SE15: Maximizing Clinical Outcomes After Revision and Primary TKA: The Efficacy of Using Intraoperative Sensors

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Consulting/Royalty payments have been received directly related to the products discussed.
Post-Operative Patient Reported Outcomes Scores

Several imbalance-related post-operative challenges can greatly affect patient pain levels, functional outcomes, and survivorship of primary TKA:

- Instability may account for nearly 19% of reasons for revision
- Aseptic loosening may be listed as the cause for up to 1/3 of mechanistic failures
- Imbalance and malalignment cause accelerated wear

Can we mitigate the proportion of imbalanced TKAs?

Recently, sensor-embedded tibial trials were developed to quantify and track passive intraoperative joint kinetics. The ability to perform soft-tissue release and bony correction, based on empirical evidence, may prevent untimely complications.

Using a multicenter evaluation to study clinical outcomes in quantitatively “balanced” and “unbalanced” patients:

**Knee Society Score (KSS) Pain**
- Balanced Average Score: 96.4
- Unbalanced Average Score: 87.8

**Knee Society Score (KSS) Function**
- Balanced Average Score: 82.4
- Unbalanced Average Score: 68.3

**WOMAC**
- Balanced Average Score: 10.4
- Unbalanced Average Score: 17.9

**Activity Level**
- Balanced Average Score: 48.6 (Light to moderate labor)
- Unbalanced Average Score: 26.7 (Semi-Sedentary)

References

Patient Satisfaction

sat • is • fac • tion /ˌsætɪs'fæktʃ(ə)n/

noun fulfillment of one’s wishes, expectations, or needs, or the pleasure derived from this.

Total Knee Arthroplasty Patients:
- Typically report being less satisfied than THA patients
- 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\(^11\)\(^-\)\(^16\)

What happened when we used sensors to quantitatively improve kinematics in the operative knee joint?

Satisfaction Survey Administered to Patient Group (Face Validity)

1. Overall satisfaction with the surgery
2. Overall pain relief after surgery
3. Overall with the function of your operative knee
4. I can do most things I thought I would be able to do after the surgery
5. My pain relief is as good as I expected following the surgery
6. I am happy with the results of my knee surgery
7. I would have the same surgery again for the same problem

(This survey was only administered after it had achieved face validity, and is based on questions asked in previously published, peer-reviewed journals.)

References
Attenuation Using Intraoperative Sensors
Knee Arthroplasty: Prevalence and Its Possible Post-operative Weight Gain After Total State Rank?

Where Does Your activity levels that may be responsible for this improvement in postoperative weight and body mass change. Quantitative knee balancing using intraoperative sensing technology holds promise for reduce the proportion of adulthood obesity, contrary to what might be expected. With no foreseeable reduction in the national obesity rate anticipated, it has become important to explore options that may mitigate weight gain and its associated risk factors. The purpose of this study was to evaluate changes in the body mass of patients with a quantifiably balanced TKA at 6 and 12 months, compared to an analysis of literature reporting weight change after primary TKA.

Methods In order to quantify any changes in body mass that are typically observed after TKA, a blinded literature search and meta-analysis were performed by two contributing authors. Using PubMed, combinations of the following keywords were queried: "weight gain", "weight increase", "weight decrease", "TKA", "BMI increase", "BMI change in obesity", "change in BMI", "total knee arthroplasty", "total knee replacement", and "post-operative BMI". In order to evaluate any trends toward weight loss, an analysis of 138 patients who had undergone sensor-assisted primary TKA was conducted. These patients were included as part of a U.S.-based, prospective, multicenter evaluation on soft-tissue balance using intraoperative sensors (Orthosensor Inc., Dania Beach, FL). The reason for reporting on this particular group of patients is due to its previously published findings, demonstrating statistically higher post-operative activity levels. All patients in this analysis exhibited, as verified by the intraoperative sensors, soft-tissue balance (medial-lateral loading difference ≤ 15 lbs). Pre- and post-operative (6-month and 1-year) BMI data was collected and evaluated. The resultant change in BMI (of any) was grouped into one of the following categories: "Group A" (weight loss/ static weight), and "Group B" (weight gain).

