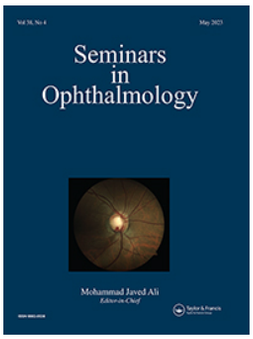

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Patient-Specific Orbital Implants Vs. Pre-Formed Implants for Internal Orbital Reconstruction

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ABSTRACT

Purpose: To compare the outcome of orbital blowout fracture repair by means of pre-formed porous-polyethylene titanium implants (PFI) vs patient-specific porous-polyethylene implants (PSI).

Methods: Retrospective cohort study. Baseline characteristics, ophthalmic examination results, ocular motility, fracture type, the timing of surgery, implant type, and final relative enophthalmos of all patients operated on for blow-out fractures in a single center were collected and analyzed.

Results: Twenty-seven patients (mean age 39 years, 9 females) were enrolled. Sixteen underwent fracture repair with PFI and 11 with PSI at 11 months (median) post-trauma. Mean follow-up duration was 1.1 years. Both groups showed significant postoperative improvement in primary or vertical gaze diplopia ($P = .03$, χ^2). Relative enophthalmos improved from −3.2 preoperative PFI to −1.7 mm postoperative PFI, and from −3.0 mm preoperative PSI to −1.1 mm postoperative PSI ($P = .1$). PSI patients had non-significantly less postoperative enophthalmos and globe asymmetry than PFI patients. The outcome was not influenced by previous surgery, age, sex, number of orbital walls involved in the initial trauma, or medial wall involvement (linear regression). Both groups sustained complications unrelated to implant choice.

Conclusion: Both PSI and PFI yielded good outcomes in this study. PSI may be a good alternative to PFI in primary or secondary orbital blowout fracture repair with less enophthalmos and globe asymmetry, in spite of the possible disadvantages of production time, a relatively larger design, and challenging insertion. Since it is a mirror image of the uninjured orbit, it may be beneficial in extensive fractures.

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Orbital blowout fracture; Orbital fracture; Patient specific orbital implants

INTRODUCTION

Orbital blowout fractures are encountered relatively commonly in the oculoplastic clinic. Selection of the type of surgery is based upon the fracture extent, ocular motility disturbances, and the presence of muscle entrapment. Fracture repair may be technically challenging. Moreover, the cosmetic outcome is not always predictable, with residual postoperative enophthalmos being a common sequela, and one that can occur even with a satisfactory postoperative result.[1,2] Residual postoperative diplopia may also occur, and it represents a major source of frustration to patients. Functional and disfiguring defects can remain despite multiple attempts to reconstruct complex bone deficits.[3,4]

Several approaches for addressing and mitigating the challenges of traditional orbital fracture repair have been recently described, and advances in imaging techniques and associated technologies have led to improved preoperative planning. High-resolution three-dimensional (3D) planning has become readily available in most modern settings, allowing more realistic presurgical planning by the surgical team. Custom-made solutions are considered to more accurately recapitulate the complex natural shape of the orbit,[5] as is the use of intraoperative stereotactic navigation, endoscopy, and augmented reality. Although these innovative surgical aids seem promising, not all oculofacial surgeons agree upon their true benefit in orbital fracture repair.

The purpose of this study is to address these questions by comparing the surgical outcome of orbital blowout fractures with the use of patient-specific implants (PSI) as well as pre-formed implants (PFI). We stratified these results based upon the number of walls involved and the number of previous repairs.

METHODS

This is a retrospective analysis of all patients operated for orbital blowout fractures at Sheba Medical Center during a 10-year period (2011–2020). All patients underwent comprehensive ophthalmic examinations, including enophthalmos and ocular motility evaluations. Pre- and postoperative computed tomography (CT) scans were performed to evaluate fracture extent and implant position. Relative enophthalmos was

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calculated as the arithmetic difference between the non-injured and the injured orbit.

