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Knotless Suture in Revision Total Joint Arthroplasty: A Prospective Randomized Controlled Trial

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1. INTRODUCTION

1.1. BACKGROUND

Total knee arthroplasty (TKA) and total hip arthroplasty (THA) have evolved into immensely successful procedures for the treatment of a variety of knee and hip joint pathologies. However, due to a number of indications, including infection, mechanical loosening, instability, polyethylene wear, stiffness, and periprosthetic fracture there remains a growing need for revision TKA and revision THA [1–3]. Revision total joint surgery is a large financial burden to the United States healthcare system with projections assuming over a 5-fold increase by 2030 [4]. Advancements in postoperative care, surgical planning, patient selection and surgical technique have improved revision TJA outcomes. However, an often-overlooked variable in revision total joints is an effective wound closure. Effective wound closure is essential in the immediate and long-term outcomes of post-operative complications, wound healing, operative efficiency, and patient satisfaction after primary or revision total joint arthroplasty[2–5].

Revision TJA is usually performed through non-naïve tissue planes creating concerns for wound healing and tissue vascularity. Incisions are typically larger than primary joint arthroplasties, may take longer to close and involve more complex closures [6,7]. Decreasing closure time is appealing as not only is it cost effective but there is data to support increased operative time increases risk for infection.

Barbed suture has been studied in primary hip and knee arthroplasty with data demonstrating faster closure times, cost efficiency, and no increase in glove perforation.[7–9] Cadaveric studies indicate barbed suture creates a more water tight arthrotomy closure, which can reduce wound drainage[10]. Prolonged wound drainage and hematoma formation increase the risk for surgical site infection and deep wound infection. [11] Biomechanical studies under cyclic loading barbed suture is equivalent to conventional interrupted closure and performed better when intentionally damaged and cycled which clinically may translate to decreased wound dehiscence.[12] Wound dehiscence is a risk factor for recurrence of infection after two stage reimplantation [13]

In the setting of revision for infection monofilament and antibacterial sutures are used to decrease bacterial adherence and load in the surgical wound. In primary total joint arthroplasty braided antibacterial absorbable suture and barbed suture have been shown to be as efficacious, with barbed suture having faster closure times and overall cost savings. [14] Monofilament barbed suture has outperformed braided suture in contaminated wound models and performed equally well as monofilament suture [15].

Our institution does a large number of revision arthroplasties, closure is determined by surgeon preference, with variability amongst surgeons. Retrospective review performed by Levine et al report no notable adverse response to barbed suture in primary or revision arthroplasty and no change in complication or wound healing rates since adopting barbed suture closure with decreased closure time. [9]. To our knowledge there has been no prospective randomized studies performed on barbed suture in the revision setting.

1.2. RATIONALE

Our study seeks to demonstrate efficacy of barbed suture closure in the revision setting. Use of barbed suture has been demonstrated to be safe in primary hip and knee surgery however no one has prospectively investigated barbed suture closure in the revision setting (9,14,16–18). Animal and biomechanical studies have shown that barbed suture is equivalent to monofilament in revision setting for infection and outperforms traditional suture for strength in arthrotomy closure. By comparing traditional closure with barbed suture, we can decrease wound closure time, control costs, and number of needles handled by operative staff without sacrificing cosmesis.

There have been no prospective randomized trials of barbed vs traditional suture in the revision setting. In a single center retrospective review Levine et al found no notable differences in wound healing or complications for primary and revision total joints treated with barbed suture closure as compared to their historic rates (9).

2. STUDY OBJECTIVES AND HYPOTHESIS

2.1. PRIMARY STUDY OBJECTIVE

Barbed suture has been demonstrated to be safe in primary hip and knee surgery and retrospective data suggests barbed suture represents no increased complications in the revision setting. Barbed suture may represent a faster, more effective way to perform revision arthroplasty closures. There are no Level I studies comparing traditional and barbed suture closure. The purpose of this study is to assess the surgical complexities of closures using closure time without sacrificing cosmesis or wound complications between the traditional closure and barbed closure.

2.2. SPECIFIC AIMS

To evaluate the closure time, wound cosmesis, and efficiency of barbed suture closure following revision total hip and total knee arthroplasty compared to traditional closure.

