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Residual Limb Health and Prosthetics

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Abstract

The residual limb of individuals with lower limb loss is dynamic tissue that is susceptible to both acute and chronic changes to limb volume and health over time. Changes in residual limb volume that affect socket fit may contribute to maladaptive gait patterns and deleterious changes to the socket/limb interface that increase harmful shear stress and contributes to residual limb skin injury. Current socket systems are static and lack the ability to provide end-users and prosthetists with patient-centric data about changes in socket fit over time. There is a need for objective clinical decision-making that results in greater prosthesis usage, improved residual limb health, and better comfort ratings for end-users. Among the socket systems available in the market, the elevated vacuum suspension system improves residual limb skin oxygenation, attenuates socket-induced reactive hyperemia and preserves skin barrier function. This suggests that such a system is compatible with imparting physiological benefits to the residual limb in people with lower limb amputations.

Keywords: amputation, prosthesis, residual limb health, transepidermal water loss, surface electrical capacitance, skin barrier, perfusion

1. Introduction

Prosthetics are artificial substitutes for body parts lost through congenital defects, injury (accident or combat-related) or disease. These devices can be worn on the outside of the body or surgically implanted and are made of a variety of materials that may serve a cosmetic and/or functional purpose. They have evolved from simple fiber-based appendages (ancient Egypt) to the sophisticated lower limb “blades” and bionic arms that enable amputees to transcend barriers to their activities. Prosthetics today are strong and light, made of aluminum, plastic or composite materials that are better molded to the patient limb. Furthermore, the advent of microprocessors, computer chips and robotic technology provide a range of motion that fits the lifestyle choices of the amputee.

Achieving a comfortable and functional connection between an amputee and their prosthetic limb is critical to the success of the prosthesis. Therefore, the socket system is the most significant component for overall success of the prosthesis [1, 2]. Plaster wraps or computer aided designs are the primary means to custom fit sockets to maximize socket performance and comfort without adversely affecting residual limb health (**Figure 1**). Currently, the lack of quantitative feedback to determine appropriate socket fit is a major drawback in this process. Prosthetists use anecdotal visual cues

combined with subjective verbal feedback from patients to minimize suspension-dependent movement between the socket and residual limb. This subjective information is used to revise socket parameters such as volume, geometry, and type of suspension to provide a “best” fit for the amputee. In day-to-day living, the volume of mature residual limb (>18 months postamputation [3]) are subject to short-term [4] and long-term [5, 6] changes in volume that compromise socket fit and performance.

More than 80% of amputations in the U.S. are the result of complications from vascular disease and diabetes [7, 8]. Less than 10% of lower-limb amputation results from trauma [9]. In the US, among those that live with a lower-limb amputation, a growing number of which are Service men and women [10–12], the limb volume changes adversely affect fit, performance, and residual limb health [6]—including skin breakdown and ulceration [13] (**Figure 1**) that can require surgical revision of the amputation. The requirement for surgical revision is known to be as high as 30% [14]. This review primarily focuses on skin health in the residual lower limb and the need for objective monitoring and evaluation of changes at the interface of the biological entity (limb skin) and the artificial entity (prosthetic limb) for sustained optimal limb health. Similar issues could apply to the residual upper limb.

