Physiological and Mechanical Effects of Prosthetic Elevated Vacuum Systems in People with Transtibial Amputation

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Abstract

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A major problem among people with a lower limb amputation is maintaining socket fit. Long-term and short-term changes of residual limb volume can alter socket fit resulting in pain, skin breakdown, or falls. Several strategies are used to accommodate the lost volume; however, many of these reduce the size of the socket potentially expediting long-term limb changes. Elevated vacuum (EV) has been used to maintain suspension and manage limb volume by evacuating the air between the prosthetic liner and the socket thus allowing fluid to be drawn into the limb. The physiological and mechanical effects of EV are not well understood as several research studies have evaluated the technique without a clear consensus. The aims of this dissertation were to evaluate the effectiveness of EV to manage limb fluid volume, model the mechanics of EV sockets, and optimize the effects of EV. A goal of this research was to better understand how EV functions and work towards establishing clinical guidelines for its use.

The clinical effectiveness of EV to manage daily residual limb fluid volume was evaluated with an in-socket volume measurement technique during a protocol representative of daily activities. Bioimpedance analysis showed that rates of overall fluid volume change were unaffected by EV use compared to suction suspension (SS) with both conditions resulting in median rates of fluid volume loss. However, EV did reduce rates of limb fluid volume change during the final portion of the protocol after an accumulation of daily activity, suggesting benefit for high-activity users.

Components of EV sockets such as liner properties, socket fit, and socket vacuum pressure interact to influence the physiological effects of EV such as limb fluid volume change and limb health. A physical benchtop model of an EV socket was developed to evaluate the ability of these EV components to influence physiology and to provide guidelines for clinical implementation of EV. Testing of this model demonstrated the ability to predict tissue vacuum pressure based on individual patient characteristics, prosthetic components, and socket fit. Additionally, the effect of EV on the residual limb tissue was found to be primarily determined by socket fit, while liner properties had minimal effect.

Ideal EV parameters may differ for each individual depending on suspension needs, socket fit, prosthetic components, and health. Mechanical and physiological effects of EV were evaluated for optimizing vacuum pressure for three individuals. Multiaxial limb-socket displacement, limb fluid volume change, and user-reported socket comfort were measured at different socket vacuum pressures. Optical coherence tomography (OCT) imaging was used to measure skin perfusion at various tissue vacuum pressures, finding a potential dependency on the state of perfusion prior to vacuum application. Limb-socket displacement was the only metric to change consistently across participants. Changes to limb fluid volume and comfort suggested a more complex relationship unique to each individual. Adjusting socket vacuum pressure to balance the mechanical and physiological effects on individuals could improve EV implementation.

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DEDICATION

To my parents for always encouraging me to learn something

Chapter 1. INTRODUCTION

1.1 PROBLEM STATEMENT

Socket fit is reported as the most important problem facing individuals with lower limb amputation using a prosthesis [1]. Residual limb volume changes both in the short- and long-term are commonly associated with negatively influencing prosthetic socket fit [2]. Mechanical coupling between the limb and socket is essential for a secure and comfortable prosthesis. Oversized sockets weaken this coupling and potentially compromise the prosthesis user's ability to ambulate safely. Additionally, a properly fitting socket allows users to transfer forces, distribute pressures, and minimize shear stress on the skin [3,4]. Poor socket fit may lead to discomfort and skin breakdown [2,5,6].

Many strategies to accommodate volume change such as prosthetic socks [7], socket inserts [8], and adjustable sockets [9,10], are reactive and function by further reducing the size of the socket expediting volume loss [10,11]. Elevated vacuum (EV) is a prosthetic technology used to secure the prosthesis to the residual limb and help manage residual limb volume changes [12]. In theory, vacuum between the prosthetic liner and socket pulls the residual limb soft tissue towards the wall of the socket. This tissue expansion lowers interstitial fluid pressure thus increasing fluid volume transport to the interstitial space. This limits fluid loss out of the residual limb and better maintains socket fit over time [13].

Several studies have evaluated the effectiveness of this technology to control residual limb volume [13–17]. The results of these studies failed to reach a clear consensus on the capabilities of EV to manage limb volume. Interpretation of the results were limited by study methods. With the exception of Sanders et al. [13], each of these previous studies reported out-of-socket limb volume measurements which require the socket to be doffed [14–17]. Residual limb fluid volume changes rapidly with the removal of the socket, and these changes vary by individual [18]. In-socket residual limb volume measurements, such as those from bioimpedance analysis, are most relevant for evaluating the effectiveness of volume accommodation strategies such as EV. Another methodological limitation of these studies is that they primarily evaluated volume change during a single activity (i.e. walking) over a short time period ranging from 3 minutes [13] to 30 minutes [17]; therefore, results may not be indicative of volume changes over an entire day of various activities using EV.

Research regarding the mechanisms of action and physiological effects of EV is also limited. A recent systematic review emphasizes the need for more evidence-based research related to the physiological effects of EV [19]. Only one group has quantitatively assessed limb health and blood flow in lower-limb prosthesis users with EV compared to locking pin or suction sockets, demonstrating that long-term use of EV may improve skin perfusion and preserve skin barrier function [20]. Studies have investigated clinical uses of negative pressure outside of the field of prosthetics. Specifically, lower body negative pressure (LBNP) [21–23], negative pressure wound therapy (NPWT) [24], and intermittent negative pressure (INP) [25] have been used to influence macro- and microcirculation. These studies provide physiological context to EV, yet additional research is needed to verify specific physiological effects within the socket. Optical coherence tomography (OCT) has been recently been introduced as a means of evaluating residual limb health [26] and may have potential to evaluate the acute effects of tissue vacuum pressure that may occur in an EV socket.

In a survey of 155 prosthetic professionals, many indicated that they agreed with the benefits of EV such as decreased limb-socket displacement (pistoning) (97%), improved proprioception (93%), and improved overall quality of life (87%), among others. However, the survey also indicated that many practitioners see the need for careful evaluation, training, and maintenance when using EV (90%) [27]. In some cases, EV has caused the occurrence of skin issues such as blisters [17,28]. This issue was identified by 78% of the surveyed practitioners [27]. Blisters from EV may develop into larger skin problems or prosthesis disuse if not addressed. Despite these risks, limited evidence-based recommendations towards the use of EV have been scientifically established or evaluated to guide the clinical implementation of EV. Socket vacuum pressure used in EV varies among individuals both clinically and in research. Socket vacuum pressure is often based on patient preference, but it is unknown if patient preference maximizes beneficial physiological effects while minimizing limb-socket movement. Users are often unable to distinguish between small changes in vacuum pressure, though these small changes may be influencing residual limb mechanics and physiology [29]. Pressures between -7 inHg and -23 inHg have been reported in the literature with little information on how changing pressure affects physiology [27]. Research considering comfort as well as physiological and mechanical effects of socket vacuum pressure would improve implementation of EV and help prevent improper use.

Residual limb fluid volume changes create prosthetic fit challenges for many individuals with lower limb loss, and current accommodation strategies do not provide sufficient volume recovery. While EV may provide benefit to many users, objective research is needed to support broad clinical use. Beyond suspension and volume management, EV has also been useful for improving balance, gait, transfers [30,31], and limb health [28]. Despite the perceived benefits, many insurance providers consider EV investigational or unproven [32]. The purpose of this research is to study the physiological and mechanical effects of EV in order to evaluate the clinical utility of EV and target the optimization of EV in transtibial prosthetic users. This research will provide scientific understanding within a clinical context to the EV platform leading to more efficient implementation of the technology ultimately improving prosthetic socket fit and leading to better quality of life for people with transtibial limb loss.

1.2 SPECIFIC AIMS

The goal of this research was to provide an investigation regarding the clinical utility of EV by seeking to better understand its physiological and mechanical effects. Ultimately, this work will help to better inform the clinical implementation of EV. The following aims were completed towards this goal:

1.2.1 *Aim 1: Assessing the Utility of Elevated Vacuum to Manage Daily Residual Limb Fluid Volume*

A fixed-order crossover design was conducted to assess the clinical utility of EV to manage residual limb fluid volume during the course of an approximately 5.5-hour activity protocol. Using bioimpedance analysis, in-socket residual limb fluid volume was continuously monitored as current electronic EV users (n=12) completed two sessions separated by approximately one week. Participants used their standard EV system in the first session, and in the second session, the vacuum pump was disabled to create a suction suspension system (SS) system, a common suspension system in prosthetic practice [33]. In-socket vacuum pressure was recorded to ensure appropriate vacuum was applied during each session. The following hypotheses were evaluated:

1. The use of EV will result in lower overall rates of residual limb fluid volume change during the activity protocol compared to SS.
2. Rates of limb fluid volume change will not differ between cycles of the activity protocol when using EV.

3. Rates of residual limb fluid volume change will vary by activity with EV and SS
    a. Rates of limb fluid volume gain will be greater walking with EV compared to SS
    b. Rates of limb fluid volume loss will be greater standing with EV compared to SS

1.2.2 *Aim 2: Modeling the Mechanics of Elevated Vacuum in Prosthetic Sockets*

Complex mechanical and physiological variables interact within an EV socket. An EV socket model was developed using a domed carbon fiber layup to evaluate the relationship between liner properties, dome volume (socket fit), socket vacuum pressure, and resulting tissue vacuum pressure. Changes to tissue vacuum pressure and liner displacement were measured while liner properties, dome volume (socket fit), and socket vacuum pressure were varied. The following hypotheses were evaluated:

1. Tissue vacuum pressure within the modeled EV socket environment may be predicted based on liner volume displacement
2. Tissue vacuum pressure may be modified by adjusting socket fit, socket vacuum pressure, and liner tensile stiffness
    a. Increasing socket vacuum pressure will linearly increase liner displacement
    b. Increasing liner displacement results in linearly increasing tissue vacuum pressure
    c. Liners with high tensile stiffness will have higher resistance to displacement under socket vacuum pressure than liners with low tensile stiffness
    d. Increasing dome volume (poorer socket fit) will result in increasing liner volume displacement and tissue vacuum pressure at maximum socket vacuum pressure

1.2.3 *Aim 3: Optimizing the Physiological and Mechanical Effects of Elevated Vacuum*

This aim evaluates the potential to determine an optimum socket vacuum pressure from limb movement, fluid volume change, skin perfusion, and user reported comfort. Current transtibial EV users (n=3) visited the lab for two test sessions. The first session involved a socket scan and OCT imaging. The scan was used to create an instrumented EV socket with inductive distance sensors embedded into the socket wall. Skin perfusion was determined at various vacuum pressures from OCT images using vessel area density (VAD). Once the socket was prepared, a second visit was conducted to fit each participant to the instrumented socket. An activity protocol was then executed while measuring limb movement, limb fluid volume, and user comfort as socket vacuum pressure was varied. Using these data, the sensitivity of limb movement, fluid volume, skin perfusion, and comfort to changes in vacuum pressure was identified for each individual to work towards an optimal vacuum pressure. The following hypotheses were evaluated:

1. The effect of vacuum on skin perfusion will be based on a threshold vacuum pressure. Below threshold, increasing tissue vacuum pressure will increase skin perfusion above baseline values (i.e. atmospheric pressure). Above threshold, increasing tissue vacuum will decrease perfusion below baseline.
2. Changing socket vacuum pressure while walking will influence limb fluid volume recovery, limb-socket displacement, and user comfort.
    a. Rates of limb fluid volume recovery will increase as vacuum pressure increases
    b. Beyond initial vacuum application, user-reported comfort will be insensitive to changes in socket vacuum pressure
    c. Limb-socket displacement will decrease as socket vacuum pressure increases
    d. Vacuum greater than -11 inHg will minimally decrease limb-socket displacement [34]

Chapter 2. BACKGROUND

2.1 SIGNIFICANCE

In 2005 over 600,000 people were living with major lower limb loss in the United States [35]. Prevalence is growing due to better trauma care and the rising rates of diabetes and vascular disease [2,35]. Half of these major lower limb amputations occur at the transtibial level, and although prosthetic technology allows patients to regain many lost functions, quality of life is often negatively affected [5].

The transtibial prosthesis consists of three main components, the foot, the pylon, and the socket. The socket is the most important aspect of the prosthesis, for it creates the interface between the prosthesis and residual limb. In a survey of 92 individuals with lower limb amputation, the most important issue when using a prosthesis was socket fit [1]. A significant contributor to poor socket fit is limb volume fluctuation [1,2]. Many prosthesis users lose residual limb fluid volume over the course of a day leading to poor socket fit [2,36]. As the socket becomes loose, pressure is increased at bony prominences causing discomfort. If accommodations are not made, poor socket fit can lead to skin breakdown and instability reducing user mobility and preventing normal daily function [2,5,6].

Researchers have sought a better understanding of limb volume changes through the measurement and monitoring of volume changes over time. Additionally, clinical strategies have been developed to accommodate volume change in prosthesis users through behavioral intervention or socket technology, yet the problem persists and remains an important issue among prosthesis users. One of these technologies, elevated vacuum (EV), has been increasing in popularity; however, the effectiveness and mechanism of action have been insufficiently investigated. Further research into this technology is needed to better inform clinical decisions regarding its use in transtibial prosthesis users.

2.2 EXTRACELLULAR FLUID TRANSPORT

Extracellular fluid is the primary fluid responsible for residual limb volume change [18].

2.2.1 *Structure and Function of Extracellular Fluid*

Extracellular fluid (ECF) represents all body fluid outside of cells, approximately one third of the total body water in humans. Conversely, intracellular fluid (ICF) consists of the fluid within cells [37]. Plasma and interstitial fluid (including lymph fluid) are the main components of extracellular fluid comprising of at least 97% of the ECF [38]. Interstitial fluid (IF) consists of water, proteins, ions, and additional metabolic substrates surrounding the cells and is maintained within the interstitium of various bodily tissues. Along with the fluid component, the interstitium has a structural component consisting of collagen fibrils and glycosaminoglycans (GAGs) [39,40]. These structural components compose the "ground structure" of connective tissue in which cells and microcirculatory elements function. The entangling of GAGs and collagen fibrils provide elasticity to the structure to resist interstitial deformation and maintain interstitial volume [39]. Additional elements such as hyaluronic acid and proteoglycans are constrained to collagen fibrils to form the interstitial matrix.

The transportation of nutrients and waste products between blood, interstitium, and cells is essential to tissue viability [39]. ECF provides the medium for the exchange of substances between cells through dissolving, mixing, and transporting. Complex homeostatic mechanisms function to stabilize the ECF composition. The circulatory system consistently distributes ECF throughout the body. Hormones are able to be spread rapidly between cells, and waste products are distributed and removed from circulation at key points ensuring no localized accumulation develops [38].

2.2.2 *Fluid Exchange and Movement*

Arterial blood plasma, interstitial fluid, and lymph interact at blood capillaries. Water can move freely across capillary walls. Capillary blood pressure from the arterial end is greater than the hydrostatic pressure in the tissues. Water and other small molecules thus move from the capillaries to the interstitial fluid. This equalizes the crystalloid osmotic pressure [38,41]. Molecules that are too large to cross the capillary walls are plasma albumin, plasma globulins, and fibrinogen. The concentration of these substances increases as the blood moves to the venous end of the capillary. This colloid osmotic pressure works to draw water back into the capillary. This constant and rapid exchange as water moves out of and back into the capillary ensures that the ideal cell environment is maintained. A small portion of fluid is not drawn back into the capillaries, but is collected by the lymphatic system and eventually reenters the circulatory system. Lymph moves through lymph vessels to lymph nodes where waste products are removed and white blood cells added [38,41].

2.2.3 *Response to External Pressure*

In normally hydrated tissue, 65% to 75% of an externally applied load is transmitted to the interstitial fluid [39]. As described by Reddy [20], when external load, such as that occurring within a socket, is applied to soft tissue, the tissue deforms based on the connective tissue matrix resulting in the instantaneous occlusion of some blood vessels while other vessels are occluded within a few minutes as the load propagates to deeper tissue [21]. Conversely, the slow viscous movement of interstitial fluid and ground substance out of the region of pressure occurs in the order of several hours [21-23].

Volume loss due to external pressure may affect long-term tissue health and permanent residual limb volume loss. Reddy proposes a damage mechanism of interstitial fluid volume loss [20]. Interstitial fluid functions to provide cells with nutrients and a means of waste removal. As interstitial fluid is forced out of a region under load, blood and lymph vessels are occluded and contact stresses are induced between cells disrupting their normal functions. If enough interstitial fluid is evacuated, microvasculature may be damaged during load removal inadvertently releasing proteins to neighboring tissues. This, as well as lymphatic dysfunction and smooth muscle hypoxia under load, contribute to an accumulation of waste products and enzymes ultimately resulting in tissue necrosis. This tissue damage may cause high rates of atrophy in the residual limb quickly degrading socket fit.

2.3 BIOIMPEDANCE ANALYSIS

Bioimpedance is the ability of biological tissue to impede electric current [42]. Bioimpedance analysis, the non-invasive use of electrical current to measure characteristics of tissue, has been used in a variety of clinical applications largely in determining body composition such as total body water (TBW) and fat mass (FM) [43]. Most notable, bioimpedance analysis can be used to assess ECF and ICF volume within living tissue even in specific limb segments of interest [44].

2.3.1 *Theory*

Electrical properties of biological tissue may be classified as active or passive. Active response (bioelectricity) occurs when biological tissue elicits electricity from ionic activities inside cells (e.g. electrocardiographs [ECG] and electroencephalograph [EEG]) [42]. When an external electrical current source stimulates biological tissue, a passive response occurs. The concept of impedance is generalized from Ohm’s Law for use with alternating current [44]. Impedance (Z) is a complex quantity constructed of resistance (R) from total body water and reactance (X_C) from capacitance of the cell membrane shown in Equation 2.1 and Equation 2.2 [43].

$$Z = R + jX_C \tag{2.1}$$

$$|Z| = \sqrt{R^2 + X_C^2} \tag{2.2}$$

The opposition to current flow, resistance (R), is characterized by the shape of an object and depends on the length (L), surface area (A), and material type, described by resistivity (ρ). The resistance to voltage change across an object defines reactance, which is inversely related to signal frequency (f) and capacitance (C). Variations of resistance and reactance within different parts of the body can be measured to quantify biological variables [45].

The conducting components of the human body are known as fat free masses (FFM). FFM conduct electrical current through electrolytes dissolved in body water [43]. Blood and muscle are electrolyte-rich tissue, thus conduct current well and are considered electrically active. Alternatively, fat, bone, and air filled spaces are poor conductors [46,47]. These conductive elements of biological tissue in vivo are commonly modeled as an electric circuit (Figure 2.1) in which resistance of extracellular fluid is arranged in parallel to the capacitance cell membranes and the resistance of intracellular fluid [48,49]. In this model, the resistances are in opposition to alternating current (AC) through extracellular and intracellular paths. Reactance is due to the capacitive nature of the cell membranes creating a delay in conduction [44].

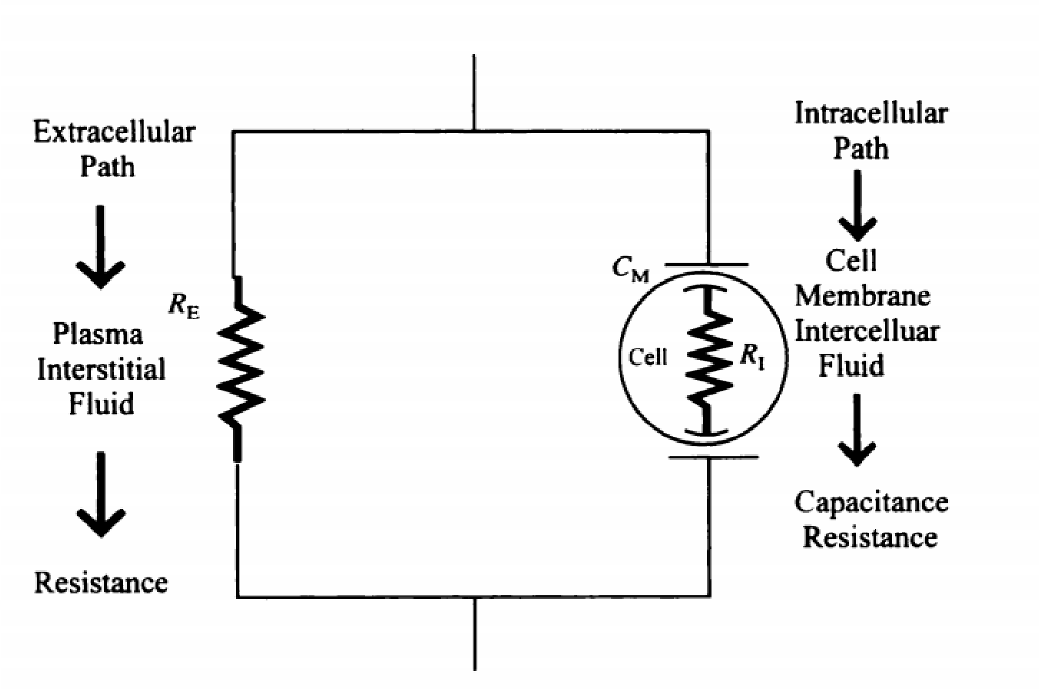

Figure 2.1. Circuit modeling biological elements. R_E = extracellular resistance; C_M = membrane capacitance; R_I = intracellular resistance. Adapted from [45].

Clinical applications of bioimpedance analysis have featured single-frequency bioimpedance analysis (SF-BIA) and multiple frequency bioimpedance analysis (MF-BIA) in which a range of frequencies is applied known as bioimpedance spectroscopy (BIS). Single-frequency bioimpedance has primarily been used to estimate total body water (TBW) by employing a 50 kHz AC current. BIS allows the differentiation between extracellular and intracellular fluid by using a broad range of frequencies [43]. In addition to whole body estimations, segmental bioimpedance allows individual segments of the body such as the trunk and extremities to be analyzed [50].

2.3.2 *Bioimpedance Spectroscopy*

BIS typically applies a frequency range from 4 kHz to 1 MHz. At low frequencies (<50 kHz), the current does not penetrate the cell membrane and passes through the extracellular fluid and the measurement corresponds primarily to ECF resistance. At high frequencies (>200 kHz), current conducts through both ICF and ECF and corresponds to total resistance of all conducting tissue or TBW (Figure 2.2).

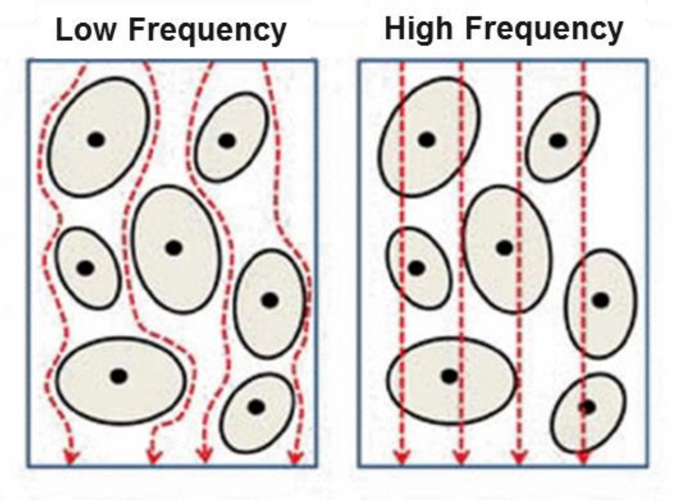

Figure 2.2. Current (dashed lines) moving through the body. During low frequency current travels in the extracellular space, and during high frequency current conducts through both intracellular and extracellular space. Adapted from [51].

The Cole model as shown in Figure 2.1 is based on the determination of resistance at zero frequency (R_0) and resistance at infinity frequency (R_{inf}) to predict ECF and TBW, respectively [49]. The impedance locus is fit with a least-squares nonlinear curve fit developed by Cole and revised by De Lorenzo et al [49,52]. The determined electrical resistance is inversely related to fluid volume [47]. Fluid volume is estimated by applying the values from the Cole model to volume conduction models based on mixture theory. Mixture theory generalizes the conductivity of a heterogeneous entity based on the distribution of conductive and non-conductive materials in the body [44,53]. Fenech and Jaffrin introduced Hanai's conductivity theory for volumetric calculations with Equation 2.3 to account for non-homogeneity of non-conducting tissue within the limb [52–54]:

$$V_{ECF} = \left(\frac{\rho_{ECF} C}{R_{ECF}}\right)^{2/3} \times \frac{L^{5/3}}{(4\pi)^{1/3}} \tag{2.3}$$

This equation assumes the limb segment to be a cylinder with an average circumference (C) and length (L). ECF resistance (R_{ECF}) is determined from the Cole model in bioimpedance analysis, and ρ_{ECF} is the specific resistivity of extracellular fluid.

In previous studies, TBW and ECF were significantly correlated with measured values based on radioisotopic dilution of deuterium and bromide [46,48,55,56]. Additionally, limb-segment muscle volume determined by bioimpedance calculations highly correlated with MRI-determined muscle volume [57]. Segmental bioimpedance has been performed on the trunk, arm, and leg [50,58,59].

2.3.3 *Applications in Prosthetics*

Blood plasma and interstitial fluid are the primary fluids responsible for residual limb volume changes [18] suggesting changes in these fluids will be reflected in the V_{ECF} measurement of bioimpedance analysis. Sanders et al. first applied segmental bioimpedance analysis to the prosthetics field, specifically in transtibial prosthesis users [60].

Previously a custom designed stationary unit was used to measure residual limb fluid volume changes while transtibial participants walked on a treadmill, sat, and stood [61]. Long-term, out-of-lab monitoring has been possible through the creation of a custom portable unit to allow more clinically relevant monitoring of prosthesis users in free-living environments [62,63]. To conduct and measure signal from the residual limb, thin custom electrodes made of electrically conductive tape (ARCare 8881, Adhesives Research Incorporated, Glen Rock, PA, USA) (0.05mm thickness) and hydrogel (9880, 3M, St. Paul, MN, USA) are placed on the limb according to anatomical landmarks for consistency and validity. The electrodes are covered on the limb with Tegaderm Transparent Film Dressing (3M, St. Paul, MN, USA) (thickness 0.03 mm). These electrodes tolerate wear within the prosthetic socket and are thin enough not to disrupt socket fit [61]. Thin wires (0.76 mm) from the electrodes run along the user's leg and connect to the bioimpedance system. The portable system is worn on a waist pack and weighs approximately 400g (Figure 2.3) [62,63].

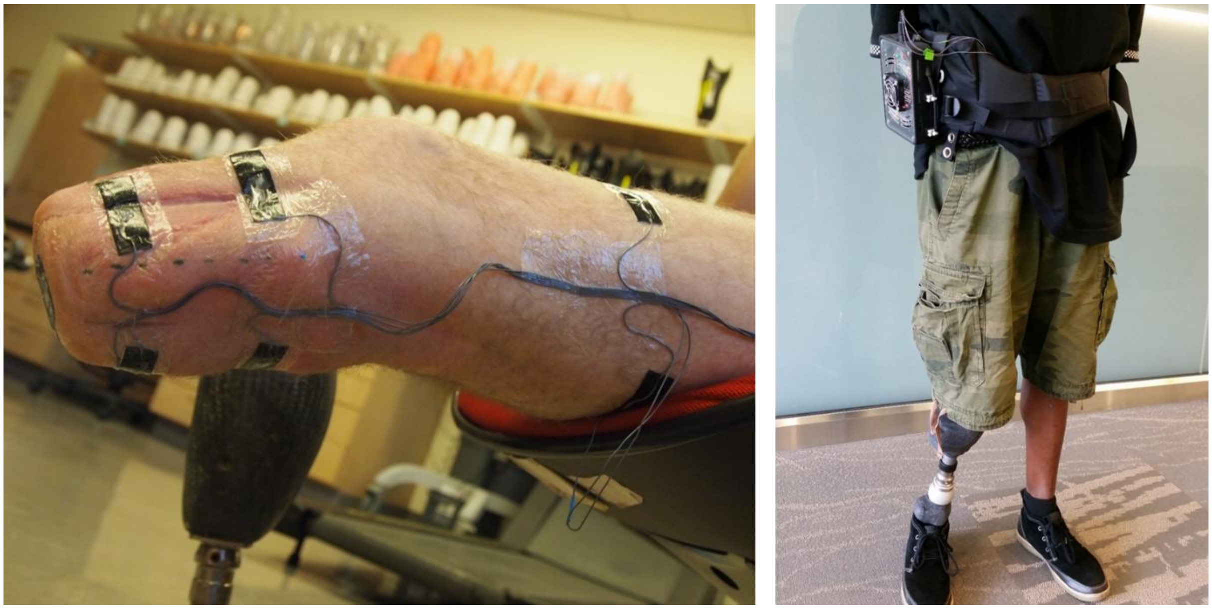

Figure 2.3. Portable bioimpedance analysis system. Bioimpedance electrodes placed on a residual limb (left) and a transtibial prosthesis user wearing a portable bioimpedance device on a waist belt. From [62].

An alternating current (AC) stimulus of about 300 µA over a range of frequencies from 3 kHz to 1 MHz is injected across the current-injection electrodes placed proximally and distally on the residual limb. Each frequency is applied for approximately 1 ms, and the entire sweep allows sampling at 30 Hz [63]. Voltage is sensed by two pairs of voltage-sensing electrodes which span the measurement area of interest, the portion of the residual limb within the socket. Anterior and posterior channels are measured. These regions within the limb are separated by fascial layers and the interosseous membrane (Figure 2.4) [61]. Previous instruments have been capable of resolving limb fluid volume changes of less than 0.1% [10].

