Specialist prosthetics

The Pohlig Bionic Socket System (PBSS)

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New perspectives for prosthetic fittings after transfemoral amputation

The Pohlig Bionic Socket System (PBSS) (Fig. 1) is a newly developed concept in modern prosthetic socket technology. Conventional methods of socket formation were reassessed, user-specific needs were determined, and newer methods of socket design were developed. Based on the premise that the prosthetic socket – the direct link between the user and the prosthesis – is the most important component of a prosthesis, a team of experienced prosthetists defined new approaches for determining socket design and customised socket fabrication. While some ideas are still in the concept phase, the first approaches for major innovations in transfemoral prostheses have already been tested in approx. 75 prosthetic fittings.

Key words: bionic socket system, above knee prosthesis, HTV-silicone-socket, 3-D-Scan, PBSS-Stabilizers, PBSS-Air, Portsystem, Acuclosure-spots, Pohlitherm-element

Introduction

The fathers of orthopaedic technology already concentrated on the idea of optimising prosthetic sockets, as have all following generations, in order to enable patients to deal with many different everyday situations better, with less pain and more comfortably.

For prosthetic fittings after transfemoral amputation, the ischium plays a critical role, which also manifests itself in the embedding technology. The horizontal oval and quadrilateral socket shapes, oriented towards the functional form, which are not state of the art anymore but are still widespread today despite the antiquated embedding technology, are focused on the pelvic bone, which is very narrow distally, with its tuberosity-supporting seat. During the stance phase up to 80 per cent of the body weight transfer or absorption is concentrated at certain points. As a result, the load line (the centroid of the area) lies in the frontal plane along the mediolateral socket axis with 40 per cent distance in the medial direction and 60 per cent in the lateral direction. Since the ischial tuberosity is positioned anatomically very far in the medial direction and unfortunately also far in the dorsal direction to the load line, static problems for prosthesis wearers are inevitable in these socket shapes. A torque arises during load bearing. The pelvis rotates forwards and downwards in the sagittal plane. The pelvic tilt angle increases [1]. In the frontal plane the pelvis tilts towards the healthy side. The prosthetic socket "shifts" in the lateral direction.

The vertical load bearing principle in the shape of the tuberosity seating changed fundamentally in 1983, when John Sabolich from Oklahoma introduced the so-called CAT-CAM technology (Contoured Adducted Trochanteric-Controlled Alignment Method) [2]. His prosthetic socket did without both a tuberosity seat and the ventral pad at the height of Scarpa's triangle, which had been necessary with the earlier socket shapes for positioning the tuberosity on the seat.

However, the ischium-encompassing socket form prevailed in orthopaedic technology only very slowly, since performing the adaptation is technically difficult, and the personnel and material demands are very high. The basis of a successful fitting of transfemoral amputees with prosthetic sockets with an ischium-encompassing socket form are extremely precise modelling of the transfemoral residual limb and systematic modelling technology specially attuned to the criteria of the elongated oval socket [2].

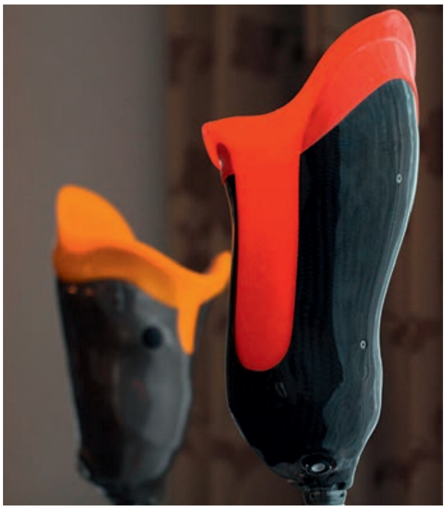

Fig. 1 The Pohlig Bionic Socket System

The nomenclature changed over time. The CAT-CAM socket became the IC socket (Ischial Containment socket). New variants and modified embedding principles such as the ramus containment design of M.A.S. socket technology (Marlo Anatomical Socket) were added to this. In 2002, Marlo Ortiz integrated components of the quadrilateral socket system into his M.A.S. technology. He wrote: "In 1999, one of the patients insisted on an extremely low posterior socket end to improve the cosmetic appearance of his buttocks. Surprisingly, it was determined in the process that this made it so much easier to contain the ischial tuberosity and a part of the pubic ramus completely, since there is no support or containment of the gluteus in this socket. To provide better rotation control, the frontal area of the socket was modified so as to resemble the classic quadrilateral shape. The anterior wall was lowered radically in order to allow the full extent of active and passive hip movement." [4]

