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Systematic Review

What Is the Best Evidence for Management of Displaced Midshaft Clavicle Fractures? A Systematic Review and Network Meta-analysis of 22 Randomized Controlled Trials

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Abstract

Background Displaced mid-third clavicle fractures are common, and their management remains unclear. Although several meta-analyses have compared specific operative techniques with nonoperative management, it is not possible to compare different operative constructs with one another using a standard meta-analysis. Conversely, a network meta-analysis allows comparisons among more than two treatment arms, using both direct and indirect comparisons between interventions across many trials. To our knowledge, no network meta-analysis has been performed to compare the multiple treatment options for displaced clavicle fractures.

Questions/purposes We performed a network meta-analysis of randomized, controlled trials (RCTs) to determine from among the approaches used to treat displaced midshaft clavicle fractures: (1) the intervention with the highest chance of union at 1 year, (2) the intervention with the lowest risk of revision surgery, and (3) the intervention with the highest functional outcome scores. Secondarily, we also (4) compared the surgical subtypes in the available RCTs on the same above endpoints.

Methods MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials were reviewed for relevant randomized controlled trials published up to July 25, 2018. Two hundred and eighty four papers were reviewed, with 22 meeting inclusion criteria of RCTs with appropriate randomization techniques, adult population, minimum of 1 year follow-up and including at least one operative treatment arm. In total, 1002 patients were treated with a plate construct, 378 with an intramedullary device, and 585 patients were managed nonoperatively. Treatment subtypes included locked intramedullary devices (56), unlocked intramedullary devices (322), anterior plating (89), anterosuperior plating (150), superior plating (449) or plating not otherwise specified (314). We performed a network meta-analysis to compare and rank the treatments for displaced clavicle fractures. We considered the following outcomes: union achievement, revision surgery risk and functional outcomes (DASH and Constant Scores). The minimal clinically important difference (MCID) was considered for both Constant and DASH scores to be at 8 points, representing the average of MCID scores reported for both DASH and Constant in the evidence, respectively.

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Each author certifies that his institution waived approval for the reporting of this investigation and that all investigations were conducted in conformity with ethical principles of research.
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Results Union achievement was lower in patients treated nonoperatively (88.9%), and higher in patients treated operatively (96.7%, relative risk [RR] 1.128 [95% CI 1.1 to 1.17]; p < 0.001), Number needed to treat (NNT) = 10). Union achievement increased with any plate construct (97.8%, RR 1.13 [95% CI 1.1 to 1.7]; p < 0.0001, NNT = 9) and with anterior or anterosuperior plates (99.3%, RR 1.14 [95% CI 1.1 to 1.8]; p < 0.0001, NNT = 8). Risk of reoperation, when considering planned removal of hardware, was similar across all treatment arms. Lastly, operative treatment outperformed nonoperative treatment with minor improvements in DASH and Constant scores, though not approaching the MCID. At the subtype level, anterosuperior plating ranked highest in DASH and Constant functional scores with mean differences reaching 10-point improvement for Constant scores (95% CI 4.4 to 2.5) and 7.6 point improvement for DASH (95% CI 5.2 to 20).

Conclusions We found that surgical treatment led to a greater likelihood of union at 1 year of follow-up among adult patients with displaced mid-third clavicle fractures. In aggregate, surgical treatment did not increase functional scores by amounts that patients were likely to consider clinically important. Use of specific subtypes of plating (anterior, anterosuperior) resulted in improvements in the Constant score that were slightly above the MCID but did not reach the MCID for the DASH score, suggesting that any outcomes-score benefits favoring surgery were likely to be imperceptible or small. In light of these findings, we believe patients can be informed that surgery for this injury can increase the likelihood of union incrementally (about 10 patients would need to undergo surgery to avoid one nonunion), but they should not expect better function than they would achieve without surgery; most patients can avoid surgery altogether with little absolute risk of nonunion. Patients who opt for surgery must be told that the decision should be weighed against complications and the possibility of undergoing a second procedure for hardware removal. Patients opting not to have surgery for acute midshaft clavicle fractures can be told that nonunion occurs in slightly more than 10% of patients, and that these can be more difficult to manage than acute fractures.

Level of Evidence Level I, therapeutic study.

