

## Comparison of 3-D Plates and Conventional Miniplates in the Management of Symphysis and Parasymphysis Fracture of the Mandible: A Single-Blinded Randomized Controlled Trial

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### ABSTRACT

**Objective:** To compare the surgical outcome and postoperative complications of symphysis and parasymphysis fractures in 3-D and conventional miniplating systems.

**Study Design:** Randomized Controlled Trial.

**Place and Duration of Study:** Department of Oral and Maxillofacial Surgery, Combined Military Hospital, Peshawar Pakistan, from Aug 2023 to Sep 2024.

**Methodology:** According to the inclusion criteria, 33 patients were eligible who were then divided into two groups. The anterior mandible fractures in Group A (n=17) were treated with 3-D mini plates, and those in Group B (n=16) were treated with conventional mini plates.

**Results:** Demographic characteristics were compared but none were found to be statistically significant. Out of enrolled 33(58.0%) patients, were randomized into two groups: 17(27.4%) in Group A (3-D plating) and 16(25.8%) in Group B (conventional miniplates). The results observed were not statistically significant for stability, pain, and wound dehiscence in three consecutive follow-up visits ( $p$ -value>0.05). However, malocclusion, evident on the first postoperative day in 4(25.0%) patients of Group B, was found to be statistically significant (0.027).

**Conclusion:** Better surgical outcomes and minimal postoperative complications were noted among patients offered 3-D plates compared to conventional miniplates and appreciable results were noted, especially in achieving satisfactory occlusion.

**Keywords:** Mandibular Fractures, Maxillofacial Injuries, Open Fracture Reduction, Oral Surgical Procedures.

**How to Cite This Article:** Khan A, Usman CM, Afzal M, Ghufuran HA, Khan MWU, Lateef M. Comparison of 3-D Plates and Conventional Miniplates in the Management of Symphysis and Parasymphysis Fracture of the Mandible: A Single-Blinded Randomized Controlled Trial. *Pak Armed Forces Med J* 2025; 75(6): 1245-1249. DOI: <https://doi.org/10.51253/pafmj.v75i6.13405>

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### INTRODUCTION

Among maxillofacial fractures, the nasal, zygomatic, and mandible are the culprit bones to fracture owing to their prominence and location on the face. Compared to the nasal and zygomatic bones, the horseshoe-shaped, diarthrodial mandible has a complex anatomy hosting important craniofacial structures and functions.<sup>1,2</sup> Common causes of mandible fractures are road traffic accidents, falls, gunshot injuries, interpersonal violence, and sports activities.<sup>3</sup> In the anatomic distribution of mandible fractures, the symphysis or parasymphysis accounts for 19.5% of injuries.<sup>4</sup> Closed reduction with a few weeks of maxillomandibular fixation (MMF) was performed initially, but the long duration of MMF increased patient reluctance, poor oral hygiene, and functional problems.<sup>3</sup> Now, open reduction and internal fixation (ORIF) with miniplates along 'the ideal lines of osteosynthesis' is the preferred treatment

modality for non-comminuted mandible fractures.<sup>5</sup> However, sufficient stabilization was not provided by monocortical, semi-rigid, miniplate fixation, and superimposed MMF was necessary.<sup>6</sup> Therefore, 3-D plates were introduced, consisting of a quadrangle shape: a 2x2 4-hole plate joined by four interconnected crossbars.<sup>7</sup> This geometric configuration offered resistance in the 3D plane<sup>8</sup> as the parasymphysis and symphysis regions experience the most torsion and torque, a single 3-D plate is better than two miniplates. In developed countries, studies showed 3-D plates used on different anatomic regions of the mandible, but this is not a routine.<sup>9</sup> Local use of 3-D plates is still uncommon with only one study regarding the angle region being documented.<sup>10</sup> Considering this knowledge gap, this study was carried out to validate the effectiveness of 3-D miniplates compared to conventional system in terms of stability, malocclusion, pain, and wound dehiscence to provide surgeons with new insight into treating and managing mandibular parasymphysis and symphysis fractures with better surgical outcomes, improving patients well-being.

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Received: 21 Apr 2025; revision received: 09 Oct 2025; accepted: 10 Oct 2025

## METHODOLOGY

This randomized controlled trial (IRCT20230420057970N1) was conducted in the Department of Oral and Maxillofacial Surgery, 30 Military Dental Center, Combined Military Hospital, Peshawar, from August 08, 2023, to September 09, 2024, after approval from the Ethical Review Committee through letter number 3943-1, dated April 29, 2022. The sample size was calculated using the Cleveland Clinic Risk Calculator with a confidence interval of 95%, a level of significance of 5%, a power of the study of 80%, and a margin of error 5%. Considering a 60%<sup>11</sup> anticipated dropout rate, the final estimated sample size came out to be 62 with 31 in each treatment group.

