The Effect of Congruent Tibial Inserts in Total Knee Arthroplasty: A Network Meta-analysis of Randomized Controlled Trials

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Abstract

Objective

This study aims to determine whether modern ultracongruent tibial inserts are associated with different outcomes in Total Knee Arthroplasty (TKA).

Background

Ultracongruent fixed-bearing (UCFB) and medial congruent fixed-bearing (MCFB) inserts have been known to be effective in total knee arthroplasty with patient satisfaction. Nonetheless, no supporting evidence to date exists to rank the clinical outcomes of these various congruent inserts in TKA.

Methods

We searched for PubMed, Embase, The Cochrane Central Register of Controlled Trials, Web of Science, and Scopus up to May 15, 2022. We selected studies involving an active comparison of UCFB or MCFB in TKAs. We performed a network meta-analysis (NMA) of randomized controlled trials (RCTs) and compared different congruent inserts. We ranked the clinical outcomes by SUCRA score with the estimate of the best treatment probability. Our primary outcomes were revision rates and radiolucent lines. Secondary outcomes were functional scores, including the range of motion (ROM), the Knee Society Score (KSS), Oxford Knee Score (OKS), and WOMAC.

Results

18 RCTs with 1793 participants were obtained. The MCFB performed similar revision rates as CRFB and PSRP. CRFB and UCFB had the lowest radiolucent lines. UCFB and MCFB had the best OKS score overall.

Conclusions

The ranking probability for better clinical outcomes in congruent inserts demonstrated the superiority of congruent tibial inserts, including UCFB and MCFB. UCFB may be associated with improved postoperative functional outcomes. However, integrating future RCTs for high-level evidence is necessary to confirm these findings.

1. INTRODUCTION

Bearing designs for total knee arthroplasty (TKA) have evolved over time to improve clinical outcomes. Traditional designs include posterior-stabilized (PS) and cruciate-retaining (CR) fixed-bearing, and mobile-bearing designs. Fixed-bearing designs provide rigid fixation of polyethylene inserts within the tibial implant. While mobile-bearing designs were developed to improve conformity and lower contact stresses with the goal of pursuing native knee kinematics. However, complications such as bearing dislocations have been reported for mobile-bearing designs, while high contact stresses with polyethylene wear were reported for PS designs. A recent meta-analysis has not proven one superior to another, including revision rates, aseptic loosening, radiographic loosening/osteolysis, and functional outcomes.

Ultracongruent (UC) and medial congruent (MC) fixed-bearing designs have been developed to improve the clinical outcomes of TKA in the past few decades. The UC design has a higher anterior lip of insert instead of post-cam mechanism to control posterior translation of the tibia in flexion after sacrificing the posterior cruciate ligament (PCL), while the MC design provides greater conformity of the medial compartment. The advantage of UC/MC design includes preventing post
cam wear, post fracture and less bone loss of femoral condyle notch. However, despite these potential advantages, concerns also have been raised. Some studies have suggested that UCFB designs may be associated with decreased range of motion (ROM) compared to traditional posterior stabilized fixed-bearing designs (PSFB). [7, 15–18]. Additionally, some studies have raised concerns about the potential of early loosening due to the restriction of rotational freedom of the femur and increased stress on the tibial bone surface. [19–21] Despite these concerns, UCFB designs have been adopted by most of the major prosthetic knee systems manufacturers such as the Persona knee system (Zimmer-Biomet), E-motion/Columbus (Aesculap), Genesis II (Smith and Nephew), and AMK (Depuy Synthes Model of the Anatomic Modular Knee).

Given the conflicting results and concerns regarding UCFB designs, it is important to determine if these designs are associated with superior/inferior outcomes in current TKA. The objective of this study is to conduct a network meta-analysis of randomized controlled trials to compare the clinical outcomes of various congruent tibial inserts in TKA, including UCFB designs, and determine if they are associated with different outcomes.

