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ORIGINAL RESEARCH ARTICLE

Quantitative and Qualitative Comparison of a New Prosthetic Suspension System with Two Existing Suspension Systems for Lower Limb Amputees

ABSTRACT

Eshraghi A, Abu Osman NA, Karimi MT, Gholizadeh H, Ali S, Wan Abas WAB: Quantitative and qualitative comparison of a new prosthetic suspension system with two existing suspension systems for lower limb amputees. Am J Phys Med Rehabil 2012;91:1028–1038.

Objective: The objectives of this study were to compare the effects of a newly designed magnetic suspension system with that of two existing suspension methods on pistoning inside the prosthetic socket and to compare satisfaction and perceived problems among transtibial amputees.

Design: In this prospective study, three lower limb prostheses with three different suspension systems were fabricated for ten transtibial amputees. The participants used each of the three prostheses for 1 mo in random order. Pistoning inside the prosthetic socket was measured by motion analysis system. The Prosthesis Evaluation Questionnaire was used to evaluate satisfaction and perceived problems with each suspension system.

Results: The lowest pistoning motion was found with the suction system compared with the other two suspension systems ($P < 0.05$). The new suspension system showed peak pistoning values similar to that of the pin lock system ($P = 0.086$). The results of the questionnaire survey revealed significantly higher satisfaction rates with the new system than with the other two systems in donning and doffing, walking, uneven walking, stair negotiation, and overall satisfaction ($P < 0.05$).

Conclusions: The new suspension system has the potential to be used as an alternative to the available suspension systems. The pistoning motion was comparable to that of the other two systems. The new system showed compatible prosthetic suspension with the other two systems (suction and pin lock). The satisfaction with donning and doffing was high with the magnetic system. Moreover, the subjects reported fewer problems with the new system.

Key Words: Amputees, Prostheses, Personal Satisfaction, Rehabilitation

Transtibial prosthetic designs incorporate suspension systems consisting of liners and coupling components. Manufacturers continuously seek improvement in prosthetic components.[1,2] The contours and buildups on the polyethylene foam liner (Pelite) worn inside the prosthetic hard socket help retain the prosthesis. A belt or strap also sometimes provides an extra means of security. Suspension sleeves, pulled over the prosthesis to give extra suspension, were introduced as an added feature, and later, silicone liners were invented to improve suspension by establishing a firm bond between the residual limb and the liner.[3,4] Internal pin lock systems and, recently, single or multiple hypobaric seals around the liners were developed as alternatives to external accessories. Improved suspension has been reported in objective and subjective studies as an advantage of silicone liners.[4] Silicone liners are less bulky than other types of suspension. Enhanced suspension and cosmesis have produced higher satisfaction rates among transtibial amputees.[5,6]

Satisfaction is said to be correlated with low piston motion, decreased unwanted sounds during functional tasks, and ease of don and doff.[7–9] A suspension system should not only retain the prosthesis to the residual limb but also provide comfort, enhanced function, and ease of don and doff. The ease and simplicity of donning and doffing are of critical importance among prosthetic users.[10,11] The users have reported difficulty in the proper alignment of pins in the pin lock systems. These systems may also cause a phenomenon called "milking" caused by tissue stretch at the pin site, particularly during the swing phase of gait.[12,13] This milking might be the cause of pain and discomfort at the distal end of the residual limb, particularly during swing.

Researchers have investigated the pros and cons of different transtibial suspension systems both objectively and subjectively. The studies have targeted different determinants of successful prosthetic provision; lack of pistoning has been one of the main variables that indicate proper socket fit.[14] Some research studies have shown preferences for the pin lock and suction systems with total-surface–bearing sockets over the polyethylene foam liners used with patellar tendon–bearing sockets,[4,7,15,16] which exert high pressures on the residual limb.

