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

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14. ABSTRACT The purpose of this project is to develop a highly flexible sub-ischial prosthetic socket with assisted-vacuum suspension for highly active persons with transfemoral amputation. The Specific Aims are to: A1. Develop a highly flexible socket with sub-ischial trim lines; A2. Develop durable liners and sealing sleeves; A3. Develop/identify an appropriate vacuum pump; A4. Evaluate system performance with military amputees; and A5. Develop education materials. During Year 4, we completed the tasks in Aims 1, 2 and 5, completed the original and supplemental tasks in Aim 3, and are working on the tasks in Aim 4. We are ready to disseminate our technique using the plan developed as part of Task 12d. Publications are underway.						
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INTRODUCTION

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

BODY: PROJECT PROGRESS

What follows is a description of the work conducted during Year 4 of our project. Our progress is presented with respect to the Aims and Tasks described in our grant application, with progress on each task indicated on the corresponding section of the approved statement of work (Gantt chart). Overall, we have completed the tasks in Aims 1, 2 and 5, completed the original and supplemental tasks in Aim 3, and are working on the tasks in Aim 4. We will execute the dissemination plan developed as part of Task 12d and complete Aim 4 during the second year extension without funds. Publications are underway.

Task 1 Initial preparatory activities

Gantt Chart	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
Progress Made												
Task Scheduled												
Task 1 Initial preparatory activities.												
1a Convene initial project meeting.												
1b Prepare and submit IRB application.												

1a Convene initial project meeting: *This task is complete.*

1b Prepare and submit IRB application: *This task is complete.*

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

Gantt Chart	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
Progress Made												
Task Scheduled												
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.												
2a Reverse engineer hand-fabricated socket to build 3D CAD model.												
2b Perform mechanical simulations on hand fabricated 3D model.												
2c Develop simple parametric 3D CAD model using "ladle frame" design.												
2d Perform mechanical analyses.												
2e Develop 3D CAD rectification techniques for semi automated design of "ladle frame" socket from digitized limb shape.												

Task 2a Reverse engineer hand-fabricated socket to build 3D CAD model and FE model: *This task is complete.*

Task 2b Perform mechanical simulations on hand-fabricated 3D model: *This task is complete.*

Task 2c Develop a simple, parametric 3D CAD model using “ladle-frame” design: *This task is complete.*

Task 2d Perform mechanical analyses: *This task is complete.* A manuscript describing our FE analysis has been submitted for publication to the *Journal of Rehabilitation Research and Development* (See Appendix A for abstract of this manuscript).

Task 2e Develop 3D CAD rectification techniques for semi-automated design of “ladle-frame” socket from digitized limb shape: *This task is completed.* Summarized below with Task 11e.

Task 3 Advanced manufacturing of sub-ischial sockets

During Year 4, Northwestern University biomedical engineering graduate student, Brian Robillard, passed his Master’s thesis in June 2014 (a copy of the thesis can be found in Appendix B). As part of that work a single shot molding technique was developed that successfully fabricated three transfemoral sockets. These sockets – referred to as advanced manufacturing (AM) sockets – were comprised of a rigid frame fabricated from a Stratasys 400mc fused deposition modeler that was sandwiched between a nylon fabric layup and urethane resin. The sockets demonstrated success in controlling thickness and maintaining the shape of the original residual limb geometry. Additionally, the modified ISO 10328 standard was used to test the static strength of the sockets and was recommended as a metric for testing sockets to allow for sockets fabricated with different techniques to be compared using a common, standardized metric. The three sockets we fabricated were tested to failure and compared to NU-FlexSIV Sockets and hybrid sockets – sockets fabricated with AM materials but with a conventional technique. The AM sockets failed at lower forces than the AM and hybrid sockets. Examination of the failed sockets suggested that this was due to (1) an insufficient fabric layup at the very distal portion of the socket, and (2) a sharp transition between the body of the rigid frame and the distal portion that encapsulated the distal adapter. This process and results of testing were described in a manuscript submitted for publication to the *Journal of Rapid Prototyping* (See Appendix C for abstract of this manuscript).

Finite Element Analysis was used to explore the potential influence of design changes on AM socket failure, namely the design of the distal portion of the frame. A simplified model of the socket was created that examined the effect of uniform load on only the distal portion of the rigid frame. Two new frame designs were tested. The first slightly smoothed the transition between the body of the frame and the distal portion that contained the distal adapter, and the second completely blended the transition between the body of the frame and the distal portion that contained the distal adapter. Results of the simulation demonstrated that the new frame designs, when subjected to forces that caused the original frame design to fail, experienced significantly less stress. Future attempts at fabricating AM sockets should adopt the new design of the distal end in order to increase the fracture strength of the sockets. A more detailed summary can be found in Appendix D.

Gantt Chart	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.												

Task 3a Establish criteria and techniques for multi-shot cavity molds: *This task is complete.*

Task 3b Develop degassing techniques for liquid resin molding: *This task is complete.*

Task 3c Develop proximal brim vacuum seal: *This task is complete.*

Task 3d Develop mechanical interlock molding techniques: *This task is complete.*

Task 4 Mechanical bench testing of sockets and liners

Gantt Chart	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 indenter tests of elastomers.												
4d Perform sitting durability tests.												
4e Perform cyclic evacuation tests.												

Task 4a Perform peel tests of bond strength: *This task is complete.*

Task 4b Perform socket strength and deflection tests: *This task is complete.*

Task 4c Perform indenter tests of elastomers: *This task is complete.*

Task 4d Perform sitting durability tests: *This task is complete.*

Task 4e Perform cyclic evacuation tests: *This task is complete.*

Task 5 Solicit feedback from human subjects

Gantt Chart	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
Progress Made	[Progress bar showing completion up to Q3 of Year 3]															
Task Scheduled	[Task bar showing completion up to Q3 of Year 3]															
Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users.																
Task 5 Solicit Feedback from human subjects.																
5a Perform subject fittings with advance manufactured sockets. Assess results and obtain feedback from subjects.	[Gantt chart for Task 5a showing progress up to Q3 of Year 3]															

Task 5a Perform subject fittings with advance manufactured sockets. Assess results and obtain feedback from subjects: *The originally planned portion of this task is complete and additional work is in progress.* With the discontinuation of Polytol, we have explored different options for definitive socket fabrication. Various polyurethane and silicone resins have been tested in fabrication to try to re-create the somewhat unique properties of Polytol. Both the silicone and urethane casting resins provide similar properties to the Polytol lamination but have their own challenges. The polyurethane resins we have utilized have been very sensitive to moisture and the type of barriers used in fabrication such as polyvinyl acetate (PVA) bags. The polyurethane has a tendency to stick to the PVA resulting in an inconsistent finish. The silicone resin does not stick to PVA but has a thicker consistency, which makes it more difficult to impregnate the fibers during lamination. Despite these issues, both resins may be viable options with some fine tuning of the fabrication process.

A second option is the use of a flexible inner material and a rigid outer laminated socket which is more typical of the frame type transfemoral sockets used clinically. A newly introduced material by Medi (Bayreuth, Germany) allows for a different approach to this type of fabrication. MediFlex EVA is a material that seems to provide 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 this material can be fabricated with a thinner and lighter profile than the other laminated flexible materials we have tried. We have been able to construct a frame with lower proximal trim lines using this material while allowing the liner to reflect over the edge and seal with a sleeve that is mounted between the rigid and flexible components. Test Subject #1 is in the process of being fitted with this socket design for further testing.

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	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
	Progress Made	Task Scheduled	Progress Made	Task Scheduled	Progress Made	Task Scheduled	Progress Made	Task Scheduled	Progress Made	Task Scheduled	Progress Made	Task Scheduled	Progress Made	Task Scheduled	Progress Made	Task Scheduled
Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis.																
Task 6 Determine range of volumes to be evacuated from transfemoral sockets of highly active prosthesis users.																
6a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test).																
6b Evaluate time needed to evacuate sockets of transfemoral prosthesis users.																
6c Compare results of 6a and 6b.																

Task 6a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test): *This task is complete.*

Task 6b Evaluate time needed to evacuate sockets of transfemoral prosthesis users: *This task is complete and preparation of publications is underway.* We have collected and analyzed data from 18 subjects with unilateral transfemoral amputation. Figure 1 shows that for standing the OttoBock Harmony ePulse takes significantly longer to evacuate the socket to 17inHg ($p=0.004$), with the WillowWood LimbLogic VS having a faster evacuation rate ($p=0.001$). A publication based on the standing and walking data is being prepared.

Task 6c Compare results of 6a and 6b: *This task is complete.* *In vivo* results in Task 6b are comparable to results from Task 6a: 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).

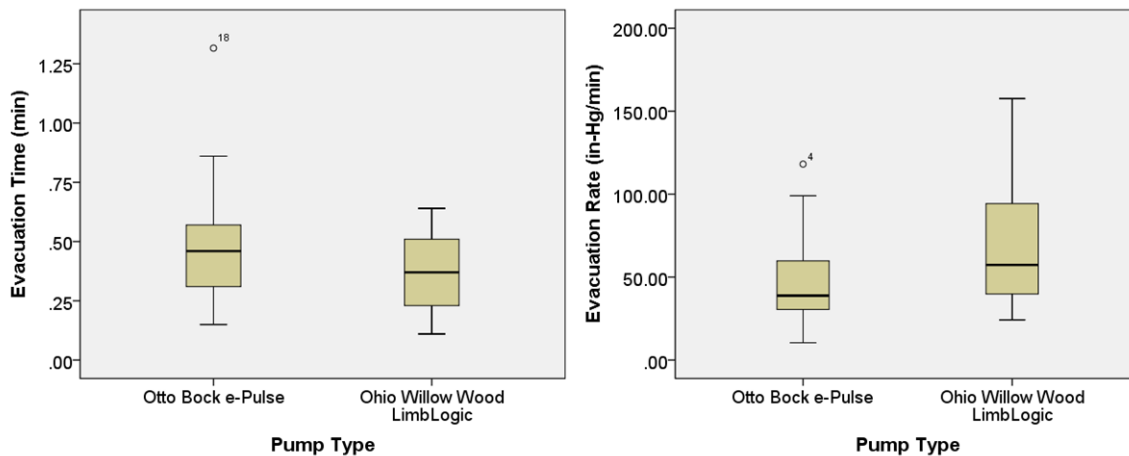


Figure 1 Evacuation time and rate for two commercial prosthetic vacuum pumps during quiet standing in persons with transfemoral amputation (n=18).

Task 7 Characterization of mechanical and electrical pumps

Gantt Chart	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
	Progress Made											
Task Scheduled												
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 is complete.*

Task 7b Characterize pumps based on cycles and time to pull specific vacuum levels: *This task is complete.*

Task 7c Publish a journal article on the characterization of the mechanical pumps: *This task is complete. A manuscript was published in the Journal of Rehabilitation Research and Development (Appendix E).*

Task 8 Finalize vacuum pump design

Gantt Chart	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
	Progress Made											
Task Scheduled												
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 is complete.

Aim 3 Supplemental Tasks

Supplemental Task 1 Build three hybrid vacuum pumps.

Gantt Chart	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
Progress Made				
Task Scheduled				
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 is complete.*

Supplemental Task 1b Prototype and machine all constituent pump parts and molds: *This task is complete.*

Supplemental Task 1c Injection mold bladders: *This task is complete.*

Supplemental Task 1d Assemble electrical pumps: *This task is complete.*

Supplemental Task 1e Assemble prototype hybrid pumps: *This task is complete.*

Supplemental Task 2 Performance testing of three hybrid vacuum pumps.

Gantt Chart	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
Progress Made Task Scheduled				
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 is complete.

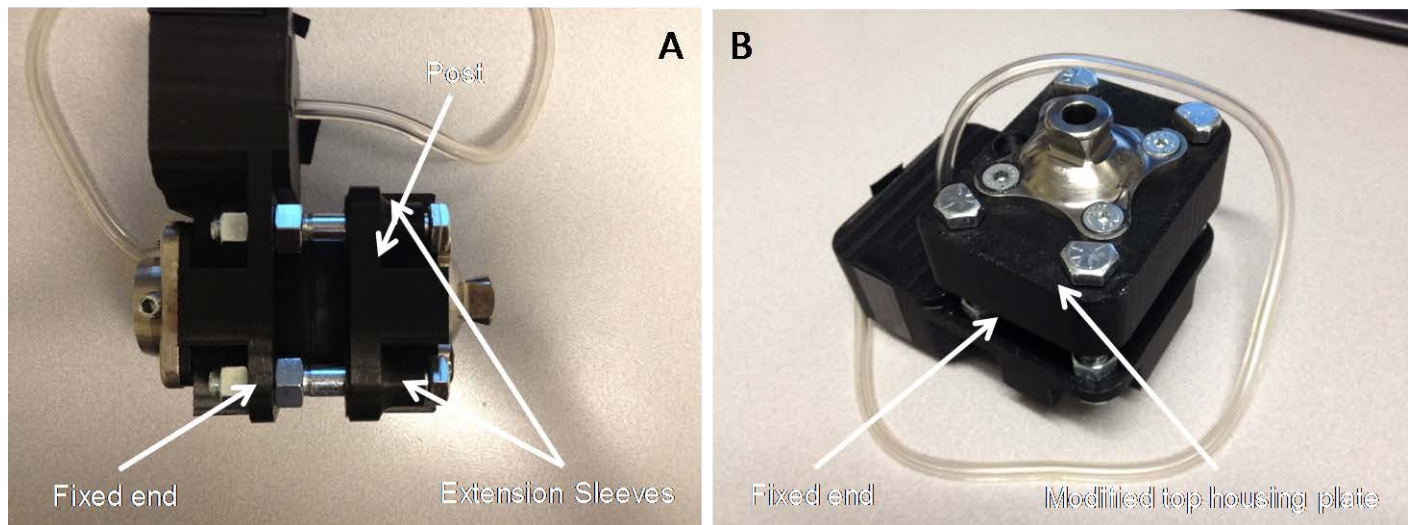


Figure 2 Second (A) and third (B) iterations of hybrid pump.

Supplemental Task 2b Evaluate time needed to evacuate sockets of transfemoral prosthesis users: *This task is complete.* Modifications to the hybrid pump to address asymmetrical compression were completed (Figure 2A) and tested with walking simulators. 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 is acting to restrict overall motion, but 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 hence, stiffer (Figure 2B) to restrict off-axis motion of the posts and limit piston binding. This iteration was tested with walking simulators and bench testing. For this third

iteration, it is apparent that off-axis motion has been limited and binding has been reduced. Results from the first walking test revealed that vacuum reached 11 inHg, which is 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.

To date, data has been collected from 4 persons 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 (Figure 3A). 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 (Figure 3B). 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 (23 minutes of total walking).

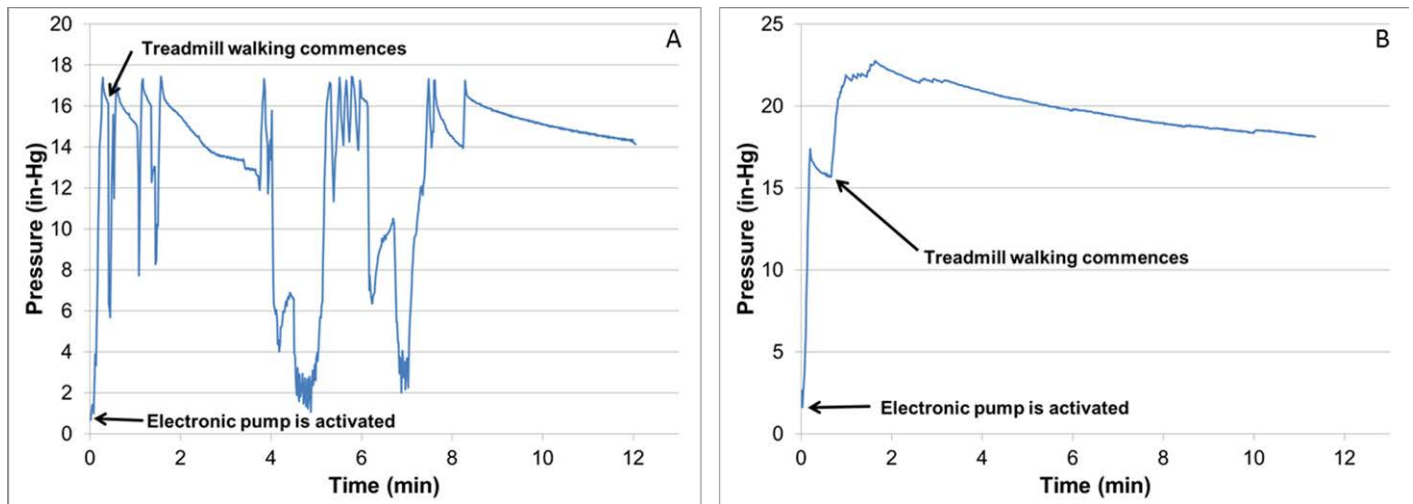


Figure 3 Vacuum level during walking with the LimbLogic (A) and hybrid pumps (B).

