

# Plate fixation versus intramedullary fixation for midshaft clavicle fractures: Meta-analysis of complications and functional outcomes

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## Abstract

**Objective:** This analysis critically compares publications discussing complications and functional outcomes of plate fixation (PF) versus intramedullary fixation (IF) for midshaft clavicle fractures.

**Methods:** Relevant studies published between January 1990 and October 2014, without language restrictions, were identified in database searches of PubMed<sup>®</sup>, Medline<sup>®</sup>, Embase and the Chinese National Knowledge Infrastructure (CNKI). Studies that compared postoperative complications and functional outcomes between PF and IF for midshaft clavicle fractures, and provided sufficient data for analysis, were included in this meta-analysis.

**Results:** After strict evaluation, 12 studies were included in this meta-analysis. Studies encompassed 462 participants in the PF group and 440 in the IF group. Study participants were followed up for  $\geq 1$  year. Outcomes were superior with IF compared with PF in terms of shoulder constant score at 6-month follow-up, fewer symptomatic hardware complications, lower rate of refracture after hardware removal and less hypertrophic scarring. In other aspects, such as functional recovery at 12-months and 24-months, Disability of Arm, Shoulder and Hand (DASH) questionnaire results at 12-month follow-up, shoulder motion range, rates of superficial infection, temporary brachial plexus lesion, nonunion, malunion, delayed union, implant failure and need for major revision, both techniques were similar.

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**Conclusions:** Findings of this meta-analysis suggest that, in many respects, IF was superior to PF for the management of midshaft clavicle fractures. This finding could aid surgeons in making decisions on the optimum internal fixation pattern for midshaft clavicular fractures.

## **Keywords**

Midshaft clavicle fractures, intramedullary fixation, plate fixation, meta-analysis

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## **Introduction**

Clavicular fracture is a common injury, accounting for 2.6–10% of all fractures in adults.<sup>1–4</sup> Approximately 80% of clavicular fractures involve the midshaft of the clavicle and >70% of midshaft clavicular fractures are displaced.<sup>4,5</sup> Conservative treatment has been traditionally considered as ‘standard treatment’ for midshaft fractures even for displaced fractures, with the expectation that even severe radiographic malalignment would not influence functional results. However, a relatively high incidence (30%) of postoperative complications and deficits in functional recovery of the shoulder has been reported in patients originally treated with conservative regimens.<sup>6–8</sup> With advancements in techniques and implants for fracture fixing, internal fixation is generally considered a better choice for these fractures than conservative treatment. Substantial controversy among surgeons regarding the optimal fixation pattern (plate fixation [PF] or intramedullary fixation [IF]) of these injuries exists and further research on better treatment options is needed.

To date, multiple forms of plating and intramedullary devices have been used to fix midshaft clavicle fractures, including precontoured dynamic compression plates (DCP), use of a reconstruction plate for PF and Knowles pinning, elastic stable intramedullary nailing with a Rockwood clavicle pin and an Acumed clavicle rod for IF<sup>9–12</sup>. PF is a popular technique providing a rigid fix, allowing early rehabilitation

protocols.<sup>13</sup> A precontoured plate, designed to parallel the S-shaped curve of the clavicle, has become a popular PF pattern. However, extensive soft-tissue dissection, implant prominence, postoperative infection, scarring, hardware failure and refracture after the removal of the plate are all negative factors for PF.<sup>14–17</sup> With IF, the soft tissue envelope, periosteum and vascular integrity can be preserved,<sup>18,19</sup> early hardware migration appears to be solved by an improved locked intramedullary device, but the issue of low biomechanical stability remains.<sup>20</sup>

Barlow et al.<sup>21</sup> and Houwert et al.<sup>22</sup> have conducted relevant systematic reviews comparing IF and PF methods of midshaft clavicle fracture repair, but with qualitative and equivocal conclusions. Duan et al.<sup>23</sup> conducted a meta-analysis of randomized control trials (RCT), but only two studies were included comparing complications and functional outcomes between methods. Several original studies comparing different methods have since been published,<sup>15,24–28</sup> which prompted this updated meta-analysis. Accordingly, the present analysis aimed to evaluate whether IF is better than PF in terms of postoperative complications and functional outcomes for the management of acute midshaft clavicle fractures.

## **Materials and methods**

### *Search strategy*

This meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses

(PRISMA) guidelines (<http://www.prisma-statement.org/statement.htm>). An electronic literature search was performed in PubMed®, Medline®, Embase and the Chinese National Knowledge Infrastructure (CNKI), to identify relevant studies published between January 1990 and October 2014. The following keywords were used: ‘clavicular’ or ‘clavicle’ and ‘midshaft’ and ‘fracture’ and ‘intramedullary’ and ‘plate’ or ‘plating’ and ‘complications’ or ‘effectiveness’ or ‘results’ or ‘outcome’. A manual search of references in the included original articles or systematic reviews was also performed, to identify any potential additional studies.

### **Inclusion criteria**

Two reviewers (H.G., T. Z.) independently evaluated the titles and abstracts of the identified papers. Only full text articles without language restriction were included in this meta-analysis. Disagreements were resolved through discussion; if they remained unresolved, a third reviewer was consulted. Inclusion criteria were RCTs or case-control or cohort studies comparing the outcomes of two methods for treating midshaft clavicular fractures, at least one set of results in each paper had to be original, the age of participants in both groups had to be <65 years (young, active participants), participants in studies were followed up for  $\geq 12$  months and sufficient data were provided to estimate the odds ratio (OR) or standardized mean difference (SMD) with 95% confidence intervals (CIs).

