



BEAR-MOON INTRA-OPERATIVE FINDINGS INCLUDING AN ANALYSIS OF REASONS FOR FAILED SCREENING FOR BEAR PROCEDURE

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Background



- Bridge-Enhanced ACL Repair (the BEAR procedure) has shown promising results
 - In preclinical testing with lower rates of osteoarthritis
 - In initial safety cohort and small clinical trials
- The BEAR-MOON multi-center randomized noninferiority clinical trial is being conducted to compare the BEAR technique against ACL reconstruction with patellar tendon autograft



Purpose



- To present the intra-operative findings from the BEAR-MOON trial cohort
- Report on the patients excluded from enrollment based on intra-operative findings



Methods



- All patients consented for the BEAR-MOON study were included
- Demographic data (age, sex, ethnicity, and time from injury to surgery)
- Baseline PROMs (IKDC, KOOS, AKPS, and Marx activity scale)
- Physical exam (range of motion, Lachman, and pivot shift)
- Intra-operative findings (length of tibial ACL stump and percent of tibial footprint attachment intact)
- The group of patients who were excluded from enrollment in the study based on intra-operative findings compared to the patients who were successfully enrolled at the time of surgery



Results



- Ninety-one patients evaluated for enrollment intra-operatively
- 84 successfully enrolled
- 7 failed intra-operative screening
- Of the 84 patients successfully enrolled:
- Mean ACL stump length was 17.3 ± 4.26
- 77 patients had 75-100% of the tibial footprint attachment intact
- 7 patients had 50-75% intact
- Of the 7 patients who failed intra-operative screening:
- Mean ACL stump length was 10.9 ± 4.56
- 4 patients had 75-100% of the tibial footprint attachment intact
- 1 patient had 50-75% intact
- The remaining two had less than 50% intact



Results



- The reasons for intra-operative screening failure were:
- ACL tibial stump less then 10mm (3 patients)
- Tibial footprint attachment less than 50% intact (2 patients)
- Concomitant bucket handle meniscus tear (1 patient)
- Tibial stump too frayed to repair (1 patient)
- No difference between groups of enrolled and failed enrollment patients in terms of demographics
- \blacksquare Age (32.9 ± 9.30 vs. 32.1 ± 12.47)
- Sex
- Time from injury to surgery $(40.4 \pm 7.83 \text{ vs. } 42.1 \pm 7.03 \text{ days})$
- No difference between groups in terms of physical exam findings and PROMs
- The only exception is a difference in Marx scores $(11.0 \pm 4.75 \text{enrolled vs. } 13.3 \pm 2.75 \text{failed (p-value=0.04)})$



Conclusions



- The majority of patients consented for the BEAR-MOON study are successfully enrolled in the study based on intra-operative findings
- Most common reason for failure because the tibial stump is too short or too much of it is not intact at the tibia
- Findings not affected by age, sex, or time from injury to surgery
- This is important information to share pre-operatively with patients considering undergoing the BEAR procedure
- Surgeons should be prepared with a back-up plan if the ACL does not appear acceptable for the BEAR procedure at the time of surgery