The unobtrusive design of the socket brim contour, free of the buttocks and intimate to the body, is appreciated by female prosthesis wearers in particular. However, its maximum reduction makes socket production somewhat difficult. Regardless of the reduction of the load bearing surfaces and the resulting added load on embedded parts of the residual limb, a design of the socket brim contours that is too deep can cause the system to fail [4].

The socket brim runs even significantly deeper when the Milwaukee design is used. According to the authors, this method completely does without the supra trochanteric lateral socket wall component and the rigid containment of the ramus. In contrast, sufficient stability when walking essentially concerns "muscular interlocking". With this socket shape, the distal femur should receive stabilisation from an L-shaped lateral posterior support structure concomitantly [5].

Randall Alley broke new ground in 2011 with the creation of the HiFi interface module and the transfemoral compression socket. Thus he introduced the new idea of osseoperception, measured the compressibility of the soft tissue and clamped the musculature of the residual limb guide area by means of four sturdy struts running longitudinally around the femur arranged at 90° angles to each other [7].

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, it is possible in many cases to do without embedding the pelvis (tuber ischiadicum) in the prosthetic socket, according to Alley. The idea that the partial compression HiFi stabilisation socket implements is certainly an innovative one. However, it remains to be seen whether the technology can meet the European requirements.

Despite the range of available variants, the hydrostatic support has remained just as much the standard for effective power transmission as bone locking. It can of course happen that

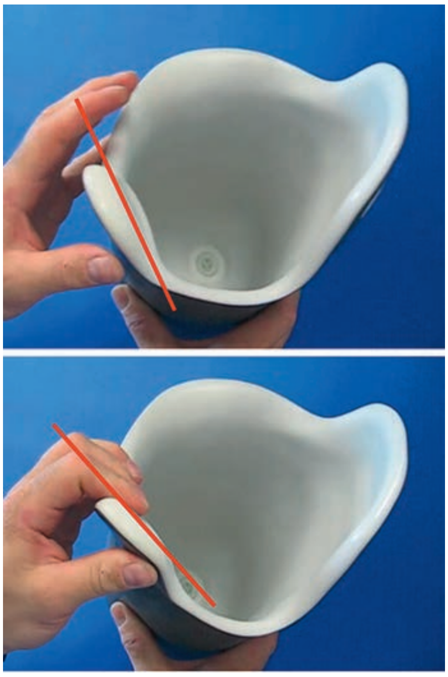

Fig. 2 *Adaptive ramus embedding in the PBSS socket, rotatable mounting.*

the contractility of the musculature allows a long muscular transfemoral residual limb to compensate for the gait-stabilising medial support on the proximal socket end during walking. However, what happens with transfemoral residual limbs that are less muscular or have very soft connective tissue, or even short ones? The biomechanics of walking and the associated force vector that arises in the stance phase due to the shift of the centre of gravity of the body over the prosthetic leg cannot be eliminated. Especially with just those residual limb characters indicated above, the musculature often is not or is no longer able to provide this stabilisation; therefore the centring and stabilising function of the medial embedding of the ramus or ischial ramus cannot be disputed. This is efficient and, when placed at the right location, is able to provide the desired medio-lateral stabilisation and thus prevent the prosthetic socket from shifting in the stance phase.

In particular, a rotatable mounting of the medial embedding, which, embedded in an HTV silicone contact socket, permits adaptive behaviour in different load situations, has proved successful here (Fig. 2).

