Propensity for Clinically Meaningful Improvement and Surgical Failure After Anterior Cruciate Ligament Repair

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Background: Primary repair of the anterior cruciate ligament (ACL) confers an alternative to ACL reconstruction in appropriately selected patients.

Purpose: To prospectively assess survivorship and to define the clinically meaningful outcomes after ACL repair.

Study Design: Case series; Level of evidence, 4.

Methods: Included were consecutive patients with Sherman grade 1-2 tears who underwent primary ACL repair with or without suture augmentation between 2017 and 2019. Patient-reported outcomes (Lysholm, Tegner, International Knee Documentation Committee, Western Ontario and McMaster Universities Osteoarthritis Index, and Knee injury and Osteoarthritis Outcome Score [KOOS] subscales) were collected preoperatively and at 6 months, 1 year, and 2 years postoperatively. The minimal clinically important difference (MCID) was calculated using a distribution-based method, whereas the Patient Acceptable Symptom State (PASS) and substantial clinical benefit (SCB) were calculated using an anchor-based method. Plain radiographs and magnetic resonance imaging (MRI) were obtained at 6 months, 1 year, and 2 years postoperatively.

Results: A total of 120 patients were included. The overall failure rate was 11.3% at 2 years postoperatively. Changes in outcome scores required to achieve the MCID ranged between 5.1 and 14.3 at 6 months, 4.6 and 8.4 at 1 year, and 4.7 and 11.9 at 2 years postoperatively. Thresholds for PASS achievement ranged between 62.5 and 89 at 6 months, 75 and 89 at 1 year, and 78.6 and 93.2 at 2 years postoperatively. Threshold scores (absolute/change based) for achieving the SCB ranged between 82.8 and 96.4/17.7 and 40.1 at 6 months, between 94.7 and 100/23 and 45 at 1 year, and between 95.3 and 100/29.4 and 45 at 2 years. More patients achieved the MCID and PASS at 1 year compared with 6 months and 2 years. For SCB, this trend was also observed for non-KOOS outcomes, while for KOOS subdomains, more patients achieved the SCB at 2 years. High-intensity signal of the ACL repair (odds ratio [OR], 31.7 [95% CI, 1.5-73.4]; $P = .030$) and bone contusions on MRI (OR, 4.2 [95% CI, 1.7-25.2]; $P = .041$) at 1 year postoperatively were independently associated with increased risk of ACL repair failure.

Conclusion: The rate of clinically meaningful outcome improvement was high early after ACL repair, with the greatest proportion of patients achieving the MCID, PASS, and SCB at 1 year postoperatively. Bone contusions involving the posterolateral tibia and lateral femoral condyle as well as high repair signal intensity at 1 year postoperatively were independent predictors of failure at 2 years postoperatively.

Keywords: ACL; clinical outcomes; MCID; PASS; repair; SCB

Acute ruptures of the anterior cruciate ligament (ACL) are common injuries that impede function and necessitate surgical intervention in active patients and those with concurrent injuries that, left untreated, would result in further morbidity. Although initially treated with repair, high early failure rates resulted in a paradigm shift toward performing reconstruction of the ACL.[8,26] However, advancements in arthroscopic techniques and associated instrumentation has led to recent interest in performing primary repair of the ACL, the purported benefits of which include decreased morbidity, accelerated rehabilitation with early return to activities, and preservation of the native ACL, leading to the recovery of normal biomechanics and proprioception.[1,9,26] As primary ACL repair continues to be explored as a potential option in the setting of acute partial or complete proximal ACL tears,[28] it is imperative to better understand the clinical outcomes of this procedure and the expected trajectory of patient function.

Recent studies have sought to examine the safety and efficacy of ACL repair, while few have compared the

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outcomes of ACL repair directly with those of ACL reconstruction.[12,13,33,34] van der List et al[32] performed a systematic review and meta-analysis of primary arthroscopic repair of proximal ACL repairs and reported that failure rates among primary repair, repair with static augmentation, and repair with dynamic augmentation ranged between 7% and 11% at mean 2.1-year follow-up. They also found that functional outcome scores exceeded 85% of the maximum scores; however, all but 1 study were retrospective without a control group. When compared with primary ACL reconstruction, recent randomized controlled trials have demonstrated that several different methods of primary ACL repair are noninferior in terms of subjective patient-reported outcomes, knee laxity, and failure at short-term follow-up.[11,15,19] Despite reported clinical improvement and statistical noninferiority among these studies, it remains poorly understood as to whether the improvements experienced after ACL repair at short-term follow-up represent clinically meaningful changes. Furthermore, there remains a paucity of literature that has sought to identify factors associated with repair failure.

Surgical candidacy for primary ACL repair is dependent on tear morphology and patient-specific factors.[29] Given the importance of appropriately selecting surgical candidates for this procedure, it is imperative to better understand the propensity to achieve a clinically meaningful improvement or an acceptable symptom state after ACL repair. Furthermore, it would be of clinical benefit to determine which factors are associated with surgical failure.

The purpose of the current study was to prospectively assess survivorship and to define clinically meaningful outcomes after ACL repair. We hypothesized that patients would achieve high rates of clinically meaningful outcomes at short-term follow-up and that we would identify several factors associated with achieving these outcomes.

METHODS

Patient Selection

Institutional review board (IRB) approval was obtained previously for the prospective collection of data on ACL repair patients; the current study was determined to be exempt from IRB approval because of the retrospective nature of the collected data. We retrospectively reviewed data from consecutive patients who underwent primary repair with or without suture augmentation of ACL tears between January 1, 2017, and December 31, 2019. Inclusion criteria included patients with Sherman type 1 or 2 ACL tears (Table 1),[25] which would potentially be amenable to primary repair (Figure 1).[30] Exclusion criteria included Sherman type 4 to 5 injuries or ACL remnants of insufficient quality where an ACL reconstruction was necessary.