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 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 (Figure 4). This experiment represents an ideal scenario, in which a canister (Canister 'C' - test volume of 6.36 in³) 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.

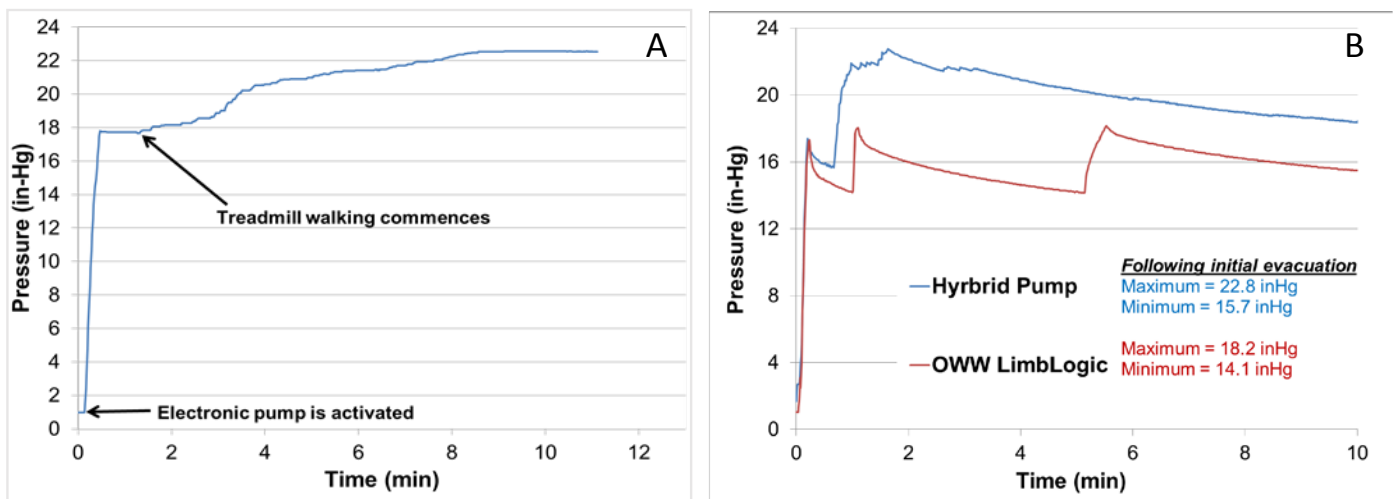


Figure 4 (A) Vacuum level during treadmill walking with the Hybrid pump and simulator boots. (B) Vacuum level during treadmill walking of a single above-knee prosthesis user with the WillowWood LimbLogic VS and Hybrid pump.

Supplemental Task 2c Compare results of Supplemental Tasks 2a and 2b to previous results from Tasks 6a and 6b: *This task is complete.*

Supplemental Task 3 Finalize vacuum pump design.

Gantt Chart	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
Progress Made				
Task Scheduled				
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 is complete.*

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.

Supplemental Task 3b Prepare and submit presentations/publication on hybrid pump design and performance results: *This task is complete.* A technical note describing the pump design and operational feasibility was submitted to *Medical Engineering Physics* (See Appendix F for abstract of this manuscript).

Aim 4 Evaluate system performance with transfemoral prosthesis users

Work on Aim 4 will continue during the extension without funding.

Task 9 Conduct performance evaluation with human subjects

Gantt Chart	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
Progress Made																
Task Scheduled																
Aim 4 Evaluate system performance with transfemoral prosthesis users.																
Task 9 Conduct performance evaluations with human subjects.																
9a Transfer socket casting and rectification skills/knowledge.																
9b Recruit and test human subjects.																
9c Publish results if appropriate.																

Task 9a Transfer socket casting and rectification skills/knowledge: *This task is complete.*

Task 9b Recruit and test human subjects: *This task is in progress.* Data collection is underway. Completion of this task at the Center for the Intrepid/Brooke Army Medical Center was more difficult than anticipated due to unanticipated complications scheduling subjects over the duration of the study protocol. To date, 5 subjects have been recruited for the study. Subject 1 has changed limb volume considerably since the initial casting and new sockets are currently under construction. Subject 2 has completed testing. Subject 3 has completed testing in his sub-ischial socket and is expected to complete follow-up testing within the next month. Subject 4 withdrew from the study due to unanticipated relocation. Subject 5 has completed baseline testing in his ischial containment socket and is currently participating in his accommodation time with the sub-ischial socket. Two additional subjects have been identified to meet the final count of six and will be consented upon receipt of the no cost extension. The research staff at the Center for the Intrepid at Brooke Army Medical Center have requested Institutional Review Board approval to add additional subjects to the protocol to reach the intended number of six subjects.

Preliminary comments by subjects suggest 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 (Figure 5) 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 $12.5 \pm 1.2^\circ$ with the sub-ischial socket and the hip was able to achieve extension during walking. An abstract reporting preliminary results of this testing has been submitted for presentation at the American Academy of Orthotists and Prosthetists 2015 Annual Meeting (Appendix G).

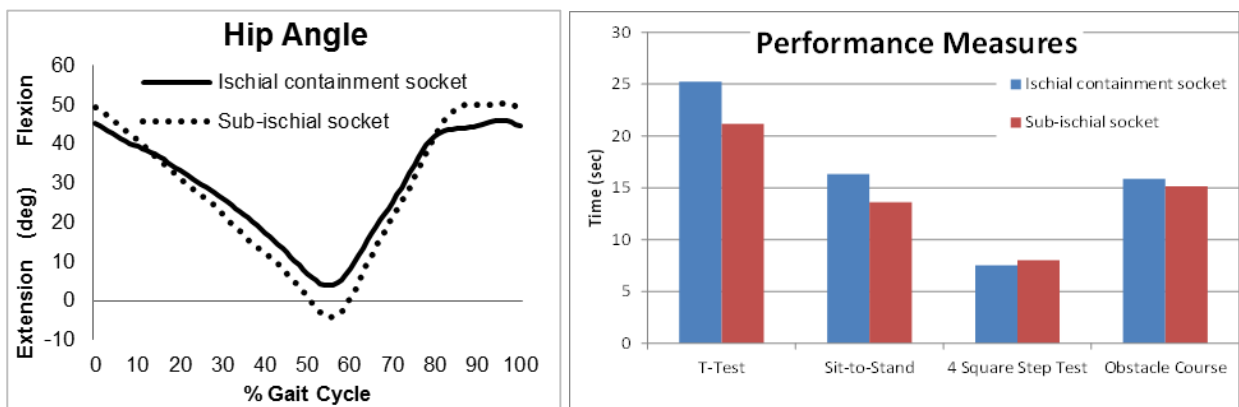


Figure 5 Performance data from first subject to complete testing.

Task 9c Publish results if appropriate: *Delayed until end of extension without funding.*

Aim 5 Develop education materials for sub-ischial socket design

Task 10 Develop a quantification tool for socket rectifications

Gantt Chart	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 is complete.*

Task 10b Develop shape registration scheme: *This task is complete.*

Task 10c Test program accuracy: *This task is complete.* Based on the digitization of 30 cast pairs, a template for use in CAD rectification has been created using ShapeMaker software. This template was shared with Advanced O & P Solutions, the owners of ShapeMaker for further evaluation.

Task 11 Quantify rectifications for multiple amputees

Gantt Chart	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 is complete.*

Task 11b Obtain range of negative casts: *This task is complete.* We collected 34 pairs of casts.

Task 11c Digitize casts: *The task is complete.* 30 pairs of casts have been digitized using the process described in Tasks 10a and 10b.

Task 11d Assess digitized shapes: *This task is complete.*

Task 11e Generate representative 3D models: *This task is complete.* A paper describing quantification of rectifications for our subischial socket was submitted to Prosthetics and Orthotics International (See Appendix H for abstract of this manuscript).

Task 12 Create education materials

Gantt Chart	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
	Progress Made															
Task Scheduled																
Aim 5 Develop education materials for sub-ischial socket designs.																
Task 12 Create education materials.																
Task 12a Consult with NUPOC on the design/creation of education material.																
Task 12b Develop education material.																
Task 12c Solicit feedback on education material from prosthetists.																
Task 12d Develop plan for dissemination of education material.																

Task 12a Consult with NUPOC on the design/creation of education material: *This task is complete.*

Task 12b Develop education material: *This task is complete.* Instructional manual ready for submission to the Northwestern University Innovation and New Ventures Office (INVO) for registration of copyright.

Task 12c Solicit feedback on education material from prosthetists: *This task is complete.*

Task 12d Develop plan for dissemination of education material: *This task is in progress.* Pilot instructional courses have been presented at the International Society for Prosthetics and Orthotics (ISPO) World Congress in February 2013, ISPO Norway Seminar in October 2013, American Academy of Orthotists and Prosthetists Annual Meeting in February 2014, and the Canadian Association of Prosthetics and Orthotics Annual Meeting in August 2014. According to an article in the April 2014 issue of The O&P Edge, “The Academy Celebrates 40 Years,” our presentation “Subischial Socket with Vacuum Assisted Suspension for Persons with Transfemoral Amputation” was among the most popular. As a result we were invited to present a webinar which was

broadcast live on August 26, 2014, and also archived on the American Academy of Orthotists and Prosthetists Paul E. Leimkuehler Online Learning Center (http://www.oandp.org/olc/course_video.asp?frmCourseId=8E117078-AC6F-446C-BE3B-62E1560FCE5D).

The webinar was well-received by the 47 registered participants. Feedback from participants included:

“I’d like to congratulate you...for your thoughtful presentation...it was refreshing to see a balanced and well-evidenced presentation...The fact that you’ve developed a socket technique that improves comfort for people living with transfemoral amputation, without detriment in function or gait, is a great contribution.”

“Excellent information. Excellent format. Superb presentation.”

“I was struck by just how clearly you presented the rationale for the project and talked through the outcomes data you had. It was very easy to digest and the key messages really sang out.”

Work on Task 12d will continue during the extension without funding where we will execute the dissemination plan we have developed.

Task 13 Final project meeting

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

Task 13a Convene final project meeting: *Delayed until end of extension without funding.*

KEY RESEARCH ACCOMPLISHMENTS

- Socket performance has been characterized (Aims 1-3).
- Multiple hybrid pump designs have been completed (Aim 3).
- Instructional materials and a continuing education course have been created (Aim 5).
- Template for use in CAD rectification has been created (Aim 5).
- Began disseminating our research through publications and presentations.

REPORTABLE OUTCOMES

Publications	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 E
	Komolafe O, Caldwell R, Hansen A, Fatone S (submitted) Finite Element Analysis of Rigid Frame Designs for Transfemoral Prosthetic Sockets. Journal of Rehabilitation Research and Development.	Appendix A
	Robillard B, Komolafe O, Caldwell R, Fatone S (submitted) Fabricating Prosthetic Sockets with Additive Manufacturing Technology. Rapid Prototyping Journal.	Appendix C
	Fatone S, Tucker K, Johnson WB, Caldwell R (submitted) Quantification of Rectifications for Subischial Socket. Prosthetics Orthotics International.	Appendix H
	Major M, Caldwell R, Fatone S (submitted) Evaluation of a hybrid vacuum pump to provide vacuum-assisted suspension for above-knee prostheses. Medical Engineering Physics.	Appendix F
Abstracts	Robillard B, Komolafe O, Caldwell R, Fatone S (2013) Fabricating prosthetic sockets with rapid prototyping technology (poster). Biomedical Engineering Society (BMES) Annual Meeting, September 25-28, Seattle, Washington.	Appendix I
	Caldwell R, Komolafe O, Fatone S (2014) Clinical outcomes using a new subischial socket with vacuum assisted suspension: the NU-FlexSIV. World Congress OTWorld 2014, May 13-16, Leipzig, Germany.	Appendix J
	Esposito ER, Fatone S, Wilken J, Caldwell R, Fergason J (submitted) 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, 2015, New Orleans, Louisiana.	Appendix G
	Fatone S, Caldwell R (submitted) Northwestern University Flexible Subischial Vacuum Socket (NU-FlexSIV). World Congress of the International Society for Prosthetics and Orthotics, June 22-25, 2015, Lyon, France.	Appendix K
Presentations	Fatone S (2013) Evaluation of Subischial Sockets for Persons with Transfemoral Amputation. Invited Speaker, ISPO Norge Seminar on “Lower Limb Socket Design and Rehabilitation”, October 22-23, Oslo and Akershus University College, Norway.	
	Fatone S, Caldwell R (2014) Subischial Socket with Vacuum Assisted Suspension for Persons with Transfemoral Amputation. 40th American Academy of Orthotists and Prosthetists Annual Meeting & Scientific Symposium, February 26-March 1, Chicago, Illinois.	
	Fatone S, Caldwell R (2014) Invited presentation, Subischial Socket with Vacuum Assisted Suspension for Persons with Transfemoral Amputation. 19th Biennial Canadian Association of Prosthetists and Orthotists Conference, August 6-9, Halifax, Nova Scotia, Canada.	
	Fatone S, Caldwell R (2014) Subischial Socket with Vacuum Assisted Suspension for Persons with Transfemoral Amputation. American Academy of Orthotists and Prosthetists Webinar Series, August 26. Archived online at http://www.oandp.org/olc/course_video.asp?frmCourseId=8E117078-AC6F-446C-BE3B-62E1560FCE5D	
	Fergason J (2014) Managing Combat Amputees, Prosthetic Experience. Invited presentation, International Society for Prosthetics and Orthotics Annual Scientific Meeting, Royal College of Physicians, London, October 3-4.	
People	Our graduate student, Brian Robillard, applied for and was offered a position as an Associate Consultant at Mars & Co. in Connecticut.	

CONCLUSIONS

The socket we have developed is a flexible sub-ischial transfemoral prosthetic socket, which we have dubbed the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket. While we lost our preferred flexible material for definitive socket fabrication, multiple other options have been explored and appear to be viable substitutes. Now that socket performance has been characterized (Aims 1-3) and instructional materials created (Aim 5), dissemination is needed. Hence, we plan to train Certified Prosthetists to cast, fit, and fabricate this custom socket for their transfemoral amputee patients. Like all prosthetic sockets, the NU-FlexSIV Socket must be custom made for individual patients following a typical manual fabrication process of patient evaluation, casting the residual limb, rectifying the positive model, fabricating the check socket, and fitting and dynamically aligning the socket. This manual process can only be conveyed through in person, hands-on education. We believe that such courses will be well attended based on initial enthusiasm for the topic generated by our presentations throughout this past year.

REFERENCES

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.

APPENDICES

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

APPENDIX B Robillard BJ (2014) Design of a Process for Fabricating Prosthetic Sockets with Additive Manufacturing Technology. Master of Science Thesis, Northwestern University, Evanston IL.

APPENDIX C Robillard B, Komolafe O, Caldwell R, Fatone S (abstract of submitted manuscript) Fabricating Prosthetic Sockets with Additive Manufacturing Technology. *Rapid Prototyping Journal*.

APPENDIX D

APPENDIX E 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.

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APPENDIX H Fatone S, Tucker K, Johnson WB, Caldwell R (abstract of submitted manuscript) Quantification of Rectifications for Subischial Socket. Prosthetics Orthotics International.

