IJMA

International Journal of Medical Arts

Volume 7, Issue 6 (June 2025)

http://ijma.journals.ekb.eg/

P-ISSN: 2636-4174

E-ISSN: 2682-3780

Available online at Journal Website
https://ijma.journals.ekb.eg/
Main Subject [Orthopedic Surgery]

Review Article

Functional Outcomes of Nonoperative versus Operative Management of Displaced Fractures of the Middle One-Third Clavicle in Adults: A systematic Review.

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Article information

Received: 27- 02- 2024

Accepted: 07-04-2025

DOI: **10.21608/ijma.2024.270657.1939**.

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Citation: Elsebai M, Yasseen IA, Ibrahim MAA. Functional Outcomes of Nonoperative versus Operative Management of Displaced Fractures of the Middle One-Third Clavicle in Adults: A systematic Review. IJMA 2025 June; 7 [6]: 5792-5798. doi: 10.21608/ijma.2024.270657.1939.

Abstract

Background: Clavicular injuries represent 2.6% of all bone fractures, with the most common site being the middle one-third. The functional outcome of nonoperative versus operative management is still debated.

Aim of the work: The current work aimed to primarily compare the operative versus nonoperative management of displaced middle one-third fractures of the clavicle in adults with regard to functional outcome. And to compare the rate and type of complications as a secondary objective

Methods: An electronic medical database search was conducted to perform this systematic review. The records were pooled and reviewed according to the defined inclusion and exclusion criteria, and a critical assessment was performed. Data was extracted from eligible records, tabulated, and interpreted.

Results: A total of 5 studies met the inclusion, exclusion, and quality assessment criteria. The data were then grouped according to defined time points during follow-up. The functional outcome of patients who underwent surgery were found to be greater than those who underwent conservative treatment at most time points. The overall complication rate was higher in the nonoperative group. The incidence of nonunion and malunion were greater in the nonoperative group, while hardware-related problems were greater in the operative group.

Conclusion: Operative intervention was found to have a superior functional outcome at different time points during treatment. It had a lower overall complication rate. However, it introduces its own set of surgery and hardware related problems. We suggest a shared decision making approach where most eligible patients would undergo primary fixation according to their needs, while the rest would try nonoperative management and only progress to operative management based on an early predictive model or on treatment failure.

Keywords: Operative; Nonoperative; Clavicle; Functional; Complications.

INTRODUCTION

Fracture of the clavicle represents 2.6% of all bone fractures, with the most common site being the middle one-third. The incidence of this fracture is approximately 80% of all clavicle fractures and nearly 45% of those in the shoulder girdle [1].

The incidence increases in children and young individuals, and it is more prevalent in males. Approximately 30% of fractures in males occur between the ages of 13 and 20 years, while only 20% of clavicle fractures in women occur in the same age group [2]. Most fractures involve the left clavicle more than the right clavicle [approximately 60% of the fractures occur on the left side]. In later decades, the incidence of clavicular fractures gradually decreases before increasing again in older individuals [1]

The functional outcome of nonoperative versus operative management is still widely debated. Some authors claim that operative management have a better short-term functional outcome, early return to activity, better cosmesis and overall patient satisfaction, with lower reported rates of nonunion. It was thought that it is even advantageous in terms of cost-effectiveness. However, operative management has been associated with a high risk of surgery-related complications and the risk of reoperation. The long-term functional outcomes were similar in both cases [3,4]. On the other hand, some authors believe that nonoperative management achieved similar functional results in some cases [5], or even to be plane better in case of some forms of this fracture [6].

AIM OF THE WORK

The current work aimed to compare the nonoperative versus operative management of a displaced fracture of the middle one-third of the clavicle in adults regarding the functional outcome as a primary objective. And to compare the rate and type of complications as a secondary objective.

