

Review Article

A meta-analysis of random controlled trails comparing plate fixation using unicortical and bicortical screws in palm fracture of cadaveric models

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Abstract: Background: A meta-analysis was carried out to compare the results, including bone mineral density, stiffness, load to failure and bone screw interface fracture rate between unicortical and bicortical screws in palm fracture of cadaveric models. Method: We searched the database of Embase, PubMed and Cochrane Library to indentify the relevant studies from the year of 2004 to 2016. All the random controlled trails, which were published to compare the plate fixation using unicortical and bicortical screws in palm fracture of cadaveric models, were enrolled in the study. All the included results were conducted by using the method of meta-analysis. Result: The databases were derived from four studies, including 174 created palm fractures in the cadaveric models, while half of the palm fractures adopted plate fixation using unicortical screws and the other half of the palm fractures adopted plate fixation using bicortical screws. No significant differences were found in the results of bone mineral density, stiffness and load to failure [MD=0.01, 95% CI (-0.02, 0.04), P=0.28; MD=-54.50, (-139.53, 30.54), P=0.21; MD=-16.81, (-206.17, 172.54), P=0.86]. The group of unicortical screw has more bone screw interface fracture rate when compared with the group of bicortical screw [RR=1.32, 95% CI (1.01, 1.73), P=0.04]. Conclusion: No significant difference was detected for the results of bone mineral density, stiffness and load to failure. However, the group of unicortical screw has more bone screw interface fracture rate when compared with the group of bicortical screw.

Keywords: Unicortical screw, bicortical screws, phalanges fracture, metacarpal fracture, cadaveric models, random controlled trails

Introduction

Palm fractures, including metacarpal and phalangeal fractures, are common injuries to the hand surgeon and the treatments are mainly based on the presentation of the fracture, degree of displacement, and difficulty in maintaining fracture reduction [1-4]. Stable fractures do not require surgical treatment, while all other fractures should be considered for additional stabilization-Kirschner wires, simple lag screws, plates or intramedullary nailing [2, 5-9]. It has been confirmed that bicortical screws with dorsally applied plates is the most popular and widely adopted way for the management of metacarpal and phalangeal fractures among these fixation methods, as it can provide superior biomechanical strength [10, 11].

Fambrough and Green [12] even reported tendon rupture as a complication of bicortical fixation in fractures in the hand due to attrition caused by proud screw placement. Under this situation, unicortical fixation has some practical and theoretical advantages over bicortical fixation: it avoids the risk of over-drilling of the volar cortex and injury to the flexor apparatus and neurovascular bundles; there are no proud volar screws and intra-operative radiography is not required to check screw length [13].

There are several cadaveric studies designed as randomized controlled trials (RCTs) which compare bicortical with unicortical fixation for metacarpal and phalangeal fracture models with regard to biomechanical properties [14-17]. The results and conclusions regarding that whether unicortical fixation is effective and

Table 1. Characteristics of the eight studies included in the meta-analysis

Study	Country	Mean age (year)	No. of palm bone	Gender	Study design
		Uni/Bi	Uni/Bi	Female/Male	
E. DONA 2004 [14]	Australia	65	9/9	None	RCT
Mohamed 2008 [15]	UK	72	20/20	1/3	RCT
R. Afshar 2012 [16]	Malaysia	63	10/10	None	RCT
J. K. Dickson 2016 [17]	UK	82.6	48/48	None	RCT