TABLE 1
Sherman et al[25] Classification of ACL Tear Location[a]

Sherman Tear Grade	Description
1	Proximal avulsion from femoral condyle
2	Tear involving proximal 1/3 of ACL substance
3	Tear involving midsubstance of ACL
4	Tear involving distal 1/3 of ACL substance
5	Distal avulsion from tibial insertion

[a]ACL, anterior cruciate ligament.

Indications and Surgical Technique

The decision to perform isolated ACL repair or augment the repair was determined intraoperatively. We chose to perform isolated ACL repair when 1 or both bundles of ACL were consistent with a Sherman type 1 injury. If, during diagnostic arthroscopy, a Sherman type 2 injury of ≥1 of the ACL bundles was observed, an ACL repair with suture augmentation was performed. If magnetic resonance imaging (MRI) was initially suggestive of a Sherman type 1 or 2 tear, but this was disproven arthroscopically, ACL reconstruction was performed.

Briefly, the ACL remnant was sutured using an interlocking Bunnel-type suture, and a self-retrieving suture passer (First Pass; Smith & Nephew) was subsequently introduced through the anteromedial (AM) portal (Figure 2, A and B). Next, suturing of the ACL remnant was performed, starting from the intact tibial end to the most proximal aspect of the stump using a No. 0 high-resistance suture (Ultrabraid; Smith & Nephew), with 3 stitches placed using the same limb of the suture and the other limb kept under tension. The arthroscope was then switched to the AM portal and the free limb of the suture passed through the anterolateral portal and loaded into the suture passer, after which stitches were thrown in the same way as the first limb. Therefore, both ACL bundles were sutured

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Ethical approval for this study was waived by Centro Artroscópico Jorge Batista.

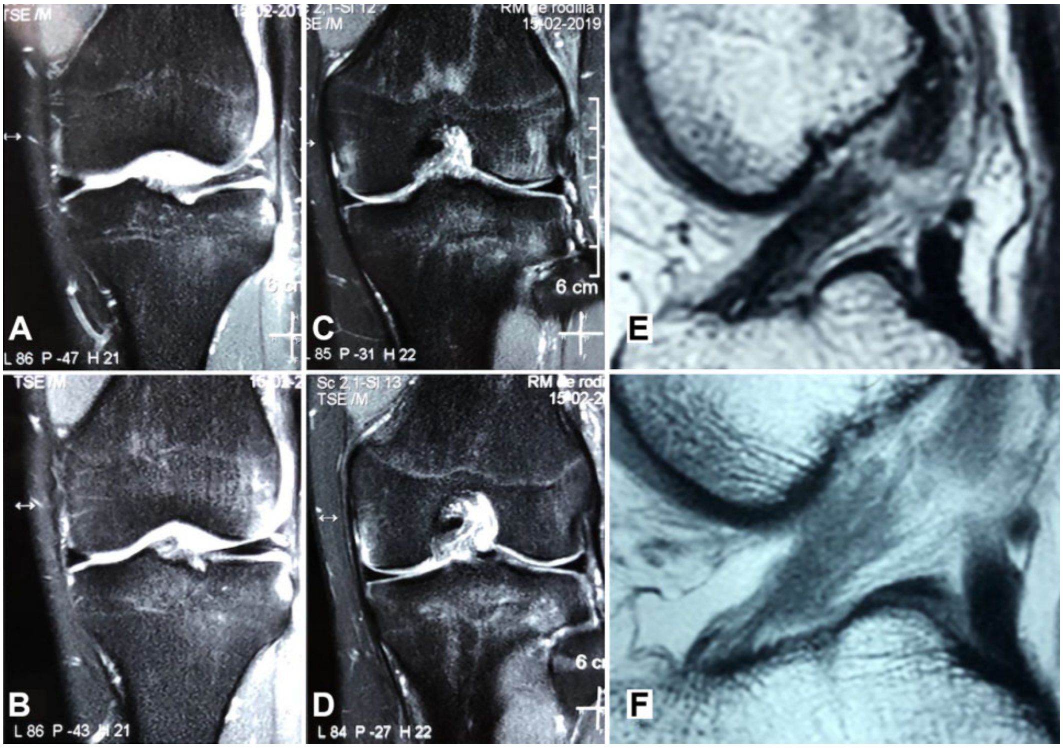

Figure 1. Magnetic resonance imaging scans of an acute, proximal anterior cruciate ligament (ACL) tear. (A-D) Coronal T2 weighted images with sequences progressing posteriorly to anteriorly demonstrating edema in the proximal aspect of the ACL. (E-F) T1-weighted sagittal images demonstrating attenuation in the proximal one-third of the ACL.