Pistoning is defined as the vertical displacement mainly occurring within the prosthetic socket either between the residual limb and the liner or between the liner and socket wall.[17] Improper suspension might result in residual limb skin problems, gait deviations, and discomfort.[8,18] Several methods have been used for measuring the pistoning inside the prosthetic socket.[16] This has been mostly conducted by radiography,[8,18] ultrasound,[19] and computerized tomography.[20] A recent method used a photographic technique for evaluation of piston motion between the liner and the socket.[21,22] Finally, the use of motion analysis systems by reflective markers was recently introduced to measure pistoning.[7] The very same method was adopted in this study to evaluate the effect of the newly designed suspension system on pistoning.[7] Pistoning measurement has been mostly performed through gait simulation because either evaluation during the real gait had been detrimental to the amputee or some technical limitations hindered the measurement during the real gait.[14]

Qualitative surveys in the field of prosthetics have frequently used the Prosthesis Evaluation Questionnaire (PEQ) to investigate the effects of prostheses on the quality-of-life among individuals with amputation. Good reliability and validity have been reported for the PEQ.[23] The PEQ research on prosthesis satisfaction has revealed that donning and doffing might play important roles in amputees' satisfaction.[24]

Although silicone suspension systems such as the pin lock and the hypobaric seal-in liners are said to provide enhanced suspension for lower limb prostheses,[4] some disadvantages such as increased pain at the residual limb and difficulty of donning and doffing are also attributed to them.[7] To overcome some of the disadvantages of the pin lock and suction suspension systems, the authors of the current study invented, produced, and evaluated a new prosthetic suspension system compared with the pin lock and suction systems. The purposes of this study were to compare the new suspension system with the two existing methods of suspension in the pistoning motion between the prosthetic liner and the socket and to compare satisfaction and perceived problems of transtibial amputees. The authors hypothesized that the new suspension system will cause less pistoning compared with the pin lock system, whereas the resultant pistoning will be higher than that of the suction suspension system. The authors' other hypothesis was that there will be a significant increase in satisfaction rates with the new suspension system than with the other two systems.

METHODS

Participants

Ten individuals with transtibial amputation were selected as a convenience sample to participate in this prospective study. The inclusion criteria were unilateral transtibial amputation, activity levels of K2–K3 according to the American Academy of Orthotists & Prosthetists,[25] residual limbs free of wound and pain, no upper limb disability, experience with silicone liners, no volume fluctuation in the residual limb, and the ability to ambulate independently. The stump length, measured from the inferior edge of the patella to the distal end of the stump, had to be no less than 13 cm. All participants used transtibial prostheses with the pin lock suspension system before the initiation of this study. Table 1 lists the individual characteristics of all subjects. The University of Malaya Ethics Committee approved this research study. The subjects were required to sign a consent form to enter this study, and the researchers considered each subject as his own control.

Three prostheses were fabricated for each subject by a single registered prosthetist to ensure uniform design, alignment, and fit. Three suspension systems were selected, including the new lower limb suspension design (Fig. 1). The other two systems were (1) the shuttle lock and pin (Dermo Liner with Icelock-clutch 4 H214 L 214000) and (2) the suction suspension (Seal-In X5 Liner with Icelock Expulsion Valve 551). Other prosthetic components were common among the three prostheses (Flex-Foot Talux and Tube adaptor).

Transparent thermoplastic material ensured that the sockets were total-surface bearing[7] and had visible walls, through which the researchers could detect the internal features. The processes of checkout, gait evaluation, and gait training were performed in the Brace & Limb Laboratory, University of Malaya. Furthermore, the PEQ required at least 1 mo of prosthetic use for each prosthetic type to allow for adaptation to the new prostheses.

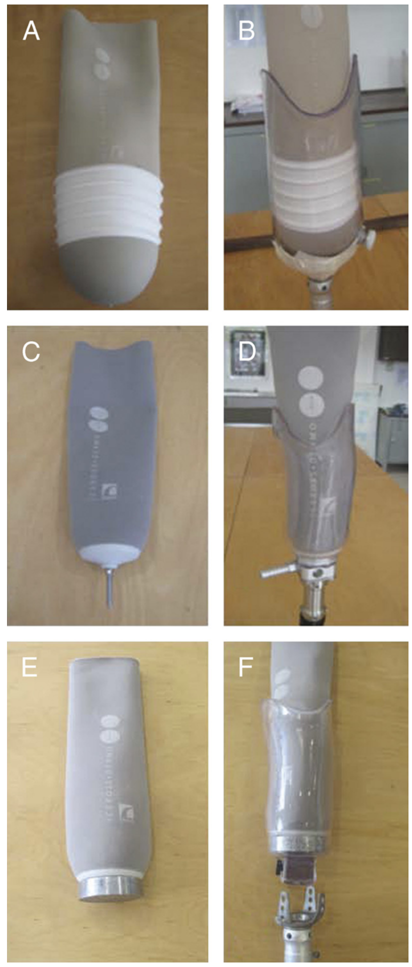

FIGURE 1 *Three suspension systems used in this study. A, Seal-In X5 liner; B, transparent socket and valve; C, Dermo liner with pin; D, transparent socket and shuttle lock; E, Dermo liner with distal cap; F, transparent socket and new magnetic lock.*

