LACK OF COMPLICATIONS OF THE HYDROXYAPATITE ORBITAL IMPLANT IN 250 CONSECUTIVE CASES*

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INTRODUCTION

INTEGRATED ORBITAL IMPLANTS ARE DESIGNED TO PROVIDE IMPROVED motility of the ocular prosthesis.[1] This is accomplished by connecting the moving orbital implant powered by extraocular muscles to the relatively stationary overlying prosthesis. Historically, there has been a general hesitancy of ophthalmic surgeons to use an integrated orbital implant after enucleation, because it often became infected or extruded. Such problems with integrated orbital implants were common with the exposed implants that were used in the 1940s and 1950s.[1-3] To allow direct integration of the implant with the overlying prosthesis, a portion of the anterior surface of these implants was purposely not covered by human tissue. Unfortunately, this exposed portion of the implant served as a site for tissue infection, tissue erosion, and eventual implant extrusion. These experiences demonstrated that an integrated orbital implant should be buried, not exposed. It should be covered completely by conjunctiva so as to prevent the unacceptable complications of the prior implants.

The hydroxyapatite orbital implant is a buried orbital implant that can be integrated to the overlying prosthesis.[4-8] It was devised by Dr Perry and associates, who studied the performance of the implant initially in animals and later obtained approval by the Food and Drug Administration for its use in humans in 1989.[5] To obtain maximal prosthesis motility, the implant can be connected to the prosthesis via a peg that is placed into a conjunctival-lined orifice in the vascularized buried implant.[9] The vascularization of the implant is encouraged by its totally porous framework and is important in

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preventing infection and extrusion. This is a tremendous improvement over the integrated orbital implants that were used in the past.

We report our experience with 250 consecutive cases of hydroxyapatite orbital implant placed after enucleation. We emphasize the complications of this procedure and their management.

PATIENTS AND METHODS

We reviewed the charts and examined prospectively all our patients who had a hydroxyapatite orbital implant placed after enucleation. We identified 250 consecutive patients who had the implant placed since we first used it, in January 1990, up to the end of the study period, December 1992. The implant was used only for patients who had enucleation and was not used after evisceration. The selection of patients suited for the hydroxyapatite orbital implant has been discussed by us previously.[7]

The parameters evaluated in this study included ocular diagnosis prior to enucleation, reason for enucleation, and prior ocular surgery or ocular treatment. The size and shape of the hydroxyapatite implant and the use and preparation of the sclera covering of the implant in each case were recorded. Early and late postoperative problems and their management were recorded. Those patients who elected to have the placement of the peg had prior gadolinium-DTPA enhanced magnetic resonance imaging to precisely evaluate the degree of implant vascularity.[10] Early and late postoperative problems after drilling were recorded and their treatments were evaluated.

Our technique of enucleation and hydroxyapatite implantation has been recently described[7] and is similar to other published techniques.[4-6] Under local or general anesthesia, the patient is prepared for enucleation. Contrary to some surgeons, we do not inject retrobulbar vasoconstrictors in eyes harboring intraocular malignant neoplasms, because of risk of globe perforation and tumor seeding. After the limbal peritomy is completed, all six extraocular muscles are sequentially identified, tagged with 5-0 polyglactin 910 (Vicryl) sutures, and disinserted from the episclera with as little manipulation of the globe as possible. The medial rectus muscle stump is grasped with a straight clamp, and the globe is carefully pulled anterolaterally to allow for ease of severing the optic nerve from the nasal side with appropriately designed enucleation scissors. In patients with retinoblastoma, we attempt to obtain a long section of optic nerve with the globe.[8-11] In patients with tumors, we do not clamp, snare, or cauterize the optic nerve before cutting it, because of the trauma and pressure induced on the nerve and globe and the difficulty in histopathologic interpretation of the damaged optic nerve margin. After removal of the globe, hemostasis is achieved with

gauze or digital pressure and liquid thrombin. We avoid cautery of the orbital tissues because of the difficulty in localizing the exact bleeding site and the heat-induced tissue shrinkage causing subsequent cosmetic enophthalmos.

We generally use a 20-mm sphere in adults and children older than 36 months, and we use an 18-mm sphere in young children. In infants less than 6 months old, we generally employ a 16-mm implant. We soak the brittle hydroxyapatite sphere (Integrated Orbital Implants, San Diego, CA) in balanced salt solution and then wrap it with fresh or banked sclera that has been screened for infectious disease, cancer, and other diseases using the same protocol that is used nationally for corneal donor tissue. The sclera is pretreated with antibiotics and 10% povidone-iodine (Betadine).[7,12,13] It is tightly wrapped around the hydroxyapatite sphere and sutured with 5-0 polyglactin 910 (Vicryl) suture, leaving a 12- to 14-mm round opening in the sclera at the site of the posterior aspect of the implant. Four rectangular scleral windows (6 × 5 mm) are fashioned for anatomic insertion of the rectus muscles to allow fibrovascular ingrowth at these sites. The scleralized implant is then soaked in antibiotic solution until it is placed in the orbit.

After complete orbital hemostasis, the prepared implant is inserted into the muscle cone of the orbit, and all six extraocular muscles are attached to their anatomic sites on the scleralized implant. The rectus muscles are pulled through the scleral windows and tied in apposition to the hydroxyapatite sphere. The oblique muscles are attached in their anatomic positions directly on the scleral surface. A thick bed of Tenon's fascia is closed over the implant so that the implant is deeply buried in the mid to posterior orbit. The conjunctiva is closed with a running absorbable suture. A large conformer is placed, antibiotic ointment is instilled, and a heavy pressure dressing is worn for at least 24 hours. The patient is fitted with a standard prosthesis 3 to 6 weeks after the surgical procedure.

