EGYPTIAN DENTAL JOURNAL
www.eda-egypt.org
VOL. 71, 2093:2102, JULY, 2025
PRINT ISSN 0070-9484 • ONLINE ISSN 2090-2360
ORAL SURGERY
Submit Date : 24-05-2025 • Accept Date : 25-06-2025 • Available online: 10-07-2025 • DOI : 10.21608/edj.2025.388362.3494

PATIENT SPECIFIC 3D PRINTED TITANIUM MESH VERSUS COMPUTER GUIDED CALVARIAL BONE GRAFT FOR ORBITAL FLOOR RECONSTRUCTION (A RANDOMIZED CLINICAL TRIAL)

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ABSTRACT

Objective: In order to shed light on implant selection and application for globe position restoration and long-term enophthalmous prevention, the purpose of this study is to evaluate clinical enophthalmous assessment and gaze persistence in relation to orbital floor fractures using two different reconstruction materials.

Materials & Methods: 32 participants with recent unilateral orbital floor fractures were randomly assigned to 2 equal parallel groups for this study, the first group (study group) Patients were treated using 3D printed Patient Specific Titanium Mesh (PSTM) and the second group (control group) were treated using guided Calvarial graft, which took place between March 2022 and January 20224. Evaluations of clinical enophthalmous assessment and gaze persistence were carried out.

Results: Regarding Restoration of Clinical exophthalmometry (enophthalmous) correction (P-value > 0.05), the study finds no differences between the two groups. However, PSTM achieves superior results in Gaze Persistence.

Conclusion: Within the constraints of this investigation, the following conclusions could be drawn. Firstly, a patient-specific titanium implant compared to treatment of orbital fracture using guided calvarial bone shows no significant difference in clinical exophthalmometry. Secondly, in terms of gaze persistence consumption and donor sight morbidity, Patient specific PSTMs performed marginally better.

KEYWORDS: implants, PSTM, orbital mesh, guided calvarial graft and patient-specific implants.

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INTRODUCTION

Orbital floor fractures are a common consequence of midface trauma, often resulting from blunt force injuries such as road traffic accidents, assaults, or sports-related impacts. These fractures can lead to herniation of orbital contents into the maxillary sinus, causing clinical complications such as enophthalmos, diplopia, and restricted ocular motility due to changes in orbital volume and muscle entrapment [1]. The thinness of the orbital floor, particularly in the posteromedial region, makes it susceptible to "blowout" fractures, where the bone fails under hydraulic pressure or direct force transmission [2]. Timely and precise reconstruction is essential to restore anatomical integrity, prevent long-term functional deficits, and optimize aesthetic outcomes, making the choice of reconstructive material a critical consideration in surgical management.

Following facial trauma, orbital fractures are extremely prevalent. A thorough oculo-facial examination and radiologic imaging are part of the evaluation of a patient with a suspected orbital wall injury. It may be necessary to do surgery with or without an implant to treat enophthalmos, diplopia, or both. [3]

The orbit has an average volume of 30 cm3 and is fashioned like a quadrilateral pyramid made up of seven bones. It is a paired, transversely oval, cone-shaped osseous chamber that is formed and circumscribed by the viscero-cranium, anterior and middle cranial bases. [4]

Enophthalmos or so-called hypophthalmos may be caused by eye globe displacement due to bony orbital cavity enlargement [5]. A "sunken eye" in the acute post-traumatic stage may be caused by the so-called "retraction syndrome"; an entrapment of the inferior rectus muscle makes the superior rectus muscle exerting a strong counter-action inward pull of the eye ball. The Enophthalmos degree is usually related to the severity of the trauma.[6]

Ti-mesh has demonstrated excellent biocompatibility and integration of fractured bones. These attributes, along with low infection rates, excellent flexibility, and high resiliency, make it a strong candidate for upcoming CAD/CAM technologies, such as laser centering techniques in 3D printing. High stability and rare dislodgment cases also contribute to low implant migration coefficient.[7]

Through the use of virtual surgical planning (VSP), which is a digital process that manipulates large-scale imaging data in three dimensions, it is possible to create customized implants and surgical guides as well as replicate intricate anatomic models. Oral and maxillofacial surgeons now have access to crucial tools because of these improvements. Every stage of the workflow process—image modality selection, data collection, patient workup, virtual planning session, and surgical execution—affects how well these virtually planned cases turn out. The likelihood of success in the operating room can be increased by carefully planning ahead, even if every step of the case is crucial.

