Repair versus reconstruction of proximal anterior cruciate ligament tears

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The objective of this prospective randomized controlled trial is to compare the outcomes of arthroscopic primary repair of proximal ACL tears with the current gold standard of ACL reconstruction.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON52403

Source
ToetsingOnline

Brief title
REPAIR

Condition

- Bone and joint injuries
- Tendon, ligament and cartilage disorders
- Bone and joint therapeutic procedures

Synonym
anterior cruciate ligament, knee ligament

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: We hebben 5000 euro gekregen van de NVA (Nederlandse Vereniging van Arthroscopie)

Intervention

Keyword: anterior cruciate ligament, primary repair, proximal tear, reattachment

Outcome measures

Primary outcome

The primary outcome of this study is the subjective IKDC score [46] which consists of the patients subjective evaluation of their knee function.

Secondary outcome

The secondary outcomes of this RCT include (I) other subjective outcome measures, (II) objective measures, and (III) return to sports following both treatments.

I. Other subjective outcomes consisting of:

- Preinjury and postoperative Tegner score [47]
- Lysholm score [48]
- Knee Injury and Osteoarthritis Outcome Score (KOOS) score [49]
- Forgotten Joint score [50]
- Patient satisfaction is collected using the NRS scale (range 0 - 10). and pain is also assessed using the NRS scale (range 0 - 10)

II. The objective outcomes consist of the failure rate, reoperation rate, contralateral injury, and clinical stability.

- Failure is defined as symptomatic instability with activities, or a (traumatic) rerupture.
- Reoperation is defined as any new operation on the same knee for any reason

(e.g. symptomatic meniscus tear, hardware irritation, infection or stiffness/arthrofibrosis).

- Contralateral injury was defined as a complete ACL rupture of the contralateral ACL.

- Clinical stability will be assessed using the IKDC objective questionnaire that is completed by the researcher [51] and will be measured using the KT-1000 in mm of anteroposterior translation compared to the contralateral ACL. Clinical instability is defined as either 2+ laxity with Lachman examination, 2+ anterior drawer or 2+ pivot shift during clinical examination, or a KT-1000 side to side difference of >5mm.

III. Return to sports will be reviewed in two ways and will be assessed at short-term and longer-term follow-up visits.

- Return to preinjury level of sport (preinjury Tegner level)

- Return to sport in general (Tegner score of 6 or higher) or not returning to sport (Tegner score of 5 or lower)

IV. Osteoarthritis will be reviewed at ten-year follow-up

- Radiographs will be performed of both knees and compared

Study description

Background summary

Historical overview

The first documented surgical treatment of an anterior cruciate ligament (ACL) consisted of open primary repair in 1895 when Mayo Robson repaired a proximally avulsed ACL and posterior cruciate ligament (PCL) back to the femur in a 41-year old male with good outcomes at six-year follow-up [1]. In the twentieth century, Ivar Palmar [2, 3] and Don O*Donoghue [4, 5] further reported on open primary repair as a treatment of ACL injuries, and in the early 1970s open primary repair became a popular treatment for ACL injuries [6-9].

Feagin and Curl were the first to present the outcomes of open primary repair at the AAOS in 1972 and noted good outcomes at short-term follow-up [8]. A few years later in 1976, however, they noted a deterioration of outcomes at mid-term follow-up in their cohort [10]. Several other surgeons similarly noted good short-term [11-16] but disappointing mid-term outcomes [17-21]. With these disappointing mid-term results and the promising early results of ACL reconstruction, several (randomized) prospective studies were started in the 1980s comparing open primary repair with open ACL reconstruction [19, 22-24]. These prospective studies noted more reliable outcomes with ACL reconstruction when compared to primary ACL repair, which led to an abandonment of open primary repair and to the current gold standard of ACL reconstruction for all patients [9].

