

Plating versus intramedullary fixation for mid-shaft clavicle fractures: a systemic review and meta-analysis

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ABSTRACT

Background. Plate fixation and intramedullary fixation are the most commonly used surgical treatment options for mid-shaft clavicle fractures; the latter method has demonstrated better performance in some studies.

Objectives. Our aim was to critically review and summarize the literature comparing the outcomes of mid-shaft clavicle fracture treatment with plate fixation or intramedullary fixation to identify the better approach.

Search Methods. Potential academic articles were identified from the Cochrane Library, MEDLINE (1966-2015.5), PubMed (1966-2015.5), EMBASE (1980-2015.5) and ScienceDirect (1966-2015.5). Gray studies were identified from the references of the included literature.

Selection Criteria. Randomized controlled trials (RCTs) and non-RCTs comparing plate fixation and intramedullary fixation for mid-shaft clavicle fracture were included. Data Collection and Analysis. Two reviewers performed independent data abstraction. The I^2 statistic was used to assess heterogeneity. A fixed- or random-effects model was used for the meta-analysis.

Results. Six RCTs and nine non-RCTs were retrieved, including 513 patients in the intramedullary fixation group and 521 patients in the plating group. No significant differences in terms of the union rate and shoulder function were found between the groups. Patients in the intramedullary fixation group had a shorter operative time, less blood loss, smaller wound size, and shorter union time than those in the plating group. With respect to complications, significant differences were identified for all complications and major complications (wound infection, nonunion, implant failures, transient brachial plexopathy, and pain after 6 months). Similar secondary complications (symptomatic hardware, hardware irritation, prominence, numbness, hypertrophic callus) were observed in both groups.

Conclusions. Intramedullary fixation may be superior to plate fixation in the treatment of mid-shaft clavicle fractures, with similar performance in terms of the union rate and shoulder function, better operative parameters and fewer complications.

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Additional Information and Declarations can be found on page 14

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Keywords Mid-shaft clavicle fractures, Meta-analysis, Plating fixation, Intramedullary fixation

INTRODUCTION

Clavicular fractures are common, comprising 2.6–10% of all fractures (*O'Neill et al.*, 2011), and approximately 80% of clavicle fractures involve the middle shaft. The majority of these clavicle fractures occur in patients who are younger than 40 or older than 70 years (*Kim & McKee*, 2008). Non-operative therapy can be successful, with high union rates that may be maintained for decades. Although only 7% of patients with clavicle fractures developed nonunion after conservative treatment, 46% of patients in the study of *Nowak*, *Holgersson & Larsson (2004)* had persistent symptoms 10 years after the injury. Based on recent studies, there has been a trend toward the surgical treatment of clavicle fractures.

More than 50% of clavicle fractures are displaced (*Postacchini et al.*, 2002). Displaced fractures carry a risk of malunion or nonunion, both of which result in non-satisfactory function. According to *Zlowodzki et al.* (2005), the overall nonunion rate for clavicle fractures was 5.9%, whereas the rate for displaced fractures was 15.1%. Recent prospective randomized studies have reported superior functional results with intramedullary nailing (*Smekal et al.*, 2009) or plating (*Society*, 2007) compared with conservative treatment. Moreover, a recent meta-analysis revealed a significantly lower nonunion rate after surgical treatment (*Zlowodzki et al.*, 2005). Early surgical intervention has therefore been suggested to improve outcomes and to decrease the rates of nonunion and symptomatic malunion in mid-shaft clavicle fractures with the following features: open injury, shortening or displacement >20 mm, multiple trauma, floating shoulder, or cosmetic concerns (*Society*, 2007; *Hill*, *McGuire & Crosby*, 1997).

Plate fixation is the standard surgical therapy for mid-shaft clavicular fractures (Ali & Lucas, 1978). A 2.2% nonunion rate was reported in a review synthesizing the results of earlier studies on displaced clavicular fractures treated by plate fixation (*Zlowodzki* et al., 2005). However, clavicular plates require larger skin incisions and extensive soft tissue stripping, which increase the risk for nonunion and wound infection. Moreover, clavicle re-fracture occurred after plate removal in 0–8% of the patients (Bostman, Manninen & Pihlajamaki, 1997; Poigenfurst, Rappold & Fischer, 1992). The Knowles pin, the Rockwood pin, and the titanium elastic nail (TEN) have been developed to minimize postoperative complications (Jubel et al., 2003). From a biomechanical perspective, intramedullary implant positioning is ideal (Mueller et al., 2008). With the advantages of intact hematoma maintenance, less soft tissue dissection and periosteal stripping, all of which can accelerate fracture healing, intramedullary fixation has been gaining attention for its superior performance. Unfortunately, hardware migration (including medial migration and lateral perforation) has been a problem with intramedullary fixation. The rate of TEN migration ranges between 4.5% and 26.6% in the literature (Meier, Grueninger & Platz, 2006; Kettler et al., 2007). Overall, different complication rates were reported for these two fixation methods, but no significant differences were

noted for most of them. Significantly more instances of symptomatic hardware, infection, nonunion, wound dehiscence, and refractures were reported with plate fixation than with intramedullary fixation in studies (*Lee et al., 2007; Saha et al., 2014; Narsaria et al., 2014*). Furthermore, mobilization after intramedullary fixation requires more attention because conduction stabilization is weaker with intramedullary fixation than with plate fixation (*Frigg et al., 2009*).

