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Conservative Vs operative management of displaced midshaft clavicle fracture: A comparative study

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Abstract
Background: Clavicle fracture is one of the common fractures accounting for 2.6-12% of all fractures and 44-66% of shoulder fractures. Mid-clavicle fractures account for almost 80% of clavicle fractures. Most of the these fractures were treated conservatively in past but recently there has been an increasing tendency for operative management. Though many studies have been conducted to assess the benefit of primary surgical management against conservative management, no consistent results have been obtained to show which one is better. So, this study was carried out to compare the radiological and functional outcome following conservative management to that of operative management with open reduction and internal fixation (ORIF) with plating for displaced midshaft clavicle fractures.
Methods: In a single centre, prospective clinical trial, 60 patients with displaced midshaft fracture of the clavicle were systematically randomized (alternate patient) into either operative treatment with plate fixation or non-operative treatment with clavicle brace and arm sling. Outcome was analysed in terms of functional outcome and radiological union by standard follow-up, Constant and Murley shoulder score and plain radiographs. All sixty patients completed six month follow up and there was no difference between two groups with respect to patient demographics, mechanism of injury and fracture pattern.
Result: There was no significant difference in Constant shoulder score between the two groups. The mean time of union was 14.57 weeks in operative group compared to 16.04 weeks in nonoperative group (p value=0.191). There were two non-union in nonoperative group compared to none in operative group. The complications in operative group were mainly hardware related (four had loosening of screw, two had implant failure and one had infection). At six months after surgery patient were more likely to be satisfied with the results in operative group compared to nonoperative group (p=0.02).
Conclusion: Six months after a displaced midshaft clavicular fracture, nonoperative treatment resulted in higher malunion and non-union rate but similar functional outcome and union time compared to operative management. However, patients were more likely to be satisfied in operative group compared to nonoperative group.

Keywords: Floating hip, Acetabulum Fracture, Femur Fracture

Introductions

Clavicle acts as bony connection between thorax and shoulder girdle while contributing to movements around the shoulder [1]. It transmits weight from the appendicular skeleton to the axial skeleton. It is one of the common bones to fracture accounting for 4-12% of all fractures and 44-66% fractures around shoulder. Mid-clavicle fractures account for almost 80% of clavicle fractures [2]. In 94% of cases it follows direct trauma whereas rest cases occur due to fall on outstretched hand [3]. Midshaft fracture commonly occurs in young adult whereas lateral and medial end clavicle fracture is more common in elderly [4, 5]. More than 200 methods of operative and nonoperative methods for management of clavicle fractures have been described [6]. These methods can be roughly divided into operative and non-operative methods. Most commonly used non-operative method is clavicle brace and an arm sling. It has advantage of being non-invasive, absence of exposure to anaesthesia as well as absence of operative complications. However, nonoperative methods are said to be associated with risk of non-union, residual deformity and patient dissatisfaction. Most clavicular fractures still are treated closed and heal uneventfully without serious consequences [7].

Non-operative management was widely recommended for middle third fracture given higher union rate with non-union of 0.03 to 6.2% [8, 9] However, with recent studies showing non-

union rates up to 15% and patient dissatisfaction of up to 31%, there is increasing trend for operative management [10]. Three types of fixation are available for middle-third clavicle fractures: intramedullary devices, plates and external fixators [6]. Intramedullary fixation can be accomplished with smooth or threaded K- wires, Steinman pins, Knowles pins, Hagie pins, or cannulated screws. With intramedullary devices, there is less surgical dissection and soft tissue stripping with less hardware prominence. However, there is the possibility of pin migration and poor rotational control during overhead abduction of shoulder [6]. External fixation of the clavicle is indicated for severe open fractures with poor quality overlying skin. External fixation may also be indicated for treatment of clavicle fractures in the face of infection or infected non-unions following plate removal. Even in these cases, plate fixation should be considered first and used whenever possible [6]. Plating of acute clavicle fractures, when indicated, is advocated as the preferred fixation method by many authors. Biomechanically, plate fixation is superior to intramedullary fixation as it better resists the bending and torsional forces that occur during elevation of the upper extremity above shoulder level. Patients treated with plate fixation can be allowed full range of motion once their soft tissues have healed. Disadvantages of plate fixation include the necessity for increased exposure and soft-tissue stripping, potential damage to the supraclavicular nerves, which cross through the surgical field, slightly higher infection rates and the risk of refracture after plate removal. These complications can be reduced by careful soft tissue handling, minimal periosteal stripping and meticulous plate fixation [6]. We compare the conservative and operative management of midshaft displaced clavicular fracture.

