

A comparison of trans-tibial amputee suction and vacuum socket conditions

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Abstract

Daily volume loss of the stump leads to a poor fit of the prosthetic socket. A method of preventing this volume loss and maintaining a good fit was developed. A vacuum (-78 kPa) was drawn on the expulsion port of a total surface-bearing suction socket to hold the liner tightly against the socket. Stump volume of 10 trans-tibial amputees was measured prior to and immediately after a 30 minute walk with normal and vacuum socket conditions. Under the normal condition, the limb lost an average of 6.5% of its volume during the walk. In contrast, with the liner held tightly by vacuum, the limb gained an average of 3.7% in volume. It is believed that the difference observed between conditions resulted from a greater negative pressure developed during the swing phase of gait with the vacuum condition. X-rays revealed that the limb and tibia pistoned 4mm and 7mm less, respectively, under the vacuum condition. The combination of reduced pistoning and maintenance of volume is thought to account for the more symmetrical gait observed with the vacuum.

Introduction

It is common knowledge among amputees and prosthetists that the stump loses volume daily, resulting in a poor fit of the socket. Despite recent advances in technology that allow prosthetists to more accurately fit liners and sockets to the limb, the chief complaint of amputees continues to be a poor socket fit

(Roberts, 1986) as volume is lost during the day. Since this daily volume loss has never been documented in the scientific literature, a pilot study on 4 trans-tibial amputees was conducted to determine whether the stump loses volume daily and to what extent. Stump volume was measured throughout an 8 hour workday. All 4 amputees lost volume when using a total surface bearing suction socket. Volume loss ranged from 4 to 10% with approximately 90% of this loss occurring during the first 2 hours of the workday. Limb volume loss was re-measured on 2 of the amputees on additional workdays with the same results.

Volume loss leads to a poor socket fit characterised by increased movement (pistoning) of the stump within the socket (Commeyan *et al.*, 1996; Commeyan *et al.*, 1997; Grevsten, 1978; Grevsten and Erikson, 1974), areas of high pressure and shear stress (Hachisuka *et al.*, 1998; Sanders *et al.*, 1992; Silver-Thorn *et al.*, 1996; Sonck *et al.*, 1970; Zhang *et al.*, 1998; Zhang *et al.*, 1996), a loss of contact and proprioception between the socket and the limb (Dingwell *et al.*, 1996; Sabolich, 1994), and even an inadvertent exiting of the limb from the socket. In contrast, a good prosthetic fit effectively transfers forces between the limb and socket while providing a comfortable environment by minimising local areas of high pressure and shear stress (Hachisuka *et al.*, 1998; Sonck *et al.*, 1970).

Daily volume loss occurs as a result of pressure and shear stresses between the limb and socket. Studies have shown that both normal pressure and shear stress applied to soft tissues cause blood occlusion, volume loss, and, in some cases, skin ulceration (Bader *et al.*, 1986; Bennett *et al.*, 1979; Carlson, *et al.*, 1995; Golbranson, *et al.*, 1988; Grevsten, 1978;

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Grevsten and Erikson, 1974; Hachisuka *et al.*, 1998; Naylor 1955; Roberts, 1986; Staats and Lundt, 1987; Zhang *et al.*, 1988; Zhang *et al.*, 1996). The total surface-bearing suction socket and liner are slightly undersized to ensure good contact with the stump. This places the limb under pressure, which leads to volume loss (Vaitl *et al.*, 1997; Wolthuis *et al.*, 1975). As the limb loses volume, it settles distally in the socket, which leads to areas of high pressure and shear stress around bony prominences. These high pressure points are common areas of skin ulceration (Carlson *et al.*, 1995; Grevsten 1978; Grevsten and Erikson, 1974; Hachisuka *et al.*, 1998; Roberts, 1986; Sanders *et al.*, 1992; Zhang *et al.*, 1998; Zhang *et al.*, 1996).

Trans-tibial amputees use a variety of methods to compensate for daily volume loss. The most common is to add socks over the liner. Some amputees insert pieces of elastic polymer to compensate for volume loss in specific areas. Socket walls have also been developed to compensate for limb volume changes. These include walls with air or water bladders that can be inflated to fill the void. The problem with all these compensatory methods is that they restore pressure on the stump, which may cause additional volume loss.

Although the added materials or bladders compensate for the volume lost, the fit is compromised as compared with the fit when the socket was first donned. Each time volume compensation is performed, whether it is to add material, air, or water, the amount of deformable material increases between the limb and the socket. As a result, positive transfer of forces and moments to the socket is compromised. This may lead to poorer control of the prosthesis.

