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METHODS TO PREVENT THE STRESS SHIELDING EFFECT IN IMPLANT–BONE SYSTEM (REVIEW)

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ABSTRACT

Statistical data of many national registers and medical societies show that aseptic instability of the hip joint prosthesis is one of the main obstacles in the path to application of orthopedic implants. One of the causes for aseptic instability is manifestation of stress shielding effect, which is due to mismatch of the moduli of elasticity of the implant and bone tissue. Methods are considered, which allow lowering the modulus of elasticity of the metal implant, bringing it closer to the respective modulus of elasticity of bone tissue. It is found that reaching the posed goal by replacement of the traditional metals, which are used for implant manufacture, by alloys with much lower modulus of elasticity, is a task, which has not been solved technologically in their mass production. The currently most common methods of lowering the modulus of elasticity of orthopedic implants were analyzed, and their advantages and short-comings are indicated. The most serious problem in mass application of advanced additive technologies in implant manufacture is their labour- and material consumption. It is found that application of surface modification technologies, in particular plasma methods of porous coating deposition is the most affordable and effective method of lowering the modulus of elasticity of the implant surface, contacting the bone, with a high probability of reduction of the stress shielding effect manifestation.

KEYWORDS: orthopedic implant, titanium alloys, modulus of elasticity, porous coatings, surface modification

INTRODUCTION

Mass commercialization and technological achievements of the several recent decades shifted dynamics of the society to the side of more sedentary life style that is related with increased index of body weight which has a detrimental effect on a state of locomotor apparatus [1] and results in many diseases, including osteoarthritis of hip and knee joints [2]. As for 2014 up to 15 % of planet’s population [3] suffered from osteoarthritis [3]. In view of global aging of the population and change of the life style the scientists predict that more and more people will suffer from orthopedic diseases [4] in future.

However, when physiotherapy and therapeutic treatment can not improve patient’s state an endoprosthesis replacement, i.e. replacement of a joint with orthopedic implant by means of surgical intervention, is used in order to reduce painful sensation and restore joint functionality. This allows patients to come back to normal quality of life and demand for orthopedic implants rises together with intensive development of implantation technologies [5].

Current technologies of endoprostheses manufacture allow producing standard implants (Figure 1, *c*) as well as individual ones, i.e. formed with consideration of all defects of a bone of a specific patient (Figure 1, *d*) [6] providing porous or trabecular surface structure. Nevertheless, increase of the cases of disease among young people provokes a need of noticeable increase of endoprostheses life. Virtually, most of the young patients with overweight, which require replacement of a hip joint, will need that their prosthesis operates for 50 and more years [7]. At that, the work [8] had an assumption that only 58 % of the patients could count on trouble-free operation of an artificial hip joint for at least 25 years.

One of the main reasons of implant reject is its aseptic loosening due to decrease of density of a bone tissue that is caused by insufficient loading, which affects the bone surrounding the endoprosthesis, since the bone tissue is formed and fixed in a direction of mechanical stress effect [9]. In the literature such a phenomenon is called “stress shielding”. It is caused by the fact that the implants are made of the metals and alloys the elasticity modulus of which is significantly higher the corresponding characteristic of the bone tissue that results in appearance of the tangential stresses in a zone of contact between the bone and its substitute [10].

Among the metallic materials of biomedical designation the most widespread are titanium and its alloys due to exceptional biocompatibility, excellent corrosion resistance and low specific weight in combination with high mechanical characteristics [11]. One of the most widespread materials being used in manufacture of the substitutes of highly-loaded joints such as hip, knee and shoulder is the ($\alpha+\beta$)-titanium alloy Ti–6Al–4V (VT6) [13]. It has high indices of mechanical properties due to such alloying components as aluminum which greatly strengths α-phase and decreases alloy density as well as allows reaching significant strengthening with preserva-

