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TITLE: Functional Performance Evaluation of the Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation

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14. ABSTRACT
This project was a clinical trial to compare the new prosthetic socket we developed (the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket) with the current standard of care socket (the Ischial Containment (IC) Socket). The primary aims of the study were to (1) assess if the NU-FlexSIV Socket was more comfortable than the IC Socket; (2) to assess if the NU-FlexSIV Socket resulted in better functional performance than the IC Socket; and (3) to assess if the NU-FlexSIV Socket resulted in better quality of life and satisfaction with device (i.e. prosthesis) than the IC Socket. We enrolled 30 participants and 25 completed the study with full (n=18) or partial data (n=7). The results suggest that, after 7 weeks accommodation, the NU-FlexSIV Socket was significantly more comfortable and led to significantly greater satisfaction with device than the IC Socket in persons with unilateral transfemoral amputation with relatively high mobility. Other patient-reported outcomes, timed performance tests, and gait biomechanics were no different between sockets.

15. SUBJECT TERMS
Prosthetic Socket, Artificial Limbs, Prosthesis, Transfemoral Amputee, Gait, Socket Comfort

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INTRODUCTION

This project was a clinical trial to compare the new prosthetic socket we developed for persons with transfemoral amputation (the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket) with the current standard-of-care socket (the Ischial Containment (IC) Socket) with the goal of demonstrating comfort, and possibly functional, superiority. It is expected that the availability of a more comfortable and functional socket will contribute to improving the quality of life (QOL) of persons with transfemoral amputation. This clinical trial was an assessor-blinded prospective randomized crossover trial wherein participants with unilateral transfemoral amputation were randomized to using one of the two socket conditions before crossing over to the other socket condition. The trial was balanced such that all subjects received all treatments (i.e., both socket conditions) and that all subjects participated for the same number of periods (i.e., two). The primary aims of the study were (1) to demonstrate if the NUFlexSIV Socket was more comfortable than the IC Socket; (2) to demonstrate if the NU-FlexSIV Socket resulted in better functional performance than the IC Socket; and (3) to demonstrate if the NU-FlexSIV Socket resulted in better QOL and "satisfaction with device" (i.e. prosthesis) than the IC Socket.

KEYWORDS

Prosthetic Socket, Artificial Limbs, Prosthesis, Transfemoral Amputee, Gait, Socket Comfort

ACCOMPLISHMENTS

Major goals of the project

Aim 1: To demonstrate if the NU-FlexSIV Socket is more comfortable than the IC socket.

Aim 2: To demonstrate if the NU-FlexSIV Socket results in better functional performance than the IC socket.

Aim 3: To demonstrate the NU-FlexSIV Socket will result in better quality of life and "satisfaction with device" (i.e. prosthesis) than the IC socket.

Accomplishments under these goals

This clinical trial aimed to compare comfort, function, QOL and satisfaction with device of the NU-FlexSIV Socket to the standard-of-care IC Socket in people with unilateral transfermoal amputation. We hypothesized that the NU-FlexSIV Socket, compared to the IC Socket, would:

- Hypothesis 1 (H1): provide increased comfort (primary outcome),
- Hypothesis 2 (H2): result in faster times to perform timed performance-based tests (the 5-Times Rapid Sit-to-Stand Test (RSTS), Four Square Step Test (4SST), and T-Test of Agility (T-Test)),
- Hypothesis 3 (H3): have better patient-reported lower extremity functional status, satisfaction with device, and health-related QOL as assessed with the Orthotic and Prosthetic Users' Survey (OPUS).

Additionally, to assess whether removal of the proximal brim improved gait biomechanics, we hypothesized that the NU-FlexSIV Socket, compared to the IC Socket, would:

- Hypothesis 4 (H4): allow greater prosthetic side hip range of motion (ROM) leading to increased prosthetic side step length, and hence walking speed at 7 weeks.

Specifically, we thought that if hip ROM increased in the NU-FlexSIV Socket, it would be due to greater hip extension. Hence, secondarily, both maximum hip extension and flexion were assessed to identify their contributions to potential changes in hip ROM.

To confirm whether coronal plane stability was unaffected by lack of ischial containment, we hypothesized that:

- Hypothesis 5 (H5): lateral trunk flexion over the prosthetic limb and step width would not differ between the NU-FlexSIV Socket and IC socket at 7 week.

This clinical trial was prospectively registered (https://clinicaltrials.gov/ct2/show/NCT02678247) and approved by the Northwestern University Institutional Review Board (IRB, STU00201300), the Jesse Brown Veterans Affairs Medical Center IRB (830879), and the Department of Defense Human Research Protections Office (A-18924). Prior to participation, all participants provided written informed consent.

This trial was a prospective, assessor-blinded randomized crossover trial. Computer-generated, random allocation with blocks of random size was used to assign the initial socket. Trial design was balanced with all participants receiving both sockets and participating for both periods. Socket order for each participant was enclosed in a sequentially numbered, opaque, sealed envelope, and concealed from the investigators until after participant enrollment. Blinding of participants to the sockets was not possible given that the sockets have different geometries and were worn by participants for 7 weeks. Assessors were blinded to timed performance measures.

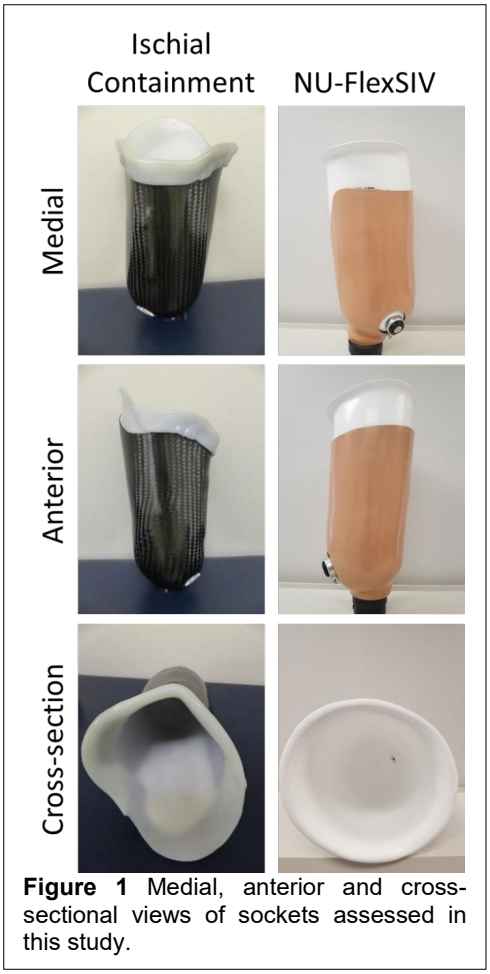

Figure 1 Medial, anterior and cross-sectional views of sockets assessed in this study.

A convenience sample of participants was recruited by referral of local prosthetists. Participants were included if they: 1) were ≥21 years of age, 2) had a unilateral transfemoral amputation, 3) used a prosthesis for ≥2 years, 4) had a residual limb that was stable in volume and free from any wounds, 5) had no previous experience with a sub-ischial socket, 6) were sufficiently physically fit to participate in the study (meaning that they were classified as Medicare Functional Classification Level (MFCL) K3 or K4[1] by one of the study prosthetists), and 7) were able to complete all study visits. Participants were excluded if 1) the residual limb femur was <12.7cm as that is a limitation for the NU-FlexSIV Socket,[2] 2) they had other co-morbidities affecting function, and/or 3) they did not speak and read English.

Every participant received 2 new prosthetic sockets each custom-fabricated by a single but different Certified Prosthetist (Ryan Caldwell with ~10 years of clinical experience providing the NU-FlexSIV Socket and John Angelico with ~30 years of clinical experience providing the IC Socket). Design specifics of each IC Socket were determined on a per-participant basis by the prosthetist using standard clinical practice procedures.[3] As shown in Figure 1, IC Sockets consisted of a flexible inner socket with rigid, laminated frame using either skin-fit suction suspension with a one-way valve or liner with internal seal or locking mechanism. NU-FlexSIV Sockets consisted of a silicon liner and Flex EVA inner socket (both from Össur, Reykjavik, Iceland), rigid laminated outer socket, and vacuum-assisted suspension.[2] Knees, pylons and feet were standardized within participants. To minimize the burden of learning to walk with a different knee, participants wore their usual prosthetic knee. However, all participants were provided with a foot with Unity mechanical vacuum pump (Össur, Reykjavik, Iceland), chosen because it could interface with any component, and be used with both sockets but provide vacuum-assisted suspension for use with the NU-FlexSIV Socket.

Sockets were worn full-time for 7 weeks, with testing at 1, 4 and 7 weeks post-socket delivery. The primary outcome was change in Socket Comfort Score (SCS)[4] at 7 weeks. Secondary outcomes at 7

weeks included the Orthotic and Prosthetic Users' Survey (OPUS)[5] to assess lower extremity functional status, health-related QOL and satisfaction with device, as well as the 5-Times Rapid Sit-to-Stand Test,[6, 7] Four Square Step Test,[8] and T-Test of Agility[9-11] to assess functional performance. Quantitative gait analyses were also conducted during each data collection session using a 12-camera digital motion analysis system (Motion Analysis Corporation (MAC), Santa Rosa, CA, USA). Kinematic data were acquired at 120Hz while the subjects walked at 3 self-selected speeds along a 10-meter walkway (normal, slow and fast speeds, in that order). A minimum of 5 trials were collected per speed and averaged for analysis. At each data collection session, motion analysis was conducted first, followed by administration of the OPUS and then the other performance-based measures. The OPUS was administered seated for 10-20 minutes and thus provided an opportunity for the subject to rest and for the possible effects of fatigue on the functional data to be minimized.

