Anterior Cruciate Ligament Reconstruction Plus Lateral Extra-articular Tenodesis Has a Similar Return-to-Sport Rate to Anterior Cruciate Ligament Reconstruction Alone but a Lower Failure Rate

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Purpose: To determine whether the addition of lateral extra-articular tenodesis (LET) to anterior cruciate ligament reconstruction (ACLR) would improve return-to-sport (RTS) rates in young, active patients who play high-risk sports. **Methods:** This multicenter randomized controlled trial compared standard hamstring tendon ACLR with combined ACLR and LET using a strip of the iliotibial band (modified Lemaire technique). Patients aged 25 years or younger with an anterior cruciate ligament–deficient knee were included. Patients also had to meet 2 of the following criteria: (1) pivot-shift grade 2 or greater, (2) participation in a high-risk or pivoting sport, and (3) generalized ligamentous laxity. Time to return and level of RTS were determined via administration of a questionnaire at 24 months postoperatively. **Results:** We randomized 618 patients in this study, 553 of whom played high-risk sports preoperatively. The proportion of patients who did not RTS was similar between the ACLR (11%) and ACLR-LET (14%) groups; however, the graft rupture rate was

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Members of the STABILITY Study Group are listed in the Appendix.

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significantly different (11.2% in ACLR group vs 4.1% in ACLR-LET group, $P = .004$). The most cited reason for no RTS was lack of confidence and/or fear of reinjury. A stable knee was associated with nearly 2 times greater odds of returning to a high-level high-risk sport postoperatively (odds ratio, 1.92; 95% confidence interval, 1.11-3.35; $P = .02$). There were no significant differences in patient-reported functional outcomes or hop test results between groups ($P > .05$). Patients who returned to high-risk sports had better hamstring symmetry than those who did not RTS ($P = .001$). **Conclusions:** At 24 months postoperatively, patients who underwent ACLR plus LET had a similar RTS rate to those who underwent ACLR alone. Although the subgroup analysis did not show a statistically significant increase in RTS with the addition of LET, on returning, the addition of LET kept subjects playing longer by reducing graft failure rates. **Level of Evidence:** Level I, randomized controlled trial.

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Contemporary single-bundle anterior cruciate ligament reconstruction (ACLR) techniques have been shown to perform well subjectively. However, reinjury rates of up to 23% have been reported in patients younger than 25 years.[1,2] Furthermore, return−to−preinjury sport rates after ACLR have been reported to be as low as 50% to 60%.[3-5]

On the basis of the renewed interest in anterolateral reconstruction to improve knee stability, we performed a randomized clinical trial comparing traditional single-bundle hamstring ACLR versus ACLR augmented with lateral extra-articular tenodesis (LET) in patients younger than 25 years with a desire to return to sport (RTS) (STABILITY study).[6] The 2-year outcomes from this study showed that the addition of LET to traditional ACLR with hamstring autograft leads to statistically and clinically significant decreases in the clinical failure rate (persistent asymmetrical rotatory laxity and graft rupture) from 40% to 25% and in the graft rupture rate from 11% to 4%. Currently, there is a lack of sufficiently powered and methodologically rigorous randomized trials that have examined whether ACLR with LET has an effect on RTS in young patients who are considered at higher risk of early graft failure.[7]

The purpose of this study was to determine whether the addition of LET to ACLR would improve RTS rates in young, active patients who play high-risk sports. The hypothesis was that by improving the rotatory stability of ACLR by augmenting with LET, we would observe an improvement in the RTS rate compared with patients treated with ACLR alone.

Methods

Study Design and Participants

This study was a pragmatic, parallel-group, multicenter randomized clinical trial in which young patients with anterior cruciate ligament (ACL) deficiency were randomly allocated to either ACLR alone or ACLR with LET. Seven study centers in Canada and two centers in Europe actively recruited patients. The study was approved by Western University's Research Ethics Board and local research ethics boards at each institution and was registered on ClinicalTrials.gov (NCT02018354). A full study protocol has previously been published.[8]

In brief, patients were approached for participation if they were aged between 14 and 25 years, had an ACL-deficient knee, and were at high risk of reinjury. A high risk of reinjury was defined as the presence of 2 or more of the following criteria: (1) participation in a competitive pivoting sport,[5,9] (2) pivot-shift grade 2 or greater, and (3) generalized ligamentous laxity (Beighton score $\geq$ 4) or genu recurvatum greater than 10°.[10] Patients were ineligible if any of the following criteria were present: (1) previous ACLR in either knee, (2) multi-ligament injury ($\geq$2 ligaments requiring surgical attention), (3) symptomatic articular cartilage defect requiring treatment other than debridement, (4) greater than 3° of asymmetrical varus, and (5) inability or unwillingness to be followed up for 2 years postoperatively.

After determination of eligibility including a willingness to participate, patients were randomized in a 1:1 ratio to either ACLR alone or ACLR with LET. Computer randomization was performed at the time of surgery after arthroscopy to confirm eligibility. Randomization was stratified by surgeon, sex, and presence or absence of meniscal repair requiring more conservative rehabilitation in permuted block sizes of 2 and 4 to ensure that any difference in outcome attributable to these factors was balanced between groups.

Study Treatments

All patients underwent anatomic ACLR with hamstring autograft performed in a standardized fashion across the study sites. In patients randomized to receive LET, surgeons performed a modified Lemaire technique.[11] Detailed information on the surgical techniques used in the STABILITY 1 study has been previously published.[8]

All patients, regardless of group allocation, received preoperative and postoperative verbal and written standardized instructions for rehabilitation, focusing on early range of motion and weight bearing as tolerated, unless a meniscal repair dictated otherwise. The patients' physical therapists also received a copy of the standardized protocol. A brace was not routinely used. The full rehabilitation protocol can be found in

Appendix Figure 1 (available at www.arthroscopyjournal.org).

