

Methodology of Choice of Orbital Implants and Surgical Outcomes in Orbital Fracture Patients

Santanu Das^{1*}, Nayana Nagesh², Raghuraj Hegde³, Niveditha H⁴

¹MS Ophthalmology, Department of Ophthalmology, Kempegowda Institute of Medical Sciences, Bangalore, India

²Junior Resident, Department of Ophthalmology, Kempegowda Institute of Medical Sciences, Bangalore, India

³Consultant Oculoplasty and Ocular Oncology Services, Department of Ophthalmology, Kempegowda Institute of Medical Sciences, Bangalore, India

⁴Professor and HOD, Department of Ophthalmology, Kempegowda Institute of Medical Sciences, Bangalore, India

***Corresponding Author:** Santanu Das, Department of Ophthalmology, Kempegowda Institute of Medical Sciences, Bangalore, India, Email: shannn04@gmail.com

Abstract

Purpose: To determine when and why to use Titanium or Porous Polyethylene (PPE) implant in orbital fracture repair and the surgical outcomes.

Methods: 54 patients from January 2018 to June 2019 attending the emergency and outpatient department with confirmed orbital fractures on CT orbits were included for this prospective study. They were divided into 3 groups based on the severity of the fracture. Type 1 fracture (single wall fracture, displacement $\leq 1\text{cm}^2$) type 2 fracture (>1 wall fracture, displacement $1-2\text{cm}^2$) and type 3 fracture (orbital fracture plus other facial bone fractures with displacement $>2\text{cm}^2$). A thorough ophthalmic evaluation was done for all the patients. All the patients were started on broad-spectrum antibiotics and steroids and if any adnexal injuries were present a thorough saline wash and regular dressing was done. Surgery was done within 10-14 days of admission. Only titanium and porous polyethylene implants were used in this study after analysing the type of fracture and the amount of displacement present on CT scan. Patients were followed up at 1 week, 1, 3, 6 months and 1 year respectively.

Results: Type 2 and type 3 fractures were repaired using titanium (48 patients) and type 1 fractures (7 patients) with PPE implants. There were no incidences of implant extrusion or displacement. The most common post-operative complication encountered was mild to moderate scarring which was treated with 5FU+ Triamcinolone injections. Only 1 patient had MRSA infection leading to removal of the implant. Apart from these post-operative results both functional and cosmetic outcomes were satisfactory in both the groups.

Conclusion: We thereby conclude that both the implants are excellent as well as safe for reconstructing fractures. Titanium is good in type 2 and type 3 fractures whereas PPE is good in small floor fractures.

Keywords: Orbital fractures, Orbital implants, Titanium, Porous Polyethylene, type 1 fracture.

1. INTRODUCTION

Orbital fractures are common and constitute approximately 18 to 50% of all craniomaxillofacial traumas depending upon region. [1] Their management is not only difficult but also challenging as one has to not only correct the functional defects like enophthalmos, diplopia, muscle entrapment and extraocular muscle movement restrictions but also needs to restore the normal orbital contour, volume, vision as well as the facial aesthetics by not giving rise to any iatrogenic ectropion and entropion.

Reconstructing the orbit is challenging because in case of a fracture the bony walls are

comminuted and there might be missing bone fragments. [2] Therefore, it is very important to reconstruct the missing bone. There has been a debate not only about the indications and timings of surgery but also regarding the best possible implant available for reconstructing the orbit. [3]

An ideal orbital implant should have the following properties: [4]

- The ability to bend into the proper anatomical shape
- Radio opacity
- Permanent stability
- Biocompatibility

Although there are a lot of materials available to reconstruct the orbit, in this prospective study we will not only describe when and where to use titanium and porous polyethylene implants and also which one is better in which conditions.

2. MATERIALS AND METHODS

The present study adheres to the rules and regulations of the Declaration of Helsinki and has been cleared by the institutional ethics committee. Before doing any investigation or procedure on the patients a detailed written informed consent was taken from each patient.

54 patients who came to the emergency and ophthalmology outpatient department from January 2018 to May2019 with confirmed orbital fractures on CT- scan were taken up for the study. 12 were female whereas 42 were male. Patients with isolated medial wall, lateral wall and roof fractures with no functional deficits were not included in the study.

