

Dynamic interface pressure distributions of two transtibial prosthetic socket concepts

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Abstract—In this study, we investigated and compared the dynamic interface pressure distribution of hands-off and hands-on transtibial prosthetic systems by means of pressure mapping. Of the 48 established unilateral amputees recruited, half ($n = 24$) had been wearing pressure-cast prostheses (IceCast Compact) and the other half ($n = 24$) had been wearing hand-cast sockets of the patellar tendon bearing design. We measured the dynamic pressure profile of more than 90% of the area within each prosthetic socket by means of four Tekscan F-Scan socket transducer arrays. We compared the interface pressure between socket concepts. We found that the distribution of dynamic pressure at the limb-socket interface was similar for the two intervention (socket prescription) groups. However, a significant difference was found in the magnitude of the interface pressure between the two socket concepts; the interface pressures recorded in the hands-off sockets were higher than those seen in the hands-on concept. Despite the differences in interface pressure, the level of satisfaction with the sockets was similar between subject groups. The sockets instrumented for this study had been in daily use for at least 6 months, with no residual-limb health problems.

Key words: amputee, dynamic interface pressure, hand cast, patellar tendon bearing, pressure cast, pressure measurement, prosthesis, prosthetic socket, rehabilitation, transtibial.

INTRODUCTION

An estimated 5,500 people in the United Kingdom require a lower-limb amputation each year, and of these,

some 70 percent are fitted with transtibial prostheses [1]. A major problem for people with transtibial prostheses is failure to accept and use their prosthesis because of discomfort experienced at the prosthetic socket interface [2–4]. Consequently, the prosthesis supplied can have a major impact on the patient's quality of life. To give the best prospect of continued use, the prosthesis must be comfortable and functional for the user. Although evidence-based practice is paramount to the provision of optimum care and enhancing quality of life for the amputee, a limited amount of evidence is available to prescribing clinicians that provides a clear understanding of what constitutes a “good socket fit.” Residual limb-socket interface pressure has been cited as an important consideration for assessing user comfort [5–15]. A wide variety of pressure measurement systems have been employed. However, most researchers use a limited number of small discrete transducers to study the pressure changes during amputee gait. Sanders et al. described a study in which a

Abbreviations: ANOVA= analysis of variance, A/P = anterior/posterior, PTB = patellar tendon bearing, SD = standard deviation.

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maximum of 13 such sensors was used [16], and a similar system was used by Zachariah and Sanders [17]. These studies were not able to create an overall picture of the pressure distribution of the surface of the investigated prosthetic socket during amputee gait.

A research team based at the University of Strathclyde has reported a number of pilot studies showing that dynamic residual limb-socket interface pressure data can be recorded for more than 90 percent of the interior surface of a transtibial socket [9,14,18]. They compared a hands-off pressure-casting concept and a hands-on casting concept for a single subject using a validated pressure measurement system [8]. The sockets were instrumented with four Tekscan™ transducer arrays (Tekscan, Inc; Boston, Massachusetts), comprising a total of 350 individual sensing points. Data, sampled at 150 Hz, resulted in more than 50,000 pressure measurements for a single prosthetic step. This unique validated setup allows critical areas to be determined, rather than having transducers placed on areas presumed to be of interest. The transducer configuration of the Tekscan system does not interfere with the clinical use of the prosthesis, unlike other systems in which holes have to be drilled and tapped in the socket and transducers screwed to the socket.

Radcliffe and Foort developed the theoretical basis of a transtibial socket shape in relation to residual-limb characteristics [19]. This theory was clarified and adapted by Klasson, who described the most likely load transfer elements available within the soft tissues and the “ideal” pressure distribution over a selected bony area to avoid or minimize local peak pressures [20]. Klasson also advocated that a pressure-casting technique (hands-off method) has superior potential to create the “ideal” pressure distribution than the routine hand-cast technique (or hands-on method). The understanding of the mechanisms that contribute to an acceptable prosthetic system and a “good fit” concept is hampered by the complexity of the soft tissue behavior within the socket and by the alignment of the various components of a transtibial prosthesis.

The aim of this study was to investigate and to compare the dynamic interface pressure distribution and patient satisfaction of a hands-off prosthetic system (Ice-Cast® Compact) and a hands-on prosthetic system (patellar tendon bearing [PTB]) for a transtibial amputee population. This investigation was granted ethical approval by the Local Regional Health Authority and University Ethics Committees (ref EC/03/S/66). This article reports on the interface pressure measurements

within the prosthetic socket. Patient satisfaction and activity levels were also assessed for each subject with a validated questionnaire and activity monitor. The findings of these outcome measures are reported elsewhere.

METHODOLOGY

A total of 48 patients from the West of Scotland Mobility and Rehabilitation Centre at the Southern General Hospital in Glasgow participated in the study. These patients all had an established unilateral amputation of at least 1 year and had been wearing their current prosthesis on a daily basis for normal activities of living for at least 6 months. In this set of patients, 24 had been using transtibial prostheses with the pressure-cast prosthetic socket concept, incorporating a silicone liner, and 24 had been using prostheses with a hand-cast socket of the PTB design, with a Pe-Lite liner. The group sample size of 24 would allow us to detect a clinical difference of 10 kPa between the paired average peak pressures for both sockets, with a 5 percent level of significance, and achieve a statistical power of 80 percent based on the pilot studies described in the “Introduction” [9,18].

