Orbital Implants in Enucleation Surgery

A Report by the American Academy of Ophthalmology

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Objective: To compare prosthetic and implant motility and the incidence of complications associated with porous and nonporous enucleation implants.

Methods: Literature searches conducted in January 2002 for 1985 to 2001 and May 2002 for October 2001 to 2002 retrieved relevant citations. The searches were conducted in MEDLINE and limited to articles published in English with abstracts. Panel members reviewed the articles for relevance to the assessment questions, and those considered relevant were rated according to the strength of the evidence.

Results: A randomized clinical trial and a longitudinal cohort study detected no difference in implant or prosthetic movement between nonpegged hydroxyapatite porous and spherical alloplastic nonporous implants. No controlled studies were retrieved that investigated whether pegging porous implants improves prosthetic movement. Several case series indicate that patients with pegged hydroxyapatite implants have some degree of improved prosthetic motility. Longitudinal cohort studies show that sclera-covered hydroxyapatite implants have higher exposure rates than sclera-covered silicone implants, and unwrapped porous polyethylene implants have higher exposure rates than unwrapped acrylic implants. There are numerous case series that document a wide range of implant exposure rates in patients with various enucleation implants. It is difficult to compare complication rates among implant types because patient populations vary, surgical techniques differ, and follow-up periods are often limited.

Conclusions: Based on one randomized clinical trial, spherical alloplastic nonporous and nonpegged porous enucleation implants provide similar implant and prosthetic motility when they are implanted using similar surgical techniques. Coupling the prosthesis to a porous implant with a motility peg or post appears to improve prosthetic motility, but there are few available data in the literature that document the degree of the improvement. There is a widely variable incidence of porous implant exposure, but certain surgical techniques and the type of wrapping material seem to reduce the exposure rate. Additional research is needed to document the long-term incidence of complications related to porous enucleation implants and associated surgical techniques. This includes the use of wrapping materials and what procedural modifications, both surgical and prosthetic, are most effective in reducing these complications. *Ophthalmology 2003;110:2054–2061 © 2003 by the American Academy of Ophthalmology.*

Introduction

The American Academy of Ophthalmology prepares Ophthalmic Technology Assessments to evaluate new and existing procedures, drugs, and diagnostic and screening tests. The goal of an Ophthalmic Technology Assessment is to systematically review the available research for clinical efficacy, effectiveness, and safety. After appropriate review by all contributors, including legal counsel, assessments are submitted to the Academy's Board of Trustees for consideration as official Academy statements. A variety of factors impact the success and complications associated with the enucleation procedure, including patient selection, surgical technique, type of implant, and prosthetic fit. The purpose of this assessment is to compare the motility and incidence of complications associated with the use of porous and nonporous implants in enucleation surgery.

Background

Enucleation may be performed to treat a variety of conditions including intraocular malignancy and severe ocular trauma as well as blind, painful, or disfigured eyes. The goals of enucleation are to remove the diseased globe and create a functional socket that facilitates the fitting and retention of an ocular prosthesis. An implant is usually inserted at the time of enucleation. This implant serves to

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partially fill the void left by removing the eye and reduces the potential for a volume deficit within the socket. Attachment of the extraocular muscles to the implant or its wrapping material is believed to improve implant motility and reduce the risk of implant migration. The efficiency of transmitting movement from the implant to the prosthesis determines the degree of prosthetic motility. Movement is transmitted from traditional nonporous spherical implants through the surface tension at the conjunctival–prosthetic interface and movement of the fornices. Quasi-integrated implants (Allen, Iowa, Universal) have irregularly shaped surfaces that create an indirect coupling mechanism between the implant and prosthesis that imparts greater movement to the prosthesis. Directly integrating the implant to the prosthesis through an externalized coupling mechanism would be expected to improve motility further. Historically, implants that directly attached to the prosthesis were unsuccessful because of chronic inflammation or infection arising from the exposed nonporous implant material.

The modern age of integrated implants began in 1989 when an implant made from hydroxyapatite received Food and Drug Administration approval. The porous nature of this material allows fibrovascular ingrowth throughout the implant and permits insertion of a coupling device without the inflammation or infection associated with earlier types of exposed integrated implants. In a secondary procedure, an externalized, round-headed peg or screw is inserted into the implant. The prosthesis is modified to accommodate the peg, creating a ball-and-socket joint. Porous polyethylene enucleation implants have been used since at least 1989.[1] Polyethylene also becomes vascularized, allowing placement of a titanium motility post that joins the implant to the prosthesis in the same way that the peg is used for hydroxyapatite implants. The potential benefits of porous implants include improved prosthetic motility and a lower incidence of implant migration and extrusion.

