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# Hydroxyapatite-Based Synthetic Orbital Implants

## THE AUTHOR



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## ABSTRACT

Orbital implants replace the volume lost by an enucleated eye, implant motility to the prosthesis and maintain cosmetic symmetry with the fellow eye. Various types of implant materials have been tried over centuries, and presently available hydroxyapatite-based porous implants are the latest ones with their biocompatibility, bioactivity, fibro-vascular tissue growth and improved motility. Synthetic hydroxyapatite-based implants have the advantages of tailor-made properties and are commercially popular for many other advantages.

## KEYWORDS

synthetic hydroxyapatite, orbital implant, tailored properties, implantation  
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## 1 Introduction

When the eye of a person is damaged due to injury or disease, the surgeon removes the eyeball from the orbit to avoid the risk of life or risk to the other eye of the patient. This operation can be enucleation surgery, i.e. removal of the eyeball itself without cutting into or dissecting it, while leaving surrounding tissues intact or visceration surgery, i.e. removal of the contents of the eye globe while leaving the sclera and extraocular muscles intact. But there are very common post-operative problems after such operations, including orbital floor rupture and significant loss of orbital tissues after the loss of the eye, which results in an anophthalmic appearance with retraction of the upper eyelid. The eye surrounding the extraocular muscle that controls the movement of the eye and adjacent orbital tissues may prolapse through the fracture, resulting in malposition of the eye. To counter these problems, eye surgeons attempt to mechanically replace the lost eye with an ocular implant to fill up the orbital volume lost and to achieve proper rehabilitation of the anophthalmic patient.

The orbital implant occupies the cavity of the eyeball and maintains the natural structure of the eye while remaining invisible from outside.

In the past, a large number of materials have been tried as ocular implants but with poor success stories. Most of the implants were found unsuitable due to various reasons and were discarded one after another. Until the nineteenth century, artificial eyes were made of metal, which were soon discarded as they were expensive, heavy and painful to wear. In 1884, Mules first introduced the hollow glass sphere as an implant [1]. This sphere offered some support for the upper eyelid but resulted in downward pressure on the lower lid and sag characteristic of long-term anophthalmic patients. In 1941 Ruedemann [2] introduced a much lighter, acrylic-based, partially exposed orbital implant. But secondary strabismus procedures were often required to correct late position problems; this implant was also eventually abandoned. People then tried to work on the design of Ruedemann's orbital implants [3]. The designs that modified partially exposed implants resulted in good motility to the artificial eye but were prone to infection and extrusion.

The first-ever hydroxyapatite-based orbital implant was inserted by Dr. Arthur Perry in 1985, after several years of preliminary research [4]. He developed porous implants

by processing a specific genus of reef-building coral. Porous implants capable of sustaining fibro-vascular growth are termed as integrated implants. The porous implant was easily attached to the eye muscles, and the tissues that covered the implant resulted in much improved motility of the implant, giving it the appearance of a natural eye and also providing resistance to infection, migration and extrusion [5–7]. For even better movement, a peg may be used to connect the artificial eye to the implant. In this way, small, darting movements of the natural eye can be imparted in the artificial eye. The result is a more natural-looking artificial eye, which is difficult to distinguish from the natural eye.

Hydroxyapatite,  $\text{Ca}_5(\text{PO}_4)_3(\text{OH})$ , usually written as  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ , is the principal inorganic constituent of bone and teeth. The chemical similarity of HAp to bone and its excellent biocompatibility and bioactivity have attracted the attention of medical professionals. Figure 1 shows the microstructural similarity between human bone and hydroxyapatite [8]. For the last several years, hydroxyapatite ceramics in different forms (block, granules, coating) have been used widely in the field of orthopaedics [9–13] and dentistry [14–16]. The use of hydroxyapatite as an ocular implant is a relatively new development [4, 17–24].

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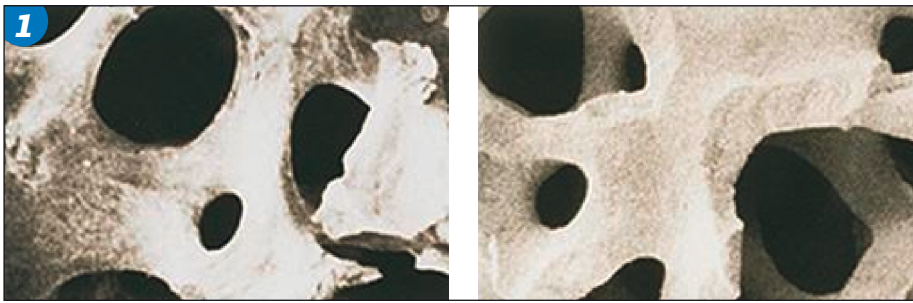


