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An experimental study of the interface pressure profile during level walking of a new suspension system for lower limb amputees

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ABSTRACT

Background: Different suspension systems that are used within prosthetic devices may alter the distribution of pressure inside the prosthetic socket in lower limb amputees. This study aimed to compare the interface pressure of a new magnetic suspension system with the pin/lock and Seal-In suspension systems.

Methods: Twelve unilateral transtibial amputees participated in the study. The subjects walked on a level walkway at a self-selected speed. The resultant peak pressure with the three different suspension systems was recorded using F-socket transducers.

Findings: There were significant statistical differences between the three studied suspension systems. Pair-wise analyses revealed that the mean peak pressure (kPa) was lower with the magnetic system than it was with the pin/lock system over the anterior and posterior aspects during one gait cycle (89.89 vs. 79.26 and 47.22 vs. 26.01, respectively). Overall, the average peak pressure values were higher with the Seal-In system than they were with the new magnetic lock and pin/lock system.

Interpretation: The new magnetic system might reduce the pressure within the prosthetic socket in comparison to the pin/lock and Seal-In system during one gait cycle. This is particularly important during the swing phase of gait and may reduce the pain and discomfort at the distal residual limb in comparison to the pin/lock system.

1. Introduction

Suspension systems are necessary components of lower limb prostheses and they are used to create a secure coupling between the residual and prosthetic limbs. The majority of contemporary suspension systems utilize silicone liners as the preferred suspension system (McCurdie et al., 1997). Lower limb amputees have stated preference towards these silicone liners as a result of the fact that these systems provide a close match to the residual limb, superior suspension, improved appearance and better function (Baars and Geertzen, 2005). In general, there is a high overall satisfaction with prosthetic devices that incorporate silicone liners as suspension systems (Eshraghi et al., 2012a). There are a variety of silicone suspensions in use that are coupled to the hard socket either by a distal single pin or through circumferential seal or seals that produce vacuum at the socket wall. Prosthetic hard sockets that are used with silicone suspension should be undersized to ensure a total-surface bearing fit. Research has revealed that a total-surface bearing socket exposes the soft tissue to tolerable compression (Laing et al., 2011). On the other hand, bony structures are stabilized within the residual limb; therefore the skin may not be damaged due to unbearable excessive pressure when these liners are in use (Wlodarczyk, 2007). Moreover, total-surface bearing sockets coupled with enhanced vacuum (for instance by Seal-In liners) might control volume fluctuation and perspiration. At the same time, piston motion or displacement within the socket and thereby shear force will be reduced.

Some researchers have attempted to evaluate the load applied to the residual limb either through completion of clinical assessments that use different types of transducers (Convery and Buis, 1999; Laing et al., 2011; Polliack et al., 2000; Sanders, 1998; Zhang et al., 1998) or through simulation techniques (Commean et al., 1997; Lin et al., 2004; Silver-Thorn and Childress, 1996). Friction within the prosthetic socket has a two-fold effect as it helps to retain the prosthesis on the residuum but at the same time it may distort the soft tissue (Mak et al., 2001). If large friction occurs at an interface, stress may be localized and this can lead to the deformation of the remaining tissue. Conversely, Zhang et al. found that lubricating the skin will increase the interface pressure (Zhang et al., 1996). Few research studies have dealt with the effect of liners and prosthetic sockets on the pressure applied to the residual limb. Without understanding the changes imposed on the soft tissue and skin by different socket designs and suspension systems, it is not possible to evaluate the overall prosthetic fit. Moreover, prosthetic interface pressure is believed to be a determinant of the amputees' comfort (Dou et al., 2006; Jia et al., 2004; Sanders et al., 2006; Sewell et al., 2000).

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Research has shown that pin liners exert compression on the residual limb proximally and tension distally during the swing phase of gait. This skin stretch at the pin site is called milking. This milking phenomenon is probably the cause of the short (edema and redness) and long-term (discoloration and thickening) transformations that are observed, particularly at the distal end of the residuum (Beil and Street, 2004). This compression can result in pain, discomfort and residual limb atrophy or volume loss.

