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Am. J. Sports Med. 2007; 35; 1131 originally published online Apr 23, 2007;

DOI: 10.1177/0363546507301318

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Risk of Tearing the Intact Anterior Cruciate Ligament in the Contralateral Knee and Rupturing the Anterior Cruciate Ligament Graft During the First 2 Years After Anterior Cruciate Ligament Reconstruction

A Prospective MOON Cohort Study

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Background: The risk of tear of the intact anterior cruciate ligament in the contralateral knee after anterior cruciate ligament reconstruction of the opposite knee and the incidence of rupturing the anterior cruciate ligament graft during the first 2 years after surgery have not been extensively studied in a prospective manner. Clinicians have hypothesized that the opposite normal knee is at equal or increased risk compared with the risk of anterior cruciate ligament graft rupture in the operated knee.

Hypothesis: The risk of anterior cruciate ligament graft rupture and contralateral normal knee anterior cruciate ligament rupture at 2-year follow-up is equal.

Study Design: Cohort study; Level of evidence, 2.

Methods: The Multicenter Orthopaedic Outcome Network (MOON) database of a prospective longitudinal cohort of anterior cruciate ligament reconstructions was used to determine the number of anterior cruciate ligament graft ruptures and tears of the intact anterior cruciate ligament in the contralateral knee at 2-year follow-up. Two-year follow-up consisted of a phone interview and review of operative reports.

Results: Two-year data were obtained for 235 of 273 patients (86%). There were 14 ligament disruptions. Of these, 7 were tears of the intact anterior cruciate ligament in the contralateral knee (3.0%) and 7 were anterior cruciate ligament graft failures (3.0%).

Conclusion: The contralateral normal knee anterior cruciate ligament is at a similar risk of anterior cruciate ligament tear (3.0%) as the anterior cruciate ligament graft after primary anterior cruciate ligament reconstruction (3.0%).

Keywords: ACL; reconstruction; graft failure; contralateral

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Presented at the 32nd annual meeting of the AOSSM, Hershey, Pennsylvania, June 2006.
No potential conflict of interest declared.

The risk of tears of the intact anterior cruciate ligament (ACL) in the contralateral knee after an ACL graft reconstruction has not been extensively studied. Anecdotally, clinicians have hypothesized that the opposite normal knee is at equal or increased risk compared with the risk of ACL graft rupture in the operated knee. The knowledge of the risk is important for appropriate evidence-based patient counseling regarding risk of ligament disruption. This knowledge also allows potentially refocusing rehabilitation equally on the normal knee to prevent injury. Identifying the risk factors for disruption will allow clinicians to design prevention strategies for both knees in the future. No studies have prospectively identified the risk of tears of the intact ACL in the contralateral knee after ACL reconstruction. Several studies have suggested the incidence of tears of the intact ACL in the contralateral knee is comparable with ACL graft rupture.^{4,13}

The Multicenter Orthopedic Outcome Network (MOON) group was established in 2001 to determine the prognosis and predictors of ACL reconstruction outcomes. The ideal design to answer these questions is a prospective longitudinal cohort for the highest level of evidence. Our hypothesis for this study was that the incidence of tears of the intact ACL in the contralateral knee would be no different than ACL graft ruptures 2 years after unilateral ACL reconstruction.

METHODS

The MOON group began enrolling after Institutional Review Board (IRB) approval all ACL reconstruction patients at 6 sites (Washington University in St. Louis, Vanderbilt University Sports Medicine, Cleveland Clinic Foundation, Ohio State University, University of Iowa, and Hospital for Special Surgery) by 8 physicians (RW, KS, CK, EM, AA, RP, JA, RM). A prospective longitudinal cohort design was established to determine the prognosis (incidence of normal ACL tear and ACL reconstruction graft tear) as well as their predictors in this study. Preoperatively, subjects completed an 11-page form that included the mechanism of injury, a series of validated patient-oriented outcome questionnaires (including Knee Injury and Osteoarthritis Outcome Score, Western Ontario and McMaster Osteoarthritis Index, Marx, SF-36, and IKDC), sports participation history, comorbidities, demographics, prior surgery on either knee, and any ongoing therapies (eg, glucosamine, bracing, NSAIDs). The surgeon completed a detailed examination under anesthesia including the "normal" knee and detailed operative assessment and treatment of meniscus and articular cartilage injuries. The details of ACL reconstruction and rehabilitation milestones were recorded. A more detailed description of the surgeon documentation is detailed in previous studies.^{17,18}