A thorough ophthalmic evaluation was done for each of them which comprised of visual acuity testing for both distance and near, colour vision testing, anterior segment evaluation, eliciting pupillary reflexes, diplopia charting, extraocular movement examination and posterior segment evaluation using Indirect Ophthalmoscopy and B-Scan.

CT-Scan orbits 1mm cuts, bone windows, axial coronal and sagittal views with 3D-reconstruction was done for all the patients following which they were divided into 3 groups that is patients with type-1, type-2 and type-3 fractures.

Type-1 fracture- Single wall fracture, displacement $\leq 1\text{cm}^2$

Type-2 fracture->1 wall fracture, displacement 1-2 cm^2

Type-3 fracture - Orbit plus other facial bone fractures and displacement >2 cm^2

Figure 1 shows the CT-Scan pictures of type 1 type2 and type 3 fractures.

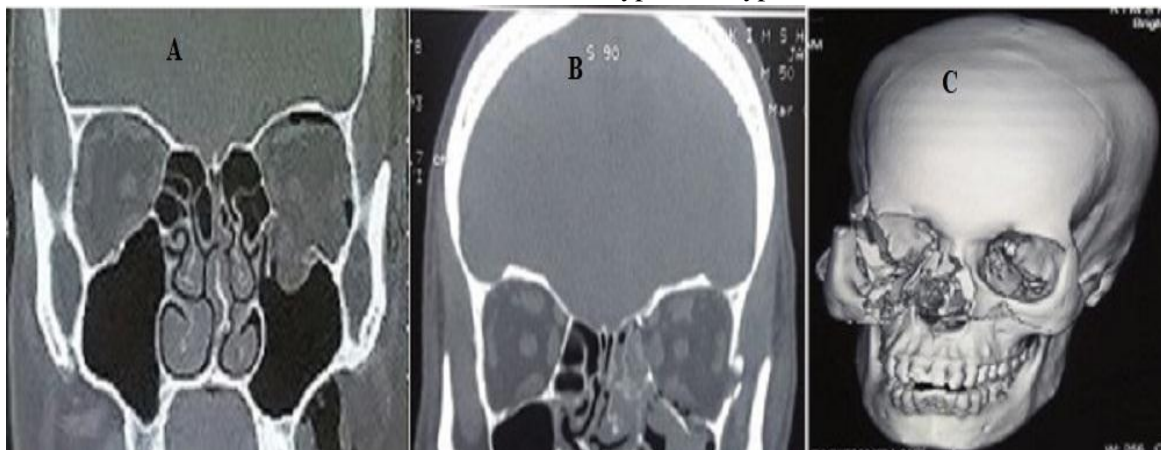


Figure1: (A) Type-1 fracture, 1(B) Type-2 fracture, 1(C) Type-3 fracture

Following admission all the patients were put on intravenous broad-spectrum antibiotics, Metronidazole and Amikacin along with analgesics and intravenous steroids to reduce the inflammation and periorbital swelling. Patients with associated head injury were put on intravenous Mannitol and one antiepileptic. Thrice daily random blood sugar monitoring was done. In patients with optic neuropathy intravenous methyl prednisolone 1 gram was given for 3 days. All the surgeries were done within the first 10 days of accident under general anaesthesia and were done by a single surgeon. Before the surgery titanium implants were autoclaved whereas porous polyethylene implants were kept in the formalin chamber overnight before usage.

All the surgeries were done by the same surgeon through the transconjunctival route using the

swinging eyelid technique. We used either a titanium combined orbital implant or a porous polyethylene sheet (Biopore) depending upon the type of fracture.

For all type-1 fracture patients PPE was used whereas for type-2 and type-3 fracture patients prefabricated combined titanium orbital implant was used. The factors based upon which the implants were chosen are summarized in table 1 Forced duction test (FDT) was done for every patient before starting the surgery as well as once the surgery was complete to rule out any mechanical restriction and iatrogenic entrapment. Titanium implant was placed over the palatine bone and fixed to the inferior orbital rim using 6mm*1.5mm screws while PPE was placed in the orbital cavity and no glue was used to fix it.

