

User-perceived skin-health benefits of a vented prosthetic suspension system in individuals with transfemoral amputation: a randomized crossover trial

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Article

Keywords: transfemoral amputation, prosthetic liner, prosthetic socket, residual limb skin health, sweat management, passive ventilation

Posted Date: October 14th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-10829338/v1>

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Additional Declarations: Competing interest reported. All authors are employees of Össur, the manufacturer of the investigational devices evaluated in this study. Össur sponsored and funded the study.

Abstract

Individuals with transfemoral amputation (TFA) often experience skin problems and discomfort related to excessive sweating and sweat accumulation at the skin-liner interface of their prosthesis, impacting suspension, mobility, and quality of life. Effective prosthetic solutions for sweat management remain limited despite technological advancements. The AeroFit system (Össur ehf), a novel vented liner and socket system, was designed to promote sweat evaporation and airflow. In a randomized controlled cross-over trial at seven U.S. clinics, 56 TFA participants (mean age 56.3 ± 13 years) were enrolled, with 48 completing alternating 4-6-week periods using both vented AeroFit system and non-vented comparator system. Primary outcome was prosthetic evaluation questionnaire residual limb health subscale (PEQ-RLH); secondary outcomes included activity restriction (TAPES-R), quality of life (EQ-5D-5L), and prosthesis use (Q-TFA). Linear mixed effects models showed the AeroFit system significantly improved perceived skin health versus the non-vented comparator (overall cohort $P = 0.0163$; group with pre-existing self-reported skin issues $P = 0.0145$). Non-inferiority for activity, prosthesis use, and quality of life confirmed ventilation did not compromise function or comfort. The AeroFit system offers clinically meaningful improvement in perceived residual limb skin health for TFAs affected by excessive sweating and related skin problems.

Introduction

In 2019, there were 2,309,000 people living with limb loss in the USA [1]. Approximately 91% of these individuals had undergone lower extremity amputations (LEA), and about 40% of those were at the transfemoral level [2]. Globally, an estimated 57.7 million people were living with traumatic limb amputation in 2017 [3] and the number of amputations is projected to double by 2050 [1]. This highlights the substantial worldwide need for effective prosthetic rehabilitation solutions. For many lower limb prosthetic users (LLP), prosthetic rehabilitation relies on a socket-based prosthesis to connect the residual limb to the prosthesis, providing load transfer, stability, and suspension for mobile prosthesis users. Modern liners act as the skin-socket interface, improving comfort and suspension [4].

Skin problems among lower limb prosthetic users are highly prevalent and have been reported to range from 15% to 41% [5]. Dudek et al. reported that 40.7% of residual limbs experience at least one skin issue a year [6]. Dermatologic conditions, such as ulcers, cysts, and dermatitis, can cause significant discomfort and functional loss, emphasizing the need for careful management and regular monitoring to maintain the well-being of the residual limb. Among residual limb skin problems LLPs complain about, perspiration is particularly common. Meulenbelt et al. found that 63% of LLPs reported at least one skin problem, with excessive perspiration being the most commonly reported problem (32%) [7].

According to a review by Ghoseiri and Safari, more than 53% of LLPs report feeling discomfort due to excessive heat and sweating [8] and in a study by Berke et al. 67 out of 68 individuals with transfemoral amputation were bothered by heat and sweat inside the socket, with 70% of all study participants experiencing this issue [9]. These findings show how common perspiration problems are among LLPs.

Sweat accumulation at the skin-liner interface affects prosthesis use and is widely reported to negatively influence both suspension and residual limb skin health as increased motion in the socket may lead to skin breakdown [10].

Increased movement at the interface between the residual limb and liner, due to perspiration, can contribute to loosening of the prosthesis and even complete suspension loss causing a need for frequent prosthesis removal to dry the sweat of the limb or liner. Increased movement at the interface and irritation from the presence of sweat may also raise the risk of tissue injury such as blisters, rashes, folliculitis, and infection [5][11]. The occlusive environment created by the liner may contribute to accumulation of sweat on the residual limb, increase the likelihood of skin maceration, and poor odor, which can add to user discomfort and residual limb concerns [10]. Maintaining healthy skin and secure suspension is essential for effective use of a lower limb prosthesis [12]. These complications can force amputees to limit their prosthesis use, disrupt rehabilitation, and may negatively impact mobility and participation in daily life [13]. In fact, issues related to sweating have been identified as some of the most prevalent and limiting problems among prosthesis users [14].

Few management options for excessive perspiration at the skin-liner interface are available. Topical hypoallergenic antiperspirants are often the first-line approach as a treatment but can come with side effects. Other treatments are oral anticholinergic medications such as glycopyrrolate and injectable medications with botulinum toxin. Other modalities reported as potential treatments are laser therapy, microwave thermolysis, fractional microneedle radiofrequency, high-intensity ultrasound, and iontophoresis. [15][16]. Although these approaches may help manage excessive sweating, they primarily target the symptom rather than the prosthetic interface environment in which the sweat or moisture accumulates.

Despite remarkable advances in prosthetic technology in recent years, sweat accumulation on the residual limb within prosthetic liner and socket systems remains a widespread and persistent problem for transfemoral lower limb prosthesis users (TFA), frequently cited as the leading complaint impacting their comfort and quality of life [17]. Currently there are only a few single prosthetic components available that specifically target sweat or residual limb moisture management, such as moisture wicking or absorbing socks (not for transfemoral level amputation), phase-change material liners, and perforated liners, while new socket technologies are still in development [15]. This indicates that, despite recognition of excessive sweating as an important clinical and functional problem, dedicated prosthetic solutions for managing the residual limb microclimate are limited.

The body's natural thermoregulatory response to increased metabolic demands is to produce sweat to cool down through evaporation. For LLPs, this process is further challenged by the reduced skin surface area available for heat dissipation, necessitating higher sweat rates from the residual limb. Research has shown that change in residual limb skin temperature during exercise does not explain the thermal discomfort experienced [18]. Instead, user-perceived thermal discomfort has been found to be more strongly associated with sweating [19]. This suggests that the goal of a sweat-managing prosthetic

suspension system should be to create an optimal microclimate around the residual limb to allow for effective evaporation to support cooling and thereby maintain favorable skin temperatures [19]. Focus group consensus by Knight et al. suggests that passively ventilated liner-socket systems may improve residual limb health and comfort, without compromising function or mobility of the user [20].

There remains a need for a prosthetic socket assembly that can effectively regulate the microclimate at the skin-device interface by facilitating airflow, supporting sweat evaporation and thereby reducing the build-up of sweat [14]. A system that facilitates ventilation and evaporation at the residual limb interface may therefore address both the physiological need for heat dissipation and moisture regulation and the clinical need to maintain skin health, suspension and prosthetic function.

