Frobell RB, Roos HP, et al. Treatment for acute anterior cruciate ligament tear: five year outcome of randomised trial. BMJ 2013;346:f232 doi: 10.1136/bmj.f232

Design: Randomized clinical trial

Study question: In physically active people with an acute ACL tear who are participating in physical therapy, are there long-term differences between those who have early surgery and those who have optional delayed surgery?

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
    - PT was supervised by experienced physiotherapists at nine outpatient clinics
    - 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)
    - 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:

- In 2010, Frobell et al published two-year followup data for the two groups
- Three outcomes were taken in the 2010: 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
    - KOOS has a scale for activities of daily living (ADL) but this was specified as a secondary outcome
    - The clinically meaningful difference between groups was set at 10 points for the KOOS
    - 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
- 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
- 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)
- In the 62 patients randomized to early surgery for the 2010 study, 61 underwent early ACL reconstruction, and data were available for 62 patients at 24 months
- In the 59 randomized in 2010 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
    - An additional 7 patients in the delayed optional group had surgery between 2 and 5 years; at the end of that time, 30 of the 59 patients had had ACL surgery and 29 had not had surgery
- Similarly to the pattern seen in the 2010 study, the 5 year outcomes remained similar between the two groups
    - The mean change in KOOS from baseline to 5 years was 42.9 points for the early surgery and 44.9 points for the optional delayed surgery
    - The authors also found no statistically significant differences for any of the five subscales of the KOOS, for the SF-36, or for the Tegner activity scale
- Mechanical stability as assessed by the Lachman and pivot shift tests, which were better in the early surgery than the optional delayed group
    - The Lachman test was normal in 45/58 (76%) of early surgery patients and normal in 19/58 (33%) of optional delayed patients
    - The pivot shift test was normal in 45/58 (76%) of early surgery patients and normal in 23/58 (40%) of optional delayed patients
- Weight-bearing radiographic images were available for 113 index knees

    - Radiographic osteoarthritis (OA) was assessed separately for the tibiofemoral and the patellofemoral articulations
    - The definition of tibiofemoral OA approximated the definition of Grade 2 OA on the Kellgren-Lawrence scale
    - Patellofemoral OA was defined 2 or more marginal osteophytes
    - At 5 years, the authors found no statistically significant differences in the occurrence of radiographic OA; 13 knees had tibiofemoral OA, 22 had patellofemoral OA; in 6 knees, both tibiofemoral and patellofemoral OA were detected, with no differences between the original treatment groups
        - Patellofemoral OA was more common among patients who had had ACL reconstruction with patella tendon procedures than in those with hamstring graft procedures
- 61 knees had meniscus surgery over the 5 year period, 29 in the early surgery group and 32 in the optional delayed group; the rates of surgery were similar
- There were 4 graft ruptures over the five years, of whom two had a revision procedure and two declined revision
- There were no differences in outcomes between the 29 patients who never had surgery and the patients who did have surgery

Authors' conclusions:

- In this five year trial of young active people having rehabilitation for an ACL tear, a strategy of early reconstruction did not offer any important advantages over a strategy of optional surgery deferred to a later time; about half of the patients assigned to optional delayed surgery never needed an operation
- The results do not apply to professional athletes or to moderately active people, but clinicians should be encouraged to consider rehabilitation as a primary option after an acute ACL tear

Comments:

- At five years, 30 of the 59 patients in the optional delayed group had had ACL reconstruction, but the indications for their surgery (subjective instability with a positive shift test, requesting surgery for other reasons) is not clear
- Less than one quarter of patients at five years were active at their pre-injury level (23% of the early ACL reconstruction and 20% of the optional delayed group), and the median Tegner activity scale (4 for both groups) was much lower than the median pre-injury score of 9; the effects of an ACL tear appear to be long-lasting, but the intervention group does not appear to make a difference
- 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 five years as a treatment plan which refers the patient for surgery within ten weeks of injury, and may reduce the frequency of surgery by one half