• Clinical Research •

Comparison between local-made and imported porous polyethylene orbital implant: a randomized controlled equivalence trial and multicenter study

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Abstract

● **AIM:** To compare the exposure rate, infection rate, percentage of enhancement, and success rate between Medpor and the three-dimensional printed polyethylene (3DP-PE) orbital implant in a preliminary report.

● **METHODS:** This prospective, randomized, equivalence, controlled trial was conducted at two institutes. The equivalent margin was ±10%. The sample size for the equivalence trial was 174 participants per group. Patients who were eligible for enucleations received either Medpor or 3DP-PE implants based on a randomized block of six. The surgeries were performed by five oculoplastic surgeons. The assessor and patients were masked. The magnetic resonance imaging (MRI) of the orbit was performed at least 6mo after operation and the fibrovascular ingrowth was analyzed using the Image J software. Follow-up continued at least 1y after surgery. The intention to treat and per protocol approaches were used.

● **RESULTS:** Totally 128 patients met the criteria in the report. Fifty Medpor and 55 3DP-PE cases completed the trial. The most common cause of blindness was trauma. The mean follow-up times of Medpor and 3DP-PE were 33 and 40mo respectively. The exposure rate was not statistically significant between two groups (6.0% and 7.3%), P<0.05, 95%CI (-9.8%, +12.0%). The success rates were 94% (Medpor) and 92.7% (3DP-PE). No postoperative infection was reported. Nine patients had MRI tests and two had implant exposures with 66.3% enhancement at 75mo (Medpor) and 58% enhancement at 57mo (3DP-PE) postoperatively.

● **CONCLUSION:** There is no statistically significant difference in exposure rate and success rate between Medpor and 3DP-PE in enucleation in the report. However, we cannot conclude that they are equivalent in terms of the exposure rate and success rate because the 95%CI is wider than ±10%. The infection rate is equivalent in both groups.

● **KEYWORDS:** orbital implants; eyeball enucleation; polyethylene; blindness; eye injuries; orbit
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INTRODUCTION

Porous polyethylene orbital implant is a standard treatment for eye removal surgery. The main advantage of a porous implant over a non-porous implant is to promote vascularization, improve motility and decrease migration and extrusion[1]. Porous polyethylene orbital implant has been claimed to be superior to other porous implants in terms of capability to suture to the implant directly[2].

We have developed a new three-dimensional printed polyethylene (3DP-PE) orbital implant since 2011[3]. A previous published study in animals did not find any infections or adverse systemic reactions[4]. In our previous study, we reported long-term outcome in terms of safety (infection and tissue reaction to the implant) and efficacy (exposure rate and grades of fibrovascular ingrowth into the implant) of the 3DP-PE implant for both enucleation and evisceration in 21 patients which were followed up for at least 12mo. We have found that the 3DP-PE orbital implant is safe in terms of infection rate in the long-term follow-up[5].

Medpor (Stryker; Kalamazoo, MI) was the only commercial porous polyethylene orbital implant available in our country in 2011. Both Medpor and 3DP-PE are porous polyethylene orbital implants with different fabricating techniques. This study aims to compare between the 3DP-PE and Medpor in an equivalence trial. The primary objective of this study is to compare exposure rates in enucleation between both implants. The secondary objectives are to compare the infection rate, the percentage of fibrovascular ingrowth in the implants and the success rate. We hypothesized that the 3DP-PE orbital implant would achieve equivalent exposure rate, infection rate, percentage of fibrovascular ingrowth and the success rate compared to Medpor implant.

SUBJECTS AND METHODS

Ethical Approval We conducted a prospective, randomized, equivalence, controlled trial, patient and assessor blinded clinical trial at Department of Ophthalmology, Mettapracharak (Wat Rai Khing) Hospital and Department of Ophthalmology, Songklanagarind Hospital, Prince of Songkla University, Thailand. The study was approved by the Ethics Committee from both institutes (No.1/2554 and No.55-183-19-1-2 respectively). The research adhered to the tenets of the Declaration of Helsinki and was registered at the clinical trials registry (Identifier, NCT01312545).

