ORIGINAL ARTICLE

# A Randomized Controlled Trial on Outcomes of Polymethylmethacrylate and Hydroxyapatite Implants in Evisceration: Introducing the Four-Petal Myoconjunctival Technique

Suppapong Tirakunwichcha, MD[1], Panida Potita, MD[1], Tiparut Thithuan, MD[2], Supanida Limpongsanurak, MD[1], Pakaporn Kittichokechai, MD, FICO[3], Thanchat Jienmaneechotchai, MD[4]

[1] Department of Ophthalmology, Faculty of Medicine, Chulalongkorn University and King Chulalongkorn Memorial Hospital, Thai Red Cross Society, Bangkok, Thailand; [2] Department of Ophthalmology, Pathumthani Hospital, Pathum Thani, Thailand; [3] Department of Ophthalmology, Chonburi Hospital, Chonburi, Thailand; [4] Department of Ophthalmology, Faculty of Medicine Siam University, Pranangklao Hospital, Nonthaburi, Thailand

**Objective:** To compare the success rate of scleral-wrapped polymethylmethacrylate (PMMA) and hydroxyapatite (HA) orbital implants in primary evisceration using the four-petal myoconjunctival technique.

**Materials and Methods:** A randomized controlled trial was conducted. All enrolled patients underwent primary evisceration with the four-petal myoconjunctival technique. The primary outcome measured was the success rate of wearing an ocular prosthesis eight weeks post-surgery without complications. Secondary outcomes included orbital implant motility, prosthetic motility, and the incidence of post-operative complications.

**Results:** Thirty-one patients were analyzed, with 17 patients in the PMMA group and 14 in the HA group. The success rate for wearing an ocular prosthesis was 100% in the PMMA group and 93% in the HA group (p=0.45). At eight weeks postoperatively, orbital implant and prosthetic motility were comparable between the PMMA and HA groups across all gaze directions. Mean implant movements in both groups ranged from 3.8 to 5.6 mm, with no statistically significant differences between them (p>0.05). One patient in the PMMA group experienced wound dehiscence, while one in the HA group developed a conjunctival cyst.

**Conclusion:** At eight weeks, both wrapped PMMA and HA implants showed comparable outcomes in prosthesis wear and motility. The four-petal technique was effective with minimal complications, making PMMA a practical option in resource-limited settings.

**Keywords:** Evisceration; Four petal evisceration; Orbital implant; Polymethylmethacrylate; Hydroxyapatite; Myoconjunctival attachment

Received 10 March 2025 | Revised 5 July 2025 | Accepted 30 July 2025

**J Med Assoc Thai 2025;108(9):739-46**

**Website:** http://www.jmatonline.com

Evisceration is a surgical procedure commonly performed on eyes that have become non-functional due to conditions such as untreatable endophthalmitis, painful blind eye, trauma, or phthisis bulbi[1-4]. In a study surveying members of the American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS)[5], 72% of respondents reported preferring evisceration for the treatment of medically refractory endophthalmitis. The primary goals of evisceration include alleviating pain, removing sources of infection, and preparing the orbit for prosthetic rehabilitation. Surgical techniques vary among surgeons. Success in this procedure is often measured by the prevention of complications such as orbital implant exposure, extrusion, and infection, as well as by achieving sufficient volume augmentation and preserving the conjunctival fornix for effective prosthetic fitting[6,7].

Ensuring optimal prosthetic motility and maintaining normal eyelid function are key challenges in evisceration, and orbital implants play a crucial role in achieving these outcomes. Different materials have been utilized for orbital implants, each with its own set of advantages and disadvantages. Historically, bio-integrated porous implants like hydroxyapatite (HA) have been valued for their ability to integrate with surrounding tissues, potentially reducing risks such as implant migration and extrusion. On the other

**Correspondence to:**

Potita P.

Department of Ophthalmology, King Chulalongkorn Memorial Hospital and Faculty of Medicine, Chulalongkorn University, 1873 Rama 4 Road, Pathumwan, Bangkok 10330, Thailand.

Phone: +66-2-2564000

Email: panidapotita@gmail.com

**How to cite this article:**

Tirakunwichcha S, Potita P, Thithuan T, Limpongsanurak S, Kittichokechai P, Jienmaneechotchai T. A Randomized Controlled Trial on Outcomes of Polymethylmethacrylate and Hydroxyapatite Implants in Evisceration: Introducing the Four-Petal Myoconjunctival Technique. J Med Assoc Thai 2025;108:739-46.