METHODS

A review of the literature was carried out using the following medical databases: PubMed, Cochrane, and Google Scholar. The following search strings were used in each data base: [Midshaft AND clavicle AND fracture; Middle AND one-third AND clavicle AND fracture; [Operative OR nonoperative OR conservative OR surgical] AND clavicle AND fracture AND functional outcome; [Operative OR nonoperative OR conservative OR surgical] AND clavicle AND fracture AND complication].

After the search strings were used in the databases mentioned above, a reference list was generated for each string. The search strategy followed these eligibility criteria to select the records to be included in this systematic review:

Inclusion criteria:

Any record with level of evidence 1-4, including case control studies, randomized control trials [RCTs], cohort studies. Records including adult patients aged 18-60 years with fractures in the middle one-third of the clavicle. Studies comparing nonoperative versus operative management of fractures in the middle one-third of the clavicle. English literature only. Orthopaedic journal articles published in the past 10 years. Human studies. Access to full free article. Articles that adhered to the quality assessment and risk of bias measures used in this study.

Exclusion criteria:

Middle one-third fractures of the clavicle that are associated with other clavicular injuries. Non-clinical studies. Case reports. Surgical technique articles without reported outcomes. Duplicate articles by the same author unless the follow-up period was longer. Studies describing outcomes other than functional outcome, symptomatic nonunion, malunion and surgical complications. The free 'evidence synthesis tool and database' provided by the website CADIMA.info was used to compile the different strings into one merged reference list. An initial automated scan was performed by CADIMA.info to remove possible duplicates, and the results were reviewed to ensure that the automated process did not remove any non-duplicate records. The list of records was then reviewed again at two stages: title and abstract, and full text. At each stage, records were reviewed according to the aforementioned inclusion and exclusion criteria. Only records that were relevant in the title and abstract screening progressed to the full-text stage for further assessment. The remaining records were then subjected to the critical assessment process.

Critical Assessment:

To accurately assess the possible risk of bias and the quality of each study, information was gathered from each paper, and then the Cochrane Collaboration tool 2 [RoB2] [7] was used for randomized control trials. For nonrandomized studies, the Methodological Index for Nonrandomized Studies [MINORS] criteria were used [8].

The Cochrane tool for assessment of risk of bias, second version [RoB 2], is the recommended tool for randomized trials included in Cochrane Reviews. Bias can occur in a number of domains. Each domain focuses on a different part of the trial, including the trial design and the execution and reporting of the results.

Within each domain, there is a group of signaling questions that are designed to obtain information about a part of the trial that may be affected by bias. An algorithm then suggests a possible judgment for risk of bias based on the answers provided for the aforementioned questions. A judgment can be of "High" risk of bias or "Low" risk or can only show 'Some concerns'. The records deemed to be of "low risk of bias" according to the RoB2 algorithm and a subsequent human revision were included in this study.

In the Methodological Index for Nonrandomized Studies [MINORS] [8], the items are scored in the following manner: a score of zero is given if the item is not reported, a score of one if it's inadequately reported, and a score of two if it's reported and adequate.

The global ideal score is 16 for non-comparative studies and 24 for comparative studies. All the records in this study are comparative; hence, the Ideal score was 24. For this study, a score of 14 was considered poor, 15-22 was considered moderate, and 23-24 was considered high quality. Only studies of "High Quality" were included.

The data was then extracted from eligible recorded, tabulated and interpreted. Preferred reporting items for systematic reviews and meta-analyses [PRISMA] was used to report the current systematic review.

RESULTS

Records were subjected to the quality assessment process via the MINORS tool and ROB2 tool, the results are shown in [Table 1], and [Table 2]. A flow diagram representing the process is presented in figure [1].

A total of 5 records met the inclusion, exclusion and quality assessment criteria. The type of intervention and measure of functional outcome are shown in [**Table 3**]. The functional outcome was assessed mostly by the Disabilities of the Arm, Shoulder, and Hand [DASH] score [9], an abridged version of the DASH scoring system called Quick Dash [qDASH] [10], and the Constant–Murley score [11] [CMS]. The shoulder pain and disability index [12] [SPADI] was also used by a single study, along with the Short Form-36 [13].

