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Study of Comparison of Bite Force between Conventional and 3D Miniplate in Mandibular Fractures

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Abstract: ***The face serves a crucial role in human interaction and injuries to it result in devastating emotional sequelae. Maxillofacial injuries have attained a prominent position in today's era. Very few clinical trials have been performed to compare clinical outcome between conventional miniplates and 3D miniplates in the management of mandibular fractures in which bite force is used to measure the function rehabilitation. Aims & objectives: the present study was conducted to determine and compare bite force in mandibular fracture patients treated with 2.0 mm 3D miniplate and 2.0mm conventional miniplate and their comparison of bite forces with control group. Results: All patients were evaluated for the following parameters such as pain , biteforce , swelling , infection , fracture stability, occlusion, , mouth opening, surgical ease , cost effectivity , malocclusion and hardware exposure. Conclusion: With regard to this particular study, it can be concluded that use of 3-D miniplate is a viable option for fixation of mandibular fracture routinely. This study should evoke more inquisitiveness on evaluation of bite forces in various maxillofacial treatment procedures like bite force in patients with facial deformity undergoing orthognathic surgery as well as patients treated with implant supported prostheses***

Keywords: mandibular fracture, conventional miniplate, 3D miniplate, bite force, swelling, infection, occlusion

1. Introduction

Face serves a crucial role in human interaction & injuries to it result in devastating emotional sequelae.

Maxillofacial injuries have attained a prominent position in today's era. Traffic accident, interpersonal violence, falls, sports injury and industrial trauma have increased overall incidence of maxilla facial injuries.

The main goal in the treatment of fracture is to predictably restore pre injury anatomical form associated aesthetics and function. This must be accomplished by means which produces the least disability ,minimum risk and shortest recovery.

Traditionally treatment of mandibular fracture as been done by immobilizing the jaws using various wiring techniques. During the past four decades various methods of direct fixation are used via open approach and applying different techniques of plate and screw osteosynthesis.

Michelet et al(1973)[1] and later Champy et al(1978)[2,]popularized miniplate osteosynthesis and standard fixation method in maxillofacial and craniofacial surgeries. Unlike rigid fixation, miniplates provide functionally stable fixation which prevents micromotion of the bony fragments under function.

More recently 3D titanium plates & screws have been developed by Farmand M(1992)[3] with a quadrangular design formed by joining 2 miniplates with interconnecting crossbars that allow easy adaptation of plate to bone without distortion.

Unlike compression and reconstruction plates, their stability is not derived from thickness of plates. In combination with screws monocortically fixed to outer cortex, the rectangular plate forms a cuboid that possesses 3D stability. Because the screws are placed in a box configuration on both sides of the fracture rather than on a single line, broad platforms are created that may increase the resistance to torsional forces along the axis of the plate.[4]

Very few clinical trials have been performed to compare the clinical outcome between conventional miniplates and 3D miniplates in the management of mandibular fractures in which bite force is used to measure the function rehabilitation.

2. Materials and Methods

A randomized prospective study was done in the Department of Oral and Maxillofacial Surgery of Babu Banarasi Das College of Dental Sciences, Lucknow, India.40 patients with mandibular fracture were randomly selected requiring open reduction and internal fixation. Patients were categorized into 2 groups with 20 patients in each group. Informed consent was taken prior to surgery.

Group 1-20 patients were treated with 2mm conventional titanium miniplate and screws placed according to Champy's principle under general/local anaesthetia.

Group 2-20 patients treated with 2mm 3-D titanium miniplate & screws placed under general/local anaesthesia .

Inclusion Criteria

1) Adequate dentition to perform bite force measurements.
2) Absent or minimal dental restorations.
3) No sensitivity or pain on percussion on teeth to be tested.
4) Patients willing to participate in study after written informed consent.

Exclusion Criteria

1) Presence of mobile or tender teeth.
2) Complete edentulous patients.
3) Partially edentulous patient missing with molar and incisor.

Aim
To determine & compare bite force between mandibular fracture patients treated with 2.0 mm 3D miniplate and 2.0mm conventional miniplate & their comparison with control group.

Objectives
1) To compare bite force between 3D miniplate and standard miniplate & their comparison with control group.
2) To measure bite force in right and left molars & incisors.

