Winner of the O'Donoghue Sports Injury Award

Lateral Extra-articular Tenodesis Reduces Failure of Hamstring Tendon Autograft Anterior Cruciate Ligament Reconstruction

2-Year Outcomes From the STABILITY Study Randomized Clinical Trial

Alan M.J. Getgood,* MD, FRCS(Tr&Orth), Dianne M. Bryant, MSc, PhD, Robert Litchfield, MD, FRCSC, Mark Heard, MD, FRCSC, Robert G. McCormack, MD, FRCSC, Alex Rezansoff, MD, FRCSC, Devin Peterson, MD, FRCSC, Davide Bardana, MD, FRCSC, Peter B. MacDonald, MD, FRCSC, Peter C.M. Verdonk, MD, PhD, Tim Spalding, FRCS, and the STABILITY Study Group

Investigation performed at The Fowler Kennedy Sport Medicine Clinic, Western University, London, Ontario, Canada

Background: Persistent anterolateral rotatory laxity after anterior cruciate ligament (ACL) reconstruction (ACLR) has been correlated with poor clinical outcomes and graft failure.

Hypothesis: We hypothesized that a single-bundle, hamstring ACLR in combination with a lateral extra-articular tenodesis (LET) would reduce the risk of ACLR failure in young, active individuals.

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

Methods: This is a multicenter, prospective, randomized clinical trial comparing a single-bundle, hamstring tendon ACLR with or without LET performed using a strip of iliotibial band. Patients 25 years or younger with an ACL-deficient knee were included and also had to meet at least 2 of the following 3 criteria: (1) grade 2 pivot shift or greater, (2) a desire to return to high-risk/pivoting sports, (3) and generalized ligamentous laxity (GLL). The primary outcome was ACLR clinical failure, a composite measure of rotatory laxity or a graft rupture. Secondary outcome measures included the P4 pain scale, Marx Activity Rating Scale, Knee injury Osteoarthritis and Outcome Score (KOOS), International Knee Documentation Committee score, and ACL Quality of Life Questionnaire. Patients were reviewed at 3, 6, 12, and 24 months postoperatively.

Results: A total of 618 patients (297 males; 48%) with a mean age of 18.9 years (range, 14-25 years) were randomized. A total of 436 (87.9%) patients presented preoperatively with high-grade rotatory laxity (grade 2 pivot shift or greater), and 215 (42.1%) were diagnosed as having GLL. There were 18 patients lost to follow-up and 11 who withdrew (~5%). In the ACLR group, 120/298 (40%) patients sustained the primary outcome of clinical failure, compared with 72/291 (25%) in the ACLR+LET group (relative risk reduction [RRR], 0.38; 95% CI, 0.21-0.52; $P < .0001$). A total of 45 patients experienced graft rupture, 34/298 (11%) in the ACLR group compared with 11/291 (4%) in the ACL+LET group (RRR, 0.67; 95% CI, 0.36-0.83; $P < .001$). The number needed to treat with LET to prevent 1 patient from graft rupture was 14.3 over the first 2 postoperative years. At 3 months, patients in the ACLR group had less pain as measured by the P4 ($P = .003$) and KOOS ($P = .007$), with KOOS pain persisting in favor of the ACLR group to 6 months ($P = .02$). No clinically important differences in patient-reported outcome measures were found between groups at other time points. The level of sports activity was similar between groups at 2 years after surgery, as measured by the Marx Activity Rating Scale ($P = .11$).

Conclusion: The addition of LET to a single-bundle hamstring tendon autograft ACLR in young patients at high risk of failure results in a statistically significant, clinically relevant reduction in graft rupture and persistent rotatory laxity at 2 years after surgery.

Registration: NCT02018354 (ClinicalTrials.gov identifier)

Keywords: anterior cruciate ligament reconstruction; lateral extra-articular tenodesis; anterolateral complex; graft failure; young patients

Traditional, single-bundle anterior cruciate ligament (ACL) reconstruction (ACLR) techniques have been demonstrated to provide good subjective results; however, multiple studies have shown that many patients continue to

The American Journal of Sports Medicine
2020;48(2):285–297
DOI: 10.1177/0363546519896333

experience objective rotatory laxity as measured by the pivot-shift test.[38,45] A positive pivot-shift test and persistent rotatory laxity have been shown to correlate with poor clinical outcomes, graft failure, and the subsequent need for revision surgery.[4] The rate of revision surgery has been shown to be higher in young patients returning to pivoting sports such as soccer, rugby, and basketball.[3,57,58]

Modifications of surgical techniques including double-bundle reconstruction[62] and anatomic single-bundle reconstruction[7,42] have been proposed in an attempt to address the problem of persistent anterolateral rotatory laxity. Although a number of biomechanical studies have shown improvements in rotatory control with these techniques,[28,30,60] no clinical study has resulted in superior patient-reported outcomes over conventional techniques.[35,53] Additionally, higher failure rates have been reported in a number of studies in which an anatomic surgical technique was performed, suggesting that a more anatomic ACL graft placement may lead to greater forces being placed on the ACL graft, resulting in a subsequent increase in risk of graft rupture.[9,42]

More recently, a significant focus has been placed upon the anterolateral complex (ALC), a combination of structures on the lateral side of the knee that have been demonstrated to aid in the control of anterolateral rotatory laxity.[8,15,20,39] The ALC includes the superficial and deep iliotibial band (ITB), the capsulo-osseous layer of the ITB,[19,27] and a thickening of the lateral capsule referred to as the anterolateral ligament (ALL).[8,54,55] Cadaveric studies have shown that in conjunction with ACLR, lateral extra-articular tenodesis (LET) is an excellent surgical technique to control anterolateral rotatory laxity of the knee due to injury or deficiency of the ALC.[14,22,23] LET is not a new concept. It was originally used to treat the ACL-deficient knee in the absence of intra-articular reconstruction techniques.[26] A number of procedures have been described, each having the common goal of placing a lateral soft tissue restraint a distance from the central pivot of the knee, thereby improving the mechanical advantage to control rotation when treating the ACL-deficient knee.[59] With the advent of intra-articular reconstruction, in particular the introduction of arthroscopic techniques, LET went somewhat out of fashion, particularly in light of a number of clinical studies that did not demonstrate any advantage of its use.[2,41] However, a number of more recent systematic reviews and meta-analyses have clearly demonstrated that the addition of LET to an intra-articular ACLR helped control rotatory laxity as measured by the pivot shift.[10,20,49] What is clear from these studies is that no adequately powered, methodologically rigorous study has been performed to detect a clinically relevant reduction in ACLR failure after a combination of an intra-articular ACLR with LET in patients who are thought to be at higher risk of early graft rupture.[20,31]

The purpose of this study was to determine whether single-bundle hamstring ACLR combined with a modified Lemaire LET results in a reduced rate of ACLR failure, compared with ACLR alone, in young patients undergoing ACLR who have risk factors that are thought to place them at high risk for graft rupture. The null hypothesis was that ACLR with LET offers similar outcomes compared with ACLR alone in patients who are at high risk of graft rupture.

METHODS

Study Design and Participants

This study was a pragmatic, parallel groups, multicenter, randomized clinical trial in which young patients with ACL deficiency were randomly allocated to undergo ACLR alone or ACLR with LET. A total of 7 study centers in Canada and 2 centers in Europe actively recruited patients. The study was approved by the Health Sciences Research Ethics Board at Western University and at local research ethics boards at each institution and was registered on Clinical Trials.gov (NCT02018354).

A full study protocol has previously been published.[16] Patients were approached for participation if they were between 14 and 25 years old, had an ACL-deficient knee, and were thought to be at higher risk of reinjury based on the presence of 2 or more of the following factors: (1) participation in competitive pivoting sports,[6] (2) presence of a grade 2 pivot shift or greater, (3) generalized ligamentous laxity (Beighton score of 4 or greater[5]) or genu recurvatum greater than 10°.[32] Patients were ineligible if any of the following were present: (1) previous ACLR on either knee, (2) multiligament injury ($\geq$2 ligaments requiring surgical attention), (3) a symptomatic articular cartilage defect requiring treatment other than debridement, (4) greater than 3° of asymmetric varus, (5) unable or unwilling to be followed up for 2 years postoperatively, (6) skeletally immature.

After willingness to participate was determined, arthroscopy of the knee was performed to confirm study eligibility. If eligible, the patient was then randomized in a 1:1 ratio, via telephone or a web-based software program (Empower Inc), to undergo either an ACLR alone or an

*Address correspondence to Alan M.J. Getgood, MD, FRCS(Tr&Orth), Fowler Kennedy Sport Medicine Clinic, 3M Centre, University of Western Ontario, London, ON N6K 4P3, Canada (email: alan.getgood@uwo.ca).

All authors are listed in the Authors Section at the end of this article.

Submitted July 6, 2019; accepted November 18, 2019.

Presented at the annual meeting of the AOSSM, Boston, Massachusetts, July 2019.

One or more of the authors has declared the following potential conflict of interest or source of funding: The Stability Study was funded by a research award from the International Society for Arthroscopic Knee Surgery and Orthopaedic Sports Medicine (ISAKOS). A.M.J.G. has received royalties from Smith & Nephew and Graymont Inc and consulting fees from Smith & Nephew, Ossur, and Olympus. R.L. has received consulting fees from Smith & Nephew. R.G.M. has received speaker fees from Bioventus, Pendopharm, Smith & Nephew, and Sanofi. T.S. has received speaking fees from Conmed, Smith & Nephew, and Joint Operations and consulting fees from Conmed. P.C.M.V. has received speaking fees from Conmed and Smith & Nephew and consulting fees from Conmed. L.A.H. has received speaking fees and consulting fees from Conmed. AOSSM checks author disclosures against the Open Payments Database (OPD). AOSSM has not conducted an independent investigation on the OPD and disclaims any liability or responsibility relating thereto.

