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Prosthetic sockets of polymerized metal: materials, design, technology

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Abstract

The process of fabricating polymerized metal sockets for above-knee and below-knee prostheses is described. The technique is based on pulse stamping of metal blanks over a matrix imitating the negative mould of the stump and subsequent polymeric coating by vibro-vortex spraying.

The monitoring of more than 500 patients fitted with metal-polymer sockets since 1978 is reported.

Introduction

Prosthetic sockets are the most important elements of lower limb prostheses and the selection of materials, their designs and the associated technology development remain urgent problems with respect to patients' comfort as well as the technological and cost aspects of their manufacture.

Physiologically and biomechanically acceptable conditions for stump environment and function are ensured by accurate fitting of the socket and making use of the flexible, thermal, hygienic and other properties of material and design. The required accuracy in individual fitting of the sockets, the cost and complexity of maintaining the equipment, the necessary skills of the personnel, both the active and passive time needed for all operations and other aspects of manufacture are in the end determined by technological feasibility. Prosthetic sockets should be strong and durable enough to tolerate a tensile stress of at least 20 MPa and a flexural stress of at least 15 MPa.

Wide-scale application of homogeneous materials (wood, natural leather, plastics, light metal alloys) clearly indicate that these materials and structures made of them as well as the processing methods employed cannot meet the complexity of up-to-date requirements. Considerable progress was made with composite systems which included materials with a wide range of properties ensuring the desired quality characteristics of prosthetic sockets. Composite systems for prosthetic sockets, developed at present, consist mainly of polymers, thereby causing certain drawbacks in their fabrication and application, e.g., continuous manufacturing time and loss of material strength as a result of aging and other factors.

Socket fabrication

The authors' approach to developing composite systems is based on the use of a metal former in the basic socket design which is then shaped individually by means of technological operations and finally coated with polymers.

An aluminium alloy, having plastic deformations within the range of 25% is used as a metal former. Polymeric composition is utilized as a non-metal coating.

The technology of fabricating polymerized metal receptacle sockets is based on pulse stamping of metal blanks over the matrix imitating the negative mould of the stump and subsequent polymeric coating by means of vibro-vortex spraying. The main stages of the technological process of fabricating a socket for a below-knee prosthesis will be described.

Initially a negative mould of the stump is made by means of plaster bandages. Woven socks pulled over the stump provide for the required thickness of a metal blank and polymeric coating. The negative mould obtained in this way is placed in a steel box and the space between the mould and the box is filled with a rapidly solidifying substance, for example, a solution of plaster or a mixture of melted

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paraffin and stearine. The negative mould can be also obtained directly in a plaster solution.

A cylindrical or cone-shaped blank is placed into the inner cavity of the matrix which is then filled with water. The stamping of a blank over the matrix is carried out in the specially designed Pulse Stamping Device — PSD–03.

The operating principle of the device is based on the explosion of a gas charge made up of a stoichiometric mixture of propane or butane with oxygen which fills the power unit of the device, the initial pressure of gases ranging from 0.1 to 0.6MPa. The power unit is a pipe structure, one end of which is shut and has a spark-plug, the other end is open and is sealed with a single use hermetic plug. In the case of the explosion of a gas charge in water, the major portion of energy is concentrated, not in a blast wave, but in a hydraulic flow (up to 80%) which lasts longer than the blast wave, providing slow deformation of the parts being stamped (up to 40 m/sec.). Under these conditions the parts are formed not only due to expansion of the material of the blank but also due to drawing off the excess into the areas of plastic deformation. In this way breakage of blanks and dangerous thinning of the material can be avoided.

The number of stamping cycles is determined depending on the length of the stamped part because the effective pulse loading area ensuring reliable stamping is 10–15mm. Overall stamping time for one socket in a four-cycle operation does not exceed six minutes.

After stamping the part is removed from the matrix, cut off along the upper edge and tried on the patient. At that time the shape of the socket can be corrected easily, if necessary, due to the plastic properties of aluminium alloys, and the required thickness of the polymeric coating is also determined.

In further stages of the technological process the socket is connected with other parts and the polymeric coating is applied on the receptacle module.

For the coating foaming polyethylene has been chosen which is applied on the metal surface by means of vibro-vortex spraying according to Erikson. Adhesion strength is 13–15mm when the metal-polymer system is pressed until ply separation of the plymeric coating occurs with a cross cut. Thickness of the coating can be preset within the range from 0.8 to 6.5mm, thus making it possible to control the accuracy of fitting the socket to the stump. The coating can be removed from metal by means of burning, for example, and then reapplied. That is why when the stump no longer matches the socket volume as, for example, occurs due to atrophy of the soft tissues, it is possible to continue use of the prosthesis after the reapplication of a coating of the required thickness. This technique has proved to be especially effective in early prosthetic fitting.

The forming frames for above-knee sockets were fabricated in 20 standard sizes of aluminium blanks which were corrected with respect to the peculiarities of individual stumps. The high strength of the metal and the sound technological processing permits the manufacture of window sockets and the shaping of convexities capable of weight-bearing over the subtrochanteric area of the femur.

The technology for individual fabrication of the metal frame for an above-knee prosthetic socket by means of the pulse stamping technique is currently being developed. The polymeric coating and the method of its application is the same as for below-knee sockets.

Results

Since 1978 more than 500 patients who were supplied with above and below-knee prostheses with metal-polymer sockets have been monitored. Due to the high accuracy of socket fitting and good hygienic properties of the material the patients concerned did not suffer from those stump disorders which are typical of poor fitting.

Both the weight of the metal-polymer receptacle module (250g for below-knee prostheses, 400g for above-knee prostheses) and their durability are highly appreciated by the patients. In addition, the technological feasibility of the process lends itself to an industrial application for manufacturing the prosthetic sockets.