The use of the subjects’ existing socket was possible because the pressure sensors did not interfere with the socket configuration. The pressure measurement system selected to monitor and record the interface pressure between the residual limb and prosthetic socket was a validated 6-channel F-Scan system (Tekscan), and the system software used was version 5.24 with synchronized video capture.

Four channels were designated to the prosthetic socket (sensor type 9811), while the remaining two channels were used for two additional in-shoe sensors (sensor type 3000) in order to measure the loading pattern and magnitude of the weight transfer during gait. This measurement was considered important because when the interface pressure between the socket and the residual limb is analyzed, distinguishing between the effects of axial loading and generated couples and moments is not possible. Therefore, additional information, such as force transmission through the feet, is required.

Synchronized Video Recording

A digital video camera was positioned with a viewing field that captured a single prosthetic step within the middle of the walkway track. The camera was connected

to the system, and a synchronized recording (pressure data and video) was captured.

Transducer Placement

Four socket transducer arrays were placed inside the prosthetic socket of all subjects using the same positioning protocol. This procedure was followed to ensure identical placement and enable direct comparisons to be drawn. This protocol included the establishment of an anterior/posterior (A/P) axis with the midpatellar bar as reference point and a medial/lateral axis perpendicular to the A/P axis. The longitudinal midline of the sensor array was used as the reference line to “mate” the specific axis. The distal patella border provided the boundary for the upper edge of the anterior, medial, and laterally positioned sensor arrays. However, the posterior array was placed approximately 1 cm below the popliteal trim line.

Each transducer array was individually trimmed to fit the complex contours of a prosthetic socket, allowing more than 90 percent coverage. The four socket transducer arrays were positioned inside the prosthetic socket using nonvolatile spray glue (**Figure 1**).

The sensor arrays then measured the normal interface pressure at the four aspects of the socket (anterior, medial, posterior, and lateral).

We are aware of the limitations of the pressure measurement system employed, including hysteresis, drift, susceptibility to curvature and temperature, crosstalk, loading range, and loading rate [8]. Inaccuracies between individual cells have also been highlighted. However, by adopting a strict protocol to precondition, equilibrate, and

calibrate the sensor arrays in situ before use, we can minimize the variation and inaccuracy of data recordings. Furthermore, the strength of the F-Scan system is in the number of pressure cells recorded and not the data from an individual cell. As this study is based on pressure mapping (high/low areas) rather than absolute data, use of these relatively low-cost pressure sensors is justified.

Preconditioning, equilibration, and subsequent calibration were achieved with use of a custom-made calibration platform (**Figure 2**). A series of balloons placed inside the prosthetic socket and inflated to a known pressure (100 kPa) provided a repeatable loading pattern. The transducers were first preconditioned by performing a 30-cycle dynamic loading sequence before equilibration and calibration.

The two prosthetic socket concepts examined during this investigation warranted two different approaches to positioning of the transducer arrays in relation to the liner material. Transducers could be positioned between the Pe-Lite liner and limb interface for hand-cast PTB style sockets because the Pe-Lite liner was incorporated into the calibration process.

However, the sensors could not be placed next to the subject’s skin within the pressure-cast socket because the liner could not remain in the socket during the calibration process since its elastic behavior creates an initial tension, leading to an unknown additional pressure that cannot be replicated during the calibration procedure. This elastic behavior would also create signal drift of the F-Scan equipment.

We conducted preliminary studies to determine whether a measurable difference existed in transducer output depending on its placement inside or outside of the silicon liner. These studies involved placing a transducer array on one side of a liner in a purpose-built rig and recording its output when subjected to known loading patterns generated by a programmable computer numerical controlled machine. Two different dynamic loading patterns, point loading and uniform pressure, were used. This process was repeated with the transducer array on the other side of the liner. Each test was preceded by a 30-cycle preconditioning sequence. No detectable difference in output related to transducer placement was detected.

Walkway

A predetermined walkway was established along the length of the clinic room. Before undertaking any recording in this study, subjects were asked to walk several lengths

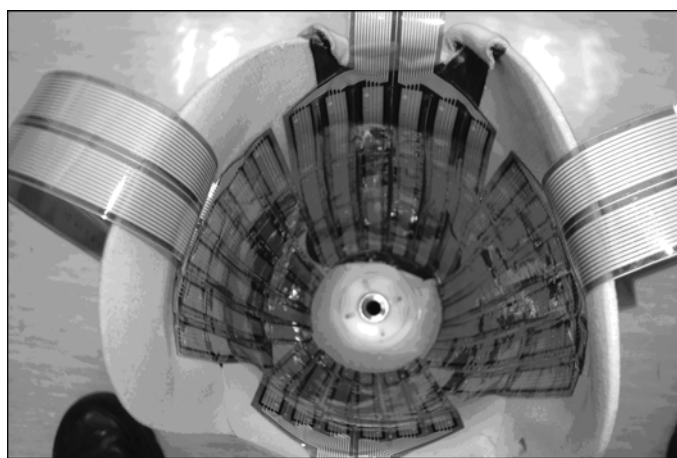


Figure 1.
View inside prosthetic socket.

