Earlier Resolution of Symptoms and Return of Function After Bridge-Enhanced Anterior Cruciate Ligament Repair As Compared With Anterior Cruciate Ligament Reconstruction

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Background: Bridge-enhanced anterior cruciate ligament repair (BEAR) has noninferior patient-reported outcomes when compared with autograft anterior cruciate ligament reconstruction (ACLR) at 2 years. However, the comparison of BEAR and autograft ACLR at earlier time points—including important outcomes such as resolution of knee pain and symptoms, recovery of strength, and return to sport—has not yet been reported.

Hypothesis: It was hypothesized that the BEAR group would have higher outcomes on the International Knee Documentation Committee and Knee injury and Osteoarthritis Outcome Score, as well as improved muscle strength, in the early postoperative period.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: A total of 100 patients aged 13 to 35 years with complete midsubstance anterior cruciate ligament injuries were randomized to receive a suture repair augmented with an extracellular matrix implant (n = 65) or an autograft ACLR (n = 35). Outcomes were assessed at time points up to 2 years postoperatively. Mixed-model repeated-measures analyses were used to compare BEAR and ACLR outcomes. Patients were unblinded after their 2-year visit.

Results: Repeated-measures testing revealed a significant effect of group on the International Knee Documentation Committee Subjective Score ($P = .015$), most pronounced at 6 months after surgery (BEAR = 86 points vs ACLR = 78 points; $P = .001$). There was a significant effect of group on the Knee injury and Osteoarthritis Outcome Score-Symptoms subscale scores ($P = .010$), largely attributed to the higher BEAR scores at the 1-year postoperative time point (88 vs 82; $P = .009$). The effect of group on hamstring strength was significant in the repeated-measures analysis ($P < .001$), as well as at all postoperative time points ($P < .001$ for all comparisons). At 1 year after surgery, approximately 88% of the patients in the BEAR group and 76% of the ACLR group had been cleared for return to sport ($P = .261$).

Conclusion: Patients undergoing the BEAR procedure had earlier resolution of symptoms and increased satisfaction about their knee function, as well as improved resolution of hamstring muscle strength throughout the 2-year follow-up period.

Registration: NCT02664545 (ClinicalTrials.gov identifier)

Keywords: anterior cruciate ligament; human; ACL reconstruction; ACL repair; bridge-enhanced ACL repair; implant-enhanced ACL repair; BEAR

Primary repair of the anterior cruciate ligament (ACL) has been used to treat small numbers of patients with ACL injuries, with some studies demonstrating limited success in selected populations, particularly older patients with proximal tears.[29,49] However, the high failure rate of this technique in younger patients with midsubstance injuries,[13] combined with 2 randomized controlled trials reporting no benefit of primary repair over nonoperative treatment,[39,47] led to the broad abandonment of this technique in favor of repair combined with ACL reconstruction (ACLR)[9] and eventually to reconstruction alone.[27,51]

ACLR has been shown to achieve significant improvement in patient-reported outcomes and physical examination findings after surgery, yet >30% of patients continue to have an abnormal knee examination outcome as measured using the International Knee Documentation Committee (IKDC) objective score at 1 year postoperatively.[2,11,16]

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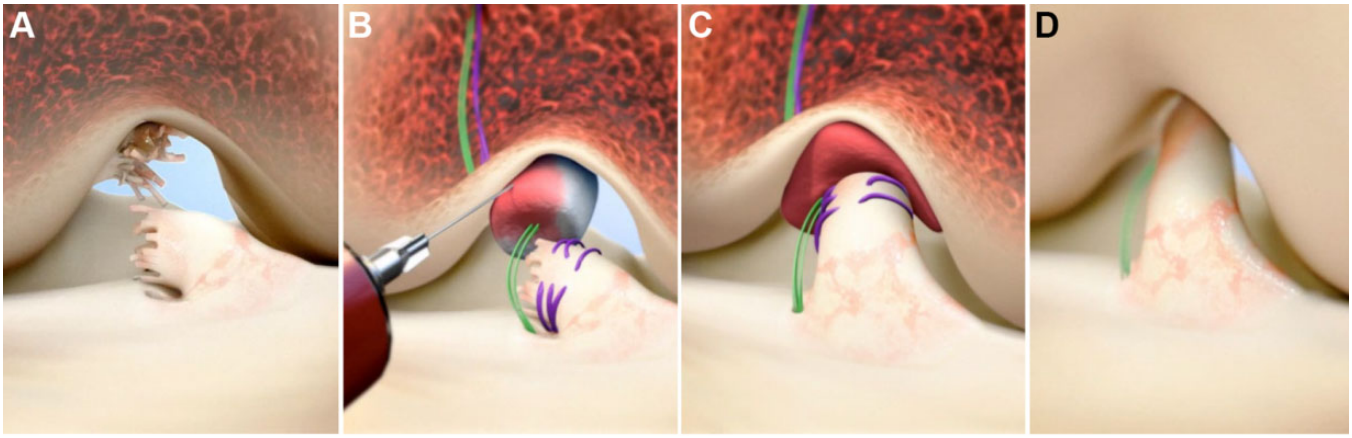

