



## Comparison between operative and nonoperative treatment methods in the management of comminuted fractures of the clavicle

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**Objectives:** To evaluate the outcome and satisfaction of closed treatment versus open reduction and internal fixation in comminuted clavicular fractures.

**Methods:** Sixty patients with displaced clavicular fractures were randomized into operative (29 patients) and nonoperative (31 patients) groups. Three patients in the operative group did not accept the surgery, and seven patients in the nonoperative group did not complete the one-year follow-up. Outcomes were assessed using the Disability of the Arm, Shoulder and Hand (DASH) score, Constant shoulder score, specific questions regarding patients' final satisfaction, physical examination, measurement of the shortening of the clavicular length, and plain radiographs.

**Results:** There was one nonunion in the operative group and one in the nonoperative group. The nonunion in operative group was the result of the only infection in this group. Four malunions were developed in the operative group and nineteen malunions in the nonoperative treatment, ( $p < 0.001$ ). Three patients in the operative group were completely dissatisfied with their treatment. Eighteen patients in the nonoperative group were partially satisfied. Pain was the main reason for dissatisfaction in this group. The mean shortening of the clavicle was 26.5 mm in the nonoperative group and 4.0 mm in the operative group. The mean DASH score for the operative and nonoperative groups were 8.6 and 21.3, respectively ( $p < 0.001$ ); and the Constant shoulder scores were 89.8 and 78.8 ( $p < 0.001$ ).

**Conclusion:** Open reduction and internal fixation of comminuted fractures of the clavicle using a reconstruction plate is an effective treatment modality. Despite the variety of complications, this method has a higher satisfaction rate than conservative treatment.

**Key words:** Bone fracture; clavicle; comminuted fracture; open reduction.

Fractures of the clavicle are the second most common fractures in the human body and represent 4% of total human fractures.<sup>[1]</sup> Two distinct mechanisms of trauma have been defined for this fracture. In simple falling down, the fracture is usually minimally displaced and simple. In a high-speed road accident, fracture of the clavicle usually occurs from direct trauma and is comminuted. The conservative treat-

ment of clavicular fractures is a well-known strategy<sup>[2]</sup> More recent studies have shown that relying only on traditional methods for conservative treatment without considering character of fracture may lead to higher incidence of nonunion.<sup>[3-5]</sup> Furthermore, comminuted diaphyseal fractures of the clavicle are at risk for symptomatic malunion.<sup>[6,7]</sup> Many reports have demonstrated that late neurovascular compression and a

decrease in shoulder motor strength is not unusual with closed treatment strategies.<sup>[8-10]</sup> However, establishment of the anatomy of a comminuted clavicular fracture through open reduction may be demanding, and the complication rate could be high.

Most of the studies on the outcome of surgical treatment of clavicular fractures are designed with a mixed population of patients, including both simple and comminuted fractures.<sup>[11,12]</sup> This prospective randomized controlled study was conducted to compare results of open reduction and internal fixation (ORIF) versus conservative treatment in pure comminuted fractures of the midshaft clavicle. The hypothesis was that in comminuted fractures of the clavicle, despite of a high variety of complications, the ORIF method would have a better satisfaction rate.

## Patients and methods

This study was designed and performed in a tertiary trauma center. The affiliated emergency department was asked to include all patients with clavicle fractures in a special unit that was responsible for conducting the study. Patients with eligible criteria were selected from this pool of patients and entered the study. Inclusion criteria for patients were as follows: (1) A comminuted, displaced midshaft fracture of the clavicle, (2) age in the range of 18 to 65 years old, and (3) no medical contraindication for general anesthesia. Comminution was defined as having three or more fragments in the fracture site as seen on primary radiography of patients. Exclusion criteria included the following: (1) Any fracture in an upper extremity distal to the shoulder, (2) concomitant fracture in the distal or medial third of the clavicle, (3) any weakness in the upper extremity resulting from a head or neurovascular injury, (4) pathological fracture, (5) an old fracture (more than three weeks prior to accident), and (6) inability to complete the follow-up.

