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Original Article/นิพนธ์ต้นฉบับ

Long-Term Outcomes and Measuring Vascularisation of Three-Dimensional Printed Porous Polyethylene Orbital Implant in Enucleation and Evisceration

ผลการศึกษาระยะยาวและการวัดปริมาณหลอดเลือดของลูกตาเทียมชนิดโพลีเอธิลีนที่ขึ้นรูปจากเครื่องพิมพ์สามมิติเพื่อใช้ในการผ่าตัดเอาตาออกแบบทั้งลูกและแบบเหลือตาขาว

Sunisa Sintuwong, MD[1]
สุณิสา สินธุวงศ์, พ.บ.[1]

Kanjana Leelapatranurak, MD[1]
กาญจนา ลีลาภัทรานุรักษ์, พ.บ.[1]

Mingkwan Lumyongsatien, MD[1]
มิ่งขวัญ ลำยองเสถียร, พ.บ.[1]

Ornvenus Nimitwongsakul, MD[1]
อรวีณัฏฐ์ นิมิตรวงศ์สกุล, พ.บ.[1]

Jugchawin Kanokkantapong, MD[1]
จักรชวิน กนกกันฑพงษ์, พ.บ.[1]

Arpha Pornseth, MD[1]
อาภา พรเศรษฐ์,พ.บ.[1]

Puwat Charukamnoetkanok, MD[1]
ภูวัต จารุกำเนิดกนก, พ.บ.[1]

Waraporn Suvannapruk, BSc[†]
วราพร สุวรรณพฤกษ์ วท.บ.[†]

Jintamai Suwanprateeb, PhD[†]
จินตมัย สุวรรณประทีป, ปร.ด.[†]

[1]Department of Ophthalmology, Mettapracharak Hospital, Nakhon Pathom, Thailand

[2]National Metal and Materials Technology Center, National Science and Technology Development Agency, Pathumthani, Thailand

[1]ศูนย์การแพทย์เฉพาะทางด้านจักษุวิทยา โรงพยาบาลเมตตาประชารักษ์ (วัดไร่ขิง)

[2]ศูนย์เทคโนโลยีโลหะและวัสดุแห่งชาติ สำนักงานพัฒนาวิทยาศาสตร์และเทคโนโลยีแห่งชาติ

Abstract

Objective: To report the long-term outcome in terms of safety and efficacy of a new three-dimensional printed polyethylene (3DP-PE) orbital implant in patients who required orbital reconstruction after eye removal and to measure area of fibrovascular ingrowth in the orbital implant by using ImageJ software.

Methods: Prospective, consecutive selection in 21 patients which met the criteria. Each case had evisceration, enucleation, or secondary orbital implant performed by one of three oculoplastic surgeons. A gadolinium-enhanced, 1.5-Tesla MRI scan was performed at least 6 months after surgery. The follow-up time was at least 12 months. Safety was measured in terms of infection and tissue reaction to the implant. Efficacy was measured in terms of exposure rate, grades of fibrovascular ingrowth and postoperative results in long-term follow-up. Comparison of vascularisation of first and second MRI scans was measured by subjective technique and ImageJ software.

Results: The mean age was 40.4 ± 15.3 years old (range, 18-73 years old). 57.1% of patients had evisceration procedures. The mean follow-up time was 64.0 ± 37.4 months (range, 18-128 months). No postoperative infection was reported. The exposure rate was 19%. A total of four patients had two MRI scans and 75% of patients had increased enhancement at the second MRI scan, using subjective technique and ImageJ software. The correlation in interpretation of enhancement techniques between subjective technique and ImageJ software was 50%.

Conclusion: A 3DP-PE orbital implant is safe in terms of infection rate in long term follow-up.

