NHS
Purchasing and Supply Agency
Centre for Evidence-based Purchasing

Evidence review

Pain-free artificial lower limb patient interfaces

CEP 07029

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Verdict

RECOMMENDED

SIGNIFICANT POTENTIAL

EVIDENCE INCONCLUSIVE

NOT RECOMMENDED

Informing procurement - Encouraging innovation

Contents

Summary

Traditionally, artificial (prosthetic) limbs are interfaced to amputees' residual limbs (stumps) via custom-made sockets. The fit of the socket has been shown to be of critical importance to prostheses users and is influenced by several factors. Researchers have investigated different socket concepts and fitting parameters (e.g. liner choice, suspension method) and shared their own experiences of particular products and techniques. While pros and cons have been highlighted, there is little consistent agreement in the research literature regarding the most effective way of interfacing a prosthetic limb to an amputee's stump.

Evidence reviewed

The quality of study design is variable, with small subject populations and the use of different outcome measures making inter-study comparison difficult. This combined with the individual nature of residual limbs and the unique requirements of each amputee, may explain the lack of agreement in the literature.

CEP's verdict – Evidence inconclusive

Further research is required to improve the understanding of biomechanical variables at the stump/socket interface (e.g. pressure, friction, temperature, moisture accumulation) and their relationship with user comfort levels. Knowledge of how such variables influence user comfort and the extent to which they can be managed using different fitting options and techniques may lead to improvements in quality of socket fit and subsequently change the way prosthetic lower limbs are procured and fitted.

Introduction

Background

The fit of the socket used to interface an external prosthesis to an amputee's residual limb has been shown to be of critical importance to prostheses users [1]. Previous authors have investigated the incidence of residual limb pain and documented prosthetic use and satisfaction among amputee populations [1,2,3,4,5]. Socket fit and residual limb pain have been shown to be primary reasons for dissatisfaction with artificial lower limbs. Dillingham *et al.* [4] showed in a study of 78 trauma-related amputees that, although 95% tended to wear their prostheses extensively (>80hr/week), only 43% reported satisfaction with prosthetic comfort. Similarly, Nielsen found that out of 109 amputees, 57% reported moderate to severe pain most of the time while wearing their prosthesis.

Many factors have the potential to influence socket fit and comfort levels. While some of these factors can be managed through good design and appropriate selection of socket fitting parameters, others, such as co-morbidity and soft tissue properties, may preclude the development of pain-free interfaces in some cases. Given the individual nature of residual limbs and the unique requirements of each amputee, prosthesis prescription requires a flexible approach, with design choices considered in light of an individual's personal priorities and goals. Limb fitting processes and design decisions must combine sound research evidence with clinical experience and reliable assessment techniques.

Scope

The findings of a literature review undertaken to examine the evidence base surrounding the measurement, manufacture and fitting of lower-limb prosthetic sockets are presented. Recommendations are made based on the review findings.

Methods

Project Approach

A large volume of literature exists in this area. To facilitate the literature search and appraisal process, socket measurement, manufacture and fitting processes have been expanded into the following areas:

1. Socket Design
2. Socket Liners
3. Suspension
4. Limb Components
5. Casting
6. Rectification
7. Checking Processes
8. Limb Alignment

Search Strategy

Literature searches were performed in Medline, Embase and ISI Web of Knowledge using combinations of the following keywords: amputee, amputation, socket, comfort, pain, prosthetic, prosthesis, prostheses and residual limb. Keywords more specific to the 8 areas listed above were used to 'drill down' into each sub-process. In addition, ECRI's Health Technology Assessment Information Service (HTAIS) was used to check the following databases:

- PubMed (National Library of Medicine)
- The Cochrane Library (John Wiley & Sons, Ltd.)
- Cumulative Index of Nursing and Allied Health Literature (CINAHL)
- International Health Technology Assessment (IHTA) database
- Healthcare Standards (HCS) database.

The citation index within ISI Web of Knowledge was use to follow up on references within key papers.

Socket Design

It is widely recognised that the design and fit of a prosthetic socket is critically important in the successful rehabilitation of lower limb amputees. Previous authors have described a number of prosthetic socket designs, detailing the underlying biomechanical principles and clinical indicators. Fergason and Smith [6] provide a good summary of socket designs for trans-tibial amputees, while trans-femoral sockets have been discussed by Kapp [7] and Schuch and Pritham [8]. Carroll [9] provides a useful overview of lower extremity socket design.

Numerous opinions exist regarding the weight-bearing characteristics that a prosthetic socket should possess and the validity of the underlying biomechanical principles. Many comparative studies have been published, particularly for trans-tibial sockets, comparing the comfort and pressure distribution associated with different socket designs and investigating clinical indicators.

Schuch and Pritham [8] provide a valuable descriptive comparison of quadrilateral (quad) and ischial containment (IC) sockets. Lee *et al.* [10] compared the pressure distribution at the stump socket interface within quad and IC sockets for 2 trans-femoral amputees. The IC sockets for each subject displayed a more even pressure distribution. In a subjective evaluation both subjects showed a preference for the IC socket, although reasons are not reported.