Figure 1. Stepwise demonstration of the BEAR technique using the extracellular matrix scaffold. (A) In this technique, the torn ACL tissue is preserved. (B) A whipstitch of No. 2 Vicryl (Ethicon) (purple suture) is placed into the tibial stump of the ACL. Small tunnels (4 mm) are drilled in the femur and tibia, and an EndoButton (Smith & Nephew) with 2 No. 2 Ethibond (Ethicon) sutures (green sutures) and the No. 2 Vicryl ACL sutures attached to it is passed through the femoral tunnel and engaged on the proximal femoral cortex. The Ethibond sutures are threaded through the scaffold and tibial tunnel and secured in place using an extracortical button. The scaffold is then saturated with 5-10 mL of the patient's blood, and (C) the tibial stump is pulled into the saturated scaffold. (D) The ends of the torn ACL then grow into the scaffold, and the ligament reunites. Image used with permission from Murray et al.[34] ACL, anterior cruciate ligament; BEAR, bridge-enhanced ACL repair.

These factors may be part of the reason that 35% of the patients undergoing ACLR will not return to their prior levels of sports.[4-6,45] While a great deal of research has been conducted in an attempt to improve these outcomes, the majority of these changes have not led to meaningful improvements in patient-reported outcomes[8,24,26,28,48,53]; in fact, some have led to worse outcomes.[20]

The bridge-enhanced ACL repair (BEAR) technique was developed to augment the natural biological healing of midsubstance ACL tears. The BEAR technique utilizes an implant saturated with autologous blood (BEAR Implant; Boston Children's Hospital), which is placed between the torn ligament ends during suture repair (Figure 1). In preclinical animal models, the BEAR technique has shown comparable mechanical properties to and a lower incidence of posttraumatic osteoarthritis than ACLR.[32,52] In addition, the BEAR technique avoids donor site morbidity associated with autograft reconstruction.[29,49] The 2-year postoperative results of the BEAR technique as compared with ACLR in a prospective randomized clinical trial have been recently reported,[33] and findings included noninferior patient-reported outcomes and instrumented laxity of the knee as well as improved hamstring strength. There was no significant difference in revision ACL surgery rates (14% for BEAR vs 6% for ACLR; $P = .32$), and patients who had a conversion from BEAR to ACLR had similar outcomes at 2 years to those who had a primary reconstruction.[33]

The objective of the current investigation was to compare patient-reported and functional outcomes of the BEAR and ACLR procedures at specified time points during the first 2 years after surgery and to compare the timing of medical clearance for return to sports after each procedure.[33] We hypothesized that at 6 months after surgery, the BEAR

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group would have higher IKDC and Knee injury and Osteoarthritis Outcome Score (KOOS) values, as well as improved muscle strength and hop testing, when compared with the ACLR group and that these differences would lessen over time.

METHODS

This randomized controlled trial (BEAR II trial) consisted of 100 patients undergoing surgery for an acute ACL injury.[33] Patients were blinded to which treatment they received and were unblinded after the 2-year follow-up visit was completed. An independent examiner was blinded to the surgical side and study group assignment when performing the arthrometer testing and physical examination until the end of each visit when effusion was assessed after removal of the sleeves. Institutional review board approval was obtained before the start of the BEAR II trial, and all patients granted their informed consent.

Methods Used to Minimize Potential, Actual, or Perceived Bias

This study underwent a comprehensive review by a panel of medical device experts at the US Food and Drug Administration before receiving investigational device exemption status (G150268). These experts were appointed by the administration without input from the investigative team, and the outcome measures for the study were approved by that panel before the start of the study. The defined outcome measures and study design were also registered on ClinicalTrials.gov (NCT02664545) before the start of the study. Patient recruiting and consent, as well as data collection and entry into the database and statistical analysis, were performed by investigators with no financial stake in any commercial interest that stood to gain from the results of this study. All physical examination and functional measurements were taken by licensed examiners independent of the surgical team, who were blinded to the procedure and surgical limb. Bilateral knee sleeves were placed by the research coordinators before the examiner met with the patient to perform the tests. This study was overseen by a data safety monitoring board, with the members approved by the institutional review board and the Boston Children's Hospital Conflict of Interest Committee. A clinical research manager and a study monitor, who were independent of the orthopaedic surgery department, were appointed by the Clinical Research Center at Boston Children's Hospital to oversee and monitor the study.

Study Patients

All study patients presented with a complete ACL tear, were aged 13 to 35 years, were <45 days from injury, had closed physes, and had at least 50% of the length of the ACL attached to the tibia (as determined from a preoperative magnetic resonance imaging scan). A total of 100 patients were randomized in an approximate 2:1 ratio to undergo either the BEAR procedure (n = 65) or autograft ACLR (n = 35). The tibial stump length was measured as the linear distance from the center of the tibial attachment site to the most superior fibers of the tibial remnant.[36] A permuted block randomization scheme was used with sequentially numbered sealed envelopes and block sizes of 3 and 6. Three experienced fellowship-trained sports medicine surgeons were involved in the study (L.J.M., Y.Y., D.K.). The choice of autograft was limited to bone–patellar tendon–bone (BPTB) or hamstring by study design, as those were the 2 autografts commonly employed by the participating surgeons. The choice of autograft was left to the discretion of the surgeon and patient, and given the randomized format of the study, it was established through preoperative clinic discussion in all cases. Randomization was then stratified by the intended source of graft (hamstring or BPTB) should the patient be randomized to undergo ACLR.

