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*Research Article*

## **A Comparative Study Of Titanium Vs Stainless Steel Miniplate Fixation In The Management Of Mandibular Anterior Fracture**

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### **ABSTRACT**

**AIM:** The aim of study was to evaluate the biocompatibility of Titanium miniplates over stainless steel miniplates in mandibular anterior fracture.

**Methodology:** The present study was carried out in the Department of Oral & Maxillofacial Surgery, Teerthanker Mahaveer Dental College And Research Centre, Moradabad. A total number of 20 patients with isolated mandibular fracture (single or multiple) without pre-existing infection and comminution were selected. Patients were randomly divided into 2 equal groups of 10 patients each. Group A patients underwent osteosynthesis using TITANIUM miniplates while Group B patients underwent osteosynthesis using STAINLESS STEEL miniplates. Fractures were treated under LA/GA by the same oral and maxillofacial surgeon. Pain (in Visual Analogue Scale score), swelling, infection, wound dehiscence, hardware failure was measured postoperatively on 1<sup>st</sup> week, 1<sup>st</sup> month and 3 months.

**Results:** In this study the mean age of patients in group A 30.7 and Group B 26.8 and the total mean age of all patients was 28.8. Out of total patients 60% patients were male and 30% patients were female. Road traffic accident was the most common cause of injury (55%). Right Parasymphysis alone was the commonest site of fracture comprising of 60% followed by left Parasymphysis (30%). Symphysis alone was the least common site of fracture (10%). Majority of patients were treated by intraoral approach i.e 17 (85%) and remaining 3 (15%) by extraoral approaches. Majority of patients (75%) were treated under General anesthesia and 25% patient with local anesthesia. At 1 week interval, the mean pain score in Group A was  $5.7 \pm 6.74$  and in Group B it was  $6.30 \pm 6.74$ . At 6 months none of the patients in Group A and Group B had pain. At none of the time intervals, a statistically significant difference was observed between two groups ( $p > 0.05$ ). Infection was observed in only 2 (10%) patient in Group B. Statistically, there was no significant difference between two groups ( $p > 0.05$ ) at any time interval. Only 2 (10%) patient in Group B had hardware failure. Statistically, there was no significant difference between two groups at any time interval ( $p > 0.05$ ). At 1 week interval, the mean swelling score in Group A was  $15.02 \pm 1.36$  and in Group B it was  $17.4 \pm 1.05$  a statistically significant difference was observed between two groups ( $p < 0.05$ ). Whereas on 1 month the mean swelling score in Group A was  $11.9 \pm 1.57$  as compared to  $13.8 \pm 1.38$  in Group B statistically significant difference was observed between two groups ( $p < 0.05$ ). From 3 months onwards the mean swelling score in Group A was  $10.1 \pm 8.7$  and in Group B it was  $11.29 \pm 1.75$ . No statistically significant difference was observed between two groups ( $p > 0.05$ ). At 6 months the mean swelling score in Group A was  $10.2 \pm 9.18$  and in Group B it was  $10.4 \pm 0.95$ . No statistically significant difference was observed between two groups ( $p > 0.05$ ).

**Conclusions:** In this study of short duration it is showed that the titaniumminiplates were more biocompatible when compared to stainless steel miniplates as evident by rate of infection, pain,swelling,wound dehiscence and hardware failure. but there is no statistical significant difference found between titanium and stainless steel miniplates in treatment of mandibular anterior fracture.

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## **Introduction-**

Human beings have suffered from painful injuries from time immemorial. Since then he has constantly strived hard to find some method of treating himself. We will never know with certainty the time when an early homosapien first adjusted a fracture dislocation. Perhaps it happened in early Stone Age that a broken extremity was splinted with wood or bamboo sticks embedded in clay that was allowed to harden.

In the era of increasing auto mobilization, industrialization and technology, the treatment of maxillofacial injuries has attained a prominent position. Road traffic accidents, which are becoming more and more frequent, particularly have brought about an increase in maxillofacial injuries. The head being the exposed part of the body is involved in highest percentage of injuries of all body regions. The other causes of maxillofacial injuries are interpersonal violence, falls, sporting injury and industrial trauma<sup>1</sup>. Long term sequel of untreated or poorly treated fractures include various impairments such as; functional, aesthetic, neurological, and psychological. The facial skeleton can be roughly divided into three areas: the upper one third, the middle one third and the lower one third. The most common facial fractures are in the mandible (61%), followed by maxilla (46%), zygoma (27%) and nasal bones (19.5%). Injury to temporomandibular joint complex is a frequent finding. In other words we can say that the fracture of the mandible worldwide occurs more frequently than any other fracture of the facial skeleton<sup>12</sup>.

