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Research Article

Distal Radius Volar T Plate Versus Distal Clavicle Pre-Contoured Locking Plate in Neer 2b Distal Clavicle Fractur: A Randomized Controlled Trial

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Abstract

Background: The purpose of the current study was to compare the clinical and radiographic outcomes of distal radius volar T plate and pre-contoured locking plate in distal clavicle fracture.
Methods: A total of 60 patients with Neer 2b distal clavicle fracture were included in this study and underwent open reduction and internal fixation (ORIF) between March 2019 and November 2020 via two different plates, distal radius volar T plate and distal clavicle pre-contoured locking plate. All patients were followed at least two years post-operative. Union rate, time to union, need to device removal, and Constant-Murley score (CMS) were assessed among them.
Results: In all patients, the bony union was achieved without wound-related complications. The mean time to union in distal radius volar T plate group was 3.3 ± 0.6 months and in the pre-contoured locking plate group was 3.6 ± 0.7 (P = 0.14). The mean CMS was 93.1 ± 2.2 and 92.1 ± 2.5 in T plate group and pre-contoured plate group, respectively (P = 0.09). Five cases with T plate and eight cases with pre-contoured plate were candidates for device removal (P = 0.53).
Conclusion: Distal radius volar T plate could be a reasonable choice to manage Neer 2b distal clavicle fracture as it restores functional range of motion (ROM) with excellent bone union and without the necessity of device removal, besides its economical price.

Keywords: Clavicle; Bone Fractures; Fracture Healing; Treatment

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Background

Clavicle fracture is one of the most common fractures encountered in the emergency department (ED), and 2.6%-4% of all adult fractures are due to it (1, 2). The most frequent fracture site is midshaft fractures, followed by the distal end, which constitutes 21-28 percent of all clavicle fractures, and up to 52% are displaced (1, 3). Edwards et al. reported that 15% of clavicular fractures were distal and more likely to be associated with delayed or non-union than midshaft fractures (4).

There are many classification systems for this fracture, but Neer's classification is chosen in order to manage and predict its prognosis (5). According to this classification, the fracture is categorized based on its location to coracoclavicular (CC) ligaments. Type 1 is a fracture occurred lateral to CC ligaments, type 2 occurs medial to it, type 3 is associated with intra-articular involvement, type 4 occurs in pediatrics, and type 5 is an avulsion fracture of CC ligaments. Type 2 is subclassified as 2a where both conoid and trapezoid ligaments are attached to the distal fragment, while in 2b, the conoid is detached from the proximal fragment, and the trapezoid is attached to the distal. Cho et al. described type 2c (6), in which both conoid and trapezoid are detached from the proximal fragment that is not amenable to traditional hardware (7).

As a result of the significant mechanical demands related to these specific anatomic considerations, type II fractures are difficult to stabilize by non-operative methods and have a 30% rate of non-union (8). Therefore, non-union rates of type 2 fractures are high, quoted at 22%-33% in the literature (4, 5, 9). Because revision surgery of established non-unions can be very challenging, there is increasing support in the literature suggesting that these fracture types should be treated surgically (4, 5, 10-15). Treatment and prognosis of the distal clavicular fracture depend on the integrity of CC ligaments and fracture displacement, which make the fracture unstable; hence, the treatment of type 2b remains controversial, and there is no preferred treatment up to now (16).

There is a dearth of research on the best way to treat these unstable fractures; hence, we aimed to compare the distal radius T plate with clavicular pre-contoured locking plates in Neer 2b distal clavicular fracture (Figure 1).

Figure 1. A T-plate

Methods

After ethicl approaval from the Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran (IRSBMUMSP.REC.1400.779), the present prospective, randomized controlled trial (RCT) compared the efficacy of pre-contoured locking plate and 3.5 mm T plate in the treatment of Neer 2b distal clavicular fracture.

The study participants included 60 patients who presented to the ED of Taleghani Hospital, Tehran, with Neer 2b distal clavicular fracture from March 2019 to November 2020. Upon admission, the patients were randomly assigned to one of the distal radius volar T plate or distal clavicular pre-contoured plate using the flipping coin method/random numbers generated by the random allocation software.

Patients with multiple injuries, pathological fracture or refracture, non-union, abnormal shoulder function before injury (rotator cuff injury, frozen shoulder), and previous surgical treatment for the clavicle or concomitant ipsilateral fractures of the shoulder girdle were excluded from the study.

All the surgeries were performed by the same surgical team in the same laminar air flow operating room. Patients were given one gram of cefazolin intravenously within 30 minutes prior to skin incision, and general anesthesia was administered in all cases with a similar protocol.

