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# RECTANGULAR GRID MINIPLATE VERSUS TWO CONVENTIONAL MINIPLATES FOR TREATMENT OF MANDIBULAR ANGLE FRACTURES (RANDOMIZED CLINICAL TRIAL)

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## ABSTRACT

**INTRODUCTION:** Mandibular fracture is the most common type of trauma with various fixation modalities. One of these modalities is the use three-dimensional miniplates (3D) miniplate system.

**OBJECTIVES:** To compare the efficacy of rectangular grid miniplate with two standard miniplates in the management of mandibular angle fractures.

**MATERIALS AND METHODS:** Fourteen patients were randomly divided into two groups each including seven patients. Group A received Rectangular grid miniplate, and group B received two conventional miniplates. Clinical assessment visits are scheduled after 24 hours, one, four, six, and twelve weeks. A radiographic examination was done after twelve weeks to calculate the average bone density along line of fracture.

**RESULT:** After twelve weeks, both groups had normal occlusion, no wound infection or dehiscence, normal sensory function and a statistically significant reduction in pain intensity ($p<0.001$). The average bone density improved statistically significantly in both groups A ($p<0.001$) and B ($p<0.001$) when comparing post-operative 12 week values to pre-operative values.

**CONCLUSION:** Rectangular grid miniplate in mandibular angle fractures fixation provides a predictable and stiff fixation option that can withstand functional loads and allow early return of patients to normal life.

**KEYWORDS:** Mandibular fracture, Osteosynthesis, Rectangular grid miniplate.

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## INTRODUCTION

The primary priorities of fixation of mandibular fracture should be to reinstate the patient's function and appearance (1). Rigid internal fixation (RIF) was introduced in the maxillofacial area the first time in the late 1970s (2,3). Champy et al.,(4) assumed that osteosynthesis using miniplates has become an important fixation technique of craniofacial fractures (2). Methods of open reduction for fractures of mandible have largely altered and differed mostly in recent decades (5). However, no consensus has yet been reached on the optimal treatment strategy (6).

Using 3D miniplate in 1992 as a technique of rigid fixation improved the treatment of mandibular fractures because they withstand torsional stresses (6,7). The plate's form is not three dimensional. As a result, the term 3-D miniplate is incorrect (6,7). It resists three types of forces; shear, bending, and torsional forces (2). In comparison to conventional miniplates, the 3-D plating technique utilises fewer plates and screws, which reduces time of the operation, cost and foreign material (2). This was concluded by Zix et al., (8) Farmand and Dupoirieux (9). The rectangular grid miniplate is installed in the neutral zone of the mandibular angle region with monocortical screws and has the advantage of using only 4 screws. There is less pressure on the plate against the bone surface, and there is therefore less vascular rupture, thus reducing complications (10).

Due to presence of interconnecting cross struts, the 3-D miniplates are considered two miniplates attached to each other, which prevent any torsion movements at the fracture line (10).

With 3D miniplates, a broad-band platform is formed due to the arrangement of the screws in the shape of a box on both sides of the fracture, which resist the bending and twisting among the plate's long axis, decreasing the possibility of extending the region of the lower border of the fracture area (11, 12). Unlike lag screw that utilizes the head to cause the compression, the differential pitch pulls the segments towards each

other (8). This study compared the use of Rectangular grid miniplate fixation to traditional miniplate fixation in angle fractures.

The null hypothesis stated that there was no difference in terms of clinical stability of the fracture segment and bone density along the site of fracture between the rectangular grid plate and the 2 conventional miniplates in mandibular angle fracture fixation.

## MATERIALS AND METHODS

After receiving ethical permission from the Alexandria University Faculty of Dentistry's Research Ethics Committee, a prospective randomised controlled clinical study with a one-to-one allocation ratio was conducted.

Patients

The participants in this study were fourteen patients with mandibular angle fractures who were chosen from the Emergency Department of Alexandria University Teaching Hospital. Before the procedure, all patients signed an informed consent form at Alexandria University Faculty of Dentistry Oral and Maxillofacial Surgery Department.

