Anterior Cruciate Ligament Reconstruction Augmentation With Bone Marrow Aspirate Concentrate, Demineralized Bone Matrix, and Suture Tape Shows No Difference in Outcomes—But Faster Functional Recovery—Versus Non-augmented Anterior Cruciate Ligament Reconstruction

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Purpose: To compare outcomes after anterior cruciate ligament reconstruction (ACLR) with bone marrow aspirate concentrate (BMAC), demineralized bone matrix (DBM), and suture tape augmentation (STA) versus ACLR without biological augmentation or STA. **Methods:** We performed a prospective randomized controlled trial at a single institution to compare ACLR with BMAC, DBM, and STA (group A) versus ACLR without biological augmentation or STA (group NA). The study sought to include 100 patients. Skeletally mature patients younger than 25 years received quadriceps tendon autograft, whereas patients aged 25 years or older underwent allograft ACLR with an all-inside technique. Patients with concomitant meniscal pathologies were included. The primary outcomes compared were range of motion (ROM), limb symmetry, and patient-reported outcomes. Secondary outcomes included radiographic outcomes and surgical complications. Univariate and mixed-model regression analyses were used to compare outcomes. **Results:** Fifty-nine patients were included (29 patients in group A [11 female patients, 38%] and 30 patients in group NA [15 female patients, 50%]). Early ROM at 6 weeks (125° of flexion vs 109° of flexion, $P < .0001$) and limb symmetry at 12 weeks (80.6% vs 36.7% [delta, 43.9%], $P < .001$) were significantly improved in group A. At 2 years, International Knee Documentation Committee scores were similar (91.1 ± 12.7 vs 85.3 ± 10.8, $P = .109$). Quality-of-life subscores of the Knee Injury and Osteoarthritis Outcome Score were significantly enhanced in group A (85.2 ± 20.9 vs 72.1 ± 20.4, $P = .042$). In 22 patients (12 in group A and 10 in group NA), computed tomography scans were obtained at 6 months to compare bone tunnel healing. Overall, the mean increase in bone tunnel diameter was significantly smaller in group A than in group NA. No difference in graft rerupture or reoperation rate was observed. Reoperations were performed for stiffness in 7 of 59 patients (11.9%) (3 [10%] in group A vs 4 [13%] in group NA; $P > .999$). **Conclusions:** There were no differences in International Knee Documentation Committee scores between groups at 2-year follow-up. Functional outcomes including early ROM and limb symmetry were significantly improved in patients who received ACLR with BMAC, DBM, and STA. **Level of Evidence:** Level II, randomized controlled trial.

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Anterior cruciate ligament (ACL) tear is a common and devastating injury, and patients who sustain this injury are at risk of short- and long-term morbidity, which includes subsequent ACL tear.[1-3] In the short term, younger patients who return to high-demand physical activity are particularly vulnerable to

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subsequent ipsilateral or contralateral ACL injury.[4-10] Overall graft rerupture rates have been reported to be up to 6% to 11%, with second rupture rates in the range of 20% to 40%.[7] Despite advances in surgical techniques and graft choice, significant reductions in graft rerupture rates have not been reported.

Efforts to improve healing potential and expedite recovery after anterior cruciate ligament reconstruction (ACLR) with the use of biological and mechanical graft augmentation continue to be investigated in the literature.[11-15] A recently published ACLR technique uses both biological augmentation (bone marrow aspirate concentrate [BMAC] and demineralized bone matrix [DBM]) and mechanical augmentation (suture tape augmentation [STA]) to potentially accelerate graft healing, expedite recovery, and reduce graft failure rates, particularly in the short term when grafts are vulnerable to rerupture because activity levels are gradually increased.[16] BMAC contains growth factors and pluripotent mesenchymal stem cells (MSCs), which have been shown to positively impact healing and biomechanical strength of ACLR graft.[17,18] DBM contains osteoinductive properties that consist of a collagen scaffold and bone morphogenetic proteins and other growth factors that promote bone formation via endochondral ossification; in addition, DBM has the potential to create a direct bone-tendon fibrocartilaginous insertion site similar to the native enthesis in tendon and ligament injuries.[12,19] Finally, the addition of an ultrahigh-molecular-weight polyethylene or polyester suture tape confers biomechanical stability and protects the graft during the processes of graft healing and ligamentization.[13,16]

Studies investigating the biological and biomechanical benefits of BMAC, DBM, and STA have been performed separately, but evaluations of their cumulative impact on clinical outcomes have been limited to this point.[11,14,20] Augmenting ACLR with BMAC, DBM, and STA combines biologics and suture tape to potentially maximize their clinical benefit.[21,22] The purpose of this study was to compare outcomes after ACLR with BMAC, DBM, and STA versus ACLR without biological augmentation or STA. The hypothesis was that ACLR with BMAC, DBM, and STA compared with ACLR without biological augmentation or STA would lead to improved functional outcomes and patient-reported outcomes (PROs) early after surgery.

Methods

This study was approved by the Institutional Review Board at Marshall University and registered on ClinicalTrials.gov (identifier NCT04178538). Consolidated Standards of Reporting Trials (CONSORT) guidelines were used to ensure important methodologic information was presented. A single-blinded, prospective randomized controlled trial at a single institution was performed to compare the outcomes of 100 patients who underwent ACLR with BMAC, DBM, and STA (group A, "augmented") or ACLR without biological augmentation or STA (group NA, "non-augmented"). Study enrollment took place from December 2019 to September 2021. Skeletally mature patients younger than 25 years received quadriceps tendon autograft, whereas patients aged 25 years or older underwent allograft ACLR with an all-inside technique. Patients aged 14 to 60 years were eligible, and those with associated meniscal pathologies were included. The exclusion criteria were as follows: (1) multiligament surgical procedures (concomitant posterior cruciate ligament, medial and/or lateral collateral ligament, and posterior medial and/or lateral corner reconstruction), (2) previous ipsilateral ACLR, (3) patients who were currently pregnant or nursing, (4) patients with current infections at the operative site, and (5) patients with Workers' Compensation claims. The number of patients who declined to participate in the study was not recorded. Patients were randomized via a computer-generated algorithm, which assigned 30 patients to either group A or group NA in a sequentially numbered fashion (1:1 ratio). Treatment allocation was then placed in a sealed envelope by a research assistant independent from the study. The envelope was stored in a secure space until the time of surgical scheduling, at which time the envelope was opened by the operating surgeon without disclosing the treatment arm to the patient. Therefore, the treating surgeon was not blinded to allocation. Patients and research staff (therapists and assistants administering PROs) remained blinded to treatment group.

