Primary Placement of a Hydroxyapatite-coated Sleeve in Bioceramic Orbital Implants

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- PURPOSE: To study a new surgical option of primary placement of a hydroxyapatite-coated sleeve into the Bioceramic implant during enucleation or evisceration.
- DESIGN: Retrospective, observational case series.
- METHODS: A standard enucleation or evisceration was performed, followed by the preplacement of a hydroxyapatite-coated sleeve into the Bioceramic implant. Care must be taken to ensure the sleeve has been positioned centrally when the implant is put inside the orbital socket. Complications such as sleeve exposure, Bioceramic implant exposure, and infection were closely observed.
- RESULTS: Twenty-seven patients were treated in above fashion with five enucleation and 22 evisceration procedures. Five of the sleeves have exposed spontaneously during 1 to 4 months after original surgery. They had no further complication, except for one sleeve around which there were visible Bioceramic spicules attributable to long-term corticosteroid usage. The remaining 22 sleeves that did not spontaneously expose pursued secondary exposure of the sleeve and peg insertion by the conjunctival cutdown procedure 3 months postoperatively. One sleeve was medially positioned far away from the implant center. Re-insertion of new sleeve and peg was scheduled 2 weeks later. One additional sleeve was obliquely positioned after conjunctival cutdown procedure. Fortunately, all 27 patients were successfully fitted with a peg-coupled prosthesis with good motility.
- CONCLUSIONS: Primary placement of a hydroxyapatite-coated sleeve into the Bioceramic implants has several advantages, including high patient acceptance, technical simplicity, and an office-based conjunctival cutdown pegging procedure. By avoiding the expense of postoperative imaging studies and additional prosthetic modification, a more rapid and efficient rehabilitation is possible. (Am J Ophthalmol 2005;139:235-241. © 2005 by Elsevier Inc. All rights reserved.)

Hydroxyapatite orbital implants are commonly used during enucleation, evisceration, and secondary orbital implant surgery. This implant is made of material similar in nature to the mineral component of human bone (calcium phosphate), and is biocompatible, nontoxic, and nonallergic. Its extensive pore system permits fibrovascular ingrowth, which helps the implant to resist migration and infection. By attaching the extraocular muscles and coupling the prosthesis to the orbital implants using sleeve and peg, a wide range of prosthetic movements can be obtained, which allows for a more lifelike quality in the prosthetic eye.

Another porous orbital implant recently available, the Bioceramic orbital implant, made of aluminum oxide (Al₂O₃), is a ceramic biomaterial that has been used for more than 30 years in the orthopedic and dental fields. Aluminum oxide has been made into a porous spherical implant (FCI, Moulineaux, France) for use in anophthalmic sockets. Jordan and associates described their experiences in 107 patients with the Bioceramic orbital implant over a 36-month period. They concluded that the Bioceramic orbital implant represented an alternative porous orbital implant that is biocompatible with orbital tissues, easy to manufacture, structurally strong, and less expensive than other commercially available porous orbital implants (for example, Bio-Eye hydroxyapatite implant). Problems encountered with its use are similar to those seen with the Bio-Eye orbital implants but appear to occur less often.

Despite its successes, there are some challenges to the hydroxyapatite-coated sleeve and peg coupling system. A second surgical procedure is required to anchor the hydroxyapatite-coated sleeve and peg, and it is sometimes difficult to place and align the sleeve and peg precisely on the surface of Bioceramic implant. The additional procedure of placing motility peg in any setting may result in increased complications with the implant (e.g., implant exposure around peg) and with the peg itself (e.g., peg extrusion and pyogenic granuloma formation). Finally, the cost of adjunctive radiologic imaging (bone, computed tomographic, or magnetic resonance imaging scan) to confirm implant vascularization if needed, a second surgical procedure to place the peg system, and postoperative prosthesis modification is also high. The waiting time for a
second surgical procedure (usually 6 months after operation) is very long for patients who often desire early coupled prosthetic rehabilitation. It may be the topic of interest to develop some technical modifications to simplify the procedure of placing motility peg and achieve early coupled prosthetic fitting.