Porous enucleation implants currently are fabricated from a variety of materials including natural and synthetic hydroxyapatite, aluminum oxide, and polyethylene. Hydroxyapatite implants are spherical and made in a variety of sizes. Aluminum oxide and porous polyethylene implants can be obtained in spherical and nonspherical shapes and in different sizes. The surgeon can alter the contour of porous implants before insertion, and it is also possible to modify the contour in situ, although this is sometimes difficult.

Description of the Procedure

When performing enucleation surgery, some surgeons inject subconjunctival and/or retrobulbar local anesthetic, even in patients under general anesthesia. The conjunctival peritomy is performed at the corneal limbus, preserving as much healthy tissue as possible. Anterior Tenon's fascia is separated from the sclera. Blunt dissection in the four quadrants between the rectus muscles separates deep Tenon's fascia. Sutures may be passed through the rectus muscles before their disinsertion from the globe. Some surgeons also suture one or both oblique muscles. Traction sutures or clamps may be applied to the horizontal rectus muscle insertions to assist in rotating and elevating the globe during the ensuing dissection. Tenon's capsule may be opened posteriorly to allow visualization of the optic nerve. The vortex veins and posterior ciliary vessels may be cauterized before dividing the nerve and removing the eye. Alternatively, the optic nerve may be localized with a clamp before transection. Hemostasis is achieved with either cautery or digital pressure.

The orbital implant is inserted at the time of enucleation. An appropriately sized implant should replace the volume of the globe and leave sufficient room for the ocular prosthesis. Enucleation implants are available in a variety of sizes that may be determined by using sizing implants or calculated by measuring globe volume or axial length of the contralateral eye.

In the past, spherical nonporous implants were placed in the intraconal space and the extraocular muscles were either left unattached or were tied over the implant. Wrapping these implants allows attachment of the muscles to the covering material, a technique that seems to improve implant movement and reduce the incidence of implant migration. Porous implants may be saturated with antibiotic solution before insertion. Because the brittle nature of hydroxyapatite prevents direct suturing of the muscles to the implant, these implants are usually covered with some form of wrapping material. The muscles are attached to the implant in a technique similar to that used for spherical nonporous implants. The muscles may be directly sutured to porous polyethylene implants either by passing the suture through the implant material or by using an implant with fabricated suture tunnels. Some surgeons also wrap porous polyethylene implants either to facilitate muscle attachment or to reduce the risk of implant exposure. A variety of wrapping materials have been used to cover porous implants, including polyglactin or polyglycolic acid mesh, heterologous tissue (bovine pericardium), homologous donor tissue (sclera, dermis), and autogenous tissue (fascia lata, temporalis fascia, posterior auricular muscle, rectus abdominis sheath).

Fenestrations in the wrapping material are created at the insertion sites of the extraocular muscles, allowing the attached muscles to be in contact with the implant and improving implant vascularization. Drilling 1-mm holes into the implant at the muscle insertion sites is performed to facilitate vascularization of hydroxyapatite implants.[2] Tenon's fascia is drawn over the implant and closed in one or two layers. The conjunctiva is then sutured. A temporary ocular conformer is inserted at the completion of the procedure and is worn until the patient receives a prosthesis 4 to 8 weeks after surgery.

An elective secondary procedure is required to place the coupling peg or post in those patients who desire improved prosthetic motility. That procedure is usually delayed for at least 6 months after enucleation to allow time for implant vascularization. Technetium bone or gadolinium-enhanced magnetic resonance imaging scans are not now universally used, but they have been used to confirm vascularization before peg insertion. Under local anesthesia, a conjunctival incision is created at the peg insertion site. A hole is created into the porous implant to allow insertion of the peg or post.

The prosthesis is then modified to receive the peg or post. Some surgeons have preplaced coupling posts in porous polyethylene implants at the time of enucleation.[3] The post may spontaneously expose or is externalized in a later procedure via a conjunctival incision.

Resource Requirements

In May 2002, the manufacturer's price for a hydroxyapatite implant was $650. Porous polyethylene implants are priced at $400 to $650, depending on volume ordered. Aluminum oxide implants cost $450. By comparison, acrylic and silicone enucleation spheres cost $15 to $50. Charges for nonautogenous wrapping materials (polyglactin mesh, donor sclera, donor dermis) vary from $100 to $400. No special instrumentation is necessary to insert porous implants. Patients who proceed with coupling peg or post insertion incur additional imaging, facility, physician, and ocularist expenses.