Mandibular fractures are more common than middle third fracture (anatomical factor). It could be observed either alone or in combination with other facial fractures. Minor mandibular fracture may be associated with head injury owing to the cranio-mandibular articulation<sup>3</sup>. Mandibular fracture may compromise the patency of the airway in particular with loss of consciousness. It has been found that fracture of mandible can occur with frontal impact force as low as 425 lb (190 Kg) (Condylar fracture). Fracture of condyle is regarded as a safety mechanism to the patient. Frontal force of 800-900 lb (350-400 Kg) is required to cause symphysial fracture<sup>4</sup>. Mandible is

more sensitive to lateral impact than frontal one. Frontal impact is substantially cushioned by opening and retrusion of the jaw (Nahum 1975). Long canine tooth and partially erupted wisdom represent line of relatively weakness. Fracture of the mandible generally does not go unnoticed because it is the only facial bone that is moveable. It is usually very painful; worsening with mastication and speech movements, and if left untreated, may cause facial asymmetry<sup>3,4</sup>.

The symphysis and parasymphysis are one of the most frequently fractured sites in the mandible after the angle and the condyle making up 18-20 % of the mandibular fractures in adults<sup>5</sup>. Forces applied to the mandible cause varying zones of tension and compression, depending on where the bite force is located. The superior portion of the mandible is designated as the tension zone and the inferior portion is designated as the compression zone<sup>5</sup>.

Surgical treatment of mandibular fractures has advanced significantly, semi rigid internal fixation and early return to function have replaced the use of wire osteosynthesis and prolonged use of maxillomandibular fixation (MMF)<sup>6</sup>. In the past few decades, interest has increased in the different methods of open reduction and internal fixation (ORIF)<sup>7</sup>. Clinical research studies for management of mandibular fractures were focused to achieve pre traumatic restoration of esthetics and function with minimum complications and cost. Some controversies still remains in the literature regarding the optimal treatment modality for mandibular fracture in symphyseal or parasymphyseal region. Miniplate osteosynthesis first introduced by Michelet and further development by Champy are standard for the treatment of mandibular fracture<sup>7</sup>. Champy described the ideal lines of the osteosynthesis on which plates have to be applied to resist torsional forces<sup>8</sup>. The technical advantages of miniplates are small size and easily adapted monocortically on bone. They provide functional stability since the system is biomechanically balanced. But one of the most significant drawbacks was the phenomenon of stress shielding atrophy of the bone under the rigid plate which makes the bone vulnerable to refracture once the plates were removed. Although gold, silver, copper and its alloys lead and

aluminum and its alloys were tested. Stainless steel emerged through the era as the new corrosion resistant material. At about the same time or later on the other metals or alloy like titanium were introduced with claims of advantages over the classic stainless steel.

Champy popularized the treatment of mandible fractures with miniplate fixation along the ideal lines of osteosynthesis. This is a form of load-sharing osteosynthesis to be applied in simple fracture patterns having an acceptable amount of bone stock<sup>9</sup>. The ideal line of osteosynthesis in the symphysis/parasymphysis/body region runs at the vertical height of the tooth apices from the canine region to the oblique line. This carries into the oblique ridge which turns into the anterior outer rim of the ramus. All biomechanical models developed to date have shown that two points of fixation (ie, two plates) provide much more stability than a single one. The basal triangle decreases the bone buttressing and interfragmentary support. This condition demands a degree of stability beyond pure load sharing. The superior border plate is positioned on the ideal line of osteosynthesis. The inferior border plate is located at the base of the mandibular symphysis/parasymphysis/body in a longitudinal field below the course of the mandibular canal<sup>3</sup>. Champy suggested that when the plates are placed along the ideal line of osteosynthesis they give maximum stability and proper osteosynthesis. ORIF with stainless steel miniplates and screws has proven to be the most effective method, associated with minimal morbidity, early mobilization and return to work. When planning a surgical strategy for these fractures, we need to have reliable stabilization of fractured segments during mastication for optimal and uneventful osteogenesis of reparative bone. During mastication relatively high torsional forces were generated in parasymphyseal region and required more secure stabilization of fracture segments. Champy et al did a series of experiments and recommended osteosynthesis of parasymphysial fractures by fixation of two miniplates, one at the inferior border of the mandible and the other below the apices of teeth to act as a tension band, to neutralize the torsional forces generated during mastication and to allow optimal healing at fractured site<sup>10,11,12</sup>.

Dispensing the intermaxillary fixation allows the patient to protect their airway more effectively and facilitates postoperative function and nutrition with an early return to work. When absolute stability of the fragments is achieved, immediate postoperative jaw function is possible.

Titanium was first used in 1940s was shown to be not only bio compatible but had a tendency for osteointegration and had excellent corrosion resistance. Titanium has proven its suitability as an implant material for the bone-plates, because of its excellent biocompatibility and corrosion resistance. Titanium is a highly reactive metal, forms a dense, coherent passive oxide film  $\text{TiO}_2$  which prevents the ingress of corrosion products into the surrounding

tissues<sup>6</sup>. Biomechanically titanium has a high tensile strength and a low modulus of elasticity.

