A Prospective, Non-randomized, Multi-Center Investigation of All-suture-based Repair of Horizontal Meniscal Tears (STITCH Study)

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STUDY PROTOCOL

1. ABBREVIATIONS, ACRONYMS AND DEFINITIONS

All Suture-Based Technique: A repair technique (all-inside, inside-out, outside-in or combination thereof) utilizing only suture without implanting any other material intended to anchor and/or replace suture material.
BMI: Body Mass Index
Complex Tear: Multiple discreet tears, tears with multiple planes, or meniscal tissue incapable of holding suture.
Consented Patient: A patient who, after the screening process, grants consent to participate in the trial.
CFR: Code of Federal Regulations
CRF: Case Report Form; includes all study forms.
Enrolled Subject: A patient who has been consented, meets all criteria for inclusion immediately prior to treatment and receives all suture-based repair of meniscal tear.
HT: Horizontal tear (of the meniscus); the majority of the tear is oriented primarily (but not exclusively) parallel to the plane of knee joint dividing the structure into superior and inferior flaps. For the purpose of this protocol, HT includes obliquely-oriented tears. These tears may open at the central apex or along the inferior surface of the meniscus. Some horizontal tears may have a radial component (bird beak) in the central White Zone.
HIPAA: Health Insurance Portability and Accountability Act
IKDC: International Knee Documentation Committee
IRB: Institutional Review Board
ISAKOS: International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine
KOOS: Knee injury and Osteoarthritis Outcome Score
PCL: Posterior Cruciate Ligament
Protocol Deviation: A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that is under the Investigator's control and that has not been approved by the IRB.
Protocol Violation: A protocol violation is a deviation from the IRB-approved protocol that may affect the subject's rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data.
Red Zone: The well-vascularized peripheral-most ~30% of the meniscus.
Red-White Zone: The transition between the outermost and innermost portions of the meniscus where vascularity diminishes from peripheral to central.
Subject: A consented patient who has been enrolled in the study.
White Zone: The inner (avascular) one-third of the meniscus.

2. PROTOCOL SYNOPSIS

Study Title	A Prospective, Non-randomized, Multi-center Investigation of All Suture-based Repair of Horizontal Meniscal Tears
Protocol Number	CTX-CP001
Study Objectives	The primary objectives of this study are to document horizontal meniscus tear repair, characterize the reoperation survival curve and assess improvements in knee pain and function.
Study Design	Interventional, non-randomized, single-arm assignment, open label clinical trial of suture-based meniscal repair.
Endpoints	Freedom from reoperation of the index meniscus repair site at 6 months, 1 year, and 2 years; Improvements in knee pain and function as measured by KOOS, IKDC Knee evaluation, Lysholm Knee scale and Tegner Activity Scale
Subject Population	The study population will include 30 otherwise healthy subjects 18 to 60 years of age (inclusive), enrolled at up to 10 investigational sites in the United States, who have a horizontal meniscus tear.
Analysis Populations	Data obtained from all enrolled subjects will be analyzed on a per-treatment (PT) basis, which will include all enrolled subjects who receive the protocol-defined treatment of suture-based meniscal repair.
Study Duration	Subjects will be followed for a total of 2 years.
Screening Inclusion Criteria	Subjects of either gender ***may be*** eligible for inclusion in the study only if they meet ***all*** of the following criteria at screening: • Able and willing to give informed consent by voluntarily providing written informed consent in accordance with governing Institutional Review Board • 18 to 60 years of age, inclusive at the time of screening; • History indicative of meniscal pathology (e.g., pain, mechanical symptoms described as locking, clicking or giving way); • Physical exam consistent with meniscus tear (e.g., locked joint, joint line tenderness and/or pain on meniscal compression);

	• If prior ligament reconstruction, the study knee is clinically stable; • Preoperative MRI evidence consistent with a horizontal/oblique meniscus tear in the symptomatic compartment; • Healthy and not pregnant
Screening Exclusion Criteria	Subjects ***will be*** excluded from the study for ***any*** of the following reasons during screening: • Arthritis in the study knee (Kellgren-Lawrence Grade 3 or higher); • Body Mass Index (BMI) ≥35 kg/m^2; • Previous meniscal repair or meniscectomy of the study meniscus; • Unstable knee; • Malalignment of the study knee >5 degrees and/or requiring osteotomy and/or correction; • History of constitutional/systemic inflammatory/arthritic problem or pain condition, history of knee infection, vascular condition of legs, benign neoplasms of knee, hepatitis, HIV, drug/alcohol abuse, tobacco abuse, cancer; • Expected to undergo any other primary treatment of the knee; • Any concomitant painful or disabling disease, condition or post-procedure status of either lower extremity that would interfere with evaluation or rehabilitation of the study knee. • Pregnant or planning to become pregnant in the next 2 years.
Arthroscopy Inclusion Criteria	Consented subjects ***may be*** included in the study only if, upon arthroscopic inspection, their meniscal study lesion meets ***all*** of the following criteria established by the International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine (ISAKOS): • Zone location: circumferential location of tear includes locations within 10mm of the peripheral rim of the meniscus; • Radial location: any location from anterior to posterior; • Tear pattern: primarily horizontal or oblique in orientation (not to exceed 45 degrees from horizontal);