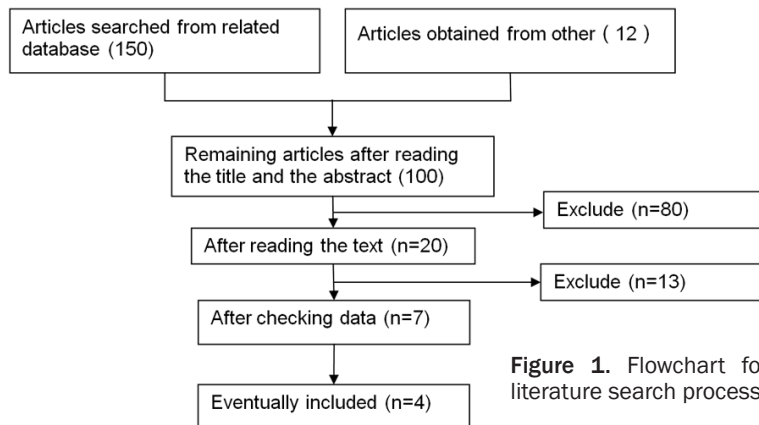


Figure 1. Flowchart for literature search process.

strong enough as bicortical fixation are not identical and systematic. So a meta-analysis and system review which adopts the standards of the international Cochrane Collaboration is urgently required to assess the experiment results of these cadaveric studies.

Methods

Search strategy

We used the databases of EMBASE, PubMed, and Cochrane Library to pick out the relevant literatures from their inception to the year of 2016. Cadaveric studies designed as RCTs which compare unicortical and bicortical screws fixation for metacarpal and phalangeal fracture were identified and analyzed. The search terms of the study are unicortical screw, bicortical screw, phalangeal fracture, metacarpal fracture.

Selection criteria

The following criteria should be met for the enrolled studies: (1) Randomized controlled trials comparing unicortical and bicortical screws fixation for metacarpal and phalangeal fracture

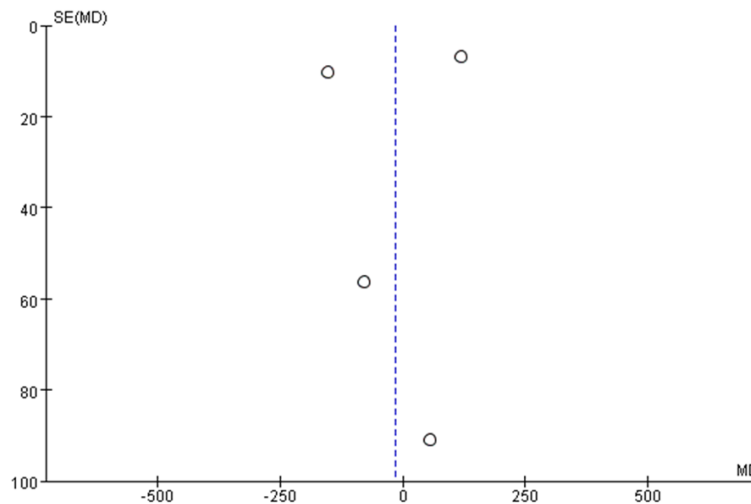
es; (2) Included articles should be written in English; (3) The bone specimens should be free from any metabolic bone disease interfering with bone mineral density or its mechanical properties of the bone; (4) The study reported detailed outcomes of unicortical and bicortical fixation for metacarpal and phalangeal fracture (5) All the enrolled articles in the study are full-text without data loss. We also excluded the articles without a clear description of data regarding intervention details. The articles of clinical case and animal experiment are also excluded. Citations from two independent investigators confirm inclusion or exclusion of the studies. The opinion from the third investigator should be adopted if disagreements existed between the previous two investigators.

Data extraction and quality assessment

Four results, which include bone mineral density, stiffness, load to failure and bone screw interface fracture rate, are considered to measure the difference between unicortical and bicortical screws fixation in metacarpal and phalangeal fracture of cadaveric models. Two independent investigators extracted the following information from the enrolled studies by using a standardized collection: country of the enrolled studies, mean age of the enrolled cadaveric models, gender of the enrolled cadaveric models, number of palm bone and study design (Table 1). Two independent investigators carried out the quality assessment of the enrolled RCTs by using the tool of Cochrane Risk of Bias [18]. Six terms have been collected to assess the quality bias, including random sequence generation, allocation concealment, participants and personnel/outcome assessment, incomplete outcome data, selective reporting and other bias; enrolled studies with one or two negative terms are considered to be with a moderate risk of bias, while studies with three or more negative terms were qualified with high risk of bias [18]. Opinions with the

