Original Article - Retrospective Study

Surgical Correction of Diplopia in Orbital Fracture: Influence of Material and Design

S. M. Balaji, Preetha Balaji

Director and Consultant, Oral and Craniomaxillofacial Surgeon, Balaji Dental and Craniofacial Hospital, Chennai, Tamil Nadu, India

Abstract

Purpose: The purpose of this study is to compare the association of diplopia after orbital fracture repair using titanium mesh and high-density polyethylene-coated titanium mesh. **Materials and Methods:** Retrospective review of records of consecutive patients who presented for primary/secondary correction of orbital fracture attending author's institute was done. Patients attending the institution between January 2013 and December 2017 (5 years' period) fulfilling the inclusion and exclusion criteria were included for this study. **Results:** In all, 44 patients, who fulfilled the inclusion and exclusion criteria, were included in the study. The mean age was 31.86 ± 9.1 years and the mean period of follow-up was 9.37 ± 2.1 months postoperatively, with a range of 6.5–24 months. There were 65.91% males, and the most common etiology was road traffic accident (50%). In all, 11 (25%) cases had postoperative diplopia. Of the 11 cases that had diplopia, 6 had Class 1 and 5 had Class 2 diplopia. Of these 11 cases, 8 cases had completion or partial resolution of diplopia by the end of 8 weeks' period, and in 3 cases, it persisted even after 3 months of care. The occurrence of diplopia was compared by demographic factor using Chi-square test, and the mesh type was only statistically significant ($P = 0.026$). **Discussion:** The present study indicates that both types of mesh provide reliable, clinically better results. However, with passage of time, it was clinically observed that removing uncoated mesh poses extreme difficulty by the adherences and growth penetrating the meshes. In certain instances, clinically, it was observed that such adhesions may be a cause of compromise of eyeball movement. **Conclusion:** Noncoated titanium orbital implants may lead to the adherence of orbital and periorbital structures, resulting in restrictive diplopia. High-density polyethylene-coated titanium mesh shows better performance as compared to noncoated mesh in preventing adherence situations.

Keywords: Diplopia, double vision, facial fracture, orbital adherence syndrome, orbital fractures, titanium mesh

Introduction

Fractures of orbital bone are reported in 30%–55% of all instances of facial fractures.[1-4] In humans, the orbit is made up of parts of the maxilla, zygoma, palatine bones, lacrimal bone, sphenoid, frontal, and the thin lamina papyracea of the ethmoid bones.[5] Mechanisms of the orbital fractures are explained by the buckling and hydraulic theories.[6] Each of the theories is valid under clinical situations. Irrespective of the mechanism, subsequent to the impact of the trauma (by the force or the subsequent developing increased intraorbital pressure), orbital contents are often expulsed through the weakest of the bony orbital walls – usually the medial and floor. When the orbital contents exonerate through the fractured area or the bone is comminuted, there would be a requirement to repair the orbital walls.[6] Several materials are being used to correct the defect. The material ranges from preformed to custom titanium mesh, bone grafts, cellulose acetate sheet porous polyethylene-coated titanium mesh materials and a host of other materials. Of all these, titanium mesh is described as an ideal clinical choice of alloplastic material for orbital grafts.[7,8]

Reports indicate that delayed treatment (beyond 48 h) and trap door fractures are the other most common factors that lead to postoperative diplopia or double vision. Postoperative diplopia is known and common squeal to treated/untreated orbital fractures. The other complications of orbital fractures include abnormality in extraocular muscle (EOM) movement,

Address for correspondence: Dr. S. M. Balaji, Balaji Dental and Craniofacial Hospital, 30, KB Dasan Road, Teynampet, Chennai - 600 018, Tamil Nadu, India.
E-mail: smbalaji@gmail.com