As part of a more detailed study, Hachisuka *et al.*[11] investigated user satisfaction with total surface bearing (TSB) sockets via a questionnaire sent out to 23 outpatients who had recently changed from patella tendon bearing (PTB) designs. Following the change, 50% of subjects were 'satisfied' with the TSB socket and 25% were 'somewhat satisfied'. Three items – 'comfort to wear', 'ease to swing the prosthesis' and 'piston movement during walking' were considered advantages of TSB sockets. Donning and doffing the prosthesis was considered a disadvantage of the TSB socket. Clinical reasons for the change of socket are not reported. Also, no information is provided regarding the subject group's satisfaction with their original PTB socket. The authors acknowledge that the subjects are not representative of the below-knee amputee population due to the small sample size and high proportion of trauma related amputations.

Goh *et al.* [12] evaluated the stump/socket interface pressures in amputees wearing a socket developed by a pressure casting system (PCast). Five unilateral amputees took part in the study. A PCast test socket incorporating 16 pressure measurement sites was manufactured for each subject. A hydrostatic pressure profile was not evident during standing or gait, which agrees with the findings of Convery and Buis [13].

Goh *et al.* [14] compared the pressure distribution at the stump/socket interface for PCast and PTB sockets. One PTB and one PCast socket was fabricated for 4 subjects, each incorporating pressure transducers. Consistent results between subjects could not be demonstrated. The authors comment that pressure distribution at the interface is dependent on many more factors than just socket design, which may explain the varied results. Factors such as residual limb shape, thigh muscle strength and limb alignment are all likely to influence the pressures measured [14].

Kahle [15] carried out a comparative study involving 25 unilateral trans-tibial amputees (20 peripheral vascular disease (PVD), 4 trauma, 1 congenital). A PTB socket and a hydrostatic socket were fabricated for each subject and they were asked to state their preference. Details of the methods used are limited. Also, no information was presented regarding how the subject's preference was assessed. Results state that 17 subjects preferred the hydrostatic, 4 preferred the PTB and 4 rejected both. Even with the limitations of this study in mind, it does highlight the subjective nature of socket selection. For example, some subjects stated that they liked the hydrostatic socket due to the uniform pressure distribution, others cited this as the reason they disliked the hydrostatic socket.

Yigiter *et al.* [16] compared PTB and TSB sockets fitted for 20 unilateral trans-tibial amputees (all trauma related amputations). Following a 10-day acclimatisation period, a number of gait variables were assessed for each subject on each socket. 'Weight acceptance on the amputated side advanced to a more normal level with TSB prostheses ($p<0.05$)'. The study did not involve any more direct measurements of socket pressures or comfort scores for the two socket types.

Selles *et al.* [17] compared functional outcomes and cost efficiency of TSB and PTB sockets. A total of 36 subjects were recruited to the study and, following baseline measurements with PTB sockets, were randomly assigned to one of two groups. The first group was fitted with TSB sockets and the second was fitted with a new PTB socket. At baseline and following 3 months use with the new sockets, subjects were asked to record their subjective experiences using parts of the Prosthetic Evaluation Questionnaire (PEQ). Items included in the customised PEQ instrument were 'prosthesis function', 'mobility', 'satisfaction', 'pain' and 'phantom pain'. At baseline there was no significant differences between the results of each group. At follow-up, changes in the PEQ scores for both groups were relatively small, and none of the changes were statistically significant. The authors reported that despite several subjects in each group recording lower PEQ scores at follow-up, only 1 subject in each group decided not to keep the new socket after the 3-month period.

When interpreting the results of comparative studies, it is interesting to note that no reference is made to intra-method consistency. As stated by Convery *et al.* [18], 'the consistency of production methods must be known before a reliable comparison between methods can be made'. Without knowledge of intra-method consistency it is impossible to draw any conclusions when comparing socket designs.

Socket Liners

Socket liner materials are thought to provide skin protection and reduce friction between the socket and the skin of the residual limb, thus creating a more comfortable interface. A number of authors have published their own clinical experiences with various types of socket liner [19, 20, 21, 22, 23]. Authors concerned with the Icelandic Roll-On Silicone Socket (ICEROSS [24]) report that in general, amputees considered the ICEROSS to provide improvements [23], although appropriate patient selection is vital [22]. Indicators for the use of ICEROSS have been reported to be shear sensitive skin, and pistoning and suspension difficulties, whereas contraindications were found to be ulceration, unhealed scars and poor patient commitment to prosthetic rehabilitation [21]. Lake and Supan [25] reported an increased incidence of contact dermatitis in amputees switching to a silicone liner. Strong trends were noted indicating that the incidence of dermatological problems is influenced by aging, activity level and ‘use patterns’.

Hatfield and Morrison [20] presented their experience of Alpha (Ohio Willow Wood Company) polyurethane gel liners (both cushion and locking types). All subjects using Alpha cushion liners (16) reported improved comfort compared to their previous prostheses, although it is not clear how comfort was measured. 4 subjects had a return of sores whilst using the cushion liners and 2 needed a new socket because of a change in stump volume. 15 of the 16 subjects chose to continue wearing the socket with Alpha cushion liner in preference to their previous socket. Previous prosthesis prescription is not reported for all subjects. The duration of cushion liner use was up to 12 months, with a mean of 6.6 months. 43 liners were issued during this study period (range 1-6 per person).

