Long-term surgical outcomes of porous polyethylene orbital implants: a review of 314 cases

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ABSTRACT

Purpose This study reports on the long-term surgical outcomes after the insertion of porous Medpor orbital implants into anophthalmic sockets.

Methods A retrospective chart review of 314 eyes from 314 patients who underwent evisceration, enucleation and secondary procedures using Medpor orbital implants was completed focusing on implant-associated complications and their corrective methods as surgical outcomes.

Results The mean follow-up was 50 months (range 6–107 months). The most common complication was blepharoptosis (n=33, 10.5%). Other postoperative complications were exposure (n=14, 4.5%) and implant infection (n=3, 1%). The complications were successfully managed by surgical repair and/or conservative care.

Conclusion Using Medpor resulted in similar surgical outcomes, in terms of the types and frequencies of complications, as other kinds of porous orbital implants.

Medpor (Porex Surgical, Inc, College Park, Georgia, USA) is a porous form of polyethylene that is now widely used with hydroxyapatite to compensate for the loss of volume in an anophthalmic socket after enucleation or evisceration. In addition to its use in anopthalmic socket surgery, Medpor is commonly used in craniofacial reconstruction surgery. Because the average pore diameter of Medpor is greater than 150 μm, which is above the standard limit (100 μm), this material allows the ingrowth of host orbital vasculature and soft tissue, which integrates the implant with the host's body. Medpor is a firm material that is easily manufactured by heating small polyethylene spheres.[1–3]

Tissue ingrowth through the pores allows for biointegration, which reduces the risk of extrusion and exposure. Furthermore, Medpor reduces the infection rate because the invasion of vascular structures through the pores of the orbital implant enables an immune response to infection, and antibiotics can also be delivered by systemic administration to the orbital implant.[4 5] However, it is possible for an abscess to develop in the internal lacuna of Medpor, and connective tissue may erode due to the rough surface.[6 7] Therefore, the most serious complications associated with integrated orbital implants after evisceration or enucleation are still exposure and infection. Although efforts have been made to reduce these complications, the reported rates vary from 0% to 21%.[8–15]

However, few studies have reported on the general postoperative complications after Medpor implantation in a large cohort. Alwitry *et al*[16] reported long-term follow-up results (6 years) of porous polyethylene spherical implants after enucleation and evisceration in 106 patients, but this report placed emphasis on the superiority of operative techniques such as evisceration or enucleation, which is insufficient for a general assessment of the long-term surgical outcomes of Medpor orbital implants.

We report here on the long-term surgical outcomes of 314 patients who underwent enucleation, evisceration, or secondary orbital implantation with a porous polyethylene (Medpor) orbital implant at our hospital, and compare these outcomes with those of previously published research.

PATIENTS AND METHODS

We performed a retrospective chart review of 314 patients who underwent primary placement of a porous polyethylene orbital implant after enucleation, evisceration, or secondary implantation by an oculoplastic surgeon (SWY) at Seoul St Mary's Hospital between 1998 and 2008. All patients provided fully informed written consent for surgery, and all patients were followed up for more than 6 months after surgery. Patient demographics, indications for the procedure, type of procedure, size of the implant placed, duration of follow-up, any complications encountered and patient management procedures were recorded. Enucleation was only performed for patients in whom evisceration was contraindicated; for example, if there was suspicion of an intraocular tumour on clinical examination or imaging study or those cases in whom it was too difficult to perform an evisceration due to severe phthisis or severe retrobulbar damage.

A 360° peritomy was performed at the limbus for enucleation, and the four quadrants were bluntly dissected to release the conjunctiva and Tenon's capsule from the globe. The four rectus muscles were identified and isolated using muscle hooks. The muscles were cleaned of tendon and were secured with locked 5-0 polyglactin (Vicryl; Ethicon Inc., Johnson & Johnson Co., Somerville, New Jersey, USA) sutures before being detached from the globe. The dissection continued posteriorly, and the superior and inferior oblique muscles were cut. The optic nerve was transected with blunt curved scissors. The loose globe was removed, and haemostasis was secured with monopolar diathermy and pressure application. A sizing ball was used to assess the residual intraconal volume, and implant size was chosen to allow tension-free closure of the anterior ocular tissue. A porous polyethylene (Medpor) implant was left within its sterile

Table 1 Patient demographics

Characteristic	Enucleation (N=43)	Evisceration (N=229)	Secondary orbital implantation (N=42)	Total (N=314)
Age, years (range)	46.81 (2–78)	51.54 (2–87)	47.25 (1–77)	50.35 (1–87)
Gender (M:F)	19:24	112:117	20:22	151:163
Follow-up, months (range)	44 (6–92)	46 (6–107)	58 (6–87)	50 (6–107)

N, number of patients.

package, and allowed to bathe fully in 10 ml saline with 80 mg gentamicin sulphate (Gentamicin; Kukje Pharm, Seoul, Korea) for 30 min. The implant was inserted intraconally, and the rectus muscles were attached directly to the implant. Tenon's capsule and conjunctiva were closed in layers with 6-0 polyglactin sutures (Vicryl; Ethicon Inc.).

