

# Role of Patient Specific Implant in Reconstruction of Post Traumatic Orbital Defects: A Comparative Systematic Review

Dr. Aayushi Vora,<sup>1</sup> Dr. Neha Vyas,<sup>2</sup> Dr. Prashant Malik,<sup>3</sup> Dr. Raj Madhani<sup>4</sup>

**1. Dr. Aayushi Vora**

Department of Oral and Maxillofacial Surgery, Ahmedabad Dental College and Hospital, Near Hare Krishna Mandir, Bhadaj, Ahmedabad, Gujrat-382115

**2. Dr. Neha Vyas**

Department of Oral and Maxillofacial Surgery, Ahmedabad Dental College and Hospital, Near Hare Krishna Mandir, Bhadaj, Ahmedabad, Gujrat-382115

**3. Dr. Prashant Malik**

Department of Oral and Maxillofacial Surgery, Ahmedabad Dental College and Hospital, Near Hare Krishna Mandir, Bhadaj, Ahmedabad, Gujrat-382115

**4. Dr. Raj Madhani**

Department of Oral and Maxillofacial Surgery, Ahmedabad Dental College and Hospital, Near Hare Krishna Mandir, Bhadaj, Ahmedabad, Gujrat-382115

## CORRESPONDING AUTHOR

**Dr. Aayushi Vora**

902, Shivalik Paradise, Nehrunagar Crossroads,  
Ambawadi, Ahmedabad - 380015

**Mobile** - +91-7228030300

**Email** - aayushivora17@gmail.com

### Abstract

**Background:** Maxillofacial injuries of middle third of the face commonly involves the orbital skeleton and range from the subtle blow-out fracture following simple blunt or low-velocity trauma to the highly complex orbital communication resulting from motor vehicle accidents and projectiles, such trauma to the orbit and surrounding facial structures often leads to orbital deformity and incapacitating visual dysfunction .We performed a systematic review to evaluate the role of patient-specific implants in orbital reconstruction and to compare it with conventional reconstruction methods with respect to operative time, orbital volume reconstitution, enophthalmos and diplopia.

**Material and Methods:** A literature search was conducted using the English-language databases EMBASE, MEDLINE, PUBMED and the COCHRANE LIBRARY, as well as local databases containing publications from 2006 to 2022.

**Results:** fourteen studies (n=737 patients) met the inclusion criteria. Overall, the use of patient specific implants for the orbital repair when comparing with conventional in terms of intra operative duration, post- operative orbital volume difference and enophthalmos, however in terms of presence of post - operative diplopia there is no significant difference in either.

**Conclusion:** Patient specific implants are easy to manipulate, insert and anchor. They accurately reproduce orbital contours thus restoring orbital volume. This leads to reduced operative time and an improvement in functional and aesthetic outcomes of post-traumatic orbital reconstruction.

**Keywords:** Orbital fracture' or 'Orbital implants' or 'Reconstructive surgical procedures' or 'Maxillofacial injuries' or 'Patient specific implant'.

## INTRODUCTION

Maxillofacial injuries of middle third of the face commonly involves the orbital skeleton and range from the subtle blow-out fracture to the highly complex orbital communication, such trauma to the orbit and surrounding facial structures often leads to orbital deformity and incapacitating visual dysfunction.

Orbital repair can be Immediate or Delayed. Management of these injuries is challenging as clinical outcomes, both functional and aesthetic, may not always be immediately obvious. Untreated cases or delayed treatment of orbital fractures may lead to ocular motility deficits, reduced visual acuity, persistent enophthalmos, sensory disturbance, diplopia, orbital cripples, continuous CSF leak,. Therefore, primary reconstruction of orbit is important for successful surgical outcomes following orbital fracture.

The main aim of Orbital reconstruction is to produce an entirely successful functional and cosmetic result. Most widely used materials for reconstruction of the orbital walls, floor include autologous bone, cartilage, titanium mesh, High-Density Porous Polyethylene. The advantages of conventional reconstruction methods are availability, cost-effectiveness, allows intra-operative contouring and biostability. The use of autologous and alloplastic materials, except titanium, and calvarian bone grafts have complications, such as foreign body reactions, resorption, displacement and late enophthalmus.