The elastic moduli of titanium is approximately half that of stainless steels and therefore create less risk of stress protection of bone<sup>11</sup>. It also had excellent ductility and totally nontoxic. These observations prompted a study, a study to compare titanium bone plates and screws with stainless steel bone plates and screws used in the treatment of mandibular fracture ORIF with titanium miniplates and screws has proven to be the most effective method, associated with minimal morbidity, early mobilization and return to work<sup>12</sup>. When planning a surgical strategy for these fractures, we need to have reliable stabilization of fractured segments during mastication for optimal and uneventful osteogenesis of reparative bone. During mastication relatively high torsional forces were generated in parasymphyseal region and required more secure stabilization of fracture segments. Champy et al did a series of experiments and recommended osteosynthesis of parasymphysial fractures by fixation of two miniplates, one at the inferior border of the mandible and the other below the apices of teeth to act as a tension band, to neutralize the torsional forces generated during mastication and to allow optimal healing at fractured site.

#### Materials and Method-

This prospective study was conducted on 20 trauma patients having mandibular anterior fracture without any systemic disease reported in the department of oral and maxillofacial surgery in Teerthanker Mahaveer Dental College Moradabad.

Proper case history was taken (Annexure-1). All clinical and radiological examinations were done to achieve the diagnosis of mandibular symphysis or Parasymphysis fracture. Patient were advised for all haematological investigation. All patients were explained in detail about the surgical procedure and due consent was taken from them (Annexure-2).

20 patients were randomly divided into two group of 10 patients i.e Group A and Group B.

Group A: Group A patients were treated by titanium miniplates.

Group B: Group B patients were treated by stainless steel miniplates.

Regardless of the groups all the patients were operated either under local anaesthesia or general anaesthesia with nasotracheal intubation.

#### INCLUSION CRITERIA:

1. Patient were selected randomly irrespective of age, sex, religion and socio economic status.
2. Patient were selected on the basis of site and location of mandible fracture including, symphysis, parasymphysis region.
3. Patient who were willing participate in this study.

#### EXCLUSION CRITERIA:

1. Participants who did not meet the criteria were excluded.
2. Pregnant and lactating women were not included in the study.
3. Medical compromised patient.

4. Comminuted Mandibular fracture.
5. Fractures others than specific sites.

## **METHODOLOGY**

### **Surgical Approach for group A:**

Erich's arch bars were placed and IMF was done under LA. After standard painting and draping the intraoral mandibular vestibular degloving approach was used. A curvilinear (vestibular) incision 5 mm apical to the mucogingival junction was given. The mentalis muscle was exposed and incised perpendicular and deep to the bone, leaving a flap of muscle attached to bone for closure. A full thickness mucoperiosteal flap was raised carefully keeping the mental neurovascular bundle intact. If the existing cut of lacerated wound was present extraorally, then that was used to expose the fracture site.

### **Reduction and Fixation**

After obtaining adequate exposure of the fractured segments, the segments were manipulated with reduction forceps and anatomical reduction was achieved. After reduction of the fractured segments, intraoperative intermaxillary fixation was done to achieve the satisfactory occlusion. Fixation of the fractured segment was achieved by using two 2mm/2.5 mm (4 hole with gap and 2 hole with gap) conventional miniplate with 2.5x8mm/2.5x10mm or 2mm x 10mm/2x8 mm/2x6mm screws. Adequacy of fixation and occlusion were rechecked after placement of the conventional miniplate.

### **Closure**

The area was irrigated and adequate hemostasis was achieved. The inner layers of the wound was closed using 3-0 Vicryl and mucosal layer was closed with 3-0 silk. Intermaxillary fixation was released and an adhesive pressure bandage was given extraorally.

### **Surgical Approach for group B:**

Erich's arch bars were placed and IMF was performed under LA. After standard painting and draping the intraoral mandibular vestibular degloving approach was used. A curvilinear (vestibular) incision 5 mm apical to the mucogingival junction was given. The mentalis muscle was exposed and incised perpendicular and deep to the bone, leaving a flap of muscle attached to bone for closure. A full thickness mucoperiosteal flap was raised carefully keeping the mental neurovascular bundle intact. If the existing cut of lacerated wound was present then that was used to expose the fracture site.

### **Reduction and Fixation**

Adequate exposure of the fractured segments was obtained. The segments were manipulated with reduction forceps and anatomical reduction was achieved. After reduction, intraoperative intermaxillary fixation was done to achieve the satisfactory occlusion and fractured segments were fixed with bone plates. Two 2mm/2.5 mm, miniplate were adapted and fixed with using screws (2mm x 8mm/2x10 mm/2x6

mm/2.5x8 mm/2.5x10 mm) 5mm above the lower border of mandible and a second 2mm, 2 hole with gap miniplate was adapted and fixed with using 2 screws (2mmx 6mm) above at the distance of 5mm from the lower miniplate. Adequacy of fixation and occlusion were rechecked after placement of the miniplates..

