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Socket Interface Pressure and Amputee Reported Outcomes for Comfortable and Uncomfortable Conditions of Patellar Tendon Bearing Socket: A Pilot Study

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The objectives of the current study were to compare intra-socket pressure differences between comfortable and uncomfortable socket conditions, and the usefulness of subject perception of satisfaction, activity limitations, and socket comfort in distinguishing between these two socket conditions. Five unilateral trans-tibial amputees took part in the study. They answered the Socket Comfort Score (SCS) and Trinity Amputation and Prosthetic Experience Scale (TAPES) questionnaires before the interface pressure (in standing and walking) was measured for the uncomfortable socket condition at five regions of the residual limb. Participants were then provided with a comfortable socket and wore it for two weeks. Participants who were satisfied with the socket fit after two weeks repeated the SCS and TAPES questionnaires and interface pressure measurements. The differences between the test results of the two conditions were not statistically significant, except for the interface pressure at the popliteal region during the early stance phase, TAPES socket fit subscale, and the SCS. Due to large variability of the data and the lack of statistical significance, no firm conclusion can be made on the possible relationship between the interface pressure values and the patient-reported outcomes of the two socket conditions. A larger sample size and longer acclimation period are required to locate significant differences.

Keywords: socket comfort, socket fit, interface pressure, physical activity

Introduction

Lower-limb amputees rely on a prosthesis to restore functional mobility. A prosthetic socket is an interface between a prosthesis and the residual limb with socket comfort being the primary issue for amputees (Legro et al., 1999). During static and dynamic situations, forces and moments transfer from the socket to the skeletal structures via soft tissue. However, the residual limb soft tissue is not physiologically designed to tolerate these forces and moments. Therefore, the challenge is to create a socket with an interface pressure that has a stiff coupling with bony skeleton and yet does not over stress the soft tissue (Sanders, 2005).

The patellar tendon bearing (PTB) socket, introduced by Radcliffe and Foort in the 1960s (Radcliffe & Foort, 1961), is still one of the most commonly used socket types (Friel, 2005). According to the PTB principles, the residual limb is loaded proportionally to the "load tolerance" of underlying soft tissue and bony prominences. More pressure is applied to the patellar tendon (PT), popliteal (POP) areas and the medial flare (MF) of the tibia; whereas less load is applied to bony prominences such as fibular head (FH), tibial crest and anterior distal (AD) (Radcliffe & Foort, 1961).

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Socket manufacturing in most cases is based on a prosthetist's skill, past experience, and input from amputees. Prosthetists have no quantitative way of assessing socket fit (Sewell, Noroozi, Vinney, & Andrews, 2000). In clinical situations, socket fit alterations and possible adjustments are performed based on an amputee's sensation of comfort and perception of excessive localized pressure and/or pain (Kim, Lim, & Hong, 2003; Silver-Thorn, Steege, & Childress, 1996). Absence of protective sensation in peripheral vascular disease (PVD) and diabetic patients, the most prevalent cause of amputation (Gordois, Scuffham, Shearer, Oglesby, & Tobian, 2003; Jude, Oyibo, Chalmers, & Boulton, 2001; NASDAB, 2009), jeopardizes such qualitative inputs for socket fit.

Sockets usually have a good fit at first, but in many amputees, the residual limb volume decreases constantly (Sanders, Zachariah, Jacobsen, & Fergason, 2005). Long-term volume loss of residual limb leads to problems in establishing an accurate and comfortable socket fit and so increases pressure ulcer risk (Sanders et al., 2005; Sanders & Fatone, 2011). The neuropathic amputees cannot feel the discomfort caused by hypoxemia of local tissues exposed to excessive pressure because of socket fit deterioration following residual limb volume loss (Bergstrom, 2005). Skin problems also affect prosthesis use and amputee activity (Meulenbelt, Dijkstra, Jonkman, & Geertzen, 2006). Thus, measuring interface pressure could be useful in socket design evaluation (Mak, Zhang, & Boone, 2001) and in discovering the conditions risky to residual limb soft tissue such as excessive interface pressure.