For randomization purposes, thirty sealed, opaque envelopes containing the written word "closed" were mixed with thirty sealed envelopes containing word "ORIF". A nurse who was not involved with the study selected one of the envelopes to determine the type of treatment.

## Technique

### *Closed method*

After the surgeon was notified by the nurse that he should perform the closed method, the patient was

brought to the casting room and a commercial sling was provided for him/her to prevent the elbow from sagging. Then, an elastic cotton band was wrapped around the patient's chest and arm to limit abduction and external rotation of the arm. No attempt was made for closed reduction.

### *Surgical method*

After preparing and draping under general anesthesia, with the patient in a semi-sitting beach position, an oblique incision was made just over the fracture site. If any superficial sensory nerves were in the way of dissection, then they were saved. Before reduction of the medial and lateral segments, the third fragment was reduced and fixed to one of the main lateral or medial segments of the clavicle using a 3.5 mm lag screw. Any additional fragments were also reduced and fixed with lag screws or sutures according to the size of the fragment. The whole complex was fixed with a number 3.5 reconstruction plate. The plate was present and positioned on the superior surface of the clavicle. The fascia was closed with absorbable sutures and the skin with nylon sutures. The patient's arm was fixed to the body with adhesive tape, and once the patient was able to sit up, a simple sling was supplied for him/her. The sutures were removed after 10 days, and passive range of motion exercises were started. At three weeks post operation, strengthening exercises were begun and progressed during the following three weeks.

## Outcome assessment

For study purposes, we evaluated all patients at one month, three months, and one year after operation. Nonunion was defined as a lack of cortical bridging on radiography of the clavicle 6 months after surgery. Shortening was defined as more than a 10 mm difference in the length of the clavicle when compared with the opposite side. Malunion was considered as an adverse effect when patients with abnormal radiographic contour were symptomatic in terms of pain, weakness, or neurovascular symptoms. Complications of surgery including infection, plate breakage, plate elevation, and hypertrophic scar formation were evaluated and recorded in each follow-up visit.

Both objective and subjective parameters were evaluated using the DASH score (which is a patient oriented outcome scale) and Constant shoulder score.

Patients were also asked to state their level of satisfaction as dissatisfied, partially satisfied or completely satisfied. They were also asked to identify the main reason for dissatisfaction. The length of the affected clavicle was measured using a measuring tape, and it was compared with the length of the normal side. The amount of shortening, in millimeters (mm), was recorded. The range of motion of the shoulder was measured using an orthopedic goniometric device for abduction, forward flexion, and external rotation at 45° abduction and was compared with the normal side. During each visit, radiographs were taken and union was evaluated. Weakness of the limb was evaluated by asking patients if they noticed any weakness in the power of abduction. The surgeon drew the configuration of each fracture complex on the operation sheet.

### Statistical analysis

According to our power analysis, 60 patients represented a sufficient sample size for demonstrating a difference in the outcomes of each group. We used the SPSS version 9 software package to analyze our results. Student's t test was used to compare the numerical results of the scaling systems. Nominal variables were tested by chi-square or Fisher's exact test. A p value of <0.05 was considered statistically significant.

### Results

From October 2007 to April 2009, 60 patients with a comminuted fracture of the clavicle were enrolled in this study. Twenty-nine patients were randomized to

the operative group and 31 to the closed group. Seven patients in the closed group did not complete their one-year follow-up, and three patients in the operative group did not accept surgery. These cases were excluded from the study, which left 24 patients receiving the closed treatment method compared with 26 patients receiving the open technique. Table 1 shows the demographic data for both groups. Twenty fractures had more than three fragments. In 15 cases in the operative group, there was at least one vertically aligned fragment. There were 12 open fractures. The mean age of patients was 33.4 years old. Forty-one patients were male and nine were female.

