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Patient-Specific Implant for Primary Orbital Reconstruction: A Case Report

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ABSTRACT

The main aim of orbital fracture reconstruction is to restore the functional and aesthetic components of the eye. However, it is known that surgery for complex three-dimensional anatomy of the orbit is always a challenge. With recent advancements in technology, surgical predictability and outcomes have greatly improved. Several methods for orbital reconstruction surgery have been documented such as virtual surgical planning, intraoperative navigation, intraoperative imaging, and the use of patient-specific implant (PSI). PSI made of titanium can be designed by using a computer-aided design process and manufacturing (CAD-CAM) of CT-scan routinely used during diagnostic imaging. With precise analyses in shape and size followed by personalised implant design, the surgical precision can be alleviated further and at the same time, the surgical duration could be reduced with anticipation of better surgical outcomes. However, meticulous planning needs to be done preoperatively, with the timing of the surgery being an important factor. In the present case, pure orbital blowout fracture primarily treated with a personalised-implant solution derived from 3D-printing technology is described. Both pre-surgical and surgical workflow of this computer-assisted surgical method is elaborated. PSI for primary orbital reconstruction can be regarded as a viable alternative surgical solution including its working timeframe and adherence to the surgical protocol or algorithm.

Keywords: *Blowout fracture; orbital fracture; orbital reconstruction; patient-specific implant*

INTRODUCTION

Orbital bone is a prominent anatomical feature with a complex three-dimensional structure that is prone to fracture from falls, sports injuries or motor vehicle accidents. Orbital blowout fracture (OBF) is one of the most common facial bone fractures and should be approached with considerable attention (Ahmad Nasir *et al.*, 2018). It may cause serious complications such as diplopia, limitation of extraocular movement and enophthalmos (Zhang *et al.*, 2012). OBF reconstruction requires special care because its management may compromise the patient's vision and potentially introduce facial anatomical changes (Manson *et al.*, 1986).

The major goal of orbital reconstruction is to achieve good aesthetics and functional outcomes, reduce morbidity and prevent further post-surgical complications. Although certain management aspects of orbital fractures, particularly the timing and reconstructive material, remain controversial, the goal of the treatment remains the same, which is to restore the orbital volume with anatomical restoration to pre-injury states. It is well acknowledged that careful planning and timing of the repair is crucial, as a delay in treatment or insufficient initial treatment may cause alterations in the facial architecture, resulting in poor outcomes (Nazimi *et al.*, 2019).

As time has progressed, the management of orbital fractures has also evolved. New surgical modalities and planning have not only improved the understanding about this complex surgical procedure but also the outcomes of surgery. Surgical advances, such as the use of surgical navigation systems in orbital reconstruction surgery, can provide real-time intraoperative positioning and assist in locating the reconstruction position to ensure the accuracy of the reconstruction (He *et al.*, 2020). Intraoperative imaging is another modality that can be used to further enhance reconstruction accuracy (Heiland *et al.*, 2005; Cannizzaro *et al.*, 2017; Nazimi *et al.*, 2019). In addition, a surgical plan incorporating the use of a custom orbital implant may lead to predictable aesthetic and functional outcomes. With advancement in technologies, including three-dimensional printing (also known as additive manufacturing), a patient-specific implant (PSI) can be constructed from the patient's diagnostic computed tomography (CT) scan data (Lim *et al.*, 2015) and utilised in surgery. Stereolithography modelling derived from Standard Triangulation Language (STL) fabrication based on the mirror image of the unaffected side in unilateral orbital injury can be used to yield a custom titanium implant design for orbital fracture reconstruction (Jansen *et al.*, 2018). This will, in turn, provide considerable benefits and potentially ensure optimal primary reconstruction to prevent the need for surgical revision or secondary repairs and reduce any surgical complications that could derive from unsuitable or malpositioned orbital implants.

We present a case of primary orbital fracture reconstruction by using a titanium PSI, which is not yet a common surgical practice in Malaysia. The objective of this illustrated case was to highlight the advantage of a PSI and the different surgical algorithm that may be required in managing such cases.

