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Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets

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Abstract—Interface pressures were measured during ambulation with a normal total-surface weight-bearing suction socket and a vacuum-assisted socket. The vacuum-assisted socket has been shown to eliminate daily volume loss. Urethane liners were instrumented with five force-sensing resistors to measure positive pressures and one air pressure sensor at the distal end of the liner to document negative pressures. Nine unilateral transtibial amputees participated in the study. The vacuum-assisted socket created significantly lower positive-pressure impulse (42.8, 39.6 kPa•s) and peak pressures (83.5, 80.0 kPa) during the stance phase. The pressure impulse (–10.5, –13.3 kPa•s), average (–21.2, –26.5 kPa), and peak (–28.5, –36.3 kPa) negative pressures during swing phase were significantly greater in magnitude with the vacuum-assisted socket. We believe that lower positive pressures seen during stance using the vacuum-assisted socket reduces the fluid forced out and greater negative pressures seen during swing increases the amount of fluid drawn into the limb, thereby preventing volume loss.

Key words: *amputee, interface pressure, limb volume, socket, vacuum.*

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INTRODUCTION

The successful fitting of a prosthetic socket results in the effective transfer of forces from the socket to the residual limb such that the amputee can maintain daily activities without damaging tissue or experiencing pain. Achieving the proper fit is challenging because of the inherent difficulties of requiring previously non-weight-bearing tissues to accept high pressures during ambulation. The task is further complicated by the long-term and short-term changes in residual limb volume that can affect the fit of the socket [1–5]. Loss of limb volume can cause bony prominences to accept more of the load during weight bearing and allow greater pistoning of the socket during ambulation. Misfit sockets can cause pain, skin irritation, or skin ulcers, which may result in the amputee being unable to use the prosthesis until the skin has healed [6–9]. When questioned, lower-limb amputees rated socket fit as the most important issue they face in using a prosthesis [10].

To maintain proper socket fit and to compensate for the daily limb-volume loss, amputees add socks or other materials throughout the day. Board documented that using a vacuum-assisted total-surface weight-bearing socket on transtibial amputees could eliminate daily volume loss [11]. Thirty minutes of walking resulted in an average gain of 3.7 percent (–1.6 to 8.0 percent) of limb volume in the vacuum-assisted socket as compared to losing 6.5 percent (–1.7 to –11.3 percent) of limb volume when walking in the normal total-surface weight-bearing socket without vacuum-assist. Maintaining limb volume preserves the fit of the socket, reducing pain and skin irritation. External pressures applied to the skin have been shown to affect the volume of the limb. Positive pressures decrease the volume of the limb while negative pressures increase limb volume [12–17]. Different responses in limb volume to the type of socket implied that the pressure distribution between the two socket conditions might be different [11]. The current study hypothesized that the vacuum-assisted socket reduces the positive pressures during stance and increases the magnitude of the negative pressures on the limb during swing phase as compared to the normal total-surface weight-bearing socket.

METHODS

Interface pressures between the skin and liner were measured during ambulation and then compared between the normal and vacuum-assisted conditions. Each liner was instrumented with five force-sensing resistors (Interlink Electronics, Camarillo, California), capable of measuring positive pressures through contact. One air pressure sensor (Endevco Corptation, San Juan Capistrano, California) measured negative pressures at the distal end of the limb with the use of a full bridge configuration.

Contact sensors, 0.6 mm thick and 18 mm in diameter, were calibrated by pressure being applied with an inflatable air bladder while the sensor was placed on a flat piece of urethane of Shore OO 45 durometer. Pressures ranging from 0 kPa to 150 kPa were randomly applied twice in increments of 10 kPa while the voltage outputs were recorded for each sensor. A piecewise regression was fitted to the data in which an exponential equation was applied from 0 kPa to 30 kPa, and an equation of the fourth power was fitted from 30 kPa to 150 kPa. The curvilinear output resulted in decreasing precision with increasing pressure. From 0 kPa to 80 kPa, the average residual was ±0.95 kPa (0.40 to 2.63) and ±2.45 kPa (1.0 to 4.07) from 80 kPa to 150 kPa.

A sealed chamber attached to a syringe was used for the calibration of the air pressure sensor. The syringe was drawn so pressures were created in 10 kPa increments from 0 kPa to –80 kPa. A linear regression equation was fitted to the output voltages with an average residual of ±0.12 kPa (0.04 to 0.26).