Materials and Methods

The study was done at the tertiary care trauma centre between October 2017 to October 2020. There were 30 patients in each group. All the patients with isolated closed displaced traumatic mid-clavicular fractures without neurovascular involvement between age group 16-60 years were included in the study (Figure 1). Patients were enrolled from the emergency department and every alternat patient were enrolled between the two groups. Group A underwent conservative management and Group B underwent open reduction and internal fixation with a plate.

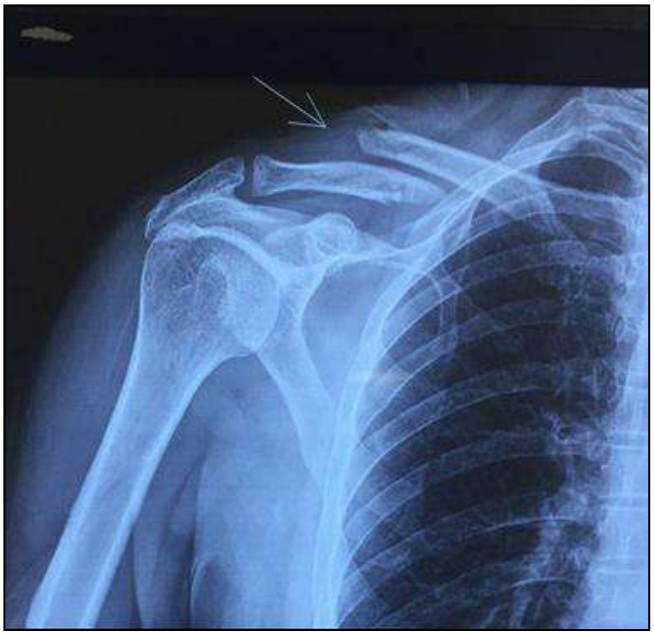

Fig 1: Pre-operative Anteroposterior radiograph showing Midshaft clavicle fracture.

Surgical Management

Patient was taken on operating table in beach chair position. Anterior approach was used and an oblique 8-10cm incision was made along the inferior border of the clavicle under general anaesthesia. Fracture reduction with minimal periosteal stripping attempted using reduction holding forceps (Figure 2). The plate was contoured to the shape of the clavicle. Autogenous iliac crest bone grafting was performed in severe comminution in the inferior surface to avoid non-union or fixation failure or metal breakage caused by tension. Final fixation confirmed using fluoroscopic guidance (Figure 3). Final x rays obtained in the immediate post-operative period (Figure 4). Patients were given intravenous antibiotics for a period of 3 days and then discharged. The patients were given arm sling for two weeks. After two weeks suture removal was done, and range of motion (Figure 5) was started.

