Modified Iliotibial Band Tenodesis Is Indicated to Correct Intraoperative Residual Pivot Shift After Anterior Cruciate Ligament Reconstruction Using an Autologous Hamstring Tendon Graft

A Prospective Randomized Controlled Trial

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Background: The indications for the addition of anterolateral soft tissue augmentation to anterior cruciate ligament (ACL) reconstruction and its effectiveness remain uncertain.

Purpose: To determine if modified iliotibial band tenodesis (MITBT) can improve clinical outcomes and reduce the recurrence of ACL ruptures when added to ACL reconstruction in patients with a residual pivot shift.

Study Design: Randomized controlled trial; Level of evidence, 2.

Methods: Patients with a primary ACL rupture satisfying the following inclusion criteria were enrolled: first ACL rupture, involved in pivoting sports, skeletally mature, no meniscal repair performed, and residual pivot shift relative to the contralateral uninjured knee immediately after ACL reconstruction. Patients were randomized to group A (no further surgery) or group B (MITBT added) and were followed up for 2 years. The patient-reported outcome (PRO) measures used were the International Knee Documentation Committee (IKDC) score, Knee injury and Osteoarthritis Outcome Score (KOOS) subscale of sport/recreation (Sport/Rec), KOOS subscale of quality of life (QoL), Lysholm knee score (LKS), Tegner activity scale (TAS), recurrent ACL ruptures, or need for further surgery in either knee. Analysis of variance was used to compare PROs; the Wilcoxon test was used for the TAS; and the chi-square test was used for recurrence of ACL ruptures, meniscal injuries, and contralateral ACL ruptures ($P < .05$).

Results: A total of 55 patients were randomized: 27 to group A (female:male ratio = 15:12; mean age, 22.3 ± 3.7 years) and 28 to group B (female:male ratio = 17:11; mean age, 21.8 ± 4.1 years). At 2-year follow-up, group A had a similar IKDC score (90.9 ± 10.7 vs 94.2 ± 11.2; respectively; $P = .21$), lower KOOS Sport/Rec score (91.5 ± 6.4 vs 95.3 ± 4.4, respectively; $P = .02$), similar KOOS QoL score (92.0 ± 4.8 vs 95.1 ± 4.3, respectively; $P = .14$), lower LKS score (92.5 ± 4.8 vs 96.8 ± 8.0, respectively; $P = .004$), lower TAS score (median, 7 [range, 7-9] vs 8 [range, 8-10], respectively; $P = .03$), higher rate of recurrence (14.8% vs 0.0%, respectively; $P < .001$), similar rate of meniscal tears (14.8% vs 3.6%, respectively; $P = .14$), and similar rate of contralateral ACL ruptures (3.7% vs 3.6%, respectively; $P = .99$) relative to group B.

Conclusion: The augmentation of ACL reconstruction with MITBT reduced the risk of recurrent ACL ruptures in knees with a residual pivot shift after ACL reconstruction and improved KOOS Sport/Rec, LKS, and TAS scores.

Registration: ACTRN12618001043224 (Australian New Zealand Clinical Trials Registry)

Keywords: ACL reconstruction; iliotibial band tenodesis; augmentation; recurrence; pivot shift

Although the management of anterior cruciate ligament (ACL) ruptures has improved, up to 25% of patients undergoing ACL reconstruction do not make a complete recovery in terms of patient-reported outcomes (PROs), knee kinematics, and return to sports.[3,14,16,18] Technical factors only account for some of these failures. Residual anterolateral rotatory instability (ALRI) associated with a positive pivot shift after ACL reconstruction is one factor associated with poor functional outcomes.[4,18,25,59] There is substantial evidence that damage to the anterolateral soft

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tissues may contribute to instability, but there is debate as to which are the most important structures.[§] A study by Guenther et al[19] suggested that the anterolateral soft tissues function together like a sheet of tissues or as the "anterolateral complex" (ALC).

There has been renewed interest in the augmentation of ACL reconstruction with extra-articular anterolateral soft tissue reconstruction, or tenodesis, to correct residual ALRI. The indications for such procedures remain uncertain. The use of an ALC procedure may be indicated only in the subgroup of patients with an increased risk of poor outcomes, further surgery, or graft ruptures. This group includes those with a higher-grade pivot shift before surgery,[31] which is associated with greater laxity of the knee,[34,65] as well as those with increased laxity on manual testing after surgery.[58] The severity of the pivot shift has been correlated with functional instability, patient dissatisfaction, activity limitation, poor knee function, limited sports participation, and lower functional knee scores.[25] Incomplete correction of the pivot shift after ACL reconstruction may be an indication to perform an ALC procedure.