Table 2. Quality assessment of the included RCT

Study	Random sequence generation	Allocation concealment	Blind	Incomplete outcome data	Selective reporting	Other bias
			Participants and personnel/ Outcome assessment			
E. DONA 2004 [14]	Unclear	Unclear	Yes/Yes	No	Unclear	Unclear
Mohamed 2008 [15]	Unclear	Unclear	Yes/Yes	No	Unclear	Unclear
R. Afshar 2012 [16]	Unclear	Unclear	Yes/Yes	No	Unclear	Unclear
J. Kdickson 2016 [17]	Computer	Unclear	Yes/Yes	No	Unclear	Unclear


Figure 2. Funnel plot of the publication bias.

RevMan 5.2 software, was used to check the enrolled results; while symmetrical plot means the low publication bias of the enrolled RCTs. We also conducted the sensitivity analyses to check the strength of outcomes and to explore influence of the trial design and methods on the effect size, which is carried out by deleting the lowest quality study and rechecking the results; no obvious differences of the results means the low sensitivity.

Results

Literature search and evaluation

Figure 1 shows the flowchart of the retrieved and excluded articles. The author initially searched 162 papers, which included 150 papers searched from the related database and 12 papers obtained from other source. Reviews, letters, duplicates, and papers with irrelevant purposes or designs were eliminated. Only 100 papers were left after reading the title and abstract. 80 articles were excluded after reading the whole texts. 7 articles remained after checking content. Only 4 articles, published from the year of 2004 to 2016, were eventually included in the meta-analysis [14-17]. All the included articles are random controlled trials.

The enrolled 4 articles included 74 created metacarpal and phalangeal fractures in the cadaveric models, while half of the fractures adopted plate fixation by using unicortical screws and the other half of the palm fractures adopted plate fixation by using bicortical screws. The clinical characteristics of the studies are presented in **Table 1**.

senior author should be adopted if conflicts regarding literature search, study selection, and data extraction exist between the two independent investigators.

Data synthesis and analysis

We used the software of RevMan 5.2 provided by Cochrane Centre to carry out the meta-analysis. The data analyses were carried out by using two-sided tests, with a significance level of $P < 0.05$. We also carried out the heterogeneity checking of the included results by using I^2 , and the result was considered to represent no significant heterogeneity when the value of I^2 was less than 50%. The random effects model was used if possible sources of significant heterogeneity were detected ($I^2 \geq 50\%$), while fixed effects model was applied in cases of no significant heterogeneity ($I^2 < 50\%$). The relative risk (RR) and 95% confidence intervals (CI) were calculated for dichotomous variables, while a mean difference (MD) and 95% CI were applied for those data, which involved quantitative measurement. The funnel plot, produced by

Unicortical and bicortical screws for palm fracture

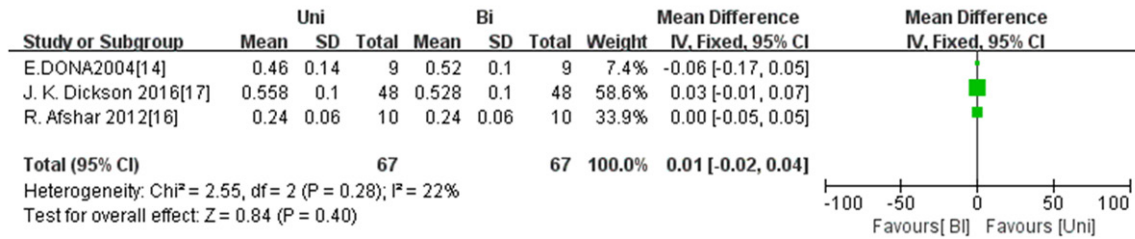


Figure 3. Forest plot of the bone mineral density for unicortical and bicortical screws.