### **Quality assessment and data extraction**

The quality of studies was evaluated by the tool recommended in the Cochrane Handbook 5.1.0: ‘The Cochrane collaboration’s tool for assessing risk of bias’, which was used by Fang et al.<sup>29</sup> This scale includes six major potential sources of bias, including sequence generation, allocation concealment,

blinding, incomplete data, selective outcome reporting and other outcomes reporting. Data were carefully and independently abstracted from eligible studies by the same two reviewers (H.G., T.Z.). The following basic characteristics were abstracted from each study: first author’s name; publication year; patients’ age and sex; follow-up duration; definition and numbers in each IF and PF group; the number of studies providing information for each surgical method.

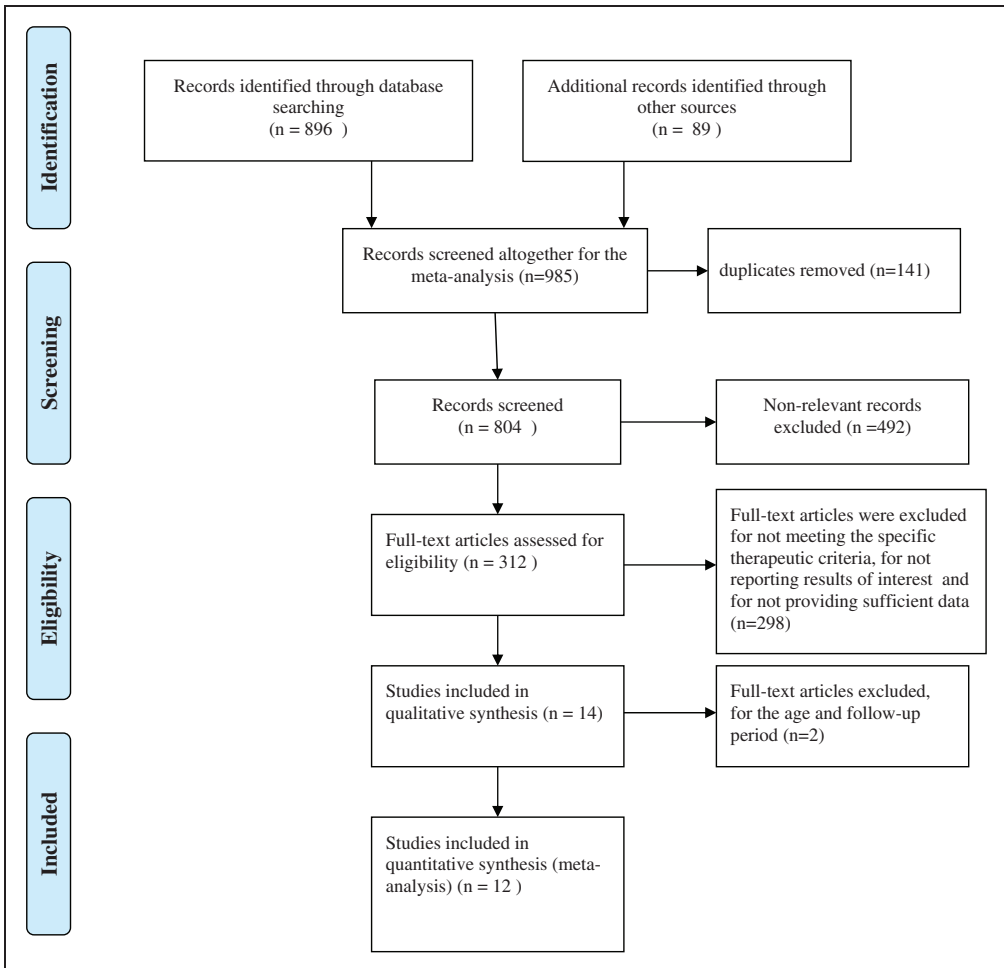
### **Statistical analyses**

Odds ratios and 95% CI were estimated and pooled across studies to assess for any differences between the two methods. A  $P$ -value < 0.05 was considered significant. Heterogeneity among studies was tested by  $Q$ -statistics, with significance set at  $P < 0.10$ <sup>30</sup> and further measured by  $I^2$  statistics, with  $I^2 > 50\%$  indicating significant inconsistency. A random-effects model was used to calculate pooled ORs in the case of significant heterogeneity ( $P < 0.10$  or  $I^2 > 50\%$ ); otherwise, a fixed-effects model was used.<sup>31</sup> The outcome of the meta-analysis for variables was summarized graphically using forest plots. Publication bias was assessed and presented using funnel plots. For any variable presenting with large heterogeneity, a sensitivity analysis, excluding outlier studies, was conducted to investigate the source of heterogeneity. All analyses were performed using Stata® software, version 11.0 (Stata Corp., College Station, TX, USA).

## **Results**

### **Basic information**

The initial database search yielded 985 papers: 673 were excluded as they were in an inappropriate format (e.g. abstracts, letters, meeting reports, same data reported at different time-points); 193 were excluded for not meeting the specific therapeutic methods according to the study criteria; 76 were



**Figure 1.** Flow diagram of literature search strategy to identify manuscripts to compare complications and functional outcomes of plate fixation (PF) or intramedullary fixation (IF) for midshaft clavicle fractures, according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

excluded as the reported results were outside the interest of this study; 29 were excluded as they did not provide sufficient data for the meta-analysis; one study was excluded as its follow-up period was too short (mean of 5.9 months),<sup>32</sup> one study was excluded as its participants were not within the specified age criteria.<sup>33</sup> The remaining 12 studies were eligible and were included in this meta-analysis. The search procedure is presented in Figure 1.

