The following institutions have contributed research to this field of study:

- Advocate Health Care
  
- Bone & Joint Institute

- Cleveland Clinic

- Cleveland State University

- Emory Saint Joseph’s Hospital

- Florida Orthopaedic Institute
The following data is a compilation of biomechanical and clinical research performed during 2015, either in collaboration with or independent from OrthoSensor, Inc. The content herein is to be used for reference only.
<table>
<thead>
<tr>
<th>Page</th>
<th>Section</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Clinical Outcomes</td>
<td>6-Month Clinical Results: Sensor-Assisted TKA vs. Manual TKA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>90-Day Physical Therapy Analysis and Post-Operative Complications</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patient Satisfaction: Multicenter Results and Meta-Analysis</td>
</tr>
<tr>
<td>9</td>
<td>Economics</td>
<td>Cost-Effectiveness of Sensor-Assisted TKA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Projected Costs of Early Revision TKA: Multicenter Study</td>
</tr>
<tr>
<td>11</td>
<td>Surgical Techniques</td>
<td>Patellar Position Affects Intraoperative Compartmental Loads During Total Knee Arthroplasty: A Pilot Study Using a Novel Radiofrequency Knee Soft Tissue Balancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ensuring a Stable Total Knee Arthroplasty: Sensor-Guided Techniques Used to Quantify Sagittal Plane Balance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>How Does the Cement Mantle Affect Intercompartmental Joint Balance?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bony Cuts or Soft-Tissue Release? Using Intra-Operative Sensors to Refine Balancing Techniques in TKA.</td>
</tr>
<tr>
<td>16</td>
<td>Revision Total Knee Arthroplasty</td>
<td>The Use of Sensor Technology Allowing Implant Salvage In Selected Cases of Revision Total Knee Arthroplasty: A Two-Case Retrospective Case Series</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Using Intraoperative Sensing Technology to Guide Revision in the Chronically Painful Total Knee: Two-Patient Consecutive Case Series</td>
</tr>
<tr>
<td>20</td>
<td>Biomechanical Evaluations</td>
<td>Relating TKA Tissue Release to Joint Response Using an Instrumented Trial Implant</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Accuracy of Balancing at Total Knee Surgery Using An Instrumented Tibial Trial</td>
</tr>
</tbody>
</table>
6-Month Clinical Results: Sensor-Assisted TKA vs. Manual TKA

Data from 30 consecutive sensor-assisted patients was compared with that of 30 consecutive manual TKA patients implanted with the Smith & Nephew JOURNEY II Cruciate-Retaining Total Knee System from the same surgeon during the same year. There was no significant difference between the two groups with respect to age, gender and BMI.

SUMMARY

Pre-operatively, the VERASENSE patient group consistently scored lower than the manual TKA group. However, the VERASENSE group improved between 1.5 and 2 times faster by 6-months, post-operatively.

Additionally, both active and passive ranges of motion measured during physiotherapy were significantly higher in the VERASENSE group. This is significant, given published literature showing a correlation between improved range of motion and a decreased incidence of manipulation procedures following primary TKA.1,2

**IMPROVEMENT RATE OF VERASENSE GROUP**

**(TIMES FASTER THAN MANUAL TKA)**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>KSS Pain</td>
<td>1.69</td>
</tr>
<tr>
<td>KSS Function</td>
<td>1.66</td>
</tr>
<tr>
<td>KSS Total</td>
<td>1.68</td>
</tr>
<tr>
<td>Oxford Knee Score</td>
<td>1.5</td>
</tr>
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</table>

Intraoperative and follow-up data from 100 consecutive VERASENSE Sensor-Assisted TKA patients were compared with that of 100 consecutive manual TKA patients, each implanted with the Smith & Nephew LEGION Posterior Stabilizing Total Knee System. The two groups were matched for age, gender, marital status, insurance type, smoking proclivity and BMI.

SUMMARY
There was a significantly higher occurrence of stiffness and subsequent need for manipulation in the manual TKA group within the 90-day window.

By 90 days post-op, all modes of range of motion were higher in the VERASENSE group. There was also a 70% decrease in the incidence of manipulation, as compared to the manual TKA group.

