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Modeling the Mechanics of Elevated Vacuum Systems in Prosthetic Sockets

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Abstract

Elevated vacuum (EV) is suggested to improve suspension and limb volume management for lower limb prosthesis users. However, few guidelines have been established to facilitate configuration of EV sockets to ensure their safe and proper function. A benchtop model of an EV socket was created to study how prosthetic liner tensile elasticity, socket fit, and socket vacuum pressure affect liner displacement and subsequent pressure on the residual limb. A domed carbon fiber layup was used to represent an EV socket. Inserts were used to simulate various air gaps between the socket and liner. Various prosthetic liner samples were placed under the carbon fiber layup. Liner displacement and the corresponding pressure change underneath the liner were measured as vacuum was applied between the liner sample and socket wall. Tissue vacuum pressure increased linearly with socket vacuum pressure until the liner contacted the socket wall. Predicted tissue vacuum pressure matched well with experimental results. Findings suggest that the effect of vacuum pressure on the residual limb is primarily determined by air gap distance. The developed model may be used to assess effects of EV on residual limb tissues based on an individual's socket fit, liner characteristics, and applied vacuum. Understanding the physiological

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Data processing: RTY

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Declaration of Competing Interest

The authors declare no conflict of interest.

ETHICAL APPROVAL

Not required.

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effects of EV on the residual limb could help practitioners avoid blister formation and improve EV implementation.

Keywords

Amputee; negative pressure; prosthetic socket; artificial limbs; model; residual limb; suspension; suction

INTRODUCTION

A secure and comfortable socket fit is essential for lower limb prostheses users to establish optimal coupling between the prosthesis and residual limb. This coupling allows the user to transfer forces, maintain suspension during ambulation, and distribute pressures on the skin during weight-bearing [1-3]. One of the most important issues facing individuals with lower limb amputation is maintaining socket fit as residual limb volume changes [4,5]. Volume changes occur throughout the day as fluid shifts within the residual limb soft tissues as a result of prosthetic socket stresses [6]. These changes in volume and shape degrade socket fit, potentially leading to discomfort, skin breakdown, poor gait patterns, and falls [6-8].

Elevated vacuum (EV) is a technology used to secure the prosthesis to the residual limb and help manage residual limb volume changes, leading to a more stable socket fit [9]. A typical EV system features a liner, a sealing sleeve, and a vacuum pump. The pump evacuates the air between the liner and the socket wall, creating a negative pressure environment within the socket [10]. The liner and residual limb tissues are pulled to the wall of the socket, limiting movement in all directions. One of the primary benefits of EV is a superior mechanical connection between the residual limb and prosthesis. Use of EV, for example, has demonstrated less vertical limb displacement compared to other suspension methods [10-14]. EV may also benefit limb physiology by helping to draw fluid into the limb during tissue expansion [15]. Studies have shown that using EV resulted in less residual limb volume loss compared to suction suspension [11,15,16]. Additionally, EV use has been suggested to improve limb health [17-19]. These effects may account for improved functional outcomes and increased user-reported satisfaction in several EV studies [18-24].

Despite the potential benefits of EV, clinical implementation of this technology has been difficult due to fabrication cost, fitting challenges, component maintenance, and possible injury to the residual limb when vacuum is applied [12,18,20]. In a survey of 155 prosthetic professionals, nearly 90% thought EV needed careful evaluation to maintain function [20]. Regular maintenance of the liner, socket, and sleeve is necessary to prevent the loss of vacuum. Additionally, Klute et al. found that EV prostheses required more check sockets and time to adequately fit than prostheses with pin suspension [12]. In some cases, particularly when air is caught between the liner and skin, EV has been associated with blisters on the residual limb [12,18,20,24], an issue identified by 78% of surveyed practitioners [20]. In cases of poor socket fit, air gaps are created between the limb and the socket wall. When the liner is pulled to the socket wall under vacuum, the local volume under the liner increases and pulls on the local residual limb tissue. Excessive stress on the

skin may lead to separation of the epidermis and dermis, creating a fluid filled cavity or bruising [25]. Blisters from EV may develop into larger problems if not addressed.

