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Comparative Evaluation of Clinical Outcome Including Neurosensory Deficit and Pain Score Variables Using Rigid Internal Fixation with Three-Dimensional Miniplate Internal Fixation in Simultaneous Angle and Contralateral Body/Parasymphysis Fractures of the Mandible: A Prospective, Randomized Controlled Study

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Abstract

Purpose There have been numerous advancements in the strategies used for treating mandibular fractures in the present times, while open reduction and internal fixation is still accepted as the most preferred treatment option for such fractures despite numerous drawbacks. The aim of the present prospective, randomized controlled study was to evaluate the clinical outcome including neurosensory deficit and pain score variables in mandibular fractures that were treated using rigid internal fixation with three-dimensional (3D) miniplate internal fixation.

Materials and Methods For the present study, a total of 20 patients of either sex in an age range of 18 to 55 years with simultaneous angle and contralateral body/parasymphysis fractures of the mandible were included, while the clinical

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outcome was compared in relation to the two groups wherein different treatment options were used including using rigid internal fixation in one as against 3D miniplate internal fixation in the other.

Results Pairwise comparison of pain scores in Group I and Group II patients by the Mann–Whitney U-test at different time zones revealed the results to be statistically significant for all pairs except when the findings were compared between 1 month and 3 months after the procedure in Group II patients. Also, significant recovery was observed in both Group I and II patients during healing when assessed preoperatively to 1 month and then 3 months after the procedure with the results being statistically highly significant in case of the variations observed in relation to the neurosensory deficit observed at different time zones for both Group I and II patients ($p = 0.0001$).

Conclusion Based on the results obtained, it can be concluded that 3D miniplate-led osteosynthesis was found comparable to the osteosynthesis accomplished using reconstruction plates during fixation of unfavorable body/parasymphysis fractures of mandible in study, providing optimal stability, while satisfactorily meeting the biomechanical requirements for occlusal loading, and an early return to normal function.

Keywords

- rigid internal fixation
- 3D miniplates
- simultaneous angle and contralateral body/parasymphysis fractures
- randomized controlled study
- open reduction and internal fixation (ORIF)

Introduction

Mandibular fractures are the most common fractures seen (61%) in relation to the various parts of the skull and face (maxilla [46%], zygomatic arch [27%], and nasal bones [19.5%]). Also, road traffic accidents (RTAs), interpersonal violence (IPV), falls, industrial accidents, and sports-related trauma constitute the most frequently reported etiologies behind the occurrence of such fractures.[1] These fractures may be unilateral or bilateral, single or multiple, and may occur as direct and/or indirect fractures.[2] According to Ellis,[3] the forces acting across the fractured fragments become more complex in case of double fractures with higher torque moment arm and thus, greater forces over the fractured segments. Also, since in case of double fractures, there is a change in the dynamics of the impact of the forces acting across the fractured bones, a single miniplate often does not suffice treatment and fails to counter the intricate forces acting across the fractured bone fragments.[3] It is due to this reason that management in case of double fractures calls for simultaneous rigid internal fixation in one, while nonrigid fixation in the other fractured bone fragment. Traditionally, the four main objectives of treating mandibular fractures have included a near-perfect anatomical restitution, immobilization of fractured fragments, fixation of immobilized fragments, and an early restoration of normal jaw function.[4] In this pretext, numerous developments have taken place in last few decades in relation to the strategies used for treating mandibular fractures, while open reduction and internal fixation (ORIF) is still accepted as the most preferred treatment option for such fractures despite numerous drawbacks.[5–8] Champy et al[7] suggested the technique of engaging single cortex for achieving rigid osteosynthesis, while a plethora of studies including the study conducted by Theriot et al[9] contradicted the same. Again, Prein and Kellman[6] and Spiessl[10] emphasized on the need for the fixation to sustain entire functional load (load-bearing osteosynthesis) and stability of the fracture assemble to obtain rigid fixation in case of comminuted mandibular fractures for achieving adequate bone healing with reduced chances of secondary infections. The same principles are, also, applicable to situations wherein mandibular osteosynthesis is achieved with the help of reconstruction and/or universal plates with the main advantage in this being significant reduction in the time required for maxillo-mandibular fixation (MMF).[11] In similar context, the three-dimensional (3D) titanium plating system, first introduced by Farmand,[12] is a relatively new concept for the treatment of mandibular fractures. The geometry of 3D plating system allows stability in all three dimensions due to increased number of screws offering resistance against the forces.[13] The other potential advantages of 3D miniplates over rigid reconstructions and the conventional miniplate systems include an easy technique for their fixation and their sophisticated adaptation to the fractured bone without getting deformed or displacing the fractured bone fragments.[14] Studies suggest simultaneous angle and contralateral body/parasymphysis fractures to be the most common mandibular fracture pattern observed.[15–19] Also, mandibular fractures are seen to not only lead to definite changes in the skeletal architecture, but also sustain injuries to the masticatory muscles and the associated neurovascular structures. Surgically treating these fractures, thus, aims at restoration of the skeletal form of the mandible along with early return to normal function.[20] The aim of the present prospective, randomized controlled study was to evaluate the clinical outcome including neurosensory deficit and pain score variables in mandibular fractures that were treated using rigid internal fixation with 3D miniplate internal fixation.

Materials and Methods

Study Design and Settings

In the present prospective, randomized controlled study, 20 patients who reported for the treatment of simultaneous angle and contralateral body/parasymphysis fractures of the mandible were included.

