A Study of Residual Limb Health

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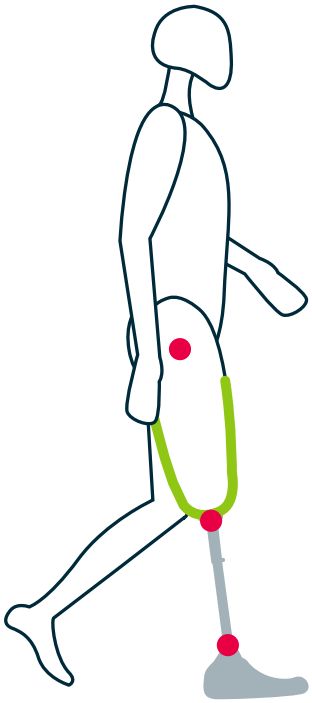
Residual Limb Health

While prosthetic technology edges ever closer to restoring natural performance, there is also a more basic consideration – the residuum-socket interface. Even with the world's most advanced prosthetic limb, if it is not comfortable to wear and walk with, amputees will not use it. Socket fit and comfort are inextricably linked to residual limb health, making this a critical element in achieving and maintaining a successful prosthetic prescription.

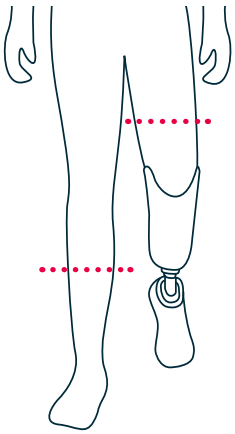


In addition to the **ankle, knee** and **hip**, the **residuum-socket interface** acts as an extra lower limb joint

Biomechanically, the residuum-socket interface behaves as an extra joint in the lower limb[1–3]. There is potential for relative movement in three directions and relative rotation about three axes[1,2]. With excessive movement, a loose joint can lead to wear (e.g. chafing and rubbing) and a loss of control. To further complicate matters, the residuum size and shape can vary and the loads applied to it are drastically different to what nature intended.

Another consideration must be the cause of the amputation in the first place. The biggest causes of amputation in the developed world are vascular health problems, such as diabetes[4]. Over 23 million Americans (7% of the population)[5] have been diagnosed with the condition, costing $237 billion in direct medical costs in 2017[6] – an increase of 35% since 2012[7]. In the UK, it costs £1.5 million an hour[8] (or 10% of the total NHS budget) to treat the 3.8 million diagnosed with the condition[9].

A common side effect of dysvascular conditions is poor circulation that results in the formation of ulcers and wounds. When excessive pressure and shear loads act on the soft tissue, it is susceptible to damage and can't heal as quickly because poor circulation does not allow enough blood transport of nutrients to, and waste product removal from, the affected area[10,11]. A large proportion of these healthcare costs relates to the treatment of these ulcers and wounds[12]. Another side effect is nerve damage, resulting in reduced sensation that can lead to delays in detection of tissue damage, allowing time for wounds to become infected[13]. Diabetic foot ulcers are a



60.7%

The incidence of dysvascular amputees needing a second amputation within 5 years of the first[15]

leading cause of amputation[12] and residual limb pressure ulcers are a leading cause of reamputation[14–16]. Following a dysvascular amputation, there is a 21% chance that a second, more proximal amputation will be required within a year[14–16]. The rate of contralateral amputation is higher for amputees with diabetes than those without[14].

Three areas must be considered in order to make the socket connection as sympathetic and compatible as possible.

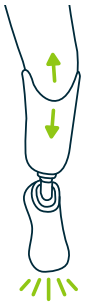
Suspension

This is the method through which the socket is secured to the residual limb. A strong connection reduces relative movement of the limb inside the socket and thereby improves prosthetic attachment. The user's proprioception or awareness of where their prosthesis is will be improved, reducing the chance of tripping. Many factors can affect suspension and socket fit.

Relative Movement

The axial movement of the residual limb relative to the socket is known as pistoning. A prosthetist will aim to minimise this movement because it can lead to high pressures and loading rates at the distal end of the residuum and shear forces along its length. Additionally, pistoning can affect prosthetic control. A poor connection affects the user's proprioception, leading to inconsistent foot placement, ground clearance and even tripping, which can, in turn, severely affect confidence. It is well known that lower limb amputees have a high risk of falling, with 58% falling at least once every 12 months[17]. Many also report a loss of prosthetic confidence and greater fear of falling[17].

