The effects of a modified passive socket system on short-term changes in residuum volume and comfort: A preliminary study in trans-tibial amputees

Abstract

***Background**:* Changes in residuum volume are a common problem in lower limb amputees during prosthesis usage, and can lead to poor suspension, impaired gait and tissue damage. Residuum volume can be affected by the in-socket air pressure, which will influence fluid flow in and around the residuum. The use of "active" pumps to reduce air pressure has been shown to conserve the residuum volume, but these are expensive and unlikely to be widely available. An alternative, passive approach, based on Boyles' Law, is to introduce a larger distal void volume at the end of the socket and hence reduce the change in pressure for a given change in volume.

***Objectives**:* To compare the performance across 3 test-conditions (passive – conventional, with standard distal void; passive – with increased distal void; and active system) in terms of residuum volume changes and comfort.

***Study design**:* Repeated measures experiment under three test-conditions.

***Methods**:* Five trans-tibial amputee participants (3 males and 2 females), aged between 27 and 67 years, and of mobility grade K2 or K3, were fitted with a bespoke test-prosthesis that was adapted to include the 3 test-conditions. Residuum volume was measured before and after walking under each test-condition (presented in a random order). Comfort was also assessed after walking with each test-condition.

***Results**:* The reduction in residuum volume, relative to the baseline volume, was higher for the conventional passive system (4.2% ± 2.8%) compared to the modified passive (1.4% ± 1.4%) and active (1.6% ± 1.1%) systems.

***Conclusion**:* The use of a passive suspension system with an increased distal void within the socket may help to stabilise the residuum volume during prosthesis usage.

Word count: (270 words)

Clinical relevance

This study investigates the effects of a modified passive socket system on short-term changes in residuum volume and comfort. The performance of the passive system in maintaining the residuum volume may be improved by fabricating the prosthetic socket with a larger distal void volume (additional ~100 ml).

Word count: (47 words)

Keywords

Socket, suspension, air-pressure, volume, residuum, comfort.

Background

Maintaining a secure and intimate fit between the prosthetic socket and the residuum is widely recognised as the most important factor in prosthesis usage. Changes in the residuum volume of lower limb amputees can cause discomfort, impair gait and limit the mobility of the affected individual (1). Prosthesis users with compromised cardiovascular circulation may encounter increases in residuum volume, particularly when not wearing the prosthesis. Swelling which occurs during prosthesis use is much less common, but can lead to high socket-residuum interface pressures, restrict the blood circulation into the residuum and cause tissue damage and necrosis (2). More commonly, a reduction in residuum volume during prosthesis use can occur, resulting in a loose fitting socket (1, 3). This in turn can cause 'pistoning' (relative movement between the residuum and socket), resulting in gait asymmetry and postural problems (4), residuum pain (5), and, in the longer term, tissue damage (6).

One factor which may impact on how the residuum volume changes with time is the in-socket air pressure. Many lower limb prosthetic sockets will have air pockets, particularly at the distal end. In some types of socket, these are required, particularly if the cut end of bone is relatively prominent and space is needed to protect this from impacting upon the distal end of the socket (6). However, the pressure exerted upon the fluid within the residuum by trapped air, or an effective vacuum, within the distal part of the socket may affect the transfer between this fluid and the general circulatory system, thereby affecting the volume of the residuum itself. A larger distal void volume within the socket could reduce the changes in pressure and hence stabilise the residuum volume. Therefore, changing the size of the distal void volume, and the effects of this on residuum volume, was the key focus of this study.