The vented liner and socket system (AeroFit) is a novel suspension interface, designed to facilitate airflow and promote sweat evaporation and reduce humidity build-up at the skin liner interface during ambulation. A previous pre-market study demonstrated that AeroFit's ventilating function reduced relative humidity build-up at the skin-liner interface and reduced perceived sweat, while maintaining suspension, stability, and user comfort [21]. These findings were consistent with user perceptions of reduced perceived sweat, suggesting that improvement in microclimate regulation may have a meaningful clinical benefit.

The present clinical investigation was conducted to evaluate the effectiveness and user-reported clinical benefits of the vented AeroFit system compared to conventional non-vented suspension interface. The primary objective was to assess user-perceived residual limb health, with secondary outcomes including activity restriction, prosthesis use, and quality of life. By directly addressing excessive sweating and sweat retention at the residual limb interface, this study aimed to determine whether the AeroFit, vented silicone liner and socket system, can contribute to healthier, more comfortable, and more functional prosthetic use for individuals with transfemoral amputation.

Results

Participants Demographics

Fifty-nine subjects were screened, of whom three did not meet the inclusion criteria. Fifty-six transfemoral amputees were enrolled, including 13 (23%) females and 43 (77%) males.

The average age at enrollment was 56.3 ± 13 years (mean $\pm$ SD), fifteen (27%) were 65 years or older. The highest portion of the participants were amputated due to trauma, or 55%, followed by vascular diseases at 23%, cancer at 4%, infections at 9% and other reasons at 9%, see details on participants demographics in Table 1.

Table 1
Participants Demographics

	Recruited	Analyzed
	(N = 56)	(N = 48)
Gender		
Female	13 (23.2%)	11 (22.9%)
Male	43 (76.8%)	37 (77.1%)
Age at enrollment		
Mean (SD)	56.3 (13.0)	55.8 (12.0)
Median [Min, Max]	57.5 [24.0, 84.0]	56.5 [29.0, 77.0]
Skin issues		
No	17 (30.4%)	14 (29.2%)
Yes	39 (69.6%)	34 (70.8%)
Hyperhidrotic		
No	37 (66.1%)	30 (62.5%)
Yes	19 (33.9%)	18 (37.5%)
Reason for Amputation		
Cancer	2 (3.6%)	2 (4.2%)
Infection	5 (8.9%)	5 (10.4%)
Other	5 (8.9%)	0 (0%)
Trauma	31 (55.4%)	29 (60.4%)
Vascular disease	13 (23.2%)	12 (25.0%)
Height (cm)		
Mean (SD)	175 (8.75)	175 (8.76)
Median [Min, Max]	178 [152, 188]	178 [152, 188]
Weight (Kg)		
Mean (SD)	88.0 (14.7)	88.7 (13.5)
Median [Min, Max]	87.5 [52.0, 122]	87.5 [64.0, 122]
Amputation Side		

	Recruited	Analyzed
	(N = 56)	(N = 48)
Gender		
Left	32 (57.1%)	27 (56.3%)
Right	24 (42.9%)	21 (43.8%)
Years Since Amputation		
Mean (SD)	8.42 (9.31)	8.53 (9.66)
Median [Min, Max]	6.00 [1.00, 44.0]	5.50 [1.00, 44.0]
Assistive Devices		
No assistive device	33 (58.9%)	27 (56.3%)
Cane	10 (17.9%)	9 (18.8%)
Walker	9 (16.1%)	8 (16.7%)
Other	4 (7.1%)	4 (8.3%)

Eight subjects withdrew prior to inclusion in the intention-to-treat (ITT) population (ITT population comprised all enrolled participants who reached Visit 3). Reasons were participant-initiated withdrawal due to dissatisfaction ($N = 4$; dissatisfaction with suspension), participant-initiated withdrawal due to intervention preference ($N = 1$; rejection of the socket type), investigator-initiated withdrawal due to a medical condition ($N = 1$; severe weight loss), and participant-initiated withdrawal due to participant burden/time ($N = 2$; time investment).

Forty-eight subjects were included in the ITT and final analysis. Of these, four discontinued after Visit 3 and were retained in the ITT cohort: treatment discontinuation due to dissatisfaction ($n = 1$; dissatisfaction with suspension), adverse event skin rash ($N = 1$; work-related skin rashes), adverse event injury ($N = 1$), and lost to follow-up ($N = 1$). Forty-four subjects completed per protocol, see Fig. 2.

Within the ITT/final analysis cohort ($N = 48$), 34 subjects were designated to the skin-issue subgroup and 14 to the subgroup without skin issues. Using a post hoc baseline subgroup definition based on baseline HDSS scores, participants were further classified as hyperhidrotic ($N = 18$) or non-hyperhidrotic ($N = 30$), with one hyperhidrotic participant reporting no skin issues.

Perceived residual limb health PEQ-RLH confirmed a statistically significant treatment effect both for the skin issue subgroup ($P = 0.0145$) and the whole cohort ($P = 0.0163$), supporting the primary hypothesis that the AeroFit system improves perceived residual limb skin health both for the skin-issue group and all users of the intervention (see Fig. 3A and 3B).

PEQ-RLH Question 1 scores, on sweat, differed significantly between device conditions at Visit 3 and Visit 4, demonstrating less reported sweating inside the prosthesis when participants used AeroFit system compared to the non-vented comparator system ($P < 0.001$) (Fig. 3C).

At baseline, the hyperhidrotic subgroup reported statistically significantly worse sweating within their prosthesis, as assessed by PEQ-RLH Q1 sweat question, than the non-hyperhidrotic subgroup ($P = 0.011$) (Fig. 4). This finding demonstrates agreement between the HDSS-based subgroup classification and PEQ-RLH sweat ratings, indicating that both measures capture a similar patient-perceived burden of sweating.

HDSS scores were lowest during AeroFit use in both the overall cohort (Fig. 5A) and the skin-issue subgroup (Fig. 5B), indicating lower self-reported sweating severity with the AeroFit system. This finding was consistent across both ABA and BAB treatment sequences (Fig. 6). In contrast, baseline sweating severity was highest in both the overall cohort and the skin-issue subgroup.

Non-inferiority was demonstrated for activity restriction, TAPES-R, (mean difference - 0.77 (95% CI -1.77 to 0.38), prosthesis use (mean difference - 3.92 (97.5% CI -5.98 to 1.09), and quality of life, EQ-5D-5L, (mean difference 0.009 (97.5% CI -0.040 to 0.050) between vented and non-vented conditions, confirming that improved ventilation did not compromise function or general comfort, see Table 2 for endpoint results, acceptance criteria and multiple testing strategies. Notably, mean difference for both TAPES-R and prosthesis use also satisfied the truncated Hochberg gatekeeping criteria (97.81% CI), ensuring that the overall familywise error rate remained controlled while allowing progression to the quality of life endpoint. None of the results demonstrate any correlation with geographical location, study site, sweat management treatments or seasonal and climate-related factors.

