BEAR (Bridge Enhanced ACL Repair) Implant

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Device

The BEAR is a cylindrical, bovine collagen implant utilized in anterior cruciate ligament (ACL) repairs. It stabilizes autologous blood (injected into the implant) into the gap between the torn ligament ends, forming a clot.[1,2] According to the manufacturer, the implant protects the clot from the synovial environment and "supports cell migration and proliferation".[2] Within eight weeks it is resorbed and replaced with new tissue, which preserves the native ACL and eliminates need for a donor site.[2]

Actions for Consideration

Partner: Identify orthopedic surgeons and the appropriate clinical and non-clinical value analysis team members. An assessment of financial impact should be considered. Reimbursement specialists may be particularly helpful within this category.

Connect: Collecting and reviewing physician data including usage and cost, of current implants will help inform impact if this technology is adopted. Reimbursement information should be attained. Identify evidence related to specific product and share with stakeholders.

Communicate: Educate the team on product information and physician utilization, and develop a common goal. Discuss pricing, reimbursement, and develop strategies to manage use. Robust data sharing will not only enhance discussions, but may lead to actionable conversations between peers. Education for staff will be an important part of a successful adoption, partnering with supplier will be beneficial.

HealthTrust Resources: Access the Clinical Knowledge Insights Library to find other relevant documents and toolkits with actionable information. Examples for this product include resources on value analysis, physician engagement, and clinical trials.[3] Network on HealthTrust Huddle, our member community that shares ideas and seeks guidance from colleagues.[4]

FDA Approval

The BEAR has FDA approval through De Novo classification, DEN200035 (regulation number 888.3044).[5] Indications for use:

> "The BEAR® (Bridge Enhanced ACL Repair) Implant is a bovine extracellular matrix collagen-based implant for treatment of anterior cruciate ligament (ACL) injuries. The BEAR® Implant is indicated for skeletally-mature patients at least 14 years of age with a complete rupture of the ACL, as confirmed by MRI. Patients must have an ACL stump attached to the tibia to construct the repair."[5]

Clinical Evidence

Studies directly comparing outcomes utilizing BEAR versus other ACL repair techniques are limited. Samples are included below. Of note, all studies reviewed included authors with equity interest in Micah Orthopedics which was "formed to work on upscaling production of the BEAR scaffold".[6]

- In a 2020 prospective randomized trial by Murray et al. 100 patients were randomized to receive either BEAR (n=65) or autograft ACL repair (n=35). They were evaluated up to the two-year mark with International Knee Documentation Committee (IKDC) scores and anteroposterior knee (AP) laxity. They

concluded noninferiority in patient-reported outcomes and AP knee laxity, with "significantly" higher mean hamstring muscle strength, in the BEAR group. Limitations included the difference in number of patients in each group, the majority of patients in the autograft group having hamstring harvest, and the majority of surgeons involved not having prior BEAR experience. Conflicts of interests (COI) reported Murray being the founder, paid consultant, and equity holder in Miach Orthopaedics, Inc., another author being the husband of Murray with the same conflicts, and a third being a paid consultant and equity holder as well. There was a COI management plan in place overseen by committees Boston Children's Hospital and the FDA.[6]

- A 2020 cohort study by Freiberger et al. analyzed blood counts in 61 patients who underwent BEAR ACL repairs to compare the effect of higher platelet counts on ACL cross-sectional area and signal intensity 6 months post repair. They concluded that platelet counts did not have any significant effect on either parameter and suggested further studies on biological markers that may affect ACL healing outcomes. Limitations included short duration of follow up, potential for sex of the patient to influence cross-sectional area, small cohort, and analysis of limited blood components. COI mentioned several authors and Boston Children's having equity interests in Miach Orthopaedics and receiving royalties from Springer.[7]
- A nonrandomized controlled trial of 20 patients (10 BEAR and 10 autograft) compared reported post-operative pain scores. They concluded that both groups had "similar" pain scores at two weeks through 2 years post operatively. Limitations included sample size, potentially for underestimation of patient self-reported quantity of opioid consumption, and generalizability of study. COI mentioned include multiple grants and several authors being equity holders in Miach Orthopaedics.[8]

Physician Advisor Insight

A panel of orthopedic surgeons within our HealthTrust Physician Advisor Network offered the following insight with regard to the BEAR implant[9]:

- Potential exclusion for any patient with a chronic ACL injury, a lax or stretch ACL injury, or a multi ligamentous knee injury.
- The implant needs good midterm and long-term outcome studies for general adoption of this technique and product.
- Potential benefits include avoiding the complications associated with gravesite harvest and avoiding donor site pain and infection risk.
- May impact incidence of re-rupture when allograft is used compared to traditional graft, such as hamstring or bone-patellar tendon-bone autograft.
- Due to already positive outcomes of current techniques, benefit undetermined without additional evidence.
- May have a good role in treating certain patient populations.

Summary

Careful review and understanding of physician interest and outcomes will help determine direction and potential opportunity. Share data and evidence to engage physicians and enhance decision making. Identifying a physician champion to help guide peer discussions around use and potential guideline development are important steps. When considering the addition of new product/technique, ensure appropriate support is provided from the supplier and/or physician peer.

References

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