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enophthalmos, orbital volume disparity-related complications, herniation of extraocular muscle and orbital fat tissue, lack of orbital soft-tissue restoration, EOM injury, motor nerve injury, and extraocular muscle cicatricial contraction and adhesion formation.[9,10] These factors can contribute to varying grades of diplopia that would contribute to functional disabilities and may compromise the quality of life. Of these, significant diplopia and extraocular movement restriction are common complications after orbital fracture repair. A recent report highlights the high incidence of diplopia with the use of porous titanium mesh implants and emergence of a syndrome referred to as orbital adherence syndrome (OAS) wherein the mesh attaches to the orbital tissues, especially through the pores in the mesh.[8]

In this part of the world, literature report of diplopia subsequent to orbital fracture correction is sparse. In this manuscript, an attempt is made to study using archival records of the treated diplopia cases and present a single, tertiary center's experience with diplopia correction.

Materials and Methods

A retrospective review was conducted identifying all patients >18 years of age at our institution between January 2013 and December 2017 (5 years' period) who underwent orbital fracture repair (primary or secondary correction), with or without other facial fractures. Patients who (1) were without adequate details or follow-up of at least 6 months' postsurgically; (2) had severe nerve injury that impaired the eyesight; (3) had issues with diplopia or similar eye problem before the trauma; and (4) had bilateral orbital bone fractures were not included in the study. Patients of either gender who had consented for the surgery were enrolled for this study. The anonymized data collected included age, gender, etiology (assault/road traffic accidents/trauma), side involvement (left/right), site of orbital fracture (combined [floor and medial wall], floor alone, internal and rim, medial wall alone), occurrence of other facial bone fracture (with other facial bone fractures, isolated orbital fracture), repair (primary/secondary), time phase of correction (0–14 days, 15–30 days, 30+ days), and the mesh material used (noncoated/coated with polyethylene).

The outcome was presence and grade of diplopia. For the purpose of this study, diplopia (persisting for more than 1-month postoperative) Class 0: Without diplopia; Class 1: Peripheral vision diplopia >15''; Class 2: Positive front and read bits 15'') without diplopia, but diplopia in the other direction; and Class 3: Positive front and read a <15'' diplopia.[11]

Patient assessment: All patients presenting with orbital fracture (primary repair) or a revision of an unsuccessful/unsatisfactory previous orbital fracture reduction (secondary repair) were included in this study. All imaging modalities were used to identify the extent of damage and healing (for secondary repairs) to develop a treatment plan [Figures 1-3]. The orbital correction was carried out in conjunction with other facial fracture reduction procedures or in isolation. In any case, using either a transconjunctival or a subciliary incision approach, orbital fracture repair operations were carried out. For medial wall, appropriate methods were employed. Fracture site was completely exposed, separated and relieved of the incarcerated soft tissues if any.

Lateral canthotomy, if required, was performed when and where necessary. Entrapment of inferior rectus muscle, periorbital fat, and musculature, if any, was carefully released. Spicules of bone or other grafts from previous surgery were carefully trimmed or manipulated.

Orbital margins, walls was fixed using appropriate materials along with correction of orbital defect. Volumes of the orbit, if required, were raised using standard procedures. In situations where grafting was required, the recipient site was properly prepared. The titanium mesh was placed subperiosteally and screwed in position. This ensured that the graft stays in position and does not interfere with globe position with later remodeling of the orbital volume. Either a porous titanium (thin sheet of cartilage placed over this mesh to prevent adherence) or a more advanced polyethylene-coated titanium orbital mesh was used [Figures 4-7].[9,10]

After securing the mesh, globe was carefully placed with respect to the equator and level at straight gaze. The layers were closed. No suture was placed for transconjunctival approach. For the subciliary incision, layered closures were performed using vicryl, and skin incision was closed by 6-0 Ethilon. Routine postoperative instructions for orbital surgeries, antibiotics, and nonsteroidal anti-inflammatory drugs were given as required to the patients. Patients were followed up weekly for the initial 4 weeks and at least 12 weeks after the operation.

Statistics

All data were entered into Statistical Package for Social Services (SPSS, IBM, IL, USA, version 17.0) and analyzed. Descriptive statistics and Chi-square statistics were presented for the predicator and outcome variables. $P < 0.05$ was considered statistically significant.