### POST-OPERATIVE COMPLICATIONS

<table>
<thead>
<tr>
<th></th>
<th>MANUAL TKA</th>
<th>VERASENSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>71%</td>
<td>89%</td>
</tr>
<tr>
<td>Infection</td>
<td>8%</td>
<td>7%</td>
</tr>
<tr>
<td>Other</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Manipulation</td>
<td>2%</td>
<td>7%</td>
</tr>
</tbody>
</table>

### POST-OPERATIVE JOINT STIFFNESS

<table>
<thead>
<tr>
<th></th>
<th>MANUAL TKA</th>
<th>VERASENSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>76%</td>
<td>92%</td>
</tr>
<tr>
<td>No</td>
<td>24%</td>
<td>8%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>MANUAL TKA</th>
<th>VERASENSE</th>
<th>P-VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Operative Range of Motion</td>
<td>105.7</td>
<td>102.4</td>
<td>0.214</td>
</tr>
<tr>
<td>Pre-Operative KSS Function</td>
<td>55.5</td>
<td>48.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-Operative Stiffness</td>
<td>24</td>
<td>8</td>
<td>0.002</td>
</tr>
<tr>
<td>Post-Operative Complications</td>
<td>29</td>
<td>12</td>
<td>0.002</td>
</tr>
<tr>
<td>Surgical Interventions within 90 Days</td>
<td>25</td>
<td>10</td>
<td>0.004</td>
</tr>
</tbody>
</table>
TOTAL KNEE ARTHROPLASTY SATISFACTION:
- Patients typically report being less satisfied than THA patients\(^1\)\(^-\)\(^3\).
- The average proportion of TKA patients reporting post-operative satisfaction is 81%\(^4\)\(^-\)\(^13\).
- Low satisfaction levels are multifactorial and may be due to increased pain, decreased function, mismanaged expectations or a combination of all three factors\(^5\)\(^-\)\(^6\).

WHAT HAPPENED WHEN WE SENSORS WERE USED TO QUANTIFY BALANCE AND IMPROVE KINEMATICS IN THE OPERATIVE KNEE JOINT?

Saturation Survey Administered to Patient Group (Face Validity)

**PRIMARY TKA PATIENTS REPORTING SATISFACTION**

Average Patient Satisfaction Reported in Literature 81% (Brown-Forsythe=3.048; homogeniety <0.001; df=11)

Sensor-Assisted Patients Exhibiting Balance 97% P < 0.001

PATIENT-REPORTED SATISFACTION: “SATISFIED” TO “VERY SATISFIED” COMPARISON TO LITERATURE


Quality Adjusted Life Year (QALY) is a measurement of cost-effectiveness of a medical treatment or surgical intervention. The QALY output is based on how much a patient’s quality of life improves as a result of a given treatment or intervention. A robust QALY analysis will take into account an individual’s life expectancy, any potential future adverse events associated with the treatment and any decrease in effectiveness of the treatment over time.

The QALY output indicates a number of years of “perfect health” that is added to a patient’s life as a result of treatment. Reimbursement for medical and surgical intervention is given to treatments which add “perfect health” years to a patient’s lifespan and do not exceed $50,000 in cost per year added.1, 2 The lower the cost and higher the extension of life, the higher the clinical and economic efficacy of the treatment.

**Average benefit of manual TKA: 2.02 QALYs**

**SENSOR-ASSISTED WOMAC AS QUALITY OF LIFE MEASURE**

Based on:
- Life expectancy (85 years F; 80 years M)
- 3% declination rate (per year)
- 5% revision at 15 years

**SUMMARY**

Average Sensor-Assisted QALY in 120 multicenter patients: 3.6

Calculated Incremental Cost Effectiveness Ratio: $500/QALY (vs Manual TKA)

Therefore, sensor-assisted TKA is highly cost-effective and may add more “perfect health” years to a patient’s life than manual TKA alone

Highest QALY: Obese patients - 5.5 (P=0.039) | < 70 years old - 5.3 (P<0.001)

The overall revision rate for TKA in the United States has been reported at 12-13% annually.\textsuperscript{1,2} With over 1/3 of these reported to occur within the first two years,\textsuperscript{3} approximately 4.5% of total knee arthroplasties result in early revision.

The annual financial burden for revision TKA is 2.7 billion dollars; each procedure commands an average of over $73,000 in hospital charges.\textsuperscript{4,5}

In a multicenter evaluation, 278 patients received sensor-assisted total knee arthroplasty. At 3-years since the initiation of the study, only 0.4% of the cohort (n=1) has had revision surgery.

Patellar Position Affects Intraoperative Compartmental Loads During Total Knee arthroplasty: A Pilot Study Using a Novel Radiofrequency Knee Soft Tissue Balancer

SCHNASER, E; LEE, Y; BOETTNER, F; GONZALEZ DELLA VALLE, A.

INTRODUCTION

• Soft tissue imbalance leads to suboptimal results in TKA surgery.
• In order to assess the balance in flexion, the extensor mechanism is usually lateralized or everted.
• The lateralized (or everted) extensor mechanism may act as a lateral tether, artificially increasing the loads in the lateral compartment.
• **Goal of the study:** to assess the intraoperative compartment loads during TKA with different positions of the patella and extensor mechanism.
• We hypothesized that the position of the patella during gap assessment influenced the distribution of loads on the medial and lateral compartments of the knee.

