DYNAMIC INTRAOPERATIVE SENSING TECHNOLOGY IN TOTAL KNEE ARTHROPLASTY

ABSTRACTS FOR BIOMECHANICAL AND CLINICAL INVESTIGATIONS
The following institutions have contributed research to this field of study:

- Bone & Joint Institute
- Cleveland Clinic
- Cleveland State University
- Columbia University Medical Center
- Florida Orthopedic Institute
- Holy Cross Hospital
- Hospital for Special Surgery
- Joint Implant Surgeons
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.
Modified MCL Release Technique
Sensor-Guided Technique Used to Quantify Intercompartmental Balance in TKA

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

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. All soft-tissue release techniques were recorded. “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.
Computer-Assisted Orthopaedic Surgery During TKA is Insufficient for Ensuring Ideal Joint Reconstruction

JON DOUNCHIS MD, GERALD JERRY MD, GREGORY GOLLADAY MD

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.
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 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: 61.4° - 82.3°). The
combined (left/right) angle was 71.1°±33.6° (Range: 57.6°-83.2°). The two methods resulted in a 3.4° difference, with the 3TT reference being more externally rotated.

**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.

**Figure 2**

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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 possibly 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.
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.
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

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

**CONTINUED**

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

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

The characteristics of the clinical use of VERASENSE are similar for primary and revision TKA for the supported knee implant families and sizes.
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.
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 recut 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.

The characteristics of the clinical use of VERASENSE are similar for primary and revision TKA for the supported knee implant families and sizes.
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.
Post-Operative Weight Gain After Total Knee Arthroplasty: Prevalence and its Possible Attenuation Using Intraoperative Sensors

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

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 to 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 the 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 micro-electronics 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

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

PATRICK MEERE MD, CHRISTOPHER BELL MS, ILYA BORUKHOV BSc, 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, i.e., 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.
THIGH PULL TEST IN TKR: EQUIVALENT OR DIFFERENT THAN HEEL PUSH

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).

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 measured 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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### KNEE 1

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**Applied Forces**
- 0 Newtons
- 20 Newtons
- 35 Newtons
- 50 Newtons

Contact Forces measured by tibial trial and HKA angle measured by navigation.

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### KNEE 2

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**Applied Forces**
- 0 Newtons
- 20 Newtons
- 35 Newtons
- 50 Newtons

Contact Forces measured by tibial trial and HKA angle measured by navigation.
ABSTRACT
The achievement of a well-balanced total knee arthroplasty is necessary for long-term success. We hypothesize that the dislocation of the patella during surgery affects the distribution of loads in the medial and lateral compartments. Intraoperative load sensors were used to record medial and lateral compartment loads in 56 well-balanced TKAs. Loads were recorded in full extension, relaxed extension, at 45 and 90° of flexion at full gravity-assisted flexion, with the patella in four different positions: dislocated (everted and not), located, and located and secured with two retinacular sutures. The loads in the lateral compartment in flexion were higher with a dislocated patella than with a located patella (P < 0.001). A lateralized extensor mechanism artificially increases in the lateral compartment loads in flexion during TKA surgery. Instruments that allow intraoperative soft tissue balance with the patella in a physiologic position are more likely to replicate postoperative compartment loads. Level of evidence: II (prospective comparative study).
Quantifying the Kinetic Variability Inherent in Cementing Technique During TKA

MARTIN ROCHE MD, KEVIN WANG MD, LEAH ELSON BS, CHRISTOPHER ANDERSON MS

INTRODUCTION

Aseptic loosening has been reported to be the most common, contemporary mode of total knee arthroplasty failure. It has been suggested that the etiology of revision due to loosening can be attributed, in part, to joint imbalance and the variability inherent in standard surgical techniques. Due to the high prevalence of revision, the purpose of this study was to quantify the change in kinetic loading of the knee joint before versus after the application of the final cement-component complex.

METHODS

Ninety-two consecutive, cruciate-retaining TKAs were performed, between March 2014 and June 2014, by two collaborating surgeons. Two different knee systems were used, each with a different viscosity cement type (either medium viscosity or high viscosity). All knees were initially balanced using a microelectronic tibial insert, which provides real-time feedback of femoral contact points and joint kinetics. After the post-balance loads were captured, and the surgeon was satisfied with joint balance, the final components were cemented into place, and the sensor was re-inserted to capture any change in loading due to cementing technique.