Table 2

Endpoints: acceptance criteria, multiple testing strategies, and results N is the number of participants included in the analysis for the given endpoint. Values are mean $\pm$ SD (superiority endpoints) or LMER-estimated mean difference d with 97.5% CI for non-inferiority endpoints. P-values are derived from linear mixed-effects models. Multiplicity was controlled using a hierarchical gatekeeping strategy across three families of hypotheses (H1–H5). Family 1 (H1, H2) was tested in fixed sequence at one-sided $\alpha = 0.025$. Upon success, Family 2 (H3, H4) was tested using the Truncated Hochberg procedure with truncation fraction $f = 0.75$, allocating $\alpha = 0.025$ across the two hypotheses. If both H3 and H4 passed (as they did), the full α was considered spent, and Family 3 (H5) was tested at $\alpha = 0.025$. Effect size is measured as Cohens d (small = 0.2, medium = 0.5, and large = 0.8). Conditional d : Measures effect size relative to within-subject variation.

Family	#	Endpoint	Test Methods	Multiple testing strategy	N	Acceptance Criteria	Results	Effect Size
1	1	Use of AeroFit system improves stump skin health for individuals with skin issues*	PEQ-RLH	Fixed Sequence procedure	34	$P < 0.025$	0.71 ± 0.28 $P = 0.0145$	0.621
	2	Use of AeroFit system improves stump skin health*	PEQ-RLH		48	$P < 0.025$	0.59 ± 0.24 $P = 0.0163$	0.527
2	3	Activity restriction is non-inferior when using AeroFit system	TAPES-R	Gatekeeping test strategy with Truncated Hochberg procedure	48	$d > 0.7915$	$d = -0.77$ [-1.77–0.38]	N/A
	4	Prosthesis use is non-inferior when using AeroFit system	Q-TFA / PUS		48	$d > -12$	$d = -3.92$ [-5.98–1.09]	N/A
3	5	Use of AeroFit system provides non-inferior	EQ-5D-5L		48	$d > -0.078$	$d = 0.0088$ [-0.040–0.050]	N/A

Family	#	Endpoint	Test Methods	Multiple testing strategy	N	Acceptance Criteria	Results	Effect Size
		quality of life						

Adverse Events

Five adverse events were reported during the investigation. Three events were serious, but all were assessed as unrelated to the investigational devices and procedures. One subject fell which resulted in back injury, one subject was involved in a car accident, one subject died due to health-related issues. Two non-serious events were assessed as device related. One was an anticipated event related to skin rashes where the device was not used according to device labelling.

One subject experienced an unanticipated adverse event characterized by distal residual limb discomfort and pain accompanied by skin discoloration. Further evaluation suggested that the event was associated with the ventilation feature. Effective suspension depends on maintaining an intact seal, a deep distal invagination of a scar was present in this case that compromised vacuum integrity and reduced suspension effectiveness.

Discussion

The results of this clinical investigation demonstrate that the vented AeroFit system significantly improves user-perceived residual limb skin health compared to the non-vented comparator system for transfemoral amputees. This effect was consistent in both the overall cohort and in the subgroup of participants with pre-existing skin issues, supporting the primary hypothesis. Adverse event rates were similar between the vented and non-vented conditions, indicating that the observed skin-health benefit was achieved without compromising safety. Other outcomes, including prosthesis use, activity and quality of life demonstrated non-inferior between the vented and non-vented systems, indicating that the observed improvement in residual limb skin health was achieved without compromising other clinically relevant user-reported outcomes.

Baseline sweating severity was reported highest in both the overall cohort and the skin-issue subgroup which may partly be explained by the fact that participants were assessed while using their existing prosthetic systems, for which socket fit quality was unknown. Poor fit can expose the residual limb to uneven loading, shear forces, and localized pressure, increasing the risk of skin problems [11]. Following baseline assessment, all participants received a new liner-socket system, and improvements in fit alone may have improved comfort and reduced perceived sweating. In addition, subjective ratings may have been influenced by expectation or novelty effects associated with receiving a new prosthetic device, potentially contributing to improved outcomes independent of the device's specific clinical effect.

State-of-the-art transfemoral sockets use a soft solid elastomeric liner for cushioning and load distribution and a rigid outer material for load transfer and support. Both the liner and rigid socket

materials are non-conductive, non-breathable, and insulate the limb, they can promote heat and sweat build-up [40]. This creates a humid physiologically unfavorable microclimate around the residual limb that limits heat exchange, airflow, and sweat/moisture evaporation, thereby retaining sweat at the skin-liner interface [41][42]. Consistent with the findings of Gnyawali et al. [21], the AeroFit system reduces the retention of sweat within the socket. The results of the present study therefore support the hypothesis that improved microclimate regulation at the residual limb-socket interface contributes to better user-reported residual limb health.

Phase change material (PCM) liners do not provide prolonged effective solutions, with no significant differences compared to conventional gel liners [43]. Perforated liners have been shown to reduce sweat accumulation on transtibial residual limbs and improve residual limb health outcomes [44][45]. In a cross-sectional study, Davies et al. (2020) reported significantly better residual limb health scores among established users of perforated liners compared with users of non-perforated liners, as measured using the PEQ Residual Limb Health subscale [30]. While these findings are consistent with the improvements observed in the current study, important methodological differences should be considered. Davies et al. compared two independent groups of prosthesis users; individuals already prescribed perforated liners and a control group using non-perforated liners [30]. In contrast, the present study employed a within-subject design in which each participant evaluated both vented and non-vented conditions, thereby serving as their own control. This design reduces the influence of inter-individual differences such as activity level, residual limb characteristics, skin condition, and personal preferences. Furthermore, users in the perforated liner group of Davies et al. had already adopted and continued to use the technology. The within-subject comparison used in the current study may therefore provide a more direct assessment of the perceived impact of the ventilation feature on residual limb health. Additionally, the technologies evaluated by Davies et al. and the current study differ substantially. The perforated liner relies on perforations through the liner wall to transport moisture away from the skin surface. By contrast, the AeroFit system incorporates a vented liner-socket pathway designed to facilitate moisture transfer and airflow through the prosthetic interface. Therefore, although both studies address sweat management, direct comparison of the magnitude of observed effects should be interpreted with caution due to differences in device design, suspension systems, and study methodology.

