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MIDSHAFT FRACURES OF THE CLAVICLE: A META-ANALYSIS COMPARING SURGICAL FIXATION VIA ANTEROINFERIOR PLATING VERSUS SUPERIOR PLATING

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ABSTRACT

Objective: Tto compare the outcomes of clavicle fracture fixation using anteroinferior versus superior plate placement.

Methods: We performed a meta-analysis of studies that have reported on outcomes following superior or anteroinferior plate fixation for acute midshaft clavicle fractures (OTA 15-B). A computerized literature search in the Pubmed, Scopus, and Cochrane Library databases was utilized to identify relevant articles. Only full text articles without language restrictions were evaluated. The inclusion criteria consisted of: 1) fracture of the midshaft clavicle; 2) surgery for acute fractures (within one month of the fracture); 3) adult patients (16 years of age and older); and 4) open reduction and internal fixation with plate application in either the anteroinferior or superior position. Studies were excluded if they did not specify plate location, evaluated multi-trauma patients, investigated minimally invasive procedures, or studied operations for revision, nonunion, malunion, or infection. The primary measured outcomes were symptomatic hardware (implant prominence or irritation) and surgery for implant removal. The secondary outcomes were time to union, fracture union, nonunion, malunion, DASH score, Constant score, and implant failure. Frequencies and proportions of cases were recorded for binary outcomes, while means and standard deviations were recorded for continuous outcomes. Other summary statistics provided were used to impute means and standard deviations under the assumption of normality when these were not reported. Continuous outcomes were compared between groups using linear mixed effects models, while binary outcomes were compared using mixed effects logistic regression models, including fixed group effects and random study effects. P-values less than 0.05 were considered statistically significant. All analyses were performed using SAS v. 9.4

(SAS Institute Inc., Cary, NC).

Results: A total of 1,428 articles were identified amongst the three databases, of which 897 remained after removing duplicates. From that pool, 57 relevant studies were evaluated. Articles were excluded due to an inability to specify plate location (6), a subject pool not exclusively consisting of acute fractures (4) or midshaft fractures (2), a minimally invasive surgical approach (6), use of non-standard plates (1), poor reporting of functional outcomes (2), and a duplicate group of patients (2). This left 34 articles to be used in the meta-analysis. Of these, 8 studies reported on patients with anteroinferior plating (N=390) and 27 studies reported on patients with superior plating (N=1104). No significant differences were found with respect to the functional shoulder scores (DASH and Constant) between the two groups. There was no significant difference between each group for the probability of having a union (p=0.41), malunion (p=0.28), nonunion (0.29), or implant failure (p=0.39). Patients in the superior plating group had a significantly higher probability of suffering from symptomatic hardware (0.17) as compared to patients in the anteroinferior plating group (0.08), (p=0.005). Additionally, the superior plating group had a significantly higher rate of surgery for implant removal (0.11 versus 0.05), (p=0.008).

Conclusion: The findings of this investigation demonstrate that plating along the superior and anteroinferior aspects of the clavicle lead to similar operative outcomes with respect to union, nonunion, malunion, and implant failure, as well as similar functional outcomes scores. Plates applied to the superior aspect of the clavicle are associated with higher rates of symptomatic hardware and more frequent implant removal.

Keywords: clavicle; fracture; plate fixation; open reduction and internal fixation; hardware prominence; hardware removal

INTRODUCTION

Clavicle fractures are common injuries, occurring at a rate of approximately 5.8 per 10,000 persons per year in the United States[1]. The middle third region of the clavicle is the most frequently affected area, comprising up to 81.3% of these fractures[2]. In 1960, Neer reported a nonunion rate of 0.1% in conservatively treated patients with middle third fractures as compared to a nonunion rate of 4.6% in those treated with open reduction and internal fixation[3]. Based on these historical results, clavicle fractures have traditionally been treated conservatively with a period of brief immobilization[4].