Primary Objective

1. To compare surgical complexity of the closures based on closure time

Secondary Objectives

1. To evaluate the cost effectiveness of using bidirectional barbed suture compared with traditional sutures in revision knee and hip arthroplasty
2. To evaluate prevalence of complications (including needle sticks and glove perforations) of using barbed suture in revision total joint arthroplasty
3. To evaluate the cosmetic result of barbed versus traditional suture in revision total joint arthroplasty
4. To quantify the number of sutures used for each type of closure
5. To perform cost analysis to determine most cost-effective closure

2.3 ENDPOINTS

Primary Endpoint

1. Measure the time needed to properly close the wound with each technique

Secondary Endpoints

1. Record all complications (including needle sticks and glove perforations) and infections related to the wound closure
2. Calculate the cost difference based on supplies, personnel, and OR time between each technique
3. Gather pictures of wound following closure to evaluate the cosmetic result of barbed versus traditional suture in revision total joint arthroplasty using the Patient and Observer Scar Assessment Scale (POSAS)
4. Calculate the number of suture used and length of incision for each technique

3. STUDY DESIGN/METHODOLOGY

3.1. STUDY DESIGN

This is a prospective, randomized, controlled trial, parallel four-arm design, single-center study to compare barbed versus traditional suture closure in revision total knee and total hip arthroplasty.

3.2. STUDY INTERVENTIONS & RANDOMIZATION

3.2.1. STUDY INTERVENTIONS

3.2.1.1. Revision Total Knee

For revision total knee arthroplasty all closures will be performed with knee in approximately 45 degrees of flexion.

Group #1:
Traditional closure will consist of arthrotomy (deep layer) closed with figure of eight number 1 vicryl plus followed by closure of the intermediate layer with 0 Vicryl plus. The intermediate layer will be performed at surgeon's discretion especially in thin patients. Subdermal layer with 2-0 vicryl suture followed by subcuticular 3-0 monofilament suture (monocryl PLUS, Ethicon; Johnson & Johnson) and Dermabond advanced. This is considered routine care at NYU Langone Orthopedic Hospital. There is no established protocol for suturing the wound.

Group #2:
The barbed suture closure will consist of number 2 Stratafix symmetric PDS PLUS for the arthrotomy, intermediate layer will be performed at surgeon's discretion in thin patients, if performed will entail stratafix spiral, subdermal 2-0 stratafix spiral monocryl plus. Followed by subcuticular 3-0 stratafix spiral monocryl plus suture and Dermabond advance. This is considered routine care at NYU Langone Orthopedic Hospital. There is no established protocol for suturing the wound.

3.2.1.2. Revision Total Hip

Group #1: Conventional closure

1. The capsule will be closed with Vicryl Plus number 1
2. Deep fascia with figure of eight interrupted number 1 braided absorbable suture (Vicryl plus, Ethicon; Johnson &Johnson, Somerville, NJ)
3. Subdermal fat layer simple interrupted knots using number 2-0 braided absorbable sutures (Vicryl plus)
4. Subcuticular 3-0 monofilament suture (monocryl plus , Ethicon; Johnson & Johnson)
5. followed by the use of skin adhesive (Dermabond Advanced, Ethicon; Johnson &Johnson).

Group #2: Barbed suture closure

1. The capsule will be closed with stratafix symmetric PDS Plus
2. Deep fascia will be closed with Stratafix Symmetric PDS Plus (Stratafix symmetric PDS plus, Ethicon; Johnson &Johnson, Somerville, NJ)
3. Subdermal layer with running number 2-0 barbed suture (stratafix symmetric PDS CT-2, Ethicon; Johnson & Johnson, Somerville, NJ)
4. Subcuticular suture with stratafix spiral monocryl plus, Ethicon
5. followed by the use of skin adhesive (Dermabond advanced, Ethicon; Johnson &Johnson).

Table 2.

	Active Arm	Control Arm
Capsule	SXPP1A445 (24 inch) Symmetric PDS PLUS-Number 1	Vicryl Plus Number 1

Fascia	SXPP1A445 (24 inch) Symmetric PDS PLUS-Number 1	Vicryl Plus Number 1
Subdermal	SXPP1B414 (27 inch) 2-0 Stratafix Spiral PDS Plus Violet 70cm CT-2	Vicryl Plus 2-0
Subcuticular	SXMP1B104 Stratafix spiral monocryl plus 3-0	Monocryl 3-0
Skin	Dermabond Advanced	Dermabond advanced

All the devices used in this study are 510(k) cleared.

