DYNAMIC INTRAOPERATIVE SENSING TECHNOLOGY IN TOTAL KNEE ARTHROPLASTY

ABSTRACTS FOR BIOMECHANICAL AND CLINICAL INVESTIGATIONS
The abstracts contained herein are from studies that have proven the clinical effectiveness of using intraoperative sensing technology to drive quantitative, evidence-based decisions during total knee replacement.
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Use of Smart Trials for Soft-Tissue Balancing in Total Knee Replacement Surgery

KENNETH GUSTKE MD

Smart trials are total knee tibial trial liners with load bearing and alignment sensors that will graphically show quantitative compartment load-bearing forces and component track patterns. These values will demonstrate asymmetrical ligament balancing and misalignments with the medial retinaculum temporarily closed. Currently surgeons use feel and visual estimation of imbalance to assess soft-tissue balancing and tracking with the medial retinaculum open, which results in lower medial compartment loads and a wider anteroposterior tibial tracking pattern. The sensor trial will aid the total knee replacement surgeon in performing soft-tissue balancing by providing quantitative visual feedback of changes in forces while performing the releases incrementally. Initial experience using a smart tibial trial is presented.
INTRODUCTION

Post-operative clinical outcomes of total knee arthroplasty (TKA) are dependent on a multitude of surgical and patient-specific factors. While appropriate balance and mechanical alignment of the prosthetic joint are of foremost concern during reconstruction, it is known that rotational alignment in TKA is an equally critical factor which affects kinematic knee function and long-term survivorship.

1. The transepicondylar axis is a widely used anatomical reference to set femoral component rotation. Other referencing landmarks have also been advocated but there is no universally accepted gold standard. Optimal rotation of the tibial tray also has no gold standard, but the medial third of the tibial tubercle is commonly used. Literature has suggested that implantation methods, which reference the medial-third of the tibial tubercle, reduce positioning outliers with more consistency than using other anatomical landmarks.

2. The purpose of this study is to use data collected from intraoperative sensors to assess the rotational accuracy of using the medial-third of the tibial tubercle in 145 TKAs.

METHODS

The data for this study was retrieved from 145 consecutive patients who underwent primary TKA from a single, highly experienced surgeon. Femoral component rotation was assessed using Whiteside’s line and the transepicondylar axis. Patellar tracking was also used as a surrogate measure for appropriate rotation. Intraoperative loads were recorded for pre- and post-release joint states and any soft-tissue releases were documented. Tibial tray rotation was initially established by location of the mid-medial third of the tibial tubercle. The tray was stabilized with an anterior-medial pin to allow for rotational adjustments, while preventing translation. The knee was taken into extension, and the femoral condylar contact points on the articular surface of the tibial insert were displayed on a computer screen. Rotational adjustments of the tibial tray were evaluated in real-time, as the surgeon corrected any tibiofemoral incongruency and tray malpositioning. The initial and final angles of tibial tray rotation were captured with intraoperative video feed, and recorded. A z-test of proportional differences between pre- and post-rotational correction was performed to assess the statistical significance of malrotation present in this cohort.

RESULTS

All patients in this study received a primary TKA, using the mid-medial third of the tibial tubercle to determine tibial tray rotation. After the sensor-equipped trial insert was placed, it was shown that 63.1% of patients exhibited asymmetrical tibiofemoral contact in extension. Of those patients, 70% were shown to have internal rotation; 30% were shown to have external rotation. The average tibiofemoral incongruency deviated from a neutral position (with either internal or...
external orientation) by 6.3°±4.3°, ranging from 0.5° to 19.2°. The z-test of proportional differences yielded a p-value <0.0001, indicating that the number of patients with tibio-femoral incongruency within this cohort is statistically significant. The confidence interval of this cohort—set at 95% confidence—was calculated to be between 44.8% and 71.8% of tibio-femoral incongruency. This data suggests that the use of the tibial tubercle as a reference point is not only inaccurate, but also highly variable.

DISCUSSION

Tibiofemoral incongruency in TKA is associated with unfavorable clinical outcomes, which have a potential to lead to poor function, patient dissatisfaction, and decreased implant survivorship. While no gold standard anatomic landmark currently exists for positioning the tibial tray, the mid-medial third of the tibial tubercle is widely used as a reference. However, the data from this evaluation demonstrates that, not only is this landmark consistently insufficient for establishing optimal rotation (p<0.0001), but that it had guided the surgeon to an average of 6.3° outside of the optimized implant congruency zone. The 95% upper and lower confidence limits span 27%. This large interval indicates that the rotational alignment of the tibial tray—based on the location of the mid-medial third of the tibial tubercle—is not only inaccurate, but also highly variable in its inaccuracy. One particular study, conducted by Barrack et al., has shown that as little as 4.6° of internal rotation can cause anterior knee pain. Berger, et al. reported that 5°-8° of tibio-femoral malrotation leads to patellar maltracking, and multiple studies assert that internal rotation of the tibial tray is the most common form of malrotation. Based on real-time, intraoperative sensor data, care should be taken when utilizing the tibial tubercle as the sole rotational landmark for the tibial tray. Postoperative functional outcomes will be evaluated in order to define how improved implant congruency affects overall patient satisfaction, functional outcomes, and implant survivorship.
INTRODUCTION

During primary total knee arthroplasty, the surgeon may encounter excessive medial collateral ligament tension while addressing a varus knee. This may be due to medial ligament/capsular complex contractures, and/or, due to the creation of a 0 degree mechanical axis in a varus knee. This tension leads to increased loading in the medial compartment, which contributes to an unbalanced extension and flexion gap. If uncorrected, this imbalance can lead to unfavorable clinical outcomes, including pain, accelerated polyethylene degradation, joint instability, and limited ROM. Currently, intercompartmental soft-tissue balance is obtained by a subjective surgeon’s “feel”. However, this method of judging soft-tissue tension is both variable and unreliable. Most surgeons can detect gross instability, but judging ligament tension is difficult. The following technique describes the integration of intraoperative microelectronic tibial inserts to assess and modify ligament tension, utilizing real-time dynamic sensor feedback.

METHODS

500 TKAs were performed between September 2012 and April 2013, by three collaborating surgeons. All surgeons used the same implant system, compatible with an embedded microelectronic tibial insert with which to receive real-time feedback of femoral contact points and joint kinetics. Intraoperative kinematic data, displayed loading patterns consistent with identifiable intercompartmental imbalance through a full ROM. All mediolateral imbalance, secondary to an excessively tight medial compartment, was addressed with the technique described herein.

