Use of custom fabricated surgical jig to improve surgical outcomes in open reduction internal fixation of unilateral orbital fractures: A prospective clinical study

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Abstract:
PURPOSE: The aim of the study was to assess the efficacy of virtual planning and surgical guide jig to improve surgical outcomes of open reduction and internal fixation with restoration and correction of orbital volume (OV) in unilateral orbital wall fractures.

METHODS: Fifteen patients with unilateral orbital fractures were assessed with ophthalmologic and radiographic parameters. The orbit was divided into three zones on computed tomography to localize defects. Fractures were coded into Fx Mx Rx Lx (F = Orbital Floor, M = Medial Wall, L = Lateral wall, R = Orbital Roof) based on pattern and specific wall involved. 1-mm sections were used to make stereolithographic models, design the custom fabricated surgical jig for intraoperative use as a guide.

RESULTS: Pre- and postoperative ophthalmological parameters, OV, were compared with the contralateral normal orbit serving as the reference. Postoperative ophthalmological parameters showed significant improvement in terms of visual acuity, enophthalmos, dystopia, and traumatic optic neuropathy. OV changes were concentrated in Zones 2 and 3. OV showed adequate restoration postoperatively.

CONCLUSION: The surgical jig served as an efficient guide to improve surgical outcomes of open reduction internal fixation. Preplanned intraoperative positioning helped achieve adequate anatomical reduction and fixation with an adequate reconstruction of OV aiding the effective transfer of virtual surgical plan on the table with improved surgical outcomes in clinical performance and functional restitution.

Clinical trial registration: The Clinical Trials Registry of India (CTRI) Registration No.: CTRI/2019/11/021929.

Keywords: Orbital fractures, orbital reconstruction, orbital volume, orbital wall fractures, surgical jig, surgical outcome, traumatic optic neuropathy

INTRODUCTION
The orbit is a unique anatomical structure that houses orbital contents like a glass jewel box. Poorly treated orbital wall fractures (OWFs) culminate into long-term complications. The balance between the skeletal frame and the soft tissue appendages within is so subtle that even modest change leads to gross outcomes.

Computed tomography (CT) scans in different planes can calculate the discrepancy in the orbital volume (OV) and compare it with the normal contralateral orbit. Computer-aided surgery and three-dimensional stereolithographic models (3D-SM) are noninvasive methods for precise surgical planning before surgery.

With emerging trends in imaging, utilization of 3D-SM and patient-specific implants (PSIs) OV measurements are becoming key parameters governing orbital reconstruction. Even with the increasing use of PSI and virtual surgical planning (VSP), there is a paucity of evidence concerning intraoperative surgical guides. The use of an intraoperative guide in some form can improve the surgical outcomes, particularly in...
a grossly mutilated orbit with no stable bony landmarks. The use of PSI with navigation has bridged this gap but remains an expensive proposition.

The rationale of the study was to evaluate whether VSP can be effectively used to fabricate a surgical jig to enhance accuracy and precision. The study aimed to assess the efficacy of VSP with mirrored 3D-SM and surgical jig as a guide to improve surgical outcomes of open reduction and internal fixation (ORIF) with the restoration of OV in injuries with unilateral OWFs.

**METHODS**

**Study design and sample**

This was a prospective clinical study conducted from December 2019 to September 2020. Prior clearance was obtained from the Institutional Ethical Review Committee. The study was registered with the Clinical Trials Registry of India (CTRI) Prospectively (Registration No.: CTRI/2019/11/021929).

The study population comprised of patients with clinical and radiological features of craniofacial fractures with unilateral OWFs. Patients with unilateral one or more OWFs confirmed with CT with or without resultant bone loss, presenting within 10 days of injury in the age group of 18–60 years were included in the study. Patients with systemic comorbidities, bilateral fracture involvement, ocular findings due to nontraumatic etiologies, pure ophthalmic injuries without OWFs, and bone loss necessitating bone grafting were excluded.

The sample size was calculated using G*Power by using an effect size of 0.86 calculated from means and standard deviations to achieve the power of study of 0.8.

**Preoperative variable and ophthalmological assessment**

Patients underwent thorough assessment by an ophthalmologist at the time of presentation for clinical ophthalmological parameters [Table 1]. Patients with traumatic optic neuropathy (TRON) were prescribed intravenous (IV) methylprednisolone for 2 weeks before ORIF.

