

Frobell RB, Roos EM, Roos HP. A Randomized Trial of Treatment for Acute Anterior Cruciate Ligament Tears. N Engl J Med 2010;363:331-42.

Design: Randomized clinical trial

Study question: In physically active patients with an acute tear of the anterior cruciate ligament who are enrolled in an active physical therapy program, is there a difference in outcome between early and delayed surgery for the ACL tear?

Population/sample size/setting:

- 121 young active adults (32 women, 89 men, mean age 26) treated for acute ACL injury in orthopedics and sports science departments in Denmark and Sweden
- Eligible patients had rotational trauma to a previously uninjured knee within the previous four weeks, a physical examination concluding that the ACL was unstable, and a Tegner Activity Score (TAS) between 5 and 9 prior to injury (5 means participation in recreational sports and 9 represents competitive sports at a nonprofessional level)
- Exclusion criteria were a total collateral ligament rupture and a full-thickness cartilage lesion seen on MRI, previous knee surgery other than diagnostic arthroscopy on the affected knee, earlier major injury to the index knee, concomitant severe injury to the contralateral knee, and meniscal tears whose rehabilitation (e.g., bracing) would interfere with the ACL rehabilitation protocol

Interventions and comparisons:

- All patients participated in a structured 24 week rehabilitation program of graduated weight-bearing, stationary biking, and balance/coordination goals
 - o PT was supervised by experienced physiotherapists at nine outpatient clinics
 - o PT 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 patients could progress from one level to the next
- Patients were randomized into two groups: PT plus early ACL reconstruction (n=69) and PT plus optional delayed ACL reconstruction (n=72)
 - o However, 20 were later found to be ineligible due to MRI or baseline arthroscopy findings, leaving 121 in the analysis (early surgery, n=62, optional delayed surgery, n=59)
- In the early surgery group, ACL reconstruction was done under general anesthesia within 10 weeks of the knee injury, with the technique (patellar tendon vs. hamstring tendon) left to the choice of the surgeon
- In the optional delayed surgery group, patients followed the PT program and were operated on (1) if they requested surgery, and (2) had both self-reported ACL instability and a positive pivot shift test

Outcomes:

- Outcome evaluations were done at 3, 6, 12, and 24 months after randomization
- Three outcomes were taken at each visit: the Knee Injury and Osteoarthritis Outcome Score (KOOS), the SF-36, and the TAS
- Primary outcome was the change from baseline to two years in four of the five subscales of the KOOS: pain, symptoms, difficulty in sports and recreational activities, and quality of life
 - o KOOS has a scale for activities of daily living (ADL) but this was specified as a secondary outcome
 - o The clinically meaningful difference between groups was set at 10 points for the KOOS
 - o Some exploratory outcomes were measured: the Lachman test for knee stability, results of the pivot shift test, and KT1000 arthrometry to assess anteroposterior translation of the knee joint
- In the 62 patients randomized to early surgery, 61 underwent early ACL reconstruction, and data were available for 62 patients at 24 months
- In the 59 randomized to delayed optional surgery, none underwent surgery at 3 months, 3 had surgery by 6 months, 13 had surgery by 1 year, and 23 (37%) had undergone surgery at 2 years
- At 2 years, both groups had improved equally in the 4 KOOS subscales which were the primary outcome: 39.2 and 39.4 in the early versus delayed groups respectively
- Some of the exploratory secondary endpoints favored the early surgery group over the delayed group; normal results on the Lachman test were recorded in 65% of the former and in 29% of the latter; normal results on the pivot shift test were reported in 75% and in 47% of patients respectively
- The two groups did not differ significantly with respect to the frequency of adverse events (3 ACL graft ruptures in the early surgery group and 1 in the delayed group)

Authors' conclusions:

- In physically active adults with acute tears of the ACL, early ligament reconstruction does not measurably improve functional outcomes compared to optional delayed surgery
- If a structured physical therapy program is used as a first approach to these patients, more than half of ACL reinstructions may be avoided

Comments:

- While the elements of the physical therapy exercises are illustrated in the appendix to the study, neither it nor the original study protocol clearly designate how many sessions of supervised PT were part of the rehabilitation program

- Therefore, it is not clear whether the participants were given a small amount of direct instruction for home exercise, or whether they attended PT frequently for more extensive supervised exercise
- The study recruited participants who were more physically active than the general population; a minimum Tegner score between 5 and 9 was an entry criterion
 - A Tegner score of 5 means participation in competitive sports and heavy labor; a score of 9 means competitive sports at lower divisions, just below that of professional or elite athletes
 - The median Tegner score of 9 would mean that at least half of the participants were highly competitive athletes
- The authors used only four subscales of the KOOS as the primary outcome, and relegated the ADL part of the KOOS to the status of a secondary outcome (while retaining participation in sports as part of the primary outcome)
 - This indicates the main interest of the authors in studying the effects of ACL reconstruction in a mainly sports medicine setting
 - However, this may not limit the application to a less active population, since the differences between early and delayed ACL reconstruction would probably be more easily detected in people who are placing greater stresses on the knee joint
 - On the other hand, the study population is also more likely than the general population to participate fully in a PT program structured around graduated levels of exercise, and referring a less active population to the same kind of program may not produce the same effects
- At the authors note, there was not a comparison with a sham operation, and studies comparable to those done for lavage in osteoarthritis of the knee and for partial meniscectomy in degenerative meniscal tears have not yet been done
 - However, with lavage and meniscectomy, a sham operation is feasible because of the nature of the operations; ACL reconstruction involves drilling tunnels for threading the harvested ligaments, and a sham operation would be highly impractical
- Two years of followup is not sufficient to detect the occurrence of sequelae such as osteoarthritis, and the authors planned to publish a later followup study to detect such developments
- For both groups, fewer than half of the patients (44% of the early surgery and 36% of the optional delayed group) had returned to the pre-injury level of activity
 - The median Tegner activity scale, which had been 9 in both groups, was also lower at 2 years (6.5 for the early surgery group and 5 for the optional delayed surgery group)
- The tests for mechanical stability were done by an unblinded examiner, and assessment bias is a possibility

- The patient is a passive participant in a clinical test for stability, and effects of active physical therapy (such as muscle training) which can compensate for a degree of ligamentous laxity, are removed from the equation, and these clinical tests are not robust measures of knee function with daily activity

Assessment: Adequate for some evidence that in the setting of acute ACL tears, a treatment plan which refers the patient to physical therapy with an option for delayed surgery can be expected to be as successful at 24 months as a treatment plan which refers the patient for surgery within ten weeks, and may make many ACL operations unnecessary