Review Article Comparison of intramedullary nailing versus plating fixation in the treatment of adult diaphyseal both-bone forearm fractures: a meta-analysis

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Abstract: *Purpose*: The purpose of this meta-analysis was to determine whether plating or intramedullary nailing (IMN) for adult diaphyseal both-bone forearm fractures (BBFF) provides better clinical outcomes. *Materials and methods*: MEDLINE, EMBASE, Google Scholar and The Cochrane Library were comprehensively searched until July 31, 2016. Both retrospective study and prospective trails about comparison of dual IMN or hybrid fixation versus dual plating fixation in the treatment of adult diaphyseal BBFF were included. Using RevMan5.3 software, data of functional recovery, the union time, operating time and complication was extracted for meta-analysis. *Results*: The pooled analysis showed similar results in the union time, functional recovery and the rates of complications, but showed a significant difference in operating time. *Conclusions*: This meta-analysis demonstrates similar radiographic outcomes, functional outcomes and complications in the treatment of adult diaphyseal BBFF with the comparison between plates and IMN. IMN fixation for these fractures seems to be an alternative and effective treatment with shorter operating times and minimal invasion.

Keywords: Forearm fractures, intramedullary nail, plate osteosynthesis, adult, meta-analysis

Introduction

The forearm fractures, especially diaphyseal both-bone forearm fractures (BBFF), has become one of the most common fractures in clinical orthopaedics, and its incidence has gone up to 5.4% of all fractures in children, around twice as many as adult [1]. Both ulna and radius fractures need more anatomical reduction and rotation stability due to the rotation function of the forearm. Nonsurgical management is associated with a high rate of nonunion or malunion and commonly results in dysfunctional forearm, therefore, surgical treatment is more recommended for BBFF [2-5]. Currently, the main surgical methods are plate and screw fixation or intramedullary nails fixation. Advantage of plating fixation is visually anatomical restoration, but the disadvantages are more damaged soft tissues, sporadic complications such as delayed union, nonunion, infection, nerve injury or refracture [6-13]. The largest advantage of intramedullary nails is minimally invasive, but the shortcoming is relatively poor capacity to control the rotation [14-16].

Which one can get better clinical outcomes? For children, there still lack of a final verdict, even though a number of studies in the form of systematic review or meta-analysis were published [17-19]. Even so, they provided plenty of evidence in the treatment of children diaphyseal forearm fractures and gave corresponding guidance for implant choice. Regrettably, for adult diaphyseal BBFF, we could not search any relevant systematic review or meta-analysis. In recent years, however, some randomized controlled trials and retrospective studies have been published to discuss this controversial question that allows us conducting a metaanalysis. And, the purpose of this meta-analysis

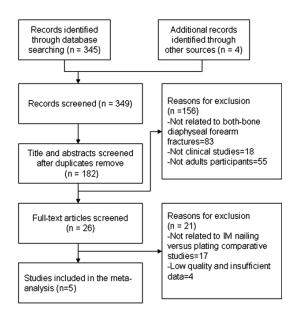


Figure 1. Flow chart for study selection.

was to determine whether plating or intramedullary nailing for BBFF in adult provides better functional outcomes, radiographic outcomes and the rates of complications.

Materials and methods

Protocol and registration

There were no protocol and registration in this meta-analysis.

Eligibility criteria

We looked for the clinical studies related to IM nailing or hybrid fixating versus plating comparative research in the treatment of adult bothbone diaphyseal forearm fractures with a period of follow-up at least one year.

Information sources

Four electronic databases included Medline, EMBASE, Google Scholar and The Cochrane Library, were comprehensively searched until July 31, 2016.

Search

We used the keywords individually or in combination as diaphyseal/shaft forearm fractures, radius and ulna fractures/both-bone fractures, plate/plating versus/and/or nail/nailing, hybrid fixation.

Study selection

Inclusion criteria included diaphyseal bothbone forearm fractures, intramedullary nailing or hybrid fixation versus dual plating comparative studies, adults participants (age>18), and English language studies. While exclusion criteria included single bone fractures, Monteggia, Galeazzi, intra-articular elbow or wrist fractures, studies investigating only intramedullary nailing or only plating, case reports, editorials, comments, letters, guidelines, protocols, cadaveric studies, or not adult participants (age range 0-18).

