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Coralline hydroxyapatite sphere in orbit restoration

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ABSTRACT: Purpose. *To restore the anophthalmic socket, primarily or secondarily, using a hydroxy-apatite sphere (HA).*
Methods. *We used HA in 33 patients (25 male, 8 female), aged from 4 to 68 years (mean 38.1 years) for 19 primary and 14 secondary implantations. HA spheres measured 16 mm in one patient, 18 mm in 21 and 20 mm in 11. The spheres were wrapped in donor sclera preserved in absolute alcohol. All six extraocular muscles were isolated, in the cases where this was possible. Buccal membrane was grafted in three patients to restore the fornices. Drilling was done on four patients using a 3.8 serrated plastic sheath.*
Results. *During follow-up of 7 - 69 months we observed no complications except for slight edema in the immediate postoperative period. All patients gained very good to excellent motility of the implant, acceptable symmetric appearance in the case of primary implantation, and a dramatic improvement of facial appearance in the case of secondary implantation.*
Conclusions. *HA spheres are an excellent orbital implant for primary and secondary restoration of the anophthalmic socket causing no serious complications (Eur J Ophthalmol 1999; 9: 302-8)*

KEY WORDS: Hydroxyapatite implant, Orbit restoration, Enucleation, Secondary implantation

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INTRODUCTION

Enucleation of the bulbus is always a difficult decision for the ophthalmologist and it is considerably more difficult for the patient to accept it. The deformity resulting from face asymmetry after enucleation affects the patient's personality and often causes psychological problems. The surgeon's basic concern is to restore normal facial appearance, with good artificial eye motility (1).

In the last 100 years many procedures have been applied, with a wide variety of intraorbital implants designed to give better prosthetic movement (2-3). Although the results have been good enough from an esthetic viewpoint, many problems arise as regards motility, such as extrusion, migration, inflammation and infection. Surgeons have therefore sought new materials to overcome the complications.

In 1989 Perry introduced an implant constructed from a new material, hydroxyapatite (HA), which comes from marine coral after a special biochemical process. It is well tolerated and complications arising from the synthetic materials are minimal (2-5).

In this paper we present our experience in the past six years, concerning the behavior of the HA implant used for restoration of the orbit after enucleation or evisceration, or in anophthalmic sockets.

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METHODS AND PATIENTS

We implanted porous hydroxyapatite spheres in 33 patients. Age ranged between 4 and 68 years, with an average of 38 years. The main reason for primary and secondary implantation was traumatic injury of the eye. Table I summarizes the reasons for the primary and secondary operations. Primary implantations were performed in 19 patients, secondary implantations in 14 patients. In six patients, the HA sphere was implanted in enucleated eyes without an intraocular implant. The enucleation had been performed 0.5 to 45 years before secondary implantation. In two patients, the HA sphere was implanted in previously eviscerated eyes with no implant, after 12 years and 5 months. In six patients a previously inserted orbital implant was replaced for different reasons. Two of these patients were unsatisfied with their facial appearance on account of enophthalmus and poor motility of the artificial eye. In one patient a conical double-plate implant that had been implanted 24 years before was removed because of orbital inflammation and fistula formation. One patient had lost a silicone sphere implant six months after the implantation. In one patient the implant had migrated three months after the implantation and in one a silicone sphere was replaced twice, with two successive implantations of HA spheres that became exposed and finally had to be removed.

Preoperative study of each patient included a detailed history, photography of the face, evaluation of the position and motility of the eyelids, evaluation of the status of the orbit and, in cases with uveal melanomas, a full laboratory work-up for metastases. In patients where enucleation or evisceration had been done earlier a CT-scan of the orbits in coronal and axial sections was taken preoperatively to assess the status of the orbit and the position and quality of the extraocular muscles (Fig. 1).

