

# Prospective Trial of a Treatment Algorithm for the Management of the Anterior Cruciate Ligament–Injured Knee

Donald C. Fithian,\* MD, Elizabeth W. Paxton, MA, Mary Lou Stone, RPT, William F. Luetzow, MD, Rick P. Csintalan, MD, Daniel Phelan, MD, and Dale M. Daniel, MD  
From the Southern California Permanente Medical Group, El Cajon, California

**Background:** Specific guidelines for operative versus nonoperative management of anterior cruciate ligament injuries do not yet exist.

**Hypothesis:** Surgical risk factors can be used to indicate whether reconstruction or conservative management is best for an individual patient.

**Study Design:** Prospective nonrandomized controlled clinical trial; Level of evidence, 2.

**Methods:** Patients were classified as high, moderate, or low risk using preinjury sports participation and knee laxity measurements. Early anterior cruciate ligament reconstruction (within 3 months of injury) was recommended to high-risk patients and conservative care to low-risk patients. It was recommended that moderate-risk patients have either early reconstruction or conservative care to the day of presentation. Assessment of subjective outcomes, activity, physical measurements, and radiographs was performed at mean follow-up of 6.6 years.

**Results:** Early phase conservative management resulted in more late phase meniscus surgery than did early phase reconstruction at all risk levels (high risk, 25% vs 6.5%; moderate risk, 37% vs 7.7%,  $P = .01$ ; low risk, 16% vs 0%). Early- and late-reconstruction patients' Tegner scores increased from presurgery to follow-up ( $P < .001$ ) but did not return to preinjury levels. Early-reconstruction patients had higher rates of degenerative change on radiographs than did nonreconstruction patients ( $P < .05$ ).

**Conclusions:** Early phase reconstruction reduced late phase knee laxity, risk of symptomatic instability, and the risk of late meniscus tear and surgery. Moderate- and high-risk patients had similar rates of late phase injury and surgery. Reconstruction did not prevent the appearance of late degenerative changes on radiographs. Relationship between bone contusion on initial magnetic resonance images and the finding of degenerative changes on follow-up radiographs were not detected. The treatment algorithm used in this study was effective in predicting risk of late phase knee surgery.

**Keywords:** anterior cruciate ligament (ACL); outcomes; nonoperative; natural history; prospective controlled study; treatment algorithm

Recent surveys of practicing orthopaedic surgeons in Canada and the United States have indicated that considerable uncertainty remains about the management of ACL injuries.<sup>26,28</sup> Specific management guidelines for operative versus nonoperative care do not exist, in part because there are few prospective studies comparing early operative and nonoperative (or delayed operative) treatment of ACL injuries. Prospective studies and well-documented database series<sup>1,3,6,9,18,25,27</sup> have documented that early ligament reconstruction after ACL injury is efficacious in reducing the risk of subsequent meniscal injury and late

surgery, compared to nonoperative treatment. However, Daniel et al<sup>6</sup> showed that ACL reconstruction does not always yield improved outcomes compared to the natural history and pointed out that patients who were able to “cope” with ACL deficiency may actually have better outcomes in some respects than do patients who have reconstruction. Other studies<sup>33,34</sup> have also been unable to demonstrate higher activity levels among patients who have had reconstruction compared to those who have not.

In caring for individual patients, the risks and expense of surgery must be weighed against the risks of sports disability, knee dysfunction, and reinjury that are associated with conservative management. Most authors agree that there is a “high-risk” patient (eg, the young, competitive athlete) who should be treated with early ligament reconstruction to reduce the risk of subsequent injury and sports disability.<sup>†</sup> Yet clearly not all patients who tear the

\*Address correspondence to Donald C. Fithian, MD, Department of Orthopedic Surgery, 250 Travelodge Drive, El Cajon, CA 92020 (e-mail: donald.c.fithian@kp.org).

No potential conflict of interest declared.

<sup>†</sup>References 1, 6, 8, 12, 17, 22, 23, 29, 36, 37.

TABLE 1  
Surgical Risk Factor

KT-1000 Arthrometer Manual Maximum Injured-Normal Difference, mm	Sports Hours per Year: Level I or II Jumping or Cutting Sports <sup>19</sup>		
	<50	50-199	>200
<5	Low	Low	Moderate
5-7	Low	Moderate	High
>7	Moderate	High	High

ACL need to have it reconstructed.<sup>2,6,30</sup> Daniel et al<sup>6</sup> described a population of individuals who coped satisfactorily with ACL deficiency over an extended period of time. The line of distinction between patients who will benefit from early ACL reconstruction and those who will not benefit has not clearly been drawn.

For counseling patients at the time of ACL injury, it clearly would be of great value to quantify risk of subsequent surgery among patients evaluated with an ACL injury. In the study by Daniel et al,<sup>6</sup> a number of factors were found to be associated with the need for late surgery for either a meniscal tear or an ACL reconstruction. Stepwise discriminant analysis revealed that the 2 most important variables for predicting late meniscal or ligament surgery were (1) the total preinjury hours per year of participation in International Knee Documentation Committee (IKDC) level I and II (jumping and cutting) sports<sup>19</sup> and (2) the KT-1000 arthrometer manual maximum injured minus normal displacement difference in the first 3 months after ACL injury.<sup>7</sup> No additional variables improved the ability of the model to predict which patients would have late meniscal or ligament surgery. Daniel et al hypothesized that these 2 variables could be used in combination to assign a surgical risk factor (SURF) for a given patient presenting in the acute or subacute phase after an ACL injury.<sup>5</sup>

The purpose of this study was to prospectively test a treatment algorithm in the care of patients presenting with acute ACL tears. The algorithm assigns patients to 1 of 3 risk levels using the SURF (Table 1) at the time of presentation after acute ACL injury. We studied the effectiveness of the algorithm in (1) returning recreational athletes to jumping and cutting sports, (2) preventing secondary knee injuries and surgery, and (3) preventing changes of joint arthrosis as evidenced by radiographs.

## METHODS

### Patient Sample

This prospective study was approved by an institutional review board. Between December 1992 and August 1996, 310 patients presenting to our acute knee injury clinic met the criteria for entry into this study, which are listed in Table 2. Twenty-three patients (8%) declined to participate

in the study after this initial contact. This left 287 (92%) eligible patients who were enrolled in the study.

