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The impact of custom cutting guides on patient satisfaction and residual symptoms following total knee arthroplasty

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ABSTRACT

Background: Custom cutting guides (CCGs) in total knee arthroplasty (TKA) use preoperative three-dimensional (3-D) imaging to manufacture cutting blocks specific to a patient's anatomy. The purpose of this study was to evaluate the impact of CCGs versus standard intramedullary and extramedullary guides on patient-reported satisfaction and residual symptoms following TKA.

Methods: A retrospective, multicenter study was performed to compare a magnetic resonance imaging-based CCG system versus standard instrumentation. All patients received the same, cemented, fixed-bearing, cruciate-retaining component, and had a primary diagnosis of osteoarthritis. Data was collected by an independent, third party survey center blinded to surgical technique that administered telephone questionnaires assessing patient satisfaction and symptoms. Patient age, gender, minority status, education level, income, length of follow-up, and pre-arthritic UCLA scores were considered potential confounders and accounted for using multivariate logistic regression analyses.

Results: 448 patients (107 CCGs, 341 standard) were successfully interviewed. At a mean follow-up of three years, there was no difference in percentage of patients reporting their knee to feel "normal" (74% CCG versus 78% standard, $p = 0.37$). Residual symptoms including knee stiffness (37% CCG versus 28% standard, $p = 0.08$) and difficulty getting in and out of car (34% CCG versus 30% standard, $p = 0.40$) remained high. Multivariate regression analyses demonstrated no differences between the two cohorts for both patient-reported satisfaction and residual symptoms (odds ratios 0.72 to 1.48; $p = 0.10$ to 0.81).

Conclusion: When interviewed by an independent, blinded third party, the use of CCGs in TKA did not improve patient-reported satisfaction or residual symptoms versus the use of standard alignment guides.

1. Introduction

While total knee arthroplasty (TKA) is a commonly performed and highly successful surgical procedure [1–4], recent reports have shown the percentage of patients who remain "unsatisfied" following TKA to be as high as 15% to 30% [5–7]. Bourne et al. [5] performed a cross-sectional study of patient satisfaction after 1703 primary TKAs, demonstrating approximately 19% of patients to be unsatisfied with their outcome, with pain relief varying from 72 to 86%, and the ability to perform specific activities of daily living from 70 to 84%. Furthermore, Parvizi et al. [8], in a survey of 661 young, active TKA patients, demonstrated only 66% to report their knee to feel "normal," with persistent pain in 33%, stiffness in 41%, grinding or other noise in 33%, and a high incidence of residual symptoms. Thus, there remains a significant margin for improvement in the clinical outcomes achieved with TKA, and surgical techniques continue to be modified with the goal of improving patient satisfaction and function.

A recent modification of surgical technique has been the introduction of custom cutting guides (CCGs), in which preoperative three-dimensional (3-D) imaging is used to manufacture cutting blocks specific to a patient's anatomy. Potential benefits of CCGs include a decrease in operative time, instrument trays required, the ability to preoperatively plan a patient's component size and position, and an improvement in the postoperative target alignment versus conventional alignment methods [9–12]. However, these potential benefits and the cost-effectiveness of this technique have not been proven [13–16]. Furthermore, although several reports have examined the ability of CCGs to avoid outliers and attain alignment targets, no studies to our knowledge have specifically evaluated the impact of CCGs on patient-perceived satisfaction and function.

The purpose of this study was to evaluate the impact of CCGs versus standard instrumentation using an independent, blinded telephone survey center to evaluate patient satisfaction and the presence of residual symptoms when performing a TKA targeting a neutral, mechanical alignment. As recent investigations have failed to demonstrate clinical

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improvements (based on surgeon-derived outcome measures) in patients receiving CCGs [17–19], our hypothesis was that the use of CCGs would not improve patient-perceived outcomes following TKA versus the use of standard alignment methods.

2. Materials and methods

Prior to initiation of this study, institutional review board (IRB) approval was obtained at the Washington University School of Medicine to serve as the coordinating center. One other institution and an independent third-party survey center (University of Wisconsin Survey Center [UWSC]; Madison, WI) was enlisted to participate. Each participating center obtained approval from its IRB of oversight. Modern multimodal pain management and rapid mobilization protocols were used, and all patients received a mid-vastus surgical approach.

Investigators queried their total joint registries and compiled a list of patients meeting the inclusion criteria, who had undergone a primary TKA within one to four years of the commencement of the study, and had a minimum of one year of clinical follow-up. Prior to initiation of this study, CCGs had been used in total knee arthroplasty at each institution for greater than one year. Total knee arthoplasties were performed targeting a neutral mechanical axis with both CCGs (Signature™, Biomet Inc., Warsaw, IN, USA; CCG cohort) and standard alignment methods (intramedullary and extramedullary alignment guides; Standard cohort), respectively. During the period in question, all patients without contraindication to a magnetic resonance imaging (MRI) examination were offered the use of CCGs by the operating surgeon. Patients willing to receive a MRI and have their surgical procedure scheduled far enough in advance to have the CCGs manufactured self-selected themselves to be in the CCG cohort. During this time period, approximately 23% of all primary TKAs were performed using CCGs.

