

# Open reduction and plate fixation compared with non-surgical treatment for displaced midshaft clavicle fracture

## A meta-analysis of randomized clinical trials

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### Abstract

**Backgrounds:** There is no consensus concerning whether surgery or non-surgical treatment is preferred for displaced midshaft clavicle fracture. We performed a meta-analysis of randomized controlled trials (RCTs) to compare healing effects and cosmetic results between surgery and non-surgery.

**Methods:** We retrieved RCTs regarding open reduction and plate fixation (ORPF) and non-surgical method for the treatment of displaced midshaft clavicle fracture published before June 2018 from PubMed, EMBASE and Cochrane Library. The difference between the two treatments was comparatively discussed in aspects of nonunion, malunion, functional outcome, cosmetic results, and complications.

**Results:** Nine RCTs were included. The results showed that ORPF is advantageous over the non-surgical treatment in terms of nonunion rate (RR, 0.11[95%CI, 0.06–0.23]), malunion rate (RR, 0.16[95%CI, 0.08–0.35]), appearance dissatisfaction rate (RR, 0.35[95%CI 0.23–0.55]), and shoulder appearance defect rate (RR, 0.06[95%CI, 0.02–0.17]). The non-surgical treatment showed lower rate of complication (RR, 1.60[95%CI, 1.02–2.53]) and no significant differences were found between the 2 treatment groups with respect to functional outcome (disabilities of the arm, shoulder and hand (DASH) questionnaire score) (MD, –4.17[95% CI, –9.35 to 1.01]).

**Conclusions:** This meta-analysis updated previous results. The current findings suggested that ORPF yielded better efficacy than conservation treatment for displaced midshaft clavicle fracture from perspectives of fracture healing and appearance.

**Abbreviations:** DASH = disabilities of the arm, shoulder and hand, ITT = intent-to-treat, ORPF = open reduction and plate fixation, OTA = orthopedic trauma association classification, PP = per-protocol, RCTs = randomized clinical trials.

**Keywords:** meta-analysis, midshaft clavicle fracture, non-surgical treatment, open reduction and plate fixation

Editor: Goran Augustin.

This study was supported by National Natural Science Foundation of China (NSFC) (11671168), Science and Technology Developing Plan of Jilin Province (No. 20170101061JC). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

The authors report no conflicts of interest.

Supplemental Digital Content is available for this article.

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Medicine (2019) 98:20(e15638)

Received: 23 October 2018 / Received in final form: 17 April 2019 / Accepted: 18 April 2019

<http://dx.doi.org/10.1097/MD.0000000000015638>

## 1. Introduction

Midshaft clavicle fracture is a common injury accounting for 81% of all clavicle fractures and is often accompanied by displacement.<sup>[1]</sup> In the past, non-surgical treatment was preferred for midshaft clavicle fracture, even in the case of obvious displacement, because it resulted in extremely low nonunion rate.<sup>[2,3]</sup> However, some scholars recently found that the nonunion rate of displaced fracture after non-surgical treatment is greater than previously reported.<sup>[4,5]</sup> Currently, there is consensus on non-surgical treatment for midshaft clavicle fracture without displacement. However, the optimal treatment for displaced midshaft clavicle fracture is disputed.<sup>[6]</sup>

The goal of clavicle fracture treatment is to achieve bony union while minimizing dysfunction, morbidity, and cosmetic deformity.<sup>[6]</sup> The present meta-analyses focused on common outcomes such as nonunion rate, malunion rate and disabilities of the arm, shoulder and hand (DASH) score, and also paid attention to appearance-related indicators which were ignored by many published meta-analyses.<sup>[7–13]</sup>

Some published meta-analyses<sup>[7,9]</sup> also included non-randomized controlled trials, which reduces the level of evidence. We included only randomized clinical trials (RCT) studies and updated original studies.<sup>[14–16]</sup> Given the potential for clinical

heterogeneity between different surgical procedures such as intramedullary fixation and open reduction and plate fixation (ORPF), we selected only the more widely used ORPF and compared it with non-surgical treatment. We also found that the problem of confusing intent-to-treat (ITT) analysis and per-protocol (PP) analysis existing in most published studies. After comprehensive consideration, we decided to conduct the meta-analysis according to the ITT principle.

The main purpose of this RCTs-based meta-analysis is to compare healing effects and cosmetic results of ORPF vs non-surgical treatment for displaced midshaft clavicle fracture. We hope this study will provide more useful evidence for clinical decisions.

## 2. Methods

This study was conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions<sup>[17]</sup> and the PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-Analyses.<sup>[18,19]</sup>

### 2.1. Literature retrieval

Two authors (MQ and SSZ) independently searched PubMed, Embase, and Cochrane Library for English literature in June 2018 using following keywords and their synonyms: “clavicle”, “fracture”, “surgical procedures”, and “midshaft” (see Supplemental Content, <http://links.lww.com/MD/C975>, which provides the complete search strategy). In addition, we manually searched references of published meta-analyses and systematic reviews to include additional qualifying studies.

