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CLINICAL AND RADIOGRAPHIC ASSESSMENT OF EARLY VERSUS DELAYED REDUCTION IN ORBITAL TRAUMA: RANDOMIZED CLINICAL TRIAL (RCT)

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ABSTRACT

Aim of the study: This study aimed at clinical & radiographic assessment of early versus delayed reduction in orbital fractures.

Methodology: Twenty patients with orbital fractures were randomly allocated equally into two groups; Group I underwent Open reduction internal fixation (ORIF) within the first week following the trauma; meanwhile the other group (Group II) underwent delayed surgical intervention (ORIF) more than two weeks after the trauma. Clinical assessment was conducted to precisely evaluate any limitations in ocular motility and the presence of diplopia. For radiographic assessment, each patient underwent computed tomography (CT) scanning twice. Preoperative CT scans were performed to evaluate bone structures and fractures, while immediate postoperative CT scans were obtained to assess globe positioning in terms of exophthalmos or enophthalmos and to measure orbital volume for comparison with the unaffected contralateral side.

Results: All patients in both Groups I & II exhibited a 2 mm improvement in enophthalmos/exophthalmos. All cases of infraorbital hypoesthesia resolved by the final follow-up, and no complications related to orbital implants occurred. In terms of orbital volume, Group I had an average postoperative volume of 31.87 mm^3 in the fractured orbits, compared to 38.36 mm^3 in the contralateral orbits ($P = 0.003$). Group II showed a postoperative volume of 30.19 mm^3 in fractured orbits and 34.43 mm^3 in contralateral orbits ($P = 0.023$); reflecting significant improvement in both groups with no significant difference.

Conclusion: Both groups showed comparable results in terms of clinical and radiographic outcomes.

KEYWORDS: Orbital fractures, orbital reconstruction, timing, ORIF, trans-conjunctival approach.

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INTRODUCTION

Orbital fractures are among the most commonly encountered facial fractures and present a challenging clinical scenario. Various classification systems describe orbital fractures; they can vary in severity from simple isolated to more complex multi-wall fractures. Depending on the extent of the injury, complications can arise, significantly impacting both function and esthetic. (1–3)

The orbit's anatomy is complex consisting of different seven bones that build a protective shield for the eye. This complexity complicates the evaluation and management of orbital fractures making precise assessment essential to prevent complications. Furthermore, concomitant globe injuries account for 29 % of orbital fractures which necessitates appropriate clinical and radiographic examinations to assess the extent of these traumatic injuries and associated globe injuries. Advances in imaging techniques, especially computed tomography (CT), have significantly improved diagnostic accuracy, enabling clinicians to effectively evaluate fracture patterns and assess soft tissue involvement. Such innovations have enhanced treatment planning, ultimately helping to reduce the risk of long-term complications. (1,4–6)

Management strategies for orbital fractures remain a topic of debate among maxillofacial surgeons and are tailored to the specific type, timing, and severity of the injury. The choice of appropriate treatment modality either conservatively with close observation or surgical intervention is based on the clinical, radiographic findings and additionally on the assessment of the risk and benefit of each treatment modality. Surgical techniques range from minimally invasive endoscopic procedures to complex open repairs, depending on the extent of the damage and time of the injury. The goals of surgery are not only to restore the anatomical structure of the orbit but also to re-establish proper orbital bones alignment and function while achieving an aesthetically pleasing outcome. There are several surgical approaches for orbital repair including sub-ciliary, trans-conjunctival and others. Moreover, several bone implants can be used for fracture repair including titanium mesh, porous polyethylene, autogenous bone grafts and different types of alloplastic materials. (1,7–9)

Despite the significant advancements in diagnostic and treatment modalities of orbital fractures, the appropriate timing for surgical intervention continues to spark debate. Some research suggests that performing surgical repair within two weeks of injury is linked to more favorable outcomes regarding complete restoration of ocular mobility and resolution of diplopia. On the other hand, other studies advocate delayed surgical intervention (> 2 weeks). Nonetheless, there is lack of evidence for how early surgical treatment of orbital fractures should start and how prognosis is influenced when surgical treatment is delayed. Additionally, disorders of traumatic ocular mobility occasionally undergo spontaneous recovery with subsequent no need for surgical intervention. (10–12)

Consequently, this research aimed at further assessment of early versus delayed management of orbital fractures in terms of clinical and radiographic outcomes.