RESULTS

Of the 92 TKAs performed, 42% of patients required post-cement correction due to changes in loading. Of the entire cohort, 41% of patients were also classified as “imbalanced”, post-cementing, as defined previously in literature. The average absolute value of the post-cementing change to intercompartmental loading was 28.2 lbs. (324.8 lbs.). Of those patients with excessive changes to joint loading, 84.2% exhibited the majority of change to loading in the medial compartment, which is theorized to be due to the right-handedness of both surgeons and angle of impaction. There was a highly statistically significant relationship between post-cementation loading changes and proportion of imbalance (P <0.001). There was no significant difference in average loading values, or occurrence of imbalance, between either component systems or cement types.

DISCUSSION

Joint imbalance and loosening substantially contribute to the current 2.7 billion dollar TKA revision burden in the United States. The post-cementing imbalance, as detected by the sensor in this study, demonstrates how using quantified methods in TKA may mitigate imbalance-related complications. By using technology to guide the surgeon through appropriate kinetic correction, the subtleties in imbalance, despite a symmetrical flexion gap, can be corrected for more effectively than by subjective surgeon “feel.” Longer clinical follow-up of these patients will be necessary to track the outcomes associated with quantifiably balanced joint loading.
Comparing Modes of Soft-Tissue Release: Is a Multiple Needle Puncturing Technique as Safe and Effective as Transection?

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

INTRODUCTION
Instability after total knee arthroplasty (TKA) represents, in excess of, 7% of reasons for implant failure. This mode of failure is correlated with soft-tissue imbalance, and has continued to be problematic despite advances in implant technology. Thus, understanding the options available to execute safe and effective soft-tissue release is critical to mitigating future complications due to instability. This study aimed to use intraoperative sensors to evaluate a multiple needle puncturing technique (MNPT), in comparison with traditional transection-based release, to determine its biomechanical and clinical efficacy.

METHODS
Seventy-five consecutive, cruciate-retaining TKAs were performed, as part of an 8-site multicenter study. All procedures were performed with the use of an intraoperative sensor to ensure quantitative balance, as per previously reported literature. Of the 75-patient cohort, 50 patients were balanced with the MNPT; 20 patients were balanced with traditional transection. All patients were followed out to 1-year, and administered KSS, WOMAC, and satisfaction. Alignment and ROM was captured for all patients, pre-operatively and at the 1-year follow-up interval.

RESULTS
All patient joints could be released to a balanced joint state, regardless of technique used. There was no significant difference between the two groups (MNPT vs. transection), pre-operatively, with respect to range of motion or alignment (114° MNPT; 114° transection). At 1-year, post-operatively, there was no significant difference in WOMAC score, KSS scores, satisfaction, or ROM (Respectively: 13.1 MNPT vs. 14.6 transection; 174.9 MNPT vs.176.5 transection; 31.7 “Very Satisfied” MNPT vs. 32.2 “Very Satisfied” transection; 124° MNPT vs. 125° transection). No adverse outcomes related to balancing technique have been reported.

DISCUSSION
Instability contributes to the current 2.7 billion dollar TKA revision burden in the United States. Understanding the efficacy of different techniques in soft-tissue balancing may help to mitigate unfavorable complications. In this study, it was found that the MNPT is just as safe and effective at achieving soft-tissue balance as transactional release techniques, and showed no deviation from the achievement of optimal post-operative outcomes at 1-year. This technique, when used with intraoperative sensors to quantify joint balance, may thereby offer a more controlled way to release soft-tissue, incrementally, to achieve precise balance. Clin Orthop Relat Res. Under Review.
A Clinical and Economic Literature Review of Three Modalities in Technologically Assisted TKA

WILLIAM LEONE MD

INTRODUCTION
The rate of technological innovation in procedural total knee arthroplasty has left little time for critical evaluation of a new technology before the adoption of even newer modalities. With more drastic financial restrictions being placed on operating room spending, orthopaedic surgeons are now required to provide excellent results on a budget.

It is integral that both clinical efficacy and cost-effectiveness of these intraoperative technologies be fully understood in order to provide patients with effectual, economically conscious care. The purpose of this qualitative analysis of literature was to evaluate clinical and economic efficacy of the three most prominent technologies currently used in TKA: computer navigation, patient-specific instrumentation, and kinetic sensors.

METHODS
Three hundred and ninety one publications were collected; 100 were included in final qualitative analysis. Criteria for inclusion in the analysis was defined only insofar as that each piece assessed one of the above listed aspects of the three technologies. Literature included in the final evaluation contained background information on each respective technology, clinical outcomes, revision rates, and/or cost analyses. All comparisons were conducted in a strictly qualitative manner, and no attempts were made to conduct interstudy statistical analyses due to the high level of variability in methodology and data collected.