TABLE I - HYDROXYAPATITE ORBITAL IMPLANTATION IN 33 PATIENTS

Reason for implantation	Primary	Secondary	Total
trauma	8	7	15
choroidal melanoma	8	2	10
microphthalmols	1	1	2
endophthalmitis	1	1	2
buphthalmus	1	1	2
retinoblastoma		2	2
Total	19	14	33

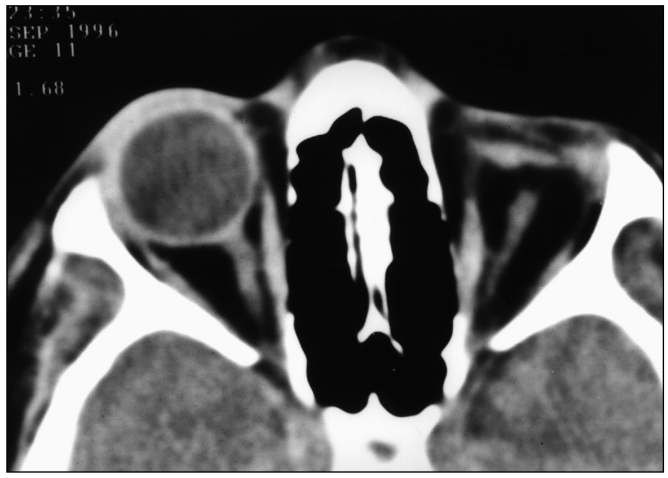

Fig. 1 - *Computerized tomography scan of the orbits. Axial view. Left anopthalmic socket. The position of the medial and lateral rectus muscles is clear.*

All patients were operated with general anesthesia and under the microscope. The following technique was used: a 4/0 silk suture was placed through the upper and lower lid in order to define the upper limit of the tarsus and fornix. This also isolated and protected the levator muscle and permitted identification of the superior formix to prevent it from being shortened during closure of the anterior Tenon's capsule.

A 20-mm HA sphere was used in 11 patients, an 18-mm in 21 patients and a 16-mm one in a 4-year-old boy. All implants were wrapped in donor sclera preserved in absolute alcohol, supplied by the Eye Bank of Greece. Before use, the sclera was soaked for 30 minutes in saline solution which was changed 3-4 times in order to hydrate the sclera and remove all alcohol, thus eliminating post-operative edema. A 5/0 Vicryl tight running suture was used to suture the sclera over the implant.

Four 3x7 mm scleral windows were cut out around the anterior pole and a circular opening, 5 mm in diameter, was created on the posterior pole. The four recti muscles were secured to the appropriate scleral openings with 6/0 Vicryl suture. The two oblique muscles were secured to their anatomical positions directly to the sclera without scleral openings. The Tenon's capsule was closed with multiple interrupt-

