



Stability and Clinical Outcomes of Angle Fracture Fixation Using Sagittal Split Plate (SSOP) Versus Two Miniplates: Randomized Clinical Trial

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Abstract The aim of this study was to compare the stability and clinical outcomes between the two miniplates and sagittal split plate (SSOP) in angle fracture fixation. Thirty-eight patients with a mandibular angle fracture were selected and divided randomly into two groups. Intervention was treated with SSOP, and the control group was treated with conventional two miniplates. Clinical evaluation included occlusion, edema, nerve affection, wound dehiscence and mouth opening. Radiographic parameters included the measurement of inter-ramus distance, inter-mental distance and bone density. All clinical parameters were evaluated at one week, one month and three months intervals. Radiographic parameters were evaluated immediately postoperative, and after three months. Results showed that SSOP had less postoperative complications (10.50%) than the two miniplates (31.60%). It can be concluded that both methods offered high performance in management of mandibular angle fractures. However, SSOP group had a significantly shorter operating time, increased bone density and less edema.

Clinical trial registration number: NCT03839368.

Keywords SSOP · Miniplates · Titanium miniplate · Angle fracture fixation

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Introduction

The mandible is a unique “U-shaped” bone that articulates with the skull at the temporomandibular joints and with the maxilla through the dental functional occlusion forming the esthetics of the face. Mandibular bone fracture is very common due to its protrusion and it accounts for 36–59% of all maxillofacial fractures. Angle fractures are considered the second most common mandibular fracture (26%) after parasymphyseal fracture (40%). Several anatomical factors account for this, including the decrease of cross-section of bone as the alveolar ridge converges more medial, the unerupted or impacted third molar creates an area of weakness at the angle region, and the abrupt change in bone trajectories between body and ramus at the angle area. Moreover, its complex biomechanics makes angle fracture treatment very challenging thus accounting for the high rate of postoperative complications compared to other mandibular fractures (up to 32%) [1–3].

According to favourability of angle fracture, open or close reduction can be used to fix the angle fracture. Closed reduction can be used in minimally or nondisplaced biomechanically favorable fractures splinted by the periosteum, which can be treated by maxillomandibular fixation successfully, while open reduction and internal fixation can be used in displaced unfavorable angle fracture and in cases where closed reduction is contraindicated [4, 5]. There are different techniques of fixation for treating angle fractures that have been reported in the literature. Although during the last two decades, miniplates have been widely used in angle fracture fixation as it provides the most stable means of fixation at the tension zone of the mandible, providing functionally stable fixation [6–9].

Champy et al. [10] recommended single miniplate at superior border which provides functionally stable fixation

and it is a reliable, simple and a time saving method in fixation of angle fracture. However, Champy technique was not sufficient in case of severely displaced fractures or in cases where much rigid fixation is needed as in unfavorable angle fractures [10–12]. Many in vitro studies have shown splaying of the lower border of the mandible due to loading forces which resulted in the use of a second miniplate at the inferior border to provide stable fixation under functional loading, especially if it was associated with anterior mandibular fracture. Also, the use of two miniplates had high complication rate due to greater periosteal and muscle stripping in the angle region, compromising the blood supply and healing [9, 10, 13–15].

In 2014, Suer et al. [16] developed a new miniplate design to provide a reliable rigid and simple technique for angle fixation. This plate has less metal material and holes. In addition, it has one straight section and two lateral extensions which offered more resistance and stability to the lateral displacing forces at the fracture site than conventional single miniplates [16]. Despite great advantages that was concluded from this in vitro study, no clinical comparative studies have been conducted in the use of this new design. This new plate design resembles the design of sagittal split osteotomy plate (SSOP). SSOP is a plate from MatrixORTHOGNATHICTM Planting System Surgical Technique DePuy Synthes that is used in fixation of bilateral sagittal split osteotomy (BSSO) [17]. SSOP was used in 2017 by Carl Bouchard [18] who conducted a retrospective study to report the complications associated with mandibular angle fractures on 78 patients and used SSOP in 32 patients. The aim of this study was to compare the stability and the clinical outcomes between the two miniplates and SSOP in angle fracture fixation.

