patents, with machine-classified Google Scholar results, and Japanese and South Korean patents.

APPENDIX T – MANUSCRIPT PUBLISHED IN JOURNAL OF MEDICAL DEVICES

Evaluation of a Prototype Hybrid Vacuum Pump to Provide Vacuum-Assisted Suspension for Above-Knee Prostheses

Matthew J. Major
Jesse Brown VA Medical Center,
Northwestern University Prosthetics-Orthotics Center,
680 North Lake Shore Drive, Suite 1100,
Chicago, IL 60611
e-mail: matthew-major@northwestern.edu

Ryan Caldwell
Scheck and Siress Orthotics and Prosthetics,
Northwestern University Prosthetics-Orthotics Center,
680 North Lake Shore Drive, Suite 1100,
Chicago, IL 60611
e-mail: ryan.caldwell@northwestern.edu

Stefania Fatone
Northwestern University Prosthetics-Orthotics Center,
680 North Lake Shore Drive, Suite 1100,
Chicago, IL 60611
e-mail: s-fatone@northwestern.edu

Vacuum-assisted suspension (VAS) of prosthetic sockets utilizes a pump to evacuate air from between the prosthetic liner and socket, and are available as mechanical or electric systems. This technical note describes a hybrid pump that benefits from the advantages of mechanical and electric systems, and evaluates a prototype as proof-of-concept. Cyclical bench testing of the hybrid pump mechanical system was performed using a materials testing system to assess the relationship between compression cycles and vacuum pressure. Phase 1 in vivo testing of the hybrid pump was performed by an able-bodied individual using prosthesis simulator boots walking on a treadmill, and phase 2 involved an above-knee prosthesis user walking with the hybrid pump and a commercial electric pump for comparison. Bench testing of 300 compression cycles produced a maximum vacuum of 24 in-Hg. In vivo testing demonstrated that the hybrid pump continued to pull vacuum during walking, and as opposed to the commercial electric pump, did not require reactivation of the electric system during phase 2 testing. The novelty of the hybrid pump is that while the electric system provides rapid, initial vacuum suspension, the mechanical system provides continuous air evacuation while walking to maintain suspension without reactivation of the electric system, thereby allowing battery power to be reserved for monitoring vacuum levels. [DOI: 10.1115/1.4030507]

Keywords: prosthesis, vacuum, suspension, socket

Introduction

Prosthetic sockets are secured to the limb by suspension mechanisms of which there are many types, including mechanical (straps, pin locking liners) and suction (liners, one way valves, vacuum pumps) systems. Introduced and adopted in the late 1990's, vacuum pumps used to suspend a socket on the residual limb are referred to as VAS [1]. Pumps create a negative pressure differential relative to atmospheric pressure by evacuating air from between the surface of a liner clad residual limb and the interior of a prosthetic socket [1]. Evidence of the suggested benefits of VAS over suspension techniques such as suction and pin-locking liners have been described as: reducing residual limb volume fluctuations that compromise socket fit [1–4], improving gait symmetry [1], reducing residual limb pistoning [1,5], and facilitating limb healing [3,6–9]. In particular, VAS has been proposed as an effective suspension strategy for short residual limbs [10] and brimless sockets that may enhance user comfort [11,12].

Current pump designs are either mechanical or electrical [13]. The advantage of mechanical pumps is that there is no need to charge or replace batteries, they are less noisy, they are mostly maintenance free and field serviceable if issues arise, and will work continuously as long as the user is walking. Mechanical pumps require multiple steps with the prosthesis to reach the recommended vacuum [14], delaying achievement of optimal suspension and coupling. For example, according to the manufacturer the Otto Bock Harmony® P3 should reach 15 in-Hg within 50 steps. A smaller pump like the Össur Unity™ may take even more time to evacuate the same volume to the same vacuum pressure. Loss of active vacuum when not walking can lead to the need to re-establish vacuum, potentially contributing to trauma of the residual limb soft tissues. Mechanical pumps are infrequently used in transfemoral prostheses possibly because their flow rate is insufficient to rapidly evacuate the relatively larger air space as compared to a transtibial socket. With larger volumes, such as are found in transfemoral sockets or double wall socket designs, establishing the required vacuum level before walking may be even more crucial.

Electric pumps pull and monitor vacuum even while not walking. This allows them to initiate vacuum before walking, ensuring that the residual limb is completely seated in the socket and avoiding suspension issues that contribute to skin problems. For example, clinically, prosthesis users complain that when sitting for a period of time, socket fit is altered and they need to reseat their limb into the socket when they resume standing. Reseating has the tendency to allow the liner to move away from the residual limb creating a suspension issue that contributes to skin abrasion. The ability to maintain vacuum and a correct position within the socket at all times is particularly critical for users that have sensitive skin, significant bony prominences or open sores. The disadvantages of electric pumps are that they are noisy, need charging, and are not easily field serviced.

A hybrid vacuum pump that incorporates both an electric and mechanical pump is proposed as a modular prosthetic component to generate VAS of transfemoral prosthetic sockets irrespective of the state of the user while maximizing battery life and minimizing noise. It would act such that the electric pump operates initially to rapidly draw a threshold vacuum with the mechanical pump maintaining that vacuum during prosthesis use when air slowly leaks back into the interface. Importantly, during daily activity the electric pump ensures that vacuum suspension is maintained during stationary periods (e.g., standing and sitting) and the mechanical pump maintains suspension during ambulation (e.g., walking and transfers). This technical note describes the design of a hybrid vacuum pump and demonstrates operational feasibility.

Materials and Methods

Hybrid Pump Design. A prototype hybrid prosthetic pump, dubbed the Northwestern University Hybrid Integrated Prosthetic Pump Initiative (HIPPI) was fabricated (Fig. 1), including a rubber bladder to act as the mechanical pump system, electronics for the electric pump system, and housing that was built from polycarbonate–acrylonitrile-butadiene-styrene (PC-ABS) plastic using an additive manufacturing (fused deposition modeling) 3D printer (Stratasys, Eden Prairie, MN). Although the PC-ABS housing is porous, the sealed bladder of the mechanical system is attached to the volume of interest via tubing and does not require

Manuscript received January 13, 2015; final manuscript received April 3, 2015; published online August 6, 2015. Assoc. Editor: Carl Nelson.

 Copyright © 2015 by ASME

Downloaded From: http://medicaldevices.asmedigitalcollection.asme.org/ on 10/03/2015 Terms of Use: http://www.asme.org/about-asme/terms-of-use

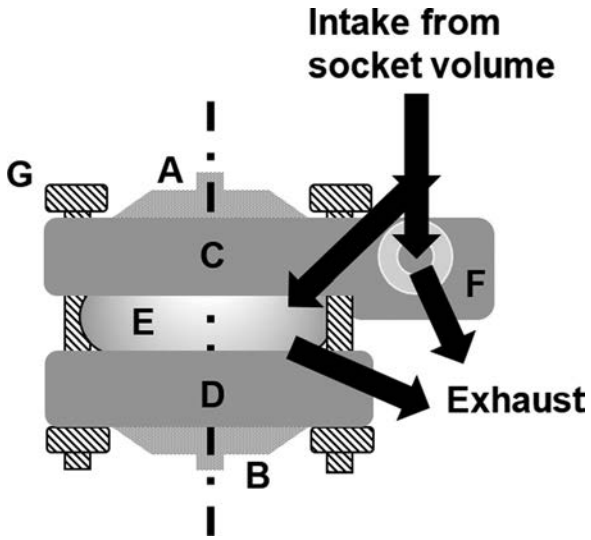


Fig. 1 Schematic of the hybrid pump design. Constituent parts include: (*a*) proximal female pyramid adapter, (*b*) distal male pyramid adapter, (*c*) proximal housing plate, (*d*) distal housing plate, (*e*) bladder pump (mechanical system), (*f*) electric pump (electric system), and (*g*) threaded posts (×4). The threaded posts act as guide rails during cyclical compression and extension of the bladder. The solid arrows indicate air flow from the socket volume during operation.

the housing to be airtight but only act as compression plates. The mechanical and electric pump systems attach to the desired evacuation volume through a parallel connection and a system of one-way valves. The mechanical system pulls air from the evacuation volume as the bladder expands, and forces this air through an exhaust as the bladder compresses during load-bearing. The electric system pulls air from the evacuation volume through a pump that is activated by a DC motor and can be programmed to reach an upper vacuum pressure threshold when activated and reactivate when a defined lower threshold is reached. Pyramid adapters (Otto Bock, Duderstadt, Germany) were fixed to the proximal and distal ends of the pump housing to allow for integration within a modular prosthetic system. The concept of the hybrid pump is that prior to walking the electric system would rapidly evacuate air to create a desired vacuum pressure for socket suspension, and during walking when leakage of the vacuum is likely to occur, the mechanical system is continuously engaged to maintain a sufficient level of vacuum pressure. A patent has been granted on the hybrid pump design [15].

Bench Testing Protocol. Prior to in vivo testing, bench testing of the hybrid pump was performed using a materials testing system (Model 8800, Instron, Norwood, MA). The protocol for bench characterization was modeled upon a previously established protocol [13]. The pump was secured in the testing machine, preloaded to 20 N, and underwent 300 cycles of compression and release at a cyclical loading rate of 23 mm/s with two dwell periods of 0.16 s at minimum and maximum displacement, a simulated cadence of 100 steps/min. The vector of applied load coincided with the longitudinal axis of the pump and was measured with an integrated uniaxial load-cell. The compression displacement was 10 mm, which represented effective bottoming out and full compression of the bladder. The pump was attached to a sealed canister of 6.36 $in.^3$ volume to simulate the average evacuation volume to create VAS in a transfemoral prosthetic socket [13]. A digital vacuum pressure gauge (model 2L760, DigiVac; Matawan, NJ) measured the real-time pressure level in the sealed canister. Bench testing was performed three times to estimate the average time and number of "steps" required to achieve a vacuum pressure of 17 in-Hg, a common vacuum pressure for socket suspension as recommended by vacuum pump manufacturers



Fig. 2 Walking simulator boots. Prosthetic components attach distal to the foot plate and mimic transtibial prosthesis use.

[13], as well as the initial linear rate of pressure creation as approximated by a linear best fit and the maximum force attained during cyclical testing.

In Vivo Phase 1: Walking Simulator. The first phase of in vivo testing involved a single participant (35 yrs, 185 cm, 78 kg) walking on a treadmill with walking simulator boots (Fig. 2) and the hybrid pump installed between the plantar surface of the right leg boot and a prosthetic foot. A prosthetic foot and pylon were attached to the left leg boot and adjusted to eliminate leg length discrepancy. Athletic trainer shoes were donned on each foot to improve plantar surface friction with the treadmill belt. The pump was attached to the same sealed canister as used during bench testing and the digital vacuum pressure gauge was used to measure real-time pressure in the canister. Prior to walking, the electric system was used to create vacuum in the canister and, when the pressure reached approximately 17 in-Hg, the subject walked for 10 minutes at a speed of 0.53 m/s (a speed that was considered comfortable and safe by the participant). This in vivo testing was used to determine if the prototype would sustain the loads encountered during operation and if the mechanical system would continue to create vacuum during walking when under operational loads. Real-time pressure level in the sealed canister was collected during testing as measured by the digital vacuum pressure gauge (DigiVac).

In Vivo Phase 2: Transfemoral Prosthesis User. The second phase of in vivo testing involved a unilateral transfemoral prosthesis user (54 yrs, 183 cm, 97.5 kg, left side amputation due to trauma) walking on a treadmill under two conditions:

(1) the original prosthetic setup consisting of a KX06 knee (Endolite, Miamisburg, OH), highlander foot (Freedom Innovations, Irvine, CA), subischial socket with a Relax 3 C liner (Medi, Whitsett, NC), and the LimbLogic electric pump (Ohio WillowWood, Mt. Sterling, OH), and
(2) the original socket integrated with a 3R60 knee (Otto Bock, Duderstadt, Germany), solid ankle cushioned heel foot (Kingsley Mfg. Co., Costa Mesa, CA) and the hybrid pump installed between the distal end of the socket and the knee joint (Fig. 3).

For both pump units, the electric system was programmed to create a maximum vacuum setting of approximately 17 in-Hg and the minimum allowable vacuum before reactivation was set at

Downloaded From: http://medicaldevices.asmedigitalcollection.asme.org/ on 10/03/2015 Terms of Use: http://www.asme.org/about-asme/terms-of-use

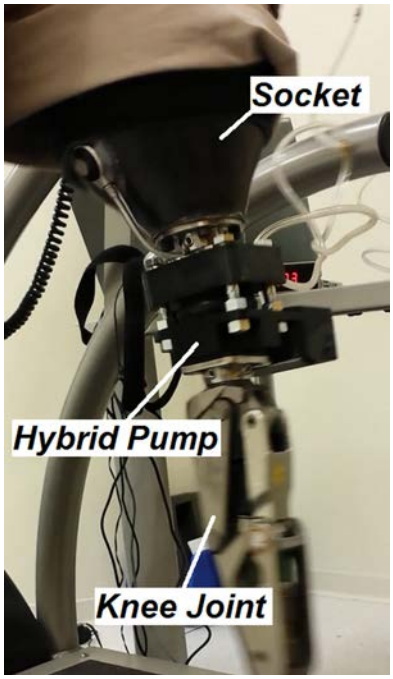


Fig. 3 Location of the hybrid vacuum pump for use within a transfemoral prosthesis. Pyramid adaptors fixed to proximal and distal ends of the pump housing were used for installation of the pump between the socket and knee joint, respectively.

13 in-Hg. Prior to walking, the electric system was used to create vacuum in the socket for suspension and when the pressure reached approximately 17 in-Hg, the subject walked for 10 min at a speed of 0.53 m/s (a speed that was considered comfortable and safe by the participant). This in vivo testing was used to determine if the prototype would sustain the loads encountered during operation in a transfemoral prosthesis when installed proximal to the knee joint, if the mechanical system would continue to create vacuum during walking when under operational loads, the time required to obtain 17 in-Hg vacuum pressure through the electric system, and the number of times the electric system reactivated due to the lower vacuum threshold being met. Real-time pressure level in the prosthetic socket was collected during testing as measured by the digital vacuum pressure gauge (DigiVac).

Ethical approval was obtained from the University Institutional Review Board and participants provided informed consent prior to in vivo data collection.

Results

An example of the bench testing results is presented in Fig. 4(*a*). The average maximum vacuum pressure was 24 in-Hg achieved after 112 cycles. On average, the desired vacuum pressure of 17 in-Hg was achieved after 13 cycles and the linear rate of evacuation was approximately 1.1 in-Hg/cycle. The average maximum force achieved during cyclical testing was 720 N.

Results from the walking simulator (phase 1) and transfemoral prosthesis user (phase 2) are presented in Figs. 4(*b*) and 4(*c*), respectively. The prototype sustained the loads applied during both in vivo testing scenarios. Testing with the walking simulator demonstrated that the electric system created an initial vacuum, while subsequent walking continued to increase vacuum pressure through activation of the mechanical system. During phase 2 testing, the commercial electric pump and hybrid pump achieved a maximum vacuum pressure of 18 in-Hg and 23 in-Hg, respectively. Using the electric system, the commercial pump and hybrid pump both achieved 17 in-Hg in approximately the same amount of time: 14 s. While the commercial pump was required to reactivate twice during the 10 min walk session, the additional vacuum

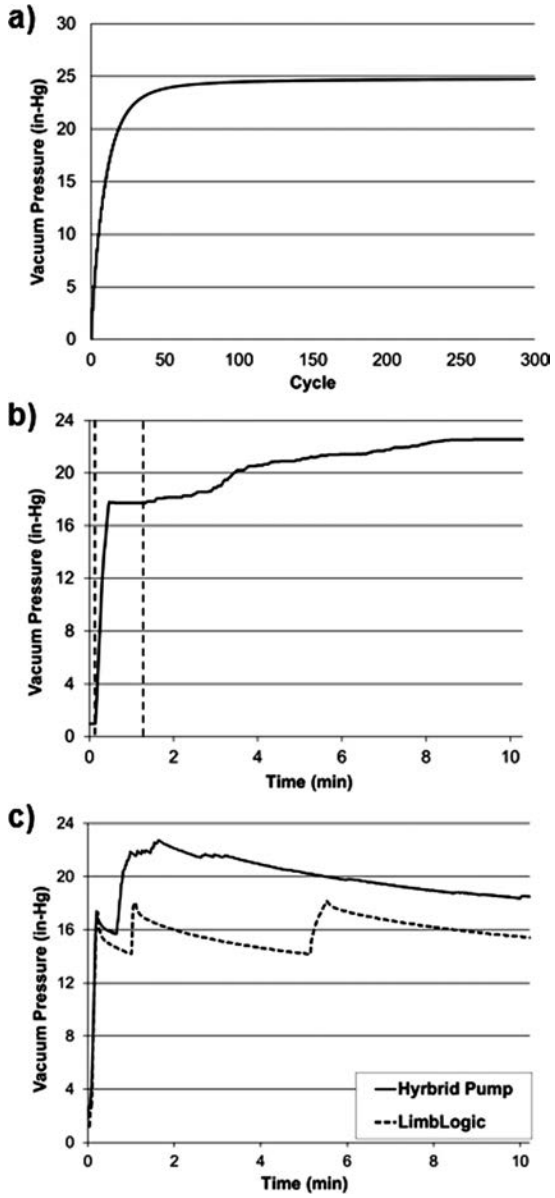


Fig. 4 Results from (*a*) bench testing, (*b*) in vivo walking with simulator boots (the first and second dashed vertical lines represent the initiation of the electric system and walking, respectively), and (*c*) in vivo walking of a transfemoral prosthesis user with a commercial electric pump (Ohio WillowWood LimbLogic) and the hybrid pump

created by the mechanical system during the initial portion of walking prevented the hybrid's electric pump from reactivating. Although vacuum was created and sustained by the mechanical system during the start of walking, this function appeared to be less effective as walking progressed and the hybrid pump demonstrated similar leakage to that of the commercial unit.

Discussion

This study described the proof-of-concept testing of a hybrid pump unit to be integrated with a transfemoral prosthesis for the purpose of VAS. Bench testing indicated that by solely using the mechanical pump system only 13 cycles (or steps) would be necessary to achieve the desired vacuum pressure of 17 in-Hg when maximum compression (10 mm) of the bladder occurs resulting from 720 N of force (approximately 92% of body weight for an 80 kg user) applied along the longitudinal axis of the unit. When the hybrid pump is installed within walking boots to simulate

Downloaded From: http://medicaldevices.asmedigitalcollection.asme.org/ on 10/03/2015 Terms of Use: http://www.asme.org/about-asme/terms-of-use

integration with a transtibial prosthesis, the hybrid pump behaved as expected. The electric system initially created vacuum and walking continued to increase the vacuum pressure due to cyclical activation of the mechanical system. Importantly, the pump sustained the moments and loads applied during this form of testing, and the effectiveness of the mechanical system was not compromised during operation.

Results from in vivo testing with a transfemoral prosthesis user demonstrated promise for the utility of the hybrid pump. As expected, the hybrid pump was capable of achieving the desired level of vacuum similar to a commercial electric pump, and due to the creation of additional vacuum through activation of the mechanical system, prevented the electric system from reactivating. Reduced dependence on the electric system will save battery power and therefore reduce the frequency of battery charging. However, although the mechanical system created vacuum initially, this system became less effective as walking continued beyond approximately 1.5 min. One possible reason for this diminished function is a subtle modification in the participant's gait, which may have placed the hybrid pump under moments and loads not encountered during bench testing and when walking with the simulator boots. The use of a four-post system to guide the housing plates during bladder compression created a rocking motion (asymmetric compression) that restricted the bladder from achieving full compression and hence compromised its function. This issue will be addressed in subsequent design iterations to eliminate asymmetric compression during operation in a transfemoral prosthesis. Further evaluation of design iterations will also characterize the passive physical properties (i.e., stiffness and damping) of the hybrid pump and observe the effects of these properties on user performance [16,17] for design optimization.

Overall, this testing demonstrated the utility of a hybrid pump design, specifically for those users who may experience excessive time to create sufficient vacuum pressure for suspension when using only a mechanical pump due to their light weight (e.g., elderly), or who desire immediate use of their prosthesis postdonning (e.g., individuals who engage in sporting activity or the military). The use of a hybrid pump will quickly achieve the desired vacuum pressure such that the user may immediately begin walking with their device and this walking will sustain vacuum pressure due to continuous activation of the mechanical system. Importantly, as the mechanical system sustains adequate levels of vacuum pressure, this decelerates drainage of the battery in which power is only used to monitor vacuum pressure level and not for reactivating the electric system, which uses proportionally larger amounts of energy. Additionally, we have the ability to set the electric system to activate only when there is a critical loss of vacuum, further reducing battery demand. The pumps can also work independently if there is a malfunction with either individual system, creating a nice fail-safe. Although the hybrid pump appears to operate well for integration with a transtibial prosthesis, subsequent design iterations and testing will focus on improving its functional reliability for transfemoral prosthesis application.

Acknowledgment

The U.S. Army Medical Research and Materiel Command Acquisition Activity, 820 Chandler 10 Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office (Award No. W81XWH-10-1-0744). The content of this presentation does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred. The authors would like to thank Sean Wood for writing the program used to collect data, William Brett Johnson and Oluseeni Komolafe for their assistance with data collection, and Brian Robillard for his assistance with computer drafting and fabrication of the prototype.

References

[1] Board, W. J., Street, G. M., and Caspers, C., 2001, "A Comparison of Trans-Tibial Amputee Suction and Vacuum Socket Conditions," Prosthet. Orthotics Int., **25**(3), pp. 202–209.
[2] Goswami, J., Lynn, R., Street, G., and Harlander, M., 2003, "Walking in a Vacuum-Assisted Socket Shifts the Stump Fluid Balance," Prosthet. Orthotics Int., **27**(2), pp. 107–113.
[3] Gerschutz, M. J., Denune, J. A., Colvin, J. M., and Schober, G., 2010, "Elevated Vacuum Suspension Influence on Lower Limb Amputee's Residual Limb Volume at Different Vacuum Pressure Settings," J. Prosthet. Orthotics, **22**(4), pp. 252–256.
[4] Beil, T. L., Street, G. M., and Covey, S. J., 2002, "Interface Pressures During Ambulation Using Suction and Vacuum-Assisted Prosthetic Sockets," J. Rehabil. Res. Dev., **39**(6), pp. 693–700.
[5] Klute, G. K., Berge, J. S., Biggs, W., Pongnumkul, S., Popovic, Z., and Curless, B., 2011, "Vacuum-Assisted Socket Suspension Compared With Pin Suspension for Lower Extremity Amputees: Effect on Fit, Activity, and Limb Volume," Arch. Phys. Med. Rehabil., **92**(10), pp. 1570–1575.
[6] Hoskins, R. D., Sutton, E. E., Kinor, D., Schaeffer, J. M., and Fatone, S., 2014, "Using Vacuum-Assisted Suspension to Manage Residual Limb Wounds in Persons With Transtibial Amputation: A Case Series," Prosthet. Orthotics Int., **38**(1), pp. 68–74.
[7] Traballesi, M., Averna, T., Delussu, A. S., and Brunelli, S., 2009, "Trans-Tibial Prosthesization in Large Area of Residual Limb Wound: Is it Possible? A Case Report," Disability Rehabil. Assistive Technol., **4**(5), pp. 373–375.
[8] Traballesi, M., Delussu, A. S., Fusco, A., Iosa, M., Averna, T., Pellegrini, R., and Brunelli, S., 2012, "Residual Limb Wounds or Ulcers Heal in Transtibial Amputees Using an Active Suction Socket System. A Randomized Controlled Study," Eur. J. Phys. Rehabil. Med., **48**(4), pp. 613–623.
[9] Arndt, B., Caldwell, R., and Fatone, S., 2011, "Use of a Partial Foot Prosthesis With Vacuum-Assisted Suspension: A Case Study," J. Prosthet. Orthotics, **23**(2), pp. 82–88.
[10] Carvalho, J. A., Mongon, M. D., Belangero, W. D., and Livani, B., 2012, "A Case Series Featuring Extremely Short Below-Knee Stumps," Prosthet. Orthotics Int., **36**(2), pp. 236–238.
[11] Kahle, J. T., and Highsmith, M. J., 2014, "Transfemoral Interfaces With Vacuum Assisted Suspension Comparison of Gait, Balance, and Subjective Analysis: Ischial Containment Versus Brimless," Gait Posture, **40**(2), pp. 315–320.
[12] Kahle, J. T., and Highsmith, M. J., 2013, "Transfemoral Sockets With Vacuum-Assisted Suspension Comparison of Hip Kinematics, Socket Position, Contact Pressure, and Preference: Ischial Containment Versus Brimless," J. Rehabil. Res. Dev., **50**(9), pp. 1241–1252.
[13] Komolafe, O., Wood, S., Caldwell, R., Hansen, A., and Fatone, S., 2013, "Methods for Characterization of Mechanical and Electrical Prosthetic Vacuum Pumps," J. Rehabil. Res. Dev., **50**(8), pp. 1069–1078.
[14] Otto Bock HealthCare, 2009, "Harmony P3 Instructions for Use," Otto Bock HealthCare LP, Duderstadt, Germany.
[15] Caldwell, R. J., Hansen, A. H., Wood, S. M., Chen, W., Radcliffe, R. A., Yngve, K. A., Kuhar, B. E., Nelson, A. J., and Nickel, E., 2012, U.S. Patent No. 13/529,833.
[16] Major, M. J., Twiste, M., Kenney, L. P., and Howard, D., 2011, "Amputee Independent Prosthesis Properties—A New Model for Description and Measurement," J. Biomech., **44**(14), pp. 2572–2575.
[17] Major, M. J., Kenney, L. P., Twiste, M., and Howard, D., 2012, "Stance Phase Mechanical Characterization of Trans-Tibial Prostheses Distal to the Socket: A Review," J. Rehabil. Res. Dev., **49**(6), pp. 815–829.

Downloaded From: http://medicaldevices.asmedigitalcollection.asme.org/ on 10/03/2015 Terms of Use: http://www.asme.org/about-asme/terms-of-use

APPENDIX U – HYBRID PUMP TECH ALERT 2016

Northwestern | INVO

Innovation and New Ventures Office

HYBRID PROSTHETIC VACUUM PUMPS FOR LOWER LIMB AMPUTEES

THE NEED

Persons with amputation prefer prostheses that provide maximum functional restoration and comfort. Overall, a total of ~700,000 amputations happen annually, generating a $1Bn prosthetics market. Vacuum assisted suspension reduces relative motion between the prosthetic socket and residual limb, improving force transfer, function, comfort and soft tissue health. However, current prosthetic vacuum pumps, being either mechanical or electrical, can be noisy, have a tall build height, and/or take time to generate vacuum. There is need for a vacuum pump of low build height that can work quietly, and quickly generate vacuum when desired while conserving battery life throughout the day.

NU INNOVATION OVERVIEW

Northwestern investigators have developed unique prosthetic solutions that include multiple designs of hybrid (mechanical and electrical) vacuum pumps. The mechanical aspect of these designs use either a bladder or a diaphragm to create negative pressure. Both designs have a lower build height than commercially available mechanical pumps, making them suitable for use in-line with sockets, especially in transfemoral (above-knee) prostheses. Working in concert with an electrical pump, both hybrid pump designs offer the quietness of mechanical actuation, with the speed of electrical actuation.

TECHNOLOGY SUMMARY

Various suspension systems have been developed for coupling a prosthetic limb to a residual limb. Our earlier bladder-based hybrid pump design generated a clinically acceptable level of vacuum but was less robust to out-of-plane movements during compression than the subsequent diaphragm-based design. While both designs provide for a lower build height than existing mechanical pumps, the space savings are greater with the diaphragm-based design.