Data collection process

After duplicates removed, two researchers independently screened the titles and the abstracts based on the inclusion and exclusion criteria. Then, in the state of full-text articles investigation, the two researchers should reach a consensus that which article be included or excluded. Any disagreements were discussed and resolved with a third researcher.

Data items

Clinical outcomes were the time to union (according to the outcomes of sequential radiographs) and the time of the operating process. Functional recovery comparison were assessed with three indicators, including Grace and Eversmann rating system (GERS) (divided with four rating based on union status and rotational range of motion in the forearm) [20], Disabilities of the Arm, Shoulder and Hand (DASH) score (range, 0-100, with 0 as the best result) [21], and the range of motion measured by a goniometer. The side effects were assessed with four most frequently occurring complications in the included studies (nonunion, refracture, nerve palsy and infection).

Risk of bias in individual studies

Two independent researchers were in charge of methodological quality assessment for each included study with the bias risk assessment tools of Cochrane Handbook 5.1.0, in which seven quality criteria were assessed, including random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting, and other

Study	Design	Groups	Sample size (n)	Sex Female, (n (%))	Age (years)	Open frac- tures (n (%))	AO classification type A3:B3:C (n)	Fixation method	Average follow-up (months)
Behnke et al. 2012	RPS	Control	27	10 (37%)	31.6±16.4	6 (22%)	25 (A3+B3):2	Both-bone 3.5 mm DCP or LCP fixation	16.5M
		Experimental	29	6 (21%)	31.9±13.5	4 (14%)	27 (A3+B3):2	Interlocking ForeSight nail for ulnar and plate for radius	16.5M
Ozkaya et al. 2009	RPS	Control	22	7 (32%)	32 (18-69)	2 (9%)	NR	Both-bone DCP fixation	30M
		Experimental	20	6 (30%)	33 (18-70)	1 (5%)	NR	Both-bone locked intramedullary nail fixation	23M
Lee et al. 2014	RCTs	Control	32	10 (31%)	40.3±10	10 (31%)	14:18:0	Both-bone 3.5-mm LCP fixation	20M
		Experimental	35	12 (34%)	43.1±11	9 (26%)	16:19:0	Both-bone locked intramedullary nail fixation	20M
Zhang et al. 2015	RCTs	Control	21	9 (43%)	38.1±12.4	Be excluded	NR	21 cases Both-bone plate fixation	23.4M
		Experimental	66	31 (47%)	37.4±14.1	Be excluded	NR	 22 cases both-bone locked IM nailing; 21 cases plate fixation of ulna and locked IM nailing of radius; 23 cases locked IM nailing of ulna and plate fixation of radius; 	23.4M
Kim et al. 2015	RPS	Control	31	11 (35%)	46.6 (15-82)	11 (35%)	12:8:11	Both-bone DCP fixation	16.8M
		Experimental	16	6 (38%)	48.6 (15-81)	5 (31%)	5:6:5	Locked IM nailing of ulna and plate fixation of radius or plate fixation of ulna and locked IM nailing of radius	15.1M

Table 1. Characteristics of included studies

Annotation: RPS=Retrospective study; DCP=dynamic compression plates; LCP=locking compression plates; IM=intramedullary.

	Behnke et al. 2012	Ozkaya et al. 2009	Lee et al. 2014	Zhang et al. 2015	Kim et al. 2015
Random sequence generation	Н	Н	L	L	Н
Allocation concealment	Н	Н	Н	Н	Н
Blinding of participants and personnel	Н	Н	U	U	Н
Blinding of outcome assessors	Н	Н	Н	Н	Н
Incomplete outcome data	L	Н	L	Н	Н
Selective reporting	L	L	L	L	L
Other bias	U	U	U	U	U

Table 2. Assessments of risk of bias of eligible studies

Annotation: L=low risk, U=unclear risk, H=high risk.

bias. Every quality criteria could be classified in 3 grades: low risk, unclear risk, or high risk. Similarly, a third investigator was consulted to resolve the disagreements.

