

# COMPARATIVE STUDY OF TITANIUM MICRO PLATES VERSUS BIORESORBABLE PLATES IN THE OSTEOSYNTHESIS OF ISOLATED ZYGOMATIC BONE FRACTURES

Rizwan Arshad<sup>1</sup>, Muhammad Muddassar<sup>2\*</sup>, Maria Rabbani<sup>2</sup>, Shakeel Ahmed<sup>2</sup>, Adil Umar Durrani<sup>3</sup>, Faiza Gulfam<sup>3</sup>

<sup>1</sup>PNS Shifa Hospital, Karachi, Pakistan

<sup>2</sup>Islam Dental College, Sialkot, Pakistan

<sup>3</sup>Foundation University College of Dentistry, Islamabad, Pakistan.

## ABSTRACT

**Background/objective:** Osteosynthesis is a popular way of treating facial hard tissue injuries since the late fifties. However, the introduction of bioresorbable material opens the new horizon of discussion about the efficacy of the various materials in the medical world. The purpose of this study was to compare two different materials, titanium and poly L(L/D)Lactide acid, in terms of the clinical efficacy and the incidence of postoperative complications.

**Material and Methods:** All 50 patients of zygoma fracture were divided into two groups, i.e.; with Titanium osteosynthesis at zygomaticofrontal suture site and zygomaticomaxillary suture site and the experimental group with bioresorbable osteosynthesis at above-mentioned sites. Each group comprised of 25 patients equally. The pre- and post-operative osseous alignment, aesthetics, paresthesia, limited mouth opening, and infection were noted in the follow-up visits after 24 hours, 72 hours, one week, and three weeks postoperatively.

**Results:** After twenty-four hours of the time period, 4% of patients treated with bioresorbable plates were reported with infection postoperatively. Whereas after a three-day interval 16% of the patients developed an infection after the treatment, 8% each in both titanium and bioresorbable plates groups. 4% of cases treated with resorbable plates were reported with infection at 24 hours postoperatively. There were cases (16%) that exhibited a more or less level of infection after three days (8% from titanium and 8% more from resorbable plates). Osseous mal-alignment was observed postoperatively (8% in titanium and 4% in bioresorbable groups). The sensory disturbance was noted in 16% of the cases in total, 12% in the titanium group and 4% in bioresorbable plate groups. In total, in 6% of the cases hardware was removed, and in 94% no hardware was removed. The titanium implant plates were withdrawn in 8% of cases in group A. Similarly, bioresorbable implant plates were removed in 4% of the cases in Group B.

**Conclusion:** Results from this study revealed comprehensive support to use resorbable plates in terms of good mouth opening and less hypoesthesia as compared to titanium plates.

**Key words:** Maxillofacial fractures, midface injury, zygomatic fracture, ORIF, Titanium plates, bioresorbable plates, poly L Lactide acid.

## Introduction

Midface injuries in Pakistan accounted for approximately 30% of all maxillofacial injuries <sup>1</sup> as compared to 15% to 45% in the international literature. Zygomatic bone fractures are not rare in facial trauma and it occurs mostly among men in the third decade of life <sup>1</sup> and accounts for 45% of all mid-face fractures <sup>2</sup>. Zygomatic bone fractures are the second most common fractures of the facial skeleton after nasal bone fractures <sup>3</sup>. The zygomatic region is the most prominent portion of the face after nasal bone and mandible. The zygomatic bone is the principle buttress between the cranium and maxilla. The prominence of

zygomatic bone predisposes it to bear the brunt of facial injuries <sup>4</sup>. Causes of a zygomatic bone fracture include road traffic accidents, interpersonal violence, gunshot, sports injuries, and occupational injuries <sup>5</sup>. In the clinical examination, the most common sign and symptoms are swelling, periorbital ecchymosis, subconjunctival hemorrhage, diplopia, paresthesia, facial deformity, and soft tissue trauma. Occasionally limitation of mouth opening and restricted lateral jaw movements are also observed <sup>6</sup>.

