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# Clinical Studies between OsteoMesh and Titanium Mesh

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## Abstract

**I**n this paper, we seek to compare the efficacy of polycaprolactone with titanium mesh in reconstruction of orbital fractures. In a prospective randomized controlled trial conducted between August 2004 and July 2006, 80 patients with orbital fractures were recruited into the study. These patients were randomized to receive either titanium or polycaprolactone. Following a comprehensive preoperative and postoperative protocol, these patients were followed up by both the plastic surgeon and the opthalmologist up to a year. Out of 80 patients, 63 completed the study and 19 were excluded for various reasons. Of the remaining 44 patients, there were 49 reconstructions. (polycaprolactone: n=29, titanium:n=22) When evaluated at 1, 3, 6 and 12 months, there was no statistically significant difference between the two groups in terms of diplopia, enopthalmos and limitations in gaze. In both groups, all patients achieved functionally and aesthetically good outcomes. Polycaprolactone is comparable to titanium long considered the gold standard for repair of orbital fractures and holds immense potential in view of its bioresorbable properties.

### Introduction

Isolated or combined fractures of the orbit are frequently seen in our hospitals and are often co-managed by both the Departments of Plastic Surgery and Ophthalmology. Clinically, fractures may present with marked chemosis, periorbital hematomas, hypoaesthesia of the infraorbital nerve and traumatic optic neuropathy. Long term sequelae include diplopia, limitations in gaze, hypoglobus and enopthalmos. An ideal implant material for orbital reconstructions should be inert, resistant to infections, provide rigid stability and free of any potential complications eg migration or extrusion of the implant. Titanium meshes have long been considered the gold standard for repair of orbital defects. The ease of use, the ability of titanium mesh to conform to the contours of the orbit and its strength makes it an ideal material for reconstructing these defects. Over the past 20 years, alloplastic biodegradable materials have emerged as alternatives, gaining popularity due to its lack of soft tissue immune response, adequate structural support and osteoconductive nature. More recently, polycaprolactone, an FDA approved polymer was proposed as an implant material for orbital defects

based on its above properties. In view of the above-mentioned, a clinical trial is initiated to investigate the effectiveness of polycaprolactone mesh compared to titanium mesh in reconstruction of the orbit.

### Materials and Methods

The Osteopore PCL (Polycaprolactone) Scaffold™ of OsteoMesh™ acts as a bone void filler. The shape of the OsteoMesh™ (Figure 1) conforms to the defect, thus maximizing direct contact with viable host bone. It is intended for the use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects. It is also for use in the augmentation or restoration of bony contour in the craniofacial skeleton.

Figure 1: OsteoMesh™

Patients with orbital floor fractures who expressed consent to be entered into the study, were randomized into either the titanium mesh or PCL implant group – estimated 40 per year for 2 years. Diagnosis was made clinically and with CT scans. A brief synopsis of the clinical investigative plan is as follows:

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Initial assessment of the eye – diplopia, visual acuity & range of movement of the affected eyeball, were performed.

1. Surgery was performed in the operating theatre. Under general anesthesia, a lateral canthotomy incision and a transconjunctival approach (Figure 2) was made for all cases. Adequate exposure of all defects was obtained by a subperiosteal dissection of the orbit following which, the implants were inserted with no fixation by screws or sutures. All orbital defects were completely exposed and the orbital soft tissue was reduced under direct vision. Forced duction test was performed before the start of surgery and again, before wound closure to ensure no entrapment of orbital tissue. Surgery was completed by closure of the wound in layers.
2. Early postoperative assessment was performed on the 1st post operative day for visual acuity, diplopia and range of movement.
3. On discharge, the patient was given a follow-up for removal of stitches (1week) & reviewed on the 3rd, 6th and 12th month post-operation.
4. Visual acuity, range of movement of the affected eyeball, diplopia and enophthalmos was assessed in these follow-up appointments.
5. Eye movements were examined in all 9 directions. Clinically significant diplopia was defined as double vision in the primary position and within 30 degrees of gaze sufficient to interfere with the patient's daily activities, and not just in the extremes of gaze.