MATERIAL AND METHODS

• 56 PS TKAs (53 patients)
• Medial parapatellar approach
• Femur prepared with a 5° valgus cut and rotation parallel to the epicondylar axis (anatomic rotation)
• The tibia was resected with a 0 degree posterior cut, perpendicular to the mechanical axis
• Extension and flexion gaps balanced with laminar spreaders and blocks
• Soft tissue releases were performed to obtain ≤3mm gap variance between the medial and lateral compartments.
• After achieving balance, trial components were inserted
• A radiofrequency-based electronic load sensor deviced with a shape and thickness of the selected polyethylene insert was inserted and locked in the tibia tray (VERASENSE Knee System - Orthosensor Inc., Dania Beach, FL)

RESULTS

**MEAN LOADS IN THE MEDIAL COMPARTMENTS**

Significantly lower loads were observed in the medial compartment with the patella lateralized or everted at 45°, 90°, and full flexion (p<0.001).

**MEAN LOADS IN THE LATERAL COMPARTMENTS**

A lateralized or everted patella resulted in significantly higher lateral compartment loads at 45 and 90 degrees of flexion.

**MEAN ABSOLUTE LOAD DIFFERENTIAL BETWEEN MEDIAL AND LATERAL COMPARTMENTS**

The highest load differentials between the medial and lateral compartments were seen at 45° and 90° of flexion with a lateralized or everted patella, supporting the theory of “tether effect” produced by the extensor mechanism.

**MEAN TOTAL LOADS**

The total loads observed with the patella lateralized or everted were significantly lower than those observed with a reduced patella at high knee flexion.
OrthoSensor.com | 12 | VERASENSE

Patellar Position Affects Intraoperative Compartmental Loads During Total Knee Arthroplasty: A Pilot Study Using a Novel Radiofrequency Knee Soft Tissue Balancer

SCHNASER, E; LEE, Y; BOETTNER, F; GONZALEZ DELLA VALLE, A.

(CONTINUED)

- Loads measured in the medial and lateral compartment in 5 knee positions with the patella in 4 separate positions (40 data points per knee)
  - Knee positions:
    1) Full gravity-assisted extension
    2) Relaxed extension
    3) 45° of flexion
    4) 90° of flexion
    5) Full gravity-assisted flexion
  - Patellar positions:
    1) Everted
    2) Lateralized
    3) Reduced in the trochlea
    4) Reduced in the trochlea with the retinaculum provisionally closed
- Outcome variables:
  1) Medial compartment loads
  2) Lateral compartment loads
  3) Load differential (load shift)
  4) Absolute load differential
  5) Total loads

DISCUSSION

- The loads in the medial and lateral compartments are affected by the position of the patella and the extensor mechanism.
- A progressive shift of loads from the medial to the lateral compartment was detected with progressive knee flexion.
- The load changes suggests that the lateralized extensor mechanism acts as a tether for the lateral compartment predominantly at 45° and 90° of flexion
- Assessment of knee balance in flexion with the patella lateralized or everted, may lead the surgeon to overestimate the loads in the lateral compartment.

RESULTS 2

MEAN LOAD DIFFERENTIAL BETWEEN MEDIAL AND LATERAL COMPARTMENTS

A shift in loads from the medial to the lateral compartment was seen with progressive knee flexion. The shift of loads from the medial to the lateral compartment was greater with lateralized or everted patella.

--- PLWOC - Patella located in trochlea without provisional retinacular closure.
--- PLWC - Patella located in the trochlea with provisional retinacular closure.
--- PL - Patella lateralized.
--- PE - Patella everted.

DISCLOSURES: Paid consultant for Intralign; YL:None; FB: Paid consultant for DJOrtho, Smith & Nephew, OrthoDevelopment; AGDV: Paid consultant for Orthosensor, Microport, Link Bio, Orthodevelopment

Ensuring a Stable Total Knee Arthroplasty: Sensor-Guided Techniques Used to Quantify Sagittal Plane Balance

MARTIN ROCHE, MD; KENNETH GUSTKE, MD; GREGORY GOLLADAY, 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 producing real-time feedback of femoral contact points and joint kinetics. Intra-operative kinetic 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 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. (FIGURE 1)

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. Excessive excursion of the femoral contact points across the bearing surface and femoral contact points translating through the anterior third of the tibial trial were indications 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 excessively 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.
How Does the Cement Mantle Affect Intercompartmental Joint Balance?

BACKGROUND
- Obtaining joint balance is a crucial aspect for maximizing post-operative clinical outcomes1-4.
- Significant changes in alignment/balance may occur during final implantation, even with the use of navigated bony cuts5.
- The added thickness of the cement mantle has been observed to affect the mechanical axis and flexion/extension gaps6.

PATIENTS & METHODS
- 93 sensor-assisted TKAs evaluated for pre- and post-cementation balance.
- All patients were balanced (mediolateral loading differential ≤ 15 lbs.) prior to cementation.
- 2 surgeons/2 experience levels: Surgeon 1 > 15 years of practice; Surgeon 2 < 5 years of practice.
- 2 cement types/viscosities (medium, high).
- 3 knee systems: (Stryker® Triathlon®, Zimmer Biomet NexGen®, Zimmer Biomet Vanguard®).