RESULTS
Navigation: Navigation was designed to reduce alignment and component positioning outliers. Many surgeons have argued that its results are no better than that achieved by manual techniques. Some studies have shown that clinical outcomes have improved in navigated TKA patients, but an abundance of research suggests that this is not the case. In consideration of the expense of this technology, coupled with inconclusive results, navigation does not, at this time, seem to fit the schema for significantly reducing the rate of revision and operative cost.

PSI: Patient-specific instrumentation was designed to reduce the expense of navigation systems, simplify computer-assisted methods, and improve functional outcomes. However, a majority of research has suggested that PSI is either no better, or even worse, at alignment accuracy than manual techniques. Very few publications have been able to attest to any significant increase in functional outcomes scores of PSI patients, over the scores of navigation or manual TKA.

Kinetic Sensors: Kinetic sensor technology has been engineered to quantify soft-tissue balance, improve rotational alignment, and decrease the risk of post-operative complications. Albeit a young device, the sparse literature that exists shows promising results. The margin of error for detecting loads has been shown to be low, the sensors have successfully measured subtle imbalance that leads to altered gait kinematics, and has shown significant improvement.
in several patient-reported outcomes measures in balanced patients.

**DISCUSSION**

This review shows that not all modalities are created equal, and demonstrates that the cost of some technologies may not yield a clinical or time-saving payoff for the patient and hospital. While kinetic sensor devices seem to be the most promising modality, more research will be necessary to confirm its advantages over time. But, great care must be taken when adopting any novel technology; “new” does not always mean “improved”.
Maximizing Clinical Outcomes after Revision and Primary TKA: The Efficacy of Using Intraoperative Sensors

WAEL BARSOUM MD, THOMAS COON MD, ALEJANDRO DELLA VALLE MD, JON DOUNCHIS MD, GREGORY GOLLADAY MD, KENNETH GUSTKE MD, GERALD JERRY MD, KENNETH KRESS MD, WILLIAM LEONE MD, PATRICK MEERE MD, MARTIN ROCHE MD, PETER WALKER PhD

INTRODUCTION

Ensuring soft-tissue balance in total knee arthroplasty (TKA) is a critical factor in both short- and long-term clinical outcomes. Yet, current manual techniques—including gap balancing and measured resection—have done little to stymie the proportion of post-operative complications associated with tissue imbalance. Furthermore, these methods are often highly variable, based on surgeon technique and patient anatomy. The difficulty in balancing the soft-tissue envelope, no doubt, originates from the subjective nature associated with assessing ligamentous tension and laxity; surgeons rely on “feel” and visual interpretation rather than quantitative values. While an experienced surgeon can detect gross instability, subtle tissue imbalance can easily go unnoticed by current standards of practice. The purpose of the previous 3 years of both lab and clinical research has been to test the efficacy associated with incorporating intraoperative sensing technology into surgical workflow; and to determine if clinical outcomes can be improved with a quantifiably balanced soft-tissue envelope.

METHODS

During revision and primary TKA, disposable, wireless, intraoperative sensors were used to quantify dynamic soft-tissue loading and femoral contact point position on the surface of the tibial plateau. These sensors were engineered with accelerometer and force vector detection technology in order to project the dynamic intra-articular kinetics of the knee joint onto a display screen. Via biomechanical and clinical studies, values for kinematic “balance” and surgical algorithms were developed. These algorithms were employed, intra-operatively, and all patients have been followed out to 3-years. All patients have been administered KSS, WOMAC, and satisfaction surveys to monitor clinical outcomes.

RESULTS

The authors, from 8 different U.S. medical centers, have utilized intraoperative sensing technology to quantify soft-tissue balance, since 2011, in both primary and revision TKA. Through biomechanical lab analyses, clinical data capture, and patient outcomes, soft-tissue induced loading values and surgical algorithms have been developed, based on dynamic sensor feedback.