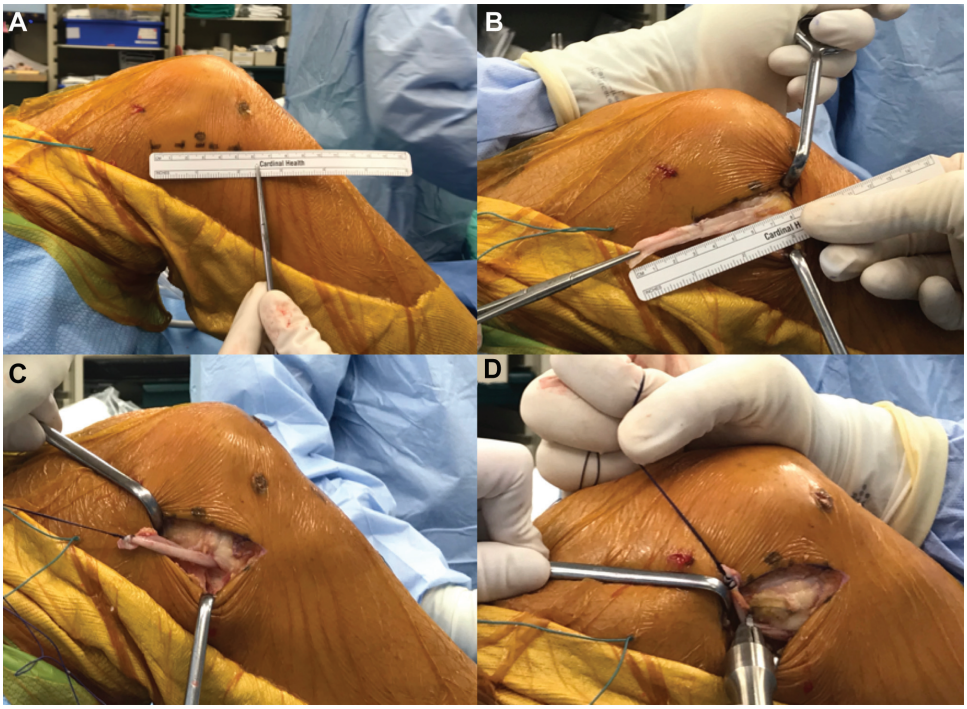

Figure 1. Lateral extra-articular tenodesis procedure. (A) Right knee at 90° of flexion demonstrating the position of a 5- to 6-cm incision placed just posterior to the lateral femoral epicondyle. (B) A 1 × 8–cm strip of the posterior half of the iliotibial band is fashioned leaving the attachment at the Gerdy tubercle intact. (C) The whipstitched free end of the graft is passed deep to the fibular collateral ligament close to its femoral attachment. (D) The graft is attached to the metaphyseal flare of the lateral femoral condyle in close proximity to the distal Kaplan fiber attachment. The graft is fixed with a Richards staple (Smith & Nephew) with the knee held at 60°-70° of flexion, neutral rotation, with minimal tension applied to the graft. The graft is then folded back on itself and sutured.

ACLR with LET. The randomization was stratified by surgeon, sex, and meniscal repair that would alter rehabilitation in permuted block sizes of 2 and 4 to ensure that the difference in outcome attributable to these factors was balanced between groups and that groups were similar in size.

Study Treatments

All patients, regardless of group allocation, underwent a hamstring autograft ACLR performed in a standardized fashion across all study sites. Specifically, an anatomic transportal femoral tunnel drilling technique was used. If the diameter of the hamstring ACL graft was less than 8 mm, the semitendinosus tendon and/or gracilis was tripled or quadrupled to achieve a larger graft diameter.[31] The maximum final graft diameter was then recorded. Femoral fixation was provided by a cortical suspensory fixation device (Endobutton CL, Smith & Nephew Inc; Exobutton, Conmed) and tibial fixation provided by interference screw with or without a back-up screw or staple fixation.

Of those patients randomized to receive LET, surgeons used a modified Lemaire technique (Figure 1).[34] An oblique skin incision was made between the lateral femoral epicondyle and Gerdy tubercle, measuring approximately 5 cm. A 1 × 8–cm strip was harvested from the ITB, leaving the attachment at the Gerdy tubercle intact. The proximal end of the ITB graft was whipstitched using a No. 1 Vicryl suture. The fibular collateral ligament (FCL) was identified, and the ITB graft was passed deep to the FCL and then fixed to the distal femur just anterior to the intermuscular septum and proximal to the femoral attachment site of the FCL using a barbed Richards fixation staple (Smith & Nephew). Fixation was performed with the knee at 60° to 70° of flexion and the tibia at 0° of rotation. Minimal tension was applied to the ITB graft. The free end of the ITB graft was then looped back onto itself and sutured via the No. 1 Vicryl suture. The ITB defect was then partially closed up to and not including the transverse retinacular ligament.

All patients, regardless of group allocation, received the same preoperative and postoperative oral and written standardized instructions for postoperative rehabilitation. The postoperative rehabilitation program focused on early range of motion and weightbearing as tolerated, unless a meniscal repair dictated otherwise. The patient's physical therapist received a copy of the standardized protocol. A brace was not routinely used. A detailed description of the postoperative rehabilitation protocol can be found in the Appendix (available in the online version of this article). No specific return to sports criteria were used, although surgeons were encouraged to wait at least 9 months after surgery before allowing return to high-risk sport, and a similar timeline was suggested in the standardized physical therapy protocol distributed to physical therapists.

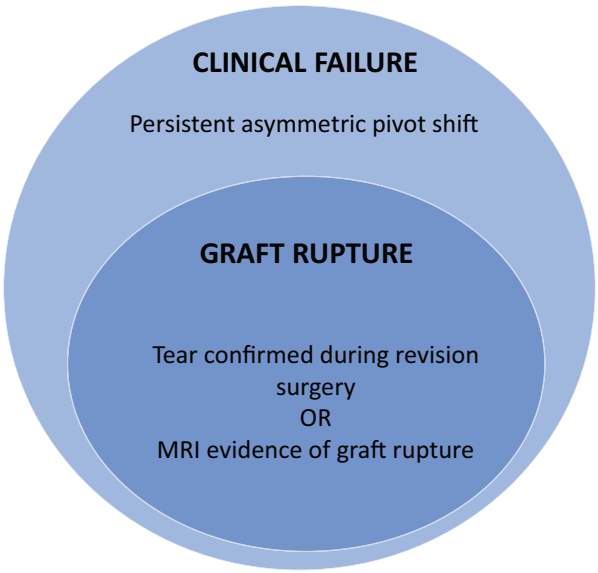

Figure 2. Diagram illustrating the composite primary outcome of anterior cruciate ligament reconstruction clinical failure.

Outcome Measures

Patients were evaluated at 3, 6, 12, and 24 months after surgery. A Tubigrip elastic bandage that covered the knee and distal thigh was worn by the patient to ensure that the skin incision used to perform the LET was not visible, thus ensuring that the examiners were blinded to group allocation.

The primary outcome was ACLR clinical failure, a composite measure of rotatory laxity defined as 1 or more of a persistent (detected at $\geq$2 visits) mild asymmetric pivot shift (grade 1), a moderate or severe (grade 2 or 3) asymmetric pivot shift at any follow-up visit, or a graft rupture. Graft rupture was defined as a tear of the graft confirmed by either magnetic resonance imaging or arthroscopic examination (Figure 2).

The pivot-shift test has been reported by Scholten et al[48] as the most specific of all clinical ACL tests (with a specificity of 0.97-0.99 and sensitivity of 0.18-0.48). The presence of a positive pivot-shift test after ACLR is a well-accepted definition of a failed ACLR.[35,37] A systematic review has also shown that a positive pivot-shift test correlates with a poor functional outcome.[4] An appropriately trained clinician who was not a member of the surgical team, blinded to group allocation, performed the assessment of the primary outcome at each visit. The pivot shift was graded as per the International Knee Documentation Committee (IKDC) as either equal (grade 0), a + glide (grade 1), a ++ clunk (grade 2), or +++ gross reduction (grade 3).[17]

Secondary outcome measures consisted of a range of patient-reported outcome scores including the P4, Marx Activity Rating Scale, ACL Quality of Life Questionnaire (ACL-QOL), IKDC score, and the Knee injury Osteoarthritis and Outcome Score (KOOS). The P4 consists of 4 items that address pain intensity in the morning, afternoon, evening, and with activity over the past 2 days.[51,52] Each item is scored on a 0- to-10 numerical rating scale; therefore, the total P4 scores can vary from 0 (no pain) to 40 (the highest possible pain level). The Marx Activity Rating Scale asks the patients to indicate how often each of 4 movements (running, cutting, deceleration, pivoting) were performed over the past year at their healthiest, most active state. Each item is scored from 0 (less than once per month) to 4 (>4 times per week) for a maximum score of 16.[33] The ACL-QOL is a disease-specific quality of life scale consisting of 5 domains that cover physical symptoms, occupational concerns, recreational activities, lifestyle, and social and emotional aspects.[36] Each item has one 100-mm visual analog scale response option, with labeled anchors at 0 mm (eg, extremely difficult) and 100 mm (eg, not difficult at all). Scores are calculated by summing the items to a total average score out of 100%, where 100% represents the best possible score. The subjective IKDC score is an 18-item, region-specific, patient-reported questionnaire containing the domains of symptoms, function, and sports activities.[24] Response types include 5-point Likert scales, 11-point Likert scales, and dichotomous "yes or no" responses. The IKDC has been proven to be a valid and reliable instrument for patients who have knee injury and disability.[21] The KOOS[46,47] is a 42-item knee-specific questionnaire with 5 separately reported domains, including pain (9 items), other symptoms (7 items), function in daily living (17 items), function in sports/recreation (5 items), and knee-related quality of life (4 items). Domain scores represent the average of all items in the domain standardized to a score from 0 to 100 (worst to best). This instrument has face validity, has demonstrated construct validity and excellent test-retest reliability for each domain (range, 0.75-0.93), and has been shown to be responsive to change.[56,46,47]

Adverse Events

Due to past concerns of complications associated with lateral tenodesis, any adverse event that occurred during the study period associated with the LET was recorded prospectively. Range of motion was measured in a standardized manner with a handheld goniometer to document motion loss, and any other signs of clinical problems such as persistent effusion or wound complications were recorded.