The modified iliotibial band tenodesis (MITBT) procedure has been shown to improve ALRI after revision ACL reconstruction in vivo using computer navigation.[49] This particular technique allows the surgeon to examine the knee for residual ALRI and adjust the tension to correct it. For these reasons, we used incomplete correction of the pivot shift at the time of surgery as a potential indication to perform MITBT.

The goal of this study was to determine if the addition of MITBT improves clinical outcomes and/or reduces the risk of recurrent ACL ruptures in patients in whom ACL reconstruction did not restore normal anterolateral stability at the time of surgery, as determined by the pivot-shift test. Our null hypothesis was that the addition of MITBT does not influence PROs or recurrence rates after ACL reconstruction.

METHODS

Patients presenting to the main author (M.P.) between July 1, 2014, and January 1, 2017, with a primary ACL rupture and who satisfied the inclusion criteria in Table 1 were invited to take part in the study. The ACL rupture was confirmed using both magnetic resonance imaging (MRI) and arthroscopic surgery. The presence of a residual pivot shift relative to the contralateral knee could only be determined after the completion of ACL reconstruction while the patient was still under general anesthesia. For this reason, all patients had to consent to take part in the study before undergoing their ACL reconstruction with the knowledge that they may or may not be included in the study.

TABLE 1
Inclusion and Exclusion Criteria for Patient Recruitment[a]

Inclusion Criteria	Exclusion Criteria
ACL rupture (diagnosed on MRI and at arthroscopic surgery)	Other ligament injury greater than grade 1 or reparable meniscal tear
Skeletally mature	Previous ACL injury in either knee
Noncontact ACL injury	Unwilling to be randomized to either treatment group
Involved in twisting/pivoting sports	More than 6 weeks after ACL injury
ACL reconstruction performed within 6 weeks of injury	Not fit for general anesthesia
Pivot shift of at least 1 grade higher than contralateral knee after ACL reconstruction	Rheumatoid arthritis, connective tissue disease, or autoimmune disease

[a]ACL, anterior cruciate ligament; MRI, magnetic resonance imaging.

For all patients, age, sex, body mass index (BMI), time between injury and surgery, and posterior tibial slope (PTS) were recorded. An increased PTS is associated with ACL graft ruptures,[5,8] and this was measured on lateral radiographs as described by Webb et al.[64] Patients were enrolled in the study if the pivot shift in the operative knee was $\geq$1 grade greater than that of the contralateral knee after ACL reconstruction. They were informed that they may have an extra incision performed at the site of the MITBT procedure with a potentially increased risk of surgical complications and postoperative pain. If patients declined to take part in the study, they underwent standard isolated primary ACL reconstruction.

After the administration of general anesthesia and before the application of the tourniquet, both knees underwent an examination under anesthesia. The pivot-shift test was performed in the standard manner as described previously,[15,22,30,35] and results were graded as 0 (none), 1 (glide), 2 (clunk), or 3 (gross). The tourniquet was applied and inflated before the pivot-shift test was repeated and results graded on the operative side.

Immediately after ACL reconstruction was performed, the pivot-shift test was repeated. If the pivot shift was $\geq$1 grade greater than that recorded for the uninjured contralateral knee, patients were randomly allocated to either undergo no further surgery (group A) or undergo the addition of MITBT (group B). Randomization was performed

[§]References 9, 24, 26, 27, 37, 45, 46, 51, 63.

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using a computer-generated random number assigned to the patient. This was done at the time of surgery by theater personnel not involved in the procedure. Blinding of the patient and surgeon was not possible because of the presence of the additional incision required for the MITBT procedure.

All patients followed the standard postoperative protocol for ACL reconstruction. Patients were allowed to return to competitive twisting and pivoting sports at 9 months after surgery if they described their knee as symptom-free and their strength, balance, proprioception, jumping, and landing techniques were similar in both legs.