### **Closure**

The area was irrigated and adequate hemostasis was achieved. The deeper layers of the wound was closed using 3-0 Vicryl® and mucosal layer was closed with 3-0 silk. Intermaxillary fixation was released and an adhesive pressure bandage was given extraorally.

### **Post operative care**

Postoperatively I.V. antibiotics and analgesics used were Injection (Amoxicillin + Clavulanic acid) 1gm twelve hourly combined with Injection Metronidazole 500mg/100ml eight hourly and Injection diclofenac 75mg twelve hourly I.M. prescribed. Postoperative 5 days IV antibiotics were administered followed by 5 days of oral administration. The patients were put on Injection Dexamethasone 8 mg twelve hourly IV postoperatively and the dosage tapered down in the subsequent 2 days to decrease oedema and inflammation in the surgical site. If any subsequent infection occurred the antibiotics were changed according to the culture and sensitivity reports. patients were put on postoperative IMF. Elastics for a period of 3-7 days was placed for cases where occlusion was unsatisfactory postoperatively.

- Patients were adviced to take soft diet postoperatively for next 15 days.

- Extra oral Pressure dressing ( DYNAPLAST) was placed post-operatively for 48 hours.

- Chlorhexidine mouthwash was advised to all the patients after 24 hours post-operatively for next 15 days.

Radiograph was taken postoperatively to check the adequacy of reduction and fixation. After discharge the patient were recalled on the 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month and respectively. On each appointment apart from the routine examination pain, postoperative swelling, infection, wound dehiscence, hardware failure .

Patient was evaluated post-operatively done under following parameters:

1. Pain: Pain magnitude were assessed by a visual analogue scale (VAS) (photo) with horizontal line that ran from (0 mm)“no pain” to(10 mm) “worst pain”.

2. Swelling: For assessing the dimensions of swelling measuring tape was used to measure swelling in two dimensions only. The measuring points used were the edge of the tragus of the ear on the operated side to the corner of mouth and gonion to lateral canthus of eye of the operated side.

3. The distance between the tragus and the corner of mouth was added to the distance between the gonion and lateral canthus of eye over the maximum convexity of the soft tissues and the average of measurements was then recorded in centimeter (cm).

4. Infection: Present- if one of the following present-

- 1.Redness
  - 2.Pus discharge
  - 3.Sinus
- Absent-if all these indicators are absent.
4. Wound dehiscence: Present/Absent.
  5. Hardware failure(exposure/fracture of plate): Present/Absent.

#### **Follow up:**

Clinically patients were evaluated 1 week, 1 month, 3 month, and 6 month  
Radiographically patients were evaluated postoperatively, 1 month, 3 month and 6 month for any malunion, nonunion and resorption around screws.

#### **STATISTICAL TOOLS EMPLOYED:**

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 20 statistical Analysis Software. The values were represented in Number (%) and Mean $\pm$ SD.

#### **Result-**

The present study was carried out in the Department of Oral & Maxillofacial Surgery. A total number of 20 patients with isolated mandibular fracture (single or multiple) without pre existing infection and comminution were selected. Patients were randomly divided into 2 equal groups of 10 patients each. Group A patients underwent osteosynthesis using TITANIUM miniplates while Group B patients underwent osteosynthesis using STAINLESS STEEL miniplates. The healing of fracture was assessed clinically and radiologically. Data was subjected to statistical analysis using SPSS version 20. Comparison of study groups based on post-operative evaluation of infection, malocclusion, pain, wound dehiscence and swelling was done using Independent T test;  $p \leq 0.05$  was considered to be statistically significant.

Road traffic accident was the most common cause of injury (55%). Fall from height, assault and other etiologies comprised 15% of the study subjects each (TABLE-1).

The age of patients ranged from 18 to 65 years. Majority of patients were within 26 to 35 years of age (50%). The 40% of patient are in age group of 18 to 25 year of age. There were only 5% patients aged above 45-55 years. Mean age of the patients was 28.7 years. (TABLE-2). Majority 12(60%) of patients were males. Only 8 (40%) were female. (TABLE-3).

Right Parasymphysis alone was the commonest site of fracture comprising of 60% followed by left Parasymphysis (30%). Symphysis alone was the least common site of fracture (10%) (TABLE-4). Majority of patients were treated by intraoral approach i.e. 17 (85%) and remaining 3 (15%) by extra oral approaches. (TABLE-5) Preoperative occlusion was found to be deranged in all the patients in both the groups. The functional occlusion was achieved postoperatively in all the patients (TABLE-6). Study subjects were divided into two groups Group-A treated with titanium miniplates and Group-B with stainless steel miniplates (TABLE-7). Majority of patients (75%) were treated under General anesthesia and 25% patient with local anesthesia. (TABLE-8)