Rubin and associates\textsuperscript{13,14} developed a technique to place a motility coupling post (MCP) into porous polyethylene orbital implants at the time of enucleation. There were no infections, wound dehiscences, malpositions, or extrusion of the posts in their series. Only minor complications of pyogenic granuloma (two cases) and conjunctival overgrowth (one case) were noted. They concluded that MCP placement at the time of enucleation in selected patients is an effective and efficient surgical option.\textsuperscript{14} To facilitate early coupling and simplify the pegging procedure, we placed a hydroxyapatite-coated sleeve into a Bioceramic orbital implant at the time of enucleation or evisceration and planned a peg placement 3 months later.

PATIENTS AND METHODS

ALL PATIENTS WHO UNDERWENT PRIMARY PLACEMENT OF the hydroxyapatite-coated sleeve were highly motivated for early coupled prosthetic fitting. The exclusion criteria included underlying vasculopathy (diabetes, vasculitis, or history of chemotheraphy or radiotherapy), endophthalmitis, and patients younger than 15 years. Intraoperative requirements included adequate conjunctiva to close the wound without tension. Institutional Review Board Ethics Committee approval was obtained in this study.

In the case of enucleation, immediately after a standard enucleation, the posterior Tenon was widely opened with blunt dissection. The implant was wrapped with vicryl mesh (Ethicon, Somerville, New Jersey). Before placement into the orbital socket, an 18-gauge needle was used to prepare a pilot hole into the vicryl mesh wrapped Bioceramic implant. (FCI, Moulineaux, France) A hand drill sleeve driver (FCI, Moulineaux, France) was used to preplace a hydroxyapatite-coated sleeve (FCI, Moulineaux, France) into the implant. The head of the hydroxyapatite-coated sleeve was positioned to protrude 1 to 3 mm above the surface of the Bioceramic implant (Figure 1A). After preplacement of a hydroxyapatite-coated sleeve into Bioceramic implant, the implant was slid into orbital socket, while the anterior conjunctiva and Tenon capsule were retracted. A 1.5×1.5-cm piece of donor sclera was put on the top of the sleeve, with a buttonhole for the sleeve. The four rectus muscles were sutured 3 to 5 mm from the anterior surface of sleeve onto the donor sclera and vicryl mesh. The Tenon capsule and conjunctiva were meticulously closed with minimal tension using an interrupted buried 6-0 polyglactin suture. A polymethyl methacrylate conformer was placed within the conjunctival fornices, and antibiotic ointment was applied, and the eyelids were typically closed with a central suture tarsorrhaphy.

In the case of evisceration, a cornea-preserved standard evisceration was performed, followed by preplacement of a
hydroxyapatite-coated sleeve into unwrapped Bioceramic implant (as described above) (Figure 1B). The implant was placed in the eviscerated shell if the space was large enough. If the eviscerated shell space was not large enough, a further circular opening of the scleral shell around the optic nerve was made to allow the posterior part of the implant to move into the orbital space. Usually, extra cuts were made in a circular fashion around the optic nerve so that it became disinserted from the eviscerated scleral shell. Care must be taken to ensure that the hydroxyapatite-coated sleeve is positioned centrally when the implant is put inside the eviscerated scleral shell. Closure of sclera-corneal wound was performed with 5-0 polyester sutures. The 2- to 3-mm buttonhole of central cornea was created to let the hydroxyapatite-coated sleeve protrude from the surface of cornea. The Tenon capsule and conjunctiva were closed over the cornea as the same fashion as that in the enucleation procedure. A conformer was put in the conjunctival fornix, and terramycin ointment was applied.

Routine examinations were performed at 1 week, 1 month, and 2 months after surgery. Patients were monitored postoperatively for the evidence of spontaneous exposure of the sleeve, infection, and early exposure of the Bioceramic implant. Secondary exposure of the sleeve and the peg insertion was scheduled 3 months after initial surgeries.

