

Assessment Of Subcondylar Fracture Treated Using Two Four-Hole Straight Miniplates Versus The Synthes® Matrixmandible Trapezoidal Plate: Randomized Controlled Trial

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ABSTRACT: *Background and objective: The purpose of this research was to evaluate subcondylar fracture treated with two four-hole straight miniplates versus the MatrixMANDIBLE Trapezoidal plate. Patients and Methods: A total of 18 patients having subcondylar fractures indicated for open reduction and plate fixation were chosen from the outpatient clinic of the Department of Oral and Maxillofacial Surgery, Faculty of Oral and Dental Medicine, Cairo University, and randomly divided into two equal groups. Intervention group was treated using MatrixMANDIBLE Trapezoidal plates, and the control group was treated using two four-hole miniplates (2.0): one is parallel to the mandible's posterior border and the other is parallel to the sigmoid notch. The clinical and radiological outcomes of the treatment such as accuracy of reduction and stability of fixation, pain, occlusion, mandibular movements, facial nerve affection and time of operation were assessed and statistically analyzed. Results: There were no statistically significant differences among the two groups in all comparisons except time of operation, as MatrixMANDIBLE Trapezoidal plates were time saving. Conclusion: MatrixMANDIBLE Trapezoidal plate has clinical and radiographic outcomes comparable to two four-hole miniplates, offering less hardware and less operative time.*

KEYWORDS: *Subcondylar fracture, fixation, MatrixMANDIBLE, trapezoidal plate.*

INTRODUCTION

Condyle fractures in diagnosis, classification, and treatment are one of the most controversial maxillofacial injuries [1,2].

One-third of all mandibular fractures involve the condylar region [3-5].

The anatomical level of the fracture is among the most common classifications: condylar head, neck, and base [6,7]; large fractures with little bone accessible for fixation are typically non-surgically handled, while low displaced fractures are mostly surgically handled by reduction and stable internal fixation [1].

The primary focus changed somewhat from the open versus closed treatment discussion to more particular surgical issues [8].

Concepts for rigid internal fracture fixation have changed significantly over the last decade in the condylar area (base, middle, high neck and head) [9], however the question of how best to stabilize the reduced fracture is still open [10].

Therefore as originally suggested, adaptation of a single four-hole miniplate did not offer dynamic osteosynthesis and resulted in fracture of the plate during function [11]. The fulfilment of dynamic osteosynthesis was accomplished by two plates fixation (one miniplate parallel to condylar axis and the second miniplate parallel to mandibular notch); where single plate parallel to condylar axis is utilized to minimize fracture and second plate parallel to mandibular notch offers dynamic osteosynthesis [12].

However it is difficult to adapt two miniplates in the condylar axis region and demonstrating longer operating time due to constriction of condylar neck [13].

Four screws can also be difficult to insert in the smaller condylar segment and can be particularly challenging for the condylar fracture in minimally invasive approaches [14].

Previous studies demonstrating the use of two miniplates in subcondylar fractures reported percentages of facial nerve affections [15-17].

Another plating system was proposed; SYNTHES® Matrix MANDIBLE trapezoidal plates (Synthes 1301 Goshen Parkway, West Chester, Pa19380) that meets the criteria of two single straight miniplates with reduced hardware thus provides lower rate of infection, loosening of screws and requires reduced exposure & less operating time, thus preventing facial nerve damage as compared to two four hole straight miniplates [13].

The aim of this study is to assess subcondylar fracture treated using the two four-hole straight miniplates versus the Matrix MANDIBLE Trapezoidal plate.

PATIENTS AND METHODS

Eighteen patients (10 male & 8 female) with unilateral subcondylar fracture alone or along with other concomitant fractures, which required open reduction and rigid fixation of the subcondylar fracture and any other concomitant fractures were chosen from the outpatient clinic of the Department of Oral and Maxillofacial Surgery, Faculty of Oral and Dental Medicine, Cairo University.

Inclusion and Exclusion Criteria

Inclusion criteria were:

- 1) Age of a patient over 18 years of age.
- 2) Patient's consent to participate.
- 3) Subcondylar fracture with obvious displacement of the condylar and/or shortening of the height of the mandible's ascending ramus.
- 4) Sufficient dentition to reproduce the occlusal relationships.

Exclusion criteria were:

- 1) Low fractures of subcondylars without apparent displacement.
- 2) 2) Non-successful prior surgery.
- 3) Previous history of temporomandibular joint dysfunction.