RESULTS

By using the VERASENSE™ knee application, surgeons closed the medial capsule, guided the joint through dynamic motion, and received real-time feedback regarding femoral contact point position and mediolateral intercompartmental loads (measured in lbs.). Mediolateral imbalance in flexion, mid-flexion, and extension was defined as an intercompartmental loading difference of >15 lbs. If a surgeon encountered excessive medial tension, they utilized a “pie crusting” technique described by Bellemans, et al. This method uses a 19-guage needle to sequentially and gradually release individual fibers of the MCL (superficial and deep), and medial capsule. The surgeon directs the knee into a position of maximal tension, and elongates the defined fibers in situ. The anterior fibers were addressed for flexion gap tension, and the posterior fibers addressed the extension gap. Successful release of the MCL was defined as an intercompartmental loading difference of ≤15 lbs (Figure 1).
DISCUSSION

Mediolateral intercompartmental imbalance, secondary to ligament tension or laxity, can lead to a poor functional outcome post operatively. Unfortunately with no prior data to judge this critical dimension of joint reconstruction, surgeons have based their approach on traditional methods of subjective surgeon judgment. However, by using a modified releasing technique, with real-time sensor data, the surgeon can release tension in the MCL with quantified dynamic feedback. This gradual, digitally guided ligamentous release may prove to be a safer method than traditional releases, and allows the surgeon to ensure that both compartments of the bearing surface are loading proportionately. Further follow-up will be required to evaluate the clinical outcomes of patients who have undergone release with these techniques.
INTRODUCTION
Proper soft-tissue balance is important for achieving favorable clinical outcomes following TKA, as ligament imbalance can lead to pain, stiffness or instability, accelerated polyethylene wear, and premature failure of implants. Until recently, soft-tissue balancing was accomplished by subjective surgeon feel and by use of static spacer blocks. Now, nanosensor-embedded implant trials allow surgeons to quantify peak load and center of load in the medial and lateral compartments during the procedure, and to adjust ligament tension and implant positioning accordingly. The purpose of this 3-year, multicenter study is to evaluate 500 patients who have received primary TKA with the use of intraoperative sensors in order to correlate quantified ligament balance to clinical outcomes.

METHODS
To date, 7 centers have contributed 215 patients who have undergone primary TKA with the use of intraoperative sensors. Patients are seen at a pre-operative visit (within 3 months prior to surgery), and post-operatively at 6 weeks, 6 months, and at 1, 2, and 3-year anniversaries. Standard demographic and surgical data is collected for each patient, including: age at time of surgery, BMI, operative side, gender, race, and primary diagnosis. At each interval, anatomic alignment and range of motion are assessed; KSS and WOMAC evaluations are administered; and a set of standard radiographs is collected, including: standing anteroposterior, standing-lateral, and the sunrise patellar view. Intraoperative loads were recorded for pre- and post-release joint states. “Optimal” soft-tissue balance was defined as a medial-lateral load difference of less than or equal to 15 lbs.

RESULTS
The average age of this cohort was 70 years: 63% are female and 37% are male, with a mean BMI of 30.6. Ninety five percent of cases had a primary diagnosis of osteoarthritis. The majority of cases (72.5%) exhibited suboptimal soft-tissue balance (>15 lbs. of medial-lateral compartmental loading difference) prior to ligamentous release. Using the intraoperative sensor for guidance, 82% (p<.01) of patients were released and confirmed to exhibit a state of optimal joint balance at closure. Patient self-reported outcome scores—both KSS and WOMAC—showed significant improvement (p<.01) from the pre-operative interval to the 6-month follow-up interval. The average increase for KSS at 6 months was 60 points.

DISCUSSION
Optimized ligament balance using intraoperative sensors led to significant improvement in KSS and WOMAC scores at a 6-month follow-up interval in 215 knees. Notably, the 60-point average increase in KSS, at 6 months, is approximately 200% greater than historical data, obtained from existing literature, using traditional methods of TKA balancing. Measuring the effect of specific
ligamentous releases on subsequent load and balance can potentially enable the development of release algorithms to guide surgeons to balance TKA using sensor data. Further, correlating quantifiable data on peak load and center of load to patient outcomes will help clarify what truly defines “optimum balance.” Additional study subject accrual and further longitudinal follow-up is needed to affirm the early observation that sensor-quantified soft-tissue balancing improves patient outcomes in TKA.
INTRODUCTION
Accurate alignment of components in total knee arthroplasty (TKA) is a known factor that contributes to improvement of post-operative kinematics and survivorship of the prosthetic joint. Recently, CAOS has been introduced into TKA in effort to reduce positioning variability that may deviate from the mechanical axis. However, literature suggests that clinical outcomes following TKA with CAOS may not present a significant improvement from traditional methods of implantation. This would infer that achieving correct alignment, alone, might be insufficient for ensuring an optimal reconstruction of the joint. Therefore, this study seeks to evaluate the importance of soft-tissue balancing, through the quantification of joint kinetics collected with intraoperative sensors, with or without the combined use of CAOS.

METHODS
Seven centers have contributed 215 patients who have undergone primary TKA with the use of intraoperative sensors. Of the 7 surgeons contributing patients to this study, 3 utilize CAOS; 4 utilize manual techniques. Along with standard demographic and surgical data being collected as per the multicenter study protocol, soft-tissue release techniques and medial-lateral intercompartmental loads—as indicated by the intraoperative sensors—were also captured pre- and post-release. “Optimal” balance was defined as a medial-lateral load difference of ≤15 lbs. A chi-squared analysis was performed to determine if the percentage of soft-tissue release was significantly different between the two groups: patients with CAOS, and patients without CAOS.

RESULTS
Of the 215 patients (35% with CAOS, 65% without CAOS) who have received TKA, using intraoperative sensors to assess mediolateral balance, 92.6% underwent soft-tissue release. Stratifying this data by surgical technique: 89% of the patients with CAOS, and 94% of patients without CAOS, were released. A chi-squared analysis—with 3 degrees of freedom; and 99% confidence—was executed to determine if the 5% difference between the two groups was significant. The analysis showed that there was no significant difference between the two groups, thus we can conclude that soft-tissue release is as equally necessary in the CAOS TKA group, as it is in the traditional TKA group.

DISCUSSION
It is widely accepted that correct alignment of TKA components contributes to improved kinematic function of the affected joint. Recently, technology has been developed to digitally guide surgeons through bony cuts, thereby decreasing the incidence of deviation from the mechanical axis. However, alignment may not be the foremost contributing factor in ensuring an optimal joint state. In this evaluation, 92.6% of the cohort required some degree of releasing...
of ligamentous structures surrounding the knee joint, regardless of intraoperative technique used. A chi-squared analysis of the data supports the claim that soft-tissue release is used in nearly all cases, irrespective of the use of CAOS (p<0.001). This suggests that soft-tissue release is necessary in nearly all cases, even after appropriate alignment has been digitally verified. The data strongly supports the idea that obtaining an optimally functioning joint is multifactorial, and that alignment may play a more minor role in achieving ideal joint reconstruction than previously assumed, being superseded by the necessity to achieve soft-tissue balance.
Ensuring a Stable Total Knee Arthroplasty: Sensor-Guided Techniques Used to Quantify Sagittal Plane Balance

KENNETH GUSTKE MD, GREGORY GOLLADAY MD, MARTIN ROCHE MD, PATRICK MEERE MD, LEAH ELSON BSc, CHRISTOPHER ANDERSON MS

INTRODUCTION

Flexion instability of the knee accounts for, up to, 22% of reported revisions following TKA. It can present in the early post-operative phase or present—secondary to a rupture of the PCL—in the late post-operative phase. While most reports of instability occur in conjunction with cruciate-retaining implants, instability in a posterior-stabilized knee is not uncommon. Due to the prevalence of revision due to instability, the purpose of constructing the following techniques is to utilize intraoperative sensors to quantify flexion gap stability.

METHODS

500 posterior cruciate-retaining TKAs were performed between September 2012 and April 2013, by four collaborating surgeons. All surgeons used the same implant system, compatible with a microelectronic tibial insert with which to receive real-time feedback of femoral contact points and joint kinetics. Intraoperative kinematic data, as reported on-screen by the VERASENSE™ knee application, displayed similar loading patterns consistent with identifiable sagittal plane abnormalities. These abnormalities were classified as: “Balanced Flexion Gap,” “Flexion Instability” and “Tight Flexion Gap.” All abnormalities were addressed with the techniques described herein.