The use of systems that can encourage the stability of residuum volume, and hence promote effective suspension, is clearly of great benefit. Board et al (2001) (7) compared the gait of trans-tibial amputees using two different suspension systems, the 'passive' Suction Socket Suspension System (SSSS) and the 'active-pump' Vacuum-Assisted Suspension System (VASS) (7). They found residuum volume was better maintained when walking with the VASS than with the SSSS and suggested that an in-socket active

vacuum system could maintain residuum volume by balancing fluid flow between the residuum and circulatory system. Beil et al (2002) (2) proposed that below-atmosphere in-socket air pressure may reduce the reduction in residuum volume while walking with a prosthesis (2). However, residuum volume changes were not measured in this study (2). Sanders et al (2014) (1) and Youngblood et al (2020) (8) used a bio-impedance-based system to assess the fluid volume changes inside the residuum while using different suspension systems (SSSS and VASS). The system which created the lowest air pressure was shown to be the most effective in reducing the reduction in fluid volume in the residuum seen during periods of upright mobility (2, 8). Gerschutz et al (2010) (9) compared short-term changes in residuum volume while wearing the SSSS and VASS and long term changes while wearing the VASS. They reported that the residuum volume decreased more while walking with the SSSS when compared to the VASS (9). Also, they found an improvement in residuum volume retention and wound healing with long-term VASS usage (9). In order to understand the factors impacting on the effectiveness of VASS systems Youngblood et al (2020) (10) designed a bench-top model of a VASS socket, in which the air gap between the distal surface of the liner and the internal wall of the socket could be systematically varied between 2.5mm and 10mm. The elastic response of tissue was modelled using a large air-filled cylinder. For three different values of air gap, and a range of different liners, vacuum pressure was applied between the liner and internal wall of the socket and the resultant simulated tissue pressure was measured. They found that the size of the air gap was the primary determinant of tissue pressure (10). The findings of one of the in-vivo studies indicated that applying a low in-socket air pressure can enhance the blood supply into the residuum (9). Although the mechanisms of fluid circulation in the residuum are still unclear, some of the literature suggests that maintaining a low in-socket air pressure may help to reduce the changes in residuum volume. Unfortunately, active systems are often expensive, require a specialist to fit, and involve a time-consuming fitting and adjustment processes. The recent study by Youngblood et al (10) also suggests the safety and/or effectiveness of active devices may be compromised by poorly fitting sockets. This study explored whether similar outcomes and benefits to a VASS can be achieved using a modified passive Suction Socket Suspension System (modified SSSS) with a manual expulsion valve and a larger distal volume.

Methods

Design of the study

This study was designed to investigate the effects of a modified passive socket suspension system on short-term changes in residuum volume and comfort. Residuum volume was measured before and after walking with the test-prosthesis under 3 test-conditions (*Table 1*), in the same day. The order of the test-conditions was randomised across the participants to minimise possible order-related effects. Socket comfort was also assessed after each test-condition.

Table 1: Test-conditions.

Test-condition	Socket configuration
A	Test-socket with a small distal void volume and the Limb-Logic Communicator switched OFF (SSSS with small distal void volume)
B	Test-socket with a large distal void volume (~100 ml) and the Limb-Logic Communicator switched OFF (SSSS with large distal void volume)
C	Test-socket with a small distal void volume and the Limb-Logic Communicator switched ON (VASS with small distal void volume)

Participants and recruitment

Following ethical approval from the XXX (XXX) (HSCR 15-127) and the XXX (XXX) (16/NI/0151), 5 amputee participants (3 males and 2 females), aged 49.2 ± 16.6 years, height 1.73 ± 0.07 m, mass 85.8 ± 18.2 kg, 25.8 ± 12.6 years since amputation, and K2/K3 mobility grade (11) (*Table 2*) were recruited for this study. The participants were recruited from the XXX and through the XXX.

The inclusion criteria were to: unilateral trans-tibial amputation level; self-reported problem with changes in residuum volume or socket ‘pistoning’; a minimum distance between the distal end of residuum and

the floor of 27 cm (to allow for assembly of the test-prosthesis); a minimum distance from the mid-patellar tendon to the distal end of the residuum of 10 cm (to enhance the seal performance and hence, provide suction suspension system); over 18 years old; able to walk continuously and comfortably for at least 200 metres during each test-condition; and able to understand both written and spoken English. The exclusion criteria were to: self-reported history of falls or dizziness while standing or walking; unhealthy residuum (evidence of cuts, or open wounds); and/or history of renal failure (to refer the changes in residuum volume to the suspension system, not to other factors such as renal failure).

