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Walking in a vacuum-assisted socket shifts the stump fluid balance

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Abstract

Gains in stump volume have been documented in trans-tibial amputees while walking in custom made under-sized, total surface-bearing, vacuum-assisted sockets (Board *et al.,* 2001). These gains raised doubts as to whether the sockets were truly under-sized and concerns that using an over-sized socket with vacuum-assist could lead to swelling, resulting, in discomfort or pain. The purposes of the present study were to determine if: (a) walking in a vacuum-assisted socket causes the stump to retain or gain volume in excess of the available socket volume and (b) the resulting increase in stump volume with an over-sized socket causes discomfort, pain, and/or the skin to redden. The results of this study showed the stump retained or gained volume in excess of the available socket volume while walking in vacuum-assisted sockets of various sizes. The stump lost less volume than predicted, or gained volume, in under-sized sockets. It also gained more volume than predicted in over-sized sockets. No discomfort, pain, or skin reddening, resulting from the volume gain was reported by any of the subjects after walking in an over-sized socket. This change in fluid balance towards a net gain supports the findings by Board *et al.* (2001) that vacuum-assist ensures a good fit during the day in ambulatory trans-tibial traumatic amputees with mature stumps.

Introduction

To ensure a secure fit between the stump and prosthesis, the circumferences of total surface-bearing, suction suspension sockets are typically under-sized by approximately 4-6% (TEC Interface Systems, Inc.). While this initially provides positive linkage, the compressive pressure produced by the under-sizing causes volume loss in the limb after donning the socket, thereby deteriorating the fit (Board *et al.,* 2001; Grevsten, 1971; Staats and Lundt, 1987). One of the authors' earlier studies revealed that mature stumps of traumatic trans-tibial amputees using total surface-bearing, suction suspension sockets, lost an average of 6.5% in volume during walking (Board *et al.,* 2001). Conversely, when the liners were anchored to the socket with a high vacuum of - 78kPa (vacuum-assisted), the same amputees gained an average of 3.7% in stump volume. This gain in volume in an under-sized socket raised doubts as to whether the sockets were truly under-sized. The observed change in limb volume from a net loss to a net gain also raised concern that using an over-sized socket with vacuum-assist could lead to swelling, resulting in discomfort or pain. The current study was thus conducted to test two hypotheses: (a) walking in a vacuum-assisted socket causes the stump to retain or gain volume in excess of the available socket volume and (b) the resulting increase in stump volume with an over-sized socket causes discomfort, pain, and/or the skin to redden.

Methods

The current experiment was designed to study the changes in stump volumes of trans-tibial

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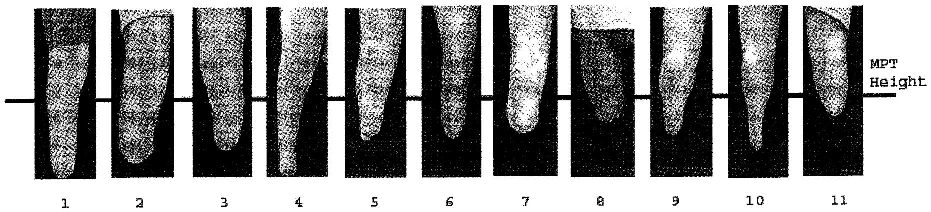

Initial	1205	1055	627	605	602	566	479	437	354	318	278
Under-sized	1194	1017	585	610	651	500	469	428	364	330	252
Neutral	1331	1134	682	651	679		473	449			264
Over-sized	1351	1219	739		713		527	464			275

Fig. 1. Photographs of the stumps aligned vertically on mid-patellar tendon height and arranged horizontally in order of descending volume. The volumes (cc) of the stumps measured prior, between and after the three walks are listed below the corresponding photographs. Subjects 4, 6, 9 and 10 did not walk in the over-sized socket and subjects 6, 9 and 10 did not walk in the neutral socket.

amputees while walking in under-sized, neutral and over-sized vacuum-assisted sockets. Stump volumes were measured using an alginate casting method. Subjects were questioned whether they experienced discomfort or pain due to the increase in volume with the over-sized socket after the walk.