The inclusion and exclusion criteria were as follows. To establish the incidence of tears of the intact ACL in the contralateral knee, there could be no prior knee surgery, and a normal Lachman and negative pivot-shift test were documented for the contralateral knee by examination under anesthesia. On the basis of the IKDC criteria, the knee was deemed "normal." Only unilateral primary reconstructions

without prior surgery were included for the ACL-reconstructed knee. Exclusion criteria were multiple ligament-injured knees that required surgical treatment of additional ligament injuries. All meniscus and articular cartilage injuries and treatment were included. Thus, this was the first ACL reconstruction on 1 knee with a documented normal contralateral knee.

At the patient's 2-year follow-up anniversary he or she was contacted by the central research hub and asked to complete the same outcome questionnaire and specifically questioned on the phone regarding any additional surgery, especially ACL reconstruction on either knee. Every repeat surgical procedure was documented to confirm that the contralateral normal knee ACL was torn and underwent reconstruction or that the ACL graft was torn and underwent revision reconstruction. For this study, all patients were enrolled in the calendar year 2002 (January 1-December 31), and 2-year follow-up was initiated in calendar year 2004 and completed in early 2005 (January 1, 2004-April 1, 2005). Recurrent ligament disruption was defined as the first occurrence of a revision ACL reconstruction for ACL graft failure or primary ACL reconstruction for the previously normal contralateral knee ACL tear. Anterior cruciate ligament reconstruction techniques included both endoscopic and rear-entry by fellowship-trained sports medicine physicians. The Fisher's exact test (2-tailed) was used to calculate an exact probability value for the relationship between dichotomous variables. Analysis was performed with open source R statistical software (www.r-project.org; GNU Project, Free Software Foundation, Boston Mass) available at <http://cran.us.r-project.org>.

RESULTS

Four hundred thirty-seven unilateral ACL reconstructions were enrolled in the cohort (Figure 1). The predominant graft choice was autograft bone-tendon-bone and hamstring; however, a minority had allografts (Table 1). One hundred sixty-four were excluded based on documented previous surgery or an abnormal contralateral knee. Two hundred seventy-three subjects met the inclusion criteria of the total enrolled ACL reconstructions in 2002. Patient participation in the prospective cohort was 99%. Surgeon compliance with enrollment was 98%. Patient completion of the entrance questionnaire was 98%. Two-year follow-up was obtained on 235 for an 86% follow-up rate.

All subsequent reported ligament disruptions that underwent reconstruction, either contralateral primary or revision of failed ACL grafts, were performed by MOON surgeons and verified by review of operative records. The cohort had a median age of 23 years (mean, 24 y; range, 11-54 y), and 47% were women. There were 14 ligament disruptions, corresponding to an overall incidence of 6.0%. Of these 14 ligament disruptions, 7 were tears of the intact ACL in the contralateral knee (3.0%) and 7 were ruptures of the ACL graft (3.0%). Hence, the event rates for normal knee ACL tear (requiring ACL reconstruction) and ACL graft tear requiring revision ACL reconstruction appear to