Statistical Analysis

We estimated that within this group of high-risk patients, the absolute risk (AR) of clinical failure (as defined above) in the patients who underwent ACLR would range from 25% to 35%.[29,31,37,57] It was thought that a relative risk reduction (RRR) in ACLR failure rate of at least 40% would merit a change in practice (ie, is of sufficient magnitude to warrant the additional costs related to the LET procedure). Thus, with 255 patients per group and a type I error rate of 5%, we would have approximately 80% power to detect the RRR in rate of clinical failure in the LET of 40% or greater. Because we expected a combined withdrawal and loss-to-follow-up rate of about 15%, we aimed to recruit a total of 600 patients (300 per group).

All patients were analyzed in the group to which they were randomized (ie, intention to treat principle). For the

primary outcome, we calculated the AR of clinical failure in each group, the RRR, and the risk difference (RD) of clinical failure with 95% CIs around each estimate, using a Mantel-Haenszel test (random effect of surgeon) to determine the significance of the association between the addition of LET and ACLR failure rates. The number needed to treat (NNT) was calculated to describe the number of patients who needed to receive LET to prevent 1 clinical failure over the first 2 postoperative years. We conducted the same analysis for graft rupture.

For the secondary outcome measures (P4, ACL-QOL, KOOS, IKDC), the mean and standard error for each group at each time point were calculated with the mean between-group difference with 95% CI at 1 and 2 years postoperatively. We used an analysis of covariance where the preoperative (baseline) score was used as a covariate. We also conducted nonparametric tests of the distribution and median values between groups and found similar results.

We conducted a sensitivity analysis using the multiple imputation function in SPSS (IBM version 25) and used the fully conditional specifications approach where potential predictors of missingness (center and visit) and outcome (sex, group allocation, and data collected for all visits of the same outcome measure) were included as predictors and imputed to improve the accuracy of predictions. We used 15 iterations, conducted a diagnostic evaluation on the data from each iteration, and conducted the analyses using the pooled data sets.

RESULTS

Patient Characteristics

Enrollment of patients occurred between January 2014 and March 2017. Of the 1033 patients screened for eligibility (Figure 3), 367 were ineligible and 48 declined participation. Thus, 618 patients were randomized; 589 completed the study, with 18 patients lost to follow-up and 11 withdrawals (5% attrition rate). No statistical differences were found between groups for any patient characteristics (Table 1). Importantly, the mean age of the patients was 18.9 years (range: 14-25 years) with over two thirds being involved in contact pivoting sports, 436 patients (87.9%) presenting preoperatively with high-grade rotatory laxity (grade 2 pivot or greater) and 215 patients (42.1%) diagnosed as having GLL, representing a cohort of patients at high risk of ACLR failure.

Primary Outcome

In the ACLR group, 120 of 298 (40%) patients sustained the primary outcome of ACLR clinical failure compared with 72 of 291 (25%) ACLR+LET patients (RRR, 0.38; 95% CI, 0.21-0.52; $P < .0001$). The RD was 15.5% (95% CI, 8%-23%). The NNT was 6.7; that is, approximately 7 patients with an ACL rupture need to undergo LET during ACLR to prevent 1 patient from experiencing clinical failure (persistent rotatory laxity or graft rupture) over the first 2 years postoperatively. In total, 45 patients

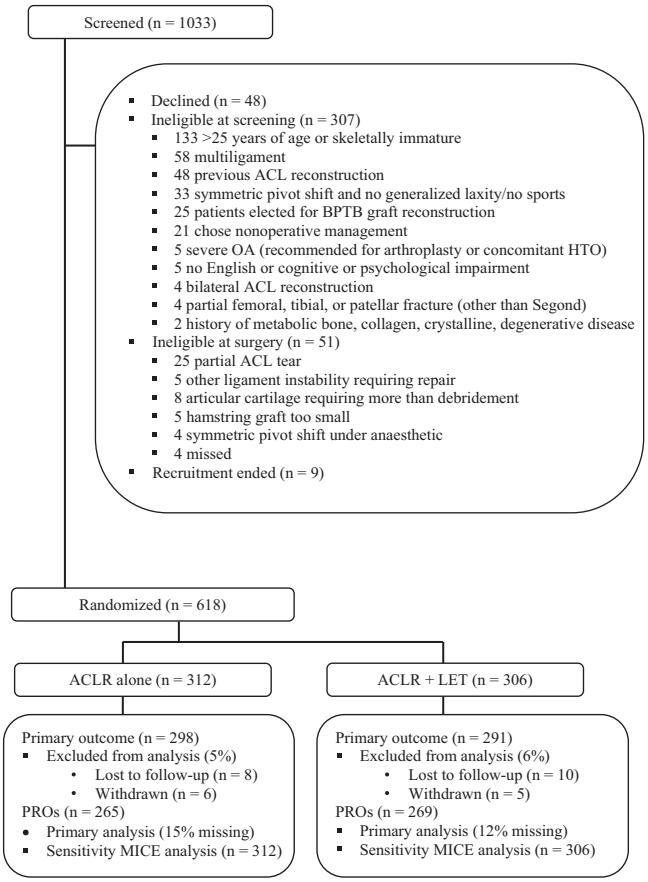

Figure 3. CONSORT (Consolidated Standards of Reporting Trials) flow diagram for the Stability Study. ACL, anterior cruciate ligament; ACLR, anterior cruciate ligament reconstruction; BPTB, bone–patellar tendon–bone; HTO, high tibial osteotomy; LET, lateral extra-articular tenodesis; MICE, multivariate imputation by chained equations; OA, osteoarthritis; PRO, patient-reported outcome.

experienced graft rupture, 34 of 298 (11%) in the ACLR group compared with 11 of 291 (4%) in the ACL+LET group (RRR, 0.67; 95% CI, 0.36-0.83; $P < .001$). The RD was 8% (95% CI, 3%-12%). The NNT was 14.3; that is, approximately 14 patients need to be treated with LET at the time of ACLR to prevent 1 patient from graft rupture over the first 2 years postoperatively.

Clinical failure and graft rupture were further broken down by age category, as shown in Figure 4. This shows that the failures were primarily in patients younger than 20 years, with the addition of the LET being protective for both age groups.

Secondary Outcomes

For both groups, pain was minimal by 3 months (approximately 8/40 on the P4) but was less in the ACLR-alone group compared with the ACLR+LET group (adjusted mean difference, –1.6; 95% CI, –2.7 to –0.6; $P = .003$). This difference was not observed past 3 months

TABLE 1
Patient Characteristics[a]

	ACLR Alone	ACLR+LET	*P* Value
Sex, male, n (%)	151 (48)	151 (49)	.44
Age, y	18.8 ± 3.2	19.1 ± 3.3	.33
Height, cm	173 ± 9	172 ± 9	.29
Weight, kg	71.8 ± 14.8	71.3 ± 14.3	.75
BMI, kg/m^2	23.8 ± 3.7	24.0 ± 3.8	.68
Beighton score, 0-9	3.1 ± 2.7	3.0 ± 2.8	.58
Eligibility criteria, n (%)[b]			.37
+GLL, +pivot, +sport	125 (40)	124 (41)	
+GLL, +pivot, –sport	11 (4)	9 (3)	
+GLL, –pivot, +sport	28 (9)	17 (6)	
–GLL, +pivot, +sport	144 (47)	153 (50)	
Time from injury to surgery, mo	8.1 ± 18.9	9.3 ± 16.7	.41
Operative limb dominant, n (%)	161 (52)	156 (52)	.98
Noncontact mechanism of injury, n (%)	176 (74)	166 (72)	.32
Sport played at time of injury, n (%)			.06
Soccer	100 (32)	122 (39)	
Basketball	54 (18)	36 (12)	
Football or rugby	54 (18)	56 (19)	
Downhill skiing	16 (5)	13 (4)	
Volleyball	19 (6)	12 (4)	
Other	66 (21)	66 (22)	
Sport played at time of RTS, n (%)			.38
Soccer	72 (23)	81 (26)	
Basketball	37 (12)	27 (9)	
Football or rugby	27 (9)	30 (10)	
Downhill skiing	13 (4)	10 (3)	
Volleyball	16 (5)	15 (5)	
Other	99 (32)	87 (28)	
Did not return to sport	47 (15)	56 (18)	
Smoking status, n (%)			.49
Current smoker	17 (5)	16 (5)	
Ex-smoker	11 (4)	6 (2)	
Nonsmoker	279 (91)	279 (93)	
Graft source, n (%)			.57
Semitendinosus and gracilis tendons	301 (96)	297 (96)	
3 strand	2 (<1)	2 (<1)	
4 strand	140 (45)	135 (44)	
5 strand	119 (38)	119 (39)	
6 strand	38 (12)	39 (13)	
Semitendinosus tendon	11 (4)	11 (4)	
3 strand	5 (2)	3 (1)	
4 strand	6 (2)	8 (3)	
Graft diameter, mm, median (min, max)	8 (6, 10)	8 (6, 10)	.32
Meniscectomy, n (%)			
Medial	21 (7)	18 (6)	.22
Lateral	67 (22)	54 (18)	.35
Both	11 (4)	12 (4)	.38
Meniscal repair, n (%)			<.05
Medial	75 (24)	91 (20)	
Lateral	36 (12)	24 (8)	
Both	19 (6)	18 (6)	
Change in rehabilitation due to meniscal repair, n (%)	51 (16)	50 (16)	.84
Chondral defect, ICRS >3 any compartment, n (%)	15 (5)	14 (4)	.52
Time to RTS, mo, median (IQR)	11 (8-14)	11 (8-17)	.01
Exposure to sport, mo, median (IQR)	13 (4-16)	13 (5-15)	.40

