# THE IMPLANT MATERIAL FOR MAXILLOFACIAL SURGERY

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## Introduction

New biocompatible materials are developed to replace the lost or traumatic organs. In particular, the implants made of metallic, ceramic, polymeric and composite materials are used in orthopaedic stomatology and maxillofacial surgery [1].

Alumina ceramics are the recognized material for implantology because they are corrosion-resistant, chemically inert and possess good tissue compatibility. The elastic moduli of ceramics and bones are close in magnitude [2].

The ceramic dental implants are produced by different comopanies in Europe, the USA and Japan. German scientists used high purity alumina [3], Russian and Ukrainian researchers introduced special additions to alumina [4]. In Poland the corundum implants were successfully applied to replace the vertebrae [5].

The objective of the present work was to study the compatibility of ceramic material Alumag-1 and to examine its behaviour in clinical practice.

## Experimental procedure

$Al_2O_3$ fibres with an addition of MgO were employed as starting material to prepare corundum ceramics. These fibres were chosen because of their chemical stability, porosity, developed surface, and capability of forming both dense and porous ceramic materials on sintering. Synthesis of oxide fibres was made according to the earlier elaborated method [6]. The prepared fibres were crushed, ingots were moulded and sintered at 1500-1600°C. Formation of ceramic fibres and their structures were investigated by thermal analysis, X-ray phase analysis, IR spectroscopy and scanning electron microscopy. Density, porosity, hardness, and strength of the prepared ceramic materials were determined by standard methods. Specific surface of fibrous powders was determined by the BET method, with the use of the isotherms for porous material sorption-desorption of benzene vapours.

Sanitary-and-chemical studies were performed by the standard methods [7]. Biomedical tests were made on mice, guinea-pigs, rabbits, and dogs.

Observation periods were from 1 week to 1 year. Morphological examinations of the section of a bone tissue taken at a place of contact with an implant were made by an optical microscope. Preparations were decalcified and colored with hematoxylin and eosin.

For clinical trials the miniplates with four holes were produced from the material Alumag-1. Clinical tests were executed at the maxillo-facial surgery department of Minsky State Medical Institute and at 9 Clinical hospitals.

## Results and discussion

The fibrous powders were pressed into plates, which were thermally treated in a special regime up to 1550-1600°C. Their apparent specific density was 3.9 g/cm$^3$, bending strength - 310-325 MPa, compressive strength - 3200 MPa, hardness - 88-90, Young's modulus - 370 GPa, electrical resistivity - $0.5\times10^{14}$ Ωcm and thermal conductivity - 20 W/mK. The obtained samples were subjected to multiple heating in the air at 200°C, followed by cooling. Structure and physico-mechanical properties of the samples did not change, i.e. they were capable of enduring hot sterilisation.

To assess biocompatibility of the prepared material the sanitary and hygiene and toxicological studies were performed and revealed high chemical stability in neutral, alkaline and acidic media. The material was ranked among low-toxic and low-hazard substances (IV hazard class according to GOST 12.1.007-76) and did not cause any irritating or allergic effects. The reaction of the surrounding tissues and the symptoms of common toxic effect were not observed during 12 months after the implantation of aluminium oxide ceramics into the muscle tissue of the guinea-pigs.

Biomedical tests were also performed on big animals (dogs). Under intravenous thiopental narcosis into the dog's corpus and ramus of the mandible, an aluminium oxide ceramic implant was inserted in the artificial defect of the mandible. After 1, 2, 3, 4 weeks and 1 year, animals were taken out of experiment and the mandible bone sections together with the implants placed there were extracted. Experimental times to observe morphological changes of bone tissues implanted with ceramics were chosen on the basis of the literature data [8].

Altogether 142 preparations of bone sections being in contact with the corundum implant were examined. Microscopic studies of decalcified bone tissue sections revealed that in one week after the implantation, some fibrous and osteogenic tissue cords with developed trabeculas of a young bone appeared at the contact place. No inflammation signs were observed. In two weeks after the operation, a reclaim continued to mature. In three weeks a relationship between the newly formed bone bars and collagenous fibres did not change, i.e. the bone reclaim continued to mature at the place of contact with the implant. In four weeks the newly formed bone in the form of coarse cords and extensive fields separated by fatty bone marrow-filled cavities was found at places of contact of the implant with the matured bone. It was revealed that a gentle fibrous tissue with a great number of vessels appeared in some medullar cavities. After a year the mature bone with well-developed bars and fatty bone marrow was found at the defect place.

During clinical trials the following medical instruments were used: a set of standard screw-drivers for carrying out an osteosynthesis with the help of miniplates, a set of punches for making holes in a bone, a standard set of screws for osteosynthesis of mandibles, drilling device, a complete set of miniplates of alumina ceramics with 4 holes. The plates of Alumag-1, prepared for operation, were sterilised by a dry-heat method at 180-200°C for 60 min.

Before the operation the patient was subjected to splinting of both jaws. The operation of osteosynthesis was conducted under endotracheal anasthesia with endonasal intubation. During the operation the bite was confronted in the central occlusion and temporarily fixed by rubber rings or metallic ligatures.

The access to the jaw fragments was accomplished from an external incision, at a distance of 2 cm from the mandible edge. After denudation of the field of fracture and skeletization of the mandible fragments they were repositioned. Then a perceiving platform for miniplate was built on the external cortical surface of the mandible. The shape and dimensions of the perceiving platform should be perfectly adjusted to the surface of the miniplate in order to create close contact of the plate and the mandible and to avoid fractures of the ceramic plate after the operation. To make the perceiving bed for the plate, a cylindrical cutter with rounded edges was used. With the help of this cutter all roughness was polished away from the external cortical plate of the mandible and then the miniplate was inserted.

