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Medical aspects of prosthetics in lower limb amputees with use of digital technologies

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Abstract

Introduction Digital technologies used for lower limb amputation patients wearing prostheses are mostly experimental due to the complexity involved in model development of the stump socket. **The objective** was to develop a technique for additive manufacturing of lower limb prosthetic sockets to minimize negative results using a three-dimensional model of a prosthetic socket and considering anatomy and functionality of the stump. **Methods** The review included 20 lower limb amputees who were assigned to 3 groups depending on the method of stump scanning. **Results** The results of prosthetics were evaluated with the stump scanned naked (n = 9), covered with a silicone cloth (n=6) and with the use of embedded components (n = 5). The results of clinical and instrumental examination showed the advantage of the scanning method offered. The symmetry index for the time of foot roll-over was 0.55 ± 0.14 in the first group, 0.63 ± 0.07 in the second group, and 0.85 ± 0.04 in the third group. **Discussion** The best results of prosthetics in third group were associated with the most favorable load distribution in the receiving cavity of the prosthetic socket due to embedded components. In these cases, processing the digital model was simplified with no need to unload bone prominences. With scanning of a naked stump, processing a digital model was complicated and required professional skills. This solution had the potential to prevent any sort of direct physical contact to avoid inadequate modeling of the computer model of the prosthetic socket. The use of a silicone liner allowed reducing the pressure on the bone prominences. With a sharply skeletonized stump, the elastic properties of the liner were not enough and could cause injury to the tissues. Conclusions The findings suggested that improved quality of prosthetics was dependent on the technique used to scan the stump. The use of pre-installed embedded components allowed for effective load distribution in the prosthetic socket and created favorable conditions for prosthetic use.

Keywords: additive technologies, prosthetic socket, prosthesis, scanning, below knee amputation, digital model

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INTRODUCTION

Broad-scale development of digitalization of different aspects of human life is also reflected in medicine, namely, in prosthetics for people with amputated limbs. The advantage of the technology includes the automated work of a prosthetist reducing the role of the human factor in the manufacturing of prosthetic and orthopaedic products. The first attempts to formalize the process of manufacturing the stump sockets were made in the middle of the last century. An example of this was a sleeve of maximum readiness that could be offered for a particular patient from a standard range [1]. However, the technology had no wide applications due to the high variability of the anatomical features of the amputated limb and unavailability of tailored sockets for the transtibial stump. Additive technologies using 3D printing were helpful in the solution of the problem [2, 3]. Prosthetic socket is the most important component of a prosthesis. The final result of prosthetics depends on the quality of the manufacture.

With an adequately fabricated socket, the result of prosthetics will be positive, regardless of the functionality of the prosthetic modules. This principle also applies to additive technologies [4]. The process of manufacturing stump sockets using additive technologies includes the following steps: scanning of the stump, computer processing of an electron geometric model (EGM), printing of a receiving sleeve with a 3D printer [5–7]. Scanning of the stump and processing of a digital model of the amputated limb are most critical steps in the chain [8].

Despite the deceptive simplicity of the process, this type of prosthetics has not been introduced into mass production at prosthetic and orthopaedic enterprises and is mostly experimental. The descriptions are not included in the technical information published by the leading manufacturers of prosthetic and orthopaedic products, such as OTTO-BOKK, Blechtford, Ossyur. The technology is also unavailable in the national standards of the Russian Federation [9–11]. The complexity of computer correction of EGM using the available software [12] can be one of the reasons for the slow introduction of additive technologies into the prosthetic practice and leads to insufficient correspondence of its parameters to the anatomical and functional features of the amputated limb.

The aim of our work was to develop a methodology that would increase the percentage of positive results with the use of digital technologies in the prosthetic patients after transtibial amputation, and create conditions for the introduction into the large-scale prosthetic and orthotic supply system.