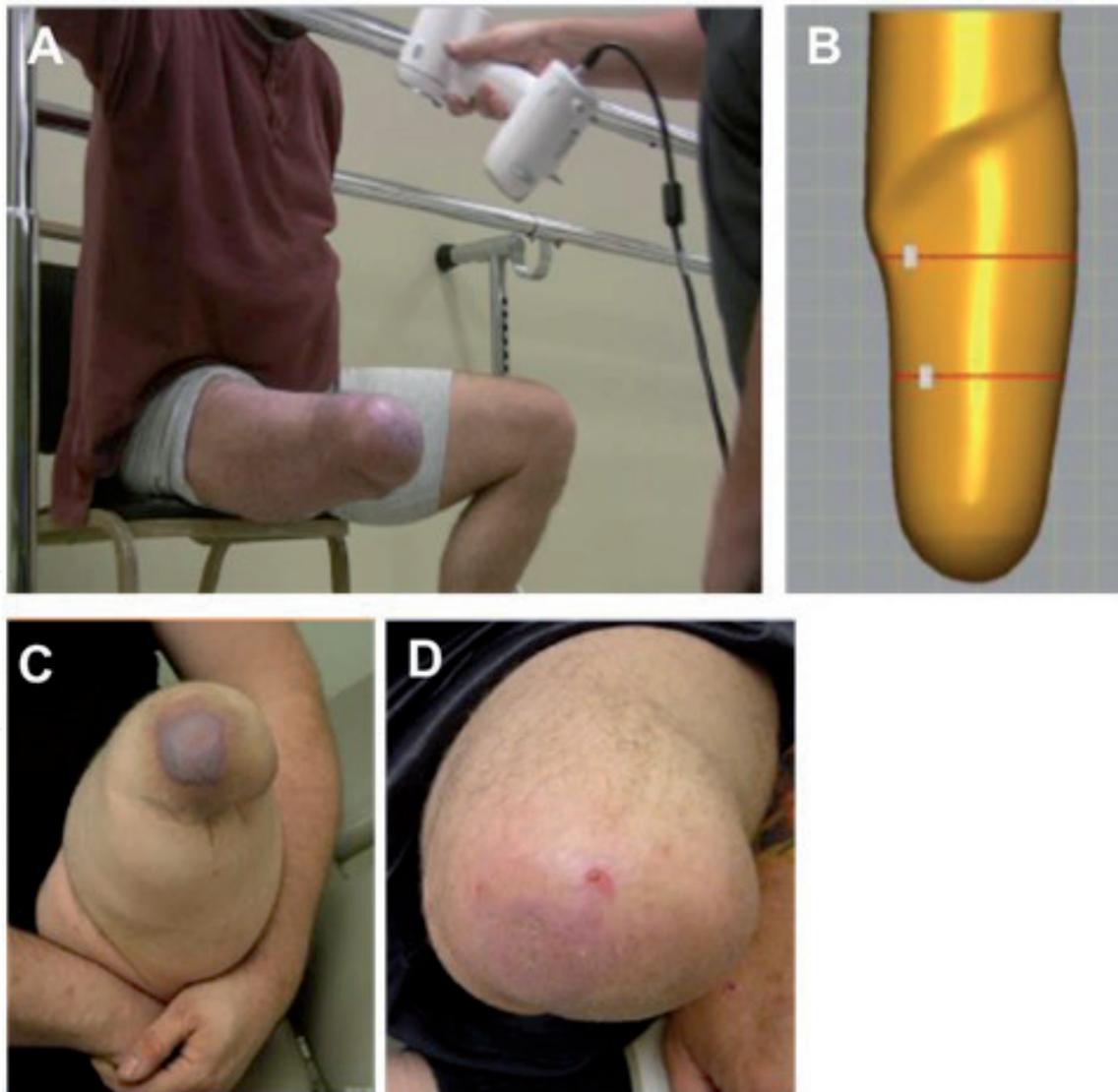


Figure 1.

(A) Prosthetists use a scanning device to digitize limb shape. (B) Digital model is modified to create a positive mold for socket fabrication tailored to the residual limb. (C) Tissue injury as a result of using a pin-locking suspension system. (D) Injury healed once the amputee was fit and began wearing an elevated vacuum suspension socket (EVS).

2. Overview of the prosthetic lower limb

2.1 Components

There are two main types of prosthetics that replace a partial or complete loss of the lower limb and these include: (a) below the knee or transtibial (TT), where a prosthetic lower leg is attached to an intact residual upper limb, (b) above the knee or transfemoral (TF), where a prosthesis replaces the upper and lower leg and knee. Each of these types of prostheses is composed of key parts: the prosthetic limb, a socket (interface between the biological component (e.g., patients' body) and the artificial limb), the attachments and the control system.

2.2 Socket systems

The piece that interfaces between the residual limb/body part and the artificial limb is called the socket and is typically molded around a plaster cast taken from the residual limb. A range of suspension systems are available for use on amputees and the choice of socket primarily depends on subjective information obtained by the prosthetist. The fit of a socket has to be precise or the artificial limb may cause discomfort or tissue damage resulting in the inability to wear the prosthesis for a time and leading to surgical interventions.

The most common systems in use are pin/shuttle lock, suction, and vacuum. The pin/lock system uses a padded liner with a pin on the end which is inserted into a shuttle lock built into the bottom of the connecting socket. A modification of this system is the lanyard, which connects the socket to the liner and limits shear and rotation. The suction system has a soft liner, a one-way valve and a sealing valve. Suction enables even adhesion to the interior surface of the socket and lowers the friction and shear. The vacuum system actively creates a seal around the socket and liner and enhances the adhesion of the limb to the socket, thereby regulating residual limb volume changes and promoting better circulation and reduced shear. The pin-lock is most popular but is associated with issues such as bell clapping (lateral displacement), pistoning (vertical displacement) (**Figure 2**) and distal tissue stretching (milking) which result in complications such as gait asymmetry, skin sores, and stump pain at the distal end. Suction and vacuum systems help minimize these complications and are currently popular (~95%) among Service Members and veterans with limb loss.