1-mm CT orbit scans in axial, coronal, and sagittal sections were evaluated for the presence of rim and OWFs. The site, number, and the fracture patterns were graded and assigned a specific code as Fx Mx Rx Lx (F = Orbital Floor, M = Medial Wall, L = Lateral wall, R = Orbital Roof). X was coded as 0 when no fracture involvement was seen, 1 in linear, 2 in comminuted, 3 in comminuted fracture with bone loss, and 4 in pure blow-out OWFs.

DICOM images were processed with Mimics (Materialise version 20) to create a virtual image to measure OV. The orbits were divided into three zones based on four anatomical landmarks on the medial wall: commencement of optic canal (OC), posterior ethmoidal foramen (PEF), anterior ethmoidal foramen (AEF), and anterior lacrimal crest (ALC).[45] The points were transferred on the lateral wall by drawing a perpendicular to these points [Figure 1] delineating Zone 1 (Z1, posterior orbit) from

| Table 1: Clinical ophthalmological evaluation parameters with scoring criteria |
|---------------------------------|------------------|
| **Clinical ophthalmological findings** | **Scoring** |
| Altered VA | 0-Normal VA 6/6 |
| | 1-Decreased VA <6/6 |
| | 2-Count fingers |
| | 3-Perception of hand movements |
| | 4-Perception light+ve |
| | 5-Perception light –ve |
| Abnormal PR | 0-Absent |
| | 1-Present |
| VF | 0-Normal |
| | 1-Impaired |
| EP | 0-Absent |
| | 1-Present |
| Abnormal EOM | 0-No restriction in all nine gaze |
| | 1-Mild restriction (specify direction) |
| | 2-Moderate restriction (specify direction) |
| | 3-Severe restriction (specify direction) |
| DP | 0-Absent image separation (no diplopia) |
| | 1-Image separation present (diplopia present with specified direction) |
| OD | 0-Normal |
| | 1-Inferiorly placed |
| | 2-Laterally placed |
| TRON | 0-Absent |
| | 1-Present |
| VEP | 0-Absent |
| | 1-Present |
| CDs | 0-No significant difference |
| | 1-Appreciable difference present |

VA: Visual acuity, PR: Pupil reactivity, VF: Visual field impairment, EP: Enophthalmos, EOM: Extraocular motility, DP: Diplopia, OD: Orbital dystopia, TRON: Traumatic optic neuropathy, VEP: Visual evoked potential, CDs: Color desaturations

the commencement of OC to PEF, Zone 2 (Z2, middle orbit) from PEF to AEF, and Zone 3 (Z3, anterior orbit) from AEF to ALC.

Virtual mirroring of the unaffected side was done to define the amount of correction required by superimposing the normal orbit on traumatized orbit. Designing of Jig was done with VSP using mirrored volumetric data as a reference. The Jig was designed to rest on adjacent stable orbital rims and maxillary teeth [Figure 2a]. Designing of orbital floor implants was done using STL fabricated after virtual mirroring. Stock implants were cut to size and contoured based on these models and served as a jig when multiple walls were involved. In this way, the designed orbital floor implant itself served as an intraoperative jig [Figure 2b]. For a single wall, a resin jig was made on mirrored STL models which acted as a template against which the displaced fragments were reduced, assembled, and the holes predrilled. The contoured orbital mesh was fixed with screws into the predrilled holes. In another case scenario where more than one wall was reconstructed, intermediate resin jig was avoided and the orbital mesh plate and limbs were adapted on mirrored 3D-SM such that holes
were made on stable bone fragments for fixation [Figure 3]. 3D Print of custom fabricated jig was done using Stratasys Fortus 380 MC utilizing ABS-M30i (biocompatible plastic) for 3D printing. The study population comprised 15 patients with 13 (86.66%) males and 2 (13.33%) females. Mode of injury was road traffic accidents (RTA) in 14 (93.33%) patients and industrial accident in 1 (6.67%) patient. There were 5 (33.3%) right and 10 (66.7%) left-sided fractures. The mean age was 36 ± 9.4 years, ranging from 24 to 58 years. Demographic characteristics of patients and associated fracture patterns are described in Table 2.

Of total 60 orbital walls, fracture patterns comprised of 15 (25%) comminuted and 19 (31.66%) linear OWFs. The lateral wall was involved in 14 out of 15 patients (93.3%), orbital floor in 12 (80%) patients, orbital roof fractures in 6 (40%), and medial wall in 2 (13%) patients. Two-walled orbital fractures were most common, \( n = 8 \) (53.3%), followed by three, \( n = 4 \) (26.7%). In two-walled fractures, the lateral wall and orbital floor were most common. In three-walled fractures lateral wall, orbital floor and orbital roof were most commonly involved.