MATERIAL AND METHODS

The review was based on the results of prostheses used for 20 amputees who were supplied with therapeutic and training prostheses manufactured through additive manufacturing technologies. The study involved patients aged 18 to 74 years with no defects and diseases of the stumps that prevent prosthetics. There were 16 male and 4 female patients. The inclusion criterion was the presence of unilateral amputation at the level of the upper and middle third of the tibia. The exclusion criteria were cases with tibial stump that required surgical or conservative treatment for prosthesis. Written consent was obtained from all patients for experimental prosthesis and using instrumental and clinical examination.

The study was performed in accordance with the ethical standards of the Declaration of Helsinki of the World Medical Association "Ethical principles for conducting scientific medical research involving humans" as amended in 2000, "Rules of Clinical Practice in the Russian Federation", approved by Order of the Ministry of Health of the Russian Federation dated June 19, 2003 No. 266. The study received a favourable opinion from the relevant research ethics committee approved by the Ethics Committee at the Federal State Budgetary Institution Federal Research Center named after N.I. G.A. Albrecht, the Ministry of Labor of Russia. The tasks included development of medical and technical requirements for receiving sleeves of tibia prostheses, testing various methods for scanning a stump, improvement of the scanning methods and subsequent processing of an electronic model of the tibial stump, 3D print of the sleeves performing experimental prostheses.

We had formulated medical and technical requirements for stumps manufactured with additive technology including:

– the use of the principle of full-contact prosthesis with the distal portion of the stump being borne with the weight;

– the load in the receiving sleeve to be distributed mainly to areas that are most adapted to the weight including patellar tendon, the medial tibial condyle, the lateral surfaces of the stump towards the tibia and fibula, and the towards the buttend of the stump with a short tibial stump;

– bone protrusions including the fibular head, Gerdy tubercle, tibia crest and the bone saw should be free from the load;

– the inner surface of the sleeve should be smooth, without constrictions and folds providing a good contact for the stump tissues and the wall of the stump sockets matching volumetric dimensions of the stump.

The manufacturing process of the receiving sleeve included scanning of the stump, digital processing of an electronic model, modeling of the size and shape of an individual module, orientation of the adjustment and connection device (ACD) relative to the biomechanical axis of the lower limb, 3D print of the receiving sleeve. Scanning was produced with the Structure Sensor Pro scanner [13]. Scan processing and sleeve modeling were performed using Meshmixer [14], Rodin4D [15], Autodesk Fusion 360 [16] software. Idea Maker program was used for preparation for 3D print [17]. A Raige3DPro2Plus 3D printer with a PETG (polyethylene terephthalate glycol) filament was used for printing [18]. Considering that the stump scanning was the most important stage for prosthesis manufacturing various options were employed. Patients were divided into three groups depending on the scanning method used. Patients of the first group (n = 9) had a bare stump scanned, scanning for patients of the second group (n = 6) was produced with a silicone cover on. Scanning for patients of the third group (n = 5) was performed with the technology offered using individually manufactured embedded components. The preparation of the tibial stump for scanning was identical for the three groups. The patient was seated on a chair with the stump slightly bent at the knee joint. The flexion angle was dependent on the length of the stump and measured 25° with a short stump, 15° with a stump in the middle third and 10° with a long stump. The operator scanned the stump from all sides, so that the entire surface of the stump was enclosed by the scanner lens. Since the shape of the stump scan was significantly different from the sleeve shape, correction of the EGM model was produced with the above software. The most complex adjustment was produced for patients of the first group and included unloading of the stump areas that were not adapted to pressure and transferring them to areas capable of receiving it.

The method of digital processing of receiving sleeves was as follows. Successful modeling of the tibia socket required a high-quality 3D scan of the stump that reflected all the anatomical features of the stump and embraced the entire surface [19, 20]. The EGM modeling algorithm with the digital method was similar to the modeling of a gypsum positive using traditional methods. Tibial condyles, fibula head, the tibial crest and tuberosity, the bone saw, in particular, were moulded using the CADS (computer-aided design system) Rodin4D, especially in the area of (Fig. 1). The EGM model was corrected according to the parameters mentioned in Table 1.

