

Standardized Approach to Quantitatively Measure Residual Limb Skin Health in Individuals with Lower Limb Amputation

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Objective: (1) Develop a standardized approach to quantitatively measure residual limb skin health. (2) Report reference residual limb skin health values in people with transtibial and transfemoral amputation.

Approach: Residual limb health outcomes in individuals with transtibial ($n=5$) and transfemoral ($n=5$) amputation were compared to able-limb controls ($n=4$) using noninvasive imaging (hyperspectral imaging and laser speckle flowmetry) and probe-based approaches (laser doppler flowmetry, transcutaneous oxygen, transepidermal water loss, surface electrical capacitance).

Results: A standardized methodology that employs noninvasive imaging and probe-based approaches to measure residual limb skin health are described. Compared to able-limb controls, individuals with transtibial and transfemoral amputation have significantly lower transcutaneous oxygen tension, higher transepidermal water loss, and higher surface electrical capacitance in the residual limb.

Innovation: Residual limb health as a critical component of prosthesis rehabilitation for individuals with lower limb amputation is understudied in part due to a lack of clinical measures. Here, we present a standardized approach to measure residual limb health in people with transtibial and transfemoral amputation.

Conclusion: Technology advances in noninvasive imaging and probe-based measures are leveraged to develop a standardized approach to quantitatively measure residual limb health in individuals with lower limb loss. Compared to able-limb controls, resting residual limb physiology in people that have had transfemoral or transtibial amputation is characterized by lower transcutaneous oxygen tension and poorer skin barrier function.

Keywords: amputation, transtibial, transfemoral, residual limb, prosthesis

INTRODUCTION

FOR INDIVIDUALS WITH lower limb loss, a prosthetic socket system serves as a rehabilitative tool to restore appearance and loss of function due to

amputation. Critical to the success of a lower limb prosthesis is the fit and comfort of the socket and liner that interface with the residual limb. By design, lower limb sockets are

typically reduced in volume as compared to the residual limb (*i.e.*, 5% global volume reduction) to ensure intimate fit for optimal control and performance. Tight fitting liners are also worn over the residual limb to improve comfort and buffer against the compressive and shear stress forces that limbs are subjected to with routine prosthesis use. Over time, however, soft tissues of the residual limb that are not accustomed to bearing body weight are repeatedly challenged by normal and shear stress associated with prosthesis use.¹ This leads to a high incidence of skin-related health problems for individuals with lower limb loss,²⁻⁵ including irritation, swelling, blisters, abrasions, corn/callus formation, and ulceration. In extreme cases where residual limb wounds do not heal, surgical revision of the amputation may be required.⁶ In that light, the health of the residual limb is also a critical determinant of prosthesis performance and rehabilitation, as individuals with limb loss that encounter skin health problems will have limited ability to continue using their prosthesis.

Quantitative measures of residual limb health are not well defined. Here, we seek to develop a methodological approach to reproducibly quantify residual limb skin health by leveraging technological advances in noninvasive imaging (hyperspectral and laser speckle imaging) and noninvasive probe-based measures of oxygenation (transcutaneous oxygen measurement [TCOM]), perfusion (laser doppler flowmetry [LDF]), skin barrier function (trans-epidermal water loss [TEWL]), and skin hydration (surface electrical capacitance [SEC]). Baseline resting measures of residual limb skin health are reported in individuals with transtibial and transfemoral amputation as compared to able-limb controls.

CLINICAL PROBLEM ADDRESSED

Skin breakdown and ulceration are problems associated with prosthesis use.²⁻⁵ Currently, there is a lack of knowledge surrounding the effects of the prosthetic socket interface on the health of the residual limb. The current work describes a standardized approach to measure salient residual limb skin health outcomes. This approach can be leveraged to design and test next-generation prosthetics or other therapeutic interventions with a focus on preserving residual limb health for individuals with lower limb loss.