CASE REPORT

A 33-year-old female patient was referred to us after sustaining injuries from falling down the stairs. On day 4 post-trauma, clinical examination showed that she had sustained a superficial laceration in the left temporal region, with minimal left periorbital bruising and reduced sensation over the left cheek region. The X-rays from the primary clinic were insufficient to rule out the involvement of orbital fracture, although clinically she presented with a mildly reduced left palpebral aperture and mild enophthalmos (Fig. 1A). In addition, neither diplopia nor left eye motility restriction was recorded. A subsequent CT scan one week after the trauma confirmed a left pure OBF with herniation of orbital content into the adjacent maxillary sinus and a change in the inferior rectus muscle vector (Fig. 2). We arrived at a diagnosis of left pure OBF with a calculated fracture size of 406 mm^2 (OsiriX version 8.2.0; Pixmeo, Geneva, Switzerland). Subsequent eye assessment confirmed a 4 mm enophthalmos of the left eye and a reduced palpebral aperture of 3 mm compared to the uninjured contralateral side. However, the left eye remains without diplopia and with full extraocular movements. Considering the patient's large fracture size (Jacquiery Type IV), reconstruction surgery for the orbital floor using a titanium PSI was planned.

Fig. 1 (A) Reduced palpebral aperture and mild enophthalmos of the left eye as observed prior to the surgery; (B) Postoperative review eight weeks after the surgery showing corrected left eye enophthalmos with no other fracture or surgical complication.

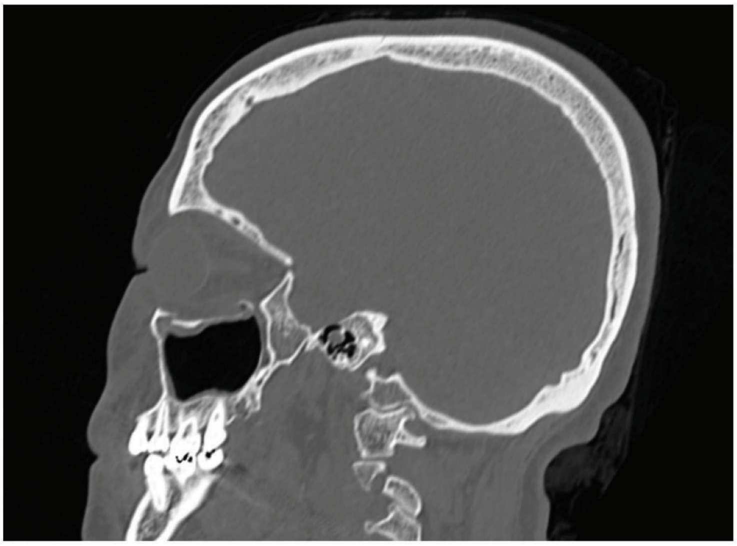

Fig. 2 Sagittal view of left orbital floor blowout fracture with herniation of orbital content into adjacent maxillary sinus and change in inferior rectus muscle vector.

Prior to surgery, the PSI was designed based on Digital Imaging and Communications in Medicine (DICOM) data. After discussion, fabrication, clearance from medical device authority and delivery time for the PSI took approximately three weeks. It is important to note that the use of PSIs in our centre was previously only for secondary or delayed reconstruction. We further explored the use of a PSI for primary reconstruction in this case mainly because of the complexity of the fracture size and the theatre restrictions for "routine" operations employed during the COVID-19 pandemic. Ideal or early surgical intervention within two weeks of injury was not possible for this same reason, which provides the opportunity for a different surgical algorithm to be explored. In addition, due to the reduction in theatre time, utilisation of both intraoperative navigation and/or intraoperative imaging was not possible. Hence, a decision was made to carry out the PSI method, although there was no previous experience of how long the design/process would take to be ready for a primary surgical repair. The authors hope that the present case can be a reference for surgeons in optimising alternative pre-surgical treatment workflows and technical preparations for future potential or similar cases.

First, the DICOM data were retrieved from a high-resolution scanning protocol (uncompressed standard; slice thickness and increment ≤ 0.625, voxel size 0.5 × 0.5 × 0.5 mm, zero gantry tilt) according to the manufacturer's scanning protocols. The data were first checked to ensure an adequate bilateral orbital scan, anonymised and securely transferred to a three-dimensional design and production collaborator (Meticuly Co. Ltd., Thailand). Similarly derived STL data for the contralateral, uninjured orbit was also shared to serve as a design reference. A choice of two STL design methods can be used, namely: iPlan CMF (Brainlab CMF iPlan 3.0.5; Brainlab®, Feldkirchen, Germany) or ProPlan CMF (Depuy Synthes, Solothurn, Switzerland; and Materialise, Leuven, Belgium). Following data transfer, design and fabrication of the orbital implant, final data generation of the PSI was performed in binary STL format. These data were again shared by the engineer, tested in virtual surgical planning prior to surgery and assessed as to whether further modification was required (Element; Brainlab®, Feldkirchen, Germany). The titanium PSI was fabricated once both parties reached agreement over the final design. Utmost priority and consideration were given to three different areas of concern: adequate coverage of the orbital floor defect; final plate position and its stability by incorporation of two implant "rest" designs at the inner aspect of the inferior rim (Fig. 3); and sufficient extension of the plate for proximal stability at the posterior ledge and lateral end of the inferior orbital fissure (Fig. 4).