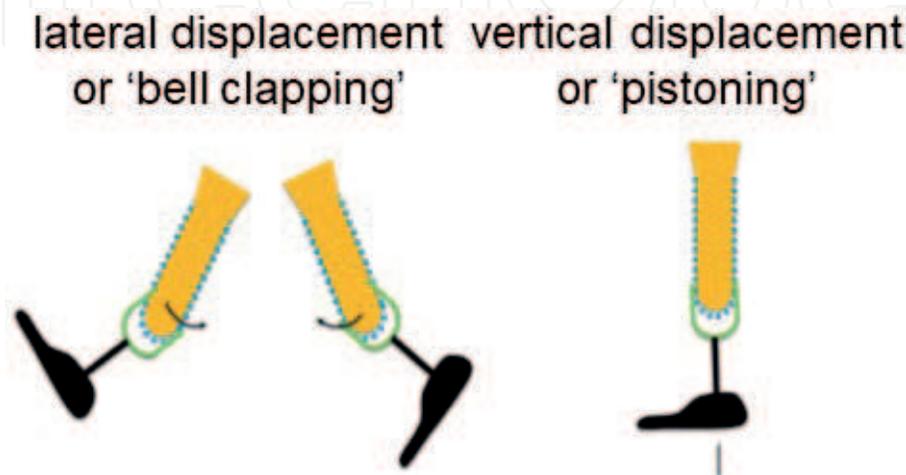


Figure 2. Classification of residual limb movement within the socket. The timing and waveform profile are distinct in each of these types of movements.

2.3 The socket/limb interface

The importance of the socket/limb interface has been highlighted in several published reports. The primary concerns reported from prosthesis users include the fit of the artificial limb and comfort. A study by Klute et al., identified that the time-consuming prosthesis fitting process can contribute to excess pressure and friction on the residual limb, resulting in skin and deeper tissue damage and related pain and discomfort [15]. The outcome of this study emphasized the need for a fitting process that included objective measures to complement and improve user feedback.

Several studies employing radiological [15–17], acoustic [18], and optical [19] approaches have been used to analyze the movement of the residual limb within the socket of lower limb systems. These have numerous shortcomings primarily related to lack of clinical translatability and testing capability in a limited range of movements. The LimbLogic[®] vacuum system developed as a result of a Veterans Affairs (VA) grant funded collaborative work with Ohio Willow Wood was commercialized for clinically relevant quantification of prosthetic socket performance. Elevated vacuum suspension (EVS) [20, 21] (**Figure 3**) creates subatmospheric pressure between the prosthetic socket and liner worn over the residual limb. Studies performed with this system identified that variances among individuals may be a result of different gait styles, tissue types, residual limb geometries, prosthesis weight distribution, and socket fit. The results demonstrated that elevated vacuum pressure data provide information to quantify initial socket fit and monitor changes from an initial set point. The correlation between displacement and vacuum pressure fluctuation was dependent on socket fit. In general, higher vacuum pressure settings resulted in the lower amounts of displacement and vacuum pressure fluctuation within each socket fit condition. However, the rates of decreases created distinct trends in the data that correlated to particular fit conditions.

Therefore, the effectiveness of lower limb prosthesis is largely measured by its ability to minimize in-socket movement of the residual limb, conserving residuum health. Movement of the residual limb within the prosthetic socket contributes to increased risk of skin ulceration [22]. Technological advancements in residual limb scanning and socket manufacturing have empowered prosthetists to design and

