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Comparison between two techniques for surgical repair of the acutely torn anterior cruciate ligament

A prospective, randomized follow-up study of 48 patients

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This prospective, randomized study was designed to evaluate the early outcome of ACL repair with biologic or synthetic augmentation. Forty-eight consecutive patients with an acute proximal rupture of the ACL were included. The repairs in 22 patients were augmented with the Kennedy Ligament Augmentation Device (LAD), while 26 patients received a repair augmented with an autologous bone-patellar tendon-bone graft. All patients followed a standard rehabilitation protocol. Follow-up evaluations at 1 and 2 years postoperatively were based on the Tegner activity level, Lysholm functional score, clinical instability tests and KT-1000 arthrometer measurements. There were no significant differences in activity level or functional score between the LAD and patellar tendon groups at the 2-year follow-up. Ten patients in the LAD group (46%) sustained reruptures of the ACL and LAD at the 2-year follow-up, while two patients in the patellar tendon group had a KT1000 side difference of 4 mm or more. However, none of the patients in the patellar tendon group had a positive pivot shift. During the first postoperative year, 8 patients (31%) in the patellar tendon and 2 in the LAD group (9%) underwent arthroscopic debridement for correction of an extension deficit. These range of motion complications were probably related to the anterior placement of the tibial tunnel and the conservative rehabilitation protocol. Because of the unacceptable high incidence of reruptures in the LAD group, we concluded that the augmentation technique with the LAD is unacceptable.

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In the past, acute primary repair was a common treatment for rupture of the ACL (1). However, several recent long-term follow-up studies have concluded that the results of this procedure deteriorate with time (2, 3). Today, the Palmer repair technique is considered inadequate. Because of evidence of a proprioceptive function of the ACL (4, 5), some surgeons attempt to preserve the ACL remnant with its blood supply and nerve endings by performing repair with augmentation techniques. Some of these augmentation procedures have shown promising results (6–8). In a two-year prospective, randomized study, Engebretsen et al. (9) found that knees with ACL repairs augmented with the Kennedy Ligament Augmentation Device (LAD, 3M Company, St. Paul, MN, USA) had a consistently higher recurrence of instability than repairs augmented with a bone-patellar tendon-bone graft. The location of the ACL ruptures in the Engebretsen study were either proximal, distal or in the midsubstance. These different locations of the ruptures, in addition to the technique used to suture the remnants of the ACL to the augmentation, were considered to be important factors leading to the high percentage of reruptures at follow-up. The present study was designed to exclude these factors. Only proximal tears were included, and the Palmer technique (1) was used for repair before the addition of the augmentation. This article presents

the results of a 2-year follow-up of two groups of patients with proximal ACL ruptures, comparing the outcome of acute repair with LAD or bone-patellar tendon-bone augmentation.

Material and methods

Patients

Forty-eight consecutive patients with acute proximal ACL ruptures seen during the period from December 1989 to April 1992 were included in this study. The mean age of the patients was 25 years (range 15–42). There were 18 men and 30 women. Sporting activities accounted for 94% of the injuries, with soccer (29%) and team handball (48%) being the major contributors. Patients with concomitant meniscal ruptures and medial collateral ligament injuries grade I and II were included in the study, while those with posterior cruciate or lateral collateral ligament ruptures were excluded. No patients had their collateral ligaments repaired. After the proximal ACL rupture was confirmed through arthroscopy under epidural anesthesia, the patient was randomized to one of two surgical procedures; acute repair with LAD augmentation or bone-patellar tendon-bone augmentation. When it was decided to end the inclusion period, there were 22 patients in the LAD group and 26 in the patellar tendon group. There were no statistically significant differences between the groups with regard to preinjury activity level, age, sex, or additional ligament or meniscal injuries.

Treatment

The surgery in both repair groups was performed with a miniarthrotomy through the central portion of the patellar tendon.