All patients underwent surgical intervention with open reduction and internal fixation (ORIF) in a beach-chair position with the affected arm in a mobile position. A transverse skin incision was made upon the clavicle with lateral extension to the lateral edge of the acromion. The acromioclavicular (AC) joint capsule was not incised. After sharp dissection of the periosteum and debridement of fracture hematoma, the fracture was sparingly exposed. To gain anatomical reduction, the fracture was temporarily reduced using two Kirschner wires (K-wires) as temporary arthrodesis of the AC joint or using reduction forceps. The position was assessed using fluoroscopy. The AC joint was located by the temporary insertion of a needle. The plate was centered onto the clavicular shaft, and after confirmation of correct plate positioning in fluoroscopy, screw holes were consecutively drilled.

The arm was immobilized in a sling and swathe after surgery, and patients began physiotherapy on the first postoperative day following standard rehabilitation protocol. Passive abduction and flexion were restricted to 90° for the first six weeks. With decreasing pain, this training was progressed with strengthening exercises of the rotator cuff and shoulder muscles. Return to sport activity of the upper extremities was allowed after 6 months.

The patients were finally followed-up for two years to assess the clinical outcome of the procedures with respect to postsurgical complications, including infection, nonunion, and decreased range of motion (ROM), as well as the functional state of the shoulder using the Constant-Murley score (CMS) (17). In order to judge better functional states, the comparison of CMS was made 6 months later.

Our study was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences with a certain ethical approval code. The study objectives and steps were explained to the patients before the intervention. Then, they gave written informed consent for participation. Besides, they were ensured of the confidentiality of their data.

For statistical analysis, results were presented as mean ± standard deviation (SD) for quantitative variables and were summarized by frequency (percentage) for categorical variables. T-test and Mann-Whitney U test examined the measured variables between the 2 groups to define differences between them when the distribution of data was normal or not, respectively. The categorical items were compared using the chi-square test or Fisher's exact test if required. P-values ≤0.05 were considered statistically significant. For the statistical analysis, the SPSS statistical software (version 23.0, IBM Corporation, Armonk, NY, USA) was used.

Results

This RCT was conducted in order to compare two traditional plates in the treatment of Neer 2b distal clavicular fracture. 60 patients, including 23 men and 37 women, enrolled in this study.

3.5 mm T plate was used for all 30 patients in the first group, and an anatomical locking plate was used for the members of the latter group (Figure 2).

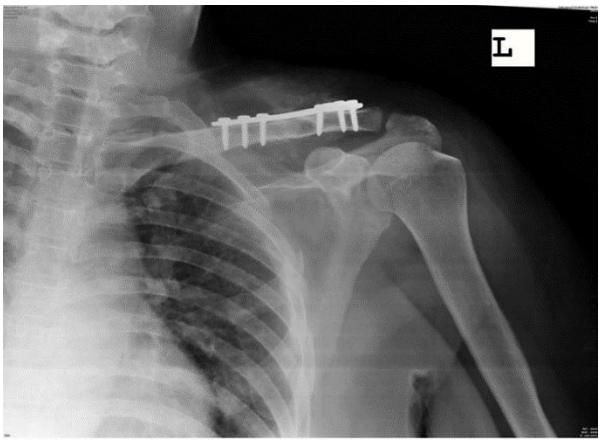

Figure 2. A patient with left clavivle fracture treated with T plate

Average age of the T plate group and the anatomical locking plate group was 31.9 ± 9.4 and 32.5 ± 8.6 years, respectively. The most common mechanism of trauma was road traffic accidents (RTA) in both groups. There was no obvious diversity between the two groups regarding the demographic factors such as age, sex, mechanism of trauma, and side of the trauma, which are compared and summarized in table 1.

Table 1. The demographic data of both groups

Variable		3.5 mm T plate (n = 30)	Anatomical plate (n = 30)	P
Age (year) (mean ± SD)		31.9 ± 9.4	32.5 ± 8.6	0.82
Gender [n (%)]	Men	10 (33.3)	13 (43.3)	0.59
	Women	20 (66.6)	17 (56.6)	
Mechanism of trauma [n (%)]	Vehicle accident	16 (53.3)	15 (50.0)	0.74
	Falling down	5 (16.6)	4 (13.3)	
	FFH	3 (10.0)	6 (20.0)	
	Sports accident	6 (20.0)	5 (16.6)	
Side of trauma [n (%)]	Right	14 (46.6)	18 (60.0)	0.43
	Left	16 (53.3)	12 (40.0)	

FFH: Falling from height; SD: Standard deviation

The average clinical follow-up was 26.2 and 28.1 months in the T plate group and anatomical locking plate group, respectively.

The outcomes of this study, including time to union, device removal, and CMS are shown in table 2.

Table 2. Comparison of study outcomes between T-plate and anatomical plate groups

	T-plate	Anatomical plate	P-value
Time to union (month) (mean ± SD)	3.3 ± 0.6	3.6 ± 0.7	0.14
Need for device removal [n (%)]	5 (16.6)	8 (26.6)	0.53
Infection [n (%)]	0 (0)	0 (0)	-
Nonunion [n (%)]	0 (0)	0 (0)	-
CMS (mean ± SD)	93.1 ± 2.2	92.1 ± 2.5	0.09

CMS: Constant-Murley score; SD: Standard deviation

All of the patients showed excellent bone union, and there was no wound-related complication. Although the patients using the anatomical locking plate needed more time to a union than those using the 3.5 mm T plate, no significant differences were observed (P = 0.14). Plates needed to be removed in 5 patients in the 3.5 mm T plate group and 8 patients in the anatomical locking plate group (P = 0.53). The mean scores assessed by the CMS scale had no significant difference between the two groups of patients (P = 0.09). Participants in the 3.5 mm T plate group had a mean score of 93.1, while the participants in the anatomical locking plate group had a mean score of 92.1 (Figure 3).