Four to 6 months after the implant is placed, the patient may maximize motility of the prosthesis by undergoing placement of a connecting peg. The orbital tissue is imaged with gladolinium-DTPA enhanced magnetic resonance imaging to assess fibrovascular ingrowth into the implant.[10] If ingrowth is adequate, then the implant is drilled with a 10 × 3 mm bit on a hand drill. A temporary peg is placed, and 3 to 4 weeks later this is replaced with a permanent smooth peg in the office.[7,14] The back surface of the prosthesis is then reshaped by an ocularist to conform exactly to the peg contour. A ball and socket connection of the peg to the prosthesis is made, and the prosthesis rests on the peg and moves directly with the peg.

RESULTS

There were 250 consecutive patients in this prospective study who had enucleation and hydroxyapatite implantation. We had no cases of evisceration in our series. There was once case of a secondary implant, and the remaining 249 cases were primary implants. The mean follow-up was 23 months (median, 17 months; range, 6 to 42 months). The clinical reasons for enucleation included uveal melanoma in 157 cases, retinoblastoma in 70 cases, blind painful eye in 22 cases, and medulloepithelioma in 1 case (Table I). There were no cases of enucleation for endophthalmitis. The cause of the blind painful eye included complications of extensive trauma in 12 cases, neovascular glaucoma in 4 cases, large uveal metastases nonresponsive to conservative measures in 2 cases, intraocular invasion of squamous cell carcinoma of the conjunctiva in 1 case, and massive tuberculoma of the uvea and sclera with dehiscence of the sclera in 1 case.[15] In two of the eyes with uveal melanoma, there was massive extraocular extension that required lateral orbitotomy and modified exenteration removing the globe and the pseudoencapsulated extraocular tumor.[16] The extraocular muscles and peripheral orbital tissue were preserved, and a hydroxyapatite sphere was successfully employed.

Forty-seven of the patients had prior treatment before enucleation, which included shielded plaque radiotherapy in 18 cases, external beam radiotherapy to the globe and orbit in 6 cases, multiple surgical repairs for a traumatized ruptured globe in 17 cases, partial lamellar sclerouvectomy for a uveal tumor in 5 cases, and multiple conjunctival excisions for conjunctival squamous cell carcinoma in 1 case (Table II). It is calculated that the orbital tissue receives 0 to 200 cGy from a properly shielded iodine 125 plaque with radiation doses used for a uveal melanoma. The orbital tissue received 4,000 to 5,000 cGy in those eyes treated with external beam radiotherapy. The surgical technique was minimally modified, as needed, for those patients with prior surgery. The patients who had prior procedures (including irradiation) on the affected eye experienced no excessive complications and tolerated the implant well.

In all cases the implant was wrapped in sclera that was pretreated with antibiotics and povidone-iodine. We did not use irradiated sclera. The implant was spherical in all cases and was not decapitated anteriorly or reshaped in any way. In children less than 6 months old, we used a 16-mm implant, depending on the orbital volume; in children 6 months to 3 years old, we used an 18-mm implant; and in patients older than 3 years, we used a 20-mm implant. We did not use a 22-mm implant in any case.

Of the 250 cases, we considered 140 patients eligible candidates for peg placement (Table III). Of the 140 eligible patients, 109 were satisfied with

TABLE I: REASONS FOR ENUCLEATION IN 250 CONSECUTIVE CASES OF HYDROXYAPATIDE ORBITAL IMPLANTATION

DIAGNOSIS	NO.
Uveal melanoma	157
Retinoblastoma	70
Blind painful eye*	22
Medulloepithelioma	1
Total	250

*Blind painful eye was caused by extensive trauma after repair in 12 cases, neovascular glaucoma in 4 cases, persistent hyperplastic primary vitreous in 2 cases, uveal metastases in 2 cases, intraocular involvement with conjunctival squamous cell carcinoma in 1 case, and massive tuberculoma in 1 case.

TABLE II: PRIOR TREATMENT TO EYE OR ORBIT IN 250 CASES OF HYDROXYAPATITE ORBITAL IMPLANTATION

TREATMENT	NO.
Plaque radiotherapy	18
Ruptured globe repair (multiple operations)	17
External beam radiotherapy	6
Partial lamellar sclerouvectomy	5
Conjunctival tumor resection	1

TABLE III: REASONS FOR AND AGAINST PEG PLACEMENT IN 250 CASES OF HYDROXYAPATITE ORBITAL IMPLANT

REASON	NO PEG PLACEMENT (n = 219)	PEG PLACEMENT (n = 31)
Improved motility	—	31
Satisfied with motility	109	—
Patient age < 6 yr	70	—
Implant age < 6 mo	37	—
Patient dead	3	—

their cosmetic appearance and motility and preferred not to have the peg placed. A peg was successfully placed in the other 31 cases. We prefer to wait until the implant is 6 months from the time of placement to allow adequate fibrovascular ingrowth, and we prefer the patient to be at least 6 years of age so that cooperation with the ocularist is adequate for ideal prosthesis revision; therefore, we consider these two patient groups temporarily ineligible for peg placement.