Instrumentation of each liner required that the contact sensors be attached to the liner mold before pouring to ensure they would be flush with the inner liner wall. Tubing containing the wires was run within the liner wall from the sensor out through the proximal edge of the liner. Thus, an air vent was maintained for proper sensor function and subjects would not be caused discomfort from wires against the skin. Because of a large variation in residual limb size and shape, a general pentagon pattern was used for sensor placement so that the sensors would be on areas of soft tissue. Soft tissue, as opposed to thin tissue covering bony prominences, was studied, since pressure changes in these areas were expected to have the greatest impact on limb volume change. The first contact sensor was centered on the gastrocnemius below the brim of the socket and was referred to as the "proximal sensor." One contact sensor was placed on each side of the proximal sensor at the distal end of the liner, avoiding the acute curvature at the distal end. These were labeled "distal medial" and "distal lateral," accordingly. The final two contact sensors were placed on the medial and lateral aspects of the liner at the vertical midpoint between the proximal and distal contact sensors and identified as "mid medial" and "mid lateral." The sensors spanned from the lateral aspect of the residual limb along the posterior of the limb to the medial aspect. No sensors were placed on the anterior aspect of the residual limb because of the bony prominences. The general pattern and relative size of the contact sensors are shown in **Figure 1**.

A 1 cm^3 cavity was created at the distal end of the liner in which the air pressure sensor was placed during testing. Any extra space in the cavity was filled with cloth and held in place with a thin piece of urethane tape. The thin (0.6 mm), flat sensor wire was run along the limb and out the proximal liner. Vaseline was placed around the wire upon its exit from the liner so air would not be drawn in during ambulation.

Each subject was provided a custom instrumented nonpin urethane liner of Shore OO 45 durometer and a total-surface weight-bearing check socket manufactured by TEC Interface Systems, Inc. They were undersized by 10 and 4 percent, respectively. A 0.3 mm thick nylon sheath was worn over the liner to allow it to be slipped into the socket. A urethane suspension sleeve was worn over the proximal half of the socket and distal three-fourths of the thigh. The sleeve not only suspended the leg but also enclosed the airspace created by the nylon

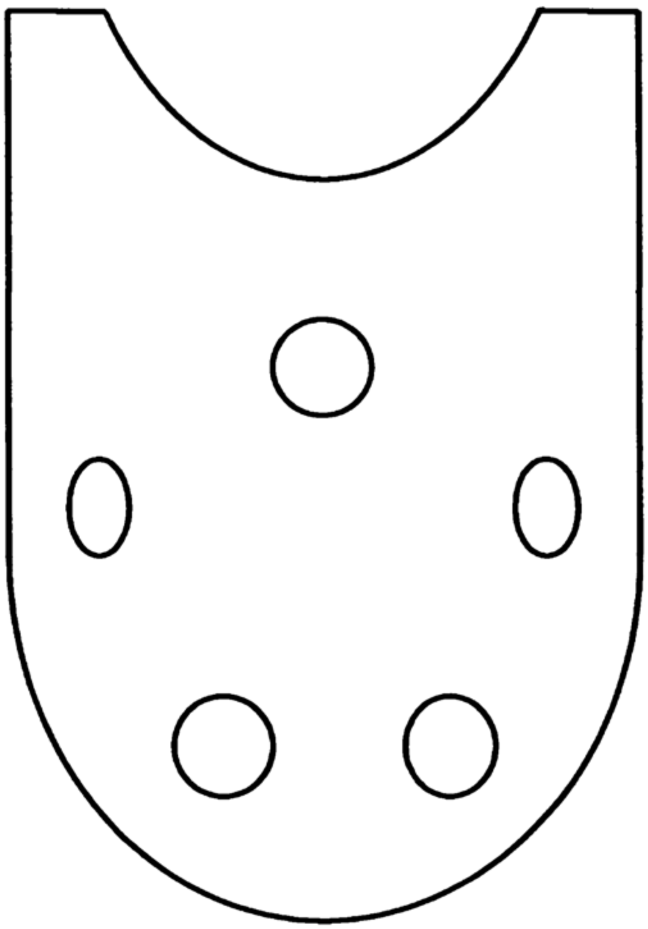

Figure 1.
Illustration of sensor placement as viewed from posterior of residual limb.

sheath by sealing against the socket and proximal border of the liner. Under normal conditions, the exit port at the distal end of the socket would have a one-way check valve to release air. The vacuum-assisted condition was created by drawing –69 kPa (–20 inHg) of pressure through the one-way check valve with a vacuum pump. The limb was not exposed to this applied negative pressure, since the airspace was contained between the liner and the socket by the suspension sleeve. The prosthetic system was completed with a pylon and SACH (solid ankle cushioned heel) foot for each subject.