A porous polyethylene titanium (Medpor®, Stryker Craniomaxillofacial, MI, USA) implant was used in the PFI group, while a custom-made porous polyethylene (Su-Por®, Poriferous GA, USA) implant was used in the PSI group. The standard implant can be on hand when needed, but for the latter, the CT data of the specific patient's defect area need to be transmitted to the Poriferous engineering team in Michigan, USA, which applies its 3D imaging technology in collaboration with the local operating surgeon who uses the data on the patient's anatomy to design an implant tailored to meet the needs of both the patient and the surgeon. Once a final design has been decided upon, the production tools are manufactured with computerized numerical control techniques. The tools are then applied in a process that utilizes heat and pressure to form the porous polyethylene into the final implant shape. The average time needed for the process of ordering the implant and its delivery to the hospital for use was two weeks. Two sterile implants are provided for each scheduled operation. Also provided is a non-sterile template made of the same Su-Por biomaterial as the final implant, as well as a 3D-printed physical model of the patient's skull/orbits including the defect area for accurate intraoperative implant placement (Figure 1). The implants are made of pure porous polyethylene without any additives or stabilizers. Of note, these PSI cost around 1,500 USD each, comparable to the PFI used in the current study.

PFI were used on most patients in our department until 2018, when they were replaced by PSI after obtaining approval from the procurement department at Sheba Medical Center. The study was approved by the local institutional review board of the hospital, and informed consent was waived for this retrospective and anonymous analysis. The report adhered to the ethical principles outlined in the Declaration of Helsinki as amended in 2013.

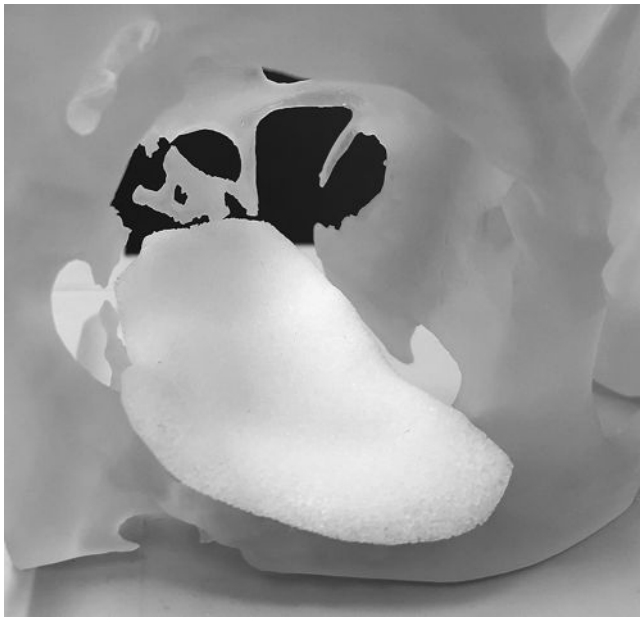

Figure 1. Patient-specific implant to repair a 27-year-old man with a combined left orbital floor and medial wall fracture, along with a 3D-printed physical model of the patient's defect area for accurate intraoperative implant placement.

Surgical Technique

All surgeries were performed with the patient under general anesthesia. A forced duction test was performed at the beginning of each surgery, and any motility limitations were noted and marked. A swinging eyelid incision was used for all cases of orbital floor fractures, and an additional trans-caruncular incision was used to repair concomitant medial wall fractures. Blunt subperiosteal dissection was carried out to delineate the full length of the fracture, after which the posterior ledge was exposed. Any incarcerated orbital tissue within the sinuses was gently released and replaced into the orbit. Any existing scar tissue was excised. The implant in the PFI group was trimmed so that it could safely cover the full extent of the fracture on stable orbital bones. The PSI was used as provided by the manufacturer without further preoperative or intraoperative manipulations. A zero-degree 4 mm endoscope was used in selected cases to ensure accurate implant position at the posterior aspect. A forced duction test was performed at the end of surgery, and when needed, additional release of peri-implant tissue was performed. The surgical incision was sutured with interrupted 7/0 and 6/0 polyglactin 910 sutures (Vicryl®, Ethicon, New Brunswick, New Jersey, USA).