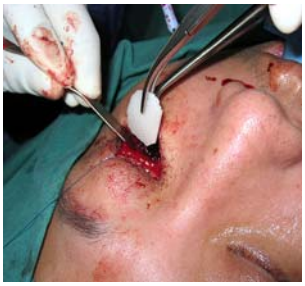

Figure 2: Intra-op insertion of OsteoMesh™

6. Enopthalmos, due to enlargement of orbital cavity and subsequent backward and downward displacement of the globe into the bony orbit, was defined as 2mm or more relative to the opposite site using Hertel's Exopthalmometer, an instrument which measures the difference between the anterior corneal surface and the lateral orbital rim. The enophthalmos assessment is an excellent outcome indicator of the effectiveness of the PCL scaffold in the reconstruction of the orbital floor. As the scaffold is resorbable, it will slowly break down & disappear as new bone forms. This is the ideal situation as no foreign material will be present in the patient's orbit after the whole of the implant is resorbed (~2 years).
7. Implant related complications eg. infection, exposure, extrusion, seromas, persistent edema or pain were also documented.
8. CT scans were carried out at the 6th and 12th month follow-up. This was an objective assessment of the effectiveness in reconstructing the fractured orbital floor. The scan allowed the measurement of the orbital volume of the affected side & its comparison to the non-affected side.

**Results**

There were 80 patients who were recruited initially. 63 patients completed the study. 19 were excluded for various reasons. Some had ophthalmic operations not related to the primary orbital pathology eg Laser-Assisted In Situ Keratomileusis (LASIK) for correction of visual acuity. Some had recurrent trauma to the eye in study. In our multi-ethnic population, the Chinese predominated our study, accounting for 49% of all cases. Age ranged from 19 to 64 years, with a mean of 35. The demographics of the patients in the 2 groups are presented in Table 1. Types of fractures are presented in Table 2.

| | Sex (Male/Female) | Mean age (Years) | Total |
|---|---|---|---|
| PCL group | 23/4 | 32.3 | 27 |
| Titanium group | 19/3 | 38.4 | 22 |

Table 1: Patients between August 2004 and July 2006

| Types of fractures | Polycaprolactone group (n=27) | Titanium group (n=22) |
|---|---|---|
| Floor | 23 | 20 |
| Lateral wall | 12 | 12 |
| Medial wall | 6 | 10 |
| Roof | 2 | 3 |

Table 2: Locations of fractures

PCL group: The mean age was 32.3 years in this group. There were 23 males and 4 females. Diplopia and enopthalmos were the more common post operative consequences. 8 (29.6%) patients had diplopia at 1 month. At the last follow up, diplopia persisted in 2(7.4%) of them.

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There were 8 patients who developed enopthalmos during the follow up period, 2 of whom had residual enopthalmos at the end of 1 year follow up. None of them required corrective surgery. Neither was the degree of enopthalmos functionally or aesthetically disturbing to the patient. One patient had enopthalmos persisting from before the operation. His fracture involves all 4 walls of the orbit and he also sustained complete ptosis of his right eye. This patient is still on follow up with us and there may be plans for corrective surgery.

4 (14.8%) patients had limitations in eye motility at 1 month but their symptoms improved throughout the follow up period. None of them have gaze disturbances at the end of the follow up period. Complications of PCL Scaffold are shown in Figure 4. Throughout the course of follow up, the group tolerated PCL well, with no patient developing adverse reactions towards the study material eg pain, scarring, sterile sinus collections, ectropions or excessive debris production. There were no documented cases of migration, extrusion or protrusion of implant. None of the patients required a second operation for removal of implant.

