The aim of this study was to assess fracture stability and postoperative complications in patients with isolated mandibular angle fractures after open reduction and fixation with external oblique ridge six-hole non-compression Suer K miniplate compared to lateral border conventional six-hole non-compression titanium straight miniplate. The study was conducted on 24 patients divided randomly into two equal groups according to the used plates. Intraoperative time was measured, occlusion and edema were assessed in both groups. Postoperative CT was performed immediately and after 3 months. Intraoperative was longer for the study group (43.6 ± 8.7 minutes) compared to the control group (36.3 ± 11.2 minutes), with no statistical significance difference between the two groups (P-value 0.09). Regarding occlusion and edema, the study group showed slightly better results after 1 week and 1 month, with no statistical significance difference between the two groups (P-value 0.59, 0.478, 0.53, 0.53, respectively). Interramal distance change showed highly stable and comparable results (0.067 ± 0.063 mm control, 0.073 ± 0.044 mm study) with no statistical significance difference between the groups (P-value 0.76). This study showed that Seur K plate is a safe and effective alternative to the single miniplate in treating non comminuted minimally displaced angle fractures.
This philosophy gained a great popularity throughout years. Since then, a controversy has been raised regarding the philosophy of rigid fixation using two plates versus the philosophy of functional stable fixation using one plate. A new miniplate design was introduced by Suer et al combining advantages of both the transbuccal lateral cortex approach and Champy intraoral approach. The new non-compression Suer K miniplate has one straight section with 4 holes to be placed along the external oblique ridge, and two lateral extensions to extend on the lateral cortical plate aiming to displacing the lateral forces that are exerted on the miniplate.

The new plate was assessed using both an experimental study and a finite element analysis and showed promising results regarding resistance to lateral displacement, vertical compressive, and tensile forces. Nevertheless, no previous clinical have been conducted on this new plate. The aim of this study was to answer the following clinical question: In patients with isolated mandibular angle fractures indicated for open reduction and internal fixation, what will be the effect of using external oblique ridge six-hole non-compression Suer K miniplate on fracture stability and postoperative complications compared to lateral border conventional six-hole non-compression titanium straight miniplate?

**PATIENTS AND METHODS**

**Trial design**

This was a randomized controlled trial conducted on patients with isolated mandibular angle fractures indicating the need of open reduction and internal fixation using plates and screws. Patients were randomly divided into two equal groups according to the plates used for fracture fixation. The six-hole non-compression titanium Suer K miniplate fixed on the external oblique ridge was used for the study group, while conventional six-hole non-compression titanium straight miniplate fixed on the lateral cortex was used for the control group.

**Participants**

This study was conducted on 24 patients recruited consecutively from the out-patient clinic, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Cairo University. Patients were selected according to the following criteria: 1. Adult patients 2. Isolated, non-comminuted mandibular angle fractures indicated for open reduction and internal fixation 3. Sufficient dentition to establish proper occlusion. Exclusion criteria: 1. Patients with any medical condition that contraindicates the surgical procedures or affect predictable outcome 2. Infected fracture and osteomyelitis. All operations were performed by the same surgical team. The study followed the Declaration of Helsinki on medical research.

All patients were operated under general anesthesia. The fractures were exposed through an intraoral incision along the external oblique ridge. (Figure 2)

**Interventions**

A brief medical and dental history was taken followed by clinical and radiographic examination using panoramic radiograph to assure patients accordance with the eligibility criteria. (Figure 1) Demographic characteristics, fracture characteristics, and base line outcome variables data were collected for all enrolled patients.
and transbuccal approach with small skin incision and a transbuccal trochar (Figure 3).

**Figure 3:** Conventional six-hole straight miniplate adapted and fixed on the lateral surface of the external oblique ridge.

while for the study group, six-hole K miniplate was used. The Suer K plate has one straight section with 4 holes and two lateral extensions, each has one hole, but the proximal extension is longer. The straight section was adapted superiorly on the external oblique ridge, and the lateral extensions were bent over the external oblique ridge buccally. The plate was finally screwed to the bone using a combined oral and transbuccal approach using small skin incision and a transbuccal trochar (figure 4).