Results

In all, 44 patients, who fulfilled the inclusion and exclusion criteria, were included for the study. The mean age was 31.86 ± 9.1 years and the mean period of follow-up was 9.37 ± 2.1 months postoperatively, with a range of 6.5–24 months. There were 65.91% males and the most common etiology was road traffic accident (50%) followed by trauma (38.64%). The right side was the involved side (65.91%) in majority of the cases. Floor and medial orbital floor fractures were the common sites (54.55%), while medial wall fractures were the least common one (6.82%). In 36 (81.82%) instances, there was concomitant other facial bone fractures. Of the 44 cases, 29 (65.91%) cases had been previously operated for orbital fractures elsewhere and operated again for unsatisfactory results. The time between the

Figure 1: (a) Frontal view showing orbital asymmetry; (b) Worm's view showing enophthalmos of the right eye

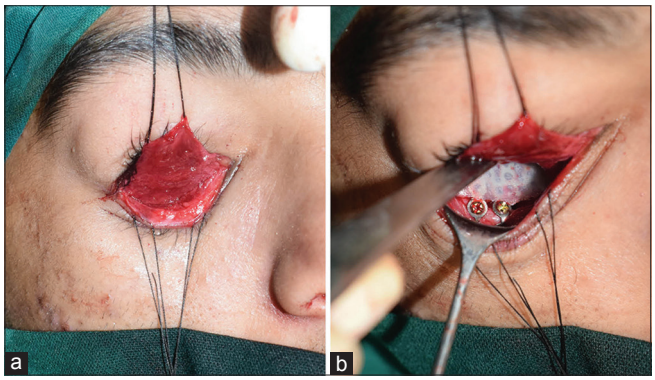

Figure 3: (a) Intraoperative view showing eversion of the right lower eyelid following trans conjunctival incision; (b) Intraoperative view showing reconstructed right orbital floor with high-density polyethylene-coated titanium mesh

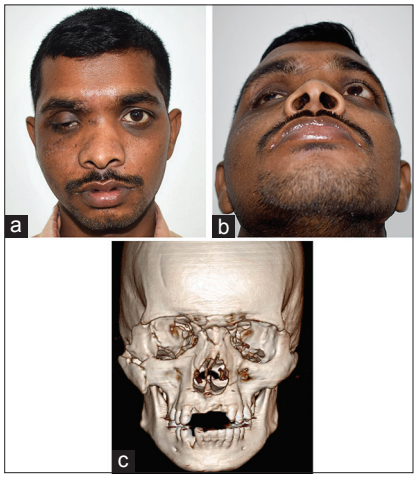

Figure 5: (a) Frontal view showing orbital asymmetry and ptosis of the right eye; (b) Worm's view showing enophthalmos of the right eye; (c) Computerized tomography scan showing right orbital floor and lateral orbital wall fracture

trauma and surgery, in majority of cases (50%), was between 15 and 30 days of the trauma (first surgery, in case of secondary treatment). In 23 cases, noncoated mesh was used to recreate the lost bony orbit [Table 1].

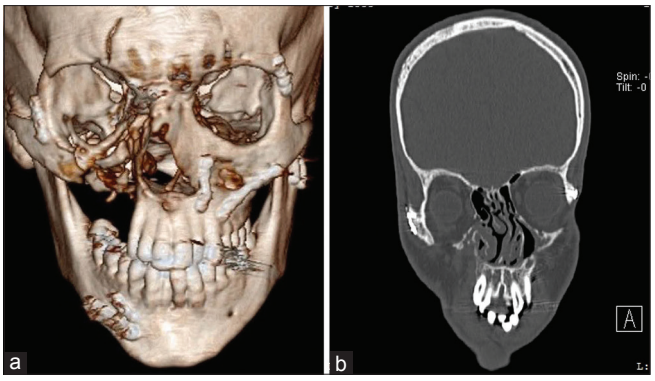

Figure 2: (a) Computerized tomography scan showing right orbital floor and medial orbital wall fracture; (b) Computerized tomography scan showing right orbital floor fracture, medial orbital wall fracture, and herniation of the orbital contents