DOI: 10.35755/jmedassocthai.2025.9.739-746-02804

hand, inert materials like polymethylmethacrylate (PMMA) are favored for their ease of handling and cost-effectiveness, particularly in settings with limited resources[8].

Previous studies have explored the outcomes associated with various implant materials and surgical techniques in evisceration. For instance, Dutton reported the use of HA implants after enucleation or evisceration surgery, underscoring their potential for bio-integration and improved motility[9]. Trichopoulos & Augsburger[10] compared porous and non-porous orbital implants, reporting a significantly higher proportion of patients with non-porous implants experienced orbital implant migration compared to those with porous implants. However, the rate of implant exposure was low and did not differ significantly between the two groups. Massry & Holds[11] reported that dividing the sclera into two flaps, detaching them from the optic nerve, and securing them over any standard-sized orbital implant allows for the placement of various implant sizes. This evisceration technique has shown excellent outcomes with minimal complications. Traditional evisceration techniques often limit the ability to use larger orbital implants, particularly when the infected cornea must be removed. The present study aimed to address how to place larger orbital implants-especially in cases where porous materials are not available or feasible for most ophthalmologists while minimizing the risk of implant migration and improving overall orbital motility.

In the present study, the authors performed a four-petal myoconjunctival evisceration technique that integrates wrapped orbital implants with extraocular muscle attachment to the conjunctival fornix. This method provides posterior scleral relaxation, allowing for the placement of a larger orbital implant, overcoming the limitations of traditional evisceration techniques that often restrict implant size. Unlike four-petal traditional methods[12], which used non-wrapped PMMA implants and were associated with complications such as implant migration, the present study technique involved wrapping the PMMA implant to enhance stability and motility. This also allowed for a direct comparison with HA, a bio-integrated material known to reduce implant migration.

The primary goal of the present study was to evaluate the success rate of this surgical technique by comparing wrapped bio-integrated porous HA implants with inert PMMA implants, using the same procedure for both. The findings have important clinical implications, especially for general ophthalmologists and oculoplastic surgeons in resource-limited settings, where maintaining high success rates with accessible PMMA implants and simplified techniques is essential.

## Materials and Methods

The present study was a randomized controlled study conducted at King Chulalongkorn Memorial Hospital between December 2018 and May 2023. The study included patients over 15 years of age with untreatable severe corneal ulcer, untreatable endophthalmitis, panophthalmitis, painful or non-functional eye, and phthisis bulbi. Exclusion criteria were complex underlying diseases precluding general anesthesia, severe orbital fractures affecting orbital volume, severe orbital trauma causing significant conjunctival or extraocular muscle injury, unsuitability for primary orbital implant placement, and intra-orbital tumors.

Thirty-two patients with non-functional eyes were enrolled and underwent primary evisceration using the four-petal technique with scleral-wrapped orbital HA or PMMA implants. The procedures were performed by a single surgeon (ST). Informed consent was obtained both orally and in writing, and participants were randomly assigned to either the HA group with 15 cases, or the PMMA group with 17 cases, using a block of four. The co-investigator generated the block of four and random allocation sequence. The allocation sequence was concealed in sealed envelopes. Patients were enrolled by clinical fellows, who opened the envelopes and assigned patients to each group only after they had been prepared for surgery. Both the participants and outcome assessors were blinded to group assignments throughout the study. Orbital implant size was determined based on the axial length of the contralateral eye minus two millimeters[13]. The surgeon selected and unveiled the appropriate orbital implant during surgery, using the same technique for all cases. Postoperative assessments were conducted by a different physician (PP). The present study was approved by the Institutional Review Board (IRB) in accordance with the Declaration of Helsinki (approval number 0291/2022) and was registered at ThaiClinicalTrials.org (TCTR20181127003).