ACL Reconstruction Technique

The technique used was similar to that described in the literature.[47] Standard knee arthroscopic surgery was performed, during which all pathological abnormalities within the knee were documented and treated. If meniscal repair was performed, the patient was excluded from the study, as the patient's rehabilitation would differ significantly from that after ACL reconstruction with or without partial meniscectomy. A doubled autologous hamstring tendon graft was used to form a quadruple-bundle graft. The size of the femoral and tibial ends of the graft was measured and recorded. The femoral tunnel was drilled via the anteromedial portal with the knee in full flexion, as posterior as possible within the footprint to leave 1 mm of bone behind the aperture. The tibial tunnel was centered one-third of the way along a line joining the medial tibial spine to the anterior horn of the lateral meniscus. The graft was secured with screws made of poly-L-lactic acid-hydroxyapatite material (BIORCI-HA; Smith & Nephew). Research has demonstrated that this tunnel positioning and graft fixation will correct the pivot shift in knees with an isolated ACL rupture.[47,48]

MITBT Procedure

This procedure was performed in a manner similar to that described in the literature.[49] A 1-cm strip of the iliotibial band was harvested, preserving its distal attachment. The graft was passed from superficial to deep, around the proximal lateral collateral ligament, before being passed into a bone tunnel immediately posterosuperior to the iliotibial band attachment on the tibia. The tension in the looped graft was increased by pulling on the lead suture, which was attached to the end of the iliotibial band strip and exited the tibial tunnel via the medial cortex of the tibia. The tension was adjusted and the pivot-shift test was repeated until the grade was the same as that recorded for the uninjured contralateral knee. The iliotibial band loop was then secured with a third BIORCI-HA interference screw.

Primary Outcomes of Interest and Follow-up

The following validated PRO measures were used:

1. Subjective International Knee Documentation Committee (IKDC) score[2,36]
2. Knee injury and Osteoarthritis Outcome Score (KOOS) subscales of quality of life (QoL) and sport/recreation (Sport/Rec)[32,52]
3. Lysholm knee score (LKS)[6,7]
4. Tegner activity scale (TAS)[7,32,60]

The PRO measures were completed before surgery and at 2 years after surgery. Patients were seen at 10 days, 6 weeks, 6 months, 1 year, and 2 years after surgery.

The other primary outcome of interest was the recurrence of ACL ruptures. Secondary outcomes of interest included any further surgery to the injured knee, ACL ruptures in the opposite knee, or any complication. The patients were assessed and all data were recorded in a computerized database in the surgeon's consulting rooms at each review.

Ethical approval was granted by the ethics committee of the hospital where the surgical procedures were performed. This randomized controlled trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12618001043224). The study was prospective with 2 parallel treatment groups and simple 1:1 randomization.

Statistical Analysis

Statistical analysis was performed using SPSS computer software (version 22; IBM). The baseline characteristics of the 2 groups were compared using the chi-square test for sex and grade of pivot shift in both the injured and contralateral knees, and analysis of variance was used for age, BMI, PTS, time before surgery, IKDC score, KOOS Sport/Rec score, KOOS QoL score, LKS score, and graft size. For the TAS score, nonparametric analysis using the Wilcoxon test was performed. Follow-up data were analyzed to compare the 2 groups with respect to changes in scores within groups and between groups using analysis of variance for IKDC, KOOS Sport/Rec, KOOS QoL, and LKS scores and the chi-square test for recurrence of ACL ruptures, contralateral ACL ruptures, and further surgery on the injured knee. The Wilcoxon test was used to compare the changes in TAS scores.

Ethical approval allowed patients to be enrolled in the study until it was large enough to detect a significant difference in recurrence rates between the groups at 2-year follow-up. A pre hoc power analysis was not performed. A post hoc power analysis was then performed to determine if the study size was sufficient to detect a statistically significant difference between the 2 groups with respect to all the primary outcomes of interest. These were the following PRO measures: subjective IKDC score, KOOS QoL and Sport/Rec subscales, LKS, and TAS, as well as recurrent ACL ruptures.