The ability of the AeroFit system to facilitate airflow and promote evaporation appears to address the core problem of sweat accumulation on the residual limb without compromising suspension or increasing friction-related skin breakdown [10]. In addition, by reducing sweat retention, the AeroFit system may help mitigate the risk of developing dermatologic conditions such as rashes, blisters, and infections that have been shown to compromise prosthesis use, mobility, and participation in daily life [6] [13].

In summary, the results of this study demonstrate that the AeroFit system significantly improves user-perceived residual limb skin health and reduces the burden of sweat accumulation inside transfemoral prosthetic sockets. Statistically significant improvements in PEQ-RLH scores were observed in both the overall cohort and the subgroup of participants who reported skin issues at baseline. The greatest

benefits were seen among participants with hyperhidrosis, suggesting that AeroFit may be particularly advantageous for individuals prone to excessive sweating. Importantly, these improvements were achieved without compromising prosthesis use, activity levels, or health-related quality of life, as demonstrated by non-inferiority results for the TAPES-R, Q-TFA, and EQ-5D-5L outcomes. Together, these findings suggest that the AeroFit vented liner and socket system represents a meaningful advancement in prosthetic interface technology, providing improved skin health and user comfort for individuals with transfemoral amputation, particularly those affected by excessive sweating and related skin concerns. Further research may help delineate long-term benefits and explore optimal patient selection for this intervention.

There are limitations to this study, one is the open-label design, which may introduce bias in self-reported outcomes. However, the use of validated questionnaires and the cross-over design help to mitigate these effects. Additionally, the study focused on short- to mid-term outcomes; future research should include longer-term follow-up to assess sustained benefits and potential impacts on long-term skin health.

Although the sample size was sufficient to identify differences in primary outcomes, it was not large enough to permit comprehensive subgroup analyses based on variables such as age, sex, etiology of amputation, or comorbid conditions. No differences were found when comparing vascular versus traumatic group with respect to PEQ-RLH. Including pre-adapted Direct Socket TF users limited the recruitment potential as other socket solutions are common. As noted in the results, one participant withdrew from the study due to rejection of the socket type. Although the participant had been fitted with a Direct Socket for some time prior to study inclusion, they had not fully adapted to the design prior to enrollment, which may have influenced their acceptance of the intervention and willingness to continue participation.

The scope of this study was limited to single suspension type, single seal-in suspension, as the AeroFit System is currently only available with single seal. Keeping the socket design and suspension type consistent between investigational device and comparator, enabled isolation of the ventilation effect. While the results indicate that similar benefits may extend to other socket designs, further investigation may be required to evaluate the performance of AeroFit technology in different socket and suspension systems.

Conclusion

The vented AeroFit liner and socket system significantly improved user-perceived residual limb skin health compared with non-vented suspension interface in transfemoral prosthesis users. Improvements were accompanied by reduced perceived sweating and were achieved without compromising prosthesis use, activity, or health-related quality of life. These findings provide clinical evidence that enhanced ventilation and microclimate regulation at the residual limb-prosthetic interface can deliver meaningful benefits for prosthesis users, particularly those affected by sweating-related skin concerns. AeroFit

offers a meaningful advancement in prosthetic technology and has the potential to enhance quality of life for individuals with transfemoral amputation.

Methods

Ethical Approval

and Study Population

This investigation was sponsored by Össur Iceland ehf. (Reykjavik, Iceland), the authors' employer, and was conducted at seven prosthetics and orthotics clinics in the United States between June and December 2023. Ethical approval for all participating sites was granted by Advarra Institutional Review Board (Columbia, MD, USA), acting as the single central IRB for the investigation (Pro00070417), prior to the enrolment of any participant. The investigation and enrollment of the 59 participants was performed in accordance with relevant guidelines and regulations and with the ethical principles of the Declaration of Helsinki. Registration at ClinicalTrials.gov was performed before initiation (NCT05925712, registered 31. May. 2023). Written informed consent was obtained from all participants prior to any investigational activity.

All activities took place at established prosthetic and orthotic out-patient clinics with an existing transfemoral caseload, under a signed agreement with the sponsor; no per-site enrolment limits were applied. At each site, a Local Principal Investigator screened and consented participants, fitted the devices and collected data. All devices were fitted by a certified prosthetist (CPO/CO/CP) who had completed device-specific training.

Participants had to meet the following inclusion criteria: transfemoral amputation, or congenital transverse deficiency at a femoral level (unilateral or bilateral), activity level K1-K4 [22], body weight between 50 and 136 Kg, residual limb matching the silicone liner profile, and subject socket height per liner profile sufficient according to the manufacturer's instructions. In addition, all subjects had to be using Seal-In Silicone liner and Direct Socket TF (Össur Iceland ehf) or AeroFit Seal-In liner (Össur Iceland ehf) and AeroFit Socket (Össur Iceland ehf) as their current prosthetic application for more than three months, have the cognitive ability to understand all instructions and questionnaires in the study, and be 18 years or older.

Exclusion criteria included participation in another research study that might affect the study's participation or results, and users who had received Botox injections as a treatment for residual limb perspiration issues within the past four months before the study start.

Investigational Device and Comparator

The investigational device was the AeroFit System (AeroFit®, Össur ehf, Reykjavik, Iceland) a vented prosthetic liner and socket system comprising a vented 3D printed AeroFit Seal-In silicone liner and a vented AeroFit Socket. The liner is designed to allow airflow and movement of moisture vapor through

the prosthetic interface. It allows sweat to move both transversely away from the skin through the liner and longitudinally towards the proximal edge of the liner and socket. This dual directional movement of air and moisture prevents sweat from getting trapped between the liner and skin. The liner is split into a proximal vented part and suspending part below a circular seal ring to provide secure suspension in the distal part where the socket does not have any vents. The AeroFit Socket is a custom-made fiberglass socket, made directly onto the user's residual limb. The AeroFit Socket features specifically designed vents in predefined areas allowing moisture vapor to exit from the liner-socket area to the outside.

The non-vented comparator system consisted of standard Seal-In silicone liner used with the same socket, with the vents filled with a silicone filler to prevent ventilation. This allowed for a controlled comparison between the vented vs. non-vented device conditions by removing any aspects related to the fit of the rigid socket.

