Surgeon Assessment of Gapping Versus Kinetic Loading Using Intraoperative Sensors During TKA

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Abstract

Purpose: The purpose of this study was to determine if using a sensor-equipped tibial insert would reduce medial (MED) and lateral (LAT) gapping and create more equivalent compressive forces in the MED and LAT compartments.

Methods: 7 orthopedic surgeons each performed bilateral TKA on complete lower extremity cadaveric specimens. Left TKA was performed first without the use of the instrumented tibial insert. With trial components placed, the patella was reduced and joint capsule closed with towel clips. Surgeons performed varus and valgus stress tests on each knee and the mm of MED and LAT gapping were recorded. Compressive forces in the MED and LAT compartment were measured at 10°, 45°, and 90° of flexion. Sensor-assisted TKA was then performed on the right knee and compressive forces and gapping were again recorded. MED, LAT, and total mediolateral (ML) gapping and MED and LAT compressive forces were compared between conventional TKA and sensor-assisted TKA with paired t-tests.

Results: Sensor-assisted TKA resulted in significantly reduced MED (1.2 vs. 1.9 mm, $p < .001$), LAT (0.8 vs. 1.4 mm, $p = 0.003$), and total ML gapping (2.0 vs. 3.4 mm, $p < .001$). There were no differences in the MED and LAT compressive forces between conventional and sensor-assisted TKA. However, sensor-assisted TKAs demonstrated greater MED compartment forces as the knee was flexed whereas conventional TKAs had greater LAT forces.

Conclusions: Sensor-assisted TKA significantly reduced MED and LAT gapping with the knee in 20° of flexion. Future clinical studies are needed to determine the most appropriate compressive forces in the MED and LAT compartments.

Keywords: total knee replacement, ligament balancing, laxity, instability, Kinetic Sensors

Level of Evidence: AAOS Therapeutic Level II

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Introduction

Independent of mechanical axis restoration and joint line inclination, proper balance of the soft tissues of the knee has become one of the primary principles in achieving successful total knee arthroplasty (TKA). [10] A balanced extension gap is routinely achieved by releasing structures on the tight or concave side of the knee deformity. For example, medial structures are released to balance a varus knee and, with a valgus knee, lateral structures are released. The inability to achieve proper varus-valgus balance of the knee may result in patient discomfort and/or dissatisfaction secondary to either restricted range of motion or mediolateral instability. [4,14] Furthermore, unequal contact forces between the medial and lateral compartments could increase the risk of accelerated wear and/or premature failure of the polyethylene. [22]

Due to the potentially increased risks of a poor clinical outcome or revision, instrumented methods to assist surgeons when balancing the knee have been developed. An electronic load-sensing tibial trial system has been developed to quantify the magnitude and location of compressive forces in the medial and lateral compartments. The sensor replaces the standard tibial trial insert and fits exactly into the tibial tray, and is used only during the trial-ing process (Figure 1). Dual kinetic loading plates coupled

Figure 1. Sensor-equipped tibial insert being placed.

with a microprocessor relay loading values and femoral contact point position in real-time to a display screen. All sensor data is displayed graphically and superimposed on a virtual sensor image (Figure 2). Peak loading values and tibiofemoral contact point position in the medial and lateral compartments are displayed separately, and can be tracked through the full range of motion. The sensor system also captures the relative rotational alignment of the tibial tray, in relation to the femur, by measuring the peak

Figure 2. An example of the real-time force readings provided by the software's graphical user interface. In this example, the knee is well balanced with 19lbf in the medial compartment and 16 lbf in the lateral compartment.

contact point position in the medial and lateral compartment.

In theory, by providing surgeons with real-time information about mediolateral force asymmetries throughout the full range of motion, instrumented balancing systems may allow for more consistently balanced TKAs. For the current study, we questioned whether use of a load-sensing tibial trial system would allow surgeons to more consistently balance the knee with reduced medial and lateral gapping. We also questioned whether the use of the load-sensing tibial trial would result in more symmetrical medial and lateral compressive forces throughout the range of motion. We hypothesized that sensor-assisted TKAs would demonstrate significantly lower medial and lateral gapping, as well as more symmetrical compressive forces in the medial and lateral compartments than conventional TKAs.