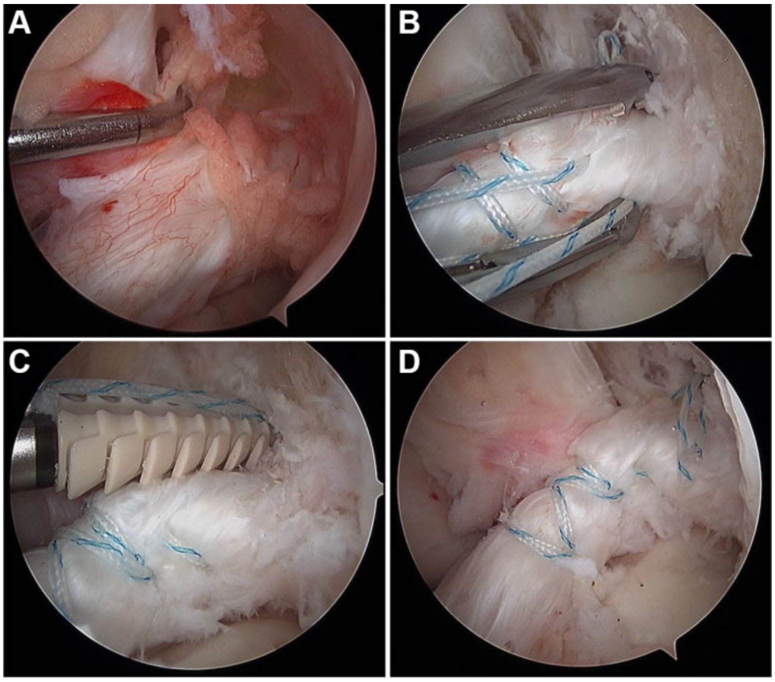

Figure 2. Arthroscopic images of an isolated anterior cruciate ligament (ACL) repair. (A) Arthroscopic confirmation of proximal ACL tear using probe. (B) Bunnel-type suture introduced into anteromedial and posterolateral bundles. (C, D) Knotless anchor being introduced into femoral tunnel and tightened.

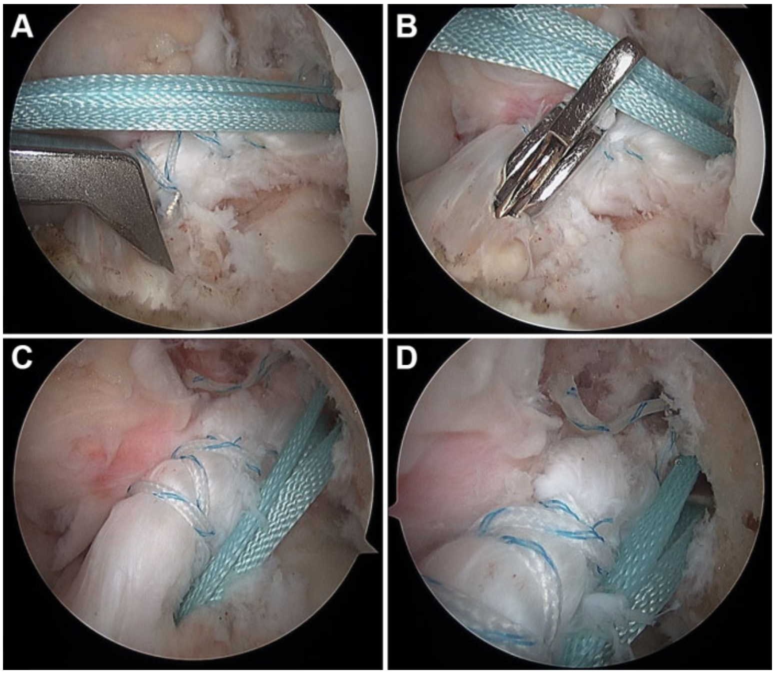

Figure 3. Arthroscopic images of an anterior cruciate ligament repair augmented with Ultratape augmentation. (A, B) Ultratape being introduced into anchor repairing the anteromedial bundle and subsequently being grabbed with suture retriever. (C, D) Ultratape subsequently passed into tibial tunnel and tightened with biotenodesis screw.

with the same suture. The knee was then flexed to 90°, and a 3.2-mm drill was placed into the AM portal to drill the footprint of the ACL. The sutures were then passed through a 4.5-mm knotless anchor (Footprint Ultra; Smith & Nephew) and introduced into the joint through the AM portal (Figure 2C). Sutures were then tightened and the anchor introduced into the tunnel (Figure 2D). When proximal avulsions of both the AM and the posterolateral (PL) bundles were observed, both anatomic bundle ligament insertions were recreated at the respective footprints, as is the surgeon's preference. When tears were present in the AM bundle, the ligament was fixed at 90° of flexion. For tears involving the PL bundle, the ligament was fixed in hyperflexion (>100° of flexion). Remnants of the sutures were then cut flush, and the tension of the ACL was checked with a probe and an intraoperative Lachman test.

When suture augmentation was desired, a 4.5-mm anchor preloaded with a doubled Ultratape suture (Smith & Nephew) was deployed into the femur after a tunnel was created into the PL bundle footprint with the knee hyperflexed. The augmentation suture tape was then introduced into the anchor repairing the AM bundle (Figure 3A,B). The tibial tunnel was created in the anterior half of the ACL tibial insertion with an ACL aimer guide and a 4.5-mm Endobutton reamer. It was then fit with a 7-mm conical interferential screw. Finally, an arthroscopic suture retriever was introduced into the joint through the tibial tunnel to pass the double Ultratape into the tunnel, and with the knee in 20° of flexion, the sutures were tightened and a 7 × 25–mm biotenodesis screw (Biocomposite; Smith & Nephew) was used for tibial fixation (Figure 3, C and D).

Rehabilitation

Postoperative management was similar regardless of isolated ACL repair and ACL repair with suture augmentation. A knee brace locked in extension was used for the first 2 weeks with immediate full weightbearing. Once use of the knee brace was discontinued, physical therapy was initiated with the same protocol used as for an ACL reconstruction. Progressive range of motion exercises, patellar mobilization, and isometric quadriceps contraction were stimulated with the expectation of normal walking, full-extension, and 110° of flexion at 1 month after surgery. Noncontact sports (swimming or cycling) were allowed 2 months postoperatively, while running was permitted at 4 months. If strength and physical function tests compared with the contralateral limb were restored, return to pivoting sports was allowed at 7 to 8 months postoperatively.