Materials and Methods

Study Design

That was a randomized controlled clinical trial conducted on 38 patients with angle fracture and an age range between 17 and 52 years old, with a mean age of 28.26 for both groups. Patients were divided randomly and equally into 2 groups. The control group was fixed using 2 miniplates. [Straight plate without stem 12.000.08 (Anton Hipp instradments and implants, Fridingen, Germany)]. Patients in the intervention group were fixed using the SSOP [Matrix Sagittal Split Plate, curved with intersection bar, 6 holes; 1.0 mm thick (Depuy Synthes, Switzerland)]. Patients were recruited from the out-patient clinic of the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Cairo University and Nasser Institute Hospital for research and treatment, Cairo, Egypt. The study followed the Declaration of Helsinki on

medical research and the study was approved by the research ethics committee of Cairo University.

Sample Size Calculation and Randomization

The sample size was calculated based on the proportions of overall complications in study groups of Ellis et al. [19] study. Using a power of 80 and 0.05% significance level, we needed to study 16 patients in each group. The number was increased to a total sample size of 19 in each group to compensate for attrition during follow up. Sample size calculation was achieved using GPS: Power and Sample Size calculation software Version 3.1.2 (Vanderbilt University, Nashville, Tennessee, USA) [9, 17]. Patients were allocated to either group using simple randomization according to a random sequence (allocation ratio 1:1) generated by (www.random.org). This study was conducted in a double-blind manner.

Eligibility Criteria

Patients were selected according to the following criteria: fully or partially dentulous adult patients, unfavorable unilateral angle fracture or unilateral angle fracture associated with anterior mandibular fracture were included, free from any systemic disease or bone diseases. Any patients with bilateral or comminuted angle fractures, midface fractures, infected or edentulous patients and smokers were excluded. Patients were assessed clinically to assure their correspondences with eligibility criteria. Preoperative panoramic radiograph followed by facial bone CT were done. Eligible patients signed an informed consent before their participation in the study.

Data Analysis

Statistical analysis was performed using SPSS (Statistical package for the social sciences- IBM® SPSS® Statistics Version 20 for Windows, IBM Corp., Armonk, NY, USA). Quantitative data was represented as mean \pm standard deviation. Data were explored for normality using Kolmogorov–Smirnov and Shapiro–Wilk tests. For parametric data, Student's t-test was used to compare variables between the two groups. For nonparametric data, Mann–Whitney U test was used to compare variables between the 2 groups. Qualitative data will be represented as percentage or frequency. Chi-square test and Fisher's exact test were used to compare variables between the two groups. Spearman correlation coefficient was used to assess inter-observer agreement. The results were considered statistically significant if the P value was less than 0.05.

Surgical Procedure

Surgical procedure was done under GA through nasotracheal intubation. Transoral incision was done followed by reflection of the periosteum to expose anterior border of ramus, buccal cortex and external oblique ridge, so that fracture line can be exposed. Inter-maxillary fixation was done to restore occlusion. In case of SSOP fixation, minimal bending (if needed) was done to the plate before its fixation to adapt passively on the superior border of buccal cortex. Then, transbuccal trocar was used to drill 2.0 mm mini monocortical screws using a drill of 1.5 diameter with copious saline irrigation and fixation of the SSOP was done. (Figs. 1, 2). While in case of two miniplates, further reflection and stripping of periosteum from buccal cortex was done till exposing inferior border of the mandible. The two miniplates were then bent to follow the contour of the buccal cortex, where the first plate was placed superiorly and the second plate was placed inferiorly parallel to the inferior border of the mandible. Screws of the first plate were fixed monocortically, while the second plate was fixed bicortically using transbuccal trocar. (Fig. 3). Nine cases in the intervention group were associated with parasymphyseal fracture, 9 cases of control group were associated with parasymphyseal fracture and 1 case with body fractures. These fractures were reduced and fixed using 2 miniplates or superior miniplate and inferior 2.3 plate. All surgical procedures were performed by the same team. The operating time was measured using stopwatch from the start of the incision, reflection, adaptation and bending of the plates to the mandible until the end of drilling of the last screw.



