

Elevated vacuum suspension preserves residual-limb skin health in people with lower-limb amputation: Randomized clinical trial

Cameron Rink, PhD;¹ Matthew M. Wernke, PhD;² Heather M. Powell, PhD;³ Surya Gynawali, PhD;¹ Ryan M. Schroeder, BS;² Jayne Y. Kim, MS;³ Jeffrey A. Denune, CP;² Gayle M. Gordillo, MD;^{1,4} James M. Colvin, MS;² Chandan K. Sen, PhD^{1*}

¹Department of Surgery, Comprehensive Wound Center, and Dorothy M. Davis Heart and Lung Research Institute, The Ohio State University Wexner Medical Center, Columbus, OH; ²Ohio Willow Wood Company, Mt. Sterling, OH; ³Department of Biomedical Engineering, The Ohio State University, Columbus, OH; ⁴Department of Plastic Surgery, The Ohio State University Wexner Medical Center, Columbus, OH

Abstract—A growing number of clinical trials and case reports support qualitative claims that use of an elevated vacuum suspension (EVS) prosthesis improves residual-limb health on the basis of self-reported questionnaires, clinical outcomes scales, and wound closure studies. Here, we report first efforts to quantitatively assess residual-limb circulation in response to EVS. Residual-limb skin health and perfusion of people with lower-limb amputation ($N = 10$) were assessed during a randomized crossover study comparing EVS with nonelevated vacuum suspension (control) over a 32 wk period using noninvasive probes (transepidermal water loss, laser speckle imaging, transcutaneous oxygen measurement) and functional hyperspectral imaging approaches. Regardless of the suspension system, prosthesis donning decreased perfusion in the residual limb under resting conditions. After 16 wk of use, EVS improved residual-limb oxygenation during treadmill walking. Likewise, prosthesis-induced reactive hyperemia was attenuated with EVS following 16 wk of use. Skin barrier function was preserved with EVS but disrupted after control socket use. Taken together, outcomes suggest chronic EVS use improves perfusion and preserves skin barrier function in people with lower-limb amputation.

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INTRODUCTION

Shear stress, compression, and moisture exposure associated with prosthesis use cause soft tissue injury to the residual limb of people with amputation, who are highly susceptible to skin breakdown and ulceration [1]. According to a voluntary survey of 872 people with lower-limb amputation, 63 percent reported prosthesis-related skin problems in the month prior to completing a

Abbreviations: EVS = elevated vacuum suspension, HR = heart rate, LDF = laser Doppler flowmetry, SD = standard deviation, SoC = standard of care, TCOM = transcutaneous oxygen measurement, TcPO₂ = transcutaneous oxygen tension, TEWL = transepidermal water loss, TF = transfemoral, TT = transtibial.

*Address all correspondence to Chandan K. Sen, PhD; The Ohio State University Comprehensive Wound Center, 473 W 12th Ave, Columbus, OH 43210; 614-247-7658; fax: 614-247-7818. Email: chandan.sen@osumc.edu
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residual-limb health questionnaire [2]. Of responders, 53 percent reported skin problems caused by occlusion and 43 percent reported mechanically induced skin problems that included blisters (19%), callus (15%), or abrasions (15%) [2]. Because skin health problems can necessitate the disuse of the prosthesis, maintaining residual-limb health in order to lead an active lifestyle is a key issue for the ~1.6 million Americans who live with lower-limb amputation [3]. Achieving a comfortable and functional connection between a person's residual limb and their prosthetic limb is therefore important to the success of the prosthesis. To that end, the socket system is recognized as a critical component of the prosthesis that when optimally designed and fitted should enable people with amputation to maintain daily activities without injury or experiencing pain [4].

Advances in socket design over the past two decades have led to the development of novel methods to suspend the residual limb in the prosthesis. Elevated vacuum suspension (EVS) sockets use an active vacuum system to remove air between the liner and socket, generating a negative pressure environment that tightly secures the residual limb inside the socket. Note that vacuum-assisted suspension is another term used in the literature to describe EVS. Both terms differentiate the suspension method from passive suction or valve systems. EVS sockets continue to grow in popularity on the basis of improved fit and function [5–8] through a reduction of pistoning [5,9–11] and residual-limb volume management [5,12–13]. A recent systematic review of EVS studies [14] identified only two peer-reviewed journal publications related to the effects of EVS on residual-limb physiology [5,15] and underscores the need for more evidence-based research in this underserved field. The lack of objective data on the physiological effects of EVS represents a critical barrier to develop the overall clinical significance of the socket platform on residual-limb health. Studies designed to directly test the effect of EVS on residual-limb skin health and blood flow have yet to be reported. In that light, there is a clear need to improve upon the rigor of prosthesis and residual-limb research in order to identify and develop best practices for amputee care. The current work represents first efforts to quantitatively assess skin health and perfusion in people with transtibial (TT) and transfemoral (TF) amputation using EVS as compared to standard of care (SoC) pin-locking or suction sockets as controls.