Questions for Assessment

The focus of this assessment is to address the following questions:

- Is there any difference in prosthetic and implant motility between patients with porous and nonporous enucleation implants?
- Is there any difference in the complication rates of porous and nonporous enucleation implants?

Description of Evidence

The literature search was conducted in January 2002 in MEDLINE for 1985 to 2001. A follow-up search was performed in May 2002 for October 2001 to 2002. These searches were limited to articles published in English with abstracts. The Cochrane Library of clinical trials was also investigated. The search words were combinations of the MeSH terms *eye enucleation, orbit/anatomy and histology*, *orbit/surgery*, and *orbital implants.* These searches retrieved 87 citations. Abstracts of meeting presentations were not subject to peer review and were not included in the analysis.

The authors reviewed the abstracts retrieved in the literature search and selected 49 articles of possible clinical relevance for review. The authors then read these complete articles and selected 42 of sufficient clinical relevance for review by the panel methodologist, who assigned one of the following ratings of strength of evidence to each of the selected articles. A level I rating is assigned to properly conducted, well-designed randomized clinical trials; a level II rating is assigned to well-designed cohort and case–control studies; and a level III rating is assigned to case series.

The published peer-reviewed literature includes a single randomized clinical trial[4] (assigned a level I rating) and three additional studies[5–7] that received a level II rating (Table 1). In the randomized clinical trial, amplitude of movement of the ocular prosthesis was measured among subjects who had previously been randomized to receive either an acrylic or a hydroxyapatite spherical enucleation implant.[4] One of the studies that received a level II rating also focused on motility, but measurements were made of implant movement rather than prosthesis movement.[5] The other studies that were assigned level II ratings involved evaluation of postoperative complication rates among patients who received various types of orbital implants. Lee and associates[6] studied patients who had undergone enucleation for retinoblastoma, and Nunery and associates[7] compared complication rates among patients who had received either hydroxyapatite or silicone orbital implants. All other reports were assigned a level III rating and consisted mainly of clinical case series.

Several factors contribute to the difficulty of comparing complication rates by type of implant and evaluating the role of possible risk factors. In at least some of the studies, these include small numbers of subjects (large sample sizes are needed to evaluate relatively uncommon complications), limited duration of follow-up, lack of use of multivariate methods of analysis, the existence of many potentially confounding variables including different surgical techniques, and use of several different types of implants. Standardized quality of life assessments were not applied in any of the studies. Porous and nonporous implants are also used in evisceration and secondary socket reconstruction, but the profile of complications may be different for these procedures. Whenever possible, only information on the use of implants in the enucleation procedure was considered in evaluating the published results.

Published Results

Is There Any Difference in Prosthetic and Implant Motility between Patients with Porous and Nonporous Enucleation Implants?

Implant or prosthetic movement can be subjectively graded or measured. The amount of excursion has been directly measured (in millimeters) or electronically calculated using a search coil. In a randomized clinical trial (level I), Colen et al[4] compared the saccadic amplitudes of prostheses worn by patients with nonpegged hydroxyapatite (n = 14) and acrylic implants (n = 16). There was no significant difference in horizontal and vertical saccadic amplitudes between the two groups. A level II study found no difference in movement of 31 hydroxyapatite and 45 nonporous spherical implants.[5] Data analysis in this report was complicated because the patients with hydroxyapatite implants were significantly younger than those with nonporous implants. Implant movement appeared to decrease with age in both groups. This study also demonstrated improved movement of larger implants irrespective of material. Although the relatively small sample sizes of these studies may have limited their statistical power, they suggest that there is no difference in either prosthetic or implant movement be-