Pressure data were collected with the use of a 12-bit A/D (analog-to-digital) board (Keithley Instruments, Cleveland, Ohio) at 100 Hz for 8 s per trial. A computer was used to record the data.

Nine unilateral, transtibial amputees who regularly used a urethane liner and total-surface weight-bearing socket completed the study. Mean age was 46 (33 yr to 65 yr), mean limb maturity was 18 yr (6 yr to 32 yr) and none of the subjects had vascular complications. The Institutional Review Board at St. Cloud State University approved all testing procedures. Upon arrival on the testing day, the prosthetic leg was dynamically aligned with standard alignment procedures. Each subject randomly began with either the normal (N) or vacuum-assisted (V) condition and alternated between the conditions throughout the session until at least three trials of each condition had been completed, N-V-N-V-N-V or V-N-V-N-V-N. Each trial consisted of the subject walking over the ground for 20 m next to a string that was controlled at a speed of 4 km/h. Data for five steps were collected once the subject had reached a steady state walk to avoid times of acceleration or deceleration. An assistant walked behind the subject to hold the sensor wires while the researcher walked alongside with the computer.

We identified toe-off and heel strike as the rapid fall and rise, respectively, in pressure of the distal pressure sensor. Its output, as opposed to the five contact sensors, was more sensitive to the vertical movement of the limb within the liner that occurred at these critical events. The greatest negative and positive slopes were calculated for each trial. When the slope reached a value that was half of the maximum negative or positive slope of that trial, we identified that moment to be toe-off or heel strike.

A pressure impulse value for stance and swing phases was calculated by one finding the area under the respective positive and negative pressure curves. An overall average pressure during stance was calculated for each of the five contact sensors, and one overall average pressure for the swing phase was calculated with the air pressure sensor. Peak positive and negative pressures were identified for each step with a 0.1 s average for each sensor.

The following leg geometry measures were made on each subject. Total-surface area, distal surface area, length, and taper of the residual limb were estimated from dimensional data. A truncated cone model was used for the estimation of the total-surface area, which was measured from mid-patellar tendon to the distal end of the limb. Distal surface area was of the spherical end of the limb. Limb length was from mid-patellar tendon to the distal end of the limb. Limb taper was described by the measurement of the angle created against a vertical line by the lateral tibial condyle and the lateral aspect of

Journal of Rehabilitation Research and Development Vol. 39, No. 6, 2002

the distal end of the stump. Prosthetic leg weight was obtained for each subject.

Three two-factor repeated measures of analysis of variances (ANOVAs) (a = 0.05) were used to determine if there was a difference between the socket conditions in pressure impulse values, average pressures, and 0.1 s peak pressures for the five contact sensors during stance phase. Three single-factor ANOVAs (a = 0.05) were run for one to determine if the air pressure sensor had a difference in pressure impulse value, average pressure, and 0.1 s peak pressure between the two socket conditions during swing phase. Relationships between pressures and leg geometry measures, such as angle of taper, limb length, and surface area, were determined with the use of a Pearson correlation coefficient.

RESULTS

No significant differences in the positive and negative pressures were found between the five steps within the trials or between the three trials of the same socket condition. A sample pressure output of one step is provided in **Figure 2**. The pressure impulse values and peak pressures calculated during stance were significantly lower (p = 0.000, p = 0.003) with the vacuum-assisted socket. The pressure impulse data are provided in **Table 1** while peak pressures are listed in **Table 2**.

The impulse, average, and peak pressure values calculated for the swing phase were significantly greater in magnitude with the vacuum-assisted socket (p = 0.000, p = 0.000, p = 0.001). The data are listed in **Table 3**.

Various residual limb measurements for each subject are listed in **Table 4**. Pearson coefficients of determination of 0.43, 0.11, 0.12, and 0.21 were calculated for the correlation of the average negative pressure impulse with angle of taper, length, total-surface area, and distal surface area, respectively.

