Long-term follow-up of ACL-reconstruction using patellar tendon graft versus hamstring tendon graft

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Protocol:

Participating parts

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Introduction

Rupture of the anterior cruciate ligament (ACL) is a common soft-tissue knee injury, and has increased in number over the last twenty years [1, 2]. Reconstructing the ligament may be important for maintaining the stability and preventing further damaging of the knee [1]. The two most commonly used grafts in reconstructions are the autologous patellar tendon grafts and hamstring tendon grafts [3, 4].
There is yet to be a universally established agreement regarding which reconstruction method of an ACL is preferred [3-7]. The method using the central third of the patellar tendon with proximal and distal bone blocks as the replacement has been used since the late 80s and is well documented with good results [6, 8]. When the technique using the hamstring tendon grafts was introduced, its popularity increased [7, 9]. Arguments favoring each of the methods depend on which variables one values the most. In some studies, the patellar tendon group reported problems regarding anterior knee pain and decreased sensitivity of the knee, whereas for the hamstring tendon group there was reported increased weakness of the hamstring muscles and knee laxity [5, 6, 8]. However, the overall assessment and satisfaction in multiple short-term/semi-long studies have shown little to no difference [6, 8, 10].
The aim of this prospective randomized multicenter study is to compare the use of bone-patellar tendon-bone (BPTB) grafts and double-looped semitendinosus gracilis (DLSG) grafts for reconstruction of the anterior cruciate ligament, 17-20 years after the surgery. The null hypothesis is that there will be no significant differences at this long-term follow-up evaluation between the two methods.

Method and material of the first study

Drogset et al. recruited 115 patients with rupture of the anterior cruciate ligament in the period of 2001-2004, and randomized them to either reconstruction with bone-patellar tendon-bone (BPTB) grafts fixed with metal interference screw graft, or double-looped semitendinosus gracilis (DLSG) grafts fixed with Bone Mulch Screws and WasherLoc Screws [6]. The surgeries were performed at four different hospitals.
After one and two years, the patients were examined by an independent observer, using a series of objective tests, as well as recording the patients' subjective opinion of their knee function. The subjective tests used were Tegner's activity score, Lysholm's functional score and Modified Cincinnati Score. The objective tests used were Lachmann's test, pivot shift and KT-1000, as well as Cybex and Biodex to measure muscle strength.

Inclusion and exclusion criteria from the original study, which also will be used for this study:
<u>Criteria for inclusion:</u>

Primary reconstructions of isolated ACL-ruptures. Surgery at least 6 weeks after injury. Age 18-45 years.
The patient must understand and accept the written consent. The written consent must be signed by the patient before surgery. Normal two-plane X-ray of the knee.

Criteria for exclusion:

>5mm + chronic MCL-injury in the same knee.
Patient with major additional injury in the knee: combined instability, cartilage injuries Outerbridge grade 3-4 and at least 1cm in diameter on the femoral condyle and major meniscal lesions with meniscal repairs.
Patients having problems following the protocol.
The patient does not understand the written consent or will not sign it.
Patients with a history of alcohol or drug abuse the last three years.
The patient has received any investigational drugs within 30 days prior to admittance to this study.
The patient has O.A., podagra, RA, Bechterew's disease or chondrocalcinosis.
The patient has malalignment with more than 5 degrees valgus and no varus compared to a normal knee.
The patient has patellofemoral instability.
The patient is obese with BMI>30.
The patient has a present or former serious illness that makes follow-up or rehabilitation of the patient difficult.
Former major surgical procedures in the same knee, including prosthesis.
Treated or untreated anterior cruciate ligament injury in the other knee.

Method and material

The present study is a long-term follow-up of a prospective randomized multicenter study. The patient recorded outcome scores will be Tegner's activity score, Lysholms's functional score and the Knee injury Osteoarthritis Outcome Score (KOOS). The examinations include Lachmann's test, pivot shift and KT-1000. We also plan to include radiographs to evaluate the degree of arthrosis 17-20 years after the surgery, and Cybex or Biodex to examine the hamstring and quadriceps strength. The radiographic positioning will be knee AP weight-bearing standing bilateral and lateral view, as well as skyline projection. The Kellgren-Lawrence classification will be used to assess the degree of osteoarthritis.

Even though 115 patients were included in the original study, we will only attempt to contact 114 due to lost inclusion-papers between the 2-year and 7-year follow-up [8]. During the spring of 2022, the patients will receive an invite to participate in the follow-up study. Following this, we will call the patients to uncover different circumstances that might exclude certain patients from the clinical assessment. This includes revision of the reconstruction in question, total knee replacement or total knee arthroplasty, and if the knee had been injured beforehand. The clinical examination will be carried out by both a medical student and an experienced orthopedic surgeon. Hopefully all the patients will be examined over the course of two days at each location, and if needed, the rest will be examined at a later date. We will try to accommodate for the patients' needs as much as possible.

Hypothesis

Our hypothesis is that there will be no difference in the long-term outcome between the two groups. However, it will be interesting to see how many patients have received a prosthesis, and how many patients struggle with arthrosis. As the previous follow-up studies showed a significant difference in total flexion work between the two groups, we will be interested in detecting a persistent difference between the groups.
Another interesting aspect will be the rate of graft failure between the two groups. Other studies, such as Freedman et al., Wagner et al. and Samuelsen et al. have shown a lower rate of graft failure in the BPTB grafts compared to the DLSG grafts [11-13]. While Sajovic et al. showed the opposite; lower rate for the DLSG grafts compared to the BPTB grafts [10]. Our original study has yet to show any difference regarding this.