Table 1. Level I and II Studies

Study	Type of Study	Level of Evidence	Number	Results	Comments
Colen et al*	Randomized controlled trial: adult patients with enucleation due to intraocular melanoma	I	Enucleation = 34 Acrylic = 16 Hydroxyapatite = 14 Controls = 21	No statistically significant difference in horizontal and vertical saccadic amplitude of movement of the prosthesis	The amount of time between surgery and measurement of movement varied considerably (3–23 mos), although the means were similar in both groups (4.6 mos, 10.7 mos)
Custer et al†	Longitudinal cohort study: anophthalmic patients of all ages	II	Alloplastic = 76 Hydroxyapatite = 31	No statistically significant difference in horizontal and vertical movement of the implant	Analysis complicated by age difference of patients in the two groups
Lee et al‡	Longitudinal cohort study: pediatric retinoblastoma patients	II	Patients = 109 Sockets = 110 (2 patients excluded due to recurrent retinoblastoma)	30 of 108 sockets had exposure over median follow-up of 21.6 mos (range = 3.0–55.0); statistically significant differences in implant type and covering material calculated with univariate and linear logistical regression	No details of multivariate analysis presented
Nunery et al§	Longitudinal cohort study: primary and secondary implants in adult patients	II	Hydroxyapatite = 59 Silicone = 78	Statistically significant difference in exposure rate between hydroxyapatite and silicone enucleation implants	Mean follow-up: hydroxyapatite 9.7 mos, silicone 5.1 mos

*Colen TP, Paridaens DA, Lemij HG, et al. Comparison of artificial eye amplitudes with acrylic and hydroxyapatite spherical enucleation implants. Ophthalmology 2000;107:1889–94.
†Custer PL, Trinkaus KM, Fornoff J. Comparative motility of hydroxyapatite and alloplastic enucleation implants. Ophthalmology 1999;106:513–6.
‡Lee V, Subak-Sharpe I, Hungerford J, et al. Exposure of primary orbital implants in postenucleation retinoblastoma patients. Ophthalmology 2000;107:940–5, discussion 946.
§Nunery WR, Heinz GW, Bonnin JM, et al. Exposure rate of hydroxyapatite spheres in the anophthalmic socket: histopathologic correlation and comparison with silicone sphere implants. Ophthal Plast Reconstr Surg 1993;9:96–104.

tween sclera-covered spherical nonporous and nonpegged hydroxyapatite implants.

Although it is generally accepted that integrating the prosthesis to a porous implant with peg insertion enhances prosthetic movement, there is little available evidence in the literature that documents the degree of improvement. Kawai and colleagues[8] measured greater prosthetic movement in a group of seven patients with a specially designed pegged hydroxyapatite implant than in three control patients with semi-integrated magnetic implants. Analysis was not performed in this level III study to determine if this difference was statistically significant. In another level III study, Shields et al[9] subjectively graded prosthetic movement and found that patients with pegged hydroxyapatite implants were more likely (43%, 6 of 14) to have "excellent" large-degree movement compared with patients without pegs (21%, 18 of 85). Small-degree prosthetic movements were similar in the two groups. The literature search did not find any articles that compared the movement of porous polyethylene with either nonporous or hydroxyapatite implants. Comparison between porous implants and quasi-integrated implants also was not reported.

Is There Any Difference in the Complication Rates of Porous and Nonporous Enucleation Implants?

Implant material and structure may impact the incidence of several complications associated with the enucleation procedure including implant migration, infection, exposure,

and extrusion. Of these, implant exposure and extrusion have been most extensively reported in the literature. A variety of factors affect the likelihood that an implant will become exposed. Poor wound closure, an infected surgical field, an excessively large implant, or a poorly fitting conformer or prosthesis can contribute to wound breakdown and exposure. Implant exposure is believed to be more common in patients who require enucleation after extensive trauma or multiple prior ocular procedures. Early repair of wound dehiscence occasionally will salvage an acutely exposed nonporous implant. However, chronically exposed nonporous implants will usually extrude or require removal. Exposed porous implants generally do not extrude, because there is fibrovascular ingrowth into the posterior implant holding it within the socket. Exposure of porous implants does not always result in loss of the implant, and small exposures may spontaneously heal. A variety of procedures has been described to repair large or chronic exposures.

