

Hydroxyapatite Orbital Implants-Our Local Experience

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Abstract

Hydroxyapatite orbital implants were first introduced by Arthur Perry in 1985 and approved by the Food and Drug Administration for general use in 1989. Since its inception, it has become a popular orbital implant as it combines biocompatibility with improved motility. At the Singapore National Eye Centre, twenty consecutive patients underwent hydroxyapatite implantation from June 1993 to June 1996.

Seventeen patients who had a follow-up time of more than 6 months were analysed retrospectively. Sixteen had enucleation while one had evisceration performed. The implant size used was either 18 or 20 mm. Seven primary and 10 secondary hydroxyapatite implants were performed in 17 patients ranging in age from 20 to 65 years. Six consisted of coralline hydroxyapatite while the remaining 11 were made of artificial hydroxyapatite.

In the follow-up time of 6 to 16 months (mean 10.2 months), there have been no cases of infection, extrusion or migration. Two patients who had implant exposure were managed surgically with fascia lata grafts and have healed well.

It appears that hydroxyapatite is the implant of choice for an anophthalmic socket. It becomes incorporated by the patients own tissues and once vascularised, it is less likely to migrate or extrude. The complication rate is low and implant exposure, if it occurs, can be easily managed.

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Introduction

The first hydroxyapatite orbital implant was described by Arthur Perry in 1985.¹ It was derived from porous marine coral which allows a fibrovascular ingrowth, integrating it into the recipient's tissue. At that time, hydroxyapatite had been used by the orthopaedic and maxillofacial surgeons^{2,3} for bone grafting for at least a decade and had been found to be biocompatible, non-toxic and well-tolerated. It was only in 1989, that the Food and Drug Administration, USA, approved the use of coralline hydroxyapatite for orbital implantation.

Since then, hydroxyapatite has gained popularity as the implant of choice. A survey in 1992 of 5439 intraorbital implants showed hydroxyapatite to be the most commonly used orbital implant by ophthalmic plastic surgeons in North America⁴ as it has been found to have very low rates of implant extrusion, migration or rejection.

Materials and Methods

We conducted a retrospective analysis of 17 consecutive patients who underwent hydroxyapatite implantation from June 1993 until June 1996. Three patients who

were foreigners were excluded from this study as they had a short follow-up time of under 3 months.

Of the 17 patients, 7 had primary implants while 10 were referred for a secondary implant. Of these, 6 had post enucleation socket syndrome while 4 had extrusion of a previously implanted glass ball. Of the implants used, 11 were made of artificial hydroxyapatite while 6 consisted of coralline hydroxyapatite carved into a sphere.

Surgical Technique

A similar surgical technique was used in all the patients. A standard enucleation with tagging of the extraocular muscles with absorbable sutures was performed. The orbit was then sized with silicone or acrylic spheres to determine the size of the hydroxyapatite implants to be used. The gas-sterilised hydroxyapatite sphere was first soaked in a solution of gentamicin, 80 mg diluted in 10 ml of balanced salt solution for 15 minutes before use. Preserved eye bank sclera that had been screened for infections using the same protocol for corneal donor tissue, was used in all the patients except in one patient who underwent evisceration. This was sutured around the implant with 5/0 vicryl (polyglactin

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910 suture) to form a baseball like covering. Four rectangular scleral windows (3×7 mm) at positions approximating the insertions of the recti were then cut through the sclera to increase vascularisation of the implant (Fig. 1).

The prepared hydroxyapatite implant was then inserted into the posterior tenon space. The recti muscles were then individually sutured to the anterior lip of the scleral windows using 6/0 vicryl sutures. Tenon's fascia was then closed over the implant with 6/0 vicryl sutures followed by conjunctival closure with 8/0 vicryl or silk sutures. A methylmethacrylate conformer was then placed into the fornices and pressure bandage applied for 24 to 48 hours.

A custom-made ocular prosthesis was fitted approximately 6 to 8 weeks after surgery.