Of the 287 patients who entered the study, 210 (73%) returned for the follow-up evaluation. One patient was eliminated from the analyses because she received surgery elsewhere, and documentation regarding that surgery was not available. This resulted in a sample of 209 patients who were representative of the initial 287 patients in age, preinjury sports hours, and preinjury Tegner activity scores. Eleven of the 209 patients (5%) sustained injuries to their nonindex knees during the course of the study. These patients were excluded from analyses in which comparisons to the nonindex knee influenced outcome variables of interest.

### Patient Management

The SURF score was incorporated into our management algorithm for all patients who were enrolled in the study (Table 1). Patients were assigned to 1 of 3 groups (high, moderate, or low risk) based on initial knee stability testing and their preinjury levels of sports participation. Early ACL reconstruction (E-RECON), defined as within 3 months of ACL injury, was recommended to those patients in the high-risk category, whereas conservative treatment (CONS) was recommended to those in the low-risk group. To reduce treatment bias in the moderate-risk group, we recommended either E-RECON or CONS based on the preferences of the senior orthopaedic surgeon staffing the knee injury clinic on the day of presentation. Author D.C.F., who staffed the clinic every Thursday, recommended E-RECON for moderate-risk patients. Authors D.M.D. and W.F.L., who staffed the clinic on Mondays, recommended CONS. This method of allocation takes into account existing clinical uncertainty about treatment indications in this group of patients. Although it does not remove bias as well as true randomization does, it satisfied the ethical concerns of the treating physicians and in this case was acceptable to a larger proportion of patients (92%) than we would anticipate if treatment allocation had been truly randomized. At the initial evaluation, we documented all associated injuries, and MRI was recommended in all moderate-risk patients, regardless of treatment.

### The MRI Technique and Evaluation

All 72 patients in the moderate-risk group were recommended to have an MRI. Fifty-seven patients had MRIs within 4 weeks of injury. The MR examinations were performed using a 1.5-T Magnetom (Siemens Medical Systems, Erlangen, Germany). The imaging technique that we use in clinic has been published previously.<sup>11</sup> Special techniques for high-resolution evaluation of the articular cartilage<sup>32</sup> were not employed. Images were evaluated for the presence of effusion, signal abnormalities of the menisci, bone contusions, osteochondral injuries, and attenuated or discontinuous fibers of the ACL, PCL, and collateral ligaments.

The MR images were not used to guide management decisions but merely to document the condition of the knee

TABLE 2  
Study Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Examination of knee within 4 weeks of index injury	Prior index knee or contralateral knee injury, ailment, or history of prior surgery
KT-1000 arthrometer measurements (MEDmetric Corp, San Diego, Calif) indicate an injured minus normal knee anterior displacement difference of 3 mm or more on the 20-lb, 30-lb, or manual maximum test	Other lower extremity ailments
	PCL injury
	Varus or valgus instability > grade II
	History of patellar injury or ailment
	Lower limb fracture

as a baseline for subsequent symptoms and findings on radiographs. In other words, although clinicians and patients were not blinded to the results of the MR images, all management decisions were based on symptoms and findings on physical examination, including ligament arthrometry testing. There were no displaced or locked menisci noted on any of the images. Furthermore, MR imaging with standard sequences such as those used in this study has not been found reliable in predicting reparability of meniscus tears. For this reason, the mere appearance of an abnormal meniscus signal did not result in a recommendation of surgery.

### Conservative Management Protocol

Patients who selected conservative management were allowed to bear weight as tolerated. They were started immediately on a program of nonimpact closed chain strengthening and range of motion exercises. Patients were allowed to start jogging and performing sport-specific drills between 6 and 12 weeks after injury. Patients were encouraged to avoid any competitive situations (including one-on-one drills and scrimmages, in addition to games) for 3 months. They were permitted to participate in all sports at 3 months unless symptomatic with IKDC level I and II activities (jumping and cutting).<sup>19</sup> Functional ACL bracing was not routinely recommended. If patients had instability with level I or II activities, we recommended that they either undergo ACL reconstruction or eliminate the activity that provoked the symptoms. If a patient asked for a brace to continue with these activities against our recommendations, an off-the-shelf functional brace was prescribed. Compliance with the conservative rehabilitation regimen was not monitored.

### Surgical Technique, Postoperative Rehabilitation

All ACL reconstructions during this study used midthird patellar tendon autograft and were performed endoscopically (single incision), following the technique originally described by Jackson et al<sup>20</sup> with minor modifications. Grafts were secured with metal interference screw fixation in the femur and interference screw or suture-and-post fixation in the tibia depending on graft-tunnel length compatibility. Postoperatively, patients wore a long leg splint

in full knee extension for 4 weeks. Patients were allowed full weightbearing in the splint and removed the splint 4 times a day for range of motion exercises. Activities were progressed gradually according to knee stability and strength, as well as limb control, pain, and effusion. Patients were allowed to return to full sports participation between 6 months and 1 year, when range of motion was full and strength indices were above 80% compared to the opposite, nonoperated limb. Functional bracing was not routinely prescribed after ACL reconstruction.

Patients underwent manipulation under anesthesia if full motion had not returned by 3 months postoperatively. Arthroscopy was recommended to all patients during the study who complained of joint line pain, effusion, or other symptoms suggesting intra-articular abnormality that persisted for at least 6 weeks. If a meniscus tear was encountered during arthroscopy, the meniscus was repaired if bleeding could be established along the periphery to support healing of the tear. If bleeding could not be induced, the loose fragment was removed. Lateral meniscal tears that were not clearly unstable were documented and left alone according to the recommendations of Fitzgibbons and Shelbourne.<sup>16</sup> Arthroscopic debridement of a "cyclops" lesion was required in a small group of patients who lacked full extension and had an audible or palpable "thunk" in terminal active knee extension,<sup>21</sup> in whom intra-articular scar tissue had accumulated around the graft as it entered the tibial tunnel. Tibial hardware removal was performed at least 6 months postoperatively in several patients who developed pain over prominent tibial hardware.