Table1:

Factors based upon which the implant was chosen are:
1. Type of fracture
2. Amount of displacement
3. Severity of the fracture
4. Age of the patient
5. Old or new fracture
6. Financial status of the patient

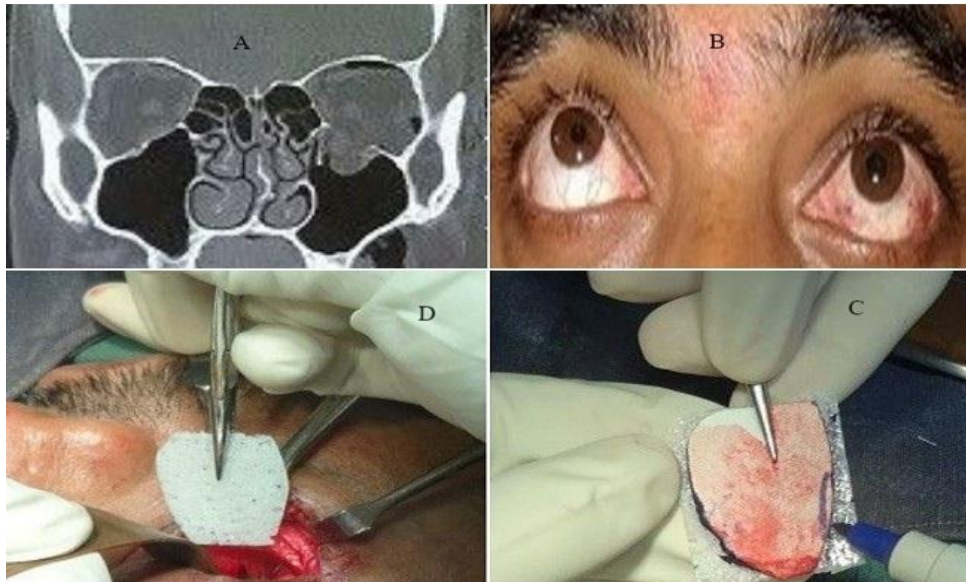


Figure2: (Surgical technique of repairing a type 1 orbital fracture with PPE)

Figure: 2(A) Type 1 orbital fracture with only left sided inferior wall fracture with inferior rectus entrapment, 2(B) Left sided superior gaze restriction, 2(C) The PPE implant is being cut as per the shape and size of the orbital cavity, 2(D) The PPE implant is being placed in the orbital cavity.

In the post op period, all the patients were put-on broad-spectrum antibiotics, oral steroids to reduce the swelling and inflammation, analgesics and one antibiotic steroid eye drop. For all patients in the post-operative period regular dressing along with visual acuity testing,

assessment of extra ocular movements, diplopia charting and anterior segments evaluations were done. Post-operative CT-scan was done for all patients to ascertain whether the implant, extra ocular muscles and orbital contents are in proper orientation or not.



Figure3: (Surgical technique of repairing a type 2 orbital fracture with titanium implant)

Figure3: 3(A) Type 2 orbital fracture with right sided inferior wall, lateral wall and ZMC fracture, 3(B) Prefabricated combined titanium implants is being moulded to form the postero-medial bulge, 3(C) The inferior orbital rim is being fixed with a 6-hole orbital plate and 6mm*1.5mm screws, 3(D) The titanium implant is placed in the orbital floor and fixed with screws over the inferior orbital rim.

Following discharge, they were followed up at 1 week, 1 month, 3 months, 6 months and at 1 year.

3. RESULTS

In our study 42(78%) patients were male and 12(22%) patients were female and the most common cause of orbital fractures amongst our patients being road traffic accident (RTA).51

patients had RTA (93.3%), 3(6.6%) patients gave history of self-fall. 2-wheeler accident was the most common mode of RTA in our patients.

Seven patients had Type1, fifteen had Type2 and thirty-three had Type 3 fractures in our study as shown in Table 2.