In the past few decades, many researchers have investigated the interface pressure between the residual limb and socket. Most of these studies report the effects of different prosthesis components on interface pressure in a good socket fit condition (Dumbleton et al., 2009; Sanders, Lam, Dralle, & Okumura, 1997; Sanders, Zachariah, Baker, Greve, & Clinton, 2000; Wolf, Alimusaj, Fradet, Siegel, & Braatz, 2009).

Only two studies have examined the interface pressure changes during long-term intervals (Sanders, Fergason, Zachariah, & Jacobsen, 2002; Sanders et al., 2005). Sanders et al. examined interface pressure changes followed by residual limb changes as a result of amputee weight loss in a case study. They claimed that interface pressure value after weight loss in monthly intervals was increased compared to the beginning of the study (percentage differences were greater than 50%), and adding sock layers could not compensate it (Sanders et al., 2002). Another study of Sanders et al. on interface pressure changes over six months showed significant increase of interface pressure at all 13 sites evaluated ($p < .05$). The increases for peak pressure one, two, and three during walking were 2.3, 1.9, and 0.3 kPa/month, respectively (Sanders et al., 2005). Nevertheless, the effects of interface pressure differences on an amputee's comfort, activity level, and the real difference of interface pressure between comfortable and uncomfortable socket conditions are not clear. Therefore, information about interface pressure in uncomfortable and comfortable socket conditions and its effect on an amputee's physical activity is lacking. If we analyze socket interface pressure by healthy amputees with their comments about comfortable and uncomfortable socket conditions, we can diagnose safe and risky conditions of socket fit. This may be useful in expert systems of socket design and to avoid skin damage of neuropathic amputees.

Previous studies have shown that the Novel Pliance X system (Germany) incorporating capacitive pressure sensors, designed for socket-residual limb interface pressure measurement, has an acceptable accuracy and reliability (Lai & Li-Tsang, 2009; Polliack, Sieh, Craig, Landsberger, McNeil, & Ayyappa, 2000). The sensors have 12.95% hysteresis error, 9.96% accuracy error, and 6.20% drift error (Polliack, Craig, Sieh, Landsberger, & McNeal, 2002). Furthermore, the authors reported that in a clinical test–retest experiment, the sensors did not show a noticeable drift.

Therefore, the objectives of the current study were investigation of (1) whether Intra-socket pressures are different between comfortable and uncomfortable conditions of the PTB socket design, and (2) whether subject reports of satisfaction, activity limitation, and socket comfort are capable of distinguishing between these two socket conditions.

Methods

Subjects

Six unilateral transtibial amputees were recruited for this study. The ethical approval was granted by the ethics committee at USWR (University of Social Welfare and Rehabilitation). Subjects gave informed written consent before the start of the test sessions. The inclusion criteria consisted of amputation due to traumatic injury, use of PTB socket with removable polypropylene closed cell foam (Pelite) liner, decision to replace their socket due to discomfort, pain or poor socket fit due to residual limb volume loss (i.e., other parts of the prosthesis were intact), healthy residual limb skin, medium residual limb length (∼10–30 cm), using definitive socket for at least six months, and no phantom pain. Exclusion criteria were suffering from PVD and/or diabetes, discomfort after using new socket, and having an obvious cognitive disorder. Our sampling method was convenience sampling, and we interviewed below the knee amputees who had requested a socket replacement at Tehran Kawthar Orthotic and Prosthetic.

Prosthetic Intervention

Each amputee was evaluated by two prosthetic socket conditions, uncomfortable and comfortable. They had been wearing their former modular prosthesis with PTB socket, Pelite liner, and SACH foot for at least six months. They all decided to replace their sockets because of discomfort and/or pain due to residual limb volume loss. The main complaints were socket-residual limb instability and feeling of insecurity due to loose socket. Amputees added socks to compensate for the loose fit. The mean sock thickness for the uncomfortable condition was 3.84 mm (SD: 3.42). Subject number three was also suffering from pain at the distal point of the tibia. For each subject, a new PTB socket with a Pelite liner was manufactured and aligned with the previous prosthetic foot.

Pressure Measurement

The Novel Pliance X system (Germany) was used to measure interface pressure between the residual limb and the socket. The manufacturer's representation of the Pliance system in Tehran calibrated it at the beginning of the study. Before each data collection, zeroing was done, meaning that all preexisting pressures on each sensor were ignored.

