The purpose of this study was to determine whether the use of computer-assisted surgery can improve the clinical results in total knee arthroplasty (TKA) compared with conventional methods of TKA.

A literature search of PubMed (1966 to August 2011), CENTRAL (Cochrane Controlled Trials Register; issue 3, 2011), and EMBASE (1984 to August 2011) was conducted. Randomized, controlled trials detecting the clinical outcomes of TKA with or without the use of computer-assisted surgery were identified. A meta-analysis of these clinical trials was then performed. Twenty-one articles were included in the meta-analysis. The results confirmed that operative time was significantly increased with the use of computer-assisted TKA (mean standard difference, 14.68; 95% confidence interval [CI], 11.74 to 17.62; \( P < .00001 \)), whereas no significant difference existed between the 2 groups regarding the total operative blood loss (mean standard difference, \(-54.38\); 95% CI, \(-119.76\) to 11.00; \( P = .10 \)). As for other clinical outcomes, including the Knee Society Score (mean standard difference, 4.47; 95% CI, \(-1.05\) to 9.99; \( P = .36 \)) and range of motion (mean standard difference, 1.38; 95% CI, \(-1.43\) to 4.18; \( P = .34 \)), the use of computer-assisted TKA did not help to improve function recovery postoperatively.
Total knee arthroplasty (TKA) has evolved into a reliable, reproducible, and successful procedure for patients with advanced knee arthritis, with implant survival now approaching 95% at 15 years. It is projected that if the prevalence rates of knee arthritis remain stable, the demand for this operation in the United States will increase to 3.48 million procedures annually by 2030. The success of this operation as measured by pain relief, improved function, greater patient satisfaction, and implant longevity is predicated on numerous factors, including patient characteristics, implant selection, operative technique, component positioning, and limb alignment. Recently, the literature has shown that malalignment reduces implant longevity and generates a high revision rate in TKA. As a result, greater attention is being paid to better implant positioning to get a good clinical outcome.

Computer-assisted surgery aimed at improving the accuracy of implant positioning and extremity alignment is now frequently used in TKA. To date, an increasing number of studies have evaluated the precision of implant positioning with the use of a navigation system in TKA, and many have shown a better restoration of the mechanical leg axis and a more appropriate balance of the soft tissues, at least fewer outliers outside critical ranges compared with conventional TKA. Therefore, computer-assisted TKA is gaining in popularity because it may yield better clinical outcomes.

Several clinical studies have verified that optimal positioning and alignment of prosthetic components are crucial to optimal long-term outcomes, and that malalignment of the mechanical axis >3° of varus or valgus will result in a higher failure rate. Computer-assisted TKA involves a different method that uses kinematical determination of the hip center, as well as landmarking the center of the ankle, so that the overall alignment may be less affected by preoperative angular deformity. However, a laboratory study with tibia bone models showed that image-free computer-assisted TKA tended to cut the tibia in varus- or valgus-deformed knees.

Although many studies exist regarding computer-assisted TKA, few have assessed the clinical results. No evidence of improved clinical results has been reported with the use of computer-assisted TKA; however, no meta-analysis answers this question. The purpose of this study was to determine whether the use of computer-assisted TKA has improved clinical results compared with conventional methods.

**Materials and Methods**

**Literature Search**

A written, prospective protocol defined the objectives, search criteria, study selection criteria, data elements of interest, and plans for analysis. PubMed (1966 to August 2011), CENTRAL (Cochrane Controlled Trials Register; issue 3, 2011), and EMBASE (1984 to August 2011) were searched by adopting the following terms and Boolean operators: “total knee replacement,” “alignment,” “navigation,” “imageless,” “image-free,” and “computer-assisted.” The search strategy was the combination of Mesh terms with free text lists. The manual searching of reference lists from potentially relevant articles was performed to identify any additional studies that may have been missed using the computer-assisted strategy.

**Selection Criteria**

Two reviewers (C.X., K.L.) independently reviewed titles and abstracts of all citations identified by the literature search. Potentially relevant studies were retrieved and selection criteria applied. The inclusive criteria were studies: (1) that compared computer-assisted TKA with conventional TKA, regardless of the underlying condition or disease; (2) that were prospective, randomized, and controlled; (3) where the age of the patient population was older than 18 years; (4) that were published in English; (5) with full text available; and (6) with clinical outcomes. The following exclusive selection criteria were set: (1) nonrandomized trials studies; (2) studies without useful information available; and (3) studies not published in English.

