DISCOVERY EXPRESS

Progress Toward Optimizing Prosthetic Socket Fit and Suspension Using Elevated Vacuum to Promote Residual Limb Health

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Objective: Prosthetic sockets are custom made for each amputee, yet there are no quantitative tools to determine the appropriateness of socket fit. Ensuring a proper socket fit can have significant effects on the health of residual limb soft tissues and overall function and acceptance of the prosthetic limb. Previous work found that elevated vacuum pressure data can detect movement between the residual limb and the prosthetic socket; however, the correlation between the two was specific to each user. The overall objective of this work is to determine the relationship between elevated vacuum pressure deviations and prosthetic socket fit.

Approach: A tension compression machine was used to apply repeated controlled forces onto a residual limb model with sockets of different internal volume.

Results: The vacuum pressure–displacement relationship was dependent on socket fit. The vacuum pressure data were sensitive enough to detect differences of 1.5% global volume and can likely detect differences even smaller. Limb motion was reduced as surface area of contact between the limb model and socket was maximized.

Innovation: The results suggest that elevated vacuum pressure data provide information to quantify socket fit.

Conclusions: This study provides evidence that the use of elevated vacuum pressure data may provide a method for prosthetists to quantify and monitor socket fit. Future studies should investigate the relationship between socket fit, limb motion, and limb health to define optimal socket fit parameters.

Keywords: Boyle's Law, pistoning, displacement, prosthetic interface

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INTRODUCTION

In an effort to maximize comfort and function of a prosthetic limb, a prosthetist custom fits the prosthetic socket to the residual limb of their patient. To achieve an appropriate fit, the prosthetist must determine the appropriate socket shape, socket volume, and method of suspension. Current clinical practices require the prosthetist to determine these factors based on their own clinical experiences, visual and verbal feedback during static and dynamic check socket fittings, and knowledge about the patient's lifestyle, ability, and residual limb characteristics. To date, there are no clinically relevant methods to provide the prosthetist with quantitative feedback assessing socket fit.

Achieving a proper socket fit is critical to the success of the prosthesis. Two surveys administered to lower limb prosthesis users indicated

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the high prevalence of skin sores or irritation occurring within the socket, with fit likely being a contributing factor.[1,2] If unresolved, these skin issues can necessitate the disuse of the prosthesis. A published study has documented that the use of elevated vacuum suspension (EVS) to hold the prosthesis onto the residual limb can result in wound healing when the socket is determined to be properly fit by an experienced prosthetist.[3] The beneficial changes in skin health and circulation of the limb resulting from the use of EVS have recently been objectively quantified using a series of novel approaches.[4]

Data from a microprocessor-controlled EVS may provide an appropriate measurement of socket fit. EVS creates subatmospheric pressure between the prosthetic socket and liner worn over the residual limb. Previous studies found that this subatmospheric pressure fluctuates during gait, and the degree of fluctuation is dependent on the level of vacuum pressure in the socket.[5] An explanation of what this pressure fluctuation means can be made by understanding Boyle's Law.[6] According to Boyle's Law, pressure is inversely proportional to volume when temperature and the amount of gas remain constant. In other words, if there is a change in negative pressure, it must be the result of a change in volume of space between the liner and socket, and therefore there must be movement of the residual limb relative to the socket. This is a reasonable assumption for a sealed socket environment over a short period of time.

The application of this law to the prosthetic socket was previously evaluated. The change in subatmospheric pressure during level-ground walking was compared to an inductive proximity sensor mounted to the distal end of the socket of five amputee subjects.[7] A strong linear correlation between a decrease in the change in vacuum pressure waveform magnitude and a decrease in vertical displacement measured by the proximity sensor was found. Interestingly, the slopes of the regression lines were subject specific. The variance among individuals may be a result of different gait styles, tissue types, residual limb geometries, prosthesis weight distribution, and socket fit. The purpose of this new study was to understand the contribution of socket fit to this variance through the use of a controlled benchtop model. The hypotheses tested were that (1) the vacuum pressure–displacement relationship would be dependent on socket fit and (2) applying elevated vacuum pressure over a greater surface area would reduce distal displacement of the socket relative to a limb model.