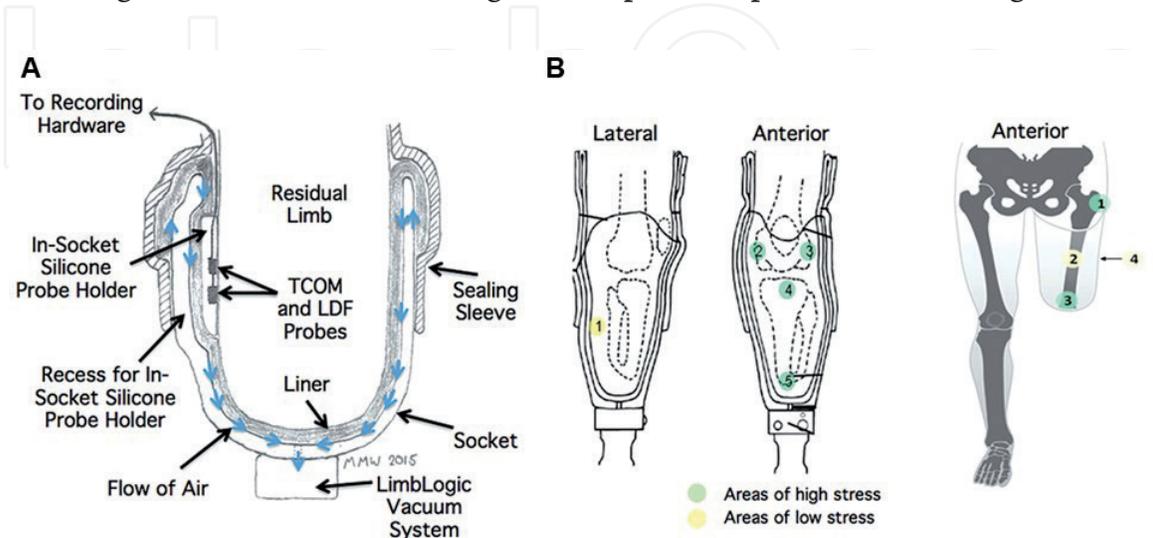


Figure 3. Elevated vacuum suspension schematic and probe measurement points. (A) Illustration of test socket with recess for in-socket silicone probe holder. (B) Residual-limb measurement sites. Green and yellow indicate measurement sites of high and low stress, respectively. LDF = laser Doppler flowmetry, TCOM = transcutaneous oxygen measurement (reprinted with permission from Rink et al. [20]).

fit customized sockets that account for unique amputee residual limb shape and volume. However, unlike the rigid socket that is fixed in geometry and volume, the morphometry of the residual limb is dynamic. Mature residual limbs experience diurnal changes in volume of up to 2% [4] because of a number of factors including activity level, ambient environment, body composition, dietary habits, and hormones [6]. Furthermore, chronic remodeling of a mature residual limb can result in even greater (~10%) volume changes over the course of weeks [23] and months [5]. Thus, socket fit and residual limb movement in the socket are subject to time-dependent changes. Because socket movement increases risk of residuum dermal injury and ulceration [22], there is a clear need to evaluate the efficacy of using a socket monitoring system that can quantify residual limb movement inside the socket to aid in the socket fitting process. Such a system has the potential of minimizing risk to residual limb health [6] while maximizing functional performance.

3. Residual limb health

3.1 Issues with prosthesis fitting

Achieving a comfortable and functional connection between an amputee and their prosthetic limb is critical to the success of the prosthesis. Therefore, the socket system is the most significant component for the overall rehabilitative success of the prosthesis [24, 25]. Socket comfort is achieved by appropriately loading and off-loading the residual limb, where the optimal biomechanical performance of the prosthesis is achieved by transfer motions of the residual limb without loss or excess motion to the prosthesis. In an effort to maximize socket performance and comfort without adversely affecting residual limb health, a prosthetist custom fits a socket for every patient using plaster wraps or computer aided design. Currently, this process suffers from a lack of quantitative feedback to determine appropriate socket fit. Prosthetists aim to create a comfortable and intimate socket interface, but current approaches are limited as they rely on anecdotal visual cues along with subjective verbal feedback from the patient. Prosthetists then use this information to revise socket parameters such as volume, geometry, and type of suspension to provide a “best” fit for a patient.

In light of the subjective inputs that currently inform prosthesis form, fit, and therefore function, there is a clear need to provide objective measures to optimize prosthesis fitting and provide continual feedback to both end-user and prosthetist as the residual limb volume and shape are susceptible to change over time. Under the current paradigm of prosthetic socket fitting, inadequate and/or misinformation communicated to the prosthetist can lead to sub-optimal fit and comfort of the prosthetic system. This contributes to repeat clinical visits to rectify areas of discomfort, or in more extreme cases rejection of the prosthesis and preference toward other assistive devices such as wheelchairs. Two surveys administered to lower limb prosthesis users indicated a high prevalence of skin sores or irritation occurring within the socket, with fit likely being a contributing factor [24, 25]. If left unresolved, such limb health issues may necessitate disuse of the prosthesis.

3.2 Injuries of the residual limb

Most amputees have an active and satisfying quality of life with a majority that wear a prosthesis at least 7 h a day to aid in mobility and everyday living. An improper fit or alignment, lack of adequate gait training and development of poor

habits are common features of a vast majority of amputees who use a prosthesis resulting in at least one deviation or problem. The increased load or weight is often placed on the intact limb as a result of these deviations can cause discomfort or pain in the joints and lead to some form of degenerative joint disease or disability in extreme cases. Three of the most common secondary complications in lower-limb amputees due to compensatory and/or altered stresses are osteoarthritis, osteoporosis and back pain.