The demographic data of the included records were extracted, most of the patients were approximately 30 years old with the majority of patients being male in both the nonoperative and operative groups [**Table 4**].

Different follow-up time points were used in the 5 records including 6, 12, and 24 weeks as well as 9 months.

As shown in **Table [5]**, **Nicholson et al** [14] reported that although there was a gradual decrease in the mean of DASH score for both nonoperative and operative groups, this decrease was not significant at any of the 6, 12, or 24 weeks' follow-up time points.

On the other hand, **Koç et al** [15] reported that during the final evaluation at 9 months, the SF-36 physical score was significantly better in the operative group than the nonoperative group, but the SF-36 mental score had no significant difference between both groups. Meanwhile, the combined SPADI [disability + pain] total score was significantly better in the operative group.

In the study done by **Naveen et al** [16] the results showed that there was a significant difference between both groups, with the operative group scoring better at 6, 12 and 24 weeks of follow-up. **Shetty et al** [17] indicated that there was no significant difference between both groups at 6 weeks nor at 24 weeks. **Rageeb et al** [18] reported that the operative group had better DASH scores at the final evaluation at 24 weeks.

Table [6] shows a visual representation of the effect of operative intervention at 6, 12 and 24 weeks. A significant advantage is indicated by a green arrow, a non-significant advantage is indicated by a black arrow, and the size of the arrow represents a more significant result.

Regarding the secondary objective, 2 of the studies did not report the complication rate in either group. The remaining 3 studies reported a higher rate of complications in the nonoperative group. In the nonoperative group, the 3 studies reported various complications like symptomatic malunion, nonunion, droopy shoulder, complex regional pain syndrome, and limited range of movement. On the other hand, in the operative group, 2 studies reported complications in terms of malunion, scar-related problems, and hardware prominence, while 1 study reported that there were no complications in the operative group. [**Table 7]**

Table [1]. Results of the ROB2 assessment tool

Study ID	D1	D2	D3	D4	D5	Overall		
2. Subodh Kumar	-	-	+	+	+	-	+	Low risk
7. Guanggao Li	+	+	-	!	+	-	!	Some concerns
9. J.A. Nicholson	+	+	+	+	+	+	-	High risk
17. Eric Smith	+	+	!	+	+	!	**D1**	*Randomization process*
18. Sanath Kumar Shetty	+	+	+	+	+	+	**D2**	*Deviations from the intended interventions*
19. Anand SR	!	+	+	+	-	-	**D3**	*Missing outcome data*
26. V. Abhilash Rao	!	-	+	+	-	-	**D4**	*Measurement of the outcome*
29.Ravi Pratap Singh	!	+	+	!	-	-	**D5**	*Selection of the reported result*

Table [2]: Results of the MINORS tool.

