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E-mail: jzus@zju.edu.cn

Effects and complications of placement of motility coupling post in porous polyethylene orbital implants

Hong-guang CUI, Rong-rong HU, Hui-yan LI[†‡], Wei HAN

(*Department of Ophthalmology, the First Affiliated Hospital, School of Medicine, Zhejiang University, Hangzhou 310003, China*)

[†]E-mail: lihuiyan93@yahoo.com.cn

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Abstract: Objective: To investigate the effects and complications of primary and secondary placements of motility coupling post (MCP) in the unwrapped porous polyethylene orbital implant (PPOI) following enucleation. Methods: We investigated 198 patients who received PPOI implantation following the standard enucleation procedure in the First Affiliated Hospital, School of Medicine, Zhejiang University, Hangzhou, China, from 2002 to 2004. These patients were subgrouped into PPOI-only patients (112 cases, received PPOI following enucleation), primary MCP patients (46 cases, received primary placement of MCP during PPOI operation), and secondary MCP patients (40 cases, received secondary placement of MCP 6 months after the initial surgery). Effects and complications among these three groups were compared. Results: The PPOI-only patients took shorter treatment course when compared with other two MCP groups (P<0.001), without significant difference noted between the two MCP groups. However, the two MCP groups had better prosthetic motility than PPOI-only group (P<0.001), without significant difference between the two MCP groups. In the early stage, 2 eyes in the PPOI-only group and 1 eye in the primary MCP group had PPOI infection. In PPOI-only group, 3 (2.68%) eyes had PPOI exposure, which occurred after fitting the prostheses; 4 eyes (8.70%) in primary MCP group and 1 eye (2.50%) in secondary MCP had PPOI exposure, which occurred before fitting the prostheses. After prosthesis was fit successfully, the excessive discharge and granuloma were 33.9% and 1.79% in PPOI group-only, 53.3% and 8.9% in primary MCP group, and 52.5% and 7.5% in secondary MCP group, respectively. Conclusion: Both primary and secondary placements of MCP into the PPOI following enucleation can help patients to obtain desirable prosthetic motility, but may be associated with more complications. The primary placement of MCP with skilled operation in selected patients is more recommendable than secondary placement.

Key words: Porous polyethylene orbital implant (PPOI), Motility coupling post (MCP)
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INTRODUCTION

Currently, high density porous polyethylene orbital implant (PPOI) is widely used after enucleation or evisceration. Unwrapped PPOI, which allows the growth of fibrovascular tissues into the implant, is usually applied together with the placement of a motility coupling post (MCP) (Hsu *et al*., 2000; Rubin *et al*., 2000; Chen and Cui, 2006; Trichopoulos and Augsburger, 2005). After the MCP placement, a motility peg directly transfers movements of the implanted PPOI to the prosthesis and greatly improves its motility (Guillinta *et al*., 2003). Pegging of the PPOI may also reduce the weight of the prosthesis on the lower eyelid. Previously, MCP placement required a second surgery usually at least 6 months after enucleation, resulting in more medical cost and complications with the PPOI and MCP (Jordan, 2001; Jordan *et al*., 1999; Lin *et al*., 2002). During the past decade, there have been some studies about primary insertion of an MCP into the PPOI after evisceration or enucleation (Rubin *et al*., 2000; Hsu *et al*., 2000; Tawfik and Dutton, 2004). Animal studies demonstrated the good tolerance of primary placement of an MCP into PPOI. The extent of fibrovascular tissue ingrowth and vascular density also verified that the

‡ Corresponding author

initial screw insertion did not adversely affect the healing process after PPOI implantation (Hsu *et al*., 2000). However, Rubin *et al*.(2000) reported some complications, including pyogenic granuloma and conjunctival overgrowth, and suggested that MCP placement be combined with PPOI after enucleation in selected patients.

To our knowledge, there is no report that compares PPOI implantation followed by the primary and secondary MCP placements with the one without further MCP placement. In this study, we investigated the effects and complications of primary and secondary MCP placements after PPOI.

