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Biomechanical properties of composite compact-porous titanium produced by electric discharge sintering

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Abstract. The main disadvantage of currently used endosteal implants is their unsatisfactory biostable performance. Under action of functional stress caused by flaws of the design or lower mechanical characteristics the areas of stresses extreme concentration exceeding strength limits of bone tissue appears in the bone surrounding the implant that leads to the tearing away the implant. The problem of specific pressure lowering on the bone and uniform distribution of stress is solved by two ways: the increase of the implant area and the search of implant materials with optimum biomechanical properties. Porous materials of spherical titanium powders have adjustable pore size and large unit surface area, as well as possess high biologic compatibility with living tissue. This allows reduction of the rejection reaction due to a more even stress distribution around the functioning implant. Clinical results show that such implants have more stable physical and chemical properties.

1. Introduction

One of the area of application of composite titanium-based materials in medicine is implantation of artificial devices of various forms and purposes into the human body for replacement, reconstruction or repair of tissues and organs. For instance, according to the World Health Organization an uptake of patients older than 35 on the problems of restoring the function and aesthetics of dental system accounts for 98,8 % of the global population. Most of these complaints are related to the diseases leading to partial or complete loss of dentition, and can be solved by using various prosthetic devices with implants.

A review of scientific and medical literature on endosteal implantation [1-5] shows that the most widely used methods of ensuring human life activity are those based on scientific developments in production of new materials for manufacturing of medical devices.

The main disadvantage of currently used endosteal implants is their unsatisfactory biostable performance. Implants suffer heavy axial and bending stresses that transmit to the supporting bone. Concurrently, imperfect design solutions or wrong choice of materials cause formation of areas in the bone surrounding the implant where excessive stress concentration exceeds the limits of durability of the bone. This results in formation of traumatic capsule of connective tissue around the implant, and consequently, implants rejection. There are two ways of solving the problem of reducing the unit pressure on the bone surrounding the implant and ensuring uniform stress distribution in it: by

increasing implant area and by searching for implant materials with optimum biomechanical properties.

The use of devices with a surface layer of porous titanium powder [2] in modern medicine, especially in implant surgery, is conditioned by their important advantages in comparison to currently used cast titanium products with modified surface morphology. The porous layer formed by sintered powder has ramified spatial structure with a reduced modulus of elasticity. By its parameters it is well suited to penetrate bone tissue, allowing fixing the implant in the body of the patient for a lifetime. [3]. Adjustable pore size and large unit surface area allows even distribution of functional stress and reduction of the rejection reaction. Clinical results show that implants with a porous surface have more stable physical and chemical properties [4, 5].

The paper presents the structural and biomechanical properties of the compact-porous material composed of spherical titanium powders obtained by pulsed electric current sintering.

2. Materials and methods of research

One of the possible methods offered for producing the compact-porous material with a porous layer of spherical titanium powders is Electric Discharge Sintering (EDS). The EDS technology is based on a high voltage discharge of a capacitor bank through metal powder, contained in a dielectric mold between the electrode punches [6].

Experimental samples were produced by using commercially pure Russian titanium brand VT1-0 GOST 19807-91, which is close, by its chemical composition, to titanium brand Grades 1-4 ISO 5832/II or ASTM F 67-89 (Table 1).

Brand\Element	N (%)	C (%)	H (%)	Fe (%)	O (%)	Ti (%)
BT1-0	0,04	0,05	0,008	0,15	0,1	the rest
Grade 1	0,03	0,1	0,0125	0,2	0,18	the rest
Grade 2	0,03	0,1	0,0125	0,3	0,25	the rest
Grade 3	0,05	0,1	0,0125	0,3	0,35	the rest
Grade 4	0,05	0,1	0,0125	0,5	0,5 (0,4)	the rest

Table 1. Chemical composition of the titanium brands GOST19807-91 and ISO5832/II (ASTM F 67-89).

Spherical titanium powders produced by plasma dispersion in the vacuum of the rotating consumable electrode [7] had a nearly ideal spherical shape (Figure 1).

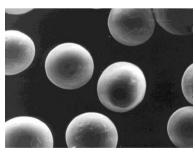


Figure 1. Particles of a spherical titanium powder, x50.

