

Five-Year Clinical Outcomes of a Randomized Trial of Anterior Cruciate Ligament Treatment Strategies: An Evidence-Based Practice Paper

Kyle Harris, MS, ATC*; Jeffrey Bradford Driban, PhD, ATC, CSCS†; Michael R. Sitler, EdD, ATC, FNATA‡; Nicole M. Cattano, MPH§; Jennifer M. Hootman, PhD, ATC, FNATA, FACSM||

*Department of Health, Physical Education and Nursing, Bucks County Community College, Newtown, PA; †Division of Rheumatology, Tufts Medical Center, Boston, MA; ‡Biokinetics Research Laboratory, Athletic Training Division, Department of Kinesiology, Temple University, Philadelphia, PA; §Department of Sports Medicine, West Chester University, PA; ||Division of Adult and Community Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, Atlanta, GA

Reference/Citation: Frobell RB, Roos HP, Roos EM, Roemer FW, Ranstam J, Lohmander LS. Treatment for acute anterior cruciate ligament tear: five year outcome of randomised trial. *BMJ*. 2013;346:F232.

Clinical Question: Does early anterior cruciate ligament (ACL) reconstruction with rehabilitation lead to better patient-reported outcomes and a lower incidence of osteoarthritis at 5 years postinjury compared with delayed ACL reconstruction with rehabilitation?

Study Selection: This randomized controlled trial with extended follow-up at 5 years postrandomization was conducted in 2 Swedish orthopaedic departments.

Data Extraction: The authors studied a total of 121 moderately active adults (age = 18–35 years) with an acute ACL rupture in a knee with no other history of trauma. Excluded were patients with a collateral ligament rupture, full-thickness cartilage defect, or extensive meniscal fixation. One patient assigned to the early ACL-reconstruction group did not attend the 5-year follow-up visit. Patients were randomly assigned to (1) an early ACL reconstruction plus structured rehabilitation group (n = 62, surgery within 10 weeks of injury) or (2) optional-delayed ACL reconstruction plus structured rehabilitation group (n = 59). The primary outcome measure was change in the average of 4 out of 5 subscales of the Knee Injury and Osteoarthritis Outcome Score (KOOS). The authors also assessed crude KOOS (combined 4 subscales), KOOS subscale scores, general physical and mental health (Short-Form 36), activity level (Tegner Activity Scale), mechanical knee stability (Lachman and pivot shift tests), meniscal surgery status, and presence of knee osteoarthritis on radiographs.

Main Results: Among patients randomized to the optional-delayed ACL-reconstruction group, 30 (51%) opted for an ACL reconstruction. The treatment groups had comparable 5-year

patient-reported outcomes and changes in patient-reported outcomes (eg, knee pain, knee symptoms, activities of daily living, sport and recreational levels, knee-related quality of life, general physical health, and general mental health). Patients in the optional-delayed ACL-reconstruction group had greater mechanical knee instability than patients who received early ACL reconstruction; however, this was primarily among the patients opting for conservative management alone. In the overall sample, 61 knees (51%) required meniscal surgery over 5 years, regardless of treatment group. At 5 years, radiographs were available for 113 patients (93%). Overall, 29 patients (26%) had knee osteoarthritis at 5 years. Specifically, 13 patients (12%) developed tibiofemoral radiographic osteoarthritis (9 patients [16%] in the early ACL-reconstruction group, 4 [7%] in the optional-delayed ACL-reconstruction group) and 22 (19%) developed patellofemoral osteoarthritis (14 patients [24%] in the early ACL-reconstruction group, 8 [15%] in the optional-delayed ACL-reconstruction group). Patients with patellar tendon grafts (n = 40) had a greater incidence of ipsilateral patellofemoral osteoarthritis than patients with hamstrings tendon grafts (n = 51), but the 2 groups had similar incidences of ipsilateral tibiofemoral osteoarthritis. Six knees (5%) had both tibiofemoral and patellofemoral osteoarthritis.

Conclusions: Early ACL reconstruction plus rehabilitation did not provide better results at 5 years compared with optional-delayed ACL reconstruction plus rehabilitation. Furthermore, the authors found no radiographic differences among patients with early ACL reconstruction, delayed ACL reconstruction, or no ACL reconstruction (rehabilitation alone).