CLINICAL PROBLEM ADDRESSED

Prosthetic socket fit greatly impacts prosthesis comfort, function, and acceptance; however, there is currently no method to objectively quantify fit. Prosthetist must base socket fit decisions on previous experiences, visual inspection, and verbal feedback from their patients to determine the appropriateness of a particular socket fit and the need for a new socket. This subjective data can be difficult to document and thus does not provide strong evidence that can be presented to third-party payers, explaining the need and benefits of a prosthetic socket. Failure to properly monitor and adjust socket fit can result in injury to the residual limb tissues, reduced functional performance during daily activities, and decreased satisfaction with the prosthesis.

MATERIALS AND METHODS

Equipment

Leveraging the mechanical tension–compression testing platform previously used to evaluate the strength of various sockets[8] (Fig. 1); researchers were able to control the magnitude, direction, and frequency of load application. Load was applied in a cyclic manner, oscillating between –30 lb (compression) and +60 lb (tension) at a frequency of

Figure 1. The tension–compression testing platform used in the study. *Circles* indicate the connection points of the socket and residual limb model to the tension–compression machine.

0.65 Hz. The load condition was chosen after preliminary tests were completed and the frequency was chosen to represent a cadence of 78 steps per minute. The testing procedures were completed for an in-line axial load condition. Custom pin joints were used to enable connection of the residual limb model to the testing machine.

A residual limb model was made from a rigid plastic core and compliant gel covering formed in a conical shape. The initial shape was drawn in SOLIDWORKS (SOLIDWORKS Corp., Waltham, MA) and was designed to have a conical shape with a consistent taper toward the distal end. The digital files were used to make two foam positive models with the Omega® CAD software and Carver (The Ohio Willow Wood Company, Mt. Sterling, OH). One positive model was an exact copy of the drawn dimensions and the second was the same profile with a global 40 sock-ply volume reduction (generated using Omega software). Thermoplastic check sockets were then pulled over the foam models. Fabrication of the residual limb models began with the reduced volume check socket. A vertical alignment jig was used to orient the check socket and position a steel pipe in the center of the socket. A two-part thermoset plastic was mixed and poured into the check socket to a predetermined height (1.5″ below the proximal socket edge). After 1 h, the plastic core and pipe were removed from the check socket and the other check socket was oriented using the same vertical jig as before. The thermoset core was then placed inside the check socket, 1.5″ from the proximal edge of the check socket, and visual inspection was used to ensure even spacing around the entire core. Alpha thermoplastic elastomer gel (The Ohio Willow Wood Company) was then poured into the space between the check socket and thermoset core to a height 1.5″ above the proximal edge of the thermoset core. After 1 h, the limb model was removed from the check socket and inspected for any fabrication errors.

Next, three different clear thermoplastic check sockets were fabricated (Fig. 2). To generate the socket shapes, a fabricless silicone liner and fabric-covered stabilizing sock were donned over the residual limb model. An Omega Scanner was used to digitize the resulting limb model shape. Modifications to this base shape were made in the Omega software to create two additional foam models, one that was +1.5% globally expanded and one that was –1.5% globally reduced. Thermoplastic material was then heated and pulled over the residual limb model, liner, and stabilizing sock directly to create the neutral socket and over the two foam models to create the expanded and reduced sockets. Each socket was cut to an initial height of 13″. Epoxy and fiberglass wrap were used to secure the distal components to the sockets. The final steps were to add the LimbLogic® vacuum pump and distal valve (The Ohio Willow Wood Company) to the sockets.

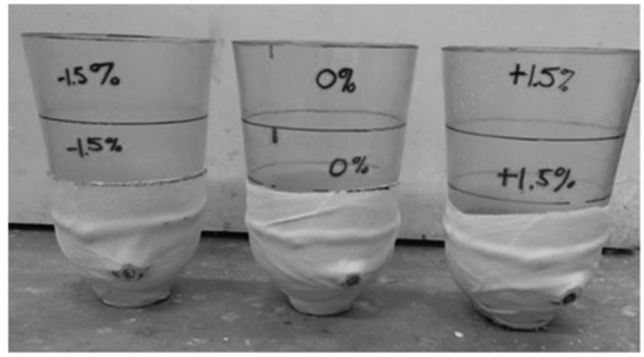

Figure 2. The three thermoplastic sockets used in the study. The 0% socket had total contact with the limb model, the –1.5% socket had an air gap between the distal end of the socket and the limb model, and the +1.5% socket had an air gap between the side wall of the socket and the limb model. After completion of the first round of the protocol, the sockets were cut at the proximal *black line* and the protocol repeated.

