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ASSESSMENT OF POSTOPERATIVE COMPLICATIONS OF THREE-DIMENSIONAL TITANIUM PLATES IN COMPARISON TO CONVENTIONAL MINIPLATES IN FIXATION OF THE MANDIBULAR FRACTURES- A PROSPECTIVE, RANDOMIZED, DOUBLE-BLINDED, UNICENTRIC, CONTROLLED CLINICAL TRIAL.

Clinical Research

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ABSTRACT

Aim: Assessment of postoperative complications of three-dimensional titanium plates in comparison to conventional miniplates in fixation of the mandibular fractures

Materials and methods: This study has conducted the Department of Oral and Maxillofacial Surgery, Kannur Dental College, Anjarakandy, Kannur, India. Both the study and the control group contained 15 patients each who reported to our department for the management of their mandibular fractures. After attaining adequate access to the fracture site and stable occlusion, fixation was done using the technique to which the patient was assigned. Patients who were assigned to have the 3D plates were assigned to group I and the patients who had conventional miniplate fixation were assigned to group II.

Result: There were no statistical significance in any of the complications

Conclusion: The usage of 3D plates doesn't have any impact on the outcome of the surgery and also doesn't provide any definitive advantage over the conventional miniplates in the outcome of the surgery.

KEYWORDS

INTRODUCTION

In recent decades, the proverb of "time is of the essence" is playing an important role in the day to day life of the population. With reference to maxillofacial surgery, one of its translation meant an immediate return to function post-trauma to the maxillofacial structure. This led to the wide held acceptance of semi-rigid fixation of fractured segments, which aided the patient to return to the day-to-day life as early as possible. From the time of Hippocrates, for managing mandibular fracture, a wide array of open reduction and rigid internal fixation has been employed through the time which varies from wire osteosynthesis. lagscrews to 3-dimensional (3D) plates (Mukerji, Mukerji, & McGurk, 2006). One other essential advantage of rigid fixation is the ability to avoid maxillomandibular fixation postoperatively which decreases the patient morbidity.

In the last decades, miniplates scored over all of them with their ease of application, less technique sensitivity, and consistent results with the occlusion-inherently becoming the favourite of the oral and maxillofacial surgeons (Bui, Demian, & Beetar, 2009). Miniplate fixation was limited in providing only two-dimensional stability. Hence, the need for further stability led to the introduction of 3D plates. Unlike the conventional plating system, it does not derive its strength from its bulkiness, rather it is from its design. Fixed with monocortical screws on the outer cortex, these 3D plates constitutes a cuboid shape which imparts its 3D stability (Zix, Lieger, & Iizuka, 2007). They receive the nomenclature 3D miniplates, not because of their design, but the stability which they provide in three dimensions (Farmand, 1995). Since they are two different linear plates connected with a vertical strut, it has increased resistance to gap opening at the inferior border caused by the masticatory forces (Wittenberg, Mukherjee, Smith, & Kruse, 1997). However, the 3D plating system for the management of the mandibular fracture is still in its nascent stages. A recent survey indicates that out of 104 North American and European Arbeitsgemeinschaft fur Osteosynthesefragen and Association of the Study of Internal Fixation surgeons, surgeons who incorporated this system in regularity was a mere 6%.

Various researches have demonstrated that unlike conventional miniplates, the 3D plating system was able to attain more favourable biomechanical behaviours. Hence, the aim of this study was to analyze the "Assessment of postoperative complications of three-dimensional titanium plates in comparison to conventional miniplates in fixation of the mandibular fractures".

MATERIALS AND METHODS

This study has conducted the Department of Oral and Maxillofacial Surgery, Kannur Dental College, Anjarakandy, Kannur, India. The study design was formulated following the STROBE guidelines and consent was obtained from the institutional ethical committee (IRB No.-KDC/ETH/16/OMF13/1). This was a prospective, randomized, double-blinded, unicentric and controlled clinical trial.

Both the study and the control group contained 15 patients each who reported to our department for the management of their mandibular fractures. The patients who fulfilled the inclusion criteria were selected and informed consent was obtained. The patients were randomly assigned to each group following the lottery method where a random person in the Department of Oral and Maxillofacial Surgery would pick the lot. By this method, 30 patients were selected and assigned to each group equally. The sample size constituted patients who were undergoing treatment for a fracture. The study commenced in March 2017 and was terminated once the required sample was attained. The inclusion and exclusion criteria are as follows

INCLUSION CRITERIA

1. Fracture mandible without gross-comminution of the fracture segments
2. Fracture mandible with no/minimal displacement of fracture segments
3. Dentulous mandible
4. Fracture at a single anatomical location per case

Exclusion criteria

1. Severely infected fractures with a large hematoma
2. Grossly comminuted fractures with extensive damage of fractured bony segments
3. Fractures present other than or along with mandibular fracture
4. Cases where the outer cortical plate is fractured obliquely, resulting in too thin a portion of the mandible for retention of screws
5. Patients who are below 18 years of age
6. Medically compromised patients

The surgeries were performed under general anaesthesia via naso-endotracheal intubation. Following the aseptic procedures, local

anaesthetic with 1:100000 adrenaline was administered at the surgical site. This was followed by the placement of maxillomandibular fixation (MMF). Accessing the surgical site was either through the existing lacerations, or using intraoral/extraoral incisions for performing the ORIF procedure.