DISCUSSION

Current results indicate that the pressures applied to the residual limb are altered when a high vacuum is applied to the exit port of a normal total-surface weight-bearing socket. A link established between external pressure and limb volume might help explain the loss of limb volume while amputees wore the normal total-surface weight-bearing socket and volume gain or maintenance with the vacuum-assisted socket previously documented

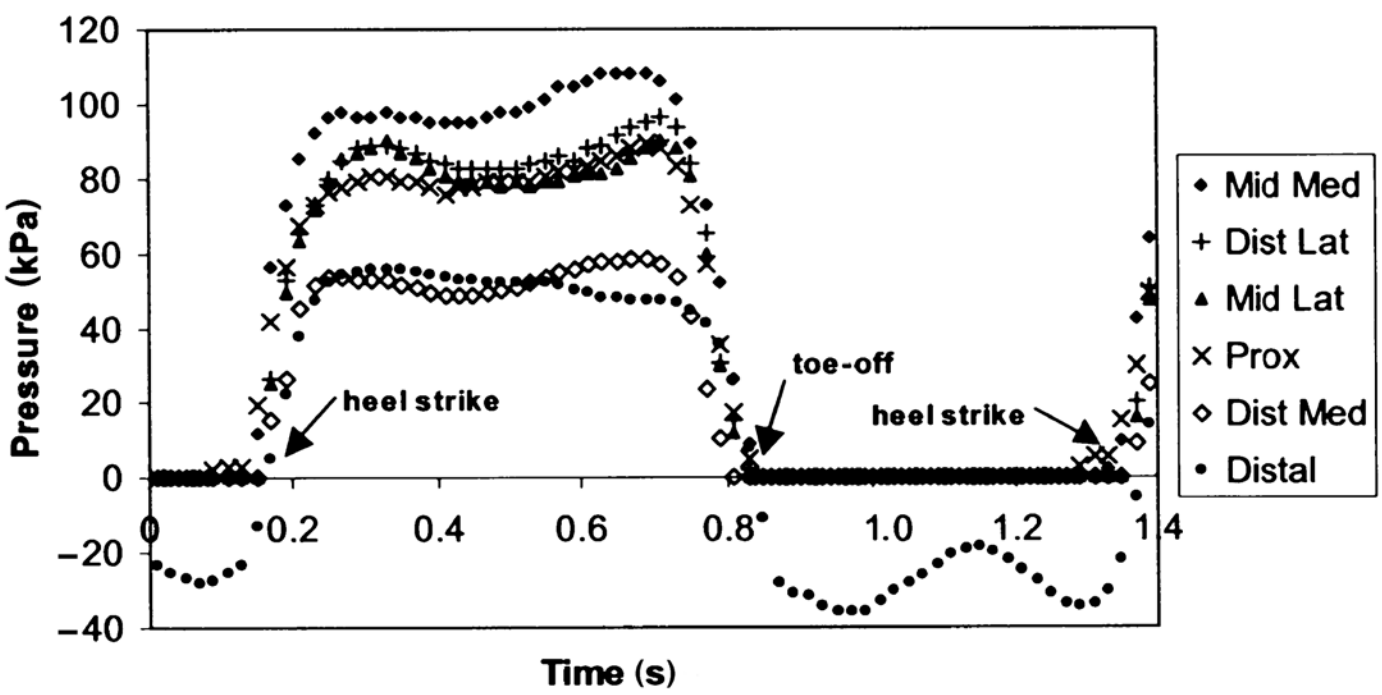

Figure 2.
Sample pressure output of five contact sensors and one air pressure sensor during one step.

Table 1.
Pressure impulse values (kPa•s) for five contact sensors during stance phase.

Subject	Normal P	Normal MM	Normal DM	Normal ML	Normal DL	Vacuum-Assisted P	Vacuum-Assisted MM	Vacuum-Assisted DM	Vacuum-Assisted ML	Vacuum-Assisted DL
1	33.3	38.7	39.8	43.5	55.9	31.6	36.3	38.6	42.6	53.8
2	73.1	38.3	14.8	68.9	37.7	70.0	36.4	17.0	62.3	31.4
3	53.8	54.5	51.0	55.8	60.9	54.4	58.3	50.5	51.8	59.4
4	25.1	21.8	51.2	48.9	52.1	20.5	19.7	46.2	43.7	46.5
5	35.1	37.8	44.1	37.1	37.2	31.0	32.9	38.3	33.7	31.0
6	60.3	40.3	25.1	45.1	34.3	55.6	34.4	24.3	40.0	31.7
7	38.5	45.9	35.7	48.7	33.1	38.5	40.5	33.0	42.6	32.8
8	47.2	59.2	28.5	50.4	49.5	42.0	54.5	26.2	42.8	44.3
9	19.6	39.5	34.3	37.1	41.7	20.7	33.8	32.5	35.7	38.0
Avg	42.9	41.8	36.1	48.4	44.7	40.5*	38.5*	34.1*	43.9*	41.0*
Overall Avg	—	—	42.8	—	—	—	—	39.6*	—	—

*Significantly ($p < 0.05$) different from normal.
P = proximal, MM = mid medial, DM = distal medial, ML = mid lateral, DL = distal lateral

Table 2.
Peak pressure (kPa) for five contact sensors during stance phase.