Patients were followed up for a minimum of 2 years after surgery. Primary outcome measures included functional recovery, rerupture rate, and International Knee Documentation Committee (IKDC) score. At the preoperative appointments, demographic information was collected and patients completed baseline PROs, which included the IKDC score and visual analog scale pain score. To assess functional recovery, all patients underwent range-of-motion (ROM) examination via a goniometer at 2 and 6 weeks, and at 12 weeks, limb symmetry testing was performed physical therapists who were blinded to treatment group. Limb symmetry testing included single hop for distance, triple hop for distance, crossover hop for distance, and 6-m timed hop. The results were averaged for each patient to give the percentage of limb symmetry. If patients were unable to perform functional limb symmetry testing for safety reasons at the therapist's discretion, the percentage was recorded as 0% (3 patients in group A and 7 patients in group NA). If they did not follow up to undergo functional testing, they were not excluded from analysis. Patients completed PROs at 2 weeks, 6 weeks, 12 weeks, 6 months, 1 year, and 2 years postoperatively, including the IKDC score, visual analog scale pain score, Knee

Injury and Osteoarthritis Outcome Score (KOOS) subscales, Veterans RAND 12-Item Health Survey score, Lysholm knee score, and Marx activity score.

Secondary outcomes included radiographic outcomes and surgical complications (reruptures and reoperations). In both groups, the first 12 patients underwent computed tomography (CT) scans at 6 months postoperatively to evaluate for femoral and tibial bone tunnel enlargement (BTE). This was performed to evaluate for differences in bone tunnel width between patients in group A and those in group NA. During initial enrollment, informed consent for CT scanning was obtained for the first 12 patients in each group. Twenty-four patients were selected to limit cost and radiation exposure. At the time of 6-month follow-up, 2 patients in group NA decided not to undergo CT scans; therefore, there were 10 patients in group NA compared with 12 patients in group A. An independent, blinded, musculoskeletal-trained radiologist reviewed the CT scans and reported femoral and tibial tunnel widths at the point of maximum diameter. For the femoral tunnel, axial and coronal views were used to measure the maximum width of the tunnel; for the tibial tunnel, sagittal and coronal views were used. For analysis, the difference between the measured width and the tunnel width created at the time of surgery was determined, and the mean differences in femoral and tibial tunnel widths were compared between group A and group NA.

Surgical Technique

All patients received ACLR via an all-inside technique performed by 1 of 3 fellowship-trained orthopaedic surgeons (C.D.L., D.L., or J.J.). Patients younger than 25 years received quadriceps tendon autograft, and those aged 25 years or older received a quadriceps tendon GraftLink allograft (LifeNet, Virginia Beach, VA) per the preferred treatment of the senior author (C.D.L.). After quadriceps tendon autograft harvest, a FiberTag (Arthrex, Naples, FL) was applied and attached to a TightRope RT implant (Arthrex) on the femoral side and Attachable Button System (ABS; Arthrex) on the tibial side of the graft. For allograft, a TightRope BTB implant (Arthrex) was placed on the femoral side and an Attachable Button System was placed on the tibial side. Standard diagnostic arthroscopy was performed in all patients. All meniscal repairs were performed with an all-inside technique. ACLR with BMAC, DBM, and STA was performed as previously described.[22] In brief, prior to tourniquet insufflation, approximately 60 mL of bone marrow was aspirated from the proximal lateral tibia, which was then concentrated into 3 mL of BMAC. During drilling of the femoral tunnel, a shaver was used with a GraftNet (Arthrex) to also harvest autograft, which was combined with the BMAC and 5 mL of DBM to create the composite graft. Prior to tensioning the graft, the composite mixture was injected into both the femoral and tibial tunnels (Fig 1). An InternalBrace (Arthrex) was passed through the femoral titanium button to run alongside the graft in reinforcement fashion. The InternalBrace was tensioned with the knee in full extension and secured distally with a SwiveLock anchor (Arthrex) prior to tensioning of the graft in extension. In group NA, neither biological augmentation nor STA was used.

Postoperative Rehabilitation

The same postoperative rehabilitation program was used in both groups. Patients were allowed to bear weight as tolerated immediately after surgery. A hinged knee brace was locked in extension during ambulation for the first week after surgery; it was then unlocked until patients achieved full extension without lag. Patients who underwent concurrent meniscal repair were restricted to partial weight bearing immediately after surgery, and ROM was limited to less than 90° when seated. If patients in either group did not have full extension by 6 weeks, they were treated with arthroscopic release and/or manipulation under anesthesia (MUA). A progressive ROM and therapeutic exercise program was also implemented. Closed-chain strengthening and proprioception exercises were initiated at 6 weeks postoperatively. Patients were allowed to begin straight-ahead running at 12 weeks. If patients passed return-to-sport testing, they were released to return to sports at approximately 6 months postoperatively. Both groups progressed as tolerated. The treating therapist was blinded to treatment group when administering the rehabilitation protocol to each patient.

Statistical Analysis

For the sample size calculation, an a priori power analysis using G*Power (version 3.1)[23] was performed. The primary outcome of interest was ACL rerupture rate, which is typically 6% to 10%. Originally, our study expected to recruit 50 patients in each arm (treatment and control) based on availability. With assumptions of 80% power, a type I error rate of 0.05, and an initial ACL rerupture rate of 6% to 10%, the required effect size for a 1-tailed Fisher exact test would have been 26% to 32%. With assumptions of 10 measures with 3 to 7 measurements each, 0.25 as a correlation between measurements, and a presumed "medium" effect size of 0.5 standard deviations (SDs) between groups, the power using Holm-Bonferroni correction (type I error = 0.05/10) is 80% to 90% for the original sample size. However, study enrollment was significantly slowed by the coronavirus disease 2019 (COVID-19) pandemic; after a preliminary analysis of functional results and PROs, it was decided to conclude the enrollment phase at 30 patients/group. A post hoc analysis with PROs used as primary outcomes showed that with a type I error (α) of 0.05 and type II error (β) of 20% (or 80% power) for 2-sided t tests, the achieved power with 29 group A