### Follow-up Evaluation

The mean time from injury to follow-up was 6.6 years (range, 3-10 years). The follow-up evaluation consisted of the Short Form-36 (SF-36); the IKDC form; Lysholm and Tegner scores; physical examination including the pivot-shift and Lachman tests, KT-1000 arthrometer testing, and functional strength testing; and plain radiographs in all patients. A registered physical therapist (M.L.S.) conducted all of the follow-up evaluations. At the time the study was designed, we had planned to conduct bone scans in a sample from each risk and treatment group. However, during the final phase of the study, it became necessary to

**KEY**

**Early** = Within 3 months of initial ACL Injury  
**Late** = More than 3 months of initial ACL Injury

☐ = **RECON** (Early and late ACL reconstructed patients)  
 ☐ = **NON-RECON** (No early or late ACL reconstruction)

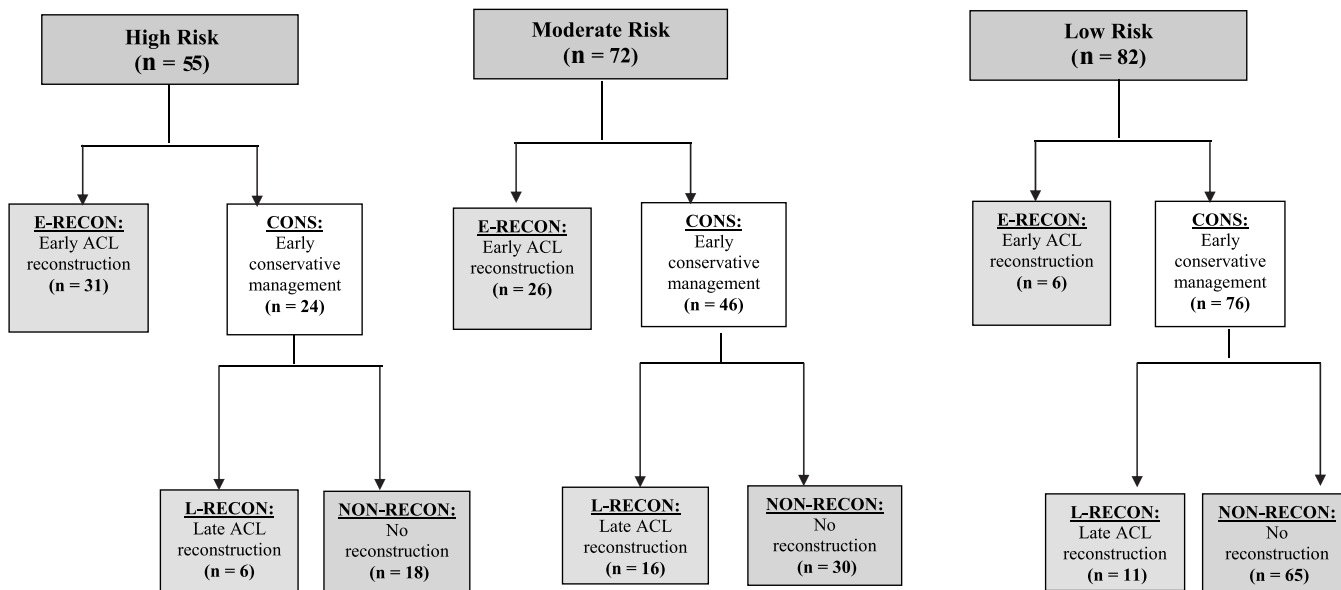


Figure 1. The ACL treatment by risk group.

divert funds from scintigraphy toward recruitment efforts to obtain maximum patient follow-up.

Radiograph Scoring

Standard radiographic views, including standing anteroposterior and lateral projections, were performed on all patients at final follow-up. Films were evaluated by author R.P.C. for the development of degenerative changes according to the IKDC radiograph grading system as specified in the IKDC 2000 standard instructions. Radiographic scores were compared by treatment and risk group, and they were compared to initial MR images to determine the predictive value of bone contusion and osteochondral injury with respect to subsequent degenerative changes on radiographs.

Analytical Design and Statistical Analyses

To analyze the effects of early management on late outcomes, we compared the E-RECON and CONS groups. To evaluate the effects of reconstruction in patients with ACL injury, we compared nonreconstruction (NONRECON) patients to E-RECON and late-reconstruction (L-RECON, >3 months from initial injury) patients. If no statistical differences were noted between E-RECON and L-RECON groups, these 2 groups were combined (RECON) to enhance the statistical power of comparisons between reconstruction and nonreconstructive management of the ACL deficiency. To answer specific questions about the

risks associated with delaying reconstruction, we compared E-RECON and L-RECON groups.

The  $\chi^2$  and Fisher exact tests were used to assess group differences in categorical variables. The Mann-Whitney test and Kruskal-Wallis 1-way analysis of variance (ANOVA) test by ranks were used to evaluate group differences in variables with nonnormal distributions. Independent *t* tests and 1-way ANOVAs were applied to assess group differences in continuous variables with normal distributions. The Wilcoxon signed rank test was used to compare preinjury activity and sports hours to those at follow-up. In the moderate-risk group, absolute risk reduction (ARR) and number needed to treat (NNT) were calculated to compare the effectiveness of CONS and E-RECON in reducing late (>3 months from initial ACL injury) meniscus surgery or ACL reconstruction. The level of statistical significance was set at *P* = .05.

RESULTS

Patient Demographics

Figure 1 presents predicted risk level, treatment recommendations, and treatment selected. There were 55 high-risk, 72 moderate-risk, and 82 low-risk patients who completed the study. Although E-RECON was recommended to all high-risk patients and CONS was recommended to all low-risk patients, 24 of the 55 high-risk patients (44%)



TABLE 3  
Patient Demographics<sup>a</sup>

	High		Moderate		Low	
	CONS	E-RECON	CONS	E-RECON	CONS	E-RECON
Mean age, y (SD)	37 (14)	32 (12)	38 (14)	35 (10)	45 (11)	42 (9)
Gender, % female	46	42	61	54	54	17
Mean preinjury sports I and II hours (SD)	408 (246)	458 (429)	266 (315)	230 (195)	35 (51)	95 (71)
Median preinjury Tegner score	6	7	6	7	5.5	6

<sup>a</sup>CONS, conservative treatment; E-RECON, early reconstruction.

selected CONS, and 6 of the 82 low-risk patients (7%) selected E-RECON. In the high- and moderate-risk groups, patients who followed the recommended treatment and those who did not follow the recommended treatment were similar in age at time of injury, preoperative KT arthrometer measurements, preinjury sports hours, and preinjury Tegner scores. Patients in the low-risk category who received the recommended treatment and those who did not follow the recommended treatment were similar in age and preinjury Tegner scores. However, patients in the low-risk group who elected surgery against our recommendation reported higher mean preinjury sports hours than those who accepted our recommendation of conservative treatment.

During the study period, some CONS patients went on to have L-RECON (>3 months after the initial injury). In the high-risk group, 6 of the 24 CONS patients had L-RECON, resulting in final counts of 37 undergoing either early or late ACL reconstruction (RECON) and 18 having no early or late ACL reconstruction (NONRECON). Within the moderate-risk group, 16 of the 46 CONS patients had L-RECON, resulting in a total of 30 NONRECON and 42 RECON patients. In the low-risk group, 11 of the 76 CONS patients had L-RECON, resulting in 65 NONRECON and 17 RECON patients at follow-up.