MATERIAL AND METHODS

Study Design

This randomized study included 20 patients with orbital fractures since (August 2023 to January 2025); Patients were selected from Out Patient Clinic of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Cairo University). This study was approved by the research ethics committee of Faculty of Dentistry, Cairo University with the reference number: 70723. The study was performed as the CONSORT guidelines 2010 **(Figure 1)**.

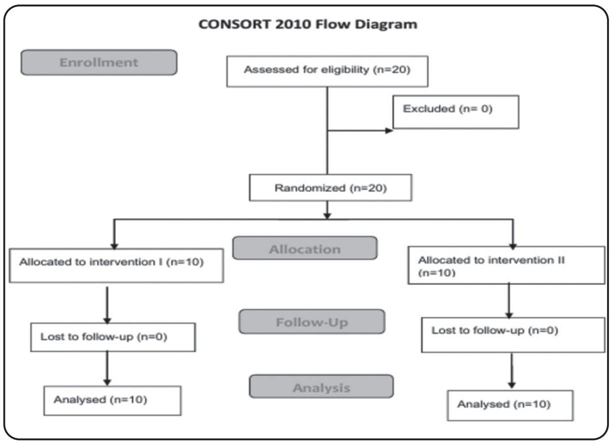

Fig. (1): CONSORT statement flow chart

Randomization and Allocation

Participants in this study were allocated randomly into two equal groups without bias. Randomization was performed using computer-generated random sequence, and allocation concealment was carried out using sealed opaque envelops ensuring blinding was preserved throughout the study. Group I underwent Open reduction and internal fixation (ORIF) within the first week following the trauma event, while Group II underwent delayed surgical intervention (ORIF) more than two weeks after the trauma. Patients were selected according to the following inclusion criteria: (1) patients with at least a unilateral orbital fracture indicated for ORIF, either alone or in combination with other facial fractures, (2) patients with an age range from 18 to 50 years, (3) both sexes were included, (4) patients with a good general condition allowing major surgical procedures under general anesthesia & (5) patients with physical and psychological tolerance. Meanwhile, the following exclusion criteria were adopted; (1) patients with mal-union fractures, (2) patients not fit for general anesthesia, (3) patients with significant concomitant facial fractures, (4) patients with high risk systemic diseases interfering with normal bone healing & (5) patients with physical and psychological intolerance.

Intervention

The operation was performed under general anesthesia with oral intubation under complete aseptic condition according to the standard oral and maxillofacial operating room procedures. Careful examination of the orbital fractures and forced duction test were performed for accurate assessment of the orbital fractures and ocular mobility. Then a corneal shield was placed for corneal protection and two traction sutures through the tarsal plate were placed in the lower eyelid using 4-0 black silk. After that, the orbital rim was exposed via trans-conjunctival approach (retro-septal approach) to gain access to the fractured segments. Then the fractured segments were reduced and assessed. The fractured segments were fixed using 2.0 Titanium plate utilizing bone screws. Then another forced duction test was performed after fixation to ensure that there was no muscle entrapment. The trans-conjunctival incision was sutured via running 5-0 gut sutures. Finally the lower eyelid was suspended using Frost suture. [13]

Clinical assessment

Patients were evaluated for persistent diplopia, and gaze disturbances; subjectively and documented clinically using a binary classification (yes/no).

Radiographic Assessment:

For each patient in both groups, CT scan of the facial bones (Axial cuts, DICOM file, Gantry tilt zero and minimal thickness of 0.6mm) was obtained pre-operatively for accurate assessment of the side and type of fractures, degree of displacement, and the presence of additional facial fractures.

Additionally, another immediate postoperative CT scan of the facial bone was obtained (using the same preoperative imaging protocol) for assessment of the surgical outcomes in all patients of both groups.

The DICOM images were imported to Mimics 19.0 *(Materialise, Leuven, Belgium)* and assessed by two oral and maxillofacial radiologists (15+ years of experience).