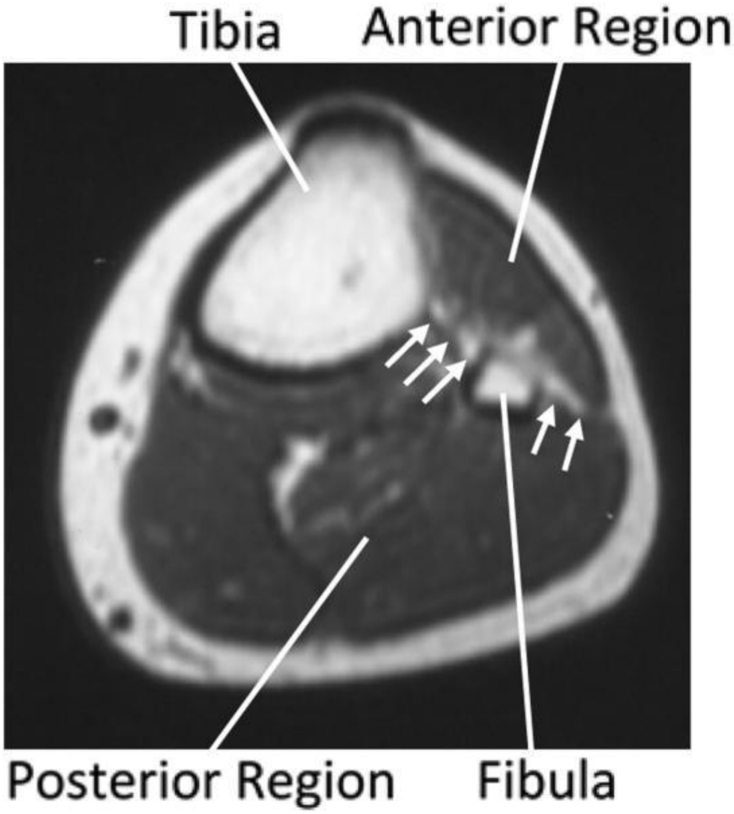

Figure 2.4. Cross-section of the lower limb. Note the regions of bioimpedance measurement (anterior and posterior) and the interosseous membrane (indicated by arrows). From [61].

2.4 RESIDUAL LIMB FLUID VOLUME CHANGE

2.4.1 *Sources of Volume Change*

Residual limb volume changes are typically most severe following the amputation surgery due to post-operative edema and injury to the limb [64–67]. Edema is the pathological accumulation of intracellular and extracellular fluid [68]. Muscle atrophy and general muscle activity also play a factor in post-operative volume changes [64–66].

Residual limbs reach maturity near 12-18 months when shape and volume reach relative stabilization [2]. Changes still occur on a daily and long term basis, but vary greatly between individuals depending on comorbidities, prosthesis fit, activity level, and dietary habits [2]. Limb volume change in mature residual limbs is most often attributed to a combination of factors relating to venous and arterial vasculature as well as fluctuations in interstitial fluid volume [18,69]. The arterial system delivers blood to the residual limb, and blood is returned to the heart throughout the venous system. Fluid moves from the vasculature at the capillaries where it enters the interstitial space and the lymphatic system eventually re-entering venous vasculature. Rapid changes are typically associated with the arterial and venous systems, while interstitial fluid moves more slowly. Residual limb volume change likely occurs when the exchange of interstitial fluid from the arterial system is out of balance with uptake to the venous system [18]. Therefore, the interstitial fluid is important towards influencing socket fit [2].

Previous studies have shown activity and socket size to be key contributors to limb volume changes. Comparing fluid volume changes in a normal and oversized (+6%) socket, Sanders et al. found that participants experienced greater morning-to-afternoon rates of loss in the anterior and anterior-distal regions of the limb [70]. These high rates of loss were attributed to focused interface normal and shear forces anteriorly due to the high sagittal plane bending moment of the socket. In addition, the use of prosthetic socks to accommodate the larger socket may have induced greater stresses on the limb from reduced mechanical limb-socket coupling.

Daily activities such as standing, walking, and sitting have been shown to have varying impacts on residual limb volume change [71]. Sanders et al. studied the residual limb fluid volume changes of 24 participants over a protocol featuring equal durations of sitting, standing, and walking [71]. Standing was the dominant force of limb volume loss. All of the participants lost fluid volume while standing with equal weight bearing (average rate of -0.4%/min). Pressures applied to the limb during weight bearing are transferred to the interstitial space in the residual limb forcing fluid out of the limb through venous transport. Walking and sitting each averaged an increase of 1% over the session. Surprisingly, 16 participant gained limb fluid volume while walking. Muscle activity, elevated arterial drive, and pressure release during swing phase are thought to contribute to fluid gain while walking [71,72]. Variability across subjects as to fluid volume patterns of gain and loss led to the creation of fluid volume profiles, which may be helpful for predicting volume change and creating accommodation strategies.

2.4.2 *Measurement Techniques*

The ability to measure and track changes to residual limb volume is important for understanding sources of change and developing volume management strategies. A number of methods have been developed for measuring residual limb volume in clinical studies including water displacement, casting, anthropometric measurements, optical scanning, laser scanning, MRI, and bioimpedance analysis [2].

Water displacement measures water displaced from a cylinder as the residual limb is inserted into the cylinder. Fernie et al. found this method repeatable within about 1.0% [73]. Inconsistent vertical motion and surface tension may affect measurement accuracy [73,74]. A variation of this technique first requires a cast of the limb. A positive model is created and then measured using water displacement [2,75]. Anthropometric measurements feature the use of a tape measure and calipers to record distances between anatomical landmarks and circumferences, which are then inputted to an anthropometric model to calculate volume [64,67]. Error for this method is estimated to be between 2.4% and 5.7% [2]. Optical scanning has allowed for repeatable and rapid measurements using either a silhouetting [76,77] or fringe projection method [75,78] though positioning can be difficult. Laser scanning has also been used to measure the residual limb volume [79–81]. This method minimized distortion but also required potentially difficult positioning [2]. Magnetic resonance imaging (MRI) has been used to characterize residual limb volume [82], but is not widely used due to temporal and financial requirements [2].

Volume change has been difficult to measure in the above mentioned methods largely due to the need to remove the residual limb from the socket [2] which in itself causes major changes in residual limb volume [18,83]. Segmental bioimpedance allows in-socket limb fluid volume measurements by relating the electrical resistance of the residual limb to extracellular and intracellular fluid volumes [52]. This method measures fluid volume, not total limb volume as with most other techniques. This method has been highly correlated to limb segment muscle volume determined from MRI [60] and has seen promising uses in prosthetics [10,36,60,62,70,83–85].

2.4.3 *Management Strategies*

Several means for accommodating for limb volume loss are available to prosthesis users. The most common method for accommodating to residual limb volume change is the addition or removal of prosthetic socks [7,86]. Prosthetic socks are woven fabric applied between the liner and socket or between the limb and liner. Volume accommodations may be adjusted based on both the thickness (i.e. ply) and layering of prosthetic socks [87–89]. Socks create a soft layer between the limb and the socket, weakening the important mechanical connection [2]. Socks create a level of inconvenience for the user in that they require the prosthesis to be removed to make accommodations.

Other strategies involve socket inserts or the use of adjustable-paneled sockets. These technologies change the shape and size of the socket to conform to the residual limb. The use of both socks and adjustable-paneled sockets have been shown to further reduce the volume of the residual limb as socket volume is reduced [10,84]. Furthermore, these methods of volume compensation are reactive and are limited in their capacity to induce volume recovery, thus further propagating the problem and potentially increasing the need for a new socket.

Socket release (i.e. short-term removal or doffing of the prosthesis) is an alternative strategy that may help prosthesis users recover fluid volume during times of resting [62,83,85]. In a short-term laboratory evaluation, doffing the prosthesis or both the prosthesis and liner for 30 minutes improved residual limb fluid volume recovery and retention compared to leaving the prosthesis on the limb [85]. During multiple 6-hour testing sessions, intermittent doffing was compared to no accommodation strategy. Doffing the prosthesis twice for 20 minutes provided accommodation by reducing overall fluid volume loss for traditional socket users (i.e. not elevated vacuum or suction) [62].

Elevated vacuum systems have been indicated as a means to control residual limb volume changes [14,15]. Clinical implementation of this technology can be difficult due to cost and frequent maintenance of liners, sockets, and sleeves to prevent the loss of vacuum [17,27,28]. Gholizadeh et al. notes that elevated vacuum needs careful evaluation and can cause blistering if used improperly [27].

2.5 ELEVATED VACUUM

2.5.1 *System and Theory*

Elevated vacuum (EV) describes a specialized technique used with artificial limbs to maintain suspension and manage residual limb volume changes. A typical system, shown in Figure 2.5, features a liner, a sealing sleeve, and an air evacuation pump.

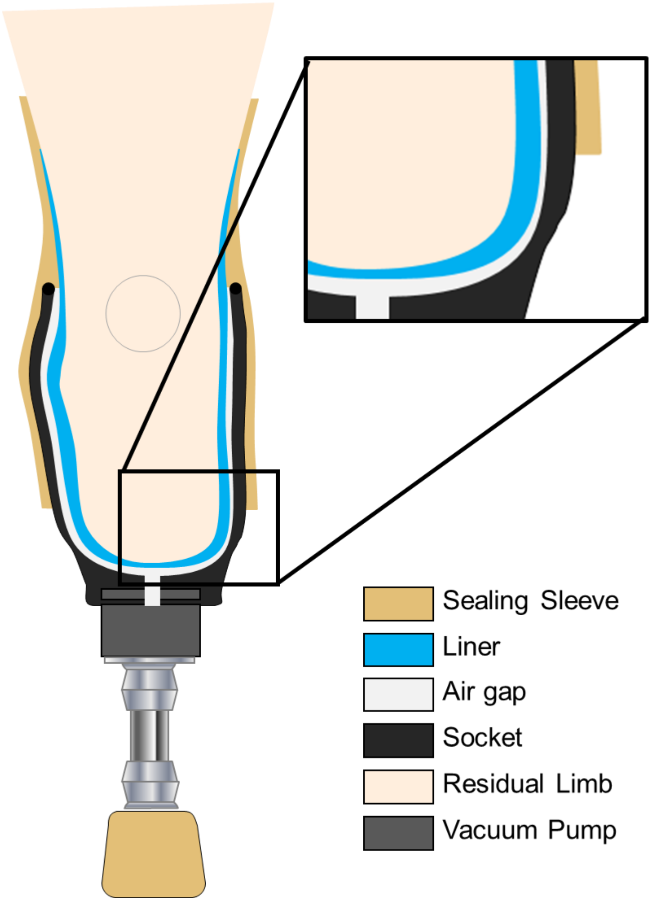

Figure 2.5. Typical elevated vacuum system with limb-socket interface detail. Adapted from Prosthetic Design Solutions, LLC.

The mechanical or electrical pump evacuates the air between the liner and the socket wall to maintain a continuous negative pressure environment within the socket [90]. The socket is typically sealed proximally with an external sealing sleeve, though some systems seal internally with a hypobaric sealing membrane around the liner [27]. This approach is more proactive than adjustable sockets and requires less maintenance from the user since it is acting continuously. EV attempts to promote natural fluid exchange to regulate volume in the residual limb, reduce stresses to the limb, and improve suspension and balance. As the pump removes air from between the socket and the liner, the liner and tissue within the liner are pulled to the wall of the socket limiting movement in all directions.

2.5.2 *Suspension and Limb Health*

Elevated vacuum systems have become popular in populations desiring continued levels of suspension during a variety of activities [91]. Studies have suggested that elevated vacuum acts a powerful suspension method [14,90,92–94]. Board et al. measured vertical displacement with x-ray and loads representative of swing phase to compare elevated vacuum and suction [14]. A similar comparison was made by Gerschutz et al. using distally placed inductive sensors to dynamically measure displacement [94]. Klute et al. employed a 12-camera motion analysis system to compare limb displacements with elevated vacuum and locking pin systems [17]. Each of these studies showed less vertical displacement with elevated vacuum suggesting improved socket fit. The relationship between displacement and socket fit was investigated by Wernke et al. using a benchtop set-up with a tension compression machine as vacuum pressure and fit were varied [34]. The vacuum pressure-displacement relationship was dependent on vacuum level and socket fit. The benefits of elevated vacuum have also led to some improved functional outcomes and self-reported satisfaction in prosthesis users [27,28,30,95–98], though these have largely been reported in case studies.

Elevated vacuum has been thought to improve overall residual limb health based on self-reported questionnaires, clinical outcomes, and wound closure studies. Rink et al. quantitatively assessed residual-limb circulation with elevated vacuum using a randomized crossover study design [20]. Ten participants with lower limb amputation (five transtibial, five transfemoral) were assessed to compare elevated vacuum with a non-elevated vacuum control over a 32-week study period. Non-invasive measures included transepidermal water loss, laser speckle imaging, and transcutaneous oxygen. Functional hyperspectral imaging techniques were also used. Rink et al. describes these measures in detail [99]. Following 16 weeks of EV use residual limb oxygenation during treadmill walking was improved and prosthesis-induced reactive hyperemia was attenuated compared to other suspension methods. Overall, outcomes suggest long-term use of elevated vacuum helps to improve perfusion and preserve skin barrier function.

2.5.3 *Limb Fluid Volume Management*

EV is used clinically for maintaining residual limb fluid volume. The mechanism of this approach to better maintain fluid volume is speculated to function by the negative pressure pulling the liner to the wall of the socket and expanding the liner volume and the tissue within the liner. This tissue expansion lowers interstitial fluid pressure thus increasing fluid volume transport to the interstitial space limiting fluid loss out of the residual limb and better maintaining socket fit over time [13]. The expansion of the residual limb tissue due to the liner volume expansion is consistent with Boyle's law [34,100]. For comparing the same substance under two different volumes (V), Equation 2.4 is applicable for pressure (P):

$$V_1P_1 = V_2P_2 \tag{2.4}$$

Boyle's Law states that as volume increases, the pressure of the gas decreases in proportion, and as volume decreases, the pressure of the gas increases. As the volume contained within a liner increases during vacuum application, the residual limb tissue expands due to the lower pressure. This is assuming temperature and the amount of gas remains unchanged.

Several studies have examined the effect of elevated vacuum on residual limb volume with mixed results. Board et al. compared limb volume change using alginate casting and water displacement techniques after 30 minutes of treadmill walking in suction suspension and EV suspension (-23 inHg) [14]. Suction suspension uses a one-way valve expulsion port, sealing sleeve, and the user’s body weight to expel air through the valve to create a small negative pressure during swing phase [33]. With elevated vacuum, participants (n=10) not only lost less residual limb volume than when using suction suspension, but actually gained volume. Beil et al. measured interface pressures during ambulation with suction and EV prosthetic sockets using liners instrumented with force sensing resistors [101]. They found that the EV socket created significantly lower positive-pressure impulses and peak pressures during stance phase. Beil et al. believe the lower positive pressures during stance phase with the EV socket reduce the amount of fluid forced out of the limb. Goswami et al. evaluated residual limb volume changes with alginate casting and water displacement techniques under elevated vacuum (-23 inHg) in different socket sizes finding that after walking for 18 minutes the fluid balance of the residual limb experienced a net gain in all socket sizes [15]. Gerschutz et al. examined the limb volume changes of one transtibial prosthesis user after doffing the socket and 10 minutes after doffing the socket using an optical limb-scanning technique. Comparisons were made with the absence of elevated vacuum (i.e. suction), 10 inHg of vacuum, and 15 inHg of vacuum. Results suggest volume retention was improved with elevated vacuum.

A randomized cross-over study by Klute et al. showed no effect of elevated vacuum when limb volumes (n=5) after 30 minutes of treadmill walking were no different compared with using a locking pin suspension system [17]. All five participants wore locking pin systems at the time of recruitment and received a three-week acclimation period for each study intervention. Limb volume was measured using an optical measurement system before and after walking for 30 minutes. Other outcome measures included activity level, residual limb vertical displacement (pistoning), and a self-report questionnaire, the Prosthesis Evaluation Questionnaire (PEQ) [102].

Activity levels were significantly lower with EV, though pistoning was slightly less with EV. Many PEQ results favored the locking pin suspension.

A major limitation of these previous studies was that the limb had to be removed from the socket before the volume measurement, for volume is known to change rapidly upon socket removal [2,83]. Using bioimpedance analysis, Sanders et al. showed residual limb fluid volume increased during short term walking for healthy subjects (i.e. no vascular disease or diabetes) using various elevated vacuum devices in a small case study, though this trend often persisted when vacuum was off or lock-and-pin was used [13]. All of these studies only examined a single activity (i.e. walking) over a small segment of an amputee's day and should not be used to generalize the effect of elevated vacuum on daily limb fluid volume. Sanders et al. identified a number of variables as potentially influential when comparing to elevated vacuum [13]:

- Limb soft tissue mechanical consistency
- Size of residual limb relative to size of socket
- Socket shape
- Subject health
- Time after doffing when using out-of-socket measurement techniques
- Time into session when measurements are made
- Ordering of interventions within a session
- Time of testing
- Use of elevated vacuum as the regular prosthesis (i.e. subject accommodation)
- Weight differences between prostheses being tested

2.5.4 *Other Negative Pressure Applications*

The use of air pressure to influence peripheral circulation was introduced in the 1800's [103]. Expanding from this, Sinkowitz and Gottlieb used a constant negative pressure to improve peripheral circulation in lower limbs [104]. This exposure to negative pressure as it relates to lower body negative pressure (LBNP) and leg negative pressure (LNP) has demonstrated the ability to alter local vascular transmural pressure and result in increased fluid volume [21–23]. However, constant application of negative pressure has been shown to elicit a vasoconstrictor reflex resulting in a reduction of blood flow in some cases [25,105]. Early studies alternating positive and negative pressure demonstrated increased skin temperature, improved wound healing, and improved pain management [106,107]. Short oscillations of intermittent negative pressure (INP) applied to extremities have been shown to increase arterial blood flow [108–110]. INP applied using cycles of 10 seconds at -40 mmHg (1.6 inHg) and 7 seconds at atmospheric pressure has been suggested to bypass the vasoconstrictor effect of the venoarterial reflex [25,110,111]. Sundby et al. evaluated blood flow in the foot at various sequences of negative pressure showing the timescale of expected changes with negative pressure application (Figure 2.6). Peak blood flow velocity (44% from baseline) occurred approximately 4 seconds after application of negative pressure. The authors noted the importance of arteriolar vasomotion and capillary flow motion to tissue viability [25].

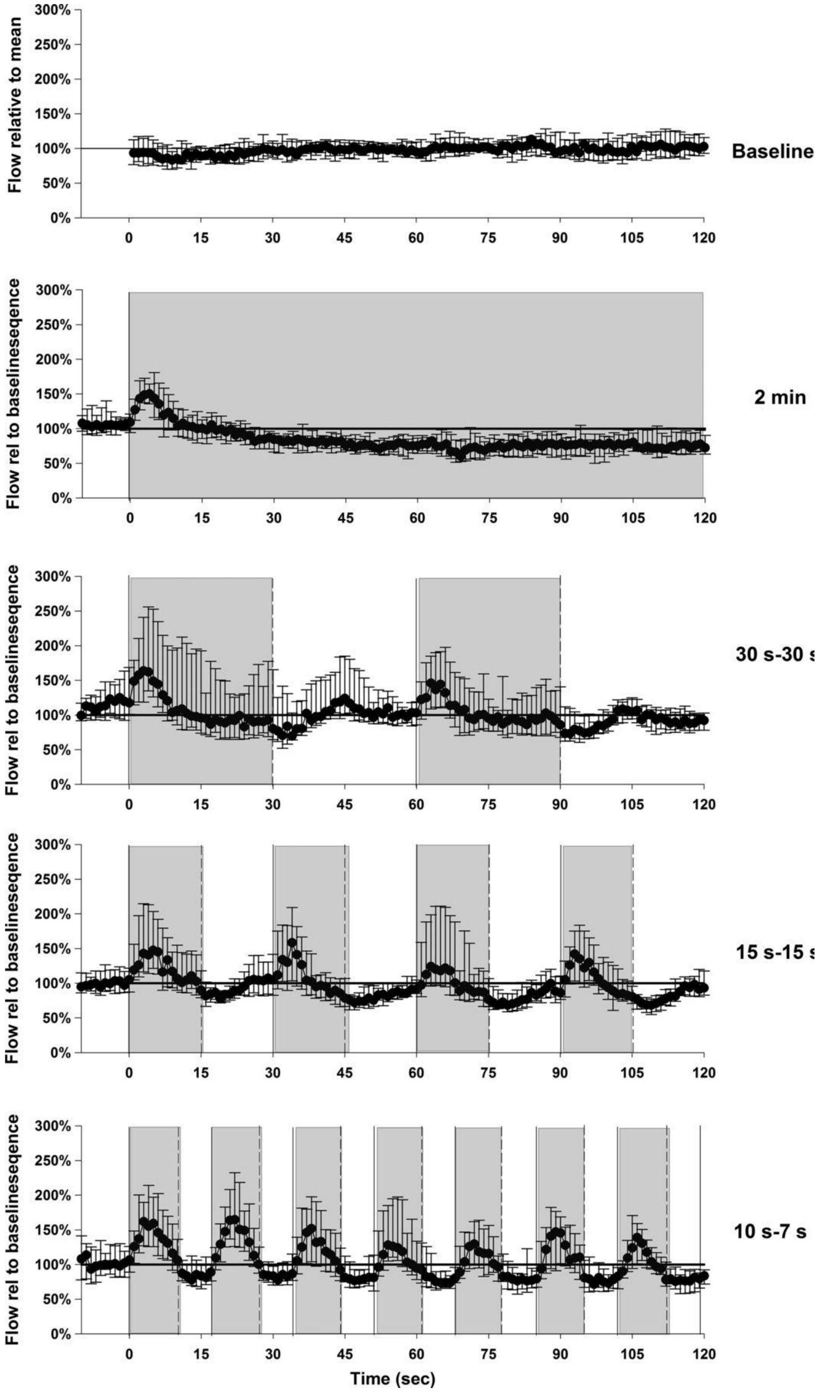

Figure 2.6. Blood flow velocity in the dorsal pedis-posterior tibial artery. Blood flow velocity was measured by ultrasound Doppler during various sequences of negative pressure. Gray indicates negative pressure application. From [25].

Another clinical application of negative pressure is negative pressure wound therapy (NPWT), which is used to treat acute and chronic wounds. Continuous or intermittent negative pressure is applied to a sealed wound dressing to facilitate drainage and expedite the rate of healing particularly in compromised patient populations [112]. Of particular interest, a specific range of NPWT has been shown to increase blood flow in the vicinity of the wound site [112–118]. Morykwas et al. used a porcine model to demonstrate increased blood flow in both subcutaneous tissue and muscle using laser Doppler needle probes [112]. Incrementally increasing negative pressure from 0 mmHg to -400 mmHg (0 inHg to -15 inHg), authors saw peak flows at -125 mmHg (-5 inHg). These flows declined after 5 to 7 minutes of continuous negative pressure application. While the multimodal mechanisms of NPWT are still being researched, the application of negative pressure displaces excess fluid around the wound to decompress small blood vessels [112].

Studies have also used visualization techniques to evaluate the effect of negative pressure on microcirculation. Ichioka et al. used intravital microscopy on the wound bed of a mouse model at 0 mmHg, -125 mmHg (4.9 inHg), and -500 mmHg (-20 inHg). The -125 mmHg group increased local blood flow while the -500 mmHg group gradually decreased. The control group showed no significant changes (Figure 2.7).

Researchers have continued to seek an understanding of the impact of varying negative pressure in NPWT applications [119]. Compiling of these studies indicate that the therapeutic range of negative pressure is -50 mmHg to -150 mmHg (Figure 2.8). These studies reinforce the notion that negative pressure may be used to positively influence local blood flow; however, care must be taken not to exceed the therapeutic range. The concept of a therapeutic range is likely to apply to elevated vacuum use in prosthetics as well.

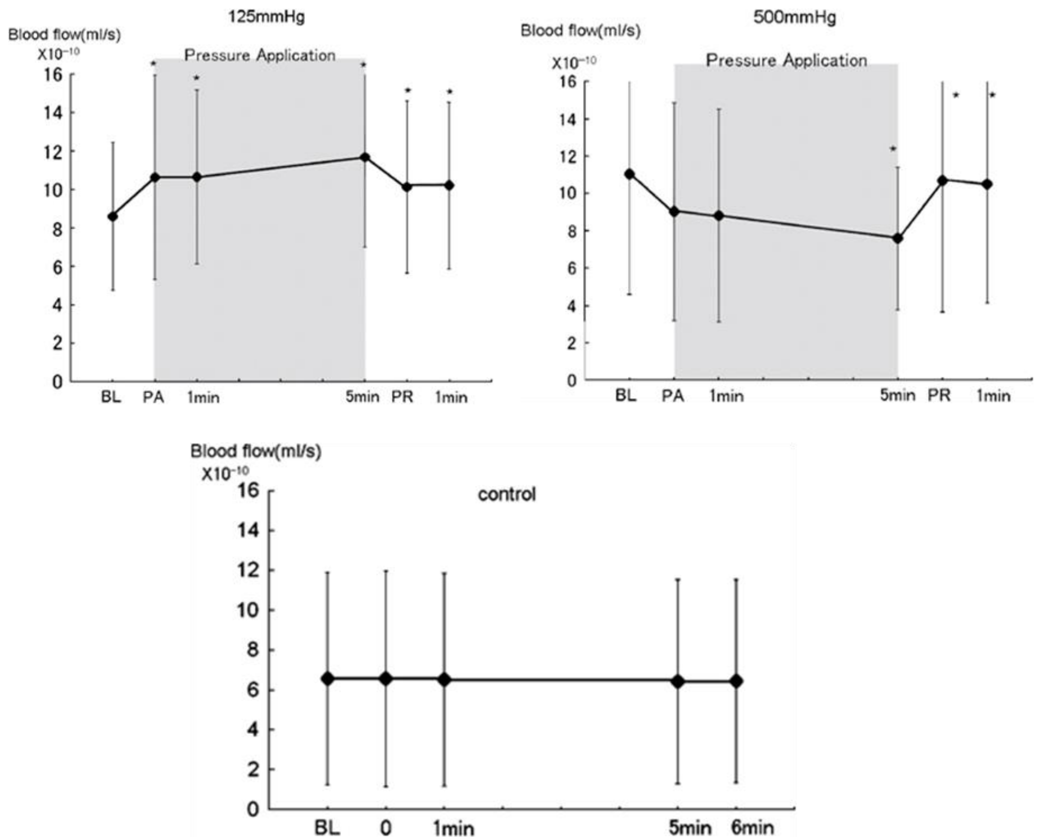

Figure 2.7. Blood flow in mouse model using intravital microscopy. -125 mmHg increased in blood flow while -500 mmHg decreased in blood flow after negative pressure application. No changes were seen in the control. From [114].

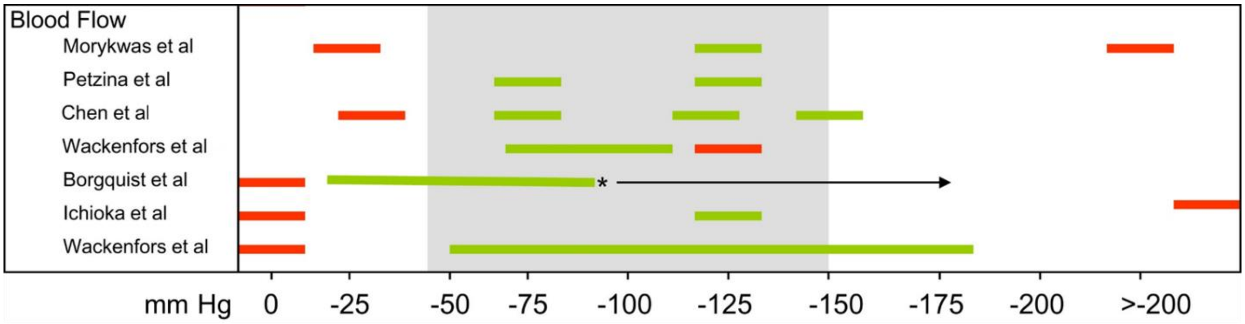

Figure 2.8. Result of various negative pressure in NPWT on blood flow. Green indicates ranges of beneficial effects. Red indicates ranges of no effect or detrimental effect. * indicates that higher levels may be effective (arrow), but no further benefit. The gray region shows the proposed therapeutic range of negative pressure based on previous studies. Adapted from [119].

Chapter 3. ASSESSING THE EFFECTIVENESS OF ELEVATED VACUUM TO MANAGE DAILY RESIDUAL LIMB FLUID VOLUME

3.1 INTRODUCTION

Daily limb volume loss is a challenge for many individuals with transtibial amputation [2]. Residual limb fluid volume loss is not only detrimental to limb health [39], but greatly impacts the fit of the prosthetic socket [1]. As the residual limb reduces in volume, the socket may become loose adversely affecting interface pressures and shear stress distributions [120]. Poor socket fit may lead to skin breakdown, poor gait, and injurious falls [2].

Advances in prosthetic socket technology have served to increase the number of volume accommodation strategies available to individuals with lower limb amputation. Strategies such as prosthetic socks, pads, and adjustable paneled sockets are only temporarily effective and often lead to additional volume loss [10,11]. Other strategies, such as socket release [62,85,121], may be effective but are not always convenient for many users. Elevated vacuum (EV), a suspension method that applies continuous negative pressure between the liner and socket [14,17,90,93,94], has been suggested as a strategy for preventing or slowing daily residual limb change [14]. In theory, EV has been suggested to influence fluid volume by reducing residual limb pressures during stance phase loading and increasing negative pressure during swing phase. The reduced pressure between the prosthetic liner and the prosthetic socket lowers interstitial fluid pressure. This results in increased fluid volume transport to the interstitial space, reducing residual limb volume loss and better maintaining socket fit over time [13]. Beil et al. measured interface pressures during ambulation with suction suspension and EV prosthetic sockets using liners instrumented with force sensing resistors [101]. Suction suspension (SS) uses a one-way valve expulsion port, sealing sleeve, and the user's body weight to expel air through the valve to create negative pressure during swing phase [33]. They found that the EV socket created significantly lower positive-pressure impulses and peak pressures during stance phase. Beil et al. suggested that the lower positive pressures during stance phase with the EV socket reduce the amount of fluid forced out of the limb.

Research assessing the effectiveness of EV in managing residual limb volume has shown inconsistent results [13–17]. Board et al. compared prosthesis users' limb volume change using alginate casting and water displacement techniques after 30 minutes of treadmill walking in SS and EV (-23 inHg) [14]. Participants not only lost less residual limb volume with EV but gained volume. Goswami et al. evaluated residual limb volume changes with alginate casting and water displacement techniques under EV (-23 inHg) in different socket sizes, finding that increasing socket size resulted in increasing volume gains after walking for 18 minutes [15]. Gerschutz et al. examined limb volume changes of one transtibial EV prosthesis user with an optical limb-scanning technique. Results suggested volume retention was improved with EV compared to SS. Using bioimpedance analysis during short-term walking segments, Sanders et al. showed that the effectiveness of EV to reduce residual limb fluid volume losses or increase gains was inconsistent among EV users in a series of case studies [122]. A randomized cross-over study by Klute et al. showed no effect of elevated vacuum when limb volume changes (n=5) after 30 minutes of treadmill walking were no different compared with using a locking pin suspension system [17]. Limb volume was measured using an optical measurement system before and after walking.