Fig. 1 • The microstructural similarity of human bone (left) and hydroxyapatite (right) [8]

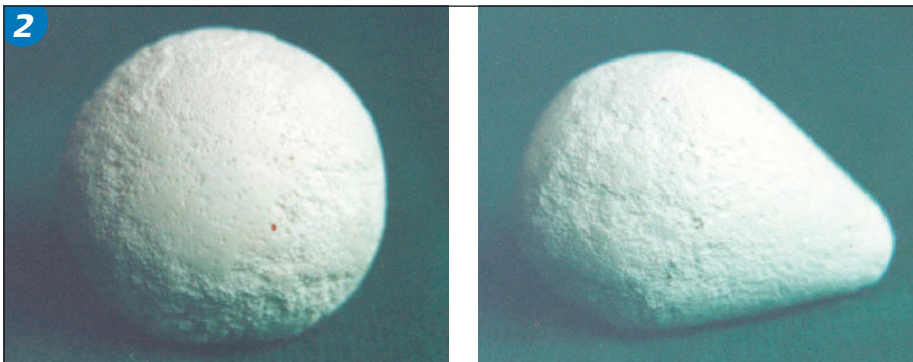


Fig. 2 • Synthetic hydroxyapatite-based orbital implants: spherical (left) and conoidal (right) [30]

### 1.1 Orbital implant: socio-economic scenario

Globally, about 160 million people are blind or one-eyed, with India alone having nearly 20 million. Half of them are anophthalmic and mostly come from economically backward classes. In India, these people face a peculiar problem. They are not declared as physically challenged to receive special support from the government, but they are also not accepted by society due to their “repulsive” appearance [25].

This social hindrance has demanded a natural look for the defective eye, though artificial, which has resulted in the development of synthetic orbital/ocular implants. Initially, the demand for implants was met by glass, coral or polymer-based materials, which are not only expensive but also showed post-operative complications, mostly infection and exposure. Also, these implants, having poor motility, do not provide a natural look as compared to the other normal eye.

### 1.2 Synthetic orbital implants

There are two types of hydroxyapatite-based orbital implants available. The first is natural coral based, and the second is a synthetically prepared material [26]. Natural coral-based porous hydroxyapatite ocular implants were the first integrated implants that were commercially prepared and received FDA approval in 1989. But because of their natural availability, they suffer from a large number of drawbacks [27]:

- Availability of natural commercial sources of coral is irregular
- the chemical composition of natural sources may vary widely due to the presence of magnesium, sodium, chloride and fluoride ions, affecting the implant's properties
- tailor-making of orbital implants with respect to porosity and pore size is not possible
- the rough outer surface of the implant abrades the overlying conjunctiva and Tenon's capsule and results in exposure and extrusion of the implant
- the implant cannot be used as such without wrapping with donor sclera or coating
- additional surgery is needed to harvest a donor sclera and
- there are chances of HIV infection through donor sclera.

Synthetic material-based implants allow much improved control over size, weight, total porosity and porous structure and can easily be tailored to the requirements of better implantation [27–28]. The term synthetic refers to the synthetic/artificial manufacturing technique of hydroxyapatite using highly pure precursor materials by a research-developed process that produces highly porous, fully interconnected, biocompatible implants. Control over each step of the manufacturing process provides the flexibility of tailoring the properties with respect to total mass, porosity, pore size and distribution and surface roughness of the product and allows complete tailor-making

of the implant. In addition, the whole manufacturing process is economical and suitable for industrial/commercial production.

### 1.3 Advantages of synthetic hydroxyapatite-based implants

**Synthetic preparation:** Materials are synthetically prepared by wet chemical technique [27, 29] using pure chemical reagents, resulting in control over preparation technique and purity.

**Tailor-made:** The smooth, highly porous, controlled pore size and structure allows the implant to be easily invested by the fibrovascular tissues of the orbit, increasing the stability of the implant in the socket. A special design (conoid) also invites faster tissue in-growth. Figure 2 shows both the spherical and conoidal shaped orbital implants.

**Biocompatibility:** Hydroxyapatite is a biocompatible material, which integrates in the human body without any reaction or rejection.

**Bioactivity:** Hydroxyapatite is a bioactive material, which reacts in a positive manner to form bonds with local cells. The adnexal tissues integrate with the orbital implants and provide stability and motion to the orbital implants.

