Philippine Journal of Science
129 (2): 93-99, December 2000
ISSN 0031 - 7683

Bioceramic Orbital Plate Implant

J.P. Reyes[1*], J.R. Celorico[1], L.C. dela Cuesta[1],
J.M. Filo[1], L.G. Daan[1], S.T. Bernardo[1] and J. Abano[2]

[1]Materials Science Division, Industrial Technology Dev't Institute
DOST Comp.,Gen. Santos Ave., Bicutan, Taguig, Metro Manila, Philippines
[2]Department of Opthalmology, Santo Tomas University Hospital
España, Manila, Philippines

Porous biphasic calcium phosphate bioceramic orbital plate implant consisting of about 77% β-TCP and 23% HAp was developed as a low cost alternative to commercially available orbital plate implant. The pore size of the material, which is 198 microns, contributed to the early fibrovascular ingrowth into the pores of the plate implant. Twelve (12) orbits of six (6) adult domestic cats underwent orbital plate implantation. Results of biocompatibility tests show the excellent potential of the developed bioceramic orbital plate implant for orbital floor fracture reconstruction. It is biocompatible, allows vascularization, resistant to resorption, and has proven to have physiological bone induction as well as bone conduction properties.

Keywords : bioceramic, orbital plate implant, bone induction, bone conduction, Hydroxyapatite, biphasic

The remarkable progress of ceramics in recent years has resulted in the development of materials with chemical, physical and mechanical properties that are suitable for biomedical applications. Ceramic materials used for this purpose are known as bioceramics and their fields of application include orthopedic, odontosthomathology, ophthalmology, plastic and cosmetic surgery (Ravaglioli & Krajewski 1992). Among the bioceramic materials that are being developed, calcium phosphate, $Ca_3(PO_4)_2$, has been extensively studied due to its chemical composition and crystalline structures, which is similar to the inorganic substance of the human body.

Calcium phosphates are group of compounds that are naturally found in human bones and teeth. They exist in different crystalline phases and only hydroxyapatite (HAp) and tricalcium phosphate (TCP) is commonly used in biological systems as artificial tooth roots, bone and joint implants. Recently, HAp has been successfully used as an orbital plate implant (Karesh & Dresner 1994). As seen in Fig. 1, orbital plate implants are utilized for orbital floor reconstruction. It is used to replace the orbital floor fracture of an individual as a result of both direct and indirect (blowout) from striking objects causing compressive force that lead directly to buckling of the postero-medial part of the maxillary bone. Orbital floor repair entails freeing the prolapsed orbital tissues and the placement of an orbital plate implant over the fracture to prevent recurrent prolapse and adhesion (Rubin & Bilyk 1994).

Autogenous bone grafts have been used traditionally as the reconstructive material for orbital floor fractures since they provide viable sources of osteoblast for osteoproduction, skeletal framework to replace bone tissue loss (osteoconduction), and ability to stimulate new bone formation (osteoinduction). However, they are being criticized for their unpredictable resorption (Holmes 1979).

These drawbacks initiated the birth of porous alloplastics such as coralline hydroxyapatite in 1986 and porous polyethylene "medpor" in 1991. This new generation orbital implant substitutes provided osteoconduction and osteoinduction properties (Lemke

---

[*] Corresponding author: joyes@sun1.dost.gov.ph

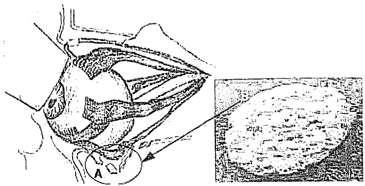

Figure 1. Orbital floor fracture (marked A) for reconstruction utilizing orbital plate implant (marked B).

& Kikkawa 1986, Lavernia & Schoelung 1991). Unfortunately, these implants are acquired through importation only and the use of coralline hydroxyapatite implants is not widely accepted because of their high cost of US $650.00 per implant. The growing concern to lower the cost of these materials has initiated an interest to locally develop a new material for orbital plate implants that contain two phases (biphasic) of calcium phosphate, hydroxyapatite and β-tricalcium phosphate. The study also aims to evaluate the biocompatibility of the bioceramic orbital plate implant and demonstrate its potential as a low cost alternative to coralline hydroxyapatite.