Study ID	1. Ha Yong Kim	3. Valentino Coppa	4. Ajay Shukla	5. Nicholas Lake	6.Mohsen Khorami	8. Gian Mario Micheloni	10. Mehmet Rauf Koç	12. B. M. Naveen	13. Lars Eden	14. Camille Echalier	15. R.K.S. Dhakad	16. Barış Özkul	20. Rajinder Kumar	21. Koramutla Harsha	22. Amrinder singh	23. Madhusudan Kumar	24. D. Y. Patil	25. Sagar RK	26. Mohammed Rageeb	27. Sachin Y. Kale	28. Amit Mishra	31. Eeshan Bhardwaj
1. A clearly stated aim	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
2. Inclusion of consecutive patients	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
3. Prospective collection of data	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
4. Endpoints appropriate to the aim of the study	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	2	2	2	2	2	1
5. Unbiased assessment of the study endpoint	0	0	0	0	0	0	2	2	0	2	0	0	2	0	0	0	0	0	2	0	0	0
6. Follow-up period appropriate to the aim of the study	2	1	1	2	1	2	2	1	2	1	0	2	1	1	1	1	1	0	2	0	2	1
7. Loss to follow up less than 5%	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
8. Prospective calculation of the study size	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
9. An adequate control group	0	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
10. Contemporary groups	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
11. Baseline equivalence of groups	2	2	2	2	2	2	2	2	1	1	1	2	1	2	1	0	1	2	2	0	0	2
12. Adequate statistical analyses	2	2	2	2	2	2	2	2	2	2	1	2	1	2	1	1	1	2	2	2	2	2
GLOBAL SCORE	20	21	21	22	20	21	24	23	21	22	18	22	21	21	19	16	19	20	24	18	20	20
Final Assessment	Moderate quality	Moderate quality	Moderate quality	Moderate quality	Moderate quality	Moderate quality	High quality	High quality	Moderate quality	Moderate quality	Moderate quality	Moderate quality	Moderate quality	Moderate quality	Moderate quality	Moderate quality	Moderate quality	Moderate quality	High quality	Moderate quality	Moderate quality	Moderate quality

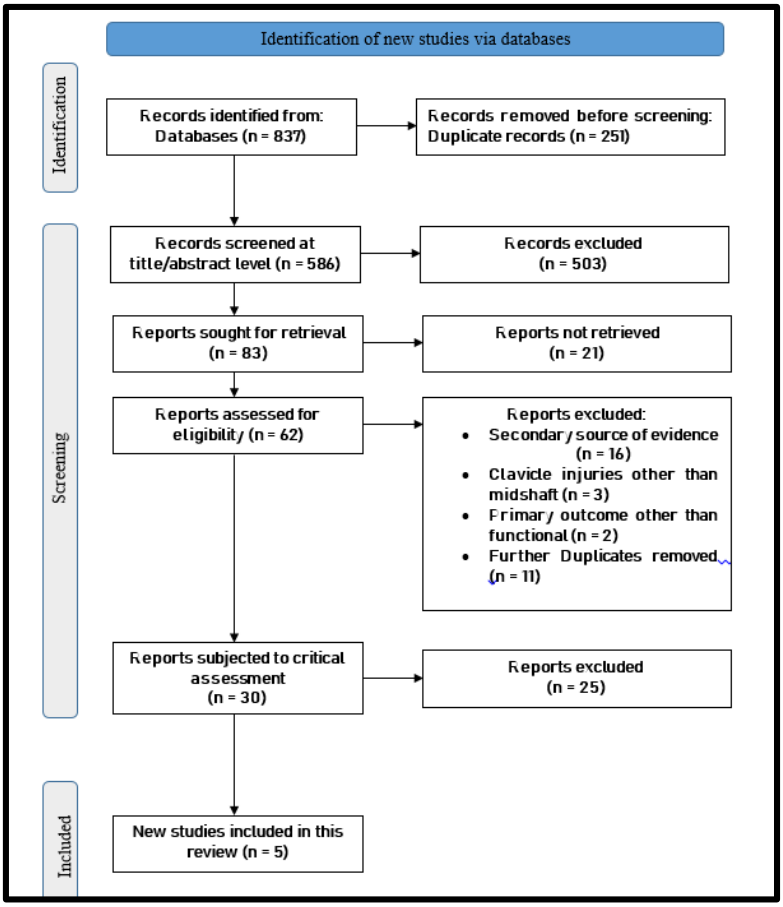

Figure [1]: Flow diagram

Table [3]: Intervention, and functional outcome measures of the included records.