In 1991, Sherman et al. were the first attempting to understand the disappointing mid-term outcomes of open primary repair by performing an extensive subgroup analysis [21]. The authors noted a trend towards better outcomes in selected patients: outcomes were better in patients with proximal avulsion type tears and good tissue quality and were inferior in midsubstance tears and/or with poor tissue quality. Unfortunately, the inclusion of the aforementioned prospective trials was already completed before the study by Sherman et al., and thus the prospective trials contained all tear types including midsubstance tears that had inferior results: this may explain the unreliable results of open primary repair in these trials (as none of these studies assessed tear location)

When critically reviewing the historical literature, and learning from these findings by Sherman et al., it can be noted that the results of open primary repair of proximal tears were good. Van der List and DiFelice performed a systematic review of all historical studies on open primary repair and noted outcomes were indeed better in studies with proximal tears [25]. The outcomes of open primary repair of proximal tears were very good, even compared to modern standards, with 83 to 90% clinical stability, 80% return to sports, 79% good to excellent Lysholm score and 86% satisfaction in 539 patients in 11 studies. These findings indicate that primary repair may have been prematurely abandoned for all tear types and perhaps should have been maintained as a good treatment option for proximal tears. This would have led to a *tear type dependent approach* in which primary repair can be performed for proximal tears and reconstruction for midsubstance tears rather than our current *one size fits all* approach. Furthermore, outcomes of primary ACL repair can be expected

to even be better when benefiting from modern development, such as arthroscopy and modern rehabilitation.

Advantages

Arthroscopic primary ACL repair has some potential advantages over ACL reconstruction. Firstly, with primary ACL repair the native tissue can be preserved along with proprioception, which is not the case with ACL reconstruction. Secondly, primary ACL repair is a less invasive surgery when compared to ACL reconstruction as no tunnels need to be drilled and no graft tissues need to be harvested, leading to less surgical morbidity [26-28], faster return of range of motion and fewer complications [29]. Thirdly, in case of failure of both treatments, revision surgery following primary repair can be considered a primary reconstruction surgery, whereas revision of reconstruction surgery is often complicated and leads to inferior outcomes compared to primary reconstruction [30, 31]. Finally, primary ACL repair, with the preservation of native tissues and minimal invasiveness, leads in experimental and long-term follow-up studies to a lower incidence of osteoarthritis when compared to ACL reconstruction [32-35]. This is important as there is large consequence for the patient and a high economic burden for society with the occurrence of osteoarthritis following ACL reconstruction.

Disadvantages

There are also potential disadvantages of primary ACL repair. First, it can be expected that there is a higher rerupture and instability rate following repair versus reconstruction when looking at the studies from the 1970s and 1980s. Although current studies with only proximal tears do not show this [36-41], this should be take into account. Second, there is a possibility that too many patients will be operated with this technique (see section J). In the Netherlands, patients are currently first treated conservatively for 6 weeks to evaluatie which patients will become symptomatic and need to undergo surgical reconstruction. Because a part of the ACL patients do not develop symptoms (often these are less active patients or patients that prefer to stop sports participation over surgery), there is with the ACL repair treatment the risk that too many patients will undergo surgery (it is not evaluated which patients will be symptomatic). It is attempted to decrease this risk by only treating active patients (age 15 - 50 years and only patients who want to continue sports participation), but this risk cannot be excluded.

Recent literature

Recently there has been a renewed interest in primary ACL repair. Learning from past experiences (i.e. only treating proximal tears), and benefiting from modern developments (i.e. arthroscopic surgery, modern rehabilitation), several authors have performed arthroscopic primary repair of proximal ACL tears [36-39]. DiFelice et al. were the first to perform arthroscopic primary ACL

