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Nonoperative vs Operative Treatment of Displaced Mid-Shaft Clavicular Fractures: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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ABSTRACT
Introduction: Among the general population, clavicle fractures are quite prevalent. Displaced midshaft clavicle fractures are still debatable in terms of the best way to treat them. The efficacy and safety of nonoperative therapy vs open reduction and internal fixation (ORIF) for displaced midshaft clavicle fractures in adults was evaluated by a comprehensive review and meta-analysis of randomized controlled trials (RCTs). **Materials and methods:** RCTs evaluating outcomes of interest among conservative therapy and ORIF of mid shaft clavicular fractures were sought by searches of major databases for example PubMed, Embase, Web of Science, and Scopus. We extracted data on functional outcomes; including Constant Murley score (CMS) and Disability Assessment of Shoulder and Hand (DASH), time to go back to work, and complication rate, involving nonunion, malunion, and secondary surgery. **Results:** We found 9 RCTs that fulfilled our inclusion criteria, with a total of 1259 cases, 626 cases experienced nonoperative treatment and 633 cases underwent clavicular plating. Based on our research, we found that nonoperative treatment was related to greater nonunion rates contrasted with ORIF. However, both techniques had similar functional outcomes, time to return to work, and rates of secondary surgery. **Conclusion:** Although conservative treatment and plating demonstrated different effects on nonunion rates of mid shaft clavicular fractures, no treatment modality was found to be superior in light of functional outcomes, time to get back to work, and secondary surgery. More homogenous, high-quality RCTs with longer follow-up durations and larger sample sizes are recommended.
Key words: Clavicle; Nonoperative; Plating; Nonunion

INTRODUCTION
Clavicular fractures are very frequent, and account for a nearly 10 percent of adult fractures [(1)]. Middle third clavicular fractures are the commonest, representing 80% of all fractures of the clavicle [(2)]. The traditional treatment option for clavicular fractures is conservative treatment using an arm sling or a figure-8 harness [(3)]. Being a safe and cost-effective option, nonoperative treatment is widely accepted by surgically unfit or undemanding patients. Nevertheless, the results of conservative treatment are not always satisfactory [(4)]. High risk of nonunion, shoulder problems and persistent pain has been reported [(5)]. Therefore, the operative management by compression plating or intramedullary nailing has gained large popularity recently [(6,7)].

Several studies have evaluated mid-shaft clavicular fractures have been studied extensively; however, the results are still ambiguous regarding the safety and efficacy of nonoperative versus operative therapy [(8-10)]. To help direct future clinical practice, researchers conducted a meta-analysis of RCTs comparing the effectiveness also safety of nonoperative management versus ORIF during the previous decade for adult displaced midshaft clavicle fractures.

MATERIALS AND METHODS
We carried out the systematic review in accordance with the criteria provided by Preferred Reporting Items for Systematic Reviews along with Meta-Analyses (PRISMA). The databases of Embase, PubMed, and Web of Science were researched beginning in January 2013 and continuing through June 2023.These are some of the search phrases that were used: (Clavicle) AND (Operative OR ORIF OR Plating) AND (Nonoperative OR Conservative). Endnote X9 software (Thomson Reuters, New York, NY, USA) checked for duplication after importing results.

Exclusion criteria were applied to the remaining publications' titles and abstracts: non-English articles, recommendations, or classifications, reviews, case reports, brief case series, or conference papers, letters to the editor, animal and in vitro experiments and unrelated research.

Next, relevant full-text papers were retrieved and evaluated. Included studies matched these criteria: RCTs comparing nonoperative and ORIF for displaced middle third clavicular fractures, minimum 6-month follow-up and extracting result data for comparison.

Data extraction and quality assessment:
Both the assessment of the list of prospective references as well as the extraction of the data were carried out by two separate reviewers. When it was required, a third reviewer was contacted to determine any ambiguities concerning eligibility. The 1st author, year of publication, country, number of cases in every group, participants' sex and age, method of fixation, length of follow-up and findings of interest, such as CMS, DASH, time to complete work again, nonunion rate, malunion rate, and secondary surgery, were taken from investigates that fulfilled the inclusion criteria. We utilized the quality assessment tool [(11)] developed by the Cochrane Collaboration so as to determine the potential for bias in the RCTs that were utilized in the analysis.