Author/ Year	Type of Study	Nonoperative Management	Operative Management	measure of Functional Outcome
Nicholson 2021	RCT	not-specified	Plate fixation	Quick DASH
Koç 2022	Prospective/cohort	not-specified	Plate fixation	SPADI
Naveen 2017	Prospective/cohort	Figure-of-eight bandage and Sling	Plate fixation	Constant and Murley
Shetty 2017	RCT	Clavicle Brace and Sling	Plate fixation	DASH
Ghadeer/ Rageeb 2018	Prospective/cohort	Sling	Plate fixation	DASH

Table [4]: Demographic data of the selected studies

Author/year	Nonoperative group				Operative group			
	Male	Female	Total	Mean Age	Male	Female	Total	Mean Age
J.A. Nicholson 2021	66	10	76	32.7	74	12	86	31.9
Mehmet Rauf Koç 2022	43	17	60	33.1	26	9	35	35.3
B. M. Naveen 2017	27	3	30	35.2	26	4	30	32.4
Sanath Kumar Shetty[1] 2017	11	3	14	27.5	14	2	16	27.5
Mohammed Rageeb 2018	10	2	12	30.4	11	1	12	29.8
TOTAL	157 [81.8%]	35[18.2%]	192[100%]	32.7	151[84.4%]	28[15.6%]	179[100%]	32.1

Table [5]: Functional Outcome scores of the included studies.

Author/Year	Outcome Measure	Follow-up Time Points	Non- Operative Group	Operative Group	P
J.A. Nicholson 2021	Quick DASH*1 [Mean]	**6 weeks**	25.5	22.9	0.358
		12 weeks	11.8	10.4	0.532
		24 weeks	5.8	5.2	0.701
Mehmet Rauf Koç 2022	SF-36*2 [Physical Score] [Mean]	**9 months**	47.5	52.6	0.003
	SF-36*2 [Mental Score] [Mean]	**9 months**	52.0	50.0	0.868
	SPADI*3 [Total Score Mean]	**9 months**	31.1	26.0	0.005
B. M. Naveen 2017	CMS *4 [Mean]	**6 weeks**	63.9	71.8	0.001
		12 weeks	75.8	83.6	0.001
		24 weeks	89.6	94.0	0.001
Sanath Kumar Shetty 2017	DASH*5 [Mean]	**6 weeks**	59.1	53.4	0.256
		24 weeks	8.6	7.8	0.861
Mohammed Rageeb 2018	DASH*5 [Mean]	**24 weeks**	22.3	11.3	0.005

1* A lower score is better. 2* higher is better. 3* higher is better. 4* A higher value is better. 5* A lower value is better.

Table [6]: Advantage of operative intervention.

	6 weeks [Intervention advantage]	12 weeks [Intervention advantage]	24 weeks Intervention advantage]	9 months Intervention advantage]
J.A. Nicholson 2021 [QDASH]	▲	▲	▲	
B. M. Naveen 2017 [CMS]	▲	▲	▲	
Sanath Kumar Shetty 2017 [DASH]	▲		▲	
Mohammed Rageeb 2018 [DASH]			▲	
Mehmet Rauf Koç 2022 [SPADI]				▲

Table [7]: Complication rates of the included studies

Author/Year	Nonoperative Group Complication Rate [N & %]	Operative Group Complication Rate [N & %]
J.A. Nicholson 2021	Not reported	Not reported
Mehmet Rauf Koç 2022	Not reported	Not reported
B. M. Naveen 2017	9 [30%]	6 [20%]
Sanath Kumar Shetty 2017	6 [42.8%]	0 [0 %]
Mohammed Rageeb 2018	10 [83.3%]	2 [16.6%]

DISCUSSION

The discussion is being shifted from routinely managing clavicular midshaft fractures nonoperatively, to early operative fixation. Currently, there is a strong impression that operative management is associated with better functional outcomes, shorter recovery times, and fewer complications. A review of recent similar studies revealed that while operative management is superior in some aspects, such as a lower risk of nonunion and symptomatic malunion, it has some drawbacks and introduces a new set of surgery-related problems. This study was conducted to systematically review the currently available literature and reach a conclusion on whether or not the operative management is superior to nonoperative management, primarily in terms of functional outcome. Also, as a secondary objective, to clarify whether the associated surgery-related complications are warranted and less risky than the known complications that arise from nonoperative management.

