# Volume interface issues between the residuum and prosthesis in lower limb amputees and their current solutions – a literature review

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Year 4

**Abstract**

In the lower limb amputee population, effective rehabilitation is dependent upon the success of the prosthesis design, in regards to comfort and usability. However, there is poor prosthesis satisfaction and a large abandonment rate owing to interface issues between the prosthetic socket and residual limb. Volume fluctuation in the residuum has been identified as a key interface issue addressed inadequately by current prosthetic designs. This report conducted a literature review addressing the following aims: i) what is the current research status in long and short-term volume change in different categories and levels of lower limb amputees, ii) what are the current residuum volume management technologies, iii) which are most effective and are potential candidates for further development.

Using Ovid MEDLINE, EMBASE and Web of Science, 55 studies were identified on long and short-term volume change in lower limb amputees and numerous technological solutions, with considerable progress being made over the last decade. Long term stabilisation of the residuum was found to occur between 12 & 18 months post-operatively. Short term diurnal variations in volume change were found to be influenced by category and level of amputation, daily activity levels and volume accommodation strategies such as doffing of the prosthesis and prosthetic sock wearing. Adjustable and vacuum sockets and proposed smart technologies are potential overall solutions to volume change, and limb volume stabilisation in diabetic and dysvascular amputees. Proposed designs of smart socket include adjusting the socket size on volume change via sensors to maintain a good fit between limb and prosthesis. However, as there is a lack of standardised design protocols and most evidence focuses on traumatic transtibial amputees, further research is required to give greater confidence to these conclusions.

## Introduction

In England, the prevalence of lower limb amputees (LLA) is 26.3 per 100,000 per year with significantly greater rates in the north (1, 2). The WHO estimates that there are ~40 million amputees globally (3), with the majority caused by peripheral vascular disease (4). Conflicts in Syria and Iraq have recently led to an increase in combat related amputations (3, 4, 5). In the future, these figures are predicted to increase because of rapid increases in diabetes and vascular disease in conjunction with greater life expectancy.

Aetiology of LLA in the UK:

1. Vascular disease – 90%, consisting of peripheral arterial disease (PAD) – 60%, Diabetes mellitus (DM) type 2 – 30%
2. Trauma – 5%
3. Neoplasms – 1%
4. Other – 4% (6)

Regardless of aetiology, LLA causes physical disability that has a negative impact on quality of life (7). Apart from the great disability of relearning to walk, substantial residual limb volume and shape change post-operatively and diurnal volume change in "mature" limbs causes limb-prosthesis interface issues (5). Poor socket fit leads to pain and pistoning (residual limb slides up and down within the prosthetic socket while moving), which generates heat and humidity, resulting in skin blistering and infection. Furthermore, high pressure and shear stress on limb tissues can cause pressure sores and many amputees will have poor healing ability due to existing PAD or DM. In addition, altered stress distribution and limb loading by the socket reduces proprioception and alters gait biomechanics, resulting in excessive energy use whilst mobilising and an increased risk of falls (3, 8, 9). Any combination of these factors can ultimately lead to poor prosthesis satisfaction. Abandonment rate is approximately 25-57% (3) and results in further loss of mobility and independence. Currently there are many designs of socket available, however none adequately address the issues listed above and there is no guidance on which socket solution is best suited to different categories of amputee.

Traditional sockets are not volume adjustable and layers of socks between the liner and socket are needed to accommodate volume changes. Other styles of socket such as manually adjustable sockets have limitations such as over-tightening which may lead to long term consequences in stump deformation, mass loss and pressure damage (3). Furthermore, the constant need to make volume adjustments to the size of the socket to combat short term diurnal residuum volume change through adjustable mechanisms or addition of socks or doffing the prosthesis itself is impractical for many individuals, especially when not at home. This limits their choice of daily activities, reduces their quality of life and leads to negative health outcomes associated with a more sedentary existence.

The aims of this review, which differentiates it from other reviews on volume change in LLAs (3, 4, 5, 9, 10), were to:

1. Elucidate the current status of research in short and long-term volume change in the residuum compared to a review by Sanders & Fatone in 2011 (5). Their systematic review in 2011 investigated what is known on measurement and management of residuum volume change in LLAs and how this change effects clinical care in these patients.
2. Investigate if amputation type affects short term residuum volume changes.
3. Summarise current volume accommodation technologies to find the most effective and suggest which could be developed further.

Short term residuum volume change will be defined as daily volume change and volume fluctuations in residuum on activity. Long term volume change will be defined as change in residuum volume from amputation to 18 months and onwards. This review further differs from others of this nature, as it focuses on the research status in volume changes in LLAs, whereas many additionally include pressure and temperature change (3).