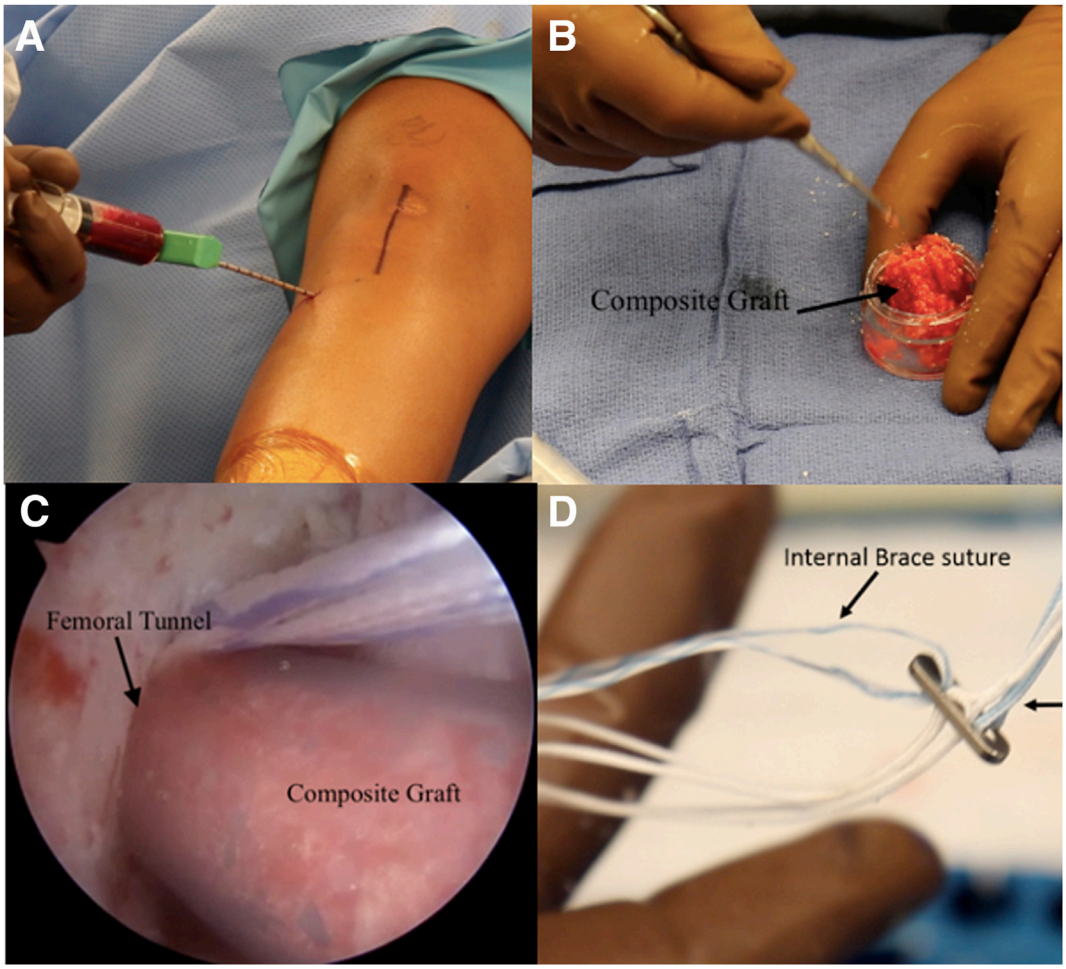

Fig 1. Depiction of augmented anterior ligament reconstruction technique. (A) Approximately 60 mL of bone marrow is aspirated from the proximal lateral tibia, which is then concentrated into 3 mL of bone marrow aspirate concentrate. (B) Composite graft consisting of autograft bone, bone marrow aspirate concentrate, and demineralized bone matrix. (C) Insertion of composite graft into femoral tunnel. (D) InternalBrace suture (arrow) passed through femoral titanium button.

patients and 30 group NA patients was 43% to 62% for a medium effect size.

Descriptive statistics were performed. Continuous data were presented as means, SDs, and 95% confidence intervals (CIs). Categorical data were described as frequencies and percentages. Baseline demographic and procedural data after randomization were presented. We performed unadjusted comparisons of demographic characteristics (age, sex, body mass index [BMI], and so on), incidence of concomitant meniscal tears, operative time, radiographic outcomes, and PROs. The minimal clinically important difference (MCID) and patient acceptable symptomatic state (PASS) levels of IKDC scores were also reported; previous reports have identified an MCID of 11.5 points and PASS threshold of 75.9 points within 1 to 5 years after ACLR to be clinically significant.[24-27] In addition, mixed-model analysis was performed, accounting for repeated measures for the same individual over time. Results were presented as adjusted means with 95% CIs. *P* values were not adjusted for multiple comparisons; therefore, readers may consider them as is or from the perspective of a Bonferroni or other adjustment. Statistical analysis was performed with R software (version 4.2.1) and the ImerTest package for mixed models (GitHub, Indianapolis, IN).

Results

Patient Demographic Characteristics and Procedural Data

Study enrollment was significantly slowed by the COVID-19 pandemic; therefore, 60 of 100 patients were enrolled (30 patients/group). One patient in group A withdrew on the day of surgery and was excluded from analysis. Therefore, 59 patients were included (29 patients in group A [11 female patients, 38%] and 30 patients in group NA [15 female patients, 50%]) (Fig 2). Overall, after randomization, age (mean ± SD) was 22.8 ± 9.2 years and 21.5 ± 7.7 years in

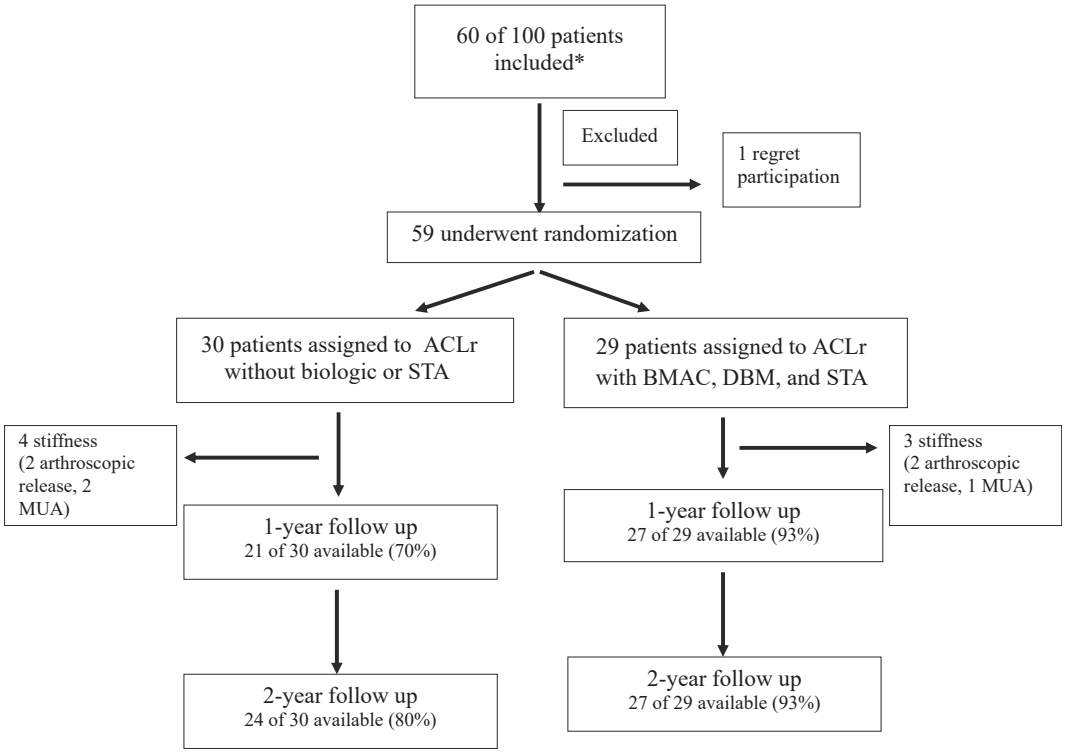

Fig 2. Flow diagram with inclusion, exclusion, randomization, and follow-up. Study enrollment took place from December 2019 to September 2021. Study enrollment was significantly slowed by the coronavirus disease 2019 (COVID-19) pandemic (asterisk); therefore, 60 of 100 patients were enrolled (30 patients/group). (ACLr, anterior cruciate ligament reconstruction; BMAC, bone marrow aspirate concentrate; DBM, demineralized bone matrix; STA, suture tape augmentation; MUA, manipulation under anesthesia.)

group A and group NA, respectively, and BMI (mean ± SD) was 28.2 ± 7.3 and 26.1 ± 5.9, respectively (Table 1). The distribution of autograft versus allograft was similar (72% in group A vs 73% in group NA).

