International Journal of Research in Orthopaedics
Zahid SH et al. Int J Res Orthop. 2025 Jan;11(1):105-111
http://www.ijoro.org

Original Research Article

DOI: https://dx.doi.org/10.18203/issn.2455-4510.IntJResOrthop20243894

A comparative study of anatomical plate fixation versus intramedullary nailing of middle-third clavicle fractures in Al-ameen medical college hospital

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Received: 26 September 2024
Revised: 08 November 2024
Accepted: 14 November 2024

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ABSTRACT

Background: Clavicle fractures constitute 5% of adult fractures. About 80% involve the midshaft, with more than 70% displaced. Many plate and intramedullary fixation systems have been used. However, the best fixation method is still debated. Surgery includes ORIF with Anatomical Plate and CRIF with TENS. Each technique has its own advantages and disadvantages.
Methods: 40 patients with displaced middle-third clavicle fractures were prospectively randomly assigned to two groups, Group-A (plating group) and Group-B (nailing group), with an equal number of 20 patients in each. The outcomes were evaluated based on Union-time, Complications, Visual-Analog-Scale for pain. The assessment of shoulder function was conducted using the DASH score.
Results: 9 (45%) of Group A patients achieved union in 6-7 months and 11 (55%) in 8 months, mean union time being 7.5 months. 4 (20%) had implant prominence, 3 (15%) had hypertrophic scar, 1 (5%) had plate-end protrusion post-union, and 2 (10%) had surgical site infection managed by intravenous antibiotics. In group B, 16 (80%) patients achieved union by 6-7 months and 4 (20%) by 8 months, mean union-time being 7.1 months. 3 (15%) patients had nail-end prominence, 3 (15%) had nail-end irritation by 4 months, one (5%) had nail-end protrusion by 6 months, and one (5%) had medial migration by 8 months. No surgical site infection occurred.
Conclusion: Plating provides firm fixation, greater rotational stability for displaced middle-third clavicular fractures. Complications with plating like scarring, implant prominence, irritation are significantly lesser in nailing. Both fixations provide good functional outcome.

Keywords: Clavicle, Fracture fixation, Intramedullary, Titanium, Plating

INTRODUCTION

The clavicle provides structural support between the shoulder and the rest of the skeleton. Clavicle is a link between axial and appendicular skeleton. Abbott et al, and Frutos have suggested the role of clavicle in transmitting force from the upper limb to the axial skeleton.[1] The clavicle has several important functions. It acts as a bridge connecting the upper limb to the thoracic cage, which helps to stabilize the shoulder girdle, while allowing the arm to perform a full range of movement. In addition, it functions as an attachment for muscles, provides protection to vital neurovascular structures, supports respiratory function and has a significant aesthetic role in a person's physical appearance. These important functions can be damaged by fracture of the clavicle.[2,3] Traditionally, middle-third clavicle fractures have been treated non-surgically with strapping and clavicular brace, figure of eight bandage, but these pose challenges such as "mal-union", non-union' which are being reported more recently leading to a gradual shift towards internal fixation as a treatment alternative.[4] Due to the drawbacks of

conservative management, a number of plate and intramedullary fixation devices such as dynamic compression plate (DCP), tubular plates, reconstruction plates, Knowles pin, rock wood pin, titanium elastic nail, external fixator have been used.[5-9]

Plate fixation and intramedullary nailing are two frequently employed surgical methods.[10] However, there is conflicting information regarding their relative efficacy. As per various studies conducted, Plate fixation provides immediate rigid fixation and may be less technique-sensitive. Intramedullary fixation is less invasive, with benefits of immediate stability to the involved bone segment which permits early mobilization and returns to normal activities with low complications, reduced implant prominence and better cosmetic results.[11]

The objective of this prospective study was to assess and evaluate the clinical outcomes of plate fixation versus intramedullary treatment for displaced middle-third clavicular fractures.

METHODS

The current study is a prospective study carried out at Al-Ameen Medical College Hospital from July 2022 to June 2024. A total of 40 patients with displaced middle-third clavicle fractures were included in this study. The mean age of the participants in the study was 41 years.

Ethical approval

Obtained from Institutional Ethical Committee, Al-Ameen Medical College, Vijayapura, Karnataka, India (Figure 5)

Statistical analysis

Tool used to analyse the data was Microsoft Excel.

Inclusion criteria

Age more than 10 years & less than 70 years. All middle-third shaft fractures of clavicle.

Exclusion criteria

Age less than 10 years & more than 70 years. Lateral 1/3rd shaft fractures. Comminuted fracture of clavicle. Associated neurovascular injury. Open fracture.