This study aims to evaluate clinical enophthalmous assessment, length of operation, and gaze persistence associated with orbital floor fractures in order to provide light on implant selection and use for globe position restoration and long-term enophthalmous avoidance.

MATERIAL AND METHODS

This Study was carried out in Oral & Maxillofacial Surgery (OMFS) Departments at Faculty of Dentistry – Cairo University from October 2021 to June 2023.

The inclusion criteria in this paper was as follows:

1. individuals who had contralateral healthy, non-operated orbit and a unilateral orbital floor fracture, either alone or in conjunction with other facial fractures.

2. Patients who had presented with fresh trauma not more than 14 days.
3. both genders were included in the study.

Exclusion criteria will include Patients with craniofacial anomalies or syndromes, irradiation in the head and neck region less than six months to a year prior to the procedure, mental health issues or irrational expectations, inability to tolerate follow-up intervals or patient who had previous orbital reconstruction.

The study design was Randomized Clinical Trial, Convenient sample. The final total sample size was planned to be 32 cases, 16 cases in each group with equal probabilities for intervention and allocation ratio (1:1). Each group of patients received a single treatment simultaneously. This randomized clinical trial was approved by the Ethical Committee of Faculty of Dentistry, Cairo University.

The patients were randomly assigned into two identical groups according to a computer- generated randomization list by using special software:

- **Study group (Group 1):** Patients with unilateral orbital fracture treated using 3D printed Patient Specific Titanium Mesh (PSTM)
- **Control group (Group 2):** Patients with unilateral orbital fracture treated using guided Calvarial Bone Graft.

Pre-surgical preparation:

A. medical history and data collection:

- Historical data were gathered including medical, dental, familial and previously carried-out surgical operations' history.
- The personal data (age, sex & mechanism of injury) and chief complains were gathered and recorded.
- Clinical measurements were taken to ensure patient adherence to our initial inclusion criteria prior to further investigations.
- A multi-slice CT scan was requested in a digital form (Dicom files) with a slice thickness and distance no more than 1 mm with a gantry entry zero position.

A pre-operative examination of forward displacement of the eye using a Hertel Exophthalmometer and upward gaze were done and documented.

B. Pre-operative Virtual Surgical Planning

For Control Group:

(1) Dicom files from previously ordered CT Scan were imported to Mimics®* Software. after bone thresholding and bone segmentation (Fig 1 A&B), virtual bone reduction using mirror of the unaffected side as a guide (Fig 1 C).

(2) Orbital floor defect is identified and outlined, producing a defect shell which was adapted on parietal bone at the most satisfying location according to most thickness and curvatures mimicking orbital floor.

(3) Using 3-Matic ®[2] software, a surgical cutting guide is produce into a certain thickness (at least 2mm) and rechecked on 2D and 3D views to insure maximum adaptability virtually, then (. STL) files is exported to 3D Printer with using Poly-lactic acid (PLA) Fused Filament Fabrication (FDM) material for Guide and Model Printing. (Fig 1 D).