The system incorporates five capacitive sensor pads (4×4 matrix, 1 mm thickness, and 20×20 mm^2 area). Each sensor pad can measure a pressure range from 20 to 600 kPa. The surface area of a single sensor is 0.25 cm^2, thus, 16 sensors in a sensor pad cover a 4 cm^2 area. These sensor pads are flexible and can be located over the curvatures (e.g., fibular head) without losing total contact with the limb; therefore, all sensors within a sensor pad were contributing to the data. We selected the mean pressure value (MPV), which is the average value over 16 sensors of each sensor pad.

Questionnaires

The Persian version of Trinity Amputation and Prosthetic Experience Scale (TAPES; Gallagher & MacLachlan, 2000; Mazaheri et al., 2011) and Socket Comfort Score (SCS; Hanspal, Fisher, & Nieveen, 2003) were used. Validity and reliability of both TAPES and SCS had been previously confirmed. TAPES can be used for analyzing an amputee's satisfaction with prosthesis and activity restriction level; its test–retest reliability was confirmed for an interval of 5–7 days between sessions (Intra-class Correlation Coefficient [ICC] ranged from 0.68 to 0.89; Mazaheri et al., 2011). SCS is a simple numerical scale from 0 to 10, where 0 corresponds to the least comfortable and 10 the most comfortable imaginable socket (Hanspal et al., 2003). The authors indicated that the SCS was shown to have a high sensitivity (76%) for change in socket comfort and was suggested for successive visits (Hanspal et al., 2003).

Data Collection

During a data collection session, subjects arrived at the biomechanics laboratory of the university with their uncomfortable prosthesis at midmorning. At the start of each session, subjects were asked to reply to the TAPES and SCS questionnaires. Then pressure sensor pads were attached using adhesive tape to five anatomical landmarks of the residual limb with the most clinical interest: MF, PT, FH, POP, and (AD). The PT sensor was attached at the mid line of the patellar tendon and POP sensor was located at the mid-line of the posterior-proximal part of the leg, two centimeters lower than the PT level (Figure 1). Then amputees donned their prosthesis with the same number of sock layers as normal incorporating the Pelite liner. Afterwards, subjects walked for 10 minutes, then the interface pressure values were recorded for two standing conditions for 60 seconds: (a) half body weight, and (b) full body weight supported by the prosthetic limb. In both conditions, a scale was placed under the prosthetic limb foot. Then subjects walked along the lab hallway (8 m long) in a straight line at their own selected speed. At the end of this distance, they waited for a couple of seconds and returned. Each standing and walking test was performed twice.

Then the uncomfortable socket was replaced with a new socket made and aligned by a single certified prosthetist. Amputees were asked to use the new prosthesis for at least two weeks. If they were satisfied with socket comfort, they were called to the testing laboratory, and the whole procedure was repeated. In all sessions, the sensor pads were attached by one person according to the residual limb anatomical features to avoid inconsistency.

Data Analysis

The MPV of 10 seconds for each repetition of the standing tests was selected. We used the ICC to test for the intra-session reliability of sensor placement and the pressure measurement values. An ICC value greater than 0.7 is regarded as an acceptable test reliability (Campbell, Machin, & Walters, 2007). As all values showed reliability of ICC > 0.7, we calculated the average of the two tests. Five walking cycles from each repetition were selected and averaged. Previous studies have shown that the interface pressure values during the stance phase of the gait cycle show two peaks corresponding to early stance (ES) and late stance (LS), and a minimum value at mid stance (MS), similar to the pattern of ground reaction force (Fish & Nielsen, 1993; Sanders, Daly, & Burgess, 1993). Therefore, in the current study, we chose two peak values at (ES) and (LS) and the minimum value at the (MS) (labeled as PPV); for statistical analysis, no data filtering was performed. The paired sample t-test was used to assess the statistical significance between the two measurements. When the normal distribution could not be justified (using Shapiro-Wilk test), the Wilcoxon-signed ranks test was used.

Results

Subjects

Six subjects were recruited to the study, but five subjects (all males) completed the test sessions. One amputee did not perform the second test session because excessive pressure on his popliteal region led to his dissatisfaction with the new socket. Their demographic information is presented in Table 1.

