Journal of Zhejiang University SCIENCE B
ISSN 1673-1581 (Print); ISSN 1862-1783 (Online)
www.zju.edu.cn/jzus; www.springerlink.com
E-mail: jzus@zju.edu.cn

High density porous polyethylene material (Medpor) as an unwrapped orbital implant

CHEN Yan-hong, CUI Hong-guang[†‡]

(*Department of Eye Center, the First Affiliated Hospital, School of Medicine, Zhejiang University, Hangzhou 310015, China*)

[†]E-mail: chg96@hzcnc.com

Received Mar. 27, 2006; revision accepted June 22, 2006

Abstract: Objective: To introduce the clinical effect among patients who received an unwrapped orbital implant with high density porous polyethylene material (Medpor) after enucleation or evisceration. Methods: Retrospective analysis of a series of 302 patients with anophthalmia who underwent placement of an unwrapped high density porous polyethylene orbital implant. We compared the patients (n=180) who accepted primary implant placement with those (n=122) who accepted secondary implant placement. Parameters evaluated included: age at time of surgery, date of surgery, sex, implant type and size, surgery type, the surgical procedure and technique performed, and complications. Results: The time of follow-up ranged from 2.0 to 58.0 months (mean 32.5 months). A total of 5 of 302 (1.66%) cases had documented postoperative complications. The following problems were noted after surgery: implant exposure, 3 patients (0.99%); implant removed due to orbital infection, 1 patient (0.34%); ptosis, 1 patient (0.34%). There were no significant complications observed in other 297 cases and all implants showed good orbital motility. The clinical effect of primary implant placement is better than that of secondary placement. Conclusion: High density porous polyethylene material can be used successfully as an unwrapped orbital implant in anopthalmic socket surgery with minimal complications. The material is well tolerated, nonantigenic and has low rate of infection and migration.

Key words: Orbital implants, High density porous polyethylene, Correction of orbital abnormality
doi:10.1631/jzus.2006.B0679 **Document code:** A **CLC number:** R779.64

INTRODUCTION

Enucleation or evisceration has been performed at least since the 16th century. Many materials and implant types have been used to restore orbital volume and some prosthetic motility. High rate of extrusion and infections led to the design of completely buried integrated implants. In the past 11 years, coralline hydroxyapatite (HA) has been the currently widely used implant material because of its high biocompatibility and anti-inflammation properties. But the material is rough in the surface and therefore covering of sclera or fascia is essential for the attachment of extraocular muscles. This may represent a risk to the patient for transmission of infectious disease. If the rough surface of the implant was uncovered or inadequately vascularized, it may cause erosion of the overlying conjunctiva and Tenon's capsule even implant exposure at last (Buetter and Bartley, 1992; Remulla *et al*., 1995; McNab, 1995; Oestreicher *et al*., 1997).

We describe our experience with 302 patients who underwent enucleation, evisceration, or secondary implant placement who had reconstruction with high density porous polyethylene (Medpor) as an unwrapped ocular implant. The material is a synthetic material formed by the polymerization of ethylene molecules under high pressure and temperature and is pliable enough to allow direct suturing of the extraocular muscles (Karesh and Dresner, 1994). There is no wrapping material to act as a barrier to the fibroscular ingrowth in the sphere. The functional and cosmetic results to date have been excellent, and complications have been minimal (Trichopoulos and Augsburger, 2005).

[‡] Corresponding author

MATERIALS AND METHODS

Materials

Three-hundred and two patients were referred to the oculoplastic service of the Eye Center, the First Affiliated Hospital of Zhejiang University for enucleation or evisceration. The implants were placed in 156 women and 146 men. The mean age was 38.2 years (median, 38.2 years; range 8 to 62 years). The indications for surgery were intraocular malignancy in 18 patients, painful blind eyes due to end-stage glaucoma, diabetes or trauma in 265 patients and endophthalmitis in 19 patients. Primary implant after enucleation was performed in 180 cases and secondary implant in 122 cases. All operations were performed by the same surgeon with the standard technique. Most of the implants measured 20-mm in diameter, in some cases, 18- or 22-mm spheres were used depending on the orbital volume.

Methods

The implant was prepared before beginning the surgery. The high density porous polyethylene material was placed directly in gentamicin solution (80 mg diluted in 10 ml of balanced salt solution for 15 min before use). Enucleation was performed by opening the conjunctiva for 360° around the corneal limbus. Anterior Tenon's capsule was separated from its attachment to sclera just behind the limbus and bluntly dissected from the globe in four quadrants between the rectus muscles using Stevens scissors. Each of the four rectus muscles was isolated with a muscle hook, a double-armed 5-0 Vicrryl suture passed through its insertion and secured with a locking stitch at each side, and the muscles were then cut from the globe. A gently curved enucleation scissors was used to bluntly dissect through the posterior layer of Tenon's capsule and incise the optic nerves as far posterior in the orbit as possible. Bleeding was controlled with gauze soaked in 1% phenylephrine HCl and digital pressure for 5 min. Steel ball was used as necessary to control any persistent bleeding from the posterior orbit.