Study Population

For the present study, a total of 20 patients of either sex in an age range of 18 to 55 years with simultaneous angle and contralateral body/parasymphysis fractures of the mandible with no evidence of any gross infection at the time of treatment were included in the study, while patients in whom fractures were found to be secondarily infected, patients with comminuted fractures, children, patients in mixed dentition period, and edentulous patients were excluded. Also, patients who were unable to abide by the need for a 3-month meticulous follow-up to report findings were excluded from the present study. The treatment prescribed was scheduled for surgical management under required conscious sedation, and local or general anesthesia as per the patient-specific requirements.

Sampling of Study Population/Patient Categorization

The patients were divided into two groups based on the two different treatment options used including a Group I wherein the treatment strategy included use of rigid fixation (reconstruction plate) at body/parasymphysis fracture sites and nonrigid (functional) fixation with conventional, 2-mm, 4-hole with gap miniplate at the angle region (►**Fig. 1**); and Group II which included use of 3D miniplate fixation at body/parasymphysis fracture sites, and nonrigid (functional) fixation with conventional, 2-mm, 4-hole with gap miniplate at the angle region (►**Fig. 2**). The allocation of patients to the two groups was done using a simple randomization method to avoid selection bias in the study population.

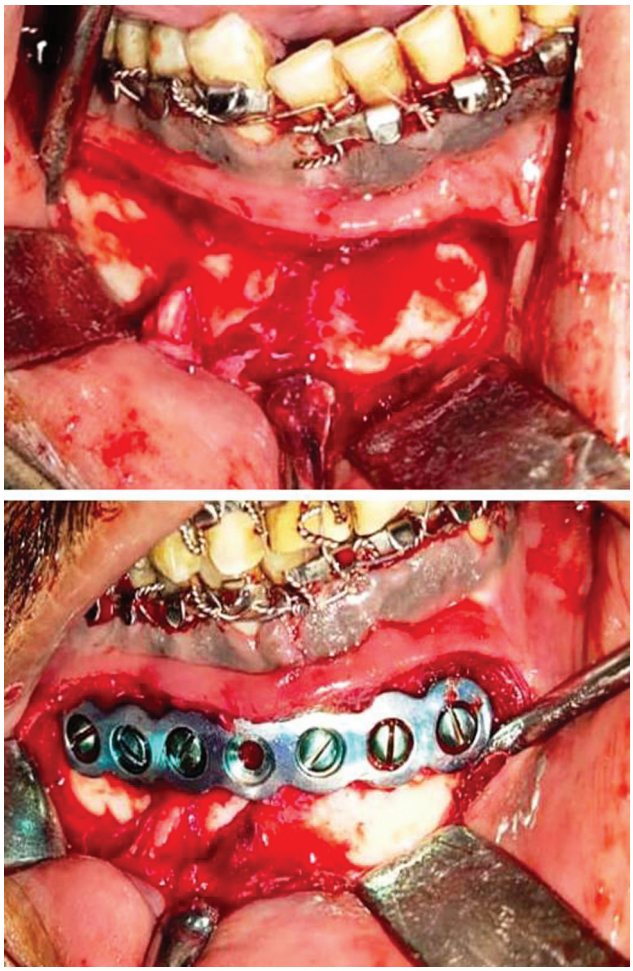

Fig. 1 Exposure of the fractured segment; and Treatment option used in case of Group I patients showing rigid fixation (reconstruction plate) at body/parasymphysis fracture site, with nonrigid (functional) fixation with conventional, 2-mm, 4-hole with gap miniplate at angle region- Plating through intraoral approach.

Management of Patients and Data Collection

Preinjured occlusion was restored using arch bars and MMF (►**Figs. 3** and **4**), while patients were evaluated for their demographic profile and fracture characteristics pre- and postoperatively. The data obtained were compiled on MS Office Excel Sheet (version 2010, Microsoft Redmond campus, Redmond, Washington, United States).

Postoperative Care

All the patients were prescribed systemic antibiotics and anti-inflammatory drugs for a period of 7 days and also, chlorhexidine rinses three times a day with reinforcement of oral hygiene instructions. Also, the patients were kept on soft/semi-solid/liquid diet for 2 to 4 weeks depending on the requirement.

Clinical and demographic variables assessed at the time of inclusion in the study:

- Demographic variables assessed.
- Details about age and sex, and mode of injury in the patients.
- Fracture characteristics assessed.

Details about site of fractures, displacement of fractured fragments (undisplaced, minimally displaced, and/or displaced), presence of tooth in line of fracture, status of tooth in line of fracture (mobile/firm, fractured [Yes/No, decayed [Yes/No], and whether indicated for removal [Yes/No]).