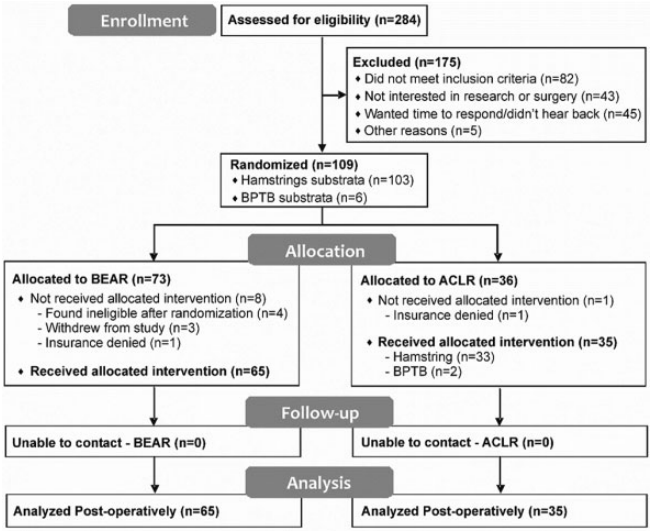

Figure 2. CONSORT diagram detailing patient flow through the study, which resulted in 65 patients receiving the BEAR and 35 receiving ACLR. Patients were evaluated at time points up to 2 years after surgery.[33] ACLR, anterior cruciate ligament reconstruction; BEAR, bridge-enhanced anterior cruciate ligament repair; BPTB, bone–patellar tendon–bone (autograft).

Patients were excluded from enrollment if they did not meet all of the inclusion criteria, they had a history of ipsilateral knee surgery or prior infection in the knee, or they had risk factors that might adversely affect ligament healing (nicotine/tobacco use, corticosteroids in the past 6 months, chemotherapy, diabetes, inflammatory arthritis). Patients were excluded if they had a displaced bucket-handle tear of the medial meniscus requiring repair; however, patients with all other meniscal injuries were included. In addition, patients were excluded if they had a full-thickness chondral injury, a grade 3 medial collateral ligament or posterior cruciate ligament injury, a concurrent complete patellar dislocation, or a posterolateral corner injury requiring operative treatment. A CONSORT (Consolidated Standards of Reporting Trials) diagram of patient flow through the study is provided in Figure 2.

Implant

The BEAR implant passed all biocompatibility and sterility testing.[41] The implant was composed of extracellular matrix proteins, including collagen, that were obtained from bovine tissue. The efficacy of the implant for stimulating ACL healing was demonstrated in preclinical studies,[19,25,32,37,52] and the patients who had the BEAR procedure in this trial had noninferior outcomes to those in the ACLR group at 2 years after surgery.[33]

Implant-Enhanced ACL Repair Surgical Procedure

After the induction of general anesthesia, an examination was performed to verify the positive pivot shift on the injured side and to record the Lachman test, range of motion, and pivot-shift examination results on both knees. A knee arthroscopy was performed, and any meniscal injuries were treated. The procedure has been described in detail.[33] In brief, a suture cinch was anchored to the femur and tibia and used to reduce excess anteroposterior (AP) laxity. The BEAR implant had 5-10 mL of autologous blood added to it and was placed in the intercondylar notch through a medial mini-arthrotomy. The tibial stump was pulled into the implant using a previously placed whipstitch. The knee was brought into extension and closed in layers.

ACLR With Autologous Hamstring Tendon or BPTB Graft

A standard hamstring autograft procedure was performed using a quadruple-bundle semitendinosus-gracilis graft (n = 33) or central-third BPTB autograft (n = 2) using suspensory fixation proximally (EndoButton; Smith & Nephew) and an interference screw (BioRCI HA; Smith & Nephew) for tibial fixation.

Postoperative Rehabilitation

All patients and physical therapists were blinded to the surgical procedure group of the patient, and all patients underwent a standardized rehabilitation protocol based on the MOON group guidelines,[54] as previously described.[33] In brief, all patients used a locking hinged brace (TScope; Breg) to limit joint range of motion from 0° to 50° of knee flexion for 2 weeks and from 0° to 90° for the next 4 weeks, unless they had a concomitant meniscal repair, in which case the brace range was restricted to 0° to 40° for the first 4 weeks before increasing to 0° to 90° of flexion. All patients were partial weightbearing for 2 weeks and then weightbearing as tolerated with crutches until 4 weeks. Both groups were recommended to use a functional ACL brace (CTi; Ossur) for 6 to 12 weeks and then for cutting and pivoting sport activities for 2 years.

Outcome Measures

Patient-Reported Outcomes. The IKDC subjective score and KOOS instrument have been used to assess patient-reported outcomes after ACL surgery.[17,18,23,40,44,46] The IKDC subjective score is a 10-item questionnaire regarding knee symptoms, sports activities, and function. The KOOS consists of 5 subscales—Pain, Symptoms, Activities of Daily Living, Sports, and Knee-Related Quality of Life—and has been validated for patients undergoing ACL surgery.[40,44] Both questionnaires were administered preoperatively, as well as 1 and 2 years postoperatively; the IKDC was also administered at 3 and 6 months postoperatively.

