2016 CLINICAL RESEARCH SUMMARY
The following institutions have contributed research to this field of study:

- Advocate Health Care
  - Inspiring medicine. Changing lives.
- BONE & JOINT INSTITUTE
- COLUMBIA UNIVERSITY MEDICAL CENTER
- Cleveland Clinic
- Cleveland State University
- Florida Orthopaedic Institute
- HEDLEY ORTHOPAEDIC INSTITUTE
- Holy Cross Hospital
THE FOLLOWING VERASENSE™ DATA IS A COMPILATION OF BIOMECHANICAL AND CLINICAL RESEARCH PERFORMED DURING 2016, EITHER IN COLLABORATION WITH OR INDEPENDENT FROM ORTHOSENSOR® INC. THE CONTENT HEREIN IS TO BE USED FOR REFERENCE ONLY.
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 interval1-8

CONCLUSION:
The Verasense Group exhibited the highest reported satisfaction among contemporary technologic and manual surgical modalities for the same 3-year post-op interval.

**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 WITH 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.**

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.
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:
REVISIONS TKAs USING VERASENSE

<table>
<thead>
<tr>
<th></th>
<th>PRE-OP PLAN</th>
<th>PROCEDURE POST-VERASENSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL r-TKA</td>
<td>70%</td>
<td>41</td>
</tr>
<tr>
<td>PARTIAL r-TKA</td>
<td>5%</td>
<td>5</td>
</tr>
</tbody>
</table>

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

AVERAGE REVISION TKA IMPLANT COSTS

- TOTAL REVISION
  - TIBIA-ONLY REVISION: $2,880
  - POLYETHYLENE EXCHANGE: $980
  - REPRESENTS 2/3 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 BILLION² 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)

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

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.

<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>
</tr>
</thead>
<tbody>
<tr>
<td>MEDIAL COMPARTMENT</td>
<td></td>
<td></td>
<td></td>
</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>
</tr>
<tr>
<td>LATERAL COMPARTMENT</td>
<td></td>
<td></td>
<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>
</tr>
<tr>
<td>90°</td>
<td>16.1 (7-38) (8)</td>
<td>28.4 (0-73) (29)</td>
<td>.21</td>
</tr>
</tbody>
</table>

SD, STANDARD DEVIATION


OrthoSensor.com | 11 | VERASENSE
Intraoperative Load-Sensing Variability During Cemented, Posterior-Stabilized Total Knee Arthroplasty

**PURPOSE:**
To understand the utility of using sensing devices when evaluating pre- and post-trialing load conditions during TKA.

**METHODS:**
Kinematic data from 54 TKA surgeries was captured and analyzed. Specific conditions evaluated include: loading conditions before and after cementation, and any changes to the state of balance between trialing and final implantation.

**RESULTS:**
- There was agreement between loading conditions, during trialing and final implantation, in the medial compartment only.
- The lateral compartment exhibited higher degrees of variability between the trialing and final implantation phase.

**CONCLUSION:**
THE USE OF INTRAOPERATIVE SENSORS PROVIDES OBJECTIVE FEEDBACK ABOUT THE BEHAVIOR OF EACH COMPARTMENT, INDEPENDENTLY. THIS MAY ALLOW SURGEONS TO CORRECT RESIDUAL IMBALANCE IN AVOIDANCE OF FUTURE POST-OPERATIVE COMPLICATIONS.

Algorithmic Pie-Crusting of the MCL Guided by Sensor Technology Affects the Use of Constrained Inserts During TKA

**PURPOSE:**
To determine if targeted, algorithmic soft tissue release, performed with the use of intraoperative sensors, is effective and has any effect on the need for mechanical implant constraint.

**METHODS:**
This study evaluated 75 sensor-assisted TKAs versus 225 manual TKAs. The authors compared the clinical efficacy of sensor-assisted TKA using a pie-crusting technique to release the medial soft-tissue sleeve. The authors also evaluated the incidence of using constrained inserts in sensor-assisted versus manual TKA.

**RESULTS:**
- There was a significant decrease in the use of constrained inserts in the sensor-assisted group versus the manual group
  - 8% VERASENSE VS. 18% MANUAL (P = 0.002)
- Sensor-assisted TKA showed similar functional improvement in ROM and KSS scores, post-operatively.

**CONCLUSIONS:**
- GIVEN SIMILAR IMPROVEMENT IN ROM/KSS, SENSOR-ASSISTED TKA IS AS SAFE AND EFFECTIVE AS TRADITIONAL TECHNIQUES.
- ADDITIONAL CONCLUSION: THE DECREASED USE OF CONSTRAINED INSERTS IN THE SENSOR-ASSISTED GROUP MAY LEAD TO DECREASED OPERATIVE SPENDING.

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

PURPOSE:
To understand the effect of surgical corrections on inter-compartmental balance during primary TKA.

METHODS:
101 TKA cases were performed with the use of sensors to display intra-articular loading values in the medial and lateral compartment, in real-time. The goal of each procedure was to equalize loads in the medial and lateral compartment (load distribution ratio: 0.5).