Data Collection

Demographic data were collected preoperatively, while procedural data were collected following each operation. On radiographs, the posterior tibial slope (PTS) and Kellgren-Lawrence (KL) osteoarthritis grade were recorded at 6 months, 1 year, and 2 years postoperatively. MRI scan analysis was also conducted at these time points, where the incidence of meniscal lesions, cartilage lesions, bone contusions involving the medial aspect of the lateral femoral condyle and PL tibial plateau, and the repair signal intensity were recorded. The integrity of the repair was evaluated and defined at the proximal, middle, and distal aspects of the ligament in every case. With regard to signal intensity, low signal was defined as a continuous and homogeneous ligament appearing black in color. Medial signal was defined as a ligament in which no black color was apparent, but rather appeared gray, with the borders of the ligaments not well-defined. This ligament is therefore not homogeneous, but slightly heterogeneous, although it can still be recognized entirely from proximal to distal. Finally, high signal was defined when the ligament was clearly heterogeneous in appearance.[7,31] All MRI scans were performed at the same facility for quality consistency. All measurements were made by a single observer (J.P.B.), who was the senior surgeon involved in this work and who has >30 years of clinical experience.

Clinical and functional outcomes were assessed using KT-1000 knee laxity measurements using 89 N of force and patient-reported outcome measures administered routinely preoperatively and at 6 months, 1 year, and 2 years postoperatively. Outcome measures included in the current study were Lysholm, Tegner, International Knee Documentation Committee (IKDC), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and Knee injury and Osteoarthritis Outcome Score (KOOS) subdomains (Pain, Symptoms, Sport/Rec, Quality of Life [QOL], and Activities of Daily Living [ADL]).

ACL repair failure was defined as surgical failure as determined through clinical evidence of laxity on physical exam in the postoperative follow-up period or MRI evidence of rerupture. Rerupture of the ACL was documented when evidence of complete discontinuity of fibers of the ACL either at the repair site or at a different site than the original repair were observed on MRI scans.

Statistical Analysis

All statistical analyses were performed using Stata Version 16.1 (Stata). Normality of data was investigated before all analyses, after which the appropriate parametric or nonparametric testing was performed.

Quantification of clinically meaningful outcome thresholds was performed using a distribution-based method for the minimal clinically important difference (MCID) and anchor-based method for the Patient Acceptable Symptom State (PASS) and substantial clinical benefit (SCB).[3,17,22,23] For the MCID, threshold values were quantified as one-half of the standard deviation of the change in outcome score between the preoperative assessment and follow-up at 6 months, 1 year, and 2 years.[6,16]

The PASS was established prospectively using the following anchor question: "Taking into account all the activities in your daily life, your level of pain, and your current level of function, do you consider the current state of your knee as satisfactory?" Patients were required to answer yes or no to this question at 6 months, 1 year, and 2 year follow-up. Receiver operating characteristic (ROC) analyses were then performed, after which the Youden index method was applied to determine the threshold value for the PASS at which both sensitivity and specificity were optimized; this value was subsequently used to assess PASS achievement percentages.[36]

The SCB was established prospectively using the following anchor question: "Since your ACL repair surgery, how would you rate your overall physical ability?" with possible responses being "no change," "slightly worse," "worse," "much worse," "slightly improved," "improved," or "much improved." Patients who answered "no change," "slightly worse," or "slightly improved" constituted the no improvement group, while those answering "much improved" constituted the substantial improvement group. After defining these 2 groups, SCB was created for absolute 6-month, 1-year, and 2-year outcome scores as well as for the change in outcome scores over the study period.[2] Likewise, ROC analyses were then performed after which the Youden index method was applied to determine the threshold value for the SCB at which both sensitivity and specificity were optimized,[36] and this value was subsequently used to assess SCB achievement percentages.

Descriptive statistics for the study cohort were quantified using means with standard deviations or frequencies with percentages where appropriate. Repeated-measures analysis of variance was implicated to test within-patient differences in the degree of knee laxity between preoperative and postoperative time points, while independent *t* tests were used to investigate potential differences in knee laxity between the operative and nonoperative knee at all time points. Paired *t* tests were used to investigate outcome improvement between the preoperative and postoperative follow-up time points for raw outcome data. Pearson and point-biserial correlation analysis were performed to investigate the patient- and imaging-based characteristics associated with surgical failure. Subsequently, a multivariate logistic regression model was constructed to determine which variables were independently associated with surgical failure. Statistical significance was considered to be $P < .05$ in all analyses.

RESULTS

Characteristics of the Study Population

A total of 120 patients undergoing primary ACL repair were included in the final analysis. The mean age and body mass index of the study population were 29.9 ± 10.5 years and 24.2 ± 3.2 kg/m^2, respectively. The mean duration of symptoms from the time of injury to ACL repair was 6.9 ± 8.9 weeks (range, 1-52 weeks). A total of 85 (70.8%) of patients were male and 113 (94.2%) were athletes (reported being involved in at least a recreational sport). ACL repair augmentation was performed in 58 (48.3%) of cases and 53 (44.6%) of patients had Sherman type 2 ACL tears. Concomitant procedures were performed for additional injuries in a total of 41 cases. These included 28 partial meniscectomies for meniscal tears, 6 chondroplasties (4 patellar, 1 trochlear, 1 medial femoral condyle) for cartilage defects, 4 medial collateral ligament (MCL) repairs for MCL tears, and 3 meniscal repairs (2 lateral, 1 medial).