Key Words: knee, anterior cruciate ligament reconstruction, osteoarthritis

COMMENTARY

Reconstruction is often recommended after anterior cruciate ligament (ACL) rupture. However, some clinicians advocate nonsurgical treatment or at least attempting

nonsurgical treatment with an optional-delayed ACL reconstruction. Unfortunately, the literature comparing the long-term efficacy of these treatment strategies is scarce, of low methodologic quality, marred by inconsistent surgical methods (eg, different ACL grafts, various levels of

meniscal resection), and lagging behind rapidly changing surgical standards. Based on the available literature, 32% to 51% of patients who underwent ACL reconstruction had tibiofemoral knee osteoarthritis at 10- to 14-year follow-up compared with 24% to 42% of patients who received nonsurgical care.¹ Patients undergoing ACL reconstruction may have a higher prevalence of knee osteoarthritis later in life, but until this recent high-quality randomized clinical trial by Frobell et al,^{2,3} no definitive data were available to compare treatment strategies. This clinical trial is the only study to directly compare early ACL reconstruction with an optional-delayed ACL-reconstruction treatment strategy.

The current results by Frobell et al² are an extended follow-up of the randomized clinical trial.³ In the initial article,³ the authors described no differences among treatment strategies in patient-reported outcomes over the first 2 years of follow-up.³ Based on the results of this clinical trial,^{2,3} participants with early ACL reconstruction did not experience better outcomes at 2 or 5 years than participants who received optional-delayed ACL reconstruction. Furthermore, the authors found no differences at either time point among participants with early ACL reconstruction, delayed ACL reconstruction, or no ACL reconstruction (rehabilitation alone). Therefore, contrary to current practice, Frobell et al² concluded that “these results should encourage clinicians and young active adult patients to consider rehabilitation as a primary treatment option for an acute ACL tear.”²

Among participants randomized to the optional-delayed ACL-reconstruction group, 30 participants (51%) opted for a delayed ACL reconstruction.² Twenty-three of these participants decided to undergo the delayed surgery within 2 years of ACL injury. Accordingly, patients need to be informed that both treatment strategies may have similar outcomes and that if conservative treatment fails, it will likely be within the first 2 years postinjury. Although they were not the focus of the current study, patient demographics and activity levels may be important for determining why 49% of participants responded favorably to nonsurgical treatment.^{1,4} Some of these participants may be copers: ACL-deficient individuals who sufficiently stabilize the knee to allow them to return to physical activity without episodes of instability. Another group of these participants may be adapters, who change their level of activity to function without an ACL. Unfortunately, adapters may be the predominant group of patients after an ACL injury, which is concerning because 1 goal of an ACL reconstruction is to promote a safe and effective return to physical activities. At 2 years postinjury, Frobell et al³ found that only 44% and 36% of participants with early or optional-delayed ACL reconstruction, respectively, had returned to their preinjury level of activity. At 5 years, 20% to 22% of participants undergoing early ACL reconstruction, delayed ACL reconstruction, or rehabilitation alone were competing at their preinjury level of activity.² However, in the original study, the authors did not define participants as copers or adapters, which makes it difficult to determine why some participants returned to competition and others did not. Within the sports medicine community, we must recognize this as a sign that our current strategies may be failing to achieve the goal of a

safe return to preinjury competition for most ACL-injured patients.

This study also provides some of the best estimates for the incidence of knee osteoarthritis after different ACL treatment strategies. Frobell et al² reported that 26% of patients (n = 29) had radiographic knee osteoarthritis within 5 years of injury, regardless of the treatment strategy. Furthermore, 61 patients from the clinical trial had magnetic resonance imaging at baseline (<5 weeks), 3 months, 6 months, 1 year, and 2 years postinjury. These patients had cartilage thinning in the trochlea and cartilage thickening in the central medial femur (possibly from cartilage swelling), regardless of treatment.⁵ These cartilage changes may indicate that the path to joint failure begins within the first 2 years after an ACL injury. Ostensibly, within 5 years after injury, the risk of developing knee osteoarthritis is elevated. This risk may be attributed to the injury and not be ameliorable by current treatment strategies, such as those assessed by Frobell et al.² Some ACL-injured patients, regardless of treatment strategy, may be burdened by knee osteoarthritis for more than half their lives, which may lead to considerable psychosocial and economic costs (eg, health care expenses, work loss). Such an outcome is not acceptable for this patient population, and as a health care community, we must strive to find strategies to reduce the risk of knee osteoarthritis and its long-term consequences (eg, pain, disability).