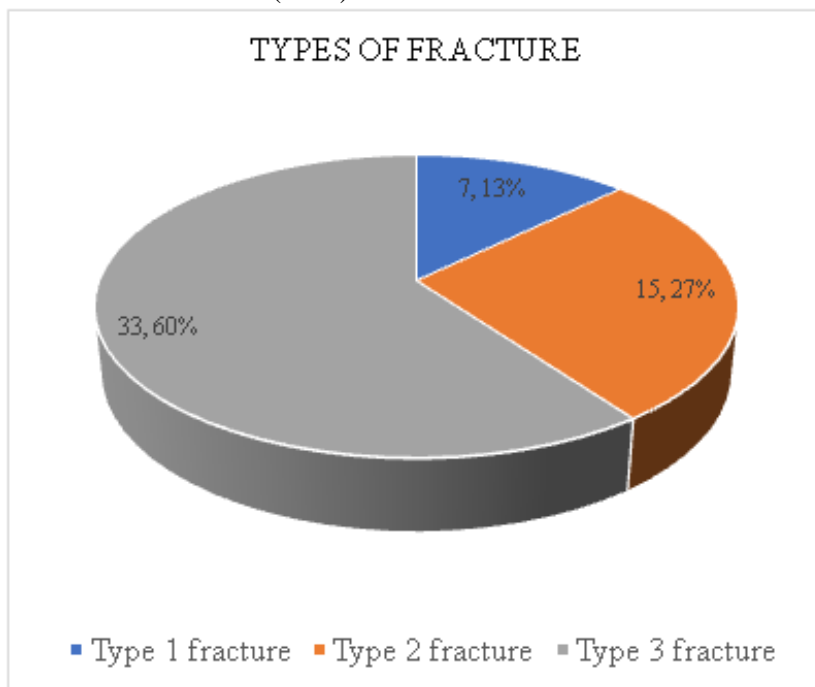


Figure4: Types of Fracture

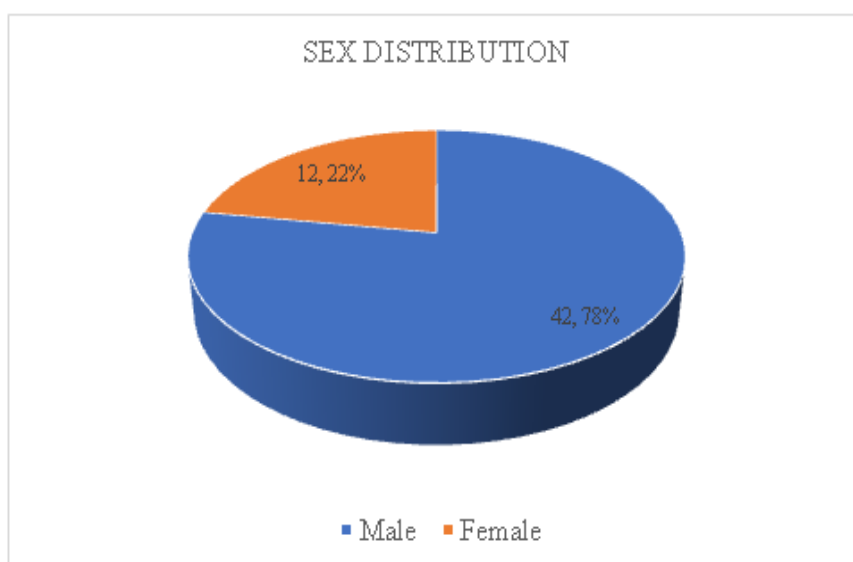


Figure5: Sex Distribution

Table2: Types of Fracture

Type of fracture	Number of patients	Implant used
Type 1 fracture	7	Porous polyethylene
Type 2 fracture	15	Combined medial wall, floor, lateral wall titanium implant
Type 3 fracture	33	Combined medial wall, floor, lateral wall titanium implant

In the group treated with PPE implant 2 patients out of 7 had persistent diplopia and extraocular muscle movement restriction as depicted by the

bar diagram in figure 6. One patient had multiple nerve palsies while the other patient had uncontrolled diabetes which led to a delay

in surgery and subsequently had to undergo strabismus surgery after 6 months following which their diplopia in the primary gaze resolved. 1 patient in the group treated with PPE implant had traumatic optic neuropathy.

6/18 at 1-year post op while the remaining 6 patients had normal 6/6 vision in the pre-op and post-op period. 3 patients had enophthalmos in the preop period which resolved following surgery.