**Figure 4:** A) The new non-compression Suer K miniplate with 4 holes straight section to be placed along the external oblique ridge, and two lateral extensions to extend on the lateral cortical plate aiming to displacing the lateral forces that are exerted on the miniplate. B) Suer K miniplate adapted and fixed in place.

Finally, IMF was removed, occlusion was checked, and incision was closed. No rigid postoperative IMF was used for any patient; however, elastics were used if indicated and left as long as necessary to obtain the proper occlusion. Antibiotics were prescribed for 7 days postoperatively, and patients followed a soft diet for 2 weeks.

**Outcomes**

Intraoperative time was measured from the start of incision till fixation. Surgeon’s assessment of ease of plate application and fixation was categorized as simple, some difficulty, or very difficult. All patients were followed up clinically at 1 week, 1 month, 3 months, and 6 months to assess wound problems as dehiscence, infection, plate exposure. Occlusion was also assessed for each patient and categorized in one of three grades.

Grade I: Satisfactory with complete interdigitation and no intervention needed. Grade II: Minimal derangement indicating the need of the correction using spot grinding, or elastic IMF. Grade III: Gross derangement with functional disability indicating the need of reoperation.

Edema was assessed using four grades. Grade 0: No edema. Grade 1: Mild edema, perceivable on palpation only. Grade 2: Moderate edema, local and evident on inspection. Grade 3: Severe edema, extended swelling. Mouth opening was assessed by asking the patient about pre-traumatic mouth opening restoration.

The overall complications were then recorded for each patient as either complicated case or not. Any case with infection indicating incision and drainage, plate removal, non-union/malunion was considered as complicated case. Any patient with wound dehiscence, disturbed occlusion, persistence edema, and non-restored mouth opening after 3 months was considered also as complicated case.

CT scans were performed for each patient immediate postoperatively and after 3 months, and radiographic outcomes were assessed by the radiologist using 3D surgical planning software (Mimics 19.0; Materialise NV, Leuven, Belgium). Fracture reduction and fragments alignment was evaluated as good, moderate, or poor by a surgeon not involved in the surgical procedures. Bone density was measured at the fixation site at immediate and 3 months CT, and the different between the two time points was calculated. The inter-ramal distance was measured as the distance between the two lingule for each patient at immediate and 3 months radiographs. Fracture stability was calculated for each patient as the absolute difference between 3 months and immediate radiographs. (Figure 5)

**Figure 5:** Interramal distance measured using 3D surgical planning software.
Statistical methods
Statistical analysis was performed using SPSS (Statistical package for the social sciences- IBM® SPSS® Statistics Version 22 for Windows, IBM Corp., Armonk, NY, USA). Quantitative data was represented as mean ± standard deviation. Data was 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 non-parametric data, Mann-Whitney U test was used to compare variables between the two groups. Qualitative data was represented as percentage or frequency. Chi-square test and Fisher's exact test were used to compare variables between the two groups. The results were considered statistically significant if the P value was less than 0.05.

RESULTS

This was a randomized controlled trial conducted on 24 patients suffering from isolated angle fracture with mean age of 27.58 ± 10.97 years. The trauma was mainly due to motor vehicle accidents followed by interpersonal violence, sport injury, and fall from height (54.16 %, 20.83 %, 16.67%, 8.33%, respectively). The right side was affected in 58.33 % of the patients, and the left side in 41.67%. The mean age for control and study groups was comparable, and there was no statistical difference between the two groups (28.75 ± 13.09, 31.25 ± 12.38 years, P-value 0.64). Male patients over numbered females in both groups (control: 75% males, 25% females; Study: 83.3% males, 16.7% females), and there was no statistical significance difference (P-value 0.62).

