PRIMARY REPAIR OF ACL INJURIES

New Advances
Bridge-Enhanced ACL Repair (BEAR)

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Winner of the O'Donoghue Award

Bridge-Enhanced Anterior Cruciate Ligament Repair Is Not Inferior to Autograft Anterior Cruciate Ligament Reconstruction at 2 Years

Results of a Prospective Randomized Clinical Trial

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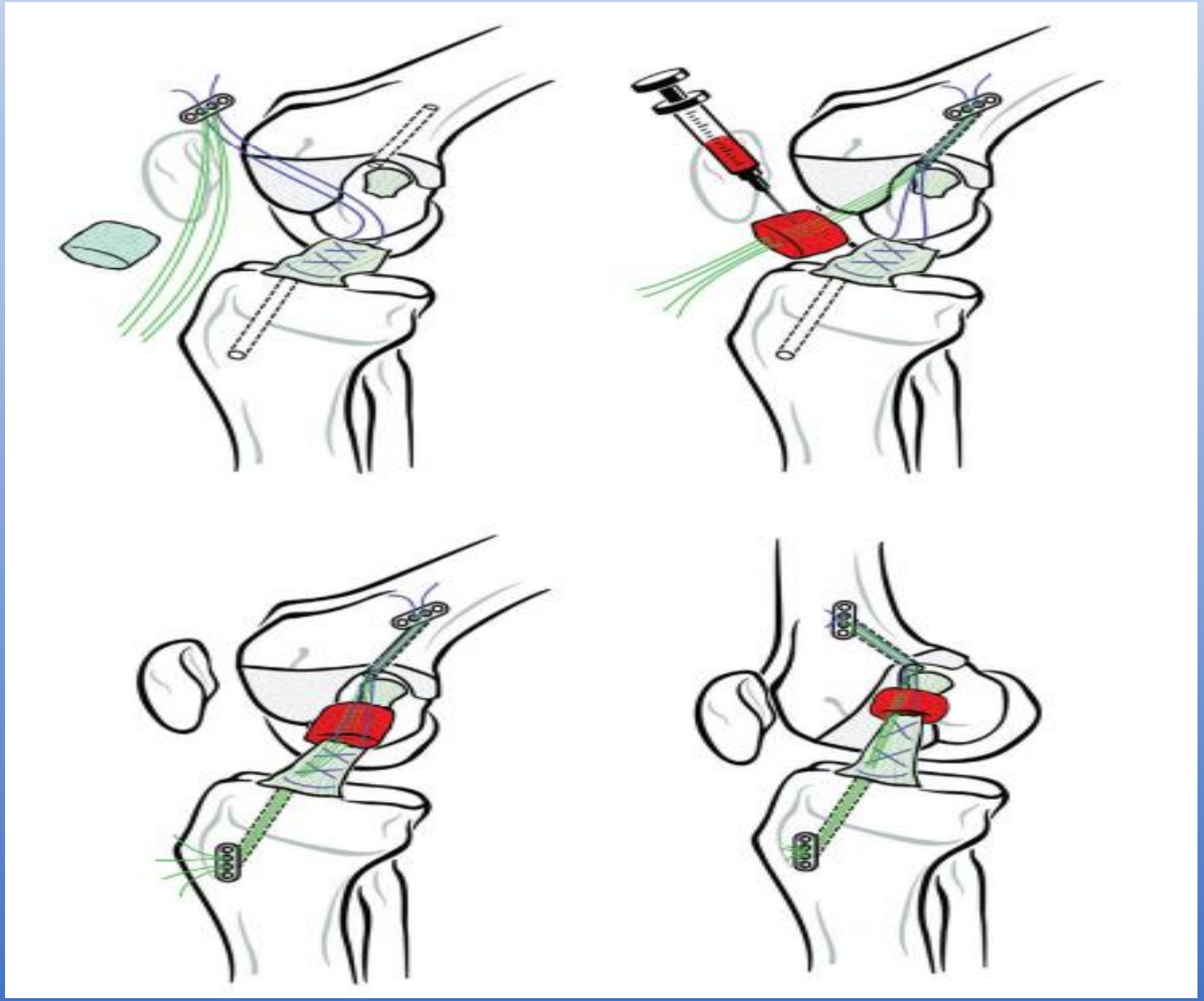
Investigation performed at Boston Children's Hospital, Boston, Massachusetts, USA

Why this Report is significant

- Until 1980's primary repair of the ACL was attempted but failure rate was reported to be as high as 50% at 2 years have been reported even recently, thus tendon replacement serves as standard of care
  - Feagan; Am J Sports Med; 1976
  - Gagliard; Am J Sports Med; vol 47; 2019
- Has been felt that the intra-articular nature of the ACL results in premature dissolution of the fibrin clot which inhibits gap healing and does not allow native ACL to perform the basics of ligament repair- cell and vessel proliferation, cell migration and production of collagen scar mass
- The BEAR Bridge Enhanced ACL Repair involves placing a resorbable protein-based implant containing autologous blood in the gap between the 2 torn ends of a midsubstance ACL tear in combination with suture repair of the ligament and use of a suture cinch to reduce the knee joint
  - By bridging gap, absolute end to end approximation is not needed