Post-operative radiographic assessment:

In all patients of both groups the following measurements were obtained, then the results were compared

Enophthalmos/ exophthalmos assessment

On the axial cut immediately below the level of optic foramen, the maximum linear distance measured from the middle of superior orbital fissure till the maximum bulging point of the eye globe in the surgically corrected orbit and in the unaffected contralateral orbit **(Figure 2, Figure 4).**

Orbital volume measurements:

The volume of orbit in both the surgically corrected and unaffected orbit was obtained by semiautomatic segmentation using Mimics Medical 19.0 and started by customizing the threshold of soft tissue. The threshold range was manually adjusted by changing the minimum and maximum values (-700 and +225); only to include the voxels falling within the designated soft tissue range and a color-coded mask was automatically created. The mask was cropped to be confined to the orbit borders only to include the most posterior, medial, lateral, superior, and inferior points of the orbit.

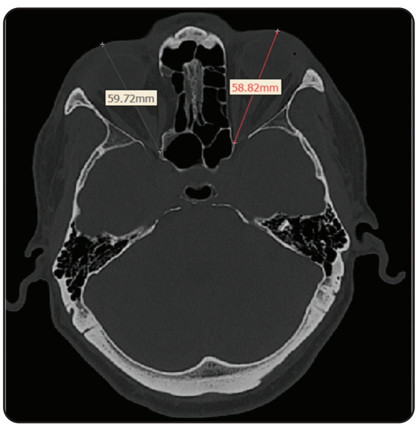

Fig. (2): Axial cut of patient in group I for linear measurements of the (globe-apex) distance as an indicator of enophthalmos.

In all cases, nearby contacting soft tissue voxels were inadvertently included within the predefined ROI giving inaccurate estimation. Consequently, editing was conducted by erasing areas of over-estimated areas or even adding deficient un-segmented areas. The volume of the final mask of orbit was calculated and 3D orbit volume was reconstructed (**Figure 3 (a, b) and Figure 5 (a, b)).**

All the measured were recorded and prepared for statistical analysis.

Descriptive statistics were reported as range, mean ± standard deviation (SD), and percentages where applicable. Comparisons between study groups were performed using Student's t-test or one-way ANOVA for independent samples, while within-group comparisons were analyzed using the paired Student's t-test. A P-value of less than 0.05 was considered statistically significant.

All statistical analyses were conducted using SPSS version 18 (Statistical Package for the Social Sciences; SPSS, Inc., Chicago, IL, USA) on Microsoft Windows.

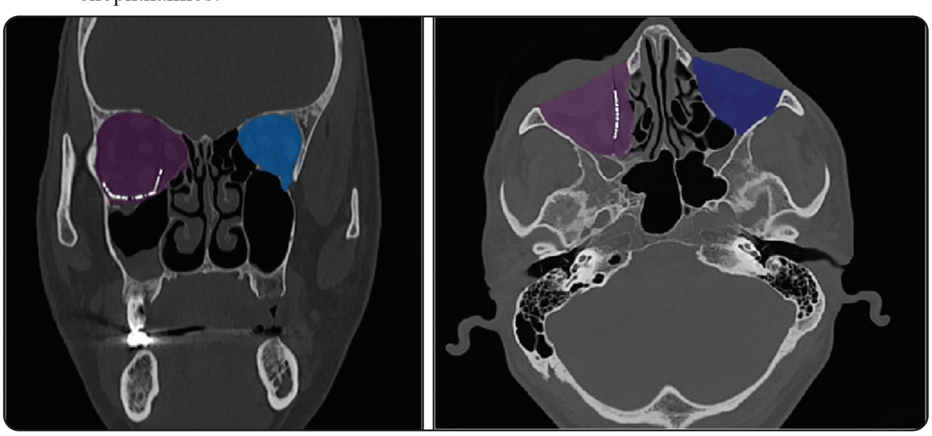

Fig. (3) (a): Coronal and axial cuts of patient in group I of semiautomatic segmentation of the orbital soft tissue contents by thresholding to calculate the orbital volumes.