New Suspension System

The new suspension system used in this study consisted of (1) a cap matched to the distal end of

TABLE 1 Subjects' characteristics

Subject No.	Age, Yrs	Height, cm	Mass, kg	Amputated Side	Cause of Amputation	Stump Length, cm[a]	Mobility Grade[b]
1	42	173	75	Left	Diabetes	13	K2
2	37	168	90	Left	Trauma	14.5	K3
3	30	182	60	Left	Trauma	15	K3
4	72	166	75	Left	Diabetes	13.5	K2
5	46	167	64	Right	Trauma	16	K3
6	35	170	99	Right	Diabetes	14	K2
7	49	164	57	Right	Diabetes	15	K3
8	53	177	60	Left	Diabetes	14	K3
9	41	168	72	Right	Trauma	13	K2
10	33	171	86	Left	Trauma	17	K3

[a]Stump length: from the inferior edge of the patella to the distal end of the stump.
[b]Based on the American Academy of Orthotists & Prosthetists.

the silicone liner and (2) a magnetic lock system embedded in the distal end of the hard socket (Fig. 1). The cap was a cup-shaped metal component with the same diameter of the distal liner. It was connected to the liner by a screw in the middle and a silicone adhesive. The cap was filled with the silicone adhesive all around the central screw. A mechanical switch button enabled the two modes of connecting or disconnecting the liner and the hard socket; it was designed to allow easy detachment of the liner from the socket. Nevertheless, the lock did not fail after it was switched on, which is an advantage as a security assurance for the amputees. When the switch button was turned on, a magnetic field was produced, and switching off the button would weaken the magnetic field so that the suspension failed (the liner was detached from the socket). The system was tested under tensile loading by the universal testing machine (Instron 4466). It could tolerate 350 N of tensile loading before the liner was released from the socket.

Equipments and Experiments

After the completion of 4 wks of prosthetic use for each system, the subjects attended the motion laboratory for quantitative study. The order of prosthetic suspension system use was randomized for every subject. To investigate the pistoning inside the prosthetic socket, the researchers adopted the static method using a seven-camera Vicon 612 motion system (Oxford Metrics, Oxford, United Kingdom). Sixteen reflective markers of 5-mm diameter were attached to each subject's prosthetic and sound lower limbs according to the Helen Hayes marker set. The lateral distal end of the socket and the lateral proximal socket wall were selected to locate the tibia and knee markers on the prosthesis, respectively. Because it was attempted to measure the pistoning between the liner and the socket, two extra markers (paper thin) were attached to the liner under the functional knee joint level and 5 cm below that.[7] The accuracy level of the motion analysis system was less than ±0.1 mm.[26]

The subjects stood on a platform. The researchers measured the pistoning by the gait simulation method through load application.[7,14,18,27] Double-limb and single-limb support with the prosthesis were considered compressive loadings. The subjects were required to perform single-limb stance on the prosthetic limb (full weight bearing). Then, they stood on both limbs to fulfill the semi–weight-bearing step. For tensile loading, the subjects had to hang their prosthetic leg from the platform edge (non–weight bearing). Next, three loads of 30, 60, and 90 N were added consecutively to the prosthetic foot. The swing phase of gait has been previously replicated by similar loads.[7,18,21,27] To determine the pistoning, the distance between the markers on the liner and on the socket was calculated in each loading condition.

To ensure the safety of the participants, a handrail was located close to the platform during the experiments. The subjects could hold the handrail if they could not maintain their balance. The entire loading process was repeated five times for each subject. The mean and peak displacement values for each single trial were calculated. The average values of the five trials were used for the statistical analyses. All experiments were also repeated in two separate sessions (with a 1-wk interval) by two different observers to investigate the reliability of the method. Moreover, the authors wanted to examine whether marker placement by different observers might introduce error.