2. METHODS

2.1 Research Protocol and Search Question

The research protocol for this study was developed to answer the following PICO question: In patients undergoing total knee arthroplasty, do congruent tibial inserts result in lower revision rates, fewer radiolucent lines, and better clinical outcomes compared to traditional tibial inserts? The search protocol was based on the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and was registered with The International Prospective Register of Systematic Reviews (PROSPERO) in January 2020. Both cohort studies and randomized controlled trials were included in the analysis. The present study did not involve individual patient data, and informed consent of participants was not applicable.

2.2 Eligibility Criteria and Primary Outcome

To be eligible for inclusion in this study, studies had to meet the following criteria: 1) included patients who underwent TKA with various congruent tibial inserts; 2) clearly defined the congruency of the insert used; 3) be a cohort or randomized controlled trial study published in the English language up to May 15, 2022; 4) reported the primary outcome of interest: revision rates and radiolucent lines. Secondary outcomes of interest included functional scores such as range of motion (ROM), the Knee Society Score (KSS), Oxford Knee Score (OKS), and Western Ontario and McMaster Universities Arthritis Index (WOMAC). Studies were excluded if they met any of the following criteria: 1) were single-arm follow-up studies, case reports, case series, reviews, basic science experiments, or animal or cadaver studies; 2) included patients who underwent immunosuppression; 3) were conference abstracts.

2.3 Search Strategy and Study Selection

To identify relevant studies for inclusion in this study, we conducted a systematic search of multiple databases including PubMed, Embase, The Cochrane Central Register of Controlled Trials, Web of Science, and Scopus. The search was performed using a combination of keywords and medical subject headings (MeSH) that were adjusted for each database. The most recent search was conducted on May 15, 2022. Additionally, we also conducted a recursive search by reviewing the bibliographies of obtained articles.

We employed a two-step review process to evaluate the articles identified through the search. In the first step, two independent reviewers (YLT, SHLT) evaluated the titles and abstracts of the articles to determine their eligibility for inclusion in the study. In the second step, the full text of relevant articles was reviewed by the same two independent reviewers (YLT, SHLT) to assess their qualification for inclusion. Any disagreements between the reviewers were resolved through discussion.

2.4 Data Collection and Quality Assessment
The following data were extracted from each included study: author, year of publication, region of study, data source, study design, period of study, study arms, sample size, patient age, inclusion criteria, and the specific definition of each treatment arm.

Two independent reviewers (YLT, SHLT) assessed the risk of bias and overall quality of each study using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) assessment tool. This tool was used to evaluate the confidence in effect estimates. Any discrepancies in the assessment of risk of bias or study quality were resolved through discussion between the reviewers.

2.5 Statistical Analysis and Quantitative Data Synthesis

A frequentist random-effects network meta-analysis (NMA) was conducted to compare the different congruent designs of TKA. This method allows for both direct and indirect comparisons among the included studies. Heterogeneity among the studies was evaluated using the $\tau^2$ statistic, with values of 0.04, 0.16, and 0.36 corresponding to low, moderate, and high degrees of heterogeneity, respectively.

To examine the potential for small-study bias such as publication bias, comparison-adjusted funnel plots and Egger tests were used. Subgroup analysis was performed based on treatment comparison to evaluate potential confounders. The probability of each treatment group being the best for the target outcomes was ranked using the surface under the cumulative ranking curve (SUCRA), which reflects the percentage of an intervention that was the best without uncertainty. Ranking plot is a graphical representation that shows the relative ranking of different interventions or treatments based on their effectiveness or outcomes. It helps to visually compare and assess the performance of each treatment option. The potential inconsistency between the direct and indirect evidence in the network was evaluated using the loop-specific and node-splitting models. Additionally, a design by treatment interaction model was used to evaluate global inconsistency within the entire NMA.

3. RESULTS

3.1 Literature Search and Selection Process

Our literature search identified a total of 661 articles through database searching. After removing duplicates and screening the titles and abstracts, 194 full-text articles were reviewed for eligibility. Ultimately, 18 studies were included in the network meta-analysis. The selection process is summarized in Figure 1.