The emergence and widespread availability of computer- assisted surgery, including CAD/CAM processes, has precipitated the development of individualised implants. There are two forms available: 1) entirely patient specific implants (PSI) 2) hybrid patient specific implants (hybrid PSI) -

conventional implants that are manipulated and contoured preoperatively on patient-specific, three-dimensional (3D) models created through stereolithography from CT imaging.

The aim of this systematic review is to evaluate the role of PSI in orbital wall repair and to compare the clinical outcomes in terms of operative time, orbital volume reconstitution, enophthalmos and diplopia following orbital reconstruction using PSI compared to conventional methods in orbital wall repair following trauma.

## MATERIAL AND METHODS

### Search Approach

A rigorous search for the articles on to the role patient specific implants in the management of orbital wall fracture was conducted. The search was conducted in multiple stages. The initial step involved a search for existing systematic review of literatures on the subject with the help of electronic databases like PUBMED, EMBASE, MEDLINE, COCHRANE LIBRARY, SCOPUS. The phrases used for the search were 'Orbital fracture' or 'Orbital implants' or 'Reconstructive surgical procedures' or 'Maxillofacial injuries' or 'Patient specific implant'. The next step involved a manual search of reference articles to identify other relevant articles for the final selection

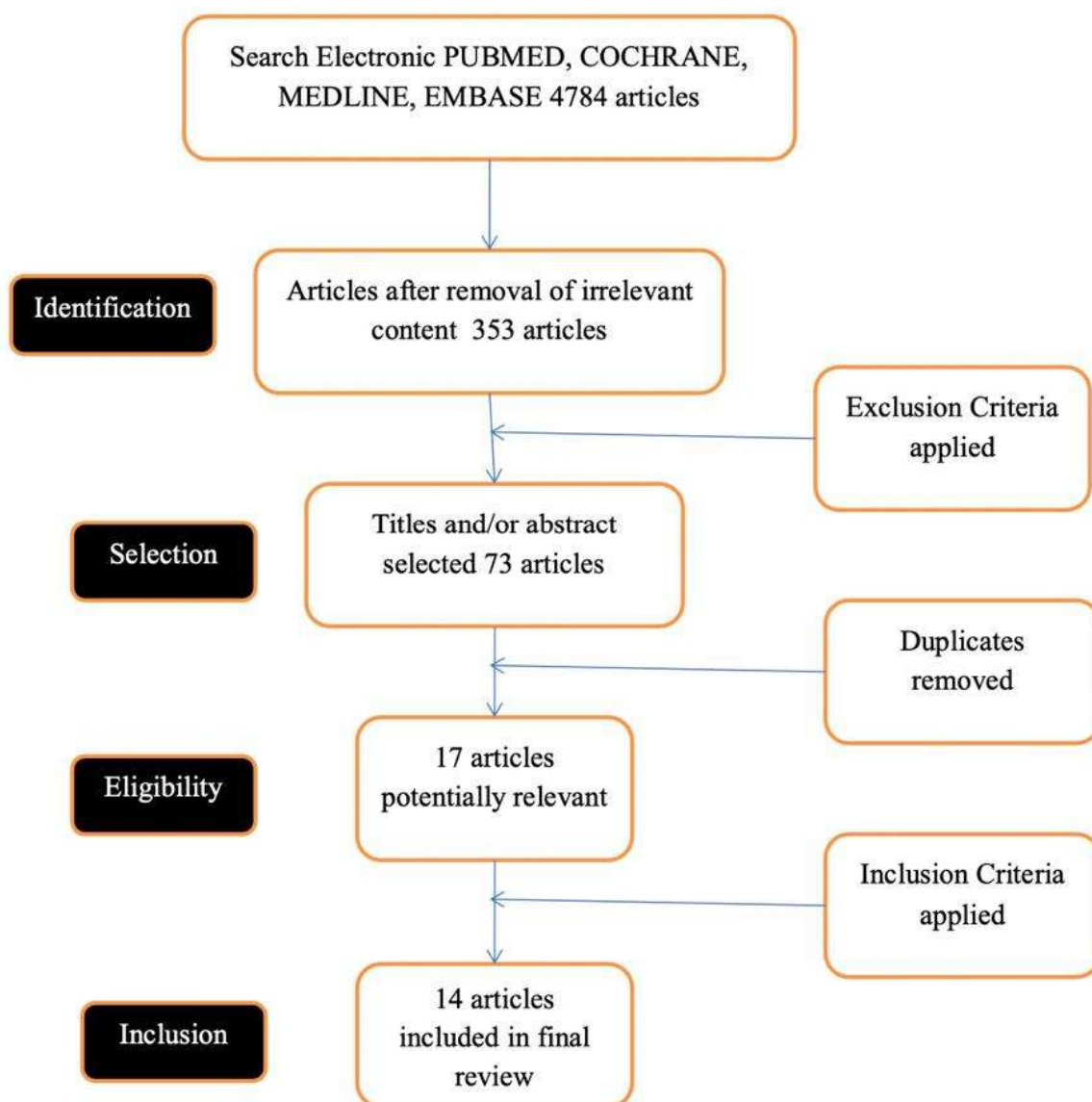
### Inclusion Criteria

Cross sectional studies, observational studies, prospective studies, retrospective studies, Case control and cohort studies, Controlled Clinical trials, English Language, Implants were patient-specific, achieved either through bespoke fabrication based on CAD/CAM technologies (PSI) or through pre-operative bending of plates using patient-specific 3D modelling (hybrid-PSI) for post traumatic orbital wall repair.

### Exclusion Criteria

Orbital reconstruction performed for non-traumatic indications, inaccurate data for analysis, incomplete data for analysis, insufficient description of post-operative outcomes.