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APPENDIX J Caldwell R, Komolafe O, Fatone S (2014) Clinical outcomes using a new subischial socket with vacuum assisted suspension: the NU-FlexSIV. World Congress OTWorld 2014, May 13-16, Leipzig, Germany.



A Finite Element Analysis of Rigid Frame Designs for Transfemoral Prosthetic Sockets

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Manuscript Subtype:	Technical Reports
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Complete List of Authors:	Komolafe, Oluseeni; Northwestern University, Physical Medicine and Rehabilitation Caldwell, Ryan; Northwestern University, Physical Medicine and Rehabilitation Hansen, Andrew; Minneapolis VA Medical Center, VA; University of Minnesota, Physical Medicine and Rehabilitation Fatone, Stefania; Northwestern University, Physical Medicine and Rehabilitation
Keywords:	Transfemoral socket, Flexible socket, Fenestrated socket, Window Cut-Out, Rigid Frame, Finite Element Analysis, Simulation, Socket Displacement, Regional Socket Displacement, Sagittal Socket Displacement

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3 JRRD at a Glance
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5 Title: A Finite Element Analysis of Rigid Frame Designs for Transfemoral Prosthetic Sockets
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10 Despite the clinical practice of increasing flexibility through selective removal of material in rigid
11 prosthetic sockets, there is little understanding of the relationship between the geometry of the resulting
12 rigid frame and socket flexibility. In this study, a computational model was used to systematically explore
13 this relationship. Six different rigid frame designs of a Transfemoral prosthetic socket were analyzed and
14 their displacements reported as measures of socket flexibility. The study expands knowledge of
15 contributions of specific rigid frame design features and represents an important step in the creation of an
16 analytical tool to enable clinically relevant outcome-driven design.
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3 Short Title: FEA of Transfemoral Socket Rigid Frames
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8 Title: A Finite Element Analysis of Rigid Frame Designs for Transfemoral Prosthetic Sockets
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34 or the policy of the Government, and no official endorsement should be inferred.
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1 Abstract

2 Despite the prevalent use of window cut-outs (fenestrations) in prosthetic sockets, there is little
3 understanding of how the resulting rigid frame geometry affects clinically measures as socket
4 flexibility. The aim of this research was to assess the relationship between the design of the rigid
5 frame component of the socket and the overall prosthetic socket flexibility using a finite element
6 simulation. Six loading simulations of the Northwestern University Flexible Sub-Ischial Vacuum
7 (NU-FlexSIV) socket were performed. Each simulation corresponded to one of three clinically
8 available rigid frame designs (Set 1) and a second set of three conceptual rigid frame designs (Set
9 2). The results showed that in all simulations, the maximum displacements of the rigid frames
10 occurred at the onset of the single limb stance period of a normal gait cycle. The results also
11 showed the displacements calculated within the completely rigid frame (i.e., no fenestrations) were
12 lower than those of the two fenestrated frame designs – confirming users’ subjective reports of
13 “less flexibility” of the completely rigid frame. This study represents an important step in the
14 creation of an analytical tool to enables *a priori* assessment of the effects of specific design
15 features on clinically relevant measures such as socket flexibility.

16 Key Words

17 Transfemoral socket, Flexible socket, Fenestrated socket, Window Cut-Out, Rigid Frame, Finite
18 Element Analysis, Simulation, Socket Displacement, Regional Socket Displacement, Sagittal
19 Socket Displacement

20 Abbreviations

21 Finite Element – FE; Three-Dimensional – 3D; Northwestern University Flexible Sub-Ischial
22 Vacuum - NU-FlexSIV; Computer Aided Design – CAD; Ground Reaction Forces – GRFs;

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.

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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 express my gratitude to Dr. Suzanne Olds for supporting me through my masters program.

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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 process 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 WillowWood (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 part 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.

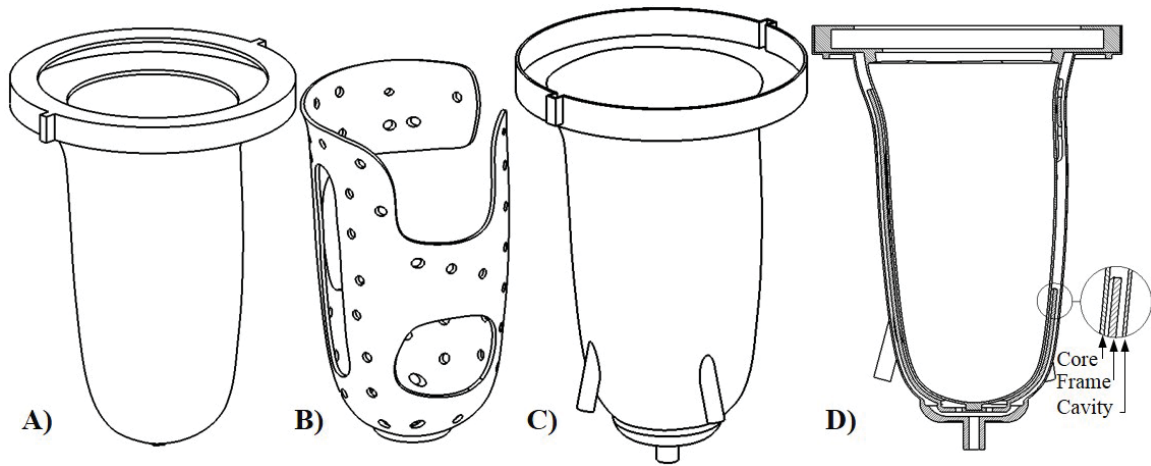


Figure 2.1. CAD models of mold components: (A) Core, (B) Frame, (C) Cavity, and (D) cross section of assembled mold

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 overflow 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.

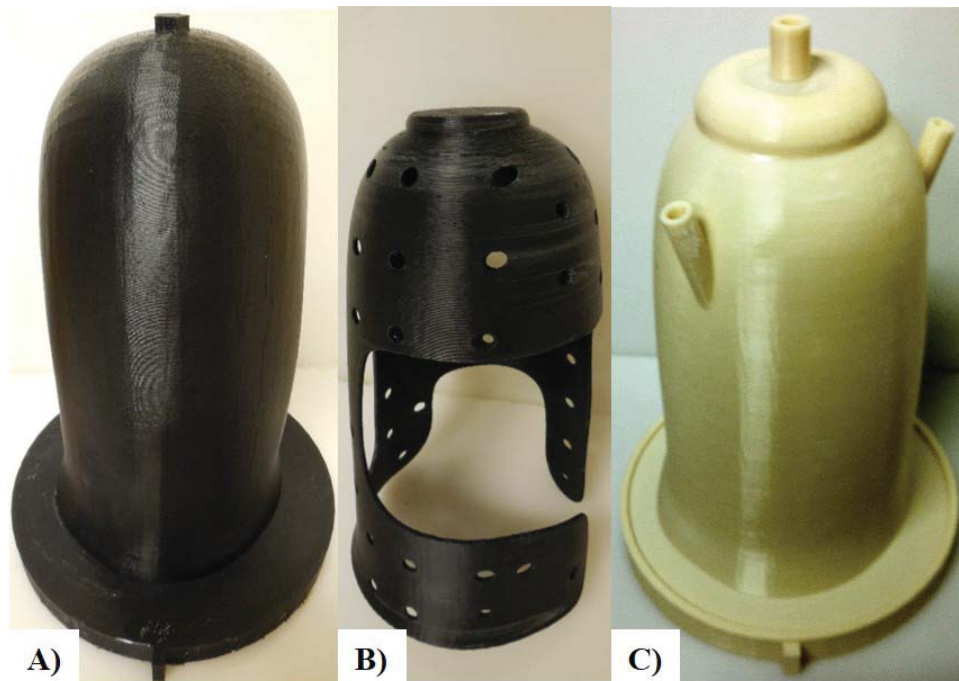


Figure 2.2. Fabricated components: (A) core, (B) frame, and (C) cavity

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.

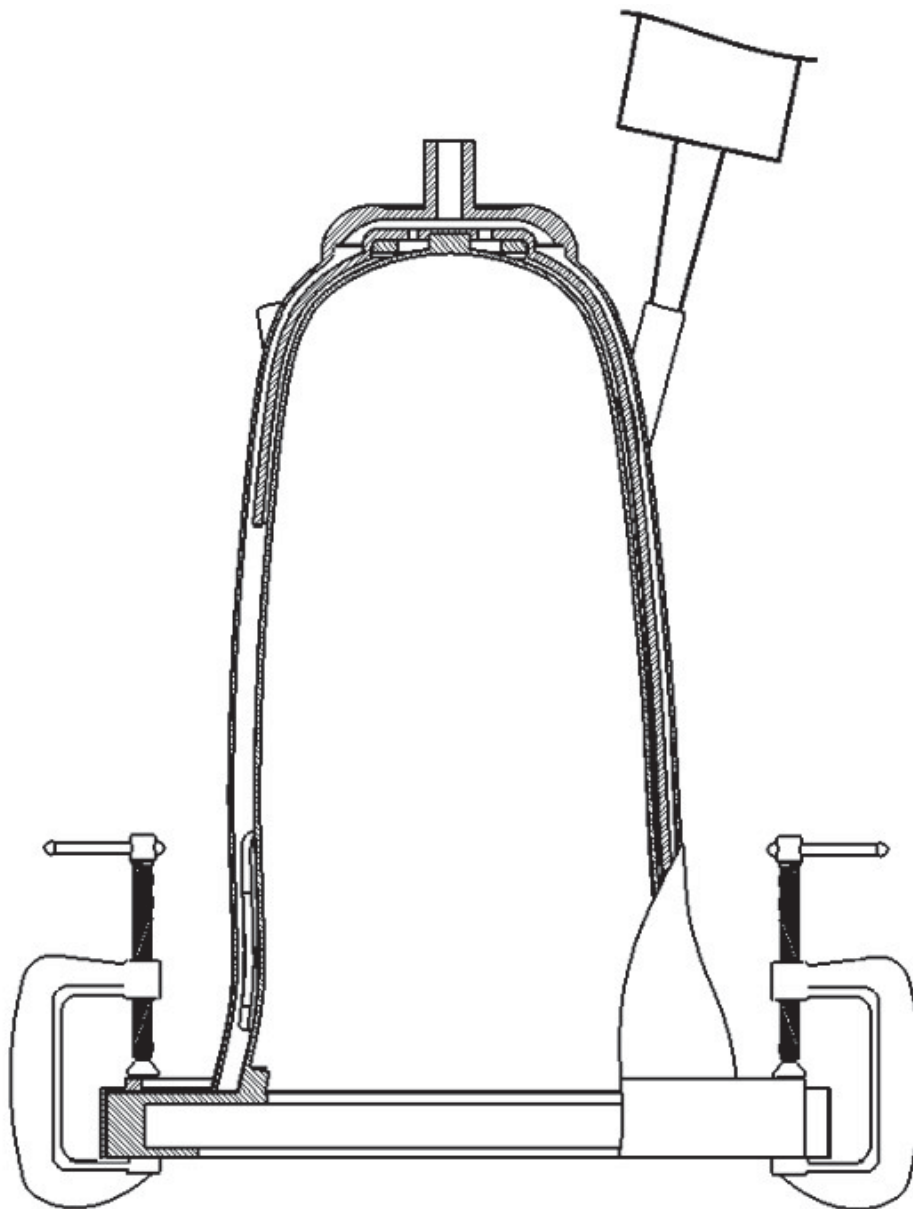


Figure 2.3. Partial cross-sectional schematic of pour setup showing the insertion of material

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

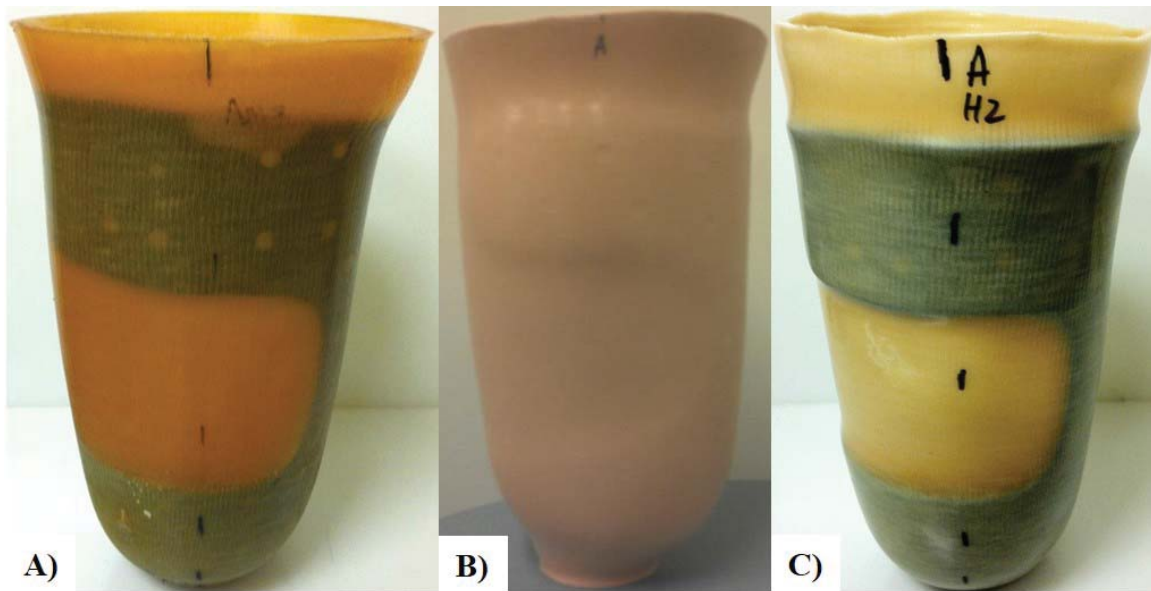


Figure 2.4. Anterior views of (A) AM socket , (B)NU-FlexSIV Socket, and (C) hybrid socket

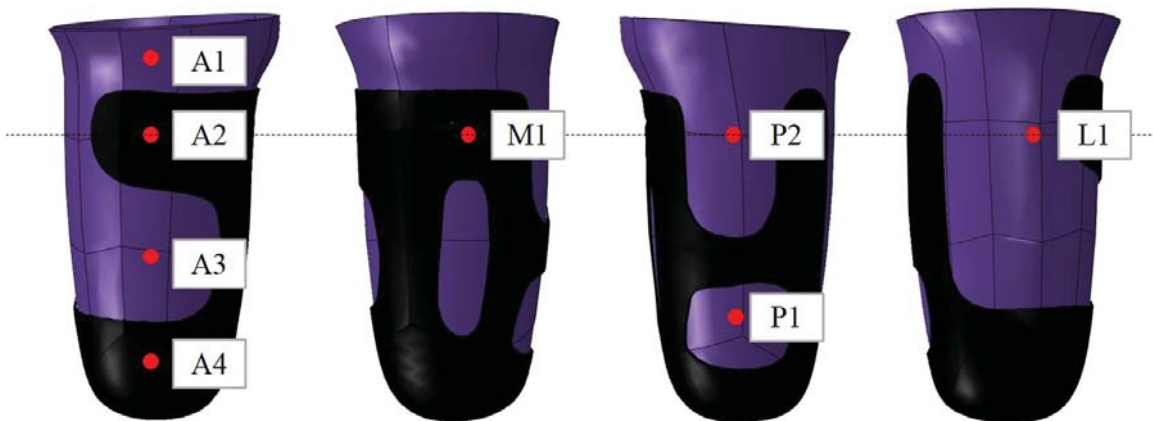


Figure 2.5. Locations of thickness measurements from anterior, medial, posterior, and lateral views

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.