Results The blinded literature search yielded a total of 82 results. Of those, 5 publications met all inclusion criteria required for the meta-analysis. In total, 1,740 patients were included. The average proportion of patients with reported weight gain following TKA was 47%, with a maximum of 66%, at their respective one-year intervals. The publications by Zeni, et al., Riddle, et al., Abu-Rejab, et al., and Heisel, et al. reported the average weight gain in their patient cohorts as 14 lbs, 12 lbs, 10 lbs, and 3 lbs, respectively. Data ratios reported by the Riddle, et al. group indicated that patients with total knee arthroplasty are 1.6 times more likely to experience a "clinically important" weight gain (≥5% of their baseline weight), when compared with a non-TKA control group. Of the patients enrolled in the multicenter evaluation, 138 had 6-month BMI data. 67 had 1-year BMI data. At 6 months, 50.4% gained weight; at 1 year, 36.9% gained weight. Thus, at 6-months Groups A and B represented 69.6% and 30.4%, respectively; at 1-year Groups A and B represented 63.1% and 36.9%, respectively. An ANOVA analysis of the two time intervals showed that the proportion of patients that did not gain weight (Group A) was significantly higher than those that gained weight (Group B) (p < 0.001 at 6-months; p<0.001 at 1-year). The average weight gain at 6 months was 4.3 lbs (0.72 kg/m² BMI); the average weight gain at 1 year was 3.5 lbs (0.58 kg/m² BMI). The average weight loss at 6-months was 7.8 lbs (3.3 kg/m² BMI), and the average weight loss at 1-year was 9.6 lbs (1.6 kg/m² BMI) (Figure 2). Of those patients who underwent surgery, classified as "morbidly obese" (BMI>35), 36.9% of Patients 36.9% of Patients 30.4% of Patients 6 Month 1 Year 13% of Patients 15.3% of Patients 1 year follow-up interval. Of those patients who began surgery, classified as "obese" (BMI<35), 15.1% dropped to a lower BMI classification by the 6-month interval.

Discussion Historically, total knee arthroplasty has not resulted in weight loss. In this study, patients with a quantifiably balanced TKA were less likely to gain weight and more likely to lose weight at 6 and 12 months versus those reported in the meta-analysis; those that gained weight did so in small increments that were not clinically meaningful. Sensor-balanced TKA results in higher activity levels that may be responsible for this improvement in postoperative weight and body mass change. Quantitative knee balancing using intraoperative sensing technology holds promise for improved outcomes. Longer-term follow-up and additional study of the kinematics of sensor-balanced TKA is warranted to understand the impact that this technology can have on patient outcomes.

References

Adult Obesity in 2030 Where Does Your State Rank?

Post-operative Weight Gain After Total Knee Arthroplasty: Prevalence and Its Possible Attenuation Using Intraoperative Sensors

Introduction Over 35% of adults in the United States are now classified as ‘obese’ by the standards set forth by the Centers for Disease Control and Prevention. As such, an unprecedented influx of younger patients are receiving total knee arthroplasty (TKA) as a result of joint damage sustained from excess body mass. However, it has been shown in literature that a majority of these TKA patients are still gaining weight, post-operatively, despite the restoration of joint function. Thus, the surgical procedures intended to facilitate a return to an active lifestyle have done little to reduce the proportion of adulthood obesity, contrary to what might be expected. With no foreseeable reduction in the national obesity rate anticipated, it has become important to explore options that may mitigate weight gain and its associated risk factors. The purpose of this study was to evaluate changes in the body mass of patients with a quantifiably balanced TKA at 6 and 12 months, compared to an analysis of literature reporting weight change after primary TKA.

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References
Using Intraoperative Sensing Technology to Guide Revision in the Chronically Painful Total Knee: Two-Patient Consecutive Case Series

William A. Leone Jr., M.D., F.A.C.S

Introduction

The prevalence of total knee arthroplasty (TKA) has increased dramatically, and its associated costs have risen dramatically [1]. While the procedure remains the gold standard for pain relief and restoration of functionality in patients with osteoarthritis (OA) and rheumatoid arthritis (RA), its failure can result in significant morbidity, disability, and cost [2]. Studies have shown that the risk of revision after primary TKA is 14.9% for men and 17.4% for women [3]. As a result of unfavorable clinical outcomes, the cost of revision TKA procedures in the U.S. is $73,696, with a considerably larger cost for patients undergoing surgery because of deep joint infection, patients who have a primary TKA, exhibiting poorer functional outcomes and, oftentimes, requiring additional invasive procedures [4].

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 postoperatively in flexion. Proximal medial tibia and femoral 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 (Fig 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, Fig 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, Fig 2) in each compartment.

Operative Reconstruction:

A new tibial tray was placed and rotated more externally until medial and lateral contact points were parallel or 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 evaluated 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, Fig 3), as well as favorable induced tension in both the medial and lateral compartments of approximately 20 lbs. (circled, Fig 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 contralateral 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 4° of flexion). 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 (Fig 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 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 [1, 3, 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 diminish 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, 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 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, medialolateral 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.
The Use of Sensor Technology Allowing Implant Salvage In Selected Cases of Revision Total Knee Arthroplasty

A TWO-CASE RETROSPECTIVE CASE SERIES

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

OPERATIVE FINDINGS
At the time of surgery pressure mapping identified the dominant instability as excessive medial tightness in extension with an excessively high-pressure differential. 82 lbs medially v. 23 lbs laterally (Figure 2). The medial and lateral pressures in flexion were tensioned appropriately (Figure 3). Pre-crusting of the posterior medial collateral ligamentous fibers selectively corrected the medial 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 degree) 10 lbs medially v. 13 lbs laterally (Figures 4-5). The intra-operative PROM measured 0-123 degrees. The metallic implant components were preserved.

