

Cross Bracing Protocol for Anterior Cruciate Ligament (ACL) Rupture Has Unacceptably High Failure Rate Relative to Surgical Stabilization: A 2-year Controlled Cohort Study

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Abstract

Objective: To compare the clinical outcome of patients electing to undergo the Cross Bracing Protocol (CBP) for ACL rupture with those choosing surgical stabilization. **Design:** Observational prospective cohort study with 2-year follow-up. **Setting:** Private subspecialist sports orthopedics and sports medicine practice. **Patients:** The 80 patients who both entered and completed the study were skeletally mature 16 to 40 years old, presenting with an acute noncontact isolated ACL rupture, taking part in pivoting sports and intent on returning to that activity. ACL rupture was diagnosed on both clinical assessment and MRI. Patients were fit for general anesthetic and free of significant medical conditions. **Interventions:** Group A (40 patients) underwent surgical stabilization, and group B (40 patients) followed the CBP. The groups were similar regarding the following independent variables: age, body mass index, gender, dominance of the injured knee, and posterior tibial slope ($P > 0.05$). **Main outcome measures:** Recurrent instability, incidence of meniscal tears, and the following patient-reported outcome measures (PROMs); Tegner Activity Scores; Knee Injury Osteoarthritis Outcome Score subscales of sport/recreation and knee-related quality of life; subjective International Knee Documentation Committee score; and Lysholm Knee Score. **Results:** Group B had significantly higher risk of recurrent instability (70% vs 2.5%, $P < 0.001$), medial meniscal tear (62% vs 2.5%, $P < 0.001$), and inferior performance on all PROMs ($P < 0.001$). **Conclusions:** The CBP is associated with an unacceptably high rate of recurrent instability when used to treat ACL ruptures in patients taking part in pivoting sports.

Key Words: anterior cruciate ligament, reconstruction, physiotherapy, bracing

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INTRODUCTION

There are vastly conflicting data in the literature regarding the efficacy of nonoperative treatment of ACL rupture.^{1–6} This may be related to variations in how an ACL rupture is diagnosed, the inclusion criteria, the treatment protocol used, what outcomes of interest were used, and how these were measured. Some research is confounded by reliance on MRI for both the diagnosis of ACL rupture and grading the healing of ACL injuries, the accuracy of which is variable or unknown.^{1,2,7}

Similarly, success rates after surgical treatment of ACL rupture can vary greatly. Rates of return to competitive sport after ACL reconstruction have been reported to be as low as

55%, but this is a crude measure of the success of surgery on account of the multiple variables involved in the patient's final decision to return to play.⁸ The technical success of the surgery is one of these variables, and this, in turn, is influenced by multiple variables including graft positioning, graft fixation, and the use of anterolateral augmentation procedures. Research performed by the authors over the last 15 years has shown that failure rates of less than 2% per year are possible after ACL reconstruction.^{9,10} This can be achieved when surgical reconstruction corrects the anterolateral rotatory instability in the ACL deficient knee using optimal tunnel position,¹¹ aperture fixation of the graft,¹² and a modified ITB tenodesis when indicated.^{9,10,13}

There has been renewed interest in nonoperative treatment of ACL rupture after the publication of an unblinded case series with only 12-month follow-up, which reported a 90% healing rate on MRI imaging using the Cross Bracing Protocol (CBP).¹⁴ The novel component of the CBP involves holding the knee flexed at 90° for a period of 4 weeks. The rationale proposed is that this is the angle at which the centers of the footprints of the ACL on the femur and tibia are closest together, and therefore, there will be sufficient approximation of loose torn fibers to exclude synovial fluid from the gap and thus enable bridging clot formation with subsequent ligament healing similar to that which occurs in an extrasynovial environment.¹⁴

The objective of our study was to compare the 2-year clinical outcomes in those patients presenting to the main

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All data were collected as part of the main author's routine practice and were stored on a securely protected database and remained anonymous for the analysis. None of the authors have any conflict of interest regarding the conduct of this trial. The study was approved by the ethics committee at the hospital where the ACL reconstructions were performed, and regional ethics approval was deemed unnecessary.

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author and treated with the CBP and physiotherapy, relative to those treated with surgical stabilization. Our null hypothesis was that the CBP would have similar clinical outcomes to that after surgical stabilization.

