

Comparative effectiveness of treatment options for displaced midshaft clavicle fractures

A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS

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Aims

The aims of this network meta-analysis (NMA) were to examine nonunion rates and functional outcomes following various operative and nonoperative treatments for displaced midshaft clavicle fractures.

Methods

Initial search strategy incorporated MEDLINE, PubMed, Embase, and the Cochrane Library for relevant randomized controlled trials (RCTs). Four treatment arms were created: nonoperative (NO); intramedullary nailing (IMN); reconstruction plating (RP); and compression/pre-contoured plating (CP). A Bayesian NMA was conducted to compare all treatment options for outcomes of nonunion, malunion, and function using the Disabilities of the Arm Shoulder and Hand (DASH) and Constant-Murley Shoulder Outcome scores.

Results

In all, 19 RCTs consisting of 1,783 clavicle fractures were included in the NMA. All surgical options demonstrated a significantly lower odds ratio (OR) of nonunion in comparison to nonoperative management: CP versus NO (OR 0.08; 95% confidence interval (CI) 0.04 to 0.17); IMN versus NO (OR 0.07; 95% CI 0.02 to 0.19); RP versus NO (OR 0.07; 95% CI: 0.01 to 0.24). Compression plating was the only treatment to demonstrate significantly lower DASH scores relative to NO at six weeks (mean difference -10.97; 95% CI -20.69 to 1.47).

Conclusion

Surgical fixation demonstrated a lower risk of nonunion compared to nonoperative management. Compression plating resulted in significantly less disability early after surgery compared to nonoperative management. These results demonstrate possible early improved functional outcomes with compression plating compared to nonoperative treatment. Surgical fixation of mid-shaft clavicle fractures with compression plating may result in quicker return to activity by rendering patients less disabled early after surgery.

Cite this article: *Bone Jt Open* 2021;2-8:646–654.

Keywords: Midshaft clavicle fractures, Network meta-analysis, Non-operative, Compression plate, Reconstruction plate, Intramedullary nail

Introduction

Following recent trends towards more aggressive fixation, multiple randomized controlled trials (RCTs) have compared rates of union, functional outcomes, and complication rates following select operative and nonoperative management of displaced mid-shaft clavicle fractures.¹⁻⁵ While previous studies have shown improved union rates with surgical fixation, the impact on functional outcomes

is less clear. The inclusion of various plate types into an overarching “surgical fixation group” may explain why differences in functional outcomes have not been seen.

The aim of this study was to perform a comprehensive network meta-analysis (NMA) examining union rates and functional outcomes following nonoperative treatment (NO), intramedullary nailing (IMN), and plate osteosynthesis of clavicle fractures.

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doi: 10.1302/2633-1462.28.BJO-2021-0112.R1

Bone Jt Open 2021;2-8:646–654.

