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Clinical and statistical stump characteristics for identifying contraindications to prosthesis

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Abstract

Introduction Limb amputation impacts physical activity and quality of life. Complications of limb amputation and prosthesis are essential for individuals who are losing limbs from vascular diseases and in military casualties.

The **objective** was to identify contraindications to prosthesis based on clinical and statistical stump characteristics.

Material and methods Medical records of 253 lower limb amputees aged 18 to 85 years including 15 individuals with bilateral amputations and 238 with unilateral amputations caused by mine blast injuries, vascular diseases and infections, peacetime injuries, congenital anomalies, osteomyelitis, osteosarcoma. Assessment of the amputee was produced by multidisciplinary teams at the prosthetic orthopedic company, military hospitals, medical and preventive healthcare institutions in 2023. The patients' stumps were examined radiologically and with ultrasound. A total 228 prostheses were manufactured including 120 for tibia and 108 femur amputees. Stabilometric platform and a rehabilitation complex were used for suitable alignment of lower limb prostheses.

Results The stump defects that complicated prosthesis included osteophytes, the fibula cut located distally to the tibia cut, the bone cut protruding to under the skin or a scar, foreign bodies of soft tissues, stiff scars, high location of truncated muscles. Prosthesis was complicated in 59 cases (23.3 %), of which 33 patients (56 %) had absolute contraindications.

Discussion The findings indicated the importance of timely assessment and preparation of stumps for effective prosthesis. Modern technologies and rehabilitation methods help improve quality of life of amputees. Pain and psychological difficulties were the main problems associated with primary permanent prosthesis. The multidisciplinary approach appeared to be practical for successful prosthesis and rehabilitation of patients. Limb amputation caused by combat injuries and other reasons is associated with physical challenges affecting the patient's quality of life.

Conclusion A failure to maintain proper prosthetic socket fit is an absolute contraindication to prosthesis preventing the patient from prosthetic use after amputation. Inadequately cut tibia, club-shaped or excessively conical stump, a stump being too short or too long, osteomyelitis, impaired wound healing or ulcer, ligature fistulas are relative contraindications.

Keywords: amputation, stump, prosthesis, rehabilitation, multidisciplinary approach, digital technologies, clinical analysis, digital twins, soft tissue visualization, digital rehabilitation

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INTRODUCTION

Limb amputation impacts physical activity and quality of life. According to WHO, there are about 40 million people living with limb stumps due to amputation or congenital anomaly [1]. Complications of limb amputation and prosthesis are essential for individuals who are losing limbs from vascular diseases and in military casualties.

The most common causes leading to lower limb amputation are obliterating endarteritis, diabetes mellitus including diabetic foot syndrome, oncopathology, trauma including industrial injuries, those resulting from road accidents and natural disasters, and combat injuries [2]. Lower limb amputations can be caused by venous and arterial thrombosis of the lower limbs with the development of acute thromboembolism of major vessels, untimely treatment, inadequate patient monitoring, or a lack of understanding of the pathogenesis of the pathogen at the initial stage of the COVID-19 pandemic [3]. Chronic ischemia can induce bleeding disorder in the compromised limbs and lead to a multiple increase in proximal thromboses and high amputations [4].

Quite often, amputation of a limb segment can be performed significantly more proximal than the level of the affected area,which is caused by the surgeon's need to complete the treatment quickly and at once, neglecting the topographic and anatomical levels of injury and functional changes in the remaining tissues. High amputations can interfere in the prosthesis adaptation process, causing greater difficulty for young disabled individuals [5]. When a lower limb amputation is considered, preservation of the knee which plays an important role in the biomechanics of the musculoskeletal system and proprioceptive innervation [6] allows for optimal functional recovery [7].

The absence of a limb joint, coupled with painful sensations in the stump, leads to the fact that amputees can develop self-stigmatization, feelings of self pity, distorted body image, cognitive rejection of what happened and low motivation for prosthetic use [8]. On the other hand, maintaining stumps that are too short without disarticulation in the overlying joint can also lead to complications during prosthetics, increasing or declining recovery and adaptation periods, due to the need for more careful adjustment of the prosthetic socket [9]. However, high amputations are still performed today, and rehabilitation of the patients is to be arranged by selecting optimal prosthetic designs. Characteristics of the affected area with tissue deficiency and specificity of the transplanted skin are essential as supporting areas upon completion of free autoplasty in the postoperative period and, in some cases, can result in defects and diseases of the formed stumps. Higher amputation and reduced loading on the grafted skin can be practical in the scenario [10].

