Orthotics and Prosthetics

A Prosthetic Socket Technology for Transfemoral Prosthesis Users that Improves Active Range of Motion and Reduces Socket Impingement

Problems with current transfemoral prosthetic sockets include that they restrict function, are uncomfortable, and cause residual limb problems. Lack of socket comfort is the most common complaint of prosthesis users. Development of a sub-ischial socket with lower proximal trim lines may address these problems contributing to improving quality of life (QOL) for transfemoral amputees. Researchers at Northwestern University (Chicago, Illinois) developed and evaluated the use of a new sub-ischial socket, the Northwestern University Flexible Sub-Ischial Vacuum (NU-FlexSIV) Socket. This new socket technique was developed by the research team to provide a more comfortable alternative to current transfemoral sockets. The NU-FlexSIV Socket 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 (*Fatone and Caldwell 2017a, 2017b*; Figure 1). Use of the NU-FlexSIV Socket was evaluated using gait analysis, socket comfort score, and performance-based outcome measures (Rapid-Sit-To-Stand, Four-Square-Step-Test, and Agility T-Test) in two transfemoral prosthesis users. The NU-FlexSIV Socket was compared to ischial containment sockets. For both subjects, comfort was better in the NU-FlexSIV Socket, while gait and clinical outcomes were generally comparable between sockets (*Fatone and Caldwell 2017a*; Figure 2).

FIGURE 1: Demonstrating flexibility of the NU-FlexSIV Socket
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To address complementary challenges, the project also included developing a hybrid vacuum pump and a simple, inexpensive technique for perforating a silicone prosthetic liner to expel sweat (*Caldwell and Fatone 2017, Caldwell et al. 2015, Komolafe et al. 2013, Major, Caldwell, and Fatone 2015a, Major, Caldwell, and Fatone 2015b*; Figure 3). Expulsion of sweat through the perforations was demonstrated by pouring water into the liner, folding the proximal, open end of the liner to create a seal, and forcing water droplets to escape the perforations with some resistance. Additional evidence that water escaped was seen by the wet patches that formed on the

exterior fabric of the perforated liner after active wear. Initial clinical experience suggested that expulsion of sweat occurred and user feedback indicated improved prosthesis use as a result (*Caldwell and Fatone 2017*).

To the best of our knowledge, this is the first teachable sub-ischial socket technique that results in improved comfort and comparable function to ischial containment sockets. The researchers have been awarded follow-on funding to evaluate the functional performance of the NU-FlexSIV Socket in a clinical trial.

The NU-FlexSIV Socket may improve comfort and function in Service members with transfemoral amputations allowing them to return to a more active lifestyle and improve QOL.

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FIGURE 2: Demonstrating range of hip motion with the NU-FlexSIV Socket (Figure used with permission from the authors)

FIGURE 3: A, Interior of liner showing perforations. B, Exterior of fabric covered liner showing wet patches where sweat was absorbed during active wear. These sweat patches appeared after approximately 5 minutes of light jogging indoors in a patient that has reported sweating as a problem. (Figure 2 from Caldwell and Fatone (2017) used with permission from the authors)

REFERENCES:

Caldwell, R., and Fatone, S. 2017. "Technique for Perforating a Prosthetic Liner to Expel Sweat." Journal of Prosthetics and Orthotics 29 (3):145-147. doi: 10.1097/jpo.0000000000000136.

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. 2015. "Vacuum Pump Systems for Prosthetic Limbs and Methods of Using the Same." US. Patent 9,066,822 B2, filed June 21, 2012, and issued June 30, 2015.

Fatone, S., and Caldwell, R. 2017. "Northwestern University Flexible Subischial Vacuum Socket for Persons with Transfemoral Amputation: Part 2 Description and Preliminary Evaluation." Prosthet Orthot Int 41 (3):246-250. doi: 10.1177/0309364616685230.

Fatone, S., and Caldwell, R. 2017. "Northwestern University Flexible Subischial Vacuum Socket for Persons with Transfemoral Amputation-Part 1: Description of Technique." Prosthet Orthot Int 41 (3):237-245. doi: 10.1177/0309364616685229.

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):1069-78. doi: 10.1682/JRRD.2012.11.0204.

Major, M. J., Caldwell, R., and Fatone, S. 2015. "Comparative Effectiveness of Electric Vacuum Pumps for Creating Suspension in Transfemoral Sockets." Journal of Prosthetics and Orthotics 27 (4):149-153. doi: 10.1097/jpo.0000000000000073.

Major, M. J., Caldwell, R., and Fatone, S. 2015. "Evaluation of a Prototype Hybrid Vacuum Pump to Provide Vacuum-Assisted Suspension for Above-Knee Prostheses." J Med Device 9 (4):0445041-445044. doi: 10.1115/1.4030507.