A new prosthetic suspension system has been developed by the authors (Eshraghi et al., in press). This study aimed to compare the effect of this new prosthetic suspension system with pin/lock and Seal-In systems with regard to the interface pressure that is produced between the liner and socket. The researchers hypothesized that the new suspension system would result in less traction at the distal end of the residual limb and lower compression proximally in comparison to the pin/lock liner. The researchers also assumed that the Seal-In liner would offer similar interface pressure to the new suspension system, particularly at the distal region of the stump.

2. Methods

Fifteen amputees agreed to participate in the study as sample of convenience and were asked to sign a written consent form. Ethical approval was obtained from the University of Malaya Ethics Committee prior to the study. The subjects were required to conform to the following criteria in order to be included in the study: no ulcer on the residuum, no volume change at the residual limb and the ability to ambulate without assistance. As the minimum length for eligibility to use Seal-In liners is 11 cm based on the manufacturer guidelines, only those amputees with adequate residuum length were eligible to participate. The subjects were also considered for participation if they had used prosthesis in the last 6 months.

Each subject was provided with three new prostheses, each of which incorporated a different suspension system: (a) the new magnetic suspension system, (b) a pin/lock liner and (c) a suction Seal-In suspension. All the procedures from the casting to prosthetic alignment were performed separately for each prosthesis by one of the researchers (a registered prosthetist). All the prostheses incorporated a Flex-Foot Talux. All the experiments were carried out in the Motion Analysis Laboratory at the University of Malaya, while the subjects walked on the level ground wearing each of the three prostheses.

The new suspension system comprised (a) a mounting plate coupled to the distal end of the silicone liner and (b) a magnet assembly embedded in the distal end of the hard socket (Fig. 1). The plate was a cup-shaped metal part that had a diameter that matched that of the distal liner. A screw through the middle of the plate connected the plate to the liner. The plate was filled with the silicone adhesive all around the central screw (Eshraghi et al., in press). A mechanical switch knob enabled the attachment to and detachment from the liner and the hard socket. When the switch knob was rotated, a magnetic field was produced and rotation in the opposite direction weakened the magnetic field so that the suspension failed (the liner was detached from the socket).

Dermo® liner (Össur, Reykjavik, Iceland) was used with both of the new suspension systems and the pin/lock suspension. The suction Seal-In system was a Seal-In® X5 liner (Össur, Reykjavik, Iceland) and an expulsion valve was mounted on the hard socket (Fig. 1).

In order to check the interface pressure, four F-socket transducers 9811E (Tekscan Inc., South Boston, USA) were employed. It is generally accepted that the sensors used to measure for interface pressure should be as thin as possible (Kim et al., 2003). The paper-thin F-socket sensors had a thickness of 0.18 mm, good flexibility and high resolution. The sensor mats were trimmed according to the residuum counters and were located on the anterior (Ant), posterior (Pos), medial (Med) and lateral (Lat) surfaces of the residuum. In order to avoid displacement, adhesive spray (3M Spray Mount Adhesive, 3M corporate, St. Paul, USA) was employed to secure the sensor mats to the residual limb before the silicone liners were rolled on the transducers (Fig. 2).

Fig. 1. New magnetic suspension system.

Prior to the experiments, the transducers were calibrated to eliminate variation between each load cell. Following the manufacturer's instructions, two processes of equilibration and calibration were performed. The sensors were inserted individually into a pressure bladder connected to an air compressor and a constant pressure of 100 kPa (20 psi) was applied for equilibration. Next, the calibration was accomplished according to each subject's body weight.

In order to identify the gait cycle, force plate data was simultaneously gathered alongside the pressure data using two Kistler force plates at 50 Hz. The subjects were asked to walk at a self-selected speed on a 10-meter walkway. Prior to the data collection, the participants practiced the procedure. The frequency of data acquisition was 50 Hz. The subjects completed five trials on the walkway. The average of the middle steps (excluding the two first and the two last) for the five trials was chosen for the analyses.

The assumption of normality and homogeneity of variance was verified using the Kolmogorov–Smirnov test. Afterwards, the differences in peak pressure values were defined within four transducer sites (anterior, posterior, medial, lateral) and suspension systems using a 4×3 (sensor$\times$ suspension systems) repeated measure analysis of variance (ANOVA). If the ANOVA showed significant differences, paired-samples t tests were used to compare mean peak pressures in different regions of the socket among the three suspension systems. Each sensor was further divided into three sub-regions, namely, proximal, middle and distal. All the statistical analyses were accomplished using SPSS 20.0 (SPSS, Chicago, IL, USA).