### 2.2. Inclusion and exclusion criteria

Inclusion criteria were as follows:

1. patients: those diagnosed with displaced midshaft clavicle fracture;
2. intervention: ORPF;
3. comparison: non-surgical treatments, including slings, bandages, and other physical therapies;
4. containing at least one of the following outcomes: appearance-related data, malunion, nonunion, and functional outcome;
5. study design: RCT;
6. follow-up time  $\geq 6$  months.

Exclusion criteria were as follows:

1. patients: minors, athletes or soldiers and patients belonging to other unique groups;
2. cadaveric specimens and biomechanical studies;
3. cohort studies, case reports, meta-analyses, and systematic reviews;
4. investigation of underlying diseases that influence fracture healing.

### 2.3. Data extraction

Collected data included general characteristics and measurement results. General characteristics consisted of: first author, year of publication, journal name, number of patients, age, follow-up time, fracture classification (Orthopedic Trauma Association classification<sup>[20]</sup> or Robinson classification<sup>[21]</sup>), and specific surgical and non-surgical treatment options. The primary outcome of this meta-analysis were nonunion and DASH score.

The secondary outcomes included malunion, appearance dissatisfaction, and shoulder appearance defect.

Some studies did not report actual standard deviation of continuous data. After failing to contact the original authors to obtain the original data, data conversion was performed according to the instructions described in the Cochrane Handbook for Systematic Reviews of Interventions.<sup>[17]</sup> As for the study by Canadian Orthopedic Trauma Society (COTS),<sup>[22]</sup> in which results were present in the form of images, GetData Graph Digitizer was used to obtain raw data from the images. Two authors (MQ and SSZ) independently extracted all data. A third author (LT) was responsible for data accuracy recheck. If no agreement was achieved, the dispute was resolved through discussion and agreement was eventually reached.

### 2.4. Methodological quality assessment

According to the modified Jadad scale<sup>[23]</sup> for methodological quality evaluation, scores of 1 to 3 denote low quality and scores of 4 to 7 denote high quality. Following the instructions of the Cochrane Handbook for Systematic Reviews of Interventions,<sup>[17]</sup> we also assessed the risk of bias in each study from the following aspects: random sequence generation, allocation concealment, blinding, incomplete data results, selective reporting, and other biases. Two authors (MQ and SSZ) independently performed quality assessment. If no agreement was achieved, a third investigator (WLG) mediated the dispute after discussion.

### 2.5. Statistical analysis

Considering that ITT estimate is more realistic, and PP is related to the violation of randomization principle, imbalanced sample sizes, and non-compliance with interventions, which may lead to conclusions exaggerating the therapeutic effect,<sup>[24,25]</sup> we conducted the meta-analysis according to the ITT principle.

Data were processed using RevMan (version 5.3, Cochrane Collaboration). The treatment effects were expressed as risk ratios (RR) and 95% confidence intervals for dichotomous results, and mean differences (MD) and 95% confidence intervals for continuous results. Heterogeneity across the studies was assessed with chi-square analysis, with  $P < .05$  being considered significant. A random-effects model was used for significant heterogeneity and a fixed-effects model for insignificant heterogeneity. When heterogeneity was significant, a sensitivity analysis was performed by deleting one study at a time to find possible sources of heterogeneity. As recommended by the Cochrane Handbook for Systematic Reviews of Interventions,<sup>[17]</sup> when the number of included studies was greater than or equal to 10, publication bias was examined using a funnel plot. All analyses were based on previous published studies; thus, there was no requirement to provide ethical approvals or patient consents.

## 3. Results

### 3.1. Literature retrieval

In total, 506 articles were retrieved through database search and 2 articles through manual search. After excluding duplicates, 406 articles were included for further analysis. Two authors independently screened these articles according to the exclusion criteria by reading titles and abstracts, and 13 articles were left. Besides 1 study<sup>[26]</sup> whose full text cannot be obtained, 3 articles including