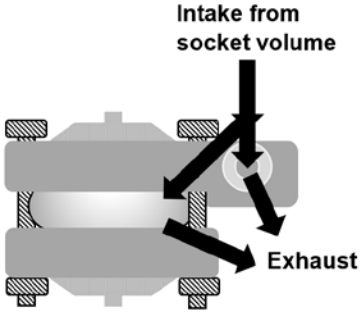
Advantages

- Hybrid function (mechanical and electrical pumps working in concert to provide mostly unobtrusive, quiet operation with minimal need for battery recharging).
- Small build height (can fit between the prosthetic knee and socket in an above-knee prosthesis).
- Diaphragm requires minimal displacement/excursion to function and hence minimizes range-of-motion added to prosthesis.

Applications

- For use by persons with lower-limb amputation as a mechanism to hold the prosthetic socket onto the residual limb.
- Improves upon the size and function of existing prosthetic vacuum pumps.







Figures adopted from Major, Caldwell, Fatone, J Med Devices 2015

STANDARD OF CARE/COMPETITIVE LANDSCAPE

Pumps currently on the market are either mechanical or electrical. No hybrid pump (combining electrical and mechanical) is commercially available. With the exception of the OWW LimbLogic and Otto Bock E2 pumps, no other in-line electrical pump is available for use with transfemoral amputees.

STAGE OF DEVELOPMENT

A prototype has been built and tested (Publication).
A diaphragm prototype has been built and bench tested: (https://northwestern.box.com/s/mop86jlalak6w89oua7sso34okh1dajs)

IP STATUS

Filed provisional application 62/214,560 (NU2013-184).

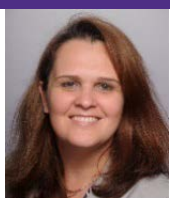
Issued 9,066,822 pending 14/730,806 & 14/730,816 (NU2011-089).

FACULTY &INVENTOR CONTACTS



Stefania Fatone, PhD, is an Associate Professor in Physical Medicine and Rehabilitation at Northwestern University, and leads the research projects that supported design of these pumps. Her team includes Northwestern University inventors **Ryan Caldwell, CP, Matthew J Major, PhD, and Andrew Hansen, PhD,** the latter previously at Northwestern University, now at VA and UMN.

INVO CONTACT



Dimitra Georganopoulou, Ph.D.
Innovation & Commercialization Officer
Medical Devices
Contact Info:
(t) 847.467.3095
(e) d-georganopoulou@northwestern.edu

APPENDIX V – SUMMARY OF RESULTS FROM 3 SUBJECTS TESTED AT CFI/BAMC

Development of Sub-Ischial Prosthetic Sockets with Assisted-Vacuum Suspension for Highly Active Persons with Transfemoral Amputations (Aim 4) – Summary Report

Subjects and Conditions

Three subjects have fully completed the study. Each subject wore an Ischial-Containment (IC) socket at enrollment and a Sub-Ischial (SI) socket was fabricated for the study.

Subject Demographics & Sub-Ischial (SI) Accommodation

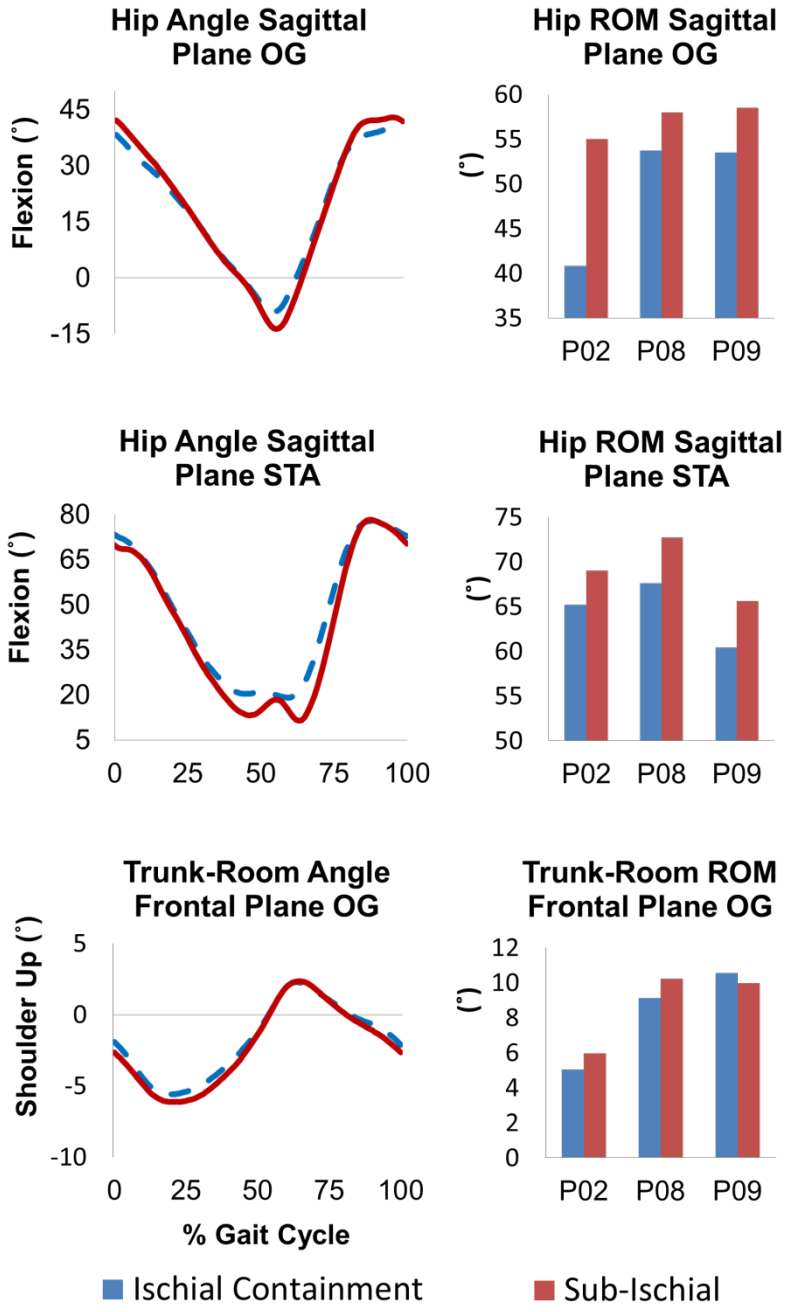
Subject	Gender	Age (yrs)	Height (m)	Mass (kg)	Time in SI socket
P02	M	35	1.86	95	8 weeks
P08	M	33	1.72	77	3 days*
P09	M	30	1.85	94	9 weeks

*Quick return to duty

Overground and Stairs Gait Biomechanics

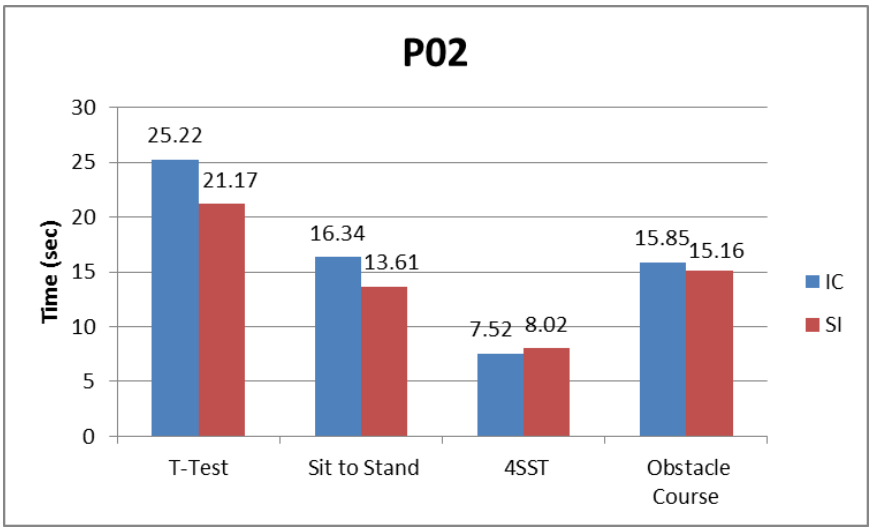
An assessment of hip and trunk biomechanics was performed while subjects wore each socket during level over-ground walking (OG) and ascending a 16 step staircase (STA). Mean differences were compared between sockets for hip and trunk ROM during OG walking and for hip ROM during STA. The differences during OG walking were compared to minimal detectable change values (MDC) [*Wilken et al. 2012*].

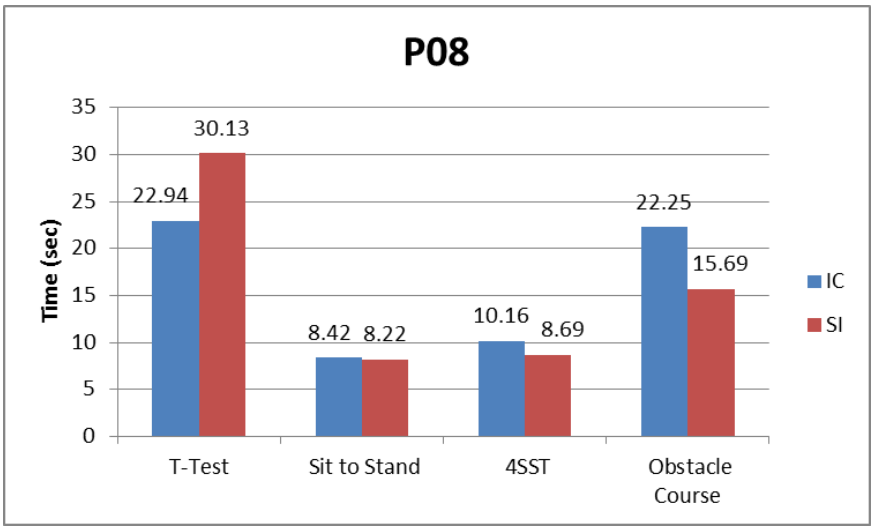
Sagittal plane hip angle data during OG walking showed an average 7.8˚ increase in hip ROM in the SI socket as compared to the IC socket. Each subject's increase in sagittal plane hip ROM during OG walking was greater than the MDC (3.2˚). Sagittal plane hip angle data during STA showed an average 4.7˚ increase in hip ROM in the SI socket compared to the IC socket (MDC not available). For all subjects, hip extension increased during both OG walking and STA in the SI as compared to the IC socket. There was no consistent change in frontal plane trunk ROM between the IC and SI sockets in OG walking and the difference for all subjects was below the MDC (1.1˚).

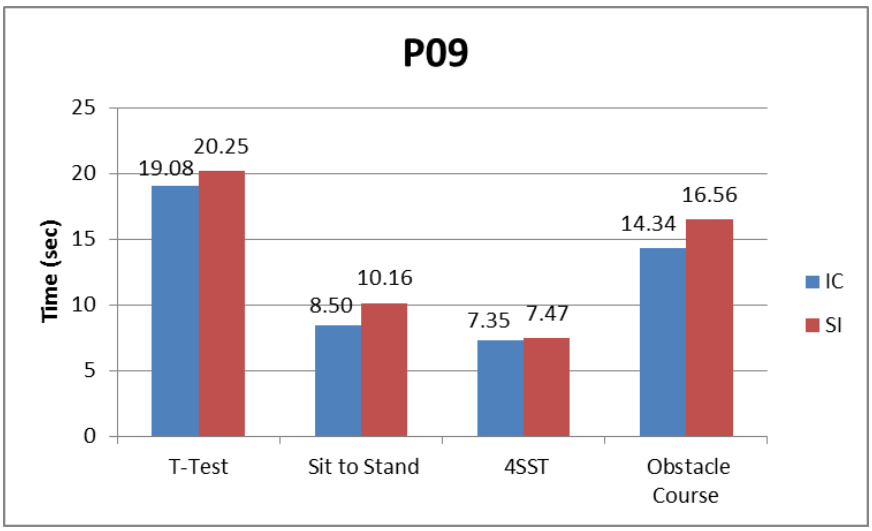

Hip Angle Sagittal Plane OG
Flexion (°)
45
30
15
0
-15
Hip ROM Sagittal Plane OG
(°)
60
55
50
45
40
35
P02
P08
P09
Hip Angle Sagittal Plane STA
Flexion (°)
80
65
50
35
20
5
0
25
50
75
100
Hip ROM Sagittal Plane STA
(°)
75
70
65
60
55
50
P02
P08
P09
Trunk-Room Angle Frontal Plane OG
Shoulder Up (°)
5
0
-5
-10
0
25
50
75
100
% Gait Cycle
Trunk-Room ROM Frontal Plane OG
(°)
12
10
8
6
4
2
0
P02
P08
P09
Ischial Containment
Sub-Ischial

Performance Measures: T-Test, Rapid Sit-to-Stand, 4 Square Step Test (4SST), Obstacle Course

There was not an overall improvement in the time to complete the performance measures while wearing the SI socket compared to the IC socket. The Rapid Sit-to-Stand and Obstacle Course was completed faster in the SI socket by 2/3 subjects (P02 and P08). The T-Test was completed faster in the IC socket by 2/3 subjects (P08 and P09) and the 4SST was also completed faster in the IC socket for 2/3 subjects (P02 and P09). While MDC values have been published for performance measures for able bodied individuals, none are yet available for individuals with amputation to help better interpret these changes.

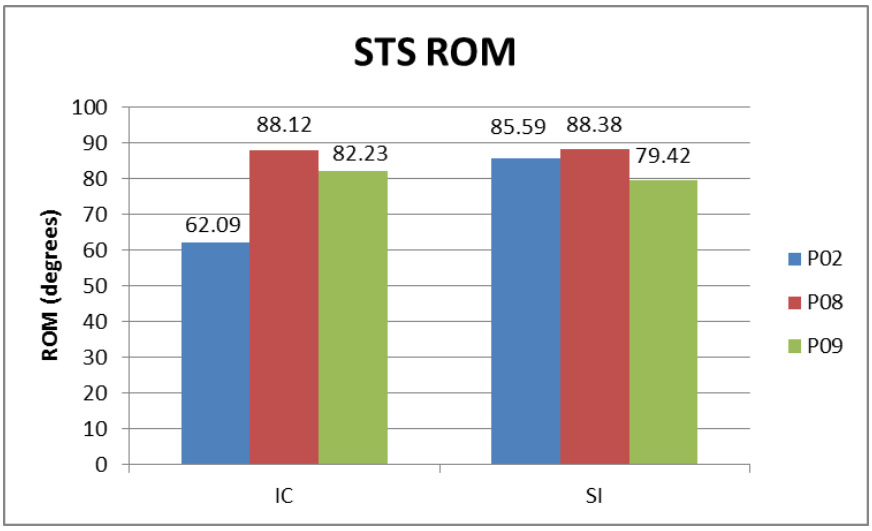






Rapid Sit-To-Stand (STS): Range of Motion

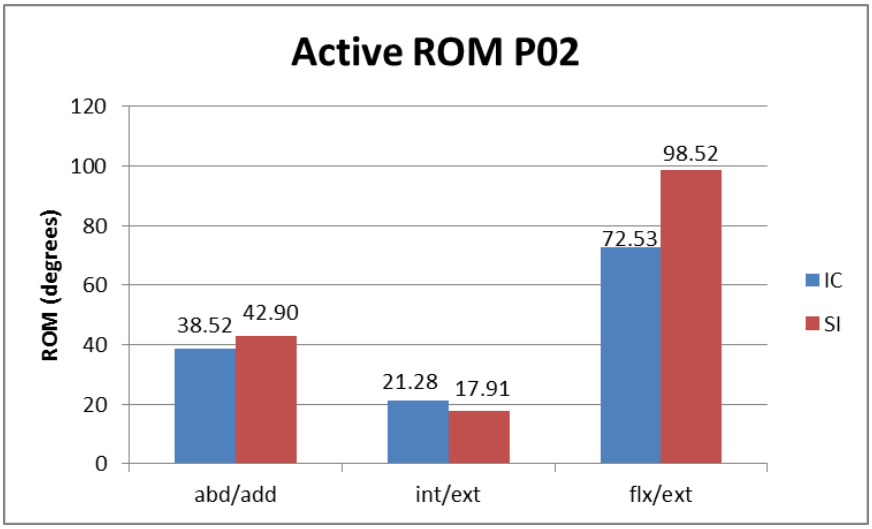
There was not an overall improvement in hip ROM during the Rapid Sit-to-Stand while wearing the SI socket compared to the IC socket. The average hip ROM for 5 repetitions of the Rapid Sit-To-Stand activity was greater in the SI socket for P02 and P08 and less for P09 compared to the IC socket.

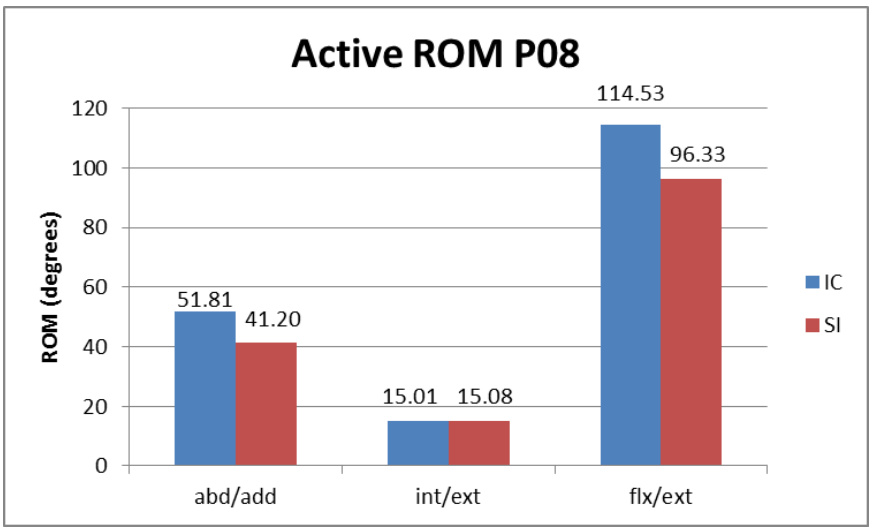


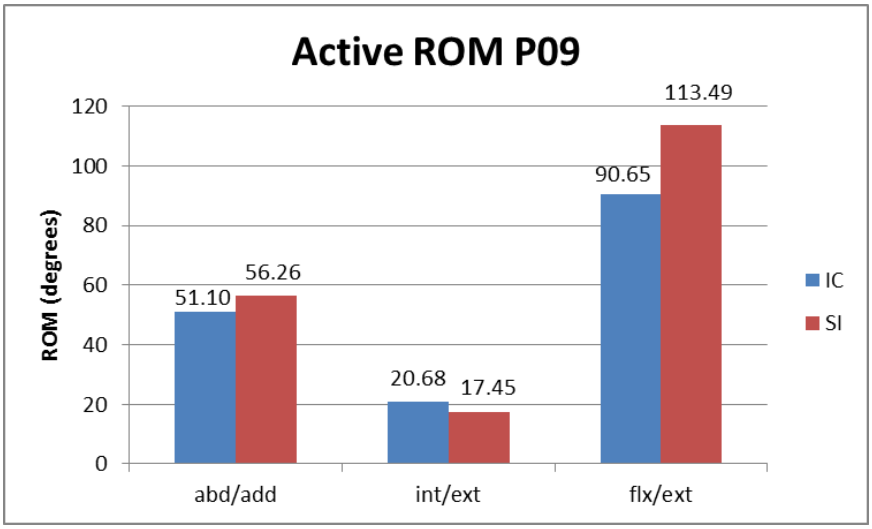
Active Hip Range of Motion and Peak Angles

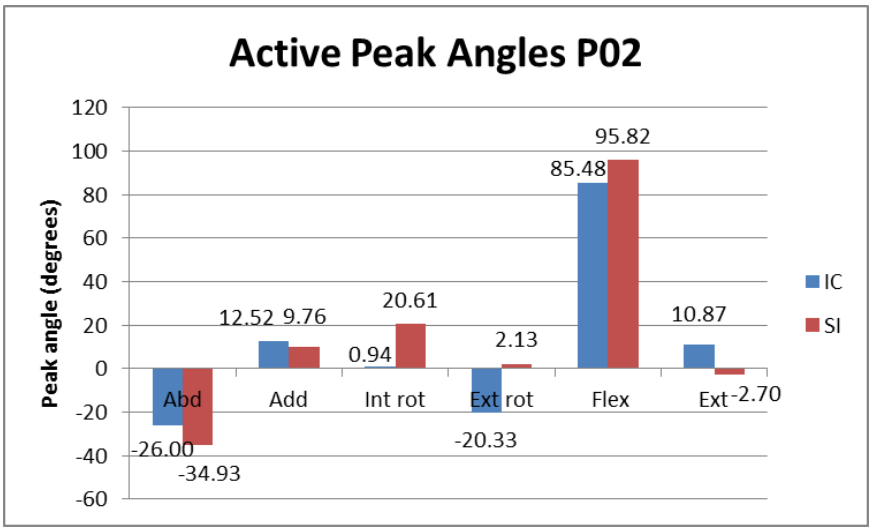
Active hip ROM was measured with a motion capture system while the subject maximally moved the affected limb along the sagittal, frontal, and transverse planes. In the three planes there was not a consistent increase in hip ROM in the SI socket compared to the IC socket. In the frontal and sagittal planes, P02 and P09 increased and P08 decreased active hip ROM in the SI socket. In the transverse plane, P02 and P09 decreased active hip ROM in the SI socket and P08 had the same active hip ROM in both sockets.

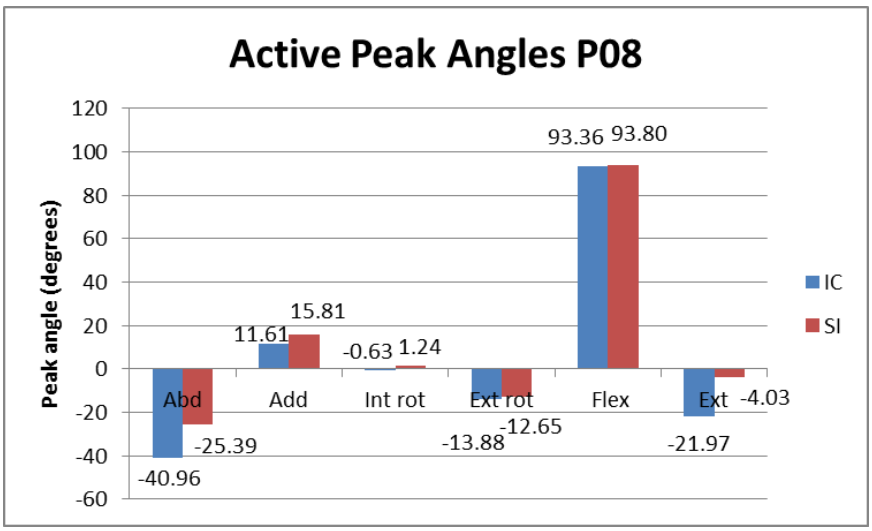
The peak angles for active hip ROM show P02 and P09 increased sagittal plane hip ROM in the SI socket by increasing both flexion and extension. P02 and P09 increased frontal plane hip ROM in the SI socket by increasing abduction. P08 reduced sagittal plane hip ROM in the SI socket by decreasing extension and reduced frontal plane hip ROM by decreasing abduction. The peak ankles in the transverse plane show mixed results between subjects and sockets with P02 showing greater internal rotation in the SI socket and greater external rotation in the IC socket while P09 showing the opposite response.

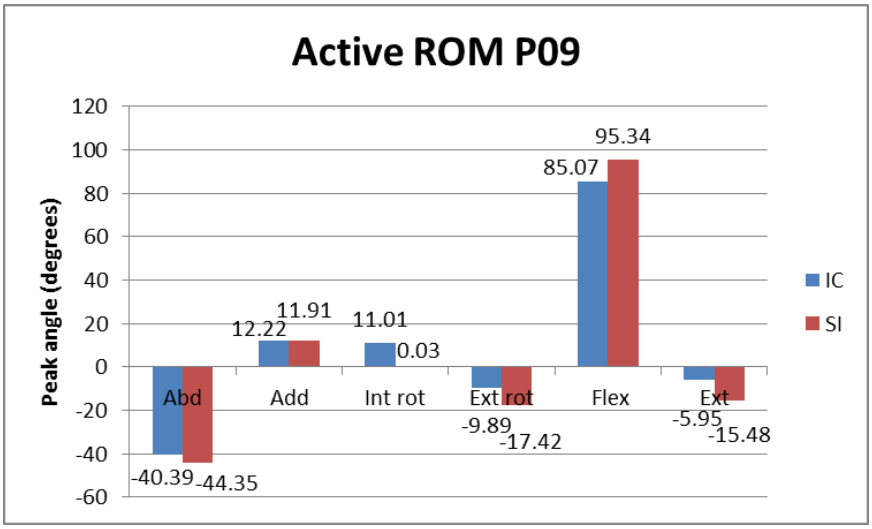



Active ROM P08
ROM (degrees)
120
100
80
60
40
20
0
51.81
41.20
15.01
15.08
114.53
96.33
abd/add
int/ext
flx/ext
IC
SI


Active ROM P09
ROM (degrees)
120
100
80
60
40
20
0
51.10
56.26
20.68
17.45
90.65
113.49
abd/add
int/ext
flx/ext
IC
SI


Active Peak Angles P02
Peak angle (degrees)
120
100
80
60
40
20
0
-20
-40
-60
-26.00
-34.93
12.52
9.76
0.94
20.61
-20.33
2.13
85.48
95.82
10.87
-2.70
Abd
Add
Int rot
Ext rot
Flex
Ext
IC
SI



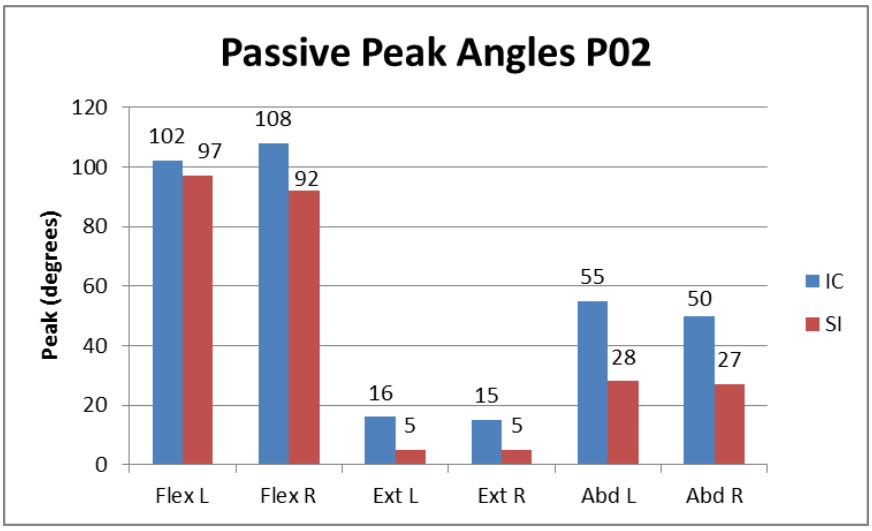


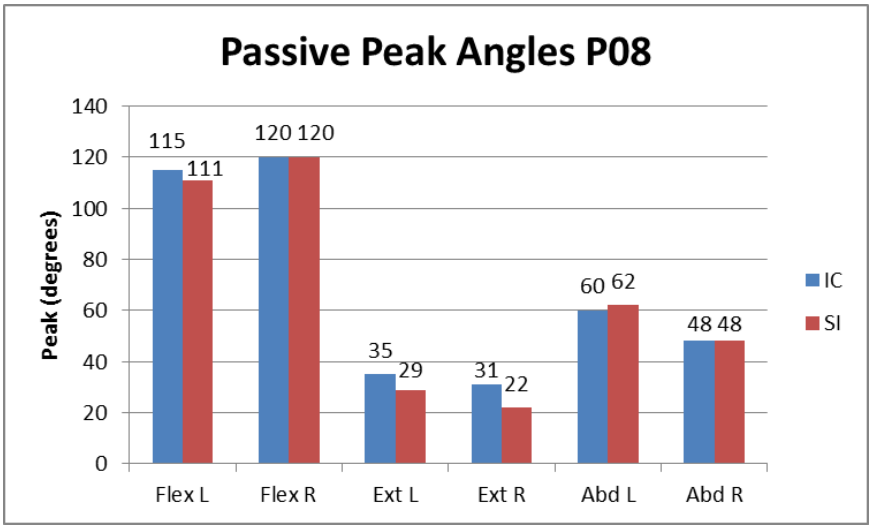
Passive Peak Hip Angles

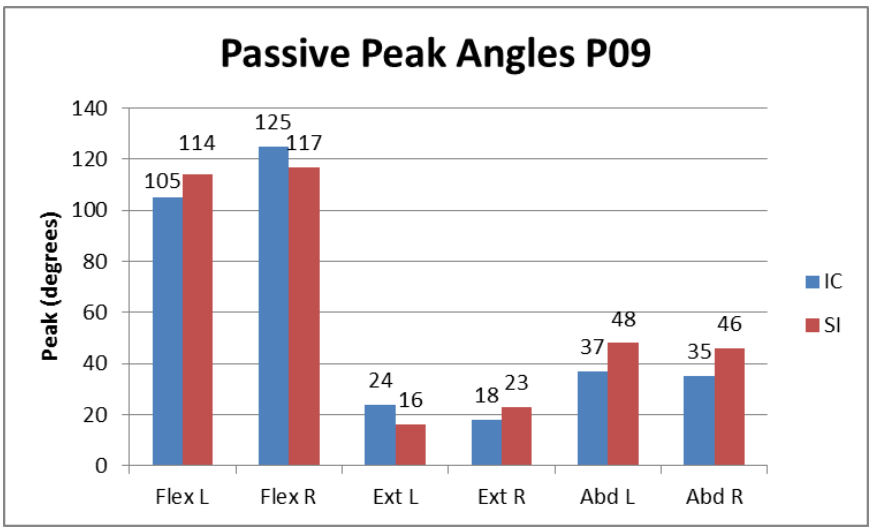
Passive Peak Hip Angles were measured with a goniometer while the subject was lying down and not wearing a socket. The affected and unaffected limbs were moved separately by a clinician into maximum flexion, extension, abduction, and adduction. The labels of IC and SI refer to the testing session in which the passive range of motion was measured. The affected limb on all subjects was the left limb.

