

Comparison of intramedullary versus extramedullary alignment technique in total knee arthroplasty

A PRISMA-compliant meta-analysis

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Abstract

Background: This meta-analysis aimed to compare the efficacy of intramedullary and extramedullary femoral alignment technique in treating total knee arthroplasty (TKA) patients.

Methods: PubMed, Embase, Cochrane library, Chinese National Knowledge Infrastructure, and Weipu databases were electronically searched. Potential clinical studies that investigated the effect and safety of intramedullary versus extramedullary femoral alignment technique in TKA patients were searched. The primary outcome was lower limb coronal alignment. Stata 12.0 was used for meta-analysis.

Results: This meta-analysis included 12 prospective randomized controlled studies that reported data on 935 TKA patients. No significant difference was noted in lower limb coronal alignment, coronal alignment of femoral component, sagittal alignment of femoral component and tibial slope between intramedullary and extramedullary alignment techniques ($P > .05$). Further, extramedullary alignment technique significantly decrease the total blood loss than intramedullary alignment technique (weighted mean difference: -86.52 ; 95% confidence interval: -115.05 – -57.99 ; $P = .000$) and subsequently transfusion rate (risk ratio: 0.57 ; 95% confidence interval: 0.41 – 0.79 ; $P = .000$). Finally, there was no significant difference between intramedullary and extramedullary alignment techniques in terms of the total complications ($P > .05$).

Conclusions: The present meta-analysis showed that intramedullary and extramedullary femoral alignment technique had comparable precise profiles. And extramedullary femoral alignment technique could reduce blood loss and blood transfusion. Total complications were comparable between the groups. More randomized controlled trials with large samples are required to verify the comparison of intramedullary and extramedullary femoral alignment technique in TKA patients.

Abbreviations: CI = confidence interval, RCTs = randomized controlled trials, RR = risk ratio, TKA = total knee arthroplasty, WMD = weighted mean difference.

Keywords: extramedullary, intramedullary, meta-analysis, total knee arthroplasty (TKA)

1. Introduction

Total knee arthroplasty (TKA) has become a successful surgical procedure for relieving pain and restoring function in patients with end-stage osteoarthritis of the knee.^[1] It is reported that there are approximately 600,000 TKA procedures performed in the US every year and the number of TKAs is increasing year by year.^[2] Life of the implant prosthesis is influenced by many factors including the limb alignment, surgical techniques and postoperative management.^[3] Correct balancing of soft tissues and reconstruction of the mechanical axis

of the lower limb is crucial for successful TKA procedures.^[4] Some researchers consider intramedullary alignment procedures was more accurate than extramedullary alignment technique. Meding et al^[5] revealed that intramedullary alignment was not as precise using the extramedullary system after follow-up to 15 years post-TKA. The survivorship between these 2 techniques were not statistically significant. Thus, the author suggested the choice of either alignment system should be determined by the patient's anatomy. Another study also revealed that nearly 8.5% TKA patients with intramedullary alignment had an unsatisfactory mechanical axis.^[6]

ML, JL, and SH contributed equally to this work.

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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In recent years, extramedullary instruments techniques have been significantly improved by newly designed mechanical axis marker systems. Several studies have also demonstrated the comparable effects between intramedullary and extramedullary alignment techniques. Zahn et al^[7] found that navigation intramedullary and extramedullary instrumentation provided equal precise positioning of the tibial component. Ku et al^[8] performed a retrospective study and identified that extramedullary mechanical guide provides similar postoperative alignment as intramedullary mechanical guide but caused less blood loss.

Another great advance in TKAs is that surgeons focused on minimizing the postoperative drainage. As for intramedullary alignment, reaming is necessary and thus various complications (blood loss, hypoxia, and fat embolism) cannot be ignored.

Therefore, it would be appulsive to carry out a meta-analysis to draw a more accurate conclusion about the advantage and disadvantage between intramedullary and extramedullary alignment technique in TKA patients. The purpose of the current meta-analysis was to compare results concerning the precise

and potential complication of intramedullary and extramedullary alignment technique in TKA patients.

2. Material and Methods

This review was conducted according to the guidelines outlined in Preferred Reporting Items for Systematic Reviews and Meta-Analysis statement.

2.1. Data source and study searches

PubMed, Embase, Cochrane library, Chinese National Knowledge Infrastructure, and Weipu databases were searched from the inception dates to March 2020 using the keywords “intramedullary,” “extramedullary,” “alignment technique,” “total knee arthroplasty,” “total knee replacement,” “TKA,” and “TKR.” Study searches were performed blindly by 2 people (Ming Li, BD and Jun Li). References of the included articles were searched by hand to check for possible relevant articles.