LAD technique. The LAD consists of a flat band of braided polypropylene. With the aid of a drill guide, a 2-mm-diameter Steinmann pin was placed from the anteromedial aspect of the proximal tibia to just anterior and medial to the anatomic tibial attachment of the ACL. This hole was overdrilled with a 4-mm-diameter cannulated reamer. The posterior edge of the tibial tunnel was chamfered to prevent abrasion of the LAD. A small notchplasty was performed. The over-the-top position was identified and chamfered with a curved rasp to obtain a small groove. The LAD was passed through the tibial tunnel and fixed to the anteromedial tibia with the belt buckle staple technique. Multiple loop sutures were then placed in the ACL remnant in an anteromedial to posterolateral direction. The drill guide was used to pass a 2-mm Steinmann pin through the lateral femoral condyle into the center of the anatomic femoral attachment of the ACL. The LAD and sutures on the anteromedial side of the remnant were routed over-the-top, while the posterolaterally oriented sutures were brought out through the hole in the lateral femoral condyle. The sutures were tied over the posterior portion of the femoral condyle with the graft under manual pretension and the knee in 20° of flexion. The magnitude of pretension applied for all procedures in this study was at a level sufficient to prevent greater than 3 mm of anterior tibial displacement during the Lachman test. The LAD was then fixed to the lateral femoral condyle with 6 kg of pretension at 20° of flexion using staples and the belt buckle technique.

Patellar tendon technique. Biologic augmentation was performed by harvesting a graft from the central one-third of the patellar tendon, with patellar and tibial bone blocks measuring approximately 25×10×5 mm. With the aid of a drill guide, a Kirschner wire was passed from the anteromedial aspect of the proximal tibia, emerging 5 mm anterior and medial to the center of the anatomic tibial attachment of the ACL. This hole was overdrilled with a 10-mm cannulated reamer. A notchplasty was performed. The drill guide was used to place a second K-wire posterior and superior to the anatomic ACL attachment on the femur. This hole was also overdrilled to 10 mm. Multiple loop sutures were placed in the ACL remnant in an anteromedial to posterolateral direction. The graft was brought into the joint through the tibial tunnel. The proximal bone block and posterolateral sutures were passed out the femoral tunnel. The anteromedial sutures were routed over-the-top. The bone block was fixed in the tibial tunnel with an interference screw. The sutures through the ACL remnant were tied over the lateral femoral condyle while under manual pretension with the knee at 20° of flexion, as described in the LAD augmentation technique. With the knee at 20° of flexion and manual pretension applied, the graft was then fixed in the femoral tunnel with an interference screw. Care was taken to not cut the sutures in the tunnel.

Rehabilitation

Postoperatively, all 48 patients were placed in a brace that allowed a range of motion of 20° to 90° for 6 weeks. The patients were prohibited from weight-bearing during this period. For the next 2 weeks, the brace was unlocked, permitting free range of motion, and the patients were allowed partial weight-bearing. No dynamic strength exercises were permitted for the last 30° of extension during the first 12 weeks. No contact sports were allowed during the first year after surgery. All patients followed a standard rehabilitation protocol administered by the same group of physical therapists.

Follow-up evaluation

The patients were evaluated prospectively by one orthopedist (TG) at 1 and 2 years after repair surgery. All the 48 patients completed the follow-up. The preinjury and postoperative level of activity was evaluated with the Tegner activity level score (10). Functional status was graded according to the score designed by Tegner & Lysholm (10), which emphasizes pain, instability and locking. Physical examination included an assessment of the range of motion, and the evaluation of knee stability by manual and arthrometer testing. Anterolateral rotatory instability was evaluated by the Macintosh, Slocum or flexion-rotation drawer tests, and was graded as negative, trace positive (1+), moderate (2+) or severe (3+). Anterior instability in 20° of flexion was evaluated by the Lachman test and was graded as negative, slight (1+, <5 mm), moderate (2+, 5–10 mm) or severe (3+, >10 mm), compared to the normal knee. Anterolateral and anterior instability grades of 2+ and 3+ were considered unstable. Instrumented testing of anterior laxity was performed with a KT-1000 arthrometer (MEDmetric, San Diego, CA, USA) at 20° and a 89 N (20 lb) load level. Side-to-side differences of 3 mm or less were graded as stable, and 4 mm or more as unstable. Isokinetic strength of the quadriceps and hamstrings was also evaluated using the Biodex system (Biodex Corporation, Shirley, NY, USA). The tests were performed in extension and flexion at 60°/s and 240°/s, and the strength of the injured side was compared to that of the normal side. Peak torque and total work were measured.