Materials and Methods

Synthesis of Biphasic Calcium Phosphate Ceramic

Analytical grade limestone, $CaCO_3$ (99%, <44μm) and dicalcium phosphate dihydrate, $CaHPO_4.2H_2O$ (99%, <44 μm) were used as starting materials. The batch was prepared by weighing mixtures of $CaCO_3$ and $CaHPO_4.2H_2O$ with Ca/P ratio ranging from 1.5 to 1.67. The mixtures were milled in polyethylene bottles for 24 hours in water using zirconia grinding balls and then followed by oven drying at 80° C for 24 hours. Calcination of the dried powder was carried out from 700°C to 1000°C at a heating rate of 200°C/h until the desired temperature has been reached.

Fabrication of Bioceramic Orbital Plate Implant

Slurries were initially prepared by milling mixtures of calcined biphasic calcium phosphate powder and binder, local kaolin clay, for several hours in methanol. The addition of clay as binder was varied from 5 to 20% based on the dry weight of the calcined powder. Forming of porous ceramics was done using rectangular shaped molds made of polymers. After forming, the polymeric molds were saturated with the biphasic calcium phosphate containing slurries and then dried at 110° C for several hours. It was followed by sintering in a tube furnace at 1280° C for 3 hours to obtain the porous biphasic calcium phosphate ceramics. The crystalline phases present in the porous ceramics were identified by X-ray diffraction. Microstructures were observed by scanning electron microscope(SEM) JEOL JSM-T20 operating at 15-20 kv.

Clinical Application of Bioceramic Orbital Plate Implant

Twelve orbits of six adult cats were used with weights ranging from 2.5-3 kg. The guidelines of the Association for Research in Vision and Ophthalmology (ARVO) were observed during the tests. Each cat was anesthesized with intramuscular Ketamine (30 mg/kg/ IM), atropine sulfate (0.1ml/IM) and Midazolam (0.2 ml/ IM). The surgical field was carefully scrubbed with 10% povidine iodine and the incision site was infiltrated with a mixture of 2% lidocaine with 1:10,000 epinephrine. Creation of a 6mm curvilinear subciliary skin incision was done and was carried down towards the sub-periosteum, a membrane of connective bone tissue. Careful blunt dissection to expose the floor of the lower orbit with periosteal levator, a muscle that serves to raise a body part, was performed. The posterior medial aspect of the orbital floor was fractured by chisel and rongeur creating a fracture defect of 2 mm in diameter.

The presoaked (in gentamycin) bioceramic orbital plate was implanted over the area of defect (Fig. 2). Orbital plate maybe trimmed to fit the contours of the defect. The subperiosteum was carefully sutured using 4.0 vircyl. This was followed by skin closure with simple interrupted 4.0 silk sutures. Daily examination, application of antibiotic and wound cleaning were done. The right orbit of each cat was labeled A and the left as B. The orbital plate implants of the right orbit of each cat (A) were harvested at 1 month post operation and that of the left (B) at 3 months. Microsections of decalcified plate implants were taken and stained with hematoxylin and eosin for histological examination. The stained microsections were examined by light microscope and parameters such as evidence of vascularization of the plate implant, bone regeneration, presence of any signs of necrosis, infection and inflammation were noted.

Figure 2. Orbital plate implant (A) implanted over the area of defect.

Results and Discussion

Synthesis of Biphasic Calcium Phosphate Ceramic

Biphasic calcium phosphate powders were initially synthesized from the mixtures of $CaHPO_4.2H_2O$ and $CaCO_3$. Figure 3 shows the X-ray diffraction patterns of $CaHPO_4.2H_2O$ and $CaCO_3$ mixtures after milling and calcination at 700° C to 1000° C. It can be seen that the onset for the formation of two phases of calcium phosphate, HAp and β-TCP, was observed at 700° C (Fig. 3b). The presence of $CaCO_3$, which is one of the starting materials, was also detected suggesting the reaction to form the two phases had not been completed. At 800°C, 900°C and 1000°C no detectable $CaCO_3$ peaks were identified implying complete reactions (Fig. 3c-e). From these results, calcination of $CaHPO_4.2H_2O$ and $CaCO_3$ mixtures to simultaneously form the two phases of $Ca_3(PO_4)_2$ was selected at 800°C since it was at this temperature that complete formation of HAp and β-TCP was first observed.