3. Results

Out of 15 subjects, three subjects were withdrawn from the study as they failed to complete the fitting and gait training sessions. The demographic data of the remaining 12 subjects is depicted in Table 1.

The analyses of data for four sensor arrays (three regions for each) were performed for the three suspension systems. First, the data was normalized to 100 percent of gait cycle. Repeated measure analysis of variance showed significant differences between the studied systems in some of the sensor sites during one gait cycle. Table 2 represents the average peak pressure values and the significant differences observed. There were also significant differences evident between

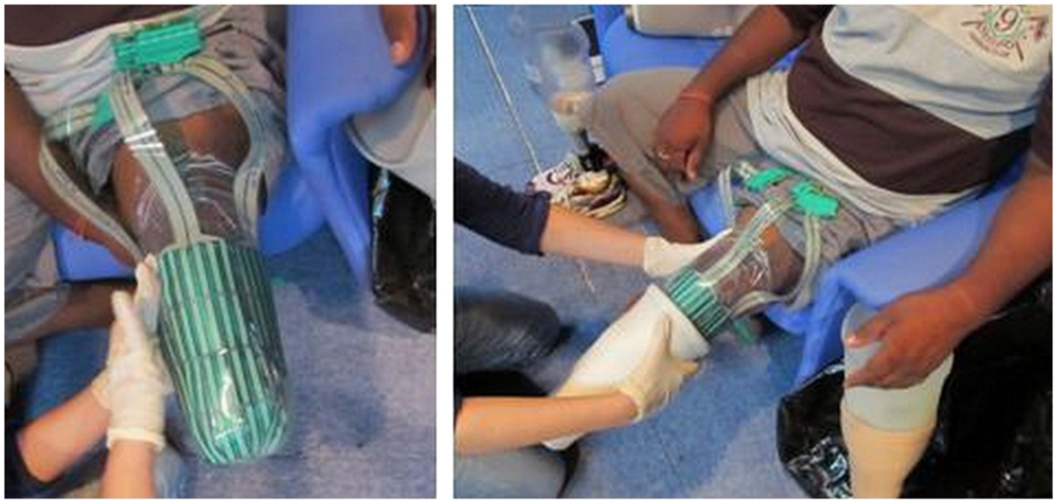

Fig. 2. The sensor arrays mounted on the subject's residual limb.

the four sensor sites for each system. In the case of the magnetic lock, there was significant increase in the mean peak pressure at the anterior surface in comparison to the posterior, medial and lateral (79.26 vs. 26.01, 38.07, and 27.41 respectively). The same was true for the pin/lock and Seal-In systems (Table 2).

For the Seal-In liner, the mean peak pressures (APP) were higher in the proximal and middle of the sensor compared to the distal region at the anterior, posterior and medial surfaces of the residuum. Overall, the APP of the four sensor array sites during one gait cycle was higher for the Seal-In system compared to both the pin/lock liner and the new magnetic system.

The whole surface APP at the anterior aspect was lower with the magnetic system than it was with the pin/lock system during one gait cycle (79.26 vs. 89.89 kPa, $P=0.034$, $t=2.581$). There was also increased APP with the pin/lock system at the posterior aspect of the residual limb during gait cycle (47.22 vs. 26.01 kPa, $P=0.000$, $t=9.254$). Comparative analysis of the pin/lock system to the new magnetic system revealed that there was no significant difference between the two during the stance. Nevertheless, significantly less mean peak pressures were seen with the new system during the swing phase of gait (Table 3).

Overall, the highest percentage of change was recorded for the posterior sensor between the new magnetic lock and the Seal-In system (60.16%) and the least was between the pin/lock and new magnetic lock at the medial surface (2.90%). When comparing the new magnetic lock with the pin/lock system, the percentage of change for all four sensor sites was more than 10%, with the exception of the medial site.

With regard to the distribution of pressure over the anterior surface, the largest change was seen immediately after heel strike for the pin/lock and Seal-In systems during one gait cycle. Conversely, the largest change was observed at late stance with the new magnetic system (Fig. 3). As for the posterior surface, a more homogenous pattern was seen for all the suspension systems during gait, with the greatest change at early stance (Fig. 3).

