CLINICAL RESEARCH SUMMARY
VERASENSE Sensor-Assisted Total Knee Arthroplasty offers proven clinical and economic advantages for surgeons and hospitals.

A MULTI-CENTER RANDOMIZED CONTROLLED TRIAL PROVED THAT – WITHOUT VERASENSE – TKAs ARE ONLY BALANCED APPROXIMATELY 50% OF THE TIME [P.4]

PROVEN RESULTS

A multicenter randomized controlled trial, a prospective 3-year multicenter study, and additional research have proven the following clinical and economic benefits from the use of VERASENSE in Sensor-Assisted TKA:

98% OF BALANCED PATIENTS REPORT BEING SATISFIED TO VERY SATISFIED 3 YEARS POST-OP [P.5]

SIGNIFICANTLY HIGHER FORGOTTEN JOINT SCORES COMPARED TO UNBALANCED PATIENTS [P.6]

DECREASED THE NEED FOR ALL-COMPONENT REVISION BY FACILITATING IMPLANT COST MITIGATION [P.9]

ALMOST 75% LOWER RATE OF SOFT TISSUE BALANCE-RELATED EARLY REVISION TKA (<2 YEARS) COMPARED TO NATIONAL AVERAGES [P.10]

VERASENSE PATIENTS REQUIRE LESS PT AND 67% FEWER MUAs POST-OP [PP.6-8]
Investigations & Key Takeaways

**CLINICAL OUTCOMES**

4 Is a Surgeon-Defined “Balanced Knee” Following Total Knee Arthroplasty Really Balanced?
   ▶ Without VERASENSE, TKAs are only balanced approximately 50% of the time.

5 Patient-Reported Satisfaction: 3-Year Multicenter Results
   ▶ VERASENSE Sensor-Assisted TKA resulted in an increase to 98% patient-reported satisfaction at three years post-op.

6 Randomized Controlled Trial - Does a Balanced TKA Produce a More Forgotten Joint?
   ▶ Patients with quantitatively balanced TKA have statistically significant higher forgotten joint scores than patients with unbalanced TKA based on 6-week, 6-month and 1-year outcomes data (p<0.05).

7 Decreased Risk of 90-Day Post-Op Complications (MUA)
   ▶ VERASENSE Sensor-Assisted TKA resulted in statistically significant reduction in MUA.

8 Improved Physical Therapy and Short-Term Clinical Outcomes
   ▶ VERASENSE patients have shown statistically significant improvement of PROMs and Physical Therapy performance.

**ECONOMICS**

9 Cost Mitigation During Revision TKA
   ▶ Use of VERASENSE in revision TKA can potentially result in cost savings due to a decreased need for all-component revision.

10 Potential for Reducing Incidence of Early Revision TKA
   ▶ A VERASENSE multicenter study showed a significantly lower rate of early revision TKA compared to national averages.

**SURGICAL TECHNIQUES**

11 Can We Really “Feel” a Balanced Total Knee Arthroplasty?
   ▶ Results from this study show that VERASENSE assists surgeons in decreasing the incidence of outliers in loading across the knee joint.

12 Accuracy of Manual Surgeon-Defined Assessment of Soft Tissue Balance in TKA In Comparison to VERASENSE Sensor-Guided Measures – Can We Detect An Unbalanced Knee?
   ▶ Surgeon assessment is a poor predictor of knee compartmental loads and balance.

13 Knee Balancing in Total Knee Arthroplasty Using the VERASENSE Articular Insert. Findings of a Prospective Cohort Study
   ▶ Results have challenged traditional concepts of knee balancing.
Is a Surgeon-Defined “Balanced Knee” Following Total Knee Arthroplasty Really Balanced?

PURPOSE
Residual soft tissue imbalance in TKA may cause instability, leading to greater pain and worse function. This study compared blinded surgeons’ subjective, feel-based evaluation of TKA balance to quantitative, intra-op VERASENSE load measurements. It was hypothesized that the surgeon-defined assessment is a poor predictor of the actual state of soft tissue balance in TKA.

METHODS
• 170 primary TKA patients
• At the end of each case, surgeons were asked to provide a manual assessment of balance in extension and flexion
• Quantified balance data—blinded to the surgeon—was then captured with VERASENSE intraoperatively
• Mismatch between VERASENSE balance data and surgeon-defined assessment were analyzed (BALANCED = M/L load differential ≤ 15 lbf)

RESULTS
• By surgeon feel, all knees were deemed to be acceptably balanced in both extension and flexion
• Blinded VERASENSE data showed only 51% (n=86) of surgeon-guided TKAs were quantifiably balanced.