Strength Testing. Lower extremity strength measures were performed at 6 months, 1 year, and 2 years after surgery, with hamstring and quadriceps strength measured at 3 months. All measures were performed in duplicate on each side, and the duplicate measurements were averaged for further analysis. Results were normalized by expressing the surgical knee result as a percentage of the contralateral knee result for strength testing. Hamstring, quadriceps, hip abductor, hip adductor, and hip extensor isometric muscle strength was measured using a handheld dynamometer (Microfet 2; Hoggan Scientific, LLC).

Hop Testing. The single hop, triple hop, 6-m timed hop, and crossover hop were performed at 6 months, 1 year, and 2 years after surgery as previously described.[38] All measures were performed in duplicate on each side, and the duplicate measurements were averaged for further analysis. Results were normalized by expressing the surgical knee as a percentage of the contralateral knee.

Time to Clearance for Return to Sports. Patients were cleared for return to sports at the operating surgeon's discretion based on subjective symptoms including no concerns of knee instability, physical examination findings, and return of near-full muscle strength. Time to clearance was recorded as the number of days between surgery and the visit with the surgeon where the patient was cleared to return to cutting and pivoting sports.

Marx Activity Score. The sport played by the participant and its associated degree of cutting and pivoting were recorded at baseline and postoperative 1 and 2 years. The Marx score was also recorded at those time points, as a frequency measure of cut and pivot activities (0, lowest level of activity; 16, highest).[30] Level 1 sports involved regular cutting and pivoting motions and included soccer, lacrosse, basketball, football, field hockey, and rugby. Level 2 sports included lower levels of cutting and pivoting, such as ice hockey, volleyball, tennis, skiing, and softball. Level 3 sports had no cutting and pivoting (eg, running, biking, and swimming).

Instrumented AP Knee Laxity. Arthrometer testing (KT-1000; MEDMetric) was used to measure the anterior displacement of the tibia with respect to the femur under 130 N of applied anterior force and performed at 6 months, 1 year and 2 years after surgery. Arthrometer testing was performed in duplicate on each leg, and both values were recorded. The results were reported as a side-to-side difference (mean for the operated knee minus mean for the contralateral knee).

Range of Motion. Passive flexion and extension of the knee were measured at 2 and 6 weeks, 3 and 6 months, and 1 and 2 years after surgery. Range of motion was measured with the patient lying supine, with the use of a goniometer and the examiner blinded to the operative side via knee

sleeves. Measurements were made on both legs, and the difference between the surgical and contralateral sides was recorded.

Statistical Analysis

For baseline comparison of continuous variables between the BEAR and ACLR treatment groups, *t* tests and Wilcoxon Rank Sum tests were used. Cochran-Armitage test and Fisher exact test were used for group comparisons on ordinal and categorical outcomes, respectively. Mixed-model repeated-measures analyses (SAS, PROC MIXED) were used to compare the BEAR and ACLR groups on each outcome measure across postoperative time points. The model included fixed factors representing treatment group, assessment time, and group × time interaction. The number of assessment time points varied across outcome measures. *F* tests for simple effects were used for preplanned comparisons of treatment groups at each assessment time. All means presented represent least square means, which adjust for missing data attributed to missing patient visits. Survival distributions associated with time to clearance for return to sports were compared between the BEAR and ACLR groups per a log-rank test. Patients who were lost to follow-up or reinjured before clearance were censored at the time of last follow-up or reinjury. One additional patient with ACLR was censored at the time that a decision was made to have additional surgery. All analyses were performed using SAS Statistical Software Version 9.4 (SAS Institute). Statistical significance was determined based on $P < .05$, with no adjustment for multiple testing.

RESULTS

Baseline Characteristics and Intraoperative Findings

The baseline characteristics and intraoperative findings of both groups have been reported.[33] In brief, the BEAR and ACLR groups were similar in age, sex, race, and body mass index ($P \geq .11$ for all comparisons). The median times from injury to surgery were similar in the 2 groups: 36 days (interquartile range, 29-42 days) for BEAR and 39 days (interquartile range, 33-43 days) for ACLR ($P = .15$). The majority of initial injuries in both groups were noncontact and occurred during level 1 sports participation ($P = .94$) (Table 1). The rates of associated injuries have been reported, and there were no significant differences between the groups for ipsilateral revision ACL surgery, contralateral ACL surgery, or additional surgical procedures on the surgical knee.[33]

TABLE 1
Baseline Activity Characteristics of the Study Groups[a]

	BEAR (n = 65)	ACLR (n = 35)	*P*
Noncontact injury	48 (74)	29 (83)	.46
Playing a sport at injury	64 (98)	35 (100)	≥.99
Sports level at injury[b]			.94
Level 1	49 (77)	26 (74)	
Level 2	14 (22)	9 (26)	
Level 3	1 (2)	0 (0)	

[a]Data are presented as n (%). ACLR, anterior cruciate ligament reconstruction; BEAR, bridge-enhanced anterior cruciate ligament repair.
[b]BEAR group, n = 64.

