Anterior Cruciate Ligament Reconstruction Using Bone Patellar Bone or Quad Tendon Autograft With or Without Lateral Extra-Articular Tenodesis in Individuals Who Are at High Risk of Graft Failure (STABILITY 2)

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University of Pittsburgh

CONSENT FOR **ADULTS** TO ACT IN A RESEARCH STUDY

STABILITY 2

ACL Reconstruction +/- Lateral Tenodesis with Patellar vs. Quad Tendon

TRADITIONAL RANDOMIZATION

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KEY INFORMATION FOR THE STABILITY 2

Prior to joining our research study, the STABILTY 2 study, we want to share key information about the study with you. We want to summarize five topics for you prior to reviewing the consent form.

1. This is a voluntary research study
   You are being invited to participate in a research study because your surgeon has determined that you have a torn anterior cruciate ligament (ACL) and you have elected to undergo surgery to reconstruct (replace) this ligament. Participation in this study is voluntary. Whether or not you choose to participate in this study will have no effect on your relationship with your physician and the medical care you will receive.

2. Purpose of this research study
   Young, active individuals, such as yourself, that undergo anterior cruciate ligament reconstruction (ACLR) tend to be more likely to re-injury their knee which can often lead to future knee pain and instability, limited physical activity and arthritis.

   We are conducting this study to determine the most effective surgical treatment for your ACL and lessen the likelihood that you suffer a re-injury of the ACL. By improving the surgical procedures for ACLR, we aim to achieve less symptoms and better function and quality of life and an improved ability to return to sports.

3. Summary of Study Activities
   The purpose of this multicenter study is to compare outcomes between patients who will undergo different types of ACL reconstruction. All patients will have a tendon from their own knee used to reconstruct the ACL. You will have a tendon taken from above your knee cap (quadriceps tendon) or below your kneecap (patellar tendon). Additionally, some people will have an added surgical procedure on the outside of your knee, which is called a lateral extra-articular tenodesis (LET). A lateral extra-articular tenodesis is when the surgeon creates a new ligament-like structure using a strip of the iliotibial band taken from the side of your knee. The typical surgery for an ACL tear is ACL reconstruction without the lateral extra-articular tenodesis. Some studies have shown that young individuals who return to pivoting and/or contact sports following ACL reconstruction have a risk of re-tearing their ACL more commonly. This study is designed to look at whether or not graft type (quadriceps tendon vs. patellar tendon) and adding this extra procedure to your surgery reduces the risk of re-injury to the ACL in young individuals like yourself.

   Your surgery to reconstruct the ACL will be done with one of the following:

   1. Quadriceps Tendon
   2. Quadriceps Tendon with Tenodesis
   3. Patellar Tendon
   4. Patellar Tendon with Tenodesis

Prior to the surgery, researchers on this study will randomize (i.e. a coin toss) to determine if your ACL reconstruction will be done with your patellar or quadriceps tendon. They will also randomize if the LET procedure will or will not be added to your ACL surgery.

We will follow-up with you as you undergo treatment and recovery after surgery for 2 years. We would like to meet with you at your regularly scheduled office appointments with your surgeon before surgery and at 6 weeks and 3, 6, 12 and 24 months after surgery. These visits with your surgeon occur whether or not you choose to participate in the study. During these visits we will review your medical records, ask that you fill out questionnaires electronically, examine the stability and range of motion of your knee and strength of your thigh muscles. We will also ask you to perform several hopping and jumping tests.

We will request your contact information so that we can contact you for these follow-ups. We will also request demographic information for descriptive purposes.

4. Risks and side effects related to ACL reconstruction and the LET procedure
   All subjects in this study will undergo ACL reconstruction surgery by your surgeon as part of standard of care. Your surgeon will review the overall risks of surgery during your surgical consultation as well as any risks or complications associated with each possible surgical group you may be randomized to.

   Falling and re-injury of your knee may occur when you perform the hopping or jumping tests however, these risks are no greater than those encountered with typical post-operative rehabilitation and participation in sports.

   For a more complete list of risks, see the ***What are the possible risks, side effects, and discomforts of this research study?*** section below.

