Intraorbital Implants After Enucleation and Their Complications

A 10-Year Review

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Background: Many different types of orbital implants have been used after enucleation. Associated complications such as infection, exposure, extrusion, and ptosis have been reported.

Objective: To describe 342 consecutive patients who underwent enucleation with intraorbital implant placement at the Bascom Palmer Eye Institute, University of Miami School of Medicine, Miami, Fla, during the past 10.5 years and their complications.

Methods: Medical records of orbital implantation after enucleation performed by 3 surgeons (T.G.M., D.T., and T.J.) were reviewed retrospectively. Demographic data, ocular diagnosis, previous ophthalmic surgery, implant characteristics, and postoperative complications were described in all patients, with a minimum of 2 months' follow-up, using a standardized format.

Results: Eleven complications were observed in 7 patients. Four patients had exposure of the implant, and 1 of these patients developed associated infection. Three patients developed pyogenic granulomas, 1 patient developed ptosis requiring surgical intervention, 1 patient had long-term orbital discomfort, and 1 patient developed an inclusion cyst.

Conclusion: Complications after enucleation with orbital implant placement are minimal and are observed with both porous and acrylic orbital implants.


Removal of an eye for treatment of ocular disease was first described by Bartisch in 1583.1 The modern form of this operation was introduced in 1841 by Farrell and Bonnet, and in 1885, Mules placed the first orbital implant after evisceration.2 A year later, Frost described the utility of orbital implant placement after enucleation surgery. In 1941, Ruedemann proposed the use of partially exposed, integrated implants with the attachment of extraocular muscles to allow for better prosthesis movement; he acknowledged the potential risks of extrusion and infection. Use of completely buried integrated implants began in the 1950s, bringing improved cosmesis but relatively poor motility.

An ideal orbital implant should offer excellent motility, cosmesis, and few complications. Various orbital implant configurations are available.3,12 Different materials may be used to create orbital implants, including cartilage, bone, fat, cork, rubber, gold, silver, silk, wool, aluminum, ivory, petroleum jelly, acrylics, silicone, quartz, glass, titanium, and porous materials such as polyethylene and hydroxyapatite (HA).13-19

Other buried, quasi-integrated, irregularly shaped implants derived from acrylics have been used.3,6,9 In these, muscles are passed through tunnels, as in the Allen implant, or through grooves, as in the Iowa and Universal implants.

Currently, porous spherical implants are most widely used. Porous polyethylene is made from synthetic, high-density polyethylene powder that is easily molded into shapes.10 Hydroxyapatite, a porous material derived from reef-building coral of genus Porites, was introduced as a buried orbital implant by Perry in 1985.18,20 These porous spherical implants are nontoxic, nonallergenic, and biocompatible, and they become integrated into the host by fibrovascular ingrowth.16,19,21,22 Fibrovascular ingrowth offers the theoretical advantages of less implant extrusion or mi-
**PATIENTS AND METHODS**

**PATIENTS**

Institutional Review Board approval from the University of Miami was obtained before chart review. A retrospective chart review was performed for 405 patients who underwent primary enucleation with orbital implant placement (performed by T.G.M., D.T., and T.J.) at Bascom Palmer Eye Institute from January 1, 1987, to June 30, 1997. All these cases were analyzed, but data are reported only on 342 patients who had at least 2 months' follow-up. Mean patient age at surgery was 49 years (range, 0.17-91 years). Mean follow-up was 97.2 weeks (median, 78 weeks; range, 8-460 weeks). One hundred eighty-seven patients (54.7%) were male and 155 (45.3%) were female. The demographics of this cohort included 228 whites (66.7%), 47 African Americans (13.7%), 48 Hispanics (14.0%), 12 others (3.5%), and 7 unknowns (2.0%).

Reasons for primary surgery included diagnoses of uveal melanoma in 104 patients (30.4%), retinoblastoma in 39 (11.4%), ruptured globe in 14 (4.1%), blind painful eye in 162 (47.4%), metastatic cancer in 2 (0.6%), and other various diagnoses in 21 (6.1%) (Table 1). In total, 208 patients had undergone treatment before enucleation, with 6 patients undergoing plaque radiotherapy, 5 undergoing external beam radiation therapy, 9 undergoing ruptured globe repair, and 188 undergoing a spectrum of other ophthalmic surgeries. Final histopathologic diagnoses included atrophy bulb, phthisis bulb, rupture secondary to trauma or corneal ulceration, neovascular glaucoma secondary to central retinal vein occlusion or Coats disease, proliferative vitreoretinopathy, retinal detachment, malignant melanoma, medulloepithelioma, endophthalmitis, persistent hyperplastic primary vitreous, microphthalmos, and squamous cell carcinoma with intraocular extension.