The connection between the residual limb and the socket can be improved by creating a vacuum between them. One way of achieving this is to wear a suspension sleeve over the top of the socket, in order to create an air tight seal around the residual limb. A one-way valve is fitted at the distal end of the socket and as the amputee puts weight on their prosthesis, air is expelled from the valve. Next, when the limb is lifted, the valve doesn't allow air to pass back into the socket, creating negative pressure around the interface and a strong connection over the whole residuum surface. This method of suspension is sometimes called 'suction suspension'.



Elevated Vacuum reduces pistoning, compared to pin-lock[20], by

83%

This method of suspension can be further enhanced by drawing more air from the interface, increasing the level of vacuum generated with the use of a mechanical or electrical pump. This is known as Elevated Vacuum (EV). EV has been shown to be very effective at minimising pistoning, with reductions of over 69% and 83%, compared to suction[18,19] and pin-lock[20] suspensions, respectively. Many researchers and practitioners have reported similar observations[21–24]. One study found that none of its trans-tibial EV users reported multiple falls, while 75% of the non-EV users did[25].

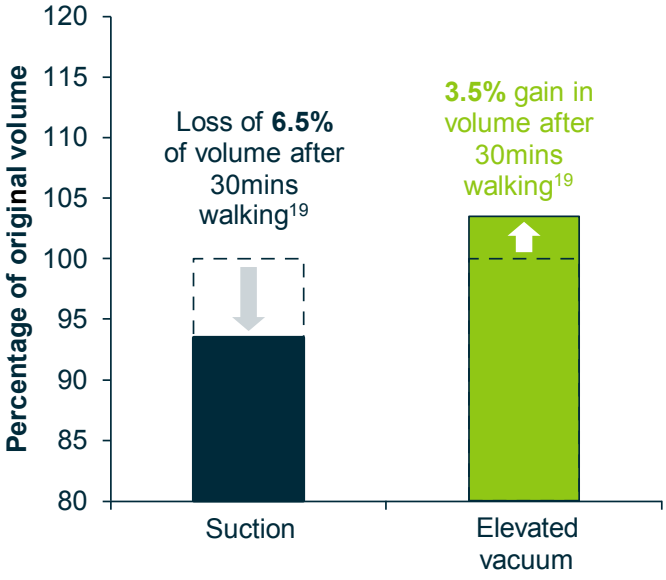
Other research used functional clinical tests to determine the effect of EV on the capabilities of elderly, dysvascular amputees[26] – a group that is particularly susceptible to falls[27,28]. This study showed significantly improved results in balance tests for both K3 and K2 mobility walkers.

Improvements at the residuum-socket interface can influence the whole body. Better foot clearance reduces the need for gait compensations, like vaulting – many studies have described improvements in the symmetry of amputees' gait patterns when using EV, compared to other suspension methods[19,21,29,30].

Residuum Volume

The volume of the residual limb is another factor that influences socket fit and comfort. While a socket might be a perfect fit for the residual limb when cast, a loss of fluid over the course of the day affects limb volume and socket fit. A loose fitting socket will not only be less comfortable but it will also allow greater relative movement, hindering control and leading to chafing. This is a common problem; and while the magnitude and rate of daily changes are dependent on activity[31,32], a residual limb can change in volume by 12.6% over a two week period[33].

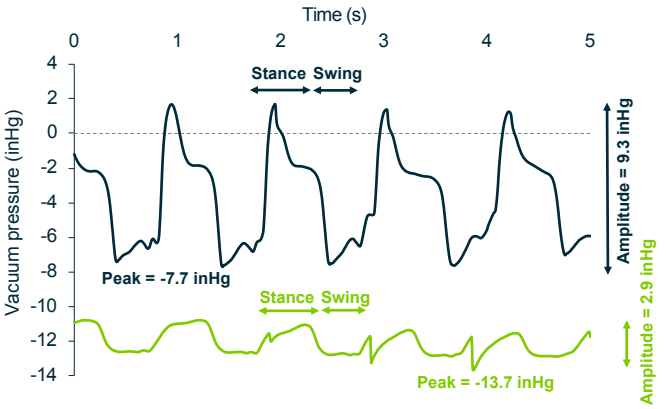
One of the first scientific publications on EV investigated the effect it had on residual limb volume[19]. Eleven amputees had their residuum volume measured before and after walking for 30 minutes, with both suction and EV suspension. While with suction there was a mean 6.5% loss in volume, for EV there was a mean 3.7% increase in volume. Other studies have since confirmed the observation that residuum volume loss is prevented by EV[21,34–36], which implies a better socket fit is maintained.



The vacuum created in the socket encourages blood flow into the residual limb, increasing the delivery of oxygen and the removal of waste product. This is especially beneficial for dysvascular amputees, who often have restricted circulation.