Bite Force Recorder
All bite force measurement was recorded by using bite force recorder designed at RDSO (Research Design & Standard Organization) Lucknow. It consists of 4 strain gauges mounted on steel bar, forming a wheat stone bridge. Load changes in the steel bar produce a measurable voltage change across the 4 strain gauges, which are converted into kilogram force in digital display.

3. Results

All patients were evaluated on the pre operative,1st post operative day,1st post operative week,2nd post operative week,1st post operative month& 3rd post operative month for following parameters such as pain, bite force , swelling ,infection, occlusion, mouth opening, cost effect& malocclusion.

All the measurements were made with the subject seated with the head upright, looking forward & in an unsupported natural head position. Patient was instructed to bite on the blade covered with latex glove of the bite force gauge to the maximum level. Data were collected and tabulated using Microsoft excel and the statistical analysis was done using SPSS version 22.0 statistical analysis software. The values were represented in Number (%) and Mean±SD.

Control group bite force ranges from 36-40 kg in molar region and 13-15 kg in the incisor region. The data of both the group were compared independently with control group and it was found that functional forces are restored in 4 to 6 weeks and maximum bite forces in 8 weeks.

Pain was calculated on Visual analogue scale (1-10) with 4 domains: No pain (0), Mild (1-4), Moderate (5-7), Severe (8-10), no statistically significant result were found at all intervals. Initial follow up showed mild to moderate pain which later subsided.

Operating time was recorded in minutes from incision placed to the time of closure. The result were analyzed that less time was required in group II (58.60 min.) compared with the group I (66.9 min.)

Cost effectiveness was recorded for all the money spent on purchasing the Conventional miniplate or the 3 dimensional miniplate and the screws required for the purpose of the surgery. Cost of the hardware found to be less in anterior region with group II compared with group I where in posterior region group I found low priced then in group II.

Occlusion was graded as Satisfactory – No gap between upper and lower first molars, Mildly deranged – Gap of 1 – 2mm between upper and lower first molar and Deranged – Gap more than 2mm between upper and lower first molars. The results showed that there was no significant post operative occlusal disturbance among both the groups at various follow ups.

Mouth opening was graded as Adequate - Inter incisal width more than 3cms and Inadequate - Inter incisal width less than 3cms. 13 patients from group I and 9patients from group II had inadequate mouth opening at 1st post operative day and on subsequent follow-ups there was adequate mouth opening among all the patients.

Swelling was measured– present or absent. Few patients reported with swelling in both the groups which gradually subsided on 1st month post operative follow up.

Infection was considered to be present if redness, pus discharge and sinus were present. The results showed that infection was present among 4 patients in group I and 3 patients from group II at post operative 1st week follow up which gradually resolved during next follow ups.

There were 2 cases of exposure of plate 1 patient from each group at 1st postoperative Week which was resolved by chlorine water dressing while allover patients in group II had to undergo plate removal.

Comparison among both the groups with respect to fracture stability at all time intervals was found to be statistically not significant i.e. on pre operative , 1st, 7th ,14th,30th and 90th postoperative days (Fisher's exact test: $p > 0.05$) and only two cases at 1st post operative day from group I were found to be unstable.

The results of this suggest that fixation of mandibular fracture with 3dimensional miniplates (3D) provides three dimensional stability, carries low morbidity rates with advantages of greater stability, less precision required in plate adaptation, and less alteration in the periosteal blood supply which allow for faster recovery and also generates greater bite force.

4. Discussion

The objectives in the treatment of mandibular fracture are to re-establish normal Occlusion and masticatory function with minimal disability and complications. Conservative treatment is performed by immobilizing the mandible for the duration of healing period by inter maxillary fixation achieved by dental wiring, arch bars, cap splints and gunning splints.

Currently, open reduction and internal fixation with plates is used to immobilize fragments of the jaw in which morbidity advantage is that the normal function is restored within day of treatment.[5]

The miniplates are applied close to thetension zone of mandible. The screws are monocortical to prevent injury to the dentitionand inferior alveolar nerve.[6]

Various material are used for the fixation, such as stainless steel, titanium and biodegradable plates in which titanium is the metal of choice, mainly because of its high biocompatibility and ease of manipulation.9 Titanium 3Dplating system was developed by Farmand (1992)[3]to meet the requirements of semi rigid fixation with lesser complications.