Introduction

Clavicle fractures are relatively common, accounting for more than 4% of all fractures in adults [3]. These fractures occur most frequently in individuals younger than 50 years, particularly in young males [22, 28, 30, 32, 35]. Thus, the substantial impact of these injuries on the short- and long-term quality of life of young, active people is of great importance because of the societal implications of work absenteeism or the need for modified duties [15, 19]. Despite the prevalence of clavicle fractures, treatment strategies remain unclear, particularly in patients with displaced midshaft clavicle fractures [8, 21, 31, 33]. Surgical management entails the use of either a plate or an intramedullary device, both of which have several subtypes [37]. Some plate subtypes are precontoured and some vary by location (anterior, anterosuperior, or superior). Intramedullary devices may or may not be cortically locked.

Although several randomized controlled trials (RCTs) have been performed, a trial with study arms for multiple possible treatment options—allowing for direct comparisons of each—has not been performed. For data from a trial to be included in a meta-analysis, the treatment groups and outcome measures must be the same as those in all other included trials. Most meta-analyses to date have reported a limited number of comparisons and have thus excluded a considerable portion of published RCT data on clavicle fracture treatment [17, 18, 29]. Recent meta-analyses of treatments of midshaft clavicle fractures have failed to conclusively demonstrate whether operative treatment is preferred, and if so, what type of surgical intervention is best because these meta-analyses have not been able to compare all treatment options, nor use all data from all published RCTs [2]. For our study, we hope to discover whether operative treatment is preferred to nonoperative treatment and if so, in which patient and with what construct.

When compared with a standard meta-analysis, a network meta-analysis (NMA), has the advantage of comparing multiple treatment options with one another at one time, using direct and indirect treatment comparisons to arrive at a more precise estimate of treatment effects [10]. Network meta-analyses not only summarize the treatments that have been directly compared with one another, but also they compare two treatments that have not previously been studied in head-to-head RCTs, using network relationships of common treatment arms [45]. This allows for the inclusion of data from all published trials regardless of treatment, as long as the trials report the outcome of interest. Furthermore, the methodology of a network meta-analysis allows for relative ranking of the treatments for each outcome of interest. A standard meta-analysis can only compile evidence from direct comparisons and will not be able to offer a relative effect of, for example, superior plates compared with anterosuperior plates if no trial specifically used that comparison [2, 40, 48, 49, 52, 53]. In contrast, a network meta-analysis estimates the relative ranking of these treatments, as long as each was compared with a common comparator in another trial (for example, each separate plating technique compared with nonoperative management).

We therefore performed a network meta-analysis of randomized, controlled trials to determine from among the approaches used to treat displaced midshaft clavicle fractures: (1) the intervention with the higher chance for union, (2) the intervention with the lowest risk of revision surgery, and (3) the intervention with the highest functional outcome scores. Secondarily, we also (4) compared the surgical techniques evaluated in the available RCTs on those same endpoints.