Keywords: Prosthesis, Orbit, Reconstruction, Eye

บทคัดย่อ:

วัตถุประสงค์: เพื่อรายงานผลระยะยาวเกี่ยวกับความปลอดภัยและประสิทธิผลของลูกตาเทียมโพลีเอธิลีนใหม่ที่ขึ้นรูปจากเครื่องพิมพ์สามมิติในผู้ป่วยที่ต้องการผ่าตัดเอาตาออกและวัดพื้นที่การงอกของหลอดเลือดในลูกตาเทียมโดยใช้ซอฟแวร์อิมเมจเจ

วัสดุและวิธีการ: การศึกษาไปข้างหน้า เรียงตามลำดับผู้ป่วยที่เข้าเกณฑ์จำนวน 21 ราย ผู้ป่วยแต่ละรายได้รับการผ่าตัดเอาตาออกแบบเหลือตาขาวไว้ หรือเอาตาออกทั้งลูก หรือผ่าตัดใส่ลูกตาเทียมเป็นครั้งที่สองโดยจักษุแพทย์ตกแต่งและเสริมสร้างหนึ่งในสามคน หลังผ่าตัดทำการตรวจ MRI ที่ระยะเวลาอย่างน้อย 6 เดือน ติดตามผลเป็นเวลาอย่างน้อย 12 เดือน ความปลอดภัยวัดจากการติดเชื้อและปฏิกิริยาของเนื้อเยื่อต่อลูกตาเทียม ประสิทธิผลวัดจากอัตราการโผล่ของลูกตาเทียม เกรดการงอกของหลอดเลือดเข้าไปในลูกตาเทียม และการติดตามผลการผ่าตัดในระยะยาว การเปรียบเทียบการงอกของหลอดเลือดในลูกตาเทียมครั้งแรกและครั้งที่สองใช้วิธีอัตนัยและซอฟแวร์อิมเมจเจ

ผลการศึกษา: อายุเฉลี่ย 40.4 ± 15.3 ปี (ช่วง 18-73 ปี) ได้รับการผ่าตัดเอาตาออกแบบเหลือตาขาว 57.1% ค่ากลางในการติดตามอาการเท่ากับ 64.0 ± 37.4 เดือน (ช่วง 18-128 เดือน) ไม่มีการติดเชื้อหลังผ่าตัด อัตราการโผล่ของลูกตาเทียมเท่ากับ 19% ผู้ป่วยจำนวน 4 รายได้รับการทำ MRI จำนวน 2 ครั้ง และ 75% ของผู้ป่วยมีการเพิ่มของหลอดเลือดในการทำ MRI ครั้งที่สอง โดยการวัดแบบวิธีอัตนัยและซอฟแวร์อิมเมจเจ ความสอดคล้องกันของการแปลผลด้วยวิธีทั้งสองเท่ากับ 50%

สรุป: ลูกตาเทียมชนิดโพลีเอธิลีนที่ขึ้นรูปจากเครื่องพิมพ์สามมิติปลอดภัยไม่มีการติดเชื้อหลังผ่าตัด ในการติดตามผลระยะยาว

Introduction

The aims of the orbital implant insertion after enucleation or evisceration are to restore the volume of the orbit, improve motility and also the external appearance of the patients. The porous or integrated orbital implant has become more common since natural hydroxyapatite orbital implants were introduced in ocular socket reconstruction. The porous orbital implant allows vascular and fibrovascular ingrowth into the implant. This vascularisation promotes implant motility, decreases migration and extrusion.[1] At this time, the materials of porous implants range from synthetic hydroxyapatite, aluminium oxide and polyethylene. There are pros and cons among them. The benefit of polyethylene over synthetic hydroxyapatite and aluminium oxide is that it is possible to suture directly to the implant without the need for any wrapping. However, in our experience, we have found that the current commercially available polyethylene (Medpor, Stryker, Kalamazoo, MI, U.S.A.) is not easy to suture and it also takes time for the implant to uptake antibiotic solution. Moreover, it is not easy for surgeons to shape its surface to refit the orbit.