In a longitudinal cohort study (level II) performed between 1988 and 1991, Nunery et al[7] found a statistically significant difference ($P = 0.043$) in exposure rate between donor sclera-covered hydroxyapatite (n = 27) and silicone enucleation implants (n = 48). The three hydroxyapatite exposures (11.1%, 3 of 27) were detected 27 days, 1 month, and 6 months, respectively, after surgery. All of the exposed implants required later removal. None of the 48 sclera-covered silicone implants became exposed. Late implant exposures would not have been detected in this study because of the limited average follow-up (hydroxyapatite, 9.7 months; silicone, 5.1 months). In a larger case series evaluating only covered (sclera, fascia) silicone implants, Nunery encountered only a single exposure among 119 implants after an average follow-up of 45 months.[10] Li and colleagues[11] followed a group of 86 primary and 2 secondary enucleation implant patients an average of 320 days after surgery. This level III study detected higher exposure rates with unwrapped porous polyethylene (2 of 21) and Gelfoam (Pfizer, New York, NY) or polyglactin mesh–wrapped porous polyethylene implants (2 of 15) than with unwrapped acrylic (0 of 40), tissue-wrapped porous polyethylene (0 of 8), and hydroxyapatite implants (0 of 4). The difference in exposure rates between unwrapped acrylic and unwrapped porous polyethylene implants was statistically significant. Small sample sizes may have limited the comparison of the other groups. Christmas et al[12] reported a level III study of hydroxyapatite, porous polyethylene, and various nonporous enucleation implant patients followed for an average of 97.2 weeks. Exposures developed in 3 of the 275 (1.1%) sclera-covered hydroxyapatite patients 7, 180, and 420 days, respectively, after enucleation. One of these implants required removal. None of the 22 porous polyethylene implants became exposed. It was not stated how many of the polyethylene implants were wrapped before insertion. The sample sizes for many of the implant types in this study were too small to allow comparison of exposure rates.

Oestreicher et al[13] performed a level III study of enucleation and secondary socket reconstruction in patients who received hydroxyapatite implants. Exposure developed in 9.4% (3 of 32) of implants wrapped in polyglycolic acid mesh but in none of the 62 sclera-covered implants ($P < 0.02$). Although mean follow-up for the entire series was 9.6 months, the patients with polyglycolic acid mesh–covered implants underwent surgery later in the study, which resulted in shorter follow-up times. None of the exposed implants required removal. These authors indicated that placement of polyglycolic acid mesh–covered implants more posteriorly within the orbit was critical in reducing the exposure rate when this covering material was used.

A case series (level III) with limited follow-up (1–10 months) reported a similar experience with polyglactin mesh–covered hydroxyapatite implants.[14] Exposure developed 4 weeks after surgery in two of four patients in whom the muscles were attached at "their standard location." No exposures were encountered in the 38 patients in whom the muscles were advanced "anterior to their standard location." Kaltreider and Newman[15] noted a 16.7% (20 of 120) exposure rate in a level III series of patients who received primary sclera-covered or polyglactin mesh–covered hydroxyapatite implants. The exposure rate for each wrapping material was not stated. The exposures developed 6 days to 11 months after enucleation. Two of the exposed implants were eventually removed. Although multivariate analysis was not performed, these authors felt that most exposures could have been prevented with anterior advancement of the extraocular muscle attachments and posterior positioning of the implant within the socket.

The following level III case series also document enucleation implant exposure rates. Comparison of different reports is confounded by the use of different surgical techniques and variation in the patient populations. Fan and Robertson[16] observed two cases of exposure that required implant removal among 186 patients (1.1%) with acrylic Allen enucleation implants. The exposures were detected at 5.3 years and 11.5 years, respectively, after surgery. Four additional patients required further treatment for superficial tissue breakdown without exposure. The lengthy follow-up in this study (mean = 7.8 years) allowed Kaplan–Meier analysis that estimated an ultimate exposure rate of 3% at 20 years after surgery. Leatherbarrow et al[17] experienced no extrusions among the 19 cases of sclera-covered or Mersilene (Ethicon, Inc., Somerville, NJ) mesh–covered acrylic spherical implants in patients who were observed for an average of 31 months after enucleation. Two of these patients required further surgery for conjunctival wound dehiscence.

Dutton[2] encountered no exposures among a group of 45 sclera-covered hydroxyapatite implants inserted during enucleation (mean follow-up = 10.4 months). Shields et al[18] reported four cases (1.6%) of conjunctival erosion and presumed implant exposure in a series of 249 enucleation procedures and one secondary socket reconstruction followed for an average of 23 months after placement of sclera-covered hydroxyapatite implants. The erosions appeared 1, 6, 7, and 12 months, respectively, after surgery. None of the exposed implants required removal. Meanwhile, Buettner and Bartley[19] experienced an exposure rate of 14.3% (4 of 28) in their primary enucleation patients who received donor sclera-covered or dura-covered hydroxyapatite implants (mean follow-up = 8 months). The exposures were all detected within 4 months of surgery. None of these