## SEARCH RESULTS



**TABLE 1: TYPE OF IMPLANT USED FOR ORBITAL FLOOR RECONSTRUCTION**

Sr No.	Author	Year of Publication	Implant Type- Conventional	Implant Type-Patient Specific
1	Schon et al	2006	NR	individual titanium mesh (Synthes, Paoli, USA) using CAD-CAM
2	Guo et al.	2009	Autologous calvarial bone graft	Titanium mesh (OsteoMed Co), pre-contoured on patient-specific 3D-printed patient mod
3	Scolozzi et al	2010	Orbital titanium mesh plate (manufacturer not disclosed)	Pre-formed orbital titanium mesh plates (Synthes)
4	Mustafa et al.	2011	NR	Titanium mesh (manufacturer not disclosed) pre-contoured on 3D-printed patient model
5	Gander et al.	2014	NR	CAD-based: KLS Martin individual-
6	Fan et al.	2017	MEDPOR TITAN Orbital floor implant	MEDPOR TITAN Orbital floor implant – 3D printed (manufacturer not disclosed)
7	Raisian et al.	2017	Titanium mesh (manufacturer not disclosed)	Titanium mesh (manufacturer not disclosed) pre-contoured on 3D-printed patient model
8	Kim et al.	2017	SynPOR titanium mesh (Synthes)	SynPOR PSI titanium mesh (Synthes)
9	Zielinski et al.	2017	Orbital titanium mesh plate (manufacturer not disclosed)	CAD-CAM based Titanium mesh, UHMWPE, ZrO <sub>2</sub>
10	Chepurnyi et al.	2020	Orbital titanium mesh plate (manufacturer not disclosed)	SLM titanium PSI (KLS Martin)
11	Khomutinnikova et al.	2020	Reperen polymer implants (38.4%), Konment metal implants (30.8%), Synthes implants	Individualised polytetrafluoroethylene implants (Ecoflon)
12	Sigron et al.	2020	Matrix MID- FACE Pre-formed orbital plates (Synthes)	Matrix MID- FACE orbital plates (Synthes) or MODUS Midface OPS 1.5 plates, pre-contoured on patient-specific 3D mod
13	Gupta et al.	2021	Porous poly-ethylene (Biopore™) sheet	Titanium mesh (manufacturer not disclosed) pre-contoured on patient-specific 3D-printed model
14	Zimmerer et al	2022	Matrix MID- FACE Pre-formed orbital plates (Synthes)	CAD-based: KLS Martin individual-ised implants; pre-contoured Orbital Floor Mesh Plates (Synthes) Non-CAD-based: Orbital Floor Mesh Plates (Synthes), Syn- POR Titanium Reinforced Fan Sheets (Synthes), Stryker MED- POR Orbital Reconstruction Implants