Radiographic Analysis

The PTS and the KG grade were assessed prospectively on radiographs of the knee at 6-month, 1-year, and 2-year time points. The PTS and KG grade were measured using previously validated methods.[14,27] A total of 110 patients had radiographs available at the 6-month time point, 98 at the 1-year time point, and 94 at the 2-year time point. The mean PTS was 6.4° ± 1.3° (range, 3°-9°) at each time point ($P > .05$). At 6 months postoperatively, 7 (5.8%) patients had KG grade 1 osteoarthritis, at 1 year 13 (10.8%) had KG grade 1 osteoarthritis ($P = .086$), and at 2 years 15 (12.5%) had KG grade 1 osteoarthritis, while 1 (0.08%) patient had KG grade 2 osteoarthritis ($P > .05$ compared with 6-month and 1-year time points).

MRI Scan Analysis

MRI scan analysis was available for 110 patients at all follow-up time points. The 6-month follow-up revealed that a total of 19 (17.3%) patients had evidence of bone contusions involving the PL tibial plateau or medial aspect of the lateral femoral condyle, 17 (15.5%) patients had meniscal lesions, and 2 (1.7%) had cartilage lesions. A total of 11 meniscal lesions involved the medial meniscus, while 6 involved the lateral meniscus. At 1 year, the incidence of bone contusions and meniscal lesions remained unchanged, although 1 additional cartilage lesion was noted (increase from 1.8% to 2.7%). There was no change between 1 and 2 years postoperatively. No changes were statistically significant.

Repair signal was noted to be low in 11 (10%) patients, medium in 71 (64.6%) patients, and high in 28 (25.4%) of patients at 6 months. At 1 year, low signal intensity was observed in 39.4% of patients, whereas the proportion of patients with medium (52.5%) and high (8.1%) signal intensity decreased. This trend continued at 2 years postoperatively where the greatest proportion of patients had low signal intensity (70.2%), followed by medium (26.2%) and high (3.6%) intensity.

Repair signal was low in 2 patients, medium in 27 patients, and high in 16 patients with suture augmentation, while it was low in 9 patients with suture augmentation, medium in 44 patients, and high in 12 patients with isolated ACL repair at 6 months postoperatively ($P = .059$). At 12 months postoperatively, a significantly higher proportion of patients with suture augmentation had high signal intensity versus though with isolated repair (n = 7 versus n = 1; $P = .007$). At 24 months postoperatively, there were again no significant differences in signal intensity ($P = .40$).

Clinical and Functional Outcomes Analysis

In terms of objective knee laxity as measured with KT-1000, preoperative knee laxity in the ACL-injured knee was significantly greater than that of the contralateral uninjured knee preoperatively (13.1 ± 1.9 vs 4.5 ± 1.7 mm; $P < .001$). Compared with preoperative values, laxity in the operative knee was decreased significantly at 6 months (5.4 ± 2.0 mm), 1 year (5.4 ± 2.3 mm), and 2 years (4.9 ± 2.5 mm) ($P < .001$ for all). No significant differences were observed between knee laxity values between the 3 follow-up time points. Furthermore, in comparison with the laxity in the uninjured contralateral knee (4.5 ± 1.7 mm), laxity in the ACL-repaired knee was not significantly different at 6 months (5.4 ± 2.0 mm), 1 year (5.4 ± 2.3 mm), or 2 years (4.9 ± 2.5 mm).

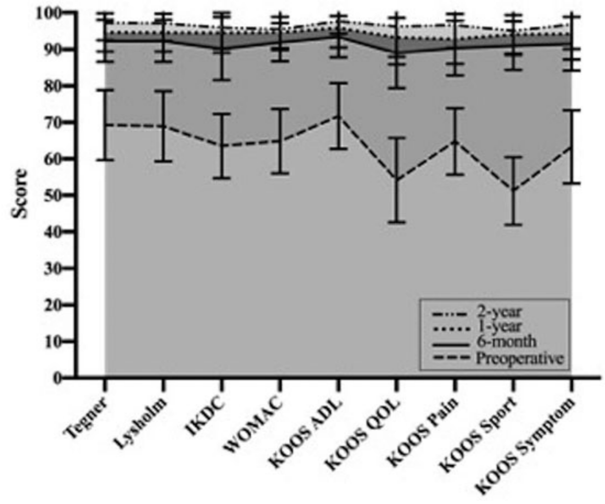

Figure 4. Fill-plot demonstrating improvement in patient-reported outcome scores preoperatively to 6 months, 1 year, and 2 years after anterior cruciate ligament repair. Error bars represent the SD of the mean, whereas points across the line demonstrate the mean value of each outcome, respectively. The shaded areas represent the improvement in scores over time. Preoperative scores were the lowest, and scores significantly increased at 6 months, 1 year, and 2 years postoperatively. ADL, Activities of Daily Living; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; QOL, Quality of Life; Sport, Sport and Recreation; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

All patients experienced significant improvements in all administered outcomes on average at a minimum of 6 months, 1 year, and 2 years postoperatively compared with their preoperative state ($P < .0001$ for all) (Figure 4). A subanalysis of patients with and without suture augmentation was performed at the latest follow-up. Compared with patients with suture augmentation, there were no statistically differences on any outcome metrics: Tegner (9.7 ± 0.8 vs 9.7 ± 1.3; $P = .98$); KOOS–Pain (96.9 ± 0.70 vs 96.2 ± 1.4; $P = .61$); KOOS–Symptoms (96.9 ± 0.9 vs 96.9 ± 1.3; $P = .98$); KOOS-QOL (96.3 ± 1.2 vs 96.4 ± 1.4; $P = .94$); KOOS–Sport/Rec (95.3 ± 1.0 vs 94.8 ± 0.82; $P = .78$); KOOS-ADL (97.8 ± 0.5 vs 97.5 ± 0.6; $P = .70$); WOMAC (95.6 ± 0.8 vs 95.3 ± 0.7; $P = .8$); IKDC (95.9 ± 0.9 vs 96.3 ± 0.6; $P = .74$), or Lysholm (97.2 ± 0.6 vs 97.1 ± 0.80; $P = .89$).