CONCLUSIONS
WITHOUT VERASENSE, TKAS ARE ONLY BALANCED APPROXIMATELY 50% OF THE TIME.
SURGEON-DEFINED ASSESSMENT CORRELATES POORLY WITH SENSORIZED FEEDBACK.
QUANTITATIVE SENSOR DATA MAY PROVE USEFUL TO HELP ENSURE A BALANCED TKA.
Patient Reported Satisfaction: 3-Year Multicenter Results

**PURPOSE**
This sensor-assisted, multicenter study cohort was prospectively assessed for concluding (3-year) patient-reported outcomes. Scores were compared to existing peer-reviewed publications reporting a similar follow-up interval (2-3 years) to determine the impact of consistent TKA soft tissue balance on patient satisfaction.

**METHODS**
- 129 sensor-assisted patients (quantifiably balanced)
- 7-question survey administered (5-point Likert scale)
- Literature review conducted via PRISMA guidelines

**RESULTS**
- 98.3% of balanced, sensor-assisted patients reported being “satisfied” to “very satisfied” at 3-years post-op
- On average, 87% of patients reported being “satisfied” to “very satisfied” in comparative literature during the same follow-up interval

**CONCLUSION**
THE VERASENSE GROUP EXHIBITED THE HIGHEST REPORTED SATISFACTION AMONG CONTEMPORARY TECHNOLOGIC AND MANUAL SURGICAL MODALITIES FOR THE SAME 3-YEAR POST-OP INTERVAL.

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*Dr. Martin Roche participated in this research and is Founder and Chief Medical Officer of OrthoSensor, Inc.*

Randomized Controlled Trial – Does a Balanced TKA Produce a More Forgotten Joint?

**PURPOSE**

The Forgotten Joint Score-12 (FJS-12) is a PROM evaluating the degree to which a patient is able to forget about their joint following surgery. The aim of this study was to measure post-operative joint awareness in patients with and without a quantifiably balanced knee following primary TKA.

**METHODS**

**BLINDED MANUAL vs. UNBLINDED VERASENSE TKA BALANCING**

- 267 patients thus far blindly-randomized into two groups:
  - Sensor-guided TKA with quantified, **UNBLINDED** VERASENSE balancing
  - Surgeon-guided TKA with **BLINDED** VERASENSE load measurement
- Intra-op sensors utilized in all cases. BLINDED group TKAs were balanced using standard, manual techniques, with VERASENSE data collection blinded to the surgeon.

**RANDOMIZED GROUPS WERE POOLED POST-OP AND RE-STRATIFIED BY STATE OF SOFT TISSUE BALANCE:**

- **BALANCED** = M/L load differential ≤ 15 lbf through ROM
- **UNBALANCED** = any M/L load differential > 15 lbf

**PATIENT COHORTS**

<table>
<thead>
<tr>
<th>TOTAL ENROLLED</th>
<th>UNBALANCED</th>
<th>BALANCED</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-WEEK DATA</td>
<td>220</td>
<td>92</td>
</tr>
<tr>
<td></td>
<td></td>
<td>128</td>
</tr>
<tr>
<td>6-MONTH DATA</td>
<td>149</td>
<td>59</td>
</tr>
<tr>
<td></td>
<td></td>
<td>90</td>
</tr>
</tbody>
</table>

**PRELIMINARY RESULTS**

**BALANCED PATIENTS REPORTED BEING LESS AWARE OF THEIR JOINT REPLACEMENT COMPARED TO UNBALANCED PATIENTS AT BOTH 6-WEEKS & 6-MONTHS POST-OP.**

**BALANCED patients showed:**

- Fewer physical therapy sessions
- Fewer 90-day complications

**CONCLUSIONS**

Patients with quantitatively balanced TKA have statistically significant higher forgotten joint scores than patients with unbalanced TKA based on 6-week, 6-month and 1-year outcomes data (P<0.05).

Fewer physical therapy visits and fewer complications may translate to potential cost savings.


Longer-term follow-up data evaluating FJS-12 and additional PROMs along with the economic implications is ongoing.
Decreased Risk of 90-Day Post-Op Complications (MUA)

THE USE OF ELECTRONIC SENSOR DEVICE TO AUGMENT LIGAMENT BALANCING LEADS TO A LOWER RATE OF ARTHROFIBROSIS AFTER TOTAL KNEE ARTHROPLASTY

PURPOSE

Manipulation under anesthesia (MUA) is a common treatment for stiffness and arthrofibrosis post-TKA. Studies show a higher degree of success when treatment is performed earlier (<3 mo.) post-TKA; however, bundled payments models focusing on a 90-day episode of care may not provide reimbursement within this timeframe.