In operative group, one patient developed nonunion (Fig. 1). In this case, an infection developed, and the plate was removed 4 months after the operation. This patient was of old age, and because of mild symptoms, nonunion was neglected. In four patients, due to the severity of comminution, anatomical reduction could not be achieved. In two patients, the most medial screw became dislodged, which led to the plate becoming partially elevated (Fig. 2). This produced discomfort for patients, and the plate was removed 6 months after surgery in one case. The mean length discrepancy between affected and normal clavicles was 4 mm. None of patients complained of the appearance or balance of their shoulders. The range of motion of all patients was near normal (less than a 5% decrease), except for four patients, in whom abduction and external rotation was limited to 85-90% of the normal side. One

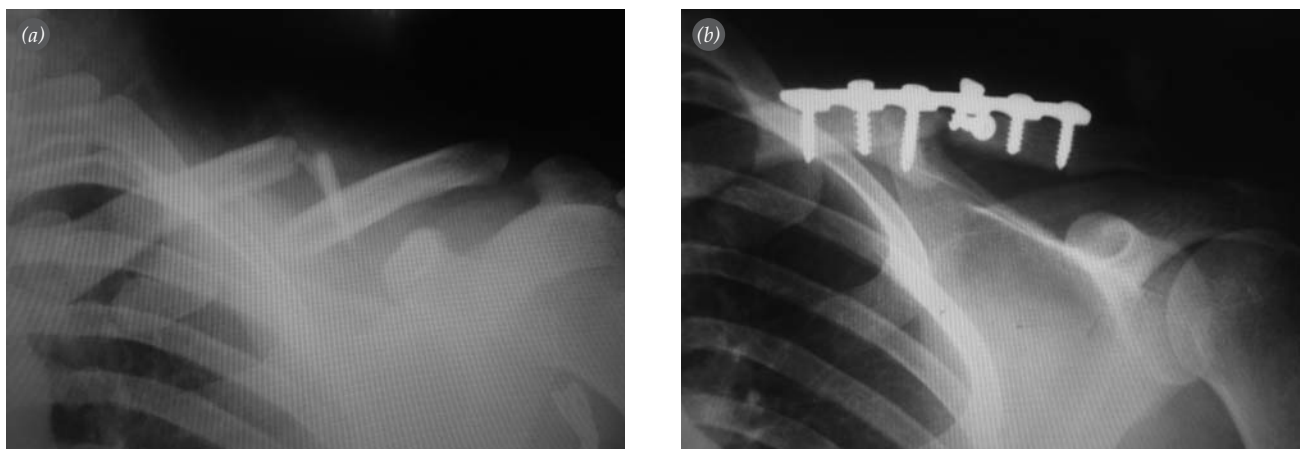


Fig. 1. (a) Preoperative radiograph; (b) Postoperative radiograph after six month show no evidence of union.

**Table 1.** Demographic data of the nonoperative and operative groups (mean, number or percentage of patients).

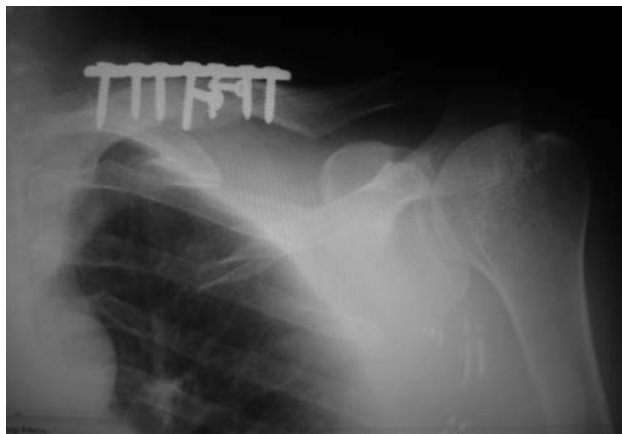
	Operative group	Nonoperative group	p value
Mean age (years)	36.0	35.3	0.146
Sex (female/male)	20/6	21/3	0.281
Number of fragments greater than three	12	8	0.476
Open fracture	7	5	1.000
Dominant side	54%	50%	0.281