RESULTS

Balanced Flexion Gap

Flexion balance was achieved when femoral contact points were within the mid-posterior third (Figure 1) of the tibial insert, symmetrical rollback was seen through ROM, intercompartmental loads were balanced, and central contact points displayed less than 10 mm of excursion across the bearing surface during a posterior drawer test.

Flexion Instability

The femoral contact point tracking option dynamically displayed the relative motion of distal femur to the proximal tibia during the posterior drawer test, and through range of motion. Excessive excursion of the femoral contact points across the bearing surface, and femoral contact points translating through the anterior third of the tibial trial, was an indication of laxity in the PCL.

Surgical correction requires use of a thicker tibial insert, anterior-constrained insert, or a posterior-stabilized knee design (Figure 2).

Tight Flexion Gap

Excessive tension in the PCL was displayed during surgery via femoral contact points and excessive high pressures in the posterior compartment during flexion. When a posterior drawer test was applied no excursion of the femoral tibia contact point was seen.
Ensuring a Stable Total Knee Arthroplasty: Sensor-Guided Techniques Used to Quantify Sagittal Plane Balance

Excessively high loading in the posteromedial compartment was corrected through recession of the PCL using an 19 gauge needle or 11 blade. Additional tibial slope was added when excessive loads were seen in both compartments (Figure 3).

DISCUSSION

Flexion gap instability, or excessive PCL tension, is a common error resulting in poor patient outcomes and early revision surgery. The techniques described, utilized intraoperative sensor data to address sagittal plane abnormalities in a quantified manner. By using technology to guide the surgeon through appropriate sagittal plane correction, the subtleties in soft-tissue imbalance or suboptimal bone cuts can be accounted for, which otherwise may be overlooked by traditional methods of subjective surgeon “feel.” Longer clinical follow-up of these patients will be necessary to track the outcomes associated with quantifiable sagittal plane balance.
A New Method for Defining Balance: Promising Short-Term Clinical Outcomes of Sensor-Guided TKA

KENNETH GUSTKE MD, GREGORY GOLLADAY MD, MARTIN ROCHE MD, LEAH ELSON BSc, CHRISTOPHER ANDERSON MS

Recently, technological advances have made it possible to quantify pounds of pressure across the bearing surface during TKA. This multicenter evaluation, using intraoperative sensors, was performed for two reasons: 1) to define “balance” 2) to determine if patients with balanced knees exhibit improved short-term clinical outcomes. Outcomes scores were compared between “balanced” and “unbalanced” patients. At 6-months, the balanced cohort scored 172.4 and 14.5 in KSS and WOMAC, respectively; the unbalanced cohort scored 145.3 and 23.8 in KSS and WOMAC (P < 0.001). Out of all confounding variables, balanced joints were the most significant contributing factor to improved postoperative outcomes (P < 0.001). Odds ratios demonstrate that balanced joints are 2.5, 1.3, and 1.8 times more likely to achieve meaningful improvement in KSS, WOMAC, and activity level, respectively.
The Relationship of the Medial 1/3 of the Tibial Tubercle to the Posterior Aspect of the Tibia

MARTIN ROCHE MD, JERRY D’ALESSIO PhD, MARK KESTER PhD

INTRODUCTION
Proper tibial rotation has been cited as an important prerequisite to optimal total knee replacement (Figure 1). The most commonly recognized rotational landmark is the medial 1/3rd of the tibial tubercle. The purpose of this study was to quantify the amount of variability this structure has from a common reference point, along with possible variations based on how this reference structure is defined.

METHODS
Subjects were prospectively scanned into a Virtual Bone Database (Stryker Orthopaedics, Mahwah, NJ), which is a collection of body CT scans from subjects collected globally. Only CT Scans that met the following qualifications were accepted: ≤1 mm voxels and had slice thickness that was equal to the spacing between the slices (≤ 1.0mm), Gantry/detector tilt must 0°, gathered in a non-reconstructive mode and raw DICOM files. All CT scans displayed cropped bones were excluded. SOMA (Stryker An unique tool with the ability to take automated measurements of quantities such as distances, angles or circle diameters on a large number of pre-segmented bone samples was then used to perform calculations represented in this study. (Figure 2)

Demographic information (ethnic origin, gender, age, height, weight) for each subject was recorded were known. For the analysis, The mechanical axis of the tibia (MAT) was established by connecting the center of the proximal tibia to the center of the ankle. From the MAT, a perpendicular resection plane was made orthogonally and 9mm from the most proximal portion of the lateral condyle. This plane was then used as a virtual simulation plane to establish the points for the remaining structures which was the medial 1/3rd of the tibial tubercle and the posterior notch of the PCL insertion.

The following axes were identified: Medial 1/3rd of the tibial tubercle (3TT) (line between the Medial 1/3rd of the tibial tubercle and the posterior notch of the tibia); Medial 1/3rd of the tibial tubercle (3CTT) (line between the medial 1/3rd of the tibial tubercle and the center of the tibia); and the posterior axis (line connecting the two most posterior points of the tibia at the virtual resection plane). Measurements made were the Angle of MAT and the 3TT Line and Angle of the MAT and the 3CTT Line.

RESULTS
CT Scans of the Left Knees (n=524), Right Knees (n=527), and combined left/right knee (n=1051) were collected for this study. The mean 3TT angle for the left knee was 74.6°±3.0° (Range: 60.2° – 84.8°) and right knee was 74.5°±3.0° (Range: 65.1°- 85.1°). The combined (left/right) angle was 74.5°±3.0° (Range: 60.2°-85.1°). The mean 3CTT angle for the left knee was 71.2°±3.6° (Range: 57.6° – 83.2°) and right knee was 71.1°±3.5° (Range: 61.4° - 82.3°).
The relationship of the medial 1/3 of the tibial tubercle to the posterior aspect of the tibia

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**Discussion**

The tibial tubercle is a common landmark used to set the rotation of the tibial component in total knee replacement regardless of the tray design. Utilizing the posterior aspect of the tibia provides a common reference point to establish variations that could exist with this landmark. The amount of variation of the tibial tubercle can vary by over 25 degrees based on method of establishing the reference.
The Importance of 2mm and 2 Degrees in Total Knee Balancing

PETER WALKER PhD, PATRICK MEERE MD, CHRISTOPHER BELL MS

INTRODUCTION
The purpose of balancing in total knee surgery is to achieve smooth tracking of the knee over a full range of flexion without excessive looseness or tightness on either the lateral or medial sides. Balancing is controlled by the alignment of the bone cuts, the soft tissue envelope, and the constraint of the total knee. Recently, Instrumented Tibial Trials (OrthoSensor) which measure and display the location and magnitude of the forces on the lateral and medial condyles, have been introduced, offering the possibility of predictive and quantitative balancing. This paper presents the results of experiments on 10 lower limb specimens, where the effects of altering the bone cuts or the femoral component size were measured.

METHODS
A special leg mounting rig was fixed to a standard operating table. A boot was strapped to the foot, and the boot tracked along a horizontal rail to allow flexion-extension. The initial bone cuts were carried out by measured resection using a navigation system. The trial femoral component and the instrumented tibial trial were inserted, and the following tests carried out:

Sag Test; foot lifted up, the trial thickness chosen to produce zero flexion.
Heel Push Test; heel moved towards body to maximum flexion.
Varus-Valgus Test, AP and IXR Tests were also carried out, but not discussed here.

RESULTS
For an initial state of the knee, close to balanced, the lateral and medial contact forces were recorded for the full flexion range. The mean value of the contact forces per condyle was 77.4N, the mean in early flexion (0-60 deg) was 94.2N, and the mean in late flexion (60-120 deg) was 55.7N. The difference was due to the effect of the weight of the leg. One of the following Surgical Variables was then implemented, and the contact forces again recorded.