**Data Extraction**

Two investigators independently collected the data using a predesigned form. The differences were resolved before data entry. The specific data extracted on study design included evaluation of the adequacy of methods of randomization (sequence generation) and their follow-up. The main characteristics of included studies were extracted, including the following items: operative time, total blood loss (record from redivac drain content), Knee Society Score, range of motion (ROM), and complications.

**Methodological Assessment**

The methodology of included trials was assessed mainly for the 2 domains of randomization (sequence generation and follow-up examination), whereas the other 2 domains of allocation (concealment and blinding) cannot be easily performed and thus cannot be assessed due to the nature of surgery. Randomized trials with adequate method of randomization generation were considered to be at a low risk for bias and were placed in Group A, whereas randomized trials with an inadequate or unclear method of randomization generation were considered to be at a relatively high risk for bias and were placed in Group B. Group A trials with inadequate follow-up or report of results were also placed in Group B. A subgroup meta-analysis according to different types of trials was performed to detect whether differences existed in the pooled estimated effect between Group A (trials with a low risk of bias) and Group B (trials with a high risk of bias).

**Statistical Analysis**

If several trials were available for a specific topic, meta-analysis was per-
formed using Revman 5.1 software (Cochrane Collaboration, Oxford, United Kingdom) with a fixed-effects model and random-effects model. Statistical heterogeneity between trials was evaluated by the Cochran chi-square test and defined at \( P < .1 \). As for dichotomous outcomes, pooled odds ratio (OR) was calculated using the Mantel-Haenszel fixed-effect model. If results were heterogeneous (\( P < .1 \)), a random-effects model was used. Pooled OR was presented as standard plots with 95% confidence intervals (CI). Regarding those continuous outcomes, the pooled mean difference was calculated using the inverse variance fixed-effect model. If results were heterogeneous (\( P < .1 \)), a random-effects model was used. Pooled mean difference was presented as standard plots with 95% CI. Subgroup meta-analysis and sensitivity analysis were also performed in an attempt to explore the potential source of heterogeneity. Funnel plots were used to assess the publication bias.

RESULTS

Figure 1 shows details of study identification, inclusion, and exclusion. PubMed, EMBASE, and CENTRAL searches under the defined terms yielded 738 articles. Of these, 36 relevant randomized trials were found, and full-text of these trials were retrieved. After applying those to selection criteria, 21 articles with clinical outcomes were included in this meta-analysis. Among these studies, 11 studies\(^1,4,6,18-25\) with an adequate method of randomization generation and a low risk of bias were placed in Group A, and 10 studies\(^26-35\) with a relatively high risk of bias were placed in Group B. All included trials adequately performed and reported the results of follow-up. Characteristics of included studies are described in the Table.

In total, the analysis comprised 2658 patients. Among these patients, 1376 were randomly allocated to the computer-assisted TKA group and 1282 to the conventional TKA group. Two included trials\(^25,30\) had 3 groups (1 with computer-assisted TKA, 1 with minimally invasive surgery, and 1 with conventional TKA). In the current meta-analysis, computer-assisted TKA and conventional TKA were included. Regardless of the type of computer-assisted system used, randomized trials were included in this meta-analysis if the procedure was performed with the guidance of the navigation system in the computer-assisted TKA group. In these included trials, the OrthoPilot Navigation System (B. Braun Melsungen AG, Tuttingen, Germany) and Stryker navigation systems (Kalamazoo, Michigan) were mainly used.

Operative Time

Seven studies reporting operative time were included.\(^1,19,21,26,28,31,32\) In total, the meta-analysis was performed on 743 patients. Of these patients, 374 patients were operated on using computer-assisted TKA and 369 patients using conventional TKA. The chi-square test for heterogeneity on all 7 studies was 11.53 (\( df = 6 \); \( P = .07 \)), and a random-effects analysis model was performed. The meta-analysis detected a significant difference between the 2 groups with regard to operative time (mean standard difference, 14.68; 95% CI, 11.74 to 17.62; \( P < .00001 \)) (Figure 2), showing that the operative time of computer-assisted TKA was significantly longer compared with that of conventional TKA.