Passive peak hip angles did not consistently change between sockets or subjects. P02 decreased passive peak hip angles in the SI socket testing session compared to the IC socket testing session for all measures. P08 decreased or maintained the same passive peak hip angles in the SI socket testing session compared to the IC socket testing for all measures except affected limb abduction. P09 increased

passive peak hip angles in the SI socket testing session compared to the IC socket testing session for all measures except affected limb extension and unaffected limb flexion.



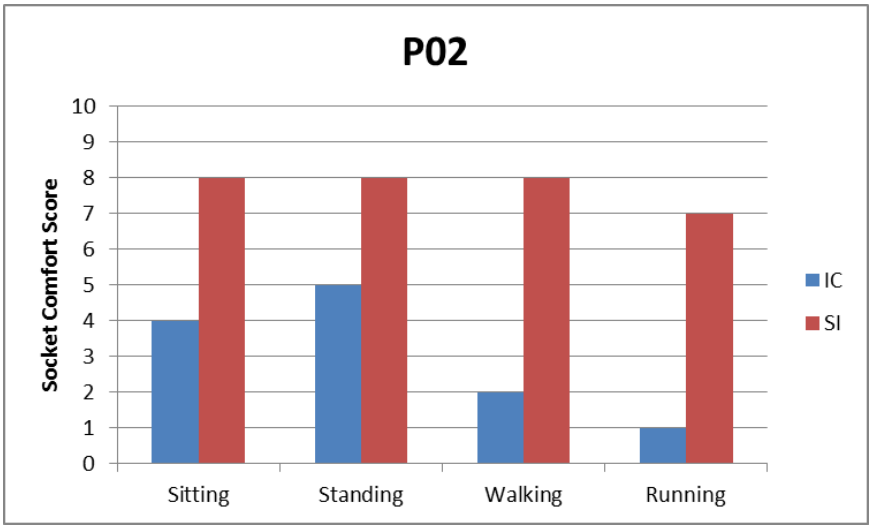


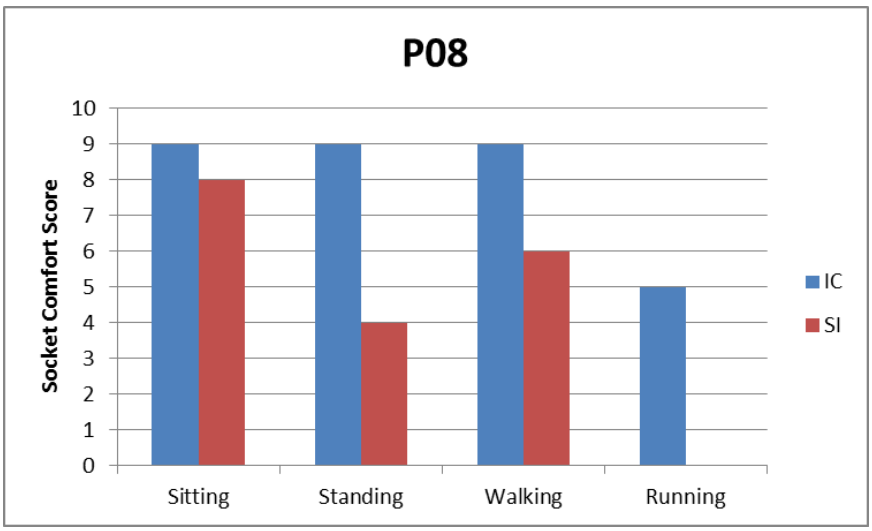


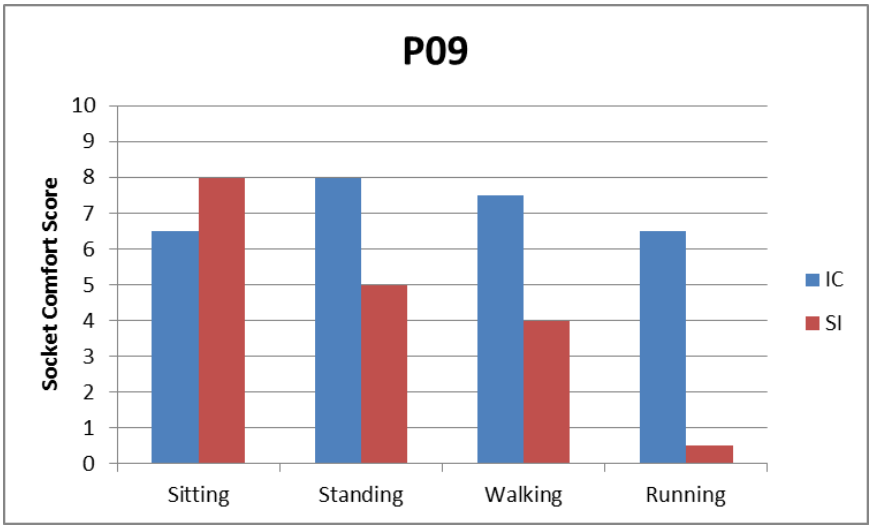
Socket Comfort Score

Socket Comfort Score for sitting, standing, walking and running in the IC and SI sockets was captured on a 0-10 scale with 0 representing the most uncomfortable socket fit and 10 representing the most comfortable socket fit the subject could imagine.

There was not a consistent response across subjects for any of the activities. 2/3 subjects preferred the SI socket for sitting and 2/3 subjects preferred the IC socket for standing, walking, and running.







Exit Interview Responses

An unscripted interview was conducted to capture feedback on each socket. The results showed a consistent preference for the SI socket for activities such as cycling and squats but overall preference for daily use was mixed.

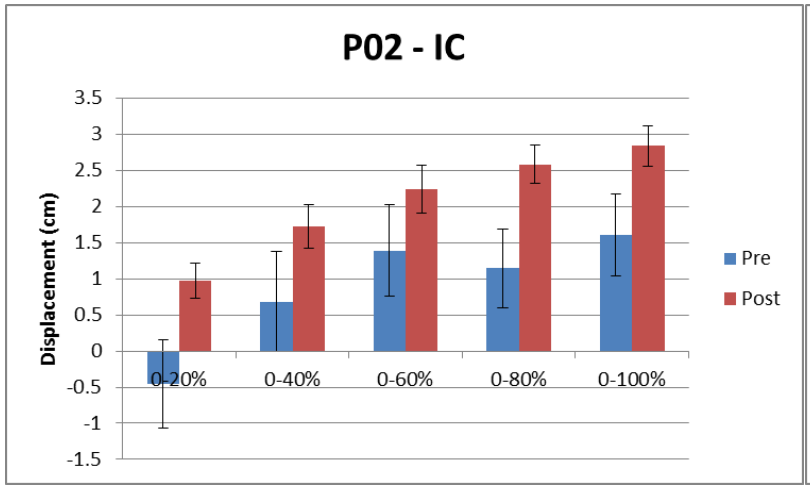
Activity	Sub-Ischial (SI)	Ischial Containment (IC)	No Preference
Daily use	P02	P08, P09	
Cycling, Squats	P02, P08, P09		
Sitting	P02, P09		P08

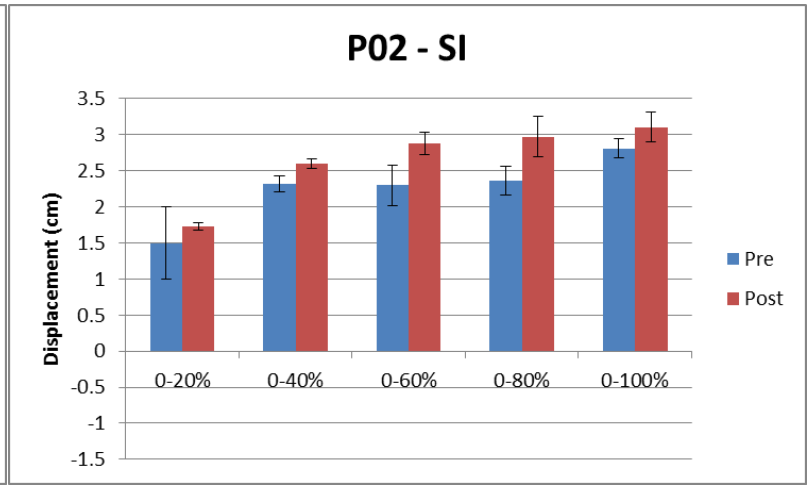
Fluoroscopy

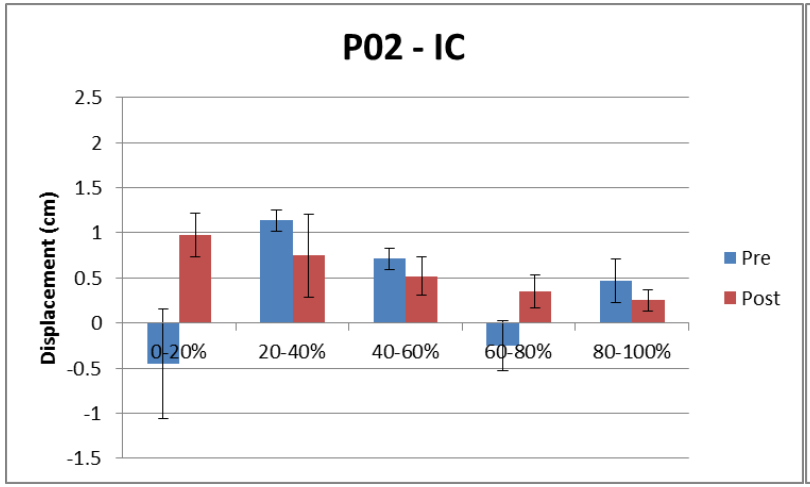
The vertical positions of the distal femur within the ischial containment (IC) and sub-ischial (SI) sockets were determined for each of six weight bearing conditions using video fluoroscopy (0-100% body weight in 20% increments). Displacement was defined as the difference in position of the distal portion of the femur relative to the socket adapter between weight bearing conditions. The figures show displacement values in cm between different weight bearing conditions prior to (Pre) and following (Post) 10 minutes of treadmill walking. Displacement values are shown for 3 subjects (P02, P08, and P09) during use of the IC and SI sockets. Each plot represents the average of 3 fluoroscopic images taken of the socket with standard deviation bars.

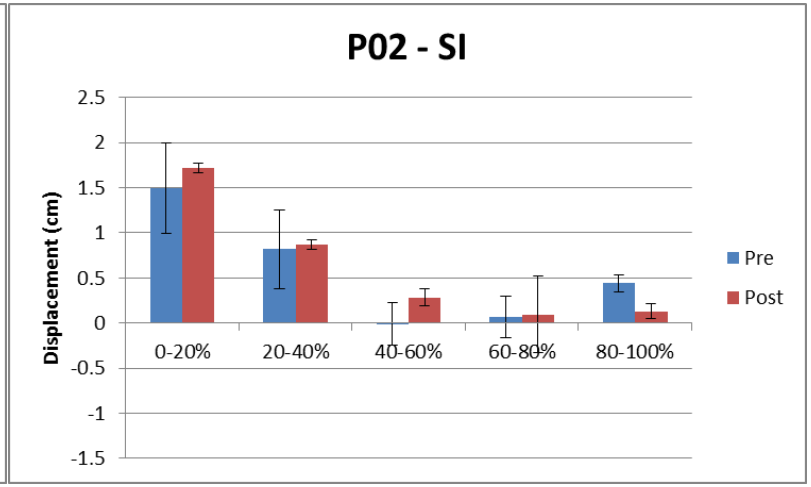
Total limb displacement varied between the three subjects, ranging from 1.5-4.5 cm. Some data showed maximal displacement at 80% loading rather than 100% which could be due to artifacts, changes in muscle activation between conditions or adjustment in body position as the subject balanced loading between limbs. There was no clear trend when comparing between sockets or between pre/post-exercise conditions.

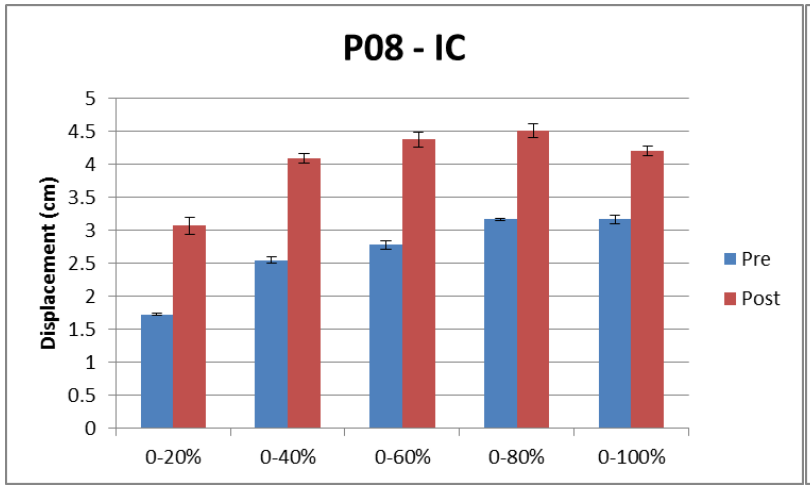
A review of incremental displacement between adjacent levels of weight bearing revealed that the displacement seen between 0-20% accounted for most of the displacement measured (bottom figures), with a general decrease in displacement as the limb is further loaded. This particular trend was evident for subjects P08 and P09, but more variable for P02. No other trends in incremental displacement were observed when comparing between sockets or between pre/post-exercise conditions.

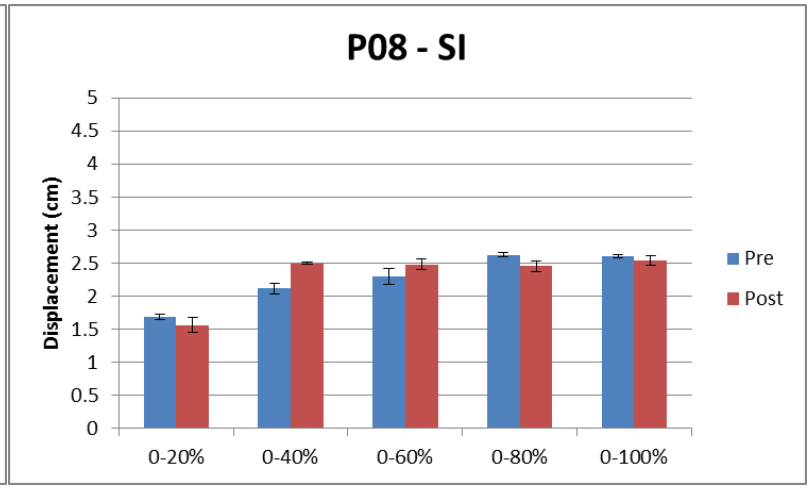

P02 - IC
Displacement (cm)
3.5
3
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
0-20%
0-40%
0-60%
0-80%
0-100%
Pre
Post

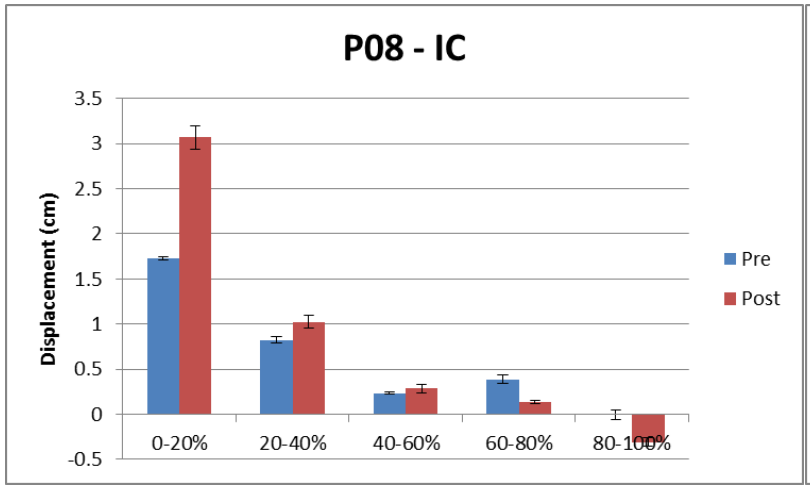

P02 - SI
Displacement (cm)
3.5
3
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
0-20%
0-40%
0-60%
0-80%
0-100%
Pre
Post

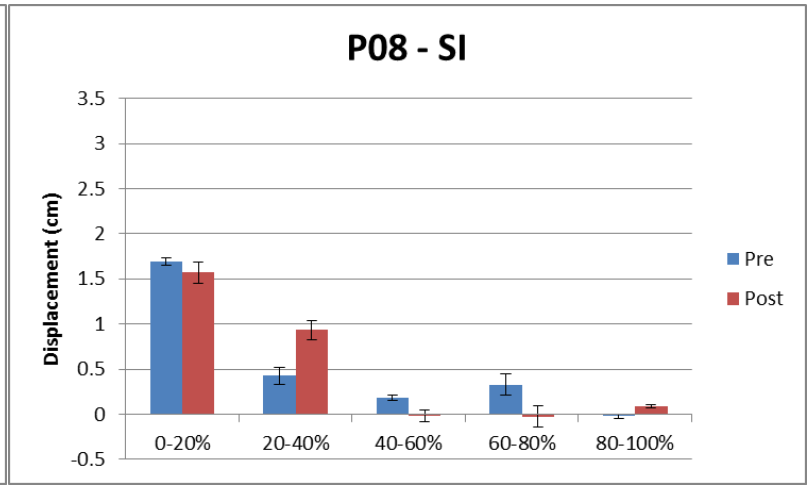

P02 - IC
Displacement (cm)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
0-20%
20-40%
40-60%
60-80%
80-100%
Pre
Post

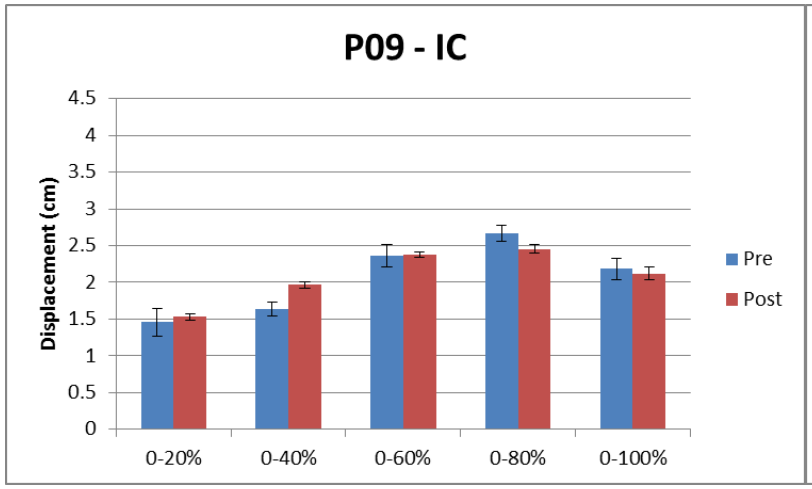

P02 - SI
Displacement (cm)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
0-20%
20-40%
40-60%
60-80%
80-100%
Pre
Post

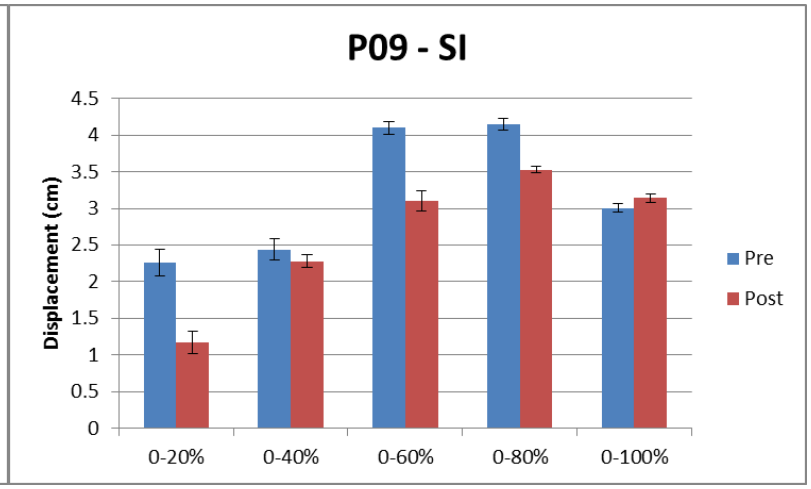

P08 - IC
Displacement (cm)
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
0-20%
0-40%
0-60%
0-80%
0-100%
Pre
Post

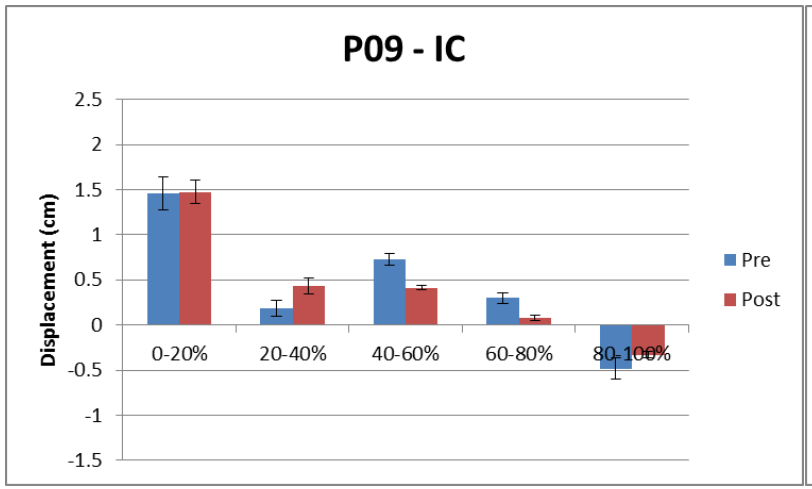

P08 - SI
Displacement (cm)
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
0-20%
0-40%
0-60%
0-80%
0-100%
Pre
Post

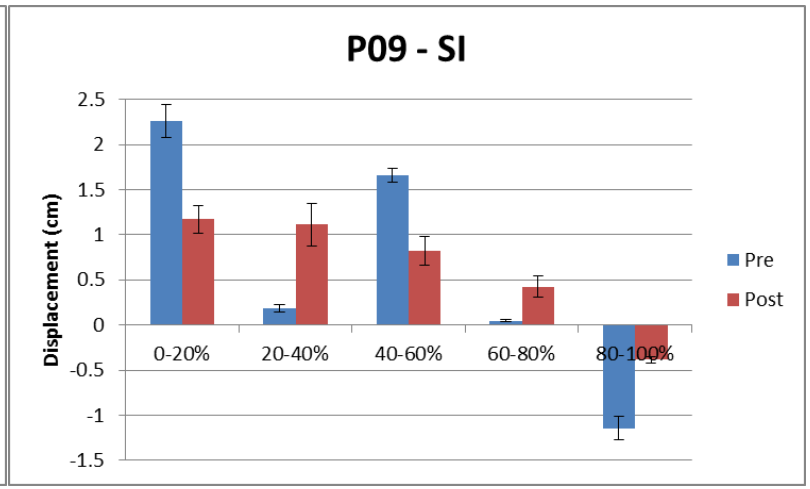

P08 - IC
Displacement (cm)
3.5
3
2.5
2
1.5
1
0.5
0
-0.5
0-20%
20-40%
40-60%
60-80%
80-100%
Pre
Post


P08 - SI
Displacement (cm)
3.5
3
2.5
2
1.5
1
0.5
0
-0.5
0-20%
20-40%
40-60%
60-80%
80-100%
Pre
Post


P09 - IC
Displacement (cm)
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
0-20%
0-40%
0-60%
0-80%
0-100%
Pre
Post


P09 - SI
Displacement (cm)
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
0-20%
0-40%
0-60%
0-80%
0-100%
Pre
Post


P09 - IC
Displacement (cm)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
0-20%
20-40%
40-60%
60-80%
80-100%
Pre
Post


P09 - SI
Displacement (cm)
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
0-20%
20-40%
40-60%
60-80%
80-100%
Pre
Post

References

Wilken, J.M., Rodriguez, K.M., Brawner, M., Darter, B.J., 2012. Reliability and Minimal Detectible Change values for gait kinematics and kinetics in healthy adults. Gait & Posture 35, 301-307.

APPENDIX W – CFI/BAMC ABSTRACTS AND POSTERS

Sub-Ischial Prosthetic Sockets Improve Hip Range of Motion and Performance for Individuals with Transfemoral Amputations

Elizabeth Russell Esposito[a], Stefania Fatone[bc], Jason Wilken[a], Ryan Caldwell[cd], John Fergason[a]

[a]Center for the Intrepid, Dept. Orthopaedics and Rehabilitation, Brooke Army Medical Center; [b]Dept. Physical Medicine and Rehabilitation, Northwestern University; [c]Northwestern University Prosthetics-Orthotics Center; [d]Scheck and Siress, Schaumberg IL

INTRODUCTION

Persons with transfemoral amputation (TFA) represent approximately 20% of all persons with amputation in the general population (Owings et al. 1998) but the proportion of service members with transfemoral amputations is higher than the general population (31%) (Stansbury et al. 2008). These individuals are typically young, with excellent premorbid health and many wish to return to premorbid activity levels and have higher functional expectations (Pasquina et al. 2006) than the older, dysvascular amputee. Improvements in prosthetic componentry, including socket design and suspension, have critical impact on the functional abilities of individuals with TFA. Traditional designs include ischial containment sockets which limit hip range of motion and function (Tranberg et al. 2011). New sub-ischial designs, which incorporate vacuum suspension to maintain the socket-limb interface, may improve hip range of motion and overall function.