Summary measures

We used RevMan5.3 software provided by the Cochrane collaboration for statistical analysis. Odds ratio (OR) was used in count data as the effect size, while mean difference (MD) in measurement data, 95% confidence intervals (CI) was adopted for both of them. And a *P*-value of 0.05 was considered as statistically significant.

Synthesis of results

According to heterogeneity measure standard $(l^2=50\%)$, if no significant heterogeneity between the results (*P*>.10, $l^2<50\%$), we chose the fixed-effect model for meta-analysis. On the contrary, if sensitivity analysis can not modify the high heterogeneity (*P*≤.10, $l^2\geq50\%$), we preferred a more moderate statistical method by using a random-effect model.

Risk of bias across studies

To observe publication bias with a funnel plot is a frequently-used method, but it has little meaning if not included more than five studies.

Additional analyses

Divided as two groups, respectively both-bone plate fixation versus both-bone IMN fixation and both-bone plate fixation versus hybrid fixation, subgroup analyses were applied in the comparison of the union time, GERS, the range of motion, and the incidences of nonunion. We had not conducted a sensitivity analyses in this meta-analysis because of the little number of included studies.

Results

Literature search

The search process is shown with detail in Figure 1 (Figure 1). Finally, A total of five studies (299 participants), which sample size ranged from 16 to 35 with a mean of 25, were included in our meta-analysis [22-26]. There are three Retrospective comparison studies [22, 23, 26], and the other two are prospective randomized trials [24, 25]. Two of the included studies compared dual plating with dual intramedullary nails [23, 24], two compared dual plating with hybrid fixation (IMN for ulna and plate fixation for radius or plate fixation for ulna and IMN for radius) [22, 26]. One study not only achieved clinical comparison of the four different fixations, but also carried out a cadaveric study [25]. The characteristics of all the five studies are demonstrated in Table 1.

Quality assessment of the included studies

As shown in **Table 2**, only two studies were RCTs. None of included researches reported information regarding allocation concealment or blinding of participants and study personnel, but each study had a comparable baseline features between control groups and experimental groups in sample size, sex and age distribution, open fractures number, AO classification type distribution, and the follow-up time. In addition, reporting bias was evaluated as low risk for the all included studies for their detailed message of withdraw or follow-up losing. At last, we assessed the other bias as unclear risk because of no relevant material or other information

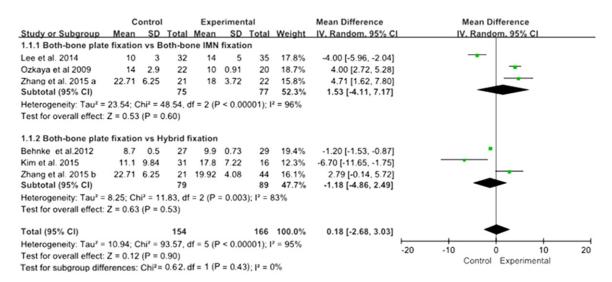


Figure 2. Forest plot of subgroup analysis comparing the union time (weeks).

could be acquired from the Internet. On the whole, it was moderate to the overall quality of the included studies.

Meta-analysis results

Time to union: All the five studies recorded the union time and thus were enrolled for evaluation. The random-effect model was used for this subgroup analysis as the high heterogeneity between the studies (chi²=93.57, df=5, l²=95%). The pooled analysis showed similar results in the time to union (MD=0.18, 95% Cl=-2.69 to 3.03, P=0.43), indicating that fixation method does not a decisive factor in union of adult diaphyseal BBFF (**Figure 2**).

Functional recovery

In functional recovery comparison, all the five studies used GERS, three of them added the DASH score as an indicator, and two studies compared the range of motion in the last follow-up. For GERS, we compared the events evaluated as the grade of excellent and good. The fixed-effect model was used for statistical analysis of GERS (chi²=6.99, df=5, l²=28%) (Figure 3A), and the range of motion (chi²=3.37, df=3, I²=11%) (Figure 3B), but random-effect model was used for DASH scores (chi2=9.57, df=2, I²=79%) (Figure 3C). There was no statistically significant difference of this three pooled results (GERS: OR=0.78, 95% CI=0.46 to 1.32, P=0.36; range of motion: MD=1.95, 95% CI=-3.02 to 6.93, P=0.44; DASH scores: MD=-2.91, 95% CI=-7.24 to 1.42, P=0.19). From the analysis result above, it imply that both-bone IMN

fixation or hybrid fixation will not result in worse functional recovery compared to dual plating fixation in adult diaphyseal BBFF.