The patients were randomly allocated into two groups, Group A (plating group) and Group B (nailing group), with an equal number of 20 patients in each group.

Procedure

After obtaining fitness for surgery and informed and written consent from the patient, and pre-anaesthetic examination, the patient is prepared for the surgery. In the operation theatre (OT) patient is instructed to lie down on the OT Table in supine position. Brachial block is administered and the parts are prepared, scrubbed, painted and draped.

Anatomical plate fixation

A sterile longitudinal incision is taken over the fracture site (Figure 1-A), fine soft tissue dissection is done and fracture site is exposed. Reduction is attempted with Bone-holding Forceps (Fig. 1-B) and an Anatomically contoured plate (Figure 1-C&D) is fixed over the reduced fracture site with the help of screws. Reduction is confirmed under C-ARM guidance. Thorough wash is given with saline and betadine and suturing is done in layers and the surgical wound is closed. An arm pouch is provided for the operated arm.

TENS nailing

A sterile longitudinal incision was made vertically about 2 cm lateral to the sternoclavicular joint (Figure 2A), and a bone awl was used to make an entry in the anterior cortex of the bone (Figure 2B). Throughout the procedure, accurate anterior-posterior (AP), caudal, and cranial views were obtained. The TENS was inserted from the medial end and advanced through the fracture site until the tip of the nail was engaged in the supero-lateral cortex of the lateral end of the clavicle. The TENS was of the appropriate size. The nail's size was determined by multiplying the canal diameter in millimeters by 0.4. Wound was closed surgically and sterile dressing done. Operated arm was supported by arm pouch.

Post-operative protocol and follow-up

For each of the two groups Five days of intravenous antibiotics were followed by seven days of oral antibiotics. An arm pouch was used to immobilize the operated arm. On the second post-operative day, the wound was examined, and an X-ray was obtained to examine the alignment of the fracture fragments. The patients were discharged with the arm pouch. Patients were examined on every two weeks, one month, six months, and one year. After two weeks, rehabilitation was started. Gentle pendulum exercises were allowed within the arm pouch. In the first two months, a limited range of motion was permitted for the shoulder, with abduction restricted to 80 to 90 degrees. After three months, active range of motion in all planes was allowed. Results were evaluated in relation to union, visual analogue scale for pain, and complications We evaluated shoulder function using the DASH score.

RESULTS

A total of forty patients, 20 in each group, were studied in this study. Table 1 shows the clinical and demographic features of the patients. These clinical and demographic characteristics did not significantly differ between the two groups.

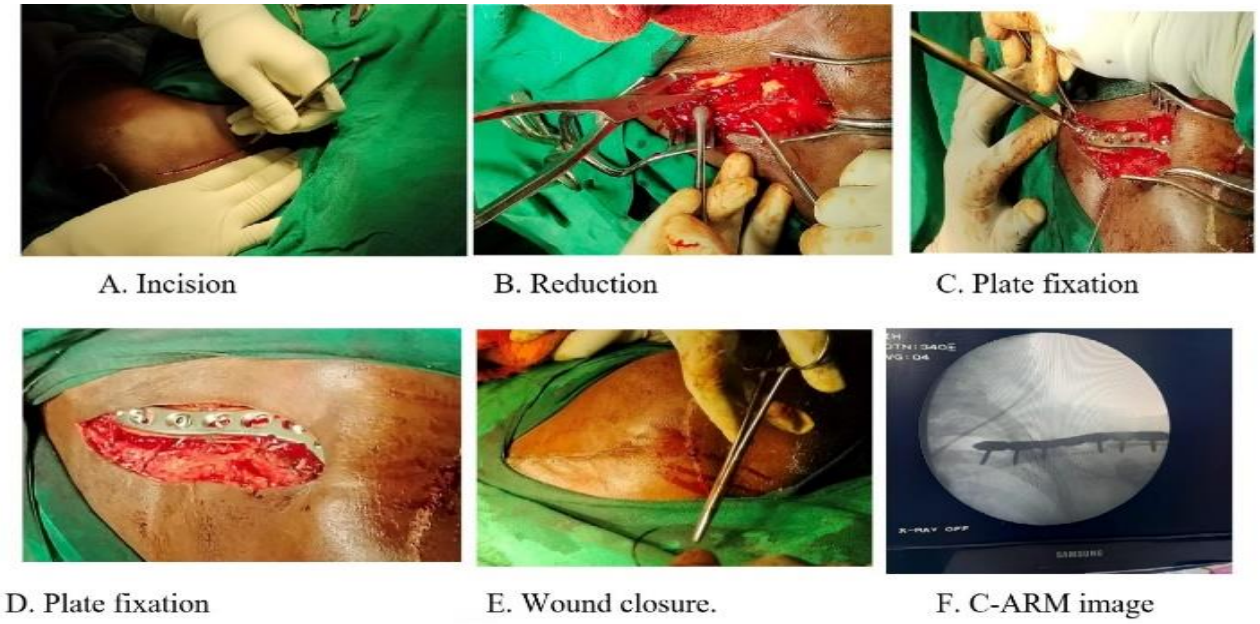

Figure 1 (A-F): Open reduction and internal fixation with anatomical plate.