About 75% of patients with lower-limb prosthetics have skin problems [26, 27]. The lack of a normal pressure-distributing anatomy the residual limb is prone to issues such as elevated shear forces, stress risers, increased humidity, and prolonged moist contact within the prosthesis, which can contribute to ulceration. Ulcers or pressure sores, are the most common skin conditions in prosthetic users [24]

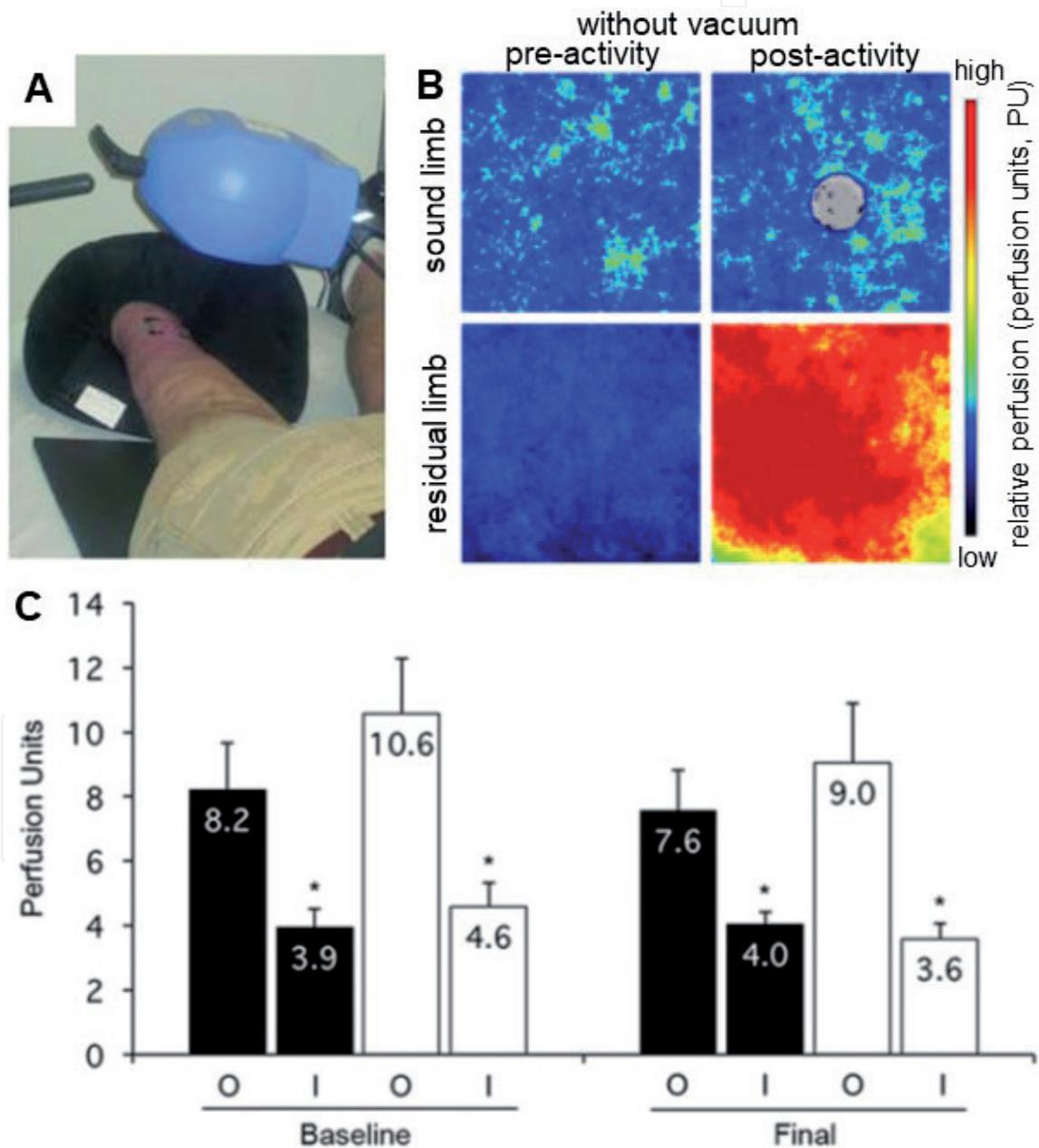


Figure 4. Laser speckle imaging (LSI) for skin perfusion. (A) Black box over trans-tibial amputee represents field of view (FOV) for perfusion mapping and quantification. (B) Representative perfusion maps acquired pre- and post-activity (over-ground walking) in sound and residual limb. (C) Perfusion 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 SE (shown as error bar). * $p < 0.05$ O vs I within gp at time point (reprinted with permission from Rink CL et al. [33]).

and can vary in size and magnitude requiring prolonged recovery time out of the prosthesis, a new socket fitting and sometimes surgical interventions [26, 27].