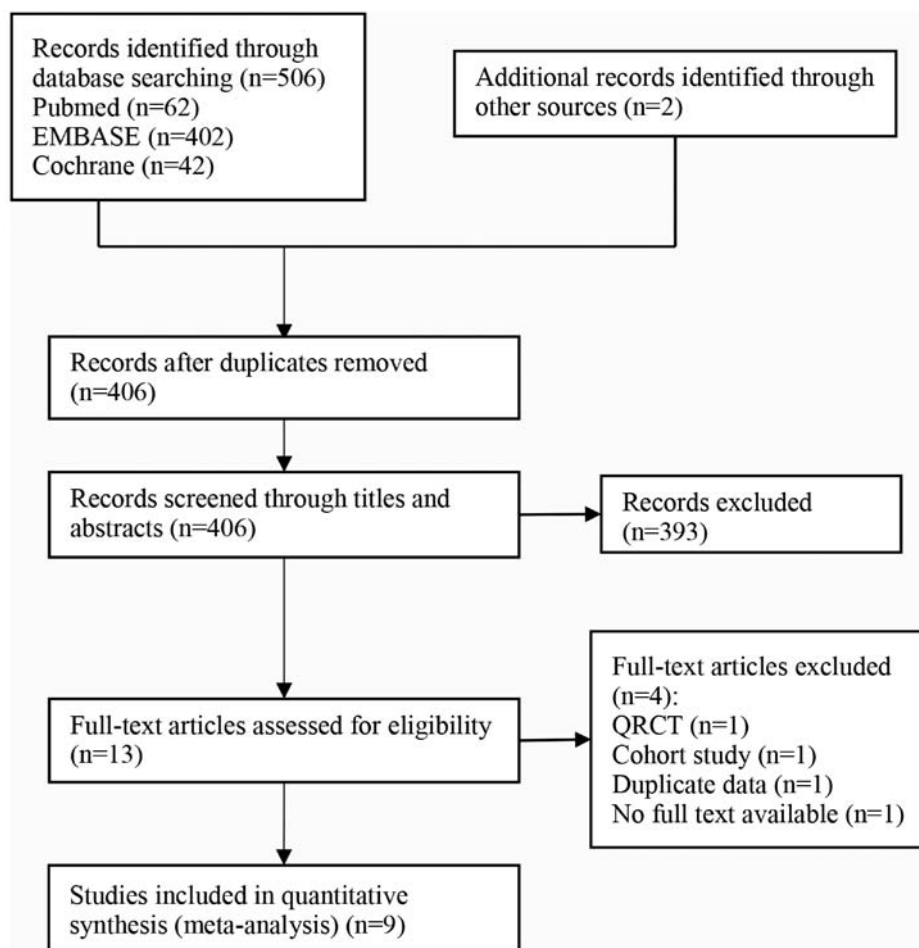


Figure 1. Flowchart of study selection.

1 QRCT,<sup>[27]</sup> 1 cohort study,<sup>[28]</sup> and 1 duplicate study (Summary and Review)<sup>[29]</sup> were excluded after reading the full texts. Finally, 9 RCTs<sup>[14–16,22,30–34]</sup> were included in the present meta-analysis. The details of the literature retrieval were shown in the flowchart (Fig. 1).

### 3.2. Study characteristics and methodological quality

The general characteristics of 9 studies were shown in Table 1. In total, 1135 patients were included, consisting of 568 patients receiving ORPF treatment and 568 patients receiving non-surgical treatment. We included only displaced midshaft clavicle fractures (including Robinson type 2B1 (displaced OTA 15B1 and B2) and type 2B2 (OTA 15B3)<sup>[20,21]</sup>). Open fractures were not included in all trials except for that performed by Mirzatooei et al.<sup>[31]</sup> Due to the features of trials on this topic, blinding was rarely used in included studies. Table 1 listed the modified Jadad score for each study. The RevMan software's bias evaluation results were shown in Figures 2 and 3.

## 4. Outcomes

### 4.1. Nonunion

All 9 studies provided data on nonunion. In the study by Shetty et al,<sup>[15]</sup> nonunion did not occur in both groups, and therefore this study was not merged. Figure 4 showed the results of meta-

analysis. The test for heterogeneity was not significant ( $P = .67$ ,  $I^2 = 0\%$ ). Using the fixed-effects model, the rate of nonunion was significantly lower in the ORPF group in comparison to the non-surgical treatment group (RR, 0.11 [95% CI, 0.06–0.23],  $P < .001$ ).

### 4.2. Malunion

Instead of radiographic malunion, malunion refers to symptomatic malunion, which means union of the fracture in a shortened, angulated, or displaced position combined with weakness, pain, and other sequelae. Six studies<sup>[15,22,31–34]</sup> reported symptomatic malunion, 3 of which<sup>[22,32,34]</sup> only recorded the number of patients whose symptoms were serious enough to require corrective osteotomy. In the study by Virtanen et al,<sup>[33]</sup> 2 patients had a symptomatic malunion and both of them refused surgery because they just experienced mild disability. Figure 5 showed the results of meta-analysis. The test for heterogeneity was not significant ( $P = .87$ ,  $I^2 = 0\%$ ). Using the fixed-effects model, the rate of malunion was significantly lower in the ORPF group compared with the non-surgical treatment group (RR, 0.16 [95% CI, 0.08–0.35],  $P < .001$ ).

### 4.3. Functional outcome

Six studies<sup>[16,22,31–34]</sup> evaluated 1-year DASH scores. Figure 6 showed the results of meta-analysis. The test for heterogeneity