Topical anesthesia was instilled into the conjunctival cul-del-sac, followed by a cotton pledget soaked in 2% lidocaine. The sleeve was palpated, and conjunctival cautery or cutdown procedure was applied to expose the hydroxyapatite-coated sleeve (Figure 2). The peg was inserted into the central opening of the sleeve. No suturing of the conjunctiva was required. Topical antibiotics were given, and a peg-coupled prosthetic fitting was scheduled 2 weeks after this procedure.

Follow-up for all patients was scheduled 1 week after original surgery and every month thereafter for the following 6 months. After 6 months, patients were asked to come back every 3 to 6 months.

RESULTS

TWENTY-SEVEN PATIENTS WERE TREATED IN THE ABOVE fashion with five enucleation and 22 evisceration procedures from September 2001 to February 2003. The follow-up period ranged from 11 to 27 months (mean, 19.5 months). All the operations and follow-ups were performed by one doctor (S.L.L.). Five of the sleeves (all eviscerated cases) were found to have exposed spontaneously during 1 to 4 months after the original surgery (Figure 3) (three sleeves after 1 month, 3 months and 4 months individually, and two sleeves after 2 months). All five patients had peg insertions without a conjunctival cutdown procedure and were fitted with a peg-coupled prosthesis 3 months after original surgery. They had no further complication, except one sleeve around which there are visible Bioceramic spicules because of long-term corticosteroid usage after 18 months of follow-ups. Fortu-
nately, there was no further Bioceramic implant exposure during the follow-up period. The remaining 22 sleeves did not spontaneously expose. All these 22 patients pursued secondary exposure of the hydroxyapatite-coated sleeve and peg insertion by a conjunctival cutdown procedure 3 months after original surgery. One sleeve was medially positioned and far away from the implant center after the conjunctival cutdown procedure. Re-insertion of a new hydroxyapatite-coated sleeve and peg was scheduled 2 weeks later. One additional sleeve was obliquely positioned after the conjunctival cutdown procedure. Fortunately, all 27 patients were successfully fitted with a peg-coupled prosthesis with good synchronized motility (Figure 4).

There were no wound dehiscences, infection, or extrusions of the Bioceramic orbital implants. One sleeve was found to be medially positioned far away from the implant center and required repositioning of the sleeve and peg. One additional sleeve was obliquely positioned. Fortunately, these two patients could be fitted with a peg-coupled prosthesis with acceptable synchronized motility. No patient required explantation of the Bioceramic implant.

Among the five cases with spontaneous exposure of the hydroxyapatite-coated sleeve, one patient with long-term use of corticosteroid showed Bioceramic spicules visible around the hydroxyapatite-coated sleeve. No further Bioceramic implant exposure was noted after 24 months of follow-up, and this patient complained of increased discharge from the socket.

DISCUSSION

POROUS HYDROXYAPATITE HAS BEEN SUCCESSFULLY USED as an orbital implant in enucleation, evisceration, and as secondary implant since 1985.1,2,4,15–17 Recently, another porous orbital implant, the Bioceramic orbital implant, made of aluminum oxide (Al₂O₃), has become available in a porous spherical implant (FCI, Moulineaux, France) for use in anophthalmic sockets.9 This Bioceramic orbital

FIGURE 3. Spontaneous sleeve exposure: One sleeve was found to have exposed spontaneously 5 weeks after original surgery.
implant represents an alternative porous orbital implant that is biocompatible with orbital tissues, easy to handle, structurally strong, and less expensive than other commercially available porous orbital implants.10

A benefit of using porous orbital implants is the extensive porous system permitting fibrovascular ingrowth, which theoretically may help decrease the risk of implant extrusion and infection.2,18,19 Additionally, with drilling and peg insertion, this implant can be directly coupled to the prosthesis, allowing a wide range of prosthetic movement, especially fine darting eye movements commonly seen during conversational speech.5 These movements impart a more lifelike quality to the prosthetic eye.5 Peg placement, however, is usually delayed (usually 6 months) until the implant shows a high degree of fibrovascularization ingrowths, as established by objective imaging studies, such as a bone scan or magnetic resonance imaging scan.20,21 Because the cosmetic and psychological rehabilitation of the anophthalmic patients may depend on lifelike fine movements of the prosthetic eye, searching for new techniques to facilitate earlier coupled prosthetic fitting is beneficial to patients.

