ORIGINAL ARTICLE

A Randomized Trial of Treatment for Acute Anterior Cruciate Ligament Tears

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ABSTRACT

BACKGROUND

The optimal management of a torn anterior cruciate ligament (ACL) of the knee is unknown.

METHODS

We conducted a randomized, controlled trial involving 121 young, active adults with acute ACL injury in which we compared two strategies: structured rehabilitation plus early ACL reconstruction and structured rehabilitation with the option of later ACL reconstruction if needed. The primary outcome was the change from baseline to 2 years in the average score on four subscales of the Knee Injury and Osteoarthritis Outcome Score (KOOS) — pain, symptoms, function in sports and recreation, and knee-related quality of life ($KOOS_4$; range of scores, 0 [worst] to 100 [best]). Secondary outcomes included results on all five KOOS subscales, the Medical Outcomes Study 36-Item Short-Form Health Survey, and the score on the Tegner Activity Scale.

RESULTS

Of 62 subjects assigned to rehabilitation plus early ACL reconstruction, 1 did not undergo surgery. Of 59 assigned to rehabilitation plus optional delayed ACL reconstruction, 23 underwent delayed ACL reconstruction; the other 36 underwent rehabilitation alone. The absolute change in the mean $KOOS_4$ score from baseline to 2 years was 39.2 points for those assigned to rehabilitation plus early ACL reconstruction and 39.4 for those assigned to rehabilitation plus optional delayed reconstruction (absolute between-group difference, 0.2 points; 95% confidence interval, −6.5 to 6.8; P=0.96 after adjustment for the baseline score). There were no significant differences between the two treatment groups with respect to secondary outcomes. Adverse events were common in both groups. The results were similar when the data were analyzed according to the treatment actually received.

CONCLUSIONS

In young, active adults with acute ACL tears, a strategy of rehabilitation plus early ACL reconstruction was not superior to a strategy of rehabilitation plus optional delayed ACL reconstruction. The latter strategy substantially reduced the frequency of surgical reconstructions. (Funded by the Swedish Research Council and the Medical Faculty of Lund University and others; Current Controlled Trials number, ISRCTN84752559.)

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Rupture of the anterior cruciate ligament (ACL) is a serious knee injury that affects mainly physically active young people. The injury is characterized by joint instability that leads to decreased activity, unsatisfactory knee function, and poor knee-related quality of life in the short term,[1,2] and it is associated with an increased risk of osteoarthritis of the knee.[3]

Surgical reconstruction of the torn ligament has been regarded as critical for a good outcome and is commonly performed, particularly in those wishing to resume sports activities.[2,4,5] Despite a lack of evidence from high-quality randomized, controlled trials comparing ACL reconstruction with other treatments,[2,3,6-8] at least 200,000 ACL reconstructions are performed each year in the United States, with estimated direct costs of $3 billion (in U.S. dollars) annually.[9] Structured rehabilitation supervised by a physical therapist is a central aspect of treatment,[10] although it is not always offered to patients.

We conducted a randomized, controlled trial involving young, active adults with an acute tear of the ACL to determine whether a strategy of structured rehabilitation plus early ACL reconstructive surgery is superior to a strategy of structured rehabilitation with delayed ACL reconstruction offered to subjects who continue to have symptomatic knee instability.

METHODS

STUDY DESIGN AND PARTICIPANTS

We conducted the trial (the Knee Anterior Cruciate Ligament, Nonsurgical versus Surgical Treatment [KANON] Study) in Lund, Sweden, with subjects recruited from the Department of Orthopedics at both Helsingborg Hospital and Lund University Hospital. Details of the recruitment have been reported previously.[11] The protocol was approved by the Lund University ethics committee. The study was performed in accordance with the protocol, and all subjects provided written informed consent.

Subjects 18 to 35 years of age who presented to the emergency department with recent knee trauma were screened for eligibility. Eligible subjects had rotational trauma to a previously uninjured knee within the preceding 4 weeks, ACL insufficiency as determined by clinical examination, and a score of 5 to 9 on the Tegner Activity Scale (TAS)[12] before the injury (scores range from 1 to 10, with a score of 5 indicating participation

in recreational sports, and a score of 9 indicating participation in competitive sports on a nonprofessional level). Major exclusion criteria were a total collateral ligament rupture and a full-thickness cartilage lesion visualized on magnetic resonance imaging (MRI). (Additional exclusion criteria can be found in Table A in the Supplementary Appendix, available with the full text of this article at NEJM.org.)

