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TITLE: 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 and disseminate education materials. During Year 5, we completed the tasks in 5 and worked on the tasks in Aim 4.					
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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 and deliver courses for the 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 two hybrid mechanical/electrical pumps 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 were 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. We also disseminated the sub-ischial socket technique to certified prosthetists via a pilot series of three hands-on workshops. 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. Expansion funding was recently received to conduct a randomized cross-over assessor-blinded trial comparing the sub-ischial socket to the standard of care ischial containment socket.

BODY: PROJECT PROGRESS

What follows is a description of the work conducted during Year 5 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, 3 and 5 and are working on the tasks in Aim 4. We will complete Aim 4 during the third year extension without funds. During this coming year we will continue to provide support for implementation of the sub-ischial socket in clinical practice by the participants of our pilot series of sub-ischial socket workshops via an online forum. We will also conduct a small observational clinical trial to assess the contribution of the liner and socket to the tissue stiffening proposed as the basis for socket stability with respect to the residual limb.

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.*

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

Task 3 Advanced manufacturing of sub-ischial sockets

This process and results of testing were described in a manuscript submitted for publication to the *Journal of Prosthetics and Orthotics* (see Appendix A for abstract of this manuscript).

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 Scheduled	Task Scheduled	Task Scheduled	Task Scheduled	Task Scheduled	Task Scheduled	Task Scheduled	Task Scheduled	Task Scheduled	Task Scheduled
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				
	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 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															
Task Scheduled																
Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users.																
Task 5 Solicit Feedback from human subjects.																
5a Perform subject fittings with advance manufactured sockets. Assess results and obtain feedback from subjects.																

Task 5a Perform subject fittings with advance manufactured sockets. Assess results and obtain feedback from subjects: *This task is complete.*

Our exploration of methods to manufacture the definitive flexible socket have resulted in the use of medi Flex EVA as the flexible inner socket and a rigid outer carbon fiber laminated socket (Figure 1). medi Flex EVA provides sufficient 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 very thin, light profile. 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 (Figure 2).



Figure 1 medi Flex EVA definitive socket.



Figure 2 Flexible check socket fabrication: (a) flexible inner socket with Velcro and sealing ring to hold rigid PETG outer socket in place (distal port hole for air not shown); (b) outer socket sprayed with alcohol to allow it to be pushed onto inner socket; (c) lateral and (d) anterior view of flexible inner socket inserted into outer socket and reinforced with fiberglass tape, red line indicates top of rigid socket; (e) donned socket showing attachment of barb to distal end of outer socket (vacuum is drawn from between liner and inner socket through port hole and between inner and outer socket via barb) as well as sealing sleeve (distal end of sealing sleeve can be anchored between flexible and rigid sockets if preferred); and (f) mid stance of gait with flexible check socket.

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



Figure 3 Definitive sub-ischial socket fabricated by AOPS.

replaced by a carbon fiber reinforced laminated socket (Figure 3). The definitive socket can be fabricated by the prosthetist or by a central fabrication service such as Advanced Orthotics & Prosthetics Solutions (AOPS).

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																
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.* A publication based on standing and walking hybrid vacuum pump data from persons with unilateral transfemoral amputation was published in the *Journal of Prosthetics and Orthotics* (Appendix B). A synopsis of this article was also featured on oandp.com, "[Study Examines Comparative Effectiveness of Electric Vacuum Suspension Pumps](#)" September 20, 2015.

Task 6c Compare results of 6a and 6b: *This task is complete.*

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.*

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.

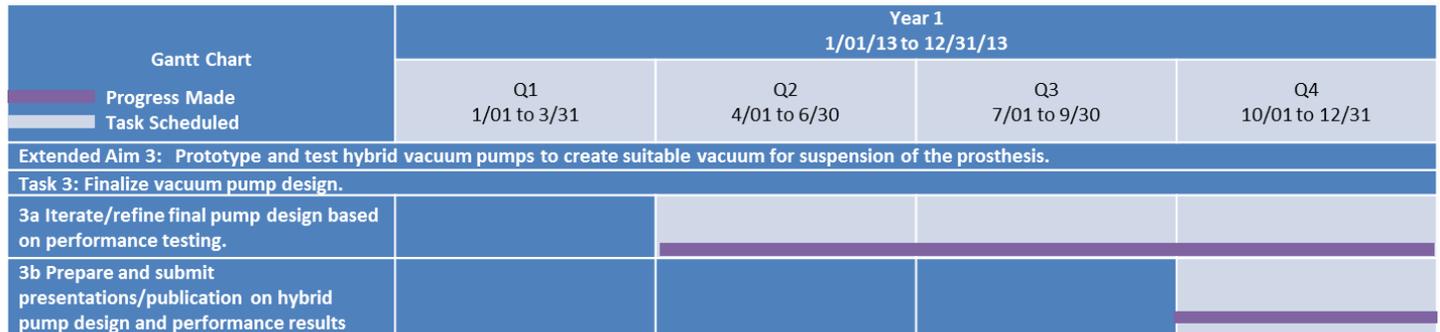
Gantt Chart	Year 1 1/01/13 to 12/31/13			
	Q1 1/01 to 3/31	Q2 4/01 to 6/30	Q3 7/01 to 9/30	Q4 10/01 to 12/31
Progress Made				
Task Scheduled				
Extended Aim 3: Prototype and test hybrid vacuum pumps to create suitable vacuum for suspension of the prosthesis.				
Task 2: Performance testing of three 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.*

Supplemental Task 2b Evaluate time needed to evacuate sockets of transfemoral prosthesis users: *This task is complete.*

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.



Supplemental Task 3a Iterate/refine final pump design based on performance testing: *This task is complete.*
Provisional patent for an alternative diaphragm design filed.

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 published in *Journal of Medical Devices* (Appendix C).

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				Extension without Funds 9/15/14 to 9/15/15				Extension without Funds 9/14/15 to 9/15/16					
	Q1 9/1 5 to 12/ 14	Q2 12/ 15 to 3/1 4	Q3 3/1 5 to 6/1 4	Q4 6/1 5 to 9/1 4	Q1 9/1 5 to 12/ 14	Q2 12/ 15 to 3/1 4	Q3 3/1 5 to 6/1 4	Q4 6/1 5 to 9/1 4	Q1 9/1 5 to 12/ 14	Q2 12/ 15 to 3/1 4	Q3 3/1 5 to 6/1 4	Q4 6/1 5 to 9/1 4	Q1 9/1 5 to 12/ 14	Q2 12/ 15 to 3/1 4	Q3 3/1 5 to 6/1 4	Q4 6/1 5 to 9/1 4	Q1 9/1 5 to 12/ 14	Q2 12/ 15 to 3/1 4	Q3 3/1 5 to 6/1 4	Q4 6/1 5 to 9/1 4	Q1 9/1 5 to 12/ 14	Q2 12/ 15 to 3/1 4	Q3 3/1 5 to 6/1 4	Q4 6/1 5 to 9/1 4		
	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.																										
9d Conduct observational clinical study.																										

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.* As noted in our Year 4 Annual Report, recruitment and retention of military amputees has been slower than anticipated due to unanticipated complications scheduling subjects over the duration of the study protocol. We have also had staff turnover both with the prosthetist working on the study and staff in the lab collecting and processing the data. The research staff at the Center for the Intrepid at Brooke Army Medical Center received IRB approval to add additional subjects to the protocol to allow recruitment of additional subjects. To date, 10 male subjects have been enrolled in the study with 3 lost to follow up (Table 1). Of the remaining 7 subjects, 6 have completed baseline biomechanics testing in their standard of care socket; 6/7 have completed baseline fluoroscopy testing in their standard of care socket; 3/7 have completed biomechanics testing in the sub-ischial socket (data for one of these subjects was presented at the 2015 American Academy of Orthotists and Prosthetists Annual Meeting, Appendix D); and 3/7 have completed fluoroscopy testing in their sub-ischial socket. All remaining patients have been fit with a sub-ischial socket and will be tested as each completes the accommodation phase.

Table 1 Subject Characteristics and Testing Timeline

Subject	Date enrolled	Age	Etiology of Amputation	Date of Amputation	Reason for withdrawal	Baseline Socket/Prosthesis			Sub-ischial Socket/Prosthesis		
						Prosthesis Description	Date biomechanics testing	Date fluoroscopy testing	Accommodation time	Date biomechanics testing	Date fluoroscopy testing
1	2012/10/29	28	Motorcycle accident	2009/3/21		IC socket with flexible brim, X3 knee, reflex rotate with Unity foot	2014/12/09	2015/07/21	None to date		
2	2012/10/29	35	Motorcycle accident	2011/8/14	N/A	IC socket with flexible brim, X3 knee, Triton Shock foot	2012/12/19	2012/12/18	8 weeks	2013/02/20	2013/02/20
3	2012/10/29	40	IED	2004/5/12		IC socket with flexible brim, X3 knee, Triton Shock foot	*	*	18 weeks	2013/05/15	2013/06/17
4	2013/02/22	31	Motorcycle accident	Unknown	Moved out of area	IC socket with flexible brim, X2 knee, Renegade foot	2013/08/05	2013/08/08	N/A	N/A	N/A
5	2014/01/31	24		2013/4/13		IC socket with flexible brim, gel seal-in liner with passive suction suspension, X3 knee, College park Truststep foot, push button rotator proximal to the knee	2014/07/01	2014/07/02	3.5 weeks (but then had 2 surgeries and needs to be recast to continue in study)		
6	2014/10/30	33	IED	2013/1	Patient moved out of the area and then forgot his sub-ischial socket when he came back for appointments at the CFI	IC socket with a flexible brim, gel seal-in liner with passive suction suspension, X3 knee, Triton Harmony foot	2015/01/23	2015/01/30	N/A	N/A	N/A
7	2014/11/21	32	IED	2012/7	Could not be fit with sub-ischial socket	IC socket with a flexible brim, gel seal-in liner with passive suction suspension, X3 knee, Triton foot	N/A	N/A	N/A	N/A	N/A

Subject	Date enrolled	Age	Etiology of Amputation	Date of Amputation	Reason for withdrawal	Baseline Socket/Prosthesis			Sub-ischial Socket/Prosthesis		
						Prosthesis Description	Date biomechanics testing	Date fluoroscopy testing	Accommodation time	Date biomechanics testing	Date fluoroscopy testing
8	2015/04/30	33	Gunshot wound	2015/1/15		IC socket with flexible brim, X3 knee and XC with Unity pump foot	2015/07/01	2015/06/24	3 days	2015/08/17 & 2015/08/19	2015/08/14
9	2015/05/04	30	Gunshot wound	2014/10/17		IC socket with flexible brim, X3 knee and Triton Shock foot	2015/07/29	2015/08/26	5 weeks to date		
10	2015/06/29	36	IED	2005/5/12		IC socket with flexible brim, X3 knee and Triton Shock foot	2015/06/30	2015/06/29	None to date		

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

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

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

Task 9d Conduct Observational Clinical Study: *In progress.* During conduct of our sub-ischial socket hands-on courses (see Task 12d), participants were able to fit a diagnostic check socket to patient models. This process begins by having the patient don the liner and, with the socket supported by a hard stand, push into a clear plastic socket that has been modified following our specific mold reduction algorithm (Figure 4). What the participants observed was that patient models who typically cannot tolerate putting weight on the end of their residual limb, were able to place almost all of their body weight on the residual limb once it was clad with the liner and socket. A simple observational clinical study will be conducted wherein a bathroom scale mounted on the hard stand will be used to assess how much weight amputees can place on the limb when it is bare, when it has only the liner, and when it has both the socket and liner. In each of these conditions the patient will also report the amount of discomfort/pain they experience. This will allow us to discern the relative contribution each component (liner and socket) makes to the ability of the amputee to bear weight on the prosthesis and provide some support for the proposed role of tissue stiffening in creating a weight bearing interface between the amputee and the prosthesis. This study will be conducted in Mr. Caldwell's clinic where he routinely fits only sub-ischial sockets.



Figure 4 Static check socket fit.

