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Problems of Increasing the Biocompatibility of Materials Used in Medicine

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Abstract

A review of modern literature on the development of biocompatible implants based on modern technologies, including bioengineering and nanostructuring, is presented. The advantages and disadvantages of implants based on metals and alloy, ways of improving their biological and mechanical properties are shown. In connection with the rapid development of many branches of science and technology, as well as in medicine, the problem arose of obtaining new materials, in particular, alloys with valuable physicochemical properties, which are used for the implant of cardiology, traumatology, orthopedics and other industries. Study of biocompatibility of medical devices based on metals and alloys, search for ways to overcome the low engraftability of implanted structures.

Keywords: *Biocompatibility; Metal Allergy; Implants; Medical Materials; Artificial Materials; "Metal" Hypersensitization*

Introduction

Study of biocompatibility of medical devices based on metals and alloys, search for ways to overcome the low engraftability of implanted structures. Implantation with artificial materials allows to return the lost functionality of human organs and tissues and today has no competition. The advantage of using metals and alloys in implantable structures is their high operational reliability, long service life, and great functionality. The nature of the interaction between the human body and the implant affects the resource intensity and wear resistance of structures. Scientific research by manufacturers of medical implants at the present stage is aimed at obtaining materials that will not have a negative effect on the human body and will ensure maximum survival rate when using them (Rozhnova: 2015).

Biocompatible properties of materials, as a rule, are reduced to the development of new methods of surface treatment and modulation of the chemical composition of implants. At the same time, the world literature demonstrates the absence of a systematic approach to studying the problem of increased sensitivity of patients to various metals and alloys ("metallic" hypersensitization), which results in the occurrence of such complications as the development of aseptic inflammation and infectious complications, instability of structures, and loss of functionality. In this regard, it is necessary to search for ways to increase the biological compatibility of materials used in medicine, based on the assessment of immune defense mechanisms and the development of an algorithm for preoperative preparation of patients (Rybakova: 2017).

Biomaterials should have certain chemical properties (absence of unwanted chemical reactions with tissues and interstitial fluids, absence of corrosion), mechanical characteristics (strength, resistance to cracking, resistance to delayed destruction, wear resistance), biological properties (absence of reactions from the immune system, consolidation with bone tissue, stimulation of osteogenesis). Biomaterials that are used as implants replacing a site of a bone (endoprostheses) or as temporary fixators for a broken bone (extramedullary plates, intramedullary rods) are also assessed by the activity of influencing the reparative capacity of the latter (Nazarov: 2018). In traumatology, metal implants take a strong place. Alloyed steels are most often used to replace large areas of bone (endoprostheses) or to restore the integrity of a broken bone (Nurmukhanbetova: 2019).

Internal fixation implants are made of materials that must, first of all, meet the objectives of providing reliable fixation of the fracture for functional treatment for a certain period - usually 12-18 months. This is a fairly long period of time, so fatigue-resistant materials are chosen. They are required to have good plasticity for the possibility of individual modeling on the bone surface, at the same time, the plastic deformation of the implant should be minimal with maximum strength after fixation on the surface of bone fragments in order to maintain them in a repositioned position even during physical exertion (Boyko: 2017).

The material used for implantation must remain biocompatible and not change its physical and chemical properties. All metals used in medicine, according to their effect on living tissues, are divided into three main groups: 1) toxic metals (vanadium, nickel, chromium, cobalt); 2) intermediate metals (iron, gold, aluminum); 3) inert metals (titanium, zirconium). Based on the results of studying electrochemical reactions, M. Pourbaix (1984) came to the conclusion that theoretically plantates, you can use either noble metals (with a purely metallic surface), or five metals, which are coated with a layer of protective oxides (Ti, Ta, Nb, Zr, Cr) (Egorov: 2014).

A biocompatible material cannot be completely "inert"; every medical device has a certain reactogenicity, i.e. causes a reaction of the surrounding tissues, and the direction of the reaction of the host organism should be decisive in the choice of material for medical use. When implanting biomaterials, first of all, it is necessary to take into account their possible general, generalized effect on the body as a whole, as well as the functioning of organs and systems remote from the implant. For example, trace impurities in titanium structures, for example, iron and chlorine, alloying components of titanium alloys, such as vanadium and aluminum, not only do not contribute to biocompatibility, but, accumulating in tissues, can have a toxic effect on the patient's body and cause instability of the components of the endoprosthesis (Harloff: 2010; Mayborodin: 2017). The term "biocompatibility" applies not only to the biomaterial and the implant as a whole, but also to the products of destruction of the biomaterial or biodegradation (Lintner: 2009; Boyko: 2017).

By modifying the properties of a biomaterial (chemical, surface, physical, etc.), it is possible to interfere with the course of the reaction they cause, adapting it to the tasks for which the biomaterial is implanted, thereby changing its biocompatibility. With the same chemical composition, it is possible to

obtain a material in which, along with biocompatible phases, will be present and incompatible or material with a minimum ability to interact with the physiological environment. Knowledge of the processes that occur during the synthesis of a material, and the ability to control them, make it possible to obtain a material with desired properties (Harloff: 2010; Savich: 2012). In each clinical case, a physician needs to have an idea of what properties the material should have to ensure the required level of interaction with tissues for a specific clinical case (Mihov: 2010; Gainutdinov: 2013).