The **objective** was to identify contraindications to prosthesis based on clinical and statistical stump characteristics.

MATERIAL AND METHODS

The study was conducted in 2023 at the prosthetic and orthopedic enterprise JSC CITO, military hospitals and medical and preventive healthcare institutions. Medical records of 253 lower limb amputees aged 18 to 85 years including 15 (5.93 %) individuals with bilateral amputations and 238 (94.07 %) with unilateral amputations. In our series, 209 cases (78 %) were classified as functional stumps, 26 cases (10 %) as low-functional, and 33 cases (12 %) as non-functional.

Type of study: clinical observational.

Study design: retrospective analysis of medical data and observations.

Inclusion criteria: patients who have undergone lower limb amputation and are at the stage of rehabilitation and prosthesis, who have expressed consent to participate in the study.

Exclusion criteria: patients with upper limb amputations, patients with exacerbation of concomitant diseases that could interfere with prosthetics, or patients who fail to obtain a complete set of medical records.

The patients' readiness for prosthetics was assessed based on the presence or absence of defects and diseases of the stumps [11].

Measurement technique The stump condition was assessed by a multidisciplinary team including trauma and orthopedic surgeons, prosthetic technicians and rehabilitation specialists. Medical documentation data (discharge summaries, inpatient cards, medical histories, prosthesis manufacturing order forms, questionnaires) and the results of 135 instrumentation examinations submitted by patients were used. The stumps were examined radiologically and using ultrasound. However, not all patients could be included in the process of taking a plaster cast and producing a trial socket, which was due to factors that prevented the patient from adapting to the prosthesis. During the study, patients were supplied with 228 prostheses including 120 for the tibia and 108 for the femur. Patients were referred for prosthesis 2–13 months after amputation, depending on objective and subjective factors.

Ethical principles All patients were informed about the conditions of the study and gave written consent to participate. The study was conducted in accordance with the Declaration of Helsinki.

Data processing The data were analyzed to assess the prevalence of stump defects and diseases, their impact on the process of prosthesis and rehabilitation.

Defects and diseases affecting the prosthetic limb significantly reduce the functionality of the stump, complicate the prosthetic process and increase the time required for rehabilitation and preparation of the truncated area for prosthesis. Such cases are classified as complicated. The functionality of the stump is determined by its condition, readiness for prosthesis and ability to accept mechanical impact from the prosthesis. The functionality of stumps is divided into three categories: functional, low-functional, and non-functional, to assess whether the stump is ready for prosthesis and develop rehabilitation strategies [12].

The level of prosthesis acquirability was determined using the COBS stabilometric platform with biofeedback and Motek C-Mill virtual reality treadmill. The exercise therapy instructor assessed the distance covered by the patient in the prosthesis, the ability to maintain balance on the platform and cope with tests on an innovative sensor treadmill. Spatiotemporal parameters including the length and width of the step were measured taking into account the difference between the left and the right (in meters), as well as dynamic parameters - walking on marks, Butterfly, Aggregated force, weight distribution supported one leg, step frequency.

The treatment goal is to improve the symmetry between the left and right steps, improve characteristics of the reaction force to the support during walking on the platform. The downloaded information serves as an important indicator of the detection and correction of pathological gait. The information obtained is important for accurate monitoring of the progress of the prosthesis acquirability and the formation of the correct motor stereotype of walking.

RESULTS

Medical records indicated wound healing of the stump by primary intention in 194 patients with sutures removed on time (Table 1). Stump diseases caused by an accompanying infection were identified as a long-term granulating wound or ulcer, wound healing by secondary intention, a fistula, osteomyelitis. Defects of the stump that complicate prosthetics were identified as osteophytes, location of the fibula cut distal to the tibia cut, protrusion of the bone cut under the skin or scar, foreign bodies in soft tissues, stiff scars, high location of truncated muscles.

