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Clinical and Radiological Outcomes of Computer-Assisted Navigation in Primary Total Knee Arthroplasty for Patients with Extra-articular Deformity: Systematic Review and Meta-Analysis

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Background: Computer-assisted navigation surgery (CAS) during primary total knee arthroplasty (TKA) may help improve outcomes for patients with extra-articular deformity (EAD); however, this has not been extensively studied. Therefore, we aimed to investigate the clinical and radiological outcomes following primary TKA using CAS in patients with EAD.

Methods: We searched Medline, Embase, and the Cochrane Library up to March 3, 2023 for studies investigating surgical outcomes of using the navigation system for TKA to treat patients with EAD. From 14 studies, 539 knees with EAD that underwent navigation TKA were enrolled. We investigated the knee range of motion (ROM), outcome scores at final follow-up (Knee Society Score [KSS] and Knee Functional Score [KFS]), and pre- and postoperative mechanical hip-knee-ankle (mHKA) angle using lower extremity scanogram. The meta-analysis was based on the single-arm method, and all data were pooled using a random-effects model.

Results: Following our meta-analyses, the mean knee ROM changed from 87.0° (95% confidence interval [CI], 75.9°–98.1°) preoperatively to 109.4° (95% CI, 97.9°–120.8°) postoperatively. The adjusted KSS was 93.45 points (95% CI, 88.36–98.54 points), and the adjusted KFS was 91.57 points (95% CI, 86.80–96.33 points) in knees with EAD that underwent CAS-TKA. As a radiological outcome, the mHKA angle changed from 169.53° (95% CI, 166.90°–172.16°) preoperatively to 178.81° (95% CI, 178.31°–179.30°) postoperatively.

Conclusions: CAS-TKA yielded positive clinical results and demonstrated a satisfactory alignment of the lower limb's mechanical axis. CAS-TKA showed promise for primary TKA procedures, demonstrating favorable clinical and radiological outcomes even in complex cases involving EAD.

Keywords: *Surgical navigation system, Arthroplasty, Replacement, Knee, Deformity, Meta-analysis*

Total knee arthroplasty (TKA) is a well-established treatment for patients with advanced knee osteoarthritis.[1-4] TKAs have been increasing worldwide due to the increasing life expectancy and participation in recreational activities;[4,5] however, patient dissatisfaction following primary TKA is still reported as 10%–12.7%.[6,7] Therefore, several advances in primary TKA, such as patient-specific instruments and enhanced recovery systems, have improved clinical outcomes.[8,9]

Computer-assisted navigation (CAS) was intro-

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duced to improve the clinical outcomes of TKA. The current use of CAS in primary TKAs demonstrated improved coronal alignment.[10-12] It allows direct alignment measurement without breaching the medullary canal, which is potentially useful when performing TKAs in patients with extra-articular deformity (EAD). In addition, the extension of preoperative varus deformity could influence the postoperative alignment; hence, more careful alignment correction is required, mainly when TKA is performed in patients with severe varus deformity.[13] However, few patients with EAD require primary TKA. Therefore, only few case series have been reported despite the longstanding use of CAS.

This study aimed to investigate the clinical and radiological outcomes following primary TKA using CAS in patients with EAD. We hypothesized that this technique would show favorable clinical outcomes and an acceptable mechanical axis of the lower extremity even in complex cases involving EAD.

METHODS

Although the present study involved human participants, ethical approval and informed consent from the participants was not required because all data were based on previously published studies that were analyzed anonymously without any potential harm to the participants. The present study was conducted in accordance with the Cochrane Reviews and the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols guidelines.[14,15]

Search Strategy

We searched Medline, Embase, and the Cochrane Library for studies investigating the treatment results of CAS in TKA for patients with EAD. An experienced librarian designed the search strategy in collaboration with the study investigators. Using an a priori search strategy, we identified articles published until March 3, 2023. To ensure the inclusion of all relevant articles, the search terms included synonyms and terms related to TKA, navigation, and EAD. We placed no restrictions on language or the year of publication. After the initial electronic search, relevant articles and their bibliographies were manually searched.

Study Selection

The inclusion criteria were based on the Population/Intervention/Comparator/Outcome/Study design (PICOS) criteria[16] as follows: "patients" with osteoarthritis and EAD; navigation TKA as the "intervention"; no "comparator"; the knee range of motion (ROM), postoperative mechanical hip-knee-ankle (mHKA) angle, and outcome scores at the final follow-up visit as "outcomes"; the "study design," which included both prospective and retrospective studies as original articles or case series; and English language. The exclusion criteria were small sample size (< 5 knees), different field of interest, and those overlapping the study population with another report.