Materials and Methods

Seven orthopaedic surgeons participated in this laboratory study, and only the lead author had prior clinical experience with the sensor-equipped tibial insert and TKA implant system utilized in this study. Five surgeons were board certified with seven to 30 years of clinical experience, and two were orthopedic residents (R5 and R4). Each surgeon was asked to perform bilateral posterior cruciate ligament (PCL)-retaining TKA on a complete lower extremity specimen. The cadaveric specimens (5 female, 2 male; Mean age = 60 years (range 31 to 78), Mean weight = 70.9 kg (range 43.2 to 113.6 kg)) were delivered to the laboratory facility in a thawed state, and the study procedures were performed over a six-hour period. None of the specimens had a history of previous knee surgery. Two specimens had bilateral degenerative changes in the knee joints at the time of surgery; however, the other speci-

mens were considered normal. One specimen with varus deformity had Outerbridge grade 4 degenerative changes to the medial and patellofemoral compartments with grade 3 changes in the lateral compartment. One specimen with valgus deformity had tricompartmental Outerbridge grade 4 changes. Each surgeon first performed a cruciate-retaining TKA on the left knee using either a medial parapatellar or subvastus approach. Measured resection techniques were utilized to determine rotation of the femoral component, and all surgeons utilized similar TKA instrument sets and trial components (Vanguard Complete®, Biomet, Warsaw, IN).

Study measurements were made once the surgeon had made all bony cuts, balanced the soft-tissue as necessary, and trial components had been placed. The tibial trial was pinned in place and a sensor-equipped tibial insert (VE-RASENSE™, OrthoSensor, Inc., Dania Beach, FL, Figure 1) was inserted in the standard tibial trial component. The sensor-equipped tibial insert featured the same articulating surface as the true polyethylene liners. Force sensors located throughout the tibial insert allowed for compressive loads in the medial and lateral compartment to be displayed wirelessly on the monitor of the accompanying tower unit. With the surgeon blinded to the measurements, the compressive forces in the medial and lateral compartments were recorded with the knee in 10°, 45°, and 90° of flexion. An evaluator that did not perform any of the surgical procedures recorded all study measurements, and pressure measurements were made with the patella reduced and the capsule closed with towel clips. Force readings were provided by the system in pounds force (lbf), and were displayed in 1 lbf increments. The amount of force asymmetry was calculated by subtracting the lateral compartment forces from the medial compartment measures. As such, negative symmetry values were indicative of greater forces in the lateral compartment and positive values associated with greater medial forces.

All seven surgeons were then asked to manually estimate the mm of medial and lateral gapping when performing varus and valgus stress tests for each of the seven specimens. Medial and lateral gapping were assessed with knee flexed to approximately 20° with the patella reduced and capsule closed with towel clips. The study surgeons manually estimated medial and lateral gapping in 0.5 mm increments. While it is common to intraoperatively manually grade mm of gapping with the knee in full extension and 90° of flexion, varus and valgus stress tests were performed at approximately 20° in this study as gapping measurements at this knee angle have been associated with patient-reported pain and function. [7] Medial and lateral gapping were recorded individually, and the total medio-

lateral gapping was calculated as the sum of both directions. Surgeons were blinded to the compressive loads and the other surgeons' gapping measurements.

Following a senior peer instructional seminar session on the clinical use of the sensor-equipped tibial insert, surgeons performed a sensor-assisted TKA on the right knee of each specimen. Surgeons were asked to again perform TKA as they normally would, but with the goal of balancing the compressive loads in the medial and lateral compartment to within 15 lbs (6.8 kg) through the use of the instrumented tibial trial. In addition to fully releasing specific structures to improve intraoperative balance, surgeons were free to use their preferred methods of soft tissue balancing such as pie-crusting or multiple needle puncturing. [9,17] Once the surgeons were satisfied with both implant alignment and soft-tissue balance, the medial and lateral gapping measurements were made, and the medial and lateral compressive forces were again recorded at 10°, 45°, and 90° of flexion.

Statistical Analyses

Paired, two-tailed t-tests were utilized to compare medial, lateral, and total mediolateral gapping between conventional and sensor-assisted TKA. Paired, two-tailed t-tests were also utilized to compare the medial and lateral compressive forces as well as the mediolateral symmetry at 10°, 45°, and 90° of flexion between conventional and sensor-assisted TKA. Statistical analyses were performed with SPSS Statistics v21 (IBM, Armonk, NJ), and $p < 0.05$ was considered statistically significant.