RESULTS

Patient Recruitment and Baseline Data

During the study period, 484 ACL reconstruction procedures were performed. Of these patients, 55 (11.4%) satisfied all study criteria and were enrolled in the study. A total of 27 patients were randomized to group A and 28

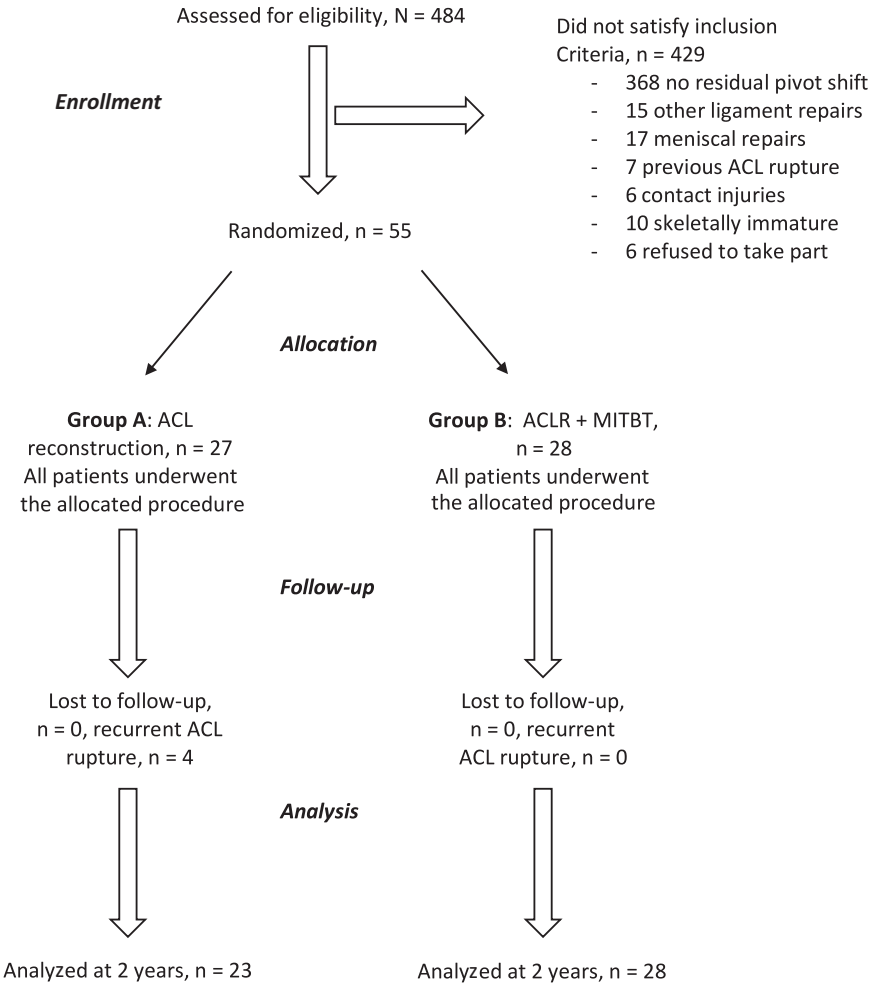

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram for the randomized controlled trial. ITB, iliotibial band; LCL, lateral collateral ligament.

to group B. In group A, patients took part in the following sports: soccer (n = 8), touch football (n = 7), netball (n = 5), rugby (n = 5), and ultimate frisbee (n = 2). In group B, patients took part in the following sports: soccer (n = 9), rugby (n = 7), netball (n = 6), field hockey (n = 3), squash (n = 1), lacrosse (n = 1), and skiing (n = 1). The female:male ratios in groups A and B were similar: 15:12 and 17:11, respectively (P = .59). Figure 1 shows the CONSORT (Consolidated Standards of Reporting Trials) flow diagram for this randomized controlled trial.

The baseline characteristics of the 2 groups are shown in Table 2. Patients were scheduled for surgery as soon as possible after the restoration of at least 90° of flexion. The ratio of female:male patients, mean age, BMI, time from injury to surgery, PTS, and graft size were similar in the 2 groups, as detailed in Table 2. The PROs before surgery are also shown. The LKS and TAS scores were recorded based on the patient's level of activity before the ACL injury. The LKS scores were similar in the 2 groups at baseline (P = .58). The TAS scores were also similar, with a median of 8 (range, 7-10) in group A versus 8 (range, 6-10) in group B (P = .70). The size of the femoral and tibial tunnels, drilled to match the diameter of the ends of the ACL graft, were similar in the 2 groups (P = .92 and P = .88, respectively). There were 5 meniscal tears treated with partial meniscectomy in group A (4 lateral, 1 medial) and 7 in group B (4 lateral, 3 medial) but no osteochondral lesions in either group.

