Original Article

Clinical Outcomes of Double Mini-Plating Compared with a Single Superior Plating in Midshaft Clavicular Fractures: A Randomized Clinical Trial Study

Meisam Jafari Kafiabadi, Amir Sabaghzadeh, Saber Barazandeh Rad, Amin Karami, Mehrdad Sadighi, Farsad Biglari

Department of Orthopedic Surgery, Clinical Research Development Unit of Shohada-e Tajrish Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Abstract

Background: In the current study, we aimed to assess the clinical outcomes of the double-plating method using 2.7 mm compression plates compared with the single superior 3.5 mm compression plating method in displaced midshaft fractures of the clavicle.

Materials and Methods: Thirty patients with midshaft fractures of the clavicle were randomly assigned into two groups. In group A, 15 patients were fixed by a double-plating technique using two 2.7 mm compression plates on the superior and anteroinferior sides of the bone. The fractures in group B were fixed by a superior plating technique using a single 3.5 mm compression plate. Intraoperative bleeding measurement, length of surgical incision, duration of procedure time, and functional scores were assessed post-surgically through one-year follow-ups.

Results: There was no significant difference between groups in terms of surgery time. Device failure was not found among all recruited patients. Incision length and device prominence complaint were significantly different between groups (P value = 0.02, P value = 0.03). Mean ± standard deviation intraoperative bleeding rate was 88.67 ± 29.96 milliliter in the double-plating group and 108.67 ± 41.72 milliliter in the other group, which was not different between these two groups (P value = 0.14). There were no signs of non-union either in radiographies or clinically.

Conclusion: Double mini-plating of diaphyseal clavicular fractures could result in a smaller surgical incision and a lower rate of prominence without affecting fixation stability and clinical outcomes in comparison with single superior 3.5 mm plates.

Keywords: Clavicle, fracture, plating

Address for correspondence: Dr. Farsad Biglari, Department of Orthopedic Surgery, Shohada-e-Tajrish Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran.
E-mail: biglari.farsad@gmail.com
Submitted: 23-Jun-2023; **Revised:** 30-Sep-2023; **Accepted:** 01-Oct-2023; **Published:** 29-Nov-2023

Introduction

Clavicle fractures are among the most frequent fractures of shoulder girdle, accounting for 10% of all fractures.[1] The midshaft region of the clavicle is the narrowest part of the bone and subsequently, fractures of this area contain more than 80% of clavicular fractures.[2] Based on the recent studies, surgical fixation of displaced middle-third clavicle fractures results in better functional outcomes than non-operative treatment. Furthermore, non-union and malunion rates after surgical treatment are considerably lower. The rigid fixation of clavicle might be challenging due to the considerable movement of clavicle in all three planes of motion. Various operative solutions for clavicle fractures have been proposed, ranging from intramedullary pinning with Kirschner wires[3] and the utilization of cannulated screws[4] to clavicle-locking plate fixations.[5] Superior plating was known as an accepted method of surgical fixation in the middle-third fractures of the clavicle. Lately, some studies have shown the benefits of double-plating for displaced fractures of the middle third of

Access this article online

Quick Response Code:

Website: www.advbiores.net

DOI: 10.4103/abr.abr_221_23

How to cite this article: Jafari Kafiabadi M, Sabaghzadeh A, Barazandeh Rad S, Karami A, Sadighi M, Biglari F. Clinical outcomes of double mini-plating compared with a single superior plating in midshaft clavicular fractures: A randomized clinical trial study. Adv Biomed Res 2023;12:265.

the clavicle.[6] However, the priority of double-plating as a surgical method of choice is yet to be defined. On the other hand, there are different combinations of 3.5, 2.7, and 2.4 mm plates in the literature.[7] Therefore, selecting the proper device for dual-plating is still unclear. Choosing the optimal surgical method provides better functional outcomes and union rate with the minimum surgical-related problems such as wound complications, bleeding, device prominence, and cosmetic issues. In the current study, clinical outcomes of double-plating method using 2.7 mm compression plates were studied and compared with a single superior 3.5 mm compression plating method in displaced midshaft fractures of the clavicle. The null hypothesis is that there is no statistically significant difference in the incidence of non-union between the two groups under investigation.