- Stratafix Symmetric PDS Plus Knotless Tissue Control Devices
  - K182873
- Stratafix Spiral Monocryl Plus Knotless Tissue Control Devices
  - K182873
- Monocryl Plus Antibacterial Suture
  - K050845
- Coated Vicryl Plus Antibacterial (Polyglactin 910) Absorbable Suture
  - K181652

The frequency of using barbed versus conventional sutures for revision total joint (knees and hips) arthroplasty is approximately 75% conventional and 25% barbed at NYU Langone Health.

3.2.2.RANDOMIZATION

Once Revision TJA candidates are successfully screened, patients meeting eligibility criteria will be randomized into either the barbed or conventional closure group. After informed consent is obtained and the screening interview is conducted, the principle investigator/sub- investigator or research assistant will electronically randomize a patient to a study group (barbed or conventional closure group) using the REDCap database (web-based secure database application).The NYU Statistics Department will provide the randomization scheme that will be used within the REDCap database to randomly assign patients to one of the two treatment groups. Each patient who qualifies for entry into the study will be assigned a unique study number in chronological order.

4. STUDY POPULATION

The study population will include patients undergoing revision total joint arthroplasty by surgeons from NYU Langone Health. All patients who present for evaluation for revision total joint arthroplasty will be screened to determine their study eligibility. Only patients who meet inclusion criteria based on the study screening protocol will be eligible for study participation.

4.1. INCLUSION CRITERIA

1. Patients ≥ 18 years of age

2. Surgical candidates undergoing revision total knee or total hip arthroplasty for one of the following indications second stage of two stage reimplantation for infection, mechanical loosening, instability, polyethylene wear, stiffness, or periprosthetic fracture

4.2 EXCLUSION CRITERIA

1. Patient is ≤ 18 years of age
2. Patient is unable to provide written consent
3. Patient has active infections in the operative leg/joint
4. Known Allergy to Suture material
5. Underlying Dermatological diseases affecting surgical site including dermatitis, eczema, or psoriasis; connective tissue or vascular disorders or diseases that would adversely affect wound healing; metastatic cancer; renal insufficiency (dialysis); steroid dependence; malnourishment; and other disease processes resulting in an immunocompromised state. Diabetes, smoking and obesity will be allowed as they are frequent comorbidities in our revision joint population
6. Anterior total hip replacement
7. Stage 1 of two stage revision for infection
8. Closure performed by plastic surgeon, including flap coverage

Vulnerable populations will not be enrolled in this study.

5.1 Withdrawal Criteria

1. Failure to attend regularly scheduled follow up appointments
2. Deviation from closure protocol

9. STUDY PROCEDURES/DATA COLLECTION

a. SCREENING STUDY PROCEDURES

Subjects will be recruited by prescreening participating surgeons' clinic and surgical schedules. Prior to consenting, research personnel will evaluate all patients to determine if subjects meet the inclusion and exclusion criteria. Participants will continue the use of all medications deemed necessary by their medical doctor during the study period. All patients eligible for enrollment will be asked to sign a consent form prior to beginning the study by a study team member (sub-investigator, research coordinator, etc.).

b. INFORMED CONSENT

Written informed consent will be obtained from all subjects before any study related procedures are performed. The investigator(s) has both ethical and legal responsibility to ensure that each subject under consideration for enrollment is given a full explanation of the study. This process must be documented on a written Informed Consent Form (ICF) that has already been reviewed and approved by the same Institutional Review Board and/or Independent Ethics Committee (IRB/IEC) responsible for approval of the protocol. Each ICF shall include the elements required by Food and Drug Administration (FDA) regulations in 21 (CFR) Part 50 and International Committee on Harmonization (ICH) Good Clinical Practice (GCP).

Once the investigator or designated research personnel have fully explained the study and answered all the potential questions the participant may have and it is agreed that the participant understands the implications of participating, the IRB approved informed consent form should be signed and dated by all applicable parties in accordance to the IRB/IEC requirements. Study team should give a copy of the signed consent form to the participant and the original should be kept in study subject binder or regulatory binder. Explanation of study and the signing of the informed consent must occur prior to the subject's participation in the trial.

If the patient meets the study entry criteria, the study will be introduced to them by study personnel. A thorough explanation of the study will be provided to the patient and sufficient time will be provided for the potential subjects to thoroughly read the consent form, ask and have all questions about study participation answered,

and make an informed decision to participate. The prospective participants will be encouraged to discuss the study and their potential participation in the study with their family members or significant others. The patient must be able to read the consent form in order to participate in the study. The patient will either provide a written signature to signify their agreement to participate in the study or they will decline study participation. In cases in which the patient decides not to participate in the study, they will be provided with the standard of care at the institution for their surgical procedure.