40 locking liner users also took part in Hatfield and Morrison’s study. 20 out of 40 reported improved comfort and 10 out of 40 reported improved suspension. 17 of the 40 subjects using locking liners had previously used the ICEROSS suspension system. 9 of these subjects reported improved comfort, 2 no change in comfort, 4 worse comfort and for 2 the effect was not known. 6 reported worse suspension on changing from ICEROSS to Alpha locking liners, 6 no change, 2 an improvement, and for 3 subjects the effect was not known. No correlation was found between time since amputation and comfort, and age and comfort when using Alpha locking liners. It is not clear how comfort was assessed. Hatfield and Morrison [20] reported that locking liners are unlikely to provide comfort for patients whose stumps are intolerant of distal support and advise care in those with reduced sensation as improved comfort and suspension may lead to increased use of the prosthesis and the development of ulceration. These authors also advise that when it comes to liner prescription, ‘careful selection of patients and detailed discussion with them about the possible benefits and disadvantages of cushion and locking liners is essential to ensure maximum benefits and to avoid costly inappropriate prescription’.

Coleman *et al.* [26] examined patient satisfaction, pain, socket comfort (assessed using the Socket Comfort Score - Hanspal *et al.* [27]), daily ambulatory function (using an activity monitor), physical changes and patient comments associated with the use of Alpha suspension liners with distal locking pin and Pe-lite liners with neoprene suspension sleeves. 13 subjects completed the study (all trauma related amputations). Each subject wore 1 system for 3 months after a stable comfortable fit was achieved, then switched to the other using the same procedures. Subjective preference and overall ambulatory activity heavily favoured the Pe-lite system over the Alpha system. No differences were found in satisfaction, pain, or comfort results between liner types.

Sanders *et al.* [28] tested the mechanical performance of 15 elastomeric socket liner materials including various silicone gel and silicone elastomer products. Material samples of all products where tested under compressive, frictional, shear, and tensile loading conditions and classified according to their response. The results of this mechanical testing may help clinicians select a particular liner based on the properties they desire. The testing forces used in this study reflect those measured at a number of interface locations during walking, but not those at the patellar-tendon. Therefore 'stresses applied during testing were lower than patellar-tendon stresses and those experienced during running'. All liners tested in this study were new and so no conclusions can be drawn about durability or mechanical degradation over time (although this has previously been dealt with by Emrich and Slater [29]).

Emrich and Slater [29] carried out a comparative analysis of 4 socket liner materials (Bock-Lite, Pedilin, silicone, and polyurethane). Resistance to compressive force, shear stress abrasion resistance, and coefficient of friction were measured for each material. These tests also dealt with the materials resistance to cyclic testing which offers valuable information when considering the wear properties and likely failure modes. Emrich and Slater's testing showed that silicone and polyurethane had the higher coefficients of friction and Pedilin and Bock-Lite have better resistance to shear stress abrasion, making them far more durable than silicone and polyurethane.

In 2005, Van de Weg and Van der Windt [30] published the results of a survey of the effects of interface types on patient satisfaction and perceived problems among trans-tibial amputees. A questionnaire (based on the PEQ) was sent out to 353 patients in the Netherlands. Patients were classified into one of three groups: 1) polyethylene foam inserts (PEF), 2) silicone liners (SIL), and 3) polyurethane liners (PUL). A total of 220 patients responded (62%). The response rate of each group is not reported. Daily wear time was not significantly different between groups. Durability was considered to be significantly poorer for PUL compared with SIL and PEF. Differences in total scores on the satisfaction scale between inserts and liner types were not significant. These authors concluded that 'evidence to support the presumed surplus value of liners is scant'. 'The study's findings show that, with respect to use, satisfaction, and perceived problems, patients using different interface types do not report significant differences to a large extent'. The authors note that considering the 62% response rate, non-response bias cannot be ruled out.

The findings of Van de Weg and Van der Windt contradict those of Astrom and Stenstrom [31], who reported that polyurethane liners increased comfort considerably. In this study socket comfort was estimated with respect to skin condition, temperature and pressure and recorded on a 5-point scale. As pointed out by Van de Weg and Van der Windt, in Astrom and Stenstrom's study, 20 out of the 29 subjects had stump problems and for 18 pain was a limiting factor in walking distance. It is therefore likely that some degree of selection bias is present.

Van de Weg and Van der Windt suggest that further (preferably prospective) studies need to be carried out to determine which systems are most comfortable and offer least complaints.

Baars and Geertzen [32] provide a useful literature review of the possible advantages of silicon liner use in trans-tibial prostheses. They noted that potential benefits of socket liners are often assumed from the properties of the materials, rather than clinical research. They concluded that 'there is little clinical evidence in the literature to support the positive qualities of the silicon liner socket use in the trans-tibial prosthesis' (largely due to low quality in study design). They recommend 'further research with an adequate study design, homogenous population and objective study parameters to show objectively the advantages of silicon liner socket use in trans-tibial amputees'.

Suspension

Narita *et al.*[33] compared the swing phase stability and suspension effect of TSB (ICEROSS suspension) prostheses with that of PTB (cuff suspension) prostheses using X-ray and cineradiography techniques. A total of 9 trans-tibial amputees took part in the study (10 limbs). All subjects had previously used a PTB prosthesis before changing to TSB. Static X-rays where taken of each limb (wearing each socket type) in both weight bearing and suspension conditions. The predicted effects of centrifugal force during swing were simulated by attaching a 5kg mass to the end of the limb during static image capture. The movement of the stump was calculated by comparing static images taken in weight-bearing and suspension positions. Cineradiography images were taken during treadmill walking for 3 of the 9 subjects (wearing both socket designs). The distance between the tibial end and the base of the socket was measured at weight bearing and during suspension. Under both test conditions (X-ray and cineradiography) the translation of the TSB prosthesis was significantly lower ($p<0.05$) than that of the PTB. Also, using the cineradiography images, the angle between the tibial shaft and the axis of the prosthesis was measured. It was concluded that the stability of the TSB prosthesis was superior to that of the PTB during swing. The increased stability and improved suspension of the TSB socket may imply superior comfort for some users.