	• Compartment: either lateral or medial, but not both; • Opposite compartment meniscal tear (if present) limited to the central portion (i.e., Zone 3/"white zone"); • Tear amenable to repair with all suture-based techniques.
Arthroscopy Exclusion Criteria	Subjects ***will be*** excluded from the study if their study meniscus lesion meets ***any*** of the following criteria at arthroscopy: • Tear pattern: primarily vertical longitudinal or radial in orientation; • Partial meniscectomy of any portion of the study meniscus extends beyond the central portion (i.e., Zone 3/"white zone"); • Intact or partially intact meniscus tear that, in the opinion of the Investigator, does not require repair; • Poor meniscal tissue quality such that it will not hold a suture; • Any portion of the meniscus repair that, in the opinion of the Investigator, is best treated using an implant other than suture; • Clinically significant (zone 1 and/or zone 2) tear in the contralateral compartment to the study meniscus; • Performance of a significant concomitant procedure intended as a therapeutic intervention on the study knee; • Arthritis in the surgical knee Modified Outerbridge Grade III or higher.
Study Visits	Screening (Study Visit 1): Informed consent, screening eligibility criteria, demographics, patient reported outcomes, MRI (within 6 months) and X-rays (within 6 months); Procedure (Study Visit 2): Arthroscopy eligibility criteria, enrollment, meniscal-repair, images, complications; details of pathology and procedure 1st postop [Day 7-15] (Study Visit 3): Complications; 2nd postop [Day 90±7 days] (Study Visit 4): Complications, patient reported outcomes; 3rd postop [Day 185±14 days] (Study Visit 5): Complications, patient reported outcomes, visual examination of meniscus tear (when available);

	4th postop [Day 365±30 days] (Study Visit 6): Complications, patient reported outcomes, MRI; 5th postop [Day 730±30 days] (Study Visit 7): Complications, patient reported outcomes, X-Rays;
Rehabilitation Plan	All subjects will follow their Investigator's preferred rehabilitation plan. At a minimum, all subjects must meet the following post-operative thresholds: • Weight bearing as tolerated • Hinged knee brace locked in extension when walking (4-6 weeks), released to 90 degrees for sitting/driving • No squatting or stand up/sit down motions until after 6 weeks post-op • No cutting or pivot sports until after 6 months post-op
Sponsor	Ceterix Orthopaedics 959 Hamilton Avenue Menlo Park, CA 94025 (650) 316-8660

3. INTRODUCTION, BACKGROUND AND RATIONALE

This document is a protocol for a human research study. This study is to be conducted in accordance with United States government research regulations, applicable international standards of Good Clinical Practice and institutional research policies and procedures.

3.1. Background

Meniscal pathology, primarily in the form of a tear, is very common and frequently symptomatic. In the United States alone, over 500,000 meniscectomies were performed in 2006.[1] Historically, treatment for meniscal tears consisted of open total meniscectomy. As surgeons began evaluating the long-term impact of total meniscectomy and, in parallel, as biomechanical studies began demonstrating the vital importance of the meniscus on knee function,[2,3,4,5,6,7,8,9] it became apparent meniscectomy had consequential and deleterious effects on the knee over time.[10.,11,12,13] An interest in improving the treatment of meniscal pathology emerged in the orthopedic community.

As the understanding of the importance of the meniscus evolved, so too did technologies enabling surgeons to perform more specific and limited procedures on torn menisci with arthroscopic approaches.[14] As a result, many patients have undergone arthroscopic-assisted meniscus-preserving surgery (limited removal, repair or a combination of the two procedures) over the past 30 years. Compared to outcomes when total meniscectomy was standard of care, clinical outcomes for patients with meniscal tears today have improved substantially.[15] Although less

anatomical destruction is the preferred strategy, when a tear is deemed not amenable to repair, partial meniscectomy is the next line of treatment.