Statistical Analysis

The difference in numeric variables (such as visual acuity [VA], intraocular pressure [IOP], and relative enophthalmos) was calculated by the Wilcoxon signed-rank test separately for the PSI and PFI groups before and after the procedure. The differences in numerical variables between the groups were calculated using the Wilcoxon Mann Whitney U-test, as was linear logistic regression to evaluate the influence of different variables (timing of surgery, number of walls involved, and previous surgery) on surgical outcome. Crosstabs with the chi-square analysis and the Fisher's exact test were applied to calculate differences in categorical variables (such as ocular motility disturbances and globe asymmetry). Non-parametric tests were used because of the relatively small study group. Snellen acuity was converted to logarithm of minimal angle of resolution values. The statistical analysis was carried out with Microsoft Excel™ 2019 (Microsoft® Corporation, Redmond, WA) and SPSS ™ version 26 (SPSS©, Inc., Chicago, IL).

RESULTS

The 27 study patients had a mean age of 39 ± 16 years (range 17–70 years) and included 9 females (33%). Fifteen patients (56%) had 1 failed surgical fracture repair prior to the current admission. Sixteen patients now underwent fracture repair with PFI, and 11 underwent repair with PSI. Surgery was performed after a median of 11 months post-initial trauma (mean 25 ± 48 months, range 0–240). The average follow-up time was 1.1 years. Eight patients were operated on the right side and 19 on the left.

Fifteen patients had preoperative primary or vertical gaze diplopia, which was unresolved by the surgery in seven patients ($P = .03$, chi-square), four of whom received PFI and three who received PSI. The preoperative differences in the enophthalmos and diplopia in both groups were not significant. Both groups showed similar improvement in diplopia after fracture repair. All 27 patients had sustained floor injury, 14 (52%) had a concomitant medial wall fracture, 10 (37%) had a zygomaticomaxillary complex (ZMC) fracture, and 5 (19%) had a roof fracture. Seventeen patients had at least two wall involvements.

The patients in both groups were similar in age, sex, type of fracture, and ocular examination ($P > .05$ for all). The demographics of the study population are summarized in Table 1. Time to surgery since the orbital trauma was longer in the PSI group ($P = .01$, independent samples Mann–Whitney U test), and the PSI group also had higher rates of secondary repairs ($P = .005$, chi-square).

The postoperative VA and IOP remained unchanged in both groups, but they both showed significant improvement in globe position post-fracture repair. The enophthalmos improved from −3.2 preoperatively to −1.7 mm postoperatively in the PFI group ($P = .1$), and from −3.0 mm preoperatively to −1.1 mm postoperatively in the PSI group ($P = .1$, Wilcoxon signed-rank test, statistical trend). All but 1 PSI patient had at least one failed internal orbital reconstruction by means of a PFI with an average postoperative enophthalmos of 3.2 mm (Figure 2 and Figure 3). Of note, in cases of secondary repair, the PSI were designed according to the postoperative CT images.

The final extent of enophthalmos was less in the PSI group although this did not reach a level of significance (independent samples Mann–Whitney U-test). Similarly, globe symmetry (defined as delta exophthalmos less or equal to 1 mm between the injured and non-injured sides) was more common in the PSI group, but also not significantly (chi-square with Fisher's

Table 1. Baseline characteristics and surgical outcome of 27 patients operated for orbital blowout fracture.