Recruitment began in April 2016 and ended in May 2019. Of the 30 subjects enrolled in the study, 18 attended each data collection session, 7 attended some but not all data collection sessions, and 5 withdrew without any data being collected (Appendix A: CONSORT Flow Chart). For the 25 subjects who participated in some or all data collection sessions 14 were allocated to start with the IC Socket and 11 with the NU-FlexSIV Socket. Subjects were relatively young with a mean age of 45.9 (SD = 13.7) years and mostly male (n=19), with a mean mass of 88.6 (SD=19.7) kg and height of 177.2 (SD=11.6) cm. They were all experienced prosthesis users having had their amputation for a mean of 23.2 (SD=15.8) years. Etiology of amputation was primarily due to trauma (n=15) and cancer (n=7), with a few due to a vascular issue or infection (n=3). Subjects had relatively high mobility levels, with all being classified as Medicare Functional Classification Levels of K4 (n=18) or K3 (n=7) by the study prosthetists. The Amputee Mobility Predictor with Prosthesis[1] was used to quantify mobility capability, with a mean score of 42.7 (SD=2.6). See Appendix B: Participant Characteristics and Appendix C: Sockets and prosthetic components worn during the study.

For comparisons of the primary and secondary outcomes at week 7, we used two different approaches. First, we tested for differences in the outcomes at week 7 by using paired t-tests to compare the cross-sectional mean values. Second, we fit linear mixed models to all of the available data for each of the outcomes with random slope and random intercept to account for the changes in outcome values that may have taken place over time. In order to confirm whether pre-study SCS influenced the results, we fit both unadjusted and models adjusted for SCS in the pre-study socket (Appendix D: Details of pre-study prosthesis). Significance of tests for SCS, performance-based measures, and OPUS modules was set at $\alpha = 0.05$ (H1-3). For gait biomechanics, significance was set at a Bonferroni adjusted $\alpha = 0.017$ for H4 and $\alpha = 0.025$ for H5. If sagittal plane hip ROM was significantly different between sockets at week 7, we followed up with comparison of maximum hip flexion and extension using paired t-tests set at $\alpha = 0.05$.

The mean differences (NU-FlexSIV Socket minus IC Socket) at 1, 4, and 7 weeks were 1.1 (Standard Deviation, SD=2.2), 1.8 (SD=2.9), and 1.5 (SD=1.5), respectively. At 7 weeks, the mean SCS for IC and NU-FlexSIV Sockets were significantly different: 7.0 (SD=1.7) and 8.4 (SD=1.1), respectively ($p<0.001$, 95% Confidence Interval (CI) of difference = [0.8, 2.3]). In general, 16 of 19 subjects rated the NU-FlexSIV Socket as more comfortable at 7 weeks, with 4 subjects exceeding the MDC_{90} of 2.7.[12] Results from the linear mixed effects model, accounting for all data points at 1, 4, and 7 weeks, showed that the SCS for the NU-FlexSIV Socket was 1.7 (Standard Error, SE=0.45) points higher compared to the IC Socket ($p<0.001$). When adjusting for pre-study socket SCS in the model, the NU-FlexSIV Socket was estimated to be 2.1 (SE=1.0) points higher than the IC Socket ($p=0.05$). Since, pre-study socket SCS was not associated with the outcome, we excluded it from further consideration in the mixed effects models for the secondary performance-based and patient-reported outcomes.

For the performance-based tests and OPUS modules, there were no significant differences between NU-FlexSIV and IC Sockets whether assessed using paired t-tests or linear mixed effects models with the exception of OPUS Satisfaction with Device. With the linear mixed effects model, the NU-FlexSIV Socket scored slightly higher for OPUS Satisfaction with Device, with a difference of 2.7

(SE=1.2, p=0.03) compared to the IC Socket at week 7. See Appendix E: Results of paired t-tests for H1-3 and Appendix F: Results for linear mixed models for H1-3.

Figure 2 illustrates the results of the gait biomechanics variables at week 7. For the participants who completed data collection for both sockets at week 7, paired t-tests did not support the H4 but did support H5: there were no significant differences in any of the gait variables between sockets when participants walked at their self-selected normal speed (Appendix G: Results of paired t-tests for H4 and H5). Similarly, paired t-tests at 7 weeks did not support H4 for slow self-selected walking speed, but prosthetic side sagittal plane hip ROM was significantly greater for the NU-FlexSIV Socket at fast self-selected walking speed (p=0.016). However, neither maximum hip extension nor flexion were significantly different between sockets at fast self-selected walking speed. H5 was supported as there was no significant difference for either variable (lateral trunk flexion or step width) at either slow or fast self-selected speed.

When all participants and all study time points were assessed using linear mixed models, H4 was partially supported for normal self-selected walking speed (Appendix H: Results of linear mixed models for H4 and H5). There was a significant main effect of socket with prosthetic side sagittal plane hip ROM being significantly greater for the NU-FlexSIV Socket (p=0.013). However, there was no effect of socket, time, or socket by time for prosthetic limb step length or walking speed. When assessing whether the increased prosthetic side hip ROM for the NU-FlexSIV Socket was due to increased hip extension or flexion, neither were significantly different (p≥0.238) between sockets for normal self-selected walking speed. H5 was supported as there was no significant main effect for either variable (lateral trunk flexion or step width).

For self-selected slow and fast walking speeds, H4 was also partially supported; there was a significant main effect of socket with prosthetic side sagittal plane hip ROM being significantly greater for the NU-FlexSIV Socket at both slow (p<0.001) and fast (p=0.016) self-selected walking speeds. However, there was no effect of socket, time, or socket by time for prosthetic limb step length or walking speed. When assessing whether the increased prosthetic side hip ROM for the NU-FlexSIV Socket was due to increased hip extension or flexion, there was a significant main effect of socket at self-selected fast walking speed with prosthetic side sagittal plane hip flexion being

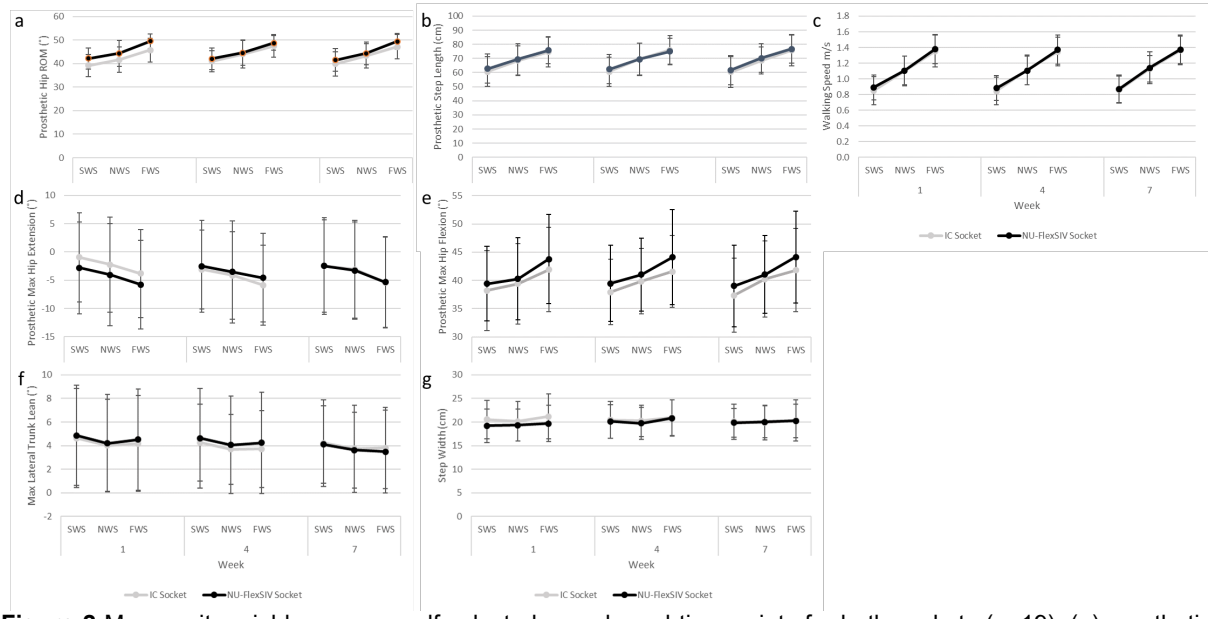

Figure 2 Mean gait variables across self-selected speeds and time points for both sockets (n=19): (a) prosthetic hip range of motion (ROM), (b) prosthetic side step length (c) walking speed, (d) prosthetic side maximum hip extension, (e) prosthetic side maximum hip flexion, (f) maximum lateral trunk lean over prosthetic limb in stance and (g) step width.

significantly greater for the NU-FlexSIV Socket (p=0.006). H5 was supported as there was no significant main effect for either variable (lateral trunk flexion or step width) at slow or fast self-selected walking speed.

Finally, adverse events were frequent but relatively minor (Appendix I: Adverse events). Nineteen of 25 participants chose to remain in the NU-FlexSIV Socket upon study completion.

Overall, the results suggest that, after 7 weeks accommodation, the NU-FlexSIV Socket was more comfortable with greater satisfaction with device than the IC Socket and did not compromise gait biomechanics related to hip ROM and coronal plane socket stability in people with unilateral transfemoral amputation and K3/K4 mobility levels. Other patient-reported outcomes and function (based on timed performance tests) were no different between sockets.

During the course of this project, we gave 13 presentations nationally and internationally resulting in 2 published conference abstracts and a best paper award from the Australian Orthotic and Prosthetic Association conference in 2018. A manuscript reporting the results of the primary, performance-based, and patient-reported outcomes has been submitted for publication. A second manuscript reporting on the results of the gait biomechanics has been drafted and will be submitted for publication shortly.