METHODS

The study protocol and experimental procedures were reviewed and approved by the institutional review board of The Ohio State University Wexner Medical Center. The study took place at The Ohio State University Wexner Medical Center.

Study Design

Ten people with unilateral lower-limb amputation (5 TT, 5 TF) were recruited to participate in the study. Eligible participants were all adults aged 18 to 65 yr with a unilateral TT or TF amputation with an unimpaired contralateral limb, were able to ambulate on a prosthesis, were not diagnosed with renal failure, were nonsmokers, and were not an existing EVS prosthesis user. Half of the subjects used suction suspension sockets and the other half used pin-locking suspension (**Table**). A randomized crossover design was employed such that half of the subjects began the study with their SoC nonvacuum prosthesis (group A), while the other half began testing with their EVS test socket (group B) fabricated by the study prosthetist. The allocation schedule was maintained by an independent party from the researcher enrolling and assessing subjects. This independent party would notify the study prosthetist when the subject reported for treatment 1 socket fitting. After 16 wk of use, subjects in groups A and B crossed over to use either the EVS socket or their existing socket, respectively. During each 16 wk

Table.
Subject demographics.

Patient	Group	SoC Suspension	Age (yr)	Sex	Amputation Etiology
01-TT	B	Suction	68	M	Traumatic
02-TF	A	Pin-Locking	67	M	Cancer
03-TF	A	Suction	30	M	Traumatic
04-TT	A	Pin-Locking	42	M	Traumatic
05-TF	A	Pin-Locking	45	M	Cancer
06-TT	B	Suction	48	M	Traumatic
07-TF	A	Pin-Locking	43	M	Traumatic
08-TF	B	Suction	46	M	Vascular
09-TT	B	Pin-Locking	54	F	Infection
10-TT	B	Suction	28	M	Traumatic

F = female, M = male, SoC = standard of care, TF = transfemoral, TT = transtibial.

interval, skin health and perfusion measurements were acquired at baseline (week 0) and final (week 16) time points. Independent of the subject group, a unique test socket was fabricated for each subject to acquire in-socket perfusion measurements during baseline and final time point visits. This socket was designed to work as either a suction or EVS socket depending on the subject's designation at the time of visit, was made from the same modified digital shape as the EVS socket, and included a recess to accommodate in-socket perfusion probes (**Figure 1(a)**). Using the same test socket for the four data collection time points enabled repeated measures and comparison across treatment groups without interference because of socket shape.

Socket Fabrication and Fitting

Members of group A started in their existing socket and suspension system during the first 16 wk treatment interval (non-EVS). Members of group B started the study in an EVS socket fit by the study prosthetist prior to the first 16 wk treatment interval. EVS was enabled by the LimbLogic Vacuum System (Ohio Willow Wood Company; Mt. Sterling, Ohio). Digital scans of the resid-

ual limb wearing a prosthetic liner were taken using the Omega System (Ohio Willow Wood Company), and a global 5 percent reduction was used to generate the socket shape and to fabricate the test socket for each subject. During their first visit, subjects of both groups were also fit with their test socket to be used during baseline and final study visits. This test socket facilitated in-socket measurement probes by including a recess for a silicone probe holder (**Figure 1(a)**), enabling the collection of skin tissue oxygenation and perfusion data as described in the "In-Socket Probe Measurements" section. After completing treatment 1 of the study, subjects of each group once again met with the study prosthetist and were either fit with an EVS socket (group A) or returned to the socket system worn at the time of study enrollment (group B).

Study Visits

To ensure consistency in data collection, subject visits at baseline and final time points followed identical protocol procedures. Out-of-socket skin health measurements and out-of-socket imaging were performed on the residual limb and the sound limb prior to test socket donning.