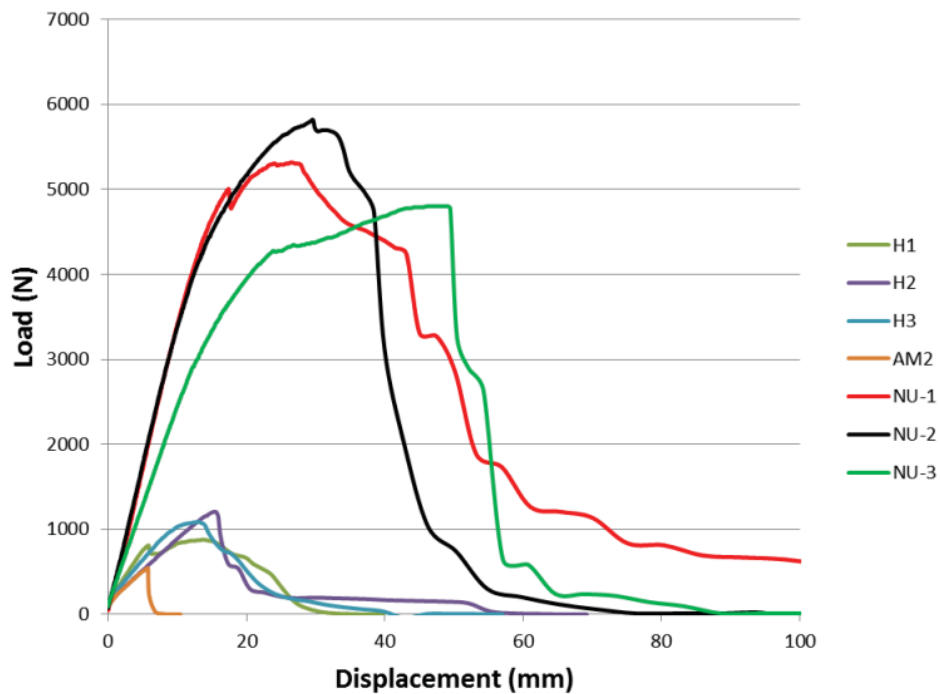


Figure 2.7. Force-displacement curves generated during static testing (WillowWood, 2014b)

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 a 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 project 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.

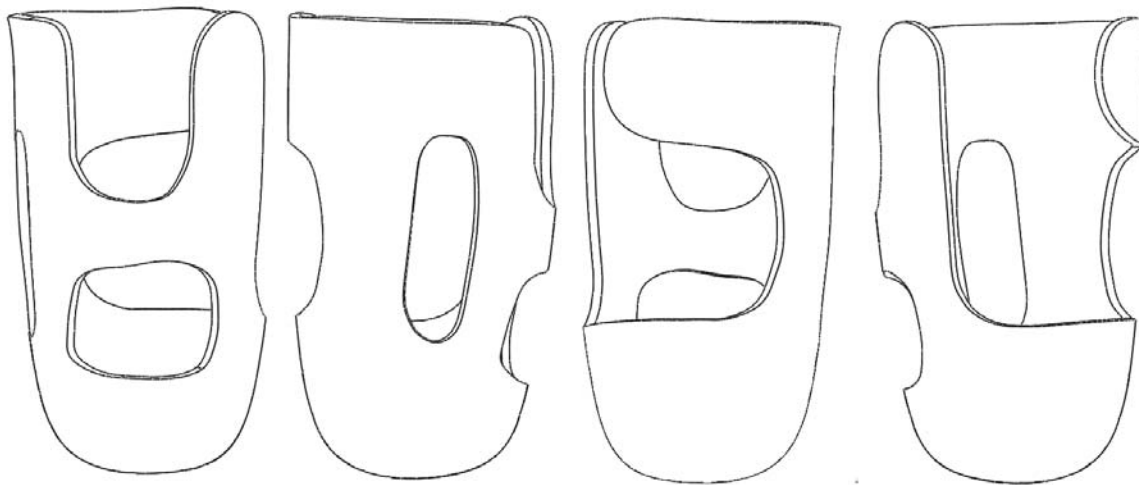


Figure 3.1. A uniform thickness frame from posterior, medial, anterior, and lateral views

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.

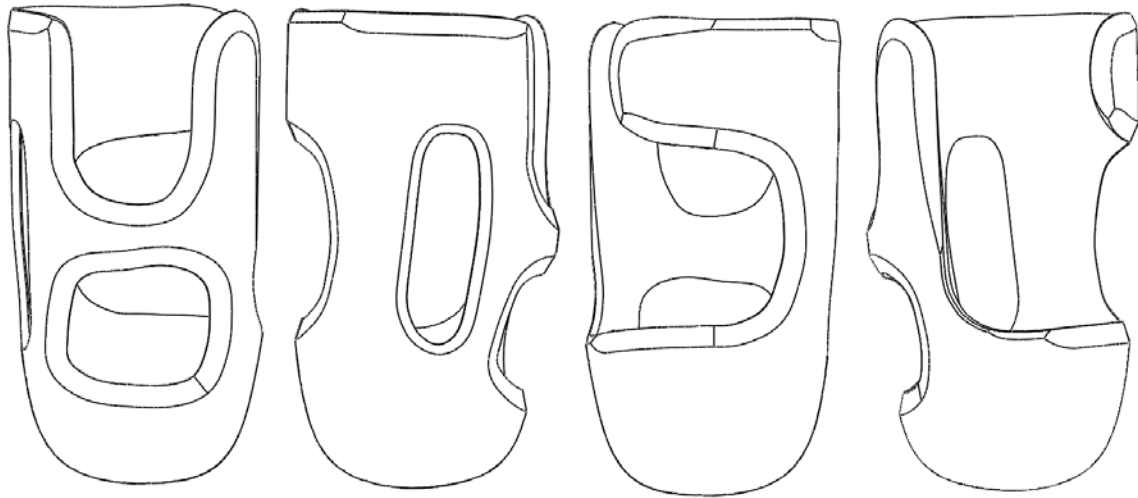


Figure 3.2. A gradated thickness frame from posterior, medial, anterior, and lateral views

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

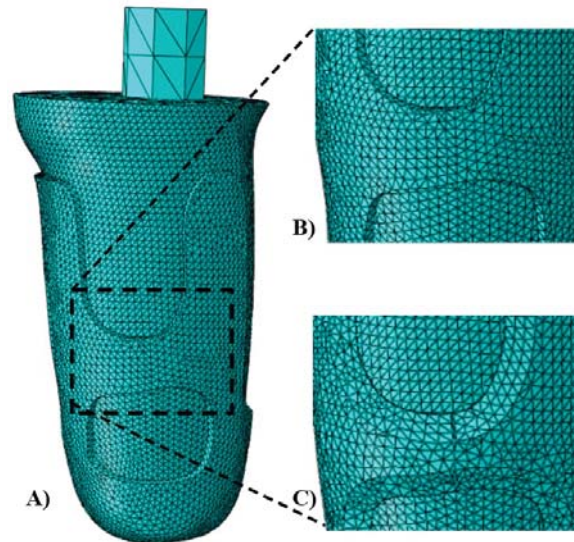


Figure 3.3. Anterior view in Abaqus of (A) NU-FlexSIV model, (B) uniform frame, and (C) gradated frame

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.

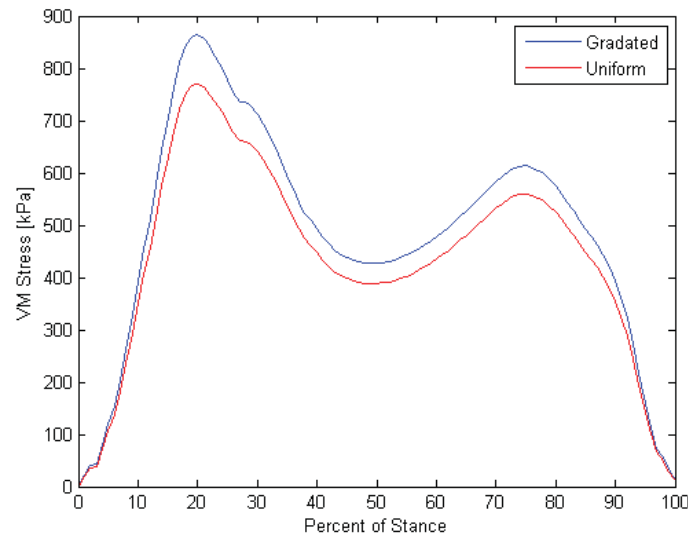


Figure 3.4. Global VM stress on gradated and uniform frames

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.

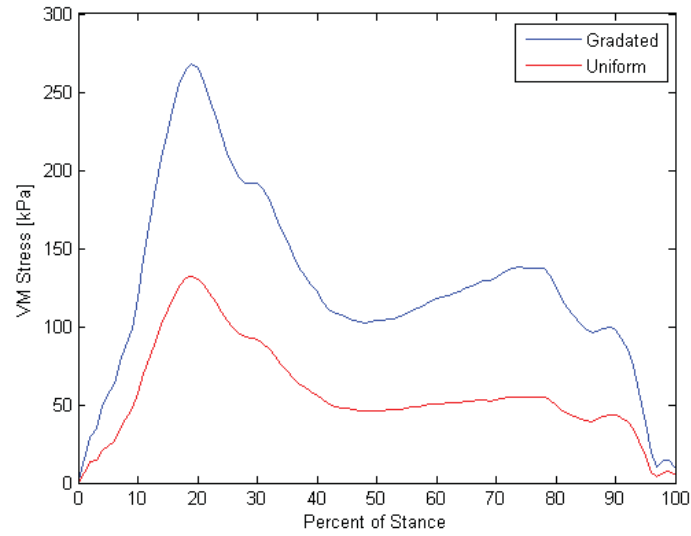


Figure 3.5. Local VM stress on edge of gradated and uniform frames

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.

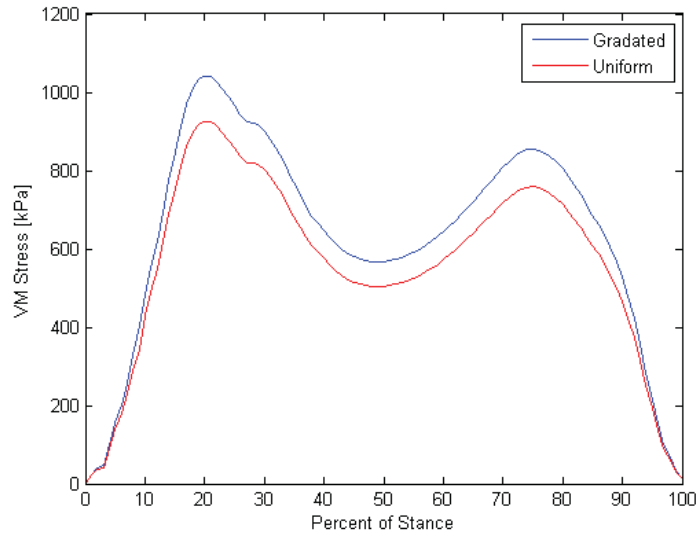
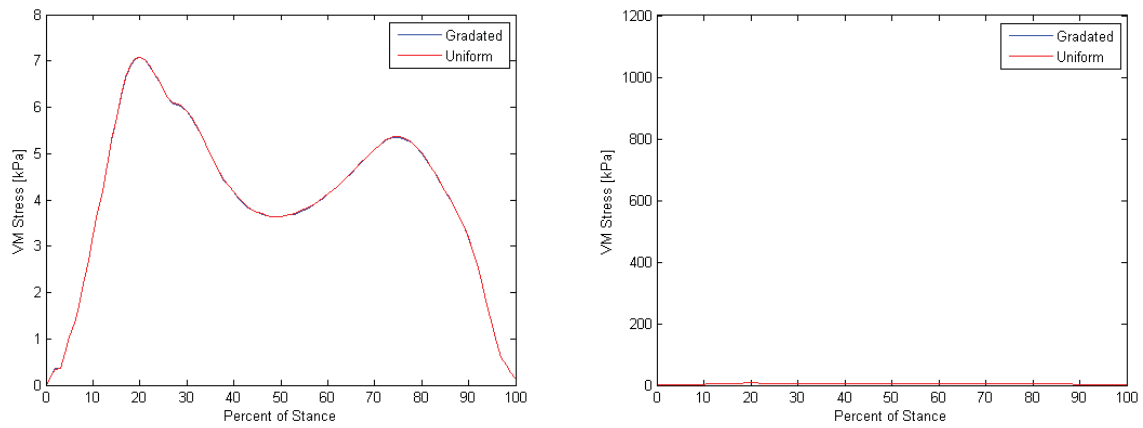


Figure 3.6. Local VM stress on gradated and uniform frames without edges

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

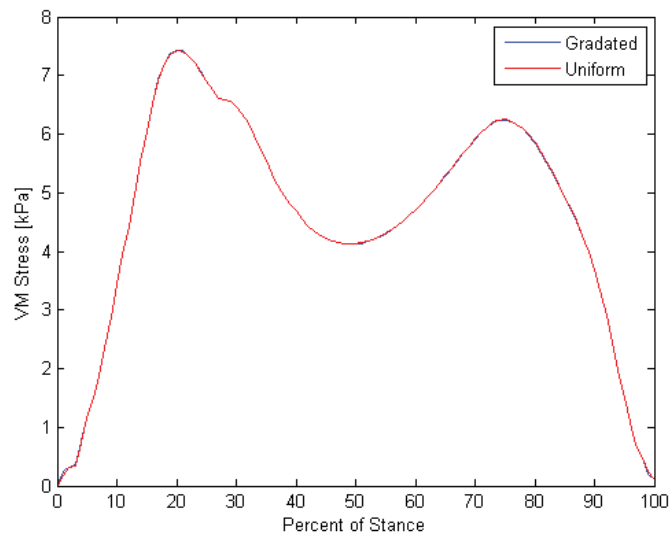


Figure 3.8. Local VM stress on residual limbs at edge of frames

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.

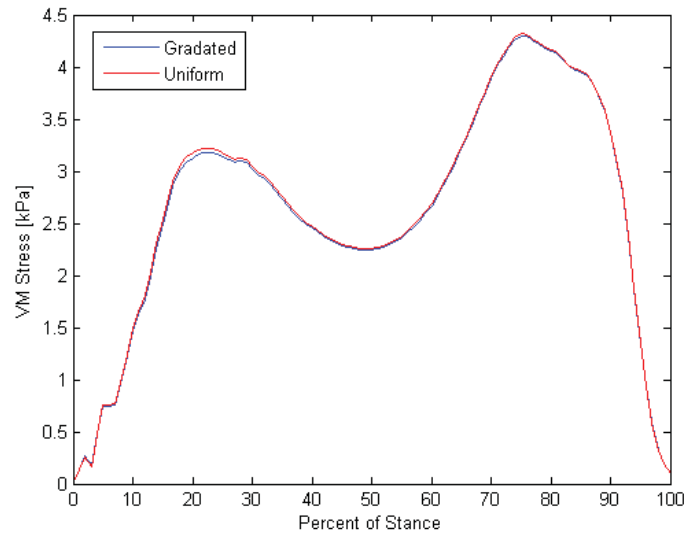


Figure 3.9. Local VM stress on residual limb at lateral extension

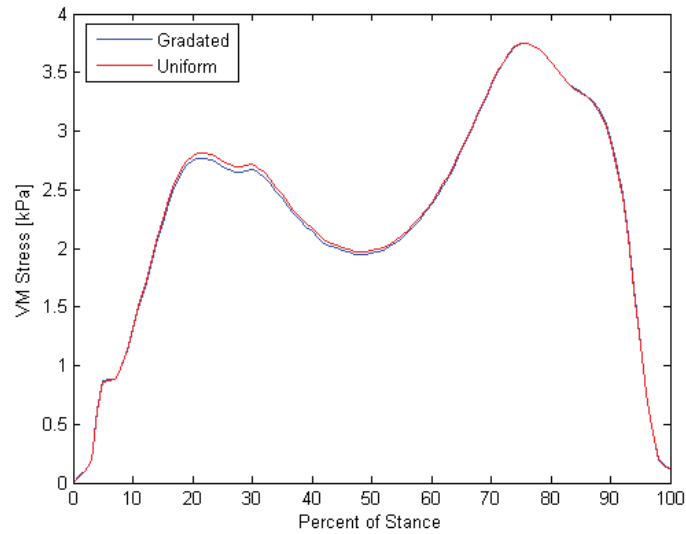


Figure 3.10. Local VM stress on residual limbs at posterior buttress

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.

