Original Article

EVALUATION OF TWO DIFFERENT THREE-DIMENSIONAL TITANIUM MINIPLATES IN TREATMENT OF MANDIBULAR SUBCONDYLAR FRACTURES (RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

Introduction: Recently, three dimensional plates were introduced to treat mandibular fracture aiming to neutralize compressive, tensile and torsional force and thus providing better stability across the fracture line. Studies have been conducted to evaluate efficacy of these plates ,which include a wide array of configurations, in treatment of mandibular subcondylar fractures.
Objectives: To compare the efficacy of rhombic three-dimensional plate versus trapezoidal three-dimensional plate in treatment of mandibular subcondylar fractures. Objectives: To compare the efficacy of rhombic three-dimensional plate versus trapezoidal three-dimensional plate in treatment of mandibular subcondylar fractures.
Methodology: Twenty patients with mandibular subcondylar fractures indicated for open reduction were recruited in the study. Patients were randomly divided into two equal groups; group A was treated with the rhombic three-dimensional plate, while group B was treated with the trapezoidal three-dimensional plate. Both groups were followed up clinically and radiographically for a period of 6 months to evaluate the patients mandibular movements, mandibular deviation on mouth opening and bone density in the fracture line.
Results: There was no statistically significant difference between the two groups regarding mandibular movements and mandibular deviation in mouth opening. However, group B showed a significantly higher mean bone density in the fracture line than group A.
Conclusion: Both rhombic and trapezoidal plates are effective in treatment of subcondylar fracture with minimal complications. Furthermore, trapezoidal plates provides a better fracture stabilization and thus better bone healing when compared to the rhombic plate.
Key Words: Subcondylar fracture, three-dimensional plates, trapezoidal plate, rhombic plate

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INTRODUCTION

The mandibular condyle is considered a weak spot in the mandibular anatomy and are very vulnerable to fracture with frontal and lateral blows to the mandible. Moreover, condylar fractures accounts for around 1820%- of maxillofacial fractures and can be classified based on anatomy into intracapsular condylar head fractures, extracapsular condylar neck fractures and extracapsular subcondylar fracture. [1]

Management of condylar fractures can be achieved by either closed or opened reduction according to the amount of displacement. Open reduction and internal fixation (ORIF) is indicated when the amount of displacement is greater than 10o or when the posterior facial height is reduced by more than 2 mm especially with bilateral condylar fractures. [2- 4]

Studies proved that when open reduction is indicated, subcondylar factures needs at least two miniplates placed in a diagonal pattern parallel to the posterior and anterior border of the condyle to neutralise both compressive and tensile forces along the fracture line. [5],[6]

Recently, many forms of three dimensional miniplates were introduced for fixation of condylar fractures aiming to stabilize the condyle three dimensionally and at the same time providing an option smaller in size than the two miniplates and thus can be placed in high condylar fractures where there is no space for two miniplates. Furthermore, three dimensional plates make conservative surgical approaches including intraoral approaches and endoscopic approaches more feasible. [7],[8]

Through out the last decade, many forms of three dimensional condylar plates were introduced including A shaped plates, lamboid plates, delta plates, rhombic plates which is a modification for the delta plates and trapezoidal plates. All these plates aim at stabilizing condylar fractures through neutralizing compressive, tensile and shear forces.

Several clinical and biomechanical studies were conducted

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on some of these plates to compare their performance. [9- 12]

The null hypothesis of the study was that there will be no significant difference between the subcondylar fractures treated by Rhombic plate and those treated with the Trapezoidal plate in terms of range of mandibular movements and bone density in the fracture line.

The objective of our study is to compare both clinically and radiographically the effect of three dimensional rhombic plate versus trapezoidal condylar plate (TCP) in the fixation of mandibular subcondylar fractures.

MATERIALS AND METHODS

This study is a randomized controlled clinical trial conducted on 20 patients recruited from the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria university; the sample size was based on a statistical sample size estimation. In addition, all patients signed an informed consent stating the benefits and complications of the procedure.