Subjects We recruited patients between August 2012 and December 2020.

Inclusion criteria The inclusion criteria were patients who were more than or equal to 18 years old, had good consciousness and could communicate. The causes of blindness were phthisis bulbi, painful blindness, intraocular tumor and severe ruptured eyeball.

Exclusion criteria We excluded patients who had a history of prior enucleation or evisceration, recent eye infection within 6mo and could not follow up for at least one year.

Methods The allocation sequence was generated by a computerized program using block of six with varying block size with allocation concealment. Eligible patients scheduled for enucleation surgeries were allocated to have either Medpor or 3DP-PE implants and informed consent was obtained. The operations were performed by three oculoplastic surgeons from Mettapracharak (Wat Rai Khing) Hospital (Sintuwong S, Leelapatranurak K, and Lumyongsatien M) and two oculiplastic surgeons from Songklanagarind Hospital (Aryasit O and Preechawai P). All patients were followed up, each having at least four visits after surgeries (at 1wk, 1, 6 and 12mo) with another oculoplastic surgeon (Nimitwongsakul O). The assessor and patients were masked to implant types. Data was collected, then validated and analyzed by staff at the Center of Excellence for Biomedical and Public Health Informatics (BIOPHICS). The primary outcome was the exposure rate and the secondary outcome was the infection rate, the percentage of fibrovascular ingrowth of both implants and the success rate. The vascularization of both implants was measured using the magnetic resonance imaging (MRI) of the orbit and Image J software.

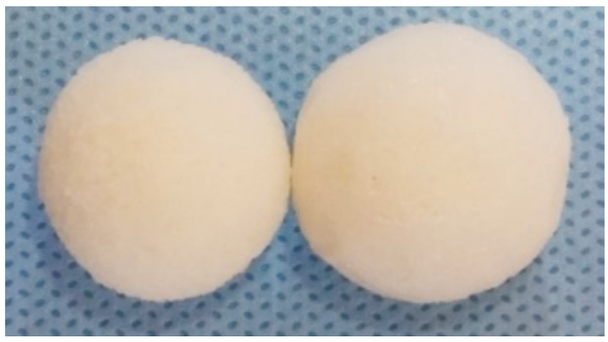

Figure 1 The three-dimensional printed polyethylene (3DP-PE) orbital implants (18 and 20 mm).

Three-dimensional Printed Polyethylene Orbital Implant The 3DP-PE implant (Figure 1) was prepared by a previously described technique[3,5-6]. In summary, high density polyethylene granules (Bangkok Polyethylene Co., Ltd, Thailand) were obtained and ground down to achieve a mean particle size of 305 mm. Maltodextrin (sourced from Shandong Duqing, Inc., China) and poly(vinyl alcohol) (sourced from Sigma-Aldrich, USA) having particle size of 80-100 mm, were then mixed with polyethylene granules at the ratio of 20%:10%:70% by weight. This mixture was loaded in a three-dimensional printing machine (Z400, Z Corporation, USA) and 16, 18, 20, and 22 mm spheres were printed using the commercial water-based binder ZB7 (Z Corporation, USA). After fabrication, specimens were left in the printing machine for 2h, then removed and left in the atmosphere for 24h. The specimens were then air blown to remove any unbound powder and heat treated by using a wet salt bed technique[5-6]. In brief, the samples were heated at 145℃ for 1h, sonicated in water and heat treated again in a salt powder bed (using Prungtip salt, Thailand) at 145℃ for another 2h. All the samples were then cleaned in deionized water, dried and packed in a pouch before being sterilized by ethylene oxide gas. The 3DP-PE

orbital implants had been studied for safety in pigs' skull and no signs of infection were found after implantation for 20wk (Khongkhunthian P, unpublished data 2009) and no adverse systemic reactions were reported in a study using the implant as an onlay bone graft in the mandibles of 12 New Zealand white rabbits for 24wk[3]. Compared to the Medpor implant[2], the 3DP-PE scored well for suturing and shaping ability and also for antibiotic solution uptake.