There were 108 female patients and 101 male patients, with a mean age at follow-up of 39 years (range, 16-69 years). The mean number of preinjury level I and II sports hours reported by patients was 217 hours (range, 0-2416 hours). The median preinjury Tegner score was 6 (range, 1-9). Eighty-two percent of the ACL injuries occurred during sports participation. The most common activity at the time of injury was snow skiing (23%) followed by soccer (15%), basketball (13%), and football (7%).

Table 3 presents patient demographics by risk and treatment group. The sample consisted of 63 E-RECON and 146 CONS patients. Within the high- and moderate-risk groups, E-RECON and CONS patients were similar in age, gender, preinjury Tegner scores, and preinjury sports hours. Thus, within the high- and moderate-risk groups, the E-RECON and CONS groups were well matched for all variables thought to affect outcomes after ACL injury. In the low-risk category, age and preinjury Tegner scores were similar for E-RECON and CONS patients. However, the E-RECON patients (n = 6) reported higher mean preinjury level I and II sports hours than did CONS patients in the low-risk category.

## Late Surgery

Figure 2 is a flow chart showing the distribution of late surgeries according to whether the ACL was reconstructed and the timing of the reconstruction. Table 4 presents late surgeries (>3 months after initial ACL injury) for E-RECON and CONS patients. The E-RECON patients were less likely to have late surgeries (10/63, 15.9%) than were CONS patients (49/146 patients, 34%;  $P = .009$ ). The CONS patients were more likely to have late meniscus surgery ( $P < .001$ ) than were E-RECON patients. Of the 3 patients requiring ACL revision, 2 patients had returned to sports and sustained a reinjury. In the third patient, the graft had stretched out and the patient complained of knee instability symptoms.

Late surgery for meniscal tear or persistent symptomatic ACL insufficiency was of particular interest to us. The CONS patients in all risk groups were more likely to have late meniscus problems (meniscal repair, meniscectomy) or ACL surgery than were E-RECON patients. This difference was statistically significant within the moderate-risk group ( $P = .01$ ) (Table 5).

## Algorithm Effectiveness

We evaluated the effectiveness of our treatment algorithm in reducing the risk of late surgery (ACL reconstruction/revision, meniscal surgery). Patients in the low-risk CONS group had fewer late surgeries (16%) than did the moderate- and high-risk CONS groups combined (33%;  $P = .008$ ), indicating less risk for late surgery within this low-risk group. Within the moderate-risk group, the E-RECON group had less (7%) late surgery than did the CONS group (33%;  $P < .001$ ). In the moderate-risk group, E-RECON resulted in an ARR of 0.29 (95% confidence interval,  $\pm 0.056$ ). This suggests that within the moderate-risk group, 1 late surgery will be prevented with every 3 ACL reconstructions (NNT).

## Sports Hours and Activity

From preinjury to follow-up, E-RECON and CONS patients in all risk groups (except the low-risk E-RECON group) reported a reduction in sports level I and II hours ( $P < .001$ ) (Figure 3) and in Tegner scores ( $P < .01$ ). Figure 4 displays Tegner scores by L-RECON, E-RECON, and

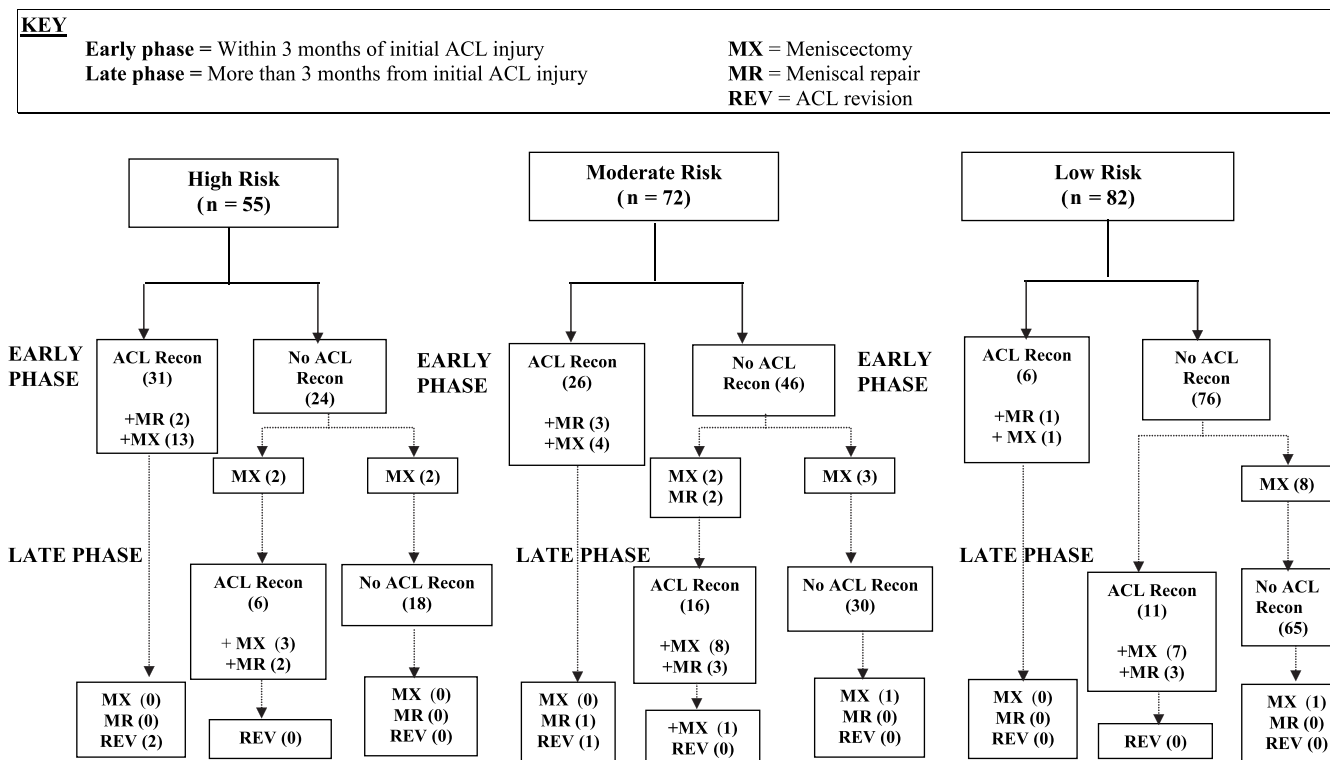


Figure 2. Subsequent ACL and meniscal surgery by treatment and risk group. Recon, reconstruction.

