

## A Randomized Control Trial Comparing Operative and Non-operative Treatment of Acute Displaced Distal Clavicle Fractures

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### Abstract

**Background:** The clavicle fractures are most common in children and young adults which majorly occur in person younger than 25 years. In addition to this, the treatment through surgical approach is considered when patients have high potential for non-union with more than 15-20 mm clavicle shortening. The exercise and proper monitoring of the complications is helping to understand the recovery and improvement in the physical health of the individual. However, the high impact on the bones and lack of care during the non-surgical approach for treatment is leading the patients to surgical process. The surgical process is involving open reduction and internal fixation. The process is including the plates and screws to align the bones. Additionally, surgical treatment is involving pins and screws that also used for holding the fracture bone in good position and put it back in right place.

**Aim:** The study aims to understand a randomized control trial comparing operative and non-operative Treatment of Acute Displaced Distal Clavicle Fractures

**Method:** For the study randomized controlled trail process was used at SCB Medical College between August 2019 to October 2021. The study was completed under the instruction of the ethical committee and approved. For the study 18-60 years population was considered who has the issues related to completely displaced, closed, Neer type II distal third clavicle fracture. Moreover, the demographic were calculated focusing the mean, SD and percentage.

**Results:** The number of non-operative patients was 33 and mean value of age and BMI was 42.1 and 24. Here female patients were 12.2% and male was 87.8%. The most numbers of mechanisms of injury among non-operative patients was cycling and sports both were 36.6%. For the operative patients, the mean value for age and BMI was 42 and 23.8. There were 22.2% women and 77.7% were men. The highest mechanism of injury among operative patients was cycling 40.7% and fall 25.9%. There was no significant difference was found in DASH score. There was no significant difference found in VAS score for pain between the surgical and non-surgical (mean=13.0) groups for study. At 1 year (p =0.54).

**Conclusion:** The outcome of study has failed to identify the difference in functional outcome between surgical and non-surgical as the non-operative functions lead to more complications including the moderate rate of non-union. Moreover, the non-surgical patients were not satisfied with the treatment and recovery.

**Keywords:** distal clavicle fractures, operative treatment, nonoperative treatment, functional outcome

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## Background

There are different types of fractures have a significant impact on the physical health of the people and requires the proper treatment for better recovery. The clavicle fractures are most common in children and young adults which majorly occur in person younger than 25 years [1]. The common mechanism of injury is a forceful fall with the arm at the side which occur during sports, fall from bike and stairs. Diagnose of issues can be made by history and physical examination and appropriate radiography that help to confirm the treatment option. However, the most clavicle fractures occur in the mid-shaft and treated with non-operative approach, but the injured person is having issues related to trauma then surgical approach for treating the people is considered [2]. In addition to this, the treatment through surgical approach is considered when patients have high potential for non-union with more than 15-20 mm clavicle shortening [3].

Distal fractures are classified based on the relationship to coracoclavicular ligaments. However, most of the distal fractures are treated using non-operative approach but the level of shortening to clavicle lead to surgical treatment [4]. The major symptoms of clavicle fracture involve the sagging of the shoulder downwards and forward, inability to lift the arm, grinding sensation when try to raise the arm, brushing, swelling and tenderness over the collarbone. The care professionals analyzing these symptoms for confirming the distal clavicle fracture and select the treatment options [5]. Apart from this, the major causes of fracture involve the direct blow to the shoulder and fall onto an

outstretched arm. However, this kind of fracture might occur in a baby during the passage through the birth canal [6].

To identify the conditions and issues related to clavicle fracture among the people, there are different types of approaches are used that involve the X-rays to confirm the damage. The physical examination is also providing the information, but the X-rays are providing the pinpoint location and severity level of the break [7]. Moreover, the Computerized Tomography (CT) scan is also used for analyzing the level of severity of the clavicle fracture. Now, for the treatment of the patients, the non-operative functions are involving the arm support, medication, physical therapy and follow-up care [8].

These are having a significant impact on the recovery of the patients considering the level of severity. The exercise and proper monitoring of the complications is helping to understand the recovery and improvement in the physical health of the individual. However, the high impact on the bones and lack of care during the non-surgical approach for treatment is leading the patients to surgical process. The surgical process is involving open reduction and internal fixation [9]. The process is including the plates and screws to align the bones. Additionally, surgical treatment is involving pins and screws that also used for hold the fracture bone in good position and put it back in right place. Apart from this, the pain management therapies are also used for the offering the treatment to the operative patients [10]. Rehabilitation is specific exercise that helps to restore movement and strengthen the shoulder. This is provided by professional care

workers for improving the health conditions of the patients [11].

### Aim

The study aims to understand a randomized control trial comparing operative and non-operative Treatment of Acute Displaced Distal Clavicle Fractures

### Method and material

This was a randomized controlled trial conducted at SCB Medical College between August 2019 to October 2021. This study was approved by the research ethics committee of the institution. Potential patients were identified on presentation to the emergency department or fracture clinic. The inclusion criteria for study considered the age 18–60 years of age, who were facing issue related to displaced bone, Neer type II distal third clavicle fracture.