The incidence of concomitant meniscal tears was similar between group A and group NA (18 patients [62%] and 22 patients [77%], respectively; $P = .363$). In addition, the number of patients who received meniscal repair was similar between groups (lateral repair, $P = .657$; medial repair, $P = .515$) (Table 1). Total operative time was significantly longer in group A (127.3 ± 29 minutes vs 111.7 ± 24.8 minutes, $P = .031$).

ROM and Limb Symmetry

For all patients, terminal flexion ROM was greater in group A at 2 weeks (87° vs 58°, $P < .001$) and 6 weeks (125° vs 109°, $P < .0001$). At 12 weeks, on the basis of functional hop testing, limb symmetry was higher in group A (80.6% vs 36.7% [delta, 43.9%]; $P < .001$).

Patient-Reported Outcomes

At 2 years after surgery, PROs were available in 51 patients (86.4%) (27 in group A [93%] vs 24 in group NA [80%], $P = .142$; Table 2). At 2 years, IKDC scores were similar (91.05 ± 12.7 in group A vs 85.32 ± 10.81 in group NA, $P = .109$). However, KOOS quality-of-life (QOL) subscores were significantly better in group A than in group NA at all 3 time points (67.41 ± 18.43 in group A vs 52.60 ± 18.42 in group NA at 6 months, $P = .006$; 80.6 ± 18.6 vs 58 ± 29.8 at 1 year, $P < .0001$; and 85.19 ± 20.8 vs 72.1 ± 20.4 at 2 years, $P = .042$). In addition, 1-year differences in Lysholm knee scores (89.5 ± 12.0 in group A vs 81.9 ± 14.6 in group NA, $P = .049$) and KOOS Jr. scores (90.4 ± 9.6 in group A vs 83.6 ± 13.7 in group NA, $P = .048$) were observed (Table 2). Mixed-model analysis that accounted for repeated measures for the same individual over time found a significant effect of ACLR with biological augmentation and STA on KOOS QOL scores ($P = .001$, Table 3). At 2 years, 22 of 24 patients (92%) in group NA achieved the MCID for the IKDC score compared with 26 of 27 (96%) in group A ($P = .596$). In addition, PASS thresholds were achieved in 20 of 24 patients (83%) in group NA compared with 26 of 27 (96%) in group A ($P = .120$).

Radiographic Outcomes

CT scans were obtained 6 months after surgery in 12 patients in group A compared with 10 patients in group

Table 1. Patient and Procedure Characteristics After Randomization

	Group A (n = 29)	Group NA (n = 30)
Age (years)	22.8 ± 9.2 (19.4-26.1)	21.5 ± 7.7 (18.7-24.2)
Sex (n, % female)	11 (38%)	15 (50%)
Height (inches)	67.5 ± 3.8 (66.2-68.9)	67.1 ± 4.2 (65.6-68.5)
Weight (pounds)	179.7 ± 55.9 (159.4-200)	168 ± 46 (151.9-184.1)
Body-mass index (kg/m^2)	28.2 ± 7.3 (25.5-30.8)	26.1 ± 5.9 (24-28.2)
Quadriceps Autograft (n, %)	21 (72%)	22 (73%)
Autograft Tunnel Diameter (mean, mm)		
Femoral Tunnel	9.10 ± 0.52	9.20 ± 0.53
Tibial Tunnel	9.14 ± 0.53	9.16 ± 0.42
Autograft Length (mean, mm)	68.33 ± 2.35	68.14 ± 2.49
Quadriceps GraftLink Allograft (n, %)	8 (28%)	8 (27%)
Allograft Tunnel Diameter (mean, mm)		
Femoral Tunnel	9.13 ± 0.44	9.13 ± 0.35
Tibial Tunnel	9.25 ± 0.38	9.25 ± 0.38
Allograft Length (mean, mm)	70.5 ± 0.93	69.38 ± 1.06
Meniscus Tear (n, %)	18 (62%)	22 (77%)
Lateral	13 (72%)	17 (77%)
Medial	8 (44%)	14 (64%)
Bilateral	8 (44%)	9 (41%)
Meniscus Repair (n, %)		
Lateral	9 of 13 (69%)	13 of 17 (76%)
Medial	8 of 8 (100%)	12 of 14 (86%)

NOTE. Patient characteristics. Data presented as mean ± standard deviation (95% confidence intervals).

Group A, "Augmented": Anterior cruciate ligament reconstruction (ACLr) with bone marrow aspirate, demineralized bone matrix, and suture tape augmentation; Group NA, "Non-Augmented": ACLr without biologic or suture tape augmentation.

NA. In these patients, mean age (27.2 ± 10.4 years in group A vs 23.8 ± 8.6 years in group NA, $P = .415$) and BMI (30.4 ± 5.0 in group A vs 27.2 ± 5.6 in group NA, $P = .178$) were similar. Overall, the average increases in bone tunnel diameter measured were significantly smaller in group A than in group NA on all 4 views analyzed (Table 4) The greatest increase was found on the sagittal view of the tibial bone tunnel; on this view, group A patients were found to have a significantly smaller mean increase in tunnel diameter compared with group B (mean, 2.10 mm [95% CI, 1.6-2.6 mm] vs 5.62 mm [95% CI, 4.1-7.2 mm]; $P = .0014$; Fig 3).