The reduction of zygomatic bone fractures can be achieved by extra-oral or intra-oral means. Because of the less time consumption, simplicity and less hospital stay, reduction methods have been used for centuries <sup>7</sup>. Closed reduction

procedures have some drawbacks. The proper anatomical osseous alignment of fractured bone cannot be observed with a direct vision intra-operatively. Secondly, the patient may suffer from post-reduction instability due to the muscle contraction forces and post-operative radiograph becomes necessary to see the anatomical reduction<sup>8,9</sup>.

After observing all the disadvantages of closed reduction, open reduction technique was started to have better access and proper anatomical bony assessment. A number of clinical and experimental studies have found strong evidence of superiority and better long-term fracture stability with the use of a plating system when compared with wire fixation in the treatment of zygomatic fractures<sup>10,11</sup>.

While searching for an 'ideal' material for zygomatic osteosynthesis, clinical scientists have progressed from using stainless steel and Vitallium implants to almost universally adapted titanium. The formerly used stainless steel or cobalt-chromium alloy can introduce a risk of malignant tumor formation, corrosion, metal toxicity, allergy, and interference with X-ray imaging, computed tomography, and magnetic resonance imaging. Titanium fulfills one of the most important prerequisites for an osteosynthesis material by evoking only a minimum, if at all any inflammatory reaction, and has been shown repeatedly in various scientific studies to provide the biological basis of osseointegration<sup>12</sup>. This obviously results in a more harmonious acceptance of the implant by the body and has remarkably reduced the incidence of infection and implant rejection.

However, different reasons such as implant palpability, wound dehiscence, sensitivity to cold stimuli, and implant failure have led to frequent episodes of implant removal<sup>13</sup>. The great majority of plate removals were performed because of subjective discomfort. 20-30% of patients eventually needed to have their plates removed<sup>14,15</sup>.

Biodegradable osteosynthetic materials are synthetic polymers that are made by the combination of amorphous and crystalline polymers named semi-crystalline polymer and known for their advantages over metal osteosynthesis due to their disappearance over time, which obviates any desire for implant removal and minimizes the risk of complications from remaining hardware<sup>16</sup>. Researchers advocating, this type of fixation method favor its use as these plates are sufficiently strong to be an effective alternative to metallic systems, avoid potential odontogenic injury, easy to adapt to the bone surface, and allow the use of a freehand technique during fracture repair<sup>17</sup>. There is no long-term implant palpability, temperature sensitivity or visibility, lack of interference with imaging techniques, enabling the fracture and bone healing to be easily

observed, eliminating the need for removal surgery, reduced risk of cross-infection as the implants are supplied sterile making their use more cost-effective, does not complicate placement of dental implants, and does not appear to interfere with the normal healing pattern of the fractured zygomatic bone<sup>18</sup>. Considering all these advantages, still, opponents of bioresorbable fixation argue that the mechanical properties of resorbable osteosynthesis are not equivalent to their titanium counterparts, and this means that an additional mean of fixation may be required. They also argue that manipulation of these plates may be difficult with the more technical expertise required<sup>19</sup>.

In contemporary maxillofacial surgery, bioresorbable bone fixation is becoming an alternative treatment in trauma, orthognathic, and craniofacial surgery<sup>20</sup>. The fast development of new bioresorbable materials has expanded the application to an area where a few years ago only rigid fixation by metal plates and screws was possible<sup>21</sup>. Resorbable polymers have been used for biomedical applications, especially in surgical sutures for a long time. The disadvantages of titanium led to their application in ORIF<sup>22,23</sup>.

No study in Pakistan has been conducted yet to compare the use of titanium and bioresorbable plates and screws in the osteosynthesis of isolated zygomatic bone fractures. Therefore, the objective of the present study was to compare these two different materials based on the measurement of clinical efficacy and the incidence of postoperative complications.

## Materials and Methods

This non-randomized clinical trial was carried out in the Department of Oral and Maxillofacial Surgery, Pakistan Institute of Medical Sciences, Islamabad, Pakistan after approval from the Institutional Review Board following the inclusion and exclusion criteria.

## Inclusion Criteria

The patients having isolated zygomatic bone fracture reporting within seven days of injury were included in this study.

## Exclusion criteria

- i. Bony diseases (Metabolic, Neoplastic, and inflammatory).
- ii. Patients having diplopia.
- iii. Fractures of other associated facial bones.
- iv. Already treated zygomatic bone fracture.
- v. Immunocompromised patients.
- vi. Comminuted zygomatic bone Fracture.