The basic concept of 3D fixation, as explained by Farmand M (1992)[3], is that a geometrically closed quadrangular plate secured with bone screws creates stability in three dimensions. The stability is gained over a defined surface area and is achieved byits configuration and not by thickness or length. The large free areas between the platearms and minimal dissection permit good blood supply to the bone.10

Zix et al. (2007)[7] concluded that 3D plating system has a compact design and easier alternative to conventional miniplates for the treatment of mandibular angle fractures. Hughes et al (2000)[8], Feledy J et al.(2004)[9],Gaurav M et al. (2012)[10], Sebastian H et al. (2012)[11], Malhotra et al. (2012)[12], also showed that the 3D plating system offers more favorable biomechanical behavior than the conventional miniplatesin terms of stability and strain resistance in different regions of mandible.

The present study comprised of 40 patients divided into two groups.

Group-I constituted patients treated with 2.0mm conventional titanium miniplate and screws placed according to Champy's principle under general anesthesia / local anesthesia.

Group-II included patients treated with 2.0mm 3-dimensional titanium miniplate and screws placed under general anesthesia / local anesthesia.

Out of 40 patients, 34 were male and 6 female. This male dominance was also reported by Adi et al.(1990[13], Haug et al.(1996)[14], Bataineh (1998)[15], Shapiro et al. (2001)[16], Dongas et al. (2002)[17], Ogundare et al. (2003)[18], Ahmed et al. (2004)[19], Sakr K.et al. (2006)[20], and Brasileiro et al. (2006)[21] and Natu S et al. (2012)[22], is probably due tohigher level of physical activity among men as they are still the bread winners in this part of the country.

Assault was the cause of mandibular fractures in 19 cases, road traffic accident in 16 cases, and fall in 4 cases and in 1 case it was sports related injury. The results were similar to Anayenchi et al (2010)[23] where injuries were inflicted by either blunt or penetrating forces or a combination of both. Fist was found to be common means of assault in 56.2% of the patients. Weapons were used in 37.0%. On the contrary, Kumar P et al (2012)[24] reported that road traffic accident was the most common cause of mandibular fractures in (85%) cases, followed by interpersonal violence and falls. This distribution compared favorably with the results obtained by Schuchardt et al (1982)[25] who found road traffic accidents to be the cause in 35.6% cases, fist fights in 31.8% and work related accidents and sports accidents in 11.6% and 3.3% cases respectively. The difference in the etiology of mandibular fracture by various authors could be attributed to difference in social setup, culture and governance other than the level of education which also influence the behaviour of individual belonging to that particular society.

In our study mandibular angle was the most common site of fracture (43%)

Followed by body (34%), parasymphysis (18%), and subcondylar fracture (5%). This result was in accordance with Perez et al (2011)[26] who proposed two reasons justifying Mandibular angle fractures representing the largest percentage of mandibular fractures.

The first reason is the presence of thinner cross sectional area relative to the neighboring segments of the mandible. Second is the presence of third molars, Particularly the impacted third molar, which weakens the region by reducing bone volume.

The two groups were compared for the 12 parameters. The patient's bite force was evaluated pre-surgically on the day of surgery, after 1 day, 1 week, 2 week, 1 monthand 3 months postoperatively. Each parameter was evaluated with the help of a scoring system on every visit of the patient.

Pain associated with the procedure was recorded for Group I and Group II. Patients preoperatively and during various follow up stages based on a visual analogue scale (1-10). Chi square test was applied to compare the average pain scores between the two groups at all time intervals. However, there was no significant difference between the pain scores of the two groups. The higher pain scores on day 1 for group Ipatients were perhaps due to the wide surgical exposure required for adaptation and manipulation of the champy's miniplate and more working time required for the surgical procedure. This result is similar to that of Kumar P et al (2012)[24], who found that the higher pain scores on 2 weeks for champy miniplate as compared to 3-D mini plate which was due to higher incidence of infection and mobility at the fractured segments,& Gandi L (2012)[27], who suggested that there is significant decrease in pain 3rd post operative day to 6th post operative week in all the patients.