Complications of the hydroxyapatite orbital implant were few and included conjunctival thinning without erosion in 8 cases, conjunctival erosion in 4 cases, presumed orbital infection in 1 case, and peg extrusion in 2 cases (Table IV). Five of the eight cases (62%) of conjunctival thinning and three of the four cases (75%) of conjunctival erosion occurred in children under 5 years of age. There were no cases of orbital hemorrhage, implant migration, or implant extrusion.

TABLE IV: COMPLICATIONS OF HYDROXYAPATITE ORBITAL IMPLANTATION AND THEIR MANAGEMENT IN 250 CONSECUTIVE CASES

COMPLICATION	NO.	MANAGEMENT OF COMPLICATION
Conjunctival thinning	8	Adjust prosthesis vault and fit, observation
Conjunctival erosion*	4	Adjust prosthesis vault and fit, scleral patch graft and conjunctival flap
Orbital hemorrhage	0	—
Oribital infection	1	Intravenous antibiotics (implant retained)
Implant migration	0	—
Implant extrusion	0	—
Peg extrusion	2	Remove granulation tissue in drilled peg hole

*Conjunctival erosion due to flat or irregular vault on posterior surface of prosthesis in three cases and poor surgical wound closure in one case.

In cases of conjunctival thinning, the treatment was prosthesis adjustment and careful observation in all cases. In cases of conjunctival erosion, the treatment was surgical repair and prosthesis adjustment in three of the four cases. Those three cases had a poorly fitting prosthesis with pressure points on the conjunctival surface that lead to the erosion at 6, 7, and 12 months postenucleation, respectively. The erosion in these three cases measured approximately 4 mm in diameter, and the underlying sclera was melted at the site of erosion. Two of the three cases were managed by the same ocularist and had a fairly flat posterior prosthesis vault that needed to be more highly vaulted (Fig 1). In the last of the three cases, erosion developed 12 months after enucleation, and orbital magnetic resonance imaging showed deficient vascular ingrowth within the central portion of the implant (Fig 2). The fourth case of conjunctival erosion occurred 1 month after enucleation and was due to inadequate would closure. All cases of conjunctival erosion were repaired with conjunctival wound repair initially, and three subsequently required a scleral patch graft/conjunctival flap for adequate closure.

The two cases of peg extrusion were first recognized at 1 and 7 months after peg placement, respectively. Both were due to granulation tissue filling the orifice for the peg and pushing the peg out. In no cases did the peg simply fall out of its otherwise normal orifice. In three cases, there was a subtle but audible click of the peg on the back of the prosthesis in extreme gaze.

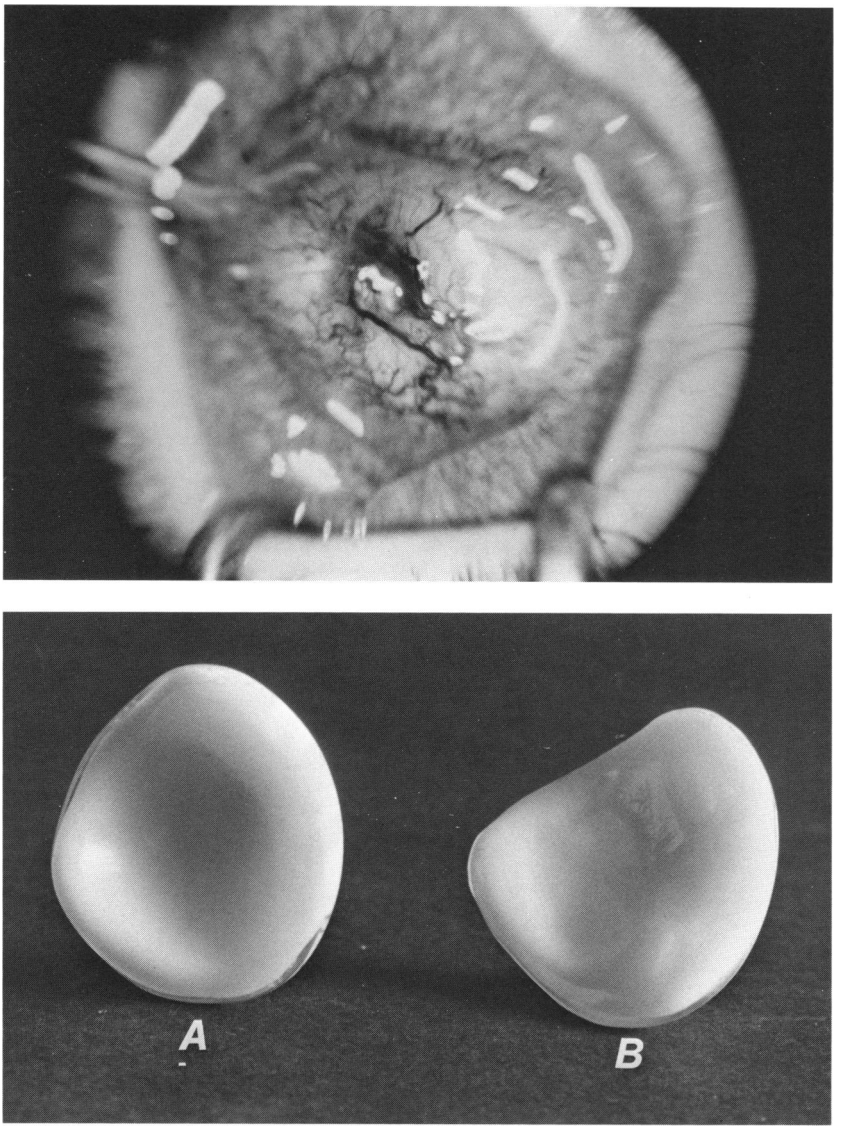

FIGURE 1
Top: Small conjunctival erosion 7 months after hydroxyapatite placement in a child. Bottom: Prosthesis vault was flat and caused pressure necrosis, presumably leading to erosion. A, normal prosthesis vault; B, flat irregular prosthesis vault.

