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Current Data Do Not Support Routine Use of Patient-Specific Instrumentation in Total Knee Arthroplasty

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ABSTRACT

The purpose of this systematic review and meta-analysis is to compare patient-specific instrumentation (PSI) versus standard instrumentation for total knee arthroplasty (TKA) with regard to coronal and sagittal alignment, operative time, intraoperative blood loss, and cost. A systematic query in search of relevant studies was performed, and the data published in these studies were extracted and aggregated. In regard to coronal alignment, PSI demonstrated improved accuracy in femorotibial angle (FTA) ($P = 0.0003$), while standard instrumentation demonstrated improved accuracy in hip-knee-ankle angle (HKA) ($P = 0.02$). Importantly, there were no differences between treatment groups in the percentages of FTA or HKA outliers (>3 degrees from target alignment) ($P = 0.7$). Sagittal alignment, operative time, intraoperative blood loss, and cost were also similar between groups ($P > 0.1$ for all comparisons).

Total knee arthroplasty (TKA) is one of the most commonly performed musculoskeletal procedures in the United States with approximately 719,000 performed annually [1]. Given projected increases in population size and longevity, the incidence of TKA is predicted to rise in the future, reaching an estimated 3.48 million by 2030 [2]. Perfecting surgical technique for TKA is therefore of paramount importance.

In recent years, there has been an increased focus on the influence of limb alignment and component position on longevity and outcomes after TKA [3]. Technological advancements aimed at improving limb alignment and component position include computer-assisted surgery (CAS) and patient-specific instrumentation (PSI). Meta-analyses comparing CAS versus conventional TKA have demonstrated mixed results with regard to component orientation and mechanical axis [4,5] with no difference in functional outcomes [6]. The drawbacks of CAS include difficulty with accurate intraoperative landmark registration, increased set-up and operative time, increased perioperative cost, risk of pin loosening and pin-site fracture, and a substantial learning curve [7,8].

Patient-specific instrumentation (PSI) was introduced with the goals of improving alignment through preoperative navigation, reducing operative time by minimizing intraoperative decision making, and decreasing perioperative cost by limiting the number of instrument trays required per procedure. This technology employs advanced imaging (MRI or CT) to generate an ideal cutting guide based on the patient's anatomic parameters. Both femoral and tibial cutting guides are generated; these guides determine the location of the bone cuts; the size, position, and rotation of the components; and the alignment of the limb. In recent years, several comparative studies and randomized controlled trials that compare patient-specific versus standard TKA instrumentation have been published. Individually, these studies have failed to substantiate the theoretical benefits of PSI. To our knowledge, no systematic review or meta-analysis of these studies has been performed.

Therefore, the purpose of this study is to perform a systematic review and meta-analysis of the current evidence comparing standard instrumentation to patient-specific instrumentation for TKA with regard to: (1) coronal alignment, (2) sagittal alignment, (3) operative time, (4) intraoperative blood loss, (5) transfusion requirement, and (6) perioperative cost.

Materials and Methods

We performed a systematic query using both the Medline and Embase computerized literature databases in search for articles containing the keyword terms “total knee arthroplasty” and “patient-specific.” The search was performed on May 1, 2013, and all studies published prior to that date were considered. In addition to this primary search, we performed a secondary search by scrutinizing all references cited in the articles retrieved from the primary search in order to identify additional studies of interest. Three independent evaluators reviewed all articles retrieved from the primary and secondary searches using the systematic strategy outlined below.

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The evaluators were blinded with regard to the determinations of the other evaluators.

Studies were included in the systematic review and meta-analysis if they met the following criteria: (1) they compared patients who underwent TKA with standard instrumentation to those who underwent TKA with patient-specific instrumentation and (2) they reported post-operative coronal alignment, post-operative sagittal alignment, operative time, intraoperative blood loss, transfusion requirement, and/or perioperative cost. Review articles, technique descriptions, and editorials were excluded.

The initial combined Medline and Embase search using the aforementioned keyword terms yielded 207 unique articles. The titles of these studies were independently reviewed by all three authors (PBV, MH, GCL). Studies that were clearly irrelevant to the topic in question based on their title (113 in total) were eliminated. The abstracts of the remaining 94 articles were then independently scrutinized by all three authors. Studies that clearly did not meet the inclusion criteria based on the information contained in their abstracts (61 in total) were eliminated. The remaining 33 abstracts were determined to meet the inclusion criteria by at least one author, so the corresponding full texts were independently reviewed by all three authors. After full text review, 26 of these studies were unanimously eliminated by all three authors because they failed to meet the inclusion criteria. Therefore, seven articles were ultimately retained from the primary search. At every phase of review, if one or more authors selected a study, that article moved on to the next phase. In the final phase of review (full text review), there was no disagreement over which studies should ultimately be included. All references cited in the articles retrieved in the initial query were then compiled in our secondary search. These references were screened in the same manner as the articles from the primary search (title review then abstract review then full text review). Two additional studies that met the inclusion criteria were retained from the secondary search. Therefore, nine total studies were used for data retrieval (Fig. 1) [9–17].