Suction blister formation is dependent on a variety of physiological factors that are related to the mechanical integrity and strength of the adhesion between the dermis and epidermis. Individual health characteristics such as age, disease, and smoking are known to affect the adhesion strength. Additionally, external factors such as tissue vacuum pressure, area of application, time of application, and temperature also influence suction blister formation [25,26]. Characteristics of the prosthesis, such as liner properties, air gap distance, and socket vacuum pressure magnitude also affect the vacuum pressure experienced by residual limb tissues. Currently, little is known about how these variables affect tissue vacuum pressure and the overall function of the EV system. This is partly due to the complex shape and intimate fit of prosthetic sockets, complicating direct measurement of these variables. As a result, few evidence-based recommendations regarding the clinical use of EV have been established to guide practitioners. For example, socket vacuum pressure selection is often based on patient preference or suspension needs [27], but few studies have evaluated the effects of different vacuum levels on short- or long-term limb health [28].

The purpose of this study was to evaluate the effects of EV socket variables such as prosthetic liner tensile elasticity, socket fit, and socket vacuum pressure on tissue vacuum pressure using a geometrically simplified benchtop model of an EV socket. We hypothesized that the tissue vacuum pressure would be directly related to the displacement of the liner and corresponding change in air volume beneath the liner as stated by Boyle's Law. Additionally, we expected different combinations of liner properties, air gap distance, and socket vacuum pressure would have different effects on liner displacement and tissue vacuum pressure. For example, we expected that a liner with high tensile elasticity would displace less and result in lower tissue vacuum pressure at a given socket vacuum pressure than a liner with lower tensile elasticity. Results of this study may enhance understanding regarding the function of EV systems and their influence on limb physiology.

METHODS

Socket Model

A benchtop model was created to simulate the environment of an EV socket (Figure 1). A 0.6 cm thick, 30.0 cm by 30.0 cm nylon sheet raised approximately 4 cm with leveling mounts was used as a base. Liner samples of various elastomer and fabric combinations were cut to flat sheets and placed on top of the base. A square (20.0 cm by 20.0 cm) carbon fiber layup with a central dome (7.6 cm diameter, 1.0 cm height) was fabricated to simulate a carbon fiber socket with a local region of misfit. The diameter of the domed region was selected to fit within the posterior width of a residual limb approximately 30.0 cm in circumference. The carbon fiber layup was placed over the liner, and a polyurethane sealing ring (11.4 cm inner diameter) cured on the fabric backing of each liner created an airtight seal with the carbon fiber layup. An electronic vacuum pump was used to apply vacuum pressure to the dome via a threaded barb value, similar to how a prosthetic vacuum pump would in an EV socket. Applied vacuum pressure was controlled by a digital pressure sensor

(26PCCFB6G, Honeywell, Morris Plains, NJ) and custom LabVIEW program (National Instruments, Austin, TX).

Socket and Tissue Vacuum Pressure

Vacuum pressure between the domed carbon fiber layup and liner sample, referred to here as the socket vacuum pressure, was measured with a differential pressure sensor (HSCMRND030PD3A3, Honeywell, Morris Plains, NJ) and a custom data acquisition unit. Vacuum pressure underneath the liner, termed here tissue vacuum pressure, was similarly measured through a threaded barbed valve centered on the bottom face of the nylon base.

Liner Displacement Measurement

An inductive distance sensor-target system [29,30] was used to record the air gap distance as the surface of the liner displaced towards the interior of the dome under vacuum. The system consisted of an inductive sensing chip (LDC1614, Texas Instruments, Dallas, TX), a custom flexible coil antenna (diameter 32.0 mm, thickness 0.15 mm), a capacitor (220 pF), and a magnetic polymer target. Previous studies have used this method to measure socket-to-liner distance and limb movement within a prosthetic socket [31,32]. A circular magnetic polymer target (4.1 cm diameter, 0.5 mm thickness) was heat bonded onto the fabric backing of each liner sample. The target material consisted of thermoplastic elastomer, iron powder (85% by weight), and mineral oil [41]. The target was covered by a thin circular piece of cloth (96% cotton and 4% spandex, 0.75 mm thickness) to allow air movement over the target when it contacted the interior dome surface. The low-profile flexible antenna was embedded between layers of carbon fiber and Nyglass (Paceline, Matthews, NC) in the domed carbon fiber layup (Figure 2). The antenna, driven by the inductive sensing chip, and capacitor operated as an inductor–capacitor (LC) tank oscillator to generate a magnetic field, as described in detail previously [29]. When the target entered the magnetic field, the sensor oscillation frequency was altered as a function of the target's distance.

