

## A Randomised Control Study Comparing the Efficacy of Resorbable Transosseus Ligature and Titanium Miniplates for Fixation of Maxillofacial Fractures in Young Patients

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**Abstract:** *Aim:* To compare the efficacy of bioresorbable polydioxanone suture for transosseous fixation to that of titanium miniplates for maxillofacial fractures

**Materials and methods:** This study was conducted in the department of oral and maxillofacial surgery, Govt dental college, Bangalore. Of a total of 20 patients involved in the study, fixation of fracture in 10 patients was achieved by transosseous ligation by means of polydioxanone. Whereas the other 10 received titanium miniplates. In case of mandibular fractures, MMF was done for a period of 6 weeks to achieve occlusion and provide stability.

**Results:** Stable fixation was achieved in both the groups, showing a satisfactory and an uneventful healing. Polydioxanone provides adequate stability for fixation and was found to be a promising material which could save considerable cost and eliminate the need for a second procedure, thereby greatly diminishing the morbidity to which the patient is exposed.

**Conclusion:** Resorbable polydioxanone can be successfully used in maxillofacial fractures treatment. In cases of minimally displaced fractures, immediate and rigid fixation of facial fractures with PDS ligatures yield excellent results.

**Key words:** Polydioxanone ligature, transosseous fixation, titanium miniplate fixation.

**Key message:** Polydioxanone suture material was found to be a promising material which could save considerable cost and eliminate the need for a second procedure, thereby greatly diminishing the morbidity to which the patient is exposed.

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### I. Introduction

Traumatic injuries to the face are witnessed since the beginning of the time and the incidence of maxillofacial injuries are alarmingly increasing due to high speed vehicles, poor road conditions and too many automobiles. They make up about 42% of all forms of injuries, of which road traffic accidents and direct assault contribute up to 34%

Management of trauma has greatly evolved since the earliest description, of supportive bandages to other means like splints, circumferential wiring and extra-oral pin fixation techniques to stabilize fractures<sup>1</sup>. It was only after the Second World War, there was a considerable development in techniques from closed reduction to an approach of open reduction with direct fixation using and bone plates.

The use of metallic materials has often required their removal during the post-healing period. In rigid fixation, there is higher incidence of malocclusion and micro fracture at the fracture ends. Loosening and corrosion may occur causing pain and inflammation<sup>2</sup>.

Even the titanium which is supposed to be the most bio-compatible material available, has shown metal ions release after six months and significant increase in titanium content and deposition into organs such as lungs, spleen, liver and kidneys<sup>3</sup>.

Metals have also been attributed to cause secondary infection and interference with the placement of prosthetic appliances. Other disadvantages of metallic device include backward scattering in patients undergoing radiation therapy and formation of artefacts in computed tomography and magnetic resonance imaging.<sup>4</sup>

This has led to the search for bio-compatible and resorbable material, which provides adequate tensile strength for normal healing of bone, eliminating the risk of secondary infection, non-interference with advanced investigative procedures and placement of prosthetic appliance which would be particularly useful in apprehensive patients, where retrieval of material is difficult and avoids second surgical procedures.

Quayle and Badrawy in 1984 were the first to clinically and experimentally evaluate polydioxanone material in various maxillofacial surgical procedures<sup>5</sup>.

Polydioxanone is a synthetic resorbable material available in various forms such as monofilament suture, foil and plates. Breaking strength is 8.54 and its absorption is complete within 180 days<sup>6</sup>.

It has been used widely as suture material in gynaecology and obstetrics, abdominal wound closure, colonic surgery, vascular surgery, angioplasty, paediatric cardiovascular surgeries, cataract surgeries inguinal surgery and plastic surgery.

Efforts have been made in this study to evaluate monofilament polydioxanone in the management of maxillofacial fractures as substitute to stainless steel wire based on its biomechanical properties.

