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Imageless Computer Navigation in Total Knee Arthroplasty Provides Superior Short Term Functional Outcomes: A Meta-Analysis

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ABSTRACT

Computer navigation in total knee arthroplasty (TKA) is intended to produce more reliable results, but its impact on functional outcomes has not been firmly demonstrated. Literature searches were performed for Level I randomized trials that compared TKA using imageless computer navigation to those performed with conventional instruments. Radiographic and functional outcomes were extracted and statistically analyzed. TKA performed with computer navigation was more likely to be within 3° of ideal mechanical alignment (87.1% vs. 73.7%, $P < .01$). Navigated TKAs had a higher increase in Knee Society Score at 3-month follow-up (68.5 vs. 58.1, $P = .03$) and at 12–32 month follow-up (53.1 vs. 45.8, $P < .01$). Computer navigation in TKA provides more accurate alignment and superior functional outcomes at short-term follow-up.

Over the last 30 years, computers and robotics have become increasingly integrated into surgical procedures. Due to the relative stability of bony anatomy, orthopaedics has been an especially fertile ground for computer-assisted surgery. In the late 1990s, two teams, one led by Picard and Leitner in France [1,2], the other led by Krackow in Buffalo, New York [3], concurrently developed the technology for modern imageless computer-assisted total knee arthroplasty (TKA). Approved by the FDA in 2001 [4], these systems utilize infrared communication to track the spatial positioning of patient anatomy and surgical equipment. The system's subsequent calculations allow the surgeon to evaluate bony cuts prior to their execution and also allow the surgeon to check these cuts after they are performed [5,6].

This computer-assistance is intended to produce more reliable results for TKA. As it is an emerging technology, published results are relatively new. Previous meta-analyses have been forced to include non-randomized trials or exclude functional outcomes [7–9]. To our knowledge, this is the first meta-analysis of imageless computer assisted TKA that exclusively includes Level I studies with true randomization and adequate analysis of both radiographic alignment and clinical outcomes. We hypothesize that imageless computer navigation improves TKA short term functional outcome scores by producing superior post-operative alignment.

Materials and Methods

Protocol

This is a meta-analysis of all Level I randomized controlled trials comparing conventional primary TKA versus TKA using imageless computer-assisted navigation in the English language literature. Our meta-analysis was conducted with guidance by the Cochrane Handbook for Systematic Review of Intervention Version 5.1.0 [10] and with additional input from the PRISMA Statement [11].

Search Strategy

We searched MEDLINE via PubMed, EMBASE via OVID, Scopus, and the Cochrane Central Register of Controlled Trials (CENTRAL) using the following Boolean string: (knee arthroplasty OR knee replacement) AND (computer OR computers) AND (assisted OR navigated OR navigation) AND (conventional OR standard OR manual). Additionally, the bibliographies of identified papers were reviewed for additional relevant papers.

For inclusion in our meta-analysis, a study had to 1) report patient outcomes following primary TKA done with and without imageless computer-assisted navigation. The study must have 2) employed true randomization as defined by the Cochrane Collaboration and must have been 3) reported in an English-language manuscript. Lastly, the study needed to 4) report one of the primary outcomes of our meta-analysis – either radiographic post-operative alignment as measured radiographically, or patient functionality as measured by an appropriate scoring system (e.g. KSS, WOMAC, etc.) or both.

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Studies were excluded if allotment was determined by pseudorandomization. In order to focus strictly on imageless navigation technology, we excluded any studies that used image-based computer navigation. Studies with intra-patient bilateral comparison were excluded. Studies were not included if their outcomes were neither radiographic nor functional (e.g. fat emboli, gait analysis or blood loss).

All three-arm studies were treated in an identical fashion. To minimize any extraneous factors, we included the two arms in which the only variable altered was the addition or subtraction of computer assistance. In instances where a single study served as the foundation for multiple papers, any redundant data was excluded, with inclusion of only the most recent paper.

Assessment of Study Validity/Risk of Bias

We utilized the Cochrane Collaboration's tool for assessing risk of bias in random sequence generation, allocation concealment, and blinding of participants, personnel and outcome assessors. In instances where the manuscript did not contain enough information to assess the risk of bias, the authors were emailed for clarification [7,12–18].

Data Collection Process

Two independent reviewers collected data into an electronic data collection form created in Microsoft Excel 14.2.2 (Redmond, WA). Where necessary, study authors were contacted by e-mail for clarification of published results. All final values were confirmed prior to handoff to our statistician.