Eleven (11) healthy, trans-tibial unilateral amputees, who lost their limbs either due to trauma or birth defects, participated in the study. The average age of the subjects was 45 years (27-66) and mass of 83kg (59-107). Their stumps were mature, ≥3 years, varying widely in volume (278-1205cc) and length (4.5-17.5cm), as listed in Table 1 and shown in Figure 1. In order to prevent factors other than socket size from affecting volume changes, the dietary practices of the subjects were controlled. They were asked to, and reported to have consumed a balanced diet, stayed hydrated, avoided strenuous excercise and refrained from consuming alcoholic beverages in the 24 hours preceding testing. Approval for the subjects' participation was in accordance with the

Table 1. Stump characteristics.

Subject	Maturity (yrs)	Circumference (cm)		Length (cm)	Taper (°)	Bones present
		Proximal	Distal			
1	3	33.0	22.5	17.5	5	Both
2	18	38.0	31.0	10.0	6	Both
3	15	33.0	27.0	9.0	6	Both
4	25	27.0	16.5	17.0	6	Tibia
5	8	32.5	21.0	9.5	11	Tibia
6	10	30.0	24.0	9.0	6	Both
7	19	30.5	28.0	7.5	3	Both
8	43	32.0	26.5	5.0	10	Both
9	33	29.5	15.5	12.0	11	Tibia
10	22	28.5	11.5	12.5	12	Tibia
11	34	33.0	22.5	4.5	20	Both
Average	21	31.5	22.4	10.3	9	

guidelines established by the St. Cloud State University Institutional Review Board.

A single gel liner and 3 vacuum-assisted sockets with the following target circumferential size variations were fabricated using computer aided design and manufacturing techniques for each subject: 4% under-sized, neutral and 4% over-sized of the donned liner. These correspond to targets of -8, 0 and ±8% differences from the donned liner volumes, since volumes increases as the square of the circumferences. The actual volume differences of the 3 sockets were -13% (±3.5), -4%(±1.3) and +9% (±4.3) of the donned liner, respectively. Imprecision in the casting and fabrication techniques were responsible for the discrepancies between the target and actual socket volumes. The reported socket volumes are estimated to be within ±2% of the actual volumes based on digitiser calibration. To maintain consistency in socket design, all total surface-bearing, vacuum-assisted sockets and polyurethane liners were made by the same technicians and manufacturer (TEC Interface Systems Inc., Waite Park, MN). A one-way valve at the distal expulsion port allowed air to exit the socket.

The soft-gel polyurethane liners (shore OO 45 durometer) were approximately 7mm thick and reduced in circumference by a standard 10%. Each liner was custom-fit to the shape of the subject's stump. Proximal flow of the donned liner when inserted into the under-sized socket was at least 1cm in all cases on the day of testing, providing confirmation of under-sizing. The liner extended approximately 6cm above the top of the socket. A urethane sleeve was placed over the proximal one-half of the exterior socket wall, portion of liner that extended out of the socket and distal three-quarters of the thigh, creating a seal between the socket and liner, and preventing the high-vacuum in the liner/socket airspace from extending to the limb.

Limb circumferences were measured proximally at mid-patellar tendon height, and distally just above the sharp taper at the end of the limb. Limb length was recorded as the distance between the 2 circumferences. Limb taper (θ) was estimated with respect to the long axis of the limb using the following formula: $\theta =$ atan [(proximal – distal limb radii)/limb length]. Photographs of the limb were also taken prior to the experiment.

Stump volume was measured by marking the limb at three equidistant positions, at the height of the mid-patellar tendon, and casting it in an alginate-water mixture (0.45g/L) at 30°C for 90 seconds. The impression of the stump thus formed, was filled with water up to the three markers. The volume of water, using a weight to volume conversion, determined the limb volume of each subject. Extensive pilot testing was performed to improve the precision of volume measurement. Of the factors studied including brand of alginate, water temperature, rate of expansion of alginate and reproducibility of defining the water fill level, the last factor introduced the greatest source of potential random error. In repeatability studies using a standard synthetic male mould of a stump, precision of the alginate casting technique was determined to be approximately ≤±2% (12cc). The possibility of the stump changing volume during the three-minute casting period was not examined because of the inability to measure repeated instantaneous volumes. In the current study, since the stumps tended to increase in volume during walking, they would be expected to lose volume upon exiting the socket. If the stump lost volume during casting, the conclusion that vacuum-assist changes the fluid balance to a net gain would be understated.