A 360° peritomy was performed for evisceration, and an incision was made circumferentially in the sclera approximately 1–2 mm from the limbus. An evisceration spoon was used to separate the uveal tissue from the scleral shell, and the globe contents were delivered. The inside of the globe was then cleaned and debrided with a gauze swab. Anterior relaxing incisions were made in the sclera, avoiding the rectus muscles. Additional relaxing incisions were made at the equator level circumferentially. An appropriately sized Medpor implant was inserted using the same method as for enucleation. The implant was inserted, and the scleral shell was closed with 5-0 polyglactin (Vicryl; Ethicon Inc.) interrupted sutures using the wrapping method. Tenon's capsule and conjunctiva were closed in layers with 6-0 polyglactin (Vicryl; Ethicon Inc.) sutures, respectively.

Horizontal conjunctival incisions were made during secondary implantation, and any pseudocapsule was dissected and removed. An appropriately sized Medpor orbital implant was inserted, and the last step consisted of meticulously closing the anterior and posterior Tenon's capsule and conjunctiva as separate layers with 6-0 polyglactin (Vicryl; Ethicon Inc.) sutures.

After all the procedures were done, a conformer was inserted, and antibiotic ointment was placed on the ocular surface to prevent dehiscence and infection of the initial wound. The conformer was maintained for 4 weeks. Further follow-up visits were scheduled at 2, 4, 6 and 8 weeks, 6 and 12 months, and every 12 months thereafter.

The postoperative complications found during the follow-up period were classified into orbital implant, conjunctiva and lid abnormality groups, and we performed surgical or medical management according to the types and severity of the postoperative complications.

RESULTS

A total of 314 cases was identified, and the mean follow-up period was 50 months (range 6–107 months). Forty-three patients (13.7%) underwent enucleation, 229 (72.9%) underwent evisceration, and 42 (13.4%) underwent secondary orbital implantation (table 1). Trauma was the most common original cause of the need for enucleation or evisceration, accounting for 173 patients (55.2%). Glaucoma made up a large portion of the original causes for performing an evisceration rather than other procedures (14.8% vs 2.3% and 14.8% vs 9.5%). Infection or inflammation was a more common reason for performing enucleation or secondary orbital implantation instead of evisceration. Enucleation was performed in cases with a suspicious or confirmed ocular tumour (table 2).

The orbital implant size ranged from 14 to 22 mm, with the most common being an 18-mm implant (52.2%). The most common type of implant used in surgery was an orbital sphere type, the rest being either the Medpor smooth surface tunnel (SST) implant or the Medpor multipurpose conical orbital implant (MCOI) (table 3).

The most common postoperative complication was blepharoptosis (10.5%), followed by eye discharge (6.4%), implant exposure (4.5%), conjunctival contracture (4.5%), ectropion (3.5%) and implant infection (1%) in a total of 314 patients. The overall postoperative complication incidences were 72.1% (31/43) in patients who received enucleation, 27.1% (62/229) in patients who received evisceration and 59.5% (25/42) in patients who received secondary orbital implantation. The most common postoperative complication was blepharoptosis in all three groups (table 4).

All three patients with an implant infection underwent implant exchange. *Staphylococcus aureus* was cultured in two cases, and *Streptococcus epidermidis* was cultured in one case (table 5). All 14 cases of implant exposure were significant in size, which required operative intervention with an alloderm graft or sclera. Four patients (28.6%) who received enucleation, eight patients (57.1%) who received evisceration and two patients (14.3%) who received secondary orbital implantation were included in these 14 cases. After this surgical intervention, two cases of implant exposure recurred. One of these cases underwent an implant exchange, and the other case underwent implant removal (table 6). The four cases of giant papillary conjunctivitis were recovered with conservative care, and removal was performed in two cases of conjunctival cyst and granuloma. Nine cases of fornix contracture (9/14, 64.3%)