All eligible subjects received standardized information about the trial orally, in writing, and by DVD.[11] They were randomly assigned by computer-generated random numbers in permuted blocks of 20 to undergo either structured rehabilitation plus early ACL reconstruction (referred to as the early-reconstruction group) or structured rehabilitation with the option of delayed ACL reconstruction for those with symptomatic knee instability who met specific protocol guidelines (referred to as the optional delayed-reconstruction group) (see the Supplementary Appendix). An investigator who was not involved in the randomization procedure prepared all sequentially numbered, opaque, sealed envelopes containing the assigned interventions to ensure that the sequence was concealed. For the subjects' convenience, MRI was performed at the time of randomization, but the results were not available until 2 to 3 days later, at which time the MRI findings were used to confirm that the inclusion criteria were met, including the presence of acute ACL tears (see the Supplementary Appendix). Randomization was performed without knowledge of the MRI findings, and the MRI scans were assessed without knowledge of the assigned intervention. None of the study funders had any role in data collection, storage, or analysis; in the writing of the manuscript; or in the decision to submit the manuscript for publication.

STUDY TREATMENTS

All subjects followed a rehabilitation protocol consistent with the consensus in the literature[13] (see Appendix A in the Supplementary Appendix). Rehabilitation was initiated before or at the time of randomization and was supervised by experienced physical therapists at nine outpatient clinics. The protocol included goals for range of motion, muscle function, and functional performance at each of four levels, and these goals had to be met before a subject could progress to the next higher level. Slower progression was expected in the subjects assigned to rehabilitation plus ACL re-

construction. Pain and swelling slowed progression, and subjects in whom these problems persisted were scheduled to see the treating clinician.

In the subjects randomly assigned to structured rehabilitation plus early ACL reconstruction, surgery was performed within 10 weeks after the injury by one of four senior knee surgeons, each of whom performed more than 40 ACL reconstructions annually. The choice of procedure depended on the surgeon's preference. The patella–tendon procedure,[14] used in 25 subjects, involves the central third of the ipsilateral patellar tendon as an autograft with fixation of the bone blocks within the tibia and femur; the hamstring–tendon procedure,[15] used in 36 subjects, involves a four-layer autograft made up of folded-over gracilis and semitendinosus muscle tendons. In randomized trials, these two methods have resulted in similar outcomes.[16,17] Surgery was performed while the patients were under general anesthesia, and meniscal surgery was carried out as needed, followed by ACL reconstruction. The subjects randomly assigned to structured rehabilitation plus optional delayed ACL reconstruction followed the rehabilitation protocol. Subjects in this group were referred for delayed ACL reconstruction, performed by the same surgeons who performed the surgical procedures in the early-reconstruction group, if they chose surgery and if prespecified criteria were met (self-reported symptomatic instability caused by ACL insufficiency and a positive pivot shift test [as described in Table B in the Supplementary Appendix]).

OTHER TREATMENTS

Baseline MRI verified ACL rupture, meniscal tears, and other injuries (Table 1, and the Supplementary Appendix). In both groups, meniscal tears were treated with partial resection or fixation when indicated by MRI findings and clinical signs (see the Supplementary Appendix). In subjects assigned to rehabilitation plus early ACL reconstruction, additional meniscal surgery was performed if unstable meniscal tears were identified during the baseline surgery. Meniscocapsular separations of less than 10 mm were treated with arthroscopic fixation. Fixation of larger meniscal tears required a change in the postoperative rehabilitation regimen and therefore resulted in exclusion from the study (Fig. 1, and the Supplementary Appendix). During follow-up, 24 subjects had signs of a meniscal tear and were treat-

ed by means of arthroscopic surgery (Table D in the Supplementary Appendix).

OUTCOME MEASURES

Subjects were evaluated 3, 6, 12, and 24 months after randomization. At each visit, subjects completed the Knee Injury and Osteoarthritis Outcome Score (KOOS), Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), and TAS questionnaires before seeing the clinician.

The primary outcome was the change from baseline to 2 years in the average score for four of the five KOOS subscales, covering pain, symptoms, difficulty in sports and recreational activities, and quality of life (KOOS$_4$), with scores ranging from 0 (worst) to 100 (best).[19,20] KOOS has been validated and is used for patients undergoing ACL reconstruction.[19,20,22-24] Prespecified secondary outcomes included results on all five KOOS subscales (the fifth scale being activities of daily living), the scores on the SF-36 physical and mental components (range, 0 [worst] to 100 [best]),[21] results on the TAS,[12] the area under the curve (AUC) for the development of absolute scores (KOOS$_4$ score per visit × time to follow-up [in days]) from baseline to 2 years, and the percentage of subjects with a KOOS quality-of-life score below 44 (a prespecified cutoff value consistent with a report of more than moderately decreased knee-related quality of life) between 6 months and 2 years. Subjects reported their preinjury TAS score at baseline and their score at each follow-up visit; we compared scores between groups as well as the percentage of subjects in each group whose TAS score at 2 years was at least as high as their preinjury score.