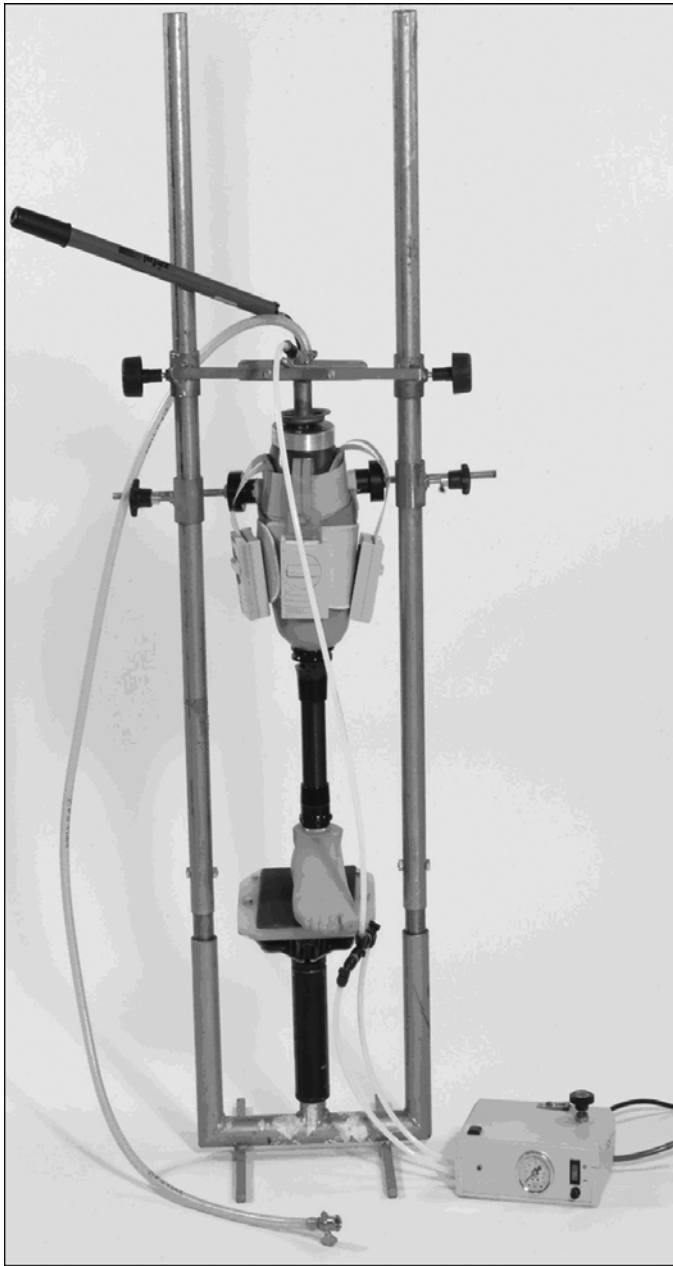


Figure 2.
Calibration platform.

of the walkway to familiarize themselves with the protocol and to become accustomed to the instrumented prosthesis. An identical protocol was followed for each subject to minimize variations in recordings.

Data Acquisition

The data acquisition parameters were set to record 12 seconds of information with a 150 Hz sample frequency.

The F-Scan system calculates the data from all of the individual transducer cells on each of the four arrays and displays the mean pressure value for each of the four transducer arrays for each time frame (**Figure 3**). The area within each array for which the mean pressure value is calculated can be further subdivided. For the purposes of this investigation, each array was subdivided in two: a proximal region and a distal region. Subjects completed approximately eight or nine consecutive steps on the prosthesis with these parameters. A single step, representing a typical pattern for that subject, was selected for further analysis. This analysis included socket-pressure readings and synchronized foot data.

Analysis of Results

Upon examination of the interface pressure output, we found that the prosthetic socket interface pressure followed a wave pattern similar to that typically associated with the foot. Three points of interest were present during the stance phase: weight acceptance, mid stance, and forward progression [21]. The peaks during early stance and late stance and the lowest point at mid stance were identified (points 2, 4, and 3, respectively, **Figure 3**). Points 1 and 5 are heel contact and toe-off phases of the gait cycle, respectively.

All analysis was performed with the Minitab statistical package, version 14 (Minitab, Inc; State College, Pennsylvania). Unless otherwise stated, all levels of significance were set at 5 percent. In order to examine the differences in the dynamic interface pressures throughout

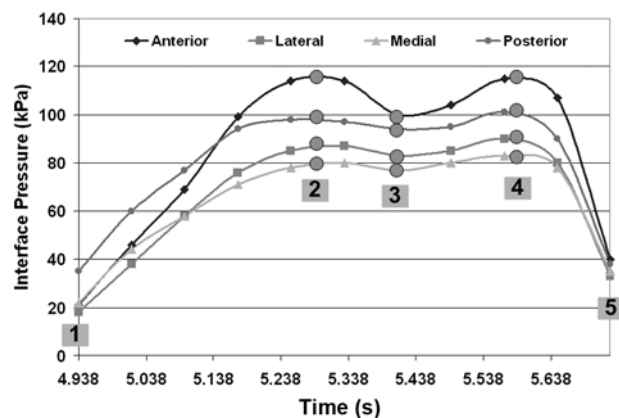


Figure 3.
Typical interface pressure at residual limb-socket interface: points selected at peak values. 1 = heel contact, 2 = peak early stance, 3 = low mid stance, 4 = peak late stance, 5 = toe-off.

the sockets between the two socket designs, we used a three-factor, repeated measure analysis of variance (ANOVA). Significant interactions between the two groups were further analyzed with a Tukey post hoc test. A two-independent sample *t*-test or a Mann-Whitney two-independent sample test was used to assess differences between the two groups at specific regions.