**TABLE 2: POSTOPERATIVE PARAMETERS IN INCLUDED STUDIES**

Sr No.	Author	Year of Publication	Postoperative Parameters			
			Orbital Volume	Operative Duration	Enophthalmos	Diplopia
1	Schon et al.	2006	PSI	PSI	ND	ND
2	Guo et al.	2009	PSI	NA	ND	ND
3	Scolozzi et al.	2010	ND	NA	ND	NA
4	Mustafa et al.	2011	PSI	PSI	ND	ND
5	Gander et al.	2014	PSI	PSI	NA	NA
6	Fan et al.	2017	NA	PSI	PSI	NA
7	Raisian et al.	2017	NA	NA	PSI	ND
8	Kim et al.	2017	NA	ND	ND	ND
9	Zielinski et al.	2017	PSI	PSI	ND	ND
10	Chepurnyi et al.	2020	PSI	ND	PSI	PSI
11	Khomutinnikova et al.	2020	NA	NA	ND	ND
12	Sigron et al.	2020	ND	PSI	NA	NA
13	Gupta et al.	2021	NA	NA	PSI	ND
14	Zimmerer et al	2022	PSI	PSI	NA	ND

**NA:** Not Available; **ND:** No Difference

## RESULT

The extracted data and the characteristics of the studies included in the final analysis. It includes 14 studies, from these 10 studies were retrospective, 3 studies were prospective, 1 study was randomised control trial.

Total 737 participants of Orbital fracture treated with either Conventional implants or PSI. In included studies the etiology of orbital fracture is trauma. Out of 737 participants 330 were treated with Conventional method and 407 were treated with PSI/ Hybrid-PSI made up of titanium. Out of 737 participants 373 were male and 199 were female. All the age groups were included in the

study. All the authors have mentioned about the follow up period ranging from 1 week post-operatively to 5 years.

### Operative Duration

Three studies provided detailed data on the operative duration for the orbital reconstruction between PSI and conventional implant. Fan et al. observed that the average operative duration was significantly shorter in the PSI group-75.34 min compared to the control group-95.37 min. Sigron et al. observed 57.30 min and 99.80 min for PSI group and conventional group respectively. Zimmerer et al. observed the operative duration of 60 min for PSI group and 71 min for conventional group.

### **Orbital Volume**

Three studies provided detailed data on comparison of orbital volume between PSI and conventional implants. Zimmerer et al. observed that precision was better in orbital reconstruction using PSI. Guo et al. reported no significant difference in PSI group, but did report a significant difference in conventional group, suggestive of better adaptation to pre-traumatic orbital volume with the use of the PSI group. Scolozzi et al. found a significant orbital volume difference between pre-operative unaffected orbit and post-operative orbit in the conventional group, but not in the PSI group.

### **Enophthalmos**

Three studies reported post-operative enophthalmos between conventional and PSI groups. According to Khomutinnikova et al. pre-operatively 82.9% of patients in the PSI group and 76.9% in the conventional group showed enophthalmos, reducing to 17.1% and 38.5%, respectively, post-operatively. According to Guo et al. there were no significant difference between groups. According to Fan et al. and Raisian et al. there is significant difference between the two groups, more better results with PSI. Gupta et al. observed statistically significant improvement in enophthalmos in the PSI group.

### **Diplopia**

Ten studies reported on the presence of post-operative diplopia. Gupta et al. found no difference in post-operative diplopia between the PSI and conventional group. Guo et al. reported an incidence of pre-operative diplopia of 51.4% in the PSI group and 30.8% in the conventional group. This improved to 8.6% and 26.9% respectively. Zimmerer et al. found no significant difference between conventional and PSI groups in post-operative diplopia at 12-week follow-up. Of the 7 studies reported reduced frequencies of diplopia in PSI compared to conventional implant.