The patients were selected following these bases:

*Inclusion criteria*

- Mandibular angle fracture.
- Recent trauma (< 5 days).
- Adult patients from 20-40 years old with no gender predilection.
- Fractures that require open reduction and internal fixation.

*Exclusion criteria*

Evidence of infection.
Pathologic fracture.
Old fracture.
Completely edentulous patient.
Medically compromised patient.

Patients were randomly allocated using computer based site (www.randomizer.org) into two groups, each with seven patients, with group A receiving Rectangular grid miniplate and group B receiving two conventional miniplates.

Materials (Figure 1)

Rectangular grid miniplate is a 3-dimensional plate with 1mm thickness. It can be considered as a 2 miniplates connected by cross struts, consequently preventing torsional forces at the area of fracture.

The plate stability does not depend on the thickness of the plate, however it depends on its format. Employing mono-cortical screws forms a cuboid that gives tridimensional stability to the system.

Rectangular grid miniplate is installed in the neutral zone (between tension and compression zones) of the mandibular angle using mono-cortical screws and an extraoral approach.

Four mono cortical screws 2.0mm in diameter and 8 mm in length were used in the configuration of a box on both sides of the fracture, increasing the resistance towards twisting and bending along the long axis of the plate (Manufactured by Bio Materials Korea Osteosynthesis: Seoul, Korea. www.biomk.com).

The regular miniplate is of 1.0mm thickness and made from pure titanium. The screw used is mono-cortical, made from titanium alloy, 2.0mm in diameter and 8.0mm in length. A minimum of 4 or 5-hole plate with 4 mono cortical screws is used (Manufactured by Stema Medizintechnik GmbH: Stockach, Germany. www.stema-medizintechnik.de).

Methods

*Pre-operative assessment and examinations*

The patients' full medical histories were obtained. A full clinical, intra-oral and extra-oral, examination was performed by inspection to look for any swelling, ecchymosis, bleeding, soft tissue laceration, hematoma formation, occlusal disturbances and mandibular deviation during opening and closing, as well as any step deformity, tenderness, segmental mobility and changes in bone contour by palpation.

A computed tomography (CT) scan was performed prior to surgery to assess fracture line extension, displacement, and involvement of important structures at the fracture site (Figure 2A, 2B).

*Surgical phase*

To avoid infection after surgery, Cefotaxime 1 gm/12 hours (Cefotax, E.I.P.I.C.O., Egypt) was given as a prophylactic antibiotic before surgery. All patients were given general anaesthesia and nasal intubation throughout the surgery. Sterile towels and swabs soaked in povidone-iodine solution (Betadine 7.5 percent; Purdue Products L.P.) were used to prepare the surgical site. With an extra-oral submandibular incision, after Maxillo-Mandibular Fixation (MMF), the fracture was exposed and reduced manually, holding the bone segments in place and visually assessing the reduction by aligning the buccal cortex and lower border.

For group A, securing a rectangular grid miniplate on the neutral zone of the mandibular angle area (Figure 3A). For group B, conventional two miniplates according to Champy's osteosynthesis lines were used (Figure 3B). The platysma layer was sutured with continuous suture using vicryl 3-0. This was followed by an interdermal layer sutures using vicryl 3-0, finally, a running subcuticular or simple interrupted suture for skin closure was performed using proline 5-0.

*Post-operative phase*

All patients were given post-operative medication including Intravenous cefotaxime 1 gm/12 hours for the first day followed by Amoxicillin + clavulanate 1 gm (Augmentin 1gm: GlaxoSmithKline, UK) twice daily for the next 5 days, Metronidazole 500mg (Flagyl 500mg: GlaxoSmithKline, UK)

every eight hours for 5 days, α-chemo-trypsin (Leurquin France, packed by Amoun pharmaceutical CO.S.A. E-Egypt) ampoules as anti-oedematous once daily for 5 days, Diclofenac potassium 50mg (cataflam 50mg: Novartis-Switzerland) every eight hours for 5 days and Chlorhexidine (Hexitol 125mg/100ml, concentration 0.125%: Arabic drug company, ADCO) antiseptic mouth wash. For one month, patients were instructed to eat soft foods and practise proper oral hygiene.

