PROTOCOL

Prospective Clinical Study Evaluating Tibiofemoral Rotational Alignment using Intraoperative Sensing during Total Knee Arthroplasty

Clinical Investigation Approval/Agreement

I, _____ (name of Principal Investigator), as Principal Investigator for this Clinical Research Study have read and agree with the study design described within this clinical research protocol. I agree to follow the protocol as described above and abide by the rules and regulations set forth within it and the Code of Federal Regulations.

_____ _____

Signature of Principal Investigator Date

Statement of Confidentiality and Sponsor Address

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B. Associates involved with the study under the direct supervision of the Principal Investigator; and

C. Members of the Institutional Review Board.

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1. INTRODUCTION

The success of total knee arthroplasty (TKA) depends on a multitude of surgical factors, including appropriate rotational alignment of the prosthetic components [11]. Despite the high success rate of TKA, early post-operative complications can occur as a result of poor rotational positioning of one or both components [5, 8, 18], which may ultimately require revision surgery [11, 13]. Complications indicative of tibiofemoral rotational incongruency may present early in the post-operative period with patient complaints of anterior knee pain, joint stiffness, the sensation of instability, and difficulty navigating stairs and inclined planes. It has been reported that the incidence of anterior knee pain may be as high as 20% after a TKA [1, 10, 14]. Clinical examinations of these incongruent patients can reveal restricted range of motion, patellar crepitus, patellar maltracking (tilt - dislocation), and significant rotational mismatch displayed by rotational gait disturbances (foot progression angle) [3, 4, 6, 14, 16-18]. Suboptimal outcomes due to incongruency, which have been well documented in literature, may be associated with only small rotational deviations of the tibial and femoral components. For instance, Barrack, et al. reported that as little as 6.2° of internal rotation (IR) of the tibial component is associated with postoperative anterior knee pain [1]. Berger, et al. showed that combined IR of the tibial and femoral components from 3° to 8° was correlated with patellar subluxation, and 7° to 17° of combined IR correlated with observed patellar dislocation or patellar prosthesis failure [2].

While there are advocated methods for establishing optimal rotation of the femoral component, no such reliable method currently exists for positioning the tibial tray [12]. Thus, surgeons must rely upon anatomic landmarks to guide proper tibial component orientation. These landmarks include: the projected femoral transepicondylar axis, medial third of the tibia, posterior condylar line of the tibia, mid-sulcus of the tibia spine, malleolar axis, patellar tendon, and axis of the second metatarsal [12]. However, difficulty may exist in identifying these landmarks during surgery. Poor intraoperative visibility, coupled with variations in patient anatomy, can contribute to unfavorable positioning. It has been suggested that aligning the tibial tray to the mid-third of the tibial tubercle may reduce positioning outliers with more consistency than referencing other anatomic landmarks [15]. Yet, reliance on these landmarks is still subject to variability [12, 19] and may not provide the precision necessary to avoid complications, such as those described by studies conducted by Barrack, et al. and Berger, et al. As such, an obvious need exists to refine clinical technique, and to explore new methods to optimize tibiofemoral implant congruency.

Recently, technology has made it possible to embed microelectronics into the standard tibial trial [9] (VERASENSE™ Knee System, OrthoSensor, Dania FL). This array of sensors provides dynamic intraoperative feedback regarding tibiofemoral position and quantitative pressure at peak contact points in the medial and lateral

compartments during TKA trailing. Utilizing sensor-derived data, the surgeon can now evaluate intercompartmental loading throughout the range of motion and correct for soft-tissue abnormalities while receiving real-time feedback regarding joint position and the tibiofemoral relationship defined by the contact point location.

2. STUDY DESIGN

The study is designed as a prospective, randomized (two-cohort) double-blinded clinical evaluation and will be conducted at multiple centers throughout the United States. Approximately 500 patients will be included and followed for a period of 2 years. Clinical Assessments will be performed at baseline, 6 weeks, 6 months, 1 and 2 years after surgery.

3. OBJECTIVES

The objectives of the study are twofold: 1) Evaluate how intra-operative sensing may assist the surgeon with tibiofemoral rotational alignment by testing the precision and variability of setting tray rotation to the mid-third of the tibial tubercle. 2) Understand if patients with a combined axial rotation couple at the tibiofemoral joint and quantitative intercompartmental balance, achieved with the use of VERASENSE, exhibit less post-operative knee pain and improved clinical outcomes. Radiographic outcomes will also be assessed to measure post-operative alignment and to evaluate the prevalence and location of radiolucency and/or osteolysis.

Hypothesis: TKA with VERASENSE results in a more reliable and precise option for establishing implant-to-implant congruency and joint balance leading to less knee pain, faster return to normal activities and higher patient satisfaction compared to TKA without VERASENSE.

The secondary objectives of the study are to establish correlations between the intraoperative VERASENSE data, the surgeon's perception of balance and patient outcomes in addition to understanding any learning curve associated with using new technology.