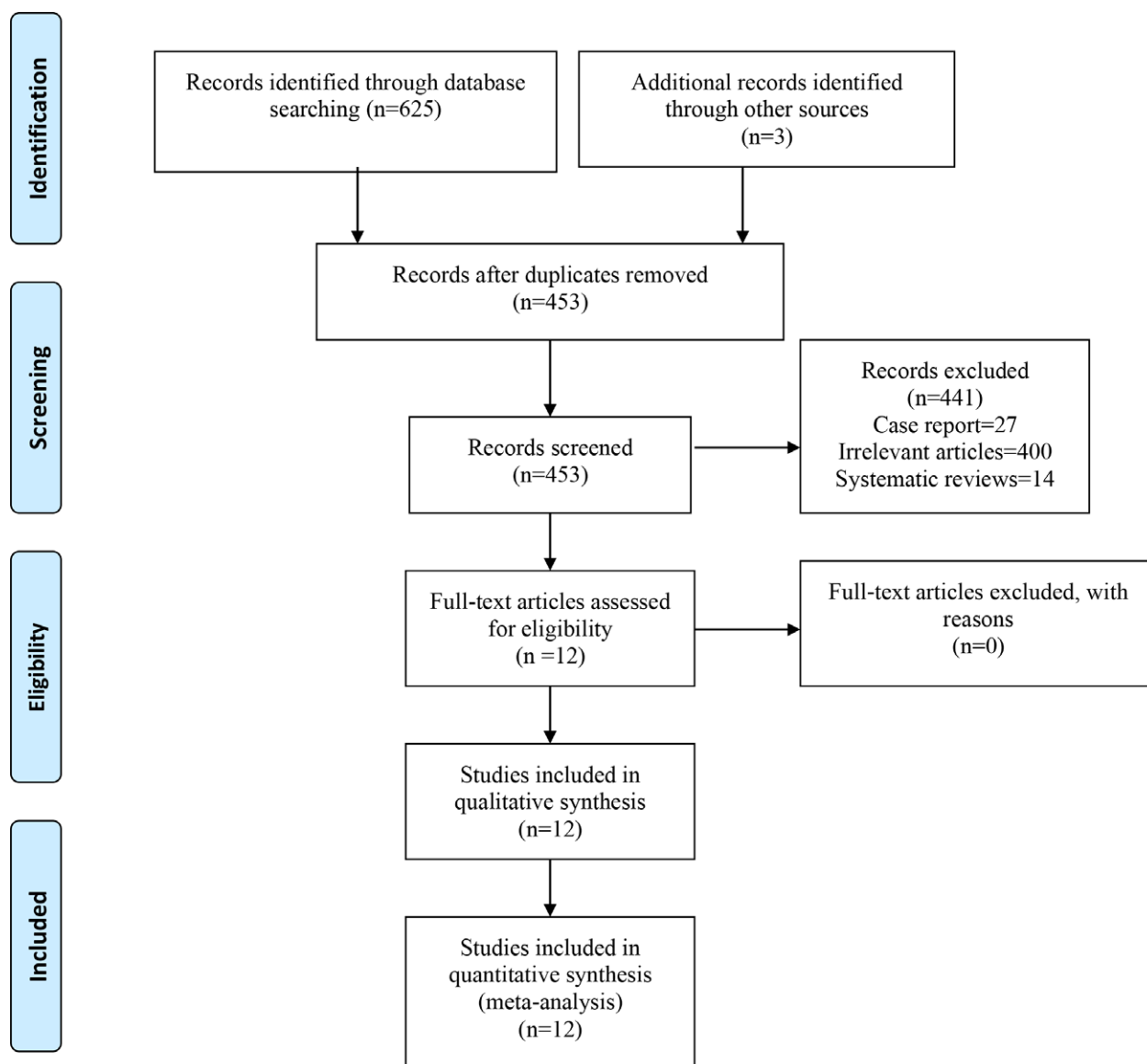


Figure 1. The flow chart of literature screening.

2.2. Selection criteria

The inclusion criteria were formulated based on the PICOS (participants; intervention, comparator, outcomes and study) criteria: Patients were prepared for TKA; studies comparing the preciseness of intramedullary and extramedullary alignment technique; randomized controlled trials (RCTs); and studies that reported at least one of the outcomes. Exclusion criteria were: There were studies without sufficient data reported; non-RCTs; and case studies and reviews. There were no restrictions on year of publication or publication status.

2.3. Study selection

Duplicated studies were checked and merged together using the software EndNote X7 version 17.0 (Clarivate Analytics, Philadelphia). Then, 2 reviewers independently reviewed all titles and abstracts and deleted researches which were clearly irrelevant. After that, full texts of all remaining studies were reviewed to determine whether or not to include them in this study. In addition, when ambiguity or uncertainty existed between the 2 reviewers, discussion with a third senior reviewer was required until consensus was reached.

2.4. Risk of bias assessments

Two authors (Shuai Hu and Bingshen Jia) performed risk of bias assessment according to the Cochrane Collaboration tool. The evaluation index main included 7 items: randomization sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other bias. Each term was classified as “low,” “unclear” and “high” according to the Cochrane Collaboration tool. Agreement between reviewers were calculated using STATA 12.0 (STATA Corp., College Station, TX) and shown as κ value.

2.5. Data extraction

Two authors (Ming Li and Jun Li) independently extracted the following information: Study general characteristics: first author, publication year, and country; Patients information: sample size, age, study type, and body mass index; Treatment

information: total knee system and extramedullary system; Primary outcome: lower limb coronal alignment, coronal alignment of femoral component, and sagittal alignment of femoral component; Second outcomes: tibial slope, total blood loss, transfusion rate, and total complications. Data was extracted by 2 authors (Jing-zhao Hou and Hong-wei Bao) and entered into a pre-built Microsoft Excel (Microsoft Excel 2016, Microsoft, Redmond, WA) spreadsheet and diversity on obtained information was discussed.

2.6. Data analysis and statistical methods

The data referring to evaluations through sagittal alignment of femoral component, tibial slope, and blood loss were compared between groups of intramedullary and extramedullary. The heterogeneity was tested with I^2 , and in case of a significant heterogeneity ($I^2 > 50\%$), random-effect model and sensitivity analysis would be employed, while fixed-effect model would be selected when presenting with excellent homogeneity. Funnel plot would be used to detect the existing publication bias. The statistical significance was defined at a 2-sided P value of $<.05$. The statistical procedures were conducted through Stata software (version 13.0, Stata Corp LLC, College Station, TX).

3. Results

3.1. Study retrieving and selection

We identified a total of 625 articles identified following the initial literature search and additional 3 records from other sources, of which 173 were excluded following duplicates removed. Then through reading the full text, 441 articles were excluded for failing to meet study inclusion criteria. Reasons for exclusion of these studies included: case reports ($n = 27$), irrelevant articles ($n = 400$), and systematic reviews ($n = 14$). We ultimately identified a total of 12 studies^[9–20] that met with inclusion criteria for this meta-analysis, incorporating 935 patients (intramedullary = 469, extramedullary = 466). Study selection is outlined in Figure 1.