RESULTS

Subject Demographics

In total, 48 subjects participated in the study, and their demographics are shown in **Table 1**.

Socket Interface Pressure

Using the average interface pressure data for the selected steps for all 48 subjects, we found a significant difference between the three points within stance ($p < 0.001$.) Performing Tukey post hoc tests on this data, we

found that this difference occurred between mid and late stance ($p < 0.01$). The ANOVA interaction plot is shown in **Figure 4**. The graph in **Figure 4** displays the increase in interface pressure at late stance for each of the proximal and distal zones of the anterior, medial, posterior, and lateral sensor arrays.

No significant differences were found in the dynamic mean interface pressure distribution during stance phase between the two groups for any of the regions of the prosthetic socket ($p = 0.3$). Late stance has been selected for illustration purposes. **Figure 5** provides a visual indication of this result for each of the proximal and distal zones of the anterior, medial, posterior, and lateral sensor arrays.

We performed Mann-Whitney independent sample tests for each region to determine whether a significant difference in interface pressure existed between the two socket concepts. The alpha level was reduced by a factor of three from 0.05 to 0.017 for these tests in accordance with the Bonferroni correction factor [22].

Table 1.

Demographic information for subjects using hands-off ($n = 24$) and hands-on ($n = 24$) prosthetic socket concepts.

Variable	Group	<i>n</i>	Mean \pm SD	Range	Statistical Difference (<i>p</i> -Value)
Sex (Male/Female)	Hands-Off	20/4	—	—	—
	Hands-On	20/4	—	—	—
Side of Amputation (Left/Right)	Hands-Off	14/10	—	—	—
	Hands-On	12/12	—	—	—
Reason for Amputation (PVD/Other)	Hands-Off	4/20	—	—	—
	Hands-On	8/16	—	—	—
Age (yr)	Hands-Off	—	50.04 \pm 11.89	25–69	0.01
	Hands-On	—	60.54 \pm 14.85	29–89	
Body Mass Index	Hands-Off	—	27.63 \pm 4.99	17.92–36.44	0.57
	Hands-On	—	28.52 \pm 5.44	20.26–38.59	
Residual Limb Measurements					
Circumference at Patellar Tendon (m)	Hands-Off	—	0.334 \pm 0.033	0.285–0.400	0.43
	Hands-On	—	0.327 \pm 0.031	0.260–0.375	
Length (m)	Hands-Off	—	0.141 \pm 0.019	0.105–0.175	0.01
	Hands-On	—	0.123 \pm 0.025	0.07–0.18	
Cross-Sectional Area Patellar Tendon Level (m ²)	Hands-Off	—	0.009 \pm 0.002	0.006–0.013	0.45
	Hands-On	—	0.008 \pm 0.001	0.005–0.011	
Surface Area (m ²)	Hands-Off	—	0.042 \pm 0.011	0.029–0.076	0.67
	Hands-On	—	0.039 \pm 0.001	0.021–0.057	
Volume (m ³)	Hands-Off	—	0.031 \pm 0.008	0.019–0.056	0.39
	Hands-On	—	0.027 \pm 0.008	0.014–0.043	

PVD = peripheral vascular disease, SD = standard deviation.

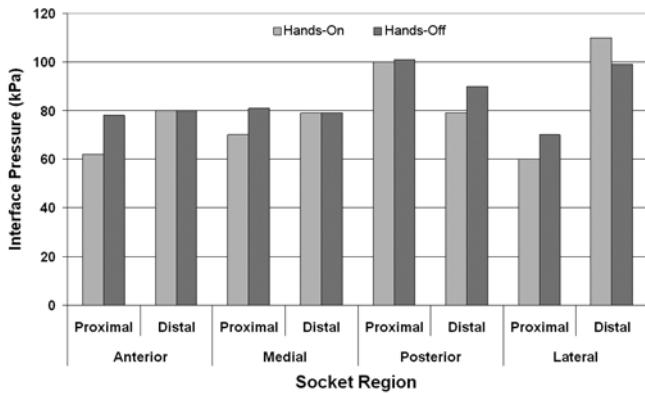


Figure 4. Dynamic pressure distribution: Pressure profile during late stance.

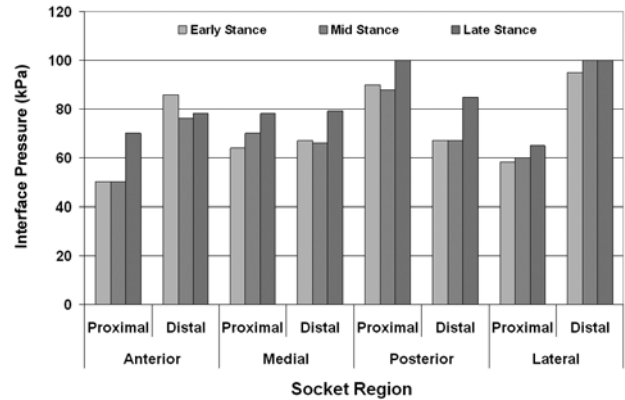


Figure 5. Pressure distribution throughout the socket during stance.

The mean dynamic interface pressures are shown in **Table 2** for each region in which significant differences were seen between groups. **Table 2** specifies the interface pressure, standard deviation (SD), and level of significance.

Figure 6 shows the magnitude of the average interface pressure for both socket types at the eight regions within the prosthetic socket at the three points within a stance. We should note that the straight lines connecting the data points (early stance, mid stance, and late stance) were drawn only to aid visualization of the relative values of these data points and do not represent the variation of pressure between these points.