### Statistical Analysis

For the analysis R version was used and different mean, SD and percentage were analyzed to get the desired outcome. To get the primary outcome, the study has focused on the DASH score considering the two different groups such as operative and non-operative. The results were considered significant at p, 0.05. Statistical analysis was performed using R version.

### Sample Size Calculation

DASH shoulder function scores using health conditions of the patients were considered for the study. For the current study, 60 patients were analyzed for clavicle fracture treatment using the operative and non-operative functions.

### Results

**Table 1: Basic characteristics**

	All patients (n=60)		Non-operative (n=33)		Operative (n=27)		P-value
	Mean	SD	Mean	SD	Mean	SD	
Age	41.4	±11	42.1	±12	42	±10.1	0.88
Body mass index	23.9	±3.6	24	±2.8	23.8	±4.4	0.78
<b>Sex</b>							0.49
Women	10	16.6	4	12.1	6	22.2	
Man	50	83.3	29	87.8	21	77.7	
<b>Mechanism of injury</b>							0.04
Cycling	23	38.3	12	36.6	11	40.7	
Fall	12	20	5	15.1	7	25.9	
Vehicle collusion	6	10	3	9.0	3	11.1	
Sports	15	25	12	36.6	3	11.1	
Others	4	6.6	1	3.3	3	11.1	
<b>Dominant extremely effects</b>	22	36.6	11	33.3	11	40.7	0.58
<b>Side of injury</b>							0.21
Left	35	58.3	19	57.5	16	59.2	
Right	25	41.6	14	42.4	11	40.7	
<b>Smoking</b>							0.9
Non-smoker	37	61.6	20	60.6	17	62.9	
Smoker	23	38.3	13	39.3	10	37.0	

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The number of non-operative patients was 33 and mean value of age and BMI was 42.1 and 24. Here female patients were 12.2% and male was 87.8%. The most numbers of mechanisms of injury among non-operative patients was cycling and

sports both were 36.6%. Apart from this, the dominant extremely effects were found among 33.3% patients. Moreover, most numbers of patients 57.5% in non-operative group were having injury at left side and smokers 60.6%.

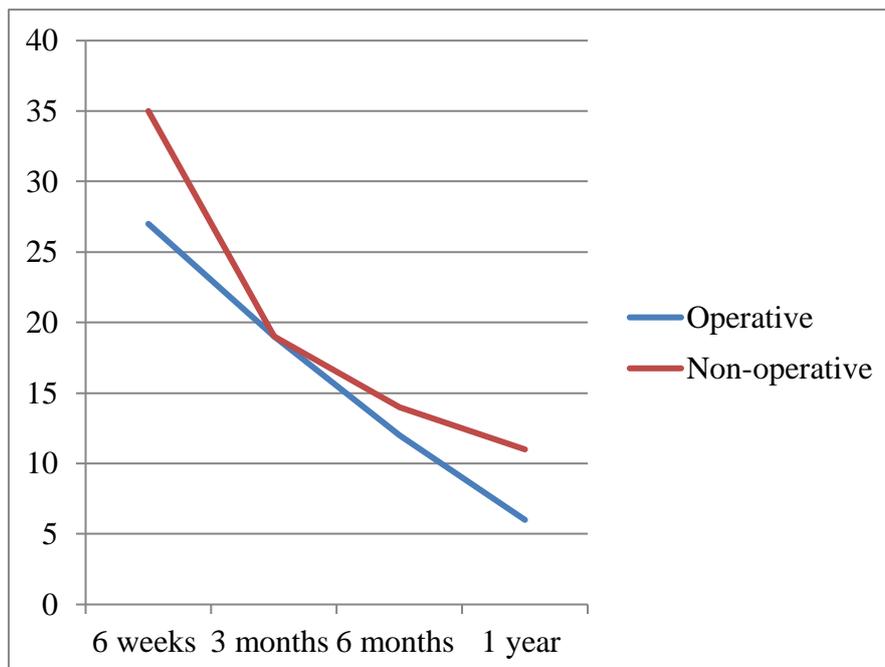
For the operative patients, the mean value for age and BMI was 42 and 23.8. There were 22.2% women and 77.7% were men. The highest mechanism of injury among operative patients was cycling 40.7% and fall 25.9%. The dominant extremely effects were found among 40.7% patients in operative group. The 59.2% patients were having injury at left side and 40.7 were at right side. Apart from this, 62.9% patients were non-smoker and 37.0% were smoker.

**Table 2: Dash score**

Time duration	Dash score	
	Operative	Non-operative
6 weeks	27	35
3 months	19	19
6 months	12	14
1 year	6	11

As per the analysis no significant difference was found in DASH score for

surgical (mean=6) and non-surgical (mean=11) groups after 1 year (p = 0.37)



**Figure 1: Dash score**

**Constant score**

The constant score was analyzed and it was found that there was no significant difference in between the surgical and (mean=90.1) and non-surgical (mean=90) groups at 1 year ( $p = 0.89$ ).