Several meta-analyses comparing plate and intramedullary fixation were published from 2011 to 2015 (*Duan et al., 2011; Houwert et al., 2012; Barlow, Beazley & Barlow, 2013; Zhu et al., 2015*). However, the studies included were not exactly comparable, and fewer than 5 RCTs or quasi-RCT (qRCT) studies were included. Here, we review and summarize all of the RCTs and non-RCTs comparing plate and intramedullary fixation in the hopes of presenting useful data to identify the better treatment choice and to confirm the findings of these studies.

MATERIAL AND METHODS

Inclusion and exclusion criteria

Trials with the following characteristics were included: (1) RCTs or non-RCTs, (2) patients with midshaft clavicle fractures from trauma and without pathological fractures, (3) comparison of the results of intramedullary and plating fixation, and (4) full-text articles. We excluded articles that were duplicate reports of earlier trials or post-hoc analyses of RCT data and articles without an available full-text version. Studies including patients suffering multiple traumas were also excluded.

Search strategy

Electronic searches of the Cochrane Library, MEDLINE (1966-2015.5), PubMed (1966-2015.5), EMBASE (1980-2015.5) and ScienceDirect (1966-2015.5) as well as other Internet databases were performed to identify trials, according to the Cochrane Collaboration guidelines. We used the following search terms and different combinations of Medical Subject Heading (MeSH) terms and textual words: "clavicle or clavicular," "fracture," "midshaft or mid-shaft," "intramedullary," "plate, plates or plating." Manual searches, including those of the reference lists of all included studies, were used to identify trials that the electronic search may have failed to identify. Two reviewers (Yan Gao and Zhao-Yu Chen) independently assessed the titles and abstracts of all of the reports identified by the electronic and manual searches. There was no restriction on language. When inclusion was unclear based on the abstracts alone, the full-text articles were retrieved. Any disagreements were resolved through discussion.

Assessment of methodological quality

Quality assessment of RCTs and non-RCTs was conducted according to a modification of the generic evaluation tool used by the Cochrane Bone, Joint and Muscle Trauma Group (*Handoll et al., 2008*) or the index for non-randomized studies form (*Slim et al., 2003*). The methodological quality of each trial was scored from 0 to 24. Disagreements were resolved by consensus or by consultation with the senior reviewer (Wei Chen).

Data extraction

Two authors (Yan Gao and Yue-Jv Liu) independently extracted data from the included articles. Information regarding the study design, patient demographics, inclusion and exclusion criteria, interventions, outcomes, follow-up duration and rate of loss to follow-up for each treatment group were extracted. When continuous outcomes were published as the median and range in the original papers, the mean value and standard deviation were estimated using the formula provided by *Hozo*, *Djulbegovic & Hozo* (2005) Data were managed using Review Manager (RevMan) 5.1 software (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark). We attempted to contact authors for supplementary information when the reported data were inadequate.

Data analysis and statistical methods

The meta-analysis was conducted using RevMan 5.1 for Windows (Cochrane Collaboration, Oxford, United Kingdom). Statistical heterogeneity was assessed for each study, using a standard Chi square test, with significance set at a *P* value of 0.1, which was measured by the I^2 statistic. When $I^2 > 50\%$, P < 0.1 was considered to be significant heterogeneity (*Higgins et al., 2003*). Therefore, a random-effects model was applied for data analysis (*Lau, Ioannidis & Schmid, 1997*). A fixed-effects model was used when no significant heterogeneity was found. In cases of significant heterogeneity, subgroup analysis was performed to investigate sources. The odds ratio (OR) and 95% confidence interval (CI) were calculated for dichotomous outcomes, whereas the mean difference (MD) and 95% CI were used for continuous outcomes.

RESULTS

Literature search

Figure 1 shows a flow chart of the study selection and inclusion process. The search strategy identified 194 citations; of these, six RCTs and nine non-RCTs met the predefined inclusion criteria for data extraction and meta-analysis.

Study characteristics

Individual patient data were obtained from these articles. Population information is summarized in Table 1. These studies included 513 patients in the intramedullary fixation (IF) group and 521 patients in the plate fixation (PF) group, excluding those lost to follow up. Between-group differences in the baseline characteristics were not found. The quality assessment scores of the studies ranged from 17 to 20.

Risk of bias assessment

For the RCTs, unclear blindness was the major problem (details are provided in Table 2). For the nine non-RCTs, no prospective calculation of the sample size was described. Moreover, no information regarding the unbiased assessment of study endpoints was available. Only five studies reported the relevant information regarding the prospective collection of data. The methodological quality assessment is illustrated in Fig. 2.

Table 1 Characteristics of included studies.