[a]Values are reported as mean ± SD unless otherwise noted. ACLR, anterior cruciate ligament reconstruction; BMI, body mass index; GLL, generalized ligamentous laxity; ICRS, International Cartilage Repair Society; IQR, interquartile range; LET, lateral extra-articular tenodesis; RTS, return to sport.

[b]Plus symbol indicates the feature is present; minus symbol indicates the feature is absent. GLL refers to a Beighton score ≥4 or knee hyperextension of ≥10°; pivot refers to a preoperative asymmetry grade 2 or more; sport refers to a participation in organized sports.

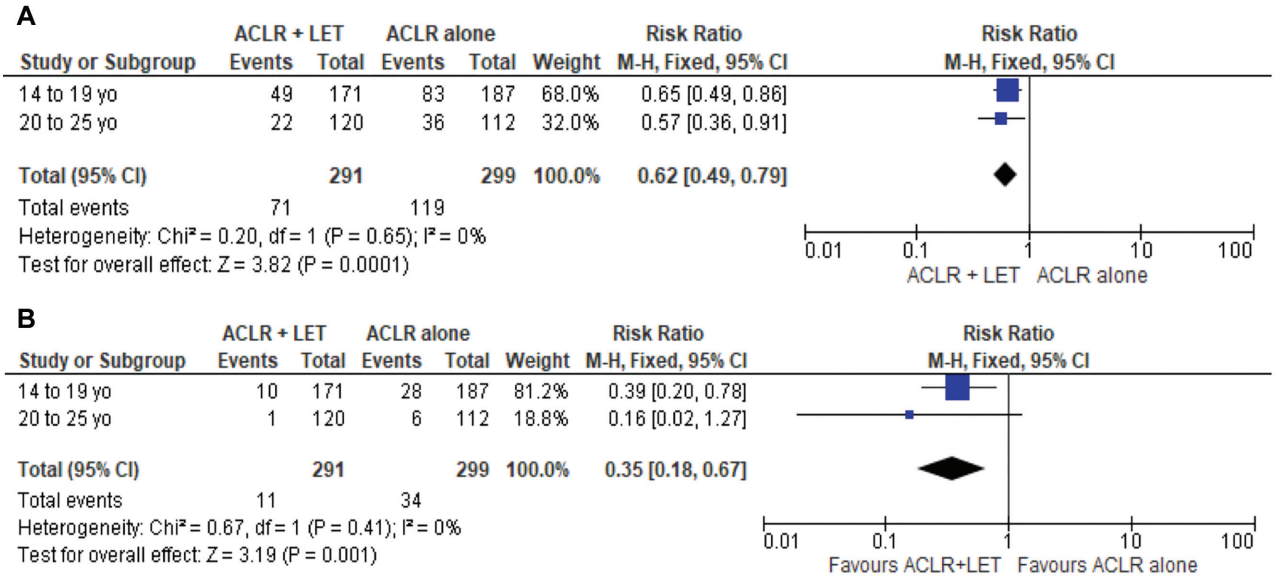

Figure 4. Forest plots showing (A) clinical failure by age 14-19 years and 20-25 years and (B) graft failure by age 14-19 years and 20-25 years. ACLR, anterior cruciate ligament reconstruction; LET, lateral extra-articular tenodesis; M-H, Mantel-Haenszel.

postoperatively (Table 2). Figure 5 presents the median and interquartile range of the same data by group and by visit.

As shown in Table 1, there was a slight delay to return to sports for the ACLR+LET group ($P = .01$) with no difference in months of exposure to sport ($P = .4$). Importantly, no difference was found in the type of sports that patients returned to postoperatively. Furthermore, both groups had a similar Marx Activity Rating Scale score at baseline and 24 months postoperatively (Table 2). Preoperatively, the median activity rating was nearly maximal for both groups. However, by 24 months postoperatively, both groups were approaching a similar level of activity as preoperatively with a distribution that implies a greater proportion of patients in the ACLR-alone group with lower levels of activity (Figure 6).

The ACL-QOL disease-specific questionnaire showed continuing and similar improvement in quality of life between the 2 groups over the first 2 postoperative years after ACLR (Figure 7). The knee-specific IKDC (Figure 8) and all domains of the KOOS (Figure 9) were statistically different at 3 and 6 months postoperatively in favor of the ACLR-alone group. These differences were no longer present at 12 and 24 months postoperatively. Nonparametric tests of the medians and distributions for all 3 outcome measures showed similar or even less impressive between-group differences. Analyses of between-group differences using repeated measures were not statistically significant.

Safety

Overall, the number of LET-related complications or adverse events was low (Table 3). The addition of LET resulted in an increased number of patients reporting hardware irritation in the LET group (14 vs 4). In the LET group, 13 of 14 patients reported pain or sensitivity over the LET staple, and 1 of 14 had pain over the ACLR staples. Of the 13 patients with LET hardware pain, 10 patients elected to have the LET staple removed. All patients reporting pain over the ACLR staples elected to have them removed.

No difference in range of motion was observed between the 2 groups at 12 and 24 months (Table 4).

DISCUSSION

The most important finding from this study was that the addition of LET to a single-bundle hamstring tendon autograft ACLR in patients younger than 25 years significantly reduced the composite primary outcome of graft rupture and persistent rotatory laxity (clinical failure) compared with conventional ACLR alone. To our knowledge, this is the first adequately powered study that has shown a clinically significant reduction in failure rates when comparing 2 different ACLR surgical techniques specifically in a young cohort of patients.

Multiple studies have demonstrated that age is a significant predictor of ACL graft rupture, likely as a result of the increased level of sports participation.[31,57] Most randomized studies investigating ACLR surgery have included all patients with an ACL injury and have not specifically focused on patients in the younger, high-risk age group. By limiting inclusion to patients between 15 and 25 years of age and requiring patients to have a number of physical characteristics associated with high-grade rotatory laxity, we ensured that our study involved patients who were deemed as being at high risk of reinjury, which is clearly demonstrated by the event rate that we observed between the 2 patient groups. Notably, the addition of LET to the hamstring tendon autograft ACLR resulted in an RRR in graft rupture of 66% (95% CI, 0.35-0.81) and an RRR in ACLR clinical failure (graft rupture plus persistent

TABLE 2
Results of Patient-Reported Outcomes for Each Group Over Time[a]

