

THREE-DIMENSIONAL V-SHAPED PLATE VERSUS TWO CONVENTIONAL MINIPLATES FOR TREATMENT OF MANDIBULAR ANGLE FRACTURE (RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

BACKGROUND: The only mobile bone in the facial skeleton is the mandible, which is responsible for different functions as mastication. Mandibular fractures are one of the most common among maxillofacial fractures. The 3D V shaped plate is one of the newly designed plates for management of mandibular angle fracture.

Objective: to evaluate the efficacy of a 3D V-shaped miniplate versus two standard miniplates in treating mandibular angle fractures.

MATERIALS and methods: 16 patients, who had a recent mandibular angle fracture, were assigned randomly and divided into two groups. Group A, consisting of 8 patients, underwent treatment using a 3D V-shaped plate, while group B, also consisting of 8 patients, underwent treatment using two conventional miniplates. Clinical follow-ups were conducted over twelve weeks to assess postoperative occlusion, mouth opening, and bite force. A radiographic evaluation was also conducted after six months to evaluate consolidation of bone and the mean bone density along the fracture line.

Results: Patients in both groups demonstrated satisfactory occlusion, mouth opening, and bone healing at the end of the follow-up intervals. There was no statistical significance between the two groups in terms of bite force, mouth opening and bone density.

CONCLUSION: 3D V-shaped plate can achieve satisfactory clinical and radiographic results as conventional miniplates. The 3D V-shaped plate offers the benefits of less operating time for reduction and fixation, as well as easier manipulation compared to conventional miniplates.

KEYWORDS: Mandibular fracture, Osteosynthesis, 3D V-shaped plate, conventional miniplates.

RUNNING TITLE: V-shaped plate and conventional miniplates in angle fracture.

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INTRODUCTION

Mandibular fractures are the second most prevalent fractures in the craniofacial bones, following nasal fractures (1). The reason behind this can be attributed to its prominence and position (2).

The most predominant etiological cause of mandibular fracture is road traffic accidents (RTA)⁽¹⁾. Also, mandibular fractures have been documented to be caused by assaults, sports injuries, and falls from a height (2).

Mandibular angle fractures constitute over 30% of all mandibular fractures (3). The higher occurrence of mandibular angle fractures can be attributed to the existence of the lower third molar and the constricted cross-section of the angle of the mandible (2). Mandibular angle fractures are usually unfavorable owing to the movements of the medial pterygoid, temporalis, and masseter muscles, which result in the superomedial displacement of the proximal segment (4).

Open reduction and internal rigid fixation are typical procedures used to treat displaced angular fractures (5). Rigid internal fixation is now a core principle in maxillofacial surgery. The primary advantages of rigid fixation include the prevention of intermaxillary fixation (IMF), early restoration of function, and promotion of bone healing (6). Lag screws, reconstruction plates, miniplates, dynamic compression plates, and three-dimensional (3D) plates are all part of the rigid fixation techniques (7).

Because 3D plating techniques typically use fewer plates and screws, they decrease the operating time, treatment expenses, and foreign materials used (8). A 3D V-shaped plate has been designed to treat mandibular fractures by incorporating both Champy's (9) ideal lines of mandibular osteosynthesis and the use of two miniplates; the upper one follows the mandibular tension zone, and the lower one follows the

compression zone (10). The 3D V-shaped plate is a low-profile one that provides reduction and consolidation for both superior and inferior borders (11).

A V-shaped plate is specifically intended to improve biomechanical performance by minimizing strain, stress, and displacement within the plate, as compared to using either a single or two miniplates system (12). When a single plate is used in the tension zone, shear, and bending forces at the superior border of the mandible induce motion along the longitudinal axis of the plate, leading to an expansion of the fracture at the lower border of the mandible (13).

Additionally, it was hypothesized that the V-shaped plate would experience less deformation in comparison to the standard miniplate (14). The design of the V plate aims to minimize vertical movement compared to the traditional I-shape plate, hence improving stability. This may be attributed to the connection of one side of the V plate. Consequently, the V-shaped plate is designed to withstand vertical forces significantly better than parallel conventional miniplates (15).