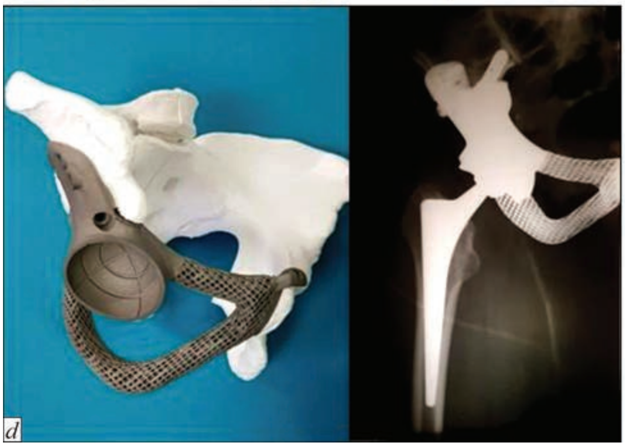

Figure 1. General view of endoprosthesis replacement: *a* — proximal part of femoral bone (*1* — whirlbone; *2*, *3* — head and stem of endoprosthesis respectively); *b* — femoral bone – endoprosthesis – hip bone system; *c* — standard endoprostheses; *d* — mock-up and X-ray picture of individual endoprosthesis after implanting

tion of sufficient ductility [14]. However, regardless high indices of mechanical strength and wear-resistance the service life of any metallic implants rigidly fixed in the bone tissue is greatly limited due to unconformity of the elasticity moduli of the bone tissue and implant material.

The phenomenon of stress shielding slows down the processes of shape restoration and healing of the bone that decreases density of the bone tissue with increase of its porosity [11]. This can provoke reject in implant operation, namely instability of fixation of the implant in a bone due its structural changes. The instability of endoprosthesis results in increase of defectiveness of a bone and requires repeated, i.e. revision surgery. At that the revision surgeries are undesirable since they have high cost and higher risk of the postoperative complications. Therefore, search of the ways of increase of service life for the endoprosthesis is a relevant task for today not only in the field of medicine, but materials science and mechanical bioengineering as well.

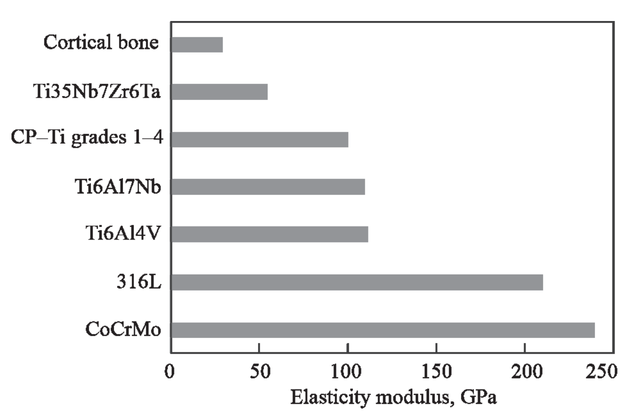

Figure 2. Moduli of elasticity of metallic materials for implants in comparison with cortical bone tissue [15]

MATERIALS AND METHODS

The most widespread methods for shielding stress prevention are application of low modulus alloys, providing a porous structure to the implants and application of the implants with functionally-gradient coatings of different porosity.

The current trends towards low-modulus materials resulted in development of new alloys with better relationship of bone-implant elasticity moduli. Thus, there are attempts to replace the main and the most widespread ($\alpha+\beta$)-titanium alloy Ti6Al4V by β-titanium alloys, doped with niobium, zirconium and tantalum (Ti13Nb13Zr, Ti29Nb13Ta4.6Zr), the modulus of elasticity of which can be lower than 50 GPa[16]. At that the values of elasticity modulus of a cortical bone tissue is changed from 5 to 23 GPa. This characteristic makes approximately from 112 to 240 GPa, respectively (Figure 2), for such most widespread materials being used for implants' manufacture as titanium alloy Ti6A14V, stainless steel 316L and cobalt-chromium alloy CoCrMo.

Recent results of development of alloy Ti35Nb7Zr6Ta, the modulus of elasticity of which was approximated to the modulus of elasticity of the cortical bone tissue for the purpose of prevention of its resorption, turned to be successful [17]. However, β-phase alloys have lower strength than alloys with α- and $\alpha+\beta$ phases and their synthesis today is much more expensive in comparison with traditional ($\alpha+\beta$) alloys [18]. Therefore, solution of the indicated problem in short-term perspective by means of mass application of these low modulus alloys is impossible.

The simplest technological solution for suppression of the effect of stress shielding and acquiring the positive results as for extension of their service life is a provision of a porous structure [19] to the metallic implants, including using porous coatings [20]. Besides, it is known that [21] roughness of the implant surface promotes its osseointegration. Thus, the investigations [22] showed improved attachment of the bone to the implant due to reproduction of a bone inner porosity on its surface. The implant is fixed by means of a joining between the bone and its porous matrix as a result of bone growth in the implant pores and provides not only fixation, but also a system that allows transfer of loading from the implant to the bone [23].