Grouping of the patients

Patients were divided into 2 groups; 9 patients each: Control Group: underwent open reduction & internal fixation under general anesthesia using double 4-hole straight miniplates. Intervention Group: underwent open reduction & internal fixation under general anesthesia using 4-hole synthes trapezoidal plate.

Preoperative Assessment

- Detailed Medical History.

Clinical Examination: done to check for:

- 1) Occlusal derangement.
- 2) Maximal Inter-incisal opening (MIO).
- 3) Deviation of the mandible on opening.
- 4) Concomitant mandibular fractures.

Radiographic Assessment:

Patients of both groups were subjected to standard orthopantomograms to measure the loss of height of the ramus as follows:

- 1) Through both gonial angles, a reference line was drawn.
- 2) The perpendicular distance among the condyle's topmost point and the reference line was measured.
- 3) The difference was used as a measure of the difference in ramus length among the non-fractured and the fractured sides (loss of ramus height) [18] (Fig.1).



Fig. 1: Measuring the loss of ramus height on preoperative OPG of one of the study cases with right subcondylar fracture

Surgical Procedures

In all procedures operating time was calculated. Intermaxillary fixation was performed using Erich arch bars or IMF screws and 0.5 stainless steel wires.

A Blair (Modified Risdon or retromandibular) incision was used. A skin incision about 3 - 4 cm long, was marked 2 cm below and posterior to the inferior border of the mandible. Dissection through the subcutaneous tissue was conducted following skin incision in all directions, enabling exposure of the posterior fibers of the platysma muscle. Until the pterygomasseteric sling and the periosteum were encountered, the dissection was carried out towards the posterior border of the ramus. An incision was made through the pterygomasseteric sling using diathermy. A subperiosteal dissection using a periosteal elevator was performed allowing the approach and exposure to the angle of the mandible and the lateral part of the ramus extending to the sigmoid notch where a sigmoid retractor was applied. In the control group, two 2.0 mm straight four-hole titanium miniplates were used to fix the fracture where one miniplate was positioned parallel to condylar axis and a second miniplate parallel to sigmoid notch. In the intervention group, the fracture was fixed using a 1.0 mm Matrix Mandible trapezoidal four-hole subcondylar plate. Two screws were placed in the ramus and two screws in the fractured condylar segment (Fig.2).

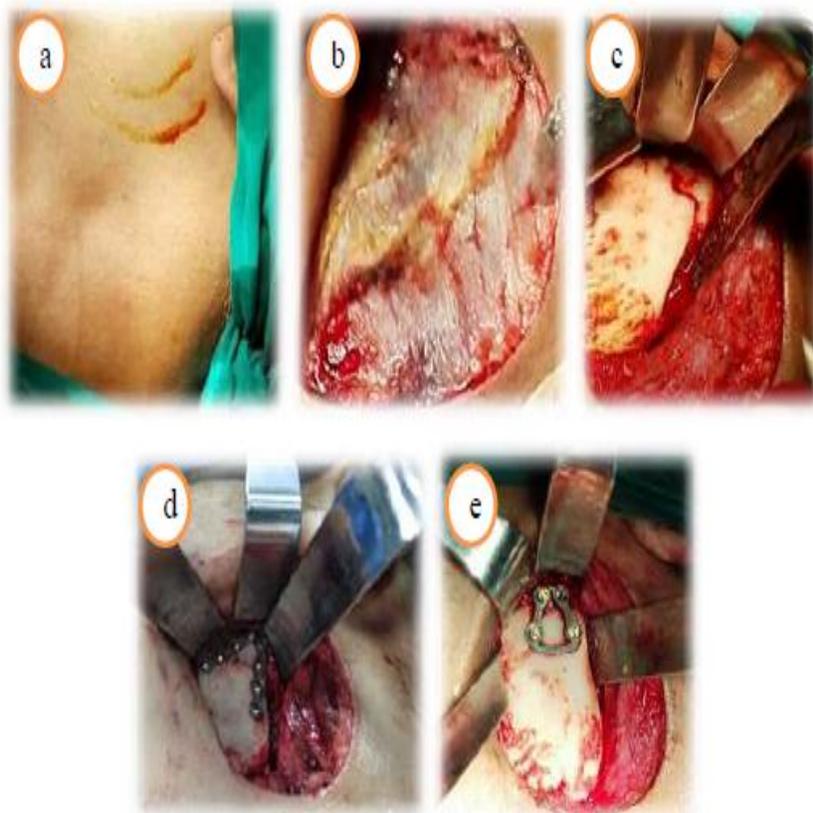


Fig. 2: (a) Incision marking, (b) Subcutaneous Dissection, (c) Exposure of the fracture line, (d) Two straight 4-hole miniplates fixation, (e) MatrixMandible trapezoidal subcondylar plate fixation