MUA rates were compared for manual TKA versus VERASENSE Sensor-Assisted TKA to determine if consistent soft-tissue balance had any effect on the rates of 90-day post-op complications.

METHODS

MUA RATE: VERASENSE VS. NON-SENSOR

• 252 sensor-assisted vs. 690 non-sensor
• All cases were performed by the same surgeon.
• There were no significant cohort demographic or co-morbidity differences.
• No difference in outcomes was seen based on implant type, age or BMI.

RESULTS

VERASENSE: STATISTICALLY-SIGNIFICANT REDUCTION IN MUA

• 67% decrease in rate of MUA
• 62% of observed MUAs were within the 90-day post-op interval

CONCLUSIONS

VERASENSE CAN MITIGATE 90-DAY POST-OP COMPLICATIONS THROUGH SOFT-TISSUE BALANCE. A DECREASE IN MUAS SHOULD REDUCE OVERALL TKA READMISSIONS AND LESSEN THE COSTS AND RISKS CURRENTLY UNDER FOCUS THROUGH CMS’S COMPREHENSIVE JOINT REPLACEMENT PAYMENT PROGRAM.

**PURPOSE**

The use of sensorized technology in TKA may help to mitigate early soft-tissue complications and thereby improve functional outcomes over manual techniques. In order to evaluate the clinical efficacy of sensor-assisted TKA at an early follow-up interval, 114 patients were evaluated using patient reported outcomes scores and clinical range of motion (ROM) measurements.

**METHODS**

**VERASENSE VS. MANUAL TKA BALANCING**
- 57 consecutive sensor-assisted vs. 57 consecutive manual
- All cases were performed by the same surgeon with the same implant system.
- There were no significant cohort demographic or co-morbidity differences.

**RESULTS**

**VERASENSE: HIGHLY STATISTICALLY-SIGNIFICANT IMPROVEMENT ACROSS ALL OUTCOME MEASUREMENTS**
- Faster improvement in PROMS (KSS, Oxford)
- Significantly higher Clinic ROM and improvement in Clinic ROM from Pre-op
  (P=0.002 AND P<0.001, RESPECTIVELY)
- More patients achieved active deep flexion (>115 DEG.) during physical therapy
  - 52% VERASENSE vs. 42% MANUAL

**CONCLUSIONS**

VERASENSE HAS SHOWN STATISTICALLY SIGNIFICANT IMPROVEMENT OF PROMS & PHYSICAL THERAPY PERFORMANCE.

AN INCREASE IN PHYSICAL THERAPY PERFORMANCE AND SHORT-TERM OUTCOMES DURING RECOVERY AND REHAB SHOULD TRANSLATE TO SHORTER TREATMENTS AND LOWER OVERALL COSTS IN THE COMPLETE TKA EPISODE OF CARE.

**KSS FUNCTION**

**IMPROVEMENTS PRE-OP TO 6 MONTHS**

<table>
<thead>
<tr>
<th>Measure</th>
<th>MANUAL</th>
<th>VERASENSE</th>
<th>P-VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ΔKSS Pain</td>
<td>29</td>
<td>36</td>
<td>0.001</td>
</tr>
<tr>
<td>ΔKSS Function</td>
<td>23</td>
<td>27</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ΔKSS Total</td>
<td>52</td>
<td>63</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ΔOxford</td>
<td>13</td>
<td>17</td>
<td>0.025</td>
</tr>
<tr>
<td>ΔClinic ROM</td>
<td>9°</td>
<td>20°</td>
<td>&lt;0.001</td>
</tr>
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Cost Mitigation During Revision TKA

**COST SAVINGS WHEN PLANNED TOTAL REVISION CHANGED TO PARTIAL REVISION TREATING THE ’LOOKS GOOD, FEELS BAD’ KNEE BY DIAGNOSING SOFT TISSUE IMBALANCE**

**PURPOSE**

Despite long-term success rates associated with total knee arthroplasty (TKA), a large proportion of patients continue to report dissatisfaction with their surgical outcomes. Complications such as pain, stiffness, or instability can reduce a patient’s quality of life and may be attributed to soft-tissue imbalance. The cause of imbalance related complications is often difficult to diagnose, but if unresolved may lead to early total revision surgery. However, these procedures are associated with a higher risk of post-operative complications, elicit longer rehabilitation regimes, and can become a financial burden to the patient and healthcare provider. Therefore, the purpose of this study was to determine if the use of intraoperative sensors during revision TKA led to a decreased need for all-component revision.