Acrylic implants used in this series included the sphere (8 patients), Iowa (29 patients), and Universal (1 patient) types (Table 2). Microporous implants were limited to HA (275 patients) and porous polyethylene (Medpor) (22 patients). Implants made of silicone (6 patients) and glass (1 patient) were also used. In 288 patients (84.2%), the implant was wrapped in a donor scleral shell. The mean implant size was 20 mm (median, 20 mm; range, 14-22 mm). Drilling for peg placement was performed on 5 HA implants.

**SURGICAL TECHNIQUE**

This technique has been reported previously. Briefly, enucleation was performed by opening the conjunctiva and the Tenon capsule for 360° around the corneal limbus with Wescott scissors. Hemostasis was achieved with wet field cautery. The 4 quadrants were opened using Stevens scissors. Each of the 4 rectus muscles was isolated on a muscle hook and cleaned of surrounding Tenon attachments; secured on a double-armed 5-0 polyglactin suture, with locking bites at each end; and then disinserted from the globe. The superior and inferior oblique muscles were dissected from the globe. The optic nerve was cut deep within the orbit with the Foster enucleation snare or with long Metzenbaum scissors. The globe was removed from the socket and was sent to the pathology laboratory for evaluation in all cases. If the implant was covered in donor sclera, windows were made. The implant was placed into the orbit. The 4 rectus muscles were sutured securely into the scleral windows. The Tenon capsule was closed in a double-layered fashion using interrupted 5-0 polyglactin sutures. The conjunctiva was closed with running 7-0 polyglactin suture. An antibiotic ophthalmic ointment was applied to the wound, and a conformer was inserted. A pressure patch was then applied.

The socket was evaluated at each postoperative visit. Socket motility was determined subjectively by assessing the patient’s ocular motility in cardinal positions of gaze. The cosmetic appearance was determined subjectively by evaluation of eyelid contour and symmetry with the fellow eye. Complications throughout the postoperative period were recorded.

**RESULTS**

Postoperative follow-up was recorded for an average of 97.2 weeks (median, 78 weeks; range, 8-460 weeks). During this period, no instance of orbital hemorrhage or implant migration was noted. Complications occurred in 7 patients (Table 3). These complications were noted 7 days to 25 months after placement of the intraorbital implant. These patients ranged in age from 4 to 89 years (mean, 56.3 years) and included 3 males and 4 females. Six patients had received treatment or surgery before enucleation. Final histopathologic diagnoses included retinoblastoma, traumatic rupture, perforated corneal ulcer, endophthalmitis, and phthisis bulbi.

Four cases of exposure of the implant were noted, 1 related to a recurrent infection and 2 related to conjunc-

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**Table 1. Indications for Enucleation**

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<th>Indication</th>
<th>No. (%) of Patients Reviewed</th>
<th>No. of Patients With Complications</th>
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<tr>
<td>Uveal melanoma</td>
<td>104 (30.4)</td>
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<tr>
<td>Retinoblastoma</td>
<td>39 (11.4)</td>
<td>1</td>
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<tr>
<td>Ruptured globe</td>
<td>14 (4.1)</td>
<td>2</td>
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<tr>
<td>Blind painful eye</td>
<td>162 (47.4)</td>
<td>3</td>
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<tr>
<td>Metastatic cancer</td>
<td>2 (0.6)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>21 (6.1)</td>
<td>1</td>
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tival dehiscence or to paucity of conjunctiva covering the implant. Two of these patients had a small area of exposure, with 1 healing spontaneously and 1 undergoing drilling with peg placement in the area of exposure. The other 2 patients had larger areas of exposure resulting in partial extrusion of the implant; both patients underwent implant removal, with 1 undergoing implant exchange.

Excessive orbital pain was noted in 1 patient who had long-term discomfort for more than 3 years. In this patient, the Iowa implant was replaced with a sphere.

One patient had significant ptosis after enucleation and placement of the orbital implant. The ptosis was greater than 2 mm, and surgical repair was recommended.

Three patients developed pyogenic granulomas within the socket. In all 3 patients these granulomas were excised, but in 1 patient multiple recurrences of inflammation were observed. One inclusion cyst of the socket was observed without treatment.

None of the patients with complications had undergone drilling or peg placement before the complication.

Patients were typically fitted with a prosthesis approximately 6 to 8 weeks after surgery. All patients had good socket motility and good cosmesis.

An ideal orbital implant should yield excellent motility and cosmesis with few complications. Many authors have suggested that an implant that is completely buried will minimize migration and extrusion. Attachment of the extraocular rectus muscles to the implant results in improved motility and cosmesis. The microporous HA implant fulfills these criteria and, therefore, has come into popular use, as demonstrated by this series. Other implants, such as the porous polyethylene sphere (Medpor) and acrylics, including the sphere and the older quasi-integrated Iowa and Universal implants, were also used after primary enucleation in this series. Simple spheres composed of silicone and glass were used less frequently.