Beil *et al.* have published papers relating to interface pressures within pin and suction suspension systems [34], and also between suction and vacuum-assisted prosthetic sockets [35]. In both cases interface pressures are measured during ambulation using force sensing resistors and air pressure sensors. These studies discuss the pressure distribution at the interface for each of the suspension systems, although do not include any information relating to how the measured pressures affect the comfort of the user.

Limb Components

The majority of component related research focuses on gait variables and/or oxygen consumption. A small number of these studies also investigate the effect of components on the comfort of the prosthesis. Comfort related studies involve rigid and shock absorbing pylons, torque absorbers and energy storage and return (ESAR) feet.

Pylons

Berge *et al.* [36], Gard and Konz [37] and Buckley *et al.* [38] assess the effect of shock absorbing pylons (SAPs) within a prosthesis. Berge *et al.* [36] found that there was no increase in the level of comfort perceived by subjects using the SAP (compared to a rigid pylon). However, Gard and Konz and Buckley *et al.* contradict this. They reported that subjects experienced a greater level of comfort when using a prosthetic limb which included a SAP. The different outcomes reported by these authors could be due to the different methods used. The study by Berge *et al.* blinded the subjects to the type of pylon used, although each subject trialled only one type of pylon. Gard and Konz and Buckley *et al.* provided each subject with two different prostheses, one with the rigid pylon and one with the SAP (an Endolite Telescopic Torsion Pylon), although the studies were not blind.

Gard and Konz stated that perceived differences in the feel of a prosthesis which includes a SAP might be due to very slight changes that may not be detected through established gait analysis parameters. In an attempt to overcome this, they analysed the rate of limb loading during gait to identify force transients. Results showed that the force transients in the residual limb reduced by up to 60% with the inclusion of the SAP, implying a more uniform rate of limb loading in early stance. No difference was found in the peak loads applied to the prosthesis.

Buckley *et al.* did not measure any forces during ambulation, but did find that the inclusion of a SAP reduced oxygen consumption during gait. They hypothesised that this decrease may be due to 'reduced, or better controlled, vertical elevation of the subject's centre of mass as a consequence of altered limb stiffness'. They also hypothesised that this could explain the perceived increase in subjective comfort ratings. All the studies used a small number of subjects (15, 10 and 6, Berge *et al.,* Gard and Konz, and Buckley *et al.*, respectively). All authors used only trans-tibial amputees and these were predominantly trauma related.

Torque Absorbers

Van der Linden *et al.* [39] investigated the influence of a torque absorber on the gait variables of 2 trans-femoral amputees. Both subjects were male, around the same age (48 years old) and were provided with identical limb builds (IC sockets). The study did not directly assess the influence of a torque absorbed on socket comfort. However, it was observed that with the inclusion of the torque absorber the rotation between the socket and the foot was greater than in the prosthesis without. The authors stated that this could 'indicate that the socket is allowed to rotate with the stump, which implies that motion between the stump and the socket may have been reduced'. This lead to a conclusion that the inclusion of a torque absorber reduces shear forces and consequently reduces pain. No firm conclusions regarding torque absorbers and socket comfort can be drawn based on this study.

Feet

Graham *et al.* [40] compared the results of gait analysis, timed walks and socket comfort scores for trans-femoral amputees wearing a Multiflex foot and an energy-storing foot (Vari-flex). Six subjects participated in the study, all of whom were male, aged between 38 and 50 years and at least five years post-amputation. Each subject walked with both types of feet. The subjects had no stump problems prior to the study.

Kinematic and kinetic gait data were collected at 'preferred' and 'brisk' walking speeds. Following instrumented gait analysis, subjects walked around a circuit, which was both indoors and outdoors, and included variations of camber and surface. Using the prosthetic socket fit comfort score [27], subjects recorded their level of comfort immediately after walking this circuit. Graham *et al.* reported 'most patients reported that comfort had improved with the Vari-Flex foot, although this was not statistically significant'.

Casillas *et al.* [41] compared the effects of an energy-storing foot and a solid-ankle cushion heel (SACH) foot with respect to bioenergetic factors such as oxygen consumption. The main difference between this and other studies was that they carried out the research on two different populations; those who had a traumatic amputation and those who had a vascular amputation. As part of their research

Casillas *et al.* [41] carried out a survey on the satisfaction of the users with each foot. For the 'traumatic' population it was found that user satisfaction increased when using the energy-storing foot, although the extent to which this is based on socket comfort is not known. User satisfaction was not recorded for the vascular amputees.

Studies to date have highlighted areas in which component selection may have an effect on socket comfort. However, considering the small and narrow subject groups and the absences of blind testing, results should be interpreted with caution.

Casting

Studies in this area tend to describe alternative casting or manufacturing techniques and compare these to existing practices. Outcome measures generally rely on subjective feedback from users to rate the relative fit of sockets produced via different methods [42] or involve a comparison of successful fitting rates [43].

Casting techniques described include variations on the pressure casting concept [12, 44, 45], sand casting [43] and digital modelling (CAD) [42, 46, 47, 48, 49, 50, 51, 52]. Buis *et al.* [53] investigated the casting consistency of traditional 'hands-on' PTB and 'hands-off' ICECAST concepts (using a manikin stump model). Data-capturing performance was more consistent when a hands-off method such as the ICECAST concept was used.