PATIENTS AND METHODS

Patients

A total of 198 patients who underwent the surgery of PPOI of Medpor biomaterial (Porex Surgical Inc., Newnan, Georgia, USA) from June 2002 to December 2004 in the First Affiliated Hospital, School of Medicine, Zhejiang University, Hangzhou, China, were included in the study. Preoperative exclusionary criteria included underlying vasculopathy (diabetes, vasculitis, history of chemotherapy or irradiation) and the age limit of <10 years. Based on patients' willingness, 112 patients did not have insertion of MCP (PPOI-only group, 79 males, 33 females, aged (42.89±11.74) years), 46 had MCP placement (Porex Surgical Inc., College Park, GA, USA) during PPOI surgery (primary MCP group, 33 males, 13 females, aged (41.78±11.93) years) and the remaining 40 had MCP placement 6 months after PPOI surgery (secondary MCP group, 28 males, 12 females, aged (42.43±12.00) years). The reasons for enucleation were listed in Table 1. This study followed the guidelines of the Declaration of Helsinki, and informed consent was obtained from each patient. Institutional Review Board approval was obtained for this retrospective review.

Table 1 Indications for implantation of porous polyethylene orbital implants

Indications	Number of patients with/without MCP placement		
	Without (*n*=112)	Primary (*n*=46)	Secondary (*n*=40)
Ruptured globe	47	20	18
Painful blind eye	16	11	10
Endophthalmitis	12	3	2
Malignancy	19	6	2
Atrophic globe	18	6	8

PPOI implantation and MCP placement

All the operations were executed by the same surgeon. In PPOI-only group, following a standard enucleation procedure, a suitable PPOI was carefully put into the orbital socket of each patient. The implant sizes ranged from 18~22 mm (Table 2) and all the PPOIs were spherical in shape. The four rectus muscles were sutured to the implant with 5-0 polyglactin sutures (Vicryl Ethicon Endo-Surgery Inc., New Jersey, USA), and then the Tenon's capsule and conjunctiva were meticulously enclosed with 6-0 polyglactin sutures without tension. The prosthesis was fitted 4~8 weeks after this procedure.

Table 2 Sizes of porous polyethylene orbital implants

Implant size (mm)	Number of patients with/without MCP placement		
	Without (*n*=112)	Primary (*n*=46)	Secondary (*n*=40)
18	9	3	2
20	21	8	7
22	82	35	31

In the primary MCP group, following the same enucleation procedure, MCPs were screwed into PPOIs with a hand drill and screwdriver (Porex Surgical Inc., Newnan, Georgia, USA) and positioned to protrude 3 mm above the surface of the implant. Then the Medpor implant was inserted into the orbital socket of each patient. Care was taken to put the MCP upward vertically and adjust it to be located in the central position. The four rectus muscles were sutured to the PPOI with 5-0 polyglactin sutures, and then the Tenon's capsule and conjunctiva were closed in separate layers over the protruding MCP with 6-0 polyglactin sutures. According to the spontaneous exposure of an inserted MCP, prosthesis was fitted 4~8 months after surgery. When the MCP did not expose spontaneously within 10 months after surgery, it was externalized with a conjunctival cut-down procedure under superficial anesthesia, and then prosthesis was fitted 1 month later.

In secondary MCP group, an MCP was inserted into the PPOI implanted 6 months ago after conjunc-

tival cut-down procedure under topical anesthesia. A preplaced hole matching the MCP was drilled at the back of prosthesis, which was fitted 1 month later.

All patients were followed up every week in the first month and every month in the following 9 months. Later, follow-up ranged from 12 to 18 months according to actual situations. MCP extrusion, complications of PPOI-MCP, prosthetic motility, and total treatment course were all documented. The prosthetic motility was measured by an Arc perimeter (Suzhou Medical Appliance Co., Suzhou, China). Patients were asked to turn their eyes to the right and left sides horizontally to the largest extent and the central reflect light point of the pupil on the Arc perimeter was recorded, and hence the mobility angle was determined.

Statistical analysis

Statistical analysis data were presented as mean±*SD* for continuous variables. The comparisons of the continuous variables among the groups were analyzed by using the *P* value test. Categorical variables were compared by using the χ^2 test.

