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Development of personalized approach to the reconstruction of bone tissue defects using porous ceramic osteoimplants

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Abstract. A fundamentally new complex technique for preoperative planning and creation of individual implants from ceramics for the reconstruction of the maxillofacial region is clinically applicable and in demand in modern trends of reconstructive surgery were developed and approved. The developed method implies using of alumina based ceramic material, which meets the requirements for medical materials used in reconstructive surgery.

It was shown that by varying the initial composition of the ceramic powder material, it is possible to achieve structural and mechanical affinity with the surrounding bone tissue. Building a 3D model of an osteoimplant on the basis of a computed tomography of the patient avoids the need for additional resection of the bone tissue and ensures complete geometric conformity of the osteoimplant to the prosthetic area.

The method was approved by the reconstruction of the patient's skull-orbital complex using a three-dimensional personalized ceramic implant. The complete absence of the inflammatory reaction after surgery was observed.

1. Introduction

Despite the small proportion of maxillofacial tumors (about 0.5%) in the overall structure of malignant tumors, their treatment is one of the most difficult problems in modern oncology [1]. The peculiarity of the maxillofacial region structure causes the rapid spread of the tumor process along the bone structures and soft tissues of the near regions. The local prevalence of tumors requires extensive resections leading to the formation of postoperative defects, but the possibility of reconstructing the defects with the body's own tissues is limited. Thus, the problem of finding new, safe, effective techniques for the reconstruction of the maxillofacial region defects is urgent task.

In modern reconstructive surgery research is aimed at developing an individual technology of endoprosthesis of the skull facial region. This direction contributes to the rapid development of 3D technology and 3D printing [2].

This may be the solution in developing a method for individual implants for reconstruction of maxillofacial area defects by using 3D prototyping technologies, ensuring the structural identity of the implant with bone tissue by organizing a hierarchical pore structure and identity of the implant mechanical properties to the properties of bone tissue.

At the present time, due to the combination of high chemical, corrosion and wear resistance and high strength there is a steady tendency to replace metals and polymers in artificial implants with ceramics [3, 4]. A special attention among the materials used for bones prosthetics deserve oxide ceramics, such as zirconia and alumina [5, 6]. These ceramics are close to the inorganic matrix of bone



tissue by the type of chemical bond and included in the ISO registry as materials for osteoprosthetics (ISO #6474-1:2010). Al_2O_3 and ZrO_2 are not perceived by the body as heterogenous and biochemical reactions at the interface with bone can lead to tissue invasion into the implant pore volume and provide conditions for osteogenesis [7-9]. Further, unlike metals and polymers, ceramic can be sterilized by all currently used methods: dry-heat cabinet, autoclaving, exposure to ozone, ultrasound and ionizing radiation.

The aim of this study is to develop a new approach to the personalized reconstruction of the bone defects of the maxillofacial region with implants based on alumina ceramic.

2. Materials and experiments

A virtual planning of the maxillofacial area defect reconstruction with 3D model of implant was used. Procedure of implant modeling was based on the data of the preoperative spiral computed tomography of the patient's maxillofacial region. The use of such technique and the close cooperation of the surgeon and the engineers at the stage of preoperative planning allow creating an implant as close as possible to a specific reconstructive task. [10, 11]

Ceramic osteoimplant was obtained using the method of precision additive prototyping with complex volumetric configuration. An inverse matrix of the implant 3D model was obtained, into which the fluid mass based on ceramic powder and organic plasticizers was injected into matrix with subsequent annealing and sintering, leading to the consolidation of ceramic powder into a 3D ceramic osteoimplant with a complex geometry and pore structure. The pores were obtained due to the burning out of the organic plasticizer and pore-forming particles during annealing.

Sample of an osteoimplant was obtained for the reconstruction of the cheek-orbital complex. The created implant replicate the shape and contours of the defected bone area of the facial part of the skull, figure 1.



Figure 1. Ceramic osteoimplant skull-orbital complex and model of patient's skull.

Structural and mechanical studies of the material of the endoprosthesis were carried out: the microstructure was studied using scanning electron microscopy; flexural strength by three point bending method.

Obtained ceramic implant was sterilized by dry-heating and autoclaving. Implant fixation was carried out by mini-screws to the bone edges of the defect with subsequent control of fixation and covering with surrounding soft tissues and skin grafts.