**Table 1**  
**Characteristics and methodological qualities of the included studies.**

Study (author/yr)	Journal	No. of Patients Randomized (ORPF/NT)	Age† (yr)		Follow-up months	Fracture Type*	ORPF	NT	ORPF	NT	Jadad Score
			ORPF	NT							
Ahrens <sup>[14]</sup> 2017	J Bone Joint Surg Am.	154/147	36.1 ± 12.3 (18–65)	36.4 ± 11.8 (18–65)	9	Robinson classification	Precontoured titanium plate	Slings	Precontoured titanium plate	Slings	5
COTS <sup>[23]</sup> 2007	J Bone Joint Surg Am.	67/65	33.5 (16–60)	37.2 ± 11.2 (>18)	12	Completely displaced midshaft clavicular fractures	Limited contact dynamic compression plate (n = 44), Reconstruction plate (n = 15), Precontoured plate (n = 4), Other plate (n = 4)	Slings	Limited contact dynamic compression plate (n = 44), Reconstruction plate (n = 15), Precontoured plate (n = 4), Other plate (n = 4)	Slings	4
Melean <sup>[30]</sup> 2015	J Shoulder Elbow Surg.	34/42	38.1 ± 13 (>18)	37.2 ± 11.2 (>18)	12 ± 2	Robinson classification	3.5-mm locking Compression Plate (n=12) LCP reconstruction plates (n=22)	Slings	3.5-mm locking Compression Plate (n=12) LCP reconstruction plates (n=22)	Slings	4
Mirzaboloei <sup>[31]</sup> 2011	Acta Orthop Traumatol Turc.	29/31	36.0 (18–65)	35.3 (18–65)	12	Comminuted, displaced clavicular midshaft fractures	3.5-mm reconstruction plate (superior)	Slings and an elastic cotton band	3.5-mm reconstruction plate (superior)	Slings and an elastic cotton band	4
Robinson <sup>[32]</sup> 2013	J Bone Joint Surg Am.	95/105	32.3 ± 10.9 (16–60)	32.5 ± 12.5 (16–60)	12	Robinson classification 2B	Locking clavicle plate	Collar and cuff	Locking clavicle plate	Collar and cuff	3
Sheety <sup>[15]</sup> 2017	Journal of Clinical and Diagnostic Research.	16/14	20–50	20–50	6	Closed AO type A and B midshaft clavicular fractures with mild to moderate displacement	Locking compression plate	Clavicle brace application and arm pouch application	Locking compression plate	Clavicle brace application and arm pouch application	2
Tamaoki <sup>[16]</sup> 2017	J Bone Joint Surg Am.	59/58	30.5 ± 9.6	34.6 ± 12.6	12	AO/OTA classification	3.5-mm reconstruction plate (anterior)	Figure-of-eight harness	3.5-mm reconstruction plate (anterior)	Figure-of-eight harness	5
Virtanen <sup>[33]</sup> 2012	J Bone Joint Surg Am.	28/32	41 ± 10.8 (18–60)	33 ± 12.0 (18–60)	12	AO/OTA classification	3.5-mm reconstruction plate (anterior)	Slings	3.5-mm reconstruction plate (anterior)	Slings	5
Woltz <sup>[34]</sup> 2017	J Bone Joint Surg Am.	86/74	38.3 ± 12.7 (18–60)	37.2 ± 12.5 (18–60)	12	Robinson classification	Precontoured plate (n = 68) (superior, anterior, anterosuperior)	Slings	Precontoured plate (n = 68) (superior, anterior, anterosuperior)	Slings	3

NT = non-surgical treatment, ORPF = open reduction and plate fixation, OTA classification = orthopaedic trauma association classification.

† The data were given as the mean ± SD, with the age range in parentheses.

\* The data were given as the number of patients with the percentage in parentheses.

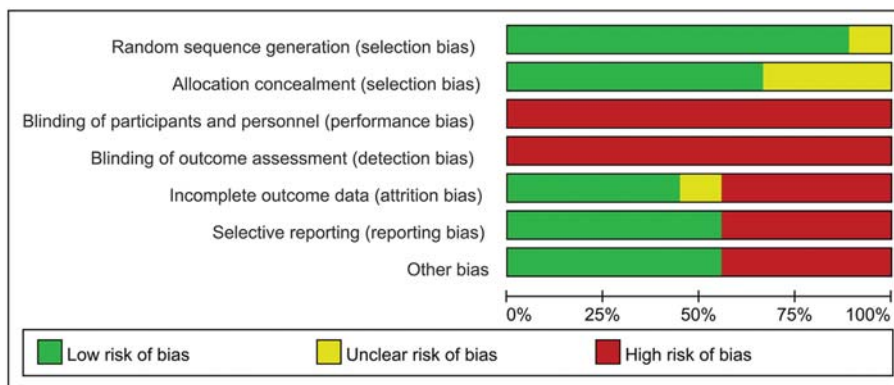


Figure 2. Risk of bias graph: a review of the authors' judgements about each risk of bias item presented as percentages across all included studies.

was significant ( $P < .001$ ,  $I^2 = 93\%$ ). Using the random-effects model, there was no significant difference between the 2 groups in term of DASH score (MD,  $-4.17[95\%CI, -9.35$  to  $1.01]$ ,

$P = .11$ ). Sensitivity analysis did not find a clear source of heterogeneity.