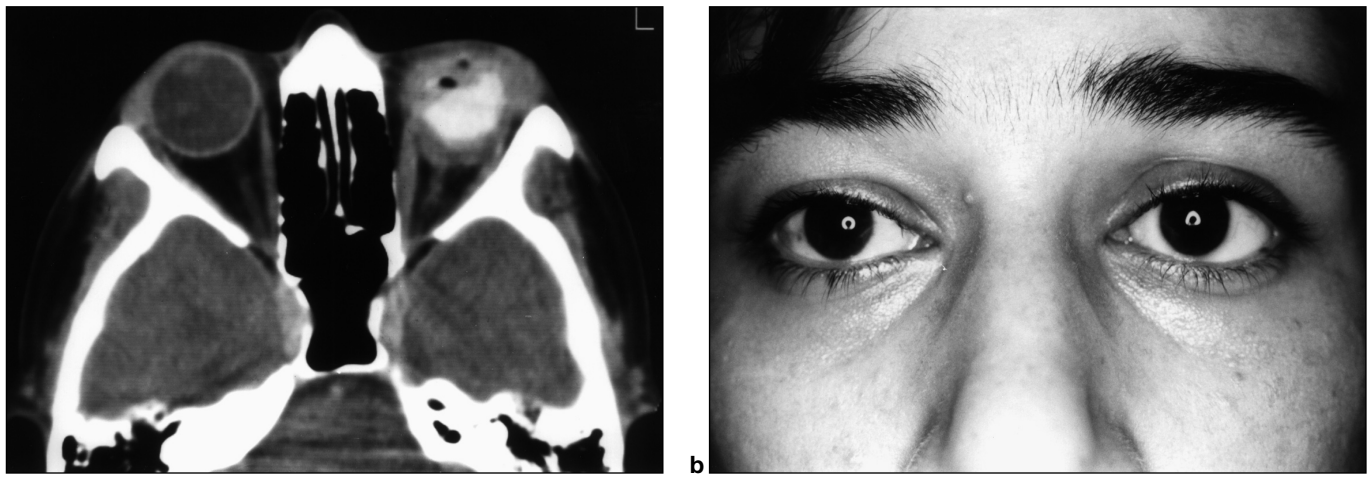

Fig. 2 - ***a)*** *Computerized tomography scan of the orbits. Axial view. Left anopthalmic socket with implant. Air is present in the socket, denoting fistula formation. There is peri-implant inflammation and an increase in the diameter of the medial rectus muscle due to inflammation.* ***b)*** *The same patient after replacement of the previous implant with an HA sphere.*

ed 5/0 Vicryl sutures, trying to avoid tension over the implant. The conjunctiva was sutured with a tight running 6/0 Vicryl suture.

Bupivacaine with lignocaine was injected intraorbitally - retroimplant or paraimplant - to avoid postoperative pain. Before the tight patching, a mixed antibiotic and corticosteroid ointment was used and an acrylic conformer was placed in the fornices. A Frost's suture was placed in both eyelids and removed on the 2nd or 3nd day after the operation depending on orbital edema.

At the beginning of the operation the patient received an IV injection of 8 mg dexamethasone phosphate and a second-generation cephalosporin. After the operation, anti-inflammatory and antibiotic medications were administered systematically for five days. Iced pads were used on all eyes on the first postoperative day.

All patients had a custom-fitted conformer put in place for 40 days after surgery. After that period the oculist provided them with an artificial eye.

Primary implantation

A 360° peritomy of the conjunctiva was performed, trying to preserve as much conjunctiva and Tenon's capsule as possible to enable us to close them over the implant without tension at a later stage. All six extraocular muscles were isolated by removing their sheaths approximately 1 cm from the point of insertion and securing them with double-armed 6/0 Vicryl sutures as in standard strabismus surgery. After removal of the globe the posterior hole of the Tenon's capsule was inspected. If the hole was too small it was enlarged with scissors so the implant could be placed behind the capsule, deep inside the orbit.

Secondary implantation

During secondary implantation tissues were gently manipulated mainly by blunt dissections. The implant was inserted deep into the orbit after removal of the connective tissue. Tenon's capsule was closed in multiple layers. Preservation of the conjunctiva was crucial for the formation of the fornices. Additional tissue (buccal membrane graft) was used in three patients to achieve this. The buccal membrane was placed over the sutured Tenon's capsule covering the area of the implant and secured with tight running 6/0 Vicryl to the conjunctival edges.

Evisceration

In the two previously eviscerated eyes with no implant, a careful approach of the coloboma revealed all six extraocular muscles quite easily.

Enucleation with no implant

In the cases where enucleation dated a long time back, the main problem was identification and isola-

tion of the muscles. A lot of connective tissue adheres to the sutured ends of the muscles, and careful manipulation of the tissues enables the surgeon to recognize this. A CT scan and details of the previous operation help too. During isolation there is a great danger of shortening the muscle. In five patients all six extraocular muscles were identified and tied, but in one patient with atrophy only the four recti muscles were identified.

Replacement of the implant

The implant was replaced in three patients. After identification of the muscles and careful disinsertion of the existing implant the pseudocapsule was removed in order to gain access to the vascularized orbit. In one patient with an infected implant and fistula, the medial rectus muscle was melted at the point of attachment to the implant. Deep blind sutures were passed through the muscle belly and secured to the equator of the implant without a scleral window (Fig. 2).

Migration or extrusion of the implant

In these situations the anatomy of the socket is changed. Depending on how the implant had moved from its original position, connective strands develop as an extension of the muscle. Careful manipulation and identification of these strands is needed to reveal the muscles. Once muscles have been isolated the procedure is carried out as previously described.