MATERIALS AND METHODS

The study protocol and experimental procedures were reviewed and approved by the Institutional Review Board of The Ohio State University Wexner

Medical Center. Participants provided written informed consent according to proposal guidelines before study visits. Both able-limb control participants (AL, $n=4$) and individuals with unilateral lower limb amputation ($N=10$) were included in the study. Eligible participants were adults with a unilateral transtibial (TT, $n=5$) or transfemoral (TF, $n=5$) amputation, able to ambulate on a prosthesis (either suction or pin-locking suspension), were not diagnosed with renal failure, and did not smoke. Residual limbs of participants were inspected by a certified and licensed prosthetist for indications of skin health problems before enrollment. At the time of the study, neither prosthetist nor participant reported any residual limb skin health problems related to prosthesis use or otherwise. Subject demographics are in Table 1.

Study visits

To standardize the collection of data, all subjects followed an identical protocol of procedures to measure residual limb skin health. Out-of-socket imaging and probe-based measurements were acquired before donning a liner for probe-based in-liner measurements. Individuals with lower limb amputation were acclimated to out-of-socket resting conditions for 15 min before acquiring skin health measures (TEWL, SEC) and noninvasive imaging (hyperspectral and laser speckle flowmetry [LSF]). After imaging, participants were fitted with a gel silicone probe holder for baseline measures without the liner donned. Next, subjects donned liners and acclimated to the liner for 15 min before acquiring LDF and TCOM data. Able-limb participants wore an identical liner with the distal end cut open as a sleeve. All measures were recorded while resting in a supine position.

Probe-based measurements

TCOM and LDF were used to quantify residual limb oxygenation and perfusion respectively using a PeriFlux 5000 system (PeriMed, Inc., Stockholm, Sweden) as described.⁷ Tegaderm™, an oxygen permeable adhesive dressing, was used to seal a reservoir beneath the TCOM probe. The reservoir contained buffered saline solution for measurement of dissolved oxygen. All probes were held in place by a silicone gel insert (Fig. 1). The length of the silicone insert was cut to match the length of the residual limb for each subject.

Imaging-based measurements

Laser speckle flowmetry (LSF, PeriCam PSI NR System; PeriMed) was used to acquire perfusion maps over the residual limb under resting physiological conditions in AL, TT, and TF subjects.⁸ A

Table 1. Subject demographics

Patient ID	Group	Etiology of Amputation	Prosthesis Suspension	Years Since Amputation	Age	Gender
AL-01	Able-limb	—	—	—	26	F
AL-02	Able-limb	—	—	—	28	F
AL-03	Able-limb	—	—	—	28	M
AL-04	Able-limb	—	—	—	26	M
TT-01	Transtibial	Traumatic	Suction	15	68	M
TT-02	Transtibial	Traumatic	Pin-locking	15	42	M
TT-03	Transtibial	Traumatic	Suction	12	48	M
TT-04	Transtibial	Infection	Pin-locking	12	54	F
TT-05	Transtibial	Traumatic	Suction	11	28	M
TF-01	Transfemoral	Cancer	Pin-locking	10	67	M
TF-02	Transfemoral	Traumatic	Suction	10	30	M
TF-03	Transfemoral	Cancer	Pin-locking	17	45	M
TF-04	Transfemoral	Traumatic	Pin-locking	5	43	M
TF-05	Transfemoral	Vascular	Suction	2	46	M

F, female; M, male.

square field of view (FOV) border (35 × 35 mm) was centered over the target site of the residual limb to be used for TCOM measurements. Perfusion units were averaged over the FOV. Lower limb tissue oxygen saturation (StO₂) maps were generated using an OxyVu-2 Hyperspectral Camera (Hyper-Med, Burlington, MA).⁹ The hyperspectral camera was calibrated before each subject visit using a CheckPad and fiduciary marker provided. 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. StO₂ values were averaged over the FOV.