Opportunities for training and professional development provided by the project

Nothing to Report.

Dissemination of results to communities of interest

The NU-FlexSIV Socket technique, which was developed by Dr. Stefania Fatone (Principle Investigator) and Ryan Caldwell, CP, at Northwestern University using prior Department of Defense (DOD) funding (#W81XWH-10-0744) is close to achieving the objective of becoming a clinical standard-of-care for persons with transfemoral amputation, as it is being actively used in clinical practice throughout the world.[13]

As a technique the NU-FlexSIV Socket needs to be taught to Certified Prosthetists who, given the practical nature of their profession, prefer to learn through hands-on workshops. Hence, a 2-day hands-on workshop certified for education credits by the American Board for Certification in Prosthetics, Orthotics and Pedorthics (ABC) was developed. Teaching of the NU-FlexSIV Socket technique began in 2015 under the prior award and has been described as “straightforward and reproducible”.[2] Since 2015, Dr. Fatone and Ryan Caldwell, CP, have together conducted 24 hands-on workshops (see https://www.nupoc.northwestern.edu/research/projects/lowerlimb/dev_subischial.html for a list of workshops held to date) and taught the socket technique to 136 prosthetists in the US and 127 prosthetists internationally. Other prosthetists have implemented the technique after hearing a presentation or webinar, or reading a publication.[2, 14-16] Prosthetists have begun to report their experiences and findings in conference presentations[17] and publications.[18]

The results of this clinical trial were described in each workshop. The data from this clinical trial is an important element providing prosthetists confidence to implement this technique in their clinical practice. Persons with transfemoral amputation attend these workshops and are fit by the prosthetists we teach, helping them learn about the socket. Similarly, didactic portions of the course, particularly those that discuss the results of this clinical trial, have been attended by physical therapists involved in amputee gait training and physicians who prescribe prostheses.

Plans for next reporting period

Nothing to Report.

IMPACT

Impact on the development of the principal discipline of the project

The results of this project provide evidence that the NU-FlexSIV Socket is a viable alternative socket design for persons with unilateral transfemoral amputation who are community ambulators. Publication of the results of this clinical trial will help further clinical implementation by providing physicians and prosthetists evidence to support prescription of the NU-FlexSIV Socket.

The NU-FlexSIV Socket also provides researchers a platform to assess socket function. For example, we are conducting a DOD funded pilot clinical trial (W81XWH19-1-0507) exploring the effect of transfemoral socket design on hip muscle function (see https://www.nupoc.northwestern.edu/research/projects/lowerlimb/dod_sawers_fatone.html for a description of the project).

The results of this trial were used to support an application submitted in June 2020 to the DOD JWMRP 2020 for a clinical trial to assess use and benefits of the sub-ischial socket for persons with transfemoral amputation (TFA) and lower mobility levels.

Impact on other disciplines

Nothing to Report.

Impact on technology transfer

Nothing to Report.

Impact on society beyond science and technology

Nothing to Report.

CHANGES/PROBLEMS

Changes in approach and reasons for change

Nothing to report.

Actual problems or delays and actions taken to resolve them

Nothing to report.

Changes that had a significant impact on expenditures

Nothing to report.

Significant changes in use or care of human subjects

Nothing to report.

PRODUCTS

Publications, conference papers, and presentations

Journal publications

Fatone S, Caldwell R, Angelico J, Stine R, Kim K-Y, Gard S, Oros M (submitted November 2020) Comparison of Ischial Containment and Sub-Ischial Sockets on Comfort, Function, Quality of Life and Satisfaction with Device in Persons with Transfemoral Amputation: a randomized crossover trial. Archives of Physical Medicine and Rehabilitation. Federal support acknowledged: yes.

Stine R, Caldwell R, Angelico J, Major MJ, Gard S, Oros M, Fatone S (prepared for submission) Comparison of Ischial Containment and Sub-Ischial Socket Effects on Gait Biomechanics in People with Transfemoral Amputation: a 3 randomized crossover trial. Federal support acknowledged: yes.

Other publications, conference papers, and presentations

Caldwell R, Fatone S (2021) Transfemoral Socket Design: Northwestern University Sub-ischial Socket Technique. Hanger LIVE, February 4-5, virtual meeting.

Caldwell R (2020) NU Flex-SIV Sub-Ischial Socket Techniques and Research Results. Invited speaker in symposium “Transfemoral socket design in the US and Germany: What is the state of the art?” OT World Congress, October 27-29, virtual meeting.

Fatone, S and Caldwell R (2020) Development, Research and Dissemination of the Northwestern University Sub-Ischial Socket Technique. Minneapolis VA Research Service Conference Series, January 14, Minneapolis, MN.

Fatone S (2019) The Northwestern University Flexible Sub-Ischial Socket Technique: Development, Research, and Dissemination. Invited Presentation, AOPQ-AQIPA 2019 Congress, October 18-20, St-Hyacinthe, Quebec, Canada.

Fatone S, Caldwell R, Angelico R, Subramanian V, Stine R (2019) Evaluation of Socket Comfort and Functional Performance for Persons with Transfemoral Amputation: Interim Analysis. International Society for Prosthetics and Orthotics World Congress, October 5-8, Kobe, Hyogo, Japan. Abstract Book, Prosthetics and Orthotics International, 43(1S):73. (Included in Appendix J)

Fatone S (2019) Development and Dissemination of the Northwestern University Flexible Sub-Ischial Socket Technique. Invited presentation, ISPO Canada and RehabWeek, June 24-28, Toronto, Canada.

Fatone S (2019) The Northwestern University Flexible Sub-Ischial Socket Technique: Development, Research, and Dissemination. Invited presentation in the session “Innovations in Socket Design and Manufacturing” at the Orthotic and Prosthetic Innovative Technologies Conference (OPTech), May 16-18, Ann Arbor, Michigan.

Fatone S (2019) The Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket: Development, Research and Dissemination. Invited presentation, Iowa Prosthetic, Orthotic and Pedorthic Association, April 6, Des Moines, Iowa.

Fatone S, Caldwell R, Stine R, Subramanian V, Angelico J (2018) Evaluation of the NU-FlexSIV Socket for Persons with Transfemoral Amputation. Australian Orthotic and Prosthetic Association, October 4-6, Gold Coast, Australia. ***Won the Guild Best Presentation Award.***

Fatone S, Caldwell R, Angelico J (2018) Evaluation of the NU-FlexSIV Socket for Persons with Transfemoral Amputation: Interim Results. NUPOC Biennial Symposium for Initiative ’93, March 13, Chicago, IL.

Fatone S, Caldwell R, Angelico J (2018) Evaluation of the NU-FlexSIV Socket for Persons with Transfemoral Amputation: Interim Results & Clinical Commentary. Scheck & Siress Education Fest, April 27-28, Lombard, IL.

Fatone S, Caldwell R, Stine R, Tran L, Angelico J (2018) Evaluation of the NU-FlexSIV Socket for Persons with Transfemoral Amputation: Interim Results. American Academy of Orthotists & Prosthetists Annual Meeting & Scientific Symposium, February 14-17, 2018, New Orleans, LA. Abstract in Journal of Prosthetics and Orthotics, 30(S2):22. (Included in Appendix J)

Fatone S, Caldwell R, Stine R, Tran L, Angelico J. (2017) Evaluation of the NU-FlexSIV Socket for Persons with Transfemoral Amputation: Interim Results. Midwest Chapter of the American Academy of Orthotists and Prosthetists, November 11, Chicago, IL.

Fatone S, Caldwell R (2016) Socket-Related Research Collaborations at Northwestern University. Scheck Fair. April 8-9, Lombard, IL.

Website(s) or other Internet site(s)

Project page on the NUPOC website:
https://www.nupoc.northwestern.edu/research/projects/lowerlimb/FunctionalPerfEvalNUFlexSIV.html

Clinical trial registration: https://clinicaltrials.gov/ct2/show/NCT02678247

Other Products

Research data has been shared on the Northwestern University DigitalHub:

https://digitalhub.northwestern.edu/files/ebae21d9-ab26-4ff5-8e67-829ebb5a5b9d

https://digitalhub.northwestern.edu/files/c0f58d29-3754-4de0-b7c4-0ff6ad6b654d

https://digitalhub.northwestern.edu/files/99e72db7-6f0b-4a9e-b97b-320f0ee46dcd

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Individuals who have worked on the project

Name:	Stefania Fatone, PhD, BPO(Hons)
Project Role:	NU Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-5802-035X
Nearest person month worked:	2
Contribution to Project:	Oversaw and managed all aspects of the project including IRB, technical reporting, subject recruitment, data collection, data analysis, presentations and publications.

Name:	Steven Gard, PhD
Project Role:	Site PI (JBVAMC)
Researcher Identifier (e.g. ORCID ID):	0000-0002-4251-2464
Nearest person month worked:	1
Contribution to Project:	Oversaw and managed aspects of the project involving the JBVAMC. Maintained allocation envelopes, assisted with data collection as necessary, and contributed to publications.

Name:	Michael Oros, CPO
Project Role:	Site PI (Scheck & Siress)
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Oversaw and managed aspects of the project occurring at Scheck & Siress. Contributed to publications.

Name:	Ryan Caldwell, CP
Project Role:	Research Prosthetist
Researcher Identifier	N/A

(e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to Project:	Recruited subjects, fabricated and fit NU-Flex Sockets to subjects, and contributed to data analysis, presentations and publications.

Name:	John Angelico, CPO
Project Role:	Research Prosthetist
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Recruited subjects, fabricated and fit IC Sockets to subjects, and contributed to presentations and publications.