At 1 week interval, the mean pain score in Group A was  $5.7 \pm 0.674$  and in Group B it was  $6.30 \pm 0.674$  whereas on 1 month the mean pain score in Group A was  $0.20 \pm 0.42$  as compared to  $0.40 \pm 0.51$  in Group B. From 3 month onwards none of the patients in Group I had any pain whereas at 3 month the mean pain score in Group B was  $0.1 \pm 0.31$ . At 6 months none of the Group A patients had pain, however, 2 patient of Group B had mild pain (score 3). At none of the time intervals, a statistically significant difference was observed between two groups ( $p > 0.05$ ) (TABLE 9). Infection was observed in only 2 (10%) patient in Group B at 3 months. Statistically, there was no significant difference between two groups ( $p > 0.05$ ) at any time interval (Table 10). Only 2 (10%) patient in Group B had hardware failure at 3 months interval. Statistically, there was no significant difference between two groups at any time interval ( $p > 0.05$ ) (Table 11). At 1 week interval, the mean swelling score in Group A was  $15.02 \pm 1.36$  and in Group B it was  $17.4 \pm 1.05$  a statistically significant difference was observed between two groups ( $p < 0.05$ ). whereas on 1 month the mean swelling score in Group A was  $11.9 \pm 1.57$  as compared to  $13.8 \pm 1.38$  in Group B statistically significant difference was observed between two groups ( $p < 0.05$ ). From 3 month onwards the mean swelling score in Group A was  $10.1 \pm 0.87$  and in Group B it was  $11.29 \pm 1.75$ . No statistically significant difference was observed between two groups ( $p > 0.05$ ). At 6 months the mean swelling score in Group A was  $10.2 \pm 0.918$  and in Group B it was  $10.4 \pm 0.95$ . No statistically significant difference was observed between two groups ( $p > 0.05$ ) (TABLE-12).

**TABLE- 1: Present table showing the various Etiological factors for maxillofacial trauma.**

| Etiology              | Number of patients | Percentage |
|-----------------------|--------------------|------------|
| Road Traffic accident | 11                 | 55         |
| Fall                  | 3                  | 15         |
| Assault               | 3                  | 15         |
| Other                 | 3                  | 15         |
| Total                 | 20                 | 100        |

Table1: Shows the Distribution of study subjects based on Etiological factors for maxillofacial trauma. Out of the total of 20 patients mostly patients underwent RTA i.e 55 % followed by fall, assault,others 15%.

**TABLE 2: Present table showing the age distribution among patients.**

| AGE   | FREQUENCY | PERCENTAGE(%) |
|-------|-----------|---------------|
| 18-25 | 8         | 40            |
| 26-35 | 10        | 50            |
| 36-45 | 0         | 0             |
| 46-55 | 1         | 5             |
| 56-65 | 1         | 5             |
| Total | 20        | 100           |

**Table2:** shows the distribution of study subjects based on age distribution Out of the total of 20 patients mostly patients lies in age group of 26-35 followed by 40% in age group of 18-25 and 5% 46-65 group.

**TABLE 3: Distribution of study subjects based on Gender**

| GENDER | FREQUENCY | PERCENTAGE |
|--------|-----------|------------|
| MALE   | 12        | 60         |
| FEMALE | 8         | 40         |
| TOTAL  | 20        | 100        |

Table 3 shows the distribution of study subjects based on Gender. Out of the total of 20 subjects there were 12males and 8 females. The gender distribution in the study groups was 7 males, 3 females and 6 males, 4 females in groups A and B respectively.

**TABLE 4: Present table showing frequency distribution of fracture type.**

| TYPE OF FRACTURE    | NO. OF PATIENTS | PERCENTAGE |
|---------------------|-----------------|------------|
| LEFT PARASYMPHYSIS  | 6               | 30         |
| RIGHT PARASYMPHYSIS | 12              | 60         |
| SYMPHYSIS           | 02              | 10         |
| TOTAL               | 20              | 100        |

Table 4 shows the distribution of study subjects based on fracture site Out of the total of 20 subjects there were 12 patients with right parasymphysis fracture followed by 6 patients with left parasymphysis and 2 patients with symphysis fracture.

**Table-5: Distribution of study subjects based on surgical approach**

| Approach   | Group A | Group B |
|------------|---------|---------|
| Intra-oral | 9       | 8       |
| Extra-oral | 1       | 2       |

Distribution of study subjects based on the surgical approach used is shown in table 5; it was observed that intra oral approach was the most common surgical approach used. Intra oral approach was used in 9 and 8 study subjects in group A and B respectively. Extra oral approach was used in 1 subject in group A and 2 subjects in group B.