Study	Time	Туре	Invent	ion	Age	(years)	Gende	r(F/M)	Follow-	up(months)
			IF	PF	IF	PF	IF	PF	IF	PF
Lee YS et al.	2007	RCT	Knowles pin	DCP	60.4(50-81)	56.7(52–79)	32(19/13)	30(17/13)		30
Lee YS et al.	2008	RCT	Knowles pin	DCP, tubular and reconstruc- tion plate	40.1	38.2	56(19/37)	32(12/20)		12
Ferran NA et al.	2010	RCT	Rockwood Pin	LC-DCP	23.8(13-42)	35.4(16-53)	17(14/3)	15(13/2)	12.7 ± 3.5	12.1 ± 5.7
Assobhi JE et al.	2011	RCT	Titanium elastic nail	3.5 mm recon- struction plate	30.3 ± 4.8	32.6 ± 5.9	19(16/3)	19(17/2)	14.5 ± 1.5	18.6 ± 3.8
Narsaria N et al.	2014	RCT	Titanium elastic nail	3.5 mm DCP	38.9 ± 9.1	40.3 ± 11.2	33(9/24)	32(6/26)		24
Saha P et al.	2014	RCT	Titanium elastic nail	Locking plate	33.3 ± 11.8	33.0 ± 12.6	34(4/30)	37(7/30)	24.6 ± 2.4	25.1 ± 3.3
S, Thyagarajan D et al.	2009	nRCT	Rockwood Pin	LC-DCP	28(15-56)	32.1(17-46)	17(1/16)	17(2/15)	5.9	(4-11)
Liu HH et al.	2010	nRCT	Titanium elastic nail	Reconstruction LCP	33.6 ± 13.5	31.7 ± 9.7	51(19/32)	59(30/29)	17.7	(12–27)
Kleweno CP et al.	2011	nRCT	Rockwood Pin	Reconstruction plate or locking plate	35(16–56)	28(16-46)	18(3/15)	14(4/10)	8(3–28)	17(4–58)
Fu TH et al.	2012	nRCT	Knowles pin	Reconstruction plate	35.2 ± 14.5	39.9 ± 14.8	53(15/38)	40(17/33)	15(12–153)	14(12–92)
Chen YF et al.	2012	nRCT	Titanium elastic nail	3.5 mm recon- struction plates	38(26.5–58)	46.5(36.5–58.8)	25(15/10)	32(14/18)		12
Tarng YW et al.	2012	nRCT	Titanium elastic nail	Reconstruction plates	34.3(20-59)	36.5(19-63)	57(16/41)	84(23/61)		24
Wijdicks FJ et al.	2012	nRCT	Titanium elastic nail	Reconstruction plate or locking plate	39.4 ± 14.1	33.1 ± 15.6	43(10/33)	47(14/33)	6(5–12)	8(2–15)
Wenninger JJ et al.	2013	nRCT	Rigid Hagie pin	3.5 mm recon- struction plate or LC-DCP	25.2(18–51)	26.9(20-49)	33(1/32)	29(3/26)		12
Jones LD et al.	2014	nRCT	Titanium elastic nail	Ν	Ν	Ν	25	24	30(12–54)

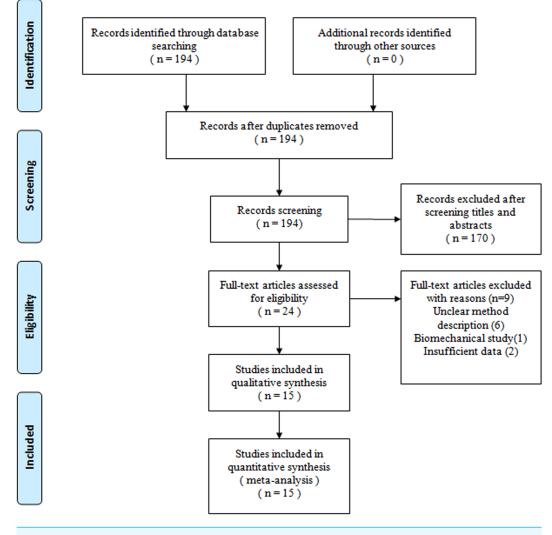


Figure 1 Flow chart showing identification and selection of cases.

Meta-analysis outcomes Blood loss

Blood loss was reported in five studies (*Liu et al., 2010b*; *Chen et al., 2012*; *Tarng et al., 2012*; *Saha et al., 2014*; *Narsaria et al., 2014*), including 200 patients in the IF group and 244 patients in the PF group. The mean blood loss and standard deviation were estimated from the study of *Tarng et al. (2012)*. Greater blood loss was observed in the PF group than in the IF group (MD = -64.14; 95% CI: [-66.88 to -61.40]; P < 0.001; Fig. 3).

Operative time

Operative time was reported in seven studies (*Lee et al.*, 2008; *Liu et al.*, 2010b; *Assobhi*, 2011; *Chen et al.*, 2012; *Tarng et al.*, 2012; *Narsaria et al.*, 2014; *Saha et al.*, 2014), including 275 patients in the IF group and 295 patients in the PF group. The mean operative time and standard deviation were estimated from the studies of *Tarng et al.* (2012) and

Table 2Quality assessment for randomized trials.

Quality assessment for randomized trials	Lee YS (2007)	Lee YS	Ferran NA	Assobhi JE	Narsaria N	Saha P
Was the assigned treatment adequately concealed prior to allocation?	1	1	2	2	2	1
Were the outcomes of participants who withdrew described and included in the analysis?	2	2	2	2	2	2
Were the treatment and control group comparable at entry?	2	2	2	2	2	2
Were the outcome assessors blinded to treatment status?	2	0	2	0	0	0
Were the participants blind to assignment status after allocation?	0	0	0	0	0	0
Were the treatment providers blind to assignment status?	0	0	0	0	0	0
Were care programs, other than the trial options, identical?	2	2	2	2	2	2
Were the inclusion and exclusion criteria clearly defined?	2	2	2	2	2	2
Were the interventions clearly defined?	2	2	2	2	2	2
Were the outcome measures used clearly defined?	2	2	2	2	2	2
Were diagnostic tests used in outcome assessment clinically useful?	2	2	2	2	2	2
Was the surveillance active, and of clinically appropriate duration?	2	2	2	2	2	2

Narsaria et al. (2014). The operative time was shorter in the IF group than in the PF group (MD = -22.30; 95% CI [-30.42 to -14.18]; P < 0.001; Fig. 4). High heterogeneity $(I^2 = 95\%)$ was found and was not significantly reduced when the analysis was performed using only four RCTs (*Lee et al., 2008; Assobhi, 2011; Narsaria et al., 2014; Saha et al., 2014*) (MD = -24.72; 95\% CI [-34.40 to -15.04]; P < 0.001).