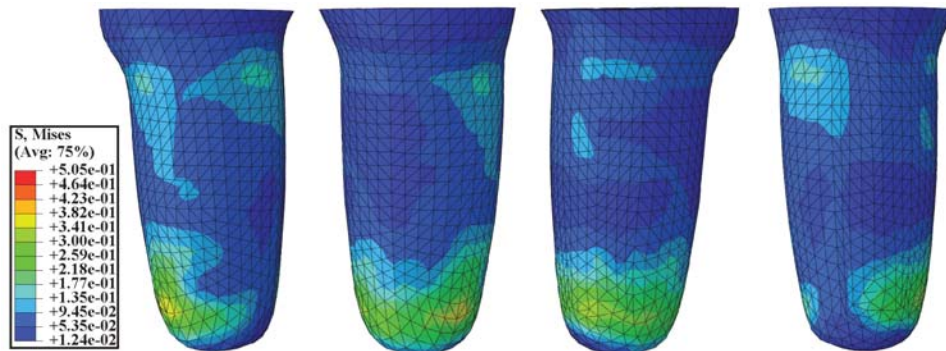


Figure 3.11. VM stress distributions on uniform thickness socket model from posterior, medial, anterior, and lateral views

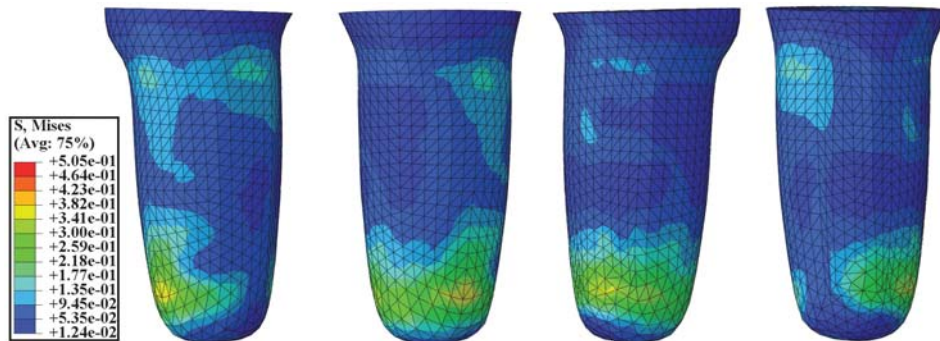


Figure 3.12. VM stress distributions on gradated thickness socket model from posterior, medial, anterior, and lateral views

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 feasibility, it may be worth fabricating a frame with ULTEM 9085. The flexural modulus of ULTEM 9085 is more than 30% greater 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.

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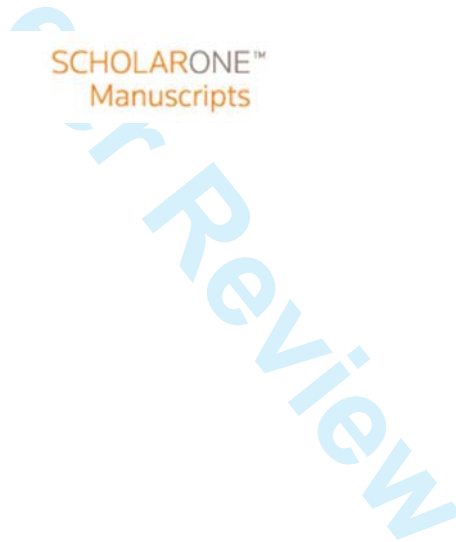
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Fabricating Prosthetic Sockets with Additive Manufacturing Technology

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Article Title Page

1
2 **[Fabricating Prosthetic Sockets with Additive Manufacturing Technology]**
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75
76 **Structured Abstract: (250 words)**

77
78 **Purpose**

79 The purpose of this project was to develop a technique for fabricating flexible transfemoral sockets utilizing
80 additive manufacturing (AM) technology.

81
82 **Design/methodology/approach**

83 Using an iterative design process, a process was developed that used a Stratasys Fused Deposition
84 Modeler to fabricate flexible transfemoral sockets with a molding approach. The AM sockets were subjected to
85 structural testing using a modified International Organization for Standardization (ISO) standard for performance
86 testing of lower limb prosthetic components. Northwestern University Flexible Sub-ischial Vacuum – NU-FlexSIV
87 Sockets – flexible transfemoral sockets – and hybrid sockets – sockets fabricated with the conventional technique but
88 using AM materials – were also tested, and the yield strengths and compression points of the three socket types were
89 compared.

90
91 **Findings**

92 The NU-FlexSIV Sockets outperformed the hybrid and AM sockets during static strength testing.

93
94 **Research limitations/implications (if applicable)**

95 The AM technique was limited by the materials available for use with the Stratasys system as the strength of
96 the NU-FlexSIV socket was unmatched by the strength of the AM socket.

97
98 **Practical implications (if applicable)**

99 The molding approach allowed for the introduction of manual fabrication materials to AM sockets, increasing
100 the AM socket strength. The modified ISO standard was recommended as a standardized metric for socket strength
101 testing.

102
103 **Social implications (if applicable)**

104
105 **Originality/value**

106 The AM approach successfully controlled socket thickness, the novel molding technique combined AM
107 materials and manual fabrication materials, and the controlled examination of two socket fabrication techniques
108 allowed for separate socket fabrication techniques to be compared by a standard metric.

109
110 **Keywords:**

111 Advanced Manufacturing Technologies
112 Fused deposition modelling
113 CAD/CAM
114 Rapid prototyping
115 Flexibility
116 Moulding

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Article Classification:
Research paper

For internal production use only

Running Heads:

Summary of FEA work

Brian Robillard

May 3, 2014

Goal: To explore alternate designs of the distal portion of the PC-ABS frame that can withstand greater stresses.

Problem: Consistent with static proof tests of other prosthetic sockets [1] NU-FlexSIV sockets tested to date all failed at the very distal portion of the socket where it interfaces with the distal adapter [2]. Clinical use of NU-FlexSIV sockets fabricated using standard manual processes has demonstrated their ability to withstand daily use without frequent failures. NU-FlexSIV sockets manufactured using additive manufacturing techniques failed at lower loads than those manufactured using manual processes. This difference in strength was attributed to differences in the extent of fabric layup in the distal portion of the socket. The AM sockets lacked a thorough fabric layup at the distal portion of the sockets, causing the AM sockets to fail at the sharp transition between the body of the frame and portion of the frame that encapsulated the distal adapter. This transition point is illustrated in Figure 1.

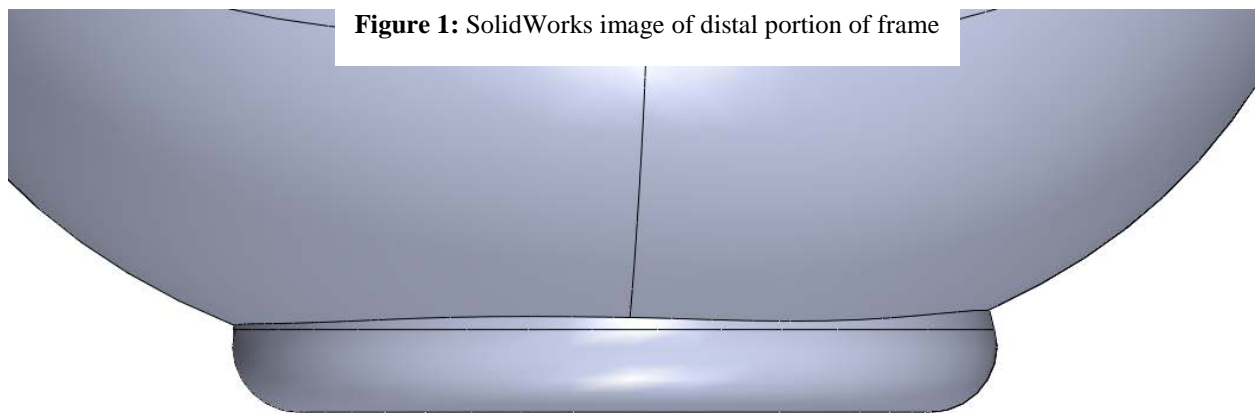


Figure 1: SolidWorks image of distal portion of frame

Approach: Use Abaqus to explore the effect of modified distal geometries on the stress levels experienced by the distal portions of the sockets. The frame was simplified to only include the distal portion.

Model setup:

Three separate distal frame designs were examined in Abaqus. They are as follows:

1. Frame design used in WillowWood static strength testing. Referred to as “WillowWood.”

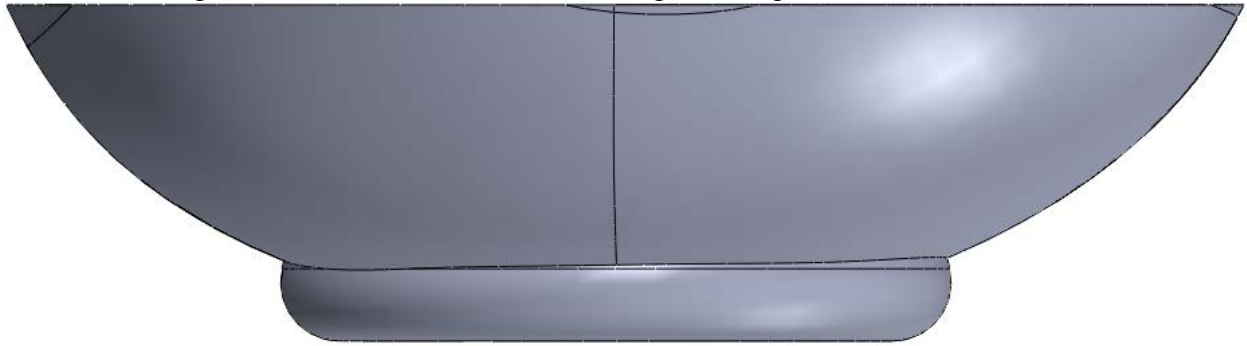


Figure 2: Distal portion of frame used for WillowWood testing

2. Frame design where the very distal portion is blended. Referred to as “blended.”

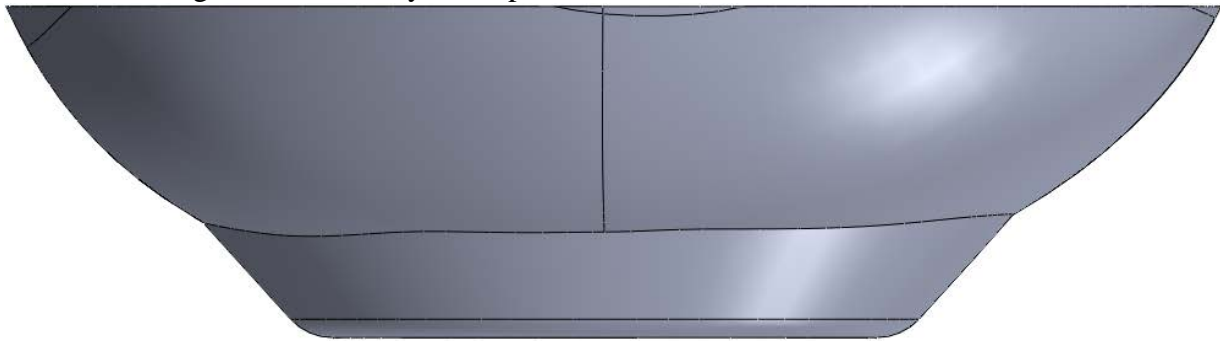


Figure 3: Distal portion of blended frame design

3. Frame design with uniform distal portion. Referred to as “uniform.”

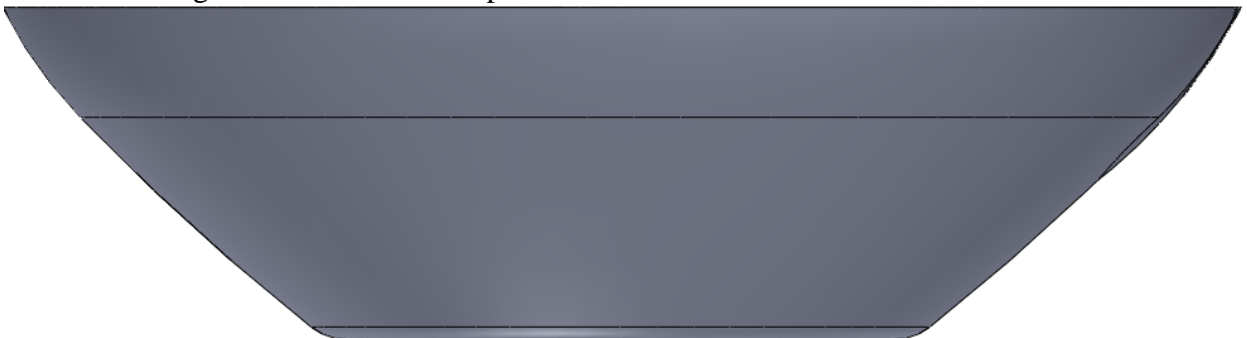


Figure 4: Distal portion of uniform frame design

Material setup:

The frames were made of PC-ABS. The following material properties of PC-ABS were determined experimentally during a flexural test of 5 specimens:

Young’s Modulus: 1774.861858

Poisson’s ratio: 0.06

The plastic region of deformation was input from data acquired from static proof testing and illustrated in Figure 5.

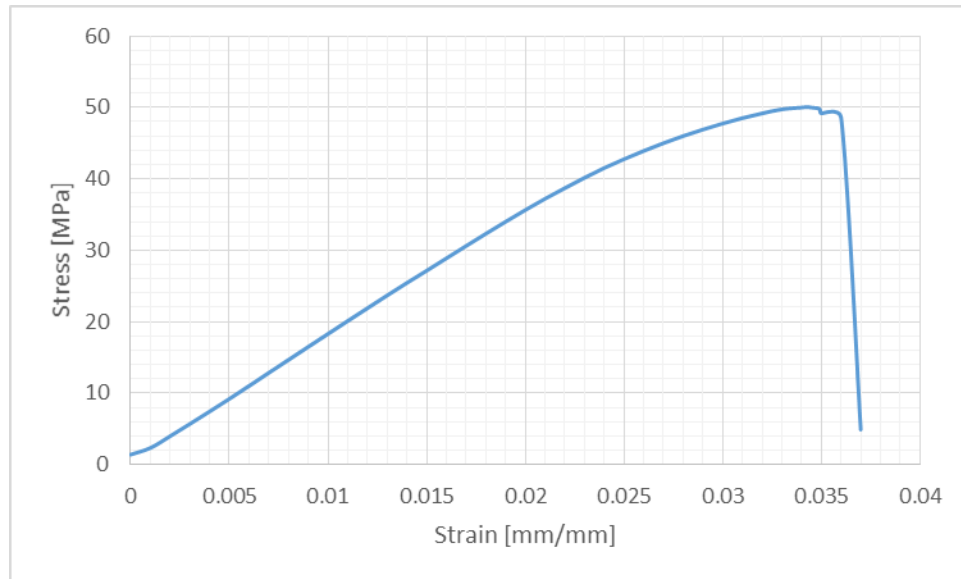


Figure 5: Stress-strain curve from PC-ABS flexural testing

Load: A uniform load of 250 N/s was applied to the model. This was done to replicate the load rate of the WillowWood testing [3]. Further, the top of the model was rotated 5° towards the posterior portion of the socket in order to replicate the WillowWood testing set up of pre-flexion [3]. The first model that was loaded was the WillowWood frame design shown in Figure 2. It was loaded until the fracture point was reached. These same loads were then applied to each of the other designs (Figures 3 and 4). Each of the parts were loaded for the same amount of time.

Results:

The stress and strain experienced by the nodes were averaged at every time increment and plotted for each distal frame design. The plotted results can be seen in Figure 6. The von Mises stresses for the three distal frame designs are visualized in Figure 7. The model views are, from left to right, anterior, lateral, posterior, and medial.