Table 3. Overall estimations of meta-analysis

Results	No of study	No. parm bone		MD or OR (95% CI)	P	Heterogeneity
		Uni	Bi			
Bone mineral Density (g/cm ²)	3	67	67	0.01 [-0.02, 0.04]	0.28	I ² =22%
Stiffness (N/mm)	2	57	57	-54.50 [-139.53, 30.54]	0.21	I ² =55%
Load to failure (N)	4	84	84	-16.81 [-206.17, 172.54]	0.86	I ² =99%
Bone screw interface fracture rate	3	64	64	1.32 [1.01, 1.73]	0.04	I ² =99%

Quality assessment

We used the tool of Cochrane Risk of Bias to assess quality of the enrolled RCTs [18]. **Table 2** shows the results of the quality assessment. For the term of random sequence generation [17], one article provided the method of computer-generated randomization table, while the other three articles did not provide the method [14-16]. Two points should be noted if allocation sequence has been concealed for the enrolled study. Firstly, the person who generates the allocation sequence should not be the person who determines eligibility and entry of the cadaveric models; secondly, if possible the mechanism for treatment allocation should use people not involved in the trial [19]. The result of such term is unclear, as all the enrolled studies have not provided specific information about the two above points [14-17]. It was also believed that outcomes and measurements of the RCTs were not likely to be influenced by lack of blinding, and the risks of performance and detection bias did not exist as all the objects of the enrolled studies were cadaveric models [14-17]. All the involved results provide complete outcome data. We are not sure whether selective reporting and other bias existed in the included studies as no more information was provided.

Publication bias and sensitivity analysis

Publication bias assessment was carried out by funnel plot produced by the software of

RevMan 5.2. **Figure 2** shows the symmetrical funnel plot, which means no significant publication bias exist among the enrolled studies. We carried out the sensitivity analysis by deleting the lowest quality study, and the results show that no marked difference in the relative risk and heterogeneity for the result of interest.

Bone mineral density

Bone mineral density, which is a measure of bone density, reflects the strength of bones as represented by calcium content [20]. The measurement of BMD is also the way to detect osteoporosis, which is a systemic bone disease characterized by reduced mineralization and microarchitecture changes of the bone, resulting in increased bone fragility and susceptibility to fracture with considerable morbidity and mortality [21]. Different methods have been described to measure the BMD, such as T-Scores by Heel QUS and DXA in HRPZII [21]. Three articles have been enrolled to evaluate the result of BMD [14, 16, 17]. Fixed effect was applied to the meta-analysis as no heterogeneity was found among the included studies (I²=22%). We found no significant difference between plate fixation using unicortical and bicortical screws in palm fracture of cadaveric models [MD=0.01, 95% CI (-0.02, 0.04), P=0.28] (**Figure 3**; **Table 3**).

Stiffness of the fixation

In order to throw some light on the controversial issue of the optimal stiffness in fracture

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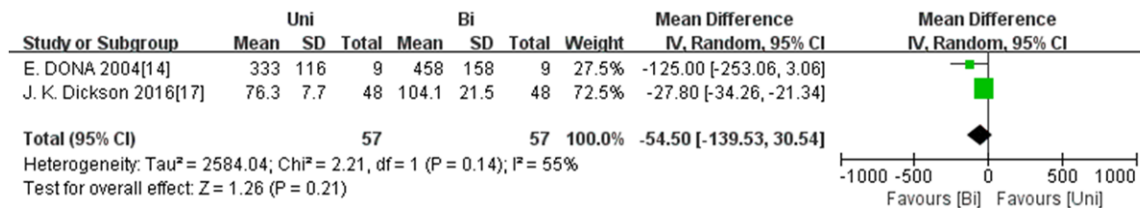


Figure 4. Forest plot of stiffness of the fixation for unicortical and bicortical screws.