Skin health measurements

TEWL and SEC were measured at four unique sites across AL, TT, and TF participants using a DermaLab Combo instrument (Cortex Technology, Hadsund, Denmark).¹⁰ Measurement sites included areas of low stress (site 1 TT, sites 2 and 4 TF) and high stress (sites 2, 3, 4 TT, sites 1 and 3 TF). AL measurement sites were matched to TT sites.

Data analysis

Raw data from the LDF and TCOM probe were analyzed using semi-automated MATLAB code as the mean ± standard error (SE) value recorded during a 1-min period while in the defined resting state. Out-of-socket imaging data were analyzed using MATLAB code that averaged signal intensity

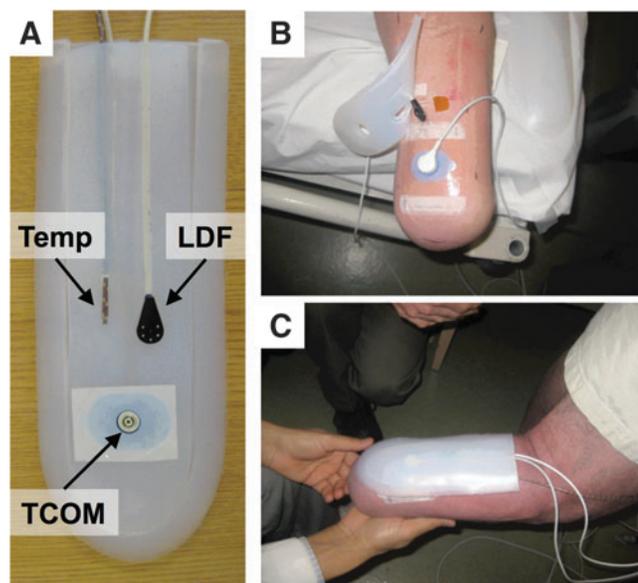


Figure 1. Silicone gel probe holder for in-liner measurement. (A) Temperature, TCOM, and LDF probes were embedded in a silicone gel insert to enable real-time measurement of limb temperature, oxygenation, and perfusion respectively. (B) Placement of probes on residual limb of transtibial participant. Oxygen permeable Tegaderm™ was used to adhere the TCOM probe to the limb. (C) The silicone gel insert enabled reproducible placement and spacing of probes and buffered against the liner from pressing probes tightly against skin. LDF, laser doppler flowmetry; TCOM, transcutaneous oxygen measurement.

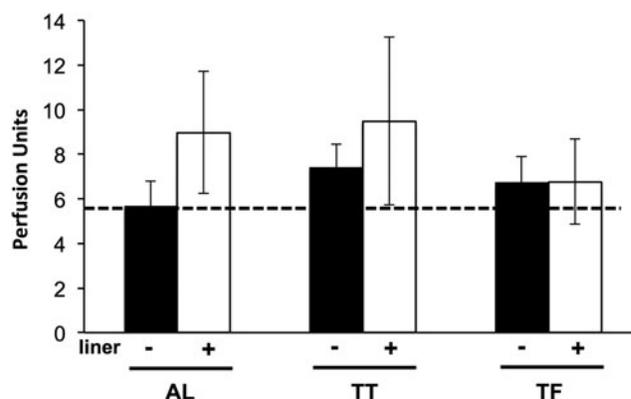


Figure 2. Laser doppler flowmetry. Limb perfusion was measured by LDF probe in able-limb (AL, n=4), transtibial (TT, n=5), and transfemoral (TF, n=5) participants while resting with liner off (-) or on (+). Data are mean ± SE. Dashed line represents mean value of AL without liner. SE, standard error.