Wound size

Six studies reported the size of the surgical wound (*Lee et al.*, 2007; *Liu et al.*, 2010b; *Assobhi, 2011; Tarng et al.*, 2012; *Fu et al.*, 2012; *Narsaria et al.*, 2014). The wound size was smaller in the IF group than in the PF group (MD = -5.07; 95% CI [-6.00 to -4.13]; P < 0.001; $I^2 = 97\%$, Fig. 5). This result did not significantly change when the result of *Liu et al.* (2010a) was excluded because of a significantly larger wound size (MD = -4.36; 95% CI [-5.22 to -3.50]; P < 0.001).

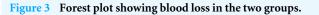
Hospital stay

The length of hospital stay was reported in five studies, including 3 RCTs (*Lee et al., 2007*; *Assobhi, 2011*; *Narsaria et al., 2014*) and 2 non-RCTs (*Liu et al., 2010b*; *Tarng et al., 2012*). Two studies (*Liu et al., 2010b*; *Assobhi, 2011*) provided the original mean and standard deviation, while the other studies published the median and range. The length of hospital stay was shorter in the IF group than in the PF group, regardless of whether the meta-analysis was performed on all of the included studies (MD = -1.31; 95% CI [-1.69 to -0.93]; *P* < 0.001; *I*² = 80%; Fig. 6), on RCTs only (MD = -1.57; 95% CI [-2.30 to -0.84]; *P* < 0.001; *I*² = 85%), or on only the studies providing the original mean and standard deviation (MD = -0.98; 95% CI [-1.36 to -0.59]; *P* < 0.001).

	A clearly stated aim	Inclusion of consecutive patients	Prospective data collection	Appropriate endpoints	Unbiased assessment of the study endpoint	Appropriate follow-up period	Less than 5 % loss to follow-up	Prospective calculation of the sample size	An adequate control group	Contemporary groups	Baseline equivalence of groups	Adequate statistical analyses
Chen, YF 2012	•	•	ŧ	•		•	•		•	•	•	•
Fu TH 2012	•	+	ŧ	÷		÷	÷		÷		+	•
Jones, LD 2014	•	•		•		•	•		•	•	•	•
Kleweno, CP 2011	•	•	•	•		•			•	•	•	•
Liu HH 2010	•	•	•	•	•	•	•		•	•	•	•
S, Thyagarajan D 2009	•	•		•		•	•		•	•	•	•
Tarng, YW 2012	•	•	•	•		•	•		•	•	•	•
Wenninger JJ 2013	•	•		•		•	•		•	•	•	•
Wijdicks FJ 2012	•	•		•	•	?	•		•	•	•	•

Figure 2 Quality assessment for non-randomized trials.

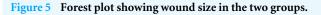
		IF			PF			Mean Difference		Mean Di	fference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% Cl	Year	IV, Fixed	, 95% Cl
Liu HH 2010	67.4	36.7	51	127.9	48.8	59	2.9%	-60.50 [-76.52, -44.48]	2010	<u> </u>	
Chen, YF 2012	65.1	26.5	57	116.3	42.3	84	5.8%	-51.20 [-62.56, -39.84]	2012		
Tarng, YW 2012	12	1.25	25	77.5	8.75	32	79.8%	-65.50 [-68.57, -62.43]	2012		
Saha P 2014	47.7	44.7	34	116.5	38.6	37	2.0%	-68.80 [-88.30, -49.30]	2014		
Narsaria N 2014	70	15	33	130.8	21	32	9.5%	-60.80 [-69.70, -51.90]	2014		
Total (95% CI)			200			244	100.0%	-64.14 [-66.88, -61.40]		•	
Heterogeneity: Chi ² =	6.69, df	= 4 (P	= 0.15)); I² = 40	%					-100 -50 1	1 50 100
Test for overall effect	Z = 45.8	3 (P <	0.0000	01)						Favours IF	



		IF			PF			Mean Difference		Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	Year	IV, Random, 95% Cl
Lee YS 2008	27.5	10.3	56	68.4	19.6	32	20.1%	-40.90 [-48.21, -33.59]	2008	
Liu HH 2010	72.8	26.3	51	75.8	23	59	19.0%	-3.00 [-12.30, 6.30]	2010	
Assobhi JE 2011	44.1	9.1	19	68.1	10.9	19	20.5%	-24.00 [-30.38, -17.62]	2011	+
Tarng, YW-2012	32	2.75	25	65	2.5	32	0.0%	-33.00 [-34.38, -31.62]	2012	
Chen, YF 2012	48.3	19.8	57	66.5	22.5	84	20.2%	-18.20 [-25.24, -11.16]	2012	
Narsaria N 2014	40.2	6.75	33	58.4	8	32	0.0%	-18.20 [-21.80, -14.60]	2014	
Saha P 201 4	51.2	16.2	34	67.8	14.4	37	20.2%	-16.60 [-23.75, -9.45]	2014	-
Total (95% CI)			217			231	100.0%	-20.73 [-31.78, -9.68]		•
Heterogeneity: Tau ² =	144.31;	Chi ^z =	= 45.41	df = 4 (P < 0.0	00001)	; I ^z = 91 %			
Test for overall effect:	Z = 3.68	(P = 0	0.0002)							Favours IF Favours PF