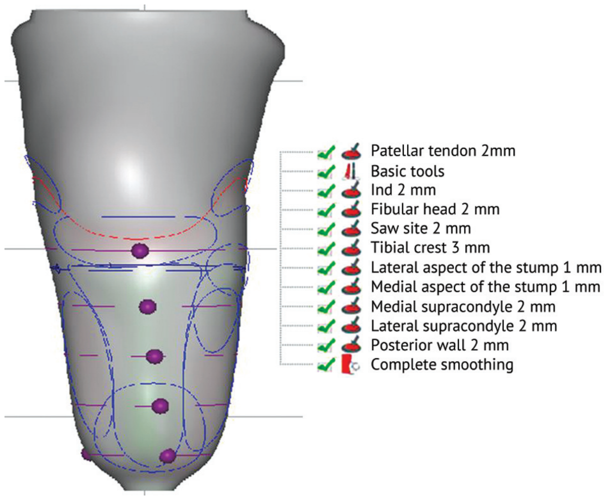

Fig. 1 Algorithm of operations and model with modification zones

Table 1

Simulation parameters of the electron-geometric model

Stump areas to be loaded	Patellar tendon, mm		-2.2
	Medial tibial condyle, mm		-2.0
	Lateral stump surfaces, mm:	lateral	-1.0
		medial	-1.0
Stump areas to be unloaded	Fibular head, mm		+2.6
	Tibial crest, mm		+3.1
	Saw site, mm		+3.5

An additional 3.5 cm on average was included in the EGM for lengthening the receiving sleeve to allow a contact-support element (CSE) to be placed under the stump (Fig. 2). This space was used later for the installation of CSE that could be manufactured individually from foamed polyethylene, silicone or being commercially available.

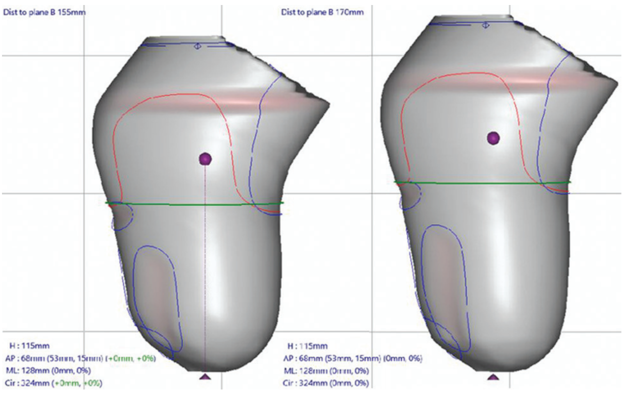

Fig. 2 EGM of the receiving sleeve of the tibia, view from the medial surface: (a) distance from the distal plane to the point measuring 155 mm; (b) distance from the distal plane to the point measuring 170 mm

Patients of the second group had the stump scanned with a silicone cover on, according to the method described above. The proximal edge of the sleeve was marked only when processing the EGM. The areas of the stump that required unloading were not modeled with the silicone layer of the sheath ensuring uniform distribution of the load over the entire surface of the stump, and thickened distal part of the sheath made provided the end support of the stump.

Our original technique of scanning the tibial stump was used for patients of the third group with pre-fabricated CSE and cushion pads to provide a socket corresponding to the anatomical and functional features of the truncated limb. The technology was based on the principles of full-contact prosthesis that were commonly used in the manufacture of tibial prostheses at the G.A. Albrecht Centre [21]. The technology included the production of an individual CFU and cushion pads made of foamed materials (foamed polyethylene, polyurethane). The purpose of a tailored CSE was to:

– provide partial support on the end of the stump for even distribution of the load on the proximal surface of the stump;

– reduce piston-like movements of the stump in the receiving cavity;

– prevent venous stasis in the distal part of the stump that could occur due to clamping of the saphenous veins with excessive load on the sleeve wall;

– increase the contact surface between the wall of the sleeve and the surface of the stump that provided feedback in the human-prosthesis system for confident control of the prosthesis.