5. Reasonable expected benefits
   Subjects may benefit from enhanced follow-up and monitoring.

   There is also the potential for reduced injury risk in those participants who receive a lateral extra-articular tenodesis.

6. Alternative procedures or treatment
   If you decide that you are not interested in participating in the study, you can continue with your treatment as decided by you and your surgeon, which may include one of the four treatment options in this study or reconstruction with a hamstring tendon or allograft tendon.
   Your participation in this research study will have no effect on your current or future medical care at this hospital or with an affiliated health care provider.

Why is this research being done?
After anterior cruciate ligament reconstruction (ACLR) there are high rates of re-injury in young active individuals, which is associated with worse outcomes and a greater likelihood of arthritis. Improved methods of surgery to reduce that risk of re-injury to the ACL are important to avoid future knee pain and instability, limited physical activity and arthritis.

This study is being done to determine if the use of the tendon from above your knee cap (quadriceps tendon) or from below your knee cap (patellar tendon) either with or without additional surgery on the outside (lateral side) of your knee, which is called a lateral extra-articular tenodesis, reduces the risk of re-injury of the ACL, results in less symptoms and better function and quality of life and an improved ability to return to sports.

Who is being asked to participate in this study?
You are being asked to participate in this study because you are an athlete between 14 and 25 years of age, have stopped growing and you are being seen by your orthopaedic physician for an ACL tear that requires surgery. If you participate in this study, we will randomize the tendon that will be used to reconstruct your ACL, and if the surgeon will or will not perform a lateral extra-articular tenodesis during surgery. Randomization is a process that assigns you by chance, rather than by choice, to surgery with either a portion of your quadriceps tendon or patellar tendon with or without a lateral extra-articular tenodesis. Randomization is like the flip of a coin and gives you equal possibility of being in either group. We will use a computer program to randomly assign you to one of the groups. If you elect not to be in this research study, your surgery will continue as scheduled, and you, in consultation with your surgeon, will determine the tendon that will be used to reconstruct your injured ACL, and the need to do a lateral extra-articular tenodesis.

If you elect to participate in the study, you will be randomized to one of the four groups below:

1) Use of your quadriceps tendon with a lateral extra-articular tenodesis
2) Use of your quadriceps tendon without a lateral extra-articular tenodesis;
3) Use of your patellar tendon with a lateral extra-articular tenodesis;
4) Use of your patellar tendon without a lateral extra-articular tenodesis

All groups will undergo standard rehabilitation protocol after surgery.

What procedures will be performed for research purposes?

The following activities will be performed <u>prior</u> to your surgery:

<u>Contact Information (Research Activity)</u>
We will ask you for your contact information including your name, date of birth, address, phone number, and email address. Additionally, we will ask you to provide the name and contact information for several other individuals who will know your whereabouts if we cannot get in touch with you. This information will be kept by the research team with your surgeon, so that they can contact you throughout this research study.

Demographic Information (Research Activity)
Demographic information that will be recorded include your date of birth, age, sex, weight, height, body mass index (BMI), education level, sports activity level, work activity, marital status, and smoking history. This form will be completed at the pre-surgery visit.

Sports Activity Questionnaires (Research Activity)
You will complete a questionnaire at baseline that asks about your sports activities and participation. It will include questions related to the frequency you perform running, jumping, cutting and pivoting activities as well as the sport(s) and level of sport(s) that you participated prior to your ACL injury. You will be asked similar questions as you recover from surgery at 6, 12 and 24 months after surgery.

History of Injury and Treatment to your Knees and Physical Examination (Standard of Care Activity)
The physical examination will include measurement of the range of motion and looseness (laxity) of both of your knees. Examining the laxity of your knee involves moving your lower leg forward, backward and side-to-side to determine the stability of your knee joint. The physical examination is done for normal clinical purposes but will be recorded for use in this research study. We will also review and record the results of any x-rays or MRI that were done for your knee before and after surgery.