Pressure Values

The MPV differences between uncomfortable and comfortable socket conditions in all standing tests were not statistically significant ($p > .05$; Table 2). However, the results show that in the semi-weight bearing condition, in a comfortable socket compared to uncomfortable socket, the interface pressure increased at the POP region but decreased at the FH, PT, AD, and MF regions (in a descending order). Also, in the full weight-bearing tests

Table 1. Demographic information of subjects.

Demographic Information	Min	Max	Mean (±SD)
Age (year)	35.00	52.00	43.40 (± 7.16)
Weight (Kg)	75.00	105.00	87.20 (± 12.46)
Residual limb length (cm)	12.00	26.50	19.10 (± 5.35)
Time after amputation (year)	1.00	30.00	18.60 (± 13.99)
Time using current prosthesis (year)	0.83	16.00	5.56 (± 6.02)

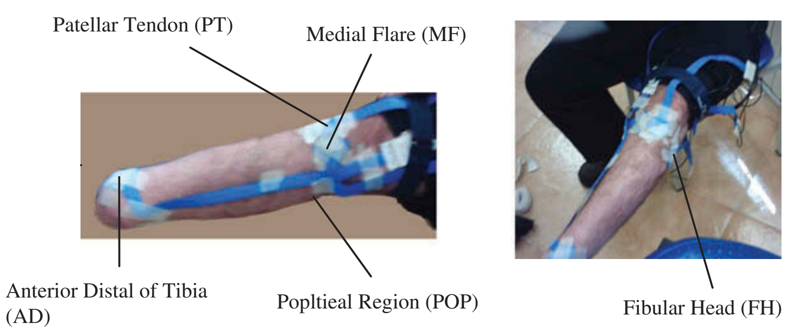

Fig. 1. Senor fixation on residual limb.

Table 2. Mean pressure value (kPa) during standing.

Site/ Socket Fitting Condition		Semi-weight bearing				Full weight bearing			
		Uncomfortable	Comfortable	Significance ($p < .5$)	Percentage difference	Uncomfortable	Comfortable	Significance ($p < .05$)	Percentage difference
MF	Mean	18.65	17.06	0.78	−8.53%	34.60	38.64	0.57	11.68%
	(SD)	(10.87)	(8.33)			(20.41)	(15.49)		
	Min	9.74	9.22			11.62	21.20		
	Max	34.09	24.61			58.19	53.79		
PT	Mean	61.43	28.72	0.28	−53.25%	53.72	88.14	0.53	64.07%
	(SD)	(72.74)	(24.97)			(50.78)	(72.83)		
	Min	6.47	13.17			5.99	18.72		
	Max	168.32	66.02			107.48	189.72		
FH	Mean	44.57	11.84	0.46	−73.44%	15.45	19.81	0.73	28.22%
	(SD)	(70.75)	(12.41)			(13.13)	(18.06)		
	Min	6.38	0.22			0.74	4.98		
	Max	150.52	25.24			28.28	45.85		
POP	Mean	15.57	22.84	0.15	46.69%	21.96	31.63	0.34	44.03%
	(SD)	(10.27)	(12.88)			(19.08)	(31.38)		
	Min	2.06	3.69			2.42	1.78		
	Max	26.48	30.94			46.59	60.86		
AD	Mean	47.92	32.70	0.27	−46.54%	59.74	57.46	0.95	−3.82%
	(SD)	(28.33)	(21.95)			(26.44)	(39.76)		
	Min	23.70	17.45			30.92	7.65		
	Max	78.71	65.28			87.34	98.77		

Note: AD, Anterior distal; FH, Fibular head; MF, Medial flare; POP, Popliteal; and PT, Patellar tendon.

with a comfortable socket, larger interface pressure was applied to PT, POP, FH, and MF regions (in a descending order), and less pressure was applied to AD than the uncomfortable socket (Table 2).

The MPVs of each sensor pad for entire walking cycle in uncomfortable and comfortable socket conditions are shown in Figure 2. There was no statistically significant difference in the PPVs of the walking test between the two socket conditions except for the POP region in (ES) ($p = .04$) in which the comfortable socket resulted in a larger PPV value (Table 3).

