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Review

Little clinical advantage of computer-assisted navigation over conventional instrumentation in primary total knee arthroplasty at early follow-up

Tao Cheng [a], Xiao-Yun Pan [a,b], Xin Mao [a], Guo-You Zhang [c,d], Xian-Long Zhang [a,*]

[a] Department of Orthopaedic Surgery, Shanghai Sixth People's Hospital, Shanghai Jiao Tong University School of Medicine, 600 Yisan Road, Shanghai 200233, People's Republic of China
[b] Department of Orthopaedic Surgery, The Second Affiliated Hospital of Wenzhou Medical College, 109 Xueyuan West Road, Wenzhou 325027, Zhejiang Province, People's Republic of China
[c] Department of Hand and Plastic Surgery, The Second Affiliated Hospital of Wenzhou Medical College, 109 Xueyuan West Road, Wenzhou 325027, Zhejiang Province, People's Republic of China
[d] Department of Dermatology, University Hospital Schleswig-Holstein, University of Lübeck, 160 Ratzeburger Allee, Lübeck 23538, Germany

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ABSTRACT

Purpose: Even though computer-assisted navigation systems have been shown to improve the accuracy of implantation of components into the femur and tibia, long-term results are lacking and there is little evidence yet that navigation techniques also improve functional outcomes and implant longevity following total knee arthroplasty (TKA). The aim of this study was to summarize and compare the clinical outcomes of total knee arthroplasties (TKAs) performed using navigation-assisted and conventional techniques.
Methods: The study was conducted according to the guidelines described in the Cochrane Handbook for Systematic Reviews of Interventions and Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statements. Methodological features were rated independently by two reviewers. A meta-analysis of randomized controlled trials (RCTs) or quasi- randomized controlled trials (qRCTs) was carried out to evaluate the efficacy of CAS versus conventional TKA. Data were pooled in fixed and random effects models and the weighted mean difference (WMD) and odds ratio (OR) were calculated. Heterogeneity across studies was determined, and subgroup analyses by the type of navigation system (image-based or image-free navigation system) were conducted.
Results: Twenty-one studies that included 2333 knees were collected from different countries. The surgical time was longer for CN TKA than for the conventional procedure. There was no significant difference in the Knee Society Score between the two groups at the 3-month and 6-month follow-up. The rates of postoperative complications in patients who had CN TKA were similar to those in the patients who had conventional TKA.
Conclusion: No significant differences in short-term clinical outcomes were found following TKAs performed with and without computer navigation system. However, there is clearly a need for additional high-quality clinical trials with long-term follow-up to confirm the clinical benefits of computer-assisted surgery.

Contents

* Corresponding author. Tel.: +86 21 64369181; fax: +86 21 64701361.
E-mail address: zhangxianlong2009@hotmail.com (X.-L. Zhang).

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1. Introduction

Total knee arthroplasty (TKA) is a common orthopedic procedure, generally performed in elderly arthritis patients [1–3]. TKAs are conventionally performed with the use of intramedullary or extramedullary jig-based alignments and achieve a high rate of success [4–6]. However, recent studies have shown that achieving optimal implant alignment can be difficult with current techniques, even for experienced surgeons [7–10]. Based on the theoretical assumption that the use of computer-assisted navigation in TKAs may improve implant alignment and increase implant longevity [11], computer-assisted surgery is becoming increasingly common in TKAs [12–24].

Significant improvements in component orientation and mechanical leg axis have been reported when using image-based and image-free computer navigation systems, particularly in TKAs with knee deformities [10,25–41]. However, the better alignment achieved in computer-navigated (CN) TKAs did not necessarily result in better clinical outcomes [18,32,42–45]. Exact informations on the clinical results are needed to determine potential advantages of CN TKAs. This information would be even more valuable when obtained by meta-analysis and systematic review, which combines or integrates the results of several independent clinical trials to increase statistical power.

The primary purpose of this study was to determine if CN TKA makes possible better clinical outcomes for operative patients as evaluated Knee Society Score (KSS) and complication rates than the conventional technique. The secondary purpose was to ascertain if a CN TKA results in increased operative time and reduced blood loss compared with a conventional TKA.