Upon reviewing the available data, the initial impression was that, given enough time, both operative and nonoperative management had similar functional outcomes. The operative management approach seemed to have a clear advantage in the short-term results but the advantage becomes less distinguished in the medium-to-long-term, which is more relevant to real-world, post-treatment scenarios.

To further investigate this hypothesis, the functional results of each study were grouped by time points as shown in [**Table 6**], the results were grouped at 6, 12 and 24 weeks of follow-up. Only one study had a relatively longer follow-up period of 9 months, so its results are also individually listed at this time point. Three studies reported functional outcome results at 6 weeks. **Nicholson *et al.*** [14] and ***Shetty et al.*** [17] reported a non-significant advantage to the operative group, while ***Naveen et al***. [16] reported that the operative group had a significantly better scores at 6 weeks. The impression here is that after 6 weeks of treatment, the operative intervention is generally better even though a significant advantage could only be elicited in one study. Two studies reported the functional outcome results at 12 weeks. **Nicholson *et al.*** [14] reported a non-significant advantage to the operative group, while **Naveen *et al***. [16] reported a significant difference in favor of operative intervention. According to these results, Operative intervention is more advantageous at this time point. Most of the reported results converged at 24 weeks, **Nicholson *et al.*** [14] and **Shetty *et al*** [17] reported a non-significant advantage to the operative group. It is worth noting that the gap in the results between both groups was considerably smaller, which supports the initial hypothesis that given enough time, both interventions will reach a similar functional outcome. On the other hand, **Naveen *et al***. [16] and **Rageeb *et al.*** [18] reported a significant difference in favor of surgery at this time point. The impression at this time point is that while the difference in the functional outcome is smaller after 24 weeks, operative management still holds the advantage. Finally, **Koc *et al***. [15] reported their radiological and functional results at 9 months, and it showed a significant advantage in favor of operative intervention. Given that this is the only study that included a relatively longer follow up period, the impression here is that operative intervention holds a clear advantage over nonoperative management in the long term. Although some data supported the initial hypothesis, the overall findings are in contrast to it. It shows a clear advantage in functional outcome to the operative intervention at all-time points, including the long term advantage.

Regarding the secondary outcomes, the rate of complications was reported in 3 studies. **Naveen *et al***. [16] reported that the most common complication was malunion with cosmetic deformity, followed by nonunion. They reported only 1 patient in the nonoperative group who had a restricted range of motion. The complications in the operative group were mostly due to hardware and scar problems, with only 1 patient in the operative group reported to suffer from malunion. **Shetty *et al.*** [17] reported that the incidence of malunion was significantly greater in the nonoperative group, as none of the operative group patients suffered from malunion or any other complications. **Rageeb *et al.*** [18] reported that the nonoperative group had a higher rate of complications. The most common complications were also nonunion and symptomatic malunion. They also reported other complications in this group such as droopy shoulder and complex regional pain syndrome. Of the included studies, this study had the highest rate of complications in the nonoperative group, comprising more than 80% of the conservatively treated patients. The operative group had a 16% complication rate and consisted of 2 patients with hardware irritation and inscional numbness.