The purpose of the cushion pads was to create a softened contact of the bone protrusions with the wall of the sleeve to prevent injury to the soft tissues. The manufacturing technology of CSE was as follows. A cone-shaped blank was cut out 5–6 cm using a sheet of foamed polyethylene or polyurethane 20 mm thick larger than the diameter of the stump. The blank was heated in a heating cabinet at a temperature of 120–130 °C for 10–15 minutes. At the next stage, the workpieces heated in a heating cabinet were placed on the end of the stump, and the assistant pulled on a nylon cover from above. The workpiece was tightly crimped according to the shape of the distal part of the stump by the hands of a technician who performed the modeling of the CFE until the workpiece was completely cooled. The CSE produced in this way was cut circularly along the upper edge within its irregularities and defects formed during the molding. Then, the side walls were cut with a knife and processed on a cone-polishing machine until they became thinner to smoothly transit to the distal part of the stump.

Cushioning pads cut out of a sheet of foam material 4–5 mm thick were used to unload bone protrusions (the fibular head, the tibial crest at the site of the bone saw). Gaskets were heated in a heating cabinet at a temperature of 120º and blocked along the stump. Before scanning, the FOE was placed under the end of the stump, the pads were mounted over the bone protrusions. A thin nylon or silicone cover was pulled on top, which the patient hold taut. It was necessary to ensure that the pads did not move from the bone protrusions, and the CFU was a continuation of the patient's stump (Fig. 3).

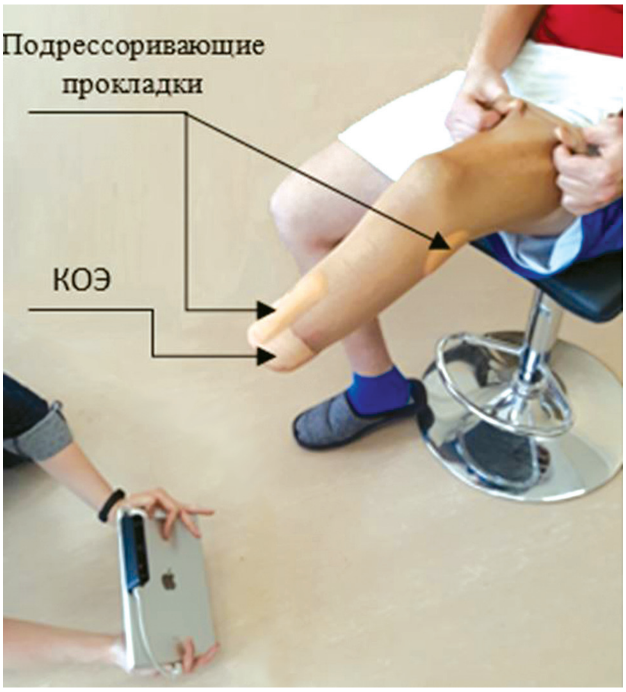

Fig. 3 Positioning of the stump before scanning

The use of prefabricated CSEs and cushion pads allowed for an EGM to look at the unloading zones with no need to model these zones. This greatly simplified the process of digital processing of the model and eliminated possible errors that could lead to a negative result. The formation of the proximal edge of the receiving sleeve was performed according to generally accepted principles [22–23] and was common for all groups during EGM processing [22–23].

Sleeves with a gripping patella of the PTS type (Prothese-Tibiale-Supracondylienne), with a cut-out patella of the PTB type (Patellar-Tendon-Bearing) or KBM (Kondylen-Bettung-Münster) are commonly used for manufacturing tibial prostheses. The shape of the proximal part of the receiving sleeve depends on the length of the stump. A sleeve with a PTS type kneecap grip can be used for a short tibial stump after amputation at the level of the proximal metaepiphysis providing reliable fixation of the limb in the socket.

