

A Novel Patient-specific Titanium Mesh Implant Design for Reconstruction of Complex Orbital Fracture

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Background: Complex orbital fractures, including orbital rims and walls, require precise reconstruction. A titanium-based patient-specific implant (PSI) benefits over other implants when challenged with narrow surgical space and designable implant fixation point.

Methods: This is a prospective noncomparative case series to evaluate the effect of complex orbital reconstruction using the newly designed lateral fixation patient-specific implant. The PSI was individually fabricated by 3D reconstruction using the mirrored nonaffected orbit as a template. The fixation point was at maxillary or zygomatic bone, depending on the bony remnant. Outcomes were obtained from computed tomography scan to compare orbital tissue volume and exophthalmometry value by posterior clinoid method before and after the surgery and also between both orbits in each patient.

Results: Sixteen patients with complex orbital fracture with inferior orbital rim defect were enrolled. Seven were previously repaired with other implants. Compared with the preoperative measurement, the postoperative mean difference of orbital volume and exophthalmometry value between both eyes was significantly decreased (reduction of the mean difference of 2904.40 mm³; $P < 0.001$ and 2.89 mm; $P < 0.001$, respectively). The mean orbital volume and exophthalmometry value between affected and unaffected eyes were not different after surgical correction ($P = 0.57$ and $P = 0.28$, respectively). There was one infected wound from retained foreign body and one unresolved vertical diplopia after the reconstruction.

Conclusions: Reconstruction of complex orbital fractures using the novel designed-PSI had excellent outcomes. Appropriate implant design with caution of orbital anatomy and placement techniques are keys for successful results. (*Plast Reconstr Surg Glob Open* 2022;10:e4081; doi: [10.1097/GOX.0000000000004081](https://doi.org/10.1097/GOX.0000000000004081); Published online 27 January 2022.)

INTRODUCTION

Reconstruction of complex orbital fractures involving both multiple wall fractures with posterior edge and

inferior orbital rim defects is challenging due to the intricate and complex 3D shapes with limited intraoperative view and no standard implant fixation point. Titanium mesh is a preferred implant in this situation due to its ability of rigid fixation with screw. Before the 3D printing technology era, individualization of implant contour and fixation point were impossible. Free-hand bending and preformed standard plates could be poorly-fitted and could lead to visual disturbance and unaesthetic results such as enophthalmos and displacement of the implant.^{1,2} Accordingly, the customized and patient-specific implant (PSI) model was found to have better outcome and lower revision rate.³⁻⁵

The purposes of this study were to evaluate the results of a newly designed lateral fixation titanium PSI in complex orbital wall reconstruction and to demonstrate its

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effectiveness by measuring orbital volume change and distance from the tip of the posterior clinoid process to the posterior corneal surface of the globe conveying correction of enophthalmos.

MATERIALS AND METHODS

Patients

The prospective noncomparative case series design of this study was approved by the institutional review board and ethics committee, Faculty of Medicine, Chulalongkorn University. All patients who had a unilateral complex orbital wall fracture with inferior orbital rim defect were recruited and underwent an orbital reconstruction using PSI performed by a single surgeon (PS) at King Chulalongkorn Memorial Hospital, Bangkok, Thailand between November 2018 and March 2021.

Indications for orbital reconstruction are as follows: (1) persistent diplopia with limitation of eye movement within 30 degrees of the primary position; (2) significant enophthalmos which exceeds 2mm and is cosmetically unacceptable; (3) large fractures involving at least half of the orbital floor. Only multiple wall fracture cases with posterior edge and inferior orbital rim defects, including those with comminuted mid-facial fracture and malunion of zygomaticomaxillary complex, were selected for PSI placement. Bilateral cases and patients who had PSI placement for volume augmentation in anophthalmic socket were excluded from the study.

Informed consent was obtained from all patients. Pre and postoperative CT scans with image-guided surgery protocol for craniomaxillofacial scanning parameters were performed. Data of baseline characteristics (including age, gender, baseline ophthalmic examination and duration from time of injury to surgery) were gathered. Some distinct characteristics of the cases were also observed (eg, diplopia and concomitant orbital foreign body). All cases were late surgical repair.