Geometry of the Network: Nonunion

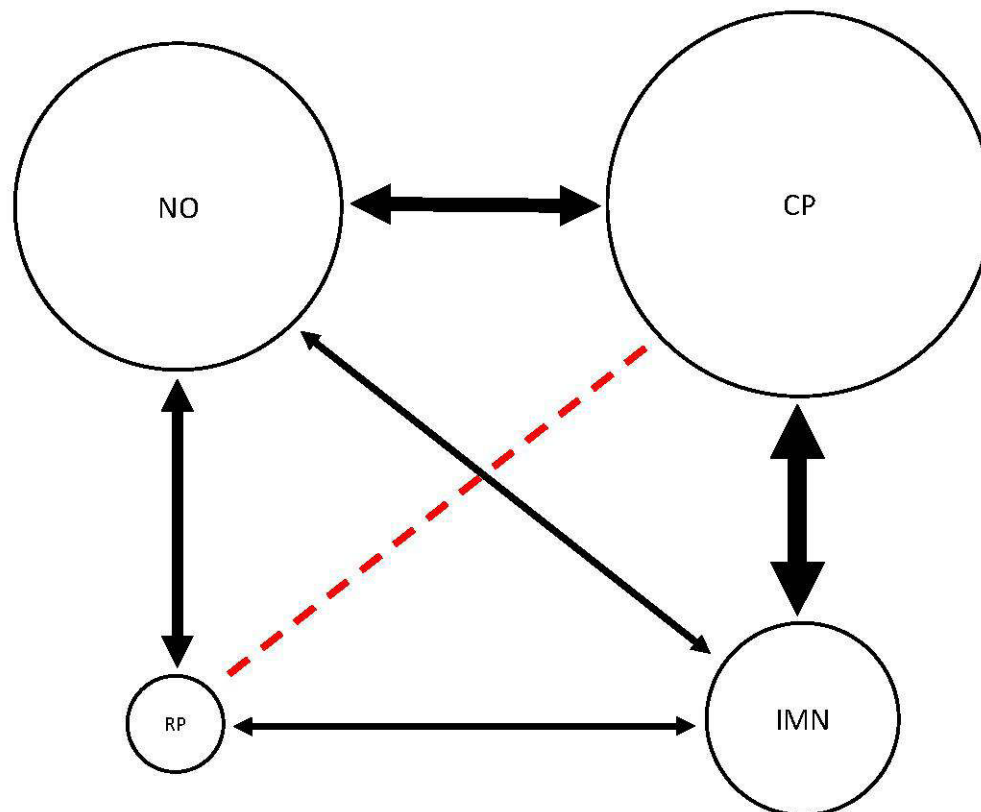


Fig. 1

Diagram demonstrating the geometry of the network for nonunions. Solid arrows represent direct estimates between treatment methods. Dashed line represents indirect estimates made between compression plating and reconstruction plating. CP, compression plate; IMN, intramedullary nail; NO, nonoperative management; RP, reconstruction plate.

Furthermore, we sought to determine if outcomes differed between compression/precontoured clavicular plates (CP) and reconstruction plates (RP). To our knowledge, there is only one other NMA comparing operative fixation of mid-shaft clavicle fractures with nonoperative management.⁶ Axelrod et al⁶ investigated rates of union, risk for reoperation, and functional outcomes after clavicle fracture fixation. Their comparison of surgical subtypes investigated differences between locked intramedullary devices, unlocked intramedullary devices, anterior plating, anterosuperior plating, and superior plating. Despite focusing on plate position, they combined all types of plates (compression and reconstruction).

Our study is the first to specifically compare compression plating with reconstruction plating and determine if rates of union and functional outcomes differ between the two. Moreover, Axelrod et al⁶ only assessed functional outcomes at the one-year mark, whereas we sought to analyze functional outcomes at both the six-week and one-year time points. In this way, we were able to investigate early functional outcomes, which are a key consideration when deciding a treatment course as it may impact

patients' ability to return to work sooner, as well as resuming independent activities of daily life (ADLs) and recreational activities.

Methods

In detailing our methods and outcomes, we followed the PRISMA guidelines⁷ for systematic reviews incorporating network meta-analysis reporting.

Search methods for identification of studies. With the assistance of a university librarian (NB), a systematic search strategy incorporating MEDLINE, PubMed, Embase, and the Cochrane Library computerized literature databases was developed to find relevant RCTs from inception to 1 January 2020. Search terms included "clavicle/injury", "orthopaedic fixation device", and "treatment outcomes". Two independent reviewers (JM, SM) assessed database search results by title and abstract. All abstracts were reviewed for duplicated articles. If an abstract was found to be relevant to the study, the potential article was reviewed in full to determine eligibility. The bibliographies and citations of relevant articles were screened to ensure no articles