Three-dimensional printing is a manufacturing technique that has been adopted in many fields of medicine including to produce orbital implants. We adopted this technique to fabricate porous orbital implants by using two-stepped heat treatment process coupled with large-sized polyethylene powder printing so the implant has high porosity and large pore size. The three-dimensional printed polyethylene (3DP-PE) orbital implant has pore sizes ranging from 140 to 830 μm, with porosity of 61.9% which is greater than those of Medpor. These properties allow the 3DP-PE implant to be sutured easily and allow the rapid uptake of antibiotic solution into the implant according to the report by Suwanprateeb J et al.[2] A previous study in animals did not find any infections or adverse systemic reactions using an onlay bone graft in the mandibles of New Zealand white rabbits for 24 weeks.[3] This can confirm the safety of the 3DP-PE implant in animal study.

In this study, we prospectively studied the 3DP-PE orbital implant in a series of patients whose eyeballs had to be removed in consecutive cases. The study aimed to evaluate postoperative infection, exposure rate, to determine the fibrovascular ingrowth in the 3DP-PE orbital implant using MRI of the orbit with Gadolinium uptake, and also long-term postoperative results.

Materials and Methods

We recruited all consecutive patients who met the age and language criteria. Patients who were more than 18 years old, could co-operate and understand Thai language were recruited. These patients had either painless or painful blindness, phthisis bulbi or needed to reconstruct the orbit to fit new prostheses. Patients who had prior eye infections up to 6 months prior to examination, immune suppression, orbital fracture, orbital radiation, chemotherapy or who could not be followed-up for at least 12 months post-surgery were excluded from the study. The operations were performed by three oculoplastic surgeons (authors SS, KL, and ML). Data was collected for patients who had operations between July 2009 and December 2016 and the latest follow-up time was until December 2020. Informed consents were obtained. The study was approved by the Mettapracharak (Wat Rai Khing) Hospital Research Ethics Committee (METTA-REC).

The research adhered to the tenets of the Declaration of Helsinki.

The three-dimensional printed polyethylene orbital implant (3DP-PE)

Porous polyethylene orbital implant (Figure 1) was prepared by the technique as described previously.[2,4] 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) with a particle size of 80–100 mm. were mixed with the 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 mm., 18 mm., 20 mm. and 22 mm. spheres were printed using the commercial water-based binder ZB7 (Z Corporation, USA). After fabrication, the specimens were left in the printing machine for 2 hours, then removed and left in the atmosphere for 24 hours. 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°C for 1 hour, sonicated in water and heat treated again in a salt powder bed (using Prungtip salt, Thailand) at 145°C for another 2 hours. All the samples were then cleaned in deionized water, dried and packed in a pouch before being sterilised by ethylene oxide gas. The 3DP-PE orbital implants have been studied for safety in pigs' skulls and no signs of infection were found after implantation for 20 weeks (Khongkhunthian P., unpublished data 2009) and no adverse systemic reactions were reported in the New Zealand study cited above.[3] Compared to the Medpor implant,[2] the 3DP-PE scored well for suturing and shaping ability and also for antibiotic solution uptake.

Figure 1 Three-dimensional printed polyethylene (3DP-PE) orbital implants

Evisceration and Enucleation

Standard eviscerations and enucleations were performed under general anesthesia. For enucleations, the surgeons sutured the four recti muscles to the implants in every case. Posterior sclerotomy or scleral relaxing incision was applied in some cases of evisceration. A 3DP-PE implant was soaked and pores filled with gentamicin (40 mg/ml) solution by negative pressure technique before insertion. In a case with a contracted socket, a buccal mucosal graft was harvested and placed between superior edge of the conjunctiva after enucleation. A fornix deepening suture was used in some cases.

MRI of the orbit

Nine patients were sent to have MRI scans at least 6 months after surgery, of these, five patients underwent a second MRI scan. Of the remaining patients, some declined to have MRI scans and others did not attend their appointments. A whole-body 1.5 Tesla Siemens

Symphony MRI model (Siemens, Erlangen, Germany) was used. T1-weighted (TE/TR=680/11) images were obtained. 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 5 minutes of Gadolinium injection. The central part of the implants and areas of fibrovascular ingrowth were marked on the image by a technician and verified by a neuroradiologist. The grades of enhancement of the fibrovascular ingrowth in the 3DP-PE implants were classified (by subjective technique) according to the studies of Klapper SR. et al[7] and Galluzzi P. et al[8]. The percentage of enhancement in the implants of the patients who had two MRI scans were also measured by ImageJ software (NIH, Bethesda, MD).