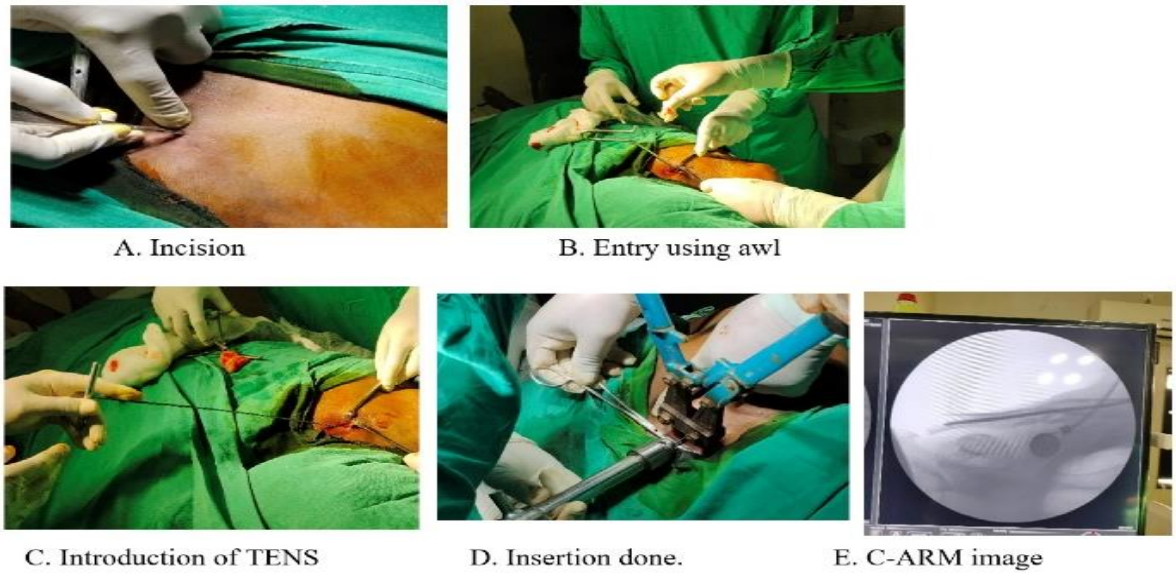

Figure 2 (A-E): Closed reduction and internal fixation with titanium elastic nail.

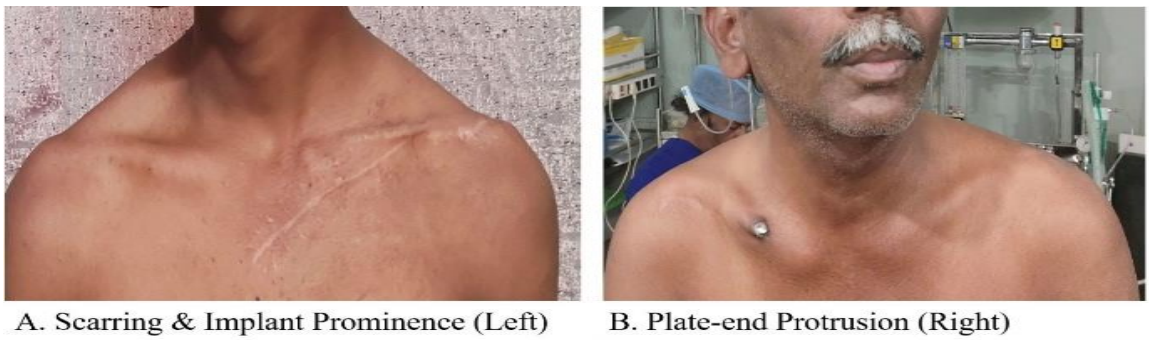

Figure 3 (A and B): Post-operative complications encountered in open reduction and internal fixation with anatomical plate.

A. Nail-end Prominence (Right) with nail-end protrusion in same patient after 6 months

Figure 4 (A and B): Post-operative complications encountered in closed reduction and internal fixation with titanium elastic intramedullary nailing.