TABLE 4  
Types of Late Surgeries by Surgical Group<sup>a</sup>

Late Surgery	E-RECON (n = 63)		CONS (n = 146)	
	No.	%	No.	%
ACL reconstruction			33 <sup>b</sup>	23
Scope	4	6	20	14
Excision of cyclops <sup>21</sup>	2	3	0	0
ACL revision	3 <sup>c</sup>	4.8	0	0
Hardware	1	2	2	1
Meniscal repairs	1	1.6	8	5.5
Manipulation under anesthesia	0	0	2	1
MX/PMX <sup>d</sup>	0	0	21 <sup>b</sup>	14

<sup>a</sup>E-RECON, early reconstruction; CONS, conservative treatment.

<sup>b</sup>P < .001.

<sup>c</sup>P < .05.

<sup>d</sup>MX/PMX, total or partial meniscectomy.

NONRECON groups. From preinjury to follow-up, all groups reported decreases in Tegner activity scores ( $P < .001$ ). The E-RECON and L-RECON patients reported significant reductions in Tegner scores from preinjury to presurgery ( $P < .001$ ) and significant increases in Tegner scores from presurgery to follow-up ( $P < .001$ ). At follow-up, the E-RECON patients reported higher Tegner activity scores than did the NONRECON ( $P < .001$ ) and L-

TABLE 5  
Patients With Late ACL Reconstruction, ACL Revision, or Meniscal Surgery by Risk and Treatment Group<sup>a</sup>

Predicted Risk Group	E-RECON		CONS	
	No.	%	No.	%
High (n = 55)	2/31	6.5	6/24	25
Moderate (n = 72)	2/26	7.7	17/46 <sup>b</sup>	37
Low (n = 82)	0/6	0	12/76	16

<sup>a</sup>E-RECON, early reconstruction; CONS, conservative treatment.

<sup>b</sup>P < .05.

RECON patients ( $P = .007$ ). The NONRECON patients had lower Tegner scores than did both L-RECON and E-RECON patients at follow-up ( $P < .001$  and  $P = .007$ , respectively). At follow-up, 52% of the NONRECON, 52% of the E-RECON, and 37% of the L-RECON patients returned to preinjury or higher levels of activity.

### Instability (Full Giving-Way) Episodes

The E-RECON and L-RECON patients reported similar rates of instability episodes ( $P = .55$ ) (Table 6). The NONRECON group reported a higher instability rate than did the combined RECON group ( $P = .009$ ). The NONRECON patients within each risk category reported higher instability rates (high, 22%; moderate, 13%; low, 11%) than did

TABLE 6  
Patient Outcomes by Treatment Group<sup>a</sup>

	NONRECON (n = 113)	E-RECON (n = 63)	L-RECON (n = 33)	RECON (n = 96)
Full giving-way episodes	15 (13%)	3 (5%)	0 (0%)	3 (3%)
Pain ≥ frequent, %	63	60	53	58
Pain > mild, %	19	10	19	13
Problems, %				
Swelling	23	20	31	24
Walking	7	2	0	1
Climbing	19	5	16	9
Stairs	24	14	16	14
Kneeling	44	62	59	61
Squatting	47	30	23	27
Running	41	15	37	23
Lateral motion	46	26	23	25
Cutting	52	26	39	31
Jumping	32	19	31	23
Mean Lysholm total score (SD)	88 (14)	92 (10)	91 (8)	92 (10)
Mean Short Form-36 (SD)				
Physical function	82 (20)	92 (13)	87 (19)	90 (15)
Role physical	80 (35)	92 (24)	94 (20)	93 (23)
Bodily pain	58 (30)	64 (30)	64 (29)	64 (30)
General health	77 (19)	83 (14)	78 (18)	81 (16)
Vitality	63 (20)	71 (15)	68 (19)	70 (16)
Social function	87 (19)	95 (12)	91 (14)	94 (12)
Role emotional	85 (32)	95 (17)	94 (18)	94 (17)
Mental health	78 (16)	84 (10)	78 (18)	82 (14)
International Knee Documentation				
Committee final score, %				
Normal	10	33	33	33
Nearly normal	23	53	45	50
Abnormal	66	12	23	16
Severely abnormal	2	2	0	1

<sup>a</sup>NONRECON, nonreconstruction; E-RECON, early reconstruction; L-RECON, late reconstruction; RECON, early and late reconstruction combined.

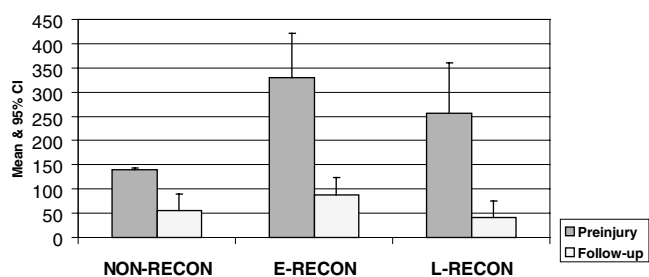


Figure 3. Level I and II sports hours by treatment group. CI, confidence interval; NONRECON, nonreconstruction; E-RECON, early reconstruction; L-RECON, late reconstruction.

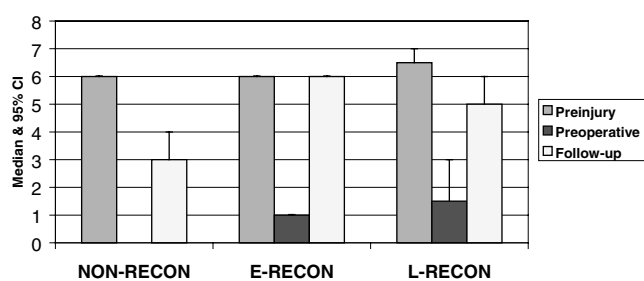


Figure 4. Tegner scores by treatment group. CI, confidence interval; NONRECON, nonreconstruction; E-RECON, early reconstruction; L-RECON, late reconstruction.

RECON patients (high, 0%; moderate, 7%; low, 0%), but comparisons reached significance only in the high-risk category ( $P = .009$ ) because of risk category sample sizes.