METHOD

The Brooke Army Medical Center Institutional Review Board approved this study and informed consent was obtained from subjects prior to participation. Six male service members between the ages of 18 and 45 with unilateral TFA and residual limb lengths of at least 4 inches are undergoing assessment in two socket and suspension designs: (1) Ischial containment sockets with cushioned gel liners and (2) Sub-ischial sockets with active vacuum suspension. All subjects wore the X3 knee (Ottobock, Duderstadt, Germany), an energy-storage-and-return foot and were given a minimum of 6 weeks accommodation time in each socket condition.

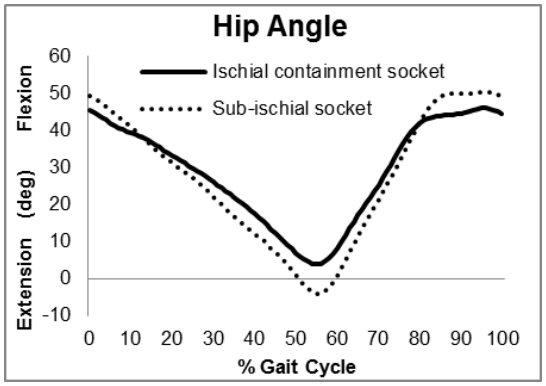
Testing took place in the ischial containment socket followed by the sub-ischial socket. Subjects underwent a series of range of motion, performance, and biomechanical tests. A 26-camera motion capture system (120 Hz, Motion Analysis Corp., Santa Rosa, CA) tracked trajectories of 57 markers secured to anatomical landmarks and body segments. Specifically, thigh and pelvic segments were tracked during active hip range of motion in the sagittal and frontal planes, a 5-time sit-to-stand test and at standardized walking speed. A T-test, which incorporates speed and agility with forward and backward running and side shuffling, was recorded for time.

Marker data were tracked and exported to Visual3D (C-Motion Inc., Bethesda, MD) for further analysis. Hip joint angles were calculated during the range of motion, performance task and 5 walking trials.

RESULTS

Thus far all subjects indicated that they preferred the sub-ischial to their ischial containment socket. One common theme was the ability to sit without the socket beneath the ischium.

Data from the first subject to complete the full testing protocol showed that the sub-ischial socket resulted in 10° greater active peak hip flexion, 13° greater active peak hip extension and 9° more hip abduction; sit-to-stand time improved by almost 2 seconds; hip range of motion increased 20.6°; T-test performance improved by 4 seconds (16%). Across 5 walking trials, hip range of motion increased 12.5° ± 1.2° with the sub-ischial socket and the hip was able to achieve extension during walking (Figure 1).



DISCUSSION & CONCLUSIONS

Speed, agility, and hip range of motion were expected to improve when subjects wore the sub-ischial socket with vacuum suspension due to the lower proximal trim lines. The inclusion of additional subjects will determine if greater hip range of motion during walking may improve overall walking ability and potentially lessen the need for gait compensations. High patient satisfaction with the sub-ischial socket supports further investigation of this new socket design.

CLINICAL APPLICATIONS

Sub-ischial sockets with active vacuum suspension are emerging as viable options for active individuals with TFA.

REFERENCES

Owings and Kozak. Vital Health Stat. 13 (139), 1998.
Stansbury et al. J Orthop Trauma. 22(1), 43-46, 2008.
Pasquina et al. J Prosthet Orthot. 18(6), 119-122, 2006.
Tranberg et al. Gait Posture. 33(2), 165-168, 2011.

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

American Academy of Orthotists & Prosthetists
41st Academy Annual Meeting & Scientific Symposium
February 18 - 21, 2015

The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, Department of Defense or the U.S. Government.

EFFECT OF SOCKET DESIGN AND SUSPENSION ON WALKING MECHANICS

[1] Starr E. Brown, [1,2] Elizabeth Russell Esposito, [1,2] Andrea Ikeda, [1] John Fergason, [3] Ryan Caldwell, [3] Stefania Fatone, and [1,2] Jason M. Wilken

[1] Center for the Intrepid, Brooke Army Medical Center, JBSA Fort Sam Houston, TX
[2] Extremity Trauma and Amputation Center of Excellence
[3] Northwestern University Prosthetics-Orthotics Center, Chicago, IL
email: starr.e.brown2.ctr@mail.mil

INTRODUCTION

Socket design is one of the most important considerations in creating a prosthesis. The standard of care for individuals with a transfemoral amputation (TFA) is an ischial containment (IC) socket, which includes a proximal brim encompassing the ischium and greater trochanter (Fig 1). The proximal brim of the IC socket can cause discomfort, increased pressure and limited hip range of motion (ROM) [1,2]. During walking, limited hip ROM can lead to unhealthy compensatory strategies [1].

Advancements in socket suspension have allowed prosthetists to design sockets that eliminate ischial containment. Vacuum-assisted socket suspension aims to reduce motion between the residual limb and socket [2]. With improved coupling, the proximal brim of a socket can be lowered below the ischial tuberosity. A socket with sub-ischial (SI) trim lines would potentially allow greater hip motion and increased comfort during sitting [3]. However, lowering the proximal brim may affect socket stability during walking [4]. Therefore, the purpose of this study was to compare walking biomechanics and patient satisfaction with IC and SI sockets in individuals with unilateral TFA.

METHODS

Three male subjects with a unilateral TFA participated in the study (Table 1). Each subject wore an IC socket at enrollment and an SI socket was fabricated by a prosthetist for the purpose of the study. A gel liner was worn with both sockets. The IC socket used passive suction suspension and the SI socket used vacuum-assisted suspension. All subjects wore an X3 microprocessor knee (Ottobock, Germany) and energy storage and return prosthetic foot. Subjects participated in a biomechanical gait assessments according to Wilken et al. [5] in the IC and SI sockets on separate days while walking at a self-selected pace on level ground (OG) and ascending a 16 step staircase (STA). Hip and trunk ROM differences between sockets were compared to minimal detectible change (MDC) values reported using identical methodology [5].

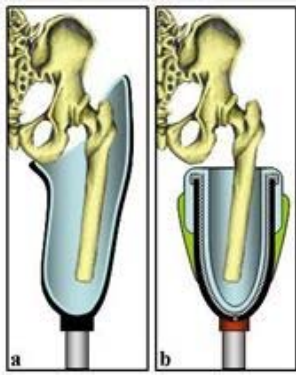


Figure 1:
(a) Ischial Containment (IC) socket. Proximal brim contains ischium and greater trochanter.
(b) Sub-Ischial (SI) socket. Lower proximal trim line does not contain ischium.

Image courtesy of NUPOC.

Subject	Age (years)	Height (m)	Mass (kg)	IC Walking Speed (m/s)	SI Walking Speed (m/s)
P01	35	1.86	94.8	1.23	1.18
P02	33	1.72	77	1.24	1.18
P03	30	1.85	94	1.42	1.39

Table 1: Patient demographics and self-selected walking speeds in ischial containment (IC) and sub-ischial (SI) sockets.

RESULTS AND DISCUSSION

There was an average 7.8 degree increase in sagittal plane hip ROM for all subjects during OG walking in the SI socket as compared to the IC socket (Fig

2). Each subject's increase was greater than the MDC (3.2 degrees) suggesting there is a true difference between the IC and SI sockets. Similarly, there was an average 4.7 degree increase in hip ROM during STA in the SI socket compared to the IC socket, but MDC values are not available for this activity. For all subjects, hip extension increased during both OG walking and STA (Fig 2) in the SI as compared to the IC socket. However, self-selected walking speed (Table 1) was slightly faster in the IC socket indicating that increased hip extension in the SI socket did not result in increased walking speed.

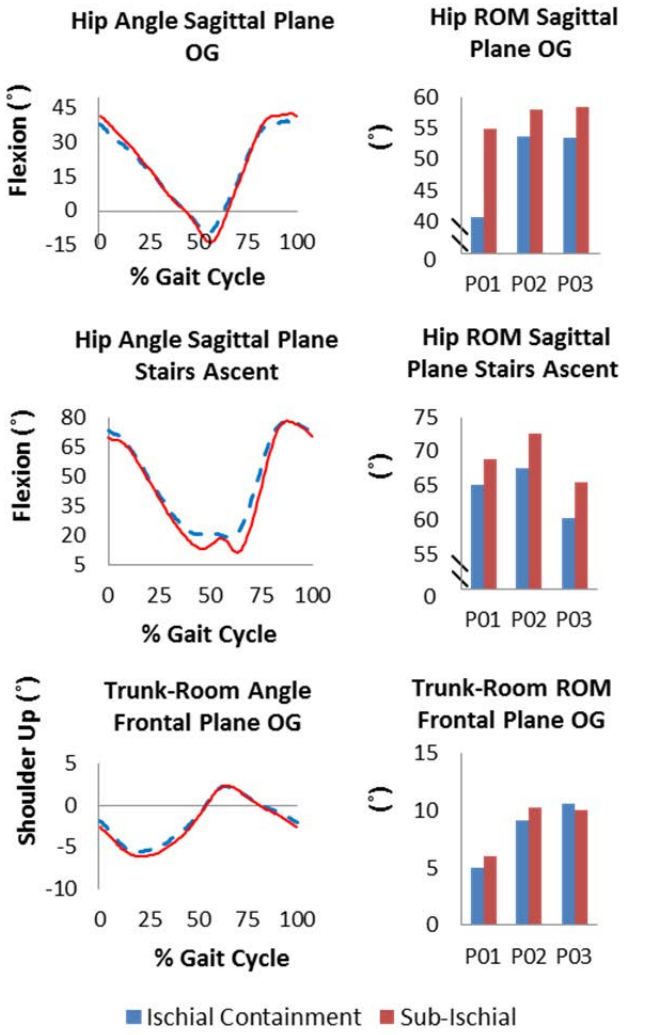


Figure 2: Left column mean data during gait cycle of sagittal plane hip angle during over ground (OG) walking (top) and stairs ascent (STA) (middle) and frontal plane trunk-room angle during OG walking (bottom). Right column shows individual subject ranges of motion (ROM).

There was no consistent change in frontal plane trunk ROM between the IC and SI sockets (Fig 2) in OG walking and the differences for all subjects were below the MDC (1.1 degrees). This suggests that lowering the proximal trim line may not change coronal plane socket stability [6]. Trunk kinematics were not assessed for STA due to varied handrail use.

Subject feedback revealed that P01 preferred the SI socket and P02 and P03 preferred the IC socket for daily use. However, all subjects preferred the SI socket for activities that required large hip ROM such as cycling and squats. Sitting in the SI socket was more comfortable for P01 and P03, while P02 was equally comfortable sitting in either socket.

CONCLUSIONS

Individuals with TFA who wear a SI socket walk with greater sagittal plane hip ROM with no increase in frontal plane trunk ROM relative to an IC socket. There was a consistent preference for the SI socket for activities such as cycling but overall preference for daily use was mixed. The results of this study indicate a SI socket may have hip ROM and comfort advantages compared to an IC socket. However, an increase in sample size is necessary to determine a clear preference for comfort and daily use.

REFERENCES

1. Tranberg R, et al. *Gait Posture* **33**, 165-168, 2011.
2. Kahle JT, et al. *Gait Posture* **40**, 315-320, 2014.
3. Fairley M. *The O&P Edge*, March 2008.
4. Dillon M. *12th World Congress ISPO'07*, Vancouver, Canada, 2007.
5. Wilken JM, et al. *Gait Posture* **35**, 301-307, 2012.
6. Fatone S, et al. *JRRD* **51**, 1217-1228, 2014.

ACKNOWLEDGEMENTS

Support provided by CDMRP – Peer Reviewed Orthopedic Research Program Award W81XWH-10-0744.

The views expressed herein are those of the authors and do not reflect the policy or position of Brooke Army Medical Center, the US Army Medical Department, US Army Office of the Surgeon General, Department of the Army, Department of Defense or US Government.

EFFECT OF SOCKET DESIGN AND SUSPENSION ON WALKING MECHANICS

[1]Starr E. Brown, [1,2]Elizabeth Russell Esposito, [1,2]Andrea Ikeda, [1]John Fergason, [3]Ryan Caldwell, [3]Stefania Fatone, [1,2]Jason M. Wilken

[1] Center for the Intrepid, Brooke Army Medical Center, JBSA, Ft. Sam Houston, TX, USA
[2] Extremity Trauma and Amputation Center of Excellence,
[3] Northwestern University Prosthetics-Orthotics Center (NUPOC), Chicago, IL, USA

INTRODUCTION

- Standard of care for individuals with a transfemoral amputation is an ischial containment (IC) socket
- Proximal brim of IC socket can cause
  - Discomfort
  - Increased pressure
  - Limited hip range of motion (ROM) [1,2]
- Limited hip ROM during walking can lead to unhealthy compensatory strategies [1]
- Advancements in socket suspension have allowed prosthetists to design sub-ischial (SI) sockets that eliminate ischial containment. Vacuum-assisted socket suspension aims to reduce motion between the residual limb and socket [2]. With improved coupling, the proximal brim of a socket can be lowered below the ischial tuberosity.

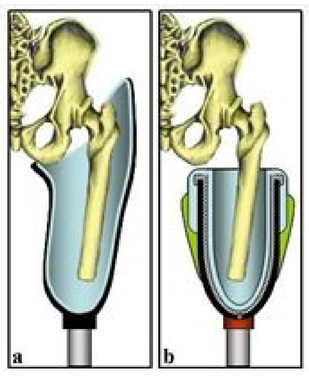


Figure 1. Ischial containment socket on left and sub-ischial socket with vacuum-assisted socket suspension on right. Sub-ischial socket has a lower proximal brim eliminating ischial containment. Image courtesy of NUPOC.

- Potential benefits of SI socket and vacuum-assisted socket suspension
  - Less motion between socket and limb [2]
  - Greater hip ROM
  - Increased comfort during sitting [1,3]
- Potential concern
  - May affect socket stability (frontal plane relative motion between the socket and the residual limb) during walking [4]
- **Purpose:** To compare walking biomechanics and patient satisfaction with IC and SI sockets in individuals with unilateral transfemoral amputation

METHODS

- **Inclusion Criteria:**
  - 18-45 years old
  - Unilateral transfemoral amputation
  - Residual limb length minimum of 4 inches
  - No prior experience with vacuum-assisted socket suspension
- Each subject wore an IC socket at enrollment and an SI socket was fabricated for the study

Subject Demographics & Sub-Ischial (SI) Accommodation

Subject	Gender	Age (yrs)	Height (m)	Mass (kg)	Time in SI socket
P01	M	35	1.86	95	8 weeks
P02	M	33	1.72	77	3 days*
P03	M	30	1.85	94	9 weeks

* Quick return to duty

- Prosthetic components
  - IC - passive suction suspension
  - SI - vacuum-assisted suspension
  - Gel liner with both sockets
  - X3 microprocessor knee, Ottobock, USA
  - Energy storage and return prosthetic foot
- Assessment of hip and trunk biomechanics during gait at a self-selected walking speed
  - Level over ground (OG) walking
  - Ascending 16 step staircase (STA)



Figure 2. Ischial containment socket with passive suction suspension on left and sub-ischial socket with vacuum-assisted socket suspension on right. Both sockets worn with a gel liner, X3 microprocessor knee and energy storage and return foot.

- Mean differences compared between sockets
  - Hip and trunk ROM during OG walking
  - Hip ROM during STA
  - Differences during OG walking were compared to minimal detectable change values (MDC) [5]

RESULTS

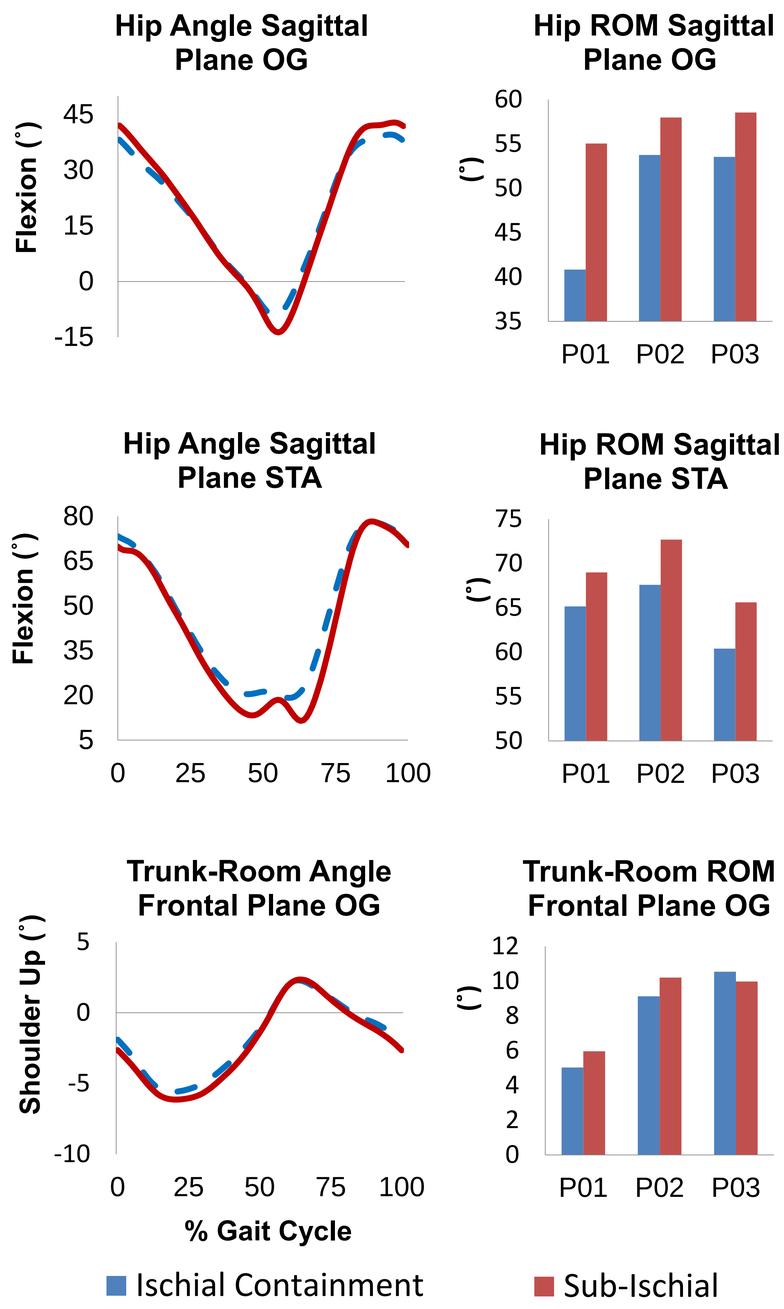


Figure 3. Left column: mean data during gait cycle of sagittal plane hip angle during over ground (OG) walking (top) and stairs ascent (STA) (middle) and frontal plane trunk-room angle during OG walking (bottom). Right column: individual subject ranges of motion (ROM) for same activities and joint/segment.

- There was an average 7.8˚ increase in sagittal plane hip ROM during OG walking in the SI socket as compared to the IC socket. Each subject's increase in sagittal plane hip ROM was greater than the MDC (3.2˚).
- There was an average 4.7˚ increase in hip ROM during STA in the SI socket compared to the IC socket. MDC not available.
- For all subjects, hip extension increased during both OG walking and STA in the SI as compared to the IC socket.
- There was no consistent change in frontal plane trunk ROM between the IC and SI sockets in OG walking and the difference for all subjects was below the MDC (1.1˚).

Self-Selected Walking Speed (m/s)

Subject	Overground (OG)		Stairs Ascent (STA)	
	Ischial Containment (IC)	Sub-Ischial (SI)	Ischial Containment (IC)	Sub-Ischial (SI)
P01	1.23	1.18	0.33	0.32
P02	1.24	1.18	0.38	0.40
P03	1.42	1.39	0.45	0.40

- Self-selected walking speed was overall faster while walking in the IC socket compared to the SI socket. All differences per activity were less than 0.1 m/s.

Socket Preference

Activity	Sub-Ischial (SI)	Ischial Containment (IC)	No Preference
Daily use	P01	P02, P03	
Cycling, Squats	P01, P02, P03		
Sitting	P01, P03		P02

CONCLUSIONS

- Walking with a SI socket resulted in greater sagittal plane hip ROM during OG walking and STA compared to walking with an IC socket.
- The difference in hip ROM during OG walking was greater than the MDC [5] indicating a true difference exists between the sockets.
- Hip extension increased during both OG walking and STA in the SI as compared to the IC socket. However, self-selected walking speed was overall faster in the IC socket indicating increased hip extension did not result in increased walking speed.
- During OG walking the SI socket did not increase frontal plane trunk ROM relative to an IC socket. When socket stability is compromised, individuals may compensate with increased lateral trunk displacement [6]. Therefore, this suggests lowering the proximal brim may not affect frontal plane socket stability.
- There was a consistent preference for the SI socket for activities such as cycling and squats but overall preference for daily use was mixed.
- The results of this study indicate a SI socket may have hip ROM and comfort advantages compared to an IC socket without affecting socket stability. However, an increase in sample size is necessary to determine a clear preference for comfort and daily use.

REFERENCES

1. Tranberg R, et al. *Gait Posture* **33**, 165-168, 2011.
2. Kahle JT, et al. *Gait Posture* **40**, 315-320, 2014.
3. Fairley M. *The O&P Edge,* March 2008.
4. Dillon M. *12th World Congress ISPO'07,* Vancouver, Canada, 2007.
5. Wilken JM, et al. *Gait Posture* **35**, 301-307, 2012.
6. Fatone S, et al. *JRRD* **51**, 1217-1228, 2014.

Acknowledgements

The U.S. Army Medical Research and Materiel Command Acquisition Activity, is the awarding and administering acquisition office (Award #W81XWH-10-1-0744).
The authors thank the members of the Military Performance Lab at the Center for the Intrepid for their contributions in data collection and processing.

The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army or the Department of Defense or the U.S. Government.

Effect of Socket Design and Suspension on Walking Mechanics

Starr E. Brown[1], Elizabeth Russell Esposito[1,2], Andrea Ikeda[1,2], John Fergason[1], Ryan Caldwell[3], Stefania Fatone[3], and Jason M. Wilken[1,2]

[1]Center for the Intrepid, Brooke Army Medical Center, Ft. Sam Houston, TX, USA
[2]DoD-VA Extremity Trauma and Amputation Center of Excellence
[3]Northwestern University Prosthetics-Orthotics Center, Chicago, IL
E-mail: starr.e.brown2.ctr@mail.mil
Word Count: 350/350

The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army or the Department of Defense or the U.S. Government.

BACKGROUND: Socket design is one of the most important considerations in creating a prosthesis. Individuals with a transfemoral amputation (TFA) are most commonly prescribed an ischial containment (IC) socket, with a proximal brim encompassing the ischium and greater trochanter. The proximal brim can cause discomfort and limit hip range of motion (ROM). Advancements in socket suspension have improved coupling between the residual limb and socket allowing the proximal brim to be lowered. It is hypothesized that a vacuum-assisted socket suspension with sub-ischial (SI) trim lines would potentially allow greater hip motion without affecting socket stability during walking. Therefore, the purpose of this study was to compare walking biomechanics with IC and SI sockets in individuals with TFA.

METHODS: Three male subjects with a unilateral TFA participated in the study. Each subject wore an IC socket at enrollment and an SI socket was fabricated for the study. A gel liner was worn with both sockets. The IC socket used passive suction and the SI socket used vacuum-assisted suspension. All subjects wore an X3 microprocessor knee and energy storage and return prosthetic foot. Subjects participated in biomechanical gait assessments in the IC and SI sockets on separate days while walking at a self-selected pace on level ground (OG) and ascending a 16 step staircase (STA). Hip and trunk ROM differences between sockets were compared to minimal detectible change (MDC) values reported using identical methodology.

RESULTS AND DISCUSSION: Sagittal plane hip ROM increased 7.8 degrees on average (SD=5.6) during OG walking in the SI compared to the IC socket. Each subject's increase was greater than the MDC (3.2 degrees), suggesting a true difference exists between the sockets. Similarly, there was an average 4.7 degree (SD=0.8) increase in hip ROM during STA in the SI compared to the IC socket, but MDC values are not available for STA. There was no consistent change in coronal plane trunk ROM between the sockets in OG walking and all subjects' differences were below the MDC (1.1 degrees). This suggests lowering the proximal trim line increases sagittal plane hip motion but does not change coronal plane socket stability.

APPENDIX X – SUBMITTED ABSTRACT ISPO 2017

EFFECT OF INTERFACE COMPONENTS ON RESIDUAL LIMB WEIGHT-BEARING TOLERANCE IN THE NORTHWESTERN UNIVERSITY FLEXIBLE SUB-ISCHIAL VACUUM (NU-FLEXSIV) SOCKET

BACKGROUND

Lower limb prosthetic sockets interface with soft tissues that are ill-suited to the loading that occurs during activities. Additionally, the transected bone at the distal end is unable to tolerate loading at full body weight (BW) (1). Hence, sockets must be designed to support the body and enable effective load transfer during activities by distributing weight bearing forces comfortably over the residual limb. Transfemoral sockets typically distribute weight bearing forces through a proximal brim that provides some pelvic support, however in the newly proposed Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket, all weight bearing loads must be borne by the thigh.

AIM

The aim of this study was to assess the relative contribution of interface components (liner and socket) on the ability of persons with transfemoral amputation (TFA) to bear weight comfortably on the residual limb.

METHOD

Subjects with unilateral TFA who wore a NU-FlexSIV Socket participated in a single visit. During a static assessment of socket fit, with a digital scale attached to a hard support surface, the subject applied weight onto the residual limb for three trials each of three randomly presented residuum conditions: bare limb, liner clad limb, and wearing the same liner and socket. Subjects were instructed to transfer as much weight onto the residual limb as tolerable while holding onto a walking frame for balance. For each trial, weight and pain were recorded on an 11-point ordinal scale (where 0 = no pain and 10 = the most intense pain imaginable). The magnitude of BW and pain level for each condition was compared with a repeated-measures one-way ANOVA and Friedman's test, respectively (α=0.05), with a Bonferroni correction used to account for multiple post-hoc pairwise comparisons.

RESULTS

Thirteen subjects participated in the study (3 females; mean age 50±13 years; height 179±9 cm; weight 80±17 kg; residual limb length 24±3 cm). Subjects wore a variety of liners, including medi Relax 3C (n=1), Össur Seal-In X (n=8), and Össur Synergy (n=4). Soft tissues were classified as firm (n=4), medium (n=6) and soft (n=3). There was a statistically significant ($p<0.001$) difference in both pain and percentage BW between residuum conditions (Figure 1). While BW difference was significant between each condition, pain difference was only significant between the liner+socket and other two conditions. With a bare limb subjects placed a mean of 22±16% BW on their residual limb with a median pain score of 4 (interquartile range, IQR, 3-5); with the liner only subjects placed a mean of 30±18% BW on their residual limb with a median pain score of 5 (IQR 3-5); and with the liner and socket subjects placed a mean of 84±9% BW on their residual limb with a median pain score of 0 (IQR 0-1).

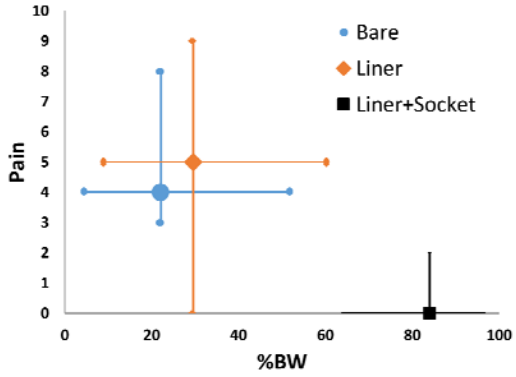


Figure 1. Mean % body weight (BW) and median pain for each condition. Bars denote maximum and minimum for each variable. *Note: This figure is not meant to explain effects of BW on pain.*

Pain changes for the liner and socket condition compared to the other two conditions exceeded the minimally clinically important difference (MCID) reported for chronic musculoskeletal pain of 1 point (2).

DISCUSSION & CONCLUSION

Using the same technique of weight bearing on a scale, Persson and Liedberg (1) reported that persons with transtibial amputations tolerated between 3-79% BW on the bare residual limb and persons with transfemoral amputations tolerated 10-39% BW. Our transfemoral data are comparable at between 4-52% BW on the bare residual limb.

