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

Ryan Caldwell, CP/L FAAOP, and Stefania Fatone, PhD, BPO(Hons), Northwestern University Prosthetics-Orthotics Center (NUPOC)

Background

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



Purpose of the Project

To develop a more comfortable socket technology for highly active persons with transfemoral amputations (TFA).

- Develop the clinical technique for socket fitting and fabrication
- Perform preliminary performance tests Β.
- Disseminate the technique to prosthetists

Transfemoral Socket Design Comparison

Ischial Containment (Standard of Care)

The most proximal aspect of the socket includes ischial ramal containment and trim lines proximal to the ischial tuberosity



NU-FlexSIV (New Design) Trim lines typically 25mm distal to the ischial tuberosity do not impinge on the pelvis

References: (1) Mak et al. J Rehabil Res Dev. 2001;38(2):161-74. (2) Mak 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-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.



 Suspension Interface

Components

Novel Sub-Ischial Transfemoral Socket





- Lower proximal trim lines
- Flexible socket construction
- Vacuum assisted suspension

A. Clinical technique for NU-FlexSIV fabrication and fitting

Novel to our technique is use of a transtibial silicone liner for a transfemoral limb along with casting the limb in a sitting position





Rectification mapping provides quantification of the magnitude and location of plaster to be removed from the positive residual limb model



Improve comfort and possibly function



Clinical decision making algorithm assists the prosthetists with residual limb evaluation, liner selection, and mold reductions



Fabrication of both flexible check socket and final flexible definitive socket has been described

B. Preliminary performance results on two test subjects

Age		
Sex		
Height (cm)	
Weight (kg)	
Amputatio	n	
Cause of Amputation		
Time since	Amputation	l
Activity Level (
Subject 1		
	Ischial Containment	Sub-isch
Rapid Sit to Stand*	11.81	11.66 (-1.

Four Square 10.6 (+10.2%) 9.52 Step Test* Agility T Test** 26.81 (-0.8%)

No change in coronal plane trunk range of motion and inconsistent changes in hip extension during walking.

C. Dissemination of the technique to prosthetists



Trained 30 Certified Prosthetists from around North America in 2015 through continuing education, hands-on workshops. Additional national and international workshops scheduled for 2016.

The NU-FlexSIV Socket is the first teachable sub-ischial socket technique that results in improved comfort and comparable function to ischial containment sockets.

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Conclusions