Two people were available for each of the walking trials, in case an extra person was needed to ensure the safety of the participant. In addition, a gait belt around the patient's pelvis was available to increase safety during testing. This approach minimised the risk of injury if a trip or fall occurred and is common practice when testing particularly vulnerable populations.

141 Table 2: Participants' characteristics.

Participant	Gender	Age (Years)	Height (m)	Mass (Kg)	Time since amputation (Years)	Cause of amputation	Amputation side	Mobility grade (*)
1	Male	67	1.79	101	32	Trauma	Left	K3
2	Female	37	1.64	85	4	Vascular	Left	K2
3	Female	27	1.67	57	27	Congenital	Left	K3
4	Male	58	1.80	102	30	Trauma	Left	K2
5	Male	57	1.74	84	36	Trauma	Right	K2
Mean ± SD		49.2 ± 16.6	1.73 ± 0.07	85.8 ± 18.2	25.8 ± 12.6			

142 (*) K-levels refer to the Medicare Functional Classification Levels (MFCLs) (11). K3 level corresponds
143 to community ambulation; K4 corresponds to recreationally active.

144

145 ***Equipment***

146 A bespoke test-prosthesis was built to allow participant trials to be undertaken while walking with a
147 SSSS, a modified SSSS, and a VASS (*Table 1*), as shown below in *Figure 1*.

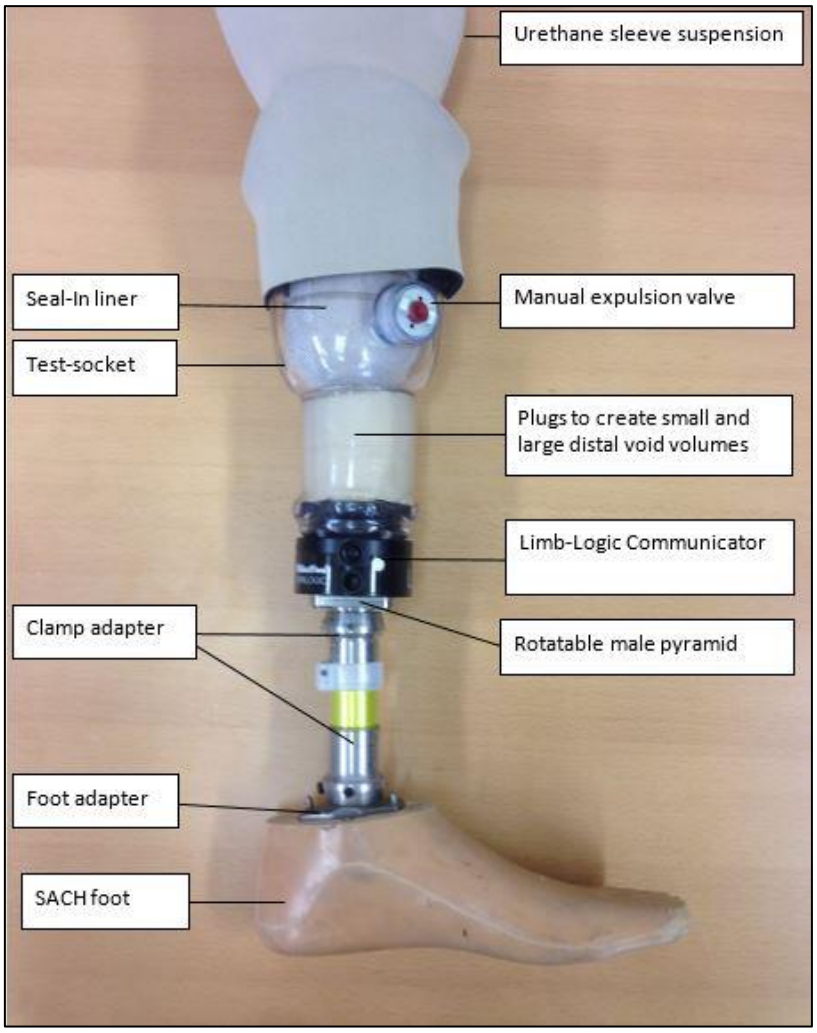

Figure 1: The main components of the test-prosthesis.

