Fachliteratur Prothetik

Pohlig Bionic Socket System (PBSS) - Initial Clinical Experience with an Innovative System

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The optimal fitting of the socket remains a challenge for technicians and physicians, especially after a transfemoral amputation. The Pohlig Bionic Socket System (PBSS) aims to optimize the fitting process and make it as reproducible as possible with an entirely new, technically comprehensive fabrication concept. However, aside from objective criteria, the patient's comfort is the most important criterion for assessing success. The objective of this study was a clinical examination of the first patients that were fitted using PBSS in order to obtain initial data on the efficacy of the new technologies.

Key words: socket, transfemoral amputation, fitting, clinical examination after fitting with a prosthesis

Introduction

Socket innovations remain a problematic area in exoprosthetics. Despite decades of efforts to optimise the link between the prosthesis and the patient, especially after transfemoral amputations, there is often still no satisfactory solution for essential aspects such as rotational stability, precise fit, or thermal regulation. After the quadrilateral socket shape, which is now deemed outdated, the narrow mediolateral socket shape was established only slowly in orthopaedic technology because fitting is associated with extremely high personnel and material demands and an extremely precise model of the femoral residual limb must be made, requiring a systematic modelling technique adapted especially to the criteria of the narrow mediolateral socket shape [1, 2].

Nevertheless, the concept of the narrow mediolateral socket remained the basis for further developments; the CAT-CAM socket led to the IC socket (ischial containment socket) and new versions such as the M.A.S. socket (Marlo Anatomical Socket) were developed. In 2002, Marlo Ortiz eventually integrated components of the quadrilateral socket system into his M.A.S. technique [3]. The unobtrusive design of the socket brim contour, free of the buttocks and close to the body, is especially appreciated by female prosthesis wearers, although the maximum reduction of load-bearing surfaces and resulting excessive loads can lead to a failure of the system [4].

Randall Alley broke new ground in 2011 with the creation of the HiFi interface module and the transfemoral compression socket, which introduced the concept of osseoperception. For the first time, the compressibility of the soft tissue was measured and the muscles of the area guiding the residual limb were enclosed by means of four struts placed longitudinally around the femur at 90° angles to each other [5].

The positioning and also the strength of the compression of these zones is determined during plaster casting with a standardised device ("imager") whose metal struts are placed horizontally on the residual limb. With this method, Alley states that it is often possible to dispense with embedding the pelvis (ischial tuberosity) in the prosthetic socket.

However, determining the shape and creating the functional form of the prosthetic socket remain factors of uncertainty.

The fitting result differs significantly from OT technician to OT technician even when the same methods are used. It also does not seem possible to reproduce the exact shape and volume of the socket form. Furthermore, the quality of the plaster cast is affected just as much by the technician's manual skill as by the wrapping method applied, the tension of the plaster bandages and, because of the moulding grip, the form of the guide zones. The soft tissues are manipulated by the orthopaedic technicians to varying degrees – resulting in uncontrollable displacement.

With this in mind, the Pohlig Bionic Socket System (PBSS) [6], in addition to stabilising the distal socket, aims to maximise freedom of movement in an objectively reproducible process. The shape is measured without contact using a scanner on a seating unit that can be adjusted in three dimensions designed especially for the PBSS. After the appropriate preparation, the definitive scan takes only 45 seconds, during which time the muscles are tensed to ensure a perfect impression (Fig. 1). Later, all the circumferences of the residual limb are also measured using a measuring tape standardised by a pneumatic spring. The residual limb is also measured ultrasonically so that the muscle structures, possible ossification or exostosis, and especially axial muscle gaps can be identified and marked. This allows the stabilisers to be positioned much more precisely (Fig. 2).

However, the clinical assessment of the quality of the socket remains complex. In addition to all the technical aspects and objective criteria that orthopaedic technicians and physicians apply, the subjective assessment by the respective patient is the gold standard – the mobility grade, correct prosthesis structure, modules used, or underlying diseases always have an effect on the patient's overall well-being. A clinical study is needed to determine whether the considerable technical complexity of the PBSS will actually result in a significant improvement over established socket technologies for patients.

The aim of this study was therefore to evaluate the first patients to be fitted with the new system as closely as possible to identify possible strengths and weaknesses of the system at an early stage. A comparison of literature was also carried out to allow an assessment of the results in the specific context.

Methods

The study design is a pilot study in the sense of a consecutive case study. After approval by the Bavarian ethics committee, all patients who were fitted with this prosthesis were invited to a follow-up examination.