After attaining adequate access to the fracture site and stable occlusion, fixation was done using the technique to which the patient was assigned. Removal of the tooth in the fracture line was removed if they were Grade III mobile/fractured/carious/pathologically involved. Patients who were assigned to have the 3D plates were assigned to group I (Figure 1) and the patients who had conventional miniplate fixation were assigned to group II (Figure 2). The 3D plates were placed in such a manner that the horizontal crossbars were perpendicular to the fracture line. The 3D plate used was 2 mm titanium rectangular plate and was fixed using 8 mm self-threading screws. The group II miniplates were fixed in a conventional manner following Champy's principle. In the anterior region, fixation was done using 2 mm 4 hole with gap plates and 1.5 mm 2 hole with gap miniplates and in the body and posterior region, a 2 mm 4 hole with gap miniplates was used along with 8 mm self-threading screws. All the plates and screws were made of titanium.

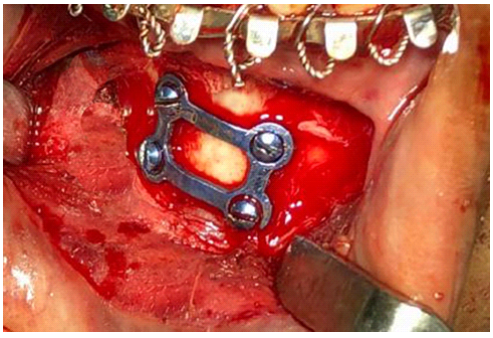

Figure 1- 3D plate fixation

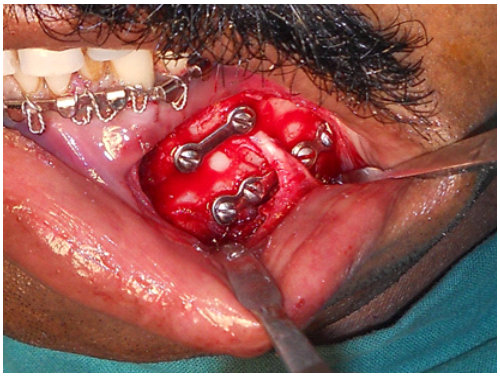

Figure 2- Miniplate fixation

Once the fixation was attained, MMF was released and intraoperative stability of the fracture was checked. Once the stability was satisfactory, and after achieving proper haemostasis, wound closure was done. All patients receive intravenous antibiotics throughout the length of their hospital stay. Postoperative orthopantomograms were taken to confirm the postoperative assessment. The arch bar was removed at the end of six weeks.

During the postoperative period and follow-up visits, the evaluation was performed by an oral and maxillofacial surgeon who was blinded and was with similar levels of experience as the operating surgeon. The evaluating surgeon was provided with a data sheet to enter the findings and the same was followed during the follow-up visits. The following parameters were assessed during the evaluation

1. Pain- American Academy of Physical Medicine and rehabilitation pain level scale was used for assessment.
2. Infection
3. Mobility between the fracture segment- manual assessment by grasping the mandible on either side of the fracture using thumb and fourth finger followed by gentle manipulation.
4. Occlusion derangement
5. Paresthesia- Used Von Frey hairs for preoperative and postoperative assessment.
6. Implant failure- By radiographic assessment
7. Wound dehiscence
8. Trismus
9. Non-union
10. Mal-union
11. Tooth root damage due to fixation-pulp vitality testing

All the complication, if present, were managed accordingly. Data collection and organization was made with commercially available software. Statistical analysis was performed using the SPSS software package. This included both Fisher's exact test and Chi-Square test and results were considered statistically significant is the $p<0.005$.

RESULTS:

Thirty patients were included in the study-15 patients in each group. In group I there was 14 male patients and one female patient with a mean age of 31.31. In group II, there were 13 male patients and two female patients with a mean age of 29.22.

Postoperative pain was assessed and both the groups had the same levels of pain score during the review periods which was again non-significant. The postoperative occlusal discrepancy was present in both groups with an equal distribution of three patients (20%) with the statistical analysis yielding a p-value of *one* denoting no significance for either group. There was no incidence of paresthesia or prolonged anaesthesia in group I while in group II, two patients reported with paresthesia (13.33%)- yielding a p-value of 0.211, this also was deemed statistically non-significant.

There were no incidences of infection, mobility, implant failure, wound dehiscence, trismus, non-union, and mal-union. The 10th-day follow-up, one-month follow-up and 3-month follow-up, the patients showed improvements in their complication with appropriate management protocols.

