Manufacturing technology of individual stump socket for prevention of re-amputation at prosthetics of lower extremities

***Abstract* — The technology of manufacturing of individual stump socket for the patient with lower limb amputation is proposed. The technology includes using of a vacuum system, strain gauges, feedback sensors, an automated design system and 3D printing. The proposed system prevents the re-amputation of the lower extremity of the patient. It also eliminates the use of plaster casts and shortens the production time of the finished stump socket to two days.**

***Keywords* — re-amputation of the lower extremity, prosthesis, limb prosthesis, CAD / CAM technology, stump socket.**

I. INTRODUCTION

Each year, 280 to 300 lower limb amputation operations are performed per million inhabitants. In Europe, this figure is 250 operations per million inhabitants. In Ukraine, the number of amputees is about 450 per one million inhabitants. The total number of lower limb amputations in Ukraine in 2018 was about 16,000 [1].

Worldwide statistics on the causes of amputations take into account 5 fundamental differences and different pathological conditions: occlusive arterial disease, traumas, infections, tumors, congenital malformations.

Due to the multidisciplinary approach to diabetes treatment, the number of amputations in people with the disease has been able to significantly reduce or limit interventions at the foot level. In developing countries, on the contrary, the number of patients with vascular disease is increasing and the incidence of infectious complications requiring amputation is decreasing.

The situation with age distribution of statistics looks quite different (Table I) [2].

TABLE I. PATIENTS' AGE AND CAUSES OF AMPUTATIONS

Age, years	**Violation arterial patency**	**Traumas**	**Tumors**
0-20	<1%	90%	5-10%
20-60	30%	60%	5-10%
>60	80-90%	10%	5%

Little known is the fact that there are significant differences depending on the level of amputation (Table II)[4]. Typical levels of amputation for arterial obstruction in 80-90% of patients are hip, tibia, including exerticulation in the knee. In the case of amputations at the level of the hip joint, on the one hand, and the foot, on the other, are completely different indicators.

TABLE II. AMPUTATION LEVEL DEPENDING ON THE CAUSE

Amputation level	**The cause of the amputation**		
	Violation of patency of the arteries	***Traumas***	***Tumors***
Exarticulation in the hip joint	25%	25%	50%
Hip / shin	80-90%	5-10%	5%
Foot	50%	50%	5%
The upper limb	1%	90%	5-10%

A special group consists of so-called multiple amputations. With any type of arterial obstruction there is a threat to both extremities. In fact, all patients with vascular disease sooner or later have to have a second limb amputation.

Accidents are often the cause of amputations. Both upper and lower extremities are damaged by motor vehicle accidents due to frostbite, electric burns and fighting. It is also worth mentioning the various birth defects, although they are quite rare [3].

Currently, there are two opposing points of view when it comes to the development of the stump socket. The conventional style of execution loads specific areas of the stump socket, which are considered especially resistant to pressure. Over time, the specific pressure that the stump undergoes can lead to problems with limited blood flow and atrophy of the soft tissues. The second idea, known as hydrostatic, is to distribute the load evenly over the entire surface of the stump, as if suspended in a liquid [4]. This method is especially difficult to put into practice because the anatomical structures of the stump have different densities, so they have different tolerance to pressure and generally do not meet the definition of the hydrostatic system.

The receiving sleeve, which is made without considering the distribution of loads on the stump, can adversely affect the tissues of the stump and create the conditions for re-amputation. Therefore, it is important to combine the above two approaches to the fabrication of the stump socket, which will ensure a comfortable location of the stump and minimize the possibility of problems with limited blood flow and atrophy of soft tissues.

II. MATERIALS AND METHODS

In Ukraine, special attention should be paid to limb amputations resulting from a military conflict. On the basis of Military medical therapeutic and diagnostic clinical center the analyzed 129 victims, whom underwent amputation of lower limbs.

The mean age of the patients studied at the time of injury was 33.04 ± 1.15 years, the youngest was 18.9 years, the oldest was 60.3 years. The analysis of lower limb amputations depending on the level of limb segment loss is given in Table III.