For all over stance, the average peak pressure at the distal region of the anterior surface remained higher than the proximal portion for all three suspension types (Fig. 4). The distal area of the posterior surface demonstrated lower pressure than the proximal region. The only exception was the Seal-In system, which produced higher pressure at the middle region in comparison to the proximal area.

4. Discussion

A number of studies have investigated the effect of different casting techniques and prosthetic components, including suspension and alignment changes, on the in-socket interface pressure (Boutwell et al., 2012; Jia et al., 2004; Sanders, 1998; Sanders et al., 1997; Wolf et al., 2009). Even distribution of pressure is considered to be the ideal condition in a prosthetic socket (Mak et al., 2001). This study assessed the effect of a newly-designed magnetic suspension system on pressure profile within a prosthetic socket compared to that of two existing systems (pin/lock and Seal-In).

When each suspension type was individually evaluated, the pressure was almost distributed evenly at the posterior, medial and lateral surfaces. Nevertheless, the anterior surface accepted the highest pressure magnitudes of all the four limb surfaces (Table 2). The average pressure magnitudes during one gait cycle were less than 200 kPa that mirrored the findings of previous studies that had assessed

Table 1
Demographic characteristics of the participants.

Variable	Results
Sex	9 Males (75%) 3 Females (25%)
Age (year)	46.86 (12.3)
Height (cm)	170.46 (4.9)
Body mass (kg)	73.60 (11.5)
Side of amputation (%)	Right (66.6%) Left (33.3%)
Cause of amputation (%)	Diabetic (58.3%) Trauma (41.6%)
Residual limb length (mm)	14.96 (1.2)

Table 2
The average peak pressure (kPa) for whole sensor sites at the anterior, posterior, medial and lateral residual limb.

Suspension type Sensor site	Ant Mean (SD)	Pos Mean (SD)	Med Mean (SD)	Lat Mean (SD)
Pin/lock[1]	89.89 (26.4)	47.22 (17.7)	39.21 (18.1)	31.65 (15.2)
New magnetic lock[2]	79.26 (23.2)	26.01 (13.3)	38.07 (12.5)	27.41 (9.8)
Seal-In liner[3]	119.43 (30.8)	65.29 (16.6)	53.50 (21.7)	52.55 (14.5)
Sig. (two tailed)*	1,2 (0.042) 1,3 (0.017) 2,3 (0.026)	1,2 (0.003) 1,3 (0.011) 2,3 (0.000)	1,3 (0.034) 2,3 (0.027)	1,3 (0.023) 2,3 (0.015)

Ant = Anterior; Pos = Posterior; Med = Medial; Lat = Lateral.
* "1,2", "1,3" and "2,3" indicate that significant differences ($P<0.05$) were found between each two suspension systems based on the paired-samples t tests.

Table 3
The average peak pressures (kPa) based on the liner type and sensor sites during the swing phase of gait (n = 12).

	Ant Mean (SD)			Pos Mean (SD)			Med Mean (SD)			Lat Mean (SD)		
	P	M	D	P	M	D	P	M	D	P	M	D
Pin/lock[1]	21.74 (7.3)	10.07 (2.4)	20.03 (7.8)	24.77 (9.6)	11.06 (3.2)	17.74 (7.1)	14.03 (4.9)	15.77 (5.7)	13.24 (6.3)	13.77 (2.2)	14.23 (4.0)	10.12 (2.1)
Magnetic lock[2]	9.65 (3.5)	10.01 (4.9)	9.74 (5.7)	9.53 (1.1)	9.83 (3.4)	9.92 (2.5)	11.20 (4.2)	10.96 (4.7)	11.68 (3.1)	11.07 (4.8)	11.47 (3.7)	10.14 (3.6)
Seal-In liner[3]	72.26 (25.1)	74.2 (17.6)	76.2 (22.3)	40.19 (10.0)	44.80 (15.6)	45.30 (18.4)	30.13 (9.1)	32.51 (12.7)	31.53 (6.5)	34.37 (10.2)	32.50 (9.1)	31.40 (7.7)
Sig. (two tailed)*	1,2 (0.032)	1,3 (0.000)	1,2 (0.024)	1,2 (0.008)	1,3 (0.000)	1,3 (0.000)	1,3 (0.034)	1,3 (0.013)	1,3 (0.003)	1,3 (0.004)	1,3 (0.006)	1,3 (0.001)
	1,3 (0.001)	2,3 (0.000)	1,3 (0.003)	1,3 (0.000)	2,3 (0.000)	2,3 (0.000)	2,3 (0.012)	2,3 (0.005)	2,3 (0.003)	2,3 (0.011)	2,3 (0.005)	2,3 (0.000)
	2,3 (0.000)		2,3 (0.000)	2,3 (0.000)								