Patients with quantifiably balanced soft-tissue (mediolateral incompartmental loading difference <15 lbs.), have reported significantly higher satisfaction, better outcomes, less pain, and more rigorous activity levels than quantifiably unbalanced patients, at 6-month (published), 1-year (published), and 2-year intervals. In using sensing technology in revision TKA, metal components were able to be spared, and patients have returned to function.
CONTINUED

DISCUSSION AND CONCLUSIONS

Until recently, orthopaedic surgeons did not have the ability to quantify induced ligamentous loading values. This inability to objectively diagnose and treat soft-tissue imbalance has led to a continuation of avoidable soft-tissue related post-operative complications. However, intraoperative sensing technology has recently been developed to assist the surgeon in quantifiably measuring soft-tissue tension. Using this information, a group of surgeons—from 8 U.S. medical centers—have developed loading-based algorithms for addressing various soft-tissue problems in both revision and primary TKA. As a result, balanced patients have shown significant improvement in all patient-reported outcomes measures (KSS, WOMAC), and satisfaction. The data collected over the last 3 years suggests that incorporating intraoperative technology to guide subjective surgical methods: 1) leads to improved short- and long-term clinical outcomes, 2) may reduce the cost associated with exchanging metal components during revision, and 3) may contribute to a decreased incidence of revision surgery.

The characteristics of the clinical use of VERASENSE are similar for primary and revision TKA for the supported knee implant families and sizes.
Relating TKA Tissue Release to Joint Response Using an Instrumented Trial Implant

JAYSON ZADZILKA, ROBB COBRUNN, TARA BONNER, CHRIS ANDERSON, ALISON KLIKA, WAEL BARSOUM, GUSTAV FISCHER, JASON HALLORAN

INTRODUCTION
Improper soft-tissue balancing can result in postoperative complications after total knee arthroplasty (TKA) and may lead to early revision [1-3]. A single-use tibial insert trial with embedded sensor technology (VERASENSE from OrthoSensor Inc., Dania Beach, FL) was designed to provide feedback to the surgeon intraoperatively, with the goal to achieve a "well-balanced" knee throughout the range of motion [4]. The purpose of this study was to quantify the effects of common soft-tissue releases as they related to sensor measured joint reactions and kinematics.

METHODS
Robotic testing was performed using four fresh-frozen cadaveric knee specimens implanted with appropriately sized instrumented trial implants (implant geometry was based on a currently available TKA system). Sensor outputs included the locations and magnitudes of medial and lateral reaction forces. As a measure of tibiofemoral joint kinematics, medial and lateral reaction locations were resolved to femoral anterior-posterior (A-P) displacement and internal-external (I-E) tibial rotation (“AFD” and “ITR” in Fig 1, respectively). Laxity style joint loading included discrete applications of +/- 100 N A-P, +/- 3 N/m I-E and +/- 5 N/m varus-valgus (V-V) loads, each applied at 10, 45, and 90° of flexion. All tests included 20 N of compressive force. Laxity tests were performed before and after a specified series of soft-tissue releases, which included complete transection of the posterior cruciate ligament (PCL), superficial medial collateral ligament (sMCL), deep MCL (dMCL) and the popliteus ligament (Table 1). Sensor outputs were recorded for each quasi-static test. Statistical results were quantified using regression formulas that related sensor outputs (reaction loads and kinematics) as a function of tissue release across all loading conditions. Significance was set for p-values $\leq 0.05$.

RESULTS
Tissue releases, and in particular the sMCL and PCL, led to multiple findings, many of which were dependent on flexion (Table 2). For PCL resection, at 10° of flexion lateral and total joint loads decreased, whereas at 45 and 90° lateral load increased. PCL release also off loaded the medial compartment at 90° flexion. In addition, there was a significant anterior shift of the femur that increased with flexion angle, while tibial rotation was only affected at 90°. sMCL release decreased the total load across all flexion angles, and impacted the medial load at 10° only. Release of the popliteus increased medial and total joint loads at 10° only (not shown).

DISCUSSION
One critical aspect of TKA is achieving appropriate soft-tissue balance to maximize postoperative performance. In this study, the sensor provided a direct measurement of joint loading and kinematics, which were related to surgically relevant soft-tissue releases. Results showed the
sMCL to decrease joint loads and flexion dependent changes after PCL release, likely an indication of bundle specific response. Future work should be performed to examine the roles of individual ligament bundles, as well as graded effects of tissue releases. Overall, the results corroborate previous findings and provide a new and direct look at the role of ligaments in TKA.

SIGNIFICANCE
This study quantified relationships between surgically relevant tissue states and joint response in TKA. The data has the potential to be applied intraoperatively to guide soft-tissue releases in an effort to obtain a well-balanced knee.