implants was removed. Ashworth et al[20] reported on 32 patients with sclera-covered hydroxyapatite enucleation implants. Three patients (9.4%) developed implant exposure during the mean follow-up period of 15 months. These exposures were successfully treated with donor scleral and/or mucous membrane patch grafts. McNab[21] encountered two exposures among a series of 25 (8%) sclera-covered primary hydroxyapatite implants followed for an average of 16.9 months. Neither implant needed to be removed. Gupta and colleagues[22] used bovine pericardia–wrapped hydroxyapatite implants. After a mean follow-up of 1.73 years, they observed a single case of wound dehiscence among 27 patients (3.7%) who underwent enucleation for choroidal melanoma. Another group used this same wrapping material when various porous implants were inserted in patients who underwent enucleation or socket reconstruction. Three of the 55 hydroxyapatite and none of the 22 porous polyethylene implants became exposed during the mean follow-up interval of 11.8 months.[23]

In a case series by Remulla et al,[24] exposures developed in 9% (8 of 87) of enucleations in which either hydroxyapatite or porous polyethylene implants were used. Unwrapped porous implants were more likely to expose than implants wrapped with either autologous or homologous tissue ($P < 0.05$). Seven of the exposures appeared within 5 months of surgery, and the other exposure presented 30 months postoperatively. Three of the exposed implants were removed. Karesh and Dresner[1] implanted uncovered porous polyethylene implants in patients who underwent evisceration (n = 5), socket reconstruction (n = 11), and enucleation (n = 6). There were no exposures during the average follow-up period of 19 months. Rubin and colleagues[25] reported two cases of conjunctival dehiscence without exposure in 45 patients observed for at least 1 year after primary or secondary placement of fascia-covered conical porous polyethylene implants. De Potter et al[26] did not find any exposures among 10 patients with sclera-covered porous polyethylene implants observed for 12 months. Anderson et al[27] implanted quasi-integrated porous polyethylene implants without complications in 24 patients who underwent enucleation, evisceration, or socket reconstruction.

Several publications have investigated the complication rates of different enucleation implants in children with retinoblastoma. A level II study of pediatric retinoblastoma patients observed for an average of 21.6 months documented the following exposure rates with different implants: Castroviejo, 70% (7 of 10); noncovered porous polyethylene, 62% (8 of 13); noncovered acrylic spheres, 8% (4 of 50); Mersilene-wrapped acrylic spheres, 53% (9 of 17); and polyglactin mesh–covered hydroxyapatite, 11% (2 of 18).[6] Exposures developed 1 to 630 days after enucleation. Thirty-five percent of the children who required pre-enucleation local treatment or systemic chemotherapy developed exposures, whereas this complication occurred in 20% of the patients who needed only enucleation. Univariate and linear logistical regression analysis revealed that implant type and covering material had a significant effect on the exposure rate ($P < 0.001$). Karcioglu et al[28] reported a case series of 34 noncovered porous polyethylene implants in children who underwent enucleation for retinoblastoma. Eight (23.5%) of the implants become exposed during the follow-up period of 1 to 48 months, seven of which ultimately required removal. Exposures developed an average of 18.9 months after surgery. Four of the 11 patients who received pre-enucleation or postenucleation radiation developed later exposure. Christmas et al[29] reported a single case of "epithelial breakdown" among a series of 103 sclera-covered hydroxyapatite implants placed in children under age 15 (mean follow-up of 164 weeks). Eighty-six percent of these children were treated for retinoblastoma. Thirteen children had been treated with preoperative radiation.

Patients with porous implants may develop complications related to the elective placement of the motility peg or post. Since its introduction, there have been several modifications to the hydroxyapatite implant pegging system. A polycarbonate peg was initially used, and later a threaded polycarbonate sleeve with a removable internal peg was developed. Jordan and Klapper have documented the frequency of symptoms and complications associated with these designs and with a newer hydroxyapatite-coated titanium peg and sleeve system. Fewer complications were reported with the titanium peg and sleeve.[30] Even with this system, however, 35.2% of patients (19 of 54) reported problems during the 3- to 30-month follow-up period, including socket discharge (9.2%), pyogenic granuloma formation (14.8%), the peg falling out (9.2%), conjunctival erosion (3.7%), and loosening of the sleeve (3.7%). Rubin et al[3] reported few complications with primary placement of motility coupling posts in porous polyethylene implants. The post spontaneously exposed in 10 of the 32 patients. Secondary surgical exposure of the post was performed in three additional patients. Pyogenic granulomas developed in two patients, and there was conjunctival overgrowth of the post in one additional patient. The duration of follow-up after exposure of the post was not stated.