Inclusion criteria for this study were: 1) males or females at least 18 years of age and skeletally mature; 2) patients requiring primary knee surgery due to non-inflammatory arthritis (degenerative joint disease) such as osteoarthritis, traumatic arthritis, or avascular necrosis; and 3) use of the same cemented, fixed-bearing, posterior cruciate-retaining component with patella resurfacing (Vanguard; Biomet Inc., Warsaw, IN, USA). Exclusion criteria were: 1) subjects with a history of previous infection or sepsis in the knee joint, fracture, or dislocation, 2) patients with extensive medical comorbidities including hypertension, renal failure, coronary artery disease, liver disease, sickle cell disease, inflammatory arthropathy, respiratory disease, cancer, etc., which would limit their activity level, and 3) patients who received revision surgery since their index procedure.

In the CCG cohort, select magnetic resonance imaging scans were performed of the hip, knee, and ankle, from which a preoperative 3-D image of the knee was generated. The optimal size, position, and alignment of the implants were templated, with the goal of achieving an overall, neutral mechanical alignment, and femoral and tibial component alignments perpendicular to each, respective mechanical axis in the coronal plane. Once approved by the surgeon, rapid prototyping technology was used to fabricate disposable CCGs specific to each patient's anatomy, and the CCGs were used to perform the distal femoral and proximal tibia resections intraoperatively, and to set component rotation [20]. In the Standard cohort, conventional extramedullary tibial and intramedullary femoral alignment guides were used to perform the proximal tibial and distal femoral resections, respectively. Again, the goal was to achieve an overall, neutral mechanical alignment, with the femoral and tibial components aligned perpendicular to each, respective mechanical axis in the coronal plane.

The UWSC was selected for their expertise in collecting health data for state and federal agencies, and for having no affiliation with any of the participating centers [21,22]. The UWSC, in collaboration with the coordinating center, designed an instrument that would collect specific data regarding the level of satisfaction, function, residual symptoms, and ability to return to the most preferred preoperative activity one to four years after TKA [8,23,24]. The survey was administered utilizing computer-assisted telephone interviewing. Only the contact information and date and side of surgery were provided to the UWSC. Interviewers read a telephone script to obtain verbal consent before administering the survey. A screening section ensured that participants met the inclusion criteria, and the full questionnaire was administered to those patients who both provided verbal consent and were determined to be eligible and capable to participate. All interviews were conducted in English. The telephone survey protocol included 25 telephone call attempts per patient. In general, cases involving refusals to participate were called back in an attempt to convert the refusal into a completed interview. If a second refusal occurred, no further attempts were made. The final data were sent from the UWSC via a secure website in SPSS format (Version 16.0, SPSS Inc., Chicago, Illinois) [8].

To assess each patient's activity level, the University of California at Los Angeles Activity (UCLA) Score was determined [25]. Patients were asked about their activity level prior to the onset of their arthritic symptoms, which was recorded as the "pre-symptomatic" UCLA score. The satisfaction section was constructed from a review of recent investigations detailing patient satisfaction and function following TKA [5,6,23]. Questions selected were based on previous studies determining factors most important to patients, and/or most highly correlated with patient satisfaction as reported by Bourne et al. [5] and Noble et al. [6]. For purposes of analysis, the responses were grouped into two broad categories of either "never/rare" or "sometimes/often/frequent," replicating the methodology described by Bourne et al. [5]. Patients were also asked if their operated knee felt "normal" to them, as described by Noble et al. [6]. The patient specific functional scale (PSFS) [26–28] was incorporated to determine whether there were one or more recreational activities critical to the patient, of which they had to limit their preoperative participation because knee symptoms. The percentage of patients who returned to this critical activity following surgery was determined.

The principal questions related to satisfaction consisted of asking the patient regarding overall function of the knee, the ability to perform normal activities of daily living, and satisfaction with the degree of pain relief. The principal questions related to symptoms inquired about the presence of any pain or stiffness in the knee, audible noises from the knee including popping, clicking or grinding, and experiencing any swelling or a sense of tightness in the knee. To assess function, the patient was asked about the ability to get in and out of a car, getting in and out of a chair, going up and down stairs, and the presence of any limp [8,23].

Four hundred forty-eight patients were successfully interviewed: 107 with CCGs and 341 with standard instrumentation. The response rate to the telephone survey administered was 66% (107 of 162 patients contacted) in the CCG cohort and 63% (341 of 538 patients contacted) in the Standard cohort. A response rate of greater than 60% was targeted as Fincham et al. has noted this to be the goal of studies implementing a telephone survey methodology [29].

A post hoc power analysis was conducted to assess the research question that there would be no difference in the percentage of patients noting overall satisfaction with the function of their knee between the CCG and standard cohorts. It was determined that a sample size of 100 patients in each cohort would provide appropriate power (beta level = 0.80, alpha level = 0.05) to detect a 7 percentage point difference in patients noting overall satisfaction with the function of their knee. To compare patient characteristics, Chi-square tests or Fischer's exact tests were performed on categorical variables, while non-parametric Wilcoxon rank sum tests were used for continuous variables. Univariate logistic regression was conducted first to explore the association between the cutting guide and outcome of interest, then multiple logistic regression analyses were used to further confirm the association. Demographic and clinical variables such as age, gender, minority status ("minority" considered black, Hispanic, or other), education (less than high school versus high school graduate and above), income (less than USD 25,000 per year versus >25,000), length of follow-up, and pre-symptomatic UCLA scores