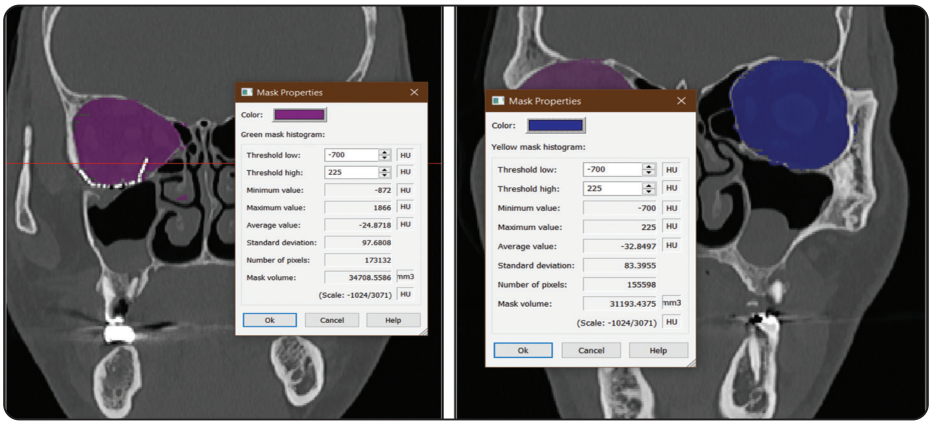

Fig. 3 (b) The volume of the orbit with fracture and the contralateral side was reconstructed with a calculated value of 34.70mm³ and 31.19 mm³respectively.

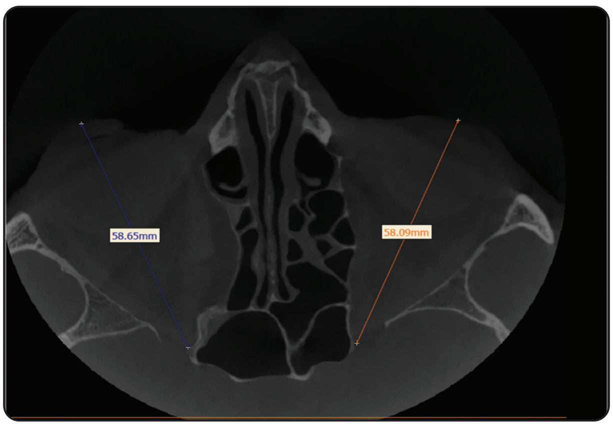

Fig. (4) Axial cut of patient in group II for linear measurements of the (globe-apex) distance as an indicator of enophthalmos.

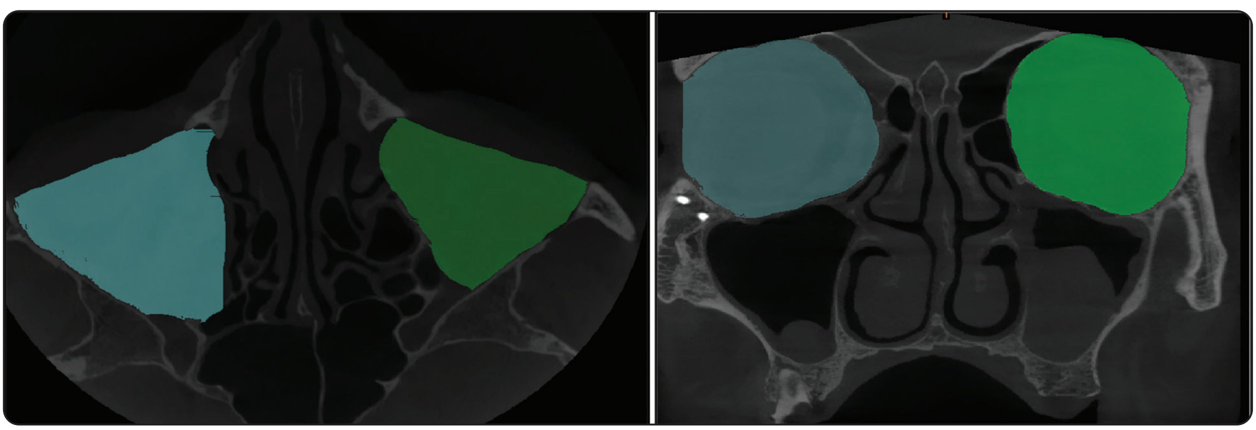

Fig. (5) (a) Coronal and axial cuts of patient in group (2) of semiautomatic segmentation of the orbital soft tissue contents by thresholding to calculate the orbital volumes

