Universitat de Girona
Facultat de Medicina

ALL-INSIDE VERSUS TRANSTIBIAL TECHNIQUE IN ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

A randomized controlled clinical trial

FINAL DEGREE PROJECT

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ABBREVIATIONS

ACL: Anterior Cruciate Ligament

PCL: Posterior Cruciate Ligament

MCL: Medial Collateral Ligament

LCL: Lateral Collateral Ligament

AM: Anteromedial

PL: Posterolateral

BMI: Body Mass Index

KT-1000: Knee Test 1000

MRI: Magnetic Resonance Image

ROM: Range of Motion

AI technique: All-inside technique

TT technique: Transtibial technique

ESR: Erythrocyte Sedimentation Rate

CRP: C-reactive protein

VAS: Visual Analogue Scale

IKDC: International Knee Documentation Committee

OTS: Orthopaedic and Trauma Surgery

CAP: Centre d'Atenció Primària

SPSS: Statistical Package for the Social Science

NHS: National Health System

1. **ABSTRACT**

Background: Anterior cruciate ligament (ACL) tear is one of the most frequent injuries of sports medicine. Surgical reconstruction remains the most used treatment after an ACL tear grade III. An emerging procedure, the all-inside technique, was reported to have less postoperative pain comparing to the conventional and most used transtibial procedure. Nonetheless, low evidence is available and functional results (such as range of motion or ligament laxity) obtained after both techniques have not been assessed.

Hypothesis and objectives: All-inside technique will present better functional results (expressed as range of motion) than the conventional transtibial technique, in patients aged 18-50 years old undergoing ACL reconstruction. The aim of this study is to evaluate the functional results obtained after two different techniques of ACL reconstruction, all-inside and transtibial procedures. We will also collect other data and compare the pain, the subjective knee's functionality and report postoperative complications of patients during two years.

Design and setting: A randomized, single-blind, controlled clinical trial will be carried out in Hospital Universitari Dr. Josep Trueta, in Girona, within the Orthopaedics and Trauma Surgery Department from March 2017 until September 2023.

Participants: Men and women aged 18-50 years old, with a diagnosed ACL injury grade III, produced at least 21 days before the surgery, without concomitant ligament injuries, chondral debridement or documented osteoarthritis in ipsilateral knee.

Methods: A non-probabilistic, consecutive method of recruitment will be used. 148 patients with an ACL tear grade III will be randomly assigned, in a 1:1 ratio, to one of the treatment groups, either all-inside technique or transtibial one. Patients will be assessed during two years after the surgery, evaluating range of motion (total range, flexion and extension), ligament laxity (KT-1000 arthrometer), pain (Visual Analogue Scale) and knee's functionality (IKDC and Lysholm scores). We will also report any complication that may be developed. T-student's test will be used for the statistical analysis of the mean range of motion obtained after both techniques. A confidence interval of 95% will be assumed and $p<0.05$ will be considered statistically significant.

Key words: anterior cruciate ligament, reconstruction, all-inside technique, transtibial technique, range of motion, ligament laxity, functional, outcomes.

2. INTRODUCTION

The anterior cruciate ligament (ACL) is the most common injured knee ligament and it is one of the most devastating and frequent injuries in sports medicine. Usually affects young people due to sports activities or road accidents (1). Complete ACL rupture can induce other pathological knee conditions including knee instability, damage to menisci and early osteoarthritis (2).

2.1 ANATOMY OF THE KNEE

The knee is a diarthrodial joint that allows simultaneously rotation and flexo-extension and is composed by two different articulations: femorotibial joint and patellofemoral joint **(Fig. 1)**. It is responsible to the sustainment and transmission of loads in the lower limb (3).

The bony architecture of the femur, tibia, and patella contribute to the stability of the knee joint, along with static and dynamic restraints of the ligaments, capsule, and musculature crossing the joint. Furthermore, two menisci, external and internal, enhance the conformity and contact surface, allowing displacement and rotation of these bones (4).
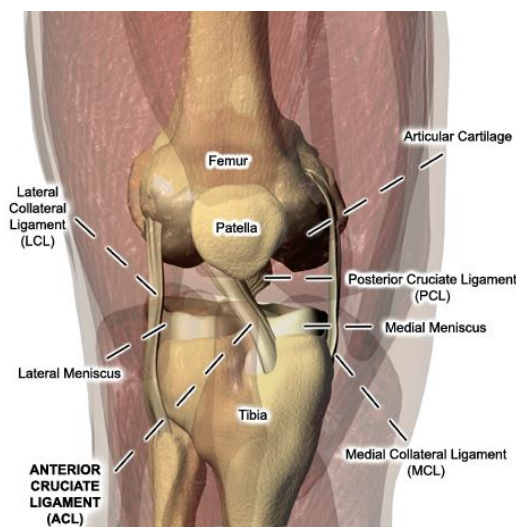
Figure 1. **Anatomy of the knee** (5).