The volume of the air chamber varied a little for each participant, as typical prosthetic practice during rectification is to leave a small distal void in the socket. In pilot work[1], eleven prosthetists in Jordan, Saudi Arabia and the UK were asked to estimate the depth of plaster they would typically add to the distal end of a trans-tibial cast. Estimates varied from 0cm (in the case of manufacturing a socket to be used with a silicon liner) to 0.5-1cm for a socket to be used with a soft pedilin socket. Based on this, 7 randomly selected residual limb models were extended by 1 cm distally using Omega Tracer CAD

[1] Estimating the distal void volume between residuum and socket based on typical prosthetist's practice.

software and the resulting model volume compared with the original. The findings suggested a typical value for the distal void to be around 60 ml. We fabricated the cylindrical distal void (or air chamber) to be around 100ml in volume, to be of a similar scale to the original distal volume, while also being implementable. In the 'active volume' configuration, the socket distal void was filled with the three plugs (*Figure 2*). All three plugs were made from closed cell foam (i.e. rigid pedilin foam).

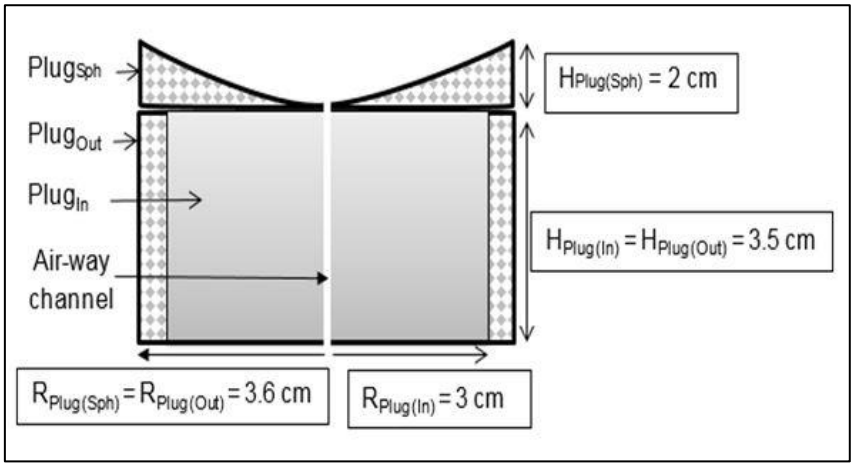

Figure 2: A schematic drawing, showing the geometry of the plugs (side view). During test-conditions A and C, all plugs will be kept for small distal void volume, while PlugIn will be removed to create a large distal void volume (additional 100 ml), for test-condition B.

Residuum volume measurement

The OMEGA tracer system (Ohio Willow Wood, Ohio, USA) is extensively employed within clinical practice to provide 3-Dimensional (3D) images of residuum's. In our study, it was used to measure the volume of each participant's residuum, with the liner (Iceross Seal-In X5 (3mm), Ossur, Iceland, made of silicone) already donned. This approach also allows for the markers used by the scanning system to estimate volume to remain in place across the test conditions. A hand-held laser scanner was connected to a laptop installed with OMEGA Tracer Software. Targets were attached to the participants' silicone liner covering their residuum, to enable the scanner to capture the geometry of the residuum (plus liner). The volume of particular interest lied distal to a user-defined plane on the 3D model that was created by the OMEGA Tracer software. The plane was calculated in the software using the reflective targets placed on

the distal end of the patella and a line connecting two reflective targets attached on the lateral aspect of the residuum at the proximal and distal ends. The distal end of the patella was considered as a reference point. Around 50 retro-reflective, glass bead markers were placed on the liner for image capture; however, the number of markers varied based on the participant's residuum volume.

