Manufacture Method of Forearm Prosthesis
Combined Sockets for Complex Prosthetics

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Abstract

Background: The shape and dimensions of the stump do not coincide, according to anatomical and physiological considerations, with the shape of the inner surface of the socket. They change during the operation of the prosthesis due to temperature, blood pressure, intensity of the load, concomitant diseases.

Objective: Forearm stump of mans with age 40-55 years. Reason for amputation is trauma.

Method: Develop designs of combined sockets depending on the defect of the stump and its level with embedded covers or elements dampening peak loads and measuring piston movements with different sockets.

Results: Stump reciprocating movement in the prosthetic socket was reduced.

Conclusion: Embedded covers and elements dampening peak loads allow to realize better feedback. Patients get one more factor to use their prosthetic in daily life.

Keywords: Upper limb; Sockets; Manufacturing method; Results of practical prosthetic

Introduction

When using a prosthesis, the covering tissues of the stump experience stresses [1-3], which are the main cause of inconvenience, pain and injury, reducing the positive effect of rehabilitation [4-7]. The anatomical and functional features of the forearm stump are characterized by a significant number of bone protrusions, covered only by skin and small volume of soft tissues, so there are few areas that can withstand the stresses arising from the prosthesis use [8-11]. These features greatly complicate the optimal distribution of pressure in the socket of the prosthesis and increase the risk of traumatization of the skin. This is connected with a high percentage of development of vices and diseases of the forearm stump [12-16].

The situation is significantly complicated by the already existing vices and stump diseases. It is known that besides the congenital pathologies and errors of the technique of amputation and prosthetics, in a number of cases the development of vices and diseases of the forearm stems is a consequence of the truncated limb adaptation to the new conditions of functioning [17-20]. In the course of this process, a number of morpho functional changes occur that are associated with compensatory-adaptive reactions of the stump tissues to unrelated loads, in particular, hypertrophy of the skin of the stump having a reduced resistance to mechanical stress and a pronounced atrophy of the subcutaneous fat. There are also significant changes in blood circulation in the stump, which, on the one hand, is associated with morphological changes in the walls of the vessels that lead to their obliteration, and on the other hand, with a significant decrease in muscle mass [21-26]. This leads to chronic hypoxia of stump tissues and a decrease in their tolerance to stress. And in the future, in the course of a prolonged load on the truncated limb, the compensatory mechanisms fail and the pathological changes in the tissues of the stump develop, manifested as vices and diseases [27].

This situation leads to the need for the use of additive damping elements, especially for active prostheses of the upper limbs. Over the long history of prosthetics, many attempts have been made to use various softening materials—the lining of the inner surface of the sleeve with soft skin, the embedded elements of felt, rubber, leather, sponge, etc., but they did not provide sufficient cushioning and protection of the tissue [28-31]. Their main disadvantage was the absence of a reliable fixation of the prosthesis and, consequently, the impossibility of eliminating the piston-like movements of the stump in the socket.

At present, the most common method of forearm prosthetics is the use of prostheses with full-contact sockets. Numerous
domestic and foreign studies on the properties of these types of prostheses have shown their beneficial effect on the clinical and functional state of the truncated limb [32-36].

It was found that a more even distribution of the load along the surface of the stump promotes the normalization of the function of the muscles of the truncated limb, and the activation of blood circulation in the truncated segment. In addition, the presence of a partial support on the butt end of the stump improves the musculo-articular sensitivity of the stump, facilitates the appearance of feedback or a “sense of contact with the object” when used, especially prostheses with a traction control system and working prostheses.

However, when using prostheses with full-contact sockets made from sheet thermoplastics or layered plastics based on orthocrylic resins, the skin of the stump is often traumatized by the rigid wall of the receiving sleeve. This problem is most relevant for the stump of the forearm.

Materials and Methods

10 young and middle-aged patients (from 18 to 45 years old) who underwent amputation due to injuries and who did not suffer from any diseases of the musculoskeletal system were involved in the survey. Patients had no limitation of mobility in the preserved joints of the truncated limb, previously prosthetics, and trained in the use of prostheses.

