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Biomechanical aspects of endo-exo-prosthetics of the lower limbs

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The prospects of creating new opportunities in the rehabilitation of patients with limb amputations are generally associated with the method of osseointegration and endo-exo-prosthetics (EEP). The results of the practical application of the method indicate attention to the analytical consideration of all its components, all stages. Objective. To substantiate the expediency and directions of research and development of the theoretical and practical principles of EEP from the standpoint of the full cycle, including both the problems of osseointegration and functional qualities, constructive and technological principles regarding the prostheses themselves, the methodology of the process of mastering and using them. Results. Considered biomechanical and other arguments, which substantiate the objects of research and development of medical-technical and medical-technological means, including the constructions of endo-exo-prostheses, methods of learning to use them, evaluation of the quality of locomotion, increasing the reliability of the «implant-bone» contact. The design principle of a hip prosthesis with a removable unloading module is proposed, which is installed at the stage of mastering the prosthesis, and in necessary cases, during constant use. The possibilities of the method of recognizing biomechanical patterns of movements for teaching patients to walk on prostheses, for adjusting functional nodes and assessing the quality of prosthetics are shown. Conclusions. The problem of endo-exo-prosthetics is considered for the first time from the standpoint of the requirements for the functions and qualities of the prostheses themselves. Reasoned directions of application and significance of clinical, experimental and mathematical biomechanics methods for analysis and development of the functional structure of endo-exo prostheses, to reduce risks when using them.

Із методикою остеоінтеграції та ендо-екзо-протезування (ЕЕП) пов'язуються перспективи створення нових можливостей у реабілітації пацієнтів з ампутаціями кінцівок. Результати практичного її застосування вказують на увагу до аналітичного розгляду всіх складових її етапів. Мета. Обґрунтувати доцільність та напрями проведення досліджень, розробок теоретичних і практичних засад ЕЕП з позицій повного циклу, включаючи як проблематику остеоінтеграції, так і функціональні якості, конструктивні та технологічні принципи стосовно самих протезів, методології процесу освоєння та користування ними. Результати. Розглянуто біомеханічні й інші аргументи, якими обґрунтовуються об'єкти досліджень, розробок медико-технічних і медико-технологічних засобів, у тому числі конструкцій ендо-екзо-протезів, методик навчання користуванню ними, оцінювання якості локомоції, підвищення надійності контакту «імплантат – кістка». Запропоновано конструктивний принцип протезу стегна зі знімним розвантажувальним модулем, який встановлюється на етапі його освоєння, а в необхідних випадках і за постійного користування. Показані можливості методу розпізнавання біомеханічних образів рухів для навчання пацієнтів ходінню на протезах, для налагодження функціональних вузлів й оцінювання якості протезування. Висновки. Проблема ендо-екзо-протезування вперше розглянута з позицій вимог до функцій та якостей власне протезів. Обґрунтовані напрями застосування та значення методик клінічної, експериментальної та математичної біомеханіки для аналізу й розробки функціональної структури ендо-екзо-протезів, для зменшення ризиків під час користування ними. Ключові слова. Ендо-екзо-протезування, вимоги до функцій ендо-екзо-протезів, біомеханічні образи (патерни) рухів.

Keywords. Endo-exo-prosthetics, requirements for the functions of endo-exo-prostheses, biomechanical patterns of movements

Introduction

Prostheses of the lower limbs are attached to the body through the receiving socket, ensuring the power and control interaction between it and the patient. The quality of the socket largely determines the locomotor capabilities of the patient, the degree of his rehabilitation, and therefore it has always been in the center of attention of specialists in the field of prosthetic care and orthopedics. No less time and resources were spent on the search for its optimal forms and suitable materials, individual manufacturing technologies, than on the development of functional nodes of prostheses. But in terms of its influence on the result of rehabilitation, the socket still remains a limiting factor due to the traumatic contact with the soft tissues of the stump, due to the destructive effect on the entire musculoskeletal system, because it is impossible to bring its load pattern closer to the norm. The consequence of this is that, sooner or later, in the history of patients there are records of the appearance of diseases of the stump or spine or joints as a “result of irrational prosthetic care”. There are also limitations in controlling the prosthesis through the movements of the stump, so its contact with the socket is considered in this sense as a kind of a “false joint”.