An appropriately-sized high density porous polyethylene spherical implant was placed into the enucleation cavity after all bleeding had been controlled. Using the previously placed 5-0 polyglactin sutures in the muscle insertions, the muscles were sutured to the implant sphere to approximate their normal insertions. Only very superficial bites were required to attach the muscles. Some pressure is necessary to push the needle through the implant pores. After the implant was correctly positioned in the orbit, the anterior portion of Tenon's capsule and the conjunctiva were closed separately over the implant with interrupted 5-0 polyglactin sutures. A conformer was placed in the fornices, until a permanent prosthesis is fashioned.

In the secondary implantation cases, the extraocular muscles were identified after dissection in the walls of Tenon's capsule, then they were isolated and sutured to the implant in the way described above. If the muscles could not be identified clearly, Tenon's capsule in the region of the fibrosed muscle insertions was sutured directly to the implant.

All patients were fit with a permanent prosthesis 4 to 6 weeks after surgery.

RESULTS

Postoperative follow-up for this group of patients averaged 32.5 months (range, 2.0~58 months). A total of 5 of 302 (1.66%) cases had documented postoperative complications. During the follow-up implant exposure was observed in 3 cases (0.99%) due to the insufficient Tenon's capsule closure and all cases were successfully repaired with surgery. Implant infection was observed in 1 case (0.34%), and the implant was removed 6 months after surgery; and bacterial culture revealed infection of *Staphylococcusaureus*. One case (0.34%) presented secondary ptosis. All sockets showed good to better motility after orbital implanting.

DISCUSSION

In the past tens years, implantation of porous material was the first choice to correct the orbital abnormality after eyeball enucleation or evisceration. In 1985 coral porous hydroxyapatite, which was firstly used by Perry (1991), has been the currently widely used implant material because of its high biocompatibility and anti-inflammation properties. However, the material is rough in the surface and therefore covering of sclera, fascia, dermis, poly-

glactin mesh, bovine pericardium, and many others is essential for the attachment of extraocular muscles (Jordan *et al*., 1998; Gayre *et al*., 2001; Naugle *et al*., 1999; Kao and Chen, 1999). Furthermore, smooth covering decreases the abrasion to the surrounding orbital tissues. Implant exposure is the most common complication, as the incidence rate reported from 1.6% to 25%, resulted from the material quality, surgical skills or failure in vascularization of the implant due to the surface covering. The complications induced by the surface covering materials are also known as the reason of implant extrusion of dislocation (Lee *et al*., 2000; Jordan and Klapper, 1999).

Porous polyethylene (Medpor) orbital implants were introduced in 1989, with a pore size of the current implant is approximately 400 μm. The Medpor implants have several advantages over other similar implants: smooth sphere surface which makes it easy to be implanted. The structure is not brittle, and extraocular muscles can be sutured directly to the implant without the need to drill holes or wrap the implant, ensuring tissue ingrowth to reduce the rate of extrusion (van Acker and de Potter, 2001). These unwrapped orbital implants eliminate the theoretical risks of immunologic reaction directed against the wrapping tissue and transmission of infectious agents.

In this study of 302 cases with Medpor implantation, only 3 cases (0.99%) of implant exposure were observed. One case of implant removal was conducted 6 month after implantation due to intra-orbital infection. One case of secondary ptosis was noticed and frontal muscle suspension was then performed. There were no other complications in the remaining 297 cases (98.34%). The success rate of implantation surgery was 99.67% (301/302), while the incidence rate of implant extrusion was 0.99% (3/302). In addition, 2 patients of Medpor implantation were chosen at random for MRI examination. The results showed the existence of fibrovascular tissue ingrowth even at time of 1 month after the surgery. The result of our study is consistent with that reported in (de Potter *et al*., 2000).

Our experience based on 302 cases (success rate 98.34%) includes: First, close suturing of Tenon's capsule. Three cases of implant exposure were observed about 1 month after the implantation surgery. We think it happened due to insufficient Tenon's capsule closure. The capsule split as the result of tissue edema. Then implant exposure had not been further observed during the follow-up because No-pull suturing of the capsule was conducted. The membrane between the rectus muscles should be kept intact during the isolation of the muscles. Shearing of the membrane always induces the retraction of the Tenon's capsule that makes it difficult to cover the whole implant surface. The size of the Medpor implant was equal to that of the steel ball used to enlarge the orbital socket. After the Medpor implant was inserted into the socket, the four edges of Tenon's capsule were clipped by forceps and blunt isolation dissection was made in the deep orbital cavity inferior to the implant. The implant was then covered by the no-pull Tenon's capsule. Second, attention should be paid on the fixation of the rectus muscles to the Medpor surface. To our experience, suturing the muscle should be in the position superior to that of the routine procedure, which can keep the implant stable and reduce the tension of Tenon's capsule. Last, when the incision was closed, the conjunctiva should be dissected free from the underlying Tenon's capsule and these two tissue layers should be stitched separately.