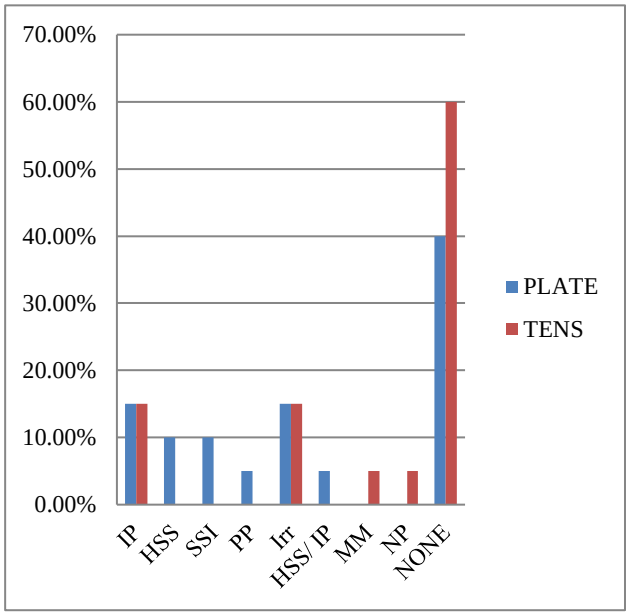

Figure 5: Complications encountered among both groups.

IP: implant prominence; HSS: hypertrophic surgical scar; SSI: surgical site infection; PP: plate protrusion; IRR: implant irritation; MM: medial migration of nail; NP: nail protrusion.

The factors which were insignificant on comparison included the above demographic factors (Table 1) as well as visual-analog scale, range of motion and DASH Score at 6 months, being similar for both groups. Significant factors on comparison between the two groups included intra-operative blood loss, duration of surgery, union time and post-operative complications (Table 3), all being less in the nailing group compared to the plating group as shown in the tabular column (Table 2).

Union was attained by 9 (45%) of Group A patients in 6-7 months and by 11 (55%) in 8 months, with a mean union time span of 7.5 months. The mean DASH score at the end of 6th month for plating group was found to be 18.7. Four (20%) had prominence around the implant, three (15%) had hypertrophic scars (Figure 3A), one (5%) had post-union plate-end protrusion (Figure 3B), and two (10%) had surgical site infections treated with intravenous antibiotics.

In group B, the mean union time was 7.1 months, with 16 patients (80%) reaching union by 6-7 months and 4 patients (20%) by 8 months.

The mean DASH score at the end of 6th month for nailing group was found to be 11.88. Three (15%) of the patients had nail-end prominence, three (15%) had nail-end irritation by four months, one (5%) had nail-end protrusion by six months, (Figure 4-A) and one (5%) had medial migration (Figure 4-B) by eight months. These complications were managed post-union by implant removal. There was no surgical site infection. Commonest site for metastasis was regional lymph node. 8 patients had secondary deposits in liver, 2 were having deposit in anterior abdominal wall and two females were having secondary deposits in both ovaries.

Table 1: Demographic and clinical profiles of the patients belonging to both groups.

Demographic characters		Group A (Plating N=20)		Group B (TENS, N=20)	
		No. of patients	%	No. of patients	%
Age group (in years)	11-30	4	20	6	30
	31-50	10	50	8	40
	51-70	6	30	6	30
Gender	Male	16	80	14	70
	Female	4	20	6	30
Mechanism of injury	Fall	9	45	7	35
	RTA	11	55	13	65
Side of injury	Right	12	60	13	65
	Left	8	40	7	35

Table 2: Factors significant on comparison between the plating and nailing groups.

S. No.	Factors of significance	Plating		Nailing		P value (<0.05 is significant)
		Mean	S.D.	Mean	S.D.	
1.	Intra-operative blood loss (in ml)	117.75	19.499	67.80	13.652	<0.001
2.	Duration of surgery (in minutes)	114.00	20.105	68.40	12.696	<0.001
3.	Union Time	7.50	0.607	7.10	0.553	<0.03

Table 3: Post-operative complications observed among both groups.