Enucleation After informed consent was obtained, patients were scheduled to have enucleation surgeries. Standard enucleations were performed under general anesthesia. Most surgeons sutured four recti muscles to the implants directly, some surgeons wrapped implants with autogenous donor sclera before suturing four recti muscles. Both types of implants were soaked and pores filled with gentamicin (40 mg/mL) solution by negative pressure technique before insertion[5]. In a case with a contracted socket, a buccal mucosal graft was harvested and placed between superior edge of the conjunctiva after enucleation. Fornix deepening sutures were used in some cases.

Definitions Exposure was defined by the resolution of tissues over the anterior surface of an implant. Infection was defined by the presence of pus or abscess at or around an implant. It can be diagnosed clinically or confirmed by the histopathology report after the explantation. The success rate was defined as the percentage of participants without postoperative implant exposure. The time frame was within 12mo after the date of surgery.

Magnetic Resonance Imaging of the Orbit To assess the degree of vascularization into the implant, some patients who agreed to benefits and risks of the MRI tests were sent to have MRI scans at least 6mo after surgery. A whole-body 1.5 Tesla Siemens Symphony MRI model (Siemens, Erlangen, Germany) was used. T1-weighted (TE/TR=680/11) images were obtained in both institutes. The imaging sequences had an imaging matrix of 224×320 and a field of view of 160 mm. The slice thickness was 3 mm. Axial, coronal and sagittal enhanced T1-weighted images were obtained within 5min of Gadolinium injection. The central part of the implants and areas of fibrovascular ingrowth were marked on the axial image by one of the authors (Sintuwong S). The percentage of enhancement in the implants was measured by Image J software (NIH, Bethesda, MD, USA).

Percentage of Fibrovascular Ingrowth in the Implant by Measurement the Area of Enhancement Using Image J Software Image J software for Windows was downloaded from https://imagej.nih.gov to a personal computer, and the MRI scan image file (Tag Image File Format; TIFF file) of the selected implant (the center of the implant in T1-weighted with Gd with fat suppression) was opened from the File menu. To measure the area of enhancement, the author (Sintuwong S) used the thresholding process to highlight pixels in the image. This was done first by converting the image to grayscale (choosing image > type >8-bit). Then the Freehand selection tool was used to draw the outline of the implant. The Edit>Clear outside tool was used to clear the outer part of the outline. We then calculated the selected (total, X) area by using the Analyze>Measure command. The duplicate command (image>duplicate) was used to copy the area within the outline. By using the image>adjust>threshold tool, the pixels in one grayscale photo that represent vascularization turned red. We then adjusted by moving the scroll bars until the red areas were very similar to the areas of enhancement in another grayscale photo. We used the Rectangular selection tool, to limit the area of image analysis. In the Analyze >Set Measurement tool, we checked the "Area" and "Limit to Threshold" boxes to measure only the highlighted pixels within the selected rectangular area. The "Measure" analytical tool (Analyze>Measure) within the software was used to measure the area of highlighted pixels in the rectangular area (Y). The author (Sintuwong S) measured the area of enhancement of the implants three times and the average of these measurements was calculated. Lastly, the percentage of enhancement of the implant was calculated on the basis of dividing the average area of enhancement by the average total area of the implant (Y/X).

Statistical Analysis The sample size was calculated by using an equivalence formula. From the literature and our own experiences, the success rate for Medpor[7] and 3DP-PE were 92% and 94% respectively and the difference (D) of the success rate between two groups was 10%. The sample size with a ±10% equivalent margin should be 174 participants per arm. As a preliminary report, we enrolled about 50 participants per group. Descriptive statistics were calculated using mean±standard deviation (SD), median (interquartile range; IQR) for continuous data and percentage for nominal data. A Chi-square test was used to compare the exposure rate, infection rate and success rate between two groups. The analysis adhered to the "intention to treat" and "per protocol" approaches. All statistical data analyses were performed by SPSS for Windows, version 28.0 (IBM, Armonk, NY, USA).