Exploratory outcomes included knee stability, as determined with the use of the Lachman test; results on the pivot shift test; and findings on KT1000 (MEDmetric) arthrometry, an instrumented test to assess anteroposterior translation of the knee. These assessments were performed by one of two experienced clinicians, both of whom were aware of the treatment assignments.

We performed a post hoc analysis based on the treatment received: rehabilitation plus early ACL reconstruction, rehabilitation plus delayed ACL reconstruction, or rehabilitation alone.

ADVERSE EVENTS

Clinic records were reviewed for all study visits and for appointments that took place outside the study. The computerized medical records system

Table 1. Baseline Characteristics of the Study Participants.*

Characteristic	Rehabilitation plus Early ACL Reconstruction (N=62)	Rehabilitation plus Optional Delayed ACL Reconstruction (N=59)	P Value
Age — yr	26.3±5.1	25.8±4.7	0.55
Female sex — no. (%)	12 (19)	20 (34)	0.07
Body-mass index	24.4±3.2	23.8±2.6	0.26
Injury to right knee — no. (%)	33 (53)	33 (56)	0.77
College education or equivalent — no. (%)	21 (34)	23 (39)	0.56
Living with parents — no. (%)	16 (26)	14 (24)	0.79
Married (living with partner) — no. (%)	27 (44)	25 (42)	0.90
Working full-time or part-time — no. (%)	42 (68)	37 (63)	0.56
Student — no. (%)	13 (21)	21 (36)	0.07
Participating in sports when injured — no. (%)†	62 (100)	57 (97)	0.14
Anteroposterior knee laxity — no. (%)‡	61 (98)§	58 (98)¶	0.97
MRI findings			
Total ACL rupture — no. (%)	62 (100)	58 (98)‖	0.30
Meniscal injury — no. (%)**	39 (63)	30 (51)	0.18
KOOS score††			
$KOOS_4$	37.2±15.6	36.8±11.9	0.87
Pain	57.3±17.7	57.3±16.8	0.99
Symptoms	48.5±17.6	47.3±15.3	0.68
Function in activities of daily living	66.9±18.1	69.1±18.2	0.51
Function in sports and recreation	14.6±21.1	13.6±17.2	0.79
Knee-related quality of life	28.3±17.7	28.7±14.6	0.89
SF-36 score‡‡			
Physical component	47.0±15.6	47.3±10.5	0.90
Mental component	67.2±20.2	65.3±18.5	0.60
Score on Tegner Activity Scale§§			0.89
Median	9	9	
Interquartile range	7–9	7–9	