In group A patients with CT scans, the distribution of autograft and allograft was equal (6 patients each), whereas in group NA patients with CT scans, 6 received autograft reconstruction and 4 received allograft. When those who received autograft were compared, the mean increase in tunnel diameter was smaller on all 4 views in group A versus group NA (mean, 0.48 ± 1.5 mm vs 2.2 ± 0.9 mm for axial view of femur [$P = .045$], 0.25 ± 0.67 mm vs 2.7 ± 1.7 mm for coronal view of femur [$P = .014$], 2.2 ± 0.8 mm vs 4.7 ± 1.9 mm for sagittal view of tibia [$P = .025$], and 0.45 ± 0.69 mm vs 1.8 ± 1.1 mm for coronal view of tibia [$P = .03$]). In patients who received allograft, the mean increase in tunnel diameter was smaller in group A than in group NA on 2 views (mean, 1.6 ± 0.9 mm vs 3.1 ± 0.3 mm for axial view of femur [$P = .01$] and 2.0 ± 0.9 mm vs 7.0 ± 2.8 mm for sagittal view of tibia [$P = .03$]). When all patients who received autograft versus allograft were compared (group A and group NA), the mean increase on the tibial coronal view was found to be smaller in those who received autograft (1.13 ± 1.1 mm for autograft vs 2.89 ± 2.4 mm for allograft, $P = .05$). The other 3 views were similar.

Complications

At 6 weeks, 3 patients in group A had stiffness: 2 patients underwent arthroscopic release and MUA, and 1 patient underwent MUA only. In group NA, 4 patients had stiffness: 2 patients each underwent arthroscopic release and MUA. No patient sustained ACL reinjury at 2 years postoperatively.

Discussion

The results of this study show that there were no differences in IKDC scores between groups at 2-year follow-up. However, functional outcomes including early ROM and limb symmetry were significantly improved in patients who received ACLR with BMAC, DBM, and STA. The numbers of patients who met the MCID and PASS at 2 years were similar. Operative time was on average 15 minutes longer in group A. On postoperative CT scans, the increase in BTE was significantly smaller in group A. Overall, 11.9% of

Table 2. Patient Reported Outcomes

	Group A (27, 93%)	Group NA (24, 80%)	Delta* (Mean, 95% CI)	*P*-Value
Visual Analog Scale (VAS)				
Pre-Op	2.61 ± 1.96 (1.89-3.32)	3.03 ± 2.36 (2.15-3.90)	−0.448 (−1.371, 0.475)	.342
2 Week	4.01 ± 1.86 (3.33-4.70)	3.09 ± 2.35 (2.24-3.95)	0.932 (0.009, 1.854)	.048†
6 Weeks	1.54 ± 1.43 (1.02-2.06)	1.60 ± 2.00 (0.86-2.34)	−0.081 (−1.003, 0.842)	.864
12 Weeks	1.08 ± 1.50 (0.50-1.66)	1.47 ± 1.84 (0.79-2.15)	−0.422 (−1.367, 0.522)	.381
6 Months	1.07 ± 1.33 (0.57-1.56)	0.91 ± 1.77 (0.20-1.62)	0.020 (−0.943, 0.983)	.967
1 Year	0.73 ± 1.00 (0.36-1.11)	1.39 ± 1.83 (0.60-2.17)	−0.705 (−1.705, 0.296)	.168
2 Year	0.83 ± 1.45 (0.28-1.38)	1.09 ± 1.46 (0.50-1.67)	−0.238 (−1.208, 0.731)	.630
International Knee Documentation Committee (IKDC) Score				
Pre-Op	51.09 ± 16.12 (45.22-56.96)	47.00 ± 14.60 (41.60-52.41)	4.093 (−2.750, 10.935)	.241
2 Week	23.18 ± 7.19 (20.52-25.84)	25.28 ± 14.70 (19.92-30.63)	−2.245 (−9.085, 4.595)	.520
6 Weeks	48.82 ± 12.67 (44.21-53.43)	49.67 ± 14.89 (44.06-55.29)	−0.516 (−7.412, 6.380)	.883
12 Weeks	67.03 ± 14.33 (61.52-72.54)	61.50 ± 14.25 (56.03-66.98)	5.824 (−1.289, 12.938)	.109
6 Months	82.24 ± 11.11 (78.12-86.35)	78.37 ± 12.40 (73.41-83.33)	4.637 (−2.497, 11.772)	.203
1 Year	87.71 ± 11.62 (83.33-92.10)	80.85 ± 14.28 (74.74-86.96)	6.914 (−0.501, 14.328)	.068
2 Year	91.05 ± 12.70 (86.07-96.03)	85.32 ± 10.81 (80.99-89.64)	5.883 (−1.302, 13.067)	.109
Marx Activity				
6 Months	9.64 ± 5.39 (7.65-11.64)	7.42 ± 6.47 (4.83-10.00)	2.040 (−1.061, 5.142)	.197
1 Year	10.96 ± 6.05 (8.68-13.24)	9.14 ± 5.32 (6.87-11.42)	2.103 (−1.098, 5.304)	.198
2 Years	9.11 ± 6.06 (6.83-11.40)	6.63 ± 4.92 (4.66-8.59)	2.502 (−0.620, 5.623)	.116
Lysholm Knee Score				
6 Months	87.68 ± 12.73 (82.97-92.39)	85.63 ± 14.70 (79.74-91.51)	2.191 (−5.117, 9.500)	.557
1 Year	89.52 ± 11.99 (85.00-94.04)	81.86 ± 14.55 (75.63-88.08)	7.626 (0.037, 15.214)	.049†
2 Years	92.22 ± 12.17 (87.63-96.81)	85.96 ± 15.27 (79.85-92.07)	5.763 (−1.599, 13.126)	.125
6 Month Knee Injury and Osteoarthritis Outcomes Score (KOOS)				
Pain	90.18 ± 7.73 (87.32-93.04)	89.70 ± 8.53 (86.29-93.11)	0.603 (−3.898, 5.104)	.793
Symptoms	85.20 ±10.41 (81.35-89.06)	81.85 ± 12.46 (76.86-86.83)	3.328 (−2.921, 9.576)	.297
ADL	96.17 ± 4.28 (94.58-97.75)	95.47 ± 5.60 (93.22-97.71)	0.815 (−2.170, 3.800)	.593
Sport/Rec	78.77 ± 17.49 (72.17-85.36)	78.32 ± 17.54 (71.15-85.48)	1.168 (−8.035, 10.372)	.804
Quality of Life	67.41 ± 18.43 (60.59-74.24)	52.60 ± 18.42 (45.23-59.97)	16.002 (4.696, 27.309)	.006†
KOOS Jr Score	84.63 ± 10.04 (80.91-88.34)	82.60 ± 9.89 (78.64-86.55)	2.374 (−3.441, 8.190)	.424
1 Year KOOS				
Pain	93.21 ± 7.52 (90.37-96.05)	88.36 ± 10.56 (83.84-92.88)	4.541 (−0.125, 9.206)	.056
Symptoms	87.96 ± 8.36 (84.81-91.11)	81.46 ± 13.95 (75.50-87.43)	6.108 (−0.363, 12.580)	.064
ADL	97.71 ± 5.05 (95.81-99.62)	95.17 ± 7.84 (91.82-98.52)	2.479 (−0.626, 5.585)	.118
Sport/Rec	89.60 ± 12.58 (84.67-94.53)	79.50 ± 21.70 (70.22-88.79)	8.951 (−0.562, 18.463)	.065
Quality of Life	80.56 ± 18.62 (73.53-87.58)	58.04 ± 29.85 (45.27-70.80)	22.122 (10.466, 33.779)	.000†
KOOS Jr Score	90.35 ± 9.56 (86.74-93.95)	83.56 ± 13.68 (77.71-89.41)	6.062 (0.049, 12.074)	.048†
2 Year KOOS				
Pain	95.06 ± 8.35 (91.91-98.21)	93.29 ± 7.50 (90.28-96.29)	1.341 (−3.192, 5.875)	.562
Symptoms	91.14 ±10.26 (86.27-95.01)	85.42 ± 14.24 (79.72-91.12)	5.418 (−0.874, 11.711)	.091
ADL	98.26 ±7.2 (96.10-100.41)	96.69 ± 4.41 (94.93-98.45)	1.332 (−1.676, 4.340)	.385
Sport/Rec	93.33 ± 14.72 (87.44-99.22)	83.86 ± 15.70 (77.44-90.27)	9.276 (−0.128, 18.681)	.053
Quality of Life	85.19 ± 20.88 (77.31-93.06)	72.14 ± 20.44 (63.96-80.31)	11.817 (0.440, 23.194)	.042†
KOOS Jr Score	93.17 ± 9.66 (89.45-96.88)	89.70 ± 12.01 (84.90-94.51)	2.743 (−3.149, 8.634)	.362