Table 3 enlists comparisons of clinical ophthalmological parameters. Of the total 15 patients, 10 (66.67%) had impaired VA preoperatively, of which 6 (60%) had decreased VA, 3 (30%) could count fingers, and 1 (20%) perceiving only hand movements. Postoperatively impaired VA persisted in 5 (33.33%) patients \( (P = 0.002) \). Abnormal pupil reactivity (PR) was recorded preoperatively in 7 (46.7%) and postoperatively in 1 (6.7%) patient \( (P = 0.016) \). Visual field impairment was seen in 5 (33.33%) preoperatively and in 1 (6.7%) postoperatively \( (P = 0.063) \). Enophthalmos was present preoperatively in 12 (73.3%) patients, resolved postoperatively in 10 \( (P < 0.001) \). Enophthalmos remained unresolved in 2 (13.3%).

No significant correlation was noted between the number of walls fractured and enophthalmos. 6 (40%) patients had mildly restricted extraocular motility and 2 (13.3%) had moderate...
restriction preoperatively. Only 1 (6.7%) patient had mild restriction postoperatively ($P = 0.008)$. Diplopia was present preoperatively in 3 (20%) patients which resolved in all patients postoperatively. 11 (73.3%) patients had orbital dystopia preoperatively. Near normal correction was achieved in 5 (45.4%), 3 (27.3%) were over-corrected, and no correction was achieved in 3 (27.3%) ($P = 0.002$).

TRON was present in 6 (40%) patients preoperatively, persisting in 2 (13.33%) patients postoperatively ($P = 0.043$). TRON incidence was highest in patients where the orbital roof was involved. The Chi-square test for association between TRON and VA showed $P = 0.010$. PR was absent in all 6 (100%) ($P = 0.010$). Abnormal visual evoked potential (VEP) was recorded in 5 (33.3%) patients, resolved in all but 1 (6.7%) postoperatively ($P = 0.063$).

Comparison of zone-wise OV and mean total OV distribution is presented in Table 4. Comparison of postoperative volume to that of the normal orbit showed no significant difference ($P = 0.185$) indicating near-normal correction and adequate orbital reconstruction.

### Table 2: Demographic characteristic of patients and the associated fracture pattern

| Age (years) | Gender | Etiology of trauma | Fractured side | Fracture pattern (F=Floor, M=Medial wall L=Lateral wall, R=Roof) |
|-------------|--------|--------------------|----------------|---------------------------------------------------------------|
| 42          | Male   | RTA                | Right          | F2 M1 L1 R0                                                  |
| 24          | Male   | RTA                | Right          | F0 M0 L1 R2                                                  |
| 47          | Male   | IA                 | Right          | F2 M0 L1 R0                                                  |
| 35          | Male   | RTA                | Left           | F2 M2 L1 R2                                                  |
| 34          | Male   | RTA                | Left           | F1 M0 L2 R0                                                  |
| 33          | Male   | RTA                | Left           | F1 M0 L2 R2                                                  |
| 38          | Male   | RTA                | Left           | F1 M0 L1 R1                                                  |
| 58          | Male   | RTA                | Left           | F2 M0 L2 R0                                                  |
| 33          | Female | RTA                | Left           | F1 M0 L1 R0                                                  |
| 29          | Male   | RTA                | Left           | F0 M0 L1 R0                                                  |
| 36          | Male   | RTA                | Left           | F0 M0 L1 R1                                                  |
| 46          | Female | RTA                | Left           | F2 M0 L0 R0                                                  |
| 25          | Male   | RTA                | Right          | F2 M0 L1 R2                                                  |
| 42          | Male   | RTA                | Left           | F1 M0 L1 R0                                                  |
| 24          | Male   | RTA                | Left           | F2 M0 L1 R0                                                  |

RTA: Road traffic accident, IA: Industrial accident

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**Figure 3:** (a) Preoperative frontal profile showing ptosis and orbital dystopia with the left eye. (b) Preoperative sagittal CT of traumatized orbit showing orbital floor defect with herniated orbital contents. (c) Virtual image showing designing of surgical jig for orbital floor on virtual model of the fractured orbit. (d) 3D printed surgical jig for orbital floor placed on stereolithographic model. (e) Intraoperative view showing adaptation of surgical jig on the infraorbital rim. (f) Intraoperative view showing precise adaptation of precontoured orbital floor mesh on the orbital floor and the rim. (g) Postoperative sagittal CT image showing seating of orbital floor mesh on the posterior ledge. (h) 2-week postoperative frontal profile showing correction of dystopia and reduced enophthalmos with some residual postoperative swelling. CT: Computed tomography, 3D: Three dimensional