Results

Seventeen patients were involved in the study; 10 were males and the remaining 7 were females. Their ages ranged from 20 to 65 years. Of the 7 patients who had primary implants, 5 had phthisis bulbi from previous trauma and one had a painful blind glaucomatous eye. These 6 patients were enucleated and hydroxyapatite implant inserted primarily. One patient who had endophthalmitis was eviscerated and hydroxyapatite implanted at the same operation. Ten patients underwent secondary implantation. Four patients had extrusion of a previously implanted glass ball implant. The remaining 6 had poor cosmesis secondary to post-enucleation syndrome. Of the 6, 2 had an existing

undersized glass ball implant removed and this was exchanged for a hydroxyapatite implant. Nine patients had 18 mm diameter implants while 8 had 20 mm diameter implants. The follow-up time ranged from 8 to 42 months (mean 18.2 months). During that time, there were no cases of infection, extrusion or migration. Two patients had implant exposure at 1 week and three months postoperative respectively. The first patient was a 39-year-old male who had endophthalmitis resulting in phthisis bulbi (Fig. 2) and moderate socket contracture prior to enucleation and implantation of a 18 mm hydroxyapatite sphere. A 5 mm diameter dehiscence exposing the underlying sclera was noted at 1 month postoperative (Fig. 3). This was initially repaired using a pedicle conjunctival graft. One week later, a 2 mm diameter area of exposed implant was seen and repaired using autologous fascia lata graft (Fig. 4). The patient has now been followed up 38 months postoperatively and there has been no further complications (Fig. 5).

The second patient was a 65-year-old female who suffered blinding eye trauma during World War II. Evisceration of the phthisical eye with glass ball implantation was performed in 1988. Implant extrusion was noted in 1995. Secondary implantation of a 18 mm diameter hydroxyapatite implant was performed. Three months postoperatively, a 2 mm diameter conjunctival dehiscence was seen at the suture site. This was repaired with autologous fascia lata. Postoperatively, she has been well and has been wearing her prosthetic eye for 1 year.



Fig. 1. Four rectangular scleral windows at positions approximating the insertions of the recti were then cut through the sclera to increase vascularisation of the underlying implant.



Fig. 2. Thirty-nine-year-old male with endophthalmitis resulting in phthisis bulbi Of the left eye.

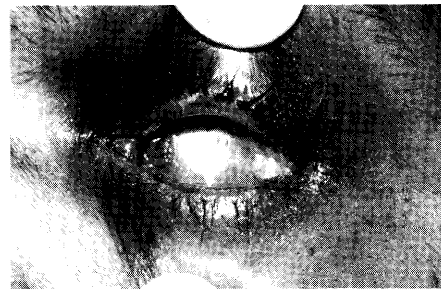


Fig. 3. Five mm diameter conjunctival dehiscence exposing underlying sclera.



exposure autologous fascia

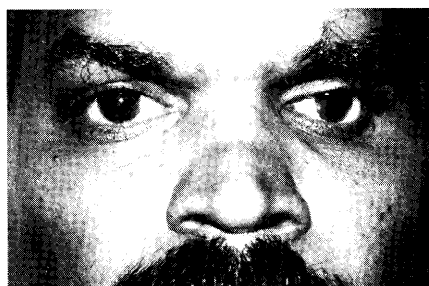


Fig. 5. Patient wearing ocular prosthesis after repair of implant exposure.

Discussion

The first enucleation was performed four centuries ago without anaesthesia and involved excision of the globe after first prolapsing the eyeball with a needle. It was only in 1841, that a more modern surgical technique enable placement of an orbital implant.⁵ In 1885, Mules⁶ introduced the use of a hollow glass sphere at the time of evisceration and although motility was poor, this was hailed as the first successful implant as infection and exposure rates were low. Orbital implants can either be integrated or non-integrated. Integrated implants had extraocular muscles attached to the orbital implant while non-integrated implants were simple spheres buried beneath the conjunctiva and Tenon's capsule with no attachment to the extraocular muscles. Cutler⁷ and Ruedemann⁸ introduced a semi-buried integrated implant which produced good motility and cosmesis as recti muscles were sutured and fixated to the implant. Unfortunately, infection and extrusion were serious problems as these implants had portions that were exteriorised to the conjunctival surface. By the 1950s, these implants were largely abandoned leading to a resurgence of the glass ball implant.

In 1985, Arthur Perry⁹ introduced a new integrated orbital implant using hydroxyapatite derived from marine coral. Since then, the popularity of hydroxyapatite implants has increased. A survey of orbital implants in 1992 showed it to be the most commonly used orbital implant by ophthalmic plastic surgeons in North America.⁴

Coralline calcium carbonate undergoes a hydrothermal exchange reaction converting it to hydroxyapatite which is a naturally occurring mineral in the body. Hydroxyapatite resembles cancellous bone and is made up of an interconnecting porous matrix with an average pore size of 0.5 mm. When used as an orbital implant, it becomes incorporated by the patients' own tissues and once vascularised, it is less likely to migrate or extrude. When coupled to an artificial eye, it enables the artificial eye to move in conjunction with the normal eye.