Preparation of 3D-printed PSI

To fabricate the PSI, imaging data from the CT scan were transformed into a 3D file with a segmentation process in the anatomical bone region of interest. Three-dimensional reconstruction of the affected orbit was performed by using the mirrored nonaffected orbit as a template. The extent of the PSI was lined along with the fractured site but was limited anterior to the inferior orbital fissure, and maximal implant size was recommended by the surgeon (Fig. 1). The mirroring technique was based on the use of the mid-sagittal plane as a reference. The anatomical mesh implant with screw hole fixation at maxillary or zygomatic bone was then created using mirrored and nonmirrored bone as a guide. The PSI was manufactured by selective laser melting using titanium alloy Ti-6Al-4V (Meticuly Co., Ltd., Thailand) with a plate thickness of 0.45 mm and a screw hole diameter of 0.16 mm. A rapid prototype model of the affected orbit with position of the fixation point was also created for intraoperative guidance.

Takeaways

Question: What was the precision of the lateral fixation PSI in orbital wall fractures without posterior bone edge and standard fixation point defect including malunion zygomaticomaxillary complex and comminuted mid-facial fracture reconstruction?

Findings: The difference of orbital volume and exophthalmometry value between affected and unaffected eyes of 16 patients with complex orbital fractures was reduced. The values between affected and unaffected eyes were not different after reconstruction.

Meaning: The novel designed-PSI enables precise reconstruction and should be considered as a cost-effective alternative.

Surgical Procedure

The orbital floor was approached through a preseptal transconjunctival or swinging eyelid incision. Medial orbital wall was approached through a transcaruncular incision. Patients who previously underwent orbital repair with transcutaneous incision (subciliary or subtarsal) were exposed to the defected field via the previous incision. Orbital foreign bodies and pre-existing orbital floor implants including any plate and screws at inferior orbital rim, if present, were removed. Herniated orbital contents were repositioned, and orbital wall defects were reconstructed using the PSI implant. The anterolateral aspects of the PSI were secured to the remaining orbital rim of the maxillary or zygomatic bone using a titanium screw. The screw fixation point was at maxillary bone, if present, and at zygomatic bone when there was a complete inferior orbital rim defect. Sub-orbicularis oculi fat, malar fat, and pre-existing scars were transposed to cover the anterior edge of the implant. Periosteum and the conjunctival wound were closed with interrupted 5-0 and 7-0 vicryl sutures, respectively.

Orbital Volume Measurement and Exophthalmometry Measurement by Posterior Clinoid Method

Orbital volume was determined from preoperative and postoperative 3D reconstructed CT scans. Due to the absence or malposition of lateral orbital rim, the posterior clinoid method was chosen for exophthalmometry measurement. It was obtained from the axial plane of the CT scan with single measuring line from tip of the posterior clinoid process to the posterior corneal surface of the globe.⁶

Descriptive statistics were used to evaluate baseline characteristics with mean and SDs used for quantitative variables and counts and percentage for categorical variables. Continuous parametric data were analyzed by paired sample *t* test. A *P* value of less than 0.05 was considered statistically significant, and all analyses were conducted using SPSS software, version 22 (SPSS, Chicago, Ill).

RESULTS

Initially, eighteen patients with complex orbital fractures underwent reconstruction with PSI during the

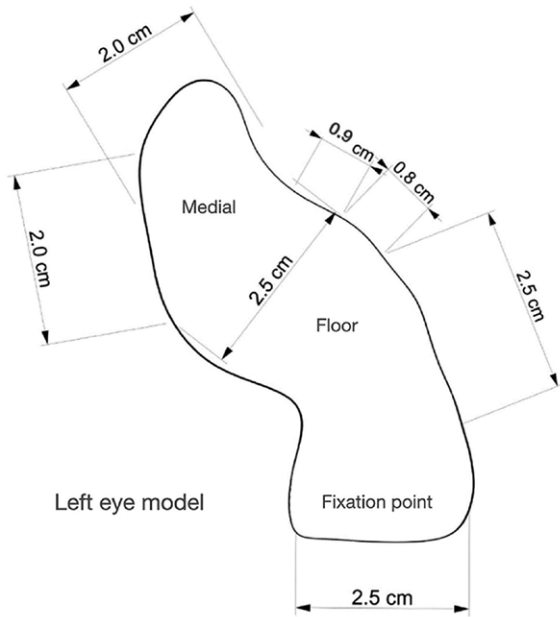


Fig. 1. Illustration of the maximum recommended size of PSI for orbital reconstruction. It should be noted that the size of PSI was limited by the feasibility of transconjunctival placement.