* Plus–minus values are means ±SD. ACL denotes anterior cruciate ligament, and MRI magnetic resonance imaging. The body-mass index is the weight in kilograms divided by the square of the height in meters.
† Details are provided in Table C in the Supplementary Appendix.
‡ The Lachman test was used to assess anteroposterior laxity of the knee at rest in a semiflexed position. Scores range from 0 to 3, with 0 indicating normal laxity and 3 indicating severely increased laxity. Knees with increased laxity (scores 1 to 3) are represented.
§ In one knee, anteroposterior laxity could not be assessed owing to pain. MRI and arthroscopy confirmed a total ACL rupture.
¶ In one knee, anteroposterior laxity was found to be normal at baseline, but MRI and arthroscopy confirmed a total ACL rupture.
‖ In one knee, MRI could confirm only a partial rupture. A positive pivot shift test conducted by two independent clinicians confirmed total ACL rupture.
** Meniscal injury was classified as increased signal extending to at least one articular surface of the meniscal body.[18] Knees could have more than one meniscal injury reported within the meniscal body. Details are provided in Table C in the Supplementary Appendix.
†† For all five subscales, the Knee Injury and Osteoarthritis Outcome Score (KOOS) ranges from 0 to 100, with higher scores indicating better results. Results at 2 years are shown for $KOOS_4$, which includes four subscales: pain, symptoms, function during sports and recreation, and knee-related quality of life.[19,20]
‡‡ Scores on the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) range from 0 to 100, with higher scores indicating better results.[21]
§§ The Tegner Activity Scale assesses activity level with specific emphasis on the knee. Scores range from 1 (least strenuous activity) to 10 (high knee-demanding activity on a professional level).[12]
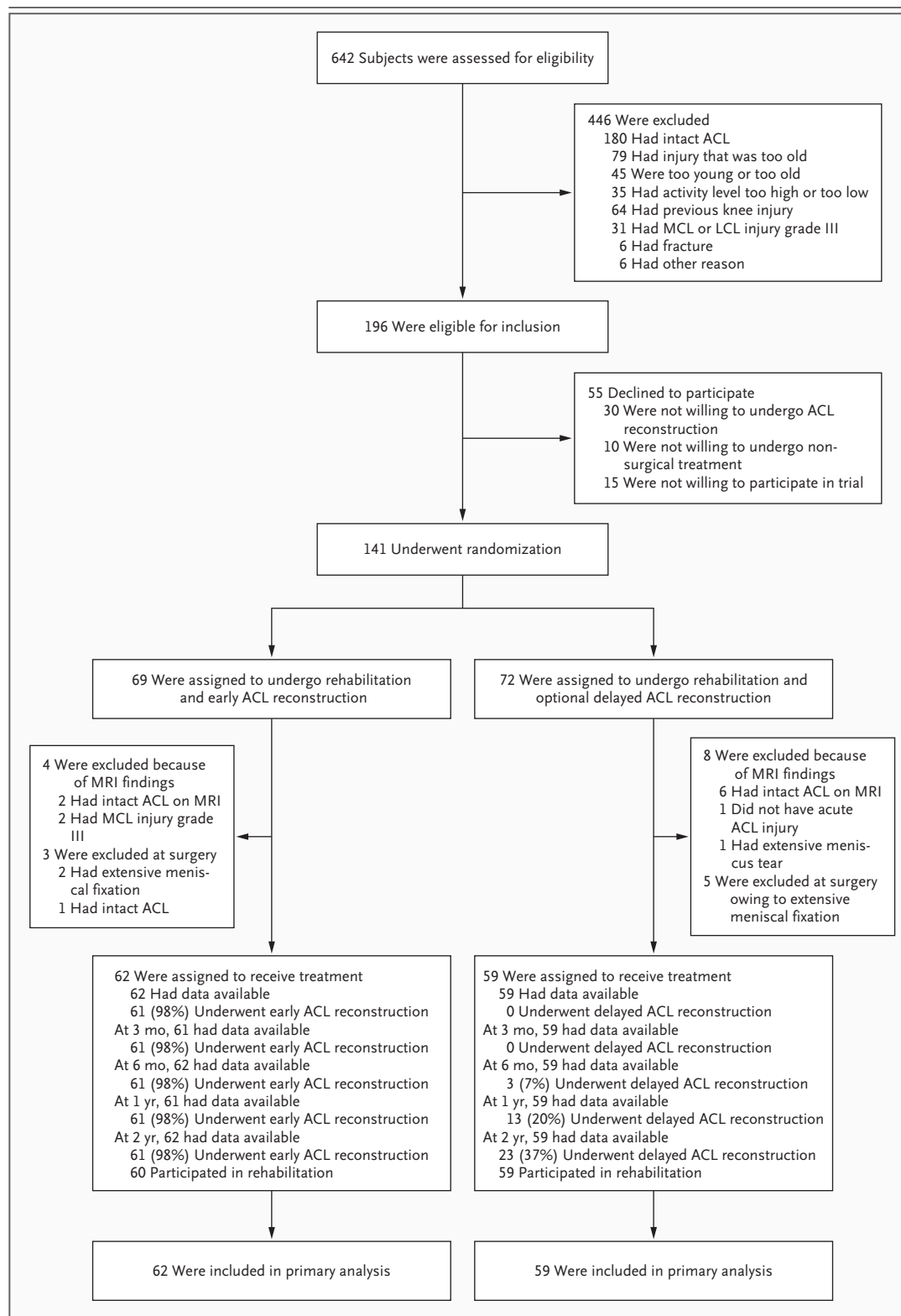
Figure 1. Enrollment and Randomization of Subjects.

ACL denotes anterior cruciate ligament, LCL lateral collateral ligament, MCL medial collateral ligament, and MRI magnetic resonance imaging.

for the health care region was searched for any patient visit to any health care facility during the 2-year follow-up period, and any adverse events were identified. Anesthesia and surgery records were retrieved for all surgical procedures, including the initial study treatment. At the 2-year study visit, the subjects filled out questionnaires to report any adverse events, illnesses, and medication use since the start of the study. Physical therapists involved in the study reported any adverse event that interfered with rehabilitation (Table 2, and the Supplementary Appendix).

STATISTICAL ANALYSIS

All subjects who were assigned to treatment, excluding the 20 who were deemed ineligible after randomization, were included in the efficacy analyses. Between-group comparisons of the primary end point were made with the use of analysis of covariance stratified by site and adjusted for baseline $KOOS_4$ scores. A confidence interval excluding differences greater than 10 units between groups was interpreted as indicating the absence of a clinically meaningful difference.[25]

Other end points were analyzed with the use of analysis of covariance (KOOS and SF-36 scores), the Mann–Whitney U test and the Kruskal–Wallis test (TAS score and $KOOS_4$ AUC, respectively, for the two groups in the intention-to-treat analysis and the three groups in a post hoc as-treated analysis), and the chi-square test (frequency of a return to preinjury TAS score, positive Lachman and pivot shift tests, and severely decreased knee-related quality of life). The frequencies of meniscal resection, procedures requiring general anesthesia, and the distribution of adverse events were compared between the two groups with the use of the binomial test for two Poisson-distributed variables.