REFERENCES
The Use of Sensor Technology Allowing Implant Salvage In Selected Cases of Revision Total Knee Arthroplasty: A Two-Case Retrospective Case Series

PATRICK MEERE MD

ABSTRACT
Costly revision total knee arthroplasty continues to place an increased burden on the United States healthcare system. In light of highly variable revision rates between medical centers, new sanctions have been placed on reimbursement strategy, from the Centers for Medicare and Medicaid, that will financially penalize healthcare providers for unplanned patient readmissions before 90-days following surgery. For the benefit of both patient and healthcare provider, and in effort to reduce unplanned readmissions, new technology has been developed to provide surgeons with objective feedback during surgery. In this case study, the surgeon uses a new, wireless sensor to guide revision procedures and to mitigate unnecessary component exchange. Patients report marked increases in WOMAC, KSS, and range of motion. Use of the wireless sensor shows that implant salvage is possible guiding surgeons to specific abnormalities.

The characteristics of the clinical use of VERASENSE are similar for primary and revision TKA for the supported knee implant families and sizes.
Using Intraoperative Sensing Technology to Guide Revision in the Chronically Painful Knee: A Two-Patient Case Study

WILLIAM LEONE MD

ABSTRACT

The number of revision total knee arthroplasties (TKAs), performed annually, is expected to rise, in concert with the exponential demand for primary surgical procedures. These costly revision cases will continue to place an increased financial strain on an already burdened healthcare system. Therefore, it is imperative to explore methods which may provide more objective data to surgeons performing these complicated revision surgeries. Access to more empirical data may assist surgeons in more appropriate operative planning, and may mitigate the need for total component exchange. In this case study, the surgeon uses a disposable, intraoperative sensing device to guide complex procedures in patients presenting with chronic pain. At 6-weeks, both patients exhibit alleviated pain, increased function, and highly favorable outcomes.

The characteristics of the clinical use of VERASENSE are similar for primary and revision TKA for the supported knee implant families and sizes.
Sensor Technology in Total Knee Arthroplasty

KENNETH GUSTKE MD

ABSTRACT
Total knee replacement surgery is highly successful in terms of component survival. However, approximately 20 percent of patients report dissatisfaction with their outcome. It is speculated that many of these patients may have soft tissue imbalance or maltracking components which can lead to stiffness or subtle instability. Surgeons currently rely on subjective feel and visual estimation to determine if the total knee has proper soft tissue balance. Surgical experience and case volume play a major role in each surgeon’s relative skill in balancing the knee properly.

Sensor technology incorporates embedded microelectronics in a trial tibial insert. While the surgeons performs a passive range of motion with trial components in place, quantified pounds of pressure and tracking patterns in the medial and lateral compartments are demonstrated on a graphical interface. The surgeon can decide whether to accept the knee balance, perform a soft tissue release, or redo a bone cut. If soft tissue balancing is performed, the surgeon can visualize changes in compartment pressures on the graphical interface as sequential soft tissue releases are performed with a pie-crusting method. Minimal bone recuts are being used more frequently.

A multi-center evaluation utilizing sensor technology has demonstrated significantly improved outcomes when the compartment pressures were within 15 pounds of each other.
Accuracy of Balancing Total Knee Arthroplasty Using an Instrumented Tibial Trial

PATRICK A MEERE MD, SVENJA SCHNEIDER BS, PETER WALKER PhD

ABSTRACT

During 101 total knee surgeries, initial bone cuts were made using navigation. Lateral and medial contact forces were determined throughout flexion using an instrumented tibial trial. Balancing was defined as a ratio of the medial/total force, exact balancing being 0.5. Based on the initial values, surgical corrections were selected to achieve balancing. The most common corrections were soft-tissue releases (63 incidences), including MCL, postero-lateral corner, postero-medial corner, and changing tibial insert thicknesses (34 incidences). After final balancing, the mean ratio was 0.52 +/- 0.14, between 0.35 and 0.65 being achieved in 80% of cases. In 84% of cases, only 0-2 corrections were required. The average total force on the condyles was 215 +/- 86 Newtons. The methodology was an efficient quantitative method for achieving balance.
Surgeon Assessment of Gapping Versus Kinetic Loading Using Intraoperative Sensors During TKA

PATRICK A MEERE MD, JUSTIN G LAMONT MD, JORGE BAEZ MD, MICHAEL N KANG MD, VIJAY J RASQUINHA MD, CHRISTOPHER R ANDERSON MS, CALE A JACOBS PhD

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.
Are We Putting too Much Pressure on our Total Knee Arthroplasties?

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INTRODUCTION
Balancing techniques in total knee arthroplasty are often based on surgeons’ subjective judgment. However, newer technologies have allowed for objective measurements of soft-tissue balancing. This study compared the use of sensor technology to the 30-year surgeon experience with respect to: 1) compartment pressures; 2) soft-tissue releases; and 3) implant congruity.