TABLE III. CHARACTERIZATION OF THE LEVEL OF LOWER LIMB AMPUTATION (N = 129)

Name of surgery	**Number of operations**	**% of lower limb amputations**	**% of all amputations (n=191)**
Exarticulation at the level of the hip joint	5	3,9%	3,1%
Amputation at the level of the upper third of the thigh	4	3,1%	2,5%
Amputation at the level of the middle third of the thigh	34	26,4%	21,4%
Amputation at the level of the lower third of the thigh	12	9,3%	7,5%
Amputation at the level of the upper third of the shin	16	12,4%	10,1%
Amputation at the level of the middle third of the shin	17	13,2%	10,7%
Amputation at the level of the lower third of the shin	20	15,5%	12,6%
Amputation of the foot at the level of the ankle joint	4	3,1%	2,5%
Amputation of the foot by Shopar	5	3,9%	3,1%
Foot amputation for Lisfranc	4	3,1%	2,5%
Atypical amputation of the anterior foot	2	1,6%	1,3%
Exaltation of the phalanges of the toes	6	4,7%	3,8%
TOTAL	129	100,0%	81,1%

The level of amputation of the lower extremity depends on the distribution of loads on the stump socket and the scheme of its manufacture. Two-thirds (87, or 67.4%) of lower limb amputations account for the level of the middle third of the thigh and shin. In general, amputation of the limb segment (105, 81.4%) was predominant among the lower extremity operations, whereas joint limb exarticulation was performed (24, 18.6%). The proximal segment of the lower extremity (hip and femur) accounted for 55 (42.6%) operations, the tibia - 53 (41.1%) amputations, and the distal segment (foot and fingers) - 21 (16.3%) operations.

When schematizing research material, the following assumptions are required:

- The stump is schematized by two homogeneous isotropic layers of bone and muscle.
- The elasticity of the materials is assumed to be ideal, ie the solids can change their shape and volume under the influence of external forces, but then, after removal of the load, completely restore the original state.
- There are no initial voltages in the model.

When constructing a geometric model, it is necessary to simplify the real shape of the object under study. It should be noted that when constructing the model, we neglect some of the properties of the real object, and leave the most significant. Thus, in the automatic design program, it is most important to pay attention to the places of the stump that can withstand the load and protrusions of bones that cannot withstand the load (Fig. 1, 2) [5].

