Partial Tear Label Expansion Clinical Summary

BEAR® Implant

BRIDGE ENHANCED ACL RESTORATION

Purpose Statement

Compare outcomes of BEAR Implant patients with partial ACL tears to those with complete ACL tears, providing clinical evidence to support the BEAR Implant's label expansion for partial tear treatment.

Study Overview

- Data was assessed from patients in the BEAR III trial, a prospective multicenter single-arm cohort study of the BEAR Implant that enrolled 151 subjects across 7 different locations.
- Primary outcomes were the IKDC Subjective Knee Evaluation score and IKDC Objective Physical Exam score at 2 years post-op.
- Secondary analyses included the rate of adverse events (AEs) and serious adverse events (SAEs) in both subgroups.

Key Results

- At all timepoints, subjects with a partial tear had similar IKDC Subjective scores to subjects with a complete tear, with IKDC scores in both age groups increasing at each visit from baseline to two years of follow-up.
  - This primary effectiveness endpoint was consistent with outcomes from the pivotal BEAR II study, a randomized trial comparing the BEAR Implant to ACLR.
- IKDC Physical Exam results were comparable between the partial and complete tear subgroups at both the 1-year and 2-year follow-ups.
  - This included a Lachman Test at 1-year post-op, which demonstrated similar knee laxity between both subgroups.
- The rate of any AE was similar between the partial and complete tear groups. SAEs and ACL revisions were numerically higher in the complete tear group.
  - Of note, none of the partial tear patients retore their ACL.

Conclusion

The BEAR Implant is as safe and effective in patients with partial ACL tears as those with complete ACL tears, supporting the BEAR Implant's expanded indication.

Miach Orthopaedics