Intraoperative was longer for the study group (43.6 ± 8.7 minutes) compared to the control group (36.3 ± 11.2 minutes), but there was no statistical significance difference (P-value 0.09). Surgeon’s assessment of ease of plate application and fixation for the control group was 75% simple, 16.7% some difficult, and 8.3% very difficult. While for the study group was 83.3% simple, 16.7% some difficult, but there was no statistical significance difference between the two groups (P-value 0.59).

No patients showed dehiscence in the control group, while one patient (4.17%) in the study group showed wound dehiscence. There was no statistical significance difference between the two groups (P-value 1). The dehiscence occurred after 12 days and was treated using saline irrigation, antiseptic mouthwash and oral hygiene measures until complete healing.

In control group, the occlusion was satisfactory in 9 patients (75 %) and 3 patients (25%) showed minimal derangement after 1 week. After 1 month, 2 patients (16.7%) only showed minimal derangement. After 3 months, the occlusion was satisfactory in all patients.

For one patient the occlusion was corrected using spot grinding, while for the other two patients, elastic IMF was used, and satisfactory occlusion was restored. In the study group, the occlusion was satisfactory in 11 patients (91.7 %) and one patient (8.3%) showed minimal derangement after 1 week. After 1 month, the occlusion was satisfactory in all patients. The patient with minimal derangement was treated by elastic IMF. The study group showed slightly better results after 1 week and 1 month, but there was no statistical significance difference between the two groups (P-value 0.59, 0.478, respectively).

In the control group, 10 patients (83.3%) showed mild edema and 2 patients (16.7%) showed moderate edema after 1 week. After 1 months, 10 patients (83.3%) showed no edema and 2 patients (16.7%) showed mild edema which resolved in the next follow up. In the control group, 11 patients (91.7%) showed mild edema and 1 patient (8.3%) showed moderate edema after 1 week. After 1 months, 11 patients (91.7%) showed no edema and 1 patient (8.3%) showed mild edema which resolved in the next follow up. The study group showed slightly better results after 1 week and 1 month, but there was no statistical significance difference between the two groups (P-value 0.53, 0.53, respectively).

In control group, the mouth opening was not restored in 7 patients (58.3 %) after 1 week. After 1 month, 4 patients still have non restored mouth opening (33.3 %). In the next follow up all patients restored pretraumatic mouth opening. In study group, the mouth opening was not restored in 6 patients (50 %) after 1 week. After 1 month, 4 patients still have non restored mouth opening (33.3 %). In the next follow up all patients restored pre-traumatic mouth opening. Both groups showed comparable results at different time point, with no statistical significance difference (P-value 1). Regarding over all complication and clinical assessment all cases in both groups was considered as uncomplicated cases.

For radiographic outcomes, fracture reduction was assessed as good for all patients except 1 patient in the control group, and there was no statistical significance difference (P-value 1). Interramal distance change showed highly stable and comparable results (0.067 ± 0.063 mm control group, 0.073 ± 0.044 mm study group) with no statistical significance difference between the groups (P-value 0.76). The bone density was comparable for both group at immediate and 3 months postoperative assessment (Control: 776.2 ± 59.1, 1105.6 ± 93.4 HU; Study: 783.3 ± 143.2, 1048 ± 80.4 HU), and there was no statistical significance difference between the groups (P-value 0.87, 0.55, respectively). The bone density change was also comparable in the two groups (Control: 329.4 ± 73.8 HU; Study: 300.6 ± 116.4 HU), and there was no statistical significance difference between the groups (P-value 0.48).
DISCUSSION

Several treatment modalities of isolated mandibular angular fractures were developed throughout the last years in the literature; however, the original Champy’s technique still one of the most commonly used techniques to treat it. Champy et al depends in their theory on the analysis of the regional dynamic forces fall on the angle bone. Analysis of bone mechanics at the angle region revealed that angle fractures under function tend to splay along the superior border due to the tension forces while inferiorly the compression forces tend to close the fracture bony edges together. Based on this analysis, numerous authors applied a single miniplate on the superior border of the external oblique ridge to control the fragments in mandibular angular fractures.[10,19]