The time between doffing and completion of image capture was not recorded in this study. However the scanning was performed by an experienced prosthetist (lead author), who judged himself to be reasonably consistent in the performance of the measurements. Trial runs prior to the full protocol suggested the time was around a minute.

In-socket pressure control with the VASS

The Limb-Logic communicator (Ohio Willow Wood, Ohio, USA) is a type of VASS, which can be used in conjunction with lower limb prostheses to create in-socket vacuum pressure, with a view to maintaining residuum volume. The Limb-Logic Communicator can run under 3 different modes.

1) Standard mode: The vacuum pump is activated to create a vacuum, based on the standard mode setting (Set point and standard range). For example, if the set point is 14 inHg with a range of 4 inHg, the vacuum pump will not turn on until the vacuum drops to 10 inHg and then the pump will turn on to restore the vacuum towards the target of 14 inHg;

2) Adaptive mode: The vacuum pump is activated to create a vacuum, based on the standard mode setting (Set point and standard range) during walking, and resting setting (Resting set point and resting range) during resting. Hence, mode 1 will activate the pump similarly while walking and resting, while mode 2 will differ the pump activation between walking and resting;

3) Standby mode: The vacuum pump will be deactivated and will not create any vacuum.

Under all 3 modes of the vacuum pump, the level of the in-socket vacuum pressure is shown through the dialogue and analogue displays.

Referring to *Table 1*, our study was designed to compare the use of the SSSS (condition A), modified SSSS (condition B), and VASS (*Table 1*, condition C). Standby mode was selected during test-conditions A and B to deactivate the vacuum pump (passive system). For test-condition C, the VASS (active system) was required and, hence, Standard mode was selected with a set point and standard range of 14 inHg and 4 inHg, respectively. This setting was based on the advice of the manufacturer, Ohio Willow Wood.

Experimental procedure

Following appropriate ethical and fitting protocols, data were collected for the three test-conditions (*Table 1*). Flat reflective markers were placed on the silicone liner to measure the residuum volume using a laser-based scanner system (see "Residuum volume measurement" above). Participants were asked to be seated for 20 minutes prior to testing while wearing the silicone liner only to reach a relatively steady-state residuum volume ($V_{baseline}$). After measuring the Residuum volume ($V_{baseline}$) the participants then donned the test prosthesis and walked for approximately 5 minutes to allow RVCs to occur. Afterwards, participants sat down to remove the socket while keeping the liner donned, and the volume of their residuum plus liner was measured (V_{doff}) using the OMEGA Tracer system. $V_{baseline}$ was measured before walking, for each of the three test-conditions. Comfort was assessed using the Socket Comfort Score (SCS), which was introduced by Downie et al (12) and validated by Hanspal et al (2003) (13). This is effectively a 'likert' scale, using a rating of 0 (for complete discomfort) and 10 (for optimum comfort). These tasks were repeated for all the 3 test conditions (see *Table 1*).

Data analysis

OMEGA Tracer software was used to calculate the residuum volume prior to and after the walking trials, for the 3 test-conditions. Residuum volume was measured between two transverse planes at the distal end of the patella and distal end of the residuum (see "Residuum volume measurement" above). Finally, Residuum Volume Changes (RVCs) was calculated as follows:

$$RVCs = \frac{V_{doff} - V_{baseline}}{V_{baseline}} * 100\% \quad (1)$$

Where, $V_{baseline}$ and V_{doff} are the residuum volume before and after walking with the test-prosthesis.

Participants' comfort data were scored between 0 (complete discomfort) and 10 (highest comfort).

