EXPERIMENTAL METHODS FOR CLINICAL PRACTICE

Osteal Integration of Porous Implants from Titanium Nickelide

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The microstructure of preparations from porous titanium nickelide was studied 4.5 months and 1.5 years after operations on the anterior compartments of the spine. Organic tissues of different morphology, compactness, and thickness occupied 100% of analyzed surface 1.5 years after implantation, while after 4.5 months the pores were filled by 60%. The content of calcium and phosphorus elements in surface pores after 1.5 years was close to their concentrations in human bones.

Key Words: *bone integration; porous implant; titanium nickelide*

Implants from porous titanium nickelide are widely used for repair of defects in cancellous and tubular bones in surgery on the joints, primarily in surgery of the spine. All constructions from porous titanium nickelide are intended for single life-time implantation. Bone tissue is assumed to grow into open pores on the implant surface and is formed in pores from cell structures brought with blood. Bone integration provides stable position of the implant and prevents its destruction under the effect of functional loading throughout the life span [1-3].

Experiments were carried out on various animals (rodents, dogs, sheep) for evaluation of the period needed for bone integration, the degree of pore filling with the bone, and quantitative assay of mineral components of the bone [4].

However, we found no reports about the structure of porous implants in human body.

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We evaluated the degree of bone tissue integration in the porous implant and measured calcium and phosphorus content in the bone tissue in implant pores at different levels of its volume.

MATERIALS AND METHODS

We evaluated the degree of bone tissue integration into porous titanium nickelide constructions implanted to two patients for creation of the L_5-S_1 vertebrae arthrodesis and replacement of destroyed C_5-C_6 vertebrae.

In patient K. (36 years) with second-degree isthmic spondylolystesis, interbody spondylodesis with a porous screw implant from titanium nickelide was carried out at L_5-S_1 level on May 30, 2006 (Fig. 1, *a*, *b*). On September 2, 2007 the patient was hospitalized at Department of Neurosurgery with severe craniocerebral trauma. After his death the osteal block with porous implant was removed. The construction was completely consolidated with bone tissue and it was impossible to separate it. The bone block was plunged in 7% neutral formalin.

Patient K., 51 years, was hospitalized on December 3, 2007, at Neurosurgery Clinic of Municipal Hos-

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pital No. 29 in Novokuznetsk. He complained of pain in the upper limbs and presented with clinical picture of neurological disorders caused by compression of the spine by porous implant. Ventral polysegmentary spondylodesis was carried at the level of C_4-C_6 on July 11, 2007 with gross errors (Fig. 2, *a*).

On December 6, 2007 the implant was removed in order to eliminate spinal compression. After ineffective attempts at separation of the implant, the construction was fragmented by crown cutters, bone forceps, and conchotomes. The implant fragments from surface and deep layers were placed into different flasks with 7% formalin.

The microstructure of the preparations was studied under an Axiovert-200M optic microscope. After drying at 50°C for 48 h in a dry hot camera the preparations were embedded in epoxy resin. The surface was polished using diamond pastes with 60/40 to 3/2 μ granularity, applied to paper. Final polishing was carried out with a 1/0.5 μ diamond paste applied to silk cloth.

The microstructure of preparations was examined by high resolution light microscopy by comparing the phase contrast (obtained by optical differentiation interference contrast) and bright-field images. Due to difference in the path of coherent polarized light beams reflected by the surface of different compactness, it is possible to detect thestructural characteristics of tissues incorporated in titanium nickelide pores.

Chemical composition of the preparations was evaluated by microroentgenospectral analysis on a CMEBAX-MICROBEAM device at accelerating voltage (20 kV) and beam path of 10^{-8} A. The locality of analysis was about 3 μ^3. The specimens not conducting electric current were sprayed with an electroconducting coating (gold). The content of elements in the studied phases was evaluated by conversion of the intensities of characteristic lines in the sample and reference sample using standard software making use of the ZAF correction method.