**Table-6 : Comparison of preoperative and postoperative Occlusion arrangement.**

| Occlusion arrangement | Preoperative |         | Postoperative |         |
|-----------------------|--------------|---------|---------------|---------|
|                       | Group A      | Group B | Group A       | Group B |
| Deranged              | 20           | 20      | 0             | 0       |
| Intact                | 0            | 0       | 20            | 20      |

Table 6 shows the distribution of study subjects based on Occlusion arrangement. Out of 20 subjects occlusion was deranged preoperatively in all cases and angle class1 postoperatively.

| GROUP              | FREQUENCY | PERCENTAGE |
|--------------------|-----------|------------|
| A (Titanium)       | 10        | 50         |
| B(stainless steal) | 10        | 50         |
| TOTAL              | 20        | 100        |

**Table - 7: GROUP DISTRIBUTION among patient.**

**TABLE 8: Present table showing type of Anesthesia used among patient.**

| ANESTHESIA         | NO.OF PATIENTS | PERCENTAGE |
|--------------------|----------------|------------|
| LOCAL ANESTHESIA   | 5              | 25         |
| GENERAL ANESTHESIA | 15             | 75         |
| TOTAL              | 20             | 100        |

Table 8 shows the distribution of study subjects based on Type of Anesthesia used. Out of 20 subjects 75% of patients treated under General anesthesia followed by 25% of patients treated under local anesthesia.

**TABLE 9 : Comparison of Pain (VAS scale) in Group A and B.**

| Follow up period | Group A (n=10) |       | Group B (n=10) |      | 'p'   |
|------------------|----------------|-------|----------------|------|-------|
|                  | Mean           | SD    | Mean           | SD   |       |
| 1 week           | 5.7            | .674  | 6.3            | 1.52 | 0.062 |
| 1month           | 0.20           | 0.421 | 0.40           | 0.51 | 0.355 |
| 3 month          | 0              | 0     | 0.1            | 0.31 | 0.343 |
| 6 month          | 0              | 0     | 0              | 0    | 0     |

Distribution of study subjects based on the Pain assessment used is shown in table 10; it was observed that at none of the time intervals, a statistically significant difference was observed between two groups ( $p>0.05$ ).

**Table 10: Comparison of Infection in Group A and Group B**

| Time intervals | Group A (10=20)                |   | Group B (n=10)                 |    | statistically significant difference |       |
|----------------|--------------------------------|---|--------------------------------|----|--------------------------------------|-------|
|                | No. of patients with infection | % | No. of patients with infection | %  | $\chi^2$                             | P     |
| 1 Wk           | 0                              | 0 | 0                              | 0  | —                                    | —     |
| 1 mths         | 0                              | 0 | 0                              | 0  | —                                    | —     |
| 3 mths         | 0                              | 0 | 0                              | 0  | —                                    | —     |
| 6 mths         | 0                              | 0 | 2                              | 10 | 1.053                                | 0.305 |

(Chi-square test)

On comparing the study groups based in occurrence of post-operative infection it was found that 2 subjects in group B presented with post-operative infection. This difference was statistically not significant ( $p>0.05$ ).

**Table 11: Comparison of Hardware Failure in Group A and Group B**

| Time intervals | Group A (n=10)                |   | Group B (n=10)                |    | Significance of difference |       |
|----------------|-------------------------------|---|-------------------------------|----|----------------------------|-------|
|                | No. of patients with swelling | % | No. of patients with swelling | %  | $\chi^2$                   | P     |
| 1 Wk           | 0                             | 0 | 0                             | 0  | —                          | —     |
| 1 mths         | 0                             | 0 | 0                             | 0  | —                          | —     |
| 3 mths         | 0                             | 0 | 0                             | 0  | —                          | —     |
| 6 mths         | 0                             | 0 | 2                             | 10 | 1.053                      | 0.305 |

**TABLE-12: : Comparison of Swelling in Group A and Group B.**

| Follow up period | Group A (n=10) |      | Group B (n=10) |       | 'p'   |
|------------------|----------------|------|----------------|-------|-------|
|                  | Mean           | SD   | Mean           | SD    |       |
| 1 week           | 15.2           | 1.36 | 17.4           | 1.05  | 0.000 |
| 1month           | 11.9           | 1.57 | 13.87          | 1.38  | 0.008 |
| 3 month          | 10.1           | .875 | 11.29          | 1.759 | 0.72  |
| 6 month          | 10.20          | .918 | 10.4           | .950  | .607  |

## Discussion-

The present study was carried out in the Department of Oral & Maxillofacial Surgery. Total number of 20 patients with isolated mandibular fracture without pre-existing infection and comminution were selected. Patients were randomly divided into 2 equal groups of 10 patients each. Group A patients underwent osteosynthesis using Titanium miniplates while Group B patients underwent osteosynthesis using Stainless steel miniplates.

Michelet *et al.* developed the concept of miniplates osteosynthesis in the late 1960s. In 1973, they published a report documenting the successful use of a

small plate and monocortical screws for the treatment of mandibular fractures<sup>43</sup>. The original goal of miniplate osteosynthesis was to provide stable mandibular fracture reduction without requiring interfragmentary compression or maxillomandibular fixation. Studies performed in the early 1970s at the Group d'Etude en Biomecanique Osseuse et Articulaire de Strasbourg demonstrated that the miniplate achieves this goal by neutralizing undesirable tensile forces while retaining favourable compressive forces during function<sup>17</sup>.