METHODS
We prospectively compared patients who received sensor-guided soft-tissue balance (n=10) to a manual gap-balancing cohort (n=12). Wireless, intra-operative sensor tibial inserts were used to measure intra-compartmental pressures. The surgeon was blinded to the values in the manual gap-balancing cohort. In the sensor cohort, the surgeon was unblinded, and ligamentous releases were performed in order to balance compartmental joint pressures. Pressure measurements were taken in both compartments at 10°, 45°, and 90°.

RESULTS
The sensor cohort had lower medial and lateral compartment loading at 10°, 45°, and 90°. The sensor group had lower mean differences in inter-compartment loading at 10° (-5.6 vs. -51.7 lbs), 45° (-9.8 vs. -45.9 lbs), and 90 degrees (-4.3 vs. -27 lbs) compared to the manually-performed cohort. There were 10 soft-tissue releases in the sensor cohort. In the gap-balanced cohort, the tibial tray was positioned at a mean of 9° of external rotation, whereas the sensor-guided cohort had 6 knees placed in a mean of 3° internal rotation and 4 in a mean of 3° external rotation.

CONCLUSION
Sensor-balanced TKAs provide objective feedback to perform releases to improve knee balancing and implant congruity.
Optimization of Tissue Properties Using an Instrumented Trial Knee Implant

JASON HALLORAN PhD, ROBB COLBRUNN PhD, CHRISTOPHER ANDERSON MS

INTRODUCTION
Understanding the relationship between knee specific tissue behavior and joint contact mechanics remains an area of focus. Seminal work from 1990’s established the possibility to optimize tissue properties for recreation of laxity driven kinematics (Mommersteeg et al., 1996). Yet, the uniqueness and validity of such predictions could be strengthened, especially as they relate to joint contact conditions. Understanding this interplay has implications for the long term performance of joint replacements. Development of instrumented knee implants, highlighted by a single use tibial insert trial with embedded sensor technology (VERASENSE, Orthosensor Inc.), may offer an avenue to establish the relationship between tissue state and joint mechanics. Utilization of related data also has the potential to confirm computational predictions, where both rigid body motions and associated reactions are explicitly accounted for. Hence, the goal of this work was to evaluate an approach for optimization of ligament properties using joint mechanics data from an instrumented implant during laxity style testing. Such a framework could be used to inform joint balancing techniques, improve long term implant performance, and alternatively, qualify factors that may lead to poor outcomes.

METHODS
Experimentation was performed on a 52 year old male, left, cadaveric specimen. Joint arthroplasty was performed using standard practice by an experienced orthopedic surgeon. To mimic passive intraoperative loading, laxity loading at 10°, 45° and 90° flexion, which consisted of discrete application of anterior-posterior (+/- 100N), varus-valgus (+/- 5 Nm) and internal-external (+/- 3 Nm) loads at each angle, was performed using a simVITRO robotic musculoskeletal simulator (Cleveland Clinic, Cleveland, OH). Experimental results included relative tibiofemoral kinematics and sensor measured metrics (Fig 1). The finite element model was developed from specimen-specific MRIs and solved using Abaqus/Explicit. The model included the rigid bones, appropriately placed implants and relevant soft-tissue structures (Fig. 1). Ligament stiffness values were adopted from the literature and included a 6% strain toe region. Sets of nonlinear springs, defined using MR imaging, comprised each ligament/bundle. Optimization was performed, which minimized the root mean squared difference between VERASENSE measured tibiofemoral kinematics and sensor measured metrics (Fig 1). The finite element model was developed from specimen-specific MRIs and solved using Abaqus/Explicit. The model included the rigid bones, appropriately placed implants and relevant soft-tissue structures (Fig. 1). Ligament stiffness values were adopted from the literature and included a 6% strain toe region. Sets of nonlinear springs, defined using MR imaging, comprised each ligament/bundle. Optimization was performed, which minimized the root mean squared difference between VERASENSE measured tibiofemoral mechanics and the model predicted values. Ligament slack lengths were the control variables and the objective included each loading state and all contact metrics (D, AFD, ML, and LL). TM Figure 1