Results

Medial, lateral, and total mediolateral gapping were significantly reduced when using the instrumented tibial trial (Table 1). While the medial and lateral compressive forces, and mediolateral symmetry did not statistically differ between conventional and sensor-assisted TKA at 10°, 45°, or 90° of flexion ($p > 0.05$, Table 2), there was a shift from greater lateral compressive forces without the sensor to greater medial forces when using the device as the knee was flexed (Figure 3).

Discussion

The primary purpose of this study was to determine if the use of a load-sensing tibial trial would reduce medial

Figure 3. As the knee was flexed from 10° to 90°, there was a shift from greater compressive forces (lbf) in the lateral compartment forces during conventional TKA whereas the sensor-assisted TKAs had greater medial forces as the knee was flexed. The mean difference between the medial and lateral compartment forces at 10°, 45°, and 90° are presented for the two types of TKA. Zero represents equivalent forces in the medial and lateral compartments, positive values are indicative of greater forces in the medial compartment, and negative values are indicative of greater forces in the lateral compartment.

	Conventional TKA	Sensor-assisted TKA	p
Medial Gapping	*1.9 ± 1.4	*1.2 ± 0.9	< 0.001
Lateral Gapping	*1.4 ± 1.3	*0.8 ± 0.9	0.003
Total Mediolateral Gapping	*3.4 ± 2.1	*2.0 ± 1.4	< 0.001
Medial Compressive Force			
10° knee flexion	20.3 ± 39.4	7.3 ± 8.4	0.38
45° knee flexion	6.3 ± 6.2	10.6 ± 12.6	0.33
90° knee flexion	5.6 ± 5.3	9.9 ± 10.5	0.33
Lateral Compressive Force			
10° knee flexion	10.7 ± 8.5	7.3 ± 6.7	0.52
45° knee flexion	8.9 ± 3.8	4.7 ± 5.8	0.14
90° knee flexion	7.0 ± 5.0	6.3 ± 5.0	0.85

*significantly different (p < 0.05)

Table 1. Comparison of medial, lateral and total mediolateral gapping (mm ± standard deviation), as well as medial and lateral compressive forces (lbf ± standard deviation) between conventional and sensor-assisted TKAs.

	Cadaver							
	1	2	3	4	5	6	7	Mean
Conventional TKA								
Medial gapping	1.7	1.4	0.1	2.9	3.9	2.1	1.3	1.9
Lateral gapping	2.9	1.0	0.7	1.2	1.0	2.1	1.2	1.4
Medial compressive force	8	0	2	6	12	16	0	6.3
Lateral compressive force	3	11	6	12	14	8	8	8.9
Sensor-assisted TKA								
Medial gapping	0.3	1.2	1.1	1.9	2.1	0.9	0.9	1.2
Lateral gapping	0.3	0.3	1.8	0.7	1.1	0.9	0.4	0.8
Medial compressive force	35	0	3	8	5	20	3	10.6
Lateral compressive force	1	0	0	13	0	8	11	4.7

Table 2. Midflexion medial and lateral gapping (mm) and compressive forces (lbf) of the conventional and sensor-assisted TKAs performed in each cadaveric specimen. Gapping and compressive force measurements were taken at 20° and 45° of knee flexion, respectively.

and lateral gapping. Our hypothesis was supported, as medial gapping was significantly reduced from 1.9 mm to 1.2 mm (p < 0.001) and lateral gapping was significantly reduced from 1.4 mm to 0.8 mm (p = 0.003). The secondary hypothesis was that the mediolateral compressive forces would be more symmetrical when using the load-sensing tibial trial. This hypothesis was not supported, as no statistical differences in medial forces, lateral forces, or mediolateral asymmetry were noted between conventional and sensor-assisted TKA.

It was; however, interesting that there appeared to be a shift from greater lateral forces at higher flexion angles with conventional TKA to greater medial forces with sensor-assisted TKA. In the native knee, lateral laxity is greater than medial laxity, and is in part responsible for allowing lateral femoral rollback as the knee is flexed. [20] Having slightly greater compressive forces in the medial compartment with greater lateral laxity during TKA may promote more normal kinematics with a medial pivot and lateral femoral rollback. [5,8] In the current study, sensor-assisted TKAs demonstrated this pattern, with equivalent medial and lateral forces at 10°, but greater in the medial compartment at 45° and 90°. On the contrary, conventional

TKAs had greater forces in the medial compartment at 10°, but were greater in the lateral compartment at 45° and 90°.