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
	 Progress Made Task Scheduled											
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.*

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
	Progress Made											
Task Scheduled												
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.*

Task 11c Digitize casts: *The task is complete.*

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

Task 11e Generate representative 3D models: *This task is complete.*

of Certification (BOC). Over the course of two days, participants engaged in didactic lectures, demonstrations and hands-on activities designed to teach attendees how to cast, rectify, fit and align a sub-ischial check socket (see course agenda in Appendix E) (Figure 5). Patient models responded positively to the comfort, range of motion and stability of the sub-ischial socket while prosthetists described the technique as “*straight forward, reproducible.*” Our courses were highlighted in the September issue of the Northwestern Research News (“[Researchers Showcase Prosthetic Socket Design](#),” 2015;8(1):11).



Figure 6 Images from sub-ischial courses: (a) Stefania Fatone and Ryan Caldwell lecturing; (b) participants took casts of their patient models; (c) Ryan Caldwell demonstrated each step in fabrication and fitting, e.g. model rectification; (d) participants rectified their positive models; (e) NUPOC faculty John Brinkman and NUPOC student Allison Bast provided technical support, helping to blister form a check socket; (f) participants undertook initial static check socket fit; (g) participants adjusted sockets as necessary by heating or adding pads; (h) participants aligned their sockets in the Milmo jig; (i) participants attached the barb and reinforced sockets; and (j) patient models walked on the check sockets.

Having the prosthetists participate in the sub-ischial socket course with their own patient and being able to take home the socket and liner was intended to incentivize ongoing implementation of the sub-ischial socket technique in their clinical practice. However, we anticipate that as prosthetists do this, they will encounter additional questions or issues with which they need help. To efficiently facilitate ongoing learning and troubleshooting for all course participants we have created an online forum for early adopters of the sub-ischial socket using HipChat.com. The forum is a collaborative platform where early adopters can ask questions, share information about their experiences fabricating and using the socket, and exchange advice and troubleshooting tips with each other and the research team. Appendix F shows screenshots of initial activity on the forum by participants from our three courses. We will continue to moderate and support this ongoing educational activity during the 6th year extension without funds. We believe that this will ensure that our dissemination activities gain long-term traction with these early adopters.

While conducting the courses a number of good project suggestions were made by course participants. One in particular was quite straightforward and can be easily conducted in Mr. Caldwell’s clinic, helping extend our understanding of how the socket functions. Currently, we theorize that stability of the socket on the residual limb is achieved by the undersized liner and socket compressing the residual limb, stiffening the soft tissue, and decreasing relative motion of the limb within the socket. A simple test will be conducted this coming year to assess the extent to which the liner and socket contribute to this effect (see Task 9d).

Dissemination activities also included presentations at the Midwest Chapter of the American Academy of Orthotists and Prosthetists Annual Meeting in May 2015 and the International Society for Prosthetics and Orthotics World Congress in June 2015. Additionally, we have submitted an abstract to the 2016 OT World Congress (Appendix G) and Ryan Caldwell has been invited to present at the 2016 American Academy of Orthotists and Prosthetists Annual Meeting as part of a panel on “Modern Transfemoral Socket Alternatives and Technologies: The science behind TFAs.”

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				Extension without Funds 9/15/14 to 9/15/15				Extension without Funds 9/14/15 to 9/15/16			
	Q1 9/1 5 to 12/14	Q2 12/15 to 3/1	Q3 3/15 to 6/1	Q4 6/15 to 9/1	Q1 9/1 5 to 12/14	Q2 12/15 to 3/1	Q3 3/15 to 6/1	Q4 6/15 to 9/1	Q1 9/1 5 to 12/14	Q2 12/15 to 3/1	Q3 3/15 to 6/1	Q4 6/15 to 9/1	Q1 9/1 5 to 12/14	Q2 12/15 to 3/1	Q3 3/15 to 6/1	Q4 6/15 to 9/1	Q1 9/1 5 to 12/14	Q2 12/15 to 3/1	Q3 3/15 to 6/1	Q4 6/15 to 9/1	Q1 9/1 5 to 12/14	Q2 12/15 to 3/1	Q3 3/15 to 6/1	Q4 6/15 to 9/1
	Aim 5 Develop education materials for sub-ischial socket designs.																							
Task 13 Final project meeting																								
Task 13a Convene final project meeting.	Progress Made			Task Scheduled																				

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

KEY RESEARCH ACCOMPLISHMENTS

- One patent granted and another provisional patent filed for multiple hybrid pump designs (Aim 3).
- Pilot series of continuing education courses held successfully (Aim 5).

REPORTABLE OUTCOMES

Patent	Caldwell R, Hansen A, Wood S, Chen W, Radcliffe R, Yngve K, Kuhar B, Nelson AJ, Nickel E. Vacuum Pump Systems for Prosthetic Limbs and Methods of Using the Same . United States Patent 9,066,822. Issued on June 30, 2015.	
	Caldwell RJ, Major MJ Vacuum Pump Systems for Prosthetic Limbs and Methods of Using the Same. Serial No. 62/214,560. Filed September 4, 2015.	
Publications	Robillard B, Komolafe O, Caldwell R, Fatone S (submitted) Fabricating Prosthetic Sockets with Additive Manufacturing Technology. Journal of Prosthetics and Orthotics.	Appendix A
	Major M, Caldwell R, Fatone S (2015) Comparative effectiveness of electric vacuum pumps for creating suspension in transfemoral sockets. Journal of Prosthetics and Orthotics, 27(4):149-153.	Appendix B
	Major M, Caldwell R, Fatone S (2015) Evaluation of a hybrid vacuum pump to provide vacuum-assisted suspension for above-knee prostheses. Journal of Medical Devices, 9(4):044504. doi:10.1115/1.4030507.	Appendix C
	Fatone S, Caldwell R (2015) Instructional Manual for NU-FlexSIV Socket. Northwestern University Prosthetics-Orthotics Center, Chicago IL. ©2015 – Stefania Fatone and Ryan Caldwell. All rights reserved.	
Abstracts	Russell Esposito E, Fatone S, Wilken J, Caldwell R, Ferguson J (2015) Sub-Ischial Prosthetic Sockets Improve Hip Range of Motion and Performance for Individuals with Transfemoral Amputations. 41st American Academy of Orthotists and Prosthetists Annual Meeting & Scientific Symposium, February 18-21, New Orleans, Louisiana.	Appendix D
	Fatone S, Caldwell R (submitted) Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation. OT World Congress, May 3-6, 2016, Leipzig, Germany.	Appendix F
Presentations	Fatone S, Caldwell R (2015) An Introduction to Sub Ischial Sockets with Vacuum Assisted Suspension. Midwest Chapter, American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Session, May 27-29, Rosemont, IL.	
	Fatone S, Caldwell R (2015) Northwestern University Flexible Subischial Vacuum Socket (NU-FlexSIV). World Congress of the International Society for Prosthetics and Orthotics, June 22-25, Lyon, France.	

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. We successfully trained 30 Certified Prosthetists to cast, fit, and fabricate this custom socket for their transfemoral amputee patients.

APPENDICES

APPENDIX A Robillard B, Komolafe O, Caldwell R, Fatone S (abstract of submitted manuscript) Fabricating Prosthetic Sockets with Additive Manufacturing Technology. *Journal of Prosthetics and Orthotics*.

APPENDIX B Major M, Caldwell R, Fatone S (2015) Comparative effectiveness of electric vacuum pumps for creating suspension in transfemoral sockets. *Journal of Prosthetics and Orthotics*, 27(4):149-153.

APPENDIX C Major M, Caldwell R, Fatone S (2015) Evaluation of a hybrid vacuum pump to provide vacuum-assisted suspension for above-knee prostheses. *Journal of Medical Devices*, 9(4):044504. doi:10.1115/1.4030507.

APPENDIX D Russell Esposito E, Fatone S, Wilken J, Caldwell R, Ferguson J (2015) Sub-Ischial Prosthetic Sockets Improve Hip Range of Motion and Performance for Individuals with Transfemoral Amputations. 41st American Academy of Orthotists and Prosthetists Annual Meeting & Scientific Symposium, February 18-21, New Orleans, Louisiana.

APPENDIX E Agenda for NU FlexSIV Socket Courses.

APPENDIX F Screenshots from online, post-course forum.

APPENDIX G Fatone S, Caldwell R (submitted) Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation. OT World Congress, May 3-6, 2016, Leipzig, Germany.

APPENDIX A

JPO: Journal of Prosthetics and Orthotics

Fabricating Prosthetic Sockets with Additive Manufacturing Technology

--Manuscript Draft--

Manuscript Number:	JPO14-375
Full Title:	Fabricating Prosthetic Sockets with Additive Manufacturing Technology
Short Title:	
Article Type:	Original Research Article
Keywords:	Advanced Manufacturing Technologies; Fused deposition modelling; CAD/CAM; Rapid prototyping; Prosthetic socket
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Abstract:	<p>Abstract:</p> <p>Introduction Prosthetic sockets are typically fabricated with rigid materials using manual techniques. While rigid sockets transmit loads between the residual limb and prosthesis, they tend to be uncomfortable. The Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) socket was developed to improve comfort by increasing socket flexibility. The socket is manually fabricated and consists of a rigid frame for structural load transmission sandwiched within layers of flexible resin - creating selective flexible and rigid regions in a manner similar to current fenestrated sockets. However, overall flexibility of the socket might be further improved by having greater fabrication control of the socket's dimension parameters than is currently possible using manual fabrication techniques. Hence, the purpose of this project was to develop an additive manufacturing technique for fabrication of the NU-FlexSIV transfemoral socket and to assess the extent to which socket component thickness could be controlled and overall socket strength maintained.</p> <p>Materials and Methods A process was developed using a Stratasys Fused Deposition Modeler to fabricate flexible transfemoral sockets with a molding approach. The additive manufactured sockets were subjected to structural testing using a modified International Organization for Standardization (ISO) standard for performance testing of lower limb prosthetic components. Manually fabricated flexible transfemoral sockets (the NU-FlexSIV Socket) - and hybrid sockets manually fabricated using additive manufacturing materials were also tested. The yield strengths and compression points of these three socket types were compared.</p>

Results

The additive manufactured sockets successfully fit the intended mold and thickness was consistent with the intended thickness demonstrating control of one socket dimension parameter. However, the manually fabricated NU-FlexSIV Sockets outperformed the hybrid and additive manufactured sockets during static strength testing.

Conclusions

A new approach to the use of AM in prosthetic socket fabrication has been developed. The AM technique was limited by the materials available for use with the Stratasys system as the strength of the NU-FlexSIV socket was unmatched by that of the additive manufactured and hybrid sockets. The molding approach allowed for the use of manual fabrication materials as part of the additive manufactured sockets, however, further refinement of the molding approach would also improve strength. The modified ISO standard may be considered a standardized metric for strength testing of additive manufactured sockets to allow comparison of different proposed approaches.

APPENDIX B

Comparative Effectiveness of Electric Vacuum Pumps for Creating Suspension in Transfemoral Sockets

Matthew J. Major, PhD, Ryan Caldwell, CP, Stefania Fatone, PhD, BPO(Hons)

ABSTRACT

Introduction: There is increasing evidence to support the benefits of vacuum-assisted suspension (VAS) as a means of securing lower-limb prosthetic sockets to the residual limb. As use of VAS increases, there is need to assess comparative effectiveness of different vacuum pumps. This study conducted in vivo tests to evaluate the effectiveness of two commercial electric pumps, the Ohio Willow Wood LimbLogic and Otto Bock Harmony e-pulse, in transfemoral sockets.

Materials and Methods: Tests evaluated (1) the rate and time of evacuation for each pump to achieve a clinically recommended socket-liner interface pressure of 17 in-Hg below atmospheric pressure while 18 subjects stood quietly and (2) the number of times each pump reactivated during 10 minutes of treadmill walking by 9 subjects to reestablish 17 in-Hg below atmospheric pressure after initial evacuation.

Results: During quiet standing, each pump displayed an S-shape temporal profile of vacuum pressure until 17 in-Hg below atmospheric pressure was achieved. Across participants, the LimbLogic pulled vacuum at a faster rate than the e-pulse (62 vs. 39 in-Hg/min) and required less time to achieve the desired pressure (22 vs. 27 seconds). However, the LimbLogic reactivated once during walking to account for vacuum leakage, whereas the e-pulse did not reactivate.