Currently, a large number of implants and structures are being developed and put on the market, characterized by different chemical composition of the material, processing method, etc., however, a wide range of used structures does not allow avoiding a significant number of complications, the most frequent of which is component instability.

The process of decomposition of non-viable materials upon contact with living tissues, cells and biological (bodily) fluids is called biodegradation (BD). The mechanism of biodegradation can be very diverse - from corrosion of metals, phagocytosis of calcium phosphates and collagen, to chemical replacement of corals with hydroxyapatite (https://medbe.ru/materials/biomekhanika).

Currently widely used in medicine (dentistry, orthopedics, surgery), domestic and foreign alloys on a cobalt-chromium base, including the cobolt-chromium alloy (CCS) known in the CIS, contain a total of at least 85 wt% of such elements, like cobalt and chromium. As a result, they have increased resistance to corrosion damage, not only in biological environments. According to this parameter, they are not inferior to alloys of noble metals, practically do not interact with strong inorganic oxidants, such as nitric, sulfuric acids, aqua regia (Maksyuta: 2011; Komissarova: 2019).

Unique casting characteristics (high level of fluidity and small shrinkage of cobalt alloys) provide the possibility of obtaining and successful operation of cast thin-walled (up to 0.12 ... 0.15 mm) parts of removable and non-removable solid cast structures for medical purposes (Maksyuta: 2011).

A.A. Egorov and a number of scientists from the Novosibirsk State Medical University have studied that ceramic implants, in comparison with implants from titanium alloys, have comparable or better performance. Excellent strength and wear resistance, thermal and corrosion resistance, four-point bending strength of ceramics over 750 MPa are guaranteed, for example, by the requirements of the new international standard ISO 6474-2: 2012. The result of this analysis is an overview of the use of various materials in dental implantation. Comparison of the aesthetic parameters and durability of titanium or metal alloy implants with ceramic analogs showed that at the current level of the structural state of ceramic materials for dentistry, it is important to improve their own methodological approaches towards the widespread use of ceramic implants and the creation of various ceramic monoimplants to improve the results of treatment of patients with secondary partial or complete adentia with concomitant bone tissue deficiency using dental implantation methods (PogosyanEgorov: 2014; Zholudev: 2019; Pogosyan: 2016).

Technologies for producing cast medical products from alloys based on titanium, zirconium and cobalt are considered. The melting of alloys and production of blanks was carried out in electron-beam foundries. The intensification of the processes of refining alloys was provided due to the electromagnetic stirring of the melt (Ladokhin: 2015).

Scientists Yu.G. Alekseev, Korolev A. Y., Niss V.S. determined the roughness of the working surfaces is one of the most important characteristics of such products. Traditional surface finishing processes for cobalt-chromium alloy implants are based on mechanical and electrochemical methods. The disadvantages of mechanical methods are low productivity, susceptibility to the introduction of foreign particles, difficulties in processing complex geometric shapes. For electrochemical technologies, the

materials under consideration are difficult to machine; in the processes of their polishing, harmful electrolytes are used, consisting of acid solutions. As an alternative to the existing methods, the use of an environmentally friendly method of electrolyte-plasma polishing has been proposed, the main advantage of which is the use of aqueous solutions of salts with a concentration of 3-5% as electrolytes (Alekseev: 2019).

To obtain highly refined billets (ingots) from alloys based on Co — Cr and Co — Cr — Ni with increased corrosion resistance and performance parameters that meet ISO standards for medical alloys, the Physico-Technological Institute of Metals and Alloys of the National Academy of Sciences of Ukraine tested new technological processes using combined vacuum-induction and electron-beam heating of the melt in vacuum. Ceramic materials have been selected and a technology has been developed for producing shell molds for the manufacture of cast structures for medical purposes with a reduced content of harmful impurities, non-metallic inclusions and gases (Maksyuta: 2011; Kuznetsov: 2018).

According to the analysis by A.A. Sultanov, Yu.Yu. Pervov on the modern understanding of the influence of the physicochemical properties of implants on inflammatory foci in the tissues surrounding the osseointegrated implant, a review of modern materials, metals and their alloys, as well as their oxides used for implantation and prosthetics, analyzed their biological, physicochemical, medico-technical properties. The work of scientists on the criteria for choosing the heads of the implant in contact with its surface with the epithelium of the gingival cuff, as well as on the biocompatibility of the implant with the tissues of the oral cavity. A review of works devoted to the study of the response of epithelial cells of the gingival cuff and bone tissue cells to the implantation of a dental implant is briefly presented. Analyzed are scientific materials devoted to the study of the degradation of the implanted material, which is one of the factors that reduce its properties and affect the tissue surrounding the implant. Possible complications arising from the introduction of implanted materials into the body, as well as the dependence of the course of complications on changes in the physicochemical properties of materials during their operation are indicated. Aspects of microbial contamination of the surface of dental implants and its relationship with biodegradation of the material are considered (Sultanov: 2019).