Among the included trials, group A included 3 trials\(^1,19,21\) and group B included 4 trials,\(^26,28,31,32\) so subgroup meta-analyses were performed of these trials. In group A, the operative time of computer-assisted TKA was significantly longer than that of conventional TKA (mean standard difference, 13.70; 95% CI, 7.58 to 19.82; \( P < .0001 \), random model) (Figure 2). Similarly, the operative time of computer-assisted TKA was also significantly longer compared with that of conventional TKA in group B (mean standard difference, 13.70; 95% CI, 7.58 to 19.82; \( P < .0001 \), random model) (Figure 2). The chi-square test for heterogeneity in the 2 subgroup analyses was \( P = .07 \) and \( P = .13 \), respectively, demonstrating no evidence of statistical heterogeneity in group B.

Blood Loss

Five studies reporting blood loss results were included.\(^7,21,27,29,31\) Overall, the analysis included 326 patients in the conventional TKA group and 321 patients in the computer-assisted TKA group. All of the included studies adequately reported the total operative blood loss (record from redivac drain content) for the 2 groups. The pooled estimates were statistically heterogeneous (chi-square test = 11.39 \( [df = 4 \); \( P = .02 \)\]), and thus a random model was used. Combined results from the studies showed no difference between the computer-assisted TKA and conventional TKA groups (mean standard difference, \( -5.43; 95\% CI, -11.97 \) to 1.10; \( P = .10 \)) (Figure 3).

Knee Society Score

Five trials reporting Knee Society Score results were included.\(^10,21,30,35\) A total of 334 randomized patients were operated on using either computer-assisted TKA (\( n = 171 \)) or conventional TKA (\( n = 163 \)). The Knee Society Score, a disease-specific outcome measurement, was well reported.
in all included trials. The chi-square test for heterogeneity in all 5 trials was 1.52 (df = 4; P = .82). No evidence of statistical heterogeneity was demonstrated, and a fixed-effects analysis model was performed. The pooled results for change in Knee Society Score at the end of follow-up showed that no significant difference was detected between the 2 groups (mean standard difference, 4.47; 95% CI, −1.05 to 9.99; P = .36) (Figure 4).

Group A included 3 trials19-21 and group B included 2 trials,30,35 so subgroup meta-analyses were performed. However, as shown in Figure 3, no difference was found in Knee Society Score between the 2 subgroups in group A (mean standard difference, 6.92; 95% CI, −0.68 to 14.51; P = .07, fixed model) and group B (mean standard difference, 1.73; 95% CI, −6.30 to 9.76; P = .67, fixed model). Pooled es-

<table>
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<th>Study</th>
<th>Sample Size, No.</th>
<th>Men, %</th>
<th>Mean Age, y</th>
<th>Operation Time, min</th>
<th>Blood Loss, mL</th>
<th>Knee Society Score</th>
<th>ROM, deg</th>
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Abbreviations: deg, degrees; NA, not available; ROM, range of motion; SD, standard deviation.

aData presented for computer-assisted total knee arthroplasty/conventional arthroplasty.
timates of the above 2 subgroup analyses showed no statistical heterogeneity ($P = .96$ and $P = .44$, respectively). From these analyses, the use of computer-assisted TKA may not improve postoperative Knee Society Scores.

**Range of Motion**

Three trials reporting postoperative ROM were included.\(^2\) The chi-square test for heterogeneity on all included trails found no statistical heterogeneity ($P = .44$), and a fixed-effects analysis model was also used. The results from the 3 trials were combined and a significant difference was not detected regarding postoperative ROM in patients between the computer-assisted TKA and conventional TKA groups (mean standard difference, 1.38; 95% CI, −1.43 to 4.18; $P = .34$) (Figure 5).

**Complications**

Twelve trails comprising 1657 patients and reporting postoperative complications were included.\(^6\) According to these trials, the main postoperative complications were deep infection, thrombosis, and delayed wound healing. The incidences of postoperative complications were 4.9% and 5.8% in the computer-assisted TKA and conventional TKA groups, respectively. The chi-square test for heterogeneity was 14.84 ($df = 11$; $P = .19$), indicating no statistical heterogeneity on all included trails; a fixed-effects analysis model was also used. The overall pooled OR of postoperative complications showed no significant difference between the 2 groups (OR, 0.93; 95% CI, 0.60 to 1.43; $P = .73$, fixed model) (Figure 6), indicating that the use of computer-assisted TKA may not reduce postoperative complications compared with conventional TKA.