**METHODS**

**58 REVISION TKA PROCEDURES**

- 7 sites, 7 surgeons
- Patients reported with idiopathic pain, instability and/or stiffness.
- Radiographs showed acceptable component alignment with symmetrical joint gaps.
- Patients reporting pain had culture-negative aspiration findings.

**RESULTS**

**REVISION TKAS USING VERASENSE**

- **70% SCHEDULED FOR TOTAL REVISION**
  - TOTAL r-TKA: 41
  - PARTIAL r-TKA: 53

- **88% OF PLANNED TOTAL REVISIONS CHANGED TO PARTIAL REVISIONS** (N=36)

**AVERAGE REVISION TKA IMPLANT COST**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cost (USD)</th>
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<tbody>
<tr>
<td>TOTAL REVISION</td>
<td></td>
</tr>
<tr>
<td>Tibia Component</td>
<td>$2,880</td>
</tr>
<tr>
<td>Polyethylene</td>
<td>$980</td>
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</tbody>
</table>

*Represents ⅔ Of Medicare DRG

**CHANGES TO PARTIAL REVISION (N=36)**

- 10 tibia-only, 26 polyethylene exchange

**ESTIMATED COST SAVINGS: $4,990 PER CASE**

- In 36 of 58 cases, expected total revisions changed to partial revisions, which equates to a theoretical implant cost savings of $179,640.

**CONCLUSIONS**

**VERASENSE CAN FACILITATE IMPLANT COST MITIGATION DURING TKA REVISION**

**POTENTIAL COST SAVINGS OF PARTIAL REVISIONS**

- Shorter OR time, length of stay
- Less instrumentation, OR supplies
- Lower risk of complications (e.g., infection, fracture)
- Shorter, easier post-op rehabilitation regime
- Less bone stock loss, internal constraint for patient

Potential for Reducing Incidence of Early Revision TKA

FINANCIAL BURDEN OF TKA REVISIONS: 2013 MEDICARE PROVIDER ANALYSIS AND REVIEW FILE (MED PAR)1

The annual healthcare financial burden of revision TKA is estimated at $2.7 BILLION based on average hospital charges of 73 thousand dollars per case. Analysis of facility costs and Medicare reimbursements shows over 90% OF HOSPITALS LOSE MONEY ON REVISION TKA, with a loss of nearly $10,000 PER PROCEDURE.

SENSOR-ASSISTED TKA: MULTICENTER STUDY

TKA EARLY REVISION BURDEN (<2 YEARS, SOFT-TISSUE COMPLICATIONS)

APPROXIMATELY 2.6% OF TOTAL KNEE ARTHROPLASTIES RESULT IN EARLY REVISION RELATED TO SOFT-TISSUE COMPLICATIONS*4

VERASENSE: ONLY 1 OF 143 PATIENTS (0.7%) REVISED WITHIN 2 YEARS9

* VERASENSE CANNOT PREVENT REVISION DUE TO INFECTION

VERASENSE multi-center study patients showed an almost 75% LOWER RATE OF REVISION TKA compared to national averages. This reduction represents clinical and financial benefit to both patients and providers.

1 Medicare Provider Analysis and Review File. 2013: Centers for Medicare & Medicaid Services Database – Primary and Revision TKA.
Can We Really “Feel” a Balanced Total Knee Arthroplasty?

PURPOSE

Intraoperative sensors were used in blinded (control) and unblinded cohorts to compare the “feel” of an experienced surgeon to sensor-generated data in order to evaluate appropriate TKA balance through a range of motion.

METHODS

• A total of 22 primary TKA patients, in 2 groups (12 manual, gap-balanced; 10 VERASENSE, sensor-assisted), were evaluated for any differences in mediolateral loading and soft-tissue release type performed.
• Intraoperative sensors were used in both groups.
• The surgeon (30 years of experience) was blinded to the sensor data in the manual group, and was able to use the sensor data in the sensor-assisted group.

RESULTS

• The VERASENSE cohort exhibited lower overall loading, in both the medial and lateral compartments, than the manual group.
• Intercompartmental loading through the range of motion was significantly more symmetrical in the VERASENSE group than the manual group.

CONCLUSION

SENSOR-ASSISTED SURGERY PROVIDES OBJECTIVE DATA THAT MAY ASSIST SURGEONS IN DECREASING THE INCIDENCE OF OUTLIERS IN LOADING ACROSS THE KNEE JOINT.