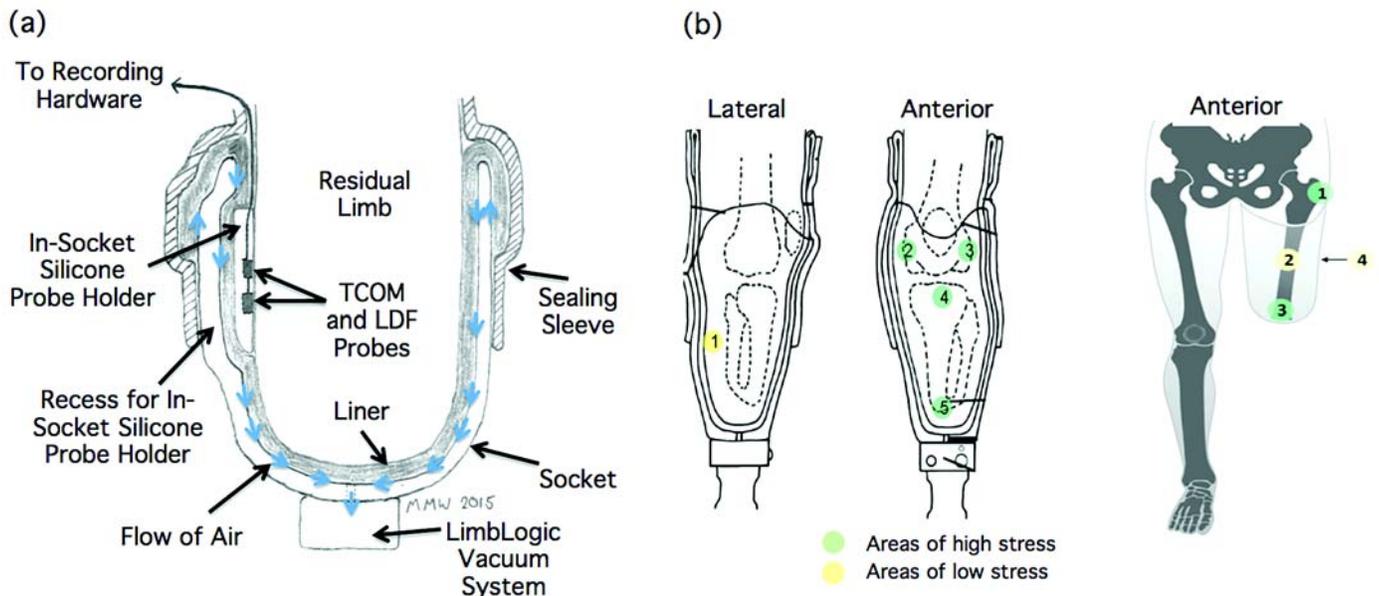


Figure 1.

Elevated vacuum suspension schematic and probe measurement points. **(a)** Illustration of test socket with recess for in-socket silicone probe holder. **(b)** Residual-limb measurement sites. Green and yellow indicate measurement sites of high and low stress, respectively. LDF = laser Doppler flowmetry, TCOM = transcutaneous oxygenometry.

Subjects were acclimated to out-of-socket resting conditions for 15 min prior to acquiring transepidermal water loss (TEWL) and pre-activity hyperspectral images. After imaging, participants were fitted with the gel silicone probe holder and liner for out-of-socket laser Doppler flowmetry (LDF) and transcutaneous oxygen measurement (TCOM) at rest. Subjects were acclimated to the liner for 15 min, after which LDF and TCOM were acquired over a 1 min period. Next, subjects donned their test sockets with in-socket probes and rested in a supine (TF) or prone (TT) position for 15 min to acclimate their residual limb to in-socket resting conditions. Following probe acclimation, subjects were guided by a research nurse into a static position with body weight bearing on their residual limb for in-socket LDF measurement over a 1 min period. Next, subjects were guided through an activity episode by walking on a treadmill at a self-selected pace. Subjects were fitted with a heart rate (HR) monitor and given up to 12 min to raise their HR to the target determined by the following **Equation**:

$$\text{Target HR} = (220 - \text{age}) \times 0.667$$

Once the target HR was acquired, subjects continued walking at their target HR for 5 min. Subjects adjusted the speed of the treadmill as needed to maintain their target HR under the guidance of a research nurse. TCOM was measured and analyzed during the final minute of this 5 min period. If a subject was unable to achieve the target HR within the first 12 min of walking, the 5 min collection period would begin at the 12 min mark. Upon completing the activity episode, subjects removed their test sockets, and postactivity out-of-socket hyperspectral imaging was acquired 1 min after socket doffing. For consistency, images were always acquired on the residual limb prior to the sound limb. Risk of study outcomes being confounded by rapid changes to limb shape after socket doffing [16] were mitigated by strictly adhering to protocol time intervals for data collection and by the nature of the pair-matched study design.