data collection period. Two patients were excluded, one with anophthalmos and the other with bilateral orbital fractures, leaving a total of 16 patients (nine men, seven women) included in the study for data analysis. The mean age of patients was 36 (19–55) years, and all patients had traumatic injury. Seven patients had previous repair with unsatisfactory outcomes using conventional implants. The average time from injury to surgery with PSI was 2.8 years (range 1–4 years).

Compared with preoperative value, there was a significant decrease in postoperative mean difference of orbital volume between eyes (reduction of the mean difference = 2904.40 mm^3 , $P < 0.001$). Similarly, the postoperative mean difference of the exophthalmometry value between eyes was significantly decreased (reduction of the mean difference = 2.89 mm , $P < 0.001$). After reconstructive surgery with PSI, the mean orbital volume and the exophthalmometry value between affected and unaffected eye was not statistically different ($2503.82 \pm 454.04 \text{ mm}^3$; $P = 0.57$ and $1.09 \pm 0.26 \text{ mm}$; $P = 0.28$, respectively) (Table 1). During the 6-month follow up period, there was one case of infected wound from retained orbital wooden foreign body that required implant removal and one case of unresolved vertical diplopia that required extraocular muscle surgery.

DISCUSSION

Orbital wall reconstruction can be performed with various kinds of implant materials^{7,8} and contouring methods.^{3–5,9} Absorbable material with less long-term complication is more ideal than titanium mesh in most situations, except for large multiple wall fractures without stable placement points.^{8,10–12} The risk of implant malposition increases with larger fracture size and rigid fixation with

screw is usually required.² Considering implant bending methods, preformed titanium mesh and free-hand bending or customized 3D-printed prototype assisted bending of a standard plate works well in most cases where the inferior orbital rim is intact or can be reconstructed concomitantly. Nevertheless, many studies have shown better outcomes and lower revision rates with PSI.^{3–5}

In pure orbital wall fracture, the necessity of PSI is still debated due to its significantly higher cost. However, in cases of malunion zygomaticomaxillary complex and comminuted mid-facial bone fracture for those who lack proper fixation point for standard implant, other implants are not optimal solutions when compared with PSI. From our study, the reconstruction of complex orbital fractures using a lateral fixation designed PSI provides not only stability for the fracture site but also yields precise outcomes. We found no significant difference of the orbital volume and exophthalmometry value between the affected and unaffected orbits after reconstruction. Enophthalmos was improved and cosmetically acceptable in all cases as shown in an example patient (Fig. 2).

Late postoperative infection was found in one patient due to retained wooden foreign body, and the removal of the PSI was needed. One case with three previous surgeries had persistent diplopia from hypertropia after PSI orbital reconstruction of four wall fractures. This patient first presented with mark enophthalmos and limitation of eye movement due to poor orbital repair technique with medial and inferior rectus incarceration to the previous implant. Surgeons should be cautious of globe misalignment before placement of PSI implant, aiming for full correction in severe contracted orbital soft tissue and marked limited extraocular movement.

All cases in our study had delayed surgery due to unstable condition: seven had previous surgeries, five had concurrent life-threatening injuries requiring medical attention, two had chronic osteomyelitis at the fracture site, and two had globe rupture with ophthalmic complications. We confirmed the results from a prior study that delayed primary surgery did not result in worse outcomes when compared with early surgery.¹³ However, fibrosis and scar adhesion may obliterate surgical plan and obscure landmark anatomy in patients with previous surgery. Additionally, the infraorbital nerve and rectus muscle may be displaced significantly and were prone to iatrogenic injury. A CT navigation system was utilized in three of those cases.^{14,15}

Although the PSI is highly precise and offers excellent clinical outcomes with significantly lower revision rates when compared with other orbital implants,² one particular disadvantage of titanium mesh PSI, other than its high cost, is the requirement of material designing beforehand. It cannot be bent or adjusted during the time of procedure. Thus, the reconstruction has to be delayed subsequent to fabrication of the implant. However, this may change in the future with possible real-time design and intraoperative manufacturing. The limitation of this study included a small number of patients, and the quantitative results might be impacted by measurement inaccuracy caused by human error.