Patients had to fulfil the following criteria to be recruited

in the study: 1- patients with age range from 20- 40 years old, 2- patients having displaced condylar fracture indicated for open reduction. Furthermore, patients with relevant systemic diseases contraindicating surgery or affecting bone healing and comminuted fractures were excluded from the study. [10]

The patients were randomly assigned equally into two groups using computer generated method (Randomizer. org, Pensylvania, USA); group A was treated using the three-dimensional rhombic plate, while group B was treated using the three-dimensional trapezoidal plate.

Blinding was done by giving assigning a number for each patient by an assistant. A copy of this number was kept in an envelope indicating to which group the patient belongs. This envelope was kept by a trial independent individual who was assigned the role of opening it only at the time of intervention; so that the group to which the patient is allocated was concealed from the investigator. [13]

Materials :

Two types of three dimensional miniplates were used in this study: 1- The rhombic plate (KLS Martin, Tuttlingen, Germany) which is manufactured of pure titanium grade 2 and with a thickness of 1mm; they are secured in place with 5 titanium screw with 2mm head diameter. 2- The tapezoidal plate (Traumec, Brazil) which is also manufactured of titanium and secured in place using 4 titanium screws.

Methods :

Preoperative phase

Thorough history was taken for all the patients followed by extra oral and intraoral clinical examination by inspection and palpation. Moreover, radiographic examination was done using computed tomography (CT) to confirm the diagnosis, detect the amount of fracture displacement and for treatment planning.

Operative phase [11] (Figure 1,2)

Figure (1): A: Preoperative CT, B: Fixation with rhombic 3D plate, C: immediate postoperative CBCT, D: 6 months postoperative CBCT.

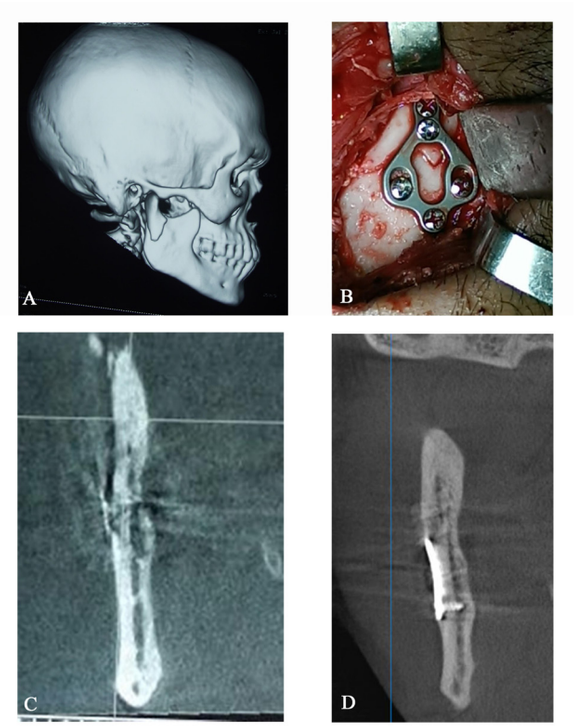
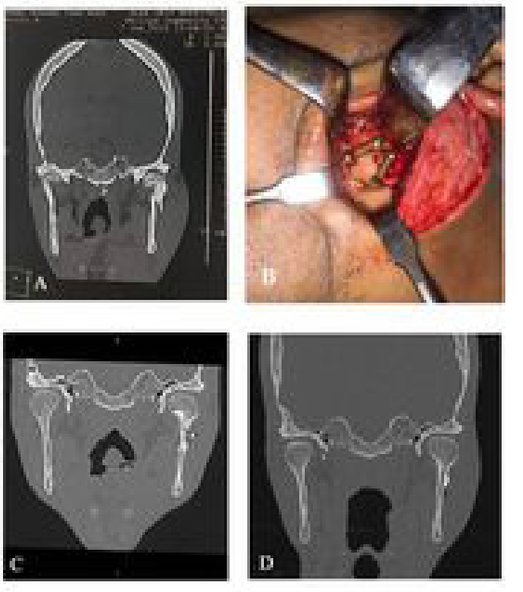


Figure (2) : A: Preoperative CT, B: Fixation with trapezoidal 3D plate, C: immediate postoperative CBCT, D: 6 months postoperative CBCT.