Skin Health Measurement

To assess skin health in response to prosthesis suspension, TEWL, a measure of skin barrier function [17], was quantified using a TEWL meter (DermaLab Combo, Cortex Technology ApS; Hadsund, Denmark) [18]. TEWL measurements were acquired out-of-socket. A 1 cm diameter probe was placed over the area of interest, and

the relative humidity directly above the skin was quantified with respect to the relative humidity within the ambient environment. Skin measurements were taken from five different locations on the TT subjects and four different locations on the TF subjects, representing general areas of high and low compressive stress within prosthetic sockets (**Figure 1(b)**).

Out-of-Socket Imaging

Lower-limb tissue oxygen saturation maps were generated using an OxyVu-2 Hyperspectral Camera (HyperMed; Burlington, Massachusetts) [19]. The hyperspectral camera was calibrated prior to each subject visit using a CheckPad and fiduciary marker provided. A square field of view border (35 × 35 mm) was centered over the target site of the residual limb used for in-socket TCOM measurements. The camera head was fixed parallel to the residual-limb skin surface at a distance of 43 cm, enabling a consistent 100 μm image resolution across subjects. After imaging of the residual limb, the same procedure was repeated at a matched site on the sound limb.

In-Socket Probe Measurements

TCOM and LDF were acquired using a PeriFlux 5000 system (PeriMed Inc; Stockholm, Sweden) [20], with probes held in place using an in-socket silicone probe holder. Measurements were acquired continuously during protocol activities, and values were averaged over a 1 min period as defined previously.

Data Analyses

Out-of-socket imaging data were analyzed using MATLAB code (MathWorks; Natick, Massachusetts) that averaged signal intensity over the 35 mm × 35 mm field of view. Results are reported as the percentage change between pre- and postactivity data values. Raw data from the LDF and TCOM probe were analyzed using semiautomated MATLAB code as the mean ± standard deviation (SD) value recorded during the 1 min defined resting position and during the final minute of the treadmill walking activity. Differences in out-of-socket perfusion and in-socket perfusion at rest as measured by LDF were analyzed using a two-tailed paired Student *t*-test. *p*-Values less than 0.05 were considered statistically significant. LDF data were excluded from analysis during activity because of motion artifact noise generated by treadmill walking. TCOM determination of residual-limb oxygenation was recorded during activity. Differences between

out-of-socket and in-socket tissue oxygenation during the walking activity were assessed using a two-tailed, paired Student *t*-test. *p*-Values less than 0.05 were considered statistically significant. The mean TEWL values for all subjects at baseline and final time points were calculated across all measurement sites as well as separately for high and low stress areas. Differences between the time points and suspension treatments were analyzed using a two-tailed paired Student *t*-test. *p*-Values less than 0.05 were considered statistically significant. During postcollection data analysis of all outcomes, individual data points that were greater than ± 3 SDs from the group mean were identified and excluded as outliers. No data points were excluded as outliers in **Figure 2**. In **Figure 3**, two data points were excluded as outliers from baseline/out-of-socket SoC (>4 SD, and >43 SD, respectively), two data points were excluded as outliers from baseline/in-socket SoC (both >3 SD), and one data point was excluded as outlier from final/out-of-socket EVS (>3 SD). In **Figure 4**, one data point was excluded from baseline/activity SoC (>4 SD), and one data point was excluded from final/activity SoC (>8 SD). In **Figure 5**, one data point was excluded from final/SoC (>7 SD). Raw data outliers from probe-based measurements were reviewed and attributed to motion artifacts known to produce abnormally high LDF measurements and loss of TCOM probe connectivity producing abnormally high values. No explanation was readily apparent for the abnormally high hyperspectral data point.

RESULTS

For each treatment group, five subjects were randomly assigned, received the intended treatments in the correct order, and were analyzed for the primary outcomes.