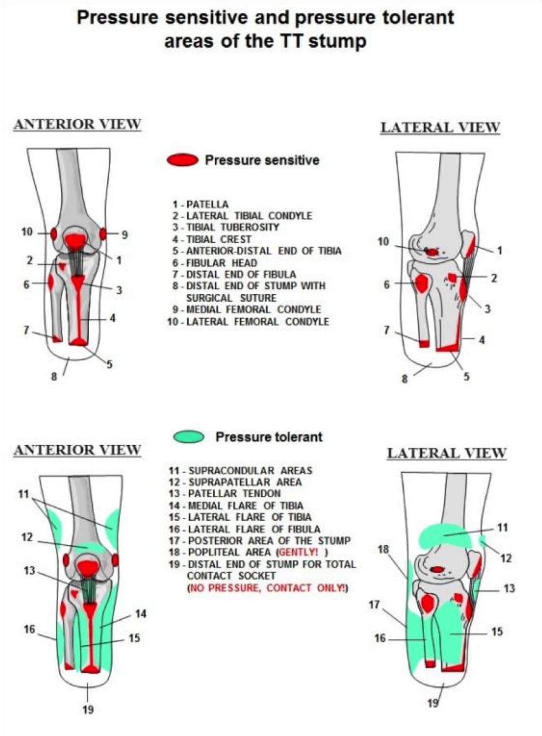

Fig. 1. Pressure sensitive and pressure tolerant areas of the TT stump

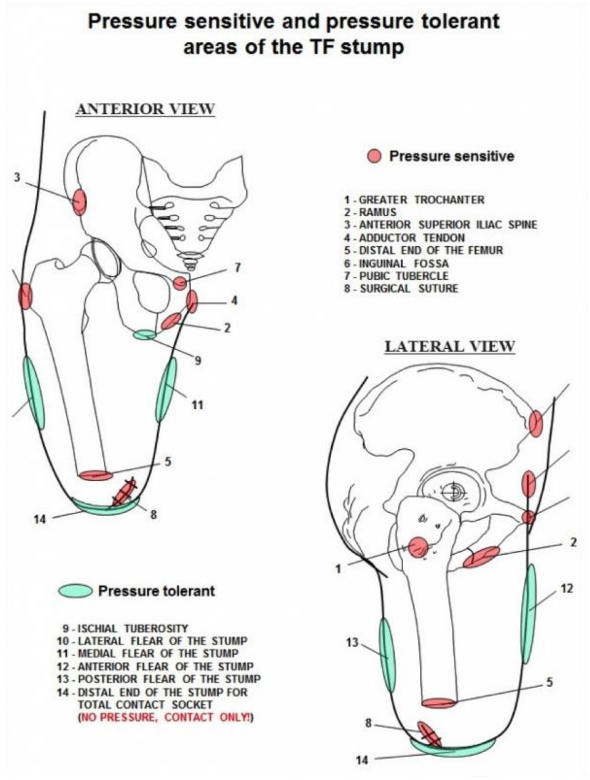

Fig. 2. Pressure sensitive and pressure tolerant areas of the TF stump

III. MANUFACTURING TECHNOLOGY OF INDIVIDUAL STUMP SOCKET

According to the operation of the coulter, the tolerance for the standard deviation of the model is about 0.3 - 0.5 mm: the maximum value can be balanced by the deformability of the sleeve made of polymer material, the minimum value can be offset by the use of a cotton sock worn on the stump. Pre-designed scheme for manufacturing and testing of individual stump socket (Fig. 3.).

The forces transferred from the stump to the prosthesis (and, accordingly, to the support) and vice versa, from the support to the stump, are divided into:

- Load forces (patient vertical load);
- Traction forces (in the transfer phase);
- Bending moments (medio-laterally, antero-posteriorly);
- Torque moments (mainly in hinges);
- Torsion moments (around vertical axes).

These forces arise with physical regularity, they are inevitable and cannot be "eliminated" even with the best prosthesis.

To reduce the impact of these forces, it is necessary to optimally create the shape and contours of the stump socket.

Stump socket must satisfy the following basic requirements:

- Place the volume of the stump;
- Transfer forces (in statics and dynamics);
- Transmit movement;
- Attach the prosthesis to the stump.

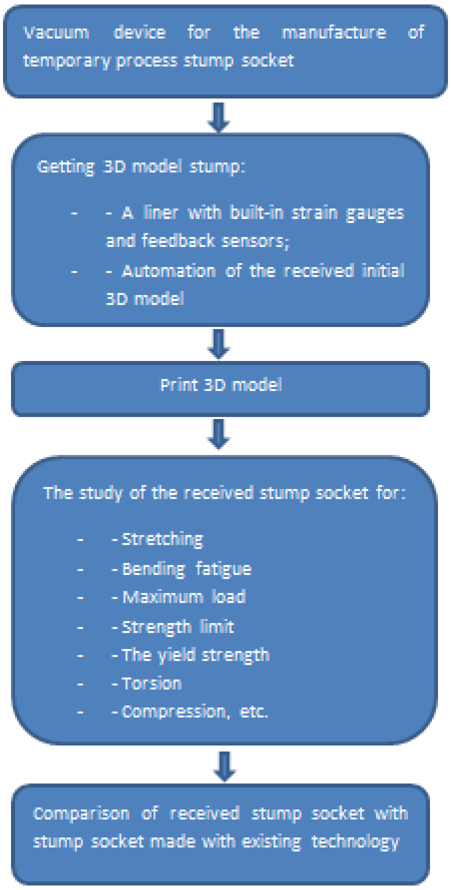

Fig. 3. Scheme of manufacturing and testing of the individual stump socket

Comparison of the characteristics of the received stump socket with the existing one is planned to be carried out on the basis of the Kiev state experimental prosthetic orthopedic enterprise with the written consent of patients and in the presence of a rehabilitation physician.