In the pre-operative period, his vision was counting fingers at 2 metre which improved to

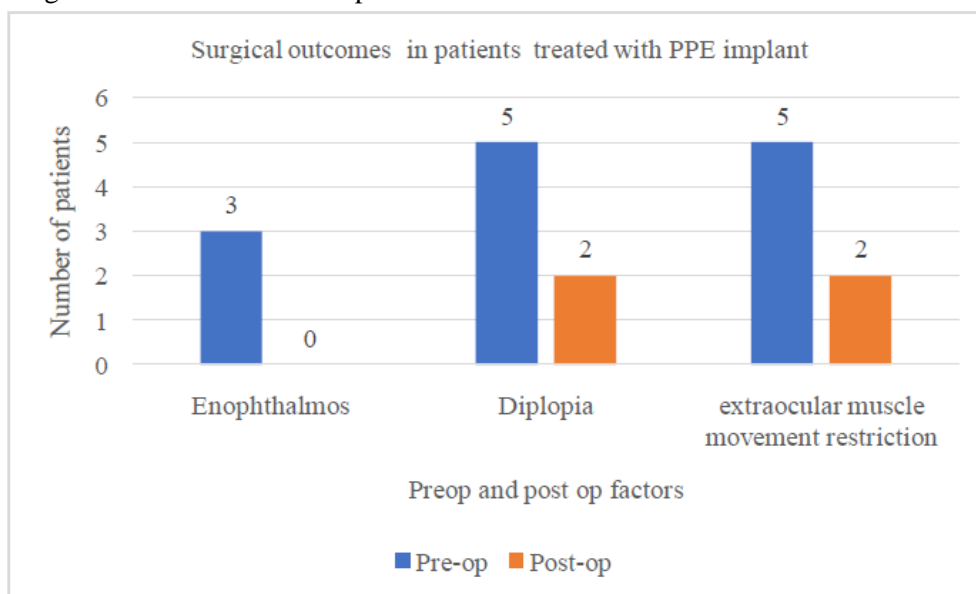


Figure6: Surgical outcomes in patients treated with PPE implant

In the group treated with titanium implant 43 patients had enophthalmos, 7 had diplopia and 9

patients had motility restriction in the pre-operative period as depicted in figure 7.

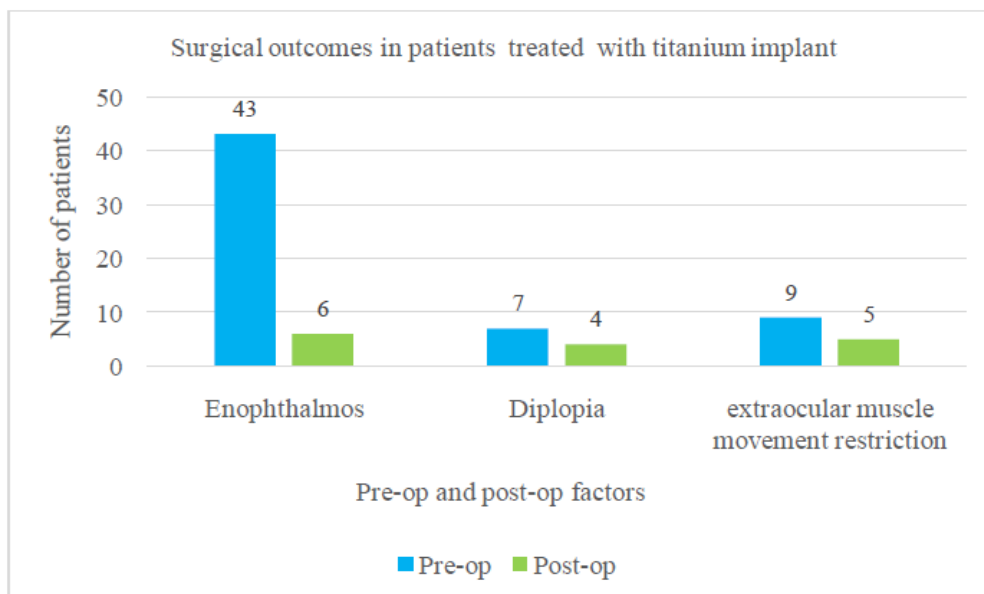


Figure7: Surgical outcomes in patients treated with titanium implant

6 patients had persistent enophthalmos in the post-operative period mainly due to the severity of their fractures. 4 patients had persistent diplopia 6 months follow up because these patients had type 3 comminuted fractures with severe extraocular muscle damage leading to muscle hypotrophy. All 4 patients underwent strabismus surgery after 6 months of orbital

fracture repair. 5 patients had persistent motility restriction at 6 months follow up. Out of these 5 patients 2 had associated multiple nerve palsies whereas the remaining 3 patients had severe type 3 orbital fractures with associated damage to the extraocular muscles. 3 patients without any nerve palsies underwent strabismus surgery after 6 months post-op.