Later, another debate was raised regarding using the plate anteriorly on the external oblique ridge via intraoral approach or on the lateral border via combined approach, intraoral and transbuccal approaches.[20, 21] In a meta-analysis, Al-Moraissi et al compared the use of one miniplate anteriorly along the external oblique ridge using intraoral approach versus lateral cortex using intraoral and transbuccal approaches and revealed that the transbuccalca placed miniplate showed superior results over the transorally plate. [2]

Several trials were done to design geometric miniplates[22,23,24,25,26] and their results were compared to the single mono-cortical non compression miniplates. A significant decrease was seen in the incidence of postoperative complications using geometric miniplates than with conventional miniplates.[2] B.T. Suer et al, designed a new non-compression K-miniplates. Suer K-miniplate has the advantages of Champy miniplate as a simple technique using simple miniplate, in addition to the advantages of the lateral border plates in neutralizing the lateral forces falling on the miniplate.[17] In this study we aimed to compare Suer K- miniplate versus the lateral border conventional six-hole straight miniplate in fixation of isolated angular fractures regarding the fracture stability and the incidence of postoperative complications.

In this study we choose the control group to be the lateral border single miniplates that utilize intraoral and transcucal approaches not the traditional Champy miniplate that extend anteriorly on the external oblique ridge because the superior results of it based on the meta-analysis done by Al-Moraissi et al [2], faci et al [4] and studies done by Sugar AW et al [29], Kumar S et al [20], Laverick S et al [22] and Wan K et al. [13]

Postoperative complications were comparable in both groups. The study group showed mucosal dehescence in only one case (4.17%) 12 days postoperative follow-up and resolved by 2 weeks. Subsequent follow-up visits demonstrated no evidence of dehescence recurrence or infection. While no cases showed dehescence in the control group. The dehescence in the Suer K -miniplate may occurred due to the more superficial position of the plate with the thin covering mucosa in comparison to the lateral border miniplate. These results were much less than Pandey et al dehescence percentage of 33.3% of cases [22] and Pal et al [21] that showed dehescence percentage of 11% of cases.

The operating time of Suer K-miniplate was longer than the lateral border miniplate. This finding was consistent with studies done by Mishra et al [21], Jain et al [28] and Singh et al [29] who found that the geometric miniplate system took more time in the angle region as compared with single miniplates. However there was no significant difference between the two groups and this is similar to Al-Moraissi et al results (p = 0.141 between two groups).[2]

The postoperative mouth opening in both groups showed almost equal results at different time point and there wasn’t statistical significance difference between the two groups. This may slightly differs from Mishra et al [21] results at 7th postoperative day findings as there was a significant difference between the geometric miniplates and the single miniplate. This may be due to their design of the geometric plate that needed more perioisteal stripping than the Suer K-miniplate. However the postoperative mouth opening at the end of the follow up showed similar results with Mishra et al [21] and Vineeth et al.[24]

Regarding the occlusion, the Suer k-miniplate showed superior results by the end of the 1st month but there wasn’t statistical significant difference between the two groups by the end of (3) months postoperative. Vineeth et al [24] showed no difference in the postoperative occlusion neither one month, (3) months postoperatively.

For radiographic outcomes both groups showed highly stable fixation and there was no significant statistical difference between the two groups by the end of the follow up period. These findings are similar to Mishra et al [21], Vineeth et al [24]; however the initial stability in both studies was higher in the Suer K miniplate. This finding may be due to the box plate design of their geometric plate which differs from Seur k-miniplates that we used in our study.

The Suer K plate showed promising and comparable results. It is a safe and effective alternative to the single miniplate in treating non comminuted and minimally displaced mandibular angle fractures; subjected to further studies with larger sample size.

CONFLICT OF INTEREST

This clinical study was self-funded by the author, with no conflict of interest.
REFERENCES