Subjects walked 3 times, 18 minutes each, on a treadmill at zero inclination and constant speed of 4.5km/hr (2.8mph) while wearing the 3 vacuum-assisted sockets attached to an external vacuum pump drawing -78kPa (-23inHg) at the expulsion port. The order of the 3 walks was under-sized, neutral and over-sized sockets. This fixed order was selected to avoid the potential problem of early termination of the experiment as a result of the possible discomfort or pain when using the over-sized socket. While walking in the under-sized and neutral sockets, a single nylon sheath (0.25mm) was placed over the liner. The subjects wore 5 sheaths to fill at lest half the space in the over-sized socket, thus allowing 7 of the 11 subjects to complete the walk while leaving space for the stumps to expand. Throughout the experiment, all subjects were kept adequately hydrated, drinking 290cc (10 ounces) of water 30 minutes prior to testing. Stump volumes were measured before, between and after the three walks. The time between each walk was 10-15 minutes, with volume

Table 2. Volumes (cc) up to mid-patellar height of the under-sized (u), neutral (n) and over-sized (o) sockets, sheaths and liners worn in the sockets, portion of liner that flowed proximally out of the under-sized socket and the resulting volumes available to the stump in the socket. Neutral and over-sized sockets were not contructed for subject 10 because of her small diameter stump.

	Sockets			Sheaths			Liner	Liner flow	Available to stump		
Subjects	u	n	o	u	n	o	u,n,o	u only	u	n	o
1	1598	1746	1992	17	17	85	616	23	988	1113	1291
2	1217	1327	1530	15	15	74	326	27	902	986	1130
3	1120	1218	1302	12	12	58	591	23	540	615	652
4	1059	1153	1279	13	13	64	597	19	468	543	618
5	725	788	856	10	10	50	220	23	518	558	586
6	662	800	951	10	10	52	265	21	408	525	634
7	775	845	992	11	11	53	402	21	384	432	537
8	551	600	651	8	8	40	189	22	376	403	421
9	651	709	846	10	10	48	378	21	284	322	420
10	552			9	9	43	363	20	201		
11	361	394	429	7	7	33	133	23	244	254	263
Average	843	958	1083	11	11	55	371	22	483	575	655

measurements being performed within the first three minutes of exiting the socket.

Two (2) of the subjects were also tested while seated for 20 minutes to record any changes in their stump volumes when wearing the over-sized socket without sheaths, but with a constant -78kPa drawn on the expulsion port.

Available socket volume was defined as the volume for the stump in a donned socket. Available socket volume was calculated by subtracting the volumes of the sheath(s) and liners up to mid-patellar tendon height (three markers), from socket volume up to the same height. In the under-sized socket, the volume of liner that flowed out of the socket was geometrically estimated for each subject and added to the available socket volume. The available volumes for the stumps in the under-sized, neutral and over-sized sockets were 483, 575 and 655cc, respectively, as listed in Table 2.

The stump was visually inspected immediately after exiting the socket for discernable changes in volume and reddening of the skin. After each walk, the subjects were asked whether there was any discomfort or pain associated with volume changes.

Statistical comparisons were limited to the 7 subjects who were able to walk in all 3 sockets. A single factor, repeated measures ANOVA was used to test for significant differences between stump volumes in the 3 socket conditions, followed by a post-hoc analysis of the means using paired t-tests. An alpha of .05 was selected for the level of significance.

Results

The average initial stump volume of the 7 subjects who successfully walked in all three sockets was 669cc. Post-walk stump volumes for these same subjects averaged 657, 716 and 755cc in the under-sized, neutral and over-sized sockets, respectively. The estimated volumes available for their stumps in the respective sockets were 565, 623 and 697. With the exception of Subject 7 in the over-sized socket, all post-walk stump volumes were larger than predicted based on the volumes available in the sockets, demonstrating a change in the fluid balance towards a net gain as shown in Figure 2. The average stump volumes were 92, 93 and 58cc larger ($p<0.05$) than the volumes available in the under-sized, neutral and over-sized sockets, respectively. The subjects lost an average of only 12cc in the 104cc under-sized, socket. In the neutral socket that was under-sized by 46cc, the subjects gained 47cc. The subjects

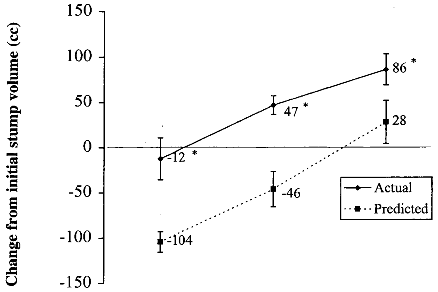

Fig. 2. Average changes in volume from the initial stump volume after walking in the under-sized, neutral and over-sized sockets (n=7). The predicted changes are based on the volume available to the stump in the respective sockets. * = significantly different from predicted change. The errors bars are ± 1 standard error.

gained 86cc in the 28cc over-sized socket. All of these differences were significant. The 2 subjects who sat for 20 minutes in the over-sized socket (without filler material) under vacuum gained 67cc in volume, despite 102cc of over-sizing.