During the informed consent process, potential study participants will be informed that they may discontinue study participation at any time. If a study participant chooses to withdraw from the study, they will be asked to notify the principal investigator or a member of the study staff of their intentions.

Potential study participants also will be told that the principal investigator may choose to withdraw a study participant from the study for reasons related to noncompliance with the study protocol or if an event occurs that would warrant this decision. In such cases, the principal investigator will provide an explanation for the decision and the reason why the decision was made. Specific data forms will be completed to document the reasons for study participant withdrawal from the study.

c. PRE-OPERATIVE

Once revision candidates have been identified and consented, patients will be randomized to traditional vs. barbed suture closure via RedCap. Medical records will be reviewed for baseline patient characteristics, preoperative patient data and laboratory values (Table 1). Prior to operation, a clinical image of the patients existing scar will be obtained for research purposes.

Table 1. Collected Baseline Patient Characteristics

Baseline Patient Characteristics
Age
Gender
Body mass index (BMI)
Zip code
American Society of Anesthesiologist (ASA) Score
Insurance type
Preoperative complete blood count (CBC), basic metabolic panel (BMP), and hemoglobin A1c (HbA1c)
Presence of diabetes mellitus
Cigarette smoking status
E-Cigarette smoking status
Immunocompromised status
Charlson Comorbidity Index (CCI)
Indication for Revision Arthroplasty

d. PERIOPERATIVE STUDY PROCEDURAL/DATA COLLECTION

The following data points will be collected from the medical records and recorded in RedCap

1. Time of closure in seconds
2. Incision length
3. Number of sutures used
4. Any needle sticks or glove perforations
5. Type of dressing used (Aquacel or negative pressure dressing)

e. FOLLOW-UP EVALUATION

i. Post-operative hospital course

All patients will be admitted to the hospital and discharge home or to a rehabilitation facility as deemed appropriate by the care management team. All patients will be weight bearing as tolerated unless otherwise dictated by the surgeon. Any wound complications or skin irritation documented will be documented in the subjects' medical records as part of standard of care.

ii. FOLLOW-UP EVALUATION

Patients will be assessed at the two to four standard of care post-operative visits up to six months. As part of standard of care, at each visit the patient will be evaluated for any complications including:

a. superficial: skin irritation, erythema, suture spitting, cellulitis, superficial wound dehiscence, seroma, hematoma, prolonged wound drainage, need for oral antibiotics, post operatively
b. Deep: periprosthetic infection, arthrotomy failure, extensor mechanism failure
c. Other non-closure associated complications

For research purposes only, a clinical image of the scar will be taken and stored in the patients' medical record. Patients will be asked to fill out the patient component of the Patient and Observer Scar Assessment Scale (POSAS), surgeons will complete the observer scale. The POSAS is a validated reliable scar assessment tool used for the evaluation of linear surgical scars taking into account both surgeons and patients' perceptions. This will occur at one of the standard of care post-op appointments between 2-6 weeks after surgery.

f. SCHEDULE OF ACTIVITIES

Study Interval	**Preoperative**	**Peri-operative**	**Post-Operative**
	Screening	**Date of Surgery**	**Follow-up Visits up to 3 months (0-90 days)**
Review of demographics and preoperative variables (Table 1)	X		
Measurement of height, weight and BMI	X		
Screening—using eligibility criteria	X		
Patient Consent	X		
Preoperative image of scar	X		
Perioperative Values (Table 2)		X	
Postoperative Variables (Table 2)		X	X

Table 2. Collected peri- and post-operative variables

Perioperative Variables

Closure Time Incision Length Number of sutures used will be counted and recorded Any needle sticks or glove perforations Dressing Type Preoperative Incision Clinical Image
Postoperative Variables
Superficial wound complications: Skin irritation, erythema, suture spitting, cellulitis, superficial wound dehiscence, seroma, hematoma, prolonged wound drainage Deep wound complications: periprosthetic infection, arthrotomy failure, extensor mechanism failure Other non-closure associated complications Revision procedures for infection Revision procedures for any reason Post-operative antibiotic therapy Use of chronic antibiotic suppression therapy Post-operative Clinical Image (research only) POSAS Wound Score (research only)

10. STUDY DURATION

This study is designed as a prospective longitudinal study with participants remaining in the study for 3 months following revision total joint arthroplasty. Data collection for each individual study participant will be concluded at the 90-day post- surgical follow-up visit. Duration of the trial is expected to be two years in order to enroll an adequate number of patients and follow outcomes for at least 3 months postoperatively. The entire study is expected to last approximately 24 months.