Although repair when feasible is the current standard of care for meniscal tears,[16,17,18,19,20,21,22,23,24] it is most often performed on primarily, vertically-oriented tears for several reasons. Firstly, the anatomic constraints of the knee limit arthroscopic placement of sutures and non-suture devices in such a way that a perpendicular approach to the tear is the least technically challenging. Vertical tears present in a substantially perpendicular plane relative to the arthroscopic access ports. Secondly, the literature is replete with data demonstrating a high efficacy rates in these tears.[25,26,27,28,29,30,31]

Reparability and healing potential are not identical; however the concepts are often used interchangeably. One term is correctly applied to the technical feasibility of performing a repair and maintaining the repair integrity over time; the other is a biologic phenomenon. The current teaching regarding horizontal/oblique and tears is that they are most often irreparable.[32,33,34,35,36] As such, little clinical documentation regarding the feasibility of repairing these tears exists. Furthermore, contrary to clinical doctrine, the scant existing literature on the subject challenges the understanding of the healing potential of horizontal/oblique tears by suggesting that repair has successful outcomes anywhere from 50-100% of the time.[37,38,39,40,41,42,43,44] Clearly additional prospective assessments of horizontal/oblique tears is needed.

Horizontal tears are notable for a few reasons: 1) they are common, comprising up to 20% of meniscus tears [45,46,47]; 2) despite improvements in meniscal repair methods, the techniques have been difficult to employ successfully across these particular tears. With newer suture delivery methods enabling surgeons to more easily place sutures in patterns that reduce these tears, it is possible to further assess and document their reparability. This study will begin that process by examining and documenting the ability to successfully repair horizontal meniscus tears using all suture based techniques.

3.2. Rationale and Justification for the Study

a. Rationale for the Study Objectives

Although the clinical consensus holds that horizontal tears are often irreparable, there are no prospective, multi-center trials in the literature that document successful repair of the meniscus, surgical reoperation rates for meniscal tears and improvements in knee pain and function.

b. Rationale for Study Population

The study is limited to healthy subjects with horizontal meniscal tears. Although these injuries can occur in any age group, slightly younger age range (18-60 years of age) allows inclusion of knees with less likelihood of significant arthritic changes

which may mask measurement of knee pain and function improvements following the treatment procedure.

c. Rationale for Study Design

It is well established in the literature that meniscectomy leads to increased risk of late osteoarthritis, and conversely, that repairing the meniscus reduces this risk. The clinical consensus is that preservation of meniscal tissue should be the goal whenever possible. The alternative for these patients is meniscectomy (a failure endpoint in this study), therefore there is no available control. A prospective, non-randomized, single-arm assignment study design is the best method for obtaining objective data for clinicians and patients in weighing the viability of meniscal repair versus primary meniscectomy.

4. STUDY DESIGN

4.1. Hypotheses

No formal hypotheses testing will be done. However, primary outcome measures that will be examined include: A substantial proportion of the subjects will show meniscus healing at 6 months. The two-year reoperation survival rate will be similar or less than historical rates. Patient reported outcomes will be improved at six-months following the procedure.

4.2 General Design

The study is an interventional trial designed as a non-randomized, single-arm, open-label study of repairs of horizontal of the meniscus using commercially available products. The study will enroll 30 subjects at up to 10 investigational sites in the United States.

4.3. Objectives

The primary objectives of this study are to assess reoperation rate, improvements in knee pain and function, and meniscus repair rate following all-suture-based repair of the horizontal meniscal tear.

4.4. Potential Risks and Benefits

a. Risks of Study Participation

A subject has the risk of suture reaction, a risk that exists with any surgical procedure utilizing suture material. Additionally, although some studies suggest that repairing horizontal tears can be effective, this may not be the case in this study. Some or all subjects in the study may fail to gain relief of their symptoms or have a recurrence of their symptoms, necessitating subsequent surgical procedures to solve their pain and mechanical symptoms.

In-office needle arthroscopy (e.g. VisionScope) diagnostic testing risk is minimal. The probability and magnitude of harm or discomfort anticipated in this research study is no greater than that ordinarily encountered during the performance of routine diagnostic tests. The diagnostic device used in this study is approved for diagnostic procedures by the FDA and therefore this study does not present new risks to patients and should be considered a non-significant risk study based upon the definitions in 21 CFR 812.3. The most common risk associated with an in-office needle arthroscopy procedure is slight pressure or discomfort from needle/device insertion. Least common risks are minor bleeding in and around the joint area. And while rare, there is always a risk of infection in the joint due to the introduction of a foreign object in the body. Device-related potential complications are minimal. The currently available device (VisionScope) has already passed rigorous electrical safety, electromagnetic compatibility, biocompatibility and sterility testing from its FDA 510(k) submission process, as documented per the VisionScope Quality System Manual and filed in the FDA 510(k) summary:
http://www.accessdata.fda.gov/cdrh_docs/pdf10/K101734.pdf.
At a bare minimum, currently employed standards of care for in-office arthrocentesis techniques will be used for in office arthroscopy procedures. This includes sterile preparation with betadine and alcohol, and sterile draping.