Champy *et al.* (1978) elaborated on Michelet's work with the intraoral application of the monocortical

miniplate for the treatment of mandibular angle fracture<sup>13</sup>. The reduced size of the miniplate system offers several advantages over the larger mandibular plates. Smaller incision and less soft tissue dissection are required for their placement. In addition, miniplates can often be placed intraorally, thereby avoiding an external scar. Because of the smaller size and thinner profile of the miniplates, they are less likely to be palpable, possibly reducing the need for subsequent plate removal. The smaller size of the miniplates may decrease the degree of stress shielding seen following rigid fixation; however this remains to be demonstrated. Finally because the screws are monocortical, the plates may be placed in the areas of mandible adjacent to tooth roots with minimal risk of dental injury<sup>58</sup>.

The rationale of using miniplate plate in mandibular fracture is that the osteosynthesis achieved by plate screwed on the outer cortical plate is solid enough to support the strain developed by masticatory muscle. On the horizontal ramus, the masticatory forces create within the mandible causes elongation strain along the alveolar border and compressive strain along the lower border. Only the traction strains are injurious and have to be neutralized. The study of movements with regards to the mathematical model of mandible (Champy *et al.* 1978)<sup>13</sup>. Showed that at the level of horizontal ramus, there are almost only flexion movements, the value of which increases from the front backwards. In the anterior part of mandible, anterior to first premolar, there are mainly moments of torsion. They are higher, when they are nearer to the mandibular symphysis. Therefore the principle of osteosynthesis is to re-establish, the mechanical qualities of the mandible, taking into account the anatomical conditions. In the present study, it is seen titanium miniplates are effective in the treatment of mandibular fractures and overall complication rates are lesser as compared to Stainless steel miniplates although the difference is not statistically significant ( $p > 0.05$ )

### **Clinical Application**

Champy *et al.*<sup>13</sup>(1978), Cawood JI (1985)<sup>8</sup>, Ellis *et al.* (2002)<sup>23</sup> earlier used miniplates for the patient with mandibular fracture and found uneventful healing. The same finding was reported in our study. Intra-oral & extraoral approaches were used in all cases of monocortical plating (Champy *et al.*, 1978). A minimum of 2 screws, on each side of segment were used to prevent rotational movement of fractured fragment which was in correlation with study of Schroll (1927), Perren (1996), Spiessel (1976), Champy (1978). None of the patients were placed into postsurgical maxillomandibular fixation (Edward Ellis and John Graham 2002)<sup>23</sup>.

According to estimates of Association of Automobile Manufacturers of India (AIAMI) the number of automobiles on road has grown more than ten fold during the last ten years (Source : AIAMI website). Apart from this our centre is also tertiary centre where patients come from as far as neighboring states. In this study, road traffic accidents were found to be

responsible for majority of the fractures i.e. 11 patients (55%), which also correlates with the study of Row & William<sup>44</sup> (1968), Kruger.<sup>45</sup>(1964) and to Champy M *et al.*<sup>13</sup>, Ellis E III<sup>23</sup>, Hussain S *et al.*<sup>28</sup>, Thapliyar GK *et al.*<sup>33</sup>, Devadiga A *et al.*<sup>34</sup>, Subhashraj K *et al.*<sup>32</sup>, Okoturo EM *et al.*<sup>35</sup>

In the present study the number of male patients was higher (80%) than the number of female patients (20%), which was in accordance with the study of Ellis *et al.* (2002)<sup>23</sup>, Gabrielli *et al.*<sup>27</sup>. (2003), Cawood JI (1985)<sup>8</sup>. They demonstrated the high incidence of facial trauma in males.

In our study mean age of patients was 30.4 years of group A & 26.4 years of group B and total mean age was 29 years. Similarly, mean age of the patients in other studies were in the same range like 28.6 years in the study of Guimond *et al.*<sup>30</sup>, 26 years in Bui *et al.* study, 28 years in the study of Ellis E III<sup>46</sup> and 29 years in the study of Edward AL *et al.*<sup>36</sup>.

In our study showed in symphysis/parasymphysis fracture (alone-40% or in combination with angle or condyle-60%) frequently fractured site, usually in conjunction with other site (30 patients). This is in accordance with various study like as Ellis E III<sup>46</sup>, Hussain S *et al.*<sup>28</sup>, Parmar *et al.*<sup>11</sup> and Jain *et al.*<sup>37</sup>. Boole JR *et al.*<sup>22</sup> stated, the symphysis is one of the most frequent sites of mandibular fractures in children, and comprises about 20% of adult mandibular fractures. Symphysis/parasymphysis fractures with displacement are often fixed with 1 or 2 miniplates.

Preoperative occlusion was found to be deranged in all the patients in both the groups. Maxillomandibular fixation was done in patients, and functional occlusion was achieved postoperatively in all the patients. This study is incoherent with the study done by Edward Ellis and John Graham (2002)<sup>32</sup>.