Limiting factors for this study are a relatively short postsurgical follow-up (5 years) and the confounding effect of meniscal surgery (51% of knees), particularly within the first year after the injury and regardless of treatment strategy. Because so many knees had meniscal damage, it is difficult to determine if the osteoarthritis was attributable to the ACL injury, the meniscal injury, or both. Accordingly, the long-term implications of these ACL treatment strategies on radiographic and symptomatic knee osteoarthritis are yet to be determined.

As evidence-based clinical practice progresses, it is increasingly imperative that practitioners be aware of the long-term effects of the treatments they recommend. Clearly communicating both the positive and negative effects of various treatments will allow patients to make more informed decisions as to which treatment they receive. Based on the current research, regardless of the treatment chosen, patients who rupture their ACLs may not return to play at their previous competitive level and may develop early-onset knee osteoarthritis. Clinicians and patients should use this information when making treatment decisions.

CONCLUSIONS

Based on the randomized clinical trial by Frobell et al,^{2,3} no definitive evidence suggests that early ACL reconstruction provides superior results with regard to the development of radiographic osteoarthritis and patient-reported outcomes (eg, knee pain, general physical health, general mental health) compared with optional-delayed ACL reconstruction. Furthermore, 49% of patients in the optional-delayed group opted for rehabilitation alone.

Although patients with ACL reconstruction had significantly better mechanical knee stability than those with optional-delayed reconstruction, both groups had similar incidence rates of knee osteoarthritis at 5 years and return to preinjury activity level at 2 and 5 years posttreatment. The early onset of radiographic knee osteoarthritis and failure of most patients to return to play at their preinjury level should raise concerns among clinicians about whether current treatment strategies are effective over an extended period of time and

the need for further interventions to address the ACL-deficient knee.

DISCLAIMER

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

REFERENCES

1. Harris K, Driban JB, Sitler MR, Cattano NM, Balasubramanian E, Hootman JM. Influence of anterior cruciate ligament injuries with and without surgical reconstruction on the development of osteoarthritis of the knee: a systematic review. *J Athl Train*. In press.
2. Frobell RB, Roos HP, Roos EM, Roemer FW, Ranstam J, Lohmander LS. Treatment for acute anterior cruciate ligament tear: five year outcome of randomised trial. *BMJ*. 2013;346:F232.
3. Frobell RB, Roos EM, Roos HP, Ranstam J, Lohmander LS. A randomized trial of treatment for acute anterior cruciate ligament tears. *N Engl J Med*. 2010;363(4):331–342.
4. Snyder-Mackler L, Fitzgerald GK, Bartolozzi AR 3rd, Ciccotti MG. The relationship between passive joint laxity and functional outcome after anterior cruciate ligament injury. *Am J Sports Med*. 1997;25(2):191–195.
5. Frobell RB. Change in cartilage thickness, posttraumatic bone marrow lesions, and joint fluid volumes after acute ACL disruption: a two-year prospective MRI study of sixty-one subjects. *J Bone Joint Surg Am*. 2011;93(12):1096–1103.

Address correspondence to Kyle Harris, MS, ATC, Department of Health, Physical Education and Nursing, Bucks County Community College, 275 Swamp Road, Newtown, PA 18940. Address e-mail to kpjh85@gmail.com.

Journal of Athletic Training Manuscript Reviewers' Workshop

All current and potential reviewers are invited to join us on Tuesday, June 23, 2015, from 4-6 PM, for a session on mixed-methods design.

Tom Bowman, PhD, ATC, of Lynchburg College, will discuss research design. Heather Bush, PhD, of the University of Kentucky, will address statistical analysis. To register, please contact the Editorial Office:

phone 314-977-8591
e-mail jat@slu.edu

We look forward to seeing you in St Louis!