11. DATA MANAGEMENT

Data will be collected and managed using REDCap. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture. Monthly performance reports will summarize: patients recruited, patients successfully randomized, and the extent of follow-up for the enrolled patients. The reports also will evaluate the completeness of collected study data.

Data Collection
After the patient has enrolled in this study, data will be directly collected from the patient and supplemented with electronic medical record (EMR) chart review. Additional data may be extracted from clinical notes. All members of the team will be trained in the reproducibly collection of clinical data. All data will then be input into REDcap. A member of the research team will be present at each patient follow-up to ensure that all necessary data points are collected. In addition, the research team may assist the physician when measuring the patient's functional outcomes.

Reporting Requirements

REDCap Features

- HIPAA-compliant and secure. Data are stored on a NYU server behind firewall.
- Intuitive, web-based interface for database build, data entry, and reporting
- Data validation, audit trail, branching logic, and calculated fields

- Data dictionary for easy project edits and duplication
- Automated data export (.csv, SPSS, SAS, Stata, R)
- Data import from external sources

12. STATISTICAL ANALYSIS

Power Analysis
In our analysis if we assume an average length of closure of 30 minutes for revision with standard deviation of 5 minutes in closure time. The study is powered to compare hip and knee revisions separately. With an anticipated average decrease in closure time by five minutes, a minimum of 17 patients need to be included in each group (34 revision hips and 34 revision knees) will need be enrolled (power of 80% [alpha=0.025], one-sided). If we estimate a lost to follow up rate of 15% our recruitment goal will be set at 40 revision knees and 40 revision hips for a total of 80 revision total joints.

To perform our cost analysis, we assume a mean savings of $200 with a standard deviation of $50 (14). A minimum of 3 subjects per treatment group will need to be enrolled (power of 80% [one-sided alpha=0.025]). If we estimate a lost to follow up rate of 15%, we will have more than sufficient power with our recruitment goal at 80 enrolled patients, 40 revision TKA and 40 revision THA.

Statistical Analysis
Descriptive statistics will be used to report baseline characteristics as well as primary and secondary outcomes for the barbed suture and conventional cohorts. Outcomes will be compared between barbed suture and conventional closure (control) for the aforementioned baseline, perioperative and postoperative variables. Continuous or ordinal variables will be reported using unpaired t-tests, and all other categorical variables will be analyzed using Fisher's Exact Test. The test for primary endpoint will be one-sided (with the alternative hypothesis "mean closure time for barbed suture minus mean closure time for traditional suture <0") with a significance level of 0.025. Two-sided tests will be performed for baseline characteristics of patients and secondary endpoints with a significance level of 0.05. To further control for surgeon and evaluator variability we will also perform multivariable linear regression for continuous outcomes of interest and logistic regression for the dichotomous outcomes. Pooled and subgroup analysis for hip and knee revisions will be performed

13. PRIVACY AND CONFIDENTIALITY

Participant Confidentiality

- Any information that could identify study participants (i.e. names or medical record numbers) will not be included on RedCap. Instead, each study participant will be given a study number. Only the IRB approved study staff will be able to link the study numbers to the names of study participants.
- Data collected during the study will be stored electronically in REDCap, a cloud based electronic data management system that is password protected. Only IRB approved personnel on the study team will have access to this data.
- The names, medical record numbers, or any other unique identifiers of study participants will not be included in any publications resulting from this study.
- Research records will be stored in a research study file on an MCIT issued network drive separate from the study participants' medical records.

a. RISK AND BENEFITS

Benefits

There may be no direct benefit to subjects from participating in this study. However, it is hoped that the information gained from the study will be of benefit to others in the future.

Risks

Barbed Suture Closure
Barbed closure has the potential risks of wound dehiscence, local adverse tissue reaction, extensor mechanism failure, delayed wound healing.

Conventional method
Standard closure has been associated with longer closure time, suture spitting, local irritation reaction, suture knot burden

All suture closure has the risk of wound dehiscence, delayed wound healing, adverse tissue reaction, infection (superficial or deep) and needle sticks.