However, determining the shape and creating the initial functional form of the prosthetic socket still represent extreme uncertainty factors. The fitting result differs significantly from OT technician to OT technician when the same routines are used. Reproduction of the socket form with an exact shape and volume also does not appear to be possible. Furthermore, the quality of the plaster cast is affected just as much by the technician's technical 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. In the process the orthopaedic technician manipulates the soft tissues in very different ways, which results in imprecise displacements that are difficult to control.

When new fitting forms are initiated, the wants and needs of the users should be brought to bear in addition to the design of the form of the prosthetic socket. For this reason, in advance of the development of the PBSS technology, a patient survey was conducted on the topic of "phantom pain, residual limb pain, wants and needs" in which 120 users participated. 87 completely filled in questionnaires could be incorporated into the analysis. Besides different methods for successfully handling phantom pain, these also described various everyday problems that were clearly attributable to the shaping and structural design of the prosthetic socket.

The following clusters of concerns could be identified as critical issues:

- insufficient comfort when sitting
- loss of optimal adhesion after the prosthesis is worn for a long time
- chafing with short residual limbs and residual limbs covered with mesh grafts
- feelings of muscular tightness
- feeling of cold increased by cold sweat
- transpiration/air pockets after the prosthesis is worn for a long time
- insufficient comfort in the medio-proximal socket area

Ultimately most of the suggestions for improvement listed in addition were attributable to the design and material of the socket construction. Adaptability to everyday situations must be emphasised just as much as the desire for temperature-independent thermoregulation in the prosthetic socket. Various users report having eliminated the phantom pain successfully with acupuncture or acupressure and others with hot/cold applications. All users agreed in their evaluation and emphasis of sitting comfort. The level-congruent sitting position such as is present in the M.A.S. socket was described by all users as an enormous

Fig. 3 *Shape determination with video-based scan.*

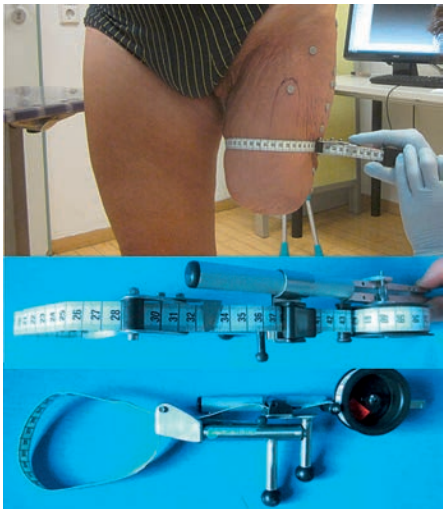

Fig. 4 *PBSS residual limb measuring tape with specified pretension through gas spring.*

enrichment and "must-have" in the prosthesis socket.

The Pohlig Bionic Socket System (PBSS)

Many problems remained unsolved, for example the question of a method for shaping that does not mistreat the residual limb. The socket design must provide optimal stability. Furthermore, it is important to improve adhesion, reduce pain and prevent iatrogenic injuries and incorrect fittings. These demands were the motive for considering a bionic prosthetic socket system. To achieve these goals, the idea was to apply parameters and methods that had previously not been considered in orthopaedic technology. The project name "PBSS" indicated the direction. "Bionic" is a combination of the words "biology" and "technology". This coinage summarises the technical implementation and application of a modern prosthetic socket system, which integrates the biological patterns into the requirements of amputated limbs. All measures should be oriented towards natural processes and alter the anatomical form and function of the human body as little as possible. With increasing experience and development of these ideas, what gradually emerged was the fact that PBSS would not become a new technology, but rather a "bundleable package" composed of a wide variety of functional units adapted to the individual circumstances of the amputee.

With an eye to the extensive development tasks, multiple 3D interface modules were acquired and video-based scanning systems were installed in 2009 after many years of weighing up and comparing various systems. After positive experiences in orthotics, it was possible to implement primary ideas in PBSS in the autumn of 2011 and perform initial test fittings. The shape is determined in a contact-free manner via a video-based scanner. That alone is not yet anything revolutionary in comparison to plaster casting. However, what is new is that, with the patient purposefully positioned on a chair specially designed for PBSS issues, the scan is performed with maximally tensed musculature (Fig. 3). The definitive scan only lasts 45 seconds but is preceded by long preparation. Patients are barely able to tense their musculature for more than 60 seconds, for which reason it is not possible to realise as perfect a relief through plaster casting as with the scanning procedure.