The 12 original articles included were published between 1999 and 2014. A total of 440 patients from these 12 studies had undergone IF; 462 had undergone PF. In each study, patients treated by each method were similar in terms of sex, side involved and injury mechanism. In two studies, patients treated with PF were significantly older than those treated with IF,<sup>28,34</sup> whereas in the other included studies, the age between the two groups was similar.

**Table 1.** Basic characteristics of participants and details of the 12 studies included in a meta-analysis comparing intramedullary fixation (IF) with plate fixation (PF) for midshaft clavicle fracture.

Author	Country, region	Publication year	IF n	PF n	IF age (range)	PF age (range)	IF, M/F	PF, M/F	Follow-up, months
Narsaria	India	2014	33	32	38.9 ± 9.1 (20–62)	40.2 ± 11.2 (18–64)	24/9	26/6	>24
Liu <sup>35</sup>	China, Taiwan	2010	51	59	33.6 ± 13.5	31.7 ± 9.7	32/19	29/30	>12
Fu <sup>25</sup>	China, Taiwan	2012	53	50	35.2 ± 14.5	39.9 ± 14.8	38/15	33/17	>12
Ko <sup>36</sup>	Republic of Korea	1999	13	18	36.6 (23–68)	43.3 (18–74)	NP	NP	>12
Lee J <sup>26</sup>	USA	2014	43	67	27.6 (14–59)	31.7 (16–68)	29/5	63/4	>15
Wenninger <sup>27</sup>	USA	2013	33	29	25.2 (18–51)	26.9 (20–49)	32/1	26/3	>12
Assobhi <sup>34</sup>	Egypt	2011	19	19	30.3 ± 4.8 (24–45)	32.6 ± 5.9 (26–49)	16/3	17/2	>12
Wijdicks <sup>28</sup>	The Netherlands	2012	47	43	33.1 ± 15.6	39.4 ± 14.1	33/14	33/10	>12
Ferran <sup>43</sup>	UK	2010	17	15	23.8 (13–42)	35.4 (16–53)	14/3	13/2	12.4 (mean)
Kleweno <sup>39</sup>	USA	2011	18	14	35 (16–56)	28 (16–46)	15/3	10/4	>12
Chen <sup>15</sup>	China	2012	57	84	34.3 (20–59)	36.5 (19–63)	41/16	61/23	>24
Lee Y <sup>18</sup>	China, Taiwan	2008	56	32	40.1	38.2	37/19	20/12	>12

PF, plate fixation; IF, intramedullary fixation; M, male patients; F, female patients.

A summary of basic characteristics is listed in Table 1.

A detailed quality assessment of the included studies is presented in Table 2.

**Postoperative complications**

Total complications were reported in four studies involving 146 IF patients and 115 PF patients. The PF group yielded a slightly higher incidence of total complications than the IF group (13.9% versus 7.5%), but the combined result did not reach significance (OR 0.54; 95% CI 0.24, 1.20; Figure 2).

Postoperative superficial infection was reported in ten studies encompassing 409 IF patients and 430 PF patients; overall, 14 (3.4%) and 19 (4.4%) patients, respectively, were infected shortly after surgery. Analysis for a combined outcome found no significant difference between surgical methods (OR 0.82; 95% CI 0.43, 1.57; Figure 3A),

with little heterogeneity ( $I^2 = 8.5\%$ ). Begg’s test showed no publication bias for this variable (Figure 3B).

Six studies involving 251 IF patients and 254 PF patients reported postoperative symptomatic hardware, which was higher in the PF group (22.4%) than in the IF group (6.0%). This result was significant, without heterogeneity (OR 0.18; 95% CI 0.10, 0.33; Figure 4).

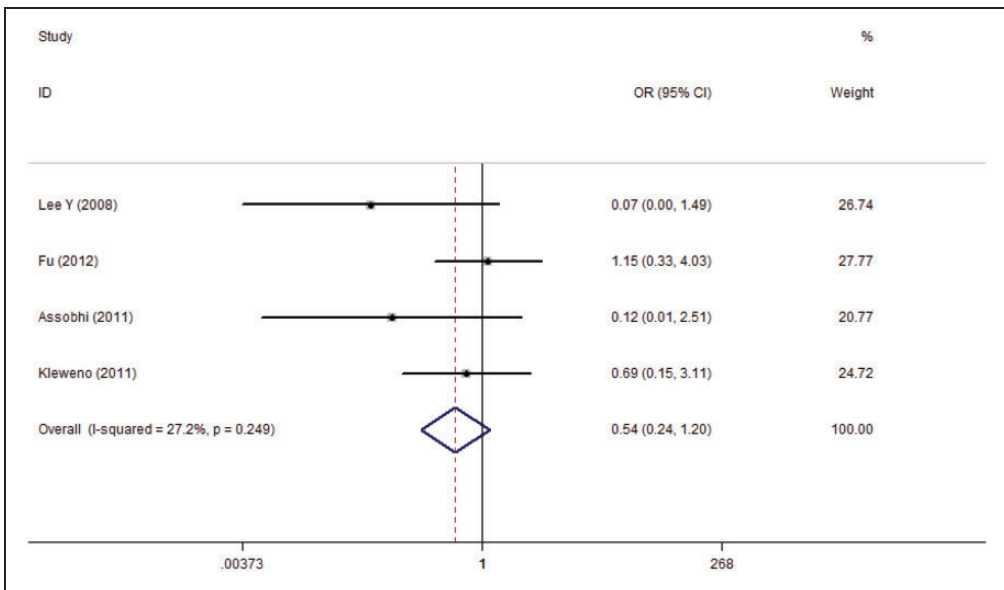
Five studies reported refracture incidence after implant removal, and found a lower incidence in IF patients compared with PF patients (0% versus 6.3%); the meta-analysis result was not significant (OR 0.17; 95% CI 0.04, 0.67; Figure 5).