Patient follow-up will be governed by the treating physician's traditional post-operative regime for knee arthroscopies and repairs.

b. Potential Benefits of Participation

A large body of evidence exists to support the concept that successful meniscus repair facilitates long-term joint preservation. In spite of this, it is uncommon for horizontal meniscus tears to be repaired. Participation in this study provides a subject the opportunity to receive a repair of the torn meniscus, which is not widely performed within the medical community. The patient will also gain the benefits of an anatomy preserving procedure and to contribute to a growing body of evidence regarding joint preservation. If the procedure is effective, subjects may obviate or substantially delay the need for additional reconstructive procedures on their knees in the future.

4.5. Study Assessments

For timing of study assessments activities and visit windows see Section 14.

a. Outcome Assessments

- International Knee Documentation Committee Subjective Knee Evaluation Form (IKDC Knee Evaluation)
- Knee Injury and Osteoarthritis Outcome Score (KOOS)
- Lysholm Knee Questionnaire
- Tenger Activity Scale
- In-office needle arthroscopy assessment of meniscus repair (when performed)

- Freedom from reoperation on the index meniscus repair site;
- Condition of meniscal tissue per MRI (Appendix 7);
- Joint condition per X-ray (Appendix 7).

b. Safety Variable (see Section 7.1 for definitions)
- Safety follow-up

c. Patient and Procedural Variables
- Patient demographics and knee pathology history
- Details of procedure
- Details of tear

5. STUDY POPULATION

5.1. Planned Number of Subjects
A total of 30 subjects will be enrolled.

5.2. Criteria for Recruitment

a. Diagnosis and Main Criteria for Enrollment
Subjects will be recruited for the study through the clinical practices of the Investigators. The study population includes otherwise healthy subjects with a symptomatic meniscus tear, who are able and willing to participate and who qualify for study inclusion based on specific eligibility criteria.

The presence of some inclusion or exclusion criteria cannot be detected by preoperative clinical or radiologic evaluations and it is only after the surgeon has inserted the arthroscope to inspect the knee joint visually that the presence of such injuries or disorders can be detected. Consented subjects will only be enrolled at the time of arthroscopy provided a qualifying meniscal tear is confirmed, no other exclusionary findings are encountered and the meniscal tear is surgically treated.

b. Inclusion Criteria

Screening Inclusion Criteria:
Subjects of either gender ***may be*** eligible for inclusion in the study only if they meet ***all*** of the following criteria:
- Able and willing to give informed consent by voluntarily providing written informed consent in accordance with governing Institutional Review Board
- 18 to 60 years of age, inclusive at the time of screening;
- History indicative of meniscal pathology (e.g., pain, mechanical symptoms described as locking, clicking or giving way);
- Physical exam consistent with meniscus tear (e.g., locked joint, joint line tenderness and/or pain on meniscal compression);

- If prior ligament reconstruction, the study knee is clinically stable;
- Preoperative MRI evidence within 6 months consistent with a horizontal/oblique meniscus tear in the symptomatic compartment
- Healthy and not pregnant

Arthroscopy Inclusion Criteria:
Consented subjects ***may be*** included in the study only if, upon arthroscopic inspection, their meniscal study lesion meets ***all*** of the following criteria established by the International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine (ISAKOS) (see Appendix 1):

- Zone location: circumferential location of tear includes locations within 10mm of the peripheral rim of the meniscus;
- Radial location: any location from anterior to posterior;
- Tear pattern: primarily horizontal or oblique in orientation (not to exceed 45 degrees from horizontal);
- Compartment: either lateral or medial, but not both;
- Opposite compartment meniscal tear (if present) limited to the central portion (i.e., Zone 3/"white zone");
- Tear amenable to repair with all suture-based techniques.

c. Exclusion Criteria

Screening Exclusion Criteria:
Subjects ***will be*** excluded from the study for ***any*** of the following reasons:

- Arthritis in the study knee (Kellgren-Lawrence Grade 3 or higher [See Appendix 4]);
- Body Mass Index (BMI) ≥35 kg/m^2;
- Previous meniscal repair or meniscectomy of the study meniscus;
- Unstable knee;
- Malalignment (> 5 degrees) of the study knee, based on X-ray within 6 months requiring osteotomy and/or requiring correction;
- History of constitutional/systemic inflammatory/arthritic problem or pain condition, history of knee infection, vascular condition of legs, benign neoplasms of knee, hepatitis, HIV, drug/alcohol abuse, tobacco abuse, cancer;
- Expected to undergo any other primary treatment of the knee;
- Any concomitant painful or disabling disease, condition or post-procedure status of either lower extremity that would interfere with evaluation or rehabilitation of the study knee.
- Pregnant or planning to become pregnant in the next 2 years.

