SECONDARY RESEARCH WITH DATA OR BIOSPECIMENS RESEARCH PROTOCOL TEMPLATE

(HRP-503c)

STUDY INFORMATION

PRO2022000776

- **Title: MRI and intra-operative planning to avoid graft-tunnel mismatch in BTB ACL reconstruction**

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- **Protocol Version and Date:**
  BTB Graft Study PRO2022000776 CJGatt v3. 6.28.2023

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1.0 Research Design

1.1 Purpose/Specific Aims

The purpose of this study is to improve our understanding of bone-tendon-bone (BTB) length and avoid graft-tunnel mismatch when performing ACL reconstruction.

A. Objectives

The aim of this study is to collect objective measurements about the knee during ACL reconstruction to aid our creation of bone tunnels and prevent graft-tunnel mismatch

B. Hypotheses / Research Question(s)

Hypothesis: MRI measurements can precisely direct required tibial tunnel location and angle

Research Questions: 1) Are MRI measurements of patellar tendon length reliably accurate as compared to intra-operative measurement of harvested tendon 2) How often is graft-tunnel mismatch a problem? 3) Is graft-tunnel mismatch more common with independent femoral tunnel drilling (vs transtibial drilling)

1.2 Research Significance (Briefly describe the following in 500 words or less)

Graft-tunnel mismatch is a recognized problem during ACL reconstruction with BTB graft. This occurs when the BTB graft harvested from the patient's knee is longer than the tunnel it is meant to fit in during ACL reconstruction. This creates a problem with graft fixation and may compromise patient outcome. Graft-tunnel mismatch incidence is unclear and methods to avoid it are not standardized. Guidelines have been suggested but not universally adopted. Some of these guidelines are based on traditional "trans-tibial" femoral drilling. With the evolution of ACL surgery, including "independent" femoral drilling, the inconsistent guidelines are further obscured.

An updated and reliably consistent technique is essential to aid the surgeon in avoiding this troublesome intra-operative complication

1.3 Research Design and Methods

Preoperative MRI measurements and intra-operative measurements (patellar tendon length, tunnel length, tibial tunnel angle and location) will be made for patients undergoing ACL reconstruction with BTB autograft. Data will be entered entered into the operative report, and then subsequent chart review will enter measurement data into an electronic RedCap data sheet post-operatively.

This is a secondary analysis protocol. Clinical outcomes and follow up are not part of the study design

A. Research Procedures

Information about graft material will be collected in the operating room, immediately before, during, and at the end of the ACLR procedure. This is currently part of the standard of care and routinely performed with ACLR surgery. Graft measurements will be uploaded into the surgical note. This will not alter the nature, timing or type of surgery, or the follow up. Secondary analysis will entail retrieval of the graft measurements from the surgical note which will be uploaded into a secure RedCAP survey.

A. Study Duration: Three years or 100 patients.

1.4 Secondary Data Collection

NA

A. Source and Context of Original Primary Collection:

Measurements will be taken from the MRI, harvested graft tissue and surgical procedure and uploaded into the surgical note.

a. **Database Location:**
Measurements will be retrieved from the patient note and uploaded into a university secured RedCAP data base.

b. **Prior Consent Considerations:** NA

B. Format and Number of Records: 100 BTB ACLR surgical procedures

C. Date Range: 7/1/2023-7/1/2026

D. Inclusion/Exclusion Criteria: Data will be gathered from patients who undergo ACLR and receive a BTB autograph.

E. Data Abstraction Form(s): attached

F. Sample Size Justification:
A target of 100 patients has been recommended by RUBIs

G. Data Analysis:
All continuous study measures will first be summarized using range, mean and standard deviation (SD), and median with interquartile range (IQR), while categorical measures will be summarized using frequency and percentage. The recorded pre-operative MRI measures will be compared to the same measures collected intra-operatively for the same patient using a paired t-test or a Wilcoxon Sign Rank test (depending on the outcome of normality testing) to determine how accurate and/or reliable the pre-operative measures are. The difference between the measurements will also be calculated in order to determine, among cases with different values, the magnitude of that difference and which direction the differences tend to skew. In order to address the outcome of "graft-tunnel mismatch", the frequency and percentage of cases with a mismatch (> 0 mm protrusion) will be calculated, and a bivariate comparison of the demographics and both pre- and intra-operative measures for those who did and did not have a mismatch will be done to determine whether any significant risk factors can be identified. In addition, logistic regression analyses will also be used in order to identify whether the risk factors identified in the bivariate analyses are independent risk factors or if there is an additive effect across multiple factors. All two-sided p-values < 0.05 will be considered as statistically significant and all statistical analyses will be performed using SAS version 9.4 or R version 4.1 (or higher).