From the titles and abstracts of the studies, 2 board-certified orthopedic surgeons (CHK and SHB), who worked as faculty members at an academic medical center, independently selected the articles for full-text review. If the abstract provided insufficient data to decide, the entire article was reviewed. At each article selection stage, the κ-value was calculated to determine inter-reviewer agreement regarding study selection. Agreement between reviewers was correlated with κ-values as follows: $\kappa = 1$ corresponded to "perfect" agreement, $1.0 > \kappa \geq 0.8$ to "almost perfect" agreement, $0.8 > \kappa \geq 0.6$ to "substantial" agreement, $0.6 > \kappa \geq 0.4$ to "moderate" agreement, $0.4 > \kappa \geq 0.2$ to "fair" agreement, and $\kappa < 0.2$ to "slight" agreement. Disagreements at each stage were resolved through discussion between the 2 investigators to reach consensus or by discussion with a third investigator (YBP), also a board-certified orthopedic surgeon, when a consensus could not be reached.

Data Extraction

The following demographic data were investigated: the total number of patients enrolled, their age, sex, study location, type of EAD, the navigation system used, and the mean follow-up period. For the meta-analysis, the following data were extracted: preoperative knee ROM, ROM at the last follow-up visit, outcome scores at the final follow-up (Knee Society Score [KSS] and Knee Functional Score [KFS]), and the pre-and postoperative mHKA angles obtained using lower extremity scanogram as radiological findings. Outcome scores, including KSS and KFS, and the changes between the initial baseline and final follow-up scores were also compared.

Risk of Bias Assessment

We assessed the methodological quality of the included studies using the methodological index for non-randomized studies (MINORS),[17] a validated tool for assessing the quality of non-randomized studies. The MINORS checklist comprised methodological items for non-randomized studies (16 points) and additional criteria for comparative studies (8 points). The maximum MINORS checklist score for comparative studies was 24 points. Two independent reviewers (CHK and SHB) performed the quality assessment. Disagreements were resolved through discussion.

Data Synthesis and Statistical Analyses

The data extraction and computation method followed the approach outlined by the Cochrane Handbook for Systematic Reviews of Interventions.[18] The method outlined by the Cochrane handbook was used in studies where the standard deviation was not reported. We assessed heterogeneity using the I2 statistic, considering 25%, 50%, and 75% as low, moderate, and high heterogeneity, respectively. Forest plots were used to present each study's outcomes and pooled effects. A p-value < 0.05 was considered statistically significant. We pooled all data using a random-effects model to avoid overestimating the study results.[19] The fixed-effects model begins with the assumption that the true effect size is similar in all included studies; therefore, we believed that the random effects model was more plausible for the current study. Funnel plots with Egger's test were drawn to assess the presence of publication bias,[20] especially for each outcome variable with at least 10 included studies;[21] if bias was present, the trim-and-fill method was applied for adjustment purposes. Aggregate data from the included studies were analyzed with a random effects model, weighted for individual study size, with R and the "metafor" package in R version 3.6.1. (R Foundation for Statistical Computing).

RESULTS

Study Identification

The process followed for study identification and selection is summarized in Fig. 1. The primary search yielded 424 studies, of which 164 duplicates were excluded. One additional article was identified through a manual search. After a review of the titles and abstracts, 22 articles remained. Subsequently, full-text articles were retrieved and reviewed, and finally 14 studies were included.[13,22-34] The inter-reviewer agreement was substantial (κ = 0.732) at the title review stage, almost perfect at the abstract review stage (κ = 0.911), and perfect at the full-text review stage (κ = 1.0).

Study Characteristics and Demographics

Table 1 shows the details of the study characteristics and patient demographics.[13,22-34] A total of 539 knees with EAD that underwent CAS-TKA were enrolled. The mean age of the participants was 67.1 years, of whom approximately 74.8% were women and 25.2% were men (predicted by the differences in reported results between studies). Nine of the 14 studies were performed in Asian countries,[13,23,25,26,28-32] 3 in Italy,[24,27,34] 1 in the United States,[22] and 1 was multinational.[33] The most common type of EAD was femoral deformity. Regarding the navigation system, iAssist (Zimmer Biomet) was the most favored, and OrthoPilot (B. Braun) was the most commonly used. The mean follow-up period of each study ranged from 5.7 to 72 months.