Pivot-Shift Grades

Among the 55 knees included in the study, the pivot shift in the injured knee before ACL reconstruction was grade 1 in 19 knees, grade 2 in 18, and grade 3 in 18. The grade of pivot shift was not influenced by the presence of an inflated tourniquet in any of the injured knees. The distribution was similar in groups A (n = 9, 10, and 8, respectively) and B (n = 10, 8, and 10, respectively) (P = .39). None of the injured knees had a grade 0 pivot shift. With regard to the uninjured contralateral knees, 45 of the knees had a grade 0 pivot shift, and 10 had a grade 1 positive pivot shift; 6 of these positive pivot shift tests were in group A and 4 were in group B. After ACL reconstruction,

TABLE 2
Baseline Characteristics of Groups A (Isolated ACL Reconstruction) and B (ACL Reconstruction Plus MITBT)[a]

	Group A (n = 27)	Group B (n = 28)	*P* Value
Female:male sex, n	15:12	17:11	.59
Age, y	22.3 ± 3.7	21.8 ± 4.1	.65
BMI, kg/m^2	21.1 ± 1.8	21.0 ± 1.5	.90
PTS, deg	9.2 ± 1.3	9.2 ± 1.4	.95
Time to surgery, d	22.0 ± 8.2	25.0 ± 10.1	.54
IKDC score	50.0 ± 7.0	50.6 ± 5.3	.73
KOOS Sport/Rec score	57.0 ± 6.8	55.1 ± 4.9	.27
KOOS QoL score	56.5 ± 6.3	57.0 ± 6.6	.77
LKS score	53.6 ± 7.3	52.6 ± 4.4	.58
Preinjury TAS score, median (range)	8 (7-10)	8 (6-10)	.70
Postinjury TAS score, median (range)	2 (1-3)	2 (2-4)	.55
Femoral tunnel, mm	8.1 ± 0.5	8.0 ± 0.6	.92
Tibial tunnel, mm	8.4 ± 0.7	8.5 ± 0.5	.88

[a]Data are presented as mean ± SD unless otherwise indicated. BMI, body mass index; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; LKS, Lysholm knee score; MITBT, modified iliotibial band tenodesis; PTS, posterior tibial slope; QoL, quality of life; Sport/Rec, sport/recreation; TAS, Tegner activity scale.

TABLE 3
PRO Scores at 2 Years After ACL Reconstruction[a]

	Group A	Group B	*P* Value	Effect Size
IKDC	90.9 ± 10.7	94.2 ± 11.2	.21	0.89
KOOS Sport/Rec	91.5 ± 6.4	95.3 ± 4.4	.02[b]	0.32
KOOS QoL	92.0 ± 4.8	95.1 ± 4.3	.14	0.65
LKS	92.5 ± 4.8	96.8 ± 8.0	.004[b]	0.96
TAS, median (range)	7 (7-9)	8 (8-10)	.03[b]	N/A
Recurrent rupture, n	4	0	<.001[b]	N/A
Meniscal tear, n	4	1	.14	N/A
Contralateral ACL tear, n	1	1	.99	N/A

[a]Data are presented as mean ± SD unless otherwise indicated. ACL, anterior cruciate ligament; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; LKS, Lysholm knee score; N/A, not available; PRO, patient-reported outcome; QoL, quality of life; Sport/Rec, sport/recreation; TAS, Tegner activity scale.
[b]Statistically significant ($P < .05$).

the pivot shift was grade 1 in 45 patients and grade 2 in 10 patients. No patients had a grade 3 pivot shift after ACL reconstruction. The distribution of grade 1 and grade 2 pivot shifts was similar in the 2 groups, being 21 and 6 in group A, and 24 and 4 in group B, respectively (P = .91). After the MITBT procedure, no patient in group B had residual pivot shift relative to the contralateral knee.