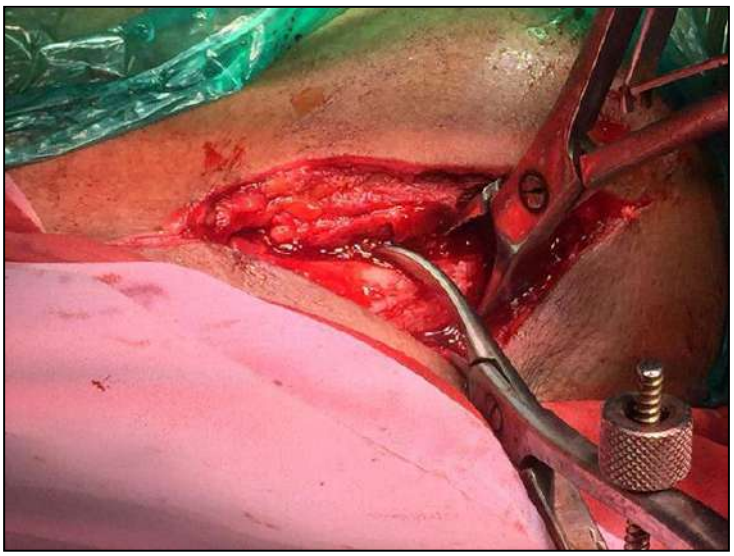

Fig 2: Intra-operative image showing fracture reduction being attempted.

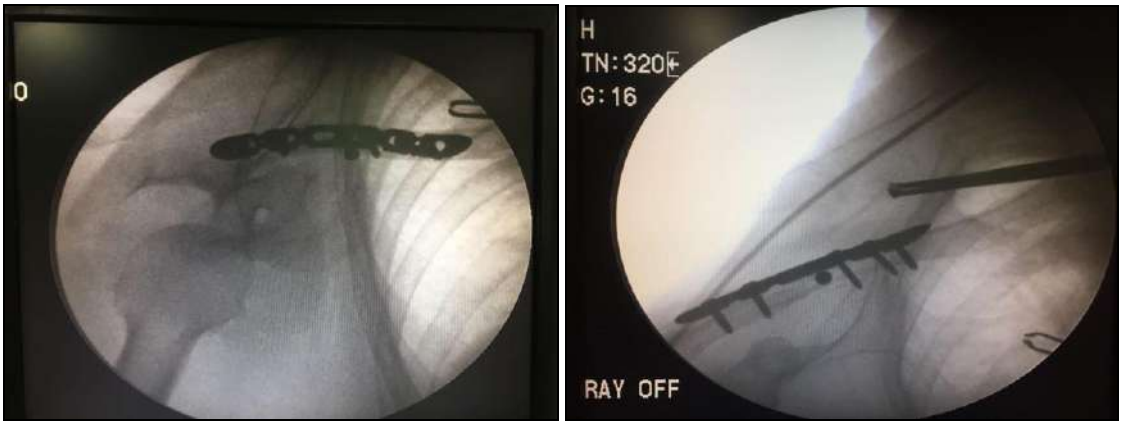

Fig 3: Intra-operative fluoroscopic image confirming final fixation.

Fig 4: Post-operative Anteroposterior radiograph.

Fig 5: Clinical pictures showing range of motion in post-op period

Conservative Management

The patient will be managed conservatively using clavicle brace and an arm sling (Figure 6) in which limb is immobilised for six weeks. After six weeks Range of motion will be started.

All the patients were followed up at two weeks, six weeks, twelve weeks, eighteen weeks and twenty-four weeks. Cases were assessed clinically at subsequent follow-up visits and results were designated as Excellent, Good, Fair and poor based on Constant and Murley scoring at the end of 6 months.

Fig 6: Managed conservatively using clavicle brace

Constant and Murley Scoring

The Constant-Murley score (CMS) is a 100-points scale composed of a number of individual parameters. These parameters define the level of pain and the ability to carry out the normal daily activities of the patient. The test is divided into four subscales: pain (15 points), activities of daily living (20 points), strength (25 points) and range of motion: forward elevation, external rotation, abduction and internal rotation of the shoulder (40 points). The higher the score, the higher the quality of the function.

Patients were graded as below with a maximum of 100 points.

