

Anterior-Inferior Plating Results in Fewer Secondary Interventions Compared to Superior Plating for Acute Displaced Mid-Shaft Clavicle Fracture

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OBJECTIVES: To determine if a difference in plate position for fixation of acute, displaced, mid-shaft clavicle fractures would affect the rate of secondary intervention.

DESIGN: Retrospective Comparative Study

SETTING: two academic Level 1 Regional Trauma Centers

PATIENTS: 510 patients treated surgically for an acutely displaced mid-shaft clavicle fracture between 2000-2013 were identified and reviewed retrospectively at a minimum of 24 months' follow-up (F/U). Fractures were divided into two cohorts, according to plate position: Anterior-Inferior (AI) or Superior (S). Exclusion criteria included age <16 years, incomplete data records, and loss to F/U. Group analysis included demographics (age, gender, BMI), fracture characteristics (mechanism of injury, open or closed), hand dominance, ipsilateral injuries, time between injury to surgery, time to radiographic union, length of F/U, and frequency of secondary procedures.

INTERVENTION: Patients were treated either with AI or S clavicle plating at the treating surgeon's discretion.

MAIN OUTCOME MEASURES: Rate and reason for secondary intervention.

STATISTICAL ANALYSIS: Fisher's exact test, T-test and Odds Ratio were used for statistical analysis.

RESULTS: Final analysis included 252 fractures/251 patients. 118 (47%) were in group AI; 134 (53%) were in group S. No differences in demographics, fracture characteristics, time to surgery, time to union, or length of F/U existed between groups. Seven patients/seven fractures (5.9%) in Group AI underwent a secondary surgery whereas 30 patients/30 fractures (22.3%) in group S required a secondary surgery. An additional intervention secondary to superior plate placement was highly statistically significant ($P<0.001$). Furthermore, because 80% of these subsequent interventions were a result of plate irritation with patient discomfort, the Odds Ratio for a second procedure was 5 times greater in those fractures treated with a superior plate.

CONCLUSIONS: This comparative analysis indicates that anterior-inferior plating of mid-shaft clavicle fractures appears to lessen clinical irritation and results in significantly fewer secondary interventions. Considering patient satisfaction and a reduced financial burden to the health care system, we recommend routine anterior-inferior plate application when ORIF of the clavicle is indicated.

Key Words: Clavicle fractures; clavicle plating; anterior-inferior clavicle plating; anterior-inferior versus superior clavicle plating; outcomes clavicle plating; secondary surgery in clavicle fractures

Level of Evidence: Therapeutic level III

Introduction

Clavicle fractures account for 5-10% of all fractures and almost half of shoulder girdle injuries^{1,2}. Most of the fractures affect the middle third of the clavicle. Literature concerning the management of displaced mid-shaft clavicle fractures has been debated over the years. Until the 1980's, conservative measures were the mainstay of treatment¹. This changed after published reports indicated that for displaced fractures, surgical treatment^{3,4} improved functional results. Even this approach has come into question again, as recent publications report no difference between operative versus non-operative therapy, with surgery increasing the complications and cost^{5,6,7}.

When operative treatment is indicated, plating is considered the preferred operative technique^{8,9}

. With this method, the plate is classically positioned on the superior surface of the clavicle. In the past several decades however, positioning the plate

on the anterior-inferior aspect of the clavicle has become popular^{10,11,12}. Its acceptance is due to the fact that drilling in the anterior-posterior diameter creates a biomechanically strong^{13,14} construct which also allows for longer screw purchase, and potentially prevents vascular damage from AP plunging. In addition, anterior-inferior plating is associated with a lower profile and therefore, theoretically less clinical irritation and need for explantation^{15,16}. Although a number of publications exist commenting on the benefits of each plating position, none have evaluated the associated patient satisfaction with plate position. The purpose of this study was to determine whether plate positioning was associated with a higher rate of implant removal and if so, what the causes for removal were.

Patients and Methods

After IRB approval, a retrospective analysis was performed of all acute displaced mid-shaft clavicle fractures (OTA 15-B¹⁷) managed surgically with a plating technique between January 1, 2000 - December 31, 2013 at two independent Level 1 Trauma Centers (Tampa General Hospital, Tampa, FL and Geisinger Medical Center, Danville, PA). Surgical indications for an acute mid-shaft displaced clavicle fracture included: an open fracture, neurovascular compromise, more than 20 mms of clavicular shortening, an associated floating shoulder, or a polytrauma/polyfracture patient requiring early weight-bearing with the upper extremity. In all other circumstances, patients were immobilized

in a sling and were followed clinically. In the event that these latter patients developed worsening pain or showed signs and symptoms of a non-union, operative treatment was offered. All patients received the same post-operative management: pendulum exercises and active range of motion starting at immediately, followed by physical therapy if needed, to improve range of motion and strength at 8 weeks.