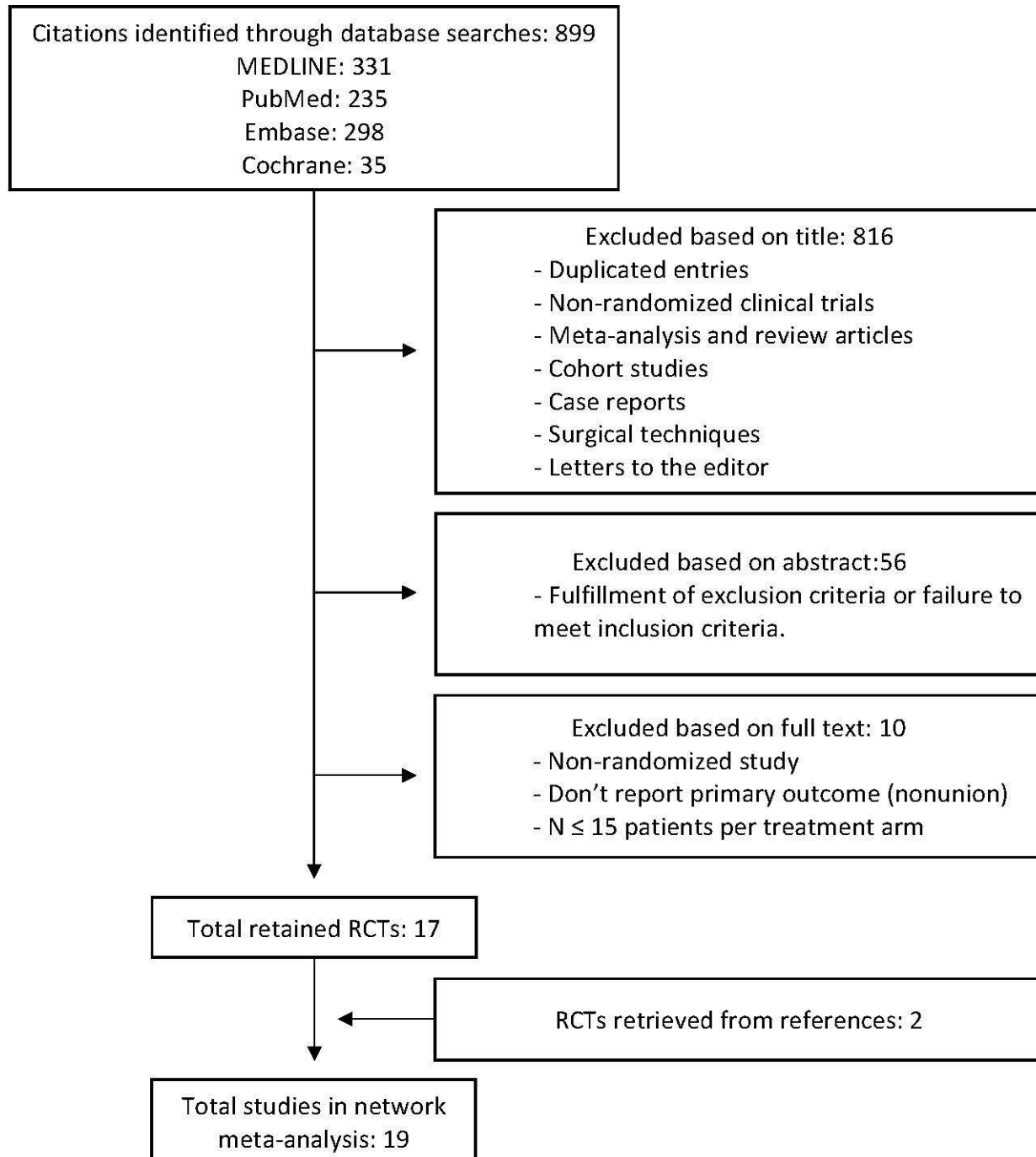


Fig. 2

Flowchart representing article selection for systematic review.

were missed. Any discrepancies between independent reviewers were resolved by discussion as a team with the senior authors (MM, ES, ND) until agreement was reached.

Criteria for inclusion. Studies meeting the following inclusion and exclusion criteria were included for final analysis. Inclusion criteria were: RCTs comparing four treatment strategies (nonoperative, intramedullary nail

fixation, fixation with reconstruction plates; or fixation with compression/pre-contoured plating) for acute, completely displaced, mid-shaft clavicle fractures in adult patients (age ≥ 18 years).

Exclusion criteria were: lack of reporting of nonunions; studies with less than 15 patients per treatment arm; randomization based on surgeons' shifts; studies comparing two similar types of treatment (e.g.

Table I. Study characteristics.