The volume of air created beneath the liner during vacuum application was geometrically estimated from the liner displacement measurement. Boyle's Law was then used to calculate the theoretical tissue vacuum pressure generated by this change in air volume. Boyle's Law states that volume and pressure are inversely related where P_1 is the initial pressure and V_1 is the initial volume. As volume increases (V_2), pressure decreases (P_2):

$$V_1 P_1 = V_2 P_2$$

The theoretical tissue vacuum pressure was compared to the experimental tissue vacuum pressure recorded by the differential pressure sensor.

Air Gap Distance

Air gap distance was varied to represent degrees of socket misfit that may exist in a prosthetic socket. Three rigid, polymeric dome inserts (VeroClear RGD810, Stratasys, Eden Prairie, MN) were fabricated with a three-dimensional printer (Objet30 Pro, Stratasys, Eden Prairie, MN) and placed in the dome to alter the air gap distance. The printed material had a manufacturer-provided modulus of elasticity of 2000–3000 MPa. The center thickness of

each insert was 2.5 mm, 5.0 mm, and 7.5 mm, respectively (Figure 3). Based on these inserts, air gap distance ranged from approximately 10.0 mm (no insert) to 2.5 mm (7.5 mm insert), though actual air gap distances varied slightly due to the thickness of the sealing ring. The inserts were used to create several different socket fit conditions (i.e., areas of local misfit within the socket). Fernie and Holliday noted that sock ply between 0% and 5% of the residual limb volume represented a “good” fit, between 5% and 10% represented an “acceptable” socket, and greater than 10% indicated that a new socket was needed [33]. Previously, a 1.8 mm radial socket size adjustment correspond to an average socket volume change of about 6% [34]. The air gap distances used in this study therefore reflect fit conditions that may be considered both clinically acceptable (7.5 mm insert) and unacceptable (no insert, 2.5 mm insert, and 5.0 mm insert).

Liner Samples

Transtibial prosthetic liners, each made from different combinations of fabric and elastomeric materials, were tested with the benchtop EV model. WillowWood (WillowWood, Mt. Sterling, OH) liners were used due to their clinical popularity [35] and previously characterized range of material properties [36,37]. Liner types included Alpha Silicone Select, Alpha Hybrid Select, and Alpha Classic Original with tensile elasticities of 3,450 kPa, 2,280 kPa, and 294 kPa, respectively [36].

Liner samples were prepared as 16.5 cm by 16.5 cm squares with 5.7 cm extended edges on each side (Figure 4). Samples were cut from the posterior proximal region of the liners where the fabric backing and liner thickness were uniform. Two liners of each type were tested. One was stretched to simulate the tension present in a donned liner and the other was tested without tension. A liner tension apparatus (Figure 4) was fabricated from a t-slot aluminum building system (80/20 Inc., Columbia City, IN). For stretched liners, polyoxymethylene (Delrin) bars were adhered to the four extended edges to affix the liner to the liner tension apparatus. To determine the representative stretch in a donned liner, four points were marked in a square pattern on the fabric backing of WillowWood Alpha Silicone Select liners. Based on the manufacturer sizing guidelines, the liners were then donned to multiple silicone limb molds from prior research participants. The distal circumference (4 cm from the distal end) of these molds ranged from 24 cm to 31 cm. The change in distance between the medial/lateral and proximal/distal points was measured at posterior locations on the liner and averaged across molds. The same square pattern was marked on the liner samples, and the liner tension apparatus was used to mirror the same stretch. A similar method was used to recreate donned tension in prosthetic socks [38]. Prior to data collection, the sealing ring and the target were applied as shown in Figure 4.