Muscle Strength Testing (Research Activity)
The strength of your thigh muscles (quadriceps and hamstrings) will be measured prior to surgery. The test will be performed using a dynamometer or crane scale (strength testing machines) with your knee bent to 90 degrees (sitting position). During the testing, you will kick your leg forward or pull your leg back into a cushioned pad or strap as hard as you can for 5-seconds. The pad or strap will be stabilized to prevent your leg from moving. Before the tests, you will be given the opportunity to practice the motion several times. You will kick out and pull back three times in each direction and both legs will be tested.

The following activities will occur <u>during</u> your surgery:

Surgical Procedure (Standard of Care Activity)
All surgeries will be performed according to established standards of care for individuals undergoing ACLR. Your surgeon will conduct an examination on your knee while you are under anesthesia. This examination will be used to determine if you continue to be eligible for this study.

As part of this examination, the surgeon will use an e-tablet application called the "Pivot App" to take measurements of your knee. Three (3) yellow stickers will be placed on the side of your knee that will be detected by the camera on the tablet. The surgeon will move your knee up and down in view of the camera while the Pivot App takes measurements of movement of the stickers.

If it is determined that you are eligible, randomization will occur. ***<u>The tendon used to reconstruct your ACL and whether or not you receive a lateral extra-articular tenodesis will be randomly determined.</u>*** The details of your surgery will be recorded for study purposes, including the findings during the

arthroscopic examination, and the surgical procedures that are used to reconstruct and/or repair the injured structures in your knee.

The following activities will be performed <u>after</u> to your surgery:

<u>Post-Operative Rehabilitation (Standard of Care Activity)</u>
After surgery, you will be referred to a physical therapist to begin your post-operative rehabilitation (physical therapy). Your physical therapist, in consultation with your surgeon, will be given a set of instructions that will assist them to plan your rehabilitation. We will ask you to complete a questionnaire about your rehabilitation activities at 6 weeks, 3, 6 and 12 months after surgery.

<u>Post-Operative Clinical Visits (Standard of Care Activity)</u>
As part of your standard treatment, you will see your orthopaedic surgeon in the office several times after your surgery over two years during your recovery. During those visits, your doctor will ask you about any knee pain or other symptoms that you are experiencing as well as how your knee is functioning during your daily and/or sports activities. Additionally, the surgeon will inspect your knee to evaluate how well your incisions are healing and to determine if you have any swelling in your knee. The doctor will also measure the range of motion of your knee and ask about additional medical tests or surgery you may have had since your last visit. Your knee joint laxity (joint looseness) will also be assessed by your doctor. The examination of the laxity of your knee involves moving your lower leg forward, backward and side-to-side to determine stability of your knee joint. This information will be collected approximately 6 weeks, and 3, 6, 12 and 24 months after your surgery during your regularly scheduled follow-up visits with your surgeon.

Additionally, your surgeon will use the PIVOT App to take measurements of your knee at 6, 12 and 24 months after surgery.

<u>Muscle Strength Testing (Research Activity)</u>
The strength of your thigh muscles (quadriceps and hamstrings) will be measured 6, 12 and 24 months after surgery in two ways. First, the strength of your thigh muscles will be measured the same way that it was measured prior to surgery using the dynamometer or crane scale. Second, your strength will be tested using a computerized isokinetic dynamometer (strength testing machine). During this test, you will kick your leg forward and pull your leg backward as hard as you can 5 times. The machine controls the speed which will be 90 degrees per second. Before the tests, you will be given the opportunity to practice the motion several times. Both legs will be tested.

<u>Functional Performance Tests (Research Activity)</u>
To assess your level of function you will perform a series of hopping and jumping tests 6, 12 and 24 months after surgery. The tests will be administered by a physical therapist, athletic trainer, kinesiologist or research assistant in your surgeon's office. While you perform these tests, you will wear a cloth sleeve to cover both knees so the tester does not know which knee had surgery. For the hop tests, we will measure how far you can hop forward once on one leg, three consecutive times on one leg and three consecutive times while crossing a line as well as how long it takes you to hop 6 meters on one leg.

Each of these tests will be performed two times on each leg and you will have the chance to practice the test several times before we measure your performance during the tests.