Rubin and associates14 developed a technique to place a motility coupling post (MCP) into porous polyethylene orbital implants at the time of enucleation. Nine (28%) out of 32 MCPs spontaneously exposed within the first 4 months, and there were no cases of infection, explantation, or gross MCP malposition in their series. In this study, we tried to place a hydroxyapatite-coated sleeve into the Bioceramic orbital implant at the time of enucleation or evisceration. Five (18%) of 27 sleeves spontaneously exposed within the first 4 months after original surgery. Rubin and associates14 found that pegs positioned less than 3 mm above the implant did not spontaneously expose, whereas pegs protruding 4 mm above the implant were much more likely to expose. In this study, the hydroxyapatite-coated sleeve was placed 1 to 3 mm above the Bioceramic implant, which may explain why there was less sleeve exposure (18% compared with 28% in Rubin’s study) in this study. These five early sleeve exposures were not associated with major complications such as implant exposure, peg extrusion, or infection in this series. Only one sleeve was found to have Bioceramic spicules around the sleeve 15 months after original surgery. No further

FIGURE 4. A 38-year-old male with primary hydroxyapatite-coated sleeve placement during evisceration and early prosthetic fitting three months after surgery; the movement of prosthesis is very satisfactory.
Bioceramic exposure was noted after 24 months of follow-up. This patient complained of increased discharge from the socket.

Furthermore, in cases of primary placement of the sleeve or MCP, migration, or rotation of the implants between its intraoperative and final postoperative position may result in decentration or misdirection of the sleeve or MCP. In Rubin’s report, there was no malposition of MCP. In this study, one sleeve was medially positioned far away from the implant center after the conjunctival cutdown procedure. Re-insertion of a new hydroxyapatite-coated sleeve and peg was scheduled 2 weeks later. One additional sleeve was obliquely positioned after the conjunctival cutdown procedure. Fortunately, these two patients could be fitted with a peg-coupled prosthesis with acceptable synchronized movements. We suggest that more care should be taken during the implantation of sleeve-inserted Bioceramic implant. And it is very important to ensure that the sleeve is in the center of the orbital socket before closure of the Tenon and conjunctival wound.

Advantages of the motility peg placement include increasing prosthetic motility (including small-angle conversational movement) and providing support of the prosthesis, which decreases the mechanical burden of the prosthesis on the lower eyelid. Several potential complications can occur after pegging the hydroxyapatite implant including a pyogenic granuloma, a clicking sound, profuse discharge, conjunctival overgrowing the peg, or implant infection. It was also found that discharge from sockets with primary placement of the sleeve was much less than those with secondary placement of hydroxyapatite-coated sleeve and peg system. It is possible that early vascular ingrowth around the primarily inserted hydroxyapatite-coated sleeve may prevent the sleeve loosening and decrease the discharge formation. Furthermore, the conjunctival cutdown procedure, which produces only a very small conjunctival opening, may prevent the complications such as pyogenic granuloma, conjunctival overgrowth, and infection.

In conclusion, primary placement of a hydroxyapatite-coated sleeve in Bioceramic orbital implant is offered as a potential surgical option. This study demonstrates the ease and predictability of this procedure with minimal complications. In selected patients, this procedure offers several advantages, including high patient acceptance, technical simplicity, and an office-based conjunctival cutdown pegging procedure. By avoiding the expense of postoperative imaging studies (to evaluate vascularization), secondary pegging surgery, and additional prosthetic modification and fitting, a more rapid and efficient rehabilitation is possible. Because of the small number of patients in this study and the short follow-up period, a larger number of patients and a longer follow-up period of study would be beneficial before making a final conclusion about this proposed technique.

REFERENCES

Biosketch

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