Materials and Methods

This study was conducted as a single-blind randomized clinical trial from January to December 2022 at the Department of Orthopedic Surgery of Shohada-e Tajrish Hospital affiliated to Shahid Beheshti University of Medical Sciences, Tehran, Iran. The ethics committee of Shahid Beheshti University of Medical Sciences approved the protocol of this study (Code: IR.SBMU.RETECH.REC.1400.518), and this study is also registered in the Iranian Registry of Clinical Trials (IRCT registration number: IRCT20211201053235N1). Study protocol link: https://www.irct.ir/trial/60348.

In this clinical trial, patients with midshaft fracture of the clavicle were enrolled in the study and candidates for surgical treatment based on the following indications. The inclusion criteria were clavicular fractures with displacement of more than 2 cm and multi-fragmented or segmental fractures. The exclusion criteria were fractures of the medial or distal third of the clavicle, cases with a different method of surgery compared with the described methods in this study, open fractures, concomitant fracture of the ipsilateral upper extremity, neurovascular injury, and history of previous injury to the same shoulder griddle. Furthermore, patients younger than 18 years old or older than 60 were excluded from the study. All participants in this study signed an informed consent form at the beginning of study.

According to Hertzog *et al*. study,[8] in pilot studies, samples ranging in size from 10 to 40 per group are sufficient to achieve possible objectives; therefore, we started this study as a pilot with fifteen patients in each group. In order to randomly divide the patients into two groups, a list of random numbers A and B (found at graphpad.com) was used. The patients were divided into two groups by the simple randomization method based on the numbers assigned to them based on the table of random numbers. The patients who met the inclusion criteria underwent surgery by a single orthopedic surgeon specialist. Assessment of patients and data collection and insertion in the SPSS software were performed by orthopedic surgeon specialist. In the SPSS file, grouping data were added by another person as groups 1 or 2. The analyzer of the data knew the allocation of patients.

All patients underwent general anesthesia, and the procedure was performed in semi-sitting position. Clavicle fractures in group A were fixed by a double-plating technique using two 2.7 mm compression plates on the superior and anteroinferior sides of the bone and six screws for each plate, a combination of at least three screws placed on each side of the fracture site, allowing the plate to maintain reduction [Figure 1]. The fractures in group B were fixed by a superior plating technique using a single 3.5 mm compression plate and eight screws or six screws plus one lag screw [Figure 2]. The plates have been made in Atlas Bone Teb Co. in Tabriz, Iran. Reduction of the fracture site and fixation quality was checked under C-ARM control. Hemovac drain was used for all the cases and removed 24 hours after surgery. Surgical wounds were closed in three layers in the same manner and with the same suture materials. The patients were advised to start active and passive shoulder range of motion. Afterward, on the 6th week of post-surgical period, they were recommended to attend strengthening exercises under the supervision of an experienced physiotherapist.

Demographic information of the patients including age, sex, body mass index, and dominant hand was collected. Baseline characteristics of patients which might be possible confounders such as being smoker or drinker, dominant side fracture, concomitant fractures, and comorbidities were collected. Furthermore, underlying medical comorbidities (diabetes mellitus, ischemic heart disease, etc.) were also recorded. The surgical-related parameters were collected and assessed, including intraoperative bleeding measurement, length of surgical incision, and duration of procedure time. The surgeon measured the amount of bleeding during the operation based on the number of bloody sterile gauze pads, surgery time was recorded by a watch and the surgical incision length was also measured with a ruler during the operation by the surgeon. All the patients were followed at 2, 6, and 12 weeks post-surgery for

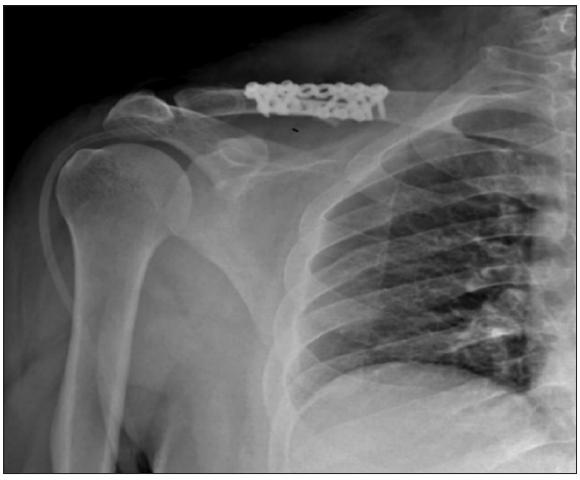

Figure 1: Right shoulder anteroposterior radiograph of a patient with diaphyseal clavicular fracture fixed by using two 2.7 mm compression mini-plates

assessment of surgical-related wound complications. Surgical wound complication and surgical site paresthesia were examined in the ward and follow-ups after operation by the surgeon. Moreover, device prominence and failure, and functional scales were investigated for 1 year postoperatively by orthopedic surgeon. Functional scales were assessed based on the American Shoulder and Elbow Surgeons (ASES) scale and Disabilities of Arm, Shoulder, and Hand (DASH) score at one-year follow-up visit. Our primary outcome was device prominence complaint. Secondary outcomes were non-union, device failure, ASES and DASH functional scores, intraoperative bleeding measurement, length of surgical incision, surgery time, surgical wound complication, and surgical site paresthesia.