Outcome Measures

Patients were asked about their preinjury and postoperative levels of sports participation (elite, varsity, competitive, recreational, or none) and type of sport (high or low risk). High-risk sports were defined as sports that require cutting and pivoting motions and landing from jumps including but not limited to soccer, basketball, hockey, volleyball, football, and rugby. The most common examples of low-risk sports included swimming and running.

Postoperatively, patients were given an RTS questionnaire to complete at 6, 12, and 24 months. For those returning to sport, the questionnaire captured the level of competition. For those returning to the same sport, the level of competition was classified as a higher level, the same level, or a lower level. The time it took for the patient to RTS was also captured. Given that, prior to injury, most of our participants were athletes participating in high-risk sports (563 of 618, 91.1%), we focused our analysis on RTS in this subgroup.

Knee stability was assessed using the pivot-shift test at each clinical follow-up by an assessor blinded to group allocation. Patients were provided a Tubigrip sleeve (Mölnlycke) to wear on the operative knee to cover surgical incisions and to blind outcome assessors to operative group. This sleeve was worn for the blinded clinical assessment and all functional tests. Graft failure or an unstable knee was defined as a pivot-shift grade of 2 or more at any study visit, a pivot-shift grade of 1 at multiple study follow-up visits, or graft rupture after RTS.[6] Patients who experienced graft rupture prior to RTS were excluded from this analysis (n = 5).

Additionally, functional outcomes including quadriceps peak torque, hamstring peak torque, the single-leg hop test, the Lower Extremity Functional Scale (LEFS), and the 4-Item Pain Intensity Measure (P4) were collected at 6, 12, and 24 months postoperatively. These outcomes have been reported in detail in previous publications.[8,12]

Sample Size and Statistical Analysis

This study was an analysis of secondary outcomes from the STABILITY 1 study. The a priori sample size was calculated for the full trial using the primary outcome of graft failure, and a minimum of 600 patients (300 per group) were required.[8] In this subgroup analysis, each treatment group was split into 4 subgroups based on the level of sport achieved within 2 years postoperatively, for a total of 8 groups. For 13 patients who were missing data on their RTS questionnaires, we were able to impute their sport and level of competition using data from their ACL Quality of Life (ACL-QOL) and Marx questionnaires to include them in the analysis.

For this study, we excluded patients who preoperatively participated in low-risk sports or no sports. To explore the prognostic factors between the original STABILITY 1 cohort and those participants included in this analysis, we used means and standard deviations for continuous variables and proportions for dichotomous variables. Patients who participated in high-risk sports preoperatively were categorized into 4 groups based on the level of sport to which they returned: (1) high-risk high-level sport, (2) high-risk recreational (low-level) sport, (3) low-risk sport at any level, or (4) no RTS. We recorded the reasons for not returning to sport for all patients who participated in sports prior to injury, regardless of the level of preoperative sports participation. Small numbers of patients in some subgroups limited our ability to perform statistical analyses with precision. In particular, few patients participating in high-risk sports preoperatively had limb symmetry index (LSI) data (n = 19) or strength data (n = 25) and did not RTS.

We used the Mann-Whitney *U* test to perform between-group comparisons within the categories of postoperative level of sports participation. We planned to look at the relation between the proportion of patients with a stable knee and postoperative RTS level and class. A stable knee was defined using the study criteria.[8] We ran this analysis using the entire cohort; we then stratified the analysis by ACLR alone and ACLR plus LET. Logistic regression was used to determine the relation between knee stability and postoperative RTS level. The odds of returning to each level of sport with a stable knee compared with an unstable knee and associated 95% confidence interval (CI) were presented graphically for each level. Patients who returned to sport prior to graft rupture were included in this analysis, and they were defined according to their laxity status at visits prior to graft rupture.

For this analysis, we evaluated strength, the LSI, the Lower Extremity Functional Scale (LEFS), and the 4-Item Pain Intensity Measure (P4) measured at 24 months postoperatively unless a patient had graft failure or a contralateral ACL rupture, in which case the measurements taken prior to the injury were used in the analysis. We used box plots to visualize these outcomes by subgroup and then performed the Mann-Whitney *U* test to compare medians and distributions between groups at each level of postoperative RTS. The level of statistical significance was set at $P < .05$.

Results

Subject Characteristics

Enrollment of patients occurred between January 2014 and March 2017. Of the 1,033 patients screened for eligibility, 358 were ineligible, 48 were eligible but nonconsenting, and 9 consented but did not undergo