Determination of Clinically Meaningful Outcome Thresholds

The MCID was calculated for all 9 outcome measures at 6 months, 1 year, and 2 years postoperatively (Table 2).

TABLE 2
MCID Thresholds and Achievement Rates at 6 Months, 1 Year, and 2 Years After ACL Repair[a]

Outcome Measure	6-Month MCID	1-Year MCID	2-Year MCID
KOOS-ADL	5.1 (92.8)	4.9 (96.2)	4.7 (96.6)
KOOS-QOL	7.2 (99.1)	6.5 (100)	6.8 (98.8)
KOOS–Pain	5.8 (92.8)	5.7 (93.3)	6.0 (92.8)
KOOS–Sport/Rec	6.0 (95.4)	5.6 (96.2)	5.7 (96.2)
KOOS–Symptoms	5.9 (98.2)	5.6 (97.1)	5.8 (94.9)
Tegner	5.2 (97.2)	5.5 (94.1)	6.1 (93.3)
IKDC	14.3 (85.6)	8.4 (94.9)	11.9 (87.6)
Lysholm	5.2 (99.1)	5.3 (98.1)	5.6 (94.5)
WOMAC	10.4 (98.0)	4.6 (100)	5.1 (99.1)

[a]Data are reported as Frequency (%). ACL, anterior cruciate ligament; ADL, Activities of Daily Living; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; MCID, minimal clinically important difference; QOL, Quality of Life; Sport/Rec, Sport and Recreation; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

TABLE 3
PASS Thresholds and Achievement Rates at 6 Months, 1 Year, and 2 Years After ACL Repair[a]

Outcome Measure	6-Month PASS	1-Year PASS	2-Year PASS
KOOS-ADL	83.8 (100)	85.7 (100)	89.7 (100)
KOOS-QOL	62.5 (99.1)	75.0 (100)	81.3 (100)
KOOS–Pain	86.1 (98.2)	83.3 (100)	86.1 (100)
KOOS–Sport/Rec	80.0 (92.8)	85.0 (97.1)	89.0 (94.4)
KOOS–Symptoms	75.0 (100)	78.6 (100)	78.6 (100)
Tegner	8.3 (95.5)	8.5 (95.2)	8.9 (91.3)
IKDC	75.9 (98.9)	80.5 (100)	88.6 (100)
Lysholm	89.0 (79.1)	89.0 (91.3)	90.0 (89.9)
WOMAC	80.3 (100)	84.8 (100)	93.2 (95.7)

[a]Data are reported as Frequency (%). ACL, anterior cruciate ligament; ADL, Activities of Daily Living; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; PASS, Patient Acceptable Symptom State; QOL, Quality of Life; Sport/Rec, Sport and Recreation; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

PASS values at 6 months, 1 year, and 2 years postoperatively can be found in Table 3. ROC curves for the PASS are available separately as Supplemental Material. The area under the ROC curve (AUC) for the PASS at 6 months ranged between 0.81 and 0.96 for KOOS and 0.84 and 0.95 for non-KOOS outcome scores (Supplemental Figure S1). The AUC for the PASS at 1 year ranged between 0.81 and 0.91 for KOOS and 0.79 and 0.84 for non-KOOS outcome scores (Supplemental Figure S2). The AUC for the PASS at 2 years ranged between 0.81 and 0.91 for KOOS (Supplemental Figure S3) and 0.97 and 0.98 for non-KOOS outcome scores.

The absolute SCB and change-based SCB for all outcome measures at each time point are displayed in Table 4, and the ROC curves for the SCB are available as Supplemental Material. The AUC for the SCB at 6 months ranged between 0.98 and 0.99 for KOOS and non-KOOS outcome scores (Supplemental Figure S4). The AUC for the SCB at 1 year ranged between 0.97 and 0.99 for KOOS and between 0.95 and 0.98 for non-KOOS outcome scores (Supplemental Figure S5). The AUC for the SCB at 2 years ranged between 0.98 and 0.99 for KOOS and was 0.99 for all non-KOOS outcome scores (Supplemental Figure S6).

The changed-based SCB for all outcome measures at each time point are displayed in Table 4, and the ROC curves for the SCB are available as supplemental material. The AUC for the SCB at 6 months ranged between 0.83 and 0.92 for KOOS and between 0.86 and 0.89 for non-KOOS outcome scores (Supplemental Figure S7). The AUC for the SCB at 1 year ranged between 0.60 and 0.84 for KOOS and between 0.65 and 0.68 for non-KOOS outcome scores (Supplemental Figure S8). The AUC for the SCB at 2-years ranged between 0.56 and 0.83 for KOOS and 0.65 and 0.78 for non-KOOS outcome scores (Supplemental Figure S9).

Survivorship and Adverse Events

At 2 years postoperatively, a total of 11.3% of patients had rerupture of their ACL. Time to rerupture ranged from 6.5 to 21 months postoperatively. Pearson and point-biserial analyses demonstrated that the following variables were associated with the risk of surgical failure: BMI (r = -0.23; P = .044), bone contusion on MRI at 1 year postoperatively (r = 0.25; P = .013), ACL repair signal at 1 year postoperatively, (r = 0.31; P = .002), and degree of knee laxity measured with the KT-1000 at 1 year postoperatively (r = 0.27; P = .009). Sherman ACL tear grade (P = .49), performing concomitant procedures at the time of ACL repair (P = .84), and repair augmentation (P = .40) were not associated with failure. Multivariate logistic regression analysis determined that high-intensity signal of the ACL repair at 1 year postoperatively (odds ratio [OR], 31.7 [95% CI, 1.5-73.4]; P = .030) and bone contusion involving the tibiofemoral compartment on MRI at 1 year postoperatively (OR, 4.2 [95% CI, 1.7-25.2]; P = .041) were associated independently with an increased risk of ACL repair failure at 2 years postoperatively.

