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Brief communication

Computed tomography confirmation of component rotation in nanosensor-balanced total knee arthroplasty

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ABSTRACT

Balanced gaps and proper rotation are felt to be essential for optimum range of motion, stability, and patellar tracking in total knee arthroplasty. The purpose of this study is to assess, using computed tomography, the rotation of femoral and tibial components in fresh-frozen human cadaver knees that have been balanced using nanosensor trials while also observing how this rotation affects measured compartment loads and requirement for ligament balancing adjustment. We found that minor degrees of rotational malalignment of the femur and tibia were common using standard instrumentation and measured resection technique. Quantitative balance and rotational congruence are aided by nanosensor guidance, and femoral malrotation of up to 8° does not appear to affect compartment loads significantly as long as rotational congruity is present.

Introduction

The demand for primary total knee arthroplasty (TKA) is increasing with nearly 3.5 million procedures estimated annually by 2030 along with a 601% increase in total knee revisions [1]. TKA is an excellent procedure with 15-year survival rates as high as 96% [2]. However, at 1 year, the dissatisfaction rate after TKA with contemporary implants can be as high as 19% [3]. Pain has been found to be a strong predictor of patient dissatisfaction after TKA [3-5]. There are many factors involved when it comes to pain after TKA, including component malrotation [6-8]. Instability and arthrofibrosis, surrogates for soft-tissue imbalances, are also major contributors to early TKA revision [9,10]. During the workup of a painful TKA, computed tomography (CT) scans may be obtained to assess rotational profiles of the femur and tibial components [11].

Malalignment is the reason for revision in 6.6%-11.8% of cases [9,12]. There are many ways to prepare the bony surfaces. Essentially jigs are used, whether computer aided or not, to make geometric cuts with the goal being to restore normal anatomic relationships. This has come under debate as to which technique produces the best results. Once bony cuts are made, the “art” of TKA lies in balancing the joint, which has traditionally been subjective, and at the surgeon’s discretion. An unbalanced joint has been linked to subsequent instability, loosening of the prosthesis, increased bearing of wear, and early revision [9,10]. A novel approach to “balance” has been recently described using tibial inserts with embedded microelectronics (“VERASENSE Knee System”, OrthoSensor Inc., Dania, FL) that provide real-time feedback on loads experienced by the medial and lateral compartments of the knee [13]. By adjusting contact points and managing soft-tissue imbalances, the “art” of TKA can become quantitative. In theory, a “balanced knee” should better distribute loads in the joint and soft tissues for improved outcome, barring any other complications commonly associated with TKA.

The purpose of this study was to evaluate the relationship between quantitatively balanced knees and their rotational profiles

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while also observing how this rotation affected measured compartment loads and the requirement for soft-tissue balancing.

Material and methods

Cadaveric preparation

The lower bodies of 3 human cadavers were used for this study. Each cadaver consisted of a pelvis and right and left lower extremities producing 6 lower extremities from 3 paired specimens. Each specimen was without prior knee surgery. All specimens were fresh frozen and kept frozen until 48 hours before planned procedures at which point they were allowed to thaw to room temperature.

Bony preparation

Each knee was prepared using intramedullary femoral and extramedullary tibial instrumentation and a measured resection technique to accept a single-radius cruciate-retaining knee. For this study, we used the Triathlon Knee System (Stryker, Mahwah, NJ). Each knee was approached through a midline incision, followed by a medial parapatellar approach. The fat pad was removed in all cases, followed by minimal soft-tissue release to expose the bony surfaces. The femur was prepared first in all cases. By referencing the anteroposterior (AP) axis of the femur as well as the posterior cruciate ligament (PCL), the femoral canal was prepared to accept intramedullary instrumentation. Distal femoral cuts were made at 5° valgus with 8 mm of resection measured from the medial femoral condyle. Femoral rotation was set parallel to the epicondylar axis. The femur was sized, and chamfer cuts were created.

