Methodological assessment of residual limb circulation and skin health in response to elevated vacuum suspension

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INTRODUCTION

Elevated vacuum suspension sockets continue to grow in popularity for improved fit, which may enhance socket comfort, function, and residual limb health. A growing number of clinical trials and case reports have supported these claims by reporting qualitative vacuum-dependent improvement in skin health (Ferraro 2011), and wound healing (Brunelli 2009, Traballesi 2009) on the basis of self-reported questionnaires, clinical outcomes scales, and wound closure studies. Here, we report on first efforts to use new technology platforms for quantitative assessment of residual limb skin health and in-socket circulation in response to elevated vacuum suspension. To do so, we developed non-invasive measurement protocols that leverage out-of-socket skin health tests (transepidermal water loss, surface electrical capacitance, cutometry, and torsional ballistometry), out-of-socket imaging (hyperspectral and laser speckle imaging) and in-socket circulation testing (transcutaneous oxygen measurement, and laser doppler flowmetry).

METHOD

All experiments were approved by The Ohio State University Institutional Review Board. *Subjects:* Method development was optimized in transfemoral and transtibial amputees under suction (no active vacuum control) and active vacuum conditions (12 inHg and 20 inHg settings). *Apparatus/Procedures:* Skin health testing was performed on both sound and residual limbs using the DermaLab™ module for assessment of skin hydration (transepidermal water loss, TEWL, surface electrical capacitance, SEC), and elasticity (cutometry, torsional ballistometry). Circulation in the sound and residual limbs was assessed using non-invasive imaging platforms to quantify skin oxygenation (Hyperspectral Imaging, HI) and perfusion (Laser Speckle Flowmetry, LSF). Real-time in-socket probe testing was developed to assess the acute response of residual limb circulation to elevated vacuum suspension. Probes include transcutaneous oxygen measurement (TCOM), and laser doppler flowmetry (LDF). *Data Analysis:* TEWL measurements were collected in both patients immediately ($TEWL_I$) after removal of the socket and liner and again after allowing the skin to equilibrate ($TEWL_E$) with air for 15 minutes. Percent reduction in TEWL following this equilibration period was calculated ($TEWL_E$- $TEWL_I$ / $TEWL_I$ *100). SEC, cutometry, and ballistometry data were exported from DermaLab™ software immediately after socket and liner removal and after equilibration with air for 15 minutes. HI and LSF data were analyzed using custom MATLAB code that averaged signal intensity over a 2.5cm x 2.5cm FOV. Raw data from the LDF and TCOM probes were analyzed using semi-automated MATLAB code as the mean ± SD value recorded during a 1min period under defined resting positions and during activity (treadmill walking).

RESULTS

Skin health measurements were successfully collected and analyzed from 5 different regions of the residual limb representing high and low pressure zones within the socket. Methodology was successfully optimized for circulation measurements at rest, standing and during activity. While imaging applications (HI, LSF) were limited to out-of-socket measurement, they will be useful in assessing chronic changes in residual limb circulation associated with long-term vacuum use. Fiduciary markers were developed for quickly defining and acquiring tissue oxygenation (HI) and perfusion (LSF) maps within minutes of socket and liner doffing. For in-socket measurements, a low-profile silicone sensor holder was developed to assist in positioning and relieve pressure of sensor probes. A key benefit of using the probe holder for in-socket testing is that it enables reproducible consistency of probe placement within and across patients. Real-time TCOM measurements during activity were enabled by adhering the probe to oxygen permeable Tegaderm™ dressing.

DISCUSSION & CONCLUSION

This work represents first efforts to develop an approach to quantitatively assess skin health and circulation in response to elevated vacuum suspension. Having established feasibility of the method, we are currently testing skin health and circulation in transfemoral (n=5) and transtibial (n=5) amputees using a crossover design under suction and vacuum conditions at intervals of 16 weeks.

CLINICAL APPLICATIONS

First to characterize skin health and circulation as described in response to vacuum suspension.

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