Study	Treatment arm (no. of participants)	Mean age, yrs (% of males)	Treatment arm (no. of participants)	Mean age, yrs (% of males)	Outcomes reported
Mirzatoolei 2011 ¹³	Reconstruction plate (6)	36 (23)	Nonoperative (24)	35.3 (14)	Nonunion, malunion, reoperation, DASH one year, Constant one year
Robinson 2013 ¹⁴	Compression plate (86)	32.3 (87)	Nonoperative (92)	32.5 (87)	Nonunion, reoperation, DASH one year, Constant one year
Virtanen 2012 ¹⁵	Reconstruction plate (26)	41 (85)	Nonoperative (25)	33 (87)	Nonunion, malunion, DASH one year, Constant one year
Tamaoki 2017 ¹⁶	Reconstruction plate (51)	30.5 (90)	Nonoperative (47)	34.6 (81)	Nonunion, reoperation, DASH six weeks and one year
Judd 2009 ²⁵	IMN (29)	28 (93)	Nonoperative (28)	25 (89)	Nonunion, reoperation
Smekal 2009 ⁵	IMN (30)	35.5 (86)	Nonoperative (30)	39.8 (86)	Nonunion, malunion, reoperation
Ferran 2010 ¹⁷	Compression plate (15)	35.4 (13)	IMN (17)	23.8 (82)	Nonunion, reoperation, Constant one year
Assobhi 2011 ¹⁸	Reconstruction plate (19)	32.6 (89)	IMN (19)	30.3 (84)	Nonunion, Constant six weeks and one year
COTS 2007 ²	Compression plate (67)	33.5 (85)	Nonoperative (49)	33.5 (69)	Nonunion, malunion, DASH six weeks and one year, Constant six weeks and one year
Narsaria 2014 ¹⁹	Compression plate (32)	40.2 (81)	IMN (33)	38.9 (72)	Nonunion, reoperation, Constant six weeks
Saha 2014 ²⁰	Compression plate (37)	33.03 (81)	IMN (34)	33.32 (88)	Nonunion, Reoperation, Constant six weeks and one year
Meijden 2015 ²¹	Compression plate (55)	38.4 (91)	IMN (62)	39.6 (97)	Nonunion, malunion, reoperation, DASH six weeks and one year, Constant six weeks and one year
Silva 2015 ²²	Reconstruction plate (29)	31.2 (85)	IMN (25)	28.3 (73)	Nonunion, reoperation, DASH one year, Constant one year
Qvist 2018 ⁴	Compression plate (64)	40 (85)	Nonoperative (60)	39 (77)	Nonunion, reoperation
Fuglesang 2017 ²³	Compression plate (63)	34.6 (86)	IMN (60)	36.4 (85)	Nonunion, reoperation, DASH six weeks and one year, Constant six weeks and one year
Ahrens 2017 ¹	Compression plate (131)	36.1 (86)	Nonoperative (123)	36.4 (88)	Nonunion, reoperation
Bhardwaj 2018 ²⁴	Compression plate (36)	32.4 (22)	Nonoperative (33)	31.7 (40)	Nonunion, malunion
King 2013 ³	Compression plate (35)	35 (54)	IMN (37)	29 (74)	Nonunion, reoperation, DASH six weeks and one year, Constant six weeks and one year
Woltz 2017 ¹²	Compression plate (84)	38.3 (93)	Nonoperative (70)	37.2 (89)	Nonunion, malunion, reoperation, DASH six weeks and one year, Constant six weeks and one year

Constant, Constant-Murley Shoulder Outcome; DASH, Disabilities of the Arm, Shoulder and Hand; IMN, intramedullary nail.

Table II. Nonunions and malunions per treatment arm.

Treatment arm	Nonunions, n (%)	Malunions, n (%)
NO	82 (14)	36 (16)
CP	9 (1.3)	1 (0.4)
RP	2 (1.2)	4 (5.6)
IMN	4 (1.2)	0 (0)

CP, compression plate; IMN, intramedullary nail; NO, nonoperative management; RP, reconstruction plate.

nonoperative treatment comparing two different types of slings); and studies published in languages other than English. In order to group the different fixation devices appropriately, studies that used a variety of fixation methods (e.g. combination of reconstruction and compression plates) were excluded, unless over 70% were treated with the same type of fixation device. Potential articles had to define “nonunion” as the lack of

radiological fracture healing by at least six months. Moreover, “symptomatic malunion” was defined as union of a fracture in a shortened, angulated, or displaced position with associated clinical sequelae.