3.2. Summaries of the included studies and patients

Publication year of the included studies was ranged from 1990 to 2015. Regarding location where the studies were performed, 2 studies were from South Korea, 2 from China, 1 from

Table 1

General characteristic of the included studies.

Study	Country	Sample size	Age	Study type	Total knee system	EM system	Follow-up
Zhang 2007	China	30/30	68.8/65.0	RCT	Gemini prosthesis (link)	Markers attached to skin	6 mo
Baldini 2008	Italy	50/50	71/70	RCT	Posterior stabilized flex fixed-bearing prosthesis (Zimmer)	An extramedullary device with preoperative templated data	3 mo
da Rocha 2015	Netherlands	22/19	61.4/62.4	RCT	Advance® Medial Pivot prosthesis	NS	NS
de Kroon 2012	Brazil	23/19	NS	RCT	Genesis II	NS	NS
Engl 1990	USA	32/40	69.1/68.7	RCT	PFC Sigma Knee system from Depuy	Hdisc-peg taped to skin for intraoperative location	3 mo
Jeon 2012	South Korea	40/40	70.1/69.2	RCT	PS prosthesis (Stryke)	Markers attached to skin	6 mo
Jung 2013	South Korea	56/50	70.4/68.5	RCT	PS prosthesis (Stryke)	Mechanical axis marker with IFD measurement	3 mo
Li 2019	China	65/68	68.5/69.4	RCT	PS prosthesis (Stryke)	Mechanical axis marker with IFD measurement	3 mo
Lozano 2008	Spain	31/39	69/70	RCT	PS prosthesis (Stryke)	Markers attached to skin	3 mo
Reed 2002	UK	54/46	69/68	RCT	Gemini prosthesis (link)	Markers attached to skin	3 mo
Blakeney 2011	Australia	36/35	NS	RCT	Genesis II total knee system (Smith&Nephew)	NS	3 mo
Chin 2005	Singapore	30/30	65.6/66.9	RCT	PFC Sigma Knee system from Depuy	Markers attached to skin	NS

EM = extramedullary, IFD = inter femoral head center distance, NS = not stated, PS = prosthesis, RCT = randomized controlled trial.

Singapore, 1 from the Italy, 1 from the Spain, 1 from Singapore, 1 from America, 1 from Brazil, 1 from the Netherlands, and 1 from the UK. The sample size ranged from 19 to 65 per study. Patients enrolled in the trial ranged in age from 61.4 to 71 years. Four studies performed PS prosthesis for total knee system, 1 performed Gemini prosthesis, 1 performed stabilized flex fixed-bearing prosthesis, 1 performed Advanced Medial Pivot prosthesis, 3 performed Genesis II, and 2 performed PFC Sigma Knee system from Depuy. Other information can be seen in Table 1.

3.3. Risk of bias

The risk of bias summary and risk of bias graph for each of the studies as assessed and the results are summarized in the Figures 2

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Baldini 2008	+	+	+	+	+	+	+
Blakeney 2011	+	+	+	+	+	+	+
Chin 2005	?	?	+	+	+	+	+
da Rocha 2015	+	?	?	?	+	+	+
de Kroon 2012	?	?	?	?	+	+	+
Engh 1990	?	?	?	?	+	+	+
Jeon 2012	?	?	?	?	+	+	+
Jung 2013	+	?	?	?	+	+	+
Li 2019	+	+	+	+	+	+	+
Lozano 2008	+	?	?	?	+	+	+
Reed 2002	+	+	+	+	+	+	+
Zhang 2007	?	?	?	?	+	+	+

Figure 2. Risk of bias summary: Review authors' judgements about each risk of bias item for each included study.

and 3 respectively. Five studies had an unclear risk of bias for random sequence generation (did not introduce the random sequence generation method), and 8 studies had an unclear risk of bias for allocation concealment. Seven studies rated unclear risk of bias for performance bias (blinding of participants and practitioners). All of the included studies are of low risks of bias of incomplete outcome data, selective reporting, and other bias.

3.4. Lower limb coronal alignment

A total of 7 studies involving 572 patients were included for the analysis of the lower limb coronal alignment. The results showed no statistical heterogeneity ($I^2 = 0.0\%$, $P = .922$) in lower limb coronal alignment after the 2 alignment techniques. The data were analyzed using a fixed-effect model. There was no significant difference between intramedullary and extramedullary alignment technique in terms of lower limb coronal alignment (risk ratio [RR] = 0.85, 95% confidence interval [CI] 0.56–1.27, $P = .426$, Fig. 4).

3.5. Coronal alignment of femoral component

A total of 6 studies totaling 530 patients reported the coronal alignment of femoral component. There was no significant difference between intramedullary versus extramedullary alignment technique in terms of the coronal alignment of femoral component (RR = 0.47, 95% CI 0.30–0.73; $P = .001$, Fig. 5).

3.6. Sagittal alignment of femoral component

A total of 6 studies with a total of 570 patients were included for analysis intramedullary versus extramedullary alignment technique on sagittal alignment of femoral component. There was no significant difference between intramedullary and extramedullary alignment technique on sagittal alignment of femoral component (weighted mean difference [WMD]: 7.73; 95% CI: -33.68–49.15; $P = .714$; significant heterogeneity; Fig. 6).

3.7. Tibial slope

Six studies totaling 436 patients provided data for the effect of intramedullary versus extramedullary alignment technique on tibial slope. The results showed high statistical heterogeneity ($I^2 = 69.6\%$, $P = .006$) in lower limb coronal alignment after the 2 alignment techniques. The data were analyzed using a random-effect model. There was no significant difference between intramedullary versus extramedullary alignment technique on tibial slope (WMD: -0.16; 95% CI: -0.53–0.22; $P = .416$; Fig. 7).