A 3D V-shaped plate was recently evaluated in numerous studies using Finite Element Analysis (FEA), a method that is employed to evaluate the stress distribution and geometric properties of plates (16). The results showed that this plate exhibited superior performance, with lower stress and strain values compared to the standard miniplates (12).

This study was conducted to evaluate the clinical and radiological outcomes of using 3D V-shaped plates compared to conventional miniplates in the treatment of individuals with recent mandibular angle fractures.

MATERIALS AND METHODS

Study Design

This study was a prospective controlled clinical trial, conducted based on the CONSORT guidelines (<http://www.consort-statement.org>). A total of sixteen patients with mandibular fractures were chosen from the cases admitted to the Emergency Department of Alexandria University Teaching Hospital. Sample size was estimated assuming a 5% alpha error and 80% study power. Sample size was based on Rosner's method (17) calculated by G* power 3.1.9.7 (18).

Patients' selection:

They were all adults with age ranging from 20 to 40 years old, with no gender predication. They were presented with recent uninfected mandibular angle fracture that needs open reduction and fixation. Medically compromised patients, patients with old or infected fracture and patients with fracture due to pathology were all excluded. The patients provided informed consent, which included a comprehensive

description of all operations, including their associated benefits and challenges. The surgical procedures were performed at the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University. The study adhered to the Helsinki guidelines for conducted human-based research. Ethical committee approval of Alexandria university's faculty of dentistry was attained (IRB:00010556-09/2023).

Randomization was conducted using computer-generated software with a 1:1 allocation ratio. In Group A, 3-D V-shaped miniplates plates were used, whereas in Group B, two conventional miniplates were used.

Materials:

3D V-shaped plate: miniplate of 1 mm thickness with seven holes, three holes in each arm in addition to a hole in its apex (Figure 1). The internal angle is angle of 30 degree which can be reduced by mild digital pressure as each treatment requires.

Two conventional miniplates: The standard miniplate is 1.0mm thickness.

Mini screws, 2 mm in diameter, were utilized in a mono-cortical fashion.

Methods:

I- Preoperative phase:

Comprehensive personal information of the patient was collected including name, age, gender, occupation, telephone number and address. Patient's past medical history or any recent illness was recorded as well. This was followed by recording every aspect related to the trauma, such as the type of assault, its cause, date, and location. Patient was then inspected for any other related injuries to the body, any lacerations to soft tissues, their level of consciousness, any bleeding, and first aid management. The Patient was then thoroughly examined both intraorally and extraorally by inspection and palpation. Any edema, facial deformity, bleeding, soft tissue laceration, malocclusion and misalignment of jaw during movement was recorded. If present, buccal ecchymosis and lingual hematoma were mentioned. Segmental mobility and the existence of anesthesia or paresthesia were also evaluated. Computed Tomography scan (CT-scan) was done to analyze the number and pattern of fracture lines, amount of displacement and tooth involvement in fracture line.

II- Surgical procedure:

1. Preoperative patient preparation: patients completed all the required laboratory tests to receive approval from the anesthesia specialist before surgery. A 1 gm dose of cefotaxime was given intravenously every 12 hours for one day to avoid postoperative infection.

2. Operative procedure: All patients were treated under general anaesthesia using nasotracheal intubation. The surgical field was

scrubbed with povidone-iodine surgical scrub solution, followed by draping of the patient with sterile towels exposing only the area of surgery. Fracture line was exposed through submandibular extraoral incision (19). Fracture line was then mobilized, any soft tissue entrapped within fracture line was removed and management of teeth in the fracture line was done either by extraction or preservation. Bone reduction into proper anatomical occlusion was executed. Inter maxillary fixation (IMF) was temporarily secured to provide proper occlusion that serves as a guide for fracture reduction.

For cases in group A, 3D V-shaped miniplate was applied (Figure 2: A). The plate was positioned in the neutral zone following Champy (9) principle, also having the benefit that one arm was on the inferior border of the mandible. Screws were placed in a crisscross manner to bring the fractured segments together. It was placed with its open end facing towards the ramus.