**Methods**

Figure 1 summarises the search method. This search included studies between January 1995 and March 2020. Databases searched were Ovid EMBASE, Ovid MEDLINE and Web of Science. The key search terms were; adult, female, male, middle aged, amputation stumps, amputees, artificial limbs, prosthesis, computer-aided design, femur, hemipelvectomy, hip joint, leg, lower extremity, disarticulation, suction, vacuum, bone neoplasms, osteosarcoma, phantom limb, time.

Inclusion criteria listed was used when screening for eligible papers:

Papers containing the following in either titles, abstracts or keywords: Residual limb volume, Residual limb shape, Type of amputation: (Transtibial amputees -TTAs, Transfemoral amputees - TFAs, TKD, THD, hemipelvectomy), Skin changes in LLAs, Volume change accommodation technology for LLAs, Management of residuum of postoperatively and quality of life.

**Figure 1: - Flow chart of study selection**

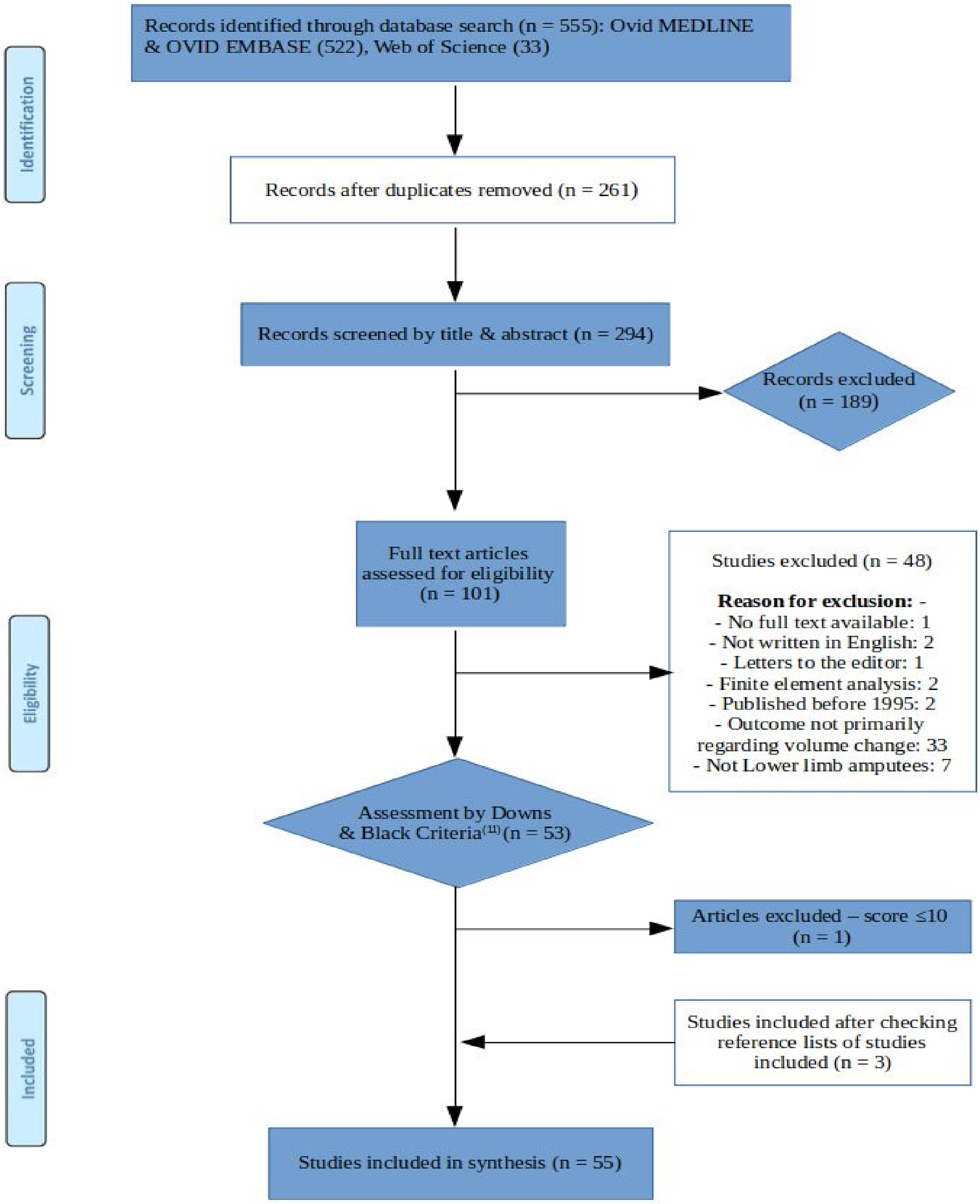

**Table 1.** A summary of key results for long and short-term volume changes in the residuum of LLAs for different categories of amputees:

| **SHORT-TERM VOLUME CHANGE** | | |
|---|---|---|
| | **TTAS** | **TFAS** |
| **DIURNALLY** | Volume decreases throughout the day (12-15).<br>Greatest volume reduction in morning.<br>Greatest volume loss in posterior compartment of thigh (15). | |
| **ON ACTIVITY** | Linear -2.2%/hr median change on cycles of sitting, standing & walking (13).<br>Sit-Stand results in greatest fluid loss & greater activity rates minimises this (16). In healthy subjects walking causes greatest fluid gains.<br>Intermittent doffing of the socket stabilises volume changes quicker (14) & volume change over time post doffing fits single term and two-term exponential functions (17, 18). | Pre & post 20-minute walk: 1.25 – 3.09% (19-22).<br>Amplitude of volume change is most influenced by physical activity. |
| **FACTORS AFFECTING AMPLITUDE OF CHANGE (12)** | Diet<br>Caffeine<br>Alcohol<br>Sock use | Doffing appears the main cause of total volume change. |
| **VASCULAR AMPUTEES** | Experience greater fluid rate & volume loss diurnally & on activity than other amputee categories (13, 16, 23-25). | |
| **DIABETIC AMPUTEES** | On activity: -3.3% mean volume change compared to -0.7% in healthy subjects (19, 24). | |
| **TRAUMATIC AMPUTEES (12)** | On standing: Residuum lost volume compared to intact limb volume gain. | |
| **LONG-TERM VOLUME CHANGE** | | |
| | **TTAS & TFAS** | |
| **RANGE OF VOLUME CHANGE** | Reduction of 17-40% volume compared to original limb (5).<br>Volume does not correlate well with limb circumference. | |

| | |
|---|---|
| **VOLUME REDUCTION POST-AMPUTATION** | Follows negative exponential function on modelling (26, 27).<br>200.5ml (9.7% initial volume) volume decrease per week post-amputation (28). |
| **TIME TO LIMB STABILISATION & FIRST PROSTHESIS FIT** | There is no exact time post-amputation that limb stabilisation occurs or for best first fit of prosthesis.<br>Time for best fit for first prosthesis ranged from 94-150 days (29-32).<br>Limb volume stabilisation occurs between 12-18 months post amputation. |
| **FACTORS AFFECTING AMPLITUDE OF CHANGE** | Fluctuations in long term volume change correspond with body weight change. |
| **CHANGES AFFECTING TFAS ONLY (26)** | Over a 10-year period one study found proximal residuum volume increased despite compressive effects of socket and liner. This is thought to be due to the more proximal location of remaining muscle bellies (26). |

## Results

### Current solutions to residuum volume change

25 papers were identified that investigated solutions to accommodate residuum volume change. They demonstrated a wide variety of socket designs and techniques available to accommodate or control residual limb volume fluctuations. Existing and developing solutions include:

1. Standard patellar surface bearing and total surface bearing sockets with no volume control (3, 9, 10).
2. Adjustable sockets with movable panels either by manual or motor control, to resize socket on residuum volume change.
3. Vacuum sockets.
4. Air or fluid-filled socket inserts (3, 33).
5. Pad inserts (3).
6. Stump socks (34).
7. Flexible volume changing & “smart” liners (3, 22 ,35) (see Table 2 & Figure 2).

**Table 2.** Current status of “smart” and electronic liner research

| PROPOSED EFFECTIVENESS | DESIGN ISSUES |
|---|---|
| Auxetic (3, 22) foam inner layer which accommodates for volume fluctuations, with an incompressible fluid matrix using pressure sensor output from an electrical sensor liner layer (22).<br><br>Has the ability to secure the prosthesis on volume fluctuation, regulate pressure and thermal distribution using real time feedback from integrated sensors (22). | Variable volume gel liners are constrained by the operating pressures required (27). |
| Proposed fluid charged liner of visco-elastic material for trade-off between pressure stability & comfort (35).<br><br>Porous matrix is elastomeric foam with a gel matrix controlling viscosity, integrated pressure sensors & a valved fluid permeable liner. Benefits are dynamic control of local high pressure contact hot spots and volume change accommodation (35). | Lack of data on how elasto-viscous material performs in dynamic gait conditions, i.e., at swing phase of gait in terms of pressure, shear and volume control. |