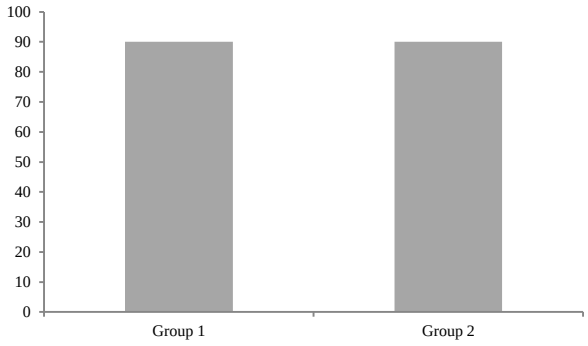

Figure 3. Bar plot of Constant-Murley score (CMS) means in T-plate (group 1) and anatomical plate (group 2) groups

At an average follow-up of at least 2 years, none of the patients complained of infection, non-union, or procedure-related complications.

Discussion

Opposing forces of the sternocleidomastoid (SCM) muscle, on the one hand, and gravity and the pull of the pectoralis muscle, on the other, may result in significant fragment displacement, particularly in unstable fractures where the medial fragment is detached from the CC ligaments (18). According to Neer, complete detachment of the CC ligaments from the medial fragment is seen in type 2b fractures (5). Therefore, Neer 2b fractures are unstable and displaced fractures. To date, there is no gold standard treatment for unstable Neer 2b distal clavicular fractures, and there is a broad spectrum of treatments from conservative management to different surgical choices with rigid or flexible fixations (16). Rigid fixation as a surgical choice means ORIF via different plates, such as hook plates, pre-contoured locking plates, distal radius locking plate, CC screws, and Knowles pin fixation (16). Panagopoulos et al. demonstrated that the hook plate fixation technique was associated with more complications, and the ideal treatment option for distal clavicular Neer 2b fractures could be open CC stabilization or locking plate fixation (19). This study was conducted to evaluate union rate, the functional outcome as CMS, and the need for device removal in distal clavicular fractures fixed via two different modalities of surgical treatment, named distal clavicular pre-contoured plate and distal radius volar T plate.

Previous studies demonstrated the benefits of distal radius T plate in the fixation of distal clavicle fractures (12). Yu et al. reported an excellent effect of bone union in six to eight weeks in six patients (20). Daglar et al. reported 14 cases who underwent ORIF with T plate and had full shoulder ROM, and noted that excellent clinical outcome was achievable (21). Abdeldayem et al. reported the same results because the shoulder ROM could be restored early, and there was not any need for device removal (22). These perfect outcomes were also repeated in studies with T plate fixation augmented with CC reconstruction techniques in Neer 2b distal clavicular fractures (18, 23-25). The superiority of this plate to the clavicular hook plate is also noted in literature (26, 27).

Our data supported the previous studies as in terms of time to the union, there is not any difference between anatomical distal clavicular plate and distal radius T plate. There was no significant difference between the rate of device removal in both groups. Last but not least criterion for this comparison was the functional outcome as measured by CMS score. Therefore, in terms of time to union, the need to device removal, and CMS score, distal radius volar T plate could be as successful as distal clavicular pre-contoured plate in treatment of distal clavicular Neer 2b fractures.

In distal fragments of greater than 25 mm, there was no difference between three different distal clavicle locking plates, and there was no need for other augment fixation procedures (28); furthermore, the cost-effectiveness of treatment in this kind of injury plays a prominent role (29).

Nevertheless, in Neer 2b distal clavicle fracture there is no need to use neither anatomical locking plates nor augment fixation procedures and it seems using a distal radius volar T plate would be as efficient as pre-contoured locking plates. Our results demonstrated that in Neer 2b distal clavicle fracture, a distal radius volar T plate could be adequate with an excellent bone union and low complication rate, as well as a good functional outcome.

The most important finding of our study was that unstable distal clavicle fractures could be managed using a distal radius volar T plate alone with a 100% union rate and CMS of 93.1, representing an almost normal shoulder functional state. The major limitation of our study is that we just included the Neer 2b distal clavicle fracture in our study, not the other classifications such as 2c.

Conclusion

Distal radius volar T plate could be a reasonable choice to manage Neer 2b distal clavicle fracture as it restores functional ROM with excellent bone union and without the necessity of device removal, besides its economical price.

Conflict of Interest

The authors declare no conflict of interest in this study.

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None.

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