Fig. 1 Showing fixation of angle fracture using SSOP



Fig. 2 Showing radiographic fixation of angle fracture using SSOP

Results

This study was conducted on 38 patients, 31 males and 7 females, with an overall mean age of 28.26 ± 9.54 , and with a mean age of 26.5 ± 7.3 for the intervention group, while 30 ± 11.3 in control group. The main cause of trauma was RTA followed by assault, fall from height and sport injury (50, 21.07, 15.78, 13.15% respectively). The control group had a longer operation time compared to the intervention group (44.5 ± 9.7 , 30 ± 8.7 respectively). There was a statistically significant difference between the 2 groups. (P value < 0.001).

All the patients were followed up after 1 week, 1 month and 3 months to assess occlusion, 100 edema, wound dehiscence, mouth opening and nerve affection (Table 1). Any patient with disturbed occlusion, persistent edema, wound dehiscence, limited mouth opening and nerve affection after 3 months was considered as a complication case and the overall complications for all the patients were calculated in each group. Radiographic outcomes were assessed immediately postoperatively and after 3 months,

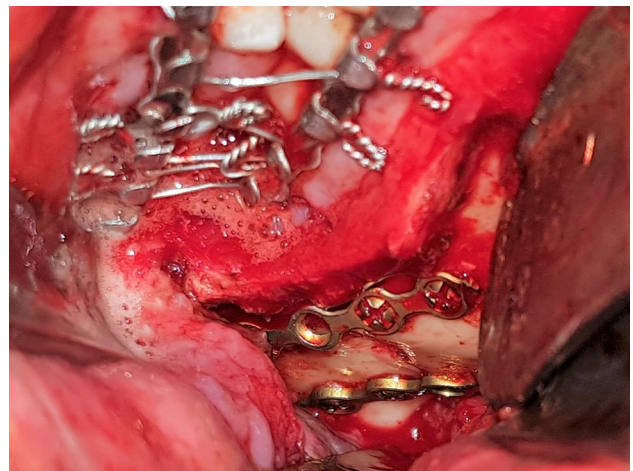


Fig. 3 Showing fixation of angle fracture using 2 miniplates

Table 1 Clinical outcomes assessment

Parameters	Assessment method
Occlusion	Grade I: slight derangement of occlusion and no need for intervention Grade II: Slight occlusion derangement that needed correction by non-surgical means (spot grinding) Grade III: gross occlusal derangement with functional disability that needed reoperation
Edema	Mild [perceivable on palpation only] Moderate [evident on inspection] Severe [gross swelling]
Infection	If incision and drainage was needed to resolve infection it would be considered as a complication
Mouth opening	Mouth opening was measured by asking the patient if the pretraumatic mouth opening was restored or not
Postoperative inferior alveolar/ facial nerve involvement	Nerve affection was assessed using two point discrimination method
Time	

using 3D surgical planning software (Mimics 19.0; Materialise NV, Leuven, Belgium). Bone density was measured at the fixation site. The inter-ramus distance was measured between the two lingula, while intermental distance was measured between the two-mental foramen, immediately postoperatively and after 3 months. The difference between the 2 measurements were calculated to assess stability (change from immediate to three months). All radiographic measures were evaluated by 2 assessors and the final value was the mean of the 2 readings.

Occlusion The intervention group showed slightly better results than the control group, but there was no statistically significant difference between the 2 groups at different time points.

Mouth opening The intervention group showed faster return to pretraumatic mouth opening than the control group, but there was no statistically significant difference between the two groups immediately post-operative, after 1 month and 3 months.

Nerve involvement The intervention group showed less sensory deficits than the control group, but there was no statistically significant difference between the two groups at different time points.

