



**Boston  
Children's  
Hospital**

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Orthopedics &  
Sports Medicine

# **Bridge-Enhanced ACL Repair (BEAR)** for Surgical Treatment of ACL Injuries

## **Sponsor**

Martha M. Murray, MD

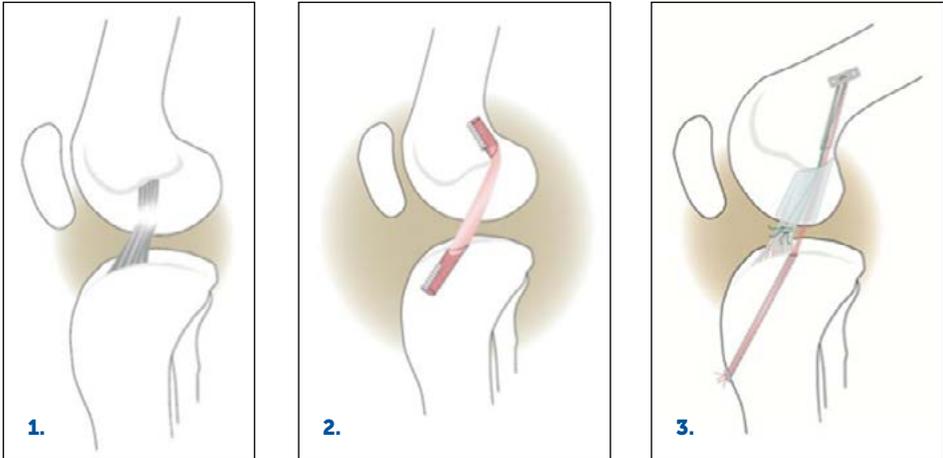
## **Principal Investigators**

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# Bridge-enhanced ACL repair at a glance



**Fig. 1** Drawing of an ACL tear. Without treatment, healing does not occur.

**Fig. 2** Drawing of an ACL reconstruction. The torn ACL is removed and replaced with a graft of tendon.

**Fig. 3** Drawing of a bridge-enhanced ACL repair. The ACL is encouraged to heal using stitches and a sponge instead of a tendon graft.

## What data suggests the BEAR procedure will work?

This procedure has been studied in pig knees and in patients in two BEAR studies.

In the pig knees, the BEAR technique resulted in a healed ACL about as strong as an ACL graft at three, six and 12 months after surgery. Pigs treated with the BEAR procedure had less arthritis than those treated with an ACL graft. Although this is promising, we do not know if these same results will be true in human knees.

In the first BEAR study, 10 patients had the BEAR procedure performed. To date, all are doing well, with knees that are working as well as the knees treated with an ACL reconstruction. In the second BEAR study, 65 patients had the BEAR procedure and we are in the process of monitoring their recoveries. These results are still early and we do not yet know how the results will hold up over time.

## What data suggests the BEAR procedure is safe?

The sponge has been made in a special facility and using techniques to minimize the chances of an infection or other complication. There were no bad reactions to the sponge or infections in the first 75 patients who had the BEAR procedure. The U.S. Food and Drug Administration has reviewed the extensive testing performed on the sponge and given its permission for this additional study in human patients.

# What is ACL reconstruction surgery?



Lyle Micheli, MD, and Martha Murray, MD, discuss bridge-enhanced ACL repair with a patient.

Anterior cruciate ligament (ACL) reconstruction is one of the most common orthopedic procedures in the United States.

Unlike other ligaments, the ends of a torn ACL do not reconnect. During an ACL reconstruction, an orthopedic surgeon removes the ends of the torn ACL and replaces them with a graft, usually two of the patient's hamstring tendons.

Although most patients are able to return to sports, the ACL re-tear rate can be as high as 20 percent for teens. Up to 80 percent of patients develop arthritis 15 to 20 years after surgery.

## What is bridge-enhanced ACL repair? (the BEAR procedure)

The new technique, bridge-enhanced ACL repair, uses stitches and a bridging scaffold (a sponge injected with the patient's blood) to stimulate healing of the torn ACL.

We have tested this new technique in animal models and 75 patients. The goal of the current study is to study the BEAR procedure in more patients to determine if patient age contributes to the success of the procedure.

## What are the differences between ACL reconstruction and the BEAR procedure?

### ACL reconstruction

- » standard care for ACL tears, proven to be safe and effective
- » requires incision to harvest the graft; other work done arthroscopically
- » requires graft harvest of patient's own tendon
- » remaining ACL tissue is removed

### Bridge-enhanced repair

- » experimental use of a bridging scaffold with some unknown risks and benefits
- » requires incision to insert scaffold; other work done arthroscopically
- » no graft harvest of patient's tendon
- » remaining ACL tissue is preserved

### Eligibility criteria

Up to 250 patients will be enrolled at Boston Children's Hospital and Rhode Island Hospital. Patients who **may** be eligible for the study:

- will be ages 12 to 80
- will have a complete ACL tear which occurred in the past 50 days or a partial tear that requires surgery
- cannot have a history of prior ACL surgery on the affected knee
- must not use tobacco, corticosteroids or have a history of diabetes or inflammatory arthritis
- must not have an allergy to bovine collagen (cow protein)

### What will I get if I am in the study?

Patients will receive an MRI scan nine months after their surgery to see how their ACL and knee are doing. Patients will undergo specific muscle strength and knee performance evaluations at six months, nine months, one year and two years after surgery. There will be no charge to the patient or their insurance for these additional tests. In addition, a credit voucher for \$50 will be provided after the completion of the two-year follow-up visit.

### What will I have to do if I'm in the study?

Patients will be asked to complete questionnaires, forms, surgery, MRIs, lab testing and physical examinations over the two-year period. The same visits required for a standard ACL surgery will apply to all patients in this study.

Visits will be for:

#### Baseline

screening, consent, questionnaires, physical exam, x-ray (possibly), labwork (possibly)

**1–2 week, 6-week and 3-month follow-ups**  
physical exam

#### 6-month follow-up

questionnaire, strength testing, physical exam

#### 9 month follow-up

questionnaire, strength testing, MRI, physical exam

#### 1-year and 2-year follow-up

strength testing, questionnaire, physical exam

**Your participation in this clinical trial, available only at Boston Children's Hospital and Rhode Island Hospital, may provide long-lasting benefits for everyone affected by ACL injuries.**

### Inquiries

Please direct all inquiries to:  
BEAR Study Coordinators  
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### Learn more

[bostonchildrens.org/aclbeartrial](https://bostonchildrens.org/aclbeartrial)