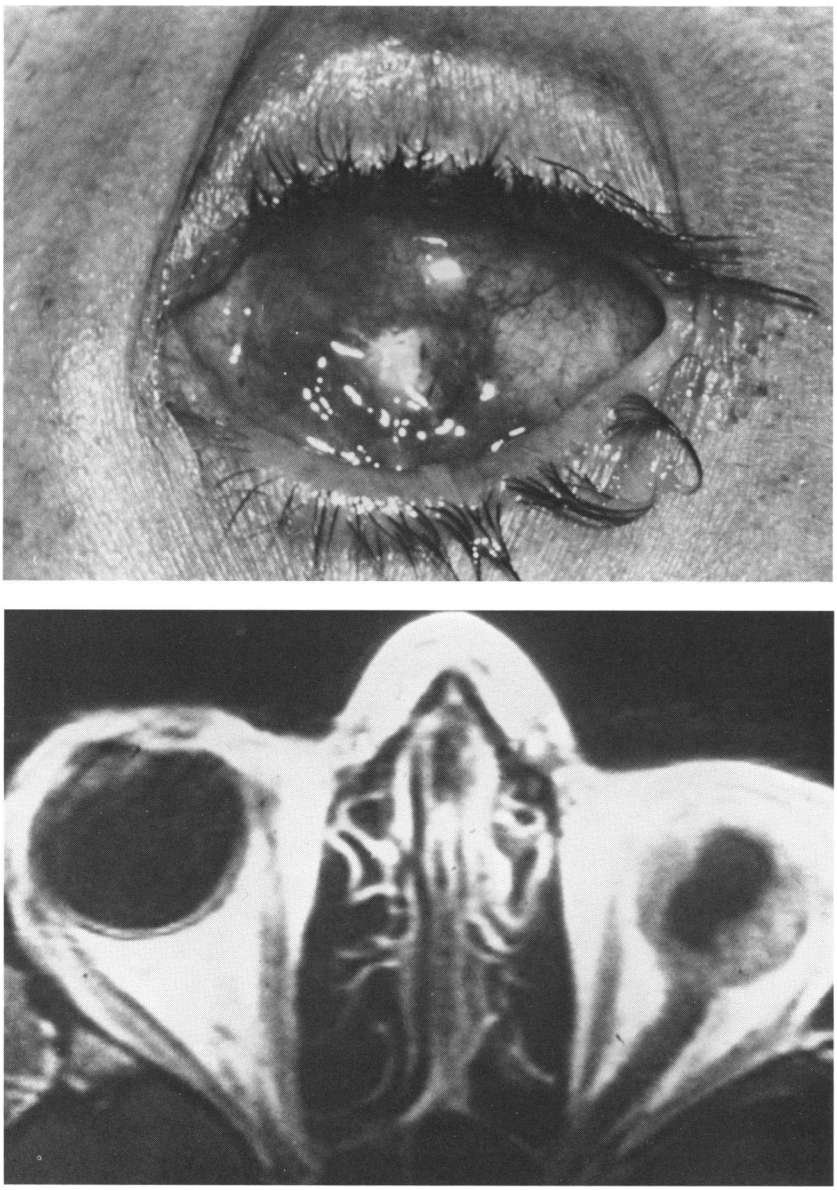

FIGURE 2
A: Erosion of conjunctiva overlying hydroxyapatite orbital implant 12 months after enucleation of large choroidal melanoma in an adult. B: Magnetic resonance imaging scan of orbit with gadopentate contrast demonstrates central area within orbital implant without enhancement, indicating poor implant vascularization. This may have contributed to overlying tissue erosion.

The case of presumed orbital infection, characterized by persistent mild pain and mucoid discharge, occurred 3 months after enucleation in a child with an upper respiratory illness. It was diagnosed and managed elsewhere; conjunctival swab and blood cultures were negative, and the problem resolved with intravenous antibiotics. The implant was retained within the orbit, and the cosmetic appearance and motility of the prosthesis were undisturbed after treatment.

DISCUSSION

Porous hydroxyapatite is a material derived from the skeletal structure of specific marine corals and is composed primarily of calcium phosphate, with a regular system of interconnecting pores of approximately 500 μm in diameter.[17,18] The porous nature of this substance encourages ingrowth of host fibrovascular tissue and converts this inert structure into living tissue, similar to bone. Hydroxyapatite has been used as a bone substitute in the fields of orthopedics and maxillofacial and dental reconstruction for the past 15 years.[17-23] The structure eventually transforms into woven and then lamellar bone over time and provides good biomechanical results.[17-23]

Over the past century most orbital implants have been nonintegrated, that is, not directly connected to the overlying prosthesis. The benefit of an integrated implant is that the ocular prosthesis has improved motility and appears more like a natural eye.[4-8] The major advantages of orbital hydroxyapatite implant over prior integrated implants are: (1) it is less likely to develop infection, because of its vascularized buried state; (2) it is less likely to migrate or extrude, because of its transformation into living tissue by fibrovascular ingrowth; and (3) it tolerates the foreign body peg, because of its conjunctiva-lined orifice for the peg, preventing direct contact with the implant.