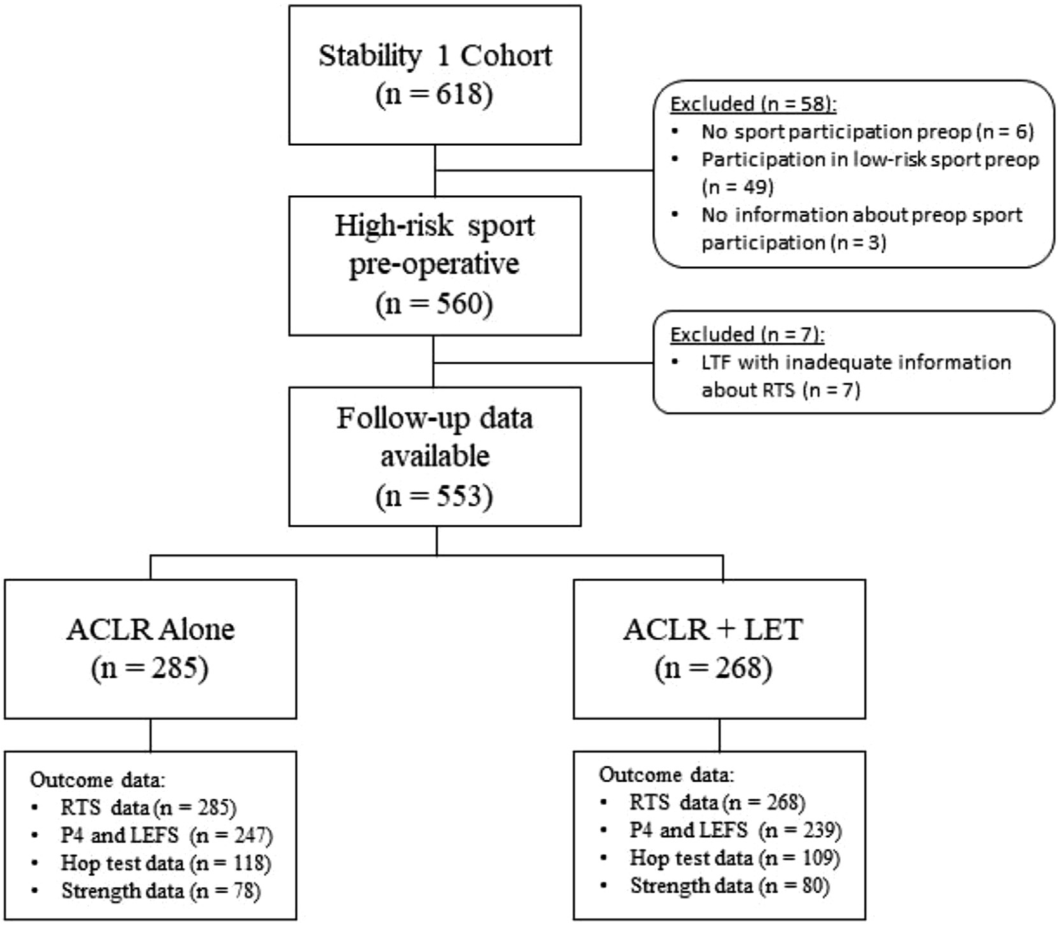

Fig 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram. (ACLR, anterior cruciate ligament reconstruction; LEFS, Lower Extremity Functional Scale; LET, lateral extra-articular tenodesis; LTF, lost to follow-up; P4, 4-Item Pain Intensity Measure; preop, preoperatively; RTS, return to sport.)

surgery. Thus, 618 patients were randomized in the STABILITY 1 study (Fig 1).

We excluded 65 patients from this analysis, including 58 who did not participate in high-risk sports preoperatively and 7 who were lost to follow-up early without providing data on RTS, which left 553 patients available for analysis (285 ACLR and 268 ACLR-LET patients). Final follow-up occurred at an average of 24.6 months (standard deviation, 1.7 months) and 24.7 months (standard deviation, 1.8 months) in the ACLR and ACLR-LET groups, respectively (range, 20.7-32.8 months). Patient-reported outcome measures (PROMs) were available for 476 of these patients (247 ACLR and 239 ACLR-LET patients). Two centers collected strength data (78 ACLR and 80 ACLR-LET patients), and two centers collected hop test data (118 ACLR and 109 ACLR-LET patients). There were no differences in any patient characteristic between the STABILITY 1 cohort and the participants retained for this analysis (Table 1). The mean participant age was 18.8 years (range, 14-25 years), with just over 75% (418 of 533) returning to pivoting sports postoperatively, representing a cohort of patients at high risk of ACLR failure.

Return to Sport

There was no significant difference in preinjury level of sports participation between patients randomized to ACLR and those randomized to ACLR-LET (Table 2). Information on RTS was available for 603 of the 618 patients (97.8%) in this study. There was no significant difference in the postoperative type of sport (high vs low risk) and level of sport between groups (Table 2). From the STABILITY 1 cohort, the proportion of patients who did not RTS was not statistically significant different between groups (11% in ACLR group vs 15% in ACLR-LET group, P = .08) (Table 2). Within the subgroup of patients who played high-risk sports preoperatively, 285 patients in the ACLR group and 268 patients in the ACLR-LET group reported on their RTS activities. A total of 76 patients who played high-risk

Table 1. Patient Characteristics for Entire STABILITY 1 Study and Restricted to Preoperative High-Risk Sport Cohort

Characteristic	STABILITY 1 Cohort (n = 618)	High-Risk Sport Cohort (n = 553)
Sex: male	302 (48.9)	265 (47.9)
Age, yr	18.9 ± 3.2	18.8 ± 3.2
Height, in	68.0 ± 3.7	68.0 ± 3.7
Weight, kg	71.6 ± 14.5	71.9 ± 14.5
BMI	23.9 ± 3.8	24.0 ± 3.7
Beighton score (0-9)	3.1 ± 2.8	3.0 ± 2.7
Group: ACLR-LET	306 (49.5)	268 (48.5)
Time from injury to surgery, mo	8.7 ± 17.5	8.4 ± 18.4
Operative limb: dominant	317 (51.3)	293 (53.0)
Mechanism of injury: non-contact	342 (73)	297 (71.9)
Marx activity rating (before injury)	12.4 ± 5.1	12.5 ± 4.9
Sport played at time of injury		
Soccer	222 (35.9)	207 (37.4)
Basketball	90 (14.6)	83 (15.0)
Football or rugby	110 (17.8)	103 (18.6)
Downhill skiing	29 (4.7)	26 (4.7)
Volleyball	31 (5.0)	30 (5.4)
Other	132 (21.4)	80 (14.5)
Preinjury level of sports participation		
Elite, varsity, or competitive	461 (74.6)	441 (79.7)
Recreational	123 (19.9)	105 (19.0)
No regular participation in sports	4 (<1.0)	0 (0)
Missing	30 (4.9)	7 (1.3)
Graft source		
Semitendinosus and gracilis	598 (96.8)	532 (96.2)
Semitendinosus	22 (3.2)	21 (3.8)
Graft diameter, median (minimum-maximum), mm	8 (6-10)	8 (6-10)
Meniscal excision		
Medial	39 (6.3)	32 (5.8)
Lateral	121 (19.6)	105 (19.0)
Both	23 (3.7)	20 (3.6)
Change in rehabilitation owing to meniscal repair	101 (16.3)	91 (16.5)
Chondral defect: ICRS grade > 3 in any compartment	29 (4.7)	25 (4.5)

NOTE. Data are presented as mean ± standard deviation or number (percentage) unless otherwise indicated.

