

A NEW BIOACTIVE BONE - REPLACING MATERIAL FOR MAXILLOFACIAL SURGERY

ULYANOVA T.M*, TITOVA L.V.*, EVTUKHOV V.L.***, CHYDACHOV O.P.***, BYKADOROVA L.G.**

*INSTITUTE OF GENERAL AND INORGANIC CHEMISTRY, NATIONAL ACADEMY OF SCIENCES, MINSK, BELARUS

**BELARUSIAN STATE MEDICAL UNIVERSITY, CHAIR OF MAXILLOFACIAL SURGERY, MINSK, BELARUS

Within the past few years a number of investigations on the contacts of a bone with an implant made of different materials: metallic, glass, crystal, ceramic, calcium phosphate as well as on metallic hydroxyapatite-coated implants have been undertaken [1,2,3]. As a result, the data obtained have been reported. In the Republic of Belarus efforts are also underway to prepare new bone-replacing materials. The researchers from the Institute of General and Inorganic Chemistry and the State Medical University have developed and examined a new calcium phosphate bioactive implant material "Kafam", meant for replacing the bony defects of a maxilla. This project was performed at a suggestion by the State Scientific Technical Programm "Stomatology and Maxillofacial Surgery".

A chemical composition of ceramics "Kafam" corresponds to that of the mineral part of a man's bone, and the calcium-to-phosphorus ratio is 1.67-1.77, depending on pre-treatment and annealing temperature. The material "Kafam" does not contain heavy admixtures bad for the man's health. The crystalline structure of calcium phosphate ceramics corresponds to that of hydroxyapatite added with small amounts of calcium and magnesium phosphate and is similar to the matrix structure of a man's bone. The material "Kafam" has a porosity of 45-65%, and a macropore size is 200-600 μm . For comparison, a macropore size of a native spongy bone of a man is within 100-800 μm .

The above material can with-stand 1hr sterilization at 180°C, preserving its structure and properties. It is fabricated in two main forms: a granulated material with a granule size from 0.1 to 2.00 mm and a block porous material with a density of 0.8-1.6 g/cm³ and a compression strength of 3500 kPA. Missing fragments of a maxilla are made of "Kafam" blocks. Comprehensive sanitary-hygienic and toxicological studies were carried out to elucidate the possibility of using a ceramic material "Kafam" in medicine. In accordance with the requirements of WHO, Medical-biological and morphological research was performed in full on small and large laboratory animals [4].

Relying on the investigations made, it was established that the developed material was not toxic and was given the 4th class of danger (GOST 12. 1.0007-88). The material "Kafam" is compatible both with a bone and with soft tissues. It is gradually resorbed and replaced with a young bony reagent.

During medical tests calcium phosphate ceramics "Kafam" with a granule size of 0.3-0.5 mm was used to fill the bony cavities of 32 patients who underwent operations. Among them, 26 patients suffered from radicular cysts of the maxilla, one-from dental retention, one-from polycystosis, one-from cystagranuloma and three - from chronic granulomatous periodontitis. In the act of operating, the bony cavities of the main group of patients were filled with the material "Kafam" at one third of volume (4

patients) or fully (28 patients) after the tumours had been removed. In all, 26 women and 6 men at the age of 14 to 50 years were operated. In addition to control patients were operated using the traditional surgical methods. It was the case when the bony cavity was filled with a blood clot.

Before and after the operation the maxillae of all patients were subjected to X-ray examination. Zonograms or dental pictures were taken with regard to medical indications. During the postoperative period medicine therapy was prescribed following the traditional scheme: antibiotics, analgetics, and local hypothermia over a postoperative area for 2 days. Every day medical examination was performed and temperature was measured. A postoperative period of all patients was taking a normal course. Sutures were removed after 6 days. No suture disjunction was seen in none of the observations.

Based on the results of the comprehensive technical and medical-biological studies, a new bone-replacing implant material "Kafam" was developed in granular and block forms. The first stage of clinical tests performed by the specialists of the chair of Maxillofacial Surgery at the State Medical University substantiated the possibility of using calcium phosphate ceramics "Kafam" for filling bony defects after benign tumours had been removed.

References

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