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The mean total OV change was 2.2 ± 1.8 cm³ between preoperative and postoperative traumatized orbit. The total OV difference between pre- and postoperative traumatized orbit was 1.9 ± 2.3 cm³. The mean total OV discrepancy of postoperative and normal contralateral orbit was 0.3 ± 1.0 cm³ implying near-normal restoration of OV. A statistically significant difference was observed between the preoperative traumatized and the contralateral normal orbit in Zones 2 and 3 (Zone 2: \( P = 0.010 \); Zone 3: \( P = 0.001 \)). A statistically significant difference in Zones 2 and 3 was observed for OV of postoperative traumatized orbit compared with the preoperative traumatized orbit (Zone 2: \( P = 0.024 \); Zone 3: \( P = 0.010 \)). Pearson correlation for enophthalmos against total and zone-wise OV volume yielded statistically nonsignificant outcomes. Mean total OV difference of preoperative and postoperative traumatized orbit in patients with corrected enophthalmos was 3.16 cm³ and 1.61 cm³ for two patients with unresolved enophthalmos.

The OVR% for 1, 2, and 3 walled fractures was 97.7%, 97.3%, and 98.5%, respectively. Whereas for the 1 case where all orbital walls were fractured, the OVR% was 109.2% indicating over-correction of the OV. The mean OVR% of the current study was 98.5 ± 4.3% indicating an overall near-normal correction of the OV. No significant difference was noted in OVR% compared with the number of OWFs (\( P = 0.065 \)).

Mean surgery duration with the jig was 143.5 ± 20.7 min ranging from 112 to 182 min. A statistically significant increase was noted in the intraoperative time as the number of orbital walls increased (\( P = 0.024 \)).

### Discussion

RTAs account for a major proportion of trauma being the sixth leading cause of death in India.[7,8] The fact that facial fractures increase the risk of injury to the ophthalmic apparatus by 6.7 times leaves one pondering whether the skeletal orbit is a boon or bane.[9]

OWFs can be isolated but when subjected to high-velocity trajectories of forces, multiple wall involvement is inevitable.
Manolidis et al. observed the most common involvement of 2 orbital walls. This study reiterates that the frequency of multiple OWFs is higher than single wall involvement. Shah describes the incidence of ophthalmic injuries in 60 patients to be 9.32% similar to other studies.

Postoperatively 6 patients of altered VA, 5 (83.33%) showed improvement to normal. Severe facial edema and altered consciousness render patients unaware and unable to complain of visual loss. The visual function must be formally evaluated by trained ophthalmologists. Amrith et al. reported a 23% incidence of altered VA with 12.5% suffering permanent visual impairment.

Postoperatively, only 1 patient showed no improvement in abnormal PR. The lack of improvement was attributed to bony impingement of the fracture extension to the OC and direct TRON.

TRON, a paradox of superficial simplicity riddled with deeply hidden complexities, has a reported incidence of 2%–5%. With clinical findings and VEP, TRON was present in 6 patients. Altered VA and abnormal PR are termed as the “cardinal clinical signs” of TRON as all patients exhibited abnormal VA and PR, thus confirming a direct correlation between VA, PR, and TRON. The real challenge here is the diagnosis based solely on clinical grounds. Nondiagnosis of preoperative TRON or overlooking the symptoms in common faith that these will subside postfixation of fractures spanning over the entire orbit.

A systematic review recommends IV steroids with more than 50% of cases showing spontaneous recovery. Surgical decompression to relieve optic sheath hematoma and edema has no proven efficacy as per another systematic review. Neuroprotective effects of steroids have been ascribed to their antioxidant properties, inhibition of free radical-induced lipid peroxidation, and reduction of swelling. Most reported studies have prescribed steroid therapy without surgical intervention to prevent more secondary injury to mitigate primary damage.

Hence, patients with TRON were prescribed a medicinal line of management with injection methylprednisolone 1 g IV 8 hourly for 5 days, continued with oral 1 mg/kg body weight 8 hourly dose tapered every 3 days by 10 mg for 2 weeks. These patients underwent ORIF only after the completion of 10 days of steroid therapy to allow for the resolution of edema. No patients underwent surgical decompression of the optic nerve region for the treatment of TRON.