NOTE. Patient-reported outcomes patient characteristics. Data presented as mean ± standard deviation (95% confidence intervals).

Group A, "Augmented": Anterior cruciate ligament reconstruction (ACLr) with bone marrow aspirate, demineralized bone matrix, and suture tape augmentation; Group NA, "Non-Augmented": ACLr without biologic or suture tape augmentation.

*Delta = differences due to group A at each time point (Group A − Group NA).

†Statistically significant.

patients had postoperative stiffness and were successfully treated with MUA with or without arthroscopic lysis of adhesions. No graft reruptures occurred in either group at 2 years postoperatively.

Efforts to improve healing potential and expedite recovery after ACLR continue to be emphasized in the literature. Recently, there has been increased interest in augmenting biological healing and the process of graft ligamentization, and there is promising evidence that the addition of stem cell products with BMAC may enhance healing and graft strength and incorporation after surgery.[11,17,28-30] Lim et al.[28] augmented ACL grafts with MSCs and observed significantly greater load to failure 8 weeks after surgery in comparison to non-augmented controls. Although several other animal studies have shown promise in reduction of bone

Table 3. *P* Values for Differences in PROs Due to ACLR With Biological and Suture Tape Augmentation (Group A), Time, and Group A × Time Interaction

PRO	Group A*	Time	Group A × Time
VAS score	.633	<.001†	.152
Marx activity score	.094	.020†	.953
Lysholm knee score	.073	.299	.447
KOOS			
Symptoms	.054	.025†	.712
Sports/recreation	.087	<.001†	.212
QOL	.001†	<.001†	.212
Pain	.234	.002†	.280
KOOS Jr	.126	<.001†	.450
ADL	.177	.151	.657
IKDC score	.101	<.001†	.279

ACLR, anterior cruciate ligament reconstruction; ADL, activities of daily living; IKDC, International Knee Documentation Committee; KOOS, Knee Injury and Osteoarthritis Outcomes Score; PRO, patient-reported outcome; QOL, quality of life; VAS, visual analog score.

*Mixed model analysis accounting for repeated measures for the same individual over time.

†Statistically significant.

tunnel osteolysis, enhancement of graft strength, and promotion of graft maturation, there has been limited clinical research using orthobiologics in ACLR surgery.[11,20] Silva et al.[20] investigated accelerated graft-to-bone healing in the femoral tunnel after hamstring ACLR with BMAC injection in 40 patients, and they concluded that BMAC had limited influence on graft healing because of nonsignificant signal on magnetic resonance imaging (MRI) at 3 months after surgery. Their study was limited by a small sample and lack of MRI evaluation beyond 3 months. Forsythe et al.[11] found that BMAC-augmented bone-tendon-bone allografts showed greater MRI signal intensity at 3 months, which indicated higher metabolic activity and accelerated graft ligamentization. These patients also had improved PROs (IKDC scores) at 9 months postoperatively compared with those undergoing standard ACLR; however, there was no difference in the proportion of patients who met the MCID for the IKDC score at 9 months, which questions the clinical difference with BMAC augmentation at longer follow-up time points.[11] In our study, group A patients received a combination of biological augmentation, which included BMAC and DBM, mixing both MSCs and osteoinductive substances, with the goal of maximizing benefit and accelerating healing. We found that group A patients achieved greater improvements in ROM and limb strength symmetry early after surgery (6 and 12 weeks); however, IKDC scores were similar at 2 years postoperatively. It is interesting to note that a comparison of KOOS QOL scores at 2 years found a large difference between groups, favoring group A (85.9 ± 20.8 vs 72.1 ± 20.4, $P = .0420$; delta, +11.817). A recent systematic review and meta-analysis of PROs measured after ACLR found that the KOOS QOL subscore was one of the most common and highly responsive measures used (9 studies with 819 patients; mean, 41.3 ± 2.1 preoperatively vs 77.2 ± 18.3 postoperatively).[31] In our study, the mean improvement in KOOS QOL scores at 2 years in group A is encouraging and indicates that biological augmentation and STA have the potential to impact patients' health status to a greater degree than ACLR without biological augmentation or STA.

BTE after ACLR is characterized by radiographic widening of the tibial and femoral tunnels postoperatively (Fig 3).[32,33] Potential reasons for BTE include biological causes, such as host immune response or heat necrosis from drilling tunnels, and mechanical causes, including graft selection, tunnel position, graft fixation method, graft motion during early rehabilitation, or initial tension applied during ACLR.[32-35] BTE occurs mostly within the first 3 months after surgery. There is a paucity of literature that has examined the influence of biologics on BTE after ACLR. In animal studies, ACLR with DBM resulted in a direct fibrocartilaginous enthesis more like the native bone-ligament interface.[12,19] The use of cultured MSCs during ACLR performed in rabbits was found to decrease BTE—potential mechanisms postulated include MSC recruitment of local osteoblasts and fibroblasts to encourage fibrocartilage formation at the graft-bone interface.[28,29,36] In our study, ACLR with BMAC, DBM, and STA resulted in less BTE compared with ACLR without biological augmentation or STA, more so in patients who received quadriceps tendon autograft. These results further reinforce the findings of recent investigations into bone healing response in biologically augmented ACLR. These results also have favorable implications for patients who require revision ACLR because less BTE after primary ACLR simplifies the creation of new tunnels during revision surgery. Indeed, future investigations assessing graft-bone healing response mechanisms and how the timing of tissue healing correlates with clinical recovery after biologically augmented ACLR are warranted.