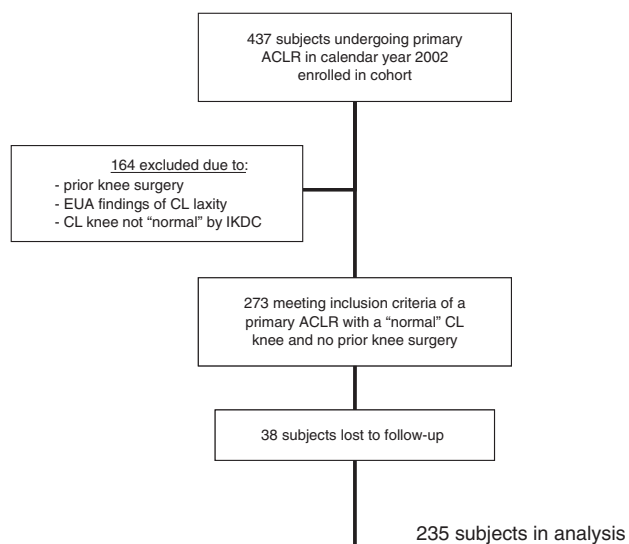


Figure 1. Flow diagram of patients through the study. EUA, examination under anesthesia; CL, contralateral.

TABLE 1
Graft Choice^a

	BTB	BTB-Quad	Hamstring	Other	Total
Autograft	102	0	115	0	217
Allograft	10	1	2	4	17
Total	112	1	117	4	234 ^b

^aBTB, bone-tendon-bone.

^bData for 1 graft choice are missing.

be similar. The overall event rate of ligament disruption, stratified by gender, was 6 of 14 in female patients and 8 of 14 in male patients. The male patients had 6 of 7 revision ACL reconstructions and 2 of 7 contralateral tears; the female patients had 1 of 7 revision ACL reconstructions and 5 of 7 contralateral tears. This difference in tearing the graft versus tearing the contralateral ACL between genders was not significant using Fisher's exact test ($P = .1212$). Of the 7 ACL graft tears undergoing revision ACL reconstruction, 6 were autograft and 1 was allograft.

DISCUSSION

This study, using a prospective longitudinal cohort, is the first to focus on the identification of tears of the intact ACL in the contralateral knee after unilateral primary ACL reconstruction. As hypothesized by the authors, the risk of ACL tear for the contralateral normal knee (3.0%) is the same as the risk for ACL graft rupture (3.0%) in the operated knee at 2-year follow-up.

Strengths of this study include the use of a prospective longitudinal cohort with a high rate of follow-up at 2 years (86%). Multiple surgeons at multiple sites using a variety of grafts for ACL reconstruction make the results generalizable to the sports medicine subspecialist performing ACL reconstructions.

Limitations of the study include the ability to detect ACL tears or graft ruptures in this cohort without on-site physician follow-up physical examination. All of the patients in this study had subsequent operations by their original surgeon, but other tears may have gone undetected. Thus, the number of tears may be slightly underestimated. However, this is a cohort of patients who have already sustained an ACL tear and who should have reasonable ability to detect a similar injury in either knee. A possibility for patient denial of a new injury could lower our ability to detect tears. Additional limitations include the short-term follow-up of 2 years and the low number of events of ACL graft rupture or tears of the intact ACL in the contralateral knee. Longer term follow-up will probably increase the number of events and make evaluation of risk factors for rupture a possibility.

Previous prospective studies of ACL reconstructions have noted the number of ACL graft ruptures as part of their follow-up evaluation. A recent systematic review of 9 prospective studies evaluating the results of hamstring tendon versus the patellar tendon autografts presented data on graft failure.^{1-3,5-7,10,12,14,16} Graft failure was defined as clinical failure, magnetic resonance imaging failure, or revision surgery and was reported in 8 of the 9 studies.^{1,2,5-7,10,12,14} Follow-up in these 8 studies ranged from 24 to 42 months. Graft failure in these studies ranged from 1.5% to 5.7%. The overall number of graft failures was 24 of 664 patients (3.6%, 95% confidence interval [CI], 2.3%-5.3%). One study presented data on tears of the intact ACL in the contralateral knee with 3 ruptures in 72 patients (4.2%).²