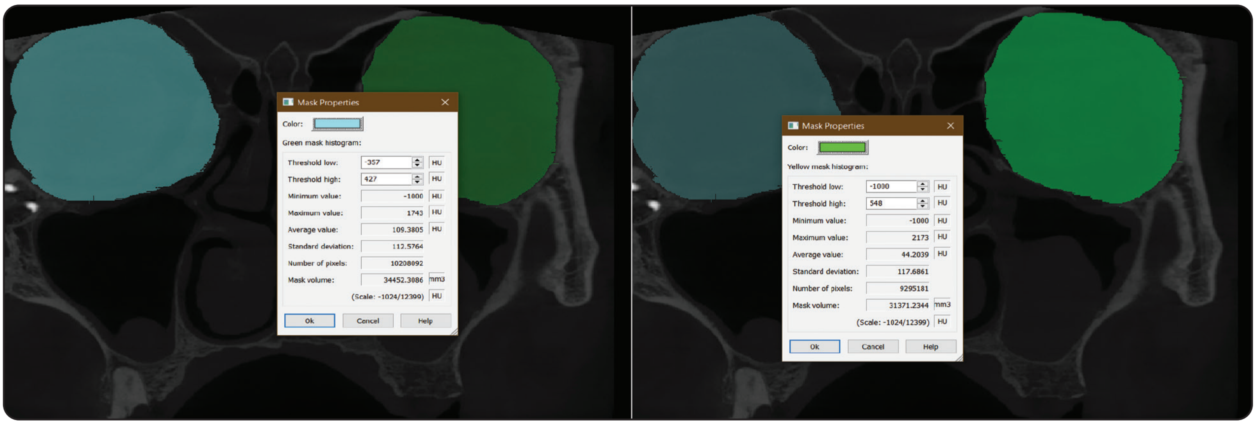

Fig. (5) (b) The volume of the orbit with fracture and the contralateral side was reconstructed with a calculated value of 34.43 mm³ and 31.37 mm³respectively.

RESULTS

The study included 20 patients, with a mean follow-up duration of 16.2 ± 3.03 months. Of these patients, 17 were male (85%) and 3 were female (15%) **(Figure 6)** the ages of the participants ranged from 17 to 45 years, with an average age of 31.4 years. The distribution of patients by age was as follows: 14 patients (70%) were under 20 years old, 3 patients (15%) were between 21 and 30 years, 2 patients (10%) were aged 31 to 40 years, and 1 patient (5%) were between 41 and 50 years **(Figure 7).**

Before surgery, 11 patients experienced restrictions in extraocular muscle movement. By the final follow-up, all cases had improved, and no residual diplopia was detected postoperatively. Infraorbital hypoesthesia was reported in six patients before surgery, but all cases had fully resolved by the final follow-up. No complications related to orbital implants, such as infection, dislocation, exposure, or vision loss, were observed throughout the follow-up period.

TABLE (1) Clinical findings:

Clinical signs	Pre-operative	Post-operative
Extraocular muscle movement restrictions	11	0
Diplopia	11	0
Infraorbital hypoesthesia	6	0