#### 4.4. Appearance dissatisfaction

Four studies<sup>[16,22,31,34]</sup> reported appearance dissatisfaction rates. Figure 7 showed the results of meta-analysis. Significant heterogeneity was detected among these studies ( $P = .03$ ,  $I^2 = 67\%$ ). Using random-effects model, there was no significant difference between the 2 groups (RR,  $0.53[95\%CI 0.23-1.25]$ ,  $P = .15$ ). Sensitivity analysis found that heterogeneity was significantly lower after removing the study by Tamaoki et al,<sup>[16]</sup> and appearance dissatisfaction rate was relatively lower in the ORPF group (RR,  $0.35 [95\% CI 0.23-0.55]$ ,  $P < .001$ ). Based on above results, we cautiously drew the conclusion that appearance dissatisfaction rate in the ORPF group was not higher than that in the non-surgical treatment group.

#### 4.5. Shoulder appearance defect

Four studies<sup>[16,22,31,32]</sup> clearly reported data on shoulder appearance (Table 2). Figure 8 showed the results of meta-analysis. The test for heterogeneity was significant ( $P < .001$ ,  $I^2 = 85\%$ ). Using the random-effects model, the aggregated results presented a significant difference favoring ORPF over non-surgical treatment (RR,  $0.15[95\%CI, 0.02-0.95]$ ,  $P = .04$ ). A sensitivity analysis in which the study by Tamaoki et al<sup>[16]</sup> was excluded resolved the heterogeneity without changing the result (RR,  $0.06[95\%CI, 0.02-0.17]$ ,  $P < .001$ ).

#### 4.6. Other complications

Complications other than nonunion and malunion are also worth of concern. Although the adverse events and complications occurred in each study varied, most studies have paid particular attention to some common problems. In the present study, we defined complication as a specific set of sequelae consisting of neurologic complication, complex regional pain syndrome, rotator cuff diseases, and complications due to operation (bent plate, plate breakage, implant failure, infection). The test for heterogeneity was not significant ( $P = .07$ ,  $I^2 = 48\%$ ) (Fig. 9). The Details of the data were shown in the Table 3. Using the fixed-effects model, the rate of complication was significant lower in the non-surgical treatment group (RR,  $1.60[95\%CI, 1.02-2.53]$ ,  $P = .04$ ).

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Ahrens 2017	+	+	-	-	+	+	+
COTS 2007	+	+	-	-	-	-	-
Melean 2015	+	+	-	-	?	-	+
Mirzatooleei 2011	+	+	-	-	-	-	-
Robinson 2013	+	?	-	-	-	+	+
Sheety 2017	?	?	-	-	+	-	-
Tamaoki 2017	+	+	-	-	+	+	-
Virtanen 2012	+	+	-	-	+	+	+
Woltz 2017	+	?	-	-	-	+	+

Figure 3. Risk of bias summary: a review of the authors' judgements about each risk of bias item for each included study. "+": risk of bias not present; "-": risk of bias present; "?": insufficient information to judge risk of bias.

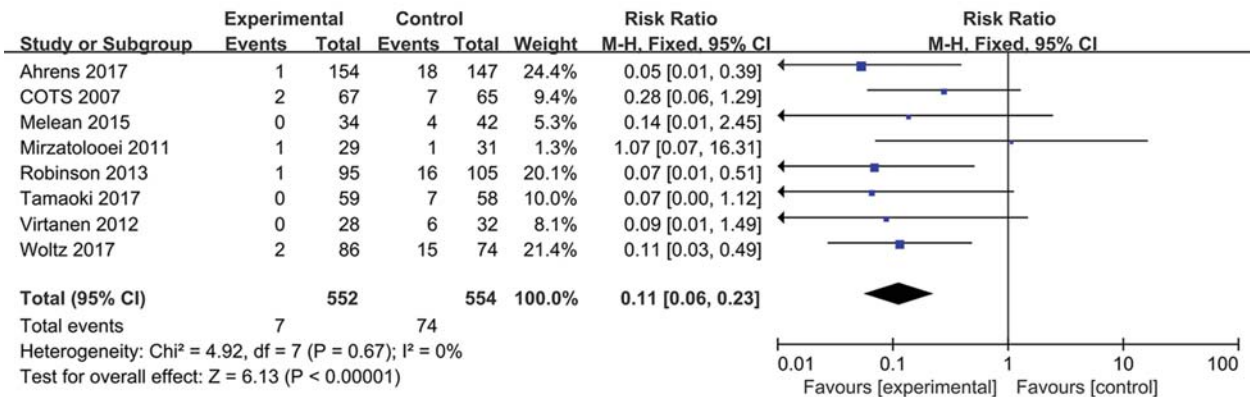


Figure 4. Forest plot showing comparison of nonunion rate between ORPF (experimental) and non-surgical treatment (control) groups. ORPF = open reduction and plate fixation.