Data synthesis. Two independent authors (JM, PS) extracted data from included studies. Standardized extraction tools with predetermined fields were used and data was compared between reviewers. Consensus was obtained from a third author (ND) when data collected by the first two independent authors did not coincide. When data was missing or clarifications were required, corresponding authors were contacted via email.

Studies were then grouped into four treatment arms: NO; open reduction and internal fixation (ORIF) with IMN; ORIF with CP; and ORIF with RP.

Primary and secondary outcomes. The primary outcome for this NMA was the rate of nonunion. Secondary

Table III. Nonunions for surgical modalities and nonoperative management.

Treatment arm	CP, odds ratio (95% CI)	IMN, odds ratio (95% CI)	RP, odds ratio (95% CI)	Nonoperative, odds ratio (95% CI)
CP	N/A	1.13 (0.37 to 4.54)	1.18 (0.28 to 8.92)	0.08 (0.04 to 0.17)*
IMN	0.88 (0.22 to 2.70)	N/A	1.03 (0.19 to 7.69)	0.07 (0.02 to 0.19)*
RP	0.84 (0.11 to 3.57)	0.97 (0.13 to 5.22)	N/A	0.07 (0.01 to 0.24)*
Nonoperative	12.5 (5.88 to 25.0)*	14.2 (5.26 to 50)*	14.2 (4.17 to 100)*	N/A

* $p < 0.05$. Each cell gives the effect of the row-defining intervention relative to the column-defining intervention.

CI, confidence interval; CP, compression plate; IMN, intramedullary nail; N/A, not applicable; RP, reconstruction plate.

outcomes included symptomatic malunions and functional outcomes at six weeks and one-year postoperatively. The specific functional outcomes analyzed were the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH), and the Constant-Murley Shoulder Outcome questionnaire (Constant).^{8,9}

Geometry of the network. Network geometry was described using network plot diagrams for each outcome. The network node size was weighted by the number of patients that received the corresponding treatment, while the lines connecting each node were weighted by the number of studies in the comparison (Figure 1).

Assessment of risk of bias. The Cochrane risk of bias assessment tool was applied to each study that met inclusion criteria.¹⁰ Since the primary outcome of this study was nonunion, this outcome was used to assess for bias in blinding of outcome assessment. Two reviewers (JM, PS) independently assessed each article for risk of bias. A third author (ND) was used to solve any discrepancies.

Statistical analysis. A Bayesian NMA was conducted using non-informative priors. The Markov Chain Monte Carlo simulation used 100,000 iterations with a burn-in period of 20,000 iterations. The Gelman Rubin statistic was used to assess convergence of the model. Inconsistency was assessed using the node splitting method. Functional outcomes were summarized as mean differences (MDs) and confidence intervals (CIs). Dichotomous variables (nonunion) were summarized as odds ratios (OR) and CIs. Results were considered statistically significant if $p < 0.05$. All analyses were conducted in R (V3.6.2) using geMTC (V0.8 to 2; Hamilton, Canada).¹¹

Sensitivity analysis. There were two studies^{2,12} in which the plates used in the operative arm were not uniform; however, the majority (at least 70%) consisted of the same type of plate. The raw data for these two studies was requested and used when available; however, when not available, the data was allocated to the treatment arm in which the majority of plates were used. Sensitivity analysis was conducted on RCTs in which the type of plate fixation used was not uniform, to determine the effect on union and functional outcomes.

Results

Article selection and study design. A systematic search yielded 899 potentially eligible articles (331 from MEDLINE, 235 from PubMed, 298 from Embase, and 35 from the Cochrane computerized literature database). Figure 2 represents the selection process for the 19 RCTs included in this NMA.^{1-5,12-25}

Study characteristics. A total of 19 RCTs consisting of 1,783 clavicle fractures were included in this NMA. Overall, 581 fractures were managed nonoperatively (sling or figure 8 brace), 346 fractures received IMN, 170 fractures received RP, and 686 fractures received CP. Table I demonstrates the characteristics of each RCT.

Network meta-analysis model. There was no inconsistency demonstrated by the node splitting analysis, as all p -values were > 0.05 . The Gelman Rubin assessment of convergence demonstrated that the model adequately converged. Figure 1 demonstrates the geometry of the network.