Conclusions: The small differences in outcome metrics between pumps suggests that they were comparable in terms of effectiveness for creating and maintaining VAS of transfemoral sockets. This study describes simple methods that can be used in future studies when comparing electric vacuum pump performance. (*J Prosthet Orthot.* 2015;27:149–153.)

KEY INDEXING TERMS: prosthesis, vacuum, suspension, socket

Prosthetic sockets form the interface between the residual limb and prosthesis, acting to support the body and transfer forces.¹ To do this comfortably and efficiently, the socket must be both well conformed and well coupled to the residual limb. Coupling has been achieved using various types of suspension mechanisms, including belts, lanyards, passive suction, locking liners, and most recently active suction using vacuum pumps.^{2,3} Poor suspension leads to problems such as “pistoning” (i.e., relative vertical motion between the socket and residual limb). It has been proposed that vacuum-assisted suspension (VAS) results in the least pistoning of current suspension systems.^{2,4,5}

Use of vacuum pumps has increased dramatically since their introduction in the late 1990s, with a reported increase in VAS device-specific Medicare billing codes from \$1.1 million in 2003 to \$7.1 million in 2013.⁶ Although initially used primarily by persons with transtibial amputation,^{7–13} vacuum pumps are now also being used by persons with transfemoral amputation.^{14–16} As more pumps become commercially available, there is need for better understanding of pump function including comparative effectiveness using standardized methods for both bench and in vivo evaluation.^{16–18} Previous work by Komolafe et al.¹⁷ described a method for bench-top performance evaluation of commercially available mechanical and electrical pumps. Gerschutz et al.¹⁸ proposed that real-time vacuum pressure monitoring was necessary to understand how vacuum varies with time and usage by patients and illustrated use of a tool for doing so in persons with transtibial amputation. Major et al.¹⁶ used both bench-top and in vivo methods to evaluate a newly designed hybrid mechanical-electrical vacuum pump in a single subject with transfemoral amputation. The purpose of this study was to conduct in vivo tests to evaluate the effectiveness of two commonly used commercially available electric pumps, the Ohio Willow Wood LimbLogic (Sterling, OH, USA) and Otto Bock Harmony e-pulse (Duderstadt, Germany), on participants with transfemoral amputation.

METHODS

This study was approved by the university's institutional review board, and participants provided written informed consent before data collection. A convenience sample of individuals with a unilateral transfemoral amputation who routinely used VAS was recruited to participate. Participants were tested at two sites,

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Disclosure: The authors declare no conflict of interest.

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a research laboratory and a prosthesis clinical facility, using each pump during two testing protocols:

1. Quiet standing—participants were instructed to stand quietly as the pressure within the socket-liner interface was brought to baseline atmospheric pressure, and a pump was then used to decrease pressure until 17 in-Hg below atmospheric pressure was achieved. This test was repeated five times.
2. Walking—participants were instructed to first stand quietly until the socket-liner interface pressure was brought to 17 in-Hg below atmospheric pressure using a pump, and then to walk at a comfortable, self-selected speed on a level treadmill (T170; Cosmed, Rome, Italy) for 10 minutes. Both pumps were programmed to allow a minimum vacuum pressure of 13 in-Hg below atmospheric pressure before reactivating to reestablish 17 in-Hg below atmospheric pressure.

The order of pump testing was randomized for each participant, and socket-liner conditions remained the same for both pumps. To ensure the same socket attachment for both pump systems, the LimbLogic pump was connected to the socket volume via a barbed fitting similar to how the e-pulse is typically connected (Figure 1).

For both test protocols, instantaneous pressure in the socket-liner interface was measured with a digital vacuum pressure gauge (model 2 L760, DigiVac, Matawan, NJ, USA) and recorded using custom Labview software (National Instruments Corporation, Austin, TX, USA). For each test protocol, the following outcome metrics were estimated:

1. Quiet standing—the rate of evacuation, estimated as the slope of a best-fit linear approximation applied to the linear portion of the pressure temporal profile, and the total evacuation time from pump activation until pressure of 17 in-Hg below atmospheric pressure was achieved. These data were analyzed using Excel (Microsoft Corporation, Redmond, WA, USA) and averaged across the five standing trials for each participant.
2. Walking—the number of times the pump reactivated to reestablish a pressure of 17 in-Hg below atmospheric pressure.



Figure 1. Image of the LimbLogic pump and barbed fitting used to connect the pump to the socket-liner volume.

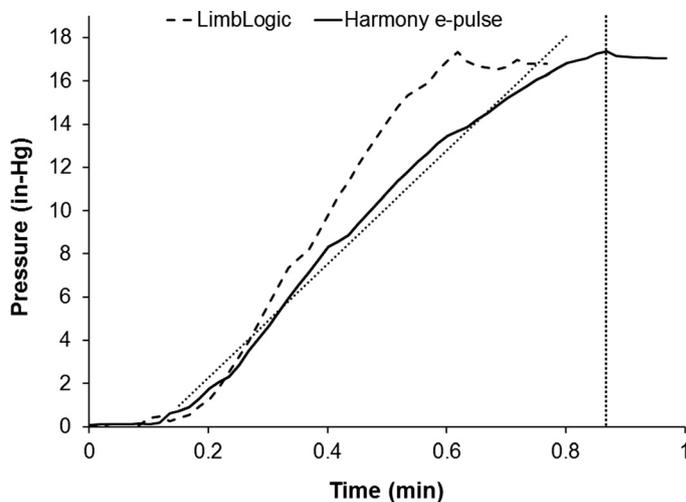


Figure 2. Representative plots of instantaneous pressure below atmospheric pressure collected during standing trials for both pumps. To illustrate the methods used for analysis, the vertical dotted line represents the estimated evacuation time of the Harmony e-pulse, and the diagonal dotted line represents the best-fit linear approximation applied to the linear portion to estimate evacuation rate. Similar analysis was applied to the LimbLogic but for the sake of clarity is not shown here.

These outcome metrics were selected as they represent clinical information that may assist with device recommendations. For example, a clinician must consider if the time required for a pump to achieve a desired level of pressure is important for a given patient based on their activity demands and need for rapidly generated suspension. In addition, as pump reactivation for reestablishing pressure levels would consume additional battery power beyond that of pressure monitoring, the number of reactivations over a specific time would suggest relative frequency of battery recharging during operation. Although pump reactivations are a necessary response due to leakage resulting from features across the entire prosthetic system, some portion of leakage may be due to pump interfacing with the prosthesis and socket-liner interface.

The Shapiro-Wilk test was used to assess data normality with the results suggesting that the data sets were of a nonnormal distribution. Consequently, the Wilcoxon signed-rank test for paired samples was used to statistically assess differences in evacuation rate, evacuation time, and number of reactivations between each pump. The critical alpha was set at 0.05, but applying a Bonferroni correction to account for the familywise type I error rate lowered this threshold to 0.02.

RESULTS

Data for the quiet standing analysis were collected on 18 individuals (13 male, 5 female, 53 ± 14 years, 177 ± 7 cm, 82 ± 8 kg), 9 of whom participated in the walking analysis (8 male, 1 female, 51 ± 13 years, 179 ± 6 cm, 84 ± 10 kg). Fewer subjects participated in the walking analysis because data were collected at two sites, and only one site was equipped with a treadmill.

A representative set of data for the temporal profile of instantaneous pressure for both pumps during the standing

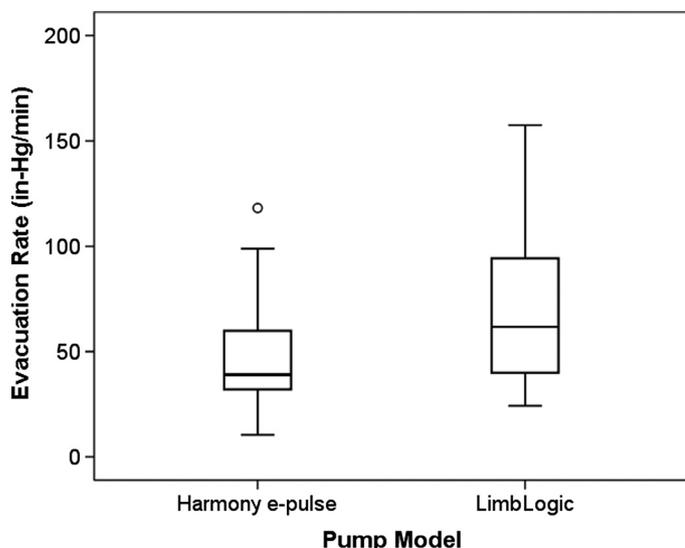


Figure 3. Box plots of evacuation rate for each pump (n = 18) during quiet standing. Median is denoted by the center line, quartiles are denoted by the box ends, maximum and minimum values are denoted by the tail ends, and circles denote outliers beyond 1.5 × box height.

protocol is presented in Figure 2, and this behavior was observed for all subjects. Each pump demonstrated a characteristic S-shape profile during evacuation, with three distinct periods of 1) accelerated, 2) constant, and 3) decelerated vacuum pressure rate. The estimated evacuation rate and time across participants are displayed in Figures 3 and 4. These indicated that the LimbLogic required less time to achieve the desired pressure level of 17 in-Hg below atmospheric pressure, and this difference was significant (Table 1). A representative set of data for the temporal profile of instantaneous pressure for both pumps during the walking protocol is presented in Figure 5, and this behavior was observed for all subjects. Both

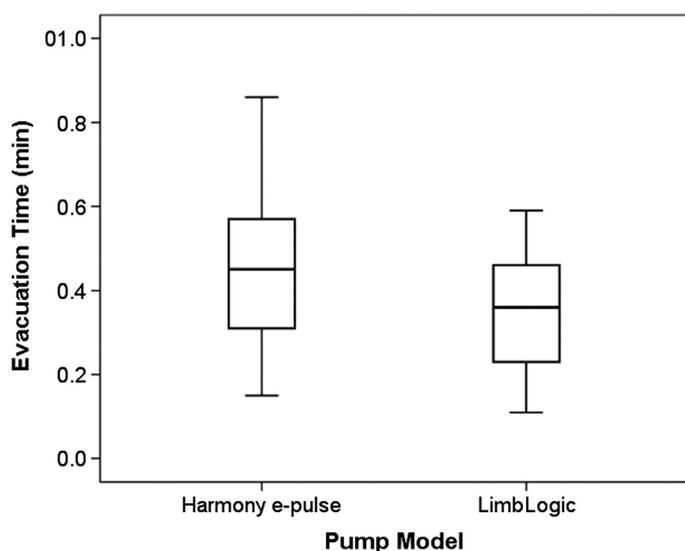


Figure 4. Box plots of evacuation time for each pump (n = 18) during quiet standing. Median is denoted by the center line, quartiles are denoted by the box ends, maximum and minimum values are denoted by the tail ends, and circles denote outliers beyond 1.5 × box height.

Table 1. Statistical results from pairwise comparisons between pump models

Outcome	P	Z	Order Effect
Evacuation rate	<0.001	153.0	OWW > OB
Evacuation time	<0.001	2.5	OWW < OB
No. pump reactivations	0.024	21.0	OWW > OB

OWW, Ohio Willow Wood LimbLogic; OB, Otto Bock Harmony e-pulse.

pumps exhibited similar profiles of pressure leakage, but the rate of leakage for the prosthetic system when using the LimbLogic was more rapid, resulting in a significantly greater median reactivation number of one, whereas the e-pulse required no reactivations (Figure 6, Table 1).

DISCUSSION

Overall, the differences in evacuation rate (23 in-Hg/min) and time (5 seconds) between both pump systems were statistically significant. Although these differences were small, they are likely clinically important. The reduced time needed by the LimbLogic system to achieve full evacuation shortens the period of noise emission and may improve patient compliance and satisfaction with pump use. In addition, less time to achieve the desired pressure level may facilitate longer periods of ideal socket fit during use.