Table 1. Comparison of Preoperative and Postoperative Orbital Volume Differences and Exophthalmometry Value Differences between the Affected and Unaffected Eyes (N = 16)

		Mean ± SE (mm ³)	P
Orbital volume	Preoperative difference	5408.22 ± 624.95	<0.001
	Postoperative difference	2503.82 ± 454.04	0.57
Exophthalmometry value	Preoperative difference	3.98 ± 0.61	<0.001
	Postoperative difference	1.09 ± 0.26	0.28

*P based on paired T-test.

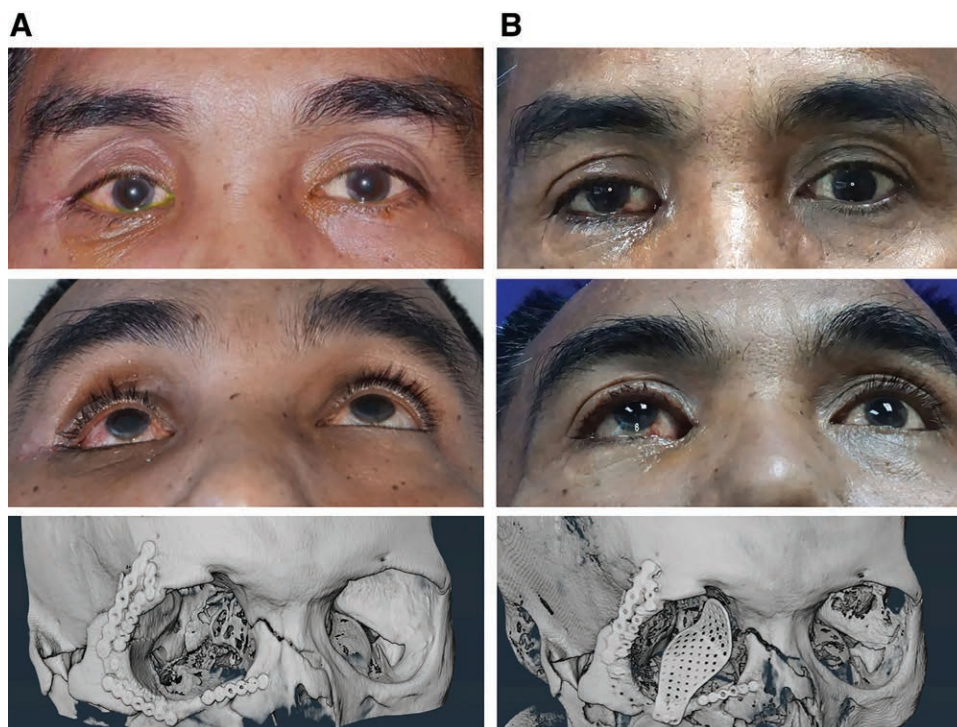


Fig. 2. A 49-year-old male patient with right orbital floor, medial wall, lateral wall, nasal, and zygomatic fractures underwent previous orbital rim repair with plate and screws and orbital wall repair with bone graft. Photographs show improvement of enophthalmos from before (A) to after the PSI surgery (B). The figures below show pre and postoperative 3D-reconstruction CT scan illustrating that only old plate and screws at the inferolateral orbital rim were removed.

CONCLUSIONS

It is shown by quantitative assessment that PSI enables precise reconstruction of complex orbital fractures with rim involvement. Individualized shape and fixation point outweigh its high cost in cases with malunion zygomaticomaxillary complex and comminuted mid-facial bone fracture. Implants that are meticulously designed to fit in the exact anatomical position of an orbit can yield excellent outcomes.

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PATIENT CONSENT

The patient provided written consent for the use of his image.

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