Table 1

Clinical data of patients obtained during the assessment of stump condition

Description	Number of cases	
	abs.	%
Wound healing by primary intention	194	76.6
Stump disorder (infection)	24	9.5
Defects of stumps	20	7.9
Painful neuromas	10	4.0
Unspecified pain in stump	4	1.6
Neuritis of the peroneal nerve	1	0.4
Total	253	100

Lower limb amputations were caused by mine-blast wounds, peacetime injuries, osteomyelitis, osteosarcoma (Fig. 1). In two cases, the limbs were unsuitable for prosthesis due to a congenitally underdeveloped limb being nonsupporting, and amputations were performed to form a stump. Diabetes and atherosclerosis diagnosed in 76 cases (30 %) led to gangrene followed by amputation. Progressive thromboangiitis, obliterating endarteritis, embolism and thrombosis of major arteries followed by critical limb ischemia were detected in 12 cases (4.7 %). These data confirm high significance of problems associated with military injuries and chronic vascular diseases in the context of limb amputation and rehabilitation potential.

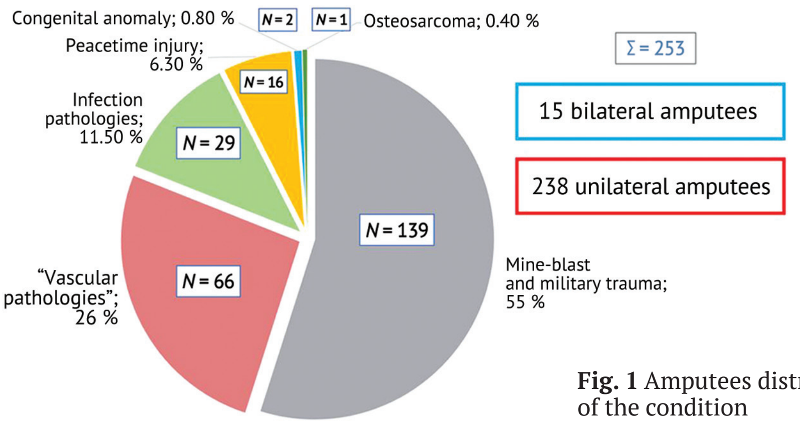

Fig. 1 Amputees distributed by a cause of the condition

Prosthetic fitting was complicated in 59 cases (23.3 %) including 33 patients (56 %) having absolute contraindications, such as stump defects or infectious complications requiring additional treatment prior to prosthesis (Fig. 2).

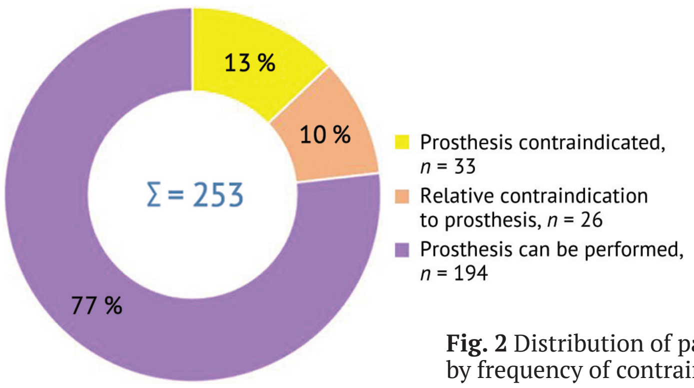

Fig. 2 Distribution of patients by frequency of contraindications

Relative contraindications included stump defects including those developed after repeated amputation, which was an absolute contraindication to prosthetics at the time of examination and required additional diagnosis and treatment procedures including reamputation. Radiographs and ultrasound facilitated verification of stump defects and justify the need for reamputation. Reamputation was performed once in 42 cases (16 %) prior to prosthetic reference, and repeated surgical interventions on the lower limb stumps had to be performed for five patients (2 %). Osteophytes were detected in three cases (1 %) after reamputation and required surgical treatment.