Questionnaire

The PEQ is a self-report instrument commonly used to evaluate prosthetic users' satisfaction with prostheses. The original version is subdivided into nine sections comprising 82 questions. Because the questions are not dependent on each other, it is possible to use them as appropriate to a given study.[23] For the qualitative analysis, a questionnaire was designed that used selected questions from the PEQ under the scales of demographic data, satisfaction, and problems. The subjects completed a separate questionnaire for each prosthetic type after they finished 4 wks of prosthetic use. The questionnaire included the following three scales:

(1) Demographic data (age, cause of amputation, weight, height, and time since amputation)
(2) Satisfaction (fitting; sitting; ability to walk on a level surface, uneven ground, and up and down the stairs; cosmesis; suspension; don and doff; overall satisfaction)
(3) Problems (sweating, wound, skin irritation, pain, pistoning within the socket, residual limb rotation inside the socket, swelling, unwanted sounds, and bad odor)

For the overall satisfaction, the participants were asked to report how satisfied they were overall with their prosthesis for the past month. The linear analog scale response format was used.[28] Each response was scaled on a 100-mm line from 0 to 100, where 0 indicated "dissatisfaction or extreme problems" with the system and 100 showed complete satisfaction or no problems."[23] A standard ruler was used to measure the distance between 0 and the vertical mark on the line.

Data Analysis

Statistical data analysis used SPSS 18.0, where *P* values of 0.05 or less were set as the level of significance. Preliminary analyses were performed to ensure the assumption of normality and homogeneity of variance. The Kolmogorov-Smirnov test showed normal distribution of all data; therefore, parametric statistical analyses were adopted. Differences in pistoning values were examined using a 6 × 3 (loadings × suspension systems) repeated-measures analysis of variance. If significant differences were obtained from analysis of variance, paired-samples *t* tests compared the positions among the three suspension systems.

Intraclass correlation coefficient was used to evaluate the repeatability of the measurements. Qualitative analyses were used to analyze the demographic information of the respondents. To analyze the patients' satisfaction and to examine problems related to the suspension types, 18 × 3 (questions × suspension systems) repeated-measures analysis of variance computed the mean scores for each question of the questionnaire to determine significant differences among the three suspension systems. If a significant effect of a suspension type was found, paired-samples *t* tests were used to find significant differences among each two suspension systems.

RESULTS

Demographic Information

All participants were men. The mean (SD) age, height, and weight of the participants were 42 (12.8) yrs, 172 (5.1) cm, and 79.5 (12.2) kg, respectively. The cause of amputation was either diabetes or trauma. The average prosthetic masses for the suction, pin and lock, and new prosthetic suspension systems among the ten subjects were 1.75, 1.86, and 1.92 kg, respectively. The intraclass correlation coefficients of intraobserver intersession, interobserver intersession, and intraobserver intrasession were 0.80, 0.72, and 0.93, respectively.

Pistoning Evaluation

The main effect of the suspension type in adding and removing (F[2,18] = 124.11, P = 0.000) through

TABLE 2 Mean pistoning values of the three suspension systems in different static positions during adding and removing loads (n = 10)

	Adding Load							Removing Load						
	FWB	SWB	NWB	30 N	60 N	90 N		90 N	60 N	30 N	NWB	SWB	FWB	
	Mean	Mean	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	ANOVA	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean	ANOVA
Suction	0	0	0.2 (0.1)	0.9 (0.4)	1.7 (0.5)	2.8 (0.5)	0.000[a]	2.8 (0.5)	2.6 (0.5)	2.6 (0.5)	2.6 (0.5)	1.0 (0.2)	0	0.000[a]
Magnetic lock	0	0	1.0 (0.6)	2.0 (0.5)	3.3 (1)	5.3 (0.7)		5.3 (0.7)	4 (0.7)	2.8 (0.8)	1.0 (0.4)	0	0	
Pin lock	0	0	1.5 (0.5)	2.7 (0.7)	4.3 (1.1)	5.8 (0.8)		5.8 (0.8)	5.4 (0.5)	4.0 (1.2)	3.6 (0.5)	0	0	
Significance (two tailed)			1–2 (0.007) 1–3 (0.000) 2–3 (0.016)	1–2 (0.000) 1–3 (0.000) 2–3 (0.004)	1–2 (0.000) 1–3 (0.000) 2–3 (0.002)	1–2 (0.000) 1–3 (0.000)		1–2 (0.000) 1–3 (0.000)	1–2 (0.000) 1–3 (0.000) 2–3 (0.000)	1–2 (0.045) 1–3 (0.000) 2–3 (0.001)	1–2 (0.000) 1–3 (0.000) 2–3 (0.000)	1–2 (0.000) 1–3 (0.000)		