Total score	Result
90-100	Excellent
80-89	Good
70-79	Fair
0-70	Poor

Radiological evaluation was done using anteroposterior radiographs of the chest including both clavicles at subsequent follow-ups. The radiographic union was defined as complete cortical bridging between proximal and distal fragments on both radiographs. Permission to carry out this study was obtained from Hospital Ethical Committee.

Result

Patient Demographics

In this study, the youngest patient was 17 years, and oldest patient was 59 years with the average age being 32.2years with a standard deviation of 11.656 (Table 1). The majority

of patients (55% of total cases) were below 30 years of age. The distribution of patients on two groups were similar on the basis of age with a mean age in a conservative group of 33.567 with a standard deviation of 12.445 and that in an operative group of 30.833 with a standard deviation of 10.847 and had no significant difference statistically (p value=0.368).

Table 1: Distribution of patients by age.

Age	Management		Total	%
	Conservative	ORIF with Plating		
<30 years	15	18	33	55
30-45 years	8	7	15	25
>45 years	7	5	12	20
Total	30	30	60	100
Mean Age: 33.567±12.445			Mean age: 30.833±10.847	

p value=0.368

Gender Distribution

In our study the majority of cases (78.3%) were male, and 21.7% were female, and the sex distribution in both groups was not statistically significant (p value=0.347) (Table 2)

Table 2: Distribution of patients by sex.

		Management		Total	%
		Conservative	ORIF with Plating		
Sex	F	8	5	13	21.7
	M	22	25	47	78.3
Total		30	30	60	100

p value =0.347

Laterality of Fracture

In this study, 31 patients (51.67%) had left sided fracture, and 29 patients (48.33%) had right sided clavicle fracture, and fracture distribution by the side on the two groups were similar with no statistical significance (p value= 0.796) (Table 3).

Table 3: Distribution by laterality.

		Management		Total	%
		Conservative	ORIF with Plating		
Injured side	left	15	16	31	51.67
	right	15	14	29	48.33
Total		30	30	60	100

p value =0.796

Pattern of Fracture

Most of the fractures were oblique accounting for 41.67% followed by transverse (40%) and comminuted fracture (18.33%) (Table 4). The characteristic of fracture pattern in both groups was identical with p-value of 0.937.

Table 4: Distribution by the pattern of fracture.

		Management		Total	%
		Conservative	ORIF with Plating		
Pattern of Fracture	Comminuted	6	5	11	18.33
	Oblique	12	13	25	41.67
	Transverse	12	12	24	40
Total		30	30	60	100

p value = 0.937

Mode of Injury

Most common mode of injury was road traffic accident (76.67%) followed by fall injury (23.33%). The distribution of patients in both groups was identical with no statistical significance (p-value = 0.542) (Table 5).

Table 5: Distribution by mode of injury.

		Management		Total	%
		Conservative	ORIF with Plating		
MOI	fall injury	8	6	14	23.33
	RTA	22	24	46	76.67
Total		30	30	60	100

p value=0.542

Union Time

The average union time in the conservative group was 16.04 weeks with a standard deviation of 4.229 and that in ORIF with plating group was 14.57 weeks with a standard deviation of 4.150 There was a reduction in the mean duration of the union when patient was managed operatively, but this reduction was not statistically significant (p value=0.191) (Table 6). There was a reduction in union time in operative group compared to the conservative group with 53.33% of fractures in an operative group united before 12 weeks whereas in conservative group 53.6% of fracture union occurred between 12-16 weeks (p value=0.292).

Table 6: Mean fracture union time.

	Management	N	Mean	Std. deviation	t value	p-value
Union time	Conservative	28*	16.04	4.299	1.324	0.191
	ORIF with plating	30	14.57	4.150		

Functional Outcome

Constant and Murley Score: The average value of Constant and Murley score in the conservative group was 94.47±7.514 and that in operative group was 96±7.909. The difference in Constant and Murley scoring of the two groups was not significant (p value=0.445)(Table 7)

Table 7: Mean Total score at twenty-four weeks.

