Early Clinical Outcomes of Bridge-Enhanced ACL Restoration (BEAR®) at a Single Institution

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INTRODUCTION: Traditional anterior cruciate ligament reconstruction (ACLR) utilizes an allograft or autograft depending on patient characteristics such as age, anatomy, and activity level. Both graft types have limitations due to their non-native biomechanical properties as well as donor site morbidity. The Bridge-Enhanced ACL Restoration (BEAR®) procedure was designed to repair and restore the native ACL. Derived from highly porous bovine-derived collagen, the BEAR implant is combined with autologous blood to promote a healing environment for the ACL to repair. The purpose of this study was to report early outcomes among the first cohort of patients undergoing BEAR at our institution.

METHODS: Our institution's IRB-approved ACL registry was used to identify the first 32 consecutive patients who underwent ACL restoration using the BEAR implant. All patients had a minimum follow-up of one year. Patient demographics and surgical details were captured. Patients returned for standard clinical evaluation postoperatively. Reoperations, ACL re-tears, and graft failures were assessed. Preoperative and postoperative patient reported outcomes (PRO) included the International Knee Documentation Committee (IKDC) score, Knee injury and Osteoarthritis Outcome Score (KOOS), Tegner activity scale, Lysholm score, and Procedure Satisfaction.

RESULTS: Mean patient age was 41.2 years (range, 15.4 to 62.2) and 56% were female. Mean time from injury to surgery is 51.0 days (±21.5) with a range of 19 to 126 days. Tear locations were classified as proximal (n=19), midsubstance (n=5), and mid to proximal (n=8). Three patients (9.4%) experienced ACL re-tears and graft failure, all of whom required revision procedures. The failures occurred at 436, 328, and 190 days postoperatively, with corresponding revision surgeries performed at 609, 431, and 309 days following the initial procedure. Mechanism of failure included a tear due to physical activity (n=2) and implant failure after the procedure (n=1). Additionally, two patients (6.3%) required secondary procedures for surgical site management unrelated to ACL failure. Among the 29 patients who did not require a revision ACL repair, statistically significant improvements in PROs were observed from preoperative to 1 year, which exceeded the minimal clinically important difference (MCID) except for KOOS symptoms (Table 1). 30.8% of patients reported that they had returned to pre-injury level of play (based on pre-injury Tegner and 1 year postoperative). At 6 months postoperatively, 88.9% of patients reported being satisfied with the results of the procedure.

DISCUSSION AND CONCLUSION: Among the first cohort of 32 patients undergoing the BEAR procedure at our institution, we observed a 9.4% failure rate at 1 year. Patients reported significant improvement in pain and function. These findings align with previously published studies on BEAR outcomes, which reported a 14% retear rate, and are comparable to retear rates observed with traditional ACLR. While ALCR utilizing an allograft or autograft remains the gold standard procedure, this study presents promising results for the ACL restoration procedure using this novel implant. Further studies should be conducted to evaluate the implant's long-term effectiveness.

Table 1. Patient Reported Outcome Measures

	Preoperative	Postoperative (1 year)	Change	p-value
IKDC total score	48.85 ± 13.52	71.11 ± 12.78	20.77 ± 14.39	<0.001
Lysholm total score	59.52 ± 20.69	82.50 ± 13.64	25.57 ± 15.74	<0.001
Tegner	2.57 ± 2.03	4.5 ± 1.74	1.93 ± 1.44	<0.001
KOOS				
Symptoms	60.74 ± 8.17	67.25 ± 13.01	2.14 ± 10.68	0.466
Pain	69.88 ± 15.31	88.62 ± 8.12	15.87 ± 12.01	<0.001
Activities of daily living	77.26 ± 16.33	95.95 ± 5.97	18.79 ± 16.64	<0.001
Sport/recreation	45.22 ± 26.48	69.50 ± 27.14	21.79 ± 21.27	<0.01
Quality of life	24.44 ± 14.67	62.35 ± 20.26	37.57 ± 16.66	<0.001

P-value comparing change from preoperative to 1 year postoperative using paired samples t-tests
Data presented as means ± standard deviations