The Journal of Arthroplasty 29 (2014) 2065–2069

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

# Patient-Specific Versus Conventional Instrumentation for Total Knee Arthroplasty: Peri-Operative and Cost Differences

Alexander M. DeHaan, MD, Jacob R. Adams, MD, Matthew L. DeHart, BS, Thomas W. Huff, MD

*Department of Orthopaedics and Rehabilitation, Oregon Health & Science University, Portland, Oregon 97239-3098*

ARTICLE INFO

*Article history:*
Received 17 February 2014
Accepted 24 June 2014

*Keywords:*
total knee arthroplasty
custom cutting blocks
patient-specific instrumentation
patient-specific total knee arthroplasty
cost-effectiveness

ABSTRACT

The role of patient-specific instrumentation in total knee arthroplasty (TKA) is yet to be clearly defined. Current evidence evaluating peri-operative and cost differences against conventional TKA is unclear. We reviewed 356 TKAs between July 2008 and April 2013; 306 TKAs used patient-specific instrumentation while 50 had conventional instrumentation. The patient-specific instrumentation cohort averaged 20.4 min less surgical time ($P < 0.01$) and had a 42% decrease in operating room turnover time ($P = 0.022$). At our institution, the money saved through increased operating room efficiency offset the cost of the custom cutting blocks and pre-operative advanced imaging. Routine use of patient-specific TKA can be performed with less surgical time, no increase in peri-operative morbidity, and at no increased cost when compared to conventional TKA.



The demand for total knee arthroplasty (TKA) has increased dramatically over the past twenty years, and is expected to increase by more than 600% by the year 2030 [1]. As a result, there is pressure on surgeons and implant companies to increase operating room efficiency and improve patient outcomes, while lowering the cost to the healthcare system. These ideas led to the development of patient-specific instrumentation in TKA, in which custom alignment guides for the femur and tibia are created from pre-operative three-dimensional magnetic resonance imaging (MRI) or computed tomography (CT) scans.

Historically, TKA has used intramedullary or extramedullary femoral and tibial guides for instrumentation. As these guides are not customized to each individual patient, the component size, rotation, position, and orientation are based upon preset valgus angles for the femur and external landmarks that can vary from patient to patient. With patient-specific TKA, the custom instruments are designed to fit to each patient's unique anatomy, with the precise orientation and component rotation built into the guide. Consequently, it was theorized that patient-specific TKA could decrease surgical time and provide improved component alignment in TKA while also streamlining the number of instrument trays required for a given case. As with computer navigation, patient specific instrumentation does not rely on instrumentation of the intramedullary canal, and as such may result in decreased peri-operative blood loss and a lower risk of fat embolism compared to conventional instrumentation [2,3]. Due to these proposed advantages, there has been a rapid increase in the use and interest in this new technology for routine TKA; specifically, its global use increased by a factor of 1.5 from 2011 to 2012 [4].

Evidence of these proposed advantages has lagged behind the growth in popularity. Preliminary results of the patient-specific instrumentation TKAs have been inconsistent across the orthopedic literature with regard to operative time [5–16], component alignment [5–7,9–14,17–22], and blood loss [5,7,8,12,14,15]. Some studies report decreased operative time and blood loss with patient-specific instrumentation, while others show the opposite. In addition, some studies have brought concern over the cost of the custom cutting jigs and pre-operative imaging, added expenditures that may not be justified for routine TKA [6,16,23]. However, many of these studies have small patient numbers and may be underpowered for what they are trying to assess. Another concern is whether or not the learning curve involved with the custom cutting guides, as with any new surgical procedure, is taken into account when comparing patient-specific and conventional instrumentation methods.

We set out to evaluate whether or not patient-specific instrumentation for TKA leads to decreased peri-operative morbidity when compared to conventional TKA through a large single surgeon case series. Additionally, we evaluated the sizing accuracy of the predicted cutting block templates in the cases utilizing patient-specific instrumentation. Finally, we evaluated the cost of this new technology, and whether any increases in operating room efficiency would justify its routine use.

## Methods

### *Study Design*

Institutional review board approval was obtained prior to beginning this retrospective review. A case list was obtained through

The Conflict of Interest statement associated with this article can be found at http://dx.doi.org/10.1016/j.arth.2014.06.019.

Reprint requests: Thomas W. Huff, MD, Oregon Health and Science University, Department of Orthopaedics and Rehabilitation, 3181 S.W. Sam Jackson Park Rd, Portland, Oregon 97239-3098.

http://dx.doi.org/10.1016/j.arth.2014.06.019
0883-5403/

a database search using the CPT code 27447 (primary TKA) between the dates July 2008 and April 2013. Subsequently, patient information was obtained through a review of each patient's clinical chart and operative record. All procedures were performed at a single institution by the senior author with the assistance of an orthopedic resident, medical student and/or physician assistant. Exclusion criteria consisted of patients who underwent bilateral TKA, unicompartmental knee arthroplasty, TKA with concurrent hardware removal from a previous operation, or revision TKA.

### *Surgical Indications & Arthroplasty Components*

The indication for TKA was tri-compartmental degenerative joint disease refractory to conservative treatment modalities including weight loss, low-impact aerobic exercise, activity modification, anti-inflammatory medications, bracing, and injections. Patient-specific instrumentation was used as the standard for all patients for the majority of the study period. The decision to proceed with conventional instrumentation was based on the patient's preference against further advanced imaging, logistical issues obtaining the advanced imaging, or if the surgery date the patient desired was to be sooner than the time required for the advanced imaging and development of the custom cutting block.