Clinical Outcome/Variables

The clinical outcome/variables were assessed to determine the role of functional, stable fixation in determining masticatory functional load at various follow-up intervals, while, also, the neurosensory deficit present after the procedure at the time of follow-ups. For this, the clinical parameters assessed at follow-up of patients included status of occlusion (satisfactory or nonsatisfactory), secondary complications in relation to the surgical wound created (cellulitis, presence of purulence, or dehiscence of wound), plate exposure, presence of granulation tissue at site of incision (Yes/No), assessment of pain rating on the basis of Visual Analogue Scale (VAS) with ratings from 0 indicative of no pain to 10 indicative of strongest pain, or discomfort that was unbearable to patients, neurosensory

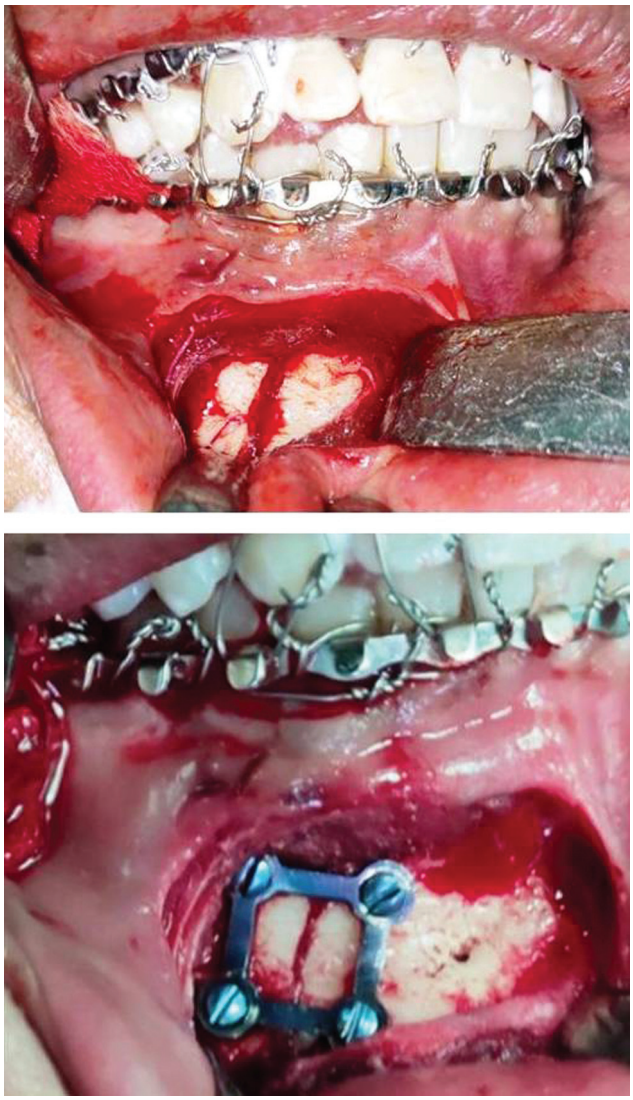

Fig. 2 Exposure of the fractured segment; and Treatment option used in case of Group II patients showing 3D miniplate fixation at body/parasymphysis fracture sites, with non-rigid (functional) fixation with conventional, 2-mm, 4-hole with gap miniplate at angle region- Plating through intraoral approach.

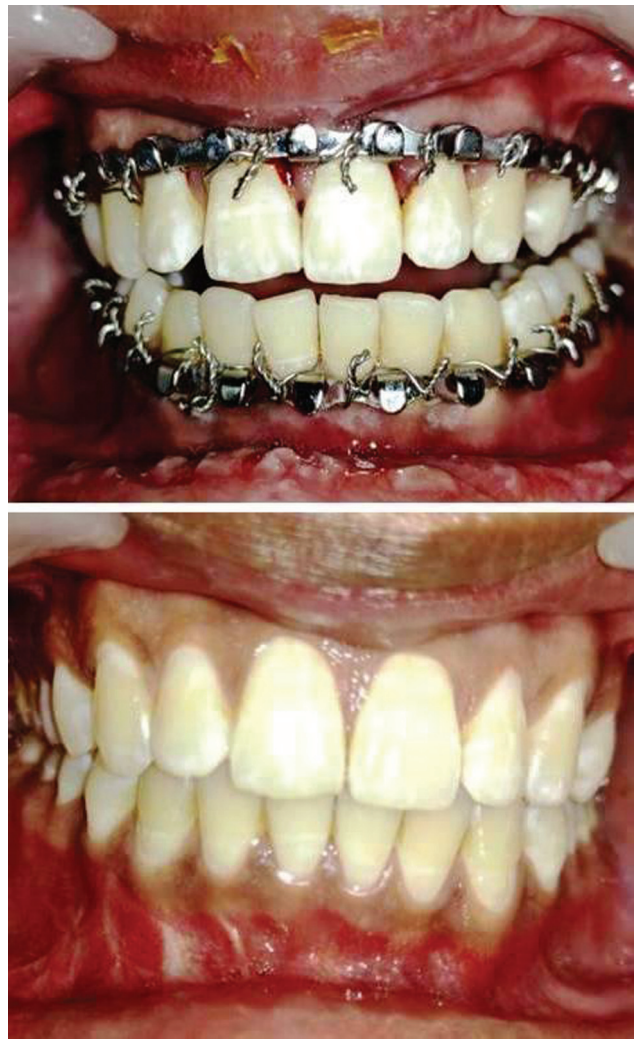

Fig. 3 Disturbed occlusion; and Restored preinjured occlusion in patient (Group I).

deficit present after the procedure (none present, hypo-, or hyper-esthetic, anesthetic, or dysesthetic), and evidence of clinical union at the last follow-up visit of the patient (Yes/No).

Radiographic Assessment

The accuracy of fracture reduction was assessed on the basis of the preoperative, immediate postoperative, and radiographs taken at l month and 3 month follow-up visits of the patients, while the radiographic assessment was done with the help of posteroanterior view mandible, and panoramic radiograph/orthopantomograph taken preoperatively to assess site of fractures, in addition to displacement, and postoperatively to assess adequacy of fracture reduction (►**Figs. 5** and **6**).