DISCUSSION

Determination of the quality of fit remains a subjective process in the clinic. We should state that no consensus exists on a suitable fitting and assessment protocol

[12]. One method for assessing socket fit in a research context is by measuring interface pressure distribution. By using the Tekscan F-Scan socket transducers, we measured the dynamic pressure profile within each prosthetic socket, thereby allowing a comparison of socket concepts.

We can see from **Table 1** that both groups were well-matched in terms of sample size. The majority of subjects were male (83%), and those subjects with amputation not related to peripheral vascular disease made up the largest proportion of subjects (75%). No significant difference existed between the two groups in terms of subject body mass index. A significant difference was seen between the two subject groups in terms of age ($p = 0.01$). This result reflects the clinical population from which the sample was taken. Despite the differences in residual-limb length, the surface area and volume of the residual limbs showed no significant differences between the two

Table 2. Mean \pm standard deviation dynamic interface pressures at each tested socket region and significant differences between groups.

Region	Early Stance			Mid Stance			Late Stance		
	Hands-Off	Hands-On	<i>p</i> -Value	Hands-Off	Hands-On	<i>p</i> -Value	Hands-Off	Hands-On	<i>p</i> -Value
Anterior Proximal	57.37 \pm 18.87	41.46 \pm 24.24	0.003	54.25 \pm 18.05	46.95 \pm 26.67	0.12	75.37 \pm 23.02	63.37 \pm 30.76	0.02
Medial Proximal	69.8 \pm 17.73	59.54 \pm 21.83	0.02	71.17 \pm 20.75	67.45 \pm 62.70	0.04	83.62 \pm 20.66	70.87 \pm 23.25	0.02
Posterior Distal	75.00 \pm 23.49	56.91 \pm 41.24	0.004	71.41 \pm 22.5	62.62 \pm 44.52	0.03	88.17 \pm 22.44	78.83 \pm 53.07	0.02
Lateral Proximal	67.71 \pm 21.07	53.91 \pm 29.07	0.02	63.13 \pm 20.79	54.63 \pm 32.91	0.045	72.88 \pm 22.44	57.83 \pm 36.51	0.009

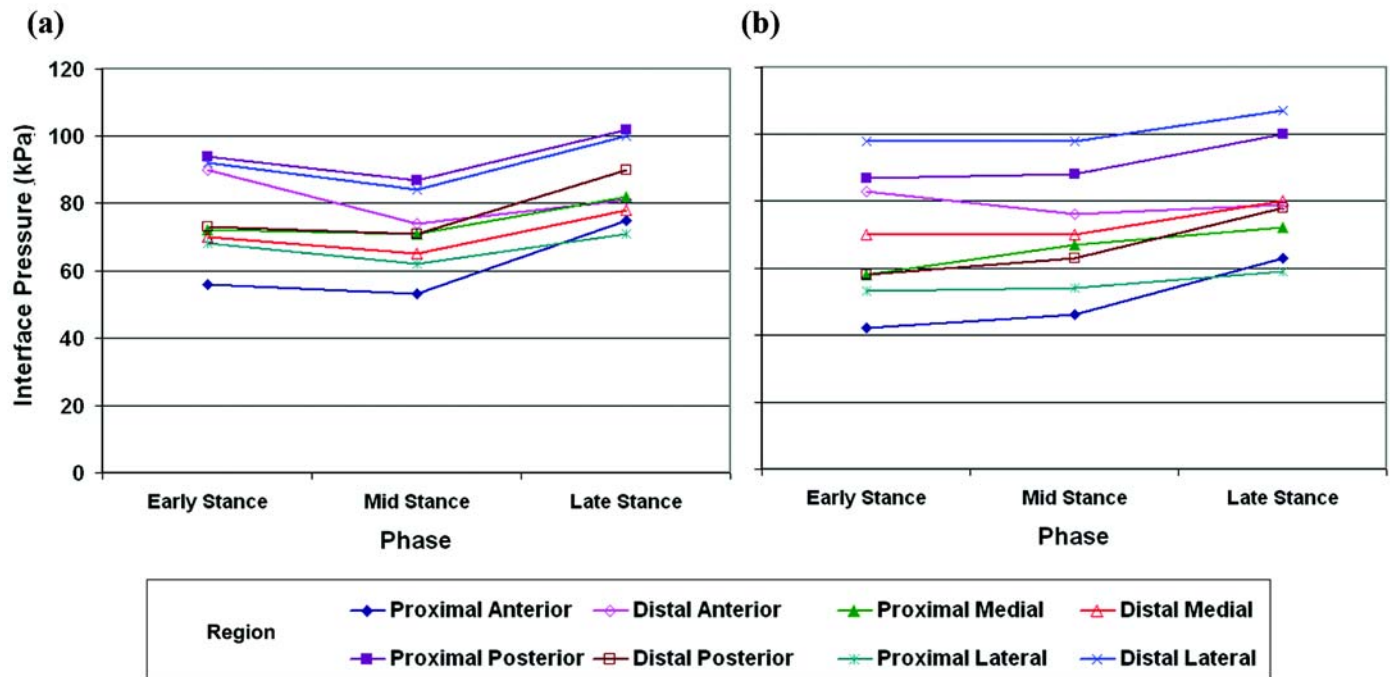


Figure 6. Interface pressure at each region within the socket throughout stance: (a) hands-off socket, (b) hands-on socket.

groups. The combined effects of body mass, residual limb volume, and surface area were also checked and found to be equal between groups.