	ACLR Alone	ACLR+LET	Adjusted MD (95% CI)	*P* Value
P4				
3 mo	6.8 ± 0.4	8.4 ± 0.4	–1.6 (–2.7 to –0.6)	**.003**
6 mo	4.5 ± 0.4	5.4 ± 0.4	–0.8 (–1.9 to 0.1)	.09
12 mo	3.1 ± 0.3	3.3 ± 0.3	0.0 (–0.9 to 0.6)	.92
24 mo	2.6 ± 0.3	2.7 ± 0.3	–0.2 (–1.1 to 0.7)	.70
Marx Activity Rating Scale				
Baseline	12.7 ± 4.7	12.1 ± 5.5	1.5 (–0.2 to 1.4)	.13
24 mo	9.6 ± 4.6	10.3 ± 4.5	–1.6 (–1.4 to 0.1)	.11
ACL-QOL				
3 mo	43.5 ± 1.0	41.6 ± 1.0	1.9 (–0.8 to 4.7)	.17
6 mo	56.5 ± 1.2	53.7 ± 1.2	2.8 (–0.5 to 6.1)	.09
12 mo	74.0 ± 1.4	69.1 ± 1.4	4.9 (1.0 to 8.7)	**.01**
24 mo	78.2 ± 1.5	76.7 ± 1.5	1.5 (–2.7 to 5.8)	.48
IKDC				
3 mo	62.9 ± 0.8	60.2 ± 0.8	2.7 (0.6 to 4.9)	**.01**
6 mo	76.7 ± 0.7	74.5 ± 0.7	2.2 (0.2 to 4.1)	**.03**
12 mo	85.0 ± 0.8	83.3 ± 0.8	1.7 (–0.5 to 4.0)	.14
24 mo	86.6 ± 0.8	87.3 ± 0.8	–0.7 (–3.1 to 1.6)	.54
KOOS Pain				
3 mo	81.5 ± 0.7	78.8 ± 0.7	2.7 (0.7 to 4.6)	**.007**
6 mo	87.6 ± 0.6	85.7 ± 0.6	1.8 (–0.2 to 3.5)	**.02**
12 mo	91.2 ± 0.6	90.2 ± 0.6	1.1 (–0.5 to 2.7)	.20
24 mo	91.9 ± 0.6	92.1 ± 0.6	–0.3 (–2.0 to 1.4)	.76
KOOS Symptoms				
3 mo	71.8 ± 0.9	67.9 ± 0.9	3.4 (1.0 to 5.9)	**.005**
6 mo	80.7 ± 0.8	77.0 ± 0.8	3.6 (1.3 to 5.9)	**.002**
12 mo	83.1 ± 0.8	82.7 ± 0.8	0.4 (–1.9 to 2.6)	.75
24 mo	84.6 ± 0.8	84.7 ± 0.8	–0.1 (–2.4 to 2.2)	.92
KOOS ADLs				
3 mo	91.0 ± 0.6	88.5 ± 0.6	2.5 (0.7 to 4.2)	**.006**
6 mo	96.1 ± 0.4	94.6 ± 0.4	1.6 (0.5 to 2.6)	**.004**
12 mo	97.2 ± 0.4	96.5 ± 0.4	0.7 (–1.4 to 1.7)	.18
24 mo	97.2 ± 0.4	97.0 ± 0.4	0.2 (–0.9 to 1.3)	.72
KOOS Recreation				
3 mo	54.8 ± 1.3	50.1 ± 1.0	4.7 (1.0 to 8.4)	**.01**
6 mo	74.2 ± 1.0	70.7 ± 1.1	3.4 (0.5 to 6.4)	**.02**
12 mo	82.5 ± 1.1	80.9 ± 1.1	1.6 (–1.4 to 4.6)	.31
24 mo	85.1 ± 1.1	85.3 ± 1.1	0.2 (–3.2 to 2.6)	.90
KOOS QOL				
3 mo	45.4 ± 1.0	42.4 ± 1.0	3.0 (0.2 to 5.8)	**.03**
6 mo	58.0 ± 1.1	54.4 ± 1.1	3.6 (0.6 to 6.5)	**.02**
12 mo	69.3 ± 1.2	65.2 ± 1.2	4.0 (0.8 to 7.3)	**.02**
24 mo	74.9 ± 1.3	75.4 ± 1.3	–1.1 (–4.7 to 2.5)	.55

[a]Values for the 2 groups are expressed as mean ± SE. *P* values in bold represent statistically significant difference. ACL, anterior cruciate ligament; ACL-QOL, ACL Quality of Life Questionnaire; ACLR, ACL reconstruction; ACLR+LET, ACLR with lateral extra-articular tenodesis; IKDC, International Knee Documentation Committee; KOOS, Knee injury Osteoarthritis and Outcome Score; KOOS ADLs, KOOS Activities of Daily Living; KOOS QOL, KOOS Quality of Life; MD, mean between-groups difference.

rotatory laxity) of nearly 40% (95% CI, 0.22-0.52). We believe that this difference is clinically important and should probably change current practice. Interestingly, the majority of graft ruptures occurred in the under-20 age group, suggesting that these patients may represent the highest risk group. However, due to the smaller number of patients and low event rate in the over-20 age group, we cannot draw firm conclusions from this with any statistical certainty. As with previous studies, the higher risk of reinjury is probably less likely to do with biological young age but more an indication of sports participation and exposure to at-risk activities.[25]

We did observe a similar activity level between groups as shown by the Marx Activity Rating Scale at 24 months postoperatively. The difference in the distribution of activity at 24 months postoperatively (Figure 6) can likely be explained by the greater number of re-ruptures in the ACLR-alone group, where patients who had a second ACLR were unlikely to have returned to full activity by study end at 24 months.

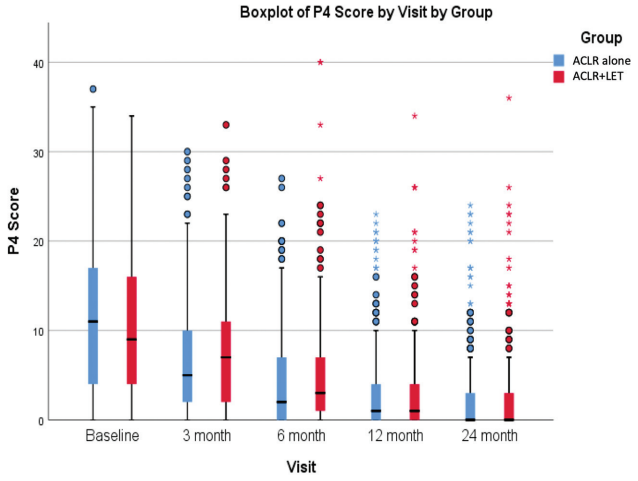

Figure 5. Boxplot showing P4 score by group by visit. Solid black lines represents group median, colored boxes represent interquartile range, whiskers represent minimum and maximum values, solid dots represent known outliers, and asterisks represent unknown outliers. ACLR, anterior cruciate ligament reconstruction; LET, lateral extra-articular tenodesis.

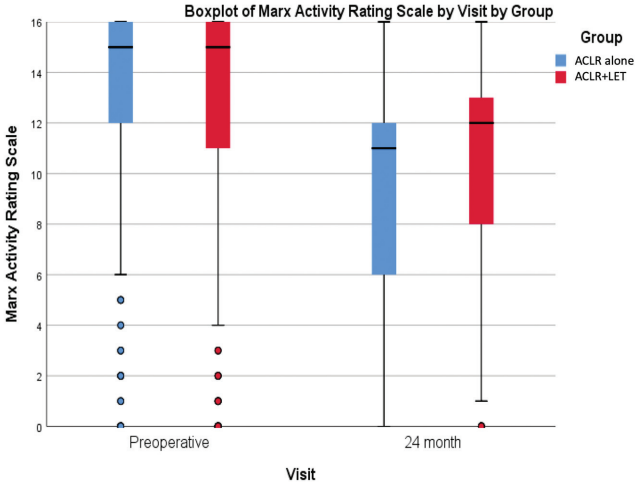

Figure 6. Boxplot showing Marx Activity Rating Scale by group by visit. Solid black lines represent group median, colored boxes represent interquartile range, whiskers represent minimum and maximum values, and solid dots represent known outliers. ACLR, anterior cruciate ligament reconstruction; LET, lateral extra-articular tenodesis.

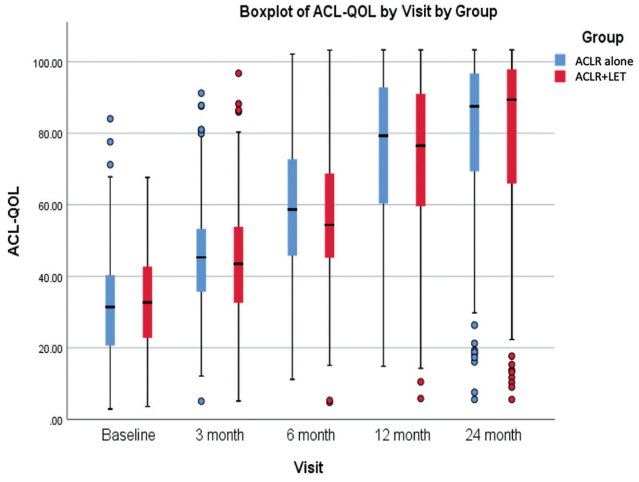

Figure 7. Boxplot showing ACL Quality of Life Questionnaire (ACL-QOL) score by group by visit. Solid black lines represent group median, colored boxes represent interquartile range, whiskers represent minimum and maximum values, and solid dots represent known outliers. ACL, anterior cruciate ligament; ACLR, ACL reconstruction; LET, lateral extra-articular tenodesis.

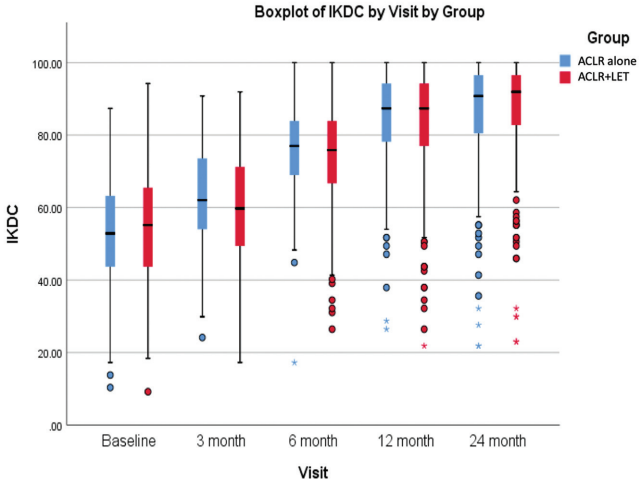

Figure 8. Boxplot showing International Knee Documentation Committee (IKDC) score by group by visit. Solid black lines represents group median, colored boxes represent interquartile range, whiskers represent minimum and maximum values, solid dots represent known outliers, and asterisks represent unknown outliers. ACLR, anterior cruciate ligament reconstruction; LET, lateral extra-articular tenodesis.