Follow-Up of Patients

For the present study, follow-up data of patients were recorded for 3 months, the results of the clinical and radiological examinations were recorded, and the two groups were analyzed and compared using appropriate tests.

Statistical Analysis Used

Statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0 (IBM, Chicago). The normality of the numerical data was checked using the Shapiro–Wilk test wherein it was found that it did not follow a normal curve, hence, nonparametric tests were used for comparisons. Inter-group comparisons were done using the Mann–Whitney U test, while intra-group analyses was done using Friedman One-Way Repeated Measure Analysis of Variance (ANOVA) by ranks (also, called Friedman test or, Friedman's two-way ANOVA) followed by post-hoc analysis by the Mann–Whitney U-test (also, known as Wilcoxon rank sum test) for pairwise comparisons among the independent groups. Also, comparison of the frequencies of categories of variables within the groups was done using Pearson's chi-squared test (χ^2 test), while for all statistical tests, $p < 0.05$ was considered statistically significant.

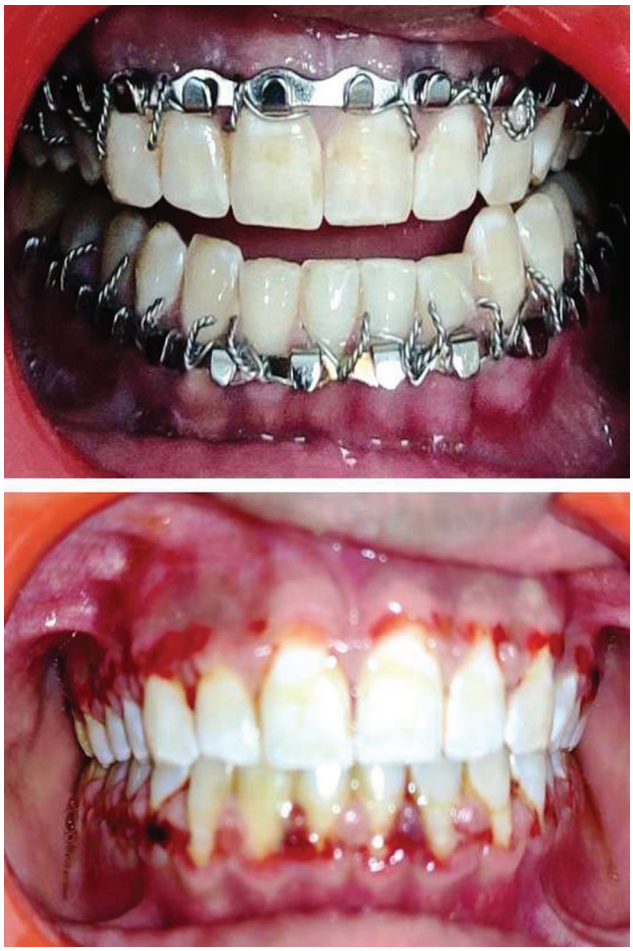

Fig. 4 Disturbed occlusion; and Restored preinjured occlusion in patient (Group II).

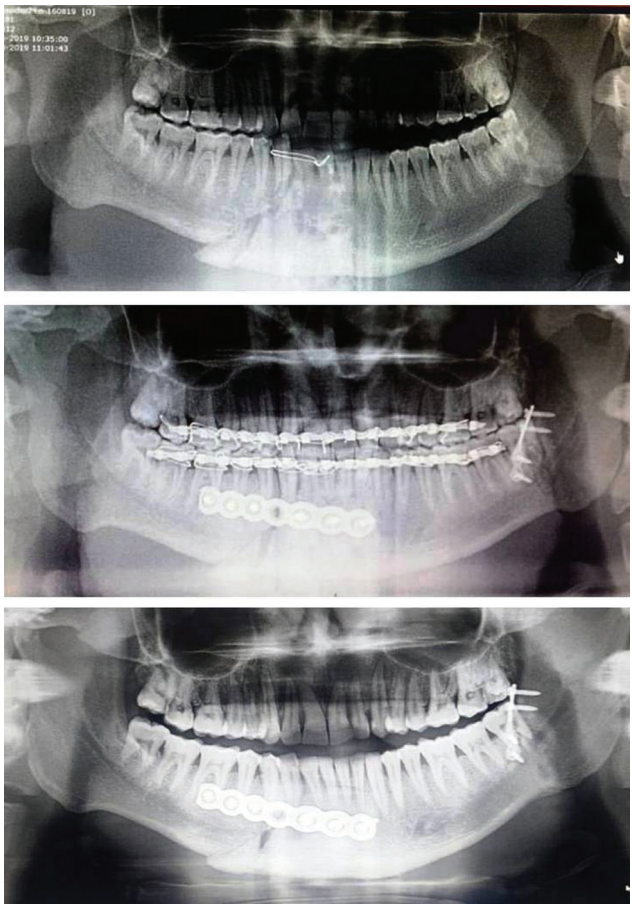

Fig. 5 Preoperative OPG; Immediate postoperative OPG; and Postoperative OPG at 3-months follow-up visit of patient (Group I).