3.3 Preserving residual limb health

Skin ulcers are typically the end result of vascular insufficiency and improper skin barrier function. Reperfusion of blood, as seen in reactive hyperemia, to nutrient- and oxygen-deprived tissue is another causative factor of tissue injury that contributes to ulcer formation [28]. In lower-limb amputation, this was identified

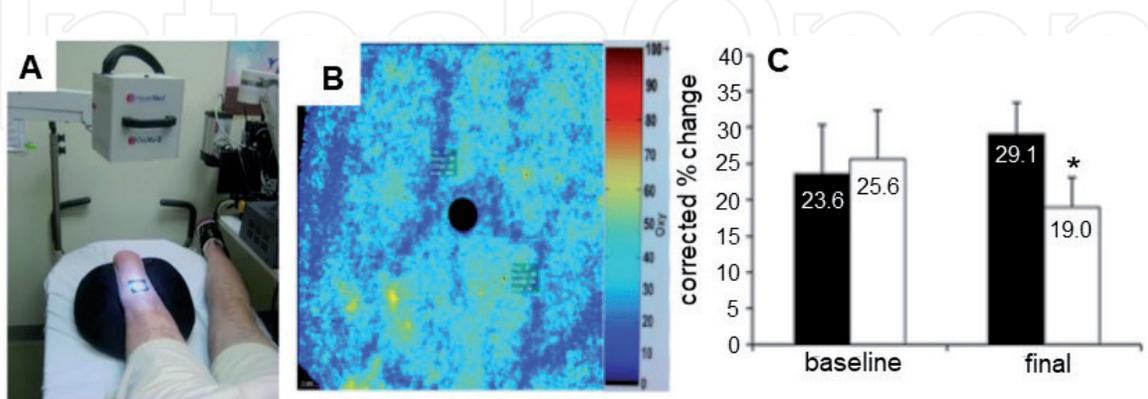


Figure 5. Hyperspectral imaging for skin oxygen saturation. (A) Black box represents field of view (FOV) for qualification of tissue oxygen saturation (StO_2) in residual limb. (B) Representative oxygen saturation map. (C) Reactive hyperemia quantified as percent changed in tissue oxygen saturation pre- and postactivity was determined in standard of care (SoC) (black bar) and EVS (white bar) socket systems at baseline and after 16 weeks of use (final). Data are mean \pm SE (shown in error bar), * $p < 0.05$ SoC vs. EVS (reprinted with permission from Rink et al. [33]).