***For Study Group*:**

1- Same steps used for Study group (segmentation, virtual reduction and mirroring), surface marking for the defect shell was then produced using 3-matic ® software. (Fig 2 A&B)

2- Extrusion of the surface marking to given thickness (not exceeding 1 mm), the primary

* MIMICS® v.19.0 software (Materialise Interactive Medical Image Control System, by Materialize NV Technology 15, BE – 3001 Leuven, Belgium)

2 3-Matic R v.13.0 software (Materialise Interactive Medical Image Control System, by Materialize NV Technology 15, BE – 3001 Leuven, Belgium)

plate was then Checked on the 2D view to ensure maximum adaptability and to check for interference between both the model and the mesh. (Fig 2 C)

3- Finishing which include plate margin smoothing, screw site placement and final Boolean Subtraction with 0.05 mm clearance. (Fig 2 D)

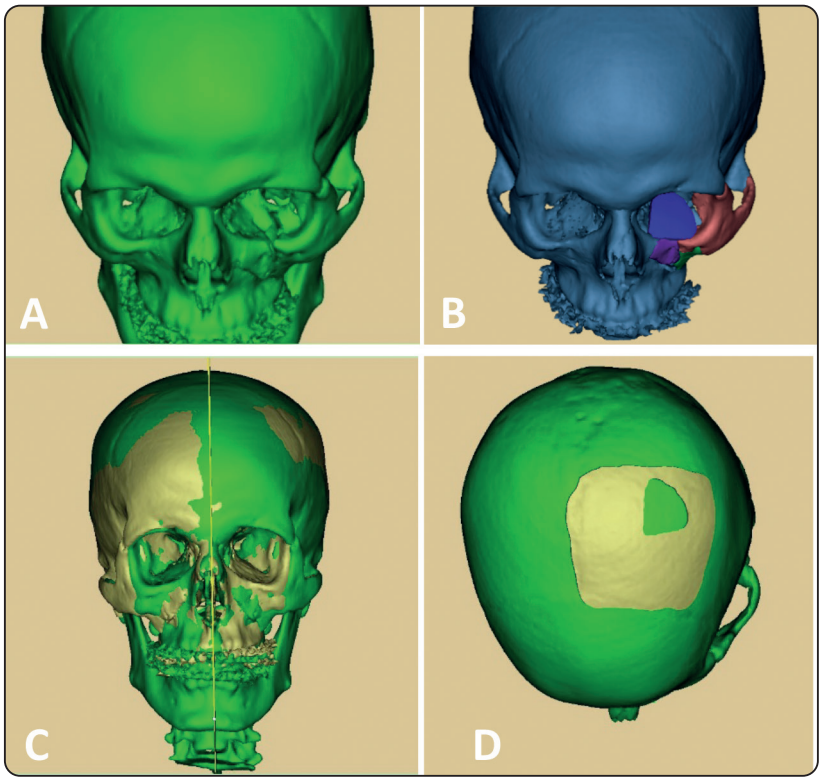

Fig. (1) Snap-shots showing Bone Thresholding (A), bone segmentation and defect Shell (B), Mirroring and virtual reduction(C) and Surgical Guide construction on the cranium (D).