The number of reactivations during walking is interesting as this activity increases the rate of battery power drainage compared with periods of pressure monitoring. A more rapid depletion of battery power would require more frequent charging to maintain socket suspension during operation. The pump-specific reasons for this difference in leakage rate despite no change in the socket is unknown and warrants further investigation as minimizing leakage would maximize battery life. Using

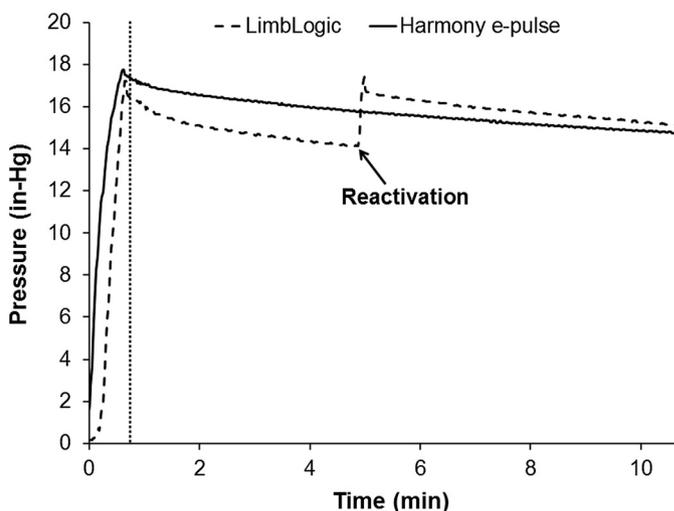


Figure 5. Representative plots of instantaneous pressure below atmospheric pressure collected during walking trials for both pumps. The first and second vertical dashed lines denote the start and finish time, respectively, of the 10 minutes of treadmill walking.

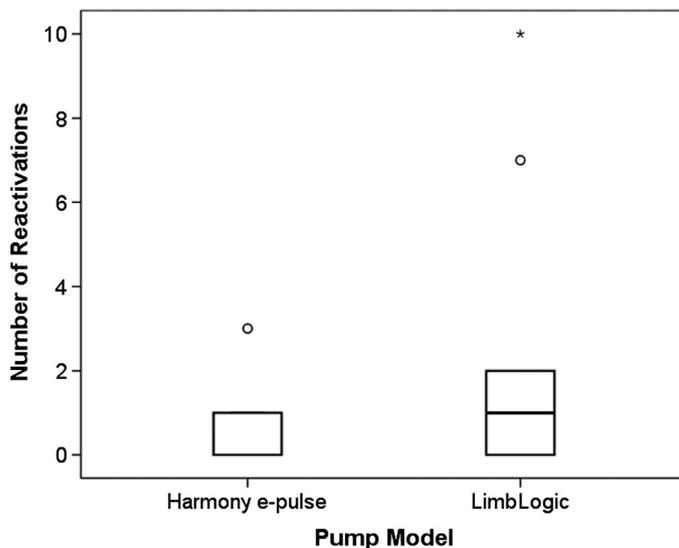


Figure 6. Box plots of number of pump reactivations during walking ($n = 9$). Median is denoted by the solid center line, quartiles are denoted by the box ends, maximum and minimum values are denoted by the tail ends, circles and asterisks denote outliers beyond 1.5 and $3 \times$ box height, respectively.

a connection (i.e., the barbed fitting) that is not commonly implemented clinically with the LimbLogic may have partially contributed to this increased rate in vacuum leakage.

In addition to these types of installation issues, future research may consider patient-specific factors that likely affect pump evacuation time and vacuum leakage (e.g., residuum dimensions, residuum tissue properties, and liner type) to develop a more nuanced understanding of pump function. Regardless, both pumps were successful in identifying a loss in pressure that necessitated pump reactivation for maintaining appropriate pressure levels for suspension. In this study, pumps were evaluated for the walking trials immediately after evacuation during standing. Clinical experience suggests that pump reactivations occur less frequently with increasing wear time, potentially due to a continuous reduction in air pockets and better seating in the socket. Future studies could explore such issues by monitoring vacuum activity outside the laboratory during prolonged usage.

Although outcome differences between pumps were statistically significant and may be clinically relevant, results from these in vivo tests suggest that both electric pump systems are equally effective in creating and maintaining socket-liner interface pressure for VAS in transfemoral sockets. Importantly, this study demonstrates the use of a simple set of experiments and limited equipment to capture clinically relevant outcome metrics for assessing the effectiveness of pumps for VAS. As use of this suspension method increases, this study addresses the need for standard methods to assess comparative effectiveness of commercial pumps. A combination of in vivo and bench testing methods are required to fully characterize the properties of these devices and their relationship with overall prosthesis function to inform clinical recommendations of appropriate prosthetic technology and development of future designs.^{16,17,19}

Clinical selection of electric pump designs is likely a function of patient activity demands, device evacuation rate, and device-related vacuum leakage.

CONCLUSIONS

Based on the time required for achieving clinically recommended levels of pressure for VAS and the number of pump reactivations to maintain that level during walking, the results from this study suggest that the LimbLogic and Harmony e-pulse are equally effective electric pumps despite the observed differences in outcome metrics. Importantly, this study aids in developing standard evaluation methods of commercial pump systems for generating clinically relevant information. Future research should consider investigations on patient- and device-specific factors related to vacuum leakage rate and methods for minimizing this leakage to maximize battery life.

ACKNOWLEDGMENTS

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REFERENCES

1. Kapp SL. Transfemoral socket design and suspension options. *Phys Med Rehabil Clin N Am* 2000;11:569–583 vi.
2. Kahle JT, Orriola JJ, Johnston W, et al. The effects of vacuum-assisted suspension on residual limb physiology, wound healing, and function: a systematic review. *Technology & Innovation* 2014;15:333–341.
3. Gholizadeh H, Abu Osman NA, Eshraghi A, et al. Transfemoral prosthesis suspension systems: a systematic review of the literature. *Am J Phys Med Rehabil* 2014;93:809–823.
4. Darter BJ, Sinitski K, Wilken JM. The effect of elevated vacuum suspension on axial bone-socket displacement in persons with a traumatic transtibial amputation. *35th Annual Meeting of the American Society of Biomechanics*. Long Beach, CA; 2011.
5. Papaioannou G, Mitrogiannis C, Nianios G, et al. Assessment of amputee socket-stump-residual bone kinematics during strenuous activities using Dynamic Roentgen Stereogrammetric Analysis. *J Biomech* 2010;43:871–878.
6. Centers for Medicare & Medicaid Services. The Part B national summary data file: prosthetic procedures (L5000-L9999). In: United States Department of Health and Human Services (ed.). 2013.
7. Beil TL, Street GM, Covey SJ. Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets. *J Rehabil Res Dev* 2002;39:693–700.
8. Board WJ, Street GM, Caspers C. A comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthet Orthot Int* 2001;25:202–209.
9. Gerschutz MJ, Denune JA, Colvin JM, et al. Elevated vacuum suspension influence on lower limb amputee's residual limb volume at different vacuum pressure settings. *J Prosthet Orthot* 2010;22:252–256.

10. Goswami J, Lynn R, Street G, et al. Walking in a vacuum-assisted socket shifts the stump fluid balance. *Prosthet Orthot Int* 2003; 27:107–113.
11. Klute GK, Berge JS, Biggs W, et al. Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: effect on fit, activity, and limb volume. *Arch Phys Med Rehabil* 2011;92:1570–1575.
12. Ferraro C. Outcomes study of transtibial amputees using elevated vacuum suspension in comparison with pin suspension. *J Prosthet Orthot* 2011;23:78–81.
13. Brunelli S, Averna T, Delusso S, et al. Vacuum assisted socket system in transtibial amputees: clinical report. *The Orthopadie Technik* 2009;II:2–8.
14. Kahle JT, Highsmith MJ. Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure, and preference: ischial containment versus brimless. *J Rehabil Res Dev* 2013;50:1241–1252.
15. Kahle JT, Highsmith MJ. Transfemoral interfaces with vacuum assisted suspension comparison of gait, balance, and subjective analysis: ischial containment versus brimless. *Gait Posture* 2014; 40:315–320.
16. Major MJ, Caldwell R, Fatone S. Evaluation of a hybrid vacuum pump to provide vacuum-assisted suspension for above-knee prostheses. *J Med Devices* 2015.
17. Komolafe O, Wood S, Caldwell R, et al. Methods for characterization of mechanical and electrical prosthetic vacuum pumps. *J Rehabil Res Dev* 2013;50:1069–1078.
18. Gerschutz M, Haynes M, Colvin J, et al. A vacuum suspension measurement tool for use in prosthetic research and clinical outcomes: validation and analysis of vacuum pressure in a prosthetic socket. *J Prosthet Orthot* 2010;22:172–176.
19. Major MJ, Kenney LP, Twiste M, et al. Stance phase mechanical characterization of transtibial prostheses distal to the socket: a review. *J Rehabil Res Dev* 2012;49:815–829.



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APPENDIX C

Evaluation of a Prototype Hybrid Vacuum Pump to Provide Vacuum-Assisted Suspension for Above-Knee Prostheses

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Vacuum-assisted suspension (VAS) of prosthetic sockets utilizes a pump to evacuate air from between the prosthetic liner and socket, and are available as mechanical or electric systems. This technical note describes a hybrid pump that benefits from the advantages of mechanical and electric systems, and evaluates a prototype as proof-of-concept. Cyclical bench testing of the hybrid pump mechanical system was performed using a materials testing system to assess the relationship between compression cycles and vacuum pressure. Phase 1 in vivo testing of the hybrid pump was performed by an able-bodied individual using prosthesis simulator boots walking on a treadmill, and phase 2 involved an above-knee prosthesis user walking with the hybrid pump and a commercial electric pump for comparison. Bench testing of 300 compression cycles produced a maximum vacuum of 24 in-Hg. In vivo testing demonstrated that the hybrid pump continued to pull vacuum during walking, and as opposed to the commercial electric pump, did not require reactivation of the electric system during phase 2 testing. The novelty of the hybrid pump is that while the electric system provides rapid, initial vacuum suspension, the mechanical system provides continuous air evacuation while walking to maintain suspension without reactivation of the electric system, thereby allowing battery power to be reserved for monitoring vacuum levels. [DOI: 10.1115/1.4030507]

Keywords: prosthesis, vacuum, suspension, socket

Introduction

Prosthetic sockets are secured to the limb by suspension mechanisms of which there are many types, including mechanical (straps, pin locking liners) and suction (liners, one way valves, vacuum pumps) systems. Introduced and adopted in the late 1990's, vacuum pumps used to suspend a socket on the residual limb are referred to as VAS [1]. Pumps create a negative pressure differential relative to atmospheric pressure by evacuating air

from between the surface of a liner clad residual limb and the interior of a prosthetic socket [1]. Evidence of the suggested benefits of VAS over suspension techniques such as suction and pin-locking liners have been described as: reducing residual limb volume fluctuations that compromise socket fit [1–4], improving gait symmetry [1], reducing residual limb pistoning [1,5], and facilitating limb healing [3,6–9]. In particular, VAS has been proposed as an effective suspension strategy for short residual limbs [10] and brimless sockets that may enhance user comfort [11,12].

Current pump designs are either mechanical or electrical [13]. The advantage of mechanical pumps is that there is no need to charge or replace batteries, they are less noisy, they are mostly maintenance free and field serviceable if issues arise, and will work continuously as long as the user is walking. Mechanical pumps require multiple steps with the prosthesis to reach the recommended vacuum [14], delaying achievement of optimal suspension and coupling. For example, according to the manufacturer the Otto Bock Harmony[®] P3 should reach 15 in-Hg within 50 steps. A smaller pump like the Össur Unity[™] may take even more time to evacuate the same volume to the same vacuum pressure. Loss of active vacuum when not walking can lead to the need to re-establish vacuum, potentially contributing to trauma of the residual limb soft tissues. Mechanical pumps are infrequently used in transfemoral prostheses possibly because their flow rate is insufficient to rapidly evacuate the relatively larger air space as compared to a transtibial socket. With larger volumes, such as are found in transfemoral sockets or double wall socket designs, establishing the required vacuum level before walking may be even more crucial.