Symptoms

Table 6 presents patient-reported pain and swelling. More than 50% of the patients in all treatment groups (E-

RECON, L-RECON, and NONRECON) reported pain in their ACL-injured knees. The RECON and NONRECON groups did not differ in the frequency with which pain in the injured knee was reported ( $P = .24$ ). Of the patients who reported pain, fewer than 20% in each treatment group reported pain that was greater than mild. Similar frequencies of swelling were also reported between RECON and NONRECON groups.

TABLE 7  
KT-1000 Arthrometer Injured-Normal Displacement by Risk and Treatment Group<sup>a</sup>

	High		Moderate		Low	
	NONRECON	RECON	NONRECON	RECON	NONRECON	RECON
Acute injury	n = 18	n = 36	n = 28	n = 38	n = 62	n = 16
30 lb	3.6 (1.6)	4.0 (2.2)	2.7 (2.7)	3.1 (1.9)	2.6 (1.6)	1.7 (1.8)
Manual maximum	5.9 (1.3)	6.2 (2.6)	5.0 (1.7)	4.8 (2.2)	4.5 (1.4)	3.7 (1.8)
Follow-up	n = 18	n = 36	n = 28	n = 39	n = 62	n = 17
30 lb	3.3 (1.5)	1.6 (1.6)	3.1 (2.1)	1.7 (2.0)	2.3 (1.8)	2.0 (2.0)
Manual maximum	4.6 (1.7)	2.7 (2.0)	4.6 (3.7)	2.6 (2.3)	3.9 (2.3)	3.0 (2.8)

<sup>a</sup>NONRECON, nonreconstruction; RECON, early and late reconstruction combined. Numbers in parentheses are SDs.

### Functional Impairment

The E-RECON and L-RECON patients reported fewer problems with squatting ( $P = .005$ ), running ( $P = .01$ ), lateral motion ( $P = .005$ ), and cutting ( $P = .015$ ) than did NONRECON patients. The E-RECON patients reported less difficulty with running than did NONRECON ( $P = .002$ ) and L-RECON patients ( $P = .025$ ). Comparisons of E-RECON, L-RECON, and NONRECON patients with respect to specific functional impairments such as difficulty with walking ( $P = .10$ ), climbing hills or ramps ( $P = .06$ ), going up or down stairs ( $P = .22$ ), kneeling ( $P = .05$ ), and jumping ( $P = .20$ ) did not reach significance (Table 6). However, when E-RECON and L-RECON patients were combined (RECON), they reported less difficulty with walking ( $P = .04$ ) and climbing hills or ramps ( $P = .047$ ) and more difficulty with kneeling ( $P = .02$ ) than did the NONRECON patients.

### Lysholm Scores

The E-RECON and L-RECON patients reported similar Lysholm scores at follow-up ( $P = .30$ ) (Table 6). The RECON patients reported higher Lysholm scores than did NONRECON patients ( $P < .05$ ).

### IKDC Scores

The E-RECON and L-RECON patients had similar IKDC scores ( $P = .54$ ) (Table 6). The RECON patients had more normal and nearly normal (83%) IKDC scores than did NONRECON patients in all risk categories (33%;  $P < .001$ ).

### SF-36 Scores

The E-RECON and L-RECON patients did not differ significantly in SF-36 scores (Table 6). The RECON patients reported higher SF-36 scores than did NONRECON patients on the physical function ( $P < .001$ ), role physical ( $P = .005$ ), bodily pain ( $P = .02$ ), vitality ( $P = .02$ ), social function ( $P = .005$ ), and role emotion ( $P = .04$ ) subscales.

The SF-36 scores were stratified by gender to control for the higher number of female patients in the NONRECON

group. Male RECON and NONRECON patients did not differ significantly on the SF-36 subscales. Female RECON patients reported higher scores than did the NONRECON females on physical function ( $P = .003$ ), role physical ( $P = .004$ ), bodily pain ( $P = .002$ ), general health ( $P = .03$ ), vitality ( $P = .01$ ), and social functioning ( $P = .04$ ) subscales. Male RECON and NONRECON patients and female NONRECON patients reported lower bodily pain scores than age- and gender-matched US norms ( $P < .001$ ). Male and female NONRECON patients also reported lower physical function scores ( $P < .01$ ) than gender- and age-related norms.

### Stability and Function Testing

Table 7 presents KT-1000 arthrometer 30-lb force and manual maximum injured-normal displacement difference at follow-up. At follow-up, high-risk NONRECON patients had a mean manual maximum difference of 4.6. This represents tightening in knees over time in some patients who do not undergo ACL reconstruction.<sup>7</sup> The RECON patients within the high-risk ( $P = .002$ ), moderate-risk ( $P = .002$ ), and low-risk ( $P = .04$ ) groups had significantly less manual maximum displacement than did the NONRECON patients in the same risk groups. Within the high-risk ( $P = .001$ ) and moderate-risk ( $P = .01$ ) groups, RECON patients also had less displacement with 30-lb force than did NONRECON patients in the same risk group.

Pivot shift was scored on a 4-point scale with 0 = none, 1 = trace, 2 = obvious, and 3 = exaggerated. Within each risk group, the RECON patients had lower pivot-shift scores than did the NONRECON patients ( $P < .001$ ). Risk and treatment groups did not differ in single-leg hop index scores ( $P = .89$ ).

### Radiographic Findings

The radiographs were scored using IKDC grading at final follow-up. The results are summarized in Table 8. The E-RECON patients had higher rates of degenerative changes on radiographs than did CONS patients at the medial (95% vs 83%;  $P = .03$ ), patellofemoral (76% vs 58%;  $P = .02$ ), and anterior (21% vs 7%;  $P = .003$ ) joint spaces at follow-up. Because some of the CONS patients went on to



TABLE 8  
Presence of Arthritis by Meniscal Status and Treatment<sup>a</sup>

	E-RECON		L-RECON		RECON		NONRECON	
	No.	%	No.	%	No.	%	No.	%
Intact meniscus (normal or repair)	35/36	97	6/10	60	41/46	89	98/111	88
Meniscectomy	19/20	95	15/17	88	34/37	92	2/2	100

<sup>a</sup>E-RECON, early reconstruction; L RECON, late reconstruction; RECON, early and late reconstruction combined; NONRECON, nonreconstruction.

have L-RECON during the study, we also compared RECON (late and early combined) to NONRECON patients (no ACL reconstruction during the study). The RECON patients had higher rates of arthrosis than did NONRECON patients at the lateral (39% vs 25%;  $P = .03$ ), patellofemoral (71% vs 57%;  $P = .03$ ), and anterior (18% vs 6%;  $P = .004$ ) joint spaces.