4. TREATMENT AND DEVICE

The intervention involves the use of VERASENSE by the surgeon during Total Knee Replacement Surgery. VERASENSE is available for use with the Stryker Triathlon Total Knee System. VERASENSE replaces the standard tibial trial inserts and is embedded with microelectronics and sensors to provide surgeons with real-time knee kinetic data. The data is wirelessly transmitted to a graphic display (VERASENSE Knee Application), allowing surgeons to quantify and assess soft tissue intercompartmental loads throughout the range of motion. The VERASENSE sensor is not an investigational device. OrthoSensor, Inc., received FDA 510K clearance in 2009. The indication for use is a tool for adjustment of the femoral knee

implant to reduce instability from flexion gap asymmetry. The VERASENSE sensor is sterile and single patient use.

4.1 – Description of VERASENSE

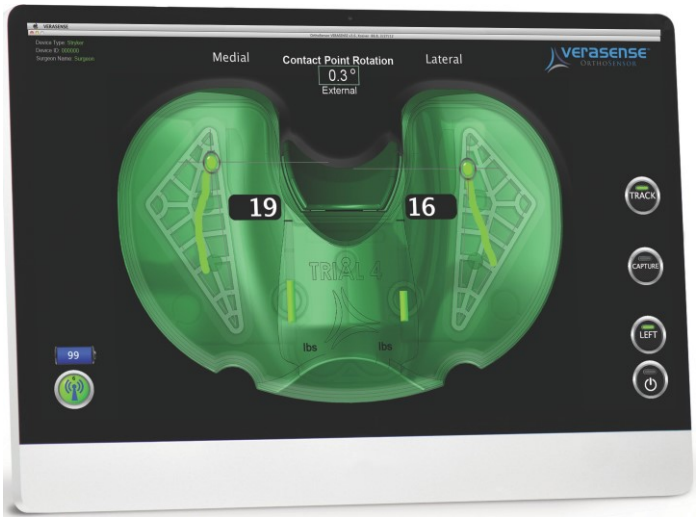
- One articulation (Figure 1): Cruciate Retaining (CR); However can be utilized with Posterior stabilizing implant designs
- Six Sizes: 2, 3, 4, 5, 6, 7
- Four attachable shim thicknesses: 9, 11, 13, and 16mm

Figure 1 – CR VERASENSE Inserts

4.2 – VERASENSE Knee Application (Figure 2)

- Graphic display is a 27” iMac with keyboard, mouse, bar-code reader, activation magnet, receiver (Antenna)
- Software application provides femoral contact point location and load values for medial and lateral condyles; kinematic tracking; tray rotation, tibia varus/valgus axis; mechanical axis

Figure 2 – Graphic Display



5. METHODS / PROCEDURES

Patients indicated for TKA and who meet all study eligibility criteria will be asked to participate in the study. Eligible patients will receive a primary unilateral PCL-retaining or – sacrificing TKA using the Stryker Triathlon Total Knee System *with* or *without* the use of the VERASENSE™ Knee System. Patients will be enrolled in a consecutive series consisting of two cohorts (Groups A and B). Both groups are described below:

Group A – Control (Surgeon-Guided) will consist of **250** consecutive patients who will undergo primary unilateral PCL-retaining or – sacrificing TKA using the Stryker Triathlon Total Knee System *without* the use of VERASENSE to guide rotational alignment and balance. **Prior to closing the arthrotomy**, **VERASENSE will be utilized in a surgeon-*blinded* fashion to record rotational alignment and intercompartmental pressures through a range of motion.**

Group B (Sensor-Guided) will consist of **250** consecutive patients who will undergo primary unilateral PCL-retaining or – sacrificing TKA using the Stryker Triathlon Total Knee System *with* the use of VERASENSE to guide rotational alignment and balance. The sensor data will be used for balancing per the VERASENSE protocol below.

Each patient will be given a unique study number once informed consent has been obtained. The investigator will be blinded to the patient study number and the patient will be blinded to his/her assigned group. It will be important that all patients remain blinded to their assigned group. The patient will be informed during the consent process that they may or may not receive their knee replacement procedure using the VERASENSE Knee System.
Radiographic outcomes will be assessed on all patients within the first 12 weeks and at the annual visits. Any postop complications will also be monitored.

Surgical Protocol – Using VERASENSE

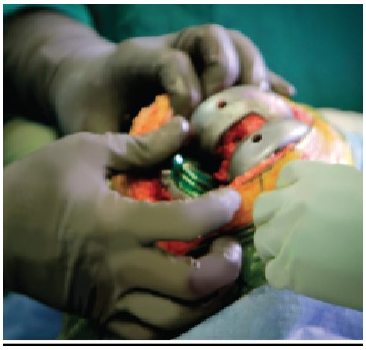
All knees will be prepared using standard instrumentation and a measured resection or gap balancing technique. The following steps will be performed when using VERASENSE:

Step 1: Establish Tibial Tray Rotation:

Select and position appropriate sized trial tibial tray. Align the tray to the anatomy (mid-medial third of the tubercle) as recommended by the manufacture's surgical technique. Insert a single anterior or posterior pin (medially or laterally) into the trial tray to allow for internal / external rotational adjustment while maintaining optimal medial / lateral coverage.