### Outcomes

The primary outcome was the success rate of evisceration using the myoconjunctival technique, defined as the ability to wear an ocular prosthesis

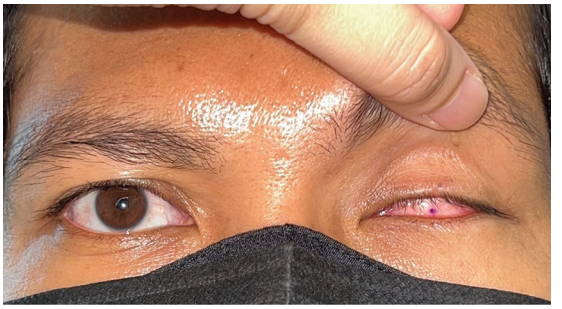

**Figure 1.** One of the participants in this study with a marking by a surgical marker pen at the center point of the conjunctiva of his left anophthalmic socket.

eight weeks post-surgery without complications, comparing the PMMA and HA groups. Secondary outcomes included post-operative complications and orbital implant and prosthetic motility between the two groups. Orbital motility was measured using a standard ruler with millimeter markings. First, a surgical marker pen was used to mark the center point on the conjunctiva of the anophthalmic socket, as shown in Figure 1. The patient was then instructed to look in left gaze, right gaze, up gaze, and down gaze, and the movement of the marked point on the conjunctiva were recorded in millimeters. These values were recorded as the orbital implant motility values, measured three times for each gaze, and averaged. Similarly, prosthetic motility was assessed by marking a reference point at the center of the ocular prosthesis. The patient was asked to look in different directions, and the movement of the reference point was recorded three times in millimeters and averaged.

### Surgical technique

The procedure was performed under general anesthesia. Subconjunctival and retrobulbar anesthesia using 2% lidocaine with adrenaline 1 to 100,000 was injected. After complete hemostasis was achieved, an eyelid speculum was inserted to widen the palpebral fissure. A conjunctival peritomy was made 360° using Wescott's scissors. A stab wound was made at the limbal area using #11 scalpel blade into the anterior chamber. The cornea was excised using scissors. Uveal tissue was separated from the sclera using evisceration spoon starting at sclera spur. The cornea and uveal tissue were sent for pathological study and culture and sensitivity in infected cases. Bleeding points were cauterized using monopolar cautery. The residual uveal tissue was denatured by absolute alcohol, and scleral cavity was thoroughly irrigated with normal saline, and any scleral melting was resected. A scleral cut was made to the equator between rectus muscles in four quadrants. The posterior sclera was circumferentially separated from the four-petal sclera using monopolar cautery without injury to the rectus muscle. The pre-measured scleral-wrapped PMMA or HA orbital implant was placed deep into the posterior orbit. In the present study technique, the scleral tissue used to wrap the orbital implant was first secured by suturing it with a double-armed 6-0 polyglactin (PGA) suture. Using the same double-armed suture, each rectus muscle was then sutured near its original insertion site, including the underlying scleral tissue to which the muscle was attached. Following this, the suture was passed through the corresponding conjunctival fornix and tied securely. This process was done for each rectus muscle individually, allowing precise alignment and stable anchoring of the muscle to both the scleral wrap and the conjunctival fornix. The upper and lower scleral petals were sutured together using an imbrication technique with #6/0 polyglactin, followed by medial and lateral part. The posterior Tenon's capsule was closed in an interrupted fashion followed by anterior Tenon's capsule in a horizontal mattress fashion using the same suture materials. The conjunctiva was closed in a continuous fashion. The suture coming out in each fornix was tied, and the proper conformer was placed, as shown in Figure 2. Temporary tarsorrhaphy with #4/0 silk suture was done and removed in the next three to four days. Postoperative Dicloxacillin, at 500 mg, was prescribed four times a day for one week, along with topical antibiotic-steroid eyedrops and ointment at bedtime. Postoperative visit at two weeks was made to evaluate the wound status and any complications. At two weeks, the orbital implant movement was measured compared to the normal eye and customized prosthesis was made. At eight weeks, the orbital implant and prosthesis movement was measured compared to the normal eye.