RESULTS

One hundred and forty-seven patients were enrolled in this study. Fifteen patients had history of surgeries before enrollments. Four patients declined to participate. Twenty-three patients had follow-up time less than 12mo. Hence, 105 patients (50 patients in Medpor group and 55 patients in 3DP-PE group) completed the trial (Figure 2). The baseline characteristics of the participants were summarized in Table 1.

Outcome Measurement Three patients (6.0%) in Medpor group and four patients (7.3%) in 3DP-PE group experienced

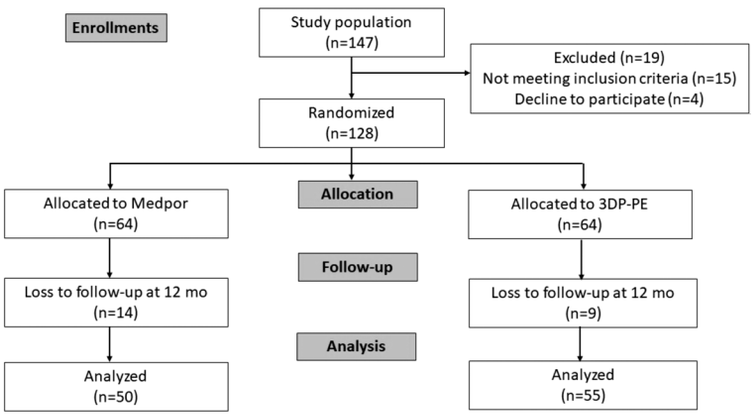

Figure 2 Flow diagram of study participants.

exposed implants (χ^2=0.07; Table 2). Hence, the success rates of both groups were 94% and 92.7% respectively. No patient had infection in both groups. There was no statistically significant difference in exposure rate between Medpor and 3DP-PE groups by the intention to treat and per protocol approaches, P<0.05, 95% confidence interval (CI; -9.8%, +12.0%). Also there was no statistically significant difference in success rate between both groups, P<0.05, 95%CI (-9.8%, +12.0%).

Other Complications For the Medpor group, there was a postoperative orbital bleeding in one case (2.0%). The patient had further workup to identify the cause of bleeding. The final diagnosis was acquired factor VIII deficiency which was successfully treated by prescribing 2 units of fresh frozen plasma. One case (2.0%) had conjunctival papillary reactions and symptoms improved after applying anti-inflammatory and antibiotics eyedrops. Seven (14.0%) cases had postoperative ptosis and underwent ptosis surgeries later. For 3DP-PE group, two (3.6%) cases had conjunctival papillary reactions and symptoms improved after applying antibiotics and anti-inflammatory eyedrops in one case and after stopping using antibiotic eye ointment in the other case. Four (7.3%) cases had postoperative ptosis and successfully underwent ptosis surgeries. No other serious adverse events were reported.

Percentages of Fibrovascular Ingrowth Using Image J Software Four patients in Medpor group and five patients in 3DP-PE group had MRI tests at least 6mo after operations. The percentages of enhancement were described in Table 3. The median percentage of enhancement in Medpor and 3DP-PE groups were 56.2 (IQR, 54.9-59.2) and 56.3 (IQR, 54.9-55.6) respectively. The MRI orbit (with Gadolinium enhancement) and Image J images of 3DP-PE and Medpor implants were shown in Figure 3.