Results

►**Table 1** presents the comparison of Group I and Group II patients in terms of gender, age (in years), mode of injury and site of fracture wherein the mean age of patients in Group I was calculated to be 33.00 ± 13.86 years as against the mean age of 31.00 ± 11.85 years in Group II patients. As far as the mode of injury was concerned, RTA followed by IPV were the most common modes of injury observed, while simultaneous angle and contralateral body fractures, followed by simultaneous angle and contralateral parasymphysis fractures, were the most common types of fractures observed for patients in both Group I and II (►**Table 1**). ►**Table 2** presents the comparison of Group I and Group II patients in terms of fracture reduction, and hardware failure as observed in Group I and Group II patients wherein fracture reduction was found to be adequate in all Group I and II patients, with no hardware failure in Group I, while one case of hardware failure as reported in Group II patients. ►**Table 3** presents the comparison of Group I and Group II patients in terms of status of occlusion observed at different time zones wherein unsatisfactory occlusion was observed in both Group I and II patients when assessed immediate postoperatively, and such cases decreased in numbers 7 days after the procedure, reducing to nil when assessed at 1 month and 3 months after the procedure for both the groups. ►**Table 4** presents comparison of Group I and Group II patients in terms of status of occlusion at different time zones by Friedman test wherein a gradual increase in the number of patients presenting with satisfactory occlusion was seen for both Group I and II patients when assessed preoperatively to 1 month and then 3 months after the procedure with statistically highly significant results ($p = 0.0001$). ►**Table 5** presents the comparison of Group I and Group II patients in terms of wound dehiscence observed at different time zones wherein one patient with wound dehiscence was observed in Group I patients when assessed immediate postoperatively, and then, 1 month and 3 months after the procedure. ►**Table 6** presents comparison of Group I and Group II patients in terms of wound dehiscence at different time zones by Friedman test wherein significant recovery was observed in both Group I and II patients during healing when assessed preoperatively to 1 month and then, 3 months after the surgical procedure. ►**Table 7** presents the comparison of Group I and Group II patients in terms of neurosensory deficit observed at different time zones wherein nine patients each in Group I and II presented with neurosensory deficit when assessed

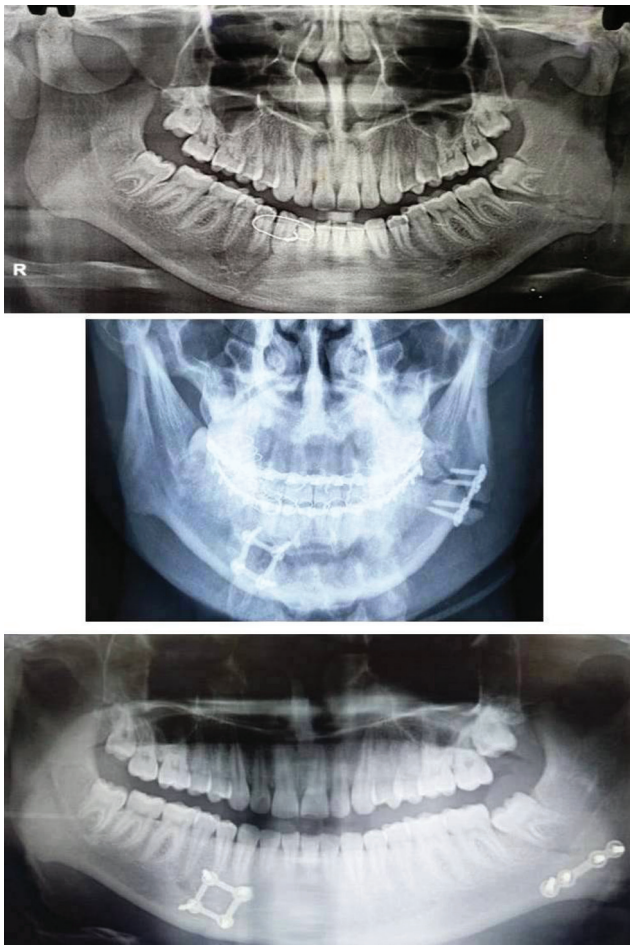

Fig. 6 Preoperative OPG; Immediate post-operative PA view mandible; and Post-operative OPG at 3-months follow-up visit of patient (Group II). OPG, orthopantomograph; PA, posteroanterior.

immediate postoperatively, which later decreased to one patient each in Group I and II presenting with neurosensory deficit as assessed 3 months after the procedure. ►**Table 8** presents comparison of Group I and Group II patients in terms of neurosensory deficit at different time zones by Friedman test wherein again significant recovery was observed in both Group I and II patients during healing when assessed preoperatively to 1 month and then, 3 months after the procedure with the results being statistically highly significant ($p = 0.0001$). ►**Table 9** presents the intra-group comparisons of mean pain scores in Group I and Group II patients at different time zones wherein a mean pain score of 8.6 ± 0.5 was observed in Group I patients when assessed preoperatively, which gradually reduced to 0.2 ± 0.4 when assessed 3 months after the procedure with the results being statistically highly significant ($p = 0.0001$). Again, statistically highly significant results were obtained in Group II patients with a mean pain score of 7.9 ± 1.0 when assessed preoperatively which gradually reduced to 0.0 ± 0.0 when assessed 3 months after the procedure ($p = 0.0001$) (►**Table 9**). Likewise, ►**Table 10** presents the inter-group comparisons of mean pain scores in Group I and Group II patients at different time zones by the Mann–Whitney U-test wherein statistically significant values were obtained on comparison between Group I and II patients in case of the mean pain scores assessed immediate postoperatively. Similarly, ►**Table 11** presents the pairwise comparisons of mean pain scores in Group I and Group II patients at different time zones by the Mann–Whitney U-test wherein results were found to be statistically significant for all the pairs except when the findings were compared between 1 month and 3 months after the procedure in Group II patients.