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The evaluation was performed by two different reviewers in independent manner, and any discrepancies were able to resolve by talking to the senior author.

Ethical Approval

The Burjeel Hospital Ethics Board approved the study.This experiment followed the World Medical Association's Declaration of Helsinki for human studies.

Statistical analysis

Review Manager, version 5.4.1 was utilized for each and every analysis of the data. (2014, The Nordic Cochrane Centre and The Cochrane Collaboration, Copenhagen, Denmark). In the case of binary outcomes, we determined the odds ratio together with the confidence interval (CI) for 95%. For continuous outcomes, we computed mean differences along with confidence intervals of 95%. We utilized a fixed-effect model with the method of Mantel-Haenszel to determine the overall effect estimate with a 95% confidence interval. This method was selected because there was no evidence of heterogeneity between the trials. In every other case, a random-effects model using DerSimonian and Laird's technique was selected as the best option. The degree of heterogeneity that existed between studies was determined with the use of the Q statistic and the I2 test, both of which indicate the amount of variation that exists in the effect estimates. A p value below 0.05 indicated statistical significance.

RESULTS

There were 1236 references found in the electronic search. Following filtering out 533 duplicates, we had 703 entries left to examine for appropriate titles and abstracts. Out of the 20 articles that met the criteria for a full-text review, only nine were accepted.
No new articles were imported after a manual search of references. Quantitative and qualitative analyses comprised data from nine studies [12–20]. The method for choosing which studies to do is depicted in Figure 1.