METHODS

Subjects

Patients presenting to the main author (MDP), both a private subspecialist sports orthopedic surgeon and sports physician, satisfying the study inclusion criteria (Table 1) were invited to take part in the study. These criteria included both clinical and MRI diagnosis of an ACL rupture.

The clinical diagnostic signs for an ACL rupture were a grade 3 Lachman test and a pivot shift of at least 1 grade higher than the contralateral uninjured knee. The pivot shift was performed in the standard manner, graded as 0 (none), 1 (glide), 2 (clunk), or 3 (gross).¹⁵ These findings have an accuracy of 93% using arthroscopy as the gold standard, with a Kappa score of 72%.^{16–18}

The presence of a meniscal tear on MRI was an exclusion criterion. This was done to select a more homogenous patient population with isolated ACL rupture. All MRIs were performed on a 3-Tesla magnet MRI machine (Siemens Magnetom Lumina, Malvern PA 19355) using standard sequences and were reported on by a radiologist with special interest in musculoskeletal MRI but not directly involved in the research. The criteria used to diagnose an ACL rupture were disruption of the continuity of the fibers or edema of the ligament. These criteria have been shown to have a sensitivities of 0.77 and 0.83, and specificities of 0.83 and 0.92, respectively.¹⁹ We used the Anterior Cruciate Ligament Osteoarthritis Score (ACLOAS) grading system for ACL injuries as used by Filbay et al in their study introducing the CBP.¹⁴ This system grades the severity of the ACL injury from 0 to 3 where grade 0 represents a normal ligament with hypointense signal and regular thickness and continuity; grade 1, a thickened ligament and/or high intraligamentous signal with normal course and continuity; grade 2, a thinned or elongated but continuous ligament; and grade 3, an absent ligament or complete discontinuity.

MRI evidence of a grade 3 injury was used as an exclusion criterion in our study because the authors felt that including these patients with either no visible ACL remnant or no ligament continuity would bias the study against the CBP due to the lack of biological potential for these injuries to heal. This is consistent with the suggestion made by Filbay et al¹⁴

that the presence of a large gap or displaced ACL remnant may indicate the need for surgical intervention.

An increased posterior tibial slope is associated with an increased risk of recurrent ACL rupture,^{20,21} and therefore, the lateral posterior tibial slope (LPTS) was measured on the MRI in all patients as described by Hashemi et al,²² and the 2 groups compared to determine if this was a potential confounding factor.

The main author set out to perform a randomized controlled trial, but patients uniformly refused to take part in a study where they did not choose their own treatment. Therefore, in this observational study design, patients selected their own treatment. Unfortunately, this loss of the position of equipoise by patients was beyond the influence of the authors and may have introduced an element of bias into the study, but it is not known which treatment group would be favored by this potential bias.

Treatment Groups

Group A: Surgical Reconstruction

Group A comprised those patients who requested surgical stabilization. As is standard practice for the main author (MDP) they were consented to undergo surgical correction of the anterolateral rotatory instability of their knee using an ACL reconstruction, and modified ITB tenodesis if indicated.⁹ ACL reconstruction was performed using a hamstring autograft. Graft positioning was in the manner described in the literature to correct the pivot shift in an ACL-deficient knee.¹¹ Aperture fixation was used in both bone tunnels to maximize correction of the pivot shift.¹² If there was a residual pivot shift at least 1 grade higher than the contralateral uninjured knee, a modified ilio-tibial band tenodesis (MITBT) was added, again as described in the literature.^{9,13}

Patients in whom the ACL was found to be macroscopically intact during arthroscopy (false positive diagnosis of ACL tear on MRI) were excluded from the study, as were those patients found to have a meniscal tear at arthroscopy (false negative diagnosis of meniscal tears on MRI).

Patients completed a standard post-ACL reconstruction protocol with the goal of returning patients to their preinjury physical activities within 9 months.