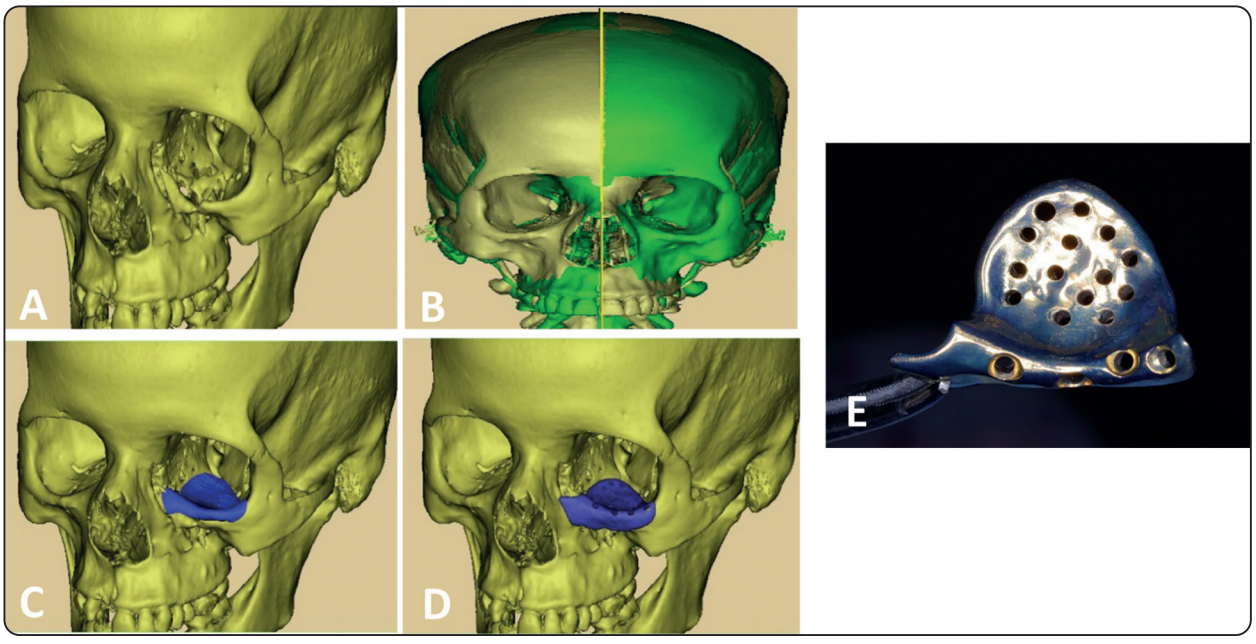

Fig. (2) Snap-shots showing Bone Thresholding (A), Mirroring and defect Shell (B), Primary shell adaptation(C), final plate adaptation on skull (D) and final 3D Printing of the PSTM (E).

Surgery:

For control group, preparation of the patient hair was done. Under General Anasthesia, a vasoconstrictor was injected into the sub-galeal plane to promote hemostasis and to help separate the tissue layers. A laterally placed incision in the parieto-temporal region was used, the incision was designed away from the graft site, as there is a tendency for the incision to scar down to the underlying graft bed. The surgical guide was positioned and checked for stability and accuracy. The borders of the required graft were marked using a micro-disk or Piezoelectric tip, then the osteotomy were further deepened and slightly beveled to the spongy diploe of the skull bone. Once the required level is reached, undermining was performed with bone chisels until the outer table of the bone lock is freed, then the bone block will be inserted and seated on the printed Skull Model to assure stability.

For all groups**,** all cases underwent surgery under General Anesthesia (GA) with Oral or Naso-tracheal intubation. To control bleeding and decrease post-operative pain, Local anesthesia {(Xylocaine HCL 2%) with vasoconstrictor (Adrenaline 1: 100,000)} was administered trans-conjunctively and subcutaneously at area of lateral canthal tendon. Surgical approach was done pre-septal trans-conjunctival with/without lateral canthotomy and inferior cantholysis according to the case. (Fig 3 A)

Periosteal elevators are used to strip the periosteum over the orbital rim and anterior surface of the maxilla and Zygoma, and the orbital floor, a broad malleable retractor was placed as soon as feasible to protect the orbit and to confine any herniating periorbital fat. (Fig 3 B)

Blunt dissection was done to expose the whole fractured floor till the area of sound bony structures. Implants of both Groups were inserted and checked for coverage, Stability and adaptation. (Fig 3 C)

Fixation using Mini or Micro-Screws for Intervention groups in the previously planned and milled holes. Fixation of Control group include single Screws through the bone graft in the lower orbital rim or an extra Micro-plate bent over the rim. (Fig 3 D)

A forced duction test is completed to ensure the complete release of the periorbital tissues and unrestricted movement of the globe.