Between January 2012 and May 2013, a total of 36 patients were fitted with a

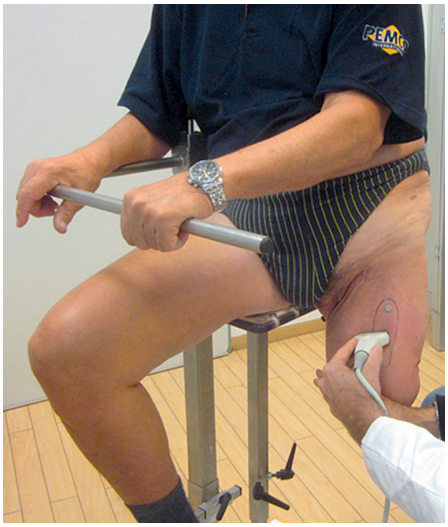

Figure 1 *The muscle gaps for positioning the stabilisers identified in the clinical examination are checked by ultrasound and theirposition is adjusted if necessary. Measurements are made on the seating unit designed for the scan in order to reproducibly associate the ultrasound data.*

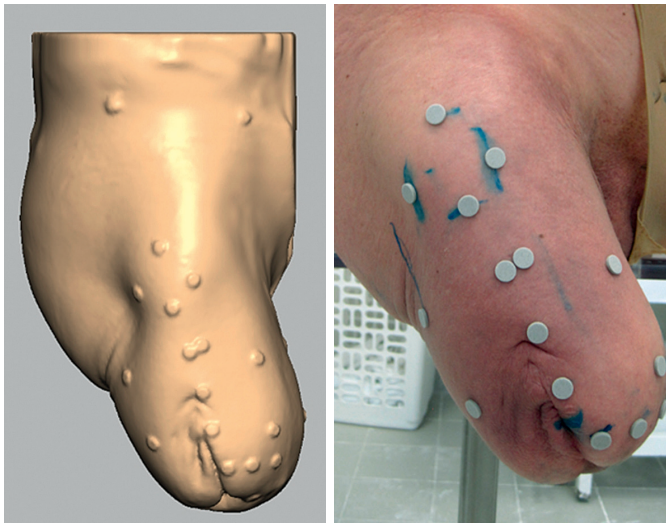

Figure 2 *Before scanning, all sites on the surface of the residual limb relevant to modelling are systematically marked. They aid geographical orientation during the modelling phase.*

PBSS, 22 of whom were available for follow-up and gave their consent to be included in the study.

The interval between the fitting and the follow-up examination was at least 8 weeks; all amputations were at least a year old so that only patients with a previous prosthesis were included. All patients were unilateral transfemoral amputees and were recruited from all mobility grades (I-IV).

Follow-up examination

The residual limb was examined clinically to identify any pressure points. The length from the greater trochanter to the end of the residual limb and the circumference of the residual limb 10 cm proximal to the end were measured and the indication for the amputation and the interval prior to fitting with PBSS were documented. Age and body mass index (BMI) were also recorded.

For the clinical evaluation, the German version of the prosthesis evaluation questionnaire (PEQ) was used [7]. The PEQ system consists of 85 questions in 7 categories to measure 9 different PEQ scores. Aside from the comprehensiveness of the PEQ system, its major advantage is that it was designed specifically for patients after amputation of the lower limb. The score is filled out by patients by placing a mark on a continuous scale, similar to the VAS system. For the analysis, these marks are assigned values between 0 and 100 to form numerical results. The respective PEQ score is then calculated as the mean value of the respective questions in all 7 categories.

The 9 PEQ scores include: (I) "Ambulation" as an indicator of the ability to walk, (II) "Appearance" for the cosmetic appearance of the fitting, (III) "Frustration" for general problems with the prosthesis, (IV) "Perceived Response", representing the reactions of third parties, (V) "Residual Limb Health" for the condition of the residual limb, (VI) "Social Burden" for social integration in everyday life, (VII) "Sounds" for problems related to sounds made by the prosthesis, (VIII) "Utility" for handling the prosthesis and (IX) "Well-Being" for the general health condition.

There were additional questions to be assessed on the scale as to how much better the fit with the PBSS was compared with the previous fitting and whether any disadvantages in the scanning method compared with the plaster cast were noted.