Experimental procedures

The residual limb model was connected to the tension–compression machine using a pin joint at the proximal connection and a pyramid adaptor at the distal connection (Fig. 1). Ten loading cycles were completed for each trial following the testing parameters described above. The independent variable for the study was the vacuum pressure setting. For each socket condition, the initial vacuum pressure was set at 0 inHg (suction condition) using the LimbLogic Communicator. The order of pressure settings tested after completing the suction trial were 7, 9, 11, 14, and 20 inHg. Between each trial, the air valve at the distal end of the socket was opened and then closed to reset the position of the limb model. After completing all of the vacuum pressure conditions, the socket was doffed from the limb model and replaced by the next socket and the same procedures followed. After completing testing of the three sockets, 4″ were cut from the proximal end of each socket and the protocol was repeated.

Data analysis and calculations

Displacement of the machine piston was recorded by the testing machine. Data from the LimbLogic vacuum pump were recorded on a separate laptop. Displacement and vacuum pressure data were processed by calculating the average absolute change (maximum–minimum) of each force cycle. The data were plotted and a second-order polynomial was fit to the data points to aid in visualizing the data trend. Note that, for the suction condition, the absolute change in vacuum pressure could not be accurately calculated. This is because, during compression, the socket experienced positive pressures, or negative vacuum level, which exceeded the measurement range of the pressure sensor. At the other end of the pressure scale, vacuum level deviations were generally indistinguishable from zero for the 20 inHg trials and evaluated as such in most cases.

RESULTS

The vacuum pressure–displacement relationship was dependent on vacuum setting and socket fit. In general, higher vacuum pressure settings resulted in lower amounts of displacement and vacuum pressure fluctuation within each socket fit condition (Figs. 3 and 4). Greater reductions in movement were experienced when changing the vacuum pressure between lower range values (7–11 inHg) relative to higher range values (11–20 inHg). However, the rates of decrease created distinct trends in the data that correlated to particular fit conditions. For the neutral fit socket, a fairly linear correlation with small changes between data points existed as the vacuum setting changed. The reduced socket produced a linear trend, but with much greater changes between data points as the vacuum setting changed. The expanded socket resulted in a less consistent correlation between vacuum pressure fluctuation and displacement. The change in data at higher vacuum settings was different from the change at lower vacuum settings, resulting in a curved regression.

Creating more contact between the socket and the limb model resulted in less displacement. The 13″ neutral fit socket condition with a vacuum setting of 20 inHg resulted in the lowest amount of displacement and vacuum pressure fluctuation, while the 9″ expanded socket resulted in the highest amount of displacement (Table 1). In fact, the 13″ neutral fit socket at vacuum settings equal or greater to 11 inHg resulted in the lowest amounts of displacement in the study. For both the neutral fit and reduced fit socket, the 13″ socket resulted in less displacement than the associated 9″ socket. The expanded socket resulted in the smallest differences in displacement between the 13″ and 9″ sockets.

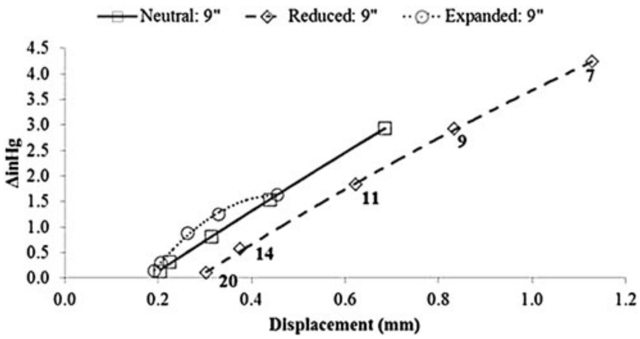

Figure 4. Data points for the three fit conditions for the 9″ socket. A second-order polynomial regression was added to illustrate the trend in the data.