Our study has demonstrated that hydroxyapatite is well tolerated in the human orbit. Our rate of complications is low and consists primarily of minor conjunctival thinning or conjunctival erosion. We believe our success can be partly attributed to covering the implant with sclera, careful generous tissue closure over the implant, and the ocularist's attention to vaulting the posterior surface of the prosthesis to prevent pressure necrosis. Although we originally did not modify the shape of the implant, we currently often shave the anterior portion of the hydroxyapatite sphere to alleviate the problem of conjunctival thinning and erosion.[6]

In assessing a patient with conjunctival thinning or erosion over an implant, we believe that the length of time since enucleation may help identify the source of the problem and aid in management. If the defect is

found in the first few weeks after enucleation, then it is likely due to inadequate wound closure after digestion of the resorbable suture. The suture may need to be replaced if the defect is large. If the conjunctival defect occurs several months or later after the implant is placed, it may be due to a poorly fitting prosthesis causing pressure necrosis, anterior orbital malplacement of the implant, inadequate closure of Tenon's fascia over the implant, or lack of implant vascularization. In those patients with late conjunctival breakdown, we first assess the fit of the prosthesis. If the posterior vault and edges of the prosthesis appear appropriate, then we address the implant itself.

We prefer to manage conjunctival thinning conservatively by observation. In those sockets with conjunctival erosion, we "roughen" the edges of the overlying conjunctiva with a blunt instrument to encourage granulation tissue. If this does not close the defect satisfactorily over a period of several months, then we revise the wound and anterior orbit by loosening all adhesions to the implant and reclosing the wound with generous Tenon's fascia and conjunctiva. If the defect persists despite this, then we dissect the tissue extensively and place a scleral patch graft if the implant sclera has melted. A generous Tenon's fascia closure and conjunctival flap are fashioned over the sclera. We have not had to exchange or remove any implant due to delayed healing of the conjunctiva.

We have not used the implant for eviscerated globes or after removal of infected globes, perhaps because most of our patients have intraocular tumors. One group reported that four of six patients who had hydroxyapatite implant after evisceration experienced tissue breakdown and exposure of the implant.[24] The evisceration was performed for endophthalmitis in two cases. They also observed would breakdown and implant exposure in 4 of 31 cases where the hydroxyapatite implant was used after enucleation.[24] In three of the four cases, the breakdown occurred 2 to 4 weeks after implant placement, and we suspect this was due to inadequate tissue closure at the time of surgery, as we observed in one of the cases that we report in this study. Fortunately, five of the eight wound breakdowns in their series healed with conservative methods without surgical intervention.[24] Others have reported six cases of wound breakdown over the hydroxyapatite implant, and these included two cases after evisceration, one after implant exchange in a previously infected socket, one after implant exchange in a socket that had extruded a silicone implant, and two after primary enucleation.[25] It seems from these reports that hydroxyapatite is less well tolerated in eviscerated eyes and those eyes with prior infection.

Hydroxyapatite is well tolerated in both adults and children.[26] We have used this material in 70 children enucleated primarily for retinoblastoma,

and it has not interfered with orbital examination. One can palpate the soft tissues around the implant to detect recurrence. Both hydroxyapatite and the previously employed polymethylmethacrylate appear densely radiopaque on computed tomography and with a low-signal intensity on magnetic resonance imaging; therefore orbital imaging is similar with the two implant materials. If retinoblastoma recurs in the orbit, it is generally noncalcified, not radiopaque, and variable in its signal intensity so that the orbitall implant should not interfere with its detection on computed tomography or magnetic resonance imaging.

One might suspect that prior radiotherapy would decrease fibrovascular ingrowth into the hydroxyapatite implant. We did not find an increased rate of complications in those patients who had prior external beam radiotherapy or plaque radiotherapy. We have not evaluated any patients who had external beam radiotherapy and subsequent hydroxyapatite implant with orbital magnetic resonance imaging for implant vascularity. Most of our patients in this grup are children who have not yet had peg placement. On the other hand, 5 of the 31 patients who had peg placement had been treated with plaque radiotherapy for a uveal melanoma prior to enucleation, and all of these patients had adequate vascularity of the implant by magnetic resonance imaging. None of these five patients have had problems with their implant or peg.

It is comforting that most patients are satisfied with their motility and cosmetic appearance without peg placement. Even without the peg, the motion of the implant in the socket is often excellent, since a portion of this motility is generally transferred to the prosthesis via conjunctival forniceal movement and conjunctival friction.[7] Only 31 of the 140 eligible patients chose to have the peg placed. The complications of peg placement are few. Two patients had extrusion of the peg due to excessive granulation tissue that could be excised and repaired. There were no infections due to the peg. Only one minor problem of a subtle audible peg click in and out of the ball-and-socket joint in extreme gaze was heard by three patients who had the peg in place. The sound was inaudible to anyone but the patient and was heard by the patient only when the gaze was extreme and the peg traveled further in the socket than the prosthesis could travel owing to the prosthesis size.

Hydroxyapatite orbital implant is well tolerated by all age-groups with few problems. We currently recommend it as the motility implant of choice. We suspect that the future will bring more improvements in this implant, and hopefully all patients who have enucleation will be provided with a moving artificial eye.