Follow up phase

A thorough follow-up was performed after 24-hours, one week, four weeks and six weeks for the assessment of the clinical parameters.

A 10-point visual analogue scale (VAS) was used to measure post-operative pain in a clinical assessment. Patients were questioned to evaluate the postoperative pain and discomfort on a scale of 0 to 10 (0-1= None, 2-4= Mild, 5-7= Moderate, 8-10= Severe).Nerve function was evaluated by asking patient if they noticed any changes in sensation (subjective assessment) and by using dental probe with pressure to notice sensory nerve change (objective assessment). The maximal inter-cuspal position (centric occlusion) to ensure proper occlusal relationship including molar relation, canine relation, and midline centralization were checked. Any occlusal disturbance including open bite or improper tooth contact was noted.Wound healing was visually observed, and any abnormalities were documented (13, 14).

An immediate post-operative CBCT-scan was performed to measure bone reduction from the buccal and lingual perspectives, and a twelve weeks CBCT-scan was done to determine average bone density at the area of fracture and correlate it to the immediate post-operative CBCT-scan (Figure 4 A, B). The on-demand software (OnDemand 3D APP-DBM, Cybermed, Seoul, South Korea) was used to estimate bone mineral density in Hounsfield Units (HU). Six measurements were taken along the fracture line, and the mean bone density was measured for each individual (15).

*Statistical analysis*

The data was entered into a computer and analyzed with IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Number and percent were used to describe qualitative data. The Shapiro-Wilk test was done to confirm the normality of the distribution. The range (minimum and maximum), mean, standard deviation, and median were used to characterise quantitative data. The significance of the acquired results was calculated at the 5% level. The following tests are used: the Chi-square test for categorical variables to compare between different study groups; Fisher's Exact test is used for chi-square correction when more than 20% of the cells have an expected count of less than 5, the t-test for normally distributed quantitative variables to compare between two periods; the Mann Whitney test for abnormally distributed quantitative variables to compare between two groups; and finally, the Friedman test for abnormally distributed quantitative variables to compare between more than two periods; and the Post Hoc Test (Dunn's) for pairwise comparisons