Advances in manufacturing processes have enabled positive moulds to be manufactured from subject-specific digital information. These methods go hand-in-hand with digital scanning techniques (CADCAM). Positive moulds are carved directly from digital files using computer numerically controlled (CNC) machining operations. Positive moulds are draped by hand as with traditional plaster techniques. CADCAM offers advantages such as easier storage of shape information and shorter fitting times (with some systems), but no comparative studies have shown clear advantages over traditional methods regarding quality of fit [47, 54, 49, 42, 52].

Another possible advantage of CADCAM is the potential to combine shape information with loading predictions calculated by finite element analysis (FEA) models. Goh *et al.* [46] described the development of a CAD-FEA technique. With further development, such tools may provide quantitative feedback to prosthetists regarding the likely load distribution within a proposed socket before they commit to manufacture. In the longer term, such a system may offer clinicians the option to set desired tissue loading conditions and initiate the production of a socket through expert systems [55]. Such a tool would represent a significant clinical advantage of CAD over traditional methods, however at present, CADCAM seems to offer no more information to the clinician than traditional plaster techniques.

Solid freeform fabrication methods [56, 57, 58] have the potential to create sockets directly from digital scans of the residual limb, eliminating the need for casting and hand lamination, and potentially reducing manufacturing costs. Authors claim that such methods also offer advantages in allowing the creation of complex geometries, expanding the options for developing socket features such as the inclusion of selectively flexible regions. Clinical advantages relating to socket comfort remain to be seen.

Rectification

During the manufacture of specific weight bearing sockets (e.g. PTB), the shape of the cast is modified (rectified) to include pressure relief over load sensitive areas and encourage weight to be taken through more tolerant regions. This process is done by hand when using plaster casting techniques. CADCAM systems enable prosthetists to interact with the digital surface so that shape changes can be incorporated prior to cast production.

Convery *et al.* [18] investigated the consistency of cast rectification in the manufacture of PTB sockets. Two prosthetists were given 5 unrectified duplicate models. Their rectified plaster models were measured to quantify the differences. In zones of major rectification, the mean difference between prosthetists was quantified as 2mm and the standard deviation about the mean was ±1mm for each prosthetist. The authors acknowledge the need for further studies with additional prosthetists to determine whether these results are typical. The extent to which these reported differences effect interface pressures and socket comfort are not reported.

Spence *et al.* [59] investigated how the pressures measured at the patellar tendon bar changed as the position of the bar varied (the original cast position, compressed 2mm and 4mm from the cast position, and relieved by 2mm from the cast position). Pressures at the patellar tendon bar were measured, along with those at other locations within the socket (including the distal end). It was found that the patellar tendon bar bears significantly more pressure than the other sites measured. Also, ‘the pressures recorded at the other test sites did not show any particular variation in pattern when the patellar tendon bar was compressed and relieved’. It was concluded that ‘the position of the patellar tendon bar did not have any effect on the pressure distribution around the socket and that it is therefore an unnecessary feature’. This study involved 5 trans-tibial subjects.

Kim *et al.* [60] carried out a very similar study to Spence’s group. Similarly to Spence, these authors found that an increase in depth of the patellar tendon bar resulted in increased pressure in the patellar tendon region. Unlike Spence, Kim’s group also found that changes in the depth of the patellar tendon bar did have an effect on the other areas studied (namely, the lateral tibial flare, lateral femoral condyle, anterior tibial crest, tibial end, and the medial tibial flare). Like Spence, Kim’s study was conducted on 5 trans-tibial amputees.

Engsberg *et al.* [61] compared rectified and unrectified sockets for trans-tibal amputees. 43 subjects took part in the study, all had mature residual limbs and were not undergoing major changes in limb volume. No subjects had constant recurring prosthetic problems. Each subject wore a prosthesis fitted with a rectified and unrectified socket for a minimum of 4 weeks each (the order of wearing was randomized). Except for the socket shape, the prostheses were the same. Each socket was fitted to wear with a three-ply sock or less. Rectified sockets were fabricated using the traditional plaster cast method. In the fabrication of the unrectified sockets, positive moulds were made using an alginate casting method (to take an exact likeness of the residual limb), whereby the subject placed his or her residual limb into an alginate liquid until the alginate gelled into a semi-solid state. The resulting positive moulds where very slightly smoothed with sanding screen but not rectified in any way. A distal end pad was included in the unrectified socket during fabrication. Gait analysis and energy expenditure data was collected from all subjects following the period of use of each socket, along with the results of the PEQ.

Engsberg *et al.* found that there was no significant difference between socket types for any of the gait variables measured (min. knee flexion in stance, min. hip flexion in stance, max. trunk lateral flexion, max. transverse plane trunk rotation, walking speed, stride length, cadence, ratio of prosthetic/non-prosthetic stance time). For both rectified and unrectified sockets, the prosthetic limb had a significantly smaller load than the non-prosthetic side. Energy expenditure was not different between socket types. The composite scores for the PEQ instrument were not significantly different between the 2 socket types. None of the individual domain scores for the PEQ were significantly different except for one - the perceived response was greater for the rectified socket than the unrectified socket. 16 of the subjects selected the rectified socket as their final prosthesis and 25 selected the unrectified socket. 2 subjects chose to use both (rectified for sedentary tasks and unrectified for exercise). As there was no significant difference in the socket selection, these authors suggest that factors such as residual limb loading, soft tissue distribution, or blood flow may be optimal for some patients in the rectified socket and for others in the unrectified socket. The authors acknowledge that unrectified sockets may not be applicable to all trans-tibial amputees as their strategy in the study was to avoid subjects with constant recurring prosthetic problems and only fit relatively uncomplicated residual limbs.