In addition to biological augmentation, the current technique uses a synthetic suture tape to enhance graft stability early after surgery. The use of synthetic devices in ACLR was introduced in the 1970s, but failures and high complication rates including effusion and synovitis were commonly encountered.[37] STA is now frequently applied for a multitude of procedures, including repair of the ulnar collateral ligament of the thumb and elbow, lateral ankle ligament stabilization, Achilles tendon repair, and ACLR.[38] The ACL graft is weakest until 6 to 12 weeks; however, this is an important time in the rehabilitation period after ACL injury to work on ROM and strengthening.[38] Biomechanical studies have supported the use of the addition of suture tape to

Table 4. Radiographic Tunnel Width at 6 Months After ACLR With BMAC, DBM, and STA (Group A) Versus ACLR Without Biological Augmentation or STA (Group NA)

					Mean Change in Femur Tunnel Width			Mean Change in Tibial Tunnel Width	
	Sex	Age, yr*	BMI	Femur Baseline, mm†	Axial, mm	Coronal, mm	Tibia Baseline, mm	Sagittal, mm	Coronal, mm
Group NA									
Patient 1	M	17	22.5	8.5	1	3	9.5	3.6	0
Patient 2	F	17	23.8	9	1.3	4.5	9.5	3.7	2.4
Patient 3	F	14	20.4	9.5	3.2	0.2	9	7.8	2.3
Patient 4	M	24	25.5	10	2.1	1.6	9	2.5	1
Patient 5	F	18	28.2	9	2.1	2.5	9.5	4.2	2.3
Patient 6	F	17	21.5	9	3.5	4.6	8.5	6.4	2.8
Patient 7	M	34	38.5	9.5	3.6	8.8	9.5	9.3	6.8
Patient 8	F	29	28.9	9.5	2.8	3.1	9.5	7.9	4.5
Patient 9	F	39	32	8.5	3	2.6	9	2.9	1.3
Patient 10	M	29	31	9	3.1	3	9	7.9	6.6
Mean (95% CI)		23.8 (18.5-29.1)	27.2 (23.8-30.7)	—	2.57 (2-3.1)	3.39 (2-4.8)	—	5.62 (4.1-7.2)	3.00 (1.6-4.4)
Group A									
Patient 1	M	17	34.5	9	−0.7	0.1	8	1.8	0.1
Patient 2	M	19	36.5	8.5	0.1	−0.7	8.5	3	1.3
Patient 3	F	18	24.5	9	0.2	0.5	8.5	3.2	1.2
Patient 4	F	19	21.9	8.5	3.2	0.6	9.5	2.1	0.1
Patient 5	M	16	25.8	9.5	1	−0.2	10	1	0.5
Patient 6	M	38	29.5	8.5	1.4	2.8	9	1.7	2
Patient 7	F	38	34.8	8.5	1	0.9	9	3.2	0.8
Patient 8	F	39	34.3	9.5	1.5	2.2	9.5	2.1	1.2
Patient 9	M	15	31.4	9	−0.9	1.2	9	1.9	−0.5
Patient 10	M	37	36.7	9.5	2.5	1.8	9	2.9	3.4
Patient 11	M	33	27	9.5	3.2	4.3	9.5	1.7	2
Patient 12	M	37	28.3	9	0.5	0.5	9	0.6	0.3
Mean (95% CI)		27.2 (21.3-33.1)	30.43 (27.6-33.3)	—	1.08 (0.31-1.9)	1.17 (0.37-2.0)	—	2.10 (1.6-2.6)	1.03 (0.4-1.6)
P value‡		.4151	.1783		.0065§	.0176§		.0014§	.0273§

A, augmented; ACLR, anterior cruciate ligament reconstruction; BMAC, bone marrow aspirate concentrate; BMI, body mass index; CI, confidence interval; DBM, demineralized bone matrix; F, female; M, male; NA, non-augmented; STA, suture tape augmentation.

*Patients younger than 25 years received quadriceps autograft, whereas those aged 25 years or older received allograft.

†Tunnel width drilled during surgery.

‡Results of 2-tailed, unpaired *t* test comparing group NA with group A.

§Statistically significant.

ACLR for increasing graft stiffness and ultimate load failure, as well as reduced elongation, while not yielding overconstraint or stress shielding of the graft.[38-41] The addition of STA to ACLR potentially allows patients to accelerate rehabilitation during the process of graft healing, and early clinical studies have shown promising outcomes.[14,15,42] In a matched comparison to standard ACLR, Bodendorfer et al.[14] reported that hamstring ACLR augmented with suture tape correlated with improved PROs, less pain, and a higher percentage of return to preinjury activity levels, as well as an earlier return to preinjury activity levels. In another matched comparison to standard ACLR, Daniel et al.[15] showed a lower risk of revision ACLR in patients who received either bone−patellar tendon−bone or quadriceps tendon ACLR with an internal brace. Their patients also showed comparable PROs and anteroposterior knee laxity measured via a KT-1000 arthrometer (MEDmetric, San Diego, CA). In our study, there were no differences in reoperation or revision rate between groups; however, 7 of 59 patients (11.9%) underwent reoperation for stiffness, with no differences between groups. This stiffness rate is slightly higher than the reported rate in the literature, typically around 5%.[43] Contributing factors to this elevated stiffness rate could include the use of quadriceps tendon autografts, which may inherently carry a higher risk of stiffness, as well as the fact that most patients underwent meniscal repair concurrently in our study.[43] In this study, all patients with stiffness were female and younger than 20 years. There was also no difference in stiffness rates between the groups in our study. Future studies of stiffness rates after biologically augmented and suture tape−augmented ACLR are needed.

Patients who sustain ACL injuries are at risk of short- and long-term morbidity, including subsequent