Union outcomes. Table II demonstrates the nonunions and symptomatic malunions that resulted from each treatment modality. All three surgical options demonstrated significantly lower odds of nonunion in comparison to nonoperative management (Table III). There were no differences in the nonunion rates between the treatment arms. Unfortunately, due to under-reported symptomatic malunion, there was not enough data available to make direct or indirect comparisons between our treatment arms.

Functional outcomes: surgery versus nonoperative treatment. Compression plating was the only surgical treatment to demonstrate less disability relative to nonoperative management at six weeks; the mean difference (MD) between CP and NO for the DASH was -10.97 (95% CI -20.69 to -1.47). This difference is above the ten-point minimal important clinical difference (MCID) established for DASH scores.²⁶ In addition, compression plating showed trends toward better early and late functional outcomes compared to nonoperative treatment: Constant scores at six weeks (MD 6.02; 95% CI -5.49 to 17.76) and one year (MD 4.73; 95% CI -0.33 to 9.96). At one year, IMN showed trends toward better functional outcomes compared to nonoperative treatment: Constant score (MD 4.51; 95% CI -0.17 to 9.75). These differences were below

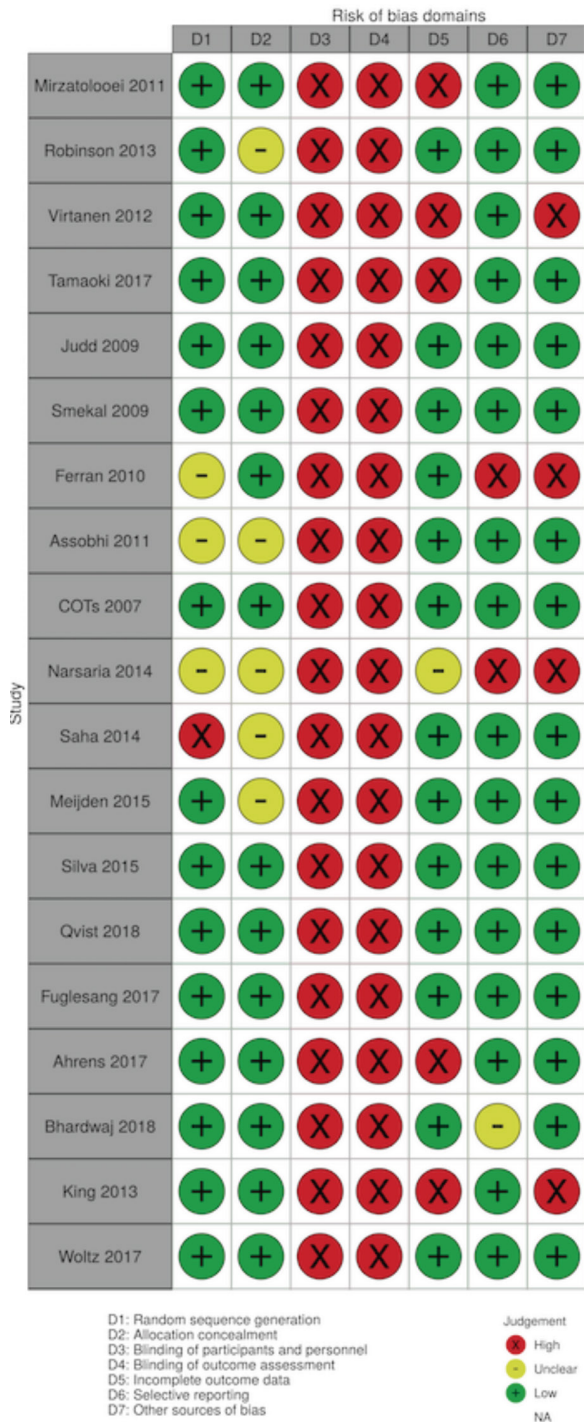


Fig. 3 Risk of bias of included studies.

the eight-point MCID established for the Constant questionnaire.

Functional outcomes between surgical methods. At six weeks, compression plating had significantly better Constant scores compared to reconstruction plating (MD 17.90; 95% CI 2.95 to 34.51) and trended towards better DASH scores (MD -6.17; 95% CI -19.99 to 8.26).