Table 1 Baseline demographic and clinical characteristics of the participants *n* (%)

Characteristics	Medpor group (*n*=50)	3DP-PE group (*n*=55)
Age, y, mean (SD)	38.1 (12.6)	40.0 (16.5)
Sex		
Male	28 (56.0)	26 (47.3)
Female	22 (44.0)	29 (52.7)
Race		
Thai	50 (100.0)	53 (96.4)
Non-Thai	0	2 (3.6)
Causes of blindness		
Congenital	11 (22.0)	12 (21.8)
Trauma	21 (42.0)	25 (45.5)
Infection	2 (4.0)	2 (3.6)
Glaucoma	4 (8.0)	8 (14.6)
Uveitis	1 (2.0)	1 (1.8)
Tumor	2 (4.0)	2 (3.6)
Other	0	1 (1.8)
Unknown	9 (18.0)	4 (7.3)
Visual acuity		
NPL	41 (82.0)	52 (94.5)
PL	7 (14.0)	2 (3.7)
HM	2 (4.0)	1 (1.8)
Side		
RE	26 (52.0)	23 (42.0)
LE	24 (48.0)	32 (58.0)
Implant number		
22	10 (20.0)	5 (9.1)
20	27 (54.0)	33 (60.0)
19	0	1 (1.8)
18	13 (26.0)	13 (23.6)
16	0	3 (5.5)
Follow-up time, mo, mean (SD)	33 (23.1)	40 (29.3)

3DP-PE: Three-dimensional printed polyethylene; NPL: No perception of light; PL: Perception of light; HM: Hand motion; RE: Right eye; LE: Left eye.

DISCUSSION

The polyethylene orbital implant is one porous implant amongst many (hydroxyapatite, aluminium oxide, *etc*). It is widely used in many countries since it can promote vascularization into the implant and improves implant motility. It is considered superior to other porous implants as it is possible to suture directly to the implant without any wrapping materials[2]. The advantage of porous over non-porous orbital

Table 2 Patients with postoperative implant exposure

Patient No./ sex/side	Age (y)	Diagnosis	Implant size (mm)	Time between operation and implant exposure (mo)	Treatment of implant exposure	Follow- up time after last treatment (mo)
Medpor						
99/F/LE	53	Painful blindness	20	63	DFG	12
100/M/LE	37	Metastatic choroidal mass	20	3	Suture	14
102/M/LE	37	Phthisis bulbi	20	3	DFG	4
3DP-PE						
23/M/LE	32	Painful blindness	20	18	Exchange with 3DP-PE no.20	37
36/M/LE	28	Painful blindness	18	14	Suture	12
93/M/LE	36	Blindness	20	49	DFG	8
101/M/RE	70	Painful blindness	20	13	DFG	24

3DP-PE: Three-dimensional printed polyethylene; M: Male; F: Female; RE: Right eye; LE: Left eye; DFG: Dermis fat graft.

Table 3 Percentage of enhancement in Medpor and 3DP-PE implants

Patient no./ sex/side	Age (y)	Diagnosis	Implant size (mm)	Time between operation and MRI (mo)	Follow-up time after surgery (mo)	Percentage of enhancement	Note
Medpor							
90/F/LE	48	Choroidal melanoma	18	7	36	53.0	
91/F/RE	23	Painful blindness	18	25	16	55.5	
94/M/LE	22	Blindness	20	7	33	56.9	
99/F/LE	53	Painful blindness	20	19	75	66.3	Exposed implant at 63mo postop.
61/M/RE	44	Phthisis bulbi	20	7	17	61.0	
89/F/LE	56	Phthisis bulbi	19	7	15	54.9	
3DP-PE							
92/F/RE	72	Choroidal melanoma	18	11	12	44.8	
93/M/LE	36	Blindness	20	15	57	58.0	Exposed implant at 49mo postop.
95/F/LE	78	Choroidal melanoma	20	13	106	56.3	

3DP-PE: Three-dimensional printed polyethylene; M: Male; F: Female; RE: Right eye; LE: Left eye; MRI: Magnetic resonance imaging.