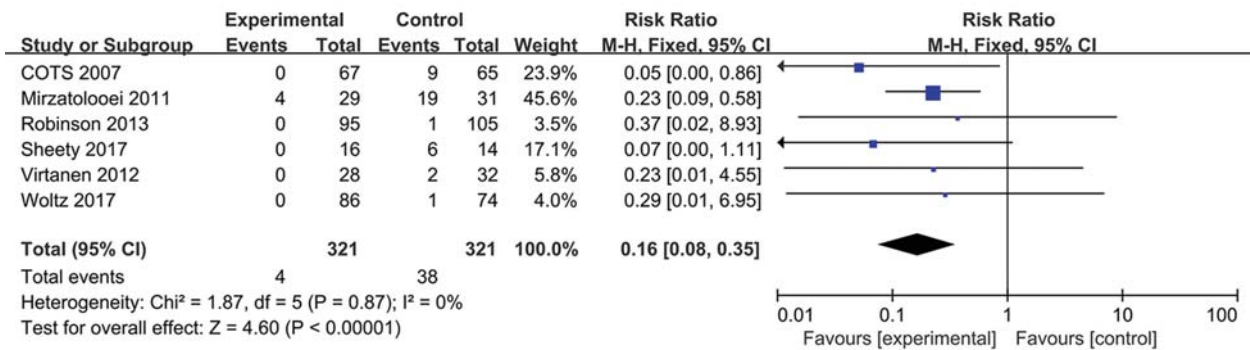


Figure 5. Forest plot showing comparison of malunion rate between ORPF (experimental) and non-surgical treatment (control) groups. ORPF = open reduction and plate fixation.

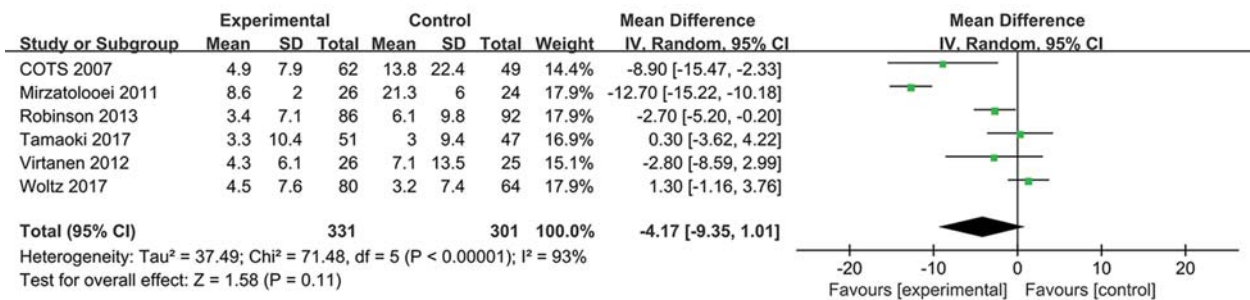


Figure 6. Forest plot showing comparison of DASH scores between ORPF (experimental) and non-surgical treatment (control) groups. DASH = disabilities of the arm, ORPF = open reduction and plate fixation.

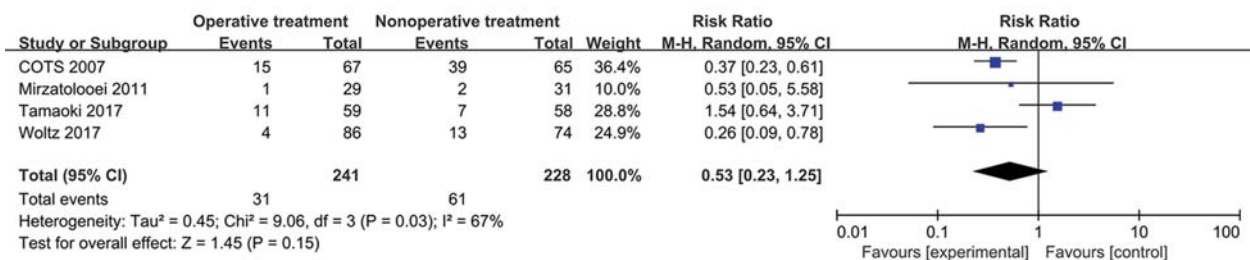


Figure 7. Forest plot showing comparison of appearance dissatisfaction rate between ORPF (experimental) and non-surgical treatment (control) groups. ORPF = open reduction and plate fixation.

**Table 2**  
**Appearance of shoulder.**

Author	Open Reduction and Plate Fixation	Non-surgical Treatment
COTS <sup>[22]</sup>	0 Shoulder droop 0 Dump and/or asymmetry	10 Shoulder droop 22 Dump and/or asymmetry
Mirzatoioei <sup>[31]</sup>	0 Absence of shoulder balance or symmetry	2 Absence of shoulder balance or symmetry
Robinson <sup>[32]</sup>	1 Shoulder droop 2 Shoulder asymmetry	15 Shoulder droop 17 Shoulder asymmetry
Tamaoki <sup>[16]</sup>	14 Shoulder droop 1 Shoulder malposition	17 Shoulder droop 7 Shoulder malposition

**4.7. Publication bias**

No more than 10 articles were included in this study. We did not report publication bias.