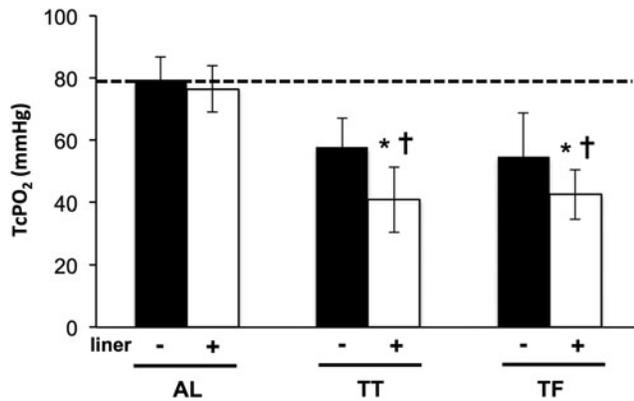


Figure 3. Transcutaneous oxygen measurement. Limb oxygenation was measured by TCOM probe in able-limb (AL, $n=4$), transtibial (TT, $n=5$), and transfemoral (TF, $n=5$) participants while resting with liner off (-) or on (+). Data are mean \pm SE. Dashed line represents mean value of AL without liner. * $p < 0.05$ versus AL (-), † $p < 0.05$ versus AL (+).

over the 35×35 mm FOV. TEWL and SEC values were recorded directly from the DermaLab Combo Instrument. All data are represented as mean \pm SE. Comparison between multiple groups was tested using analysis of variance with Tukey's *post hoc* test where $p < 0.05$ was considered statistically significant.

RESULTS

To enable reproducible probe-based measures of residual limb skin health, we developed a silicone gel insert that ensured consistent orientation and placement of probes across study subjects and buffered against the forces of the liner from pressing probes into the skin (Fig. 1). The silicone insert accommodated three probes: temperature (data not shown), LDF, and TCOM (Fig. 1A). Use of the silicone insert maintained adequate spacing and reproducible positioning of the probes from one

another. This is particularly important since the TCOM probe heats the skin surface to 43°C to cause vasodilation for the purpose of the measurement, which can otherwise interfere with the LDF measurement. The TCOM probe head is designed to lock into a small plastic reservoir filled with saline that adheres to the participant's skin by a disposable blue adhesive sticker (Fig. 1B). To maintain the integrity of the reservoir seal throughout testing conditions (liner-off and liner-on), the TCOM reservoir was adhered to oxygen-permeable Tegaderm that covered the site of measurement on the subject's skin. With the silicone insert in place, probe-based measurements could be recorded continuously with liner doffed or donned (Fig. 1C).

With the liner doffed or donned, there was no significant difference in limb perfusion within or across groups as measured by LDF (Fig. 2). Interestingly, we observed greater variability in perfusion values with the liner on. The LDF probe was highly sensitive to motion artifact that transiently increased recorded values. While subjects were measured at rest, even small movements produced large increases in LDF values that contributed to the greater standard errors observed.

Under resting physiological conditions, AL transcutaneous oxygenation measured 79.5 ± 7.4 mmHg with liner doffed and 76.5 ± 7.5 mmHg with liner donned (Fig. 3). Compared to AL controls, transcutaneous oxygen trended lower for TT and TF participants when the liner was doffed with mean TcPO₂ values of 57.8 ± 9.2 and 54.8 ± 14.0 mmHg respectively. Importantly, measured values for TcPO₂ in AL controls along with TT and TF individuals with liner doffed is consistent with physiological values reported in literature.¹¹ With liner donned, TcPO₂ was significantly lower by $\sim 50\%$ for TT and TF subjects as compared to AL controls with liner either