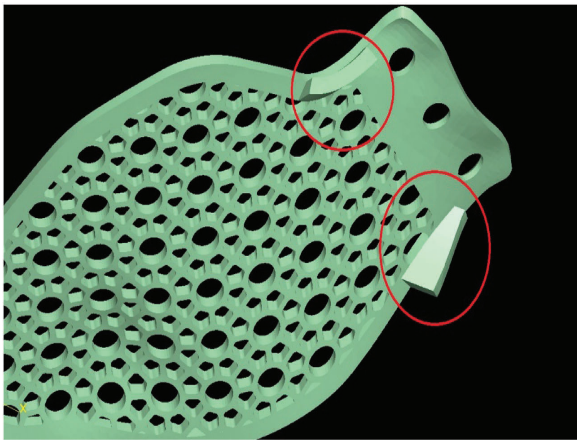

Fig. 3 Orbital PSI design modification with placement of two implant "rest" located at the inner aspect of the inferior rim.

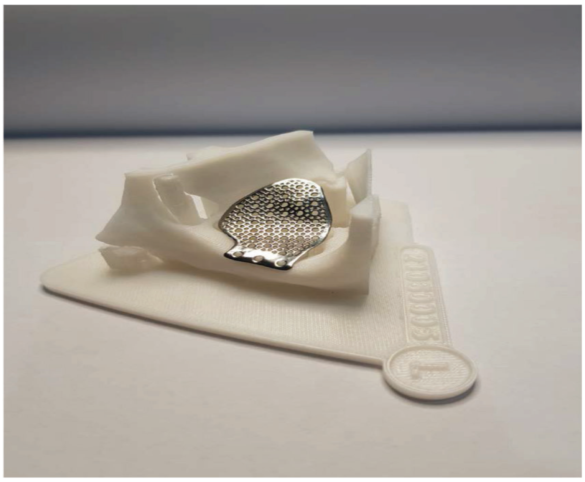

Fig. 4 Design of PSI with sufficient extension for stability at the posterior ledge and lateral end of the inferior orbital fissure. Note the "S" shape inclination towards the ledge.

Following medical device clearance and delivery of the PSI, the patient was electively admitted approximately eight weeks' post-trauma for reconstruction of the orbital floor under general anaesthesia. The transconjunctival approach using a Colorado Needle was performed, following lower eyelid retraction in the usual manner. The PSI was positioned and fixed with a single screw (Fig. 5). Improvements of the left enophthalmos were noted almost immediately following the reconstruction. A repeated forced duction test post-surgery was performed to ensure a negative result. Finally, flap closure was done in the usual manner with buried 5/0 resorbable sutures. No intraoperative navigation or imaging was used in this illustrated case.

A postoperative day 1 cone beam computed tomography (CBCT) scan was carried out for postoperative checks. Good adaptation of the PSI could be observed immediately, with retaining of the lazy S-shape orbital floor onto the posterior orbital ledge (Fig. 6). Furthermore, we performed postoperative image fusion in between the CBCT data and pre-operative simulation (Fig. 7) and found that the reconstruction was carried out according to both simulated planning and the anatomical design of the PSI. No fracture or surgical complications were observed post-surgery other than a transient and gradual improvement of infraorbital hypoesthesia, with a minimal lower eyelid ecchymosis that eventually resolved. The patient was uneventfully discharged from the ward one day after surgery. Postoperative review eight weeks after surgery showed that the left eye enophthalmos was restored, with no other fracture or surgical complications (Fig. 1b). Furthermore, the reduced sensation over the left cheek region had improved remarkably.

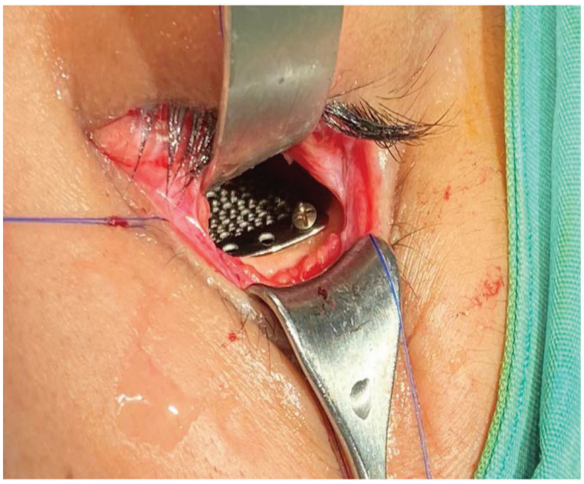

Fig. 5 PSI positioned and fixed with single screw onto the inferior orbital rim.

