Porous versus Nonporous Orbital Implants: A 25-Year Retrospective
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Although porous orbital implants for use after enucleation and evisceration had been tried and discarded over several decades, a new era in anophthalmic socket surgery began with the introduction of coralline hydroxyapatite (HA) by Dr. A. Perry in the late 1980s.1,2 The HA implant represented a new generation of buried spherical implant with an interconnecting system of pores that allowed host fibrovascular ingrowth.2,3 By drilling into the HA implant and inserting a peg, the orbital implant could be directly coupled to the overlying prosthetic eye, producing lifelike movement of the prosthesis analogous to the coupled implants of the 1940s.4 Although HA implants significantly increased the cost of rehabilitating the anophthalmic socket (e.g., higher implant costs, wrapping material costs, additional surgical time for implantation and procedures for complications or pegging, and a confirmatory bone scan), the proposed advantages of a lower migration rate, lower extrusion rate, resistance to infection, and enhanced motility were used to justify the added expense.2,3

In a 1989 survey, HA accounted for 1.5% of implants used.4 Although the response rate was only 23.3% of 300 surveys sent, the returned surveys represented 5439 implants, and a dramatic shift was seen over the next 3 years; by 1992, HA became the most commonly used implant material.4 Over the next several years, additional porous implants (e.g., synthetic HA, porous polyethylene, aluminum oxide) entered the market and were widely promoted.5 Implant companies often portrayed their porous implant as better than their competitor’s with little scientific evidence. Marketing slogans such as “the original, the leader, the total solution,” “take a closer look at a better material,” and “the best choice for implantation candidates” became common at oculoplastic surgery meetings and in oculoplastic surgery journals.6 During this same time period, I implanted more than 1500 implants, including more than 300 polymethylmethacrylate (PMMA) implants, 300+ mounded implants (e.g., Iowa, Universal, Durette [Oculo-Plastik, Inc., Montreal Quebec, Canada], Medpor Quad [Stryker Global Headquarters, Kalamazoo, MI]).7 170+ coralline HA implants, 120+ synthetic HA implants, 430+ aluminum oxide implants, 20+ porous polyethylene implants (and similar products), and more than 200 porous implants of varying material in rabbits). The expressed opinions in this report are based on this experience. The author and many others reported experience on a variety of porous orbital implants, including their benefits, problems, and complications.7–20

It was difficult to determine whether one porous implant was truly better than another.7–17 It became clear that any porous implant may be associated with complications, including conjunctival thinning, implant infection, pyogenic granulomas, socket discharge, implant infection, pain, and various pegging issues.9–11,13,14 Eventually, some surgeons began to question the use of porous implants and advocated a return to nonporous spheres because of their overall low complication rate.6,17,21,22 Spirited debate centered on multiple questions, such as which porous implant is the best, should they be wrapped, which wrap is the best, should they be pegged, which peg system is the best, who should be pegged, when should pegging be done, are porous implants truly advantageous, do they have a lower migration rate, do they have a lower extrusion rate, is there resistance to infection, and is there any motility advantage?23

With respect to implant migration, an early enucleation technique by Frost-Lange24 involved imbricating the extraocular muscles over unwrapped PMMA or silicone spheres. It has now been well established this practice leads to superotemporal implant migration in 16% or more of patients over 8 to 10 years, so it has largely been abandoned.10,25–27 Nunery et al26 and Wells and Harris27 have shown that attaching the rectus muscles in their normal anatomic position to nonporous spheres (e.g., PMMA, silicone) results in a very low superotemporal migration rate (0%–1.3%) and are stable over many years.28 Reports of superotemporal migration with porous orbital implants is not significantly different (0.5%–1.7%).29,30 However, it is my opinion if one also considers anterior migration of porous implants, the overall rate of implant migration may be higher with porous implants because this type of implant migration is seldom discussed. Anterior migration manifests as implant exposure. These cases are often lumped with other cases of implant exposure that may be due to a variety of other factors (e.g., inadequate or poor closure, infection, mechanical or inflammatory irritation from the rough surface of the of the porous implant, delayed ingrowth of fibrovascular tissue with subsequent breakdown, pressure points from a poorly fit prosthesis).31 Anterior migration is secondary to improper seating of the porous implant. Porous implants have a rough surface and drag tissue inward as they are placed into the orbit; this “Velcro” effect makes implantation technically more demanding.32 A tissue glide or wrap may help avoid this posterior drag of the anterior tissue.25 Once implanted, the overlying tissue may be closed successfully over the porous implant,
but with time any tissues dragged inward may return to their original relaxed position—a natural restitution of tissue (cactus syndrome). As this occurs, a gradual migration of the implant anteriorly with progressive conjunctival thinning and eventual breakdown over the implant (exposure) occurs. Fibrovascular ingrowth has not been shown to ensure stability of porous implants. Thus, implant migration can occur with porous or nonporous orbital implants; fortunately, the risk is low with either type of implant.