Three sockets types were made from 3mm high-pressure polyethylene sheet for three versions: a standard design (type 1), a full contact (type 2), and a composite sleeve with a 3-5mm thick foamed thermoplastic sleeve (type 3). To work on the proposed technology, a sheet of high-pressure 3mm thick polyethylene, foamed thermoplastics 3-5mm thick, modules of prosthetic forearms of the manufacturers of JSC RSC Energia, Ottobock.

Table 1: List and description of functional tests for determining the level of piston movements and comfort of the stump of the upper limb.

<table>
<thead>
<tr>
<th>No</th>
<th>Functional Test Name</th>
<th>Functional Test Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Registration at rest</td>
<td>Determination of the stump piston movements magnitude during rest</td>
</tr>
<tr>
<td>2</td>
<td>Maximum flexion</td>
<td>Determination of the stump piston movements magnitude during maximum stump flexion with prosthesis</td>
</tr>
<tr>
<td>3</td>
<td>Cargo manipulation</td>
<td>Determination of the stump piston movements magnitude during hold and lift 3kg</td>
</tr>
</tbody>
</table>

Prostheses were preliminarily given out on a test sock for 1-2 days, after which a preliminary assessment of the functionality of the prosthesis and clinical examination of the stump was carried out to exclude the influence on the research process of defects and prosthetic errors.

The survey protocol included a number of functional tests (Table 1), to determine the level of piston movements of the forearm stump with different designs of the receiving sleeves during manipulation. To measure the pistoning used a ruler: Projection of socket border during the phase lined on a stump. After the movement the distance between socket border and the rest line was measured.

In future work it is possible to use electronic system based on RFID or potentiometer to get more accurate results.

One of the approaches to reducing unwanted loads on the stump is to improve the construction and methods of socket manufacturing, and the technology of its attachment to the stump. This approach can be called conditionally direct, since it is about improving the methods of direct contact of prostheses with the human body. The main problem is that the shape of the surface of the stump cannot coincide for anatomical and physiological reasons with the shape of the inner surface of the socket. Moreover, the shape and dimensions of the stump can change during the operation of the prosthesis due to the influence of many factors (temperature, blood pressure, intensity of the load, concomitant diseases, such as diabetes, etc.).

There are two ways to solve the problem. Firstly, a digital spatial scanning of the stump shape followed by the transformation of the coordinates. Secondly—the development of receptacle designs depending on the level of defect and stump defect and the development of protective covers or embedded elements made of foamed or gel-like materials that damp the painful peak loads, thereby increasing the convenience of prosthesis using.

Studies to improve the interaction between the socket and the stump have led to the development of fundamentally new designs of combined full-contact, non-falling sockets for the forearm prosthetic using softening inserts and elements of their foamed thermoplastic materials and silicone compositions.

Experimental

The form of the stump is complex—the presence of retracted scars, clavate form or vice versa—a pronounced conical shape, so it is difficult to achieve complete contact between the skin integuments and the liner.

This problem for upper limb prostheses is not solved. For this category of disabled people, proposed a prosthetic technique with the use of a special design of a combined full contact non-dissolving socket with an inner socket. Get it by foamed polyethylene or pedilene, compensating for the bulb-shaped thickening due to the thickness of the liner walls or the manufacture of special longitudinal holes on the liner surface whose dimensions corresponded to the thickening. As practice showed, the upper opening was distal to the lower one.

The method of manufacturing this socket on a club-shaped stump is as follows: from a sheet of foamed thermoplastic material (foam polyethylene, pedilene, etc.) 4mm thick, according to the dimensions of the positive, cut out the workpiece. Then placed the billet in an oven and kept at a temperature of 70-80 °C for 2-3 minutes. The heated material became elastic and easily subjected to blocking by positive. Then removed excess material along the seam line and welded the seam together with a soldering...
iron. The inner socket (cover) obtained from this was not removed from the positive, but the socket was immediately blown from a sheet of polyethylene 3mm thick heated to a temperature of 150-160 °C. At the same time, welded the inner socket to the outer socket. After cooling the complex socket tried on the patient.

The combined complex full contact noncontiguous socket made in this way was used without additional fastening in functional cosmetic, with a traction control system and working prostheses. The received internal cover provided softening of impact loads and redistribution of pressure in a socket (Figures 1-4).