RESULTS:
- The most common corrections to achieve balance were to release the posterolateral corner, posteromedial capsule, and MCL.
- After balancing with sensor assistance, the mean load distribution ratio was 0.52.
- In a majority of cases, 0-2 corrections were required to achieve balance.

CONCLUSION:
The use of sensors in TKA can enhance balancing accuracy and result consistency with a relatively minimum number of adjustments.

Changes in Tibiofemoral Forces in Extension Before and After the Most Common Surgical Corrections

<table>
<thead>
<tr>
<th>CORRECTION</th>
<th>AVERAGE MEDIAL-TO-TOTAL FORCE RATIO BEFORE</th>
<th>AVERAGE MEDIAL-TO-TOTAL FORCE RATIO AFTER</th>
<th>SIGNIFICANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posterolateral corner release</td>
<td>0.22 ± 0.23</td>
<td>0.40 ± 0.15</td>
<td>P ≤ .0001</td>
</tr>
<tr>
<td>Posteromedial capsule release</td>
<td>0.70 ± 0.17</td>
<td>0.59 ± 0.19</td>
<td>P ≤ .001</td>
</tr>
<tr>
<td>Medial collateral ligament release</td>
<td>0.64 ± 0.14</td>
<td>0.53 ± 0.16</td>
<td>P ≤ .001</td>
</tr>
</tbody>
</table>

Total Force (N) Before and After

| Increase in tibial liner thickness  | 141.36 ± 75.35                           | 235.71 ± 0.16                            | P ≤ .0001    |

Intraoperative Kinematic Findings Using Sensors

PURPOSE:
The authors sought to learn how specific corrections—including bony corrections and ligament releases—affect in-vivo loading and dynamic kinematic signatures of the intraoperative knee.

METHODS:
In a multicenter study, 129 patients underwent primary, sensor-assisted TKA. Intraoperative loading behavior was captured, both pre- and post-correction, in the medial and lateral compartments. Type of bony correction or ligament release, with corresponding loading response, was also captured. Loading release type and effect were input into a regression analysis to determine how intra-articular loading values were affected by individual releases.

RESULTS:
- On average, 2.5 corrections (up to 8) were made in order to achieve balance. (< 15 LBF. OF MEDIOLATERAL DIFF)
- After balancing, a majority of patients displayed the heaviest loading on the medial side (61.9%).
- The difference between pre- and post-correction loading included:
  - MORE SYMMETRICAL LOADING between the medial and lateral compartments
  - LOWER LOADING OVERALL
- The most significant intraoperative corrections that contributed to change in overall loading conditions were: releasing the pes anserine, releasing the MCL, shim size increase, and bony varus correction
- The line graphs indicate the loading values, in the medial and lateral compartments, through the range of motion, and in pre- and post-correction states.

CONCLUSIONS:
WHILE BALANCING WITH THE SENSOR, OVERALL INTRA-ARTICULAR LOADING DECREASED, AND THE MEDIAL-LATERAL LOADING SYMMETRY INCREASED.

PARTICIPATING SURGEONS WERE ABLE TO MAKE TARGETED RELEASERS TO MANIPULATE A WIDE VARIETY OF STRUCTURES ON THE MEDIAL AND LATERAL SIDES.
Assessing the Predictive Capability of Specimen-Specific Knee Simulation

PURPOSE:
To assess the predictive capability of two simulated knees using comparisons with experimentally determined trends found after systematic removal of key tissues.

METHODS:
- Four cadaveric specimens (8 knees) were implanted with TKA components.
- In-vivo laxity testing was performed at 10° with combined anteroposterior, varus-valgus moment, and internal-external forces applied.
- The authors evaluated the relative accuracy of intra-operative sensor output, and simulated modelling, to in-vivo conditions.
- Conditions included knees with: fully intact ligaments, PCL release, MCL release, and popliteus release, successively.

RESULTS:
There was favorable agreement between the sensor output and simulation, both of which accurately described the joint kinematics for each scenario.

CONCLUSION:
SENSOR-ASSISTANCE DURING TKA MAY PROVIDE SURGEONS WITH AN ACCURATE DEPICTION OF NON-NATIVE INTRA-ARTICULAR JOINT KINEMATICS.
Tibiofemoral Forces for the Native and Post-Arthroplasty Knee: Relationship to Maximal Laxity Through a Functional Arc of Motion

PURPOSE:
The authors used intraoperative sensors to define force and laxity conditions in a CR knee design in order to quantify the kinematic behavior of the CR femoral single-radius knee.

METHODS:
8 cadaveric specimens (loaded). Computer navigation was combined with sensor data to define laxity and tibiofemoral contact force during manual laxity testing.

RESULTS:
- Inverse relationships were observed between laxity and contact force loading.
- There was a “roll-forward” inclination observed with respect to the tibiofemoral contact point location when the knee was taken into flexion.
- Change in the laxity of ligaments was shown to be significant past:
  - 30° in the coronal plane
  - 60° in the rotary plane

CONCLUSION:
INTRAOPERATIVE SENSORS MAY BE MORE SENSITIVE THAN MANUAL TECHNIQUES WHEN DEPICTING CHANGES IN LOADING BEHAVIOR, THROUGH THE RANGE OF MOTION, DURING TKA.

Notes