Operating time

Three included studies compared operating time between dual IMN fixation groups with dual plating fixation groups. Base on the high heterogeneity ($chi^2=72.54$, df=2, $l^2=97\%$), our meta-analysis of random-effect model showed a significant difference in operating time (MD=28.57, 95% Cl=1.84 to 55.30, P=0.04), indicating that both-bone IMN fixation costs significantly less operating time than dual plating fixation for the surgery of adult diaphyseal BBFF (**Figure 4**).

Complications

There were numbers of complications mentioned in the included studies, including nonunion, delayed union, malunion, synostosis, implant removal, refracture, nerve palsy, infection, compartment syndrome, complex regional pain syndrome and so on. But it only had sufficient data for pooled analysis in four complications (nonunion, refracture, nerve palsy and infection). Fixed-effect model was chose for the four pooled analysis as no statistically significant heterogeneity existed (nonunion: chi2= 6.85, df=4, l²=42%; refracture: chi²=0.00, df=1, l²=0%; nerve palsy: chi²=1.26, df=1, I²=20%: infection: chi²=0.33, df=1, I²=0%). The meta-analysis results showed similar results between the two treatment strategies in all of the four complications (nonunion: OR=1.84,

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IMN versus plates for adult BBFF

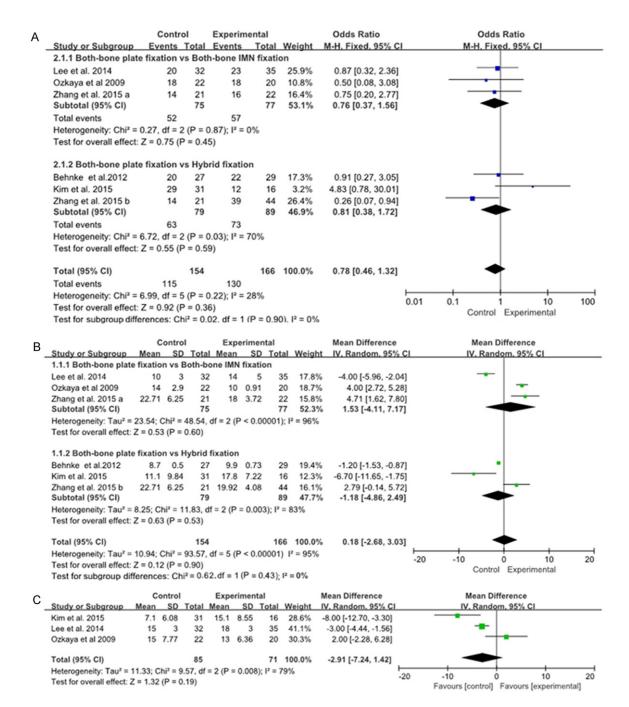


Figure 3. Forest plot comparing functional recovery. A. The rates of excellent and good assessed by GERS after treatment. B. Range of motion after treatment. C. DASH score after treatment.

	0	ontrol	Experimental			tal		Mean Difference	Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV. Random, 95% CI	I IV. Random, 95% CI		
Lee et al. 2014	74	8	32	52	10	35	34.1%	22.00 [17.68, 26.32]	•		
Ozkaya et al 2009	65	16.82	22	61	15.95	20	32.9%	4.00 [-5.91, 13.91]			
Zhang et al. 2015 a	130	15	21	70.2	16.2	22	33.0%	59.80 [50.47, 69.13]	-		
Total (95% CI)			75			77	100.0%	28.57 [1.84, 55.30]			
Heterogeneity: Tau ² = 540.52; Chi ² = 72.54, df = 2 (P < 0.00001); l ² = 97% Test for overall effect: Z = 2.09 (P = 0.04)									-100 -50 0 50 100 Favours [control] Favours [experimental]		

Figure 4. Forest plot comparing operating time (minutes) between dual IMN with dual plating.