Patient-Reported Outcomes

These are summarized in Table 3. The groups did not differ with regard to IKDC scores, KOOS QoL scores, occurrence of meniscal tears, or risk of contralateral ACL ruptures. However, group B had significantly higher scores on the KOOS Sport/Rec (95.3 ± 4.4 vs 91.5 ± 6.4, respectively; P = .02), LKS (96.8 ± 8.0 vs 92.5 ± 4.8, respectively; P = .004), and TAS (median, 8 [range, 8-10] vs 7 [range, 7-9], respectively; P = .03) relative to group A. Group A had a higher incidence of recurrent ACL ruptures (14.8%) than group B (0.0%) ($P < .001$), while groups A and B had a similar risk of contralateral ACL ruptures (4% in each group) (P = .99). All recurrences occurred as a result of a noncontact injury during sports and were confirmed with both a clinical assessment (grade 3 Lachman test result and positive pivot shift) and MRI. Of these 4 patients, 3 were male and 1 female, and their ages were between 19 and 24 years with graft sizes between 7.0 and 8.5 mm. In these 4 patients, 2 had a grade 1 pivot shift before surgery in the injured knee, and 2 had a grade 2 pivot shift. In these patients, who were all in group A, the pivot shift after ACL reconstruction was grade 1 in 3 patients and grade 2 in 1 patient.

Power Analysis

A post hoc power analysis determined that the study was sufficiently powered to detect a significant difference in KOOS Sport/Rec scores, KOOS QoL scores, LKS scores, TAS scores, and recurrence of ACL ruptures, for which a minimum study size of 42 was required to achieve a power of 80% and a 5% risk of a type I error. It was

underpowered with regard to the IKDC score, for which 140 patients were required, and meniscal tears, for which 98 were required. Recruitment was discontinued when the study was large enough to detect a significant difference in the primary outcome of recurrent ACL ruptures. The patients will be part of an ongoing follow-up study.

The difference in LKS scores seen in the 2 groups was 4.3, less than the minimal detectable change of 8.9. The difference in TAS scores seen in the 2 groups was 1.0 and thus equal to the minimal detectable change of 1.0.

Recurrent ACL Injuries and Meniscal Tears

The rate of graft ruptures in the study population over the 2-year period was 4 of 55 or 7.3%. All graft ruptures occurred in group A, with 4 of 27 or 14.8%, which was higher than that in group 2, which was 0.0% ($P < .001$). During the 2-year period, 15 of the 429 patients who did not satisfy the inclusion criteria (3.5%) tore their ACL graft. Of the 484 ACL reconstruction procedures performed during the 2-year recruitment interval, there were 19 graft ruptures or 3.9%. Within the study population, all recurrent ACL ruptures occurred in group A, and all occurred more than 12 months after surgery. The PRO data for these patients were not included in the 2-year analysis, as their low scores during the earlier rehabilitation phase of a revision procedure would have biased the results against group A.

The number of meniscal tears was similar in the 2 groups, being 4 in group A (14.8%) and 1 in group B (3.6%) ($P = .14$). The rate of contralateral ACL ruptures was also similar in both groups, being 1 in group A (3.7%) and 1 in group B (3.6%) ($P = .99$). However, the study was underpowered for these analyses. There were no osteochondral lesions in either group and no complications in either group. Apart from the patients who required revision ACL reconstruction, there were no other secondary procedures performed.

DISCUSSION

This study found that in patients with a residual pivot shift of $\geq$1 grade greater than that of the contralateral uninjured knee after ACL reconstruction, the addition of MITBT at the time of surgery reduced the risk of recurrent ACL ruptures and improved KOOS Sport/Rec, LKS, and TAS scores in patients returning to pivoting sports when reviewed at 2 years after surgery. Therefore, we reject our null hypothesis.

Most patients with an acute ACL rupture achieve an acceptable outcome after ACL reconstruction.[3,14] The challenge is to determine why some ACL grafts fail and whether this can be prevented.

Research has shown that in the presence of an isolated ACL rupture, it is possible to correct ALRI at the time of surgery using single-bundle ACL reconstruction.[47] The cadaveric study performed by Noyes et al[43] suggested that ACL reconstruction was able to restore native kinematics and rotational stability in all knees, even those with a grade 3 pivot shift and physiological laxity.