VEP was used to confirm damage to visual pathway, believed to be reliable to assess visual function. Five patients presented with abnormal VEP of which all improved except one. The color desaturation test assesses the integrity of the optic nerve by testing the ocular sensitivity to red color but there is the questionable benefit of this test if both eyes are affected.

Enophthalmos occurs more frequently in orbital floor fractures than with medial wall fractures with the force of gravity displacing intraorbital contents into the maxillary sinus. Fractures that involve >50% of the floor, defects >1 cm² in area, and hypoglobus or enophthalmos >2 mm need surgical attention and intervention. Floor defects may not necessarily cause enophthalmos if the integrity of the soft tissue fascial sling supporting the eye is intact. The orbital suspensory system is an architectural marvel wherein Lockwood’s suspensory ligament carries the globe like a hammock.

Although not blinding, diplopia and motility disorders are equally dysfunctioning and disturbing with a high reported incidence of 74.5%. Diplopia resolved completely posttreatment in all patients.

The globe can be compared to a ball housed in a cup: the skeletal orbit. OV measured on imaging can help determine the degree of discrepancy as compared to the normal and serve as a guide for restoration. Near normal OV restoration was achieved in 9 patients, with slight under-correction in 4 patients and overcorrection in 2. The mean OV of the postoperative orbit was comparable to the normal contralateral orbit indicating near-normal correction paralleled to OV measurements in the literature.

Orbital defects have been classified based on a combination of fractures spanning over the entire orbit. In the present study, the spatial division of the orbit into zones based on lines connecting standard landmarks on the medial wall helped to decipher zone-wise OV discrepancy.

Volume disparities were most commonly a direct result of comminution in Zone 3.

The highest volume discrepancy and restoration were seen in Zone 3 followed by Zone 2 with no change in Zone 1. Postoperative comparison with the normal contralateral orbit indicated good restoration with significantly better correction of Zone 3 as compared to Zone 2. Critical evaluation of the zonal influence indicates chances of enophthalmos to be higher in Zone 3 rather than Zone 2.

The efficacy and utility of a surgical jig and custom-designed orbital implant as a guide to improving the surgical outcomes were evaluated by calculating OVR%. The mean OVR% showed near-normal OV reconstruction for all patients. Three-walled involvement showed better outcomes than two. Even multiple OWFs were effectively corrected with the use of surgical jig and VSP.

The intraoperative surgical time was increased with multiple OWFs as the jig required stable adjacent bone which was
not available at all times. Limited surgical access rendered stabilizing and delineating fixation points difficult.

The outline and designing of a jig required proficiency by the skilled operator according to the defect and need of reconstruction. VSP is a giant leap forward to attain precision in orbital reconstruction, but the entire process is demanding in terms of time and involves a steep learning curve. Virtually designed surgical jig served as a useful tool to achieve precision in orbital reconstruction. The limitations of the current study are lesser sample size and absence of a comparator group to correlate different treatment modalities.

Ophthalmic injuries due to OWFs have a significant impact on function mandating thorough evaluation by an ophthalmologist. The authors propose a new classification for orbital fractures using Fx Mx Rx Lx coding to denote the involved walls and fracture severity allowing categorization from a treatment perspective.

**Conclusion**

The intact contralateral orbit served as a reference to evaluate symmetry, postoperative correction achieved, the precision of reconstruction, and to monitor clinical progress throughout follow-up. With VSP, it served as a template for reverse engineering of implants and fabrication of surgical jig.

Specific areas of OV discrepancy were concentrated in the middle and anterior zone reflecting in the ophthalmic parameters. Delineation into three zones accurately traced the zones contributing to volume discrepancies allowing precise consideration.

The surgical jig was deemed fit to be used intraoperatively achieving adequate anatomical reduction. The prebending of stock implants on mirrored 3D-SM enabled it to function as a jig in multiple OWFs saving valuable intraoperative time. In the absence of navigation and intraoperative CT, it rendered safe application without causing trauma to the deep orbit. Surgical jig aided the effective transfer of VSP intraoperatively and improved surgical outcomes in terms of clinical performance and functional restitution.

In summary, the use of VSP in orbital fractures is feasible. The surgical jig facilitates precise, near-normal OV restoration as an inexpensive adjunct to routine ORIF. To achieve optimum results, tailor-made implants should be focused upon to enable structural OV reconstruction. There is an urgent need to develop methods for soft tissue volumization as restitution of its delicate network is equally important as skeletal reconstruction.

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**Conflicts of interest**

There are no conflicts of interest.

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