The ability to bear full BW on the residual limb is important given that it occurs with every step. The developers of the NU-FlexSIV Socket propose that this is accomplished by a total surface bearing socket that globally compresses the soft tissues, thereby stiffening them (3). This idea is not new (4), however, the degree to which limbs can be compressed and the socket successfully donned has increased with availability of more compliant socket materials. Most recently, this idea has been proposed as the underlying principle for the compression and release socket, which applies three or more localized, longitudinal areas of high compression to the residual limb (5). By contrast, the NU-FlexSIV Socket provides high global compression via an undersized liner and socket (3). This study provides some indirect support for this proposed theoretical role of tissue stiffening in creating a hydrostatic weight bearing interface between the amputee and the prosthesis and demonstrates that the socket is the major contributor.

REFERENCES

1. Persson & Liedberg, Prosthet Orthot Int 1982;6:147-51.
2. Salaffi et al. Eur J Pain 2004;8:283-91.
3. Fatone & Caldwell, Prosthet Orthot Int (in press).
4. Redhead, Prosthet Orthot Int 1979;3:126-36.
5. Alley et al. J Rehabil Res Devel 2011;48:679-96.

APPENDIX S - ACCEPTED ABSTRACTS AAOP 2017

QUANTIFICATION OF RECTIFICATIONS FOR THE NORTHWESTERN UNIVERSITY FLEXIBLE SUB-ISCHIAL VACUUM (NU-FlexSIV) SOCKET

Fatone, S., PhD, BPO(Hons),[1] Tran, L., MS,[1] Tucker, K., BS,[1] Johnson, W.B., PhD,[1]
Mowrer, C., CPO,[2,3] Caldwell, R., CP[1,2]
[1]Northwestern University Prosthetics-Orthotics Center, Chicago IL; [2]Scheck & Siress Prosthetics, Orthotics and Pedorthics, Oakbrook Terrace, IL; [3]Advanced Orthotic and Prosthetic Solutions, Hickory Hills, IL

INTRODUCTION

The fit and function of a prosthetic socket depends on the prosthetist's ability to properly design the socket's shape to distribute load comfortably over the residual limb. Traditionally, the prosthetist achieves the desired shape by either removing or adding plaster to specific regions on a positive plaster model of the residual limb. As proposed by Sidles et al.[1] rectification maps can be used as a tool to teach prosthetists how to modify a positive mold for specific socket designs. We recently developed a new socket technique for persons with transfemoral amputation named the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket[2]. The aim of this study was to quantify the rectifications required to fit the NU-FlexSIV Socket in order to teach the technique to certified prosthetists as well as provide a central fabrication option via Computer Aided Design-Computer Aided Manufacture (CAD-CAM).

METHOD

The following steps were taken to quantify the rectification process for the NU-FlexSIV Socket: (1) create a pair of negative cast molds (NCMs) of unrectified and rectified positive molds, (2) digitally scan each pair of NCMs, (3) align each pair of NCM scans using a closest point algorithm, and (4) calculate the difference in depth at each point between each pair of NCM scans. The average of the differences in depths across each pair of NCM scans was used to create an average rectification template[3]. The average template was shared with a central fabrication facility to assess how it performed when used to fulfill requests for CAD-CAM fabrication of the NU-FlexSIV Socket.

RESULTS

30 unrectified and rectified cast pairs from NU-FlexSIV Sockets that were successfully fit in clinical practice were collected and scanned to create 30 color-coded rectification maps. The rectification maps confirmed that for the NU-FlexSIV Socket, plaster from the positive mold was primarily removed from the proximal-lateral and posterior regions; no plaster was added (Figure 1). The average template was used to fabricate fifteen NU-FlexSIV Sockets for five certified prosthetists (CPs). Feedback from the central fabrication facility indicated that the template worked reasonably well for the initial check socket; typically, the only adjustment needed was to add a pad to tighten up the proximal medial-lateral dimension.

Awarded and administered by the U.S. Army Medical Research and Materiel Command Acquisition Activity (#W81XWH-10-1-0744).

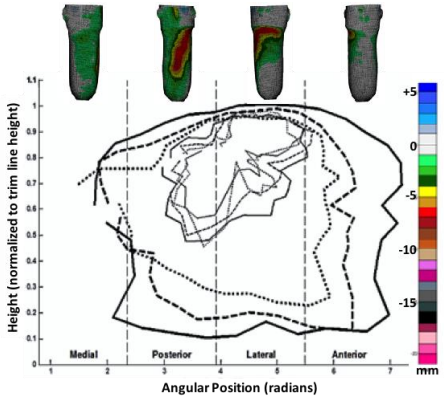


Figure 1 Illustrative color-coded rectification map shown above contour plot of the average template.

DISCUSSION

Rectification maps quantified the depths and contours of the modifications that were made for the NU-FlexSIV Socket. The exemplar rectification map was used as part of a series of 2-day hands-on continuing education workshops to teach CPs the rectification process required to fit and fabricate the NU-FlexSIV Socket[2]. 28 of the 30 CPs who participated in these courses successfully fit a check socket version of the NU-FlexSIV Socket on their first attempt and described the process as *"straight forward, reproducible"* [2]. Initial experience using the average template as part of central fabrication of the NU-FlexSIV Socket suggests that the template currently underestimates the magnitude of material removal needed in the proximal-lateral region. The 30 cast pairs used to create this initial template were collected during a period when the technique was not at full maturity and likely incorporate greater variability than the current technique. Having taught a fully mature version of the technique successfully, we are currently collecting more cast pairs to help refine this aspect of the average template.

CONCLUSION

Rectification maps and a template quantified rectifications needed to fit the NU-FlexSIV Socket.

CLINICAL APPLICATIONS

Rectification maps and template help communicate an important step in the fabrication of the NU-FlexSIV Socket facilitating dissemination of the technique and providing an alternative fabrication option via CAD-CAM and central fabrication.

REFERENCES

1. Sidles et al. J Prosthet Orthot, 1, 149-153, 1989.
2. Fatone S, Caldwell R. Prosthet Orthot Int, in press.
3. Lemaire et al. IEEE Trans Rehabil. Eng, 4, 303-309, 1996.

HYBRID VACUUM PUMP FOR VACUUM-ASSISTED SUSPENSION IN TRANSFEMORAL PROSTHESES

Major MJ[1,2], Caldwell R[1,3], Hansen A[4,5], Fatone S[1]

Northwestern University Prosthetics-Orthotics Center[1], Jesse Brown VA Medical Center[2], Scheck & Siress Prosthetics Orthotics and Pedorthics[3], Minneapolis VA Health Care System[4], University of Minnesota[5]

INTRODUCTION

Evidence suggests that vacuum assisted suspension (VAS) reduces relative motion between the residuum and prosthetic socket to improve force transmission, comfort and soft tissue health (1, 2). VAS is achieved through evacuation of air between the liner-clad residuum and prosthetic socket by vacuum pumps. Commercial pumps often have a tall build height and can be noisy (electric) or require extended time to generate vacuum (mechanical). There is need for a low-profile pump for use with transfemoral prostheses that works quietly and quickly generates vacuum when desired while conserving battery life. This study describes a hybrid vacuum pump, known as Northwestern University Hybrid Integrated Prosthetic Pump Initiative (HIPPI), that was developed to address this need by integrating electric and mechanical function into a single design (Patent US9066822, Pending 62/214,560) (3).

METHOD

The HIPPI concept relies on combined electric and mechanical function to create vacuum within the liner-socket interface. Two prototypes were developed (first with a bladder and then with a diaphragm); the bladder pump, was evaluated on the bench, and during walking using prosthesis simulators as well as a transfemoral prosthesis.

Subjects: Able-bodied individual (simulator test) [35 years, 185 cm, 78 kg]; unilateral transfemoral amputee (prosthesis test) [54 years, 183 cm, 97.5 kg].

Apparatus: A digital pressure gauge (DigiVac, Matawan, NJ) monitored vacuum during all testing with the bladder pump.

Procedures: Bench testing: A hydraulic machine (Instron, Norwood, MA) subjected the HIPPI to 300 cycles of 10 mm displacement. Simulator testing: Subject walked (0.53 m/s) for 10 min after the electric pump generated 17 in-Hg. Prosthesis testing: Subject walked (0.53 m/s) for 10 min after the electric pump generated 17 in-Hg using two pumps: 1) LimbLogic electric pump (Ohio WillowWood, Mt. Sterling, OH), and 2) HIPPI bladder pump.

RESULTS

Bladder and diaphragm pump prototypes and vacuum gauge pressure results for the different conditions of testing the bladder prototype are shown in Figure 1.

DISCUSSION

Testing demonstrated that the HIPPI bladder prototype can rapidly generate vacuum through the electric system, and sustains vacuum during walking through the mechanical system to minimize electric reactivation and maximize battery life. Off-axis loading of the bladder during walking encouraged a redesign that included a diaphragm component that, due its cup architecture, provided for more reliable function.

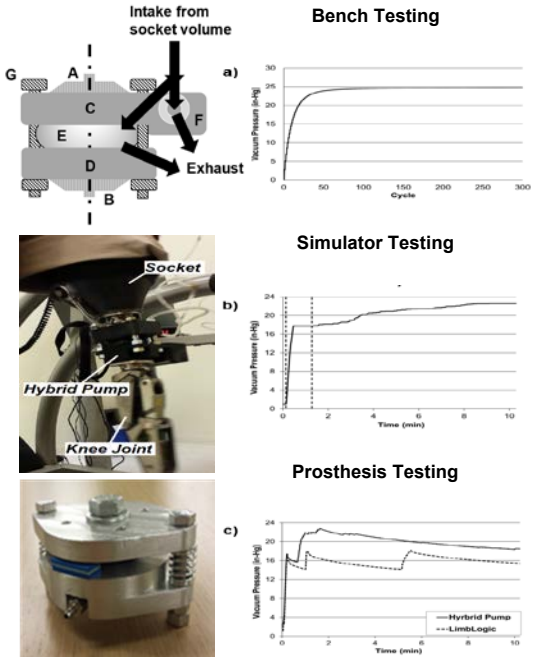


Figure 1. Top Left: HIPPI schematic (bladder pump): A&B) pyramid adapters, C&D) housing plates, E) bladder, F) electronics, and G) guide posts. Solid arrows indicate air flow. Middle Left: Transfemoral prosthesis installation. Bottom Left: HIPPI diaphragm prototype. Right: Vacuum gauge pressure for different testing conditions. For simulator testing, first and second dashed vertical lines represent initiation of the electric system and walking, respectively.

CONCLUSION

Testing has confirmed proof-of-concept that the HIPPI can generate VAS in transfemoral prostheses.

CLINICAL APPLICATIONS

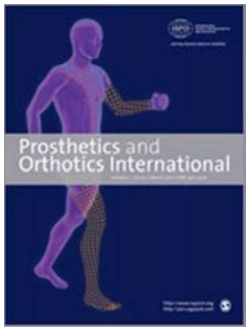
The HIPPI has utility for users who experience excessive time to create sufficient vacuum when using only a mechanical pump (e.g., elderly) and risk incurring residuum trauma, or who desire immediate use of their prosthesis post-donning (e.g., engaging in sporting activity or the military).

REFERENCES

1. Board et al. Prosthet Orthot Int 25:202-9, 2001.
2. Gerschutz et al. J Prosthet Orthot 22:252-6, 2010.
3. Major et al. J Med Devices 9:044504, 2015.

Awarded and administered by the U.S. Army Medical Research and Materiel Command Acquisition Activity (#W81XWH-10-1-0744).

APPENDIX Y - ACCEPTED MANUSCRIPT: PROSTHETICS AND ORTHOTICS INTERNATIONAL



QUANTIFICATION OF RECTIFICATIONS FOR NORTHWESTERN UNIVERSITY FLEXIBLE SUB-ISCHIAL VACUUM (NU-FlexSIV) SOCKET

Journal:	*Prosthetics & Orthotics International*
Manuscript ID	TPOI-2016-0147
Manuscript Type:	Original Research Reports
Keywords:	prosthetic design < prosthetics, CAD-CAM, fabriation techniques, prosthetics
Author-supplied Keywords:	rectification map, sub-ischial prosthetic socket, artificial limbs

SCHOLARONE™
Manuscripts

ABSTRACT

Background: The fit and function of a prosthetic socket depends on the prosthetist's ability to design the socket's shape to distribute load comfortably over the residual limb. We recently developed a sub-ischial socket for persons with transfemoral amputation: the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket. This study aimed to quantify the rectifications required to fit the NU-FlexSIV Socket in order to teach the technique to prosthetists as well as provide a Computer Aided Design-Computer Aided Manufacturing (CAD-CAM) option. **Methods:** A program was used to align scans of unrectified and rectified negative molds and calculate shape change as a result of rectification. Averaged rectifications were used to create a socket template, which was shared with a central fabrication facility engaged in provision of NU-FlexSIV Sockets to early clinical adopters. Feedback regarding quality of fitting was obtained. **Results:** Rectification maps created from 30 cast pairs of successfully fit NU-FlexSIV Sockets confirmed that material was primarily removed from the positive mold in the proximal-lateral and posterior regions. The template was used to fabricate check sockets for 15 transfemoral amputees. Feedback suggested that the template provided a reasonable initial fit with only minor adjustments. **Conclusion:** Rectification maps and template were used to facilitate teaching and central fabrication of the NU-FlexSIV Socket. Minor issues with quality of initial fit achieved with the template may be due to inability to adjust the template to patient characteristics (e.g. tissue type, limb shape) and/or the degree to which it represented a fully mature version of the technique.

Word Count: 250

CLINICAL RELEVANCE: Rectification maps help communicate an important step in the fabrication of the NU-FlexSIV Socket facilitating dissemination of the technique, while the average template provides an alternative fabrication option via CAD-CAM and central fabrication.

Word Count: 33

Introduction

The fit and function of a prosthetic socket depends on the prosthetist's ability to design the socket's shape to distribute load comfortably over the residual limb. Traditionally, the prosthetist achieves the desired shape by either removing or adding plaster to specific regions on a positive mold of the residual limb[1]. With the advent of Computer Aided Design-Computer Aided Manufacturing (CAD-CAM), rectifications can also be accomplished by digitally manipulating either a scan of the residual limb or a scan of the negative mold of the residual limb[1-5]. In either case, rectifications are performed in a manner specific to each socket design.

Since 2010, we have worked to develop a new sub-ischial socket for persons with transfemoral amputation: the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket[6, 7]. This socket was designed to improve comfort by eliminating the proximal brim typical of Ischial Containment sockets, which are the current standard of care[8]. The proximal brim has been shown to significantly reduce hip motion compared to motion without a socket[9, 10] and lack of socket comfort is a primary complaint of prosthesis users[11-13]. The NU-FlexSIV Socket combines lower trim lines with flexibility to improve comfort. Preliminary evaluation of socket use demonstrated that the NU-FlexSIV Socket improved comfort with comparable gait and functional outcomes compared to the Ischial Containment socket[7].

While function with sub-ischial or brimless sockets has been reported[7, 14-17], only the NU-FlexSIV Socket design has been described in detail with demonstrated ability to be taught to Certified Prosthetists[6]. As taught through hands-on workshops, fabrication of the NU-FlexSIV Socket follows conventional steps of casting a negative mold of the residual limb and then rectifying a positive plaster mold[6]. Teaching of this technique relied in part on development of both a Clinical Algorithm that describes how to determine the magnitude and location of

rectifications, and rectification maps[6]. Rectification maps, presenting difference in shape between the residual limb and the resulting socket, were first proposed by Sidles et al.[18]. Using this process, the shape of the residual limb and socket are measured and the two shapes aligned. Matching points on the surface of the residual limb and socket are identified and the distance between them computed. A three dimensional picture of the residual limb with a color map of the distances between each point is then created. Sidles et al.[18] proposed that rectification maps could be used to (1) teach students the rectification techniques used by successful prosthetists and compare their own attempts, (2) develop a quantitative description of methods of rectification, and (3) help develop better design tools for CAD-CAM of sockets. Rectification maps can be compared qualitatively, or the shape and/or volume change quantified. The aim of this study was to quantify the rectifications required to fit the NU-FlexSIV Socket in order to teach the technique to prosthetists as well as provide a central fabrication option via CAD-CAM as an alternative to manual mold rectification.

Methods

Pairs of negative cast molds (NCMs) of above-knee residual limbs were collected by author RC as a by-product of his clinical practice. They represented the rectifications used with patients who were successfully fit with a NU-FlexSIV Socket. The University's Institutional Review Board approved a waiver of consent for this study because the NCMs were not directly linked to the patients they came from and were a by-product of the fabrication process. Using the method described by Sidles et al.[18] the following steps were taken to quantify the rectification process: (1) incorporated alignment markers into the positive mold, (2) created a pair of NCMs of the unrectified and rectified positive molds, (3) scanned each pair of NCMs, (4) aligned each pair of

NCM scans, (5) calculated the difference in depth between each pair of NCM scans, and (6) averaged the difference in depth across pairs of NCM scans to create a rectification template. To prepare for steps 1 and 4, a custom set of three cross-shaped alignment markers were 3D printed from Polycarbonate/Acrylonitrile Butadiene Styrene (PC-ABS) plastic using a Stratasys Fused Deposition Modeler 400mc (Stratasys, Ltd., Edina, MN). Two markers were 40x40x10 mm and one marker was 40x50x10 mm in dimension (Figure 1A).

1. Incorporate Alignment Markers into Positive Mold

Standard clinical procedures were followed to create first a negative and then a positive mold of each patient's residual limb. The negative mold of the residual limb was taken by wrapping fiberglass bandage circumferentially around the liner-clad limb as described in Fatone and Caldwell[6]. When preparing the negative mold for filling with liquid plaster, a generous extension of fiberglass or plaster bandage was added proximal to the intended socket trim line in order to create a proximal section in the positive mold to which alignment markers could be attached (Figure 1B). This extended section was not modified during the rectification process. Three alignment markers were nailed to the positive mold, proximal to the proximal socket trim line: the largest marker was placed in line with the anterior midline and the other two markers on the medial and lateral midlines (Figure 1F). A carpenter's set square was used to ensure that the medial and lateral markers were placed in line with the anterior marker (Figures 1C, 1D, 1E).

2. Create a Pair of NCMs of the Unrectified and Rectified Positive Molds

Prior to and following rectification of the positive mold for a NU-FlexSIV Socket, a cast sock was placed over the positive mold and a negative fiberglass wrap of the positive mold was

made that incorporated the proximal alignment markers. This resulted in a pair of unrectified and rectified NCMs for each residual limb.

3. Scan each Pair of NCMs

Digital scans of each NCM were taken to acquire their spatial polar coordinates, which would be used to quantify the differences in shape and depth between each pair of unrectified and rectified NCMs. Rectification of the NU-FlexSIV Socket is based on a quadrant system wherein plaster is removed primarily from the lateral and posterior quadrants[6]. Hence, prior to scanning the NCMs, unrectified regions of the positive mold were colored with a black permanent marker so that they could be registered by the digital scanner. These regions included the cross-shapes of the three alignment markers and a black rectangle drawn on the distal medial wall (Figure 2). The inner surface of each NCM was then digitally scanned using a Provel d1 Digitizer (Provel, Cle Elum, WA). The digital scans were processed using ShapeMaker software (S&S ShapeMaker, Hickory Hills, IL) and the registered alignment landmarks labeled as follows: Anterior, Medial, Lateral (from the three cross-shapes) and MW1, MW2, MW3, and MW4 (from the four midpoints of each side of the rectangle drawn on the distal medial wall).

4. Align each Pair of NCM Scans

A MATLAB script was used to align the unrectified NCM scan and its corresponding rectified NCM scan with respect to the seven landmarks extracted in step 3 above so that corresponding unrectified regions of the scans coincided with one another. The alignment procedure began by slicing each scan along its longitudinal axis (Z-axis) and, for each slice, calculating the centroid. A linear regression was performed to find the best fit line for all centroids,

which was used to define the long axis of each scan. The NCM scans were rotated and translated to align these long axes with the global z-axis. The anterior markers were then brought into alignment with the global x-axis and translated along the z-axis so that the two markers coincided. Next, four regions of commonality between the unrectified and rectified NCM scans were defined according to the positions of the landmarks: three regions were centered about the alignment markers placed proximally and the remaining region was centered about the four landmarks that defined the medial wall. These regions were used to refine the alignment using an iterative closest point algorithm[19, 20] (Figure 3A).

5. Calculate the Difference in Depth between each Pair of NCM Scans

Once the NCM scans were properly aligned, a MATLAB script was used to calculate differences in the shape and depth between the unrectified and rectified NCMs. Vertices from the rectified shape were projected onto the unrectified shape along their vertex normal and the differences between scans quantified by subtracting the vertices from their corresponding projected points. A color coded scale with units in millimeters was used to indicate the depth of rectification. Negative numbers were used to indicate that plaster was removed from the positive mold, while positive numbers were used to indicate addition of plaster. However, only negative numbers were needed since the NU-FlexSIV Socket technique requires only removal of plaster. The color-coded rectification maps for each pair of NCM scans revealed the depth and shape of the modifications that were made to each positive mold (Figure 3B). The outer edges of each colored region on the rectification map formed loops that we refer to the loops as contours.

6. Average the Differences in Depth across Pairs of NCM Scans to Create an Average Rectification Template

To identify a general pattern of rectifications, another MATLAB script was used to take an average of all the rectification maps. Coordinates along the contours of the rectification maps were defined by their position along the longitudinal axis (Z) and their angular position about the longitudinal axis (θ). The Z components were normalized by the height of the trim line as measured directly beneath the lateral marker. The contours were grouped together according to their depth, arc measure about the longitudinal axis, and length along the longitudinal axis. The mean of the Z and θ coordinates for each group of contours was calculated and then subtracted from each of the coordinates to center the data. Then, following the example of Lemaire and Johnson[3], the 3D contours were simplified by projecting them onto a 2D graph with axes labeled θ and Z. This θ-Z plane was divided radially into 10° sections, and points within each section were averaged together to yield an average contour. The mean of the original group of coordinates was then added back to each of the newly averaged coordinates to place them in the original reference frame of the cast. Figure 3C shows the resulting average contours on the θ-Z plane.

The average template created with the above process was shared with a central fabrication facility to assess how it performed when used to fulfil requests for CAD-CAM fabrication by early clinical adopters of the of the NU-FlexSIV Socket following workshops held in 2015[6]. As is typical in the central fabrication of prosthetic sockets, Certified Prosthetists sent unrectified NCMs of the residual limb, which were then digitally scanned and rectified by the central fabrication facility using the NU-FlexSIV Socket template[5]. The template was applied in proportion to the circumference and length of the unrectified NCM digital scan. The digital scan is referenced by vertical slices with a fixed number of polar coordinates per slice. A resolution of 1.5mm slices

with 190 points per slice were used, which allowed for data points every 2°. Once the template was applied, a blending function was used to smooth out the transition between contour regions within the template. A foam positive mold was carved into the rectified shape and a diagnostic check socket fabricated and sent to the prosthetist for fitting to the patient. If necessary, modifications were made by the prosthetist to the diagnostic socket to improve fit. For the NU-FlexSIV Socket, modifications consisted of gluing foam pads to the inner surface of the proximal socket to reduce volume and/or heating and flaring the socket where increased volume or less proximal edge pressure was desired. Once the prosthetist and patient were satisfied with the fit of the diagnostic socket (with or without modifications), the socket was returned to the central fabrication facility for definitive socket manufacture. This was accomplished by scanning the inner surface of the diagnostic socket to capture the adjusted shape and carving a new positive mold from a foam block so that the definitive NU-FlexSIV Socket could be fabricated.

Results

Thirty pairs of unrectified and rectified casts were collected from patients of author RC who were successfully fit with a NU-FlexSIV Socket as part of their clinically prescribed care. All sockets achieved total contact without any socks between liner and socket. The color-coded rectification maps and average template confirmed that for the NU-FlexSIV Socket, plaster from the positive mold was primarily removed from the proximal-lateral and posterior regions (Figures 3B and 3C). As shown in the contour map of the average template in Figure 3C plaster removal was deepest in the center of the contours and gradually spread out from the center.

The average template for the NU-FlexSIV Socket was used by the central fabrication facility to create diagnostic check sockets for 15 transfemoral amputee patients ordered by five

Certified Prosthetists. Feedback from the central fabrication facility suggested that the template provided a reasonable initial fit as typically the only adjustment made to the check socket was to add a pad to decrease the proximal medio-lateral dimension of the socket intended to improve coronal plane stability of the socket with respect to the residual limb.

Discussion

While other researchers and clinicians have begun to evaluate the performance of sub-ischial or brimless sockets[21-23], to our knowledge, no one else has yet described a technique for fabricating and successfully fitting sub-ischial sockets[6]. This study describes rectification maps and an average template specific to the NU-FlexSIV Socket to facilitate teaching and central fabrication of this socket technique.

Rectification maps such as those calculated in this study have been used to compare consistency of cast rectifications between prosthetists[24], build CAD-CAM templates[2, 3, 25], and to assess CAM sockets[4, 5]. As proposed by Sidles et al.[18], rectification maps can also be used as a tool to teach prosthetists how to modify a positive mold for specific socket designs. Additionally, Sidles et al.[18] noted that the alignment used to compute rectification maps is convention-dependent: choose the alignment that minimizes the amount of material added or removed or choose an alignment that preserves anatomic landmarks known to be invariant (e.g. the tibial crest in a transtibial socket or in our case the distal medial wall). We chose to use the latter because the NU-FlexSIV Socket requires removal of material in only a single contiguous rectification spanning the lateral and posterior regions.

Rectification maps of the NU-FlexSIV Socket were used as part of a series of 2-day hands-on continuing education workshops to teach Certified Prosthetists the rectification process required

to fit and fabricate the NU-FlexSIV Socket[6]. The color-coded rectification maps depicted that the target areas for removing plaster from the positive mold are the proximal-lateral and posterior regions (Figure 3B). The shape of plaster removal was described as being that of a boomerang, beginning proximal-laterally and wrapping posteriorly. It was previously reported that 28 of the 30 Certified Prosthetists who took the NU-FlexSIV Socket courses held in summer 2015 successfully fit a check version of the NU-FlexSIV Socket on their first attempt with only minor adjustments needed[6]. Adjustments typically consisted of gluing a foam pad to the inner surface of the socket to decrease either the proximal medio-lateral dimension or the proximal anterior-posterior dimension and/or heating and flaring the medial or posterior trim line where increased volume or less proximal edge pressure was needed. Patient models were able to walk comfortably in the rigid check socket with little visual change in gait when compared to their regularly used socket.

In calculating the rectification maps and template for the NU-FlexSIV Socket, a MATLAB script was written to align digital scans of unrectified and rectified NCMs and calculate changes in the shape as a result of rectification. Negative casts constructed from fiberglass bandage can warp and create the appearance of changes where there actually were none. Scanning unrectified and rectified positive molds directly rather than negative casts may help simplify and improve accuracy of the alignment process. This would also avoid introducing variability during scanning from orientation of the NCM in the scanner. If digital scans were taken of a single positive mold before and after rectification it would eliminate errors from warping and decrease the degrees of freedom for orientations from 3 to 1, simplifying the alignment process.