In recognising that these compensatory methods make the situation worse, the current project attempted to develop a socket that prevented the volume loss altogether. A high vacuum was pulled on the outside surface of the liner, holding it tightly against the socket. The limb was sealed from and not exposed to this applied vacuum. The thought was that the stump would maintain its volume as the skin remained in contact with the anchored urethane liner. To test this idea, stump volume was measured throughout another workday on the same 4 trans-tibial amputees using the high vacuum. Results showed that the 4-10% daily volume loss observed with the normal suction socket

was prevented with the high vacuum. While these results were promising, many factors were not controlled, such as diet, hydration, and activity level. In addition, the statistical power was low because of the small sample size. Realising the limitations of the pilot study, the present study was conducted to compare the volume changes associated with normal and vacuum conditions using a total surface-bearing suction socket. In addition, the functional effects of vacuum were evaluated by comparing pistoning and symmetry of gait between the conditions.

Method

A comparison between normal and vacuum conditions was performed with regards to volume change, pistoning of the limb, and gait symmetry. Volume was measured by casting the limb prior to and following 30 minutes of walking. Stump displacement was measured with x-ray while a static, extraction force was applied. Gait symmetry was evaluated during the 30 minute walk using cinematography.

Eleven (11) subjects were drawn from a pool of trans-tibial unilateral, traumatic amputees who could walk 30 minutes on a treadmill: 11 were used in the pistoning testing and 10 were used for the volume and gait testing. The mean amputee age was 45 years (32-64 years), body mass 83kg (56.2-95.3kg), height 1.67m (1.40-1.83m), and limb maturity 15.2 years (6-41 years). All subjects were cleared for participation in accordance with the guidelines established by the St. Cloud State University Institutional Review Board.

TEC Interface Systems, Inc. constructed a custom total surface-bearing suction socket for each subject. Subjects were fitted with urethane liners and suspension sleeves, and acrylic copolymer (PETG) test-sockets. Their stumps were vacuum-cast with plaster, and these casts were used to construct sockets and liners. Liners were roughly undersized by 10% and sockets by 4%.

A single-ply (0.25mm) nylon stocking was placed over the liner for easing the liner and limb into the socket and maintaining an airspace between the socket and the liner. The liner extended approximately 3-8cm above the top of the socket. Once the limb was seated in the socket, a urethane sleeve was placed over the proximal one-half of the exterior socket wall and

distal three-quarters of the thigh. The sleeve sealed with both the socket and the portion of the liner that extended above the socket. This created a small (75-150ml) sealed air space between the liner and the socket (interface space). Each of the sockets had an air expulsion port on the distal-posterior aspect. All these socket components are shown in Figure 1.

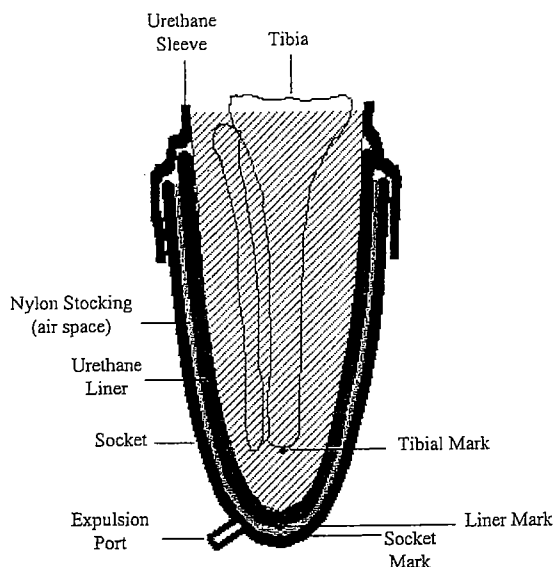


Fig 1. Illustration of socket components worn by the subjects.

In the normal condition, the port was fitted with a one-way valve that allowed air to be evacuated from the interface space. For the vacuum condition, the one-way valve was removed and a -78kPa (-23 inHg) vacuum was drawn in the interface space. An electric vacuum pump was tethered to the exit port to maintain the vacuum throughout the 30 minute treadmill walk. The prosthetic system of 8 of the subjects consisted of a SACH foot, while 3 subjects used a Flex-foot. A licensed prosthetist aligned each prosthesis for gait by adjusting pyramids located at each end of the pylon. Alignment was not changed between trials.