RESULTS

Optically compact tissue reflecting the structure of inert mineral phase of the bone was detected in pores

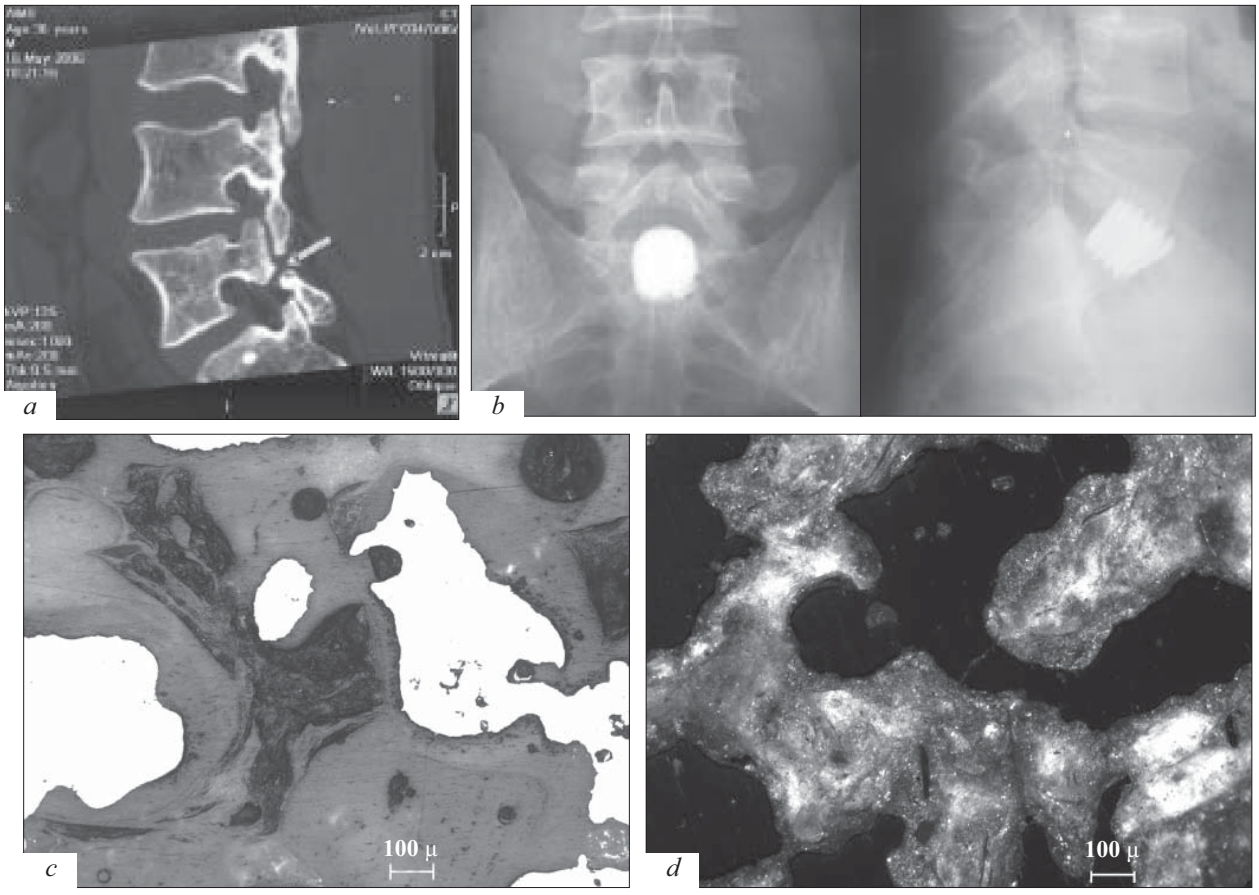

Fig. 1. Osteointegration of a porous implant 1.5 years after the operation. *a*, *b*) before and after inter-body spondylodesis operation in patient K. aged 36 years; *c*) surface microstructure of implant (bright-field image), 100% incorporation of bone tissue in the pores; *d*) microstructure of deep pores of the implant (optical differential interference contrast method), 100% compact incorporation of biological tissue of different morphology in the pores.

close to the implant surface 1.5 years after interbody spondylodesis. Optical density in the median part of the pore is reduced in the bright-field image, creating the picture of trabecular network of bone tissue with alternation of strips with different optical density. A thin edge of the tissue with uneven thickness and granular structure is directly adjacent to the metal surface (Fig. 1, *c*, *d*).