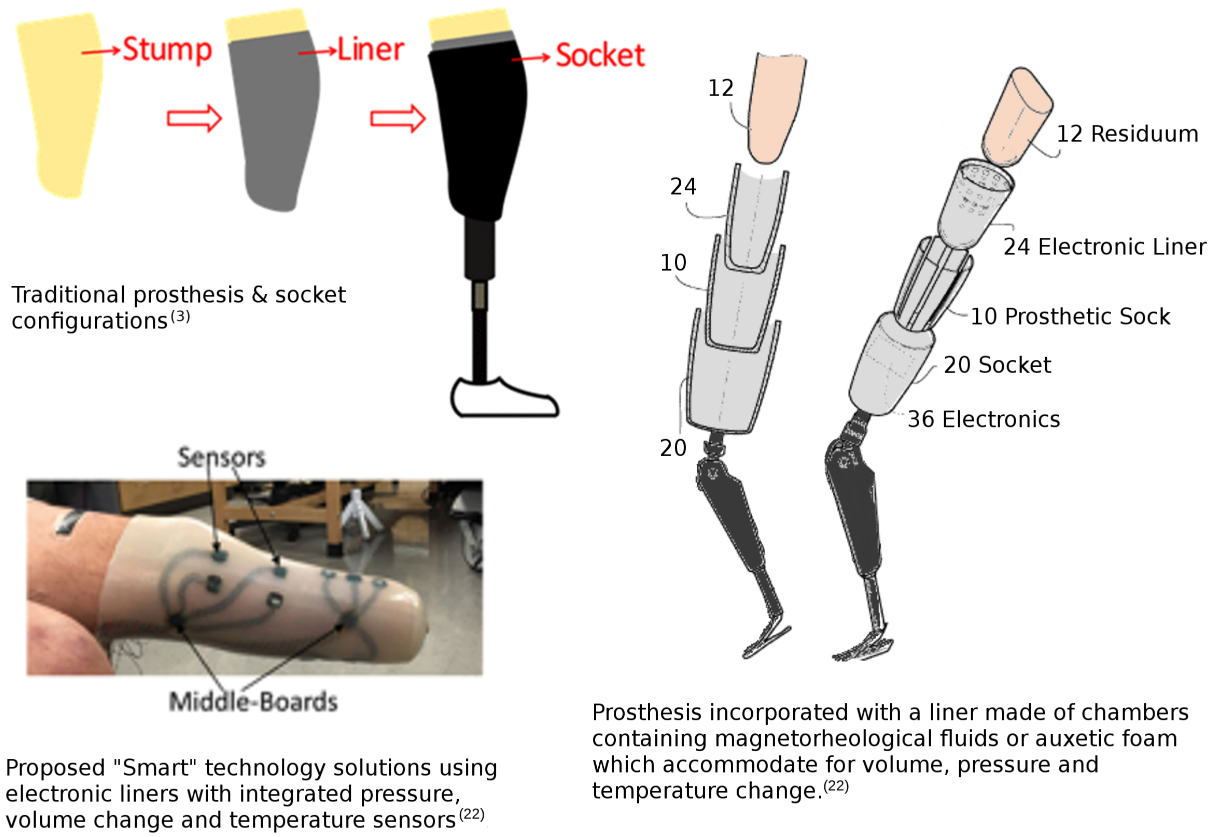


**Figure 2.** Traditional prosthesis & socket configurations with the residuum & proposed "smart" prosthesis solutions.

## Discussion

Compared to other reviews (3, 4, 5, 9, 10), this report elucidated the status of research progress in short and long-term volume changes in the residuum since Sanders & Fatone in 2011 (5), investigated if volume change is affected by different categories of amputation and summarises current volume accommodation technologies finding which may be most effective and could be further developed. 55 studies conveying 38 years of research were reviewed, the majority covering the past 23 years. Limb volume decreases post-operatively following a negative exponential function with the rate reduction greatest post amputation and then slowing gradually over time (range -5.0 – -35.0% volume loss at the first 100 – 200 days in TTAs (29, 32)). This is thought to be due to changes in soft tissue distribution, muscle atrophy, venous sufficiency and decreasing post-operative oedema. Stabilisation in volume occurs between 12 & 18 months with no exact time for first prosthesis fit identified. The timing of prosthesis fit is important as muscle atrophy and patient de-conditioning may potentially lengthen rehabilitation and reduce long term functioning (29, 36). Short-term changes follow diurnal variations (range -11.0 – +7.0%) (3). Residuum volume is found to decrease throughout the day, with rate of loss highest in the morning with posterior leg compartments in TTAs having greatest fluctuation. Generally, volume loss is greatest on standing, and walking in healthy subjects can lead to volume gain (5, 14-16, 18, 20, 25, 37). This is believed to be due to increased arterial drive and explains why those with PAD who have poor blood flow to the lower limbs lose volume on standing and walking (14, 16, 37). Several studies demonstrated intermittent doffing of the socket throughout the day is effective in volume management.