## **II. Materials and methods**

This study was conducted in the department of oral and maxillofacial surgery, Govt dental college, Bangalore.

### **Aims And Objectives:**

1. To compare the efficacy of polydioxanone for fixation of maxillofacial fractures with that of titanium miniplates
2. To evaluate post-operative healing of fractures.
3. To assess whether the degradation end product interfere with bone healing or not.
4. To avoid possibility of second surgical procedure for the removal of fixation devices.

**Inclusion criteria** were as follows:

1. Age group of 10-20 years
2. Minimally displaced mandibular and le fort 1 fractures
3. Those requiring open reduction and internal fixation
4. Those willing to participate in the study

**Exclusion criteria** were as follows:

1. Fractures of more than 15 days duration.
2. Patients suffering from any systemic illnesses or syndromes
3. Severely displaced or comminuted fractures

Twenty cases with minimally displaced mandibular and le forte 1 fractures were selected. They were then randomly divided into two groups:

Group A: those receiving resorbable polydioxanone fixation (study group)

Group B: those receiving titanium miniplates (control group)

## **III. About polydioxanone**

Polydioxanone: Gauze 2 monofilament no.1 was used for transosseous wiring.

Polydioxanone is a colourless, crystalline polymer prepared by polymerizing the monomer paradioxanone in the presence of a suitable catalyst. Glass transition temperature of polydioxanone is -16°C. At this temperature, material becomes brittle and rigid. Melting point of this material is 110°C.<sup>7</sup>

At room temperature it is rubber like and ductile. Coloured polymer is produced by adding D and C blue no 6 or D and C violet no 2 dye during polymerization. Polydioxanone show a mean breaking strength is 6.08kg, late retrieval breaking strength is 5.55kg. Polydioxanone retains 70% of breaking strength after 28 days and 13 % after 56 days of implantation.<sup>6, 8</sup>

### **Uses**

Intended for use, where absorbable suture or ligature is indicated. Particularly applied where longer wound support is required. Being absorbable should not be used in conjunction with prosthetic devices. Recommended storage conditions are below 25°C away from moisture and direct heat. Shelf life is five years.<sup>9, 10</sup>

### **Methods**

The surgical procedure, its advantages, possible risks and complications were explained in detail to the patients and consent was obtained.

## **IV. Surgical procedure**

The surgical approach for all the fractures was extra-oral under general anaesthesia. The mandible was approached through standard submandibular incision. Zygomatic complex fracture via lateral eyebrow and infraorbital incisions. After adequate exposure of the fracture segment, the segments were manipulated with bone reduction forceps and periosteal elevator and satisfactorily reduced. Intra-oral occlusion was achieved with Erich arch bar and intermaxillary fixation. Once the occlusion was achieved, in the study subjects, four/two bur holes were made, on either side of fractures protecting the underlying tissues with periosteal elevator. The

fixation was accomplished by means of transosseous ligature of polydioxanone suture material. The third knot should necessarily come on the primary knot. Whereas in the control group, fixation was achieved using titanium miniplates. The wound was thoroughly irrigated and closed in layers using chromic catgut and black silk or cyanoacrylate skin adhesive in some cases. Intermaxillary fixation was maintained for 4-6 weeks and removed when the fracture fragments were clinically united.

PNS view for zygomatic complex fractures and orthopantomograph for mandibular fractures were taken after 24hrs and later periodic radiographs were taken to evaluate the bone healing.

Patients were followed-up for:

- Wound healing
  - Resolution of post-operative oedema.
  - Evaluating signs of infection
  - Restoration of occlusion
  - Any residual deformity.
- Patients were put on antibiotics and analgesics for atleast 7 days post-operatively.

## **V. Results**

A total of ten patients with facial fractures were treated with transosseous PDS ligature. In this study, one case of Le fort I fracture, two cases of zygomatic complex fractures and seven cases of mandibular fractures were treated with the ligature. Among those treated with miniplates, 6 were mandibular fractures, and 3 le fort I fractures. The various aspects evaluated are recorded in the master chart.