**Minimal revision surgery:** Synthetic implants offer nearly zero post-operative complications and provide excellent motility and negligible exclusion rates, thereby minimizing revision surgery.

**Commercial aspect:** The synthesis process allows industrial production with an economic edge.

## 2 Experimental

### 2.1 Methodology of manufacturing

Hydroxyapatite powder was synthetically prepared through a wet chemical method using medical-grade reactants dried and mixed with powdered medical-grade naphthalene. The mixer was homogenized, iso-statically pressed and subsequently shaped and designed to a predetermined size through turning in a CNC lathe. Shaped pieces were then processed through highly controlled drying and firing and passed through stringent quality controls. Next, the fired products were pasteurized in an autoclave, packed individually under precaution and sterilized under gamma radiation of 2.5 MRad dosage using a  $Co_{60}$  isotope source.

### 2.2 Size of the implant

Size of the implant plays a vital role as it has to fill a certain volume that was covered by the eyeball in the orbit. Ideally about 65–70% of the volume should be filled by the implant, and 30–35% should be con-

## HIGH-PERFORMANCE CERAMICS

**Table 1 • Characteristics of synthetic hydroxyapatite-based orbital implants [30]**

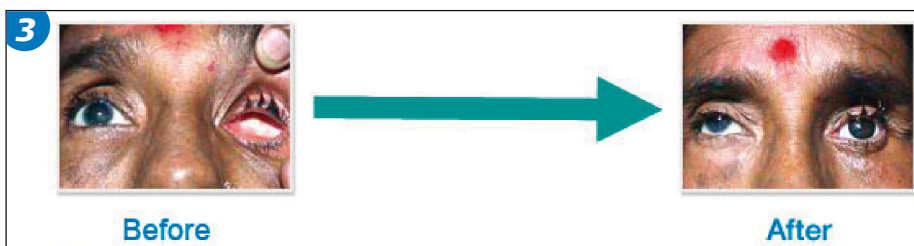
Formula	$\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$
Bulk density / $\text{g}/\text{cm}^3$	0.6–0.7
Specific weight per unit / g	<2
Porosity / %	70–75
Pore size (by microscopic study) / $\mu\text{m}$	100–300
Unit volume / $\text{cm}^3$	3–4
Flexural strength for solid HAP / MPa	>25
Compressive strength for solid HAP / MPa	>120
Shapes	spherical, conoid
Types of surgery	evisceration, enucleation

**Table 2 • Prosthetic movements [8]**

Degree of movement / °	Percent of cases / %
<10	0
10–20	56
>20	44

**Table 3 • Volume replacement**

Difference with fellow eye / mm	Percent of cases / %
0–1 mm	86.6 %
1–2 mm	13.3 %

**Fig. 3 • Transformation of appearance of a patient after implantation of the implant**

tributed by the prosthesis. Depending on the patient, his or her orbit volume size will vary, and a wide range of implant sizes are required. In this aspect, synthetic orbital implants have the edge for their tailor-made properties. Any implant of a smaller dimension has a higher tendency to migrate, increases the chances of extrusion and may develop higher sulcus deformity. On the other hand, an excessively larger implant may cause tension on the conjunctival wound and may result in wound gap and implant exposure. Generally, an implant size of 16–18 mm is required for infants, 18–20 mm is required for children and 20–22 mm is required for adults. Commercially, a range from 14–22 mm sizes is available for synthetic hydroxyapatite-based implants. Additionally characteristics of these implants can be found in Table 1.

### 2.3 Post-operative information

Tables 2–3 provide post-operative information on synthetic hydroxyapatite-based implants.

### 2.4 Transformation of appearance [30]

Figure 3 shows how appearance can be transformed with a synthetic implant.

### 3 Summary and outlook

The chemical and microstructural similarities of human bone and hydroxyapatite has made the hydroxyapatite-based porous orbital implants biocompatible and bioactive. Again, the pore size and structure allows fibro-vascular growth within the implants, resulting in much better fixing and nearly nullifying the chances of exposure and extrusion and improving motility, unlike the stone/metal/glass/polymer-based ones which had many disadvantages and high rates of exclusion. Synthetic hydroxyapatite-based implants allow much improved control over size, weight, total porosity and porous structure and can easily be tailored to the requirements for better implantation. Much improved tailor-made properties and sizes allow the implants to fit to the eye orbit of the damaged eye and provide higher motility due to their lightweight, porous structure. Tissue in-growth makes the defective eye more natural-looking and difficult to distinguish from the natural eye.

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