Arthroscopy Exclusion Criteria:
Subjects ***will be*** excluded from the study if their study meniscus lesion meets ***any*** of the following criteria at arthroscopy:

- Tear pattern: primarily vertical longitudinal or radial in orientation;
- Partial meniscectomy of any portion of the study meniscus extends beyond the central portion (i.e., Zone 3/"white zone");
- Intact or partially intact meniscus tear that, in the opinion of the Investigator, does not require repair;
- Poor meniscal tissue quality such that it will not hold a suture;
- Any portion of the meniscus repair that, in the opinion of the Investigator, is best treated using an implant other than suture;
- Clinically significant (zone 1 and/or zone 2) tear in the contralateral compartment to the study meniscus;
- Performance of a significant concomitant procedure intended as a therapeutic intervention on the study knee;
- Arthritis in the surgical knee Modified Outerbridge Grade III or higher [See Appendix 2 and 3]).

5.3. Withdrawal Criteria

Subjects may withdraw from the study at any time prior to the subject's expected completion and for any reason without prejudice to further treatment. Subjects considered treatment failures will be withdrawn from the study to receive appropriate alternative treatment.

A subject's participation in the study may be discontinued at any time prior to the subject's expected completion at the discretion of the Investigator or Sponsor. Reasons for removing a subject from the study include, but are not limited to, the following:

- The subject is uncooperative in adhering to the protocol requirements, including failure to participate in rehabilitation;
- The Investigator believes it is in the best interests of the subject;
- The subject withdraws consent.

The Investigator will attempt to document the subject's reason for withdrawal on the study completion CRF.

If a subject fails to attend study visits, every attempt shall be made to contact the subject prior to considering the subject lost to follow up and withdrawing the subject from the study.

Subjects who are withdrawn from the study will not be replaced.

6. METHODS AND PROCEDURES

6.1. Method for Assigning Subjects

This trial is a single-arm, nonrandomized, open label study; assignment and blinding procedures are not required.

6.2. Study Visits and Procedures

The schedule of events for subjects in this study is shown in Section 14. Subjects will be followed a total of 2 years following the index procedure. The study will close when the last subject entering the trial has completed the last study follow-up.

a. Screening Visit (Study Visit 1); within 4 weeks of the procedure

Subjects will be preliminarily screened for inclusion in the study when the Investigator evaluates them for knee pain. If a subject qualifies for inclusion in the study by meeting ***all*** of the screening inclusion criteria and meeting ***none*** of the exclusion criteria, then the study procedure, including the risks and benefits of participation, will be discussed with the subject. If the subject consents to participate, written informed consent with the Subject Informed Consent Form (see Appendix 5) will be obtained prior to initiating any tests or assessments not otherwise considered standard-of-care for the condition for which he or she is being evaluated.

The Subject will be provided with a copy of the signed Subject Informed Consent Form. The original will be kept in a secure location at the study site. If the Subject is subsequently enrolled in the study, a copy of the Subject's signed Subject Informed Consent Form will be placed in the Subject's study binder along with completed CRFs. Study binders will be stored in a secure location. In order to maintain Subject confidentiality, the Sponsor will not receive a copy of the signed Subject Informed Consent Form and will rely on the Investigator to ensure that ALL Subjects have reviewed and signed the Subject Informed Consent Form prior to collecting any study-directed information or undergoing any study-directed treatment.

If a subject qualifies for inclusion in the study by meeting ***all*** of the screening and preoperative baseline clinical inclusion criteria and meeting ***none*** of the pre-arthroscopy exclusion criteria, the subject will be provisionally enrolled and scheduled for arthroscopy. The subject's demographic information relevant to study variables will be collected at the Screening Visit. Subjects will also complete KOOS, IKCD Subjective Knee Evaluation, Lysholm Knee Questionnaire and Tegner Activity Scale outcome assessments.

b. Surgery and Rehabilitation (Study Visit 2)

Arthroscopy Procedure

Investigator-specific standard-of-care arthroscopy will be performed. Intraoperative eligibility criteria will be evaluated. If ***all*** of the arthroscopy inclusion criteria are met and ***none*** of the arthroscopy exclusion criteria are met, the subject will be eligible for study enrollment. The subject is officially enrolled in the trial when the meniscal repair is completed.