For cases in group B, 2 conventional miniplates were applied with at least 4 or 5-holes (Figure 2: B).

In both groups the incised wounds were closed in layers.

For better comparison regarding the clinical performance of the v-plate, Operating time was assessed in both groups. The measured time was that required for adaptation and fixation of either type of plates. The reported time from both groups was recorded and compared.

3. Early postoperative care: All patients were instructed to apply ice pack extra-orally starting immediately postoperatively for 24 hours followed by hot fomentation until edema subsided. Antibiotics were prescribed in the form of Intravenous cefotaxime 1 gm/12 hours for the first day followed by Amoxicillin + clavulanate 1 gm (Augmentin 1g manufactured by GlaxoSmithKline) twice daily for the following 5 days. Analgesics and anti-inflammatory medications were administered as Diclofenac potassium 50mg tablets (Cataflam 50 mg, Novartis, Switzerland) every eight hours for 5 days. Chlorhexidine antiseptic mouthwash was prescribed to all patients. All patients were instructed to eat soft, fluid, high-protein, high-calorie foods for 4 weeks postoperatively.

III- Follow up phase:

Clinical evaluation: A thorough follow-up was performed after 24-hours, one week, four weeks and six weeks, 12 weeks. Postoperative occlusion was assessed to guarantee the appropriate occlusal relationship, which encompasses molar relation, canine relation, and midline centralization. Any occlusal disturbance, such as an open bite or inappropriate tooth contact, was documented. Maximum interincisal opening was evaluated and measured in mm to determine the progress of

healing, muscular tone recovery, and recovery of normal maximal mouth opening.

2. Bite force measurement:

Bite force measurement was conducted using Pressure Indicating Film. It's a distinctive and user-friendly tool that accurately displays the force distribution and intensity between two teeth that are in contact. It's formed of two sheets, one surface is covered with a thin coating of color-forming material that is micro-encapsulated, while the other surface is coated with a layer of material that develops color. Applying force to the film leads to rupture of the microcapsules, resulting in a high-resolution "topographical" image that shows the difference in pressure across the contact surface. The product is available in three categories: Low (25-100 kg/cm²), Super low (5-25 kg/cm²), and Ultra-low (2-6 kg/cm²). Ultra-low type was used in measuring bite force in this study. After asking the patient to bite on the sheet for 5 seconds, a magenta color is obtained that exhibited a direct correlation between its intensity and the magnitude of the applied force (Figure 3). The color calibration Swatch and processed Pressure Indicating Films were scanned. The Photoshop CS6 software was utilized to measure the color density of the film and establish a correlation with the color swatch to ascertain the level of pressure exerted on the film. The force was quantified by correlating the pixel count with a predetermined surface area, and subsequently calculated using the formula: Force = Pressure × Surface area.

3. Radiographic evaluation:

Immediate CBCT scan was to assess the adequacy of fracture line reduction and fixation, and then another CBCT was taken 6 months later to estimate the mean bone density at the fracture line in comparison with the immediate postoperative scan (Figure 4,5).

On CBCT, bone mineral density was calculated in Hounsfield Unit (HU) using the on-demand software. Six measurements were taken along the fracture line, then the mean was calculated for every patient.

IV- Statistical analysis of data:

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) The Shapiro-Wilk test was used to verify the normality of distribution. Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR). The significance of the obtained results was judged at the 5% level.