Current tendencies of automation development and computerization initiated the direction of additive manufacturing technologies (AT) known as 3D-printing technologies. They are also used for decrease of effect of stress shielding by means of production of structures with a gradient of size and shape of the pores from the surface to the center of the part [24]. Such implants have a series of unique advantages such as high biocompatibility, open interconnected structure of the pores, which promotes growth of the bone tissue, and elasticity modulus close to bone one [25].

The most widespread methods of AT for manufacture of metallic structures with functional gradient are the methods of selective laser and electron-beam melting [26]. The gradient structures obtained by AT methods allow decreasing the elasticity modulus due to the presence in them of significant volume of pores [27]. There is a wide assortment of the implants with through porosity as well as solid base with present porous structure on their surface. They are produced by such well-known manufacturers as Zimmer Biomet Trabecular Metal™, Lima Corporate Trabecular Titanium, Gruppo Bioimpiant Fin System, Permedica Orthopedics Trabecular Titanium TRASER (Figure 3).

The most significant obstacle on a way of mass application of AT in manufacture of implants is their labor intensity and material consumption. At that all the manufacture stages should be agreed from the side of doctors as well as engineers.

In turn there is a problem of high cost of consumables for manufacture of 3D-implants and their limited by chemical composition assortment in the market. Current state of development of AT does not allow printing using different materials in one stage, and their replacement takes place only after complete termination of the process and performance of operations on cleaning from previously used material. Therefore, today these technologies are profitable only in those cases when other methods can not be used or complexity of open surgical treatment requires production of individual implants [29].

The powder sintering technologies have also found their application for manufacture of implants in orthopedics. These implant production technologies include the most widespread processes of pressing, spark plasma sintering and stamping of powder billets. The advantage of these methods lies in the fact that the raw

Fiugre 3. Implants of known manufacturers produced using AT [25]: *a* — Zimmer Biomet Trabecular Metal ™; *b* — Lima Corporate Trabecular Titanium; *c* — Gruppo Bioimpiant Fin System; *d* — Permedica Orthopedics Trabecular Titanium TRASER®

materials are the powders of metals, alloys, ceramics and other materials [30]. Using them it is possible to obtain the products with set characteristics and sizes since a wide spectrum of metal powders allows selecting the properties of these powders and predict them in finished products. Powder metallurgy technologies can provide production of high-porosity materials that affects the decrease of stress shielding effect. The review [31] shows the positive aspects of application of high-voltage current discharge for production of porous materials from powders of titanium, niobium and tantalum, which can be successfully used in medicine.

Work [32] demonstrates application of a method of spark plasma sintering of titanium powders with 110 μm average diameter of particles of compacts which had porosity at a level of 28 % and compression elasticity modulus of 7.9 GPa. Such indices of elasticity modulus lie in a range of change of a corresponding characteristic of the cortical bone tissue, thus, application of such coatings allows obtaining the significant success in suppression of the effect of stress shielding.

In work [33] the specimens with open porosity in 70–80 % range were made from spherical particles of titanium alloy of 0.5–1.0 mm diameter and demonstrated the value of elasticity modulus of 0.86 GPa, close to the indices of a corresponding characteristic of the trabecular bone tissue.

The main disadvantage of the methods of powder metallurgy lies in the fact that the technological process requires long-term holding of the specimens at high temperature and the indices of implants' strength often appear to be insufficient. One of the methods for solving the problem of increase of mechanical characteristics is application of double sintering. This allows increasing the strength of porous specimens for more than 2 times without noticeable decrease of porosity part [34]. However, additional technological operations of holding at high temperatures for a sufficiently long time rise energy capacity of the production process and, as a result, its cost and can change structure of the output material.