RESULTS
There was no significant difference in incidence of imbalance with respect to:
- Cement Type (P=0.429).
- Surgeon Experience (P=0.456).
- Knee System (P=0.792).

CONCLUSIONS
- There is a high level of loading variability associated with cementation of TKA components.
- There is a significant incidence of imbalance after cementation.
- Neither cement viscosity nor surgeon experience contributed to the large proportion of post-cementation imbalance.
- Intraoperative sensors may help mitigate residual imbalance after cementation.

REFERENCE
1) Babazedah S, Stoney JD, Lim K, Chiou P. The relevance of ligament balancing in total knee arthroplasty: how important is it? A systematic review of the literature. Orthop Rev. 2009; 1(26); 70-78.
Bony Cuts or Soft-Tissue Release? Using Intra-Operative Sensors to Refine Balancing Techniques in TKA.

PURPOSE
This research uses intraoperative sensor data and patient-reported outcome scores to define a possible kinetic templating threshold, which may dictate surgical correction of bone versus soft-tissue release.

METHODS
A retrospective analysis of 122 sensor-guided TKA patients was conducted. Forty pounds-force was used as a templating threshold, above which bone was corrected and below which soft-tissue was corrected. All patients were categorized in three groups based on load threshold and performed correction.

RESULTS
The patient groups that followed the surgical algorithm reported significantly higher clinical outcomes scores at 1-year.

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

PATRICK A. MEERE, MD
DEPARTMENT OF ORTHOPAEDIC SURGERY NYU HOSPITAL FOR JOINT DISEASES

CASE I

PATIENT: 57 year old female, 18 months after a primary total knee arthroplasty.

CLINICAL PRESENTATION: Persistent pain, swelling and instability. Inability to stand, walk or perform stairs without significant pain and stiffness. No improvement despite diligent and supervised physiotherapy for over a year. Complains of inability to fully stretch. Positive antalgic gait with 10 degrees lack of extension contracture, further passive flexion range up to 95 degrees. Positive chronic effusion and periarticular swelling. No gross opening during varus or valgus stress test. Negative sag, less than 2 mm anterior draw in flexion. Radiographs show a satisfactory alignment and sizing with no evidence of malrotation (Figure 1)

INTENDED PLAN: Open arthrotomy, lysis of adhesions, probable femoral revision with distal femoral recession to regain flexion / extension balance.

OPERATIVE FINDING: At the time of surgery load mapping identified the dominant instability as excessive medial tightness in extension with an excessively high load differential: 82 lbf medially v. 23 lbf laterally (Figure 2). The medial and lateral loads in flexion were tensioned appropriately (Figure 3). 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 load balance. The resultant loads in supported extension were 36 lbf medially v. 32 lbf laterally and in flexion (90 degrees) 10 lbf medially v. 13 lbf laterally (Figures 4-5). The intra-operative passive range of motion (PROM) measured 0-123 degrees. The metallic implant components were preserved.

RESULTS:

Post-Operative Course: The WOMAC scores improved from 46.2 (pre-op) to 86.2 at 6 weeks and 88.6 at 8 months post-operatively. The total Knee Society Score (KSS) improved from 70 points (pre-op) to 169 points at 8 months. The KSS pain and function separately improved from 25 to 89 points and 45 to 80 points respectively. The PROM improved from 10-90 degrees (pre-op) to 0-122 and 0-127 for the same post-op intervals. The improved range was preserved to date.

FIGURE 1
FIGURE 2 Extension
FIGURE 3 Flexion
FIGURE 4 Extension
FIGURE 5 Flexion

CASE II

PATIENT: 77-year-old female with recent MCL injury on 10-year-old left TKA.

CLINICAL PRESENTATION: Three months of instability, persistent pain diffusely in the left knee after sustaining an accidental fall in a department store. Prior to this the clinical function was good and there was no radiological evidence of wear on her posterior stabilized left knee total knee arthroplasty performed over 10 years ago (Figure 6). Subsequent to the fall with hyperdeviation and forceful flexion, the patient developed recurrent and persistent instability of the left knee. Physical exam confirmed a grade II laxity of the medial collateral ligament with dull point tenderness at the femoral insertion point. There was associated multidirectional instability, recurrent effusion, synovitis and periarticular tissue edema. The PROM was -3 to 107. The valgus stress test at 10 degrees of flexion showed 5mm medial opening with a soft endpoint. On varus stress the lateral joint opened by 3mm. The anterior drawer test showed anterior translation by 4mm (grade 2). The posterior draw was stopped by the post.

INTENDED PLAN: The patient was indicated for a left knee open arthroscopy, synovectomy, and lysis of adhesions, possible primary medial collateral ligament repair, probable augmentation of tibial liner with soft tissue recalibration with the use of pressure mapping technology, possible full revision to a Total Stabilized TKA based on medial opening stability and ability to generate sufficient and functional contact resting loads.