Consistency

When sensory control of the lower limb joints is lost, it is essential that the replacement behaves in a predictable way. Consistency of performance is vital for providing prosthetic confidence. In terms of socket suspension method, this means providing the same strong connection throughout a gait cycle, from one step to the next, and day-to-day, over the lifetime of the socket.



The difference between the vacuum levels generated by suction suspension, and those generated when using EV, can be demonstrated by using a pressure gauge[37]. Commonly, when the user bears weight on their prosthesis during stance phase, with suction suspension, the magnitude of the vacuum is low. When the leg is lifted into swing phase, the vacuum increases in magnitude (becomes more negative), holding the socket to the residual limb. Comparatively, EV retains a high level during stance phase – higher, in fact, than the peak swing phase vacuum with suction. Additionally, the difference between stance and swing phase is less pronounced, so that the vacuum level is more consistent throughout the gait cycle. For the amputee illustrated in the graph above[37], EV gave an approximate 85% increase in peak vacuum magnitude and an approximate 67% reduction in the 'amplitude' of the vacuum measurement signal.

Loading and Wound Care

The skin and soft tissue of the residual limb are particularly susceptible to damage and breakdown. Scarring from the amputation surgery may complicate prosthetic fitting with adhesions or areas of invagination. Tissue may be further affected by other comorbidities, such as dysvascularity and in the event of breakdown, which prevents prosthetic use, there will be a serious impact on the individual's quality of life.

It is reported that 41% of lower limb amputees experience residual limb skin and soft tissue problems, including ulcers, wounds and dermatitis[38,39]. Resolving socket comfort issues has the potential to drastically reduce the required number of clinic visits, while at the same time increasing the amount of time the user is able to wear their prosthesis, improving their quality of life.

Unnatural Loading

Of the reported residual limb skin problems, 25% are pressure ulcers[38]. The residual limb is particularly vulnerable to loading. Naturally, this part of the body would not be loaded in this way. Additionally, post-amputation, scar tissue is susceptible to damage due to its inelastic nature, especially if it is adherent. As a consequence, successful prosthetic rehabilitation should aim to reduce the magnitude of the loads at the residuum interface, as well as the rate at which these loads are applied.

While studies have found no significant difference in the peak positive pressure during stance phase between pin-lock and suction suspension[40], EV has been shown to reduce mean interfacial peak pressures by 4% and reduce mean pressure impulses by 7.5%, compared to suction[41]. In a survey of world-leading prosthetists, 71% agreed that EV reduced interface pressure, compared to other suspension methods, while 91% agreed it improved comfort for the patient[21]. This may explain why Socket Comfort Score (SCS) improves when using EV[42].

Changes elsewhere in the prosthetic limb can have a knock-on effect to the forces transferred to the residual limb. For example, the viscoelastic movement of hydraulic ankles, plantarflexing at heel strike, helps to attenuate the load transferred to the residuum. It reduces the peak pressure transferred to the residual limb by up to 81% and decrease the rate of loading by up to 87%, compared to rigidly attached prosthetic feet[43]. These reduced loads may be protective against the development of pressure ulcers and other skin damage.

Hydraulic ankles reduce peak residuum pressures by up to

81%

and loading rates by up to

87%[43]

It is important to remember that it is not just the residual limb, but the whole body that is subjected to unnatural loads. Gait compensations will affect the residual knee contact forces also, but research has shown that EV reduces this impact, compared to suction suspension[44]. Hydraulic ankles also reduce the demand placed on the sound limb while walking[45,46] and standing[47]. Additionally, they have been shown to reduce peak plantar-pressure under the contralateral foot[48] – something that may be of particular benefit to dysvascular amputees to protect against foot ulcers and a second contralateral amputation.

Wound Management

Residual limb health issues are by no means limited to ulcers[38]. Skin irritation and blisters can develop into wounds, which become painful, are susceptible to infection and may limit prosthetic use. This has severe implications for the user's mobility and quality of life[49].

Negative Pressure Wound Therapy (NPWT) is a common technique in medicine to promote faster healing of wounds[50,51]. The effectiveness of this technique to heal wounds following amputation surgery has been demonstrated[52]. Patients treated with NPWT have shown significantly higher frequencies and rates of wound healing than control subjects[52].

The evidence in prosthetics literature points towards EV having a similar effect. Many studies have looked at patients with existing residual limb wounds, reporting that the use of EV has allowed wearers to continue using their prosthesis whilst their wound healed[53,54] and, as an added bonus, wounds tended to heal at a faster rate when compared to alternative suspension systems[55]. Expert opinion[21] and clinical case studies[56] agree that EV is less painful than other suspension methods. As a consequence of these findings, many patients are more comfortable and more satisfied wearing their prosthesis[57,58].