None of the seven subjects who walked, nor the two that sat, in the over-sized socket reported discomfort or pain, or redness of the skin because of the gain in stump volume; ≤164cc (18%).

Discussion

The results of this study of vacuum-assisted suspension showed that the stump tends to lose less volume than predicted, or gain volume, in an under-sized socket. The results also showed that the stumps gain more volume than predicted in an over-sized socket. This confirms the first hypothesis that walking in a custom-fit, total surface-bearing, vacuum-assisted socket changes the fluid balance of the stump toward a net gain for all socket sizes. No discomfort, pain, or reddening of the skin, resulting from volume gain was reported by any of the subjects following the walk in the over-sized socket.

Previous research in the author's laboratory has shown that a vacuum-assisted socket shifts the fluid balance in the stump from one of a net loss (-6.5%) to net gain (+3.7%) in traumatic trans-tibial amputees while walking (Board *et al.,* 2001). In this previous study, each subject walked in a custom-fit, total surface-bearing socket, once with and once without a 78kPa vacuum drawn at the expulsion port. Application of the high vacuum anchored the liner to the socket, causing a 27% increase in negative pressure on the limb during the swing phase and a 7% decrease in positive pressure during the stance phase (Beil *et al.,* 2002). Both of these pressure changes, but principally the increase in negative pressure, are thought to be responsible for shifting the fluid balance to a net gain (Guyton and Hall, 2000; Mellander and Albert, 1994). In the current study, in the sitting condition where the limb was not exposed to the negative pressure of swing phase, the fluid shift reverted back toward a net loss. The stump only expanded to fill approximately 2/3 of the available socket space while sitting in the over-sized socket under vacuum.

In previous work (Board *et al.,* 2001), the authors unexpectedly found that all but one of the subjects gained volume while walking in the standard 4-6% under-sized socket with vacuum-assist. At that time, it was questioned whether the sockets were under-sized because it was assumed that the limb could not expand in volume beyond the available socket volume. The findings of the current study show that it is possible to retain or gain volume in excess of the available socket volume. Post-walk stump volumes exceeded the available socket volumes as shown in Figure 2. The stumps lost an average of 2% of volume in the under-sized socket, but based on the amount of under-sizing, they were predicted to lose 15%. Also unexpectedly, the stumps gained 5% in the neutral socket despite it being under-sized by 7%. These findings agree with the 3.7% volume gain observed by Board *et al.* (2001) in under-sized sockets. A similar shift in fluid balance was observed with the 3% over-sized socket; the subjects gained 11% in volume. These findings are interpreted to mean that the 27% higher negative pressures measured by Beil *et al.* (2002) in the vacuum-assisted socket during swing phase cause the fluid balance in the stump to shift toward a net gain. The authors suggest that the limb is able to attain a volume in excess of the available socket volume by drawing fluid into the soft tissues of the stump (Aratow *et al.,* 1993; Lundvall *et al.,* 1996; Musgrave *et al.,* 1969; Wolthuis *et al.,* 1975). causing the tibia to ride higher in the socket as shown in Figure 3.

A second possible explanation for the stump volume exceeding the available socket volume is that the liner was driven proximally out of the rigid socket as the stump gained volume, in effect increasing the available socket volume.

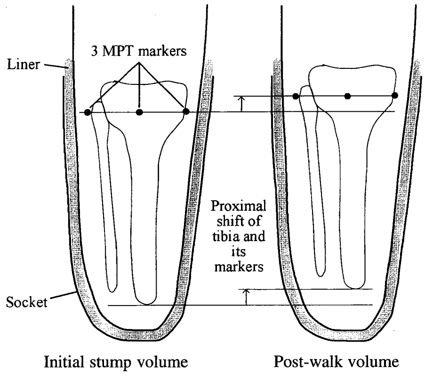

Fig. 3. Proposed proximal shift of tibia to explain how stump volume can exceed the available socket volume following a walk.