Sleeves without capturing the patella of the PTB or KBM type can be used for a tibial stump in the middle third and below. Movements in the knee joint are not limited with these designs. A silicone knee pad is additionally used to fix the prosthesis to the leg. The results of prosthetics were evaluated using clinical and instrumental methods in accordance with GOST R 53871-2021 "Methods for assessing the rehabilitation effectiveness of lower limb prosthesis" [24]. Duration of prosthetic use, pain, appearance of abrasions, namin, and hemodynamic disturbances in the truncated limb were evaluated during physical examination. The instrumentation examination was performed using the DiaCled-M hardware-software complex [25] which was used to record the temporal characteristics of the step, the time of the rolling over the foot of the prosthetic and preserved limb. The obtained data were processed using the SPSS Statistics 28 program. The nonparametric Mann-Whitney U-test was used for small independent samples. Differences between samples were considered statistically significant at $p \leq 0.05$.

RESULTS

Clinical assessment of the results of prosthetics was performed using the following principle. Patients with poor outcomes experienced pain in the stump, discomfort when walking. Physical examination showed hyperemia of the skin at the sites of excessive load and venous stasis in the distal stump. They could walk for at least 15–20 min. Patients with fair outcomes had slight or no pain. No trophic disorders were noted in the tissues of the stump. They could use the prosthesis for 1–3 hours per day. Patients with a good result had no pain, discomfort at the gait and trophic disorders. Walking time was not limited. The results with experimental prostheses are presented in Table 2.

As can be seen from the presented data, the number of fair and poor results was approximately the same in the first group. Poor results in the first group of patients were caused by insufficient conformity of the socket to the anatomical shape of the stump that resulted in abrasions, creases, discomfort and limited time for using the prosthesis. The outcomes in the second group of patients were more positive and were associated with the use of a silicone cover providing less pressure in the problematic areas due to damping. The patients had greater comfort of prosthesis use preventing the occurrence of trophic changes on the limb. The best results were observed in the third group of patients whose stumps were scanned using the method we offered with a pre-installed CSE and cushions. In this case, minimal correction of the EGM was required that resulted in reduced percentage of inadequate manipulations in the socket modeling and allowed effective unloading of the stump areas that were not adapted to the load. Clinical findings were confirmed by the results of instrumentation examination that are presented in Table 3.

Patients whose stump was scanned with pre-installed CSE and spring elements showed a significantly better result as compared to the first group of naked stump scan (Mann-Whitney U-test 35, $p < 0.05$). There were also statistically significant differences between the third and second groups (Mann-Whitney U-test 13, $p < 0.05$). The highest symmetry factor (0.85 ± 0.04) was observed in patients of the third group that indicated absence of discomfort at the gait and a higher quality of prosthesis.

There is a clinical instance of an 18-year-old patient Z. diagnosed with a stump of the left tibia in the lower third. He had never used a prosthesis. A therapeutic and training leg prosthesis was manufactured using additive technology. The prosthesis with the PTB socket had full contact with CSE, without a silicone cover unloading bone protrusions having attachment with silicone knee pad. He learned to walk using the prosthesis (Fig. 4) and could ambulate without additional support on discharge.

The result of the instrumentation examination of patient Z. is shown in Figure 5.

Table 2

Results of prosthetics with experimental prostheses

Scanning technique	Poor (n)	Fair (n)	Good (n)
First group, naked stump scan	4	5	–
The second group, scanning with a silicone cover	–	3	3
Third group, scanning with pre-installed CSEs и cushions	–	–	5

Table 3

The results of the instrumentation estimation using the HSC "DiaSled-M" (data are presented as M ± Sd, where M is the mean value, Sd is the standard deviation, n is the number of patients)

Group	Roll phase, sec. (values are average for the group)		Symmetry factor
	prosthetic leg	intact leg	
First group, naked stump scan (n = 9)	0.5 ± 0.16	0.9 ± 0.12	0.55 ± 0.14
The second group, scanning with a silicone cover (n = 6)	0.7 ± 0.08	1.1 ± 0.13	0.63 ± 0.07
Third group, scanning with pre-installed CSEs и cushions (n = 5)	0.6 ± 0.08	0.7 ± 0.09	0.85 ± 0.04

a b

Fig. 4 Patient Z. using an experimental therapeutic and training prosthesis (a), an electron-geometric model of a receiving sleeve (b)