Postoperative Care

Tight elastics were applied on the already placed arch bar or IMF screws for 3-4 days and then followed by guiding elastics for minor correction of the occlusion.

Analgesics, anti-inflammatory drugs, antibiotics, and antiseptic mouthwash were used for 5 days postoperatively. Skin sutures were removed 1 week postoperatively.

Patients have been advised to stay for 4-6 weeks on a soft diet to avoid any undue forces to the reduction site. Mouth opening exercises performed for 6 to 8 weeks.

Postoperative clinical assessment

Patients were clinically evaluated at weeks 1 (T4), 2 (T5), 4 (T6), 8 (T7), 12 (T8) and 24 (T9) postoperatively to check for:

- 1) Facial nerve Affections were assessed clinically using the House-Brackman grading system (Table 1).
- 2) Occlusion was carefully inspected to check for any gross occlusal derangements.
- 3) Maximal interincisal opening (MIO) using a ruler.
- 4) Deviation of the mandible to the right or left.
- 5) Pain using a visual analogue scale (0-100).

Postoperative radiographic assessment

- 6) At the 2nd day after surgery (T3) and at 6 months (T9), a Computed tomography was taken to check for the accuracy of reduction and stability of fixation (Fig.3).

Table 1: House-Brackman Grading System(House JW, Brackmann DE: Facial nerve grading system. Otolaryngol Head Neck Surg 1985, 93:146–147.)

Grade	Description	Characteristics
I	Normal	Normal facial function in all branches of the nerve.
II	Slight	Gross: Slight weakness at close examination, slight synkinesis. At rest: Normal tone & symmetry. Motion: Mouth: Slight asymmetry.
III	Moderate	Gross: Obvious facial asymmetry, but not disfiguring. Synkinesis is obvious, but not severe. Hemi-facial spasm or contracture may occur. At rest: Normal tone & symmetry. Motion: Mouth: Slight weakness with maximum effort.
IV	Moderately Severe	Gross: Asymmetry disfigures and/or manifests facial weakness. At rest: Normal tone & symmetry. Motion: Mouth: Asymmetrical with maximum effort.
V	Severe	Gross: Only slight, barely noticeable, movement. At rest: Asymmetrical facial appearance. Motion: Mouth: Slight movement.
VI	Total	No facial function.

