Bridge-Enhanced ACL Repair (BEAR) vs. ACL Reconstruction for Surgical Treatment of ACL Injuries

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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 10 patients. The goal of the current study is to study the BEAR procedure in more patients to determine if the new technique is as good as ACL reconstruction for a larger number of patients.

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
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 the first BEAR study.

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. However, these results are still early (the first patient surgery was February 2015), 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 10 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.
Eligibility Criteria
Up to 100 patients will be enrolled. Patients eligible for the study:

- will be ages 14 to 35, but need to have closed growth plates
- will have a complete ACL tear which occurred in the past 30 days
- cannot have a history of prior 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)

Patients will be randomly assigned to have the BEAR procedure (two-thirds of patients) or a standard ACL reconstruction (one-third of patients) and will not be told which group they are in until two years after their surgery.

What will I get if I am in the study?
Patients will receive up to four MRI scans and sets of X-rays over the 10-year period of the study to see how their ACL and their knee are doing. Patients will undergo specific muscle strength and balance testing and knee performance evaluations at six months and one year, two years, six years and 10 years after surgery. These will be at no charge to the patient or their insurance. In addition, parking vouchers for doctor’s visits will be provided, as well as credit vouchers for $50 after each of the visits at one and two years after surgery, and $100 after each of the visits at six and 10 years after surgery.

What will I have to do if I’m in the study?
Patients will be asked to complete questionnaires, forms, surgery, MRIs/X-rays, lab testing and physical examinations over the 10-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, labwork
- 1–2 week, 6-week and 3-month follow-ups questionnaire and physical exam
- 6-month followup questionnaire, strength and balance testing, MRI, labwork
- 1-year followup strength testing, questionnaire, physical exam
- 2-year, 6-year and 10-year follow-ups questionnaire, strength and balance testing, MRI and X-ray

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

Inquiries
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