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AeroFit®

Whitepaper

AeroFit®

Liner and socket interfaces require the residual limb to be enclosed with materials that are highly resistive to heat conduction leading to increased sweat. Despite substantial technological advances in prosthetics, current prostheses have not been able to resolve the issue.[1]

Sweat accumulation on the residual limb skin inside the socket is a common problem for amputees and is the leading complaint resulting in reduced quality of life.[2]

Residual limb skin problems in prosthetic users with conventional sockets are highly prevalent. In a study by Meulenbelt et al., 63% of individuals with lower limb amputation reported having one or more skin problems, and thereof, profuse sweating was the most frequently reported skin problem (32%).[3] According to a literature review by Ghoseiri and Safari[1], at least 53% of prosthetic users complain about thermal-related discomfort inside their prosthesis and that number goes as high as 66%, as reported by Berke et al.[4]

Residual-limb skin problems have been shown to affect prosthetic use negatively and the ability to perform activities of daily living (ADLs), such as household tasks and social functioning.[5] Excess perspiration on the residual limb can cause foul odors and has been associated with residual limb skin pathologies such as maceration, dermatitis, fungal infection, ulceration, and verrucous hyperplasia.[10] Poor residual limb skin health has also been associated with reduced walking distance, less time spent in the prosthesis[6] and to negatively affect the suspension between the limb and the socket.[7]

Reviews by Ghoseiri & Safari[1] and Klute et al.[9] discuss that future research should focus on improving the prosthetic solutions with regards to reducing sweat while still maintaining suspension, weight-bearing comfort, and residual limb stability.

The Össur AeroFit system is a transfemoral breathable prosthetic interface, combining the AeroFit Seal-In liner and AeroFit Socket.

The AeroFit Seal-In liner is a transfemoral silicone liner that covers the residual limb and provides an interface between the residual limb and the socket of the prosthesis. The device forms a suspension system that creates a vacuum below the level of the seal that reliably suspends the residual limb in the prosthesis.

The device features a revolutionary 3D silicone structure that allows for the free movement of air and humidity. Both air and humidity can then transit in any direction through the patented silicone structure, and away from the skin.

The AeroFit Socket converts a TF socket into a breathable device by installing vents, while maintaining the Seal-In suspension functionalities. The vents are installed using the AeroFit Toolkit and detailed installation instructions.

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> **Never had a sweat incident in my life with [the test liner] ... It was comfortable because it kept my leg from sweating and getting nasty.**
>
> *- Transfemoral User -*

The AeroFit system has undergone extensive clinical testing with the target user group. Three comprehensive clinical studies have been carried out using AeroFit.

Study 1

Initially, a traditional feasibility study[11] was conducted early in the development process providing invaluable feedback regarding sweat reduction, promoting the continuation of product development.

Study 2

Later, during the final development stages, results from a pivotal confirmatory study[12,13] established the clinical effectiveness of AeroFit in reducing sweat on the residual limb while ensuring socket comfort, suspension, and stability. It also confirmed that the users experienced significantly less sweat on their skin during activities.

Study 3

Outline

The third study[14] employed a randomized controlled, cross-over design involving fifty-six individuals with transfemoral amputation, 13 females and 43 males, recruited from seven prosthetic clinics across six states in the USA. This investigation evaluated users' perceived residual limb skin health, activity, prosthesis use, quality of life, prosthesis slippage (looseness), the need to remove the prosthesis, and incidents of complete loss of suspension between the breathable AeroFit system and conventional non-breathable Seal-In suspension system.

Methodology

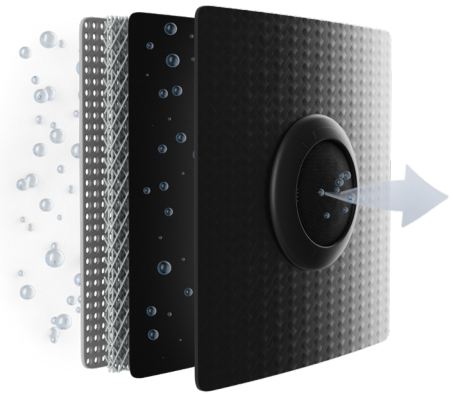
Subjects were randomized into two groups with two treatment conditions each. Group 1 started using the AeroFit system (A), and Group 2 started using the conventional suspension system (B), then they crossed over to the other system two times (ABA/BAB). Each treatment condition lasted 4-6 weeks. This required four visits to the subject's clinic. During each visit the subjects completed questionnaires on their perceived residual limb skin health and other outcomes, and their treatment condition was crossed.

Results

The study results demonstrated statistically significant improvement in perceived residual limb skin health for individuals with transfemoral amputation. Other patient reported outcomes, such as activity and prosthesis use showed comparable results between AeroFit and the conventional liner and socket. The results also indicated a reduced need to remove the liner to dry the limb or liner, as well as incidents of complete loss of suspension.

Conclusion

AeroFit introduces a ventilating feature, improves perceived limb health and retains the advantages of state-of-the-art Seal-In suspension technology, thereby creating a healthier environment around the residual limb.



Clinical Benefits

Reduced sweat within the liner

AeroFit significantly reduces sweat build-up on the skin when compared to using conventional silicone liner and socket.[13]

In study 2 , the aim was to measure relative humidity and temperature at the skin-liner interface while participants walked on a treadmill in a heated room.
The study results confirmed that significantly less sweat accumulates in the liner and no significant temperature changes show when using the breathable AeroFit system compared to a conventional Seal-In suspension system.

Reduced perceived sweat

AeroFit is perceived by users to reduce the sweat on the skin when compared to using conventional silicone liner and socket.[13]

In the aforementioned study, participants were asked about their perceived sweat in the liner after completing their walk in the heated room. Overall, users reported perceiving significantly less sweat when using the AeroFit system compared to the conventional Seal-In suspension system.

Improved perceived residual limb skin health

AeroFit is perceived to improve residual limb skin health when compared to using conventional silicone liner and socket[14].

The results from study 3 demonstrated that AeroFit significantly enhances perceived residual limb skin health, as evidenced by statistically higher PEQ-RLH scores. Skin health measures conducted with a subset of users supported these findings, showing significantly lower transepidermal water loss (TEWL) for the AeroFit system. Lower TEWL indicates improved skin barrier function, thereby reflecting increased skin health.

Improved quality of life with Direct Socket

Quality of life is improved compared to using ischial containment sockets and other traditional sockets designs.[14,15]

The third study also assessed users' quality of life using the widely utilized and validated EQ-5D-5L tool. The results confirmed that the quality of life with the AeroFit system was comparable to that with the Direct Socket. Previous research has demonstrated that the Direct Socket improves quality of life compared to ischial containment and other traditional socket designs[15]. Given the current study's findings, which show comparable performance in terms of quality of life to the Direct Socket, it appears that AeroFit with Direct Socket may offer an improved quality of life over ischial containment sockets and other traditional designs.

Conclusion

Today's liners and sockets often lead to excessive perspiration. Silicone liners offer protection and comfort to sensitive areas of the residual limb in the socket but trap the sweat within, which leads to sweaty, sensitive skin more likely to macerate and blister. Sweating is part of the thermoregulation system of the human body.

The AeroFit system has the advantage, above all other available solutions, of bringing to users both a breathable liner and a ventilated socket. This whole suspension interface maintains the benefits of the state-of-the-art vacuum suspension solutions by providing coupling to the residual limb along with the protection and comfort of the silicone liner. Adding the ventilating feature creates a healthier environment around the residual limb, which has been demonstrated with this investigation results.

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