Recent evidence has challenged the notion that the majority of clavicle fractures should be treated conservatively. Hill and colleagues evaluated 52 consecutive patients treated nonoperatively for a completely displaced clavicle fracture and found that 15% of patients had a nonunion and 31% were not satisfied with their results[5]. A systematic review of 2144 midshaft clavicle fractures found a nonunion rate of 15.1% amongst conservatively treated displaced clavicle fractures, and surgical treatment significantly reduced the risk of nonunion[6]. Moreover, conservative treatment of midshaft fractures may result in compromised shoulder function. In 2006, McKee et al. evaluated 30 patients treated conservatively after displaced midshaft fractures and found a mean Constant score of 71 points and a mean DASH score of 24.6 points, indicating substantial disability[7].

In light of this evidence, there has been a recent trend towards operative treatment of displaced midshaft clavicle fractures. Studies have demonstrated that surgical treatment with

open reduction and plate fixation is associated with improved outcomes and a decreased risk of complications, specifically a faster time to union, fewer nonunions and malunions, and better shoulder function scores[8,9]. There are two common approaches for plate fixation, with the plate applied either to the superior or anteroinferior aspect of the clavicle[10]. Anteroinferior plate fixation may be desirable to superior fixation due to less prominence of the plate and, in turn, fewer subsequent procedures for implant removal. In a study by Collinge et al., only 2 of 58 patients who underwent anteroinferior plate fixation had implant irritation that required removal[11]. Conversely, in the 2007 Canadian Orthopaedic Trauma Society (COTS) study, 11 of 62 patients who underwent superior plate fixation had implant irritation or prominence, and 5 patients required implant removal[8].

Despite the potential advantage of utilizing anteroinferior plate fixation, there is minimal evidence comparing these two techniques. One investigation that directly compared these approaches found that the two groups had a similar time to union and union rate, however patient-reported implant prominence was nearly double in the superior group[12]. Implant removal also occurred more frequently in the superior group, but the difference was not statistically significant. The purpose of the present investigation was to perform a meta-analysis of studies that have reported on outcomes following superior or anteroinferior plate fixation for acute midshaft clavicle fractures. We tested the hypothesis that anteroinferior plate fixation would lead to less implant prominence and fewer subsequent procedures for implant removal as compared to superior plate fixation.

METHODS

This meta-analysis was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and the Cochrane Handbook for Systematic Reviews Interventions[13,14].

Search Strategy

An electronic literature search was performed in the Pubmed, Scopus, and Cochrane Library databases to identify relevant studies between January 1960 and November 2015. The following keywords were used: “clavicle” and “fracture” and “plate” or “plating” or “plated.” A manual search of the references of the selected studies was also performed to identify any additional potential articles that may meet inclusion criteria.

Inclusion Criteria

Two reviewers (A.N. and P.S.V.) evaluated the titles and abstracts to identify relevant studies. Disagreements were discussed to determine a resolution. Only full text articles without language restrictions were considered. The inclusion criteria consisted of: 1) fracture of the midshaft clavicle; 2) surgery for an acute fracture (within one month of the injury); 3) adult-aged patients (16 years of age and older); and 4) open reduction and internal fixation with plate application in either the anteroinferior or superior position. The exclusion criteria were: 1) inability to specify plate location; 2) patients with multi-system trauma; 3) minimally invasive procedures; and 4) operations for revision, nonunion, malunion, and/or infection. Articles with different study designs such as randomized controlled trials and cohort studies (prospective or

retrospective) were evaluated. Case studies, meta-analyses, and systematic reviews were not considered.

Data Extraction

The same two reviewers carefully and independently extracted data from eligible studies. The following basic characteristics were recorded from each study: 1) first author's name; 2) title of study; 3) year published; 4) journal; 5) patients' age; 6) number of patients; 7) plate location; and 8) follow-up period. The primary measured outcomes were symptomatic hardware (implant prominence or irritation) and surgery to remove symptomatic hardware. The secondary outcomes were time to union, fracture union, nonunion, malunion, DASH score, Constant score, and implant failure (defined as plate breakage) [15,16]. Both primary and secondary outcomes were extracted from the studies according to their availability, as it was common for studies to examine some but not all of the outcomes. For continuous outcomes, the mean and standard deviation were also recorded. If the mean or standard deviation was not available but a substitute (e.g., median, IQR, range) was available, this was recorded and used to estimate the standard deviation and mean.

