A Novel Technique Using Sensor-Based Technology to Evaluate Tibial Tray Rotation

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Abstract

Rotational tibiofemoral congruency and centralized patellar tracking are critical technical factors that affect the postoperative success of total knee arthroplasty (TKA). Several techniques are used to position the femoral component, but there is no validated method for achieving the ideal rotational position of the tibial component. It has been suggested that referencing the midmedial third of the tibial tubercle intraoperatively mitigates positional outliers. This study used data collected from intraoperative sensors to quantify the variability associated with using the midmedial third of the tibial tubercle in 170 patients undergoing primary TKA. With the sensor-equipped trial insert in place, the knee was taken into extension and the location of the femoral condylar contact point on the articular surface of the tibial insert was displayed. Rotational adjustments of the tibial tray were evaluated in real time as the surgeon corrected tray malpositioning. The initial and final angles of tibial tray rotation were captured and recorded with intraoperative video feed. When referencing the tubercle, 53% of patients had asymmetric tibiofemoral congruency in extension. Of those patients, 68% had excessive internal rotation of the tibial tray relative to the femur and 32% had excessive external rotation. The average tibiofemoral incongruency deviated from a neutral position by 6° (range, 0.5°-19.2°). Data from this evaluation suggest that use of the tibial tubercle to maximize tibiofemoral congruency is highly variable and inconsistent for confirming the final rotation of the tibial tray. [Orthopedics. 2015; 38(3):e217-e222.]
The success of total knee arthroplasty (TKA) depends on a multitude of surgical factors, including appropriate rotational alignment of the prosthetic components. Despite the high success rate of TKA, early postoperative complications can occur as a result of poor rotational positioning of 1 or both components, which ultimately may require revision surgery.

Complications that indicate tibiofemoral rotational incongruency (ie, rotational mismatch between the femoral and tibial components, as shown in Figure 1) may present early in the postoperative period with symptoms of anterior knee pain, joint stiffness, the sensation of instability, and difficulty navigating stairs and/or inclined planes. The incidence of anterior knee pain may be as high as 20% after TKA. Clinical examination of patients with incongruency can show restricted range of motion, patellar crepitus, patellar maltracking (tilt-dislocation), and significant rotational mismatch as shown by gait disturbance (foot progression angle). Suboptimal outcomes as a result of incongruency have been well documented and may be associated with small rotational deviations of the tibial and femoral components. For instance, Barrack et al reported that as little as 6.2° internal rotation of the tibial component is associated with postoperative anterior knee pain. Berger et al showed that combined internal rotation of the tibial and femoral components of 3° to 8° correlated with patellar subluxation and combined internal rotation of 7° to 17° correlated with observed patellar dislocation or patellar prosthesis failure.

Although methods have been advocated for establishing optimal rotation of the femoral component, there is no reliable method for positioning the tibial tray. Thus, surgeons must rely on anatomic landmarks to guide orientation of the tibial component. These landmarks include the projected femoral transepicondylar axis, the medial third of the tibia, the posterior condylar line of the tibia, the midsulcus of the tibia spine, the malleolar axis, the patellar tendon, and the axis of the second metatarsal. However, it may be difficult to identify these landmarks during surgery. Poor intraoperative visibility and native variations in patient anatomy can contribute to unfavorable positioning.

It was suggested that aligning the tibial tray with the mid-third of the tibial tubercle can reduce positioning outliers more consistently than referencing other anatomic landmarks. However, reliance on these landmarks is subject to variability and may not provide the precision necessary to avoid complications, such as those described by Barrack et al and Berger et al. There is an obvious need to refine the clinical technique and explore new methods to optimize tibiofemoral implant congruency.

The goal of this study was to use intraoperative sensing to test the precision and variability of setting tray rotation to the mid-third of the tibial tubercle as well as to evaluate how intraoperative sensing technology may assist surgeons in rotational correction.

**MATERIALS AND METHODS**

**Patient Profile**

A retrospective review, with institutional review board exemption under 45 CFR 46.101(b)(4), was conducted for this evaluation of consecutive patient data. No patients were excluded from analysis for any reason.

One hundred seventy patients underwent primary TKA during a 10-month period between 2012 and 2013 performed with the use of the VERASENSE Knee System (OrthoSensor, Inc, Dania, Florida). One high-volume, arthroplasty-trained surgeon performed all TKA procedures using the Triathlon Cruciate-Retaining Knee System (Stryker Orthopedics, Mahwah, New Jersey).

Deidentified surgical and demographic data were obtained for every patient, including age, body mass index, sex, ethnicity, and intraoperative tray rotation (pre- and postcorrection, if applicable) as digitally indicated by the VERASENSE Knee System.

**Device and Tray Rotation Assessment**

The VERASENSE sensors, validated for use in quantifying bearing surface loading, contact point position, and alignment, were custom engineered with Stryker geometric specifications to replace the use of the polyethylene tibial trial and to collect data during the normal surgical workflow.

