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TRAPEZOIDAL CONDYLAR PLATE (TCP) VERSUS TWO MINIPLATES IN TREATMENT OF SUBCONDYLAR FRACTURE (A RANDOMIZED CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: Condylar fracture is a common mandibular fracture which accounted for 25–40%. There is much controversy in condylar fracture diagnosis and management. For several years, the preference was toward closed reduction to avoid surgical complications. Nowadays the preference started to change towards open reduction because of the late complications that might happen in case of closed treatment. Numerous plate designs had been emerged for internal fixation of the condyle and subcondylar region. Trapezoidal Condylar Plates (TCP) has been developed particularly for the fixation of low and high subcondylar fracture.

OBJECTIVES: comparison between the TCP and standard two miniplates in fixation of subcondylar fracture clinically and radiographically.

METHODOLOGY: Twenty patients with subcondylar fracture were treated with open reduction and internal fixation, 10 patients underwent TCP fixation (Group I) and 10 patients underwent two miniplates fixation (Group II). Intraoperatively, the application time for each plate type was compared. Postoperatively, clinical and radiographical follow up were in intervals of 1 week, 1 month then 6 months.

RESULTS: Intraoperatively, TCP showed less application time and more convenient use than two miniplates. Clinically, most of the cases reached normal Helikmo index score at 6 months. the two treatment groups had no statistically significant differences. At 1 month, pain was subsided in all patients. The computed tomographs of the 20 patients indicated a proper anatomical reduction. Along the 6 months, all cases showed stable fixation without significant change in ramus height or condylar angulation.

CONCLUSION: The use of TCP showed comparable results to two miniplates in fixation of subcondylar fractures.

KEYWORDS: Subcondylar fracture, Trapezoidal condylar plate, two miniplates.

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INTRODUCTION

Condylar fracture considered a common mandibular fracture, accounts for 25–40% (1). There is much controversy in condylar fractures regarding the choice to intervene surgically or not, the proper approach to be used and the ideal plating system for the situation (2,3).

Several classification attempts have been done to classify condylar fracture. *Loukota et al.*(4) Reported sub-classification for condylar fracture condylar neck fracture (High), condylar base fracture(base), intracapsular fracture. Another detailed classification according to the condyle place (dislocated, displaced, deviated, undisplaced) is commonly used. (5).

Ellis and Throckmorton (6) enumerated three management options either closed with intermaxillary fixation and functional therapy (CTR), only functional therapy and open reduction and internal fixation (ORIF). For several years, closed reduction has been preferred over open reduction to avoid surgical complications as facial nerve injuries and scarring. Nowadays, the preference started to change towards open reduction. As a result of the need of long term intermaxillary fixation (IMF) and resultant long-term complications of closed treatment (suboptimal occlusion, deviation during the mandibular movements, chronic pain, arthritis, late temporomandibular joint (TMJ) dysfunction and asymmetry (7).

Al-Moraissi and Ellis (8) confirmed in their meta-analysis that surgical management of condylar fractures provides better outcomes than closed reduction.

A study by *kuntamukkula et al* (9) at 2018 stated that surgical modality with accurate anatomical reduction of condyle maintains the harmony between the TMJ and other parts of the stomatognathic system.

Owing to the improved diagnostic and surgical methods and concepts recently, the surgical indications have included the previously believed inoperable conditions as high condylar and intracapsular fractures (10).

Ellis and colleagues (11) advised the need for open treatment in edentulous patients and in those missing posterior dentition which maintain vertical mandibular height. *Schneider* et al (12) proposed indications for open reduction as follow: The angulation between segments ranged from 15^0-45^0 or 2mm or greater segments overlap.
Several established approaches described to access condylar neck/head fractures: intraoral, submandibular, retromandibular, preauricular, and retroauricular. The choice of a particular approach depends on the location of the fracture (13).

Numerous plate designs have been evolved for internal fixation of the condyle and subcondylar fracture: single miniplate, double miniplates, 3D plates (trapezoidal, rhombic, and delta plates), lag screws, and resorbable plates. Although single miniplates can be adequate in properly aligned fragments, the stresses usually higher than the limits of one miniplate and require second plate fixation (14). However, the amount of bone in the condylar neck may be not adequate for placement of more than 2 screws (15). The geometric plates have been designed to provide a smaller hardware; compared to two miniplates, for the small sized condylar segment. In addition, the smaller the hardware is the lower infection rate and the less dissection needed resulting in less facial nerve injury risk (16,17).