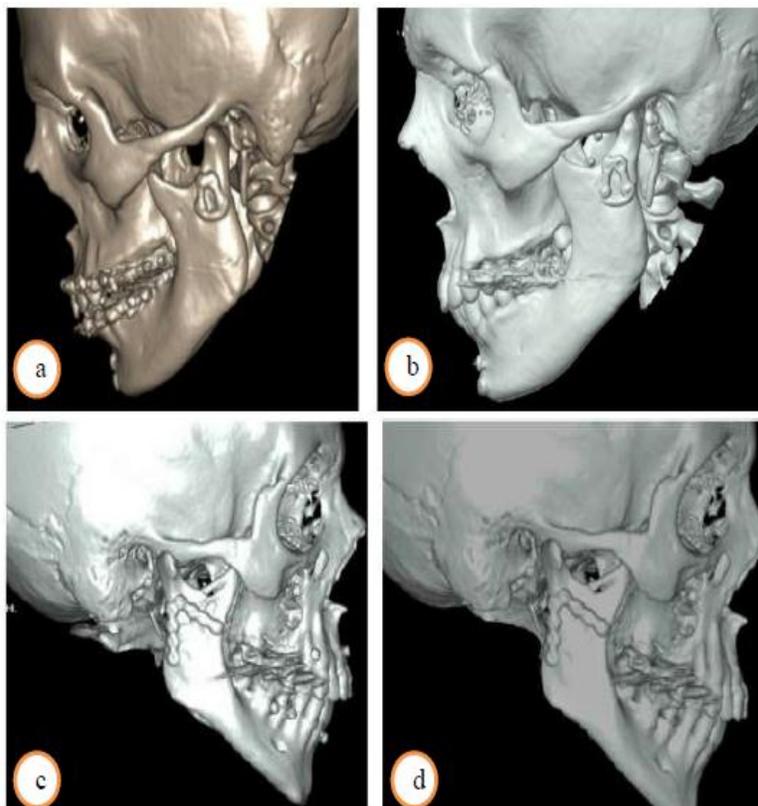


Fig. 3: (a) 3D CT of one of the intervention cases 2 days postoperative, (b) 3D CT of the same intervention case 6 months postoperative, (c) 3D CT of one of the control cases 2 days postoperative, (d) 3D CT of the same control case 6 months postoperative

RESULTS

The study included 18 patients, 10 males (4 interventions & 6 controls) and 8 females (5 interventions & 3 controls). For the 18 included patients ages ranged from 18 - 40 years with a mean of 29 years. The most prevalent etiology in our study was road traffic collisions (77.8%). Time elapsed since injury recorded means of 13.89 hours and 15.89 hours in intervention and control groups respectively.

Preoperative clinical records

Occlusion was deranged preoperatively in all patients. Maximum interincisal opening (MIO) recorded means of 13 mm & 15.11 mm for intervention and control groups respectively. Of the 18 patients included in the study, there was lateral deviation on opening to the fracture side in 15 patients, while only 3 patients showed no lateral deviation on opening. Concomitant mandibular fractures were found in 15 patients, while only three patients had isolated subcondylar fractures. Pain scores recorded means of 60 & 61.11 in intervention and control groups respectively (Table 2).

Table 2: Frequency (N) and percentage (%) for occlusion derangement, lateral deviation on opening and concomitant mandibular fractures as well as mean (SD) MIO and pain (VAS) for intervention and control groups preoperatively

			Intervention		Control		p-value
Preop. Clinical Records	Occlusal Derangement [N (%)]	No	0	0.0%	0	0.0%	1.00
		Yes	9	100.0%	9	100.0%	NS
	MIO (Mean ± SD)		13.0	4.1	15.1	4.2	0.303 NS
	Lateral Deviation [N (%)]	No	2	22.2%	1	11.1%	0.796 NS
		Yes (to Left)	4	44.4%	5	55.6%	
		Yes (to right)	3	33.3%	3	33.3%	
	Concomitant Injuries [N (%)]	No	1	11.1%	2	22.2%	0.730 NS
Yes		8	88.9%	7	77.8%		
Pain (VAS) (Mean ± SD)		60.0	12.2	61.1	11.6	0.847 NS	

Postoperative clinical records

Operation Time:

The trapezoidal miniplate group demonstrated significantly shorter mean operation time (2:21 hours) than the two straight miniplates group (2:37 hours) (Fig.4a).

Reduction of Displacement:

The anatomic reduction of the subcondylar area was perfect in all cases in the immediate postoperative (T3) period as well as 6 months postoperatively (T9).

Facial Nerve Functionality (House-Brackman Grading):

The intervention group demonstrated non-significantly lower facial nerve affections than the control group during the first three months postoperatively with no more than grade II affection in both groups. After three months of surgery all cases of both groups demonstrated complete facial nerve functionality (100%) (Fig.4b).

Occlusion:

None of the 18 patients had malocclusion postoperatively, however 5 patients had mild occlusal disharmonies immediately postoperative that were easily managed with selective grinding.

Lateral Deviation on Opening:

None of the 18 patients demonstrated postoperative lateral deviation on opening.

Pain:

Pain was normally experienced after surgeries then it decreased significantly after one week recording a mean of 33.33 in both groups then starting to subside gradually till it disappears completely by the postoperative 8th week (Fig 4c).

Maximum interincisal opening (MIO):

At two months postoperatively, the mean MIO in all our patients was nearly maximum (44.94 mm) (Fig.4d).