Study Design

The investigation design was a prospective, multicenter, open-label, block randomized controlled, cross-over (ABA/BAB) design. Data collection and randomization was done using an Electronic Data Capture (EDC) system (Greenlight Guru Clinical, Indianapolis, USA). Participants were randomized to one of two crossover sequences; ABA or BAB. Condition A was the vented AeroFit system and condition B was the non-vented comparator system. Block randomization with random block sizes was used. Randomization IDs (1–60) were generated by the EDC and equally allocated between treatment groups. No site stratification was applied. Randomization was performed within the EDC by the Local Principal Investigator at Visit 1, after consent and enrolment were recorded. The sequence and block sizes were generated and held by the system and were not distributed to sites; each allocation was released only at the point of randomization, so enrolling and assigning personnel could not foresee upcoming assignments. Group 1 followed the ABA sequence, beginning with the AeroFit System, crossing over to the non-vented comparator system, and then returning to the AeroFit system. Group 2 followed the BAB sequence. Each device condition lasted for 4–6 weeks, with clinic visits between conditions, four visits in total. At each visit, patient-reported outcomes were collected using the EDC and participants crossed over to the next assigned device condition, see Fig. 1. The condition change involved replacing the liner and socket vents. Vents were either filled with a silicone filler and used with the Iceross Seal-In liner (condition B) or left unfilled and used with the AeroFit Seal-In liner (condition A). Each subject used the remaining part of their current prosthetic system (prosthetic foot, pylon, knee, etc.) with both device conditions. Due to the nature of external prosthetics and ensuring patients safety, blinding to device conditions was not possible. However, the analysis was conducted in a blinded manner, with groups coded until completion of the primary analysis. Because the intervention is a non-pharmacologic prosthetic interface and requires an accommodation period, the second study period served as a stabilization phase rather than a washout; therefore, only visits 3 and 4 were used for confirmatory analyses to minimize period and carryover effects.

Anticipated harms were pre-defined using the device's ISO 14971 risk files. Safety was evaluated through a dual approach: a specific subset of harms was assessed systematically via Patient-Reported Outcome (PRO) questionnaires at the end of each treatment period, see below, while other adverse events were captured non-systematically via spontaneous reporting. Harms were attributed to the device used during that specific period.

A new socket was fabricated for all subjects during the first study visit and used throughout the complete study procedure. Two pairs of identical liners, for both device conditions (vented and non-vented), were provided for their daily use for alternation between liners daily. This is a recommended practice to allow cleaning and air-drying liners between use. Between study visits, the pair of liners not in use were kept at the study site to prevent use of the wrong set of liners during each intervention period.

Outcome Measures and Hypotheses

The primary hypothesis was that use of the AeroFit system would improve perceived residual limb skin health compared to the non-vented comparator system. Perceived residual limb health was assessed using the PEQ-RLH (Prosthetic Evaluation Questionnaire - Residual Limb Health), a validated subscale of the PEQ [23][24] which evaluates common skin issues such as sweat, odor, swelling, and irritation. For ease of administration and interpretation, items were rated on a 10-point Likert scale (higher scores indicate better skin health), as this format is more familiar and easier for the patient population to use [25]. While VAS may show slightly greater variability, both methods have comparable responsiveness [26] [27].

The investigation focused on patient-reported outcomes on perceived skin health, activity restrictions, quality of life, and prosthetic use in a randomized cross-over design. The PEQ-RLH has been used to report on socket related skin health [28][29][30] and found reliable for this purpose [31][32].

To ensure the intervention did not negatively affect activity levels, the activity restriction subscale of the TAPES-R (Trinity Amputation and Prosthesis Experience Scales – Revised) was used [33]. TAPES-R's internal consistency has been reported to be strong in this population [34]. This widely used measure assesses limitations in daily activities, with higher scores reflecting greater restriction. Effects on prosthetic use were monitored with the Prosthetic Use Score from the Q-TFA (Questionnaire for Persons with Transfemoral Amputation), a validated tool for both socket and osseointegrated prosthesis users [35].

Quality of life was assessed with the EQ-5D-5L, a standardized instrument suitable for LEA [36], which covers five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D-5L provides both a health profile and a single index value and has been administered to inform about health-related quality of life [37].

The Hyperhidrosis Disease Severity Scale (HDSS), a single-item 4-point scale (single item, range 1–4; higher = greater severity), was used to assess the severity of sweating and its impact on daily activities

[38][39] Scores above 2 indicate severe hyperhidrosis.

Information on sweat management methods in use before and during the investigation period was collected using a simple question asked at each investigation event: *Do you use any sweat managing treatment for your residual limb(s)? Check all that apply. The response options were: 1. Topical antiperspirant; 2. Oral medication; 3. Other; 4. No treatment.*

Statistical Analysis

All statistical analyses were performed according to a predefined statistical analysis plan, in a blinded manner, with treatment groups coded until completion of the primary analysis. Analyses were conducted for the full study cohort and for subgroups. The subgroups were skin-issue group and hyperhidrosis group. The skin-issues group was determined by participants scoring < 7 on Prosthesis Evaluation Questionnaire – Residual Limb Health (PEQ-RLH) items Question 1 or Question 4 at baseline (visit 1). Question 1 is: *Over the past four weeks, rate how much you sweat inside your prosthesis (in the sock, liner, socket)* and question 4 is: *Over the past four weeks, rate any rash(es) that you got on your residual limb.* The hyperhidrosis subgroup was defined post-hoc as participants scoring 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) at baseline (visit 1), rating in which corresponded to sweating that was barely tolerable or intolerable and frequently or always interfered with daily activities.

Sample size was determined a priori using PEQ-RLH data from the preceding AeroFit Alpha investigation ($n = 16$; 7.646 ± 2.233 vs 8.479 ± 1.210 , paired $r = 0.554$), giving $d_z = 0.448$. Assuming a Wilcoxon signed-rank test for matched pairs, two-sided $\alpha = 0.05$ and 85% power, G*Power indicated 49 completers were required (47 assuming normality; 58 with a 10% smaller effect). Allowing 20% attrition, the recruitment target was ≥ 59 . Forty-four participants completed per protocol and 48 were analyzed, marginally below target. No interim analyses or stopping rules were pre-specified.

Repeated-measures data were analyzed using mixed-effects models to account for within-subject correlation, missing observations, and unbalanced data structures. Missing data was not imputed, and the results are valid under the missing at random assumption. Linear mixed-effects models (LMMs) were used for all outcomes. Subject and study site were included as random intercepts to account for hierarchical data structure and between-subject and between-site variability. Treatment, period, and sequence were included as fixed intercepts to account for period and sequence effects.

Model assumptions for LMMs were evaluated using a combination of visual diagnostics (histograms, Q-Q plots, and residual-versus-fitted plots) and formal statistical tests of normality. When residual diagnostics indicated deviations from normality, sensitivity analyses were performed to assess the robustness of model estimates.

Statistical tests for all endpoints were one-sided. The nominal significance level was defined as a priori in the study protocol, with a primary $\alpha = 0.025$ applied to confirmatory endpoints. Control of the family-wise error rate across multiple endpoints was achieved using gatekeeping, including predefined fixed-

sequence and truncated Hochberg, testing procedures specified in the protocol, rather than post-hoc multiplicity adjustments. Exact p-values are reported where applicable.