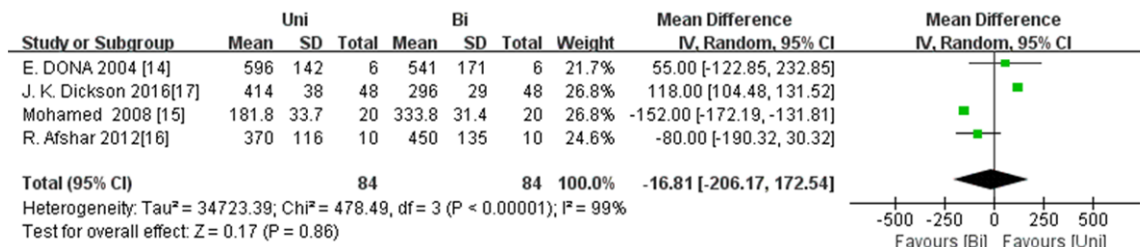


Figure 5. Forest plot of load to failure for unicortical and bicortical screws.

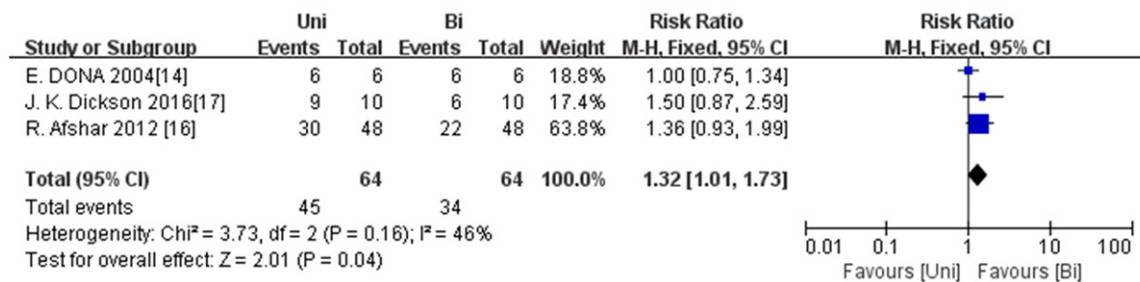


Figure 6. Forest plot of bone screw interface fracture rate for unicortical and bicortical screws.

fixation, the result of stiffness of the fixation was measured. Two articles have been enrolled in the study [14, 17]. We adopted random effect for the meta-analysis as significant heterogeneity was detected between the included studies ($I^2=55\%$). No significant difference was found between plate fixation using unicortical and bicortical screws in palm fracture of cadaveric models for the result of stiffness of the fixation [MD=-54.50, 95% CI (-139.53, 30.54), $P=0.21$] (Figure 4; Table 3).

Load to failure

Load to failure was defined as the point at which the load reached to the peak point (the peak pull-out force) and then abruptly decreased, with increasing displacement [15]. We enrolled four RCTs to measure the results [14-17]. Significant heterogeneity was found among the included studies and random effect was

applied to the study ($I^2=98\%$). No significant difference was found between plate fixation using unicortical and bicortical screws in palm fracture of cadaveric models for the result of load to failure [MD=-16.81, 95% CI (-206.17, 172.54), $P=0.86$] (Figure 5; Table 3).

Bone screw interface fracture rate

The most common mode of failure for both groups was for a fracture to occur at the bone screw interface, it is vital to compare the bone screw interface fracture rate between the two groups [17]. Three articles have been enrolled in the study [14, 16, 17].

Significant heterogeneity was found among the included studies and random effect was applied to the study ($I^2=46\%$). The group of palm fracture with unicortical screw seems to have higher bone screw interface fracture rate

when compared with the group of palm fracture with bicortical screw [MD=1.32, 95% CI (1.01, 1.73), P=0.04] (**Figure 6; Table 3**).