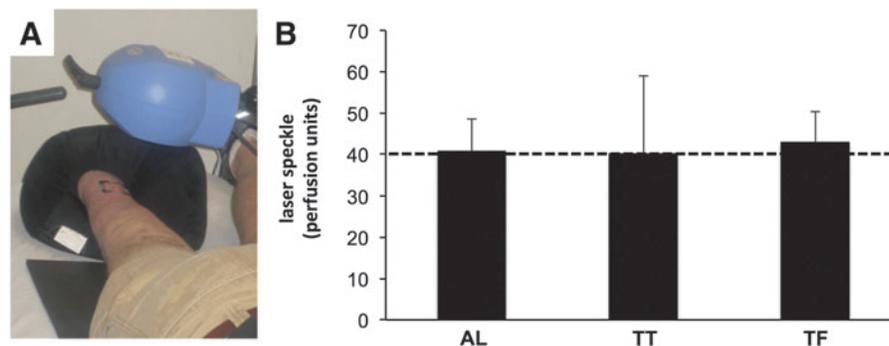


Figure 4. Laser speckle flowmetry. Skin perfusion was mapped over a 35×35 mm field of view (A) using LSF in able-limb (AL, $n=4$), transtibial (TT, $n=5$), and transfemoral (TF, $n=5$) participants while resting without a liner. (B) Relative perfusion (arbitrary perfusion units) was quantified over the field of view and averaged across subjects within groups. Data are mean \pm SE. Dashed line represents mean value of AL participants. LSF, laser speckle flowmetry.

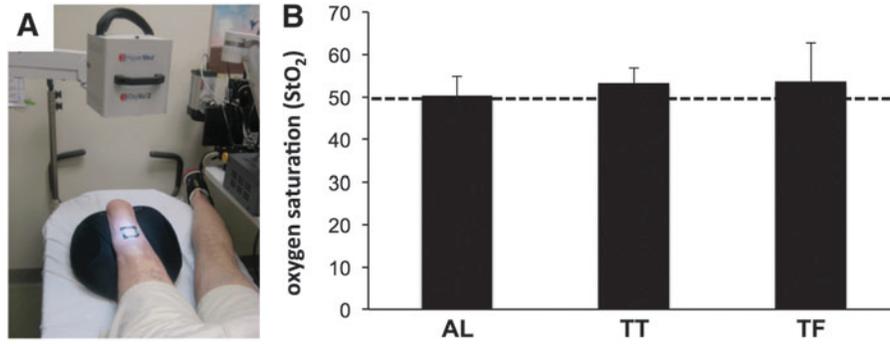


Figure 5. Hyperspectral imaging. Skin oxygen saturation was mapped over a 35×35 mm field of view (A) using a hyperspectral camera in able-limb (AL, n=4), transtibial (TT, n=5), and transfemoral (TF, n=5) participants while resting without a liner. (B) Oxygen saturation (StO₂) was quantified over the field of view and averaged across subjects within groups. Data are mean ± SE. Dashed line represents mean value of AL participants.

donned or doffed (41.0±10.4 and 42.6±7.9 mmHg respectively, Fig. 3).

Laser speckle and hyperspectral imaging were performed under resting conditions with images acquired from sites that covered areas used for probe-based measures (Figs. 4A and 5A). Consistent with LDF measurement, no significant dif-

ference was detected in skin perfusion as measured by LSF (Fig. 4B). Oxygen saturation, as measured by the hyperspectral camera, was also unchanged across AL, TT, and TF subjects (Fig. 5B).

TEWL, a measure of skin barrier integrity, was measured at four distinct sites representing areas of high- and low-stress for prosthesis contact with