**Figure (1):** Rctangular grid miniplate and miniplate.

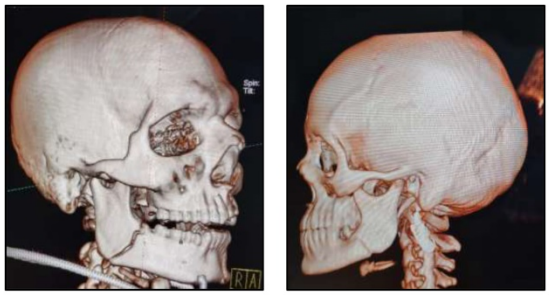


**Figure (2):** Preoperative CT-scan (a: group A, b: group B).

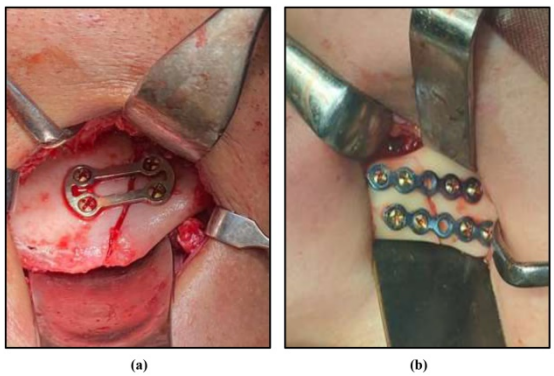


**Figure (3):** Fixation of fracture line (a: a rectangular grid miniplate, b: two conventional miniplates).

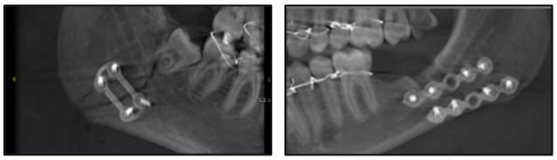


**Figure (4):** Postoperative CBCT-scan (a: a rectangular grid miniplate, b: two conventional miniplates).

## RESULTS

Cases were divided into two groups each with of 7 patients; group A (study group) was treated with a rectangular grid miniplate while group B (control group) was treated with conventional two miniplates. The patients were between the ages of 20 and 40 years with the mean age of both groups of 29.57 ±6.61 years. The included population sample showed a higher percentage of males (64.3%) in comparison to females (35.7%).

The cause of the trauma was (57.1%) road traffic accidents (n=8), assaults in five patients (35.7%) and claimed falls in one patient(7.1%).

In this study, seven patients had angle fractures on the right side and seven patients had fractures on the left side. During the study, (35.7%) of all cases did not have tooth in fracture line (n=5). On the other hand, (28.6%) had lower right 8 (n=4) and (35.6%) had lower left 8 (n=5) (Table 1). In five cases, the lower wisdom tooth involved in the line of fracture was extracted (two cases in group A and three cases in group B).

*Clincal Evaluation*

All of the patients examined were followed for 12 weeks after surgery. As compared to the 24h postoperative values, according to the VAS, in both groups all patients had a statistically significant reduction in pain intensity during the follow-up duration (P value <0.001) (Figure 5).

All of the patients exhibited normal occlusal and intercuspal relations, according to the occlusal review. During the follow-up period, there was no need for selective grinding, selective extraction or any occlusal modification.

One patient in each group (A) and (B) presented with postoperative inferior alveolar nerve sensory impairment. During follow up, the two patients in both groups still complained of persistent sensory nerve disturbance which improved gradually over time and at 6 weeks postoperatively normal sensation was restored (Table 2).

In both groups, no patients had wound infection. In group A, one patient had a postoperative wound dehiscence after the first week of surgery, which was managed with proper wound care. However, at the end of the follow-up phase, the wound had healed due to secondary intention. In group B, no patients developed any wound disturbance.

*Radiographic Evaluation*

Regarding the immediate post-operative scan, both study and control groups showed statistically insignificant difference in bone density(P= 0.521). The mean immediate post-operative bone density for the study group was 385.3 ±47.88 HU, while a mean of 402.3 ±47.88 HU was reported in the control group.

A mean three months postoperative bone density calculation for the study group was 922.1 ± 104.1 HU, while a mean reported value of 952.8 ± 53.40 HU was revealed in the control group. The intergroup comparison regarding the three months postoperative mean bone density was statistically insignificant (P= 0.500).

In both groups, the difference between the three months and the immediate mean bone density was statistically significant (P<0.001* and P<0.001* respectively) (Table 3).

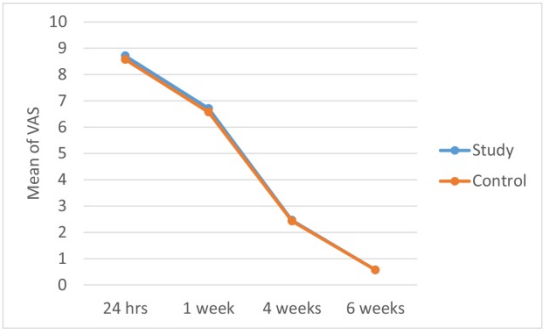


**Figure (5):** Comparison between the different studied periods according to VAS in each group.

**Table (1):** Distribution of the studied cases according to different parameters in total sample (n = 14)

| Parameter | o. | |
|---|---|---|
| Side | | |
| Right | | 0.0 |
| Left | | 0.0 |
| CT_ tooth in fracture line | | |
| None | | 5.7 |
| Lower right 8 | | 8.6 |
| Lower left 8 | | 5.7 |