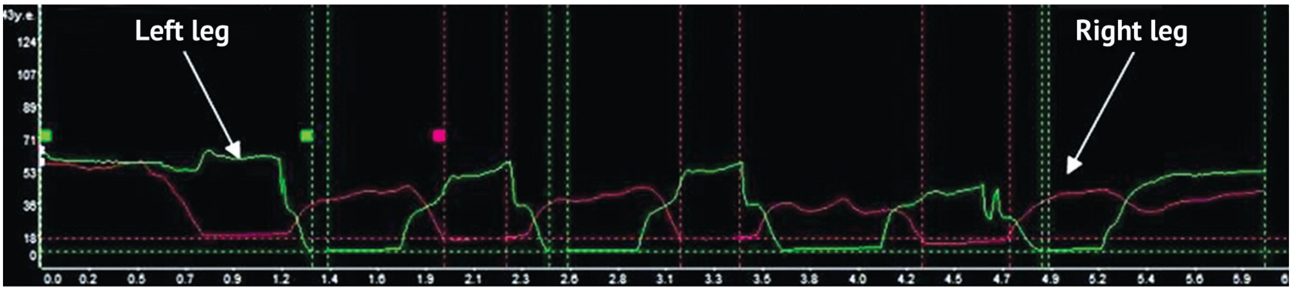

Fig. 5 Diagram of the integrated loads on the legs of patient Z. at the gait measured with the HSC "DiaSled-M"

The graphic structure are significantly similar for both legs that indicated a symmetrical gait and absence of pain in the truncated limb with use of the prosthesis. The rollover time from heel to toe was 0.6 sec. in the amputated limb and 0.7 sec. in the normal limb. The symmetry coefficient was 0.85.

DISCUSSION

The sleeve is the most important part of the prosthesis to ensure adaptation to the shape of the amputated extremity of individuals with lower-limb amputation. The main objective of the study was to develop an additive technology for manufacturing a stump receiver with the shape that would most fully correspond to the anatomical and functional features of the amputated limb. Manufacturing of the stump socket included three stages: scanning of the amputated limb, creation of an EGM, modeling of the initial model using software (CAD) and being consistent with the anatomical and functional features of the stump, printing a receiving sleeve with a 3D printer. Scanning and processing of the EGM of the receiving sleeve were most crucial in the process aimed at unloading of the stump areas that were not adapted to pressure and transferring them to load-tolerant areas. The process was similar to the processing of a positive plaster cast in the traditional fabrication approach for prostheses [26–28]. From our point of view, the main disadvantage of the technique was the lack of direct contact between the prosthetist and the patient. It was difficult to identify and adequately model the corresponding parts of the stump with EGM. Some authors [29] suggest combining EGM with a tomogram of an amputated limb to improve the quality of modeling. The technique can improve EGM processing but is difficult to be used with inaccessible tomography and the presence of radiation exposure. The most common stump scanning is performed with a silicone sheath on [30–32].

Elastic properties of the cover are helpful for reduced pressure on problematic areas. However, the damping properties of the silicone sheath can be limited with a sharply skeletal stump and lead to tissue injury with the wall of the receiving sleeve in the distal parts, in particular. The price of silicone covers is quite high that leads to a significant increase in the cost of the entire prosthesis.

The method offered for scanning transtibial stump with pre-installed embedded elements can be considered as one of the options for obtaining EGM. The technique allowed us to significantly simplify the process of EGM formation with no need for digital modeling of the distal part of the stump and areas of bone prominences. The availability of an individually manufactured CSE made of foam materials can simplify the process of regulating the load on the distal stump and prevent the occurrence of pathological conditions associated with irrational prosthesis.

CONCLUSION

1. The result of prosthesis after lower limb amputation using additive technologies largely depends on the method of scanning of the amputated limb.

2. The technique offered for scanning the transtibial stump with pre-installed embedded elements could simplify the subsequent computer processing of EGM and improve the quality of prosthesis by forming a receiving cavity of the prosthesis in accordance with the anatomical and functional features of the amputated limb.

3. The technology of additive manufacturing of stump receivers can be used for primary prosthesis after transtibial amputation in inpatient and outpatient settings.

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