**5. Discussion**

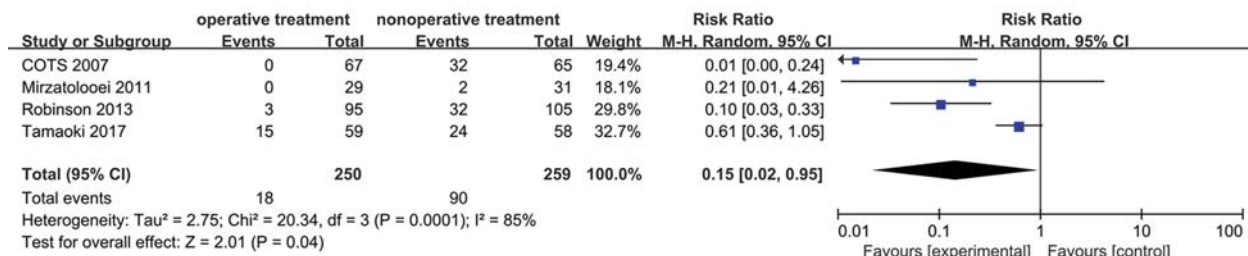
Our result revealed that, compared to the non-surgical treatment group, ORPF group exhibited better or at least comparable results in all outcomes except for the rate of complication.

We noticed that some original RCTs<sup>[14,16,22,33]</sup> clearly pointed out that their data processing was in accordance with ITT principles. For example, in the study by COTS,<sup>[22]</sup> a patient from the ORPF group refused surgery and suffered from nonunion. Though the patient did not actually receive surgical intervention,

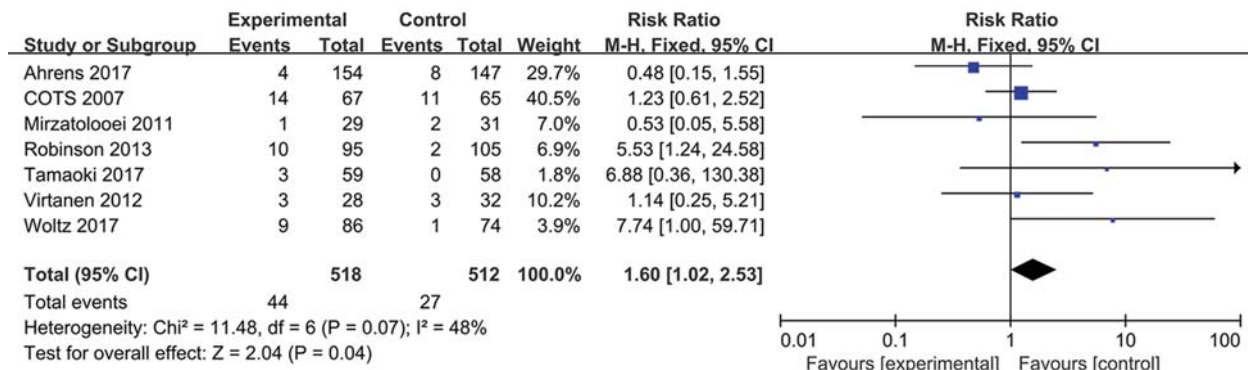
the author counted the nonunion in the ORPF group according to the ITT principle. Ignoring this kind of information, authors of previous meta-analyses<sup>[7,9-13]</sup> excluded patients who were lost to followed-up, but meanwhile included those who did not completed their original assignment. As a result, they confused ITT analysis and PP analysis. We have avoided such mistakes by conducting the meta-analysis according to the ITT principle.

The result of present study on the rate of nonunion was consistent with previous meta-analyses.<sup>[7,9]</sup> The non-union rate in the ORPF group was significant lower than that in the non-surgical group. This study showed that nonunion accounted for 1.3% of 552 patients receiving ORPF, compared with 13.4% of 554 patients following non-surgical treatment. A study of non-operative nonunion patients by Virtanen et al<sup>[33]</sup> found that half of the patients who shifted more than 1.5 times the clavicle width had nonunion.

The rate of malunion in the ORPF group was significantly lower than that in the non-surgical treatment group (1.8% vs 17.1%). In the past, it was thought that malunion was only an imaging problem and did not require treatment. However, more and more evidence showed that it was a distinct clinical entity and could cause appearance changes and bone or nerves dysfunction. In the study by McKee et al,<sup>[35]</sup> 13 of the 16 patients with malunion complained of unsatisfactory appearance of the shoulders, and they indicated that there was shoulder discomfort or tendency to slip during backpacking. In many studies, the main complication of patients with malunion was pain.<sup>[36-39]</sup> Ledger et al<sup>[39]</sup> performed self-administered questionnaires and bio-mechanical tests on 10 patients with malunion, and the results



**Figure 8.** Forest plot showing comparison of shoulder appearance defect rate between ORPF (experimental) and non-surgical treatment (control) groups. ORPF = open reduction and plate fixation.



**Figure 9.** Forest plot showing comparison of complication rate between ORPF (experimental) and non-surgical treatment (control) groups. ORPF = open reduction and plate fixation.