When rectifying manually, a Clinical Algorithm[6] that considers residual limb characteristics such as tissue type and limb shape, is used to determine the magnitude and location

of plaster removal from the positive mold, resulting in some variation across patients. The Clinical Algorithm leads prothetists to choose target circumferential reductions of 6-5-4%, 5-4-3%, or 4-3-2% gradated from proximal to distal. However, in developing the template for the NU-FlexSIV Socket, 30 cast pairs representing varying limb characteristics were collected and their rectifications averaged together regardless of the target reduction actually performed. Hence, when using the template the magnitude of material removal applied digitally was exactly the same for each residual limb. It is therefore not surprising that initial experience using the average template, which applies the least circumferential reductions as part of central fabrication of the NU-FlexSIV Socket, suggested that it often underestimated the magnitude of material removal needed in the proximal-lateral region. This issue may be addressed by comparing the circumferences of the template-modified model to the original model and the circumferences adjusted based on the prosthetists evaluation of tissue type to better match the 6-5-4%, 5-4-3%, or 4-3-2% gradation suggested by the Clinical Algorithm. A more sophisticated template would allow the CAD-CAM user to enter patient-specific residual limb characteristics similar to those used in the Clinical Algorithm and auto-adjust the template to ~~potentially~~ achieve a more precise fit for that individual patient.

An additional factor to consider when evaluating performance of the average template, is that the 30 cast pairs used to create the initial template were collected during a period when the technique was not fully mature. Early on, the technique was likely more variable and/or less aggressive in the amount of plaster reduction than the current technique. Having taught a current version of the technique successfully, collection of additional cast pairs using the more mature technique may help further refine the average template.

Conclusion

In summary, rectification maps help communicate an important step in the fabrication of the NU-FlexSIV Socket, facilitating dissemination of the technique to other prosthetists. Rectification maps were averaged to create a NU-FlexSIV Socket template that provides a central fabrication option via CAD-CAM as an alternative to manual mold rectification.

Word Count: 3055~~2929~~

Declaration of Conflicting Interest

The Authors declare that there are no conflicts of interest with the exception of authors RC and CM, who are employed by Scheck and Siress Inc., the company that provided us access to ShapeMaker software at no cost. Scheck and Siress also owns Advanced O&P Solutions (AOPS) which was the central fabrication facility that trialed our template as part of the provision of commercial central fabrication services to prosthetists.

Author RC is also an employee of Northwestern University in which capacity he was the co-developer with author SF of the socket technique and contributed intellectually to the rectification maps and template development, as well as drafting of the manuscript for clinical interpretation. Author RC provided all negative cast models used in the analysis as a byproduct of his clinical practice.

Author CM was not involved in the study until template development was finished and shared with AOPS. He oversaw use of the template in the central fabrication process and provided feedback on the template's performance. He also contributed to the last paragraphs of the Methods and Results sections that describe the use of the template in central fabrication.

The decision to submit this manuscript for publication was made solely by the principal investigator (author SF). Study data is stored on a password-protected computer to which authors RC and CM do not have access.

Authorship Contributions

All authors contributed to the drafting and editing of this manuscript and approved the final version. Drafting and revision of this manuscript was undertaken primarily by authors SF, WJ, LT, and RC. Author KT contributed to the Methods section that described the quantification of rectifications. Author CM contributed to the last paragraphs of the Methods and Results sections that described the use of the template in fabrication.

References

1 Boone DA, Harlan JS, Burgess EM. Automated fabrication of mobility aids: review of the AFMA process and VA/Seattle ShapeMaker software design. *J Rehabil Res Dev* 1994; 31:42-49.

2 Lemaire ED, Bexiga P, Johnson F, Solomonidis SE, Paul JP. Validation of a quantitative method for defining CAD/CAM socket modifications. *Prosthet Orthot Int* 1999; 23:30-44.

3 Lemaire ED, Johnson F. A quantitative method for comparing and evaluating manual prosthetic socket modifications. *IEEE Trans Rehabil Eng* 1996; 4:303-309.

4 Sanders JE, Severance MR. Assessment technique for computer-aided manufactured sockets. *J Rehabil Res Dev* 2011; 48:763-774.

5 Sanders JE, Severance MR, Myers TR, Ciol MA. Central fabrication: carved positive assessment. *Prosthet Orthot Int* 2011; 35:81-89.

6 Fatone S, Caldwell R. Northwestern university flexible sub-ischial vacuum socket for persons with transfemoral amputation: Part 1 description of technique. *Prosthet Orthot Int* in press;

7 Fatone S, Caldwell R. Northwestern university flexible sub-ischial vacuum socket for persons with transfemoral amputation: Part 2 preliminary evaluation. *Prosthet Orthot Int* in press;

8 Muller MD. Transfemoral Amputation: Prosthetic Management. In: Krajbich JI, Pinzur MS, Potter BK and Stevens PM, editors. Atlas of Amputations and Limb Deficiencies: Surgical, Prosthetic, and Rehabilitation Principles. 4th ed. Vol 2. Rosemont, IL: American Academy of Orthopaedic Surgeons. 2016. p. 537-554.

9 Hagberg K, Haggstrom E, Uden M, Branemark R. Socket versus bone-anchored trans-femoral prostheses: hip range of motion and sitting comfort. *Prosthet Orthot Int* 2005; 29:153-163.

10 Zachariah SG, Sorenson E, Sanders JE. A method for aligning trans-tibial residual limb shapes so as to identify regions of shape change. *IEEE Trans Neural Syst Rehabil Eng* 2005; 13:551-557.

11 Dillingham TR, Pezzin LE, MacKenzie EJ, Burgess AR. Use and satisfaction with prosthetic devices among persons with trauma-related amputations: a long-term outcome study. *Am J Phys Med Rehabil* 2001; 80:563-571.

12 Pezzin LE, Dillingham TR, Mackenzie EJ, Ephraim P, Rossbach P. Use and satisfaction with prosthetic limb devices and related services. *Arch Phys Med Rehabil* 2004; 85:723-729.

13 Berke GM, Fergason J, Milani JR, Hattingh J, McDowell M, Nguyen V, et al. Comparison of satisfaction with current prosthetic care in veterans and servicemembers from Vietnam and OIF/OEF conflicts with major traumatic limb loss. *J Rehabil Res Dev* 2010; 47:361-371.

14 Brown SE, Esposito E, Ikeda A, Fergason J, Caldwell R, Fatone S, et al. Effect of socket design and suspension on walking mechanics. Annual Meeting of the American Society of Biomechanics. 2016 August 2-5. Raleigh, North Carolina.

15 Esposito E, Fatone S, Wilken J, Caldwell R, Fergason J. Sub-ischial prosthetic sockets improve hip range of motion and performance for individuals with transfemoral amputations. American Academy of Orthotists and Prosthetists Annual Meeting & Scientific Symposium. 2015 February 18-21. New Orleans, Louisiana.

16 Kahle JT, Highsmith MJ. Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure, and preference: ischial containment versus brimless. *J Rehabil Res Dev* 2013; 50:1241-1252.

17 Kahle JT, Highsmith MJ. Transfemoral interfaces with vacuum assisted suspension comparison of gait, balance, and subjective analysis: ischial containment versus brimless. *Gait Posture* 2014; 40:315-320.

18 Sidles JA, Boone DA, Harlan JS, Burgess EM. Rectification maps: a new method of describing residual limb and socket shapes. *J Prosthet Orthot* 1989; 1:149-153.

19 Besl PJ, Mckay ND. A method for registration of 3D shapes. *IEEE Trans Pattern Anal Mach Intell* 1992; 14:239-256.

20 Zhang ZY. Iterative point matching for registration of free-form curves and surfaces. *Int J Comput Vision* 1994; 13:119-152.

21 Kahle JT, Highsmith JM. Biomechanical superiority of brimless versus ischial ramus containment (IRC) sub atmospheric transfemoral interfaces. American Academy of Orthotists and Prosthetists Annual Meeting & Scientific Symposium. 2011 Orlando, Florida.

22 Kahle JT, Highsmith MJ. Sub atmospheric transfemoral interfaces-comparing isichial containment to brimless. American Academy of Orthotists and Prosthetists Annual Meeting & Scientific Symposium. 2012 21-24 March. Atlanta, Georgia.

23 Strachan E, Davis A, Wontorcik L. Stride-to-stride temporo-spatial gait variability and vacuum pressure deviation of trans-femoral amputees ambulating with sub-ischial prostheses. American Academy of Orthotists and Prosthetists Annual Meeting & Scientific Symposium. 2011 16-19 March. Orlando, Florida.

24 Convery P, Buis AW, Wilkie R, Sockalingam S, Blair A, McHugh B. Measurement of the consistency of patellar-tendon-bearing cast rectification. *Prosthet Orthot Int* 2003; 27:207-213.

25 Lemaire E. A CAD analysis programme for prosthetics and orthotics. *Prosthet Orthot Int* 1994; 18:112-117.

Figure Captions

Figure 1 Preparation of the positive mold: (A) 3D printed alignment markers, (B) positioning largest marker on proximal mold extension in line with the anterior midline, (C, D, E) using carpenter's set square to position medial and lateral markers, and (F) final position of all three alignment markers.

Figure 2 Alignment landmarks in the negative cast mold enhanced with a black marker pen to facilitate recognition during scanning into ShapeMaker software.

Figure 3 Comparison of casts before and after alignment: (A) Juxtaposition of unrectified and rectified casts before alignment. (B) From left to right: medial, posterior, lateral, and anterior views of rectification map from a single representative subject. Color coded scale indicates the difference in position (in mm) of corresponding points between unrectified and rectified casts. (C) Average template depicted as the average contours from 30 casts plotted on the θ-Z plane.

Figure 1

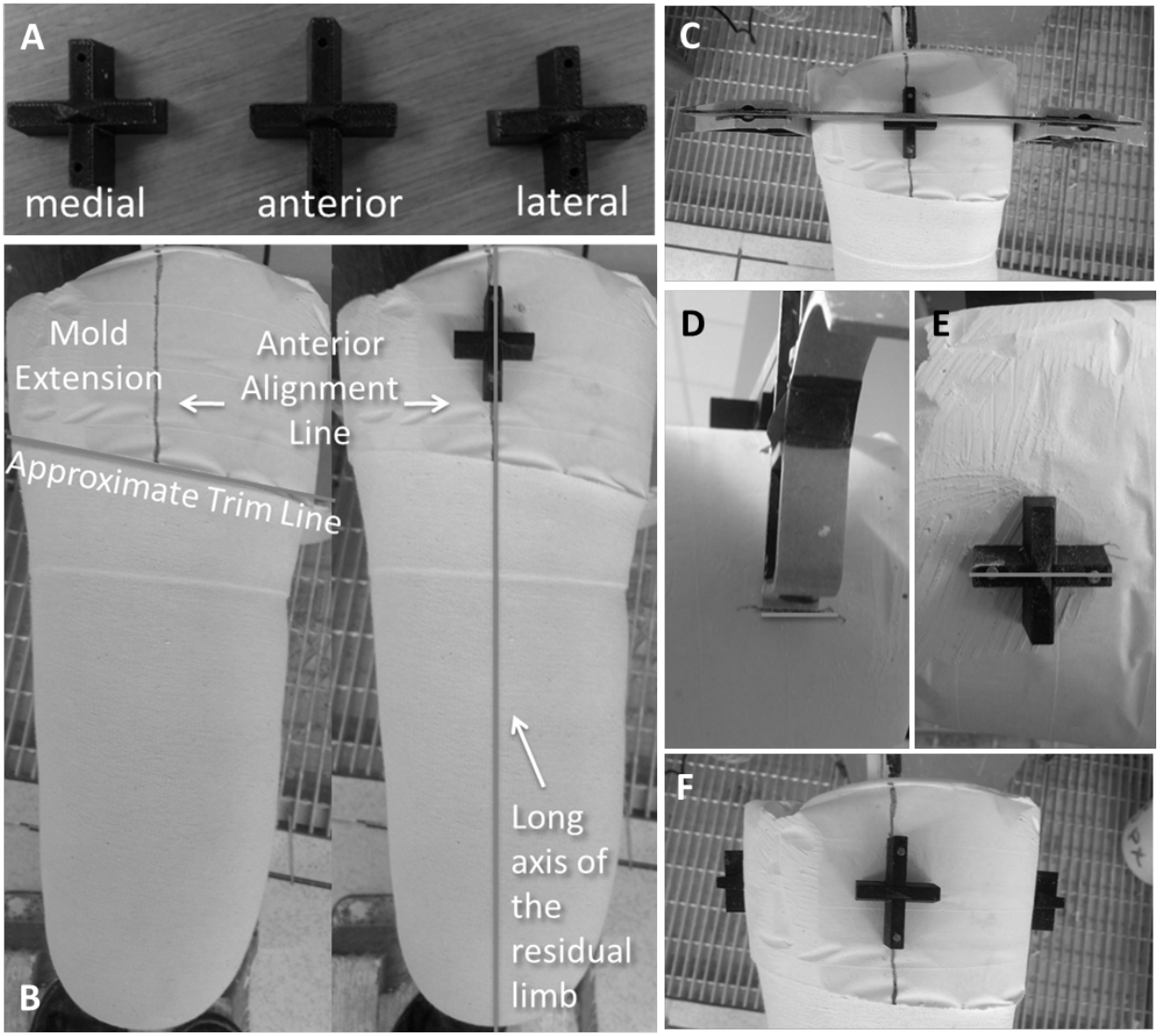
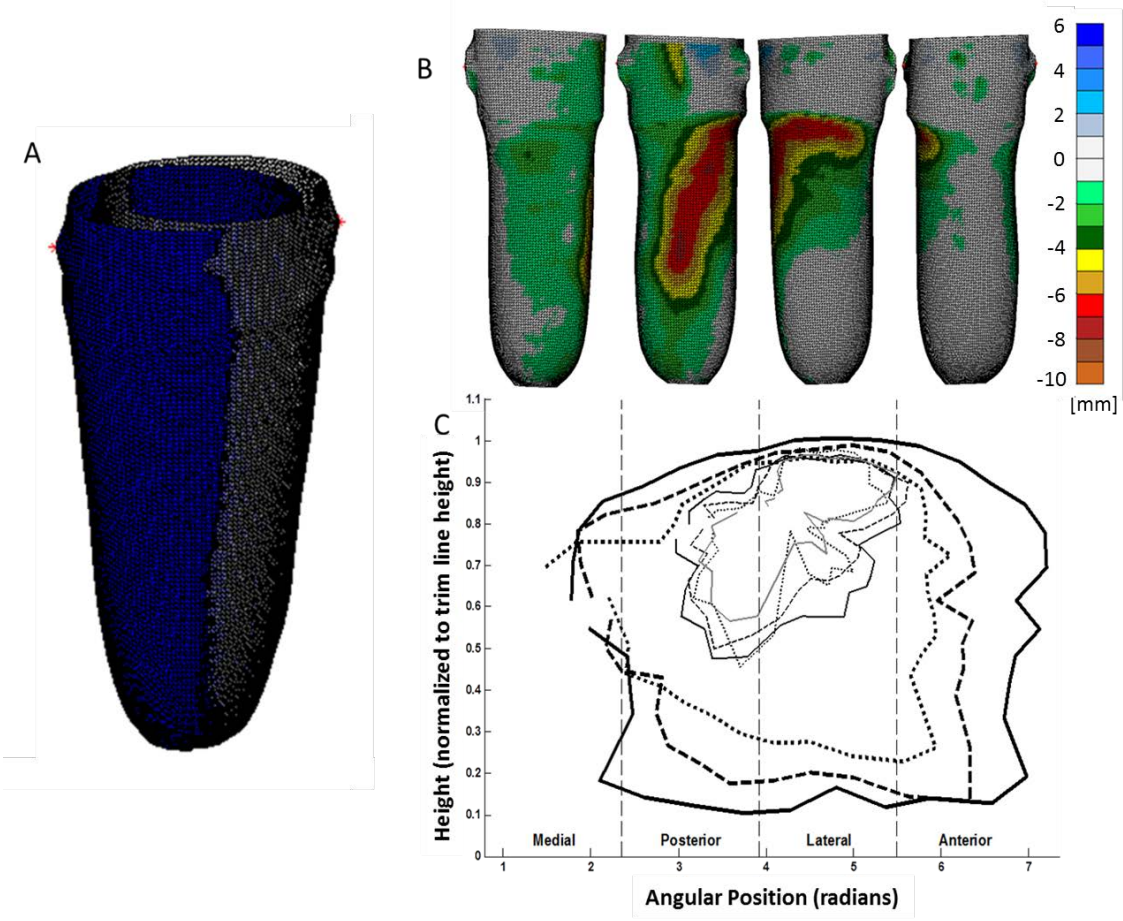

A
medial
anterior
lateral
B
Mold Extension
Anterior Alignment Line
Approximate Trim Line
Long axis of the residual limb
C
D
E
F

Figure 2



Figure 3


A
B
6
4
2
0
-2
-4
-6
-8
-10
[mm]
C
Height (normalized to trim line height)
1.1
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Medial
Posterior
Lateral
Anterior
1
2
3
4
5
6
7
Angular Position (radians)

APPENDIX Z – EDUCATION MATERIAL PRESENTED AT CONFERENCES AND MEETINGS

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.

ISPO **NORGE** | International Society for Prosthetics and Orthotics

Invitation to Seminar:

Lower Limb Socket design and rehabilitation

Tuesday 22nd October 2013 9:00 -17:00 and Wednesday 23rd October 2013 9:00 -15.00

Location:

Oslo and Akershus University College

Pilestrede 46

Kurs og Konferansesenteret

Target group:

Doctors, physiotherapists, nurses, prosthetists & orthotists (CPO)

Application: www.ispo.no/seminar before 15.10.2013

Seminar fee:

Normal Price:	**2 Day`s**	NOK 2500, 00	ISPO Norway Member	NOK 1750, 00
	students:	NOK 1250,00	ISPO Norway Student Member	NOK 875,00
	1 Day	NOK 2000, 00	ISPO Norway Member	NOK 1400, 00
	students:	NOK 1000, 00	ISPO Norway Student Member	NOK 700,00

Practical information:

Refreshments:

Lunch, fruit and coffee and tea will be provided. Please give us notice if you have any dietary requirements (e.g. gluten free, vegetarian)

Parking:

Available in the Frydenlund car park, see link for prices and map
http://www.europark.no/cms/right/p-hus-i-oslo/frydenlund-p-hus/index.htmlAccommodation
Accommodation is available at the RICA Holberg: Please state that you are attending this seminar and your reference number sent to you with your confirmation of registration.
http://www.rica.no/Hoteller/Rica-Holberg-Hotel/
Alternative accommodation is available at Cochs Pensjonat
http://www.cochspensjonat.no/

Welcome!

Preliminary program

	Tuesday 22nd October 2013	Wednesday 23rd October 2013
9.00 - 10.00	**Opening** President ISPO Norway	**Trine Kaastad - Norway** Amputation surgery and modern holistic rehabilitation of the amputee
	Marlo Ortiz - Mexico M.A.S. and other socket design	**Safran Möller - Sweden** Rehabilitation of amputees in relation with modern materials and components.
10.00-10.30	**Break**	**Break**
	Harald Steen - Norway Biomechanics situation in prosthetic sockets	**Stefania Fatone - USA** Prosthesis socket design, research for the future.
	Stefania Fatone - USA TF socket without bone weight bearing	**Rune Nilsen - Norway** Lower limb prosthetics development the clinical approach
12.00-12-30	**Lunch**	**Lunch**
	Daniel Merbold - Germany TTSM socket design With practical demonstration	**Jette Schack- Norway** Gait training with prosthetic user
	Panel discussion between speakers	**Group discussion**
End	**17.00**	**End of seminar 15.00**

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"**

Organized Session

AAOP 2014, February 28-March 1, Chicago IL

Title of Proposed Session:
Subischial Socket with Vacuum Assisted Suspension for Persons with Transfemoral Amputation

Name of Chair with professional designation:
Stefania Fatone, PhD, BPO(Hons),
Associate Professor, Department of Physical Medicine and Rehabilitation
Feinberg School of Medicine, Northwestern University, Chicago IL, USA

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

Session Description

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 provides insights into the potential benefits of this socket for persons with transfemoral amputation.

Proposed Speakers

Name	**Affiliation**	**Email address**
Ryan Caldwell, CP	Northwestern University Scheck & Siress Pedorthics, Prosthetics and Orthotics	r-caldwell@northwestern.edu
Stefania Fatone, PhD, BPO(Hons)	Northwestern University	s-fatone@northwestern.edu

oandp.com

Your Resource for Orthotics & Prosthetics Information

OPIE Software

You are here:

- Home
  - Associations
    - The Academy Celebrates 40 Years

The Academy Celebrates 40 Years

The O&P EDGE
April 2014

By Andrea Spridgen

Content provided by *The O&P EDGE*
Current Issue - Free Subscription - Free eNewsletter - Advertise

Exclusive live coverage from *The O&P EDGE*

About 1,650 attendees braved the cold weather in Chicago, Illinois, February 26–March 1, as the American Academy of Orthotists and Prosthetists (the Academy) celebrated its 40th anniversary at its Annual Meeting & Scientific Symposium. The meeting kicked off Wednesday evening with the opening session, during which Michelle Hall, CPO, FAAOP, the Academy's president, stressed the value of volunteerism within the O&P profession and the Academy. She emphasized the need for practitioners to get actively involved in professional organizations and their communities to increase awareness of the profession in the current climate of Medicare audits and other administrative challenges.



The 2014 class of Academy fellows, from left: Jacqueline M. Valdez, CO, FAAOP; Timothy A. Marrin, CPO, FAAOP; Richard L. Riley, CP, FAAOP; Timothy B. Shride, CPO, FAAOP; Michael W. Magee, CPO, FAAOP; Eric Neufeld, CPO, FAAOP; and Leigh Davis, MSPO, CPO, FAAOP. *Photographs courtesy of The Academy.*

The Academy awards were also presented at the opening session. Carl Caspers, CPO, was honored with the Titus-Ferguson lifetime achievement award in recognition of the impact he has made on the growth and development of the O&P profession. In accepting his award, he acknowledged the important role teamwork played throughout the years he spent developing products for the prosthetics industry, such as the TEC soft liner and what is now known as the Ottobock Harmony® Vacuum Management System. The Distinguished Practitioner award was presented posthumously to Arturo Vaìzquez Vela, CPO, CPO (M), CFom, FAAOP, in recognition of his personal dedication and leadership to the advancement of the O&P profession; his wife, daughter, and son accepted the award in his honor. Jonathan Naft, CPO, LPO, received the Clinical Creativity Award; JoAnne Kanas, DPT, CPO, received the Clinical Commitment Award; and Kenton R. Kaufman, PhD, PE, received the Academy's Research Award. An honorary Membership Award was presented to Stuart L. Weinstein, MD, and posthumously to Ignacio Ponseti, MD. Christopher Robinson, MS, MBA, CPO, ATC, FAAOP, received the Outstanding Educator Award. A new award was introduced this year as well, the Carlton Fillauer Prize for Outstanding Contribution to Prosthetics Science and Practice, which was presented to Phil Stevens, MEd, CPO, FAAOP.

The Thranhardt Lectures were presented Thursday morning in a stand-alone session with top awards going to Shane Wurdeman, PhD, MS, CP, for "Stride-to-Stride Fluctuations are Related Before and After Adaptation for an Appropriate Prosthesis," and Liang-Wey Chang, PhD, CO, PE, for "Ankle Push-off and Mechanical Energy Flow in Human Gait."


Hall presenting the Titus-Ferguson Award to Caspers.

Thursday through Saturday offerings also included professional development sessions, instructional courses, and symposia presentations, free-paper and poster presentations, demonstrations and discussions of clinical and practice management techniques and issues, manufacturer workshops, and product preview presentations. This year, all upper-limb prosthetic content was scheduled on a single day, which Academy representatives said was well received. There were also full-day pedorthic and technician education programs. A total of 100 continuing education credits were available throughout the symposium, and organizers estimated that an individual could earn up to 40 credits. The most popular sessions included "Challenging Prosthetic Case Presentations," "Scoliosis BAIST [Bracing in Adolescent Idiopathic Scoliosis Trial] Outcomes," "3D Printing and Additive Manufacturing: The Wave of the Future," "Subischial Socket with Vacuum Assisted Suspension for Persons with Transfemoral Amputation," and "If You Don't Know Your Numbers, You Don't Know Your Business!"

Among the special events offered this year was the Northwestern University Prosthetics-Orthotics Center (NUPOC) Education, Research, Gait, and Outcomes Soiree. Attendees at this event were shuttled to the NUPOC facility to view short presentations and demonstrations on gait measurement tools, clinically relevant research, and 3D fabrication, among other topics. There was also time for socializing and bidding on auction items at the Orthotic & Prosthetic Activities Foundation's (OPAF's) annual fundraiser, which was held in conjunction with the NUPOC Soiree.

The exhibit hall, with 180 exhibitors, was well attended, and product display showcases provided demonstrations and opportunities to earn continuing education credits as well.

The Academy's 41st Annual Meeting & Scientific Symposium is scheduled for February 18-21, 2015, in New Orleans, Louisiana.

SHARE

Like Be the first of your friends to like this.

Comment on this article by sending an e-mail to editor@opedge.com

Advertisement



Advertisements

- Paceline/Rx Textiles We are proud to introduce our new company name: Paceline. Everything else—from the high quality of our products to the close collaboration of our team with yours—will remain the same.
- Apis Footwear Mt. Emey premier diabetic footwear package. Accommodate, never correct. Charcot, edema, bunion, and hammer toes—they are all covered.
- Össur Americas The Unity sleeveless vacuum is compatible with a wide variety of Flex-Foot feet, including low-profile and microprocessor solutions. Contact your Össur representative today to get certified.
- medi USA - Prosthetic The medi 4Seal TFS Liner has integrated seals for reliable and secure grip, EZ-Glide plus outer surface (no donning aids or sprays required), and excellent tissue control due to full-length matrix.

OT World 2014

Coauthors

Caldwell RJ, Komolafe OA, Fatone, S

Title: 150 characters

Clinical outcomes using a new subischial socket with vacuum assisted suspension: the NU-FlexSIV

Summary: 300 characters

The interface between socket and residual limb is crucial to the overall success of the prosthesis user. Improved technology in liners and active vacuum systems allows prosthetists to lower transfemoral socket trim lines without compromising clinical outcomes.

Introduction: 1000 characters

There are two basic designs of prosthetic sockets for persons with a transfemoral amputation in use today both of which intentionally interact with the pelvis. Lowering the proximal trim line of a transfemoral socket is appealing because the proximal brim contributes to discomfort during sitting and limits hip range of motion. However, lower trim lines challenge conventional understanding of the biomechanics of transfemoral sockets, especially regarding coronal plane stability. A subischial socket has been proposed with proximal trim lines located distal to the ischial tuberosity and not intended to interact with the pelvis. Working in concert with vacuum assisted suspension, the Northwestern University Flexible SubIschial Vacuum (NU-FlexSIV) socket was designed to allow greater range of motion, increased comfort, and uncompromised control for the transfemoral prosthesis user. Socket design is described and case studies are presented to illustrate clinical outcomes.

Methods: 1000 characters

The NU-FlexSIV socket system was developed iteratively over many clinical fittings and then reverse engineered to improve understanding of function. The current design consists of an undersized flexible single-wall socket with an embedded frame, an undersized silicone liner reflected over the proximal socket edge and a sealing sleeve. The undersized socket and liner compress the limb, stiffening the soft tissue. This stiffening is thought to decrease relative motion of the residual limb within the socket. The embedded frame allows force transmission between the residual limb and prosthesis while maximizing overall socket flexibility. The impression is taken over the silicone liner with the patient seated with the limb flexed and abducted to allow gravity to pre-modify the tissues. Rectifications specific to this socket design are made to the positive model to ensure comfort and coupling in sitting and standing.

Results: 1500 characters

Approximately 100 clinical fittings have been conducted with this socket technology. Examples of clinical case studies will be presented demonstrating application of the NU-FlexSIV socket system. Cases with varying limb tissue types; limb lengths and skin conditions will be presented. Videos of subjects will be used to demonstrate symmetrical and uncompromised gait comparing subischial and ischial containment sockets. Improvements in limb health and tissue quality after use of the NU-FlexSIV socket system will be highlighted.

Conclusion: 1000 characters

We have developed a new socket for use by persons with transfemoral amputation that appears to provide improved comfort without loss of function. Clinically we have observed no detriments to gait compared to conventional sockets, tissue issues have improved, and an increase in subjects overall activity levels.