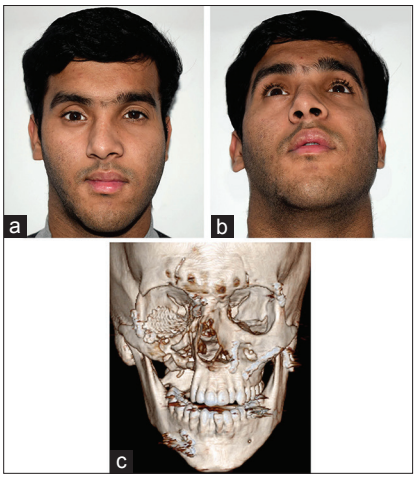

Figure 4: (a) Postoperative view showing corrected orbital asymmetry; (b) Postoperative Worm's view showing corrected enophthalmos; (c) Postoperative computerized tomography scan showing high-density polyethylene-coated titanium mesh used to reconstruct the right orbital floor and medial orbital wall

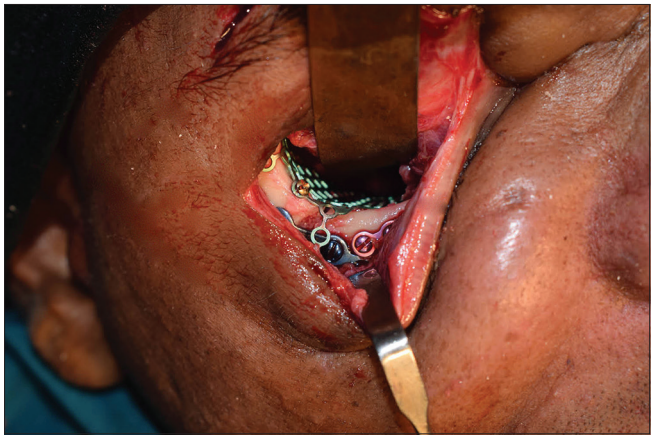

Figure 6: Intraoperative view showing reconstructed right orbital floor and lateral orbital wall with titanium mesh

In all, 11 (25%) of cases had postoperative diplopia. Of the 11 cases that had diplopia, 6 had Class I and 5

Table 1: Demographics of the study population (*n*=44)

Parameter	Sub-group	*n*=44	Percentage
Gender	Female	15	34.09
	Male	29	65.91
Etiology	Assault	5	11.36
	Road Traffic Accidents	22	50.00
	Trauma	17	38.64
Side involvement	Left	15	34.09
	Right	29	65.91
Site of orbital fracture	Combined (Floor and Medial wall)	24	54.55
	Floor alone	12	27.27
	Internal and Rim	5	11.36
	Medial wall alone	3	6.82
Occurrence of other facial bone fractures	With other facial bone fractures	36	81.82
	Isolated orbital fracture	8	18.18
Repair	Primary	15	34.09
	Secondary	29	65.91
Time limit	0 to 14 days	14	31.81
	15 to 30 days	22	50.00
	30 + days	8	18.18
Mesh Material used	Non-coated	23	52.27
	Coated	21	47.73
Post-operative Diploipa	No	33	75.00
	Yes	11	25.00
Mean age (in years)	31.86±9.1		