The data gathering is significantly more extensive than in the established methods:

- All residual limb measurements are taken in order to determine the reduction quotients with a special measuring tape equipped with a gas spring (Fig. 4).
- Gathering sonographic data provides interesting information on the contour of the musculature and possible ossifications or exostoses.
- Because of their particular significance, the axial gaps in the muscle at the position of which the PBSS residual limb stabilisers are integrated into the socket must be determined and marked sonographically (Fig. 5).

The 3D modelling, which currently includes 43 actions, then follows based on bionic data. Here as well it is strictly ensured that the relief of the residual limb surface is retained optimally in order to offer the musculature free spaces in which it can expand during contraction.

The PBSS residual limb stabilisers, whose format is about 4 to 6 mm, serve the biomechanical purpose of using the gaps in the muscle and pushing the musculature apart gently. The manipulation increases the distance between the origin and the insertion. The pre-loading of the musculature, which has an extremely positive effect on the residual limb for controlling the prosthesis, benefits from this action (Fig. 6). Residual limb stabilisers do not serve the purpose of compressing the soft tissues of the residual limb more strongly; on the contrary. Comparing the sockets designed with PBSS technology to CAT-CAM or M.A.S. sockets, PBSS actually provides a greater volume with optimised guide properties. It makes sense that this benefits socket comfort.

The best possible adhesion between the residual limb and the prosthetic socket is achieved in transfemoral prosthetics by vacuum-stabilised HTV silicone contact sockets, which can be fabricated in various Shore hardness grades depending on the residual limb proportions [9]. This fabrication method also offers the greatest variety of manipulation options, so nothing stands in the way of taking the greatest variety of design supplements into account and integrating them into the prosthetic socket.

The volume of a transfemoral residual limb is not constant. Illnesses, weight loss or athletic activity can cause an incongruity between the residual limb and socket receptacle volume, with the result that the guide properties become significantly worse. The Air Contact System (ACS) makes it possible for the wearer of the prosthesis to adapt the prosthetic socket to the current dimensions of the residual limb [4]. During athletic activity, the connection between the residual limb and socket can be optimised with the filling chambers through variable adjustment of the area cross-section. More precisely, the air chambers have a similar effect and in practice have also been arranged similarly to the stabilisers mentioned above. It was possible to develop the ACS technology further for the PBSS concept into the

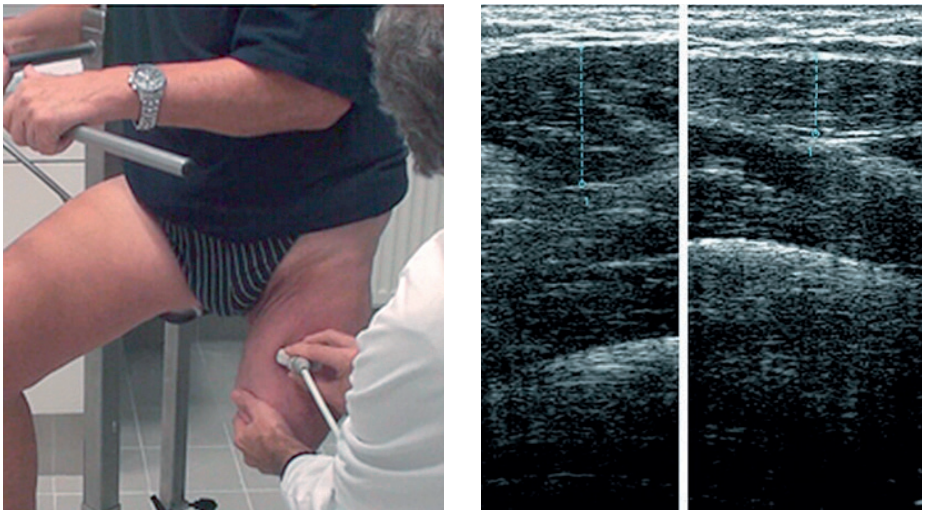

Fig. 5 Determining the residual limb characteristics with ultrasound.