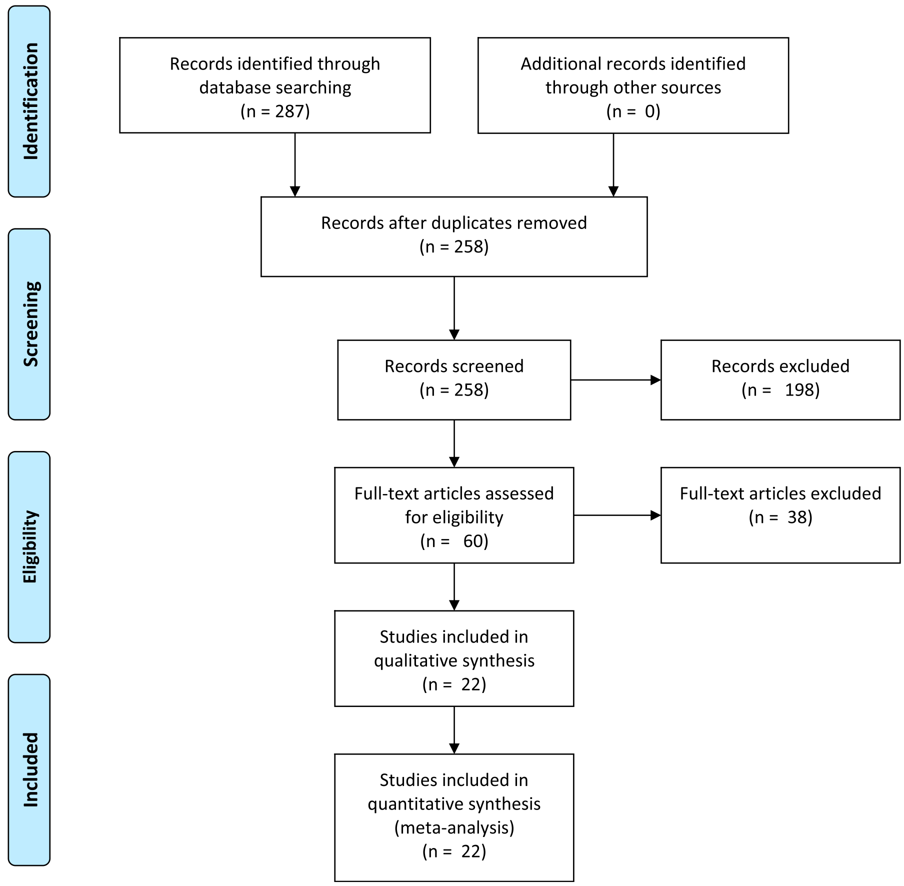

Fig. 1 This PRISMA flow diagram depicts outcomes of the primary study review and screening of studies.

Materials and Methods

Search Strategy and Criteria

This meta-analysis was conducted and reported in accordance with the Cochrane Handbook for Systematic Reviews of Interventions [12] and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses protocol [38]. This meta-analysis was prospectively registered in the PROSPERO registry (ID: CRD42018086023).

Search Strategy

We searched MEDLINE, PubMed, Embase, and Web of Science for RCTs examining the treatment of displaced midshaft clavicle fractures. The search was conducted on November 15, 2017 and was repeated on July 25, 2018. The inclusion and exclusion criteria were determined a priori, excluding trials without an operative treatment arm and those using quasi randomization techniques. Trials included were those that adhered to strict randomization principles, only recruited adult patients, and had full texts available in English (see Appendix, Supplemental Digital Content 1, http://links.lww.com/CORR/A230). Search terms were generated through consultation with a clinical epidemiologist and librarian (see Appendix, Supplemental Digital Content 2, http://links.lww.com/CORR/A231).

Trial Selection

Two reviewers (SE, DEA) independently screened all articles at the title, abstract, and full-text stages. Any discrepancies were resolved by automatic inclusion to avoid premature exclusion of relevant articles. Discrepancies at the full-text stage were resolved by consensus between the two reviewers. If a consensus could not be reached, a third author (HJ) who is a content expert was consulted. The level of agreement was calculated for each stage using a kappa (κ) statistic, and was interpreted according to McHugh's recommendations [24]. The initial search identified 284 potentially relevant citations. Twenty-two RCTs were eligible for inclusion (Fig. 1). The agreement between the two blinded reviewers was excellent (κ = 0.825 [95% CI 0.71 to 0.86]). All 22 studies were published between 2007 and 2017. Ten studies [1, 7, 20, 26, 34, 36, 41, 44, 47, 50] compared operative and nonoperative treatment, and 12 studies [4, 5, 6, 9, 11, 23, 25, 27, 39, 42, 46, 51] compared two different types of operative treatment. Sixteen trials [1, 4, 5, 7, 11, 23, 25, 26, 27, 36, 39, 42, 44, 46, 47, 50] included a treatment arm of plate fixation, and 12 trials [4, 5, 6, 9, 11, 20, 23, 27, 34, 41, 46, 51] included an arm of intramedullary device fixation (Fig. 2). Previous meta-analyses were excluded (see Appendix, Supplemental Digital Content 3, http://links.lww.com/CORR/A232). Anterosuperior plates are all those listed as anterosuperior or precontoured. The overall network geometry and the network geometry for each outcome appears are presented in a standard fashion (Fig. 3; see Appendix, Supplemental Digital Content 4, http://links.lww.com/CORR/A233).

Study Demographics

A total of 2139 patients were randomized across the 22 RCTs, and 1965 patients completed at least 1 year of follow-up. The mean length of follow-up was 14 months (± 4). The mean age of the combined patients was 37 years, and 81% of the patients were male. Treatment groups included nonoperative management (n = 585), plate construct (n = 1002) and intramedullary device (n = 378). Treatment subtypes included locked intramedullary devices (n = 56), unlocked intramedullary devices (n = 322), anterior plating (n = 89), anterosuperior plating (n = 150), superior plating (n = 449) or plating not otherwise specified (n = 314).