ACLR, anterior cruciate ligament reconstruction; BMI, body mass index; ICRS, International Cartilage Repair Society; LET, lateral extra-articular tenodesis.

sports prior to ACL rupture did not RTS postoperatively (34 in ACLR group [12%] and 42 in ACLR-LET group [16%], $P = .20$).

Reasons for Not Returning to Sport

Six patients who did not RTS had an early complication or adverse event: 1 had an early infection followed by graft rupture at 3 months (ACLR group), 1 had excessive stiffness and underwent manipulation under anesthesia and arthrolysis (ACLR group), 1 had a cyclops lesion requiring debridement (ACLR group), 2 had failed meniscal repairs (1 in ACLR group and 1 in ACLR-LET group), and 1 still complained of hamstring pain at 24 months postoperatively (ACLR group). Other reasons cited by patients for not returning to sport included losing interest or being too busy, having a lack of confidence and/or fear of reinjury, not yet being cleared to play, feeling unfit or not making the team, graduating school or aging out, and being out of season (Table 3). The most common reason for not returning to sport cited by both groups was lack of confidence and/or fear of reinjury (15 of 34 in ACLR group vs 15 of 42 in ACLR-LET group) (Table 3).

Associations Between RTS Level and Knee Stability

Of the 122 patients who were participating in high-risk sports prior to injury who either did not RTS or returned to low-risk sports postoperatively with available clinical outcomes, 46 (37.7%) had a persistent asymmetrical pivot shift without graft rupture (28 in ACLR group and 18 in ACLR-LET group; odds ratio [OR], 0.60; 95% CI, 0.29-1.21; $P = .15$). Of those who returned to high-risk sports, 23.0% (85 of 370) had a persistent asymmetrical pivot shift without rupture (48 in ACLR group and 37 in ACLR-LET group; OR, 0.80; 95% CI, 0.50-1.30; $P = .37$). Unfortunately, 9.3% of patients (43 of 464) experienced graft rupture after returning to sport (32 in ACLR group and 11 in ACLR-LET group; OR, 0.35; 95% CI, 0.17-0.71; $P = .004$).

There was a pattern showing a dose-response relation between the proportion of patients with a stable knee and a return to increasingly demanding activity

Table 2. Return to Sport by Group at 24 Months Postoperatively

Preoperative Sport	Postoperative Level	ACLR (n = 312)	ACLR-LET (n = 306)	*P* Value
High risk		285 (93.1)	268 (87.9)	.49
	High risk			
	Elite, varsity, or competitive	136 (44.4)	120 (39.3)	
	Recreational	80 (26.1)	82 (26.9)	
	Low risk			
	Elite, varsity, or competitive	8 (2.6)	5 (1.6)	
	Recreational	27 (8.8)	19 (6.2)	
	Did not return to sport	34 (11.1)	42 (13.8)	
Low risk		19 (6.4)	27 (8.9)	.27
	Low risk			
	Elite, varsity, or competitive	13 (4.4)	12 (3.9)	
	Recreational	5 (1.7)	13 (4.3)	
	Did not return to sport	1 (0.3)	2 (0.7)	
No sports participation	No sports participation	1 (0.3)	3 (1.0)	.37
Missing		7 (2.2)	8 (2.6)	.78

ACLR, anterior cruciate ligament reconstruction; LET, lateral extra-articular tenodesis.

postoperatively (Table 4). Having a stable knee was associated with over 1.5 times higher odds (OR, 1.92; 95% CI, 1.11-3.35; $P = .02$) of successfully returning to a high-risk high-level sport compared with having an unstable knee. The odds of returning to a high-risk low-level sport (OR, 1.74; 95% CI, 0.96-3.14; $P = .07$) and low-risk sport were similar to the odds of not returning to sport at all with a stable knee compared with a knee with laxity. To test the robustness of this effect, we ran an adjusted model that included age and treatment group (ACLR alone or ACLR plus LET) in which the significant relation remained. This analysis is further stratified by treatment group in Table 5, showing greater stability in the ACLR-LET group at each level of RTS compared with the ACLR group.

Associations Between RTS and Performance-Based Outcomes

Because there were small numbers of patients who participated in only low-risk sports prior to ACL rupture, this analysis was limited to those who participated in high-risk sports preoperatively.

Strength. Figure 2 shows the median peak torque for the quadriceps ratio over ordered categories of demand for postoperative sport. The ACLR group had greater symmetry than the ACLR-LET group among patients not returning to sport ($P = .005$); otherwise, no statistically significant differences were found. For the hamstring ratio, patients who returned to high-risk sports had better symmetry than those who returned to low-risk sports or who did not RTS ($P = .001$). The hamstring-to-quadriceps ratios (operative side) were similar across demand categories. The only statistically significant difference between groups was observed in patients who did not RTS ($P = .018$).