Measurement the area of enhancement using ImageJ software

Image J software for Windows was downloaded from https://imagej.nih.gov to a personal computer, and the MRI scan image file of the selected implant was opened from the File menu. The Freehand selection tool was used by author (SS) to draw the outline of the implant. To measure the area of enhancement, the author (SS) 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 by chosing the area within the outline by using Duplicate command. By using the Image > Adjust>Threshold tool, the pixels that represent vascularization turned red. We then adjusted until the red areas were very similar to the areas of enhancement in the 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 within the software was used to measure the area in the outline. The author (SS) used the measurement a total of three times, and the average of these measurements was calculated (Figure 2). 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.

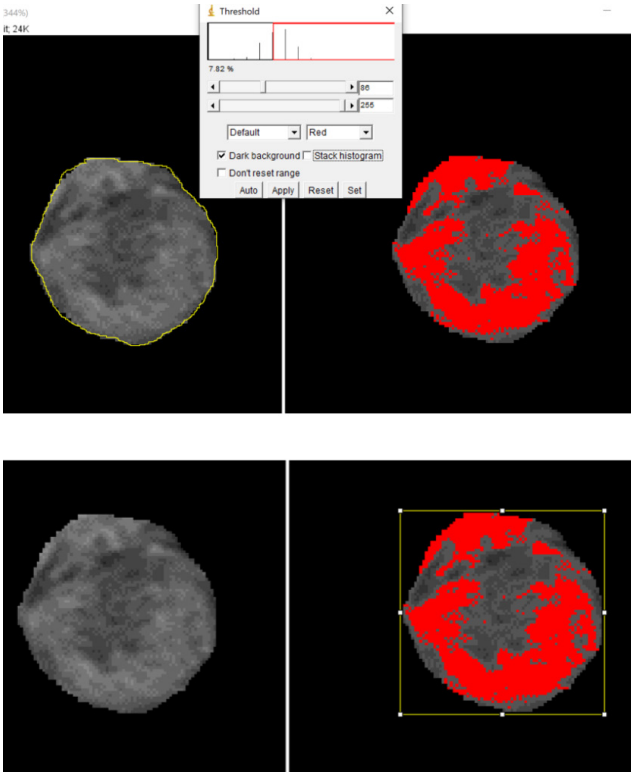

Figure 2 Measurement the area of enhancement using ImageJ software. The Freehand selection tool was used to outline the implant (top left). The author (SS) adjusted until the red areas were very similar to the areas of enhancement in the grayscale photo (top left and right). A rectangular selection was drawn at the border of the implant (bottom right)

Statistical analysis

Descriptive statistics were presented using mean ± SD for continuous data and percentage for nominal data. All statistical data analyses were performed by SPSS for Windows, version 28.0 (IBM, Armonk, NY, U.S.A.).

Results

A total of 21 patients met the criteria. The male patients (52.4%) were slightly predominant. The mean age was 40.4 ± 15.3 years old (range, 18-73 years old). The left eyes (71.4%) were more prominent. The primary diagnoses were painful blindness (47.6%), anophthalmic socket (19.0%), blindness (14.3%), phthisis bulbi (14.3%), and microphthalmos (4.8%) respectively. Trauma was the most common cause of blindness in this study (61.9%). The mean follow-up time was 64.0 ± 37.4 months (range, 18-128 months). Among types of operation, evisceration was the most common procedure (57.1%) (Figure 3) and one patient had secondary orbital implant insertion. The two most common implant sizes were 18 (47.1%) and 20 mm. (41.1%). No postoperative infections were found. The main implant-related complication was implant exposure (19.0%) (Table 1). The exposed implants were not sent for culture. Time between operation and implant exposure was between 1 to 2 months. The period of follow-up after the last surgery ranged from 61 to 128 months. No further implant exposures were reported.