Discussion

The aim of the present prospective, randomized controlled study was to evaluate the clinical outcome including neurosensory deficit and pain score variables using rigid internal fixation with 3D miniplate internal fixation in simultaneous

Table 1 Comparison of Group I and Group II patients in terms of gender, age (in years), mode of injury, and site of fracture

Variable	Group I	Group II	Total	*p*-Value
Gender				
Male	10	10	20	1.0000
Female	0	0	0	
Age (in years)				
Mean ± SD	33.00 ± 13.86	31.00 ± 11.85	32.00 ± 12.60	0.7330
Mode of injury				
Road traffic accidents (RTAs)	8	6	14	
Interpersonal violence (IPV)	2	2	4	
Fall	0	1	1	1.0000
Sports injury	0	1	1	
Site of fracture				
Combined angle and contralateral body fracture	11	10	21	1.0000
Combined angle and contralateral parasymphysis fracture	9	10	19	

Table 2 Comparison of Group I and Group II patients in terms of radiographic assessment of fracture reduction and hardware failure

Variable	Group I	Group II	Total	*p*-Value
Fracture reduction				
Adequate	10	10	20	1.0000
Inadequate	0	0	0	
Hardware failure				
No	10	9	19	1.0000
Yes	0	1	1	
Total	10	10	20	

Table 3 Comparison of Group I and Group II patients in terms of status of occlusion at different time zones

Time of assessment	Group I	Group II	Total	χ^2-Value	*p*-Value
Preoperative					
Satisfactory	0	0	0	–	1.0000
Unsatisfactory	10	10	20		
Immediate postoperative					
Satisfactory	3	4	7	0.2200	0.6390
Unsatisfactory	7	6	13		
7 days after procedure					
Satisfactory	7	8	15	0.2670	0.6060
Unsatisfactory	3	2	5		
1 month after procedure					
Satisfactory	10	10	20	–	1.0000
Unsatisfactory	0	0	0		
3 months after procedure					
Satisfactory	10	10	20	–	1.0000
Unsatisfactory	0	0	0		
Total	10	10	20		

Note: χ^2-Value: Chi-square value.

Table 4 Comparison of Group I and Group II patients in terms of status of occlusion at different time zones by Friedman test

Time zone	Group I			Group II		
	Satisfactory	Unsatisfactory	Total	Satisfactory	Unsatisfactory	Total
Preoperatively	0	10	10	0	10	10
Immediate postoperatively	3	7	10	4	6	10
7 days after procedure	7	3	10	8	2	10
1 month after procedure	10	0	10	10	0	10
3 months after procedure	10	0	10	10	0	10
Total	30	20	50	32	18	50
Friedman test	32.5000			32.6390		
p-Value	0.0001[a]			0.0001[a]		

[a]*p*-Value < 0.001 (statistically highly significant).

Table 5 Comparison of Group I and Group II patients in terms of wound dehiscence at different time zones

Time of assessment	Group I	Group II	Total	χ^2-Value	*p*-Value
Immediate postoperative					
No	9	10	19	1.0530	0.3050
Yes	1	0	1		
7 days after procedure					
No	10	10	20	0.2670	0.6060
Yes	0	0	0		
1 month after procedure					
No	9	9	18	–	1.0000
Yes	1	1	2		
3 months after procedure					
No	9	10	19	1.0530	0.3050
Yes	1	0	1		
Total	10	10	20		

Note: χ^2-Value: Chi-square value.

angle and contralateral body/parasymphysis fractures of the mandible. A significant observation made in the present study was that combination of rigid fixation with functional fixation had better occlusal outcome in double fractures of the mandible. Also, these patients did not require prolonged MMF permitting early mobilization of jaws. The major goals behind mandibular fracture treatment include an early reinstatement of preinjured anatomic form, while meeting the functional requirements with same efficiency with a special emphasis on establishing a satisfactory occlusion. These goals can be achieved with closed reduction of fractures using MMF for a defined time period depending on the age and type of fracture.[4] This treatment method, though, suffers from an important setback by putting the patients on relatively prolonged periods of compromised jaw functions during which the patients have difficulty in chewing food and maintaining oral hygiene. It is because of these aforesaid compromises that a shift in the pattern toward ORIF technique is observed in the treatment of mandibular fractures to overcome the shortcomings of the closed reduction methodology. There has been a tremendous improvement in ORIF methodology, and the design of the plates/screws used, and surgical techniques followed for placing them on fracture site with a major goal behind this being: to be able to achieve primary bone healing. An important question that arises here is to assess if there are any significant differences in the requirements of the type of the hardware used for reduction of the fractures. In this pretext, the results of the study conducted by Ellis[3] showed a significantly higher rate of complications in the nonrigid fixation group making the author conclude that although functional fixation may work well in the case of single or isolated fractures of the mandible, they might not give satisfactory results in terms of secondary complications when applied to double fractures of the mandible. It is on the basis of these considerations in the mentioned study that in a total of 20 patients included in the present study, the treatment strategy adopted for patients in Group I used rigid fixation (reconstruction plate) for body/parasymphysis fractures along with nonrigid (functional) fixation with conventional, 2-mm, 4-hole with gap miniplate at angle region, while in the case of Group II patients, the treatment strategy included use of 3D miniplate fixation for the body/parasymphysis fractures with nonrigid (functional) fixation with conventional, 2-mm, 4-hole with