		IF			PF			Mean Difference	Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	Year	IV, Random, 95% Cl
Lee YS 2008	4.1	0.3	56	8.4	1.6	32	17.4%	-4.30 [-4.86, -3.74]	2008	3 🗕
Liu HH 2010	11.9	4.4	51	22.3	4.5	59	11.7%	-10.40 [-12.07, -8.73]	2010) ←
Assobhi JE 2011	4.3	0.8	19	8.5	1.6	19	16.3%	-4.20 [-5.00, -3.40]	2011	-
Tamg, YW 2012	З	0.3	25	7.5	0.3	32	18.4%	-4.50 [-4.66, -4.34]	2012	2 •
Fu TH 2012	5.3	0.9	53	8.4	0.5	50	18.2%	-3.10 [-3.38, -2.82]	2012	•
Narsaria N 2014	4.5	0.6	33	10.2	0.9	32	18.0%	-5.70 [-6.07, -5.33]	2014	
Total (95% CI)			237			224	100.0%	-5.07 [-6.00, -4.13]		•
Heterogeneity: Tau ² =	= 1.24; C	hi²=	181.52	, df = 5 ((P < 0	.00001); l ² = 97°	Х		
Test for overall effect	: Z = 10.5	9 (P	< 0.000	001)						-10 -5 0 5 10 Favours IF Favours PF



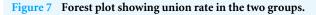
		IF			PF			Mean Difference		Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	Year	IV, Random, 95% Cl
Lee YS 2007	6.2	1.25	32	9.1	2.5	30	10.0%	-2.90 [-3.89, -1.91]	2007	
Liu HH 2010	4.6	2.1	51	5.9	2.6	59	11.8%	-1.30 [-2.18, -0.42]	2010	
Assobhi JE 2011	1.4	0.5	19	2.3	0.8	19	22.3%	-0.90 [-1.32, -0.48]	2011	
Tarng, YW 2012	3	0.25	25	4	0.25	32	29.5%	-1.00 [-1.13, -0.87]	2012	•
Narsaria N 2014	1.4	0.25	33	2.8	0.75	32	26.5%	-1.40 [-1.67, -1.13]	2014	•
Total (95% CI)			160			172	100.0%	-1.31 [-1.69, -0.93]		•
Heterogeneity: Tau ²	= 0.13; C	hi ² = 2	0.48, d	f= 4 (P :	= 0.00	04); P=	: 80%			
Test for overall effec	t Z = 6.68) (P < (0.0000°	I)						Favours IF Favours PF



Union rate and union time

The union rate was reported in all of the included studies. Neither total nor subgroup analysis of RCTs and non-RCTs revealed significant differences between the fixation methods (OR = 1.41; 95% CI [0.73–2.75]; P = 0.31), (OR = 2.20; 95% CI [0.57–7.77]; P = 0.27), and (OR = 1.23; 95% CI [0.56–2.66]; P = 0.61; Fig. 7). Union time data were extracted from four RCTs (*Lee et al., 2008; Assobhi, 2011; Saha et al., 2014; Narsaria et al., 2014*) and two non-RCTs (*Liu et al., 2010b; Chen et al., 2012*). The results based on all of the included studies showed shorter union times in the IF group than in the PF group (MD = -16.25; 95% CI [-28.03 to -4.47]; P = 0.007; Fig. 8). The union time was also shorter in the IF group than in the PF group when the analysis was performed only on RCTs (MD = -26.40; 95% CI [-46.20 to -6.61]; P = 0.009).

	IF		PF			Odds Ratio		Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl	Year	M-H, Random, 95% Cl
5.1.1 results of RCT								
Lee YS 2007	32	32	29	30	5.1%	3.31 [0.13, 84.32]	2007	
Lee YS 2008	56	56	31	32	5.1%	5.38 [0.21, 136.05]	2008	
Ferran NA 2010	17	17	15	15		Not estimable	2010	
Assobhi JE 2011	19	19	18	19	5.0%	3.16 [0.12, 82.64]	2011	
Narsaria N 2014	32	33	32	32	5.1%	0.33 [0.01, 8.49]	2014	
Saha P 2014	34	34	36	37	5.1%	2.84 [0.11, 71.99]	2014	
Subtotal (95% CI)		191		165	25.3%	2.21 [0.52, 9.43]		
Total events	190		161					
Heterogeneity: Tau ² = 0.0	00; Chi² =	1.74, d	f = 4 (P =	0.78);1	z =0%			
Test for overall effect: Z =	1.07 (P =	0.28)						
5.1.2 results of nRCT								
S, Thyagarajan D 2009	17	17	16	17	5.0%	3.18 [0.12, 83.76]	2009	
Liu HH 2010	46	51	53	59	33.9%	1.04 [0.30, 3.64]	2010	-
Kleweno, CP 2011	18	18	13	14	4.9%	4.11 [0.16, 108.88]	2011	
Tarng, YW 2012	25	25	31	32	5.0%	2.43 [0.09, 62.19]	2012	
Wijdicks FJ 2012	43	43	47	47		Not estimable	2012	
Chen, YF 2012	49	53	49	50	10.7%	0.25 [0.03, 2.32]	2012	
Fu TH 2012	56	57	81	84	10.1%	2.07 [0.21, 20.45]	2012	
Wenninger JJ 2013	33	33	29	29		Not estimable	2013	
Jones, LD 2014	25	25	23	24	5.0%	3.26 [0.13, 83.90]	2014	
Subtotal (95% CI)		322		356	74.7%	1.26 [0.54, 2.92]		•
Total events	312		342					
Heterogeneity: Tau ² = 0.0)0; Chi² =	3.59, d	f = 6 (P =	0.73);1	z = 0%			
Test for overall effect: Z =	0.53 (P =	0.60)						
								-
Total (95% Cl)		513		521	100.0 %	1.45 [0.70, 3.00]		-
Total events	502		503					
Heterogeneity: Tau ² = 0.0)0; Chi² =	5.76, đ	f = 11 (P :	= 0.89);	l² = 0%			
Test for overall effect: Z =								Favours IF Favours PF
Test for subaroup differe	nces: Chi	² = 0.44	l. df = 1 (l	$P = 0.5^{\circ}$	I), I ≃ = 0%			