It is planned to automate the original 3D model obtained using the Autodesk Inventor software. It is suggested that the material for 3D printing of the model is a carbon fiber with photopolymer.

IV. CONSTRUCTION OF THE GEOMETRIC MODEL OF THE STUMP SOCKET

The comfort and functionality of the lower leg prosthesis is determined mainly by the loading and unloading areas. This applies to both the stump socket and the biomechanical proofreading of the prosthesis construction scheme.

All forces between the amputee and the prosthesis, whatever the origin, whether static or dynamic, are transmitted through the contact surface of the stump socket - stump.

Theoretically, the load can be minimized by enlarging the surface of the receiving sleeve. It works in prosthetics within acceptable limits; however, it is not true that a uniform physiological load distribution is created at the uniform load distribution at the contact surface. The distribution of the load in the sleeve should not occur by physical, but by physiological criteria. It is necessary to take into account the places that are capable and unable to withstand the load .

In statics, equilibrium must be established, that is, the forces transferred from the prosthesis to the support must become identical to the forces transferred from the support to the prosthesis. However, because these forces are counterintuitive, they compensate for each other.

For a patient with an amputated lower extremity, this means that in the upright position, standing 50% of the body weight, it transfers to the prosthesis (and the remaining 50% through a healthy limb is transferred to the support), and the resultant of all emerging forces and moments is in the plane of support.

Prosthesis on bent knee bending is indicative in the presence of a bending contracture. The bending angle depends on the bending contracture angle. It is recommended to design the receiving sleeve so that the angle of construction is close to the line of the contracture.

The shape of the contact receiving plane must, completely repeating the shape of the stump, completely wrap the stump so that soft fabrics are exposed when loading or unloading the piston effect. This supports the transport of venous blood from the stump, preventing skin blueness.

The full-contact TSB (Total Surface Bearing) receiving sleeve (Fig. 4) has advantages over the PTB, KBM, PTS stump socket designs, which are expressed in the load distribution over the entire surface of the stump with a decrease in pressure concentration into individual sections. Full contact with the truncated limb improves blood circulation and conjunctivity in the stump – prosthesis system.

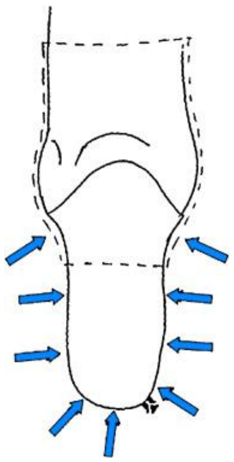

Fig. 4. Scheme of full-contact TSB stump socket

CONCLUSION

The technology of manufacturing of individual stump socket for the patient with lower limb amputation is proposed. The technology includes using of a vacuum system, strain gauges, feedback sensors, an automated design system and 3D printing.

The proposed technology of manufacturing a prosthesis stump socket involves the study of loads on the surface of the patient's stump, which will ensure a comfortable location of the stump and minimize the possibility of problems with limited blood flow and atrophy of soft tissues.

Advantages of the proposed technology:

- prevents the re-amputation of the lower extremity of the patient;
- may exclude the using of plaster casts;
- shortens the production time of the finished stump socket to two days;
- cosmetic role: the outer surface of the stump socket is smoothed, you can choose the color to print the stump socket.

The receiving sleeve will be made statically error-free and will not cause any knocking, bending, and torque that would not be compensated by the resulting interaction forces, called support reactions. From this it follows that the patient should not tilt either frontally, laterally or dorsally, and the corresponding hinges (knee and hip), should not be subjected to bending moments of a large order, which would be different from those affecting the joints of a healthy limb.

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