The studies (level III) summarized in this assessment suggest that the exposure rate of porous enucleation implants is similar to or higher than that reported for Allen implants, acrylic spheres, and silicone spheres. Some authors have experienced a significantly higher incidence of complications with hydroxyapatite and porous polyethylene implants. Patient selection, covering material, and surgical technique may impact the exposure rate of these implants. Many exposed porous implants do not require removal because some exposures spontaneously heal and others can be surgically repaired.

Conclusions

When a similar surgical technique is used, there seems to be no difference in implant or prosthetic motility between nonpegged porous enucleation implants and donor sclera-covered nonporous spheres based on one level I randomized clinical trial. Porous implants that have been integrated to the prosthesis with a motility peg or coupling post appear to have some degree of improved large-amplitude prosthetic motility, although there is no level I evidence in the literature to substantiate the degree of improvement achieved. Small-degree prosthetic motility (as seen in "conversation-

al" movement) has been subjectively graded as similar for integrated and nonintegrated porous implants.

There is great variability among the reported exposure rates for porous implants, which seem to be affected by surgical technique and type of wrapping material. Some surgeons have reported a low incidence of exposure rates, similar to that for nonporous implants. The literature contains other reports documenting significantly higher exposure rates with porous implants. Secondary insertion of a motility peg may be associated with additional complications, many of which are minor, whereas others result in the need for additional surgery.

Future Research

The literature contains many reports of surgeons' experience with porous implants. The usefulness of many of these studies is limited by their short follow-up after implant insertion, and longer term studies are necessary to determine if late exposures are associated with porous implant materials. Additional research is needed to clarify the role of wrapping material in enucleation surgery and to answer the questions:

- Is wrapping necessary? Which wrapping material is superior?
- Are complications such as inflammation or transmitted infection associated with certain wrapping materials?

Although it is generally assumed that integrating porous implants with motility peg insertion improves prosthetic motility, additional controlled studies with large sample sizes are needed to quantify the degree of improvement that is possible and to answer the questions:

- To what degree is quality of life improved after porous implants have been pegged?
- Is the improved motility sufficient to justify the greater expense of porous implants and peg insertion?

Studies are needed to report the success of motility post insertion in porous implants made of materials other than hydroxyapatite.

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Category	Abbreviation	Specific Financial Interests
Product	P	Financial interest in equipment, process, or product presented.
	Pc	Such interest in potentially *competing* equipment, process, or product.
Investor	I	Financial interest in a company or companies supplying the equipment, process, or product presented.
	Ic	Such interest in a potentially *competing* company.
Consultant	C_	Compensation received within the past 3 years for consulting services regarding the equipment, process, or product presented.
	Cc_	Such compensation received for consulting services regarding potentially *competing* equipment, process, or product.
		Examples of compensation received include:
	C1 or Cc1	1. Retainer
	C2 or Cc2	2. Contract payments for research performed
	C3 or Cc3	3. Ad hoc consulting fees
	C4 or Cc4	4. Substantial nonmonetary perquisites
	C5 or Cc5	5. Contribution to research or research funds
	C6 or Cc6	6. Contribution to travel funds
	C7 or Cc7	7. Reimbursement of travel expenses for presentation at meetings or courses
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References

1. Karesh JW, Dresner SC. High-density porous polyethylene (Medpor) as a successful anophthalmic socket implant. Ophthalmology 1994;101:1688–95, discussion 1695–6.
2. Dutton JJ. Coralline hydroxyapatite as an ocular implant. Ophthalmology 1991;98:370–7.
3. Rubin PA, Fay AM, Remulla HD. Primary placement of a motility coupling post in porous polyethylene orbital implants. Arch Ophthalmol 2000;118:826–32.
4. Colen TP, Paridaens DA, Lemij HG, et al. Comparison of artificial eye amplitudes with acrylic and hydroxyapatite spherical enucleation implants. Ophthalmology 2000;107:1889–94.
5. Custer PL, Trinkaus KM, Fornoff J. Comparative motility of hydroxyapatite and alloplastic enucleation implants. Ophthalmology 1999;106:513–6.
6. Lee V, Subak-Sharpe I, Hungerford JL, et al. Exposure of primary orbital implants in postenucleation retinoblastoma patients. Ophthalmology 2000;107:940–5, discussion 946.
7. Nunery WR, Heinz GW, Bonnin JM, et al. Exposure rate of hydroxyapatite spheres in the anophthalmic socket: histopathologic correlation and comparison with silicone sphere implants. Ophthal Plast Reconstr Surg 1993;9:96–104.
8. Kawai S, Suzuki T, Kawai K. Mobility of hydroxyapatite orbital implant covered with autologous sclera. Jpn J Ophthalmol 2000;44:68–74.
9. Shields CL, Shields JA, De Potter P. Hydroxyapatite orbital implant after enucleation: experience with initial 100 consecutive cases. Arch Ophthalmol 1992;110:333–8.
10. Nunery WR, Cepela MA, Heinz GW, et al. Extrusion rate of silicone spherical anophthalmic socket implants. Ophthal Plast Reconstr Surg 1993;9:90–5.
11. Li T, Shen J, Duffy MT. Exposure rates of wrapped and