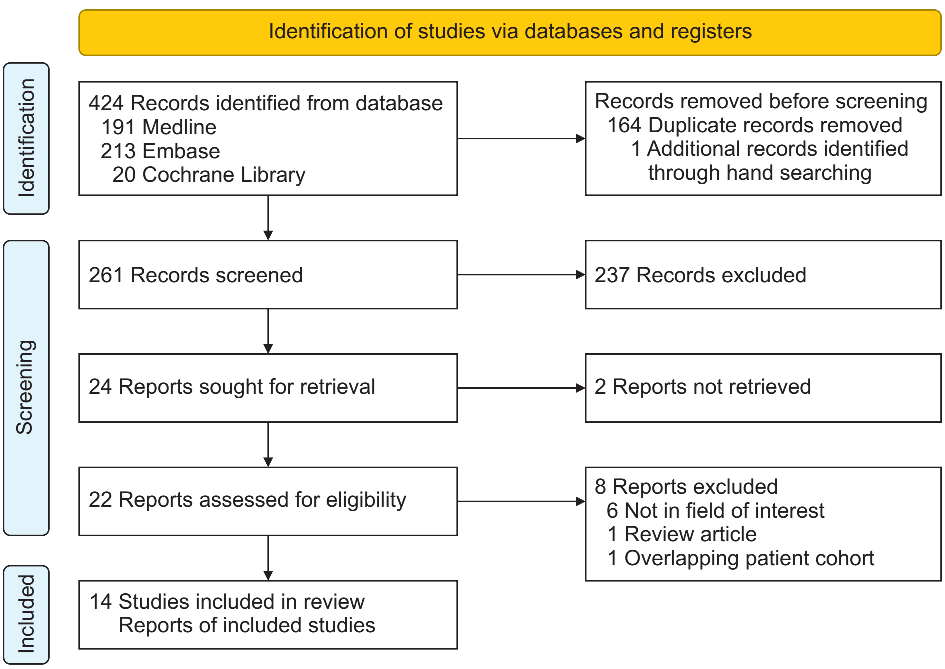

Fig. 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 flow diagram for identifying and selecting the studies included in this meta-analysis.

Table 1. Characteristics and Demographics of Participants in the Included Studies

Study	Journal	Location	Study type	Level of study	Type of EAD	Navigation system	No. of enrolled patients	Age (yr)	Male : female	FU period (mo)	MINORS score
Bae et al. (2017)[13]	*J Arthroplasty*	Republic of Korea	Comparative study	III	EA femur	Vector Vision 1.1 (Brainlab)	40	66.9	4 : 30	72	18
Bottros et al. (2008)[22]	*J Arthroplasty*	USA	Case series	IV	EA femur	Striker Navigation System (Stryker)	9	NA	NA	18.9	10
Cho et al. (2020)[23]	*J Orthop Surg (Hong Kong)*	Republic of Korea	Cohort study	III	EA tibia (tibia vara)	OrthoPilot (B. Braun)	246	72.47	NA	NA	16
Cozzi et al. (2019)[24]	*Joints*	Italy	Observation study	III	NA	iAssist (Zimmer Biomet)	13	63.7	8 : 5	5.7	10
Lee et al. (2014)[25]	*J Orthop Surg Res*	Taiwan	Comparative study	III	EA femur (lateral bowing)	CT-free navigation system (Brainlab)	55	75	NA	49	18
Liu et al. (2013)[26]	*Eur J Orthop Surg Traumatol*	China	Observation study	III	EA femur, tibia (congenital)	Striker Navigation System (Stryker)	8	68.63	3 : 5	> 24	10
Matassi et al. (2019)[27]	*J Arthroplasty*	Italy	Cohort study	III	EA femur ± tibia	iAssist (Zimmer Biomet)	18	63.7	9 : 9	> 6	10
Nam et al. (2020)[28]	*J Orthop Surg (Hong Kong)*	Republic of Korea	Observation study	III	EA femur (lateral bowing > 5°)	Imageless Navigation System version 2.6 (Brainlab)	89	72.25	4 : 85	NA	16
Pietsch et al. (2021)[29]	*Arch Orthop Trauma Surg*	Austria	Case series	IV	EA femur ± tibia	iAssist (Zimmer Biomet)	10	58.1	2 : 8	39.6	10
Rhee et al. (2013)[30]	*Knee Surg Relat Res*	Republic of Korea	Case series	IV	EA femur ± tibia	Image-free Medtronic Electromagnetic knee navigation system (Zimmer)	13	69	4 : 9	37.2	10
Shao et al. (2012)[31]	*Orthopedics*	China	Observation study	III	EA femur ± tibia	Imageless Striker Navigation System 3.1 (Stryker)	12	65.6	7 : 5	12.3	10
Tani et al. (2018)[32]	*Acta Ortop Bras*	Japan	Case-control	III	EA femur ± tibia	CT-free navigation system (Brainlab)	7	75	1 : 6	NA	18
Thienpont et al. (2013)[33]	*Knee*	Belgium Austria Egypt USA	Case series	IV	EA femur ± tibia	Signature (Biomet), PSI (Zimmer), My Knee (Medacta), Hafez Guide (Dr. Hafez)	10	58.5	6 : 4	40.8	10