Nine patients had an MRI scan of the orbit after the first operation. The mean period between operation and first MRI scan was 8.0 ± 2.0 months (range, 6.0-12.0 months). These were assessed by the subjective technique.[7,8] Accordingly, two (22.2%) patients were classified as having grade 2 enhancement, five (55.6%) patients were classified as having grade 3 enhancement and two (22.2%) patients were classified as having

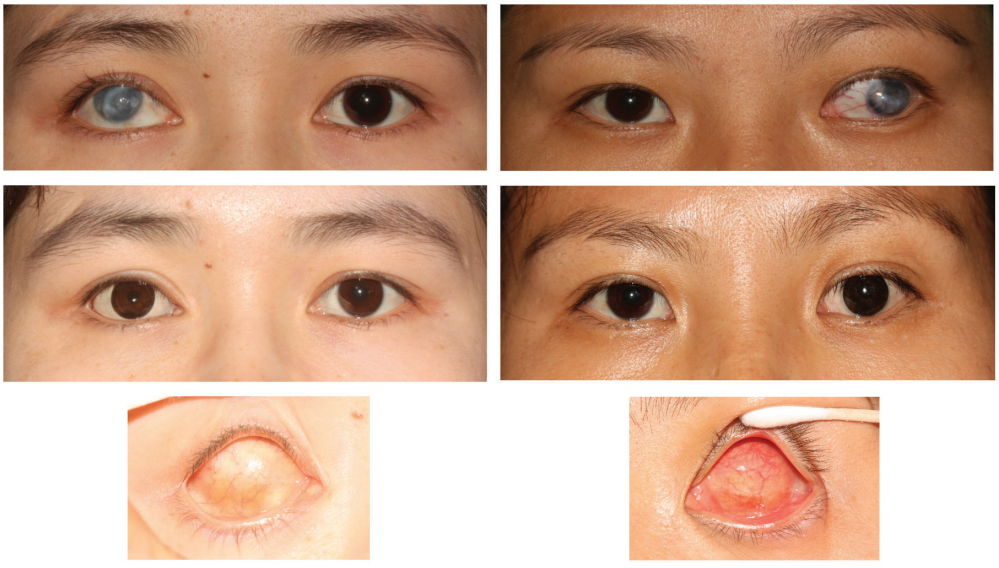

Figure 3 Preoperative (top), postoperative (middle) photos and the sockets (bottom). (left) The eviscerated patient (at 17 month-follow-up) had levator advancement in right upper lid one year after evisceration. (right) The enucleated patient (at 30 month-follow-up) had no additional surgeries.

Table 1 Four patients with exposed implants

Patient No. /sex/side	Diagnosis	Operation	Implant size (mm.)	Time between operation and implant exposure (mo.)	Treatment of implant exposure	Follow-up time after treatment (mo.)
1/F/OS	Blindness	Evisceration	20	2	Enucleation with 3DP-PE implant	97
2/M/OS	Phthisis bulbi	Evisceration	18	1	Enucleation with 3DP-PE implant	128
3/M/OD	Phthisis bulbi	Enucleation with buccal graft	20	1	Dermis fat graft	100
4/M/OS	Painful blindness	Enucleation	20	2	Dermis fat graft	61

M, male; F, female; OD, right eye; OS, left eye

grade 4 enhancement at first MRI scan (Figure 4).

