

RESEARCH ARTICLE

Precontoured Locking Plate Treatment in Mid-Shaft Clavicle Fractures: Outcomes and Complications with a Minimum of 2- Years Follow up

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Abstract

Background: The aim of this study was to evaluate functional outcome and complications with a long term follow up (minimum of 2 years post-operative) in patients with mid-shaft clavicle fractures treated with precontoured locking plates.

Methods: We included 41 patients. Goniometric measurement of shoulder range of motion (ROM) was performed, as well as functional evaluation using the rating scale shoulder of the University of California (UCLA), the Constant scale, score of disability of the arm, shoulder and hand (DASH) and visual analog scale (VAS). Postoperative complications, implants removal rates and new x-rays were analyzed.

Results: The mean postoperative follow-up was 41.5 (24; 69. SD 13.4) months. Mean shoulder anterior elevation was 168.5° (120; 180. SD 22.9). The average value obtained for abduction was 175.2° (150; 180. SD 27.8), as to internal and external rotations, these were not affected. DASH 1.27% (0%; 25%. SD 4.3), UCLA 33.6 points (20; 35. SD 3.5), Constant 90.5 points (50; 100. SD 11.2) and VAS was 0 in 34 patients (83%). Complications: mild residual pain (3), hypoesthesia of the infraclavicular area (2), and rupture (1) and loosening (1) of the implant. hardware removal due to intolerance (2 cases) and new osteosynthesis due to acute implant rupture (1 case).

Conclusion: Our experience after a mean follow-up of 41.5 months with precontoured locking plates for the treatment of displaced mid-shaft clavicle fractures has shown good functional results, with low complication and reoperation rate.

Level of evidence: IV

Keywords: Clavicle, Complications, Fractures, Hardware removal, Osteosynthesis, Outcomes, Plates

Introduction

Clavicle fractures represent 2.6 to 4 % of all fractures in adults. 18% take place in the lateral third, 2% in the medial third, and the remaining 80% are mid-shaft fractures. Of this, about 50% are

displaced (1).

Open reduction and internal fixation with plates and intramedullary nails are the most commonly used options in displaced mid-shaft fractures (1-5). Plates

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appear to be more popular: different types have been reported, such as tubular plates, dynamic compression plates (DCP), reconstruction plates, and more recently precontoured locking plates. Nevertheless, there is a lack of information about the last ones regarding their long term results such as re-operations and complications after surgical treatment.

The aim of this study is to describe long term functional outcomes and complications in patients with mid-shaft clavicle fractures treated with precontoured locking plates.

Materials and Methods

This study was approved by our institutional ethics committee (Acta no 57)-

This is a retrospective cohort design. Participants were identified in our health record database, in 2015. Inclusion criteria was age over 18 years old and diagnosis of mid-shaft clavicle fractures treated with precontoured locking plates from 2009, when this type of surgery began to be performed, until 2013 to ensure at least 2 years of follow up after surgery. The participants were called by phone to invite them to participate and arrange an interview and a final evaluation visit.

Demographic data, post-operative care and time after surgery, osteosynthesis characteristics, were recorded in the final visit [Table 1].

Physical examination to assess functional evaluation was performed in the visit, and a new x-rays was performed. Previous and postoperative x-rays were compared to measure any complications or associated injuries.

Active shoulder range of motion measurements were performed using a manual goniometer, taking as a reference for maximum anterior elevation and abduction a value of 180°, for internal rotation reaching the interscapular region (7th thoracic vertebrae -T7- : 100°/110°) and for external rotation 80°.

For functional evaluation we used the following scores: UCLA Shoulder rating scale, this scale evaluates five different items and total score range between 2-35 (35 is the best outcome possible) (6).

The Constant Shoulder Score (K) measures four domains and range between 0 to 100 (100 is better function) (7).

Table 1. Demographics variables in percentages

DEMOGRAPHICS VARIABLES	
Age (mean+/-deviation)	33.5+/-12.9
Gender (%males)	85%
Affected side (%right)	46%
Dominant side (%right)	87%
Follow up (mean+/-deviation)	41.5+/-13.4
Classification AO (A-B-C)%	(41, 44, 15)

The Disabilities of Arm, Shoulder and Hand Score (DASH) with optional sport/work items (8), briefly attribute scores of 1 to 5 on 30 items related to functional activities and symptoms in last week; a further optional module contains four items related to disability levels among musicians and athletes. The raw score is then transformed to 0 to 100 (100 maximum disability)

Visual Analog Scale (VAS) for pain is a continuous single item scale, comprised of a horizontal 100 millimeters line. 100 means "worst imaginable pain".