**Table (2):** Comparison between the two studied groups according to sensory nerve function.

| Sensory nerve function (Disturbance) | Study (n = 7) | | Control (n = 7) | | $\chi^2$ | FE p |
|---|---|---|---|---|---|---|
| | o. | | o. | | | |
| 24hr | | 4.3 | | 4.3 | .0 | .000 |
| 1 week | | 4.3 | | 4.3 | .0 | .000 |
| 4 weeks | | 4.3 | | 4.3 | .0 | .000 |
| 6 weeks | | .0 | | .0 | | |

$\chi^2$: **Chi square test** FE: **Fisher Exact**
p: p value for comparing between the two studied groups

**Table (3):** Bone density at the fracture line in the two study groups

| Bone density | Study (n = 7) | Control (n = 7) | t | p |
|---|---|---|---|---|
| Immediate | | | | |
| Mean ±SD. | 385.3 ± 47.88 | 402.3 ± 47.88 | | |
| Median (Min. – Max.) | 353.9(339.9 –447.9) | 413.3(311.9 –465.5) | 0.661 | 0.521 |
| 3 months | | | | |
| Mean ±SD. | 922.1 ± 104.1 | 952.8 ± 53.40 | | |
| Median (Min. – Max.) | 931.5(709.0 –1031.2) | 962.2(871.9 –1021.6) | 0.695 | 0.500 |
| $t_0$ ($p_0$) | 17.249* (<0.001*) | 17.249* (<0.001*) | | |

SD: **Standard deviation** **t: Student t-test** **$t_0$: Paired t-test**
p: p value for comparing between the two studied groups
$p_0$: p value for comparing between **Immediate** and **3 months**
*: Statistically significant at $p \leq 0.05$

## DISCUSSION

The thin bone and the attachment of powerful elevator muscles creates a great demands on the selected treatment modality for the treatment of mandibular angle fractures (8, 16). The aim of this work was to evaluate the clinical and radiological efficacy of a rectangular grid miniplate to two traditional miniplates in the management of mandibular angle fractures.

78.6% (n=11) of the enrolled patients suffered from multiple mandibular fracture lines, of which 71.4% (n=10) are presented with two fracture sites. These findings agreed with those of El-Mahallawy et al., (17) and Rashid et al., (18) who reported of 72.25% and 61%. of cases with multiple mandibular fractures respectively.

In both groups of this study, an extraoral approach was utilized for fracture line exposure. It allowed better fracture reduction and better accessibility and thorough fracture line debridement before the application of the fixation device. Melek et al., (19) and Kanubaddy et al., (20) utilized an extraoral approach for angle fracture fixation where a three-dimensional grid plate was implanted. Both studies reported easier application of the grid plate with better accessibility.

In this study, extraction of the mandibular wisdom tooth implicated in the line of fracture was required in 35.7% (n=5). Nima et al., (21) reported that only symptomatic teeth should be removed, and that if extraction is performed it does not raise the risk of infection or nonunion. They also stated that extraction of tooth in fracture line makes the choice of an intraoral approach a more complicated maneuver, where surgeons should opt for an extraoral approach owing to the increased displacement that occurred with the extraction (21).

Bilal et al., (22) reported that an extraoral approach in mandibular angle fracture management showed significant pain and edema reduction when compared to both trans-buccal and intraoral approaches. Therefore, the choice of the most appropriate technique for the mandibular angle fractures fixation must not be solely based on complication rates, it usually must be correlated to the operating surgeon training and experience, the trauma center equipment availability, the nature of fracture line, and time lapsed from trauma till operation.

Through the follow up period a self-evident statistically significant decrease in pain levels was subjectively reported by the enrolled patients when evaluated using VAS (*$p<0.001$*). This is a logical premise considering that the implanted fixation device achieved an adequate stabilization of the fracture line which allowed a proper function with pain elimination. A similar decrease was reported by Melek et al., (19). There were no statistically significant differences between the two groups, where both held a p value<0.001.