Healthier Tissue

By creating a vacuum around it, blood is drawn into the residual limb, providing better circulation. This makes the tissue healthier by bringing in a better supply of nutrients and improving the removal of waste products. Non-invasive probing techniques have been used to demonstrate how EV preserves skin health on the residual limb[59]. EV improved tissue oxygenation during walking, decreased trans-epidermal water loss and attenuated reactive hyperaemia, compared to other prosthetic suspension methods. The researchers who performed the study suggested that decreasing trans-epidermal water loss preserves the skin barrier function, which protects against ulcer formation.

Climate

Modern prosthetic sockets and liners are made from impermeable materials that act as insulators and create a hostile environment around the residuum. Temperature and humidity can directly influence not only the mechanical behaviour of the interface (e.g. sweat acting as a lubricant),

but also the health of the skin and soft tissue of the residual limb.

The problem of excessive residual limb sweating has a real effect on the quality of life of amputees[60,61], with up to seven out of ten amputees are adversely affected[60,62]. Another study found that 66% of amputees reported that the amount they sweat really affects their daily activities[63]. Contrast this with 2.9% of the general population who are medically diagnosed as suffering from excessive sweating[64], also known as hyperhidrosis, and the size of the problem becomes clear.

There are many factors that contribute to this issue. It is known that trans-tibial amputees use proportionally more energy than able-bodied people during the course of their daily activities. For unilateral trans-tibial amputees, the increased effort can range from 10 to 40%, while for bilateral trans-tibial amputees, it is more likely to be closer to a 40% increase[65]. As with any increase in energy consumption, this leads to an increase in body temperature. The body's natural cooling response is sweat production.

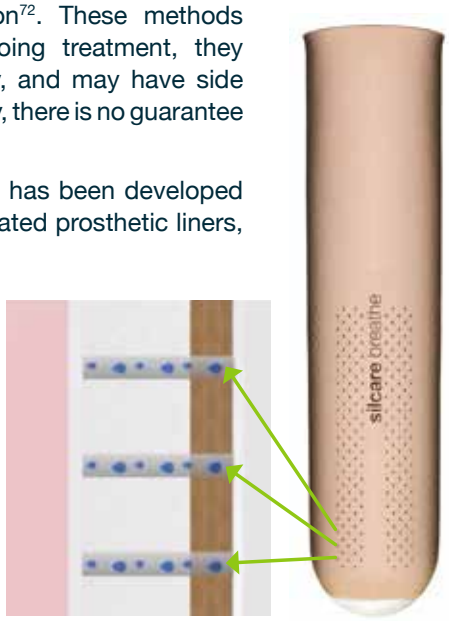
The rate of heat transfer between an object and the surrounding environment is proportional to the surface area of the object. After a below-knee amputation, a person's surface area has been reduced by 10-15%[66]. Consequently, the rate at which they can cool down is reduced. For individuals with limb loss the problem of overheating is more acute.

Localised sweating on the residual limb is particularly common due to the popularity of prosthetic liners made from cushioning materials, such as TPE gel, polyurethane or silicones. Unfortunately, while effective at reducing interface stress, these impermeable[67] liners with poor thermal conductivity[68,69] can add to the overheating problem. Sweat remains on the skin surface, unable to evaporate[70]. They also create a closed micro-climate that is moist, warm and nutrient-rich – an ideal breeding ground for bacteria. With the sweat unable to transport away, skin problems, such as dermatitis, are likely to occur[70,71]. This can be particularly problematic for the vulnerable residual limbs of older, vascular amputees. With limited mobility already, any residuum pain or problem may further restrict prosthesis use, resulting in social isolation and reduced independence.

Excessive sweating effectively lubricates the 'extra joint' at the socket interface, which can lead to pistoning, decreasing ground clearance and making a trip or fall more likely to occur. In order to compensate, an amputee may walk with gait abnormalities, making the overall gait pattern less energy efficient, further compounding the problem of overheating.

Many different approaches have been experimented with to reduce residual limb sweating. Antiperspirant sprays are available, along with more drastic solutions such as Botulinum Toxin injections, electrical stimulation and even surgical intervention[72]. These methods often involve ongoing treatment, they can be very costly, and may have side effects. Additionally, there is no guarantee of success.