Hop Test LSI. The LSI was similar between groups for all categories of RTS. The median LSI in each group was 0.95 or higher, with the 25th percentile greater than 0.90 for all groups at all levels (Fig 3). Further exploration of each of the 4 hop tests revealed similar results between groups.

Patient-Reported Function and Pain. There were no significant differences in patient-reported function or pain between groups (Fig 4).

Discussion

The most important finding from this study is that most patients who played sports preoperatively were able to RTS by 2 years postoperatively. By breaking down the types of sport to which individuals returned,

Table 3. Reasons Cited for Not Returning to Sport After Surgery Provided by Patients Who Were Participating in Sports Preoperatively

	Patients Who Did Not Return to Any Sport (n = 76)	
Reason	ACLR Alone (n = 34)	ACLR-LET (n = 42)
Significant reinjury or complication	2	0
Lost interest or too busy	6	9
Lack of confidence and/or fear of reinjury	15	15
Not yet cleared to play	2	0
Decline in physical fitness	6	9
Out of season	1	1
Aged out or graduated	4	6

NOTE. Patients could give more than 1 reason; patients who were not participating in sports preoperatively were not included.

ACLR, anterior cruciate ligament reconstruction; LET, lateral extra-articular tenodesis.

Table 4. Proportion of Patients With Stable Knees by Postoperative RTS Level and Classification

Level	Unstable (n = 139), n	Stable (n = 414), n	Proportion, %
No RTS	27	49	64.5
Low-risk sport	22	37	62.7
High-risk low-level sport	39	123	75.9
High-risk high-level sport	51	205	80.1

RTS, return to sport.

we were able to better establish the intensity of play and, as such, obtain a more complete picture of the risk of reinjury that occurs with RTS after ACLR. Most of the patients in our patient cohort were involved in high-risk sports at the time of injury. Of these, 76% were able to return to high-risk sports, with a further 11% returning to lower-risk sports but remaining active. If we include patients playing low-risk sports before injury who returned to the same level, approximately 87% of our patient cohort was able to RTS by 2 years after ACLR. Although there were no significant differences between groups in terms of those patients returning to high-risk levels of sport, patients who did return to high-risk high-level sports had a 70% relative risk reduction in graft failure if additionally treated with LET, mirroring what was observed in the full trial that included all patients. This finding further shows that having a more stable knee is a significant factor in an athlete's return to high-risk sports at a high level of play.

These findings contrast with those of a systematic review by Ardern et al.,[3] who showed that only 63% of patients could RTS after ACLR. This difference may be explained by the eligibility criteria for the STABILITY 1 study that limited the study sample to young, active individuals (<25 years of age, involvement in sports, and/or hypermobility), who are more likely to have the time, energy, and/or opportunity to RTS. Our findings are similar to those of a study by Lai et al.,[13] in which an 83% RTS rate was observed in a cohort of elite athletes. As such, the results of our study may not be generalizable to the normally distributed ACL-injured population. However, a systematic review and meta-analysis by Kay et al.[14] also determined that there is a high rate of RTS in adolescents after ACLR (>90%), indicating that a number of other factors may prevent older patients from returning to sport. In our study, several participants reported either that they had lost interest in returning to sport, likely owing to school or work commitments being too heavy, or that they aged out of being eligible for participation. It is possible that older populations of patients have a greater amount of these sorts of issues because of more demanding work and family life commitments.

One interesting finding is that patients with greater rotational stability of the knee, whether this was due to the addition of LET or not, had a greater chance of returning to high-risk high-level sports postoperatively. Return to high-risk low-level sports and low-risk sports was not associated with greater stability. Although analyzing the cohort together allowed us to detect a pattern of increased knee stability in patients who returned to increasingly demanding levels of sport, there were no differences between ACLR with the addition of LET and ACLR without the addition of LET in RTS rates by 24 months after surgery for the level of sport and the degree of risk associated with the sport for subsequent ACL rupture. This is likely because of the size of the effect, given that even using the full sample size without stratifying by group, we observed that the 95% CIs were wide, with the lower limit approaching the line of no difference. Relatively few patients did not RTS or returned to low-risk sports in our study, and the statistical power decreases further when we compare the ratio of patients with stable and unstable knees within these groups. Knee stability is one of many factors that may affect a patient's decision to RTS after ACLR, as shown in Table 3, which may also explain why the 2 groups were similar in terms of RTS. Our results did show that the ACLR-LET group had a slightly higher proportion of patients with a stable knee at each level of RTS, a potentially interesting finding given the significant difference in graft ruptures between the 2 groups after returning.[6]

Although our RTS rate was high, there were still a number of patients who did not RTS postoperatively, even with a stable knee. Some patients indicated that

Table 5. Proportion of Patients With Stable Knees by Postoperative RTS Level and Classification Stratified by Treatment (ACLR Alone or ACLR-LET)

Level	ACLR Alone			ACLR-LET		
	Unstable (n = 88)	Stable (n = 197)	Proportion, %	Unstable (n = 57)	Stable (n = 211)	Proportion, %
No RTS	14	20	58.8	13	29	69.0
Low-risk sport	15	20	57.1	7	17	70.8
High-risk low-level sport	26	54	67.5	13	69	84.1
High-risk high-level sport	33	103	75.7	24	96	80.0

ACLR, anterior cruciate ligament reconstruction; LET, lateral extra-articular tenodesis; RTS, return to sport.