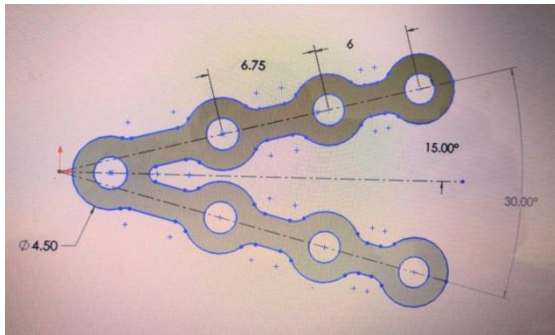


Figure (1): V-shaped plate design

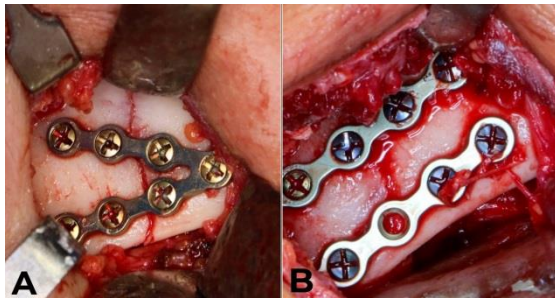


Figure (2): Reduction and fixation of mandibular angle fracture: (A: using V-shaped plate -B: using standard miniplates)



Figure (3): Bite force measurement using pressure indicating film

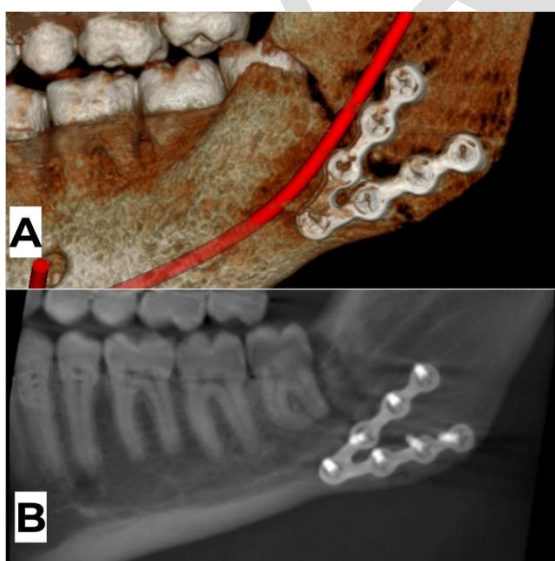


Figure (4): Postoperative CBCT scan for V-shaped plate: (A: 3D view - B: Panoramic view)

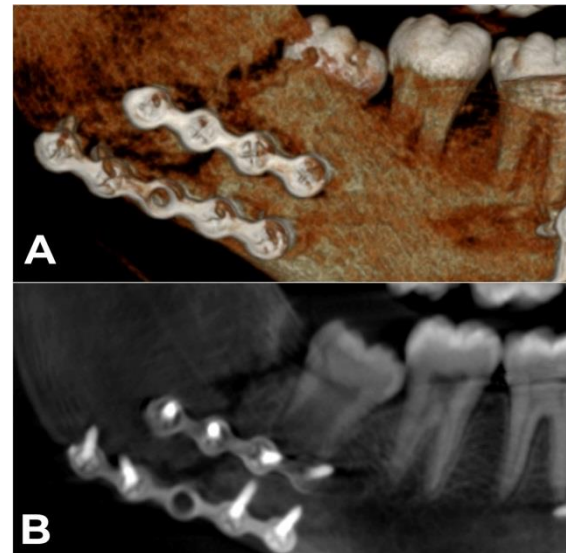


Figure (5): Postoperative CBCT scan for Standard miniplates: (A: 3D view - B: Panoramic view)

RESULTS

Intraoperative time:

Time for manipulating the plates, reduction and fixation required was recorded for all cases in both groups. The mean operating time required for the study group (group A) was 18.0 ± 1.31 minutes, whereas the mean operating time required regarding the control group (group B) was 23.88 ± 5.36 minutes. A statistically significant difference was observed between the two groups at a significance level of $p < 0.05$ (Figure 6).

Clinical evaluation data:

All patients exhibited adequate occlusion during the follow up periods in both groups. Maximum mouth opening was assessed throughout the follow up periods. After the first week, the study group had an average mouth opening of 17.88 ± 3.44 mm whereas the control group had an average of 16.50 ± 4.11 mm. All patients regained their normal mouth opening at 12 weeks follow-up. The average mouth opening for the study group was measured at 36.13 ± 3.94 mm, while for the control group it was 34.75 ± 3.49 mm. There was no notable significant difference observed between the two groups in terms of their mouth opening.