There has been a large amount of work done in developing techniques that could be used to inform the rectification process. Many studies investigate pressure and shear force distribution within sockets (summarised in Appendix). Such studies generally use instrumented sockets, computational models or pressure measurement devices within the socket.

Methods used to determine the load tolerance of residuum tissues have been described using ‘indentation’ tests [62, 63, 64]. Also, imaging methods have been suggested to inform FEA models and enable clinicians to make decisions regarding the relative load tolerance of particular regions [50, 65, 66]. Given the disadvantages of x-ray computed tomography (CT) and magnetic resonance imaging (MRI) (cost, access to scanner, and ionising radiation in the case of CT), ultrasound (US) may be the most viable imaging modality [65]. It may be possible to combine conventional B-mode scanning with probe positional information (such as that offered by CADCAM measuring systems) to reconstruct 3-dimensional models of the residuum and display the internal structure [67, 68]. Although this is a theoretical possibility, the clinical value would depend on the accessibility and usability of the software, as well as the clinical practicalities of image acquisition protocols.

Limb Alignment

The literature relating to the effect of alignment on socket comfort has little crossover regarding the alignment settings under investigation. Generally, interface pressures and shear forces are measured as predictors of comfort levels.

Seelen *et al.* [69] measured the interface pressures using sensor strips placed on the stump, parallel to the longitudinal axis. The liner and socket were fitted over the sensor strips. Interface pressures were measured during static and dynamic loading scenarios and under three different wedging conditions (0.5cm heel wedging, 0.5cm forefoot wedging and no wedging). All 17 trans-tibial subjects (11 male, 6 female) wore PTB sockets and 6mm silicone liners. Subjects wore their own feet and walked at their own comfortable walking speed over a distance of approximately 40m.

It was found that under static conditions, heel wedging reduced the pressures at the patellar tendon region by an average of 30.4%, but increased those at the distal stump by an average of 40%. Forefoot wedging lead to a significant decrease of 30% near the tibial end. These results were statistically significant ($p < 0.05$). The dynamic data set showed that the only statistically significant change in pressure, for all wedging conditions, was that at the tibia end when the heel had been wedged. In this case the pressure increased by an average of 11.5% ($p < 0.05$) compared to non-wedged conditions. In general, results showed that ‘antero-posterior realignment of the ankle joint does affect stump/socket interface pressure distribution in trans-tibial amputees in a systematic, consistent manner’.

Seelen’s results contradict those of Sanders and Daly [70], who found that changes in dorsiflexion/plantarflexion angle (with no translational compensation) had ‘minimal effect on pressure maxima and resultant shear stress maxima at most of the sites for most of the alignment modifications’. Sanders and Daly’s results disagree with the results of some earlier studies that measured large pressure changes resulting from changes in ankle dorsiflexion/plantarflexion angle [71, 72]. Sanders and Daly hypothesised that these differences may be due to subject differences, and differences in measuring techniques. Variations in limb build are also likely to have influence results. These factors may also account for the different results reported later by Seelen's group.

Sanders and Daly [70] also noted that 'changes in interface stresses from session to session tended to be greater than those for different alignment settings, suggesting that subjects compensated well for misalignment but less well for session differences'.

Sanders *et al.* [73] studied the effects of angular (plantarflexion/dorsiflexion) and translational misalignments at the ankle on shear forces and pressures at the stump/liner interface. Contrary to their following study [70], Sanders *et al.* [73] presented results in which 'over half of the anterior sites showed significant pressure and resultant shear stress changes for misaligned settings compared with nominal alignment'.

It seems from these studies that alignment changes influence the pressures and shear forces at the stump/socket interface, and therefore have the potential to influence user comfort and pain. How significant this influence is, and the extent to which research evidence can be used to reliably predict the effect in clinical situations, remains to be seen.

Checking Processes

During socket fitting a prosthetist has little information regarding the load distribution on the soft tissues and is forced to rely on experience and indirect indications of load to gauge socket fit [74]. Clinically, this is done using clear plastic check sockets, through which the prosthetist is able to visually inspect areas of tissue loading.

Sewell *et al.* [75] developed a checking method to provide both qualitative and quantitative information. Sewell's group used photoelastic techniques to identify areas of high pressure within a clear check socket. The most effective technique required the subject to don a silver nylon sock before the prosthesis, then by shining a polarised light on the socket, contours of the stress or strain differences where visualised on the socket surface. The colours and/or distance between the contours can be assessed via colour contour maps using a polariscope.

The technique was shown to produce results comparable to the traditional check socket and offered the advantage that it is possible to record the change in contours over several fitting sessions. At present the described technique can only be used to assess static loading and no numerical values are provided for the stump/socket interface pressures (colour maps only).

A number of other checking/monitoring techniques have been described using instrumented sockets and/or interface transducers to assess the load distribution at the stump/socket or stump/liner interfaces (statically and during gait). These have been summarised in the Appendix. Despite their use in research studies, these technologies have yet to be adopted into routine clinical practice [76].