All patients were operated and general anaesthesia with nasotracheal intubation. Maxillomandibular fixation (MMF) was achieved to secure occlusion. The appropriate extra oral surgical approach was determined based on the level of fracture and the amount of displacement followed by dissection to expose the fracture line. Reduction was achieved using bone clamp followed by fixation using rhombic plate in group A and using trapezoidal plate in group B.

After fixation, the MMF was removed and the wound closure was achieved in layer using resorbable polylactatic polyglycolic acid sutures (Vicryl, Ethicon, USA) for the deep layer and non resorbable 5 0 polypropylene suture (Prolene, Ethicon, USA) for the skin layer.

Postoperative phase

Postoperative medications were prescribed for the patient including Amoxicillin clavulanate 1 gm intravenously for 5 days postoperatively (Augmentin, GlaxoSmith-Kline, UK) and Diclofenac sodium 75 mg intravenously (Cataflam, Novartis, Basel, Switzerland). In addition, patients were instructed to adhere to postoperative care instruction and the sutures were removed after one week.

Follow up phase

All patients were followed up clinically at 1 week, 3 weeks, 3 months and 6 months postoperatively to check mandibular movement in all 3 planes (maximal mouth opening and protrusive and lateral excursive movements) and deviation in mouth opening. These measurement was done using a mm ruler. In addition, wound healing was followed up and any infection or complication was recorded.[11]

Moreover, radiographic follow up using cone beam computed tomography (CBCT) was done at immediate postoperatively and after 6 months to measure the bone density in the fracture line. The bone bone density was measured using CBCT software (OnDemand3D, Cybermed, South Korea) at six different points across the fracture line and the mean was calculated. In addition, any cases of non union or facture in plates and screws were noted.[11]

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Categorical data were represented as numbers and percentages. Chi-square test was applied to compare between two groups. Alternatively, Fisher Exact correction test was applied when more than 20% of the cells have expected count less than 5. For continuous data, they were tested for normality by the Shapiro-Wilk test. Quantitative data were expressed as mean and standard deviation. Student t-test was used to compare two groups for normally distributed quantitative variables .

Significance of the obtained results was judged at the 5% level.

RESULTS

This study was conducted on 20 patients (18 males and 2 females). Their age ranged from 22- 40 years old with a mean of 26.5 years old. The patients were clinically and radiographically followed up for 6 months postoperatively. Clinical follow up **(Table 1)**

	Group A (n = 10)	Group B (n = 10)	Test of sig.	p
Maximal mouth opening				
Week 1	23.3 ± 4	24.3 ± 4.2	t=0.542	0.594
3 weeks	29.1 ± 5.3	29.4 ± 5.5	t=0.124	0.903
3 months	34.5 ± 3.7	34.4 ± 5.2	t=0.050	0.961
6 months	39 ± 2.4	39.1 ± 4	t=0.068	0.947
Protrusive movement				
Week 1	4.5 ± 1.4	5 ± 1.2	t=0.832	0.416
3 weeks	5.5 ± 1.8	6.7 ± 1.4	t=1.668	0.113
3 months	7.7 ± 1.6	7.8 ± 1.1	t=0.163	0.872
6 months	8.9 ± 1	8.8 ± 1	t=0.221	0.828
Lateral movement				
Week 1	5 ± 0.9	4.7 ± 1.4	t=0.557	0.584
3 weeks	7.4 ± 1.1	6.3 ± 1.4	t=1.955	0.066
3 months	8.9 ± 1.1	8.9 ± 0.9	t=0.0	1.000
6 months	9.8 ± 1.1	10.1 ± 1.1	t=0.600	0.556
Deviation on mouth opening				
Week 1	5(50%)	6(60%)	χ^2=0.202	^{FE}p=1.000
3 weeks	2(20%)	3(30%)	χ^2=0.267	^{FE}p=1.000
3 months	0(0%)	0(0%)	–	–
6 months	0(0%)	0(0%)	–	–
Bone density in fracture line				
Immediate postoperative	234.8 ± 70.6	197.4 ± 40.7	t=1.450	0.168
6 months	1072.1 ± 83.5	1200.1 ± 78.3	t=3.535*	0.002*
Increase	837 ± 140	1003 ± 97.87	t=3.062*	0.007*