The trapezoid plate has been compared to the five plates available for condylar fracture by finite element analysis and it has been found that it has a superior performance among the available three-dimensional miniplates. Superior on both rigidity of osteosynthesis and in low bone strain (18).

In another comparative study by *Darwich et al* (19) TCP was superior than two miniplates as the peak displacement was close to normal mandibular model. As they concluded, it is more logical that to put 2 plates with 8 screws would be more stable than one plate with 4 screws but that wasn`t what they found.

Meyer et al (20) Developed the Modus Trapezoidal Condylar Plates for subcondylar fracture osteosynthesis. They suggested that the TCP is considered the perfect design for condylar fracture as it follows the tension lines anteriorly and resist the bending strains posteriorly (21).
Several studies evaluate biomechanically TCP but only some studies evaluate the use of TCP in condylar fracture clinically.(17,22) Fewer studies compare the use of TCP clinically with other methods of fixation (23).

We aimed in this study is to compare the use of TCP versus the standard two miniplates clinically and radiographically in subcondylar fracture treatment.

The null hypothesis assessed in this study is that there is no clinical or radiographical difference between using the two modalities in the management of subcondylar fractures.

MATERIALS AND METHODS

A randomized clinical trial included twenty patients selected from those admitted to Oral and Maxillofacial Department, Faculty of Dentistry, Alexandria University. The ethical approval was acquired from the Research Ethics committee, Faculty of Dentistry, Alexandria University. The patients were informed about the benefits and risks of the procedure that will be performed and an informed consent was signed by each participant.
The inclusion criteria were as follow: fit patients aged from (20-40) years old, has subcondylar fracture with difficulty of obtaining adequate occlusion, condylar angulation $\geq 10°$, shortening of the ascending ramus height ≥ 2 mm and dislocation of the condyle from the glenoid fossa (12). The exclusion criteria were patients $<$ 20 years of age, having associated mental or physical problems contraindicate surgery or with undisplaced condylar fracture that doesn`t affect occlusion. Patients complying with the inclusion criteria will be randomly assigned by computer generated randomization(24) into one of the two groups:
Study group (I): trapezoidal condylar plate (TCP).
Control group (II) : Two miniplates.

The patients underwent open reduction and internal fixation through preauricular incision with retromandibular extension. Group I was treated by 4-holes TCP (trapezoidal condylar plate, Traumec, Brazil) and Group II was treated by two 4-holes miniplates (KLS Martin, Tuttlingen, Germany).
Preoperative preparation

Each patient had received Amoxicillin/Clavulanate potassium (Augmentin, GlaxoSmithKline, Brentford, London) 1 gm IV twice daily, Diclofenac potassium (Cataflam, Novartis, Basel, Switzerland) 75 mg IV. Patients were instructed to perform oral hygiene measures.
Surgical procedure:

After scrubbing with betadine and draping, injection of epinephrine 1:100000 along the incision line. The incision started from the preauricular area within the preauricular crease then an inverted L-shaped following the earlobe crease. Then incision descended inferiorly 2 cm onto the neck, but not over the mandibular angle. The flap was raised over superficial muscular aponeurotic system (SMAS) till reach the anterior edge of the parotid gland. The parotid-masseteric fascia was then incised to allow access to the masseter. Facial nerve branches were encountered on the surface of the masseter muscle in some cases and avoided. The masseter was then dissected bluntly with the same direction of the nerve fibers till gaining access to the fracture. The fracture was then reduced, and placement of the plates was done, either two miniplates or TCP according to groups allocation. Closure of the extraoral wound was done in layers using 4-0 vicryl for subcutaneous tissues and 6-0 prolene for the skin. (Fig. 1)

Intraoperatively, fixation apparatus evaluation was done by measuring the time needed from the start of adaptation till the end of fracture fixation of each plate type and compare between them.
Postoperative phase

The patients continued the preoperative antibiotics for three days postoperatively, then Amoxicillin/Clavulanate potassium (Augmentin, GlaxoSmithKline, Brentford, London) 1 gm tablets twice daily for 5 days and Diclofenac potassium (Cataflam, Novartis) 50 mg tablets three times daily. Chlorohexidine mouth wash was instructed for all patients for maintenance

of good oral hygiene. Patients were instructed for application of cold fomentations on the extra oral surgical site for 10 min/1hour in the first postoperative day, followed by warm fomentations starting from the second postoperative day for 3 days. Patients were placed on a soft diet for 4-6 weeks. Sutures were removed after 7-10 days.