Outcomes

IKDC Subjective Score (Patient-Reported Outcome). For both groups, mean IKDC scores improved significantly from 3 months to 2 years postoperatively ($P < .001$) (Table 2). The BEAR group had significantly higher IKDC scores than the ACLR group across postoperative assessments ($P = .015$). Mean IKDC scores were not significantly different between groups at 3 months postoperatively, but at 6 months, the BEAR group had significantly higher scores ($P = .001$). The BEAR group continued to have higher mean IKDC scores at 1 and 2 years; however, these differences were not statistically significant.

KOOS (Patient-Reported Outcome). Across the postoperative assessments, significant group differences were observed for the KOOS-Symptoms subscale, with higher means scores associated with the BEAR group ($P = .010$) (Table 2). The BEAR group had significantly better KOOS-Symptoms scores than the ACLR group at 1 year ($P = .009$), while at 2 years the BEAR scores remained higher, although these results were not significant ($P = .111$). There were no significant differences between groups in KOOS subscales of Pain, Activities of Daily Living, Sports, or Quality of Life. Mean KOOS–Quality of Life scores improved significantly between 1 and 2 years in both groups ($P = .002$).

Muscle Strength. The BEAR group had superior hamstring strength across postsurgical assessments ($P < .001$). This difference was present at all periods studied ($P < .001$) (Table 3). At 6 months, the BEAR group's hamstring strength was a mean 93% of the contralateral knee as compared with 59% in the ACLR group. Quadriceps strength was not significantly different between the groups ($P > .20$ for all) but improved over time in both groups ($P < .001$). The ACLR group had greater hip adductor strength overall ($P = .027$), with this effect most notable at 6 months and 1 year ($P = .067$ and .075, respectively). There was some evidence that differences in hip extensor strength were time dependent (group × time interaction, $P = .06$): the BEAR group had superior hip extensor strength at 6 months as compared with the ACLR group ($P = .017$) but not at 1 or 2 years ($P > .40$).

Hop Testing. Across the postoperative time points, analyses revealed that all hop testing outcomes were similar between the groups. On testing of individual time points, the only significant difference was in the 6-m timed hop at 2 years, in which the BEAR group was significantly slower than the ACLR group ($P = .017$), as previously reported.[33] Single hop, triple hop, and 6-m timed

TABLE 2
IKDC Subjective and KOOS Subscale Scores Between Groups[a]

	ACLR		BEAR					
Parameter	No.	Mean ± SD	No.	Mean ± SD	*P*	P_{Group}	P_{Time}	$P_{Group \times Time}$
IKDC						**.015**	**<.001**	.203
3 mo	32	65.3 ± 11.6	63	67.9 ± 10.3	.293			
6 mo	34	77.7 ± 11.6	64	85.8 ± 11.4	**.001**			
1 y	33	83.9 ± 12.2	64	87.1 ± 11.0	.195			
2 y	34	84.6 ± 13.2	62	88.8 ± 13.2	.094			
KOOS subscale								
Symptoms						**.010**	.166	.405
1 y	33	82.0 ± 12.2	64	88.3 ± 9.3	**.009**			
2 y	33	85.2 ± 11.9	61	89.1 ± 12.0	.111			
Pain						.163	.973	.314
1 y	33	91.3 ± 7.1	64	94.4 ± 6.6	.084			
2 y	33	92.4 ± 9.1	61	93.3 ± 10.1	.633			
ADL						.228	.934	.912
1 y	33	97.9 ± 4.2	64	98.7 ± 2.3	.395			
2 y	33	97.8 ± 5.5	61	98.7 ± 4.5	.324			
Sports						.330	.205	.925
1 y	33	82.9 ± 19.0	64	85.8 ± 15.6	.439			
2 y	33	85.3 ± 18.2	61	88.6 ± 18.4	.385			
Quality of Life						.167	**.002**	.980
1 y	33	64.4 ± 17.5	64	69.4 ± 19.7	.231			
2 y	33	71.0 ± 20.1	61	76.1 ± 19.8	.224			

[a]Bold *P* values indicate statistically significant differences ($P < .05$). ACLR, anterior cruciate ligament reconstruction; ADL, Activities of Daily Living; BEAR, bridge-enhanced anterior cruciate ligament repair; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score.

hop all improved significantly over time for both groups ($P < .002$ for all).

Clearance for Return to Sports. The Kaplan-Meier survival estimates of time to clearance for return to sports are shown in Figure 3. The earliest clearance date was 171 days (5.7 months) after surgery. By 1 year, an estimated 88% of the BEAR group and 76% of the ACLR group had been cleared to return to sports. Overall, there was no significant difference in the time-to-clearance distribution between the groups ($P = .261$, log-rank test).

Marx Activity Score. Across postoperative time points, there were no significant group differences on the Marx activity scores ($P < .755$) (Table 4). At 2 years, 46% of the BEAR group and 41% of the ACLR group reported a return to an equivalent or better Marx activity score relative to baseline, with no significant difference noted between groups ($P = .665$).

Instrumented AP Knee Laxity. Across all the postoperative time points, there was no significant differences between groups on AP laxity of the knee ($P = .913$). There was also no significant difference between the groups at 6 months, 1 year, or 2 years after surgery when measured using the KT-1000 arthrometer ($P > .36$ for all) (Table 5).

