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Treatment of clavicle fracture using wise lock clavicle hook plate and wise lock superior anterior clavicle plate

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ABSTRACT

Background: Clavicle fracture is common in adults associated with high non-union rate and post-operative complications. The aim of this prospective study was to reduce the postoperative complications in clavicle fracture (Type 15-A2 and 15-B1) by using wise lock plates (manufactured by Auxein Medical Private Limited).

Methods: In this prospective study of 25 patients (11 patients had 15-A2 fracture, 14 patients had 15-B1 fracture) recruited with one year follows up period followed by physical exercises after one month of the surgery. The fractures were treated with two different plates: 3.5 mm wise lock clavicle hook plate and 3.5 mm wise lock superior anterior clavicle plate. X-ray was used to check the union, non-union. Functional outcome of the patients were assessed by the visual analogue scale (VAS) score at post-operative follow up at 4 weeks, 12 weeks, 6 months and 1 year.

Results: Postoperative outcome was good with none of the patients showing non-union or delay in the union of fracture site. The encountered complication registered were residual pain which was mild (4 cases), and hypoesthesia (2 cases).

Conclusions: Osteosynthesis of clavicle fracture with 3.5 mm diameter locking plates attributed as superior, anterior and hook plating system showed excellent results with low rate of complications.

Keywords: Clavicle fracture, Medial end, Diaphyseal fracture, Partial articular fracture, Simple fracture, Clavicle hook plate, Locking plates

INTRODUCTION

Clavicle fractures are common in adult population, due to thin structure and super facial location of the bone. With less protection from muscle or fat, 69–82% of midshaft clavicle fractures occurs due to the slightly curved nature of the middle third and lack of articular support through muscles and tendons.¹ While the medial-end clavicle fractures are rare and make up only 2%-10% of all clavicle fractures, this type of fracture is usually caused by direct, high-energy trauma such as bike crash and also secondary to a fall, aggression or firearm wound.^{2,3} Based on the anatomy, clavicle fracture are classified in to three parts (a) clavicle, proximal (medial) end segment (b) clavicle, diaphyseal segment and (c) clavicle, distal (lateral) end segment.⁴

The location of the fracture, along with degree of displacement and association of surrounding structures, is important to consider for treatment. There are two primary categories for treatment of clavicle fractures operative and non-operative. Non-operative, or conservative treatment involves immobilization using a sling or brace, whereas operative management can involve an open reduction internal fixation (ORIF), intermedullary fixation or external fixation.⁵

Operative management of clavicular fractures includes external fixation, intramedullary fixation, and osteosynthesis with a plate and screws. Plate osteosynthesis has the benefit of offering much more rigid fixation with more rotational control of the fracture. Study reported a union rate of 97% in 232 athletes who underwent plate osteosynthesis, with only 1 deep infection and 4 superficial infections.⁶

The aim of this prospective study was to treat the Clavicle fracture (15-A2 and 15-B1) with 3.5 mm wise lock clavicle hook plate and 3.5 mm wise lock superior anterior clavicle plate (Auxein Medical Pvt. Ltd.) and to reduce the postoperative deformities and infections.

METHODS

This was a prospective study conducted at Mesoamerican University, Quetzaltenango, Guatemala from April 2016 to December 2017 with a one year follow-up. 25 patients were observed in the present study. The mean age of the patients at surgery was 32.5 years (range, 18–60 years). The cause of injury was a sports injury, road accident and fall and slip.

Patients with clavicle fracture 15-A2 and 15-B1 (classified as per orthopedic trauma AO classification) were included in the study. The complete surgical treatment was performed by qualified orthopedic surgeon.

According to American Society of Anesthesiologists Physical Status classification System (ASA Grade), out of 25 patients; 23 patients were having Grade I (Healthy patients) and 2 patients felt under Grade II (Patients with mild systematic disease) with no report of previous surgery on the affected fracture.

Indigenously manufactured implants were used as per treatment plan. The osteosynthesis was performed by using the 3.5 mm wise lock clavicle hook plate (14 patients) and 3.5 mm wise lock superior anterior clavicle plate (11 patients). Implants used in the surgery were prepared from stainless steel alloy as per ISO 5832-1 and titanium alloy Ti-6AL-4V as per ISO 5832-3 (Auxein Medical Pvt. Ltd, Sonipat). All patients were treated with titanium alloy implants.

Stabilization of the bone plates [3.5 mm wise lock clavicle hook plate and 3.5 mm wise lock superior anterior clavicle plate] were done using 3.5 mm cortical screw and 3.5 mm wise lock screw. In case, rigid stabilization was not achieved using screws then fixation with metal wire was supplemented. The length of the hook was 10 mm, but hook depths of 12, 15, or 18 mm can be used after measuring the acromion thickness (Figure 1 and Figure 2). Holes in the shaft of the plates

are used to bring the plate to the bone with cortical screws and allow the adjustment of the plate position.



Figure 1: 3.5 mm wise lock clavicle hook plate.



Figure 2: 3.5 mm wise lock superior anterior clavicle plate.

The surgery was performed with the patient under general anesthesia. 1 month post-surgery X-ray was used to evaluate the results. With recommendation of general physical exercises the imaging data showed good position of implants. Using the 10 point score info system, visual analogue scale was used to assess the result.