All analyses were performed using R version 4.3.3 (R Foundation for Statistical Computing), primarily employing the lme4 and lmerTest packages for mixed-effects modeling, with additional validated packages used for ordinal models, diagnostics, and sensitivity analyses.

Statistical Analysis

All statistical analyses were performed according to a predefined statistical analysis plan, in a blinded manner, with treatment groups coded until completion of the primary analysis. Analyses were conducted for the full study cohort and for subgroups. The subgroups were skin-issue group and hyperhidrosis group. The skin-issues group was determined by participants scoring < 7 on Prosthesis Evaluation Questionnaire – Residual Limb Health (PEQ-RLH) items Question 1 or Question 4 at baseline (visit 1). Question 1 is: *Over the past four weeks, rate how much you sweat inside your prosthesis (in the sock, liner, socket)* and question 4 is: *Over the past four weeks, rate any rash(es) that you got on your residual limb*. The hyperhidrosis subgroup was defined post-hoc as participants scoring 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) at baseline (visit 1), rating in which corresponded to sweating that was barely tolerable or intolerable and frequently or always interfered with daily activities.

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Declarations

Acknowledgement

The authors gratefully acknowledge the participating clinics and Local Principal Investigators for their expertise and contribution to the conduct of this study. Special thanks are extended to Ashton Groves (Reach Orthotics and Prosthetics Services, Virginia), Cara Negri (Gainesville Prosthetics, Florida), Jeffrey A. Denune and Mark Ford (NuTech Institute LLC, Indiana), Kristen John (Oakland Orthopedic, Michigan), Matt Roberts (SRT Prosthetics & Orthotics NPC, Indiana), Michael Perez (Perry Prosthetics, Ohio), and Stephen Parkinson (Baker Orthotics and Prosthetics, Texas).

Author Contributions

Author initials used below: J.V.K. (Jóna Valgerður Kristjánsdóttir), R.S. (Reynir Scheving), B.P.S. (Benedikt Þorri Sigurjónsson), K.L. (Knut Lechler) and T.F. (Thor Fridriksson).

All authors contributed to conceptualization, methodology and study design; Investigation and data collection: J.V.K., R.S.; Formal analysis and statistics: B.P.S., R.S.; Data curation: B.P.S., R.S.; Writing of original draft: J.V.K., K.L.; Writing, review and editing: all authors; Supervision and project administration: J.V.K., K.L., T.F. All authors read and approved the final version of the manuscript.

Data Availability Statement

The datasets generated and analysed during the current study are not publicly available but are available from the corresponding author, Jóna Valgerður Kristjánsdóttir, on reasonable request.

Competing Interests

All authors are employees of Össur Iceland ehf. (Reykjavik, Iceland), the manufacturer of the AeroFit vented liner and socket system evaluated in this study, and the investigation was sponsored by Össur

Iceland ehf. The authors have no other interests beyond employment. Participant recruitment, consent and data collection were performed by independent site investigators.

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Figures

Figure 1

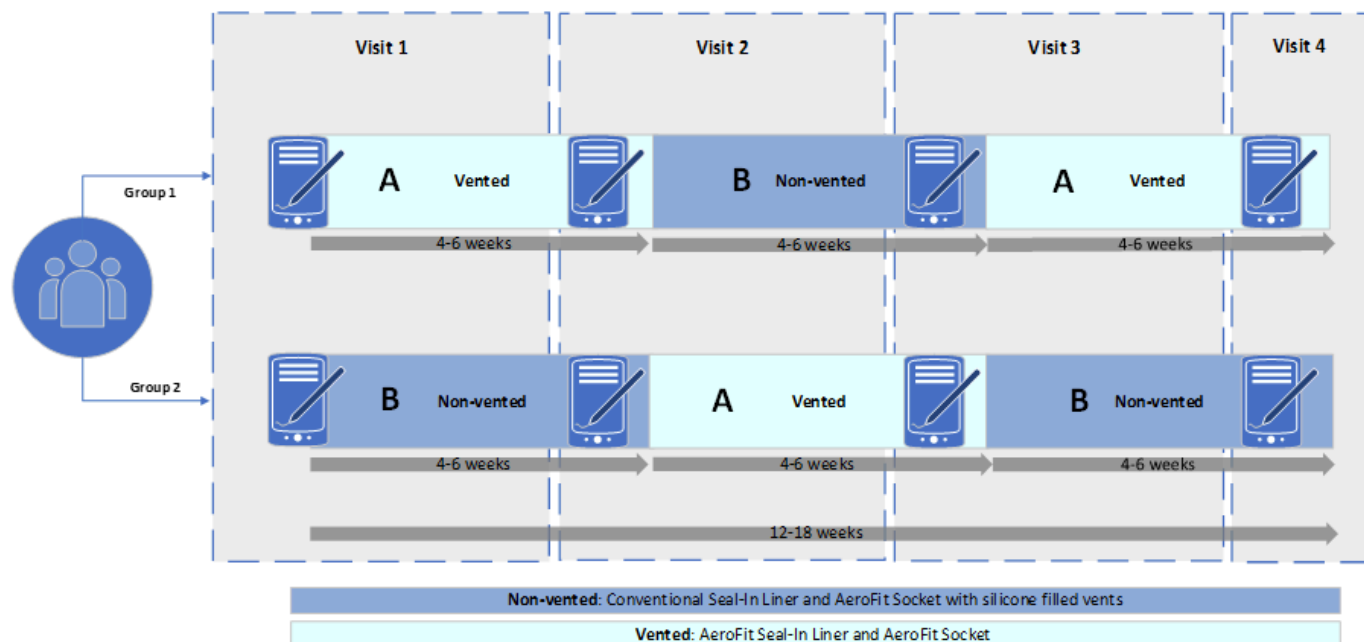


Figure 1

Study design and crossover sequence.

Participants were randomized into either ABA or BAB treatment sequences: Group 1 followed an ABA sequence, beginning with the vented liner and socket system (condition A), whereas Group 2 followed BAB sequence, beginning with the non-vented liner and socket system (condition B). Participants crossed over between conditions twice. At each crossover, both the liner and vent configuration were changed: Condition A consisted of open socket vents paired with AeroFit Seal-In liner, whereas condition B consisted of silicone-filled vents paired with the Iceross Seal-In liner. All participants continued to use the remaining components of their existing prosthetic system (foot, pylon, knee, etc.) throughout the study.