The disadvantages of prosthetic care based on the use of receiving sockets are eliminated by the implantation of a special metal structure into the bone of the stump — a pin that is brought out through the stoma in the end part of the stump and to which the prosthesis is attached. This technique, proposed by Professor R. Branemark [1], has been gaining popularity in recent years under the name osteointegration. As for its medical and technical complex in general, the name endo-exo-prosthetics (EEP) [2] most accurately corresponds and, accordingly, the term EE-prosthesis may be acceptable.

Since the appearance of the technique, the field of vision of specialists has been dominated by urgent and complex problems related, for the most part, to the process of osseointegration: the reliability of fixation of the implant — a metal pin — in the bone channel, protection against ascending infections, the search for methods of closing the stoma, etc. [3–5]. Scientific literature and other sources of information ignore the analysis and definition of requirements regarding the functions and structures of the EE-prostheses themselves, regarding the technologies for performing the entire EEP process, and the features of using the EE-prosthesis. All this research and development should consider the proper-

ties of this new method of prosthetic care and help realize its advantages as fully as possible.

Purpose: to justify the expediency and directions of research and development of the theoretical and practical foundations of endo-exo-prosthetics from the standpoint of a full cycle, including both the problems of osseointegration and functional qualities, constructive and technological principles regarding the prostheses themselves, the methodology of the process of mastering and using them.

Material and methods

Since 1990, the EEP method has been applied to at least 1,000 patients. Among the complications that accompanied this prosthetic care, a significant share is due to the violation of fixation of the pin in the bone channel, fractures of the bones and the pin itself [6–9], and the degradation of the bone tissue structure [12]. According to the considered sources, it can be concluded that such defects occur in 2–10 % of cases.

Let us consider the possible causes of such complications and options for constructive solutions for their prevention

It is known from biomechanics that normally in the phase of support during a forward push, the value of the support reaction reaches a value of 1.2–1.4 of the human weight, and the bending moment of forces acting on the bones reaches 90–140 kgf·cm [10]. Therefore, this step phase is accompanied by a cushioning process, mostly due to flexion in the knee joint (approximately 15°) and extension in the supracalcaneal-tibia (up to 20°). When walking on a hip prosthesis, the knee mechanism of which does not have a bending function, this ratio is even higher — it can reach 1.5, and the load itself is more impactful. Under EEP, the force of the supporting reaction is directly transmitted to the pin and it can be considered as a factor that affects the reliability of its landing in the bone channel. Therefore, it is necessary to install nodes with shock-absorbing functions in prostheses for EEP. This can be done by introducing a bent knee mechanism or specially designed elastic elements into the structure of the prosthesis.

Normal walking is accompanied by rotational movements in the horizontal plane, and their volume at the level of the thigh and lower leg in total reaches 30°. Lumbar support reaction forces, which are somehow related to these movements, depending on the pace, are 7–15 % of the person's weight, that is, the torque will be 20–25 Nm and more. In existing designs of prostheses, special mechanisms for restoration of rotational movements are often

absent. When walking on hip prostheses, their absence is partially compensated for by rotating the receiving socket together with an array of soft tissues, in leg prostheses by compensatory changes in the volume of rotation at the level of the hip. This indicates the expediency of installing special rotary mechanisms in the EE-prosthesis, which protects the landing of the pin in the bone channel and the pin itself from the uncompensated effect of torques of forces in the horizontal plane.