For fracture classification, we used the AO (Arbeitsgemeinschaft für Osteosynthesefragen) (9). The radiologic evaluation included posterior-anterior clavicle x-rays and 15° cephalic angle x-rays.

Statistical analysis

Categorical variables were described as number and percentage, continuous variables were described as range, mean and standard deviation according to data distribution.

The statistical analysis was performed by using Core Team (2013) and Foundation for Statistical Computing (Vienna, Austria) software.

Results

Population

59 patients met inclusion criteria, 6 of this patients did not accept the interview, 3 couldn't make it because of geographical reasons and 9 did not answer the phone call. Finally, we analyzed 41 patients.

6 women (15%) and 35 men (85%). The mean age was 33.5 (20; 59. SD 12.9) years.

Fractures and associated injuries

Out of the 41 evaluated patients, 19 (46%) had fractures on the right side and 22 (54%) on the left side. 18 (45%) were on the dominant side.

According to the AO Classification system we found 17 type A fractures (eight A1, three A2 and six A3); 18 type B fractures (eleven B1; three B2; four B3); and 6 type C fractures (four C1; one C2; one C3) [Table 1]. There were three patients who presented associated injuries: one presented a liver hematoma and a pulmonary contusion; another one an ipsilateral wrist and 5th metacarpal fracture. The third one presented 1st, 2nd, 3rd and 4th costal arch fractures ipsilateral to the clavicle fracture plus a D7 collapse.

Surgical issues, postoperative care and follow up

Indications for surgical treatment were: comminuted fractures, polytraumatized patients, and displaced fracture (define as no cortical contact between the proximal and distal fragments or shortening greater than 20mm, measure by comparative X-rays) [Figures 1; 2].

All osteosynthesis plates used were 3.5 mm diameter holes with option blocked monoaxial screws and cortical screws with the possibility of dynamic compression.

Postoperative care: all patients were instructed in the use of a sling for 15 days, after which passive, active and