Figure 2

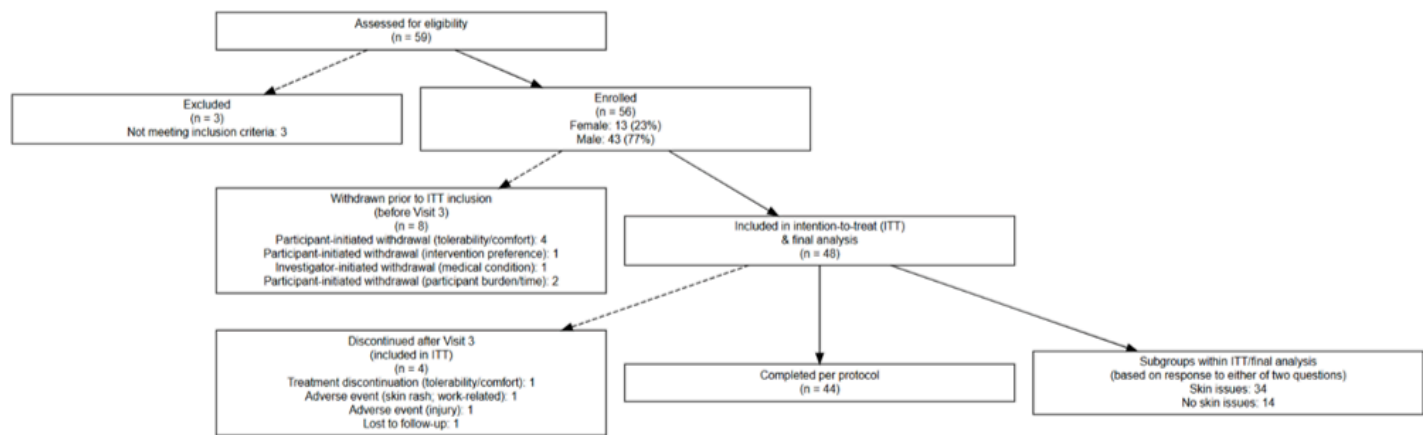


Figure 2

Participant flow through the study.

Flow diagram of participant screening, enrollment, disposition and analysis population. Of 59 subjects assessed for eligibility, 56 were enrolled and 48 included in the intention-to-treat (ITT) analysis. Eight subjects withdrew before Visit 3 and were excluded from the ITT population. Four subjects discontinued participation after Visit 3 due to intercurrent events but remained in the ITT analysis. Forty-four subjects completed the study per protocol. Based on baseline Prosthesis Evaluation Questionnaire – Residual Limb Health (PEQ-RLH) responses, 34 participants were classified as having skin issues and 14 as not having skin issues.

Figure 3

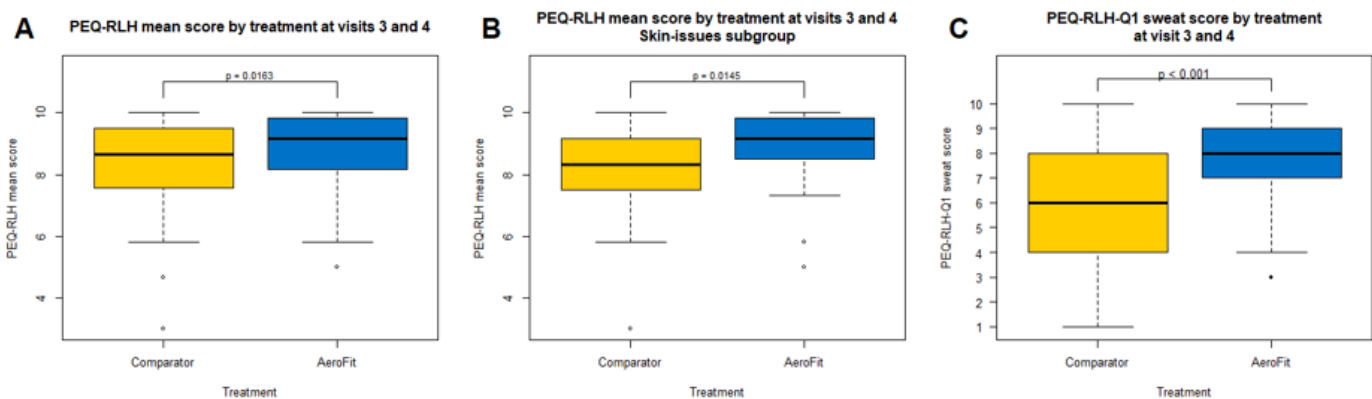


Figure 3

Perceived residual limb health

Treatment effects on PEQ-RLH scores the whole group ($P= 0.0163$) (Panel A) and for the skin-issue subgroup ($P = 0.0145$) (Panel B). Higher PEQ-RLH scores were observed during use of the AeroFit system, supporting the primary hypothesis of improved perceived residual limb skin health for all users of the AeroFit system. The median shows as a line within the box representing the interquartile range (25th–75th percentiles), the whiskers extend to values within 1.5 times the interquartile range and points beyond indicate outliers.

Figure 4

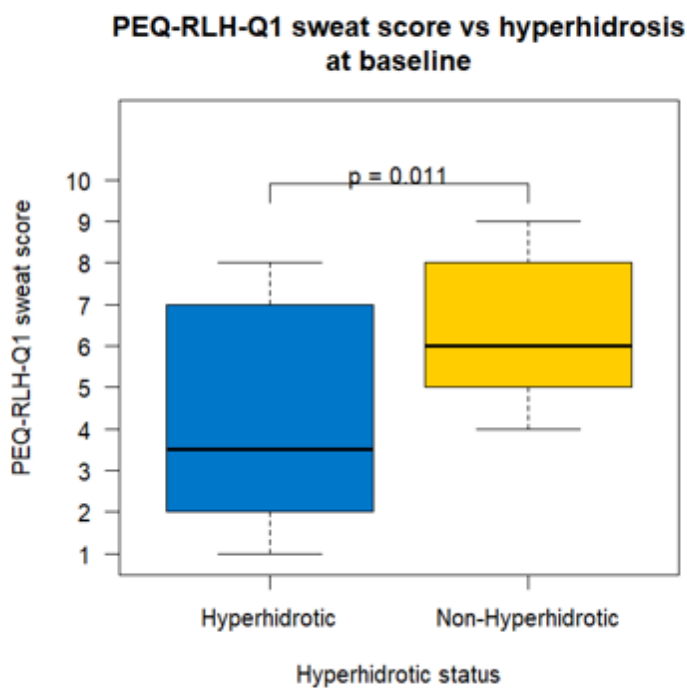


Figure 4

Ratings for PEQ-RLH Question 1 (Rate how much you sweat inside your prosthesis) at visit 3 and 4.