SUMMARY

The coral-derived hydroxyapatite sphere is a popular, new integrated orbital implant designed to provide improved motility of the ocular prosthesis following enucleation. Although the implant has rapidly become widely used by ophthalmologists, there is little information available regarding the complications of this technique in a large series of cases. We report our results on our initial 250 consecutive cases of hydroxyapatite implantation for eyes enucleated primarily for intraocular neoplasms, with specific emphasis on the complication an their management. The reasons for enucleation included uveal melanoma (157 cases), retinoblastoma (70 cases), blind painful eye (22 cases), and intraocular medulloepithelioma (1 case). Prior treatment to the eye was performed before enucleation in 47 cases and included repair of ruptured globe (17 cases), plaque radiotherapy (18 cases), external beam radiotherapy (6 cases), and others (6 cases).

During a mean of 23 months follow-up (range, 6 to 42 months), there have been no recognizable cases of orbital hemorrhage related to the implant and no cases of implant extrusion or implant migration. There was one case of presumed orbital infection (culture-negative) that resolved with intravenous antibiotics, and the implant was retained within the orbit. Other problems included conjunctival thinning in eight cases managed by observation and prosthesis adjustment and conjunctival erosion in four cases managed by combinations of scleral patch graft, conjunctival flap, and prosthesis adjustment. The conjunctival erosion was caused by a poorly fitting prosthesis in three cases and wound dehiscence in one case. The complication rate in eyes receiving prior radiotherapy or surgery was not increased. The hydroxyapatite integrated orbital implant is a well-tolerated motility implant without the high rate of extrusion and infection seen with other motility implants.

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DISCUSSION

DR JOHN D. BULLOCK. Hydroxyapatite is a form of calcium phosphate that comes from sea coral. Because of fibrovascular tissue growth into its channels, hydroxyapatite is said to possess lower extrusion, exposure, infection, and migration rates and to allow for more natural prosthetic motility than other buried, integrated implants. During the last 8 years, more than 10,000 hydroxyapatite spheres have been placed in enucleated or eviscerated orbits (A Perry, MD, personal communication, 199X).

In the present study of 250 hydroxyapatite implantations, the largest series to date, Dr Shields and associates noted one infection, four cases of exposure (1.6%), no

extrusions, and no migrations. Dutton (*Ophthalmology* 1991; 98:370-377) reported a series of 50 patients, none of whom experienced infection, exposure, or extrusion. Buettner and Barley (*Am J Ophthalmol* 1992; 113:669-673), however, observed a 22% exposure rate, while Goldberg and colleagues (*Ophthalmology* 1992; 99:831-836) reported six cases of early implant exposure, one of which became infected and needed removal. I have seen a patient with exposure and infection who was operated on by a pioneer in hydroxyapatite orbital implantation.

The vast differences in outcomes among these series may relate primarily to the indications for enucleation. The present series and that of Dutton (*Ophthalmology* 1991; 98:370-377) may be biased in that most of the patients required enucleation because of an intraocular malignancy; other series had more patients with severe trauma and infection. The latter two indications are known to adversely affect outcome.

It is somewhat difficult to evaluate current results with the present series because the authors do not compare their complication rates with those of other buried, integrated implants. Without a control group, no definitive conclusions can be made. The authors previously reported that in their last 1,000 nonintegrated sphere implantations, there were no infections or extrusions (*Arch Ophthalmol* 1992; 110:333-338). Others have noted extrusion rates of 4% (*Am Acad Ophthalmol Otolaryngol* 1952; 56:30-34) and 11% (*Today's Ocularist* 1979; 9:25-27) for unwrapped polymethylmethacrylate (PMMA) spheres, 3.3% (*Am J Ophthalmol* 1969; 67:171-188) for the Iowa implant, and 1.1% for the Allen implant (D. M. Robertson, MD, personal communication, 199X). Allen implant extrusion did not occur until more than 5 years after surgical placement. Thus the follow-up time, only up to 3½ years, in the present study relatively short. This fact also biases the results.

To date, only subjective evidence indicates a significant improvement in prosthetic movement with hydroxyapatite implantation (*Arch Ophthalmol* 1992; 110:333-338). Recently, Nerad and associates (*Ophthalmic Plast Reconstr Surg* 1991; 7:31-40) described an objective method of measuring prosthetic eye movements using a magnetic search coil. This technique should be employed to determine if (and why) motility appears to be better after hydroxyapatite implantation versus scleral-wrapped integrated PMMA sphere implantation. Also, although minimal complications are reported, the amount of improved motility after peg placement should be determined to justify an extra surgical procedure. The function of this implant-peg-prosthesis system depends on meticulous craftsmanship and surgical skill and may or may not possess long-term stability.

The main disadvantage of hydroxyapatite implantation—its cost—will continue to be a serious problem given the present economic crisis in medicine. Another synthetic material, porous polyethylene, has recently been wrapped in sclera and integrated into anophthalmic orbits (*Porous High-Density Polyethylene: A New Orbital Implant & A Comparison of Hydroxyapatite and Porous Polyethylene as Orbital Implants.* Presented at the American Society of Ocular Plastics and Reconstructive Surgeons; October 12, 1991; Anaheim, Calif.). It is too early to determine if porous polyethylene will fulfill the criteria for an ideal orbital implant. One fact is certain: Its cost is less than half that of hydroxyapatite ($650 versus $300). Future

studies should be directed at comparing the hydroxyapatite sphere with the porous polyethylene sphere, in regard to motility, complications, and long-term stability.