3.2 Study Characteristics

A total of 18 RCT studies were included in the analysis. These studies included a total of 1793 patients. The mean patient age across studies ranged from 64.9 to 72.5 years; on average, 66.8% of patients were female (range 7% to 95%). (Table 1). The studies were conducted in various countries including China (1 study, n=46), Germany (2 studies, n=229), USA (4 studies, n=718), Korea (3 studies, n=250), India (2 studies, n=178), Australia (2 studies, n=165), Japan (2 studies, n=105), UK (1 study, n=80), and Sweden (1 study, n=22). All studies were active comparator studies, with various comparisons made between different congruent tibial inserts. The specific comparisons made are detailed in the provided text. Five articles compared Ultracongruent fixed bearing (UCFB) to Standard posterior stabilized fixed bearing (PSFB), 2 compared UCFB to CRFB, 4 compared MCFB to PSFB, 1 compared MCFB to PSRP, 1 compared MCFB to CRFB, 1 compared MCFB to CRFB and PSFB, 1 compared MCFB to PSFB, 2 compared MCFB to UCFB, and 1 compared MCFB to CRFB, PFFB and PSRP.

Table 1. Study characteristics
<table>
<thead>
<tr>
<th>Study</th>
<th>Group</th>
<th>Country</th>
<th>Implant type</th>
<th>Patellar Resurfacing</th>
<th>Mean Age (SD/range)</th>
<th>Sex (M/F)</th>
<th>Follow-up (yrs)</th>
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<td>PFC Sigma, DePuy</td>
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<td>Follow-up</td>
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<td>65.5</td>
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<td>Wright</td>
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3.3 Methodological Quality and Assessment of Risk of Bias

The methodological quality of included studies was assessed using A revised Cochrane risk-of-bias tool for randomized trials 2.0 (ROB2.0). Two studies were found to not provide sufficient follow-up protocol and length of follow-up for the
outcome of interest. The strength of evidence for the outcome was based on the GRADE approach and was determined to be moderate. The network graph demonstrates the structure of our network meta-analysis, with the width of the edge corresponding to the number of studies.

3.4 Revision Rate

This outcome was reported by 11 studies with 941 participants. CRFB (0/105, 0%), MCFB (0/260, 0%) and PSRP (0/92, 0%) had no revisions. UCFB had 3 revisions (3/364, 0.8%) and PSFB had 5 revisions (5/317, 1.6%). The MCFB performed similar revision rates as CRFB and PSRP; the SUCRA plot is in Figure 2. The detailed numbers are presented in supplementary table A.

3.5 Radiolucent Line

This outcome was reported by 5 studies with 797 participants. No radiolucent lines were found in CRFB (0/215, 0%) and UCFB (0/86, 0%). 3 radiolucent lines were found in PSFB (3/301, 1%), 5 radiolucent lines were found in PSRP (5/175, 2.9%) and 10 radiolucent lines were found in MCFB (10/401, 2.5%). CRFB and UCFB were ranked the best among all the treatments for the outcome of radiolucent lines with the heterogeneity between groups not reaching statistical significance, SUCRA plot is in Figure 3. The detailed numbers are presented in supplementary table B.

3.6 Range of Motion (ROM)

This outcome was reported by 13 studies with 1651 participants. The mean ROM of UCFB was 111.63°. UCFB was not significantly different compared with noncongruent inserts, with the heterogeneity between groups not reaching statistical significance, SUCRA plot is in Figure 4. The detailed numbers are presented in supplementary table C.

3.7 Aseptic loosening

This outcome was reported by 4 studies with 369 participants. No aseptic loosening was found in MCFB (0/90, 0%). 1 aseptic loosening was found in UCFB (1/98, 1%) and 1 aseptic loosening was found in PSFB (1/181, 0.6%). MCFB was ranked the best among all the treatments with the heterogeneity between groups not reaching statistical significance. The detailed numbers are presented in supplementary table D.

3.8 the Knee Society Score (KSS)

This outcome was reported by 15 studies with 1593 participants. The mean KSS of CRFB was 78.3. The mean KSS of UCFB was 86.11. The mean KSS of PSFB was 90.75. The mean KSS of MCFB was 88.44. The mean KSS of PSRP was 92. PSRP was ranked the best among all the treatments with the heterogeneity between groups not reaching statistical significance. The detailed numbers are presented in supplementary table E.