A more precise picture of the heterogeneous tissue structure in the inner pores of the implant can be obtained by differential interference contrast method based on intensification of diffuse coherent optical radiation of different wavelengths and providing the appearance of images of compact to half-transparent organic tissues on a metal sublayer. Color image shows the morphology of the mineral complex consisting of grains less than 1 μ in size at the periphery of the pore. Organic tissues of different morphology, compactness, and thickness occupy 100% area of the analyzed surface, this indirectly indicating high integration of the implant into biological tissue.

One and a half year after implantation, the pores outside and inside the construction were completely filled with the bone tissue. Bone integration significantly improved the break resistance of porous implant, which was 9300 H (*vs.* 2500 H in an analogous porous construction), *i.e.* significantly lower than the strength of lumbar vertebral bone (13,000 H). Rotation resistance of the implant was not evaluated because of insufficient volume of the implant material.

Study of fragments of the porous construction 4.5 months after implantation showed 100% filling of the pores with bone tissue at the depth of 2-3 mm. Light areas on bright-field images corresponded to bare me-

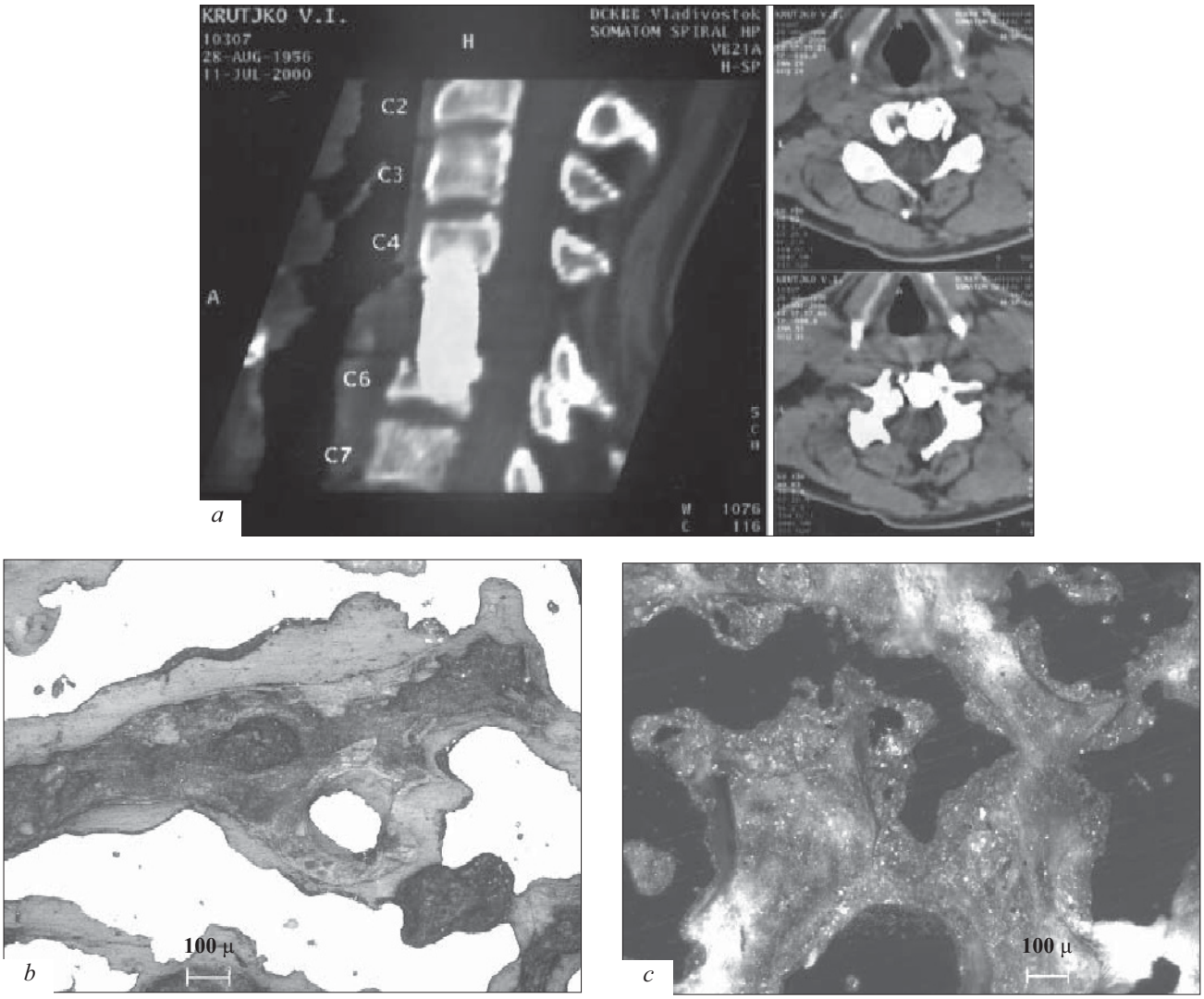

Fig. 2. Osteointegration of a porous implant 4.5 months after operation. *a*) partial prolapse of the porous implant into the spinal channel; *b*) the area of optically dense mineral matrix in the implant surface pores is $^1/_3$ of analyzed pore surface; *c*) the pores in deep layers of the implant are 60% filled by biological tissue *vs*. analyzed surface.

TABLE 1. Content of Ca^{2+} and P^{+} in Surface and Deep Layers of Porous Implants 4.5 Months and 1.5 Years after Surgical Anterior Interbody Spondylodesis

Site of sample collection	Time after implantation			
	4.5 months		1.5 years	
	±1.0 atom.%			
	Ca	P	Ca	P
Surface layers of implant	18.8	10.1	69.2	30.8
Deep layers of implant	9.4	4.3	32.6	13.4