COMPARISON OF COMPARTMENT LOAD AT VARIOUS DEGREES IN RANGE OF MOTION IN MEDIAL AND LATERAL COMPARTMENTS

<table>
<thead>
<tr>
<th>DEGREES OF FLEXION</th>
<th>VERASENSE COHORT MEAN (RANGE) (SD)</th>
<th>MANUAL COHORT MEAN (RANGE) (SD)</th>
<th>P VALUE</th>
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<tbody>
<tr>
<td>MEDIAL COMPARTMENT</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>10°</td>
<td>22.8 (16-44) (8)</td>
<td>79.3 (12-228) (62)</td>
<td>.0108</td>
</tr>
<tr>
<td>45°</td>
<td>23.1 (9-38) (8)</td>
<td>77.2 (6-177) (51)</td>
<td>.0035</td>
</tr>
<tr>
<td>90°</td>
<td>20.4 (7-38) (8)</td>
<td>55.4 (4-159) (48)</td>
<td>.0326</td>
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<tr>
<td>LATERAL COMPARTMENT</td>
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<td></td>
</tr>
<tr>
<td>10°</td>
<td>17.2 (0-38) (10)</td>
<td>27.6 (0-102) (37)</td>
<td>.39</td>
</tr>
<tr>
<td>45°</td>
<td>13.3 (4-25) (7)</td>
<td>31.3 (0-99) (38)</td>
<td>.15</td>
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<tr>
<td>90°</td>
<td>16.1 (7-38) (8)</td>
<td>28.4 (0-73) (29)</td>
<td>.21</td>
</tr>
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</table>

SD, STANDARD DEVIATION

Accuracy of Manual Surgeon-Defined Assessment of Soft Tissue Balance in TKA In Comparison to VERASENSE Sensor-Guided Measures – Can We Detect an Unbalanced Knee?

**PURPOSE**

The accuracy of surgeon-defined assessment (SDA) of soft tissue balance in TKA was compared to sensor-guided assessment with VERASENSE to assess the ability of sensor data in guiding the surgeon to achieve targeted balance. The hypothesis is that arthroplasty-trained SDA is a poor predictor of the state of soft tissue balance in TKA.

**METHODS**

- 238 single-surgeon, sensor-assisted TKAs
  - 159 varus (mean -6.5°)
  - 67 valgus (mean 7.3°)
  - 12 neutral
- Conventional intramedullary guides, same implant system for all TKAs
- Standard trial surgical assessment and prediction of knee balance status, THEN corresponding VERASENSE trial inserted to quantify balance (“balanced” = M/L difference ≤15 lbf)

**RESULTS**

**ACCURACY OF SURGEON-DEFINED ASSESSMENT OF BALANCE – 62%**
- Correct when predicting “balanced” – 61%
- Correct when predicting “unbalanced” – 65%

**CHANGE OF SURGICAL PLAN IN 38% (N=90) OF CASES**
- 29% (n=68) needed balancing
- 9% (n=22) prevented unnecessary balancing

**CONCLUSIONS**

SURGEON ASSESSMENT IS A POOR PREDICTOR OF KNEE COMPARTMENTAL LOADS AND BALANCE WITH SURGICAL TECHNIQUES THAT AIM TO IMPROVE BALANCE, IMPROVEMENTS IN QUANTIFICATION AND VALIDATION OF KNEE BALANCE ARE REQUIRED.

MacDessi S. Accuracy of manual surgeon defined assessment of soft tissue balance in TKA In comparison to VERASENSE sensor-guided measures – can we detect an unbalanced knee? AOA 2017.
Knee Balancing in Total Knee Arthroplasty Using the VERASENSE Articular Insert. Findings of a Prospective Cohort Study.

PURPOSE

The aim of this prospective study was to define the surgical techniques required to achieve optimal knee balance during VERASENSE Sensor-Assisted TKA.

METHODS

• 238 single-surgeon, sensor-assisted TKAs
  – 159 varus (mean -6.5°)
  – 67 valgus (mean 7.3°)
  – 12 neutral
• Conventional intramedullary guides, same implant system for all TKAs
• Surgeon performed standard surgical treatment, aimed for neutral mechanical alignment, and then balanced the knee as per prior published VERASENSE protocols

RESULTS

RESULTS HAVE CHALLENGED TRADITIONAL CONCEPTS OF KNEE BALANCING.

• Bone adjustments required to alter soft tissue tensions in ⅓ of cases
• Counterintuitive soft tissue releases not always on the same side as the disease pattern
• Traditional soft tissue releases may have less impact than thought
  – ITB laterally
  – Semimembranosus / PM Capsule medially

CONTINUED REFINEMENT OF TECHNIQUES TO OPTIMIZE BALANCE IS REQUIRED TO DETERMINE ASSOCIATION WITH NEWER ALIGNMENT STRATEGIES AND CLINICAL OUTCOMES.

Notes
Notes