Ant = Anterior; Pos = Posterior; Med = Medial; Lat = Lateral; P = Proximal; M = Middle; D = Distal.
* "1,2", "1,3" and "2,3" indicate that significant differences ($P<0.05$) were found between each two suspension systems based on the paired-samples t tests.

total-surface bearing systems (Beil et al., 2002; Dumbleton et al., 2009; Sanders et al., 1992; Zachariah and Sanders, 2001).

In the current study, pressure magnitudes at the anterior aspect of the limb were higher than the posterior for all the three systems during stance. These findings were contrary to those of Sanders et al. (1992). At initial stance (first peak), the average peak pressures for the posterior distal and anterior proximal areas of the magnetic system were lower than the posterior proximal and anterior distal (16.78% and 54.41%, respectively). This pattern was also repeated at the second peak (late stance), which contradicts the patterns reported by Dumbleton et al. (2009) and Sanders et al. (1992).

High interface pressures have been reported at the anterior proximal area (PTB bar) with the patella tendon bearing (PTB) sockets. Throughout stance, the distal region of the anterior surface demonstrated higher pressure than the proximal area with all the studied suspension systems. This conforms to the findings of Dumbleton et al. (2009) and suggests that a flexion moment was created at the knee. However, large differences in pressure magnitudes were seen at late stance for the anterior surface, which is similar to the findings of Goh et al. (2003a,b) but opposes the findings of Dumbleton et al. (2009). At late stance (50% of gait cycle), all the three studied systems showed lower pressure at the anterior proximal area, while Goh et al. (2003a) found a pattern similar to the PTB socket.

4.1. Magnetic lock vs. pin/lock

Different suspension systems suspend the prosthetic leg by applying pressure at dissimilar regions of the residual limb. This might significantly affect the comfort with which the amputees ambulate. Users of the pin/lock liners feel a stretch at the distal tissue of the residual limb during the swing phase (Beil and Street, 2004). At the same time, proximal tissues are exposed to high compressive pressures that will disrupt the normal fluid flow. This milking phenomenon can lead to edema and vein problems and could be the reason why pin/lock users experience skin thickening and color change, particularly at the distal region of their residuum (Beil and Street, 2004). The current study hypothesized that the new system would reduce the traction by increasing the contact area. When the results of each sensor sub region (proximal, middle, and distal) were compared between the two systems, significant differences were evident for the