At one year, the differences in DASH and Constant scores were diminished: CP versus RP (MD -0.41; 95% CI -6.58 to 5.58) and (MD 3.21; 95% CI -2.23 to 9.03), respectively. There were no other differences noted between the groups.

Assessment of risk of bias. All 19 RCTs were assessed for the risk of bias using the Cochrane risk of bias assessment tool (Figure 3). Three RCTs¹⁷⁻¹⁹ did not provide sufficient evidence describing their methodology for random sequence generation necessary to be considered low risk of bias. Saha et al²⁰ randomized based on alternatively assigning patients to a specific treatment arm resulting in a high risk of bias designation. Only 14 RCTs provided sufficient evidence to be designated a low risk of bias for allocation sequence concealment.^{1-5,12,13,15-17,22-25} Three RCTs^{13,15,16} were given high risk of bias due to loss of follow-up. Two RCTs^{17,19} were assigned high risk of bias for selective reporting due to incomplete outcome data. Bhardwaj et al²⁴ did not provide sufficient evidence to be deemed low risk of bias for selective reporting.

Sensitivity analysis. After performing a sensitivity analysis, there remained a significant reduction in the odds of nonunion with all treatment methods compared to nonoperative management (Table IV).

Due to the limited data with the exclusion of these two studies,^{2,12} we were unable to complete the network analysis for the DASH scores at six weeks. There was no difference in DASH score at one year between the operative treatment methods and nonoperative treatment group. There was insufficient data to make comparisons for early Constant scores between the operative groups and nonoperative group. Compression plating and IMN trended towards greater Constant scores at six weeks compared to reconstruction plating (MD 12; 95% CI -9.3 to 33.0) and (MD 8; 95% CI -14.0 to 27.0), respectively. At one year, compression plating and IMN trended towards better Constant scores compared to nonoperative management (MD 6.1; 95% CI -2.9, 16.0) and (MD 6.9; 95% CI -2.2 to 15.0), respectively. There was no significant difference between the Constant score at 1 year when comparing compression plating to reconstruction plating (MD 1.3; 95% CI -7.2 to 9.6).

Discussion

Nonunion. The nonunion rate for mid-shaft clavicle fractures was lower for all operative groups compared to nonoperative management in our study. In addition, there was no difference in nonunion when comparing various plating options to IMN. This was consistent with prior literature, specifically a network meta-analysis by Axelrod et al⁶ which showed that operative intervention led to a significantly higher rate of union compared to nonoperative care, but no significant difference in union rates among various operative arms.

Table IV. Nonunions for surgical modalities and nonoperative management: sensitivity analysis.

Treatment arm	CP, odds ratio (95% CI)	IMN, odds ratio (95% CI)	RP, odds ratio (95% CI)	Nonoperative, odds ratio (95% CI)
CP	N/A	0.82 (0.08 to 8.77)	1.45 (0.08 to 38.44)	0.07 (0.03 to 0.17)*
IMN	1.22 (0.11 to 12.5)	N/A	1.81 (0.10 to 37.09)	0.08 (0.02 to 0.21)*
RP	0.68 (0.03 to 12.5)	0.55 (0.027 to 10)	N/A	0.09 (0.01 to 0.29)*
Nonoperative	14.3 (5.88 to 33.3)*	12.5 (4.76 to 50)*	11.1 (3.44 to 100)*	N/A

* $p < 0.05$. Each cell gives the effect of the row-defining intervention relative to the column-defining intervention.

CI, confidence interval; CP, compression plate; IMN, intramedullary nail; N/A, not applicable; RP, reconstruction plate.

Our study is one of the few high-level studies to indirectly compare nonunion rates between reconstruction and compression plates. In a multicentre retrospective cohort study, Woltz et al²⁷ found a 12.6% failure rate following reconstruction plating of mid-shaft clavicle fractures. Gilde et al²⁸ retrospectively found more malunions and nonunions when treating mid-shaft clavicle fractures with reconstruction plates compared to compression plates; however, this did not reach clinical significance. Despite our own anecdotal experience and reports in the literature, we found no significant difference in union rates between these two plating options. This may in part be explained by potential selection or enrolment bias as comminuted, complex fracture patterns may have been less likely to be included in the majority of RCTs as most excluded open fractures, poly-trauma patients, and fractures with associated ipsilateral limb injuries. Based on the available literature, the decision to employ a particular plate versus IMN in addressing a fractured clavicle should be based on outcomes associated with those methods apart from nonunions, as these rates seem to be similar among the different treatment arms. However, it must be considered that union rates in the literature may also be related to selection or enrolment bias. It is possible that length unstable fractures were not recruited in IMN studies.