**DISCUSSION**

Controversy exists regarding the effectiveness of computer-assisted TKA in improving radiological and clinical outcomes. A previous meta-analysis conducted for alignment outcomes in computer-assisted TKA showed significant improvement in component orientation and mechanical axis when computer-assisted TKA is used.\(^3\) The study reported that

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\(^{*}\)References 1,4,6,18-20,22,23,25,32-34
the risk of >3° malalignment was significantly less with computer-assisted TKA than with conventional TKA for mechanical axis and frontal plane femoral and tibial component alignment. The results of this meta-analysis of the tibial (OR, 0.31; 95% CI, 0.16 to 0.61) and femoral slopes (OR, 0.13; 95% CI, 0.03 to 0.54) were statistically significant (P<.05) in favor of computer-assisted TKA at >2° malalignment.

In another recent meta-analysis of component alignment outcomes after imageless computer-assisted TKA vs conventional TKA, the use of imageless navigation when performing TKA improves component orientation and postoperative limb alignment. A significant reduction in the outlier rate of mechanical axis and femoral and tibial implants was found when operated using computer-assisted TKA. All meta-analyses estimated better results with computer-assisted TKA for the position of the mechanical axis (OR, 0.201; 95% CI, 0.111 to 0.324) and femoral (OR, 0.19; 95% CI, 0.077 to 0.392) and tibial implants (OR, 0.19; 95% CI, 0.068 to 0.411).

Radiological outcomes have been proven to be in favor of computer-assisted TKA; however, relatively few review studies have assessed the clinical outcome of computer-assisted TKA. The current meta-analysis is focused only on the clinical outcomes in trials that directly compared computer-assisted TKA to conventional TKA. The results confirmed that operative time was significantly increased with the use of computer-assisted TKA, whereas no significant difference existed between the 2 groups in terms of total operative blood loss. As for other clinical outcomes, including Knee Society Score and ROM, the use of computer-assisted TKA did not help improve function recovery postoperatively.

A meta-analysis and subgroup meta-analysis regarding operative time and Knee Society Score were performed for all included randomized trials. Randomized trials with an inadequate or unclear method of randomization generation were considered to be a relatively high risk of bias, and thus may have changed the pooled results. However, the pooled effects for group A trials were similar to those for group B trials, although the pooled estimates for group A trials were closer to the total pooled effects.

The current study had several limitations. Relatively large numbers of studies had to be excluded due to nonavailability of data to assess clinical outcomes of computer-assisted TKA. In most of the efficacy trials, the method of randomization generation was inadequate, and this may cause a bias. In addition, the funnel plots for pooled estimates were significantly asymmetrical, so there may be a publication bias. Only studies published in English were included, which may introduce a language bias. Finally, the computer-assisted navigation systems were different among the included trials, so an inherent bias may exist regarding the navigation system itself.

**Conclusion**

This is the first meta-analysis to assess the clinical outcomes of TKA with or without the use of computer-assisted surgery in randomized, controlled trials. Results of this meta-analysis show that computer-assisted TKA may not improve clinical outcomes. The drawbacks of computer-assisted TKA, including higher cost and longer operative time, should be taken into consideration in the clinical setting. In addition, the results show that few included studies have completed a long-term follow-up evaluation of the clinical outcomes. Individual clinical outcomes in a short-term follow-up are highly variable, and more studies are needed to confirm the effect of computer-assisted TKA on the long-term clinical outcome. Although it has been demonstrated that the use of computer-assisted TKA can improve radiological outcomes, the effectiveness of computer-assisted TKA on clinical outcomes must be confirmed by further high-quality randomized, controlled trials.

**References**

4. Choong PF, Dowsey MM, Stoney JD. Does accurate anatomical alignment result in better function and quality of life? Comparing conventional and computer-assisted total

Figure 6: Meta-analysis for complications. Abbreviations: Chi², chi-square test; CI, confidence interval; M-H, Mantel-Haenszel.