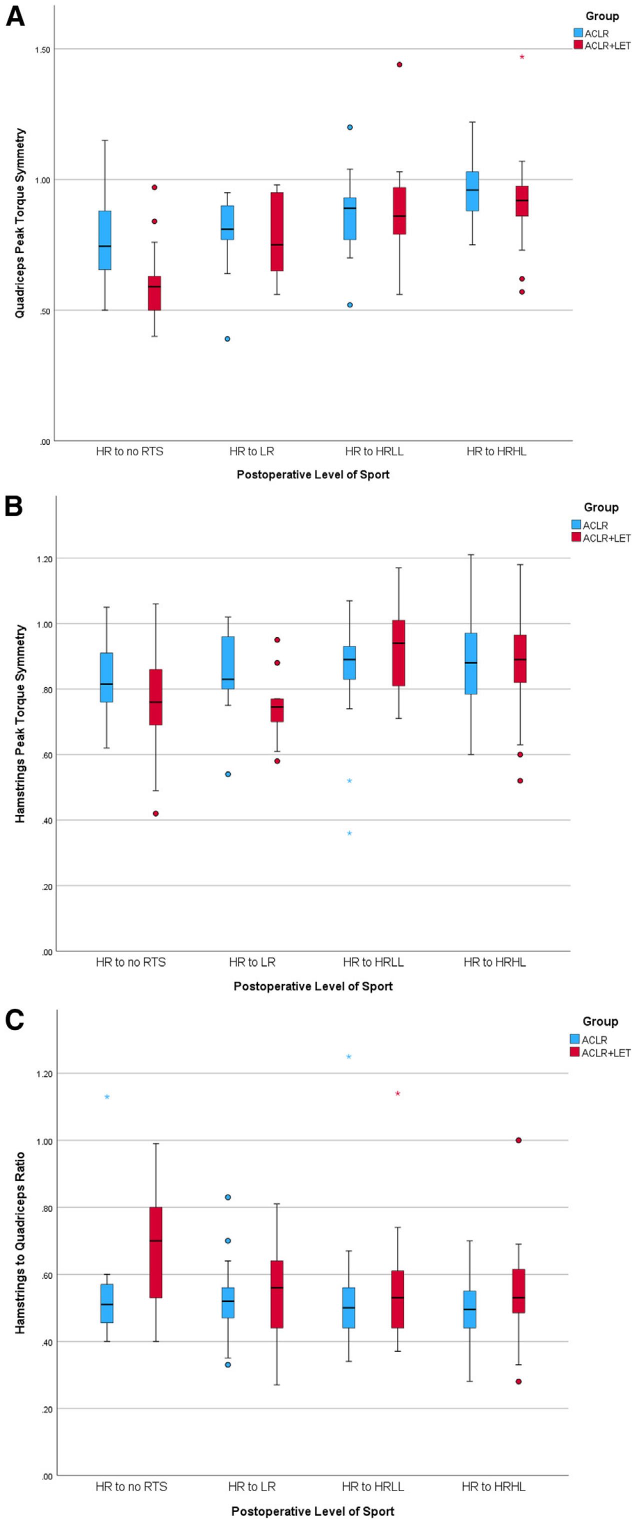

Fig 2. Strength outcomes in patients who were participating in high-risk sports preoperatively. Strength was measured after return to sport (RTS) or at 24 months postoperatively if the participant had not yet returned to sport. For those participants with graft or contralateral anterior cruciate ligament (ACL) rupture, we used the strength measurements closest to the event. The box plot illustrates the differences in the quadriceps ratio (operative to nonoperative) (A), hamstring ratio (B), and quadriceps-to-hamstring ratio (operative side) (C). Each plot illustrates the difference in strength between the study groups (anterior cruciate ligament reconstruction [ACLR] and ACLR plus lateral extra-articular tenodesis [LET]) when participants returned to different sport types (high risk [HR] vs low risk [LR]) and sport levels (high level [HL], defined as elite, varsity, or competitive, vs low level [LL], defined as recreational). Bars and whiskers represent the interquartile range for each group, with the solid black line indicating the median score, while dots represent outliers.

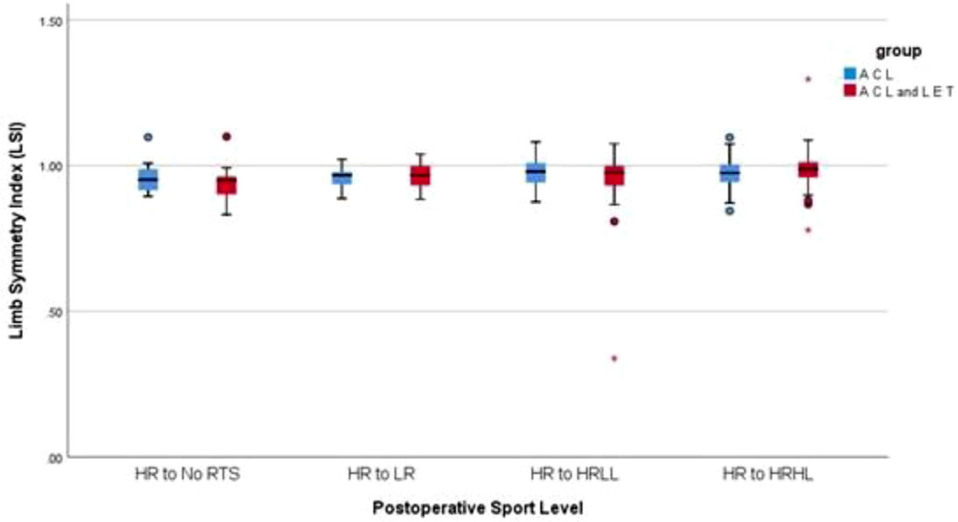

Fig 3. Limb symmetry index (LSI) in patients who were participating in high-risk sports preoperatively. The LSI was measured after return to sport (RTS) or at 24 months postoperatively if the participant had not yet returned to sport. For those participants with graft or contralateral anterior cruciate ligament (ACL) rupture, we used the LSI measurement closest to the event. The box plot illustrates the differences in the LSI between the study groups (anterior cruciate ligament reconstruction [ACLR] and ACLR plus lateral extra-articular tenodesis [LET]) when participants returned to different sport types (high risk [HR] vs low risk [LR]) and sport levels (high level [HL], defined as elite, varsity, or competitive, vs low level [LL], defined as recreational).