repair tears and noted excellent short-term outcomes in their retrospective case-series [36]. As opposed to the disappointing historical mid-term outcomes, the mid-term outcomes of their case series were maintained at mid-term 6.0-year follow-up with excellent patient reported outcomes and 1 clinical failure (9%). The same group has presented the results of their first 56 patients (Jonkergouw et al, KSSTA 2017, PMID 30612165) and reported a 10.7% failure rate, 7.1% reoperation rate and all patient-reported outcome measures (PROMs) above 90% of the maximum score. Achtnich et al. have recently assessed the outcomes in a comparative study in which they retrospectively compared the outcomes in patients with proximal avulsion type tears who were willing to undergo ACL repair (n = 20) versus who were not willing to undergo repair and thus underwent ACL reconstruction (n = 20) [37]. The authors noted similar outcomes following repair and reconstruction in functional outcomes, failure rates and stability examination in a small cohort. Three other small cohorts have reported excellent outcomes of arthroscopic primary ACL repair in level IV case series [38-41].

The current gold standard of surgically treating ACL injuries is ACL reconstruction. As all new surgical techniques, the outcomes of arthroscopic primary ACL repair need to be compared to the current gold standard of ACL reconstruction in order to assess if this treatment can be used for standard patient care, but the current literature only consists of level III or level IV studies. The ACL study group in the Netherlands agrees with the need for this study and has recently declared that *the application of primary ACL repair could be considered in an IRB-approved study until there is high

Study objective

The objective of this prospective randomized controlled trial is to compare the outcomes of arthroscopic primary repair of proximal ACL tears with the current gold standard of ACL reconstruction.

Study design

This study is a multi-center national prospective randomized controlled trial (RCT) with randomization into four treatment arms. All patients are first classified in a low and high-risk patient group.

In case a proximal (reparable) tear is present during surgery, the patient will be randomized into one of these treatment arms, and will be followed at short-, mid- and long-term follow-up.

In case a proximal (reparable) tear is not present during surgery, the patient will undergo standard reconstruction and be excluded from this study.

High-risk patients are defined as those with a higher risk for treatment

failure (i.e. high-grade rotational laxity, patients with gross hypermobility, younger patients, and/or patients performing sports at high activity level). In both groups, all patients will then be randomized into repair or reconstruction. For patients in the high-risk group, a modified lateral extra-articular tenodesis (LET) will be performed to lower the risk of treatment failure. Therefore, there will ultimately be four arms (isolated repair vs. isolated reconstruction and repair combined with LET vs. reconstruction combined with LET).

This study is a non-inferiority study with the hypothesis that arthroscopic primary ACL repair is non-inferior to arthroscopic ACL reconstruction. A non-inferiority design is chosen as it is expected that the primary repair procedure is less invasive, shorter, has less complications and has easier rehabilitation when compared to ACL reconstruction [29].

Intervention

Randomization

All patients will be consented preoperatively for the study and will sign a consent form if they wish to participate. The operation starts with a standard knee arthroscopy. It will be assessed what type of ACL tear is presented, if a proximal tear is present (i.e. if the distal remnant of the ACL is of sufficient length to be reattached to the anatomical footprint of the ACL) and if good tissue quality is present (i.e. if the anteromedial (AM) and posterolateral (PL) bundles are of sufficient quality to withhold suture passage and can be tensioned towards the femur). If these conditions are present, patients are randomized on a computer in the operating room between both treatment arms. If these conditions are not present, the patient is excluded and standard ACL reconstruction will be performed.

Surgical techniques

The surgical technique of arthroscopic primary ACL repair has been more extensively described in the literature [42-44, 52]. In brief, the ACL is sutured in alternating and interlocking Bunnel-type patterns towards the avulsed end of the ligament using FiberWire, such that the suture exits the avulsed ligament at the femoral side. Then a femoral tunnel is drilled, followed by drilling a tibial tunnel. A cortical button is then preloaded with both the repair sutures as well as a FiberTape. This construct is then retrieved through both tunnels. Distally, the FiberTape is first fixated on the tibial cortex using a second cortical button, after which it is fixated at the femoral cortex in near full extension. Finally, the repair sutures are fixated proximally over the same femoral cortical button using alternating hitches in 90 degrees flexion.