These nine studies described a total of 957 patients who had undergone total knee arthroplasty: 428 with standard instrumentation and 529 with patient-specific instrumentation. Using previously published data, it was determined that a sample size of 80 patients per group would have sufficient power (0.80) to detect a significant difference ($\alpha = 0.05$) in all primary outcomes [18]. The present study therefore met the minimum sample size requirement.

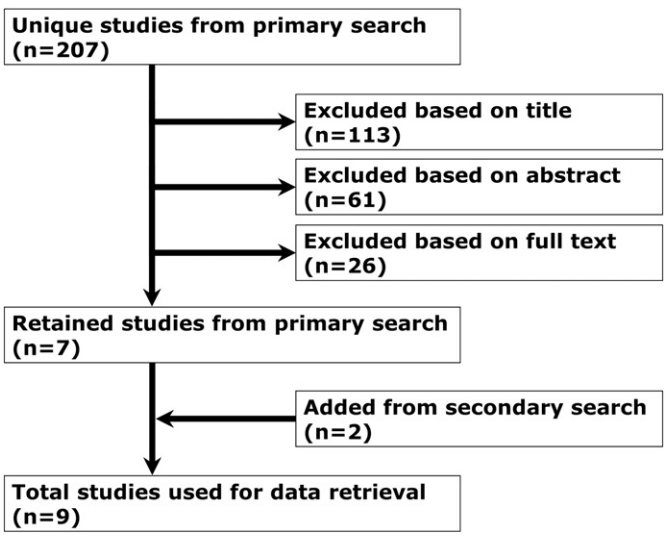

Fig. 1. Flow diagram presenting the systematic search process utilized in this study. *The search keyword terms used were "total knee arthroplasty" and "patient-specific."

The data published in the nine component studies were meticulously extracted and compiled. A random effects meta-analysis was generated using these data, allowing us to compare standard instrumentation versus patient-specific instrumentation with regard to coronal alignment, sagittal alignment, operative time, intraoperative blood loss, transfusion requirement, and perioperative cost. The meta-analysis was performed with MIX meta-analysis software (version 1.7) for Windows.

Results

The nine component studies described a total of 957 total knee arthroplasties (428 performed with standard instrumentation and 529 with patient-specific instrumentation). All cases performed with patient-specific instrumentation utilized preoperative MRI rather than CT. The details of these nine studies are shown in Table 1.

While patient-specific instrumentation demonstrated improved accuracy in coronal alignment as measured by femorotibial angle (FTA) ($P = 0.0003$), standard instrumentation demonstrated improved accuracy in coronal alignment as measured by hip-knee-ankle angle (HKA) ($P = 0.02$) (Table 2). Importantly, there were no significant differences in the ability of either technique to avoid outliers (>3 degrees from target alignment) in either FTA ($P = 0.7$) or HKA ($P = 0.7$) (Table 3).

Measures of sagittal alignment accuracy were equivalent between the two groups for both the femoral component ($P = 0.5$) and the tibial component ($P = 0.9$). The average femoral component was 7.4 degrees flexed relative to the anatomic axis of the femur in the PSI group compared to 5.3 degrees flexed in the standard instrumentation group.

Operative time was not significantly reduced in the PSI group (n = 193 knees) compared to the standard instrumentation group (n = 192 knees) ($P = 0.1$). The mean operative time in the PSI group was 93 minutes compared to 104 minutes in the standard instrumentation group ($P = 0.1$). Operative time was defined as the time from incision until dressings.

Blood loss and transfusion requirements were also similar between treatment groups. The mean intraoperative blood loss was 371 mL for the PSI group versus 384 mL for the standard instrumentation group ($P = 0.2$). Intraoperative blood loss was defined by the component studies as the amount of blood noted in the suction device prior to irrigation of the knee. Of note, this value only includes intraoperative blood loss, not postoperative blood loss. The percentage of patients requiring blood transfusion was 10.1% for the PSI group and 14.1% for the standard instrumentation group ($P = 0.1$).

Only one study presented data regarding perioperative cost [9]. That study reported a total savings of $322 per case with patient-specific instrumentation versus standard instrumentation as a result of decreased operative time and sterilization time with PSI [9]. However, once the cost of generating the custom cutting guide ($950) was taken into account, it was determined that PSI was actually more expensive than standard instrumentation by $628 per case [9]. Additionally, the cost of the preoperative MRI (varied between $400 and $1250 based on insurance) further added to the expense of PSI [9].

Four different patient-specific instrumentation systems were utilized in the component studies: Biomet Signature (6 studies, 393 TKA), Zimmer Patient Specific Instruments (1 study, 40 TKA), Smith & Nephew Visionaire (2 studies, 46 TKA), and Styker OtisMed (1 study, 50 TKA) (Table 1). Due to the limited sample sizes of these individual groups, the present study is underpowered to make statistical comparisons between PSI systems.

Discussion

Patient-specific instrumentation (PSI) was designed to improve alignment through preoperative navigation, reduce operative time by minimizing intraoperative decision making, and decrease perioperative cost by limiting the number of instrument trays required per