The knee has little inherent stability due to its shape. In order to maintain stability in this joint, stabilizers must be intact. These stabilizers of the knee can be divided in static and dynamic (4,6) **(Table 1)**:

Table 1. **Dynamic and static stabilizers of the knee joint.** Adapted from (6)

Dynamic stabilizers	Static stabilizers
Quadriceps	ACL
Semimembranosus	Menisci (external and internal)
Gastrocnemius	PCL
Pes anserinus	Joint Capsule
Biceps femoris	Patellofemoral ligaments
Tensor fasciae latae	MCL
Popliteus	LCL

The stabilization of the knee joint depends on the activity produced. During dynamic activities, knee's stabilization is controlled by a combination of passive structures, including bone and ligaments, and also by the activation of muscles that cross the joint, the dynamic stabilizers. On the other hand, at rest, stabilization depends essentially of the static stabilizers (6).

The ligaments of the knee prevent anterior and posterior tibial translation, internal and external rotation and varus and valgus **(Table 2)**. Depending on the amount that a specific structure contributes to the absorption of deforming forces, stabilizers are divided into primary and secondary (6,7).

Table 2. **Main stabilizers of knee's movements**. Adapted from (7)

Dislocation	Primary stabilizer	Secondary stabilizer
Anterior tibial translation	ACL (85%)	MCL, Posteromedial capsule
Posterior tibial translation	PCL (95%)	LCL, posterolateral capsule
Varus	In flexion: LCL (70%) In extension: Iliotibial band	Posterolateral capsule ACL and PCL
Valgus	MCL (80%)	ACL more than PCL
Internal tibial rotation	MCL	ACL
External tibial rotation	LCL, posterolateral capsule	PCL

2.2 ANATOMY, HISTOLOGY AND BIOMECHANICS OF THE ACL

The ACL extends from the posterolateral surface of the femoral intercondylar notch and courses distally and anteriorly to insert on the tibial intercondylar eminence. It is an intra-articular, extra-synovial ligament composed of collagen fibres. Due to its location, the ACL has a complex functional role, resisting anterior tibial translation and rotational loads. When the knee is extended, this ligament has a mean length of 32 mm and a width of 7–12 mm (8).

The ACL can be divided in a smaller anteromedial (AM) bundle and a larger posterolateral (PL) bundle. In the femur, PL bundle originates posterior and distal to AM bundle while in the tibia, PL bundle inserts posterior to AM bundle (9).

In extension, AM and PL bundles are parallel to each other **(Fig. 2A)**, and PL bundle is tighter than AM. During flexion, the AM bundle lengthens and becomes tighter, while there is a

shortening and loosening of the PL bundle. With increasing flexion, parallel fibre orientation is lost and femoral insertion site of the ACL becomes more horizontal, causing AM to wrap around PL bundle (9) **(Fig. 2B)**.
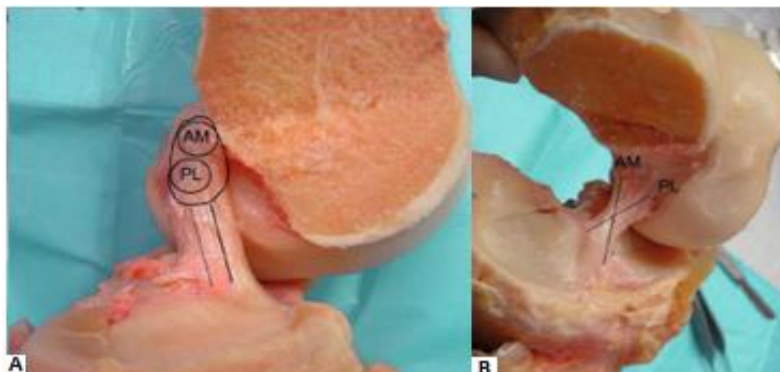
Figure 2. **Illustration of ACL anatomy. Note that there is a change in orientation in anteromedial (AM) and posterolateral bundles (PL) in extension (2A) and flexion (2B)** (9).

Histologically, the ACL is a dense collagenous tissue which microstructures follow the typical organization of other connective tissues found in human joints, even though there are some characteristic differences. This ligament is hierarchically organized into groups of parallel fibres, which are secondarily subdivided into fascicles (10).