Table 2 Original causes for anophthalmic surgery

Cause	Enucleation (N=43)	Evisceration (N=229)	Secondary orbital implantation (N=42)	Total (N=314)
Trauma (%)	21 (48.8%)	132 (57.6%)	20 (47.6%)	173 (55.2%)
Glaucoma (%)	1 (2.3%)	34 (14.8%)	4 (9.5%)	39 (12.4%)
Corneal ulcer (%)	3 (7.0%)	29 (12.7%)	4 (9.5%)	36 (11.5%)
Ocular inflammation/infection (%)	9 (21.0%)	14 (6.1%)	6 (14.4%)	29 (9.2%)
Tumours (%)	8 (18.6%)	0 (0%)	4 (9.5%)	12 (3.8%)
Others (%)	1 (2.3%)	20 (8.8%)	4 (9.5%)	25 (7.9%)

N, number of patients.

Table 3 Distribution of Medpor type check

Size, mm	Orbital sphere	SST sphere	MCOI	Total (%)
14	4	–	–	4 (1.3)
16	7	0	1	8 (2.5)
18	139	8	17	164 (52.2)
20	134	3	0	137 (43.7)
22	1	0	–	1 (0.3)
Total	285	11	18	314

SST, smooth surface tunnel; MCOI, multipurpose conical orbital implant.

received reconstruction with oral mucosa and dermis, and five cases (5/14, 35.7%) received reconstruction with alloderm (Surederm; Hans Biomed Co, Seoul, Korea). Three cases (3/4, 75.0%) of wound dehiscence, which were small and caused by an inapproximated conjunctival suture, required only conservative management, but one case (1/4, 25.0%) received an additional suture. Most of the complications associated with lid problems (39/54, 72.2%) required operative management. For the blepharoptosis (n=33) and dermatochalasis cases (n=3), 18 patients (18/36, 50.0%) received a blepharoplasty, 10 (10/36, 27.8%) received a levator resection and three (3/36, 8.3%) received levator advancement. Three patients who had a deep upper lid sulcus received silastic sheet insertion on the superior orbital wall via the skin incision. Three patients who had lower lid entropion received lower lid retractor re-insertion, and two patients received Quickert suture. Ocular pain or eye discharge was treated with conservative care, and these patients recovered.

We did not routinely use a motility coupling post (MCP) because most patients who had undergone anophthalmic surgery and obtained a sufficient conjunctival fold showed good movement without a MCP. Only 32 patients received a MCP insertion, five needed a position recorrection, and two underwent re-insertion due to failure. No infection was observed in the patients who received a MCP insertion (table 7).

Table 4 Postoperative complications

Complications		Enucleation (N=43)	Evisceration (N=229)	Secondary orbital implantation (N=42)	Total (%)
Implants	Infection	0	3	0	3 (1.0)
	Exposure	4	8	2	14 (4.5)
Conjunctiva	Giant papillary conjunctivitis	0	3	1	4 (1.3)
	Conjunctival cyst/granuloma	0	1	1	2 (0.6)
	Fornix contracture	6	7	1	14 (4.5)
	Wound dehiscence	1	2	1	4 (1.3)
Eyelid	Blepharoptosis	9	18	6	33 (10.5)
	Dermatochalasis	0	2	1	3 (1.0)
	Deep upper lid sulcus	1	4	2	7 (2.2)
	Entropion	4	5	2	11 (3.5)
Others	Pain/discomfort (>6 weeks)	1	1	1	3 (1.0)
	Discharge (>6 weeks)	5	8	7	20 (6.4)

N, number of patients.

DISCUSSION

Polyethylene is a high-density, straight-chain hydrocarbon formed by polymerisation of ethylene molecules under high temperature and pressure. Medpor is a polyporous form (150–400 μm) of polyethylene that is manufactured by heating and compacting polyethylene granules into spherical shapes of different size. This porous character enables fibrovascular proliferation of orbital tissue, reduces the risk of migration, exposure and extrusion, and minimises the risk of infection. This material is also non-toxic, non-allergenic and highly biocompatible. It is not brittle, thus allowing muscles to be sutured directly to it with no need for sclera.[1–4] Many studies have reported favourable surgical outcomes after Medpor orbital implantation.[17–22]

Medpor has a rough surface, which tends to cause erosion of Tenon's capsule and conjunctiva and eventually implant exposure. To compensate for this defect, other types of Medpor have been introduced. Medpor SST is a further refinement of the original polyporous polyethylene (Medpor). It has a smooth, porous anterior surface, which helps minimise late-implant exposures, and the suture tunnels allow for easy attachment of the rectus muscle without the use of an implant wrap. Medpor MCOI is cone-shaped, which makes it possible to provide additional volume in the orbit with a similar diameter implant. Medpor MCOI has more utility in patients with severe phthisis bulbi. Medpor is currently a very popular polyporous orbital implant material. The other orbital implant materials include hydroxyapatite and aluminum oxide.