Group B: Cross Bracing Protocol

Patients were placed in a knee brace shown to protect the ACL from strain (DonJoy X-ROM, DJO Global, TX).^{23,24} The brace was locked at 90° flexion for 4 weeks and patients followed the protocol, which has been described in detail and supervised by physiotherapists familiar with the protocol but

TABLE 1. Inclusion and Exclusion Criteria for Patient Recruitment

Inclusion Criteria	Exclusion Criteria
ACL rupture—grade 3 Lachman test with no end point, positive pivot shift test, MRI diagnosed ACL rupture, confirmed at surgery in those patients undergoing ACL reconstruction	ACLOAS grade 3 ACL rupture on MRI. Other ligament injury greater than grade 1 or meniscal tear
Skeletally mature	Previous ACL injury in either knee
Noncontact ACL injury sustained within 6 weeks of presentation	Rheumatoid arthritis, connective tissue disease, or autoimmune disease
Involved in twisting/pivoting sport with a goal of returning to the same sport	Not fit for general anesthetic
No meniscal tear diagnosed on MRI	Other indication for surgery such as meniscal tear, osteochondral fracture, loose body

ACL, anterior cruciate ligament; MRI, magnetic resonance imaging; ACLOAS, ACL osteoarthritis score.

not involved in the study.¹⁴ Patients were prescribed a prophylactic dose of rivaroxaban to reduce the risk of thromboembolism.

After 4 weeks, the range of motion (ROM) was gradually increased, aiming for full ROM at 10 weeks. Patients were weaned from the brace at 12 weeks. Patients were allowed to weight bear as tolerable as long as the ROM in the brace was restricted as described in the protocol, and the exercise-based rehabilitation was followed. Return to full sport was not permitted until at least 9 months postinjury and only if rehabilitation had been completed with a full functional recovery demonstrated on testing by the physiotherapist.

Outcomes Measures

Recurrent Instability

Patients were reviewed at 6 weeks, 6 months, 12 months, and 24 months after commencement of treatment and their knee examined on each occasion. They were asked to report any episodes of subjective instability or mechanical symptoms and if there were signs of either an MRI tear or ACL laxity an MRI was arranged. The same MRI criteria were used to diagnose an ACL tear as used before, that is discontinuity of the fibers of either the ACL or the graft. A diagnosis of recurrent instability was only made if there were also clinical signs of an ACL deficient knee, that is a grade 3 Lachman test and a positive pivot shift.

Patient-Reported Outcome Measures (PROMs)

Following are the validated PROMs used, with their minimal clinically important difference (MCID) values.

1. Tegner Activity Score (TAS)—1 point.^{25,26}
2. Subjective International Knee Documentation Committee (IKDC)—5 points.^{27,28}
3. Knee injury and Osteoarthritis Outcome Score (KOOS) sport and recreation subscale (sport/rec) & KOOS Knee-related quality of life (KR QoL)—10 points.^{29,30}
4. Lysholm Knee Score (LKS)—8.9 points.^{25,26}

The PROMs were completed by patients at baseline and repeated at 12 and 24 months postinjury. TAS at baseline referred to their level of activity before the injury. Higher scores indicate improved outcome in all these scores.

Power Analysis

Based on previous research performed by the authors using these PROMs after ACL reconstruction and power analysis calculation, a minimum study size of 46 was required to achieve a power of 80% and with a 5% risk of type 1 error using the MCID values.^{10,25}

Statistical Analysis

Baseline characteristics of the 2 groups were compared using the Pearson χ^2 test and Analysis of Variance (ANOVA), generalized linear models and multivariate tests were used for changes in PROMs, and χ^2 tests for the risk of meniscal tears and recurrent instability. All analyses were performed using 2-tailed tests. The analysis was performed at 1 year and 2 years after commencement of treatment. $P < 0.05$ was used as the level of statistical significance. The analysis was performed using IBM SPSS version 26 software.

RESULTS

A total of 139 patients presented with a primary ACL rupture diagnosed on MRI, over a period of 4 months. Figure 1 is a flowchart summarizing patient flow through the study.

Seventy-eight patients requested surgical stabilization. Of these, 18 (23%) were found to have a macroscopically intact ACL at arthroscopy. Of the 60 patients with ACL rupture confirmed at arthroscopy, 20 were excluded from the study, 13 due to the presence of a meniscal tear not diagnosed on MRI (9 lateral and 4 medial), and 7 had an MCL tear treated with bracing (3 patients) or repair (4 patients). The remaining 40 patients comprised group A. Thirty-five of these underwent an ACL reconstruction, and 5 underwent a combined ACL reconstruction and MITBT.

Sixty-one patients requested nonoperative treatment, and 40 of these satisfied the inclusion criteria comprising group B. Twenty-one patients did not meet the criteria. Eleven (18%) were found to be false positive MRI diagnoses with no clinical signs of ACL rupture. The intact ACL was confirmed with diagnostic arthroscopy in these patients. Three patients had a grade 3 injury to the MCL, and 7 patients had a meniscal tear seen on MRI (5 lateral and 2 medial).