RESULTS AND DISCUSSION
The model successfully recreated joint kinematics with average errors of 4° for rotations and 3 mm for translations, across all flexion angles (Fig 2). Though a systematic offset in D was observed, model versus experiment contact locations were also in good agreement. Reaction forces were generally over-predicted by the model, but retained the overall trend (Fig 2).
Sensitivity analysis also supported this finding. In light of the larger focus of this project, testing also included systematic removal of key tissues followed by repeat testing, as evaluated across numerous specimens. Overall, the presented framework represents a promising step towards establishing simulation-based tools able to support exploratory studies as well as the clinical decision-making process. Future work will evaluate efficacy across numerous specimens and assess sensitivity to key modeling and experimental parameters.
Can Systematic Medial Collateral Ligament Needle Puncturing Lead to a Predictable and Safe Reduction in Medial Tension During Total Knee Arthroplasty

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PURPOSE
Traditional ligament release can be unpredictable. This study examines the safety and efficacy of multiple needle puncturing technique of the MCL.

METHODS:
• Total n=10 cadavers
• 5 sets of 5 punctures performed on MCL (with 18-gauge needle)
• 5 traverse perforation made (with 11-blade)
• Pressure measurements analyzed
• Anatomic study of all MCL specimens performed

RESULTS:
• Pressure sensors correlated more closely with systematic release than gap increase
• All knees had less than 5mm of medial opening with up to 25 needle punctures
• Mean pressure decreases were 11.2, 9.4, and 9.9 psi after 5 needle punctures, and 8.1, 11.5, and 9.6 between 5 and 15 needle punctures
• Puncturing led to significant medial pressure reduction

CONCLUSIONS:
Needle puncturing of MCL leads to reliable and significant decrease in medial tension for the first 15 punctures, diminishing with 25. This method may be useful when, up to, 20 psi reduction is desired.
INTRODUCTION

The main principles behind restoring optimal function in a total knee replacement (TKR) surgery are creating aligned bone cuts, along with proper soft tissue balance throughout flexion (Whiteside 2002). Balancing of the soft tissue has been shown in previous studies to have advantages such as greater post-operative patient satisfaction and better clinical outcome (Uttit 2008, Matsuda 2005, Winemaker 2002). Balancing can be achieved through small changes in bone cuts, soft-tissue releases, changes in component size, and rotation of the tibial component (Walker et al, 2014). Until recently, balancing was based on the surgeon’s feel and use of spacer blocks or distractors, which was heavily dependent on experience and did not provide quantitative balancing data. In this study, we describe a method for quantifying balancing throughout the flexion range using an instrumented tibial trial (OrthoSensor, Inc, Dania, FL), which provides numerical intraoperative balancing data. This method has been linked to greater postoperative patient satisfaction (Gutske 2014). Notwithstanding this technological advance, the process of achieving balance is still complex and often time-consuming. In this study, we describe a method for quantifying balancing throughout the flexion range and quantify the effect of different surgical corrections on balancing. In this way, we determined how accurately balancing could be achieved within the practical time frame of a surgical procedure and how many surgical corrections were generally necessary when using an instrumented tibial trial.

METHODS

Data was obtained from 80 primary procedures using a PCL-retaining device. Initial bone cuts were made using navigation. Instrumented tibial trials were used to measure the contact forces and locations on the lateral and medial sides. These forces were generated by the pre-tensions in the collaterals supplemented by the PCL and the capsule. Video/audio recordings were made of all aspects of the surgeries. After performing bone cuts and removing osteophytes, the correct tibial insert thickness was determined using the Sag Test. The rotation of the insert was corrected by observing the contacts through the full range of flexion. The initial balancing was recorded after performing the Heel Push test. This was documented as lateral and medial contact forces as a function of flexion. The data was expressed as medial/total force ratio (total = medial + lateral), with 0.5 being equal lateral and medial forces. Surgical corrections specific to the obtained imbalance pattern were carried out, based on previous research (Walker et al, 2014). The Heel Push Test recording of load distribution was repeated after each correction and at final balancing. The load distribution was expressed as a scatter graph of lateral v. medial compartmental loads (Figure 1).
RESULTS
The initial balancing before correction showed that although the average ratio was 0.52+/-0.27 from 0-90 degrees, the data was scattered between 0.0 (lateral force only) and 1.0 (medial force only). The most common surgical corrections used to achieve balancing were: soft-tissue releases (49), changes in tibial insert thickness (27), bone adjustments (15), tibial rotational adjustments (7).

In 84% of the cases, 0-2 corrections were needed to obtain balancing (Range: 0-5). Balancing created an efficient clustering of the medial/total ratios about the 50% balanced value. 80% of the cases in early flexion (0-30 degrees) were balanced within 15% of the balanced state (79% for 30-60 deg of flexion, 77% for 60-90 deg of flexion). The mean ratio for all flexion angles was 0.52 with standard deviation of 0.16. The average total force on the condyles from 0-90 degrees was 290.5+/-166.8 Newtons (65.3+/-37.5 lbs) initially and 215.3+/-86.3 Newtons (48.4+/-19.4 lbs) after balancing.