DISCUSSION

Several works have investigated EVS and found a reduction of pistoning[5–7,9,10] and better residual limb volume management[9,11,12] ultimately leading to improved fit and function.[3,9,13,14] This study indicates another unexplored benefit of EVS; the potential to measure and identify differences in socket fit. The results support the hypotheses and found distinct trends in the data that were dependent on socket fit. It is clear that measurement and analysis of elevated vacuum pressures can yield

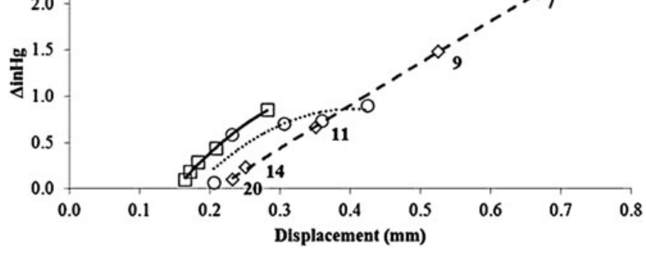

Figure 3. Data points for the three fit conditions for the 13″ socket. A second-order polynomial regression was added to illustrate the trend in the data.

Table 1. *Displacement recorded by the mechanical testing platform for each socket fit condition*

LimbLogic Vacuum Setting (inHg)	Neutral Socket Displacement (mm) 13″	Neutral Socket Displacement (mm) 9″	Reduced Socket Displacement (mm) 13″	Reduced Socket Displacement (mm) 9″	Expanded Socket Displacement (mm) 13″	Expanded Socket Displacement (mm) 9″
0 (Suction)	1.40	1.54	1.42	2.02	2.23	2.28
7	0.28	0.69	0.67	1.13	0.42	0.46
9	0.21	0.44	0.53	0.83	0.36	0.33
11	0.18	0.31	0.35	0.62	0.31	0.26
14	0.17	0.22	0.25	0.38	0.23	0.21
20	0.16	0.20	0.23	0.30	0.21	0.19
Average	0.43	0.54	0.57	0.88	0.63	0.62

information that could in turn be used to quantify socket fit. Such a tool would benefit prosthetists and their patients, particularly those patients with reduced sensation in their residual limb. The results further demonstrated that the technique is sufficiently sensitive to detect difference between sockets that are only 1.5% different in volume, and likely can detect smaller differences. Clinically, such high resolution could help prosthetists determine appropriate placement of foam and/or gel inserts, while attempting to rectify a mal-fitting socket as well as track changes in fit over time.

It is important to note that this technique is unique to elevated vacuum systems, particularly those controlled by microprocessors. Mechanically elevated vacuum systems, which remove air in the socket through the compression of a pump during gait, and passive suction suspension systems cannot properly control the specific amount of motion occurring in the socket. This technique requires the vacuum system to check in-socket motion at various vacuum pressure settings to analyze the data trend.

These results were also impacted by the amount of contact between the limb model and socket, as well as the amount of the limb model surface area under vacuum pressure. One challenge with the study was quantifying how much surface area of contact existed between the limb model and socket for both the reduced and expanded sockets (the neutral fit socket had global contact with the limb model). What is known is that surface area contact for the reduced socket occurred on the side of the limb and socket, whereas most, if not all, of the surface area contact for the expanded socket occurred at the distal end. Interestingly, for the neutral and reduced sockets where side contact with the limb occurred, there was a more linear relationship among the data. However for the expanded socket where little to no side contact occurred, there was a transition in the relationship between displacement and change in vacuum. The authors believe that the linear nature of the fits of the neutral and reduced socket fit conditions, both situations that spread the contact load over larger side surface area, tends to confirm the use of a linear model such as Boyles' law. The nonlinear behavior of the expanded fit trials in the high vacuum conditions is believed to be due to distal deformation of the small region of contact of the residual model, leading to a nonlinear stiffness in these regions of the plots. This condition is analogous to the high pressures and tissue compression that can happen when a patient bottoms out in a loose socket. In this way, detection of nonlinear behaviors may prove to be an important part of the tool being considered because it seems to imply distal loading. Shifts to the right in otherwise linear displacement/pressure curves seem to indicate sockets that are undersized and this relationship could allow tracking of socket fit once the known good fit condition baseline has been established for comparison.