Bite force measurements:

The bite force was obtained using pressure indicating film and averaged on molar region at the fractured side during the follow up period. One week after surgery, the bite force for the study group recorded a mean of 115.4 ± 19.49 N, while for the control group it recorded a mean of 107.0 ± 9.87 N. After a period of 6 weeks follow up, the mean bite force became 202 ± 19.68 N for the study group, while for the control group it became 204 ± 25.2 N. At the end of a 12-week follow-up time frame, the study group exhibited a bite force with mean of 302.9 ± 18.36 N, while for the control group the mean bite force reached 301.4 ± 17.52 N.

All cases showed significant difference during the whole follow up phase at $p \leq 0.05$ but no significant difference was observed when comparing the two groups (Table 1).

Radiographic evaluation data:

Postoperative scans, done immediately after the surgery, revealed a favorable reduction in all patients, with a well-aligned mandibular bone structure. Regarding the immediate postoperative CBCT, the study group had a mean bone density of 833.8 ± 84.61 HU, while the control group had a mean of (818.6 ± 61.01) HU). The mean bone density for both groups was calculated after a period of 6 months. The study group exhibited a mean bone density of 1637.7 ± 117.4 HU, whereas the control group showed a mean bone density of 1593.2 ± 132.0 HU. There was a lack of statistical significance in these values between the two groups. CBCT showed proper healing with

adequate alignment of bone (Table 2). Neither malunion nor nonunion was detected in any of the cases.

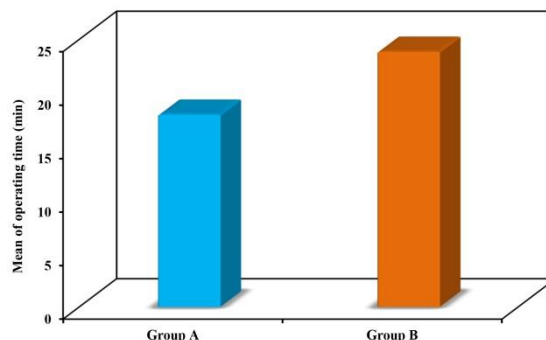


Figure (6): Graph illustrating the difference between the two studied groups according to operating time

Table (1): Comparison between the two studied groups according to bite force recovery

| Bite force recovery | Group A (n = 8) | Group B (n = 8) | p |
|----------------------|--------------------|--------------------|-------|
| 1 st week | | | |
| Min. – Max. | 85.0 – 137.0 | 94.0 – 122.0 | 0.297 |
| Mean ± SD. | 115.4 ± 19.49 | 107.0 ± 9.87 | |
| 4 th week | | | |
| Min. – Max. | 123.0 – 221.0 | 98.0 – 228.0 | 0.967 |
| Mean ± SD. | 187.1 ± 12.96 | 187.87 ± 39.9 | |
| 6 th week | | | |
| Min. – Max. | 176 – 238.0 | 153 – 233.0 | 0.862 |
| Mean ± SD. | 202 ± 19.68 | 204 ± 25.2 | |
| 12 week | | | |
| Min. – Max. | 275.0 – 329.0 | 272.0 – 324.0 | 0.870 |
| Mean ± SD. | 302.9 ± 18.36 | 301.4 ± 17.52 | |

SD: Standard deviation

p: p value for comparing between the two studied groups

Group A: Treated using 3D V shaped plate

Group B: Treated using two conventional miniplates

Table (2): Comparison between the two studied groups according to bone density

| Bone density | Group A (n = 8) | Group B (n = 8) | t | p |
|----------------|-----------------------------|-----------------------------|-------|-------|
| Immediate | | | | |
| Min. – Max. | 719.7 – 936.1 | 750.3 – 926.3 | 0.414 | 0.685 |
| Mean ± SD. | 833.8 ± 84.61 | 818.6 ± 61.01 | | |
| Median (IQR) | 836.8(759.9 – 910.9) | 812.6(764.1 – 859.4) | | |
| 6 months | | | | |
| Min. – Max. | 1455.6 – 1803.2 | 1381.7 – 1836.7 | 0.714 | 0.487 |
| Mean ± SD. | 1637.7 ± 117.4 | 1593.2 ± 132.0 | | |
| Median (IQR) | 1665.4 (1553.3 – 1702.9) | 1605.5 (1517.8 – 1640.3) | | |
| t ₀ | 16.322* | 20.656* | | |
| p ₀ | <0.001* | <0.001* | | |