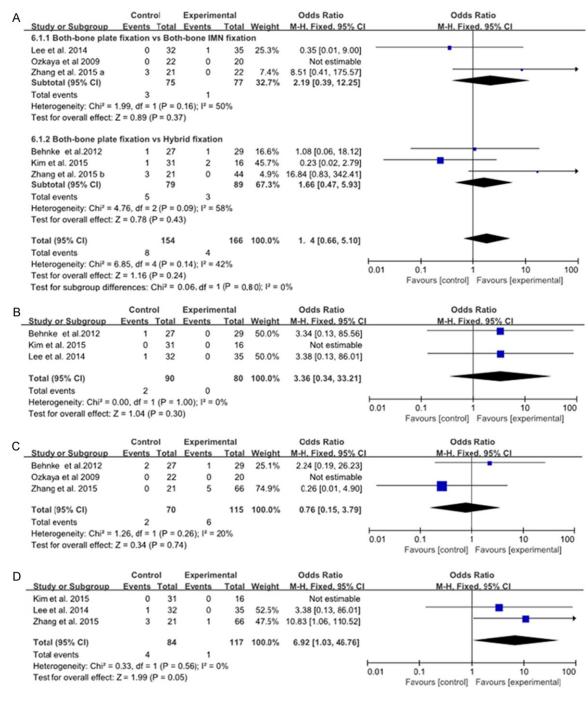


Figure 5. Forest plot and meta-analysis of complications. A. Incidence of nonunion. B. Incidence of refracture. C. Incidence of nerve palsy. D. Incidence of infection.

95% CI=0.66 to 5.10, P=0.24 (Figure 5A); refracture: OR=3.36, 95% CI=0.34 to 33.21, P=0.30 (Figure 5B); nerve palsy: OR=0.76, 95% CI=0.15 to 3.79, P=0.74 (Figure 5C); infection: OR=6.92, 95% CI=1.03 to 46.76, P=0.05 (Figure 5D)). Therefore, it suggest that the selection of fixation method (dual plating fixation, dual IMN fixation, or hybrid fixation) may not lead increasing or decreasing the incidence of some complications such as nonunion, refracture, nerve palsy or infection.

Publication bias

Publication bias was not assessed for the above outcomes because more than five studies are required to detect funnel plot asymmetry [27].

Discussion

At first, IMN for the treatment of adult BBFF was widely unaccepted as their failure to supply sufficient rotational stability [28-30]. With the improvement of implant technology, however, the second-generation nails with a constructs of interference fit, were reported their union rates at 93%-95% in some clinical practice [15, 31]. In current third-generation nails possess incorporating interlocking capability, and can afford enhanced anti-rotational stability. Some studies declared that their union rates ascend to maximum of 100% [32-34], which is absolutely comparable to the routinely used fixation of dual plating in the surgical treatment of adult BBFF. Additionally, in consideration of the superiority of IMN fixation in smaller incisions, less damaged soft tissue, no periosteal stripping, and lower risk of refracture, etc. Should surgeons reconsider to use IMN fixation for adult BBFF? In fact, this is possibly the first metaanalysis to answer this question. Our results indicated that there was no statistically significant difference between the two groups in the union time, functional recovery, or some complications such as nonunion, refracture, nerve palsy and infection. Moreover, it showed IMN fixation groups costs significantly less operating time than dual plating fixation groups.

Different from other long bone of the human body, radius and ulna possess an important function of rotation, which play a crucial role for a series of nimble movements of the upper limb. The classic concept considers the double bones of forearm as a "joint" that allows rotation of the radius around the ulna, rather than two simple "long bone" [35, 36]. Some studies thought the treatment of BBFF should follow the therapeutic principle of intra-articular fractures, so they advocated open reduction with plate fixation and opposed intramedullary fixation [37, 38]. Their main worry might be the poor ability of rotation control in IMN fixation, which may results in a high rate of bone nonunion and brings about dissatisfactory functional recovery. Nevertheless, this meta-analysis inferred similar outcomes of functional recovery included GERS, DASH scores, and the range of motion. Also, it indicated no statistically significant difference in either the union time or the rates of nonunion between the two