Loss of Confidentiality: There is a potential risk of loss of confidentiality. Every effort will be made to protect subjects' confidential information but this cannot be guaranteed. To minimize this risk, all study documentation will be stored in a password-protected HIPAA compliant computer with access granted only to specific study research personnel.

Unknown Risks: The research may involve risks that are currently unforeseeable. One of these approaches may be better than the other.

14. ADVERSE EVENTS/REACTIONS

Adverse event means any untoward medical occurrence associated with the use of the suture material in humans, whether or not considered suture related

Adverse reaction means any adverse event caused by any suture material in the study.

Suspected adverse reaction means any adverse event for which there is a reasonable possibility that the suture material used caused the adverse event. Suspected adverse reaction implies a lesser degree of certainty about causality than "adverse reaction"

Reasonable possibility. For the purpose of safety reporting, "reasonable possibility" means there is evidence to suggest a causal relationship between the suture material used and the adverse event.

Life-threatening, suspected adverse reaction. A suspected adverse reaction is considered "life-threatening" if, in the view of either the Investigator (i.e., the study site principal investigator), its occurrence places the patient or research subject at immediate risk of death. It does not include a suspected adverse reaction that had it occurred in a more severe form, might have caused death.

Serious, suspected adverse reaction. A suspected adverse reaction is considered "serious" if, in the view of the Investigator (i.e., the study site principal investigator), it results in any of the following outcomes: death, a life- threatening adverse reaction, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

Unexpected, suspected adverse reaction. A suspected adverse reaction is considered "unexpected" if it is not listed in the general investigational plan, clinical protocol, or elsewhere; or is not listed at the specificity or severity that has been previously observed and/or specified.

An abnormal test finding will be classified as an adverse event if one or more of the following criteria are met:

- The test finding is accompanied by clinical symptoms
- The test finding necessitates additional diagnostic evaluation(s) or medical/surgical intervention; including significant additional concomitant drug treatment or other therapy.

Note: simply repeating a test finding, in the absence of any of the other listed criteria, does not constitute an adverse event.

15. DATA SAFETY MONITORING

No data safety monitoring board will be created for this study. The PI is responsible for data safety monitoring of the study. The PI will review all subject safety data, specifically serious adverse events, adverse events related to bleeding and wound drainage, and infection on a quarterly basis. The predefined endpoints in any of the 4 treatment groups that would result in suspending the study are: 5 or more infections that required re-revision or wound drainage in over 50% of subjects.

16. Subject Costs and Payments

Subjects will not incur any additional costs associated with this research study. All visits and procedures are part of standard clinical care. The sutures used are within the standards of care. Patients and/or their insurance will be responsible for their total joint replacement surgery.

Patients will not be compensated for their participation in this study. This study uses standard of care visits and we expect most patients to comply with the visit schedule.

Ethicon will provide the suture used in the study at no cost to the patient or institution.

17. ETHICS/CONFLICT OF INTEREST

The clinical research study will be conducted in accordance with the current IRB-approved clinical protocol; International Conference of Harmonization (ICH) Good Clinical Practice (GCP) Guidelines adopted by the FDA; and relevant policies, requirements, and regulations of the New York University IRB, State of New York, and applicable federal agencies.

None of the principal investigators, co-investigators or study team members should perform, for any personal gain, services to any supplier of goods or services, as employee, consultant, or in any other capacity which promises compensation of any kind, unless the fact of such transaction or contracts are disclosed in good faith, and the board or committee authorizes such a transaction. Similar association by a family member of principal investigators, co- investigators or study team members or by any other close relative may be inappropriate.

This study is undertaken in good faith with Ethicon research support, the company (Ethicon Inc) will provide suture and research support for the completion of this study.

18. PUBLICATION & PRESENTATION PLAN

The dissemination of clinical data will include the timely presentation of results at the following scientific congresses and orthopedic society meetings:

- American Association of Hip and Knee Surgeons (AAHKS) Annual Meeting, Dallas, Texas
- American Academy of Orthopaedic Surgeons (AAOS) Annual Meeting

In addition, the primary investigators and co-investigators will submit a full-length manuscript summarizing the results of the study to a peer reviewed medical and/or specialty journal in orthopedic surgery. Sub-analyses of other variables and the impact on the primary outcome measures will be published as deemed scientifically appropriate.

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