3.9 the Knee Society Score- Function (KSS-F)

This outcome was reported by 11 studies with 1232 participants. The mean KSS-F of CRFB was 68. The mean KSS-F of UCFB was 50.42. The mean KSS-F of PSFB was 61.71. The mean KSS-F of MCFB was 69.14. The mean KSS-F of PSRP was 83.55. PSRP was ranked the best among all the treatments with the heterogeneity between groups not reaching statistical significance. The detailed numbers are presented in supplementary table F.

4.0 Oxford Knee Score (OKS)

This outcome was reported by 7 studies with 636 participants. The mean OKS of CRFB was 37. The mean OKS of UCFB was 40.05. The mean OKS of PSFB was 36.22. The mean OKS of MCFB was 36.46. UCFB and MCFB were ranked the best among
all the treatments with the heterogeneity between groups not reaching statistical significance. The detailed numbers are presented in supplementary table G.

4.1 WOMAC.

This outcome was reported by 7 studies with 561 participants. The mean WOMAC of CRFB was 20.8. The mean WOMAC of UCFB was 14.56. The mean WOMAC of PSFB was 18.58. The mean WOMAC of MCFB was 18.48. CRFB was ranked the best among all the treatments with the heterogeneity between groups not reaching statistical significance. The detailed numbers are presented in supplementary table H.

DISCUSSION

The study indicate that modern ultracongruent tibial inserts, specifically ultracongruent fixed-bearing (UCFB) and medial congruent fixed-bearing (MCFB) inserts, are associated with superior outcomes in Total Knee Arthroplasty (TKA). The analysis revealed that the MCFB performed similar revision rates as CRFB and PSRP. Additionally, CRFB and UCFB exhibited the lowest occurrence of radiolucent lines, suggesting improved implant fixation. Furthermore, UCFB and MCFB demonstrated the highest scores in the Oxford Knee Score (OKS), indicating superior postoperative functional outcomes. These findings highlight the potential advantages of using congruent tibial inserts, particularly UCFB and MCFB, in TKA. However, further high-quality randomized controlled trials (RCTs) are needed to validate these results and strengthen the existing evidence base. [1,3,7,8]

However, mobile-bearing designs have potential complications such as insert dislocations, and PS designs have high contact stresses and polyethylene wear. In the last decade, UC and MC fixed-bearing designs have been created to enhance TKA outcomes, with UC having an elevated anterior lip and MC offering better medial compartment conformity. [12,13,22,23] The present systematic review and meta-analysis aimed to evaluate the effectiveness and safety of congruent tibial inserts in total knee arthroplasty. [23] The results of our analysis indicate that congruent tibial inserts provide fewer radiolucent lines compared to traditional inserts. Additionally, our analysis showed that congruent inserts may lead to improved functional scores, such as the OKS. [24,25] These findings may be attributed to the higher anterior lip exactly controlling posterior translation of the tibia in flexion after sacrificing PCL requiring posterior stability. This higher anterior lip design also provides benefits such as preventing post wear, post fracture and less femoral bone loss when compared to PS design [26]. Concerns about early loosening of tibial components due to the restriction of rotational freedom of the femur with increased stress on the tibial bone surface were not really identified in the current study. [16,18]

UCFB designs have been found to have fewer overall radiolucent lines compared to other TKA designs. [25,27] One possible explanation for this finding is that the increased surface area of contact redistributes the contact stress between the tibial insert and the femoral component in UC design. This increased contact area leads to improved stability and less wear/tear on the components. [26] Additionally, the UC design may reduce the potential micromotion between the tibial insert and the femoral component, which can lead to radiolucency [15]. Another possible explanation for fewer radiolucent lines observed in UC designs may be the improved accuracy of implant positioning and alignment achieved with these new designs, which can also contribute to improved stability and reduced wear.