Studies have shown that the assessment of static loading is not an effective predictor of stump/socket interface pressures during ambulation [69, 77] nor is it the only factor related to socket comfort [14, 78]. The data collected by Seelen's group indicated that the 'magnitude of stump/socket pressure distribution in static conditions seems not to be highly predictive of stump/socket interface peak pressure behaviour in dynamic conditions'. This is confirmed by Zachariah and Sanders [77] who investigated the relationship between standing stresses and the stresses produced during gait. Yet they did conclude that static full weight-bearing stresses could be considered a satisfactory test for those developed during gait. Nevertheless, measurement of dynamic pressures and stresses would provide a more accurate and quantitative description of the pressure and stress profiles than that gained from traditional check sockets.

Conclusions

The management of biomechanical variables at the stump/socket interface is a critical consideration during prosthetic rehabilitation. Sufficient coupling is vital to enable effective control of the prosthesis, while excessive stresses are likely to cause pain and discomfort, and ultimately result in trauma to the tissues of the residuum.

A large volume of research exists in this area, exploring the influence of various socket parameters on user comfort. Studies generally rely on subjective feedback or pressure measurement techniques to provide more objective information. These approaches have been used to investigate the merit of numerous fitting options including shape capture techniques, socket designs, manufacturing methods and component selection. There is little consistent agreement in the research literature regarding the most effective way of providing a skeletal/mechanical interface.

The quality of study design is variable. Generally, studies involve relatively small subject groups (often < 25), the distribution of which is not representative of the overall amputee population. There is little consistency between studies in terms of measurement tools and outcome measures, making inter-study comparison difficult. Whilst pros and cons of particular fitting options have been highlighted, none have been shown to be consistently better than others, most likely due to the individual nature of residual limbs and the unique requirements of each amputee.

Further research is required to improve the understanding of biomechanical variables at the skin/socket interface (e.g. pressure, friction, temperature, moisture accumulation) and their relationship with levels of comfort experienced by the user. Knowledge of how such variables influence comfort and how they can be managed using the various socket fitting options and techniques may lead to improvements in the quality of socket fit and subsequently change the way prosthetic lower limbs are procured and fitted.

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Summary of studies involving interface pressure and shear force measurement

List of Abbreviations:

TT – Trans-Tibial
TF – Trans-Femoral
PTB – Patella Tendon Bearing
TSB – Total Surface Bearing
PCast – Pressure Cast
FSR – Force Sensing Resistors
PF – Plantarflexion
DF - Dorsiflexion

Authors	Objectives	Measurement Method	Findings
Dou *et al.* [79]	To analyse interface pressures during walking on stairs, slopes and non-flat ground.	Pliance pressure distribution measuring system (Novel Electronics, Munich, Germany).	Pressures measured when walking on flat ground seem not to be highly predictive of those on non-flat ground, slopes and stairs (single subject study).
Sanders *et al.* [80]	To compare diurnal and 6-month changes in stump/socket interface pressures.	13 custom-designed transducers, using strain gauges, mounted on the socket so transducer face is flush with liner.	'Long-term changes are not simply accentuated diurnal fluctuations, suggesting that different treatment methods should be used to treat each condition.'
Beil *et al.* [34]	To compare stump/socket interface pressures with pin and suction suspension systems.	Each socket was instrumented with 5 FSR to measure positive pressures (Model 402 Interlink Electronics, Camarillo CA, USA) and one air pressure sensor to measure negative pressures at distal end (Model 8515c, Endevco, San Juan Capistrano CA, USA).	'During swing, pin liners maintain compressive pressure on the proximal tissues of the residual limb while creating large suction at the distal end. This pressure combination is the likely cause of the daily and chronic skin changes often observed in pin liner users.'
Spence *et al.* [59]	To investigate the effect of patellar tendon bar position on pressure distribution with PTB sockets.	Specially designed transducers at patellar tendon, load cell (Model ELFM-B1-5L, Entran International, New Jersey, USA,) to measure normal pressures, custom built electrohydraulic transducer at distal end.	The position of the patellar tendon bar did not have any effect on the pressure distribution around the socket.
Chou et al. [81]	Investigate the effects of different walking speeds on interface pressures.	Pedar system (Novel Electronics, Munich, Germany).	Walking speed when using a multi-axis foot did not influence interfacial forces.
Goh *et al.* [12]	To investigate the stump/socket interface pressure profiles of PCast prosthetic sockets.	Specially constructed pressure transducers incorporating a load cell (model ELFM-B1-5L Entran International, New Jersey USA). The load cell was mounted flush with the inner socket wall.	A hydrostatic pressure profile was not observed during standing or gait, nor was there a standard pressure profile for the PCast socket.