OPERATIVE FINDINGS: The patient was found to have the anticipated diffuse synovitis secondary to chronic multidirectional instability. The MCL was found to be plasticly deformed by approximately 10% but with very good residual elasticity. There was no evidence of mechanical dissociation of the implants. The patient was found to have significant patella baja with arthrofibrosis of the infrapatellar ligament.

Compartmental tibial load mapping indicated insufficient load on the medial side, reflecting the known traumatic laxity of the medial collateral ligament in extension (Figure 7). To increase the contact load to an acceptable level, a liner thickness augmentation is required. This however caused overstuffing of the lateral compartment in extension.

FIGURE 6
FIGURE 7 Extension
FIGURE 8 Flexion
FIGURE 9 Extension
FIGURE 10 Flexion
CASE II (CONTINUED)

(Figure 8). This was then corrected by a rim coronal ligament release (arcuate plus 3mm of the lateral iliotibial band insertion up to Gerdy’s tubercle) on the lateral side and final liner thickness augmentation by 5mm. The coronal load balance was thus optimized to less than 10 pounds differential in extension and in flexion (Figure 9-10).

The above pathway pertains to static loads.

RESULTS:

Dynamic load evaluation through a varus / valgus maneuver (at 10 degrees of flexion) can produce load differentials that reflect the tension in the ligaments opposite to the direction of the applied force. Varus loading with 25 N force created a 20 lbf load differential on the medial compartment, representing the tightness of the lateral collateral ligament. Valgus loading with the same 25 N force generated a 17 lbf load differential, confirming the sufficient resiliency of the MCL. This ligamentous stability was deemed to be very acceptable and preferable to a full revision to a TS component.

Post-Operative Course: Discharged on post-operative day (POD) 2. Single cane on POD 10. Unassisted ambulation by POD 20 with walking tolerance of 6 blocks, no assist on stairs. Post-operative exam at 21 days reveals minimal pain or tenderness. Medial opening on valgus stress of less than 3mm. PROM: -3 to 112 degrees. The WOMAC score improved from 47.7 (pre-op) to 84.8 at 6 weeks.

DISCUSSION

In this short case series, two patients presented with chronic instability, pain, and effusion in an established TKA joint. All asymmetric loading was confirmed and corrected through the use of the intraoperative sensor system. The initial operative plan for both cases indicated a potential need for exchange of metal components. However, digital guidance provided by the sensor system obviated the need for the surgeon to exchange any metal components, thereby avoiding patient morbidities and excess cost associated with revision surgery.

In Case I, the patient presented with coronal soft-tissue imbalance, driven by excessive tension in the posterior medial collateral ligament fibers. In such cases, load mapping sensor technology helps the surgeon to define the specific deficiency and probable best correction. In many revision cases, the imbalance is coronal rather than sagittal. Thus, implant salvage may be feasible, sparing the patient the morbidity associated with a complete revision of all TKA components.

In Case II, the decision to convert an unstable TKA after a serious MCL injury relied on the subjective impression of medial joint line opening and shearing upon valgus stress testing. The adjunct use of sensor technology in this case allowed for quantified evidence of the morbid imbalance and assisted in the performance of titrated release of the relatively tighter contralateral ligament and capsule upon liner thickness augmentation. Finally, the response to physiological loading of the collateral ligaments showed symmetrical ΔP’s (rapid pressure differentials during the load impulse application and recoil). This confirmed the restoration of functional stability to the joint. Of note was the fact that the implant salvaged in this case was of a different manufacturer than that for which the sensor was designed. Nonetheless, undersizing by one size allowed for a good fit and translational stability for compression load testing purposes.

This small case series provides promising results for the efficacy of using intraoperative sensor technology during revision cases requiring the correction of instability. Further case studies and longer follow-up will need to be obtained to understand long-term outcomes.

INTRODUCTION

The popularity of total knee arthroplasty coupled with the aging population suggests a dramatic increase in revision TKA procedures. While this procedure has proven to be an effective treatment for late-stage osteoarthritis, many recipients return to clinic reporting pain and instability. Up to 20% of TKA patients are dissatisfied with their outcome. As a result of unfavorable clinical outcomes, the risk of revision after primary TKA is 14.9% for men and 17.4% for women. Revision TKA is costly, both financially and to the health of the patient. The average charge for a TKA revision surgery in the U.S. is $73,696, with a considerably larger cost for patients undergoing surgery because of deep joint infection, patients receiving a three component exchange, and patients receiving hinged or constrained condylar knee implants. The number of TKA revisions is estimated to increase by 66% with projected hospital costs in excess of $13 billion by 2030. Patients who undergo revision TKA are at a greater risk for complications than patients who have a primary TKA, exhibiting poorer functional outcomes and, oftentimes, requiring additional invasive procedures. It is imperative that more precise methods are developed to accurately guide implant positioning and soft-tissue balance during primary TKA to yield a more consistent clinical result. It is also critical that such methods are developed to diagnose specific problems during revision TKA to facilitate surgical correction and implant salvage when feasible. Therefore, the purpose of this consecutive, two-patient case series was to test the efficacy of using intraoperative sensing technology to effectively guide revision surgery in patients with debilitating and chronic pain.

