Stability of Transtibial Socket Suspension Systems for Clinical Recommendation

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Abstract

Most currently available transtibial prosthesis socket suspension systems do not adequately secure the prosthetic to the residual limb. This leads to impaired biomechanical functionality, prosthesis control, and harm to the residual limb skin. Hence, it is imperative that the optimal suspension system is determined to mitigate these effects. It is concluded that out of three suspension systems, the vacuum-assisted suspension is the optimal solution as opposed to the suction and pin-lock suspension systems. It is shown that the vacuum-assisted suspension yields the minimum amount of pistoning, the second highest negative distal interface pressure during the swing phase of the gait cycle, and the minimal amount of residual limb volume loss. Although the pin-lock suspension has a greater negative distal interface pressure, the system tightly squeezes the residual limb in the process. This indicates that the vacuum-assisted suspension is a superior solution in this respect as it produces a marginally lesser amount of pressure without bringing about residual limb skin issues.

Intended Audience: Medical practitioners that are in a position to prescribe and recommend transtibial prostheses to amputees. This paper focuses on the stability of transtibial suspension systems which is only one factor in determining the proper suspension for an amputee. Therefore, it should be used in conjunction with other information (comfort, ease of donning/doffing, cost, level of physical activity, etc.) to prescribe the system that will yield the greatest user satisfaction.

I – Introduction

There are approximately 1.3 million individuals that live with limb loss in the United-States alone. Of this population, a little over 378,000 people suffer from transtibial amputations which is an amputation that is performed across the tibia [1]. These lower limb amputations can be caused by one of many health issues such as complications from diabetes, peripheral vascular disease, and trauma related injuries [2]. Such operations often result in a significant reduction in the quality of life of amputees. The prosthetic limb was designed to mitigate this effect by reintroducing a level of limb functionality. However, a majority of the currently available prosthetic limbs do not sufficiently accomplish this objective. The suspension systems of most transtibial prostheses do not effectively secure the prosthesis to the residual limb. Therefore, it would be of interest those living with transtibial amputations to determine the suspension system that most effectively mechanically mates the prosthetic to the natural limb. To determine this, three suspension systems are considered: the vacuum-assisted suspension system, the suction suspension system, and the pin-lock suspension system. These potential solutions will be evaluated based on pistoning, distal interface pressure, and residual limb volume loss. According to these metrics, the transtibial suspension system that most effectively secures the prosthesis to the residual limb is the vacuum-assisted suspension system.

2 – Background

2.1 - Transtibial Prosthesis Background Information

The transtibial prosthesis is a prosthetic limb that is designed for amputations that have occurred across the tibia. It is composed of three primary components: the prosthetic foot, the pylon, and the socket. These parts can be seen in *Figure 1*. The prosthetic foot is the component of the prosthesis which interacts with the ground. It has the role of bearing the weight of the user and translating the forces felt at the ground to the pylon. The pylon is the shaft that connects the socket to the prosthetic foot. It also has the role of bearing the weight of the user in addition to communicating the forces from the prosthetic foot to the socket. The socket is the mount between the residual limb and the prosthetic. In other words, it is the component which houses the residual limb. It translates all the forces felt throughout the prosthetic to the natural limb as well as attaches the prosthesis to the user. The socket is the critical component of the assembly as it is the sole interface between the user's natural and artificial limbs.

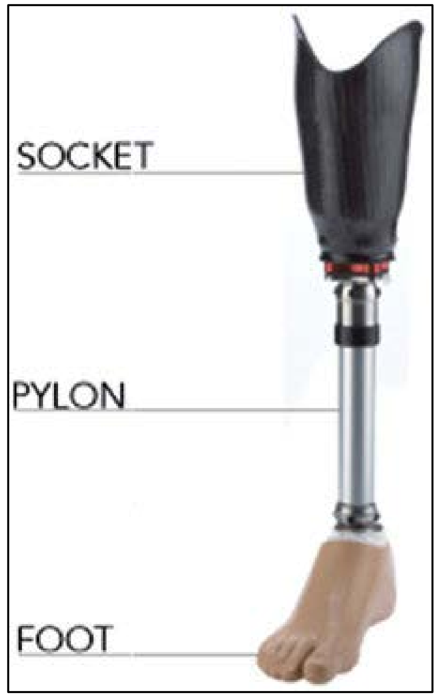

Figure 1: Primary components of a transtibial prosthesis [3].