Proposal Form for an Instructional Course
ISPO 2015, Lyon, France

Deadline 15 September, 2014

Instructions for proposers:
Please fill in this form and save it with a new name, which includes your last name.
Then email this file to the Scientific Committee ISPO2015 at **congress_scientific@ispoint.org**. Please use as Email subject title: "Proposal for Instructional Course ISPO2015"

1.Title and topic(s)

Course Title Northwestern University Flexible Subischial Vacuum Socket (NU-FlexSIV)

Select the most appropriate congress topic: *Prosthetics : Lower Limb above knee*

Select a second topic if applicable: *none*

2. Proposer/Chair of the Instructional Course

Name *Stefania Fatone, PhD*
Profession *Researcher*
Institute *Northwestern University*
City, country *Chicago IL USA*
Email *s-fatone@northwestern.edu*

3. Information for attendees

Select level > *Advanced*

Short description (40 words max) an informative and attractive pitch, to extend on the title

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.

Long description (200 words max) Clearly state learning objectives

This instructional course will describe the motivation and background for development of the Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket; describe the socket system and provide an overview of casting, fitting and fabrication; describe efforts made to understand socket function, including modeling of the socket, quantification of the rectification process and evaluation of function using motion analysis; and describe clinical experiences to date. These efforts provide insights into the potential benefits of this socket for persons with transfemoral amputation.

Teacher 1

Name *Ryan Caldwell*
Profession *Certified Prosthetist*
Institute *Northwestern University/Scheck & Siress*
City, country *Chicago IL USA*
Email *ryan.caldwell@northwestern.edu*

Teacher 2

Name	*Click and enter name*
Profession	*Click and enter profession*
Institute	*Click and enter Institute*
City, country	*Click and enter City and country*
Email	*Click and enter Email address*

Teacher 3

Name	*Click and enter name*
Profession	*Click and enter profession*
Institute	*Click and enter Institute*
City, country	*Click and enter City and country*
Email	*Click and enter Email address*

Teacher 4

Name	*Click and enter name*
Profession	*Click and enter profession*
Institute	*Click and enter Institute*
City, country	*Click and enter City and country*
Email	*Click and enter Email address*

4 Information for the scientific committee

(200 words max) Please state why this instructional course should be included in the ISPO 2015 scientific program

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 designs do not impinge on the pelvis when the hip is moved because they have intentionally lower trimlines than typical transfemoral sockets. We recently developed a new subischial socket for persons with transfemoral amputation dubbed the Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket. The socket 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 provide good functional performance for individuals with transfemoral amputations. Attendees will gain knowledge of an additional prosthetic option for the management of persons with transfemoral amputation.

5. Final remarks

Please note that ISPO does not provide financial support (e.g. registration waiver, accommodation/travel support) to the Chair or Speakers of Instructional Courses. Please ascertain the availability and willingness of your speakers to register and attend ISPO2015 before making a proposal.

Coauthors:

Fatone S, Caldwell R

Title (131/150 Characters):

Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation

Summary (220/300 Characters):

A teachable subischial socket technique, the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket that results in improved comfort and comparable function to ischial containment sockets, was developed.

Introduction (994/1000 Characters):

Current transfemoral (TF) prosthetic sockets restrict function, lack comfort and cause residual limb problems. Although designed to support the body and enable effective load transfer during walking and other activities,[1] prosthetic sockets interface with soft tissues that are neither accustomed nor well-suited to the high pressure and shear loading that occurs during prosthetic ambulation.[2] Despite high daily use (≥12 hours), lack of socket comfort is the most common complaint of prosthesis users.[3-6] Residual limb skin problems such as cysts, calluses, verrucous hyperplasia, allergic reactions, and bacterial or fungal infections have been reported by 25 to 63% of persons with amputation with a negative influence on ability to perform household tasks, prosthesis use, social functioning, and participation in sports.[3, 7-9] The development and availability of a more comfortable and possibly functional socket may contribute to improving quality of life of persons with TF amputation.

Methods (996/1000 Characters):

A TF socket technique was developed aimed at improving comfort. The Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket (Fig 1) has lower proximal trim lines that do not impinge on the pelvis; is flexible so muscles can move comfortably within the socket as they contract during activity and improve sitting comfort; and is held securely to the residual limb by vacuum pump suction as well as compression of an undersized liner and socket.[10] The socket includes a highly compressive, cylindrical fabric covered silicone liner, a flexible inner socket, and a shorter rigid outer socket with vacuum applied between liner and inner socket. An algorithm and rectification mapping were developed to facilitate decision making for socket fabrication. Socket comfort score,[11] gait analysis, and clinical outcome measures (Rapid-Sit-To-Stand, Four-Square-Step-Test and T-Test of Agility) were used to assess socket performance. A hands-on workshop to teach this technique was piloted.

Results (1500/1500 Characters):

The undersized liner and socket are used to compress the residual limb, stiffening the soft tissue and decreasing relative motion of the limb within the socket. The impression is taken over the liner with the patient seated and the limb flexed and slightly abducted, allowing gravity to pre-modify the tissues. Rectifications were quantified using a program that aligned a series of 30 scans of rectified and unrectified negative molds and calculated changes in shape. A color coded scale on the rectification map indicates the depth and contours of the rectifications required for the NU-FlexSIV Socket, showing that

plaster is primarily removed from the proximal-lateral and posterior regions, while the medial and anterior regions remain relatively untouched. No plaster is added. For 2 subjects, socket comfort increased in the NU-FlexSIV Socket compared to an ischial containment socket. Walking speed increased for the NU-FlexSIV Socket but other gait variables, including coronal plane trunk flexion and sagittal hip motion, were comparable for level ground walking. Clinical outcome measure performance was comparable in both sockets. Three workshops held in summer 2015 were attended by 31 prosthetists from the US and Canada. Attendees were taught to cast, rectify, fit and align the NU-FlexSIV Socket. Patient models responded positively to the comfort, range of motion and stability of the NU-FlexSIV Socket while prosthetists described the technique as “straight forward, reproducible”.

Conclusions (951/1500 Characters):

To the best of our knowledge, this is the first attempt to create a teachable subischial socket technique that results in improved comfort and comparable function to ischial containment sockets, confirming previous reports.[12, 13] Color coded rectification maps help communicate an important step in this socket technique, enhancing dissemination. Socket stability during walking was confirmed by lack of lateral trunk flexion and lateral socket gapping at mid stance. Clinical experience fitting this socket to nearly 100 patients confirms these research findings. Initial evaluation of the NU-FlexSIV Socket with military amputees is promising.[14] Future work includes an assessor-blinded, randomized cross-over trial comparing comfort and functional performance with the NU-FlexSIV Socket to the ischial containment socket in persons with unilateral transfemoral amputation.

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

References (914/1500 Characters):

1. Mak et al. J Rehabil Res Dev. 2001;38(2):161-74.
2. Mak et al. Ann Rev Biomed Eng. 2010;12(1):29-53.
3. Dillingham et al. Am J Phys Med Rehabil. 2001;80(8):563-71.
4. Pezzin et al. Arch Phys Med Rehabil. 2004;85(5):723-9.
5. Berke et al. J Rehabil Res Dev. 2010;47(4):361-71.
6. Limb Loss Research and Statistics Program. People With Amputation Speak Out 2012. http://www.amputee-coalition.org/people-speak-out.pdf
7. Dudek et al. Arch Phys Med Rehabil. 2005;86(4):659-63.
8. Meulenbelt et al. Acta dermato-venereologica. 2011;91(2):173-7.
9. Meulenbelt et al. Acta dermato-venereologica. 2011;91(2):178-82.
10. Board et al. Prosthet Orthot Int. 2001;25(3):202-9.
11. Hanspal et al. Disabil Rehabil. 2003;25(22):1278-80.
12. Kahle & Highsmith. J Rehabil Res Dev. 2013;50(9):1241-52.
13. Kahle & Highsmith. Gait Posture. 2014;40(2):315-20.
14. Esposito et al. 41st AAOP Annual Meeting; February 18-21, 2015; New Orleans, LA.



Figure 1 (a) NU-FlexSIV Socket, (b) and (c) range of motion; (d) single limb stance stability; (e) rectification map.

Orthotics and Prosthetics	Innovations in prosthetics and orthotics related to improving user function, reintegration, secondary health effects (residual limb health, low back pain, osteoarthritis, etc.), and quality of life. Data driven research is requested that examines advances in prosthetics and orthotics for military patients.

Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation

BACKGROUND: Current transfemoral (TF) prosthetic sockets restrict function, lack comfort and cause residual limb problems. Although designed to support the body and enable effective load transfer during activities, sockets interface with soft tissues ill-suited to the high pressure and shear loading that occurs during prosthesis use. Socket discomfort is the most common complaint of prosthesis users. Residual limb skin problems have been reported by 25%-63% of amputees with a negative influence on ability to perform household tasks, prosthesis use, social functioning, and participation in sports. The development of a more comfortable and possibly functional socket may improve quality of life of persons with TF amputation.

METHODS: A TF socket technique was developed aimed at improving comfort. The Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket has lower proximal trim lines that do not impinge on the pelvis; is flexible so muscles can move comfortably within the socket as they contract during activity and splay during sitting; and is held securely to the residual limb by vacuum as well as compression of an undersized liner and socket. The socket includes a highly compressive, cylindrical fabric covered silicone liner, a flexible inner socket, and a shorter rigid outer socket with vacuum applied between liner and inner socket. An algorithm and rectification mapping were developed to facilitate socket fabrication. Socket comfort score, gait analyses, and clinical outcome measures were used to assess socket performance. A hands-on workshop to teach this technique was piloted.

RESULTS: The undersized liner and socket are used to compress the residual limb, stiffening the soft tissue and decreasing relative motion of the limb within the socket. The impression is taken over the liner with the patient seated and the hip flexed, allowing gravity to pre-modify the tissues. Rectifications were quantified by aligning 30 scans of rectified and unrectified negative molds and calculating shape changes. These maps indicate that plaster is primarily removed from the proximal-lateral and posterior regions, while the medial and anterior regions remain untouched. No plaster is added. For 2 subjects, socket comfort increased in the NU-FlexSIV Socket compared to an ischial containment socket. Walking speed increased for the NU-FlexSIV Socket but other gait variables were comparable for level ground walking. Clinical outcome measure performance was comparable in both sockets. Three workshops held in 2015 were attended by 31 prosthetists who were taught to cast, rectify, fit and align the NU-FlexSIV Socket. Amputees responded positively to the comfort, range of motion and stability of the NU-FlexSIV Socket, while prosthetists described the technique as *“straight-forward, reproducible”*.

CONCLUSION: This is the first attempt to create a teachable subischial socket technique that results in improved comfort and comparable function to ischial containment sockets. Rectification maps enhance dissemination by communicating an important fabrication step. Socket stability during walking was confirmed by lack of lateral trunk flexion and lateral socket gapping at mid stance. Clinical socket fittings to > 100 patients confirms these findings and initial evaluation of the NU-FlexSIV Socket with military amputees is promising.

Funded by DOD Award #W81XWH-10-1-0744.

Word count: 498/500

Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation

Stefania Fatone, PhD, BPO(Hons)[1], Ryan Caldwell, CP[1,2]

[1]Northwestern University, Chicago, IL, [2]Scheck & Siress Prosthetics, Orthotics and Pedorthics, Chicago IL

INTRODUCTION

Current transfemoral (TF) prosthetic sockets restrict function, lack comfort and cause residual limb problems. Although designed to support the body and enable effective load transfer during walking and other activities,[1] prosthetic sockets interface with soft tissues that are neither accustomed nor well-suited to the high pressure and shear loading that occurs during prosthetic ambulation.[2] Despite high daily use, lack of socket comfort is the most common complaint of prosthesis users.[3-6] Residual limb skin problems such as cysts, calluses, verrucous hyperplasia, allergic reactions, and bacterial or fungal infections have been reported by 25 to 63% of persons with amputation with a negative influence on ability to perform household tasks, prosthesis use, social functioning, and participation in sports.[3,7-9] The development and availability of a more comfortable and possibly functional socket may contribute to improving quality of life of persons with TF amputation.

METHODS

A TF socket technique was developed aimed at improving comfort. The Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket (Fig 1) has lower proximal trim lines that do not impinge on the pelvis; is flexible so muscles can move comfortably within the socket as they contract during activity and splay during sitting; and is held securely to the residual limb by active vacuum as well as compression of an undersized liner and socket.[10] The socket includes a highly compressive, cylindrical fabric covered silicone liner, a flexible inner socket, and a shorter rigid outer socket with vacuum applied between liner and inner socket. An algorithm and rectification mapping were developed to facilitate decision making for socket fabrication. Socket comfort score,[11] gait analysis, and clinical outcome measures (Rapid-Sit-To-Stand, Four-Square-Step-Test and T-Test of Agility) were used to assess socket performance. A hands-on workshop to teach this technique was piloted.

RESULTS (Figure 1)

The undersized liner and socket are used to compress the residual limb, stiffening the soft tissue and decreasing relative motion of the limb within the socket. The impression is taken over the liner with the patient seated and the limb flexed and slightly abducted, allowing gravity to pre-modify the tissues. Rectifications were quantified using a program that aligned a series of 30 scans of rectified and unrectified negative molds and calculated changes in shape. A color coded scale on the rectification map indicates the depth and contours of the rectifications required, showing that plaster is primarily removed from the proximal-lateral and posterior regions, while the medial and anterior regions remain relatively untouched. No plaster is added. For 2 subjects, socket comfort increased in the NU-FlexSIV Socket compared to an ischial containment (IC) socket. Walking speed increased for the NU-FlexSIV Socket but other gait variables, including coronal plane trunk flexion and sagittal hip motion, were comparable for level ground walking. Clinical outcome measure performance was comparable in both sockets. Three workshops held in summer 2015 were attended by 31 prosthetists from the US and Canada. Attendees were taught to cast, rectify, fit and align the NU-FlexSIV Socket. Patient models responded positively to the comfort, range of motion and stability of the NU-FlexSIV Socket, while prosthetists described the technique as “straight forward, reproducible”.

DISCUSSION

To the best of our knowledge, this is the first attempt to create a teachable sub-ischial socket technique that results in improved comfort and comparable function to IC sockets, confirming previous reports with brimless sockets.[12,13] Color coded rectification maps help communicate an important step in this socket technique, enhancing dissemination. Socket stability during walking was confirmed by lack of lateral trunk flexion and lateral socket gapping at mid stance. Clinical experience fitting this socket to over 100 patients confirms these research findings. Initial evaluation of the NU-FlexSIV Socket with military amputees is promising.[14] Future work includes a DOD funded assessor-blinded, randomized cross-over trial comparing comfort and functional performance with the NU-FlexSIV Socket to the IC socket in persons with unilateral TF.

CONCLUSION

A teachable subischial socket technique, the NU-FlexSIV Socket that results in improved comfort and comparable function to IC sockets, was developed.

REFERENCES

1. Mak et al. J Rehabil Res Dev. 2001; 38(2):161-74.
2. Mak et al. Ann Rev Biomed Eng. 2010; 12(1):29-53.
3. Dillingham et al. Am J Phys Med Rehabil. 2001; 80(8):563-71.
4. Pezzin et al. Arch Phys Med Rehabil. 2004; 85(5):723-9.
5. Berke et al. J Rehabil Res Dev. 2010; 47(4):361-71.
6. Limb Loss Research and Statistics Program. People With Amputation Speak Out 2012. http://www.amputee-coalition.org/people-speak-out.pdf
7. Dudek et al. Arch Phys Med Rehabil. 2005; 86(4):659-63.
8. Meulenbelt et al. Acta dermato-venereologica. 2011; 91(2):173-7.
9. Meulenbelt et al. Acta dermato-venereologica. 2011; 91(2):178-82.
10. Board et al. Prosthet Orthot Int. 2001; 25(3):202-9.
11. Hanspal et al. Disabil Rehabil. 2003; 25(22):1278-80.
12. Kahle & Highsmith. J Rehabil Res Dev. 2013; 50(9):1241-52.
13. Kahle & Highsmith. Gait Posture. 2014; 40(2):315-20.
14. Esposito et al. 41st AAOP Annual Meeting; Feb 18-21, 2015; New Orleans, LA.

ACKNOWLEDGEMENTS

The U.S. Army Medical Research and Materiel Command Acquisition Activity, Award #W81XWH-10-1-0744).



Figure 1 (a) NU-FlexSIV Socket, (b) and (c) range of motion; (d) single limb stance stability; (e) rectification map.

Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation

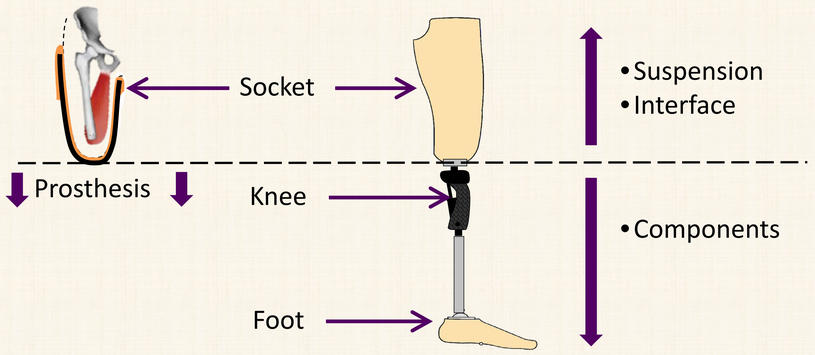
Ryan Caldwell, CP/L FAAOP, and Stefania Fatone, PhD, BPO(Hons), Northwestern University Prosthetics-Orthotics Center (NUPOC)

Northwestern Medicine®
Feinberg School of Medicine

Background

Current transfemoral prosthetic sockets restrict function, lack comfort and cause residual limb problems. Although designed to support the body and enable effective load transfer during walking and other activities (1), prosthetic sockets interface with soft tissues that are neither accustomed nor well-suited to the high pressure and shear loading that occurs during prosthetic ambulation (2). Despite high daily use, lack of socket comfort is the most common complaint of prosthesis users (3-6). Residual limb skin problems have been reported by 25% to 63% of persons with amputation with a negative influence on ability to perform household tasks, prosthesis use, social functioning, and participation in sports (3, 7-9). The development and availability of a more comfortable and possibly functional socket may contribute to improving quality of life of persons with TF amputation.

Orientation to a Transfemoral Prosthesis



Purpose of the Project

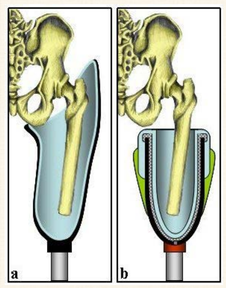
To develop a more comfortable socket technology for highly active persons with transfemoral amputations (TFA).

A. Develop the clinical technique for socket fitting and fabrication
B. Perform preliminary performance tests
C. Disseminate the technique to prosthetists

Transfemoral Socket Design Comparison

Ischial Containment (Standard of Care)

The most proximal aspect of the socket includes ischial ramal containment and trim lines proximal to the ischial tuberosity



NU-FlexSIV (New Design)

Trim lines typically 25mm distal to the ischial tuberosity do not impinge on the pelvis

NU-FlexSIV Socket

Novel Sub-Ischial Transfemoral Socket



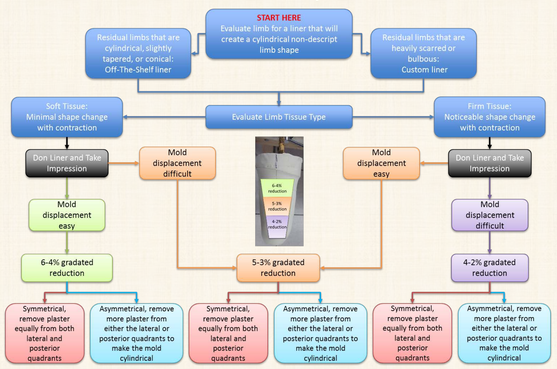
- Lower proximal trim lines
- Flexible socket construction
- Vacuum assisted suspension

→ Improve comfort and possibly function

A. Clinical technique for NU-FlexSIV fabrication and fitting

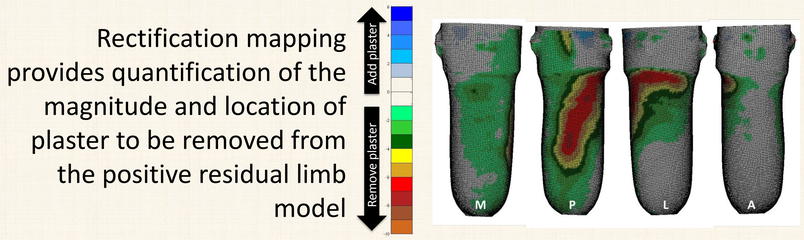
Novel to our technique is use of a transtibial silicone liner for a transfemoral limb along with casting the limb in a sitting position





Clinical decision making algorithm assists the prosthetists with residual limb evaluation, liner selection, and mold reductions

Rectification mapping provides quantification of the magnitude and location of plaster to be removed from the positive residual limb model





Fabrication of both flexible check socket and final flexible definitive socket has been described

B. Preliminary performance results on two test subjects

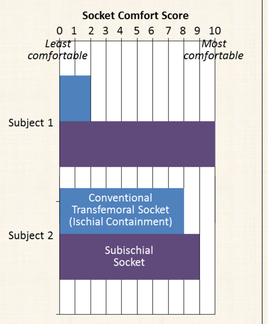




	Subject 1	Subject 2
Age	29	26
Sex	M	M
Height (cm)	181	188
Weight (kg)	84.4	89.6
Amputation	R TFA	L KDA
Cause of Amputation	Trauma	Tumor
Time since Amputation	9 years	15 years
Activity Level	Very active (construction worker)	Very active (athletic trainer)

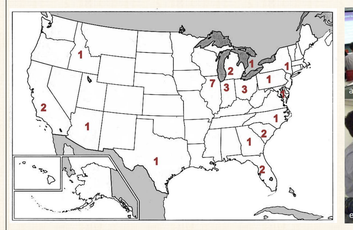
	Subject 1		Subject 2	
	Ischial Containment	Sub-ischial	Ischial Containment	Sub-Ischial
Rapid Sit to Stand*	11.81	11.66 (-1.3%)	9.41	10.46 (+10%)
Four Square Step Test*	9.52	10.6 (+10.2%)	5.47	6.95 (+21.3%)
Agility T Test**	26.6	26.81 (-0.8%)	15.75	13.1 (-16.8%)

*Percent changes do not exceed able-bodied service member's MDC's (Wilken et al. 2012)
**US service members with TFA: 27.7 ± 6 s (MDC = 3.74) (Gailey et al 2013a, b)



No change in coronal plane trunk range of motion and inconsistent changes in hip extension during walking.

C. Dissemination of the technique to prosthetists





Trained 30 Certified Prosthetists from around North America in 2015 through continuing education, hands-on workshops. Additional national and international workshops scheduled for 2016.

Conclusions

The NU-FlexSIV Socket is the first teachable sub-ischial socket technique that results in improved comfort and comparable function to ischial containment sockets.

Funding: The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. The content of this presentation does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred. Award #W81XWH-10-1-0744.

References: (1) Mak et al. J Rehabil Res Dev. 2001;38(2):161-74. (2) Mak et al. Ann Rev Biomed Eng. 2010;12(1):29-53. (3) Dillingham et al. Am J Phys Med Rehabil. 2001;80(8):563-71. (4) Pezzin et al. Arch Phys Med Rehabil. 2004;85(5):723-9. (5) Berke et al. J Rehabil Res Dev. 2010;47(4):361-71. (6) Limb Loss Research and Statistics Program. People With Amputation Speak Out 2012. http://www.amputee-coalition.org/people-speak-out.pdf (7) Dudek et al. Arch Phys Med Rehabil. 2005;86(4):659-63. (8) Meulenbelt et al. Acta Dermato-Venereologica. 2011;91(2):173-7. (9) Meulenbelt et al. Acta Dermato-Venereologica. 2011;91(2):178-82.

APPENDIX AA – NU-FLEXSIV SOCKET COURSE AGENDA

Northwestern University Prosthetics-Orthotics Center
680 North Lake Shore Drive, Suite 1100
Chicago, IL 60611
Telephone 312-503-5700
www.nupoc.northwestern.edu

NU-FlexSIV Socket

Continuing Education Course

Session 1: July 31 and August 1, 2015
Session 2: August 21 and 22, 2015
Session 3: September 11 and 12, 2015

Day 1	
7am-8am	Registration / Breakfast
8am-10am	Background Lecture: "Introduction to Subischial Socket and Vacuum Technology: The Development of the NU-FlexSIV Socket"[1] (Stefania Fatone, PhD, BPO(Hons) & Ryan Caldwell, CP/L)
10am-10.15am	Break
10.15am-11am	Liner selection and casting demonstration (Ryan Caldwell, CP/L)
11am-12pm	Participants cast patient model and pour plaster (all instructors)
12pm-1pm	Lunch
1pm-2pm	Rectification demonstration (Ryan Caldwell, CP/L)
2pm-6pm	Participants rectify casts, pull and finish check sockets (all instructors)
Day 2	
7.30am-8.30am	Breakfast / Extra lab time for participants, if needed (all instructors)
8.30am-10am	Demonstration check socket fitting (Ryan Caldwell, CP/L)
10am-10.15am	Break
10.15am-12pm	Participants set up for check socket fitting (all instructors)
12pm-1pm	Lunch
1pm-4pm	Participants fit check sockets to patient models (all instructors)
4pm-4.30pm	Final troubleshooting and Q&A (Ryan Caldwell, CP/L & Stefania Fatone, PhD, BPO(Hons))
4.30-5pm	Discussion of Definitive Socket Fabrication Options (Ryan Caldwell, CP/L & Stefania Fatone, PhD, BPO(Hons))

[1] The research project, "Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations", is funded by Department of Defense grant #W81XWH-10-0744. The course, "NU-FlexSIV Socket" is underwritten by the same DOD grant.
See: http://www.nupoc.northwestern.edu/research/projects/lowerlimb/dev_subischial.html

NORTHWESTERN UNIVERSITY

Northwestern University Prosthetics-Orthotics Center
680 North Lake Shore Drive, Suite 1100
Chicago, IL 60611
Telephone 312-503-5700
www.nupoc.northwestern.edu

Course Personnel

Stefania Fatone, PhD, BPO(Hons), Associate Professor, NUPOC, Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University.
Email: s-fatone@northwestern.edu
Dr. Fatone is Principal Investigator of the DOD-funded project "Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations" (#W81XWH-10-0744). A graduate of La Trobe University (Australia, 1995) with a Bachelor of Prosthetics and Orthotics (Honours) and a PhD in Biomechanics (2000), she joined NUPOC as a post-doctoral fellow (2000). Dr. Fatone has conducted multidisciplinary research on the effects of prostheses and orthoses on human locomotion to increase understanding, efficiency and effectiveness of P&O interventions for people with physical disability. She has more than 51 publications and frequently is invited to speak and conduct specialty courses about P&O throughout the USA and internationally.

Ryan Caldwell, CP/L, FAAOP, Visiting Fellow, NUPOC, Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University.
Email: ryan.caldwell@northwestern.edu
Mr. Caldwell is a prosthetist who specializes in Vacuum and Subischial Socket Technology, and is the primary developer of the socket technique developed by the DOD-funded project "Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations" (#W81XWH-10-0744). He completed his prosthetics and orthotics (P&O) training at NUPOC, is an ABC-Certified Prosthetist, and a Fellow of the American Academy of Orthotists and Prosthetists. An active clinician since 2001, Mr. Caldwell is a prosthetist at Scheck & Siress Prosthetics, Orthotics and Pedorthics (Schaumburg, IL). He teaches vacuum technology at NUPOC, has taught in the Physical Therapy Program at Oakton Community College, and frequently presents at professional meetings.