Table 2: Demographic parameters compared by the Diplopia status

Parameter	Sub-group	Diplopia		
		No (*n*=33)	Yes (*n*=11)	*P*
Gender	Female	10 (66.7)	5 (33.3)	0.287
	Male	23 (79.3)	6 (20.7)	
Occurrence of other facial bone fractures	With other facial bone fractures	27 (75)	9 (25)	0.687
	Isolated orbital fracture	6 (75)	2 (25)	
Repair	Primary	13 (86.7)	2 (13.3)	0.181
	Secondary	20 (69)	9 (31)	
Etiology	Assault	4 (80)	1 (20)	0.859
	Road Traffic Accidents	17 (77.3)	5 (22.7)	
	Trauma	12 (70.6)	5 (29.4)	
Side involvement	Left	10 (66.7)	5 (33.3)	0.287
	Right	23 (79.3)	6 (20.7)	
Site of orbital fracture	Combined (Floor and Medial wall)	18 (75)	6 (25)	0.528
	Floor alone	8 (66.7)	4 (33.3)	
	Internal and Rim	5 (100)	0	
	Medial wall alone	2 (66.7)	1 (33.3)	
Time phase	0 to 14 days	11 (78.6)	3 (21.4)	0.936
	15 to 30 days	16 (72.7)`	6 (27.3)	
	30+days	6 (75)	2 (25)	
Mesh material type	Non-Coated	14 (60.9)	9 (39.1)	0.026
	Coated	19 (90.5)	2 (9.5)	

had Class 2 diplopia. Of these 11 cases, 8 cases had completion or partial resolution of diplopia by the end of 8 weeks' period and in 3 cases, it persisted even after 3 months of care.

The occurrence of diplopia was compared by demographic factor using Chi-square test. Gender ($P = 0.287$), occurrence of other facial bone fractures (0.687), status of repair (0.181), etiology (0.859), laterality (side involvement, 0.287), site (0.528),

Table 3: Demographic parameters compared by the Class of Diplopia

Parameter	Sub-group	Diplopia class			
		Class 0	Class 1	Class 2	*P*
Gender	Female	10 (66.7)	4 (26.7)	1 (6.7)	0.175
	Male	23 (79.3)	2 (6.9)	4 (13.8)	
Occurrence of other facial bone fractures	With other facial bone fractures	27 (75)	5 (13.9)	4 (11.1)	0.99
	Isolated orbital fracture	6 (75)	1 (12.5)	1 (12.5)	
Repair type	Primary	13 (86.7)	1 (6.7)	1 (6.7)	0.435
	Secondary	20 (69)	5 (17.2)	4 (13.8)	
Etiology	Assault	4 (80)	1 (20)	0	0.320
	Road traffic accidents	17 (77.3)	1 (4.5)	4 (18.2)	
	Trauma	12 (70.6)	4 (23.5)	1 (5.9)	
Side involvement	Left	10 (66.7)	2 (13.3)	3 (20)	0.426
	Right	23 (79.3)	4 (13.8)	2 (6.9)	
Site of orbital fracture	Combined (Floor and Medial wall)	18 (75)	3 (12.5)	3 (12.5)	0.573
	Floor alone	8 (66.7)	3 (25)	1 (8.3)	
	Internal and Rim	5 (100)	0	0	
	Medial wall alone	2 (66.7)	0	1 (33.3)	
Time phase	0 to 14 days	11 (78.6)	2 (14.3)	1 (7.1)	0.984
	15 to 30 days	16 (72.7)	3 (13.6)	3 (13.6)	
	30+days	6 (75)	1 (12.5)	1 (12.5)	
Mesh used	Non-coated	14 (60.9)	4 (17.4)	5 (21.7)	0.042
	Coated	19 (90.5)	2 (9.5)	0	

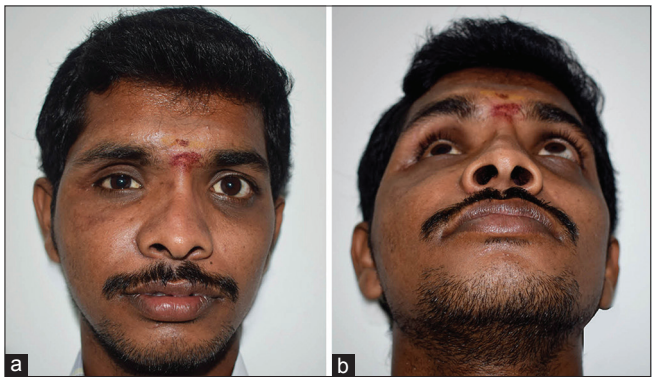

Figure 7: (a) Postoperative view showing corrected orbital asymmetry and ptosis of the right eye; (b) Postoperative Worm's view showing corrected enophthalmos

and time phase (0.936) were not statistically significant. Only the mesh type was statistically significant ($P = 0.026$) [Table 2]. On studying the grade of diplopia, it was evident that 90.5% of cases with polyethylene-coated titanium mesh had no instance of diplopia and 2 cases (9.5%) of Class 1 diplopia. The noncoated mesh had 17.4% ($n = 4$) cases of Class 1 diplopia, while 21.7% ($n = 5$) had Class 2 diplopia. The difference was statistically significant ($P = 0.042$) [Table 3].