For ACL reconstruction, autograft hamstring tendon ACL reconstruction surgery

is performed. First, autologous hamstrings (semitendinosus and gracilis tendon) are harvested and will be prepared for graft usage with a minimum graft diameter of 8mm. Then, the femoral and tibial sockets are independently drilled using a FlipCutter (Arthrex) and the graft is fixated on the femoral side and tibial side using a cortical button.

For high-risk patients, a LET procedure will be performed. With this procedure, a central strip of the proximal iliotibial band (ITB) is harvested while leaving the distal attachment at Gerdy's tubercle intact. The ITB graft is then passed under the lateral collateral ligament (LCL) and fixated on the lateral femoral condyle using an interference screw or an anchor.

Rehabilitation

Both treatment arms undergo the same rehabilitation program, and consists of a milestone based program. Early range of motion exercises are started directly postoperatively, and patients will wear a brace locked in extension during full weight bearing until quadriceps control is regained. Crutches are used for 1 to 3 weeks up to the preference of the patient. Closed kinetic chain exercises will be started immediately postoperatively. In case of meniscus repair, the first 6 weeks patients are partial weight bearing and range of motion is restricted to 0-90°. Although rehabilitation is milestone based and no strict time goals can be set, generally cycling on a bike is allowed at 3-4 weeks, running at 6-8 weeks and return to sports at 6-9 months postoperatively depending on the rehabilitation progress, muscle atrophy and return to sports battery tests with physical therapy. Patients will be under guidance of a physical therapist and undergo a criterion-based rehabilitation which is equivalent to the Dutch standard [45]. The patient and treating physician will determine the time of return to activities.

Study burden and risks

By participating in this study, patients will be treated for their ACL injury within 12 weeks of injury by either the gold standard of ACL reconstruction or primary ACL repair. Several studies have shown that there is no risk in early treatment of ACL injury by primary repair or reconstruction.

For this study patients will visit the clinic a total of 7 times of which the last 3 visits is of additional burden to the patient when compared to normal care. They will have to complete questionnaires (estimated time 10 minutes), undergo physical examination (estimated time 5 minutes), and in the last two visits they will also undergo bilateral knee radiographs to assess the incidence of osteoarthritis.

The treatment of primary ACL repair has the aforementioned risk of rerupture of the repaired ligament in which case the patient has to undergo an additional surgery to remove the repaired ligament and perform a standard ACL

reconstruction. Small cohort studies have shown that the risk of rerupture with primary ACL repair is equivalent to slightly higher when compared to the risk of rerupture with ACL reconstruction, which needs to be examined by this study.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Preoperative inclusion criteria:
- Complete primary anterior cruciate ligament injury on physical examination and MRI
- Tear in proximal quarter on MRI
- Age 18 - 50
- Preinjury Tegner activity level >=5 and desired Tegner activity level >=5
- Operation within 12 weeks of injury possible

Intra-operative inclusion-criteria:
- Sufficient tissue length for retensioning to femoral insertion
- Sufficient tissue quality to withhold sutures

Exclusion criteria

Pre-operative exclusion criteria:
- Complete ipsilateral concomitant knee ligament injury requiring surgery
- Concomitant ipsilateral knee dislocation or patellar dislocation
- Osteoarthritis KL grade >=2
- Previous ipsilateral ACL reconstruction/repair
- Intra-articular corticosteroids 6 months prior
- No understanding of Dutch language or not capable of understanding the study and participation
- No preoperative flexion of 90 degrees
- Grade 3 pivot shift indicating gross ligament instability that requires additional procedures
- Gross lower leg malalignment requiring bony osteotomies
- Muscular, neurological or vascular diseases that influence rehabilitation or surgery
- Prolonged use medication use of prednison or cytostatics
- Pregnancy during injury or surgery
- Osteoporosis that influence rehabilitation or surgery

Intra-operative exclusion-criteria:
- No complete tear at arthroscopy or only one bundle (AM or PL) with a proximal tear

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-04-2022
Enrollment:	74
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	02-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	28-10-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-11-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22748
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67842.018.20