Furthermore, return to sports was delayed by approximately 1 month in the ACLR+LET group. However, when adjusted for exposure time, the delay in return to sport could not explain the difference in clinical failure and graft rupture between groups.

Our results support the findings of recent biomechanical laboratory studies that have demonstrated current ACLR techniques do not restore native knee kinematics.[14,23] In these cadaveric studies, normal knee kinematics are restored only by the addition of LET or a reconstruction of the ALC to the intra-articular ACLR. This finding suggests that anterolateral rotatory laxity results from a combination of injury to the ACL as well as the ALC and that in certain situations an ACLR alone may be unable to completely control anterolateral rotatory laxity. Therefore, LET or reconstruction of the ALC may be necessary to restore rotation to normal.

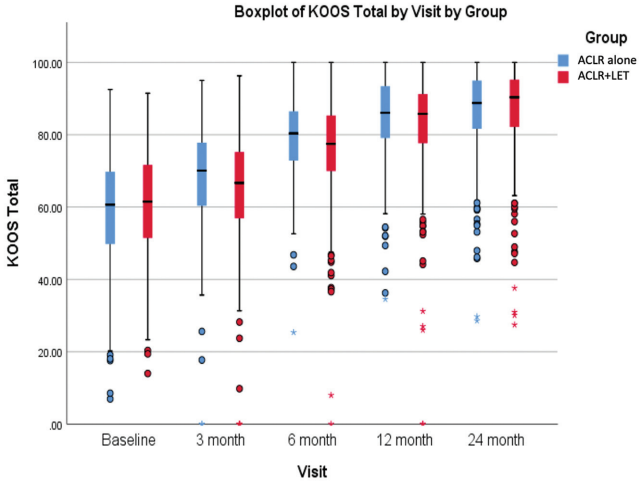

Figure 9. Boxplot showing Knee injury Osteoarthritis and Outcome Score (KOOS) total score by group by visit. Solid black lines represents group median, colored boxes represent interquartile range, whiskers represent minimum and maximum values, solid dots represent known outliers, and asterisks represent unknown outliers. ACLR, anterior cruciate ligament reconstruction; LET, lateral extra-articular tenodesis.

Although imaging and clinical studies have documented that injuries to the ALC can often be observed after an ACL injury,[13,18] it is not clear whether acute injuries to the ALC heal. Although our study demonstrates that the addition of LET decreases ACLR failure and, importantly, graft rupture rates, the question of the mechanism of action of the LET cannot be answered. One hypothesis is that LET may reduce load on the healing intra-articular ACL graft. This hypothesis is supported by a cadaveric study by Engebretsen et al,[12] who demonstrated that the addition of LET to ACLR resulted in a reduction of ACL graft strain by 43%. It is possible that LET may function to protect the ACL graft while it heals and remodels during the ligamentization phase.

This is not the first study to demonstrate the advantages of adding an extra-articular procedure to an intra-articular ACLR. Noyes and Barber[40] published a series of allograft intra-articular reconstructions augmented with LET using a strip of ITB. The investigators reported significant improvements in all outcome scores at 2 years, with a statistically significant reduction in graft failure in the extra-articular group (3%) compared with the intra-articular group (16%). More recently, Sonnery-Cottet et al[50] published a nonrandomized comparative cohort of 512 ACLRs performed with either patellar tendon autograft or hamstring tendon autograft, the latter with or without an ALL augmentation. Similar to the current study, those investigators observed that the addition of the ALL reconstruction resulted in a significantly reduced graft rupture rate.

However, a study by O'Brien et al[41] comparing bone–patellar tendon–bone autograft ACLR with or without LET in 80 patients seemed to have a huge influence on the reduced use of LET in ACLR in North America.[43] This

TABLE 3
LET-Related Adverse Events[a]

Complication/Adverse Event	Frequency, n (%)
Intraoperative	
LET graft difficulties at surgery	6 (2)
Damage to FCL attachment (repaired)	1 (<1)
Postoperative	
Hematoma over LET site	3 (<1)
ITB snapping	2 (<1)
LET hardware removal	10 (3)
Overconstrained lateral compartment	1 (<1)

[a]FCL, fibular collateral ligament; ITB, iliotibial band; LET, lateral extra-articular tenodesis.

underpowered, nonrandomized retrospective review observed no clinical differences between groups and concluded that the addition of LET conferred no benefit and may result in overconstraint of joint motion and an increased risk of lateral compartment osteoarthritis (OA). However, 2 European studies with greater than 20 years follow-up have not demonstrated an increased rate of OA development with the addition of LET.[44,61] Furthermore, a recent meta-analysis also found no correlation between LET and OA.[11] Importantly, in the current study, we did not find a significant increase in the number of serious adverse events in the LET group. We did observe that a number of patients in the ACLR+LET group reported hardware irritation that necessitated staple removal. Additionally, we found that a greater number of patients in the ACLR+LET group had higher pain scores in the first 3 months compared with the ACLR-only group. Although we noted statistically significant differences in patient-reported outcome measures out to 6 months in favor of ACLR alone, these did not reach a minimal clinically important difference for the respective scores. Longer term follow-up of our patients is required to investigate whether there are differences in lateral compartment degenerative change.

Our study has a number of limitations. First, patients were not blinded to their treatment allocation. This was not possible due to the presence of the lateral incision used to perform the LET. However, this bias was minimized by having the patients wear a Tubigrip bandage that covered the lateral incision at the time of clinical examination, and a clinician blinded to group allocation assessed the primary outcome with a second data assessor blinded to group allocation assessing secondary outcomes. A second limitation is that we used the pivot-shift test as a component of the primary outcome assessment. Although we recognize that it is difficult to standardize the pivot shift across 9 centers, we attempted to reduce the subjectivity of the test by making its interpretation as simple as possible. An asymmetric grade 1 pivot shift had to be recorded on at least 2 separate clinic visits, and the determination of an asymmetric grade 2 or 3 pivot shift had to be made only once, with no emphasis on differentiating between grades 2 and 3.

Third, we elected to use only hamstring tendon autografts for the ACLR. The use of a bone–patellar tendon–bone autograft might produce different results.[37] We chose

TABLE 4
Range of Motion Between Groups[a]

	ACLR Alone		ACLR+LET		Adjusted Mean Difference	
	Operative	Side-to-Side	Operative	Side-to-Side	Side-to-Side (95% CI)	*P* Value
Passive extension						
Baseline	–1.9 ± 0.4	1.5 ± 0.2	–2.8 ± 0.3	1.3 ± 0.2	0.2 (–0.4 to 0.8)	.43
12 mo	–3.0 ± 0.3	0.8 ± 0.2	–3.2 ± 0.3	0.9 ± 0.2	–0.1 (–0.5 to 0.3)	.63
24 mo	–3.1 ± 0.3	0.6 ± 0.1	–3.2 ± 0.3	0.8 ± 0.1	–0.2 (–0.6 to 0.2)	.27
Active assisted flexion						
Baseline	137.5 ± 0.6	–4.1 ± 0.5	138.9 ± 0.6	–3.1 ± 0.5	–0.9 (–2.2 to 0.4)	.16
12 mo	139.9 ± 0.5	–2.5 ± 0.3	139.7 ± 0.5	–2.2 ± 0.3	–0.3 (–1.2 to 0.7)	.58
24 mo	140.6 ± 0.6	–2.5 ± 0.3	140.4 ± 0.6	–2.2 ± 0.3	–0.3 (–1.2 to 0.6)	.53

[a]Values for the 2 groups are expressed as mean ± SE. ACLR, anterior cruciate ligament reconstruction; LET, lateral extra-articular tenodesis.

to use a hamstring tendon autograft for the ACLR as this was the most common ACL autograft used at the various study centers and is the most common autograft used in the majority of large ACL registry data series,[1,29,38] making the results of this study widely applicable. Based on studies demonstrating higher failure rates for hamstring autograft ACLR performed with graft diameters less than 8 mm, an attempt was made to increase graft diameter in all patients who had a graft diameter of less than 8 mm in our study.[31] A fourth limitation of our study is that due to the age limits we placed on our eligibility criteria, we cannot be certain that our findings apply to patients younger than 15 years or older than 25 years. However, we do believe that the 15- to 25-year age demographic is extremely important due to the level of competitive sports participation and the high incidence of graft ruptures reported in this population.[25,57] Another limitation is, because this was a large multicenter trial, we were unable to ensure or measure compliance to physical therapy recommendations or standardization of rehabilitation across all study sites. Although we did provide patients with standardized oral and written instructions as per the agreed upon rehabilitation protocol, it is possible that not all patients completed an ideal rehabilitation regimen. However, because of the large numbers of participants in this study, we expect that adherence to rehabilitation was balanced between groups. Finally, we did not standardize the time from surgery to return to sports. Similar to the rehabilitation protocol, patients were provided similar instructions from their treating clinicians, with a general recommendation of a minimum 9-month interval between surgery and return to sports participation. Similar to adherence to rehabilitation recommendations, we expect that patient adherence to surgeon recommendations regarding when to return to sports would be similar between treatment groups.

CONCLUSION

The addition of LET to a single-bundle hamstring tendon autograft ACLR in young patients at high risk of failure results in a statistically significant, clinically relevant reduction in graft rupture and persistent rotatory laxity at 2 years postoperatively.