Figure 2 - view of proximal tibia referencing the mid-medial third of tibial tubercle

Step 2: Sensor Insertion



Insert the VERASENSE Sensor with appropriate sized shim attached to replicate thickness of standard trial insert. In a tight knee capsule, it may be necessary to insert the VERASENSE Sensor prior to insertion of the femoral trial. DO NOT utilize excessive force or impact the sensor directly with a mallet.

Figure 3 - VERASENSE™ Sensor activated and inserted into knee

Step 3: Establish Tibial Tray Rotation Utilizing Contact Points

With the leg supported in 10° flexion, rotate the tibial tray to the most posterior contact point (internally or externally) as needed to horizontally align the medial and lateral contact points within 5° of each other. Reference protocol found in Appendix I on how to hold the leg using VERASENSE. A positive (+) value in the Contact Point Rotation (CP Rotation box) indicates internal rotation (IR); a negative (-) value indicates external rotation (ER). Figures 4-6.

When preferred tray rotation is achieved (within 5° Contact Point Rotation):

- Add additional Pin to stabilize tray
- Flex knee and confirm patellar tracking
- Record the final value

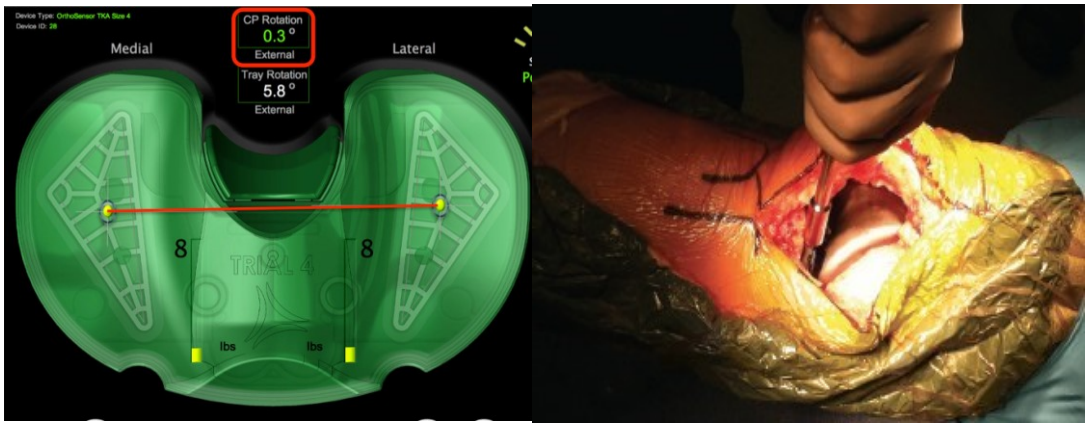


Figure 4 - VERASENSE™ Sensor as displayed on graphical user interface. CP (Contact Point) Rotation degree [in red box] references the degree of tibiofemoral incongruity. Yellow circles correspond to femoral contact points. The number 8 represents total pounds of pressure in the medial and lateral compartments

Figure 5 - Left: Medial and lateral femoral contact points (indicated by arrows) demonstrate tibiofemoral rotational incongruency, due to excessive IR of the tibial tray. Right: After correcting for IR, the femoral contact points demonstrate symmetry (indicated by arrows).

Figure 6 - Left: Example of excessive ER (indicated by arrows), as a result of referencing the mid-third of the tibial tubercle, shown by the sensor interface. Middle: Trial tibial/femoral components in place with the sensor; tibial tray visually and digitally exhibiting external rotation. Right: The tibial tray is rotated to improve congruency, as seen by the parallel contact points (indicated by arrows) on the sensor interface.

Step 4: Balance Soft-Tissue Sleeve

Once tibial tray rotation has been assessed, the medial and lateral compartment pressures will be evaluated in the coronal and sagittal planes. The soft tissue gaps will be evaluated and recorded at **10°, 45°,** and **90°** of flexion, with the hip in neutral rotation and the femur supported just proximal of to the knee. The capsule must be closed provisionally during assessment at each pose using a towel clip placed above and below the patella in the medial retinaculum. Incremental balancing using a pie-crusting technique with an 18-guage needle or #11blade scalpel is recommended to address ligamentous tension when necessary. Additional bony resections may be necessary for excessive loading (refer to surgical reference guide). Previous research evaluating the use of VERASENSE during TKA suggests a load differential of up to 15 lbs or less between the medial and lateral condyles is indicative of soft-tissue balance [7] (Figure 7). These balancing parameters will be the target in the sensor-guided group.

Figure 7 – Left: The mediolateral intercompartmental difference, pre-release, is 42 lbs. This value exceeds the 15 lb. limit, thus classifying this joint as "unbalanced." Right: The mediolateral intercompartmental difference, post-release, is 1 lb. and was classified as "balanced" upon closing.

6. CLINICAL SITES

This study will be conducted at multiple centers by experienced, high-volume surgeons in the United States

7. PATIENT SELECTION

Enrollment: Approximately 500 patients will be enrolled and followed for a period of 24 months in order to assess patient outcomes. Each center is expected to enroll approximately 100 patients (50 in each group). The investigator is responsible for evaluating each patient against the following criteria and assuring that the patient meets the following requirements in order to be enrolled in the study. Each patient must meet all the inclusion criteria and none of the exclusion criteria to be considered for enrollment.