- vii. Reported allergy to implants or any of its contents used.
- viii. Diplopia caused by muscle entrapment or due to nerve damage.

50 patients with isolated zygomatic bone fractures were included in the study. The diagnosis was established after the clinical and radiological examination. Three-dimensional CT scans were taken both pre and postoperatively. The patients were divided into two groups.

1. Group (A) containing 25 patients, were treated by rigid fixation with micro titanium plates
2. Group (B) also having 25 patients were treated by rigid fixation with resorbable plates.

In both groups, 2 point fixations were done, one on zygomatico-frontal suture and second on zygomatico-maxillary (figure 13). All the patients were operated under general anesthesia. In this study, gingivobuccal sulcus and lateral eyebrow approaches were used for exposure of fracture sites. Resorbable plates of the 1.5 mm system having a thickness of 1.0 mm and screw diameters of 1.5 mm were used in this study. The resorbable plates were made of the biodegradable self-reinforced polylactic acid copolymer system. Fractures of zygomatic bone in both groups were classified according to the classification Rows & Killey <sup>24</sup>.

The patients were examined after one week, both clinically and radiographically then after three weeks for follow up with 3-D CT Scan. The follow-up examination was done according to the pro forma designed. The clinical efficacy was determined by postoperative complications. Operating time was noted (incision till the last suture). Post-operative inflammation (after 3 hours, 24 hours, and one week post OP), paresthesia and osseous alignment were assessed. Paresthesia was assessed by questioning the patient about the alteration in sensation, and also checked practically with a sharp, blunt instrument and cotton wool and recorded repeatedly at intervals. Post-operative Inflammation was evaluated through subjective parameters (visual analog scale, VAS) <sup>25</sup>. Aesthetics were assessed by the malar symmetry classification system by Homes and Mathews <sup>26</sup>. Mouth opening was measured in between inter-incisal distance by vernier caliper.

#### Data collection procedure

All patients were selected by the above inclusion and exclusion criteria. A standard history, clinical examination, and radiographic evaluations were done by each patient. Routine radiographs of zygoma fracture; occipitomental and submentovertex view were done. O.P.G. was also taken

to see the impingement of the zygomatic arch over the coronoid process. A 3-D CT scan was advised pre and post-operatively at one and three weeks to assess the osseous alignment of isolated tripod zygoma fractures. The photographic evaluation was done to see the aesthetic appearance. All patients were also observed in the postoperative complications, i.e. paresthesia, limited mouth opening and infection documented in pro forma.

#### Data Analysis

Data was collected through proforma. The data were analyzed with SPSS version 18.0. The frequency and percentage were computed for categorical variables like age, sex, occupation, etiology and post-operative results. The 'P' value was determined through the T-test. The P-value was obtained between the two groups.

#### Results

A total of 50 patients were treated with open reduction and internal fixation, 25 patients in each group, i.e. group A and group B treated with titanium fixation and bioresorbable fixation, respectively.

Infraorbital nerve sensory disturbance was noted preoperatively as overall 76% normal sensation, and 24% paraesthesia. The titanium group was with 60% normal sensation, and 40% altered sensation of infraorbital distribution. The bioresorbable group showed 80% normal sensation and 20% paraesthesia (Table 10). The pre-operative aesthetic appearance was noted as 86% Grade III and 14% Grade IV (Table 11). The preoperative mouth opening was recorded as 25mm to 30mm (38%) followed by 31mm to 40mm (32%) and 41mm to 45mm (30%) (Table 12).

Only one case treated with resorbable plates reported with infection at 24 hours follow-up postoperatively and no patient from titanium group was reported with infection within the same duration postoperatively. There were four cases (16%) that displayed some degrees of infection after three days, two from titanium and two more from resorbable plate groups. Only one case of the bioresorbable group needed removal of implant to settle the infection and others settled with the antibiotic. Titanium cases were persistent, showing signs of infection and were settled by the removal of implants (Tables 13, 14, 15). P-value was noted as statistically significant (P-value 0.024).