The initial sample-size calculation was based on a plan to stratify according to the preinjury TAS score (5 to 7 [moderate activity level] vs. 8 or 9 [high activity level]). Assuming a standard deviation of 15 points for the primary outcome (change from baseline in the $KOOS_4$ score) and allowing for a 20% dropout rate, we estimated that 168 patients would be needed to provide 80% statistical power to detect a 10-point difference between the two groups. When 25% of the subjects in the originally estimated sample had been randomly assigned to a treatment group, a second sample-size calculation that included empirical

data was performed by an independent statistician without breaking the code. Again based on a plan for separate analyses for subjects with high and those with moderate preinjury activity levels, inclusion of 120 patients was considered sufficient to provide 80% power to detect the requisite 10-point difference. The plan to stratify according to activity level was abandoned shortly thereafter owing to low recruitment of subjects with moderate activity levels. This further reduced the necessary sample size. No interim analysis was performed. All reported P values are two-sided and were not adjusted for multiple comparisons.

RESULTS

CHARACTERISTICS OF THE SUBJECTS

Enrollment took place from February 2002 through June 2006, and the 2-year follow-up was concluded in June 2008. Of 642 subjects screened for eligibility (Fig. 1), 446 were ineligible for inclusion, and 55 of the 196 eligible subjects declined participation; thus, 141 subjects underwent randomization. The characteristics of the subjects who declined participation were similar to those of the subjects assigned to a treatment group.[11] Sixty-nine subjects were randomly assigned to undergo rehabilitation plus early ACL reconstruction, and 72 to undergo rehabilitation plus optional delayed ACL reconstruction. After randomization but before treatment, 20 of the initially eligible subjects were excluded because of findings on MRI (in 12) or baseline arthroscopy (in 8) (exclusion criteria are described in Table A in the Supplementary Appendix). Consequently, these subjects were not included in the analyses, leaving 62 subjects in the early-reconstruction group and 59 in the optional delayed-reconstruction group. The subjects who were excluded after randomization were similar to those assigned to treatment with respect to age, average $KOOS_4$ score (39.5 and 37.0, respectively), scores on the SF-36 physical and mental components (data not shown), and median TAS score (8 for both groups). The subjects in the optional delayed-reconstruction group had fewer rehabilitation visits than did those in the early-reconstruction group (mean, 53 vs. 63; P=0.05) (Table D in the Supplementary Appendix). In addition, there were no differences in baseline characteristics among the three as-treated groups (Table F in the Supplementary Appendix).

Table 2. Adverse Events.*

Adverse Event	Rehabilitation plus Early ACL Reconstruction (N=62)	Rehabilitation plus Optional Delayed ACL Reconstruction (N=59)	P Value
	number of events		
Serious events†			
Site other than index knee	10	11	0.74
Musculoskeletal‡	2	3	
Skin§	1	4	
Gastrointestinal¶	1	3	
Other‖	6	1	
Index knee	26	40	0.06
Subjective or clinical instability**	2	19	
Meniscal signs and symptoms	1	13	
Pain, swelling, or both	6	3	
Decreased range of motion	4	1	
Extension deficit	1		
Arthrofibrosis	1		
Graft rupture	3	1	
Other††	8	3	
All serious events	36	51	0.07
Nonserious events ‡‡			
Sites other than index knee	87	103	0.13
Index knee	87	44	<0.001
All nonserious events	174	147	0.29

*   This table includes all serious and nonserious adverse events that occurred in 5% or more of the subjects or in 3% or more of the subjects in one treatment group.

†   Serious adverse events were those classified as having the potential to significantly compromise clinical outcome or result in significant disability or incapacity; those requiring inpatient or outpatient hospital care; and those considered to prolong hospital care, to be life-threatening, or to result in death.

‡   Events in the early-treatment group included acute lower back pain with root symptoms and inpatient care (in 1 subject) and anterior shoulder-joint dislocation and surgery (in 1); those in the delayed-treatment group included lower back pain with lumbar disk hernia (in 1) and back pain following traffic accident (in 2).

§   Events in the early-treatment group included facial wounds after a bike accident (in 1); those in the delayed-treatment group included surgical removal of nevus (in 4).

¶   Events in the early-treatment group included acute appendicitis with surgery (in 1); those in the delayed-treatment group included gastritis with inpatient care (in 1), acute appendicitis with surgery (in 1), and Crohn's disease with inpatient care (in 1).

‖   Events in the early-treatment group included tooth fracture and tooth implant (in 1), excision of hyperplasia of the tongue (in 1), incision of atheroma of the ear (in 1), concussion with inpatient observation (in 1), metal foreign body in the eye (in 1), and diabetes mellitus (1); those in the delayed-treatment group included head contusion (in 1).