Data was statistically analyzed by SPSS software, version 26. Then, 1-sample KS test confirmed the normal distribution of data and the independent *t*-test was applied. We also used Chi-square test to compare the qualitative ratios. The significance level was considered less than 0.05. To discretional analysis of quantitative and qualitative variables, we used mean ± SD and frequency, respectively.

Results

Thirty patients with displaced midshaft clavicular fractures were recruited, and clavicles were fixed with locking plates [Figure 3]. All plates were placed on the superior aspect of the clavicle. In the dual-plate group, 15 clavicles were fixed using two 2.7 mm mini-plates in superior and anteroinferior fracture sites [Figure 1]. Baseline characteristics of patients which might be possible confounders such as being smoker or drinker, dominant side fracture, concomitant fractures, and comorbidities were analyzed between groups [Table 1]. There was no significant difference between groups in terms of these basic characteristics ($P > 0.05$).

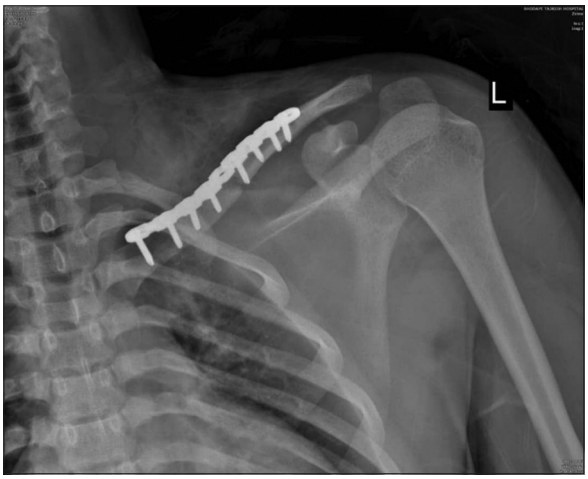

Figure 2: Left shoulder anteroposterior radiograph of a patient with diaphyseal clavicular fracture fixed by using single superior 3.5 mm compression plate

Mean ± standard deviation surgery time was 77.60 ± 20.66 minutes in the dual-plating group and 86.67 ± 28.26 minutes in the other group, which was not significantly different between groups in terms of surgery time [Table 2]. Mean ± standard deviation incision length was 7.87 ± 0.74 centimeters in the dual-plating group and 9.73 ± 1.33 centimeters in the other group, which was significantly different between these groups (P value = 0.02). Complications in the double-plate group were limited to one surgical wound complication and one surgical site paresthesia. Complications in the single-plate group were limited to two wound surgical wound complication and two surgical site paresthesia. Device failure was not found among all recruited patients. Nine patients in the single-plate group complained about device prominence (60%), which was significantly different (P value = 0.03) in comparison with four patients (26.6%) in double-plate group who had complaint about the device prominence. Mean ± standard deviation intraoperative bleeding rate was 88.67 ± 29.96 ml in the dual-plating group and 108.67 ± 41.72 ml in the other group, which was not significantly different between these two groups (P value = 0.14). Considering non-union rate of the fracture site, six months after surgery, all patients were followed up and visited. There was not any sign of non-union either in radiographies or clinically.

In the single-plate group, the average ASES and DASH functional scores at 12 months were 90.86 ± 8.78 and 4.85 ± 2.82, respectively. In the dual-plate group, the average ASES and DASH functional scores at 12 months were 94.33 ± 6.48 and 5.41 ± 3.56, respectively [Table 3]. When comparing groups at 12 months, no significant difference existed in these functional scores (P = 0.07, P = 0.36, respectively) between the single-plate and the dual-plate groups.