However, unlike hydroxyapatite implants, only relatively small case series have been published on the exposure and complication rates of Medpor orbital implants. Karcioglu *et al*[23] reported eight cases of conjunctival dehiscence exposure, five cases of fornix contracture and three cases of inappropriate volume replacement in 37 patients who underwent enucleation and Medpor orbital implantation due to retinoblastoma. Cheng *et al*[24] reported that implant exposure occurred in up to one-third of patients who received Medpor orbital implantation over a 2-year follow-up period, and this was particularly common after MCP insertion. Shoamanesh *et al*[25] reported postoperative complications in 32 patients who had received Medpor implants with a 14-year follow-up period. Baek[17] reported five cases of implant exposure and four cases of superior sulcus deformity in 36 patients after evisceration, enucleation, or secondary orbital implantation during 2 years of follow-up. We studied the overall postoperative outcomes in 314 patients over 10 years of follow-up.

Our study showed only a 1% (3/314) incidence rate of Medpor orbital implant infection, and these three cases required an

Table 5 Postoperative orbital implant infections

No	Gender/age (years)	Preoperative diagnosis	Type of surgery	Size of implant (mm)	Complication-free follow-up period (months)	MCP insertion	Cultured microorganism
1	M/39	Trauma	Evisceration	20	46	No	*S aureus*
2	M/44	Trauma	Evisceration	18	1	No	*S epidermidis*
3	M/43	Phthisis bulbi	Evisceration	18	59	No	*S aureus*

MCP, motility coupling post.

Table 6 Postoperative orbital implant exposure

No	Gender/age (years)	Preoperative diagnosis	Type of previous surgery	Size of implant (mm)	MCP insertion	Complication-free follow-up period (months)	Recurrence after management using sclera or alloderm graft
1	M/66	Trauma	Enucleation	20	None	20	None
2	M/46	Tumour	Enucleation	18	Yes	27	None
3	F/60	Ocular infection	Enucleation	18	None	30	None
4	M/49	Trauma	Enucleation	20	None	47	None
5	F/38	Trauma	Evisceration	20	None	61	None
6	M/55	Trauma	Evisceration	20	None	14	Yes (implant exchange)
7	F/44	Trauma	Evisceration	18	None	26	None
8	M/43	Trauma	Evisceration	18	None	38	None
9	M/75	Phthisis bulbi	Evisceration	20	None	55	None
10	F/68	Glaucoma	Evisceration	20	None	29	None
11	F/73	Phthisis bulbi	Evisceration	20	None	35	None
12	M/39	Trauma	Evisceration	20	None	24	None
13	F/50	Glaucoma	Secondary orbital implantation	18	None	18	Yes (implant removal)
14	M/59	Trauma	Secondary orbital implantation	18	None	38	None

MCP, motility coupling post.

Table 7 Patients with a MCP

Type of operation	No of patients
Enucleation	14 (3: recorrection, 2: succeeded after a failure)
Evisceration	13 (2: recorrection)
Secondary orbital implantation	5
Total	32

MCP, motility coupling post.

implant exchange. This rate is similar to the infection rate of the hydroxyapatite orbital implant, which ranges from 0% to 1.5%.[26 27] Postoperative implant infection using Medpor is rare, limited to only a few case reports,[5 28 29] probably because Medpor has a hydrophobic and negatively charged surface that acts as a protective envelope to inhibit the adherence of bacteria.[28]

In the present study, implant exposure occurred in 9.3% of patients who underwent enucleation and in 3.5% of patients who underwent evisceration. Alwitry *et al*[16] reported the long-term follow-up surgical outcomes (6 years) of 106 patients who underwent spherical Medpor implantation, and reported that the implant exposure rate was 6.3% (5/80) for patients who underwent enucleation and 53.8% (14/26) for patients who underwent evisceration. The original reason for the surgery was different between the study of Alwitry *et al*[16] and our study. The most common cause of anophthalmic surgery was trauma in both studies, but its frequency was different: approximately 30% in our study and up to 50% in the study by Alwitry *et al*.[16] In both studies, the surrounding tissue around the eyeball was damaged by trauma, and the degree of damage affected recovery rate and the final surgical outcome. Therefore, a simple comparison of incidence rates between the two studies has no meaning. In addition, we included data on patients who received Medpor MCOI and Medpor SST, not just the spherical Medpor, which may have influenced our results, whereas the study by Alwitry *et al*[16] only included data on patients who received the spherical Medpor.