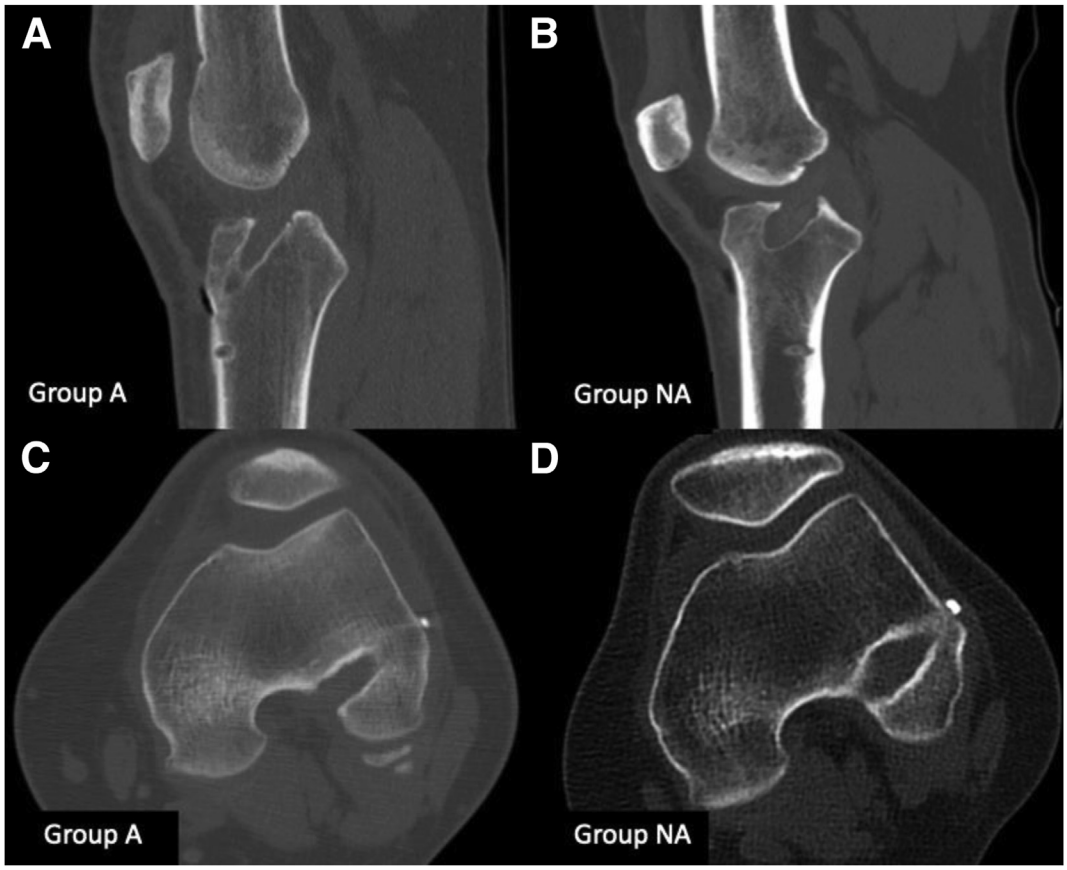

Fig 3. Postoperative computed tomography scans of right knee after augmented anterior ligament reconstructionwith BMAC, DBM, and STA versus standard anterior cruciate ligament reconstruction without biologic or STA. (A) Tibial tunnel on sagittal view after augmented ACLR. (B) Femoral tunnel on axial view after augmented ACLR. (C) Tibial tunnel on sagittal view after standard ACLR. (D) Femoral tunnel on axial view after standard ACLR.

ACL tear.[1-3] In the short term, younger patients who return to high-demand physical activity are particularly vulnerable to subsequent ipsilateral or contralateral ACL injury.[4-10] Overall graft rerupture rates have been reported to be up to 6% to 11%, with second ACL rupture rates in the range of 20% to 40%.[7] Despite advances in surgical techniques and graft choice, significant reductions in graft rerupture rates have not been reported. At a minimum, anatomic ACLR with proper tunnel placement, graft placement, and graft fixation positively influences success rates while limiting graft failure rates and the need for revision ACL surgery.[44,45] In this study, quadriceps allograft was used in patients aged 25 years or older per the senior author's preferred treatment, consistent with previous practice. No graft reruptures occurred in either group at 2 years postoperatively.

Comparison of these current outcomes requires consideration of a few key points: First, the described technique is a safe and reliable technique that uses an all-inside technique with quadriceps tendon autograft in patients younger than 25 years, which has been shown to have excellent outcomes in terms of graft survival, knee stability, and patient satisfaction.[46,47] Second, radiographic outcomes from our study indicate that the use of orthobiologics and internal bracing can further enhance these outcomes by promotion of tissue healing and provision of additional support to the reconstructed ACL. Third, in terms of recovery timelines, ACLR with biological augmentation and STA may have a faster return of function compared with ACLR without biological augmentation or STA given that large differences in ROM and limb symmetry were found early after surgery. On the basis of functional and radiographic outcomes, we hypothesize that the all-inside technique combined with the use of orthobiologics may lead to faster healing times, which may impact return-to-play times. Large longitudinal cohort trials currently underway will help to expand these findings and determine whether ACLR with biological augmentation and STA will reduce the risk of rerupture and lead to greater levels of return to sport and an earlier return to sport at performance levels equal to or better than those prior to injury.

Limitations

There are limitations to this study that should be considered. There are multiple independent variables within the augmented ACLR technique, which may raise concerns regarding which aspect of the procedure (biologics vs suture tape) contributes most to the outcomes. This study elected to compare ACLR with biological augmentation and STA versus all-inside ACLR without biological augmentation or STA to establish a baseline comparison of outcomes. In addition, the enrollment phase of this study was significantly impacted by the COVID-19 pandemic, which decreased the sample size and resultant power. The number of patients who declined to participate in the study was also not recorded. Because there is a risk of a β error owing to our small numbers, the number of subjects that would have been required to show a difference in IKDC scores at 2 years between groups was calculated; using G*Power (independent means, 2-tailed, 80% power, $\alpha = 0.05$), 83 subjects per group would have been required to detect a difference in IKDC scores between groups at 2 years. Subgroup analyses of patient outcomes stratified by age ($\geq$25 years vs <25 years) and graft type (autograft vs allograft) were intended to be included, but because of the small sample size and the risk of a type II (β) error, these analyses were unable to be performed. In addition, in patients in group A versus group NA, varying incisions at the proximal tibia were performed based on whether a needle was inserted to harvest BMAC, which may be a potential source of bias if patients realized this during follow-up. This also could have presented bias in measurements of ROM, but the physical therapists performing hop testing were not aware of the differences in incisions. One limitation to hop testing was that 4 more patients in group NA opted out of testing because of safety concerns. In addition, not all PROs were measured at baseline, which limits interpretation postoperatively. In terms of the radiographic analysis, not all patients underwent postoperative CT scans, and measurements of bone tunnels were not volumetric, which limits the power and conclusions made from this analysis. General limitations of performing ACLR with biological augmentation and STA include increased operative time and cost of the procedure, which on average increases by $2,000; however, this is variable and depends on hospital and geographic location. Finally, this was a single-center trial with a limited number of surgeons and short-term follow-up.

Conclusions

There were no differences in IKDC scores between groups at 2-year follow-up. Functional outcomes including early ROM and limb symmetry were significantly improved in patients who received ACLR with BMAC, DBM, and STA.

Disclosures

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: C.D.L. reports that financial support was provided by Arthrex; has a consulting or advisory relationship with Arthrex; and receives funding grants, speaking and lecture fees, and travel reimbursement from Arthrex. All other authors (A.L.S., S.T., R.P., G.B., V.S., K.C., D.L., J.J., T.E.H.) declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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