Pistoning was measured with x-ray while applying two static draw loads under normal and vacuum conditions. The loads of 44.5 and 88.9N tended to displace the prosthesis distally, simulating swing forces during walking and running, respectively. These loads were determined from pilot work with amputees using inverse dynamics with cameras and a force platform (Winter, 1990). Pistoning was

measured early in the morning before the limb lost significant volume. The x-rays were taken while the subject lay supine to provide an anterior view of the stump. An additional x-ray was taken while the prosthesis was unloaded to be used as a baseline measurement. The x-rays were taken 30s after the load was applied. The load sequence was randomised for each subject. Between each of the loads, the subject took several steps for approximately one-minute to reseat the stump properly in the socket.

A reference line was drawn down the middle of the socket on each x-ray. The positions of the bottom of the socket well, bottom of the liner, and the distal tibia were marked on this line as shown in Figure 1. Liner position in the socket was measured by subtracting the socket mark from the liner mark. Tibial position was measured by subtracting the socket mark from the tibial mark. The soft-tissue length, distal to the tibia, was calculated by subtracting the liner mark from the tibial mark. The liner mark, rather than the distal end of the limb, was used to calculate tissue length because the limb was often indistinguishable from the liner. It was indistinct because the soft-tissue and liner densities were similar and they remained in close contact. These lengths were scaled to real-life units using a calibrated distance. The displacements of the liner and the tibia, and elongation of the tissues were calculated by subtracting the unloaded from the loaded conditions. Repeated measures of these displacements on the x-ray images resulted in maximum differences of <1mm within and between two investigators.

Volume changes and gait symmetry were measured at the beginning and end of a 30 minute, 0% grade, 1.34-1.52ms⁻¹ treadmill walk for both the normal and vacuum conditions. The conditions were randomly assigned. Prior to the first test day, subjects were familiarised with the treadmill by walking at 1.34-1.52ms⁻¹ for 15 minutes. The controlled activity of treadmill walking was used to simulate the activity level of a typical workday. Pilot testing indicated that walking for 30 minutes at these speeds provided a volume loss equivalent to that observed during a workday.

A casting and water displacement procedure (Commean *et al.*, 1996) was used to determine the volume of the limb before and after the walk. The reliability of this procedure was $\pm <1\%$.

Volume differences were <1% between multiple volume determinations by the same investigator and between two investigators. Flat markers, 1cm in diameter, were adhered to the subject's limb in three locations around the proximal shank. The indentations left by these markers in the subsequent moulds defined a water-fill plane in volume determination. The placement of the markers was controlled within a trial by marking the skin. However, because the ink did not remain between test days, new marks were made on the second test day in approximately the same location.

The casting procedure was performed immediately after the markers were affixed. The subject's stump was submerged in an Alginate™ mixture to the superior crest of the patella. The water temperature used in the Alginate™ mixture was controlled at 29-30°C. In pilot testing, this water temperature caused neither a gain nor loss in limb volume. Immediately after this female Alginate™ mould set, the subjects removed their limb and plaster was poured into the cast to make the male mould of the limb. Once set, the plaster mould was removed from the Alginate™ cast. Thin, clear plastic was pulled over this male mould. The plastic female mould was removed from the male mould and was filled with water up to the plane formed by the three marker indentations in the cast. The water was weighed and its volume determined.

After the baseline Alginate™ mould was complete, the subject donned the test-prosthesis and walked on the treadmill. After the walk, markers were affixed according to the marks remaining on the skin after the first casting. The subject's stump was recast using the same procedure as previously described. In addition, the subject was weighed to estimate the amount of fluid lost during exercise.

Dietary practices of the subjects were controlled to prevent factors, other than the walk, from affecting volume. Subjects were asked to normalise diet and activity levels between testing days to minimise variability in hydration between testing days. The subjects abstained from alcohol, caffeine, and exercise 24 hours prior to each testing day to prevent dehydration. Subjects consumed approximately 1900ml of water the day prior and 350ml one-hour prior to testing to allow for proper hydration. A food log was kept by each subject to verify normality of diet and activity between

test days. At the second trial, all the subjects' weights were within 2% of their first trial; hence, the subjects were considered properly hydrated and were tested.

Two 60Hz cameras recorded movements of the subject during both walking trials. Cameras were gen-locked and set 9 metres from the subject, one camera perpendicular to the direction of treadmill belt travel and the other directly behind the subject. Exposure time was 1/250s. Before each trial, a calibration image was filmed.

The cinematography data were viewed by fields to determine kinematic parameters; step length and stance duration. The data taken for each side (normal and amputated) were analysed using a symmetry index (SI) formula described by Herzog *et al.* (1989):

$$SI = \left(\frac{X_A - X_N}{(X_A + X_N) / 2} \right) * 100 \quad (\text{Formula 1})$$

where X_A is the gait parameter for the amputated limb from X_N is a value for a gait parameter for the normal side. The error associated with misidentifying gait parameters by being off by one-half a field at the beginning and end of an event was $\leq 1\%$.