Overall, there were 9 complications not considering repair failure. Complications included synovitis (n = 3), hemarthrosis (n = 3), arthrofibrosis requiring manipulation under anesthesia (n = 2), and acute renal failure (n = 1).

DISCUSSION

The main findings of the current study were that (1) this series of primary ACL repair determined that the overall failure rate at 2 years was 11.3% and that the presence of tibiofemoral bone contusions or high signal intensity of the ACL repair at 1 year postoperatively was independently associated with a higher risk of failure; (2) clinically meaningful outcome thresholds for the MCID, PASS, and SCB were established at 6 months, 1 year, and 2 years after ACL repair for 9 commonly used outcome measures; and (3) patients can expect a high rate of clinically meaningful outcome achievement after ACL repair in terms of achieving

TABLE 4
Absolute and Change-Based SCB Thresholds and Achievement Rates at 6 Months, 1 Year, and 2 Years After ACL Repair[a]

	6-Month SCB			1-Year SCB			2-Year SCB		
Outcome Measure	Absolute	Change	Achieved, Absolute/ Change, %	Absolute	Change	Achieved, Absolute/ Change, %	Absolute	Change	Achieved, Absolute/ Change, %
KOOS-ADL	95.6	17.7	36.9/66.7	97.1	26.5	49.0/51.0	98.5	29.4	78.7/47.8
KOOS-QOL	93.8	31.3	26.1/53.1	98.5	32.4	34.6/62.5	100.0	33.8	44.9/75.2
KOOS–Pain	94.4	25.4	36.0/47.7	97.2	27.8	50.0/48.5	99.4	33.3	64.0/58.9
KOOS–Sport/Rec	95.0	40.1	45.9/38.7	100.0	45.0	26.9/45.2	100.0	45.0	36.7/52.2
KOOS–Symptoms	96.4	28.6	36.9/42.3	100.0	32.1	33.7/51.9	100.0	32.1	65.2/66.7
Tegner	9.4	2.2	52.7/51.2	9.5	2.3	63.8/60.6	9.73	2.4	67.4/63.7
IKDC	82.8	26.4	77.8 /51.4	95.4	27.6	65.3/67.3	98.6	32.2	37.1/51.1
Lysholm	94.0	23.0	52.7/51.8	95.0	24.0	64.4/55.8	100.0	26.4	40.4/55.6
WOMAC	90.2	23.4	67.3/62.4	94.7	27.3	45.1/54.1	95.3	29.5	80.9/62.2

[a]Change in SCB was calculated as the difference in outcome scores compared with preoperative values. ACL, anterior cruciate ligament; ADL, Activities of Daily Living; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; QOL, Quality of Life; SCB, substantial clinical benefit; Sport/Rec, Sport and Recreation; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

the MCID or PASS, whereas a considerable portion of patients fail to achieve the SCB.

A primary concern pertaining to the decision to proceed with primary repair of the ACL in the setting of acute proximal or complete midsubstance tears is the risk of rerupture. In the current series, we observed an overall 11.3% rate of ACL rerupture requiring revision ACL reconstruction. All reruptures in this series occurred beyond 1 year postoperatively, with the exception of 1 patient who was a professional soccer player who experienced a rerupture at 6.5 months postoperatively. This rerupture rate is comparable with survivorship reported in previous literature; however, it should be noted that 48% of patients had an ACL repair with suture augmentation, which may have influenced rerupture rates. Murray et al[19] reported a 14% rerupture rate using the bridge-enhanced ACL repair technique, which was not a significantly greater proportion compared with patients randomized to the ACL reconstruction arm of the study at 2-year follow-up. Notably, only midsubstance tears were included in their study, unlike the current study, which included proximal avulsions. Kosters et al[15] performed a randomized controlled trial in which they compared the efficacy of ACL repair with dynamic intraligamentary stabilization with ACL reconstruction and observed a rerupture rate necessitating single-stage ACL reconstruction of 16.3% in the repair group compared with 12.5% in the reconstruction group at 2-year follow-up. Hoogeslag et al[11] randomized 48 patients to dynamic augmented ACL suture repair or ACL reconstruction and reported an 8.7% rerupture rate in the repair group compared with a 19% rerupture rate in the reconstruction group at 2-year follow-up. To our knowledge, the current study is the largest prospective series evaluating the clinical and imaging-based outcomes of primary ACL repair for exclusively Sherman type 1 and 2 tears in which the rerupture rate was comparable but lower than previously reported. This finding confirms the plausibility of primary repair of the ACL as an efficacious approach to addressing acute ACL tears that confers sustainable integrity and function in the short term. However, patient selection is a critical aspect of the decision for ACL repair, as several studies have reported a failure rate of <5% to 10% with ACL reconstruction,[10,24] and ACL repair cannot be reliably performed in patients with Sherman type 3 to 5 tears.

Figure 5. Magnetic resonance imaging scan finding 1 year postoperatively of a right knee demonstrating a large area of bony edema in the posterolateral tibial plateau, with a lesser degree of edema at the medial aspect of the lateral femoral condyle.