Elevated Vacuum Suspension Preserved Skin Barrier Function

TEWL is a clinically relevant test used to measure skin barrier function [21]. When high and low stress areas of measurement were taken together (**Figure 2(a)**) or when they were considered separately (**Figure 2(b)** and **(c)**), there was no difference in SoC and EVS socket TEWL values at the baseline time point. After 16 wk of use, EVS significantly lowered TEWL by 19.5 percent as compared to SoC sockets when all areas were considered together (**Figure 2(a)**). When high and low stress areas were considered separately at 16 wk, EVS lowered TEWL by 20.0 percent as compared to SoC in areas of high stress (**Figure 2(b)**), while in areas of low stress (**Figure 2(c)**) TEWL trended lower in EVS socket as compared to SoC but was not statistically different ($p = 0.09$). Of note, TEWL values increased from baseline to 16 wk in SoC socket systems when high and low stress areas were considered together (**Figure 2(a)**) and when areas of high stress were considered separately (**Figure 2(b)**). Furthermore, in areas of high stress, TEWL significantly decreased over time from baseline to 16 wk time points in EVS sockets (**Figure 2(b)**).

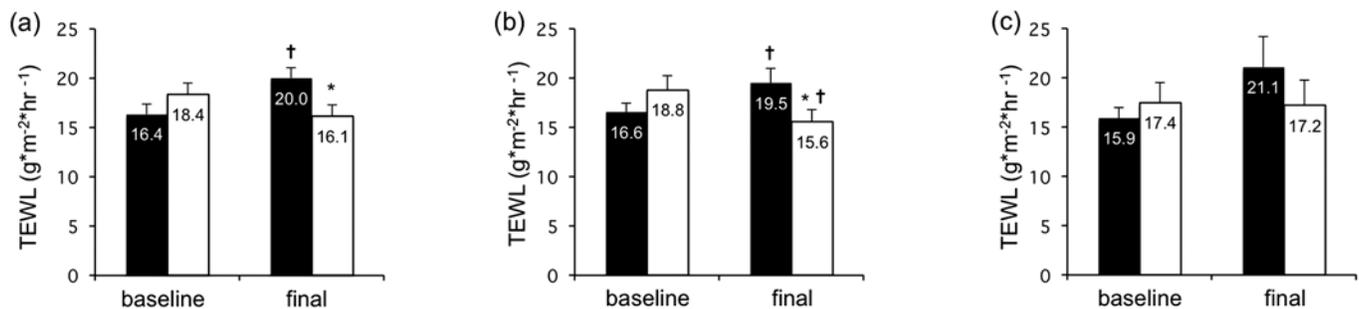


Figure 2.

Elevated vacuum suspension (EVS) lowers transepidermal water loss (TEWL) after 16 wk of use. TEWL was measured 15 min after socket doffing in people with transtibial and transfemoral amputation ($N = 10$) under standard of care (SoC) (black bar) and EVS (white bar) conditions. **(a)** TEWL as measured in all areas, **(b)** areas of high stress only, and **(c)** areas of low stress only. Data are mean \pm standard error (shown as error bars). * $p < 0.05$ SoC vs EVS within time point. † $p < 0.05$ baseline vs final within prosthesis group.

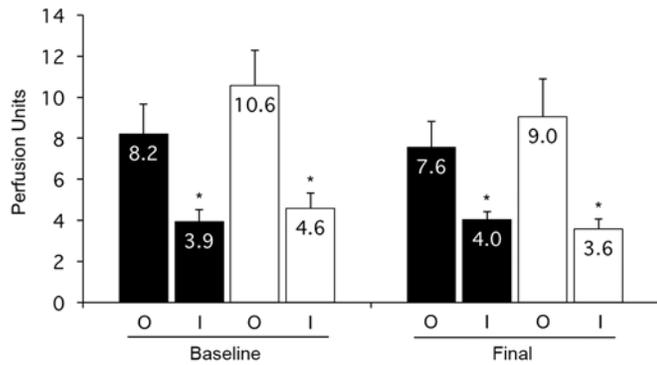


Figure 3.

Standard of care (SoC) and elevated vacuum suspension (EVS) sockets lower residual-limb perfusion at rest. Residual-limb perfusion was measured by laser doppler flowmetry out-of-socket with liner on (O) and in-socket while resting with weight bearing on the residual limb (I) under SoC (black bar) and EVS (white bar) conditions. Data are mean perfusion units \pm standard error (shown as error bar). * $p < 0.05$ O vs I within group at time point.

Standard of Care and Elevated Vacuum Suspension Lower Residual Limb Skin Perfusion at Rest

Skin perfusion was measured by LDF out-of-socket (liner only) and after donning the socket and standing with weight bearing on the residual limb at rest (**Figure 3**). SoC sockets significantly lowered residual-limb skin perfusion compared with out-of-socket values by 52.4 percent at baseline and 47.3 percent at final time points. In a similar manner, EVS sockets lowered residual-limb skin perfusion by 56.6 percent at baseline and 60.0 percent at final time points. There was no statistical difference detected in out-of-socket and in-socket perfusion measurements across suspension methods at baseline or after 16 wk of use. Furthermore, there was no statistical difference detected within prosthesis groups over time (baseline versus final).