Data Extraction

Two reviewers (SE, DEA) individually extracted data in parallel from all included articles into a Microsoft Excel (Version 16.2, Redmond, WA, USA) spreadsheet that was designed a priori. Each reviewer's data were verified by the other reviewer using a spot-check method. Extracted data included study characteristics, country of origin, financial disclosures, RCT methodology, patient demographics, operative details, radiographic and clinical outcomes, and complication and revision risk.

Risk of Bias of Individual Studies

Two reviewers (DA, SE) assessed the quality of the included studies using the Cochrane Collaboration's Tool for Assessing Risk of Bias [13]. Each of the key domains of bias and their respective components were rated as "low," "high," or "unclear." Any disagreements were resolved by consulting a third, more senior author (HJ). The overall quality of the studies was deemed to be good in a cumulative assessment of bias (Fig. 4). Eighteen of 22 studies had low risk of bias in at least four major categories of bias (Fig. 5). All included trials had at least two arms.

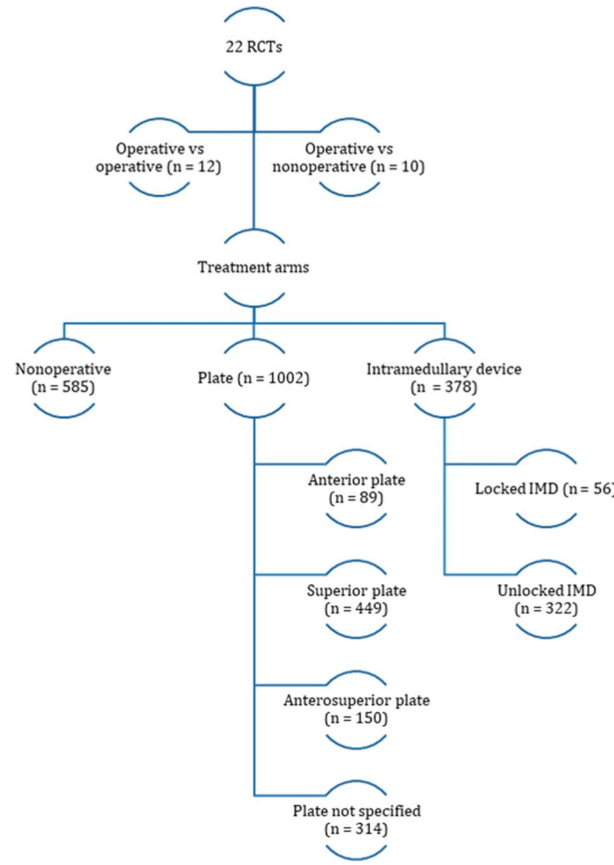

Fig. 2 Description of abstracted data from trials included in network meta-analysis.

Quality of Evidence

The overall quality of evidence was assessed using the Grading of Recommendations Assessment, Development and Evaluation approach. A checklist of items to report when reviewing a network meta-analysis was also completed (see Appendix, Supplemental Digital Content 5, http://links.lww.com/CORR/A234).

Statistical Analysis

To assess direct and indirect evidence of all clavicle fracture treatment strategies, we conducted a network