RESULTS

PPOI exposure

Table 3 shows that in PPOI-only group, 2.68% of the eyes (3/112) had PPOI exposure (4~9 mm in diameter) 2 weeks to 3 months after the surgery. Among these 3 eyes, 2 were treated with conjunctival repair and 1 with topical medications for 3 weeks. In primary MCP group, before fitting the prostheses, 8.70% of the eyes (4/46) had PPOI exposure (4~8 mm in diameter) around the MCP at (3.6±1.2) months after surgery. Among these 4 eyes, 1 (8 mm in diameter) received conjunctival repair 3 weeks later, and the other 3 healed with topical medications (antibiotics and fibroblast growth factor). In secondary MCP group, before fitting prostheses, 2.50% of the eyes (1/40) had PPOI exposure (9 mm in diameter) 3 months after surgery and healed with conjunctival repair. In this group, 6 months later, an MCP was inserted into the PPOI after conjunctival cut-down procedure for each patient. The PPOI exposure results show that the primary MCP patients had higher rate of PPOI exposure than the secondary MCP patients ($P<0.05$).

Table 3 Postoperative complications for three groups

Group	*n*	Number of patients		
		PPOI exposure	Increased discharge	Granuloma
PPOI-only	112	3 (2.68%)	38 (33.93%)*	2 (1.79%)*
Primary MCP	46	4 (8.70%)*	24 (52.17%)	4 (8.70%)
Secondary MCP	40	1 (2.50%)	21 (52.50%)	3 (7.50%)

* $P<0.05$ vs the other two groups

MCP exposure

In primary MCP group, MCPs were spontaneously exposed in 58.7% of the eyes (27/46) 2 to 8 months after surgery, 19.6% of the eyes (9/46) needed a conjunctival cut-down to expose the MCPs 10 months after surgery, and the MCPs in the remaining 10 eyes (21.7%) were never exposed until 24 months after surgery.

Infection

Table 4 shows the infection observed. In PPOI-only group, 1.79% of the eyes (2/112) had infection confirmed by bacterial culture, and the PPOIs were removed and replaced 6 months later. In primary MCP group, 2.17% of the eyes (1/46) had the MCP extrusion and subsequent excessive discharge at a month after surgery, and the discharge culture showed *Staphylococcus aureus* infection. Two and three weeks later, respectively, the MCP and PPOI were taken out from this patient, because the infection was resistant against topical and systemic antibiotic treatments.

Table 4 Infected cases of the three groups

Case No.	Group	Gender	Age (year)	Indication	Implant size (mm)	Interval after implantation (week)	Bacterial culture
1	PPOI-only	M	42	Ruptured globe	22	3	*Staphylococcus aureus*
2	PPOI-only	M	36	Ruptured globe	22	4	*Corynebacteria*
3	Primary MCP	F	45	Ruptured globe	22	4	*Staphylococcus aureus*

Discharge

An increasing discharge was found in 33.93% of the eyes (38/112) in PPOI-only group, 52.17% (24/46) in primary MCP group, and 52.50% (21/40) in secondary MCP group (Table 3). All patients could tolerate the eye discharge after fitting prostheses, except one patient in primary MCP group who had to remove MCP to stop the symptom.

Granuloma

As shown in Table 3, Granuloma on the conjunctiva was found 1.79% (2/112) in PPOI-only group. In primary MCP group, pyogenic granuloma adjacent to the MCP was found 8.70% (4/46) 5 to 12 months after surgery. In secondary MCP group, granuloma adjacent to the MCP was found 7.50% (3/40), occurring at the 6th, 8th and 11st months after surgery, respectively. The granuloma was removable by excision without recurrence.

MCP decentration

In primary MCP group, 2.17% of the eyes (1/46) had MCP decentration in early postoperative period and was screwed again at a better position, and no MCP decentration occurred in secondary MCP group.

Cluck noise

63.04% of the eyes (29/46) in primary MCP group and 85.00% (34/40) in secondary MCP group were found to have cluck noise when turning eyes.

Total treatment time

The total treatment time, defined as the interval from the initial surgery to prosthetic fitting, was (8.20±1.70) weeks in PPOI-only group, (27.96±14.30) weeks in primary MCP group, and (30.2±2.55) weeks in secondary MCP group. The PPOI-only group took the shortest treatment time in comparison with the other two groups (P<0.001) (Table 5).