AUTHORS

Alan M.J. Getgood, MD, FRCS (Fowler Kennedy Sport Medicine Clinic; Department of Surgery, Schulich School of Medicine and Dentistry, Western University; Lawson Research, London Health Sciences Centre, London, Ontario, Canada); Dianne M. Bryant, MSc, PhD (Faculty of Health Sciences, School of Physical Therapy, Western University; Fowler Kennedy Sport Medicine Clinic; Lawson Research, London Health Sciences Centre, London, Ontario, Canada); Robert Litchfield, MD, FRCSC (Fowler Kennedy Sport Medicine Clinic; Department of Surgery, Schulich School of Medicine and Dentistry, Western University, London, Ontario, Canada); Mark Heard, MD, FRCSC (Banff Sport Medicine; Department of Surgery, University of Calgary, Calgary, Alberta, Canada); Robert G. McCormack, MD, FRCSC (Department of Orthopedics, University of British Columbia, British Columbia, Canada; Fraser Orthopaedic Institute, New Westminster, British Columbia, Canada); Alex Rezansoff, MD, FRCSC (Department of Surgery, University of Calgary; University of Calgary Sport Medicine Centre, Calgary, Alberta, Canada); Devin Peterson, MD, FRCSC (Department of Surgery, McMaster University, Hamilton, Ontario, Canada); Davide Bardana, MD, FRCSC (Department of Surgery, Queen's University, Kingston, Ontario, Canada); Peter B. MacDonald, MD, FRCSC (Department of Surgery, University of Manitoba; Pan Am Clinic, Winnipeg, Manitoba, Canada); Peter C.M. Verdonk, MD, PhD (MoRe Foundation, Antwerp, Belgium; ORTHOCA, Antwerp, Belgium); Tim Spalding, FRCS (University Hospital Coventry and Warwickshire NHS Trust, Coventry, United Kingdom); STABILITY Study Group: Kevin Willits, MD, FRCSC, Trevor Birmingham, PhD, Chris Hewison, MSc, Stacey Wanlin, Andrew Firth, MSc, Ryan Pinto, MSc, Ashley Martindale, Lindsey O'Neill, MSc, Morgan Jennings, MSc, Michal Daniluk MSc (London Health Science Centre, Western University, Fowler Kennedy Sport Medicine Clinic, London, Ontario, Canada); Dory Boyer, MD, FRCSC, Mauri Zomar, CCRP, Karyn Moon, Raely Pritchett, Krystan Payne, Brenda Fan, Bindu Mohan (Fraser Health Authority, New Westminster, British Columbia, Canada); Gregory M. Buchko, MD, FRCSC, Laurie A. Hiemstra, MD, PhD, FRCSC, Sarah Kerslake, Jeremy Tynedal (Banff Sport Medicine, Banff, Alberta, Canada); Greg Stranges, MD, FRCSC, Sheila Mcrae, MSc, PhD, LeeAnne Gullett, Holly Brown, Alexandra

Legary, Alison Longo, Mat Christian, Celeste Ferguson (Pan Am Clinic, Winnipeg, Manitoba, Canada); Nick Mohtadi, MD, FRCSC, Rhamona Barber, Denise Chan, Caitlin Campbell, Alexandra Garven, Karen Pulsifer, Michelle Mayer (University of Calgary, Sport Medicine Centre, Calgary, Alberta, Canada); Nicole Simunovic, Andrew Duong, David Robinson, David Levy, Matt Skelly, Ajaykumar Shanmugaraj (McMaster University, Hamilton, Ontario, Canada); Fiona Howells, Murray Tough (Queens University, Kingston, Ontario, Canada); Tim Spalding, Pete Thompson, FRCS, Andrew Metcalfe, FRCS, Laura Asplin, Alisen Dube, Louise Clarkson, Jaclyn Brown, Alison Bolsover, Carolyn Bradshaw, Larissa Belgrove, Francis Millan, Sylvia Turner, Sarah Verdugo, Janet Lowe, Debra Dunne, Kerri McGowan, Charlie-Marie Suddens (University Hospitals Coventry Warwickshire NHS Trust, Coventry, United Kingdom); Geert Declercq, MD, Kristien Vuylsteke, Mieke Van Haver (ORTHOCA, Antwerp, Belgium).

REFERENCES

1. Ahlden M, Samuelsson K, Sernert N, Forssblad M, Karlsson J, Kartus J. The Swedish National Anterior Cruciate Ligament Register: a report on baseline variables and outcomes of surgery for almost 18,000 patients. *Am J Sports Med*. 2012;40(10):2230-2235.
2. Anderson AF, Snyder RB, Lipscomb AB Jr. Anterior cruciate ligament reconstruction: a prospective randomized study of three surgical methods. *Am J Sports Med*. 2001;29(3):272-279.
3. Ardern CL, Webster KE, Taylor NF, Feller JA. Return to sport following anterior cruciate ligament reconstruction surgery: a systematic review and meta-analysis of the state of play. *Br J Sports Med*. 2011;45(7):596-606.
4. Ayeni OR, Chahal M, Tran MN, Sprague S. Pivot shift as an outcome measure for ACL reconstruction: a systematic review. *Knee Surg Sports Traumatol Arthrosc*. 2012;20(4):767-777.
5. Beighton P, Solomon L, Soskolne CL. Articular mobility in an African population. *Ann Rheum Dis*. 1973;32(5):413-418.
6. Borchers JR, Pedroza A, Kaeding C. Activity level and graft type as risk factors for anterior cruciate ligament graft failure: a case-control study. *Am J Sports Med*. 2009;37(12):2362-2367.
7. Carmont MR, Scheffler S, Spalding T, Brown J, Sutton PM. Anatomical single bundle anterior cruciate ligament reconstruction. *Curr Rev Musculoskelet Med*. 2011;4(2):65-72.
8. Claes S, Vereecke E, Maes M, Victor J, Verdonk P, Bellemans J. Anatomy of the anterolateral ligament of the knee. *J Anat*. 2013;223(4):321-328.
9. Clatworthy M, Sauer S, Roberts T. Transportal central femoral tunnel placement has a significantly higher revision rate than transtibial AM femoral tunnel placement in hamstring ACL reconstruction. *Knee Surg Sports Traumatol Arthrosc*. 2019;27(1):124-129.
10. Devitt BM, Bell SW, Ardern CL, et al. The role of lateral extra-articular tenodesis in primary anterior cruciate ligament reconstruction: a systematic review with meta-analysis and best-evidence synthesis. *Orthop J Sports Med*. 2017;5(10):2325967117731767.
11. Devitt BM, Bouguennec N, Barfod KW, Porter T, Webster KE, Feller JA. Combined anterior cruciate ligament reconstruction and lateral extra-articular tenodesis does not result in an increased rate of osteoarthritis: a systematic review and best evidence synthesis. *Knee Surg Sports Traumatol Arthrosc*. 2017;25(4):1149-1160.
12. Engebretsen L, Lew WD, Lewis JL, Hunter RE. The effect of an iliotibial tenodesis on intraarticular graft forces and knee joint motion. *Am J Sports Med*. 1990;18(2):169-176.
13. Ferretti A, Monaco E, Fabbri M, Maestri B, De Carli A. Prevalence and classification of injuries of anterolateral complex in acute anterior cruciate ligament tears. *Arthroscopy*. 2017;33(1):147-154.
14. Geeslin AG, Moatshe G, Chahla J, et al. Anterolateral knee extra-articular stabilizers: a robotic study comparing anterolateral ligament reconstruction and modified Lemaire lateral extra-articular tenodesis. *Am J Sports Med*. 2018;46(3):607-616.
15. Getgood A, Brown C, Lording T, et al. The anterolateral complex of the knee: results from the International ALC Consensus Group Meeting. *Knee Surg Sports Traumatol Arthrosc*. 2019;27(1):166-176.
16. Getgood A, Bryant D, Firth A, Stability Group. The Stability Study: a protocol for a multicenter randomized clinical trial comparing anterior cruciate ligament reconstruction with and without lateral extra-articular tenodesis in individuals who are at high risk of graft failure. *BMC Musculoskelet Disord*. 2019;20(1):216.
17. Hefti F, Muller W, Jakob RP, Staubli HU. Evaluation of knee ligament injuries with the IKDC form. *Knee Surg Sports Traumatol Arthrosc*. 1993;1(3-4):226-234.
18. Helito CP, Demange MK, Helito PV, et al. Evaluation of the anterolateral ligament of the knee by means of magnetic resonance examination. *Rev Bras Ortop*. 2015;50(2):214-219.
19. Herbst E, Albers M, Burnham JM, et al. The anterolateral complex of the knee: a pictorial essay. *Knee Surg Sports Traumatol Arthrosc*. 2017;25(4):1009-1014.
20. Hewison CE, Tran MN, Kaniki N, Remtulla A, Bryant D, Getgood AM. Lateral extra-articular tenodesis reduces rotational laxity when combined with anterior cruciate ligament reconstruction: a systematic review of the literature. *Arthroscopy*. 2015;31(10):2022-2034.
21. Higgins LD, Taylor MK, Park D, et al. Reliability and validity of the International Knee Documentation Committee (IKDC) Subjective Knee Form. *Joint Bone Spine*. 2007;74(6):594-599.
22. Inderhaug E, Stephen JM, Williams A, Amis AA. Anterolateral tenodesis or anterolateral ligament complex reconstruction: effect of flexion angle at graft fixation when combined with ACL reconstruction. *Am J Sports Med*. 2017;45(13):3089-3097.
23. Inderhaug E, Stephen JM, Williams A, Amis AA. Biomechanical comparison of anterolateral procedures combined with anterior cruciate ligament reconstruction. *Am J Sports Med*. 2017;45(2):347-354.
24. Irrgang JJ, Anderson AF, Boland AL, et al. Development and validation of the International Knee Documentation Committee Subjective Knee Form. *Am J Sports Med*. 2001;29(5):600-613.
25. Kaeding CC, Pedroza AD, Reinke EK, Huston LJ, MOON Consortium, Spindler KP. Risk factors and predictors of subsequent ACL injury in either knee after ACL reconstruction: prospective analysis of 2488 primary ACL reconstructions from the MOON Cohort. *Am J Sports Med*. 2015;43(7):1583-1590.
26. Kennedy JC, Stewart R, Walker DM. Anterolateral rotatory instability of the knee joint: an early analysis of the Ellison procedure. *J Bone Joint Surg Am*. 1978;60(8):1031-1039.
27. Kittl C, El-Daou H, Athwal KK, et al. The role of the anterolateral structures and the ACL in controlling laxity of the intact and ACL-deficient knee. *Am J Sports Med*. 2016;44(2):345-354.
28. Kondo E, Merican AM, Yasuda K, Amis AA. Biomechanical comparison of anatomic double-bundle, anatomic single-bundle, and nonanatomic single-bundle anterior cruciate ligament reconstructions. *Am J Sports Med*. 2011;39(2):279-288.
29. Lind M, Menhert F, Pedersen AB. Incidence and outcome after revision anterior cruciate ligament reconstruction: results from the Danish registry for knee ligament reconstructions. *Am J Sports Med*. 2012;40(7):1551-1557.
30. Luites JW, Wymenga AB, Blankevoort L, Kooloos JM, Verdonschot N. Computer-assisted anatomically placed double-bundle ACL reconstruction: an in vitro experiment with different tension angles for the AM and the PL graft. *Med Eng Phys*. 2012;34(8):1031-1036.
31. Magnussen RA, Lawrence JT, West RL, Toth AP, Taylor DC, Garrett WE. Graft size and patient age are predictors of early revision after anterior cruciate ligament reconstruction with hamstring autograft. *Arthroscopy*. 2012;28(4):526-531.
32. MARS Group, Cooper DE, Dunn WR, et al. Physiologic preoperative knee hyperextension is a predictor of failure in an anterior cruciate ligament revision cohort: a report from the MARS Group. *Am J Sports Med*. 2018;46(12):2836-2841.
33. Marx RG, Stump TJ, Jones EC, Wickiewicz TL, Warren RF. Development and evaluation of an activity rating scale for disorders of the knee. *Am J Sports Med*. 2001;29(2):213-218.