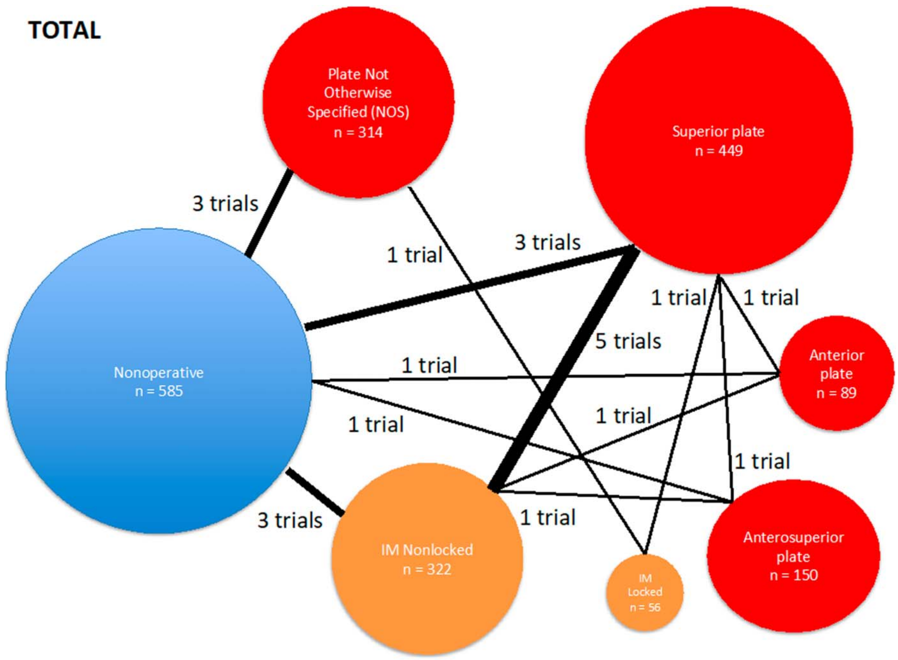

Fig. 3 This network diagram shows all relationships among the 22 clinical trials and their primary interventions; IM = intramedullary.

meta-analysis to compare treatments for four outcomes: union, revision surgery, and Constant and DASH scores at 1-year follow-up. Treatments were compared for each outcome at three levels of precision using a nested analysis strategy: operative versus nonoperative, plates versus intramedullary devices versus nonoperative, and implant subtypes versus nonoperative.

We used a Bayesian framework and a random-effects model because of the heterogeneity of the main endpoints, in particular the Constant, DASH and revision risk (I2 of 89%, 92%, and 79%) respectively.

We created a graphical framework of all trials (edges) comparing different interventions (nodes) for each outcome. The results of the network meta-analysis are reported as odds ratios (ORs) or mean differences for each outcome. We created ranking diagrams and forest plots for each outcome. Furthermore, surface under the cumulative ranking curve values were reported for each study. The surface under the cumulative ranking curve score represents the likelihood that a given treatment will rank first in a specific category; a score closer to 1 represents a greater chance that that treatment will be the best. Global inconsistency across the network model was described using the I^2 value, which represents the percentage of variation across studies that is owing to study heterogeneity [10, 14]. Inconsistency between direct and indirect evidence was assessed using the node-splitting method. All statistical analyses were performed using RevMan 5.3 (Cochrane, London, UK) and R 3.4.2.

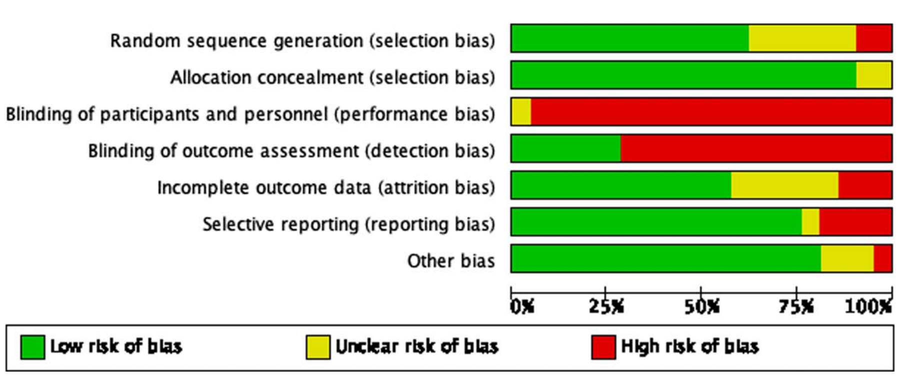

Fig. 4 This figure shows the cumulative assessment of bias for the included studies.