Complications	Group		Total (%)	Chi value	P value
	PLATE (%)	TENS (%)			
Implant prominence (IP)	3 (15.0)	3 (15.0)	6 (15.0)	8.800	0.35
Hypertrophic surgical scar (HSS)	2 (10.0)	0 (0.0)	2 (5.0)		
Surgical site infection (SSI)	2 (10.0)	0 (0.0)	2 (5.0)		
Plate protrusion (PP)	1 (5.0)	-	1 (2.5)		
Implant irritation (Irr.)	3 (15.0)	3 (15.0)	6 (15.0)		
HSS/IP	1 (5.0)	0 (0.0)	1 (2.5)		
Nail protrusion	N/A	1 (5.0)	1 (2.5)		
Medial migration	N/A	1 (5.0)	1 (2.5)		
NONE (No complication)	8 (40.0)	12 (60.0)	20 (50.0)		
Total	20 (100.0)	20 (100.0)	40 (100.0)		

DISCUSSION

The clavicle plays a crucial role in upper extremity function as well as the mechanics of the pectoral girdle. The clavicle allows for optimal function of the upper extremity as well as protects the upper extremity by dispersing the amount of force transmitted from direct contact. The positioning of the clavicle also keeps the extremity far enough away from the thorax, allowing for the range of motion (ROM) of the shoulder to be unimpeded.

Its strut-like mechanics allow the scapula to glide smoothly along the posterior wall which is critical for full upper extremity motion.[12] The anatomical location also protects neurovascular structures, including the brachial plexus, subclavian artery, and subclavian vein which, if disrupted, would greatly increase morbidity.[13]

Clavicle fractures account for 5% of all fractures in adults.[14] Approximately 80% of clavicular fractures involve the midshaft and more than 70% of such fractures are usually displaced.[15] The majority of clavicle fractures are treated non-operatively with good outcomes.[16-19]

But in recent times, there has been a shift toward a higher frequency of surgical intervention, especially for mid-shaft fractures. Numerous writers have provided evidence of decreased incidence of problems like discomfort, non-union, and instability. Additionally, individuals receiving operational therapy have shown better functional outcomes when compared to conservative measures.[17,20]

Several authors have analysed the biomechanical characteristics of plates and intramedullary implants for fractures in middle-third clavicle fractures. Golish et al. demonstrated that plate fixation provides a superior construct, demonstrating decreased displacement at fixed loads, as well as greater loads at fixed levels of displacement during a wider range of movements.

This may be of benefit in early/accelerated rehabilitation protocol.[21] But surgeons need to be aware that drilling and manipulating the fracture carries a higher risk of harming the underlying neurovascular structures. The complications associated with plate fixation are; infection, non-union, mal-union, further surgery, scarring, re-fracture after plate removal and intra-operative vascular injury.[22,23] It has been demonstrated that intra-medullary fixation causes fewer complications because it retains the soft tissue envelope and periosteum with less tissue dissection and is more cosmetically pleasing.[24] Clinical outcomes with intramedullary fixation vary, and many surgeons prefer plate fixation as the preferred operational treatment for clavicle fractures or non-unions. However, because of its minimally invasive method, intramedullary fixation is particularly effective for individuals with multiple injuries or additional shoulder conditions.[25]

During the course of the present study, various factors were noted in both plating & nailing groups, and were analysed and compared. The factors which showed no significance on comparison and did not influence the outcome of the study included demographic details of the patients such as age, sex, side of injury as well as mode of injury, duration of injury. It was found that patients with certain co-morbidities such as diabetes mellitus were at risk of developing surgical site infection especially in case of plating group, as the incision taken is of substantial length.

The factors which were found to be of significance in the comparison, included the intra-operative blood loss, duration of the surgery and time taken for fracture union. The mean intra-op. blood loss was found to be more in case of Plating than nailing group, i.e. 117.75±19.499 ml and 67.80±13.652 ml respectively. The mean duration of surgery was also found to be more in case of Plating group than nailing group i.e., 114±20.105 minutes and 68.40±12.696 minutes respectively.

Outcome in terms of the range of motion and dash score was observed to be similar and acceptable for both plating and nailing groups. However, the DASH score in case of plating group was slightly higher than nailing group, mainly due to the incidence of complications such as hypertrophic surgical scar, implant prominence, irritation in case of plating which being cosmetically less appealing, affected the DASH score in terms of capability and confidence of the patient.

Limitations of the study were, the study duration was confined to a period of only 2 years. The sample size comprised only 40 patients. The research was confined to a single location, specifically Al-Ameen Medical College Hospital.

CONCLUSION

The findings of our study indicate that although plating involves longer operative duration and greater blood loss, as well as complications like scarring, implant prominence, and surgical site infections, it provides more rigid fixation and rotational stability compared to titanium elastic nailing system (TENS) nailing. On the other hand, TENS has advantages such as shorter operating time, less blood loss, fewer postoperative complications, and minimal scarring or implant prominence, making it a more cosmetically and socially acceptable option. Both methods result in a good functional outcome.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Zahid SH, Endigeri P, Pasha RT, Bagawan R. A comparative study of anatomical plate fixation versus intramedullary nailing of middle-third clavicle fractures in Al-ameen medical college hospital. Int J Res Orthop 2025;11:105-11.