Distribution of Interface Pressure

When identifying the force patterns expected between the residual limb and the prosthesis, Radcliffe described a pattern that was shown to be influenced by the alignment of the prosthesis, muscle action, and the angular position of the residual limb with respect to the ground reaction force [23]. Radcliffe stated that the pressure profile would experience the largest change immediately after heel strike, when the ground reaction force passes from a location anterior of the knee joint to a location posterior to the knee [23]. This change in location changes the initial extension moment about the knee joint to a flexion moment.

The change in distribution over the anterior and posterior aspects of the residual limb at early stance, as described by Radcliffe [23], was not observed in the results of our investigation, and this was a surprising result given the foundation of knowledge of the research team. The pressure profiles measured for both the hands-

on and hands-off concepts indicated that on average, the interface pressure showed the greatest change between mid stance and late stance ($p < 0.001$ for both socket concepts). This contradiction concurs with two other investigations into the profile of interface pressure [24–25].

The two types of sockets in this investigation involve two different pressure-distribution concepts during casting. This difference leads to two distinct shapes of prosthetic socket. It has been shown that the pressure profile seen for the hands-off socket is more uniform than that of the hands-on socket [9], although we should note that the results described by Convery and Buis were recorded without interface liners. However, as seen in **Figure 5**, this study indicates that the dynamic pressure distributions at the limb-socket interface were similar for the two groups.

Profile Over Anterior and Posterior Aspects of Socket

Throughout stance, the interface pressure at the proximal region on the anterior aspect of the socket remains lower than the distal region. This profile suggests that at heel strike, the ground reaction force is already passing behind the knee, creating a flexion moment. At late stance,

the interface pressure at the proximal region of the anterior aspect increases, creating a more even distribution of interface pressure. This increase in proximal anterior pressure has also been shown by Goh et al. [24,26]. However, the profiles observed for the sockets instrumented by Goh et al. indicated a large difference in the distribution of pressure over the anterior aspect at late stance [24–25], which was not replicated in our study. We should note that the pressure profiles described by Radcliffe were based on normal walking patterns [23], while the profiles given by Goh et al. were recorded when the subjects were not wearing an interface liner [24–25].

Medial Lateral Distribution

Radcliffe described the alignment of the prosthetic foot to the body center of mass as creating a medially orientated ground reaction force [23]. This force, in turn, creates an adduction moment that generates higher interface pressures at the proximal region of the medial aspect and at the distal region of the lateral aspect. Although the distal region of the lateral aspect experienced high interface pressures for both groups in this study, the medial aspect did not show any difference in the interface pressure between proximal and distal regions.

Magnitude of Interface Pressure

The results from this study have shown that the distribution of pressure at the socket-limb interface is consistent between socket concepts. However, significant differences exist in the magnitude of interface pressure. Despite these variations, all subjects reported that they were content walking on their prosthesis. This was evident in their continuous use of the prostheses for daily activities.

On the basis of previous studies, the interface pressures recorded in the hands-off sockets were expected to be lower than those seen in the hands-on sockets because of the uniform pressure distribution during the casting process [9]. Significant differences between the two prosthetic socket concepts were seen in this investigation; however, the pressure-cast sockets demonstrated the higher interface pressures. In Convery and Buis, a pressure-casting system that used a fluid medium to apply a uniform loading condition with the subject's own body mass was used [9]. This method is considerably different from the hands-off system (IceCast[®] Compact) used in this study.

Anterior Aspect

Despite the indentation of the patella bar at the proximal region of the hands-on prosthetic sockets, the interface pressure was found to be greater for those subjects wearing the hands-off sockets with no indentation. In fact, at early stance, the interface pressures at the proximal region of the anterior aspect of the hands-off sockets were, on average, significantly higher than for the group wearing the hands-on sockets ($p = 0.003$). The pressures at the anterior proximal region were some of the lowest of any region within the socket.

Posterior Aspect

The distal region of the posterior aspect of the prosthetic socket, which traditionally is compressed during the casting and rectification of the hands-on socket, does experience high interface pressure throughout stance. However, **Figure 5** shows that the pressure-casting method also produces sockets with high distal-region pressure. On average, the pressure-cast prosthetic sockets have higher interface pressures recorded in this region at both early and late stance ($p = 0.004$ early stance, $p = 0.02$ late stance.)

The popliteal fossa is found at the proximal region of the posterior aspect of the residual limb. During casting and rectification of the hands-on socket, this area is indented to act as a counter force to the patella tendon bar. The principle of pressure casting using uniform pressure results in this area receiving a less aggressive depression than the hands-on method. The interface pressures recorded at this site for both concepts were seen to be much higher than those for the distal region. However, both casting concepts have produced similar interface pressures with no significant differences despite the very different shaping techniques.

Lateral Aspect

The proximal region on the lateral aspect of the socket also experiences significant differences in interface pressure between the two socket concepts at early and late stance ($p = 0.02$ early stance, $p = 0.009$ late stance). The hands-off sockets have the higher interface pressures. The distal region of the lateral aspect experiences the highest pressures recorded within the prosthetic socket, but both socket concepts have similar recorded interface pressures. This aspect also has the largest pressure gradient from proximal to distal region.