When comparing the average displacement within each socket fit condition, an interesting point becomes apparent. First, the neutral fit socket yielded the lowest averages for both the 13″ and 9″ sockets (0.43 and 0.54 mm). The reduced fit 13″ had the next lowest average, but then experienced a large jump in average for the 9″ socket (0.57 and 0.88 mm). The 9″ reduced socket fit condition yielded the highest amounts of average displacement, particularly at lower vacuum settings (not including the suction condition). This is not at all too surprising since the reduced socket created an air gap at the distal end of the socket due to hammocking. Interestingly, the expanded socket resulted in the most motion during the suction vacuum setting compared to the other vacuum settings, but resulted in the smallest differences between the two socket heights. The averages are 0.01 mm (0.63–0.62, Table 1) different in favor of the 9″ socket. The authors believe that this illustrates the importance of contact of the limb with the side of the socket to manage motion. The reduction in displacement of the expanded socket compared to the reduced socket is likely a result of the distal contact and lack of distal air gap in the expanded socket.

Since this study was performed in a controlled model-based environment, several limitations exist. First, the limb model did not match anatomical features of an amputated limb. Furthermore, the cyclic loading is not a direct simulation of the actual forces experienced during gait. All forces were applied in line with the socket. Nonvertical forces were excluded since the research team intended to remove the proximal section of the sockets. This change in lever arm length of the socket would have added confounding factors making the off-axis loading data difficult to discern. Still, the general nature of the test seemed to be a fair representation of gait, which will impose compressive and tensile forces onto the socket interface. Another limitation regarding this method, in general, is that it would not apply to traditional pin-locking sockets or other suspension methods that do not seal the interface between the limb and socket.

It should also be considered that these outcomes are purely based on a mechanical motion standpoint and do not consider the health of the residual limb. This is an area that is rather understudied.

KEY FINDINGS

- Change in EVS pressure data during gait was dependent on the quality of socket fit.
- The highest interface stiffness (minimal movement) was achieved with the Neutral Socket Fit and 13″ socket.
- The techniques and technologies used in this study will be applicable to future studies that investigate the influence of socket motion, socket fit, and vacuum pressure on the health of the residual limb.

A recent effort became the first work to objectively quantify changes in skin health and perfusion within the residual limb in response to EVS.[4] The study did not account for movement at the interface, mostly because there was not a method to quantify these data at the time of the study. The traditional teaching from Orthotic and Prosthetic educational programs is that motion should be eliminated between the residual limb and socket, although this is generally determined by visually inspecting the socket as the user ambulates. This certainly makes sense from a mechanical efficiency standpoint, but how motion impacts the health of the limb is still unclear. The results of this study found relatively smaller changes in detected motion when the vacuum system was set to higher range pressure values (11–20 inHg) compared to lower range values (9–11 inHg). Therefore, if a relatively similar level of suspension is generated at a lower vacuum setting, is there a need to draw the highest possible vacuum pressure of the pump? How did differences in vacuum pressure setting, and therefore amount of motion between the limb and socket, impact the results of the previous limb health study[4]? Should all motion totally be eliminated, or is there a threshold of movement that is optimal for the health of the limb and/or user comfort? Future studies should investigate these areas. The outcomes may potentially define optimal fit and suspension criteria that promote limb health and maximize function.

INNOVATION

Evidence reported in this study suggests that negative pressure signatures created with elevated vacuum technology during ambulation are dependent on socket fit, enabling a clinically relevant tool to aid in the socket fitting process. Future work can pair this method with objective limb health data to define optimal socket fitting parameters, thereby maximizing functional performance and comfort while promoting residual limb health. Ultimately, this work will improve amputee care and quality of life through more quantitative analysis and documentation of socket fit.

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The authors are employees of The Ohio Willow Wood Company. This article was written exclusively by the authors and no ghostwriters were involved.

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Abbreviations and Acronyms

CAD = computer-aided design
EVS = elevated vacuum suspension
inHg = inches mercury