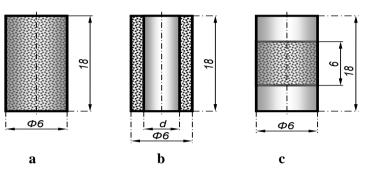
The experiments were conducted using the powders divided into fractions with particle size (0.16-0.2) mm, (0,2-0,315) mm and (0,315-0,4) mm. The powders of the selected fractions were used to produce cylindrical samples 6 mm in diameter and 18 mm length (Figure 2).

A distinct feature of obtaining the implant material samples by the developed technology is the use of EDS as an intermediate operation for preliminary formation of the porous layer. The final processing was conducted by a low-voltage pulse of electric current. This technology allows

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increasing the strength of the samples, the final sintering process is carried out at lower temperatures without the use of refractory forms and adjuvants. The concurrent shrinkage of samples is minimal, which allows avoiding the cracking and maintaining the accuracy of the geometrical sizes and forms [8].



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Figure 2. Sizes of the experimental samples of a porous (a) and 2 compact-porous material with an external (b) and internal (c) porous layer.

The microstructure of the powders and porous samples was studied on a metallographic microscope Polyvar (Reichert, Austria). The shape and the surface morphology of the powders were studied with a scanning electron microscope CamScan (Oxford, UK). The porosity of the experimental samples was determined by hydrostatic weighing. Studies of porosity distribution, pore size and the size of the contacts between powder particles in different sections of the samples were conducted in a software complex for image processing and analysis AUTOSCAN (Spectroscopic System, Belarus). The bending strength testing of the experimental samples was conducted on a universal testing machine model 1195 (Instron, UK) with the use of special tools.

3. Discussion of results

3.1. Structural properties of the porous layer

In experimental samples, there are clearly visible pores exposed over the entire surface of the powder layer formed by spherical titanium particles. (Figure 3, a).

Structural studies have shown that the porous layer has through porosity, uniformly distributed over the cross-section, with no dead-end pores.

Porosity of the obtained samples is in the range of 37% to 40% (Table 2), suggesting the absence of particle deformation and not entirely dense packing (minimum theoretical porosity of spherical powder particles of the same size forming a close-packed structure is 25.9%, maximum in free cubic packing is 47.6%). Consequently, the values of porosity for each fraction are nearly identical. The studies show that the porous layer with thickness of 2 to 3 particle diameters allows increasing by a magnitude of the effective surface area of implant interaction with the surrounding tissue without increasing its geometric dimensions. On the fractography images of the brittle fracture of the samples there are clearly visible good contacts, both between individual titanium particles in the porous layer, as well as between the particles of the porous layer and compact titanium (Figure 3, b).



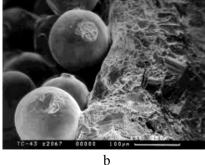


Figure 3. The external appearance (a) and morphology of a brittle fracture (b) of the experimental samples of a compact-porous titanium.

For production of endosteal implants of various designs and applications, the important characteristic that defines their consumer properties is the size of the pores where the ingrowth of surrounding tissue occurs. Research studies show [3-5] that the pore size ensuring germination and good bone implant fixation should exceed 100 microns. For practical purposes the pore size greater than 100 microns is recommended for extensive bone ingrowth and strong interface fixation to occur. The desired pore size can be achieved by using powders with different particle size (Table 2).

Table 2. Structural properties of a porous layer of the samples.

Particle size (mm)	Porosity (%)	Average pore size (µm)
0,16-0,2	37-38	56-80
0,2-0,315	37-38	80-136
0,315-0,4	38-39	127-198

3.2. Biomechanical properties

Duration of service for the implants in the human body largely depends on the mechanical properties of the materials used for their production. The elastic modulus of compact titanium and its alloys (110-112 GPa) is closest to the elastic modulus of bone (10-30 GPa) [9]. Porous layer of spherical titanium powders has lower density characteristics comparing to ones of compact material but is has nearly the same range of elastic modulus as bone tissue. (Table 3). This distinct feature of the porous titanium presents various opportunities for optimization of biomechanical properties in new constructions of surgical implants.

Table 3. The mechanical properties of a porous layer of the samples.