Much attention is always paid to the design of the prosthesis, the determination of its optimal individual parameters. According to EEP, the importance of this stage is even more significant from the point of view of the inadmissibility of creating conditions under which even minor destructive factors will act on the “pin-bone” contact. In this case, inaccuracies in the interaction of the force vectors of the support reaction and the weight relative to the biomechanical axes of the prosthetic limb can lead to the appearance of force moments that will negatively affect this contact at every step, creating pathological bending stress in it. For example, for errors in determining the optimal shoulder loading pattern of 5 mm from the center of the “pin-bone” section, a force moment of 30 Nm or more is created (depending on the person's weight). In the literature, we did not find exactly such a scheme of the prosthesis according to the EEP. That is, taking into account the problematic issues, it is necessary to: 1) develop the theoretical foundations of the construction of the EE-prosthesis scheme; 2) determine the parameters of the EE-prosthesis construction scheme depending on various factors, for example, on the level of amputation; 3) create hardware for the technological process of finding the optimal scheme with the required accuracy; 4) develop relevant technological instructions for practice. Regarding the hardware, in our opinion, it is necessary to install sensors in the design of the pin itself, which will directly measure the mechanical stress.

There was a period in the history of prosthetic care when aluminum alloys were widely used for the production of hip and lower leg sockets. This provided many technological and operational advantages, for example, a high-precision fit and the ability to adjust the shape of the socket during the use of the prosthesis. However, in winter, during a long stay of the patient in the cold, the stump became hypothermic due to contact with the metal socket, which caused negative physiological reactions. Moreover, the quantitative indicators of cold attack were determined not only by the socket, but also by the mass of the entire metal structure of the prosthesis attached to it. Ther-

mal influence of the external environment should be expected in the case of using an EE-prosthesis, only it will act through a metal pin from the inside of the stump, including from its bone channel. It is desirable that this problem be investigated by physiologists and thermal physicists, first, from the point of view of the justification of this question itself, as well as in relation to the possible influence of micro-fluctuations in the size of the pin, which will take place due to temperature changes, on the stability of its fit in the bone canal. If these assumptions are confirmed, then it is advisable to introduce elements into the design of the prosthesis that will separate the pin from its metal mass and the external environment during heat transfer.

Bone degradation and its consequences indicate that the currently common intramedullary pin design cannot be considered a definitive option. Installing a pin in the bone marrow channel means removing blood vessels from it, disrupting centrifugal blood flow, which ensures metabolic processes and microcirculation of fluids in the part of the bone that is in direct contact with the pin. That is, it is thereby doomed to degradation (loss of mineral density of bone tissue). In addition, with such a design, there is an effect of partial shielding of the load [9], that is, a functional stimulus that prevents atrophy of the stump bone. The results of stress shielding are the thinning of the cortical layer in the distal parts, which increases over time. Weakening and thinning reduces the strength of the supporting bone [12–14] and increases the risk of fracture, especially in young patients engaged in more mobile activities [15, 16]. It is desirable that a comparative analysis of the use of intramedullary construction with extramedullary becomes one of the objects of scientific research.

Household nuances should not be neglected. For example, after removing the prosthesis, the implant should not protrude from the stump, it is desirable to attach a cosmetic elastic element to it, in which protection against infections can also be installed.

Proposals and discussions

In our opinion, the introduction of a fairly simple removable unloading module into the design of the EE-prosthesis would be justified. Fig. 1 shows a diagram of such a prosthesis and its components. The shape and individual fit of the narrow cuff allows part of the load to be transferred through the tuber and soft tissues that come into contact with the cuff.

In the EE-prosthesis, the cuff is connected by two splints, which, in order to preserve rotational movements and perform some spring functions, may not be continuous, but as a set of thin plates depending

on the patient's weight. Adjustment of the redistribution of forces between the implant and the individually fitted cuff is achieved thanks to a structurally simple mechanism that allows changing the distance between the cuff and the prosthesis. In Fig. 1, it is placed at the point of attachment of the module to the prosthesis.

It will be useful, first of all, in the initial stages of prosthetic care, in the mode of training the resistance of the stump and gradually increasing the load on the implant. This process of redistribution is quantitatively objectified by measurements carried out by sensors placed, for example, in the junction of the tires to the cuff.