Development of hypertrophic scarring is an important complication that affects patients’ confidence in their appearance. Three studies reported postoperative hypertrophic scarring, with a higher incidence in PF patients (13.6%) than in IF

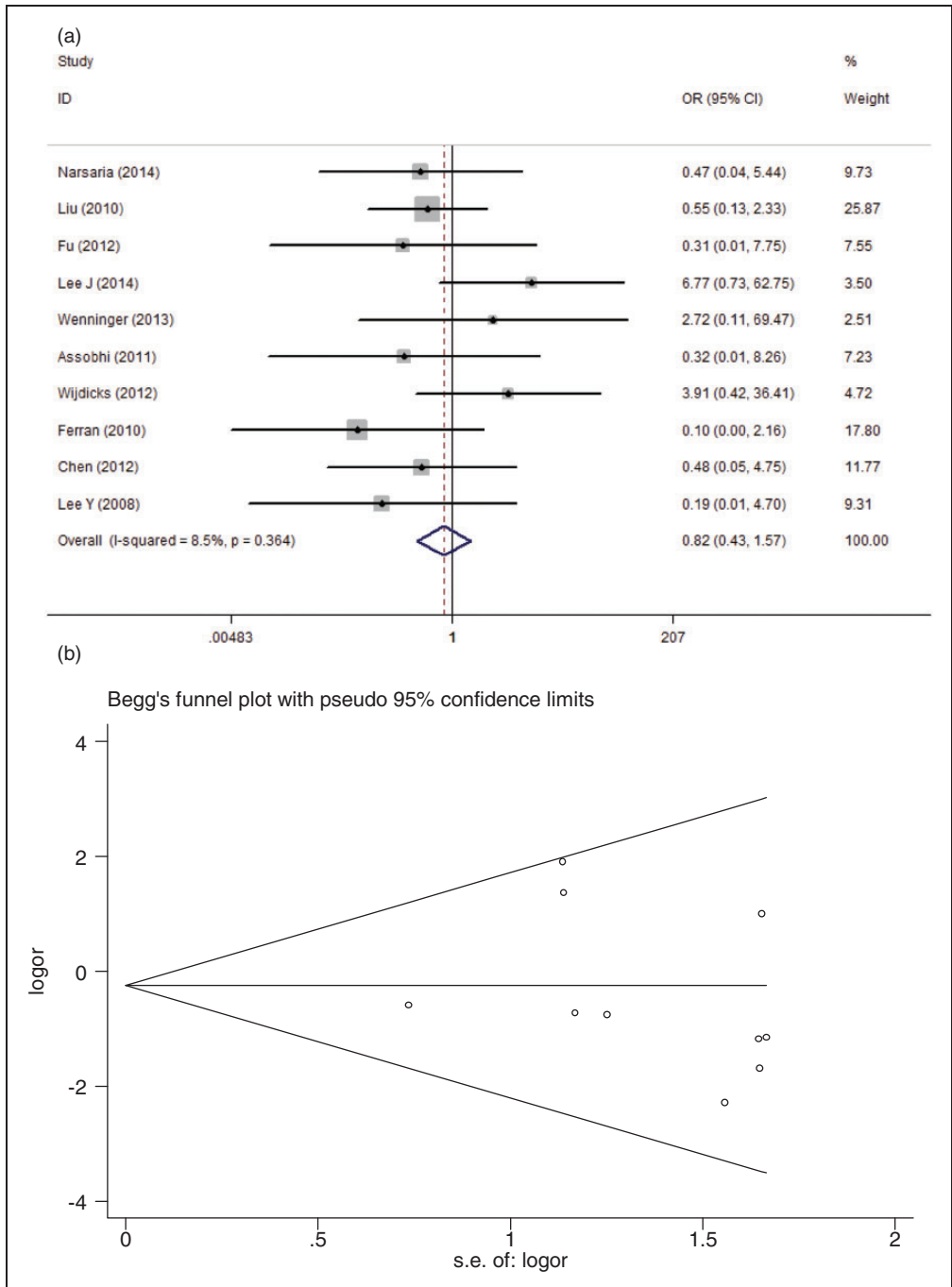
**Table 2.** Methodological assessment of articles included in a meta-analysis comparing intramedullary fixation (IF) with plate fixation (PF) for midshaft clavicle fracture using the Cochrane collaboration tool for assessing risk of bias.

Reference	Random sequence generation	Allocation concealment	Blinding	Incomplete outcome data	Free of selective reporting	Free of other bias
Narsaria, 2014 <sup>24</sup>	Yes	Yes	Unclear	Yes	Yes	Yes
Liu, 2010 <sup>35</sup>	No	Unclear	Yes	Yes	Yes	Unclear
Fu, 2012 <sup>25</sup>	No	Unclear	Yes	Yes	Yes	Unclear
Ko, 1999 <sup>36</sup>	Yes	Unclear	Unclear	Yes	Yes	No
Lee J, 2014 <sup>26</sup>	Unclear	Yes	Unclear	Yes	Yes	Yes
Wenninger, 2013 <sup>27</sup>	Yes	Unclear	Yes	Yes	Yes	Unclear
Assobhi, 2011 <sup>34</sup>	No	Yes	Yes	Unclear	Yes	No
Wijdicks, 2012 <sup>28</sup>	Yes	Yes	Yes	Yes	Yes	No
Ferran, 2010 <sup>43</sup>	No	Unclear	Unclear	Yes	Yes	Yes
Kleweno, 2011 <sup>39</sup>	Yes	Yes	Yes	Yes	Yes	No
Chen, 2012 <sup>15</sup>	No	Unclear	Yes	Yes	Yes	No
Lee Y, 2008 <sup>18</sup>	Yes	Yes	Unclear	Unclear	Yes	Yes