The present series does, however, suggest that hydroxyapatite implantation can achieve excellent motility and cosmesis with little increased risk. The authors are to be congratulated for bringing this important information to our attention.

DR RICHARD C. TROUTMAN. I enjoyed this paper because it reminded me of a problem that occupied a good deal of my attention at the beginning of my career. That was, and apparently still is, how best to enucleate or eviscerate an eye, place an orbital implant, and integrate it with a prosthesis for improved movement and cosmetic appearance. Much like today externalized pin or peg integrated implants were being advocated by Cutler, Reudemann Sr, Stone-Jardon, and others. However, secondary infection and extrusion eventually contraindicated their use. These complications, resulting in the extrusion of in excess of 90% of the pin and peg integrated implants within 5 years of placement, were documented in a retrospective national survey on orbital implants (*Trans Am Acad Ophthalmol Otolaryngol* 1952; 56:30) done under the auspices of the American Academy of Ophthalmology-Otolaryngology. From these results I will be interested to see the 5-year follow-up of this series albeit with an improved implant material.

My attempt at a solution to this dilemma was incorporate a pair of the then new, more powerful, lighter weight magnets, made from Alnico an aluminum, nickel, cobalt steel alloy, in the anterior portion of the plastic implant and the posterior portion of the prosthesis. The extraocular muscles were attached to each other through intersecting tunnels in the "magnetic" implant or sutured to a Tantalum mesh covering the anterior part the implant together with surrounding Tenons' capsule (*Arch Ophthalmol* 1950; 43;1123. & 1954; 52:58), completely burying the implant. A customized prosthesis incorporating a matching magnet was then fitted to appose the magnet in the prosthesis. This provided sufficient attraction to integrate the buried implant with the prosthesis and improved the extreme lateral and vertical movement of the artificial eye. Eventually however the weight of the magnet in the implant tended to displace it downward, the magnet in the mating prostheses became mismatched and movement was compromised. I understand that recently a stronger and lighter weight magnet has been developed which Drs Shields might consider incorporating in a hydroxyapatite implant and matching prosthesis. This would enable them to avoid the necessity to place the motility peg through the covering tissue creating an avenue for possible future infection and extrusion.

To obtain full motility it is important that the implant, of whatever design, be fixated so as to be retained in the muscle cone. I found that the patient's own sclera, left unattached to the extraocular muscles, allowed for the best retention of both magnetic and nonmagnetic buried implants. However, the pathologies for which Dr Shields and associates frequently perform their enucleations do not permit this approach. They have substituted an implant wrapped in banked sclera which eventually vascularizes, hopefully incorporating it with the hydroxyapatite implant. They might consider fenestration of their implant behind a flattened anterior surface to

more securely fixate the muscles to the porous implant through the tunnels. I found that motility imparted by my necessarily flat faced implant (because of the shape of the magnet) to a well fitted prosthesis with or without an incorporated magnet was often comparable to that of integrated implants, except in the extreme positions of gaze. In my experience it was primarily the depth of the fornices, and as the orbital fat absorbs in later life, the upper fornix in particular, that permitted or restricted the movement of the prosthetic shell. With deep and mobile fornices the movement imparted by the flat anterior face of the implant against a well designed shell often provided lifelike lateral and vertical movements without the inherent disadvantages of an exposed pin or a heavy magnetic implant (*Tran Am Acad Ophthalmol Otolaryngol* 1955; 59:43.; *Arch Ophthalmol* 1959; 62:159.).

DR ROBERT E. KENNEDY. This is a very interesting paper and discussion. A particular point of interest was the last one indicating the recent use of decalcified bone from cows from Australia. Some of you recall Dr A. Snell, Sr. who was a member of the American Ophthalmological Society, and his son who is a member. My father had the privilege of practicing with Dr Snell, Sr. before and after World War I. It was my privilege to have that opportunity for 5 years after World War II. Early in practice Dr Snell confronted me with the fact that he wondered if I had ever used decalcified bone as an orbital implant. I didn't know what he was talking about because I had never heard about it. But back in the 1930s he was using human porous decalcified bone from cadavers as an orbital implant. It was not connected with the ocular prosthesis in those days. He discussed it in detail, but I could not find any colleagues who had ever heard about it. It is interesting that he was doing this 60 years ago. I still have records from his files of patients who had this procedure done in the 1930s. Had I listened, paid more attention, and given it a try, I may have been up here a few years ago talking about it.

It would be interesting to know whether you can come up with a cheaper orbital implant. As you know Rochester, New York is considered by President Clinton to be a very well developed medical center program for patients as far as a pattern for the government to follow. But the patient coverage medical programs still consider this use of hydroxyapatite prosthesis as an experimental procedure so that they do not have to pay for the high expensive type of prosthesis at this time.

DR ROBERT G. SMALL. When the hydroxyapatite implant came on the scene several years ago many of us were skeptical because of the high cost, advertising and promotion that went along with it. There was little in the literature. Now we are beginning to see some reports. This paper by Dr Shields and colleagues is compelling. I suspect their good immediate results are due to excellent technique. However, I am concerned about high patient expectations and patient disappointment when the inevitable complications do occur.

There is known to be limited vascularization of hydroxyapatite implants in maxillofacial surgery. Vessels grow in only a few millimeters. I am curious why the socket is different and why sclera doesn't form a barrier for ingrowth of vessels. Are we sure all hydroxyapatite implants are completely vascularized?