Name:	Rebecca Stine, MS
Project Role:	Manager, JBVAMC-Motion Analysis Research Lab
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Assisted with recruitment of Veteran subjects, collected and processed gait data, and contributed to presentations and publications.

Name:	Kwang-Youn Kim, PhD
Project Role:	Statistician
Researcher Identifier (e.g. ORCID ID):	0000-0002-4168-757X
Nearest person month worked:	1
Contribution to Project:	Guided data entry into RedCAP and conducted statistical analysis.

Name:	Matthew Major, PhD
Project Role:	Statistician
Researcher Identifier (e.g. ORCID ID):	0000-0002-2330-4619
Nearest person month worked:	1
Contribution to Project:	Conducted statistical analysis.

Name:	Jessica Yohay, BS
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3
Contribution to Project:	Assisted with RedCAP data entry, assisted with data collection when needed, and assisted with preparation of technical reports. Processed gait data when Mr. Subramanian left the university. Ms Yohay left the university in June 2020.

Name:	Lilly Tran, MS
Project Role:	Research Engineer, blinded assessor
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Administered clinical outcome measures, processed gait data, and assisted with data entry into RedCAP. Ms. Tran left Northwestern University in November 2017.

Name:	Vasanth Subramanian, MS
Project Role:	Research Engineer, blinded assessor
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Replaced Ms Tran on this project. Administered clinical outcome measures, processed gait data, and prepared all data for entry into RedCAP. Mr. Subramanian left the university in July 2019.

Name:	Julia Quinlan, PhD
Project Role:	Post-doctoral Fellow (supported by ARRT training grant), blinded assessor
Researcher Identifier (e.g. ORCID ID):	0000-0001-9089-7322
Nearest person month worked:	1
Contribution to Project:	Filled in as the blinded assessor from November 2017 to March 1 2018 while we searched for a research engineer to replace Ms. Tran. Dr. Quinlan again assumed the role of blinded assessor when Mr. Subramanian left the university in July 2019.

Name:	Thomas Schnitzer, PhD
Project Role:	Co-investigator, mentor to PI
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1
Contribution to Project:	Guided and mentored PI with clinical trial processes.

Name:	RJ Garrick, PhD
Project Role:	Research Consultant
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2 (year 1 only)
Contribution to Project:	Drafted Manual of Procedures, registered clinical trial, and created RedCAP database.

Change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period

Nothing to Report.

Other organizations involved as partners

Organization Name: Jesse Brown VA Medical Center
Location of Organization: 820 S. Damen Avenue, Chicago, IL 60612
Partner's Contribution to the Project:
• Veteran subject recruitment.
• Gait data was collected in the Jesse Brown VA Medical Center Motion Analysis Research Laboratory.

Organization Name: Scheck & Siress
Location of Organization: 1S376 Summit Avenue, Court E, Oakbrook Terrace, IL 60181
Partner's Contribution to the Project:
• Subject recruitment.
• Fabrication and fitting of ischial containment sockets.

SPECIAL REPORTING REQUIREMENTS

Quad Chart attached as Appendix K.

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APPENDICES

Appendix A: CONSORT Flow Chart
Appendix B: Participant Characteristics
Appendix C: Sockets and components worn during study
Appendix D: Details of pre-study prosthesis
Appendix E: Results of paired t-tests for H1-3
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Appendix H: Results of linear mixed models for H4 and H5
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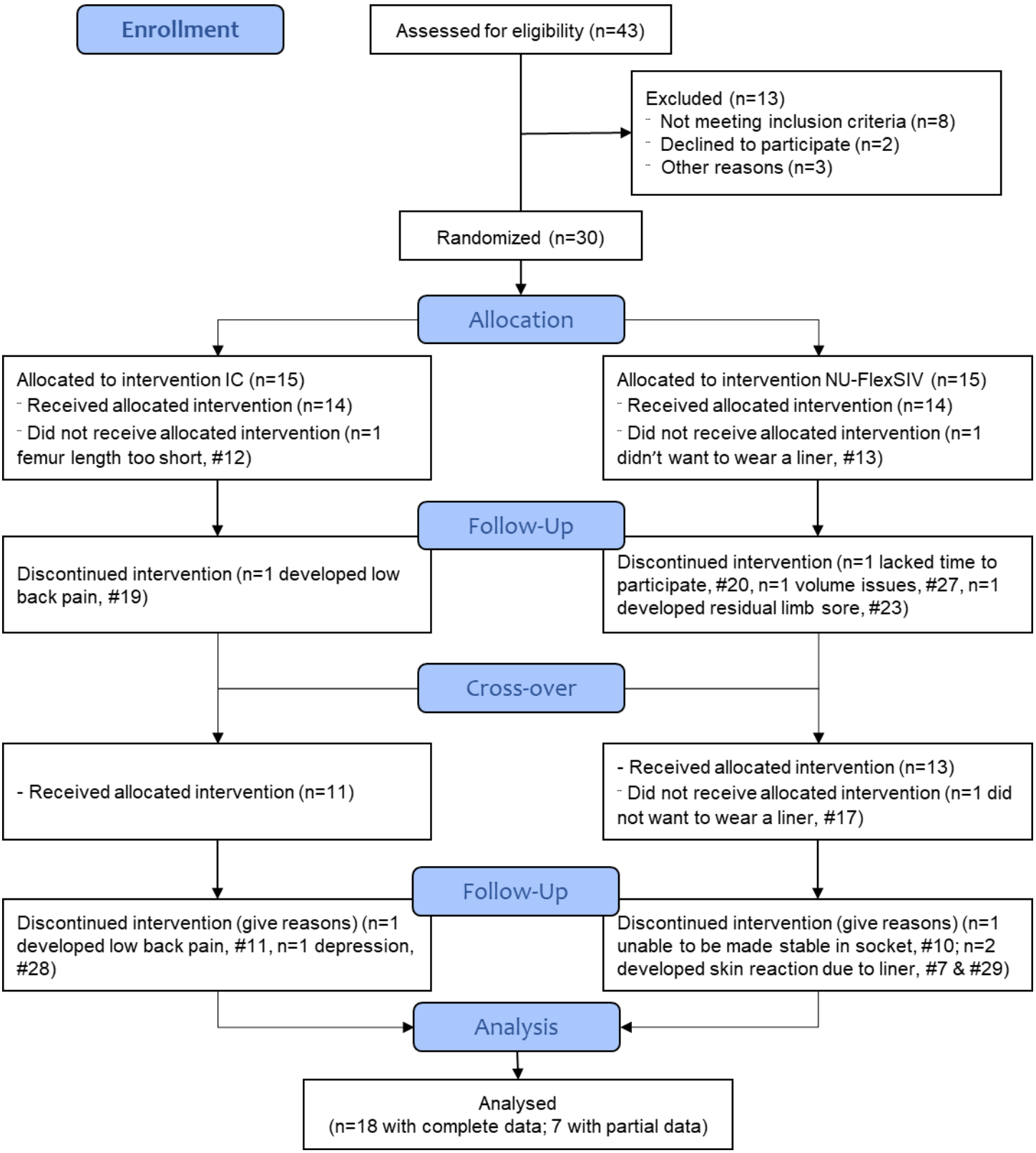
APPENDIX A CONSORT FLOW CHART



APPENDIX B PARTICIPANT CHARACTERISTICS

	Subject Number	Age (years)	Sex	Race	Height (cm)	Mass (kg)	Time Since Amputation (years)	Etiology of Amputation	Residual Limb Length (cm)	MFCL K-level	AMP-PRO Score
Completed all data collection sessions	01	50	Male	Caucasian	194.0	87.1	36	Cancer	28.6	K4	44
	02	37	Male	African American	181.5	98.6	3	Trauma	24.3	K3	36
	03	26	Female	Caucasian	148.0	53.0	17	Cancer	19.1	K3	44
	04	56	Male	Caucasian	184.0	70.8	16	Trauma	20.0	K4	43
	05	51	Male	African American	184.0	120.8	30	Cancer	30.6	K4	43
	06	46	Male	African American	184.0	64.8	37	Cancer	22.2	K4	44
	08	68	Male	Caucasian	188.5	105.9	3	Vascular	32.3	K4	44
	09	29	Female	Caucasian	158.0	61.0	24	Trauma	22.8	K4	43
	14	38	Male	African American	179.0	93.4	6	Vascular	22.5	K3	36
	15	49	Male	Caucasian	179.0	102.5	26	Trauma	27.0	K4	43
	16	54	Male	Caucasian	182.0	85.3	41	Trauma	18.4	K3	42
	18	51	Male	Hispanic	172.0	79.5	16	Trauma	28.2	K4	43
	21	47	Male	Caucasian	174.5	97.1	30	Trauma	22.9	K4	44
	22	33	Male	Caucasian	189.0	107.8	14	Cancer	31.0	K4	46
	24	59	Female	African American	172.5	69.9	35	Infection	26.0	K4	43
	25	26	Female	African American	151.5	53.6	24	Cancer	18.0	K4	45
	26	29	Male	Hispanic	182.0	98.6	3	Trauma	25.5	K4	44
	30	26	Female	Caucasian	180.0	95.2	4	Trauma	28.0	K4	44
Partial data	07	60	Male	African American	177.5	87.9	48	Trauma	24.2	K3	41
	10	72	Male	Caucasian	175.0	129.0	53	Trauma	21.5	K3	38
	11	48	Female	Caucasian	162.5	64.8	38	Cancer	23.0	K4	42
	17	59	Male	African American	171.0	97.1	44	Trauma	29.0	K4	45
	19	62	Male	Caucasian	188.0	100.2	2	Trauma	31.8	K4	44
	28	38	Male	Hispanic	184.0	94.0	4	Trauma	31.5	K3	42
	29	34	Male	Caucasian	188.0	96.3	27	Trauma	27.3	K4	45
Mean (SD)		45.9 (13.7)	Male: 19 Female: 6	Caucasian: 14 African American: 8 Hispanic: 3	177.2 (11.6)	88.6 (19.7)	23.2 (15.8)	Trauma: 15 Cancer: 7 Vascular: 2 Infection: 1	25.4 (4.4)	K3: 7 K4: 18	42.7 (2.6)

SD: standard deviation, MFCL: Medicare Functional Classification Level; AMP-PRO: Amputee Mobility Predictor with Prosthesis.