Several different types of collagen were identified in ACL (9):

- Type I collagen is the dominating collagen in the ligament and is responsible for its tensile strength.
- Type II collagen can be found near the femoral and tibial insertion sites, in fibrocartilaginous regions of ACL. It seems that the presence of type II collagen can be an indicator of applied pressure at the femoral and tibial attachment sites.
- Other types of collagen (III, IV and VI) that are less present in the structure.

In fact, there is a characteristic change in the histology of the ligament as it gets closer to attachment sites. The typical organization of the ligamentous tissue (predominantly collagen) is replaced by a zone of fibrocartilage, then a zone of mineralized cartilage and finally bone (10).

In what refers to innervation, the ACL possesses most of its neural structures (branches of the posterior tibial nerve) near the attachment sites. There are several neural receptors that assure the proprioception of the ligament. After a disruption of the ACL, there is a secondary loss or damage in mechanoreceptors and, consequently, a loss of accuracy of joint position sense (11).

The biomechanical properties of the ACL are determined by the geometry of the ligament as well as the tensile characteristics of both ligament mid-substance and ligament-to-bone insertion site. Ligaments are capable of lengthening without arriving at irreversible plastic deformation. In a load-elongation curve (also known as *stress-strain curve*, **Fig. 3**), we can observe that the ligament presents a first phase (toe region) when collagen fibres reversibly deform followed by an elastic phase that depends on the viscoelastic properties of the ligament. Yet, if ligament elongation exceeds the physiological limit (yield point), a plastic deformation occurs and there is potential failure of the ligament if continuous loads are applied (3,9,12).
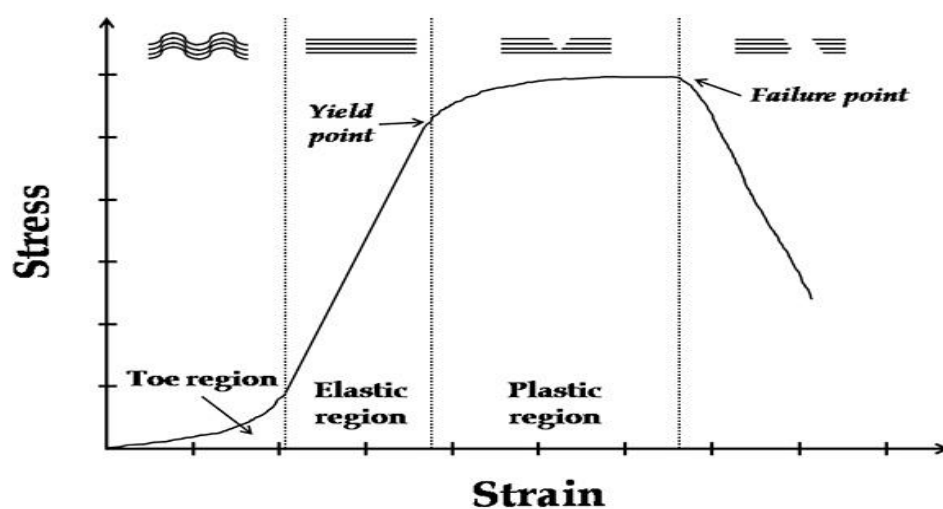
Figure 3. **Load-elongation curve. As a load is applied to the ligament, its strain/elongation also increases in four phases or regions: toe region, elastic region, plastic region and failure region. Note that when the yield point is surpassed there is already an injury in the tissue** (13).

After an ACL disruption, there is an inevitable change of knee kinematics. Anterior tibial translation as well as an increased internal tibial rotation are observed and the patient is prone to a subluxation of the femorotibial joint. To compensate the lack of function of the ACL, secondary stabilizers (of both anterior translation and internal rotation) are recruited to resist external loads and stabilize joint motion. If there is a failure (for example due to muscular fatigue) or external loads exceed the capacity of the secondary stabilizers, a subluxation of the joint will be observed (3,12).

This change in stability observed after an ACL tear leads to a change in motion pattern, to avoid certain risky movements. Furthermore, ACL-deficient knees also influence muscle activation, in an 'intrinsic' mechanism that acts to avoid pain and joint instability (14,15).

2.3 EPIDEMIOLOGY OF ACL TEARS

It is estimated that there are more than 200,000 ACL tears every year in United States and the incidence of ACL tears in general population is estimated to be 68,6/100,000 person-years. Incidence rates vary by sex, sports and, in the case of athletes, level of competition (1).