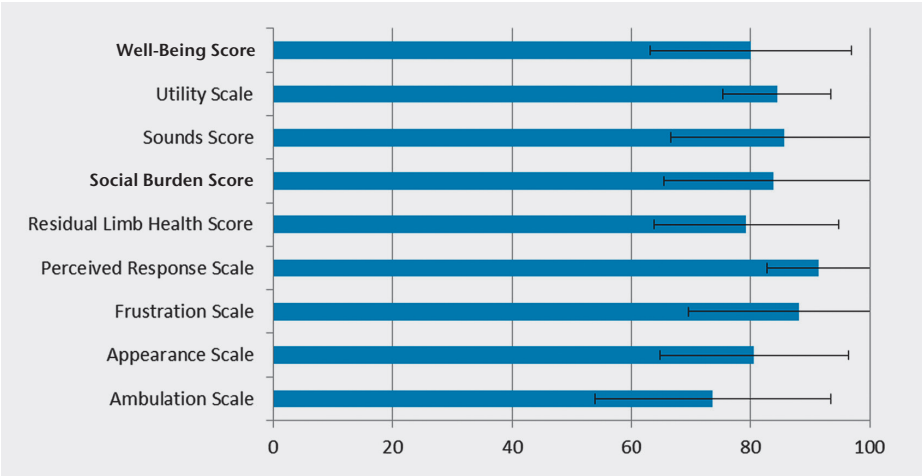

Figure 3 *Results of the PEQ scores.*

Statistical analysis

The statistical analysis of this study was performed by an independent external party (http://www.stat-up.com/de/). In addition to descriptive statistics to determine the mean value and standard deviation of the basic criteria and the PEQ scores, factor analyses were carried out to identify potential correlations among the results.

In order to consider age, gender, and mobility grade, differences between the youngest 50% and oldest 50% were tested using two-tailed t-tests with a level of significance of $p = 0.05$. It was also tested whether perceived pain played a role in the assessment of the score. A factor analysis with varimax rotation was carried out for all items of the questionnaire related to the perception of pain.

This showed clearly that there were two main factors: The first factor (F1) describes the frequency or duration of all pain perceived (i.e. not only phantom limb pain and residual limb pain, but also pain in the other leg or back pain), the second factor (F2) describes the intensity of the pain and the resulting burden – again based on all types of pain. Using reliability analyses, the questions that are representative for these factors were selected (Cronbach's alpha 0.859 for F1 and 0.982 for F2) and then designated "FD score" ("frequency-duration score") or "IB score" ("intensity-burden score").

	mean value	standard deviation
Ambulation Scale	73,6	19,8
Appearance Scale	80,6	15,8
Frustration Scale	88,1	18,3
Perceived Response Scale	91,5	8,8
Residual Limb Health Score	79,3	15,5
Social Burden Score	83,9	18,4
Sounds Score	85,7	19,1
Utility Scale	84,5	9,0
Well-Being Score	80,1	16,9

Table 1 *Results of the PEQ scores.*

	mean value	(SD)	p value (two-tailed)
Well-Being Score			
under 55	87,9	12,01	
over 55	74,6	17,98	0,051
Ambulation Scale			
under 55	82,7	14,53	
over 55	67,3	20,95	0,054
Frustration Scale			
under 55	95,7	4,99	
over 55	82,7	22,29	0,061

Table 2 *Differences in PEQ scores by age.*

To test whether the pain actually played a role in the assessment of the other scales, the correlations between the values measured for the FD and IB score and the values of the other scores were then examined.

Results

Patients

A total of 22 patients were examined, 17 men and 5 women. The BMI was below 30 in all patients, the mean age was 58 years, and mobility grades were I (2 patients), II (2 patients), III (15 patients) and IV (3 patients).

The reason for amputation was vascular occlusion in 7 patients, trauma in 11 patients, tumour disease in 2 patients and another 2 patients had suffered a severe, unmanageable infection after a knee replacement. The residual limb length varied from 20 to 38 cm (mean 28.6 ± 5.2 cm), the circumference of the residual limb from 18.7 to 58 cm (mean 40.6 ± 11.5 cm).

PEQ scores

The PEQ score was good to excellent in all categories (Fig. 3). In particular, the categories "Utility", "Frustration" and "Residual Limb Health" were assessed to be representative for the quality of the socket fitting and were rated 79% or more of the possible maximum value (see Fig. 3, Tab. 1).

For the specific question as to whether PBSS resulted in an improved fit in comparison with the previous prosthesis, the average improvement in the socket fit was reported to be 80%. Furthermore, patients found no disadvantages in scanning compared with the plaster cast technique.

Correlation analyses

Taking age, gender and mobility grade into consideration at a level of significance of 0.05, no significant differences were found. However, due to the small sample size, it can be assumed that the differences between the youngest 50% and the oldest 50% would be significant in a larger sample size, especially with respect to the "Ambulation Scale", "Frustration Scale" and "Well-Being Score". In these three scores, the evaluation tended to be poorer with increasing age (Tab. 2).

While no correlation was found between the frequency and duration of phantom limb pain or residual limb pain and the other scores, using the IB score, a definite trend toward a negative correlation was found based on the Pearson correlation; this was significant with respect to the "Utility Scale" (r = – 0.463, p = 0.035). Consequently, a lower IB score as an indicator for greater perceived pain tended to lead to higher scores in the other scales. This tendency indicates that patients with increased general perception of pain benefit more from PBSS than those with a weaker general perception of pain. In the clinical context, that can be interpreted to mean that any improvement of the pain is perceived more strongly by these patients.

Comparison of literature

After a corresponding literature search, three studies were selected that used the PEQ system for a similar question [7, 8, 9]. The results for the respective PEQ scores were tested statistically against the results of this study.