Several other studies have investigated prosthetic interface pressure distributions. Zachariah and Sanders investigated interface pressure in the transtibial prosthetic socket [17]. The aim of that study was to determine the differences in pressure between standing and walking. However, Zachariah and Sanders' results also showed a similar pattern to the results of our investigation [17]. Zachariah and Sanders also found that the interface pressures showed a regional dependence, although the maximum interface pressure occurred at the anterior distal region [17]. The pressures reported by these investigators are average peak pressures recorded during a number of steps and the timing of these peaks is not indicated [17]. But Zachariah and Sanders' results highlight the variation in interface pressure between subjects [17]. Although general trends could be seen between the two subjects tested, the variation in interface pressure was great. Sanders et al. employed 13 triaxial transducers to record the interface pressure and shear stresses in transtibial sockets [16]. Although no transducers were placed on the medial aspect of the socket, the results from the other aspects indicated similar results to those seen in our investigation. At the first peak in interface pressure, the anterior distal and posterior proximal regions exhibited pressures much higher than those in the anterior proximal and posterior distal regions. This pattern also contradicts the pattern given by Radcliffe [23]. At the second peak, the same pattern is seen, once again agreeing with our results.

The residual limb consists of areas of thin tissue coverage over bony prominences and areas of thicker tissue. This difference in tissue properties was the idea behind the PTB casting and rectification technique [19]. The aim is to permit a greater deformation of the softer tissues whilst reducing the deformation of the more bony areas. However, we have shown that the distribution of pressure over the residual limb is consistent regardless of the pressure concept applied during casting, as shown in **Figure 6**. The regions with higher interface pressures in the pressure-cast socket correspond to higher pressures in the PTB cast.

DELIBERATION

This study used normal prosthetic socket interface pressure mappings in order to investigate aspects of socket concepts. Certain elements of the results came as a sur-

prise to us. However, we should emphasize that claiming specific merits for any socket concept is impossible because the socket is only one item within the prosthetic system. Alignment, prosthetic foot characteristics, and compliance of materials, as well as the socket shape and dimensional aspects, to name a few, will influence normal pressure distribution. As a consequence, distinguishing between a pressure reading originating from axial loading or one generated by couples and moments is not possible.

Future work will concentrate on interface shear mapping and the investigation of other hands-off casting concepts, including the use of a liquid loading medium instead of a gas-based casting device.

CONCLUSIONS

Previous findings have stated that, because of the uniform pressure-casting method, certain hands-off concepts will produce a prosthetic socket with lower and fewer peak pressures. However, this result was not confirmed in this investigation. The interface pressures recorded between the residual limb and the prosthetic socket showed consistent distributions between prosthetic socket groups, despite different casting concepts. Our results also showed that the recorded interface pressures were highest for the hands-off concept and not, as expected, for the hands-on sockets.

Although similarities in pressure profiles were seen between the two concepts, smaller variations in interface pressures were measured in the hands-off subject group. This finding is demonstrated in the lower SD values seen in **Table 2**. A smaller variation in interface pressure may lead to a more consistently fitting socket for the patient, improving the regularity of fit of subsequent prosthetic sockets.

Although higher pressures were found in the pressure-cast sockets, the subjects wearing these sockets did not complain of discomfort. Although pressures in the hand-cast sockets were lower, pressure gradients were steeper. These steeper gradients would generate higher levels of shear stress. Most likely, interface shear as well as internal soft tissue shear (including boundary shear) are the main areas of concern, as suggested by Sanders et al. [14]. The philosophy described by Klasson whereby the "stiffest" path principle is implemented for the load transfer from socket to the weight-bearing structure (the

skeleton) more than likely results in higher pressures but considerably reduced shear effects [20]. This hypothesis, of course, should be investigated further, although initial findings in this study suggest that shear stress did not cause discomfort in the subjects tested.

Despite differences in interface pressure levels between the two groups, all prosthetic sockets instrumented had been in daily use for at least 6 months, without the user experiencing residual-limb health problems. Further work will need to be conducted to determine whether those who do experience discomfort when wearing their prosthetic limbs have interface pressures outside the levels found in this study.