The PPV differences (for walking tests) between uncomfortable and comfortable socket conditions can be seen in Table 3. Although not statistically significant, in the comfortable socket condition, the mean PPV values were smaller at the FH and AD regions compared with the uncomfortable socket condition during the entire stance period. Also, in the comfortable socket, the mean PPV at PT and MF regions was smaller at the (ES) and (MS) but larger at the (LS) compared to the uncomfortable condition. Mean PPV of PT in the (LS) was larger than MF.

Questionnaires

The SCS value was significantly higher in the comfortable socket ($p < .05$) Table 4).The mean values of “activity restriction” and “satisfaction” scales of the TAPES questionnaire did not show a significant difference between uncomfortable and comfortable socket conditions (p > .05; Table 4). However, the “socket fit” subscale of the “satisfaction” scale of TAPES showed a significant difference between the two socket conditions ($p < .05$; Table 4).

Discussion

Long-term changes of interface pressure as a result of residual limb volume loss could affect an amputee’s comfort and satisfaction with a prosthesis as well as the daily activity level. Quantification of interface pressure and qualitative data about amputee satisfaction and function for uncomfortable and comfortable socket conditions can provide useful information relevant to determining proper and improper socket fitting conditions. This may be useful for neuropathic amputees who lack protective sensation in the residual limb.

Although we did not quantify the residual limb-socket volume relations, in the uncomfortable socket condition, subjects had to add many sock layers between residual limb and socket, and all participants complained of “loose” socket fit. The socket volume of each subject was relatively larger than the residual limb, and amputees added sock layers to compensate for excess socket-residual limb movement during weight bearing. In a case study, Sanders et al. (2002) reported that adding sock ply after residual limb volume loss fails to restore the interface pressure to the previous values. The interface pressure with sock ply addition was higher distally than proximally compared to a socket with no socks. The authors indicated that the subjects in their study had their residual limb atrophied locally and the residual limb moved down the socket and, as a result, the interface pressure at the distal residual limb and the PT increased. In the present study, the interface pressure differences between comfortable and uncomfortable socket conditions were not statistically significant, except for the POP region in the (ES) phase of walking. However, the results of walking tests, although not