### **DISCUSSION**

Orbital reconstruction following trauma is complicated by the limited operative view and the complexity of the anatomical region. For the orbital reconstruction, attempts have made to develop fully customized PSI to accurately replicate the complex anatomy of the orbital region.

The current systematic review was undertaken with inclusion of 14 studies to know the role of PSI in orbital repair and to compare the clinical outcomes of PSI compared to conventional methods in orbital repair following traumatic orbital injury.

3 studies identified significantly shorter operative duration in the group of patients undergoing reconstruction with PSI when compared to conventional implants.

3 studies reporting on changes in orbital volume identified significantly better outcomes with the use of PSI, in terms of reduction in the orbital volume difference between affected and unaffected orbits, or degree of precision in the reconstruction. While the remaining articles found no difference in the conventional and PSI groups when compared for post-operative orbital volume. Three studies found a significant benefit of PSI in improving post-operative enophthalmos. Ten studies reported for the presence of post-operative diplopia, of the 7 studies reported reduced frequency of post-operative diplopia in the PSI group, while remaining studies found the presence of post-operative diplopia in both the groups.

This all favours the use of PSI for the orbital repair when comparing with conventional in terms of intra-operative duration, post-operative orbital volume difference and enophthalmos, however in terms of presence of post-operative diplopia there is no significant difference in either.

### **CONCLUSION**

In conclusion, the use of titanium mesh for orbital reconstruction has been shown to be safe and effective. PSI accurately reproduce orbital contours thus restoring orbital volume, reduces operative time and improves functional and aesthetic outcomes of post-traumatic orbital reconstruction. Cases where the infraorbital buttresses and posterior orbital ledge are preserved there is no significant differences in clinical efficacy between PSI and conventional groups. But cases requiring cantilevered reconstruction, including those with zygomatic or maxillary fragment repositioning, preference should be given to the PSI procedure for both effectiveness and predictability.