3.8. Total blood loss

Data for the effect of intramedullary versus extramedullary alignment technique on total blood loss were available in 6 studies. The results showed high statistical heterogeneity ($I^2 = 96.0\%$, $P = .000$) in total blood loss after the 2 alignment techniques. The data were analyzed using a random-effect model. Extramedullary alignment technique significantly reduced the total blood loss as compared to intramedullary alignment technique (WMD: -86.52; 95% CI: -115.05--57.99; $P = .000$; Fig. 8).

3.9. Transfusion rate

Six studies addressed the comparison of intramedullary versus extramedullary alignment technique on transfusion rate. The results showed no statistical heterogeneity ($I^2 = 0.0\%$, $P = 1.000$) in transfusion rate the 2 alignment techniques. The

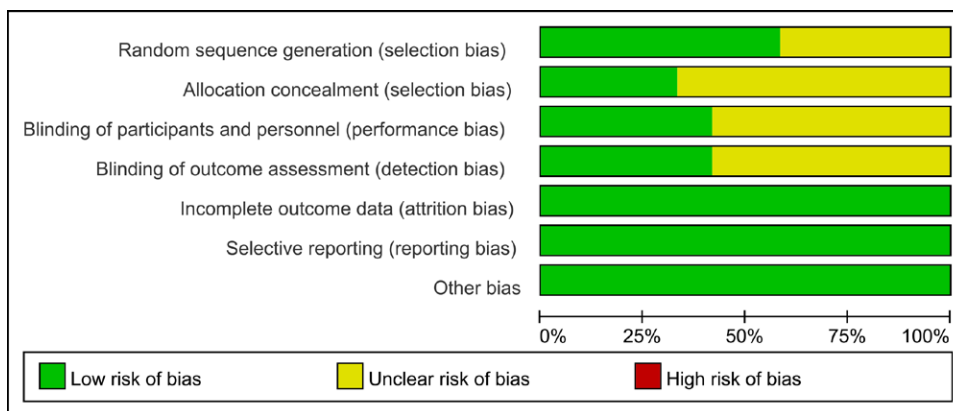


Figure 3. Risk of bias graph. Green, low risk of bias; red, high risk of bias; yellow, unclear risk of bias.

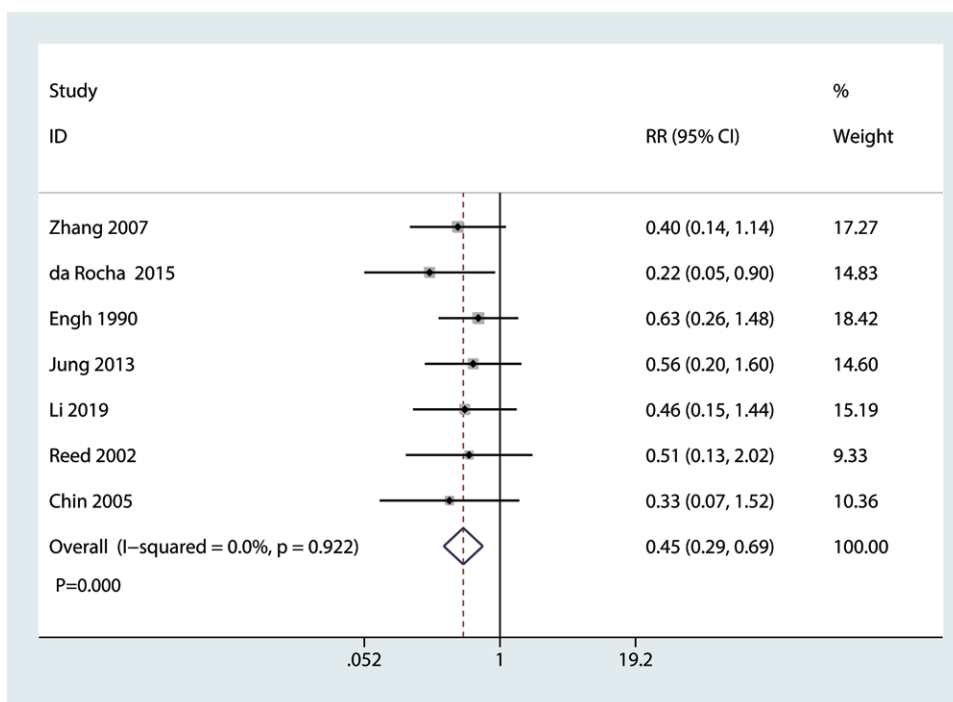


Figure 4. Postoperative lower limb coronal alignment of intramedullary and extramedullary alignment technique in total knee arthroplasty.

data were analyzed using a fixed-effect model. Extramedullary alignment technique was associated with a decrease of the transfusion rate than intramedullary alignment technique (RR: 0.57; 95% CI: 0.41–0.79; $P = .000$; Fig. 9).

3.10. Total complications

Seven RCT studies, from 2005 to 2019, that compared intramedullary versus extramedullary alignment technique on total complications. The results showed no statistical heterogeneity ($I^2 = 0.0\%$, $P = .959$) in transfusion rate the 2 alignment techniques. We analyzed these trials using a fixed-effect model. There was no significant difference between intramedullary versus extramedullary alignment technique on total complications (RR: 0.89; 95% CI: 0.55–1.42; $P = .620$; Fig. 10).

3.11. Publication bias and sensitivity analysis

No significant publication bias was observed for lower limb coronal alignment (Fig. 11). Additional sensitivity analyses which

excluded individuals in turn did not change the overall results (Fig. 12).