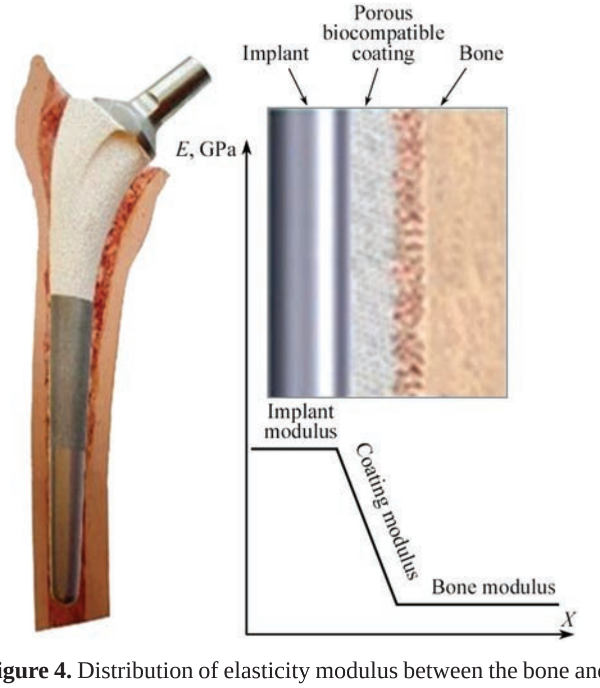

Figure 4. Distribution of elasticity modulus between the bone and the implant

Application of functionally-gradient coatings with different volume porosity provides a progressive approximation of the elasticity modulus from the implant to the bone as a result of multilayer coating (Figure 4). This permits prevention of appearance of the stresses which result in its delamination from a core in a zone of contact of the first layer with the maximum elasticity modulus as well as suppress the effect of stress shielding in a zone of contact of the last layer, which has the lowest elasticity modulus, with the cortical bone tissue [35].

The high efficiency of application as the implants of combined structure is shown by intraosseous plates with compact part from VT1-0 alloy. They were coated using the method of vacuum sintering by porous coating from titanium powder made by the technology of cold double sided pressing. As a result the bone tissue being formed around the implant actively penetrates inside it, providing, thus, its secondary fixing, and presence of porosity in the coating leads to decrease of elasticity modulus [36].

In work [34] a double-layer coating with pore sizes of 800–900 and 600–700 μm, respectively (Figure 5) was formed by means of burning of titanium powders on a surface of dental implant at 1233 and 1623 K temperatures.

Spark plasma sintering [37] is also used among the methods of powder metallurgy for modification of the surface of implants by means of deposition of the porous layers. Bending strength and elasticity modulus of the coatings from alloy Ti6A14V, produced by this method, made 128–178 MPa and 16–18 GPa, respectively, that corresponds to a range of changes of respective characteristics of the cortical bone tissue [38].

The main disadvantage of the burning methods for production of porous structures from powder materials on the implant surface, as in the case with the processes of volume pressing and sintering, is the indices of coating strength and the high temperatures of treatment in course of a long interval of time. For example, in order to obtain the powder coatings from titanium alloy Grade 4 (ASME standard alloy) with a level of volume porosity in 30–50 % range, which provides the elasticity modulus close to corresponding value of the cortical bone tissue, it is necessary to sinter them at 1000–1100 °C temperatures during 2 h [39].

A technology of laser modification of a surface of metallic materials became popular in recent time. In it the laser is used as a heat source (Figure 6). This technology of deposition of gradient coatings on the products from

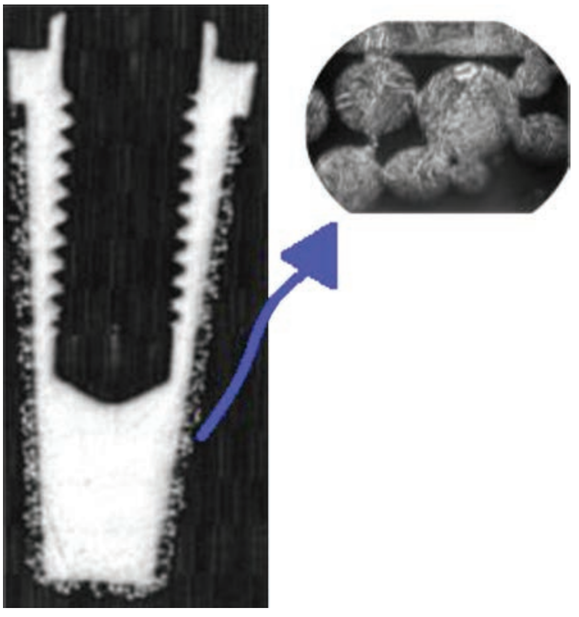

Figure 5. Porous coating on dental implant produced by burning of layers of titanium powder [34]