While the results of the current study demonstrate improved mediolateral gapping with the use of the instrumented tibial trial, the clinical use of similar devices may allow the orthopedic community to identify the balancing techniques that best promote a successful clinical outcome. To date, there is no clear consensus in the literature whether a truly balanced knee should be the goal, or if a knee with subtle lateral laxity is more likely to have a successful outcome. Proponents of a truly balanced often cite the improved range of motion and lift-off of less than 1 mm that have been associated with a well-balanced TKA. [14,23] Conversely, patients have been reported to prefer a TKA with mild to moderate mediolateral laxity than a truly balanced knee. [11] Edwards et al. first reported that Hospital for Special Surgery scores were greater for lax knees than those without mediolateral laxity. [3] Similar results have been reported by Liebs et al., stating that patients with a larger lateral gap in extension demonstrated significantly greater WOMAC pain scores than those that had increased medial gap. [13]

The debate over whether to truly balance the knee or to try to recreate the increased lateral laxity of the normal knee will undoubtedly continue and is beyond the scope of this study. Regardless of what the target balance should be, the fact remains that mediolateral laxity is multifactorial, especially when the knee is flexed. Mediolateral laxity, as well as the individual compressive forces in the medial and lateral compartments, are influenced many factors including: posterior slope of the tibial component [18], internal rotation of the tibial component [16], the condition or presence of the posterior cruciate ligament [15], and the number of releases performed to balance the extension gap. [1] Since there are many factors that influence mediolateral laxity and compressive forces, intraoperative tools that enable surgeons to make informed decisions about soft tissue balance and implant orientation throughout the range of motion are required.

This study was not without limitation. First, the ability to generalize these cadaveric results to the clinical setting will be limited. Mediolateral laxity changes as osteoarthritis progresses [19], but the majority of the knees in this study did not have degenerative changes. As such, we expect that the specimens used in this study may not have been as technically challenging to balance as an osteoarthritic knee. This may be one potential underlying reason for why no differences in mediolateral forces were noted between conventional and sensor-assisted TKAs. For example, 5/7 conventional TKAs had mediolateral symmetry within the target range of ± 15 lbs at 10° of flexion.

While this improved to 7/7 within the target range for the sensor-assisted TKAs, the potential benefit of using the sensor may have been masked by the lack of preoperative asymmetry between the medial and lateral compartments usually common to osteoarthritic joints. Second, manual gapping measurements were the primary outcome variable used to evaluate the effect of using the load-sensing tibial trial. Manual measurements of joint gapping are the most common clinical method to diagnose mediolateral instability, and are included as part of the Knee Society Knee Scoring System. [21,6] While inter-surgeon agreement in the amount of gapping may be inherently limited, previous authors have reported that varus and valgus laxity can be accurately measured [2] and that surgeons can reliably apply varus and valgus torques. [12] However, to mitigate potential errors associated with inter-surgeon agreement, we designed the study so that each surgeon's exam of the sensor-assisted TKAs was compared to that surgeon's gapping measurements of the conventional TKAs. Third, the current study utilized only PCL-retaining TKA, and further study is necessary to determine if similar results would be demonstrated when using PCL-substituting designs. Finally, this laboratory study was the initial experience with the sensor-equipped tibial insert for five of the seven surgeons. As with any new technique or technology, a learning curve is to be expected and was not controlled for as part of this laboratory study. The relative lack of familiarity of the implant system for a majority of the surgeons may have also had a debatable effect on balance, based on the relationship between the system's instrumentation and final gap sizes. Several surgeons found the final cuts to be more generous than what they were used to, thus leading to slightly greater joint laxity in extension.

In conclusion, the use of a sensor-equipped tibial insert resulted in significantly reduced medial and lateral gapping in this laboratory study. Future studies are needed to determine if similar findings are seen in the clinical setting, and large-scale prospective studies are needed to determine the TKA balancing techniques that best promote a successful clinical outcome.

Acknowledgements

Funding was provided for this study by Biomet, Inc., and study devices and equipment were provided by Ortho-Sensor, Inc.

Disclosure Statement

One or more of our authors have disclosed information that may present potential for conflict of interest with this work. For full disclosures refer to last page of this journal.

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