4. Discussion

This meta-analysis is with the largest sample size so far. We systematically analyzed the intramedullary versus extramedullary alignment technique in TKA. We observed comparable accuracy between extramedullary distal femur osteotomy and intramedullary systems in TKA patient. However, extramedullary distal femur osteotomy has led to less blood loss and subsequently lower transfusion rate.

The strengths of the present meta-analysis were as follows. First, more RCTs including more samples were included and thus would give more robust evidence. Second, current meta-analysis evaluated more clinically relevant outcomes (accuracy of femur osteotomy, blood loss and potential complications). Third, we included studies without language restriction and thus the selection bias could be reduced to a minimum. Fourth, the 7 newly enrolled studies had significant enlarged sample size, which further improve the quality of this meta-analysis.

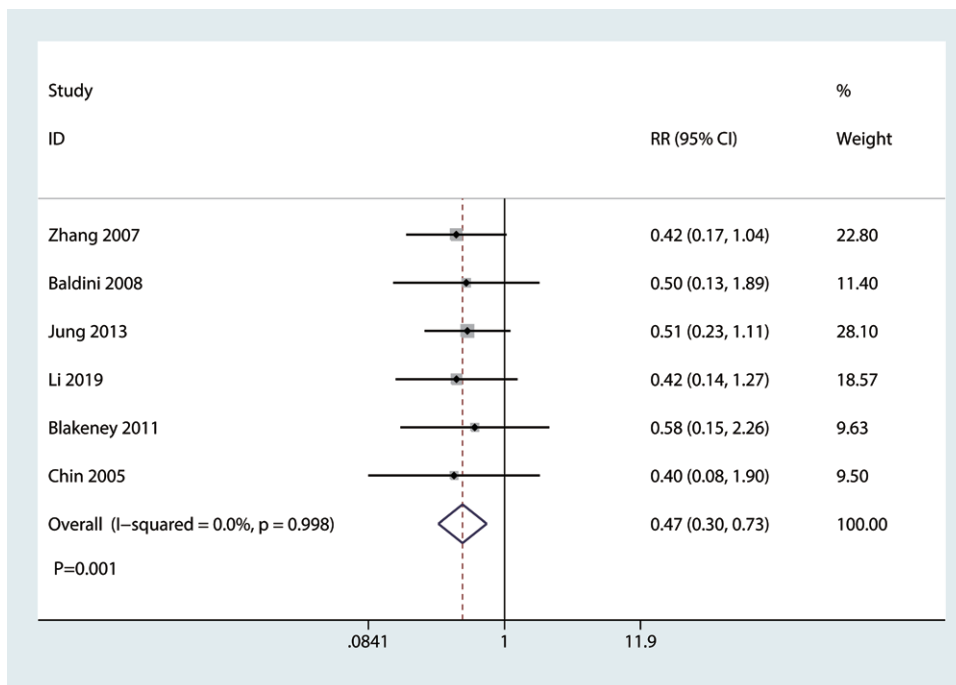


Figure 5. Postoperative coronal alignment of femoral component of intramedullary and extramedullary alignment technique in total knee arthroplasty.

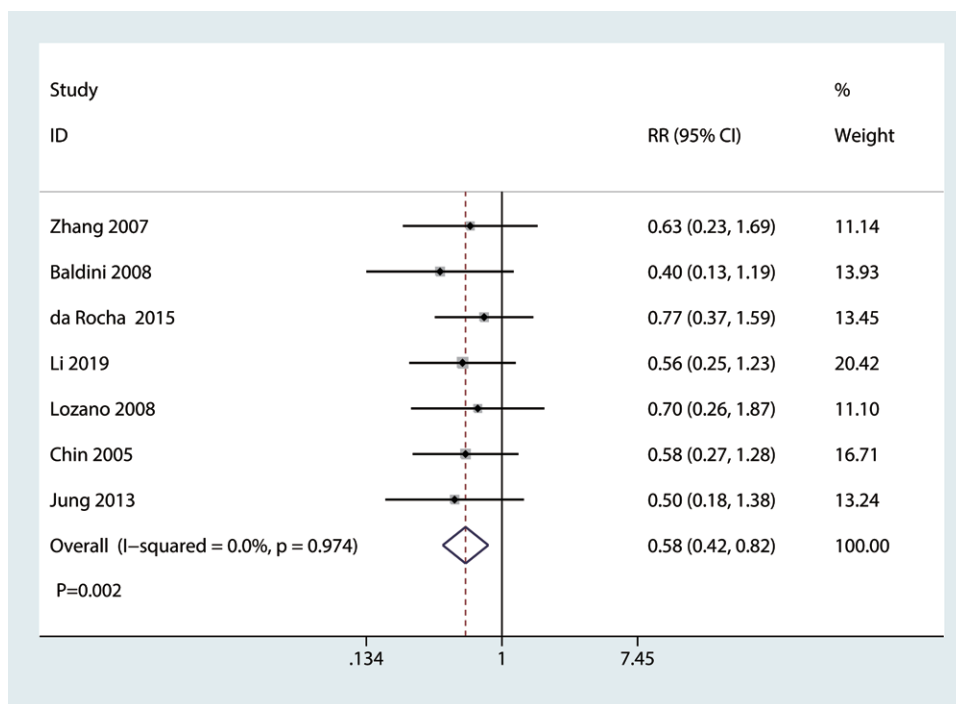


Figure 6. Postoperative sagittal alignment of femoral component of intramedullary and extramedullary alignment technique in total knee arthroplasty.

Research has demonstrated that patients' satisfaction and longevity of the prosthesis was closely connected with the accuracy of the lower limb mechanical axis. Intramedullary alignment technique was popular as the anatomical axis of the femur. In this study, we measured the accuracy of the intramedullary versus extramedullary alignment techniques in TKA patients. Most of the literatures supported that intramedullary alignment technique has superior accuracy for coronal alignment. Eng et al^[13] revealed that intramedullary

alignment technique was associated with an increase of the acceptable rate than that of extramedullary cuts. Moreover, Lotke et al^[21] found that intramedullary alignment system has more accurate rate than extramedullary alignment system (85.6% vs 72.1%). Qin et al^[22] revealed that alignment of the extramedullary distal femur osteotomy is as accurate as intramedullary systems. Potential reason may be that the extramedullary distal femur osteotomy was improved in recent years.