Patient data were entered into the study until it was sufficiently powered to test the study hypothesis, allowing for a loss of 25% of patients to follow-up. Forty patients were enrolled into each treatment group. Tables 2 and 3 detail the results of the statistical analysis. Groups A and B were similar regarding all baseline variables.

Sports Participation

In group A, there were 23 rugby players, 12 soccer players, 2 touch football, and 3 netball players. In group B, there were 20 rugby players, 9 soccer, 7 touch football, and 4 netball players. The length of time before return to sport was not recorded for each patient, but none were allowed to return to sport until they were at least 9 months after commencement of treatment. The TAS scores are an indication of the level of sport that the patient had returned to at the time reported, and these were used to compare the activity level achieved in the 2 groups.

Recurrent Instability

At 2-year follow-up, group A had a highly statistically significantly lower risk of recurrent instability when compared with group B (2.5% vs 70%, $P < 0.001$). In group A, 1 patient (2.5%) experienced recurrent instability more than 12 months postsurgery with rupture of the ACL graft diagnosed clinically and on MRI. This patient underwent a revision ACL reconstruction.

In group B, 28 of 40 patients (70%) developed on-going instability over the 2-year follow-up, 8 (20%) within the first year, and 20 (50%) within the second year. All were treated with a delayed surgical stabilization.

Meniscal Tears

Over the 2-year period, group A had a lower risk of medial meniscal tear than group B (2.5% vs 54%, $P < 0.001$). The incidence of lateral meniscal tears was also lower in group A but did not reach statistical significance (2.5% vs 9.7%, $P = 0.17$).