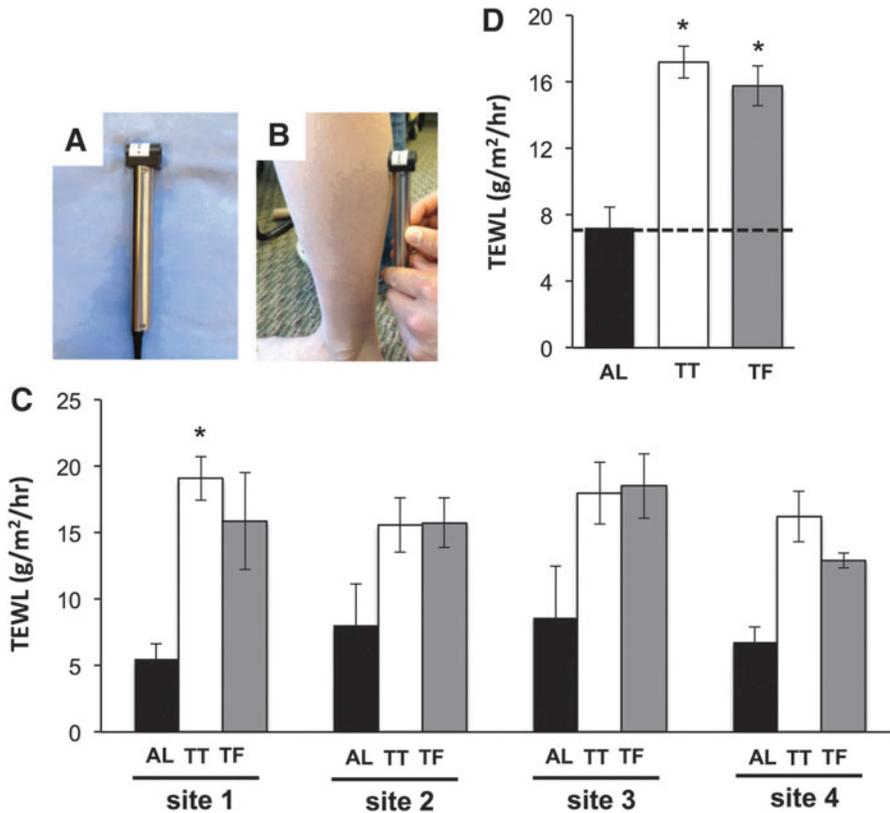


Figure 6. Transepidermal water loss. (A and B) Loss of water through the skin epidermal layer was measured by TEWL probe in able-limb (AL, n=4), transtibial (TT, n=5), and transfemoral (TF, n=5) participants while resting without a liner. Four sites of measure were acquired representing regions of low stress (site 1 TT, sites 2 and 4 TF) and high stress (sites 2, 3, 4 TT, sites 1 and 3 TF) for amputees. AL measurements were matched to TT sites. (C) Mean ± SE TEWL (g/m²/h) for sites in AL, TT, and TF groups. (D) Mean ± SE TEWL for all sites across groups. Dashed line represents mean value of AL without liner. *p<0.05 versus AL. TEWL, transepidermal water loss.

skin (Fig. 6). AL measurement sites were matched to those of TT subjects. No significant difference was detected in TEWL values across sites of measure. Within individual sites, TEWL values were significantly higher at site 1 when comparing AL and TT participants (Fig. 6C). For AL controls, TEWL across all sites averaged $7.2 \pm 1.2 \text{ g/m}^2/\text{h}$ (Fig. 6D). This value is consistent with physiological lower extremity TEWL values reported in literature.¹² In TT and TF subjects, average TEWL values across all sites were significantly higher than AL controls ($2.4\times$ and $2.2\times$ respectively, Fig. 6D). In TT participants, the average TEWL value was $17.2 \pm 1.0 \text{ g/m}^2/\text{h}$. In TF individuals, the average TEWL value was $15.8 \pm 1.2 \text{ g/m}^2/\text{h}$.

SEC, a measure of skin surface hydration, was measured at sites matched to TEWL (Fig. 7). SEC values trended higher for TT and TF subjects compared to AL controls at each site, but were not significantly different. When averaged across all sites (Fig. 7D), SEC was significantly higher in TT ($248.6 \pm 36.6 \mu\text{S}$) compared to AL controls ($79.8 \pm 5.7 \mu\text{S}$), but lower in TF ($157.4 \pm 11.2 \mu\text{S}$) as compared to TT participants.