1. Distal femoral cut; 2mm resection (2mm increase in insert thickness to preserve extension)
2. Tibial frontal varus, 2mm lateral stuffing
3. Tibial frontal valgus, 2mm medial stuffing
4. Tibial slope angle increase (5 deg baseline); +2 degrees
5. Tibial slope angle decrease (5 deg baseline); - 2 degrees
6. Increase in AP size of femoral component (3mm)

The differences between the condyle force readings before and after the Surgical Variable were calculated for low and high angular ranges. The mean values for the 10 knees of the differences of the above Surgical Variables from the initial balanced state are shown in the chart.
CONTINUED

**DISCUSSION**

From literature data, the mean tension increase in one collateral ligament is close to 25N/mm up to the toe of the load-elongation graph, and 50N/mm after the toe. Hence in the initial balanced state, the collateral ligaments were elongated by 2-4mm producing pretension. From the Surgical Variables data, up to 2mm/2deg change in bone cuts (or 3mm femcom change), and collateral ligament releases up to 2mm, would correct from any unbalanced state to a balanced state. This data provides useful guidelines for the use of the Instrumented Tibial Trials at surgery, in terms of bone cut adjustments and ligament releases.

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**SURGICAL VARIABLE EFFECTS**

The bar chart illustrates the mean value differences (N) for various surgical variables, including:
- Distal Femoral Cut 2mm
- Tibial Varus Lateral Stuffing 2deg
- Tibial Valgus Medial Stuffing 2deg
- Tibial Slope Increased 2deg
- Tibial Slope Decreased 2deg
- AP Fem Com Size Increased 3mm
- Load of Collaterals

The chart shows the effect of these variables on mean value differences, indicating how changes in these parameters affect the balance and tension in the knee joint.
Effects of Surgical Variables in Balancing of Total Knees Using an Instrumented Tibial Trial

PATRICK MEERE MD, PETER WALKER PhD, CHRISTOPHER BELL MS

Obtaining accurate bone cuts based on mechanical axes and ligament balancing, are necessary for a successful total knee procedure. The OrthoSensor Tibial Trial displays on a GUI the magnitude and location of the lateral and medial contact forces at surgery. The goal of this study was to develop algorithms to inform the surgeon which bone cuts or soft tissue releases were necessary to achieve balancing, from an initial unbalanced state.

A rig was designed for lower body specimens mounted on a standard operating table. SURGICAL TESTS were then defined: Sag Test, leg supported at the foot; Dynamic Heel Push test, flexing to 120 degrees with the foot sliding along a rail; Varus-Valgus test; AP Drawer test; Internal-External Rotation test. The bone cuts were made using a Navigation system, matching the Triathlon PCL retaining knee. To determine the initial thickness of the tibial trial, the Sag Test was performed to reach 0 deg flexion. The Heel Push Test was then performed to check the AP position of the lateral and medial contacts, from which the rotational position of the tibial tray was determined. Pins were used to reproduce this position during the experiments.

SURGICAL VARIABLES were then defined, which would influence the balancing: LCL Stiffness, MCL Stiffness, Distal Femoral Cut Level, Tibial Sagittal Slope, Tibial Varus or Valgus, and AP Femoral Component Length. Balancing was defined as equal lateral and medial forces due to soft tissue tensions throughout the flexion range, equal varus and valgus stiffnesses, and no contacts closer than 10mm to component edges. All of the above tests were then performed sequentially, and the changes in the contact force readings were considered as a signature of that Surgical Variable.

Testing was carried out on 10 full leg specimens. The Sag Test was the basic test for determining the thickness of the tibial insert. The Heel Push Test was then implemented from which force data throughout flexion was determined; followed by the Varus-Valgus Test. In a surgical case, this data will be used in a decision tree to identify which Surgical Variable required correction.

In the experiments, by obtaining the above data for each SURGICAL VARIABLE in turn, we were able to determine a SIGNATURE for each SURGICAL VARIABLE. It was found that there was considerable variation in the force magnitudes between knees. However the SIGNATURES were sufficient to point to the specific SURGICAL VARIABLE requiring correction. In some knees, although there was a dominant SURGICAL VARIABLE, even after correcting for that, there was still an imbalanced state, requiring a second correction.
This research provided the fundamental principles and data for:
1. Defining tests to be carried out at surgery, to obtain force data to determine the SURGICAL VARIABLE to correct.
2. Defining the algorithm based on Closest Approach, for building up a database of data for predictive purposes.
3. How to use the Sag Test and the Varus-Valgus test as primary indicators.
4. How to use the AP Drawer test and the Internal-External Rotation test as fine tune indicators.
Accuracy and Reproducibility of Instrumented Tibial Trial for Ligament Balancing in Total Knee Replacement

CHRISTOPHER BELL MS, PETER WALKER PhD, FREDERICK KUMMER PhD, PATRICK MEERE MD

INTRODUCTION
Balancing in total knee replacement is generally carried out using the feel and experience of the surgeon, using spacer blocks or distractors. However, such a method is not generally applicable to all surgeons and nor does it provide quantitative data of the balancing itself. One approach is the use of instrumented distractors, which have been used to monitor soft tissue releases or indicate a flexion cut for equal lateral and medial forces. More recently an instrumented tibial trial has been introduced which measures and displays the magnitude and location of the loads on the lateral and medial plateaus, during various maneuvers carried out at surgery. The data set is then used by the surgeon to determine options, whether soft tissue releases or bone cut adjustments, to achieve lateral-medial equality.

METHODS
The testing method consisted of mounting the femoral component rigidly in a fixture on the vertical arm of an MTS machine. The tibial component was fixed on to a platform which allowed varus-valgus correction, and where the component could be displaced or rotated in a horizontal plane. Two of each size times 4 sizes of production components were tested. Compressive forces from 0-400N in steps of 50N were applied and the readings taken. There were strong correlations between applied and measured forces with mean Pearson’s Correlation Coefficient of 0.958.

RESULTS
The special tests under different conditions did not have any effect on the output values. The output data proved to be repeatable under Central Loading with a maximum standard deviation of 315.36N at the highest applied force of 400N. “Low battery” did not adversely affect the data. Applying the load steadily to maximum versus load-unload-zero tests produced similar results. Lubrication versus no lubrication tests produced no changes to the results. There was no cross talk of the electronics within the device when loaded on one condyle. For both central and anterior-posterior loading, the contact points were centered medial-lateral on the GUI display, and tracked contact point translation appropriately.

Anterior-posterior loading did create output load variance at the extremes. However, it enabled the validation of the relationship of the femur on the trial surface. In addition, malrotation would be indicated by the femur riding up on the anterior or posterior tibial edges, important for soft tissue tension in all flexion angles.
CONTINUED

**DISCUSSION**

In conclusion, the sensors provided data which was accurate to well within a practical range for surgical conditions. In our separate experiments on 10 cadaveric leg specimens, even the same test under controlled conditions could produce variations of up to ±30N. Hence the sensor outputs indicated whether or not the knee was balanced to that level of tolerance, while the contact point data would indicate contacts too close to the anterior or posterior of the tibial surface.
Inter-observer Variation of Applied Force on the Knee during Mechanical Testing

PATRICK MEERE MD, MARTIN ROCHE MD, PETER WALKER PhD, CHRISTOPHER BELL MS, CHRISTOPHER ANDERSON MS

INTRODUCTION
Soft tissue balancing is necessary for a successful total knee arthroplasty (TKA) outcome. Presently, balancing is a feel based art where surgeons apply opposing maneuvers testing for translational and gap opening symmetry. Two common surgical tests are the varus-valgus and anterior-posterior drawer tests. Equal applied forces for these opposing maneuvers are necessary to test for symmetric balancing, but there is no method to measure the force applied in the operating room. Therefore this study attempted to quantify the inter-observer variation of forces applied by Orthopaedic Surgeons.