Edema There was a statistically significant difference between prevalence of edema in the two groups after 1 week and after 1 month. However, there was no statistically significant difference between the two groups after 3 months.

Wound dehiscence none of the cases in the two groups had wound dehiscence.

Overall complications showed that the intervention group (10.50%) had less postoperative complication than the control group (31.06%). However, there was no statistically significant difference between both groups.

For radiographic outcomes the correlation coefficient showed almost perfect inter-observer agreement for inter-ramus distance, inter-mental distance, and bone density (0.993, 0.992, 0.999 respectively) with no statistically significant difference (P value < 0.05).

Inter-ramus distance both groups showed high stability. In the control group, the change in inter-ramus distance was (0.09 ± 0.16), while in the intervention group it was (0.05 ± 0.04) and there was no significant difference between both groups (P value = 0.708).

Inter-mental distance both groups showed high stability. In the control group, the change in inter-mental distance was (0.13 ± 0.10), while in the intervention group was (0.08 ± 0.09) with no significant difference between both groups (P value = 0.053).

Bone density immediate postoperatively, the bone density in the control group was less than the intervention group while there was a statistically significant difference between the two groups (547.18 ± 50.25 , 783.31 ± 51.11 , respectively), (P value < 0.001). After 3 months, the bone density in the control group was less than the intervention as well, and there was a statistically significant difference between the two groups (1132.07 ± 95.47 , 1560.63 ± 147.73 , respectively), (P value < 0.001). In the control group, the change in bone density was lesser than the intervention group (584.89 ± 74.17 , 777.32 ± 124.79 , respectively) with significant difference between both groups (P value < 0.001).

Discussion

Fixation of the angle fracture can be done through different methods. Among the most commonly used methods are the use of single or two miniplates which is still controversial. Advocates of absolute rigid means of fixation

encourage the use of two miniplate, while the advocates of the functionally stable occlusion encourage the use of single plate, especially in the isolated angle fracture. That is why the aim of our prospective clinical trial was to compare the stability and the clinical outcomes between the two miniplates and SSOP which is one miniplate in angle fracture fixation (Table 2).

In non-isolated angle fracture and unfavorable angle fractures that need a more rigid means of fixation due to the complex muscle forces, the use of 3D plate is more advantageous than single miniplate and it satisfied the biomechanical requirements of occlusal loading. However, its large size entails more metal use and more dissection needed to be done to fix the plate leading to more edema postoperatively [20].

SSOP acts as a 3D miniplate that has a straight section with four holes that act as one miniplate and its two lateral arms with one screw on each side aiding in resisting torsional and rotational forces [16, 19].

No patient in this study had wound dehiscence, this could be attributed to the use of transuccal trocar in fixation of SSOP and the 2 miniplates that was in accordance with ALkan et al. [8] who concluded that transoral plate is more vulnerable to dehiscence because of the thin oral mucosal coverage and excessive bending exhibited to adapt on external oblique ridge which ultimately weakens the metal. In addition, screw loosening is more common in the transoral plate due to the decreased density of bone on the superior aspect of the mandible in comparison to the thicker lateral cortical plate of the mandible where the transbuccal plates are fixated [8, 9].

In this study, the operative time in the intervention group was significantly less than the control group. That was in accordance with Jain et al. who concluded that fixation using two miniplates is time consuming [21].

In the intervention group, no patient complained of nerve deficit, while in the control group 3 patients complained but they regained their sensations after 3 months, following the

Table 2 Descriptive statistics of clinical outcomes showing frequency & percentage of each complication in the two groups