		N	Mean	Std. deviation	t value	p value
Manag-ement	conservative	30	94.47	7.514	0.77	0.445
	ORIF with plating	30	96	7.909		

Complications

Complications including non-union and malunion were more common in a conservative group whereas

complications in the operative group were prominently related to hardware (implant failure, loosening of screw, infection). There were two cases of non-union in conservative group none of which had many limitations in range of motion with slight restriction in internal rotation and slight restriction of daily activities at six month follow up. On continued follow-up both the cases were asymptomatic with no functional restriction and no further intervention was required. There was a significantly high number of malunion in the conservative group compared to operative group (p value<0.001). Twenty-one (70%) cases in conservative group had malunited whereas only 1 (3.3%) in operative group had malunion. Despite the high incidence of malunion in the conservative group, there was no significant functional restriction of the patient apart from the appearance of the region. We had 1(3.3%) patient with an infection which became apparent after six weeks. The case was managed with implant removal, debridement, and intravenous antibiotics. The infection subsided eventually, and the fracture union was evident at 24 weeks. We encountered 4(13.3%) cases of screw loosening of which 2(6.67%) patients developed implant failure. Out of these two patients, one patient had bent plate seen at 18 weeks follow-up. The fracture had united, and the patient was managed with implant removal later. The next case had backed out of screws with loss of reduction and was managed with replating with bone graft ten weeks after initial surgery. The patient again developed implant failure after six weeks of second plating and the implant was removed, and the patient was managed with a sling. The fracture eventually united by 32 weeks and the patient had no significant functional deficit at 32 weeks.

Patient Satisfaction

Patient satisfaction was found to be significantly higher in operative group compared to the conservative group at the end of six months. It was found that 93.3% patients were satisfied with results in operative group compared to 70% in conservative group (p value<0.05) (Table 8).

Table 8: Patient satisfaction.

		Patient satisfaction	
		Yes	No
Management	Conservative	21(70%)	9(30%)
	ORIF with plating	28(93.3%)	2(6.7%)

p value=0.02

Discussion

Fracture of clavicle accounts for 2.6% to 12% of all fractures and 44% to 66% of fracture about the shoulder. About 80% of these fractures are in middle third and less often in the lateral third (15%) and medial third (5%) [2]. Different conservative treatment methods are described of which arm sling and figure of 8 bandages are commonly used. None of the methods reduce fracture, but arm sling results better patient satisfaction with lesser side effect [20]. Many earlier studies have shown excellent results with non-union rate ranging from 0.3% to 6.2% [8, 9, 36]. Recent studies have shown higher incidence of non-union with 4.5% to 9.5% in Robinson's series to as high as 15% in Hill's series [8, 10].

Plate fixation of the fracture provided immediate stabilization, pain relief and early mobilisation and resumption of preinjury activities [10, 13, 36]. Reconstruction plates when contoured and used superiorly gives stable construct, predictable union, and excellent functional outcome [28]. Complications associated with plating of clavicle include infection, hardware failure, hypertrophic scar, delayed union or non-union and need of reoperation for implant removal [18]. If hardware removal was considered Bostman *et al*. found complication rate to be as high as 43% with a reoperation rate of 14% whereas Dhoju *et al*. found it to be 10% and 25% respectively [27, 28].

Recent clinical trials comparing conservative and operative management of displaced clavicle fracture have shown varying results that ranged from similar outcome despite the treatment method to a better outcome with operative management [29, 31, 35]. Range of motion was preserved in all cases of fracture clavicle despite the method of management [29, 31, 32, 35]. Virtanen *et al*. and Judd *et al*. found similar functional outcome in terms of Constant score and DASH score whereas study done by Canadian Orthopaedic Trauma Society and Vaithilingam *et al*. showed better functional outcome with operative management [29, 31, 32, 35]. Conservative management of clavicle fracture results in higher rate of non-union and malunion compared to operative management whereas operative management results in higher rate of plate-related complications [29, 32, 33, 35].

