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Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation: Part 2 Description and Preliminary evaluation

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Abstract

Background: Current transfemoral prosthetic sockets are problematic as they restrict function, lack comfort, and cause residual limb problems. Development of a subischial socket with lower proximal trim lines is an appealing way to address this problem and may contribute to improving quality of life of persons with transfemoral amputation.
Objectives: The purpose of this study was to illustrate the use of a new subischial socket in two subjects.
Study design: Case series.
Methods: Two unilateral transfemoral prosthesis users participated in preliminary socket evaluations comparing functional performance of the new subischial socket to ischial containment sockets. Testing included gait analysis, socket comfort score, and performance-based clinical outcome measures (Rapid-Sit-To-Stand, Four-Square-Step-Test, and Agility T-Test).
Results: For both subjects, comfort was better in the subischial socket, while gait and clinical outcomes were generally comparable between sockets.
Conclusion: While these evaluations are promising regarding the ability to function in this new socket design, more definitive evaluation is needed.

Clinical relevance

Using gait analysis, socket comfort score and performance-based outcome measures, use of the Northwestern University Flexible Subischial Vaccum Socket was evaluated in two transfemoral prosthesis users. Socket comfort improved for both subjects with comparable function compared to ischial containment sockets.

Keywords

Artificial limb, prosthetic socket, gait, transfemoral amputation

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Background

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

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these problems and may contribute to improving quality of life of persons with TF amputation.

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

Dillon[18] argued that the ability of any TF socket to provide coronal plane stability may come from *either* ischial ramal containment or compression of the proximal medial soft tissue to increase stiffness. Preliminary research supports the idea that TF sockets without ischial containment (IC) rely on soft tissue compression for coronal plane stability, socket comfort, and functional gait.[8,19] A recent study using the MAS showed that both ischial ramal containment and tissue loading contribute to socket comfort: with containment tissue loading did not influence socket comfort, but with no containment the socket was comfortable only when tissue loading was high.[19] Kahle and Highsmith[8] reported that gait and balance in a brimless socket were equivalent to an ICS, without any of the gait adaptations typically associated with coronal plane instability.

The development of a more comfortable and possibly functional subischial socket may improve the quality of life of persons with TF amputation. While early reports suggest subischial sockets are feasible, no one has yet illustrated functional performance of a teachable subischial socket technique. A related article describes the design and fabrication of a new subischial socket and describes our efforts to teach this technique.[20] The purpose of this article is to illustrate the use of the Northwestern University Flexible Subischial Vacuum (NU-FlexSIV) Socket in two subjects.

Methods

With approval from the Northwestern University Institutional Review Board, two unilateral TF prosthesis users provided informed consent to participate in preliminary socket evaluation comparing functional performance of the subischial socket and ICS. All data were acquired in our motion analysis laboratory equipped with eight cameras (Motion Analysis Corporation, MAC, Santa Rosa, CA, USA) and six force plates (Advanced Mechanical Technology, Inc., Watertown, MA, USA).

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

Data were collected as each subject ambulated in each socket at self-selected normal, slow, and fast walking speeds over level ground until at least three force-plate strikes were recorded for each foot. EVa RealTime software (MAC) was used to determine the three-dimensional (3D) position of each marker relative to the laboratory coordinate system during each frame of each trial. The raw coordinate data were filtered using a second-order Butterworth bi-directional low-pass filter with an effective cutoff frequency of 6 Hz.[22] Temporospatial data and gait events were calculated using OrthoTrak software (MAC).

Additional standardized clinical outcome measures included the socket comfort score (SCS),[23] Rapid-Sit-To-Stand (RSTS) test,[24,25] Four-Square-Step-Test (FSST),[26] and Agility T-Test.[27,28] For the SCS,[23] subjects were asked, "On a 0–10 scale, if 0 represents the most uncomfortable socket fit you can imagine, and 10 represents the most comfortable socket fit, how would you score the comfort of the socket fit of your prosthesis at the moment?"

The RSTS test provides a standardized measure of active hip range of motion, lower limb muscle strength, and balance.[24] Subjects were asked to rise from a chair without arm rests five times as fast as possible with their arms folded across their chest.[24] Subjects performed two trials, with a 3-min rest period between trials.[25]

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

The Agility T-Test is typically used by athletes and includes forward, sideways, and backward running.[27,28]

Table 1. Subject and prosthesis characteristics and temporospatial data.