Postoperative assessment:

Clinical parameters:

The intervals of postoperative clinical follow ups were 1 week, 1 month then 6 months, to assess the following:

Helkimo index scores:

A simple practical systematic tool used to assess quality of life in the form of the mandibular dysfunction present.(25) It assesses the severity of five clinical signs: range of mandibular movement impairment, TMJ function impairment, masticatory muscles pain, TMJ pain and pain on movement of the mandible. The sums of the five signs` scores were recorded and graded the functional impairment into (no impairment (D0) , mild impairment (D1) , moderate impairment (D2) , sever impairment (D3)). (26)

Stability of occlusion:

Assessment of occlusion by the examiner and by the patient. Occlusion was checked in the maximal intercuspal position to ensure proper occlusal relationship including molar relation and midline centralization. Any occlusal disturbance including open bite or premature tooth contact was noted.

Pain in the TMJ:

It was subjectively evaluated with a visual analogue scale (VAS) with values from 0 (no pain) to 10 (strongest pain). The values interpreted as follows: score 0 (no pain), score 1-3 (mild pain), score 4-5 (moderate pain), score 6-7 (sever pain), 8-9 (very sever) and score 10 (worst pain).

Radiographical assessment :

The assessment was done by Computed tomograms preoperatively, immediate postoperative and 6 months follow up. The ramus height shortening of the fractured side = the ramus height of the non-fractured side - the ramus height of the fractured side. The ramus height was measured from the roof of glenoid fossa to the lower border of the mandible. (fig. 2) The aim is to check adequate reduction and stability of the fragments throughout the follow up periods as follows:

The adequacy of reduction assessment:

It was assessed by comparing the preoperative shortening with the immediate postoperative shortening.

The stability of fixation of the two study plates assessment:

It was assessed by comparing the immediate postoperative ramus height measurements with the 6 months follow up ramus height measurements.

Data statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. For categorical variables, comparison between different groups was done by Chi-square test. For Correction for chi-square when more than 20% of the cells have expected count less than 5, Fisher's Exact or Monte Carlo correction was used. For abnormally distributed quantitative variables, comparison between two studied groups was done by Mann Whitney test. For abnormally distributed quantitative variables, to compare between more than two periods or stages Friedman test was used. Significance of the obtained results was judged at the 5% level.

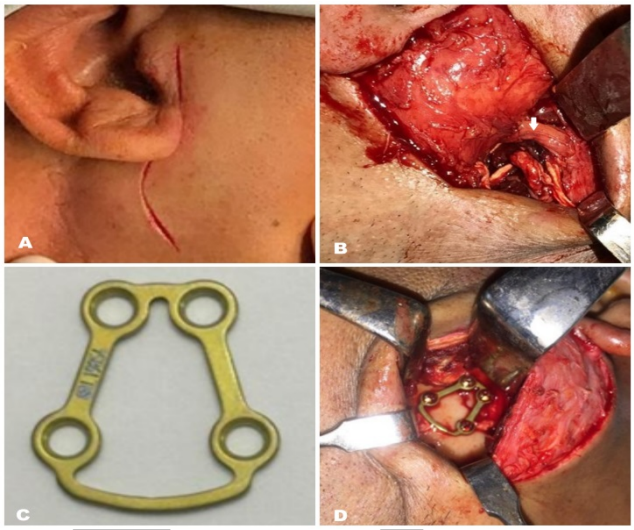

Figure 1: Showing (A) preauricular incision with retromandibular extension. (B) anteroparotid dissection, buccal branch of facial nerve (arrow) . (C) Trapezoidal Condylar miniplate (TCP). (D) fixation of subcondylar fracture using TCP.