The socket characteristics are governed by the socket shape, the socket materials, and the suspension system [4]. The suspension is the mechanism by which the prosthesis is secured to the residual limb. Its role is to create a mechanical linkage between the residual limb and the prosthetic limb that most closely mimics the continuity of a natural limb. In other words, the suspension system must connect the prosthesis to the residual limb in such a way that mitigates the perception of the tibia being formed of two disconnected bodies: the prosthetic and the residual limb. Therefore, it must generate a sufficient force to attach the socket to the natural limb to produce the least amount of relative motion between these two bodies. However, the suspension system must accomplish this task while causing no harm to the residual limb.

2.2 - Problem Definition

Most currently available transtibial socket suspension systems do not effectively secure the prosthesis to the residual limb. These shortcomings negatively affect the user which ultimately leads to their dissatisfaction with the overall prosthetic. Current prostheses with ill-fitting sockets reduce comfort, impair biomechanical functionality, and diminish the control of the prosthesis [4]. Furthermore, 82% of lower limb amputees experience residual limb skin complications; and 57% of these individuals stated that they could not use their prosthesis because of these concerns [5]. Both issues are significantly attributed to inadequate suspension systems. Functionality and control of the prosthetic are greatly diminished when there is relative motion between the limb and the prosthetic. Moreover, the same relative motion leads to friction between the residual limb which is a primary source of skin problems. Hence, the determination of the optimal suspension system for transtibial prostheses will improve the functionality as well as the comfort of the overall prosthetic limb.

2.3 - Criteria

In the goal of evaluating each of these solutions, three criteria are considered: pistoning, distal interface pressure, and residual limb volume loss.

<u>2.3.1 - Pistoning</u>

Pistoning is a crucial factor in assessing the effectiveness of the socket-limb connection. In lower limb prostheses, pistoning refers to the relative longitudinal displacement between the socket and the residual limb. In simpler terms, it describes the amount the prosthesis socket slides up and down the residual limb. This is possibly the most important factor in assessing the effectiveness of the suspension system. In fact, suspension systems that optimally mate the socket to the residual limb produce the least amount of relative motion between these two bodies. This linkage best mimics the continuity of a healthy limb because there is no relative motion between any segments in the leg as it is a rigid continuous segment. Therefore, the optimal suspension system must minimize the amount of pistoning.

2.3.2 - Distal Interface Pressure

The distal interface pressure during the swing phase of the gait cycle is an excellent indicator of the pressure that serves to fix the prosthesis to the residual limb. The distal interface pressure refers to the socket-limb interface pressure at the bottom of the residual limb. The pressure value is typically negative. The sign convention implies that negative pressures act in the direction to keep the socket in contact with the residual limb. The gait cycle is the sequence of leg movements that comprise the act of walking. The swing phase is a particular segment in the gait cycle in which the leg is swung forward after being lifted off the ground. This phase of the gait cycle is of interest as it causes the greatest tendency for the prosthesis to move down the residual limb. Therefore, the negative distal interface pressure during the swing phase quantifies the pressure acting to secure the prosthesis to the natural limb during the motion which causes the largest inclination for these two bodies to separate. Hence, the desired suspension system must have the greatest negative distal interface pressure during the swing phase as it is a measure of the pressure securing the prosthesis to the residual limb at the most critical moment.

2.3.3 – Residual Limb Volume Loss

Finally, the volume fluctuation of the residual limb is a valuable metric to evaluate the longevity of the seal between the residual limb and the socket. The volume fluctuation refers to the change in volume that the natural limb undergoes due to the use of the prosthetic. In fact, the socket pressures acting on the residual limb tend to decrease the volume of the residual limb. This results in a diminished seal between the natural limb and the socket which is an essential mechanism of suspension for the systems being considered. Given that the volume reduction of the residual limb reduces the effectiveness of the suspension, the preferred suspension system would yield the minimal amount of limb volume loss.

2.4 - Solutions

To assess which transtibial suspension is most adept at securing the prosthesis to the residual limb, three potential solutions are evaluated: the vacuum-assisted suspension (VAS) system, the suction suspension system, and the pin-lock suspension system. It is important to note that all the suspension systems being evaluated use the same socket design. Therefore, the socket type will not impact the analysis of these systems as it is a control variable.

<u>2.4.1 – Vacuum-Assisted Suspension System</u>

To begin, the vacuum-assisted suspension creates its suspension from the seal between the residual limb and the interior socket wall [6]. In many cases, a liner is worn over the residual limb to improve the seal as well as the comfort of the user. An illustration of the suspension system can be seen in *Figure 2*. The suspension is characterized by the inclusion of a vacuum element which actively removes air from the socket [6]. The vacuum pump can be actuated either electrically or mechanically. The presence of the vacuum element serves to create a sub-atmospheric pressure region within the socket. This pressure increases the force at which the socket is pressed against the residual limb which leads to a greater seal between the two bodies.