The mean period between operation and second MRI scan was 27.0±3.0 months (range, 21.0-30.0 months). Five out of the nine (55.6%) patients had a second MRI scan. One case was excluded due to poor image quality from shadow of the prosthesis (Table 2). Of the remaining four cases in this group, using the above subjective technique, three were assessed to have increased enhancement in the orbital implant at the second MRI scan, while the first case was assessed to have the same enhancement at both first and second MRI scans. Subsequent measurement by ImageJ

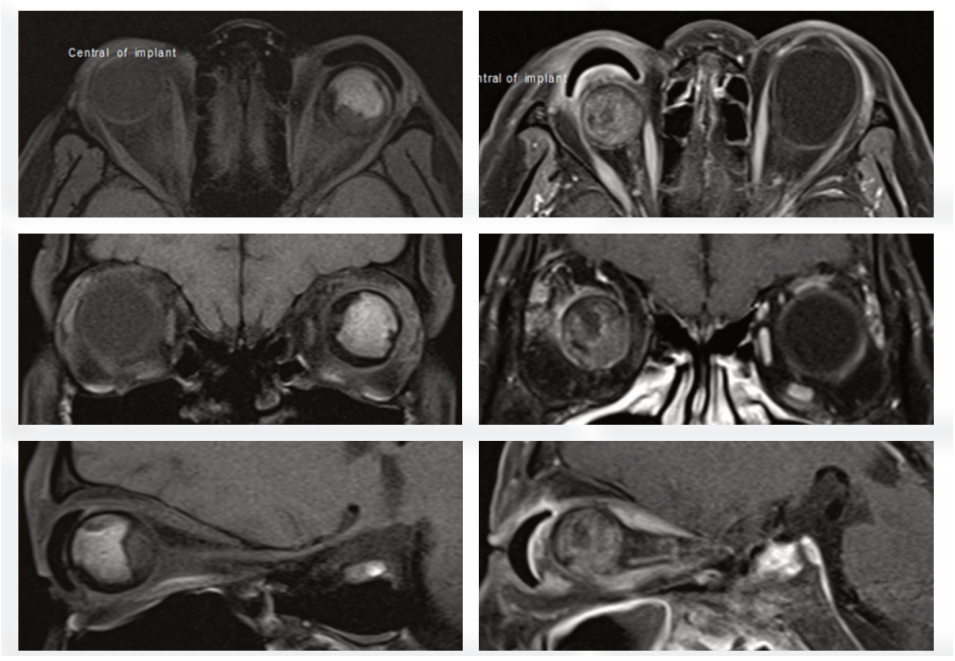

Figure 4 Post contrast T1-weighted 1.5 Tesla MRI in evisceration (left) and enucleation (right) patients. Each patient was tested in axial (top), coronal (middle) and sagittal (bottom) planes. The areas of enhancement were marked by a technician and verified by a neuroradiologist

software also showed that three out of four cases in this group had increased enhancement in the orbital implant at the second MRI scan, while the fourth case was assessed to have the same enhancement at both first and second MRI scans, the two types of measurements were not correlated in two cases (Table 2).

Table 2 Four patients who had first and second MRI orbit with Gadolinium tests.

Patient (sex/side)	Diagnosis	Operation	Time between surgery and MRI test (mo.)	
			1st MRI (MRI grade) (% of enh.)	2nd MRI (MRI grade) (% of enh.)
F/OS	Painful blindness	Evisceration	7 (3) (63.8)	27 (3) (76.5)
F/OS	Painful blindness	Evisceration	6 (3) (59.7)	21 (4) (95.9)
F/OD	Anophthalmic socket	Enucleation	8 (3) (78.8)	28 (4) (91.0)
F/OD	Microphthalmos	Enucleation with buccal graft	6 (3) (75.0)	27 (4) (74.0)

F, female; OD, right eye; OS, left eye;
MRI, magnetic resonance imaging;
MRI grade, MRI grade by subjective technique;
% of enh, percentage of enhancement measured by ImageJ software

Discussion

Orbital implant is an important factor in ocular socket reconstruction whether by enucleation, evisceration or secondary implant insertion. The first generation of orbital implants were non-integrated or non-porous orbital implants. They were made of thin and light glass, silicone and polymethylmethacrylate (PMMA), etc. The second generation was the integrated or porous orbital implant. Natural hydroxyapatite was introduced as a material for ocular implants in orbital reconstruction after enucleation and evisceration in 1985 and was approved by the US Food and Drug Administration for orbital implantation in 1989.[9] After that, other medical grade materials such as polyethylene and aluminium oxide were available. Porous orbital implants were widely used in many countries[10-17] because porous implants can promote fibrovascular ingrowth into the implant and improve implant motility, decrease migration and extrusion.[1] Among the three available materials of porous implant, porous polyethylene is the only implant that can be sutured directly on its surface without any wrapping material. The authors have experienced difficulties in suturing to the Medpor implant, also in antibiotic solution uptake and shaping the implant.

