

2-year Outcomes of Bridge Enhanced ACL Restoration in the First 100 Bridge Registry Patients

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INTRODUCTION: The purpose of this study is to review recurrent injury and reoperation rates, physical examination findings, and patient reported outcomes in the first 100 Bridge registry subjects who are 2 years postop from the Bridge Enhanced ACL Restoration (BEAR) procedure.

METHODS:

Consecutive patients with ACL injuries indicated for BEAR at 6 institutions were invited to enroll in the Bridge registry either preoperatively or at the time of their first postoperative visit after study initiation. Subjects were prospectively followed at 1-2 weeks, 6 weeks, 3, 6, 9, 12, and 24 months after surgery with physical examinations and/or surveys. Adverse events including recurrent or ipsilateral ACL injury, subsequent meniscus tears, and reoperations were recorded. Adverse events were compared between subjects whose BEAR procedure was performed using the original surgical technique versus modified surgical techniques using Fisher's Exact test. Range of motion was compared between baseline and 12 months using a paired T test. Lachman grade, firmness of endpoint, and pivot shift examinations were reported at 12 months. Patient reported outcomes (IKDC, KOOS, Marx, RSI) were compared between subjects at baseline and 6, 9, and 12 months using ANOVA.

RESULTS:

Of the 100 subjects, 94 enrolled postoperatively and 6 enrolled preoperatively. Five exited the study, and 2 completed the 9 month, but not the 12 month follow up, providing 95% minimum 2 year follow-up (mean 19.4 ± 5.83 mo, range 3-31 mo). The mean age was 31.8 ± 14.3 years and 67% were female. 55 underwent a BEAR using the original technique, while 45 underwent a BEAR with a modified surgical technique. Modifications included use of an anchor on the femoral wall or tibia, use of luggage tag style suture rather than Bunnell suturing, or use of nonabsorbable instead of absorbable sutures in the ACL stump. The overall rates of adverse events with reoperations are as follows at 2 years: 16 reoperations including 3 ACL retears with meniscus injury, 1 contralateral tear, 5 meniscus injuries without ACL re-tear (1 medial meniscus, 3 lateral meniscus, 1 medial and lateral meniscus tear), 2 manipulations under anesthesia, 1 lysis of adhesions/cyclops removal, 4 removals of retained hardware and/or suture. Overall reoperation rate was 18.2% (16/88) at 2 years (26.5% with the original technique and 7.7% with the modified technique) with 3.4% (3/88) ipsilateral ACL re-tear rate in this cohort. There were no significant differences in adverse events or reoperation rates between the original technique and the modified technique groups. Mean IKDC, Marx and RSI scores at 2 years were (N=76) respectively 87.4 ± 13.9 , 7.3 ± 5.8 , 70.3 ± 26.9 . Mean KOOS (N=76) pain, function daily living, and function sports and recreational activities were as follows: 94.6 ± 8.3 , 97.6 ± 6.8 , and 88.0 ± 16.7 . From 1 to 2 years, there were statistically significant improvements in IKDC and 3 of the 5 KOOS scales. Mean knee ROM at 12 months (N=73) for flexion was 136 ± 18.5 and active hyperextension (N=71) was 1.2 ± 3.4 . There was no significant loss of extension as compared to baseline and there was significant improvement in flexion. Lachman's (N=75) was 0-2mm in 80.05% and grade 1 in 20.0% with 93.8% having a firm endpoint (N=65). Pivot shift (N=74) was negative in 90.5% and grade 1 in 8.1%, while 1.4% had a grade 2 pivot shift at 12 months.

DISCUSSION AND CONCLUSION: The rates of adverse events status BEAR with and without modification are low at 2 years, with 2 retears occurring with return to sport prior to 1 year and one re-tear after 1 year. Excellent stability and ROM are attained at 1 year, with good PROMs at 2 years. While 2-year results of post commercialization use of BEAR are promising, further research is warranted to better understand long term outcomes with and without technique modifications.