**   Subjective instability was reported by the subject. Clinical instability was defined as anteroposterior instability, as determined by the Lachman test (grade 1 or higher), or rotational instability, as determined by the pivot shift test (grade 1 or higher).

††   Events in the early-treatment group included catching (in 1), gracilis muscle rupture (in 1), wound problem (in 1), suspected compartment syndrome (in 1), discomfort from distal-graft fixation (in 1), loose body (in 1), locking (in 1), and bone fragment (in 1); those in the delayed-treatment group included clicking (in 1), distortion (in 1), and swelling (in 1).

‡‡   Details concerning nonserious adverse events can be found in Table E in the Supplementary Appendix.

PRIMARY END POINT

Both treatment groups had improvement over the 2-year period (Fig. 2A and Table 3). There were no significant differences in the change in the KOOS$_4$ score from baseline to 2 years between the group assigned to rehabilitation plus early ACL reconstruction and the group assigned to rehabilitation plus optional delayed ACL recon-
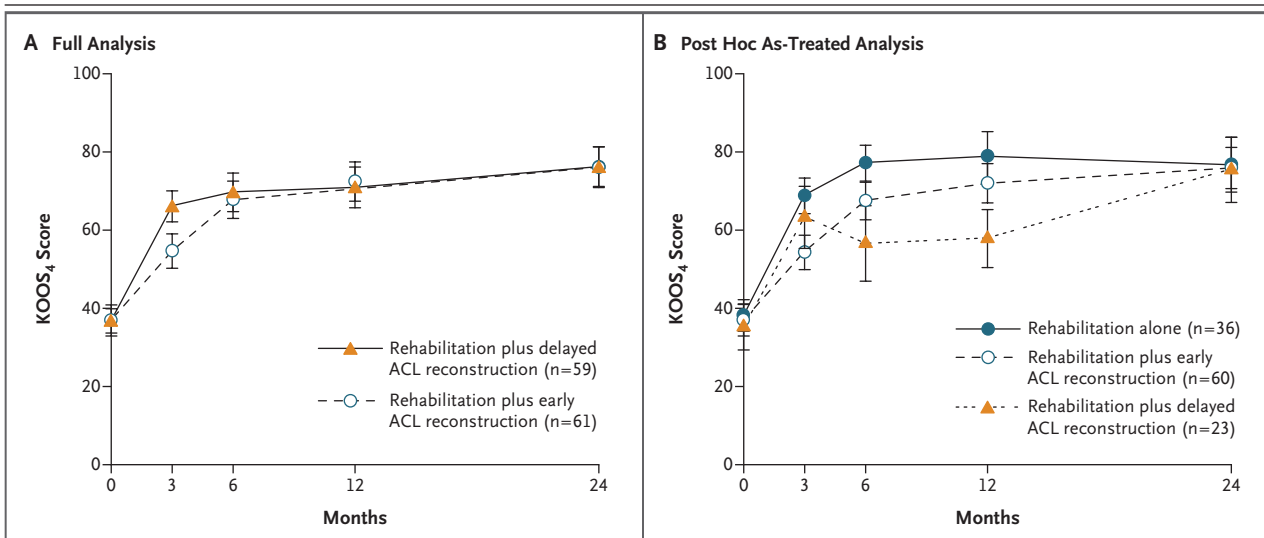
Figure 2. Mean KOOS₄ Scores during the 2-Year Study Period, According to Treatment Group.

Panel A shows results of the full analysis for 61 subjects in the group assigned to rehabilitation plus early ACL reconstruction and for 59 subjects in the group assigned to rehabilitation plus optional delayed ACL reconstruction. Data were not available at two interim visits for 1 subject in the early-reconstruction group, so these results are not included. Panel B shows the results of the post hoc as-treated subgroup analysis for 60 subjects who underwent rehabilitation plus early ACL reconstruction, 23 subjects who underwent rehabilitation plus delayed ACL reconstruction, and 36 subjects who underwent rehabilitation alone. Two subjects assigned to rehabilitation plus early ACL reconstruction completed fewer than 10 rehabilitation visits, so their results are not included. Delayed ACL reconstruction was performed between 5.5 and 19 months after randomization, so that some follow-up visits took place shortly before or after ACL surgery. The I bars indicate 95% confidence intervals. KOOS₄ denotes Knee Injury and Osteoarthritis Outcome Score for four subscales (pain, symptoms, function in sports and recreation, and knee-related quality of life).

struction (mean scores, 39.2 and 39.4, respectively; absolute difference, 0.18; 95% confidence interval, −6.5 to 6.8; P=0.96, adjusted for baseline KOOS₄ score). Of the 59 subjects in the optional delayed-reconstruction group, 23 underwent ACL reconstruction an average of 11.6 months after randomization. Of these 23 subjects, 22 met specific protocol guidelines and 1 chose delayed ACL reconstruction without reporting symptomatic instability (Table B in the Supplementary Appendix).