We have developed a new porous polyethylene orbital implant from a three-dimensional printed technique which has become common for fabricating many implants in the human body including the orbit. The three-dimensional printed polyethylene (3DP-PE) orbital implant was fabricated by a novel two-stepped heat treatment, coupled with large-sized PE powder printing to produce porosity and large pore size ocular implant that facilitates suturing and antibiotic impregnation.[2] Suwanprateeb et al[2] reported that using a scanning electron microscope (SEM), the 3DP-PE

implant (pore sizes ranging from 140 to 830 μm) had much greater porosity compared to Medpor (pore size ranging from180 to 570 μm). According to an earlier study by Suwanprateeb J et al,[2] the larger the pore size, the better the fibrovascular ingrowth. The 3DP-PE had less density and greater porosity compared to the Medpor (384.3 vs 494.3 kg/m^3 and 61.9 vs 48.4%), hence with the same dimensions, the 3DP-PE is lighter than the Medpor. It was also found that 1% methylene blue solution was taken up more rapidly and in greater quantity by the 3DP-PE than the Medpor[2].

Compared to other clinical studies relating to the Medpor implant, the mean age of patients in our study was 40.4 ± 15.3 years old (range, 18-73 years old), older than the study of Huang D. et al[18], Tabatabaee et al[17] and Naik et al.[19] There were no postoperative infections in all cases. This confirms the safety of 3DP-PE implant. For the efficacy of the 3DP-PE implant, we studied 21 patients who had operations ranging from evisceration, enucleation with or without buccal grafts and secondary orbital implant insertion. For those in the enucleation group, three patients had enucleation with buccal grafts and one patient had enucleation with buccal graft and fornix fixation. Only one patient had secondary orbital implant insertion. All patients except two in the evisceration group recovered well after the operations between 18 and 128 months. Meanwhile all patients except two in the enucleation group recovered well after the operations between 23 and 123 months.

The exposure rate in our study was 19.0% with the mean follow-up time of 64.0 ± 37.4 months (range, 18-128 months). Among our three surgeons, two surgeons had one patient with implant exposure and one surgeon had two patients with implant exposure. Among the four patients who experienced implant exposures (Table 1), two patients had evisceration operations and two patients had enucleation operations. For the evisceration group, the time between surgery and implant exposure was 2 months and 1 month respectively. The exposed implant of the first patient was removed and enucleation with a new 3DP-PE implant was carried out successfully. This patient was followed up for at least 97 months without postoperative implant exposure. The second patient had implant exposure one month after the operation. An enucleation with a new 3DP-PE implant was carried out. This patient (male) was followed-up for at least 128 months without any implant exposure. The authors consider that the reason for the implant exposure in these two eviscerated cases was because the implants were not placed in the posterior tenon space properly, because both of them exposed in the early phase after operations. Currently, traditional techniques in evisceration surgery have been replaced in favour of a four-petal technique. For the enucleation group, two patients experienced implant exposure at 1 month and 2 months respectively. The third patient (Table 1) with a history of phthisis bulbi of unknown causes, had enucleation with buccal graft (implant size 20 mm.). He had an exposed implant at one month after the operation. The patient had a small ocular socket so the surgeon had to harvest a buccal graft. The authors consider that the cause of early implant exposure may be the result of high tension on the anterior surface of the implant. Then the surgeon decided to remove the implant and harvest dermis fat for an orbital graft. The patient recovered well for at least 100 months. The fourth patient (Table 1) was diagnosed with traumatic painful blindness. He had implant exposure at two months after operation. The surgeon removed the implant and harvested dermis fat

for an orbital graft. The patient recovered well after the operation for at least 61 months. The authors consider that the causes of implant exposure in this case might be from poor vascularisation due to old age and traumatic in origin.