Table 1. Continued

Study	Journal	Location	Study type	Level of study	Type of EAD	Navigation system	No. of enrolled patients	Age (yr)	Male : female	FU period (mo)	MINORS score
Tigani et al. (2012)[34]	*Int Orthop*	Italy	Observation study	III	EA femur ± tibia	ORTHOsoft Universal Knee Navigation System (Zimmer), OrthoPilot (B. Braun), PiGalileo Navigation System (PLUS-orthopedics), GP System navigation system (Medacta), Fast Nav Simplified Knee Prosthesis Navigation System (Stryker)	9	63.4	NA	28	10
Total (average)							539	67.1		30.3	12.6

EAD: extra-articular deformity, FU: follow-up, MINORS: methodological index for non-randomized studies, EA: extra-articular, NA: not applicable, CT: computed tomography.

Risk of Bias Assessment

The mean MINORS score for methodological quality assessment was 12.6 (range, 10–18) (Table 1). Among the 8 main evaluation parameters, all studies received point deductions for the lack of prospectively collected data, an unbiased assessment of the study endpoint, and prospective calculation of sample size. Two studies received a point deduction for not reporting the follow-up period.[23,28] Only 5 studies were comparative[13,23,25,28,32] and received the scores for this domain.

Preoperative and Postoperative Knee ROM

A total of 8 studies[13,22,26,29-31,33,34] were assessed for knee ROM following CAS-TKA for EAD. The mean preoperative ROM was 87.0° (95% CI, 75.9°–98.1°), and it changed to 109.4° (95% CI, 97.9°–120.8°) at the final follow-up visit. The forest plot and additional details are shown in Fig. 2.

Outcome Scores

KSS

Eleven studies[13,22,24-27,29-32,34] were assessed for the postoperative KSS. The mean KSS was 89.56 points (95% CI, 85.62–93.51 points). Fig. 3 shows the forest plot and additional details. Publication bias was noted after the funnel plot and Egger's test (p = 0.020) (Fig. 4A). After applying the trim-and-fill method, the adjusted KSS was 93.45 points (95% CI, 88.36–98.54 points) (Fig. 4B).

KFS

Eleven studies[13,22,24-27,29,31-34] were assessed for the postoperative KFS. The mean KFS was 88.55 points (95% CI, 84.68–92.43 points). Fig. 5 shows the forest plot and additional details. Publication bias was noted after the funnel plot and Egger's test (p = 0.024) (Fig. 6A). After applying the trim-and-fill method, the adjusted KFS was 91.57 points (95% CI, 86.80–96.33 points) (Fig. 6B).

Changes of the KSS and KFS from the preoperative to the last follow-up visit

The changes of the KSS and KFS are described in Fig. 7. The mean KSS was 44.1 points (range, 24.6–62 points) preoperatively and 89.1 points (range, 81.2–95.8 points) at the last follow-up visit. The mean KFS changed from 45.1 points (range, 39.6–56.6 points) preoperatively to 87.4 points (range, 74.4–95.4 points) postoperatively. In all cases, the KSS and KFS markedly improved postoperatively compared to baseline parameters.