The system consists of a wireless microprocessor-embedded sensor (tibial trial) (Figure 2) and a graphic display module (Figure 3). Contact points at the tibiofemoral interface are shown with point markers in both the medial and lateral compartments of the virtually displayed tibial tray. Feedback on contact
point location and kinetics is updated in real time, providing the surgeon with immediate kinematic data to guide necessary correction.

Incongruency in tibiofemoral rotation is readily identified by nonparallel position of the contact point markers relative to each other. With visual feedback provided by the graphic display module, the surgeon can dynamically adjust tibial tray rotation until the contact points appear parallel, indicating rotational congruency between the components (Figure 4).

Degrees of rotation are also updated in real time through the arc of correction and are shown on the graphic display module. The difference between initial and final degrees of rotation (ie, pre- and postcorrection data) was captured and analyzed as the amount of rotational change that was required to achieve parallel contact point continuity between the femoral and tibial components (Figure 5). This digital output of degrees of rotation was used to define how far beyond rotationally neutral (or parallel, as shown on the display module) the tibial tray was for each case.

Surgical Protocol

Intraoperatively, knee joints were accessed through a midvastus approach. The surgeon performed standard bone cuts with navigation to define distal femoral and proximal tibial cuts in the sagittal and coronal planes (distal femoral and proximal tibial ±1° varus/valgus, 3° femoral flexion, 4°-5° tibial slope).

To ensure appropriate rotation of the femoral components, reducing the likelihood of femoral rotational bias on contact point location, a standard method was employed by using the epicondylar axis and confirming centralized patellar tracking after tibial rotation was determined.

Initial tibial component rotation was dictated by the posterior cruciate ligament insertion site and the midmedial third of the tibial tubercle (Figure 1). The size of the tibial component was determined after tibial coverage was maximized while rotational reference was maintained. With the knee in extension, the tibial tray was pinned in the anteromedial position to stabilize translational motion in the anteroposterior and mediolateral planes during rotational correction, as captured for this study.

With the trial components for the tibia and femur in place, the standard polyethylene trial was inserted and the knee was reduced. The knee was assessed manually to confirm that the joint did not show excessive tension or laxity in the coronal or sagittal plane. Once the appropriate tibial insert size was determined, the corresponding VERASENSE sensor was activated. The VERASENSE sensor was inserted with an appropriately sized shim to replicate the exact thickness of the standard trial that was used during initial assessment (Figure 6).

Statistical Analysis

Data analysis was performed with SPSS version 21 (SPSS Inc, Chicago, Illinois). Analysis of variance was used to assess the significance of the proportion of patients with incongruency. All possible theoretical factors that could have contributed to the proportion of observed rotational variance (including age, body mass...
index, and sex) were combined in a maximum likelihood estimation model to assess observation strength. The predictive output of the maximum likelihood model can be applied to future groups of patients matched for age, body mass index, and sex. A confidence interval was performed to assess the range of possible proportions of observable incongruency in future patient groups (confidence interval, 95%). Significance was defined as $P<.05$.

**RESULTS**

Of the 170 consecutive patients evaluated, 19% were men and 81% were women. Average body mass index was 30.0±5.7 kg/m$^2$ (range, 19.9-49.8 kg/m$^2$). The representation of ethnic groups was African American, 4.3%; white, 93.3%; and Hispanic/Latino, 2.5%. Average age was 69.1±9.5 years (range, 42-86 years).

Of the 170 patients who underwent TKA, using the mid-third of the tibial tubercle to establish initial tibial tray rotation, 53% ($P<.001$) showed a visually verifiable amount of nonparallel contact point character on the graphic user interface. The sensor system could display as little as 0.5° incongruency.

Of the patients with incongruency, 68% showed excessive internal rotation of the tibial implant relative to the femoral component and 32% showed excessive external rotation of the tibial implant relative to the femoral component, as captured by the VERASENSE Knee System (Figure 7).

The maximum likelihood estimation model, testing the theoretical likelihood of observing a similar proportion of incongruency in future patients (when referencing the mid-third of the tibial tubercle), was strong, at 82% (Figure 8).

The average amount of tibiofemoral incongruency for both internal and external rotation was 6.0°±4.0°. The range of tibiofemoral incongruency, shown as nonparallel contact point character requiring correction, was 0.5° to 19.2° as absolute values. Of the entire cohort, 35% of patients showed at least the average amount of internal tray rotation reported to contribute to anterior knee pain, as described by Barrack et al (6.2°).

The 95% confidence interval for the proportion of future patients exhibiting tibiofemoral incongruency (based on the location of the mid-third of the tibial tubercle), for those matched for age, sex, body mass index, and ethnicity, was 39.8% to 66.8%.