Our findings are consistent with previous studies that have also reported similar revision rates and radiolucent lines among different types of TKA designs [28]. The better conformity and contact area between the femoral component and the tibial plateau with UCFB may help explain the reduced radiolucent lines. This may lead to improved load distribution and reduced micromotion at the bone-implant interface, which can help prevent loosening and improve implant survival. Moreover, the reduced incidence of PS-related complications such as patellar clunk syndrome and patellar fracture may also contribute to the better clinical outcomes observed [26,29]. A recent meta-analysis was conducted by Vishwanathan et al that aimed to compare the outcomes of anterior stabilized UC and standard CR inserts in fixed-bearing primary total knee arthroplasty. [30] The study included 14 studies (3 RCTs and 11 comparative case-cohort studies), comprising 9989 knees, and found that
knee pain was better in patients that had standard CR inserts, and the quality of life was also better in patients that had standard CR inserts. However, there was a 72% lesser chance of revision TKA or change of insert for postoperative instability in knees that had been implanted with UC inserts. There was no difference in the other outcome measures.

Our study has some limitations that should be considered when interpreting the results. Firstly, although we included a large number of RCTs, the number of studies comparing CR type rotating platform with UCFB was limited. Thus, our analysis was not able to provide conclusive evidence regarding the efficacy and safety of CRRP compared to UCFB. Future studies with larger sample sizes and longer follow-up periods are needed to investigate this issue further. Secondly, the follow-up period in the included studies was relatively short, with most studies having a follow-up period of less than 5 years. Thus, our analysis may not have captured long-term complications or time dependent adverse events in TKA. Further longer monitoring of these patients to fully evaluate the safety and efficacy of these implants is our responsibility. Thirdly, there was heterogeneity among the included studies in terms of patient characteristics, surgical technique, implant design, and outcome measures. This heterogeneity may have influenced the results of our analysis and makes it difficult to generalize the findings to all patient populations and implant designs. Finally, our study only focused on the different congruent designs of tibial inserts in TKA and did not investigate other concomitant factors that may influence the outcomes of the surgery, such as patient comorbidities, different surgical technique, or implant alignment/positioning. Further studies that take these factors into account are needed to fully understand the impact of congruent tibial inserts on the outcomes of TKA.

Network meta-analysis (NMA) is a method used to compare multiple interventions in a single analysis. However, it is important to note that NMA has some limitations, such as reliance on indirect comparisons which can introduce uncertainty and bias. Additionally, NMA requires a large amount of data to be effective, and when data is limited, the results may not be as reliable. Our study found that UCFB may be associated with fewer radiolucent lines and overall better clinical outcomes compared to other congruent inserts[24]. However, it is important to consider that our study has limitations such as a small number of studies and a short follow-up period, which may affect the generalizability of the findings. Further studies with more data and longer follow-up periods are needed to confirm these findings.

**CONCLUSION**

In conclusion, our study suggests that ultracongruent fixed-bearing (UCFB) and medial congruent fixed-bearing (MCFB) inserts may be good options for total knee arthroplasty (TKA) due to their potential to improve clinical outcomes. The advantage of UCFB and MCFB over other inserts may encourage orthopedic surgeons to consider this design in their surgical decision-making. However, given that our findings are based on indirect comparisons and limited studies, caution should be exercised when interpreting the results. Future randomized controlled trials are needed to confirm our findings and provide high-level evidence, however current available evidence through our NMA encourage the usage of modern UCFB and MCFB insert designs.

**Declarations**

**Disclosures:** None of the authors have any financial disclosures.

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**References**


Figures
Figure 1

PRISMA flow diagram

Records identified through database searching
PubMed, Embase, The Cochrane Central Register of Controlled Trials, Web of Science, and Scopus
(n = 661)

Remove duplicated
(n = 352)

Title & abstract screening
(n = 309)

Remove irrelevant
(n = 194)

Full-text articles assessed for eligibility (n = 115)

Full-text articles excluded, with reasons
(n = 97)
- Wrong patient population (n = 6)
- Wrong setting (n = 17)
- Wrong study design (n = 58)
- Wrong comparators (n = 5)
- Not clearly defined the congruency of the insert used (n = 11)

Studies included in meta-analysis
(n = 18)
Figure 2

The mechanical complications analysis of revision rates and SUCRA plot

Figure 3

The mechanical complications analysis of radiolucent lines and SUCRA plot
Figure 4

The mechanical complications analysis of ROM and ranking plot

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendix.docx