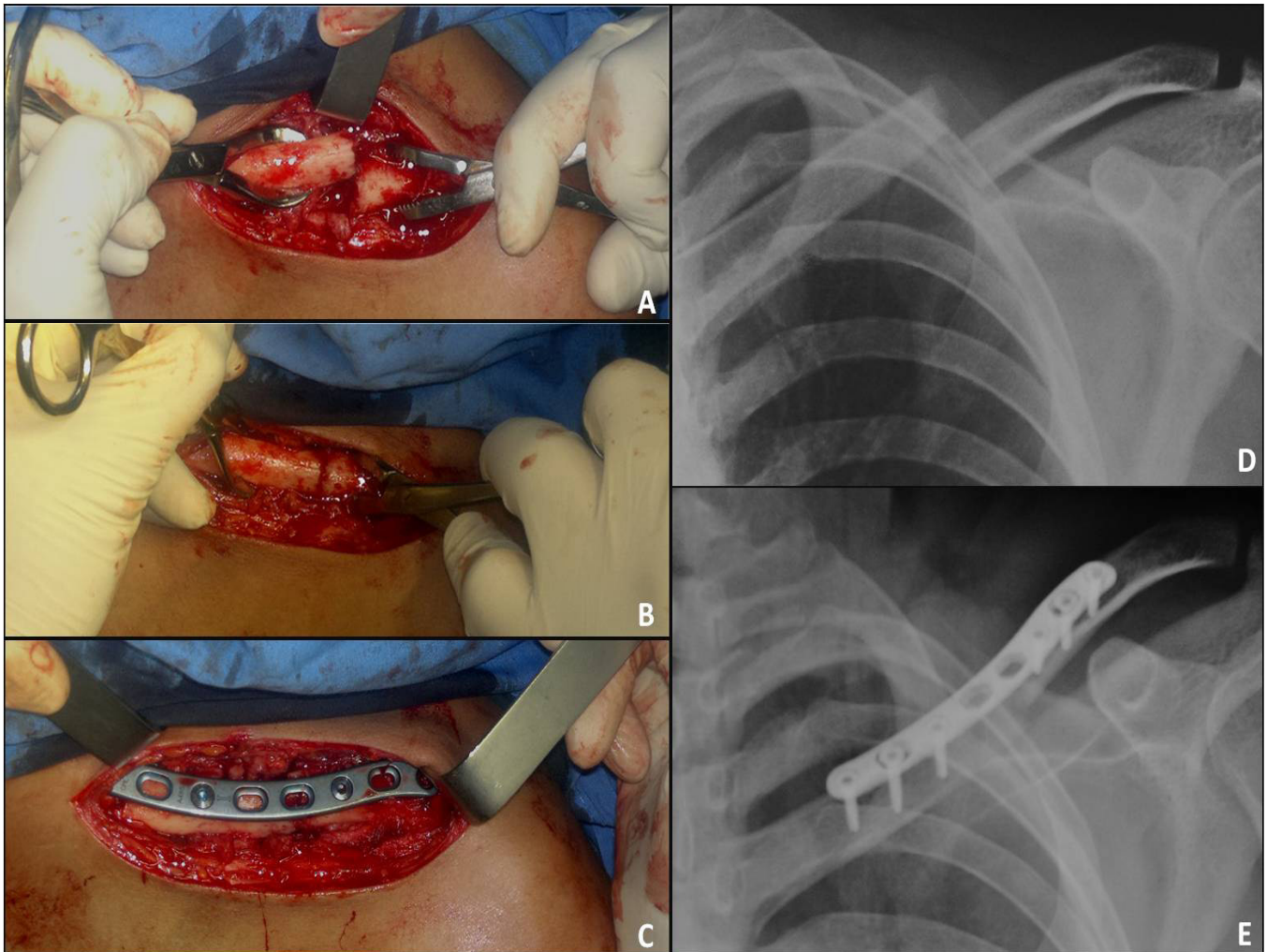


Figure 1. Fracture is exposed through a skin incision following the upper edge of the clavicle (A). Open reduction is performed (B), and the precontoured locking plate is placed on the upper face of the clavicle (C). D and E belong to the pre and postoperative x-rays, respectively.

progressive pendulum exercises were initiated. Lastly, the patients progress to resistance exercises, according to a standardized protocol.

The mean follow-up was 41.5 months (range 24 - 69, SD 13.4).

Functional evaluation

The mean maximum anterior elevation was 168.5° (range 120°-180°, SD 22.9), the mean maximum abduction was 175.2° (range 150°-180°, SD 27.8) and lastly, the external and internal rotations were not affected (80° and interscapular region respectively) [Table 2].

Mean DASH score was 1.27% (range 0%-25%. SD 4.3). UCLA score had a mean of 33.6 points (range 20-35, SD 3.5). Mean Constant Score was 90.5 (range 50-

100. SD 11.2). VAS evaluation threw a value of 3 in 2% (one patient), of 2 in 2% (one patient), of 1 in 13% (five patients), and of 0 in 83% (thirty-four patients).

Complications and reoperations

None of the patients presented delayed union or non-union. Within the complications registered we found: mild residual pain (3 cases), hypoesthesia or anesthesia of the infraclavicular area (2 cases), implant rupture (1 case). Three patients required reoperation: hardware removal due to intolerance (2 cases) and new osteosynthesis due to acute implant rupture (1 case).

This case of reoperation for rupture and release, was because the patient suffered a new trauma in the immediate postoperative period, and not due to failure of the system's stability or nonunion.