Using extramedullary instrumentation, the tibia was prepared in stepwise fashion. Rotation was set using a line connecting the midportion of the PCL and medial border of the patellar tendon. Alignment was based off the tibial crest and center of the ankle. Slope was set at 5° to be consistent with all specimens. Finally, the depth of resection was set at 10 mm based off a consistent point on the lateral tibial plateau that was two-third of the AP distance from anterior to posterior. The size of the tibia was measured based off of the lateral tibial plateau. The tibial trial was then provisionally held into place using 1 pin anchoring the trial to the lateral tibial plateau to allow rotation and thus preventing translation. The patellae were left unresurfaced in all cases.

VERASENSE knee system

The VERASENSE sensor that matched the sized tibia was activated. Starting with the smallest shim (9 mm), the VERASENSE sensor was snapped into place on the tibial trial, followed by placement of the trial femoral component. Four different shims are at the user's disposal. Starting with tibial rotation, the tibial trial was rotated so that medial and lateral contact points were located in the middle third of the AP diameter of the VERASENSE sensor and within 5° of each other as quantified on the graphic user interface. These points correlated to the femoral condyle contact with the sensor in the medial and lateral compartments, and their rotation corresponds to the fixed axis of the tibial component. Zero-degree rotation means that the condyles were in line with one another relative to the medial to lateral axis of the tibial component. Rotation was set with the knee in extension, and once the aforementioned attributes were confirmed, a second pin was placed in the anteromedial tibia to maintain tibial component rotation. Using the graphical interface, peak load in each compartment was recorded at 10°, 45°, and 90° of knee flexion, with the hip in neutral rotation and the capsule closed while making sure not to apply axial compression across the joint. Fractional soft-tissue balancing using a "pie crusting" technique [14] or repeat bony resection and adjustment of insert thickness (via shims) was performed until there was "balance" throughout the knee range of motion. Mediolateral balance has previously been defined using VERASENSE as <15lb intercompartmental load differential [13]. Flexion balance was deemed to be achieved when medial and lateral femoral contact points were within the posterior one-third of the tibial trial with knee bent at 90° during a posterior drawer test and displayed less than 10 mm of excursion.

Imaging

The 6 lower extremities were taken for CT scanning immediately after both the knees of the paired specimens were implanted with trial hardware and after balance had been achieved. Tibial polyethylene trials were inserted which matched the VERASENSE trials used for balancing. All specimens were stabilized in full extension and padded in a carrier box and then scanned in the supine position. CT resolution was set at 0.9-mm cuts so that full reconstructions of the images in the coronal, sagittal, and axial planes could be obtained. The imaging included the pelvis through the feet of each specimen. Axial imaging was then used to take measurements according to the protocol described by Berger et al. [11]. Berger et al. described quantifying the relative rotation of the components to fixed anatomic landmarks. This method primarily focuses on the posterior condylar line, the surgical epicondylar axis, and tibial tubercle axis.

Results

Femoral rotation averaged 3.3° external (range, 0.4°-8°). Tibial rotation averaged 17.6° internal rotation (range, 8.4°-28.5°) as measured on CT scan using the protocol described by Berger et al. [11]. Mechanical axis averaged 2.7° varus (range, 1.4°-4.6°). Peak contact points were maintained in the central one-third of the tibia at 10°, 45°, and 90° of knee flexion. In 2 specimens, bony recuts were used on the tibia due to excessive absolute load and load differential. Soft-tissue balancing with fractional soft-tissue release was needed in 4 of 6 specimens. Femoral rotational alignment did not correlate with the need for fractional ligament release. All knees were judged "balanced" at the conclusion of the procedure using previously established criteria for "balance" [13].

VERASENSE findings

Adjustments were required in 5 of 6 knees. Internal rotation of the tibial component was required in these 5 specimens to obtain a rotational congruence of <5°. The magnitude of tibiofemoral divergence measured 2.67° (range, 1°-5°) (Table 1). All adjustments lead to the goal of maintaining peak contact points in the central one-third of the tibia.

Five of the 6 knees required intervention beyond the initial bone cut to achieve <15 lb/in^2 intercompartmental load differential at 10°, 45°, and 90° of knee flexion. One specimen required a recut of the tibia to address both total and intercompartmental load differentials. This adjustment alone allowed for an appropriate correction, and no further soft-tissue adjustments were needed. Three of the 6 specimens required soft-tissue balancing to optimize compartment loads. All of these situations required fractional release of the iliotibial band. One specimen required the placement of a larger polyethylene trial.