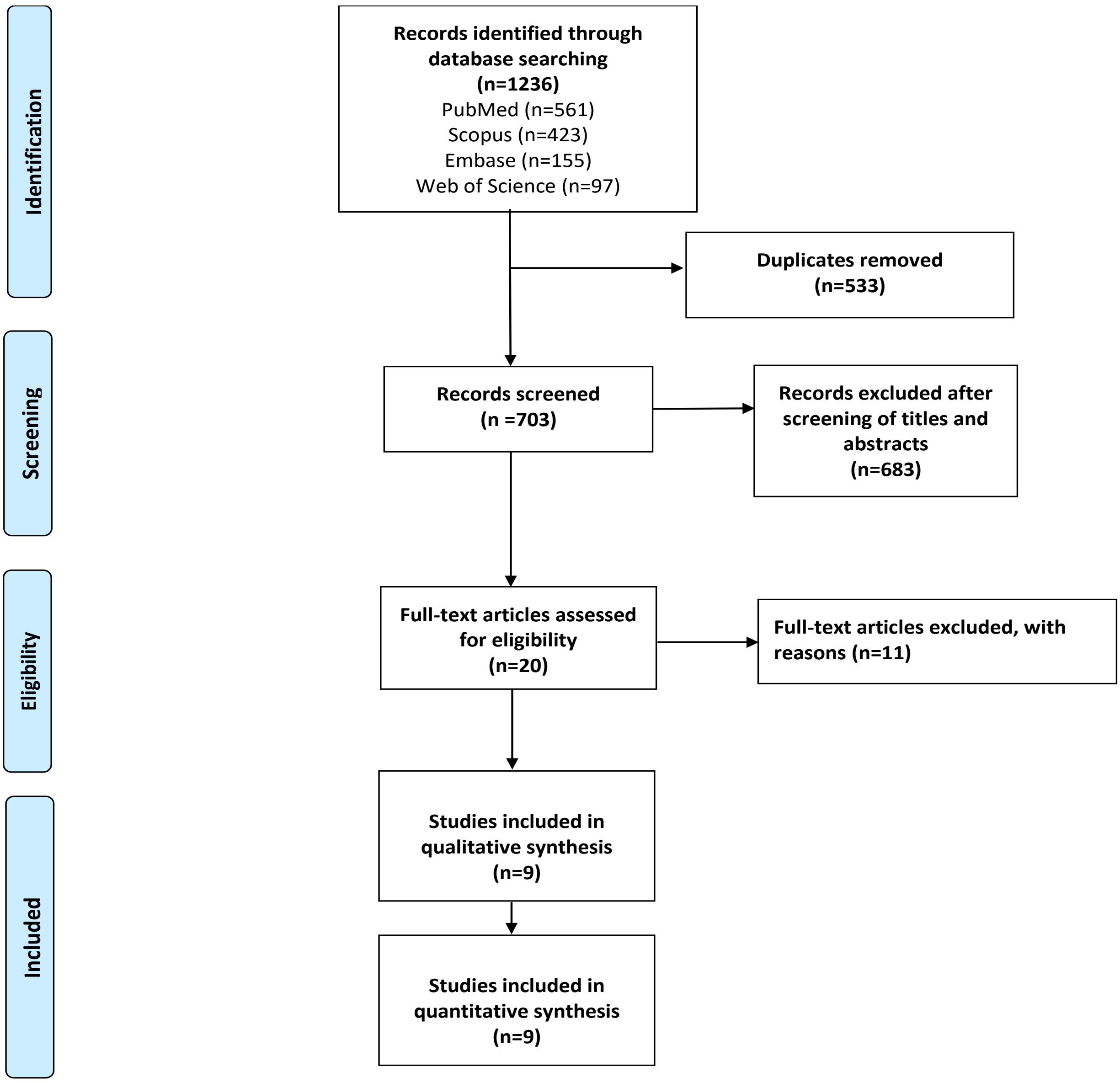

Figure 1: Flow diagram of study selection process

Table 1 summarizes study details that were considered for inclusion. There were a total of 1259 cases from 9 trials involved in the meta-analysis; 626 cases were treated non-operatively, and 633 cases received ORIF. All of the papers that were considered were randomized clinical trials. The average age across studies was 32–34 for those who did not undergo surgery and 31–64 for those who did. Among 9 and 55 months of follow-up were conducted.

Table 1: Baseline characteristics of involved studies (N = 1259)

First Author	Country	No.	Mean age (years)	Male (%)	Follow-up (months)	Non-operative	Operative
Robinson *et al.* [1]	UK	105/95	33/32	88/87	12	Collar and cuff	Locking Clavicle Plate (Acumed)
Melean *et al.* [15]	Chile	42/34	37/38	NA	12	Arm Sling	Locking Compression Plate (Synthes)
Woltz *et al.* [20]	Netherlands	74/86	37/38	89/9	12	Arm Sling	Not Specified
Ahrens *et al.* [12]	UK	147/154	36/36	88/86	9	Arm Sling	Locking Clavicle Plate (Acumed)
Tamaoki *et al.* [18]	Brazil	58/59	35/31	81/90	12	Figure-of-Eight Harness	3.5-mm Reconstruction Plate
Bhardwaj *et al.* [14]	India	33/36	32/32	39/22	24	Arm Pouch	Locking Compression Plate (Synthes)
Qvist *et al.* [16]	Denmark	71/75	39/40	77/85	12	Arm Sling	Locking Clavicle Plate (Acumed)
Woltz *et al.* [19]	Netherlands	39/40	45/46	90/90	55	Arm Sling	Not Specified
Ban *et al.* [13]	Denmark	57/54	40/39	84/84	12	Arm Sling	Locking Clavicle Plate (Acumed)

Data are presented as non-operative/operative.

Risk of bias within studies: The risk of bias in the involved investigations is depicted in Figure 2 with regards to allocation concealment, random sequence generation, evaluation of outcomes blinding, participant and staff blinding, insufficient result data, selective reporting and other biases. Except for a significant risk of performance and detection bias, all included studies exhibit a low or unclear risk across all other parameters.