Table 5 Total treatment time of the three groups

Group	*n*	Total treatment time (week)
PPOI-only	110 (2)[a]	8.20±1.70[*]
Primary MCP	45 (1)[b]	27.96±14.30
Secondary MCP	40	30.20±2.55

[a]Two infected eyes were excluded; [b]One infected eye was excluded; [*]P<0.001 vs the other two groups

Prosthetic motility

Table 6 shows the maximal horizontal prosthetic motility, which was (33.46±5.28) degrees in PPOI-only group, (43.7±4.01) degrees in primary MCP group, and (44.08±4.08) degrees in secondary MCP group. The primary and secondary MCP groups had better prosthetic motility than the PPOI-only group (P<0.001), while no significant difference was found between the primary and secondary MCP groups.

Table 6 Maximal prosthetic motility of the three groups

Group	*n*	Maximal prosthetic motility (degree)
PPOI-only	112	33.46±5.28[*]
Primary MCP	44 (2)[a]	43.70±4.01
Secondary MCP	40	44.08±4.08

[a]Two eyes were excluded with one taking removal of MCP and the other infected; [*] P<0.001 vs the other two groups

DISCUSSION

In order to achieve a better postoperative cosmetic effect, prosthetic motility is concerned the most during PPOI implantation following enucleation. However, there are no criteria for the measurement of prosthetic motility at the present (Raizada *et al*., 2007). Few data documenting the degree of improvement of prosthetic motility with a peg-coupled prosthesis are available. Some surgeons did not think that pegging is necessary for a good appearance (Kostick and Linberg, 1995; Shields *et al*., 1994). However, our study demonstrated that MCP placement can achieve better prosthetic motility, regardless of primary or secondary pegging.

There are few studies reporting the total treatment time of PPOI with MCP. In the present study, we observed that the primary and secondary MCP patients took longer time to finish treatment than PPOI-only patients. However, the treatment time in primary and secondary MCP groups could have been much shortened. In order to gain experience, we had been cautiously and conservatively waiting for cases without spontaneous exposure until 10 months after surgery in the primary MCP group, thus extending the total treatment time. In fact, the eyes without the spontaneous exposure of MCPs can be fitted at an earlier stage. In Yazici *et al*.(2007)'s study, the MCP was externalized 2 to 4 months after enucleation

surgery without a higher rate of complications, and hence the total treatment time could be shortened. However, fitting prostheses without conjunctival cut-down procedure seemed to take shorter treatment time and be a reasonable alternative.

PPOI exposure is one of the most concerned complications during the operation. Some studies reported PPOI exposure occurrence (Yazici *et al*., 2007; Cheng *et al*., 2004; Karslioglu *et al*., 2006; Alwitry *et al*., 2007) and suggested that MCP placement might have the risk of PPOI exposure and infection and must be taken care to. In our study, the PPOI exposure occurrence was low (8 eyes in total, 4.04%). For small area exposure within 2~3 weeks, eye drops (antibiotics and fibroblast growth factor, 4 times per day) and cauterization with iodine were sufficient, while amnion membrane covering was applied for the exposure larger than 8~9 mm. However, the primary MCP group had a higher rate of PPOI exposure (8.70%) than PPOI-only group (2.68%) and secondary MCP group (2.50%). In order to reduce the risk of PPOI exposure, we suggest that the suture site of Tenon's capsule and conjunctiva should be separated from the top of MCP.

Karslioglu *et al*.(2006) reported an implant infection rate of 9.48% (11/116) with pegs and 0% for the unpegged implants (0/96). We had 3 eyes (1.52%) infected, with 2 eyes in PPOI-only group and 1 eye in primary MCP group. Massive discharge was observed when the PPOI was found exposed. Bacterial culture indicated a bacterial infection. Unfortunately, these cases of infection cannot be controlled using antibiotics until the PPOIs were removed. In Cheng *et al*.(2004)'s study, one patient (5.6%) had severe implant infection with massive discharge and exposure of PPOI around the peg. Some researchers also found an increased risk of PPOI exposure and infection with MCP placement (Karslioglu *et al*., 2006; Cheng *et al*., 2004). In our study, all the three cases of infection took place within 1 month postoperatively, and the primary lesion for enucleation was ruptured globe. The eyes might have been contaminated, and therefore, it should be safer to take a secondary MCP placement of PPOI for these ruptured globes.