According to the occlusal review during the follow-up period, all of individuals exhibited normal occlusal and inter-cuspal relations, and there was no need for any occlusal modification in both groups. A comparable result was reported by Mittal et al., (23), while Melek et al., (19) reported 10% of the cases with mild occlusal derangement postoperative occlusion which required occlusion adjustment, and regained normal occlusion by the

fourth postoperative week. Hochuli-Vieira et al., (10) reported occlusal derangement in 3% of their enrolled cases which were treated with three-dimensional grid plate.

Kanubaddy et al., (20) compared the rectangular grid plate with miniplate in the management of mandibular angle fracture. They reported 20% (n=3) of the cases with mild occlusal derangement where grid plate was utilized, in comparison to 6.66% (n=1) where miniplates was utilized. There is a literature consensus regarding the reported range of patients with occlusal derangement; a range from 0-8 % was reported with miniplates (10,24), while a range of 0-20 % was reported with three-dimensional plates (10,25). The favorable occlusal outcome is attributed to the superb functional stability that was achieved across the fracture line when the rectangular grid plate was utilized with only four installed screws.

The sensory nerve appraisal is an important aspect in postoperative evaluation of any treatment modality used to manage mandibular angle fracture. Sensory nerve disruption may be preserved due to a severe fracture line displacement, poor anatomical reduction, entrapped and over-compressed nerve, or iatrogenic screw installation through the canal (26). A subjective and objective appraisal was performed for every patient in both groups and yielded only one case in each group with disturbed inferior alveolar nerve sensation in the first follow up duration (14.3% per group). In the immediate postoperative radiographic examination, no sign of screw impingement or perforation to the inferior alveolar canal was observed. Both patients had restored normal sensation at the end of the follow up phase.
de Oliveira et al., (27) conducted a systematic review for using three-dimensional strut plate in the treatment of mandibular fractures. They reported 32 cases of inferior alveolar nerve impingement when a three-dimensional plate was used in contrast to only four cases where conventional methods were utilized. This may be a point that may distinguish the rectangular grid plate from the common three-dimensional plate, where the grid plate is only fixed with four screws which decrease the probability of nerve penetration during drilling. This was presented in this study where none of the enrolled cases showed iatrogenic nerve penetration or even approximation with the installed screws in the grid plate group.

Melek et al., (19) reported a higher 30% of the cases with sensory alteration in the path of the inferior alveolar nerve where a three-dimensional plate was utilized. A similar percentage was reported by Hochuli-Vieira et al., (10) in 2011, where 33.3% of the cases manged with grid plate showed sensory nerve alteration . Hochuli-Vieira et al., (10) describes that the most plausible cause of nerve damage, where an iatrogenic injury is not evident, is fracture manipulation and the degree of fracture displacement.

Regarding the clinical appraisal in this study, no patients in both groups revealed any signs or symptoms of wound infection. Kanubaddy et al., (20) reported that 6.66 % (n=1) of the cases showed postoperative infection owing to a retained tooth. Hochuli-Vieira et al., (10) demonstrated that three dimensional plate owes a lower infection rate than conventional miniplates, where a 3–32% range is reported. Hochuli-Vieira et al., (10), encountered 4.44% (2 patients) infection rate when grid plate is utilized

Only one case (14.2%) showed postoperative wound dehiscence in the second follow up period in the study group, while none developed any wound disturbance in the control group. This patient was managed with proper wound care and healing by secondary intention occurred and matured at the end of the clincal follow-up period. In the studies were extraoral incision is utilized, no mention of wound dehiscence was reported. de Oliveira et al., (27) computed a total of 666 cases of angle fracture managed with three-dimensional plate. They reported 3.45% (n=23) of the cases showed postoperative wound dehiscence. The occurrence of intraoral wound dehiscence is usually accompanied by a devastating effect on wound healing as it acts as a source of inoculation of oral flora bacteria into a sterile area and initiation of infection event (28). In cases of extraoral incision, wound dehiscence is commonly related to the superficial skin layer due to tension and inappropriately utilized suturing technique for the closure of the outermost layer. This wound interruption event will have consequence on the overall scar formation as healing by secondary intention usually commences to gap the skin defect (22).