DISCUSSION

In 1992, Farmand developed the concept of 3D plates(Farmand, 1995) based on the principle that the quadrangle is a geometrically stable configuration for support which provides stability in three dimensions. This essentially led to the development of plates with low profile, malleability and torque resistance. The nomenclature 3D plates should not be confused with three-dimensional plates, rather it is the ability of these plates to hold the fracture fragments in three-dimensions is from where the plates derive its nomenclature(Bui et al., 2009). The stability achieved is aided by its configuration, unlike the conventional miniplates which relies mostly on the thickness of the plate (Farmand & Dupoirieux, 1992). The advantage achieved is that the 3D plates, with its lesser thickness and design, completes the fracture fixation superiorly and inferiorly at the same time, leading to time-saving and also have less implant/hardware material in the patient's body and eventually leading to a more economical treatment for the patient.

In our study, we encountered only two complications, occlusal derangement and paresthesia. Incidence of paresthesia in our study was 0 % in the study (group I) group and 13.33% in group II. This result was the same as that which was reported by Parmar et al (Parmar, Menat, Raghani, & Kapadia, 2007) and by Jain et al (Jain, Manjunath, Bhagwan, & Shah, 2010). Concomitantly there are studies done by Zix et al (Zix et al., 2007) and Guimond et al (Guimond, Johnson, & Marchena, 2005) who have reported the incidence of paresthesia as high as 25% and 60% respectively. As for the incidence of paresthesia in group II, Feller et al —(Feller et al., 2003) reported an incidence of 6% paresthesia rate, Moreno et al (Moreno, Fernández, Ortiz, & Montalvo, 2000) reported an incidence of 2.2% with Champy's principle and 3.1% paresthesia incidence with 2.7 mm AO plates for mandibular fixation. From these data, we can confer that the rate of paresthesia in our study was more than the others and may be attributed to the increased number of parasymphyseal fractures ho fixation might have led to the manipulation of the mental nerve. This phenomenon was also reported by Guimond et al (Guimond et al., 2005). Further studies need to be undertaken on this to ascertain whether the paresthesia is in fact caused by the tissue manipulation than because of the fracture fixation.

Another complication which we encountered was the presence of malocclusion post-fixation and both the groups had an equal distribution of the same. Moreno et al (Moreno et al., 2000) reported an incidence of 4.4% based on Champy's principle and 2.7% by using AO

plates. At the same time, Jain et al (Jain et al., 2010) and Bui et al (Bui et al., 2009) reported that there were no malocclusions which were noted in their study using the 3D plates.

The infection rate in our study in the immediate postoperative period and during the three-month follow–up period was 0%. Zix et al (Zix et al., 2007), Bui et al (Bui et al., 2009), Parmar et al (Parmar et al., 2007), Jain et al (Jain et al., 2010) and Guimond et al (Guimond et al., 2005) reported incidences of infection at 0%, 8.2%, 6.6%, 10% and 5.4% respectively when using 3D plates. Guimond et al (Guimond et al., 2005) reported an incidence of wound dehiscence of 2.7%, Parmar et al (Parmar et al., 2007) at 6.6%, and Jain et al (Jain et al., 2010) at 0%. Sebastian Sauerbier(Moreno et al., 2000) wound dehiscence incidence of 7.5% in the conventional miniplate system.

There was no instances of implant failure in both groups and concurs with as reported by Vineeth et al (Vineeth et al., 2013), Guimond et al (Guimond et al., 2005) and Feledy et al (Feledy, Caterson, Steger, Stal, & Hollier, 2004). But other studies by Farmand et al (Farmand & Dupoirieux, 1992) who reported treating 95 fractures of the mandible with 3D plates reported a single instance of 3D plate fracture. But it was a major and multiple instances complications in the study reported by Zix et al (Zix et al., 2007). They cited that the reduced interfragmentary cross-sectional bone surface at the fracture site to be the cause of this increased incidence rate. Goyal et al (Goyal, Marya, Chawla, & Pandey, 2011) reported that there was an increased incidence of fracture of the vertical strut of the 3D plates because of the repeated plate manipulation for precise adaptation to the bone. The conventional plates in our study did not have any incidence of fracture, but it was not in consent as reported by Vineeth et al (Vineeth et al., 2013), Xue et al (Xue et al., 2013) and Singh et al (Singh, Puri, Arya, Malik, & Bhagol, 2012) reported incidences with miniplate infection, and fracture.

Segmental mobility was present in the preoperative period but was absent in the postoperative period yielding an incidence of 0%. In contrast, Jain et al (Jain et al., 2010) reported an incidence of 10% of postoperative segmental mobility.

CONCLUSION

From this study, we came to the conclusion that the usage of 3D plates doesn't have any impact on the outcome of the surgery and also doesn't provide any definitive advantage over the conventional miniplates in the outcome of the surgery. Further studies need to be conducted to come to an absolute conclusion regarding these facts, as there are contradicting evidence to what has been the outcome of this study.

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