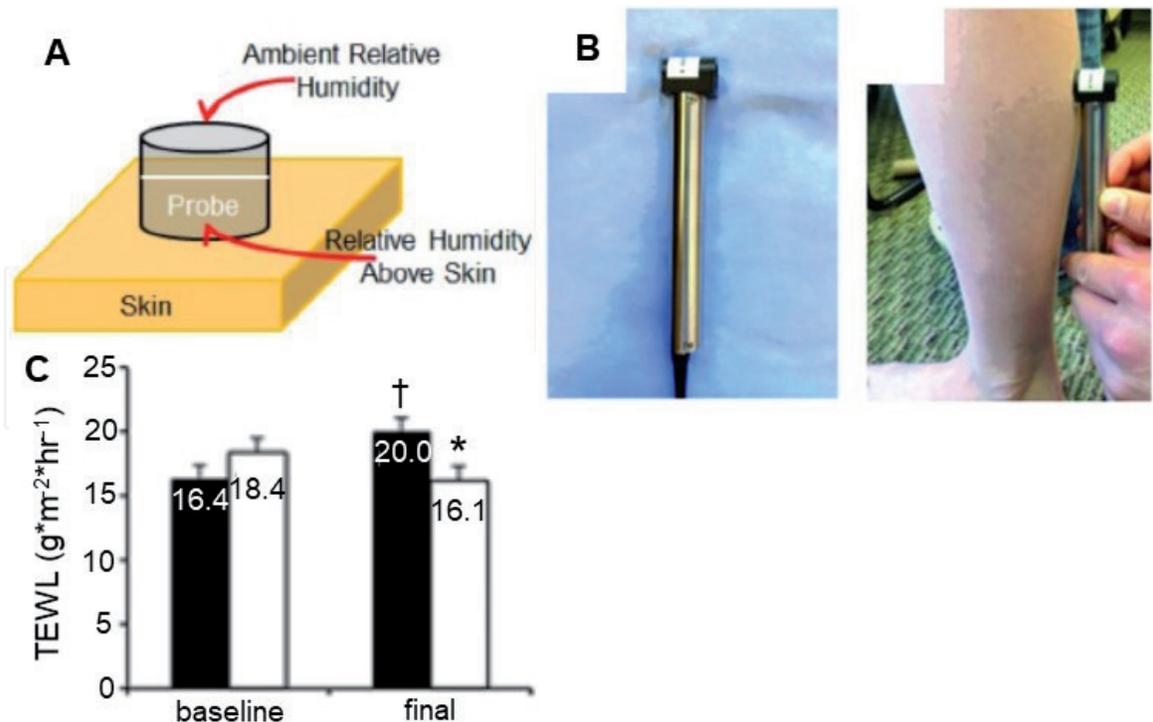


Figure 6. Transepidermal water loss (TEWL) for skin barrier function. (A) Schematic of TEWL probe over the skin as it measures differences between relative humidity of ambient air and directly above skin. (B) Photograph of a TEWL measurement. (C) TEWL was measured 15 min after socket doffing in people with transtibial and transfemoral amputation ($n = 10$) under standard of care (SoC) (black bar) and EVS (white bar) conditions. Data shown are from areas of high stress and low stress combined. Data shown are from areas of high stress and low stress combined. Data are mean \pm SE (shown as error bars). * $p < 0.05$ SoC vs. EVS within time point. † $p < 0.05$ baseline vs. final within prosthesis group (reprinted with permission from Rink et al. [33]).

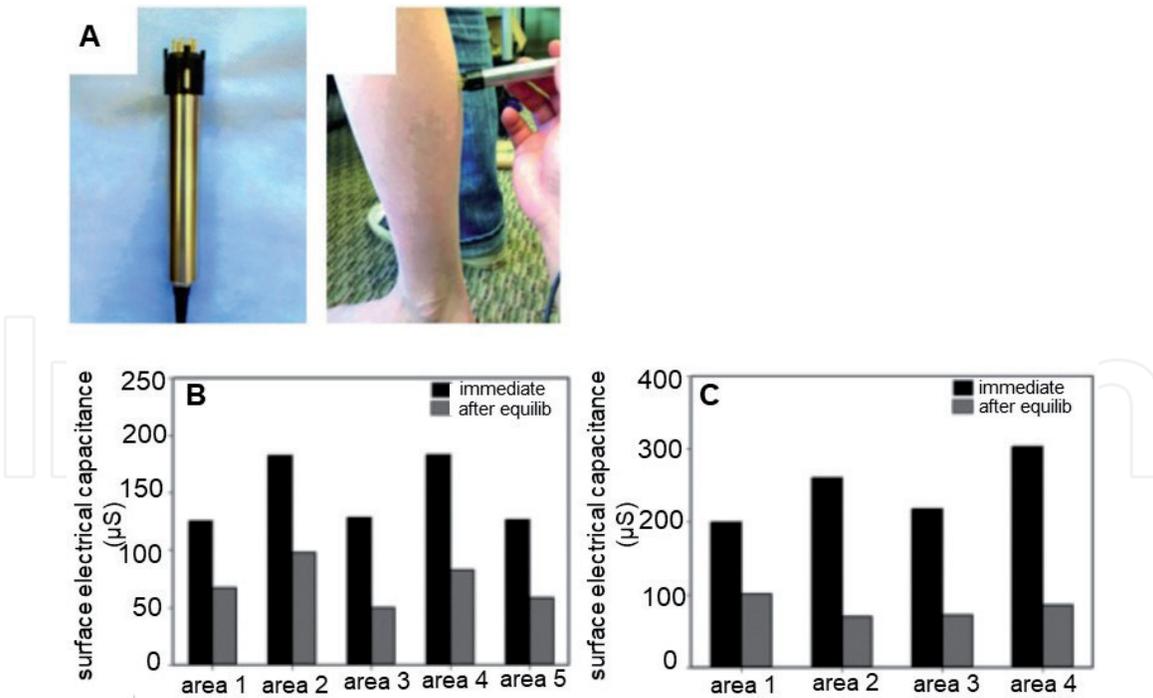


Figure 7. Surface electrical capacitance for skin hydration. (A) Close-up view of SEC probe. Photograph of SEC measurement collection from a subject. SEC measurements from (B) transtibial and (C) transfemoral subjects immediately after liner removal and after equilibration with air for 15 min (reprinted with permission from Rink et al. [33]).