This study was undertaken to compare the functional and radiological outcome in patients with fracture clavicle managed either operatively or conservatively and to access the patient satisfaction following treatment in either group (Table 9). In this study majority of the patients were young (< 30 years, mean age32.2 years) with male preponderance (Male: 78.3% versus Female: 21.7%). Stanley *et al*. had reported the bimodal distribution of clavicle fracture; the majority is occurring either before thirty years or after seventy years [3]. This finding was similar to that by Bostman *et al*., Dhoju *et al*., Douraiswami *et al*. and Vaithilingam *et al*. who have reported mean age to be 33.4 years, 31.5 years, 32.5 years and 32.9 years respectively [27, 28, 35, 37]. Similar to this study Bostman *et al*., Dhoju *et al*., Douraiswami *et al*., Judd *et al*., Postacchini *et al*., Shen *et al*. and Vaithilingam *et al*. have reported higher incidence of fracture among male [27, 28, 31, 37, 39].

Table 9: Functional result at 24 weeks.

		Result at 24 weeks			
		Excellent	Good	Fair	Poor
Conservative	24(80%)	4(13.3%)	1(3.3%)	1(3.3%)	28
	ORIF with plating	27(90%)	1(3.3%)	1(3.3%)	1(3.3%)

p value=0.665

Note: In both, the groups 93.3% patients had good and excellent outcome, and only one patient in each group had a poor outcome.

In this study majority of fracture was present on the left side (51.67%) compared to the right (48.33%). Similar to this study Judd *et al*., Postacchini *et al*. and Vaithilingam *et al*. have reported fracture clavicle to be more common in left side which was non-dominant side in most of the cases [31, 35, 39]. Most of the fractures were oblique (41.67%) followed by transverse (40%) and comminuted (18.33%). This finding was similar to that by Douraiswami *et al*. who found comminuted fractures to constitute only 24% of total cases, and rest were two-part fractures [37].

In this study, 76.67% of cases developed clavicle fractures following road traffic accident with direct impact on shoulder followed by fall injury in 23.33% of cases. Zlowodzki *et al*. and McKee *et al*. described fall or blow to shoulder as the most common mechanism for injury [24, 25]. Similar to this study Vaithilingam *et al*., Patel *et al*. and Judd *et al*. had reported road traffic accident as the most

common mode of injury accounting for 53% to 70% of cases [31, 34, 35]. This slightly higher incidence of road traffic accident as a major cause of clavicle fracture might be because of the fact this hospital is located in the region which is prone to motor vehicle accidents. In this study in patients managed operatively reconstruction plate was used in 76.7% of cases followed by a clavicular plate in 13.3% cases and semi tubular plate in 10%. A similar type of plate usage was also reported by Bostman *et al*. and Patel *et al.* [27, 34].

In this study, there was no significant reduction in time required for fracture union with the union in operative group occurring at the mean time of 14.57 weeks compared to 16.04 weeks in conservative group (p value=0.191). Consequently the majority of fractures in operative group (53.33%) united by 12 weeks whereas the majority of fractures in conservative groups (53.6%) united between 12-18 weeks period (p value=0.292) (Table 10).

Table 10: Duration of fracture union.

		Duration of union			Total
		<12 weeks	12-18 weeks	>18 weeks	
Management	Conservative	10(35.7%)	15(53.6%)	3(10.7%)	28
	ORIF with plating	16(53.33%)	10(33.33%)	4(13.33%)	30

p value=0.292

Smekal *et al*. in which union time was shortened in the operative group (12.1 weeks) when compared to conservative group (17.6 weeks).40 Judd *et al*., Patel *et al*. and Vaithilingam *et al*. also reported reduction in union time in operative group compared to the conservative group [31, 34, 35]. This relative increase in union time in an operative group in this study could be attributed to a case which had implant failure resulting into repeated surgery and delayed union and longer duration between two follow-ups thereby increasing union time. In this study, Physiotherapy was initiated in the conservative group only after six weeks of immobilization compared to early initiation of physiotherapy in other studies. This longer duration of immobilization could have resulted in the reduction in union time by reducing the motion at the fracture site.