Variable		Pre-formed Implants (N = 16)	Patient-specific Implants[a] (N = 11)
Age, y		43	34
Sex, M/F		11/5	7/4
Time to surgery, mo		10	47 ($P = .012$)[b]
Follow-up time, y		1.1	1.1
Fracture side, R/L		5/11	3/8
Average walls, n		2	2
Previous failed op., n		5 (31%)	10 (91%) ($P = .005$, χ^2)
Visual acuity	Pre-op.	20/30	20/45
	Post-op.	20/25	20/50
IOP (mmHg)	Pre-op.	12	13
	Post-op.	13	14
Axial displacement (mm)[c]	Pre-op.	−3.5	−3.1
	Post-op.	−1.6	−1.1
	Delta[d]	1.5	2

M = male; F = female; R = right; L = left; op. = operation; IOP = intraocular pressure; mo = months; y = year; n = number; pre-op. = preoperative; Post-op. = postoperative.
[a]The patient-specific implants were based on preoperative CT imaging studies.
[b]Independent samples Mann–Whitney U test (all other *P* values were non-significant). One patient was operated 20 years post-initial trauma, skewing the mean, the median was 22 months in the PSI group.
[c]Delta proptosis between injured and non-injured orbit.
[d]Arithmetic difference between preoperative and postoperative axial displacement.

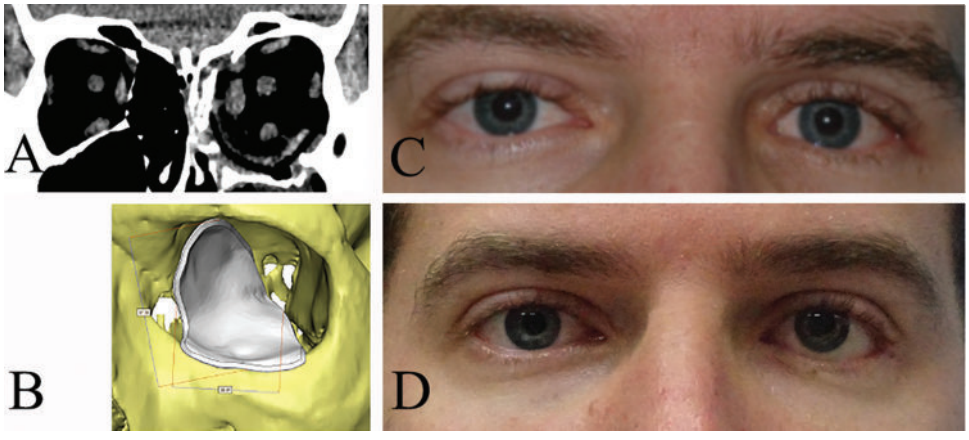

Figure 2. A. Postoperative coronal CT scan of a 30-year-old male who sustained a left orbital blow-out fracture with extensive floor and medial wall disruption during a baseball game. He underwent orbital fracture repair by a pre-formed implant (PFI). The implant can be seen situated on the orbital floor, but it does not bridge the full extent of the medial wall fracture, resulting in implant malposition and marked postoperative enophthalmos. B. Custom-made implant design based on the post-initial surgery scans. C. Image prior to patient-specific implant (PSI) surgery. D. Three months post-PSI surgery showing marked improvement in enophthalmos but lower eyelid retraction.