Fabrication of Bioceramic Orbital Plate Implant

After determining the processing conditions for the synthesis of the biphasic calcium phosphate bioceramic orbital plate implant powders, the fabrication of the plate implant was undertaken using the synthesized powders. Porous ceramics are manufactured either by the replamineform process or by impregnating porous polymeric molds with calcium phosphate powders (Lavernia & Schoenung 1991, Lelievre et al 1996). The latter method was adopted in this study. During the sintering process, the polymers saturated with the synthesized powders undergo thermal decomposition, thus leaving the ceramic materials porous.

The effect of binder addition was studied during the fabrication of the porous ceramics. Clay was selected because this material is readily available and inexpensive. After sintering at 1280°C for 3hr, formed porous ceramics collapsed upon the addition of 0-10% clay, while the addition of 15-20% clay did not collapse. These results suggest the importance of binder addition in the fabrication of the porous ceramics and the clay to be added should not be less than 15% in order to bond the particles in the materials after sintering. Figure 4 presents the XRD patterns of porous ceramics with 0,15 and 20% clay after sintering and their corresponding phase compositions are shown in Fig. 5. These phase compositions were estimated based on the diffraction peak intensity ratios using the main diffraction peaks of 2.88 ($2\theta=31.0$) and 2.82 (2q=31.6) for β-TCP and HAp, respectively. It can be seen that there is an increase in β-TCP content as the addition of clay is increased. This implies that clay could enhance the formation of β-TCP by reacting with HAp to produce TCP (Ruys et al. 1994). A 15% clay addition resulted to about 77% TCP and 23% HAp (Fig. 4). The XRD patterns of the human bones, unheated and heated at 800°C, are shown in Figure 6a-b, respectively. The presence of a single phase calcium phosphate, HAp, was noted. Biphasic calcium phosphate was developed because it offers more advantages. In addition to HAp that contributes to the direct chemical bonding with the bones, the presence of TCP promotes bone regeneration (Aoki, 1994)

The microstructure of the developed bioceramic orbital plate implant with 15% clay addition is shown in Fig. 7. It is characterized by an interconnected matrix of pores, having an average pore size of 198 microns. This pore size is more than the minimal requirement of 40 microns needed for fibrovascular ingrowth (Karesh & Dresner 1994). Large pore sizes

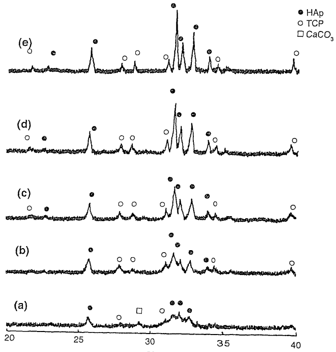

Figure 3. X-ray diffraction patterns of CaHPO$_4$×2H$_2$O and CaCO$_3$ mixtures after (a) milling for 24 hours and calcinations at (b) 700, (c) 800, (d) 900 and (e) 1000°C.

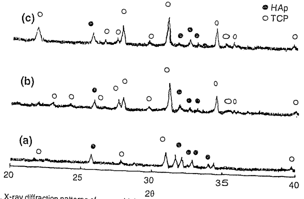

Figure 4. X-ray diffraction patterns of porous biphasic calcium phosphate ceramic with (a) 0%, (b) 15%, (c) 20% clay after sintering at 1280° C for 3 hours.

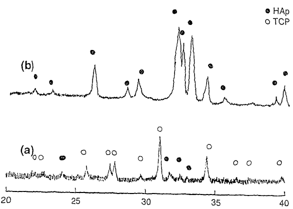

Figure 5. X-ray diffraction pattern of (a) developed biphasic $Ca_3(PO_4)_2$ and (b) human bones, heated at 800°C.

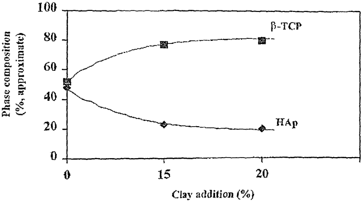

Figure 6. Phase composition of porous biphasic calcium phosphate with (a) 0%, (b) 15% and (c) 20% clay after sintering at 1280°C for 3 hours.

are more desirable in orbital implants because they allow more fibrovascular and bone ingrowth.