At 1 week interval, the mean pain score in Group A was  $5.7 \pm 0.674$  and in Group B it was  $6.30 \pm 0.674$  whereas on 1 month the mean pain score in Group A was  $0.20 \pm 0.42$  as compared to  $0.40 \pm 0.51$  in Group B. From 3 month onwards none of the patients in Group I had any pain whereas at 3 month the mean pain score in Group B was  $0.1 \pm 0.31$ . At 6 months none of the patients in both the groups had pain, however. At none of the time intervals, a statistically significant difference was observed between two groups ( $p > 0.05$ ). Infection was observed in only 2 (10%) patient in Group B at 3 months. Statistically, there was no significant difference between two groups ( $p > 0.05$ ) at any time interval.

Only 2 (10%) patient in Group B had hardware failure at 3 months interval. Statistically, there was no significant difference between two groups at any time interval ( $p > 0.05$ ). At 1 week interval, the mean swelling score in Group A was  $15.02 \pm 1.36$  and in Group B it was  $17.4 \pm 1.05$  a statistically significant difference was observed between two groups ( $p < 0.05$ ). whereas on 1 month the mean swelling score in Group A was  $11.9 \pm 1.57$  as compared to  $13.8 \pm 1.38$  in Group B statistically significant difference was observed between two groups ( $p < 0.05$ ). From 3 month onwards the mean swelling score in Group A was  $10.1 \pm 0.87$  and



in Group B it was  $11.29 \pm 1.75$ . No statistically significant difference was observed between two groups ( $p > 0.05$ ). At 6 months the mean swelling score in Group A was  $10.2 \pm 0.918$  and in Group B it was  $10.4 \pm 0.95$ . No statistically significant difference was observed between two groups ( $p > 0.05$ ).

In Group A, no patient reported with infection at follow-up of 6 months.

In Group B, two (10%) patient reported with infection follow up (3 months) who presented with extra oral sinus and pus discharge near the fracture site. Pus culture and sensitivity test was done and specific antibiotic therapy started. After antibiotic therapy improvement was seen and pus discharge stopped. Infection was because of loosening of screw. This may be attributed to the high speed drilling of bone leading to bone necrosis at the bone and screw interface and ultimately loosening of screw. Cordey and co-workers stated that the friction between the screw head and plate is the main weak point of the entire fixation (Cordey *et al.* 2000). But there was no mobility at fracture site and fracture has been united, so plate was removed. This however did not affect our final result.

Infection rate seen in our study (i.e. 10%) is in correlation with the infection rate reported in the studies of Champy<sup>13</sup> (1978) - 3.8%, Cawood<sup>8</sup>(1985) - 6%, Smith<sup>47</sup> (1991) - 2.5%, TB, Bays RA (1993)<sup>48</sup> - Our study does accordance with the study conducted by Ellis E III & Graham J<sup>23</sup>, Pilania D *et al*<sup>4</sup> and Hussain S.<sup>28</sup>

There were 2 patients in Group B with Hardware failure. Rehman AU *et al*<sup>49</sup> study plate removal of 33.3% from the fracture osteosynthesis of mandible in the body region and 18.5% in parasymphyseal region. Over all complication rate in current study was low when compared with results of other cited studies.<sup>3,10,11,17</sup> One has to keep in mind that results depends much more on the characteristics of the fracture, compliance of the patient, absence of systemic disease, postoperative care, and adherence to partial postoperative functional restrictions.

Pilania D *et al*<sup>4</sup> stated that the reduced size of the miniplate system offers several advantages over the larger mandibular plates. Smaller incision and less soft tissue dissection are required for their placement, thereby avoiding an external scar. Because of the smaller size and thinner profile of the miniplates, they are less likely to be palpable, possibly reducing the need for subsequent plate removal. Also, because the screws are monocortical, the plates may be placed in the areas of mandible dentate regions with minimal risk of dental injury.

#### Conclusion-

The study was primarily aimed to evaluate the biocompatibility of titanium miniplates over stainless steel miniplates.

Based on the finding of our study, the following conclusions were derived.

1. The most common cause of mandibular fracture was found to be road traffic accident (55%).

2. Patients in the 26-35 years of age were the predominant age group presenting with mandibular fracture (50%).

3. Males were most commonly affected with mandibular fracture (60%).

4. Parasymphysis (right and left) alone was the commonest site of fracture comprising of 30%+60% respectively followed by symphysis (10%).

5. Swelling was seen in first week at 1<sup>st</sup> follow up in 6 (30%) patients of both Group A & Group B. Swelling subsided gradually in next follow-up in all patients.

6. Infection was observed in only 2 (10%) patient in Group B at 3<sup>rd</sup> month follow-up because of loosening of screw.

7. Pain decreases significantly at 1 week, 1 month and pain was absent after 6 month In both the groups.

8. Hardware failure was observed in 2 (10%) patients in group B.

9. Wound dehiscence was observed in 2 (10%) patients in group B.

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