DOI: 10.7860/JCDR/2026/72887.22561

Research Protocol

Dentistry Section

Comparative Evaluation of the Functional and Aesthetic Outcomes of Orbital Floor Reconstruction Using Poly Lactic Co-glycolic Acid and Titanium Mesh: A Randomised Controlled Trial Research Protocol

YASH SANJAY DESHPANDE[1], NITIN BHOLA[2], ANCHAL AGARWAL[3]

ABSTRACT

Introduction: Orbital floor fractures are common facial injuries that often result in functional and aesthetic impairment. Open Reduction and Internal Fixation (ORIF) using various materials, like Poly Lactic-Co-glycolic Acid (PLGA) mesh and titanium mesh, have been employed to repair these fractures.

Need of the study: Recent advancements in hybrid bone mesh, including bioactive materials or elements to promote fracture healing, show significant promise. One such innovation involves using biodegradable PLGA material to create a bone screw mesh, which has demonstrated benefits for fracture healing and has gained interest recently. These developments aim to enhance treatment plans for patients by offering superior aesthetic and functional properties. However, evidence comparing their functional and aesthetic outcomes is limited.

Aim: The present randomised controlled trial aims to compare and evaluate the functional and aesthetic outcomes of ORIF using PLGA mesh and titanium mesh in patients with orbital floor fractures.

Materials and Methods: A randomised single-blinded controlled trial will be conducted at Siddharth Gupta Memorial Cancer Hospital (AVBRH), Datta Meghe Institute of Higher Education and Research, Sawangi, Wardha, Maharashtra, India, from September 2024 to December 2025. A total of 12 patients presenting with orbital floor fractures will be included and two parallel groups, A and B, will be allocated by randomisation and they undergo ORIF using either or titanium mesh (Group A- Control group) or PLGA mesh (Group B-Experimental group). Functional outcomes, including diplopia, enophthalmos, ocular motility, and infraorbital nerve function, will be assessed using standardised clinical measures. Aesthetic outcomes will be evaluated based on facial symmetry, globe position, and patient satisfaction using validated scoring systems. Follow-up assessments will be conducted at regular intervals of 10-15 days. An unpaired t-test will be applied for intergroup comparison, and a p-value of less than 0.05 will be considered statistically significant.

Keywords: Bioactive materials, Ethmoid, Fracture, Hybrid bone mesh, Internal fixation

INTRODUCTION

Maxillofacial trauma refers to any damage sustained by the face or jaws, encompassing various types of injuries such as skin lacerations, burns, nasal or sinus blockages, orbital socket damage, jawbone fractures, and tooth loss or breakage [1,2]. Research suggests that the incidence of orbital wall fractures is approximately 46.19 per 100,000 person-years, with a higher prevalence among males, particularly notable peaks in the age groups of 10-29 years and those over 80 years old [3].

The most common type noted was an isolated fracture situated in the inferior orbital wall (59.4%), followed by fractures confined to the inner part of the socket (23.7%), combined fractures (15.0%), and fractures affecting the nasal, orbital, and ethmoid regions [3].

Rigid fixation surgery pertains to procedures on the jaw where mesh is employed to stabilise either the mandible (lower jaw) or the maxilla (upper dental arch/palate). Any bone fixation technique lacking adequate strength to prevent interfragmentary movement during skeletal activity is categorised as non rigid. The fundamental disparity between rigid and non-rigid fixation lies in the degree of interfragmentary mobility [4].

Mesh for internal fracture fixation has been utilised for over a century. The practice of plating fractures dates back to 1895 when Lane introduced a metal plate for internal fixation, though it was eventually abandoned due to corrosion issues [5]. Subsequently, Lambotte in 1909 and Sherman in 1912 introduced their versions of internal fracture fixation plates. Despite improvements in metallurgy to enhance corrosion resistance, both designs were eventually discarded due to inadequate strength [5].

Some commonly employed instruments include titanium plates for bone fractures, nails, titanium bone screws, and rods. The use of metal mesh and screws offers advantages as they stabilise the joint and expedite the healing process [6]. Recent developments in hybrid bone mesh, incorporating bioactive elements or factors to enhance fracture healing, show promise [7]. This includes the use of biodegradable polylactic-co-glycolic acid material for designing bone screw mesh, which has proven beneficial for fracture healing and garnered increasing attention [8].