**Inclusion Criteria:** Patients with pain following a history of traumatic injury, belonging to either gender, between the ages of 18 to 50 years, classified as American Society of Anesthesiologists (ASA) Class 1, and with isolated mandible fracture were included.

**Exclusion Criteria:** Patients with infection at the fracture site, malunited fractures, comminuted fractures, panfacial trauma, bone pathology (osteomyelitis, osteoporosis, Paget's disease) or chronic illness (diabetes, asthma, hypertension) were excluded from the study.

Upon arrival at the Trauma Center, the Advanced Trauma and Life Support (ATLS) protocol was followed, and patients were assessed for eligibility through clinical examination and radiographic evaluation. Written informed consent was obtained from patients, and they were randomized into two groups by sealed envelope, in an equal distribution allocation ratio (1:1). Group-A patients received treatment with 3-D plates (case group), while Group-B patients were treated with conventional miniplates (control group). All cases were kept blind to the assigned treatment modality. All cases were treated under strict aseptic conditions, with general anesthesia and local anesthesia (1.8ml 2% Lignocaine with Adrenaline 1:100,000) administered in the fracture vicinity by a single surgical team. Temporary MMF was done using eyelets and tie wires to achieve the best possible occlusion. One titanium 3-D plate was adapted and secured with the help of titanium monocortical screws (Grade 5) around the fracture line in the subapical region. The upper holes were secured with 7mm long screws and the lower with 9mm. Muscle and mucosal closure was done and all patients were prescribed pre-operative I/V broad-

spectrum antibiotics, antiemetic and fluids for 3 days, as per protocol. Post-op MMF was only done if occlusion is not satisfactory. The patient was advised a liquid diet and strict oral hygiene instructions. In Group A, 3-D plate fixation was done with the upper crossbar in the subapical region while in Group B, conventional plating was adapted according to Champy's Line of Osteosynthesis with a 10mm space between the 2 plates. Stability was assessed clinically by manipulating the fractured segments for mobility immediately after plate fixation at one-week and one-month follow-up. Malocclusion was evaluated by clinical examination of the absence of maximum intercuspation. Wound dehiscence was noted by any plate exposure in the oral cavity, and pain was assessed by the Visual Analogue Scale (VAS). These variables were recorded at three checkpoints: the first post-op day, one week, and one month. Data not maintained for two follow-ups was discarded from the final analysis. The results obtained were analyzed in Microsoft Excel and Statistical Package for the Social Sciences (SPSS) version 22. Normality was checked with Shapiro-Wilk normality test. The median and interquartile range were calculated for non-normally distributed data. Frequencies and percentages were calculated for gender, etiology, fracture pattern, and the four variables under study for both groups. The chi-square test or Fisher test was applied to compare patients' features (stability, malocclusion, post-operative pain, and wound dehiscence) among the two treatment groups, depending on the normality of the data. In both groups, a  $p$ -value of  $\leq 0.05$  was considered statistically significant.

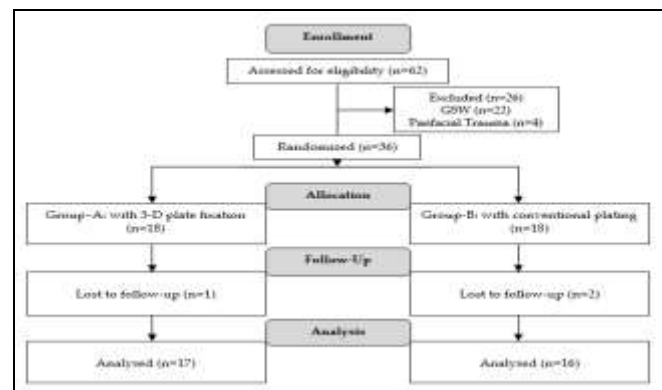


Figure: Patient Flow Diagram (n=33)