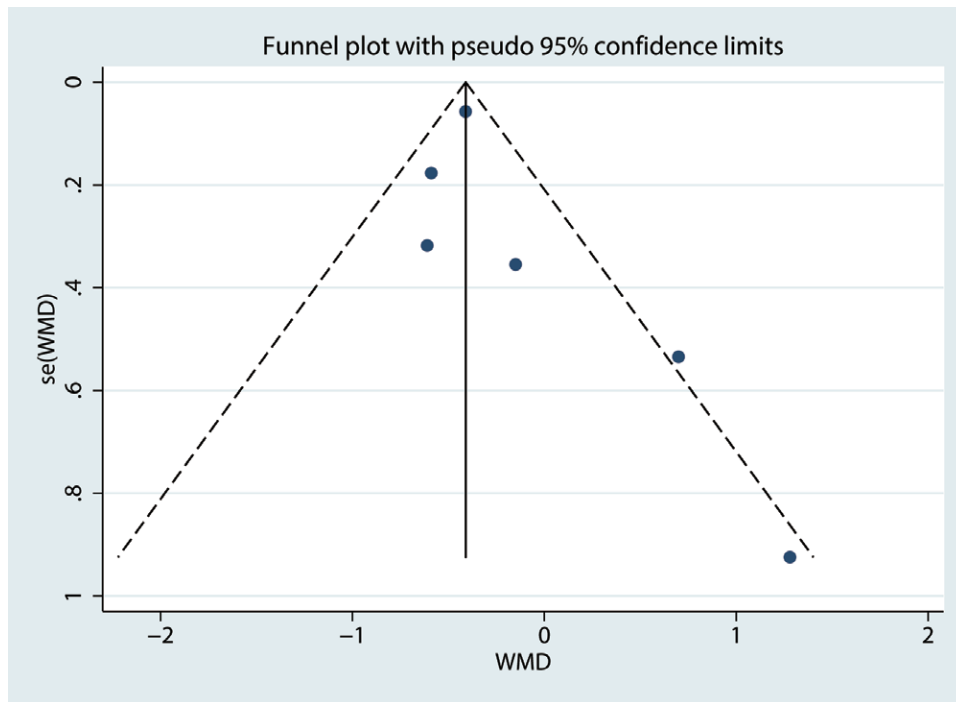


Figure 7. Postoperative tibial slope of intramedullary and extramedullary alignment technique in total knee arthroplasty.

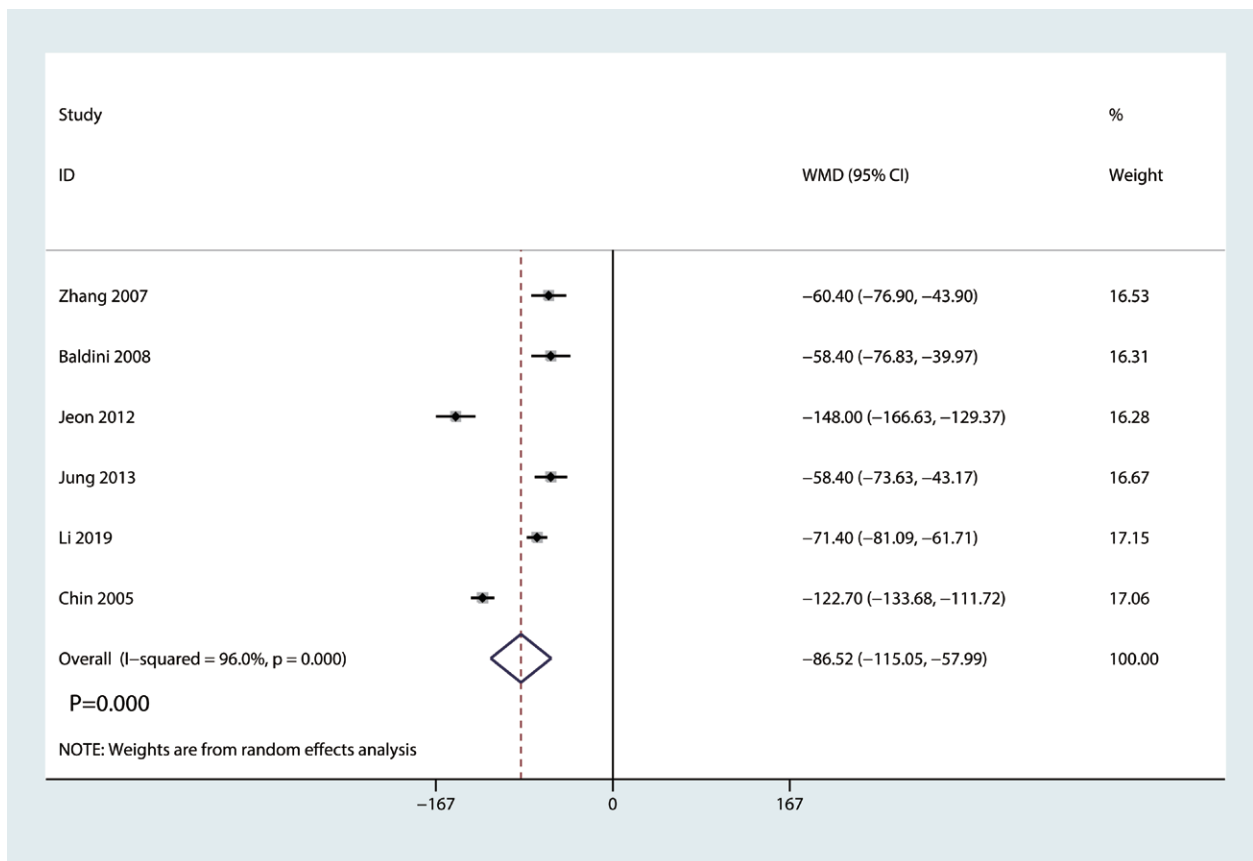


Figure 8. Postoperative blood loss of intramedullary and extramedullary alignment technique in total knee arthroplasty.