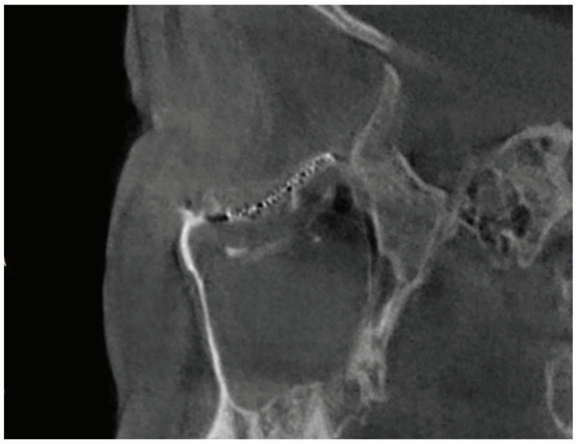

Fig. 6 PSI as viewed in sagittal section of postoperative CBCT.

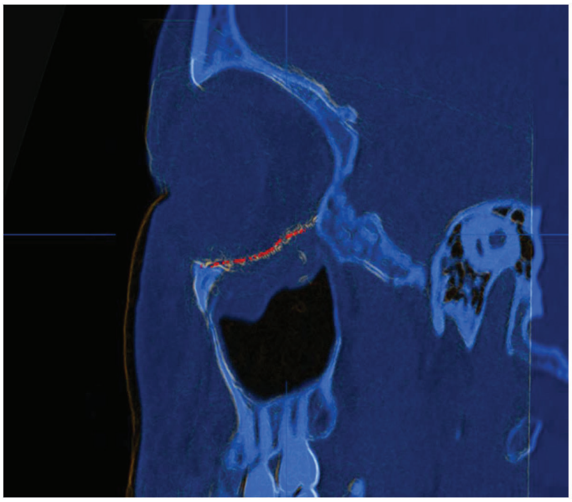

Fig. 7 Postoperative image fusion technique in between the CBCT data and pre-operative simulation confirming PSI position.

Ethics Statement

The patient was provided with a written consent for publication of this manuscript and use of the clinical images herein.

DISCUSSION

The human face consists of several complex structures, including the orbital cavity. This important midfacial structure is prone to injury in the form of pure or impure orbital fracture, depending on its mechanism of injury. The orbital floor and medial wall of the orbit are the two weakest points that serve as orbital crumple zones, where they are often fractured when subjected to trauma and may cause undesirable eye symptoms. Fractures involving both structures tend to produce undesirable eye symptoms. The complications of OBFs can be debilitating from both functional and aesthetic aspects. Diplopia and enophthalmos due to entrapment of extraocular tissue, muscle or fat in between the fracture site are common complications (Jin *et al.*, 2000; Ahmad Nasir *et al.*, 2018). As the literature suggests, an OBF can be classified into either pure or impure types, depending on the involvement of the orbital structures (Lang, 1889; Smith & Regan, 1957). In pure OBFs, although an internal orbital wall is involved, such as the floor, inferior or medial wall, the orbital rim is spared (Hazani & Yaremchuk, 2012). Our previous study showed that pure OBFs have significant prevalence (13.8%) and may cause aesthetic or debilitating functional issues such as enophthalmos and diplopia (Ahmad Nasir *et al.*, 2018). Thus, there is an urgent need for pre-surgical planning or preparation prior to treating such cases.

In a comminuted orbital wall fracture with distorted anatomy, identification of bony landmarks is crucial for the placement of orbital implants and often poses an intraoperative challenge for the surgeon (Gosau *et al.*, 2011; Nazimi & Rajaran, 2019). Good surgical outcomes without eye symptoms and with aesthetic improvement can be achieved by having accurate fracture delineation and precise positioning of the orbital implant during surgery. Various protocols and workflows of orbital reconstruction surgery have been well explored and documented to achieve the main objective of restoring the orbital volume with precise reconstruction. In recent years, computer-assisted surgery has been shown to be a crucial factor to re-establish orbital symmetry and increase the precision and safety of orbital reconstruction surgery (van Hout *et al.*, 2014; Wan *et al.*, 2015; Shin *et al.*, 2016; He *et al.*, 2020), including the use of a pre-formed or patient-specific orbital implant.