PEQ-RLH Q1 rates how much subjects sweat inside their prosthesis, with higher scores indicating less issues with sweat. At baseline, individuals with hyperhidrosis reported significantly greater sweating related issues than participants without sweating issues ($P = 0.011$). The boxplot shows the median as a line within the box, which represents the interquartile range (25th–75th percentiles), while the whiskers extend to values within 1.5 times the interquartile range and points beyond indicate outliers. Statistical significance was assessed using Student’s t -test as part of post hoc subgroup item level analysis, and corresponding p -values are shown.

Figure 5

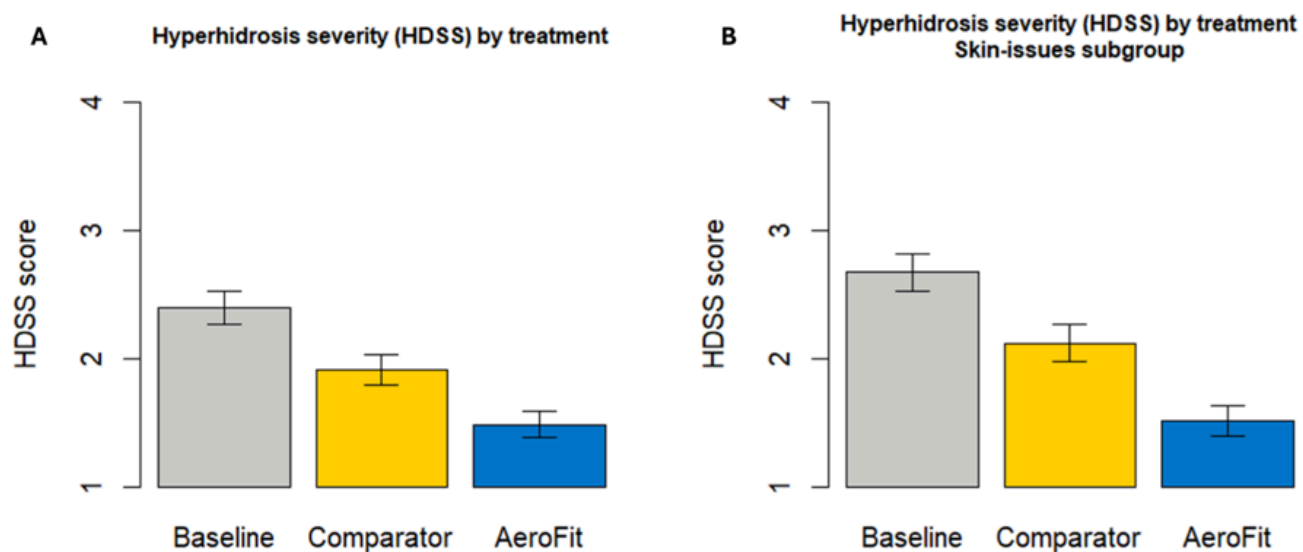


Figure 5

Sweating severity at baseline and device conditions at Visit 3 and Visit 4.

Hyperhidrosis Disease Severity Scale (HDSS) for the subjects $N=48$ on the left-hand side (Panel A) and; Skin-issues subgroup $N=34$ on the right-hand side (Panel B) between baseline and device conditions at Visit 3 and Visit 4. Bars show mean HDSS values. Error bars represent the Standard error of the Mean (SEM). Lower score indicates better outcomes.

Figure 6

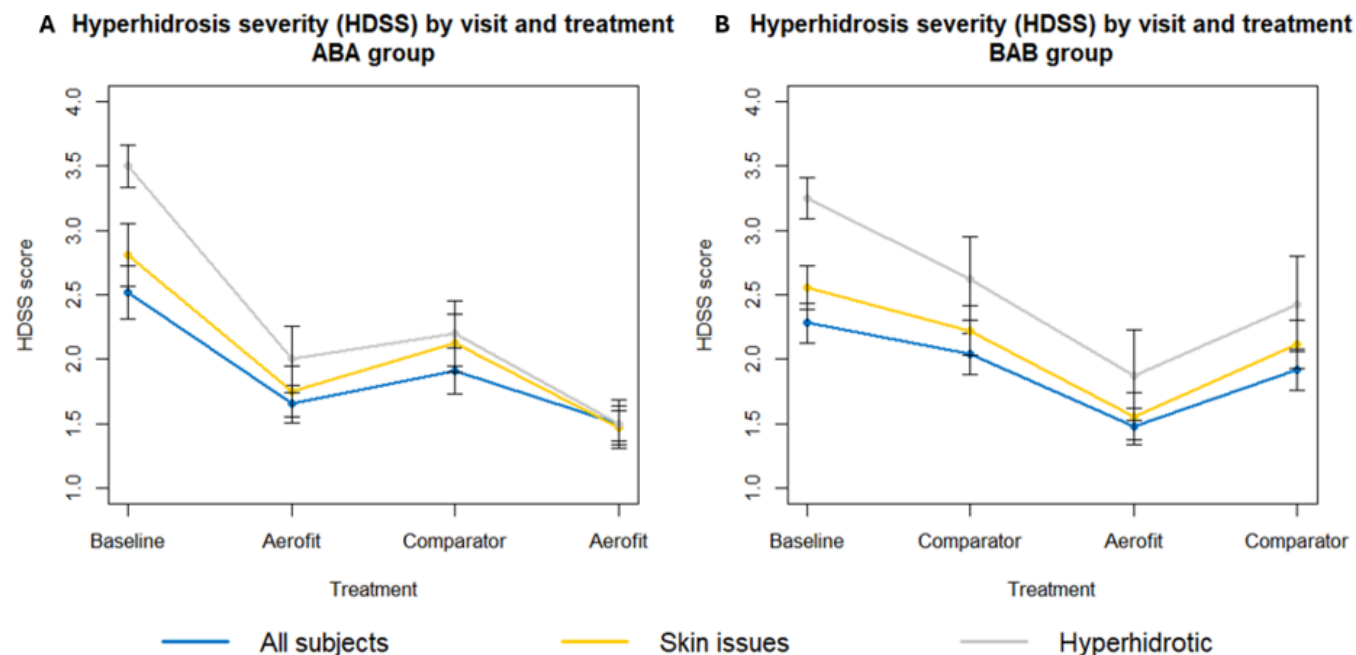


Figure 6

HDSS scores across treatment conditions in the overall cohort and subgroups.

HDSS scores for the overall cohort ($N=48$), the skin-issue subgroup ($N=34$) and hyperhidrosis subgroup ($N=18$), by treatment and randomization sequence (ABA and BAB). The graph shows mean values and error bars represent standard error of the mean (SEM). Blue lines represent the overall cohort, yellow lines represent the skin-issues subgroup, and grey lines the hyperhidrosis subgroup.