IQR: Inter quartile range

SD: Standard deviation

t: Student t-test

t₀: Paired t-test

p: p value for comparing between the two studied groups

p₀: p value for comparing between the **Immediate** and **6 months**

*: Statistically significant at $p \leq 0.05$

Group A:Treated using 3D V shaped plate

Group B:Treated using two conventional miniplates

DISCUSSION

Although there have been notable improvements in internal fixation techniques, mandibular angle fractures remain challenging. The high prevalence of postoperative complications can be attributed to the constricted cross section of the angle and the strong elevator muscles of mastication that are attached to it. These factors generate complex biomechanical forces during function. This highlights the significance of using rigid fixation in this region to preserve stability after surgery (20). Hence, the objective of this study was to assess and compare the clinical and radiological outcomes of using a 3D V-shaped miniplate versus the traditional two miniplates for treating mandibular angle fractures through an extraoral submandibular approach.

An extraoral submandibular technique was utilized in both groups to reveal the fracture line. It facilitated better alignment of the fractured bone and enhanced accessibility for removing entrapped soft tissue and debridement along the fracture line prior to application of the plates. Bilal et al. (21) found that using an extraoral approach for managing mandibular angle fractures resulted in a substantial decrease in pain and swelling compared to both procedures that include intraoral and transbuccal approaches. However, Hochuli-Vieira et al. (22) employed an intraoral incision, using a ninety-degree Modus screwdriver equipped with drills. Nevertheless, the presence and usage of angled drills and screwdrivers is insufficient to be considered a universally accepted method for treating angle fractures. Alternatively, one can use a trans-buccal trocar device in conjunction of an intraoral method. Hence, when selecting on the most suitable method for treating mandibular angle fractures, it is crucial not to rely solely on complication rates. Instead, it is important to consider factors such as the surgeon's expertise and experience, the availability of equipment needed, specific fracture type and the duration between the trauma and the surgical procedure and specific fracture type.

The reduction and fixation of a mandibular angle fracture using a 3D V-shaped plate (study group) required about 16.0–20.0 minutes, which was significantly shorter than the time required for standard miniplates (17.0–33.0 minutes), as demonstrated by the study. This comes in line with Goyal et al. (23) who noticed that the 3D plating method demonstrated easy adjustment and quicker insertion with minimum dissection throughout the surgical procedure. Parmar et al. (24) obtained similar results, showing that the 3D plating technology was superior in reduction and fixation displaced angular fracture compared to other methods as 3D plates were easily adaptable and required less time for insertion. Zix et al. (25) observed that 3D plates provide an improved

alternative compared to standard miniplates as they can stabilize both the upper and lower borders at the same time, resulting in time saving. Bendary et al. (11) mentioned in their study that 3D V-shaped plate exhibited limited dissection in relation to its geometric setup, which includes two arms with an acute angle in between. 3D V-shaped plate allowed for simple manipulation and insertion and consequently reduced duration of operation. This resulted in decreased patients' exposure to anesthetic gases and better healing at the most favorable timeframe.

During a twelve-week follow up period after surgery, patients were assessed for maximum mouth opening recovery, postoperative occlusion and recovery of bite force.

At the end of the postoperative follow up period, malocclusion was not detected in any of the cases enrolled in study or control group. The results correspond to the conclusions of Agrawal et al. (26) who didn't find any malocclusion in either the standard or 3D miniplate groups. The enhanced stability of the fractured parts and the secure alignment provided by the 3D plate design are the most probable factors contributing to this outcome. The literature review agrees also on the reported range of patients with occlusal derangement for miniplates to be 0-8% which is reported by Siddiqui et al. (27). Additionally, Melek et al. (28) observed that all participants in either group achieved adequate occlusion at the fourth week after surgery.