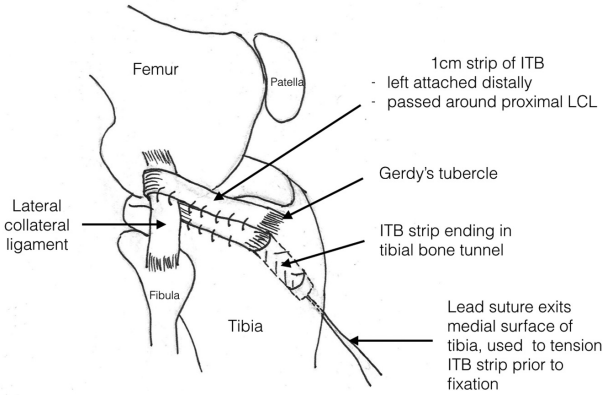

Figure 2. The modified iliotibial band tenodesis procedure. ACL, anterior cruciate ligament; ACLR, ACL reconstruction; MITBT, modified iliotibial band tenodesis.[49]

Research suggests that the presence of persistent significant anterolateral instability relative to the contralateral uninjured knee immediately after ACL reconstruction may be caused by other factors such as damage to the ALC.[1,35,45] Our study criteria attempted to recruit these patients.

Diagnostic imaging techniques are of limited value in determining whether an anterolateral procedure is indicated. Although an MRI diagnosis of ALC injuries may be possible, the reliability, accuracy, and correlation with intraoperative findings are poor.[20,21,38] The pivot-shift test remains the most practical tool available for the diagnosis of anterolateral instability.[30,35,41] The goal of most orthopaedic surgeons would be to correct ALRI, as evidenced by the pivot-shift test, and to restore the grades of the pivot shift to a value similar to that of the uninjured contralateral knee. Failure to do so may be a practical indication to add a lateral extra-articular tenodesis (LET)–type procedure.

Chronic ACL deficiency has been proposed as another indication to add MITBT on the basis that chronic instability may weaken secondary restraints in the region of the ALC.[10,55,56,62] The time between an ACL rupture and reconstruction was similar in our 2 groups ($P = .54$).

An increased PTS has also been associated with an increased risk of ACL graft ruptures.[8,29] This was measured on a true lateral view of the knee in all patients as described previously.[64] The PTS was recorded for every patient in the study, and the mean value in group A (9.2° $\pm$ 1.3°) was similar to that in group B (9.2° $\pm$ 1.4°) ($P = .95$).

There are a number of lateral extra-articular reconstructive procedures and varied schools of thought as to which structure is most important. Surgical techniques may concentrate on a component of the ALC under the assumption that this is the most important structure. The anterolateral ligament and iliotibial band are the components of the ALC that have gained the most attention, but research has not agreed on their relative importance.[23,24,36,46,55,61,63]

The cadaveric sectioning study performed by Noyes et al[42] in 2017 used a robotic simulator to measure changes in rotational stability and concluded that neither the anterolateral ligament nor iliotibial band played a significant

enough role to warrant an additional procedure. Of interest was the fact that the authors did caution that "clinical exceptions may exist, such as grossly unstable grade 3 pivot shift knees and revision knees." The authors in that study may be referring to knees with other factors contributing to ALRI, such as ALC damage.

Guenther et al[19] performed another cadaveric sectioning study and concluded that the various longitudinally orientated ligamentous components of the ALC affected knee function in a manner similar to a sheet of tissues rather than individual ligaments. On the basis of their research, it is unlikely that ALC reconstructive procedures will restore the sheetlike function of the tissues unless the technique restores the ability of the tissues to transmit forces between adjacent regions of the ALC.

MITBT is designed to provide a physiological endpoint rather than replicate specific anatomy, but from an anatomic perspective, it may bind together the tissues of the ALC and tension them to a point that the pivot shift is corrected before final fixation (Figure 2). The modification was designed to allow the minimum tension required by the anterolateral procedure to control ALRI while avoiding overconstraint. These features distinguish it from the modified Lemaire procedure used by Getgood et al.[17] Although concerns may have been raised that anterolateral soft tissue procedures may overconstrain the knee and contribute to degeneration over time,[53] research has shown that these procedures do not overconstrain the knee, nor do they increase lateral tibiofemoral contact pressure or cause loss of internal rotation as long as the graft is tensioned in neutral and not excessively.[11,33] These patients are part of ongoing research and will be monitored for the development of symptoms suggestive of degeneration.