**Table 2.** Assessment of outcomes in the nonoperative and operative groups (mean or number of patients).

	Operative group	Nonoperative group	p value
DASH score	8.6	21.3	<0.001
Constant shoulder score	89.8	78.8	<0.001
Mean length discrepancy (mm)	4.0	26.5	<0.001
Pain	2	18	<0.001
Weakness	4	10	0.059
Limitation of motion	4	18	<0.001
Neurovascular compression	0	2	0.225
Absence of shoulder balance or symmetry	0	2	0.225
Plate breakage	0	0	0
Plate elevation	2	0	1

year after the operation, the mean Constant shoulder score was 89.8. The mean DASH score after the same period of time was 8.6 (Table 2). Three patients claimed that they were completely dissatisfied with the surgery, and two others were partially satisfied (Table 3). Hypertrophic scar occurred in two female patients and was the reason for complete dissatisfaction for one of them (Fig. 3).

In closed (nonoperative) group, there was one nonunion. Malunion developed in 19 patients. Eighteen patients had more than 10 mm of shortening. The mean length discrepancy of clavicles was 26.5 mm. Two patients had shoulder imbalance, and their scapula was protruded in comparison with the normal side (Fig. 4). Two patients had signs and symptoms of neurologic claudication in their affect-

**Fig. 2.** AP shoulder radiograph showing dislodged medial screws with prominent plate.**Fig. 3.** Scar formation over the incision site.  
[Color figure can be viewed in the online issue, which is available at [www.aott.org.tr](http://www.aott.org.tr)]

ed upper extremity. Twenty patients had at least a 5% decrease in shoulder abduction and external rotation, and 15 patients lost at least 10% of their abduction. The mean constant shoulder score and DASH were 78.8 and 21.29, respectively. Eighteen patients were not satisfied by their outcome. Eighteen patients were partially satisfied. Pain was the main reason for dissatisfaction in this group.

Regarding the age, sex, number of fragments, open fractures, and dominant arm, there were no statistically significant differences between the two groups (Table 1). The p values for DASH and Constant shoulder scores were less than 0.001 (Table 2). Patients treated with the open technique were more satisfied than those treated with the closed method (Table 3). The correlation between the number of fragments and outcome in the surgical group was significant. As the number of fragments increased, the value of DASH was also increased. A 5% decrease in range of motion is negligible and is not a subjective complaint, so we took patients with at least a 10% decrease in their range of motion into account. By using this mean, more patients lost their abduction range in the closed group. The total number of complications, including malunion, was significantly higher in the closed group (Table 4). Infection, scar, painful fracture site, and numbness were the complications that were more common in the open group. The difference between the lengths of the clavicle of the two groups was significant.

## Discussion

For many years, Neers' concept of conservative treatment for clavicular fracture has ruled the treatment strategies for clavicular fractures. This concept was based on his article, which showed excellent results from conservative treatment in these fractures, with less than three nonunions out of 2,235 patients. The malunions in their study were also rare, if ever, the cause of a functional problem. Recent studies have shown that nonunion is not rare in patients with clavicular fractures. Malunions may cause disability and limb function impairment, which leads patients to seek surgical help. The population of Neers' study consisted of both adults and children, which represented the major bias of his study and was neglected for many years. It is also

**Table 3.** Patients' satisfaction rate and reasons for dissatisfaction in the nonoperative and operative groups (number of patients).

	Operative group	Nonoperative group
Partially satisfied	2	18
Completely dissatisfied	3	0
Primary reason for partial or complete dissatisfaction (n)	Scar (1) Pain and weakness (1) Repeated surgery (1)	Pain (12) Weakness (4) Imbalance (2)

**Table 4.** Complications of treatment of comminuted clavicular fractures in the nonoperative and operative groups (number of patients).