Feasibility

The strength of the study is the randomization and the long follow-up period of 17-20 years. The possible limitations are the fact that there may be a problem recruiting enough patients to the follow-up, and that we might not be able to get x-rays of the patients at the different hospitals, as this is a matter of cost and availability. In addition, the different hospitals may not have a Biodex available.

Publicity plan

The goal for the paper is to be published in an international journal and probably be presented at conferences. For article, that hopefully will be published in journals, Marko Popovic will stand as first author, and Julie Holen and Julie Myhre as contributing authors. Jon Olav Drogset will be listed last, as the main supervisor. The tentative order for the published article: Marko Popovic, Julie Holen, Julie Myhre, Ingebjørg Strand, Ingunn Fleten Mo, Tone Gifstad and Jon Olav Drogset.

Economy

Our estimated expenses include flights to Bergen and Oslo, to collect the patient data. We assume we'll need two separate trips to each city, as some patients probably won't be able to meet us for the first round. Round trip Bergen x2 ~2500 kr. Round trip Oslo x2 ~2500 kr.
To contact all the possible patients, we will send out letters before contacting them by phone. Estimated expense: 1000 kr.
Our intention is to include radiographs and Biodex as objective findings in the study. Estimated expenses for Biodex: 70000kr. Estimated expenses for radiographs: 170000kr. These are indicative prices from the companies we plan to buy the services from.
We have applied to the hospital for funding at a total of 240000kr, which has been granted. From NTNU, our university, a total of 5000kr is granted for this project.

Ethics

The REK-application was submitted on the 24th of December 2021. Application number: 391796. Additionally, the project will be reported to NSD when the REK-application is approved.

References

1. Tiamklang, T., et al., *Double-bundle versus single-bundle reconstruction for anterior cruciate ligament rupture in adults.* Cochrane Database of Systematic Reviews, 2012(11).

2. LaBella, C.R., W. Hennrikus, and T.E. Hewett, *Anterior cruciate ligament injuries: diagnosis, treatment, and prevention.* Pediatrics, 2014. **133**(5): p. e1437-50.

3. Sajovic, M., D. Stropnik, and K. Skaza, *Long-term Comparison of Semitendinosus and Gracilis Tendon Versus Patellar Tendon Autografts for Anterior Cruciate Ligament Reconstruction: A 17-Year Follow-up of a Randomized Controlled Trial.* The American Journal of Sports Medicine, 2018. **46**(8): p. 1800-1808.

4. Mascarenhas, R., et al., *Bone-patellar tendon-bone autograft versus hamstring autograft anterior cruciate ligament reconstruction in the young athlete: a retrospective matched analysis with 2–10 year follow-up.* Knee Surgery, Sports Traumatology, Arthroscopy, 2012. **20**(8): p. 1520-1527.

5. Mohtadi, N.G.H., et al., *Patellar tendon versus hamstring tendon autograft for anterior cruciate ligament rupture in adults.* Cochrane Database of Systematic Reviews, 2011(9).

6. Drogset, J.O., et al., *Autologous patellar tendon and quadrupled hamstring grafts in anterior cruciate ligament reconstruction: a prospective randomized multicenter review of different fixation methods.* Knee Surg Sports Traumatol Arthrosc, 2010. **18**(8): p. 1085-93.

7. Goldblatt, J.P., et al., *Reconstruction of the anterior cruciate ligament: meta-analysis of patellar tendon versus hamstring tendon autograft.* Arthroscopy, 2005. **21**(7): p. 791-803.

8. Gifstad, T., et al., *Long-term follow-up of patellar tendon grafts or hamstring tendon grafts in endoscopic ACL reconstructions.* Knee Surg Sports Traumatol Arthrosc, 2013. **21**(3): p. 576-83.

9. Biau, D.J., et al., *ACL Reconstruction: A Meta-analysis of Functional Scores.* Clinical Orthopaedics and Related Research®, 2007. **458**: p. 180-187.

10. Sajovic, M., et al., *A prospective, randomized comparison of semitendinosus and gracilis tendon versus patellar tendon autografts for anterior cruciate ligament reconstruction: five-year follow-up.* Am J Sports Med, 2006. **34**(12): p. 1933-40.

11. Freedman, K.B., et al., *Arthroscopic anterior cruciate ligament reconstruction: a metaanalysis comparing patellar tendon and hamstring tendon autografts.* Am J Sports Med, 2003. **31**(1): p. 2-11.

12. Wagner, M., et al., *Hamstring tendon versus patellar tendon anterior cruciate ligament reconstruction using biodegradable interference fit fixation: a prospective matched-group analysis.* Am J Sports Med, 2005. **33**(9): p. 1327-36.

13. Samuelsen, B.T., et al., *Hamstring Autograft versus Patellar Tendon Autograft for ACL Reconstruction: Is There a Difference in Graft Failure Rate? A Meta-analysis of 47,613 Patients.* Clinical Orthopaedics and Related Research®, 2017. **475**(10): p. 2459-2468.