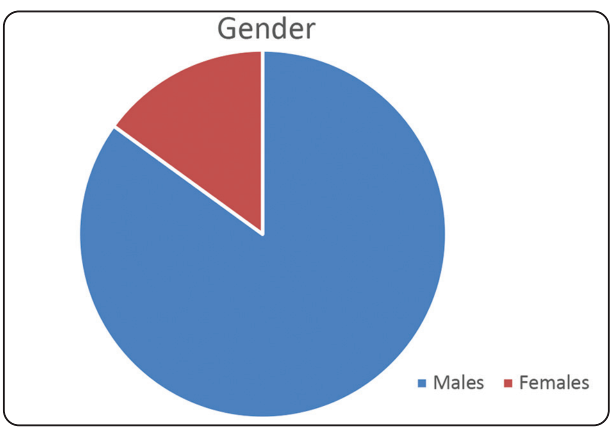

Fig. (6) Pie chart showing gender

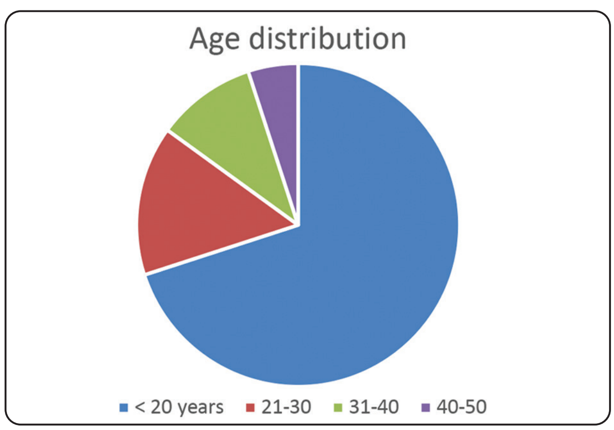

Fig. (7) Pie chart showing age distribution

Following surgery, the mean enophthalmos/ exophthalmos improved to 2 ± 1.75 mm in Group I and 2 ± 1.91 mm in Group II. In five patients with confirmed enophthalmos (41 mm) and six with exophthalmos (59 mm), as well as those at risk of developing these conditions, the mean measurement decreased from 2.2 ± 0.7 mm preoperatively to 0.6±0.3 mm postoperatively, reflecting significant improvement **(Table 2 & Figure 8)**; reflecting significant improvement in both groups with no statistically significant difference.

In Group I, the mean postoperative volume of fractured orbits was 31.87 ± 2.66 mm^3, compared to 38.36 ± 2.54 mm^3 in the contralateral orbits (P = 0.003). In Group II, the mean fractured orbit volume was 30.19 ± 2.57 mm^3 postoperatively, while the contralateral orbits measured 34.43 ± 2.59 mm^3 (P = 0.023) **(Table 3 & Figure 9)**; reflecting significant improvement in both groups with no statistically significant difference.

TABLE (2) Globe -apex linear measurement:

	Globe-apex linear measurement (mm)			
	Affected side	Contra-lateral side	Exophthalmos / enophthalmos degree	*P* VALUE
Group I	57.82±2.43	58.76 ±2.54	2±1.75	0.363
Group II	58.08±2.29	57.45±2.64	2±1.91	0.537

TABLE (3) Mean orbital volumes:

	Mean orbital volume (mm3)		
	Affected side	Contra-lateral side	*P* VALUE
Group I	31.87±2.66	38.36 ±2.54	0.003
Group II	30.19 ±2.57	34.43±2.59	0.023

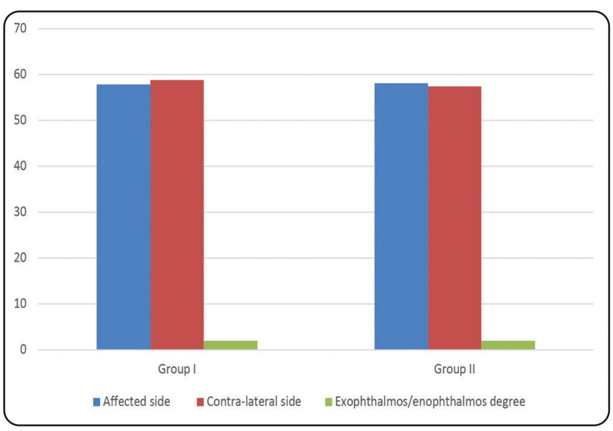

Fig. (8) Bar chart showing Globe-apex linear measurement (mm)

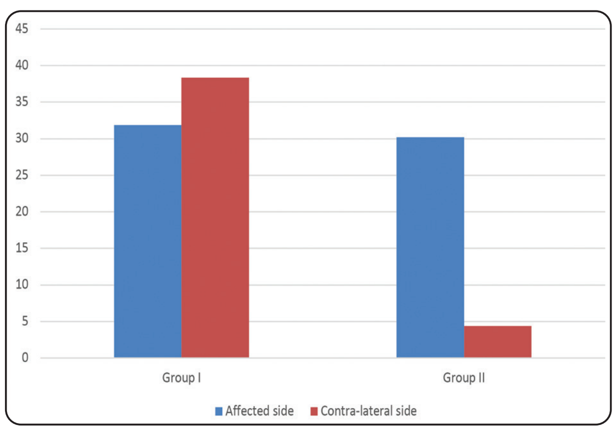

Fig. (9) Bar chart showing Mean orbital volume (mm3)

DISCUSSION

Restoration of the fractured orbital injuries to their pre-injury state presents a significant challenge primarily due to the intricate anatomy of the orbit and the delicate suspension system of the eyeball. This makes it essential to explore different surgical techniques to determine the most effective and practical approaches for orbital volume restoration. Additionally, continuous advancements in surgical methods and tools are crucial for improving treatment outcomes and ensuring the best possible recovery for patients. [1,14,15]