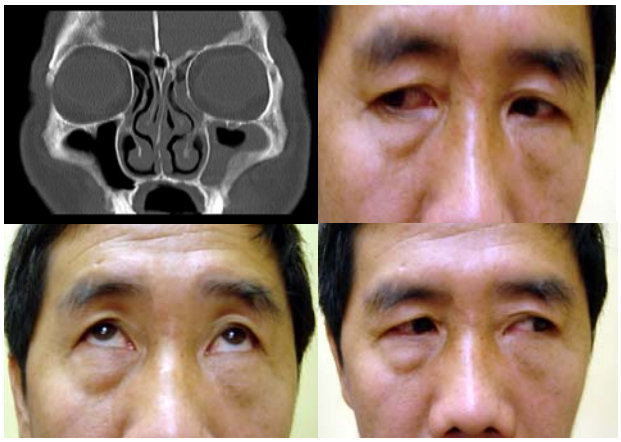

Figure 3(clockwise from top left): CT scan of left orbit showing mineralization of implant after 1 year, 3 views of patient moving eyes in various directions without hindrance

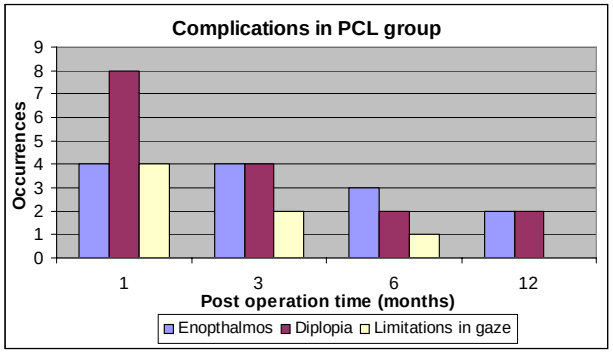


Figure 4: Complications in the polycaprolactone group

Titanium group: The mean age was 38.4 years. There were 19 males and 3 females. The incidence of ocular complications is documented in Figure 5.

The incidence of residual diplopia was higher in the titanium group compared to the PCL group. 6 (28.6%) patients had residual diplopia at the end of 1 year's follow up. There were 10 (47.6%) patients who developed enopthalmos during the follow up period.

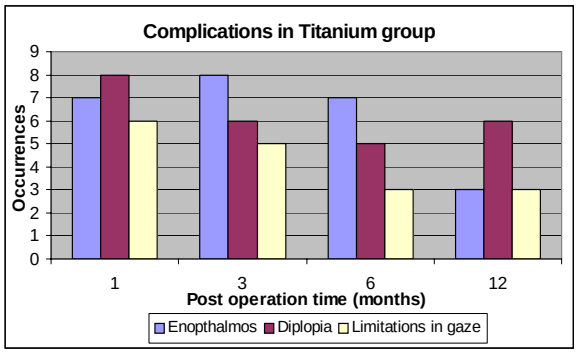


Figure 5: Complications in the Titanium group

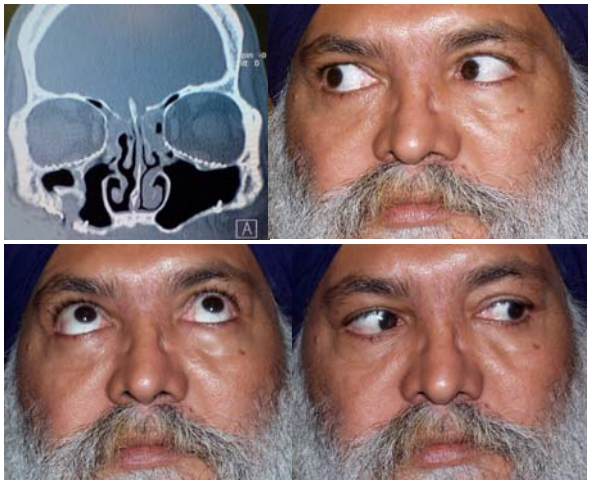

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Figure 6(clockwise from left): CT scan of both orbits with titanium mesh after 1 year, various views of patient moving eyes with no hindrance of movement after titanium reconstruction