Primary objectives:

- To evaluate the functional and aesthetic outcomes of ORIF using PLGA mesh in patients with orbital floor fractures.

- To evaluate the functional and aesthetic outcomes of ORIF using titanium mesh in patients with orbital floor fractures.

Secondary objective:

- To compare the functional and aesthetic outcomes of ORIF using PLGA mesh and titanium mesh in patients with orbital floor fractures.

Null hypothesis: There will be no significant difference in the functional and aesthetic outcomes of orbital floor reconstruction using PLGA and titanium mesh.

Alternate hypothesis: There will be a significant difference in the functional and aesthetic outcomes of orbital floor reconstruction using PLGA and titanium mesh.

REVIEW OF LITERATURE

In the realm of drug delivery systems and tissue engineering, PLGA stands as a cornerstone synthetic polymer. Its versatility and properties make it a top choice for manufacturing nano- and microparticles capable of encapsulating and delivering a wide array of hydrophobic and hydrophilic molecules, including biomolecules like proteins and nucleic acids. PLGA nano/microparticles have been examined as a delivery system for Bone Morphogenetic Protein 2 (BMP2), a key growth factor in bone tissue engineering, and the prerequisites necessary for achieving controlled delivery of BMP2 utilising PLGA particles as a primary component have been comprehensively studied [9].

In 2018, Polacco MA et al., performed a retrospective review of 87 patients, comparing the outcomes and complications of bioresorbable implants and permanent implants in orbital floor fracture repair at a rural tertiary care centre from 2011 through 2016 [10]. The main outcome measures included improvement in diplopia, ocular motility, enophthalmos, hypoglobus, and infraorbital nerve sensation. All absorbable implants were composed of Poly L-lactide/poly glycolide/poly D-lactide (PLL/PG/PDL), while the non absorbable implants included both Titanium/Porous Polyethylene (Ti/PPE) composite and Titanium (Ti) mesh. The outcomes showed no significant differences between the two groups [10].

In 2021, Sigron GR et al., conducted a study to analyse whether a preformed "hybrid" patient-specific orbital mesh provides a more accurate reconstruction of the orbital floor and better functional outcomes than a standardised, intraoperatively adapted titanium implant in 30 patients who underwent surgical reconstruction for isolated, unilateral orbital floor fractures [11]. Of these, 13 were treated conventionally by intraoperatively adjusting a standardised titanium mesh, while a "hybrid" patient-specific titanium implant was fabricated for the remaining 17 patients prior to surgery. The functional and cosmetic outcomes, in terms of diplopia, enophthalmos, ocular motility, and sensory disturbance, trended better when "hybrid" patient-specific titanium meshes were used, although the differences were statistically non significant [11].

Bone Substitute Materials (BSM) are described as a reasonable alternative to Autologous Bone (AB), simplifying the grafting procedure. A systematic review and meta-analysis analysed the influence of BSM compared to AB on treatment success in augmentation procedures of the edentulous jaw. Within the limitations of the meta-analytical approach, implant survival showed no statistically significant difference for ridge augmentation using BSM or AB [12]. These developments aim to enhance treatment plans for patients by offering superior aesthetic and functional properties. However, evidence comparing their functional and aesthetic outcomes is limited. Therefore, the present study aims to evaluate and compare the functional and aesthetic outcomes of ORIF using PLGA mesh and titanium mesh in patients with orbital floor fractures.

MATERIALS AND METHODS

A randomised single-blinded controlled trial will be conducted at Siddharth Gupta Memorial Cancer Hospital (AVBRH), Datta Meghe Institute of Higher Education and Research, Sawangi, Wardha, Maharashtra, India, from September 2024 to December 2025. This trial will involve 12 patients presenting with orbital floor fractures who will undergo ORIF using either PLGA mesh or titanium mesh. The study has received approval from the Institutional Ethical Committee (IEC) of Datta Meghe Institute of Medical Sciences, a Deemed University (IEC Number: DMIHER(DU)/IEC/2024/231). The trial has been registered on the Clinical Trial Registry of Inmdia (CTRI) web portal with the reference number REF/2024/10/093542. The study will adhere to the principles outlined in the "Helsinki Declaration" and any subsequent revisions or equivalent ethical standards. Approval will be sought in accordance with the institutional ethical guidelines set forth by the "Central Ethics Committee on Human Research" (CECHR) of the "Datta Meghe Institute of Medical Sciences."