Data was expressed by using **Mean ± SD.** SD: **Standard deviation**
t: Student t-test χ^2: **Chi square test** FE**: Fisher Exact**
p: p value for comparing between the two studied groups
*: Statistically significant at p ≤ 0.05

Table 1 : Comparison between the two studied groups according to different parameters

1- Maximal mouth opening

The mean maximal mouth opening for group A at 1 week postoperative was 23.3±4 mm while for group B the mean was 24.3± 4.2 mm . At 3 weeks postoperatively, the mean for group A was 29.1± 5.3 mm while that for group B was 29.4± 5.5 mm . Furthermore, at 3 months postoperatively the mean for group A was 34.5± 3.7 mm while that for group B was 34.4± 5.2 mm. At 6 months postoperatively the mean was 39 ± 2.4 mm for group A and 39.1± 4 mm for group B.

Regarding maximal mouth opening, there was no statistically significant difference between the two groups through out the study period.

2- Protrusive mandibular movement

The mean protrusive movement for group A at 1 week postoperative was 4.5± 1.4 mm while for group B the mean was 5 ± 1.2 mm. At 3 weeks postoperatively, the mean for group A was 5.7± 1.8 mm, while that for group B was 6.7± 1.4 mm . Furthermore, at 3 months postoperatively the mean for group A was 7.7± 1.6 mm, while that for group B was 7.8± 1.1 mm . At 6 months postoperatively the mean was 8.9 ± 1 mm for group A and 8.8 ± 1 mm for group B.

Regarding the protrusive movement, there was no statistically significant difference between the two groups through out the study period.

3- Lateral mandibular movement

The mean lateral excursive movement at 1 week postoperative was 5 ± 0.9 mm for group A and 4.7 ± 1.4 mm for group B. At 3 weeks postoperatively, the mean for group A wpostoperat.1 mm while that for group B was 6.3± 1.4 . Furthermore, at 3 months postoperatively the mean for group A was 8.9 ± 1.1 mm while that for group B was 8.9 ± 0.9 mm . At 6 months postoperatively the mean was 9.8 ± 1.1 mm for group A and 10.1 ± 1.1 mm for group B.

The difference between the 2 groups was found to be statistically insignificant through the study period.

4- Lateral deviation on mouth opening

At 1 weak postoperative, five patients in group A showed deviation on mouth opening accounting for 50% of group 1; in group B, six patients (60% of the group) showed lateral deviation on mouth opening. At 3 weeks postoperatively, the number of patient with lateral deviation on mouth opening decreased to two patients in group A (20%) and three patients in group B (30%). At 3 and 6 months postoperatively, none of the patients in both groups showed lateral deviation in mouth opening.

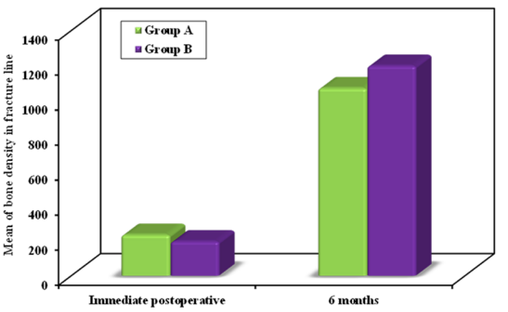
Regarding the lateral deviation on mouth opening, there was no statistically significant difference between the two groups during the study period.