Modeling Tissue Resistance

In an EV socket, the residual limb skin moves with the liner as it displaces towards the wall of the socket. Displacement of the liner depends on liner material properties (i.e., fabric and elastomer elasticity), physical constraints (i.e., socket fit), and residual limb tissue properties (i.e., soft tissue content, skin elasticity). Tissue properties vary by person and are affected by age, health, and anatomical region [39]. Preliminary testing (Appendix 1) demonstrated that the volume of air under the liner could be used to model tissue resistance. A capped

polyvinyl chloride (PVC) cylindrical tube termed the tissue resistance container was used to maintain a single tissue resistance generally representative of the soft tissues in the posterior lower limb.

Calibration

A calibration procedure was conducted before each data collection trial. Calibration points were collected at intervals of known distance. A digital caliper (CD-8" ASX, Mitutoyo, Japan) was used to determine the baseline air gap distance from the liner target to the interior dome surface. Dome inserts of known maximum thickness (2.5 mm, 5.0 mm, and 7.5 mm) were placed under the dome between the target and the sensor. For each insert, vacuum was applied at -20 inHg with an open base port (i.e., no tissue resistance) to pull the liner target to the interior insert surface. Vacuum was applied without a dome insert to establish a 0.0 mm reference. A calibration curve (interpolant – shape preserving) was fit to these five points, which included the baseline measurement.

Data Collection

Pressure on the carbon fiber layup was required to produce a consistent air-tight seal against the liner samples. A twenty-five-pound weight and clamps were used to apply pressure to the carbon fiber layup (Figure 5). To prevent interference with the inductive distance sensor, an acrylic tube spacer was placed between the weight and carbon fiber layup. For each liner sample, vacuum pressure was stepped from 0 inHg to -20 inHg, in -2 inHg increments. Tissue vacuum pressure and liner displacement were recorded at each pressure increment. A maximum vacuum pressure of -20 inHg was selected because that is the highest vacuum pressure setting available on commercial prosthetic EV pumps [40].

Data Analysis

Three separate trials were conducted with each liner sample, and data from these trials were averaged for analysis. The relationships between liner type, air gap distance, socket vacuum pressure, liner displacement, liner tension, and tissue vacuum pressure were analyzed.

RESULTS

Liner Samples

Six liners were tested, including two liners of each fabric and elastomer combination (Table 1).

Socket Vacuum Pressure

All liners displaced linearly under applied vacuum, until the liner reached the interior dome surface (Figure 6). The tissue vacuum pressure underneath the liner similarly increased with socket vacuum pressure. Once liner displacement ceased, tissue vacuum pressure remained constant. With no insert, maximum vertical displacement (i.e., at least 99% of the dome height) occurred by -6.5 inHg for stretched liners and -5.0 inHg for unstretched liners. The theoretical tissue vacuum pressure calculated from the estimated change in volume of air beneath the liner and the experimental tissue vacuum pressure are plotted in Figure 6.

Air Gap Distance

Due to variations in sealing ring height, air gap distances (i.e., distance from the liner target to the top of the dome) with no inserts ranged from 11.3 mm to 13.2 mm. As dome insert thickness increased, liner displacement towards the sensor was limited (Figure 7). Lower tissue vacuum pressures were recorded with the inserts as a smaller volume of air was created beneath the liner with applied socket vacuum. With no insert, maximum tissue vacuum pressure averaged -3.6 ± 0.2 inHg. With the 7.5 mm insert, maximum tissue vacuum pressure averaged -2.2 ± 0.2 inHg.

Liner Properties

Stretched liners demonstrated less displacement under applied socket vacuum pressure when compared to unstretched liners (Figure 8). Tissue vacuum pressure was unaffected at low socket pressure, as both stretched and unstretched liners averaged -2.2 ± 0.1 inHg tissue vacuum pressure at -2 inHg socket vacuum pressure. Tissue vacuum pressure differed by the second socket vacuum pressure (-4 inHg) due to variations in sealing ring height and maximum liner displacement between the stretched and unstretched liners. At -2 inHg socket vacuum pressure with no insert, relative liner displacement averaged $43.2\% \pm 2.6\%$ for stretched liners and $58.8\% \pm 3.6\%$ for unstretched liners (Figure 9). Liner displacement varied slightly by liner type. Of unstretched samples, 3U displaced the most (62.9%), and 1U displaced the least (56.0%). Of the stretched samples, 3S displaced the most (46.1%), and 2S displaced the least (40.9%). Although sample 1 is nearly 12 times the tensile elasticity of sample 3, displacement at -2 inHg socket vacuum pressure was similar, differing by 3.5% stretched and 6.9% unstretched.