Statistical methods

A nonparametric analysis of variance (Kruskal-Wallis test and Mann-Whitney tests) was used to determine the significance of the difference in outcome measures between the two repair groups at a follow-up time point. The Wilcoxon test for paired data was used to test for the significance of the changes in the outcome measures for a particular repair group between the 1 and 2-year follow-ups. Comparisons were considered significant at a P level of less than 0.05.

Results

The mean Tegner activity level score was significantly reduced in both groups at the 1-year evaluation, compared to the preinjury level (Fig. 1). At one year, the LAD group had a significantly lower mean activity level score (5.5) than the patellar tendon group (6.4, $P<0.02$). At 2 years, the patellar tendon patients further reduced their mean activity level to 6.1, and there was no longer a significant difference between the two groups.

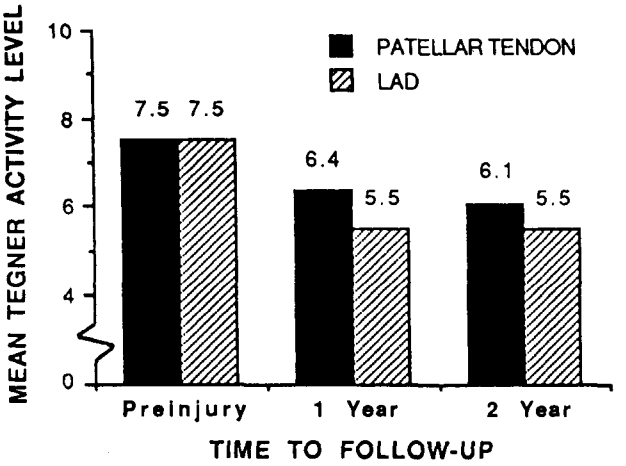

Fig. 1. Mean Tegner activity level scores before injury, and at the 1 and 2-year follow-up evaluations, for 26 patients with an ACL repair augmented with a bone-patellar tendon-bone graft, and 22 patients with a repair augmented with an LAD.

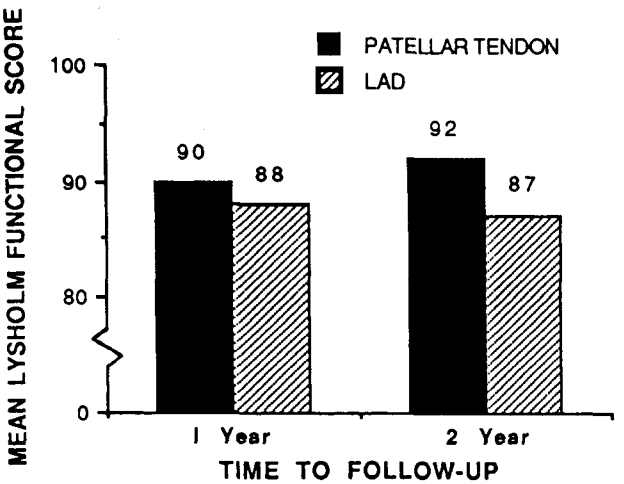

Fig. 2. Mean Lysholm functional scores at the 1 and 2-year follow-up evaluations for 26 patients with an ACL repair augmented with a bone-patellar tendon-bone graft, and 22 patients with a repair augmented with an LAD.

The mean Lysholm functional score for the patellar tendon group was higher than for the LAD group at both 1 and 2 years, but these differences were not significant (Fig. 2). The mean functional score for the patellar tendon group increased from 1 to 2 years (90 to 92), while the score for the LAD group slightly decreased from 88 to 87 points.