Functional outcomes. Our study found that compression plating resulted in significantly less disability early after surgery compared to nonoperative management; however, this functional benefit was no longer observed at one year. Patients with less disability and better functional outcomes early after surgery may return to activities sooner (e.g. work, exercise, and independent ADLs). This may have important economic and health-related implications and is a key consideration when discussing appropriate treatment options with patients. Despite improved union rates, functional superiority of operative management compared to conservative management has not been consistently borne out in the literature. This NMA supports the premise that the prior consolidation of reconstruction plating and compression plating into a single overarching category of “plate fixation” may be the reason for this inconsistency, at least early after surgery. Compression

plating provides a stable construct which is likely to result in earlier return to function compared to reconstruction plating. This is evident by our results, which revealed compression plating to be the only treatment arm to yield significantly lower disability scores in the short term compared to nonoperative management. Additionally, when comparing early functional outcomes of compression plating with reconstruction plating, results showed that compression plating had significantly superior Constant scores and trends toward better DASH scores early after surgery.

Intramedullary devices did not provide earlier functional gains compared to nonoperative management. Despite trends toward improved late functional outcomes, these were not statistically nor clinically significant. It is possible that planned removal of IMNs curbs the functional benefit that may exist between intramedullary nailing and nonoperative management. However, our study does not support that intramedullary nailing provides improved functional outcomes over other treatment methods for the management of mid-shaft clavicle fractures.

Limitations. Despite the number of high quality RCTs included in this study, there are still some limitations which could not be overcome. As not all RCTs used the DASH and Constant scores in order to assess functional data, this could have negatively affected the power of this study. In addition, as a result of our exclusion criteria 274 patients were not included in our network meta-analysis. Also, limitations in data extraction contributed to this issue with difficulties in obtaining access to original data. Specifically, this resulted in the inability to include 286 patients in the six-week Constant score analysis, 65 patients in the one year Constant score analysis, and 254 patients in the six-week DASH analysis. Two studies included a treatment arm in which multiple plate types were used; however, sensitivity analysis was performed in order to ensure that this method did not have a significant effect on the results. The rate of reoperation and other major complications (hardware failure, hardware deformity, infection, etc.) were beyond the scope of this network meta-analysis. In addition, our study does not evaluate differences in minor complications (e.g. scar formation, numbness, and other cosmetic complaints), which may be of interest to

surgeons and patients. These complications are highly subjective and were not uniformly recorded in the majority of included RCTs. Finally, healthcare expenditures continue to be an important aspect of surgical deliberation; however, a cost-benefit analysis was beyond the scope of this study.



Take home message

- Patients with displaced mid-shaft clavicle fractures may be counselled that surgical management significantly increases their chance of union.

- Open reduction and internal fixation with compression plating may result in quicker return to activity by rendering patients less disabled early after surgery.

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Funding statement:

- The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.

ICMJE COI statement:

- M. D. McKee reports consultancy for Acumed, Stryker, ITS, and Bioventus, grants/grants pending from OTA, payment for lectures from Stryker and Acumed, royalties from Stryker and ITS, and travel/accommodation/meeting expenses Stryker, ITS, and Acumed, all of which is outside of this work. N. Dehghan declares consultancy for Acumed, grants/grants pending from OTA, and travel/accommodation/meeting expenses from Stryker, all of which is unrelated to this work. E. H. Schemitsch reports consultancy for Stryker, Smith & Nephew, Amgen, Depuy-Synthes, Acumed, Medtronic, Pendopharm, Swermac, and Sanofi, grants/grants pending from Biocomposites, and royalties from Stryker and ITS, all of which is also unrelated.

Open access funding:

- This study was funded by the Orthopaedic Surgery Department at the University of Arizona College of Medicine, Phoenix, USA.

Acknowledgements:

- The authors acknowledge the assistance of Naomi Bishop.

Ethical review statement:

- This study was determined to be exempt from Institutional Review Board approval.

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