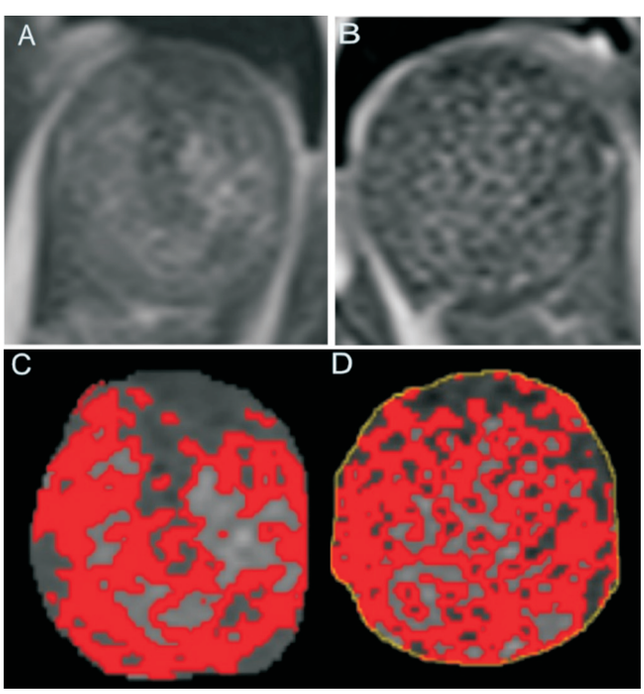

Figure 3 Images from MRI orbit and Image J software The MRI orbit with Gadolinium enhancement of one patient at 6mo after 3DP-PE (A) implant surgery and an image from Image J software (C) of the same patient. The MRI orbit with Gadolinium enhancement of another patient at 8mo after Medpor (B) implant surgery and an image from Image J software (D) of the same patient. 3DP-PE: Three-dimensional printed polyethylene; MRI: Magnetic resonance imaging.

implants for anophthalmic socket reconstruction was not concluded[8-9].

Medpor was the only commercial porous polyethylene orbital implant available in Thailand in 2011. Due to superiority of the porous polyethylene orbital implant, we have developed this type of implant with another fabricating technique. Our 3DP-PE orbital implant was fabricated by a two-stepped heat technique, coupled with large-size polyethylene powder printing. By using a scanning electron microscope, the 3DP-PE pore sizes ranged from 140 to 830 μm, the implants were lighter and had a greater and more rapid 1% methylene blue solution uptake compared to Medpor[3]. The pore size of Medpor ranged from 180 to 570 μm. The long-term safety (infection rate) and efficacy (exposure rate) in 21 patients who had 3DP-PE implantation after enucleation and evisceration was acceptable[5].

The demographic data between the two groups in this preliminary report were comparable. The most common cause of blindness was trauma, followed by congenital blindness, and glaucoma. Ababneh *et al*[10] reported that the four most common causes of eye removal in a developing country were trauma, endophthalmitis, glaucoma and keratitis which was similar to our results. However, we excluded cases with infection. Since the polyethylene orbital implant has an

advantage compared to other porous implants that we can suture directly, we chose enucleation to compare between both implants in an equivalence trial. The most common complication of enucleation is the implant exposure[1,11] then we selected exposure as an outcome measurement. Some surgeons in our preliminary trial used the donor sclera to wrap the implants because they believed this can reduce the exposure rate and this might lead to bias in the study. The authors believe that the randomization method could prevent selection bias and both groups should not differ. Fourteen patients in the Medpor group and 9 patients in the 3DP-PE group had follow-up times of less than 12mo. Ten patients refused follow-up, citing reasons of lack of finance and lack of time. Others did not attend, and could not be contacted.