DISCUSSION

The purpose of this research was to model the mechanics of an EV socket to better understand how the various components such as socket vacuum pressure, air gap distance, and liner material properties influence suspension and limb physiology. This information may assist practitioners when configuring EV prostheses to improve clinical implementation and avoid blister formation by optimizing the socket environment for individuals based on their prosthetic components. Additionally, this model may be used as a platform to test other design variables of EV prosthetic systems in people with lower limb amputation.

Contrary to the hypothesis, different combinations of liner properties, air gap distance, and socket vacuum pressure created similar effects on liner displacement, and correspondingly, on tissue vacuum pressure. This was predominantly because relatively low levels of socket vacuum pressures were needed to maximally displace each liner sample, either when stretched or unstretched. Commercial prosthetic EV pump systems reach -20 inHg [40], substantially higher than what was required to pull the liner to the wall of the socket in this model. While additional liner displacement toward the socket wall may not occur with greater socket vacuum pressure, it may be needed to prevent the limb from pulling away from the socket during stance phase when ground reaction forces are higher (i.e., during ambulation) and also during swing phase when gravity and centrifugal force are acting to pull the prosthesis away from the limb. Socket vacuum pressures greater than -6.5 inHg may

therefore be important for limiting limb movement and improving suspension and/or comfort. Additionally, data from this study showed that, once liner displacement ceased as it reached the dome, tissue vacuum pressure remained constant. This result suggests that the physiological effect of tissue vacuum pressure on the residual limb is primarily determined by air gap distance rather than applied socket vacuum. In a well-fitting or undersized socket (i.e., when air gap distance is small or non-existent), liner displacement to the socket wall and the associated physiological impact of tissue vacuum pressure will be limited. However, in the case of a poorly fitting socket or residual limb volume change (i.e., when the air gap distance is large), the liner will displace toward the socket wall, increasing vacuum pressure on the residual limb tissues. The model used in this study may therefore provide insights about tissue vacuum levels in improperly fitting or oversized sockets.

Increased tissue vacuum pressure in poorly fitting EV sockets is clinically important because it may lead to blisters. Suction blister formation has been reported to occur in less than 3 hours at pressures between -7 inHg and -20 inHg [26]. While these vacuum pressures are higher than the tissue vacuum pressures observed with the current model, many other factors such as individual health, area of vacuum pressure application, and temperature also influence the suction blister formation [25,26]. The elevated temperature within the prosthetic socket environment along with all-day wear time and compromised skin health could lead to blistering at lower tissue vacuum levels. Consistent with our hypothesis, we demonstrated the ability to predict tissue vacuum pressure using Boyle's Law as the liner displaced into the dome. With additional research on the physiological effects of vacuum pull on residual limb tissues, we may be able to use this model to identify a local socket misfit (i.e., air gap distance) that would lead to injury.

Higher resistance to liner displacement was hypothesized in liners with higher tensile elasticity, based on liner properties reported previously [36,37]. Liner type demonstrated limited impact on tissue vacuum pressure, suggesting liner material properties may be less important than air gap distance and socket vacuum pressure when configuring EV sockets. Results suggest that prosthetists may instead focus on selecting liners based on other desirable features such as limb coupling or stress distribution. The liners with the lowest reported tensile elasticity (Alpha Classic Original), showed slightly more displacement at a given socket vacuum pressure. In addition, the silicone-based liners (Alpha Silicone Select) with the highest tensile elasticity demonstrated less displacement. Stretched liners produced similar effects with slightly lower displacement at -2 inHg socket vacuum pressure for each liner type tested. However, the effects of the liner properties may differ depending on the elasticity of the underlying residual limb tissue.