Complications in our series were minimal, with a rate of 3%. Five implants underwent drilling for prosthetic integration. This small number did not allow for significant evaluation of complications related to this procedure. The final cosmetic appearance and socket or prosthesis motility were judged by the surgeon to be good in all 342 patients, and this was true even without placement of a peg in most cases of HA implantation. This observation was, however, based on a subjective grading and is, therefore, less reliable than if gauged by a standardized objective rating based on photographs and measurements. In our series, different types of implants were used, but it is difficult to determine the best type of implant based on statistical analysis with the small number of complications. Also, our review of the indications for enucleation shows no correlation of complications based on histopathologic diagnosis.

Several studies explore the use of porous implants and their complications (Table 4). Karesh and Dresner reported no extrusions, infections, or exposures of porous polyethylene implants in 21 patients after a mean follow-up of 19 months. Reported exposure rates of HA implants range from 0% to 22%, 5,23-26,29,34,37 Nunery and colleagues showed that the exposure rate of HA implants (11.1%) was higher than that of silicone spheres (0%). They also noted increased incidence of postoperative inflammation with HA implants. Buettner and Bartley proposed that exposure of HA implants is related to the inflammatory reaction incited by the implant or by delayed fibrous ingrowth. Remulla and coworkers emphasized the advantage of wrapping the implant for better protection from extrusion; these authors were unable to correlate preoperative diagnosis or treatment with exposure rates. Kim and colleagues demonstrated that, with HA implants, small areas of exposure (<3 mm) may close spontaneously but that larger defects require surgical treatment. Goldberg and coworkers suggested that

<table>
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<td>Type</td>
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<tr>
<td>Acrylic</td>
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*HA indicates hydroxyapatite.

| Table 3. Clinical Data of 7 Patients With Complications of Orbital Implants |
|-----------------------------|-----------------|-----------------|-----------------|---------------------|
| Patient No. | Type of Implant* | Wrapping | Inclusion cyst | Exposure, <5 mm | Pyogenic granuloma | Timing, d | Management                     |
| 1            | HA              | Sclera     | 14             | 180              | 750              |          | Observation, Antibiotics, healed |
| 2            | HA              | Sclera     | 14             | 21               | 14               | 14       | Recommended surgical repair     |
| 3            | HA              | Sclera     | 7              | 7                | 14               | 420      | Implant exchange                |
| 4            | HA              | Sclera     | 14             | 14               | 14               | 14       | Implant removal                 |
| 5            | Acrylic         | None       | 14             | 14               | 14               |          | Implant exchange                |
| 6            | Acrylic         | None       | 14             | 14               | 14               |          | Implant exchange                |
| 7            | Iowa            | None       | 14             | 14               | 14               |          | Implant exchange                |
use of HA implants, even with exposure, was less likely to lead to extrusion or infection compared with exposure with silicone or acrylic implants. Ashworth and colleagues\(^2\) reported 60 cases of HA implantation: 3 patients (11%) in the primary implant group had exposure and 1 patient (4%) developed orbital cellulitis. In their secondary implant group, there was 1 patient with exposure, 1 patient with conjunctival cyst, 1 patient with socket infection, and 3 patients with eccentric implants. Shields and colleagues\(^2\) described 100 cases of HA implants, among which they reported 6 patients with excessive postoperative orbital pain, 2 patients with wound edema, and 1 patient with erosion. As in the present series, Shields et al had excellent cosmesis in 98% and excellent motility in 99% of nondrilled patients. In their subsequent report of 250 patients with HA implants, Shields et al\(^2\) described 8 patients with conjunctival thinning, 4 patients with erosions, and 1 patient with orbital infection. Jordan and coworkers\(^3\) described 2 patients with abscesses found within HA implants.

The most common complication observed with the Iowa implant is late exposure of the mounds and possible extrusion of the implant. Spivey and colleagues\(^9\) also described ptosis and pain occurring with these implants. The Universal implant was designed to shorten the protracted implantation procedure and to reduce the rate of extrusion associated with the Iowa implant while still offering good motility, as demonstrated by Anderson and coworkers.\(^3\) Contraindications for the use of these quasi-integrated implants include congenital nystagmus and severe scarring. The Allen implant has been shown by Fan and Robertson\(^6\) to have a low long-term incidence of superficial tissue breakdown (2.2%) and exposure (1.1%), with satisfactory motility.

Several techniques may be used to minimize complications after enucleation with placement of orbital implants. These techniques include choosing an appropriately sized implant, positioning the implant deeply in the orbit, wrapping the implant with donor sclera, meticulously closing the anterior Tenon capsule over the implant, securing the conjunctiva over the implant with- out tension, and using a posterior vault on the prosthesis to minimize wear.

Orbital implants have been used for more than a century. Serious complications can occur, but they do so infrequently, as demonstrated by this series. Long-term benefits and risks of different implant types require ongoing evaluation.

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REFERENCES


Announcement

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