Absolute contraindications to prosthesis may include cases when specialists are unable to make a socket in such a way that the patient can bear weight on the stump and use the prosthesis. Stump diseases include neuromas of nerve stumps, painful osteophytes of bone sawing in places of limb truncation. Stump defects include protrusion of the bone-saw under the skin or scar, a more distal location of the fibula relative to the tibia, a bone stump protruding without a muscular sheath with a deficiency of soft tissue coverage at the site of the postoperative scar of the stump, and severe pain at the postoperative wound of unknown origin. Relative contraindications include inadequate bone-saw of the tibia, club-shaped or excessively conical stump, excessively short or too long stump and diseases such as osteomyelitis, long-term granulating wound or ulcer, ligature fistulas. The latter may prevent from product delivery and delayed prosthetic use. Treatment and recovery procedures including rehabilitation and exercise therapy can help eliminate the complicating factor or reduce its impact.

DISCUSSION

Conservative and surgical methods can be used to prepare patients for primary prosthesis. Experienced orthopedic surgeons can decide on the need for reamputation during the initial examination at the prosthetic enterprise. Conservative treatment, including therapeutic exercise, massage and physical methods can be offered prior to surgical intervention [13]. Medical and technical reports were issued on the need for surgical treatment of 59 patients who were examined for defective stumps and needed surgical preparation for prosthesis. The operation was performed for 17 patients (29 %). At the time of the study, not all patients gave voluntary consent to surgical treatment. Referring to the sources of the Second World War, to the classification offered by P.A. Kupriyanov and N.N. Burdenko, we grade amputations into types, systematized and confirmed by modern scientific works dividing amputations by time into primary, secondary, late and repeated amputations (reamputations) for studying clinical outcomes. This classification is relevant today, when the need for a multidisciplinary approach and timely diagnosis remains crucial to reduce complications [14].

The main idea of the work is supported by other modern authors who report the importance of adequate formation of the stump during primary amputation to minimize the risk of reamputation and improve rehabilitation prospects [15, 16].

Mine blast injuries resulted in amputation in 55 % of patients. Specific approaches to the treatment and rehabilitation are essential for the patients and those with combat injury. It is important to note that 30 % of amputations are caused by diabetes and atherosclerosis indicating the role of prevention and timely treatment of chronic diseases [17]. In modern injuries, the skin of the extremities can be compromised over a large area, which emphasizes the importance of preserving the maximum length of damaged areas with the help of early skin grafting, as discussed in classical guidelines [18] and remains relevant, especially in the modern conditions of mine-explosive wounds described in later sources [19]. The principles of surgical treatment for mine-blast wounds suggest removal of non-viable tissues of the affected lower limb in a field hospital to avoid threat risk. Further processing and formation of the stump occurs in a specialized hospital [5].

The level of amputation and proper stump formation determine how quickly the patient can initiate rehabilitation. The surgical technique of amputation is determined by the level of limb truncation and the anatomy of the segment. The level of amputation is the cornerstone of discussions between surgeons and specialists involved in prosthesis of lost limbs. The resection level selected preoperatively does not always coincide with the demarcation line of viable tissues identified intraoperatively [2, 5, 6], which can also affect the likelihood of developing defects and diseases of the stumps.

Delayed primary amputation is reported to allow minimize tissue damage and facilitate rehabilitation. Excessive resection of healthy tissue should be avoided with amputation at the level of non-viable tissue. Although some involved tissues may regain their viability after appropriate therapy, the possibility of secondary necrosis cannot be ruled out postoperatively due to local hypoxia and edema [14]. Abrasions, cracks and irritation of the skin may result from the pressure of the prosthesis on the stump. This is a rare case with a prosthesis used without a silicone cover to prevent formation of skin folds and infection. The formation of infiltrates and nodes at the prosthetic loading zones can be associated with excess skin on the stump. The resulting nodes can contribute to the formation of postoperative scars. N.N. Priorov recommended resorting to skin plastic surgery in exceptional cases to avoid wide and long flaps strengthening the transplanted skin through gymnastics and self-massage [20]. Today, these recommendations remain relevant [21].

Requirements for the stump are formulated in prosthetics manuals [10, 19] as follows: the truncated limb should be as long as possible, covered with intact skin without ulcers, bruises, abrasions, phlyctenas, and should not be excessively conical or club-shaped. The postoperative scar should be mobile, smooth, located outside the supporting zones of the receiving sleeve, the muscles should be developed. There should be no neuromas, and the bone saw should be horizontal, smooth, and joint movements are not limited [22, 23]. An additional requirement is imposed on the tibial stumps: sawing of the tibial crest should be performed at an angle of 45° to the longitudinal axis.