**Patient satisfaction****Table 3: Patient satisfaction**

Time duration	Satisfaction level	
	Operative	Non-operative
6 weeks	33.1%	4%
3 months	24.9%	0%
6 months	9.2%	7%
1 year	28.1%	20%

After 6 weeks, 3 months, 6 months and 1 year, the satisfaction level of patients was analyzed, and it was found that higher proportion of patients in non-operative were dissatisfied compared to operative patients. There was significant difference identified for 6 weeks ( $p = 0.005$ ) and after 3 months ( $p = 0.01$ ). There was no significant difference in other duration and satisfaction level of patients.

**Return to work and sports activities**

80% of the patients 48 out of 60 patients were employed and there was no significant difference. However, 78% patients of surgical group were returned to

**Pain**

There was no significant difference found in VAS score for pain between the operative (mean=13.2) and non-operative (mean=13.0) groups at 1 year ( $p = 0.54$ ).

their full sports by 6 months. These differences did not persist at 1 year as 90% of patients from surgical group returned to work and sports and 78% of non-operative.

**Fracture healing**

According to outcome of the study healing was identified among 30 patients and 10 patients had non-union with mean age of 43.6 years. 6 out of 10 patients were asymptomatic and required further intervention. 4 patients were symptomatic and requiring surgery. 20 out of 30 patients went to union and recovered through radiographic malunion.

**Table 4: Fracture healing**

Time duration	Healing score		P-value
	Operative	Non-operative	
3 months	58%	6.7%	$P < 0.001$
6 months	91%	39.9v	$P < 0.001$
1 year	97%	63%	$P < 0.01$

## Discussion

To identify the conditions and issues related to clavicle fracture among the people, there are different types of approaches used that involve the X-rays to confirm the damage. The physical examination is also providing the information but the X-rays are providing the pinpoint location and severity level of the break. Moreover, the Computerized Tomography (CT) scan is also used for analyzing the level of severity of the clavicle fracture. Now, for the treatment of the patients, the non-operative functions are involving the arm support, medication, physical therapy and follow-up care [12].

For the study, 60 patients were considered and analyzed for treatment of clavicle fracture using operative and non-operative processes. The mean age and BMI value of total patients was 41.1 and 23.9. Here total numbers of male patients was 83.3% and female was 16.6%. The mechanism of injury that analyzed in the study involve the cycling 38.3%, fall 20%, vehicle collision 10%, sports 25% and others 6.6%. Moreover, the study has analyzed the dominant extremity effects was analyzed among 36.6% of total patients. The left side injury was reported among the 58.3% and right side was reported in 41.6% patients. Apart from this, the study has analyzed the habit of smoking among the total patients and found 61.6% was non-smoker and 38.3% used to smoke. In the study of Hall et al. (2021) [13] majorly 2 groups were considered for the analysis and operative group involved. As per the outcome of the study 14 patients had hook and plate, 11 patients had precontoured distal clavicle plate and 1 was treated with 2 plates. However, only 2 patients were gone for surgical treatment.

For the current study, there was no significant difference was found in DASH score between surgical (mean=6.9) and non-operative (mean= 10.9) groups. Moreover, after 1 year (P= 0.37). There was

no significant difference in the constant score between the operative and (mean=90.1) and non-operative (mean=90) groups at 1 year (P= 0.89). Moreover, no significant difference was found in 6 weeks, 3 months and 6 months. There was no significant difference found in VAS score for pain between the operative (mean=13.2) and non-operative (mean=13.0) groups for study. At 1 year (P=0.54). Apart from this, as per the outcome of the study of Wang et al., (2015) [14], no significant difference was found between surgical and non-surgical groups and the (P=0.006) after 6 weeks and (P=0.01) after 1 year. The non-surgical group patients were highly dissatisfied after the treatment. Moreover, the DASH score of the patients was also compared and it shows no significant difference as (P=0.03) after 6 months.

For the current study, after 6 weeks, 3 months, 6 months and 1 year the satisfaction level of patients was analyzed and it was found that higher proportion of patients in non-operative were dissatisfied compared to operative patients. There was significant difference identified for 6 weeks (P=0.005) and after 3 months (P=0.01). There was no significant difference in other duration and satisfaction level of patients. The fracture healing data was available for 30 patients and 10 patients developed radiography nonunion with mean age of 43.6 years. 6 out of 10 patients were asymptomatic and required further intervention. 4 patients were symptomatic and requiring surgery. 20 out of 30 patients went to union and had fracture healing with radiographic malunion. According to analysis, the rate of union was higher in operative group compared to non-operative. As per the study of Hall et al., (2021) [15, 16] 17 patients with mean age of 43.1 have taken the non-operative treatment and one patient has the delayed union after 6 months. In the operative group, there was 1 patient with a non-union at 1 year.

## Conclusion

The study has provided comparative analysis of the operative and non-operative treatment functions of the patients with clavicle fracture. The outcome of study has failed to identify the difference in functional outcome between operative and non-operative as the non-operative functions. The study has not provided the information related to complications and moderate rate and identification of secondary surgery. Higher rate of dissatisfaction was identified among the non-surgical group as they were delayed to full recovery after 3 and 6 months.

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