Implant exposure is one of the most important complications after enucleation. It can lead to infection, poor fitting ocular prosthesis, additional surgery and increases cost of the treatment. The exposure rates between the groups were not found to be statistically different, 6.0% *vs* 7.3%, $P<0.05$, 95%CI (-9.8%, +12.0%). Custer and Trinkaus[12] reviewed the exposure rate from 49 papers, they found exposure rates ranging from 0 to 34%. Yang *et al*[1] reported exposure rate in retinoblastoma cases, and reported a decrease from 56.8% to 2.4% after changing some surgical techniques. An equivalence, randomized controlled trial was preferred to compare the novel implant (3DP-PE) with the reference implant (Medpor). A sample size calculation determined that 174 patients in each group would need to be recruited in the trial. This is very challenging for a long-term and high-cost study. A preliminary trial was therefore carried out. The exposure rate of Medpor implant was 6% and its success rate 94%. The exposure rate of the 3DP-PE implant was 7.3% and the success rate was 92.7%, which was acceptable according to other studies[1,12-13]. There was a 95%CI on the difference between the exposure rates with a margin of -9.8% to +12.0% which was higher than the equivalent margin (±10%) that we had proposed. Consequently, we cannot interpret the 3DP-PE implant as having an equivalence to the Medpor implant in terms of the exposure rate. Further testing in an equivalence trial involving 174 participants in each group is needed to compare the true exposure rates between the two groups.

Complications other than implant exposure included one patient (2%) who had massive orbital bleeding within a week after Medpor implantation. He was diagnosed with acquired factor VIII deficiency. His daughter had been diagnosed with factor VIII deficiency about one year prior to his diagnosis. Because of the natural history of the disease[14] and the patient's family history, this complication was not related to the implant. One (2%) case in the Medpor group and one (1.8%) case in the 3DP-PE group had conjunctival papillary reactions which improved after applying anti-inflammatory and antibiotics eyedrops. Vollkommer *et al*[15] reported that the implantation of porous polyethylene as a facial reconstruction material may lead to chronic inflammation and foreign body giant cell reaction over a long period of time. It is possible that the conjunctival papillary reactions in both Medpor and 3DP-PE groups could result from the implants. Another 3DP-PE case (1.8%) with conjunctival papillary reaction improved after stopping antibiotic ointment use, indicated that the reaction might have resulted from the antibiotic ointment itself. Toribio *et al*[16] found that bacteria adhere more securely to porous polyethylene than to nonporous orbital implants, therefore an infected implant should be suspected if the patient has recurrent conjunctival inflammation with discharge. Seven (14%) cases in the Medpor group and four (7.3%) cases in the 3DP-PE group had postoperative ptosis. The causes of postoperative ptosis in these patients ranged from preoperative ptosis from the underlying disease and enophthalmos, to levator aponeurosis dehiscence caused by surgical techniques, which were supported by the reports from Custer *et al*[17] and Wang *et al*[18].

An MRI of the orbit was used to measure the fibrovascular ingrowth into the implant which was confirmed by the Image J software. Only 9 patients agreed to have MRI scans. The median percentage of enhancement of the two groups were 56.2 (IQR, 54.9-59.2) and 56.3 (IQR, 54.9-55.6) which cannot be compared due to the very small sample size. Moreover, the time between the operations and MRI scans in each participant were different. Image J software is an objective method[19] used to measure enhancement in the implant referring to the fibrovascular ingrowth into the implant. The more enhancement, the more fibrovascular ingrowth in the implant. Image J software does not measure perfectly the area of enhancement. The precision of measurement depends on the resolution of the images and it was not possible for the researchers to control the enhancement scale to match the enhancement of the original image. Other than our previous report[5], have not found reports of using Image J software to calculate the enhancement in the implant. From the result (Table 3), we found two cases with implant exposure, despite having greater enhancement compared to patients with no implant exposure. These confirms that the percentage of fibrovascular ingrowth into the implant is not the only factor preventing implant exposure. Patients should have lifetime examinations after surgeries.

Limitations of this study included, first many surgeons were involved in the study so we could not control possible bias from surgical factors. Second, the number of patients who had MRI tests were small because patients declined to have the tests, due to difficulty to travel, radiation hazard avoidance, *etc*.

In summary, this is a preliminary study to compare between Medpor and 3DP-PE implants in enucleation. The infection rate was equivalent in both groups. Findings on the exposure rate were inconclusive.

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