tal surface. Fine protein-like tissue transforming into a layer of tissue of more solid structure was directly adjacent to the metal surface. Lamellar structures of different compactness, incorporating concentric formations, corresponding to the osteon, were seen in the center of the pore. All tissue types were located inside the pore in a regular order; the interface areas between these tissue types were characterized by an intricate relief and incorporated in deeper layers.

The volume of mineral matrix was 3-fold less than the volume of organic matrix and its volume was significantly less in deeper pores, which were just 60% filled in comparison with surface pores (Fig. 2, *b*, *c*).

Quantitative content of calcium and phosphorus corresponded to the results of optical studies (Table 1). The Ca:P ratio was 2:1 in all specimens. The content of calcium and phosphorus was 3-fold below the normal in all samples from surface pores of the construction removed 4.5 months after implantation. The volume of these elements in surface pores 1.5 years after implantation virtually reached the normal [1]. However, the content of calcium and phosphorus in deep pores was 2-fold lower than in surface pores.

Hence, 100% integration of the bone in the surface pores was observed 4.5 months after implantation of a construction from porous titanium nickelide. This provided stabilization of the implant in the bone tissue of the vertebral body and prevented free mobilization of the implant from the adjacent tissues. Bone tissue integration in porous implants 1.5 years after interbody corporodesis 4-fold increased the strength of the implant.

Osteointegration of the bone in porous implant meets the requirements to the use of porous constructions for repair of defects and vertebral body arthrodesis. However, it was impossible to mobilize the construction from the bone 4.5 months after implantation. Hence, absolutely strict adherence to the protocol of surgical intervention (implantation of porous constructions) is obligatory.

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