The shape of the stumps changes from club-shaped to moderately conical, the tension of tissues and skin changes, resulting in increased pain in the areas of terminal neuromas and post-amputation skin diseases. Softening inserts, silicone liners with damping properties and lodgements are used in these cases to relieve the trigger painful points of contact of the stump and the socket. Preliminary use of silicone covers during primary prosthetics was recommended to patients for an average of two weeks.

The results of this study show that the condition of the stumps is a critical factor in the success of prosthesis. Wounds healed by primary intention in most cases (76.6 %) indicating the effectiveness of surgical treatment. However, almost a quarter of patients (23.3 %) encountered problems (infections, stump defects, and painful neuromas) that complicated prosthesis. Our findings are consistent with the literature data on the importance of correct surgical technique and preparation of the stump for successful prosthesis [24]. Stump defects such as osteophytes and inadequately positioned bone cuts complicating prosthesis were detected in 7.9 % of cases. This is consistent with the data of other authors, who indicate the need for more thorough preparation and constant monitoring of the condition of the stump [25].

Failure to comply with the stages of surgical treatment, surgical principles of amputation, insufficient diagnosis and observation in the postoperative period can cause diseases and defects of the stumps, contractures of the remaining joints. This can be due to the consequences of surgical treatment and inadequate prosthesis [15, 26].

The study emphasizes the importance of stump preparation for prosthesis, which is confirmed by other studies [14, 26, 27]. Anthropometric and statodynamic characteristics of patients should be considered prior to prosthesis. Measures for preliminary formation and preparation of the stump included elastic bandaging, use of compression hosiery, polymer covers, massage, physiotherapy and exercise therapy.

Neglect of preparation for prosthesis can induce formation of problematic stumps. Strict adherence to the surgical technique and postoperative care, involvement of specialists at all stages of treatment can reduce cases of non-functional or low-functional stumps and improve the quality of prosthesis [15]. It should be borne in mind that a relatively stable stump is formed approximately 10-12 months after amputation. The stump is formed depending on the timing of the beginning of the use of the prosthesis and the activity of its use. Bandaging the limbs is essential to avoid club-shaped stumps of the femur and tibia. Stump dimensions in patients who follow recommendations for preliminary stump formation differ significantly from those in patients who do not follow the instructions.

Tissue reorganization and adaptation to new anatomical and physiological post-amputation scenario: muscle truncation, deprivation of tendon attachment zones in the distal parts, exposure of the medullary canal and trophic changes. Matching volumetric dimensions of the sleeve and the stump are important for the patient to begin use the prosthesis. Accurate dimensions of the stump and the receiving socket are difficult to arrange at the stage of manufacturing and delivery of a trial receiving socket due to the dynamic change in the volume of soft tissues of the stump of the truncated limb caused by muscle atrophy and redistribution of the load on the supporting areas. There is often a need to correct or replace the trial socket and search for an alternative silicone liner no smaller in size. With repeated corrections of the socket and changes in the fastening system, complications may develop at the contact between the socket and the stump,leading to repeated surgical interventions, repair/replacement of the receiving socket or complete prosthetic replacement [19]. Trophic disorders, trauma to soft tissues upon contact with the receiving socket slow down the rehabilitation and socialization of amputee [28].

Manufacturing the ideal socket is a complex process that involve many factors to provide long-term use, comfortable use and overall functionality of the prosthesis [29]. A personalized approach in the production of prostheses for amputees is key to the widespread adoption of technology, which should be accessible and meet the needs of the disabled person [30].

In this context, digital technologies, including the concept of digital twins, are of particular importance. The creation of personalized digital models of stumps allows us to predict the interaction of tissues with the prosthesis, adapt the socket design and increase the overall effectiveness of rehabilitation. Modern methods are used in clinical practice: from quantitative MRI (T2 mapping) to 3D modeling and biomechanical simulations. A. Gentili et al. [31] demonstrate the economic feasibility of these solutions. In conditions of limited healthcare budgets, it is important to take into account the cost of technologies and their contribution to the restoration of patients' ability to work, using cost-effectiveness assessment models (CEA, BIA, CBA).