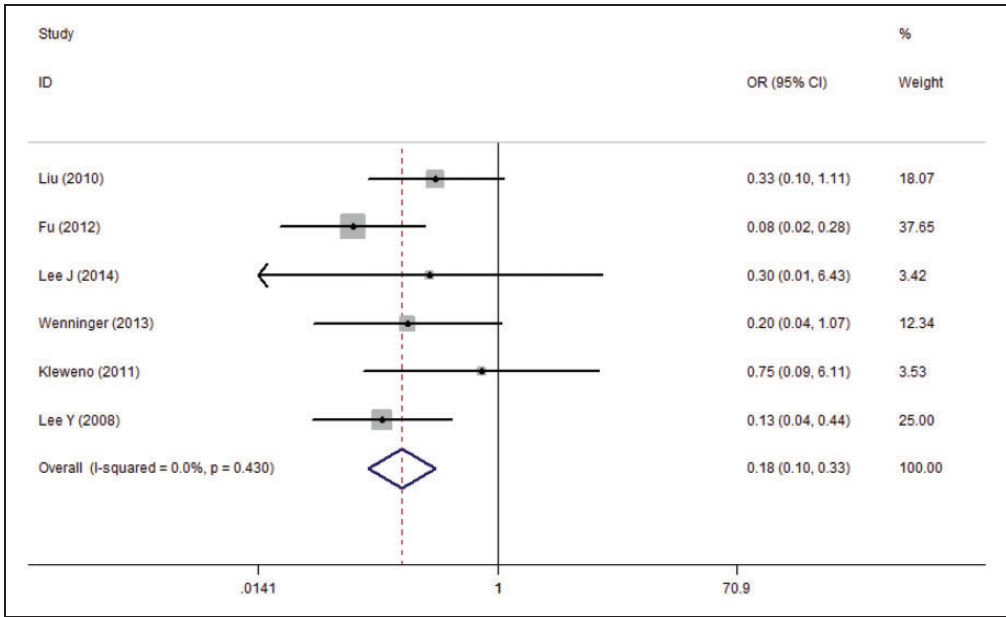
'Yes', low risk of bias; 'Unclear', unclear risk of bias; 'No', high risk of bias.



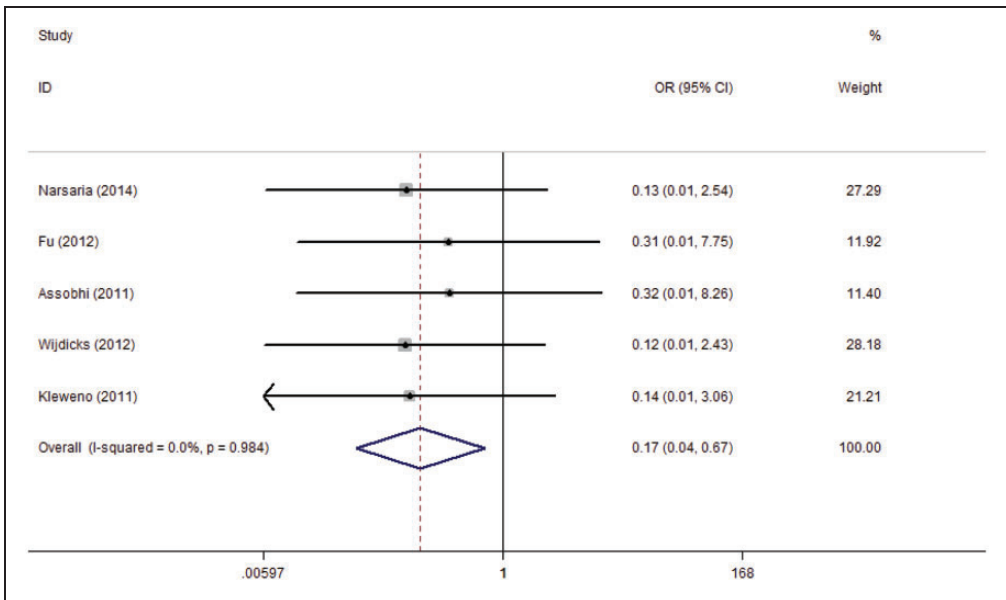
**Figure 2.** Forest plot for total complications, reported in four studies involving 146 intramedullary fixation (IF) patients and 115 plate fixation (PF) patients with midshaft clavicle fractures; overall,  $I^2 = 27.2\%$ ,  $P =$  not significant.



**Figure 3.** (A) Forest plot for superficial infection reported in 10 studies encompassing 409 intramedullary fixation (IF) patients and 430 plate fixation (PF) patients with midshaft clavicle fractures;  $I^2 = 8.5\%$ ,  $P =$  not significant. (B) Begg's funnel plot to assess publication bias of the included studies comparing the level of superficial infection between intramedullary fixation (IF) and plate fixation (PF) for midshaft clavicle fractures ( $P =$  not significant).