You will also perform a test called the Drop Vertical Jump (DVJ) test. During this test, you will drop off of a box that is 30 cm high (11.8 inches), land on both feet and then immediately jump up again, similar to rebounding for a basketball. During this test, we will observe the motion and position of your knees, leg, hips, pelvis and trunk. We will also video-record your performance of the DVJ on video so that we can review and score your performance. We will use a camera device known as Microsoft Kinect V2 along with ACL Gold Software to get precise measurements on your knee and legs during the DVJ test. You will only complete this test at 6 and 12 months after surgery.

Standing Flexion Radiograph (x-ray) (Research Activity)
Twenty-four months after surgery, you will undergo a standing flexion radiograph for research purposes identical to the one you had prior to surgery. A urine pregnancy test will be performed on all female participants on the same day prior to getting the x-ray. You will be given the results of the pregnancy test, should the test be positive. Information from this x-ray will be collected for research purposes.

Study Questionnaires (Research Activity)
You will be asked to complete various questionnaires using a computer or by completing the questionnaires on paper forms. The questionnaires will take approximately 45 minutes to complete. You will complete the questionnaires prior to surgery after you have signed this form, and 6 weeks, 3, 6, 12, and 24 months after your surgery.

The questionnaires will ask about your pain and other symptoms in your knee, your ability to perform daily activities and sports, the type and level of sport(s) that you are currently doing and how your knee affects your quality of life and emotions.

Review of Medical Records (Research Activity)
We are also requesting your authorization or permission to review your medical records; this authorization is valid for an indefinite period of time. If you participate in this study, we will record past, current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records. The information that will be recorded will be limited to information concerning the treatment you underwent for your ACL injury including: your medical care, non-operative treatment, surgical treatment, physical therapy information, any follow-up care related to your knee, and information from radiographs and MRI of your lower extremities. No research-derived information will be placed into your medical record. This identifiable medical record information will be made available to members of the research team for an indefinite period of time.

This information will be collected for all office visits related to your knee injury that you have with your physician and physical therapist.

What are the possible risks, side effects, and discomforts of this research study?

Breach of Confidentiality

Although every reasonable effort has been taken, confidentiality during Internet-based communications cannot be guaranteed and it is possible that research information, and additional information beyond that collected for research purposes, may be captured and used by others not associated with this study.

During the jump testing, we will video tape your movement from the waist down to confirm accuracy. Your face will not be recorded, and the video will be saved using an ID number and not your name.

You will not be identified in any publications or presentation of the research results.

Any paper records generated for this study will be assigned a database ID number. Information collected in this study will be stored in a locked file cabinet and/or on a password protected electronic database and will be accessible only to the research staff. The list linking the code number with your identity will be stored in a separate secure location.

We will protect the privacy and confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside of the University of Pittsburgh.

Risks of ACLR Surgery

All subjects in this study will undergo surgery for an ACL reconstruction surgery provided by your surgeon as part of standard of care. Your surgeon will review the overall risks of surgery during your surgical consultation.

For each procedure, there is a risk of pain or complications associated with removing the graft tissue. Your surgeon will review these potential risks with you. If you are selected to receive the extra-articular tenodesis procedure, there is a chance you may experience some discomfort or tightness in the side of your knee following surgery.

Testing Procedures

You may experience temporary soreness in your muscles or knee after the strength testing procedures that could last for one to two days, however this risk is similar to the development of soreness in your muscles or knee associated with the exercises that you perform during your rehabilitation. There is a rare risk (<1%) that you may suffer a strained (pulled muscle) during the strength tests. These risks will be minimized by ensuring that the testing procedures are appropriate given your level of recovery, allowing warm-up prior to the actual test and by providing instructions and closely monitoring your performance of the test.

Falling and re-injury to your knee are the risks that may be associated with performance of the hopping and jumping tests, however, these tests will not be performed until at least 6 months after surgery and the risks are no greater than those encountered with typical activities included in your post-operative rehabilitation or with your participation in sports.

Imaging
You will receive a standard knee x-ray 24 months after your surgery to look for any potential arthritis in your knee. This x-ray will expose your knee to a minimal amount of radiation. The risk associated with the amount radiation exposure that you will receive from this study is considered to be low and comparable to everyday risks. All female participants will receive a urine pregnancy test immediately prior to getting the x-ray. Pregnant females will not participate in this x-ray.