Results of this review suggest dysvascular and diabetic patients have greatest volume fluctuations in the residuum. However, this was a preliminary finding in many studies due to sample sizes and lack of quantifiable data (23). Traumatic amputees have more stable residuum volumes. This greater ability to regulate volume change is thought in part due to generally younger age and better overall health.

Lastly, the level of amputation appears to influence the amount of short term volume change in the residuum. This review concluded short term TFA volume change (19, 21, 26) may be less than that of TTAs (TFAs post 20 minute walk, range = -1.7 – 3.1% (21), TTAs post 5 minute walk, range = 2.4 – 10.9 (13, 18)). This conclusion differs from a patent by Wang et al which states that TFAs experience the largest anatomical volume fluctuations of any LLAs (21). However no citations were given for this statement, so it could not be investigated further and a search of literature did not elucidate different research.

There are multiple solutions to volume change with strategies ranging from different socket types to stump socks. However none are ideal as many solutions are uncomfortable to wear and use a lot of energy expenditure to walk (25). The majority of studies reviewed investigated the effects of vacuum suspension sockets on short term volume change or were small case studies into suitability of adjustable socket designs. Vacuum suspension may be more suitable for reducing volume fluctuations in dysvascular and diabetic amputees (25, 8, 38-41). Adjustable modular sockets are a preferable volume accommodation strategy for extreme hourly volume fluctuations (20). These findings are important because they indicate which categories and levels of amputee have the greatest predicted volume changes. This could be used to improve personalised care, as the cause of amputation could be part of the selection criteria when deciding the socket type and volume management strategies required (3, 27, 42).

The main limitation of this review is that most studies included were very small studies of traumatic TTAs. Likewise, none were randomised controlled experiments, but this likely reflects the inherent nature of the population studied. This review suggests a lack of standardised protocols for investigating each element of volume change, resulting in a lack of comparable clear data and a lack of clarity in ascertaining which part of the protocol caused greatest influence on volume change. Further statistical analysis to compare studies is needed before combining data in future reviews.

There is a risk of bias in this review's findings as most papers reviewed are from one author or associated authors. The majority of studies did not look at the outcomes of this review as their aims. This search was not a systematic review, and only papers in English were included. In attempt to counter these limitations a broader numberof papers were included, to corroborate as many results by varied authors as possible. Further research into long and short-term volume change and assessment of the suitability of current socket solutions in different categories of amputee, different patient health characteristics and levels of amputation is needed. Ideally larger sample sizes, standardisation of experiment protocol and randomisation is required to give high quality generalisable data.

Future development of automated panel adjustable sockets should be explored. Using an electronic sensor liner with a mobile app, feeding back pressure and volume data to an automated adjustable socket could be an effective solution. Additionally, steps to develop smart sockets will need to investigate the feasibility of electronic sensor liners (4, 22) with adjustable socks or sockets using carbon nanotube thin film sensors, multimodal sensors and phase change materials. This proposed configuration of liner, sock and socket could be a complete solution to pressure, temperature and volume fluctuations of the residuum.

**Conclusion**

Progress has been made in what is known about long and short-term volume change in the residuum since reviewed by Sanders & Fatone in 2011 (5). Namely, more studies exist investigating the short and long-term changes of the residuum, and though many use different experimental methods, in general findings are broadly comparable. However, due to differences in research protocols, sample sizes and data scarcity in different categories of amputees, further work is required to give confidence to insights drawn since this study. A standardised experimental protocol for this using a large-scale study of amputees would best to generate more reliable and reproducible findings. However, this is limited by the small population of amputees and ability of many to take part in studies. Further research into how the type of amputee and level of amputation affects both short term and long-term volume change of the residuum is needed. This would help generate a more complete modelling of residuum volume behaviour, and therefore guide the improvements in design of existing prosthetic technologies.

Current prosthetic technology research has shown two potential options for further development:

1. Further research to refine existing technology and development of guidance for socket prescribing in different amputee categories and levels.

2. Development of smart sockets as self-adaptive real time closed loop solution for management of volume, pressure, and temperature change.

**Acknowledgements**

Many thanks to Dr Elena Seminati, Lecturer and Research Associate in Clinical Biomechanics at the University of Bath for supervising and providing invaluable guidance for this project.

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