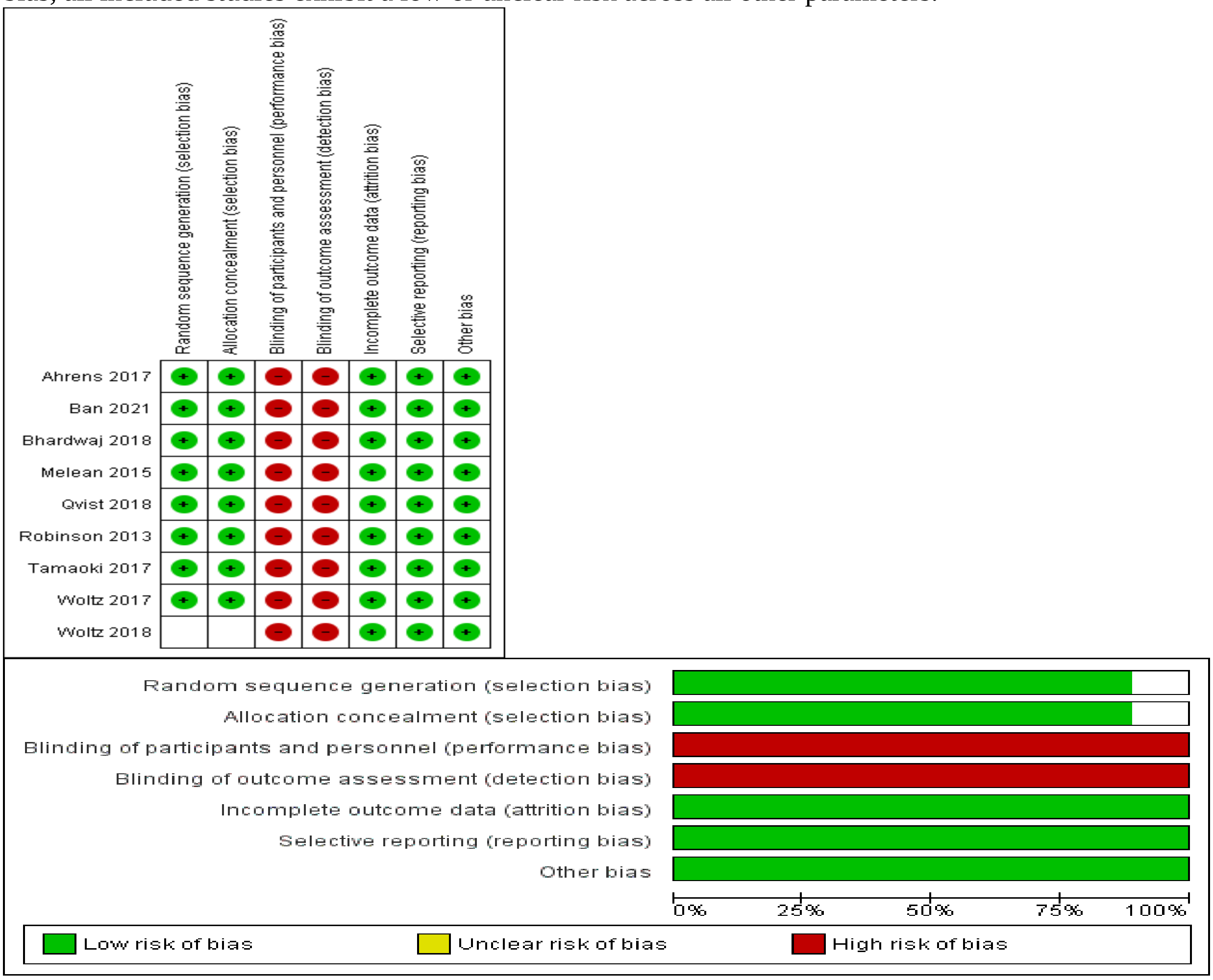

Figure 2: Risk of bias summary of included RCTs.

Meta-Analysis of Functional Outcomes

Constant Murley Score (CMS)

In all, seven studies reported on CMS, but only six studies were suitable for analysis, with 377 individuals in the nonoperative group and 396 individuals in the operative group. Because we found significant variability, we conducted our analysis using a random-effects model (I^2 = 95%, P <0 .001). The combined MD also 95 percent CIs was -4.37 (-9.52 to 0.77). The combined result demonstrated no statistically significant variance amongst groups in terms of CMS (Z = 1.66, P = 0.10) (Figure 3).

	Nonoperative			Operative				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Robinson 2013	87.8	5.8	92	92	9.3	86	18.6%	-4.20 [-6.50, -1.90]
Woltz 2017	96.6	6.4	58	95.4	7.8	75	18.6%	1.20 [-1.21, 3.61]
Ahrens 2017	89.2	8	76	91.3	8.4	88	18.5%	-2.10 [-4.61, 0.41]
Bhardwaj 2018	76.2	3.4	33	89.4	5.6	36	18.7%	-13.20 [-15.37, -11.03]
Qvist 2018	96	7.6	64	95.7	7.6	60	18.4%	0.30 [-2.38, 2.98]
Ban 2021	75.3	52.6	54	89.3	21.4	51	7.2%	-14.00 [-29.21, 1.21]
Total (95% CI)			**377**			**396**	**100.0%**	**-4.37 [-9.52, 0.77]**