Figure8: (Outcome of surgery in a type 2 orbital fracture patient)

Figure8: 8(A) Patient presented with severe periorbital oedema, 8(B) Type 2 orbital fracture with left sided inferior wall, lateral wall and ZMC fracture, 8(C) Post-operative CT Scan showing the titanium implant in place and the ZMC fracture fixed with a 6-hole orbital plate, 8(D) Final outcomes after 1 year of surgery with no functional and cosmetic deficits.

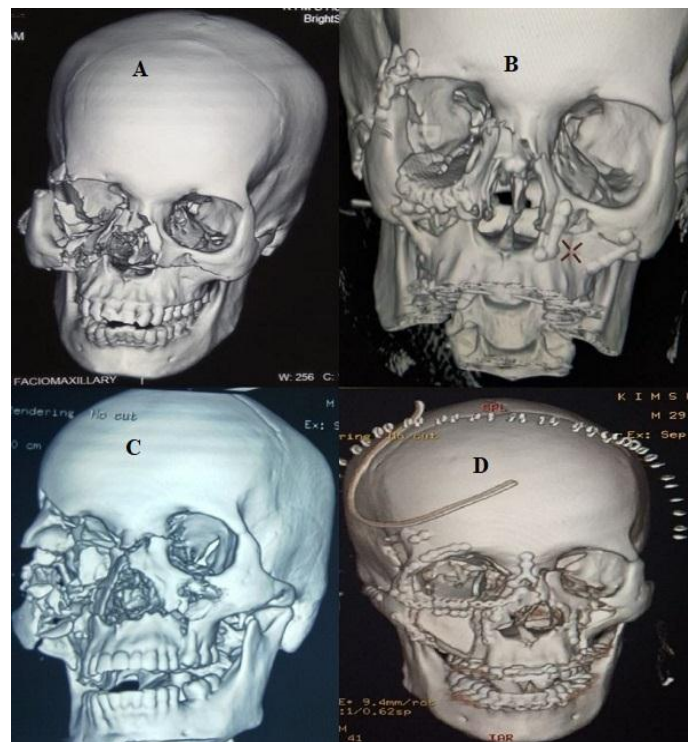


Figure9: (Outcome of surgery in type 3 orbital fracture patients)

Figure9: (A) and (C) shows the 3-D reconstruction image of 2 patients with type 3 orbital fractures including multiple facial bone fractures. (B) And (D) shows the post-operative outcome following reconstruction with titanium implant and orbital plates thereby maintaining the orbital contour and anatomy.

In our study 7 patients had traumatic optic neuropathy at the time of presentation, for them intravenous methyl prednisolone was administered before they were taken up for surgery. They were operated because 4 patients had multiple comminuted type 3 orbital fractures with distortion of orbital anatomy. The remaining 3 patients

with optic neuropathy had significant enophthalmos and were thus operated. In 4 patients vision improved to 6/12 at 1-year post-op whereas in the remaining 3 patients with multiple comminuted fractures had a vision of counting fingers at 2 metres at 1-year post op. For the remaining 47 patients, their pre-op

vision was restored in the post-operative period and there were no implant related complications which lead to a drop-in vision. In the present study only 1 patient had MRSA infection in the post-op period which was treated with broad spectrum antibiotics and removal of the titanium implant.

In the present study both the implants gave us equally good results. There was no incidence of implant extrusion, migration or malpositioning of the implant or orbital adherence in the immediate post-operative period as well as after one year of follow up.

4. DISCUSSION

Materials for orbital fracture reconstruction have been classified as: [4]

- Autologous
- Allogenic
- Alloplastic.