Statistical Analyses

Frequencies and proportions of cases were recorded for binary outcomes, while means and standard deviations were recorded for continuous outcomes. Other summary statistics provided were used to impute means and standard deviations under the assumption of normality when these were not reported. Continuous outcomes were compared between groups using linear mixed effects models, while binary outcomes were compared using mixed effects logistic

regression models, including fixed group effects and random study effects. P-values less than 0.05 were considered statistically significant. All analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC).

RESULTS

Literature Search

The initial database search yielded 1,428 articles. 897 studies remained after removing duplicate articles (Figure 1). After screening the abstracts and titles, 57 relevant studies were identified. From these, studies were further excluded due to an inability to specify plate location (6), a subject pool not exclusively consisting of acute fractures (4) or midshaft fractures (2), a minimally invasive surgical approach (6), use of non-standard plates (1), inadequate reporting of functional outcomes (2), and a duplicate group of patients (2). Thirty-four articles were used in the meta-analysis (Table, Supplemental Digital Content 1). Of these, 8 studies reported on anteroinferior plate fixation (N=390, Table, Supplemental Digital Content 2) and 27 studies reported on superior plate fixation (N=1104, Table, Supplemental Digital Content 3). The studies were all published between the years 2007 and 2015.

Surgical and Functional Outcomes

Eight studies (390 patients) in the anteroinferior group and 27 studies (1,104 patients) reported on the clavicle union rate (Table 1). The rate of fracture union was similar in the two groups: 0.97 for the anteroinferior group and 0.98 for the superior group, (p=0.41). Sufficient data was available from 4 studies (125 patients) from the anteroinferior group and 11 studies (376 patients) from the superior group to perform a meta-analysis on the average time to union (Table 2). The anteroinferior group had an average time to union of 15.82 weeks (95% CI 11.43,

20.20), while the superior group had an average of 17.12 weeks (95% CI 12.73, 21.50), ($p<0.0001$).

The DASH and Constant scores were the most commonly used functional outcome scores reported. A low DASH score and high Constant score indicate superior shoulder function. In the present analysis, adequate data was available from 3 studies (102 patients) in the anteroinferior group and 6 studies (225 patients) from the superior group to evaluate DASH score. The mean DASH score for the anteroinferior group was 5.18 (95% CI -0.60, 10.95), compared to 9.71 (95% CI 5.24, 14.19) for the superior group, ($p=0.18$). Constant score data was available in 4 studies (121 patients) in the anteroinferior group and in 17 studies (679 patients) in the superior group. There was no difference in the mean Constant score between the anteroinferior group (90.90; 95% CI 86.88, 94.92) as compared to the superior group (93.34; 95% CI 91.40, 95.28), ($p=0.27$).

Postoperative Complications

Seven studies (351 patients) in the anteroinferior group and 27 studies (1,104 patients) in the superior group reported on the rate of nonunion. The superior plating group and anteroinferior group had similar nonunion rates (0.02 versus 0.03, respectively), ($p=0.29$). Data from 5 studies (205 patients) in the anteroinferior group and 12 studies (489 patients) in the superior group was available regarding the rate of malunion. Malunions can occur secondary to poor plating technique or a loss of reduction post-operatively. The malunion rate was higher in the superior group (0.01) as compared to the anteroinferior group (0.006), but this difference was not significant ($p=0.28$) nor clinically relevant. Six studies (222 patients) in the anteroinferior group and 15 studies (624 patients) in the superior group reported on the incidence of implant

failure. The superior plating group (0.03) and the anteroinferior group (0.02) had similar rates of patients with implant failure (p=0.39).

Eight studies (390 patients) in the anteroinferior group reported on the rate of symptomatic hardware, as did 22 studies (848 patients) in the superior group. Meta-analysis found that the superior plating group had a significantly higher probability of experiencing symptomatic hardware (0.17) as compared to the anteroinferior group (0.08), (p=0.005) (Figure 2). Seven studies (371 patients) in the anteroinferior plating group and 19 studies (739 patients) in the superior plating group reported on surgery to remove symptomatic hardware. The superior plating group had a significantly higher rate of surgery for implant removal (0.11 versus 0.05), (p=0.008) (Figure 3).