Second method of manufacturing a socket on a club-shaped stump

It includes using an additional special liner from a foamed thermoplastic compensating the clavate thickening due to its thickness. Cut the workpiece into a semicircular shape with a radius of 30-50mm with thin edges 4-5mm in thickness. Superimposed the preform heated to 70 °C on the positive with an inner cover in the area of the wrist joint for alignment of the clavate thickening. Then blocked the external socket of sheet polyethylene. According to this technique, the inner socket captured only the lower third of the forearm. In this design, the combined socket did not require the manufacture of special holes in prostheses with a traction control system. This design can be used in prosthetics with a bioelectric control system, because in the locations of the sensors, the elastic material is absent and does not reduce the level of the signal from the muscular source.

Used a similar technology in the manufacture of a socket for the long stump of the forearm

To ensure full contact between the stump and the socket during the production of the negative on the short, conical and cicatricial stump, the especially carefully performed modeling in the region of the apices of the epicondyle and ulnar process of the ulna. On the posterior and lateral surfaces of the positive 5-7mm, enlarged the sites corresponding to the protuberances in the region of the ulnar process of the ulna and the condyles of the shoulder. Made them elongated in the longitudinal direction, taking into account a certain movement of the ulnar process and a change in the position of the condyles of the shoulder relative to soft tissues during movements in the elbow joint.
Then, hugging the shoulder from behind and above the condyles, the first and third fingers simulated a semi-circular pelot, and in the distal section of the negative-the palmar and back pelots, corresponding to the elbow and radius bones, flattened the negative along the entire length of the forearm in the sagittal plane. Check the shape of the rear pelot, its width should be about 15mm (Figures 5-6). Depending on the area and location of the stump scars, made sockets with embedded foamed polyethylene or of silicone composition elements (Figures 7-8). Most often with short forearm cults, observed an excess of soft tissues. When making a gypsum negative with an excess of soft fabrics, put a nylon cover on the stump, pulled through a hole made in the frozen negative, in order to distribute them more evenly.

Figure 5: Excessively short (vicious) stump of the forearm.
Figure 6: Cosmetic prosthesis on the vicious stump of the forearm.
Figure 7: Vicious forearm stump.
Figure 8: Working prosthesis on the vicious stump of the forearm.

Result

The results of measuring the piston movements are shown in Table 2.

<table>
<thead>
<tr>
<th>No</th>
<th>Functional Test Name</th>
<th>Socket type</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Registration at rest</td>
<td>12±1</td>
</tr>
<tr>
<td>2</td>
<td>Maximum flexion</td>
<td>14±1,6</td>
</tr>
<tr>
<td>3</td>
<td>Cargo manipulation</td>
<td>19±2</td>
</tr>
</tbody>
</table>

Discussion

The data obtained indicate a significant decrease in the appearance of the resulting piston motions. At a small number of patients, at the same time, observed minor deviations from the mean value. Since the study involved patients with complex stumps, it is possible to conclude that it is necessary to show such patients prostheses with receptacles according to option 3. That correlates with [37-39].

On the basis of the obtained results, it can be stated that combined full-contact, non-coincident sockets have a number of advantages over traditional (rigid) casings. They allowed to realize the following possibilities:

1. good fixation of prostheses with minimal piston-like movements, which contributes to a feeling of feedback when using workers and active prostheses with a traction control system;
2. prosthetics of disabled people with varying stump parameters;
3. providing an elastic inner surface of the covers and supporting elements, which completely repeat the contours of the stump and assume external shock loads;

4. increasing the level of cosmetic prosthetics and improving the appearance, due to the elimination of additional fastening elements [40].

Conclusion
The use of combined sockets allows you to level out minor errors in prosthetics, which reduces the consumption of materials and labor costs in the manufacture of receptacles and fitting prostheses. And this, in the final analysis, reduces the total cost of prosthetics. This is an advantage for developing countries. Practical experience in the prosthetics of the disabled with upper limb defects indicates a significant increase in the functionality of the prostheses when using individual combined sockets for the prostheses of the forearm, taking into account the anatomical and morphological features of the truncated limb.

Standard Protocol on Approvals, Registrations, Patient Consents
All patients wrote the individual protocol.

Conflict of Interest
There is no conflict of interests.

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