Heterogeneity: Tau² = 35.60; Chi² = 100.64, df = 5 (P < 0.00001); I² = 95%
Test for overall effect: Z = 1.66 (P = 0.10)

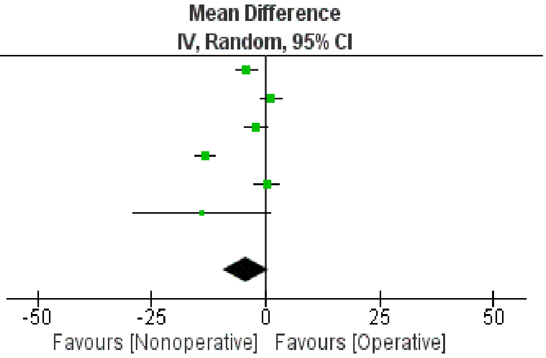

Figure 3: Forest plot of CMS shows no statistically significant variance amongst groups.

Disability Assessment of Shoulder and Hand (DASH) Score

In all, six studies reported on DASH score, with 414 individuals in the nonoperative group and 439 individuals in the operative group. Because we found significant variability, we conducted our analysis using a random-effects model (I^2 = 65%, P = 0.01). The combined MD and 95 percent Cis was 0.38 (-1.47 to 2.23). The combined result demonstrated no statistically significant variance among groups in terms of DASH score (Z = 0.41, P = 0.69) (Figure 4).

	Nonoperative			Operative				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Robinson 2013	6.1	9.7	92	3.4	7.1	86	19.4%	2.70 [0.21, 5.19]
Woltz 2017	3.2	7.4	64	4.5	7.6	80	19.5%	-1.30 [-3.76, 1.16]
Ahrens 2017	3.3	5.6	93	2.2	3.8	111	25.8%	1.10 [-0.24, 2.44]
Tamaoki 2017	3	9.4	47	3.3	10.4	51	12.7%	-0.30 [-4.22, 3.62]
Qvist 2018	2	3.8	64	3.7	7.6	60	21.3%	-1.70 [-3.84, 0.44]
Ban 2021	25.3	55.6	54	8.3	16.8	51	1.4%	17.00 [1.47, 32.53]
Total (95% CI)			**414**			**439**	**100.0%**	**0.38 [-1.47, 2.23]**

Heterogeneity: Tau² = 2.99; Chi² = 14.38, df = 5 (P = 0.01); I² = 65%
Test for overall effect: Z = 0.41 (P = 0.69)

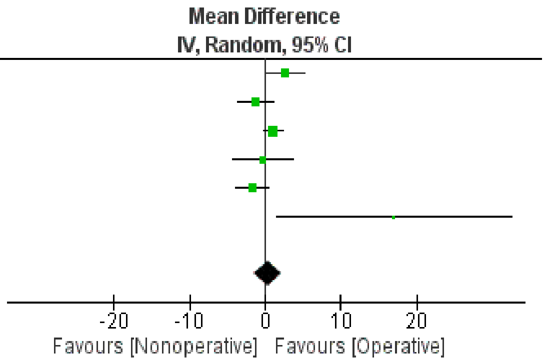

Figure 4: Forest plot of DASH reveals no statistically significant variance amongst groups.

Time to Return to Work

In all, three studies stated on time to go back to work, with 181 individuals in the nonoperative group and 171 individuals in the operative group. Because we found significant variability, we conducted our analysis using a random-effects model (I^2 = 71%, P = 0.03). The combined MD and 95% CIs was 13.05 (-3.99 to 30.09). The combined result demonstrated no statistically significant variance amongst groups in terms of time to go back to work (Z = 1.50, P = 0.13) (Figure 5).