John Brinkmann, MA, CPO, FAAOP, Instructor, NUPOC, Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University.
Email: john.brinkmann@northwestern.edu
Mr. Brinkmann joined NUPOC in 2012 after providing clinical services for more than 20 years and managing multiple P&O practices. He completed a BS in Orthotics and Prosthetics at University of Texas Southwestern in 1990 and a MA at Trinity Evangelical Divinity School (Deerfield, IL). He received a Searle Fellowship through Northwestern University and worked on "Establishing Criteria for Transtibial Impression Assessment". He sits on the AAOP Board of Directors, is immediate past chair of the Academy Gait Society, and directs the AAOP Midwest Chapter.

Mike Cavanaugh, CPO, Lecturer, NUPOC, Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University.
Email: michael.cavanaugh@northwestern.edu
Mr. Cavanaugh joined NUPOC in 2014. He is a graduate of NUPOC P&O programs and an ABC-Certified Prosthetist-Orthotist. He has 8 years of clinical experience, in addition to his background in industrial engineering and education course design. He has served as a preceptor for P&O graduate students and a mentor for P&O residents.

Course Registrar/Organizer: R. J. Garrick, PhD, NUPOC, Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University.
Email: r-garrick@northwestern.edu

APPENDIX BB – HIPCHAT ONLINE FORUM

HipChat

https://nu-flexsiv.hipchat.com/chat

Apps | NU Box | EES APMR | NUPOC | eIRB+ | Backup | Canvas | StudyTracker | Intercampus Shuttle: | Kronos

HipChat | New chat | Invite your team | Search history

Nu-flexsiv

ROOMS

NU-FlexSIV

+ Create a room

PEOPLE

Sagar Shetty

+ Invite your team

NU-FlexSIV

This is the room topic. Double click to change it.

Tuesday August 4, 2015

RJ Garrick · Aug-4 1:02 PM

Follow-up Forum: NU-FlexSIV Socket Course

What if I have questions about NU-FlexSIV after the course?
Having participated in the NU-FlexSIV Socket Course we hope you will return to your practice and continue trying to implement it with your transfemoral patients. We anticipate that as you do this you may encounter additional questions or issues with which you may need help. To efficiently facilitate ongoing learning and troubleshooting for all course participants we

Show more

RJ Garrick · Aug-4 2:09 PM



Caldwell-JTB.jpg
258K

11:44 PM
12/9/2016

APPENDIX CC – 2016 KEYNOTE PRESENTATIONS

DANSKE BANDAGISTER

Peter Rørdams Vej 11
2800 Kgs. Lyngby
Telefon +45 40 45 51 65
danske.bandagister@mail.dk

DANSKE BANDAGISTERS ÅRSMØDE DEN 1.- 2. APRIL 2016 PÅ HOTEL HESSELET NYBORG



Fagligt program

Fredag den 1. april 2016

08:00 – 09:00 Morgenkaffe - Lokale Hesselhaven

09:00 – 10:00 Generalforsamling for Lønmodtagerfraktionen - Lokale Store Hessel

09:00 – 10:00 Generalforsamling for Danske Bandagistvirksomheder - Lokale Havestuen

10:00 – 11:00 Udstilling – Lokale Hesselhaven
Kaffe og kage i udstillingsområdet

11:00 – 11:45 "Bandagistuddannelsen i Danmark" – Lokale Store Hessel
Foredragsholdere: Birgitte Foged, uddannelsesleder og
Karsten Thorø, studiekoordinator, VIA, Sundhedsfaglig Højskole, Aarhus

Status for den reviderede A-del i Danmark. Hvordan er det gået, og hvad byder fremtiden.
Karsten Thorø vil være til stede hele fredagen på årsmødet, hvor der vil være mulighed for at stille spørgsmål samt deltage i en aftagerundersøgelse, som foregår resten af fredagen.

11:45 – 12:30 "Introduktion til evidensbaseret medicin" – Lokale Store Hessel
Foredragsholder: Susanne Bloch, autoriseret bandagist

Foredraget omhandler de nationale kliniske retningslinier, evidens hierarkier samt vurdering af publicerede undersøgelser.

12:30 – 13:30 Frokost i udstillingen - Lokale Hesselhaven

13:30 – 14:00 "Sub-ischial hylsteteknik … Något nytt? " – Lokale Store Hessel
Foredragsholder: Anton Johannesson, Leg. Ortopedingenjör, PhD, Össur

Allt sedan man började at tillverka proteser, så har man förmodligen också tillverkad hylsor som kan jämföras med det vi numera kallar för Sub-ischial protes hylsteknik (SIPS).
Ofta som "plugg fit" design där suspensionen ofta var någon typ av bälten och/eller selen. Nu har denne teknik fået renässans fast nu använder vi liner och olika vakuum suspensioner.

Fagligt program

Fredag den 1. april 2016

14:00	**"Subischial Socket with Vacuum Assisted Suspension for Persons with Transfemoral Amputation" Foredragsholder: Stefania Fatone, Phd, BPO, Associate Professor, Department of Physical Medicine & Rehabilitation**	**– Lokale Store Hessel**
14:45 – 15:00	**Afrunding med mulighed for at stille spørgsmål**	

Dr. Stefania Fatone, PhD, BPO(Hons), is an Associate Professor in the Northwestern University Feinberg School of Medicine Department of Physical Medicine and Rehabilitation where she conducts prosthetics and orthotics research and teaches in the Masters of Prosthetics and Orthotics program. Dr. Fatone's research examines the effects of prostheses and orthoses on human locomotion in order to increase understanding, establish efficacy, and improve effectiveness of prosthetic and orthotic interventions for people with disability. Dr. Fatone received an undergraduate degree in Prosthetics and Orthotics and PhD from La Trobe University in Australia and then completed a post-doctoral fellowship at Northwestern University. Dr. Fatone is internationally recognized as a leading prosthetics and orthotics researcher, has received both Honorary Membership and Research Awards from the American Academy of Orthotists and Prosthetists, and has approximately 50 peer-reviewed publications.

15:00 – 16:00	**Udstilling Kaffe, kage og frugt i udstillingsområdet**	**- Lokale Hesselhaven**
16:00	**"Orthotic Management of Stroke" Foredragsholder: Stefania Fatone, Phd, BPO, Associate Professor, Department of Physical Medicine & Rehabilitation**	**– Lokale Store Hessel**
16:45 – 17:00	**Afrunding med mulighed for at stille spørgsmål**	
17:00 – 17:15	**Kort pause**	
17:15 – 18:15	**Generalforsamling i Danske Bandagister**	**- Lokale Store Hessel**
19:00	**Velkomstdrink**	**- Tranque-Bar**
19:30	**Festmiddag**	**- Blå stue**
22:00	**Musik og dans DJ, Alexander Danker**	**- Christianslundsstuen**

Fagligt program

Lørdag den 2. april 2016

07:00 – 09:00 Morgenbuffet - Restaurationen

09:00 – 09:30 ”Osseointegration i Danmark” – Lokale Store Hessel
Foredragsholder: Henrik Tingleff, autoriseret bandagist, Bandagist-Centret A/S

Det er nu 5 år siden de første patienter blev Osseointegrerede i Danmark. Oplægget giver en status over hvor mange, der har fået operationen, og hvordan det er gået.
Desuden præsenteres de nyeste tiltag for metoden.

09:30 – 10:00 CPOP – Baggrund, udvikling og status – Lokale Store Hessel
Foredragsholder: Mirjam Gismervik Bjødstrup, Fysioterapeut,
Regional koordinator, CPOP Region Syddanmark

Siden 2008 har man i Danmark arbejdet med implementeringen af opfølgningsprogram for børn og unge med cerebral parese (CPOP). Hvordan har det udviklet sig, og hvad er den aktuelle status?
Det tværprofessionelle samarbejde mellem de forskellige aktører inden for CPOP er varierende, men hvordan løfter vi opgaven som bandagister, og hvilke muligheder er der for et bedre samarbejde, for at sikre en bedre behandling af børn med CP.

10:00 – 11:00 Udstilling – Lokale Hesselhaven
Kaffe og kage i udstillingsområdet

11:00 – 11:30 ”Håndskinner i silikone” – Lokale Store Hessel
Foredragsholder: Jenny Utbult, bandagist, Olmed

Jenny Utbult arbejder som bandagist på Olmeds voksenafdeling i Stokholm, og hun vil foredrage om håndskinner i silikone til voksne med cerebral parese.

11:30 – 11:45 Kort pause

11:45 – 12:45 ”Hvor forandringsparate er I på jeres arbejdslads”. – Lokale Store Hessel
Foredragsholder: Anders Bjørk, forandringsvejleder

Anders Bjørks foredrag er inspirerende, humoristiske og praktisk funderede og henvender sig til både ledere og medarbejdere. Han kredser om emnerne forandringsparathed, medarbejdertrivsel og arbejdsglæde, og han oplever mange gange, at modstand mod nye virksomhedstiltag kan medføre mindre arbejdsglæde og trivsel og dermed blive hæmmende i det daglige arbejde. Det handler om at imødekomme forandringer positivt, og Anders Bjørk har masser af gode, konkrete forslag og eksempler på, hvordan vi gør det – forandringer er nemlig kommet for at blive.

12:45 Afslutning - Lokale Store Hessel

13:00 Sandwich to go, inkl. 1 vand

ISPO EUROPEAN CONGRESS, ROTTERDAM

Datum: donderdag, 6 oktober, 2016 tot zaterdag, 8 oktober, 2016

Dear colleagues,

On behalf of the ISPO (the International Society on Prosthetics and Orthotics) National Member Societies of Belgium, Norway, Sweden and The Netherlands I most warmly invite you to join the ISPO European Congress on Prosthetics and Orthotics 2016, October 6-8, Rotterdam, The Netherlands.

The former cruise ship ss Rotterdam (http://ssrotterdam.nl/) that brought many thousands of people to various places all over the world will now host hundreds of professionals from all over Europe.
You will be member of a multidisciplinary cross section of delegates from Europe and beyond, to share cutting-edge technology, state of the art research and lectures on assistive devices, robotics, ethics, sports medicine, reimbursement, outcome measurements.
The breathtaking scenery of Europe's largest harbour, that by Rough Guide (http://www.roughguides.com/article/rotterdam-8-reasons-to-visit-the-netherlands-second-city/), the New York Times (http://www.nytimes.com/interactive/2014/01/10/travel/2014-places-to-go.html?_r=2) and Lonely Planet (https://www.lonelyplanet.com/the-netherlands/rotterdam) is called one of the world's favourite places to visit, is now the background at which you can meet your colleagues, make new professional friends, visit the exhibitors to see their latest products and enlarge and inforce your international network to improve the quality of life for persons who may benefit from assistive devices for mobility, such as prostheses and orthoses.

With a prominent list of European and overseas speakers, the programme will include keynote lectures, free paper sessions, posters and a few focused special sessions. A number of tempting social activities aims to further enhance the congress programme.

Please scroll down for all details including registration form

Promotiefilmpje ISPO RP ISPO MPEG



Please check the website regularly for updates on the congress programme, keynote speakers, and special sessions.

I hope we will meet in Rotterdam on October 6-8,

With kind regards,

Tjerk de Ruiter, Physiatrist,
Chairman of the organising committee

Programme

Wednesday October 5, 2016

19:30 – 21:30	Registration & welcome reception ss Rotterdam

Thursday October 6, 2016

08:00 – 09:00	Registration	
09:00 – 09:15	Opening	
09:15 – 09:45	Opening by the president of ISPO International	
09:45 – 10:45	The Final Frontier: Developments in Transfemoral Sockets Keynote Lecture by Stefania Fatone PhD, Northwestern University, Chicago, USA	
10:45 – 11:15	Break	
11:15 – 12:15	Free paper session 1 "Evaluation Studies"	Free paper session 2 "Prosthetics – UL"
12:15 – 14:00	Lunch & Exhibition	
14:00 – 15:00	Free paper session 3 "Orthotics – LL"	ChiLD Symposium
15:00 – 15:30	Break	
15:30 – 16:30	Free paper session 4 "Prosthetics – LL1"	
16:30 – 17:00	Award session Best BSc & MSc theses	
	Social program, registration on site	

Friday October 7, 2016

09:00 – 10:00	Enabling technology? Managing change after amputation Keynote Lecture by Deirdre Desmond PhD, Maynooth University, Maynooth, Ireland	
10:00 – 10:30	Break	
10:30 – 12:00	Free paper session 5 "Prosthetics – LL2"	Free paper session 6 "Miscellaneous"
12:00 – 14:00	Lunch & Exhibition	
14:00 – 15:00	Free paper session 7 "Education"	Symposium: Hand Orthoses in CP
15:00 – 15:45	Break	
15:45 – 16:45	What is wrong with enhancing human capacities? A philosophical perspective. Keynote Lecture by Filippo Santoni De Sio, PhD, Delft University of Technology, Delft, The Netherlands	
16:45 – 17:00	Closure Scientific Programme	
18:30 –	Conference Dinner - ss Rotterdam	

Saturday October 8, 2016

Social program, registration on site

- Scientific Programme
  - Visit & workshop Delft University of Technology, Delft: Human-machine interaction
  - Visit & workshop Wittebroos shoes: introduction of the Dutch Shoe prescription Guidelines
- Morning run with the Rotterdam Running Ambassadors
- Architecture Tour, Rotterdam
- SS Rotterdam Tour, Rotterdam

Keynote Speakers

Thursday October 6, 09:45 – 10:45,
Stefania Fatone, Northwestern University, Chicago, USA



Stefania Fatone, PhD, BPO(Hons), is an Associate Professor in the Northwestern University Feinberg School of Medicine Department of Physical Medicine and Rehabilitation (Chicago IL USA) where she leads orthotic and prosthetic (O&P) research and teaches in the Masters of Prosthetics and Orthotics program. Dr. Fatone's research examines the effects of prostheses and orthoses on human locomotion in order to increase understanding, establish efficacy, and improve effectiveness of O&P interventions. Dr. Fatone is internationally recognized as a leading O&P researcher and has more than 50 peer-reviewed publications.

Friday October 7, 09:00 – 10:00,
Deirdre Desmond, Maynooth University, Maynooth, Ireland



Deirdre Desmond is a lecturer in Psychology at Maynooth University, Ireland and a co-director of the Dubin Psychoprosthetics Group. Her research interests are grounded in health and rehabilitation psychology, with particular focus on psychosocial adjustment to illness and injury, person-centred care, self management, patient reported outcomes measurement and assistive technology.

Friday October 7, 15:45 – 16:45,
Filippo Santoni De Sio, Delft University of Technology, Delft, The Netherlands



CV: Filippo Santoni de Sio is Assistant Professor of Philosophy and Ethics of Technology at Delft University of Technology. He received his PhD in Philosophy at the University of Turin in 2008. He has already published one monograph, two edited collections and more than thirty philosophical papers on moral and legal responsibility, the ethics of cognitive enhancement, and robot ethics. He is in the organizing committee of the Foundation for Responsible Robotics. His webpage is: filipposantoni.net

---

Travel

Delegates are responsible for making their own travel arrangements. Rotterdam can be easily reached by train, plane or car. From Rotterdam-the Hague Airport you will be at the ss Rotterdam in about 20 minutes, traveling from Schiphol Airport takes about 40 minutes. How? See the video Schiphol Airport to Rotterdam Central Station (https://www.youtube.com/watch?v=stQQpaX650w&feature=youtu.be).

Accommodation

Delegates are responsible for making their own accommodation arrangements.
Rooms on board the venue, ss Rotterdam and in the nhow Rotterdam (the highest building in Rotterdam) at the river bank, are available at reduced rates for our delegates.

ss Rotterdam:
NL: http://ssrotterdam.nl/ispo-european-congress-2016/ (http://ssrotterdam.nl/ispo-european-congress-2016/)
ENG: http://ssrotterdam.com/ispo-european-congress-2016-2/ (http://ssrotterdam.com/ispo-european-congress-2016-2/)

nhow Hotel Rotterdam:
http://www.nhow-hotels.com (http://www.nhow-hotels.com/)
For reservations at reduced rate for delegates, please contact: Michelle Kortekaas | Group & Convention Organizer
Tel: +31 (0)10 206 7651 - Mail : m.kortekaas@nhow-hotels.com (mailto:m.kortekaas@nhow-hotels.com) |

The city of Rotterdam has over 4.600 hotel beds available in the city centre in a wide range of luxury, styles, and rates, fitting everyone's preference and budget.
Several hotels are within 15 minutes walking distance from the venue of the ISPO European Congress, a.o. Hotel New York (http://www.hotelnewyork.com/), ART Hotel (http://www.hoteliers.com/en/hotels/netherlands/rotterdam/art-hotel-rotterdam/website/), Easy Hotel (http://easyhotelbenelux.com/rotterdam/about-the-hotel?gclid=CJmpv73V3MwCFRHhGwodeqoHuw), Thon Hotel (http://www.thonhotels.com/hotels/countrys/the-netherlands/rotterdam/thon-hotel-rotterdam/)and Mainport Design Hotel (https://www.designhotels.com/hotels/netherlands/rotterdam/mainport?gclid=CKOT95TX3MwCFTMo0woddRcJIA)

Venue

The venue of the ISPO European Congress is the ss Rotterdam (http://ssrotterdam.nl/).
The steamship Rotterdam is the largest oceangoing steamer ever built in the Netherlands. After its launch in 1959, it became the flagship of the Holland America Line and sailed to many parts of the world. The ship is now permanently

moored in Rotterdam's Maashaven (Meuse Harbour) near Katendrecht. The vessel's history can be felt everywhere on board. The 1950's interior and its many artworks were lovingly restored between 2005 and 2008. The hotel rooms, restaurants, conference, exposition rooms and other amenities have been thoroughly modernised and satisfy all of today's needs.

SS Rotterdam, 3e Katendrechtsehoofd 25, 3072 AM Rotterdam



Exhibition

A commercial exhibition is integrated into the interdisciplinary congress. The exhibition provides an overview of recent product innovations and technologies.
Download (/sites/www.ispo.nl/files/Registration%20form%20booth%20stand%20European%20Congress%20ISPO%20NL%202016.pdf) the exhibitor application form to secure your participation.

Congress secretariat:

ISPO NL
P.O. Box 1020
2001 BA Haarlem
The Netherlands
+31 23 551 3016
info@ispo.nl (mailto:info@ispo.nl)

Registration

Delegate registration is now open. Registration includes:

- Opening Reception at ss Rotterdam, Wednesday October 5th
- Access to the Congress Sessions including: Keynote Lectures, Oral Sessions, Poster Sessions, Exhibitions
- Lunch on October 6th & 7th
- Daily coffee breaks

• Participation Social programme Thursday evening October 6th
• Participation Social programme Saturday October 8th
• The opportunity to network and liaise with industry leaders and research colleagues

The registration fees are:
• ISPO members: € 335,00 (after Sept. 6th: € 385,00)
• Non-ISPO members: € 395,00 (after Sept. 6th: € 445,00)
• Students: € 150,00 (after Sept. 6th: € 175,00) - please, include a copy of your student card with your registration
• Congress dinner (Friday October 7): € 60,00

Personal Information

Initials *

Middel name (tussenvoegsel)

Last name *

Gender *

BIG number (NL participants only)

ISPO membership number

Contact details

Institute *

Title / Specialism *

Department *

Work address *

Work postal/ZIP code *

Work town/city *

Country *

Phone number

E-mail *

Congress participation *

- [ ] Congress participation ISPO member (€ 335,-)
- [ ] Congress participation non ISPO member (€ 395,-)
- [ ] Congress participation Student (€ 150,-)
- [ ] Opening reception Wednesday October 5th (free of charge)
- [ ] Participation Social programme Thursday evening October 6th (free of charge)
- [ ] Attending dinner Friday October 7th (€ 60,-)
- [ ] Participation Social programme Saturday morning October 8th (free of charge)
- [ ] Participation Social programme Saturday afternoon October 8th (free of charge)
- [ ] Scientific Programme Saturday morning, Visit & workshop Delft University of Technology, Delft: Human-machine interaction (free of charge)
- [ ] Scientific Programme Saturday morning, Visit & workshop Wittebroos shoes: introduction of the Dutch Shoe prescription Guidelines” (free of charge)

Register

Nieuws

ISPO European Congress 2016
06/10/2016
(/nieuws/ispo-european-congress-2016)

#ISPOWER @Rio 2016 Paralympics!
07/09/2016 tot 18/09/2016
(/nieuws/ispower-rio-2016-paralympics)

Richtlijn "Klompvoet" geaccordeerd
24/02/2016
(/nieuws/richtlijn-klompvoet-geaccordeerd-0)

ISPO
NEDERLAND

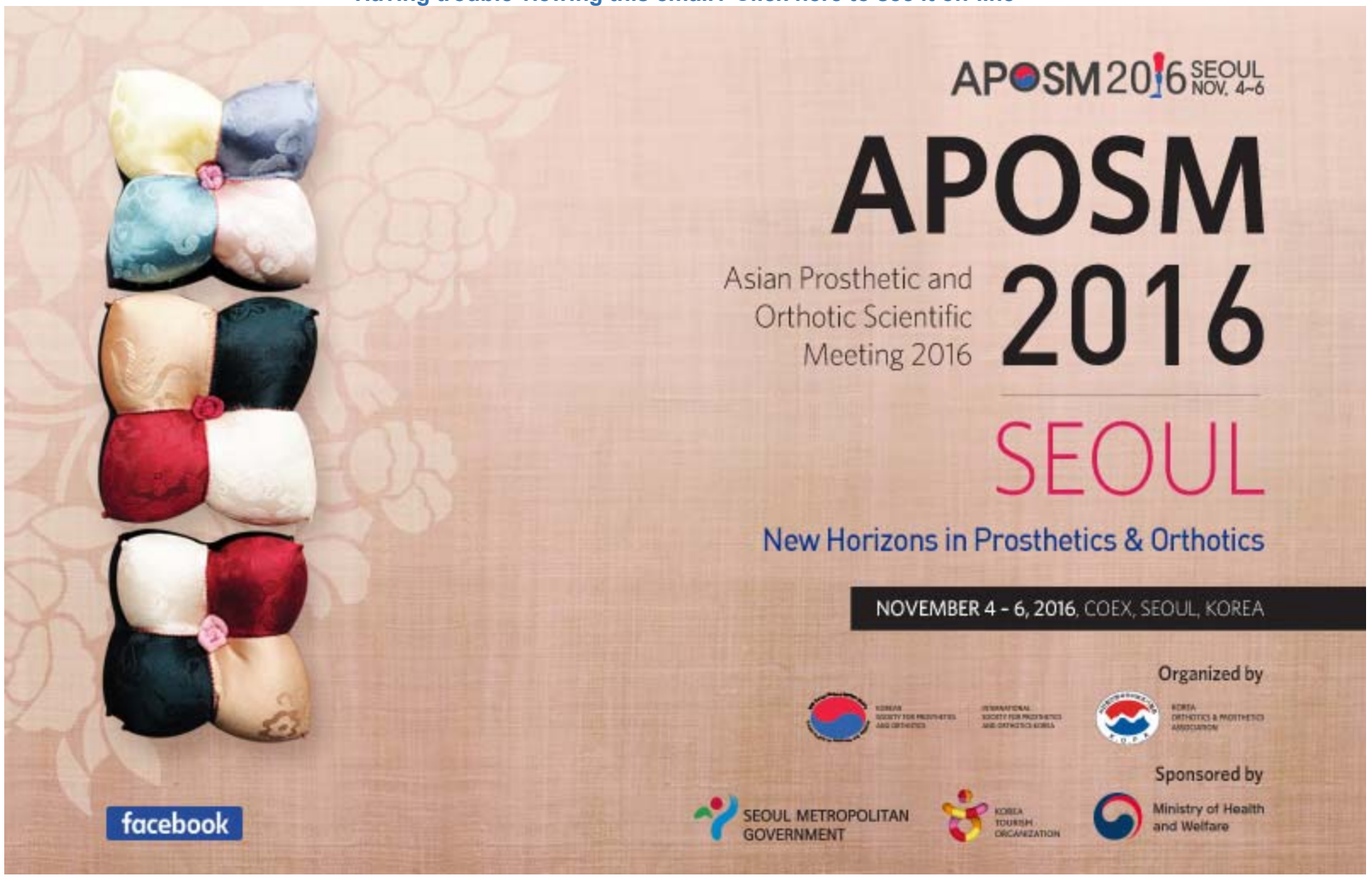
(http://www.ispo.nl/ispo-european-congress-2016)
ISPO European Congress (http://www.ispo.nl/ispo-european-congress-2016)

IDEEËN OF SUGGESTIES? (/CONTACT)

Stefania Fatone

From: APOSM 2016 <seoul@aposm2016.org>
Sent: Friday, June 03, 2016 1:36 AM
To: Stefania Fatone
Subject: [Call for Abstract] Asian Prosthetic and Orthotic Scientific Meeting 2016

Having trouble viewing this email? Click here to see it on-line



On behalf of the organizing committee, it is our great honor and pleasure to announce that the APOSM 2016 (Asian Prosthetic and Orthotic Scientific Meeting 2016) which will take place in Seoul, Korea on November 04(Fri) - 06(Sun), 2016.

APOSM is held every 2 years from 2009 in Hong Kong, and takes place around Asia countries. APOSM 2016 is an international conference which aims to provide new horizons in prosthetics and orthotics. It would be a great opportunity to share the latest knowledge in the fields of Prosthetics and Orthotics.

APOSM 2016 PROGRAM

See the Program >

Plenary Lecture 1



Flexible Subischial Vacuum Socket for Transfemoral Amputee

Stefania Fatone (PhD, Northwestern University, USA)

Plenary Lecture 2



Korean P&O: Past, present, and future

Bong-Ok Kim (MD, Chungnam National University School of Medicine, Korea)



Overview of Prosthetics and Orthotics Education, and Emergence of Assistive Technology

Eiji Tazawa (CPO, ISPO International Consultant for South East Asia, Japan)

REGISTRATION (EARLY BIRD BY AUG 5)

Go to Register >

Participants are advised to register in advance (by Aug 5, 2016) to receive the Early Registration discount.

Category	Early-bird Registration (by August 5, 2016)	Pre-Registration (by October14, 2016)	On-site Registration (during the meeting)
ISPO Non-member	$400	$500	$550
ISPO Member	$300	$400	$450
Student	$100	$100	$150
Accompanying Person		$100	
Gala Dinner Ticket		$100	
Workshop (Nov 4, Fri)		1 workshop: $200, 2 workshops: $350 * 20 seat limit per workshop	

* Registration Fee Includes: Admission to all technical sessions and exhibitions, Coffee breaks, Program book and Luncheon Seminar.

ABSTRACT SUBMISSION (EXTENDED TO JULY 31)

Go to Submit >

- Official Language: English
- All abstract submissions must follow the format of a structured abstract.:
  Background/ Aim/ Method/ Results/ Discussion & Conclusion (References optional)
- Abstracts should be 450 words or less; the submission system will not accept anything beyond that.
- How to submit: Abstracts should be submitted electronically via the website

HOW TO PARTICIPATE AS AN EXHIBITOR

Download the Form >

Make the most out of the APOSM 2016 for your business with a wonderful sponsorship opportunity. We offer a variety of sponsorship and advertisement opportunities to pay off more than you expect throughout the meeting. Our sponsorship prospectus is now available. If you need more information, please do not hesitate to contact the secretariat(seoul@aposm2016.org). All sponsorship categories are filled on first-come, first-serve basis.

KEY DATES



POSTER

ANNOUNCEMENT (ENG)

SIGN UP

Sponsored by

PLATINUM ottobock.

GOLD ÖSSUR

SILVER 正立보조기

SILVER parkeuiji

APOSM2016 Secretariat
1F Haeoreum Bldg., 16, Yeoksam-ro 17 Gil, Gangnam-Gu, Seoul 06246, Korea
Tel. +82-2-566-6031 | Fax. +82-2-566-6087 | E-mail. seoul@aposm2016.org

메일 수신을 원치 않으시면 [수신거부]를 클릭하십시오. If you don't want this type of information or e-mail, please click the [unsubscription]