The average operating time required for the placement of Champy's miniplate was 66.9 minutes where as the average operating time required for the placement of 3Dplate was 58.60 minutes. These findings were similar to the results of a study by Feledyet al (2004)[9]and Zix et al (2007)[7]on 3D plate who reported reduced average operating time (55 and 65 minutes, respectively).

The cost of implant placed in inter mental region on an average is Rs.1750 for group I and Rs.1500 for group II. This further decrease to Rs.1100 in group I and Rs.1350 in group II posterior to the mental foramen.

Restoration of pre-morbid occlusion is one of the most important goals of the management of fractures of dentofacial region. The effect of not restoring the occlusion to its original condition is disabling and can cause deleterious effects on the temporomandibular joint.

The occlusion of patients was checked preoperatively and during the follow up stages after surgery. In the present study, all the patients in Group – I and group II hadsatisfactory occlusion with 12 patients (60%) in group I and 15 patients (75%) in group IIwhere mild derangement was present in group I and group II was 8 patients (40%) and 5patients (25%) respectively on pre operative day whereas no occlusal derangement wasfound on rest of postoperative days.

In the present study, the maximal mouth opening (inter incisal width) was measured at all time intervals. 13 patients of group I and 9 patients of group II had inadequate mouth opening on 1st post operative day, which improved on subsequent follow ups. These were the patients with fracture of angle region which at times requires stripping of masseter and some fibers of temporalis to achieve proper exposure of fracture sites and therefore result in post operative trismus, otherwise all patients in both the groups resumed normal mouth opening within one week. The results were similar to Vineeth K et al (2013)[28].

In the present study, the swelling was measured at all intervals. Preoperatively 10 patients of group I and 9 patients of group II had swelling. 14 patients of group I and 16patients of group II had swelling on 1st preoperative day which gradually decreased with time.

Mandibular fractures are often contaminated by oral bacteria. Post reduction infection at the fractured site is not only the result of contamination but is also related to inadequate stability of fracture i.e. mobility of fractured segments. The rate of infection was compared between the two groups at 2 weeks and at 4weeks interval byusing Chi-square test. No statistically significant difference was found reported between Group I and Group II with respect to infection rates at 1st post operative week.

The incidence of infection for Group I was 1 case at 1st week. The incidence of infection for Group II was 3 cases at 1st week. With the use of open reduction and internalfixation, the reported incidence of infection ranged from 5% to 15.

There is paucity of information in the literature on incidence and natural history of sensory deficit associated with mandibular angle fracture. Most studies are retrospective and it is often difficult to obtain sufficient data from the patient's record toallow analysis. In our study paraesthesia was reported in 10 of 20 patients in group I and in 5 of 20 patient of group II on 1st post operative day. Both the cases had loss of sensation throughout the treatment. More traction in group I during plate fixation can be attributed to higher incidence of paraesthesia. Fischer exact test was applied and the statistical analysis showed no difference in the two groups.

The sensory disturbance identified after surgery was likely the results of manipulation of the fracture site during surgery. It also results due to screw placementin inferior alveolar canal bundle and can be avoided with the use of monocortical screws, however previous reports have cited the incidences of sensory disturbance of about 0% to 8% in monocortical screws.

In the present study, 1 patient in group-I and 1 patient in group II had hardware exposure in 1st week. This findings is similar to Vineeth K et al (2013)[28]study, in which 2(20%) patients in group-I developed infection, one in the 2nd week and one during 3rdpost operative month follow up, among them 1 patient required hardware removal along with antibiotic coverage. Our study was not in accordance with Gandi L (2012)[27], where no hardware failure is noted.

In this study, fracture stability was assessed in patients of both the groups by simple digital palpation on either side of the fracture line and checked for the fracture fragments mobility. In group-I, 2 (30%) patients presented with unstable fracture fragments on immediate postoperative day where as in group-II there were no patient showing fracture instability. At the 1st month (30th day) follow up all patients (100%) showed stable fracture fragments upon digital palpation. Although there was nostatistical difference between the two groups, the 3-Dimensional miniplates showed better initial inter fragmentary stability over conventional (2D) miniplate.