The selected ceramic miniplate was placed on the perceiving platform of the jaw so that on both sides of the fracture line there was enough room to accomodate the screws. The plate should be closely connected to the mandible surface but it is necessary to screw it very carefully, with some safety margin, in order to prevent its fracture. The fixation screws should not penetrate the zone of traumatic focus. This could lead to the development of a traumatic osteomyelitis of the mandible. The miniplate, fixed to the jaw fragments with titanium screws, is presented in Fig. 1.

In the case of bilateral osteosynthesis the fixation of jaw fragments was begun from the side with larger displacement of the osteal fragments. The stitches were put into the operational wounds only after the fixation of fracture from both sides. After the operation the fixation between the jaws was removed. The patient was extubated. In the postoperative period of two weeks the occlusion was fixed by rubber rings.

To check the quality of fixation of mandible osteal fragments with the help of the alumina ceramics plates the radiographic control was continued in the postoperative period.

During clinical testing of the investigated material 19 patients were operated. Unilateral and bilateral osteosyntheses of fractures in the field of angle and body of the mandible were carried out. After 24-30 days in all of the cases the consolidation of osteal fragments was successful.

## Conclusion

According to the results of complex sanitary, chemical and medico-biological tests, the new ceramic material Alumag-1 was found to be non-toxic and biocompatible.

The application of miniplates made of Alumag-1 provides firm fixation of osteal fragments and establishes favourable conditions for consolidation.

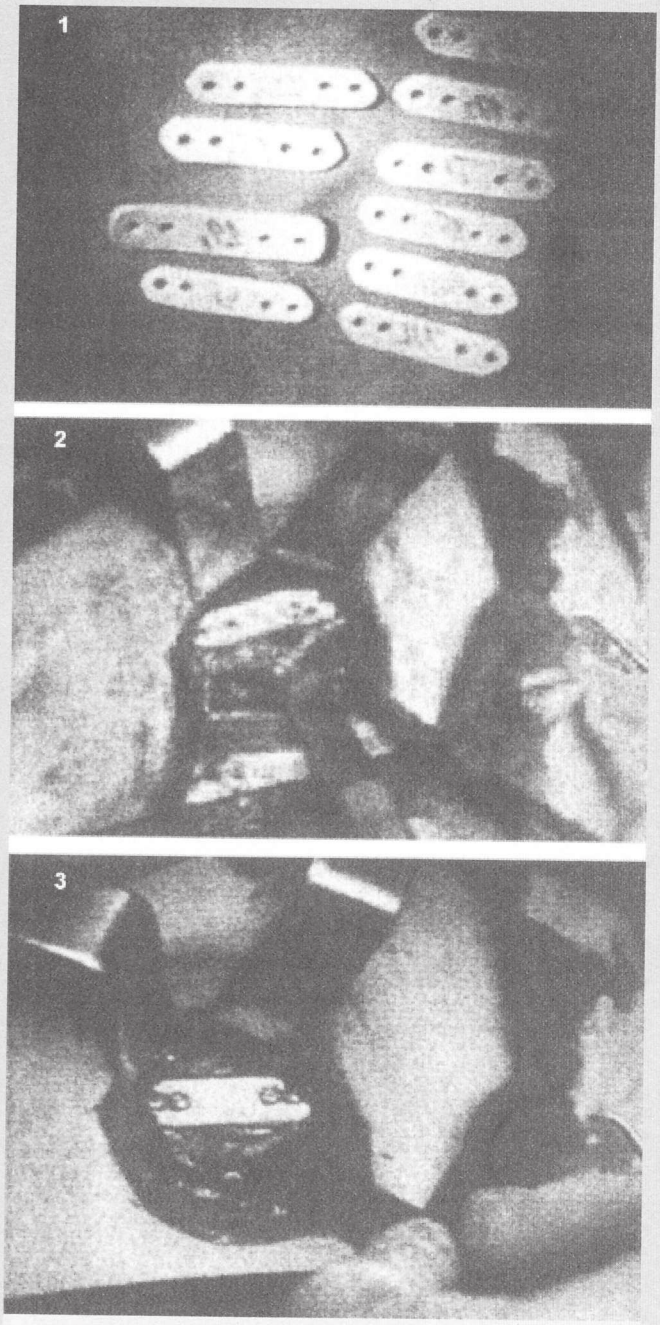


**FIG.1. The miniplates, prepared from Alumag-1 material (1), the corundum miniplate was fixed by titanium screws (3), the miniplate was placed on a perceving platform of a jaw (2).**

## References

[1]. D.F. Williams and R.Roaf Implants in surgery. M.: Medecina, (1978), 552.
[2]. G.P. Evans, J.C. Behiri, J.D. Currey, W. Bonfield // J. Mat. Sci. In Med. 1, (1990). 38-43.
[3]. I. Piesold, W. Muller, W. Glein // Stomatology, 1, (1990), 42-45.
[4]. H.A. Kalamkarov, U.V. Ionaitis, A.S. Chernikis, et all // Stomatology. 3. (1989), 49-50.
[5]. A.O. Ogonowski, I.E. Kiwerski / Mat.I Symp.Ortop. i Protet., Bialystok. (1997), 147-149.
[6]. I.N. Ermolenko, T.M. Ulyanova, P.A. Vityaz, I.L. Fedorova / Advances in Cremics. The Am. Ceram. Soc., Inc., Columbus, Ohio, 12, (1984), 826.
[7]. Toxicology and Hygiene, Application of Polymer / ed by V.E. Kovshilo M.: Medecina, - 1980.
[8]. A.A. Korzh, G. Kh. Gruntovsky, N.A. Korzh, V.T. Mikhailov, Ceramics in Orthopedics and Traumatology. Lvov: Svet, 1992, 112.