Single sample t-tests ($\alpha = 0.05$) were made on volume changes with the vacuum and normal conditions to determine if they were significantly different from zero. A single factor, repeated ANOVA ($\alpha = 0.05$), was performed to examine the effect of the vacuum on the independent factors of each gait parameter. A two factor, repeated ANOVA ($\alpha = 0.05$) was used to determine if condition (normal and vacuum) and the size of the load (44.5 N, 88.9 N) affected the amount of limb displacement.

Results

With the vacuum, stump volume increased ($p = 0.007$) an average of 3.7% (30ml) during the 30-minute walk. In the normal condition, stump volume decreased ($p = 0.000$) an average of 6.5% (52ml). The volume data are presented in Table 1.

The liner displaced 0.4cm less ($p = 0.000$) from the socket when the extraction force was applied under the vacuum condition. The tibia displaced 0.7cm less ($p = 0.000$) from the socket reference point in the vacuum condition when loaded. The amount of tissue elongation during

Table 1. Stump volumes (ml) before, 0, and at the end, 30, of the walk and percentage changes in volume for the normal and vacuum conditions.

Subject	Normal			Vacuum		
	0	30	% Change	0	30	% Change
1	400	355	-11.3	372	402	8.1
2	752	698	-7.2	708	697	-1.6
3	701	689	-1.7	697	702	0.7
4	908	855	-5.8	870	891	2.4
5	827	750	-9.3	961	962	0.1
6	843	816	-3.2	841	888	5.6
7	725	662	-8.7	732	758	3.6
8	1688	1568	-7.1	1496	1623	8.5
9	441	421	-4.5	455	474	4.2
11	417	376	-9.8	400	428	7.0
Average	809	757	-6.5	792	822	3.7

loading tended to be greater (0.3cm) in the vacuum condition but was not significantly ($p = 0.102$) different between the two conditions. Both loads produced the same ($p = 0.530$) amount of pistoning. A summary of the mean displacements and tissue elongation of the stump during the axial loading is displayed in Table 2.

Vacuum improved gait symmetry as shown in Table 3. An index of zero equals perfect symmetry between the normal and amputated limb. Step length was more symmetrical ($p = 0.000$) with the vacuum. The stance durations were also more symmetrical (p -value = +0.037) with vacuum. However, there was no significant differences over the 30 minutes with either gait event.

Discussion

The data showed significant differences between the normal and vacuum conditions with regard to volume change, pistoning of the stump, and gait symmetry. Since the two socket conditions were identical except for the application of a vacuum in the interface space and each test sequence was randomised between subjects, it can be assumed that the differences observed were a result of drawing a vacuum. Other factors (age of amputee, limb maturity, and weight loss) that may have affected volume were unrelated ($R^2 \leq 0.43$) to the change in stump volume.

The literature on stump volume loss concentrates on long-term loss (Commean,

Table 2. Mean (± 2 standard errors) displacements (cm) and tissue elongation (cm) under the normal and vacuum conditions.

Variable	Normal	Vacuum	p -value
Liner	0.5 (± 0.2)	0.1 (± 0.1)	0.000
Tibia	4.0 (± 0.4)	3.3 (± 0.4)	0.000
Tissue elongation	4.2 (± 0.3)	4.5 (± 0.3)	0.102

Table 3. Symmetry indices (± 2 standard errors) for gait parameters.

Gait Event	Normal	Vacuum	p -value
Step Length	3.33 (± 0.73)	1.27 (± 0.37)	0.000
Stance Duration	3.79 (± 0.82)	2.75 (± 0.82)	0.037

et al., 1998; Fernie and Holliday, 1982; Golbranson *et al.*, 1988; Persson and Leidburg, 1983), while daily volume loss has all but been ignored. This absence is surprising since poor fit, resulting from daily volume loss, leads to physical and financial difficulties: poor socket fit, skin ulceration, poor gait, and/or replacement of failed liners (Grevsten, 1978; Naylor, 1955; Roberts, 1986; Sonck *et al.*, 1970; Zhang *et al.*, 1998; Zhang *et al.*, 1996).

The application of the vacuum caused a 3.7% (-1.6-8.5%) gain in volume with only one subject losing volume (-1.6%). Conversely, the stumps lost an average -6.5% (-1.7 - -11.3%) under the normal condition. As the subjects did not drink any fluids during the trial and since weight loss was unrelated ($R^2 = 0.058$, $p = 0.308$) to volume change, the volume changes were most likely due to a redistribution of fluids. The observed increase in volume with the vacuum suggests that more fluid was drawn into the stump than driven out; while with the normal condition, the opposite was true.