Kim *et al.* [60]	To evaluate the effectiveness of the patellar tendon bar.	The Tekscan™ (Tekscan™ Inc., South Boston, USA) F-socket transducer.	Increasing the depth of the patellar tendon bar increases the pressure at the patellar region. Also, changes in depth have an effect on the pressure in other areas of the socket.
Seelen *et al.* [69]	To investigate the effects of alignment on pressure distribution at the stump/socket interface.	Force sensing resistor strips (IEE, FSR-649 linear array sensors, International Electronics & Engineering SARL, Luxembourg) placed parallel to the longitudinal axis of leg. A portable pressure monitoring system (IDM RIS Reha-Technik, Berlin Germany).	Statically: Heel wedging increased pressures at the patellar tendon region by 30% but decreased those at the distal tibia by 40%. Forefoot wedging increased pressures at the distal tibia by 30%. Dynamically: Pressure increased by 11.5% at the tibia end with heel wedging.
Beil *et al.* [35]	To measure stump/socket interface pressures during gait in suction and vacuum-assisted sockets.	As described for Beil *et al.* 2004.	Using the vacuum-assisted TSB socket reduced the pressure impulse and peak positive pressures during stance. During the swing phase the magnitude of the impulse, average, and peak negative pressures increased.
Polliack *et al.* [76]	The development of a prototype pressure sensor for clinical assessment of prosthetic socket fit.	4x4 matrix array of 16 capacitance pressure sensors mounted in a silicone substrate.	The prototype capacitor had acceptable levels of accuracy error, hysteresis error and drift error.
Zachariah and Sanders [77]	To determine whether standing interface stresses can be used as a predictor of walking interface stresses.	As described for Sanders *et al.* 2005. Stresses measured during both standing and walking.	During standing with equal weight on each limb, interface stresses 'were only moderate predictors of peak walking stresses'. A correlation coefficient of 0.88 was found between standing with full weight bearing on the prosthetic limb and peak walking stress.
Sanders *et al.* [82]	To investigate the effects of changes in cadence, prosthetic componentry, and time on interface pressures and shear stresses.	As described for Sanders *et al.* 2005. Measured normal and shear forces/pressures.	Week-to-week residual limb changed had more effect on interface pressures than intra-session changes in cadence or componentry.

Zhang and Roberts [83]	To compare computational analysis with clinical measurement of socket/stump stresses.	Triaxial force transducers (developed in King's College London - Willliams *et al.* [84]) mounted on a PTB socket wall. Measured normal force and shear forces in two orthogonal directions. Stresses measured during standing and walking.	The computational model predicted pressures by an average of 11% lower than those measured by the transducers. The highest measured pressure was over the patella tendon (215kPa). The highest longitudinal shear stress was over the lateral tibia (44kPa).
Convery and Buis [13]	Measurement of dynamic stump/socket pressure distributions during the stance phase of gait (TT amputee, hydrocast socket).	4 Tekscan™ (Boston, USA) FSR transducers placed within a sensing reference grid established using a socket axis locator.	Pressure gradients within the hydrocast socket were less than those within the hand cast PTB socket.
Sanders and Daly [70]	To determine the effects of sagittal plane angular alignment change on stance phase pressure and shear stresses on TT stumps.	As described for Sanders *et al.* 2005. Measured normal and shear forces/pressures.	Socket-shank angular alignment changes had minimal effect on stance phase peak pressures. Changes in session-to-session interface stresses tended to be greater than those seen between different alignment settings.
Convery and Buis [85]	To investigate the dynamic stump/socket interface pressures in a PTB socket during the stance phase of gait.	F-socket transducer (Tekscan™, Boston, USA). Transducer incorporates 96 sensor cells and uses 0.017mm thick mylar/resistive ink.	The use of the F-socket to record pressure data was confirmed providing 'a strict calibration procedure and test protocol is adopted'. The FSR established a distinct pressure pattern. The pressure within these areas varied during the stance phase of the gait, indicating the importance of measuring these interface pressures during gait.
Sanders *et al.* [73]	To determine the effects of alignment change on stance phase pressure and shear stresses on TT stumps.	As described for Sanders *et al.* [80]. Measured normal and shear forces/pressures.	Changes in interface stress were greater in the anterior socket region then in the lateral or posterior regions. This led to a conclusion that changes in alignment only had a localised effect on interface stresses.

Zhang *et al.* [86]	A clinical investigation of pressure and shear stress on TT stump/socket interface with changes in PF/DF alignment.	Triaxial force transducers developed at King's College London (Willliams *et al.* [84]).	It was found that an alignment change of 8^o produced a change in peak longitudinal shear stress of between 8% and 11.5%.
Lee *et al.* [10]	To use stump/socket interface pressures as an aid to socket design for TF amputees.	Specially constructed transducers were used, incorporating a load cell (model ELM 602-1, Entran International).	The IC socket had a more even pressure distribution compared to that of the quad socket.
Sanders *et al.* [87]	To investigate the interface pressures and shear stresses at 13 sites on a PTB socket.	As described for Sanders *et al.* [80]. Measured normal and shear forces/pressures.	During the first 50% of stance, pressures and shear stresses were maximal at the anterior distal or mid-limb sites. The maximal regions of these forces changed to the anterior medial and lateral proximal sites during the second 50%. 'Results also suggest that skin across the distal tibial crest was in tension at the times of the first and second peaks in the shank axial force'.
Silver-Thorn *et al.* [74]	A review of prosthetic interface stress investigations.	Literature review.	The development of accurate pressure measurement systems for prosthetic sockets could provide a 'diagnostic tool that can readily be incorporated into prosthetic fitting'.
Sanders and Daly [66]	To compare finite element results with experimental measurements, with respect to normal and shear stresses at the stump/socket interface during ambulation.	ANSYS® FE package (Swanson Analysis Systems, Houston PA, USA). Custom-designed transducers, using strain gauges, (6.35mm diameter) mounted to socket so face of transducer is flush with the liner.	Analytical resultant shear stress magnitudes were less than experimental values at all transducer measurement sites. Analytical normal stresses were different to experimental values.
Sanders *et al.* [88]	'To gain insight into shear stresses and parameters that affect them'.	Custom-designed transducers, using strain gauges, (6.35mm diameter) mounted to socket so face of transducer is flush with the liner.	'On tibial flares, resultant shear ranged from 5.6kPa to 39.0kPa, while on the posterior surface it ranged from 5.0kPa to 40.6kPa'.

Evidence review:
Pain-free artificial lower limb patient interfaces

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