### Statistical analysis

The sample size was calculated using a modified Cochran's formula with a type I error of 0.05, Type II error of 0.20, an effect size of 25%, and equal group proportions using a one-to-one allocation ratio, resulting in 20 participants per group. However, the present study was prematurely halted due to COVID-19, which caused follow-up losses, a shortage of available patients, and the retirement of a key researcher. Statistical analysis was performed using IBM SPSS Statistics, version 28.0 (IBM

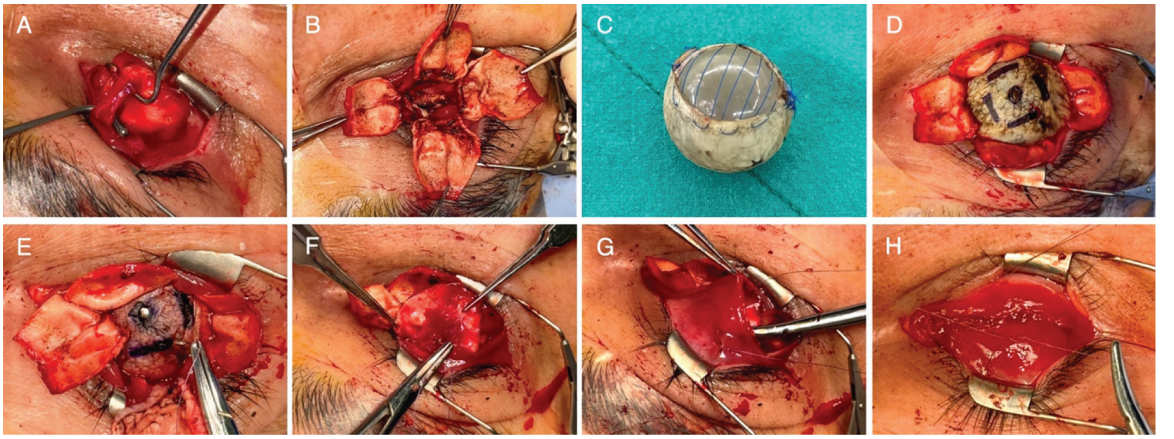


**Figure 2.** All four rectus muscles were identified using muscle hooks (A). After the intraocular contents were removed, a scleral cut was made up to the equator between the rectus muscles in four quadrants, and the sclera was circumferentially separated from the posterior pole using monopolar cautery (B). A PMMA implant was wrapped in donated human sclera and secured with 5-0 Prolene sutures (C). The suture locations for attaching the donor sclera to the four rectus muscles were marked approximately 5 mm from the center of the sclera-wrapped PMMA. The sclera-wrapped PMMA orbital implant was then placed deep into the posterior orbit (D). The wrapped sclera was sutured to each rectus muscle and then secured to the corresponding conjunctival fornix with double-armed #6/0 polyglactin sutures (E-G). After the scleral cap, posterior Tenon's capsule, and anterior Tenon's capsule were sutured, the conjunctiva was closed in a continuous fashion, and the suture emerging in each fornix was tied (H).

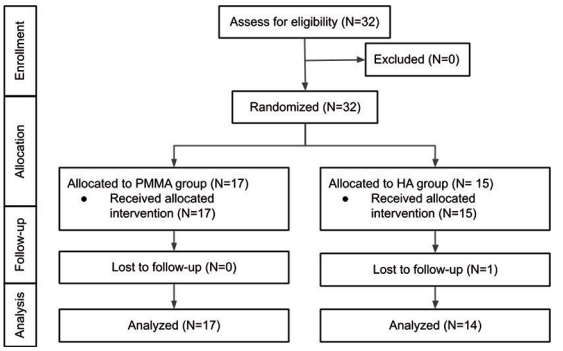


**Figure 3.** CONSORT flow diagram illustrating participant enrollment, allocation, follow-up, and analysis.

Corp., Armonk, NY, USA). Demographic data were summarized as mean ± standard deviation (SD) for continuous variables and as frequencies (%) for categorical variables. The success rate of the operation was calculated using frequencies and the chi-square test. Changes in orbital implant and prosthetic motility between the PMMA and HA groups, as well as between the 2-week postoperative period and the last visit, were assessed using paired t-tests and the Wilcoxon signed-ranked test.

## Results

The authors have recruited 17 patients in the PMMA group and 15 patients in the HA group. One patient in the HA group was excluded due to loss to follow-up after surgery. Consequently, the present study analysis included 17 patients in the PMMA group and 14 patients in the HA group (Figure 3). The mean implant sizes were 19.6±0.8 mm for the PMMA group and 18.9±1.0 mm for the HA group. The remaining demographic data for both groups is presented in Table 1.

