

Simple Reconstruction Plate in Mid-shaft Clavicle Fractures – A forgotten Tool in Modern Orthopaedic Armamentarium!

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Abstract:

Aim: To evaluate functional & radiological outcome of mid-shaft clavicle fracture fixed with simple low-profile reconstruction plate (RP) when pre-contoured locking plates (LP) could not be used due to any reason.

Material and Methods: A prospective study involving 51 patients with such fractures with 2 years follow-up was conducted wherein Constant & DASH scores, range of motion (ROM) and subjective strength was measured. A questionnaire was prepared to be answered which graded the responses from excellent to poor.

Results- Most cases achieved excellent clinical & radiological outcomes. Mean time for radiological union & return to activity was 39 days (range, 33-180 days) & 71 days (range, 8-180 days) respectively. Mean Constant & DASH score was 95.35 ± 6.26 (range, 79 to 100) & 0.98 ± 2.19 (range, 0 to 9.1) respectively. Difference between ROM & strength between operated & normal side was clinically non-significant. As per the responses in the questionnaire, majority patients (90.2%) were extremely satisfied with the procedure and its outcome. Forty seven patients (92.15%) could go back to their original occupation. There were three cases (5.88%) of delayed union and one case (1.96%) of non-union.

Conclusion: RP when used obeying the appropriate surgical principles gives excellent functional & radiological outcomes for displaced mid-shaft clavicle fractures, which are comparable to that of LP. This finding is of significance for patients from lower economic strata especially from developing & under-developed countries, for very lean patients with prominent clavicle and for patients with abnormal clavicular morphology.

Keywords: Reconstruction plate; mid-shaft clavicle; fracture; functional outcome; cost-benefit.

Introduction

Clavicle is one of the commonly fractured bones, constituting about 2-3% of all fractures of the appendicular skeleton and about 40-45% of all shoulder girdle fractures (1-3).

There are many studies which have shown superior outcomes in open reduction and internal fixation (ORIF) using pre-contoured locking plates (LP) when used in indicated fractures(3-12). LP has indeed become a standard of care in this regard. In spite of all the advantages described for LP, there is one big factor, which is neglected- unintentionally or otherwise, which is the high cost of the implant. In developing & under-developed countries cost is a big factor which merits serious consideration on the part of health care providers. The LP can be up to 10 times more expensive than the simple plates (personal communication with leading orthopaedic implant manufacturers in India) and quite probably the outcome is going to be the same irrespective of implant being used provided basic surgical principles are strictly adhered to.

Clavicle classically depicts this sad truth; mid-shaft

fractures (most common site of fracture; 70-80%) of which were until very recently were successfully fixed with non-locking plates have almost become obsolete for the same indication. Approximately 10-15% of the patients with severely displaced/comminuted clavicle fracture when advised for ORIF with LP, opt for conservative management just due to economic constraints (informal survey done at our institution). Most of these patients are laborers or daily wageworkers that rely on optimal shoulder function for their livelihood. When such fractures are conserved poor outcome is a very real possibility, which is bound to impact their professional and personal life (3,6,8,13,14).

Aim of this study was to evaluate the outcome of RP used for fixation of mid-shaft clavicle fractures when LP could not be used due to any reason.

Material and Methods

32 patients prospective study was done in 57 consecutive patients (from February 2011 to December 2013) fulfilling the inclusion criteria in a level-I trauma center and medical college hospital. Appropriate ethical clearance and informed consent from the patient was taken prior to starting the study. The patients included in the study were explicitly told about the option of LP and its difference with RP. After they consented to the use of the later and were ready to be included in the study with use of their clinical and radiological data for this purpose, they were enrolled. All patients were followed up regularly for two years. The implant was routinely removed for all cases

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Figure 1: Well healed Incisional scar Figure 2: Clinical photographs of Shoulder Range of Motion taken at 15 weeks after surgery

usually after a period of one year (however it was also removed earlier if the patient complained of hardware prominence). They were also told to visit the casualty whenever they please in case of any issues with the affected limb or with the implant.

Out of the original 57 patients, three did not complete their follow-up, two sustained fractures of the ipsilateral limb and one died due to unrelated cause. So the final study and outcome measures include 51 patients (89.47% follow-up rate).