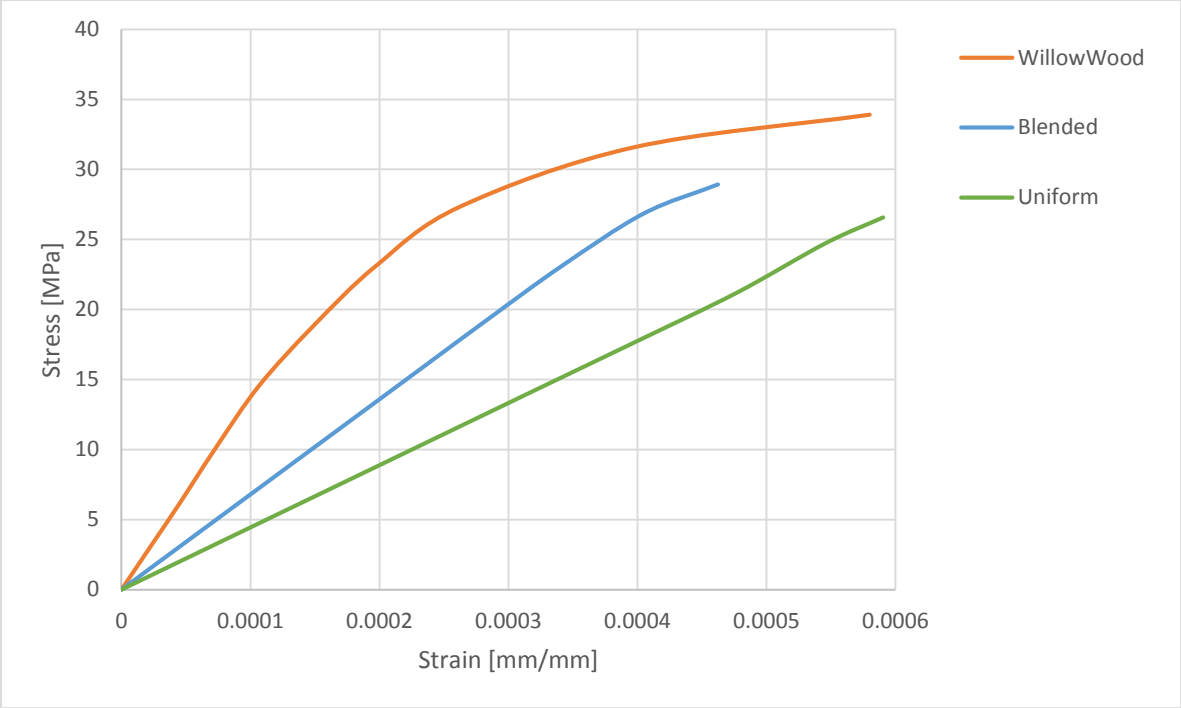


Figure 6: Stress-strain curves for distal frame designs

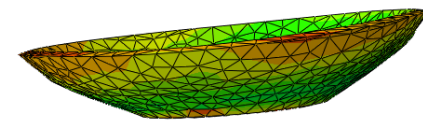
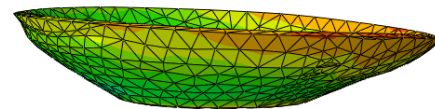
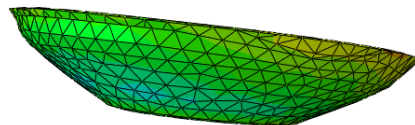
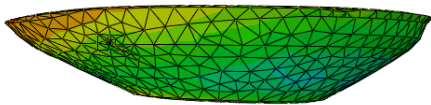
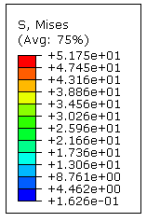
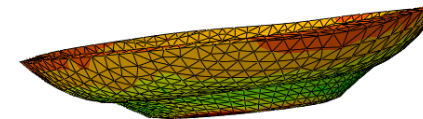
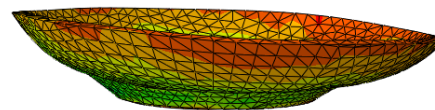
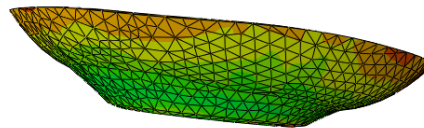
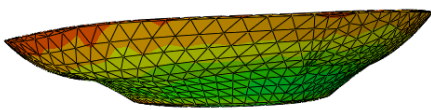
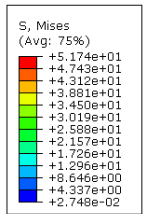
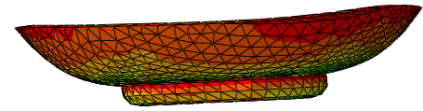
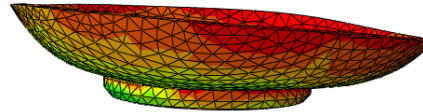
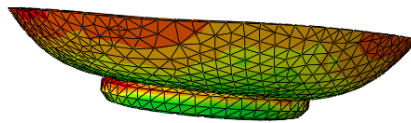
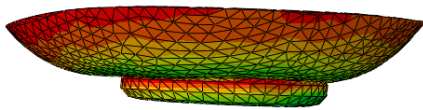
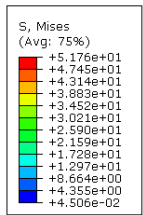


Figure 7: von Mises stress experienced by distal frame

Discussion and Conclusion:

The results demonstrated that the stresses experienced by the blended and uniform design distal frames were lower than the stresses experienced by the WillowWood frame. The region of elastic deformation appears to be extended for the blended and uniform frames, suggesting that the eventual fracture point of the designs may occur at a larger stress than the WillowWood frame. Further, Figure 7 clearly demonstrates an alleviation of stresses in the blended and uniform frames compared to the WillowWood frame. The large stresses experienced in the WillowWood frame at the transition from the body of the frame to the portion of the frame that encapsulates the distal adapter are non-existent in the blended and uniform frames. The results indicated that the added support on the distal portion of the frames decreased the stresses experienced by the frame across time. Though a thorough failure analysis was not undertaken, these results suggested that improvements can be made to the design of the distal portion of the frame in order to improve performance.

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Methods for characterization of mechanical and electrical prosthetic vacuum pumps

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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 cm³ (2 in.³) to 197 cm³ (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.

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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)	<ul style="list-style-type: none"> • 2.20 Wh nominal battery energy. • 61 kPa (18 inHg) maximum negative pressure level.
LimbLogic VS (Ohio WillowWood)	<ul style="list-style-type: none"> • 2.04 Wh nominal battery energy. • 68 kPa (20 inHg) maximum negative pressure level.
Mechanical	
Harmony P2 (Ottobock)	<ul style="list-style-type: none"> • Patient weights of 50–100 kg (110–220 lb). • Vacuum capability of 51–85 kPa (15–25 inHg).
Harmony HD (Ottobock)	<ul style="list-style-type: none"> • Patient weights of 100–150 kg (220–330 lb). • Vacuum capability of 51–85 kPa (15–25 inHg).
Harmony P3 (Ottobock)	<ul style="list-style-type: none"> • 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	Harmony P3		
		Corresponding Patient Weight (lb/kg)		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 cm³ (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 cm³ [2 in.³] to 197 cm³ [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).

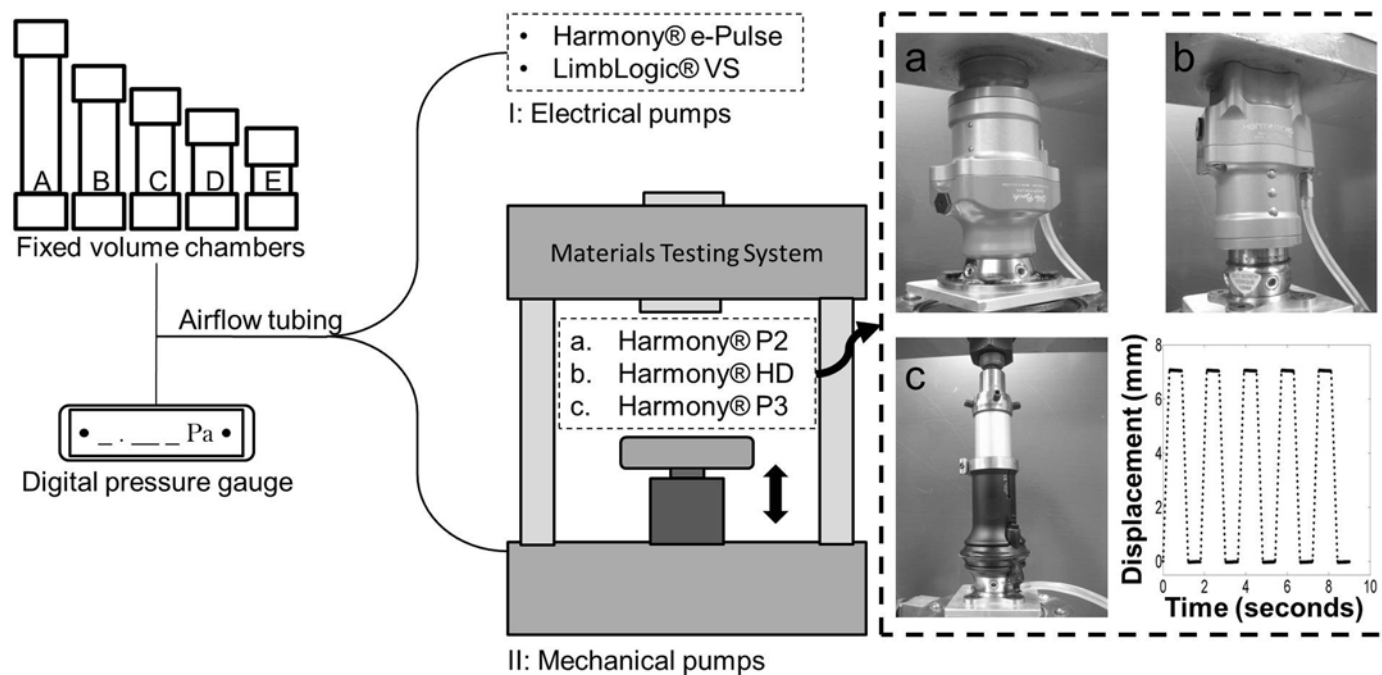


Figure 1.

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 cm³ (12.54 in.³), (B) 140 cm³ (8.52 in.³), (C) 106 cm³ (6.46 in.³), (D) 75 cm³ (4.59 in.³), and (E) 44 cm³ (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 cm³ (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.

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

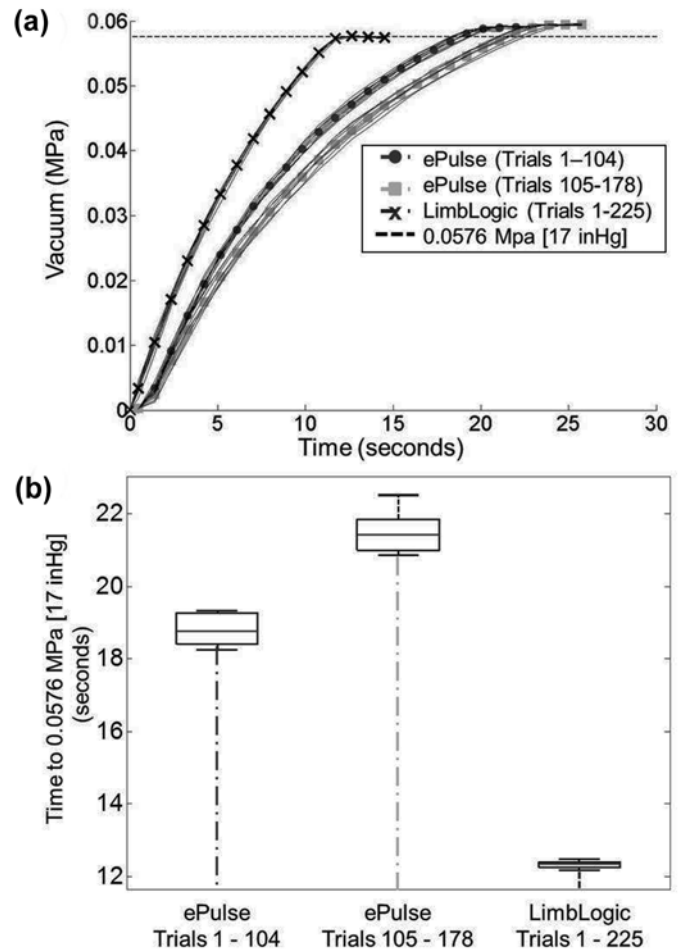


Figure 2.

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.

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.

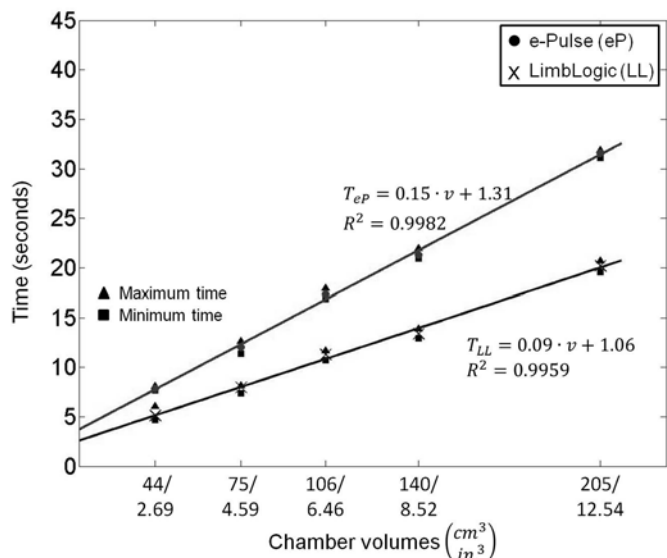
Electrical pump results. Standard evacuation pressure level was set at 57.6 kPa (17 inHg).

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 activa-

**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}).

tion 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.

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 cm³ (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

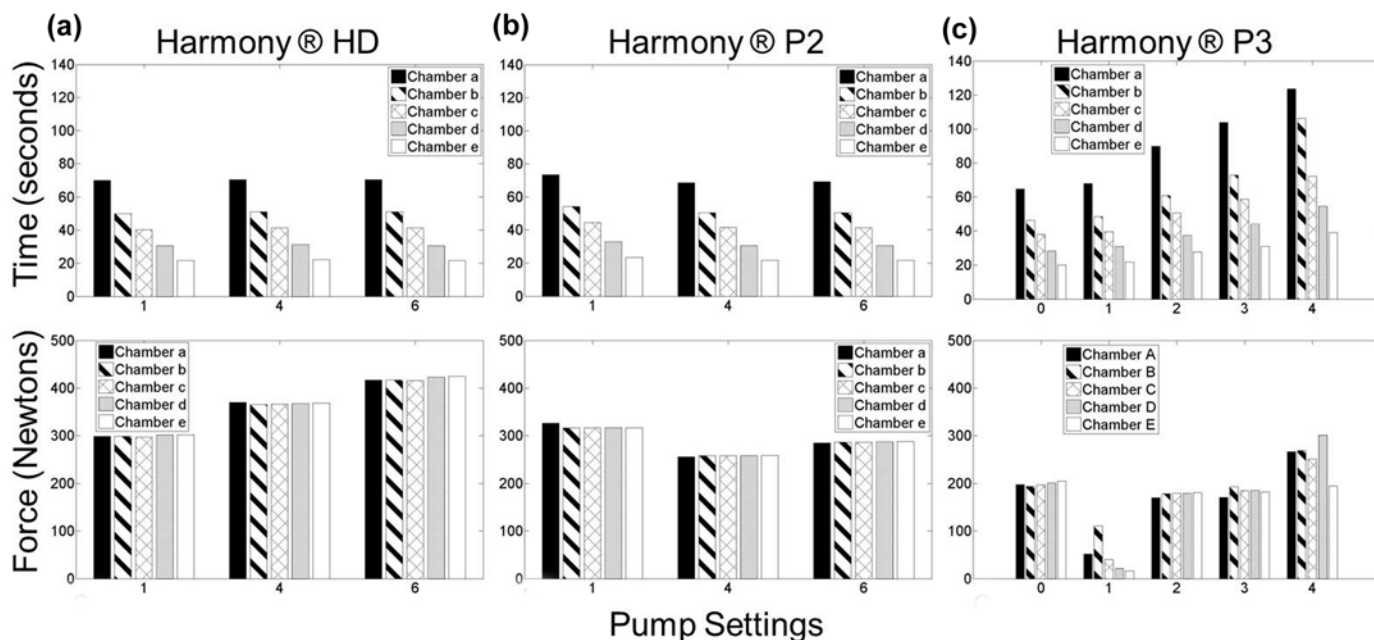


Figure 4.