Meniscal Repair Procedure

The Investigator will follow standard all-inside and/or inside-out, and/or outside-in, and/or NovoStitch arthroscopic procedures:

- Recommended spacing of sutures is 5mm;
- Video, still photographs and diagrams of the arthroscopy procedure will be captured for documentation of meniscal tear, tear preparation and tear treatment parameters. Images and diagrams will be provided to the sponsor. All patient identifying information should be removed prior to transferring images to the sponsor.

The ISAKOS Questionnaire documenting details of the meniscus tear and required excision (if any) will be completed (CRF-004, Details of Pathology). Details of the procedure will be documented (CRF-005, Details of Procedure) will be completed. It contains questions regarding the following:

- Number and configuration of sutures used;
- Repair technique and instruments;
- Meniscal repair time recorded from intraarticular introduction of suture to transection of final suture knot;
- Other intraoperative findings.

Rehabilitation Procedure
All subjects will follow their Investigator's preferred rehabilitation plan based on the particular tear and repair characteristics. At a minimum, all subjects must meet the following post-operative thresholds:

- Weight bearing as tolerated
- Hinged knee brace locked in extension when walking (4-6 weeks), released to 90 degrees for sitting/driving
- No squatting or stand up/sit down motions until after 6 weeks post-op
- No cutting or pivot sports until after 6 months post-op

c. First Follow-up [7-15 days] (Study Visit 3)

Subjects will be evaluated and a safety follow-up will be completed.

d. Second Follow-up [90 Day ± 7 days] (Study Visit 4)

All subjects will be evaluated and a safety follow-up form will be completed. In addition all subjects will complete the following:

- KOOS
- IKCD Knee Evaluation
- Lysholm Knee Questionnaire
- Tegner Activity Scale

e. Third Follow-up [185 Day ± 14 days] (Study Visit 4)

All subjects will be evaluated, and a safety follow-up form will be completed. In addition all subjects will complete the following:

- KOOS

- IKCD Knee Evaluation
- Lysholm Knee Questionnaire
- Tegner Activity Scale

Where available, subjects will undergo an in-office arthroscopy (i.g.VisonScope) to assess the tissue repair. Clinical follow-up should continue with or without the arthroscopy.

f. Fourth Follow-up [365 Day ± 30 days] (Study Visit 5)

All subjects will be evaluated, a safety follow-up form will be completed and an MRI will be performed. In addition all subjects will complete the following:

- KOOS
- IKCD Knee Evaluation
- Lysholm Knee Questionnaire
- Tegner Activity Scale

g. Fifth Follow-up [730 Day ± 30 days] (Study Visit 6)

All subjects will be evaluated, a safety follow-up form will be completed and a Standing AP x-ray will be obtained for evaluation of joint space narrowing. In addition all subjects will complete the following:

- KOOS
- IKCD Knee Evaluation
- Lysholm Knee Questionnaire
- Tegner Activity Scale

7. SAFETY MEASUREMENTS

7.1. Definitions

Complication

A complication is any untoward medical occurrence, unfavorable and unintended sign (including clinically significant abnormal laboratory finding), symptom, or condition experienced by the subject and temporally associated with the procedure whether or not considered related to the procedure.

Major Complication

Any complication attributable to the meniscal repair procedure that, in the view of either the Investigator or Sponsor, results in any of the following outcomes:

- Death;
- Life-threatening illness or injury;
- Inpatient hospitalization or prolongation of existing hospitalization;
- Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;

- Important medical events that, based upon appropriate medical judgment, require medical or surgical intervention to prevent one of the above outcomes.

7.2. Collecting, Recording and Reporting of Complications

At each contact with the subject, the Investigator will seek information on complications by specific questioning and, as appropriate, by examination. All complications definitely, probably or possibly involving the treated knee, as well as any required remedial action shall be recorded on the subject's appropriate CRF. The investigator will also be asked to assess the complication with respect to severity and relatedness to the procedure.

The minimum initial information to be captured in the subject's source document concerning the complication includes:

- Study identifier;
- Study center;
- Subject number;
- A description of the complication;
- Date of onset;
- Investigator assessment of the association between the complication and study treatment (relatedness);
- Investigator assessment of severity;
- Current status;
- Whether the complication is a major complication and reason for this classification.

The clinical course of each complication should be recorded and followed until resolution, stabilization, or until it has been determined that the surgical repair is not the cause.