With the exception of Sanders et al. [13], each of these previous studies reported out-of-socket limb volume measurements which require the socket to be doffed [14–17]. Residual limb fluid volume changes rapidly with the removal of the socket and these changes vary by individual

[18]. In-socket residual limb volume measurements, such as those from bioimpedance analysis, are most relevant for evaluating the effectiveness of volume accommodation strategies such as EV. Another methodological limitation of prior EV studies is that they primarily evaluated volume change during a single activity (i.e. walking) over a small time period ranging from 3 minutes [13] to 30 minutes [17]; therefore, results may not be indicative of volume changes that might occur over an entire day of performing various activities.

The goal of this study is to determine if EV more effectively maintains residual limb fluid volume compared to a control condition, SS. This study will overcome a number of methodological limitations of previous studies by using an in-socket volume measurement technique (i.e. bioimpedance analysis) and by incorporating activities that are more representative of typical daily activities and therefore have greater ecological validity. This study will improve understanding of EV as a clinical accommodation strategy for managing residual limb volume.

3.2 METHODS

Volunteers were recruited from the local amputee population as well as from a single prosthetic clinic located in Edmond, OK. Inclusion criteria for participation in this study were a transtibial amputation of at least 18 months and classification as a limited community ambulator with a Medicare Functional Classification Level (MFCL) of K-2 or higher. Participants were required to report using a properly fitting EV socket with an electronic vacuum pump for at least 6 hours per day. Electronic vacuum pumps provide a more controlled and continuous level of vacuum in the socket compared to mechanical vacuum pumps. Exclusion criteria included actively undergoing socket revisions and any presence of skin breakdown. A University of Washington Institutional Review Board approved the study procedures, and informed consent was obtained from each participant before beginning.

The study used a fixed-order crossover design consisting of two visits spaced apart by approximately one week. On the first test day, the participants used their regular EV system at the maximum vacuum setting within the allowable range established by each participant’s prosthetist. For the second test day, the pump was turned off (i.e. standby mode) before donning the socket to begin the activity protocol, preventing vacuum regulation and creating SS. The vacuum system was returned to each participant’s normal vacuum setting following the second test session. Suction was deemed an appropriate control due to its popularity as a standard suspension method [33]. Using suction also ensured that the same socket and components were used for each test condition. A fixed-order design was selected for safety to ensure participants were comfortable completing the protocol with their standard prosthesis before using a modified suspension during the SS condition. Test sessions were conducted remotely in Edmond, Oklahoma, as well as locally at the University of Washington campus in Seattle, Washington. During each visit, a 5.5-hour standardized protocol was conducted outside of the lab environment along indoor hallways. During the protocol a portable bioimpedance analyzer monitored residual limb fluid volume [61–63]. Within-socket vacuum pressure was also recorded to ensure proper EV and SS function. For participants using the WillowWood LimbLogic EV system (The Ohio Willow Wood Company, Mt. Sterling, OH, USA), the LimbLogic Communicator and data logging software were used to record vacuum pressure at 20 Hz. For other EV systems, vacuum pressure was measured with a differential pressure sensor (Honeywell, Morris Plains, NJ, USA) and a custom data acquisition unit.

Fluid volumes in the anterior and posterior regions of the residual limb were measured using versions of custom, portable, multi-frequency, bioimpedance analyzers developed in our lab, as described previously in detail [62,63]. Bioimpedance analysis allows for continuous in-socket limb fluid volume measurements by relating the electrical resistance of the residual limb to extracellular fluid volumes [52] and has been highly correlated to limb segment muscle volume determined from MRI [60] and has seen promising applications in prosthetics [10,60,83–85]. Thin electrodes were custom produced with a layer of electrically conductive tape (ARCare 8881, Adhesives Research Incorporated, Glen Rock, PA, USA) and a layer of hydrogel (9880, 3M, Maplewood, MN, USA). Electrodes placed on the proximal thigh and distal residual limb injected a small electrical current, approximately 300 μA peak-to-peak, across multiple frequencies between 3 kHz and 1 MHz. Additional electrodes were placed over the regions of interest on the residual limb that are within the socket, across the anterior lateral surface and centered along the posterior surface to measure voltage changes. De Lorenzo's form of the Cole model was used to determine extracellular fluid resistance values from the current and voltage values [52] and a geometric volume conduction model was then applied to determine limb extracellular fluid volume [53,54]. Sampling frequency for the instruments was 30 Hz.

Upon arriving at the testing location, participants sat for 10 minutes with their prosthesis donned to reach a homeostatic state. Then participants removed their prosthesis and bioimpedance analysis electrodes were applied to their residual limb before beginning the activity protocol. Each test protocol was broken into three cycles (Figure 3.1). These cycles consisted of three, half-hour intervals of varying activity compositions. The first two intervals were of low activity, and the third interval was of high activity. The low activity interval included a total of 2 minutes of walking, 22 minutes of sitting, and 6 minutes of standing. The high activity contained 15 minutes of walking and 15 minutes of standing. Participants were asked to stand with equal weight for several seconds at the start and end of each stand period. Brief equal-weight stands were also executed before and after each period of sitting. The equal-weight stands were essential for the analysis of bioimpedance data. Twenty-minute seated rests were placed between each cycle. A low sodium meal (i.e. lunch) was provided for the participants during the first rest of each session. The participants were provided the same meal for both test sessions.

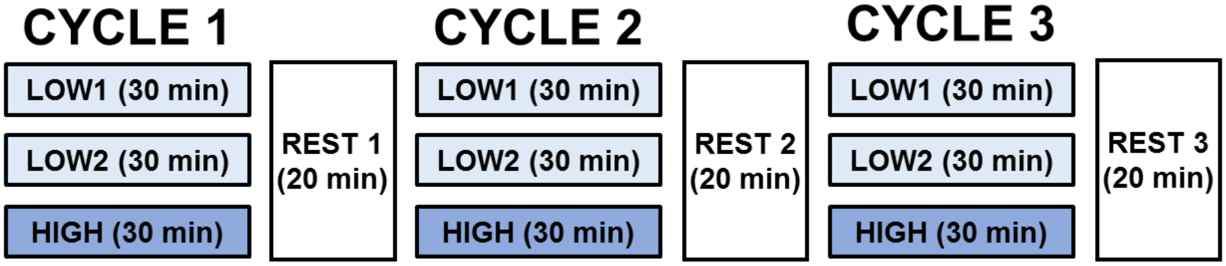

Figure 3.1. Standardized activity protocol conducted each session. Each cycle consisted of two low activity intervals (largely sitting, some walking and standing) followed by a high activity interval (walking and standing). Twenty minute seated rests were conducted between each cycle.

At the initial visit, the researchers collected participant health history, date of birth, activity information, date of amputation, amputation etiology, height, weight, residual limb length, and mid-limb circumference. Researchers also recorded notes on the characteristics of each prosthesis including EV type, sock use, EV settings, and prosthetic components such as liner type. All aspects of the prosthesis (e.g. socket, sleeve, socks, and liner) were maintained across test sessions. Participants were asked not to consume caffeine or alcohol and to maintain a consistent diet for each test day.

Times of equal-weight standing were used to track fluid volume changes over the test session. A sample plot of extracellular limb fluid volume (Vecf) over a session is shown in Figure 3.2 with the cycles and activity intervals within each cycle indicated. The fluid volume after the first cycle was considered the reference volume for each participant, consistent with previous efforts that used a similar activity protocol [62]. Fluid volume was then expressed as a percentage of that reference using Equation 3.1 [83]:

$$V_{\%}(t) = 100 \times \frac{V_{mL}(t) - V_{mL,ref}}{V_{mL,ref}} \tag{3.1}$$

The overall rate of limb fluid volume change (%/h) was calculated as the percent change from reference volume to the end of the protocol divided by elapsed time to account for slight protocol variations. For each region (i.e. anterior and posterior), the overall rate of fluid volume change for each test condition (i.e. EV and SS) was compared with the Wilcoxon signed-rank test. Non-parametric statistical tests were used because of the small sample size and non-normal distribution of the data (as determined by the Shapiro-Wilk test of normality). A significance level of 0.05 was used for all comparison expect where a Bonferroni correction for multiple comparisons was applied. Statistical tests were conducted using SPSS (IBM SPSS Statistics, Version 24.0, Armonk, NY, USA).

The rate of fluid volume change during each of the three cycles was determined to assess how the shot-term rates differed between test conditions and throughout the protocol. A linear regression was applied to the equal-weight standing points of each cycle, and a Wilcoxon signed-rank test was used to compare rates of fluid volume change during corresponding cycles across test conditions for each limb region. A Friedman test with pairwise comparisons evaluated if the rates of fluid volume change within each condition differed by cycle.

For each limb region, fluid volume change for each activity (i.e. sit, stand, walk) was segmented and summed following the reference volume after Cycle 1 and divided by the time spent conducting each activity. This cumulative fluid volume rate of change for each activity was then compared between test conditions with the Wilcoxon signed-rank test. When the distribution of median differences between test conditions was not symmetrical, the sign test was used to evaluate differences.

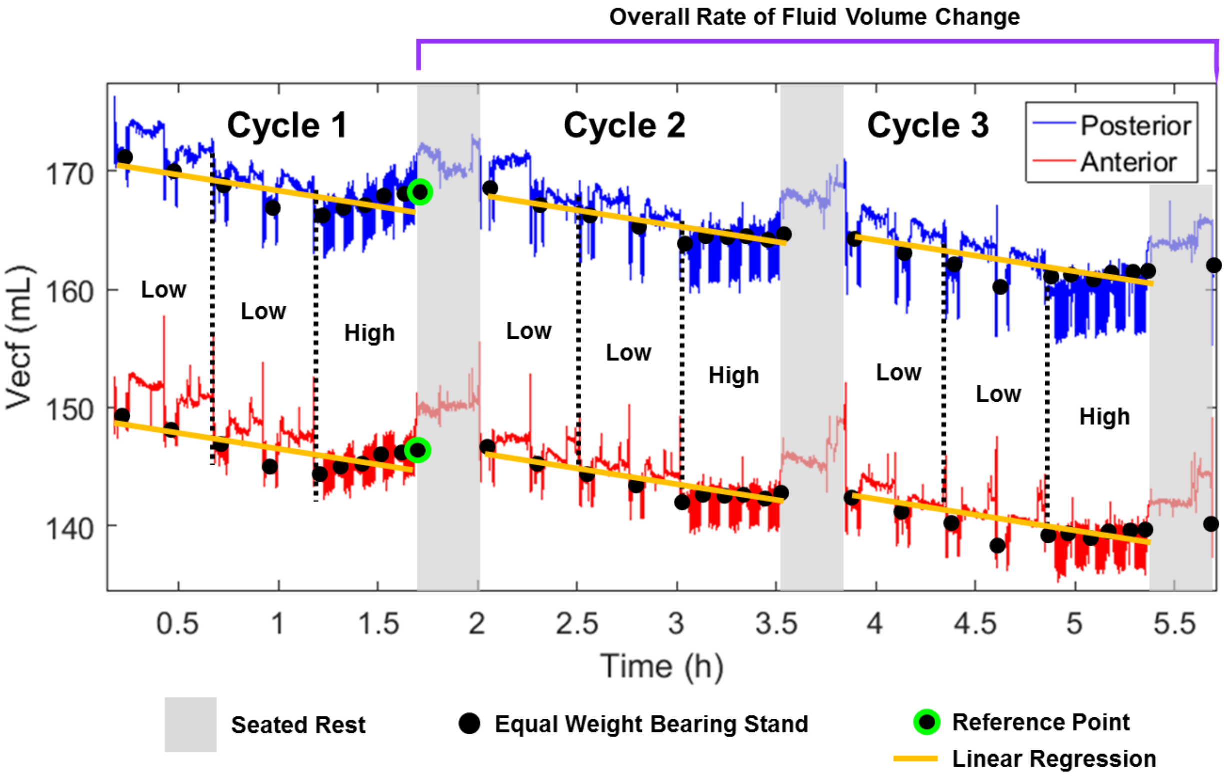

Figure 3.2. Example plot of extracellular fluid volume (Vecf). Plot shows data from Participant 5 using SS.

3.3 RESULTS

3.3.1 *Participant Demographics*

Twelve individuals with transtibial amputation were tested, including nine males and three females (Table 3.1). Five participants were diabetic and none self-reported peripheral vascular disease though four reported cardiovascular complications such as blood clots, heart attack, use of blood thinners, heart bypass, and stents. Based on reported activity, the research prosthetist classified all participants as K-3 Medicare Functional Classification Level (MFCL) except for two who were classified as K-4. Body mass index (BMI) ranged from normal (18.5-24.9) to obese (≥30).

Table 3.1. Participant characteristics.

ID #	Gender	BioZ Device Version	MFCL	Tobacco	Diabetes/ CV Issues	Etiology	Age (years)	Since Amputation (years)	Mass (kg)	Height (cm)	BMI	Limb Length (cm)	Mid Limb Circ (cm)
1	F	A	K-3	Y	N/Y	Infection	41.7	5.5	78.0	177.8	24.7	13.5	31.1
2	M	A	K-4	N	N/N	Traumatic	51.7	26.7	98.9	175.3	32.2	13.2	29.5
3	F	A	K-3	Y	Y/N	Traumatic	40.5	13.7	78.0	160.0	30.5	16.2	26.7
4	M	A	K-3	N	N/N	Traumatic	40.1	8.8	131.5	188.0	37.2	19.5	32.1
5	M	A	K-3	N	Y/N	Traumatic	66.6	46.9	102.1	167.6	36.3	15.2	29.4
6	M	B	K-3	N	Y/Y	Infection	70.9	7.0	81.6	172.7	27.4	10.5	28.9
7	M	B	K-3	N	Y/Y	Infection	72.5	7.6	127.5	195.6	33.3	16.5	30.7
8	F	B	K-3	N	Y/N	Infection	52.6	4.0	77.6	167.6	27.6	16.0	27.0
9	M	B	K-3	N	N/N	Infection	64.8	45.0	97.1	177.8	30.7	10.0	31.3
10	M	B	K-4	N	N/N	Traumatic	36.8	14.8	90.0	189.2	25.1	11.0	31.6
11	M	B	K-3	N	N/Y	Traumatic	68.9	16.1	101.8	180.3	31.3	15.0	30.2
12	M	B	K-3	N	N/N	Traumatic	48.3	3.9	122.9	172.7	41.2	19.0	37.0
						Mean	54.6	16.7	98.9	177.1	31.5	14.6	30.4
						Median	52.1	11.3	98.0	176.5	31.0	15.1	30.4
						SD	13.4	15.1	19.5	10.1	5.0	3.1	2.7
						Min	36.8	3.9	77.6	160.0	24.7	10.0	26.7
						Max	72.5	46.9	131.5	195.6	41.2	19.5	37.0

BioZ: bioimpedance; Circ: circumference; CV: cardiovascular; M: male; F: female; Y: yes, N: no

3.3.2 *Participant Prosthetic Systems*

Prosthesis characteristics for each participant are shown in Table 3.2. All participants in this study used the WillowWood LimbLogic EV system. Three participants used a traditional configuration with the pump mounted below the carbon fiber socket with an outer sealing sleeve. One participant used the WillowWood One system which featured the distally mounted pump with an inner flexible socket (thermoplastic polymer) and inner sealing sleeve. Eight of the participants used a custom prosthetic system featuring both vacuum and pin suspensions, shown in Figure 3.3. This system included an inner flexible socket attached to the WillowWood LimbLogic vacuum system. An inner sealing sleeve was applied over this inner socket, which was then inserted into a laminated carbon fiber frame with a locking pin.

For all participants, the socket environment was sealed proximally with gel-to-gel contact between a sealing sleeve and the liner. For fabric-backed liners, this required the proximal edge of the liner to be rolled down to expose the underlying gel. Sock use was consistent between and during sessions for each participant. Sock use ranged from no socks to two gel socks. Eleven participants used a user max value of -20 inHg while one participant used -10 inHg. The range value indicates how much vacuum may be lost before the pump is activated to return pressure to the set point.

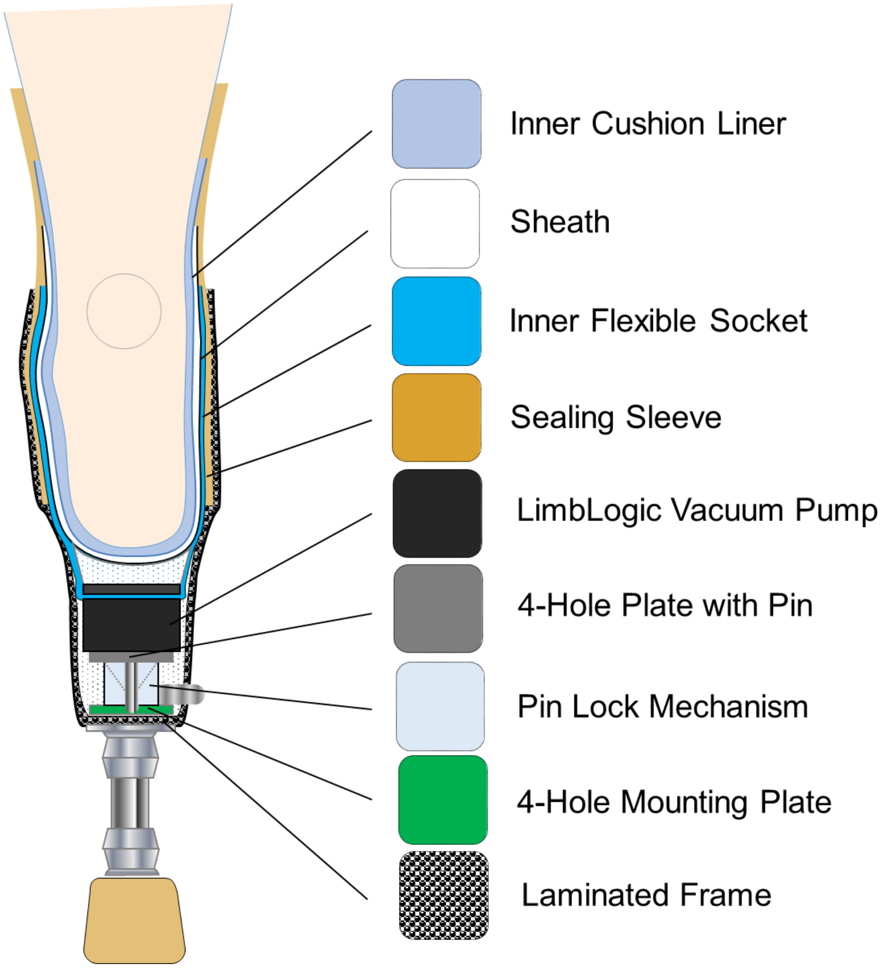

Figure 3.3. Custom style prosthesis. Eight participants used this style of socket featuring inner flexible socket with vacuum and pin suspension. Adapted from Prosthetic Design Solutions, LLC.

Table 3.2. Prosthesis characteristics.

ID #	Suspension	EV System	User Max (inHg)	Range (inHg)	Seal Type	Socks	Liner
1	Vacuum/Pin	WillowWood LimbLogic	-20	6	Inner sleeve	3 sheaths	Ottobock Uneo Unique
2	Vacuum/Pin	WillowWood LimbLogic	-20	4	Inner sleeve	1 ply	Ottobock Uneo Unique
3	Vacuum/Pin	WillowWood LimbLogic	-20	4	Inner sleeve	2 sheaths	Ottobock Uneo Unique
4	Vacuum/Pin	WillowWood LimbLogic	-20	6	Inner sleeve	4 sheaths	Ottobock Uneo Unique
5	Vacuum/Pin	WillowWood LimbLogic	-20	6	Inner sleeve	4 sheaths	Ottobock Uneo Unique
6	Vacuum/Pin	WillowWood LimbLogic	-20	6	Inner sleeve	1 sheath	Ottobock Uneo Unique
7	Vacuum	WillowWood LimbLogic	-20	6	Outer sleeve	1 sheath	Ottobock Uneo Unique
8	Vacuum/Pin	WillowWood LimbLogic	-20	6	Inner sleeve	1 sheath	Ottobock Uneo Unique
9	Vacuum/Pin	WillowWood LimbLogic	-20	6	Inner sleeve	2 sheaths	Ottobock Uneo Unique
10	Vacuum	WillowWood LimbLogic	-20	5	Outer sleeve	None	Ossur Iceross Dermo
11	Vacuum	WillowWood LimbLogic	-20	4	Outer sleeve	None	Ossur Iceross Dermo
12	Vacuum	WillowWood LimbLogic	-10	4	Inner sleeve	2 gel socks	WillowWood Alpha Duo

3.3.3 *Protocol Deviations*

Several deviations from the stated protocol were noted. A pump malfunction required Participant 6 to remove the inner socket from the carbon fiber frame to reset the pump early in the second cycle of the EV session, shifting residual limb fluid volume. As a result, the first equal weight stand point following the pump reset was selected as the reference fluid volume for this participant. All other analyses involving the second cycle of both the EV and SS session of Participant 6 began at this reference point. The pump malfunction also resulted in socket vacuum pressure outside of the indicated range in Table 3.2. Poor model fit resulted in bioimpedance signal noise in the posterior channel of Participant 9. To acquire acceptable measurement quality, data processing was modified to include a limited range of current frequencies in the model. The anterior channel was unaffected. Participant 3 and Participant 11 reported consuming caffeine on the day of the first test session. Caffeine consumption was asked to be repeated for the second test session for these participants. Restroom breaks differed for each participant causing slight variations in activity protocol timing.

3.3.4 *Socket Vacuum Pressure*

Because many of the LimbLogic units were enclosed in the carbon fiber socket, Bluetooth communication between the LimbLogic Communicator and the socket vacuum pressure sensor located in the pump unit was inconsistent. This wireless connectivity issue resulted in missing socket vacuum pressure data. The number of samples varied among participants. Additionally, the vacuum pressure sensor was limited to a range of -20.4 inHg to 0 inHg. Pressures above and below this range likely occurred during the course of each test condition; however, they were not recorded. Socket vacuum pressure distributions for each test condition are shown in Figure 3.4. These histograms indicate the number of samples (20 Hz sampling rate) recorded at each socket vacuum pressure (bin size is set to 1 inHg). A summary of socket vacuum pressure samples is presented in Table 3.3. Socket vacuum pressure among all participants averaged -15.7 ± 1.0 inHg in the EV condition and -3.3 ± 1.3 inHg in the SS condition.

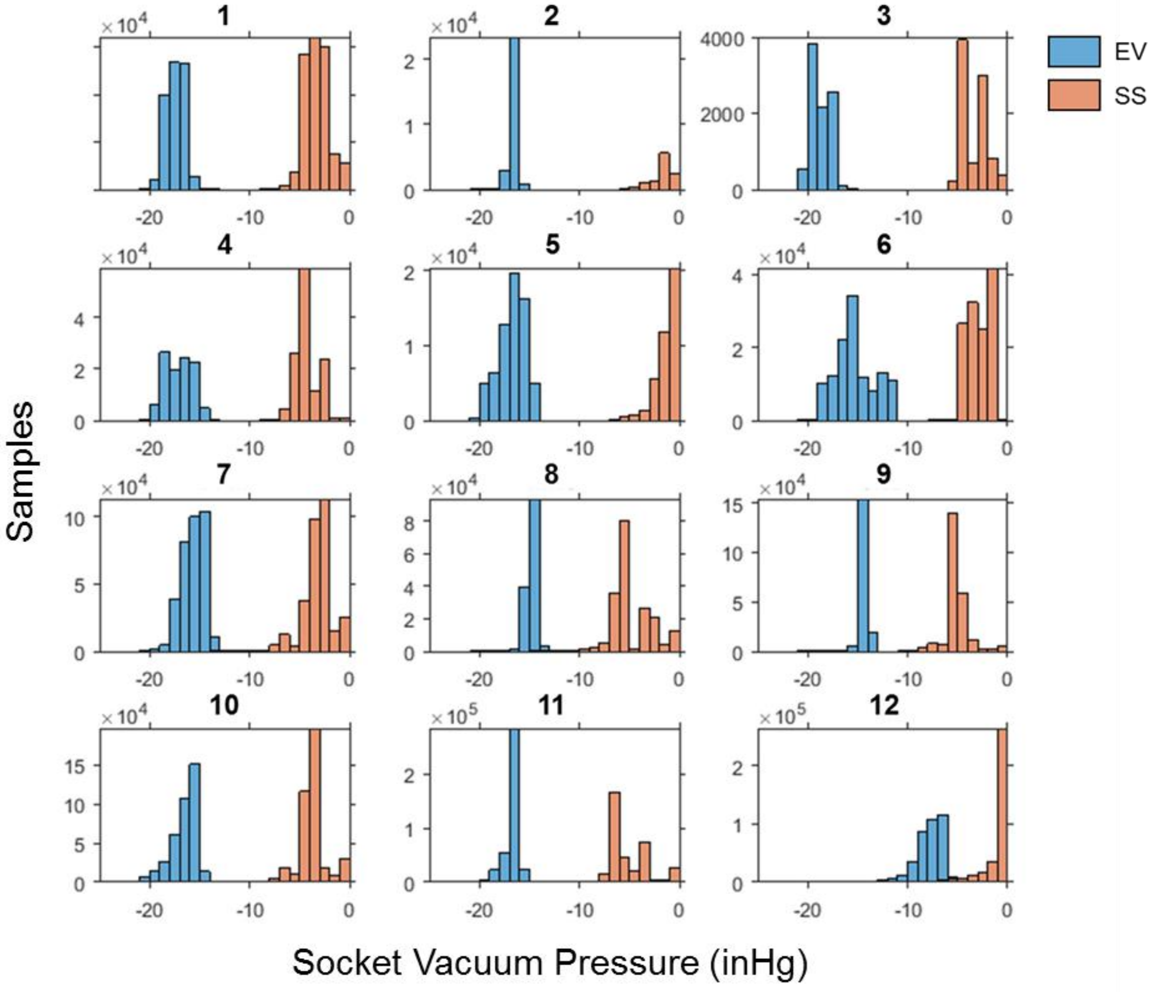

Figure 3.4. Histograms of vacuum pressure samples for each participant.

Table 3.3. Summary of vacuum pressure data. SD = standard deviation.

Session	**EV (inHg)**						**SS (inHg)**					
ID #	Mean	SD	Median	Min	Max	Samples	Mean	SD	Median	Min	Max	Samples
1	-17.4	0.9	-17.3	-20.4	-13.7	157699	-3.4	1.1	-3.7	-8.2	0.0	217074
2	-16.6	0.4	-16.6	-20.3	-15.9	27213	-1.7	1.0	-1.5	-5.9	0.0	10739
3	-18.7	0.8	-18.8	-20.4	-16.0	9195	-3.3	1.2	-3.9	-5.8	0.0	9043
4	-17.1	1.3	-17.1	-20.4	-14.0	103773	-4.3	1.1	-4.5	-8.8	0.0	127284
5	-16.8	1.3	-16.5	-20.4	-14.1	65392	-1.3	1.1	-1.0	-6.7	0.0	40302
6	-15.3	2.0	-15.7	-20.4	-11.5	122430	-2.9	1.1	-3.0	-7.6	-1.0	125374
7	-15.7	1.1	-15.6	-20.4	-13.8	341305	-3.2	1.4	-3.1	-13.6	0.0	311899
8	-14.8	0.4	-14.8	-20.4	-13.8	137580	-4.9	1.9	-5.7	-14.7	0.0	189898
9	-14.4	0.4	-14.4	-20.4	-13.9	179940	-5.1	1.2	-5.3	-11.0	0.0	239188
10	-16.5	1.3	-16.3	-20.4	-13.4	380109	-3.8	1.4	-3.9	-10.5	0.0	403856
11	-16.8	0.7	-16.6	-20.4	-15.5	390874	-5.1	1.9	-6.1	-11.1	0.0	365380
12	-7.9	1.4	-7.7	-15.4	-3.8	380432	-0.8	1.5	0.0	-10.8	0.0	347085
Mean	-15.7	1.0	-15.6	-20.0	-13.3	191329	-3.3	1.3	-3.5	-9.6	-0.1	198927
Median	-16.6	1.0	-16.4	-20.4	-13.9	147640	-3.3	1.2	-3.8	-9.7	0.0	203486
SD	2.7	0.5	2.7	1.4	3.2	143412	1.4	0.3	1.9	2.9	0.3	139357
Min	-18.7	0.4	-18.8	-20.4	-16.0	9195	-5.1	1.0	-6.1	-14.7	-1.0	9043
Max	-7.9	2.0	-7.7	-15.4	-3.8	390874	-0.8	1.9	0.0	-5.8	0.0	403856

3.3.5 *Overall Limb Fluid Volume Change*

Participants experienced a greater rates of relative fluid volume loss in the SS condition than in the EV condition. Median overall fluid volume change for the EV condition was -0.88 %/h and -1.05 %/h in the posterior and anterior regions, respectively. The SS condition resulted in a median change of -1.51 %/h posteriorly and -1.19 %/h anteriorly (Figure 3.5, Table 3.6). The Wilcoxon signed-rank test showed that no significant differences existed in either limb region between EV and SS. Examining individual results (Figure 3.5), eleven participants experienced limb fluid volume benefit (i.e. less fluid volume loss) when using EV in at least one region of the limb. Seven experienced benefit in both anterior and posterior limb regions, and only one user lost more overall fluid volume in both regions with EV. Six participants benefited when using SS in at least one limb region.