Increased discharge is the most frequent complication when prostheses were fitted. Jordan *et al*. (1999) reported that 37% of the patients pegging hydroxyapatite orbital implants had increased discharge. In our study, there was less discharge in the patients without MCP placement when compared with the two groups with MCP placement (P<0.001). The specific mechanism is still not clear. Topical glucocorticosteroid and antibiotics medications could decrease the discharge. For the case in primary MCP group, the MCP was removed, as the patient could not tolerate the excessive discharge, and the discharge significantly decreased, suggesting that the possible reason could be the placement of MCP. Increased discharge may significantly affect patients' daily life and thus deserves more attention by the clinicians.

Rubin *et al*.(2000) reported that 2 of 32 patients (6.25%) developed a pyogenic granuloma one year after prostheses fitting. In our study, the occurrence of granuloma was 8.70% and 7.50% in primary and secondary MCP groups, respectively, higher than that of Rubin *et al*.(2000)'s study. Granuloma usually emerged 6 months after surgery and was located at the base of the MCP-conjunctiva interface. Pyogenic granuloma occurs frequently in association with implant exposure and may conceal the exposure. In our cases, a small lesion of PPOI exposure could be observed after granuloma excising. Such small exposure could heal with topical medications without granuloma recurrence.

In primary MCP group, MCP decentration was found in one patient during conjunctival cut-down procedure. The MCP was replaced after drilling another hole. The safety of drilling another hole and secondary MCP placement still needs further investigation. Tawfik and Dutton (2004) reported that one patient developed a retrobulbar hematoma, which caused shift of MCP. Postoperative decentration of the MCP was subsequently noted and was treated with modifying the hollow position at the back of the prosthesis to fit the top of the peg. Yazici *et al*.(2007) reported significant MCP decentration because of implant rotation and restriction of the implant movements, developed in the early postoperative period and in the late period. Implant rotation may be due to the improper positioning of the muscles or implant during surgery, preoperative strabismus, intrinsic muscle imbalance, extraocular muscle slippage, sensorial deprivation, and postoperative orbital fibrosis. Therefore, the four rectus muscles should be evenly sutured on the surface of the implant, and the MCP should be surely inserted on the center of the orbital socket and upward vertically.

In addition, we also observed that a secondary conjunctival cut-down was not needed for the eyes without spontaneous exposure in primary MCP group.

The spontaneous exposure was not associated with any other complication, such as the implant exposure, peg extrusion, or infection. Rubin *et al*.(2000) concluded that the possibility of MCP exposure rested with fascia thickness covering the implant and distance between the top of the pegs and implant surface. In our study, the rate of the spontaneous exposure of MCP was 58.7% 2 to 8 months after implantation, higher than that of Rubin *et al*.(2000)'s result (28.13%). In our study, 10 eyes in primary MCP group with thin surficial fascia over the MCP and PPOI did not have spontaneous exposure of MCPs. These eyes were directly fitted with peg-matching prostheses, and the matching hole at the back of prostheses was enlarged accordingly. Later, all the 10 patients achieved acceptable eye motility and did not complain about audible click. No any other complications were developed at the 24 months of follow-up. Thus, for the eyes with thin fascia over the MCP and PPOI, the peg-matching prostheses could be fitted directly, without a secondary conjunctival cut-down procedure. However, for the cases with thick fascia, the conjunctival cut-down procedure might be still necessary.

CONCLUSION

Both primary and secondary placements of MCP into the PPOI following the enucleation can help patients to obtain desirable prosthetic motility, but they may be associated with more complications; patients underwent PPOI implantation without MCP placement had less complications and shorter treatment time. The primary MCP placement with skilled operation in selected patients is more recommendable than secondary MCP placement. Respects regarding the treatment should be fully considered before surgery scheme was determined, such as cosmetic effect, total treatment time, and risk of complications.

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