**Table 1.** Demographic data of patients who had evisceration with PMMA implant and HA implant

| | PMMA group (n=17) | HA group (n=14) |
|---|---|---|
| Age (year); mean±SD | 61.2±16.3 | 56.4±19.5 |
| Sex; n (%) | | |
| Male | 10 (58.8) | 7 (50.0) |
| Female | 7 (41.2) | 7 (50.0) |
| Causes of evisceration (%) | | |
| Severe corneal ulcer | 9 (52.9) | 6 (42.9) |
| Endophthalmitis | 2 (11.8) | 5 (35.7) |
| Trauma | 6 (35.3) | 1 (7.1) |
| Congenital | - | 2 (14.3) |
| Follow-up time (months); mean±SD | 22.1±16.8 | 17.1±12.3 |
| Operative time (minutes); mean±SD | 151.8±33.1 | 158.6±24.8 |

PMMA=polymethylmethacrylate; HA=hydroxyapatite; SD=standard deviation

The success rate of evisceration using the myoconjunctival technique was 100% in the PMMA group and 93% in the HA group at eight weeks post-surgery (p=0.45). At two weeks post-surgery in the PMMA group, the mean orbital implant motility was 3.8 mm for supraduction (SD 0.97), 5.1 mm

**Table 2.** Comparing orbital implant movements with prosthetic movements of PMMA group and HA group at 8 weeks after evisceration surgery

| | PMMA; mean±SD | HA; mean±SD | PMMA vs. HA | | |
|---|---|---|---|---|---|
| | | | Δ mean±SE | 95% CI | p-value |
| Supraduction | | | | | |
| Implant movements (mm) | 3.9±1.1 | 3.8±1.3 | 0.2±0.4 | −0.7 to 1.1 | 0.668 |
| Prosthetic movements (mm) | 2.8±1.2 | 2.2±0.9 | 0.6±0.4 | −0.2 to 1.4 | 0.151 |
| Δ mean±SE | 1.2±0.4 | 1.5±0.4 | | | |
| 95% CI | 0.3 to 2.0 | 0.8 | to 2.3 | | |
| p-value | 0.01 | <0.001 | | | |
| Infraduction | | | | | |
| Implant movements (mm) | 4.7±1.0 | 4.5±1.2 | 0.2±0.4 | −0.6 to 1.0 | 0.610 |
| Prosthetic movements (mm) | 3.4±2.0 | 3.4±1.0 | 0.02±0.5 | −1.1 to 1.1 | 0.969 |
| mean±SE | 1.2±0.4 | 1.1±0.3 | | | |
| 95% CI | 0.4 to 2.2 | 0.4 | to 1.7 | | |
| p-value | 0.1 | 0.004 | | | |
| Adduction | | | | | |
| Implant movements (mm) | 5.6±1.7 | 5.4±2.3 | 0.2±0.7 | −1.3 to 1.6 | 0.815 |
| Prosthetic movements (mm) | 3.5±2.0 | 2.9±1.9 | 0.6±0.7 | −0.8 to 2.0 | 0.405 |
| Δ mean±SE | 2.1±0.6 | 2.5±0.6 | | | |
| 95% CI | 0.7 to 3.4 | 1.2 | to 3.8 | | |
| p-value | 0.005 | 0.001 | | | |
| Abduction | | | | | |
| Implant movements (mm) | 5.3±1.6 | 5.2±1.7 | 0.04±0.6 | −1.2 to 1.3 | 0.948 |
| Prosthetic movements (mm) | 3.4±2.1 | 2.9±1.2 | 0.5±0.6 | −0.8 to 1.7 | 0.473 |
| Δ mean±SE | 1.9±0.4 | 2.3±0.5 | | | |
| 95% CI | 1.1 to 2.7 | 1.3 to 3.4 | | | |
| p-value | <0.001 | <0.001 | | | |

PMMA=polymethylmethacrylate; HA=hydroxyapatite; SD=standard deviation; SE=standard error; CI=confidence interval

for infraduction (SD 1.09), 5.0 mm for adduction (SD 1.18), and 5.0 mm for abduction (SD 1.62). When compared to motility on the last visit, there were no statistically significant differences in any direction. At the last visit, mean motility was 4.1 mm for supraduction (SD 0.93, p=0.58), 4.4 mm for infraduction (SD 1.19, p=0.09), 5.7 mm for adduction (SD 1.63, p=0.05), and 5.0 mm for abduction (SD 1.76, p=0.77).