This patient cohort is significant from the fact that many of these patients (37/72.55%) were from lower socio-economic strata and were involved in strenuous laboring activities. Besides them, there were 11 patients (21.57%) who were too lean & clavicle too prominent so that the

relatively thicker LP would have caused soft-tissue irritation or skin breakdown, and there were three patients (5.88%) in whom LP was initially planned to be used but the idea was dropped intra-operatively as the LP would have needed too much contouring to conform with the native clavicular anatomy of these patients which in turn would have risked the locking mechanism

Inclusion criteria:

1. Midshaft fractures
2. Skeletally mature
3. Displacement or Shortening ≥ 2 cm.

Exclusion criteria:

1. Skeletally immature
2. Undisplaced/minimally displaced fractures
3. Open fractures
4. Pathological fractures.
5. Associated head injury/ neurovascular injury/ipsilateral limb injury
6. Past history of shoulder pathology/injury
7. Condition which precluded the patient to follow post-op orders

All patients were operated in beach-chair position under general anaesthesia using standard technique(9,15,16). Contouring the plate to native anatomy is important. Proper soft tissue & skin closure leads to a cosmetically acceptable scar. (Fig 1).

The operated upper limb was immobilized in a simple sling. Pendulum exercises were started as soon as the patient tolerated. Passive range of motion (ROM) was started after two weeks, which gradually advanced to active assisted ROM at four weeks and full active ROM at six weeks (Figure 2). After this strengthening exercises were started and gradual resumption of daily activities was resumed. Generally after 12-14 weeks all patients returned to their original level of activity.

Functional outcome was measured with Constant Score & DASH score by a physiotherapist while radiological assessment was done by a radiologist

Table 1: Demographic Details

VARIABLE	NO.OF PATIENTS (n = 51)	PERCENTAGE
Mode of injury		
Road traffic accident	35	68.63
Fall on outstretched hand	11	21.57
Unknown	5	9.8
Gender		
Male	33	64.71
Female	18	35.29
Side		
Dominant	27	52.94
Non-Dominant	24	47.06
Robinson Type		
2B1	34	66.67
2B2	17	33.33

Table 2: Descriptive Statistics

VARIABLE	MEAN	SE MEAN	SD	MIN. VALUE	MEDIAN	MAX. VALUE
Age (years)	33.51	1.57	11.2	20	30	62
AB	174.09	0.486	3.47	163	174.5	179
AB N	175.95	0.287	2.05	171	176	180
ER	83.647	0.443	3.161	74	84.5	87.5
ER N	85.127	0.286	2.042	79.5	85.5	89.5
IR	66.608	0.44	3.145	59	67	74
IR N	68.608	0.402	2.869	63.5	69	75
FE	174.35	0.488	3.48	164.5	175.5	178.5
FE N	176.17	0.348	2.49	169	177	179
DASH	0.982	0.869	6.206	0	0	9.1
CS	95.353	0.869	6.206	79	96	100



Figure 3: Doubtful union at end of 18 weeks. Clinically the patient had pain, tenderness and inability to freely use the extremity.

pertaining to status of pain/complications during the study, quality of life after the surgery, return to work status and finally a question whether they would recommend the procedure to someone else or undergo the same procedure again if need arises. The response was then graded as poor, fair, good, very good and excellent.

Two sampled t-test was used to find the influence of gender, side & fracture type on functional outcome score while paired t-test was used to find statistically significant differences between ROM & strengths of operated & normal shoulder. Statistical significance was established as $p < 0.05$. All statistical analyses were performed using SPSS software Version 20.0 (SPSS Inc, Chicago, IL, USA).

Results

32 pDemographic variables are described in tables 1 & 2.

There were no major complications like neuro-vascular damage, implant fracture, skin necrosis needing secondary coverage, deep infections or frozen shoulders(17-19).

There were three cases (5.88%) of delayed union (united after 12 weeks) and one case (1.96%) of non-union (no

(none of them were part of study). Both radiological and clinical union was looked for. A general patient satisfaction questionnaire was prepared which the patient was supposed to answer at the end of the study. It contained 'YES-NO' type of subjective questions and were

Table 3: General Satisfaction questionnaire outcome

GENERAL SATISFACTION	NO. OF PATIENTS (n = 51)	PERCENTAGE
Excellent	34	66.67
Very Good	12	23.53
Good	3	5.88
Fair	2	3.92
Poor	0	0

Table 2: Descriptive Statistics

GENDER	MALE	FEMALE
Number of patients	33	18
MEAN		
DASH	0.69	1.52
CS	95.52	95.06
SD		
DASH	1.84	2.7
CS	5.52	7.47
SE MEAN		
DASH	0.32	0.64
CS	0.96	1.8
T VALUE		
DASH	1.16	
CS	-0.23	
P VALUE		
DASH	0.257	
CS	0.821	