All values are in millimeter. "1–2," "1–3," and "2–3" indicate that significant differences (P < 0.05) were found between each two suspension systems in each loading position based on the paired-samples *t* tests.

[a]Indicates significant differences among the three suspension systems from the repeated-measures ANOVA.

FWB indicates full weight bearing; SWB, semi–weight bearing; NWB, non–weight bearing; ANOVA, analysis of variance.

analysis of variance demonstrated a significant difference between the three suspension systems. There was also a significant difference between the different positions of adding and removing ($P = 0.000$). Therefore, paired-samples t tests were used to determine significant differences between each pair of suspension systems. When the base measurement at full weight bearing was compared with the peak pistoning at 90-N loading, the new magnetic system caused approximately the same amounts of pistoning as the pin and lock system ($P = 0.086$). However, the suction system (Seal-In X5) showed less pistoning compared with both the pin and lock and the new magnetic system ($P < 0.05$ for both comparisons). From semi– to non–weight bearing, mean (SD) pistoning was lower with the new magnetic lock system than with the pin lock system (1.0 [0.6] cm *vs.* 1.5 [0.5] cm, new magnetic lock system and pin lock system, respectively; $P = 0.016$), whereas the new magnetic lock system had higher mean (SD) pistoning in comparison with the suction suspension system (1.0 [0.6] cm *vs.* 0.2 [0.1] cm, new magnetic lock system and suction suspension system, respectively; $P = 0.007$). When a 30-N load was added, a significant difference was seen in the displacement with the new magnetic lock system compared with the pin lock system because the new lock resulted in less displacement ($P = 0.004$). Conversely, less pistoning occurred with the suction system than with the new magnetic lock system ($P = 0.000$). Same significant differences were seen in the pairs of magnetic-pin lock and magnetic-suction system when 60-N loads were added (both $P < 0.05$). Table 2 presents the mean displacements between the liner and the hard socket with the three suspension types under different static conditions (adding and removing loads). As the authors expected, the pistoning reduced in the process of removing the loads for all three systems. Nevertheless, the reduction did not follow the same trend that was found during