In all mandibular fractures intermaxillary fixation for a period of six weeks was done.

- Stability was good in both the groups and no case showed non-union.
- All patients responded favourably to both the treatment methods.
- Adequate jaw opening was achieved in all cases and there was no mobility of fracture segments.
- Infection was present post operatively in 2 cases treated with transosseous ligatures. However they responded well to incision and drainage with appropriate antibiotic therapy.
- Pretraumatic occlusion was achieved in all cases

Radiographically none of these cases had delayed healing and was complete within three months of time. In maxilla bur holes were not visible after 6 weeks of time and in mandible mixed radiopacity could be appreciated till three months of time.

## **VI. Discussion**

The principles of diagnosis and treatment of facial structures have dramatically changed from conservative and delayed repair to an early aggressive approach with precise anatomic fixation, allowing the return of patients to their pre-traumatic appearance. Certain broad goals are desirable in the management of osseous fractures by internal fixation, they include sufficient strength of the material used, early osseous union and as little morbidity as possible in the past, the use of metals for internal fixation has often led to the necessity of removal during post healing period. Many a times these materials have also contributed to secondary infections<sup>9,11,12</sup>.

In this study resorbable gauge 2 monofilament polydioxanone suture was used as transosseous ligature to treat facial fractures as an alternative to stainless steel wire. Healing proceeded without complications and without clinical deformity throughout the study. No detrimental inflammatory or foreign body reactions were observed.

In previous studies, it was seen to be successful as all fragments healed in good alignment and in normal time with no occurrence of infection. They recommended PDS as an alternative to stainless wire for mass trans fixation in maxillofacial surgery<sup>13, 14, 15, 5</sup>.

Out of 10 cases treated, 4 cases showed infections post operatively. In two cases stainless steel was used along with PDS and in another case, there was a carious tooth in line of fracture, infection subsided once the stainless steel and respective tooth were removed. In another case infection could be attributed to catgut, since the catgut sutures extruded out of wound and the infection was controlled with regular irrigation and appropriate therapy with removal of extruded catgut.

PDS exhibits smallest affinity towards adherence of bacteria, this may be attributed to its monofilament configuration having low surface area and its chemical structure<sup>4</sup>.

Maxillomandibular fixation was carried out over a period of six weeks in all cases of mandibular fractures, none of them had a delayed union or a non-union and pre-traumatic occlusion was achieved in all, which in principle proves the reliability of the method.

SuuronenRita in a comparative study of fixation with absorbable and metallic plates observed that absorbable material transfers the stress to healing bone preventing osteoporosis and bone atrophy. On the other

hand metallic plates deprives bone of normal stress pattern and prevents rapid formation of primary callus, enlargement of harversian canal and over a long period of time cause area of resorption and derangement in structure of the entire bone under the plate, leading to osteoporosis, bone atrophy and even to refracture<sup>2</sup>.

Polydioxanone is a synthetic polymer and its physical properties must not be judged in terms of those of stainless steel wire.

There are certain aspects of technique in relation to the use of PDS in transosseous fixation,

1. The edges of bur holes should be rounded off to prevent sharp bone edges cutting into surface of PDS ligature.
2. PDS cannot be used to tract bone fragments together in the way, which steel wire can. Its use is restricted to cases where its role is to simply appose bone fragments, which have already been correctly aligned.
3. PDS does not give the rigidity of immobilization as afforded by stainless steel wire, consequently, it is preferable to apply the intermaxillary fixation, prior tying PDS ligature, across the fragments.
4. PDS ligature should be knotted at least three times.

PDS is radiolucent and cannot be detected radiographically, thus the reducing size of the bur hole indicate absorbability of PDS<sup>5</sup>.