Post-operative osseous mal-alignment was seen in two cases in the titanium group and one in the bioresorbable plate group. It persists three weeks postoperatively (Tables 16,17). Postoperative mouth opening after one week follow up was recorded. The majority of cases were between

31mm to 40mm (46%), the rest were 41mm to 45mm (36%) and 25mm to 30mm (18%). Titanium group showed the following results after one week: 31mm to 40mm (50%), 41mm to 45mm (28%), and 25mm to 30mm (12%). Whereas the results of the bioresorbable group were 41mm to 45mm (44%), 31mm to 40mm (32%), and 25mm to 30mm (24%). Three weeks postoperatively mouth opening was dominated by 31mm to 40mm (72%) followed by 41mm to 45mm (28%). In the resorbable group, it was 31mm to 40mm (48%) followed by 41mm to 45mm (44%) and 25mm to 30mm (8%). There were two cases with limited mouth opening in the resorbable group but it was one with infection and the other with malalignment postoperatively (Tables 18,19).

Post-operative infraorbital nerve sensory disturbance after one week was noted as 92% normal sensation and 8% paresthesia. A total of four cases were reported with sensory disturbance, three were from the titanium group and one was from the bioresorbable plate group. P-value was noted as statistically non-significant (0.044). After three weeks, 1 case from titanium and 1 from the bioresorbable plate group were reported with sensory disturbance in the infraorbital nerve area (Table 20,21).

One of the determinants of the clinical efficacy of each of the two treatment modalities was aesthetics. Aesthetic disturbance of grade 2 was seen in both groups (12% of bioresorbable fixation patients and 12% in titanium fixation group) in the first 3 weeks postoperative follow-up visits (Tables 22, 23).

The operating times for the two treatment modalities were close to each other, with a little higher average for bioresorbable fixation (93.08 minutes versus 85.96 minutes for titanium fixation) (Table 24). In 6% of the cases, hardware was removed at both groups, and in 94% no hardware was removed. In group A, plates were removed in two patients, and in Group B implant was removed from one patient (Table 25).

## Discussion

In the present study, poly L. Lactic acid (PL.LA) bioresorbable plates and screws were selected, in comparison to titanium implants for fixation of the isolated zygomatic bone. Biodegradable materials for the fixation of maxillofacial fractures are becoming popular among surgeons worldwide. These materials combine the benefits of rigid fixation with the advantages of biodegradation, obviating the need for implant removal, minimizing the risk of other complications such as injuries by hardware in cases of refracture, and causing less interference with craniofacial growth in children and with postoperative

radiotherapy<sup>27,28</sup>. We used self-reinforced (SR) copolymer containing 90% L-lactide and 10% DL-lactide polymers, which retains more than 100 MPa of its strength after 6 months, which converts into carbon dioxide and water through the process of bulk hydrolysis and is absorbed completely in 18-36 months<sup>29</sup>.

Assessment of osseous alignment is one of the studied variables in the present study. It was checked pre- and post-operatively by clinical and radiographical (with conventional & 3D CT scan) examination in all patients. Titanium plates and screws have the disadvantage of interference with CT scan as metal contents show starburst shadow but resorbable plates do not. However, we couldn't appreciate the resorbable plate or screw in any radiograph available. The screw holes were appreciated in a good digital occipitomental (OM) view and a 3D CT scan model. This only gives an idea that where the screws are placed. There is a study that shows the trails of locating resorbable plates by means of ultrasound imaging technique, but ultrasound only shows the dispersed image<sup>30</sup>. Though it is useful for locating the remnants of the resorbable mass in follow-ups. On clinical assessment, pre-operatively, the researchers noted that all the patients had step deformity on palpation over the infraorbital margin, zygomaticofrontal suture, and zygomaticomaxillary buttress area. The zygoma fracture was also confirmed by the above-mentioned imaging techniques (x-ray OM view, 3D CT scan).