Patients were divided into two groups based on the position of the plate on the clavicle: Superior (S) or Anterior-Inferior (AI). The location of the plate was strictly based on surgeon preference and fracture pattern. Both institutions performed interventions using either the S or AI plating technique. Data collection included: Demographics (age, gender, BMI), medical comorbidities, smoking status, fracture characteristics (mechanism of injury, open or closed), plate size used (2.7mm or 3.5mm plate), hand dominance, ipsilateral injuries, time between injury to surgery, time to radiographic union, length of F/U, and frequency of secondary procedures. Exclusion criteria included: patients < 16 years of age, clinical or radiographic follow-up (F/U) <24 months, and/or incomplete records.

Demographic and fracture characteristics were compared using Fisher's exact test and the T-test. The rate of secondary intervention was analyzed using the Fisher's exact test and associations were reported in adjusted Odds Ratio.

Statistical significance was set at $p < 0.05$. In addition, power analysis (β) was calculated to assess the size of the effect in the population.

Results

A total of 510 acute mid-shaft clavicle fractures were initially identified, however 258 were excluded (249 had incomplete records or F/UP < 24 months, 9 were <16 years old). This left a total of 252 fractures in 251 patients for the final analysis (118=AI, 134=S). Demographics, comorbidities and fracture characteristics comparison showed no significant differences between groups (Table 1 and 2). All patients received 3.5 mm anatomic plates for their fracture. In simple fracture patterns, plates were applied in a compression fashion with lag screws through the plate, whereas in wedge or complex fractures lag screws outside the neutralization plate were employed. Main clinical complaints were irritation with overhead activities such as dressing, playing sports or reaching at or above shoulder height. Shoulder straps (bras, clothing, backpacks and handbags) that crossed perpendicular to the plate were a common complaint as well.

The average time between injury to surgery was 13 (0-55) days in AI group while the S group averaged 14 (0-68) days ($p=0.18$). Follow-up averaged 30.1 (24-149) months in the AI group and 32.6 (24-99) months in the S group ($p=0.11$). Union occurred in 117 (99%) fractures in the AI group, with one patient

developing an infected non-union. In the S group, similar results were obtained, with all patients except three (98%) healing uneventfully ($p=0.62$). The AI group achieved radiographic and clinical union at a mean of 136 (55-393) days whereas the S Group occurred an average of 152 (61-407) days ($P=0.26$).

The rate of secondary intervention was notably different. In the AI group, 5.9% (7 patients) required implant removal (5 symptomatic implants, 1 infected non-union and 1 re-fracture). In contradistinction, 22.3% (30 patients) of the S group required implant removal (25 for symptomatic implants, 3 non-unions, 1 infection, and 1 implant failure) (Table 3). The differences for implant removal between groups were highly statistically significant ($p<0.001$). Most of the secondary interventions were due to symptomatic implants (80%). The Odds Ratio for requiring a secondary intervention due to plate irritation was 5 times greater on the superior plate group. Most of the plates were removed between 12 to 24 months (6-28 months) post-injury. There was no difference in time to explantation between groups ($p>0.05$). All patient complaints improved after plate removal and almost all patients were able to resume their pre-injury activity level except for 2 patients that re-fractured their clavicle immediately after plate explantation. One patient was managed with surgery and the other one with sling immobilization.

In order to assess for any potential bias with one surgeon performing all the plate removals, the data was analyzed by surgeon with their preference for

150 plating technique and the amount of secondary surgery performed (Table 4). No
151 bias was found.

153 **Discussion**

154 Over the last decade, anterior-inferior clavicle plating for the treatment of
155 displaced mid-shaft fractures has become popular across the orthopedic
156 community. Several authors have reported good results with either plating
157 technique^(10-12, 15, 16). Advocates of the AI plating technique claim that using
158 longer screws creates a stronger biomechanical construct. Published reports
159 however are equivocal regarding which position makes the construct more
160 stable. Although Ianotti¹⁹ et al found that 3.5mm reconstruction plates applied
161 superiorly provided stiffer and more rigid constructs, they did not find any
162 differences in load to failure between the two plate positions. A recent study by
163 Partal¹³ et al in a sawbones model, reported no difference in axial or torsional
164 stiffness but noted more stability in bending stiffness for the AI placement.
165 Favre¹⁸ et al found that the AI plate placement is less likely to fail during normal
166 physiological loading. Despite the presumption that AI plating decreases the
167 risk of neurovascular damage because of the direction of drill placement, the
168 only two studies evaluating this issue provided inconclusive results.^{19,20}

169 Patients undergoing superior plating have been documented to complain
170 more of implant prominence than patients with anterior-inferior plates^{15,16}.