In a prospective nonrandomized trial evaluating the 5-year follow-up of patellar tendon versus 4-strand hamstring tendon autografts for primary ACL reconstruction, Pinczewski et al¹³ noted 3% (3 patients) graft rupture and 12% (11 patients) tears of the intact ACL in the contralateral knee rate in 90 patients after reconstruction with a patellar tendon. In the 90 patients who underwent ACL reconstruction with hamstring tendon graft, there was 8% (7 patients) graft rupture, and 9% (8 patients) tears of the intact ACL in the contralateral knee rate was noted at 5-year follow-up. Corry et al⁴ had previously presented the same cohort of patients at 2-year follow-up. The 3 patellar tendon ACL graft ruptures had been identified by 2 years, but only 2 tears of the intact ACL in the contralateral knee had been identified at 2 years. Thus, 9 additional patients had sustained tears of the intact ACL in the contralateral knee in the ensuing 3 years. In the hamstring tendon reconstruction group, 4 graft ruptures and 4 tears of the intact ACL in the contralateral knee had been identified by 2-year follow-up. Consequently, 3 additional graft ruptures and 4 additional tears of the intact ACL in the contralateral knee occurred in the ensuing 3 years.

Meta-analyses have also been performed evaluating patellar tendon and hamstring tendon autografts. In a meta-analysis including 21 studies with 1976 total patients with a minimum follow-up of 2 years, Freedman et al⁸ identified an overall graft failure rate similar to this study's of 2.4% (1.9% patellar tendon and 4.9% hamstring tendon). No mention of tears of the intact ACL in the contralateral knee was made in this meta-analysis. Yunes et al¹⁹ performed a meta-analysis of 4 studies comparing 445

patients undergoing reconstruction with patellar tendon versus hamstring tendon grafts. The failure rate was 4% for hamstring tendon grafts and 3% in the patellar tendon graft patients. No mention of tears of the intact ACL in the contralateral knee was made.

A variety of factors may contribute to the differences in ACL graft rupture and tears of the intact ACL in the contralateral knee rates noted between those studies and this study. The obviously most important factor for ACL or ACL graft tears is length of follow-up. A 2-year follow-up for an ACL reconstruction results in exposure to return to high-level sports or risky activities for a maximum of 18 to 20 months, with a typical return to sports at 4 to 6 months after ACL reconstruction. The Pinczewski study had a similar rate of ACL graft ruptures and tears of the intact ACL in the contralateral knee rate compared with this study at 2-year follow-up.¹³ At 5-year follow-up, several more tears of each type had been identified.⁴

A discussion of tears of the intact ACL in the contralateral knee introduces the concept of bilateral ACL tears. Previous studies have evaluated bilateral ACL tears to try to determine what risk factors exist.^{9,11,15} Factors proposed in the past have included gender, notch width, genetics, alignment, or inherent structural weakness. An effective sample size of 14 events precludes multivariable analysis. Hence, stratification of risk factors was limited to gender and graft type. Our study did not demonstrate a statistically significant gender or graft type difference for either ACL graft tear or contralateral ACL tear. However, 6 of 7 ACL graft failures in our cohort were in male patients, and 5 of 7 contralateral ACL tears were in female patients. Perhaps as our cohort increases in number, a gender risk will be identified. Further investigation into age and activity level confounders should be explored in this relatively high-risk population. Ongoing follow-up of subsequent years from this multicenter cohort involving larger numbers of patients will define the overall incidence and potentially have sufficient sample size for predictor assessment to identify modifiable risk factors.

On the basis of the incidence determined by our prospective database, a patient can be counseled that there is a risk of 3% for tearing the intact ACL and a similar risk of 3% of rupturing the ACL graft during the first 2 years after ACL reconstruction. We believe this information is useful for the surgeon counseling patients and their families regarding the outcome, benefits, and risks of ACL reconstruction.

ACKNOWLEDGMENT

This project was supported by Grant #1K23 AR05392-01A1 from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (Dunn, Warren R) and a Pfizer Scholars Grant in Clinical Epidemiology (Dunn, Warren R). The authors also appreciate the support of educational grants from Aircast and Smith and Nephew.

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