H. Data Management: Data will be de-identified, and numbered by surgeon's first and last initial, date of surgery (00/00/0000) and if multiple procedures are performed on that day, a numberical number 0-10. (ie: CJG.02.07.2023.2)

a. **Access**
   i. Members of the study team

b. **Storage**

i. Data will be stored within the REDCap database which is password protected for 6 years following the completion of the study.
ii. Password protected database

I. **Disposition:** Data will be deleted by study coordinator/PI at the conclusion of six year period.

J. **Intent to Contact, Identify, Re-Identify or Generate Identifiable Information:** "Not applicable"

1.5 Secondary Use of Biospecimens: NA

A. **Source and Context of Original Primary Collection:** Surgical operative notation.
a. **Prior Consent Considerations: NA**
B. **Types of Number and Specimens:** NA

2.0 Project Management

PI and Study coordinator have completed multiple studies and maintain appropriate CITI training. :

2.1 Research Staff Qualifications & Training

All participants are orthopaedic surgeons, have been involved with prior research, maintain up-to-date CITI training, and have completed COI. .

2.2 Resources Available

Rutgers IRB Oversite

2.3 Research Sites

University Orthopaedic Associates – 2 Worlds Fair Drive, Somerset, NJ 08873
University Orthopaedic Associates – 1050 Rt. 1 North, Avenel, NJ
University Orthopaedic Associates – 280 Rt. 9 North, Morganville, NJ 07751
University Orthopaedic Associates – 4810 Belmar Blvd, Wall Twp, NJ 07753

RWJMS Department of Orthopaedic Surgery.

3.0 Multi-Center Research

NA

4.0 Subject Considerations

4.1 Consent Process

NA

4.2 Waiver or Alteration of Consent Process

Requesting a waiver of consent for secondary analysis.

4.3 Risks of Harm/Potential for Benefits to Subjects

A. **Risks of Harm to Subjects:** Minimal risk of breach of confidentiality as this is secondary analysis of de-identified data
B. **Risks of Harm to Non-Subjects: NA**

C. **Minimizing Risks of Harm:** NA

D. **Potential Benefits to Subjects:** None – this is secondary analysis

E. Certificate of Confidentiality (CoC): NA

5.0 Special Considerations

NA

5.1 Health Insurance Portability and Accountability Act (HIPAA)

Requesting a waiver of HIPAA authorization to complete this secondary analysis.

5.2 Family Educational Rights and Privacy Act (FERPA)

5.3 General Data Protection Regulation (GDPR)

6.0 Reporting Results

6.1 Reporting Results Details

A. Individual Subjects' Results: NA

B. Professional Reporting: Results will be submitted for presentation and publication to professional organizations and refereed journals.

6.2 Further Secondary Uses of the Data or Biospecimens

NA

7.0 Research Repositories – Data or Biospecimens

NA

8.0 Approvals/Authorizations

Letter of Cooperation with University Orthopaedic Associates

9.0 Bibliography

1) Miller MD Hinkin DT. The "N+7 Rule" for tibial tunnel placement in endoscopic anterior cruciate ligament reconstruction *Arthroscopy* 12(1):1996; 124-125
2) Saltzman BM, Varken DT, Trofa DP, et al. An update on graft-tunnel mismatch in anterior cruciate ligament reconstruction: A survey of the experts in the field of orthopedic sports medicine demonstrates no clear consensus in management *Knee* 27:2020; 1525-1533
3) Chang CB, Seong SC, Kim TK. Preoperative magnetic resonance assessment of patellar tendon dimension for graft selection in ACL reconstruction *Americal Journal of Sports Medicine* 37(2):2009; 376-382