In a large series of hydroxyapatite implants, the rates of implant extrusion and migration have been reported to be between 0% and 1.7%.⁹⁻¹⁸ Infection rates were also low^{9,11,15-18} and even if infection occurred, the implant was generally retained in the orbit. Only four documented cases of chronic infection had to be removed.^{16,18,19} In our series, no infection, extrusion or migration was reported. The main complication was exposure of the hydroxyapatite implant. Rates of exposure have varied from 0% to 13.6% in a number of large case series^{4,9,12-15,17,18} In our series, 2 cases developed implant exposure, one in a primary implant and the other in a secondary implant. Moderate socket contracture was noted in the first patient and conjunctival dehiscence at the suture site was seen 1 month postoperatively. An

initial attempt at repair with a conjunctival pedicle flap failed and the defect healed only after the use of autologous fascia lata 6 weeks postoperatively. The second patient had a secondary implant and exposure occurred 3 months post-surgery. This was repaired with autologous fascia lata. Although exposure of the hydroxyapatite is the most frequent complication encountered, it appears to be well tolerated with no reports of migration or extrusion.

A similarly exposed silicone or methylmethacrylate implant would have been extruded. This surprising behaviour is postulated to be due to the excellent fibrovascular ingrowth into the implant. The persistent defect has also been attributed to the irritative hydroxyapatite spicules on the conjunctiva and overlying vascular tissue thereby inhibiting epithelialization resulting in a delayed ingrowth of fibrovascular tissue.²⁰

Small conjunctival defects of less than 5 mm in diameter were relatively well tolerated and could be observed for more than one year.^{15,16,19} Defects greater than 5 mm in diameter do not heal spontaneously and usually required surgical intervention. This might involve burring away avascular coral, scleral patch, demis-fat graft or fascia lata graft over the exposed hydroxyapatite and closure of the wound in layers with the help of a free or pedicle conjunctival graft.^{21,22} Wrapping the implant with sclera or polygactin,²³ posterior placement of the implant deep within the muscle cone with attachment of the extraocular muscles no more than 5 mm^{10,16,20} from the central axis of the implant allows Tenon's layer to be mobilised to create a viable bed of vascularised tissue over the anterior aspect of the implant while allowing more space anteriorly for fitting of the prosthesis. A prosthesis with a high posterior vault¹¹ also reduces pressure on the underlying implant and therefore reduces the risk of implant exposure.

Other factors which might predispose the patient to implant exposure include multiple previous surgical procedures, socket contracture, use of antimetabolites or radiation therapy as well as diabetes. Shields et al,¹² however, did not find the problem rate to vary in the eyes receiving prior radiation or surgery. Size of the implant^{16,20} is not important in determining the incidence of exposure. Shaving the anterior surface of the implant was also not effective in preventing or treating exposure.¹⁶

Other potential problems include biodegradation particularly at the tissue-implant junction due to the activity of macrophages²⁴ which might result in long-term resorption of the implant.

In our series, secondary drilling and insertion of a motility peg was not performed. Even without the peg, the patients have been pleased with the implant, attesting to the satisfaction with the motility and cosmesis

provided. Recent studies have also shown that only 2% to 23%^{11,15-17} of patients undergo second stage drilling, indicating that drilling of the implant is not always necessary but gives extra stability and improved motility to the prosthesis.

Studies have shown hydroxyapatite to be well tolerated with good motility as an orbital implant in adults and also in children as young as 1 year old. Shields et al have successfully used hydroxyapatite even in cases of tumour with no infection, extrusion or migration.¹³ It also does not appear to interfere with detection of tumour recurrence as it appears densely radiopaque on computerised tomographic scan with low signal intensity on magnetic resonance imaging. It is recommended that hydroxyapatite be used in young patients wanting maximal prosthetic motility. Its use is discouraged in cases of severe orbital and adnexal trauma, suboptimal vascularisation and poorly controlled diabetes mellitus.^{17,20}

Hydroxyapatite has also been successfully used as a secondary implant.^{9,15,17,18} In our series, all 4 patients who presented with extrusion of a previously implanted glass ball implant have done well with hydroxyapatite. With its low rates of infection, migration and extrusion, the benefits of this implant outweigh its relative higher cost especially if long term studies confirm its low complication rate.

From our experience, it appears that hydroxyapatite is the implant of choice for an anophthalmic socket. It becomes incorporated by the patients own tissues and once vascularised, it is less likely to migrate or extrude. Its complication rate is not high and implant exposure, if it occurs, can be easily managed.

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