In this study, there was no significant difference in the Functional outcome measured regarding Constant and Murley scoring between the two groups of patient. There was only 1(3.3%) poor outcome in each group, and the average Constant and Murley scoring was 94.47 in conservative and 96 in operative group. A study by Virtanen *et al*. had shown no difference in functional score, Constant and Murley score and DASH score, between operative and conservative management [32]. Similarly, Smekal *et al*. in 2009, compared intramedullary nailing to nonoperative treatment, showed similar DASH score in two groups but statistically significant but not clinically important difference in constant score between two groups [40]. Judd *et al*. also have reported similar functional outcome between patient treated operatively and conservatively [31]. A study was done by Canadian Orthopaedic Trauma Society, Wang *et al*. and Vaithilingam *et al*. have shown better functional scoring with a patient undergoing operative management compared to conservative management [29, 33, 35]. However, in all the studies there was no restriction of motion at shoulder joint in either group of patients [31, 32, 35, 40].

Malunion and Non-union was common in a patient managed conservatively whereas plate-related complications were common in operative group. There was no non-union in operative group whereas non-union in conservative group was on lower side of the values reported in various series, i.e, was 6.67% compared to 4 to 15% [8, 23]. In this study the incidence of delayed union was similar in both the groups (10% in conservative versus 13.3% in operative group). In this study, there was one case of infection in the operative group which was managed with plate removal, and debridement and the fracture eventually healed with control of infection. There were 4 cases of loosening of screws of which two had implant failure. In one case there was a bent plate which was removed after the fracture united. In the second case there was backing out of implant which was re-operated with bone grafting and replating which again failed and the patient was managed conservatively resulting in delayed union and poor functional outcome at 24 weeks.

This is similar to study done by Canadian Orthopaedic Society who found higher rate of non-union in conservative group compared to operative group (7of 49 in conservative versus 2 of 62 in operative). They also reported higher rate of symptomatic malunion in conservative group (9 of 49) compared to operative (none). Similar to this study they also had reported plate-related complications like an infection (3 cases) and hardware irritation requiring removal (5 cases) to be common complication in operative group [29]. Similarly, Patel *et al*. and Vaithilingam *et al*. had reported a higher incidence of malunion and non-union in the conservative group compared to operative group and plate-related complications in operative group [34, 35]. However Judd *et al*. had reported a higher incidence of complication in operative group (48%) compared to conservative group (7%) with a similar rate of non-union in both the groups [31].

In this study patient satisfaction was higher in operative group compared to conservative group (93.3% in operative group compared to 70% in conservative group). This is similar to study done Canadian Orthopaedic Society who had reported significantly higher patient satisfaction in operative group compared to the conservative group; 52 out of 62 patients in the operative group were satisfied compared to 26 of 49 in nonoperative group [29]. This study has few limitations like the study was carried out in a single institution, and the sample size was less. The duration of follow up was only six months. Long-term result could have been assessed on longer follow up. The need for a secondary operation for plate removal has not been mentioned in this study. Only plating of clavicle on the superior surface was considered for operative management of the patient. Other methods of operative management were not considered.

Conclusion

Six months after a displaced midshaft clavicular fracture, nonoperative treatment resulted in higher malunion and non-union rate but similar functional outcome and union time compared to operative management. However, patients were more likely to be satisfied in operative group compared to the nonoperative group. So, there is need to individualize the treatment as per the need and functional demand of the patient to give the optimum outcome. However, there is a need for multicentric trials with larger number of patients for a longer follow-up period, so that these findings could be further corroborated.

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