	Nonoperative			Operative				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Robinson 2013	24.2	35.7	92	22	32.6	86	43.6%	2.20 [-7.83, 12.23]
Melean 2015	111	33	42	87	24	34	39.8%	24.00 [11.17, 36.83]
Tamaoki 2017	127	104	47	111.7	63	51	16.6%	15.30 [-19.09, 49.69]
Total (95% CI)			**181**			**171**	**100.0%**	**13.05 [-3.99, 30.09]**

Heterogeneity: Tau² = 147.07; Chi² = 6.95, df = 2 (P = 0.03); I² = 71%
Test for overall effect: Z = 1.50 (P = 0.13)

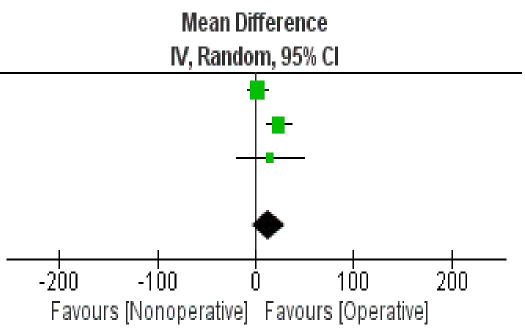

Figure 5: Forest plot of time to return to work shows no statistically significant variance among groups.

Meta-Analysis of Complications

Nonunion Rate: All studies reported on nonunion rate, with 552 cases in the nonoperative group and 572 cases in the operative group. The data showed no statistically significant distinctions among groups. As a result, the data were analyzed using a fixed-effect model (I^2 = 0%, P = 0.99). The combined OR and 95% CIs was 11.15 (5.44 to 22.85). The combined result recommended that the nonoperative group had significantly greater nonunion rates (Z = 6.58, P < 0.001) (Figure 6).

	Nonoperative		Operative			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Robinson 2013	16	92	1	86	11.9%	17.89 [2.32, 138.15]
Melean 2015	4	42	0	34	6.9%	8.06 [0.42, 155.27]
Woltz 2017	9	70	1	84	11.1%	12.25 [1.51, 99.23]
Ahrens 2017	13	110	1	130	11.3%	17.29 [2.22, 134.42]
Tamaoki 2017	7	47	0	51	5.7%	19.07 [1.06, 343.95]
Bhardwaj 2018	2	33	0	36	6.2%	5.79 [0.27, 125.25]
Qvist 2018	11	64	2	60	23.9%	6.02 [1.27, 28.41]
Woltz 2018	7	39	1	40	11.3%	8.53 [1.00, 73.01]
Ban 2021	10	55	1	51	11.8%	11.11 [1.37, 90.26]
Total (95% CI)		**552**		**572**	**100.0%**	**11.15 [5.44, 22.85]**
Total events	79		7			

Heterogeneity: Chi² = 1.41, df = 8 (P = 0.99); I² = 0%
Test for overall effect: Z = 6.58 (P < 0.00001)

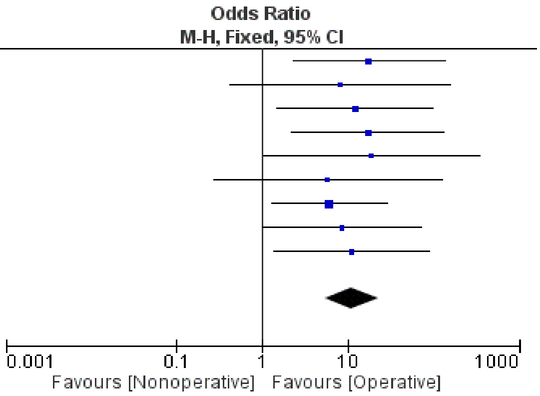

Figure 6: Forest plot of nonunion rate reveals a statistically significant variance in favor of operative group.

Malunion Rate

Four studies reported on malunion rate, with 252 cases in the nonoperative group and 260 cases in the operative group. The data showed no statistically significant distinctions among groups. As a result, the data were analyzed using a fixed-effect model (I^2 = 0%, P = 1.00). The combined OR and 95% CIs was 3.25 (0.76 to 12.85). The combined result demonstrated no statistically significant variance among groups in terms of malunion rates (Z = 1.160, P = 0.11). (Figure 7).