Table 5: Two-sample t-test for Side – DASH & Side – Constant Score (CS)

SIDE	DOMINANT	NON-DOMINANT
Number of patients	27	24
MEAN		
DASH	1.18	0.76
CS	95.81	94.83
SD		
DASH	2.7	1.44
CS	6.37	6.11
SE MEAN		
DASH	0.52	0.29
CS	1.2	1.2
T VALUE		
DASH	0.71	
CS	0.56	
P VALUE		
DASH	0.483	
CS	0.577	

Table 6: Two-sample t-test for fracture type – DASH & fracture type – Constant Score (CS)

ROBINSON TYPE	2B1	2B2
Number of patients	34	17
MEAN		
DASH	0.74	1.47
CS	96.12	93.82
SD		
DASH	2	2.53
CS	5.45	7.44
SE MEAN		
DASH	0.34	0.61
CS	0.93	1.8
T VALUE		
DASH	-1.04	
CS	1.13	
P VALUE		
DASH	0.307	
CS	0.270	

SE- Standard Error, SD- Standard Deviation, p value < 0.05 indicates statistical significance

Table 7: Comparison between range of motions of shoulder of normal & operated side

MOTION	DIFFERENCE	SD	SE MEAN	T VALUE	P VALUE
AB	-1.865	3.188	0.446	-4.18	0.000
ER	-1.48	3.455	0.484	-3.06	0.004
IR	-2	2.081	0.291	-6.86	0.000
FE	-1.814	3.189	0.447	-4.06	0.000

Difference- difference between the normal & operated side (in degrees)
 AB- Abduction, ER- External Rotation, IR- Internal rotation, FE- Forward
 Elevation (all in degrees)
 SE- Standard Error, SD- Standard Deviation, p value < 0.05 indicates
 statistical significance

signs of clinical or radiological union at six months – Figure 3). Autologous iliac crest bone grafting was done for this patient after which the fracture united uneventfully. Out of these four cases, two were chronic smokers (includes the case of non-union) and one didn't obey the post-op physiotherapy protocols and had tried to resume his work before approved by the physiotherapist.

Besides this there were four cases (7.84%) screw loosening (screws were starting to back-out and were irritating the skin) which were removed under local anesthesia on an outpatient basis. screw backing-out incidence took place after confirmed radiological and clinical union, so had no effect on the clinical outcome. Also there were two cases (3.92%) each of hypertrophic scarring and paresthesia over the upper part of chest that later resolved on its own in 10-12 weeks. One (1.96%) of the last two patients incidentally had superficial infection as well that was taken care of by antibiotics and dressings. Six patients (11.76%) patients complained of implant prominence.

Mean time for radiological union was 39 days (range, 33 – 180 days) while mean time for return to activity was 71 days (range, 8 – 180 days). Beyond 180 days in the absence of clinical/radiological signs of union, the case was considered as non-union.

The mean Constant & DASH scores were 95.35 ± 6.26 (range, 79 to 100) & 0.98 ± 2.19 (range, 0 to 9.1) respectively. The mean abduction, ER, IR and FE in degrees was 174.09 ± 3.47 , 83.65 ± 3.16 , 66.61 ± 3.14 and 174.35 ± 3.48 respectively; while the mean difference for these ROMs from normal sides in degrees was 1.87 ± 3.19 , 1.48 ± 3.45 , 2 ± 2.08 and 1.81 ± 3.19 respectively. From tables 4, 5 and 6 it can be learnt that the functional outcome was not affected by gender, side involved or fracture type.

As per table 7 & 8, the difference in the ROM and strengths between the operated and normal side is statistically significant but clinically the reflection on subjective outcome was minimal, if any (clinically insignificant). We had the patients answer a questionnaire containing questions pertaining subjective outcomes important to

our patients, which were to be answered in a 'yes-no' format. The overall satisfaction rate as per this questionnaire was quite high (46 or 90.2% patients in good or excellent category) and these patients would recommend the surgery to others or would undergo the same again if need arises in the future (Table 3).

Out of 51 patients, 47 (92.15%) could go back to their original occupation unhindered, two (3.92%) continued in their old occupations but with some pain or limitations while two (3.92%) had to change their occupation which was less demanding for their limb. Out of these latter four cases (7.84%), three cases (75%) were those who had problems with union or didn't follow the muscle strengthening protocols.