METHODS
One hemi body cadaver specimen was used for all tests. TKA was performed on the specimen with a fitted load-sensing tibial trial to measure contact forces. A hand-held dynamometer was used to measure and record applied forces. Six senior orthopaedic surgeons then performed two surgical tests three times on the specimen to measure inter-observer variation.
1. Posterior drawer was applied at 90° flexion at a force that the surgeon would normally apply during the course of a routine TKA.
2. Varus torque at the tibial malleolus was applied in supported extension (0 degrees with no sag gravitational force) until the load-sensing tibial trial recorded lift-off in the lateral compartment.

RESULTS
Inter-observer applied forces varied for both tests. The normal posterior drawer forces applied by each surgeon differed, but were all repeatable by each surgeon with small individual standard deviations (high precision). Although all tests were on the same specimen, applied varus force until lateral lift-off also varied between surgeons. Standard deviations were low for the individual surgeons with the exception of Surgeon 2.

CONCLUSION
The data shows that each surgeon was able to apply reproducible forces which is important to analyze balancing in TKA. There was however significant variance of applied forces within the group. As such we noted that the intra-observer variance was low but the inter-observer was high. The range of applied varus forces (magnitude and wave signature) to create lift-off is noteworthy given that the same specimen was used by all observers. This difference may be rooted in individual experience and habit. As long as the applied force is reproducible and consistent for each surgeon, the method of soft tissue balancing by gauging symmetrical pressure differentials and varus-valgus gap openings can be reliably utilized. Similarly, consistent forces applied as an anterior-posterior drawer test should produce reliable tracking changes of the femoral condyles onto the tibia (antero-posterior translation).
INTER-OBSERVER VARIATION OF APPLIED FORCE ON THE KNEE DURING MECHANICAL TESTING

**Figure 1:** Individual surgeon posterior drawer force.

**Figure 2:** Individual surgeon signature varus force until lateral lift-off.

**POSTERIOR DRAWER FORCE**

**VARUS FORCE UNTIL LATERAL COMPARTMENT LIFT-OFF**
The Use of Sensor Technology (ST) Allowing Implant Salvage in Selected Revision Total Knee Arthroplasty (RevTKA)

PATRICK MEERE MD, CHRISTOPHER BELL MS

INTRODUCTION
Knee instability is a leading cause of patient dissatisfaction after TKA. This can be true despite apparent satisfactory alignment. In such cases, the soft tissue imbalance is the probable source of instability. The use of pressure sensors imbedded in tibial trial liners is proving an efficient method for soft tissue envelope calibration and rebalancing at the time of TKA. When used in a revision case of a compatible implant it may prevent the need for revision of all components.

METHODS
A sample case is presented. The selection was on the basis of satisfactory radiographic alignment and clear soft tissue imbalance in the coronal plane. The revision TKA surgery focused on balance restoration through pressure mapping technique through the functional range. Pre-operative and post-operative functional scores along with clinical findings were prospectively documented up to 8 months after revision TKA.

RESULTS
The WOMAC scores improved form 46.2 (pre-op) to 86.2 at 6 weeks and 88.6 at 8 months post-operatively. The Knee Society Score for function improved from 25 to 89 (part 1) and from 45 to 80 (part 2: function). The passive range of motion (PROM) improved from 10-90 degrees (pre-op) to 0-122 and 0-127 for the same post-op intervals. At the time of surgery pressure mapping identified the dominant instability as excessive medial tightness in extension with an excessively high-pressure differential: 90 lbs medially v. 11 lbs laterally. Pie-crusting of the posterior medial collateral ligamentous fibers selectively corrected the coronal imbalance and restored complete extension. Simple liner thickness then sufficed to restore pressure balance. The resultant pressures in supported extension were 36 lbs medially v. 32lbs laterally and in flexion (90 degrees) 14 lbs medially v. 13 lbs laterally. The intra-operative PROM measured 0-123 degrees. The metallic implant components were preserved. The improved range was preserved to date.

CONCLUSION
In selected rev TKA cases soft tissue imbalance is dominant. In such cases pressure mapping sensor technology helps defining the specific deficiency and probable best correction. Frequently the imbalance is coronal rather than sagittal. In such cases implant salvage may be feasible, sparing the patient the morbidity associated with a complete revision of all TKA components.
Increased Patient Satisfaction After Sensor-Guided TKA

KENNETH GUSTKE MD, GREGORY GOLLADAY MD, MARTIN ROCHE MD, LEAH ELSON BSc, CHRISTOPHER ANDERSON MS

INTRODUCTION
The satisfaction outcomes measure has become an important facet in determining clinical outcomes, allowing the patient to provide valuable feedback about the performance of their own artificial joint. However, during the last several decades, analyses of these surveys have shown that TKA patients report worse satisfaction than THA patients, and that there is a disparity between surgeon and patient opinion. Therefore, the purpose of this evaluation was to report on the one-year satisfaction of a group of sensor-assisted TKA patients, and compare that data to the average satisfaction reported in literature, via meta-analysis.

METHODS
135 patients received sensor-assisted primary TKA and reported satisfaction at 1-year. Soft-tissue “balance” was defined as a mediolateral intercompartmental loading difference of ≤ 15 pounds; all trans-tibial loading exceeding 15 pounds of mediolateral intercompartmental difference was classified as “unbalanced”. At the one-year follow-up visit, a 7-question patient satisfaction survey was administered using a 5-point Likert scale. A meta-analysis of literature was performed to ascertain satisfaction levels commonly reported in literature.

RESULTS
The overall satisfaction of sensor-assisted patients—indicating “satisfied” to “very satisfied”—at one-year, was 94.2%. The satisfaction levels, stratified by “balanced” and “unbalanced” patients, was 97.3% and 82.1%, respectively (P=0.043). The meta-analysis, including 12 publications, representing 33,775 international TKA patients, yielded 81% of TKA patients reporting “satisfied” to “very satisfied” (B-F=3.048; homogeneity<0.001; df=11). This represents a 16% decrease from the balanced cohort evaluated in this study (P=0.001).

DISCUSSION
In this study, it was found that quantifiably balanced TKA patients exhibited significantly higher satisfaction than unbalanced patients at 1-year (P=0.043). The highest reported satisfaction in literature was 90.3%, which is still 6.4% lower than the balanced patient group (P=0.045). The results of this study suggest that there may be a way to improve patient satisfaction in TKA by quantifiably balancing soft-tissues.
Bony Cuts or Soft-Tissue Release? Using Intraoperative Sensors to Refine Balancing Techniques in TKA

KENNETH GUSTKE MD, GREGORY GOLLADAY MD, MARTIN ROCHE MD, LEAH ELSON BSc, CHRISTOPHER ANDERSON MS

INTRODUCTION

Achieving balance in TKA is critical in assuring favorable outcomes. But, in order to achieve quantifiably balanced loading values, is it more advantageous to make bony corrections or release soft-tissue? The answer to this question will be paramount in evaluating the most appropriate surgical techniques for use with new dynamic technology, thereby maximizing favorable clinical outcomes. Therefore, the purpose of this investigation was to evaluate a possible quantitative loading threshold, using intraoperative sensors, which may dictate surgical correction of bone versus soft-tissue release.