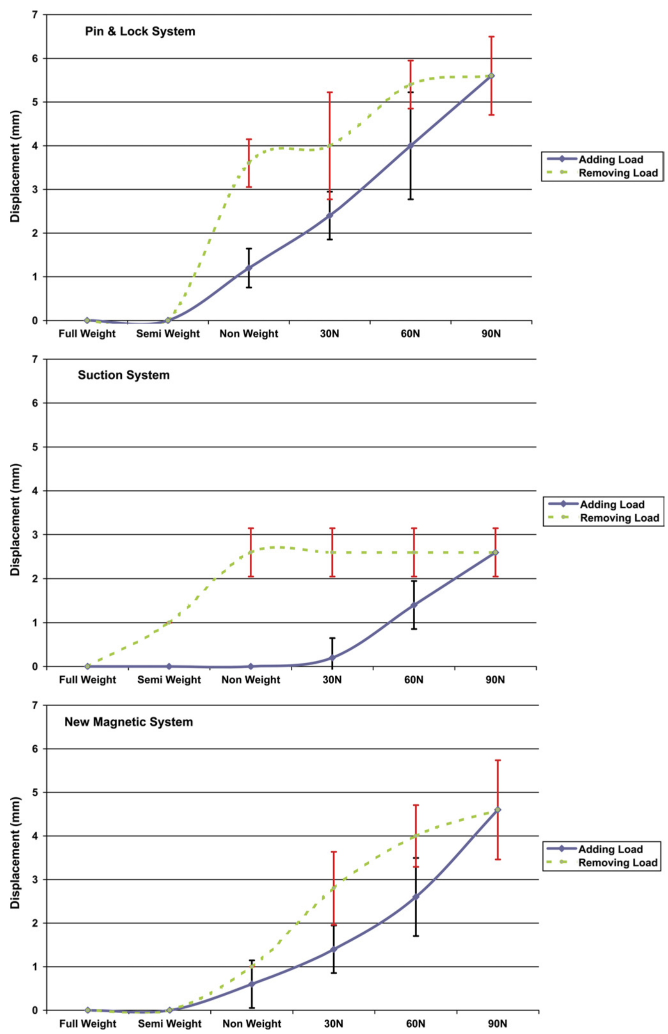

FIGURE 2 *Pistoning results for adding and removing loads in static positions for three suspension systems. (n = 10; displacement ± standard deviation).*

the adding procedure because significant differences were found between the pistoning values in adding and removing (for 30 N, 60 N, and non–weight bearing) when each system was individually studied. Figure 2 illustrates the mean pistoning values (±standard deviation) in each weight-bearing condition for the three studied suspension systems.

Satisfaction

There was a significant effect for the suspension type among all questions of the questionnaire ($F[2, 18] = 153.18$, $P = 0.000$). The questionnaire survey revealed that the overall satisfaction rate with the magnetic system was higher than with the pin lock and suction systems ($P < 0.05$ for both

TABLE 3 Mean scores of satisfaction and problems with the three suspension systems

	Suction	Magnetic Lock	Pin and Lock	Significance (*t* test)
Satisfaction				
Fitting	87.09	76.82	79.59	1–2 (0.002) 1–3 (0.003) 2–3 (0.044)
Donning and doffing	57.24	79.68	71.44	1–2 (0.000) 1–3 (0.016) 2–3 (0.000)
Sitting	79.41	76.44	68.80	1–3 (0.001) 2–3 (0.041)
Walking	65.21	84.66	72.80	1–2 (0.000) 1–3 (0.008) 2–3 (0.000)
Uneven walking	63.91	77.93	54.30	1–2 (0.000) 1–3 (0.030) 2–3 (0.000)
Stair	68.83	80.60	65.75	1–2 (0.001) 2–3 (0.000)
Suspension	93.71	81.72	75.20	1–2 (0.000) 1–3 (0.000)
Cosmesis	83.10	73.27	69.05	1–2 (0.004) 1–3 (0.000)
Overall satisfaction	63.14	83.10	75.94	1–2 (0.000) 1–3 (0.000) 2–3 (0.008)
Problems				
Sweat	64.78	60.16	55.00	1–2 (0.009) 1–3 (0.019)
Wound	95.17	75.04	81.85	1–2 (0.000) 1–3 (0.000) 2–3 (0.017)
Irritation	94.66	75.10	81.28	1–2 (0.000) 1–3 (0.000) 2–3 (0.021)
Pistoning within the socket	96.47	63.95	84.18	1–2 (0.000) 1–3 (0.000) 2–3 (0.000)
Rotation within the socket	99.57	81.65	80.18	1–2 (0.000) 1–3 (0.000) 2–3 (0.017)
Swelling	94.91	89.64	86.75	1–2 (0.017) 1–3 (0.000)
Bad smell	77.83	63.94	72.49	1–2 (0.000) 1–3 (0.007) 2–3 (0.002)
Unwanted sound	96.81	80.28	70.21	1–2 (0.000) 1–3 (0.000) 2–3 (0.003)
Pain	80.67	90.18	70.62	1–2 (0.000) 1–3 (0.000) 2–3 (0.000)

"1–2," "1–3," and "2–3" indicate that significant differences ($P < 0.05$) were found between each two suspension systems in each satisfaction/problems item based on the paired-samples *t* tests.