Two parallel groups, A and B, will be allocated by randomisation using a computer-generated table.

Inclusion criteria:

- Patients aged 18-80 years.
- Patients with untreated unilateral or bilateral orbital floor fractures.
- Patients requiring ORIF of the orbital floor will be included in the study.

Exclusion criteria:

- Patients who are unwilling to give informed consent or follow-up.
- Patients unfit for general anaesthesia, those with bone diseases, and those with comminuted fractures will be excluded from the study.

Sample size calculation:

$n = \frac{Z^2 P(1-P)}{d^2}$

- If your population is more than 10,000

Where

- Z: statistic for a level of confidence. (For the level of confidence of 95%, which is conventional, Z value is 1.96)
- P: Prevalence or proportion (P is considered 0.5)
- d: precision. (d is considered 0.05 to produce good precision and smaller error of estimate)

Z=1.96

P=Release = 0.5%

=0.005

d=Desired error of margin=6%=0.6

$n=\frac{1.96^2 * 0.005*(1-0.005)}{0.06*0.06}$

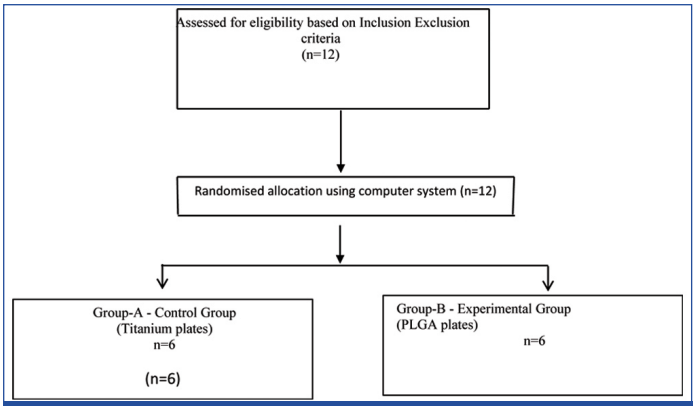
=5.30

=6 participants needed in each group

A random selection of patients from the Department of Oral and Maxillofacial Surgery outpatient department will be made based on the inclusion criteria. Two parallel groups, A and B, will be allocated by randomisation using a computer-generated table. A sample of 12 patients will be randomly split into two groups to perform the study [Table/Fig-1].

Study Procedure

After obtaining informed consent from each patient included in this study, a detailed history of each patient will be recorded. The preoperative assessment will include a thorough clinical examination



[Table/Fig-1]: Consolidated Standards of Reporting Trails (CONSORT) flowchart.

and extraoral photographs, including an orthopantomogram and radiographic analysis will include a Computed Tomography (CT) scan in all three planes (axial, coronal, sagittal) and 3D reconstruction. After fulfilling all the criteria, the patients will be operated on by a single senior surgeon with considerable experience in maxillofacial trauma, following the receipt of preanaesthetic fitness. The surgical procedure will comprise ORIF of the fractured segments and reconstruction of the orbital floor using PLGA mesh and titanium mesh. In the trial group, the fractured orbital floor will be reconstructed using bioabsorbable plates, restoring the orbital volume.

Outcomes

Patients will be evaluated based on functional and aesthetic efficiency.

A) Functional outcomes:

- Diplopia will be assessed using visual acuity tests, cover tests, and extraocular movement assessments.
- Enophthalmos will be measured using the Luedde enophthalmometer (Good-Lite USA (#781000)), and ocular motility and infraorbital nerve function will be assessed using standardised clinical measures. These will include ocular motility tests, light touch, and pain sensation using a cotton wisp and a blunt pin, comparing both sides of the face to identify differences in sensation. Patients will be asked to rate their sensation as normal, hypoesthesia (reduced sensation), anaesthesia (absence of sensation), or hyperesthesia (increased sensation).
- Temperature perception will be tested using warm and cold objects, while vibration sensitivity will be assessed by placing a 128 Hz tuning fork over the infraorbital foramen, alongside an orbital CT.

B) Aesthetics outcomes: Aesthetic outcomes will be evaluated based on facial symmetry, globe position, and patient satisfaction using validated scoring systems like the Patient Satisfaction Score. The level of patient satisfaction will be measured using a five-point Likert scale (1=very dissatisfied, 2=dissatisfied, 3=neutral, 4=satisfied, and 5=very satisfied) and a checklist.