2. Materials and methods

A systematic review was conducted according to the guidelines described in the Cochrane Handbook for Systematic Reviews of Interventions and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Statements [46,47]

2.1. Eligibility criteria

Trials included in this paper were those relevant to: (1) those patients undergoing primary TKA with a conventional technique versus a passive navigation technique, (2) Knee scores and post-operative complications as its outcome measures, and (3) the study was a published randomized or quasi-randomized controlled trial (RCT or qRCT). For trials with multiple publications we included only the most complete report for each outcome.

2.2. Literature search

To identify published reports of relevant RCTs or qRCTs we carried out highly sensitive electronic searches of relevant databases, including Medline (1995–November 2009), EMBASE (1995–November 2009), Science Citation Index (1995–November 2009), Chinese Biomedical Literature Database (2000–November 2009), Wanfang database (2000–November 2009), and Cochrane Database of Systematic Reviews and the Central Register of Controlled Trials (2000–November 2009). The following key words were considered: “computer-assisted”, “navigation”, “navigated”, “total knee arthroplasty”, “total knee replacement”. In addition, we also handsearched five major orthopedic journals, including The Journal of Bone and Joint Surgery: American and British Volumes, Clinical Orthopaedics and Related Research, The Journal of Arthroplasty, and The Knee. Searches were not restricted by year of publication or language. The last search was carried out on January 1, 2010.

2.3. Data extraction

Two reviewers independently recorded participants' characteristics, details of the surgical technique and implant used, and clinical outcomes on a data extraction form. The primary outcomes of interest included postoperative functional outcomes and complications. Secondary outcomes were intraoperative parameters (blood loss, operative time). If necessary, the primary authors were contacted to retrieve further information.

2.4. Assessment of methodological quality

Two of us independently assessed the methodological quality of each included study with respect to rating of the randomization procedure; allocation concealment; blinding of patients, clinicians, outcome assessors; statistical analysis of individual trials, and numbers of patients lost during follow-up. Any differences that could not be resolved through discussion were decided by an arbiter.

3. Statistical analysis

For meta-analysis we combined dichotomous outcome data using the Mantel–Haenszel odds ratio (OR) method and 95% confidence interval (CI). For continuous outcomes we used inverse variance weighted mean difference (WMD) and 95% CI. Publication bias was assessed using a funnel plot of the outcome measure recorded in the largest number of clinical trials. Before analyzing the data, we hypothesized that possible clinical heterogeneity may be due to differences in interventions (type of navigation system used). We used a random effects model if heterogeneity existed ($P<0.10$) and a fixed effect model otherwise. We used SPSS version 13.0 for Windows (SPSS Inc., Chicago, Illinois, USA) and RevMan 5.0 software package (Cochrane Collaboration, Oxford, United Kingdom) for final analyses.

4. Results

4.1. Study identification and study characteristics

Of the 935 articles identified in the literature search, fifty seven were considered potentially eligible on the basis of the abstract. Of these, only twenty one were RCTs or qRCT and eligible for inclusion [26,27,29–31,48–63] (Fig. 1). Eleven studies were from Europe [26,27,48,49,51,52,56–59], six were from Asia [30,50,53,54,60,61], three were from Western Australia [29,31,63] and one was from North America [55]. In most of these included studies, the demographic features of both groups were well balanced at baseline. The CN group consisted of 1225 knees (52.5%), whereas the conventional group comprised 1108 knees (47.5%). The sample sizes of the trials ranged from 26 to 467 knees. Furthermore, most studies had clear included or excluded criteria. Seventeen studies used image-less navigation system [26,27,29–31,48–52,54,55,57,60–63], whereas the other five studies used the image-based navigation system [53,56,58,59,62]. Most studies indicated that the surgeons had experience in CN TKA prior to their study, in order to avoid bias from the learning curve. The choice of implants and fixation techniques varied across studies, when reported. Table 1 presents the characteristics of the included studies.

4.2. Study quality

The methodological quality of the included studies was variable. The method of allocation sequence generation varied form study to study and included use of computers, random number tables, block randomizations, alternation, permutation