CASE I

PATIENT: 60-year old male; BMI of 33.5 kg/m2. Uni-recipient previously revised to total.

CLINICAL PRESENTATION: Persistent and debilitating pain posteromedially in flexion. Proximal medial tibia and medial joint line tenderness. Pain exacerbated with activity, often keeps patient awake at night. Exhibited a compressed, tentative and slow gait.

DIAGNOSIS: Failed left total knee replacement. Tibial component loosening; rotational incongruency between femoral and tibial components (Figure 1).

OPERATIVE FINDING: The tibial tray was found to be loose with deficiencies between the metal tray and cement while the femoral and patella components were stable and appropriately positioned.

Prior to making adjustments and removing the tibial tray, the original polyethylene insert was removed and the VERASENSE™ sensor was inserted to evaluate the pre-revision position of tibial tray rotation (with referencing to the mid-third of the tubercle) in relation to the femur. The data from the sensor (displayed on user interface depicted in Figure 1) showed excessive internal rotation of tibial component indicated by incongruent contact points on the virtual tibial surface (non-parallel contact points indicated by arrows, Figure 2). The femoral contact point on the medial surface was located in the central third of the tibial tray while the femoral contact point was displaced posterior on the lateral side. Laxity in the medial and lateral compartments was indicated by loading pressures of < 10 lbs (circled, Figure 2) in each compartment.

OPERATIVE RECONSTRUCTION: A new tibial tray was placed and rotated more externally until medial and lateral contact points were parallel (congruent) and located within the central third of the tibial tray. Five-millimeter hemiblocks were added to the medial and lateral sides of tibial component to induce normal tension in each compartment. A small cemented stem was also added for improved stability. The knee was reduced using a 13 mm VERASENSE spacer. The data measurements displayed on the user interface confirmed final rotational congruency between the femoral and tibial components (arrows, Figure 3), as well as favorable induced tension in both the medial and lateral compartments of approximately 20 lbs. (circled, Figure 3).

6-WEEK FOLLOW-UP: Patient continuing physical therapy regimen, states that he is feeling well. Patient also states that the knee feels very stable, and that he is eager to have the contra-lateral side revised as well. Patient was walking nicely without any detectable limp and no longer using an assistive device. His knee fully extended with no lag or laxity present and is able to actively flex 100°.
CASE II

PATIENT: 55-year old female; BMI of 31 kg/m²; underwent primary total knee replacement one year prior.

CLINICAL PRESENTATION: Persistent pain, swelling, and prolonged stiffness with inability to obtain full extension (lacked 14° or flexion (80°)). Previous closed manipulation under anesthesia to improve range of motion has proven futile. Persistent limp and discomfort upon walking or standing. Pain makes it difficult to get comfortable for sleep. Despite efforts by physical therapy, foot tends to externally rotate with extension.

DIAGNOSIS: Painful total knee replacement with medial instability; rotational incongruency between femur and tibia due to tibial external rotation (Figure 4).

OPERATIVE FINDING: Patient lacked 14° of terminal extension; medial laxity present in extension and various degrees of flexion. Femoral component stable and appropriately rotated relative to the epicondylar axis, though slightly lateralized. Tibial tray exhibited visual external rotation. PCL was tight with no pivot.

VERASENSE was activated and inserted prior to removing the tibial component. The sensor system confirmed both excessive external rotation of the tibial tray (non-parallel contact points indicated by arrows, Figure 5), as well lack of loading medially/ excessive loading laterally (circles, Figure 5).

OPERATIVE RECONSTRUCTION: After recutting the proximal tibia and down-sizing the tray, the appropriate size VERASENSE sensor was used to guide the optimization of tibial tray rotation (arrows, Figure 6). With rotational congruency established, the medial and lateral loading auto-equalized without intervention (circles, Figure 6). The PCL now appeared to be functioning appropriately as a result of correction of the tibial tray rotation.

6-WEEK FOLLOW-UP: Patient states that she feels very good. She repeatedly stated that the revised knee now feels like a “real knee.” Patient also states that the knee feels “sturdy” and that she is eager to begin riding her bike again. Patient stood and walked without hesitation, no presence of limp, and without an assistive device. Her range of motion was completely pain-free; she is now able to achieve full extension and 105° of flexion. She exhibited no laxity or lag.