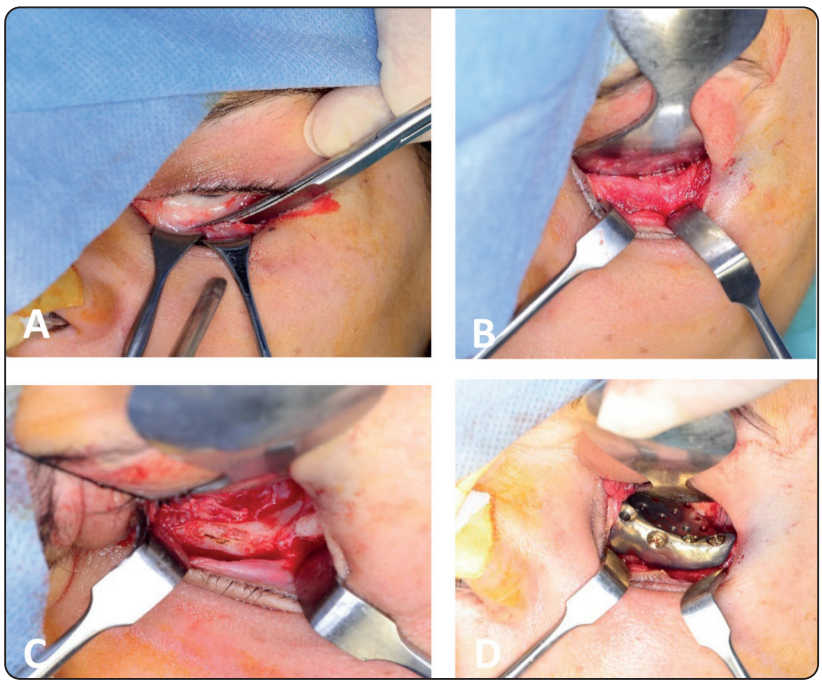

Fig. (3) Photographs Transconjuctival incision (A), Periosteal Elevation and Defect Exposure (B&C) and adaptation and fixation of the PSTM (D).

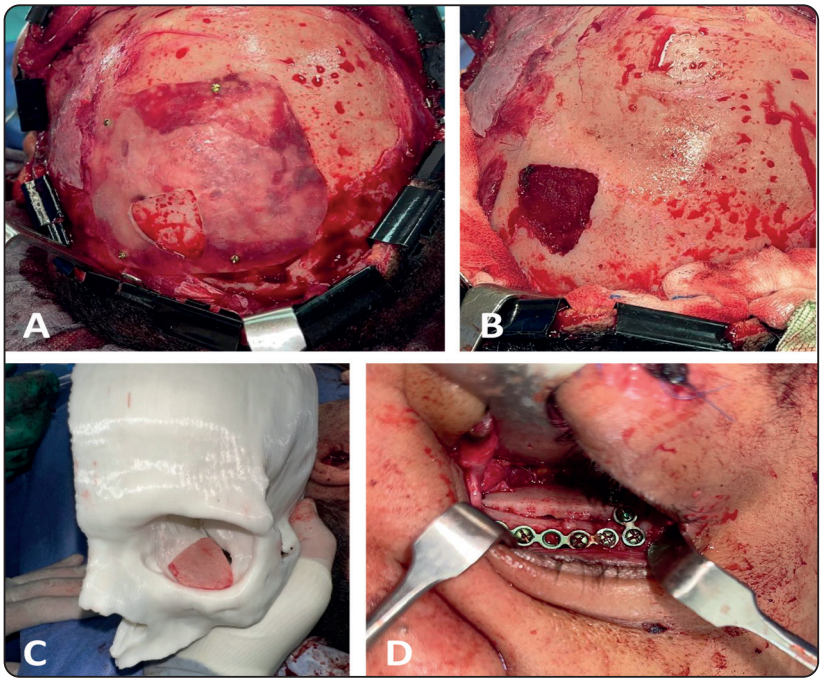

Fig. (4) Photographs showing Adaptation and Fixation of Surgical Guide (A) Harvested Graft and Checking it on printed model (B&C), Calvarial Bone Adaptation and Fixation (D).