Due to the larger sample size of 92 responders, the study "Prosthesis evaluation questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life" published by Legro et al. [6] was a good data set for comparison. Indeed the comparison showed significant differences:

The PBSS patients gave higher scores, with respect to both the "Frustration Scale" and the "Social Burden Score". In the "Utility Scale", the p value was 0.0678, slightly above the significance level of 0.05, allowing a clear trend to be seen here. Overall as well, PBSS patients indicated higher levels of satisfaction in all 9 scores.

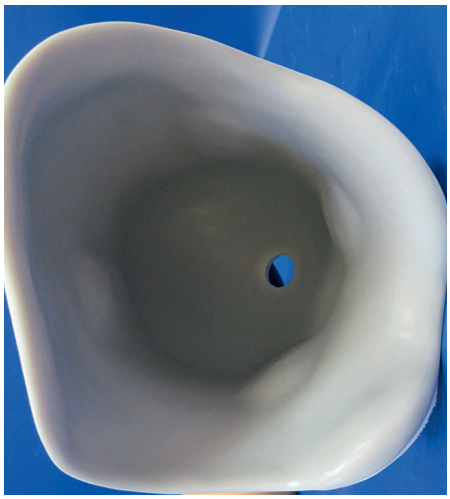

Figure 4 *Four stabilisers are integrated into the PBSS socket, the positions of which are oriented to muscle gaps.*

However, no significant difference was seen when compared with the data from Hafner and Smith [8] ("Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control"). For some scores, those surveyed in the Hafner and Smith study reported higher

values, but for others, the participants in the PBSS study.

In the comparison of the results of the study published by Theeven et al. [9] "Influence of advanced prosthetic knee joints on perceived performance and everyday life activity level of low-functional persons with a transfemoral amputation or knee disarticulation" a better evaluation of nearly all scores was observed from PBSS patients, although the differences were not significant. In the comparison of the "Utility Scale", for example, the p value was 0.0528.

Discussion

All patients benefited from the PBSS socket. Patients with a particularly high level of perceived pain apparently benefited most. The PEQ score as an evaluation system that is very detailed, but based primarily on subjective perception, showed that the results were comparable or better than in other studies.

The differences between patients younger or older than age 55 are plausible and are not attributed to PBSS. It was interesting that no correlation was found between the PEQ scores and mobility grades. This suggests that patients of all mobility grades benefit equally from the new socket system. The axial length of the PBSS stabilisers integrated in the socket correlated with the length of the residual limb. Depending on the circumference of the residual limb, the width was specified to be 45 mm ± 5 mm, height at 5 mm ± 1 mm (Fig. 4).

Especially for cases that were difficult to fit due to excessive fatty tissue in the residual limb, the impression depth could be increased with the aim of specifically stabilising the fatty tissue of these problematic residual limbs through greater compression. The fact that patients with greater sensitivity to pain tended to be more satisfied with the fitting may have been affected by this; a follow-up study of the particular benefit for residual limbs with excessive fatty tissue would appear to be useful. It should also be observed whether the ability to tense the muscles, which differs from patient to patient, has an effect on the fit (Fig. 5).

Overall, the results of this study indicate that the additional effort put into objectively reproducible, standardised fabrication is favourable for the clinical outcome. All patients reported that the socket fit was improved by this fitting. It should be stated here that this study included only patients with long-term experience who were thus particularly critical in their evaluation. No adverse events occurred. Overall, the initial results can therefore be considered to be very encouraging.

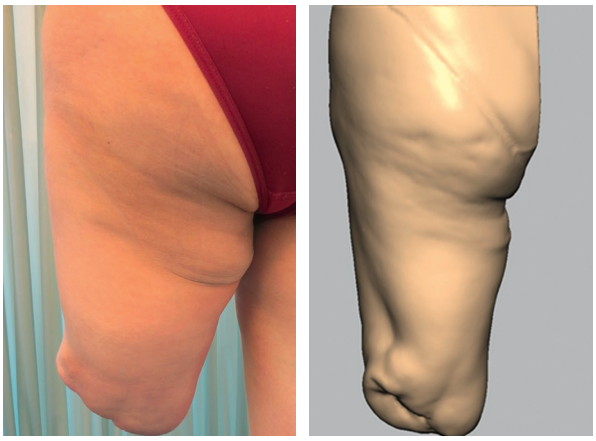

Figure 5 *Relief of the residual limb (left) without tensed muscles; relief after the shape is scanned (right) with tensed muscles.*

One limitation of this study is that it was a pilot study with a very limited number of patients and limited level of evidence due to the study design as a case series. In this study, a representative sample size with 22 of 36 cases was observed, but further studies should be conducted with a higher number of cases and a direct comparison with other socket systems.

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