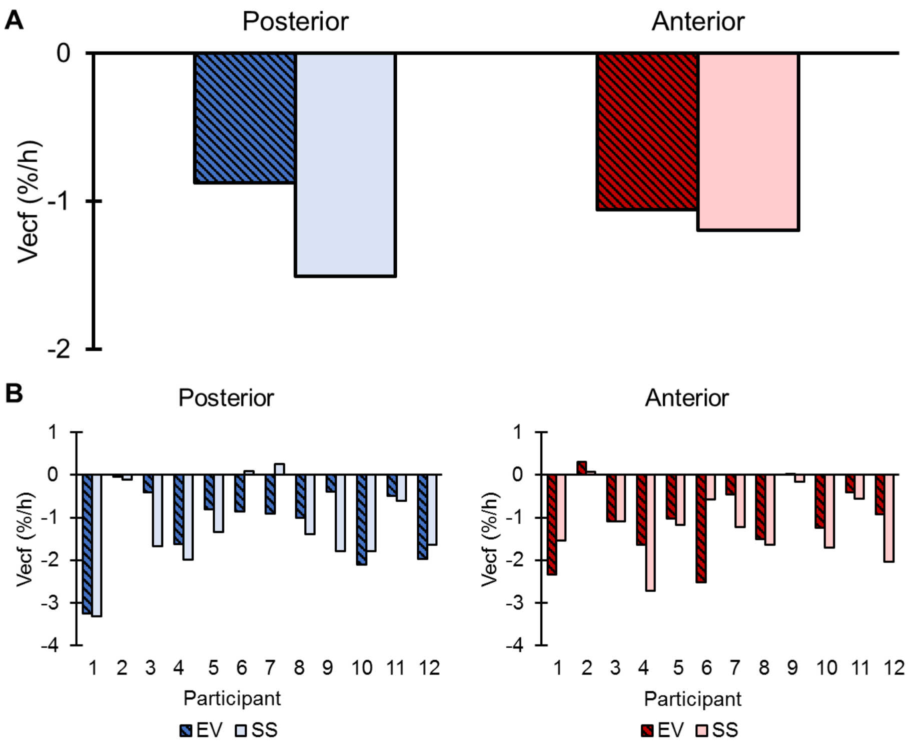

Figure 3.5. Overall median extracellular fluid volume rate of change (%/h). Calculated from the reference point for both anterior and posterior limb regions (A). Median overall extracellular fluid volume change (%/h) over the course of each session for each participant (B). Vecf = extracellular fluid volume change.

Table 3.4. Rates of overall fluid volume change for each test session.

	Rates of fluid volume change (%/h)		
	Median (Min, Max)	Mean (SD)	p-value*
Posterior			
EV	-0.88 (-3.25, -0.03)	-1.15 (0.92)	0.39
SS	-1.51 (-3.31, 0.25)	-1.27 (1.02)	
Anterior			
EV	-1.05 (-2.52, -2.72)	-1.07 (0.86)	0.16
SS	-1.19 (-2.72, 0.08)	-1.20 (0.80)	

***Wilcoxon signed-rank test**

3.3.6 *Limb Fluid Volume Change by Cycle*

Median fluid volume losses were greater earlier in the protocol for both EV and SS conditions (Figure 3.6, Table 3.5), though the only within-session significant difference occurred between Cycle 2 and Cycle 3 of the EV condition, and only in the posterior limb region (Table 3.6). Losses in each cycle were less for EV than SS; however, the only statistically significant difference between EV and SS occurred in Cycle 3 in the posterior limb region.

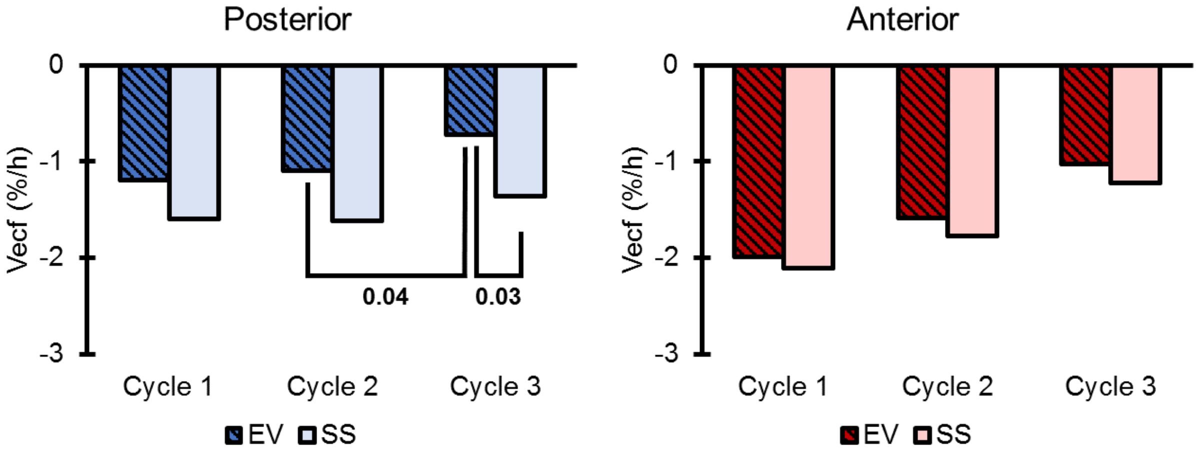

Figure 3.6. Median rates of percent fluid volume change during each cycle. Vecf = extracellular fluid volume change.

Table 3.5. Rates of fluid volume change (%/h) for each cycle and condition.

	Median (Min, Max)	Mean (SD)	p-value*
Posterior			
Cycle 1			
EV	-1.19 (-8.96, 0.93)	-1.56 (2.64)	0.24
SS	-1.59 (-9.79, 2.49)	-2.14 (3.56)	
Cycle 2			
EV	-1.09 (-6.35, -0.13)	-1.57 (1.64)	0.75
SS	-1.61 (-4.15, 1.31)	-1.65 (1.67)	
Cycle 3			
EV	-0.72 (-1.99, 2.22)	-0.58 (1.06)	**0.03**
SS	-1.36 (-1.99, 1.14)	-1.13 (0.92)	
Anterior			
Cycle 1			
EV	-1.99 (-4.00, 2.02)	-1.62 (1.88)	0.81
SS	-2.11 (-7.11, 1.30)	-2.27 (2.32)	
Cycle 2			
EV	-1.59 (-3.56, 1.30)	-1.64 (1.20)	0.24
SS	-1.77 (-3.24, 0.19)	-1.73 (1.04)	
Cycle 3			
EV	-1.02 (-1.84, 0.13)	-0.92 (0.53)	0.24
SS	-1.22 (-2.70, -0.05)	-1.16 (0.80)	

***Wilcoxon signed-rank test**

Table 3.6. Comparison of rates of fluid volume change (%/h) within a single session.

	p -value**	Pairwise Comparison	p-value***
Posterior			
EV			
Cycle 1		C2 - C1	0.221
Cycle 2	0.0498	C2 - C3	**0.014**
Cycle 3		C1 - C3	0.221
SS			
Cycle 1			
Cycle 2	0.21	N/A	N/A
Cycle 3			
Anterior			
EV			
Cycle 1		C2 - C1	0.838
Cycle 2	0.046	C2 - C3	0.025
Cycle 3		C1 - C3	0.041
SS			
Cycle 1		C2 - C1	0.838
Cycle 2	0.046	C2 - C3	0.025
Cycle 3		C1 - C3	0.041

C1 = Cycle 1; C2 = Cycle 2; C3 = Cycle 3

****Friedman test**
*****Pairwise comparison with Bonferroni correction (α = 0.017)**

3.3.7 *Limb Fluid Volume Change by Activity*

In the posterior region, EV and SS demonstrated minimal median differences in limb fluid volume change by activity as EV slightly increased limb fluid volume recovery when walking (Figure 3.7). SS increased limb fluid volume loss while standing, and EV increased limb fluid volume loss during sitting. EV increased median fluid volume recovery while walking in the anterior region (-4.6 %/h for SS to 9.6 %/h for EV). EV also increased fluid volume loss while standing and sitting compared to SS. Mean fluid volume trends for each activity were more consistent across limb regions (Table 3.4). None of the differences were statistically significant determined by the Wilcoxon signed-rank test. Individual results (Figure 3.8) show that only Participant 2 lost fluid in a region of their limb when walking with EV, and only Participant 9 gained fluid volume while standing under either test condition.

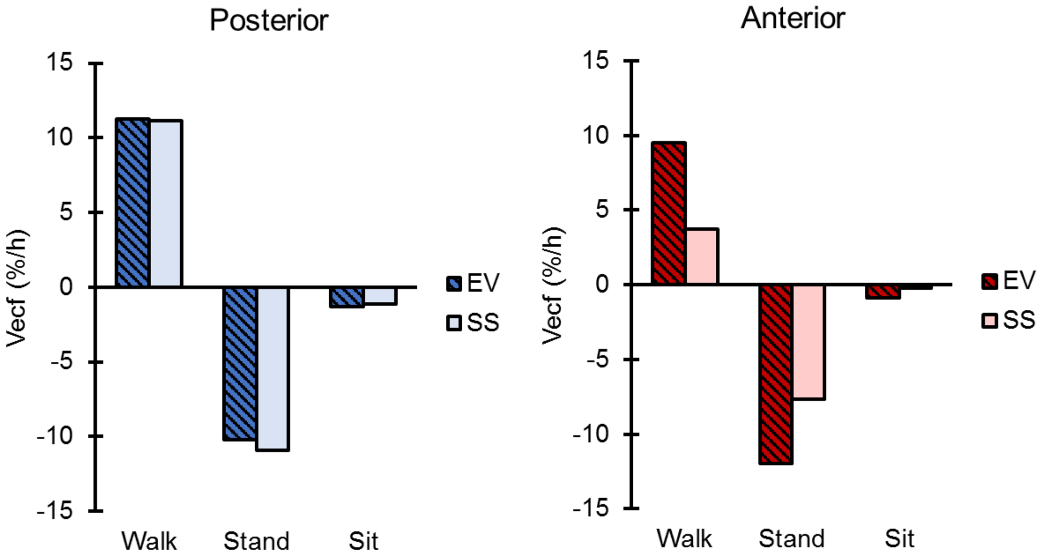

Figure 3.7. Median cumulative extracellular fluid volume rate of change by activity. Calculated from the reference point to the end of each session. Vecf = extracellular fluid volume change. Note that because each activity was normalized to time individually, the activities will not sum to the overall median rate of change in Figure 3.5.

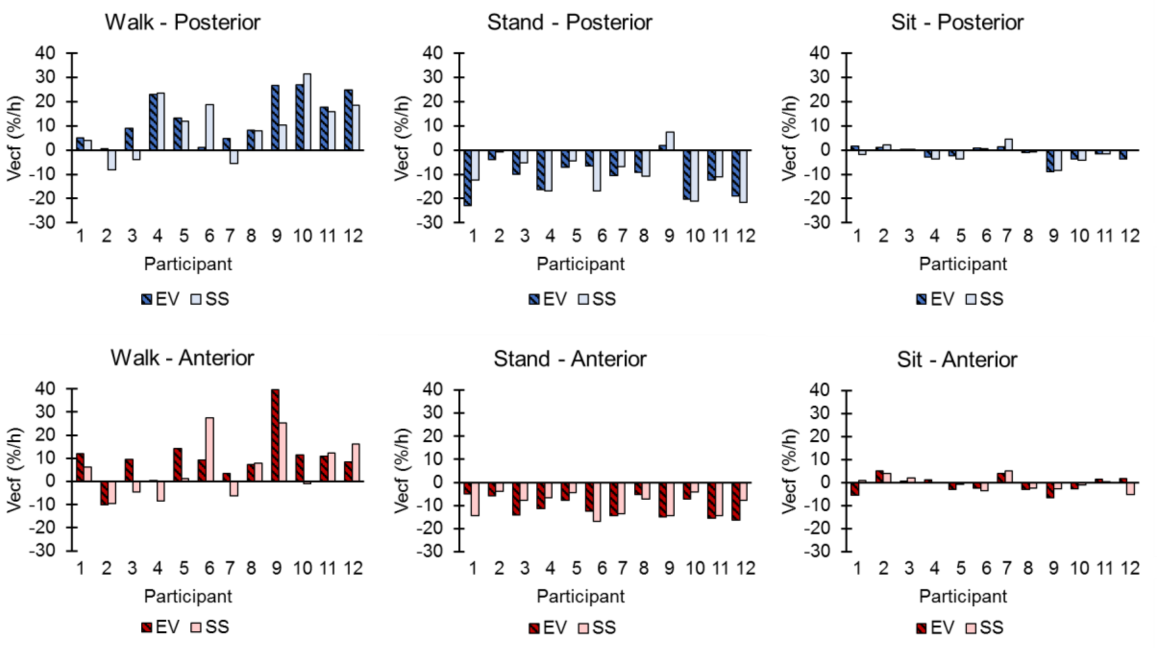

Figure 3.8. Median cumulative extracellular fluid volume rate of change by activity. Calculated from the reference point to the end of each session for each participant. Vecf = extracellular fluid volume change.

Table 3.7. Cumulative fluid volume change (%/h) by activity.

	Median (Min, Max)	Mean (SD)	p-value*
Posterior			
Walk			
EV	11.24 (0.63, 26.92)	13.46 (10.02)	0.14
SS	11.12 (-8.24, 31.57)	10.42 (12.22)	
Stand			
EV	-10.20 (-23.00, 1.80)	-11.37 (7.25)	0.24
SS	-10.91 (-21.55, 7.42)	-10.03 (8.57)	
Sit			
EV	-1.31 (-8.99, 1.63)	-1.56 (3.04)	1.00
SS	-1.15 (-8.40, 4.68)	-1.39 (3.38)	
Anterior			
Walk			
EV	9.51 (-10.15, 39.75)	9.77 (11.53)	0.77**
SS	3.72 (-9.54, 27.47)	5.55 (12.66)	
Stand			
EV	-11.94 (-16.38, -4.90)	-10.82 (4.36)	0.24
SS	-7.66 (-16.87, -3.94)	-9.56 (4.74)	
Sit			
EV	-0.87 (-6.62, 5.22)	-0.70 (3.65)	0.35
SS	-0.25 (-5.12, 5.02)	-0.20 (3.02)	

*** Wilcoxon signed-rank test (unless otherwise noted)**
****Sign test**

3.4 DISCUSSION

The purpose of this study was to compare the effectiveness of EV and SS in managing residual limb fluid volume during various activities over multiple hours of a day. Studies have demonstrated the effectiveness of EV to secure the limb within the socket [14,17,90,93,94]; however, limitations such as the use of out-of-socket volume measurements and short, single-activity protocols have made interpretation of limb volume studies regarding limb volume management difficult [13–17]. This study further contributes to the evidence regarding the ability of EV to influence residual limb volume. A better understanding of how EV affects residual limb fluid volume will allow prosthetists to make more informed clinical decisions regarding accommodation strategies to improve daily socket fit.

In this study of EV users with transtibial amputation, the use of EV significantly reduced posterior residual limb fluid volume rate of change after activity accumulation during the final cycle of an approximately 5.5-hour protocol. Overall limb fluid volume rate of loss was reduced in at least one limb region in 11 of the 12 participants. Other limb volume studies comparing the use of EV with SS have also shown less volume loss with EV [14,15]. However, exact volume change values are difficult to compare to prior studies due to the differences in protocol length and volume measurement techniques; i.e. limb fluid volume was measured in the current study, and total limb volume was measured in previous studies.

The posterior median rate of fluid volume change was significantly less in the final cycle of the EV condition after an accumulation of activity. Though the clinical significance of this difference is unclear, this may suggest that EV may be more effective as a volume management strategy in high-activity users. This is important because excess daily activity may lead to discomfort for prosthesis users as they are likely reaching their lowest limb fluid volume [62]. The significant difference measured in this study likely occurred posteriorly due to the large amount of soft tissue in this region relative to the anterior region. The posterior soft tissue may expand to the wall of the socket more easily, increasing tissue volume and likely lowering the pressure in the interstitial space to encourage volume recovery [13]. In a prior study, a similar protocol with the same activity regimen was used to evaluate how periodic doffing affected limb fluid volume changes over the course of a day using bioimpedance analysis [62]. A majority of the participants in the previous study used a locking pin suspension system (9 locking pin, 3 mechanical EV, 1 SS). The median rates of limb fluid volume loss posteriorly for each cycle were greater in the previous study compared to those rates of loss in the EV condition of the current study. Additionally, Cycle 1 rates of posterior limb fluid volume loss in the prior study were greater than those in the SS condition of the current study. The high incidence of locking pin use may account for the higher rates of posterior limb fluid volume loss in each cycle. This comparison to the prior study suggests residual limb fluid volume results may have differed had EV been compared to a suspension featuring no negative pressure (i.e. locking pin). Even in the SS condition of the current study, participants averaged -3.3 inHg of socket vacuum pressure, and socket vacuum pressures peaked between -14.7 inHg and -5.8 inHg during swing phase of gait.

Of the five participants that experienced higher rates of overall fluid volume loss with EV in at least one region of their limb, three had a history of cardiovascular complications. Of those three participants, two were also diabetic. Comorbidities such as these have been suggested to influence fluid volume change [2,122]. The magnitude of differences between overall residual limb fluid volume change under EV and SS varied greatly between individuals, suggesting that there may be opportunity to optimize vacuum to each individual by tuning EV system parameters to meet each individual's needs. Factors such as socket fit, socket components, socket vacuum pressure, individual health, and residual limb tissue content could affect each user's limb fluid volume management and suspension.

Contrary to prior studies, walking with EV did not significantly improve limb fluid volume recovery in either posterior or anterior limb regions [13–15]. Further, no significant differences were found between EV and SS regarding rates of limb fluid volume change by activity type (i.e. sitting, standing, or walking). The length of activity bouts likely influenced the rate of limb fluid volume change. In prior studies, single bouts of an activity such as walking were compared; whereas, bouts of activity in the current study varied throughout the protocol and were summed for analysis. Consistently longer bouts of an activity may be required to observe differences between EV and SS. Rates of limb fluid volume change did vary by activity type. As indicated by previous bioimpedance studies, gaining limb fluid volume while walking is not uncommon and may be due to the increased muscle activity in combination with larger arterial-to-interstitial transport [123].

In this study, the higher vacuum pressures of EV were shown to affect limb fluid volume changes compared to SS. As determined by their prosthetists, the EV systems typically operated at the highest available vacuum pressure setting (-20 inHg) for the majority of study participants. Though actual vacuum pressure distribution over the session varied by individual, this allowed for a comparison between the two ends of the EV spectrum but does not permit the evaluation of intermediate vacuum pressure settings. Intermediate vacuum pressures may improve residual limb fluid volume management in cases where EV resulted in higher rates of loss than SS. Nonetheless, a higher range of vacuum pressure has been shown to result in less limb displacement during ambulation [94]. Even if intermediate or low vacuum pressures benefit residual limb fluid volume management, the effects on suspension may be detrimental. Thus, finding the potential balance between the limb fluid volume management and the limb displacement of EV could be valuable to maximize patient care.

This study had several limitations including that the order of intervention was not randomized, thus an order effect cannot be evaluated and day-to-day variations in limb volume may have influenced results. In addition, participants were existing users of EV systems and no accommodation period was implemented for the SS condition. Results may be different when first transitioning people with transtibial amputation to EV sockets from alternative suspension systems. The EV socket designs used in the study were not consistent as many participants used a custom system with EV and a locking pin. Also, the EV socket with the deactivated pump may not have been an ideal representation of SS, due to added weight and potentially different ideal socket designs. The protocol likely required more activity than a typical day for many individuals using a prosthesis; therefore, the study protocol best matched activity likely experienced by K-3 and K-4 users. Further research will be need to determine the effectiveness of EV to manage residual limb fluid volume in lower activity users. Furthermore, this study investigated only daily residual limb fluid volume changes. The long-term impact of EV on residual limb size and shape should be studied further.

3.5 CONCLUSION

EV reduced posterior limb fluid volume change compared to SS during the final cycle of a 5.5-hour activity protocol after an accumulation of activity. This suggests EV may be more effective than SS in managing daily residual limb fluid volume particularly in high-activity users. Additionally, EV effectiveness appeared to vary by individual and activity. This may indicate that EV can be further optimized for individual users. Additional research into balancing the limb fluid volume and suspension benefits of EV across a range of vacuum pressures could further inform the clinical implementation of EV.

3.6 ACKNOWLEDGEMENTS

The authors would like to thank WillowWood for supplying the LimbLogic Communicator and vacuum pressure logging software used in this study. The authors also appreciate the support from Richard Foster, CPO, of TGG Prosthetics & Orthotics (Edmonds, OK, USA) through discussion of results in addition to participant recruitment and management as part of the remote data collection efforts.

Chapter 4. MODELING THE MECHANICS OF ELEVATED VACUUM IN PROSTHETIC SOCKETS

4.1 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 [3,4]. One of the most common problems facing individuals with lower limb amputation is residual limb volume change as it relates to socket fit [1]. Volume changes throughout the day occur as fluid shifts within the residual limb soft tissue as a result of prosthetic socket stresses [2]. These changes in volume and shape degrade socket fit, potentially leading to discomfort, skin breakdown, poor gait patterns, and falls [2,5,6].

Elevated vacuum (EV) is a prosthetic technology used to secure the prosthesis to the residual limb and help manage residual limb volume changes, leading to a more stable socket fit [12]. A typical elevated vacuum system features a liner, a sealing sleeve, and an air evacuation pump (Figure 4.1). The mechanical or electrical pump evacuates the air between the liner and the socket wall to maintain a continuous negative pressure environment within the socket [90]. The socket is typically sealed proximally with an external sealing sleeve, though some systems seal internally with a hypobaric sealing membrane around the liner [27]. As the pump removes air from between the socket and the liner, the liner and tissue within the liner are pulled to the wall of the socket limiting movement in all directions. EV has been suggested for use in populations desiring continued levels of suspension during a variety of activities [124].

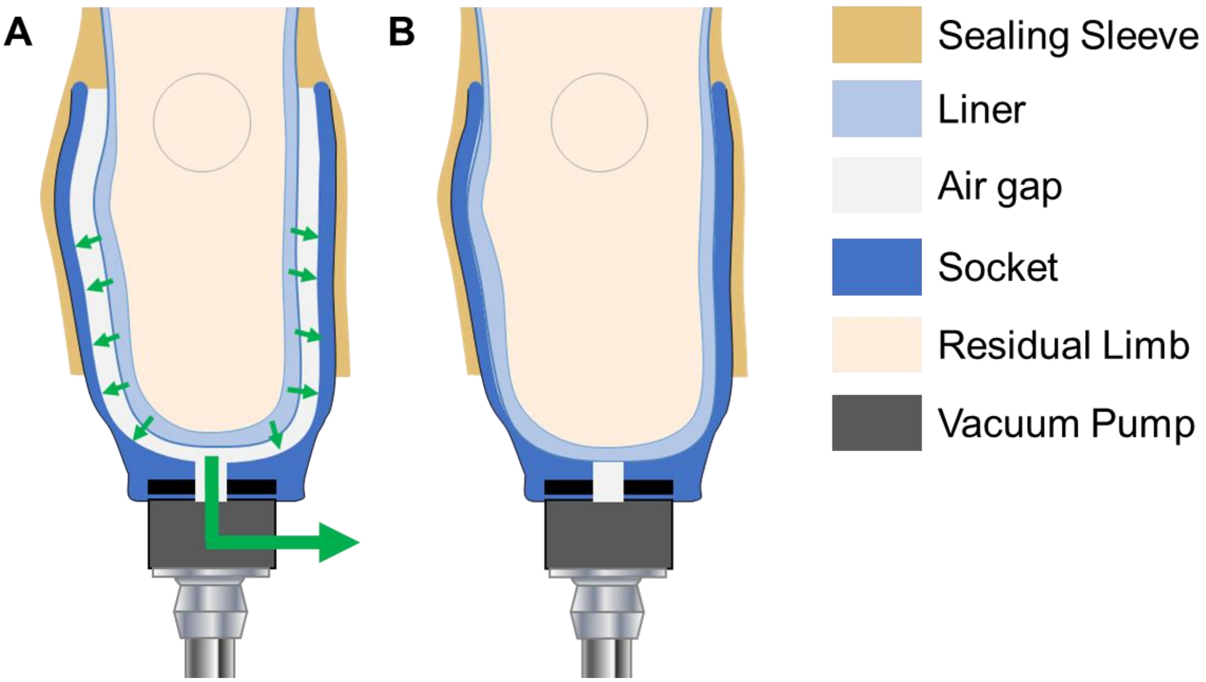

Figure 4.1. Elevated vacuum socket with sealing sleeve. (A) Before vacuum application. Green arrows indicate vacuum pull on liner as air is removed from the socket. (B) After vacuum application. Liner and soft tissue have been pulled to the socket wall. Adapted from Prosthetic Design Solutions, LLC.

One of the primary benefits of EV is a superior mechanical connection between the residual limb and prosthesis. The use of EV has demonstrated less vertical limb displacement compared to other suspension methods suggesting improved socket fit [14,17,90,93,94]. EV may also benefit limb physiology. Studies have shown that using EV resulted in less residual limb volume loss compared to suction suspension [13–15]. Additionally, limb health while using EV has been evaluated [20,28,97]. One study quantitatively assessed residual limb circulation through non-invasive methods, finding EV use over 16-weeks enhanced perfusion and preserved skin barrier function compared to non-EV use (i.e. suction and locking pin) [20]. The physiological mechanisms of EV are likely related to the stronger limb-socket coupling leading to less mechanically-induced instances of skin breakdown. Furthermore, tissue expansion to the socket wall likely helps draw fluid into the limb and maintain socket fit [13]. These effects of EV may account for improved functional outcomes and self-reported satisfaction reported in EV studies [27,28,30,95–98].

Despite the benefits of EV, clinical implementation of this technology can be difficult due to cost, maintenance, and potential for blistering [17,27,28]. Frequent maintenance of liners, sockets, and sleeves is necessary to prevent the loss of vacuum. In a survey of 155 prosthetic professionals, nearly 90% thought the use of EV needed careful evaluation and maintenance [27]. Additionally, Klute et al. found that EV prostheses required more check sockets and time to adequately fit compared to prostheses with pin suspension [17]. In some cases, elevated vacuum has been associated with skin issues such as suction blisters [17,27,28,30]. This issue was identified by 78% of the surveyed practitioners [27]. Blisters from elevated vacuum may develop into larger skin problems or prosthesis disuse if not addressed. Suction blister formation is dependent on a variety of physiological factors related to the mechanical integrity and strength of the adhesion between dermis and the epidermis. Individual health characteristics such as age, disease, and smoking are known to affect the adhesion strength. Additionally, external factors such tissue vacuum pressure, area of application, time of application, and temperature also influence the suction blister formation [125,126].

Within an EV socket, suction blisters may occur at voids of localized shape mismatch between the limb and the socket. As the liner moves radially to fill the socket void during vacuum application, liner volume increases, creating a vacuum pull on the residual limb tissue below the void. This relationship is demonstrated by Boyle’s Law which states volume and pressure of a gas are inversely related [34,100]. Liner properties, size of the void (i.e. socket fit), and socket vacuum pressure magnitude affect the vacuum pressure experienced by the residual limb tissue and the resultant physiological impact. Currently, little is known about how these variables interact within the socket to affect tissue vacuum pressure and the overall function of EV systems. This is partly due to the complex shape and intimate fit of prosthetic sockets, complicating direct measurement of these variables. As a result of this, few evidence-based recommendations regarding the clinical use of EV have been established to guide practitioners. For example, socket vacuum pressure selected for individual users may vary and is often based on patient preference and prosthetist experience, but it is unknown if preferred vacuum pressure corresponds to the pressure that is ideal for limb health.

The purpose of this study was to investigate the effects of EV socket variables such as liner properties, socket fit, and socket vacuum pressure on liner expansion and the creation of tissue vacuum pressure on the residual limb. A geometrically simplified benchtop model was developed to emulate an EV socket with the hypothesis that, by modeling the EV socket environment, tissue vacuum pressure occurring within an EV socket may be studied. This tissue vacuum information could then be applied to future studies to determine physiological effects on the residual limb. Additionally, in developing the model, we hypothesized that the relationships between liner displacement and tissue vacuum pressure would follow Boyle’s Law. Once the liner expands to the walls of the socket, liner volume displacement and tissue vacuum pressure would remain constant with increasing socket vacuum pressure. The characterization of these variables (i.e. liner properties, socket fit, socket vacuum pressure, and tissue vacuum pressure) would enhance understanding of the mechanism of EV to influence suspension and limb physiology. Additionally, results from this model could aid practitioners when configuring EV prostheses. A goal of this research was to move towards optimizing the EV socket environment for individuals based on their prosthetic components and specific physiological responses in order to avoid blister formation and improve physiological benefits of EV.

4.2 METHODS

4.2.1 *Socket Model*

A benchtop model (Figure 4.2) was created to represent an elevated vacuum socket. A 0.6 cm thick, 30 cm by 30 cm nylon sheet was used as a base raised approximately 4 cm with leveling mounts. The purpose of the base was to provide a stiff interface for the liner elastomer that would not flex under vacuum pressure. Liner samples of various materials were cut to flat sheets and placed on top of the base. A square (20 cm by 20 cm) carbon fiber layup with a central domed region (7.6 cm dome diameter, 1 cm dome height) was placed over the liner to represent the carbon fiber socket. The diameter of the domed region was selected to fit within the posterior width of a residual limb approximately 30 cm in circumference, the mean midlimb circumference in Chapter 3. The flat region of the domed layup was required to seal with the underlying liner. A threaded barbed valve was inserted in the center of the domed region. An electronic vacuum pump was controlled by a digital pressure sensor and custom LABVIEW program to apply vacuum pressure to the domed region as a prosthetic vacuum pump would in an elevated vacuum socket.