Postoperative conditions were rated in terms of pain. After osteosynthesis, X-ray was taken once every 4 weeks for all patients. These radiographs were examined for bony union, implant failure, plate migration, and widening of the hook hole. All radiographic measurements were performed by the same surgeon.

RESULTS

Out of 25 patients, 13 women (52%) and 12 men (48%) were involved in the study. The average mean age of patients was 32.5 years (Table 1). The fractures sites were on the left and the right with 13 (52%) patients having fractures on the right side and 12 (48%) patients had fractures on the left side. According to the AO classification system, the type A fractures were present in 11 (44%) patients and type B in 14 (56%) patients (Table 2). Cause of injuries with corresponding number of patients is shown in Table 3. Clinical evaluation for pain, aesthetic appearance and satisfaction with treatment was rated by patients on a VAS score (maximum score, 10 points) at the final follow-up (Table 4). The mean VAS score (maximum score, 10 points) at the final follow-up is shown in Table 5. The follow-up of patients was taken at 1, 3, 6, 9 and 12th months in a year showed good clinical results.

Table 1: Demography data (n=25).

Demography					
Average age (range)		32.5 (range, 18-60 years)			
Gender	Male	12 (48)			
N (%)	Female	13 (52)			

Table 2: Fracture characteristics (n=25).

Fracture characteristics	N (%)			
Fracture type (AO/OTA type)				
15-A2	11 (44)			
15-B1	14 (56)			
Fracture side				
Left	12 (48)			
Right	13 (52)			

Table 3: Cause of fracture with corresponding number of patients (n=25).

Cause of injury	N (%)	
Sports	5 (20)	
Road accident	14 (56)	
Fall and slip	6 (24)	

Table 4: Patient satisfaction data.

Evaluation	No. of patients	
parameter	Satisfied N (%)	Not satisfied N (%)
Pain (n=25)	21 (84)	4 (16)
Aesthetic appearance (n=25)	22 (88)	3 (12)

Table 5: VAS score (1 year clinical follow up).

VAS score (in months)	
1	0.5 (50)
3	0.4 (40)
6	0.3 (30)
9	0.2 (20)
12	0.03 (~3)

The VAS score is 0 in 18 patient's constitution 72% for while the remaining 7 patients with 28% is 1 both male and female with a follow up period of 1 year.

The criteria of inclusion were met by all 25 patients as they agreed for the interview. Some accepted it to be taken through telephonic conversation as they could not be physically present due to geographical conditions. Few agreed through video calling and the remaining to meet personally.

The mean VAS score for pain [0= no pain, 10= extreme pain] was 8.4 with 4 patients reporting pain >3. The mean VAS score for satisfaction with aesthetics was 8.3 with 3 patients reporting score >5 (0=very happy, 10=not happy). None of the patients presented any sort of associated injury.

Surgical issues, post-operative care and follow up

The patients were traumatized and had comminuted and displaced fractures. The locking plates used were 3.5 mm

diameter attributed as superior, anterior and hook plating system.

Post-operative care: The patients were instructed to use a sling for 20 days followed by exercises. The exercises were generally physic categorized as active, passive and progressive pendulum. In the end the progress of the exercises and resistance was examined according to the standard protocol.

Functional evaluation

The VAS evaluation threw a value of 2.8 (68%) in 17 patients and 3 (32%) in 8 patients.

Reoperations and complications

The surgical outcome was good with none of the patients showing non-union or delay in the union of fracture site. The encountered complication registered were residual pain which was mild (4 cases), and hypoesthesia (2 cases).

DISCUSSION

Clavicle fractures are injuries irrespective of ages. Non operative techniques have been adopted historically with greater rates of bony unions. Non operative treatments in comparison to osteosynthesis in medial end clavicle fracture and diaphyseal fracture have demonstrated very less complications.^{7,8}

Currently the treatment adopted for these fractures is ORIF. Functional impairments and pains are led due to physiological reasons such as non-union as the patients complaint about asymmetry of the shoulder, prominence of the bones, weakness and shoulder ptosis.⁹⁻¹¹

Analysis conducted by some published articles has focused on effectiveness of osteosynthesis in different aspects related to clavicle fractures.

However due to very less availability of clinical data based on long term results that have used pre countered locking pates has been a concern. Most publications represent results that based on less than one year follow up.

Our study on the other hand access treatment outcome based on 12 months follow up with favourable results. The score in functional tests of 25 patients included in our study with a year exact of follow up period were similar to the other studies with shorter follow up. With 42 patients Have et al treated ORIF with mean ages of 15.4 years.¹²

A study conducted by Zhang et al recruited 15 patients and performed osteosynthesis by obtaining a constant score of 99.¹³ Ranalletta et al used precountered licking plates and obtained good results with 97.8 constant score.

Moreover reoperation in our study was 0%, total, complication was only 4% and non-consolidation was similar to other series.^{14,15}

Very less percentage of considerable pain and dissatisfaction was reported as assessed by VAS at one year follow up from injury. With 14% pain and 0% dissatisfaction results indicated no signs of non-union and post operation conditions.

In order to determine etiology of the patients investigation is needed to counter their concerns and relationships if nay to clavicle alignment at the time of bony healing.

Our experience with the locking plates used were 3.5 mm diameter locking plates attributed as superior, anterior and hook plating system used for the treatment of medial end clavicle fracture and diaphyseal fracture showed excellent results with low rates of complications at different fracture sites. The preoperative conditions have been nil with no non-union reported.

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Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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