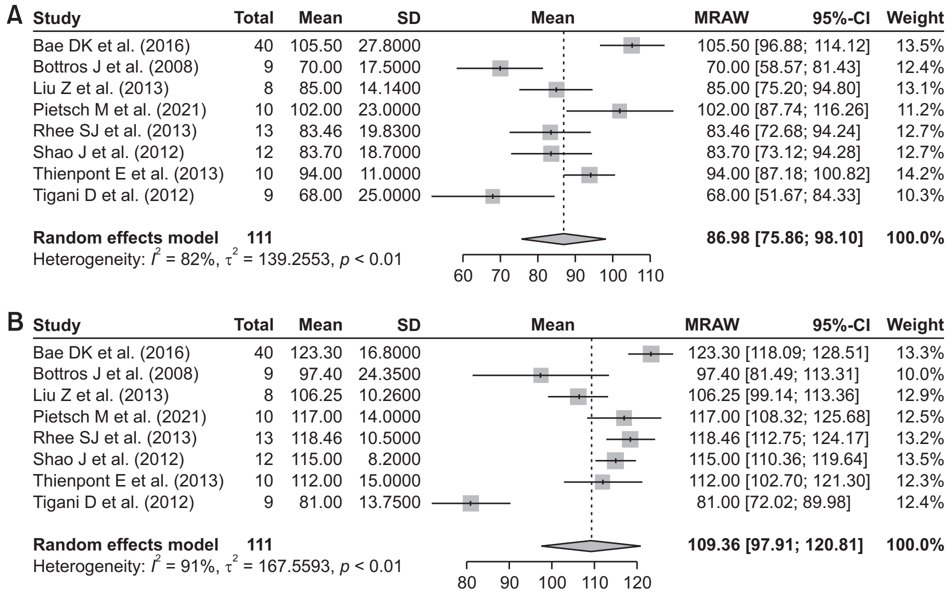

Fig. 2. Forest plot of preoperative (A) and postoperative (B) knee range of motion after computer-assisted total knee arthroplasty. SD: standard deviation, MRAW: mean raw, CI: confidence interval.

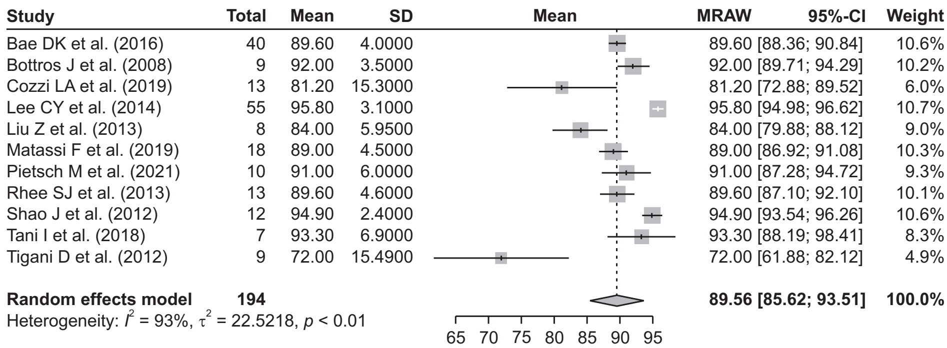

Fig. 3. The forest plot of postoperative Knee Society Score after computer-assisted navigation total knee arthroplasty. SD: standard deviation, MRAW: mean raw, CI: confidence interval.

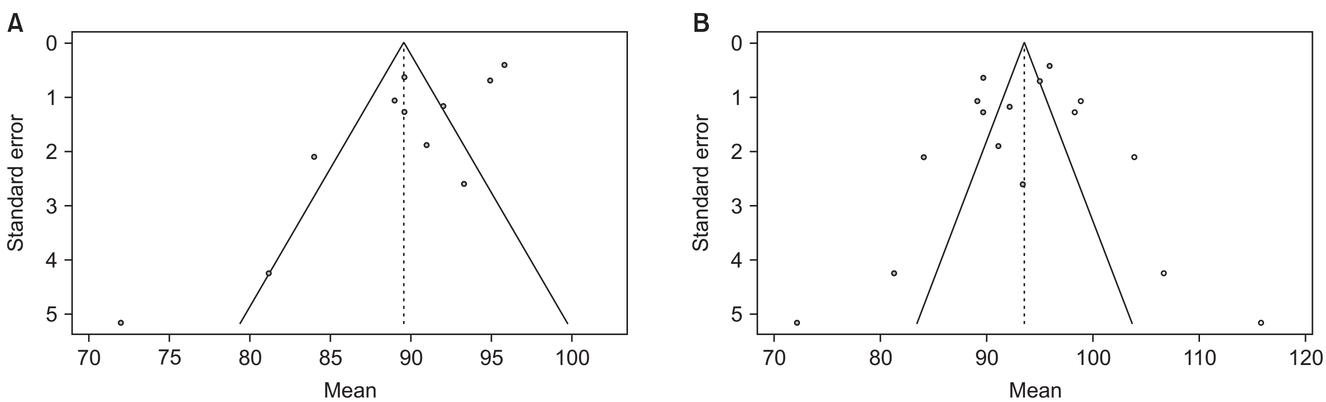

Fig. 4. Funnel plots of studies assessing the postoperative Knee Society Score. The funnel plot of Knee Society Score by original data (A), and the adjusted funnel plot after applying the trim-and-fill method (B). The filled circles represent the values of the included studies, and the empty circles were added after applying the trim-and-fill method.