This study had several limitations. The model only reproduced localized areas of misfit limited to the size of the domed region. However, misfit within a socket may be distributed throughout the entire socket and the liner would be pulled in multiple directions potentially limiting liner displacement. Further research is needed to understand how the mechanics of this situation compare to results from the current model. The simulated soft tissue used to select a tissue resistance container was created as an approximate representation of soft tissue properties, which vary across individuals by age and presence of comorbidities (e.g., diabetes) [25, 39]. Only one value of tissue elasticity, as determined by the volume of the

tissue resistance container, was used to compare across liner samples. We chose to focus on soft tissue properties of the posterior residual limb because this region is primarily responsible for residual limb volume change [6]. By modifying the volume of the tissue resistance container, researchers may be able to model EV's effect on different types of underlying tissue. Additionally, though a range of liner tensile elasticity values were tested, this study only evaluated three different liner types from a single manufacturer. Additional liner types from various manufacturers should be tested.

CONCLUSION

A benchtop model was created to study the mechanics of an EV socket. Predicted tissue vacuum pressure, based on the change in air volume beneath the liner, matched well with experimentally measured tissue vacuum pressure. The model also demonstrated, regardless of liner type and socket vacuum pressure, socket misfit (i.e., air gap distance) to be the major determining factor in influencing tissue vacuum pressure and the physiological effect of EV. The model may be used to optimize EV based on prosthetic configuration (i.e., socket fit, liner characteristics, and applied vacuum) and further develop guidelines for the clinical use of EV in lower limb prosthetic devices.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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HIGHLIGHTS

- A physical model that simulated an area of misfit in a vacuum socket was created
- Effects of socket design variables on tissue vacuum pressure were tested
- Liner-to-socket air gap distance had the largest influence on tissue vacuum pressure
- The model serves as a platform to study physiological effects of elevated vacuum

Figure 1.

Diagram of EV socket model. (A) Components of the EV benchtop model prior to vacuum application. (B) Socket vacuum pressure applied to the dome region, altering the volume below the liner resulting in a tissue vacuum pressure change recorded by a digital vacuum pressure sensor (P).

Figure 2. Carbon fiber layup with central dome region. (A) Top side of domed carbon fiber layup. (B) Thin inductive distance sensor embedded between layers of carbon fiber and Nyglass, viewed from the interior surface of the dome.

Figure 3.
Diagram indicating the four different air gap distances tested.

Figure 4. (A) Diagram of a prepared liner sample. (B) Liner tension apparatus to replicate stretch in both medial/lateral and proximal/distal directions.

Figure 5.
Data collection configuration with EV socket model for (A) unstretched liner samples and (B) stretched liner samples using the liner tension apparatus.

Figure 6. Liner displacement and tissue vacuum pressure. (A) Plot of sample 1S data collection with no insert. (B) Plot of experimental tissue vacuum pressure and theoretical tissue vacuum pressure obtained using Boyle's Law with estimated values of volume change due to liner displacement.

Figure 7.

Representative liner displacement and tissue vacuum pressure averaged across three trials for sample 1S. Numbers indicate maximum liner displacement with each insert.

Figure 8.
Liner displacement and tissue vacuum pressure for each sample.

Figure 9.
Mean relative liner displacement and standard deviation for all samples at -2 inHg socket vacuum pressure with no insert.

Table 1.

Liner sample details. Tensile elasticity values from Cagle et al. [36]. U = unstretched, S = stretched, TPE = thermoplastic elastomer.

Sample	Liner Type	Fabric Type	Thickness Unstretched (mm)	Thickness Stretched (mm)	Elastomer	Tensile Elasticity [36] (kPa)
1U	Alpha Silicone	Select	3.1	N/A	Silicone	3,450
1S	Alpha Silicone	Select	3.1	2.6	Silicone	
2U	Alpha Hybrid	Select	3.9	N/A	TPE	2,280
2S	Alpha Hybrid	Select	4.1	3.3	TPE	
3U	Alpha Classic	Original	3.3	N/A	TPE	294
3S	Alpha Classic	Original	3.5	2.6	TPE	