As the number of participants was low, no inferential statistical analysis is reported. Descriptive statistics were presented.

Results

Residuum volume changes

The residuum volume decreased by an average ± Standard deviation (SD) of 4.2% ± 2.8%, 1.4% ± 1.4%, and 1.6% ± 1.1%, relative to the baseline volume ($V_{baseline}$), under test-conditions A, B, and C respectively.

Table3: Residuum volume change relative to $V_{baseline}$ (%) across the three test-conditions, for each participant.

Participant	**Test-condition A**			**Test-condition B**			**Test-condition C**		
	$V_{baseline}^{(ml)}$	$V_{doffing}^{(ml)}$	RVCs	$V_{baseline}^{(ml)}$	$V_{doffing}^{(ml)}$	RVCs	$V_{baseline}^{(ml)}$	$V_{doffing}^{(ml)}$	RVCs
1	1312	1266	-3.5	1305	1290	-1.1	1296	1284	-0.9
2	1660	1642	-1.1	1637	1631	-0.4	1629	1613	-1.0
3	888	845	-4.8	846	814	-3.8	869	841	-3.2
4	1567	1521	-2.9	1555	1540	-1.0	1556	1547	-0.6
5	1216	1112	-8.6	1266	1257	-0.7	1260	1229	-2.5

Figure 3 shows the Residuum Volume Changes (RVCs) for the three test-conditions.

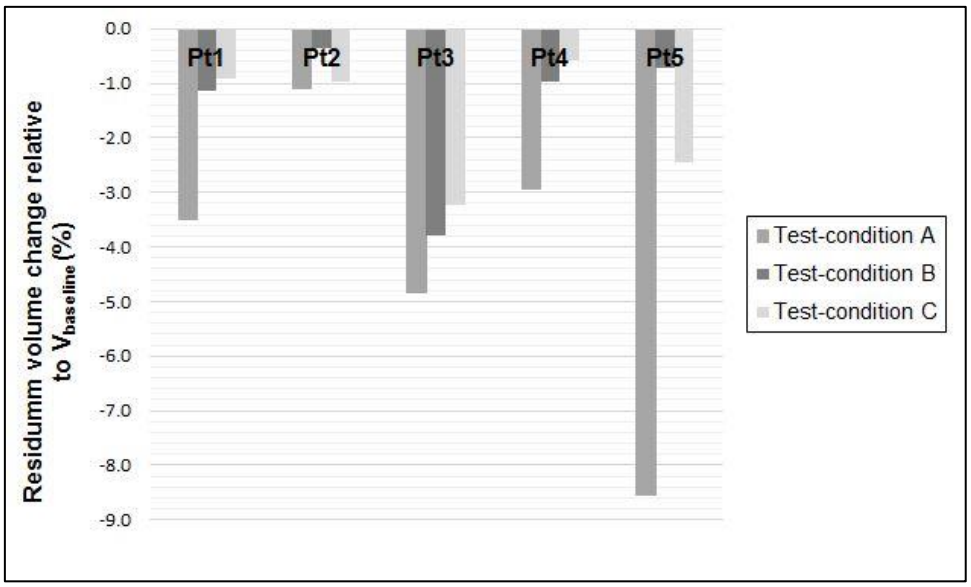

Figure 3: Residuum volume change relative to Vbaseline (%) across the three test-conditions, for each participant.

Comfort

The comfort (out of 10) average ± SD was 7.6 ± 2.1, 6.4 ± 2.1, and 7.2 ± 1.8 during test-conditions A, B, and C respectively.

Figure 4 shows the comfort scores for the three test-conditions.