Particle size (mm)	Elastic modulus (GPa)	Compressive strength (MPa)
0,16-0,2	38-41	194-198
0,2-0,315	27-30	145-149
0,315-0,4	17-21	47-51

Since endosteal implant structures typically use parts made of composition of porous and compact titanium, a research was conducted to evaluate the durability of connection of porous compact layer to the compact part of samples on a flat surface (table 4).

Table 4. The strength of a porous and compact titanium coupling.

Particle size (mm)	Shear strength (MPa)	Tearing strength (MPa)
0,16-0,2	81-85	37-43
0,2-0,315	72-76	26-29
0,315-0,4	49-53	17-19

Using of compact-porous titanium as an implant material allows a very flexible selection of their elastic characteristics in accordance with the existing bone structure. The module of the elasticity of the implant may vary in length depending on the ratio s/S, which defines the relative cross sectional area of the compact part of the implant (Figure 4).

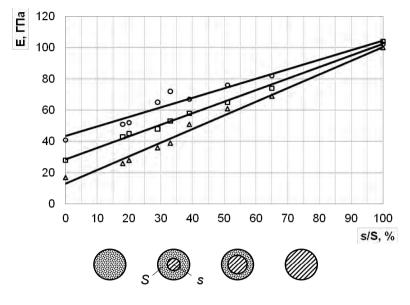


Figure 4. The dependence of a compact-porous titanium modulus of elasticity from the correlation of cross-sections

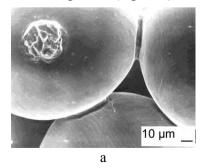
- -(0.16-0.2) mm:
- -(0,2-0,315) mm;
- \triangle -(0,315-0,4) mm

The main parameter for biomechanical assessment of strength of implant bonding with the bone (osseointegration) is shift pressure or amount of force per unit of implant surface area, which leads to the detachment of the implant from the bone. This index depends on the ratio of strength of the implant displacement to the area of its lateral surface. Comparative experimental studies conducted on fragments of animal bones with implanted samples made it possible to define shift pressure for titanium samples with various surface textures, including smooth, corrugated, helical and porous, 6 months after implantation (Table 5). The maximum cracking pressure on the porous layer of powder particles with size of (0,315-0,4) mm was 22 MPa, which exceeds the value of unit cracking pressure of implants with a smooth surface by 3.9 times, with ribbed - by 1.8 times, with threaded - by 1.2 times.

4. Application of composite compact-porous titanium.

Equipment and mechanisms for production of endosteal implants of various shapes and sizes were made based on the developed technology. Technology application allows forming porous layers one or two powder layers thick, on devices the size range of 2 mm to 100 mm.

The conducted technical, biomedical and clinical trials have shown that the compact-porous titanium implants have biomechanically optimal density and structural characteristics, does not have general toxic, irritating and allergenic effects on the body, shows a high degree of biocompatibility and osseointegration (Figure 5).



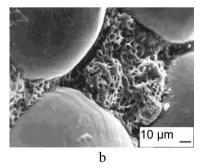


Figure 5. The structure of the porous layer of spherical particles of titanium (a) and a bone tissue germinated into it (b).

Designs of endosteal implants made of compact-porous titanium has been developed for use in dentistry, maxillofacial surgery, traumatic surgery (Figure 6), and other fields of medicine.

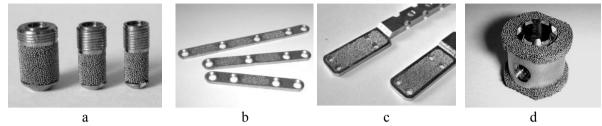


Figure 6. Medical devices made of compact-porous titanium dental implants (a), plates for the fusion of bones (b), implants of low jaw (c), and an implant for interbody fusion of the vertebrae (d).

5. Conclusions

The use of porous composite porous-compact materials in implants shows that the endosteal implants with a porous layer of spherical titanium powder possess high biological stability in the body and can be implanted for life. The results of twenty years of clinical studies show that large unit surface combined with small geometric sizes, high mechanical strength, good adaptation to the bone structure and biocompatibility provide porous-compact implant materials advantages in durability compared to the monolithic materials with surface modified by various technologies.

Clinical results

The above-described endosteal implants with a porous layer of spherical titanium powder successfully passed the certification tests and has been approved for serial production and use in medical practice in the Republic of Belarus.

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