4.1. Implication and explanation of findings

Intramedullary could significantly cause blood loss and subsequently blood transfusion. Some investigation also found that small emboli was located in the right atrium

after intramedullary technique by transesophageal echocardiography.^[23] While, extramedullary indeed has no effects on the femoral medullary cavity and thus could avoid such embolism.

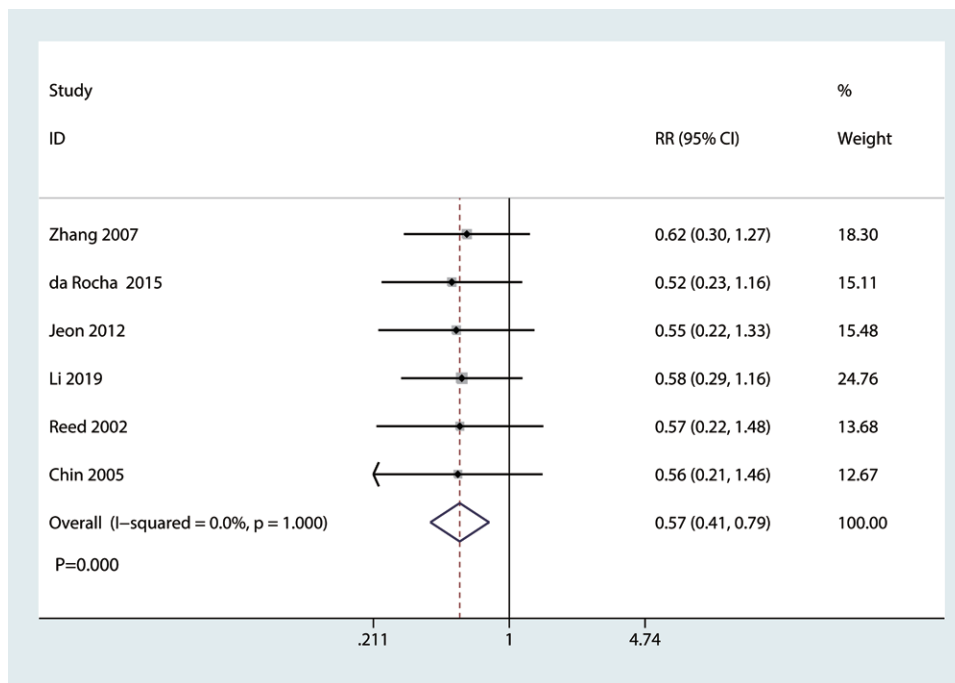


Figure 9. Forest plot for transfusion rate of intramedullary and extramedullary alignment technique in total knee arthroplasty.

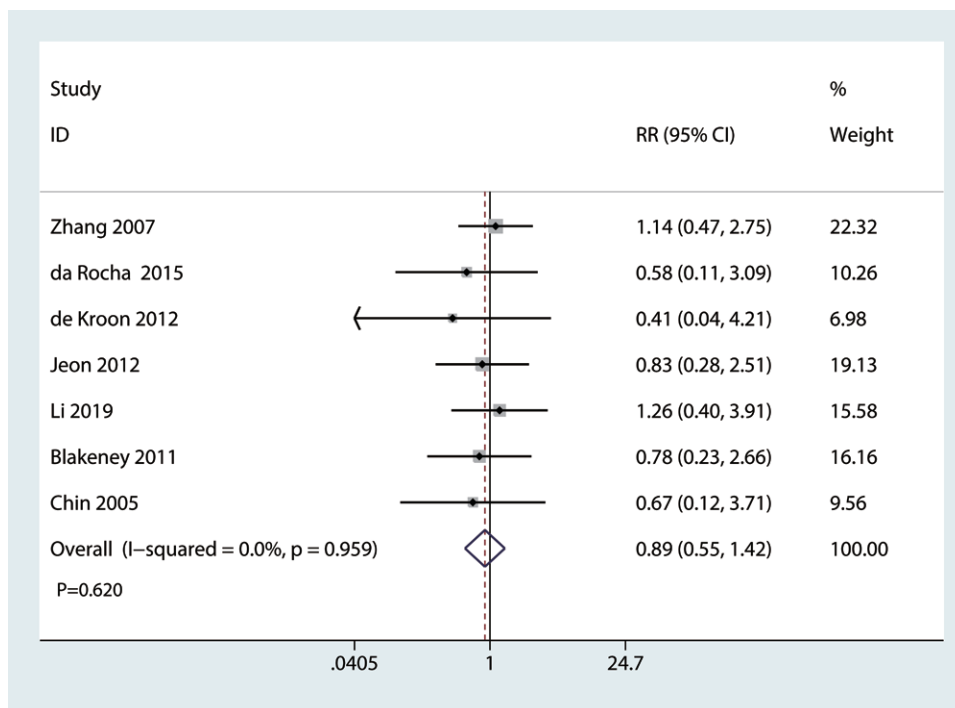


Figure 10. Forest plot for total complications of intramedullary and extramedullary alignment technique in total knee arthroplasty.