Imaging findings

The average mechanical axis of the specimens measured 2.7° of varus (range, 1.4°-4.6°). The specimen that required a recut of the

Table 1
Summary and comparison of CT-based measurements of component alignment and data obtained from Verasense tibial insert.

Radiographic rotational measurements			
Specimen	SEA to PCL	TTA to TCA	Verasense divergence
1 Right	0.4°	28.5°	1°
1 Left	3.7°	8.4°	2°
2 Right	1.9°	18.2°	−3°
2 Left	0.7°	9.5°	1°
3 Right	8.0°	23.1°	5°
3 left	4.8°	18.0°	−4°
Average	3.3°(SD, 2.9)	17.6°(SD, 7.7)	0.3° (SD, 3.3)

SEA, surgical epicondylar axis; PCL, posterior condylar line; TTA, tibial tubercle axis; TCA, tibial component axis.

tibia had a resultant mechanical axis of 2.5° of varus. Using Berger's protocol [11], femoral component rotation averaged 3.3° of external rotation (range, 0°-8°), whereas tibial component rotation resulted in 17.6° of internal rotation (range, 8.4°-28.5°) (Table 1). The magnitude of the tibiofemoral divergence among the 6 specimens averaged 0.3° (range, −4° to 5°).

Discussion

The overall goal for TKA is to reproduce and restore patient-specific neutral mechanical alignment with "balance" and stability throughout the entire flexion arc. It is estimated that up to 30% of TKAs have greater than 3° of malalignment of individual components [15]. Three degrees of malalignment have been shown to be a significant factor with TKA failure [16]. Malalignment, malposition, instability, and failure of fixation are the reasons for revision in over 50% of cases [9]. In addition to this, up to 40% of patients can feel that their expectations are not being met after TKA [17]. Dissatisfaction with pain relief after contemporary TKA can be as high as 28% [3] with up to 34% of individuals stating that their knees do not feel "normal" [18]. TKA is an art, and balancing the joint has traditionally been subjective and at the surgeon's discretion. The purpose of this study was to evaluate the relationship between quantitatively balanced knees and their rotational profiles while also observing how this rotation affected measured compartment loads and the requirement for soft-tissue balancing. It also focused on the use of microelectronic sensors intraoperatively to quantify the changes that were being made to achieve balance in the final components.

The epicondylar axis is argued to be the true flexion axis [19,20] as well as a reproducible and reliable method [21] when setting femoral component rotation. Once this rotation is set, the tibial component should be set so that there is rotational congruence. Various techniques have been described to best establish tibial rotational alignment during TKA, including using the medial third of the tibial tubercle [22], the Akagi line [23], medial third of the patellar ligament [24], posterior tibial condyles [25], transtibial axis [26], malleolar axis [27,28], range of motion [27], axis of the second metatarsal [28], and the posterior-lateral corner [21]. Eckhoff et al. [27] exposed the tendency for external rotation of the tibial component relative to the femoral component with several techniques. The average external rotation of the tibial component was 19°, 14°, 7°, 5°, and 3° for alignment techniques using the medial third of the tibial tubercle, range of motion, posterior tibial condyles, transtibial axis, and malleolar axis, respectively.

To overcome shortcomings provided with conventional instrumentation, technology is being used in several different ways to attempt to produce a reliable and more consistent way to create a neutral mechanical axis. Computer-assisted navigation, patient-matched instrumentation, and robot-assisted implantation help improve alignment over conventional instrumentation. A recent review of the literature confirmed this; however, they were unable to determine if any had a significant impact on clinical outcomes [29]. Other studies question the benefit of computer-assisted surgery claiming no statistically significant difference in mechanical axis alignment and individual component alignment when compared with conventional instrumentation as well as no improvement in clinical outcomes [30]. Gap-balanced computer-assisted navigation may produce more consistent clinical alignment than measured resection computer-assisted navigation [31]. A novel approach to "balance" has been recently described using tibial inserts with embed microelectronics ("VERASENSE Knee System", OrthoSensor, Dania, FL) that provide real-time feedback on loads experienced by the medial and lateral compartments of the knee [13]. Early results are also promising when using this technology [13,32].