Formaini¹⁵ et al noted a higher rate of additional surgery with superior plating as compared to AI placement (19% vs. 9%). Nevertheless, the data failed to reach significance in part due to the small sample size of the study. Similarly, Hulmans et al²¹ recently reported more clinical irritation with superior plating (46% vs. 22% with anterior-inferior). However, in their series, patients with superior plates did not pursue an increased incidence of plate removal (36% vs. 37%).

In this study we retrospectively reviewed the institutional experience of two academic level 1-trauma centers with two different surgical techniques for the treatment of acute displaced mid-shaft clavicle fractures. Both cohorts shared similar demographics and fracture characteristics, and there was no difference from time of injury to surgery between groups. Both groups had extremely high, and similar union rates. All patients had a minimum follow-up of 24 months. Most implant removals occurred between 12-24 months. With both groups having extremely low rates of non-union and catastrophic failure, the majority of the revision procedures therefore were for clinical irritation (5 AI vs. 25 S). This difference yielded a significantly higher reoperation rate in the S group ($P<0.001$). The Odds Ratio for secondary intervention due to symptomatic implants was 5 times greater when placing a plate on the superior surface of the clavicle. The fact that several surgeons performed and removed superior plates minimized the possibility of bias with one physician performing all the explantations.

192 The number of reoperations in the S group (22%) was similar to the one
193 reported by Leroux²² in over 1,300 clavicle fractures managed operatively. In
194 their study, a 25% reoperation rate was found. The fact that in our series, AI
195 plating resulted in only a 5.9% reoperation rate indicates a benefit in this plate
196 position.

197 Our study did suffer from certain weaknesses. Limitations associated with
198 the retrospective nature of this study exist. Additionally, patients lost to follow
199 up could have sought care with other providers for implant removal and
200 potentially change the outcome of our study. Retrospective studies are always
201 subject to inherent limitations. Despite these disadvantages, our study involved
202 two academic institutions allowing the authors to attain statistical power
203 ($\beta=0.96$) to reject the null hypothesis and extrapolate the outcomes of the study.

204 Finally, our findings also have financial implications. Walton²³ et al
205 reported that on average, the surgical management of a clavicular fracture costs
206 \$14,763 and adding a secondary surgery increases the price by 26-33%, or
207 roughly an additional \$5,173. Correlating those costs with our data reveals that
208 for every 100 clavicle fractures managed surgically, if the AI plating technique is
209 used, 17 additional surgeries could be avoided (22/100 - 5/100), at a cost saving
210 of \$87,000 (\$5173x17). This may have implications for insurers and patients as
211 well.

212 In conclusion, this study indicates that when all other variables are held
213 constant, an anterior-inferior plating technique appears to lessen clinical

irritation and results in significantly fewer secondary operations. Considering patient satisfaction and a reduced financial burden to the health care system, we recommend routine anterior-inferior plate application when ORIF of the clavicle is indicated.

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TABLE 1. DEMOGRAPHICS AND COMORBIDITIES	AI (N=118)	S (N=134)	P
<u>AGE</u>	40.3	36.3	0.09
<u>GENDER</u>	84 M (71%)	94 M (70%)	0.89
<u>BMI</u>	25.6	25.7	0.92
<u>SMOKING</u>	22 (18%)	32 (23%)	0.35
<u>DIABETES</u>	6 (5%)	5 (3%)	1

Table 2. FRACTURE CHARACTERISTICS	AI	S	P
<u>MOI</u>			
Sports	21	32	0.27
MVA/MCA*	39	50	0.51
Bike	17	10	1
Fall	27	25	0.43
Horse	3	2	1
Other	11	15	0.68
<u>OPEN</u>	1	0	1
<u>Side</u>	71 left 47 right	68 left 66 right	0.16
<u>HAND</u> <u>DOMINANCE</u>	105 right 13 left	118 right 16 left	1

297 *MVA/MCA: Motor vehicle accident/ Motor-cycle accident

Table 3.	AI	S	P
REOPERATION			
<u>SECONDARY</u>	7	30	P<0.001
<u>SURGERY</u>			
- Painful implant	5	25	P<0.001
- non-union	1	3	P=1
- other	1	2	P=1

300 Table 4: Distribution of Cases By Surgeon

Surgeon Code (Column S)	Anterior- Inferior plating	Anterior- Superior plating	Secondary procedures in Anterior- Inferior Plating	Secondary procedures in Superior Plating
1A	3	25	1	6
2A	0	9	0	3
3A	0	6	0	0
4A	1	8	0	2
5A	0	4	0	1
6A	1	6	0	1
7A	0	4	0	1
1B	3	1	0	1
2B	1	14	0	1
3B	4	3	0	1
4B	22	2	4	0
5B	3	3	0	0
6B	17	12	1	3
7B	16	0	0	0
8B	9	3	0	0
9B	8	15	1	6
10B	26	4	0	0
*	4	15	0	3

301 *Fellow or attending with less than 3 cases performed.

302 A (Institution A)

303 B (Institution B)

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ACCEPTED