Data Items

Primary outcomes extracted were measurements of post-operative alignment and post-operative functionality. Alignment included any radiographic measurement, including mechanical axes as well as femoral and tibial component alignment in the coronal and sagittal planes. Functional scores collected included the Knee Society Score (KSS) (summation of the functional and knee scores), Western Ontario and McMaster Universities Arthritis Index (WOMAC), and Short Form Health Survey 12 and 36 (SF-12 and SF-36). Operative time was collected as a secondary outcome. Study design information such as randomization method, blinding and duration of follow-up were recorded. Additionally, the implant used, the type of navigation system used, the type of manual guides used, and the use of patellar resurfacing were documented.

Synthesis of Results

For continuous variable outcomes, a fixed effect analysis model was used to measure the mean difference. For dichotomous variable outcomes, the risk difference was calculated using the Mantel-Haenszel method. A p-value of 0.05 was assigned as the threshold for significant results. Meta-analysis was performed using RevMan 5.2 software.

Results

Study Selection

Our search strategy produced 1,350 results (MEDLINE n = 407, EMBASE n = 398, Scopus n = 460, and CENTRAL n = 85) with 566 unique papers that were published through December 2012 (Fig. 1). After screening the abstracts for appropriate randomized controlled trials, we were left with 49 papers. Of these, eight were eliminated for inappropriate outcomes (i.e. gait analysis, fat emboli, blood loss or component rotation) [19–26]. Three were eliminated for using image-based (CT) computer navigation [27–29]. Twelve were eliminated for pseudorandomization or a lack of response to our request for clarification of randomization method [16–18,30–38]. Three papers were eliminated due to redundant data from a study already included in our analysis [39–41]. Two papers were eliminated because the data was presented in a format that could not be incorporated into the analysis, and the authors did not return our correspondence [12,42]. Ultimately, twenty-one papers were included in our final analysis [7,13–15,40,43–59], representing twenty unique studies, each with an imageless computer-assisted surgery treatment group [CAS] and a conventional manual guide treatment group [CONV], achieving statistical power as determined by power analysis [60].

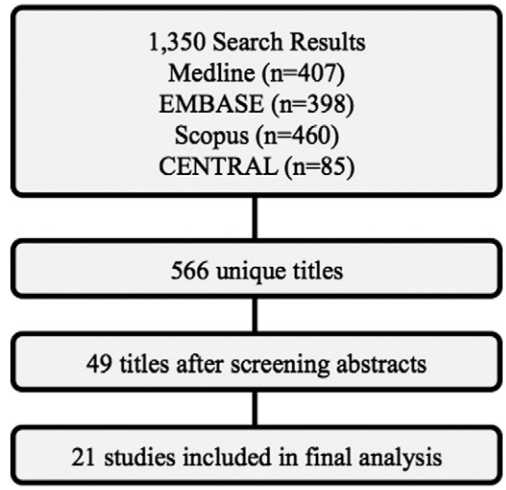

Fig. 1. The search strategy employed.

Several studies presented their results in multiple papers. In one instance, complementary data was presented in two papers and both were included in analysis [14,52]. In two other instances, deference was given to the study's paper with the largest patient sample [15,40] or the longest follow-up [39,41,61].

Three-armed studies presented a unique challenge. To retain the focus on the effect of computer navigation and to maximize inter-study compatibility, we analyzed the two treatment groups that had identical characteristics except for the addition/subtraction of computer navigation. Two three-armed studies used both CAS and a minimally invasive approach (MIS) as the two variables altered between treatment groups. From one study we included the conventional approach/CAS and the conventional approach/manual guide groups [13], from the other we analyzed the MIS/CAS group and the MIS/manual group [51]. One three-armed study contained a CAS group with NexGen implants, a manual group with NexGen implants and a manual group with Scorpio implants; we analyzed the two NexGen groups [55]. Two three-armed studies contained a CAS group, a group with intramedullary tibial guides and a group with extramedullary tibial guides [43,44]. In these two studies, we excluded the intramedullary group, as all other studies included in our meta-analysis use extramedullary tibial guides.

Study Characteristics

All of the included papers were published in 2004 or later, and over half were published in 2009 or later. These studies included a combined 869 knees in the computer-assisted groups, and 844 knees in the control groups for a total of 1,713 knees analyzed (Table 1).

Six papers were published in the *Journal of Arthroplasty*, four in *Knee Surgery, Sports Traumatology, Arthroscopy*, three in *JBJS* and two in *CORR*. *Acta Chirurgiae orthopaedicae et Traumatologiae čechoslovaca*, *BMC Musculoskeletal Disorders*, *International Orthopaedics*, *JBJS (Br)*,