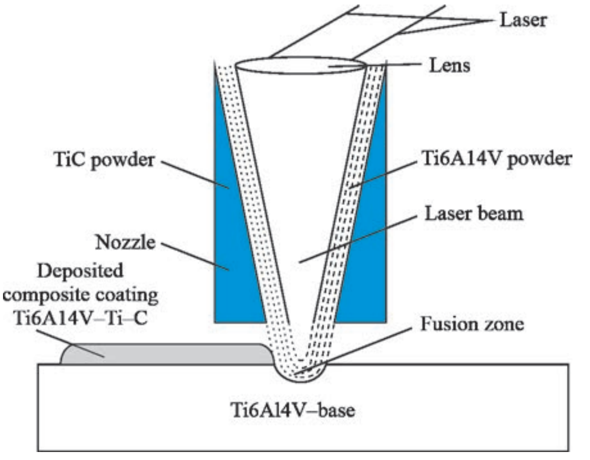

Figure 6. Scheme of the process of laser burning of powder

titanium alloys is considered as a competitive method. It allows controlling an accuracy and features of the implant surface being at that high-efficient, eco-friendly and economic from point of view of consumables [40]. However, adhesion strength of the coatings, deposited by laser burning of powder, to the base sometimes is not sufficient and applied stresses can exceed it that promotes delamination of the coating from the prosthesis surface, thus violating its function [41].

The implants with low elasticity modulus are manufacture by a known company Zimmer Biomet, a founder of patented technology of production of trabecular structure Trabecular Metal™. This structure is similar to bone tissue and consists of porous glass-like carbon coated by tantalum with the help of vacuum spraying [42, 43]. The produced implants have 80.9 % porosity, 527±27 μm size pores and elasticity modulus 3 GPa.

Current implants made using AT also simulate the surfaces with trabecular structure (Figure 7). Nevertheless, presence of the pores in their volume results in decrease of strength of such structures. This is the reason of their limited application only by those implantation places where they do not bear the main service loading. A contraindication to application of these implants in a practical aspect is the presence of a septic process at intervention since the main disadvantage of the trabecular components is the problems with their explantation [25].

In literature there are other approaches to reduction of elasticity modulus using current polymer materials such as PEEK. Thus, work [44] describes an innovative approach to decrease of the elasticity modulus of metallic implant due to application of composite carbon/polymer material (PEEK), which is formed on the surface of hip joints. Performed model experiments and numerical results indicate that a composite carbon/polymer material significantly rises the characteristics of fatigue resistance of the surface layers with distribution of applied load and its transfer to the bone. This decreases the effect of stress shielding and provides better stability of the implant during the long service life.

However, this idea of application of the coating was only modeled and was not proved by practical results which can significantly differ from the calculation ones and their application can reveal a series of other problems such as fixation of osteoblasts on the surfaces of PEEK material.

In contrast to methods mentioned above today a method of plasma spraying (Figure 8) is the most