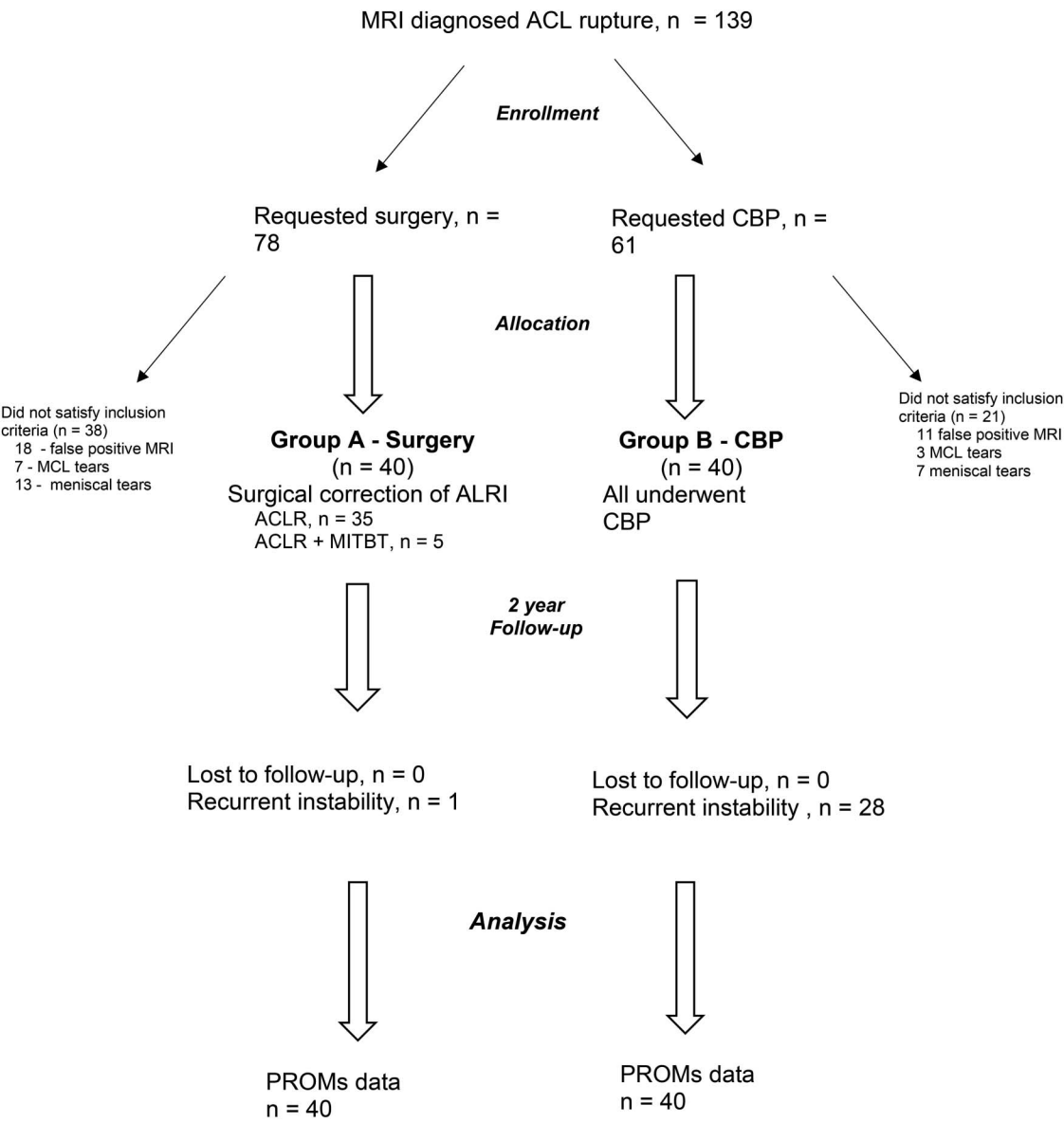


Figure 1. Patient flowchart depicting group allocation and patient follow-up. MRI diagnosed ACL rupture, n = 139. ACL, anterior cruciate ligament; ACLR, anterior cruciate ligament reconstruction; ALRI, anterolateral rotatory instability; CBP, cross bracing protocol; MITBT, modified ITB tenodesis; PROMs, patient-reported outcome measures.

Patient-Reported Outcome Measures

At 2-year follow-up, group A had greater improvement in all the PROMs relative to group B ($P < 0.001$). The results are detailed in Table 3. For those patients who developed recurrent

instability, the highest score achieved during follow-up period was used for comparative analysis. Including data after this would have disadvantaged the nonoperative group on account of the precipitous fall in scores after reinjury.

TABLE 2. Baseline Data of Groups A and B, With Results of Statistical Comparison			
	Group A (40 patients)	Group B (41 patients)	P
Gender	M:F = 14:26	M:F = 16:24	0.73
Dominant:nondominant knee injury	14:26	15:25	0.81
Age in yrs	22.1 (SD 3.8)	21.3 (3.3)	0.23
BMI	21.1(2.0)	21.4 (2.5)	0.40
PTS in degrees	8.4 (1.3)	8.3 (2.0)	0.65
TAS (preinjury)	8.3 (1.1)	8.7 (1.0)	0.33

BMI, body mass index; PTS, posterior tibial slope; TAS, Tegner activity score.
Gender and knee dominance were compared using cross-tabulation (the Pearson χ^2 test), and Analysis of Variance was used for age, BMI, PTS, and TAS before injury.

Other Outcomes

The number of contralateral ACL ruptures was 2 in group A and 1 in group B ($P = 0.31$). There were no significant complications in group A, whereas 2 patients in group B developed a deep venous thrombosis and were treated with oral anticoagulation. No patient in group A experienced stiffness resulting in less than 90° passive flexion at 6 months, whereas there were 4 patients in group B who demonstrated stiffness. The ROM in these patients ranged from a fixed flexion deformity of 10-15° to 80-90° of flexion. The stiffness in all these cases responded to physiotherapy treatment over a period of 3 to 6 months after discontinuation of the bracing. There were no infections nor unscheduled returns to the operating theater in the surgery group.

On examination of the injured knee at 2-year follow-up, none of the patients in group A had a pivot shift, whereas 22 patients in group B had a pivot shift of a least 1 grade higher than it had been at baseline, suggesting a progression of the instability in this group.

DISCUSSION

This study has found that patients with an isolated ACL rupture participating in pivoting sports treated with a combination of the CBP and physiotherapy have a highly

significantly increased risk of recurrent instability and medial meniscal tears relative to those undergoing a surgical correction of their anterolateral rotatory instability and physiotherapy. Patients undergoing reconstruction also recorded superior PROMs. Therefore, we reject the null hypothesis.