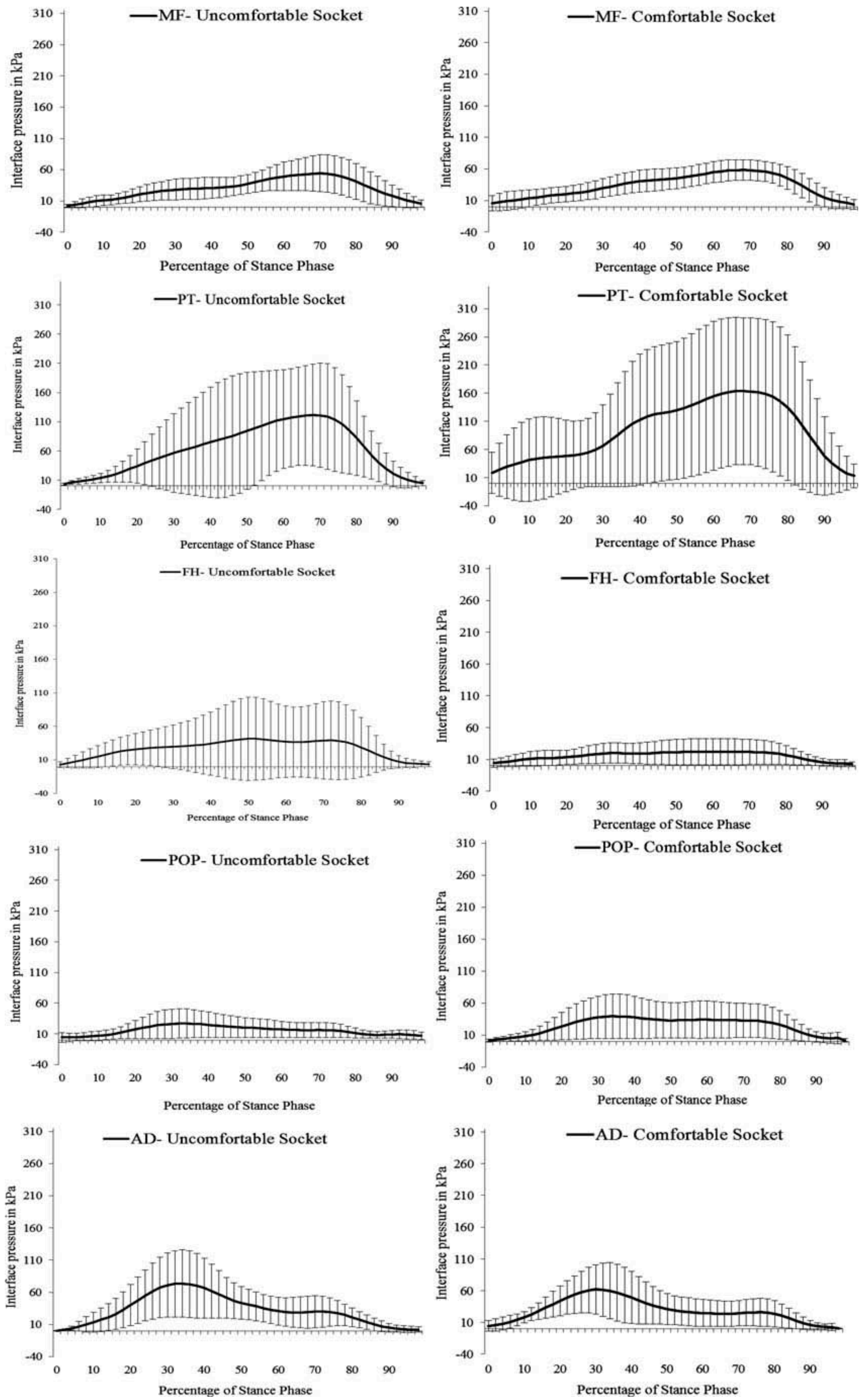

Fig. 2. Mean pressure value of walking tests for each sensor in uncomfortable and comfortable socket conditions.

Table 3. Peak pressure values (kPa) in walking tests.

Socket Fitting Condition/ Site	Gait phase	Uncomfortable			Comfortable			Percentage Difference	Significance $p < .05$
		Min	Max	Mean (SD)	Min	Max	Mean (SD)		
MF	ES	25.27	50.86	33.86 (10.90)	17.20	57.10	37.31 (16.49)	10.38%	0.96
	MS	18.31	51.29	31.07 (13.18)	22.39	58.11	37.76 (15.22)	21.53%	0.49
	LS	26.42	93.83	53.16 (25.35)	31.53	72.10	57.92 (15.65)	8.95%	0.65
PT	ES	8.84	251.68	83.21 (98.67)	11.79	171.60	80.30 (66.21)	−3.50%	0.94
	MS	7.81	241.89	78.50 (96.04)	6.15	154.79	72.58 (62.89)	−7.54%	0.89
	LS	52.84	258.45	119.67 (80.64)	68.56	404.76	166.10 (136.02)	38.80%	0.50
FH	ES	4.89	161.87	47.23 (64.98)	1.65	48.33	24.13 (20.27)	−48.91%	0.34
	MS	0.67	147.02	40.48 (60.20)	0.0	36.05	19.31 (17.31)	−52.30%	0.68
	LS	0.65	164.95	46.84 (67.15)	0.11	51.53	22.62 (21.48)	−51.71%	0.34
POP	ES	4.25	58.59	29.09 (23.61)	5.22	86.22	43.24 (33.83)	48.64%	**0.04**
	MS	2.87	36.72	18.63 (14.78)	3.84	59.56	32.64 (25.76)	75.20%	0.05
	LS	4.20	39.69	19.74 (15.04)	4.43	70.65	35.74 (28.91)	81.05%	0.06
AD	ES	48.51	140.76	83.20 (37.85)	18.50	126.30	62.12 (39.26)	−33.93%	0.40
	MS	9.81	46.83	29.50 (14.46)	12.79	58.14	28.98 (17.62)	−1.76%	0.96
	LS	15.26	53.94	35.95 (15.18)	2.67	61.32	28.94 (21.58)	−19.50%	0.54

Note: Significance difference is bolded. AD, Anterior distal; ES, Early stance; FH, Fibular Head; LS, Late stance; MF, Medial flare; MS, Mid stance; POP, Popliteal; and PT, Patellar tendon.