## RESULTS

A total of 62 patients were included in the study. Out of these, 26(41.9%) were excluded, 22(84.6%) had

comminuted mandibular fractures due to gunshot wounds, and 4(15.3%) had panfacial trauma. The remaining were randomized into Group A treated with 3-D plates (n=17) and Group B, treated with conventional miniplates (n=16). The median age of the study population was 27 years and interquartile ratio (IQR) was 10. In Group A, the median age was 29 years and IQR was 11.5, while in Group B it was 25 years and IQR was 10.5, as shown in Table-I. There were 17(100%) male patients in Group A while in Group B, there were 14(87.5%) males while females were 2(12.5%). The most common cause of mandibular fractures was road traffic accidents (RTAs) and splinter injuries in both Group A and Group B which accounted for 6(35.5%) and 5(31.3%) cases, respectively. This was followed by fractures due to falls in Group A 3(17.6%) and Group B 6(37.5%). The parasymphysis region was the most common fracture site in Group A 15(88.2%) and in Group B 14(87.5%), with the remainder being symphyseal fractures in Group A 2(11.8%) and Group B 2(12.5%). No statistically significant difference was observed for cause, fractured pattern, or gender distribution between the two groups as listed in Table-II. On the first post-op day, stability was 100% in both groups. Malocclusion was not present in Group A while in Group B, 4(25%) cases of malocclusion were present. Statistical differences proved to be significant ( $p=0.027$ ). MMF was done for 4 weeks, after which the malocclusion was resolved. Moderate pain was felt in Group A 15(88.2%) and Group B 14(87.5%) while wound dehiscence was absent in both groups as shown in Table-III. On one week follow-up. Stability was present in both groups (100%) and malocclusion was absent. Wound dehiscence occurred in Group A (5.88%) and in Group B (6.25%) but it resolved with treatment as shown in Table-IV, with no statistical difference noted. On one-month follow-up, stability was 100% in both groups with no malocclusion. All Group A patients were pain-free, and only 1(6.25%) in Group B (6.25%) reported severe pain with no statistically significant difference ( $p>0.05$ ) noted, as illustrated by Table-V.

**Table-I: Age (Median and IQR) of Study Participants (n=33)**

|                | Minimum Age (Years) | Maximum Age (Years) | Median (IQR) |
|----------------|---------------------|---------------------|--------------|
| Total (n=33)   | 19                  | 41                  | 27.0 (10.0)  |
| Group A (n=17) | 19                  | 40                  | 29.0 (11.5)  |
| Group B (n=16) | 21                  | 41                  | 25.0 (10.5)  |

IQR (Interquartile range)

**Table-II: Aetiology, Fracture Pattern, and Gender Distribution of Patients (n=33)**

| Variables        |               | Group A (3-D Plates) (n=17) | Group B (Conventional Plates) (n=16) | p-value |
|------------------|---------------|-----------------------------|--------------------------------------|---------|
|                  |               | n(%)                        | n(%)                                 |         |
| Cause            | RTA           | 6(35.5)                     | 5(31.3)                              | 0.368*  |
|                  | Splinter      | 6(35.5)                     | 5(31.3)                              |         |
|                  | Fall          | 3(17.6)                     | 6(37.5)                              |         |
|                  | Others        | 2(11.8)                     | 0(0.00)                              |         |
| Fracture Pattern | Parasymphysis | 15(88.2)                    | 14(87.5)                             | 0.948^  |
|                  | Symphysis     | 2(11.8)                     | 2(12.5)                              |         |
| Gender           | Male          | 17(100)                     | 14(87.5)                             | 0.132^  |
|                  | Female        | 0(0.00)                     | 2(12.5)                              |         |

RTA (Road Traffic Accident); Pearson's Chi-square test\*; Fischer's exact test^

**Table-III: Distribution of Outcomes of Patients on First Post-Op Day (n=33)**

| Variables        |          | Group A (3-D Plates) n=17 | Group B (Conventional Plates) n=16 | p-value |
|------------------|----------|---------------------------|------------------------------------|---------|
|                  |          | n(%)                      | n(%)                               |         |
| Stability        | Present  | 17(100)                   | 16(100)                            | --      |
|                  | Absent   | 0(0.00)                   | 0(0.00)                            |         |
| Malocclusion     | Present  | 0(0.00)                   | 4(25.0)                            | 0.027^  |
|                  | Absent   | 17(100)                   | 12(75.0)                           |         |
| Pain             | No pain  | 0(0.00)                   | 0(0.00)                            | 0.948*  |
|                  | Minimal  | 0(0.00)                   | 0(0.00)                            |         |
|                  | Moderate | 15(88.2)                  | 14(87.5)                           |         |
|                  | Severe   | 2(11.8)                   | 2(12.5)                            |         |
| Wound Dehiscence | Present  | 0(0.00)                   | 0(0.00)                            | --      |
|                  | Absent   | 17(100)                   | 16(6.25)                           |         |