Postoperative care and medications:

- Ice packs for 20 minutes/ 1 hour in the 1st 24 hrs. post-operatively.
- Warm fomentations for the 2nd 24 hrs. for 10 days post-operatively.
- (Unasyn®)* 1.5 gm intramuscular injection twice a day / each 12 hrs. for 5 days post-operatively.
- (Voltaren®)** 75 mg intramuscular injection twice a day / each 12 hrs. for 4 days post-operatively.
- (Decadron®)[2] 4 mg intramuscular injections every 6 hrs. for the first post-operative day, then half the dose every 6 hrs. at the second day post-operatively.
- (Depo-Medrol®)[3] 40 mg intramuscular injection two vials as 80 mg with the last half dose of Decadron®.
- (Tobradex®)[4] ophthalmic ointment 3 times / day for 3 days post-

All patients of both groups were examined clinically, during postoperative one week, three months and 6 months. Patients were evaluated for the following clinical parameters:

- Facial asymmetry by clinical photos.
- Enophthalmous by clinical photos and Hertel Exophthalmometer measurement.
- Eye gazes.
- Diplopia.
- Sensory nerve function of ION.

Recorded data were analyzed using the statistical package for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA). The quantitative data were presented as mean± standard

* Unasyn®, Sultamicillin, Ampicillin sodium/ sulbactam sodium, Pfizer Egypt S.A.E under authority of Pfizer Inc., USA

** [1] Voltaren®, Diclofenac Sodium, Novartis Pharmaceuticals Co.

1 Decadron®, Dexamethasone Sodium Phosphate, Msd., E.I.P. Co. under license of Merck & Co., N.J., U.S.A

2 Depo-Medrol®, Methylprednisolone Acetate, Pfizer Egypt S.A.E under authority of Pfizer Inc. U.S.A.

3 Tobradex®, Tobramycin and dexamethasone ophthalmic ointment, Novartis Pharmaceuticals Co.

deviation and ranges when their distribution was parametric (normal) while non-normally distributed variables (non-parametric data) were presented as median with inter-quartile range (IQR). Also, qualitative variables were presented as number and percentages. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk Test.

RESULTS

Gender and age distribution:

This study comprised 32 adult patients with unilateral orbital fractures; the patients' ages varied from 19 to 59 years for the PSTM group (Intervention) and the guided calvarial group (Control). The age mean ±SD for the PSTM Group was (28.60±8.37) and for the Guided Calvarial Group the mean ±SD was (36.80±13.47). In terms of gender distribution, the male to female ratio in this experiment was (24:8) due to the distribution of males to females in the control group (8:2) and the intervention group (7:3) **(Figure 5).**

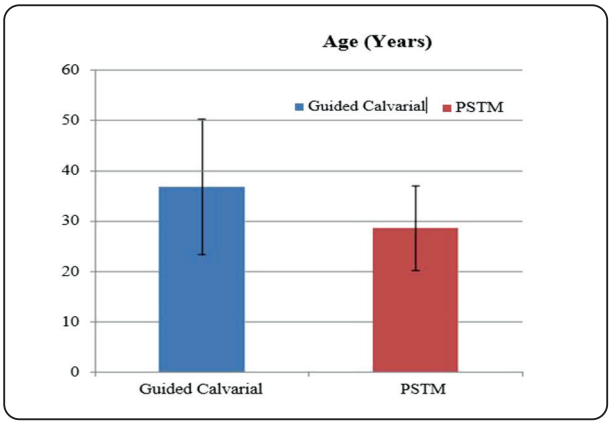

Fig. (5) Comparison between PSTM and Guided Calvarial according to Age (years).

Clinical Exophthalmometer Measurement

Exophthalmometer (mm) in Pre-Operative, Post-Operative, and MD (Pre-Post) indicates no statistically significant difference between the PSTM group and the Guided Calvarial group in this table, with a p-value of (p>0.05). **(Table 2).**

TABLE (2) Comparison between PSTM and Guided Calvarial according to Amount of change between (affected & non affected) about Exophthalmometer (mm).