Table 1: Baseline characteristics of patients randomized to dual group and single group

Variables	All participants (n=30)	Dual group (n=15)	Single group (n=15)	P*
Age (years) Mean±SD	33.23±12.25	32.66±12.29	33.80±12.62	0.80
BMI (kg/m^2) Mean±SD	23.86±4.68	24.36±4.94	23.86±4.52	0.56
Smoker *n* (%)	5 (16.7%)	3 (20%)	2 (13.3%)	0.63
Drinker *n* (%)	3 (10%)	1 (6.7%)	2 (13.3%)	0.55
Dominant hand side fracture *n* (%)	8 (26.6%)	3 (20%)	5 (33.3%)	0.36
Concomitant fractures *n* (%)	17 (56.7%)	8 (53.3%)	9 (60%)	0.72
Medical comorbidities *n* (%)	3 (10%)	1 (6.7%)	2 (13.3%)	0.55

*P value between groups is significant at the 0.05 level

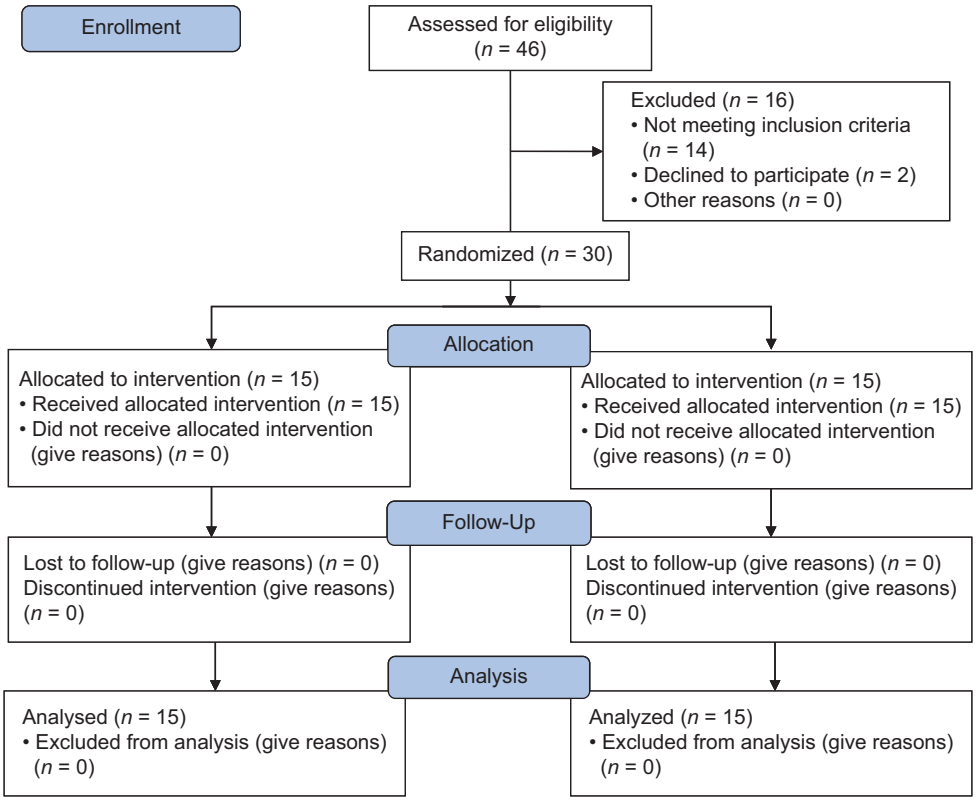

Figure 3: Flow diagram

Table 2: Comparing the two study groups in terms of intraoperative and postoperative variables

Variables	Dual-plating group (*n*=15)	Single plating group (*n*=15)	Mean difference	95% CI of difference	*P**
Incision length (cm)	7.87±0.74	9.73±1.33	-1.86	-2.67 to -1.05	0.02
Surgery time (minutes)	77.60±20.66	86.67±28.26	-9.06	-27.58 to 9.45	0.08
Surgical site paresthesia**	1 (6.7%)	2 (13.3%)			0.54
Surgical wound complication**	1 (6.7%)	2 (13.3%)			0.54
Device failure**	0	0			0
Non-union**	0	0			0
Prominent device**	4 (26.6%)	9 (60%)			0.03
Bleeding during surgery (milliliter)	88.67±29.96	108.67±41.72	-20.00	-47.17 to 7.17	0.14

**P* value between groups is significant at the 0.05 level. **Chi-square test was used to compare the qualitative ratios between groups

Table 3: Comparing functional outcomes between two groups after one year

Variables	Dual group (*n*=15)	Single group (*n*=15)	Mean difference	95% CI of difference	*P**
ASES	94.33±6.48	90.86±8.78	3.46	-2.30 to 9.24	0.07
DASH score	5.41±3.56	4.85±2.82	0.56	-1.68 to 2.80	0.36