Notification of Sponsor by Investigator

The Investigator shall notify the Sponsor of any Major Complication experienced by any subject entered into the study. Such Major Complications ***must*** be reported ***within 24 hours*** to the following:

Ceterix Orthopaedics
959 Hamilton Avenue
Menlo Park, CA
(650) 316-8660
jmccutcheon@ceterix.com

Within the following 48 hours, the Investigator shall provide further information, as applicable, in the form of a written narrative. As the Investigator learns it, significant new information shall be provided on an ongoing basis to the Sponsor.

Notification of IRB by Investigator
With one exception noted at the end of Section 7.2, all communication with an IRB is the responsibility of the Investigator. Investigator will comply with all IRB requirements for the reporting of complications. Copies of each report and documentation of IRB notification and receipt will be kept in the Investigator's study file.

An Investigator shall report to the Sponsor a withdrawal of approval by the Investigator's reviewing IRB as soon as a possible, but no later than 5 working days of the IRB notification of withdrawal.

Notification of Investigators and IRBs by Sponsor

The Sponsor shall notify all participating IRBs and participating Investigators of any withdrawal of approval of the study by a reviewing IRB within 5 working days after receipt of the withdrawal of approval.

7.3. Study Monitoring Plan, Auditing, and Inspecting

a. Study Monitoring Plan
The Investigator will allocate adequate time for any monitoring activities deemed appropriate by the Sponsor. The Investigator will also ensure that the monitor or other compliance or quality assurance reviewer is given access to all study-related documents and study-related facilities (e.g., examination rooms, radiology facility, operating room, etc.), and has adequate space to conduct the monitoring visit.

b. Medical Monitoring
It is the responsibility of the Investigator to oversee the safety of the study at his/her site. This safety monitoring will include careful assessment and appropriate reporting of complications as noted in Section 7.2.

c. Auditing and Inspecting
The Investigator will permit study-related monitoring, audits, and inspections by the IRB, the Sponsor, government regulatory bodies, and University compliance and quality assurance groups of all study-related documents (e.g., source documents, regulatory documents, data collection instruments, study data, etc.). The Investigator will ensure the availability for inspections of applicable study-related facilities (e.g., examination rooms, surgical facility, etc.).

In the course of normal study conduct or as revealed in a site monitoring or audit visit, any deviations from the protocol will be documented and as needed corrective action(s) will be initiated.

8. DATA HANDLING AND RECORD KEEPING

8.1. Data Quality Assurance

Data quality is the responsibility of the Investigator. CRF completion may be delegated to other study personnel but the Principal Investigator remains responsible for the accuracy and integrity of all data entered on CRFs. CRFs will be completed and provided to the Sponsor or its designated representative as directed, in an expedited fashion. The Sponsor will work with participating sites to secure data clarification and to obtain additional relevant medical documentation on participants enrolled into this trial.

8.2. Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study;
- Who will have access to that information and why;
- Who will use or disclose that information;
- The rights of a research subject to revoke authorization for use of one's PHI.

Case report forms will utilize an anonymous subject identifier. The identifier will be composed of the site study ID number, the first letter of the subject's first name, the first letter of the subject's last name, and a sequential subject number by site.

> Example: The subject identifier for the fourth-enrolled subject at site 02, whose name is Jane Doe, would be 02-JD-04.

The Investigator is responsible for ensuring that all CRFs and any other documents or media, such as arthroscopic video or still photos, are de-identified prior to sharing with Sponsor.

In the event a subject revokes authorization to collect or use PHI, the Investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects who have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status at the end of their scheduled study period.

8.3. Source Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, physician-completed study forms, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial.

8.4. Case Report Forms (see Appendix 6)

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, "N/D" will be entered. If the item is not applicable to the individual case, "N/A" will be entered. All entries should be printed legibly in black ink. If any entry error has been made, to correct such an error, a single straight line will be drawn through the incorrect entry and the correct data will be entered above it. All such changes must be initialed and dated. Errors will not be erased or obliterated (i.e. use of Wite-out). For clarification of illegible or uncertain entries, clarification may be printed above the item, initialed and dated.

8.5. Retention of Trial Documents and Records

Trial documents and records are to be retained at least until 2 years following the official end of the study at all sites.

9. STATISTICAL PLAN

9.1. Subject Population(s) for Analysis

Data obtained from all enrolled subjects will be analyzed on a per-treatment (PT) basis, which will include all enrolled subjects who receive the protocol-defined treatment of suture-based meniscal repair.

9.2. Statistical Methods

Appropriate descriptive statistics will be presented for baseline characteristics, procedural variables, reoperation rate of the index meniscal repair site, and major complications. Logistic regression will be fitted to determine baseline predictors of various outcome measures. Independent variables for these models will include but may not be limited to, tear compartment, circumferential length of tear, primarily horizontal vs. oblique, subject age, subject gender, subject BMI, study site, partial meniscectomy vs. no meniscectomy, meniscal surgical technique.