APPENDIX C SOCKETS AND PROSTHESIS COMPONENTS WORN DURING THE STUDY

Subject No	Allocation	Ischial Containment (IC) Socket				NU-FlexSIV Socket†			Components (same for both sockets)		End of Study Preference
		Check Socket	Socket Construction	Liner	Suspension	Check Socket	Socket Construction	Liner	Knee	Foot	
Completed all data collection sessions											
01	IC	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 3C Cushion	OttoBock[c] C-leg 3	Össur Vari-Flex Unity	NU-FlexSIV
02	NU-FlexSIV	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 3C Cushion	OttoBock C-leg 3	Össur Vari-Flex Unity	None
03	IC	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 3C Cushion	OttoBock 3R60^	Össur Vari-Flex Unity	NU-FlexSIV
04	NU-FlexSIV	2	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 3C Cushion	Össur Rheo	Össur Reflex Rotate Unity	NU-FlexSIV
05	IC	1	Flexible inner socket with external frame	Custom seal-in and 3S pin	Coyote air lock and RV slide	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 3C Cushion	OttoBock C-leg 3	Össur Vari-Flex Unity	NU-FlexSIV
06	IC	1	Flexible inner socket with external frame	Össur 3S pin	Coyote air lock	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 3C Cushion	Freedom[d] Plie	Össur Vari-Flex Unity	NU-FlexSIV

Subject No	Allocation	Ischial Containment (IC) Socket				NU-FlexSIV Socket†			Components (same for both sockets)		End of Study Preference
		Check Socket	Socket Construction	Liner	Suspension	Check Socket	Socket Construction	Liner	Knee	Foot	
08*	IC	1	Flexible inner socket with external frame	Össur Seal-in	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 3C Cushion to Össur Seal-in X§	Össur Rheo	Össur Vari-Flex Unity	NU-FlexSIV
09	NU-FlexSIV	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 3C Cushion	Össur Total Knee	Össur Vari-Flex Unity	NU-FlexSIV
14	NU-FlexSIV	1	Flexible inner socket with external frame	Össur Seal-in X5	Passive suction	1	Flex EVA inner socket, decorative lamination	Össur 3C Cushion	OttoBock 3R60	Össur Vari-Flex Unity	NU-FlexSIV
15	NU-FlexSIV	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 3C Cushion	OttoBock Genium	Össur Vari-Flex Unity	NU-FlexSIV
16	IC	1	Flexible inner socket with external frame	Össur custom silicone locking	Passive suction, pin lock and TES belt	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur Seal-in X to Össur Seal-in§	OttoBock Genium	Össur Vari-Flex Unity	NU-FlexSIV
18	IC	1	Flexible inner socket with external frame	Össur silicone locking	Passive suction and pin lock	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 4 Seal	Össur Mauch	Össur Vari-Flex Unity	NU-FlexSIV
21	IC	2	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, basalt composite laminated outer socket	Össur 4 Seal	OttoBock Genium	Össur Vari-Flex LP Unity	IC

Subject No	Allocation	Ischial Containment (IC) Socket				NU-FlexSIV Socket†			Components (same for both sockets)		End of Study Preference
		Check Socket	Socket Construction	Liner	Suspension	Check Socket	Socket Construction	Liner	Knee	Foot	
22	NU-FlexSIV	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, basalt composite laminated outer socket	Össur 4 Seal	OttoBock C-leg 4	Össur Proflex LP Unity	NU-FlexSIV
24	NU-FlexSIV	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, basalt composite laminated outer socket	Össur 4 Seal	OttoBock 3R49	Össur Proflex LP Unity	NU-FlexSIV
25	NU-FlexSIV	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 4 Seal	OttoBock Genium	Össur Proflex LP Unity	NU-FlexSIV
26	IC	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 4 Seal	OttoBock X3	Össur Proflex LP Unity	NU-FlexSIV
30	NU-FlexSIV	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur X-TF	OttoBock C-leg 4	Össur Proflex LP Unity	IC (NU-FlexSIV for cycling)
Partial data											
07	IC	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 3C Cushion	Össur Mauch	Össur Vari-Flex Unity	IC

Subject No	Allocation	Ischial Containment (IC) Socket				NU-FlexSIV Socket†			Components (same for both sockets)		End of Study Preference
		Check Socket	Socket Construction	Liner	Suspension	Check Socket	Socket Construction	Liner	Knee	Foot	
10	IC	1	Flexible inner socket with external frame	Össur Seal-in	Dual vacuum and suction expulsion valve	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur Seal-in X	OttoBock C-leg 3	Össur K2 Sensation Unity	IC
11[#]	NU-FlexSIV	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 4 Seal to Össur Seal-in X[§]	OttoBock C-leg 4	Ossur Proflex LP Unity	NU-FlexSIV
17	IC	1	Rigid laminated socket	Skin-fit	Passive suction	1	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 3C Cushion to Össur Seal-in[§]	Össur Mauch	Össur Vari-Flex Unity	IC
19[#]	IC	1	Flexible inner socket with external frame	Össur Seal-in X5	Passive suction	1	Flex EVA inner socket; decorative lamination	Össur 4 Seal	OttoBock C-leg 4	Össur Vari-Flex Unity	IC
28	NU-FlexSIV	1	Flexible inner socket with external frame	Skin-fit	Passive suction	1	Flex EVA inner socket, basalt composite laminated outer socket	Össur X-TF	OttoBock 3R80	Össur Proflex LP Unity	NU-FlexSIV
29	IC	1	Flexible inner socket with external frame	Skin-fit	Passive suction	2	Flex EVA inner socket, carbon fiber laminated outer socket	Össur 4 Seal	Össur Mauch	Össur Proflex LP Unity	NU-FlexSIV

*IC socket was remade for this subject after 3 weeks of wear. †All NU-FlexSIV Sockets used vacuum-assisted suspension. [#]Definitive NU-FlexSIV Socket was remade by central fabrication due to shrinkage that occurred during the fabrication process. [§]Cast with first liner and then changed due to issues (e.g. skin irritation, discomfort, etc.) ^Subject wore 3R60 during study which was a loaner replacement for her usual 3R95 as it was in poor condition.

APPENDIX D DETAILS OF PRE-STUDY PROSTHESIS

Subject No.	Socket Design	Liner	Socket Construction	Suspension	Knee	Pylon	Foot	Socket Comfort Score
Completed all data collection sessions								
01	IC	None: Skin-fit	Flexible inner/ Carbon frame	Passive Suction	OttoBock C-leg 3	OttoBock Torsion	Blacthford Elan	4
02	IC	None: Skin-fit	Flexible inner/ Carbon frame	Passive Suction	OttoBock C-leg 3	Standard	OttoBock Triton	4
03	NSNA	None: Skin-fit	Flexible inner/ Carbon frame	Passive Suction	OttoBock 3R95	Standard	Össur Axia	NR
04	IC	None: Skin-fit	Flexible inner/ Carbon frame	Passive Suction	Össur Rheo	Standard	Össur Reflex Rotate	5
05	Narrow ML	TPE: Locking	Flexible inner/ Carbon frame	Locking	OttoBock C-leg 3	OttoBock Torsion	OttoBock Triton	NR
06	IC	Silicone: Locking	Flexible inner/ Carbon frame	Locking	Freedom Plie	Standard	Freedom Agilix	NR
08	NSNA	Silicone: Seal-in	Flexible inner/ Carbon frame	Passive Suction	Össur Rheo	Standard	College Park Trustep	6
09	IC	Silicone: Seal-in	Flexible inner/ Carbon frame	Passive Suction	Össur Total Knee	Standard	College Park Accent	7
14	IC	Silicone: Seal-in	Flexible inner/ Carbon frame	Passive Suction	OttoBock 3R60	Standard	OttoBock SACH	4
15	IC	None: Skin-fit	Flexible inner/ Carbon frame	Passive Suction	OttoBock Genium	OttoBock Torsion	OttoBock Trias	5
16	IC	Custom Silicone: Seal-in and Locking	Flexible inner/ Carbon frame	Passive Suction and Locking	OttoBock Genium	OttoBock Torsion	OttoBock Triton	6
18	IC	Custom TPE: Locking	Flexible inner/ Carbon frame	Lanyard	Össur Mauch	Standard	Össur LP Variflex	9
21	IC	None: Skin-fit	Flexible inner/ Carbon frame	Passive Suction	OttoBock Genium	OttoBock Torsion	OttoBock C Walk (1C40)	8
22	IC	Silicone: Seal-in	Flexible inner/ Carbon frame	Passive Suction	OttoBock C-leg 4	Standard	OttoBock Triton	9