Elevated Vacuum Suspension Rescued Against Loss of Tissue Oxygenation During Activity

Motion artifacts prohibited accurate detection of perfusion during activity by LDF (data not shown). As measured by TCOM, transcutaneous oxygen tension (TcPO₂) in SoC sockets significantly decreased during activity compared with out-of-socket resting conditions (**Figure 4**). Specifically, SoC sockets reduced TcPO₂ values by

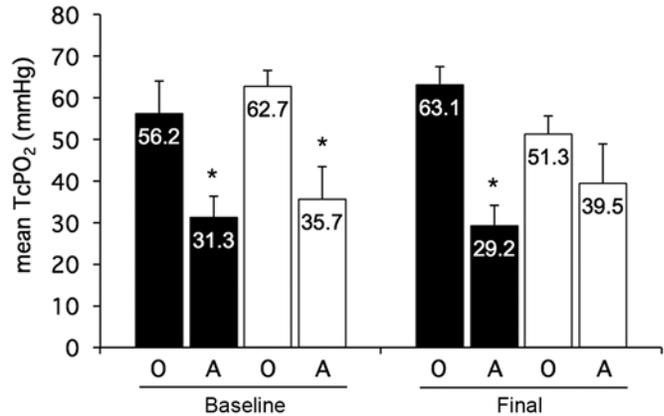


Figure 4.

Elevated vacuum suspension (EVS) rescues against loss of oxygenation after 16 wk of use. Residual-limb transcutaneous oxygen measurement (TCOM) was acquired out-of-socket with liner on (O) at rest and in-socket during activity (A) under standard of care (black bar) and EVS (white bar) conditions. Data are mean transcutaneous oxygen tension (TcPO₂) \pm standard error (shown as error bars). * $p < 0.05$ O vs A within group at time point.

44.3 percent at baseline and 53.7 percent at final time points. In EVS sockets at baseline, TcPO₂ values were reduced by 43.1 percent during activity as compared to out-of-socket values. After 16 wk of EVS use, in-socket TcPO₂ values trended lower, but there was no statistically detectable difference between out-of-socket at rest and in-socket values acquired during activity, suggesting a rescue against loss of tissue oxygenation during activity. No statistically significant difference was detected for in-socket or out-of-socket TcPO₂ values over time with EVS. However, under EVS conditions, out-of-socket TcPO₂ at rest trended lower while in-socket TcPO₂ during activity trended higher after 16 wk of use.

Elevated Vacuum Suspension Attenuated Reactive Hyperemia

Reactive hyperemia was quantified from hyperspectral images acquired pre-activity prior to socket donning and immediately postactivity within 5 min of socket doffing (**Figure 5**). At baseline there was no detectable difference in reactive hyperemia between SoC and EVS socket systems. After 16 wk of use, EVS significantly decreased reactive hyperemia in the residual limb skin by 34.7 percent as compared to SoC sockets. Of note, a

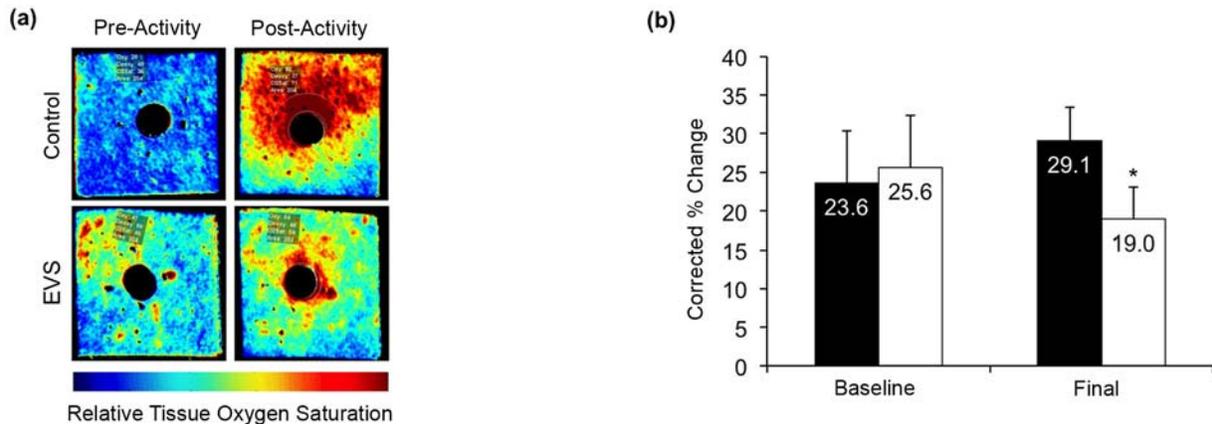


Figure 5.