## BIBLIOGRAPHY

1. Fan B, Chen H, Sun YJ, Wang BF, Che L, Liu SY, Li GY. Clinical effects of 3-D printing-assisted personalized reconstructive surgery for blowout orbital fractures. *Graefes Arch Clin Exp Ophthalmol.* 2017 Oct;255(10):2051-2057. doi: 10.1007/s00417-017-3766-y. Epub 2017 Aug 7. PMID: 28786025.
2. Guo L, Tian W, Feng F, Long J, Li P, Tang W. Reconstruction of orbital floor fractures: comparison of individual prefabricated titanium implants and calvarial bone grafts. *Ann Plast Surg.* 2009 Dec;63 (6):624-31. doi: 10.1097 / SAP.0b013e3181999df3. PMID: 19816156.
3. Gupta S, Mehrotra D, Singh PK, U V, Bhawe S, Katrolia R. Quality of life after reconstruction of traumatic orbital floor defects using titanium mesh and medpore: A randomised controlled trial. *J Oral Biol Craniofac Res.* 2021 Apr-Jun;11(2):200-203. doi: 10.1016/j.jobcr.2021.01.012. Epub 2021 Jan 29. PMID: 33665067; PMCID: PMC7897992.
4. Khomutinnikova NE, Durnovo EA, Vyseltseva YV, Gorbatoov RO. Digital Technologies in the Surgical Treatment of Post-Traumatic Zygomatico-Orbital Deformities. *Sovrem Tekhnologii Med.* 2021;12(3):55-61. doi: 10.17691/stm2020.12.3.07. Epub 2020 Jun 28. PMID: 34795980; PMCID: PMC8596248.
5. Kim YC, Jeong WS, Park TK, Choi JW, Koh KS, Oh TS. The accuracy of patient specific implant prebent with 3D-printed rapid prototype model for orbital wall reconstruction. *J Craniomaxillofac Surg.* 2017 Jun;45(6):928-936. doi: 10.1016/j.jcms.2017.03.010. Epub 2017 Mar 27. PMID: 28434826.
6. Schön R, Metzger MC, Zizelmann C, Weyer N, Schmelzeisen R. Individually preformed titanium mesh implants for a true-to-original repair of orbital fractures. *Int J Oral Maxillofac Surg.* 2006 Nov;35(11):990-5. doi: 10.1016 / j.ijom.2006.06.018. Epub 2006 Oct 17. PMID: 17049812.
7. Zieliński R, Malińska M, Kozakiewicz M. Classical versus custom orbital wall reconstruction: Selected factors regarding surgery and hospitalization. *J Craniomaxillofac Surg.* 2017 May;45(5):710-715. doi: 10.1016/j.jcms.2017.02.008. Epub 2017 Feb 17. PMID: 28318927.
8. Scolozzi P, Momjian A, Heuberger J. Computer-aided volumetric comparison of reconstructed orbits for blow-out fractures with nonpreformed versus 3-dimensionally preformed titanium mesh plates: a preliminary study. *J Comput Assist Tomogr.* 2010 Jan;34(1):98-104. doi: 10.1097 / RCT.0b013e3181ac1975. PMID: 20118730.
9. Sigron GR, Rüedi N, Chammartin F, Meyer S, Msallem B, Kunz C, Thieringer FM. Three-Dimensional Analysis of Isolated Orbital Floor Fractures Pre- and Post-Reconstruction with Standard Titanium Meshes and "Hybrid" Patient-Specific Implants. *J Clin Med.* 2020 May 22;9(5):1579. doi: 10.3390/jcm9051579. PMID: 32455967; PMCID: PMC7291031.
10. Zimmerer RM, Ellis E 3rd, Aniceto GS, Schramm A, Wagner ME, Grant MP, Cornelius CP, Strong EB, Rana M, Chye LT, Calle AR, Wilde F, Perez D, Tavassol F, Bittermann G, Mahoney NR, Alamillos MR, Bašić J, Dittmann J, Rasse M, Gellrich NC. A prospective multicenter study to compare the precision of posttraumatic internal orbital reconstruction with standard preformed and individualized orbital implants. *J Craniomaxillofac Surg.* 2016 Sep;44(9):1485-97. doi: 10.1016/j.jcms.2016.07.014. Epub 2016 Jul 21. PMID: 27519662.
11. Chepurnyi Y, Chernohorskyi D, Zhukovtceva O, Poutala A, Kopchak A. Automatic evaluation of the orbital shape after application of conventional and patient-specific implants: Correlation of initial trauma patterns and outcome. *J Oral Biol Craniofac Res.* 2020 Oct-Dec;10(4):733-737. doi: 10.1016/j.jobcr.2020.10.003. Epub 2020 Oct 9. PMID: 33088705; PMCID: PMC7567054.
12. Raisian S, Fallahi HR, Khiabani KS, Heidarizadeh M, Azdoo S. Customized Titanium Mesh Based on the 3D Printed Model vs. Manual Intraoperative Bending of Titanium Mesh for Reconstructing of Orbital Bone Fracture: A Randomized Clinical Trial. *Rev Recent Clin Trials.* 2017;12(3):154-158. doi: 10.2174/1574887112666170821165206. PMID: 28828975.

13. Gander T, Essig H, Metzler P, Lindhorst D, Dubois L, Rücker M, Schumann P. Patient specific implants (PSI) in reconstruction of orbital floor and wall fractures. *J Craniomaxillofac Surg.* 2015 Jan;43(1):126-30. doi: 10.1016/j.jcms.2014.10.024. Epub 2014 Oct 31. PMID: 25465486.
14. Mustafa SF, Evans PL, Bocca A, Patton DW, Sugar AW, Baxter PW. Customized titanium reconstruction of post-traumatic orbital wall defects: a review of 22 cases. *Int J Oral Maxillofac Surg.* 2011 Dec;40(12):1357-62. doi: 10.1016 / j.ijom.2011.04.020. Epub 2011 Aug 31. PMID: 21885249.