4.2. Recommendation and future directions

Both intramedullary and extramedullary alignment technique were performed for TKA patients. In current meta-analysis, we recommended that extramedullary alignment technique was more preferable for clinical application. Previous meta-analysis based on 4 RCTs about the precise of intramedullary and extramedullary alignment technique in TKA patients revealed that neither extramedullary nor intramedullary femoral alignment is more accurate than the other in facilitating the femoral

cut in TKA.^[24] On the basis of this, we encourage more specifically focused future RCTs that contain a greater number of patients to assess these forms of heterogeneity in their analyses. All of the included studies did not report embolism relevant outcomes thus future studies should focus on these clinical outcomes.

However, this study has several limitations that should be noted. The number of included studies is limited, and the sample size is small. Further, methodological quality varied

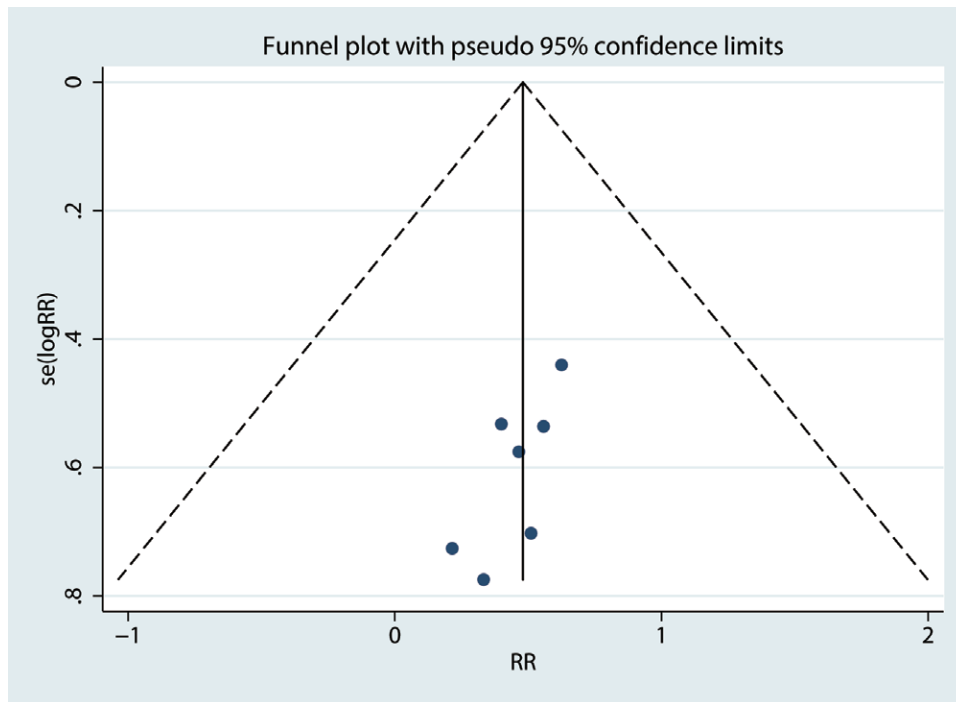


Figure 11. Funnel plot for the lower limb coronal alignment.

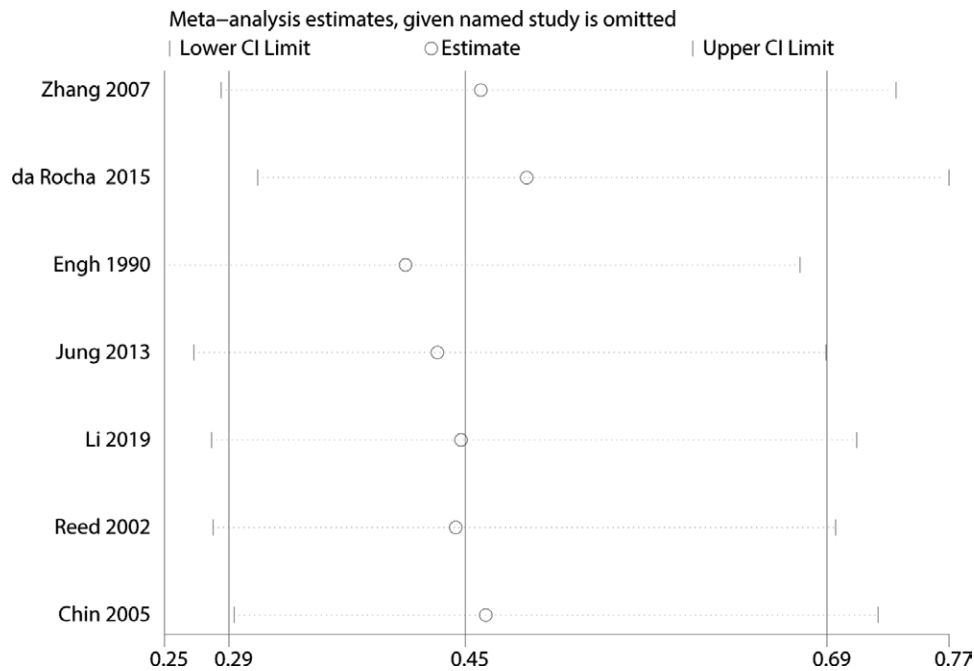


Figure 12. Sensitivity analysis for the lower limb coronal alignment.

considerably and thus need for more studies with high quality to further verify the results. Follow-up duration was short and thus may underestimate the rates of long-term complications.

5. Conclusions

The present meta-analysis showed that intramedullary and extramedullary alignment technique had comparable precise efficacy profiles. Further, extramedullary alignment technique could decrease the blood loss and transfusion rate. Further

large-scale, prospective, RCTs are required to verify the comparison of intramedullary and extramedullary alignment technique in TKA patients.

Author contributions

Conceptualization: Bingshen Jia.
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 Project administration: Shuai Hu.
 Supervision: Ming Li, Jun Li.

Visualization: Jun Li, Shuai Hu.

Writing – original draft: Ming Li.

Writing – review & editing: Shuai Hu.

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