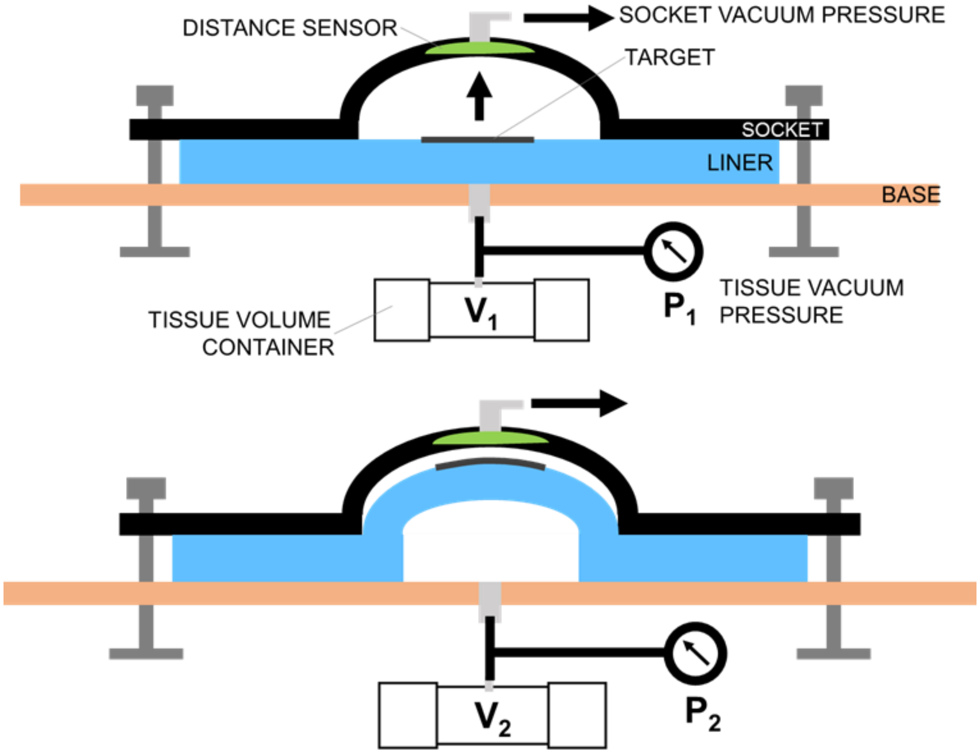

Figure 4.2. Diagram indicating components of the benchtop EV model. A demonstration of the effect of socket vacuum applied in the dome region to alter the volume below the liner resulting in a pressure change.

4.2.2 *Socket and Tissue Vacuum Pressure Measurement*

To control the vacuum pump operation, pressure was measured between the domed carbon fiber layup and liner sample with a Honeywell TruStability Board Mount Differential Pressure Sensor (Honeywell, Morris Plains, NJ, USA) and a custom data acquisition unit. This measurement is referred to as the socket vacuum pressure. At the center of the nylon base, a threaded barbed valve was inserted to allow vacuum pressure measurements underneath the liner in the space that would be occupied by residual limb tissue in a socket. This pressure was also measured with a Honeywell TruStability Board Mount Differential Pressure Sensor (Honeywell, Morris Plains, NJ, USA) and a custom data acquisition unit. This measurement is referred to as the tissue vacuum pressure.

4.2.3 *Liner Displacement Measurement*

The inductive distance sensor-target system develop previously [127] was used to record the displacement of the liner towards the interior of the domed carbon fiber socket model. An inductive sensing chip (LDC1614, Texas Instruments, Dallas, TX, USA), a custom flexible coil antenna, a capacitor, and a magnetic target create the system. The antenna and capacitor operate as an inductor–capacitor (LC) tank oscillator to generate a magnetic field. When the target enters the magnetic field, the field and thereby the sensor oscillation frequency is altered as a function of the target's distance. This has been used in previous lab efforts to measure socket to limb distance and limb movement within a prosthetic socket. The low-profile flexible coil was embedded in the wall of the flat socket model (Figure 4.3), centered in the domed region. Using a geometric model of a spherical cap and a cylinder, volume displacement was estimated from the one-dimensional liner displacement measurement.

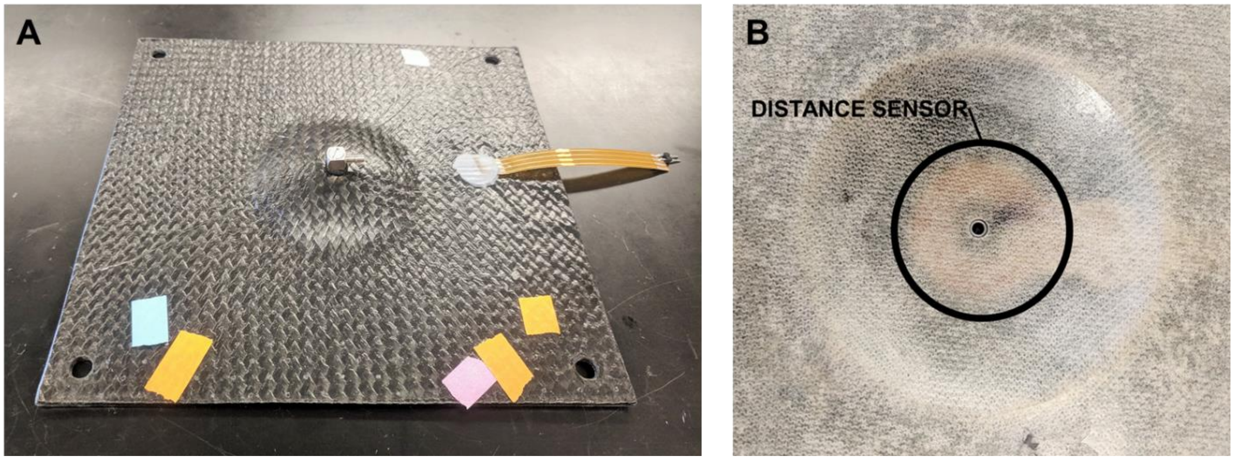

Figure 4.3. Carbon fiber layup with central domed region. (A) Top side of domed carbon fiber layup. (B) Thin inductive distance sensor embedded between layers of carbon fiber and Nyglass on bottom side of dome.

4.2.4 *Dome Volume (Socket Fit)*

Dome volume was varied to represent different sizes of voids due to varying degrees of socket fit that may exist in a prosthetic socket. Four dome volumes were evaluated (Figure 4.4) with each liner sample. Three rigid inserts were three-dimensionally (3D) printed (Objet30 Pro, Stratasys, Eden Prairie, MN, USA). The center thickness of the inserts measured 2.5 mm, 5.0 mm, and 7.5 mm. These inserts allowed four different volumes to be tested 23.3 cm^3 (no insert), 17.3 cm^3 (2.5 mm insert), 11.4 cm^3 (5.0 mm insert), and 5.7 cm^3 (7.5 mm insert). These volumes were selected to represent various degrees of socket fit that may create localized pressure within the socket. Fernie and Holliday noted that sock ply between 0% and 5% of the residual limb volume represented a "good" fit, 5% and 10% represented an "acceptable" socket, and greater than 10% signaled that a new socket was needed [66]. Previously, a 1.8 mm radial socket size adjustment was suggested to correspond to a socket volume change of about 6% [70]. The inserts used in this study therefore represent both acceptable socket fit (7.5 mm insert) and varying degrees of unacceptable fit (no insert, 2.5 mm insert, and 5.0 mm insert).

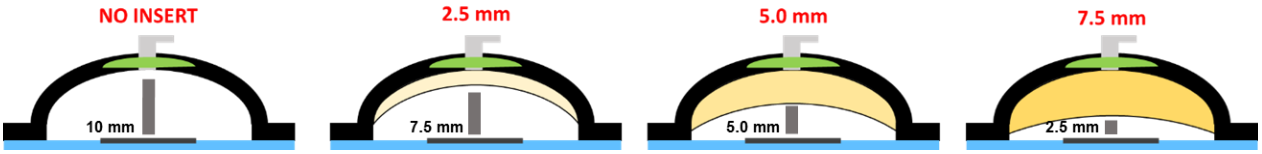

Figure 4.4. Diagram indicating different dome volumes tested. Red text indicates thickness at the center of the insert. Black text and gray bar indicate size of void from the center of the dome.

4.2.5 *Liner Tension (Liner Fit)*

Liner samples were stretched to represent the tension present in a donned liner. Unstretched liners were also tested to evaluate the effect of liner fit. A liner tension apparatus was developed from a t-slot aluminum building system (80/20 Inc., Columbia City, IN, USA) to stretch liners over the benchtop setup (Figure 4.5). To determine the appropriate liner tension, five silicone limb molds were sized for a silicone liner. Marks were made at various locations on the unstretched liner, the liners were donned on the limb molds, and distances between marks were measured to quantify liner stretch in two directions (Figure 4.6). Liner stretch was averaged across the limb molds and recreated with the liner tension apparatus for the liner samples before data collection. Based on this evaluation, approximately 3 mm of fabric stretch was applied in the medial/lateral (X) direction. Stretch in the proximal/distal (Y) direction was held at 0 mm.

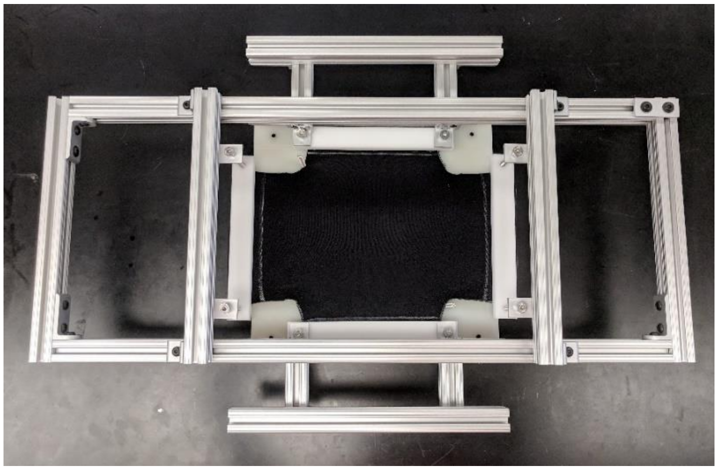

Figure 4.5. Stretcher apparatus to apply liner tension. Device allowed controlled stretch in both X and Y directions to replicate liner stretch recorded from limb molds.

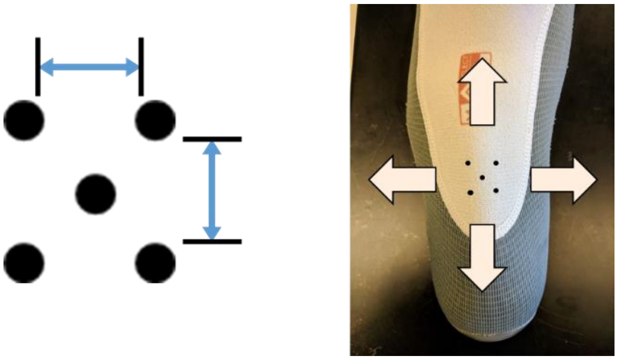

Figure 4.6. Liner stretch measurement and limb mold. Distance between marks were measured before and after the liner was donned to the limb models to quantify liner stretch.

4.2.6 *Liner Sample Preparation*

New liner samples of varying combinations of fabric and elastomeric material were tested. Two liners of each type were collected for a paired liner tension comparison. One of the two liner samples of each type was placed under tension using the liner stretcher apparatus for the test, while the other was tested unstretched. The thicker of the two was stretched due to the thinning that occurred during stretching. Unstretched liner samples were secured to the base with clamps. WillowWood liners were used in this study due to their popularity [128] and previously characterized range of material properties [129,130]. Additionally, gel profiles, gel thicknesses, and methods for liner sample preparation could be kept relatively consistent. Thermoplastic elastomer (TPE) liners were expected to provide the least resistance to socket vacuum pressure and liner displacement due to their low tensile stiffness (294 kPa, 6 mm sample). Conversely, silicone-based liners with higher tensile stiffness measurements (3,450 kPa, 4 mm sample) would show the greatest resistance to displacement by socket vacuum pressure. Hybrid liners (2,280 kPa, 6 mm sample), a TPE variant, would demonstrate intermediate resistance. Liner samples were prepared as 16.5 cm by 16.5 cm squares with 5.7 cm extended edges on each side to resemble a plus sign. The extended edges were to accommodate stretcher fixtures (Figure 4.7). These samples were cut from the posterior proximal area of full liners. This area was chosen because the fabric style and elastomeric material thickness of these prosthetic liners are more consistent. In addition, this area is near the posterior midlimb where a majority of the soft tissue of the residual limb is located. Using Loctite 409 (Henkel Adhesives, Rocky Hill, CT, USA), Delrin bars were adhered to the four extended edges of liner samples that were to be stretched. These Delrin bars were used to fix the liner to the stretcher apparatus. A polyurethane sealing ring 11.4 cm in inner diameter was cured on the fabric backing of each liner to create an airtight seal with the carbon fiber layup.

The ferrous polymer target consisted of polymer (Septon 4044), iron powder (85% by weight), and mineral oil. The circular target is formed to approximately 4.1 cm in diameter and 0.5 mm thickness. The target is covered by a thin circular piece of cotton fabric to allow air movement over the target in the EV socket model. Then using heat the target is embedded into the center of the fabric surface of each liner. When required, an elastomeric ring (Septon 4044) approximately 11.4 cm in inner diameter and 0.5 mm thick was placed between the liner and the base to create a seal below the liner.

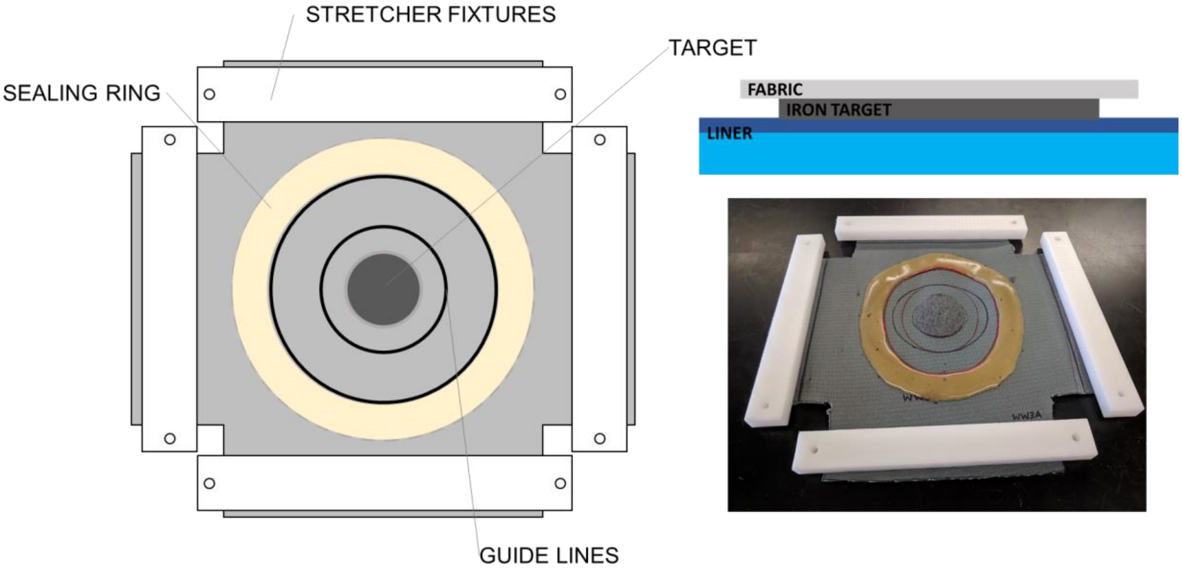

Figure 4.7. Liner sample details. Layers of ferrous polymer target application. Liner sample after being removed from the stretcher apparatus.

4.2.7 *Modeling Tissue Resistance*

As the liner displaces to the walls of the socket, the skin follows. Displacement of the liner depends on liner resistance which includes liner properties (i.e. fabric and elastomer elasticity), physical constraints (i.e. dome and insert height), and tissue properties (i.e. soft tissue content, skin elasticity). Tissue properties are not clearly specified in this model. By altering the volume of air under the liner using various sizes of tissue volume containers (Figure 4.2), we were able to modulate resistance to liner displacement without changing liner properties or physical constraints. This technique was used to represent tissue resistance in the current model. Tissue resistance varies by person and is affected by age, health, soft tissue content, and location on the limb (i.e. over muscle or over bone) [131]. In order to find the tissue volume that best represents the resistance of human tissue without biological variability, we worked with Center for Research in Education and Simulation Technologies (CREST) to formulate a silicone slab that mimics soft tissue properties of the posterior lower limb while featuring a large, flat surface that could be used with the socket model. A mixture of PlatSil Gel-25 Silicone Rubber Part A, Part B, and Smith's Theatrical Prosthetic Deadener (Polytek Development Corp., Easton, PA, USA) was combined with a weight ratio of 1:1:0.8 to create at 34 cm by 22 cm by 4 cm slab of simulated soft tissue. Similar combinations have been used to create representative human soft tissue [132]. Using the simulated soft tissue with the benchtop model, we measured liner displacement at various socket vacuum pressure and compared this displacement to the displacement that occurred with various tissue volumes. Volumes of capped polyvinyl chloride (PVC) segments were determined by measuring the weight of the mass of water need to fill the chamber and dividing by the density of water. Volume of the tubing used to connect these chambers to the system was also geometrically estimated. The tissue volume that best matched the simulated soft tissue was used with all liner samples for benchtop model tests.

4.2.8 *Calibration*

Because the inductive distance sensing system is sensitive to sensor-target alignment, a calibration procedure was conducted before each data collection trial to account for potential liner shifts on the base. The distance from the liner target to the inside top of the dome was measured to establish a starting calibration point. This distance would vary for each liner due to gel profile and sealing ring variations. Dome inserts of known thickness (2.5 mm, 5.0 mm, and 7.5 mm) were used to calibrate the inductive distance sensor by placing the insert under the dome and applying -20 inHg vacuum pressure with an open base port (no tissue resistance) to pull the liner to the top of the dome. No dome insert was used to find the 0 mm point. A calibration curve (interpolant – shape preserving) was fit to these 5 points.

4.2.9 *Data Collection*

A twenty-five pound weight was placed over the carbon fiber layup to produce consistent pressure on the liner sample. A 21 cm tall acrylic tube was used to space the weight out of range of the inductive distance sensor as to not interfere with the liner displacement measurement (Figure 4.8). The outer diameter of the tube (18 cm) was selected to sit outside of the domed region and place pressure over the sealing ring. Due to an uneven gel profile, some liner samples required additional clamps to apply sufficient pressure to seal with the carbon fiber layup. For each liner sample, vacuum pressure was stepped from 0 inHg to -20 inHg by increments of -2 inHg with the custom electronic vacuum controller. The change in tissue vacuum pressure and liner displacement was recorded. -20 inHg was selected because that is the highest vacuum pressure setting available on commercial elevated vacuum pumps used in prosthetic devices [133].

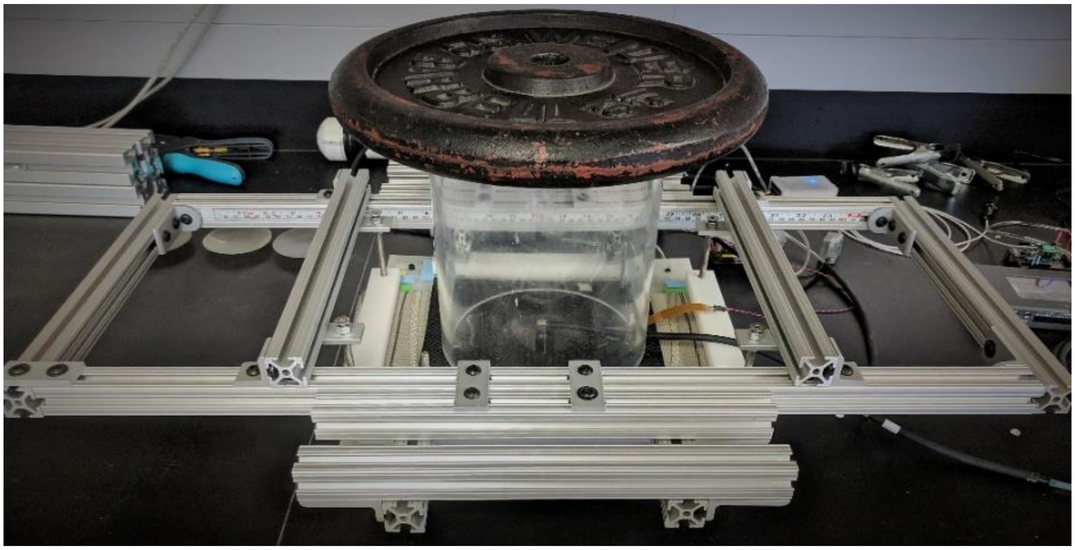

Figure 4.8. Complete data collection set-up for stretched liner samples.

4.2.10 *Data Analysis*

Three separate trials were conducted with each liner sample. Data from the three trials were averaged for analysis. Plots were analyzed to evaluate the relationship between liner types, dome volume (socket fit), socket pressure, liner displacement, liner tension, and tissue pressure.

4.3 RESULTS

4.3.1 *Liner Samples*

Eight total liners were tested, including two liners of each fabric and elastomer combination (Table 4.1). One liner sample of each combination was placed under tension using the liner stretcher apparatus. Based on liner stretch on five limb models, the average fabric marker stretch was 3 mm in the X direction (medial/lateral) and 0 mm in the Y direction (proximal/distal) (Table 4.2).

Table 4.1. Liner Samples. (S) = Stretched thickness, TPE = Thermoplastic Elastomer

Sample	Manufacturer	Model	Thickness (mm)	Gel Profile	Fabric	Size	Type	Tension
WW2A	WillowWood	Alpha Silicone	3.06	Progressive	Select	M+2	Silicone	Unstretched
WW2C	WillowWood	Alpha Silicone	3.13/2.63(S)	Progressive	Select	L2	Silicone	Stretched
WW3A	WillowWood	Alpha Classic AK	3.87/3.17(S)	Symmetrical	Select	L+	Classic (TPE)	Stretched
WW3B	WillowWood	Alpha Classic	3.69	Progressive	Select	M	Classic (TPE)	Unstretched
WW4A	WillowWood	Alpha Hybrid	3.91	Uniform	Select	M	Hybrid (TPE)	Unstretched
WW4B	WillowWood	Alpha Hybrid	4.11/3.30(S)	Uniform	Select	M+	Hybrid (TPE)	Stretched
WW5A	WillowWood	Alpha Classic	3.30	Uniform	Original	M+	Classic (TPE)	Unstretched
WW5B	WillowWood	Alpha Classic	3.45/2.60(S)	Uniform	Original	M+	Classic (TPE)	Stretched

Table 4.2. Liner stretch measurements.

Limb Model	AVG X (mm)	AVG Y (mm)
A	3	0
B	4	0
C	5	0
D	3	0
E	3	1
AVG	3	0
SD	1	0

4.3.2 *Tissue Resistance*

Liner sample WW3B was used to compare tissue volumes as varying degrees of tissue resistance. Figure 4.9 shows the relationship between socket vacuum pressure and corresponding liner displacement to the top of the domed layup without a dome insert using various tissue volumes. The lower tissue volumes required higher socket vacuum pressure to displace the liner while larger volumes required low socket vacuum to saturate the liner to the top of the dome. The simulated soft tissue is compared to these various volumes and most closely matched the 275.75 cm^3 volume. Various tissue volumes and their resulting tissue vacuum pressure at maximum socket vacuum pressure were predicted based on liner expansion using Boyle’s Law (Figure 4.10).

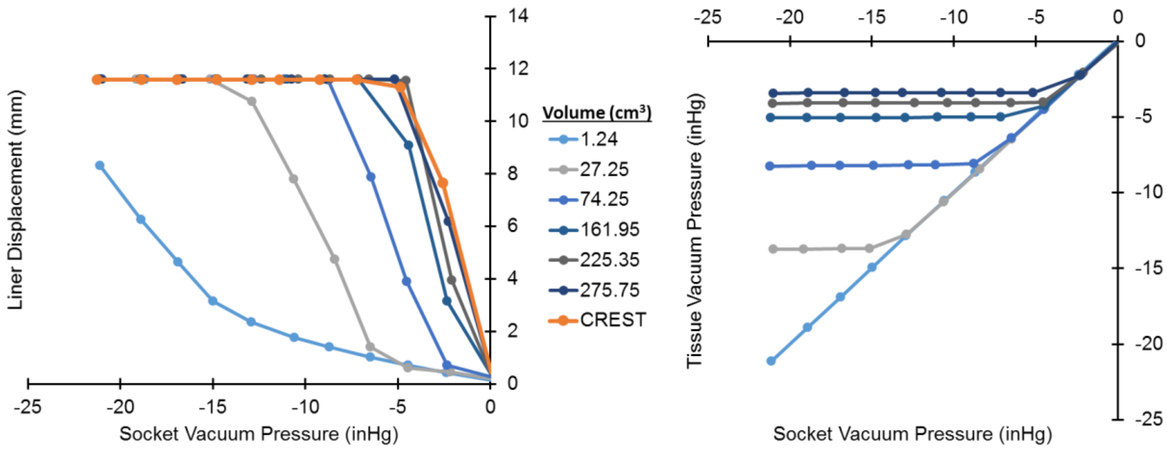

Figure 4.9. Sample testing (WW3B) with various tissue volume containers. No dome insert was used. CREST is simulated soft tissue sample. Tissue vacuum pressure could not be measured with the CREST sample.

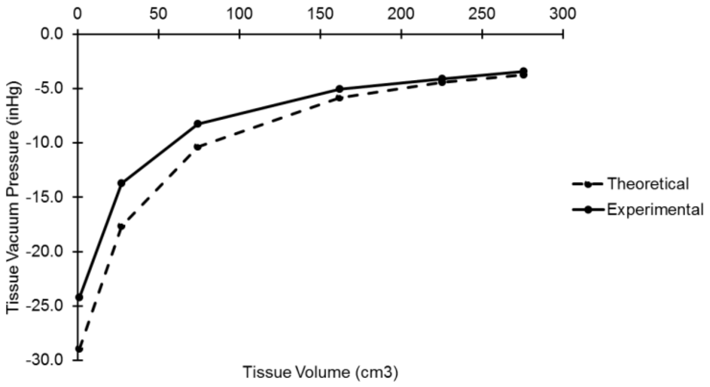

Figure 4.10. Tissue vacuum pressure prediction based on liner displacement. Theoretical and experimental max tissue vacuum pressure experienced at each tissue volume.

4.3.3 *Socket Vacuum Pressure*

In all samples, as socket vacuum was applied to the domed region, the liner displaced towards the inside of the carbon fiber dome until the liner reached the top of the dome (Figure 4.11). The increased volume beneath the liner resulted in reduced tissue vacuum pressure underneath the liner as socket vacuum pressure increased (Figure 4.11). Once liner displacement ceased due to the physical barrier, tissue vacuum pressure remained constant. This occurred at socket vacuum pressures less than or equal to -6.5 inHg. Liner displacement volume was calculated by using the liner displacement distance measurement to model a geometric volume with no dome inserts. The theoretical and experimental vacuum pressure resulting from the liner displacement volume is plotted in Figure 4.11.

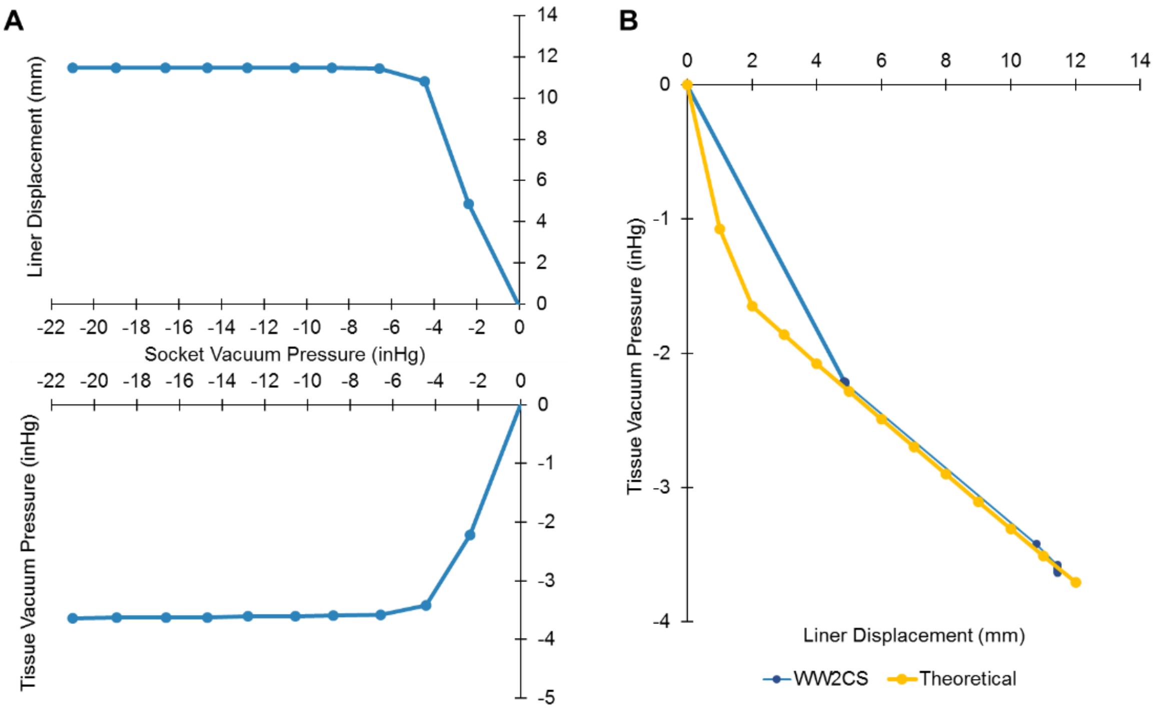

Figure 4.11. Liner displacement and tissue vacuum pressure. (A) Plot of liner displacement v. socket vacuum pressure with no insert. Plot of tissue vacuum pressure v. socket vacuum pressure. (B) Plot of experimental and theoretical Boyle's Law.

4.3.4 *Dome Volume (Socket Fit)*

The center of the dome was 10 mm high without an insert. The largest insert reduced the dome to 2.5 mm high while maintaining dome diameter. Some variation occurred as a result of the sealing ring applied to the fabric backing. Final heights ranged from 11.3 mm to 13.3 mm from the liner target to the top of the dome. The liner samples contacted the dome surface both with and without dome inserts. As dome insert thickness increased, the liner was limited as to how far it could displace towards the sensor (Figure 4.12). Because less volume was displaced by the liner with increasing insert thickness, lower tissue vacuum pressure was recorded. Although absolute displacement varied for each liner sample due to the sealing ring thickness variation, relative maximum between each insert was consistent at 2.5 mm. With no insert, maximum tissue vacuum pressure averaged -3.6 ± 0.2 inHg. The largest insert, representing minimal limb-socket mismatch, maximum tissue vacuum pressure averaged -2.3 ± 0.2 inHg.

