

Research, development and clinical applications of the Porous Hydroxyapatite Coralina[®] HAP-200 during 20 years in Cuba. Their scientific, technical and social impact

Investigación, desarrollo y aplicaciones clínicas de la Hidroxiapatita Porosa Coralina[®] HAP-200 durante 20 años en Cuba. Su impacto científico-técnico y social

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Abstract

Introduction: The Porous Hydroxyapatite Coralina[®] HAP-200 is a biomaterial for bone, developed for more than 20 years in Cuba and it has been applied with success as bone substitute and integrated ocular implant. Presently work offer a summarized information of the main results obtained in the research stage, development and clinical applications of this biomaterial in the last 20 years. **Material and Methods:** This biomaterial in form of blocks and spheres with different dimensions as well as granulated with different sizes of the particles has been evaluated with success, completing all the parameters so much physical-chemical as their behavior “in vivo”, in preclinical and clinical trial as they demand the evaluation norms for biomaterials registration of the CCEEM of the MINSAP of Cuba. They have been carried out several protocols of clinical rehearsals, so much controlled as multicentric, of postproduction, of pursuit and study of the long term clinical behavior, of extension and introduction in the National System of Health as well as the studies and design of the productive system and of quality system management that they endorse the obtaining of several certificates of sanitary registries in Cuba and in some others countries, as abroad as well as the certificates of good manufacturing practice, including the certification for the ISO 9001-2008. **Results and Discussion:** During the 20 years of clinical applications in Cuba, 15 500 patients have been treated in the odontology specialties, including maxillofacial surgery, 1 740 people have received ocular implants and 6 000 have been treated by bone defects of the long bones and others in orthopedics and thraumatology. Alone 3.1% of failure of the implants has been reported by different causes associated to the surgical treatment and in any case by reason of the biomaterial, demonstrating this last one an excellent biocompatibility with integration and incorporation to the natural dynamics of the bone tissue after the time. As a result of this work they have been published more than 100 articles and it have been formed more than 100 specialist in the different associated disciplines, including 15 thesis of degree, 10 of Specialists of First and Second Degree, 6 M.S. and 3 Ph.D Thesis. **Conclusion:** The obtained results are excellent so much from the point of view of the characteristics and estates of the biomaterial like of their behavior “in vivo” and the impact in the health and quality of our population's life. The studies realized have allowed to evaluate the estates of this biomaterial and at the same time to carry out an intense work of R+D for the search of new applications as well as the development of new products starting from the same one.

Keywords: Biomaterial; Implant; Hydroxyapatite; Bone graft substitute.