3. Results and discussions

Studies of the ceramic have shown that by introducing an organic plasticizers and different rate of pore-forming particles in the initial powder composition it is possible to control the pore structure. This approach allow to obtain two types of pores: micropores, due to the presence of space between

the particles of ceramic powder, and the macropores that inherit the configuration of pore-forming particles, figure 2.

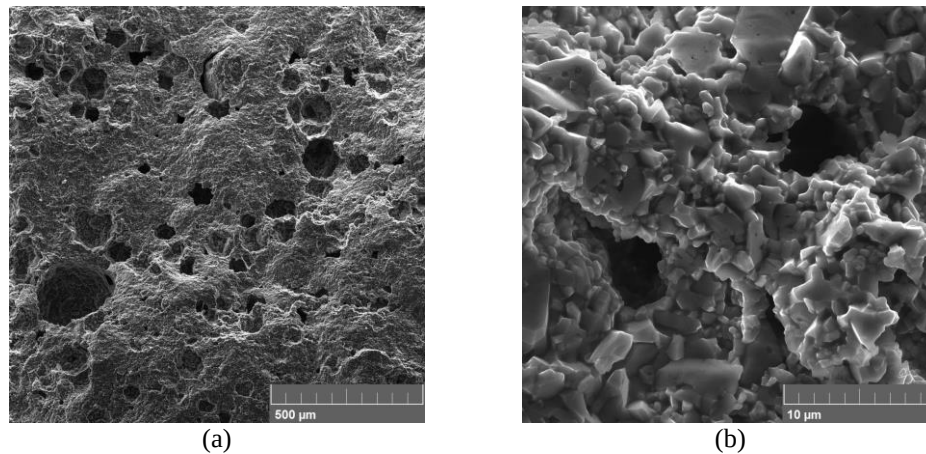


Figure 2. Pores on the fracture surface of Al_2O_3 ceramic.

The strength of alumina ceramic significantly exceeds the strength of bone tissue, which undoubtedly leads to destruction of bone tissue in the contact area of the implant-bone system due to abnormal internal stress distribution. Reducing the strength of the ceramic to the level of bone tissue strength is one of the main conditions for ensuring the biomechanical compatibility of the endoprosthesis. The organization of a developed pore structure reduces the strength of alumina ceramic to 97 MPa, figure 3, table 1. The increase of porosity leads to strength decreasing, which is consistent with the strength of various types of bone tissue [12].

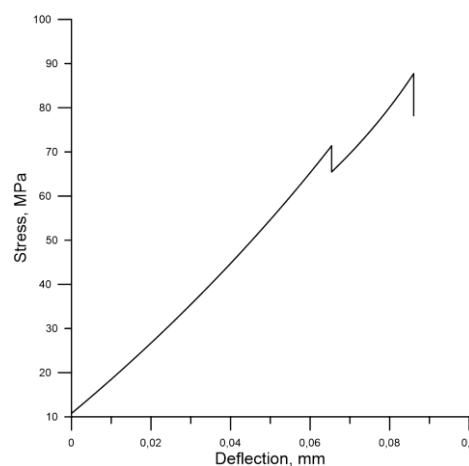


Figure 3. Stress-deflection dependence of Al_2O_3 ceramic with 53 % of porosity.

Table 1. Porosity and bending strength of Al_2O_3 ceramic

Porosity, %	Bending strength, MPa
4 %	284.5
11 %	246.3
39 %	117.2
53 %	96.6

The bones of the facial region of the skull have the most complex geometry among all the bones of the skeleton, which significantly complicates its prosthetics. The task of replacing postoperative bone defects in this case is not only the restoration of the mechanical functionality of the prosthetic area, but also more complex aesthetic aspects, such as the restoration of facial expressions, articulation and the facial contour [4]. The discrepancy between the geometry of the osteoimplant and the geometry of the resected fragment of the facial skeleton leads to limited mechanical functionality, impaired facial expression and articulation [12].

Modern reconstructive surgery of the maxillofacial area tends to single-stage procedure, reducing the number of postoperative complications, and choosing the method most safe for the patient, which will allow to achieve the earliest functional and social rehabilitation [13]. The use of generally accepted methods of postoperative bone defects of the maxillofacial region recovery (microsurgical reconstruction) have certain disadvantages: multistage, additional surgical trauma, high cost of treatment.