Electric pumps pull and monitor vacuum even while not walking. This allows them to initiate vacuum before walking, ensuring that the residual limb is completely seated in the socket and avoiding suspension issues that contribute to skin problems. For example, clinically, prosthesis users complain that when sitting for a period of time, socket fit is altered and they need to reseat their limb into the socket when they resume standing. Reseating has the tendency to allow the liner to move away from the residual limb creating a suspension issue that contributes to skin abrasion. The ability to maintain vacuum and a correct position within the socket at all times is particularly critical for users that have sensitive skin, significant bony prominences or open sores. The disadvantages of electric pumps are that they are noisy, need charging, and are not easily field serviced.

A hybrid vacuum pump that incorporates both an electric and mechanical pump is proposed as a modular prosthetic component to generate VAS of transfemoral prosthetic sockets irrespective of the state of the user while maximizing battery life and minimizing noise. It would act such that the electric pump operates initially to rapidly draw a threshold vacuum with the mechanical pump maintaining that vacuum during prosthesis use when air slowly leaks back into the interface. Importantly, during daily activity the electric pump ensures that vacuum suspension is maintained during stationary periods (e.g., standing and sitting) and the mechanical pump maintains suspension during ambulation (e.g., walking and transfers). This technical note describes the design of a hybrid vacuum pump and demonstrates operational feasibility.

Materials and Methods

Hybrid Pump Design. A prototype hybrid prosthetic pump, dubbed the Northwestern University Hybrid Integrated Prosthetic Pump Initiative (HIPPI) was fabricated (Fig. 1), including a rubber bladder to act as the mechanical pump system, electronics for the electric pump system, and housing that was built from polycarbonate-acrylonitrile-butadiene-styrene (PC-ABS) plastic using an additive manufacturing (fused deposition modeling) 3D printer (Stratasys, Eden Prairie, MN). Although the PC-ABS housing is porous, the sealed bladder of the mechanical system is attached to the volume of interest via tubing and does not require

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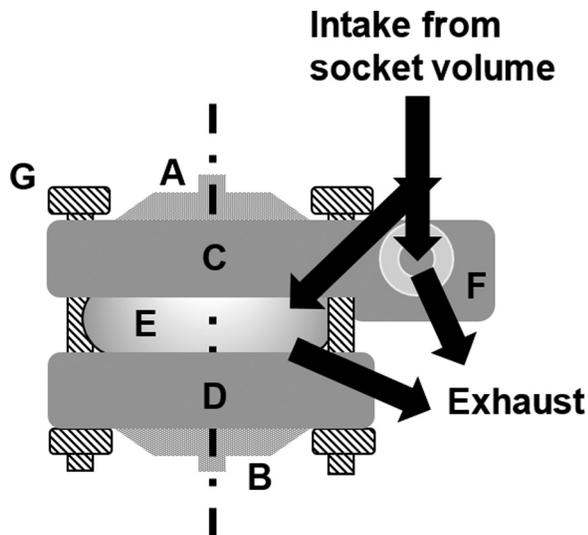


Fig. 1 Schematic of the hybrid pump design. Constituent parts include: (a) proximal female pyramid adapter, (b) distal male pyramid adapter, (c) proximal housing plate, (d) distal housing plate, (e) bladder pump (mechanical system), (f) electric pump (electric system), and (g) threaded posts ($\times 4$). The threaded posts act as guide rails during cyclical compression and extension of the bladder. The solid arrows indicate air flow from the socket volume during operation.

the housing to be airtight but only act as compression plates. The mechanical and electric pump systems attach to the desired evacuation volume through a parallel connection and a system of one-way valves. The mechanical system pulls air from the evacuation volume as the bladder expands, and forces this air through an exhaust as the bladder compresses during load-bearing. The electric system pulls air from the evacuation volume through a pump that is activated by a DC motor and can be programmed to reach an upper vacuum pressure threshold when activated and reactivate when a defined lower threshold is reached. Pyramid adapters (Otto Bock, Duderstadt, Germany) were fixed to the proximal and distal ends of the pump housing to allow for integration within a modular prosthetic system. The concept of the hybrid pump is that prior to walking the electric system would rapidly evacuate air to create a desired vacuum pressure for socket suspension, and during walking when leakage of the vacuum is likely to occur, the mechanical system is continuously engaged to maintain a sufficient level of vacuum pressure. A patent has been granted on the hybrid pump design [15].

Bench Testing Protocol. Prior to in vivo testing, bench testing of the hybrid pump was performed using a materials testing system (Model 8800, Instron, Norwood, MA). The protocol for bench characterization was modeled upon a previously established protocol [13]. The pump was secured in the testing machine, pre-loaded to 20 N, and underwent 300 cycles of compression and release at a cyclical loading rate of 23 mm/s with two dwell periods of 0.16 s at minimum and maximum displacement, a simulated cadence of 100 steps/min. The vector of applied load coincided with the longitudinal axis of the pump and was measured with an integrated uniaxial load-cell. The compression displacement was 10 mm, which represented effective bottoming out and full compression of the bladder. The pump was attached to a sealed canister of 6.36 in.³ volume to simulate the average evacuation volume to create VAS in a transfemoral prosthetic socket [13]. A digital vacuum pressure gauge (model 2L760, DigiVac; Matawan, NJ) measured the real-time pressure level in the sealed canister. Bench testing was performed three times to estimate the average time and number of “steps” required to achieve a vacuum pressure of 17 in-Hg, a common vacuum pressure for socket suspension as recommended by vacuum pump manufacturers



Fig. 2 Walking simulator boots. Prosthetic components attach distal to the foot plate and mimic transtibial prosthesis use.

[13], as well as the initial linear rate of pressure creation as approximated by a linear best fit and the maximum force attained during cyclical testing.

In Vivo Phase 1: Walking Simulator. The first phase of in vivo testing involved a single participant (35 yrs, 185 cm, 78 kg) walking on a treadmill with walking simulator boots (Fig. 2) and the hybrid pump installed between the plantar surface of the right leg boot and a prosthetic foot. A prosthetic foot and pylon were attached to the left leg boot and adjusted to eliminate leg length discrepancy. Athletic trainer shoes were donned on each foot to improve plantar surface friction with the treadmill belt. The pump was attached to the same sealed canister as used during bench testing and the digital vacuum pressure gauge was used to measure real-time pressure in the canister. Prior to walking, the electric system was used to create vacuum in the canister and, when the pressure reached approximately 17 in-Hg, the subject walked for 10 minutes at a speed of 0.53 m/s (a speed that was considered comfortable and safe by the participant). This in vivo testing was used to determine if the prototype would sustain the loads encountered during operation and if the mechanical system would continue to create vacuum during walking when under operational loads. Real-time pressure level in the sealed canister was collected during testing as measured by the digital vacuum pressure gauge (DigiVac).

In Vivo Phase 2: Transfemoral Prosthesis User. The second phase of in vivo testing involved a unilateral transfemoral prosthesis user (54 yrs, 183 cm, 97.5 kg, left side amputation due to trauma) walking on a treadmill under two conditions:

- (1) the original prosthetic setup consisting of a KX06 knee (Endolite, Miamisburg, OH), highlander foot (Freedom Innovations, Irvine, CA), subischial socket with a Relax 3 C liner (Medi, Whitsett, NC), and the LimbLogic electric pump (Ohio WillowWood, Mt. Sterling, OH), and
- (2) the original socket integrated with a 3R60 knee (Otto Bock, Duderstadt, Germany), solid ankle cushioned heel foot (Kingsley Mfg. Co., Costa Mesa, CA) and the hybrid pump installed between the distal end of the socket and the knee joint (Fig. 3).

For both pump units, the electric system was programmed to create a maximum vacuum setting of approximately 17 in-Hg and the minimum allowable vacuum before reactivation was set at

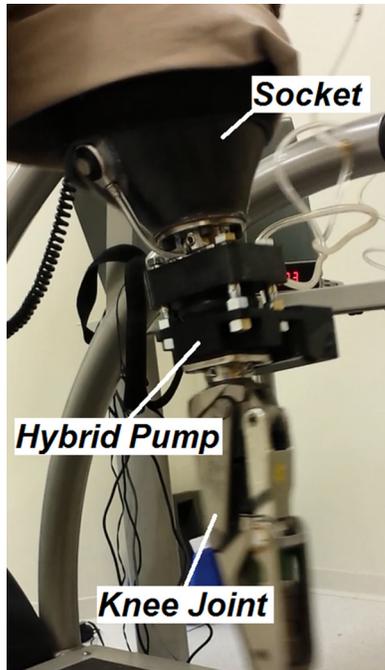


Fig. 3 Location of the hybrid vacuum pump for use within a transfemoral prosthesis. Pyramid adaptors fixed to proximal and distal ends of the pump housing were used for installation of the pump between the socket and knee joint, respectively.

13 in-Hg. Prior to walking, the electric system was used to create vacuum in the socket for suspension and when the pressure reached approximately 17 in-Hg, the subject walked for 10 min at a speed of 0.53 m/s (a speed that was considered comfortable and safe by the participant). This in vivo testing was used to determine if the prototype would sustain the loads encountered during operation in a transfemoral prosthesis when installed proximal to the knee joint, if the mechanical system would continue to create vacuum during walking when under operational loads, the time required to obtain 17 in-Hg vacuum pressure through the electric system, and the number of times the electric system reactivated due to the lower vacuum threshold being met. Real-time pressure level in the prosthetic socket was collected during testing as measured by the digital vacuum pressure gauge (DigiVac).

Ethical approval was obtained from the University Institutional Review Board and participants provided informed consent prior to in vivo data collection.

Results

An example of the bench testing results is presented in Fig. 4(a). The average maximum vacuum pressure was 24 in-Hg achieved after 112 cycles. On average, the desired vacuum pressure of 17 in-Hg was achieved after 13 cycles and the linear rate of evacuation was approximately 1.1 in-Hg/cycle. The average maximum force achieved during cyclical testing was 720 N.

Results from the walking simulator (phase 1) and transfemoral prosthesis user (phase 2) are presented in Figs. 4(b) and 4(c), respectively. The prototype sustained the loads applied during both in vivo testing scenarios. Testing with the walking simulator demonstrated that the electric system created an initial vacuum, while subsequent walking continued to increase vacuum pressure through activation of the mechanical system. During phase 2 testing, the commercial electric pump and hybrid pump achieved a maximum vacuum pressure of 18 in-Hg and 23 in-Hg, respectively. Using the electric system, the commercial pump and hybrid pump both achieved 17 in-Hg in approximately the same amount of time: 14 s. While the commercial pump was required to reactivate twice during the 10 min walk session, the additional vacuum

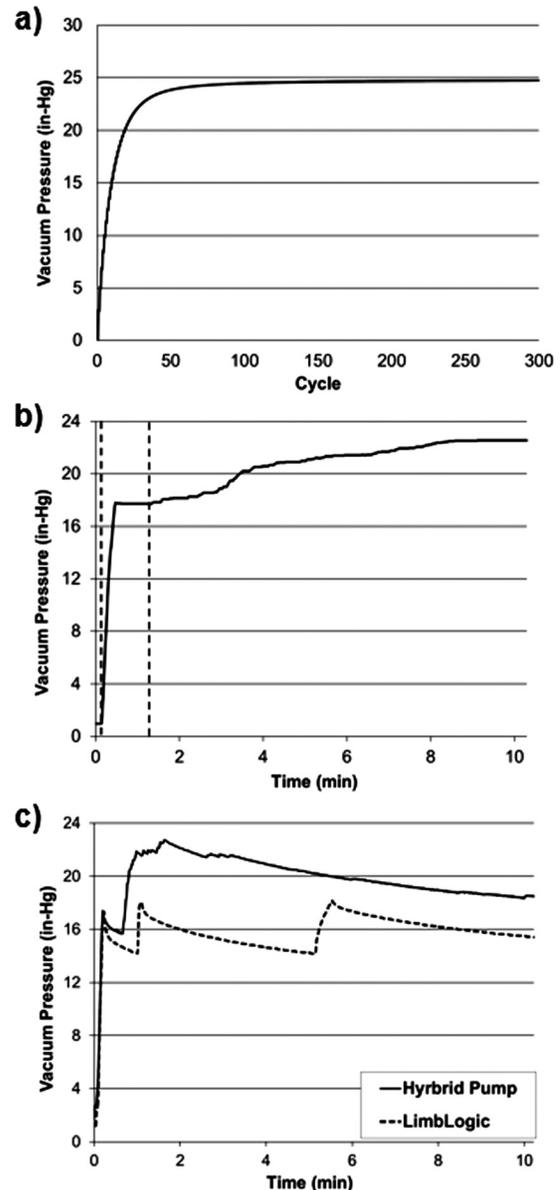


Fig. 4 Results from (a) bench testing, (b) in vivo walking with simulator boots (the first and second dashed vertical lines represent the initiation of the electric system and walking, respectively), and (c) in vivo walking of a transfemoral prosthesis user with a commercial electric pump (Ohio WillowWood LimbLogic) and the hybrid pump

created by the mechanical system during the initial portion of walking prevented the hybrid's electric pump from reactivating. Although vacuum was created and sustained by the mechanical system during the start of walking, this function appeared to be less effective as walking progressed and the hybrid pump demonstrated similar leakage to that of the commercial unit.