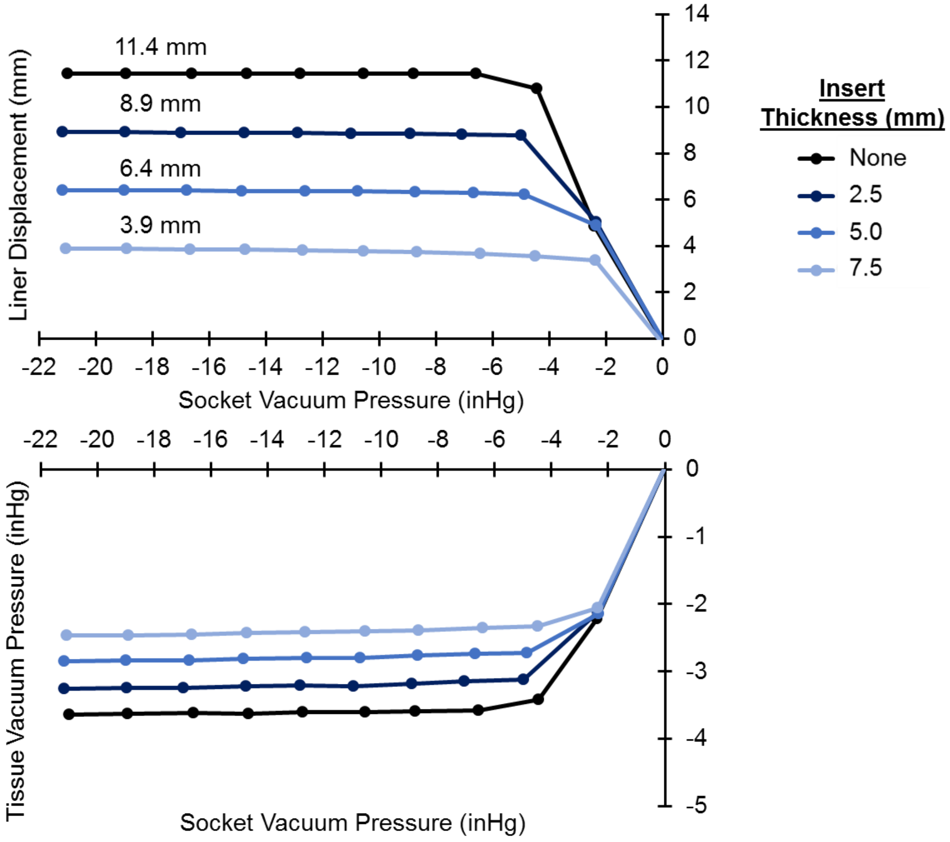

Figure 4.12. Single sample liner displacement and tissue vacuum pressure. Socket vacuum pressure was increased with dome inserts of various thicknesses for liner sample WW2C stretched.

4.3.5 *Liner Tension*

Unstretched liners demonstrated less resistance to socket vacuum pressure compared to stretched liners (Figure 4.13). With no insert, stretched liners averaged a lower initial displacement (42.2% ± 2.9%) compared to unstretched liners (56.6% ± 5.3%) at the first interval (-2 inHg set point). This difference had little effect on the tissue vacuum pressure as both stretched and unstretched liners averaging -2.2 ± 0.1 inHg tissue vacuum pressure at the same interval with no insert.

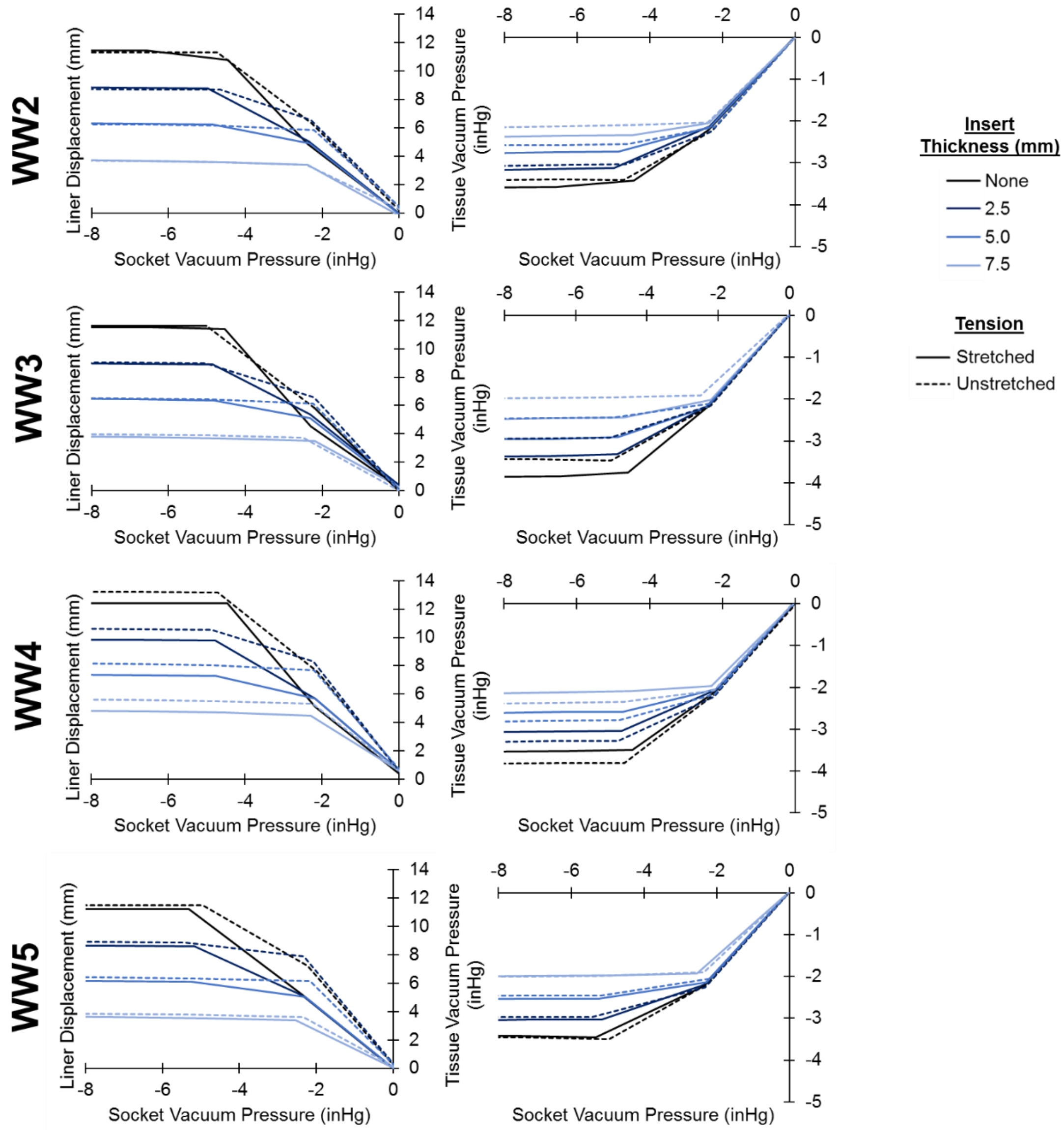

Figure 4.13. Liner displacement and tissue vacuum pressure for all samples.

4.3.6 *Liner Properties*

Based on previous work to characterize liner properties [129,130] higher resistance to liner displacement was expected to correspond to higher tensile stiffness. Liner displacement did not vary greatly between liner types, particularly stretched liners. At the first interval (-2 inHg set point), WW5 liner displaced the most for stretched (46.1%) and unstretched (62.9%), while WW3 liner displaced the least (39.2% stretched, 50.0% unstretched). By the second interval (-4 inHg set point), stretched WW2 liner was the only liner not to have saturated the dome suggesting a higher resistance to socket vacuum pressure than the other samples.

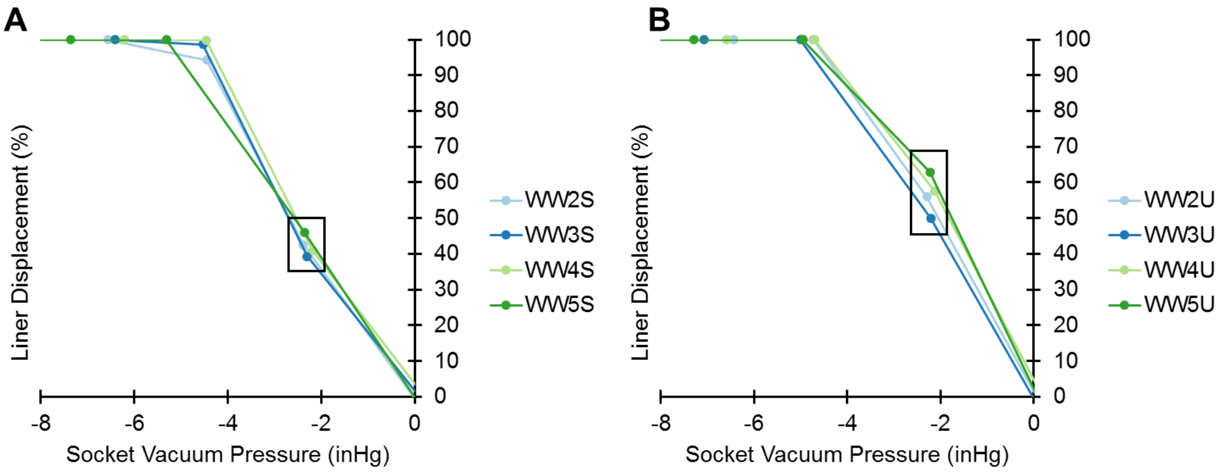

Figure 4.14. Relative liner displacement for all samples. (A) Stretched samples and (B) unstretched samples. S = stretched, U = unstretched

4.4 DISCUSSION

The purpose of this research was to model the mechanics of an elevated vacuum socket to better understand how the various components such as socket vacuum pressure, socket fit, liner fit, and liner properties interact within the socket to influence suspension and limb physiology. This information may assist practitioners when configuring EV prostheses to avoid blister formation and improve physiological benefits of EV by optimizing the socket environment for individuals based on their prosthetic components and specific physiological responses. Additionally, this model may be used as a platform to further investigate how elevated vacuum influences the socket environment in people with lower limb amputation.

Relatively low levels of socket vacuum pressures were needed to maximally displace both stretched and unstretched liners used in this study. Liners extended to the dome in a linear manner. Maximum vertical displacement of at least 99% of the dome height with no insert occurred by -6.5 inHg for stretched liners and -5.3 inHg for unstretched liners. Commercial prosthetic elevated vacuum pump systems reach -20 inHg [133], substantially higher that what is required to pull the liner to the wall of the socket. While further liner displacement may not occur, greater socket vacuum pressures increase the force required to remove the limb from the socket. Socket vacuum pressures greater than -6.5 inHg may be important for limiting limb movement and thus improving suspension and comfort.

Higher vacuum pressures may not affect liner displacement or limb physiology (i.e. tissue vacuum pressure) in a properly fitting socket due to limited liner expansion. Once liner displacement ceased due to a physical barrier, tissue vacuum pressure remained constant suggesting that tissue vacuum pressure change is dependent on liner displacement. This is consistent with Boyle's Law, which states that volume and pressure are inversely related (Figure 4.11) where P_1 is the initial pressure and V_1 is the initial volume. As volume increases (V_2), pressure decreases (P_2) as demonstrated by Equation 4.1:

$$V_1 P_1 = V_2 P_2 \tag{4.1}$$

However, in the case of a poorly fitting socket with global or localized limb-socket mismatches, the liner may continue to displacing toward socket wall, linearly increasing vacuum pressure on the residual limb tissue. We used dome inserts to represent various level of socket fit that may occur. As expected the inserts limited liner expansion volume and resulted in lower tissue vacuum pressures. Actual socket fit, especially in undersized sockets, which are common when using elevated vacuum [27] likely create even less liner displacement and subsequently lower tissue vacuum pressures. The current inserts provide a starting point to establish tissue vacuum levels in improperly fitting or oversized sockets. By varying dome volume, we are able to demonstrate how limb volume loss over the life of a socket may affect elevated vacuum mechanics by establishing a range of tissue vacuum pressures as socket fit changes.

The increased liner displacement and larger tissue vacuum pressure in poorly fitting sockets is likely the cause of blisters from elevated vacuum use. In the current study, the maximum tissue vacuum pressure resulting from the largest liner displacement (i.e. no insert) averaged -3.6 inHg. With the insert representing acceptable socket fit (7.5 mm thick), maximum tissue vacuum pressure averaged -2.3 inHg. Suction blister formation has been studied to occur in less than 3 hours at pressures between -7 inHg and -20 inHg [126]. While these vacuum pressures are higher than those observed using the current model, many other factors such as individual health, area of vacuum pressure application, and temperature also influence the suction blister formation timing [125,126]. 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.

This model may be used to identify the maximum vacuum pressure experienced by the tissue from liner expansion based on socket fit. With more information on the physiological effects of vacuum pull on the tissue, we may be able to identify a liner expansion threshold that would indicate injury. This would provide practitioners with more guidelines on how to size elevated vacuum sockets to optimize patient benefits and limit blisters from elevated vacuum excessive vacuum pressure in poorly fitting sockets. We demonstrated the ability to predict the resulting tissue vacuum pressure as the liner expands using Boyle’s Law. By knowing the initial tissue volume and geometrically estimating the change in liner volume after liner expansion into the dome, we accurately predicted tissue vacuum pressure values. A similar exercise may be conducted when evaluating a patient’s socket for use with elevated vacuum to identify what levels of tissue vacuum pressure may be expected. Future studies could observe the physiological response caused by these tissue vacuum pressures when applied directly to the skin outside of the socket environment.

Liner type demonstrated limited impact on tissue vacuum pressure based on current model parameters suggesting liner properties may be less important when configuring EV sockets. Prosthetists may focus on selecting liners based on other desirable features such as limb coupling or stress distribution. Liners with thermoplastic elastomers (TPE) which have the highest measured elasticity [129] showed slightly less resistance. In addition, the silicone-based liners with the lowest elasticity demonstrated higher resistance as hypothesized. However, as identified by Cagle et al., the fabric backing appears to play a role in elasticity [129]. WW3 and WW5 samples featured the same elastomer (TPE) but different fabric configurations. Liner tension produced similar effects by slightly increasing resistance to liner expansion for each liner type tested. These results indicated that liner size and type minimally influence elevated vacuum socket mechanics; however, these results may vary at lower tissue volumes when more tissue resistance is present. Additionally, the current model reproduces localized mismatch within the socket with the liner expanding in one direction. However, within the socket the liner may be expanding radially as vacuum is applied to the entire limb. Further research is needed to understand how the mechanics of this situation compare to results from the current model.

The model developed in this study may aid practitioners in configuring elevated vacuum sockets for their patients by informing them how individual patient, socket, and liner properties alter the effect of elevated vacuum on the residual limb. By better understanding the mechanics of an elevated vacuum socket, we can begin to study the resulting physiological response. This research is working towards optimizing the clinical use of elevated vacuum and providing guidelines for its use based on individual patient characteristics and specific prosthetic components.

This study had several limitations. The simulated soft tissue used to select a tissue volume was created as an approximate representation of soft tissue properties knowing that this varies greatly on the residual limb and between individuals. More work should be completed to characterize residual limb soft tissue properties and verify the simulated soft tissue. Additionally, only one tissue volume was used to compare across liner samples. Tissue response will vary across the limb and should be further studied. We chose to focus on tissue properties over muscle in this study because this tissue will experience the most expansion under vacuum and is primarily responsible for volume change in the residual limb. Future uses of the model could be to assess elevated vacuum at different locations and in different types of underlying tissue. Since tissue properties vary with age and comorbidities (e.g. diabetes), different tissue volumes than what was used here may be used to represent varying tissue resistances. Area over bone on the residual limb is more resistant to stretch than areas over muscle. Because of this, tissue over bone may be more susceptible to higher tissue vacuum forces as indicated by the results from lower tissue volumes indicating higher tissue resistance (Figure 4.9). This study only evaluated four different liners from a single manufacturer. Additional liner types and sizes from various manufacturers should be evaluated. The current model does not represent radially expanding liners likely to occur in an elevated vacuum socket as vacuum is applied over the entire limb.

4.5 CONCLUSION

A benchtop model was created to study the mechanics of an elevated vacuum socket. Tissue vacuum pressure increased linearly with socket vacuum pressure until the liner extended to the wall of the representative socket. At this point, the liner could not increase volume and maximum tissue vacuum pressure was reached. The larger the volume of the dome, the higher the vacuum pressures applied underneath the liner. Theoretical tissue vacuum pressure matched well with experimentally measured tissue vacuum pressure based on the liner volume displacement. Liner properties had minimal effect on liner displacement though liners under tension showed increased resistance to displacement. Regardless of liner type and socket vacuum pressure, liner volume displaced was the determining factor for tissue vacuum pressure. The model may be used to optimize elevated vacuum based on individual characteristics and further develop guidelines for the clinical use of elevated vacuum use in lower limb prosthetic devices.

4.6 ACKNOWLEDGEMENTS

The authors would like to thank WillowWood for supplying liner samples for this study and University of Washington’s Center for Research in Education and Simulation Technologies (CREST) for providing human tissue properties expertise and developing the human tissue model. Support from Jacob Brzostowski regarding construction of this project was tremendous and much appreciated.

Chapter 5. OPTIMIZING THE PHYSIOLOGICAL AND MECHANICAL EFFECTS OF ELEVATED VACUUM

5.1 INTRODUCTION

The coupling between the residual limb and the lower limb prosthesis relies on a secure socket fit and is critical to a comfortable and functional prosthesis [3,4]. Obtaining and maintaining optimal socket fit over the short- and long-term remains challenging despite recent advances in socket and suspension technology. Limb volume change is a significant contributor to poor socket fit [1,2]. As limb volume loss occurs, socket fit degrades, leading to relative motion between the residual limb and socket. Subsequently, poor socket fit may result in user discomfort, skin breakdown, gait instability, and even prosthesis disuse [2,5,6].

Elevated vacuum (EV) uses a mechanical or electrical pump to evacuate the air between the liner and the socket wall, maintaining a continuous negative pressure environment within the socket [90]. EV acts to secure the prosthesis to the residual limb and help manage residual limb volume changes [12]. A typical EV system uses an external sealing sleeve to seal the socket proximally, though some systems seal internally with a gasket sealing ring around the liner [27]. Within the socket, the liner and tissue are pulled to the wall of the socket as the vacuum pump evacuates air between the liner and socket, limiting limb movement relative to the socket during gait.

Studies have shown the mechanical impact of EV on reducing limb movement relative to other suspension methods [14,90,92–94]. Board et al. measured vertical displacement with x-ray under displacement loads representative of swing phase to compare EV and suction [14]. A similar comparison was made by Gerschutz et al. using distally placed inductive sensors to dynamically measure limb-socket displacement [94]. Klute et al. employed a 12-camera motion analysis system to compare limb displacements between EV and locking pin systems [17]. These studies all showed less vertical displacement with EV, suggesting improved suspension. The relationship between displacement and socket fit was investigated by Wernke et al. using a benchtop set-up with a residual limb model and varying vacuum pressure and fit [34]. The relationship between vacuum pressure and displacement was found to be dependent on socket fit. Based on an improvement in socket fit, several case studies have suggested EV improved functional outcomes and self-reported satisfaction in prosthesis users [27,28,30,95–98].

Related to socket fit and suspension, EV has been suggested to provide physiological benefits. Several studies have shown EV to better limit limb volume loss compared to suction suspension, particularly during walking [14,15]. EV has been thought to improve overall residual limb health based on self-reported questionnaires, clinical outcomes, and wound closure studies [28,95,97]. Rink et al. quantitatively assessed residual-limb circulation with EV compared to non-EV suspension systems (i.e. locking pin and suction) [20]. Non-invasive measures included transepidermal water loss, laser speckle imaging, transcutaneous oxygen, and functional hyperspectral imaging techniques [99]. Following 16 weeks of EV use, residual limb oxygenation during treadmill walking was improved and prosthesis-induced reactive hyperemia was attenuated compared to after 16 weeks of using a non-EV suspension method. Donning the socket was found to decrease perfusion in EV and non-EV suspension systems. Overall, outcomes suggested long-term use of EV helps to improve perfusion and preserve skin barrier function. Other clinical uses of negative pressure have examined blood flow in response to various negative pressure magnitude and application profiles. Studies in negative pressure wound therapy (NPWT) have identified a recommended therapeutic range of negative pressure between -50 mmHg and -150 mmHg (-2 inHg to -6 inHg). Above or below this range creates no effect or detrimental effects [119]. Additionally, research studies have demonstrated that intermittent negative pressure increases skin blood flow [111].

Recently, optical coherence tomography (OCT) has been introduced as a method to measure residual limb health [26] and may have potential capability to evaluate the acute effects of tissue vacuum pressure during EV on skin perfusion. From results testing the benchtop EV socket model (Chapter 4), depending on the fit of the socket, approximately -4 inHg may be applied to the underlying tissue. OCT is a non-invasive and non-contact optical imaging modality used to capture in-vivo cross-sectional volumetric images of biological tissue with 1 to 10 μm resolution [134]. OCT-based angiography (OCTA) allows for non-invasive three-dimensional (3D) visualization of the cutaneous microvasculature using moving cells, such as red blood cells, as a contrast agent. Multiple images (B-scans) are taken over a single location and compared to identify movement reflecting blood flow which can then be quantified as vessel area density (VAD) [26,135]. Compared to other measurement methods of functional characteristics of vasculature such as those used by Rink et al. [20], OCTA offers the advantage of precise depth information [136]. OCTA has been used previously in people with lower limb amputation to assess post-occlusive reactive hyperemia (RH), a measure of residual limb tissue health [26], and OCT has even been integrated with a vacuum system to visualize the formation of suction blisters in human skin [137].

Currently, minimal guidelines exist regarding the ideal socket vacuum pressure setting in EV systems, though it is recognized that optimal socket vacuum pressure may be different for each individual depending on socket fit, component selection, and residual limb tissue [94,138]. Establishing the vacuum pressure setting relies on subjective feedback and clinical experience. In the literature, pressures have principally been reported between -7 inHg and -23 inHg, though not all studies report vacuum pressure [27]. Wernke et al. noted that at vacuum pressures greater than approximately -11 inHg relatively similar levels of suspension were created in a benchtop experiment [34], but it remains to determine how different vacuum levels influence limb physiology. An optimal EV system should provide maximum suspension by minimizing residual limb movement within the socket and deliver physiological benefits to improve limb health and limb volume management without causing blistering. While previous studies have evaluated the in-socket effect of changing vacuum pressure by focusing on a singular aspect (e.g. only limb movement), a multimodal approach may be more appropriate to determine the optimal vacuum pressure setting for individual EV users, considering both the mechanical (i.e. limb movement) and physiological effects (i.e. skin perfusion, limb fluid volume).

The purpose of this study is to investigate the sensitivity of variables such as skin perfusion, limb fluid volume, limb movement, and socket comfort to changes in vacuum pressure. This research works towards determining if socket vacuum pressure can be optimized on an individual basis to maximize beneficial physiologic response and comfort while minimizing movement within the socket. We measured physiological effects such as perfusion and limb fluid volume changes through OCT imaging and bioimpedance analysis, respectively. Extending from previous work [127,139,140], multiaxial limb displacement during ambulation was measured with in-socket inductive displacement sensors, and patient-reported measures of comfort were collected across various socket vacuum pressures. Results from this study are important for the development of recommendations for use of EV systems and improving clinical care through more informed clinical decision-making regarding vacuum pressure settings.

5.2 METHODS

5.2.1 *Participants*

Volunteers were recruited from the local amputee population and study registry. For this pilot study, we targeted a sample size of 3 volunteers. Inclusion criteria for this study were individuals with transtibial amputations of at least 12 months prior. Volunteers must have been successfully using an electronic EV system with a sealing sleeve for at least 6 months. Exclusion criteria included the presence of diabetes due to the potential effects this condition has on limb sensation and microvasculature [141]. Skin breakdown and excessive scarring at the imaging site were also grounds for exclusion. Prior to enrollment, each participant provided informed consent. A University of Washington Institutional Review Board approved the testing procedures before study initiation.

5.2.2 *OCT*

The effects of various vacuum pressures on skin perfusion were evaluated using OCTA. A commercial Swept-Source OCT (SS-OCT) system (OCS1310V1, Thorlabs Inc., Newton, NJ, USA) was used to capture images (Figure 5.1). Images were taken using 2 mm by 2 mm field-of-view with 200 by 200 pixel resolution. Three-dimensional (3D) images were captured with built-in Speckle Variance OCT using five B-scan repetitions. These imaging parameters balanced field-of-view, resolution, and imaging speed. Images were collected at a depth of approximately 1 mm below the skin's surface to capture the vessels within the papillary plexus, located beneath the dermal-epidermal junction. The papillary plexus is the primary site of nutrient exchange within the tissue and is an important mediator of the inflammatory response and of vascular resistance [142]. Vessel area density (VAD) was used to indirectly measure overall perfusion of the imaged area of interest. VAD represents a snapshot of the total amount of blood flowing in a vascular bed and was determined by counting the number of vessel pixels divided by the total number of pixels in the image [143].

An EV attachment was created to enable OCT imaging before, during, and after local vacuum application without needing to manually adjust the OCT system (Figure 5.1). The EV attachment is an enclosed dome, 5.5 cm in diameter and a dome height of 2 cm, with a barbed outlet valve to enable vacuum pressure application. The top of the dome was optically transparent which allowed imaging of the skin below. An approximately 3.5 mm thick layer of elastomeric material was placed between the probe and the skin to help seal the vacuum pressure area and distribute pressure from the OCT probe. A circular window (3 cm diameter) was cut from the elastomeric material over the imaging site.

Table 5.1. Spacer label and thickness. C1 and C2 were the same spacer implemented at different times in the imaging protocol.

Spacer Label	A	B	C1	C2	E
Height (mm)	3.3	5.7	7.7	7.7	12.6

EV spacers of various thickness (Table 5.1) were used to image at multiple vacuum pressures. The spacers were used to modulate the location of the focal plane relative to the skin surface during vacuum application (Figure 5.1). After the EV spacer was in place, vacuum was applied to the EV attachment dome through a barbed outlet valve by an electronic vacuum pump controlled by a researcher using a custom LABVIEW program. Tissue displaced towards the OCT probe. When the papillary plexus was within the desired focal plane, the researcher stopped the vacuum pump. If the target location fell outside of focus between images, the researcher briefly activated the pump, returning the tissue to the appropriate level. Thicker spacers required higher vacuum pressure to displace the skin the desired distance, allowing images at various vacuum pressures for each participant.

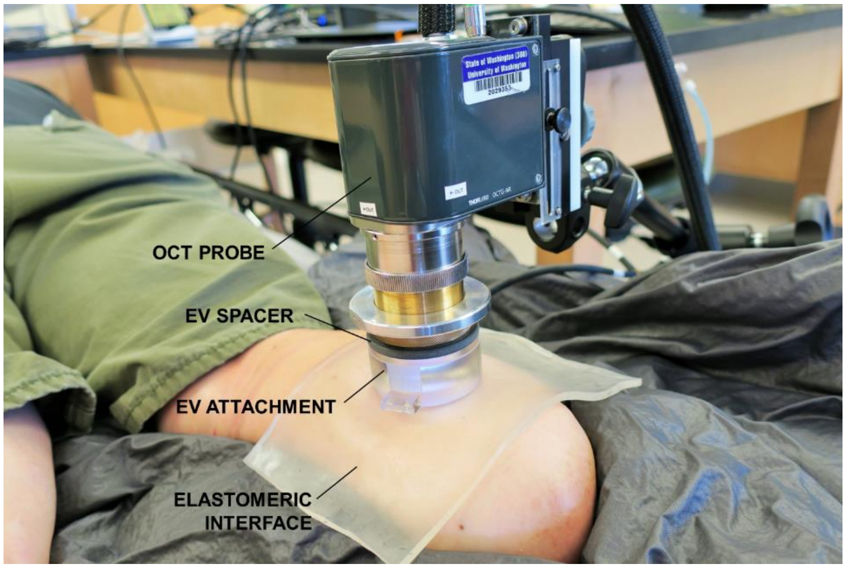

Figure 5.1. OCT system directed at the posterior aspect of the residual limb.

5.2.3 *Image Processing*

Custom processing code automatically identified the dermal-epidermal junction and segmented the range of interest below the papillary plexus for vessel analysis. This process was done manually when the algorithm was unsuccessful due to hyper-reflection from the glass slide (Participant 2). Once the region of interest was segmented, a two-dimensional (2D) maximum intensity projection image of the 3D image was produced with the maximum pixel of each A-line. VAD was based on these maximum intensity projection images. For quantification, the 2D projection images were binarized based on a threshold value established for each image set. Intensity values at or above the threshold were assigned a one and values below the threshold were set to zero. VAD was calculated by summing the total number of vessel pixels and dividing by the total number of pixels in the image. Vertical motion artifacts, often from the pulsatile flow of blood, manifest as horizontal lines in the intensity projection image. These motion artifacts were often quantified as vessels. Prior to quantification, processing code automatically identified areas of potential motion and replaced the affected pixels with zeros. Consequently, these pixels were not included in the total number of image pixels used in the VAD calculation. All motion artifact corrections were confirmed visually.

5.2.4 *Socket Sensing System*

An EV socket sensing system was assembled in order to record limb movement and socket vacuum pressure at various vacuum settings (Figure 5.2). The limb displacement sensing system included low-profile inductive distance sensors and a flexible iron-embedded elastomeric liner described in detail previously [127]. The system was adapted for use in EV sockets from use in adjustable cable-paneled sockets as described in detail previously [127,140]. In-socket vacuum pressure was measured between the instrumented socket and the ferrous liner with a Honeywell TruStability Board Mount Differential Pressure Sensor (Honeywell, Morris Plains, NJ, USA), and a custom, portable data acquisition unit powered both the socket vacuum pressure sensor and inductive distance sensors (Figure 5.3).

The inductive distance sensors consisted of a 0.15 mm thin flexible coil antenna (32.0 mm diameter), a surface-mounted capacitor, and a surface mounted thermistor (at select locations). An inductive sensing chip (LDC1614, Texas Instruments, Dallas, TX, USA) within the data acquisition unit powered the sensors. The inductor and capacitor operated as an inductor-capacitor (LC) tank oscillator. A magnetically permeable target within the sensor’s field reinforced the inductor and lowered the sensor’s oscillation frequency as the target moved closer to the sensor. The sensor output (counts) is a ratio of the oscillation frequency to an external reference clock frequency. The ferrous elastomeric liner was fabricated with a layer of iron-embedded polymer between the fabric backing and the standard commercial silicone elastomer. The target layer was 1 mm in thickness, and the polymer was 85% iron by weight.