Clinical Application of Bioceramic Orbital Plate Implant

Results of histologic examinations showed no signs of necrosis nor infection. No evidences of encapsulation was likewise noted. Grossly, the graft was pinkish and was very much secured to the adjacent bone (Fig. 8). Six (right) orbital plate implant specimens at one month showed microsections of tissue fragments composed of mature trabecula surrounded by collagenous tissue. The fragments of the tissue implants consisted of islands of osteoid surrounded by osteoblasts and set in loose connective tissue (Fig. 9). Likewise, areas of implants admixed with new forming bone were noted. Vascularization in the form of capillary buds were observed as early as one month.

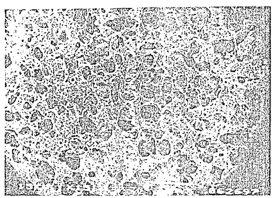

Figure 7. SEM micrographic of porous biphasic calcium phosphate depicting the interconnected matrix of pores (bar = 1mm).

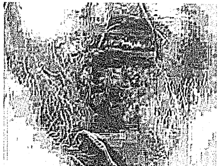

Figure 8. Relationship of the graft implant with its surrounding tissue showing no signs of necrosis nor infection.

Figure 9. Matured bone trabecula with attached implant (marked A) showing osteoid (marked B) formation at one month post implantation.

Figure 10. Islands of osteoid (marked A) containing osteoblast adhering to the loose connective tissue (or the implant) with the new forming bone at 3 months post implantation.

On the third month, six (left) orbital plate implant specimens demonstrated modest deposition of osteoid adjacent mature bone, along with fibrovascular tissue filling the implant (Fig.10).

Conclusion

Bioceramics orbital plate implant was successfully developed using calcium phosphate dihydrate and calcium carbonate as starting materials. The processing conditions for the fabrication of this material requires the calcination of the starting materials at $800^{\circ}C$ to obtain the complete formation of the two phases of calcium phosphate, hydroxyapatite and beta-tricalcium phosphate. After sintering at $1280^{\circ}C$ for 3 hours, XRD analysis showed the mineral compositions of the porous biphasic calcium phosphate ceramics to be 77% β-TCP and 23% HAp. The pore size of the material, which is 198 microns, contributed to the early fibrovascular ingrowth into the pores of the plate implant. Results of biocompatibility tests show the excellent potential of the developed orbital plate implant for orbital floor fracture reconstruction. It is biocompatible, allows vascularization, resistant to resorption and has proven to have physiological bone induction as well as bone conduction properties. Indeed this offers an attractive affordable option in reconstructive surgery.

Recommendation

The authors plan to conduct long term studies and with the approval of the institutions bioethical committee will consider human clinical trial.

References

Aoki, Hideki. 1994. Medical Application of Hydroxyapatite. Takayama Press Co., Inc., Japan.

Holmes RE. 1979. Bone Regeneration within a Coralline Hydroxyapatite Implant. *Plastic* Reconstructive Surgery. 63:626-633.

Karesh J & Dresner S. 1994. High Density Porous Polyethylene as a Successful Anophthalmic Implant. Ophthalmology. 101:1688-1696.

Lavernia C & Schoelung J. 1991. Calcium Phosphate Ceramic Bone Substitute. *Ceramic Bulletin. 1*:95-100.

Lelievre F, Bernacle-Assollant D & Tartan T. 1996. Influence of Powder Characteristics on the Rheological Behavior of Hydroxyapatite Slurries. *Journal of Materials Science: Materials in Medicine.* 7:489-494.

Lemke BN & Kikkawa DO. 1986. Repair of Orbital Floor Fractures with Hydroxyapatite Block Scaffolding. 11(2):69-73.

Ravaglioli A. & Krajewsky A. 1992. Bioceramics: Materials, Properties, Applications. Chapman and Hall, London.

Rubin Rad & Bilyk JR. 1994. *Management of Orbital* Trauma: Fractures, Hemorrhage and Traumatic Optic Neuropathy in Focal Point. Clinical Modules for Ophthalmologist, San Francisco. 12:7.

Ruys, A. J., Milthorpe, B. K., & Sorrell, C. C. 1994. Preparation of *Fibre-Reinforced Hydroxylapatite.* Interceram. 43(1) 7-9.