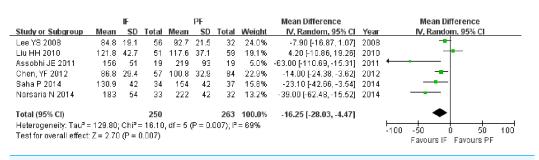


Figure 8 Forest plot showing union time in the two groups.

Shoulder score

Six RCTs (*Lee et al.*, 2007; *Lee et al.*, 2008; *Ferran et al.*, 2010; *Assobhi*, 2011; *Saha et al.*, 2014; *Narsaria et al.*, 2014) and three non-RCTs (*S et al.*, 2009; *Liu et al.*, 2010b; *Tarng et al.*, 2012), including 260 patients in the IF group and 273 patients in the PF group, published the Shoulder score. The meta-analysis based on all included studies did not show superior function in either group (MD = 1.82; 95% CI [-0.05-3.70]; *P* = 0.06; Fig. 9); similar results were observed when the analysis included only RCTs (MD = 1.42; 95% CI [-0.68-3.52]; *P* = 0.19).

		IF			PF			Mean Difference		Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	Year	IV, Random, 95% Cl
Lee YS 2007	85	8.75	32	84	10	30	7.8%	1.00 [-3.69, 5.69]	2007	-
Lee YS 2008	95.3	4.1	32	93.1	3.8	32	13.1%	2.20 [0.26, 4.14]	2008	
S, Thyagarajan D 2009	97.8	2.5	17	93.7	4.4	17	12.2%	4.10 [1.69, 6.51]	2009	
Liu HH 2010	86.7	5.3	51	88	4.8	59	13.1%	-1.30 [-3.20, 0.60]	2010	
Ferran NA 2010	92.1	6	17	88.7	9.1	15	6.7%	3.40 [-2.02, 8.82]	2010	
Assobhi JE 2011	95.5	5.3	19	89.9	11.3	19	6.4%	5.60 [-0.01, 11.21]	2011	
Tarng, YW 2012	96	2	25	92	3.1	32	14.1%	4.00 [2.67, 5.33]	2012	
Saha P 2014	92.3	4.8	34	90.7	4.6	37	12.6%	1.60 [-0.59, 3.79]	2014	+
Narsaria N 2014	94.6	3.2	33	96.2	2.6	32	14.0%	-1.60 [-3.02, -0.18]	2014	
Total (95% Cl)			260			273	100.0%	1.82 [-0.05, 3.70]		•
Heterogeneity: Tau ² = 6.0)3; Chi ≊ =	47.88	8, df = 8) (P < 0.1	00001)); l≊ = 8	3%			
Test for overall effect: Z =	1.91 (P	= 0.06)							-10 -5 0 5 10 Favours IF Favours PF
			·							Favours IF Favours PF

Figure 9 Forest plot showing shoulder score in the two groups.

Complications

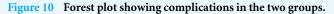
All included studies reported on complications related to IF or PF, and more complications occurred in the PF group than in the IF group (OR = 0.43; 95% CI [0.25–0.76]; P = 0.003; Fig. 10). When only the major complications (wound infection, nonunion, implant failures, transient brachial plexopathy, and pain after 6 months) were considered, the subgroup analysis also showed more major complications in the PF group than in the IF group (OR = 0.52; 95% CI [0.33–0.81]; P = 0.004). No significant differences were found in secondary complications (OR = 0.43; 95% CI [0.16–1.15]; P = 0.09).

DISCUSSION

With lower nonunion and malunion rates and better function, especially for displaced fractures, early operative interventions have become the preferred treatment method for mid-shaft clavicular fractures. This meta-analysis reviewed and summarized data from the literature comparing plating fixation and intramedullary fixation. Both surgical techniques showed similar performance in terms of the union rate and shoulder function. With less blood loss, shorter operative time, shorter hospital stay, shorter time to union, and fewer major complications, intramedullary fixation showed better results than plate fixation. Similar results were reported in a meta-analysis of open reduction and internal fixation versus TEN by *Duan et al. (2011)*, who observed no significant difference in treatment effects but more side effects in the patients treated with plates (*Houwert et al., 2012*).