Elevated vacuum suspension (EVS) attenuates reactive hyperemia. **(a)** Representative hyperspectral images acquired at the final time point from a participant with transtibial amputation pre- and postactivity. **(b)** Reactive hyperemia quantified as percent change in tissue oxygen saturation pre- and postactivity was determined in standard of care (SoC) (black bar) and EVS (white bar) socket systems at baseline and after 16 wk of use (final). Data are mean \pm standard error (shown as error bar), * $p < 0.05$ SoC vs EVS.

modest but statistically insignificant increase in reactive hyperemia was observed in SoC socket systems from baseline to final time points (**Figure 5(b)**).

DISCUSSION

Previous studies have suggested that EVS-dependent differences in the prosthetic socket residual-limb interface account for residual-limb health improvement in part by beneficial changes in residual-limb perfusion and stresses applied to the soft tissues of the residual limb. The current work was developed to directly test this knowledge gap. Of note, how the socket interfaces with the residual limb also affects gait [22], medial proximal skin pressure [15], comfort [15,22], and therefore possibly residual limb health. To eliminate socket interface as a confounding variable in the present study, the same socket design was used for SoC and EVS testing.

The physical constraints of limited space and occlusive forces for in-socket probes represent a critical barrier to characterize the physiological significance of EVS on skin health and perfusion. To overcome this barrier, we developed custom test sockets for people with TT and TF amputation that included room to embed an in-socket silicone probe holder for housing perfusion (LDF) and tissue oxygen (TCOM) measurement probes. The in-socket silicone probe holder served three important purposes:

(1) it enabled repeated measures from the same sites to be taken in study participants over time, (2) it adequately spaced the probes so as not to interfere with one another, and (3) it buffered the force of the socket from pressing the probes into the skin to prevent them from being occlusive. In preparatory studies when the gel silicone insert was not used, there was evidence of probes pressing into skin from impressions left in the residual limb after socket doffing and as evidenced by extremely low perfusion data that did not change with cuff occlusion of the residual limb. The gel silicone insert was developed in response. By the nature of the design, probes are embedded at level and parallel with the gel silicone such that they cannot be pressed into the skin. After embedding, residual-limb perfusion responded dynamically to cuff occlusion, and no visible evidence of probe impressions were observed after socket doffing. When combined with hyperspectral imaging pre- and postactivity, our approach enabled continuous assessment of residual-limb perfusion throughout the study visit.

Ulcers are the most common skin problem clinically presented in people with lower-limb amputation [23], with the incidence of chronic or chronic-recurrent ulcers as high as 50 percent in people with traumatic lower-limb amputation [24]. When encountered on the residual limb, the standard of care for ulcers typically requires disuse of the prosthesis, which negatively affects rehabilitation efforts and quality of life for people with amputation. In

extreme cases, chronic ulcers in people with amputation necessitate surgical revision of the residual limb [25–26]. Skin barrier function is a critical determinant of ulcer formation [27]. In the current study, 16 wk of EVS use preserved skin barrier function as measured by TEWL. Since vascular insufficiency is known to contribute to lower-limb ulceration [28], that EVS improves perfusion and preserves skin barrier function may be physiologically aligned.

LDF and TCOM both have a long history of clinical use to measure tissue perfusion and oxygenation, respectively, most commonly in the context of wound healing and hyperbaric oxygen studies. Notably, out-of-socket LDF and TCOM measurements have been reported in people with lower-limb amputation [29–30]. Our out-of-socket TCOM values are consistent with those that have been reported in literature [30–31]. Of note, our LDF values are also within ranges of prior publication [30] but are not directly comparable because of LDF equipment calibration techniques that employ a microsphere colloidal suspension under Brownian motion—referred to as a “motility standard.” This calibration procedure is sensitive to the exact properties of the motility standard used for that device, which is a known limitation for comparing across LDF studies [32].