At the stages of permanent use of the EE-prosthesis, various reasons can also determine the expediency of temporary or permanent installation of the unloading module. For example, when there is a need to protect the stump from various traumatic factors.

Again, let us pay attention to the fact that EEP creates new conditions for the patient's interaction with the prosthetic limb. Thus, the EE-prosthesis gives the patient more opportunities to develop compensation for the lost natural afferentation and proprioception, allows more accurate control of it. Therefore, it is necessary to strive to use these conditions to the full in order to timely form neurodynamic stereotypes that best correspond to the new conditions of prosthesis management. Let us consider one of these possible ways.

The quality of locomotion when walking on a prosthesis is higher, the more fully restored, close to normal functional coordination of movements in natural and artificial joints. This is one of the most important goals of prosthetic care, because it is in this way that the best results can be achieved in terms of all kinematic, dynamic and energy indicators of the locomotor act. The symmetry of the movements of the prosthetic and healthy limbs will mean not only the improvement of the kinematic gait pattern, bringing it closer to the norm, but also significantly reduce energy consumption.

Biomechanical images (patterns) of movements [17] provide the most complete insight into this functional interaction of joints, which can be detected and registered during normal walking and on prostheses through goniometric measurements, signal processing and their registration on two-coordinate recorders. Figure 2 shows the scheme of placement of goniometers on three joints and their connection to recorders directly or through differentiators. Patterns can be created in two-dimensional (as shown in the graphs) and multi-dimensional space from

the angular parameters of joint and hinge movements, as well as from various combinations of their first and second derivatives (i.e., joint angular velocities and accelerations). This allows us to reveal the biomechanical and biocybernetic essence of such a phenomenon as walking.

In this way, it is possible to register both single patterns during one step and overlay graphs for many. As examples, Figure 3 shows some of these patterns graphically. On the graph in Fig. 3, the angular coordinate system shows the patterns that characterize the interaction of the hip and knee joints during normal walking (solid curve) and the interaction of the hip joint of the stump and the knee mechanism during walking on a hip prosthesis (dashed curve). Regarding the discussed topic, we note three features of the patterns.

1. Normally, when walking at the same pace on a flat surface, the patterns for one person are similar at all steps. Even during walking in ideal conditions, there are slight fluctuations in the shape of the patterns, which are natural manifestations of the activity of the nervous system, which, by initiating such fluctuations, constantly trains and supports the capabilities of the muscular-nervous system in controlling movements with many degrees of freedom [18, 19]. According to the results of our research, the volume of these fluctuations is within 1–2 % of the average value.

When walking on prostheses, step-by-step fluctuations in the shape of the patterns are almost absent, so the lines of the graphs clearly overlap each other with each step. This phenomenon can be associated with compensatory reconfiguration of the movement control system to perform its functions in conditions of limited capabilities.

Normally, for changes in the pace of walking, the patterns have pronounced stability, they change insignificantly with minor deviations from the arbitrary, and in the case of slowing down or accelerating (within the limits of two-support walking), deviations of the form in some parts of the graph reach 1–4 %.

2. The patterns obtained during the walking of different people are similar in their graphic representation, they have common regularities (the same primary signs in the language of pattern recognition theory), but they also have differences that can be determined by height, weight and other individual characteristics of people.

Patterns of walking on prostheses, as can be seen from the graph in Fig. 3, a, differ from the norm (up to 10 % in the transfer phase by individual primary features, completely in the support phase), however,

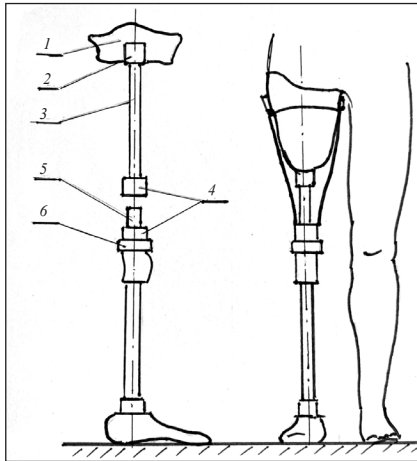


Fig. 1. Design scheme of the EE hip prosthesis with a unloading module (UM): 1 — individual cuff; 2 — tire fastening unit with load sensors; 3 — the connection node of the UM with the prosthesis; 4 — node connecting the pin of the stump with the prosthesis; 5 — unit for adjusting the degree of unloading