The power of a meta-analysis depends on the quality of the included studies. To provide better evidence for clinical application, we searched and included RCTs and non-RCTs with quality assessment scores ranging from 17 to 20. For the RCTs, the patients were randomized into two groups using an envelope method in three studies and an alternating one-by-one allocation method in the other studies. The major problem was that not enough information was provided to indicate that participants and treatment providers were blinded to the assignment status. Only two studies described assessor blinding. No prospective calculation of the sample size was described in the non-RCTs. Moreover, the assessment of the study endpoints was biased. All of these shortcomings weaken the level of evidence.

	IF		PF			Odds Ratio		Odds Ratio
Study or Subgroup		Total	Events	Total	Weight	M-H, Random, 95% Cl	Year	M-H, Random, 95% Cl
8.1.1 major complication								
Lee YS 2007	0	32	4	30	2.2%	0.09 [0.00, 1.76]		
Lee YS 2008	0	56	3	32	2.2%	0.07 [0.00, 1.49]	2008	• • • • • • • • • • • • • • • • • • • •
S, Thyagarajan D 2009	2	17	5	17	3.5%	0.32 [0.05, 1.95]	2009	
Ferran NA 2010	0	17	3	15	2.1%	0.10 [0.00, 2.16]	2010	·
Liu HH 2010	12	51	17	59	4.9%	0.76 [0.32, 1.79]	2010	
Assobhi JE 2011	0	19	3	19	2.1%	0.12 [0.01, 2.51]	2011	<
Kleweno, CP 2011	3	18	1	14	2.8%	2.60 [0.24, 28.15]	2011	
Fu TH 2012	4	43	6	47	4.2%	0.70 [0.18, 2.67]	2012	
Tarng, YW 2012	0	57	2	84	2.1%	0.29 [0.01, 6.09]	2012	
Chen, YF 2012	6	53	14	50	4.6%	0.33 [0.11, 0.94]	2012	
Wildicks FJ 2012	15	25	17	32	4.6%	1.32 [0.46, 3.82]		
Wenninger JJ 2013	1	33	0	29	2.0%	2.72 [0.11, 69.47]		
Jones, LD 2014	2	25	3	24	3.4%	0.61 [0.09, 4.01]		
Saha P 2014	0	34	5	37	2.2%	0.09 [0.00, 1.61]		← <u> </u>
Narsaria N 2014	3	33	8	32	4.1%	0.30 [0.07, 1.26]		
Subtotal (95% CI)	, i	513	Ŭ	521	46.8%	0.52 [0.33, 0.81]	2011	•
Total events	48		91			5152 [5156, 515 I]		-
Heterogeneity: Tau ² = 0.0		14 99		2 = 0.38) [,] I ² = 7%			
Test for overall effect Z =				- 0.50), 1 - 7 %			
	2.01 (1 -	0.004)						
8.1.2 secondary complic	ations							
Lee YS 2007	4	32	12	30	4.3%	0.21 [0.06, 0.77]	2007	
Lee YS 2008	4	56	12	32	4.3%	0.13 [0.04, 0.44]		<u> </u>
S, Thyagarajan D 2009	1	17	12	17	2.9%	0.03 [0.00, 0.25]		←
Liu HH 2010	4	17	12	15	3.7%	0.08 [0.01, 0.42]		
Ferran NA 2010	4	51	1	59	3.0%	4.94 [0.53, 45.67]		
Kleweno, CP 2011	2	19	2	19	3.2%	1.00 [0.13, 7.94]		
Assobhi JE 2011	4	18	7	14	3.9%	0.29 [0.06, 1.32]		
Tarng, YW 2012	4	43	8	47	4.3%	0.50 [0.14, 1.80]		_
Wijdicks FJ 2012	26	57	17	84	5.0%	3.31 [1.57, 6.96]		
Fu TH 2012	20	53	22	50	4.3%	0.08 [0.02, 0.28]		
Chen, YF 2012	22	25	22	32	4.0%	26.19 [6.03, 113.78]		
Wenninger JJ 2013	22	33	7	32 29	3.7%	0.20 [0.04, 1.07]		
Saha P 2014	13	25	15	29	3.7 % 4.5%	0.65 [0.21, 2.03]		
		34	4	24 37	4.0%			←
Narsaria N 2014	0 0	33	4	32	2.270	0.11 [0.01, 2.08]		
Jones, LD 2014 Subtatel (05%, CD	U	513	U	521	E2 31/	Not estimable	2014	
Subtotal (95% CI)		212	400	521	53.2%	0.43 [0.16, 1.15]		
Total events	93		138		0040.17			
Heterogeneity: Tau ² = 2.8			at = 13 (F	< 0.00	001); F =	85%		
Test for overall effect Z =	1.67 (P =	0.09)						
Total (95% CI)		1026		1042	100.0%	0.43 [0.25, 0.76]		•
Total events	141		229			and force, on of		-
Heterogeneity: Tau ² = 1.5		QQ /1		2 < D DO	001): 12-	77%		
Test for overall effect Z =				× 0.00	001),1 =	12.0		0.01 0.1 1 10 100
Test for subaroup differen				0 - 0 7	ov i z – 000			Favours IF Favours PF
rearior suburoup diliere	nces. offi	- 0.11	. ar = 1 ti	= 0.7	55. F= 0%	,		



Compared with open reduction and internal fixation with plates, intramedullary fixation with nails or pins has minimally invasive characteristics, including smaller skin incisions and reduced soft tissue stripping, which are attractive qualities. Therefore, less blood loss, a shorter operative time and a shorter hospital stay definitely benefitted the patients who received intramedullary fixation. Preservation of the soft tissue envelope and periosteum increases the chances of healing (*Liu et al., 2010b*). Stable fixation is another basic principle that can ensure fracture union.