Many problems with integrated implants occur late. Dr Shields had four cases requiring reoperation in an average follow-up of 1½ years. This means that in 15 years there would be 40 exposed or extruded implants in this series of 250 patients or a 16% incidence of complications.

I would like to compliment the authors on this important and interesting paper.

DR BARRETT HAIK. I have just two brief points. In the 50 cases of hydroxyapatite implants we have utilized retroauricular muscle tissue was pioneered by Dr Thomas Naugle, a colleague of mine in New Orleans, to wrap the implant. The advantage of this is to avoid using sclera from the eye bank. This decreases cost and the risk of transmission of infection. Additionally, I believe it speeds the rate of vascularization since the muscle is much less of a barrier to blood vessel penetration than is sclera. The other point I wanted to mention was that irradiated sockets do not vascularize quickly and I have three patients who underwent radiation therapy prior to enucleation where hydroxyapatite implants were not vascularized 18 months after the primary enucleation procedure. I don't know when they will be vascularized, but I do urge you to be cautious in this situation.

DR W. BANKS ANDERSON. Just a brief comment. Dr Dutton at Duke has been drilling the implant not just to fit the prosthesis peg, but before the implant is inserted. This is an attempt to see if he can stimulate more rapid vascularization of the hydroxyapatite implant.

DR BRADLEY STRAATSMA. I share the enthusiasm of the authors for this approach to reconstruction following enucleation. If exposure of the implant does occur Drs Goldberg and Shorr have used graft material from the hard palate to reconstruct and cover the exposed area. In a few of our cases that has been extremely effective and does indicate another method of repairing the process of tissue erosion without in any way disturbing the integrity of the implant.

DR W. RICHARD GREEN. I have seen about six hydroxyapatite implants that were removed because of exposure. Fibrovascular tissue extended into the interstices for only a few millimeters and was necrotic in some areas of some cases. Foreign body giant cells were present.

DR ROBERT C. DREWS. I have used hydroxyapatite and other implants over the years. When we start talking about very expensive surgery, and the possible additional surgery which may be needed to preserve the implant once it is there, I think it is important to remember that not every patient needs an orbital implant. There are patients that come to enucleation who are elderly and miserable and who don't want any further problems. There is another technique which can provide you with a good cosmetic result. Not the excellent cosmetic result of an integrated implant, but a good cosmetic result which has a zero infection rate and a zero extrusion rate. It is called simple enucleation, with no implant at all. If there is careful surgery with

preservation of the orbital fat, the vertical motility can be quite good. The horizontal motility is not as good, but for elderly patients with a blind, painful eye this can provide an end to all of their problems, at minimal cost.

DR CAROL SHIELDS. I would like to start by saying that I expected everyone to have comments on this relatively new technique with few complications. Nevertheless, there are few complications of the hydroxyapatite implant. There have been some reports describing the complications. I am not sure of the exact surgical technique of those surgeons with regard to the specifics of their tissue closure or the appearance of the prosthesis. Many of the complications reported by Beuttner and Goldberg were in eviscerated eyes. We do not use this implant in cases of evisceration, previously extruded implants, or in cases of endophthalmitis, due to the nature of our practice of ocular oncology. We prefer to use the implant in healthy people who want to have maximum motility. Contraindications occur most often in patients who have evisceration, endophthalmitis, or previously extruded implants.

There is also considerable concern regarding the cost of the implant. We believe the investment in the implant is worthwhile when considering the improved motility. It is expensive, but there will also be less costly implants in the future.

Specifically, to answer some of the questions:

I appreciate Dr Troutman's comments. He has made extensive contributions in the field of enucleation. The magnetic implant that he introduced several years ago is now being adapted to hydroxyapatite by some investigators. As Dr Troutman recommended, we are now using a flattened anterior surface on the hydroxyapatite implant to allow for a thicker central portion of the overlying prosthesis. This improves the prosthesis appearance.

I was interested to hear Dr Kennedy's comments on Dr Snell's use of decalcified bone as an implant. Hydroxyapatite is FDA approved. It is not experimental and Dr Perry completed 10 years of research with this material in humans and it gained FDA approval. It has been used for over 20 years now in the maxillofacial, dental, and orthopedic fields.

Dr Drews said we must be selective in those patients who receive the hydroxyapatite implant. We don't use this implant in older patients who might not want to have an expensive new implant.

I appreciate Dr Green's comments. Dr Green is giving us a somewhat biased perspective on failed implants because he is more likely to receive failed cases in the pathology laboratory. The implants that he studied were probably removed because they failed to vascularize.

Magnetic resonance imaging is a very good technique for identifying fibrovascular ingrowth and we have shown that these implants do become vascularized. The degree of vascularization varies. Maybe not all vascularize completely to the center of the implant. We reported one case in which we had to remove a hydroxyapatite implant 4 weeks after enucleation due to reasons of microscopic extraocular extension of a uveal melanoma and at this early period we demonstrated early fibrovascular ingrowth of several millimeters into the implant.

I appreciate Dr Straatsma's experience.

Dr Dutton, as Dr Anderson pointed out, has also had a good deal of experience with this implant. Dr Dutton drills large holes in the implant to provide more availability for ingrowth.

Someone made a comment about hydroxyapatite not showing fibrovascular ingrowth in the bone when it is used as a bone replacement material. I cannot comment on the expected findings in this situation. When hydroxyapatite is placed in the orbit, the reason it gets fibrovascular ingrowth is because it is in a purely soft tissue area. The orbit is really the first use of this material in soft tissue.