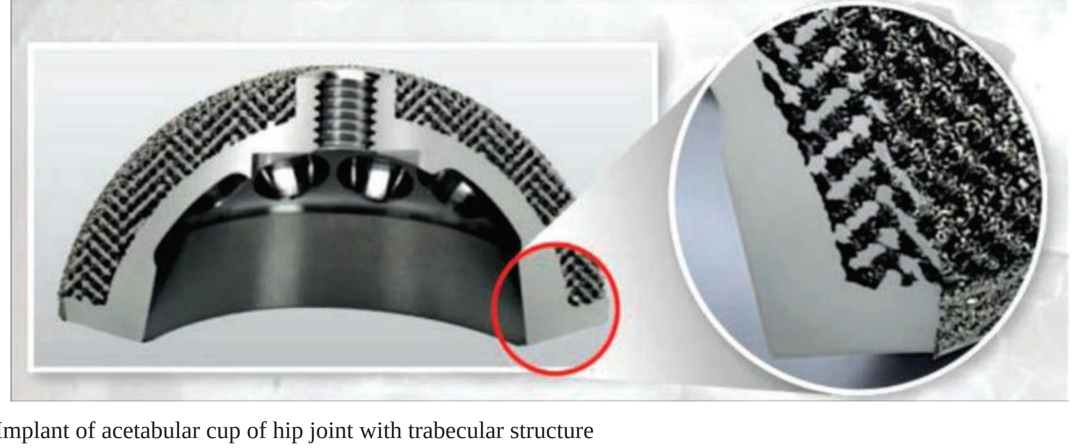

Figure 7. Implant of acetabular cup of hip joint with trabecular structure

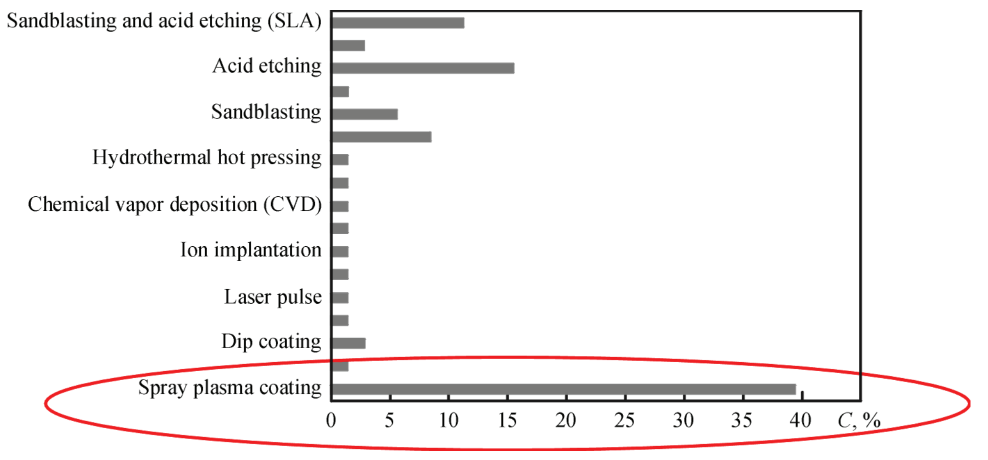

Figure 8. Distribution of technology of production of porous structures on implant surface [45]

available and technologically simple in realization of production of porous structures on the surfaces of implants with verified numerous successful results of practical application. This method attracted a lot of attention in biomedicine due to low cost, high efficiency and wide regulation of coating thickness with possibility of application of different spraying materials on the same equipment [46, 47]. Successful application of the plasma spraying for coating production is promoted by several factors, namely high efficiency of spraying process; relatively insignificant heating of a base (to > 200 °C) that decreases possibility of change of its properties; simplicity of regulation of coating production process (power characteristics of plasma can be changed technologically depending on the requirements in the process of coating production); possibility of application of automated manipulator in the process of coating deposition that promotes uniform distribution of a sprayed layer over a part surface.

Versatile and flexibility of the technology of plasma spraying allows adjusting it to almost any spectrum of materials being sprayed such as metals and their oxides, apatites and other materials [48].

There was accumulated a significant experience of application of plasma spraying for improvement of the surface of dental implants due to a plasma-sprayed layer of titanium and hydroxyapatite powder which influences the acceleration of osseointegration [49]. Among the disadvantages of given method of coating deposition are relatively not high strength of adhesion of the coating with the base as well as low coefficient of material application. Particularly, substantial losses of material will take place at spraying of implants of small size (intervertebral cages, dental implants). At that overheating of a small-size part is also possible as a result of effect of a high-temperature plasma jet. In order to reduce losses of the material provoked by the fact that part size is smaller than the spaying spot it is necessary to try to decrease the diameter of the latter.

Solution of some of the issues mentioned above is possible with the help of application of a technology of microplasma spraying developed at the PWI of the NASU. It provides formation of a plasma jet with reduced heat power and a spraying spot of small size [50]. Structural peculiarity of the equipment, namely microplasmatron in combination with technological approaches allow spraying powder as well as wire materials with formation of structures with high level of porosity and pore size to 300 μm. Such structures increase osseointegration with the bone and provide necessary indices of mechanical strength of the coating-base system [51] that permits to use them on the surfaces of endoprostheses for cementless fixation [52]. Therefore, the technology of microplasma spraying is perspective for modification of the surfaces of implants since formed by such method coatings from alloys based on titanium or zirconium with maximum possible level of porosity (25 % for titanium and 20.3 % for zirconium alloy) and elasticity modulus 12 and 5 GPa, respectively [53], allow significantly approaching them to the corresponding characteristic of the cortical bone tissue. This will promote more uniform distribution of stresses during operation of the implants.

CONCLUSIONS

1. The analysis of the modern references as for appearance of aseptic instability was carried out and it was determined that one of the reasons of its appearance is the effect of stress shielding caused by nonconformity of the elasticity moduli of the implant and the bone.

2. Such methods as application of low modulus alloys, additive manufacturing technologies, powder sintering and plasma spraying were analyzed for reduction of the elasticity modulus of the orthopedic implants for the purpose of prevention of the effect of stress shielding.

3. It was determined that today the technologies of plasma spraying are the most effective and economically feasible methods of production of porous structures on the implant surfaces. In particular, it was shown that application of the technology of microplasma spraying of the coatings on the implants'

surface removes the disadvantages typical for conventional plasma spraying as well as promotes suppression of the stress shielding effect.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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