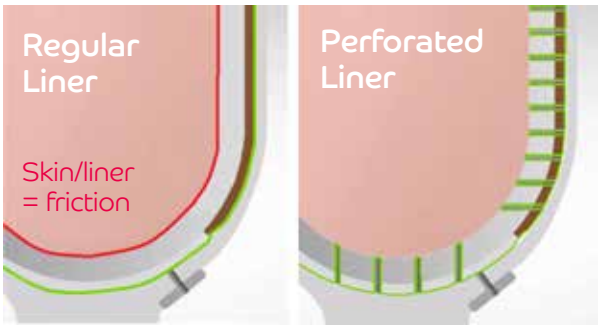
One approach that has been developed is the use of perforated prosthetic liners, which allow moisture and trapped air to move away from the skin. This keeps the residual limb dry. Research has shown the benefit this can have to skin health[73].



Combining Prosthetic Technologies

By considering the impact of different prosthetic technology on suspension, temperature, humidity and interface loads, engineers can help protect the residual limb against further health problems. Combining these technologies can further augment the benefits of each.

There is a theory that the use of EV with a perforated liner, such as Silcare Breathe, may further enhance the effectiveness for wound healing because the vacuum is acting directly on the residual limb skin[73].



EchelonVAC combines EV suspension with hydraulic ankle technology. It exploits the movement of the hydraulic piston in the ankle mechanism to draw extra air out of the socket mechanically and increase the level of vacuum inside the socket. This combines and enhances the benefits of EV with those of hydraulic ankles, including increased ground clearance[74], greater symmetry[45,75] and faster walking speeds[45,76].

Case Studies

A recent publication[73] described how these technologies can be used, individually and in combination, to help to resolve long-standing residual limb health issues.

1

One case described a 41 year old man with a traumatic trans-tibial amputation. He was a keen jogger but had problems with sweat building up in the scarring on his residual limb and causing blisters. If he jogged two days in a row, he would be in too much pain to use his prosthesis at all on the third day. Surgery was scheduled to revise the scars, in anticipation that this would help with the problem. He was fitted with a Silcare Breathe perforated, pin-lock liner and within a month he had noticed that there was much less sweat on his limb after jogging and the blistering has started to resolve. After three months, the blisters had entirely healed and he had cancelled his surgery.

2

Another case described a 45 year old man who also had a trans-tibial amputation and was keen to return to his previous active lifestyle. He regularly took part in motocross racing but he had developed a large ulcer on the back of his residual limb. He was advised by his dermatologist that the only way that it would heal would be to stop using his prosthesis for up to 5 months. His prosthetist decided instead to recast him with a Silcare Breathe perforated liner and he immediately saw the benefit. After a month, the ulcer had visibly shrunk and was being kept dry. After 13 weeks, it had healed completely.

3

The final case reported was that of a 50 year old, trans-tibial, K2 activity level amputee. He had experienced ongoing skin issues for approximately eight years, including skin maceration and infection. He was considering revision/further surgery to resolve the issues he had been experiencing. He began using a Silcare Breathe perforated liner to keep his skin dry and after a year he combined it with EV suspension and a hydraulic ankle. Following a further three months' use of this combination, the drier environment, coupled with reduced interface pressures and stronger vacuum, produced a massive improvement in skin condition.

Conclusion

Maintaining good residual limb health is crucial for any prosthesis wearer. Advances in prosthetic componentry can help to ensure a comfortable socket fit, manage the transfer of load through the limb and mitigate skin damage and infection. Combinations of different technologies work in unison to achieve the best outcomes for the user.

Perforated liners allow sweat to move away from the skin **maintaining a cool dry interface**[73]

Vacuum connection **improves proprioception and balance**[26]

Vacuum **reduces interface pressure by 7%** on average[41]

Ankle compliance with the ground **improves stability**[47]

Expulsion of air generates vacuum, **improving circulation**. This may be particularly useful for dysvascular amputees

Hydraulic ankle compliance **reduces interface pressures by up to 81%** and **loading rates up to 87%** [43]

The motion of the hydraulic ankle draws more air out and **strengthens the vacuum**

The hydraulic ankle **reduces asymmetry**[45,75] and enables a **faster walking speed**[45,76]

Improved circulation **reduces tissue fluid loss and improves oxygenation**[59]

Improved circulation **maintains residual limb volume**, helping to maintain a good socket fit[19,20,31]

Improved circulation **allows wound healing** without discontinuing prosthetic use[53-55]

A strong vacuum connection **reduces pistoning** between the residual limb and socket[18-20,22]

This improved connection increases ground clearance, which contributes to elevated vacuum **reducing the risk of trips and falls**[25]

The hydraulic ankle remains in dorsiflexion during swing, **increasing ground clearance by 18%** on average[74] **reducing the risk of trips**

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