Clinical outcome studies have also been performed investigating the use of an extracapsular augmentation procedure with revision ACL reconstruction. Ferretti et al[12,13] reported that extra-articular augmentation of revision ACL reconstruction provided a satisfactory outcome in terms of PROs with a 10% risk of re-recurrence. However, these were case series with no comparison group.[12,13] The higher risk of recurrence in their series relative to our study is likely because these were revision procedures. Lee et al[28] performed a nonrandomized retrospective study in patients undergoing revision ACL reconstruction with a 3-year follow-up. They found that the addition of anterolateral ligament reconstruction resulted in improved clinical outcomes and return to sports activity relative to ACL reconstruction, which would agree with our results. However, this was a nonrandomized retrospective cohort study. Porter et al[49] demonstrated, in a prospective comparative study, that the addition of a MITBT procedure in patients with a residual pivot shift after revision ACL reconstruction could restore rotational laxity to values similar to those seen in patients who did not require iliotibial band tenodesis, with similar activity scores at 2 years after surgery.

Other studies, using varied indications for anterolateral augmentation, have compared the outcomes of primary ACL reconstruction with and without anterolateral augmentation with mixed results.[44,57] Systematic reviews have also been performed. Rezende et al[50] analyzed randomized controlled trials of ACL reconstruction with and without LET. There was no difference in functional outcomes, but a higher proportion of patients undergoing LET had a normal or nearly normal knee on the pivot-shift and Lachman tests. Song et al[54] assessed the clinical outcomes in studies comparing ACL reconstruction and combined procedures for patients with a high-grade pivot shift before surgery. There was a higher prevalence of residual pivot shift in the isolated ACL reconstruction group (27.2%) compared with the combined group (13.3%). These systematic reviews provide evidence of the efficacy of the combined procedure in reducing the prevalence of residual pivot shift while other outcomes were similar. Although these studies did not find an improved clinical outcome, the data were pooled from studies using variable inclusion criteria.

Studies have also attempted to determine if ALC augmentation can improve graft survival. Sonnery-Cottet et al[56,57] studied the effect that an augmentation procedure had on graft rupture rates using autologous hamstring tendon grafts. These prospective studies followed up patients for an average of over 3 years and found that the graft rupture rate was 2.5 to 3.1 times less in the combined procedure group.[56,57] These nonrandomized studies agree with our study with respect to the reduced risk of recurrent ACL ruptures in patients undergoing the combined procedure. Over the 2-year follow-up period, none of our patients undergoing MITBT sustained a rupture of the ACL graft, but this figure may increase with a longer follow-up.

There are a number of weaknesses in our study. It is a relatively small, single-surgeon study. There is a larger multicenter randomized controlled trial underway that is trying to determine if a LET procedure will improve stability of the ACL-deficient knee when added to single-bundle ACL reconstruction in patients with generalized ligamentous laxity and/or a pivot shift of grade 2 or 3.[17] The results of this study are outstanding, and it remains to be seen if the outcome will assist surgeons in selecting those patients who require the described LET with its associated increased expense and risk of complications.

Another weakness in our study was that the presence of the inflated tourniquet during the performance of the pivot-shift test immediately after the completion of ACL reconstruction may have influenced the pivot shift. Deflating the tourniquet after ACL reconstruction, and before the application of dressings and bandages and/or before reinflating it again to perform an MITBT, was regarded as too great a departure from the normal routine to be considered ethical. However, we found that the inflation of a tourniquet did not alter the grade of the pivot shift in any of the knees operated on, and thus, the potential influence of the tourniquet may not be clinically significant.

We were unable to blind the patient or surgeon with regard to which group the patient was randomized to, as has been referred to above. The subjective nature of the execution and interpretation of the pivot-shift test is another weakness, but this test remains the most useful and practical clinical tool for the orthopaedic surgeon, particularly in the operative setting.[39,40] The results of the study may only apply to skeletally mature patients involved in pivoting sports and surgery performed by a subspecialist sports orthopaedic surgeon.

CONCLUSION

In conclusion, the results of this study have shown that patients with a residual pivot shift who underwent augmentation of ACL reconstruction had a decreased risk of recurrent ruptures and higher postoperative activity levels and subjective PROs. The persistence of a residual pivot shift immediately after ACL reconstruction may be considered an indication to augment the reconstruction procedure with MITBT.

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