**P* value between groups is significant at the 0.05 level

Discussion

In contrast to past studies, recent investigations showed surgical fixation leads to lower rate of non-union and better functional outcomes in patients with displaced midshaft clavicular fractures.[7] However, thin soft tissue coverage of this area makes it susceptible to surgical-related wound complications and device prominence. Single superior plating of the clavicle bone is an accepted method of surgical fixation for displaced midshaft clavicular fractures. Recent studies reported a high rate of reoperation in single superior plating due to fixation failure, deep infection, and implant irritation.[1,9,10] However, the results of previous studies were antonym.[6,11,12] The current study statistically revealed no difference in device failure, surgical wound complication, and non-union rate between double mini-plating group and single 3.5 mm plating group. In one excluded case due to different surgical methods, double mini-plates were fixed with only four

screws for each plate. Four weeks after surgery with starting shoulder range of motion, both plates failed and the patient required revision surgery. It was revealed that the fixation of mini-plates with four screws might be unreliable. Among intra-surgical parameters, incision length was statistically shorter in double mini-plating group compared with single plating group. However, surgery time and bleeding during surgery did not differ between these two groups. Zhuang *et al*. used the double-plating technique with a 3.5 mm locking plate plus a mini-plate for comminuted clavicular fractures.[6] They reported better union rate and functional outcomes of double-plating than a single 3.5 mm locking plate fixation in comminuted clavicular fractures.[6] Newly, some biomechanical studies showed the advantages of midshaft clavicular fracture fixation with double mini-plates.[7] Ziegler *et al*. reported similar biomechanical outcomes of double-plating construct in comparison with superior or anteroinferior single plating.[13] They found that the fixation of clavicular fracture with double mini-plates construction could be as stiff as single 3.5 mm plate against axial loading, bending, and torsional stress forces. Zhang *et al*. in another biomechanical study reported similar results and found no significant difference between rigidity of single- and dual-plating constructs.[13] In contrast, Prasarn *et al*. showed single superior plating with 3.5 mm locking plate was stiffer than double mini-plates construction against anterior loads, while dual-plating construction was more rigid against superior loads.[14] There was no significant difference between these two groups against axial loading and torsional forces.[14] In double mini-plating, the first plate can help us in reduction while placing the other plate, and we have more screwing points. In this fixation technique, plates act as washers for the screws and keep the anterior fragments in place.[14] In double-plating, 2.7 mm mini-plate offers good contouring due to its lower profile.[15] As opposed to mentioned studies, Boyce *et al*. in a biomechanical study showed double mini-plates fixation of the clavicle could result in lower stiffness in comparison with single 3.5 mm superior plating. There are few clinical studies in the literature about clinical outcomes of double-plate fixation of the clavicular fractures, especially double mini-plate construction. However, most of them are retrospective studies.[16] DeBaun *et al*. in a retrospective cohort study showed similar clinical outcomes of midshaft clavicular fracture fixation with dual mini-fragment plating or precontoured small fragment plating. Although the rate of symptomatic implants among single 3.5 mm plating group was more than double mini-plating group, the difference was not statistically significant.[17] Allis *et al*. and Czajka *et al*. in separate retrospective comparative studies, reported the rate of reoperation was significantly lower in dual mini-plate group compared with a single superior 3.5 mm plate group.[12,18] Recently, Sheth *et al*. in a systematic review showed the rate of device removal was significantly lower in dual-plating group compared with single plating.[9] The other parameters including union rate, clinical outcomes, and other complications were not significantly different between the groups.[9] The results of the current study showed a lower rate of device prominence in double mini-plate groups compared with superior 3.5 mm plating. In the current study, ASES and DASH scores after one year of follow-up were not statistically different between these two groups. In the single 3.5 mm plating group, sixty percent of patients complained about the prominent device, which was statistically higher than the mini-plating group. Overall, it seems double mini-plating of clavicular fractures could be an acceptable and reliable alternative for single 3.5 mm plates with similar clinical outcomes, smaller surgical incisions, and a lower rate of the prominent device.

Conclusions

According to this study, fixation of diaphyseal clavicular fractures by using two 2.7 mm compression mini-plates without affecting fixation stability and clinical outcomes could result in a smaller surgical incision and a lower rate of prominent device in comparison with a single superior 3.5 mm plates.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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