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

NU-FlexSIV: Northwestern University Flexible Subischial Vacuum Socket; ICS: ischial containment socket.
[a]Able-bodied US service member's Minimal Detectable Change (MDC): RSTS = 0.27; FSST = 0.30.[29]
[b]US service members with transfemoral amputation: 27.7 ± 6 s (MDC = 3.74).[27,28]

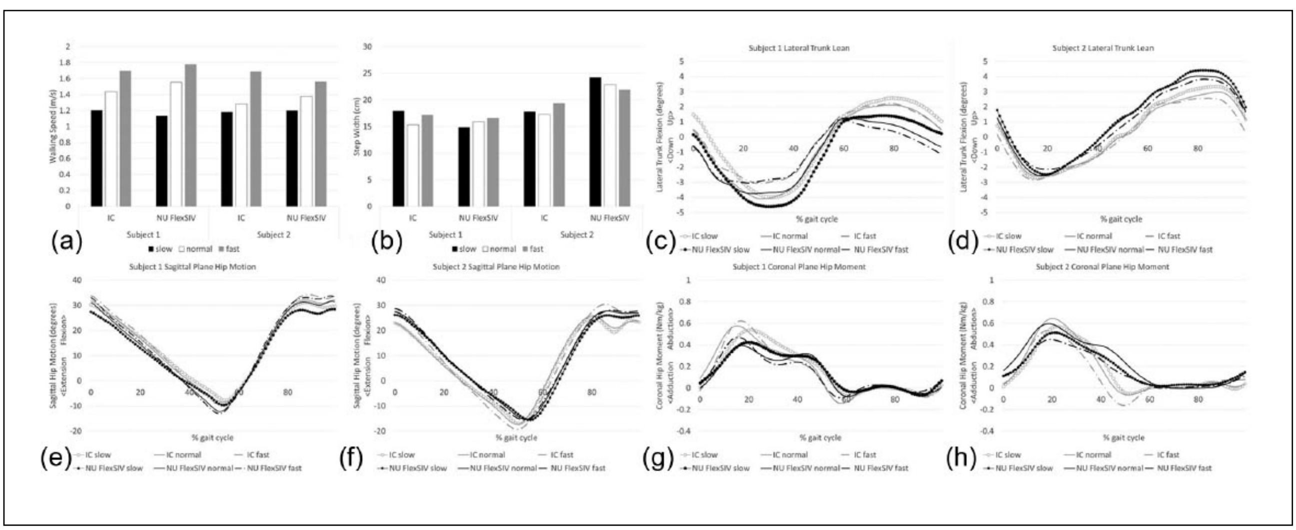

Figure 1. Selected gait data for Subjects 1 and 2 walking at three self-selected speeds (slow, normal, and fast) in an ischial containment and NU-FlexSIV Socket. (a) Walking Speed; (b) Step Width; (c) Subject 1 Lateral Trunk Lean; (d) Subject 2 Lateral Trunk Lean; (e) Subject 1 Sagittal Plane Hip Motion; (f) Subject 2 Sagittal Plane Hip Motion; (g) Subject 1 Coronal Plane Hip Moment; and (h) Subject 2 Coronal Plane Hip Moment.

Four markers were set out on the floor in the shape of a T. The subject started at the base of the T, sprinted forward to the top of the T and touched the marker, shuffled sideways and touched the marker, shuffled sideways in the opposite direction and touched the marker at the other end, shuffled back to touch the middle marker, before running backward to the initial marker. The trial was not counted if the subject crossed one foot in front of the other while shuffling sideways, failed to touch any markers, or failed to face forward throughout the test. The best time of three successful trials was used, with a 3-min rest period between trials.

Results

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

Discussion

To our knowledge, this is the first attempt to create a teachable subischial socket with the potential to be more comfortable without compromising function. Gait and clinical outcomes data suggest improved comfort and comparable function to IC sockets, confirming previous reports.[8,30] NU-FlexSIV Socket coronal plane stability during walking was confirmed by both lack of change in lateral trunk flexion (assessed with gait analysis) and lateral socket gapping at mid-stance (assessed visually). For self-selected normal walking speed, step width was slightly less for Subject 1 and within normal limits for Subject 2 for both sockets when compared to other unilateral TF amputees (20.7 ± 4.4 cm), while self-selected normal walking speed was substantially faster than other unilateral TF amputees (0.96 ± 0.01 m/s) in both sockets.[31] A report of initial evaluation of the NU-FlexSIV Socket with a military TF amputee is similarly promising.[32]

An obvious limitation of this work is the preliminary nature of socket evaluation. Subject 1 was not as accustomed to an ICS as Subject 2 and Subject 2 wore different knees with each socket. Lack of standardization of socket accommodation may have influenced the results. More definitive evaluation in the form of randomized cross-over trials comparing comfort and functional performance with the NU-FlexSIV Socket to the ICS in persons with unilateral TF amputation are needed, and fortunately underway (https://clinicaltrials.gov/ct2/show/NCT02678247).

Conclusion

Overall, this preliminary work describes a subischial socket technique that appears to be more comfortable for users and results in gait that is at least comparable to that of conventional TF sockets with a proximal brim.

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Author contribution

All authors contributed equally in the preparation of this manuscript.

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