- In animal models, the BEAR resulted in a repair with comparable mechanical properties to a healing graft with less posttraumatic osteoarthritis than what was seen in ACL reconstructed animals
  - Murray and Fleming; Am J of Sports Med ; Vol 41; 2013
- Follows the initial outcome reports of ten patients previously reported, attempting to compare outcome scores and laxity results in a longer period of follow-up
  - Murray et al; Orthop J Sports Med; 2016
- Provides a potential alternative to treating ACL deficiencies in a younger population that has a high failure rate related to compromised fixation secondary to open growth plates and significant continued growth. Modifications in tunnel position and younger patient age are the highest risk factors for graft failure
  - Parkinson et al; Am J Sports Med; Vol 15 2017

Martha M. MURRAY, MD; et al
Boston Children's Hospital

- Hypothesis
  - Patients treated with Bear would have a noninferior patient-reported outcomes (IKDC Subjective Score) and instrumented AP knee laxity (not more than 2 mm side-to-side difference) and superior muscle strength (hamstring) at 2 years after surgery when compared with patients who underwent ACLR with autograft
- Study Design: Randomized controlled Trial: Level of evidence 1
- Methods:
  - 100 pts with median Age 17 with complete midsubstance ACL injuries who had surgery within 45 days of injury
  - Randomly assigned to either BEAR (65) or autograft hamstring ACLR (35)
  - Outcomes assessed at 2 years by an independent examiner blinded to the procedure
- All patients followed identical PT protocol used at Boston's Children
- 96% returned for 2-year follow-up

- Results
  - Noninferiority criteria were met for both the IKDC Subjective Score (88.9 Bear vs 84.8 ACLR) and the side-to-side difference in AP knee laxity (1.61 BEAR vs 1.71 ACLR)
  - BEAR group had a significantly higher mean hamstring strength index than ACLR group at 2 years
  - 14 % of BEAR group had had a reinjury that required second ipsilateral ACL surgical procedure vs 6% in the ACLR group (P=.32)
    - The 8 BEAR pts converted to ACLR autograft showed similar outcomes to mi substance patients who had only primary ACL procedure
- Conclusion
  - BEAR resulted in noninferior patient-reported outcomes and AP laxity and superior hamstring muscle strength when compared with autograft hamstring ACLR at 2 year follow-up. These results suggest that longer-term studies are justified of this technique

Criteria

Inclusion

- Complete ACL tears
- <45 days from injury
- Closed growth plates
- At least 50% of the length of the ACL attached to the tibia

Exclusion

- History of previous knee surgery
- Risk factors that affect ligament healing
  - Nicotine, previous steroid inj within 6 months, diabetes, inflammatory arthritis
- Displaced bucket handle tear requiring sutures
- Full thickness cartilage lesion, grade III MCL, PLC injury

Additional BEAR Findings

- Results show effectiveness of Bear implant is the same for all tear types
  - Proximal avulsion (28%), proximal third (33%), mid substance (25%)
- As of 3/13/23
  - 751 total cases performed
  - Follow-up
    - Vast majority 6 months or less
- Cost of implant: $5000.00

Why use the BEAR

- Avoids Donor site morbidity
- Avoids Residual muscle weakness
- ***Allows for minimized damage to open growth plates and eliminates acceptance of non-anatomic tunnel position to avoid growth plate damage***
- Revisions less complicated
  - Retained hardware
  - Compromised tunnel positions
- Maintains autograft availability for potential revisions
- Potential for being the Holy Grail related to ACL complications – articular cartilage degeneration
  - Currently not proven in long-term follow-up

Issues with using the BEAR

- Expense - $5000.00 – it is an implant so issues related to being covered in an ASC if government agency payer– Medicare/Medicaid
  - Unsure if private or commercial insurers paying for it
- Does not allow for quicker Return To Sports
- Requires arthrotomy
- 2 year f/u still has higher failure rate 14% vs 6%
- FDA approved for pts with closed growth plates
  - Off label use in desired population

- Feel there is a role for the BEAR
  - Particularly in the young individual with wide-open growth plates which present with the highest failure rates
  - Also In individuals not desiring allograft but will be greater affected by donor site morbidity
- Feel results will be better in the older population as with ACL reconstruction
- Interesting to see if long term results bear out the hope for less degenerative disease in pts s/p ACL reconstruction
- Feel I would combine in with an Extra Articular Tenodesis to potentially decrease failure rate in individuals with open growth plates