Preoperative and Postoperative mHKA Angle

We extracted preoperative mHKA angle data in the coronal plane from all included studies, except 1,[24] and postoperative mHKA angle data in the coronal plane from all 14 included studies.[13,22-34] Two studies[30,34] reported valgus alignment postoperatively, while the others reported varus alignment. Varus alignment was presented as "+" values and valgus alignment as "–" values for data synthesis. Fol-

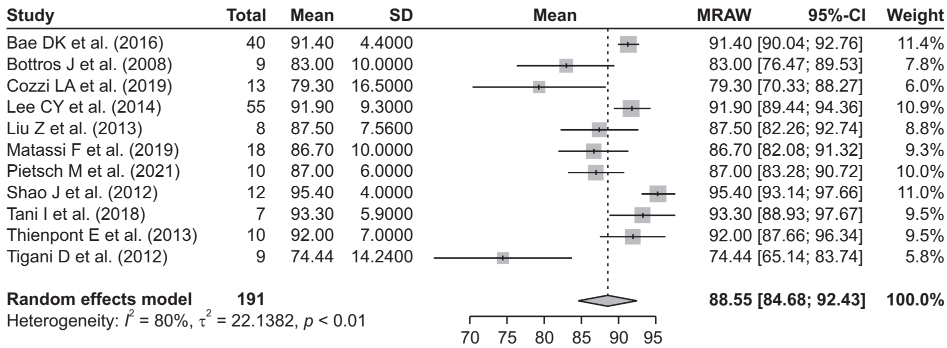

Fig. 5. The forest plot of postoperative Knee Functional Score after computer-assisted navigation total knee arthroplasty. SD: standard deviation, MRAW: mean raw, CI: confidence interval.

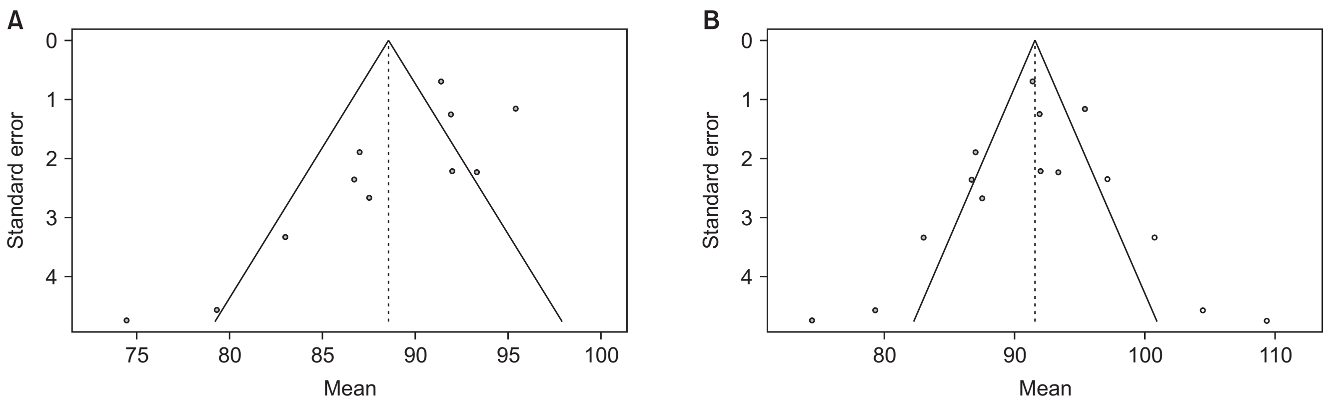

Fig. 6. Funnel plots of studies assessing the postoperative Knee Functional Score. The funnel plot of Knee Functional Score by original data (A), and the adjusted funnel plot after applying the trim-and-fill method (B). The filled circles represent the values of the included studies, and the empty circles were added by applying the trim-and-fill method.

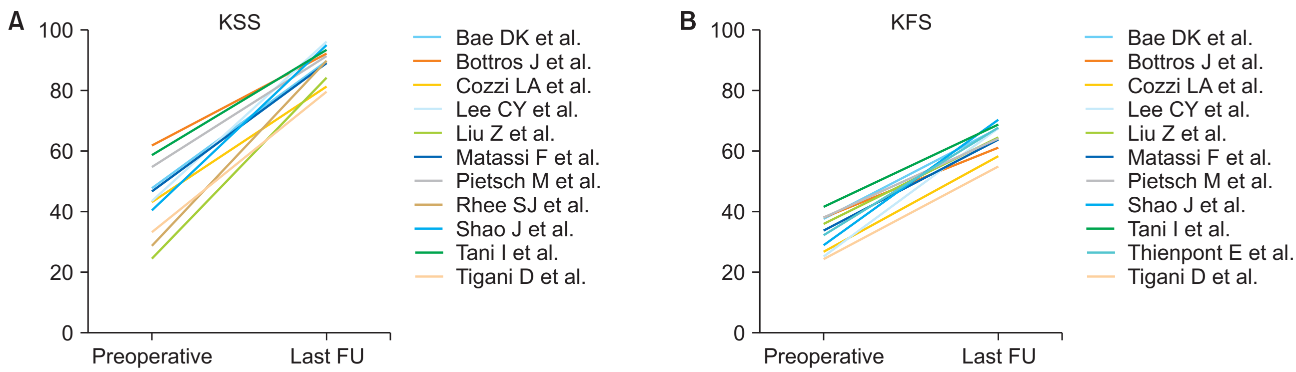

Fig. 7. Changes in Knee Society Score (KSS; A) and Knee Functional Score (KFS; B). FU: follow-up.