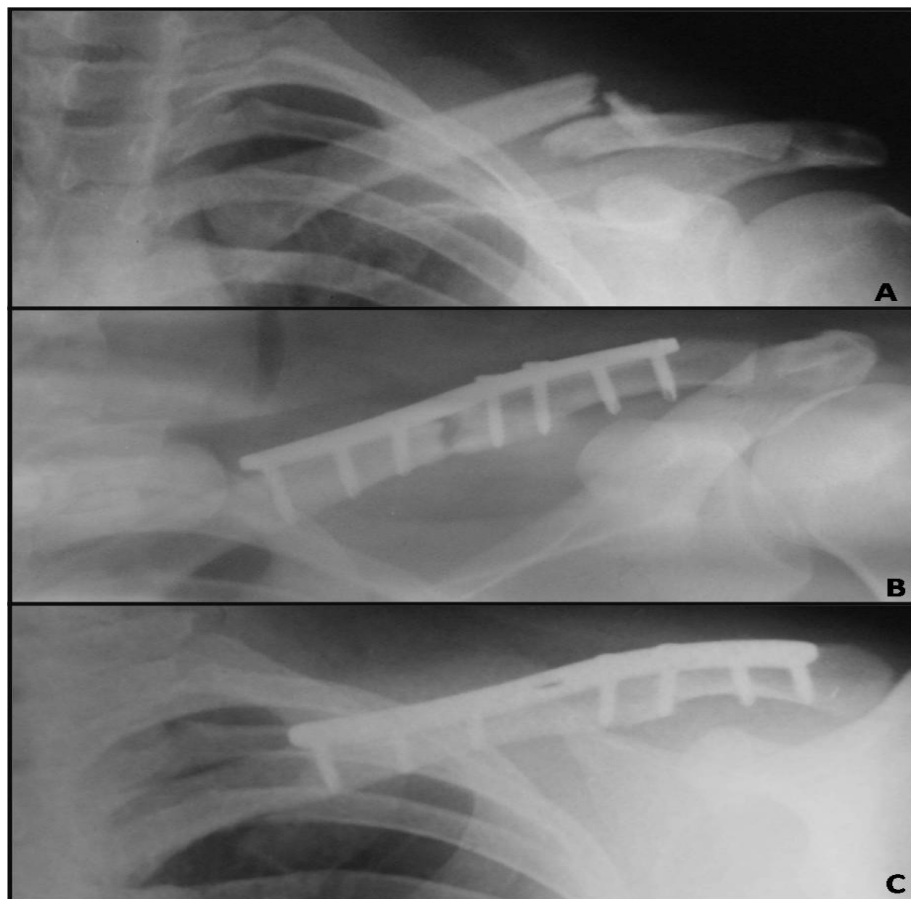


Figure 2. Preoperative (A), immediate postoperative (B) and one year postoperative (C) x-rays.

Table 2. Demographics and characteristics of patients including, age, gender, side AO classification, follow-up and functional results												
MID-SHAFT CLAVICLE FRACTURES TREATED WITH PRECONTOURED LOCKING PLATES							FUNCTIONAL EVALUATION					VAS
N°	Age	DASH		CONSTANT Dom	UCLA Classification	Follow up	DASH			CONSTANT	UCLA	
		Gender	Side				Gral	Work	Sport			
1	21	M	I	D	A1	29m	0.0	0.0	0.0	92.0	33.0	0
2	24	M	D	D	C1	52m	0.0	0.0	0.0	92.0	33.0	0
3	59	M	D	D	C1	28m	0.0	0.0	0.0	100.0	35.0	0
4	23	M	I	D	B1	64m	0.0	0.0	0.0	92.0	33.0	0
5	21	M	D	D	B1	28m	0.0	0.0	0.0	92.0	33.0	1
6	51	M	I	D	A2	44m	25.0	25.0	25.0	50.0	20.0	0
7	45	M	D	D	A3	31m	0.0	0.0	0.0	89.0	25.0	0
8	20	M	I	I	B2	61m	0.0	0.0	0.0	92.0	33.0	0
9	59	M	I	D	B1	31m	0.0	0.0	0.0	92.0	33.0	0
10	38	M	D	D	B1	24m	0.0	0.0	0.0	92.0	33.0	0
11	41	M	D	D	B2	52m	0.0	0.0	0.0	90.0	30.0	0
12	20	F	I	D	B1	41m	10.0	10.0	10.0	63.0	60.0	2