Subject No.	Socket Design	Liner	Socket Construction	Suspension	Knee	Pylon	Foot	Socket Comfort Score
24	IC	Silicone: Locking	Flexible inner/ Carbon frame	Locking	OttoBock 3R49	Standard	Blatchford Multiflex Standard foot with Ankle	9
25	IC-NPS	Silicone: Cushion with sleeve	Double Walled Socket	Passive Suction	OttoBock Genium	Standard	OttoBock TaiLor Made	5
26	IC	None: Skin-fit	Flexible inner/ Carbon frame	Passive Suction	OttoBock X3	Standard	OttoBock Triton	9
30	Modified MAS	Silicone: seal in	Flexible inner/ Carbon frame	Passive Suction	OttoBock C-leg 4	Standard-Modified for Cheetah	Össur Cheetah	8
Partial data								
07	NSNA	None: Skin-fit	Hard Socket	Passive Suction	Össur Mauch	Standard	Össur Reflex Rotate	7
10	IC	Silicone: Seal-in	Hard Socket	Passive Suction	OttoBock C-leg 3	OttoBock Torsion	Össur K2 Sensation Unity	4
11	IC	None: Skin-fit	Flexible inner/ Carbon frame	Passive Suction	OttoBock C-leg 4	OttoBock Torsion	College Park Accent	9
17	IC	None: Skin-fit	Hard Socket	Passive Suction	Össur Mauch	Exoskeletal	OttoBock Greissinger	10
19	IC	Silicone: Seal-in	Flexible inner/ Carbon frame	Passive Suction	OttoBock C-leg 4	Standard	OttoBock Triton Harmony	3
28	IC	Silicone: Seal in	Flexible inner/ Carbon frame	Passive Suction	OttoBock 3R80	Standard	OttoBock Triton Shock	3
29	IC	None: Skin-fit	Flexible inner/ Carbon frame	Passive Suction	Össur Mauch	Standard	MAKstride UltraStride	8

NR = not reported; IC = Ischial Containment; ML = mediolateral; NSNA = Normal Shape Normal Alignment; NPS = negative pressure socket; MAS = Marlo Anatomical Socket; TPE= Thermoplastic Elastomer

APPENDIX E RESULTS OF PAIRED T-TESTS FOR H1-3

Outcome Measure	Week	Ischial Containment Socket		NU-FlexSIV Socket		Difference between Sockets		95% Confidence Interval at 7 weeks	p-value
		n	mean (SD)	n	mean (SD)	n	mean (SD)*		
Socket Comfort Score	1	24	6.6 (2.1)	21	7.6 (1.8)	20	1.1 (2.2)		
	4	23	6.4 (2.6)	22	7.9 (1.6)	20	1.8 (2.9)		
	7	23	7.0 (1.7)	21	8.4 (1.1)	19	1.5 (1.5)	0.8 to 2.3	**<0.001**
5 times Rapid Sit-to-Stand (sec)	1	18	13.7 (4.5)	18	14.3 (6.5)	16	0.3 (4.7)		
	4	19	13.6 (4.5)	19	13.1 (4.3)	16	-0.8 (2.6)		
	7	20	14.5 (8.3)	19	12.9 (4.3)	17	-2.1 (6.3)	-5.4 to 1.1	0.18
Four Square Step Test (sec)	1	22	10.2 (2.4)	21	11.2 (4.0)	19	0.8 (2.7)		
	4	22	10.5 (2.5)	21	10.2 (2.6)	19	0.0 (1.5)		
	7	23	9.7 (2.2)	21	9.8 (2.1)	19	0.2 (1.3)	-0.4 to 0.9	0.47
T-Test of Agility (sec)	1	22	45.1 (15.2)	21	47.5 (13.5)	19	2.4 (6.7)		
	4	22	44.3 (13.2)	21	45.3 (12.6)	19	1.8 (4.5)		
	7	22	41.1 (12.1)	21	42.7 (14.4)	19	0.3 (3.5)	-1.4 to 2.0	0.68
OPUS Lower Extremity Functional Status (raw total score)	1	24	55.2 (11.1)	21	56.2 (11.2)	20	2.5 (6.1)		
	4	23	55.0 (13.9)	22	58.2 (11.1)	20	4.2 (11.0)		
	7	23	55.9 (13.6)	21	57.9 (10.7)	19	2.7 (8.9)	-1.6 to 7.0	0.20
OPUS Quality-of-Life (raw total score)	1	24	69.7 (13.8)	21	68.7 (15.2)	20	2.6 (8.7)		
	4	23	70.7 (15.4)	22	69.4 (15.2)	20	1.2 (12.2)		
	7	23	72.5 (15.9)	21	70.0 (16.7)	19	-1.2 (10.0)	-6.0 to 3.7	0.62
OPUS Satisfaction with Device (raw total Score)	1	24	31.5 (7.1)	21	34.8 (6.4)	20	4.0 (7.3)		
	4	23	32.0 (7.5)	22	34.1 (6.4)	20	3.0 (6.3)		
	7	23	32.9 (7.1)	21	35.2 (6.3)	19	2.6 (5.7)	-0.2 to 5.3	0.07

Bold p-value indicates that the mean difference was significant at $p<0.05$.
*Difference = NU-FlexSIV minus Ischial Containment Socket.
SD: standard deviation

APPENDIX F RESULTS OF LINEAR MIXED MODELS FOR H1-3

Outcome Measure	Estimate	Std Error	df	t-value	p-value
Socket Comfort Score	1.68	0.45	37	3.77	**<0.01**
Five times Rapid Sit-to-Stand	-2.22	1.34	18	-.66	0.11
Four Square Step Test	0.03	0.29	20	0.11	0.92
T-Test of Agility	0.43	0.79	26	0.54	0.59
OPUS Lower Extremity Functional Status	2.46	2.27	19	1.08	0.29
OPUS Quality-of-Life	-0.97	2.53	17	-0.38	0.71
OPUS Satisfaction with Device	2.75	1.21	21	2.28	**0.03**

Bold p-value indicates that the mean difference was significant at $p<0.05$.
Positive estimates indicate higher scores for the NU Flex-SIV Socket.
Std Error = Standard Error; df = degrees of freedom.

APPENDIX G RESULTS OF PAIRED T-TESTS FOR H4 AND H5

Gait Variable	Self-selected speed	Sample Size	Mean Difference between Sockets (standard deviation)*	95% Confidence Interval at 7 weeks	t-statistic	p-value	Cohen's d
Hypothesis 4 (α=0.017)							
Mean Prosthetic Side Sagittal Plane Hip Range of Motion (°)	Normal	19	-1.04 (2.87)	-2.42 to 0.34	t(18)=-1.580	0.132	-0.362
	Slow	18	-1.64 (2.95)	-3.11 to -0.18	t(17)=-2.364	0.030	-0.557
	Fast	18	-2.32 (3.69)	-4.16 to -0.49	t(17)=-2.669	**0.016**	-0.629
Mean Prosthetic Limb Step Length (cm)	Normal	19	-1.70 (3.05)	-3.17 to -0.23	t(18)=-2.428	0.026	-0.557
	Slow	18	-1.26 (5.03)	-3.76 to 1.25	t(17)=-1.060	0.304	-0.250
	Fast	18	-0.97 (3.29)	-2.60 to 0.67	t(17)=-1.248	0.229	-0.294
Mean Walking Speed (m/s)	Normal	19	-0.01 (0.1)	-0.06 to 0.04	t(18)=-0.441	0.664	-0.101
	Slow	18	0.11 (1.31)	-0.07 to 0.05	t(17)=-0.383	0.383	-0.090
	Fast	18	0.32 (1.25)	-0.06 to 0.04	t(17)=-0.536	0.536	-0.126
Secondary analysis (α=0.05)							
Mean Maximum Prosthetic Side Hip Extension (°)	Fast	18	-0.09 (4.75)	-2.45 to 2.28	t(17)=-0.077	0.939	-0.018
Mean Maximum Prosthetic Side Hip Flexion (°)	Fast	18	-2.35 (5.30)	-4.99 to 0.28	t(17)=-1.882	0.077	-0.444
Hypothesis 5 (α=0.025)							
Mean Maximum Lateral Trunk Lean over the Prosthetic Limb in Stance (°)	Normal	19	0.12 (1.35)	-0.53 to 0.77	t(18)=0.392	0.700	-0.090
	Slow	18	0.11 (1.31)	-0.54 to 0.76	t(17)=0.350	0.731	-0.082
	Fast	18	0.32 (1.25)	-0.31 to 0.94	t(17)=1.068	0.300	-0.252
Mean Step Width (cm)	Normal	19	-0.19 (3.02)	-1.64 to 1.26	t(18)=-0.274	0.787	-0.362
	Slow**	18	-0.24 (2.53)	-1.02 to 1.40	t(17)=0.396	0.697	-0.557
	Fast	18	0.15 (2.91)	-1.30 to 1.59	t(17)=0.218	0.830	-0.629

*Ischial Containment Socket minus NU-FlexSIV Socket.

**For mean step width at slow self-selected walking speed, subject 26 was an outlier but retained in the dataset for analysis with paired t-tests. Given the non-normal residual distribution for this variable, a Wilcoxon signed rank test was also conducted but it too was not significant (Z = -1.154, p = 0.248).

Bold indicates significant value.

APPENDIX H MAIN EFFECTS OF LINEAR MIXED MODELS FOR H4 AND H5

Table 1 Normal Self-Selected Walking Speed (n=25)

Gait Variable	Main effect	Numerator df	Denominator df	F-value	p-value
Hypothesis 4 (α=0.017)					
Mean Prosthetic Side Sagittal Plane Hip Range of Motion (°)	Socket	1	128	6.394	**0.013**
	Time	2	128	0.342	0.711
	Socket*Time	2	128	1.149	0.246
Mean Prosthetic Limb Step Length (cm)	Socket	1	128	0.824	0.366
	Time	2	128	0.082	0.921
	Socket*Time	2	128	0.092	0.912
Mean Walking Speed (m/s)	Socket	1	128	0.063	0.802
	Time	2	128	0.123	0.884
	Socket*Time	2	128	0.029	0.972
Secondary analysis (α=0.05)					
Mean Maximum Prosthetic Side Hip Extension (°)	Socket	1	128	0.514	0.475
	Time	2	128	0.035	0.966
	Socket*Time	2	128	0.644	0.527
Mean Maximum Prosthetic Side Hip Flexion (°)	Socket	1	128	1.403	0.238
	Time	2	128	0.084	0.920
	Socket*Time	2	128	0.003	0.997
Hypothesis 5 (α=0.025)					
Mean Maximum Lateral Trunk Lean over the Prosthetic Limb in Stance (°)	Socket	1	128	0.155	0.695
	Time	2	128	0.021	0.979
	Socket*Time	2	128	0.127	0.881
Mean Step Width (cm)	Socket	1	128	1.285	0.259
	Time	2	128	0.017	0.983
	Socket*Time	2	128	0.705	0.496

df: degrees of freedom; bold indicates significant value.