lowing the results of the meta-analysis, the mean preoperative mHKA angle was 169.53° (95% CI, 166.90°–172.16°), as varus alignment, and the postoperative mHKA angle changed to 178.81° (95% CI, 178.31°–179.30°), as varus alignment. Fig. 8 shows the forest plot and additional details.

Since more than 10 studies were included, we drew a funnel plot and Egger's test and identified no publication bias regarding the preoperative mHKA angle (p = 0.711). However, regarding the postoperative mHKA angle, publication bias was noted (p = 0.023) (Fig. 9A). The trim-and-fill method was performed to adjust publication bias, and the adjusted mHKA angle was 178.25° (95% CI, 177.64°–178.86°) (Fig. 9B).

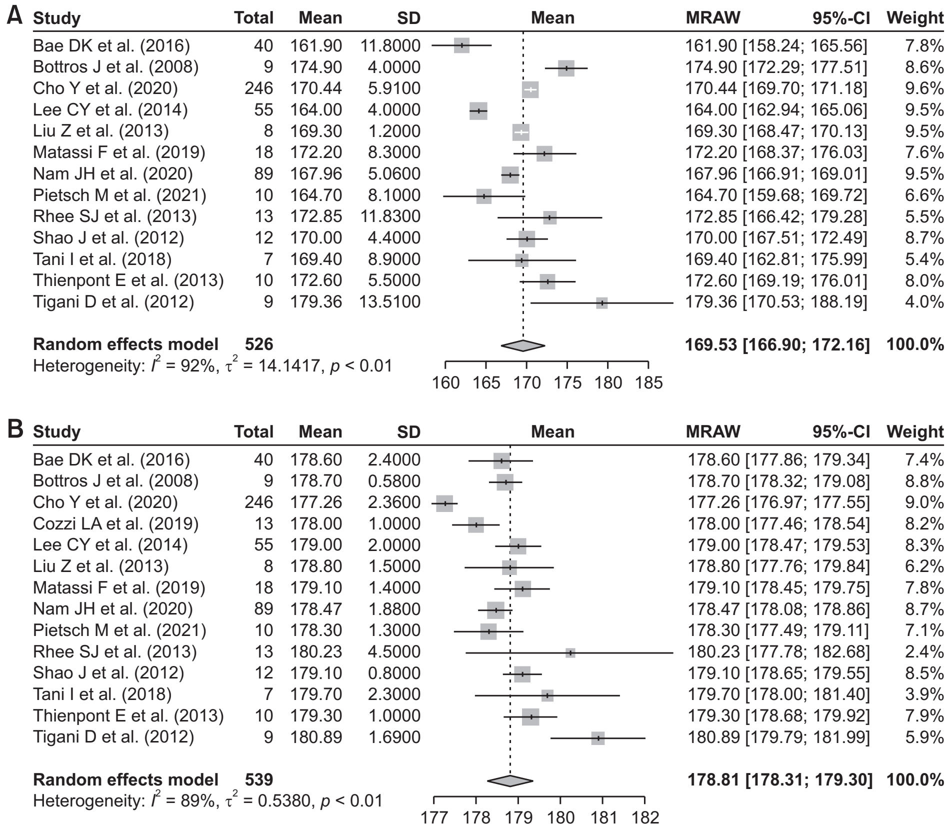

Fig. 8. The forest plots of preoperative (A) and postoperative (B) mechanical hip-knee-ankle angles after computer-assisted navigation total knee arthroplasty. SD: standard deviation, MRAW: mean raw, CI: confidence interval.