An instrumented EV socket was fabricated for each participant. A mechanical coordinate measurement system (FaroArm Platinum, FARO Technologies, Lake Mary, FL, USA) was used to record each participant's existing socket. The goal was to duplicate the shape of the participant's current socket. Two layups were used to create each instrumented socket. The first consisted of four layers of Nyglass stockinet (Paceline, Matthews, NC, USA) and epoxy acrylic resin (Paceline, Matthews, NC, USA). Sensors were placed at eight locations: anterior proximal (AP), anterior midlimb (AM), anterior inferior (AI), distal end (DE), posterior proximal (PP), posterior midlimb medial (PM), posterior midlimb lateral (PL), and posterior inferior (PI). Thermistors were used at the DE, AP, AI, and PL locations to thermally compensate the signal following a test session. Ferrite shielding was added to the back of each sensor to block electromagnetic interference from the carbon fiber. Then a single layer of carbon fiber was applied. These locations were selected as they have been used previously [140] and feature multiple levels of the residual limb, distal, midlimb, and proximal.

A multi-stage procedure was used to calibrate the sensors [127]. First, a Delrin block was placed inside a ferrous liner to establish a flat surface at the anterior midlimb section of liner. A sensor adhered to the arm of a height gauge (Mitutoyo 570-312, Aurora, IL, USA) was incrementally moved away from the liner surface at steps of 0.25 mm from 0 to 2 mm and 1 mm from 2 to 15 mm. The sensor was then moved to a height of 20 cm, outside of range of the ferrous liner. An in-socket calibration was also performed for each participant's instrumented socket and corresponding ferrous liner to establish calibration 0 mm offset for the unique socket environment. A custom silicone bladder with a proximal tubing port was placed inside the ferrous liner. The liner was then placed within the instrumented socket and the proximal edge of the liner was rolled down to cover the outside of the socket. A sealing sleeve was placed over this section of the liner, sealing the socket environment between the interior socket wall and the liner. Vacuum pressure of approximately -20 inHg was applied to conform the ferrous liner flush to the wall of the socket. The silicone bladder was then inflated to 5 psi to further expand the liner to the contours of the socket to establish the 0 mm measurement value. Prior studies in amputee subjects have shown error of less than 3% full-scale output following calibration [127].

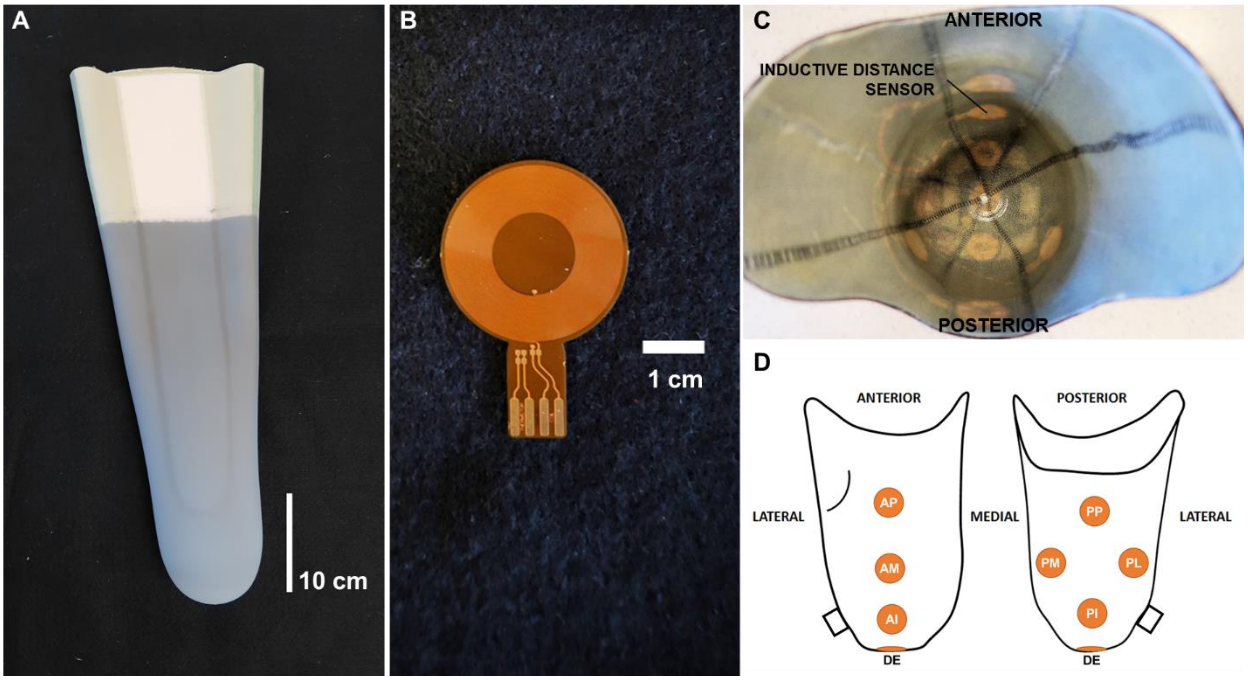

Figure 5.2. Components of the socket sensing system. (A) Ferrous elastomeric liner flipped inside out to show the layer of magnetic polymer. (B) Single inductive distance sensor. (C) Instrumented EVsocket featuring the eight inductive distance sensors embedded between layups of carbon fiber (outside) and Nyglass (inside). (D) Approximate location of the eight inductive distance sensors in each instrumented EV socket. AP = anterior proximal, AM = anterior midlimb, AI = anterior inferior, DE = distal end, PP = posterior proximal, PM = posterior midlimb medial, PL = posterior midlimb lateral.

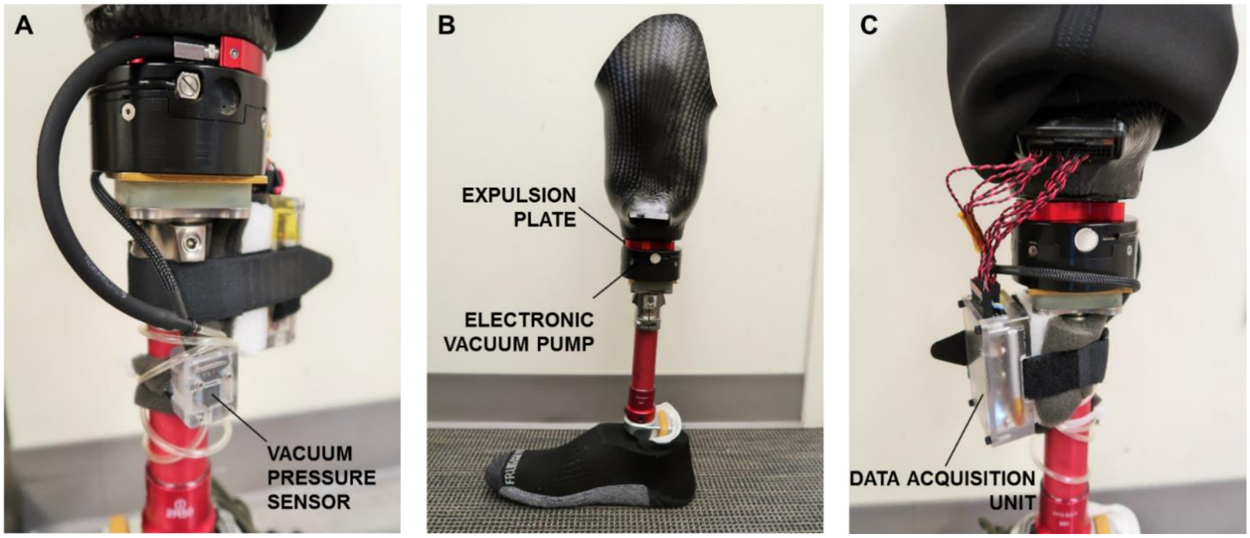

Figure 5.3. Instrumented EV test prosthesis. (A) Socket vacuum pressure sensor. (B) Expulsion plate between the electronic vacuum pump and distal end of the socket. (C) The data acquisition unit secured to the pylon of the test prosthesis operates the vacuum pressure sensor and the inductive distance sensors.

5.2.5 *Residual Limb Fluid Volume*

Limb fluid volume was measured in the posterior and anterior regions of the residual limb with a custom, portable multi-frequency bioimpedance analysis system, allowing continuous (30 Hz sampling frequency) in-socket measurement of extracellular fluid volume, described previously in detail [63]. A small electrical current (< 300 µA peak-to-peak between 3kHz and 1 MHz) was injected to custom, thin electrodes produced with electrically conductive tape (ARCare 8881, Adhesives Research Incorporated, Glen Rock, PA, USA) and hydrogel (9880, 3M, St. Paul, MN, USA). Voltage sense electrodes over the region of interest measure electrical changes within the limb. Electrode positioning is shown in Figure 5.4. Extracellular fluid resistance from the current and voltage values was determined using De Lorenzo’s form of the Cole model [52]. These resistances were converted to limb extracellular fluid volume using a geometric volume conduction model [53,54]. Bioimpedance analysis has been previously used in prosthetic applications [10,36,60,62,70,83–85,121] and has been highly correlated to limb segment muscle volume from magnetic resonance imaging (MRI) [60].

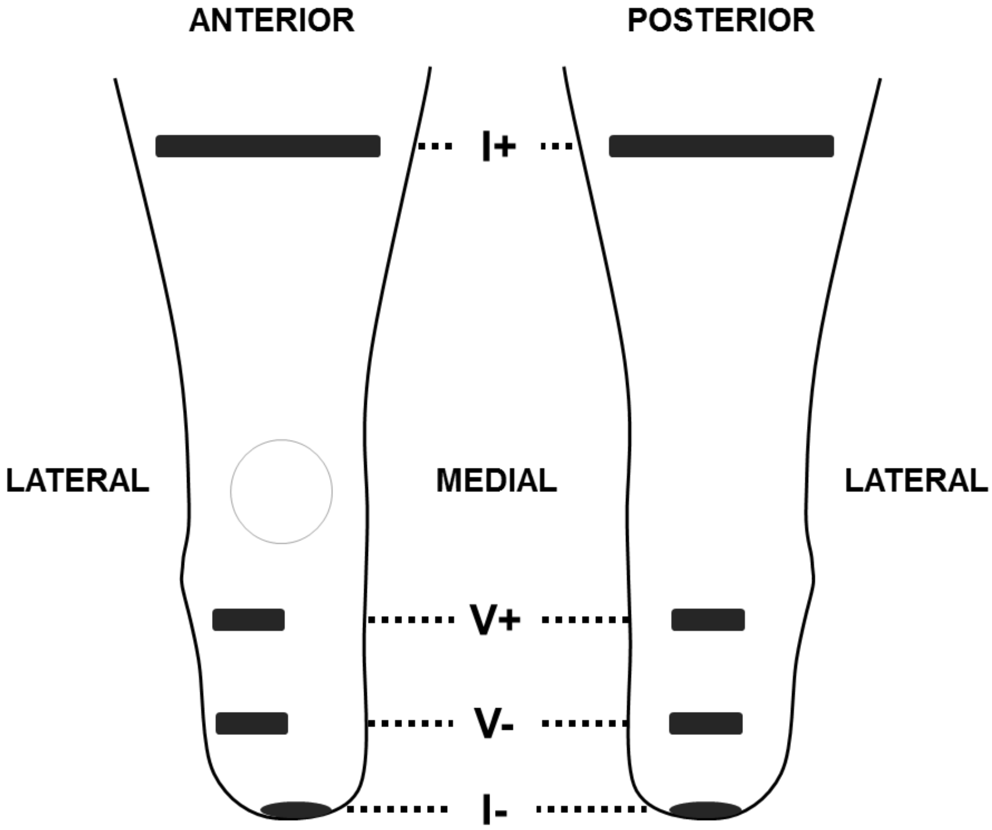

Figure 5.4. Electrode positioning for bioimpedance analysis. The current inject electrodes (I+) are placed perpendicular to the limb axis on the posterior and anterior sides of the limb. The I- electrode is placed centrally on the distal end. The anterior voltage sensing electrode are centered over the anterior lateral soft muscle compartment. V+ is at the proximal edge of the compartment, no higher than the mid-patellar tendon, and V- is at the distal end of the tibia. The posterior voltage sense electrodes are centered on the limb at the same level as the anterior electrodes.

5.2.6 *Testing Procedure*

This study consisted of two test sessions both conducted at the University of Washington (Figure 5.5). The first session began with informed consent and intake of participant health and prosthesis information. The research prosthetist evaluated the participant's activity level and assigned a Medicare Functional Classification Level (MFCL or K-Level). The interior of the participant's socket was scanned using an industrial coordinate measurement system (FaroArm Platinum, FARO Technologies, Lake Mary, FL, USA). This digital file was used to create a duplicate socket, implementing established lab protocols [70,121]. The socket was designed to be used with the LimbLogic EV system (The Ohio WillowWood Company, Mt. Sterling, OH, USA). This is an electronic EV system mounted below the socket that allows incremental changes to socket vacuum pressure settings wirelessly using the LimbLogic Communicator and accompanying computer software. This EV pump has performed well compared to other commercial EV systems [133,144].

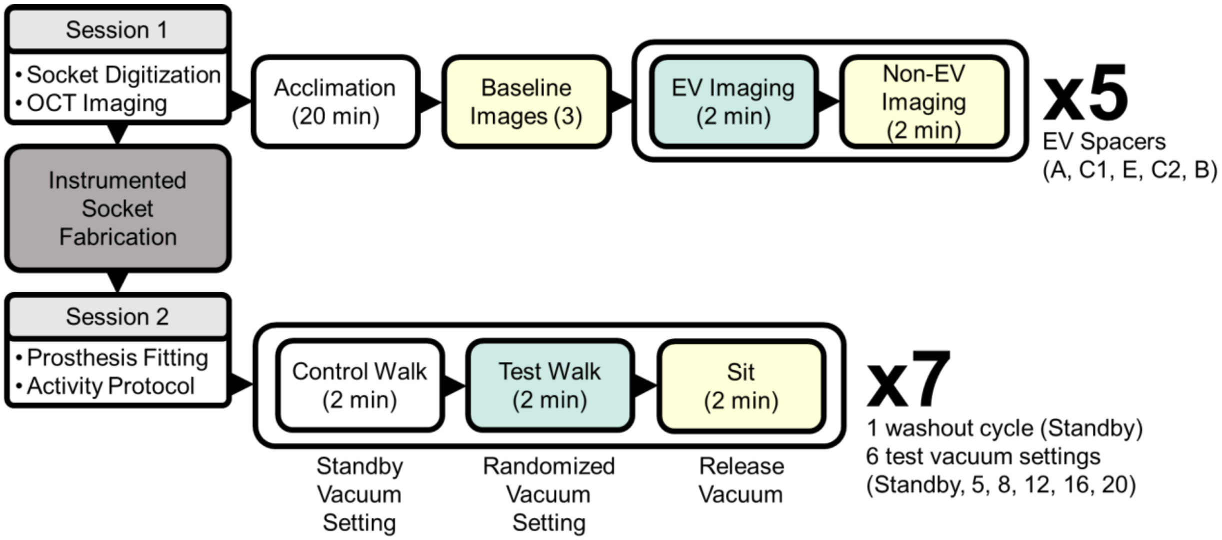

Figure 5.5. Testing procedure executed for each participant.

While the socket was being scanned, each participant underwent an OCT imaging session. Before imaging began, participants doffed their socket and liner and lay prone on a hospital bed for 20 minutes at room temperature in order to acclimate to the lab environment. This acclimation time is common for studies evaluating skin microcirculation [145,146]. A point centered on the posterior midlimb was selected as the region of interest for imaging. This region of the residual limb has the largest instance of soft tissue and allows a relatively large surface for placement of the OCT EV attachment. The temperature at the posterior aspect of the participant's residual limb was measured using a non-contact, infrared thermometer (Minitemp, Raytek, Wilmington, NC, USA) to ensure skin temperature was not elevated from the socket environment before beginning imaging. The residual limb and contralateral limb were secured using a vacuum immobilization cushion (Vak-Lok, CIVCO Radiotherapy, Orange City, IA, USA) to help limit residual limb movement. Mineral oil and a thin glass slide were placed on the imaging location, and over approximately three minutes, three baseline images under atmospheric pressure were taken. Then an incremental EV imaging protocol was conducted in cycles consisting of 2 minutes of EV imaging and 2 minutes of non-EV imaging (Figure 5.5). A previous study indicated that blood flow velocity returned to baseline in under 2 minutes following the removal of skin vacuum pressure [25]. Five cycles were executed using the various EV spacers (Table 5.1) in the following sequence: A, C1, E, C2, B. Each spacer was removed or exchanged for a smaller spacer for non-EV imaging. Images were taken approximately every 15 seconds. Preliminary tests showed that this range of spacers corresponded to vacuum pressures that may be experienced within the socket based on the benchtop EV model (Chapter 4). Additionally, the magnitude of vacuum pressure and time the pressure was applied to the skin was below that required to induce injury [126]. Following the imaging protocol and socket scan, the participant's prosthesis was returned.

After the instrumented EV socket was fabricated over several weeks, participants returned to the lab for the second test session. During the second test session, participants were fit to their instrumented EV prosthesis and ferrous liner by the research prosthetist. Components similar to those of the participant's regular prosthesis were used in the assembly of the instrumented EV prosthesis. Once comfortable, participants sat with their instrumented prosthesis donned for 10 minutes then doffed their prosthesis and liner to allow researchers to instrument their residual limb with electrodes for bioimpedance analysis. The socket vacuum pressure sensor was connected to the expulsion plate, which was mounted in line with the EV pump to record socket pressures throughout the study. The vacuum pressure sensor and data acquisition device were attached to the pylon (Figure 5.3).

Next, each participant performed an in-lab activity protocol to evaluate limb movement, limb fluid volume change, and comfort at various socket vacuum pressure settings. The protocol consisted of seven cycles with each cycle containing four minutes of walking and two minutes of sitting. The first two minutes of each walking segment were considered the control walk in which the vacuum system was set to "Standby" (SB) so that it acted as a suction suspension. The second two minutes of each walking segment was considered the test walk in which the vacuum pressure was randomized among six different settings (SB, 5, 8, 12, 16, 20). Vacuum pressure changes were made by a wireless connection to the participant's EV system. The participants were aware when the changes were made but were blinded to the test walk vacuum setting. During each sitting segment, the socket was set to SB, and the vacuum pressure was released. The first cycle of the protocol was a washout conducted at SB to allow the participant to settle in the socket. All walking was conducted on a treadmill. With 30 seconds remaining in the control walk, participants were asked to provide a socket comfort score (SCS). With 30 seconds remaining in the test walk, participants were asked to compare their socket comfort with the previous control walk with a relative socket comfort (RSC) and to provide a numerical socket comfort score (Table 5.2).

Table 5.2. User comfort questions and potential responses. Questions asked in the final 30 seconds of each control walk (SCS) and test walk (SCS, RSC).

Metric	Question	Responses
SCS	On a 0 – 10 scale, if 0 represents the most uncomfortable socket you can imagine, and 10 represents the most comfortable socket, how would you score the comfort of the socket at this moment?	Whole number between 0-10
RSC	Compared to the previous walking segment, would you rate the comfort of your socket as better, worse, little better, little worse, or no different?	Better Little Better No different/Same Little worse Worse

5.2.7 *Analysis*

Participant data were analyzed individually to determine if effects of EV could be optimized based on individual cases.

VAD was plotted over time to visualize changes as various vacuum pressures were applied. The mean VAD at each EV spacer interval was calculated, and these values were plotted to analyze trends within and between participants. Various metrics (mean, standard deviation, median, minimum, and maximum) were calculated for vacuum pressure recorded during each EV spacer interval.

Peak-to-peak (pk/pk) limb displacements were calculated for each test walk as the difference between the maximum and minimum distance for a step. Minimum values for each sensor represented limb-socket distance during the stance phase of gait, and the maximum values represented swing phase. Displacements were calculated for each step beginning with the fifth step after the start of a walk and ending with the fifth to last step of a walking segment. The steps were averaged over the walking segment to obtain one mean displacement value for each vacuum pressure setting. Mean limb displacement was compared across vacuum pressure settings. The mean displacement recorded at multiple sensors was averaged based on limb region. The distal end sensor provided vertical movement information (pistoning). Inferior, midlimb, and proximal sensors provided anterior and posterior movement along the sagittal plane. Vacuum pressure during the activity protocol was segmented into steps. Metrics of each step were then calculated (maximum, minimum, mean, and peak-to-peak) and averaged over each walking segment. Socket comfort change from the control walk to the test walk for each cycle was calculated.

Limb extracellular fluid volume data during each walking cycle were also segmented into steps using local limb fluid volume maxima. As with limb displacement data, walking segments began with the fifth step after the start of a walking segment and ended with the fifth to last step of a walking segment. Within each step, the minimum limb fluid volume was determined and then a linear regression was fit to all minima within a segment to determine the rate of limb fluid volume change within that walking segment. Results were expressed as a percentage of the reference limb fluid volume calculated as the mean of the minima during in the first 10 steps of the second cycle.

5.3 RESULTS

5.3.1 *Participants*

Three individuals with traumatic transtibial amputation participated in this study (Table 5.3). At time of enrollment, the participants were aged 48.9 years old, 37.6 years old, and 69.5 years old with 4.5 years, 15.6 years, and 16.8 years, respectively, since amputation. All participants were male. While no participants had diabetes or vascular disease, Participant 1 had a history of cardiovascular issues; he had a stroke 6 years prior.

Table 5.3. Participant characteristics.

ID #	Gender	MFCL	Tobacco	Diabetes/ CV Issues	Etiology	Age (years)	Since Amputation (years)	Mass (kg)	Height (cm)	BMI	Limb Length (cm)	Mid Limb Circ (cm)
1	M	K-3	N	N/Y	Traumatic	48.9	4.5	130.0	172.7	43.6	19.0	37.4
2	M	K-4	N	N/N	Traumatic	37.6	15.6	88.3	189.2	24.7	11.0	31.0
3	M	K-3	N	N/N	Traumatic	69.5	16.8	104.5	180.3	32.1	15.0	30.3
					Mean	52.0	12.3	107.6	180.8	33.5	15.0	32.9
					Median	48.9	15.6	104.5	180.3	32.1	15.0	31.0
					SD	16.2	6.8	21.0	8.3	9.5	4.0	3.9
					Min	37.6	4.5	88.3	172.7	24.7	11.0	30.3
					Max	69.5	16.8	130.0	189.2	43.6	19.0	37.4

CV: cardiovascular; M: male; Y: yes, N: no

All participant regularly used WillowWood LimbLogic electronic vacuum systems (Table 5.4). Participant 2 and Participant 3 did not use any prosthetic socks, while Participant 1 used two WillowWood One gel socks for the study. In his regular prosthesis, Participant 1 used an EV set point of -6 inHg. Both Participant 2 and Participant 3 used higher set points of -17 inHg and -20 inHg, respectively. EV ranges for testing were set to 4 inHg (the minimum range available), similar to those that the participants used in their regular prostheses.

Table 5.4. Prosthesis characteristics of participant's regular prosthesis.

ID #	EV System	EV Type	Set Point (inHg)	Range (inHg)	User Max (inHg)	Seal Type	Socks	Liner	Foot Type
1	WillowWood LimbLogic	Electronic	-6	4	-10	Inner sleeve	2 gel	WillowWood Alpha Duo	Dynamic
2	WillowWood LimbLogic	Electronic	-17	5	-20	Outer sleeve	None	Ossur Iceross Dermo	Dynamic
3	WillowWood LimbLogic	Electronic	-20	4	-20	Outer sleeve	None	Ossur Iceross Dermo	Dynamic

For OCT imaging, the same EV spacer intervals were used for each participant; however, vacuum pressure varied slightly among participants (Table 5.5). Similarly, for the activity protocol, while EV set points and ranges were consistent between subjects, the settings produced different actual vacuum pressure (Table 5.6). The EV set point represented the peak vacuum pressure at that setting; measured socket vacuum pressures were below this set point.

Table 5.5. OCT vacuum pressure metrics for each EV spacer interval. All values in inHg.

ID #	Spacer	A	C1	E	C2	B
1	Mean	-0.10	-1.16	-4.09	-0.82	-0.31
	SD	0.04	0.08	0.22	0.06	0.04
	Median	-0.10	-1.15	-3.99	-0.81	-0.30
	Min	-0.20	-1.41	-4.65	-1.14	-0.43
	Max	0.01	-0.97	-3.80	-0.59	-0.23
2	Mean	-0.11	-1.87	-6.57	-0.83	-0.17
	SD	0.04	0.15	0.16	0.06	0.04
	Median	-0.09	-1.84	-6.55	-0.82	-0.18
	Min	-0.21	-2.32	-6.91	-1.00	-0.35
	Max	-0.03	-1.64	-6.31	-0.71	-0.07
3	Mean	-0.03	-1.20	-5.75	-0.58	-0.15
	SD	0.03	0.16	0.23	0.06	0.02
	Median	-0.02	-1.17	-5.76	-0.57	-0.15
	Min	-0.15	-1.58	-6.24	-0.91	-0.23
	Max	0.01	-0.91	-5.33	-0.48	-0.08

Table 5.6. Socket vacuum pressures (inHg) measured for each EV test walk. Recorded during the activity protocol. SB = Standby. Standby setting deactivates the pump but allows air expulsion through a one-way valve creating suction suspension.

ID #	Setting	SB	5	8	12	16	20
1	Mean	-2.1	-3.5	-5.3	-8.8	-12.9	-17.1
	Max	1.5	-0.3	-3.9	-7.7	-12.0	-16.6
	Min	-5.2	-6.3	-7.2	-9.9	-13.6	-17.5
	Pk/Pk	6.7	6.0	3.3	2.2	1.5	1.0
2	Mean	-0.8	-2.4	-5.0	-9.6	-13.2	-17.4
	Max	0.9	-1.5	-4.4	-9.2	-12.9	-17.2
	Min	-2.6	-4.7	-7.0	-10.4	-13.7	-17.8
	Pk/Pk	3.5	3.2	2.5	1.2	0.8	0.6
3	Mean	-2.6	-4.1	-5.8	-9.3	-13.6	-17.8
	Max	1.4	-1.3	-4.3	-8.7	-13.1	-17.5
	Min	-5.4	-6.4	-7.3	-9.9	-14.0	-18.0
	Pk/Pk	6.8	5.2	3.0	1.2	0.9	0.5

5.3.2 *OCT*

Results from OCT imaging are shown in Figure 5.6. For Participant 1, increasing vacuum pressure on the skin with incrementally larger EV spacers (EV spacers A, C1, and E) progressively decreased mean VAD below baseline values. Mean VAD reached its lowest value during interval

E (-4.09 inHg) at which point vacuum pressures were reduced at C2 and B intervals (-0.82 inHg and -0.31 inHg, respectively) leading to incremental increases in VAD. Non-EV intervals after vacuum application each showed an increase in mean VAD compared to the previous interval, even increasing above baseline following A and C1 intervals.

Participant 2 had a similar reaction to Participant 1 for intervals A (-0.11 inHg) and C1 (-1.16 inHg) as mean VAD was incrementally decreased below baseline. Unlike Participant 1, non-EV intervals following A and C1 did not show mean VAD increase above baseline levels. VAD increased drastically with the application of higher vacuum pressures of interval E (-6.57 inHg). Subsequent lower levels of vacuum applications decreased VAD but none below baseline.

Trends from Participant 3 were similar to those of Participant 1. Two of the initial three EV intervals (A and E) reduced mean VAD below baseline with non-EV responses following A and C1 increasing perfusion above baseline. The first image of high vacuum application (E, -5.75 inHg) showed an increase in VAD, but values quickly dropped well below baseline. Subsequent lower vacuum pressures (C2 at -0.58 inHg and B at -0.15 inHg) increased VAD above baseline though with minimal non-EV responses.

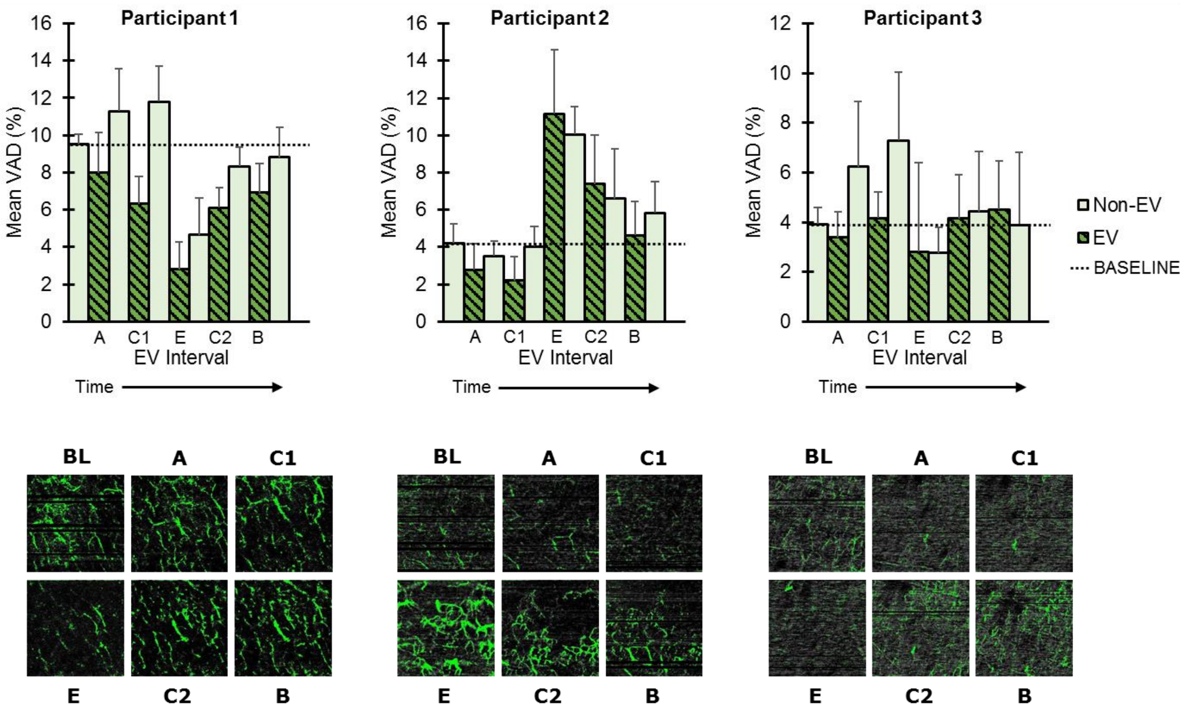

Figure 5.6. OCT imaging results for each participant. The dotted lines represent the mean VAD of the initial baseline (BL) images. Mean VAD values with standard deviation bars are shown for non-EV and EV interval. Below each plot are select max intensity projection images for each EV interval with the quantified vessels overlaid in green.