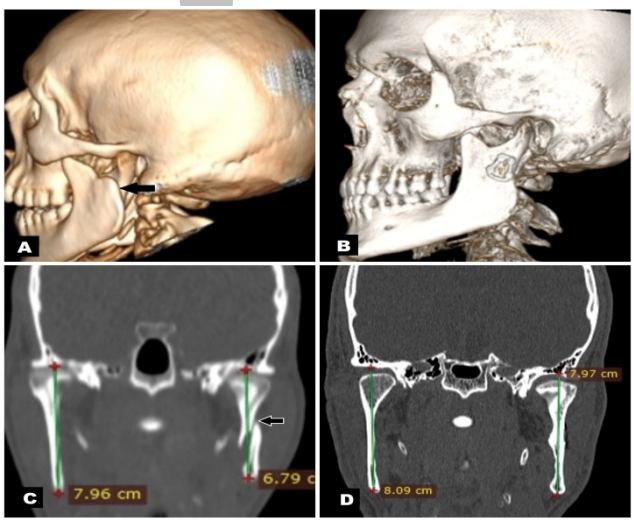

Figure 2: Showing (A) 3D CT for preoperative left subcondylar fracture. (B) 3D CT for 6 months postoperative subcondylar fracture healing and fixation by TCP. (C) coronal preoperative CT for measuring ramus height shortening of the left side in comparison to the right side. (D) coronal postoperative CT for comparing ramus height between the two sides after 6 months.

RESULTS

Our study included twenty patients; all of them were males and had unilateral subcondylar fracture. Their ages were between 23 to 40 years of age, with the mean age of 30.45 ± 5.92 years. The most common cause was road traffic

accidents (RTA) (65%) followed by falls (25%) then personal assault (10%).

low condylar fracture was presented in 13 (65%) of the cases and high condylar fractures in 7 cases (35%). Condylar dislocation was observed in 3 cases(15%).

A satisfactory fractures reduction, healing and occlusion were reached in all the patients till the end of the follow up period. None of the patients had nonunion, plate fracture, or fracture instability.

Intraoperative assessment:

The study group (I) showed statistically significant shorter application time than control group (II), with mean time of 3.80 ± 1.62 min and 16.50 ± 4.97 min, respectively. For 80% of TCP patients, the time required was under 5 mins. In comparison, 70% patients in the other group required more than 15 mins. The results were statistically significant with the P value of $p < 0.001$.

Postoperative Clinical assessment:

at 1st week , most of cases had poor Helikmo index score (D3) in both groups (group I 70% and group II 90%). The two treatment groups had no statistically significant differences regarding Helikmo index.

At 1 month follow up, the Helikmo index score improved to become D2 in 40% of cases in group I. In group II, the Helikmo index score improved in some cases but still most of the cases has D3 index (60%). The two treatment groups had no statistically significant differences.

At 3 months, most of the cases in both groups had D1 index (70% in group I and 90 % in group II). the two treatment groups had no statistically significant differences.

At 6 months, 80% of the cases in group I reached normal mandibular function without any dysfunction, only 2 patients still have mild impairment. In group II, 70 % still had mild impairment, only 30% of cases had normal functional movement. The two treatment groups had no statistically significant differences (Table.1) (Figure 3).

During the first postoperative week , 40% patients in the TCP group had mild occlusion discrepancies. In the miniplate plate group only 20% patient had an altered occlusion. The two treatment groups had no statistically significant differences in terms of post-operative occlusion. Those patients required intermaxillary elastics training for 10 days. By 1 month post-operatively, satisfactory occlusion was achieved for most of the patients, however, 1 patient in the miniplate group demonstrated unimproved occlusion which required selective grinding.

Postoperatively, 50 % of group I and 70% of group II patients reported moderate pain intensity. At 2 weeks, the pain subsides from moderate to mild in 60% of group I and 80% of group II patients. At 1 month, all the cases of both groups felt no pain. There was no statistically significant difference between the two groups.

Postoperative Radiographical assessment:

The postoperative computed tomographs of the 20 patients showed a proper anatomical reduction. Within group I, the average preoperative shortening of the ramus height was 9.60 ± 1.77 mm. The average immediate postoperative shortening was 0.77 ± 0.64 mm. There was a statistically significant difference between preoperative and immediate postoperative results. The average 6 months postoperative shortening of the ramus height was 0.92 ± 0.64 mm. This was not statistically significant in comparison to immediate postoperative results.

Within group II, the average preoperative shortening of the ramus height was 9.37 ± 1.74 mm. The average immediate postoperative shortening was 0.76 ± 0.41 mm. there was a statistically significant difference between preoperative and immediate postoperative results. The average 6 months postoperative shortening of the ramus height was 0.76 ± 0.41 mm. This was not statistically significant in comparison to immediate postoperative results. (Table 2) (Figure 4)

None of the plates in both treatment groups showed any osteosynthesis device fracture at any of the follow-up visits. One patient from group I presented with screw loosening at 6 months follow up CT.