DISCUSSION

Revision total knee arthroplasty presents intraoperative challenges to the surgeon, recovery hurdles for the patient and greatly contributes to the already staggering financial burden associated with TKA.13,6 Thus, developing new methods with which to dynamically guide the surgeon through complex cases may help more precisely diagnose the specific mechanical or soft tissue problems leading to unsatisfactory outcomes. These methods may result in a more directed approach to revision surgery, potentially avoiding the removal of some components and diminishing unnecessary soft tissue dissection or release – subsequently sparing the patient morbidity and unwarranted costs.

In this short case series, two patients presenting with chronic and debilitating pain have had revision total knee arthroplasty performed using intraoperative sensing technology. At the 6-week post-operative visit, both patients are fully ambulatory without the need of assistive devices. They report that they are satisfied with their new knee and that the knee feels “good.” Most notable is the patient from Case I. This patient had previously undergone several revision surgeries without alleviation of symptoms. However, at the 6-week post-operative interval, he no longer limps and has expressed eagerness to have his contralateral side re-operated.

Both Cases I and II presented with tibial tray malrotation, which was diagnosed and corrected with the guidance of the intraoperative sensor. In Case II, mediolateral intercompartmental loads — as well as PCL restrictions—corrected after optimizing tray rotation. No other releases were necessary. This confirmation by the sensor system obviated the need for the surgeon to further address any ligament tension. In Case I, the need for increased tension was indicated by the sensor system, prompting the surgeon to add medial and lateral hemiblocks and a thicker tibial spacer until appropriate bearing surface loading was obtained.

This small case series provides promising results for the efficacy of using intraoperative sensing during complex revision cases. Further case studies and longer follow-up will need to be obtained to understand long-term outcomes.
BACKGROUND
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

OBJECTIVES
To quantify the effects of common soft-tissue releases as they relate to sensor-measured joint reactions and kinematics, such as...
• Does PCL release affect lateral compartment load?
• Does Popliteus release affect medial compartment load?
• At what flexion angles?

METHODS
Robotic testing of specimen specific soft-tissue releases (Table 1)
• 4 total specimens
• “on” = native and “off” = full release
• Tested 4 clinically-relevant structures:
  - Popliteus
  - Posterior cruciate ligament (PCL)
  - Deep MCL (dMCL)
  - Superficial medial collateral ligament (sMCL)
LOADING: quasi-static laxity profiles included discrete states:
• 10°, 45° and 90° knee flexion
• Each flexion angle: +/- 100 N A-P, +/- 3 N/m I-E and +/- 5 N/m V-V
• Nominal 20 N compressive force for all states
ANALYSIS: regression formulas (Equation 1)
• Relate sensor output to tissue state
• Analyzed across all loading conditions
• Significance set to p ≤ 0.05

TABLE 1
<table>
<thead>
<tr>
<th>STATE (ON: 1</th>
<th>OFF: 0)</th>
<th>SPECIMEN 1</th>
<th>SPECIMEN 2</th>
<th>SPECIMEN 3</th>
<th>SPECIMEN 4</th>
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<tr>
<td>STEP #</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td>Popliteus</td>
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</tr>
<tr>
<td>dMCL</td>
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<td>1 1 1 1 1</td>
<td>1 0 0 0 0</td>
<td>1 1 1 1 1</td>
<td>1 1 1 1 1</td>
</tr>
<tr>
<td>sMCL</td>
<td>1 1 1 1 1</td>
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<td>1 1 1 1 1</td>
<td>1 1 1 1 1</td>
<td>1 .5 .5 .5 .5 1 0 0</td>
</tr>
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</table>

EQUATION 1: An example of a regression equation for Lateral Load at 10° flexion with appropriate coefficients displayed

\[
\text{Lateral Load} = 9.1 + 4.9 \times \text{varus} + 162.5 \times \text{valgus} + 148.4 \times \text{post drawer} + 121.8 \times \text{IR} - 7.4 \times \text{ER} + 66.2 \times \text{shim thickness} - 65.6 \times \text{IT band} + 0.5 \times \text{popliteus} - 164.3 \times \text{PCL} - 47.6 \times \text{sMCL}
\]
RESULTS

sMCL and PCL releases dependent on flexion (Table 2)
- Release of popliteus increased medial and total joint loads at 10° only (not shown)
- PCL resection:
  - 10° of flexion - lateral and total joint loads decreased
  - 45 and 90° flexion - lateral load increased
  - 90° flexion - off loaded medial compartment
- Significant anterior shift of femur increased with flexion angle, tibial rotation only affected at 90°
- Deep medial collateral ligament
  - No significant relationship discovered
  - Confounded on other variables
- sMCL release decreased total load across all flexion angles, impacted medial load at 10° only

CONCLUSION

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. 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.
- These data have the potential to be applied intraoperatively to guide soft-tissue releases in an effort to obtain a well-balanced knee.

FUTURE WORK:
- Examine roles of individual ligament bundles & graded effects of tissue releases.
- Computational modeling to quantify effects of clinically relevant tissue structures.