Range of Motion. Across the postoperative time points, there were no significant differences between groups on either flexion or extension deficits during the 2-year follow-up period. The BEAR group had superior range of motion in passive flexion at 3 months postoperatively ($P = .049$) (Table 6), and there was some evidence of slightly less passive extension loss in the BEAR group at 3 months ($P = .056$) and 6 months ($P = .077$). However, loss of flexion or extension was not significantly different at postoperative 1 or 2 years ($P > .34$ for all comparisons). Both groups had improved flexion and extension over the postoperative period ($P < .001$).

DISCUSSION

The results of this randomized controlled trial confirmed our hypothesis that patients undergoing the BEAR procedure had higher IKDC and KOOS outcomes as well as improved hamstring muscle strength at early time points postoperatively as compared with patients undergoing ACLR. The differences in IKDC and KOOS findings diminished over time; however, significant differences in hamstring strength persisted until the 2-year time point. These results indicated that patients undergoing the BEAR procedure had earlier resolution of symptoms and return of function than the ACLR group. However, no significant differences between the groups were noted for time to medical clearance for return to sports or for Marx activity level at 1 or 2 years. While these results may be predictable given the known donor site morbidity of autograft ACLR, it is important to note that these differences persisted into the 2-year time point. Comparison between BEAR and other techniques with less-known donor site morbidity, such as allograft ACLR or artificial ACL repair, may be warranted

TABLE 3
Muscle Strength and Hop Test Outcomes[a]

	ACLR		BEAR					
Parameter	No.	Mean ± SD	No.	Mean ± SD	*P*	P_{Group}	P_{Time}	$P_{Group \times Time}$
Hamstring						**<.001**	.112	.653
3 mo	32	62.7 ± 21.2	64	91.5 ± 15.6	**<.001**			
6 mo	34	59.0 ± 21.2	64	93.1 ± 23.6	**<.001**			
1 y	32	65.4 ± 18.1	62	96.4 ± 16.7	**<.001**			
2 y	31	63.6 ± 15.5	59	97.5 ± 26.5	**<.001**			
Quadriceps						.815	**<.001**	.340
3 mo	32	95.1 ± 19.3	64	91.7 ± 13.3	.236			
6 mo	34	90.6 ± 13.8	64	94.1 ± 15.9	.230			
1 y	32	97.0 ± 12.7	64	96.4 ± 8.7	.840			
2 y	31	101.2 ± 12.4	59	100.2 ± 12.2	.740			
Hip abductor						.332	.583	.871
6 mo	34	106.0 ± 16.8	63	102.5 ± 15.8	.339			
1 y	32	104.6 ± 18.9	61	103.8 ± 16.4	.825			
2 y	31	107.7 ± 22.5	56	105.4 ± 12.3	.544			
Hip adductor						**.027**	.271	.801
6 mo	33	100.4 ± 14.7	63	95.2 ± 12.4	.067			
1 y	32	103.1 ± 15.7	59	98.0 ± 13.3	.075			
2 y	31	99.8 ± 13.6	56	96.8 ± 10.7	.297			
Hip extensor						.217	.583	.060
6 mo	33	101.5 ± 18.1	63	109.7 ± 19.5	**.017**			
1 y	32	102.2 ± 10.9	61	105.1 ± 15.2	.407			
2 y	31	104.8 ± 17.6	57	102.8 ± 12.1	.572			
Single hop						.688	**<.001**	.170
6 mo	25	81.8 ± 19.9	52	85.7 ± 17.1	.294			
1 y	25	89.4 ± 15.5	52	92.5 ± 14.2	.398			
2 y	23	97.3 ± 13.4	42	93.8 ± 13.0	.365			
Triple hop						.420	**<.001**	.124
6 mo	23	88.7 ± 12.8	47	90.5 ± 7.7	.469			
1 y	25	94.1 ± 7.7	52	92.4 ± 10.9	.443			
2 y	22	98.7 ± 6.9	41	94.5 ± 9.7	.089			
6-m timed hop						.126	**.001**	.123
6 mo	22	107.3 ± 12.5	50	107.9 ± 17.0	.868			
1 y	23	101.8 ± 8.0	52	105.2 ± 16.6	.323			
2 y	22	95.9 ± 6.7	40	104.4 ± 10.6	**.017**			
Crossover hop						.715	.252	.775
6 mo	19	94.1 ± 11.4	44	91.9 ± 7.8	.441			
1 y	21	94.4 ± 10.1	51	94.4 ± 13.8	.982			
2 y	22	96.1 ± 7.3	39	96.3 ± 9.8	.947			

[a]Mean ± SD values represent percentage of the contralateral (injured) leg. Bold *P* values indicate statistically significant differences ($P < .05$). ACLR, anterior cruciate ligament reconstruction; BEAR, bridge-enhanced anterior cruciate ligament repair.

in the future. These studies would need to evaluate not only the short-term findings of return of strength and function but also the medium- to long-term results of both techniques so that functional and patient-reported outcomes, such as retear rates and osteoarthritis, may be accurately determined.