Continuous of Table 2.												
13	24	M	I	D	A1	31m	0.0	0.0	0.0	92.0	33.0	0
14	22	M	I	D	A3	24m	0.8	0.0	0.0	100.0	3.0	0
15	49	F	I	D	A1	36m	0.0	0.0	0.0	100.0	35.0	0
16	53	M	I	I	B1	26m	0.0	0.0	0.0	92.0	55.0	0
17	59	F	D	D	A3	34m	4.0	18.0	40.0	63.0	60.0	1
18	32	M	D	D	B2	56m	0.0	0.0	0.0	92.0	33.0	0
19	21	M	I	D	A2	32m	0.0	0.0	0.0	100.0	35.0	0
20	20	M	I	D	B1	31m	0.0	0.0	0.0	92.0	33.0	0
21	22	M	D	I	C2	27m	7.5	0.0	0.0	100.0	33.0	3
22	26	M	I	D	C1	37m	0.0	0.0	0.0	92.0	33.0	0
23	22	M	I	D	A3	43m	0.0	0.0	0.0	92.0	33.0	0
24	23	M	I	D	A3	30m	0.0	0.0	0.0	92.0	33.0	0
25	21	M	D	D	A1	31m	0.0	0.0	0.0	100.0	33.0	0
26	36	M	I	D	A1	39m	0.0	0.0	0.0	92.0	33.0	0
27	31	M	D	D	B3	29m	0.0	0.0	0.0	92.0	33.0	0
28	25	M	D	D	A2	38m	0.0	0.0	0.0	100.0	35.0	0
29	27	F	I	D	B1	38m	0.0	0.0	0.0	100.0	35.0	0
30	51	M	D	D	B1	61m	0.0	0.0	0.0	92.0	33.0	0
31	28	M	D	D	B3	42m	0.0	0.0	0.0	92.0	33.0	1
32	24	M	D	I	B3	53m	0.0	0.0	0.0	92.0	33.0	0
33	37	M	I	D	C1	67m	0.0	0.0	0.0	100.0	33.0	0
34	34	M	I	D	B1	54m	0.0	0.0	0.0	92.0	33.0	0
35	51	F	D	I	A1	24m	4.0	4.0	4.0	80.0	29.0	0
36	39	M	I	D	B3	44m	0.0	0.0	0.0	100.0	35.0	0
37	20	M	D	D	A3	58m	0.8	8.0	8.0	62.0	25.0	0
38	30	F	I	D	C3	58m	0.0	0.0	0.0	92.0	33.0	1
39	34	M	I	D	A1	69m	0.0	0.0	0.0	92.0	33.0	0
40	55	M	D	D	B1	56m	0.0	0.0	0.0	100.0	35.0	0
41	38	M	D	D	A1	51m	0.0	0.0	0.0	92.0	33.0	1

Discussion

Osteosynthesis in displaced clavicle fractures has demonstrated fewer complications than non-operative treatment (1, 10-15).

The current trend for the treatment of displaced mid-shaft clavicle fractures is ORIF. Some publications focus their analysis of effectiveness of the use of osteosynthesis in different scenarios: working population compensation, the different surgical approaches, the site of placement of the plate, different types of plates or different osteosynthesis techniques (16-22).

However, there is a lack of data about long term outcomes with the use of precontoured locking plates, since in most publications follow up is less than one year.

The scores in functional tests of the 41 patients

included in our study with three and a half years follow up, were similar to other studies with shorter follow-up.

Zhang et al in 2016 involved 15 patients with acute fractures in which “Minimally invasive plate osteosynthesis” was performed, obtaining a Constant score of 99, mean DASH score of 3.8 but with only 16.5 months follow up, no results are analyzed in relation to the parameters mentioned above (16).

Campochiaro investigated 68 clavicle fractures with 24.1 months of follow up (range 7–51) (2), obtaining the following results: a 4.1 value for DASH score, and excellent results in Constant Score (94.1) but 24% of the patients were untraceable at follow-up, and lateral clavicular fractures were also included in the analysis.

Recently, Ranalletta et al. obtained satisfactory clinical values using precontoured locking plates for the treatment of mid-shaft clavicle fractures: 1.8 for DASH Score, and 97.8 for Constant Score; however, follow up was not long (23.6 ± 10.7 months) (4). While our sample is lower, it has a longer follow up with similar results (1.27 for DASH and 90.5 for Constant). Moya et al, evaluated 34 patients with a mean follow up of 25 months (range 6-54 months) where patients achieved a mean Constant score of 85 (23).

The percentage of hardware removal due to irritation of soft tissue in our patients with a minimum of 2 years of follow-up, was only 4.86% (2 cases). Markedly lower than other series like Hulsman et al who compared the complication among top placement (68%) and anterior-inferior (51%) and Shon et al who found 15% of this complication (17,19).

Moreover, the rate of re-operations in our series (7.31%), total complications (17.07%) and the non-consolidation (0%) were similar to other series (4,19,24) and markedly lower than others such as 105 cases of Fridberg and cols, who followed part of patients within a year, and found a 23% rate of complications and 34% of reoperations. No functional patient data was available (25).

This study's limitations include its retrospective nature and the number of cases.

On the other hand, the positive aspects of this study include a final visit with a minimum of 2 years of follow-up.

Our experience with precontoured locking plates has shown excellent functional results, with a low rate of complications in different types of mid-shaft fractures.

The need for reoperation has been minimal, and we haven't observed non-union in these series.

This is why we consider the use of precontoured locking plates for surgical treatment of different types of mid-shaft clavicle fractures as a valid and proper treatment choice for this injury.

Patient consent

This study was approved by our institutional ethics committee (Acta no 57)- All procedures performed involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. We were waived of informed consent as a retrospective study.

Disclosure: The authors declare that they have not conflict of interest to declare.

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