Subject	Normal P	Normal MM	Normal DM	Normal ML	Normal DL	Vacuum-Assisted P	Vacuum-Assisted MM	Vacuum-Assisted DM	Vacuum-Assisted ML	Vacuum-Assisted DL
1	62.4	70.8	74.8	83.8	105.8	61.7	68.5	74.1	84.2	104.1
2	150.3	79.5	37.5	155.2	115.6	154.8	83.8	45.2	145.8	89.7
3	91.6	92.0	85.2	93.9	104.4	93.5	99.4	86.5	88.0	102.2
4	46.1	49.8	94.6	94.4	119.0	40.4	46.1	90.4	92.0	107.9
5	59.3	63.4	74.8	62.4	64.2	55.0	58.9	69.0	59.5	57.3
6	126.0	85.6	57.1	95.2	75.0	116.7	72.0	55.8	85.4	71.2
7	80.1	93.3	72.7	99.7	65.1	85.6	85.6	68.7	92.4	66.2
8	85.3	109.9	55.4	96.8	85.9	80.1	103.4	52.9	85.0	85.9
9	41.8	78.9	66.5	74.7	83.6	45.4	72.4	65.6	73.7	78.8
Avg	82.6	80.4	68.7	95.1	91.0	81.5	76.7	67.6	89.5*	84.8*
Overall Avg	—	—	83.5	—	—	—	—	80.0*	—	—

*Significantly ($p < 0.05$) different from normal.
P = proximal, MM = mid medial, DM = distal medial, ML = mid lateral, DL = distal lateral

by Board [11]. Positive pressures have been shown to reduce limb volume while negative pressures increase the volume of the limb [12–17]. These previous studies used lower, sustained pressures as compared to the frequent, alternating pressures that amputees are exposed to during walking, but they lend insight to the influence of external pressures on limb volume.

The repeated application of positive and negative pressures during ambulation certainly must influence limb volume. Peak positive pressures obtained in the current results were less than 150 kPa, which compare well to those pressures previously reported in the literature [18–21]. Peak negative pressure values of –7 kPa to –31 kPa reported by Chino are lower in magnitude than the range of peak pressures –17 kPa to –54 kPa found in the current study [18]. Faster walking speeds were used in the current study, which could have caused a greater draw at the distal end of the limb. A greater draw would also be expected because of the liner being anchored to the socket by the vacuum.

Ambulation with a prosthetic socket exposes the limb to a cyclic application of positive and negative pressures [18–26]. Positive pressures during stance phase are thought to drive fluid out of the limb while the negative pressures during swing phase are thought to draw fluid

Table 3.
Impulse values (kPa•s) and average and peak pressure values (kPa) attained during swing phase.

	Normal			Vacuum-Assisted		
Subject	Impulse	Average	Peak	Impulse	Average	Peak
1	−8.4	−14.6	−28.5	−9.9	−17.9	−36.3
2	−11.1	−24.0	−35.2	−13.3	−27.8	−40.4
3	−8.3	−15.0	−22.3	−9.5	−17.1	−30.9
4	−11.8	−22.9	−16.8	−16.2	−31.4	−24.5
5	−15.1	−31.3	−23.7	−18.7	−34.9	−30.8
6	−8.8	−20.0	−26.3	−11.6	−26.8	−40.8
7	−6.7	−13.4	−19.6	−9.6	−20.0	−23.3
8	−13.4	−26.6	−36.5	−17.3	−33.1	−48.0
9	−10.9	−23.5	−32.4	−14.0	−29.8	−54.3
Avg	−10.5	−21.2	−28.5	−13.3*	−26.5*	−36.3*

*Significantly ($p < 0.01$) different from normal.

Table 4.
Geometric measurements of residual limbs including angle of taper of residual with vertical, length, and estimated surface areas.