With respect to implant extrusion, when nonporous implants become exposed, they typically extrude. When porous implants become exposed, the fibrovascular ingrowth helps retain them within the orbit, often preventing complete extrusion. Although porous implant exposures can be surgically repaired by a variety of techniques, large, recurrent, or persistent exposures may require implant removal that essentially is a delayed extrusion (iatrogenic). Rather than ask whether porous orbital implants have a decreased extrusion rate, it is more prudent to ask whether they have a “decreased exposure rate.” Reported exposure rates for nonporous spherical implants (e.g., PMMA/silicone) are typically low (0%—3%). Exposure rates for porous orbital implants are generally low but can vary from 0% to 50%. Custer and Trinkhaus reviewed pooled data and found a 6.6% exposure rate in 3012 porous orbital implants compared with 2.9% in 615 nonporous implants. More recently, Wladis et al reported that rates of exposure (and extrusion) are generally comparable between porous and nonporous implants, suggesting the choice of implant may not result in a dramatic difference in this complication. Thus, there is little evidence that porous implants have a reduced extrusion or exposure rate, and in fact, it may be higher. Porous implant exposures can occur anytime, and the longer the follow-up, the greater the number of exposures.

With respect to infection, nonporous implants (e.g., PMMA/silicone) have been shown to have a low infection rate (0%—1%). Unpegged porous orbital implants also have a low infection rate (0%—2%). Pegging porous implants is associated with an increased number of complications, one of which is infection and has been reported in up to 20% of pegged orbital implants. Fibrovascular ingrowth has not been shown to afford protection against infection. Thus, there is little evidence to support the suggestion that porous orbital implants have a reduced infection rate; it is at least the same as nonporous implants, and potentially higher with a peg.

With respect to enhanced motility, peg placement has been shown to improve horizontal gaze movements in the artificial eye. There is also a more lifelike movement to the prosthesis because of the fine darting eye movements seen during conversation. However, without the peg in place, there is no proven motility advantage of porous over nonporous implants.

As with innovative implant designs from the past (e.g., Mules, Rudemann, Cutler), the initial wave of enthusiasm with porous implants has been tempered as an increasing number of surgeons recognize the touted advantages have little scientific data to support them and the implants are associated with numerous risks and complications that may be difficult to manage. However, advertising continues to promote them as the “gold standard.” Surgeons currently favor the use of porous implants even though unpegged porous implants have no apparent advantage over nonporous spheres. In my opinion, the decision to use a porous or nonporous implant is up to the surgeon and his/her patient. Porous implants are not for every patient. Those with chronic systemic disease (e.g., sarcoidosis, collagen vascular diseases) or who use immunosuppressive medication (e.g., prednisone, methotrexate) or have undergone radiation to the socket are poor candidates. Porous orbital implants are also not for every ophthalmic surgeon. Implantation requires experience and skill to appreciate multiple technical nuances. Although I continue to use porous implants, I have become very selective in who receives a porous implant and only consider their use in healthy adult patients wanting maximal prosthetic motility (pegging) and willing to accept the increased risk of complications. Ideally, the patient should live within a reasonable travel distance to maintain regular follow-up visits so that any minor implant problems can be addressed. Continued follow-up (e.g., every 1—2 years) is recommended in my view for porous implants (pegged or unpegged) because small problems (e.g., implant exposure) can often be handled within the office/minor room setting yet if unattended may develop into a larger problem (e.g., implant infection), requiring additional surgery and potentially implant removal. If there is no plan to peg, I prefer a nonporous implant (sphere or mounded). Nonporous spherical implants can be used efficiently and effectively during a primary procedure, such as enucleation or evisceration; the surgical techniques required can be mastered by most ophthalmic surgeons. Motility results are equal to that of nonpegged porous implants. Nonporous implants are inexpensive, and in a healthcare era when the global expense of a patient’s anophthalmic socket rehabilitation should be considered, a cost-conscious primary procedure with a low incidence of complications may be particularly desirable. During enucleation, it is important they be placed within a normal anatomic position and attached directly (or through a wrap) to the extraocular muscles to ensure stability in their position.

In a recent level I randomized study of porous versus nonporous implants, Ho et al reported no significant differences between HA (unpegged) and acrylic implants with response outcomes reported by patients and ocularists. The low complication rates and high levels of satisfaction among patients and ocularists should be reassuring for future patients being counseled on likely outcomes of enucleation with either of these 2 implants.

Last, it should be stated that the literature contains many reports of surgeons’ experience with porous implants. The usefulness of many of these is limited because there are several factors contributing to the difficulty in comparing various studies, including small numbers of subjects, limited follow-up, lack of use of multivariate methods of analysis, the existence of many confounding
variables (e.g., different surgical techniques, varying surgical experience, several different types of implants), and a lack of quality of life assessments.15 In Schellini et al’s30 Cochrane review of integrated versus nonintegrated implants, only 3 of 338 studies met the inclusion criterion for randomized or quasi-randomized clinical trials. Furthermore, the quality of the included studies was low.30 In a recent review by Wladis et al18 of this subject matter, only 2 of 25 articles met a level I rating (i.e., well-designed, well-conducted randomized clinical trial). I agree with Wladis et al18 and Schelleni et al30 that additional research with well-designed clinical trials would be of benefit to further assess implant types and enable additional critical assessment.18,30 Future studies should use rigorous methodology to explore the role that implant type has on outcomes of clinical relevance.18

References


Footnotes and Financial Disclosures

Financial Disclosure(s): The author(s) have no proprietary or commercial interest in any material.

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