METHODS

A retrospective analysis of 122 multicenter patients, in receipt of sensor-assisted primary TKA, was conducted. 40 lbs. was used as a threshold, above which bone was corrected; below which soft-tissue was corrected. All patients were categorized into the following groups: Group A – candidates for bony correction, but received soft-tissue correction; Group B – candidates for soft-tissue/receiving soft-tissue; Group C – candidates for bony correction/receiving bony correction.

RESULTS

The patient groups that followed the surgical algorithm appropriately (loading ≥ 40 lbs. dictates bony correction; loading < 40 lbs. dictates soft-tissue correction) reported significantly higher clinical outcomes scores (KSS and WOMAC) and satisfaction, 1-year following primary TKA.

DISCUSSION

Novel technology, such as intraoperative sensing, has provided surgeons with unprecedented access to information regarding the kinetic/kinematic nature of knee joints. In order to mitigate recurring complications after primary TKA, it is imperative that sensing output and clinical outcomes are correlated and studied in order to maximize patient benefits. In this investigation, it was observed that a 40 lb. threshold provided a clinically relevant delineation between when to correct bone, and when to adjust soft-tissue. When that algorithm was applied, patients reported significantly better clinical outcomes than when the algorithm was not applied.
Two Patient Case Series Evaluating the Utility and Cost Effectiveness of Using Intraoperative Sensors to Guide Complex Revision TKA

WILLIAM LEONE MD

INTRODUCTION
The risk of revision after primary TKA is 14.9% for men and 17.4% for women. The average charge for a TKA revision surgery is $73,696, with a larger cost for patients requiring component exchange. Revision TKA patients are also at a greater risk for complications than primary TKA patients. New methods must be developed to mitigate these unnecessary costs. The purpose of this two-surgeon case series was to test the efficacy of using intraoperative sensors to guide revision surgery in patients with chronic pain, effusion, limited ambulation, and other complications.

METHODS
Two patients received revision TKA using intraoperative sensors. The sensors were engineered to fit the geometric specifications of the polyethylene insert and were used in lieu of the trial. The sensors provided real-time kinetic feedback regarding loading and contact point location.

RESULTS
Patient 1: tray was downsized, sensor indicated malrotation. Patient 2: sensor indicated need for tibial re-cut and M/L hemiblocks. All patients report limited to no pain, improved ROM, and unassisted ambulation at 3-6 weeks.

CONCLUSIONS
All patients maintained most or all of the original components from primary surgery, despite the pre-operative indication for exchange. All patients reported markedly higher function and lowered pain levels in as little as 3 weeks. The low cost of the sensor make the technology both useful and cost effective for revision TKA.
Primary TKA Patients with Quantifiably Balanced Soft-Tissue Achieve Significant Clinical Gains Sooner Than Unbalanced Patients

GREGORY GOLLADAY MD, KENNETH GUSTKE MD, MARTIN ROCHE MD, LEAH ELSON BSc, CHRISTOPHER ANDERSON MS

INTRODUCTION
Complications reported by post-TKA patients include: pain, sensation of instability, and joint stiffness; problems that may be attributed to soft-tissue imbalance. One of the possible reasons for the substantial prevalence of such complications is the subjectivity associated with defining soft-tissue balance. Therefore, the purpose of this evaluation was to report on the disparity between the patient-reported outcomes scores of quantitatively balanced versus unbalanced multicenter patients, at 1-year.

METHODS
135 prospective patients, from 8 U.S. sites, had primary TKA performed with intraoperative sensors. Patients were classified by two groups: “balanced” (mediolateral loading differential of ≤ 15 lbs.) and “unbalanced” (mediolateral loading differential >15 lbs.), as determined by the sensor. At each follow-up visit, activity levels and patient-reported outcomes measures were administered, including: KSS and WOMAC.

RESULTS
Pre-operatively, there was also no statistical difference in alignment, ROM, outcomes measures, or demographic data between the two groups. At one year, the average total KSS score of balanced patients exceeded that of unbalanced patients by 23.3 points (P<0.001). The balanced group averaged 8 points more improvement in WOMAC scores than the unbalanced group. The balanced group’s average activity level score was 68.6; the unbalanced patient’s average activity level score was 46.7 (P=0.015). Joint state was the most highly significant variable when analyzed independently, as well as with every other possible combination of variables included in a regression model (p=0.001).

DISCUSSION
The results suggest that verifiably balanced patients not only obtain statistically significant improvement in both pain and function levels versus unbalanced patients, but that they do so in a shorter amount of time than their unbalanced counterparts. Evidence from this evaluation suggests that sensor-guided, quantifiably balanced TKA patients are statistically more likely to achieve reduced pain, improved function, and greater activity levels sooner than unbalanced patients.
Comparison of Computer-Assisted Sensor-Integrated Tibial Trial Inserts to Navigation in Total Knee Arthroplasty

DUSTIN BRIGGS MD, ADAM BUNN MD, SHANTANU PATIL MD, RICHARD WALKER MD

INTRODUCTION

Intra-operative range of motion and stability assessments are performed routinely during total knee arthroplasty (TKA) to establish optimal alignment and soft tissue balance. This study compares the applicability of a single-use, sensor integrated tibial polyethylene trial (SITT) insert, providing intra-operative compartment pressure data, to computer-assisted navigation (NAV), providing mechanical alignment data. The aim of the study was to create operating room (OR) simulations using cadaver TKA models to afford comparison of the potential intra-operative data generated by these computer-assistive TKA tools.

METHODS

TKA using a single system (Triathlon, Stryker, Mahwah, NJ) was performed in 5 fresh frozen cadaveric specimens using a navigation system (Stryker, Dallas, TX) in simulated OR conditions. Optimal mechanical alignment, bone resection, and soft-tissue balance were obtained for an 11 mm polyethylene (PE) trial insert. A SITT (OrthoSensor, Dania Beach, FL) with the topography of the TKA system, with variable thicknesses (9, 11, 13 mm), was used to assess medial and lateral compartment (MLCmpt) pressures (PSI) and pressure contact points (PCP) while simultaneously obtaining NAV varus/valgus (VV) alignment data.

RESULTS

A. SITT demonstrated greater sensitivity than NAV to tibial PE thickness. Whereas increased SITT thickness resulted in increased MLCmpt mean PSI per SITT (p=0.0002 for 9 vs 11mm PE, p=0.0001 for 11 vs 13mm) measured throughout range of motion (ROM), there was no change in VV alignment per NAV (p=0.8 for 9 vs 11mm PE, p=0.2 for 11 vs 13mm).

B. SITT demonstrated greater sensitivity than NAV to coronal asymmetry. Change in MLCmpt PSI variance per SITT throughout ROM did not correlate with evident change in VV alignment per NAV (R2<0.35 for 9mm, 11mm, 13mm, and all).

C. NAV demonstrated greater sensitivity than SITT to hyperextension. SITT demonstrated knees in hyperextension to have lower MLCmpt mean PSI than knees with a flexion contracture, with knees in 0o of flexion to have intermediate MLCmpt mean PSI.

D. SITT demonstrated greater sensitivity than NAV to the effects of closure of the patellofemoral mechanism (PFM). Whereas closure of the PFM correlated with decreased MLCmpt mean PSI (p=0.0001) and MLCmpt PSI variance (p=0.0001) per SITT, there was no change in VV alignment per NAV.