7.1 Patient Eligibility

a. Inclusion Criteria

- Patients who meet the indications for use for primary PCL-retaining TKA using the Triathlon® Total Knee System using VERASENSE™
- Subject must be diagnosed with one or more of the following conditions
  - osteoarthritis
  - rheumatoid or other inflammatory arthritis
  - post-traumatic arthritis
- Subject is likely to be available for all study visits
- Subject is able and willing to sign the informed consent and follow study procedures

b. Exclusion Criteria

- Prior Total Knee Arthroplasty
- Avascular Necrosis
- Any knee surgery other than meniscectomy (can be arthroscopic or open)
- Ligament insufficiencies, prior surgeries such as ACL or PCL reconstructions, posterolateral reconstructions, osteotomies, tibia plateau fractures
- Ipsilateral foot/ankle and hip arthritis

- Range of motion less than 90°, flexion contracture greater than 20°
- Subject has a mental condition that may interfere with the subject's ability to give an informed consent or willingness to fulfill the study requirements (i.e., severe mental retardation such that the Subject cannot understand the informed consent process, global dementia, prior strokes that interfere with the Subject's cognitive abilities, senile dementia, and Alzheimer's Disease)
- Any subjects meeting any contraindication criteria as identified in the locally approved labeling for the device should be excluded from this study.

7.2 Contraindications for the Triathlon™ Knee are:

1. Any active infection or suspected latent infection in or about the knee joint
2. Distant foci of infection which may cause hematogenous spread to the implant site
3. Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in post-operative care
4. Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis
5. Skeletal immaturity
6. Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function
7. Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of fixation of the device or to failure of the device itself

7.3 Patient Failure / Withdrawals

Removal or revision of any implant or malfunction of VERASENSE™ intra-operatively will be considered endpoints, with the patient being withdrawn from continued follow-up in the study. Every attempt must be made to ensure that all patients return for all of the post-operative assessments. However, patients are free to withdraw from the trial at any time and are under no obligation to provide a reason for doing so. All attempts should be made to ascertain whether a patient is lost to follow up, chosen not to return for follow-up or is deceased.

8. Medical Device Adverse Clinical Event Reporting

This study is not intended to prospectively assess the absolute product safety; however any device or procedure related safety issues will be documented as follows. The site will be required to transcribe onto the Safety Data CRF only those adverse clinical events that have been determined by the physician investigator to be attributable (even remotely) to 1) the knee arthroplasty procedure and/or 2) the use of the VERASENSE™ device.

The information to be captured on the CRF include the severity, relationship to knee arthroplasty procedure and the VERASENSE™ Device, outcome and treatment (when applicable).

a. Expeditious Reporting - Medical Device Reportable Events (21 CFR §803.3)

Expeditious reporting to OrthoSensor is required for any fatal or serious injury (as defined below) that in the judgment of the physician investigator may have be *attributed to the use of the VERASENSE™ device* (only), or that the device was or may have been a factor in a death or serious injury, including events occurring as a result of: (1) failure; (2) malfunction; (3) improper or inadequate design; (4) manufacture; (5) labeling; or (6) user error.

The term "Serious injury" is defined per 21 CFR 803 as an injury or illness that:

1. Is life-threatening
2. Results in permanent impairment of a body function or permanent damage to a body structure;
3. Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure

The clinical site must notify the OrthoSensor by email or telephone immediately but no later than 2 business days of any fatal or serious injury *directly attributed to the use of the VERASENSE™ device*. Notification to the IRB of record will be done according to the IRB's specific procedures. OrthoSensor will be responsible for reporting the event to the FDA according to the timelines put forth in 21 CFR 803.

8.1 Risk Benefit Analysis:

As in any surgical procedure, certain risks are associated with total joint arthroplasty. These risks include but are not limited to: anaesthetic and post-anaesthetic reactions (such as hyperaemia), allergic reactions to prophylactic antibiotics or blood transfusions, damage to blood vessels or nerves or death. Post-operatively, a patient may experience thrombophlebitis, pulmonary embolus, dislocation, pain, limp, component loosening, osteolysis due to wear debris or the need for additional surgery. Fracture of the prosthesis is a potential complication.

As all patients recruited for this study are indicated for primary total knee arthroplasty with the device described in the protocol anyway, there is no known risk associated with participating in this study.

8.2 Protocol Departures:

Any departure from the current, approved protocol is considered to be a deviation or violation. Depending on severity of the departure, the reporting timeframe for the deviation/violation will change.

The following definitions apply:

- **Violation**: protocol deviation that is IRB/FDA reportable. For example, but not limited to, Informed Consent Documents not signed before surgery, a missing or lapsed IRB approval or an ineligible subject enrolled
- **Deviation**: protocol is not being followed exactly. For example, but not limited to, visits out of window, some data not collected for that visit or source documentation not available for a visit (CRFs used as source document).

8.3 Informed consent violation:

No patient will be enrolled in the study and have any study-related procedures performed, including completing subject clinical assessments, before an approved Informed Consent Document is signed. If this occurs, this is a VIOLATION and must be reported to OrthoSensor.