DISCUSSION

There has been a trend towards surgical management of midshaft clavicle fractures in efforts to reduce the incidence of nonunion and malunion and to improve shoulder function[4-7]. Although surgical treatment has the ability to mitigate poor outcomes, it also has potential complications. A systematic review performed by Wijdicks and colleagues found that the majority of complications following plate fixation of clavicle fractures were related to implant irritation or failure[17]. Subsequent surgery may be necessary in order to treat these complications. Wang et al. performed follow up on 48 patients with middle third clavicle fractures treated with pre-contoured plates and found that 88% complained of local prominence, pain, and discomfort[18]. Ultimately 56% of the initial study group had the plates removed, and post-operatively 96% of those with plates removed were satisfied and recommended plate removal. This underscores the potential need for implant removal to achieve patient satisfaction.

Anteroinferior plate application has drawn more interest recently because it is potentially associated with less frequent implant irritation and need for implant removal as compared to superior plate application.

There are many factors that influence the approach to plate fixation for midshaft clavicle fractures including the fracture pattern, associated injuries, surgeon preference for patient positioning, and pre-existing deformity due to prior trauma. Plate fixation in the superior and the anteroinferior positions are the two most common surgical approaches. The purpose of the present investigation was to perform a comprehensive literature search and identify studies in which plate fixation was performed in either the superior or anteroinferior position in order to compare the complication rates, particularly implant prominence and need for implant removal, between these two groups. This analysis identified 8 studies in the anteroinferior plating group and 27 studies in the superior plating group. No significant differences were found between the two groups with regards to the probability of having a nonunion or malunion. The anteroinferior group had an average time to union of 15.82 weeks compared to 17.12 weeks for the superior group. Although this was statistically significant, a difference of 1.3 weeks is not a clinically significant difference. Furthermore, this may be an artificial outcome as it is difficult to assess union with an anteroinferior plate, and there is inherent variability as to when patients follow up for radiographic studies in order to make this assessment. There was no statistically significant difference between the two groups when examining their DASH scores and Constant scores. This result was expected, as both superior and anteroinferior plating methods are effective techniques for surgical treatment of clavicle fractures. With regards to implant complications, there was a significantly higher rate of patients with symptomatic hardware and patients undergoing implant removal when plating was performed on the superior aspect of the clavicle.

This finding is consistent with other studies that have suggested that plating on the superior aspect may be associated with higher rates of symptomatic hardware and implant removal [8,11,12].

We were only able to identify one study in the literature that had directly compared the two plating methods. In a retrospective review, Formaini et al. concluded that superior plating had a significantly higher incidence of symptomatic hardware compared to anteroinferior plating[12]. Their study found a trend towards an increased incidence of implant removal in the superior plating group (19% versus 9%), however this was not statistically significant. A recent randomized clinical trial comparing 37 total patients treated with minimally invasive plating found no significant differences between superior versus anteroinferior plating with regards to functional scores, time to union, and complications[19]. While this study was a randomized trial that examined plates in both positions, minimally invasive plating was performed, and this technique was excluded from the present investigation. In another recent study, retrospectively collected data of 39 patients who underwent anteroinferior plating for a displaced midshaft clavicle fracture were compared with a group of 60 patients treated with superior fixation in a prior randomized controlled trial[20,21]. Although the results demonstrated a significantly higher rate of asymptomatic patients with the plate still in place in the anteroinferior group (46% vs. 22%), univariate and multivariate regression analysis demonstrated that plate position was not significantly associated with implant-related irritation and that patient age under 40 was associated with irritation. The results of the present meta-analysis contrast those from previous studies that suggest that plate position does not correlate with symptomatic hardware and plate removal. Further randomized controlled trials may help to elucidate this question.

The current study does have some limitations. Anteroinferior plate fixation is not as frequently described in the literature, and there are few studies that directly compare