Most of the results showed a significant or an insignificant advantage in the functional outcome for the operative group. The complication rate was greater in the nonoperative group, with the most common complications being symptomatic malunion and nonunion. The operative group, however, had its own set of hardware- and surgery-related complications that were absent in the nonoperative group, albeit at a much lower overall rate. These results are in accordance with a systematic review of overlapping meta-analyses by **Zhao *et al.*** [19]. They reported that surgical intervention was associated with a better overall functional outcome and a decreased risk of nonunion; however, their findings were consistent with the notion that surgery has higher rates of implant-related complications. Another systematic review covering 1469 patients by **Lenza *et al.*** [20] pointed out that while the raw data supports the superiority of operative intervention in terms of functional outcome, they had to conclude that both operative and nonoperative management yielded similar results regarding the long-term functional outcome due to the low quality of the available data. Another systematic review by **Qin *et al.*** [21] reached a similar conclusion, further adding that while the operative group had lower rates of nonunion and malunion; the overall complication rate was greater in the operative group, such as wound infection, hardware-related problems, and frozen shoulder. On the other hand, a systematic review by **Yan *et al.*** [22] Involving 3094 patients analyzed functional outcome data after both interventions and reached the conclusion that the operative intervention had better clinical results but, was not significant enough to warrant a clear judgment. The authors also did not report the rate of complications other than nonunion and malunion. After careful consideration of this study's results along with the results of the previously mentioned studies, we would advise for a shared decision making approach. The patient should be well informed that, in terms of functional outcome and early recovery, a primary operative intervention is preferred whenever possible. This is especially true in young, active adult patients, along with patients with high shoulder load occupations. However, the patients should also be well informed that surgery has its own set of complications, and that there is a high possibility of needing a second surgery for hardware removal. In this setting, nonoperative intervention should be reserved for patients who are unfit for surgery, or simply that refuse to undergo the operation. In the latter group, operative management of malunion or nonunion should still be advised to those who develop these complications. A study by **Marsalli *et al.*** [23] revealed that patients who developed nonunion after conservative treatment achieved similar functional results after secondary surgical fixation to those who underwent primary surgical fixation. The downside was that the overall treatment time was more than double in those patients. Another study by **Chen *et al***. [24] reported that secondary fixation for clavicular nonunion with a locked compression plate and without a bone graft is possible, and that it achieved similar results to fixation with a bone graft. This further demonstrated the parity between primary and secondary fixation if treatment time was excluded. In fringe cases that can't be reliably put in either treatment groups, **Nicholson *et al.*** [25] suggested a number of early predictors that can identify cases of nonunion early after 6 weeks of nonoperative management. They declared that a QDASH score of less than 40, absence of radiographic callus, and a fracture that is mobile by examination at 6 weeks are major predictors of nonunion. In which case, nonoperative management should be discounted and shifted to operative fixation.

Another factor in the shared decision making conversation should be cost effectiveness, a study by **Sørensen *et al.*** [26] demonstrated that primary surgical fixation is in fact not cost effective, except for patients who have high-load shoulder professions. This was further proven by **Nicholson *et al.*** [27], who performed a cost analysis of both interventions. They concluded that for plate fixation to be cost effective, the benefits of surgical intervention must outweigh the benefits of conservative management for at least 24 years following the intervention. This notion is disproved by the previously discussed results.

Limitations: More high-quality studies with comparable time points are needed to further prove the viability of either treatment as the treatment of choice, as most of the included studies had a relatively short follow-up period of 6 months, and the data did not converge at all of the selected time points.

Conclusion: Operative intervention was found to have a superior functional outcome at different time points during treatment. It had lower rates of malunion and nonunion, and a lower overall complication rate. However, it introduces its own set of surgery and hardware related

problems. We suggest a shared decision making approach, where patients [especially those with high shoulder load professions] would undergo primary fixation. These patients should be advised that complications could arise from surgery and that they might require a second procedure to remove the hardware. On the other hand, patients choosing not to undergo surgery should be informed that there is a higher risk of nonunion and symptomatic malunion. While the incidence of nonunion can be lowered by using a predictive model during follow up, these patients should be informed that a delayed operation may be needed to address this complication should it arise later.

Financial and nonfinancial relationships and activities of interest: None.

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IJMA

International Journal of Medical Arts

Volume 7, Issue 6 (June 2025)

http://ijma.journals.ekb.eg/

P-ISSN: 2636-4174

E-ISSN: 2682-3780