5- Complications

One of the patients in group B showed infection in the surgical wound at the one week follow up, which was treated and cured with no effect on fracture fixation and thus the success rate was 100 % in both groups. In addition two of the patients (one in each group) showed temporary affection of facial nerve function which gradually improved within the 6 months follow up period.

Radiographic follow up **(Table (1) and Figure(3))**

Figure (3): Comparison between the two studied groups according to bone density in fracture line



The mean bone density in the fracture line at immediate postoperatively was 234.83 ± 70.6 HU in group A and 197.4 ± 40.7 HU for group B. At 6 months postoperatively, the mean for group 1 was 1072.1 ± 83.5 HU for group A and 1200.1 ± 78.3 HU for group B. In addition, the mean bone density was statistically significant higher in group B than in group A.

Moreover, the increase in bone density from immediate postoperative to 6 months was 837± 140 HU in group A and 1003 ± 97.87 HU in group B showing a statistically significant difference between the two group regarding the percent change in bone density in favour of group B. In addition, there was no incidence of plate fracture, screw loosening and non union or malunion.

DISCUSSION

In this study, the exclusion criteria included comminuted fractures and patients with systemic diseases affecting bone healing such as uncontrolled diabetes mellitus, rheumatic arthritis and osteoporosis.

This coincides with Elamir et al [14] who stated in their systematic review that both type 1 and type 2 diabetes mellitus has a negative impact on bone metabolism and thus affecting bone quality, quantity and turnover. This was confirmed by studies conducted by Napier et al [15] and Shen X[16] who also reported that diabetes impedes bone healing.

Moreover, Satoh k[17] et al who reported in their study on methotrexate drug used in treatment of rheumatic arthritis on fracture healing that methotrexate inhibits subperiosteal bone deposition leading to delayed bone healing. Furthermore, Eastel R et al [18] stated that osteoporosis is associated with an imbalance in the bone remodelling cycle leading to bone loss which can eventually lead to bone fracture and can also affect the rate of fracture healing.

In addition, the patients randomly recruited for our study were 18 males (90%) and 2 females (10%). This coincides with most studies and could be attributed to the fact that males especially in their third decade are more engaged in interpersonal violence than female.[19,20]

Regarding the mandibular movements, results of our studies showed no statistically significant difference between the two groups throughout the study period. At 6 months, the mean maximal mouth opening was 39 mm for group A and 39.1 mm for group B. Moreover, the mean protrusive movement and the lateral excursive movement were 8.9 mm and 9.8 mm respectively for group A and 8.8 mm and 10.1 mm respectively for group B. This could be owed to the fact that that fixation and stability at the fracture line in both groups was sufficient for the affected muscles of mastication to heal properly and regain the normal mandibular range of movement.

These results coincides with Elhalawani et al [21] study in 2017 in which they compared the rhombic 3d plate with two miniplates in subcondylar fracture fixation. In the rhombic plate group of their study, the maximal mouth opening at 6 months was 38.4 mm. Whereas, the protrusive and lateral excursive movements were 9.1 mm and 9.5 mm respectively.

Moreover, the study conducted by lauer et al [22] on the delta three dimensional plate stated that the mean maximal moth opening at 6 weeks follow up was 41 mm, while the protrusive movement was 5 mm and the lateral mouth opening was 6 mm. These results partly match our study regarding the mean lateral and protrusive movements. However, the maximal mouth opening values took a longer 6 months interval to reach the same values. Furthermore, results of our study resemble studies done by Leonhardt et al [23] on the rhombic plate and that conducted by Ganguly et al [11] on the delta plate.