Justification for data pooling will be made on a clinical basis.[48] These criteria call for use of the same protocol requirements at all sites, the sponsor to monitor the sites for compliance with the protocol, and the use of similar data collection procedures at all sites. Since this study does not include a control group, no analysis of the interaction of the treatment effect with clinical site is possible. Reoperation rates will be evaluated by clinical center.

Subject and reported outcome measures, KOOS, IKCD Knee Evaluation, Lysholm Knee Questionnaire and Tegner Activity Scale outcome assessments will be summarized and thoroughly characterized across time with the appropriate descriptive statistics including error measures. Statistics may include mean, mode, median, range, inter-quartile range, minimum, maximum and frequency, cumulative frequency percentage and cumulative percentage. Results will be presented in narrative and graphically.

These measures will also be analyzed using inferential statistics. As appropriate a repeated measure ANOVA or Wilcoxon signed rank test will be completed for each outcome measure. If a significant trend is identified, significance among time points, especially preoperative measures, may be further explored using the appropriate pair-wise comparisons. In all cases a p value equal to or less than 0.05 will be considered significant.

10. ETHICAL CONSIDERATIONS

10.1. IRB Review

This protocol and any amendments will be submitted to a properly constituted Institutional Review Board (IRB), in agreement with local legal prescriptions, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the Investigator and a copy of this decision will be provided to the Sponsor before commencement of this study. The Investigator should provide a list of IRB members and their affiliate to the Sponsor.

10.2. Informed Consent

All subjects for this study will be provided a Subject Informed Consent Form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. This consent form will be submitted with the protocol for review and approval by the IRB for the study. The formal consent of a subject, using the IRB-approved consent form, must be obtained before that subject undergoes any study procedure. The subject must sign and date the consent form. No surrogate for the subject may sign on the subject's behalf.

11. CONFLICT OF INTEREST

Investigators who have a conflict of interest with this study (e.g., patent ownership, royalties, or financial gain greater than the minimum allowable by their institution,

etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the Sponsor prior to participation in this study.

12. PUBLICATION PLAN

Sponsor-selected Principal Investigators will facilitate the publication of the results (in part or in whole) of the study. Neither the complete nor any part of the results of the study carried out under this protocol, nor any of the information provided by the Sponsor for the purposes of performing the study, will be published or passed on to any third party without the consent of the Sponsor. Any Investigator involved with this study is obligated to provide the Sponsor with complete test results and all data derived from the study. Interim study results may be presented or published after each study interval.

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14. STUDY ACTIVITY SCHEDULE

STUDY ACTIVITY SCHEDULE

Activity	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7
	Screen < 4 weeks	Procedure	7-15 Days	90 Day ±7 days	185 Day ±14 days	365 Day ±30 days	730 Day ±30 days
Informed consent	X						
Screening Inclusion / Exclusion	X						
Demographics / Medical History	X						
Radiographs	X[1,5]						X[1]
MRI	X[5]					X[2]	
Images		X[3]					
Arthroscopy Inclusion / Exclusion		X					
Study Procedure		**X**					
Details of Procedure		X					
Details of Pathology		X					
Safety Follow-Up			X	X	X	X	X
KOOS	X			X	X	X	X
IKDC Subjective	X			X	X	X	X
Lyshlom	X			X	X	X	X
Tenger	X			X	X	X	X
In-office Arthroscopy					**X[4]**		

[1]Standing AP X-ray
[2]MRI 1.5 T or greater, no contrast to be reviewed by independent radiologist appointed by sponsor.
[3]Video, still photographs and diagrams of procedure.
[4]If available.
[5] Within 6 months of Procedure

15. LIST OF ATTACHMENTS

Appendix 1 ISAKOS Criteria
Appendix 2 Cartilage Guidance
Appendix 3 Modified Outerbridge Scale
Appendix 4 Kellgren-Lawrence Grading Scale
Appendix 5 Subject Informed Consent Form
Appendix 6 Case Report Forms

- 001 Screening Inclusion Exclusion
- 002 Demographics and History
- 003 Arthroscopy Inclusion Exclusion
- 004 Details of Pathology
- 005 Details of Procedure
- 006 Safety Follow-Up
- 007 Complication
- 008 Details of Reoperation
- 009 Study Completion
- 010 Protocol Deviation
- 011 Data Clarification
- 012 KOOS
- 013 IKDC Subjective Knee Evaluation
- 014 Lysholm Knee Questionnaire
- 015 Tegner Activity Scale
- 016 Meniscus Repair Assessment

Appendix 7 Imaging Guidance