Although there remains interest in the nonoperative management of ACL injuries, there is little new data to support this approach. Froebel et al⁴ performed a RCT in 2010 (the “KANON study”) comparing operative treatment with nonoperative treatment with the option of later surgery if required.⁴ Patients undergoing treatment, operative or nonoperative, who remain unstable represent failures from the patient’s perspective. The risk of recurrent instability in the nonoperative group was 39% within 2 years versus 3% in the operative group (13 times higher), and the risk of meniscal tears was 22% versus 1.5% (15 times higher). Although the conclusions drawn by those authors were that attempting rehabilitation with these high failure rates was acceptable in their opinion, from the patient’s perspective, it is less likely to be acceptable. For some patients, the delay in recovery and return to competitive sport incurred by attempting a prolonged nonoperative treatment of up to 12 months, only to undergo surgery later may be unacceptable for career, financial, social, or personal reasons, if not career-ending. The KANON study excluded patients with Tegner activity

TABLE 3. Comparison of PROMs, Recurrent Instability, Contralateral ACL Rupture, and Meniscal Tears in Groups A and B at Baseline and Over the 2-year Follow-Up

	Group A (40 patients)	Group B (40 patients)	P
TAS			
Preinjury	8.3 (1.1)	8.7 (1.0)	0.33
1 yr	7.6 (0.9)	5.8 (0.8)	<0.001
2 yrs	8.1 (1.0)	5.5 (0.9)	<0.001
IKDC			
Baseline	50.1 (7.4)	50.9 (5.8)	0.29
1 yr	89.2 (2.7)	67.6 (6.1)	<0.001
2 yrs	91.0 (3.8)	66.0 (6.1)	<0.001
Sport/Rec			
Baseline	56.3 (5.3)	60.9 (5.6)	0.02
1 yr	90.2 (8.6)	65.7 (6.4)	<0.001
2 yrs	92.4 (7.6)	66.6 (6.1)	<0.001
KR QoL			
Baseline	56 (7.0)	55.0 (5.1)	0.74
1 yr	90.3 (7.7)	76 (5.6)	<0.001
2 yrs	91.1 (5.5)	72.3 (6.7)	<0.001
LKS			
Baseline	53.8 (7.4)	55 (5.9)	0.5
1 yr	91.1 (3.8)	67.5 (4.9)	<0.001
2 yrs	93.0 (4.5)	64.3 (6.4)	<0.001
Recurrent instability	1 (2.5%)	28 (70%)	<0.001
MM tear	1 (2.5%)	22 (54%)	<0.001
LM tear	1 (2.5%)	4 (9.7%)	0.17
Contralateral ACL rupture	2 (5.0%)	1 (2.5%)	0.31

ANOVA, analysis of variance; IKDC, International knee documentation committee; KR QoL, knee-related quality of life; LKS, Lysholm knee score; LM, lateral meniscus; MM, medial meniscus; TAS, Tegner activity score.

Multivariate tests using generalized linear models were used to compare the PROMs. The χ^2 test with Yates correction was used to compare rates of recurrent instability, meniscal tears, and contralateral ACL rupture.

scores of 10, and the exclusion of these patients competing at an international level would be likely to bias the study in favor of nonoperative treatment.

Other RCTs have shown contrasting results to those reported in the KANON study. The “COMPARE” study was a RCT of similar size to the KANON study and also compared early ACL reconstruction with rehabilitation followed by optional delayed ACL reconstruction.⁵ Approximately 50% of the patients in the rehabilitation group failed to regain stability and required ACL reconstruction. The early reconstruction group was found to have a higher level of knee function and sports participation.

Another larger multicenter RCT, the “SNNAP” study, in which patients with chronic ACL deficiency and functional instability were randomized to either early ACL reconstruction (156 patients) or rehabilitation (160 patients) found that reconstruction resulted in a greater improvement in patient scored outcomes (KOOS subscales) and was more cost effective in terms of quality-of-life-years than rehabilitation.¹ The rehabilitation group had a failure rate of 41% requiring surgical stabilization within a period of 18 months.

Proponents of the CBP cite an uncontrolled unblinded case series of 80 patients with only 12-month follow-up.¹⁴ The diagnosis of both the ACL rupture and its healing was based solely on MRI imaging using a grading system not validated for such. MRI has been shown to be no more accurate than clinical assessment and, like any imaging modality, has limited value as a clinical research tool.^{7,18,19} The authors themselves stated that “longer term follow-up and clinical trials are needed to inform clinical practice.” However, this did little to discourage the active promotion and enthusiastic adoption of the CBP without sufficient clinical data. The resulting violation of the position of clinical equipoise may have contributed to the reluctance we encountered when patients were asked to take part in an RCT. We would advise that patients need to be informed that the recommendation of this protocol as a reasonable treatment option is premature, lacking in evidence and associated with a risk of thromboembolic phenomena, and a recovery period of at least a similar duration to that after surgical stabilization.