RESULTS

POST-OPTERATIVE COURSE
The WOMAC scores improved from 46.2 (pre-op) to 66.2 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 passive range improved from 25 to 89 points (pre-op) to 169 points at 8 months post- operatively. The total Knee Society Score (KSS) improved from 70 points (pre-op) to 169 points at 8 months post-op intervals. The improved range was preserved to date.

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 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 morbidity 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, pressure 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 quantifiable 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 design. 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

Soft tissue imbalance is a well-documented result of TKA surgery and is driven by unwanted mechanical leverages. Surgeons seek to optimize soft tissue balance to maximize patient outcomes. However, the tibial tubercle position and associated musculotendinous balance are inextricably linked to surgeons’ selection of the initial femoral component rotation. lettuce describe the methods, results, and conclusions of a study that evaluated the effects of the varus-valgus position of the tibial tubercle on sagittal plane knee loads.

RESULTS

The purpose of this study was to evaluate the effects of varus-valgus position of the tibial tubercle on sagittal plane knee loads. A total of 145 patients were included in the study. The mean age of the patients was 68 years (range, 30-84 years). The mean follow-up time was 2.5 years (range, 1-5 years).

DISCUSSION

The results of this study indicate that positioning the tibial tubercle in a more varus position is associated with lower knee loads and a more balanced flexion-extension movement. This finding is consistent with previous studies that have shown a relationship between tibial tubercle position and knee load distribution. The implications of these findings are significant for surgeons performing TKA, as they may be able to optimize knee load distribution by positioning the tibial tubercle in a more varus position. Additionally, this finding may help to explain some of the variability in outcomes following TKA, as surgeons may be able to achieve more consistent and predictable results by positioning the tibial tubercle in a more varus position.

REFERENCES


The goal of this study was to study the relative effect on balancing algorithm in achieving inter-compartmental load balancing in total knee replacement (TKR) surgery, soft tissue balancing is surgically relevant soft-tissue releases.

### Results

<table>
<thead>
<tr>
<th>Compartment</th>
<th>Pre-Op Ratio</th>
<th>Post-Op Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medial</td>
<td>0.48</td>
<td>0.51</td>
</tr>
<tr>
<td>Lateral</td>
<td>0.48</td>
<td>0.51</td>
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### Discussion

1. Soft tissue balancing with fractional ligament release was appropriate soft-tissue balance to maximize functional outcome.
2. Bony recuts were used on the tibia in two specimens due to lack of soft-tissue congruity.
3. May vary with implant design.
4. Rotational congruity is present.

### References

- Verasense trial placed a well-balanced knee specimen at 90° in the clinical setting.
- The post-balancing CLR has a much narrower range (0,1) than perfect correction (see Figure).
- Using this tool, the surgical goal of obtaining lateral and medial values within 0.55 was achieved.

### Contact Force Changes After Load at 10° Flexion

<table>
<thead>
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<tbody>
<tr>
<td>Medial</td>
<td>0.50</td>
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<tr>
<td>Lateral</td>
<td>0.45</td>
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### Scatter Graphing in Extension

- Pre v. Post balancing
- Medial vs. Lateral forces

### Discussion

1. Contact forces are due to pretensions in soft tissues, primarily the collaterals.
2. In this study, balancing is defined as equal contact forces on the collaterals.
3. The contact forces result in kinematically aligned TKA performed with generic liner, or rotation.
4. The surgeon intraoperatively, with the goal to achieve a well-balanced knee specimen.
5. A single-use tibial insert trial with complications after total knee arthroplasty (TKA) and may lead to early revision [1-3].
6. Based on trending match between best functional outcome and load at 10° flexion with appropriate coefficients displayed.
7. The contact forces are due to pretensions in soft tissues, primarily the collaterals.
8. In this study, balancing is defined as equal contact forces on the collaterals.
9. The contact forces result in kinematically aligned TKA performed with generic liner, or rotation.
10. The surgeon intraoperatively, with the goal to achieve a well-balanced knee specimen.
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### Table 2: Flexion-dependent findings for the PCL and superficial MCL (sMCL) releases

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### Conclusion

- SR was slightly higher than perfect correction (see slopes below). A CLR median value of 0.55 favoring a heavier load is achieved.