DISCUSSION
By following a predetermined surgical correction algorithm, accurate balancing was achieved in the majority of cases within 0-2 surgical corrections. These included bone cuts and soft tissue releases. The clinical use of one strategy versus another can be determined by the amplitude of the intercompartmental load differential. Generally, load differentials in excess of 40 lbs dictate a bony trim, or joint plane inclination change, whereas smaller differentials can be handled by soft tissue releases. Because of the natural population variance in ligament stiffness there was no reference value for total contact force values. Clinically, the most important range for balancing was early flexion. Although a perfect load symmetry (0.5 ratio) might be intuitively desirable, the higher value of 0.52 may be concordant with the published varus / valgus ratio of 0.55, in healthy individuals (Heeserbeek 2008). A subsequent study is now underway to determine the effect of balancing on functional outcome and patient satisfaction scores.

CONCLUSION
Knees can be balanced within 15% of a mean value of 0.52 (medial load/total load) in 80% of cases using less than 2 surgical corrections

REFERENCES
Continued

DISCLOSURES

Borukhov I: Nothing to disclose
Meere PA: OrthoSensor: Consulting, royalties, ownership, institutional support (non-restrictive)
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Walker PS: OrthoSensor: Consulting, institutional support (non-restrictive)
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Figure 1. Scatter graph of inter-compartmental load distributions

Figure 2. Compartmental Pressure Ratio Distribution in Early Flexion before and after Balancing
Do Smart Tools Reduce the Need for Manipulation After Primary Total Knee Arthroplasty?

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PURPOSE
Sensorized trails were developed to assist the surgeon with ligamentous balancing. The purpose of this study was to retrospectively review the early results of sensor trials to determine if frequency of manipulation is decreased.

METHODS
- Total n=655 primary CR-TKAs – 343 sensor TKAs; 312 manual (2013-2014)
- Groups age, gender, and BMI-matched

RESULTS
Manipulation under anesthesia required in 13 patients, in both groups (3.8% in sensor; 4.2% in manual) (non-significant).

CONCLUSIONS
In the hands of high-volume, experienced surgeon, smart trails did not substantially reduce manipulation rate.
Bony Cuts or Soft-tissue Release? Using Intra-operative Sensors to Refine Balancing Techniques in TKA

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 in to 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 AND CONCLUSIONS
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.
Early Functional Outcomes of Cruciate Retaining Total Knee Arthroplasty Using Smart Tibial Insert Trial Technology

JEFFREY A GELLER MD

INTRODUCTION
Soft tissue balance and alignment have long been known to play an essential role in the long-term success of primary total knee arthroplasty (TKA). Until recently balance was confirmed based on intra-operative feel and experience. In this study we analyzed short-term outcomes of cruciate retaining TKA (CR-TKA) performed with a smart tibial trial device (STT), which provides real-time, intra-operative compartmental load and rotational congruency readings, to a comparable cohort of patients receiving conventional TKA where the same surgeon balanced the compartments based on feel and experience.

METHODS
Sixty seven patients received CR-TKA with STT and were matched to one-hundred non-STT consecutive controls using the same anesthesia, surgical approach, and post-operative rehabilitation and pain management protocol. Both groups were evaluated preoperatively and then post-operatively at three months and one year using Short Form 12 (SF12) and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) questionnaires. T-tests were used to compare average scores within each cohort, as well as between the two cohorts, for each time interval.

RESULTS
Patients in both cohorts had similar baseline demographics in age, sex, and pre-operative functional scores. At 3 months the STT group demonstrated slightly better but not significant WOMAC scores than the non-STT control group with function scores approaching significance (p=0.1). Additionally, those who received CR-TKA with STT had a significantly improved SF-12 physical component scores than the control group (p=0.007). In both groups the most rapid improvement occurred in the first 3 months post-op for all categories with score improvement ranging from 14 to 38. From 3 months to a year, both cohorts had a similar reduced rate of improvement in all categories except the SF12 mental component, which completely plateaued at 3 months.

DISCUSSION
Given the results of this case-control study, we conclude that STT can indeed help the surgeon balance compartmental loads and femoral-tibial rotational congruency and lead to improved short-term physical and functional outcomes in primary CR-TKA.