The HA group showed comparable results as the PMMA group, with no statistically significant differences in orbital implant motility between two weeks post-surgery and the last visit. After two weeks, mean orbital implant motility in the HA group was 3.1 mm for supraduction (SD 1.05), 4.6 mm for infraduction (SD 1.21), 4.4 mm for adduction (SD 1.69), and 4.9 mm for abduction (SD 1.87). At the last visit, mean motility was 3.4 mm for supraduction (SD 1.18, p=0.43), 4.3 mm for infraduction (SD 1.50, p=0.26), 5.4 mm for adduction (SD 2.14, p=0.06), and 5.1 mm for abduction (SD 2.27, p=0.63).

After eight weeks post-surgery, only one patient was unable to wear an ocular prosthesis due to a complication involving orbital implant exposure. Among those who could wear ocular prostheses, there was a statistically significant decrease in prosthetic movement compared to orbital implant movement, as shown in Table 2. There were no significant differences in orbital implant and prosthetic movements between the PMMA and HA groups. The actual follow-up period was 22.1±16.8 months in PMMA group and 17.1±12.3 months in HA group.

In the PMMA group, one patient experienced wound dehiscence exposing the scleral cap at two weeks post-surgery, and another developed a conjunctival cyst measuring 2 by 2 mm eleven months post-surgery. In the HA group, one patient developed a conjunctival cyst six weeks after surgery. The enophthalmos rate was 25% in the PMMA group and 0% in the HA group. Despite these complications, the two patients in the PMMA group were well-managed and able to wear an ocular prosthesis by eight weeks

post-surgery. In contrast, the patient in the HA group was unable to wear an ocular prosthesis at eight weeks post-operatively due to the need to delay fitting until after conjunctival cyst excision surgery.

## Discussion

The primary complications and outcomes of evisceration that concern the authors include orbital implant extrusion, ocular prosthesis motility, and maintaining proper orbital volume with normal eyelid function. In the conventional evisceration technique, while orbital implant and prosthesis motility are acceptable, the small size of orbital implants, at 12 to 16 mm, which can be placed within the scleral cavity often leads to orbital volume deficits and poor cosmetic outcomes. The ab interno evisceration technique[14] offers an ideal alternative by preserving intraocular volume, replacing the vitreous with suitable material to prevent globe shrinkage, and using tinted contact lenses to enhance cosmetic appearance.

When using the conventional evisceration technique but seeking to achieve appropriate orbital volume with a larger implant, posterior scleral relaxing incisions are typically performed[15-17]. Implant size is determined based on the axial length of the normal eye. In rural Thailand, where porous orbital implants are often unavailable and PMMA implants are more commonly used. The posterior relaxing technique with a PMMA implant can yield sufficient orbital volume and good cosmetic results, with prosthetic motility comparable to porous implants[18]. Although orbital implant migration is a rare complication according to previous studies[19], it remains a serious concern. Some studies suggest that implant migration does not occur following optic nerve disinsertion[20]. However, the potential for late orbital implant migration, especially with PMMA implants, underscores the need for careful surgical planning and technique. To mitigate this, the authors propose wrapping the PMMA implant with donated human sclera, covering with four layers of patient's own sclera, and securing it to the four rectus muscles[21]. This approach, using double scleral coverage by securing banked sclera to the autologous sclera, may improve implant motility, provide adequate orbital volume, and reduce the risk of implant migration, exposure, or extrusion.

Previous research by Shome et al.[22] found that the motility of a myoconjunctival PMMA implant was superior to that of a traditional muscle imbrication PMMA implant and comparable to that of a porous polyethylene implant with a scleral cap technique following enucleation surgery. In the present study, the authors found no significant difference in implant and prosthetic motility between PMMA and HA groups, consistent with prior findings comparing porous and non-porous implants[23,24]. Despite employing the myoconjunctival technique, which theoretically enhances motility, both groups exhibited similar implant movements. This suggests that implant motility is primarily influenced by surgical technique rather than implant material, particularly in non-pegged implants[25]. However, prosthetic motility was significantly inferior to implant motility, highlighting the impact of implant dynamics and the constraints imposed by prosthesis size and shape within the anophthalmic socket.