None of the cases in our study had malunion/nonunion or delayed union. These usually are the result of infection or conditions that decreases the blood supply. In the previous literature it was quoted that incidence of malunion and non union is 1% to 2%.

The forces that must be countered in mandibular body fracture have been derived from maximum voluntary bite force measurement, which in healthy adult maybe in order of 15.3KPa in the incisor and 48.3KPa and 49.3KPa in left and right molar region respectively (Ellis and Throckmorton, 1994)[29]. The amount of force the subjects with fractures can generate is much less.

Gerlach et al (2002)6 stated that maximum bite force in patient with mandibular fractures treated with miniplate osteosynthesis reaches only 31% at 1st postoperative week, compared to healthy control group. These value increase to 58% at the 6th week post operatively.

In our study, a statistically significant difference in bite force in posterior region was found between group I (6.09 kg) and group II (11.12 kg) on 1st post operative day of right molar region. Whereas in the anterior region no statistically significant difference was noted in bite forces among both the group on 1st post operative day.

In left molar region a statistically significant in bite force was noted among group I (6.09 kg) and group II (10.60 kg) on 1st post operative day. Though the two groups do not shows statistically significant reading in rest of follow ups but there was greater bite force in the group II than in group I.

Three dimensional miniplates stabilize the bone fragments in three dimensions because of the closed quadrangular geometric shape, and the ease of contouring and adapting leads to better interfragmentary stability.

Our study revealed that the maximum voluntary bite force measured in healthy Indian individuals is in a range of 35-40 kg in the molar region and 13 -15 kg in theincisor region. Females showed less bite forces when compared with males in similar age groups. Our study also showed a trend of increased bite forces with increasing agein males as well as in females.

In cases of mandibular fractures, bite forces were subnormal till 1st month, and maximum bite forces were restored by the 3rd month. There was no significant gain inbite forces after 3rd month.

Reasons for subnormal forces in mandibular fractures may be trauma tomasseter and temporalis muscle intraoperatively and protective neuromuscular mechanism of masticatory system. Further, a transfacial trochar used for instrumentation may also damage the masseter muscle. All of these mechanisms are probably responsible for a reduction in bite force after injury and open treatment. It was also observed in our study that the patient's unwillingness to bite forcefully was also a major cause in obtaining subnormal forces. This is related to both mental attitude and comfort of the dentition. Some patients were afraid to use their jaw vigorously, especially in the first few weeks. These findings are similar to a study of R Kshirsagar etal. (2011)[30] It was also similar to Gerlach et al (2002)[31]who stated that maximum bite force inpatient with mandibular fractures treated with miniplate osteosynthesis reaches only31% at 1 week postoperatively, compared to healthy control group. These values increased to 58% at the 6th week postoperatively.

Bite forces is related to a number of factors such as tactile impulses, pain and pressure reception in periodontal ligament and number of residual teeth. There is a reduction in bite force with age due to age dependent deterioration of dentition. The results of this study suggest that fixation of mandibular fracture with 3Dplates provides three dimensional stability and carries low morbidity and infection rates with better bite forces.

The only probable limitation of these plates may be extra work to be done for fixation involving the mental nerve and in cases of oblique fractures. Three dimensional miniplates provides good stability but have excessive implant material because of extra vertical bars incorporated for countering the torque forces. However operating time is less because of simultaneous stabilization at both superior and inferior borders.

The small sample size and limited follow up could be considered as the limitations of this study. It is hence recommended to have a multicentre study with alarge number of patients and correlation among these studies to authenticate our claims.

5. Conclusion

Along with the theoretical advantages of greater stability, less precision required inplate adaptation, and less alteration in the periosteal blood supply, three dimensional miniplates allow for a greater bite force. The results were almost similar to those seen with conventional miniplates (2D) osteosynthesis and showed statistically no significant difference. Larger sample size would provide appropriate conclusion. With regard to this particular study, it can be concluded that use of 3-D miniplate is a viable option for fixation of mandibular fracture routinely. This study should evoke more inquisitiveness on evaluation of bite forces in various maxillofacial treatment procedures like bite force in patients with facial deformity undergoing orthognathic surgery as well as patients treated with implant supported prostheses.

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