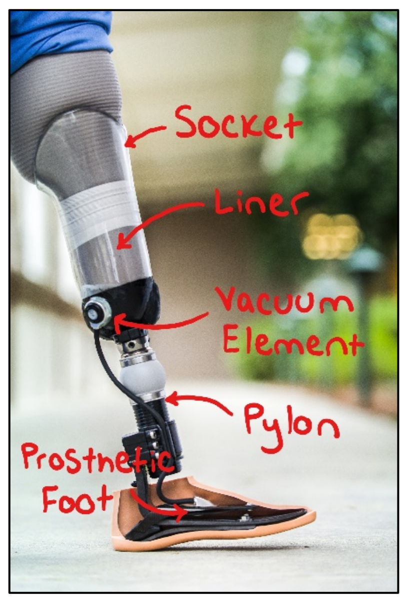

Figure 2:Picture of transtibial prosthesis with vacuum-assisted suspension system (annotations added) [7]

2.4.2 – Suction Suspension System

Next, the suction suspension system produces its suspension from the seal between the residual limb and the interior socket wall [6]. A liner is often worn over the residual limb for the same reasons as the VAS system. An example of this suspension system is shown in *Figure 3*. This suspension system is distinct from the VAS system as it does not have an active air pump to generate negative pressure within the socket. However, the suction suspension includes a one-way valve which allows air to be pushed out of the socket while prohibiting any from entering [6]. This feature allows air to be expelled from the socket when the user is donning the prosthesis which creates an airtight seal between the residual limb and the socket.

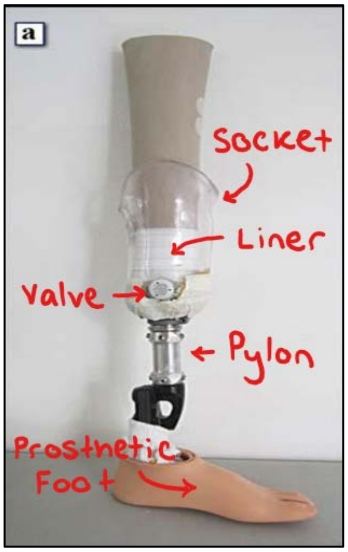

Figure 3: Picture of transtibial prosthesis with suction suspension system (annotations added) [8]

2.4.3 – Pin-Lock Suspension System

Finally, the pin-lock suspension system generates its suspension through two mechanisms which arise from the use of a pin-lock residual limb liner. The liner is equipped with a pin at the end which mechanically locks into the bottom of the socket. The primary mechanism of suspension is the mechanical linkage between the pin mounted to the padded liner and the lock in the socket. The secondary mechanism is the seal between the liner and the socket wall, although it is a less significant factor.

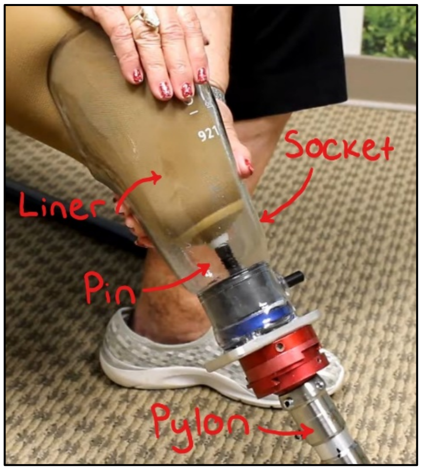

Figure 4: Picture of transtibial prosthesis with pin-lock suspension system (annotations added) [9].

3 – Analysis

To determine the optimal transtibial socket suspension system, each of the three criteria will be considered sequentially. For each criterion, the three solutions will be compared against one another to determine the best performing system for the given factor. The performance of each solution across the three metrics will be incorporated into a comprehensive analysis to establish the best overall transtibial prosthetic suspension system.