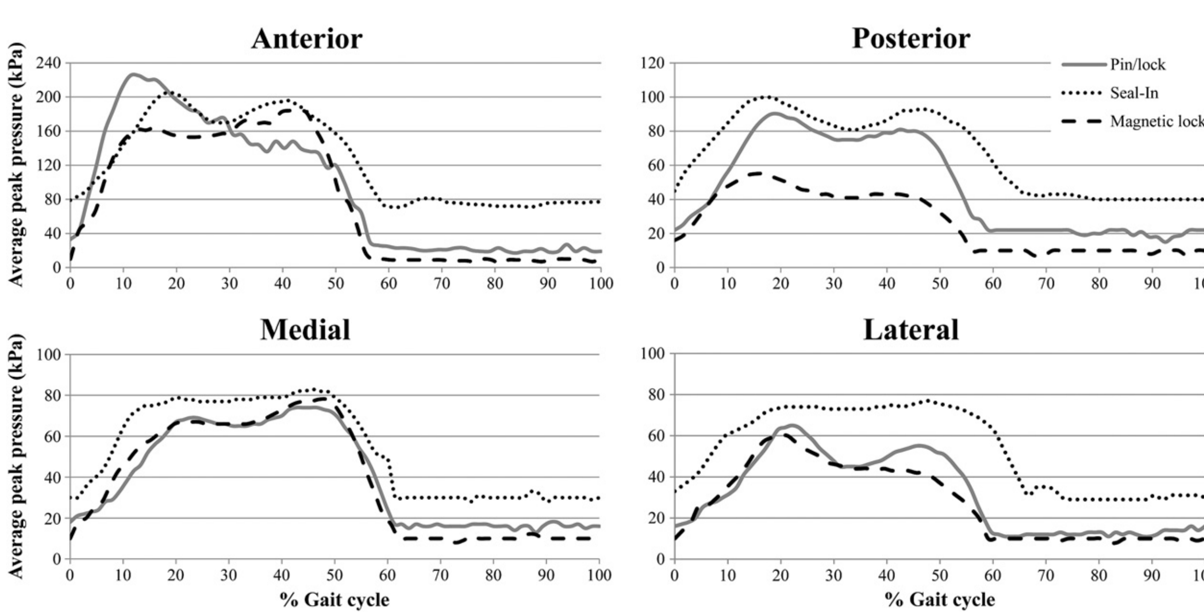

Fig. 3. Pattern of pressure acceptance over four sensor sites with three suspension systems during one gait cycle.

Fig. 4. Pressure profile with new magnetic lock (top) and pin/lock systems (bottom) during stance; right to left: early stance, mid stance, late stance. All values (average peak pressure) are in kPa.

anterior and posterior surfaces of the residual limb (Table 3). Lower peak pressures were produced at the anterior and posterior surfaces during the swing phase of gait with the magnetic system in comparison to the pin/lock. This was in agreement with the findings by Beil and Street (2004) pertaining to high average pressure with the pin/lock system. The average peak pressures at the medial and lateral sensor sites (mean of whole surface) were also lower with the magnetic system than they were with the pin/lock suspension (10.33 and 9.75 vs. 16.41 and 13.83, respectively). Yet, the statistical analyses did not show them to be statistically different.

4.2. Magnetic lock vs. Seal-In suspension

The average pressure magnitudes recorded with the Seal-In system were different from the magnetic system during swing (Table 3). A study by Beil and Street (2004) showed that the use of a suction system resulted in a more homogenous distribution of interface pressure. The current study supports their results as the pressure distribution with the pin/lock was less homogenous compared to the new magnetic lock and Seal-In systems. As compared to the magnetic system, the pressure with the Seal-In liner was mainly concentrated at the middle and distal regions of the posterior sensor during stance. This might be due to the location of seals and the fact that suction is developed mainly at the distal end where the valve is located. The mean peak pressures were generally higher with the Seal-In liner than they were with the other two systems (P values were less than 0.05 for both comparisons). This was compatible with the results of Ali et al. (in press). In the current study, the pressure values increased by 34.75% at the posterior aspect of the limb with the Seal-In liner in comparison to the pin/lock system. This difference was 40.97% for the new suspension system. The greatest change of pressure with total surface bearing (TSB) sockets and pin/lock liners in transtibial gait has been shown to occur at late stance (50% of gait cycle) (Dumbleton et al., 2009). The largest change occurred at late stance with the new system. In contrast, pin/lock and Seal-In systems showed the greatest changes at early stance.

The Seal-In suspension system has been shown to cause the least pistoning within the prosthetic socket compared to the pin/lock and new magnetic suspension systems (Eshraghi et al., in press; Gholizadeh et al., 2012a, in press). This study indicated higher-pressure magnitudes with the Seal-In system, which might clarify the lower pistoning observed previously. It can be inferred that while suction systems, such as the Seal-In, may increase the prosthetic fit, the enhanced fit and the resultant increased pressure might bring about residual limb atrophy, skin problems and interruption in blood flow to the limb (Board et al., 2001). This volume loss is commonly compensated by the addition of socks, which can worsen the atrophy.

It was a challenge to compare the results of the current study with the existing literature, as the majority of previous studies used single-spot transducers as opposed to the full-length sensors that were used in this study. Variation in geometry of residual limb could also affect the pressure measurement sites; therefore, a bigger sample size might find a relationship between the residual limb geometry and pressure profile. It is also worth investigating the pressure profile in various activities on diverse walking surfaces. Further investigations may also find association between pressure and pistoning within the prosthetic socket which can be invaluable in the design of a more balanced socket.

5. Conclusion

The current study provided some biomechanical insight into different methods of prosthetic suspension. The new magnetic suspension system might reduce the pressure over the residual limb, particularly during swing, offering the advantages of the other suspension systems while overcoming some of their weaknesses.

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