9. DATA COLLECTION

All data collection will be prospective and will be collected after the patient has voluntarily agreed to participate in the study by signing and dating an IRB-approved informed Consent and HIPAA document (as required by the local IRB). Data will be collected according to the scheme outlined in Table 1.

a. Methods:

i. Data can be collected via paper form, or entered directly to an online database, if applicable.

ii. If the site has an existing database, data may be sent to OrthoSensor via raw data format in an excel spreadsheet. If using a local database, it must be ensured that the data in the spreadsheet is compliant with the methods presented in the case report forms, as all data must be available for statistical analysis.

b. Data and Clinical Assessments:

- Patient Demographics: Age at surgery, gender, surgical side, height, weight, primary diagnosis. This data is collected from the medical record.
- Operative Data: Part Numbers (if able) or Femoral Component Type & size, Tibial Tray Type & Size, Tibial Bearing Type & Size, Patella Type & Size, OR Time, Surgical Technique, Surgical Approach, Operative Complications, Length of stay. This data is collected from the medical record.
- Length of stay, Discharge Destination: Based on the operation day and day of discharge, the length of hospital stay is determined.
- Patient Reported Outcome Measures – Perceived functioning, including pain, satisfaction and function will be measured using three patient reported outcome measures (PROMs).

- **EQ-5D**
  A standardized instrument for use as a measure of health outcome

- **Knee Society Score (2011 Version)**
  The latest version of the KSS was developed in 2011 and introduced by the Knee Society. The latest version of the KSS originates from the popular KSS (from 1989); both physician and patient derived. It includes versions administered preoperatively and postoperatively. It has an initial assessment of demographic details, including an expanded Charnley functional classification. The objective knee score, completed by the surgeon, includes a VAS score of pain, walking on level ground and on stairs or inclines, as well as an assessment of alignment, ligament stability and ROM, along with deductions for flexion contracture or extension lag. Patients then record their satisfaction, functional activities, and expectations. Given the diverse activity profiles of many contemporary patients, the functional component of the score was improved to include a patient-specific survey, which evaluates features such as standard activities of daily living, patient-specific sports and recreational activities, patient satisfaction, and patient expectations. The new Knee Society Knee Scoring System has been developed and validated, in part, to better characterize the expectations, satisfaction, and physical activities of the younger and more diverse population of current patients undergoing TKA. The score was validated in a thoughtful and methodical fashion confirming internal reliability and analyzed for differential item functioning. The new Knee Society Scoring System is broadly applicable across sex, age, activity level, and implant type. Completing the questionnaire takes 10 to 30 minutes.

- **Forgotten Joint Score (FJS)**
  The FJS is a patient reported outcome measure, consisting of 12 questions (e.g. awareness traveling in a car or climbing stairs?). It uses a 5-point Likert response format and the raw score is transformed to range from 0-100 points. High score indicates good outcome, e.g. a high degree of forgetting the joint in everyday life (forgotten joint phenomenon). The FJS has a low ceiling effect and was designed to discriminate between good, very good and excellent outcomes after TKA.

- **Knee Pain Evaluation Form**
  The knee pain evaluation will be used to assess the prevalence and location site of knee pain when applicable. This evaluation will be completed by the investigator post total knee surgery during the intervals defined in Table 1 “Schedule of study assessments”.

- Radiographic evaluation via Mediolateral and anteroposterior x-rays as is standard of care. The prevalence and location of radiolucency and/or osteolysis is evaluated on both AP and lateral views at each patient’s routine postoperative

follow-up visits. These evaluations are performed by each patient's operating surgeon.

- Complications, adverse events, and survivorship data will be collected and reported. This information will be gathered at each of the study follow-up visits.

c. Data Collection Periods:

Data will be collected pre-operatively, intra-operatively, and post-operatively at 6 weeks, 6 months, and 1 year. All time point windows are determined using the date of surgery (DOS) as day 0, including all annual visits. The visit windows are as follows:

Pre-operative: within 3 months prior to the date of the surgery excluding *Pre-operative radiographs. Pre-operative radiographs taken within 12 months of scheduled knee replacement surgery are sufficient.
Intra-operative: within 2 weeks after the date of surgery
6 weeks: DOS + 6 weeks ± 4 weeks
6 months: DOS + 6 months ± 45 days
1 year: DOS + 1 year ± 90 days
2 year: DOS + 2 year ± 90 days

Table 1. Schedule of study assessments

Data Collected	Pre-op Baseline	Operative Discharge	6 Weeks	6 Months	1 Year	2 Years
Obtain Written Informed Consent	X					
Demographics	X					
Intra Operative		X				
EQ-5D	X		X	X	X	X
New-KSS	X		X	X	X	X
FJS			X	X	X	X
Knee Pain Evaluation Form				X	X	X
Radiographic Alignment	X		X	X	X	X
Adverse Event Reporting (When Present)		**(X)**	**(X)**	**(X)**	**(X)**	**(X)**

10. Analysis to be Performed on Data (e.g. Statistical Analysis)

Analysis of the data will be performed using SPSS version 21. Comparative Statistics will be run between outcomes data stratified by both groups: Analysis of variance (AVOVA) will be used to assess the difference between each group, with post-hoc t-tests to demonstrate significance. Separate analyses will be performed to evaluate power of sample sizes and any correlative affect that demographic/clinical variables may have on patient outcomes.