STATISTICAL ANALYSIS

The Statistical Packages for Social Sciences (SPSS) version 20.0 will be used for statistical analysis. An unpaired t-test will be applied for intergroup comparisons, while a paired t-test will be used for intragroup comparisons. A p-value of less than 0.05 will be considered statistically significant.

REFERENCES

[1] Tabrizi R, Langner NJ, Pouzesh A, Arabion H. Evaluation of the biodegradable plates (PG910/PDO) for reconstruction of various sizes of orbital floor defects in the blow-out fractures. Craniomaxillofacial Trauma Reconstr. 2013;6:187-90. Doi: 10.1055/s-0033-1349205.
[2] Facial Injury Surgery Sheffield. Nicholas Lee Surg. 2024. Available from: https://nicholaslee.surgery/specialist-surgery/facial-trauma-injury-surgery/.
[3] Jung EH, Lee MJ, Cho B-J. The incidence and risk factors of medial and inferior orbital wall fractures in Korea: A nationwide cohort study. J Clin Med. 2022;11:2306. Doi: 10.3390/jcm11092306.
[4] Cornelius C-P, Ehrenfeld M. The use of MMF screws: Surgical technique, indications, contraindications, and common problems in review of the literature. Craniomaxillofacial Trauma Reconstr. 2010;3:55. Doi: 10.1055/s-0030-1254376.
[5] Uhthoff HK, Poitras P, Backman DS. Internal plate fixation of fractures: Short history and recent developments. J Orthop Sci. 2006;11:118. Doi: 10.1007/s00776-005-0984-7.
[6] Tapscott DC, Wottowa C. Orthopedic Implant Materials. In: StatPearls. StatPearls Publishing: Treasure Island (FL); 2024.
[7] Zhang M, Xu F, Cao J, Dou Q, Wang J, Wang J, et al. Research advances of nanomaterials for the acceleration of fracture healing. Bioact Mater. 2024;31:368-94. Doi: 10.1016/j.bioactmat.2023.08.016.
[8] Gentile P, Chiono V, Carmagnola I, Hatton PV. An overview of Poly(lactic-co-glycolic) Acid (PLGA)-based biomaterials for bone tissue engineering. Int J Mol Sci. 2014;15:3640-59. Doi: 10.3390/ijms15033640.
[9] Ortega-Oller I, Padial-Molina M, Galindo-Moreno P, O'Valle F, Jódar-Reyes AB, Peula-García JM. Bone regeneration from PLGA micro-nanoparticles. BioMed Res Int. 2015;2015:415289. Doi: 10.1155/2015/415289.
[10] Polacco MA, Kahng PW, Sudoko CK, Gosselin BJ. Orbital floor reconstruction: A comparison of outcomes between absorbable and permanent implant systems. Craniomaxillofacial Trauma Reconstr. 2018;12:193. Doi: 10.1055/s-0038-1651514.
[11] Sigron GR, Barba M, Chammartin F, Msallem B, Berg B-I, Thieringer FM. Functional and cosmetic outcome after reconstruction of isolated, unilateral orbital floor fractures (blow-out fractures) with and without the support of 3d-printed orbital anatomical models. J Clin Med. 2021;10:3509. Doi: 10.3390/jcm10163509.
[12] Al-Nawas B, Schiegnitz E. Augmentation procedures using bone substitute materials or autogenous bone - A systematic review and meta-analysis. Eur J Oral Implantol. 2014;7 Suppl 2:S219-34.

PARTICULARS OF CONTRIBUTORS:
1. Postgraduate Student, Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.
2. Professor and Head, Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.
3. Associate Professor, Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Yash Sanjay Deshpande,
Postgraduate Student, Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College, Datta Meghe Institute of Higher Education and Research, Sawangi, Wardha-442001, Maharashtra, India.
E-mail: yashdeshpandee@gmail.com

PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Jun 28, 2024
- Manual Googling: Jun 05, 2025
- iThenticate Software: Jun 07, 2025 (19%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: Yes (Funding will be provided by the University)
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **May 16, 2024**
Date of Peer Review: **Jul 01, 2024**
Date of Acceptance: **Jun 09, 2025**
Date of Publishing: **Mar 01, 2026**