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 deacti-

vated 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.

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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.

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Title: Evaluation of a hybrid vacuum pump to provide vacuum-assisted suspension for above-knee prostheses

Article Type: Technical Note

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Keywords: prosthesis; vacuum; suspension; socket

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Abstract: Vacuum-assisted suspension 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. 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 to maintain suspension without reactivation of the electric system, thereby allowing battery power to be reserved for monitoring vacuum levels.



Sub-Ischial Prosthetic Sockets Improve Hip Range of Motion and Performance for Individuals with Transfemoral Amputations

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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 pre-morbid health and many wish to return to pre-morbid 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.

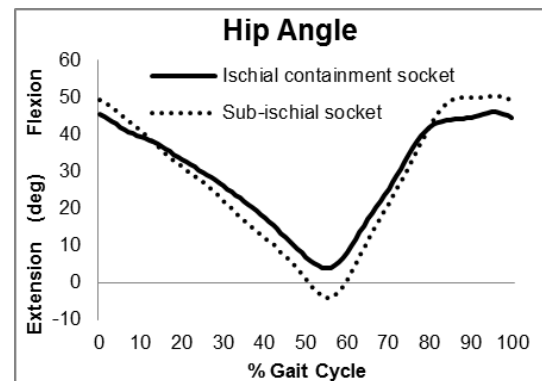
Testing took place in the ischial containment socket followed by the sub-ischial socket. Subjects underwent a series of range of motion, performance, and biomechanical tests. A 26-camera motion capture system (120 Hz, Motion Analysis Corp., Santa Rosa, CA) tracked trajectories of 57 markers secured to 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 $12.5 \pm 1.2^\circ$ 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.*

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QUANTIFICATION OF RECTIFICATIONS FOR SUBISCHIAL SOCKET

Review Copy

ABSTRACT

Background and Aim: 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. We recently developed a new subischial socket for persons with transfemoral amputation dubbed the [REDACTED] Socket. The aim of this study was to quantify the rectifications required to successfully fit an [REDACTED] Socket using rectification maps. **Technique:** A program was written to align scans of rectified and unrectified negative molds and calculate changes in the shape as a result of rectification. A color coded scale with units in millimeters was used to indicate the amount of rectification required. **Discussion:** Rectification maps reveal the depth and contours of the modifications that were made for the [REDACTED] Socket, showing that plaster was primarily removed from the proximal half of the lateral and posterior surfaces, while the medial walls remained untouched.

Word Count: 153

CLINICAL RELEVANCE:

Color coded rectification maps were used to quantify rectifications for use with the [REDACTED] Socket, helping communicate to others an important step in the application of this socket design and enhancing clinical practice and understanding.

Word Count: 35

Background Methods/Results

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.

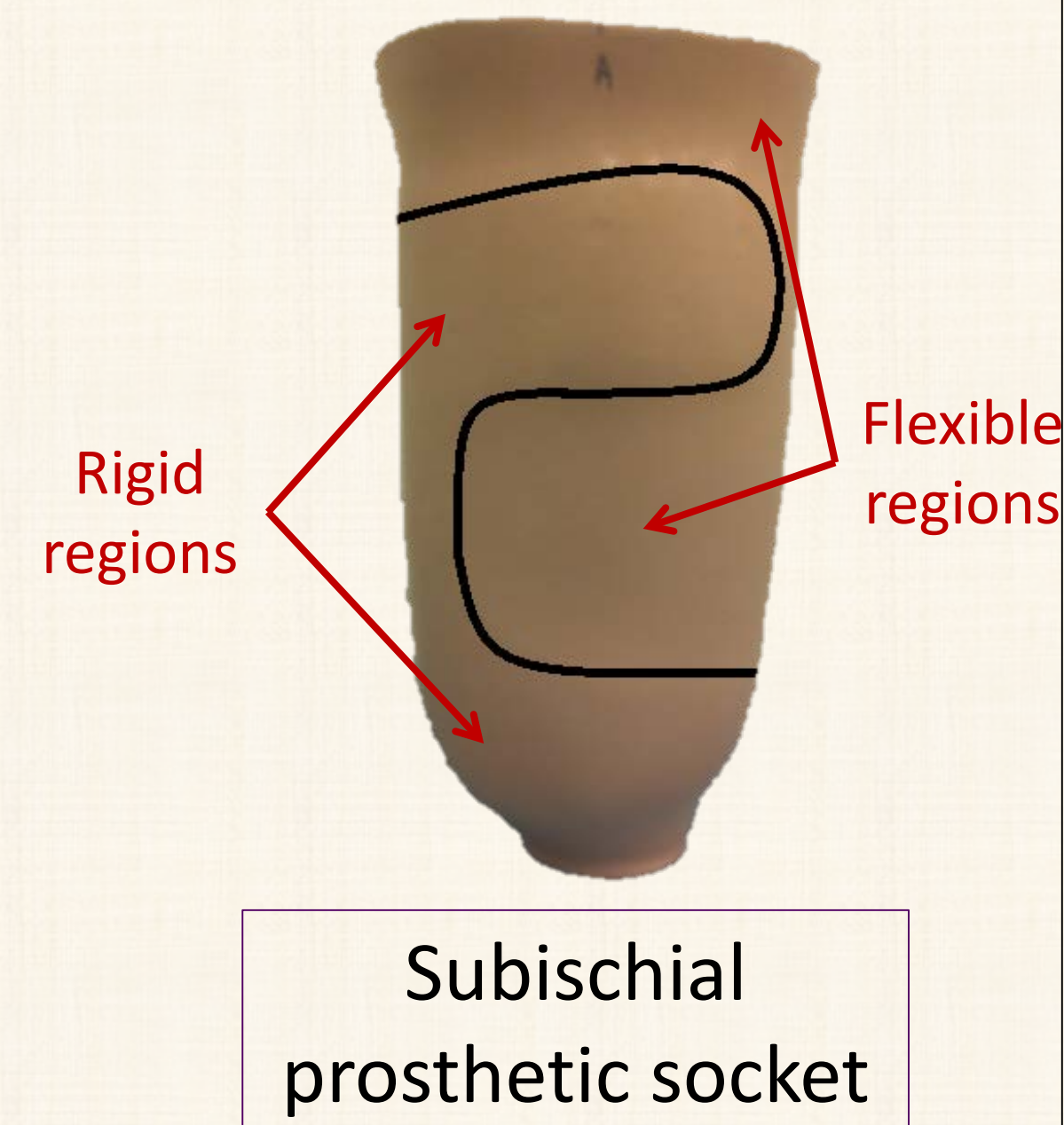
Purpose of the Study

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

Introduction

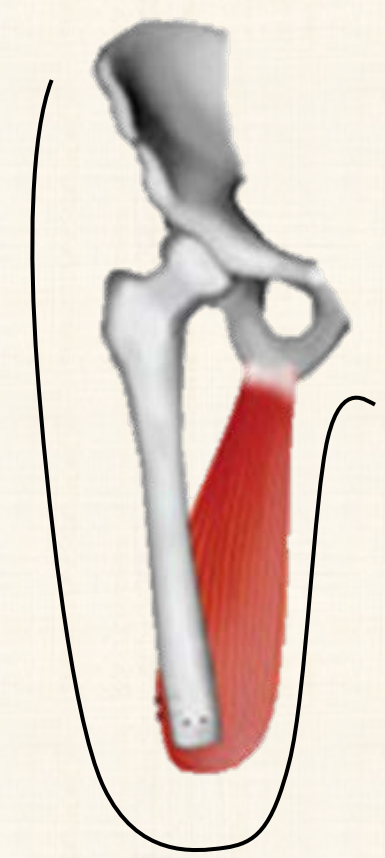
Manual Fabrication of a Transfemoral Prosthetic Socket