Subject	Taper (°)	Length	Total Surface Area (cm^2)	Distal Surface Area (cm^2)
1	7.0	20.0	634	31
2	15.0	8.0	391	32
3	5.5	16.0	743	62
4	14.0	13.0	510	26
5	9.0	12.0	630	50
6	8.5	11.5	619	70
7	7.0	11.5	668	80
8	17.0	13.0	622	44
9	11.5	12.0	542	42
r^{2*}	0.43	0.11	0.12	0.21

*r^2 is Pearson coefficient of determination of average negative impulse with angle of limb taper, length, total surface area, and distal surface area.

into the limb. The vacuum-assisted socket has shifted the balance of this fluid movement from one of net loss to one of net gain [11]. Pressures measured with the five contact sensors during the stance phase showed pressure impulse values decreased by an average of 7 percent with the vacuum-assisted socket. This small reduction likely is due to the difference in time and pressure components of the pressure impulse value. Seven of the nine subjects had reduced stance phase durations when wearing the vacuum-assisted socket. Greater than 80 percent of the sensor sites showed lower peak and average pressures for the vacuum-assisted socket as compared to the normal socket. The differences in positive pressures might be explained by the reduced pistoning of the limb in the vacuum-assisted socket previously documented by Board [11]. Perhaps this decrease in positive pressure impulse reduces the amount of fluid driven out of the limb.

Negative pressure impulse values created by the vacuum-assisted socket were found to be greater in magnitude by an average of 27 percent. We believe that the negative pressure is most accountable for the difference previously seen in limb volume changes with the vacuum-assisted socket [11]. Not only is the percent increase greater in the negative pressure impulse, but most likely it also has a greater effect. Mellander and Albert found that negative pressure has a larger influence on fluid movement than positive pressure [27]. They noted that a compressive pressure seven times that of the negative pressure was needed to create equal fluid absorption and filtration rates. The net result of the vacuum-assisted socket is a reduced drive of the fluid out of the limb and an increased draw of fluid into the limb, which may explain the previously reported difference in limb volume changes created by the two sockets [11].

One must analyze whether changing the pressures applied to the limb with the vacuum-assisted socket could affect the health of the tissue. Positive pressure has been shown to cause skin irritation and breakdown [28,29], so any reduction in the positive pressures during stance would seem to be beneficial. Negative pressure was only measured at the distal end of the residual limb. The amount of limb surface exposed to negative pressure is not known, although we believe the negative pressure decays as one moves proximally. Increasing the negative pressure on the limb might be harmful, but previous and current work with the vacuum-assisted socket has shown no redness or irritation of the distal tissues.

All subjects who participated in the study had a greater magnitude of negative pressure in the swing phase when wearing the vacuum-assisted socket. Eight of the current subjects participated in a previous volume study, and all showed the maintenance or gain in volume with the vacuum-assisted socket and loss in the normal condition [11]. Although the relative negative pressures were greater in magnitude with the vacuum-assisted socket, the absolute negative pressures were quite variable between subjects. These results imply that one subject loses limb volume at a pressure impulse value of –15 kPa•s in the normal condition while another subject gains at –15 kPa•s in the vacuum-assisted condition. No physiological threshold value was evident, but subjects experienced an average shift of 2.8 kPa•s (1.1 to 3.9) in the negative direction with the vacuum-assisted socket. Each subject may have adjusted to the pressures that are normally exerted on the limb, and the vacuum-assisted socket may have moved the pressures out of the normal range, enabling maintenance of limb volume.

An attempt was made to find factors that would help explain the variation in negative pressures between subjects. Pressure impulse values during the swing phase did not correlate well with the residual limb length, total-surface area of the residual limb, distal surface area of the limb, or weight of the prosthetic leg. A nearly significant correlation (p = 0.055) was found between the average negative pressure impulses and angles of limb taper. Those with the greatest taper had the greatest negative pressure impulse values during swing phase. Limbs with a larger angle of taper tended to be more conical as compared to limbs with a smaller angle that were cylindrical. We theorize that the conical shape allowed more vertical displacement of the liner relative to the limb during the swing phase, creating a larger negative pressure impulse. Gait was not analyzed, but we imagine that differences in gait most likely contributed to the variation of negative pressures observed during the swing phase.

CONCLUSIONS

Use of the vacuum-assisted total-surface weight-bearing socket changes the positive and negative pressures exerted on the residual limb during ambulation. Pressure impulse and peak positive pressures are reduced during the stance phase, while the magnitude of the impulse, average, and peak negative pressures is increased during the swing phase.

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