Although there are a lot of materials available for reconstruction of orbit in this prospective study, we have used only the titanium combined orbital implant and the porous polyethylene

Table3: (Types of orbital implants)

AUTOLOGOUS	ALLOGENIC	ALLOPLASTIC
Bone	Irradiated bone	Non-metallic permanent
Cartilage	Lyophilized dura	Silastic sheets
Fascia lata	Lyophilized cartilage	Bioactive glass
Periosteum	Fascia lata	Marlex mesh
	Bovine bone	Porous polyethylene
		Teflon
		Metallic- permanent
		Titanium
		Vitallium
		Resorbable material
		Polydiaxanone
		Polyglactin 910
		Polylactic/polyglycolic acid polymer

Gear et al in their study also proved that titanium implants are very good for reconstructing large defects and maintained adequate and satisfactory reduction in defects greater than 2cm which is similar to the results we obtained in our study. [6]

Han X et al found Medpor composite titanium implant to be very good in reconstructing orbital blow out fractures.7

In our study only 1patient out of 47 patients who were treated with prefabricated titanium implant had a post-operative MRSA (Methicillin Resistant Staphylococcus aureus) infection in the immediate post-operative period which led to removal of the implant thus indicating that titanium implants are very safe which is in

accordance with the results published by Sargent and Fulks who reconstructed 57 orbits with vitallium which is an alloy of titanium [8].

Although Totir M et al in their review article mentioned that PPE implant’s smooth edges and porous nature are its advantages over titanium but PPE implants are not radio-opaque therefore it can’t be seen in post-operative CT scan pictures and also because of its lack of rigidity can’t be used for correction of large defects and also it is costly when compared to titanium. [4]

After proving its competence in dental implants, bone screws and prosthetics titanium implants have become very popular amongst surgeons for the reconstruction of orbit.

Titanium is rigid and malleable and is perfect for the reconstruction of large defects where rigidity and strength are required to maintain the contour of the orbit. Also, one of its properties is to osteointegrate which was proved endoscopically by Schubert et al who found that there was incorporation of soft tissue into the orbital implant approximately 1 month after the surgery. After 2 months it was found that the whole implant has been covered by a mucosal type epithelium. [5]

Mackenzie et al who reconstructed 51 orbits with titanium implant reported only 1 case of enophthalmos with no infection which proves that titanium has very good biocompatibility and incidence of infection is very rare which is similar to the results we obtained in our study [9].

Some of the other advantages of titanium implant are that it is readily available, contouring of the implant that is making the postero-medial bulge of the orbit is easy, it is radio-opaque so it can be easily seen in post-operative CT-scan imaging. There are no donor site related complications like infection,

haematoma formation, increased post-operative recovery time, bony defect at donor site and an additional surface scar.

Some of the other complications associated with autologous grafts are that it increases operative time and sometimes bending the bone is difficult

and might even break if tried to bend it beyond its capacity. All these complications are not encountered with titanium. Lastly it is cheaper than composite implants and resorbable implants. Titanium is also corrosion resistant. [10, 11, 12]