DISCUSSION

Following lower limb amputation, a common rehabilitative goal is to return patients to a normal, productive lifestyle by restoring loss of function through the use of a prosthesis. For the 1 million+ Americans who live with lower limb amputation,¹³ a growing number of which are service men and women,^{14–16} the rehabilitative potential to return to an active lifestyle depends on their ability to use a prosthetic limb. To that end, the health of the residual limb is a critical determinant of prosthesis performance (in some cases use) that impacts quality of life for people with lower limb loss. Indeed, individuals with lower limb loss that experienced residual limb skin health problems reported a negative influence in their ability to perform household tasks, use a prosthesis, engage in social functions, and participate in sports.⁴ These quality of life indicators correlated significantly with the number of residual limb skin complaints.

To date, measures of prosthesis performance have focused primarily on fit, biomechanical gait outcomes, and self-reported user comfort and quality of life scores. While these characteristics

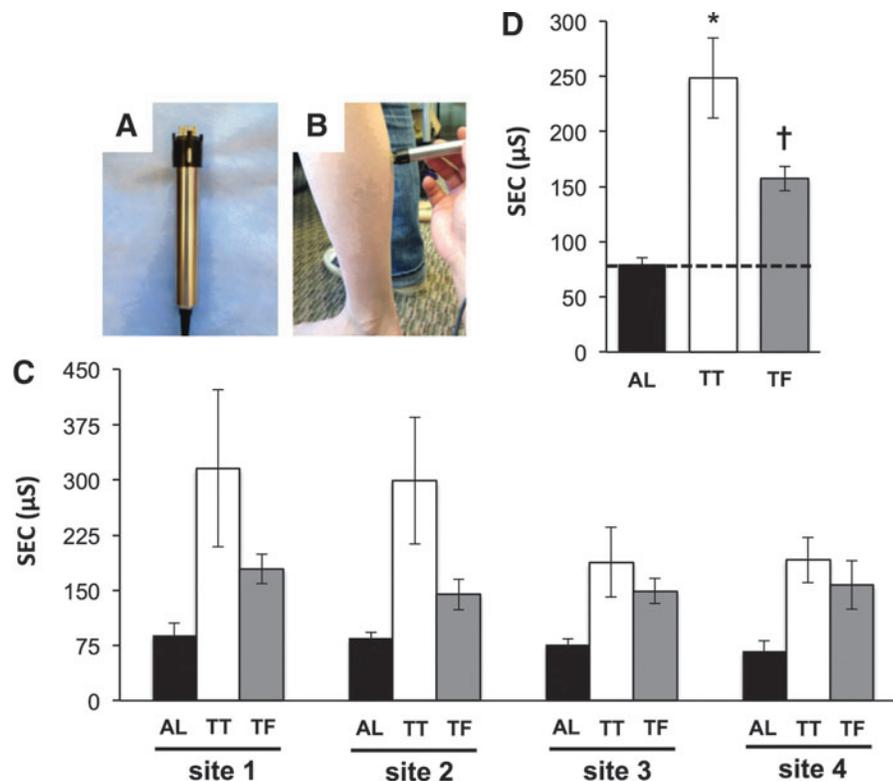


Figure 7. Surface electrical capacitance. (A and B) Skin hydration was measured by SEC probe in able-limb (AL, $n=4$), transtibial (TT, $n=5$), and transfemoral (TF, $n=5$) participants while resting without a liner. Four sites of measure were acquired representing regions of low stress (site 1 TT, sites 2 and 4 TF) and high stress (sites 2, 3, 4 TT, sites 1 and 3 TF) for amputees. AL measurements were matched to TT sites. (C) Mean \pm SE hydration (μS) for sites in AL, TT, and TF groups. (D) Mean \pm SE hydration for all sites across groups. Dashed line represents mean value of AL without liner. * $p < 0.05$ versus AL, † $p < 0.05$ versus TT. SEC, surface electrical capacitance.