Complications	Operative group	Nonoperative group	p value
Nonunion	1	1	1.000
Malunion	4	19	<0.001
Skin dysesthesia	2	0	0.491
Infection	1	0	1.000
Hypertrophic scar	2	0	0.491
Total	10	20	



**Fig. 4.** Prominence of the right shoulder due to severe shortening in a female patient with malunion. She was treated with bandage. [Color figure can be viewed in the online issue, which is available at [www.aott.org.tr](http://www.aott.org.tr)]

possible that the mechanism of injury for those fractures may be different from those seen today.

One of the major concerns in the treatment of clavicle fractures is nonunion. Karaoğlu et al.<sup>[11]</sup> published the result of conservative treatment in mid-

clavicular fractures. In their study, 23% of patients had comminution. Their overall result shows a high union rate with a conservative method. In our study, there were two nonunions, one of them occurred in the operative group. This nonunion happened because of the removal of the plate four months post operation due to infection. The infection healed, but nonunion developed. We did not treat this nonunion further because the range of motion of the shoulder and strength did not change dramatically. We also believe, in conjunction with Rosenberg et al.,<sup>[12]</sup> that full functional recovery may not be achieved with union, and some degree of pain will persist despite the union. The nonunion rate in the conservative group was 4.1%. Many studies have shown that the rate of union is much higher after the use of surgical techniques. A meta-analysis showed that the rate of union is 15.1% by nonoperative methods and 2.2% by operative methods.<sup>[13]</sup> One may expect a higher rate of nonunion in the setting of purely comminuted fractures. In many comminuted fractures, during open reduction, we have noticed that some fragments may inadvertently become detached from soft tissue leading to poor blood supply, which may play a role in the development of nonunion. In our study, the rate of nonunion was the same in surgical group as it was in the closed group. We do not have a clear explanation for this discrepancy because the only case of nonunion had been complicated by infection.

Malunion is another complication that affects the final outcome of patients. According to the definitions in this study, malunion was present in 19 cases in the conservative group and had a tremendous effect on the results of this group. We believe that it is not nonunion that affects the end results of conservative treatment, but malunion. In the surgical group, the main factor is nonunion. Because of the rarity of nonunion relative to malunion, the outcome and functional scores from surgical treatment are better than with conservative therapy.

In four patients, we were not able to perform an anatomic open reduction. Each of these cases presented with more than four fragments. Because of the severity of comminution, primary anatomic reduction was unstable, and a well-contoured plate needed to be placed smoothly on the bone to keep the complex of the fracture stable. With prebent plates, even in two planes, we could not achieve this

goal. When the screws of the prebent reconstruction plate fix the plate onto the bone, the configuration of the fracture site changed from an S shape to straight.

There were other complications in the surgical group that had a negative impact on the results. Although there were a lot of patients in the conservative group who were partially unsatisfied, only two of them were unsatisfied due to the appearance of imbalance in their shoulders. In the surgical group, one patient with scar formation was completely dissatisfied because of keloid formation. Irritation and prominence of hardware, especially on medial side, was the other reason patients insisted on early removal of the plate.

One of our common findings during surgical exposure was an anterior vertical fragment with strong soft tissue attachment. This fragment was a key element in open reduction. To perform a good reduction, we had to fix this fragment first. In some of the open fractures, this fragment was also responsible.

Notably, the main complaint of patients in the conservative group was pain, not weakness or limitation of motion. An analysis of data from the patients with conservative treatment shows that the component of the Constant score that caused lower values in the conservative group was pain. In response to the question, "What is the main reason for dissatisfaction?", 80% of patients in this group answered as "the pain".

This study has some drawbacks. First, the sample size may not have enough power to demonstrate differences in the outcomes of the two groups. Comminution is a specific and limited subgroup of clavicular fractures. A multicentric study with a larger sample size could show the differences better. Second, the amount of primary displacement was not measured. It is difficult to define the amount of displacement in comminuted fractures because some of the main fragments may be undisplaced, whereas the minor fragments may be displaced.

In conclusion, the risks and benefits of surgery for comminuted fractures of the clavicle should be considered. It is our practice to inform all women who are candidates for open reduction of the possibility for scar formation.

**Conflicts of Interest:** No conflicts declared.

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