PBSS AIR system component. What is new here is that the air chambers were integrated directly into the HTV silicone contact socket and adapt themselves during inflation to the residual limb shape in a manner congruent to the shape (Fig. 7).

In addition to the new method of form determination and the bionic design, the PBSS concept also offers innovative functional systems.

The Pohlitherm element (Fig. 8) provides a climatically comfortable temperature level through biosensors so that the residual limb can be comfortable in the prosthetic socket regardless of the external temperature. It uses the function of a Peltier element to generate heat and is placed in Scarpa's triangle, precisely above the common femoral artery, for targeted heat emission.

At the Institute of Physiology and Experimental Pathophysiology of the University of Erlangen-Nuremberg, Prof. Clemens Forster, alongside the development work on the socket components, investigated what effect point application of caloric heat in the area of the groin (above the femoral artery) has on the lower extremity.

The results were supplied by a high-resolution thermography camera. The results signaled that the sensors can be successfully manipulated by an external application.

Besides further studies on the effect of the Pohlitherm technology, a case study under medical supervision was carried out at our own company with a male transfemoral amputee subject. The measurement procedure lasted a total of 18 minutes, composed of an 8-minute heating-up phase and a further 10 minutes of controlled heat supply between 41 and 42 °C. The body temperatures before and after the heat supply ended were determined with an infrared thermometer at the following locations:

- mid residual limb left medial 31.5 °C/34.2 °C
- mid thigh right medial 33.0 °C/ 33.0 °C
- lateral residual limb end left 29.0 °C/31.5 °C
- popliteal fossa and mid lower leg right 31.0 °C/31.0 °C

Besides the influence of the climatic conditions, residual limb and phantom pain also represent a central problem for amputees. The PBSS port system (Fig. 9) creates new treatment options for physicians with the goal of no longer using medications with a systemic effect, but rather only a local effect, which can lead to a significant reduction in use of painkillers such as opiates. Causal pain treatment will be possible both with drugs through service ports and through the integration of components of Traditional Chinese Medicine (TCM). The acupuncture pressure units implemented in the PBSS socket are positioned along so-called meridians and can be manually activated by the user at intervals determined by the physician. However, the experiences and above all the design variety of the acupuncture pressure spots are too recent. The activation depth and hardness of the spots are currently still being tried out (Fig. 10).

Fig. 6 Sonography-supported determination of the position of the PBSS stabilisers.

Fig. 7 Air chamber system adapted to the residual limb shape in the PBSS.

Fig. 8 Thermoregulation with PBSS Pohlitherm.

Fig. 9 *Freely positionable PBSS port system to make local treatments possible.*

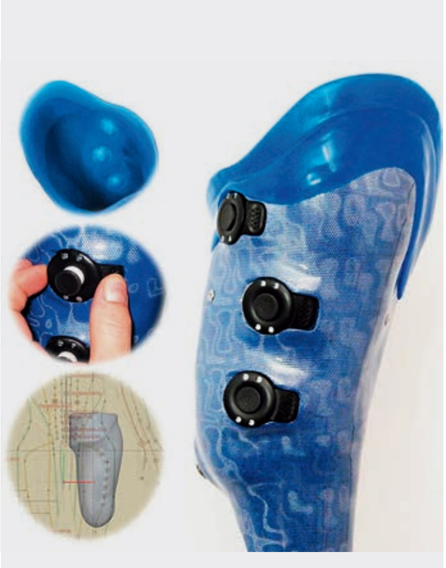

Fig. 10 *Acupressure spots in the PBSS..*

The PBSS concept has an interdisciplinary aim and intends to actively incorporate the attending physicians and the therapists into the prosthetic fitting. The diagnostic sonographic information is indispensable, as more than 70 fittings so far have confirmed. The comprehensive database with its multiple aims opens up new perspectives in leg prosthesis fitting and provides encouragement for further refining the system. The refreshingly positive feedback from patients fitted with PBSS encourages us to pursue the course further.

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