Under resting conditions, we observed that both SoC and EVS sockets lowered residual-limb skin perfusion when donned. This outcome was anticipated in light of the common prosthetist fitting practice that reduces socket volume relative to the residual limb in order to create an intimate connection between the prosthesis and person. At baseline, this result was also consistent with in-socket skin oxygenation measured during activity, where SoC and EVS sockets both significantly reduced $TcPO_2$ of skin as compared to out-of-socket measurements. Strikingly, after 16 wk of EVS use $TcPO_2$ measured during activity was no longer significantly lower than out-of-socket measurements. This outcome raises the possibility that EVS enables a stable environment for adaptive vascular remodeling to occur in the residual limb over time. This hypothesis is indirectly supported by research on the biomechanical effects of EVS in attenuating pistoning [5,9–11] and contact pressure [33], where authors suggest that putative physiological benefits of EVS stem from a superior and more stable connection between person and prosthesis. Results here from hyperspectral imaging and quantification of reactive hyperemia further support this view.

Reactive hyperemia is a well-characterized physiological response indicative of ischemia and reperfusion where there is an increase in blood flow after a period of low flow or occlusion in which metabolites released during cellular respiration accumulate and increase vascular conductance [34]. Reperfusion of blood to nutrient- and oxygen-deprived tissue results in injury distinct from that caused by ischemic insult alone and has been implicated in distinct mechanisms of tissue injury that contribute to inflammation, vascular insufficiency, and ulcer formation [35]. Clinical evidence of reactive hyperemia in people with lower-limb amputation from prosthesis use dates back to 1962 [36]. Considering we observed both SoC and EVS sockets restrict blood flow to the residual-limb skin under resting conditions as measured by LDF, we were not surprised to document reactive hyperemia in the residual limb following activity and socket doffing. Of interest, however, was that after 16 wk of use, reactive hyperemia was significantly less in the EVS sockets as compared to pair-matched SoC sockets. This outcome is consistent with improved in-socket tissue oxygenation during activity after EVS use for 16 wk and taken together suggests that long-term EVS use improves perfusion to the residual limb.

Retrospective review of the current work has helped to identify limitations in our study design. One such limitation was the inability to monitor vacuum level and daily vacuum use while not in the laboratory. Compliance was based on verbal verification of use by the participant. Future work incorporating a usage monitor to quantify daily at-home vacuum use and periods of activity is warranted. Additionally, in this study subjects were permitted to self-select vacuum levels according to their own comfort. To address these limitations in the future, we are developing hardware and software revisions that include real-time recording of in-socket vacuum levels. In this way, data analysis and interpretation can be stratified on the basis of monitored vacuum level and hours of use. A second limitation of the current work is that of sample size. While statistical conclusions were objectively measured, a larger sample size would enable a more robust statistical treatment of absolute in-socket perfusion values. On the basis of outcomes reported here, power analysis to determine sample size can be performed for future studies.

CONCLUSIONS

In summary, this prospective randomized trial in people with lower-limb amputation quantitatively assesses residual-limb skin barrier function and perfusion in response to EVS. Taken together, in- and out-of-socket perfusion measurements support long-term use of EVS in improving residual-limb skin oxygenation and attenuating socket-induced reactive hyperemia. Furthermore, EVS preserved skin barrier function of the residual limb as compared to SoC after 16 wk of use. These findings suggest that in addition to improved fit and performance benefits [5–8] ascribed to EVS, long-term use may also impart physiological benefits to residual-limb health in people with lower-limb amputation.

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Author Contributions:

Study concept and design: C. Rink, H. M. Powell, R. M. Schroeder, J. A. Denune, G. M. Gordillo, J. M. Colvin, C. K. Sen.

Acquisition, analysis, and interpretation of data: C. Rink, M. M. Wernke, H. M. Powell, S. Gynawali, R. M. Schroeder, J. Y. Kim, J. A. Denune, J. M. Colvin, C. K. Sen.

Drafting of manuscript: C. Rink, M. M. Wernke, C. K. Sen.

Critical revision of manuscript for important intellectual content:

C. Rink, M. M. Wernke, H. M. Powell, S. Gynawali, R. M. Schroeder, J. Y. Kim, J. A. Denune, J. M. Colvin, C. K. Sen.

Statistical analysis: C. Rink, M. M. Wernke.

Obtained funding: C. Rink, H. M. Powell, R. M. Schroeder, J. A. Denune, G. M. Gordillo, J. M. Colvin, C. K. Sen.

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Participant Follow-Up: The authors do not plan to inform participants of the publication of this study.

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