Table 4. Result of questionnaires.

Questionnaire			Uncomfortable socket condition			Comfortable socket condition			Relative Percentage difference	Significance
			Min	Max	Mean (SD)	Min	Max	Mean (SD)		
SCS (10)			0	7	4.80 (2.77)	3	10	7.10 (2.56)	23%	**0.03**
TAPES	Satisfaction Scale	Color (4)	2	4	3.00 (1.00)	2	4	3.20 (0.84)	5%	0.70
		Shape (4)	1	4	2.60 (1.34)	2	4	3.20 (0.84)	15%	0.31
		Sound (4)	2	4	3.20 (1.09)	1	4	2.60 (1.52)	−15%	0.46
		Appearance (4)	2	4	2.80 (0.84)	0	4	2.80 (1.64)	0%	1.00
		Weight (4)	0	3	2.40 (1.34)	3	4	3.20 (0.45)	2%	0.32
		Usefulness (4)	2	4	3.00 (0.71)	1	4	3.20 (1.30)	5%	0.75
		Reliability (4)	3	4	3.20 (0.45)	0	4	3.00 (1.53)	−5%	0.80
		Fit (4)	0	4	1.40 (1.67)	2	4	3.20 (0.84)	45%	**0.04**
		Comfort (4)	0	4	1.40 (1.67)	0	4	2.40 (1.82)	25%	0.20
		General (4)	0	4	1.80 (1.79)	2	4	3.20 (0.84)	35%	0.16
		Total (40)	18	36	24.80 (7.39)	16	40	30.00 (10.17)	13%	0.25
	Activity Restriction Level	Athletic (8)	4	6	4.60 (0.89)	2	6	4.20 (1.64)	−5%	0.14
		Functional (8)	0	3	1.20 (1.30)	0	5	1.80 (2.49)	7.5%	0.92
		Social (8)	0	3	1.40 (1.34)	0	5	1.60 (2.07)	2.5%	0.19
		Total (24)	5	11	7.20 (2.39)	4	14	7.60 (3.78)	1.67%	0.83

Note: Significant differences are bolded.

statistically significant, showed that measured PPVs at FH (during ES, MS, and LS) and AD (during ES and LS) were smaller, but larger at POP (during ES, MS) and PT (at LS) in the comfortable socket (Table 3). This could be due to the design principles of the PTB socket (Radcliffe & Foort, 1961), in which greater pressure is applied to the PT and POP regions and less over the areas with thinner soft tissue thickness. However, due to large variability of the data and the lack of statistical significance, no firm conclusion can be made on the possible relationship between the interface pressure values and the SCS of the two socket conditions.

In static semi-weight bearing tests, lower MPVs were recorded for the comfortable socket condition at all examined regions of the residual limb (especially at FH and AD)—the POP region with a 46% increase was an exception. In the static full-weight bearing tests, more MPV values at proximal regions of the residual limb with thicker soft tissue (i.e. PT region [with a 64.07% increase] and POP [with a 44.03% increase]), were seen in the comfortable socket condition. However, it was surprising that MPV of FH in the more comfortable socket condition was 28.22% higher than uncomfortable. Therefore, it seems that during full-weight bearing in the uncomfortable socket, the entire proximal region including the FH was not contributing to the weight bearing. Although these results are not statistically significant, one plausible explanation could be that in the uncomfortable socket condition, during full–weight bearing, the pressure is more concentrated over the distal residual limb and also perhaps areas not evaluated in the present study.