Patient-reported outcome data from the IKDC and KOOS subscale scores confirmed earlier return of patient satisfaction in the BEAR group. At 6 months postoperatively, the BEAR group had a mean IKDC score of 86 (women and men aged 18-35 years have mean IKDC scores of 86-89 points[1]), while the ACLR group's score was 78. The mean clinically important difference in knee function after surgery on the IKDC subjective score has been reported to range from 3 points[10] to 11.5 points[18]; thus, a difference of 8 points may be clinically significant. For the KOOS-Symptoms scores at 1 year, the difference between the means of the 2 groups was 6.3 points, which is slightly below the suggested minimal perceptible clinical improvement for the KOOS (8 points[44]). For both patient-reported outcomes, the differences between the groups were no longer significant at the later time points. It is possible that the lack of donor site morbidity from graft harvest in the BEAR group may lead to a quicker resolution of knee symptoms, improved patient satisfaction, and fewer postoperative symptoms, primarily in the early months after surgery.

The BEAR group had a more complete return of hamstring muscle strength after surgery. In the BEAR group,

hamstring strength returned to 93% of the contralateral knee at the 6-month postoperative mark and remained superior to the hamstring strength symmetry in the ACLR group at all time points. When measured at 90° of knee flexion (which isolates the gracilis and semitendinosus muscles), the BEAR group had a <10% deficit at the 3-month testing point, while the ACLR group had approximately 65% of the contralateral hamstring strength at 2 years postoperatively. There was no difference between the groups for quadriceps strength. Interestingly, despite the improved muscle strength, the BEAR group had a slower timed hop test at 2 years from injury, although there was no significant difference in the other hop test results at that time point. The reasons for this are not clear, and recent studies have suggested that the timed test is neither a valid tool for clinical decision making after ACLR[42] nor a predictor of patient-reported outcomes at 2 years after ACLR.[43] The hamstrings are noted to dynamically augment the function of the ACL, and persistently weak hamstrings have been correlated with future injury.[7,12] The observed differences in hamstring strength may lead to increased risk of reinjury in the ACLR group. In addition, persistent loss of hamstring strength after hamstring autograft reconstruction has been reported,[3,14,21] as has complete hamstring strength recovery.[22] These differences may be due to differences in the patient population (the current study was performed in young athletes, while the mean age in the prior study reporting full recovery was 30 years), measuring technique (handheld static dynamometer vs isokinetic testing), and whether the examiners were blinded to operative side. Future studies focused on this phenomenon will be useful

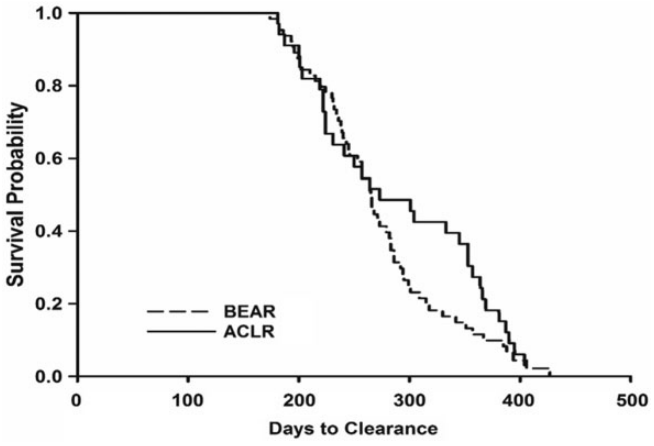

Figure 3. Survival plot for time to clearance to return to sports for participants undergoing BEAR and ACLR. ACLR, anterior cruciate ligament reconstruction; BEAR, bridge-enhanced anterior cruciate ligament repair.

TABLE 4
Marx Activity Scores[a]

Parameter	ACLR No.	ACLR Mean ± SD	BEAR No.	BEAR Mean ± SD	*P*	P_{Group}	P_{Time}	$P_{Group \times Time}$
Marx score						.755	**<.001**	.341
Baseline	34	14.7 ± 2.3	64	14.2 ± 3.2	.526			
1 y	33	10.6 ± 5.4	64	11.4 ± 4.3	.359			
2 y	33	11.0 ± 4.8	60	11.4 ± 4.7	.662			
Change from baseline to						.139	.777	.706
1 y	32	–4.3 ± 5.3	63	–2.8 ± 3.7	.145			
2 y	32	–3.7 ± 4.1	59	–2.7 ± 4.5	.301			
Return to baseline, %						—	—	—
1 y	32	43.80	63	38.10	.660			
2 y	32	40.60	59	45.80	.665			

[a]Bold *P* value indicates statistically significant difference ($P < .05$). Dashes indicate not applicable. ACLR, anterior cruciate ligament reconstruction; BEAR, bridge-enhanced anterior cruciate ligament repair.

TABLE 5
Anteroposterior Knee Laxity as Measured Using KT-1000 Arthrometer[a]

Parameter	ACLR No.	ACLR Mean ± SD	BEAR No.	BEAR Mean ± SD	*P*	P_{Group}	P_{Time}	$P_{Group \times Time}$
Knee laxity						.913	**.024**	.437
6 mo	33	2.2 ± 2.7	64	2.7 ± 2.9	.368			
1 y	32	2.7 ± 2.4	59	2.5 ± 2.7	.748			
2 y	32	1.8 ± 2.8	58	1.6 ± 3.2	.758			

[a]Mean ± SD values represent side-to-side difference in millimeters. Bold *P* value indicates statistically significant difference ($P < .05$). ACLR, anterior cruciate ligament reconstruction; BEAR, bridge-enhanced anterior cruciate ligament repair.