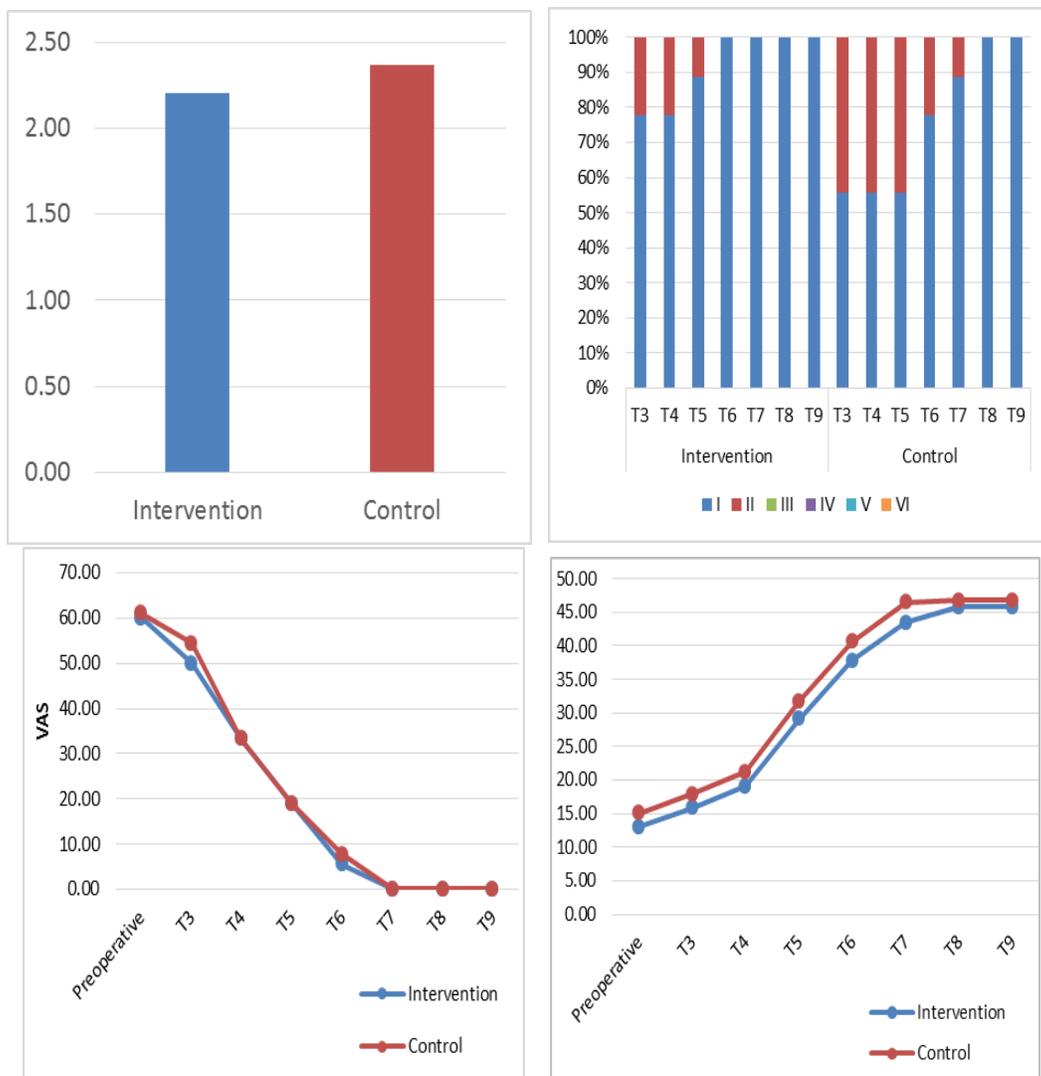


Fig. 4: (a) Bar chart showing mean operation time in intervention and control groups, (b) Stacked bar chart showing facial nerve functionality in intervention and control groups, (c) Line chart showing reduction in pain (VAS) for intervention and control groups, (d) Line chart showing increase in mean MIO (mm) for intervention and control groups

DISCUSSION

Condylar injuries are often a topic of debate and dispute between maxillofacial subjects [19]. 11-16 % of all facial fractures [20] and 30-40 % of mandibular fractures represent such trauma. [21,22]. Conventionally managed through closed therapy approaches, this type of fracture has not escaped the attention of clinicians seeking to obtain better and more consistent results by ORIF techniques [23].

For subcondylar fractures, the optimal surgical method for ORIF should have sufficient access, be less invasive, perform quickly, provide minimum morbidity and be correlated with minimal possible complications. It is possible to broadly divide surgical approaches into intraoral and extraoral. Technically, the intraoral approach is more demanding, requiring endoscopes,

particular training and longer operating periods. There are essentially three extraoral approaches, namely the preauricular, retromandibular, and submandibular.