comparisons; Table 3). Donning and doffing were easier with the magnetic suspension system compared with the pin lock system (mean score, 79.68 *vs.* 71.44, magnetic suspension system and pin lock system, respectively; $P = 0.000$) and the suction system (mean score, 79.68 *vs.* 57.24, magnetic suspension system and suction system, respectively; $P = 0.000$), with 95% confidence intervals. The subjects stated that they were more satisfied during walking and stair climbing with the new magnetic system than with the two other systems ($P < 0.05$ for both comparisons). Suspension satisfaction with the new magnetic system was similar to the pin lock system ($P = 0.062$, two tailed), whereas the suction suspension system resulted in higher satisfaction score in comparison with the new system ($P = 0.000$). The statistical analysis showed significant differences in some of the complaint/problem items ($P < 0.05$) among the three suspension systems. Pain score with the new magnetic system was significantly less than with the pin lock suspension system (90.18 *vs.* 70.62, new magnetic system and pin lock suspension system, respectively; $P = 0.000$). In addition, problems with unwanted sound were higher with the pin and lock system compared with the new system; however, the subjects experienced less unwanted sound with the suction system than with the new system ($P < 0.05$ for both comparisons). Table 3 demonstrates the mean, standard deviation, and significance values of the suspension systems with respect to the problems.

DISCUSSION

This research study compared the new suspension system with the two existing methods of suspension to investigate their effects on pistoning and patients' satisfaction. This study revealed that the new design of prosthetic suspension had the potential for use with transtibial amputees. Based on the results, the repeatability of the measurements was high and there was no significant difference between the observers.

When evaluating the authors' hypothesis regarding the difference between the pistoning with the pin lock and the magnetic system, pistoning seemed comparable from full weight bearing to 90 N for the pin lock system and the magnetic suspension system. The statistical analyses revealed higher peak pistoning with the new magnetic system in comparison with the suction system from full weight bearing to addition of the 90-N load ($P < 0.05$). Researchers have performed various evaluations of piston motion with a variety of prosthetic sockets and soft interfaces. Studies have found that total-surface–bearing sockets with silicone liners result in significantly less piston motion between the liner and the socket.[18,29] In the current study, the suction system (Seal-In X5) system resulted in the least pistoning among the three systems, which supports the findings of Gholizadeh et al.[7] The mean (SD) pistoning with the pin lock system from full weight bearing to 90 N was 5.8 (0.6) mm, which is similar to the results of the studies by Tanner and Berke,[30] Board et al.,[27] and Gholizadeh et al.[7]

None of the three systems studied demonstrated pistoning movement from full– to semi–weight bearing, which is not surprising because in the full weight-bearing position, the limb moved distally in the socket and a large force was developed between the liner and the socket that restricted pistoning strongly. Slight differences were seen in the systems' behaviors between adding loads and the reversed process of loading (removing loads), particularly for the suction system (Seal-In X5). The mean pistoning values for 60 N, 30 N, and non–weight bearing did not statistically approach the same values that were seen during adding loads (non–weight bearing, 30 N, and 60 N) when each suspension system was individually studied ($P < 0.05$ for all three systems). The exception was that with the suction system, no significant difference was seen between each single step from 60 N to non–weight bearing. This denotes a delay in the process, which might be associated with the increased friction and suction between the Seal-In X5 and the socket wall (Fig. 2). Nevertheless, further research is needed to prove this assumption.

One of the hypotheses of the authors was that there will be a significant increase in satisfaction rates with the new suspension system than with the other two systems. All three suspension systems studied in this research showed approximately high satisfaction rates among the participants. Nevertheless, the qualitative survey demonstrated significant differences in satisfaction and perceived problems with the new design compared with the pin lock and suction systems. The new magnetic suspension system resulted in higher satisfaction scores than the pin lock and suction systems only on a number of items.

The new magnetic suspension system seems to be similar to the current systems in function because it can retain the prosthesis on the residual limb during ambulation. Furthermore, the new suspension system produced less noise during walking and donning compared with the pin lock suspension system ($P = 0.003$), was much easier to don and doff compared with the suction suspension and pin lock systems ($P < 0.05$ for both), and resulted in higher overall satisfaction in comparison with both the suction and pin lock systems ($P < 0.05$ in both cases). Vacuum suspension is said to improve proprioception in prosthetic users[13]; however, the subjects of this study stated preference to the magnetic lock system over the suction system. The pin lock system resulted in higher satisfaction than the suction suspension (Seal-In X5) system, which is consistent with the results of the study by Gholizadeh et al.[7,21]

To compare the new magnetic suspension system to the pin lock suspension system, the undesirable noise of the locking system was significantly lower, whereas the amputee still felt secure from the audible feedback of the primary contact between the distal and proximal portions of the new system. Amputees can use the new system with their old liners because the cap is attached to the liner by silicone adhesive and a screw, which is similar to the screw diameter for most of the locking silicone liners in the market. However, the socket needs to be replaced to embed the distal part of the new magnetic system at the distal end of the socket.