In this study, all 6 knees were prepared using a measured resection technique and were "balanced" using the VERASENSE Knee System. The definition of "balance" has previously been defined as a stable end point in the sagittal plane with a posterior drawer test along with a load differential between the medial and lateral compartments being less than 15lb [13]. Soft tissues were balanced by fractional release or by a bony recut. Releasing tight soft-tissue structures in a stepwise fashion starting with the "tightest" structure first has been shown to be effective in other studies [33]. Using a well-known CT protocol [11], rotational profiles were generated.

Several studies have documented associations between component rotation and lack of success. Nicoll and Rowley identified 9° of tibial component internal rotation (27° from the tip of the tibial tuberosity) as the brink for pain [7]. Bell et al. evaluated painful primary TKAs using the Berger protocol in 2 demographically matched cohorts [8]. The results of that study found that component rotational values associated with painful primary TKAs were those with greater than 3.9° of femoral internal rotation, 5.8° of tibial internal rotation, 8.7° of combined rotation, or 5.6° of component mismatch. One study looking at stiff TKAs found internally rotated components in all cases with a mean combined rotation of 14.8° and mean femoral and tibial internal rotations of 3.1° and 13.7°, respectively [34]. Lakstein et al. [35] evaluated 24 patients who had TKA revision for component malrotation and found a mean of 6.8° of combined internal rotation.

This study aimed to explore the effect of balance on component rotation. Failure has been demonstrated when tibial component positioning is $<90°$ to the tibial axis and/or femoral component positioning $\geq 8°$ valgus [36]. In addition, the risk for failure has been shown to increase when compensation occurs by using one component to compensate for the other malpositioned component to attain a neutral mechanical axis [36]. It is known that malalignment affects ligamentous balance [37]. Early reports of quantitatively balanced knees are showing promise. At 6 months, "balanced" knees had greater improvements in both KSS and WOMAC scores than "unbalanced knees [13]. When comparing several variables, (age, BMI, gender, activity level, and ROM), a "balanced" joint had the biggest impact on 6-month PROMs [13]. In addition, activity level and a "balanced" joint may have a relationship [13]. "Balanced" knees have also shown greater satisfaction at 1 year (96.7%) than "unbalanced" knees [32].

There were several limitations of this study that must be acknowledged. First, the use of cadaveric specimens limits the breadth of some conclusions due to the tissue differences and lack of healing potential. Although cadavers are widely accepted as a basic science modality for testing new technology, the inherent differences between healthy and dead tissue in a study that focuses on soft-tissue tension must be acknowledged. Second, use of cadaveric specimens is a form of selection bias. Owing to the fact that our study required bilateral native knees, the observed level of joint degeneration was very small. There was also very little deformity in any of our knees at baseline, which likely contributed to us not having to perform large soft-tissue releases. Third, with n = 6, there are not sufficient data to detect all differences that could be predicted, and this could put us at risk for errors in attempting to generalize our data across larger samples. Fourth, our study only evaluated the rotational profiles and balance of the tibial and femoral components. We did not evaluate the effect of balanced rotation on the patellofemoral joint as it relates to retinacular strain and tracking. Further studies are needed to evaluate this influence. Finally, although historically there has been high reliability in computing component rotation from CT, recent studies that have looked into intraobserver reliability in calculating these values have shown less correlation [38]. Although CT offers the most easily reproducible rotational assessment models, there is still room for improvement in our analysis of the imaging and collectively drawing conclusions based on imaging in isolation.

In this study of quantitatively balanced knees, minor degrees of rotational malalignment of the femur and tibia were common using standard instrumentation and measured resection technique. Maximal femoral malrotation in these specimens was 8° external rotation, which may be the lowest limit at which significant changes in ligament tension occur. Tibial component rotation necessary to create rotational congruence resulted in tibial internal rotation in all specimens. Soft-tissue balancing adjustment was necessary in all but 1 knee, and all specimens were well balanced after ligament balancing adjustment.

Conclusions

In conclusion, this pilot study suggests that quantitative balance and rotational congruence are aided by nanosensor guidance, and femoral malrotation of up to 8° external rotation may not affect compartment loads significantly as long as rotational congruity is present. However, further studies are needed with larger sample sizes to validate.

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