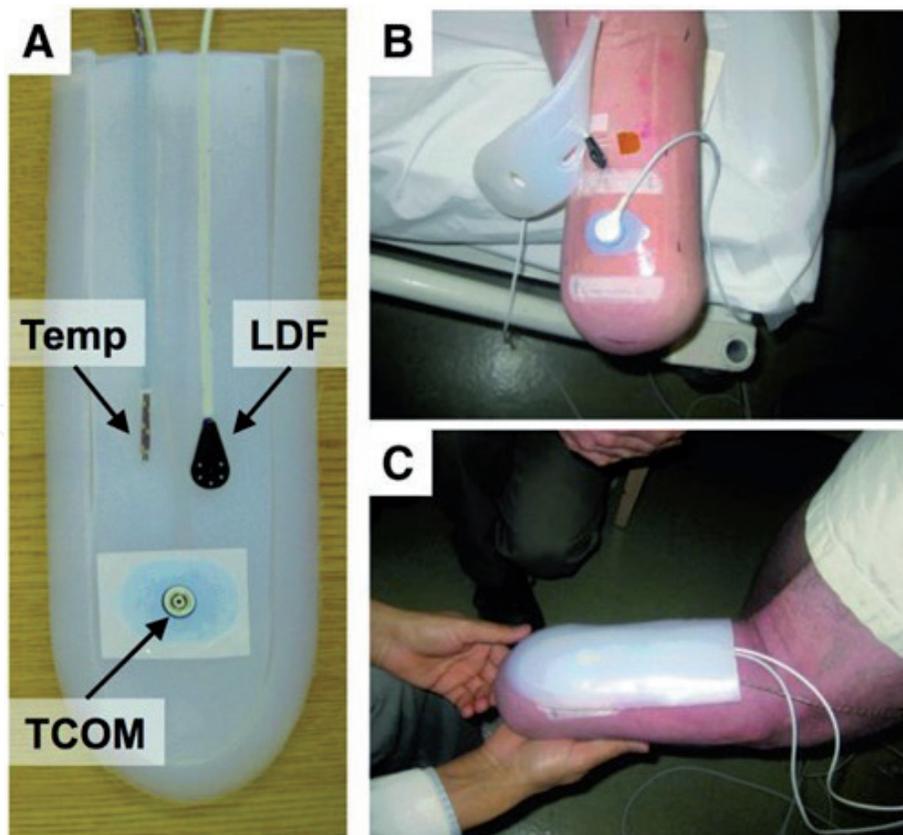


Figure 8. Silicone gel probe holder for in-liner measurement. (A) Temperature, transcutaneous oxygen measurement (TCOM) wand laser Doppler flowmetry (LDF) probes were embedded in a silicone gel insert to enable real-time measurement of limb temperature, oxygenation, and perfusion respectively. (B) Placement of probes on residual limb of transtibial participant. Oxygen permeable TegadermTM 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 (reprinted with permission from Rink et al. [33]).

as a complication of prosthesis use in the early 1960s [29]. Key among the factors to monitor in attempting to preserve and promote residual limb health would be maintenance of skin barrier function, perfusion and oxygenation.

There are few examples of evidence based research related to the effect of socket systems, particularly elevated vacuum suspension systems on limb health [30–32]. A recent study was the first to directly test the effect of EVS on residual-limb skin health and blood flow [20]. This study used a standardized non-invasive imaging (**Figures 4-7**) approach with a combination of out-of-socket imaging (e.g., hyperspectral imaging, transepidermal water loss (TEWL) and surface electrical capacitance (SEC)) and in-socket imaging (e.g., transcutaneous oximetry (TCOM), laser Doppler flowmetry (LDF)) [20, 33]. Outcomes of this study identified that elevated vacuum suspension socket systems promote better residual limb skin physiology by preserving the skin barrier function (TEWL measurements), rescuing against loss of tissue oxygenation during activity and attenuating reactive hyperemia. Customized test sockets for people with TT and TF amputations with embedded in-socket silicone probe holder (**Figures 3 and 8**) housed perfusion (LDF) and tissue oxygen (TCOM) measurement probes and enabled multiple temporal measurements from the same sites to be taken in study without the individual probes interfering with one another.

4. Summary and conclusions

Residual limb skin health is a key determinant of quality of life for individuals with lower limb amputation. Skin health problems, caused by shear forces and stress to the residual limb, are known to affect the ability of individuals with lower limb loss to perform household tasks, use their prosthesis, engage in social functions, and participate in sports. Therefore, objective measures to during socket fitting combined with real-time monitoring of skin physiological parameters such as barrier function, hydration and perfusion are likely to provide a better fitting and functional artificial limb for long-term use.

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Conflict of interest

The authors declare no conflict of interest.

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