Hinds and Girotti first identified the retromandibular incision in 1967 for good mandibular condyle exposure [24]. This incision permitted direct accessibility to the mandibular ramus and condylar process relative to the submandibular approach. The conventional retromandibular method crosses the parotid gland and involves careful dissection of branches of the facial nerve, which in 30-50 % of instances may contribute to temporary facial nerve paralysis due to intraoperative visualization of branches of the facial nerve [25, 26].

Our approach to the subcondyle and ramus area from a retroparotid path minimizes nerve injuries and gives sufficient access by pulling back the parotid gland in a higher and anterior direction and dissecting bluntly through the masseter muscle. Retroparotid is the approach and not trans-parotid or anteroparotid. To show the facial nerve branches, the parotid parenchyma is not dissected. Together with the parotid gland, the facial nerve branches are fully securely retracted superiorly and not by having a window for access among any two branches of the facial nerve. Unlike APTM or trans-parotid methods, this is where entry to the fracture site is through a window among the branches of the nerve. Without worrying of the facial nerve branches, the parotid gland could be retracted very easily since the dissection is carried out by making a cleavage between the parotid capsule and the underlying masseter muscle. In addition, the blunt dissection through the underlying masseter muscle allows broader and faster access to the fracture site after easily retracting the parotid gland.

“Functionally stable osteosynthesis” is the concept underlying open reduction and internal fixation utilizing miniplate osteosynthesis [27, 28]. In the mandibular body region, Champy defined the ideal osteosynthesis line, but owing to insufficient information, no such line was suggested in the condyle region.

To define the ideal line of osteosynthesis in the condyle region, Meyer et al. [29] tried to fill this void. In the condylar region, strain lines were found during biting forces in the area of molars. Therefore as initially suggested, adaptation of a single 4-hole miniplate did not offer dynamic osteosynthesis and resulted in plate fracture during function. The two-plate fixation (a miniplate parallel to the condylar axis and a second miniplate parallel to the mandibular notch) met dynamic osteosynthesis fulfilment, although it is difficult to adapt 2 miniplate in the condylar axis area owing to condylar neck constriction. Therefore, TCP utilization (Modus TCP 2.0 Medartis, Basel, Switzerland) has been studied by Meyer *et al.* in 2007 [30] and 2008 [14] in the open reduction and internal fixing of the fractures of the condylar. They proposed that in the anatomically constricted condylar neck area, TCP is formed for adaptation. TCP is positioned parallel to the condylar axis with one arm and parallel to the mandibular notch with another arm. This plate thus met the specifications of 2 single miniplates, however with decreased hardware. Because of its design, this plate offers three-dimensional stability. Due to decreased hardware, the infection rate is lower and allows reduced exposure as opposed to two 4-hole straight miniplates.

Our study compared the osteosynthesis in mandibular subcondylar fracture using the standard two 4-hole 2.0 mm straight miniplates versus a single Synthes MatrixMANDIBLE 1.0 mm trapezoidal-shaped miniplate. Since this plate was developed with 1.0 mm thickness, it was therefore hypothesized that it could offer better plate adaptation and reduced hardware.

In our study, a total of eighteen patients with subcondylar fractures were included which showed a high male predominance (55.55%) as compared to females (44.44%). The main etiology of the fractures was road traffic accidents in 14 patients (77.77%), and other causes in 4 patients

(22.22%). The average age was 26.7 years at the time of the injury in the intervention group and 29.1 years in the control group. The parameters listed above, such as age, gender, and etiology of fracture showed no significant differences between the two treatment groups. These results were similar to other studies [31-33].

The results of the present study showed significantly shorter operation time when using the Synthes trapezoidal-shaped miniplates as compared to using the two 4-hole miniplates which could be explained by the fact that fewer hardware would require fewer time to be fixed. This was in accordance with other studies that compared single and two miniplates in fixation of subcondylar fractures [34,35].

In our study, the anatomic reduction of the subcondylar area was perfect in all cases of both groups in the immediate postoperative period as well as 6 months postoperatively, This was similar to previous studies using TCP [14,33,36,37] thus indicating that the trapezoidal-shaped Synthes miniplates in the mandibular subcondylar region may be a good substitute for osteosynthesis.