they aged out of being eligible for sports participation or were too busy to return (Table 3), which suggests a change in priorities and potential response shift after ACLR. Response shift is a phenomenon proposed to occur after a significant life event that leads to a change in a patient's priorities.[15] This can be problematic when using PROMs to determine the effect of treatment, given that items on PROMs are designed under the assumption that patients will interpret them the same way at each visit.[16] If patients' priorities change over time, such as the role or importance of sports in their lives, so too might their interpretation of PROMs that ask questions about sports participation and function.[15] The response-shift phenomenon could help explain why the STABILITY study was able to show significant differences in clinical outcomes between the ACLR-alone and ACLR-LET groups yet no difference in functional outcomes or quality of life was observed.[6,12] Our sample includes young, active participants who may be transitioning from high school to post-secondary education or joining the workforce around the time they undergo ACLR. Although a portion of patients do not return to their baseline level of sport, they may achieve a level of function and activity that they deem satisfactory because it fits their new lifestyle. Response shift has yet to be established in patients after ACLR and should be studied further because this phenomenon can greatly affect the ability of PROMs to detect treatment effects in clinical trials.[17]

Not surprisingly, the main reason for not returning to sports reported by patients in this study was fear of reinjury. Kinesiophobia has been shown in multiple studies to be a significant factor in a patient's return-to-play status.[18,19] By developing the ACL—Return to Sport After Injury (ACL-RSI) scale, Webster et al.[20] have observed improved RTS and reduced reinjury rates in patients with higher levels of confidence. The ACL-RSI scale has now been used in multiple studies and has proved to be a very strong predictor of readiness for RTS.[21]

Although we did not use the ACL-RSI scale, we did look at a number of other postoperative factors to determine readiness for return to play. Isokinetic and isometric quadriceps strength has been used as a simple tool to determine readiness for RTS.[22,23] A number of studies have shown that quadriceps strength is an important predictor of readiness to return.[24-27] A cross-sectional study of 94 patients by Lentz et al.[24] (2012) found that the quadriceps peak torque—body weight ratio was an important contributor to their model predicting RTS at 1 year postoperatively, although it was not independently statistically significant ($P = .05$). A subsequent study of 73 participants by Lentz et al.[25] (2015) found that both quadriceps symmetry ($P = .009$) and quadriceps torque normalized for body weight ($P = .04$) were significantly higher at 6 months in patients who had returned to sport compared with those who had not. Two studies assessing factors related to psychological readiness to RTS found that quadriceps strength symmetry was associated with readiness to return to play in both male patients[27] and female patients, if the latter had a noncontact ACL tear rather than a contact injury.[26] A