In addition, Palani T et al [24] reported in their clinical study on the trapezoidal condylar plate that the maximal mouth opening at 6 months showed an average of 40 mm which matches with our findings. Moreover, Sikora M et al in their study on 113 patients with condylar fractures treated with three dimensional delta and trapezoidal plates reported an average mouth opening of 49.23 mm. In the last mentioned study, they where evaluating three dimensional plates and did not compare between trapezoidal and delta plates.

Furthermore, Chaudhary M et al [25] conducted a study on 15 mandibular subcondylar fracture cases to evaluate the trapezoidal condylar. Their study reported a range of 34 to 42 mm at 6 months follow up which coincides with the results of our study but they did not measure protrusive and lateral excursive movements. In the current study, the lateral deviation in mouth opening showed no statistically significant difference between the two groups at the different follow up periods with both groups showing no lateral deviation starting from the third postoperative month. These results are in coincidence with Palani et al [22] who reported that out of 20 patients treated with trapezoidal condylar plates only 3 patients still had deviation on mouth opening after 6 months.

Regarding the postoperative complications, only one patient in this study (5%) showed wound infection and this could be attributed to the patient not properly following wound care instructions. However, the infection was treated successfully and did not affect fracture healing. In addition, two patients (10%) showed temporary affection of facial nerve function which could be attributed to pressure on the nerve during retraction or by postoperative edema.

This is in line with the study achieved by Koirala U et al [26] evaluating the retromandibular transparotid approach for subcondylar fractures in which they recorded surgical site infection in 2 out of 35 treated patients with a percentage of 5.7%. They also reported 4 patients with transient affection of facial nerve with a percentage of 13.8%.

Furthermore, Tomar K [27] in his study evaluating the transmasseteric retroparotid surgical approach in treating subcondylar fractures stated that 4 out of 25 patients (16%) included in his study showed transient facial nerve affection which subsided within 3 weeks postoperatively.

The success rate in this study was 100 % in both groups with no incidence of plate or screw fracture or loosening. This matches findings by Leonhardt et al [23] who reported in his study evaluating the rhombic plate that 7 cases out of 81 patients needed surgical revision and thus the success rate in his study was 92.6%. In addition, a study conducted by Cortelazzi et al [28] on trapezoidal plates reported a 100% success rate despite the fact that 3 patients out of the 62 patients involved in the study showed wound infection and one of the 3 patients showed loosening in one of the plate screws but this did not affect fracture healing. These results also come in alignment with Chaudhary et al [23] study on trapezoidal plates; they also stated that the success rate was 100%.

Regarding the bone density in the fracture line, the mean for group B treated with trapezoidal plate was statistically significantly higher at 6th month postoperatively than that in the rhombic plate group. In addition the change in bone density from immediate postoperative to 6 months postoperative was also statistically significant higher in the trapezoidal plate group. This could be explained by the fact that the screw holes in the trapezoidal plate are horizontally oriented in the proximal part of the subcondylar facture; this pattern offers better stabilization of the fracture when compared to the vertical oriented screws in the rhombic plate and thus better healing across the fracture line. These findings regarding bone density are consistent with studies done by Elhalawani et al 21 who compared rhombic plates with two

miniplates in treatment of subcondylar fractures; they reported in their study that the mean bone density was higher in the rhombic plate group and attributed this to the three-dimensional stabilization of the fracture. This also coincides with Oraby et al [29] who conducted a study comparing trapezoidal plates to the two miniplates in treatment and got similar results. However, to the best of our knowledge, no studies were conducted to compare the efficacy of the rhombic three-dimensional plate to that of the trapezoidal three-dimensional plate in treatment of condylar fractures.

In conclusion, both rhombic and trapezoidal plates are effective in treatment of subcondylar fracture with minimal complications. Furthermore trapezoidal plates provides a better fracture stabilization and thus better bone healing when compared to the rhombic plate. It is recommended to perform further studies with larger sample size and to test the biomechanical properties of the two plates.

CONFLICTS OF INTEREST

There are no conflicts of interest.

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