**Table 3**  
**Complications.**

Author	Open Reduction and Plate Fixation	Non-surgical Treatment
Ahrens <sup>[14]</sup>	1 Surgical failure 1 Plate removal (serious) 2 Frozen shoulder	1 Frozen shoulder 7 Surgery within 3 months
COTS <sup>[22]</sup>	1 Early mechanical failure 3 Wound infection or dehiscence 8 Transient brachial plexus symptoms 2 Abnormality of acromioclavicular or sternoclavicular joint	1 Complex regional pain syndrome 7 Transient brachial plexus symptoms 3 Abnormality of acromioclavicular or sternoclavicular joint
Mirzatooei <sup>[31]</sup>	1 Infection	2 Neurovascular compression
Robinson <sup>[32]</sup>	2 Superficial wound infection 1 Partial wound dehiscence 2 Fracture lateral to the plate 1 Refracture 1 Bent plate 2 Rotator cuff impingement 1 Adhesive capsulitis	1 Persistent ache in the shoulder 1 Rotator cuff impingement
Tamaoki <sup>[16]</sup>	2 Superficial infection 1 bent plate	
Virtanen <sup>[33]</sup>	1 Bent plate 1 Plate breakage 1 Refracture	1 Brachial plexus irritation 2 Refracture
Woltz <sup>[34]</sup>	6 Implant failure 2 Deep wound infection 1 Superficial wound infection	1 Neurologic complications

showed that both subjective and objective shoulder functions were reduced. Besides, some studies<sup>[40–42]</sup> reported patients with thoracic outlet syndrome secondary to clavicle deformity healing. Our conclusion on malunion agreed with previous studies.<sup>[9,12]</sup>

DASH score and constant score are common functional outcomes. Compared to the study by Woltz et al,<sup>[34]</sup> there was no new data on constant score, so we only analyzed the DASH score. Unlike the previous meta-analyses,<sup>[8,10,12]</sup> after updating original literature, we found no significant difference in the DASH scores at 1-year after injury between the ORPF group and the non-surgical treatment group. The understanding of PROM (Patient-reported outcome measures) (DASH score) needs to introduce the concepts of smallest detectable change (SDC) and minimal important change (MIC). SDC is a measure of the change caused by measurement error, and MIC means the most important minimum score changes the patient considered. According to Kampen et al,<sup>[43]</sup> SDC = 16.3, MIC = 12.4, and clinically relevant differences were considered when the score change was greater than 16.3. Although the previous meta-analyses statistically indicated that the DASH score of the surgical treatment group was higher than that of the non-surgical treatment group, the score difference had no clinical significance. Three of the 6 RCTs<sup>[22,31,32]</sup> showed that the 1-year DASH score was better in the surgery group and the others showed no significant difference between the 2 groups. However, it should be noted that patients who have not yet received treatment for nonunion or malunion may affect the outcome. Mirzatooei et al<sup>[31]</sup> stated that the main factors affecting the final functional outcomes of ORPF and non-surgical treatment were nonunion and malunion, respectively. Non-surgical treatment was inferior to surgical treatment

because it led to malunion in a large number of patients. Robinson et al<sup>[32]</sup> specifically analyzed healed fractures in both groups and found that although the ORPF group had a better trend, there was no statistical difference between the 2 groups.

Although orthopedic surgeons are less focused on cosmetic results, patients are concerned about appearance. Based on the analysis of existing data, the ORPF group had better shoulder appearance than the non-surgical treatment group. In the published meta-analyses, only Xu et al<sup>[13]</sup> and Xu et al<sup>[11]</sup> analyzed appearance dissatisfaction rate. We obtained different results from updated original literature: there was no significant difference between the 2 groups. However, the heterogeneity was relatively large. Subsequent sensitivity analysis revealed that the study by Tamaoki et al<sup>[16]</sup> was a source of heterogeneity. The trial was performed in the tropical region where most people wear clothes that leave the shoulders uncovered and thus the easily exposed surgery-caused scars may lead to the high dissatisfaction rate in the ORPF group. After removing this study, the conclusion changed: ORPF resulted in lower appearance dissatisfaction rate. In conclusion, we believed that the appearance dissatisfaction rate in the ORPF group was not higher than that in the non-surgical treatment group. Appearance dissatisfaction rate is related to many factors, such as the proportion of female patients and the patient's tolerance for different appearance defects. This conclusion should be carefully understood.

The pooled result showed a lower complication rate in the non-surgical treatment group. But we can notice that in the ORPF group, severe plate-related complications such as surgical failure, plate bending, and plate breakage seldom occurred. The incidence of surgical failure was no more than 3% in all studies except for the one by Woltz et al, in which the incidence was 7%. The risk of developing plate-related complications can be reduced by using less prominent plates and improved surgical techniques.

Our meta-analysis had some limitations: First of all, most of trials had experimental design limitations, such as inability to perform double-blind evaluation, and presence of lost patients; secondly, due to the lack of sufficient literature, we failed to perform adequate subgroup analysis on the patient's gender, age, plate type, and plate position; finally, we may have omitted some non-English studies that are useful for our meta-analysis.

## 6. Conclusions

In Conclusions, current evidence indicated that the efficacy of ORPF was slightly better than that of non-surgical treatment. ORPF showed advantages in terms of nonunion, malunion, and cosmetic results than non-surgical treatment. The non-surgical treatment showed lower rate of complication and no significant differences were found between the 2 treatment groups with respect to DASH score.

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