Exophthalmometer (mm)	Type of Implant		Test value	p-value	Sig.
	Guided Calvarial (n=16)	PSTM (n=16)			
Pre-Operative					
Mean±SD	1.10±1.53	0.67±2.01	-0.687	0.492	NS
Median (IQR)	1.5 (-0.5_2.5)	1 (-1.5_2)			
Post-Operative					
Mean±SD	0.37±0.85	0.17±0.72	-1.049	0.294	NS
Median (IQR)	0.5 (0_1)	0 (0_0.5)			
MD (Pre-Post)					
Mean±SD	-0.73±1.92	-0.50±1.88	-0.250	0.802	NS
Median (IQR)	-0.5 (-1.5_0.5)	-1 (-2_1)			

Using: U=Mann-Whitney test for Non-parametric data "Median (IQR)"
NS: Non significant; S: Significant; HS: Highly significant
MD: Median difference

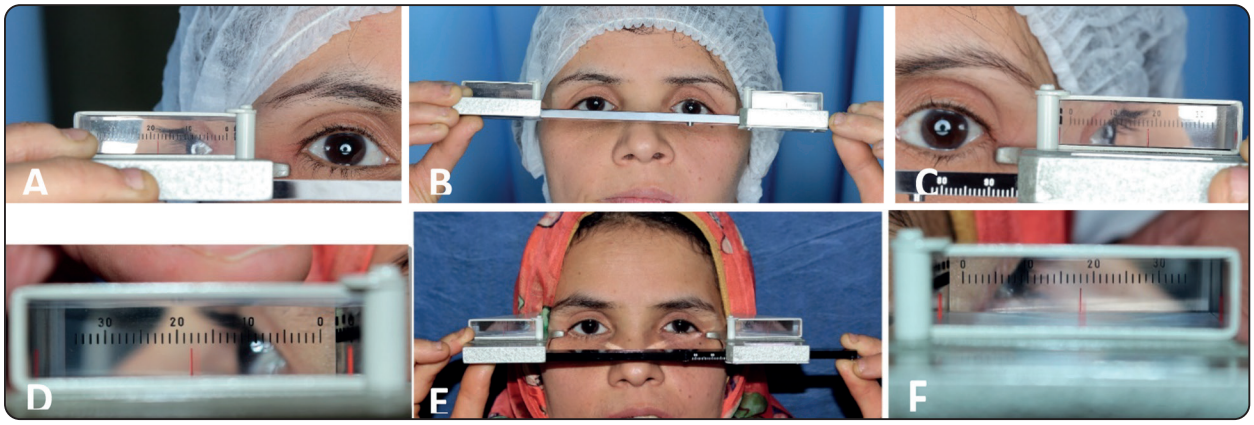

Fig. (6) Comparison between pre-operative (A-C) and post-operative (D-F) exophthalmometry reading using Hertel exopthalmometer in study group.

This table shows no statistically significant difference between PSTM group and Guided Calvarial group according to Exophthalmometer (mm) in Pre-Operative, Post-Operative and MD (Pre-Post), with p-value (p>0.05).

Concerning Gaze Persistence This table shows statistically significant higher frequency of Gaze pre-operatively in Guided Calvarial group was 7 patients (46.7%) comparing to PSTM group was 2 patients (13.3%), with p-value (p=0.046); while there is no statistically significant difference between two groups according to aesthetic post-operative, with p-value (p>0.05). **(Table 3).**

TABLE (3) Comparison between PSTM and Guided Calvarial according to Gaze Persistence.