In our study, there was a 13-fold higher incidence of meniscal tears in the patients undergoing the CBP rather than surgery. Despite the initial optimism regarding the outcome after rehabilitation quoted in the KANON study above, when Snoeker et al³¹ reviewed the same patients from that study at a 5-year follow-up they found that patients who underwent ACL reconstruction had a lower risk of medial meniscal tears and a lower risk of progression of the meniscal tears seen on MRI. Other research has reported similar findings with an increased risk of developing meniscal damage after ACL injury and use this as rationale for performing early ACL reconstruction.^{32,33} Other studies have also suggested that there may be progression of the anterolateral rotatory instability seen in ACL deficient knees over time.^{13,32}

There was a higher risk of contralateral ACL rupture in our operative group A (7% vs 2%), likely related to the higher rate of return to pivoting sports in the operative group and the high rate of failure to recover sufficiently to return to sport in the nonoperative group B.

In each of the 3 RCTs referred to above, there was a higher frequency of recurrent instability in the nonoperative group, and this tended to increase with time. In our study, the cumulative percentage of patients experiencing failure of

treatment in the physiotherapy group were 20% and 70%, at 1-year and 2-year follow-up, respectively.

Unfortunately, there are no data available from meta-analyses of level 1 studies available in the literature, whereas a systematic review of predominantly level 3 and 4 studies suggested that the knee-related quality of life was similar in patients with ACL-deficient and ACL-reconstructed knees.³⁴

The surgical goal of the main author is to correct the pivot shift using an ACL reconstruction and the addition of the MITBT only if indicated to correct a residual pivot shift. The MITBT has been shown to be more effective in its ability to reduce the risk of recurrent instability when compared with the lateral extracapsular tenodesis (LET).¹⁰ This may be related to the more precise intraoperative adjustment of the tension of the MITBT procedure to the point that it corrects the pivot shift. Group A included patients both with and without the MITBT as the end point of the surgical stabilization was correction of the pathological pivot shift rather than the use of preoperative criteria to determine if the tenodesis was indicated.

Limitations of our study include a relatively small sample size, but it was adequately powered to test our hypothesis and is larger than most studies. The study was not a RCT for reasons described above. All procedures were performed by a single subspecialist orthopedic surgeon, which limits the external validity. There are several sources of potential bias, which the authors attempted to minimize. It was not possible to blind the patients regarding their treatment. The radiologists reporting on the MRI imaging were unaware as to which treatment group patients would be allocated to. If an MRI was repeated to assist with the diagnosis recurrent ACL injury, lack of healing of the ACL ligament or a meniscal tear, it was not possible to blind them regarding whether or not an ACL reconstruction had been performed. However, they were not involved in the research and were blinded regarding whether or not the patient was part of a study. The imperfect diagnostic accuracy of the MRI may have introduced bias. Those 23% of patients in the surgical group with false positive MRI diagnoses for ACL rupture were excluded from the study, whereas there may have been a similar proportion of patients in the CBP group who also had false positive MRI and who were included in the study. This would have biased the study in favor of the CBP. Regarding PROMs, these were completed by the patient and the researchers had no influence on the scores they reported, which minimized interpretation bias. All patients attended for physiotherapy to supervise their rehabilitation. The 80 patients in the study attended multiple different physiotherapists, and it was not possible to blind the physiotherapists regarding the treatment group the patients were in. However, none of the physiotherapist were involved in the production of the research. When patients from either group complained of recurrent instability they were re-examined, and it was not possible to blind the clinician regarding their treatment group. However, to reduce bias, a diagnosis of recurrent instability was only made if there was evidence of an ACL rupture on both physical assessment and on the repeat MRI.

With these limitations in mind, we conclude that patients with an isolated ACL rupture diagnosed on both clinical assessment and MRI have a highly statistically significantly lower risk of recurrent instability and meniscal tears, if treated with surgical stabilization rather than the Cross Bracing Protocol, and improved PROMs.

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