Condylar resorption was found in one case in the ipsilateral condyle. This case was dislocated medially.

Figure (3): Comparison between the two studied groups according to Helikmo index.

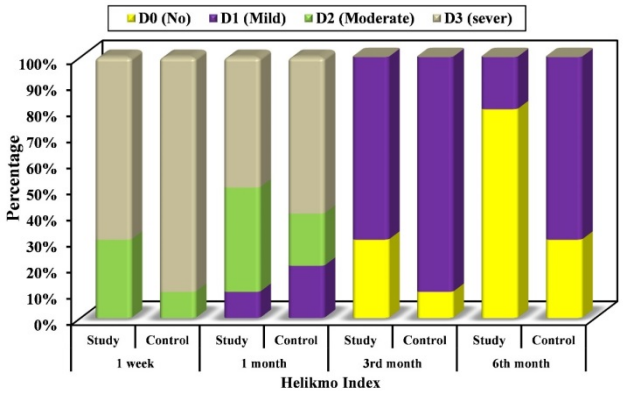

Figure (4): Comparison between the three studied periods according to ramus shortening in each group.

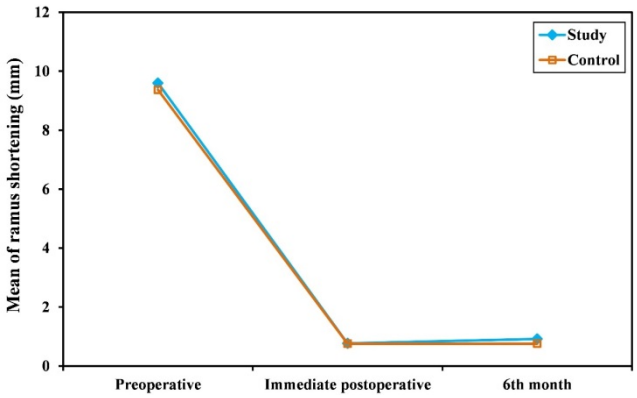

Table (1): Comparison between the two studied groups according to Helikmo index

Helikmo Index	Study (n = 10)		Control (n = 10)		p
	No.	%	No.	%	
1 week					
D0 (No)	0	0.0	0	0.0	
D1 (Mild)	0	0.0	0	0.0	FEp=
D2 (Moderate)	3	30.0	1	10.0	0.582
D3 (sever)	7	70.0	9	90.0	
1 month					
D0 (No)	0	0.0	0	0.0	
D1 (Mild)	1	10.0	2	20.0	MCp=
D2 (Moderate)	4	40.0	2	20.0	0.706
D3 (sever)	5	50.0	6	60.0	
3rd month					
D0 (No)	3	30.0	1	10.0	
D1 (Mild)	7	70.0	9	90.0	FEp=
D2 (Moderate)	0	0.0	0	0.0	0.582
D3 (sever)	0	0.0	0	0.0	
6th month					
D0 (No)	8	80.0	3	30.0	
D1 (Mild)	2	20.0	7	70.0	FEp=
D2 (Moderate)	0	0.0	0	0.0	0.070
D3 (sever)	0	0.0	0	0.0	

FE**: Fisher Exact** MC: **Monte Carlo** p: p value for comparing between the studied groups

Table (2): Comparison between the three studied periods according to ramus shortening in each group.

Ramus Shortening (mm)	Preoperative	Immediate postoperative	6th month	
Study (n = 10)				
Min. – Max.	6.70 – 12.0	0.10 – 2.30	0.20 – 2.30	p_1=0.001*
Mean ± SD.	9.60 ± 1.77	0.77 ± 0.64	0.92 ± 0.64	p_2=0.823
Median	9.75	0.65	0.75	
Control (n = 10)				
Min. – Max.	6.30 – 12.40	0.20 – 1.50	0.20 – 1.50	p_1=0.001*
Mean ± SD.	9.37 ± 1.74	0.76 ± 0.41	0.76 ± 0.41	p_2=1.000
Median	8.80	0.70	0.70	
P	0.912	0.739	0.684	

p: p value for comparing between the two groups.

p_1: p value for comparing between **Preoperative** and **Immediate postoperative**

p_2: p value for comparing between **immediate postoperative** and **6th month.**

*: Statistically significant at $p \leq 0.05$

DISCUSSION

The gold standard for fixation of subcondylar fracture is the two miniplates. However, there are some shortcomings for the use of two miniplates such as higher cost, longer operation time, demands greater tissue detachment and needs sufficient area for fixation (27).