Computer-assisted surgery techniques have been well documented and are regarded as routine practice in post-traumatic orbital reconstruction surgeries (Gellrich *et al.*, 2002; Zizelmann *et al.*, 2007). The use of pre-formed titanium mesh with intraoperative navigation and post-operative CT imaging can confirm that the three-dimensional reconstruction of the original anatomy of the orbital cavity before fracture has been achieved (Schön *et al.*, 2006). On the other hand, PSIs allow precise reconstruction of orbital fractures by using a complete digital workflow and should be considered superior to manually bent titanium mesh implants (Gander *et al.*, 2015). Similarly, intraoperative imaging, one of the components of computer-assisted orbital reconstruction, can potentially reduce the risk of orbital implant malposition (Borad *et al.*, 2017). However, in this illustrated case, we did not have the routine opportunity to use these surgical methods due to the restricted operating resources during the COVID-19 pandemic. Hence, the use of PSIs for primary orbital reconstruction to ensure surgical accuracy was explored aiming for good postoperative outcomes. The use of PSI in this case report provides an insight that this technique was helpful and help surgeons to meet the surgical demand encountered in orbital reconstruction. This is especially when different surgical algorithm and virtual planning duration is involved, as PSI is not a routine practice for primary orbital reconstruction.

The use of a PSI is imperative to overcome the challenges seen in this case. Although the operation was carried out without the use of intraoperative navigation and imaging, we found that appreciation and reconstruction of the S-shaped bulge of the orbital anatomy with adequate reach to the posterior ledge could be maintained by using a PSI. With a PSI and pre-surgical planning data, a correlation between the final orbital implant position and the pre-surgical virtually planned position can be made and compared to conventional surgery via the previously elaborated image fusion technique (Nazimi & Nabil, 2021), although in this case this was only possible postoperatively. It is also vital to highlight that a navigation system by itself cannot completely prevent malposition of the plate because the anatomy of the orbit is unique to every individual and in different operative situations (Bittermann *et al.*, 2014). Therefore, during this challenging time, both from a pandemic and a surgical point of view, the decision to undertake primary reconstruction with a PSI could reduce the risk of surgical complications resulting from an unsuitable or malpositioned implant. Because the implant could not be checked intraoperatively without the use of intraoperative navigation and imaging, a "static" reference by having three-dimensional printing of the orbital bone together with the PSI could potentially retain the surgical accuracy.

Unfortunately, although computer-assisted surgery is proven to be able to provide substantial aid to the oral surgeon in orbital reconstruction surgeries, many surgeons are still unwilling or reluctant to adopt this new method. This could be due to a lack of familiarity with the new computer-assisted protocols, a lack of understanding or confidence or a personal preference based on their professional experiences. To encourage a higher adoption rate, additional training for the surgeon may be considered, together with financial support towards the patients who are willing to undergo computer-assisted orbital reconstruction surgery to ensure promising results. Postoperative imaging is also not a routine practice in managing orbital fracture, which could hinder understanding the reasons for commonly seen complications in orbital reconstruction, such as enophthalmos and diplopia. Unsuitable or malpositioned implants could go unchecked but may be a contributing factor to these commonly seen complications.

Consideration of surgical time is another factor to be included, as a longer time is required, but not to the extent that it will inadvertently delay the surgery. In this illustrated case report, the authors are of the opinion that the time factor is the subjective surgical planning element, which depends on the overall team experience in managing such cases. As more cases can be managed with a similar algorithm, the adherence and understanding towards its process could be improved over time.

CONCLUSION

The use of a PSI for primary orbital reconstruction is a possible alternative surgical solution when we look at its working timeframe and its overall surgical protocol or algorithm. The use of an orbital PSI could be considered with or without further elements of a computer-assisted algorithm for orbital fracture reconstruction. The choice not only lies with the surgeon's discretion and experience but also largely depends on several other important factors, such as availability, cost and planning time. The incorporated anatomical design close to the pre-injury in the PSI, including its design modification, could facilitate the final implant position, especially when other modalities could not be simultaneously assembled. However, it is important that the surgeon is well versed in computers and the design protocol and adheres to the suggested surgical time. The use of a PSI for primary orbital reconstruction, as illustrated in this case, could provide an insight into how best to use some disadvantages in clinical practice, including restrictions during the pandemic and lack of theatre time, as stepping stones for venturing into other possible surgical modalities to retain precision in surgery and its outcomes.

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