This seems unlikely. Proximal polyurethane liner drive (~1cm) in an under-sized socket is observed when donning in the morning and is viewed as confirmation of a proper fit. With normal suction suspension, the stump loses volume and the liner recedes back into the socket. With vacuum-assist, the liner is anchored to the socket, preventing it from driving any further proximally or receding back into the socket. While not measured, no additional proximal drive of the liner was observed following any of the test conditions. It is therefore suggested that the available socket volume remained relatively constant.

This fluid shift from a net loss to net gain, with vacuum-assist has several important practical implications for the amputee. In a normal, total surface-bearing, suction suspension prosthesis, the stump settles distally in the socket shortly after donning because of volume loss (Board *et al.,* 2001). This increases trauma to the stump because of impact forces and friction due to pistoning. The resulting poor fit also compromises control of the prosthesis (Erikson and Lemperg, 1969; Narita *et al.,* 1997). An ambulatory trans-tibial amputee with a mature stump and stable body fluids (e.g. not on kidney dialysis or taking steroids) can minimise or avoid these problems by using a custom-fit, total surface-bearing vacuum-assisted prosthesis. Since vacuum-assist maintains or increases stump volume, peak positive pressures and pistoning are reduced, and gait becomes more symmetrical because of the improved linkage (Beil *et al.,* 2002; Board *et al.,* 2001).

One of the anticipated concerns about this fluid shift was that the stump might swell, causing discomfort or pain, if an over-sized socket was used with vacuum-assist. While such a socket is virtually non-functional, it was included in the experiment to account for the real possibility that an amputee might use vacuum-assist with an over-sized socket. Under the current test conditions, this concern proved to be unwarranted. None of the 7 subjects who were able to walk, nor the 2 that sat, in the over-sized socket, felt discomfort or pain due to the increase in volume, ≤164cc (18% of initial stump volume). Neither the researchers nor subjects were able to visually detect the volume gains or any reddening of the skin when the prostheses were doffed immediately after the walk, indicating that the volume gain occurred globally in the limb. Even larger volume gains, ≤25%, were measured in pilot work with 10% circumferentially over-sized sockets with similar results. The subjects added a sufficient number of sheaths to prevent distal end load bearing, allowing them to walk for 20 minutes. In all cases the volume gains were visually indiscernible, and there was no associated discomfort, pain or reddening of the skin. So it seems clear that a uniformly over-sized, custom-fit, total surface-bearing, vacuum-assisted socket will not lead to discomfort, pain or skin reddening as first assumed.

This conclusion is almost certainly invalid when deep voids exist in a vacuum-assisted socket. The liner and skin would be drawn into the deep voids, causing local swelling of the soft tissue and possible skin problems. Since the sockets used in the present study were free of deep voids, the minimum sized void needed to cause these problems is not known. However, observations by prosthetists who fit amputees with vacuum-assisted socket systems provide some insight. Former pin-liner users sometimes develop blisters on the distal end of the stump the first day in a vacuum-assisted socket. The prosthetists hypothesised that this skin problem is a result of the liner and skin being drawn into a distal void in the new socket. This seems probable because the blisters disappeared after filler material was added distally in the socket. The distal void is probably due to the new socket being fabricated from a mould of the stump while it still had the distal bulbous end caused by the proximal squeezing and distal draw of the pin liner. The bulbous swelling typically reduces within several hours of using a vacuum-assisted socket, thereby creating a distal void.

These observations and the findings of this study suggest that a prosthetist should fabricate a total surface-bearing socket, free of major voids, when fitting a trans-tibial amputee with a vacuum-assisted system. As the stump atrophies, sheaths and other filler materials may be added to compensate for the permanent volume loss, allowing for pain-free ambulation, Adding too much filler material proximally should be avoided since it could prevent the stump from fully seating, leaving a distal void and potentially leading to skin problems.

A custom-fit, vacuum-assisted system minimises or prevents the acute volume loss normally observed after donning the recommended 4-6% under-sized socket. This shift in fluid balance ensures that a good fit is maintained during the day in ambulatory trans-tibial amputees with mature stumps which has been shown to reduce pistoning and improve gait symmetry (Board *et al.,* 2001).

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