The subjects of this study reported that they felt more secure with the new system compared with the pin lock suspension system. They believed that with the pin lock system, they felt like they were walking on an unstable moving rod (pin), whereas when they walked with the new system, they experienced a firm, stable base of support under the residual limb. That might be associated with the cross-sectional difference between the single pin (the pin lock system) and the cup-shaped cap of the new system. Nevertheless, their subjective reports revealed that the suction system resulted in higher confidence during walking, which is consistent with the study by Gholizadeh et al.[7] that the participants reported they felt the leg to be a normal part of their body with the suction system.

The cosmesis of the new system was almost the same as that of the pin lock system ($P = 0.185$). Conversely, the subjects were more satisfied with the suction system compared with the new magnetic system in cosmesis, which can be attributed to the added components. In addition, the same problem of the pin lock system may arise with long stumps because of limited space below the socket for installation.

Effortless donning and doffing seems to result in higher overall satisfaction.[10,11] The Seal-In X5 liner has solved some of the problems with pin lock systems; however, patients still require more time and effort when donning and doffing. They also need to use lubricant sprays (Clean & Simple Lubricant spray, Ossur) to facilitate the donning process of both the liner and the socket. Moreover, hand dexterity is more critical for donning and doffing the Seal-In X5 liner compared with the Dermo liner. Rolling the Seal-In X5 is more difficult because the seals do not smoothly slide over each other unless some lubricant spray is used. The subjects of this study were mainly dissatisfied with the donning and doffing of the Seal-In X5 system; donning and doffing was significantly easier with the magnetic system. Meanwhile, the subjects of this study experienced less pistoning and rotation within the prosthetic socket with the suction system compared with the new magnetic lock system, which is consistent with the results obtained from the pistoning measurement by motion analysis system. The subjects stated preference for the new magnetic system over the Seal-In X5 and pin lock for long-term use.

Some patients have trouble aligning the pin when donning the prosthesis. In the proposed system, the distal and proximal components at the distal end of the liner and socket are easily connected as soon as the residual limb is located into the hard socket. The total contact fit also deteriorates, especially if the residual limb is pointed and bony. The new system might resolve the so-called problem of milking or distal tissue stretching caused by the pin and lock.[12,13] This milking phenomenon can also result in pain, particularly at the end of the tibia and along the tibial crest. The pin lock suspension is said to have short- and long-term negative effects on the residual limb.[12] Short-term effects are discoloration and swelling at the distal end of the residual limb, which will result in the change in soft tissue shape, skin thickness, and color in the long-term. These changes might be the result of liner elongation, which develops milking. As a result, the residual limb is compressed at the proximal end and stretches the distal soft tissue, particularly during the swing phase.[12] Nevertheless, further studies are needed to investigate the effect of this new system on milking.

Although the authors did not measure the pressure interface within the prosthetic socket, the subjects in the current study had significantly less pain with the new magnetic system compared with the pin lock suspension system ($P = 0.000$). This reduction in pain may be attributed to the evenly distributed contact pressure between the proximal part of the magnetic suspension system and the distal end of the liner. There is full contact between the proximal cap of the new system and the distal end of the liner in contrast to the pin lock suspension; therefore, it is anticipated to reduce the milking.

On the basis of the available literature and the findings of this study, it is possible to conclude that pistoning alone might not be a good indicator of clinically superior suspension systems. Satisfaction, particularly with donning and doffing, should also be taken into account when choosing a prosthetic suspension system for a lower limb amputee.

Study Limitations

The population was small with respect to the number of variables that were analyzed in the questionnaire. Long-term follow-up of the new system may further prove its potential as an alternative prosthetic suspension method. Research is ongoing on the effects of the new system on pistoning and interface pressure during walking.

CONCLUSIONS

This study introduced a new prosthetic suspension system for transtibial prostheses.

The new magnetic suspension system and the pin lock system cause comparable pistoning but higher pistoning than the suction system does. Satisfaction was improved in donning and doffing, noise, and overall satisfaction with the new magnetic lock system compared with the pin lock and suction systems.

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