Discussion

This study described the proof-of-concept testing of a hybrid pump unit to be integrated with a transfemoral prosthesis for the purpose of VAS. Bench testing indicated that by solely using the mechanical pump system only 13 cycles (or steps) would be necessary to achieve the desired vacuum pressure of 17 in-Hg when maximum compression (10 mm) of the bladder occurs resulting from 720 N of force (approximately 92% of body weight for an 80 kg user) applied along the longitudinal axis of the unit. When the hybrid pump is installed within walking boots to simulate

integration with a transtibial prosthesis, the hybrid pump behaved as expected. The electric system initially created vacuum and walking continued to increase the vacuum pressure due to cyclical activation of the mechanical system. Importantly, the pump sustained the moments and loads applied during this form of testing, and the effectiveness of the mechanical system was not compromised during operation.

Results from in vivo testing with a transfemoral prosthesis user demonstrated promise for the utility of the hybrid pump. As expected, the hybrid pump was capable of achieving the desired level of vacuum similar to a commercial electric pump, and due to the creation of additional vacuum through activation of the mechanical system, prevented the electric system from reactivating. Reduced dependence on the electric system will save battery power and therefore reduce the frequency of battery charging. However, although the mechanical system created vacuum initially, this system became less effective as walking continued beyond approximately 1.5 min. One possible reason for this diminished function is a subtle modification in the participant's gait, which may have placed the hybrid pump under moments and loads not encountered during bench testing and when walking with the simulator boots. The use of a four-post system to guide the housing plates during bladder compression created a rocking motion (asymmetric compression) that restricted the bladder from achieving full compression and hence compromised its function. This issue will be addressed in subsequent design iterations to eliminate asymmetric compression during operation in a transfemoral prosthesis. Further evaluation of design iterations will also characterize the passive physical properties (i.e., stiffness and damping) of the hybrid pump and observe the effects of these properties on user performance [16,17] for design optimization.

Overall, this testing demonstrated the utility of a hybrid pump design, specifically for those users who may experience excessive time to create sufficient vacuum pressure for suspension when using only a mechanical pump due to their light weight (e.g., elderly), or who desire immediate use of their prosthesis post-donning (e.g., individuals who engage in sporting activity or the military). The use of a hybrid pump will quickly achieve the desired vacuum pressure such that the user may immediately begin walking with their device and this walking will sustain vacuum pressure due to continuous activation of the mechanical system. Importantly, as the mechanical system sustains adequate levels of vacuum pressure, this decelerates drainage of the battery in which power is only used to monitor vacuum pressure level and not for reactivating the electric system, which uses proportionally larger amounts of energy. Additionally, we have the ability to set the electric system to activate only when there is a critical loss of vacuum, further reducing battery demand. The pumps can also work independently if there is a malfunction with either individual system, creating a nice fail-safe. Although the hybrid pump appears to operate well for integration with a transtibial prosthesis, subsequent design iterations and testing will focus on improving its functional reliability for transfemoral prosthesis application.

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References

- [1] Board, W. J., Street, G. M., and Caspers, C., 2001, "A Comparison of Trans-Tibial Amputee Suction and Vacuum Socket Conditions," *Prosthet. Orthotics Int.*, **25**(3), pp. 202–209.
- [2] Goswami, J., Lynn, R., Street, G., and Harlander, M., 2003, "Walking in a Vacuum-Assisted Socket Shifts the Stump Fluid Balance," *Prosthet. Orthotics Int.*, **27**(2), pp. 107–113.
- [3] Gerschütz, M. J., Denune, J. A., Colvin, J. M., and Schober, G., 2010, "Elevated Vacuum Suspension Influence on Lower Limb Amputee's Residual Limb Volume at Different Vacuum Pressure Settings," *J. Prosthet. Orthotics*, **22**(4), pp. 252–256.
- [4] Beil, T. L., Street, G. M., and Covey, S. J., 2002, "Interface Pressures During Ambulation Using Suction and Vacuum-Assisted Prosthetic Sockets," *J. Rehabil. Res. Dev.*, **39**(6), pp. 693–700.
- [5] Klute, G. K., Berge, J. S., Biggs, W., Pongnumkul, S., Popovic, Z., and Curless, B., 2011, "Vacuum-Assisted Socket Suspension Compared With Pin Suspension for Lower Extremity Amputees: Effect on Fit, Activity, and Limb Volume," *Arch. Phys. Med. Rehabil.*, **92**(10), pp. 1570–1575.
- [6] Hoskins, R. D., Sutton, E. E., Kinor, D., Schaeffer, J. M., and Fatone, S., 2014, "Using Vacuum-Assisted Suspension to Manage Residual Limb Wounds in Persons With Transtibial Amputation: A Case Series," *Prosthet. Orthotics Int.*, **38**(1), pp. 68–74.
- [7] Traballese, M., Averna, T., Delussu, A. S., and Brunelli, S., 2009, "Trans-Tibial Prosthesis in Large Area of Residual Limb Wound: Is it Possible? A Case Report," *Disability Rehabil. Assistive Technol.*, **4**(5), pp. 373–375.
- [8] Traballese, M., Delussu, A. S., Fusco, A., Iosa, M., Averna, T., Pellegrini, R., and Brunelli, S., 2012, "Residual Limb Wounds or Ulcers Heal in Transtibial Amputees Using an Active Suction Socket System. A Randomized Controlled Study," *Eur. J. Phys. Rehabil. Med.*, **48**(4), pp. 613–623.
- [9] Arndt, B., Caldwell, R., and Fatone, S., 2011, "Use of a Partial Foot Prosthesis With Vacuum-Assisted Suspension: A Case Study," *J. Prosthet. Orthotics*, **23**(2), pp. 82–88.
- [10] Carvalho, J. A., Mongon, M. D., Belangero, W. D., and Livani, B., 2012, "A Case Series Featuring Extremely Short Below-Knee Stumps," *Prosthet. Orthotics Int.*, **36**(2), pp. 236–238.
- [11] Kahle, J. T., and Highsmith, M. J., 2014, "Transfemoral Interfaces With Vacuum Assisted Suspension Comparison of Gait, Balance, and Subjective Analysis: Ischial Containment Versus Brimless," *Gait Posture*, **40**(2), pp. 315–320.
- [12] Kahle, J. T., and Highsmith, M. J., 2013, "Transfemoral Sockets With Vacuum-Assisted Suspension Comparison of Hip Kinematics, Socket Position, Contact Pressure, and Preference: Ischial Containment Versus Brimless," *J. Rehabil. Res. Dev.*, **50**(9), pp. 1241–1252.
- [13] Komolafe, O., Wood, S., Caldwell, R., Hansen, A., and Fatone, S., 2013, "Methods for Characterization of Mechanical and Electrical Prosthetic Vacuum Pumps," *J. Rehabil. Res. Dev.*, **50**(8), pp. 1069–1078.
- [14] Otto Bock HealthCare, 2009, "Harmony P3 Instructions for Use," Otto Bock HealthCare LP, Duderstadt, Germany.
- [15] Caldwell, R. J., Hansen, A. H., Wood, S. M., Chen, W., Radcliffe, R. A., Yngve, K. A., Kuhar, B. E., Nelson, A. J., and Nickel, E., 2012, U.S. Patent No. 13/529,833.
- [16] Major, M. J., Twiste, M., Kenney, L. P., and Howard, D., 2011, "Amputee Independent Prosthesis Properties—A New Model for Description and Measurement," *J. Biomech.*, **44**(14), pp. 2572–2575.
- [17] Major, M. J., Kenney, L. P., Twiste, M., and Howard, D., 2012, "Stance Phase Mechanical Characterization of Trans-Tibial Prostheses Distal to the Socket: A Review," *J. Rehabil. Res. Dev.*, **49**(6), pp. 815–829.

APPENDIX D



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.

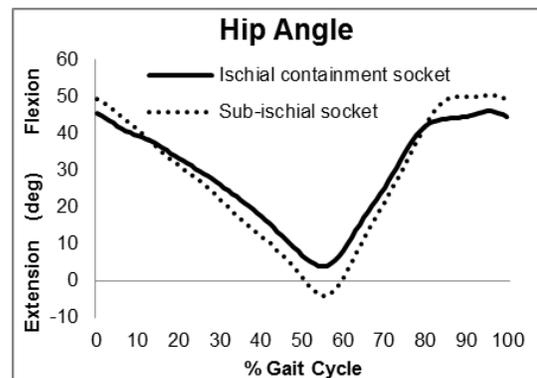
Testing took place in the ischial containment socket followed by the sub-ischial socket. Subjects underwent a series of range of motion, performance, and biomechanical tests. A 26-camera motion capture system (120 Hz, Motion Analysis Corp., Santa Rosa, CA) tracked trajectories of 57 markers secured to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



**NORTHWESTERN
UNIVERSITY**

Northwestern University Prosthetics-Orthotics Center
680 North Lake Shore Drive, Suite 1100
Chicago, IL 60611
Telephone 312-503-5700
www.nupoc.northwestern.edu

NU-FlexSIV Socket

Continuing Education Course

Session 1: July 31 and August 1, 2015

Session 2: August 21 and 22, 2015

Session 3: September 11 and 12, 2015

Day 1	
7am-8am	Registration / Breakfast
8am-10am	Background Lecture: “Introduction to Subischial Socket and Vacuum Technology: The Development of the NU-FlexSIV Socket” ¹ (Stefania Fatone, PhD, BPO(Hons) & Ryan Caldwell, CP/L)
10am-10.15am	Break
10.15am-11am	Liner selection and casting demonstration (Ryan Caldwell, CP/L)
11am-12pm	Participants cast patient model and pour plaster (all instructors)
12pm-1pm	Lunch
1pm-2pm	Rectification demonstration (Ryan Caldwell, CP/L)
2pm-6pm	Participants rectify casts, pull and finish check sockets (all instructors)
Day 2	
7.30am-8.30am	Breakfast / Extra lab time for participants, if needed (all instructors)
8.30am-10am	Demonstration check socket fitting (Ryan Caldwell, CP/L)
10am-10.15am	Break
10.15am-12pm	Participants set up for check socket fitting (all instructors)
12pm-1pm	Lunch
1pm-4pm	Participants fit check sockets to patient models (all instructors)
4pm-4.30pm	Final troubleshooting and Q&A (Ryan Caldwell, CP/L & Stefania Fatone, PhD, BPO(Hons))
4.30-5pm	Discussion of Definitive Socket Fabrication Options (Ryan Caldwell, CP/L & Stefania Fatone, PhD, BPO(Hons))

¹ The research project, “Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations”, is funded by Department of Defense grant #W81XWH-10-0744. The course, “NU-FlexSIV Socket” is underwritten by the same DOD grant.

See: http://www.nupoc.northwestern.edu/research/projects/lowerlimb/dev_subischial.html



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Course Personnel

Stefania Fatone, PhD, BPO(Hons), Associate Professor, NUPOC, Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University.