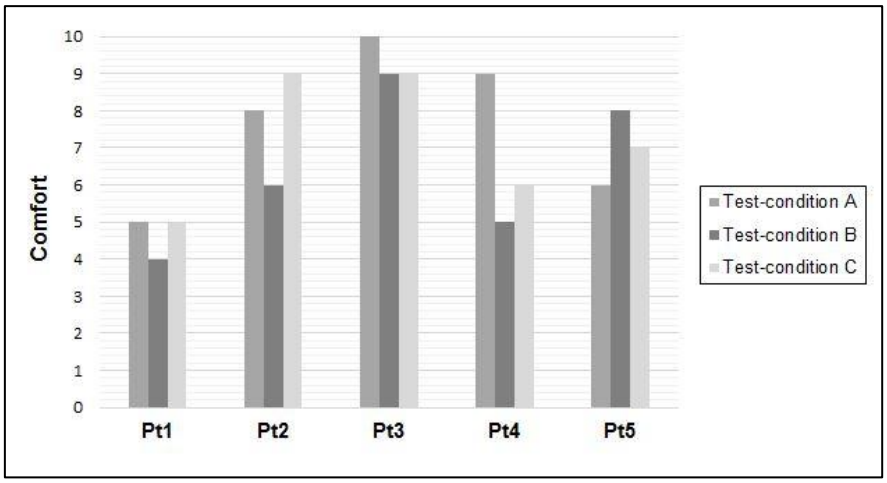

Figure 4: Mean comfort scores (0 to 10 (maximum comfort)) for the three test-conditions (Mean ± SD), for all participants.

Discussion

This study investigated the effects of a modified passive socket system on short-term changes in residuum volume and comfort.

Pts 1, 3 and 4 all showed a similar trend, with the largest decrease in volume relative to baseline seen in condition A, followed by conditions B and C. These results were broadly consistent with our assumption that using a modified SSSS with a large distal void volume (test-condition B) may decrease the in-socket air pressure and this, in turn, may reduce the volume reduction during walking, when compared to a SSSS with a small distal void volume (test-condition A). Indeed, in these three participants the reduction in RVC is similar to that achieved with a standard vacuum assist socket (test-condition C). For Pt2, the differences between test conditions were less than 1%. It was interesting to note that this participant walked with a cane which may have influenced the weight being put through the sockets. We also noted a high degree of sweating in this participant; possibly due to being new to the silicone liner (he usually wears a pelite liner). With regard to the comfort scores, condition B was ranked either the most uncomfortable or equal worst by all participants, except Pt5.

Referring to *Figure 5*, comparing the results with published data from other studies using small distal volumes (3, 7, 9) gives some confidence in the findings.

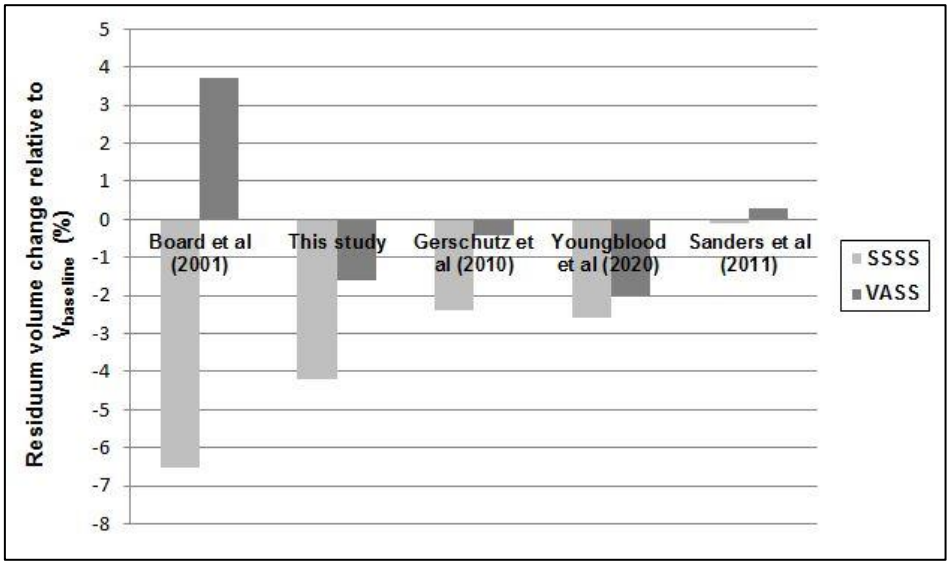

Figure 5: A comparison of residuum volume changes relative to Vbaseline (%) from this study and associated literature (1-3, 8), calculated using formula (1). Positive and negative signs indicate increase and decrease in residuum volume respectively. Note – different protocols were used in each study.