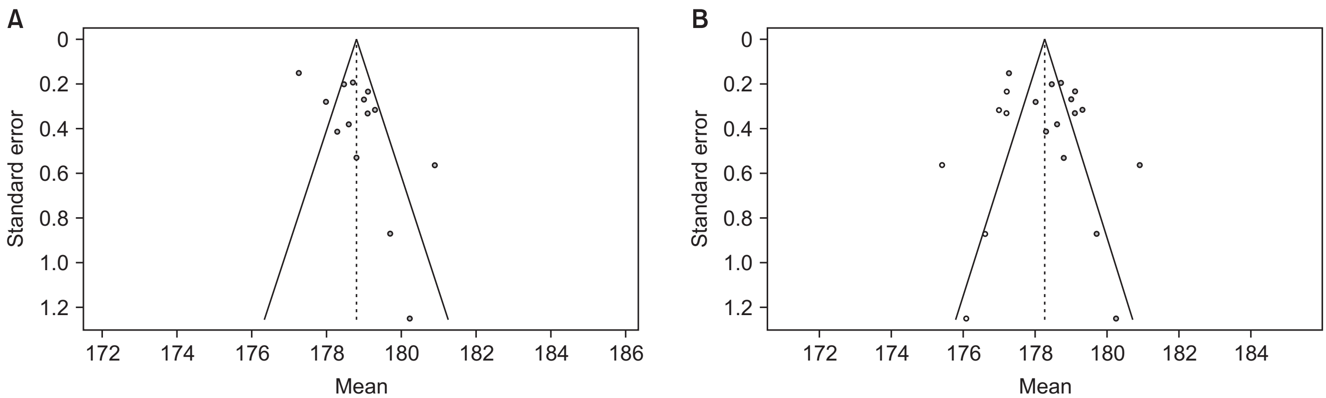

Fig. 9. Funnel plots of studies assessing the postoperative mechanical hip-knee-ankle angle. The funnel plot of postoperative mechanical hip-knee-ankle angle by original data (A), and the adjusted funnel plot after applying the trim-and-fill method (B). The filled circles represent the values of the included studies, and the empty circles were added after applying the trim-and-fill method.

DISCUSSION

The most important finding of this meta-analysis is that the clinical and radiologic outcomes following primary TKA using CAS were favorable even in complex cases with EAD. In patients with EAD, breaching the medullary canal for accurate bone resection during TKA is challenging; therefore, CAS could be beneficial. The clinical outcomes of a KSS of 93.5 points and a KFS of 91.6 points were satisfactory, and the lower limb alignment of 1.2° in this study was acceptable. These findings suggest that CAS should be applied when performing TKAs in patients with EAD.

The clinical outcomes following primary TKA using CAS in patients with EAD were favorable in this meta-analysis. A KSS of 93.5 and an adjusted KFS of 91.6 were observed. These clinical outcomes were comparable to those after primary TKA with conventional techniques in patients without EAD.[35,36] Only 3 studies compared between CAS and conventional techniques for primary TKA in patients with EAD.[13,25,32] Two studies reported no significant differences between the KSS and KFS (KSS: 95.8 vs. 94.7, $p = 0.392$; KFS: 91.9 vs. 91.0, $p = 0.643$[25] and KSS: 89.6 vs. 90.9, $p = 0.187$; KFS: 91.4 vs. 90.7, $p = 0.520$[13] for CAS vs conventional techniques, respectively). However, 1 study reported a significantly higher KFS for the CAS compared with the conventional technique (93.3 vs. 73.6, respectively, $p = 0.008$).[32] These findings suggest that the CAS could yield favorable clinical outcomes following primary TKA in patients with EAD.

This study showed favorable lower limb alignment following primary TKA using CAS for patients with EAD. A lower limb alignment with a deviation < 3° of varus or valgus was considered acceptable for TKA.[37] The mean HKA angle following primary TKA using CAS changed from 169.5° to 178.8° in this meta-analysis, indicating a deviation of 1.2° compared with the neutral alignment of the lower limb. As only 3 studies compared between CAS and conventional techniques for primary TKA in patients with EAD, these data were inadequate for a meta-analysis.[13,25,32] One study reported no significant differences in deviation (0.3° vs 0.7°, $p = 0.31$), but 2 other studies reported significant improvement in lower limb alignment using CAS compared with the conventional technique (177° vs. 174°, $p < 0.001$[25] and 1.4 vs. 3.3, $p = 0.001$[13]). Therefore, CAS could be reliable in providing desirable lower limb alignment.

This study has some limitations. First, the meta-analysis on clinical and radiological outcomes was only performed for patients who underwent primary TKA using CAS. Only 3 comparative studies were found, which were not enough for pair-wised meta-analysis. However, the pooled clinical and radiological outcomes scores were comparable with those of patients who underwent primary TKA and had no EAD. The second limitation is most included studies were conducted in Asia, which could introduce regional bias. Third, randomized controlled trials could not be included due to the lack of level-I studies. In the future, further investigations from multiple prospective randomized trials is needed.

In conclusion, CAS-TKA yielded positive clinical results and demonstrated a satisfactory alignment of the lower limb's mechanical axis. CAS-TKA demonstrated promising clinical and radiological outcomes for primary TKA procedures even in complex cases with EAD.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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