- 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

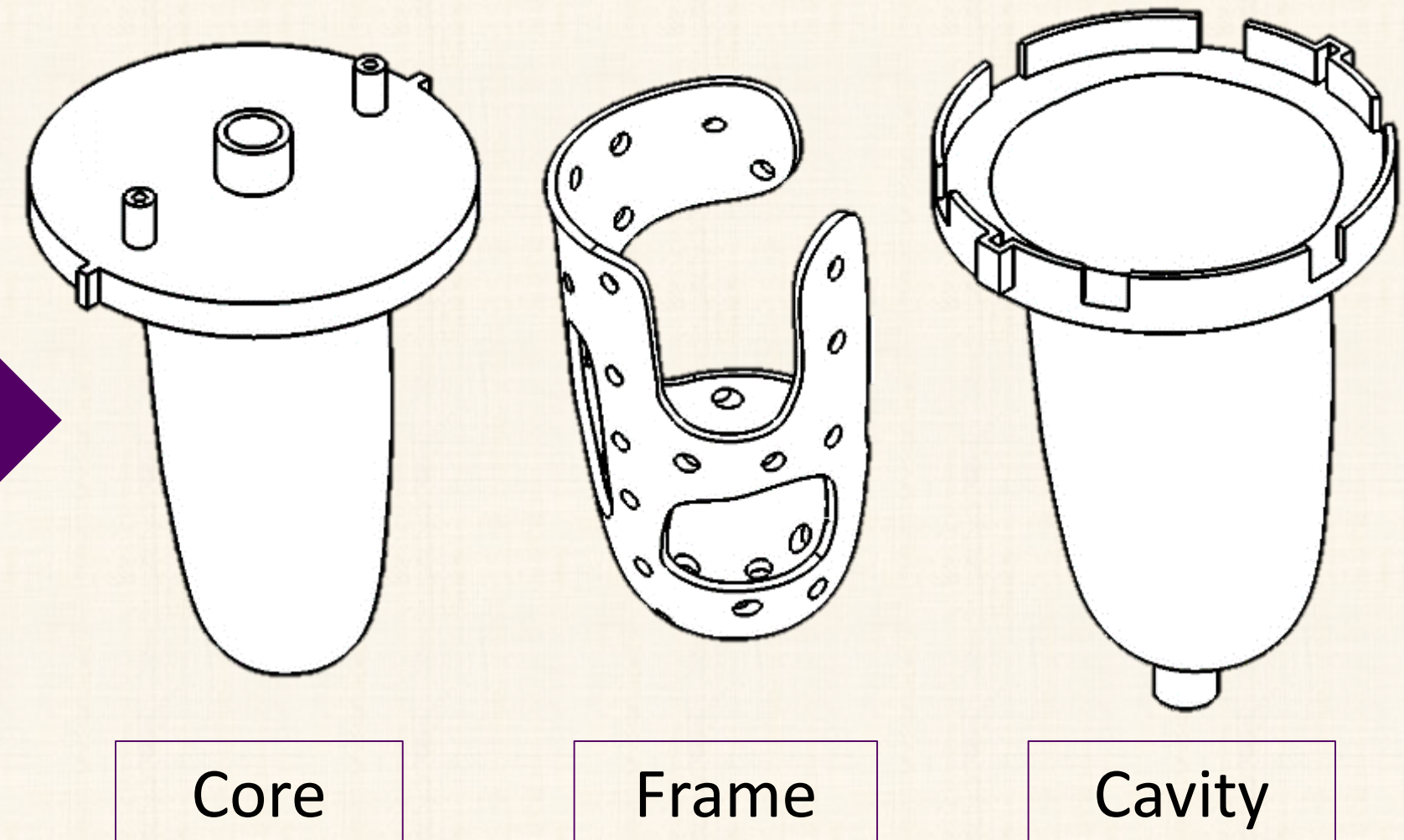


Approach Overview

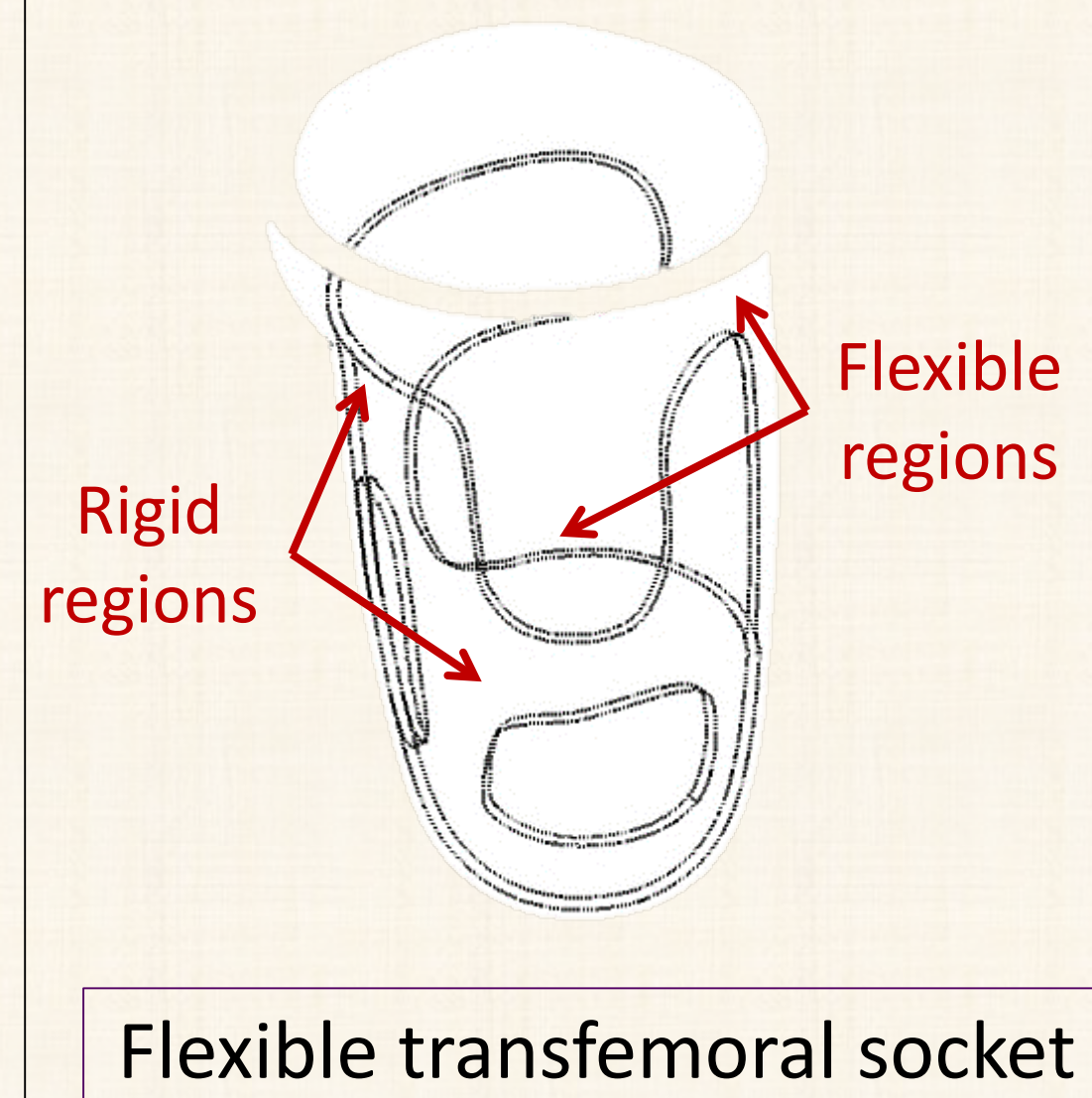
1. Scan of residual limb



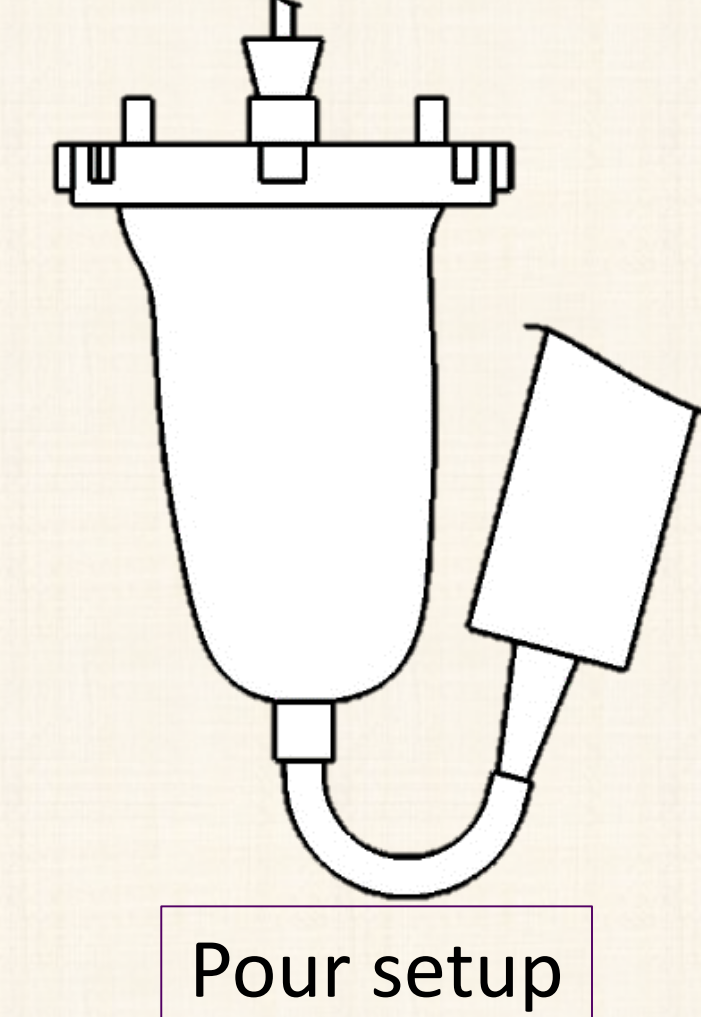
2. Design with SolidWorks



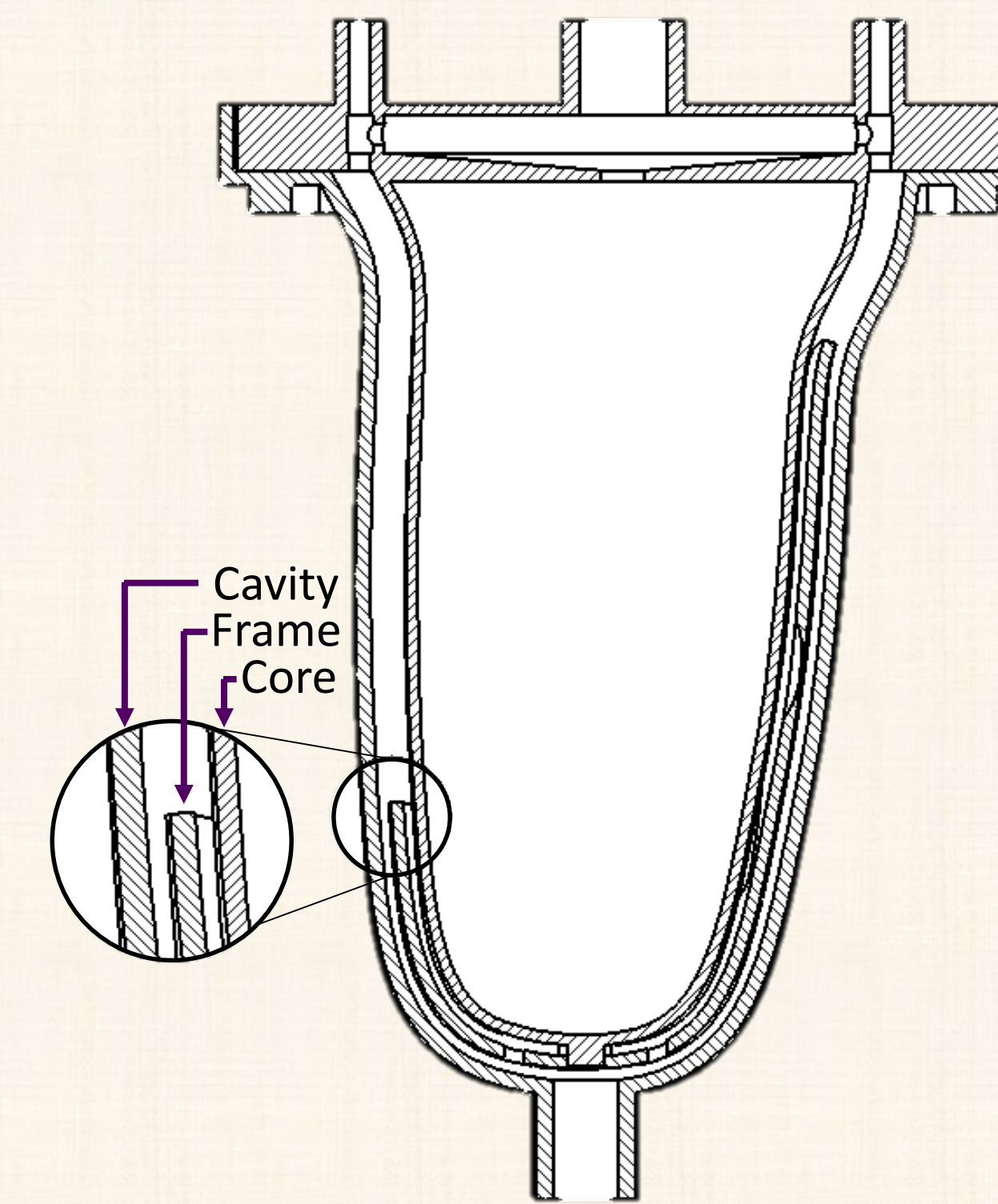
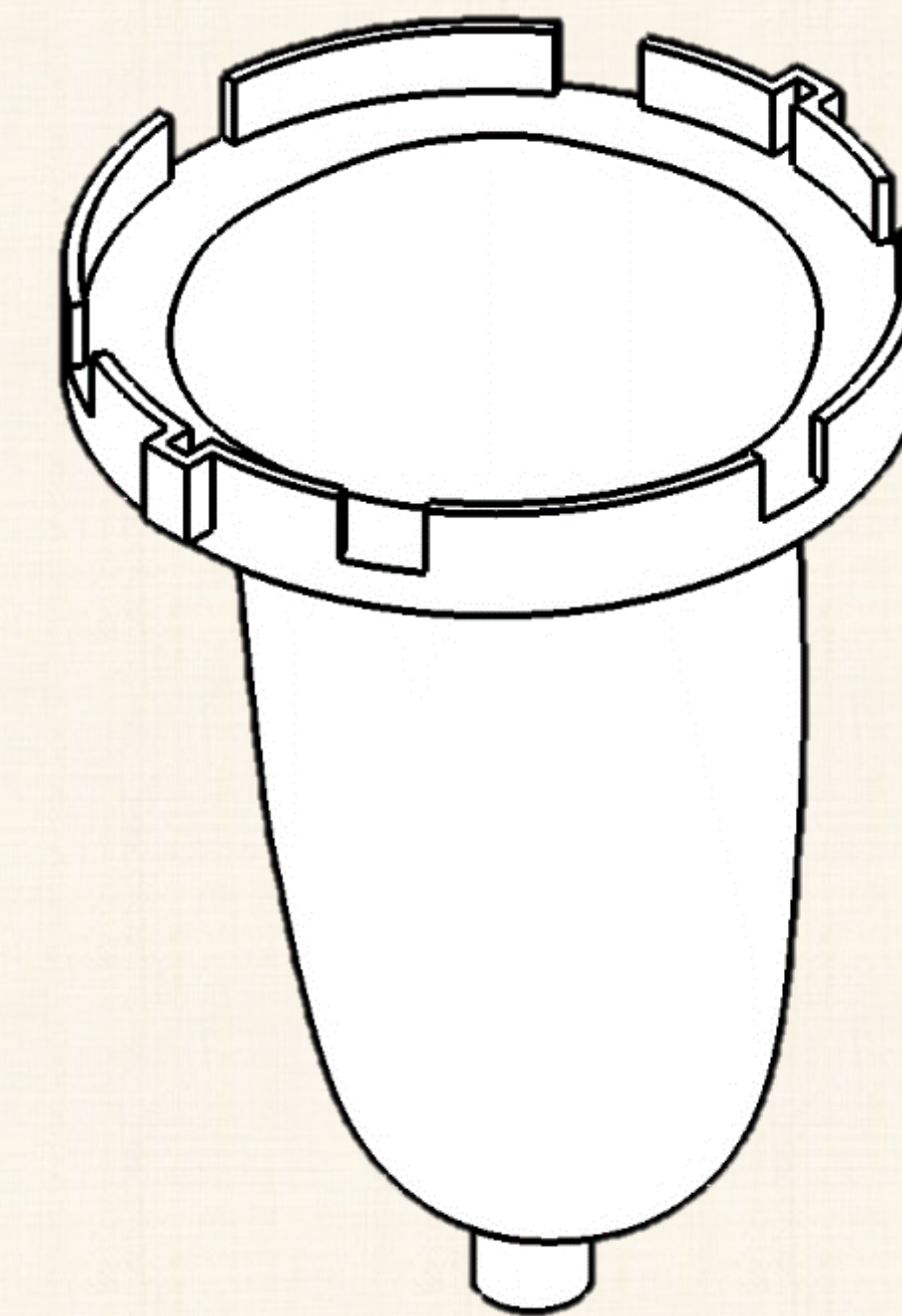
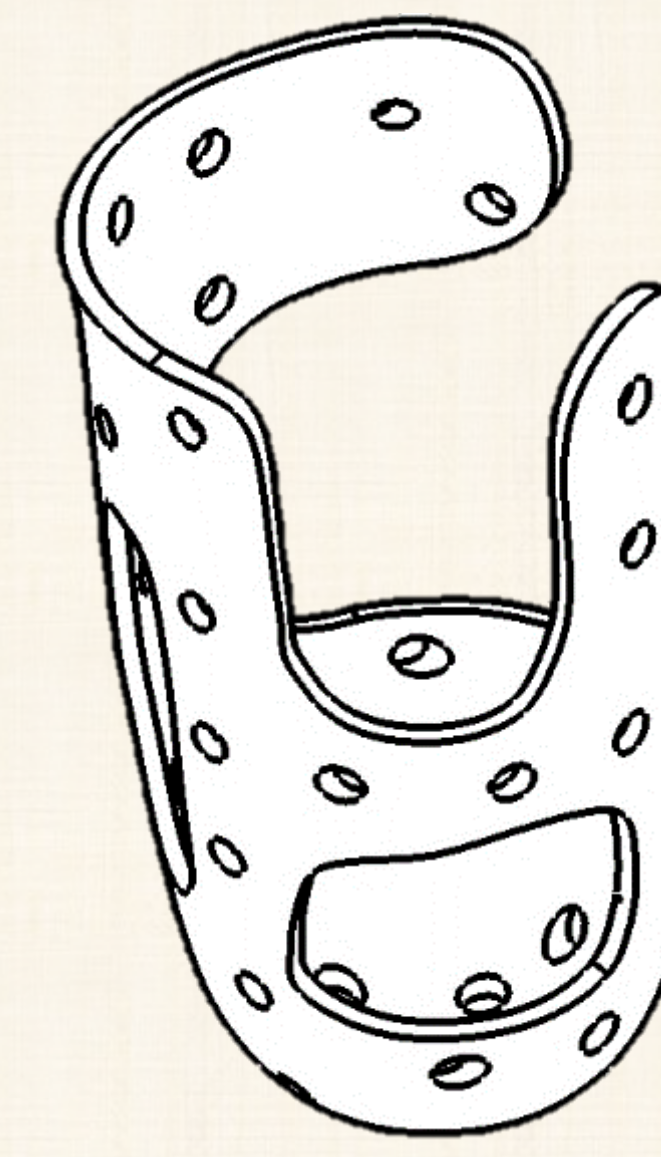
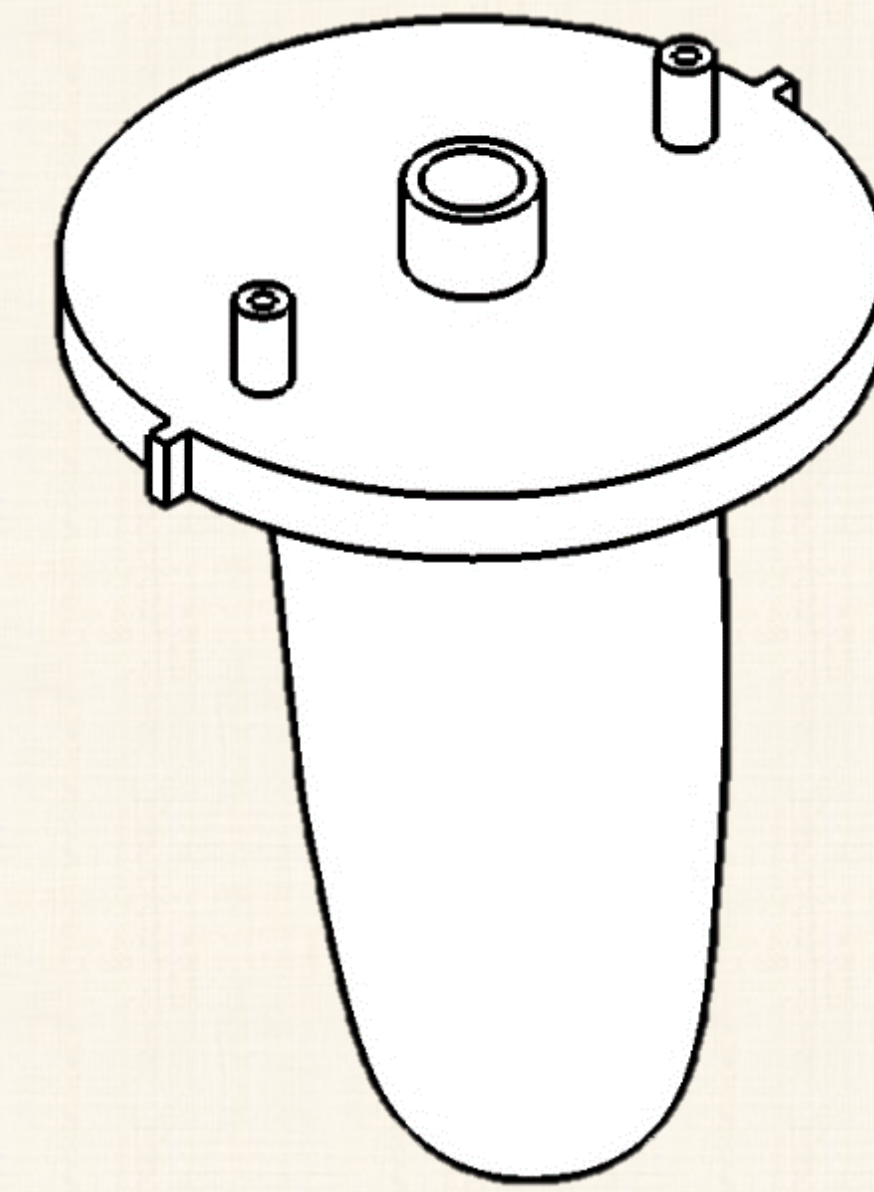
4. Fabricated Socket



3. Build components with Stratasys and pour flexible material



Mold design with CAD software (SolidWorks 2011)



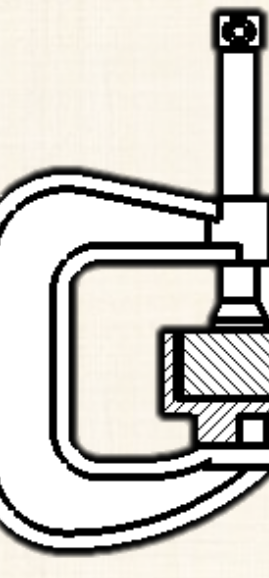
Fabrication in Stratasys Fortus 400mc Fused Deposition Modeler

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



Fabrication of socket with single-shot

- 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

Rigid regions

Conclu

The single-shot molding process for a prosthetic socket has demonstrated clinical applicability remains to be determined. The project include the following: manufacturing the rapid prototyped socket with rigid regions and the fabricated socket.

Funding Acknowledgement

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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.