TABLE 6
Range of Motion Scores[a]

	ACLR		BEAR					
Parameter	No.	Mean ± SD	No.	Mean ± SD	*P*	P_{Group}	P_{Time}	$P_{Group \times Time}$
Passive flexion ROM						.314	**<.001**	.207
2 wk	35	69.1 ± 20.5	65	71.0 ± 18.5	.514			
6 wk	35	30.3 ± 20.5	64	29.4 ± 18.8	.747			
3 mo	32	11.1 ± 16.1	64	5.2 ± 12.1	**.049**			
6 mo	34	5.9 ± 10.4	64	1.6 ± 7.6	.137			
1 y	33	4.0 ± 7.6	64	1.2 ± 5.8	.349			
2 y	33	3.2 ± 5.4	60	3.7 ± 0.9	.857			
Passive extension ROM						.228	**<.001**	.243
2 wk	35	5.5 ± 5.3	65	6.2 ± 5.0	.410			
6 wk	35	5.0 ± 4.6	64	4.3 ± 3.8	.392			
3 mo	32	3.2 ± 4.1	64	1.6 ± 2.5	.056			
6 mo	34	2.9 ± 3.4	64	1.4 ± 3.1	.077			
1 y	33	1.5 ± 2.8	64	1.4 ± 4.1	.921			
2 y	33	1.3 ± 2.4	60	1.2 ± 5.1	.975			

[a]Positive mean ± SD values in flexion and extension represent loss of motion (in degrees) as compared with the contralateral leg. Bold *P* values indicate statistically significant differences ($P < .05$). ACLR, anterior cruciate ligament reconstruction; BEAR, bridge-enhanced anterior cruciate ligament repair; ROM, range of motion.

in resolving this controversy. It is important to note that in this study, autograft hamstring tendons were used in 33 of 35 patients in the ACLR group; as such, it is likely that if a greater percentage of grafts had been taken from the extensor mechanism (quadriceps or BPTB), there may not have been as much weakness in the hamstring musculature (though other muscular deficits may have been identified). Future studies comparing BEAR and BPTB autograft have been planned to explore this possibility.

Interestingly, the differences seen between early resolution of symptoms and functional recovery within the BEAR cohort did not significantly affect the time to medical clearance for return to sports or the level of postoperative activity, as measured using the Marx activity score. This is consistent with a prior study in which patient-reported outcomes, including the IKDC subjective score, and knee laxity were not predictive of return-to-sports rates after ACLR using hamstring autograft.[31] In this study, patients in both groups were cleared for return to sports at the operating surgeon's discretion based on subjective symptoms, including no concerns of knee instability, as well as physical examination findings and return of near-full muscle strength. The Kaplan-Meier curves of the 2 groups overlapped fairly closely until the 9-month mark, at which point the BEAR group continued with the same rate of medical clearance, while that of the ACLR group decreased. This decrease persisted until a month or so after the 1-year mark, when the percentage of cleared patients again became similar in the 2 groups. By 2 years, >90% of the patients had been cleared to return to sports. This difference in the shape of the curves between 9 months and 1 year, although not statistically significant, could be due in part to the delay in the return of hamstring muscle strength, as this was one of the criteria used by the surgeons when considering medical clearance. It was also unclear what role patient-reported outcome measures played in the physician's determination for clearance for return to sports. Future studies with prespecified release criteria that encompass patient-reported outcomes, muscle strength, and functional recovery measures may facilitate our understanding of potential reasons for differences in timing to medical clearance for return to sports between the groups.

There are several study limitations to consider. This study was confined to a single institution, and while all surgeons in this study were experienced with ACL surgery, only 1 (L.J.M.) had previously performed 10 BEAR procedures[34,35]; thus, it is likely that a learning curve would have been present. In addition, the majority of patients in the autograft ACLR group had hamstring autografts; as such, conclusions of BEAR outcomes with BPTB autograft reconstruction outcomes cannot be made from these data. However, multiple randomized controlled trials have shown no significant differences in patient-reported outcomes or AP knee laxity between hamstring and BPTB autografts,[56] although studies[15,50,55] have demonstrated differences in isolated muscle strength depending on graft choice. In addition, we did not use specific return-to-sports criteria. Last, clearance for return to sports may not necessarily reflect actual return-to-sports rates, as we did not collect data confirming whether the patient resumed full sporting activity or not. We were, however, able to capture the percentage of patients in each group who returned to a similar Marx activity score at 1 and 2 years, and at 2 years, similar results were found in both groups, with approximately 40% of the patients back to their former activity levels. This is similar to prior studies. For instance, in a large meta-analysis, Ardern et al[4] reported that approximately 44% of the patients were able

to return to a similar level of competitive sports at mid-term follow-up after ACLR.

CONCLUSION

Patients undergoing the BEAR procedure had earlier resolution of symptoms and increased satisfaction about their knee function, as well as improved resolution of hamstring muscle strength. However, these differences did not reduce the time to medical clearance for return to sports, and there were no significant differences in patient-reported outcomes by the 2-year time point. In addition, while the BEAR group had improved strength, its timed 6-m hop test was slower. Whether these differences observed in the early months after ACL surgery will portend differences between the groups at longer time points requires further study.

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