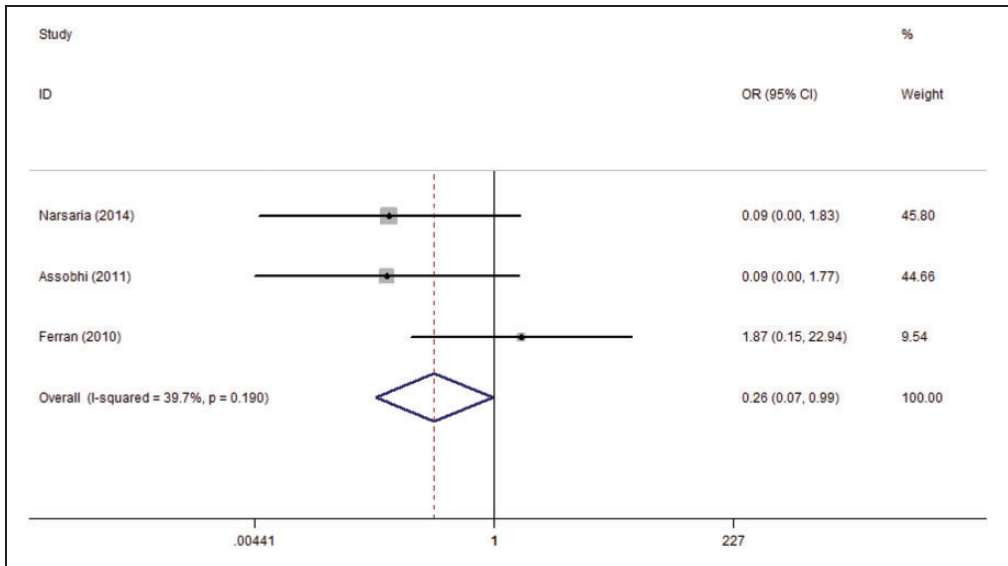


**Figure 4.** Forest plot for six studies involving 251 intramedullary fixation (IF) patients and 254 plate fixation (PF) patients which reported postoperative symptomatic hardware during recovery from midshaft clavicle fracture;  $I^2 = 0.0\%$ ,  $P =$  not significant.

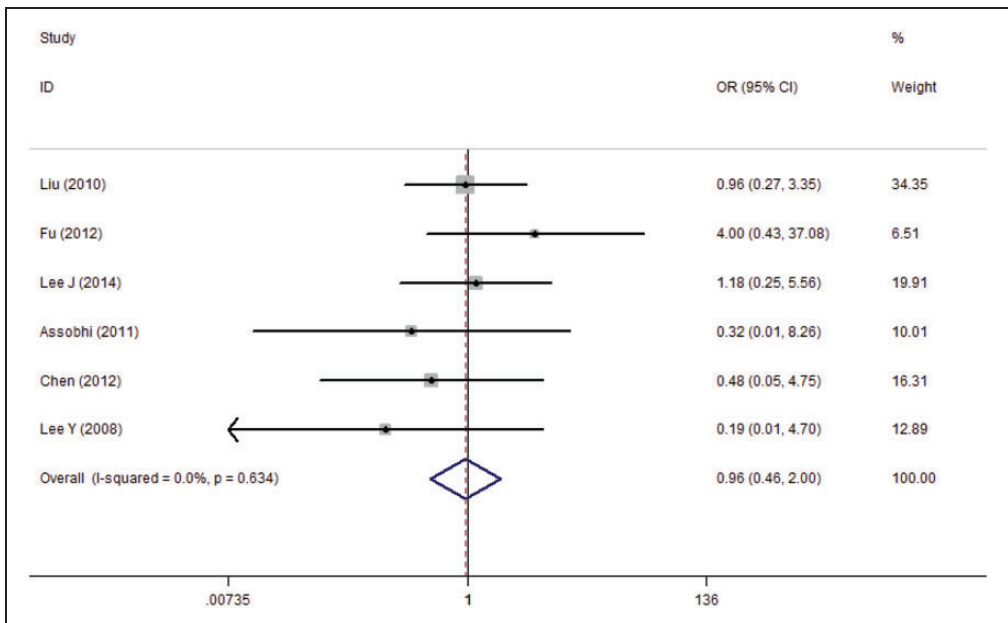


**Figure 5.** Forest plot for five studies which reported refracture incidence after implant removal in intramedullary fixation (IF) and plate fixation (PF) patients during recovery from midshaft clavicle fracture;  $I^2 = 0.0\%$ ,  $P =$  not significant.





**Figure 6.** Forest plot for three studies that reported hypertrophic scar incidence in intramedullary fixation (IF) and plate fixation (PF) patients during recovery from midshaft clavicle fracture;  $I^2 = 39.7\%$ ,  $P =$  not significant.



**Figure 7.** Forest plot for six studies reporting the incidence of nonunion in intramedullary fixation (IF) and plate fixation (PF) patients during recovery from midshaft clavicle fracture;  $I^2 = 0.0\%$ ,  $P =$  not significant.

**Table 3.** Comparative data for five variables of outcome in a meta-analysis comparing intramedullary fixation (IF) with plate fixation (PF) for midshaft clavicle fracture.

Variable	Studies, n	Pooled OR or SMD	LL 95% CI	UL 95% CI	Statistical significance <sup>a</sup>	Q-statistic for heterogeneity P-value	I <sup>2</sup> statistic %
Temporary brachial plexus lesion	2	1.69	0.31	9.19	NS	0.343	0
Nonunion	6	0.96	0.46	2.00	NS	0.634	0
Malunion	3	1.78	0.66	4.79	NS	0.763	0
Implant failure	6	1.03	0.43	2.48	NS	0.320	14.8
Major revision needed	2	0.25	0.05	1.24	NS	0.532	0

<sup>a</sup>Fixed-effects model.

I<sup>2</sup> statistic defined as the proportion of heterogeneity not due to chance or random error.

SMD, standardized mean difference; OR, odds ratio; LL, lower limit; UL, upper limit; NS, not significantly different.

patients (2.9%). The meta-analysis for combined results suggested a significant difference (OR 0.26; 95% CI 0.09, 0.99), with partial heterogeneity ( $I^2 = 39.7\%$ ; Figure 6).