In our sample, hardware failure was 0 percent. In comparison to other research [34, 38-40], plate fracturing or bending was observed exclusively in stabilized cases with a single miniplate. The explanation for hardware failure might be that if positioned conventionally along the condylar neck, this plate is situated on the compression strain lines and completely contradicts the concepts of functionally stable osteosynthesis. However, two straight miniplates (a miniplate parallel to condylar axis and second miniplate parallel to mandibular notch) as well as trapezoidal plate (placed with one arm parallel to the condylar axis and second arm parallel to the mandibular notch), stable osteosynthesis is provided and the rate of hardware failure is reduced.

The most dreaded possibility of surgical intervention for condylar fractures in general is injury to the facial nerve. In our research, the probability of facial nerve injury was assessed as per the House-Brackmann Facial Nerve Grading System [41]. To assess the direction of recovery, this grading scale is deemed to accurately define the facial function of a patient and monitor patient status over time. As a rough scale, it was developed with the goal of putting patients in general categories. It therefore has broad applications and is trusted.

In this research, transient facial nerve weakening (grade II per House Brackmann system) occurred during the first three months postoperatively in 6 patients (2 patients in the trapezoidal miniplate group and 4 patients in the two 4-hole miniplates group). It's quietly obvious that in fractures that were treated using two 4-hole straight miniplates, transient facial nerve weakening happened more often, which could be explained by the extensive stretching of the marginal mandibular nerve needed and the time the tissues remains retracted during fixation of the extra hardware in the two miniplates group.

These findings are in line with prior clinical studies [42-44]. In 30% of instances, Manisali et al. [26] documented temporary facial nerve weakness, and in 17.2% of instances, Ellis et al. [45] reported temporary facial nerve weakness, but this was resolved in all instances throughout 3 months and no permanent nerve injury was reported; this is close to our clinical follow-up where full recovery happened at 3 months in both groups.

In this study, a satisfying occlusion was observed in all patients postoperatively which is consistent with other studies in the literature [46-49]. Teeth grinding was only done in 5 patients with minor occlusal disorders induced by premature contact after surgery. Jensen *et al.* [46] stated that minor post-surgery occlusion adjustment in 6 out of 15 patients was required. In 1 of the 17 patients who experienced endoscopy-assisted surgery, Gonzalez-Garcia et al. [47]

reported minor occlusal changes. Centric occlusion in all 27 patients treated surgically without fixation was reported by Iizuka et al. [48]. In 10 surgically treated patients, Leiser et al. [49] found adequate occlusion.

At two months postoperatively, the MIO in all our patients was nearly maximum without lateral deviation and with stable individual centric occlusion and this was in accordance with Lachner *et al.* [50] who reported that all patients recovered within 8 weeks, within the usual range of motion.

Mean MIO recorded 44.94 mm (43.44 mm in the trapezoidal miniplate group and 46.44 mm in the two miniplates group). This result (MIO > 35 mm) was also reported in previous studies [9, 51-64].

However in their studies, Bhagol et al. [65] and Singh et al. [66] recorded different findings in which the mean MIO became < 35 mm. In their reports, Yamamoto et al. [67] and Leiser et al. [49] recorded larger quantities of this variable. In addition, 13 studies were analyzed in a meta-analysis performed by Nussbaum et al. [68], and the average MIO in all of them became normal. In addition, Hlawitschka and Eckelt [69] stated that post-fracture, MIO became only marginally less preferable in patients than in other individuals. In a meta-analysis, Kyzas et al. [2] analyzed 20 studies and found that MIO was normal other than in two studies.

The post-operative recovery and healing phase was uneventful in all patients except some swellings and pain. In our study pain was normally experienced after surgeries then it decreased significantly after one week recording a mean of 33.33 in both groups then starting to subside gradually till it disappears completely by the postoperative 8th week. The better stability of the fragments supplied by ORIF can be due to earlier pain resolution in our patients. These findings were similar to those of Singh *et al.*, [32], Danda *et al.* [70] and Haug and Assael [64].

CONCLUSION

From our study of 18 condylar fractures it could be concluded that the use of SYNTHES® MatrixMANDIBLE trapezoidal plate in subcondylar fractures demonstrated significantly shorter operating time and non-significantly lower facial nerve affection in the first postoperative three months than the use of two four-hole straight miniplates.

There were no statistically significant differences among the two groups concerning accuracy of reduction, occlusion, maximum inter incisal opening, lateral deviation on opening and pain.

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