11. Monitoring of data collection

The Sponsor will monitor all data collected for accuracy and completion. The site will be monitored at least once per calendar year following the initial/first-monitoring visit.

12. Patient Identification

Each patient who signs an informed consent document will be given a unique, sequential 3-digit number. The three initials of each patient will be used (first, middle, last). In the case where the subject does not have a middle initial, that placeholder will be held by a dashed line (-). This unique patient identifier will be used on all study-related documentation for each subject enrolled in the study. The patient's initials will be used to further identify the subject; no names will be used.

13. Screening Enrollment Logs

A record of all patients consented for the study, with their consecutively assigned study numbers, will be maintained in the site's Regulatory Binder. This log will be identified as the Screening/Enrollment Log. Patients who sign a consent form but who do not continue into the study for whatever reason (i.e., cancel surgery) will be assigned a unique subject identifier which **WILL NOT BE REASSIGNED** to anyone else.

14. Patient Identification

Each patient who signs an informed consent document will be given a unique, sequential 3-digit number. The three initials of each patient will be used (first, middle, last). In the case where the subject does not have a middle initial, that placeholder will be held by a dashed line (-). This unique patient identifier will be used on all study-related documentation for each subject enrolled in the study. The patient's initials will be used to further identify the subject; no names will be used.

Example: Subject number: 001.
Subject initials: FML where F = first initial, M = middle initial, L = last initial. This subject's unique identifier would be 001 and uniquely associated with the initials FML.

15. Institutional Review Board Approval and the Informed Consent Document.

It is the responsibility of the Principal Investigator to ensure that an Institutional Review Board (IRB) reviews the study and that the IRB acts in accordance with the requirements set forth in 21CFR56 – Institutional Review Boards. The Principal Investigator will forward copies of the protocol and all required documents to the IRB for review. Further, it is the Principal Investigator's responsibility to promptly inform the IRB of any revisions to the Clinical Study Protocol, to promptly report any serious medical device adverse events and/or unexpected events and to provide a periodic report of the study's progress to the IRB at intervals not to exceed 1 year. Any proposed amendment to the protocol that involves increased risk to the subject will require IRB approval prior to its enactment.

The investigator must forward written verification of the initial IRB review and approval to OrthoSensor before beginning the clinical study. The Principal Investigator must immediately forward copies of all subsequent correspondence between the Principal Investigator and the IRB concerning the continued approval of this clinical study, or withdrawal of such approval, to OrthoSensor.

16. Administrative Considerations

- **Ethics: The Declaration of Helsinki**
  In any research on human subjects, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. (21CFR312.120(3)I.9.
- **Changes to the protocol**
  OrthoSensor and the Investigator must approve any changes made to this Protocol and/or any of the appendices and are subject to the approval of the relevant Institutional Review Board(s).
- **Clinical Investigator Agreement**
  The Clinical Investigator Agreement is a written agreement to be signed by the Investigator that defines his/her responsibilities and willingness to follow the study protocol. This agreement must be signed by the Investigator and submitted to OrthoSensor before the initiation of the study.
- **Completion of the Study**
  OrthoSensor will notify the Investigator when adequate data have been collected or when the clinical evaluation is terminated for any reason.
- **Reporting of Results**
  The data collected in this study will be analyzed and compiled into a report for review by the Investigator per the contracted agreement between the Investigator and OrthoSensor. The results will be published in a scientific medical journal and will be presented at National and International congresses and symposia.

17. Contact Information

For assistance or questions regarding this evaluation, please contact the Department of Clinical and Bioengineering Research at OrthoSensor, Inc as indicated below:

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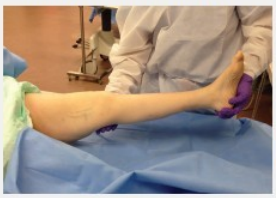
Appendix I

Holding the Leg using Verasense

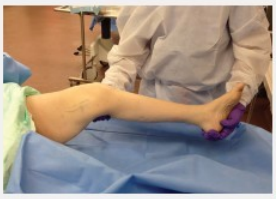
HOLDING THE LEG

For the correct depiction of intra-articular loading, in extension and flexion, the leg must be held with posterior support:



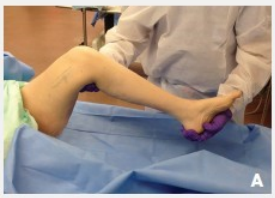
Step 1.

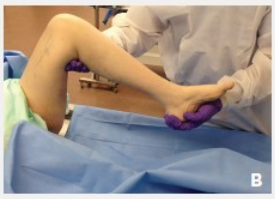
With the leg in extension, one hand is placed on the heel of the operative leg; one hand is placed under the backside of the knee, at the posterior capsule.

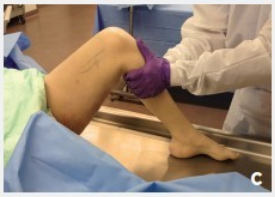


Step 2.