Roberts (1986) theorised that the cyclic pressure variations during gait found by Chino *et al.* (1975), and Pearson *et al.* (1974), might be responsible for improved circulation in the stump and, perhaps, a volume gain if the negative pressures are high enough. Since positive pressure drives fluid out of the limb and negative pressure draws fluid in (Grahn *et al.*, 1998; Linman and Weinshenker, 1996; Roberts, 1986; Vaitl *et al.*, 1997; Wolthuis *et al.*, 1975), the volume gain with the vacuum, in the present study, could be explained by a reduction in positive pressure during stance or an increase in negative pressure during swing. Although measurements of limb pressure were not performed, the authors propose that the volume gain was due to a higher negative stump pressure during swing (Grahn *et al.*, 1998; Chino *et al.*, 1975; Roberts, 1986) and not a reduction in positive pressure during stance. The authors think the negative pressure was increased in the vacuum condition because the x-ray data showed that the skin remained in contact with the anchored liner as the tibia pistoned. The resulting tissue elongation possibly caused more fluid to be drawn into the limb during the swing phase. Pilot testing of 2 of the subjects provided further evidence supporting the notion that anchoring of the liner was ultimately responsible for the increased negative pressure and volume

gain. The liners of the subjects were permanently glued to the sockets and worn for an entire workday. At the end of the workday, neither subjects had lost volume. Work is currently underway to measure the pressures and test this hypothesis.

Though the results showed that the vacuum prevented volume loss, there were 5 cases where substantial (>4%) gains in volume were observed. If the sockets were an optimal fit for each subject, they should not have gained volume but should have maintained or only slightly increased. One possibility for the volume gains may be that the subjects lost volume before arriving at the test site. Some subjects had their sockets donned for up to 2 hours prior to testing. The pressure applied by the undersized liner and socket have caused a loss. Another possibility may be that the sockets were not an optimal fit for each subject. A socket that was slightly larger or did not make total contact in all areas of the stump may have allowed for the formation of air spaces in which the limb responded by increasing volume in these areas to fill the voids. The volume gains were not perceived by the subjects.

The liner and tibia pistoned less with the vacuum than the normal condition. The liner was held tightly (0.1cm) to the socket under vacuum compared to the normal condition (0.5cm). Since the stump remained in contact with the liner under both conditions, the amount of pistoning of the stump under vacuum was also less. The reduced pistoning in this static testing with the vacuum suggests that less pistoning occurred during the walking trial with vacuum. Nine (9) out of the 10 subjects commented that their limbs were held more firmly with the vacuum condition and that it felt as if their stump pistoned less within the socket during the walk. One subject perceived no difference between the two conditions in relation to pistoning. This has possible implications for the health of the skin since cyclic shear stress at the epidermis, as occurs with walking, can lead to skin damage (Naylor, 1955).

While gait asymmetry is expected in trans-tibial amputee gait because of missing neuromuscular and skeletal structures (Winter and Sienko, 1988), the degree of asymmetry can be reduced with proper fit (Pitkin, 1997). A proper fit affords the amputee better control by providing sufficient proprioception and transfer

of forces to the prosthesis (Zahedi *et al.*, 1987). A poor fit is associated with amputees spending less time on the amputated limb (Breakey, 1976; Cheung *et al.*, 1983; Seliktar and Mizrahi, 1986; Skinner and Effeney, 1985) because the amputee is less confident of control over and position of the prosthesis (Dingwell *et al.*, 1996; Sabolich, 1994). Thus, maintaining a good fit is important to symmetrical gait.

In the present study, the stance duration and step length symmetries suggest the existence of a difference in fit between the two conditions. The vacuum improved the symmetry in stance duration, and, consequently, step lengths were also more symmetrical with the vacuum. In contrast, under the normal condition, the step length of the amputated side was 2cm longer when compared to the normal side because the amputated limb travelled further during the increased stance duration of the normal limb.

Conclusions

Proper socket fit is crucial for the comfort of the amputee, health of the skin, and performance of the prosthesis. Maintaining a good fit is difficult with the total surface bearing suction socket because the pressure that provides a good fit causes daily volume loss in the stump. As volume is lost and the fit deteriorates, the skin is thought to be subjected to higher pressure and shear forces, and possible ulceration. Drawing a high vacuum on the interface space prevents volume loss or, in some cases, causes a gain in volume. A vacuum also reduces pistoning of the stump and tibia within the socket when statically loaded. Therefore, a vacuum condition maintains a better fit and may reduce irritation of the skin. In addition, a vacuum improves gait symmetry.

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