E. SITT demonstrated greater sensitivity than NAV to rotational position of the tibial tray. Whereas tibial rotation set by SITT (based on MLCmpt anterior-posterior (AP) PCP symmetry rather than anatomically based on the tibial tubercle) resulted in increased MLCmpt AP PCP symmetry (p=0.0002), decreased MLCmpt mean PSI (p=0.03), and decreased MLCmpt
CONTINUED

PSI variance (p=0.003) throughout ROM, as measured by SITT, NAV did not appreciate a difference in VV alignment (anatomic tibial rotation mean VV 0.5° valgus, SITT tibial rotation 0.8° valgus).

CONCLUSION

In this cadaver TKA OR simulation model comparing intra-operative computer-assisted pressure (SITT) versus alignment (NAV) data adjuncts, SITT demonstrated greater sensitivity, and offered a greater abundance of data, than NAV regarding tibial PE thickness, coronal asymmetry, patellofemoral closure, and tibial tray rotation. NAV offered greater sensitivity than SITT regarding ROM, especially regarding hyperextension versus flexion contracture. Sensitivity of the two modalities to pathological conditions, and optimal corrective steps for those conditions, was not defined. Further studies in that regard should be performed to further define the potential benefit of incorporating these data into intra-operative TKA protocols.
As the proportion of adults with obesity continues to climb, so too does the need for total knee arthroplasty. Unfortunately, total knee replacement patients often experience post-operative weight gain, despite improved joint function. The purposes of this study were:

1. To execute a literature meta-analysis in order quantify the changes in body mass that are typically observed following TKA, and
2. Evaluate data from a prospective, multicenter study to assess any trends towards weight loss in a group of “balanced”, sensor-assisted TKA patients.

The literature review found that average proportion of patients who had weight gain after TKA is 47% to 66%. In literature, the average post-operative weight gain was 9.5 lbs. (1.6 kg/m² BMI increase), up to 14 lbs. (2.3 kg/m²). In the multicenter study, only 30.4% of patients and 36.9% of patients exhibited weight gain at 6 months and 1 year, respectively. At the 1-year interval, this indicates an 11% decrease from reported averages (p=0.049), up to 29% as reported by the NIH (p<0.001). The average weight gain in the multicenter patient group was 4.3 lbs. (0.72 kg/m² BMI increase) at 6 months, and 3.5 lbs. (0.58 kg/m²) at 1 year, both of which are non-clinically meaningful. The average weight loss of those in the non-gaining group was 7.8 lbs. (1.3 kg/m²) at 6 months and 9.6 lbs. (1.6 kg/m²) at 1 year. Both of these values are clinically meaningful. This evaluation demonstrates that weight gain after TKA is prevalent, but ensuring soft-tissue balance (via technologies such as intraoperative sensing) may help mitigate this expected increase in body mass.
Patellar Position Affects Intraoperative Compartmental Loads During Total Knee Arthroplasty: A pilot study using intra-operative sensing to guide soft tissue balance

ALEJANDRO DELLA VALLE MD

The achievement of symmetric loads in the medial and lateral compartments during total knee arthroplasty is necessary for long-term success. We hypothesize that the lateralization of the patella during surgery affects the distribution of loads in the medial and lateral compartments. This study used intraoperative pressure sensors to record medial and lateral compartment loads in 56 well-balanced TKAs, once the trial implants were positioned. Loads were recorded in full and relaxed extension, 45°, 90° and full flexion. The measurements were taken with the patella lateralized (everted and not everted) and with the patella relocated in the trochlea (with and without provisional medial retinacular closure). Significantly higher loads in the lateral compartment were observed at 45 and 90 degrees of flexion when the patella was lateralized (14.3lbs & 11.7lbs) or everted (14.3lbs & 13.5lbs) when compared to those observed with the patella in a physiologic position (8.5-9.2lbs). Equalization of compartment loads during TKA when the extensor mechanism is lateralized may result in uneven load distribution when the patella is in a physiologic position.
Dynamic Soft Tissue Balancing in Total Knee Arthroplasty

MARTIN ROCHE MD, LEAH ELSON BSc, CHRISTOPHER ANDERSON MS

Achieving optimal soft tissue balance intraoperatively is a critical element for a successful outcome after total knee arthroplasty. Although advances in navigation have improved the incidence of angular outliers, spatial distance measurements do not quantify soft tissue stability or degrees of ligament tension. Revisions caused by instability, malrotation, and malalignment still constitute up to one-third of early knee revisions. The development of integrated microelectronics and sensors into the knee trials during surgery allows surgeons to evaluate and act on real-time data regarding implant position, rotation, alignment, and soft tissue balance through a full range of motion.
Design and Validation of a Smart Knee Brace to Measure Varus-Valgus Stability

CHRISTOPHER BELL MS, PATRICK MEERE MD, ILYA BORUKHOV BS, PETER WALKER PhD

Evaluation of post-operative balancing outcomes after Total Knee Arthroplasty (TKA) and other procedures can be measured by stability tests, with Anterior-Posterior (AP) and Varus-Valgus (VV) stability being particularly important. AP stability can be quantified using a KT1000 device; however there is no standard way of measuring VV stability. This test is routinely carried out by surgeons in clinical evaluations, but there is no quantification of the moments applied or the resulting angular deviations between the femur and tibia. Therefore we sought to develop and validate a device and method for quantifying knee balancing by analyzing VV stability.

Our team developed a Smart Knee Brace to measure VV angular changes (see Figure 1) using two dielectric elastomer stretch sensors. The brace was secured in position with the leg in full extension and the sensors were adjusted to hold pre-tension readouts and locked. Therefore contraction and elongation of either sensor could be measured simultaneously using proprietary software. The changing values were then used to calculate the VV, femur-to-tibia, angular deviations.

The Smart Knee Brace was validated using a bilateral lower body cadaver specimen comparing the brace’s calculated VV angular changes to those from an optical surgical navigation system. The pelvis was fixed to the base of the test rig and a surgical boot was firmly strapped to the foot. A spherical bearing fixed to the base of the boot was attached to a polished stainless steel rod allowing for controlled low friction VV translations of the foot when a force was applied to the malleolus. This force applied varus or valgus moments to the knee. The thigh was secured in the rig and supported by a horizontal beam that adjusted to control angles of flexion. Surgical navigation trackers were then fixed to the femur and tibia. A subvastus approach was used and the navigation system was calibrated. The arthrotomy was then closed with towel clips. The Smart Knee Brace was strapped on and secured in position. The VV tests were then carried out on the knee prior to insertion of the TKA. Force was gradually applied for both varus and valgus moments with a wireless hand-held dynamometer up to 50N (19.8Nm) at 0 and 15° flexion. A navigated TKA was then performed to test the accuracy of the brace on a trial implanted knee and the VV tests were repeated.