Karesh et al[20] reported no implant exposure in 21 patients who received enucleation, evisceration and secondary implant insertion with the mean follow-up time of 19 months (range, 7-43 months). Naik et al[19] compared the fibrovascular ingrowth between Medpor and Medpor-Plus implants. The exposure rate in their study was 10% with the mean follow-up time of 36.7 months (range, 18-43 months). Huang et al[18] reported no implant exposure in 21 patients who underwent modified evisceration techniques. The mean time between the implantation and MRI scan in this study was 24.1 ± 19.3 months (range, 1.5-69 months). Lin CW et al[21] found that the exposure rate was 76.5% of 17 patients who had Medpor implants and the mean time to exposure was 73.4 ± 51.2 months. The exposure rate in our study is lower than Lin et al but higher than the other studies cited above. However, a direct comparison may not be possible. Our study differs from studies with a lower exposure rate in two ways. Our study had longer follow-up times. Secondly, implant exposure occurred shortly after operation, suggesting surgical factor rather than implant factor. In our study, three surgeons were included, with differing experience. Had the study only included the most experienced surgeon, the exposure rate would have been less than 19%.

The fibrovascular ingrowth into the implant was confirmed by MRI of the orbit with Gadolinium uptake. De Potter P. et al[22] reported that areas of enhancement showed as early as 1.5 months after enucleation. In this study, the first MRI scans were conducted at least 6 months after operation because it is assumed that the implant would have vascularisation within 6 months, and to limit the need for patients to be subjected to multiple MRI scans. For the results of the first MRI scan, 77.8% of patients were assessed to have a gadolinium enhancement of at least grade 3 and more than half of the patients who had second MRI tests had grade 4 enhancement (Table 2), that is the fibrovascular ingrowth into the implant increased over time for at least 28 months. A study by Huang et al[18] found that the mean interval between the evisceration and the MRI scan was 24.14 ± 19.26 months (range, 1.5-69 months).[18] He also found that the longer the time interval between the evisceration and the MRI test, the greater the increase in the grade of fibrovascular ingrowth in Medpor. This was also supported by other studies.[20,22,23] Naik et al[19] found that the mean area of vascularisation of the Medpor at 1.5 months, 3 months and 4.5 months was 58%, 70% and 75% respectively. The 3DP-PE implant did not differ from other porous polyethylene implants in terms of fibrovascular ingrowth. Measurement by ImageJ software showed that three out of four cases who had two MRI scans had an increase in enhancement in the orbital implant between the first and second MRI scans. The correlation in interpretation of enhancement techniques between subjective technique and ImageJ software was 50%. This is the first study to use ImageJ software to measure area of enhancement in the orbital implant. Further study with a larger sample size is needed.

This is a case-series study, aimed to determine the outcomes of the new 3DP-PE orbital implant described in this study in various eye removal operations and also the vascularisation into the implant after surgery. From the results of the study, on the basis of long-

term follow-up, we can be sure about the safety of the implant. In terms of efficacy, the 3DP-PE implant can be used successfully in evisceration, enucleation with or without buccal graft and fornix fixation, and also in secondary orbital implant insertion. The exposure rate is acceptable compared to other studies. The fibrovascular ingrowth of the implant after operation is also acceptable. Vascularisation may be more accurately measured using ImageJ software. The limited number of patients who had MRI scans in this study makes it difficult to draw firm conclusions about the efficacy. Another limitation of the study was that many surgeons were included in the study, which meant that it was not possible to control the surgical factors from different surgeons. In future, a larger study with a comparison group is needed.

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Address for correspondence: Corresponding author: Sunisa Sintuwong, M.D., M.P.P.M., M.Sc., Department of Ophthalmology, Mettapracharak Hospital, Nakhon Pathom, 73210 Thailand.
Email: drsunisa@gmail.com

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