In this study, each patient had one preoperative CT-Scan and two postoperative CBCT-Scans, one was taken immediately postoperatively and the other after 12 weeks.

An important element of the tomography scans is their ability to perform an indirect non-destructive appraisal of bone mineral density distribution based on the X-ray attenuation coefficient of the mineral (29,30). Kim et al (31) reported that the utilization of CBCT is highly effective method that allows for evaluation of patients' fracture healing progression over time.

In both groups and across the study follow up duration, a statistically significant increase in the calculated average bone density was reported ($P<0.001$*). A similar increase in the three months postoperative mean bone density was reported by several reports where miniplates was utilized, which is coherent with fracture healing progress (32). Melek et al., (19) performed a radiographic appraisal for using of three-dimensional plates in angle

fracture. They revealed a statistically significant increase in mean bone density across the follow up sessions (P<0.001). Their computation of the postoperative mean bone density was in accordance with the results of this study. Furthermore, a statistically insignificant (P=0.500) intergroup comparison regarding the mean bone density was reported in this study. This may conclude that the rectangular grid three dimensional plate with only four screws resulted in a comparable radiographic outcome to the well-established miniplate in fixation of mandibular angle fractures.

The main aim of internal bone fixation in mandibular fracture is to achieve a predictable primary bone healing which will result in an early return to function. This mandates absolute minimal intra-fragmentary strain with the functional load of the mandible. These favorable radiographic results may further prove that the utilization of the rectangular grid plate with only four screw in the fixation of mandibular angle fracture fulfilled the Swiss Association for the Study of Internal Fixation (AO/ASIF) requirements to have a functionally-stable fixation with a brisk recovery (33).

Since its inception, the rectangular grid plate is well known for its ability to resist three form of forces; shear, bending, and most importantly torsional forces (8,10). This feature is owed to its unique geometric configuration, where an interconnecting cross struts make the shape of the plate as if its considered as two miniplates welded to each other, diminishing the effect of any torsional strains on the fracture line. Furthermore; the box arrangement of the screw on both sites of the fracture line forms a broad-band platform which is able to resist bending and twisting among the long axis of the plate, decreasing the possibility of extending the region of the lower border of the fracture area (6,34). An added feature in the rectangular grid miniplate is that it uses less screws than the conventional method and even the traditional three-dimensional plate. This decrease the probability of iatrogenic injury, operating time, cost of treatment and foreign material (2). Lovald et al., (35) in 2009 compared the biomechanical behaviour of the three-dimensional plate and found that they are able of supporting masticatory forces during fractures healing. However, they also pointed out that, as per any miniplate fixation, dietary control is imperative.

This study is limited by the limited number of patients with only single mandibular angle fracture. Associated fractures may act as a confounding factor as it may contribute to instability at the occlusal platform, a more complex reduction of the fracture, and may affect the bone healing process (31). However, in this study none of the cases with associated fracture showed any abnormal clinical or radiographic behaviour from those with isolated mandibular angle fracture.

## CONCLUSION

Based on the favourable clinical and radiographic outcomes of this study, it may be concluded that using rectangular grid miniplate in the management of mandibular angle fractures provides a predictable and stiff fixation option that can withstand functional loads and allow early return of patients normal life. Also, the grid plate has an advantage of using only 4 screws when compared to using 2 miniplates which needs ≥ 8 screws to achieve a comparable fixation efficiency.

**CONFLICT OF INTEREST**

The authors declare that they have no conflict of interest.

**FUNDING STATEMENT**

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