unwrapped orbital implants following enucleation. Ophthal Plast Reconstr Surg 2001;17:431–5.
12. Christmas NJ, Gordon CD, Murray TG, et al. Intraorbital implants after enucleation and their complications: a 10-year review. Arch Ophthalmol 1998;116:1199–203.
13. Oestreicher JH, Liu E, Berkowitz M. Complications of hydroxyapatite orbital implants. A review of 100 consecutive cases and a comparison of Dexon mesh (polyglycolic acid) with scleral wrapping. Ophthalmology 1997;104:324–9.
14. Jordan DR, Allen LH, Ells A, et al. The use of Vicryl mesh (polyglactin 910) for implantation of hydroxyapatite orbital implants. Ophthal Plast Reconstr Surg 1995;11:95–9.
15. Kaltreider SA, Newman SA. Prevention and management of complications associated with the hydroxyapatite implant. Ophthal Plast Reconstr Surg 1996;12:18–31.
16. Fan JT, Robertson DM. Long-term follow-up of the Allen implant. 1967 to 1991. Ophthalmology 1995;102:510–6.
17. Leatherbarrow B, Kwartz J, Sunderland S, et al. The "baseball" orbital implant: a prospective study. Eye 1994;8:569–76.
18. Shields CL, Shields JA, De Potter P, Singh AD. Lack of complications of the hydroxyapatite orbital implant in 250 consecutive cases. Trans Am Ophthalmol Soc 1993;91:177–89, discussion 189–95.
19. Buettner H, Bartley GB. Tissue breakdown and exposure associated with orbital hydroxyapatite implants. Am J Ophthalmol 1992;113:669–73.
20. Ashworth JL, Rhatigan M, Brammar R, et al. A clinical study of the hydroxyapatite orbital implant. Eur J Ophthalmol 1997; 7:1–8.
21. McNab A. Hydroxyapatite orbital implants: experience with 100 cases. Aust N Z J Ophthalmol 1995;23:117–23.
22. Gupta M, Puri P, Rennie IG. Use of bovine pericardium as a wrapping material for hydroxyapatite orbital implants. Br J Ophthalmol 2002;86:288–9.
23. Gayre GS, Debacker C, Lipham W, et al. Bovine pericardium as a wrapping for orbital implants. Ophthal Plast Reconstr Surg 2001;17:381–7.
24. Remulla HD, Rubin PA, Shore JW, et al. Complications of porous spherical orbital implants. Ophthalmology 1995;102: 586–93.
25. Rubin PA, Popham J, Rumelt S, et al. Enhancement of the cosmetic and functional outcome of enucleation with the conical orbital implant. Ophthalmology 1998;105:919–25.
26. De Potter P, Duprez T, Cosnard G. Postcontrast magnetic resonance imaging assessment of porous polyethylene orbital implant (Medpor). Ophthalmology 2000;107:1656–60.
27. Anderson RL, Yen MT, Lucci LM, Caruso RT. The quasi-integrated porous polyethylene orbital implant. Ophthal Plast Reconstr Surg 2002;18:50–5.
28. Karcioglu ZA, al-Mesfer SA, Mullaney PB. Porous polyethylene orbital implant in patients with retinoblastoma. Ophthalmology 1998;105:1311–6.
29. Christmas NJ, van Quill K, Murray TG, et al. Evaluation of efficacy and complications: primary pediatric orbital implants after enucleation. Arch Ophthalmol 2000;118:503–6.
30. Jordan DR, Klapper SR. A new titanium peg system for hydroxyapatite orbital implants. Ophthal Plast Reconstr Surg 2000;16:380–7.