Board et al (2001) (7) showed that residuum volume decreased by an average of 6.5% (-11.3% to -1.7%) and increased by 3.7% (-1.6% to 8.5%), relative to $V_{baseline}$, with SSSS and VASS respectively. Board et al (2001) noted that the participants may have used their prostheses for up to 2 hours prior to the session and may not have been given enough time for the volume to return to a steady-state $V_{baseline}$. Further, they reported using slightly large-fitting test-sockets, which may also have affected the changes in residuum volume. Finally, there were differences between the amputee participants, including the cause of amputation, which may have influenced the results (7).

Sanders et al (2011) (3) reported that the residuum volume decreased by an average of 0.1% (-0.5% to 0.3%) and increased by 0.3% (-0.6% to 1.2%) while using the SSSS and VASS respectively (3). The bio-impedance technique used makes direct comparison with the results difficult. However, a few points are worth noting. In our study, an electronic vacuum pump was applied, unlike the mechanical one used in

Sanders et al (2011) (3). The electronic pump can create the vacuum pressure during walking, while the mechanical pump would release pressure above atmospheric pressure during the stance phase only. In addition, data were collected over approximately 3 hours in this study, while in Sanders et al (2011) the time period for collection was less than 40 minutes. Finally, participants in this study were not fitted with the VASS system before the second visit. By contrast, Sanders et al (2011) fitted the participants with the VASS system 3 to 4 weeks prior to data collection.

Youngblood et al (2020) (8) reported that residuum volume decreased by an average of 2.6% (0% to -4.8%) and 2% (0.2% to -5.4%), relative to $V_{baseline}$, for SSSS and VASS respectively (8). The bio-impedance technique used to measure the extracellular residuum volume estimates volume from the anterior and posterior aspects only (8), while in this study, the total residuum volume was considered. This made the direct comparison with these results hard. In this study, all the amputee participants were fitted with a bespoke test-prosthesis (i.e. same prosthetic components), while in Youngblood et al (2020) (8) the prosthetic components (suspension, seal type, socks, and liners manufacturers) differed among the participants. This study was designed with random-order test-conditions, in contrast, Youngblood et al (2020) (8) was designed with a fixed-order. Finally, participants in this study were not fitted with the VASS system before the second visit. By contrast, participants were already fitted with VASS, prior to data collection, in Youngblood et al (2020) and this may have impacted on our findings (8).

Gerschutz et al (2010) (9) reported that residuum volume decreased by an average of 2.4% (-1.6% to -2.9%) and 0.4% (-0.3% to -0.5%), relative to $V_{baseline}$, for SSSS and VASS respectively.

The main limitation of this study was the low number of participants. Although this meant that inferential statistical tests were not conducted, the case study results did suggest that the use of a larger distal volume could be worth exploring further. However, the reduction in comfort reported by most participants in the test condition B suggests an alternative design of the socket with the larger distal volume

is needed. Finally, the changes in baseline volume across conditions were a confounding factor. Future studies should explore more robust approaches to capturing residuum volume in real time, and use this method to control baseline volumes across conditions.

Conclusion

The performance of a SSSS in maintaining the residuum volume may be improved by fabricating the prosthetic socket with a larger distal void volume (additional ~100 ml); however, further studies on the effect of sweating on residuum volume changes are also required. In clinical practise, the larger distal void volume should be re-designed to provide a more aesthetic appearance than that of the test socket, improve comfort, and to reduce the overall length.

Word count: (2557 words)

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