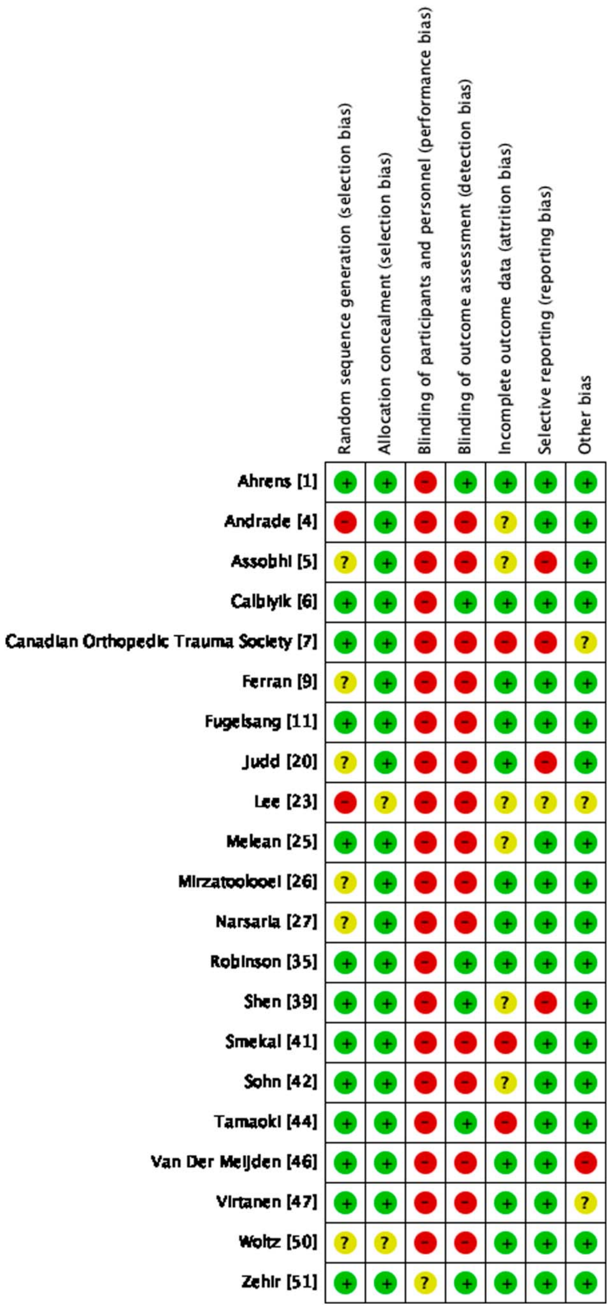

Fig. 5 A summary of the risk of bias for all included studies is shown.

Results

Outcomes

Nonunion: Surgery Versus Nonoperative Management

Operative treatment conferred a higher chance of union when compared directly with nonoperative treatment in the network meta-analysis. Union achievement was 88.9% in patients treated nonoperatively and 96.7% among those patients treated operatively (relative risk [RR] 1.128 [95% 1.1 to 1.17]; $p < 0.001$). The network meta-analysis comparing plate fixation with intramedullary devices and nonoperative management ranked plate fixation, which had yielded a 97.8% chance of union (RR 1.13 [95% CI 1.1 to 1.7]; $p < 0.0001$, NNT = 9 (Table 1).

Reoperation: Surgery Versus Nonoperative Management

Revision surgery includes all subsequent operations, including hardware removal planned before the initial surgery. The network meta-analysis that compared operative and nonoperative treatment (nine RCTs) found a relatively equal use of revision surgery between the groups, with an odds ratio of 0.85 (95% CI 0.31 to 2.5) favoring operative management. However, when plate fixation was compared with intramedullary devices and nonoperative management, plate fixation was the top-ranked treatment for avoiding revision surgery, while intramedullary devices ranked lower (Table 2).

Outcome scores: Surgery Versus Nonoperative Management

Two functional scores were reported in most studies: the DASH score (12 studies) and the Constant score (14 studies).

Constant Score

Operative management resulted in a mean difference of a 4.5-point improvement in the Constant score at 1-year follow-up compared with nonoperative management (95% CI 0.62 to 8.3) (six RCTs). These scores failed to reach historical thresholds for minimal clinically important differences (MCID) (minimum of 8) for constant scores (Table 3) [16, 43]. Management with plates ranked higher than intramedullary devices and showed a similar improvement in the Constant score of 4.5 points compared with nonoperative management (95% CI 0.081 to 8.9) (Table 3).

DASH Scores at 1 Year

The network meta-analysis revealed that patients with operatively managed fractures had a mean difference of a 3.8-point improvement in DASH scores at minimum of 1-year follow-up compared with those who did not have operative treatment (95% CI 0.43 to 8.1). This, like

Table 1. Summary of findings for the outcome of nonunion

Total studies: 17 RCTs	Top ranking intervention	Odds ratio, 95% CI (compared with nonoperative)	I^2	SUCRA	Quality of the evidence (GRADE)	Interpretation of findings
Subtype	Anterior plate	24 (22.53 to 25.57)	0%	Anterior plating: 0.980 Nonoperative: 0.025	High (randomized controlled trials without significant limitations or bias)	Anterior plating definitely superior to nonoperative
Treatment arm	Plate	6.89 (6.76 to 7.02)	25%	Plate: 0.948		Plate of all type superior to Non op
Operative vs nonoperative	Operative	4.1 (4.03 to 4.14)	32%			Operative treatment of all types superior to nonoperative