**DISCUSSION**

Ensuring appropriate tibiofemoral rotational alignment is a critical factor in component survivorship in TKA. Although there are advocated methods for establishing optimal rotation of the femoral component, no gold standard method exists for positioning the tibial tray. Eckhoff et al$^{10}$ evaluated 4 methods for determining tibial component rotation and found each to exhibit variability, with a 21° range in tibial rotation from 2° internal rotation to 19° external rotation.

This lack of a consistent and reproducible method for aligning the tibial tray has been reported as a factor contributing to excessive internal rotation and its associated complications.$^{6-8,14}$ However, this is the first report of rotational variation associated with using the mid-third of the tibial tubercle and its correction, as measured by intraoperative sensing technology.

This patient group, evaluated with the sensor, showed that the location of the mid-third tibial tubercle is highly variable and is an unreliable landmark for use in tibial component positioning. It did not consistently optimize implant congruency with the femur.

The current study found that 53% ($P<.001$) of patients had an average tibiofemoral incongruency of 6°, with a maximum value of 19.2°. The maximum likelihood estimation model indicated that a similar proportion of incongruency has a high probability of occurring in matched groups of future patients. Specifically, this finding suggests that there is an 82% chance that more than half of the patients...
in future cohorts will exhibit tibiofemoral incongruency as a result of referencing the mid-third of the tibial tubercle. The finding of 53% of patients who had incongruency in this study is positioned near the apex of the maximum likelihood curve (Figure 8), making it 1 of the most probable scenarios.

The 95% confidence interval is in agreement with the likelihood estimation model, suggesting that the number of future patients showing excessive incongruency may range from 33.8% to 66.8% when the tibial tubercle is used as a guide. Although this confidence interval would apply to patients matched to this group for age, sex, body mass index, and ethnicity, the analysis was run only on a consecutive patient basis, meaning that no patients were excluded for any reason. This may suggest that the patient group used in this study is more reflective of a broader population than a group established with the use of specific exclusion criteria.

The most important finding of the current study was that the incongruency observed with using the mid-third of the tibial tubercle is well within the range associated with postoperative complications. Therefore, reliance on the mid-third of the tibial tubercle alone does not provide the positioning precision necessary to avoid complications associated with subtle rotational incongruency.

If the observed rotational incongruency had gone uncorrected in this cohort, the literature suggests that anterior knee pain may have occurred in as many as 35% of these patients (those with incongruency ≥6.2°). These complications were potentially avoided because of correction of implant rotation, as indicated by the sensor system, to achieve full implant congruency.

Limitations

First, only 1 surgeon contributed patients to the analysis. Although it would have been optimal to collect data from several surgeons, using data from only 1 surgeon meant that the alignment of the tibial tray to the mid-third of the tibial tubercle was consistent for all patients and was not subject to variations in technique. Second, the study data were collected intraoperatively as a technique reference. This study was not intended to collect postoperative clinical outcomes strictly based on tibiofemoral rotational congruency. Future studies are needed to evaluate rotational changes and the effects on pain, function, and patient satisfaction. Third, only the Triathlon system was used in this evaluation. Thus, the rotation data presented in this study are only truly applicable to Triathlon. However, all patients who undergo TKA must contend with complications from tibiofemoral incongruency, and the findings of the current study are applicable with respect to the need for alternative positioning methods. Fourth, although consistent steps were taken to ensure appropriate alignment of every femoral component, there is still a potential for femoral bias. However, in using the data from 1 high-volume surgeon who was highly experienced with integration of the Triathlon and VERASENSE systems, potential positioning errors and technique variances were mitigated. Central patellar tracking was confirmed, with no lateral retinacular releases required. No tibial trays were rotated internally medially to the tibial tubercle medial border.

Although the mid-third of the tibial tubercle is a good starting point for setting tibial tray rotation, the results of this evaluation are clear. The inherent variations in location associated with the position of the mid-third of the tibial tubercle make it an inconsistent anatomic landmark for setting final tray rotation. However, this landmark is still used because it has been shown to reduce positioning outliers with more efficacy than other landmarks. However, the current study suggests that this method may not provide the precision necessary to avoid positioning-based complications. Because of restricted visibility of the true contact points of the implant intraoperatively, it may be difficult for the surgeon to discern slight degrees of incongruency that could lead to postoperative complications and patient dissatisfaction. The sensor system evaluated in this study provided the feedback necessary to correct for slight variances.

Conclusion

The orthopedic surgeon strives to align and rotate the tibial tray to optimize con-
gruency of TKA components, thereby ensuring optimal kinematic functioning. This study showed that using the tibial tubercle landmark solely does not consistently achieve this endpoint. Thus, there is a need for alternative methods for setting tray rotation. Focus should be placed on establishing implant-to-implant congruency rather than attempting to match implants to a potentially variable anatomic landmark. Technologic innovation with intraoperative position sensing may be more reliable than the use of anatomic land marks and a precise option for determining patient-specific implant orientation.

References