SECONDARY AND OTHER END POINTS

There were no significant between-group differences for any patient-reported secondary outcomes at 2 years, including knee-related outcomes, health status, and return to preinjury activity level (Table 3). Subjects assigned to rehabilitation plus early ACL reconstruction had greater knee stability at 2 years (Table 3). The post hoc as-treated analysis likewise showed no significant differences between the three treatment groups at the 2-year follow-up (Fig. 2, and Table G in the Supplementary Appendix).

OTHER TREATMENTS

Subjects assigned to rehabilitation plus early ACL reconstruction had a higher frequency of meniscal surgery at study initiation and a lower frequency of delayed meniscal surgery than did subjects assigned to rehabilitation plus optional delayed ACL reconstruction. Overall, the number of meniscal operations in the two groups totaled 40 and 50, respectively (P=0.20) (see the Supplementary Appendix).

SAFETY

Adverse events were common in both study groups (Table 3, and Table E in the Supplementary Appendix). The frequency of serious adverse events involving the index knee did not differ significantly between the groups (P=0.06). Three ACL graft ruptures and one case of arthrofibrosis were reported among subjects randomly assigned to rehabilitation plus early ACL reconstruction, and one ACL graft rupture was reported in a subject assigned to rehabilitation plus optional delayed ACL reconstruction. A total of 80 surgical procedures (requiring anesthesia) were performed

Table 3. Primary, Secondary, and Exploratory End Points at 2 Years.*

Variable	Rehabilitation plus Early ACL Reconstruction (N=62)	Rehabilitation plus Optional Delayed ACL Reconstruction (N=59)	P Value
Mean follow-up after randomization (95% CI) — mo	24.6 (24.4–24.7)	25.0 (24.7–25.2)	
Primary end point: mean change in KOOS$_4$ score from baseline to 2 yr (95% CI)†	39.2 (34.5–43.8)	39.4 (34.6–44.1)	0.96
Secondary end points			
Mean KOOS subscale scores (95% CI)‡			
Pain	87.2 (83.3–91.2)	87.7 (83.9–91.5)	0.87
Symptoms	78.7 (73.5–84.0)	83.0 (78.4–87.6)	0.16
Function in activities of daily living	93.5 (90.6–96.5)	94.7 (92.2–97.2)	0.68
Function in sports and recreation	71.8 (64.9–78.7)	71.2 (63.9–78.5)	0.95
Knee-related quality of life	67.3 (61.3–73.3)	63.0 (56.9–69.2)	0.28
Mean SF-36 score (95% CI)§			
Physical component	82.1 (77.2–87.0)¶	78.0 (73.0–82.9)	0.11
Mental component	88.3 (85.0–91.7)	83.8 (79.7–87.9)	0.17
Score on Tegner Activity Scale‖			0.82
Median	6.5	5	
Interquartile range	(3–8)	(4–7)	
Return to preinjury activity level or higher — no. (%)**	27 (44)	21 (36)	0.37
Exploratory end points			
Knee-stability tests			
Mean result on KT1000 test (95% CI) — mm††	6.6 (6.0–7.2)‡‡	8.3 (7.5–9.0)¶	0.001
Normal result on Lachman test — no. (%)§§	39 (65)¶¶	17 (29)¶	<0.001
Normal result on pivot shift test — no. (%)‖‖	45 (75)¶¶	27 (47)¶	0.003
Total KOOS$_4$ area under curve (in days×points)***	1638±406	1662±349	1.0
Severely decreased knee-related quality of life — no. (%)†††	11 (18)	16 (27)	0.22

* Plus–minus values are means ±SD. CI denotes confidence interval, KOOS Knee Injury and Osteoarthritis Outcome Score, and SF-36 Medical Outcomes Study 36-Item Short-Form Health Survey.
† KOOS$_4$ includes four KOOS subscales: pain, symptoms, function in sports and recreation, and knee-related quality of life. Scores range from 0 to 100, with higher scores indicating better results.
‡ KOOS ranges from 0 to 100, with higher scores indicating better results.[19,20]
§ Scores on the SF-36 range from 0 to 100, with higher scores indicating better results.[21]
¶ Data were missing for one subject.
‖ The Tegner Activity Scale assesses activity level with specific emphasis on the knee. Scores range from 1 (least strenuous activity) to 10 (high knee-demanding activity on a professional level).[12]
** Subjects were those with a score at 2 years that was the same as or higher than the preinjury score.
†† The KT1000 Arthrometer (MEDmetric) assesses the extent of anteroposterior laxity of the knee in millimeters. The mean values are the results of three tests performed at 134 newtons.
‡‡ Data were missing for three subjects.
§§ The Lachman test assesses anteroposterior laxity of the knee at rest in a semiflexed position. Results range from 0 (normal laxity) to 3 (severely increased laxity). Data include knees with normal laxity.
¶¶ Data were missing for two subjects.
‖‖ The pivot shift test assesses rotational stability of the knee at rest. Results range from 0 (normal stability) to 3 (severely increased instability). Data include knees with normal stability.
*** Results of the total area-under-the-curve analysis are shown, with higher scores indicating better results.
††† These subjects had a self-reported KOOS quality-of-life score below 44 at any visit between 6 months and 2 years of follow-up (predefined treatment-failure criterion).