At the 1-year follow-up, 5 of the patellar tendon patients (19%) and 2 of the LAD patients (9%) had an extension deficit of 5 to 10 degrees. At 2 years, only 2 patients in the patellar tendon group (8%) and 1 in the LAD group (5%) had an extension deficit of 5 to 10 degrees. There were no patients with a larger extension deficit. The mean values of the extension

deficits were not statistically different between the two groups at 1 and 2 years. During the first year after surgery, however, 8 patients in the patellar tendon group (31%) and 2 in the LAD group (9%) had arthroscopic debridement for an extension deficit of more than 10 degrees.

None of the patients in the patellar tendon group had a positive pivot shift sign (2+ or 3+) at 1 or 2 years. Six patients (27%) in the LAD group had a positive pivot shift sign at 1 year, while 11 (50%) had a positive sign at 2 years (Table 1). The differences between the groups were significant at both the 1-year ($P<0.01$) and 2-year ($P<0.0005$) follow-ups.

None of the patients in the patellar tendon group exhibited anterior instability with the Lachman test (2+ or 3+) at 1 or 2-year follow-ups (Table 2). In the LAD group, 7 patients (32%) had a 2+ or 3+ anterior instability grade at 1 year, and this increased to 10 patients (46%) at 2 years. These differences between the two groups were significant at $P<0.005$.

When tested with the KT-1000 arthrometer, 2 patients (8%) in the patellar tendon group and 7 (32%) in the LAD group had side-to-side differences of 4 mm or more (unstable result) at 1 year (Table 3). At 2 years, 2 patellar tendon patients (8%) and 10 (46%) LAD patients demonstrated unstable knees. These laxity differences were not significant at the 1-year follow-up ($P=0.055$) but were significant at 2 years ($P<0.02$).

There were no significant differences between the groups with regard to isokinetic strength testing at 1 and 2 years, except for peak torque in both extension and flexion at 240°/second at 2 years. The differences between the repaired and normal limbs were greatest for the LAD group in both extension and flexion ($P<0.04$). The mean differences in extension were 4% for the patellar tendon group, and 14% for the LAD group. The corresponding values for flexion were 0% and 10%, respectively.

At the 1-year follow-up there was no statistical difference between the groups concerning patellofemoral pain, 8 of the patients (31%) in the patellar tendon group and 2 of the patients in the LAD group (9%) complained of patellofemoral pain. At 2 years, there were only 2 patients in each group with this problem.

Table 1. Anterolateral rotatory instability determined by the Macintosh, Slocum or flexion-rotation drawer tests

Repair technique/ time to follow-up	Pivot shift grade/number of patients			
	0	1+	2+	3+
Patellar tendon				
1 year	21	5	0	0
2 years	20	6	0	0
LAD				
1 year	11	5	3	3
2 years	8	3	5	6

Table 2. Anterior instability determined by the Lachman test

Repair technique/ time to follow-up	Lachman grade/number of patients			
	0	1+	2+	3+
Patellar tendon				
1 year	15	11	0	0
2 years	15	11	0	0
LAD				
1 year	6	9	4	3
2 years	7	5	4	6

Table 3. Anterior laxity measured by KT-1000 arthrometer with 89 N (20 lb) force at 20 degrees of flexion

Repair technique/ time to follow-up	Side-to-side laxity difference (mm)/number of patients		
	0–3	4–5	>5
Patellar tendon			
1 year	24	2	0
2 years	24	1	1
LAD			
1 year	15	4	3
2 years	12	3	7

Discussion

Due to the early differences in stability results between the groups, it was decided to end the patient inclusion prior to the original goal of 40 patients in each group. Since an envelope method was used for randomization, this led to an uneven number (22/26) of patients included in the two groups.

The role of acute repair in the treatment of ACL ruptures remains controversial. It is difficult to interpret the outcome of repair procedures for the treatment of ACL ruptures because most published studies are retrospective and nonrandomized and compare different surgical techniques, rehabilitation regimens and follow-up protocols. There is a consensus that simple suture of the acutely torn ACL is inadequate because of a high incidence of reruptures and recurrence of symptomic instability (2, 3).