In the PMMA group, the authors encountered one case of wound dehiscence postoperatively, which presented as severe bacterial endophthalmitis. The patient had pre-existing conjunctival edema, symblepharon, and a shortened conjunctival fornix. Despite initial suturing attempts, the authors resorted to suturing the conjunctival edge to the scleral cap and performing temporary tarsorrhaphy. Following treatment with systemic antibiotics, antibiotic eye drops, and lubrication, the swelling significantly reduced, allowing for successful mucosal grafting from the lower lip two weeks post-operation. The wound healed well, and the patient received a prosthesis two months later. Although there is a risk of implant exposure or extrusion in evisceration with primary implant placement in acutely infected or inflamed eyes, the rate of such complications is generally acceptable[26,27]. This case underscores the challenges of managing wound dehiscence in endophthalmitis patients and highlights the importance of addressing infection and inflammation before surgery.

In the HA group, the authors observed one case of postoperative conjunctival cyst formation. The patient had a history of secondary glaucoma due to central retinal vein occlusion and had undergone trabeculectomy. The patient later developed bleb-related endophthalmitis, necessitating evisceration to control the infection. The surgery was uneventful until six weeks postoperatively, when the patient developed a conjunctival cyst and significant mucous discharge. After excision of the conjunctival cyst, the discharge decreased, and the patient was able to wear her ocular prosthesis normally. These complications were managed effectively, and patients reported satisfaction with the outcomes.

Limitations warrant consideration in the present study. The small sample size, compounded by challenges from the COVID-19 pandemic, may limit the generalizability of the present study findings. Additionally, the early termination of the study due to logistical constraints, including the retirement of the senior surgeon, restricted the ability to fully explore the new surgical technique. Another key limitation is the short follow-up period. Since complications related to orbital implant surgery often develop after six months, the findings at the eight-week mark should be interpreted with caution. Therefore, the authors can only conclude that the two implant types showed comparable short-term outcomes at the eight-week follow-up. Furthermore, motility was measured using a surgical marker and ruler, which may lack precision and introduce observer error. Future studies with larger cohorts and longer-term follow-up are needed to better assess surgical time, technical complexity, long-term outcomes, and complication rates between conventional and four-petal myoconjunctival techniques.

Despite these limitations, the present study offers important insights, particularly regarding the accessibility and affordability of non-porous implants in regions where they are more prevalent, such as Thailand. Given the scarcity of oculoplastic surgeons and the preference for non-porous implants among general ophthalmologists, the present study findings support the continued use of this approach, especially in settings where expertise in porous implants may be limited. Furthermore, the results affirm that non-porous implant insertion can optimize outcomes without compromising postoperative complications or motility, particularly in resource-constrained environments managed by general ophthalmologists.

## Conclusion

The four-petal myoconjunctival technique demonstrated its effectiveness in facilitating evisceration, providing stable implant positioning and good prosthetic outcomes. The results indicate that both wrapped PMMA and HA implants achieved comparable outcomes in terms of the ability to wear an ocular prosthesis eight weeks post-surgery with minimal post-operative complications. The technique's success, particularly with wrapped PMMA implants, suggests that it can be a practical alternative in remote areas with limited access to advanced surgical resources and expertise. Further research with larger sample sizes and longer follow-up periods is recommended to validate these findings and explore the long-term outcomes of this technique.

## What is already known about this topic?

Bio-integrated orbital implants are preferred in evisceration procedures because they reduce the risk of implant migration and allow for the use of larger implant sizes. However, their high cost and limited availability, especially in government hospitals, pose significant challenges. In contrast, spherical acrylic (PMMA) orbital implants are widely used due to their affordability, but they are typically limited by smaller implant sizes and a higher risk of migration, exposure, and extrusion.

## What does this study add?

This study demonstrates that, using the four-petal myoconjunctival technique, spherical acrylic orbital implants can be safely and effectively used. The technique allows for the placement of larger implants without increased risk of migration, exposure, or extrusion. Additionally, implant motility achieved with this method is comparable to that of bio-integrated implants.

## Conflicts of interest

The authors declare no conflict of interest.

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