Table 2 Slow self-selected walking speed (n=24)

Gait Variable	Main effect	Numerator df	Denominator df	F-value	p-value
Hypothesis 4 (α=0.017)					
Mean Prosthetic Side Sagittal Plane Hip Range of Motion (°)	Socket	1	121	**12.844**	**<0.001**
	Time	2	121	0.061	0.940
	Socket*Time	2	121	1.649	0.197
Mean Prosthetic Limb Step Length (cm)	Socket	1	121	3.068	0.082
	Time	2	121	0.085	0.919
	Socket*Time	2	121	0.172	0.842
Mean Walking Speed (m/s)	Socket	1	121	3.032	0.084
	Time	2	121	0.023	0.977
	Socket*Time	2	121	0.479	0.620
Secondary analysis (α=0.05)					
Mean Maximum Prosthetic Side Hip Extension (°)	Socket	1	121	0.545	0.462
	Time	2	121	0.010	0.990
	Socket*Time	2	121	0.842	0.433
Mean Maximum Prosthetic Side Hip Flexion (°)	Socket	1	121	2.637	0.107
	Time	2	121	0.019	0.981
	Socket*Time	2	121	0.069	0.933
Hypothesis 5 (α=0.025)					
Mean Maximum Lateral Trunk Lean over the Prosthetic Limb in Stance (°)	Socket	1	121	0.129	0.721
	Time	2	121	0.009	0.991
	Socket*Time	2	121	0.113	0.893
Mean Step Width (cm)	Socket	1	121	2.465	0.119
	Time	2	121	0.053	0.948
	Socket*Time	2	121	0.547	0.580

df: degrees of freedom; Bold indicates significant value.

Table 3 Fast self-selected walking speed (n=23)

Gait Variable	Main effect	Numerator df	Denominator df	F-value	p-value
Hypothesis 4 (α=0.017)					
Mean Prosthetic Side Sagittal Plane Hip Range of Motion (°)	Socket	1	117	**17.794**	**<0.001**
	Time	2	117	0.017	0.983
	Socket*Time	2	117	1.739	0.180
Mean Prosthetic Limb Step Length (cm)	Socket	1	117	0.180	0.672
	Time	2	117	0.017	0.983
	Socket*Time	2	117	0.303	0.739
Mean Walking Speed (m/s)	Socket	1	117	1.395	0.240
	Time	2	117	0.053	0.948
	Socket*Time	2	117	0.060	0.941
Secondary analysis (α=0.05)					
Mean Maximum Prosthetic Side Hip Extension (°)	Socket	1	117	0.137	0.712
	Time	2	117	0.018	0.982
	Socket*Time	2	117	1.303	0.276
Mean Maximum Prosthetic Side Hip Flexion (°)	Socket	1	117	**7.792**	**0.006**
	Time	2	117	0.020	0.981
	Socket*Time	2	117	0.044	0.957
Hypothesis 5 (α=0.025)					
Mean Maximum Lateral Trunk Lean over the Prosthetic Limb in Stance (°)	Socket	1	117	0.189	0.665
	Time	2	117	0.007	0.993
	Socket*Time	2	117	0.413	0.662
Mean Step Width (cm)	Socket	1	117	0.689	0.196
	Time	2	117	0.113	0.893
	Socket*Time	2	117	0.813	0.446

df: degrees of freedom, Bold indicates significant value.

APPENDIX I ADVERSE EVENTS

Subject No.	Allocation	Status	Adverse Events/Reason for Withdrawal
1	IC	completed study	Fell during testing in IC Socket week 1; Pain/discomfort on medial distal end of residual limb in IC Socket
2	NU-FlexSIV	completed study	Loss of suction in NU-FlexSIV Socket due to volume loss; Medial chafing in IC Socket
3	IC	completed study	Foot came loose in IC Socket
4	NU-FlexSIV	completed study	Residual limb blisters, itching and skin breakdown in NU-FlexSIV Socket; Residual limb abrasion in IC Socket
5	IC	completed study	Residual limb sores and irritation in IC Socket; Low back pain and skin irritation in NU-FlexSIV Socket
6	IC	completed study	Distal end residual limb discoloration in NU-FlexSIV Socket resolved with increase in liner size
7	IC	withdrew; IC socket data only	Skin reaction to silicone liner in NU-FlexSIV Socket
8	IC	completed study	Residual limb blisters in IC Socket led to socket remake with seal-in liner; blisters and volume loss with IC Socket and seal-in liner; Feeling unstable and hamstring issue on contralateral limb in NU-FlexSIV Socket
9	NU-FlexSIV	completed study	Muscle soreness in NU-FlexSIV Socket; Feeling fatigued, residual limb sores posteriorly, medial brim is bothersome in IC Socket
10	IC	withdrew; IC socket data only	Socket uncomfortable, needs cane to walk with IC Socket; Could not be stabilized in NU-FlexSIV Socket led to withdrawal
11	NU-FlexSIV	partial IC socket data	Residual limb skin irritation in NU-FlexSIV Socket; Low back pain in IC Socket led to withdrawal
12	IC	withdrew; no data	Femur too short for NU-FlexSIV Socket
13	NU-FlexSIV	withdrew; no data	Did not want to wear liner with NU-FlexSIV Socket
14	NU-FlexSIV	completed study	Fell during testing in IC Socket week 1

Subject No.	Allocation	Status	Adverse Events/Reason for Withdrawal
15	NU-FlexSIV	completed study	Residual limb blistering and muscle soreness/fatigue in NU-FlexSIV Socket
16	IC	completed study	Residual limb sore on distal end, sore spot on ischial tuberosity and muscle cramping in IC Socket; Distal end discomfort in NU-FlexSIV Socket
17	IC	withdrew; IC socket data only	Did not want to wear liner with NU-FlexSIV Socket; Hip soreness with IC Socket
18	IC	completed study	Rubbing in groin in IC Socket; Large delay during cross-over period due to unrelated illness
19	IC	partial IC socket data	Sciatica-type pain on contralateral limb, low back pain in IC Socket
20	NU-FlexSIV	withdrew; no data	Did not want to accommodate to NU-FlexSIV Socket
21	IC	completed study	Foot came loose and residual limb itching in NU-FlexSIV Socket
22	NU-FlexSIV	completed study	
23	NU-FlexSIV	withdrew; no data	Skin reaction to silicone liner in NU-FlexSIV Socket led to withdrawal
24	NU-FlexSIV	completed study	
25	NU-FlexSIV	completed study	
26	IC	completed study	
27	NU-FlexSIV	withdrew; no data	Large residual limb volume changes in NU-FlexSIV Socket led to withdrawal
28	NU-FlexSIV	partial IC socket data	Distal residual limb bruising and loss of suspension in NU-FlexSIV Socket
29	IC	partial SI socket data	Fell during testing in NU-FlexSIV Socket week 4; Residual limb sore medial proximal in NU-FlexSIV Socket
30	NU-FlexSIV	completed study	Residual limb blistering in NU-FlexSIV Socket

IC = Ischial Containment Socket; NU-FlexSIV = Northwestern University Flexible Sub-Ischial Vacuum Socket

1.2.5.d
Evaluation of Socket Comfort and Functional Performance for Persons with Transfemoral Amputation: Interim Analysis

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BACKGROUND
Ischial containment (IC) sockets for transfemoral amputees (TFA) fit intimately with the ischium, limiting hip motion and contributing to socket discomfort.[1,2] Sub-ischial sockets, such as the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket,[3] do not interact with the ischium, potentially increasing comfort. While case studies demonstrate that the NU-FlexSIV Socket potentially improves comfort with comparable functional outcomes to the IC socket,[4,5] further evaluation is needed.

AIM
The purpose of this prospective, assessor-blinded randomized cross-over clinical trial was primarily to compare comfort, and secondarily functional performance, with the NU-FlexSIV and IC sockets in persons with unilateral TFA.

METHOD
Interim analysis was conducted on the first 20 subjects of a trial that aims to recruit 30 subjects with unilateral TFA who wear IC sockets. For the trial, new sockets were fabricated with prosthetic components standardized within subjects. Patient-reported and performance-based measures collected for each socket included: Socket Comfort Score; Orthotic and Prosthetic User's Survey (OPUS); 5-time Rapid Sit-to-Stand Test (RSTS); Four-Square-Step Test (FSST); and T-Test of Agility. Participants used each socket for 7 weeks with differences in outcomes assessed using published Minimal Detectable Change (MDC) values. As the primary outcome, socket comfort was assessed using the Wilcoxon Sign Rank Test with significance set at 0.05.

RESULTS
Seven subjects withdrew at different stages of participation, leaving 12 subjects with complete data, 5 with partial data, and 3 without data. Subjects with data comprised 14 males/3 females with a mean age of 50.1±12.6, mean years post-amputation of 27.3±17.3, mean height of 177.1±11.7cm and mean weight of 89.4±21.0kg, all with K3 and K4 mobility level. Amputation etiology included 10 trauma, 5 cancer and 2 vascular. There was a statistically significant difference between sockets in terms of comfort at 7 weeks, although only one subject's change in comfort exceeded the published MDC.[6] There were no consistent differences in the other outcome measures between sockets that exceeded published MDCs.