Various treatment strategies are used to repair and improve patients' outcomes in orbital fracture injuries. A plenty of surgical approaches and different types of bone implants can be used for orbital repair and the appropriate choice is based on each case and surgeon's experience. In addition, one of debatable issues regarding management of orbital injures is the selection of the appropriate timing of surgical intervention (early/ delayed intervention). [1,7,10–12,16]

Therefore, this study targeted further assessment of early versus delayed management of orbital fractures. Assessments were conducted to evaluate both clinical and radiographic outcomes. Regarding clinical assessment, all patients were evaluated for presence of any limitations of ocular motility and for the presence of diplopia. While radiographic assessment was performed to evaluate the globe positions in terms of exophthalmos or enophthalmos and to measure the orbital volume in comparison to the unaffected contralateral side that was in agreement with **Wi JM. et al. (2017)** and **Khalaf A. et al. (2024)** [9,17]

In this study, male patients were the most commonly affected and represented (85%) which were in agreement with the studies performed by **Wong T. et al. (2000)**, **Koo L. et al. (2005)** and **Dhillon J. et al. (2024)** who concluded that males represented the higher prevalence of orbital traumatic injuries in comparison to females. [18–20]

In addition, the participants' ages ranged from 17 to 45 years, with an average age of 31.4 years and this finding was consistent with the studies performed by **Troise S et al. (2024)** and **Irfan A. et al. (2024)** that came to an end that the majority of the orbital trauma widely occurred in adult patients. [21,22]

With regards to the clinical outcomes that encountered in this study, for all patients who underwent early or delayed intervention, there was no residual diplopia postoperatively. Additionally, no complications related to orbital implants such as infection, dislocation, exposure, or vision loss were observed throughout the follow-up period. These clinical findings were compatible with the results that encountered by **Tang DT.et al. (2011)** and **Khalaf A. et al. (2024)** [9,23]

Nevertheless, **Hoşal BM. et al. (2000)** conducted a study in which seven patients experienced post-operative diplopia and they assumed that residual diplopia usually occurred with late repair. In addition, a systematic review conducted by **Damgaard OE. (2016)** concluded that residual post-operative diplopia observed more frequently with patients treated with delayed intervention. [24,25]

Moreover, with respect to the radiographic outcomes in the present study, both group I & II experienced a 2 mm improvement in enophthalmos/ exophthalmos. In addition, in terms of orbital volume, both groups had significant improvements with no significant difference. In accordance to that, **Khalaf A. et al. (2024)** reported significant improvements regarding both enophthalmos and orbital volume measurements. [9]

Damgaard OE. et al. (2016) conducted a systematic review regarding the appropriate surgical timing of orbital repair and they came to a finding that improvement of enophthalmos in both groups of patients (early/ late intervention) was comparable with no difference which was consistent with the present study. [25]

Furthermore, in a systematic review performed by **Dubois L. et al. (2015)**, they came to a conclusion that there were sufficient guidelines that support immediate repair with still no enough evidence that support late repair. [12]

Nonetheless, a systematic review conducted by **Zhang J. et al. (2022)** concluded that significant improvements in enophthalmos and diplopia were evident in patients' undergone surgical repair within two weeks of traumatic injury. [11]

Furthermore, **Hassan B. et al. (2025)** conducted a study and they reported that patients who underwent immediate surgical intervention had better results regarding improvement of post-operative enophthalmos and diplopia than patients who underwent delayed surgical repair and they recommended early repair in most of cases, while delayed repair can be performed in cases with persistent diplopia, enophthalmos and less severe injuries. [26]

Wi JM. et al. (2017) reported marked improvement with regard to the orbital volume in their research and they advocated that early intervention offered better outcomes. [17]

The current study faced few limitations which included anatomical variations and availability of patients, consequently further investigations are necessary.

CONCLUSION

Computerized measurements of the orbital volume can be used to assess the effectiveness of orbital implants in traumatic orbital injuries and provide valuable quantitative data. An immediate significant reduction of the orbital volume after surgical intervention was observed. In addition, both groups showed comparable results in terms of clinical and radiographic outcomes.

RECOMMENDATIONS

More research work that includes larger sample size & longer follow up are recommended for better assessment of both clinical and radiographic outcomes regarding the appropriate surgical timing of surgical intervention of orbital traumatic injuries.

Competing interests

No conflict of interest

Ethical approval

The Ethics and research committee, Faculty of Dentistry, Cairo University approved the study and patients' consent was obtained.

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