3.1 - Pistoning

Based on the minimization of pistoning, the vacuum-assisted suspension is the optimal solution for this metric when measured against the other suspension systems. The pistoning values for the vacuum-assisted suspension were experimentally determined using measurements of displacement between the residual limb and the socket while the test subjects weighted and unweighted the prosthetic. The VAS system yielded pistoning values of 1±3 mm [10]. The pistoning measurements for the suction suspension and pin-lock suspension systems were determined using the maximum displacement between the residual limb and the socket during a gait cycle. The suction suspension allowed for 2.5±0.4 mm of pistoning while the pin-lock suspension allowed for 5.4±0.6 mm [8]. So, the vacuum-assisted suspension produced the least amount of pistoning followed by the suction suspension, then the pin-lock suspension.

Although the methodology for measuring the pistoning for the vacuum-assisted suspension system differed from the other systems, the values are still comparable. In the experiment that measured the pistoning of the vacuum-assisted suspension, the pistoning of the pin-lock suspension system was also evaluated. Using this approach, the pistoning of the pin-lock suspension was deemed to be 6±4 mm [10]. Given that this value is comparable to the value of 5.4±0.6 mm that was determined in the other experiment [8], we conclude that the pistoning values derived from these distinct procedures are analogous.

3.2 - Interface Pressure

In terms of the maximization of the negative distal interface pressure, the pin-lock suspension system is the best solution with respect to this criterion when compared to the other systems. For each of the suspension systems, the negative distal interface pressure was obtained by measuring the peak negative pressure at the bottom of the interface between the socket and the residual limb during the swing phase of the gait cycle. It was determined that the vacuum-assisted suspension generated a peak negative pressure of -36.3 kPa [11], the suction suspension yielded a maximal pressure of -26.1 kPa [12], and the pin-lock suspension produced a peak pressure of -39.5 kPa [12]. In sum, the pin-lock suspension produced the greatest negative distal interface pressure, the vacuum-assisted suspension the second most, and the suction suspension the least.

3.3 - Residual Limb Volume Fluctuation

Based on the residual limb volume loss, the vacuum-assisted suspension represents the best suspension system for this criterion when evaluated against the other potential solutions. For both the vacuum-assisted and suction suspension systems, the volume fluctuation was measured by casting the limb before and after 30 minutes of treadmill walking. The vacuum-assisted suspension causes a residual limb volume increase of 3.7% while the suction suspension generates a decrease of 6.5% [13]. For the pin-lock suspension system, the volume fluctuation of the residual limb was quantified using an optical measurement system to determine the volume of the limb before and after 30 minutes of treadmill walking. It was determined that there was no statistically significant difference between the volume fluctuation caused by the pin-lock and vacuum-assisted suspension systems [10]. In summary, the vacuum-assisted and pin-lock suspension systems produce the least amount of volume reduction, followed by the suction suspension.

3.4 - Concluding Analysis

Based on the three criteria examined above, the optimal solution is the vacuum-assisted suspension system. In fact, it produces the least amount of pistoning which is the ideal we set out in our definition of the criterion. Furthermore, it produces the second highest negative distal interface pressure during the swing phase closely behind the pin-lock suspension. However, it is found that while the pin-lock suspension generates this distal pressure, the liner squeezes the residual limb with an excessive pressure that leads to skin issues [12]. Given that the vacuum-suspension system only produces 8.10% less distal interface pressure without causing a source of harm to the residual limb skin, it is a more favorable solution in this regard as well. Lastly, the vacuum-assisted suspension is tied for producing the smallest change in residual limb volume. In fact, it even goes so far to increase the volume of the limb thus improving the seal between the socket and limb. The summary of the results for each solution are displayed in *Table 1*.

Table 1: Summary of Criteria Results for Transtibial Suspension Systems

Criteria / Solutions	Overall Ranking	Pistoning	Distal Interface Pressure	Residual Limb Volume Fluctuation
Vacuum-Assisted Suspension	**1**	1±3 mm	-36.3 kPa	+ 3.7%
Suction Suspension	**3**	2.5±0.4 mm	-26.1 kPa	-6.5%
Pin-Lock Suspension	**2**	5.4±0.6 mm	-39.5 kPa*	+ 3.7%

**Note: Pin-lock suspension system produces high negative distal interface pressures at the expense of harmfully squeezing the residual limb [12].*

4 – Conclusion

In conclusion, the vacuum-assisted suspension is the optimal suspension system to mechanically link a transtibial prosthesis to the residual limb of its user on the basis of pistoning, distal interface pressure during the swing phase, and the volume fluctuation. Despite these findings, there are many other aspects that must be considered in the determination of suitable suspension system for a given amputee. Some of these factors include the cost, the ease of donning and doffing the prosthesis, and the user's comfort. Above all, the selection of the appropriate system is determined by the preference of the amputee.

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