Drilling

Only four of the 33 patients needed drilling and insertion of a peg. The timing for drilling depended on the evaluation of the neovascular ingrowth of the HA sphere using MRI (Fig. 3). MRI was done eight months after implantation of the HA sphere.

Drilling was done under aspetic conditions after retroimplant injection of 2 cc bupivacaine 0.5% + 3 cc lidocaine-adrenaline 2%. Before the injection the position of the future hole was marked with a pen, having been determined from the implant movements in all positions of gaze. The HA material was exposed through a small conjunctival and Tennon's capsule opening without cautery. A commercial electric drill was used to open first a 3.2 diameter lumen and finally the 3.8 diameter lumen, directed to the center of the HA sphere. Finally the plastic serrated sheath

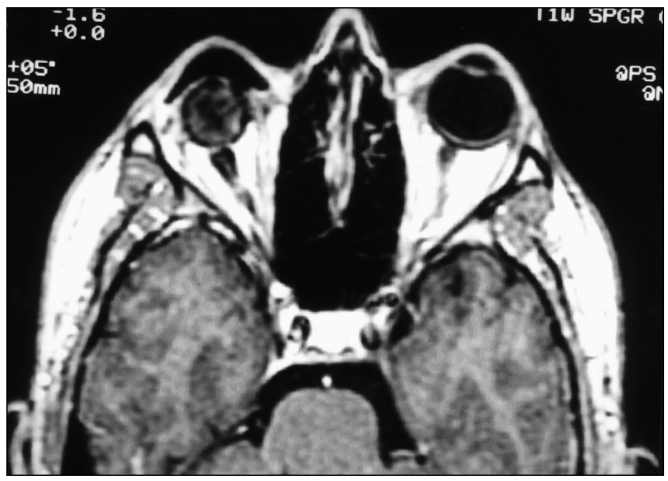

Fig. 3 - *Magnetic resonance imaging of the orbits with T1-SPGR sequence. Axial view. Right socket with HA sphere in position after IV infusion of paramagnetic contrast agent. The intense signal indicates the neovascularization of the HA.*

was inserted, with the aid of mixed ointment, and the peg was put in place.

RESULTS

The follow-up period ranged from 7 to 69 months, averaging 32 months. During this period we observed no complications except for slight orbital edema during the immediate postoperative period; this subsided with antinflammatory medication. There were no cases of orbital infection, orbital hemorrhage, implant migration or implant extrusion during the follow-up period. We had no porblems with the lids, fornices or conjunctiva, even in the cases where buccal membrane had been used. To date no patient has had to undergo additional surgery.

To judge the motility of the implant we simply place a ruler horizontally over the nose as to measure the interpupillary distance. After marking the center of the socket the patient is asked to direct the gaze right and left while reading the indication on the ruler. Then, holding the ruler vertical through the center of the socket, we examine the motility of the socket in the same way in the up and down gaze positions. Movement of the implant in all four gaze positions over 4-5 mm was judged as excellent and 1-2 mm as poor.

In primary implantation all patients had excellent movement of the implant in all directions of gaze. All

had normal face appearance with no enophthalmus, and acceptable movement of the artificial eye. All patients were satisfied with the result. In cases involving secondary implantation all patients gained a better facial appearance due to the elimination of enophthalmus and improved prosthetic fitting (Fig. 2). The movements of the implant were very good to excellent and better than before surgery. In one patient the movements of the implant were only good because of muscle atrophy, and in the patient whose medial rectus muscle was melted, the inward movement was limited to 2-3 mm.

After the drilling procedure all four patients gained slightly better movement of the artificial eye. Failure to modify the prosthesis correctly, by an inexperienced oculist, limited the final outcome in these cases.

DISCUSSION

The use of porous HA spheres as intraorbital implants has opened new horizons in orbital implantation surgery. Their advantages are well established (3, 6-7). Atoxic, non-allergic and fully biocompatible, allowing the ingrowth of new vessels, this porous material minimizes the complications of extrusion and inflammation.