Table 6 Comparison of Group I and Group II patients in terms of wound dehiscence at different time zones by Friedman test

Time zone	Group I			Group II		
	No	Yes	Total	No	Yes	Total
Immediate postoperatively	9	1	10	10	0	10
7 days after procedure	10	0	10	10	0	10
1 month after procedure	9	1	10	9	1	10
3 months after procedure	9	1	10	10	0	10
Total	37	3	40	39	1	40
Friedman test	1.0810			3.0770		
p-Value	0.7820			0.3800		

Table 7 Comparison of Group I and Group II patients in terms of neurosensory deficit at different time zones

Time of assessment	Group I	Group II	Total	χ^2-Value	*p*-Value
Preoperative					
No	7	8	15	0.2670	0.6060
Yes	3	2	5		
Immediate postoperative					
No	1	1	2	–	1.0000
Yes	9	9	18		
7 days after procedure					
No	2	1	3	0.3920	0.5310
Yes	8	9	17		
1 month after procedure					
No	5	4	9	0.2020	0.6530
Yes	5	6	11		
3 months after procedure					
No	9	9	18	–	1.0000
Yes	1	1	2		
Total	10	10	20		

Note: χ^2-Value: Chi-square value.

gap miniplate at the angle region. In 1992, Farmand[12] introduced the 3D titanium implant system for the fixation of the facial prostheses, while also suggesting osteointegration of this material with the fractured bone as the major reason for the applicability of this system in case of anatomically less favorable fractures achieving optimal clinical results. As far as the line of treatment for fracture cases included in the present study was concerned, intermaxillary fixation was done in all the patients preoperatively to achieve a state of preinjured occlusion in line with the methodology used in the studies conducted by Bolourian et al,[21] Zix et al,[22] and Rix et al,[23] who, also, advised to supplement miniplate fixation with MMF for stabilization of the occlusion. In similar context, Chritah et al,[24] also, concluded from the findings of their study that a single 2-mm locking miniplate/screw system across the Champy's line of ideal osteosynthesis in addition to four 8-mm monocortical screws and 1 week of MMF is an almost predictable and unfailing treatment option for complex mandibular fractures. Furthermore, the authors observed primary bone healing in 98% of the patients with only two patients reporting with minor complications in the form of wound dehiscence and malocclusion noted in one case each, along with a single case reporting with fibrous nonunion requiring three additional weeks of MMF. Also, no signs of malunion, hardware failure, osteomyelitis, and/or neurovascular injuries were observed in the study. Bolourian et al,[21] also, concluded similarly from the findings of their study that use of a single 2-mm miniplate secured with four 8-mm monocortical screws along the Champy's line of ideal osteosynthesis was a viable treatment option for complex mandibular fractures when combined with 2 weeks of MMF. In the present study, 7 out of 10 patients in Group I and 6 out

Table 8 Comparison of Group I and Group II patients in terms of neurosensory deficit at different time zones by Friedman test

Time zone	Group I			Group II		
	Satisfactory	Unsatisfactory	Total	Satisfactory	Unsatisfactory	Total
Preoperatively	7	3	10	8	2	10
Immediate postoperatively	1	9	10	1	9	10
7 days after procedure	2	8	10	1	9	10
1 month after procedure	5	5	10	4	6	10
3 months after procedure	9	1	10	9	1	10
Total	24	26	50	23	27	50
Friedman test	17.9490			23.0270		
p-Value	0.0010[a]			0.0001[a]		

[a]*p*-Value < 0.001 (statistically highly significant).

Table 9 Intra-group comparisons of mean pain scores in Group I and Group II patients at different time zones

Groups	Time zone	Mean ± SD	Median	Mean rank	χ^2-Value	*p*-Value
Group I	Preoperative	8.6 ± 0.5	9.0	5.0	39.3230	0.0001[a]
	Immediate postoperative	7.2 ± 0.9	7.0	4.1		
	7 days after procedure	3.5 ± 1.8	3.0	3.0		
	1 month after procedure	0.8 ± 0.6	1.0	1.8		
	3 months after procedure	0.2 ± 0.4	0.0	1.2		
Group II	Preoperative	7.9 ± 1.0	8.0	5.0	39.5650	0.0001[a]
	Immediate postoperative	5.5 ± 1.4	6.0	4.0		
	7 days after procedure	2.5 ± 1.0	2.0	3.0		
	1 month after procedure	0.4 ± 0.7	0.0	1.7		
	3 months after procedure	0.0 ± 0.0	0.0	1.4		

Abbreviations: SD, standard deviation; χ^2-Value, Chi-square value.
[a]*p*-Value < 0.001 (statistically highly significant).