All patients of isolated zygoma fracture were treated with open reduction and internal fixation technique by titanium (group A) and bioresorbable (group B) osteosynthesis randomly and anatomical alignment achieved. The author observed the osseous alignment of treated zygoma fracture with the aid of a 3D CT scan after one and three weeks of follow-up visits. In the post-operative periods, 47 (94%) patients (23 in group A and 24 in group B,) acquired aligned segment and three (6%) patients (2 in group A and one in group B) were malaligned after one week. It was noted that in group A one patient was malaligned type 2 (A), one patient with type 4 (A), according to the classification of Rowe & William (1985)<sup>31</sup>, while in the group B, only one patient got malaligned fracture type 3 (B). In the next three weeks, the results of osseous alignment remained the same. This is correlated to previous studies by Enislidis et al. and Ashish et al. which showed no or minimum malalignment when fixation is done on the vertical axis or vertical buttresses<sup>32</sup>. Group B was treated with a 6 mm screw, reports of which is encouraging for its stability and retainability of the fractured segment, especially in Zygomatico-frontal segments.

After 24 hours post-operatively wound infection was encountered in one patient treated with bioresorbable

fixation and ultimately ended with plate removal (discussed below) but no infection in titanium group is reported. After the third day, two cases of titanium fixation and two more cases of bioresorbable fixations were reported with wound infection. The titanium cases were not recovered with antibiotic therapy and plates were removed which results in the recovery. Two cases of resorbable fixations were recovered with antibiotics after one week, but one case reported with wound infection in group B was removed and the patient recovered afterward. The titanium plates were removed from the zygomaticofrontal suture and the resorbable plate was removed from the zygomaticomaxillary buttress area. This correlates with the study by Rallis et al. in which 2 out of 16 titanium plates were removed from the zygomaticofrontal suture and two from the zygomaticomaxillary buttress<sup>33</sup>.

Fracture of the zygomatic complex frequently results in sensory disturbances in the infraorbital nerve distribution. There may be a compression of this branch of the maxillary nerve and thus patient presents with the hypoesthesia and sometimes hyperesthesia of lower eyelid, lateral wall of the nose, cheek, upper lip, gingiva, and teeth of the affected side<sup>34</sup>. In the present study, authors noticed that in the pre-operative period, hypoesthesia was found in 12 patients (24%) and none of the patients presented with hyperesthesia, (in groups A and B respectively seven and five individuals were with hypoesthesia).

In the postoperative phase, the authors noted the sensation and found hypoesthesia only in four patients after one week follow-up period; in group A, one patient was with a fracture type 4 (B) and two were with type 3(A); in group B, one patient of type 3 (B) fracture presented with hypoesthesia. The sensation returned to normal in both groups after three weeks of follow-up except in two patients, one in each group, who had got hyperesthesia pre-operatively.

A number of studies show improved recovery of sensory sensation following open reduction and internal fixation<sup>35</sup>. The neurosensory alteration in the infraorbital nerve distribution area is also depicted in other studies where there was significantly improved recovery of hypoesthesia noted in minimum displaced fracture in the post-operative phase. It is correlated to the current study where hypoesthesia was seen in type 3 (A), 3 (B), and 4 (B) fracture pattern. Two patients out of four were reported with hypoesthesia after three weeks.

In the current study, the authors found that 19 patients (38%) had limited mouth opening ranging from 25mm-30mm pre-operatively, seven from group A and twelve from group B. In the postoperative phase, 9 patients (18%) were found to have limited mouth opening between 25mm-

30 mm, three from group A and six from group B in the first week of the follow-up visit. In three weeks out of nine, the mouth opening normalized in seven patients of both groups and only two patients remained with a mouth opening of 25 mm-30 mm in group B. The results are comparable with the study of Courtney<sup>36</sup>, in which he had one patient of limited mouth opening in his fifty cases, after open reduction and internal fixation of zygoma fracture. The present study is also correlated with another study<sup>37</sup>, in 13 cases of limited mouth opening were reported out of 80 patients of zygoma fracture. After open reduction and internal fixation, in the postoperative follow-up of the same period only two patients had a complaint of the limited mouth opening.

## Conclusion

The findings of the present study clearly indicate that bioresorbable plates are superior to conventional titanium plates in treating the zygomatic fracture. The findings suggest that new devices in maxillofacial trauma should be introduced, analyzed, and compared with already existing techniques for future guidance and development.

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**Corresponding Author**

**Dr. Muhammad Muddassar**

Assistant Professor  
Oral Medicine/Oral Surgery, Islam Dental College,  
Sialkot, Pakistan