In the comfortable socket, the residual limb seemed to move distally during full-weight bearing and therefore exerts some force over the FH and AD, but this perhaps happened in a way that the pressure was still below the uncomfortable threshold. Lee, Zhang, and Mak (2005) recorded the amount of pressure for pain threshold and pain tolerance of the residual limb at 11 sites using a manual indenting device. The authors reported that the PT had the highest pain threshold (780 ± 370 kPa) and was significantly different from the lowest pain threshold at the distal end of the fibula (350 ± 90 kPa).The amount of pain inducing pressure at POP was smaller than the FH (450 ± 180 kPa and 680 ± 210 kPa, respectively) . Based on the PTB design, regions with thicker soft tissue are regarded as pressure tolerant, whereas Lee et al. reported that these areas did not show a higher pressure tolerant threshold than the areas with thinner layer of soft tissue. They reasoned that these areas are "deformation tolerant" rather than "pressure tolerant" (Lee et al., 2005). The pressure values recorded for both socket conditions in the present study were far smaller than those reported by Lee et al. In the present study, for both sockets and the testing conditions, the patellar tendon area was subjected to the highest pressure. In a case series study by Zhang, Turner-Smith, Tanner, and Roberts (1998) the maximum interface pressure, in a PTB socket during standing, was recorded at the popliteal area as 125 kPa and 220 kPa, with half and full body weight, respectively. The average peak pressure ranged from 25 kPa to 320 kPa. The anterior distal of the tibia was another high peak pressure area, but the patellar tendon was not reported to have a high pressure area. Based on the results of the present study (although insignificant) and the previous studies, it may be suggested that a socket design consideration would be to adjust for residual limb volume and shape in a way that the pressure in the proximal areas with a larger soft tissue (e.g., popliteal area, and the distal areas with less soft tissue such as anterior distal of tibia) has an optimum value and perhaps is not necessarily based on the design principle of the PTB (Radcliffe & Foort, 1961). Such a design may prevent the residual limb from sinking down the socket, and therefore, the areas with less soft tissue thickness are less subjected to excessive pressure. However, more research is required to better understand the socket-residual limb interactions and also to validate the available socket designs.

Significant improvement in the SCS value and satisfaction from socket fit subscale was observed for the comfortable socket condition. The differences in the activity restriction scale of the TAPES questionnaire were not significant between the two socket conditions. A possible explanation is the small size for such a qualitative measure. None of the participants were involved in lifting heavy objects or doing vigorous activities. Maybe the uncomfortable socket did not have an effect on basic activities, or amputees decided to change the socket just before their activities were negatively affected by the socket fit. In other words, it seems that the activity restriction scale of the TAPES questionnaire is not sensitive enough to locate the activity restriction difference resulting from uncomfortable socket conditions. Many participants in Deans, McFadyen, & Rowe (2008) had also commented that athletic subscale of the TAPES questionnaire is irrelevant with regard to functional aspects of their lifestyle. However, the two-week acclimation period used in the present study may be a short time interval for a new socket condition to show a possible effect on activity restriction level. The two-week time was chosen because based on clinical experience, most complaints about the fit of a new socket are reported during this period.

The present study was conducted on five below-the-knee amputees, and the data had large variance. The large variance of the PPVs may be due to shape inconsistency of the PTB design. The PTB socket is manufactured following the residual limb manual shape capturing process using Plaster of Paris and the subsequent rectification of the 3-D plaster model of the residual limb—both of which are highly subjective and depend on the hand dexterity and skill of the prosthetist. Safari, Rowe, McFadyen, and Buis (2013) reported that the PTB design results in an inter and intra-socket shape inconsistency especially at the proximal region. Besides, the large variability in the measured interface pressure could have increased due to differences in participants' weight, duration of prosthetic use, stump length and shape, walking speed. and perhaps the difference in the local residual limb volume loss pattern.

The statistical power of this study was low (0.34). Based on the results of the present study for interface pressure in the AD region, 47 subjects are needed to find a significant mean difference of 21 kPa (SD = 50.28) with a power of 0.85. Therefore, more subjects are suggested for future studies to find a possible statistically significant difference between the two socket conditions.

We employed only five sensor pads with a relatively small surface area, so it was impossible to evaluate the entire surface area of the residual limb. Pressure measurement of a larger surface area could result in a more extensive understanding of the interface pressure profile difference between the comfortable and uncomfortable sockets. Furthermore, we did not measure socket/residual limb shape or volume. The shape and volume information, besides the interface pressure data and the amputee reported outcomes, could provide a more in depth insight into the socket-residual limb relations in comfortable and uncomfortable socket conditions. Furthermore, other socket designs (e.g. Total Surface Bearing and Hydrostatic Sockets) should be considered in future studies.

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