RCTs = randomized controlled trials; SUCRA = surface under the cumulative ranking; GRADE = Grading of Recommendations Assessment, Development and Evaluation.

constant scores, failed to meet the established 8-point MCID. At the treatment level (13 RCTs), fixation with intramedullary devices ranked first, with a mean difference of a 4.7-point improvement (95% CI -0.088 to 9.5). Although plate fixation ranked second, with a mean difference of 3.7, the 95% CI was narrower (0.31 to 7.0) (Table 4)

Comparison of Surgical Techniques

Anterior plating yielded the highest chance of union, producing a 98.0% chance of ranking first in our network meta-analysis model. The top four treatments for reducing nonunion were all subtypes of plate fixation. Union achievement was at 99.3% with either anterior or antero-superior plates (RR 1.14 [95% CI 1.1 to 1.8]; $p < 0.0001$, NNT = 8).

When considering revision surgery in the subtype comparison (22 RCTs), anterior plate fixation was associated with the lowest risk of revision surgery, closely followed by anterosuperior plates and superior plates. Unlocked intramedullary devices and unspecified plate fixation ranked lower than nonoperative management (Table 2). No subtype had a statistically greater chance at avoiding revision surgery, and heterogeneity among study subtypes was higher.

Table 2. Summary of findings for the outcome of revision surgery of all types, including routine hardware removal

Total studies: 21 RCTs	Top ranking intervention	Odds ratio, 95% CI (compared to nonoperative)	I^2	SUCRA	Quality of the evidence (GRADE)	Interpretation of findings
Subtype	Anterior plate	0.02 (< 0.001 to 1.3)	79%	Anterior plate: 0.663 Anterosuperior plate: 0.644 Nonoperative: 0.434	High (randomized controlled trials without significant limitations or bias)	Anterior plate definitely superior to nonoperative
Treatment arm	Plate	0.76 (0.075 to 9.2)	66%	Plate: 0.698		Plate of all type superior to Non op
Operative vs nonoperative	Operative	0.85 (0.31 to 2.5)	69%			Operative treatment of all type probably superior to nonoperative

RCTs = randomized controlled trials; SUCRA = surface under the cumulative ranking; GRADE = Grading of Recommendations Assessment, Development and Evaluation.

Table 3. Summary of findings for the outcome of Constant score at 1-year follow-up

Total studies: 16 RCTs	Top ranking intervention	Mean difference, 95% CI (compared with nonoperative)	I^2	SUCRA	Quality of the evidence (GRADE)	Interpretation of findings
Subtype	Anterosuperior plate	10 (4.4 to 25)	89%	Anterosuperior plate: 0.73 Superior plate: 0.611 Nonoperative: 0.025	High (randomized controlled trials without significant limitations or bias)	Anterosuperior plate definitely superior to nonoperative
Treatment arm	Plate	4.5 (0.081 to 8.9)	88%	Plate: 0.913		Plate of all type superior to nonoperative
Operative vs nonoperative	Operative	4.5 (0.62 to 8.3)	87%			Operative treatment of all type probably superior to nonoperative

RCTs = randomized controlled trials; SUCRA = surface under the cumulative ranking; GRADE = Grading of Recommendations Assessment, Development and Evaluation.

Among operative subtypes, anterosuperior plates ranked first for Constant scores with a mean difference of 10 (-4.4 to 25). This surpassed the established thresholds for MCID of Constant scores at 8. Among subtypes, anterosuperior plates were ranked the highest for DASH scores, followed by locked intramedullary devices, superior plates, and unlocked intramedullary devices. Again, at the subtype level, mean difference was 7.6-point improvement when using an anterosuperior plate, below the established threshold for MCID in DASH scores (8 points).