Pearson Chi-square test\*, Fischer's exact test ^

**Table-IV: Distribution of Outcomes of Patients at the End of One Week (n=33)**

| Variables        |          | Group A (3-D Plates) n=17 | Group B (Conventional Plates) n=16 | p-value |
|------------------|----------|---------------------------|------------------------------------|---------|
|                  |          | n(%)                      | n(%)                               |         |
| Stability        | Present  | 17(100)                   | 16(100)                            | --      |
|                  | Absent   | 0(0.00)                   | 0(0.00)                            |         |
| Malocclusion     | Present  | 0(0.00)                   | 0(0.00)                            | --      |
|                  | Absent   | 17(100)                   | 16(100)                            |         |
| Pain             | No pain  | 0(0.00)                   | 0(0.00)                            | 0.365*  |
|                  | Minimal  | 11(78.5)                  | 12(75)                             |         |
|                  | Moderate | 6(35.2)                   | 3(18.75)                           |         |
|                  | Severe   | 0(0.00)                   | 1(6.25)                            |         |
| Wound Dehiscence | Present  | 1(5.88)                   | 1(6.25)                            | 0.964^  |
|                  | Absent   | 16(100)                   | 15(93.75)                          |         |

Pearson Chi-square\*, Fischer's exact test ^

## DISCUSSION

The current study intended to assess the surgical outcome and postoperative complications between two different plating systems. Managing the mandible is challenging owing to its unique anatomy, complex functions, and multiple muscle attachments, which

significantly change the biomechanics for that part of mandible fractures as, in the fracture of symphysis and parasymphysis, the compression zone lies on the inferior border of the mandible, and the tension zone lies on the superior border, thus, this region lies in the vicinity of the midline and considering the condyle as a pivot point and the attachment of the suprahyoid muscles, torsional forces develop in this region.<sup>12</sup> We assessed per-op stability by manually manipulating the fractured segments after plate fixation. No significant difference was noted regarding perioperative stability between the plating systems, consistent with literature,<sup>13,14</sup> owing to the 3-dimensional stability offered by the extra vertical struts of the 3D plates and the proper adaptation and distance between the two conventional miniplates. However, one study<sup>15</sup> found mobility of fracture segments, one in each group, while in another study,<sup>6</sup> only in the conventional plating system. Our results are consistent with another study<sup>16</sup> where pooled results showed diminished incidence of malocclusion and wound dehiscence. Our study noted malocclusion in 4(25%) patients treated with the conventional plating system upon release of the temporary MMF, possibly due to surgical edema, muscle splinting, inadequate passive adaptation of the plate along the fracture line, or insufficient distance between the plates to exert a two-plate effect.<sup>17</sup> However, another study showed conventional miniplates to be equally efficacious and promising.<sup>18</sup> Regarding pain assessment via VAS, our results are similar to findings reported previously in literature.<sup>18,19</sup>

**Table-V: Distribution of Outcomes of Patients at the End of One Month (n=33)**

| Variables           |          | Group A<br>(3-D Plates)<br>n=17 | Group B<br>(Conventional<br>Plates) n=16 |
|---------------------|----------|---------------------------------|--|
|                     |          | n(%)                            | n(%)                                     |
| Stability           | Present  | 17(100)                         | 16(100)                                  |
|                     | Absent   | 0(0.00)                         | 0(0.00)                                  |
| Malocclusion        | Present  | 0(0.00)                         | 0(0.00)                                  |
|                     | Absent   | 17(100)                         | 16(100)                                  |
| Pain                | No pain  | 17(100)                         | 15(93.75)                                |
|                     | Minimal  | 0(0.00)                         | 0(0.00)                                  |
|                     | Moderate | 0(0.00)                         | 0(0.00)                                  |
|                     | Severe   | 0(0.00)                         | 1(6.25)                                  |
| Wound<br>Dehiscence | Present  | 0(0.00)                         | 0(0.00)                                  |
|                     | Absent   | 17(100)                         | 16(0.00)                                 |

### LIMITATION OF STUDY

This study was limited by a smaller final sample size than initially intended. The reduced sample size, primarily due to time constraints, enrollment feasibility and patient

dropouts, may have affected the statistical power and generalizability of the findings. Additionally, the single-center design and short follow-up period may limit the broader applicability of the results. Other aspects, such as the duration of the procedure, sensory deficit, infection, and bite force, could also be studied between the two plating systems.

### CONCLUSION

It was noted that 3-D plates are more effective in maintaining an ideal occlusion and excluding the need for MMF, therefore, they should be used more often in treating mandible symphysis and parasymphysis fractures.

**Conflict of Interest:** None.

**Funding Source:** None.

### Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

AK & CMU: Data acquisition, data analysis, critical review, approval of the final version to be published.

MA & HAG: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MWUK & ML: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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