Two MRI findings at 1 year postoperatively (ie, the presence of bone marrow edema involving the medial aspect of the lateral femoral condyle and PL tibial plateau [Figure 5] and high signal intensity of the ACL repair) were associated independently with repair failure at 2 years postoperatively. Specifically, the odds of ACL repair failure were increased by 420% and 3120% when the presence of bone contusions or high signal intensity were identified at 1 year, respectively.

The magnitude of these associations warrants attention and suggests that routine MRI of the operative knee at 1 year postoperatively may have considerable clinical value. Indeed, identifying these abnormalities at this specific time point may allow for more vigilance and additional interventions for at risk patients to mitigate the risk of future repair failure. These risk factors are also plausible in leading to repair failure, as bone contusions in the tibiofemoral compartment consistent with pivot-shift phenomenon may indicate fiber laxity not fully restored with the ACL repair and subsequent loss of the constraint to translation, compressive loading, and rotational stability normally conferred by the ACL, which may, in turn, lead to a bone contusion pattern involving the posterior tibial plateau and lateral femoral condyle.[18,20,21] Furthermore, high signal intensity may indicate edema, thickening, and an overall reduction in the mechanical properties of the ACL, including low tensile stress and decreased maximum load to failure of the ACL.[4,5,35]

Although previous literature has examined the clinical and functional outcomes that patients experience after undergoing primary ACL repair, the thresholds to achieve a clinically meaningful outcome and the propensity to achieve them have not been established. The current study provides a comprehensive collection of clinically meaningful outcome thresholds for 9 commonly administered patient-reported outcome measures used in the clinical setting for patients with ACL injuries. Specifically, thresholds were defined at 6 months, 1 year, and 2 years postoperatively to allow for an understanding of the trajectory of improvement across several time points after ACL repair.. Knowledge of these thresholds may allow the knee surgeon to more appropriately counsel patients preoperatively and help guide patient expectations.

Several trends were observed when quantifying the proportion of patients achieving clinically meaningful outcomes after ACL repair: (1) high rates of MCID achievement were observed in clinical and functional outcomes, including reductions in pain, as soon as 6 months after ACL repair; (2) the ability to discriminate between patients with the propensity to achieve the PASS and absolute SCB were good-to-excellent for the majority of outcome measures, with AUCs ranging between 0.80 to 0.99, while they ranged from fair to good when considering achievement of the SCB based on the change in outcome score; (3) MCID achievement remained high and consistent across all time points, though tended to be marginally lower at 6 months and 2 years compared with 1 year postoperatively; (4) for the majority of outcomes, it was more difficult to achieve an acceptable symptom state as measured by the PASS at 6 months and 2 years compared with 1 year postoperatively, though achievement rates were also consistently high; (5) SCB was generally not achieved until later in the postoperative period (at 2 years) for KOOS outcome measures by both absolute and changed-based SCB assessments, whereas trends for achieving SCB achievement for non-KOOS measures mimicked those of the MCID and PASS with an increase in achievement between 6 months and 1 year followed by a lower proportion of patients achieving the SCB at 2 years; and (6) the absolute postoperative scores required to achieve the SCB after ACL repair were very high, which is likely a function of the consistent improvement and ceiling effects seen in this patient series.

These findings suggest that clinically meaningful improvement is achieved in a time-dependent nature after ACL repair. Further, patients may experience a high rate of clinically meaningful improvement early in the short term. Furthermore, in this high-demand population, it suggests that important prognostic implications for measuring propensity for clinically meaningful outcome achievement exist at different time points, as patients in this series generally experienced a peak in improvement 1 year postoperatively. Therefore, meaningful improvement may be more difficult to achieve in the early recovery period and at longer follow-up as patients continue to test their ability to return to full activities, which is valuable information to convey during shared decision-making conversations when choosing approach to treatment. Though these trends may represent the natural course of recovery after ACL repair, another plausible explanation for the observation of time-dependent differences in outcome achievement may be the nature of the outcome measures administered, as different trends were observed for KOOS and non-KOOS outcomes. Future studies are warranted to determine which set of outcome measures best captures the timing with which clinically meaningful achievement is realized.

Limitations

A few limitations should be discussed when interpreting the results of this study. First, though the majority of patients were treated with primary repair without augmentation or bracing, almost half were treated with augmentation, and therefore the external validity of the outcome thresholds established in this study applied to other more homogeneous populations is unknown. Second, the addition of suture augmentation in select cases with Sherman type 2 tears introduces heterogeneity into the study population, and therefore the results of this study do not solely represent those of isolated ACL repair. This may also introduce a component of selection bias. Third, this prospective study followed patients over a 2-year time period, and therefore, the clinically meaningful outcome thresholds beyond 2 years remain unknown. Fourth, there was a ceiling effect observed in this study given the substantial improvements in clinical and functional outcomes observed in this population, which may have influenced the defining of the various outcome thresholds. Fifth, although KT-1000 arthroscopy values were recorded, other important measures of knee stability and function, such as pivot shift and range of motion, were not recorded and therefore could not be assessed. Sixth, all measurements were made by a single observer. Despite this individual's experience, this introduces the potential for human error into the measurements. Last, the patient population consisted primarily of young patients who were athletes, which is a function of the authors' (J.P.B., R.M., J.B.) practices, and this may also limit the generalizability of the reported findings.

CONCLUSION

The rate of clinically meaningful outcome improvement was high early after ACL repair, with the greatest proportion of patients achieving the MCID, PASS, and SCB at 1 year postoperatively. Bone contusions involving the PL tibia and lateral femoral condyle as well as high repair signal intensity at 1 year postoperatively were found to be independent predictors of failure at 2 years postoperatively. These findings may be useful when counseling patients on the trajectory of outcome improvement and in assessing overall recovery and prognosis.

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