groups. This finding should be interpreted with reasonable hypothesis that current locking IMN could effectively control the rotation displacement of the forearm fracture. A cadaveric study with forty specimen conducted by Zhang et al. found that hybrid fixation method with IMN of ulna and plate fixation of radius obtained the similar biomechanical stability compared with the dual plating fixation method, but it found dual IMN group showed significantly lower torsional stiffness when compared with dual plating fixation [25]. But we doubt whether dual IMN fixation can achieve good stability practiced on human alive instead of studying on the corpse. A plaster immobilization was frequently used to add rotation control for early postoperative patients with IMN fixation, that is to say, whether the result will be changed when loading a smaller torsion is unknown. IMN fixation minimizes the influence of local blood supply, guarantying the vigorous growth of osteotylus, which also could strengthen the stability of the fracture.

Besides, IMN fixation has the potential of taking less operating time. After the success of closed reduction or limited open reduction, two small incisions were sited at the top of olecroanon and the Lister's tubercle. The appropriate diameter and preliminary curved IM nails was inserted respectively into the adequately expanded medullary cavity, lock pins were screwed at the ends of proximal and distal at last. Unlike the layer-by-layer meticulous separation required at open reduction and internal fixation, a veteran surgeon theoretically spends less operating time by using IMN fixation [39]. Although our pooled analyses were based on very few studies, the result conformed the above assumption (P=0.04). The significant heterogeneity noted among the studies (I²=97%) can be explained by variability of the proficiency of the surgeon and the characteristics of the patient. Moreover, one of the included studies compared blood loss of dual plating fixation with dual IMN fixation. The mean blood loss was reported as 60 ml in plating fixation, and it was approximate no blood loss in IMN fixation with the closed reduction [23]. But we could not extract added data from other included studies to make a pooled analysis.

Certainly, several limitations were recognized in this meta-analysis. First, the quality of the included articles was not very high. Three of the five included studies were retrospective researches, and the other two were RCTs without specific allocation concealment or blinding. Only by evaluating this topic based on several well-designed randomized controlled trials, can we obtain convincing evidence-base to guide our clinical decisions. Second, we could not collect an ideal large sample size to conduct steadier pooled results due to a small number of analyzed studies and relatively few patients in them. Third, also as the small number of included studies, we did not present a funnel plot, thus, the publication bias in our study might not be evaluated. Finally, non-English language articles and unpublished studies were not in the scope of our investigation, which might miss some high-quality randomized controlled trials, meanwhile, narrow the breadth of literature review. These limitations should be taken into account and might bring additional uncertain factors to the findings of our study. And, researchers should seriously consider the above limitations and try to avoid them when drafting a further review. However, more highquality RCTs with large sample size are recommended to fundamental overcome the currently present limitations in this study.

At present, the effectiveness of IM nail application as a treatment method is accepted in the fractures of humerus, even served as a golden standard for the fractures of tibia and femur [15, 40, 41]. Its application in BBFF receives more and more attention at the same time. Rehman and Sokunbi put forward the best indication of IMN for the treatment of BBFF: 1) incomplete soft tissue cover; 2) multi-segmental fractures; 3) multiple injuries; 4) patients with severe osteoporosis; 5) implant remove or nonunion in plating fixation; 6) pathological fracture [42]. Saka et al. and Kose et al. successively introduced a new design IMN of radius and ulna [43, 44]. The radius nail has a parabolic shape and a volar angle at the distal side, its distal static locking screw provides more stability with three-point fixation principal. The ulna nails is mainly tubular and distal section with eight semi-oval locking holes allow sufficient number of locking nails. A single-cortex locking through the proximal oblique hole could play as a compression application if necessary. The studies also reported the biomechanical analysis and postoperative outcomes of these new design nails, and both of them received a satisfying result. So we believe, with the implant improvement, IM fixation for adult BBFF will get higher acceptability and flourishing development in the future.

Conclusion

This meta-analysis demonstrated similar radiographic outcomes, functional outcomes and complications in the treatment of adult diaphyseal BBFF with the comparison between plates and IMN. Although some methodological defects existed in the included studies, IMN fixation for these fractures seems to be an alternative and effective treatment with shorter operating times and minimal invasion. Furthermore, more high-quality RCTs with large sample size are required to enrich the evidence of this issue.

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Disclosure of conflict of interest

None.

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