	Experimental		Control			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Robinson 2013	1	92	0	86	21.9%	2.84 [0.11, 70.56]
Woltz 2017	1	70	0	84	19.2%	3.65 [0.15, 90.95]
Bhardwaj 2018	3	33	1	36	37.4%	3.50 [0.35, 35.44]
Ban 2021	1	57	0	54	21.5%	2.89 [0.12, 72.58]
Total (95% CI)		**252**		**260**	**100.0%**	**3.25 [0.76, 13.85]**
Total events	6		1			

Heterogeneity: Chi² = 0.02, df = 3 (P = 1.00); I² = 0%
Test for overall effect: Z = 1.60 (P = 0.11)

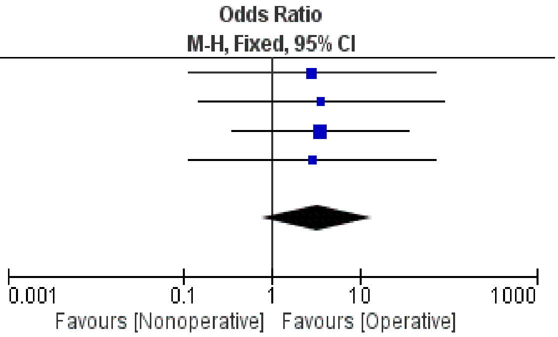

Figure 7: Forest plot of malunion rate shows no statistically significant variance among groups.

Secondary Surgery

Eight studies reported on rate of secondary surgery, with 558 individuals in the nonoperative group and 563 individuals in the operative group. The data showed no statistically significant distinctions among groups. As a result, the data were analyzed using a fixed-effect model (I^2 = 50%, P = 0.05). The combined OR and 95 percent CIs was 0.88 (0.64 to 1.21). The combined outcome demonstrated no statistically significant variance among groups in terms of secondary surgery (Z = 0.77, P = 0.44) (Figure 10). Reasons of secondary surgery are summarized in table 2.

	Nonoperative		Operative			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Robinson 2013	17	92	16	86	17.0%	0.99 [0.47, 2.11]
Melean 2015	4	42	4	34	5.0%	0.79 [0.18, 3.42]
Woltz 2017	12	70	23	84	21.8%	0.55 [0.25, 1.20]
Ahrens 2017	19	147	8	154	8.6%	2.71 [1.15, 6.40]
Tamaoki 2017	2	47	0	51	0.6%	5.66 [0.26, 120.99]
Qvist 2018	9	64	19	60	21.2%	0.35 [0.14, 0.86]
Woltz 2018	9	39	13	40	12.4%	0.62 [0.23, 1.69]
Ban 2021	15	57	14	54	13.3%	1.02 [0.44, 2.38]
Total (95% CI)		**558**		**563**	**100.0%**	**0.88 [0.64, 1.21]**
Total events	87		97			

Heterogeneity: Chi² = 14.12, df = 7 (P = 0.05); I² = 50%
Test for overall effect: Z = 0.77 (P = 0.44)

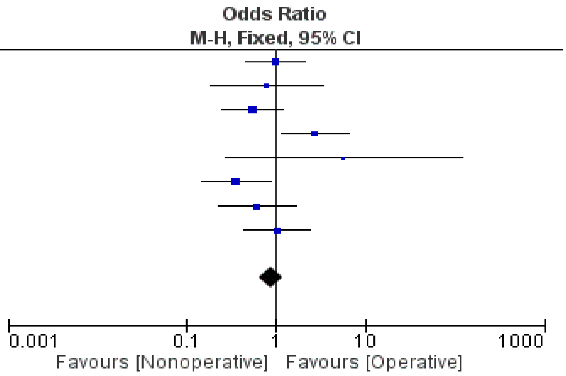

Figure 10: Forest plot of secondary surgery reveals no significant variance among groups.

Table 2: Reasons of secondary surgery in included studies.

First Author	Nonoperative	Operative
Robinson	13 nonunion, 3 bony prominences, 1 malunion	1 nonunion, 1 refracture, 1 implant failure, 1 impingement, 2 fracture, 10 plate removal
Melean	4 nonunion	4 plate removal
Woltz	9 nonunion, 1 malunion, 1 deficit, 1 removal	1 nonunion, 2 infection, 6 implant failure, 14 plate removal
Ahrens	12 fracture-related	1 implant failure, 5 plate removal, 1 fracture, 1 acromioclavicular disruption
Tamaoki	2 nonunion	None
Bhardwaj	NA	NA
Qvist	9 nonunion	2 nonunion, 1 implant failure, 16 plate removal
Woltz	7 nonunion, 1 metal failure, 1 plate removal	1 nonunion, 1 implant failure, 1 refracture, 9 plate removal, 1 other
Ban	8 nonunion, 6 bony prominences, 1 malunion	1 nonunion, 1 fracture, 12 plate removal

NA: data not available.