Full replacement of the body's own tissues with implants is possible only with full biochemically and biophysically compatibility with the surrounding tissues. From the point of view of reconstructive surgery, the implant should have a maximum affinity with the resected bone tissue of the maxillofacial region, and perform the function assigned to this region (protective, supporting, chewing, etc.) [14]. Ideal for mechanical stability of the implant is the bone tissue integration in the pore volume of implant. This leads to the stability of the implant with the functions it performs and the absence of inflammatory changes in the surrounding tissues.

By the method of creation a personalized of complex-shaped ceramic products, an osteoimplant of the skull-orbital complex was prepared and a surgical operation on its implantation was performed, figure 4 (a). In the area of reconstruction, there were no signs of active inflammation, figure 4 (b). The approach based on creating three-dimensional personalized osteoimplants from porous ceramic satisfies current trends in reducing the duration of surgery, reducing the area of bone resection and preventing the risk of complications.

It should be noted that the duration of the reconstructive surgery is reduced with using an individual ceramic implant compared to standard bone grafting from 540 to 360 minutes. An earlier restoration of the physical activity of patients in the postoperative period and a reduction of the postoperative period stay in the hospital compared to the bone grafting techniques.

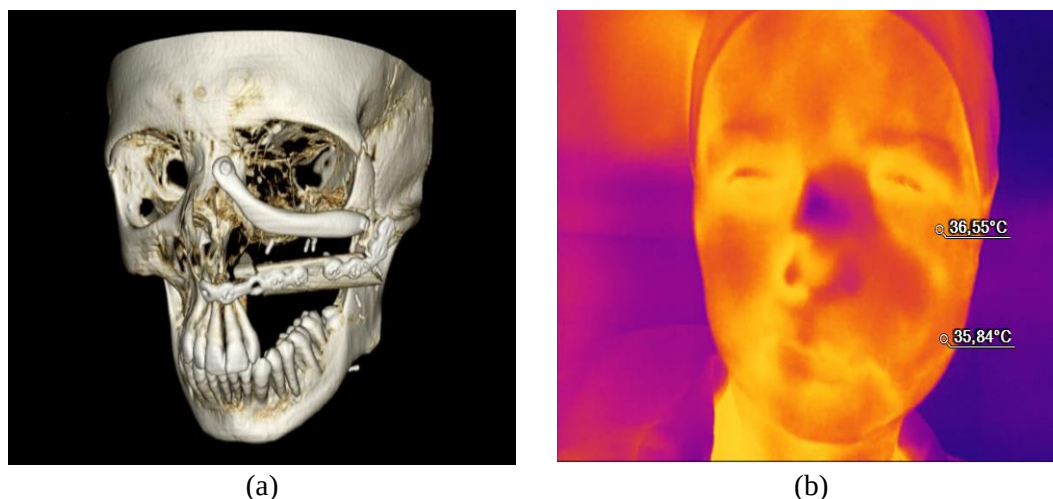


Figure 4. Ceramic osteoimplant and skull model (a); Postoperative thermogram (b).

4. Conclusions

In this study were developed a fundamentally new approach for the reconstruction of the maxillofacial area using 3D-printing technologies for producing geometrically complex ceramic-based implants.

The developed complex technique for preoperative planning and creation of individual implants from ceramics for the reconstruction of the maxillofacial region is clinically applicable and in demand in modern trends of reconstructive surgery. Performing reconstructive surgeries using ceramics implants allows to achieve high functional and aesthetic results, as well as improving the life quality of patients with maxillofacial tumors without causing additional operating injury to the patient.

The developed ceramics material meets the requirements for medical materials used in reconstructive surgery. By varying the composition of the ceramic, it is possible to achieve structural and mechanical affinity with the surrounding bone tissue. Building a 3D model of an osteoimplant on the basis of a computed tomography of the patient avoids the need for additional resection of the bone tissue and ensures complete geometric conformity of the osteoimplant to the prosthetic area.

The clinical application of the developed technique for reconstruction of the maxillofacial area allows solving a complex problem that causes social isolation and functional disability of patients after surgical removal of maxillofacial area tumors – reducing the trauma, inefficiency and cost of reconstructive operations on the craniofacial area cancer patients.

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