Nonunion is an important complication of this fracture, as it commonly necessitates a second operation for bone grafting and implant fixation. Six studies reported the incidence of nonunion, with slightly higher reports in PF patients than in IF patients (5.1% versus 4.7%). The meta-analysis result was not significant (OR 0.96; 95% CI 0.46, 2.00) without any heterogeneity (Figure 7).

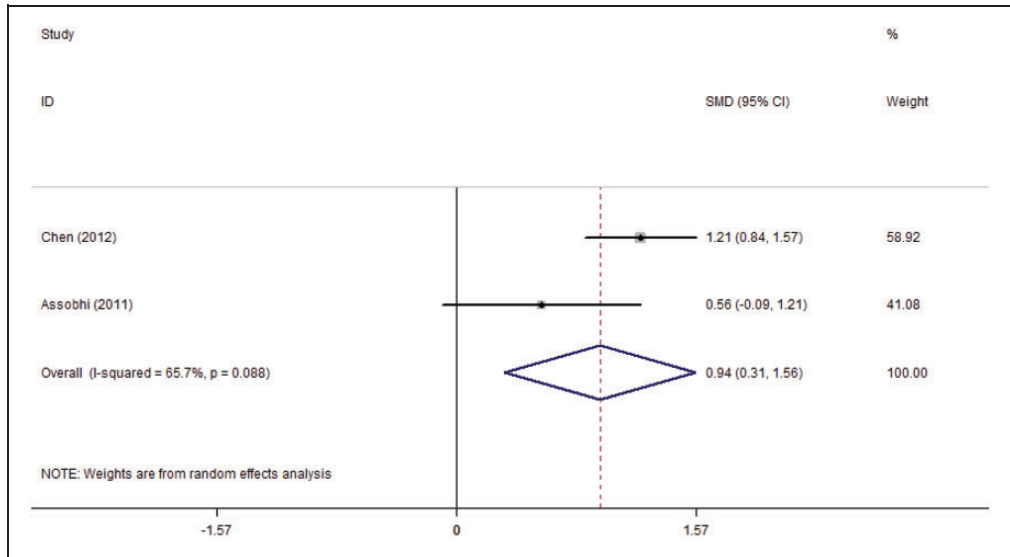
There were no significant differences in temporary brachial plexus lesion, nonunion, malunion, implant failure and the need for major revision between the fixation techniques. For these variables, there was no statistically significant heterogeneity when investigated using both  $Q$ - and  $I^2$  statistics (Table 3).

### Functional outcome and motion range

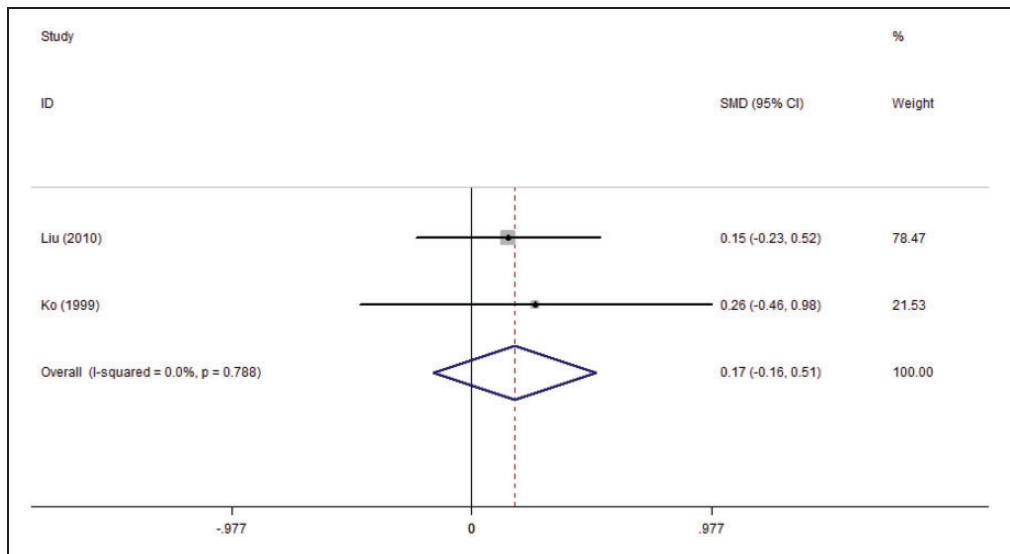
Liu et al.<sup>35</sup> and Ko et al.<sup>36</sup> reported shoulder motion in their studies, including forward flexion, abduction, external rotation and internal rotation. There were no significant differences for these items between PF and IF in the current study, and heterogeneity was not observed for any item (Table 3).

The shoulder constant score<sup>37</sup> is used to assess the extent of functional recovery, with higher scores representing better rehabilitation. Constant scores at 6 months were reported by three studies, at 12 months by three studies and at 24-months follow-up by two studies. At 6-month follow-up, patients from the IF group had a higher constant score (92.6 versus 87.2) than those in the PF group: this finding was not significant by meta-analysis (SMD 0.94; 95% CI 0.31, 1.56) but there was significant heterogeneity (Figure 8). However, at the 12- and 24-month follow-up appointments, the results between groups were not significantly different (Table 3).

The Disability of Arm, Shoulder and Hand (DASH) questionnaire<sup>37</sup> is a standardized 30-item measure evaluating patients' subjective perception of their upper extremity health status, including impairments and activity limitations. Response options range between 1 and 5, based on the ability to perform activities (1, no difficulty; 2, mild difficulty; 3, moderate difficulty; 4, severe difficulty; 5, unable); the score ranges between 0 and 100, with 0 indicating no disability and 100 indicating complete disability. In this study, DASH score at the 6-month follow-up was reported in one study,<sup>15</sup> where IF patients scored better than



**Figure 8.** Forest plot for the shoulder constant score reported in three studies at 12-month follow-up in intramedullary fixation (IF) and plate fixation (PF) patients during recovery from midshaft clavicle fracture;  $I^2 = 65.7\%$ ,  $P =$  not significant.