### Magnetic Resonance Imaging

A total of 57 (79%) moderate-risk patients had MRI within 4 weeks of injury: 32 RECON and 25 NONRECON. Seven RECON and 1 NONRECON patient had meniscectomies during the follow-up period. Patients with and without meniscal tears on MRI had similar rates of degenerative joint disease (DJD) (92% vs 94%;  $P = 1.0$ ) on follow-up radiographs. The RECON groups (69%) had more bone contusions on MRI than the NONRECON group had (40%;  $P = .03$ ). In RECON and NONRECON groups, patients with and without bone contusions differed only slightly in DJD: RECON: contusion = 91% vs no contusion = 100% ( $P = 1.0$ ); NONRECON: contusion = 100% vs no contusion = 87% ( $P = .50$ ).

### DISCUSSION

Moderate- and high-risk patients experienced similar rates of reconstruction over the course of this study. Combined rates of L-RECON and meniscus surgery were significantly higher (33%) in these groups than for the low-risk patients (16%). Specific treatment recommendations were made to all high- and low-risk patients; all patients classified as high risk were recommended to have surgery, and all low-risk patients were recommended conservative management. Treatment recommendations in moderate-risk patients were allocated based on the day of the week on which they presented to the clinic. Because of differing treatment recommendations, direct comparisons of frequencies of late surgery between moderate-risk patients and the other risk groups should be viewed with caution because of obvious treatment bias in the high- and low-risk groups. However, overall rates of ACL surgery (early plus late) can be used to determine the likelihood that patients in a particular risk category will elect to have their knees stabilized. Higher rates of E-RECON among high-risk patients resulted in rates of L-RECON that were

slightly lower than the rate of late surgery among moderate-risk patients. This represents selection bias toward early surgery in the high-risk group, but it is interesting to note that overall rates of surgery were comparable between the high- and moderate-risk groups and were significantly higher than rates of L-RECON among low-risk patients. It is also worth noting that both high- and moderate-risk groups contained significant minorities (33% and 42%, respectively) who completed the study without stabilization. These patients were able to adjust to the ACL deficiency by reducing their activity levels in lieu of ACL reconstruction. The psychology of patient choice in managing their ACL-injured knees is the subject of further study at our institution.

For moderate-risk patients, our method for allocating treatment recommendations represented a method of quasi-randomization intended to reduce treatment bias in the moderate-risk group. The outcomes in the moderate-risk category were of the greatest interest to us because of uncertainty about the best course of action at the time of ACL injury. Our findings indicated that patients in the moderate-risk category have a risk of late surgery similar to that in the high-risk category. Early ACL reconstruction in the moderate-risk category reduced the risk of late surgery from 33% to 7% ( $P < .001$ ; ARR =  $0.29 \pm 0.056$ ).

A limitation of this study was that we did not truly randomize treatment allocations. It was our feeling that few patients would have participated if the study design had required randomization of surgical and nonsurgical care. As it happened, patients were very accepting of this study design, with 92% of qualified patients agreeing to participate. Each of the treating clinicians (D.M.D., M.L.S., D.C.F., and W.F.L.) felt that sufficient uncertainty existed regarding moderate-risk patients to allow some latitude in treatment allocation. In the final analysis, by all measurable variables known to contribute to outcomes after ACL injury, the E-RECON and CONS groups within the moderate-risk category were comparable.

Another study limitation was our study follow-up rate. Although 287 of the 310 eligible patients (92%) agreed to participate in this study, only 210 of the 287 (73%) were available for follow-up. Although our follow-up rate was 73%, our final patient sample was representative of the initial 287 patients in age, preinjury sports hours, and preinjury Tegner activity scores.

This study indicated that patients who decide to have ACL reconstruction can expect significant improvement in

postoperative activity scores compared to preoperative scores. However, mean activity scores remained reduced in all groups at follow-up compared to preinjury scores. These findings agree with those reported by Roos et al<sup>33</sup> and Karlsson et al.<sup>25</sup> In our study, like that of Karlsson et al, L-RECON patients (reconstruction more than 3 months after ACL injury) had slightly lower Tegner activity scores than did E-RECON patients. Tegner scores at the time of injury were similar for both groups.

A limitation of our study was that we did not document “desired” activity level. Karlsson et al<sup>25</sup> noted that patients who underwent “subacute” (within 12 weeks) reconstruction had higher Tegner scores at follow-up compared to patients who underwent “late” (12-24 months after ACL injury) reconstruction. Interestingly, the “subacute” group also had a higher desired activity level compared to the late-reconstructed group. The desire to return to high levels of activity is therefore a potential confounder in comparing follow-up activity levels. In our study, as in the work by Karlsson et al, it is possible that a higher degree of desired activity influenced patients’ choice of treatment, as well as their final activity levels.

Late degenerative findings using IKDC criteria were mild but frequent in all risk groups, and they were more frequent in the E-RECON group. Daniel et al<sup>6</sup> reported that ACL reconstruction was associated with higher rates of late degenerative changes on radiographs than was nonoperative care. Degenerative changes were also linked to meniscectomy in that study. Subsequent follow-up of the same patients at 10 years showed slight progression of the degenerative changes, with reconstructed patients still showing slightly greater degenerative changes despite a higher rate of late meniscus injuries in the nonreconstructed knees.<sup>15</sup> The current study demonstrated, once again, that ACL reconstruction with patellar tendon autograft is associated with a slight but significant increase in the frequency of degenerative changes on radiographs in the intermediate term after an ACL tear. Pinczewski et al<sup>31</sup> reported mild degenerative changes after patellar tendon ACL reconstruction compared to changes after reconstruction using hamstring tendons. However, our results do not agree with those of an earlier report by the same group,<sup>24</sup> which indicated that nonoperatively treated patients show greater degenerative scores than do operatively treated patients. It is worth noting that Jomha et al<sup>24</sup> specifically excluded patients who were coping with ACL, so that their sample of nonreconstructed patients was by definition symptomatic and therefore biased toward a higher frequency of significant meniscal lesions.

Current IKDC recommendations indicate that follow-up radiographs should be compared to baseline films in grading progression of arthritic changes to test the assumption that differences among groups at follow-up are not confounded by previous degenerative changes. Although this seems prudent for many studies in which patients may be enrolled at various times after a significant event, patients were excluded from our study if they had sustained a previous injury in either knee. In our prior study of the natural history of the ACL-deficient knee, we documented no significant differences between any of 4 study cohorts on

baseline radiographs.<sup>6</sup> A study is currently underway at our facility to test the reliability of current IKDC scoring criteria for radiographs, which will include an analysis of the value of baseline versus follow-up comparisons in patients with no prior history of knee trauma.