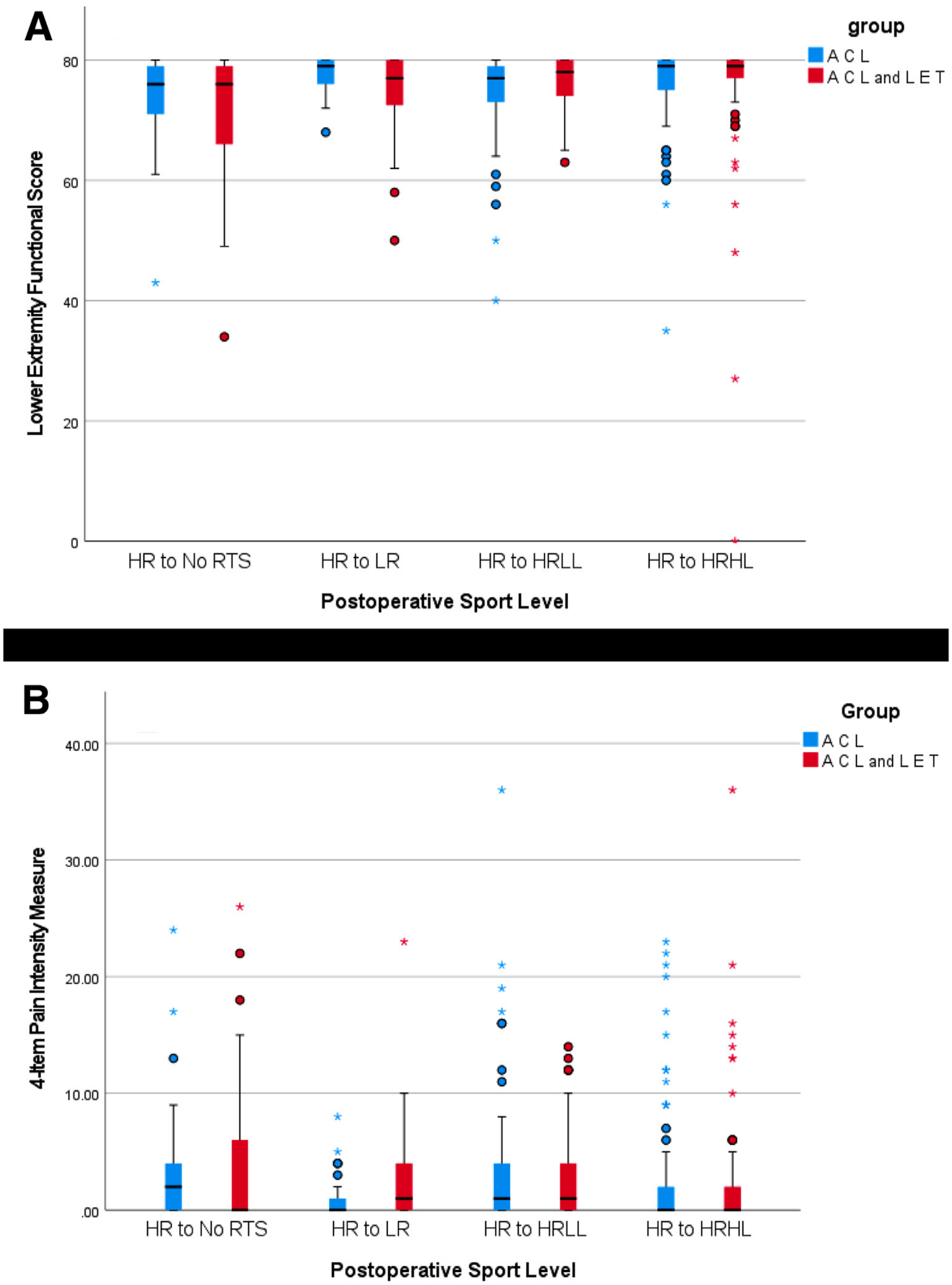

Fig 4. Patient-reported functional outcomes in patients who were participating in high-risk sports preoperatively. Questionnaires were completed at the 24-month visit unless the participant experienced graft or contralateral anterior cruciate ligament rupture, in which case we used the score from the previous visit. The box plot illustrates the differences in median scores for patients returning to increasingly more demanding levels of sport for the Lower Extremity Functional Scale (A) and 4-Item Pain Intensity Measure (B). (ACL, anterior cruciate ligament reconstruction; HL, high level; HR, high risk; LET, lateral extra-articular tenodesis; LL, low level; LR, low risk.)

similar finding was observed regarding quadriceps strength in our study, in particular quadriceps peak torque. Improvements in quadriceps peak torque ratios were associated with higher levels of RTS. The ACLR-alone group had greater symmetry between limbs, presumably owing to quicker quadriceps strength recovery compared with the ACLR-LET group.[12] The clinical significance of this observation is unclear because there were no differences in RTS between groups. It is possible that the addition of the LET provided improved knee stability to allow a return whereas the ACLR-alone group required improved quadriceps strength. However, a clear cause-and-effect relation cannot be determined, and the relation between quadriceps strength, RTS, and augmentation of ACLR with LET needs to be explored further. Hamstring strength had no impact on rates of return.

The lack of significance of the hop test LSI is another important finding from this study. This test was unable to discern differences between groups or predict the ability to RTS. This is primarily because of the ceiling effect that was observed with this test. Most patients were able to achieve at least 90% by the 6-month mark. In our experience, a qualitative assessment of movement pattern is more likely to determine whether patients are ready to return, such as determination of stiff-legged landing, trunk lean, or lack of balance, than the actual numbers recorded. There is also potential for athletes to "game the system" by recording a reduced measurement on the opposite limb, thereby achieving a better LSI. Other studies have also observed that the hop test LSI is not that predictive of a successful return[28] or a reduction in reinjury,[29,30] as we observed in this study.

On the basis of this information, many groups have recommended a batch of RTS tests to determine readiness and injury reduction risk rather than using a single modality. Kyritsis et al.[29] performed a battery of 6 tests including isokinetic strength testing at 60°/s, 180°/s, and 300°/s; a running T test; and single-hop, triple-hop, and triple−crossover hop tests. They found that athletes who did not pass all 6 tests were at a 4 times higher risk of ACL reinjury than those who passed these tests.[29] In a systematic review by Webster and Hewett,[31] passing an RTS battery of tests resulted in a reduction in the risk of subsequent graft rupture by 60% (risk ratio, 0.40; 95% CI, 0.23-0.69; $P < .001$). However, it also increased the risk of a subsequent contralateral ACL injury (risk ratio, 3.35; 95% CI, 1.52-7.37; $P = .003$).

A retrospective review of 24 professional male soccer players who received ACLR with an LET procedure showed significantly reduced anterior-posterior laxity, and the rate of return to preinjury level of sport was 91.7%.[32] A similar retrospective study of 16 high-level female soccer players who received ACLR with LET showed that all the athletes returned to the same level of sport as before injury.[33] A case series of 52 patients who received ACLR and LET with 22 years of follow-up showed that only 1 patient experienced graft failure, and there were no significant medial or lateral joint space changes.[34] Most recently, a systematic review of 19 studies (1,372 patients) showed high rates of return to play (82.8%-100%) when ACLR was performed with extra-articular augmentation.[35] Of note, in 2 of 6 studies that compared ACLR alone and ACLR augmented with an extra-articular procedure in patients competing at similar levels, a higher rate of RTS was observed with the addition of the extra-articular procedure.

Limitations

There are limitations in this study. The degree of game readiness was not assessed at the time patients did RTS. This could mean that patients in either group could have returned to their sport prior to being cleared by a medical professional—and prior to being ready to return. The amount of exposure to a specific sport was also not directly measured. It is therefore difficult to determine whether patients returned to full-intensity competition for the full duration of games versus practice sessions without collecting the amount of game time as a substitute. However, these are factors that are always challenging to measure in studies that analyze RTS after ACLR. Finally, this study involved an exploratory subgroup analysis from a larger trial. Most of our participants played high-risk sports preoperatively and postoperatively, which left us with a small number of participants within each low-risk subgroup. Few observations meant that this analysis was inadequately sized to detect statistical significance.

Conclusions

At 24 months postoperatively, patients who underwent ACLR plus LET had a similar RTS rate to those who underwent ACLR alone. Although the subgroup analysis did not show a statistically significant increase in RTS with the addition of LET, on returning, the addition of LET kept subjects playing longer by reducing graft failure rates.

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