Further complications are limited by wrapping the rough surface of the HA implant, ideally in preserved donor sclera, because this limits dehiscence of the conjunctiva and renders the whole procedure of implantation easier and safer. The alcohol preserving solution must be completely removed from the sclera tissue before the wrapping so as not to cause postoperative edema.

We used 16-mm, 18-mm and 20-mm diameter spheres. The surgeon must bear in mind that wrapping the HA ocular implant in sclera adds approximately 1.5 mm to the diameter. Larger-diameter spheres may be necessary in cases of repeated orbital surgery with fat atrophy and where there is a pre-existing condition of enophthalmos. A large implant presents the oculist with several problems. It may make it impossible to construct an artificial eye with sufficient anterior-posterior thickness to create a realistic anterior chamber depth. In addition, an artificial eye that is too thin may prevent the oculist from modifying its posterior surface after the pegging procedure (5).

The cosmetic result of the artificial eye was very satisfactory in our patients (8). This helped patients accept the removal of their eye more easily. The artificial eye moved slightly in all directions of gaze and only four patients needed drilling and insertion of a peg. However, we believe that after some years the deformation that will be caused by loosening of the eyelid will oblige most of them to proceed with drilling in order to prevent or repair this complication. One of the advantages of the pegging system is that the artificial eye is supported by the peg, not by the lower lid.

The final cosmetic outcome depends on the oculist. An experienced oculist will provide the patient with a more symmetrical facial appearance and a more natural-looking artificial eye.

We consider this a safe procedure with a low rate of complications (9). We observed no serious complications in our patients, only slight postoperative orbital edema. We encountered no conjunctival dehiscence or exposure of the implant, complications that have been reported (7, 10, 11). We believe that this is due mainly to the surgical procedure, as other writers suggest (12-15). The surgeon must perform every step very carefully, with minimal tissue distortion, and must bear in mind that the elimination of intra- and postoperative edema is vital to the final outcome. The administration of IV corticosteroids at the beginning of the operation, aggressive anti-inflammatory systemic medications in the postoperative period, the use of a conformer and the double Frost's suture, with the use of iced patches on the first day all help reduce the edema and the subsequent tension of the implant over the Tenon's capsule and conjunctiva.

In addition, we believe that the HA sphere must be wrapped and that wide windows must be opened in order to promote vascularization, as most of the problems arise when the HA fails to vascularize itself (16, 17). To increase vascular ingrowth in our patients we removed the muscle sheaths approximately 1 cm from their insertion in order to expand the muscle to the whole width of the scleral opening, where we secure it with 6/0 Vicryl. We had no problems with motility of the implant due to adhesions with this procedure. We also used wider scleral windows, to allow a larger portion of the muscle to come in to contact with the HA material. The direct contact of the posterior scleral opening with the posterior orbit after opening the

Tenon's capsule or removing the pseudocapsule of a previous implant serves the same purpose.

A disadvantage of this new material is the long time needed for the whole procedure and its high cost. Furthermore, considerable skill is required on the part of the surgeon if the operation is to give an optimal result.

The drilling procedure must only be perfomred after full vascularization of the HA sphere, to avoid complications. We proceeded with MRI examination eight months after the implantation surgery in order to allow time for vascularization (18-21). Even so the vascularization was not sufficient in one patient and we had to proceed with a second MRI after two months, thus increasing the already high cost of this procedure. Efforts have been made to overcome this problem (22). To eliminate the risk of HA exposure and later complications during the drilling procedure, we used no cauterization for bleeding, we created a small conjunctival and Tenon's capsule opening and we used the sleeved peg system (23). The main problems during this operation are the noise of the drill and the pressure on the HA sphere that can be very disturbing to the patients, who must be informed in advance about the whole procedure.

CONCLUSIONS

Having years of experience with many previous types of intraorbital implant, we consider the hydroxyapatite sphere, used in primary or secondary implantation with few complications, to be an excellent implant despite its high cost. It not only anatomically restores the orbital volume but also provides excellent motility of the artificial eye with normal facial appearance.

Surgeons performing these operations must keep in mind that for the best final esthetic results an oculist with experience in this field is essential, otherwise patients will face problems with the fitting and the quality of the artificial eye.

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