In a long-term follow-up study comparing outcomes of ACL reconstruction and outcomes of conservative care, Fink et al reported progressive arthritic changes compared to initial radiographs in both operative and nonoperative groups, noting no significant differences between the two.<sup>13,14</sup> To draw accurate inferences on the population of conservatively treated patients with ACL injury, it is important to understand the study design, sampling, and treatment bias. In contrast to the study by Jomha et al,<sup>24</sup> which was biased toward greater degenerative change in the conservatively treated sample, the San Diego Kaiser Permanente study design<sup>6,15</sup> was biased toward less degenerative change in the nonreconstructed patients. In the studies of Fink et al,<sup>13,14</sup> there was a relationship between activity level at follow-up and the degree of arthritic change on radiographs. Our current study attempted to limit bias by allocating treatment recommendations in the moderate-risk group according to the date of presentation. Although preinjury activity was effectively controlled by this method of treatment allocation, ACL reconstruction resulted in a significant increase in activity at follow-up. Of the 3 treatment groups at follow-up (E-RECON, L-RECON, and NONRECON), E-RECON patients had the highest Tegner scores and obviously had spent more time at this level than had the other groups owing to the timing of the reconstruction. This seems a likely explanation for the increased frequency of arthritis in the E-RECON group in our study, as well as in our previous studies. In any event, it seems an unavoidable conclusion that early ACL reconstruction results in higher rates of degenerative changes on radiographs at follow-up.

The development of DJD after ACL reconstruction has been documented previously by several studies.<sup>6,13-15,31</sup> Late degenerative changes on radiographs may be the result of the initial trauma, surgical intervention, meniscal injuries or surgery, or other factors as summarized by Dye et al.<sup>10</sup> One objective of this study was to determine if bone contusion, joint surface injury, and meniscal injuries seen on MRI at the time of injury are related to late radiographic signs of DJD. The E-RECON group had a higher frequency of bone contusions on initial MRI than did the CONS group; no significant differences were noted between CONS and E-RECON groups with respect to the frequency of joint surface abnormality or meniscus injuries. Bone contusion did not influence surgeons’ treatment recommendations in this study, but patients may have been more inclined to undergo ACL reconstruction if the perceived knee injury was more severe. Zeiss et al<sup>38</sup> reported that bone contusions were more commonly seen in association with complete and high-grade partial ligament ruptures than in partial ACL tears. In our study, all patients had documented complete ACL ruptures by ligament arthrometry (KT-1000 arthrometer side-to-side difference = 3 mm with manual maximum force). All 57 MR studies indicated complete ACL rupture. Two retrospec-

tive studies have indicated persistence of postcontusion signal abnormalities in follow-up MRI.<sup>4,35</sup> Costa-Paz et al<sup>4</sup> observed greater frequency of persistent abnormalities in knees with higher grade injuries on the initial examination. They reported no relationship between persistent signal abnormalities and clinical scores at follow-up. Neither study compared early bone contusion to changes on radiographs at follow-up. In the present study, we did not observe a statistically significant relationship between bone contusions at the time of ACL injury and the development of late degenerative changes on radiographs, regardless of whether patients had ACL reconstruction.

A limitation of our study was that our MR sequences were not specifically for identifying isolated articular cartilage injuries, that is, articular injuries that were not associated with subchondral bone edema. Further study may be warranted to determine whether focal articular injuries without subchondral edema have an effect on subsequent degenerative changes, but it seems reasonable to assume that joint surface injury with subchondral edema represents a more severe injury than does isolated articular injury. It is clear from our results that the presence of subchondral edema was not associated with greater degenerative changes on follow-up radiographs.

It was a surprise to us that such a large proportion of patients initially selected a treatment other than that which was recommended. This probably was a function of our knee injury clinic: patients are referred to the clinic, rather than to a specific surgeon, so the surgeon has a degree of anonymity and patients may be less likely to accept his or her recommendations than if they had sought a consultation with a specific surgeon. It is interesting to note that even among high-risk patients, a significant proportion of patients elected to try CONS. Among patients in all risk groups who subsequently went on to have L-RECON, outcomes were comparable to those of E-RECON patients in all aspects except a slightly reduced activity level at follow-up, a higher prevalence of meniscal surgery over the course of nonoperative care, and a slightly lower risk of degenerative changes on follow-up radiographs. By waiting for surgery, patients clearly were obliged to accept a reduced activity level (Figure 3). If a patient is willing to accept a reduction in activity level and an increase of approximately 20% in the risk of late meniscus surgery, our study suggests that it is reasonable to delay surgery until it is clear exactly how much disability the ACL deficiency will impose on him or her as an individual. A very clear finding of this study is that ACL reconstruction is effective in treating disability associated with ACL deficiency, even if it is done late.

## CONCLUSION

1. Nonreconstructed patients in all risk groups reported a higher frequency of full giving-way episodes, more laxity on ligament arthrometer testing, and higher pivot-shift grades than did reconstructed patients in the same risk groups.
2. Low-risk patients were less likely to require L-RECON and meniscus surgery than were moderate-

and high-risk patients, suggesting that initial conservative management is appropriate for this risk group.

3. We were unable to distinguish between moderate- and high-risk groups with respect to risk of late surgery, suggesting there are in fact only 2 risk levels for late meniscus or ligament surgery: low risk and high risk.
4. The higher frequency of meniscus tears requiring repair or meniscectomy reflected cumulative meniscal damage due to chronic ACL deficiency in the L-RECON group compared to the E-RECON group. On the other hand, clinical outcomes were similar for these 2 groups of patients, and despite the risk of tearing a meniscus during a trial of conservative management, changes on radiographs were slightly less severe in patients who had delayed reconstruction.
5. Late degenerative changes were mild but frequent in all risk groups; DJD was more frequent in knees undergoing ACL reconstruction (both late and early) than in nonreconstructed knees.
6. There does not appear to be a relationship between bone contusions on MR images at the time of ACL injury and the development of late degenerative changes on radiographs, regardless of whether patients had ACL reconstruction.

## ACKNOWLEDGMENT

This work was supported by community service funds of Kaiser Permanente and a clinical research grant from the Orthopaedic Research and Education Foundation. The authors are grateful to the members of the Southern California Permanente Sports Medicine Study Group for helpful editorial discussions.

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