34. Mathew M, Dhollander A, Getgood A. Anterolateral ligament reconstruction or extra-articular tenodesis: why and when? *Clin Sports Med*. 2018;37(1):75-86.
35. Meredick RB, Vance KJ, Appleby D, Lubowitz JH. Outcome of single-bundle versus double-bundle reconstruction of the anterior cruciate ligament: a meta-analysis. *Am J Sports Med*. 2008;36(7): 1414-1421.
36. Mohtadi N. Development and validation of the quality of life outcome measure (questionnaire) for chronic anterior cruciate ligament deficiency. *Am J Sports Med*. 1998;26(3):350-359.
37. Mohtadi N, Chan D, Barber R, Oddone Paolucci E. A randomized clinical trial comparing patellar tendon, hamstring tendon, and double-bundle ACL reconstructions: patient-reported and clinical outcomes at a minimal 2-year follow-up. *Clin J Sport Med*. 2015;25(4):321-331.
38. Mohtadi NG, Chan DS, Dainty KN, Whelan DB. Patellar tendon versus hamstring tendon autograft for anterior cruciate ligament rupture in adults. *Cochrane Database Syst Rev*. 2011;9:CD005960.
39. Musahl V, Getgood A, Neyret P, et al. Contributions of the anterolateral complex and the anterolateral ligament to rotatory knee stability in the setting of ACL injury: a roundtable discussion. *Knee Surg Sports Traumatol Arthrosc*. 2017;25(4):997-1008.
40. Noyes FR, Barber SD. The effect of an extra-articular procedure on allograft reconstructions for chronic ruptures of the anterior cruciate ligament. *J Bone Joint Surg Am*. 1991;73(6):882-892.
41. O'Brien SJ, Warren RF, Wickiewicz TL, et al. The iliotibial band lateral sling procedure and its effect on the results of anterior cruciate ligament reconstruction. *Am J Sports Med*. 1991;19(1):21-24; discussion 24-25.
42. Parkinson B, Robb C, Thomas M, Thompson P, Spalding T. Factors that predict failure in anatomic single-bundle anterior cruciate ligament reconstruction. *Am J Sports Med*. 2017;45(7):1529-1536.
43. Pearl AJ, Bergfeld JA. *Extra-articular Reconstruction in the Anterior Cruciate Ligament Deficient Knee*. Champaign, IL: Human Kinetics Publishers; 1992.
44. Pernin J, Verdonk P, Si Selmi TA, Massin P, Neyret P. Long-term follow-up of 24.5 years after intra-articular anterior cruciate ligament reconstruction with lateral extra-articular augmentation. *Am J Sports Med*. 2010;38(6):1094-1102.
45. Prodromos CC, Joyce BT, Shi K, Keller BL. A meta-analysis of stability after anterior cruciate ligament reconstruction as a function of hamstring versus patellar tendon graft and fixation type. *Arthroscopy*. 2005;21(10):1202.
46. Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. *Health Qual Life Outcomes*. 2003;1:64.
47. Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee injury and Osteoarthritis Outcome Score (KOOS)—development of a self-administered outcome measure. *J Orthop Sports Phys Ther*. 1998;28(2):88-96.
48. Scholten RJ, Opstelten W, van der Plas CG, Bijl D, Deville WL, Bouter LM. Accuracy of physical diagnostic tests for assessing ruptures of the anterior cruciate ligament: a meta-analysis. *J Fam Pract*. 2003; 52(9):689-694.
49. Song GY, Hong L, Zhang H, Zhang J, Li Y, Feng H. Clinical outcomes of combined lateral extra-articular tenodesis and intra-articular anterior cruciate ligament reconstruction in addressing high-grade pivot-shift phenomenon. *Arthroscopy*. 2016;32(5):898-905.
50. Sonnery-Cottet B, Saithna A, Cavalier M, et al. Anterolateral ligament reconstruction is associated with significantly reduced ACL graft rupture rates at a minimum follow-up of 2 years: a prospective comparative study of 502 patients from the SANTI Study Group. *Am J Sports Med*. 2017;45(7):1547-1557.
51. Spadoni GF, Stratford PW, Solomon PE, Wishart LR. The evaluation of change in pain intensity: a comparison of the P4 and single-item numeric pain rating scales. *J Orthop Sports Phys Ther*. 2004;34(4): 187-193.
52. Stratford PW, Dogra M, Woodhouse L, Kennedy DM, Spadoni GF. Validating self-report measures of pain and function in patients undergoing hip or knee arthroplasty. *Physiother Can*. 2009;61(4): 189-194.
53. van Eck CF, Kopf S, Irrgang JJ, et al. Single-bundle versus double-bundle reconstruction for anterior cruciate ligament rupture: a meta-analysis—does anatomy matter? *Arthroscopy*. 2012;28(3):405-424.
54. Vieira EL, Vieira EA, da Silva RT, Berlfein PA, Abdalla RJ, Cohen M. An anatomic study of the iliotibial tract. *Arthroscopy*. 2007;23(3):269-274.
55. Vincent JP, Magnussen RA, Gezmez F, et al. The anterolateral ligament of the human knee: an anatomic and histologic study. *Knee Surg Sports Traumatol Arthrosc*. 2012;20(1):147-152.
56. W-Dahl A, Toksvig-Larsen S, Roos EM. A 2-year prospective study of patient-relevant outcomes in patients operated on for knee osteoarthritis with tibial osteotomy. *BMC Musculoskelet Disord*. 2005;6:18.
57. Webster KE, Feller JA. Exploring the high reinjury rate in younger patients undergoing anterior cruciate ligament reconstruction. *Am J Sports Med*. 2016;44(11):2827-2832.
58. Webster KE, Feller JA, Leigh WB, Richmond AK. Younger patients are at increased risk for graft rupture and contralateral injury after anterior cruciate ligament reconstruction. *Am J Sports Med*. 2014;42(3):641-647.
59. Wood R, Marsh J, Getgood A. Anterolateral complex reconstruction: another fad or method to improve ACL outcomes? *Tech Orthop*. 2018;33(4):239-245.
60. Yamamoto Y, Hsu WH, Woo SL, Van Scyoc AH, Takakura Y, Debski RE. Knee stability and graft function after anterior cruciate ligament reconstruction: a comparison of a lateral and an anatomical femoral tunnel placement. *Am J Sports Med*. 2004;32(8):1825-1832.
61. Zaffagnini S, Marcheggiani Muccioli GM, Grassi A, et al. Over-the-top ACL reconstruction plus extra-articular lateral tenodesis with hamstring tendon grafts: prospective evaluation with 20-year minimum follow-up. *Am J Sports Med*. 2017;45(14):3233-3242.
62. Zelle BA, Brucker PU, Feng MT, Fu FH. Anatomical double-bundle anterior cruciate ligament reconstruction. *Sports Med*. 2006; 36(2):99-108.