Vascular implants in contact with blood must have high thrombotic resistance. However, in some cases, their implantation is associated with thrombus formation and subsequent violation of the patency of the blood vessel. Most often, this problem affects implants intended for the reconstruction of small-diameter vessels, which is associated with the peculiarities of hemodynamics in this part of the bloodstream. These include blood vessel prostheses, tissue engineered vascular grafts, and endovascular stents. The features of the implant material are of great importance when choosing a method for its modification in order to improve biocompatibility and thromboresistance. The prospects of creating thromboresistant vascular prostheses and stents by joint immobilization of drugs with atrombogenic properties and biologically active molecules that regulate the response to a foreign body and implant remodeling on the surface of a polymer material have been assessed (Sevostyanova: 2020).

Nowadays, dentists and orthopedic surgery use such metallic materials as stainless steel, cobalt-based alloys, titanium and its alloys (Biomaterials, biocompatibility…; Popkov: 2014; Pogosyan: 2016).

A number of advantages of titanium alloys among other metallic materials can be noted: in terms of strength characteristics, titanium alloys are not inferior to cobalt alloys and stainless steel, while in terms of specific strength (σB / ρ) they can surpass them. In addition, titanium-based alloys exhibit a significantly lower elastic modulus E (50-121 GPa) compared to other metal alloys - stainless steel (190-230 GPa) and cobalt-based alloys (200-541 GPa), which provides better mechanical compatibility of titanium alloys with bone, the modulus of elasticity of which is less than 30 GPa (Lyubchenko: 2014).

In modern medical practice, implants made of titanium or titanium alloys, which are bioinert materials, are widely used to replace damaged or defective tissue sites, but rejection of such implants occurs in 5–10% of patients. In this regard, an urgent task is to increase the biocompatibility of implants. The development of a technology for applying a biocompatible coating to titanium implants involves the introduction of hydroxyapatite into the structure of the oxide coating of a titanium implant, which increases the degree of osseointegration of the implants (Rybakova: 2016; Meissner: 2016; Altynbekov: 2014).

Existing technologies do not fully meet modern medical requirements. This problem is solved by using various coatings:

- diamond-like carbon coatings - coatings formed by co-deposition of streams of erosional arc plasma of carbon and silver. They are highly biocompatible with tissues and the physiological environment of the human body. However, due to high internal stresses and insufficient adhesion, such coatings are of limited use for protecting the surface of surgical implants (Development of biocompatible…: 2013);

- glass-crystalline coatings applied to titanium implants in the form of a prepared suspension frit with the necessary additives and fillers (Kulmetyeva: 2005);

- oxide coatings on titanium obtained using the MAO installation - electrochemical process of modification (oxidation) of the surface of valve metals and their alloys in electrolytic plasma in order to obtain oxide layers (coatings) (Abramova: 2016);

To increase the biocompatibility of coatings, scientists Ya.A. Kamenchuk, T.V. Druzhinin proposed a composite coating for implants, including hydroxyapatite (HA). Currently, natural (biological) hydroxyapatite obtained from the bones of cattle is mainly used (A method of obtaining…).

Hydroxyapatite is a mineral Ca10 (PO4) 6 (OH) 2 from the apatite group, a hydroxyl analogue of fluorapatite Ca5 (PO4) 3F and chlorapatite Ca5 (PO4) 3Cl. It is the main mineral component of bones (about 50% of the total bone mass) and teeth (96% in enamel). The combination "implant + biocompatible coating" allows to combine high mechanical properties of the base material and biological properties of the coating, which give the implant surface properties that are as close as possible to the properties of bone tissue, which improves the ability of the implant to integrate with the body (Rybakova: 2013; Khakimova: 2017).

One of the promising methods for obtaining a set of required properties is high-frequency magnetron sputtering of KF coatings. This method can be used to form dense, non-porous, with high adhesion CF coatings of controlled chemical composition on most medical materials, providing osseointegration with bone tissue (Nurmukhanbetova: 2019).

Conclusion

In the development of metal implants, cobalt-chromium alloys are used less and less in osteosynthesis of bone tissue, and tantalum and niobium implants are not widely used due to the lack of a number of important mechanical and biological properties or their high cost. The alloying components included in their composition, as a rule, are extremely toxic to fabrics. It is believed that cobalt-chromium alloys, as well as steel, despite the fact that they have high mechanical and strength characteristics, in their biocompatibility are significantly inferior to metals and alloys of the capsule group, which are

capable of forming a protective layer on their surface. The latter are rightfully considered the metals of the 21st century (Alcantara et al., 1999).

On the basis of the above studies, less often the use of cobalt-chromium implants in medicine lead to a study of the biocompatibility of this implant.

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