The primary disadvantage of this technique is use of maxillomandibular fixation for mandibular fractures. But then the fact that much of the advanced treatment aimed at avoiding maxillomandibular fixation, accepts a degree of occlusal derangement as routine notably in bone plating.

Use of PDS in infected sites, proves to be valuable where metallic devices may act as foreign body particles, necessitating delayed management until infection is controlled.<sup>16</sup> Moreover there is rarely infection or foreign body reaction observed in this technique and the need for second surgical procedure for retrieval of metallic device is eliminated.<sup>17</sup>,

Another disadvantage is extra oral scar. However if the line of incision are carefully planned and the wound is neatly sutured scars are barely seen.

## VII. Conclusion

It can be concluded that resorbable polydioxanone can be successfully used in maxillofacial fractures treatment.

- Immediate and rigid fixation of facial fractures yields excellent results, but the use of metallic plates and screws has distinct disadvantages such as loosening and corrosion, bone resorption due to stress shielding, foreign body reaction and malocclusion
- PDS is a new material, though it offers semi rigid fixation and is absorbable
- Ten cases of facial fractures treated with PDS material have given good results with respect to adequate fixation and absorbability

“Let us welcome any new method of fixation offered for the treatment of fractures but we should be discriminating and critical at first and use it intelligently, otherwise failure may not only do harm to the patient but may also bring disrepute to the method which it does not deserve”.

**Table 1: Study group (PDS ligature)**

	Age /Sex	Fracture site	Post-op IMF (week)	Jaw opening	Mobility of fragments	Infection	Occlusion	Fracture reduction
CASE 1	17/M	Lt angle	6	Adequate	Absent	Negative	Normal	Satisfactory
CASE 2	20/M	Lt par.symp	6	Adequate	Absent	Negative	Normal	Satisfactory
CASE 3	20/F	Lt angle	6	Adequate	Absent	Negative	Normal	Satisfactory
CASE 4	15/M	Lt par.symp	6	Adequate	Absent	Negative	Normal	Satisfactory
CASE 5	19/M	Lt par.symp	5	Adequate	Absent	Negative	Normal	Satisfactory
CASE 6	20/M	Rtzmc	4	Adequate	Absent	Negative	Normal	Satisfactory
CASE 7	16/M	Rtpar.symp	6	Adequate	Absent	Negative	Normal	Satisfactory
CASE 8	20/M	Rt par.symp	6	Adequate	Absent	Negative	Normal	Satisfactory
CASE 9	18/M	Rtzmc	6	Adequate	Absent	Negative	Normal	Satisfactory
CASE 10	18/M	Le fort 1	6	Adequate	Absent	Negative	Normal	Satisfactory

**Table 2: Control group (Miniplate fixation)**

	Age /Sex	Fracture site	Post-op IMF (week)	Jaw opening	Mobility of fragments	Infection	Occlusion	Fracture reduction
CASE 1	20/M	Lt angle	2	Adequate	Absent	Negative	Normal	Satisfactory
CASE 2	17/M	Le fort 1	2	Adequate	Absent	Negative	Normal	Satisfactory
CASE 3	18/F	Lt angle	2	Adequate	Absent	Positive	Normal	Satisfactory
CASE 4	13/M	Lt par.symp	1.5	Adequate	Absent	Negative	Normal	Satisfactory
CASE 5	18/M	Lt angle	1.5	Adequate	Absent	Negative	Normal	Satisfactory
CASE 6	20/M	Lt	2	Adequate	Absent	Negative	Normal	Satisfactory

		par.symp						
CASE 7	16/M	Rtpar.symp	2	Adequate	Absent	Negative	Normal	Satisfactory
CASE 8	19/M	Rt par.symp	2	Adequate	Absent	Negative	Normal	Satisfactory
CASE 9	18/M	Le fort 1	2	Adequate	Absent	Positive	Normal	Satisfactory
CASE 10	17/M	Le fort 1	2	Adequate	Absent	Negative	Normal	Satisfactory

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