What are the possible benefits from taking part in this study?
All participants in this study will benefit from enhanced follow-up and monitoring.

There is a potential for reduced injury risk in those participants who receive a lateral extra-articular tenodesis.

If I agree to take part in this research study, will I be told of any new risks that may be found during the study?
You will be promptly notified if, during the conduct of this research study, any new information arises about which tendon is best to use to reconstruct your ACL and/or if a lateral extra-articular procedure is proven beneficial or not.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?
Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed exclusively for the purposes of this research study, for example completion of study-related questionnaires or surveys. You or your insurance company will be billed in the standard manner for routine care; including the surgery, post-operative physical therapy, and follow-up visits with your physician. You will be responsible for costs not covered by your insurance carrier. These costs include any applicable co-payments, coinsurances, and deductibles.

Who will pay if I am injured as a result of taking part in this study?
If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not give up any of your legal rights by signing this form.

Will I be paid if I take part in this research study?
You will be paid up to $290 for completing all activities related to the research study. You will be paid by the local research team. The payment schedule will be as follows:

- Baseline:
    - Informed Consent and Completing Screening Procedures - $25
    - Completing baseline questionnaires and strength testing-- $25

- 6-weeks --
    - Follow-up study Questionnaires -- $20
- 3-months --
    - Follow-up study Questionnaires -- $20
- 6-months:
    - Completion of questionnaires and hop tests -- $25
    - Completion of isokinetic strength testing - $25
- 12-months:
    - Completion of questionnaires and hop tests -- $25
    - Completion of isokinetic strength testing - $25
- 24-months:
    - Completion of questionnaires and hop tests -- $25
    - Completion of isokinetic strength testing - $25

Additional payment of $50 if you complete all activities at the 6, 12, and 24-month follow-ups.

Who will know about my participation in this research study?
Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet and/or in a password protected electronic database that will be only accessible to the investigators and their staff. Your identity on these records will be indicated by a database ID number rather than by your name, and the information linking these numbers with your identity will be kept separate from the research. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical record information) related to your participation in this research study:

- Investigators from the University of Pittsburgh and Western Ontario University may review your identifiable research information (which may include your identifiable medical record information) for the purpose conducting and monitoring of this research study.

- Authorized representatives of the sponsor of this research study, National Institute of Health (NIH), may review your identifiable research information (which may include your identifiable medical record information) for the purpose of conducting and monitoring this research study.

- Authorized representatives of the Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical record information) for the purpose of monitoring the appropriate conduct of this research study.

- Information collected from this study may be shared with other investigators interested in knee injuries. The information that will be shared will be de-identified, i.e. coded and the information linking the code with your identity will be stored in a separate secure location.

- Representatives from EmPower Health Research, the online data management system used to collect your data, may have access to your identifiable information for the purposes of monitoring the quality of the data, as well as to monitor for missing or unclear data.

- Authorized representatives of the University of Pittsburgh or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical record information) related to your participation in this research study for the purpose of (a) fulfilling orders, made by investigators, for hospital and health care services (e.g. laboratory tests, diagnostic procedures) associated with research participation; (b) addressing correct payment for tests and procedures ordered by the investigators; and/or (c) for internal hospital operations (i.e. quality assurance).

- In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical record information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by state (or provincial) law, the appropriate agencies.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical record information) related to your participation in this research study for a minimum of 7 years following the final reporting or publication of the results of this project and for as long (indefinite) as it may take to complete this research study.

Is my participation in this research study voluntary?
Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will not be allowed, in general, to participate in the research study.)

Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at this hospital or with an affiliated health care provider.

Your doctor is involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before

agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research study. However, if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.

Any identifiable research or medical record information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with this institution. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at this institution or with affiliated health care provider.

If I agree to take part in this research study, can I be removed from the study without my consent?
It is possible that you may be removed from the research study by the researchers. You may be removed from the study, for example, if it is discovered during your surgery that you do not meet all the eligibility criteria.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

Any questions I have about my rights as a research participant or the research use of my medical information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

_____

Participant's Name

_____ _____

Participant's Signature Date / Time

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date / Time