5.3.3 *Limb Displacement, Limb Fluid Volume, User Comfort*

Increasing vacuum settings resulted in reduced limb movement relative to the socket (Figure 5.7). For Participant 1, mean pk/pk limb displacement during the test walk with suction suspension (SB) ranged between 3.22 mm (DE) and 0.10 mm (AP). At the vacuum setting of 20 (-17.1 inHg mean socket vacuum pressure), limb displacement at all sensed locations had been reduced to below 0.25 mm. Most displacement occurred at the distal end, while mean anterior and posterior displacement was less than 1 mm for all settings. For Participant 2, the largest displacement values were noted anteriorly, reaching 3.47 mm (AM) and 4.16 mm (AI). Displacement recorded at the posterior sensors was low for all settings with mean displacement not exceeding 0.27 mm. Unlike Participant 1, the distal end experienced minimal displacement ranging from 0.26 mm (SB setting,

-0.8 inHg mean vacuum pressure) to 0.05 mm (20 setting, -17.8 mean vacuum pressure). Participant 3 showed similar limb displacement trends to Participant 2 particularly regarding anterior displacement. AI and AM showed the largest displacement at each vacuum setting between SB and 12. Of the posterior sensors, PI detected the most displacement at each vacuum setting.

Relative percent limb movement across the entire range of displacement for each participant was consistent between limb regions (i.e. distal end, anterior mean, and posterior mean) and between participants by vacuum setting 12. (Figure 5.8). This corresponded to a mean vacuum pressure of -8.8 inHg (Participant 1), -9.6 inHg (Participant 2), and -9.3 inHg (Participant 3). Of the recorded range, limb movement was reduced 81-93%. Additional changes to vacuum setting from 12 to 20, only accounted for an additional 7-19% reduction in movement.

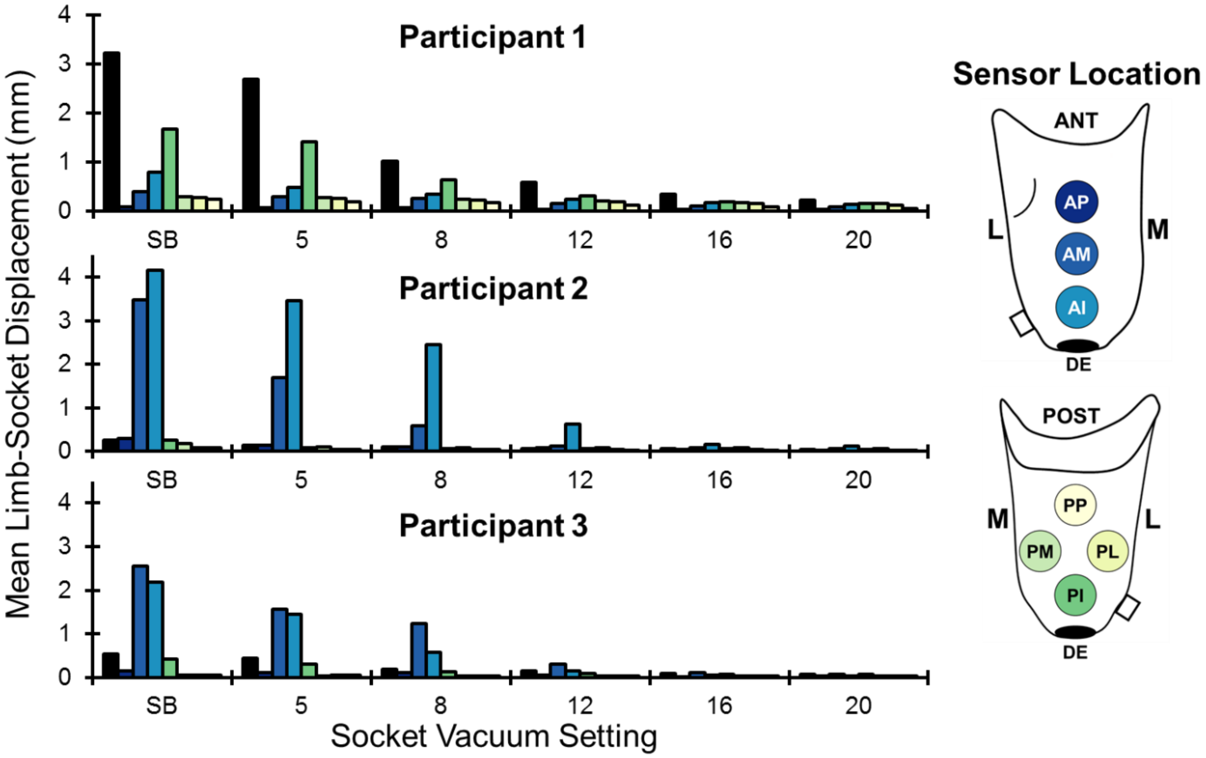

Figure 5.7. Mean peak-to-peak (pk/pk) limb displacement. Inductive distance sensor data from during the test walking segment at each vacuum pressure setting.

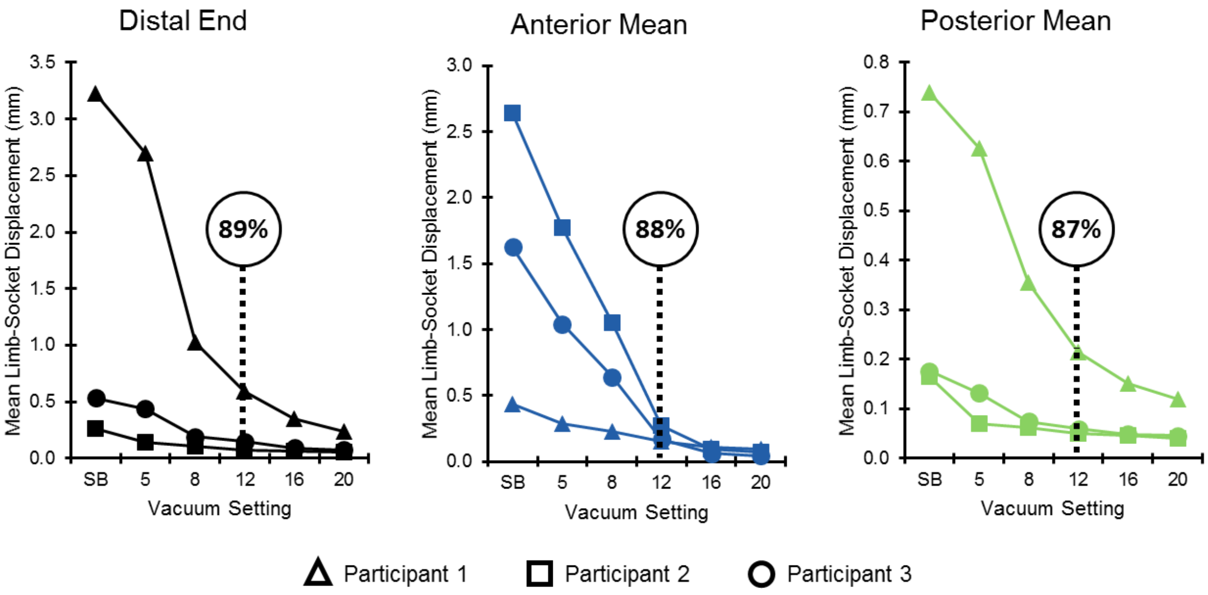

Figure 5.8. Regional summary of mean pk/pk limb displacement. Distal end includes only the DE sensor. Anterior Mean is a mean of each level of anterior sensors (AP, AM, and AI). Posterior Mean is a mean of each level of posterior sensors (PI, PM and PL mean, and PI). Dotted line and percent represent the percent of movement reduction by the indicated setting.

Anteriorly, limb fluid volume rates of change for Participant 1 were positive at each vacuum setting (Figure 5.9). Vacuum setting 16 resulted in the only posterior limb fluid volume loss as well as one of the lowest rates of anterior volume change. Rate of limb fluid volume change was most positive at the vacuum setting of 12 (mean -8.8 inHg) for both anterior (10.7 %/h) and posterior channels (7.0 %/h). For Participant 2, posterior rate of limb fluid volume change increased as the vacuum pressure increased up to vacuum setting 16. At setting 20, posterior limb fluid volume rate of change decreased slightly. The anterior region showed a less consistent trend. Settings of 8, 12, and 20 resulted in positive rates of fluid volume change anteriorly, while SB, 5, and 16 were negative. For Participant 3, posterior rates of limb fluid volume change were negative for all settings. SB (mean -2.6 inHg) resulted is the lowest rate of loss while vacuum setting 5 (mean -4.1 inHg) resulted in the highest rate of loss. From settings 5 to 20, posterior rate of volume change was gradually reduced, though only slightly. Anterior rates of limb fluid volume loss were large for vacuum settings SB, 5, and 12 (-14.7 %/h, 17.1 %/h, and -59.3 %/h, respectively), but minimal for the other settings.

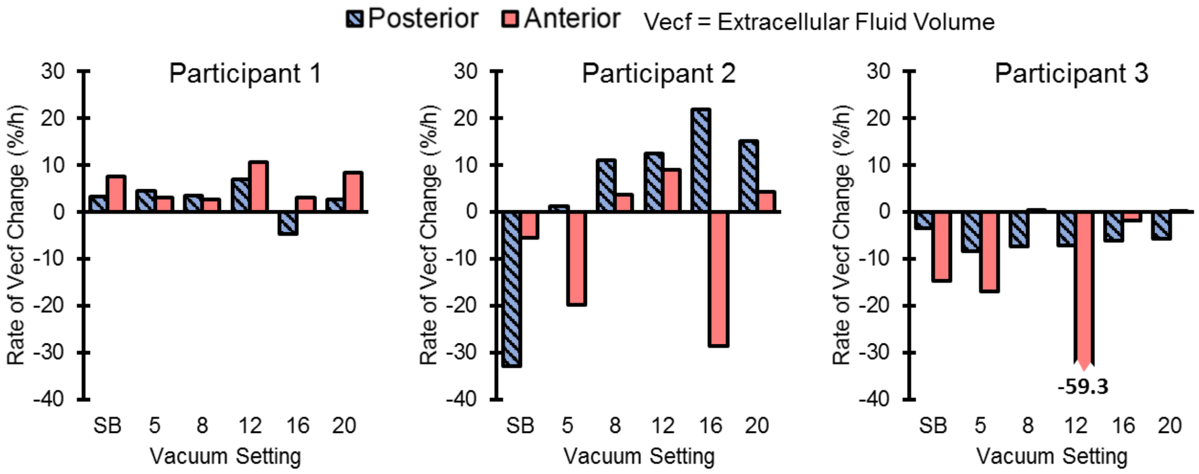

Figure 5.9. Rate of extracellular limb fluid volume (Vecf) change. Measured during the test walking segment at each vacuum pressure setting for posterior and anterior limb regions.

Socket comfort scores did not increase by more than 3 for any vacuum pressure setting compared to the control walks and never decreased comfort relative to the control walks. The change in SCS from the control walk to the test walk at each setting only increased by one for a single setting (8, mean -5.3 inHg) for Participant 1. RSC was reported as “little better” for vacuum setting 5, though this did not increase the participant’s SCS. For Participant 2, SCS increased for vacuum settings of 8 or greater with RSC as “better” for each. Settings SB and 5 resulted in no change compared to the control walk. SCS changed the most for vacuum settings of 12 and 16. For Participant 3, SCS increased for each test walk vacuum setting, even for the SB condition in which the test setting was unchanged from the control setting. Along with the SB, vacuum settings 12 and 16 also increased greatest. RSC was either “little better” or “better” for each setting.

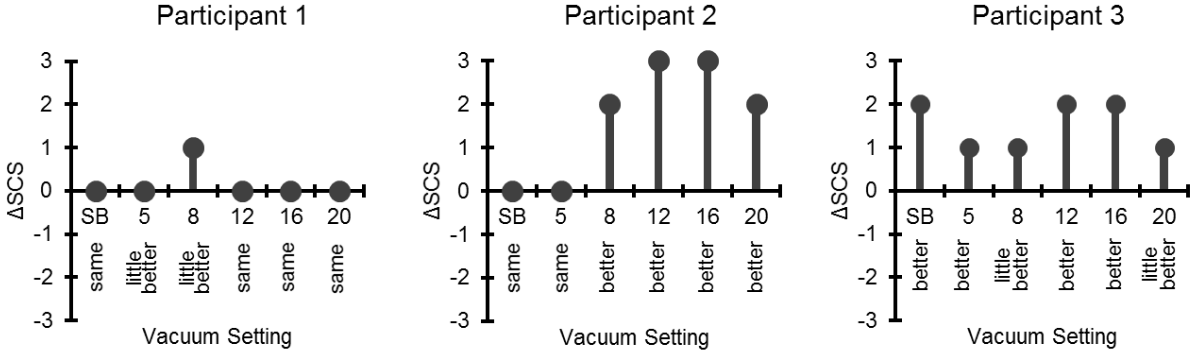

Figure 5.10. Change in socket comfort score (ΔSCS) from control to test walk. Relative socket comfort (RSC) is noted below each setting.

5.4 DISCUSSION

The purpose of this study was to investigate the response of skin perfusion, limb fluid volume, limb movement, and socket comfort to changes in vacuum pressure in transtibial users of prosthetic EV systems. Better understanding the connection between the mechanical and physiological effects due to changes in vacuum pressure may aid clinical implementation of EV technology. Additionally, prosthetists would be better informed when making changes to socket vacuum pressure settings.

5.4.1 *OCT*

The application and removal of vacuum pressure to a localized area on the residual limb modulated skin perfusion as measured by VAD. Often the application of vacuum pressure to the skin resulted in VAD decreasing below baseline values with higher vacuum pressures resulting in lower perfusion. However, perfusion for Participant 2 drastically increased with higher vacuum pressure. In several cases, particularly after the highest vacuum application when perfusion at atmospheric pressure was below baseline, the application of vacuum increased skin perfusion. The effect of different vacuum pressures is likely dependent on the state of perfusion immediately before vacuum application. This is important because many occlusive forces occur within a prosthetic socket even during non-weight bearing activities, and tissue vacuum pressure may help to increase perfusion during these instances.

Often, non-EV images showed increased skin perfusion above baseline. This may be indicative of a reactive hyperemic response to the vacuum application. Reactive hyperemia is a physiological response of skin microvasculature resulting in an increase of blood flow following stress such as vascular occlusion [26]. Despite the elastomeric interface and relatively wide EV surface, in some cases, this contact pressure from the EV attachment may have been enough to occlude or partial occlude small vessels in the skin particularly during higher vacuum when skin is pulled further into the domed EV attachment. This may have resulted in reactive hyperemia during non-EV imaging. Reactive hyperemia has been studied in EV socket previously. Rink et al. found that use of EV over 16 weeks attenuated socket-induced reactive hyperemia [20]. Better characterization of the reactive hyperemia response to different vacuum pressures may provide insights to tissue health or potential tissue adaptations to EV.

OCT may be used to identify socket vacuum pressures that most benefit perfusion. The EV socket benchtop model of Chapter 4 demonstrated that as the liner expands to the wall of a socket during vacuum application, the liner volume change could create vacuum pressure on the underlying tissue. This tissue vacuum pressure is dependent on the liner expansion volume, thus socket fit relative to the limb. The principles behind this model may be used to relate vacuum pressures applied to the skin in this study to socket vacuum pressures based on socket fit. A socket sensing system as that used here could measure liner expansion before and after vacuum application. A simplified geometric model could then be used to estimate liner volume changes and predict potential tissue vacuum pressures.

5.4.2 *Limb Displacement, Limb Fluid Volume, User Comfort*

All three participants demonstrated a reduction in limb displacement at all sensor locations as the vacuum setting was increased. Limb displacement values measured throughout the socket during the activity protocol were consistent with past research studies involving EV [14,92,94,139] and other suspension methods [127]. Distal displacement using suction suspension in a study by Gerschutz et al. was 2.65 ± 1.21 mm [94]. Other average distal displacement values were 0.80 ± 0.40 mm, 0.21 ± 0.15 mm, and 0.05 ± 0.04 mm for vacuum settings of 8, 14, and 20 respectively. Previous studies largely focused on distal end displacement; however, displacement at the anterior midlimb and anterior inferior locations were greater than the displacement on the distal end for Participant 2 and Participant 3, suggesting angular motion of the limb during walking. Wernke et al. investigated the horizontal movement within EV sockets during ambulation and found that, depending on socket fit, horizontal motion attributed 20-50% of total limb motion. Non-vertical displacement should be an important consideration for future studies regarding limb displacement and socket fit.

Traditionally, the standard of care is to eliminate motion between the socket and residual limb [34]. However, rates of limb fluid volume change did not consistently increase positively as the socket vacuum pressure setting was increased and limb-socket displacement was reduced, though the posterior region showed limb fluid volume trends that were more consistent compared to the anterior region, potentially due to increased soft tissue content posteriorly. Additionally, user comfort did not directly correspond to decreased limb movement or more positive rates of limb fluid volume change. Thus eliminating all motion with higher vacuum settings was not always advantageous for limb fluid volume or comfort. Participant 2 and Participant 3 reported larger changes in comfort at the higher end of the vacuum settings, loosely corresponding to fluid volume and limb displacement results. User comfort results suggested limited sensitivity to changes in vacuum pressure as ΔSCS did not vary by more than 1 between settings for Participant 1 and Participant 3. The clinical significance of the recorded limb-socket displacements relative to limb physiology is unclear. Though limb movement was reduced 81-93% by the vacuum setting of 12, rates of limb fluid volume change continued to vary at higher settings. This may indicate the sensitive nature of limb fluid volume or that additional factors beyond limb-socket movement are influence rates of limb fluid volume change. Since the inductive distance sensors only measured displacement between the liner and the socket, it is unclear if displacement occurred between the liner and residual limb, particularly at higher vacuum pressures when the liner was secured to the wall of the socket. Limb movement relative to the liner may also have physiological implications to influence comfort and limb fluid volume.

Tissue composition likely played an important role in regional limb displacement differences. For Participant 2 and Participant 3, the largest displacements occurred in the anterior region. Conversely, the posterior displacement in all participants was minimal. The posterior region of the limb contains more muscle tissue, while the anterior region is dominated by the tibia. During vacuum application, the soft tissue of the posterior residual limb offers less resistance to the vacuum pressure and is more readily secured to the wall of the socket. The anterior region of the limb offers more resistance to vacuum pressure, and as the bone moves in an angular motion during ambulation, posterior soft tissue is compressed, and the liner displaces from the wall of the socket at the anterior midlimb and anterior inferior locations. Participant 1 had the largest limb by midlimb circumference and this increased soft tissue may lessened the effect of bone movement on anterior limb displacement. Participant 1 also wore two gel socks between the liner and socket suggesting a poorer socket fit which may have resulted in increased distal end displacement. These socks may have also influenced perception as SCS changed minimally for Participant 1. Interestingly, Participant 1's only increases in SCS came near his regular EV set point.

Walking had been shown as a time of fluid volume recovery in previous studies [123]. Considering both fluid volume channels, maximum recovery for Participant 1 occurred at vacuum setting 12. For Participant 2, while posterior rates of fluid volume change increased positively between SB and 16 vacuum settings, anterior rate of volume change was lowest for setting 16. Vacuum setting of 20 resulted in the lowest combined rates of limb fluid volume loss for Participant 3. Though not studied here, bone displacement may play a role in the connection between mechanical and physiological effects of EV. Darter et al. studied axial bone-socket displacement in EV sockets demonstrating a 1.3 ± 0.2 cm bone-socket displacement between unloaded and full body weight conditions [93]. As the liner and soft tissue is secured to the wall of the socket during times of unloading, bone-socket displacement still occurs, potentially expanding the volume available for fluid recovery within the soft tissue.

Optimal socket vacuum pressure should balance the physiological and mechanical effects of EV. The current study evaluated short-term effects of different socket vacuum pressures, but these effects could change later in a day or over several weeks. Additionally, as socket fit degrades overtime, socket vacuum pressure needs may change. As results from Participant 1 suggest, reduced socket fit may result in larger distal displacement relative to other locations. As the liner needs to expand further to reach the socket wall in a poorly fitting socket, residual limb tissue may experience increased tissue vacuum pressure that may lead to blistering. Being able to not only adjust socket vacuum pressure, but also socket size, such as with adjustable sockets, may further the clinical utility of EV systems. Future investigations should monitor limb displacement over longer periods with different socket vacuum pressures and socket fits to determine if a control system would be beneficial to adapt to mechanical and physiological needs of individuals.

5.4.3 *Limitations*

The OCT EV imaging in this study focused on localized applications of vacuum pressure; however, these may not reflect the socket environment when vacuum pressure is applied across the whole limb. Additionally, the limb was not loaded during imaging, as in a prosthetic socket, though pressure from the edges of the EV attachment may have partial simulated a loading condition. We assessed only changes in skin perfusion, but visualization of extracellular fluid such as lymph could also be of interest and has been recently demonstrated with OCT systems [147].

During the activity protocol with the instrumented EV socket, limb fluid volume rates of change were recorded over only a short 2-minute walk segment which may have led to inconsistent results. Limb fluid volume difference between EV and suction suspension were more evident after multiple hours of activity in a previous study (Chapter 3). Additionally, limb fluid volume has shown a dependency on previous activity that may have influenced results. Walking was conducted on a treadmill which may have affected perception of user comfort and the transfer of ground reaction forces. While care was taken to create an instrumented prosthesis equivalent to participant’s regular prosthesis, the use of different components and liner may have had an effect on user perception. In addition to a longer protocol, evaluating the effects of various vacuum pressures during standing and sitting would be important.

5.5 CONCLUSION

Tissue vacuum pressure generally decreased skin perfusion but did occasionally increase perfusion following times of lower perfusion. While the highest vacuum setting did result in the least limb displacement, a large portion of the total range of movement was eliminated at lower vacuum settings. Limb fluid volume rates of change did not consistently increase with socket vacuum pressure setting, but generally increased positively at higher vacuum settings. Changes in vacuum setting did not result in large changes to socket comfort among any of the participants. Considering individual responses to each of these variables may lead to optimal vacuum pressure that balances mechanical and physiological effects of EV.

5.6 ACKNOWLEDGEMENTS

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Chapter 6. CONCLUSION

6.1 SUMMARY

Evidence-based research regarding elevated vacuum (EV) has become an important issue in the prosthetics field. This is particularly true given that current clinical recommendations for its use with regards to residual limb volume management, suspension, and limb health are limited. The continued clinical use of EV systems emphasizes the importance of understanding the mechanical and physiological effects of the technology. The development of guidelines and tools through research will allow practitioners to more effectively apply this technology clinically. The research presented in this dissertation provides a positive step towards developing evidence-based recommendations to the clinical use of EV to maximize mechanical and physiological benefits for prosthesis users.

Chapter 3 of this dissertation evaluated the effectiveness of EV to manage limb fluid volume in a clinical study. Many previous studies investigating limb volume change with EV have been limited by out-of-socket volume measurements and short, single-activity protocols. Bioimpedance analysis was used to measure in-socket residual limb fluid volume change in 12 current EV users across two test sessions, the first while using EV and the second using suction suspension (SS). Each test session consisted of a 5.5-hour standardized protocol of three cycles separated by periods of seated rests. The cycles included intervals of low activity (mostly sitting) and high activity (walking and standing only). Overall rates of fluid volume change were reduced in at least one limb region in 11 of the 12 participants with EV. Additionally, the median posterior rate of limb fluid volume change was significantly less during the final cycle of the activity protocol using EV compared to SS. Residual limb fluid volume management improved with EV after an accumulation of daily activity, suggesting that high-activity prosthesis users may benefit most from EV use. Individual effectiveness of EV to manage limb fluid volume change varied across participants and activities suggesting that the technology could be more effective if optimized to the individual based on socket fit or activity type.

A benchtop model of an EV socket was created in Chapter 4 to study the mechanics of EV components to influence residual limb physiology. The effects of EV socket variables such as liner properties, socket fit, and socket vacuum pressure on liner expansion and the creation of tissue vacuum pressure on the residual limb were investigated. A domed carbon fiber layup was used to represent an EV socket. Dome volume was varied to represent changes to socket fit. Eight liner samples of various fabric and elastomer composition were placed between the socket and a raised nylon base. As vacuum pressure was applied to the domed region, liner displacement into the dome and the pressure change underneath the liner were measured. Tissue vacuum pressure increased linearly with socket vacuum pressure and then remained constant once liner displacement ceased. Regardless of liner type and socket vacuum pressure, liner displacement volume was the determining factor for tissue vacuum pressure, stressing the importance of socket fit in determining the physiological effect of EV. Additionally, the physiological impact of EV appeared to be insensitive to liner selection. Predicted tissue vacuum pressure values based on liner volume displacement and Boyle’s Law matched well with experimental results demonstrating that the model may be used to identify tissue vacuum pressure based on individual patient characteristics, prosthetic components, and socket fit. Understanding the resulting physiological effects of EV on the residual limb could help practitioners avoid blister formation and improve benefits of EV.

Chapter 5 extended from previous studies to evaluate the sensitivity of limb movement, limb fluid volume, comfort, and skin perfusion to changes in vacuum pressure for three individuals. Optical coherence tomography (OCT) imaging evaluated the effect of vacuum on skin perfusion, finding a potential dependency on the state of perfusion prior to vacuum application. Instrumented EV sockets were created based on participant's typical electronic EV socket shape. Inductive distance sensors were embedded into the walls of the socket at select locations to measure limb movement relative to the socket. Each participant conducted an activity protocol while limb movement, limb fluid volume, and self-reported comfort were measured at various socket vacuum pressure settings. Increased socket vacuum pressure resulted in reduced limb-socket displacement for each participant; however, most limb movement was eliminated at lower vacuum pressure settings. Relative limb-socket displacement by sensor location varied for each participant suggesting unique differences perhaps related to socket fit or residual limb tissue content. The rate of limb fluid volume changes and the changes to socket comfort did not consistently increase with socket vacuum pressure, suggesting a more complex relationship potentially unique to each individual. Practitioners may use individual responses such as these to optimize socket vacuum pressure settings to balance mechanical and physiological effects of EV for improved clinical outcomes.

6.2 FUTURE DIRECTIONS

The research presented in this dissertation sought to better understand the physiological and mechanical effects of EV in people with transtibial amputation. This work progressed towards developing guidelines for EV use in order to optimize EV systems for individuals based on mechanical and physiological effects. Some of the potential guidelines identified in this dissertation relate to user activity, socket sizing and fit, liner selection, and socket vacuum pressure. Specific studies should be designed to further evaluate the validity of these guidelines and expand from these studies to larger, more diverse populations. Recommendations should continue to be refined as additional evidence becomes available. Furthermore, future research efforts should continue to evaluate if scientifically-derived optimizations improve user comfort, functional activity, and overall quality of life, among other clinical outcomes.

This research demonstrated the use of various advanced tools including a benchtop model, OCT imaging, as well as socket and physiological sensors that may be integrated to clinical care in the future; however, additional development of these technologies will be required. A practitioner could use data from these sensors such as limb-socket displacement, socket vacuum pressure, and limb fluid volume to determine socket vacuum pressure settings instead of relying on patient-reported comfort. Clinical integration of these measures will require substantial testing and commercial device development; however, improving the clinical tools available to prosthetists will advance evidence-based practices. The benchtop model presented in Chapter 4 may also serve as a platform for future development. Advancing the model to better represent the radial expansion of liners within the prosthetic socket would be a significant improvement over the current iteration. Concepts from the model may be built into a computational tool that could then be incorporated into clinical software to help practitioners evaluate socket size and shape for use in EV systems. Future research could also explore the variations in skin health and how they are impacted by liner expansion demonstrated by the benchtop model. This research suggested that individuals respond differently to EV parameters. Further identifying individual characteristics such as activity level, limb shape and size, and user health that are aligned with EV success will allow more efficient implementation of EV. The creation of predictive tools that allow practitioners to know the effects of EV on an individual before building and testing the socket could save time and money as well as increase patient safety by preventing improper uses that may cause blistering. These technologies could ultimately lead to better-informed clinical decision making regarding the use of EV.

Researchers and device developers may also build from this work to design adaptive EV technology. This may involve a control system as mentioned in Chapter 4 that can adjust socket size and vacuum pressure based on physiological and mechanical needs of specific individuals. These needs may vary depending on user activity (i.e. sitting, standing, walking, or running) or as socket fit changes over time. This research indicated that changes to relative limb-socket displacement by sensor location may suggest different levels of socket fit. Further investigation to the manifestation of poor fit in EV sockets would be needed to inform a control system design. The effects of changing the socket vacuum pressure and socket size dynamically may have unintended consequences and should be thoroughly evaluated. Additionally, research on EV effects on skin health should continue. The development of in-socket tools to evaluate skin health or indicate areas of skin stress prior to the formation of blisters would improve EV implementation, particularly for insensate populations. This dissertation evaluated changes to the socket environment for current EV users and compared the effects of EV against suction suspension. Research should also focus on the initial introduction of EV from alternative suspensions. The responses for new EV users may be different from existing users, and this response may change over time as the body may adapt to EV. This prospect further stresses the importance of sensing modalities to monitor long-term physiological and mechanical effects of EV and automatically adjust to avoid harmful situations while maximizing benefits.

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PUBLICATIONS
1. Brzostowski JT, Larsen BG, **Youngblood RT**, Ciol MA, Hafner BJ, Gurrey CJ, et al. Adjustable sockets may improve residual limb fluid volume retention in transtibial prosthesis users. Prosthet Orthot Int 2019;43:250–6.

2. **Youngblood RT**, Hafner BJ, Allyn KJ, Cagle JC, Hinrichs P, Redd C, et al. Effects of activity intensity, time, and intermittent doffing on daily limb fluid volume change in people with transtibial amputation. Prosthet Orthot Int 2019;43:28–38.

3. Sanders JE, **Youngblood RT**, Hafner BJ, Ciol MA, Allyn KJ, Gardner D, et al. Residual limb fluid volume change and volume accommodation: Relationships to activity and self-report outcomes in people with trans-tibial amputation. Prosthet Orthot Int 2018;42:415–27.

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