of 10 patients in Group II were put on 1 week of MMF which was done in accordance with the methodology used in the studies conducted by Bolourian et al[21] and Chritah et al,[24] while it was observed that after 1 week, only 3 patients in Group I while 2 patients in Group II required further MMF, and after 1 month, no MMF was required in both groups. Also, dehiscence was observed in one patient each in Group I and Group II, 1 month after the surgical procedure, wherein, in both the patients, irrigation was done and antibiotics were started, while the patients exhibited uneventful healing on follow-up visit. Again, paraesthesia was observed in three patients in Group I, while in two patients in Group II preoperatively later increasing to nine patients each in Group I and Group II immediate postoperatively, possibly due to retraction of the soft tissues for adaptation of the plates. In this case, also, the patients exhibited uneventful healing with one patient each in Group I and Group II presenting with neurosensory deficit, 3 months after the procedure. In similar context, Scolozzi et al[25] observed a relatively higher prevalence of hypoesthesia (22.2%) in relation to the inferior alveolar nerve while treating linear non-comminuted fractures of the mandible with a single 2-mm locking reconstruction plate in their study. All the patients, however, presented with a sound bone healing with no major complications in the mentioned study similar to the findings of the present study. Again, intra-group comparison of the mean pain scores by Friedman test at different time zones revealed a mean pain score of 8.6 ± 0.5 in Group I and 7.9 ± 1.0 in Group II preoperatively in the present study as per the VAS ratings, which later reduced to 3.5 ± 1.8 in Group I and 2.5 ± 1.0 in Group II patients 7 days after the procedure. A notable observation here was that at 3 months of follow-up, the mean pain score was found to be 0.2 ± 0.4 in Group I patients, which, surprisingly, reduced to 0.0 ± 0.0 in Group II patients with statistically highly significant ($p = 0.0001$) results. The differences in relation to the observed mean pain scores in Group I and Group II patients might be explained on the basis of the use of reconstruction plates

Table 10 Inter-group comparisons of mean pain scores in Group I and Group II patients at different time zones by Mann–Whitney U-test

Variable	Time zone	Group	Mean ± SD	Median	U-Value	Z-Value	*p*-Value
Pain	Preoperative	Group I	8.60 ± 0.52	9.00	29.00	−1.7260	0.0840
		Group II	7.90 ± 0.99	8.00			
	Immediate postoperative	Group I	7.20 ± 0.92	7.00	16.50	−2.6490	0.0080[a]
		Group II	5.50 ± 1.35	6.00			
	7 days after procedure	Group I	3.50 ± 1.84	3.00	35.50	−1.1820	0.2370
		Group II	2.50 ± 0.97	2.00			
	1 month after procedure	Group I	0.80 ± 0.63	1.00	32.00	−1.5100	0.1310
		Group II	0.40 ± 0.70	0.00			
	3 months after procedure	Group I	0.20 ± 0.42	0.00	40.00	−1.4530	0.1460
		Group II	0.00 ± 0.00	0.00			

Abbreviation: SD, standard deviation.
[a]*p*-Value < 0.05 (statistically significant).

Table 11 Pairwise comparisons of mean pain scores in Group I and Group II patients at different time zones by Mann–Whitney U-test

Time interval	Group I		Group II	
	Z-Value	*p*-Value	Z-Value	*p*-Value
Immediate postoperatively to preoperatively	−2.724	0.0060[a]	−2.827	0.0050[a]
7 days after procedure to preoperatively	−2.816	0.0050[a]	−2.848	0.0040[a]
1 month after procedure to preoperatively	−2.842	0.0040[a]	−2.84	0.0050[a]
3 months after procedure to preoperatively	−2.889	0.0040[a]	−2.831	0.0050[a]
7 days after procedure to immediate postoperatively	−2.814	0.0050[a]	−2.831	0.0050[a]
1 month after procedure to immediate postoperatively	−2.827	0.0050[a]	−2.859	0.0040[a]
3 months after procedure to immediate postoperatively	−2.848	0.0040[a]	−2.836	0.0050[a]
1 month after procedure to 7 days after procedure	−2.821	0.0050[a]	−2.913	0.0040[a]
3 months after procedure to 7 days after procedure	−2.831	0.0050[a]	−2.844	0.0040[a]
3 months after procedure to 1 month after procedure	−2.449	0.0140[a]	−1.633	0.1020

[a]*p*-Value < 0.05 (statistically significant).

in Group I patients which required relatively longer incisions, and thus, more dissection and extensive soft tissue manipulation for the placement of reconstruction plates that led to a significantly higher postoperative morbidity and subsequent, higher mean pain scores observed in Group I patients.

Limitations of the Present Study

One of the major limitations of the present study was the restricted sample size used in the study, though, considering the number of patients reporting to any given set-up, further multicentric studies with larger sample sizes pooled from various institutions and set-ups are required to validate the findings of the present study. This will not only standardize the treatment options/strategies used, but improve clinical outcome in terms of early return to normal mandibular function with higher masticatory performance and thus, increased efficiency of the stomatognathic system.

Conclusion

Despite the complex biomechanics involved in the case of double fractures, the results obtained in the present study did not observe significant differences in relation to the functional outcome among Group I and Group II patients apart from meager differences in terms of the pain scores recorded. Also, all the patients appreciated early return to normal mandibular function, uneventful healing, and excellent bony union at the fractured site with minimum bone loss. Based on the results obtained in the present study, it can, thus, be concluded that 3D miniplate-led osteosynthesis was found to be comparable to the osteosynthesis accomplished using reconstruction plates during fixation of unfavorable body/parasymphysis fractures of mandible in study, providing optimal stability, while satisfactorily meeting the biomechanical requirements for occlusal loading, and an early return to normal function.

Ethical Approval

All the patients were duly informed about the protocol of the study. Also, a written, informed consent was duly obtained from all the patients prior to their inclusion in the study, while ethical clearance was obtained from the Institutional Ethics Committee via Institutional Ethics Committee Letter approval no. SDDC/IEC/01–72–2022 before the start of the study.

Patients' Consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflict of Interest

None declared.

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