are undoubtedly important and likely affect residual limb health, studies have yet to directly address quantitative measures of residual limb skin health as a critical component of successful prosthesis rehabilitation. This work seeks to address this gap by presenting a standardized approach to quantitatively measure residual limb health outcomes in individuals with lower limb loss. Results are reported from amputees without residual limb skin health problems at the time of measurement. Notably, even without observable or self-reported residual limb health problems in our sample of TT and TF participants, there are clear differences in the skin health outcome measures of residual limbs as compared to AL controls. TCOM values of TT and TF participants under resting conditions were roughly half those of AL controls. Furthermore, skin barrier function of individuals with lower limb loss as measured by TEWL and SEC was significantly worse as compared to AL controls, lending credence to observations that residual limb skin is much more susceptible to breakdown and ulceration due to the repeated stress from prosthesis use.²⁻⁴ To that end, it is not surprising then that the prevalence of active skin problems in the residual limb of people with lower limb loss is as high as 36%.¹⁷

A growing body of literature is focused on how prosthesis suspension affects fit and performance in people with lower limb loss.¹⁸⁻²⁰ We recently reported on the beneficial effects of elevated vacuum suspension as they relate to residual limb health in TT and TF subjects.²¹ In light of the small sample size employed in the current study, outcomes were not stratified according to suspension type. Future efforts will be focused to investigate the relationship between suspension type and residual limb skin health.

This work is not without limitations. The average age of AL subjects was considerably younger than those of TT and TF participants against which they were compared. However, we noted that when comparing data directly between the youngest TT (28) and TF (30) participants to the AL controls, the statistically treated trends and observations of the entire group still hold (*i.e.*, mean AL TEWL across all sites = $7.2 \pm 1.2 \text{ g/m}^2/\text{h}$, 28 year old TT TEWL across all sites = $16.7 \pm 3.1 \text{ g/m}^2/\text{h}$, 30 year old TF TEWL across all sites = $19.8 \pm 4.2 \text{ g/m}^2/\text{h}$). Furthermore, the sensitivity of the LDF probe to motion artifact (even under resting conditions) raises concern as to whether LDF can reproducibly acquire meaningful data in our subject population. Additional consideration to limit motion artifact and/or report LDF variance over a time interval (*i.e.*, 10 s recording window) is warranted in future work.

KEY FINDINGS

- A standardized approach to quantitatively assess residual limb skin health in individuals with lower limb loss is presented.
- Residual limb transcutaneous oxygen tension was significantly lower in participants with lower limb loss as compared to able-limb controls.
- Individuals with lower limb loss had significantly higher TEWL and SEC in residual limb skin as compared to able-limb controls, indicative of skin barrier disruption.

In closing, this work presents a standardized approach to measure residual limb health outcomes using noninvasive imaging and probe-based approaches in people with lower limb loss. Resting physiological values for TT and TF participants that were not reporting any skin health problems at the time of measure indicate that the residual limb is more susceptible to skin barrier disruption (as measured by TEWL and SEC) and lower transcutaneous oxygen tension (as measured by TCOM).

INNOVATION

Residual limb health is a critical determinant of rehabilitative success for individuals with lower limb loss that use a prosthesis. This work is the first to describe a systematic approach to quantitatively measure residual limb health using noninvasive measures of tissue perfusion, oxygenation, and skin barrier function. Baseline measures from individuals with limb loss that use a prosthesis serve as reference values. As compared to able-limb controls, we observed lower transcutaneous oxygen tension in residual limb skin of participants with lower limb loss and greater risk for skin barrier disruption as indicated by higher TEWL and SEC.

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AUTHOR DISCLOSURE AND GHOSTWRITING

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Abbreviations and Acronyms

AL	= able-limb
FOV	= field of view
LDF	= laser doppler flowmetry
LSF	= laser speckle flowmetry
SEC	= surface electrical capacitance
StO ₂	= oxygen saturation
TCOM	= transcutaneous oxygen measurement
TEWL	= transepidermal water loss
TF	= transfemoral
TT	= transtibial