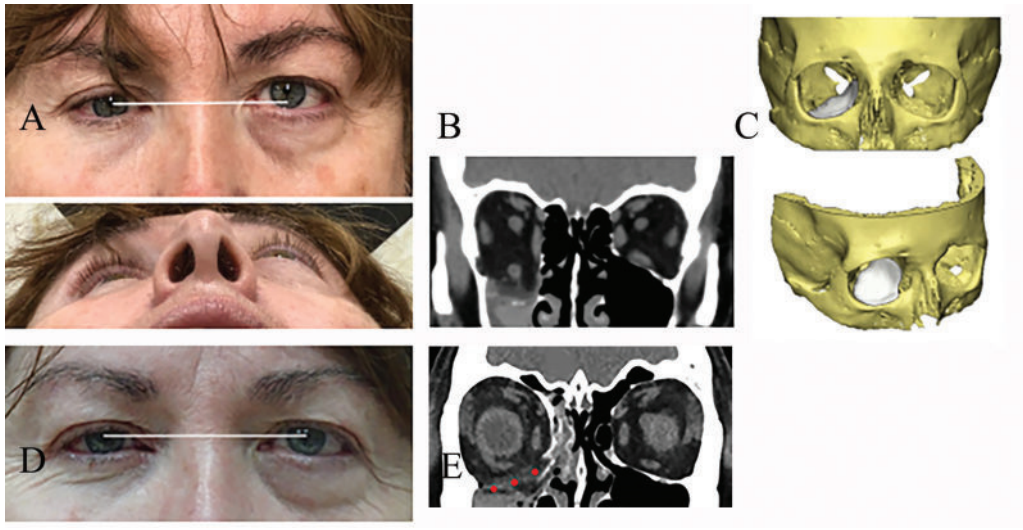

Figure 3. A. Clinical photograph of a 63-year-old female with a right orbital blowout fracture after a fall and initial repair with PFI at an outside hospital. Note the right hypoglobus better viewed in the upper image (white horizontal line) and the marked enophthalmos viewed in the lower Caldwell-Luc image. B. Coronal CT scan at presentation. The implant is situated entirely within the maxillary sinus rather than the orbital floor, therefore not supporting the internal orbital contour. C. 3D drawing of the PSI design. D. Postoperative clinical photograph after secondary fracture repair with a well-positioned PSI as can be appreciated on the postoperative scan (E).

exact test). Neither the preoperative nor the final enophthalmos were influenced by the number of orbital walls involved in the initial trauma, or by having undergone more than one procedure, having medial wall involvement, age, or sex (linear regressions).

Complications included one patient in the PFI group who had peri-implant infection attributed to implant malposition in an infected maxillary sinus. That patient underwent implant extrusion with a successful insertion of a new PFI. One patient with a large floor, medial wall, and ZMC fracture in the PSI group had VA deterioration from 20/60 to 20/400 postoperatively, most likely due to intraoperative nerve compression, and another patient in the PSI group had a soft tissue eyelid injury which was not related to implant insertion.

DISCUSSION

Our study findings support the use of PSI as a good alternative to PFI in primary or secondary orbital blowout fracture repair, with a tendency towards a slightly improved outcome. Advancement and availability of pre-surgical planning and implant manufacturing technologies during the last 2 decades have increased the applicability of PSI in craniomaxillofacial surgery.[6–8] Several case series have described the use of PSI in orbital fracture repair. In 2002, Fan et al. utilized computer-assisted volumetric measurements for volume estimation of implant design in 16 cases.[9] Those authors concluded that this approach can improve therapeutic outcomes in the correction of late enophthalmos. In 2006, Metzger et al. described the use of individual preformed titanium meshes with good results (N = 5).[10] Their preoperative planning included mirroring the unaffected side on CT imaging onto the fractured side, and applying intraoperative navigation. Mahoney et al. described 26 orbital fracture repairs using preformed implants (Medpor Titan Barrier and Anatomic Preformed Titanium plates).[5] As described by others, their preplanning included mirroring of the non-fractured orbit. Their surgery was also navigation-aided and involved the use of fixation screws to ensure a stable implant position, with excellent outcome. No screws were placed when we used either PSI or PFI implants, and the implant was stable in the orbit at the end of each procedure.

Callahan et al., Prabhu et al., and Dave et al. all demonstrated good results with relatively low-cost PSI.[3,11,12] Chen et al. recently observed that the process of creating a projected 3D mirror image may not reflect natural bony anatomy since patients may not have native symmetry of their orbits.[4] Interestingly, Callahan et al. designed two versions of each implant, the first based upon an estimation of the restored abnormal orbit and the second based upon the intact contralateral orbit mirrored to the abnormal laterality. Those authors concluded that the mirrored intact side yielded a more anatomically consistent result. Several brands of PSI are relatively expensive compared to PFI, but it is likely that PSI prices will become lower with advancing technologies and manufacturing techniques. Chen et al. described successful utilization of porous-polyethylene PSI in nine patients, also modeled after the contralateral orbits.[4] The implants were secured with titanium screw fixation, with good results. Those authors stated that this technique is particularly useful in patients with prior unsuccessful repair. In 2020, Chepurnyi et al. compared polyetheretherketone PSI with pre-bent titanium plates and conventional plates and demonstrated higher clinical efficacy in the PSI group.[13,14] Taken together, all of these case series described a favorable outcome with a good anatomic result, and unanimously advocated the use of personalized implants in oculofacial surgery.