Regarding maximum mouth opening, there was a significant increase across the subsequent study periods. Six weeks postoperatively, participants in the study group had a maximum mouth opening that ranged from 30.0 to 42.0 mm, whereas the control group had a similar range. Vineeth et al. (29) observed similar outcomes in their study. These findings align with Melek et al's (28) study, which found that both groups of patients experienced a remarkable increase in maximum mouth opening. By the third month after surgery, patients were able to resume normal mouth opening, with the space between their incisal edges of the upper and lower anterior teeth measuring about 35 to 40 mm.

The bite force of an individual is determined by the elevator muscles action of the mandible, which are controlled by the central nervous system (CNS). It is also influenced by mechanoreceptors and nociceptors and can be adjusted via craniomandibular biomechanics and reflex mechanics. Thus, measuring the biting force of individuals can be utilized in maxillofacial surgery to evaluate the effectiveness of different osteosynthesis processes. In this study, pressure-indicating film were utilized to measure bite force. Shinogaya et al. (30) conducted a comparison between the traditional unilateral strain-gage

transducer (UT) and pressure-sensitive sheets for measuring total occlusal load. They determined that the pressure indicating film is better than standard measurement tools. Two factors have been used to explain this result. First, biting force can be more accurately estimated in natural settings when it is assessed in close proximity to the intercuspal location. Secondly, parallel study of the load distribution throughout the dentition is possible.

There was no significant statistical difference in the average bite force measurements between the two groups across all the subsequent follow up time intervals. However, within each group, there was a significant difference in the average bite force values recorded at the fracture site at 1, 4, 6 weeks after the operation, and 3 months as well. According to Pepato et al. (31), individuals who have had open reduction and internal fixation in the treatment of angular fracture experienced a good functional recovery 2 months after surgery. Similarly, Saxena et al. (32) discovered a significant difference in the average bite force values between 1 and 3 months after surgery for both 3D plates and conventional miniplates.

Nevertheless, the reliability of the results remains uncertain due to significant heterogeneity influenced by characteristics such as gender, age, dentition status, and malocclusion, rather than solely the method of fixation. In comparison to the younger group, the maximal biting force of the older individuals have been found to be substantially greater. During the post-pubertal era, the maximal biting force in men grows at a faster rate compared to females, resulting in a gender-related difference. Additionally, individuals experiencing loss of periodontal attachment have demonstrated compromised sensory function, leading to diminished ability to regulate biting power.

Regarding radiographic evaluation, mean bone density was evaluated through CBCT imaging. The primary benefits of CBCT technology are its ease of use, widespread availability, low dose exposure, and ability to generate comprehensive datasets with 3D reconstructions and multiplanar cross-sectional data based on a single scan. The findings of this study demonstrated that there was a significant improvement in average bone density in both groups 6 months after surgery, which aligns with the healing process of bone following a fracture. The lack of a statistically significant difference in the mean bone density among the two groups can be attributed mostly to the fracture stability given by the plates during the healing process. Melek et al. (28) conducted a radiographic evaluation to assess the efficacy of three-dimensional plates in treating mandibular angle fractures. The study demonstrated a substantial and statistically

significant rise in mean bone density throughout the follow-up periods ($P < 0.001$). Their measurement of the mean bone density after surgery conformed to the results of the current analysis. Also, El-Nakeeb et al. (33) concluded similar results.

One important limitation of this study is the inclusion of individuals with contralateral fractures other than angle fractures. This is because there aren't sufficient instances of solitary angle fractures. Associated fractures may worsen the healing process, increase the risk of occlusal instability, need a more involved fracture reduction procedure and consequently affect the healing timeframe.

CONCLUSION

Based on the findings of this study, it can be inferred that the 3D V-shaped plate exhibited positive outcomes regarding achievement of anatomical alignment and Functional stability maintenance at both the lower and upper borders of the fracture line. It offers ease of application, better adaptation, and consequently less operating time and better healing. Yet, Radiographic and clinical results obtained are the same.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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