Initial evaluation of soft tissue should always be assessed with the leg flexed in 10° with the posterior capsule relaxed and the screw home mechanism disengaged. Failure to do so could result in the over-releasing of soft-tissue, as loads tend to increase during terminal extension due to the screw home mechanism.



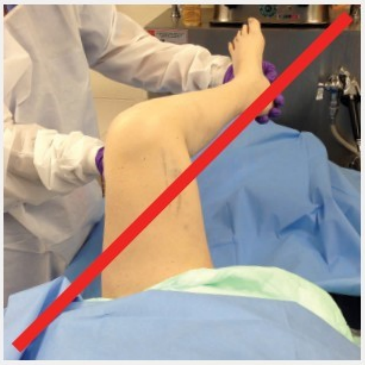




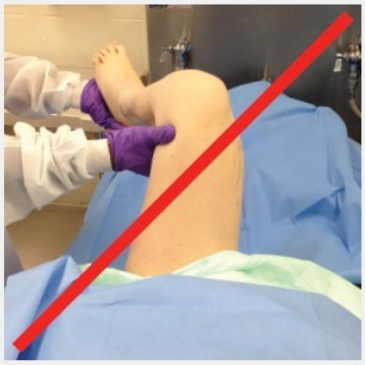
Step 3.

Soft tissues should continue to be evaluated at 45° (FIG A) and 90° of flexion (FIG B). If using a cruciate retaining component, an intraoperative posterior drawer test will allow the surgeon to assess PCL stability using the VERASENSE tracking option (FIG C).

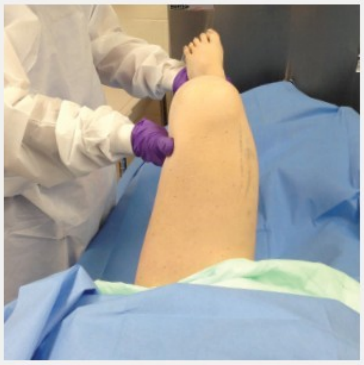
HOLDING THE LEG (CONTINUED)



INCORRECT
Abducted/Externally Rotated



INCORRECT
Adducted/Internally Rotated



CORRECT
Neutral Position

Appendix II

Surgical Reference Guide

SURGICAL TECHNIQUE QUICK REFERENCE

Authored By: Martin W. Roche, M.D.
Holy Cross Hospital, Fort Lauderdale, FL

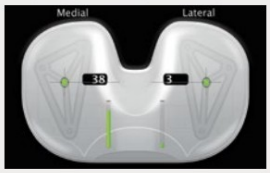
Patrick A. Meere, M.D.
NYU Langone Medical Center, New York, NY

Assess soft-tissue load references with **joint reduced and capsule closed**. Only address soft-tissues after loads have been assessed in both **extension and flexion (10°-90°)**. After any tissue release, the **leg should be "cycled"** (taken through the range of motion) several times.

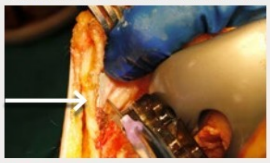
APPROACH TO VARUS KNEE

TIGHT IN EXTENSION - MEDIALLY

SENSOR PRESENTATION:

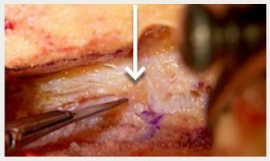


SURGICAL CONSIDERATION:



Evaluate MCL

Palpate fibers of MCL to assess tension. Release **posterior fibers of MCL** (both deep and superficial).

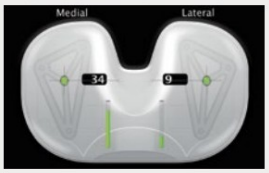


Evaluate Medial Posterior Capsule

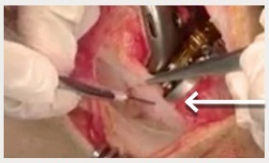
Release medial posterior capsule and/or semimembranousus at tibial attachment site.

TIGHT IN FLEXION - MEDIALLY

SENSOR PRESENTATION:



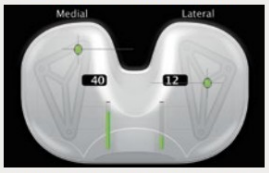
SURGICAL CONSIDERATION:



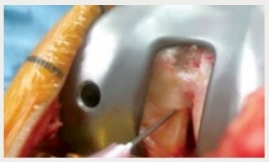
Condition 1. **Evaluate MCL**

Palpate fibers of MCL to assess tension. Release **anterior fibers of MCL** (both deep and superficial).

SENSOR PRESENTATION:



SURGICAL CONSIDERATION:

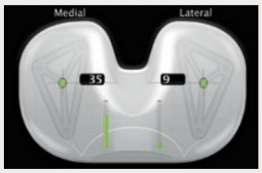


Condition 2. **Evaluate PCL**

If medial femoral contact point exhibits excessive tension and posterior positioning, release **anterolateral bundle PCL fibers**.