The shortcomings of two miniplates led to the 3-dimensional (3D) miniplates development by *Farmand* (28). The quadrilateral geometry of these plates ensures stabilizing the fracture in the three dimensions and resists torque forces, in spite of its low profile and malleability (29).

In recent literature, metal depositions have been reported beside and around the titanium miniplate or in peripheral organs following osteosynthesis. It becomes mandatory to minimize the size and number of osteosynthesis implant . TCP provides lower profile design with less material and size comparing to miniplates, that helped in creating wider space between the holes which allow better revascularization and requires less tissue dissection and retraction (30).

Regarding the fixation apparatus, we have found that it was easy to adapt the TCP along the lines of osteosynthesis in subcondylar region which is similar to what *Meyer et al.* stated in his study (21).

In our study, the mean application time for TCP was 3.80 ± 1.62 min while for the two miniplates was 16.50 ± 4.97 min and that was statistically significant. Two miniplates needs precise adaptation to the condylar ridge anatomy which explains the longer time required for two miniplate. Also, it takes time to find suitable area for accommodation of the two plates. TCP reduced thickness offers better plate adaptation and reduced hardware. Also, the small sized TCP doesn`t need large area at the proximal segment to be applied. Other studies also found that fewer hardware would require fewer time to be fixed (31,32).

The Helkimo index scoring system considered one of the best TMJ functional impairment assessment methods. Therefore, we chose Helkimo index scoring system to be used in our study. Other previous studies as well evaluated the functional outcome after condylar fracture management using the Helkimo index (33,34).

Although Helikmo scores showed no significant difference between the two groups, it gave us an overview of functional regaining process after open surgery to the condylar fractures. It was noticed that most of the impairments of the first period was in form of decrease in range of mandibular mobility, pain in two or more mandibular movements and TMJ arthralgia in coincidence to *Umstadt et al* (35).These parameters improved after the 1st month, in which only slight limitation of the range of mandibular movements still found. the rest of parameters became free at 3 months postoperatively.

The results of the present study had shown that 40% of TCP and 20% of two miniplate patients had mild occlusal derangement postoperatively. There were no

significant differences between the two groups. This finding may be due to effect of trauma on TMJ, postoperative pain and/or muscular spasm. However, at the first postoperative month, both groups had satisfactory occlusion after elastics application. One patient needed further selective grinding to reach the normal occlusion, That was consistent with other studies (32,36).

In our study, pain was normally found in the first week postoperatively. Then the intensity of pain started to resolve gradually till it subsided at most of cases after the 2nd postoperative week. We attribute early pain resolution to the low edema found postoperatively.

In the immediate postoperative CT, the bony fragments were anatomically reduced with good accuracy at all patients of both groups. by 6 months postoperatively, all fractures had satisfactory anatomic position healing without any displacement in both groups. That indicates that stability of the TCP was equal to two miniplates. That was consistent with previous studies using TCP (15,21). *El-Mahdy et al*. stated also that the TCP was a good substitute for two miniplates osteosynthesis.(32) Although it has 1 mm thickness, it gains its strength from the mechanical and geometric design of the 3D plates resulting in stabilization of fractured segments in three dimensions.

The restoration of the ramus height in the CT coronal cut was observed in all patients in immediate postoperative CT. The stability of ramus height regain was observed in 9 of 10 patients in group I and in all patients of group II after 6 months. This is similar to what stated by *lauer. et al.* (36).

In all 20 patients there was no breakage or deformation of the plates observed. similar to reports of *Meyer et al*. (21) One case of screw loosening occurred at the TCP group without affecting the fracture healing. This finding was similar to what reported in *lauer et al*.(36) In another study, screw loosening occur but within the healing period and the fracture healed improperly (37).

The limitation of the study was that it lacks bilateral fracture cases to assess the two study plates in cross section manner. larger sample of patients is required to generalized results.

CONCLUSION

TCP was able to bear masticatory forces and resist hardware failure along the follow up period as equal to two miniplates fixation. Use of TCP is more cost-effective than two-dimensional titanium miniplates as lesser number of plates and screws are needed for fixation and the lesser operation time required.

Conflict of Interest:

The authors declare that they have no conflict of interest.

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