**Figure 9.** Forest plot for the Disability of Arm, Shoulder and Hand (DASH) questionnaire<sup>37</sup> scores at 12-month follow-up reported in two studies of intramedullary fixation (IF) and plate fixation (PF) patients during recovery from midshaft clavicle fracture;  $I^2 = 0.0\%$ ,  $P =$  not significant.

PF patients, with a significantly lower score (6.6 versus 15.0). The authors also reported the outcome of DASH at the 24-month follow-up, when no significant difference was observed. A further two studies<sup>35,36</sup> reported that at the 12-month follow-up, the DASH score between IF and PF was not statistically different (SMD 0.17; 95% CI -0.16, 0.31); the meta-analysis showed no heterogeneity (Figure 9).

### Descriptive analysis

Union time was reported to be shorter with IF than with PF, but it was not possible to perform a meta-analysis on this variable due to significant heterogeneity and the different forms that the data were presented in the original studies. The American Shoulder and Elbow Surgeons (ASES) scale<sup>37</sup> is a common tool to assess shoulder function recovery. Narsaria et al.<sup>24</sup> reported that the ASES score at the 24-month postoperative follow-up was slightly higher in PF patients than in IF patients (99.4 versus 96.8), but this finding was not significantly different.

### Discussion

Midshaft clavicle fracture has traditionally been treated conservatively, without surgery, but this method has a high rate of complications.<sup>6,8</sup> Surgery appears to offer a better alternative for fractures of this type.<sup>38</sup> However, there is controversy regarding whether IF or PF provides the optimum outcome for patients. In this study, a meta-analysis of 12 original studies was used to address this key issue. The results showed that IF outperformed PF, with a lower rate of symptomatic hardware, less hypertrophic scarring, fewer refractures after implant removal and better functional outcome at the 6-month follow-up. Other complications (including overall complications, implant failure, nonunion, malunion, delayed union, the need for major revision surgery, temporary

brachial plexus lesion and reduced shoulder motion) showed no significant difference between the methods.

Surgeons commonly pay more attention to patients' complications that might affect prognosis and functional recovery; severe complications may cause secondary surgery.<sup>18,27,28</sup> A higher total complication incidence was more likely in the PF group than in the IF group<sup>18,39</sup> (OR 2.97). The complications of acute midshaft clavicular fracture in active young patients were due to surgical procedures and the actual implant itself, and less associated with the patients' underlying diseases. In this study, three implant-related complications: symptomatic hardware, hypertrophic scarring and refracture after implant removal were all more likely to occur in PF rather than IF groups. As PF generally requires a large incision, extensive exposure and soft tissue dissection, this technique is more likely to produce hypertrophic scarring, compared with IF. In a study by Kwak-Lee,<sup>26</sup> 16.4% of patients sustained symptomatic hardware or incision complications, which were attributed to intraoperative traction and/or stretching of the nerves over the plate. Refracture after hardware removal was reported to occur only in patients treated with plates, with an overall incidence of 6.3% (10/158)<sup>24,25,28,34,39</sup> mostly occurring at the junction of the middle-third and outer-third regions of the clavicle. Implant removal after fracture healing reduces the mechanical strength of the clavicle, and the screw holes create weak spots in this thin bone, which together may initiate refracture.<sup>28,39</sup>

Implant failure is an important complication that affects operative success and causes over 80% of the revision surgery for midshaft clavicular fractures.<sup>28</sup> In this analysis, the incidence of implant failure was similar in both techniques. In PF, implant failure was mainly triggered by excessive movement and often manifested as plate bending or loosening; in IF, lack of stability caused migration of

the intramedullary device.<sup>40,41</sup> Therefore, to prevent this complication, the stability of IF needs to be improved, and excessive movement, especially in the early stages of recovery from PF surgery, should be minimized.<sup>15,26,42</sup>

No significant difference was observed in shoulder motion range and functional recovery between IF and PF, except for the Constant Score at the 6-month follow-up. This suggests that IF is more likely than PF to yield a better early functional outcome, but there is no difference between the techniques at the bone union stage and the late stage of recovery. In some studies, rapid union has been confirmed with IF, which might be important in functional recovery and shoulder motion.<sup>24,26,34,39</sup>

The present study suffers from some weaknesses. Firstly, only four prospective RCTs were included in this meta-analysis, which might lower the power. Secondly, the types of fixations applied in the studies were varied and the follow-up periods of each study ranged widely. Thirdly, the age of patients in each group was not similar, except for one study. The choice of treatment was decided by the demands of each treatment, the surgeons' experience and the patients' underlying medical conditions. Advanced age generally has a negative effect on the level of function restored, and this aspect needs further future study.

Although this study had limitations that were unavoidable, it still has merit. First, the search style using both the computer and manual searching ensures a complete inclusion of relevant studies. Secondly, no significant heterogeneity was observed in most variables, except for active external rotation. This heterogeneity was diminished by sensitivity analysis, without altering the result. Lastly, but most importantly, this is the first quantitative meta-analysis to date to give a definitive preference to one of the two methods for treating complex fractures of the proximal humerus, reflecting the current status of this issue.

In conclusion, based on present evidence, IF appears to be superior to PF for the management of midshaft clavicle fractures. Compared with PF, IF provides a better shoulder constant score at 6 months and fewer incidences of symptomatic hardware, refracture after hardware removal and hypertrophic scarring. This could aid surgeons in making decisions for fixing midshaft clavicular fractures.

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### Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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