Recent studies (4, 5) have identified different types of nerve endings in the ACL and have suggested that the ACL has a proprioceptive function in the normal knee joint. In an attempt to preserve this function, different augmentation techniques have been used in conjunction with repair of the ACL. The LAD was developed by Kennedy et al. (11, 12) for the purpose of sharing load with a biologic graft in the reconstruction of the ACL, while graft growth and remodeling take place. Augmentation was also intended to allow earlier and more aggressive rehabili-

tation. The hypothesis of initial load-sharing and stress protection, followed by gradual transfer of load from the LAD to the graft, was applied by Schabus to acute ACL repair (6, 7). Promising clinical results were reported. Engebretsen et al. (13) demonstrated in a cadaver study that the LAD carried approximately 75% of the load in the repair/augmentation composite at extension and 30° of flexion, and only 25% of the composite load at 90°. This suggests that the LAD could protect the repair tissue near extension, where the ACL normally provides restraint.

The patellar tendon augmentation technique was based on the work of Cabaud et al. (14), who documented good results when the ACL was augmented with a patellar tendon graft in an animal model. Clancy et al. (6) reported a prospective study of acute ACL repairs augmented with bone-patellar tendon-bone grafts, and found that 50 of 52 patients had an excellent or good result. The purpose of using this graft as an augmentation for a repair was the hypothesis that the ACL remnants would contribute to early revascularization and nerve supply and thereby improving the early function of the construct.

In the present study, the activity level was higher in the patellar tendon group than in the LAD group at 2 years. The isokinetic muscle strength tests reflected the adequacy of the rehabilitation program; patients regained their muscular strength after only 1 year. The significant difference between the two groups at 2 years and 240°/s may reflect the functional problems in the unstable knees of the LAD group.

The main difference between the two groups, however, was detected by the stabilty tests. Seven patients (32%) in the LAD group were clinically unstable and were considered to have a rerupture at 1 year, while the number increased to 10 (45%) at 2 years. It was concluded from the manual stability tests (Lachman and pivot shift tests) that none of the patients in the patellar tendon group had a rerupture, although two patients had a KT1000 difference of 4 mm or more. Thus, we were not able to reproduce the results previously reported by Schabus et al. (6, 7). We found an even higher incidence of reruptures than previously reported by Engebretsen et al. (9) in their prospective, randomized study (approximately 15% at 2 years). This was the case although the present study included only proximal ACL ruptures and used a presumably improved surgical technique.

The reason for the high incidence of rerupture is unclear. The LAD most likely experienced high loads in extension due to the over-the-top proximal attachment, and to the high pretension at 20° of flexion as shown by Engebretsen et al. in a cadaveric study using identical surgical procedures (13). This may have led to ruptures, which probably occurred at the edge of the tibial tunnel or in the over-the-top position. The LAD was fixed on both ends with the belt buckle technique. This, in addition to the high loads in the LAD in extension, may have mechanically overprotected the repair. If the repair was totally unloaded, it would not heal. The fact that the results in the patellar tendon group were equivalent to those reported by Clancy et al. (6) does not in itself demonstrate that the augmentation technique was adequate, since the patellar tendon results may have been identical without the repair of the ACL.

Eight of the patients (31%) in the patellar tendon group and 2 in the LAD group (9%) had reoperations during the first year of follow-up because of decreased range of motion. The extension lag problems in acute patellar tendon reconstructions have been previously reported (15–17). The reason for the high number of problems in this study is probably a combination of the anteromedial placement of the tibial tunnel and the conservative rehabilitation protocol not allowing full extension for 6 weeks. The fact that there were fewer problems in the LAD group was probably due to a smaller tunnel (4 mm) and the less bulkly LAD compared to the patellar tendon in the anterior compartment. The complication was adequately managed by early arthroscopic debridement. Normal range of motion has been obtained in our present reconstructions with delayed surgery and arthroscopic/endoscopic techniques with a more posterior placed tibial tunnel, and an aggressive rehabilitation protocol allowing full weight-bearing and extension from day one. In all other aspects, the patellar tendon augmentation technique was superior to augmentation with the LAD. Based on the unacceptable high incidence of reruptures in repairs augmented with the LAD, we conclude that this procedure should no longer be used.

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