It should be borne in mind that almost all of these positive impressions were based upon the results of PSI alone and not in comparison to off-the-shelf implants. As per the current knowledge of authors, this study is the first to compare surgical outcome of porous polyethylene PSI with porous-polyethylene titanium PFI in orbital fracture repair. Of note, the PSI was used as a second intervention for most patients, while the PFI group included mostly primary procedures (P = .008). Both

groups showed significant postoperative improvement in primary or vertical gaze diplopia as well as in relative enophthalmos. Final enophthalmos and globe asymmetry were better in the PSI group, although this did not reach a level of significance, possibly because of the relatively small number of patients in each group. The surgical outcome was not influenced by the number of orbital walls involved in the initial trauma, having more than one procedure, medial wall involvement, age, or sex. Severe complications occurred in both groups, but they were attributed to surgical technique rather than to implant design.

Our current report as well as those of others has demonstrated that PSI have several major advantages over PFI. Orbital volume restoration with PSI was at least as good as that achieved with conventional implants and may be superior in selected cases. Additional studies are required to verify this observation.

Both the major advantages and disadvantages of PSI rely upon its relatively large dimensions: on the one hand, large orbital defects require larger implants, while on the other, the large size of some of these implants may hinder insertion.[4] Although the outcome was similar for single-wall compared to more extensive fractures in our series, our impression was that the use of PSI may be especially beneficial in the more complex reconstructions, such as extensive trauma or secondary repair. A common example is combined orbital floor and medial wall fractures, in which the reconstruction is challenging due to the surgical approach and implant stability.[15] That surgery normally requires meticulous manipulation of flexible implants to fit into the desired location, while the use of a 3D-printed representation may allow a more precise fit and prevent undercorrection. PSI may also be easier to utilize in late or secondary reconstructions, which are sometimes more complex and involve patients that have already experienced a nonsatisfactory outcome. Orbital floor fracture repair can successfully treat enophthalmos and diplopia in patients with delayed clinical presentation, even decades post-injury, as long as adequate volume restoration is achieved.[16]

Several disadvantages of the use of PSI bear mention. First, the larger implant size may be associated with a more robust procedure and the need for a more experienced surgeon. In this study, although a similar complication rate was observed in both groups, one major complication of a partial loss of vision was observed in the PSI group, which theoretically could have been caused by increased intraoperative globe pressure during the insertion of a large implant. Further studies are warranted to examine this possibility. A second disadvantage is implant availability: production of a PSI typically requires 1–2 weeks and therefore may not be suitable for urgent repair, such as with muscle entrapment.[4] This delay is expected to decrease as technology evolves. Third, the added financial burden of some PSI brands puts the cost-effectiveness of its use into question, although this was not the case in the current study. Nonetheless, advances in technologies and increased availability of biomaterials are expected to lower these prices, as demonstrated in recent reports.[3,11,12]

Limitations of this study stem from its retrospective nature, relatively small sample size, and the reconstructions having been performed by more than one surgeon, although most surgeries were performed by a single surgeon (GBS).

In conclusion, both PSI and PFI yielded good outcomes in this study, and PSI may be a good alternative to PFI in primary or secondary orbital blowout fracture repair. The major advantages and disadvantages of PSI derive from its relatively large dimensions and challenging insertion, higher costs, and production time. Custom-made solutions can assist in achieving optimal reconstruction. Advantages of PFI over PSI include their higher availability, lower cost, and easier intraoperative manipulation. Although the outcome for single wall was similar to that of more extensive fractures in our series, our impression was that the use of PSI may offer an advantage in complex reconstructions, such as combined orbital floor and medial wall fractures, as well as late or secondary repairs. Additional larger prospective studies that evaluate the actual benefit of PSI over PFI in orbital fracture repair are warranted.

Disclosure statement

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