The results showed similar postoperative complication rates, except the rate of fornix contracture between the patients who had received enucleation (6/43, 14.0%) and secondary orbital implantation (1/42, 2.4%). This result was caused by the fact that secondary orbital implantation was mostly considered when an unfit artificial eye was detected.

Yoon *et al*[26] reported that the rate of orbital implant exposure in 802 patients who received hydroxyapatite orbital implantation with a 15-year follow-up was 2.1%. Shoamanesh *et al*[25]

Table 8 Summary of the major studies on porous orbital implants

Complications	Material	Our study (N=314) Porous polyethylene	Alwitry *et al*[16] (N=106) Porous polyethylene	Shoamamesh *et al*[25] (N=32) Porous polyethylene	Blaydon *et al*[18] (N=136) Porous polyethylene	Yoon *et al*[26] (N=802) Hydroxyapatite
Implants	Infection	3				0
	Exposure	14	19	2	5	55
Conjunctiva	Giant papillary conjunctivitis	4	1			
	Conjunctival cyst/granuloma	1	2	2	6	2
	Fornix contracture	14		3		
	Wound dehiscence	4			1	28
Eyelid	Blepharoptosis	33		9		
	Dermatochalasis	3				
	Deep upper lid sulcus	7				
	Entropion	11				
Others	Pain/discomfort (>6 weeks)	3		1		
	Discharge (>6 weeks)	20		4		38

N, number of patients.

found that the rate of exposure was 6% for 432 patients who underwent hydroxyapatite orbital implantation and 6.25% for 32 patients who underwent Medpor orbital implantation. Baek[17] reported a rate of exposure of 13% for 36 eyes that underwent Medpor orbital implantation; however, all 36 eyes successfully recovered with a dermograft. Custer and Trinkaus[30] reported that the exposure rates were similar between hydroxyapatite (5.1%) and Medpor (4.2%) when patients with retinoblastoma were omitted from the pooled data in a meta-analysis of porous orbital implant studies. These reports show that surgical outcomes vary according to factors such as operator technique and the status of the conjunctiva around the operation site. More studies may be needed to determine conclusively whether hydroxyapatite or Medpor is superior, because few studies have focused on patients who received Medpor orbital implants.

Other postoperative complications may also occur, including conjunctival abnormalities and lid problems. Yoon *et al*[26] reported that conjunctival cysts and conjunctival wound dehiscence occurred in 0.2% and 3.5% of patients who received hydroxyapatite orbital implantation, respectively, but they did not receive pegging. No marked differences were observed between the study of Yoon *et al*[26] and our study, which showed rates of 0.6% and 1.3% for conjunctival cysts and conjunctival wound dehiscence, respectively. Shoamanesh *et al*[25] found that blepharoptosis occurred in 20.1% of patients who underwent Medpor orbital implantation, and this was the most common postoperative complication. Our study showed similar results; blepharoptosis was the most common postoperative problem, and its incidence rate was 10.5%. However, most cases of blepharoptosis successfully recovered after a blepharoplasty or other corrective operation (table 8).

MCP insertion was performed in 10.2% of the patients at our institute, which is a relatively low rate, and most underwent this procedure before 2002. MCP has been used to improve artificial eyes, but it may increase the infection rate of an orbital implant.[26] Furthermore, unskilled insertion of an MCP requires repositioning or removal and re-insertion.[31] Therefore, we do not typically perform MCP insertion if the motility of an artificial eye is satisfactory and the patient does not wish to do it.

In summary, we report a large case series of patients implanted with porous polyethylene orbital implants with an extended follow-up. We highlighted the previously undocumented general postoperative complications after Medpor orbital implantation during long-term follow-up, and no marked differences in the complications between hydroxyapatite and Medpor were observed. We also successfully resolved the postoperative complications associated with Medpor. Therefore, we suggest that Medpor produces tolerable surgical outcomes as an orbital implant because of lower material cost, convenience of the operative procedure and other advantages.

Competing interests None.

Patient consent Obtained.

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