Discussion

Most important finding of our study was that using RP for ORIF of clavicle can yield equally good results when compared with other types of fixation modes.(3,11,20–22) Our functional outcomes were comparable to majority of other studies on clavicle ORIF procedures. Adding to the fact- majority cases had an uneventful path towards full recovery and majority patients were satisfied with the procedure and would recommend the same to others or would undergo it themselves again if need arises. It is noteworthy that all patients in this cohort had lifestyle having strenuous use of the affected arm.

Earlier studies showed that conservative treatment in form of arm sling and /or figure of eight bandage resulted in good union rates and good functional outcome even when significantly displaced.(3,5,8,14,23) However more recent studies showed that outcome of such fractures, especially in presence of displacements was sub optimal. Non-union rates of displaced midshaft clavicular fractures treated conservatively was reported to be as high as 15%; higher than that reported in previous studies. Recent literature favors operative management of displaced and shortened midshaft clavicle fractures, which stands as the standard of care presently(2,3,6,12,13,19,24,25,15,26). The advantages of ORIF of clavicle include anatomical fracture reduction, faster and predictable return of function, better pain relief and improved patient satisfaction. (3,5,6,9,10,12,13).

ORIF using plates is one of the best methods to achieve anatomic reduction and good solid union. Currently precontoured LP is one of the most popularly used devices. Not so long ago RP was advocated as satisfactory option for the same but have no fallen out of vogue among surgeons after introduction of LP. No doubt, LP provide a better stability and a stronger mode of fixation which might help in earlier rehabilitation (4,11,20,22,27,28).

However, LP has one major disadvantage- high cost. This is one of the most important factors in consideration of treatment options in patients among lower socio-

economic strata and those without a health insurance. Pre-contoured LP may not always fit a perfectly on clavicle. Clavicle being a subcutaneous bone, anything less than a perfectly matched plate is bound to give skin problems. LP then needs manual contouring, which is likely to affect the locking mechanism of these plates, which in turn defeats the main purpose for using this plate!(27,28) On the other hand, RP can be easily molded depending on the anatomy without any apprehensions. Many times clinical scenario requires the screw to be inserted at an angle (lag screw through the plate). Such a liberty is not possible with LP and many times a longer plate is needed which in turn again increases the cost and complications associated with enhanced exposure(17,18). LP though is stiffer, is also thicker than its corresponding RP, which can be an issue in lean patients in form of implant prominence (3,20,22,16). Implant removal of locking plates can become more problematic especially if one considers facts like cold-welding (28).

It is often stated that RP are less stiff and unsuitable to withstand the loads exerted across the clavicle and that the screw back out can be a major issue. Previously Pai et al (22) have stated that locking plates have a better outcome especially if used in elderly patients with comparison to non-locking plates. Robertson et al and Marie C (11,29) have also biomechanically proven that locking plates are superior to non-locking plates. However, these complications were not a major issue in our study and did not affect the final outcome of the patients who experienced it.

So in patients who are from economically weaker background, RP can be a satisfactory option for LP, which in no way adversely affects the outcome nor has any increased complications rate. This study outcome can definitely be a boon for patients in developing and under-

developed countries where a large part of income in some families is spent on expensive medical care. It is also the case in patients with clavicles not conforming to the precontoured LP (in which case lot of contouring maybe needed by the surgeon increasing the operating time and also risking the loss of locking mechanism of screw heads) or in very lean patients where the relatively thicker LP might cause soft-tissue problems.

Our study is not without its own limitations. First, there was no control group in study, however the main aim of the study was to find the utility of RP today when LP cannot be used due to any reason. To compare the outcomes with other modes of fixation was never the goal. However, such a study can be worthwhile to analyze the cost-benefit analysis of various modes of fixation. Secondly, study sample of this series was relatively small for a meaningful power analysis. Thirdly, all the plates were fixed on the superior surface of the clavicle. Additional studies are desirable to see difference in outcomes using the antero-inferior approach as some previous studies have indicated that such differences might exist (30,31). Finally, findings of patients who could not be followed up till the end may have changed the outcomes of the study. However, a follow-up of 100% in a population who migrate to different cities frequently for search of livelihood is difficult to achieve.

Conclusion

ORIF of displaced mid-shaft clavicle fractures using RP is a very good cost-effective option giving excellent functional & radiological outcomes and a high patient satisfaction rate without any enhanced rate major complications related to the procedure or the implant.

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