Email: s-fatone@northwestern.edu

Dr. Fatone is Principal Investigator of the DOD-funded project “Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations” (#W81XWH-10-0744). A graduate of La Trobe University (Australia, 1995) with a Bachelor of Prosthetics and Orthotics (Honours) and a PhD in Biomechanics (2000), she joined NUPOC as a post-doctoral fellow (2000). Dr. Fatone has conducted multidisciplinary research on the effects of prostheses and orthoses on human locomotion to increase understanding, efficiency and effectiveness of P&O interventions for people with physical disability. She has more than 51 publications and frequently is invited to speak and conduct specialty courses about P&O throughout the USA and internationally.

Ryan Caldwell, CP/L, FAAOP, Visiting Fellow, NUPOC, Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University.

Email: ryan.caldwell@northwestern.edu

Mr. Caldwell is a prosthetist who specializes in Vacuum and Subischial Socket Technology, and is the primary developer of the socket technique developed by the DOD-funded project “Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations” (#W81XWH-10-0744). He completed his prosthetics and orthotics (P&O) training at NUPOC, is an ABC-Certified Prosthetist, and a Fellow of the American Academy of Orthotists and Prosthetists. An active clinician since 2001, Mr. Caldwell is a prosthetist at Scheck & Siress Prosthetics, Orthotics and Pedorthics (Schaumburg, IL). He teaches vacuum technology at NUPOC, has taught in the Physical Therapy Program at Oakton Community College, and frequently presents at professional meetings.

John Brinkmann, MA, CPO, FAAOP, Instructor, NUPOC, Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University.

Email: john.brinkmann@northwestern.edu

Mr. Brinkmann joined NUPOC in 2012 after providing clinical services for more than 20 years and managing multiple P&O practices. He completed a BS in Orthotics and Prosthetics at University of Texas Southwestern in 1990 and a MA at Trinity Evangelical Divinity School (Deerfield, IL). He received a Searle Fellowship through Northwestern University and worked on “Establishing Criteria for Transtibial Impression Assessment”. He sits on the AAOP Board of Directors, is immediate past chair of the Academy Gait Society, and directs the AAOP Midwest Chapter.

Mike Cavanaugh, CPO, Lecturer, NUPOC, Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University.

Email: michael.cavanaugh@northwestern.edu

Mr. Cavanaugh joined NUPOC in 2014. He is a graduate of NUPOC P&O programs and an ABC-Certified Prosthetist-Orthotist. He has 8 years of clinical experience, in addition to his background in industrial engineering and education course design. He has served as a preceptor for P&O graduate students and a mentor for P&O residents.

Course Registrar/Organizer: R. J. Garrick, PhD, NUPOC, Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University.

Email: r-garrick@northwestern.edu

APPENDIX F

Nu-flexiv

ROOMS

NU-FlexSIV

+ Create a room

PEOPLE

Sagar Shetty

+ Invite your team



NU-FlexSIV
This is the room topic. Double click to change it.



Stefania Fatone Hi @SagarShetty ! Thanks for signing up. Let us know if you have any questions. Aug-15 6:46 AM

- Sagar Shetty
- Stefania Fatone

Tuesday August 18, 2015

Sagar Shetty Hello Everyone! Good Morning. I just started working with a patient last week for the NU-FlexSIV socket! I would like to share pictures of the cast and modifications. Aug-18 8:29 AM

Sagar Shetty IP_Res_Ant_View.JPG 373K
Image hidden
File uploaded: https://s3.amazonaws.com/uploads.hipchat.com/371888/2547375/U7YOO9sstYbmHv/IP_Res_Ant_View.JPG Aug-18 11:55 AM

Sagar Shetty IP_Res_Lat_View.JPG 384K
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File uploaded: https://s3.amazonaws.com/uploads.hipchat.com/371888/2547375/6bwukKLgvZZDYKk/IP_Res_Lat_View.JPG Aug-18 11:55 AM

Sagar Shetty IP_Cast_Top_View.JPG 256K

File uploaded: https://s3.amazonaws.com/uploads.hipchat.com/371888/2547375/g0qtFoYhpnFv7TX/IP_Cast_Top_View.JPG Aug-18 11:57 AM

Sagar Shetty IP_Mold_Unmod_Ant_View_Markers.JPG 330K

Aug-18 11:58 AM

Attachment icon and smiley face icon

N Nu-flexiv

ROOMS

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+ Create a room

PEOPLE

- Sagar Shetty

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- Sagar Shetty
- Stefania Fatone

Sagar Shetty @RyanCaldwell any suggestions? I did a 5-4-3% reduction Aug-18 12:01 PM

Sagar Shetty @RyanCaldwell did a trial fitting today (no elevated vacuum, just suction valve to check fit). Had to lower the trimlines by at least an inch (in 1/4 inch increments) to reach a point where it did not dig into her ischium/ramus. With that resolved completely, she now started feeling pressure on the lateral distal end of the femur. She has a lot of loose tissue, so her femur moves within the residual limb on palpation without the socket. Do you think addition of elevated vacuum will stabilize the femur or do you think she may need the socket to be tighter. The socket held well even with passive suction and I did not see any gaps. I added a 3 ply sock, but the patient did not feel much of a difference with or without it. Please advise. I am attaching pictures of the fitting for reference. Aug-18 3:30 PM

Sagar Shetty IP_Test1_Pro_ant.JPG 441K Aug-18 3:31 PM



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Sagar Shetty IP_Test1_Pro_lat.JPG 499K Aug-18 3:31 PM



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Sagar Shetty IP_Test1_Pro_post.JPG 424K Aug-18 3:31 PM

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N Nu-flexiv

ROOMS

2 NU-FlexSIV

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PEOPLE

● Sagar Shetty

+ Invite your team

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● Sagar Shetty
 ● Stefania Fatone

HipChat Hi **@MichaelCavanaugh** ! Welcome to Hipchat. You can @-mention me by typing **@HipChat** and I'll tell you what HipChat can do! Aug-22 1:15 PM

Monday August 24, 2015

Ryan Caldwell **@SagarShetty** Good Morning Sagar, I apologize but my initial response did not upload properly. The pictures are very helpful and thorough which helps. Aug-24 6:44 AM
 Can you tell me the distal liner measurement for the patient and the liner type and size that you used? With the excessive soft tissue that your patient appears to have, solidification of the tissue is key. My guess is that the liner is not sufficiently undersized/stiff enough. If I can get the liner measurement/sizing/ and type, this will help me to answer your question a little better. Looking forward to it.

Sagar Shetty Hi **@RyanCaldwell** , good morning. Patients distal residuum measured 39cm, and I used the Icross synergy 36. It was pretty tight to get on. Aug-24 7:35 AM

HipChat Hi **@BradvanLenthe** ! Welcome to Hipchat. You can @-mention me by typing **@HipChat** and I'll tell you what HipChat can do! Aug-24 4:20 PM

Thursday August 27, 2015

HipChat Hi **@ChristopherHoyt** ! Welcome to Hipchat. You can @-mention me by typing **@HipChat** and I'll tell you what HipChat can do! Aug-27 10:47 PM

Monday August 31, 2015

HipChat Hi **@bucktoenges** ! Welcome to Hipchat. You can @-mention me by typing **@HipChat** and I'll tell you what HipChat can do! Aug-31 12:09 PM

buck toenges Can anyone give me info on using the medi eva material? What temp do we use, how much will the material "droop" in a frame, any set up for the model before pulling socket? Aug-31 12:14 PM

Tuesday September 1, 2015

Ryan Caldwell **@bucktoenges** This information was available on the Medi website Sep-1 9:59 AM
 The Flex EVA is a flexible inner socket material that is durable, flexible and lightweight and reduced tackiness-no lubricants required when used with the medi 4Seal TFS sealing liner. Shore hardness D39. Recommended heating temperature: 300-320°F. Available in 3 thicknesses.
@bucktoenges My technicians heat the mold slightly before pulling, and the EVA blisters very well without too much difficulty. We're looking for droop of about half of the model. Their recommendation again is for their 4Seal liner but I used either the Medi Relax liner or the Ossur Synergy. Let me know how is goes

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- Sagar Shetty
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Thursday September 3, 2015

Christopher Hoyt · Sep-3 11:23 PM
@BradvanLenthe Brad, were you the CP from Canada in the seminar? Chris Hoyt

Friday September 4, 2015

Brad van Lenthe · Sep-4 10:57 AM
Of the two Brads that were in Chicago August 21,22 I was the Canadian.

Brad van Lenthe · Sep-4 11:02 AM
@RyanCaldwell the client I brought with me to Chicago is still having discomfort from that nerve so we have not proceeded with "trial" flexible socket. Hope to get someone in soon to be able to start from scratch though.

Christopher Hoyt · Sep-4 7:03 PM
@BradvanLenthe We had a brief discussion on Saturday regarding adductor musculature, primarily the gracilis and adductor longus. As I had described to you and Lacey, the gracilis inserts on the medial tibia, while the adductor longus inserts only on the linea aspera. Longus is simply longer than brevis. Thought I was getting old and forgetting things, but on the flight back home had to look it up to confirm. Thanks for keeping me on my toes! Chris

Brad van Lenthe · Sep-4 7:18 PM
@ChristopherHoyt my bad, I guess I misunderstood the surgeon many years ago and didn't follow up on my own. The Magnus will supply most of the moving motivation to the femur, and the shorter the femur, the less Magnus is there to create that motivation. Good to be corrected

Monday September 7, 2015

HipChat · Sep-7 7:15 PM
Hi @JodiHale Welcome to Hipchat. You can @-mention me by typing @HipChat and I'll tell you what HipChat can do!

Jodi Hale · Sep-7 7:22 PM
@RyanCaldwell I have a very tall patient who will require a custom liner. Which custom liner do you use? FYI Monica is doing very well with her new socket. She has increased her daily step count from 3700 to 5200. She is having some back pain, but this seems to be resolving.

Tuesday September 8, 2015

Ryan Caldwell · Sep-8 9:15 AM
@BradvanLenthe Hey Brad,

Stefania Fatone



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PEOPLE

- Sagar Shetty
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Tuesday September 8, 2015

Ryan Caldwell · Sep-8 9:15 AM
@BradvanLenthe | Hey Brad,
I'm sorry your model is still having some difficulty with the nerve pain. Please let keep us updated and let us know how your first fitting goes.
@JodiHale | Good Morning Jodi, great news about Monica. My guess with the back pain is that she likely is using muscles to walk she had not been using as much previously. Great jump in step count.

Ryan Caldwell · Sep-8 9:24 AM
@JodiHale | For your taller patient, do you need a custom liner due to length of the liner, or due to anatomical shape? For length alone I use the Willow Wood silicone liner with the progressive profile. This again is the bk liner, that I use for ak.

Ryan Caldwell · Sep-8 9:47 AM
I posted this comment directly to a member of a group by accident, so I'm sharing it below.
The Ossur liner does a great job of grabbing onto the tissue and following the shape while the Medi liner will solidify the tissue better which would hopefully center the bone in the tissue better. This was in regards to a patient with soft tissue that felt some motion between the femur and soft tissue.

Thursday September 10, 2015

Jodi Hale · Sep-10 8:10 AM
@RyanCaldwell | Hello Ryan. Thank you for the help on my patient with the long residual limb. I have another liner question. I have a 40yo female that measures 56cm distally. do you know of a liner that would work for her?
@RyanCaldwell | Also, I do have 2 possible knee disarticulation patients that may like to try this. Just so I know, which custom liner do you use?

Friday September 11, 2015

HipChat · Sep-11 10:21 AM
Hi @JohnBrinkmann ! Welcome to Hipchat. You can @-mention me by typing @HipChat and I'll tell you what HipChat can do!

Sunday September 13, 2015

Ryan Caldwell · Sep-13 8:11 PM
@JodiHale | Hello Jodi, The liner that I use for the "larger patients" would be the seal-in x from Ossur. This liner can go up to a size 55, and I have fit quite of few of these. There is an inner matrix with this liner so undersizing can be a bit tricky. For the patient that measures 56, I would look to the size 55 liner. There could be a chance that a patient of that caliber may drop in volume rather quickly, so just be aware of it.