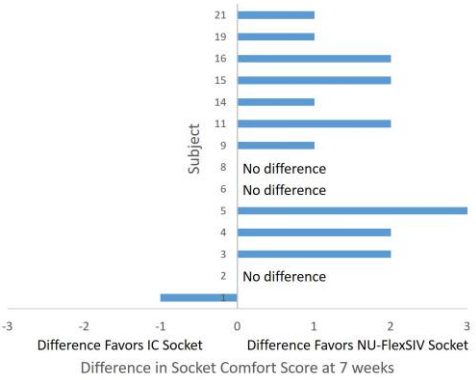

Figure 1. Difference in Socket Comfort at 7 Weeks (except subjects 11 and 19 who were compared at baseline and 3 weeks, respectively).

DISCUSSION AND CONCLUSION
Two subjects (11 and 19) did not complete IC socket testing beyond baseline and 3 weeks, respectively, due to back pain, so data were compared at these times. Eleven subjects chose to continue using the NU-FlexSIV Socket upon study completion. Interim analysis suggests comfort may be better in the NU-FlexSIV Socket with comparable function based on the assessed outcomes. These results are supported by the high proportion of subjects choosing to continue wear of the NU-FlexSIV Socket upon study completion.

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ACKNOWLEDGEMENTS
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Evaluation of the NU-FlexSIV Socket for Persons with Transfemoral Amputation: Interim Results

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INTRODUCTION

Current standard-of-care ischial containment (IC) sockets for transfemoral amputees (TFA) fit intimately with the ischium (Schuch and Pritham, 1999), limiting hip motion (Hagberg et al., 2005) and contributing to socket discomfort (Dillingham et al., 2001; Pezzin et al., 2004). Sub-ischial sockets, such as the newly described Northwestern University Flexible Sub-lschial Vacuum (NU-FlexSIV) Socket technique (Fatone and Caldwell, 2017a), do not interact with the ischium, potentially increasing hip motion and comfort. While two published cases demonstrate that the NU-FlexSIV Socket has the potential to improve comfort with comparable functional outcomes compared to the IC socket (Fatone and Caldwell, 2017b), further evaluation is needed. Hence, the purpose of this clinical trial was to compare comfort and functional performance with the NU-FlexSIV and IC sockets in persons with unilateral TFA.

METHOD

This study is a prospective assessor-blinded randomized crossover trial.

Subjects: The goal is to recruit 30 subjects with unilateral TFA. Interim analysis was on the first ten subjects (8 males/2 females; 49.5±15.4 years; 177.4±14.1 cm; 87.9±25.8 kg). Amputation etiology included five trauma, four cancer and one vascular with high mobility level (six K4 and four K3). All subjects wore IC sockets prior to the study.

Apparatus: A mix of patient-reported and performance-based measures were collected for each socket: Socket Comfort Score (SCS , 0–10 scale); Orthotic and Prosthetic User's Survey (OPUS); Lower Extremity Functional Status (LEFS); Health Related Quality of Life (HRQoL) and Satisfaction with Device (SwD) modules (0–100 Rasch Measure); 30 gait analysis; 5-time Rapid Sit-to-Stand Test (RSTS); Four-Square-Step Test (FSST); and T-test of Agility.

Procedures: Participants were randomized to using one of the sockets for six weeks before crossing over to using the other socket for six weeks, with final data collection performed at six weeks for each socket. Prosthetic components distal to the socket were standardized within subjects.

Interim Data Analysis: Differences in each outcome measure at six weeks were assessed with reference to the minimal detectable change (MDC) where possible.

RESULTS

One subject withdrew due to skin reaction to the silicone liner worn with the NU-FlexSIV Socket, and two subjects are still being tested. For the remaining seven subjects, differences between sockets in outcomes at six weeks are shown in Table 1. Differences did not consistently exceed the MDC for hip range of motion (ROM) (Wilken et al., 2012a), lateral trunk lean (Wilken et al., 2012a), RSTS (Wilken et al., 2012b) or FSST (Wilken et al., 2012b). Differences for the T-test of Agility exceeded the MDC9 for six subjects. Six subjects chose to continue using the NU-FlexSIV Socket upon study completion.

Subject	SCS	OPUS			Timed Test (seconds)		
		LEFS	HRQoL	SwD	RSTS	FSST	T-Test
1	-1	-3	**8**	**4**	1.39	**-0.98**	**-0.31**
2	0	**4**	-4	**13**	**-0.44**	**-0.34**	**-3.3**
3	**2**	0	-4	**6**	**-0.32**	0.48	**-2.41**
4	**2**	**4**	**7**	-4	**-0.27**	**-0.72**	2.24
5	3	3	**6**	**33**	**-3.36**	2.61	1.73
6	0	**12**	**2**	0	**-0.69**	**-1.13**	**-1.07**
9	**1**	**2**	-20	**28**	1.39	0.46	4.57
MDC	-	-	-	-	1.12	1.41	0.91

Subject	Walking Speed (m/s)	Step Width (CM)	Sigittal Hip ROM (degrees)	Lateral Trunk Lean (degrees)
1	**0.17**	**-1.1**	**0.12**	**-0.08**
2	**0.07**	**-1.04**	-1.44	0.42
3	-0.08	2.21	**1.5**	**-0.07**
4	**0.08**	**-2.17**	**0.79**	0.43
5	**0.03**	**-2.92**	**0.88**	**-1.38**
6	**0.03**	**-3.69**	-0.65	0.87
9	-0.08	**-3.18**	**1.46**	1.37
MDC	-	-	3.21	1.1

Table 1. Difference (NU-FlexSIV minus IC) in comfort, OPUS modules and timed performance tests at six weeks (top) and gait variables at six weeks for normal self-selected walking speed (bottom). Bold indicates differences that favored the NU-Fle xSIV Socket. ROM: range of motion. MDC: minimal detectable change.

DISCUSSION AND CONCLUSION

Interim results were mixed across subjects, suggesting no difference between sockets on any of the assessed measures despite almost all subjects choosing to continue wear of the NU-FlexSIV Socket upon study completion.

CLINICAL APPLICATIONS

The availability of a more comfortable socket, with equal or better functional performance, might improve quality of life for persons with TFA.

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ACKNOWLEDGMENT

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Functional Performance Evaluation of the Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket for Persons with Transfemoral Amputation

OR140372
W81XWH-15-1-0708

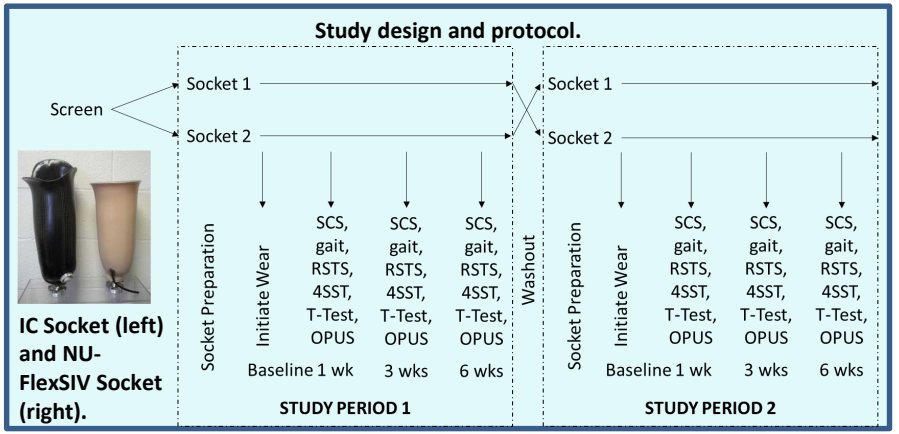
PI: Stefania Fatone **Org:** Northwestern University **Award Amount:** $1,326,755

Study Aims

- **Aim 1:** To demonstrate if the NU-FlexSIV Socket is more comfortable than the Ischial Containment (IC) socket.
- **Aim 2:** To demonstrate if the NU-FlexSIV Socket results in better functional performance than the IC socket.
- **Aim 3:** To demonstrate if the NU-FlexSIV Socket will result in better quality of life and "satisfaction with device" (i.e. prosthesis) than the IC socket.

Approach

The overall objective is to provide a more comfortable and functional prosthetic socket for persons with unilateral transfemoral amputation that will ultimately improve their quality of life. This is an assessor-blinded prospective randomized cross-over trial wherein 30 participants will be randomized to using two socket conditions (i.e., NU-FlexSIV or IC). The end points are socket comfort and functional and patient reported performance measures which will be assessed at 1, 4 and 7 weeks post socket delivery.



Data collection is complete. 30 subjects were enrolled. 25 completed the study: 18 with full data, 7 with partial data.

Timeline and Cost

Activities / CY	16	17	18
Major Task 1 Recruit 10 subjects per year			
Major Task 2 Fabricate sockets			
Major Task 3 Collect data			
Major Task 4 – Process and analyze data			
Estimated Budget ($K)	**$454K**	**$432K**	**$440K**

Updated: 12/8/2020

CY16 Goals
☑ IRB approvals (NU, VA, HRPO), clinical trial registration
☑ Recruit and test 10 subjects

CY17 Goals
☑ Recruit and test 10 subjects

CY18 Goals
☑ Recruit and test 10 subjects
☑ Final analysis and publication

Comments/Challenges/Issues/Concerns
Manuscripts submitted.

Budget Expenditure to Date
Projected Expenditure: $1,326,755
Actual Expenditure: $1,317,107