Gaze	Type of Implant				Test value	p- value	Sig.
	Guided Calvarial		PSI				
	No.	%	No.	%			
Gaze Pre-Operative							
Yes	7	43.7%	2	12.5%	3.968	0.046	S
No	9	56.2%	14	87.5%			
Gaze Post-Operative							
No	13	81.2%	16	100.0%	3333	0.068	NS
Yes	3	18.7%	0	0.0%			

Using: x^2: Chi-square test/or Number (%) or Fishers exact test, whenappropriate NS: Non significant; S: Significant; HS: Highly significant

DISCUSSION

Well-considered to be among the most common types of fractures in the maxillofacial region [8–9], orbital floor bone fractures account for roughly 30–40% of all facial fractures, whereas isolated orbital floor fractures represent a smaller subset, accounting for 4%–16% of cases. [10–11]

This trial advocated the early surgical intervention as Close to 2 weeks from the trauma in the indicated cases, as many studies advocated this after the slight resolution and healing of Peri-orbital swelling and edema for better assessment of pre-operative enophthalmous and diplopia. Two studies in the literature recommended the early surgical repair as it results in rapid improvement of ocular motility and diplopia. Due to the quick improvement in ocular motility and diplopia that occurs from early surgical repair.[12-13]

Our results regarding Clinical enophthalmous correction showed **no Statistical significance difference** (*P*-value > 0.05) between both groups at 6-months (*P*-value 0.802).

The Mean and Standard Deviation in deference between Pre- and Post-Operative in Guided Calvarial Group(Control) was (-0.73±1.92) mm with P-Value 0.154, and the PSTM group (Intervention) was (-0.50±1.88) mm with a P-Value 0.341, both groups showed **no Statistical significance difference** in terms of changes between Pre-and Post-Operative Clinical Globe Position (exophthalmometry).

Supporting our data, a study conducted by *Zimmerer et al.,* (195) patients were divided into two groups: 95 patient's received individualized orbital implants and 100 patients treated with standard preformed orbital mesh. Patient where followed up for a period over than 12 weeks and the variance of these differences between affected and unaffected globe position was 1.6 mm for standard preformed implants and 1.3 mm for individualized implants, which was also not statistically significant (p=0.423).[14]

On the other hand, a study *Subramanian, Abinaya, et al*. on the reliability of Intra- and Post-operative measurement of modified hertel exophthalmometer, a 20 patients with unilateral orbital floor fractures where assessed intraoperatively, 7 days,1 & 2 & 3 months after surgery by comparing normal to reconstructed sides. Results came in Significance manner in comparison between intra operative and 3 months after surgery where mean deference was –0.750±0.716 and P-Value 0.000*.[15]

A Systemic review by ***Kotecha, Sanjeev***, five studies reported a specified measurement of postoperative Enophthalmos between conventional and patient specific groups**.** Pooled weighted mean post-operative difference in Enophthalmos (between postoperative and unaffected orbits) was 1.39 mm (SD 1.40) for the conventional group compared to 0.55 mm (SD 0.76) for the patient-specific group. Meta-analysis, however, identified no significant difference in Enophthalmos between the two groups in these studies.[16]

A significant limitation of the Hertel exophthalmometer stems from its reliance on the lateral orbital rim or zygomatic bone as a reference point for measurement. This can pose challenges, particularly in cases involving fractures of the zygomatico-frontal region, where anatomical landmarks may be distorted or unstable. Additionally, several factors influence globe projection, including orbital fat herniation, muscle fibrosis or scarring, and prolonged surgical manipulation required for the adjustment and adaptation of semi-malleable orbital implants.[15]

Regarding Gaze Persistence, PSTM Group the Ration of Gaze – Non gaze was (2-14) preoperatively, and changed to (0-16) with no persistence in Gaze postoperatively. On the other hand, the Guided Calvarial group had a ratio of Gaze to non-gaze of (7-9) pre-operatively and changed to (3-13) Post operatively with three patients with persistent gaze after 6 months.

Persistent gaze exhibition in Control group can be interpreted due to increased thickness of graft,

less accurate contour and less smooth surface promoting muscle entrapment while inserting and adapting the Calvarial graft.[17-18]

CONCLUSION

Within the constraints of this investigation, the following conclusions could be drawn. Firstly, a patient-specific titanium implant compared to treatment of orbital fracture using guided calvarial bone shows no significant difference in clinical exophthalmometry. Secondly, in terms of gaze persistence consumption, donor sight morbidity, titanium mesh-type PSTMs performed marginally better.

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