Our study also addresses infectious and other purulent complications, which prevents successful prosthesis. This is consistent with the data presented in studies describing the increased risks of thrombosis and amputation in infections including COVID-19 indicating the importance of careful postoperative monitoring [3, 4]. Post-amputation stump diseases refer to absolute contraindications to prosthesis. Disregarding preventive immobilization, therapeutic exercise and elastic bandaging in the postoperative period are major reasons for their formation. Discussion of the presented data indicates the importance of adhering to surgical and rehabilitation principles in the treatment of amputees, implementing new technologies in the prosthetic process. Clinical data indicate the importance of careful stump preparation and proper prosthesis selection, which is consistent with international studies.

Despite the development of prosthetics over the past decades, patients may fail to use prosthetic and orthopedic products due to discomfort caused by mismatch between the receiving socket and the current dimensions and characteristics of the stump of the amputated limb [3, 16].

A limitation of this study is the lack of opportunity to observe patients before admission to the prosthetic and orthotic institution, a long-term follow-up which would provide a better picture of the long-term effectiveness of prosthesis. Nevertheless, the findings indicate the importance of a multidisciplinary approach and personalized stump preparation for successful prosthesis.

It is necessary to emphasize the importance of interdisciplinary cooperation between professionals involved in primary specialized medical care and the prosthetic experts. The correlation of amputation goals and the possibility of prosthesis is achieved by increasing competencies in these areas of knowledge, continuous training and professional communication. The scientific focus today is shifting towards progressive technologies, leaving in the shadow the need for proper consideration of current problems in the application of traditional methods. High-tech biomechanical analysis and accurate imaging are used for stump assessment to prevent complications. Innovative methods such as 3D printing, CAD/CAM, robotic prostheses and biomechanical assessment can improve patient adaptation to prostheses and rehabilitation of amputees [32].

As the number of amputees continues to grow, the approaches used to prosthetic limbs are to be improved. Growing experience in interacting with amputees entails the need to improve existing methods in the military field and in cases of providing assistance to the civilian population with truncated limbs. It is also important to consider the economic feasibility of implementing new technologies, assessing how they can achieve the maximum health benefit for people within the budget. Despite the growing interest in investing in digital health interventions, the evidence regarding cost and effectiveness of digital tools in health is scarce and limited [31]. Further studies based on a standardized approach are needed to systematically analyze incremental cost-effectiveness ratios, health and diagnostic costs and benefits, as the high cost of these technologies may be a barrier to the widespread implementation [30].

The development of quantitative criteria and standardized diagnostic methods is a priority for clinicians, which indicates the need to introduce objective scales to improve the assessment of the stump and prosthesis and reduce possible errors with use of modern technologies [23].

In our series, repeated reamputations due to pain were performed in five cases (2 %). Sometimes specialists are forced to recommend repeated amputation without pronounced pain but for the presence of radiographic osteophytes which may lead to difficulties in using the prosthetic and orthopedic device including a complete refusal to use the latter. Not all of the subjects agreed to invasive treatment, which may be dictated by the emergence of psychological barriers when realizing the prospect of re-experiencing a similar experience.

Despite identified obstacles to further prosthesis in patients, it is necessary to do everything possible to ensure that the manufactured prostheses including atypical prosthesis are convenient to use facilitating adaptation to new circumstances, return to normal life and socially useful work. The study makes an important contribution to the understanding of the problems of rehabilitation and prosthesis of amputees and confirms the need for further study in this area. The results of this analysis confirm the conclusions of a number of international sources on the importance of the correct choice of socket and careful preparation of the stump.

CONCLUSION

The majority of patients in our sample included cases caused by mine-explosive injuries. The second most common are amputation stumps in patients with vascular pathologies. The study showed that defects and post-amputation diseases complicated further prosthesis in 23 % of cases.

The impossibility of producing a socket that would allow the patient to bear weight on the stump and fully use the prosthesis is an absolute contraindication to prosthesis. Inadequate saw cut of the tibia, a club-shaped or excessively conical stump, a stump that is too short or too long, osteomyelitis, long-term granulating wound or ulcer, ligature fistulas are relative contraindications.

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Informed consent *The patients gave informed consent for publication of the findings without identification.*

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