Discussion

Compared with non-operative treatment of metacarpal and phalangeal fractures, bicortical screws with dorsally applied plates can yield favorable anchoring force and enable early postoperative mobilization [10]. However, the bicortical fixation may induce potential risk of the flexor tendons and neurovascular bundles injuries and outcomes of the unexpected injuries are disastrous and objectionable [22]. On the basis of tension band principles, bicortical screws should have no substantial impact on compressive forces. That the special biomechanical properties of metacarpals and phalanges have inspired surgeons to explore the possibility of unicortical fixation for metacarpal and phalangeal fractures to avoid flexor tendons and neurovascular bundles injuries. Moreover, unicortical screw with plate of metacarpal and phalangeal fractures is a less technically demanding and quicker procedure, which theoretically caused less soft tissue disruption, such as bleeding, swelling and synovitis and potentially fewer complications, which are likely to cause greater problems with immediate post-operative mobilization [22]. There are four cadaveric studies which compare bicortical with unicortical fixation for metacarpal and phalangeal transverse fracture concave models to figure out the possibility of unicortical fixation for metacarpal and phalangeal fractures [14-17]. All the enrolled four cadaveric studies have employed non-locking screws for the fixation and no locking screws were applied.

Just as mentioned in the results above, three of the four studies have records of bone mineral density (BMD) of cadaveric metacarpals, which is positively correlated with the pullout strength of cortical screws. And there is no significant difference of bone mineral density between bicortical and unicortical screws group. The results also demonstrate that the fixation of bicortical or unicortical technique has no significant influence on the stiffness of plates and the load to failure statistically. The internal fixation failure is an annoying complication, which may lead to nonunion and reoperation [23]. The stiffness of plates and the load to failure both reflect the rigidity of plates and the pullout

strength of cortical screws. Fusetti et al [24] reported that internal fixation failure including plate loosening and breakage accounted for 8% in the treatment of metacarpal and phalangeal fractures in 2002. The unicortical fixation will not increase the risk of plate loosening and breakage after surgery accordingly neither. However, it is apparent that bicortical fixation has an inherently higher pull-out strength as the result of the additional bone purchase on the palmar cortex of the metacarpals and phalanx [16]. The models of failure are different in both groups using a four-hole straight plate secured with two screws on either side of the fracture. The group of unicortical screw has higher bone screw interface fracture rate when compared with bicortical group according to the result. A potential reason for the result is, a tension band effect will occur on the volar surface when load is applied to a bone with unicortical fixation, which would account for the extra force required to reach failure during testing. This was, in part, supported in our study as the most common causes for fracture occur at the bone screw interface in the unicortical fixation group, which was distant from the fracture site [17].

This is the first meta-analysis of RCTs to compare the efficiency and biomechanical properties between bicortical and unicortical screws with plate in palm fracture of cadaveric models. However, the meta-analysis and systematic review of specific comparison between the two methods, which collects high quality RCTs, still remains absent. Moreover, there still exist the small sample sizes although it has been accumulated from the enrolled studies. Language bias may still exist as some excellent RCTs were written in non-English language. Significant publication bias could not be indicated by the funnel plot as only four RCTs could not maintain the true result of public bias. The value of I^2 in three results (stiffness, load to failure and bone screw interface fracture rate), which is used to evaluate the heterogeneity of the result, is more than 50%, indicating that significant heterogeneity exists in the enrolled RCTs. The subgroup analysis is difficult to carry out as only four RCTs are included in the study. The mean age of the cadavers enrolled in the meta-analysis is more than 65 years old. However, metacarpal and phalangeal fractures occur in the much younger patients.

Conclusion

No significant difference was detected for the results of bone mineral density, stiffness and load to failure. However, the group of unicortical screw has more bone screw interface fracture rate when compared with the group of bicortical screw. More RCTs, including clinical cases and concave models, are urgently needed to explore the difference between unicortical and bicortical screws with plates used in the palm fracture (metacarpal and phalangeal fractures).

Acknowledgements

Informed consent was acquired from all the authors, and no human participants were included in the study.

Disclosure of conflict of interest

None.

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