Accurate isolation of four rectus muscles, as well as the contractile ability of these muscles is important to prosthetic motility after implantation. In the procedure of secondary implantation, tracing the rectus muscle along the muscle cone will facilitate muscle isolation. We found that in the secondary implantation cases, fibrous scar was seen when the muscle tendons had been sutured together (a procedure that is always suggested in cases of eyeball enucleation without prosthetic implantation). The muscular scar decreases prosthetic motility significantly. Our suggestion is to make suturing mark for each rectus, but not to suture the muscles together in cases of enucleation. In patients that had received enucleation for a long time, contracture of the rectus muscles makes it difficult for isolation. In particular, extra traction of superior rectus muscle or superior oblique muscle will result in ptosis. In our study, a case of secondary ptosis occurred in a patient who received eyeball enucleation surgery 28 years ago. Frontal muscle suspension procedure was conduct on this patient 6 months after ptosis onset.

One case of implant infection was observed 6 month after implantation and the bacterial culture

revealed infection of *Staphylococcus aureus*. Co-current dacrocystitis was noticed in this patient, the implant was then removed and dacrocystectomy was performed.

In conclusion, the present study suggests that Medpor can be implanted directly into the orbital socket with excellent biocompatibility, prosthetic motility and little toxicity. Medpor implant provides a relatively "ideal" option in correcting orbital abnormality after eyeball enucleation or evisceration.

References

Buetter, H., Bartley, G.B., 1992. Tissue breakdown and exposure associated with orbital hydroxyapatite implants. *Am. J. Ophthalmol.*, **113**:669-673.

de Potter, P., Duprez, T., Cosnard, G., 2000. Postcontrast magnetic resonance imaging assessment of porous polyethylene orbital implant (Medpor). *Ophthalmology*, **107**(9):1656-1660. [doi:10.1016/S0161-6420(00)00249-9]

Gayre, G.S., De, B.C., Lipham, W., 2001. Bovine pericardium as a wrapping for orbital implants. *Ophthal. Plast. Reconstr. Surg.*, **17**:381-387. [doi:10.1097/00002341-200109000-00014]

Jordan, D.R., Klapper, S.R., 1999. Wrapping hydroxyapatite implants. *Ophthalmic. Surg. Lasers*, **30**:403-407.

Jordan, D.R., Gilberg, S., Mawn, L., 1998. The synthetic hydroxyapatite implant: a report on 65 patients. *Ophthal. Plast. Reconstr. Surg.*, **14**:250-255.

Kao, S.C., Chen, S., 1999. The use of rectus abdominis sheath for wrapping of the hydroxyapatite orbital implants. *Ophthalmic. Surg. Lasers*, **30**:69-71.

Karesh, J.W., Dresner, S.C., 1994. High-density porous polyethylene (Medpor) as a successful anophthalmic socket implant. *Ophthalmology*, **101**:1688-1696.

Lee, V., Subak, S.I., Hungerford, J.L., 2000. Exposure of primary orbital implants in postenucleation retinoblastoma patients. *Ophthalmology*, **107**(5):940-946. [doi:10.1016/S0161-6420(00)00016-6]

McNab, A., 1995. Hydroxyapatite orbital implants. Experience with 100 cases. *Aust. N. Z. J. Ophthalmol.*, **23**:117-123.

Naugle, T.C., Lee, A.M., Haik, B.G., Callahan, M.A., 1999. Wrpping hydroxylapatite orbital implants with posterior auricular muscle complex grafts. *Am. J. Ophthalmol.*, **128**(4):495-501. [doi:10.1016/S0002-9394(99)00159-2]

Oestreicher, J.H., Liu, E., Berkowitz, M., 1997. Complications of hydroxyapatite orbital implants. A review of 100 consecutive cases and a comparison of Dexon mesh (polyglycolic acid) with scleral wrapping. *Ophthalmology*, **104**:324-329.

Perry, A.C., 1991. Advances in enucleation. *Ophthalmol. Clin. North Am.*, **4**:173-182.

Remulla, H.D., Rubin, P.A., Shore, J.W., 1995. Complications of porous spherical orbital hydroxyapatite implants. *Ophthalmology*, **102**:586-593.

Trichopoulos, N., Augsburger, J.J., 2005. Enucleation with unwrapped porous and noporous orbital implants: a 15-year experience. *Ophthalmic Plastic and Reconstructive Surgery*, **21**(5):331-336. [doi:10.1097/01.iop.0000175034.88019.a5]

van Acker, E., de Potter, P., 2001. Implant orbitaire en polyethylene poreux (Medpor). *J. Fr. Ophtalmol.*, **24**:1067-1073.