Collected data was later processed and the Smart Knee Brace VV angular changes were compared to those values recorded by Navigation. R2 values were then calculated to validate the Smart Knee Brace’s accuracy. Excellent correlation was observed between the Smart Knee Brace and navigation angular changes (see Figure 2). The post arthrotomy R2 values were 0.9931 and 0.9845. With the trial TKA components inserted the R2 values were 0.9677 and 0.9732. Therefore we can conclude that the Smart Knee Brace can potentially be used to accurately measure and the VV deviation of the knee in a clinical setting and hence indicate stability and balance after TKA.
DESIGN AND VALIDATION OF A SMART KNEE BRACE TO MEASURE VARUS-VALGUS STABILITY

SOURCES: New York University-Hospital for Joint Diseases, New York, NY

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Figure 1: Smart Knee Brace system

Figure 2: Smart Knee Brace vs Navigation Angle measured correlation
Thigh Pull Test in TKR: Equivalent or Different than Heel Push

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PARTHIV RATHOD MD, PETER WALKER PhD

The use of smart trial components is now allowing a better assessment of soft tissue balancing at the time of total knee replacement surgery. A balanced knee can be defined as one that possesses symmetry, ie. equal and centered lateral and medial forces through the full range of flexion. There is still a need for a standard reproducible surgical test to quickly confirm optimized balancing at surgery with such devices. The Heel Push test is the established standard, by pushing the foot in a cephalad direction while supporting the thigh and keeping the leg stable in the vertical plane. A common variation of this test is the Thigh Pull test where the foot is actively assisted during the cephalad pull of the thigh through deep flexion. The test is an open chain test. The Thigh Pull test may be an improvement since the weight of the leg is alleviated and no supplemental compressive forces are introduced. The directional changes of the lower extremity are thus a result of ligamentous tension and balances. The purpose of this study is to compare the two tests using a standard testing methodology and observe the variation in kinetic parameters in a controlled biomechanical setting.

A custom mechanical rig was developed, which independently controls all six degrees of freedom about the knee joint. In addition a commercial navigation system was used to derive instantaneous alignment values and flexion angles between the tibia and femur. The pelvis was fixed to the table and the foot was fitted onto a low friction carriage along a slide rail. The knee design used was cruciate retaining. The pressure mapping system was a wireless tibial trial that provided magnitude of load per compartment.

The study is a cadaveric study. The number of specimens was ten. This preliminary report utilizes the data from two, pending final data analysis. In this experiment the leg was then tested with the Heel Push and Thigh Pull tests after obtaining optimum soft tissue balance of the cadaveric specimen. From this standard neutral state a series of single surgical variables were introduced to mimic common intra-operative surgical corrections. This was achieved through custom tibial liner and angle shims.

The results obtained from the test series defied theoretical anticipation. Though the total contact forces with heel push were generally higher than with thigh pull, the relative load distribution between compartments did not follow a trend (see Figure 1). Furthermore in deeper flexion the persistence of relatively high contact pressures would suggest that ligaments still generate intra-articular forces despite the much weaker gravitational effect. The clinical relevance lies in the asymmetry of the load distribution between medial and lateral compartment for the two methods tested. The load asymmetry as tested by the Thigh Pull test may correspond to an open chain in swing phase. This asymmetry would force some axial rotation and tibial femoral alignment deviation that can significantly affect the forces at the time of heel strike. The Heel Push test would be more representative of the compressive forces in a closed chain mode as seen during the stance phase of gait.
CONTACT FORCE DIFFERENCE

Magnitude of shaded widths corresponds to pressure differential.

CONTACT FORCE RATIO

Compartmental contact force ratio. Calculated by Medial Force / Total Force. (0-0.49 = Lateral Favored; 0.5-1 = Medial Favored).

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THIGH PULL TEST IN TKR: EQUIVALENT OR DIFFERENT THAN HEEL PUSH

SOURCES: New York University-Hospital for Joint Diseases, New York, NY
Varus Valgus Stability Must be Assessed Outside of the Screw-Home Mechanism

PATRICK MEERE MD, CHRISTOPHER BELL MS, ILYA BORUKHOV BS, PARTHIV RATHOD MD, PETER WALKER PhD

Assessing soft tissue balancing at the time of total knee replacement surgery is improving with the use of smart trial components. The use of these tools along with surgical balancing tests helps assess whether a knee is balanced. One such test, the Varus-Valgus (VV) test, focuses on the stability and balance of the collateral ligaments. A stable and balanced knee can be identified with this test as one that possesses symmetrical contact forces when equal opposing VV forces are applied. VV stability is important for stable post-operative kinematics, especially in the swing phase of gait when the screw-home mechanism is broken and there are ground reaction forces. We sought to illustrate the need to perform this test outside the screw-home mechanism to properly focus the test on the collateral ligaments in a controlled laboratory study.

A test rig was developed for mounting lower body specimens to a standard operating table. The pelvis was fixed to the base of the test rig and a surgical boot was firmly strapped to the foot. A spherical bearing fixed to the base of the boot was attached to a polished stainless steel rod allowing for controlled low friction VV translations of the foot when the torque force was applied to the malleoli. The thigh was secured in the rig to prevent femoral rotations and translations while resting on a horizontal beam that adjusted to control angles of flexion. Surgical navigation trackers were then fixed to the femur and tibia. A subvastus approach was used and bone cuts were made for the insertion of a posterior cruciate retaining total knee using an optical navigation system. The wireless instrumented tibial trial was then introduced. For all subsequent tests, the arthrotomy was closed with towel clips. Hip-Knee-Ankle (HKA) angles were measured by navigation and contact forces were measure by the tibial trial.

The VV tests were then carried out. Force was gradually applied up to 50N (19.8Nm) for both varus and valgus torques at 0 and 15° flexion. Applied forces were measured using a wireless hand-held dynamometer.

Looking at the 15° flexion tests in Figure 1, it can be concluded that this knee is unbalanced. The angular deviations at the 0° flexion tests seem symmetric, but at 15° flexion, outside the screw-home mechanism, the VV openings are not. The 15° flexion Valgus torque produced an angular change of 8 degrees which is almost double that of the 15° flexion Varus torque, thus illustrating a tighter lateral side. Lateral tightness is also represented by the greater 15° flexion Varus torque contact forces compared 15° flexion Valgus torque. The HKA angle discrepancy between 0 and 15° flexion demonstrates the importance of testing balancing outside of the screw-home mechanism in order to truly achieve post-operative stability.
VARUS VALGUS STABILITY MUST BE ASSESSED OUTSIDE OF THE SCREW-HOME MECHANISM

SOURCES: New York University-Hospital for Joint Diseases, New York, NY

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

MARTIN ROCHE MD, LEAH ELSON BSc, CHRISTOPHER ANDERSON MS

BACKGROUND
Ensuring rotational tibiofemoral congruency and centralized patellar tracking are critical technical factors that have proven to affect the post-operative success of TKA’s. Several techniques exist 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 mid-medial third of the tibial tubercle intraoperatively mitigates positional outliers.

METHODS
This study used data collected from intraoperative sensors to quantify the variability associated with using the mid-medial third of the tibial tubercle in 170 primary TKA patients. With the sensor-equipped trial insert in place, the knee was taken into extension, and the femoral condylar contact point location 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 any tray malpositioning. The initial and final angles of tibial tray rotation were captured using intraoperative video feed, and recorded.

RESULTS
When referencing the tubercle, it was found that 53% of patients exhibited asymmetrical tibiofemoral congruency in extension. Of those patients, 68% were shown to have excessive internal rotation of the tibial tray relative to the femur, while 32% exhibited excessive external rotation. The average tibiofemoral incongruency deviated from a neutral position by 6°, ranging from 0.5° to 19.2°.

CONCLUSION
Data from this evaluation suggests that the use of the tibial tubercle to maximize tibiofemoral congruency is highly variable and inconsistent for confirming the final rotation of the tibial tray.
The following institutions have contributed research to this field of study:

- NYU Hospital for Joint Diseases
- Orthopaedic Associates of Michigan
- VCU Medical Center
- Hospital for Special Surgery
- Scripps Clinic
- NCH Healthcare System
- Holy Cross Hospital
- Florida Orthopaedic Institute
- Saint Joseph Mercy Health System
- Bone & Joint Institute