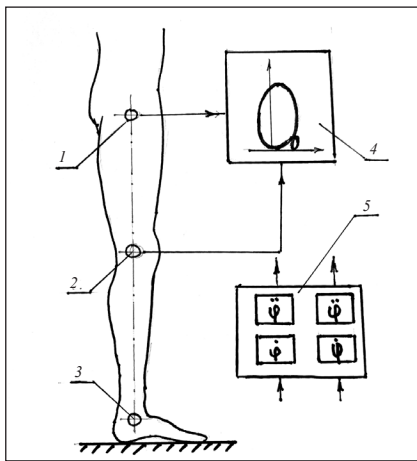


Fig. 2. Scheme of registration of biomechanical patterns of movements: 1, 2, 3 — goniometers on the hip, knee, and metatarsal-shin joints; 4 — two-coordinate recorder; 5 — differentiation unit

for the most part, they have enough in common with the norm of those primary features that allow them to be unmistakably recognized. The patterns obtained during walking on prostheses of different patients depend significantly on the level of amputation and the physical condition of the patient, on learning to walk and the formed stereotype, on the constructions of the functional nodes of the prostheses, the perfection of individual adjustment of the parameters of the knee mechanisms, feet, and on other conditions of prosthetics. Therefore, their variability among themselves is greater than during walking of healthy people and they differ significantly among themselves than patterns during normal walking.

3. Comparison of the patterns in the norm and on the hip prosthesis allows the most visual assessment of how they manifest themselves and what is the significance of the forces due to which gait is carried out. Normal gait is the result of a complex, appropriately coordinated interaction of gravitational, inertial, reactive and muscular forces. Walking on a prosthesis is carried out in conditions when the muscle resource of forces has suffered significant losses, the mass-inertial characteristics of the prosthesis are different from the norm and cause a different effect of gravitational and inertial forces, and the role of reactive forces, which a person can initiate due to back movement in the hip joint, is significantly is growing. Actually, learning to walk on a prosthesis begins with the patient mastering the ability to force the knee mechanism of the prosthesis to extend in the transfer phase due to this movement of the stump.

Drive mechanisms can be installed in the prosthesis, which, in addition to the mentioned forces, use forces from external energy sources and energy obtained through recuperation. Gait patterns in