Advanced imaging for the patient-specific instrumentation cases was based on three-dimensional MRI. There were 13 cases which were excluded from the study; these cases utilized a CT scan due to previous knee hardware or a cardiac pacemaker that prevented use of an MRI. From the computerized three-dimensional model, a disposable custom cutting block was created that would fit onto the arthritic knee. The patient-specific instrumentations system used was the Smith and Nephew Visionaire (Memphis, TN, USA) in 306 cases. The TKA components utilized were the Smith and Nephew Legion Primary Knee (Smith and Nephew Inc, Memphis, TN, USA) or the Smith and Nephew Journey Primary Knee (Smith and Nephew Inc, Memphis, TN, USA).

### *Surgical Procedure and Protocol*

Primary TKA was performed in a standard fashion utilizing a medial parapatellar approach with the use of a tourniquet in all cases. Patient-specific instrumentation utilized pre-fabricated custom cutting blocks, while conventional arthroplasty utilized intramedullary femoral and extramedullary tibial referencing. The components were cemented in position for all cases. A hemovac drain was placed at the end of the surgery and removed on post-operative day 1 for all cases.

Procedures were performed in a clean-air laminar-flow environment using body exhaust suits. Pre-operative antibiotics (routinely Cefazolin, unless otherwise indicated) were given within 1 h of incision and continued for 24 h post-operatively. For venous thomboembolic prophylaxis, all patients received mechanical compression devices while in the hospital along with pharmacologic prophylaxis, routinely consisting of Aspirin 325 mg twice daily for 4 weeks unless the patient was deemed high risk or had a history of a previous thromboembolic event. While in the hospital, patients worked daily with a physical therapist to encourage early mobilization. The patients were discharged when they were medically stable, their pain controlled on oral medication, and were ambulatory with the use of an assistive device.

### *Outcome Measures*

This study set out to answer three specific outcome measures, all of which could be answered through review of the operative data and the patient's medical record. First, we determined whether patient-specific instrumentation resulted in decreased peri-operative morbidity when compared to conventional TKA. Variables used to assess for differences between the two cohorts included tourniquet and total operative time, operating room turnover time, estimated intra-operative blood loss, change in post-operative hematocrit and hemoglobin, need for a post-operative blood transfusion, drain output, date of hospital discharge, and intra-operative complications.

Second, we evaluated the sizing accuracy of the predicted patient-specific femoral and tibial MRI-based templates. This was done through a retrospective review of the predicted template size for each case, with comparison to the component size used at the time of implantation.

Third, we assessed for the potential of any cost savings through use of patient-specific instrumentation. The cost of the pre-operative imaging ranged from \$430 to \$1360, dependent upon which local imaging center was used and the patient's insurance type. The tibial and femoral custom cutting blocks was a fixed cost at \$500. This represents a negotiated cost at our institution, which is also bundled into the overall implant cost. The cost of operating room time was \$129 per minute for the first 30 min and \$65 per minute for every minute thereafter, and accounts for the personnel, nursing, equipment, and fixed overhead costs. The cost of the implant tray sterilization was \$60 for each tray and includes the cost of the utilities, personnel, equipment, and sterilization process.

The difficulty in quantifying the true costs of the above variables comes from the inherent differences between the price that is charged versus collected, what the patient pays versus what the insurance carrier pays, along with the variable costs between institutions and imaging centers. In addition, this cost could be different for each individual based on their deductible and insurance type. Therefore to simplify the cost analysis and make it more generalizable to all patients, we used the cost that was billed to the patient based on their insurance type, with the assumption of full re-imbursement by the payer.

### *Statistical Analysis*

Statistical analyses were performed using the R language and environment [24]. With the exception of 'hematocrit change 1', all selected continuous variables demonstrated a linear relationship and were normally distributed, thus meeting the assumptions necessary for parametric analysis. We utilized classic $2 \times 2$ chi square design [25] accompanied by the phi Cramer's V post hoc testing design [26] when analyzing the associations between post-operative blood transfusion and intra-operative complications in patients receiving conventional TKA versus patient-specific TKA. When analyzing the difference in means between levels of tourniquet and total operative time, estimated blood loss, post-operative hematocrit, drain output, length of stay, and cost statistics, we utilized Levene's test for equality of variance [27] leading to a Student's t-test design [28]. For the purpose of analyzing 'hematocrit change 1' in patients receiving conventional TKA vs patient-specific TKA, a significance statistic was calculated utilizing a Mann–Whitney U testing design due to abnormal distribution [29]. All reported frequencies and significance statistics were calculated utilizing one of these three methods.

## Results

### *Patient Demographics*

356 cases of primary TKAs were performed in 303 patients during the study period. The mean patient age was 62.8 years (standard deviation 10.3 years) with a mean body mass index of 32.2 kg/m$^2$ (standard deviation 6.6 kg/m$^2$). 63.7% of cases were performed in female patients, and 51% involved the right knee. Of the 356 total cases, 306 were performed using patient-specific instrumentation and 50 utilized conventional methods of intramedullary femoral and extramedullary tibial referencing. The two cohorts were similar with regard to patient age, body mass index, and sidedness of surgery ($P > 0.05$, Table 1); however, there were gender differences between the two