TIGHT IN FLEXION AND EXTENSION - MEDIALLY

SENSOR PRESENTATION:



SURGICAL CONSIDERATION:

Condition 1. **Loads 20-40 lbs.**

Extension Balancing:

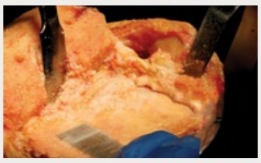
- Posterior MCL fibers released if in tension; loads rechecked.
- Posterior medial capsule checked for tension and released, if needed; loads re-checked.
- If necessary, semimembranosus can be released.

Flexion Balancing:

- Anterior MCL fibers released if in tension; loads rechecked.

SENSOR PRESENTATION:

SURGICAL CONSIDERATION:



Condition 2. **Loads > 40 lbs.**

If loads beyond 40 lbs. are displayed, consider recutting the tibia plateau **to add additional varus** alignment.

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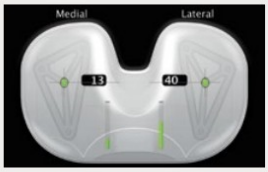
APPROACH TO VALGUS KNEE

TIGHT IN EXTENSION - LATERALLY

SENSOR PRESENTATION:



SURGICAL CONSIDERATION:

Evaluate Lateral Posterior Capsule & Arcuate

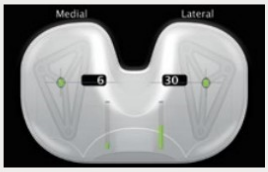
Palpate **the lateral posterior capsule** and/or the **arcuate ligament** to assess tension; release as necessary.

Evaluate IT Band

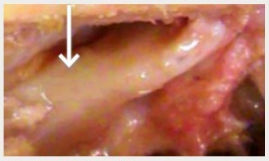
If lateral posterior capsule/ arcuate does not fully address tension, consider releasing tight fibers of the **IT band**.

TIGHT IN FLEXION - LATERALLY

SENSOR PRESENTATION:



SURGICAL CONSIDERATION:

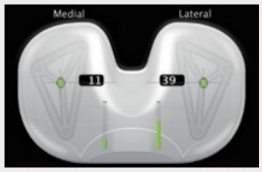


Evaluate Popliteus

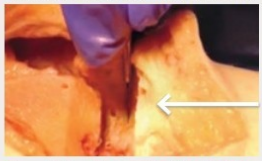
Release tight fibers of the **popliteus tendon**.

TIGHT IN FLEXION AND EXTENSION - LATERALLY

SENSOR PRESENTATION:



SURGICAL CONSIDERATION:



Condition 1. **Loads 20-40 lbs.**

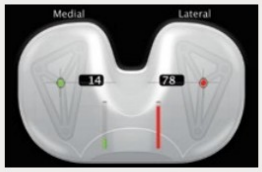
Extension Balancing:

- Release posterior lateral corner; recheck loads.
- Release posterior lateral capsule and arcuate complex; recheck loads.
- Consider releasing tight fibers of IT band, if necessary.

Flexion Balancing:

- If excessive loads are still uncorrected, then popliteus tendon is checked for tension and released.

SENSOR PRESENTATION:



SURGICAL CONSIDERATION:

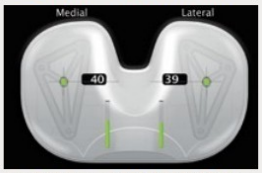
Condition 2. **Loads >40 lbs.**

If necessary, you may **recut tibial plateau** to add more valgus.

TIGHT EXTENSION GAP

TIGHT ONLY IN EXTENSION - SYMMETRICALLY

SENSOR PRESENTATION:



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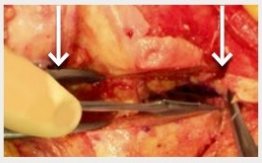
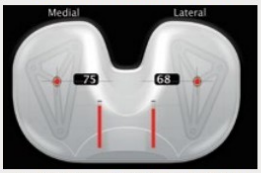


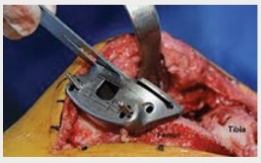
Condition 1. **Loads 20-40 lbs.**

Release **posterior capsule.**

SENSOR PRESENTATION:



SURGICAL CONSIDERATION:



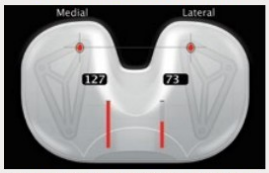
Condition 2. **Loads >40 lbs.**

If necessary, consider **recutting distal femur**.

ADVERSE FLEXION GAP

TIGHT ONLY IN FLEXION - SYMMETRICALLY

SENSOR PRESENTATION:



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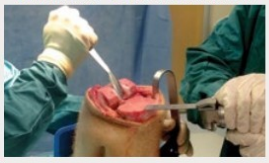
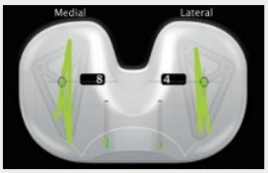


Loads > 40 lbs.

Increase **tibial slope**.

LOOSE AND/OR UNSTABLE FLEXION GAP

SENSOR PRESENTATION:



SURGICAL CONSIDERATION:

Loads < 10 lbs.

Increase thickness of **shim**.