in the early-reconstruction group and 61 in the delayed-reconstruction group (P=0.19) (see the Supplementary Appendix).

DISCUSSION

The results of this randomized, controlled trial involving physically active adults with an acute ACL rupture indicate that a strategy of early ACL reconstruction plus structured rehabilitation was not superior to a strategy of rehabilitation with the option of delayed ACL reconstruction when needed. Early reconstruction as compared with the option of delayed reconstruction did not result in a significant improvement in the primary outcome — the change in the KOOS$_4$ score between baseline and 2 years — or in any of the prespecified secondary outcomes, which included pain, symptoms, function in activities of daily living, function in sports and recreation, knee-related quality of life, KOOS$_4$ AUC, general health status, activity level, and return to preinjury activity level at 2 years.

We are aware of two prior randomized, controlled trials comparing surgical and nonsurgical treatment of ACL injuries,[26,27] but both assessed surgical repair (not reconstruction) of the torn ACL, and one[26] was limited by inconsistencies in treatment assignment and treatment indications for the surgical group.[6] Thus, high-level evidence is lacking to support the contention that outcomes are better with routine early ACL reconstruction than with an initial strategy of nonsurgical treatment.[6] Two observational studies showed similar outcomes for patients who underwent ACL reconstructive surgery and those who received nonoperative treatment of the ruptured ACL,[28,29] but the observational design precludes conclusions about cause and effect.[3,30]

Both groups in our study had substantial improvement over the 2-year follow-up period. The overall KOOS result at 2 years was similar to that in other studies of ACL reconstruction[20,22,23,31-33] and to KOOS$_4$ results 2 years after surgery for patients of similar age included in the Swedish National ACL Register (Ageberg E: personal communication).[34] The median activity scores 2 years after ACL reconstruction in our study were also similar to those reported by other investigators.[35-38] In addition, rates of normal results on Lachman and pivot shift tests at 2 years among the subjects treated with early ACL reconstruc-

tion in our trial were similar to those reported in a meta-analysis of studies of ACL reconstruction.[39] These similarities in outcomes between our results and those reported elsewhere suggest that our findings are generalizable.

With the strategy of providing structured rehabilitation alone initially instead of structured rehabilitation plus early ACL reconstruction, surgical reconstruction was avoided in 61% of the subjects without compromising the results. Our post hoc as-treated analysis identified no significant differences in self-reported outcomes at 2 years among the subjects treated with rehabilitation plus early ACL reconstruction, those treated with rehabilitation plus delayed ACL reconstruction, and those treated with rehabilitation alone (Table G in the Supplementary Appendix).

Small meniscal tears diagnosed by MRI at baseline were managed more aggressively in the subjects assigned to rehabilitation plus early ACL reconstruction and were more likely to be left untreated in the subjects assigned to rehabilitation plus optional delayed ACL reconstruction; this difference probably explains the greater frequency of meniscal surgery during follow-up in the latter group. Although the rate of adverse events in our study was higher than the reported rates in other studies of patients with ACL rupture, we believe this difference reflects our more comprehensive approach to collecting such information.[40]

Our study had certain limitations. First, we did not include a sham-surgery control group; however, the use of sham surgery as a control would have tended to bias the results in favor of early surgery. Second, assessors were aware of the treatment assignments, but they measured only knee stability. Third, we were unable to stratify study groups according to activity level, and our conclusions are best generalized to young adults who have high preinjury activity levels but are not professional athletes. Fourth, it cannot be assumed that rehabilitation programs that differ from the supervised program used in our study would result in similar findings. Finally, continued follow-up is warranted to assess longer-term outcomes, including the risk of knee osteoarthritis.[3]

In summary, our findings indicate that in young, active adults with an acute ACL tear, a strategy of structured rehabilitation plus early ACL reconstruction did not result in better patient-

reported outcomes at 2 years than a strategy of rehabilitation plus optional delayed ACL reconstruction in those with symptomatic instability. With the use of the latter strategy, more than half the ACL reconstructions could be avoided without adversely affecting outcomes.

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