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TABLE 2

<table>
<thead>
<tr>
<th>STRUCTURE</th>
<th>Flexion (deg)</th>
<th>Medial Load (N)</th>
<th>Lateral Load (N)</th>
<th>Total Load (N)</th>
<th>Int. Rotation Tib. (°)</th>
<th>Ant. Fem Displacement (mm)</th>
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<td>PCL</td>
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<td>-23.6±22.6</td>
<td>-212.4±31.8*</td>
<td>(21±2.5)</td>
<td>(10.7±1.8)*</td>
<td>(-0.5±1.5)</td>
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<td>45</td>
<td>(3.4±31.2)</td>
<td>-33.9±15.0*</td>
<td>(49.2±38.4)</td>
<td>(3.4±3.5)</td>
<td>(-7.4±1.9)</td>
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<td>90</td>
<td>-64.6±23.0*</td>
<td>-30.4±8.6*</td>
<td>(-23.1±28.1)</td>
<td>(8.9±4.3)*</td>
<td>(6.8±1.3)</td>
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<tr>
<td>sMCL</td>
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<td>(212.4±17.2)*</td>
<td>(0.6±2.1)</td>
<td>(7.4±1.9)</td>
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<td>-88.9±32.2*</td>
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<td>(5.4±2.9)</td>
<td>(1.6±1.3)</td>
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<td>(2.1±3.2)</td>
<td>(-0.5±1.5)</td>
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</table>

Accuracy of Balancing at Total Knee Surgery Using An Instrumented Tibial Trial

PATRICK A MEERE, MD, CM | PETER S WALKER, PHD | SVENJA SCHNEIDER

BACKGROUND
- In total knee replacement (TKR) surgery, soft tissue balancing is necessary for optimal functional outcomes.
- The contact forces are due to pretensions in soft tissues, primarily the collaterals.
- In this study, balancing is defined as equal contact forces on the lateral and medial condyles throughout flexion.
- Balancing relies on specific Surgical Corrections such as modifying bone cuts, releasing soft tissues, or changing component sizes (incl. liner) or rotation.
- There is a clinical need to develop an efficient predictive algorithm that can achieve balance from any starting unbalanced state through selective Surgical Corrections.

OBJECTIVES
- The goal of this study was to study the relative effect on compartmental loads produced by frequently implemented Surgical Corrections to provide guidelines for efficient and accurate balancing.
- A second goal was to evaluate the efficacy and efficiency of the balancing algorithm in achieving inter-compartmental load balancing.

MATERIALS AND METHODS
- Retrospective clinical series.
- 80 TKR cases, PCL retaining design.
- Single surgeon (PAM).
- Contact forces obtained by an instrumented tibial liner (VERASENSE™; OrthoSensor, Inc.; Dania Beach, FL).
- Standard testing: Sag test, heel push test, thigh pull test, varus-valgus in extension, anterior drawer in flexion.
- Balancing sequence: Sufficient extension space, tibial rotation, coronal symmetry in extension, flexion-extension symmetry.
- Perform common surgical corrections based on established patterns of imbalance.

SUMMARY OF RESULTS

- Contact forces on knee compartments in knee arthroplasty have a very wide distribution of magnitude prior to surgical correction (range [0 lbs., 100+lbs])
- Similarly the Contact Load Ratio (CLR) between compartments has a wide spread (SD > 0.25, range [0,1])
- Satisfactory clinical balance at surgery was obtained in 84% of cases with less than 2 surgical corrections (range [0-5])
- 69% of clinically balanced cases were within 15% of uniform balance (CLR: 0.50)
- The post-balancing CLR has a much narrower range of SD=0.16
- The mean CLR matching clinical balance (best correction) was slightly higher than perfect uniform balance. Mean CLR=0.52
- The commonest surgical corrections were soft tissue releases at 49%

DISCUSSION

The dominant finding of the study is the clustering effect of the CLR between medial and lateral compartments, which when combined with the wide range of values, suggests a Target Zone (FIGURE 2). Using this tool, the surgical goal of obtaining lateral and medial values within this zone may enhance the predictability of an improved functional outcome.

The balancing target zone brackets not only the loads in absolute values but also as a defined interval in CLR range (see slopes below). A CLR median value of 0.55 favoring a heavier load medially for instance may be consistent with the observed asymmetry of the knee as exemplified in physiological varus,1 kinematic axis,4 and joint laxity with varus/valgus strain ratio of 0.553.

An analogy can be drawn with the centralization effect of Computer Assisted Surgery on alignment. As studies have demonstrated however, this effect is insufficient to guarantee improved scores.5 On the other hand, recent studies focused on compartmental load balancing points to a remarkable improvement in functional outcome for load differences within 15 lbf. between compartments.2

This report presents initial data of a prospective IRB controlled study that intends to match patient satisfaction and functional scores to the Balancing Target Zone.