DISCUSSION

The primary goal of therapy for a clavicle fracture is bone union, followed by preservation of shoulder function and reduction of morbidity. While there is agreement that nonoperative therapy is appropriate for nondisplaced midshaft clavicle fractures, the best course of action for a displaced midshaft clavicle fracture is still up for debate.

This meta-analysis evaluated the functional results and complications of nonoperative versus surgical therapy in RCTs. Our primary result was that there was an association between nonoperative therapy and a greater risk of nonunion. Functional ratings, duration to return to work, malunion rates, and subsequent surgery rates were all about the same across the board, regardless of which therapy was chosen.

The present investigation found a statistically significant distinction in favor of the surgical group in the nonunion rate; the pooled estimate was 11.15 (95% CI [5.44 to 22.85]). Previous meta-analyses' conclusions were similar to ours. Nonunion rates for clavicle fractures treated surgically vs nonsurgically were statistically different (RR 0.12, 95% CI 0.05 to 0.29), leading the authors of that study, **Liu *et al*.** [(21)] to conclude that surgical treatment has the potential to dramatically lower the nonunion rate. Nonunion incidence showed significant variations favoring surgical over nonoperative therapy, as reported by **Wang *et al.*** (RR, 0.16; 95% CI, 0.09-0.30) [(22)]. There was inconsistency in the definition of nonunion across the involved research. It was characterized as lack of radiographic evidence of bone union at 4 months by **Ban *et al*.** [(13)], **Melean *et al*.** [(15)], **Qvist *et al*.** [(16)], 6 months by **Robinson et al.** [(17)]**, Tamaoki *et al*.** [(18)]**, and Woltz *et al*.** [(20)]**,** or nine months by **Ahrens *et al*.** [(12)]. Therefore, the nonunion data should be interpreted with caution.

Despite the statistically significant difference in nonunion rates, nonoperative and operative groups had similar rates of malunion with a combined OR of 3.25 (95% CI [0.76 to 12.85]). Similarly, previous authors reported that the risk of malunions was the same for nonoperative and operative therapy (OR 0.38, 95% CI, 0.12 to 1.19) [(23)]. On the contrary, **Qin *et al.*** found that ORIF's malunion rate was significantly less than conservative treatment's (RR 0.16, 95% CI, 0.08 to 0.35) [(24)]. The alteration in published results may be attributed to the lack of differentiation between radiographic and symptomatic malunion.

Consistent with the results of **Smeeing *et al*.** [(23)], our analysis displayed that nonoperative and operative treatment groups had comparable rates of secondary surgery with a pooled OR of 0.88 (95% CI, [0.64 to 1.21]). However, the reasons for secondary surgery were markedly different between the two groups, as demonstrated in table 2. Nonunion was the most frequent reason for secondary surgery in the nonoperative group. In the operative group, the most frequent causes of secondary surgery were scheduled plate removal due to symptomatic hardware. However, the operative group had more serious reasons for secondary surgery such as metal failure, and refracture.

We used the CMS and DASH scoring systems to compare nonoperative and operative groups in terms of functional outcomes. Our research showed that the significant difference in nonunion rates did not translate into difference in the functional results. Comparably, **Qin *et al.*** did not demonstrate any significant changes among the two treatment groups relating to the DASH score (MD -4.17, 95% CI, -9.35 to 1.01) [(24)]. In contrast, other authors have stated that both the CMS and DASH score favored operative treatment [(21, 23)].

LIMITATIONS

The main strength point of this meta-analysis was that it only involved RCTs. However, the study has a number of limitations, including small number of included articles, small sample size of most included studies, heterogeneity of plating systems, lack of consistency of the definitions of reported outcomes, and short follow-up durations.

CONCLUSION

Although conservative treatment and plating demonstrated different effects on nonunion rates of mid shaft clavicular fractures, no treatment modality was found to be superior in terms of functional outcomes, time to go back to work, and secondary surgery. More homogenous, longer follow-up durations, and high-quality RCTs with larger sample sizes are recommended.

DECLARATIONS

- **Consent for publication:** I attest that all authors have agreed to submit the work.
- **Availability of data and material:** Available
- **Competing interests:** None
- **Funding:** No fund
- **Conflicts of interest:** No conflicts of interest.

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