Stefania Fatone

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https://nu-flexiv.hipchat.com/chat/room/1590114

Apps NU Box APMR EES Google Scholar NUPOC eIRB+ Galter

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Sunday September 13, 2015

Ryan Caldwell · Sep-13 8:11 PM

@JodiHale Hello Jodi, The liner that I use for the "larger patients" would be the seal-in x from Ossur. This liner can go up to a size 55, and I have fit quite of few of these. There is an inner matrix with this liner so undersizing can be a bit tricky. For the patient that measures 56, I would look to the size 55 liner. There could be a chance that a patient of that caliber may drop in volume rather quickly, so just be aware of it.

@JodiHale For custom liners, can you tell me the difference in measurements between the distal end and the smallest point just proximal to the femoral condyles. This will help me to give a more well informed answer. Thanks...

Tuesday September 15, 2015

HipChat · Sep-15 3:06 PM

Hi @RyanSpill I welcome to Hipchat. You can @-mention me by typing @HipChat and I'll tell you what HipChat can do!

Ryan Spill · Sep-15 3:07 PM

@HipChat

HipChat · Sep-15 3:07 PM

You can ask me about:

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- search - Search your messages
- emoticons - Use emoticons in your messages
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- advanced - Power tips for power users
- integrations - Connect HipChat with other applications
- tour - Replay the initial sign-up welcome tour
- help - Print this message again

HipChat · Sep-15 3:07 PM

For example, try typing "@HipChat video."

HipChat · Sep-15 3:35 PM

Hi @EricShoemaker I welcome to Hipchat. You can @-mention me by typing @HipChat and I'll tell you what HipChat can do!

HipChat · Sep-15 8:48 PM

Stefania Fatone

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Windows taskbar: Internet Explorer, Google Chrome, Outlook, Word, EN, File Explorer, S, PowerPoint

System tray: 11:02 PM 10/3/2015

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NU-FlexSIV
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HipChat - Sep-15 8:48 PM
Hi @DeanMcCleve ! Welcome to Hipchat. You can @-mention me by typing @HipChat and I'll tell you what HipChat can do!

Friday September 18, 2015

HipChat - Sep-18 12:00 PM
Hi @MarkMiller ! Welcome to Hipchat. You can @-mention me by typing @HipChat and I'll tell you what HipChat can do!

HipChat - Sep-18 2:28 PM
Hi @JamesOlinYoungJr ! Welcome to Hipchat. You can @-mention me by typing @HipChat and I'll tell you what HipChat can do!

Saturday September 19, 2015

HipChat - Sep-19 5:30 AM
Hi @GlennSchober ! Welcome to Hipchat. You can @-mention me by typing @HipChat and I'll tell you what HipChat can do!

Tuesday September 22, 2015

Dean McCleve - Sep-22 12:17 AM
@RyanCaldwell the cancer patient I spoke to you about just had 2 stints put in limb to open arterial blood flow. What are your thoughts about elevated suction once healed?

Ryan Caldwell - Sep-22 8:26 AM
@DeanMcCleve Good Morning Dean, I don't see any reason that the patient would not be a candidate given the recent procedure. A fair number of the patients that I have fit with the system have had some revascularization prior to their amputation. Let me know how it goes

Sunday September 27, 2015

HipChat - Sep-27 2:38 PM
Hi @GordonManiere ! Welcome to Hipchat. You can @-mention me by typing @HipChat and I'll tell you what HipChat can do!

Monday September 28, 2015

Gordon Maniere - Sep-28 10:48 AM
Hi Ryan...We wanted to use the Harmony E2 vacuum on the definitive socket, what are the needed modifications to the pump and is there someone specific you speak to at Ottobock to have them make the modifications?

📎 | 😊

Stefania Fatone



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PEOPLE

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- Invite your team

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Monday September 28, 2015

Gordon Maniere · Sep-28 10:48 AM
Hi Ryan...We wanted to use the Harmony E2 vacuum on the definitive socket, what are the needed modifications to the pump and is there someone specific you speak to at Ottobock to have them make the modifications?

Tuesday September 29, 2015

Ryan Caldwell · Sep-29 8:59 AM
[@GordonManiere](#) Hey Gordon, Here are a few pictures of the modified E2 Pumps. My contact at Otto Bock would be Scott Weber. Feel free to give him a call and discuss with him the best options to making these for you. I did these myself as I like to tinker.

Ryan Caldwell · Sep-29 9:01 AM
[20130913_110552.jpg](#) 1.8MB



Ryan Caldwell · Sep-29 9:01 AM
[20130913_110608.jpg](#) 1.6MB



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Stefania Fatone



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PEOPLE

- Sagar Shetty**
- + Invite your team

Sagar Shetty (@SagarShetty)
 Available · Fri 11:58 AM · BOCP0 · sagar@bionicpo.com

Tuesday August 18, 2015

Sagar Shetty Hi Stefania, how are you? I was wondering if you could send me links to studies showing the efficacy of elevated vacuum suspension systems in amputees. I am currently seeing a patient for a socket change and am working on the NU-FlexSIV socket. I discussed benefits of elevated vacuum with the physician and asked the physician to document the need for it in the progress notes for this patient, but she did not. I was hoping to find relevant studies for my own documentation. Aug-18 11:50 AM

Stefania Fatone  Kahle 2014b.pdf 148K Aug-18 9:28 PM
 Hello @SagarShetty! In the first lecture of the course I described the findings of a systematic review of elevated vacuum. I've attached the article here for you. It includes almost all the articles published about vacuum except for one by Hoskins et al. that was published after this review and one by Arndt et al. that was not included.

Stefania Fatone  Arndt 2011.pdf 992K Aug-18 9:29 PM
 File uploaded: <https://s3.amazonaws.com/uploads.hipchat.com/371888/2249701/f8izf5XHvW11NkB/Arndt%202011.pdf>

Stefania Fatone  Prosthet Orthot Int-2014-Hoskins-68-74.pdf 2.4MB Aug-18 9:33 PM
 File uploaded: <https://s3.amazonaws.com/uploads.hipchat.com/371888/2249701/07IRwpogLANtG9u/Prosthet%20Orthot%20Int-...>

Wednesday August 19, 2015

Sagar Shetty Awesome! Thanks a ton! Aug-19 5:57 AM

Input field with a smiley icon on the right.

 Prosthet Orthot Int-2014-Hos...
Stefania Fatone

 Arndt 2011.pdf
Stefania Fatone

 Kahle 2014b.pdf
Stefania Fatone

 Prosthet Orthot Int-2014-Hos...
Stefania Fatone Aug-19 2:33 AM

 Arndt 2011.pdf
Stefania Fatone Aug-19 2:29 AM

 Kahle 2014b.pdf
Stefania Fatone Aug-19 2:28 AM

APPENDIX G

Coauthors:

Fatone S, Caldwell R

Title (131/150 Characters):

Development of the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation

Summary (220/300 Characters):

A teachable subischial socket technique, the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket that results in improved comfort and comparable function to ischial containment sockets, was developed.

Introduction (994/1000 Characters):

Current transfemoral (TF) prosthetic sockets restrict function, lack comfort and cause residual limb problems. Although designed to support the body and enable effective load transfer during walking and other activities,¹ prosthetic sockets interface with soft tissues that are neither accustomed nor well-suited to the high pressure and shear loading that occurs during prosthetic ambulation.² Despite high daily use (≥ 12 hours), lack of socket comfort is the most common complaint of prosthesis users.³⁻⁶ Residual limb skin problems such as cysts, calluses, verrucous hyperplasia, allergic reactions, and bacterial or fungal infections have been reported by 25 to 63% of persons with amputation with a negative influence on ability to perform household tasks, prosthesis use, social functioning, and participation in sports.^{3, 7-9} The development and availability of a more comfortable and possibly functional socket may contribute to improving quality of life of persons with TF amputation.

Methods (996/1000 Characters):

A TF socket technique was developed aimed at improving comfort. The Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket (Fig 1) has lower proximal trim lines that do not impinge on the pelvis; is flexible so muscles can move comfortably within the socket as they contract during activity and improve sitting comfort; and is held securely to the residual limb by vacuum pump suction as well as compression of an undersized liner and socket.¹⁰ The socket includes a highly compressive, cylindrical fabric covered silicone liner, a flexible inner socket, and a shorter rigid outer socket with vacuum applied between liner and inner socket. An algorithm and rectification mapping were developed to facilitate decision making for socket fabrication. Socket comfort score,¹¹ gait analysis, and clinical outcome measures (Rapid-Sit-To-Stand, Four-Square-Step-Test and T-Test of Agility) were used to assess socket performance. A hands-on workshop to teach this technique was piloted.

Results (1500/1500 Characters):

The undersized liner and socket are used to compress the residual limb, stiffening the soft tissue and decreasing relative motion of the limb within the socket. The impression is taken over the liner with the patient seated and the limb flexed and slightly abducted, allowing gravity to pre-modify the tissues. Rectifications were quantified using a program that aligned a series of 30 scans of rectified and unrectified negative molds and calculated changes in shape. A color coded scale on the rectification map indicates the depth and contours of the rectifications required for the NU-FlexSIV Socket, showing that

plaster is primarily removed from the proximal-lateral and posterior regions, while the medial and anterior regions remain relatively untouched. No plaster is added. For 2 subjects, socket comfort increased in the NU-FlexSIV Socket compared to an ischial containment socket. Walking speed increased for the NU-FlexSIV Socket but other gait variables, including coronal plane trunk flexion and sagittal hip motion, were comparable for level ground walking. Clinical outcome measure performance was comparable in both sockets. Three workshops held in summer 2015 were attended by 31 prosthetists from the US and Canada. Attendees were taught to cast, rectify, fit and align the NU-FlexSIV Socket. Patient models responded positively to the comfort, range of motion and stability of the NU-FlexSIV Socket while prosthetists described the technique as “straight forward, reproducible”.

Conclusions (951/1500 Characters):

To the best of our knowledge, this is the first attempt to create a teachable subischial socket technique that results in improved comfort and comparable function to ischial containment sockets, confirming previous reports.^{12, 13} Color coded rectification maps help communicate an important step in this socket technique, enhancing dissemination. Socket stability during walking was confirmed by lack of lateral trunk flexion and lateral socket gapping at mid stance. Clinical experience fitting this socket to nearly 100 patients confirms these research findings. Initial evaluation of the NU-FlexSIV Socket with military amputees is promising.¹⁴ Future work includes an assessor-blinded, randomized cross-over trial comparing comfort and functional performance with the NU-FlexSIV Socket to the ischial containment socket in persons with unilateral transfemoral amputation.

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

References (914/1500 Characters):

1. Mak et al. *J Rehabil Res Dev.* 2001;38(2):161-74.
2. Mak et al. *Ann Rev Biomed Eng.* 2010;12(1):29-53.
3. Dillingham et al. *Am J Phys Med Rehabil.* 2001;80(8):563-71.
4. Pezzin et al. *Arch Phys Med Rehabil.* 2004;85(5):723-9.
5. Berke et al. *J Rehabil Res Dev.* 2010;47(4):361-71.
6. Limb Loss Research and Statistics Program. *People With Amputation Speak Out 2012.*
<http://www.amputee-coalition.org/people-speak-out.pdf>
7. Dudek et al. *Arch Phys Med Rehabil.* 2005;86(4):659-63.
8. Meulenbelt et al. *Acta dermato-venereologica.* 2011;91(2):173-7.
9. Meulenbelt et al. *Acta dermato-venereologica.* 2011;91(2):178-82.
10. Board et al. *Prosthet Orthot Int.* 2001;25(3):202-9.
11. Hanspal et al. *Disabil Rehabil.* 2003;25(22):1278-80.
12. Kahle & Highsmith. *J Rehabil Res Dev.* 2013;50(9):1241-52.
13. Kahle & Highsmith. *Gait Posture.* 2014;40(2):315-20.
14. Esposito et al. 41st AAOP Annual Meeting; February 18-21, 2015; New Orleans, LA.