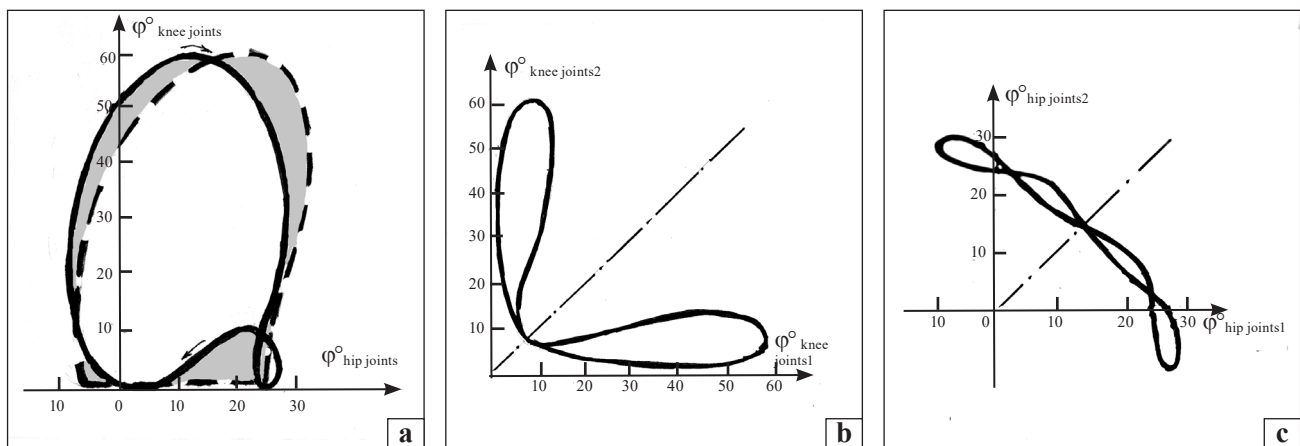


Fig. 3. Patterns that reflect the coordination of movements: a — in the hip and knee joints in normal conditions and on the hip prosthesis; b — normal in two knee joints; c — two hip joints are normal. The solid line is normal patterns, the dotted line is when walking on a hip prosthesis. The arrow on the graph is the direction of movement

the norm and on the prosthesis, superimposed on each other, show that they have a significant common part in the area covered by the graphs (Fig. 3). And this is a clear illustration of the dominance of the total contribution of gravitational, inertial and reactive forces in the transfer phase of the step at a relatively low level of participation of muscle forces. Those relatively minor differences, where the graphs do not coincide, show not only the role and share of muscle forces in the locomotor act, but also how their loss affects coordination disorders. This informative property of patterns makes them the basis of the most effective management of bionic prostheses.

Patterns can characterize the interaction of movements in both knee joints (Fig. 3, b). In the norm, this graph is completely symmetrical about the bisector. When walking on prostheses, this symmetry is significantly disturbed, and the degree of its restoration is one of the indicators of the quality of prosthetic care. The pattern (Fig. 3, c) reveals the normal interaction of two hip joints, and it also has symmetry with respect to the bisector.

Such data of our research fully coincide with the theory regarding the essence of building such a locomotor act as walking: both from the point of view of its energy sources and the organization of its effective management by kinetic and other indicators.

What significance can biomechanical patterns have for EEP? First of all, it is teaching patients to walk on a prosthesis. If from the first steps the parameters of his locomotion and their coordination in the form of patterns will approach the optimal, then this will allow the patient to form an optimal neurodynamic stereotype in the early stages of learning to walk. It is desirable that in the process of training these patterns, their changes, their comparison with the norm, should be seen not only by physiotherapists-instructors, but also by the patients themselves, for example, on a large screen at the end of the training track. That is, the display on the screen of the ideal pattern and the current one from the patient will give him the feedback that will allow him to understand the essence and direction of corrections in the management of the prosthesis and will effectively affect the process of its development. In addition, computer programs for processing patterns can also include issuing recommendations for those changes that the patient himself needs to make in controlling the prosthesis during training. The program can provide for the sounding of these recommendations, which will strengthen the effects of feedback. Such patterns and their software processing with voiced recommendations will also help the prosthetist to ad-

just the parameters of the drive mechanisms of modern prostheses not by trial and error, but based on objective corrections of the pattern to bring it closer to the desired appearance.

Conclusions

Thus, the problem of endo-exo-prosthetics in the case of amputations of the lower limbs was considered for the first time from the standpoint of the requirements for the functions and qualities of the prostheses themselves. Arguments are presented regarding the fact that at a certain stage of development and application of this new method of rehabilitation, specific needs and directions in the fundamentalization of theoretical and practical principles, the development of specialized structures and technologies are revealed. The expediency and value of clinical, experimental and mathematical biomechanics, thermophysics methods for analyzing the functional structure of EE-prostheses, for identifying and reducing risks during their use are shown. All this will make it possible to substantiate the development of the entire arsenal of medical-technical and technological means and technologies of endo-exo-prosthetics, starting from the stage of osseointegration, Separate medical-technical proposals (constructive principle of the unloading module, recognition of biomechanical patterns of movements), which not only illustrate the feasibility of such an approach, but also have practical significance.

Conflict of interest. The authors declare no conflict of interest.

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