Comparative Analysis: Statistical analysis was carried out using SPSS v.15. A comparative study was carried out using chi-square test and Fischer's exact test if the study sample was less than 5. A p value of <0.05 is statistically significant. At 1, 3, 6, and 12 months of follow up, there was no statistically significant differences between the use of titanium and PCL in the reconstruction of orbital fractures and post op ophthalmic complications of diplopia, enopthalmos and limitations in gaze. In our study, PCL is as effective as titanium when used for reconstruction of orbital defects

**Discussion and Conclusions**

Orbital fractures occur commonly. Indications for surgery include large defects, or presence of ophthalmic complications like diplopia, enopthalmos, limitations in gaze and traumatic neuropathy. The aims of surgery are precise reconstruction of shape and volume of the orbit, rigid fixation and restoration of the orbit to its pre-traumatic volume to reduce post operative complications like enopthalmos and diplopia. That being said, even with accurate reduction, end results may be compounded by scarring or atrophy of periorbital soft tissue or fats.

Despite the common occurrence of orbital fractures, controversy still remains regarding the ideal implant material and timing to surgery. The ideal implant material should be inexpensive, readily available in sufficient quantities, biocompatible, easy to contour, provide rigid support and free of any systemic effects.

In our study, properties of PCL are translated into its use for reconstruction of orbital fractures. After analyzing ophthalmic complications and monitoring for adverse effects related to implant use, we had found no statistically significant differences between the use of titanium or PCL.

No implant related complications were observed. The ease of handling allows contouring for accurate reconstruction of the internal orbit. Implant fixation and strength are determined by fibrovascular and bony ingrowth into the porous network of PCL mesh preventing loss of support of the orbital walls.

Taking into account these favorable properties, PCL appears to be an attractive alternative to its non-resorbable counterpart titanium in bridging orbital defects.

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**References**

1. Dietz A, Ziegler CM, Dacho A, Althof F, Conradt C, Kolling G,von Boehmer H, Steffen H: Effectiveness of a new perforated 0.15mm poly-p-dioxanon-foil versus titanium-dynamic mesh in reconstruction of the orbital floor. J Craniomaxillofac Surgery: 29: 82-88, 2001

2. Potter JK, Ellis E. Biomaterials for reconstruction of the internal orbit. J Oral Maxillofac 1998:99:149-154

3. Schantz JT, Lim TC, Chou N, Swee HT, KC Tan, SC Wang, Dietmar WH. Cranioplasty after trephination using a novel biodegradable Burr hole cover: Technical case report. Operative Neurosurgery. 2006 Feb;58(1 Suppl):ONS-E176;discussion ONS-E176.

4. Rohner D, Dietmar WH, KC Tan, Oberholzer M, Hammer B. In vivo efficacy of bone-marrow-coated polycaprolactone scaffolds for the reconstruction of orbital defects in the pig. J Biomed Mater Res Part B: Appl Biomater 66B: 574-580, 2003

5. Hosal BM, Beatty RL. Diplopia and enopthalmos after surgical repair of blowout fracture. Orbit: 21: 27-33, 2002

6. Karesh JW, Dresner SC. High density porous polyethylene (Medpor) as a successful anopthalmic socket implant. Opthalmology. 1994;101:1688-1696

7. Lee S, Maronian N, Most SP, Whipple M, McCulloch TM, Stanley RB, Farwell G. Porous high density polyethylene for orbital reconstruction. Arch Otolaryngol Head Neck Surg. 2005;131:446-450

8. Maas CS, Merwin GE, Wilson J et al. Comparison of biomaterials for facial bone augmentation. Arch Otolayngol Head Neck Surg. 1990;116:551-556

9. Folkestad L, Westin T. Long term sequelae after surgery for orbital floor fractures. Otolaryngol Head Neck Surg. 1999;120:914-921