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REFERENCES

- National Amputee Statistical Database. The amputee statistical database for the United Kingdom 2004/05. Edinburgh (UK): Information Services Division NHSScotland; 2005.
- McCull I. Department of Health and Social Security (DHSS). Review of artificial limb and appliance centre services: The report of an independent working party. London (UK): DHSS; 1986.
- Chadderton HC. Prostheses, pain and sequelae of amputation, as seen by the amputee. *Prosthet Orthot Int.* 1978;2(1): 12–14. [\[PMID: 724411\]](#)
- Nielsen CC, Psonak RA, Kalter TL. Factors affecting the use of prosthetic services. *J Prosthet Orthot.* 1989;1(4): 242–49. [DOI:10.1097/00008526-198907000-00008](#)
- Ferguson J, Smith DG. Socket considerations for the patient with a transtibial amputation. *Clin Orthop Relat Res.* 1999; (361):76–84. [\[PMID: 10212599\]](#)
[DOI:10.1097/00003086-199904000-00011](#)
- Kim WD, Lim D, Hong KS. An evaluation of the effectiveness of the patellar tendon bearing bar in the trans-tibial patellar-tendon-bearing prosthesis socket. *Prosthet Orthot Int.* 2003;27(1):23–35. [\[PMID: 12812325\]](#)
- Sewell P, Noroozi S, Vinney J, Andrews S. Developments in the trans-tibial prosthetic socket fitting process: A review of past and present research. *Prosthet Orthot Int.* 2000; 24(2):97–107. [\[PMID: 11061196\]](#)
[DOI:10.1080/03093640008726532](#)
- Buis AW, Convery P. Calibration problems encountered while monitoring stump/socket interface pressures with force sensing resistors: Techniques adopted to minimise inaccuracies. *Prosthet Orthot Int.* 1997;21(3):179–82. [\[PMID: 9453089\]](#)
- Convery P, Buis AW. Socket/stump interface dynamic pressure distributions recorded during the prosthetic stance phase of gait of a trans-tibial amputee wearing a hydrocast socket. *Prosthet Orthot Int.* 1999;23(2):107–12. [\[PMID: 10493137\]](#)
- Dou P, Jia X, Suo S, Wang R, Zhang M. Pressure distribution at the stump/socket interface in transtibial amputees during walking on stairs, slope and non-flat road. *Clin Biomech (Bristol, Avon).* 2006;21(10):1067–73. [\[PMID: 16919376\]](#)
[DOI:10.1016/j.clinbiomech.2006.06.004](#)
- Jia X, Zhang M, Lee WC. Load transfer mechanics between trans-tibial prosthetic socket and residual limb—Dynamic effects. *J Biomech.* 2004;37(9):1371–77. [\[PMID: 15275844\]](#)
[DOI:10.1016/j.jbiomech.2003.12.024](#)
- Mak AF, Zhang M, Boone DA. State-of-the-art research in lower-limb prosthetic biomechanics-socket interface: A review. *J Rehabil Res Dev.* 2001;38(2):161–74. [\[PMID: 11392649\]](#)
- Polliack AA, Sieh RC, Craig DD, Landsberger S, McNeil DR, Ayyappa E. Scientific validation of two commercial pressure sensor systems for prosthetic socket fit. *Prosthet Orthot Int.* 2000;24(1):63–73. [\[PMID: 10855440\]](#)
[DOI:10.1080/03093640008726523](#)
- Sanders JE, Jacobsen AK, Ferguson JR. Effects of fluid insert volume changes on socket pressures and shear stresses: Case studies from two trans-tibial amputee subjects.

- Prosthet Orthot Int. 2006;30(3):257–69.
[\[PMID: 17162516\]](#)
[DOI:10.1080/03093640600810266](#)
15. Sanders JE, Zachariah SG, Jacobsen AK, Ferguson JR. Changes in interface pressures and shear stresses over time on trans-tibial amputee subjects ambulating with prosthetic limbs: Comparison of diurnal and six-month differences. *J Biomech*. 2005;38(8):1566–73. [\[PMID: 15958212\]](#)
[DOI:10.1016/j.jbiomech.2004.08.008](#)
16. Sanders JE, Lam D, Dralle AJ, Okumura R. Interface pressures and shear stresses at thirteen socket sites on two persons with transtibial amputation. *J Rehabil Res Dev*. 1997; 34(1):19–43. [\[PMID: 9021623\]](#)
17. Zachariah SG, Sanders JE. Standing interface stresses as a predictor of walking interface stresses in the trans-tibial prosthesis. *Prosthet Orthot Int*. 2001;25(1):34–40. [\[PMID: 11411003\]](#)
[DOI:10.1080/03093640108726566](#)
18. Convery P, Buis AW. Conventional patellar-tendon-bearing (PTB) socket/stump interface dynamic pressure distributions recorded during the prosthetic stance phase of gait of a trans-tibial amputee. *Prosthet Orthot Int*. 1998;22(3): 193–98. [\[PMID: 9881607\]](#)
19. Radcliffe CW, Foort J. Biomechanics of below knee prosthetics. In: Inman VT, Eberhart HD, editors. *The patella tendon-bearing below knee prosthesis*. Berkeley (CA): University of California, Berkeley; 1961. p. 8–51.
20. Klasson B. *Appreciation of prosthetic socket fitting from basic engineering principles*. Glasgow (UK): National Centre for Training and Education in Prosthetics and Orthotics; 1995.
21. Fish DJ, Nielsen JP. Clinical assessment of human gait. *J Prosthet Orthot*. 1993;5(2):39–48.
[DOI:10.1097/00008526-199304000-00005](#)
22. Bland M. *An introduction to medical statistics*. 3rd ed. Oxford (UK); Oxford University Press: 2000.
23. Radcliffe CW. The biomechanics of below-knee prostheses in normal, level, bipedal walking. *Artif Limbs*. 1962;6:16–24.
[\[PMID: 13972953\]](#)
24. Goh JC, Lee PV, Chong SY. Stump/socket pressure profiles of the pressure cast prosthetic socket. *Clin Biomech (Bristol, Avon)*. 2003;18(3):237–43. [\[PMID: 12620787\]](#)
[DOI:10.1016/S0268-0033\(02\)00206-1](#)
25. Goh JC, Lee PV, Chong SY. Static and dynamic pressure profiles of a patellar-tendon-bearing (PTB) socket. *Proc Inst Mech Eng [H]*. 2003;217(2):121–26. [\[PMID: 12666779\]](#)
[DOI:10.1243/09544110360579330](#)
26. Goh JC, Lee PV, Chong SY. Comparative study between patellar-tendon-bearing and pressure cast prosthetic sockets. *J Rehabil Res Dev*. 2004;41(3B):491–501.
[\[PMID: 15543467\]](#)
[DOI:10.1682/JRRD.2004.03.0491](#)

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