Complications	Time	Intervention (n = 19)	Control (n = 19)	P value
Malocclusion	Pre-operative	15 (78.9%)	16 (84.2%)	1.000
	1 week	3 (15.8%)	7 (36.8%)	0.141
	1 month	2 (10.5%)	3 (15.8%)	1.000
	3 months	2 (10.5%)	3 (15.8%)	1.000
Edema	<i>Pre-operative</i>			
	No edema	2 (10.5%)	2 (10.5%)	0.855
	Mild	4 (21.1%)	6 (31.6%)	
	Moderate	11 (57.9%)	8 (42.1%)	
	Severe	2 (10.5%)	3 (15.8%)	
	<i>1 week</i>			
	Mild	16 (84.2%)	3 (15.8%)	<0.001*
	Moderate	3 (15.8%)	14 (73.7%)	
	Severe	0 (0%)	2 (10.5%)	
	<i>1 month</i>			
	No edema	16 (84.2%)	3 (15.8%)	<0.001*
	Mild	3 (15.8%)	14 (73.7%)	
Moderate	0 (0%)	2 (10.5%)		
<i>3 months</i>				
No edema	19 (100%)	18 (94.7%)	1.000	
Mild	0 (0%)	1 (5.3%)		
Limited mouth opening	Pre-operative	17 (89.5%)	16 (84.2%)	1.000
	1 week	3 (15.8%)	7 (36.8%)	0.141
	1 month	0 (0%)	3 (15.8%)	0.230
	3 months	0 (0%)	0 (0%)	1.000
Nerve affection	Pre-operative	2 (10.5%)	3 (15.8%)	
	1 week	2 (10.5%)	7 (36.8%)	0.124
	1 month	0 (0%)	3 (15.8%)	0.230
	3 months	0 (0%)	3 (15.8%)	0.230
Overall complications		2 (10.5%)	6 (31.6%)	0.232

*Significant at $P \leq 0.05$

administration of vitamin B12 injection. Nerve involvement may be due to the use of bicortical screws for the inferior plate with subsequent injury to the IAN and that was in accordance to Wusiman et al. [20] who concluded a statistically significant difference in the incidence of paresthesia with two miniplates. In 2020, Konark et al. as well concluded that the use of 3D miniplates is accompanied with less sensory deficit [22].

The significant edema that was observed in the control group, could be attributed to the need of wider access that was achieved through the increased reflection to reach the inferior border of the mandible to fix the inferior plate and the prolonged time of surgery to fix two plates, which increased the swelling and tension on sutures postoperatively. That is in accordance with Ferrari et al. who concluded that postoperative swelling and transient hypoesthesia were significantly higher for the double-plate group compared with one miniplate [23].

There were no statistically significant differences at the different observation periods in inter-ramus and inter-mental distances. The two fixation methods can hold the bony segments and resist the muscle pull and occlusal forces. The bone density in the intervention group was statistically higher than that of the control group at all follow up intervals, which makes SSOP a reliable method for the fixation of angle fracture, even if it's associated with anterior mandible fracture [22].

The percentage of postoperative overall complications in the intervention group was 10.52%, which is less than the control group (31.57%). This result is in accordance with Al-Moraissi et al. [9] and Ferreira et al. [23] whom advocated using one miniplate as it had the lowest rate of postoperative complications, unlike the two miniplates.

Conclusion

Within limitation of this study, SSOP showed that it's a rigid means of fixation as it showed high stability; evident from the significant higher bone density when compared to two miniplates fixation. SSOP which is one miniplate is a reliable method of fixation of the angle fracture even if it's associated with anterior mandibular fracture with less postoperative complications especially in edema, with significantly shorter operating time than the traditional two miniplates. Nevertheless, further studies with larger sample size is needed to provide more evidence.

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Author's Contributions All authors contributed to the study conception and design, participated in material preparation, data collection and analysis were performed by all authors. All authors participated

in the creation of this manuscript and have read and approved the final manuscript.

Declarations

Conflict of interest The authors have no conflicts of interest to declare that are relevant to the content of this article.

Consent to Participate Eligible patients signed an informed consent before their participation in the study.

Consent to Publish Patients signed informed consent regarding publishing their data and photographs.

Ethical Approval The study followed the Declaration of Helsinki on medical research and the study was approved by the research ethics committee of Cairo University.

Human Participants and Animals The study followed the Declaration of Helsinki on medical research & the study was approved by the research ethics committee of Cairo University.

Informed Consent Eligible patients signed an informed consent before their participation in the study.

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