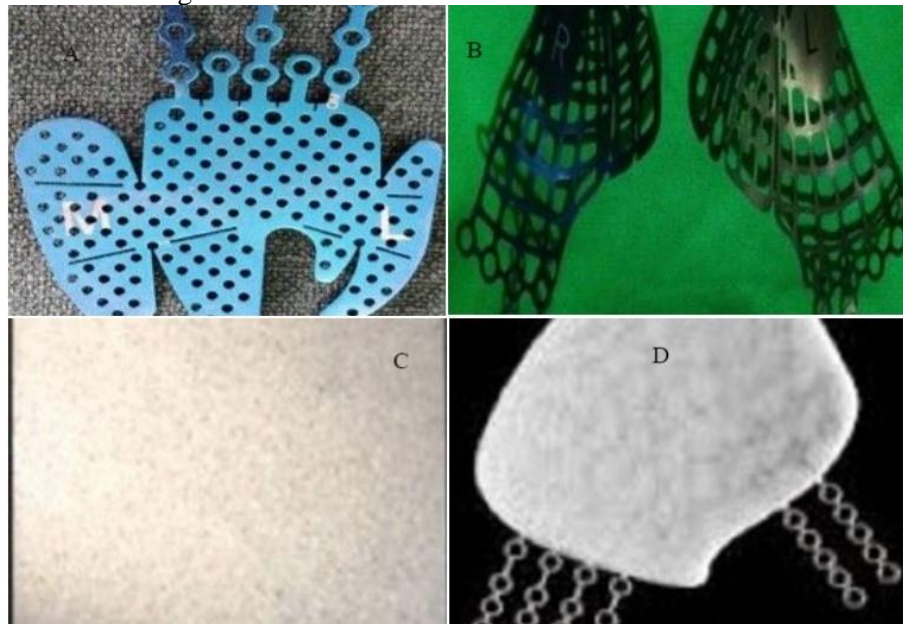


Figure10: (Types of orbital implants)

Figure10: A) Prefabricated combined titanium implant, 10(B) Titanium orbital floor only implant, 10(C) Porous Polyethylene implant, 10(D) Composite implants.

In our study we have used PPE implants to reconstruct small and single wall orbital fractures and gave us good results. It is non-absorbable as well as malleable and connective tissue can grow into the pores which give good biocompatibility and is said to have greater biocompatibility than titanium as suggested by Khorasani M et al. [13]

Romano et al used 128 PPE implants and reported only 1 case of post-operative infection which is similar to the results we obtained in our study where we used PPE implants in 7 patients and none of them reported any infection at 6 months and 1 year follow up [14].

In the study conducted by Nam et al 214 orbital floor fractures were repaired using PPE sheets. However they haven't mentioned the type of defect small or large, but reported 12 cases with complications which shows that the rate of complications with PPE implants are very minimal. [15] In our study we used PPE implants to correct small defects and therefore didn't encounter any patients with post-operative persistent enophthalmos or any infection or any other problems like implant extrusion or migration even though we didn't use any glue to fix the implant.

In a study conducted by Potter and Ellis they came to the conclusion that PPE implants can be successfully used to repair defects less than 2cm in diameter which is similar to what we have done in our study where we have used PPE implants in patients with type I fractures. [16]

Aral AM et al in their study on rabbits found that porous polyethylene implants were effective and well tolerated for reconstruction of isolated orbital floor defects. [17]

In the study conducted by Sai Krishna Degala and Soumadip Dey there were no incidence of inflammatory reaction or implant extrusion in the 12 patients taken up for study which is similar to our results. [18]

Mustafa et al reported post-operative infections in 15.38% of their patients treated with PPE implants but in our study, we didn't encounter any infection if the proper preoperative and postoperative antibiotic protocol is followed. [19]

Lee et al, Ozturk et al, using Medpor reported diplopia incidence to be 3.5%, 2.6% and respectively which is very less. [20, 21]

Buchel et al found resorbable implants to be extremely useful while reconstructing small defects upto a maximum of 2*2 cm. We didn't

use resorbable implants firstly because it is more expensive than either titanium or PPE and secondly PPE implants gave us good results while reconstructing small and isolated orbital fractures. [22]

Ellis E and Scolozzi P showed that prefabricated titanium implants have a high success rate in re-establishing pre-operative bony volume which is similar to what we found in our study as we used titanium mainly to reconstruct large defects. [23, 24]

Garibaldi et al suggested the use of composite implant as it has the advantage of both titanium and PPE and also gives very good results. [25] Patel PJ et al showed growth of fibrovascular tissue over the PPE implant in 3 human cases. [26] Villareal PM et al reported 62.5 % correction of enophthalmos, 82% correction of hypoglobus and 89.3% correction of diplopia in their study. Although they reported four cases of post-operative infection, we didn't have any incidence of infection in our study. [27]

5. CONCLUSION

In our prospective study both the implants gave us excellent results as there were no patients who came to us with complications like implant extrusion, migration or any inflammatory reactions because of the implant. Both the implants are good as they have very low rate of postoperative infection as suggested in literature and also in our study. Titanium implant has certain advantages like it has rigidity and provides excellent stability and good reduction of fractures where defects are more than 2cm and it is radio-opaque. On the other hand, PPE implants are smooth porous which allows connective tissue to grow over it and because it is smooth there are less or no chances of orbital adherence. It is excellent for orbital fractures with defect < 1.5 cm.

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