Discussion

Titanium has a low weight to strength ratio, does not corrode, is nonmagnetic, and has excellent shape memory. These properties together with the metal being bio-inert made it a widely used as a graft material. Titanium, as a biomaterial, is known to increase levels of fibroblast activity (often in bony grooves and ridges), transforming growth factor-ß and platelet-derived growth factors. Clinically, these cause titanium to stimulate an inflammatory and fibrogenic response to the surrounding tissues, The resultant of which is a better biointegration causing decreased extrusion rates and infection. However, the same pathways/responses act unfavorable when it leads to scarring and cicatrization, resulting in diplopia (when used as an orbital graft).[6,7]

It was Lee and Nunery who described the OAS, associated with titanium mesh, in 2009.[7] In their case series, they identified an extensive fibrotic reaction around the mesh, and the symptoms that regressed after the metal were removed. They proceeded to hypothesize that titanium, *per se*, was the cause of the adhesions, and such adhesions lead to the reduction in orbital function.

Later in 2013, it is reported by Lee that Kersey *et al*., based on their case series, suggested that with the orbital correction, the periorbita loses its ability to maintain the separation between orbital contents, bone, and implant. The titanium-enhanced and sustained inflammation possibly promotes adhesions between the implant and the orbital contents. These adhesions possibly impede ocular movement. The mesh also allows the remodeling fibrous tissue to "leak" through the mesh, facilitating OAS formation.[7]

From the results, it is observed that the occurrence of diplopia is not influenced by gender, other fractures, fracture sites, type of repair, etiology of fracture but only by the mesh material type. The time lapse is a crucial factor that determines the outcome of diplopia in orbital fractures. However, in the present study

design, the data regarding the same has been not deeply considered, as most of the cases are referred to the center and had surgeries earlier. The risk of hospital admission bias could have crept in. The result of the study has to be carefully interpreted, given this admission bias.

It is further evident from Table 3 that noncoated meshes are more prone to develop diplopia of higher grades, possibly by developing OAS. The occurrence of diplopia in 2 of the 21 cases of polyethylene titanium-coated mesh still indicates that there are other factors operating that create OAS. In these cases, the role of titanium as a cause or promoter of OAS can be safely ruled out, as the titanium, owing to coating, never comes into contact with orbital content or the body fluids. Yet the role of the content sinking into the mesh to create OAS cannot be ruled out. In several cases, intraoperatively, it was observed that there were adhesions between the periorbital tissues and the noncoated meshes.

The study indicates that both types of mesh provide good results. However, with passage of time, it was clinically observed that removing uncoated mesh poses extreme difficulty by the OAS and in instances causes compromise of eyeball movement.

We have earlier reported of the conditions that may predispose to postoperatively diplopia. Notably, of them were the inflammation of orbital muscle (irrespective of titanium placements), wrapping of the cartilages, if any, used, and timing of the surgeries.[9,10] The present manuscript adds one more important factor of coating of the mesh that may influence the occurrence of diplopia in cases of orbital fracture correction.

Conclusion

Diplopia is a major, unpredictable, and undesired outcome of orbital fracture correction. The etiopathology of the condition is not fully deciphered. Several studies postulate several mechanisms by which this entity arises. In the present study, the advantage of using a polyethylene-coated titanium mesh as compared to using a noncoated titanium mesh has been presented. The use of cartilaginous graft to prevent OAS with the use of noncoated titanium mesh needs to be investigated.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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