complications following anteroinferior versus superior plate fixation. Certain outcomes such as fracture time to union and shoulder function scores are influenced by follow-up intervals and by inter-examiner variability. Furthermore, studies examining various surgeons using different plate types can potentially influence outcomes. Pre-contoured plates have become the standard of care, and several retrospective reviews have suggested that their use may be associated with decreased implant prominence and need for implant removal[22-24]. In the current analysis, the details of the plate type were reported inconsistently from study to study, with many studies not specifying whether pre-contoured plates were utilized. However, 6 studies in our meta-analysis did specify using pre-contoured plates. Despite the lack of plate specificity, there are many similarities with respect to the surgical technique. All but one study was published after 2010, indicating modern plating techniques. Also, the plate size was highly consistent throughout the studies, with the majority using a 3.5-mm thickness plate. Even though the use of different plate types is a limitation to the current study, we believe there are other similarities regarding the plating techniques that can allow us to make a meaningful comparison between plating on the superior versus the anteroinferior aspects of the clavicle. The follow-up interval may also affect the development of symptomatic hardware. Of the studies included in this meta-analysis, the majority had average follow-up times of over one year. However there were a few investigations that had shorter or significantly longer follow-up. Finally, meta-analysis does not eliminate or control for bias in each of the studies, and implant removal is typically a very subjective decision between surgeon and patient and subject to multiple biases.

Despite these limitations, the strict inclusion and exclusion criteria of the present-study made the two study groups as similar as possible. The patients included in the present analysis were all adults who had open reduction and internal fixation performed with standard plates in

either the superior or anteroinferior position for isolated acute midshaft clavicle fractures. Finally, by including data from 34 different studies with 1,494 patients, this investigation provides a meaningful comparison due to the large sample size.

CONCLUSION

The current literature suggests that patients who are treated with superior clavicle plate fixation may be more likely to experience symptomatic hardware and undergo removal of implants as compared to patients who are treated with anteroinferior plate fixation. Surgeons should take into consideration the potential development of symptomatic hardware and need for implant removal when selecting their approach for plate fixation of midshaft clavicle fractures. A properly powered, randomized clinical trial of superior versus anteroinferior fixation using pre-contoured plates and objective, standardized criteria for implant removal would confirm or refute these findings.

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FIGURE LEGENDS

Figure 1. Flow chart of studies evaluated in the present meta-analysis.

Figure 2. Forrest plot demonstrating rate of symptomatic hardware by study. Studies reporting zero symptomatic hardware cases (Chen (2010)[25] and Hundekar (2013)[26]) are not displayed but were included in the meta-analysis.

Figure 3. Forrest plot demonstrating rate of implant removal by study. Studies reporting zero removed implant cases (Chen (2010)[25], Virtanen (2012)[27], Sohn (2015)[28], Hundekar (2013)[26] and Douraiswami (2013)[29]) are not displayed but were included in the meta-analysis.

	Anteroinferior P (95% CI)	Superior P (95% CI)	OR (95% CI)	p-value	ICC
Infections	0.02 (0.003, 0.14)	0.09 (0.06, 0.13)	4.38 (-0.58, 33.37)	0.15	0.007
Implant Failure	0.02 (0.004, 0.06)	0.03 (0.01, 0.06)	1.83 (0.47, 7.18)	0.39	0.20
Malunion	0.006 (0.001, 0.04)	0.01 (0.004, 0.05)	2.27 (0.51, 10.12)	0.28	0.34
Nonunion	0.03 (0.01, 0.07)	0.02 (0.01, 0.03)	0.59 (0.22, 1.57)	0.29	0.16
Union	0.97 (0.94, 0.99)	0.98 (0.96, 0.99)	1.47 (0.59, 3.67)	0.41	0.15
Complication	0.08 (0.04, 0.13)	0.17 (0.13, 0.23)	2.51 (1.32, 4.78)	0.005	0.15
Hardware Removal	0.05 (0.03, 0.08)	0.11 (0.08, 0.14)	2.36 (1.26, 4.42)	0.008	0.05

Table 1. Meta-analysis results for count variables. ICC is Intraclass Correlation Coefficient.

	Anteroinferior Mean (95% CI)	Superior Mean (95% CI)	Difference	p-value	ICC
Constant Score	90.90 (86.88, 94.92)	93.34 (91.40, 95.28)	-2.44 (-6.90, 2.03)	0.27	0.18
DASH Score	5.18 (-0.60, 10.95)	9.71 (5.24, 14.19)	-4.54 (-11.84, 2.77)	0.18	0.19
Time to union (weeks)	15.82 (11.43, 20.20)	17.12 (12.73, 21.50)	-1.30 (-1.61, -0.99)	<.0.0001	0.64

Table 2. Meta-analysis results for continuous variables. ICC is Intraclass Correlation Coefficient.