Discussion

The management of displaced midshaft clavicle fractures remains challenging. Decisions to treat fractures operatively or nonoperatively and which operative technique to use have remained difficult because it is not feasible to compare all treatment options in a multi-arm prospective study, nor a standard meta-analysis. Therefore, our research purpose was to use a network meta-analysis to pool all RCT data and summarize findings using both direct and

Table 4. Summary of findings for the outcome of DASH score at 1-year follow-up

Total studies: 13 RCTs	Top ranking intervention	Mean difference, 95% CI (compared with nonoperative)	I^2	SUCRA	Quality of the evidence (GRADE)	Interpretation of findings
Subtype	Anterosuperior plate	7.6 (5.2 to 20)	92%	Anterosuperior plate: 0.728 Intramedullary locked:0.694 Nonoperative: 0.14	High (randomized controlled trials without significant limitations or bias)	Anterosuperior plate definitely superior to nonoperative
Treatment arm	Locked intramedullary device	4.7 (0.088 to 9.5)	94%	Intramedullary device: 0.848		Intramedulllary device of all types superior to nonoperative
Operative vs nonoperative	Operative	3.8 (0.43 to 8.1)	95%			Operative treatment of all types superior to nonoperative

RCTs = randomized controlled trials; SUCRA = surface under the cumulative ranking; GRADE = Grading of Recommendations Assessment, Development and Evaluation.

indirect comparisons. As a network meta-analysis comparing all treatments for displaced midshaft clavicle fractures, to our knowledge, this study represents the largest pool of RCT data for patient functional outcomes, risk of revision surgery, and chance of union.

In considering the limitations of this study, a statistical method is only robust if used and interpreted correctly, and network meta-analyses have known limitations that should be considered when evaluating the results. Although a network meta-analysis provides a ranking of treatments, no information is conferred from the rankings on the relative magnitude of the difference between first and second place and between second and third place. Furthermore, and most importantly, was that the difference found between treatment arms was not able to reach minimal clinically important difference for both Constant and DASH scores, except at the subtype level and only in Constant scores. This substantially weakens the potential impact of our findings: operative treatments will not always yield meaningful improvement in functional outcomes compared with nonoperative treatments. Furthermore, with poor data on complications and demographics provided by the studies collected, we cannot say with confidence which patients are at highest risk for common complications, including infection and nonunion. These demographic risk factors may determine which patients should receive an operation; a population-level study focused on clavicle fractures, revisions, and nonunions should be the focus of future research.

Based on the pooling of current available evidence, we addressed the following questions: chance of union, risk of revision surgery, functional outcomes at 1 year, and choice of surgical construct.

When comparing all operative and nonoperative treatments, operative treatments offer a higher chance of union, with a high level of confidence, and low level of heterogeneity among the studies. When considering revision surgery of all causes, including routine hardware removal, operative treatment ranked higher than nonoperative treatment, but this finding was neither significant nor of large magnitude. Overall, risk of revision surgery was similar across both groups of treatment interventions.

When assessing functional scores, operative interventions ranked higher than nonoperative treatments in improving constant and DASH scores at 1 year. These differences did not meet historical thresholds for the MCID. As such, operative treatment is unlikely to yield meaningful differences in functional scores at 1 year when compared with nonoperative treatment.

Lastly, when assessing interventions by implant type, anterosuperior plating constructs offered the higher chance of union while also conferring the highest DASH and Constant scores. Anterosuperior plating surpassed thresholds for MCID when assessing Constant score, but not DASH. This may have only occurred at the treatment level as intramedullary devices and anterior plating generally scored lower than plates among functional scores. When isolating by construct type, these differences became apparent—something only possible through a network meta-analysis. However, this difference still is of questionable clinical importance to patients given that only one functional score surpassed the MCID.

The results of this network meta-analysis of RCTs represent the most current and best available evidence on the treatment of midshaft clavicle fractures, with high confidence. Surgical treatments yield a greater chance of union at 1-year follow-up among adult patients with displaced mid-third clavicle fractures, with approximately 10 patients needed to be treated to avoid one nonunion. Conversely, surgical treatment did not increase functional scores by amounts that patients were likely to consider clinically important. Only in the treatment subtype assessment did anterior and anterosuperior plates yield functional scores marginally greater than the MCID for Constant scores, but not DASH, suggesting functional score differences favoring surgery were likely to be small and of questionable value to patients.

Considering these findings, we believe patients can be informed that surgery for this injury can increase the likelihood of union incrementally, but they should not assume better function after surgery than they would achieve without surgery. Furthermore, most patients can avoid surgery altogether with little absolute risk of a nonunion, though this issue can be more difficult to manage than an acute fracture. Patients who opt for surgery need to be told that the decision should be weighed against complications and possibility of undergoing a second procedure for hardware removal.

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