The S-shaped clavicle, as the only bone connecting the upper limb with the body, behaves in a complex manner. Plate fixation is better able to resist the bending and torsional forces exerted during elevation of the upper extremity above shoulder level, thereby potentially providing a stronger construction for early rehabilitation protocols (*Golish et al., 2008*). Therefore, similar union rates can be realized by either intramedullary fixation

or plate fixation because of the sufficient blood supply and stable fixation, as observed in our present review.

Union is the fundamental factor for shoulder function recovery after fractures; for this reason, no significant difference was observed between the union rates of the groups. However, union is not the only factor that can influence clinical function after a clavicular fracture (Lazarides & Zafiropoulos, 2006). The clavicle length plays an important role in maintaining anatomical relationships (McKee et al., 2006). Malunion with more than 15 mm of shortening has been reported to result in weakness of the glenohumeral extension and abduction (Ledger et al., 2005). Compared with fixation using intramedullary devices, fixation with a contoured plate is the best choice for maintaining the S-shape and length of the clavicle, especially for comminuted fractures. TEN, a newly designed intramedullary device with a curved tip, is flexible and fixed in the cancellous substance of the distal clavicle, and it can better accommodate the S-shaped contour of the clavicle and more tightly adhere to the cortex compared with K-wires, screws, or pins. Surprisingly, clavicle shortening was reported by Chen et al. (2012), with 2 cases in the TEN group, and by Wijdicks et al., with 6 cases in the elastic stable intramedullary nail group; additionally, Saha et al., reported clavicle shortening by 6.29 ± 3.75 mm in the TEN group. We suggest that both plate and intramedullary devices can restore the clavicle to an ideal length to regain most shoulder function. The residual shortening after plate or intramedullary fixation does not significantly influence shoulder function. However, many other factors may also contribute to shoulder function.

As in the study of *Assobhi (2011)*, complications were divided into major complications (including nonunion, infection, implant failure, re-fracture, and transient brachial plexopathy) and secondary complications regarding cosmesis. Extensive soft tissue exposure carries significant risks for nonunion and wound infection in plate fixation. More re-fractures occurred in the plating group because rigid fixation could introduce stress shielding, resulting in bone weakness. Moreover, screw holes may act as focal points for stress, thereby leading to re-fracture. Hardware prominence is the major problem for intramedullary devices. In the literature, the reported rate of hardware prominence ranged from 5.2% to 38.8% with the use of an elastic intramedullary nail (*Smekal et al., 2009; Jubel et al., 2003; Frigg et al., 2009)*. Careful surgical manipulation is necessary to avoid prominence. Additionally, cosmetic problems, including hypertrophic scarring and implant prominence, were reported in some studies that showed better results for pin fixation; the lack of such cosmetic problems could be an important factor contributing to the acceptance of this method.

The physiotherapy mentioned in some studies included sling protection for 2–4 weeks post-operatively, instructions for gentle and passive range of motion shoulder movements, normal daily activities after a 4-week postoperative period, or weight lifting and the return to full activities after complete fracture healing. Because the activities were similar for both procedures, we trusted that no significant differences exist between the two procedures based on the information we could obtain.

Some limitations should be considered when interpreting these analyses. First, various intramedullary devices and plates were applied in the included studies. Accordingly,

we could only report the average performance; thus, more attention must be focused on choosing a specific pin or nail in clinical practice. The TEN was the most frequently used intramedullary device; more analysis regarding this implant will be necessary in the future. Moreover, classifying some complications as minor may be inappropriate because cosmetic problems are also important issues for female patients. More details of special interest should be considered in the future. As we were limited by unavailable data on the facilities in different cities, we could not analyze the impact of these different facilities on decision making and outcomes. Classifying and comparing outcomes in a chronological order is also difficult to perform. Despite these limitations, we have provided the most comprehensive data comparing plate fixation with intramedullary fixation in the treatment of clavicle fractures.

CONCLUSION

Based on the results of our meta-analysis, both plate and intramedullary fixation can achieve similar union rates and shoulder function. Considering the better performance of intramedullary fixation in terms of operative parameters and complications, we recommend the application of intramedullary fixation for displaced mid-shift clavicular fractures. More studies focused on comminuted fractures will be necessary in the future.

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ADDITIONAL INFORMATION AND DECLARATIONS

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Competing Interests

The authors declare there are no competing interests.

Author Contributions

- Yan Gao performed the experiments, analyzed the data, contributed reagents/materials/analysis tools, wrote the paper, prepared figures and/or tables, reviewed drafts of the paper.
- Wei Chen conceived and designed the experiments, performed the experiments.
- Yue-Jv Liu analyzed the data, contributed reagents/materials/analysis tools.
- Xu Li contributed reagents/materials/analysis tools.
- Hai-Li Wang prepared figures and/or tables, reviewed drafts of the paper.
- Zhao-yu Chen conceived and designed the experiments, wrote the paper, reviewed drafts of the paper.

Data Availability

The following information was supplied regarding data availability: Raw data can be found in Data S1.

Supplemental Information

Supplemental information for this article can be found online at http://dx.doi.org/10. 7717/peerj.1540#supplemental-information.

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