Although not all ACL tears are surgically reconstructed **(2.8 Treatment approach)**, incidence rates of ACL reconstructions are increasing and nowadays are estimated in 43,5/100,000 person-years (approximately 63% of ACL tears). The average age of people undergoing ACL reconstruction is 29 years old (16).

Sport and recreational activities provide the largest proportion of ACL tears, but the forces applied to the knee that can lead to an injury can be replicated at home as a result of a fall; workplaces that have hazards such a heavy machinery, working at heights; and road crashes. Thus, 65% of these injuries are produced in sports/recreational activities and the rest of them (35%) are produced at home, workplaces or road crashes (1).

ACL reconstructions are performed more on young male athletes than female because males participate in greater numbers in sports that are of high risk for ACL injuries. However, female athletes have a 3 to 4 times greater risk to tear their ACL than males when competing in the same sport (16,17) **(2.4 Risk Factors).**

ACL tears are often accompanied by other knee injuries, which can happen in the acute moment or after a period of time due to lack of stability. Only 20-25% of ACL tears are isolated injuries in the moment of its reconstruction (16). In 37% of patients there is a medial meniscus tear, in 16% there is a lateral meniscus tear and in 20% both menisci are affected (1). Other knee ligaments such as lateral collateral ligament, medial collateral ligament and posterior cruciate ligament can be injured, more commonly after road crashes or other high-energy discharge mechanisms. Also, in several times and especially when there is a meniscus tear, chondral lesions can be observed in arthroscopy, with a predominance of medial tibiofemoral compartment. The number of chondral lesions and complexity of meniscal tears increase with greater time from injury, especially after 5 years from injury (16,18).

2.4 RISK FACTORS

The risk factors of suffering an ACL tear have been categorized as intrinsic and extrinsic. Intrinsic variables are those inherent to the individual and extrinsic ones are external to the person (19–21)**.**

Table 3. **Summary of the risk factors of an ACL injury.** Adapted from (19,20)

	Risk factors	
Extrinsic	Surface (Shoe-surface interaction)	Artificial turf, artificial wooden floor, hot weather, high-evaporation levels, low-rainfall periods
	Level of competition	During competition (RR 30)
Intrinsic	Gender	Female (3-4 RR at the same level of competition)
	Previous injury	Increased risk of ACL graft rupture or contralateral ACL tear
	Body Mass Index (BMI)	Higher BMI increase risk, especially in female
	Genetics	Family tendency (RR 2)
	Knee alignment	Higher Q angle[1] (>14º)
	Intercondylar notch width	Low intercondylar notch width (<17mm) or reduced notch width index (Intercondylar Notch width/total femoral width)
	Tibial slope	Increased posteroinferior tibial slope[2]
	Neuromuscular factors	Increased valgus motion and increased valgus moment in landing
	General and knee laxity	Anteroposterior knee laxity and knee hyperxtension

The risk factors for ACL injury may be synergist. It has been shown that combining two or more risk factors such as low notch width (RR 3,5) and high body mass index (RR 4) increase the risk of ACL injury (RR 26,2) and that risk factors can change over time, not only the external factors but also intrinsic factors such as bony geometry that change over the growth process (21,22).

2.5 MECHANISMS OF INJURY

In sport activities, ACL disruptions usually occur through non-contact mechanisms. Only 20-30% of injuries occur after contact. Landing and deceleration-pivoting[3] manoeuvres (or *plant-and-cut*) are the main sporting tasks responsible for these injuries (23).

In basketball, the most frequent mechanism is landing and it was observed that individuals who had greater knee abduction angles at the moment of landing were more prone to an ACL disruption. Furthermore, not all athletes land with body weight equally distributed between both legs and, in consequence, dominant leg has to support more ground reaction force, increasing ACL strain and its risk to tear (21).

In sports like football or skiing, plant-and-cut movements are the most common injury mechanism (22). When the knee is in near extension (<30º), ACL strain is maximum because this limb position puts greater loads on static joint restraints (ligaments) rather dynamic

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[1] The Q angle is formed between the quadriceps tendon and the patellar tendon.
[2] The tibial slope is when the anterior elevation of the tibial plateau is higher than its posterior one.
[3] A deceleration prior to a change of direction.

(muscles, tendons). Internal tibial rotation, valgus and reduced hip flexion also increase ACL strain. Hence, in a pivoting manoeuvre reduced knee flexion, internal tibial rotation and valgus are combined and this explains why ACL tears occur more often in this position (23).

Another described injury mechanism in skiing is the 'phantom foot mechanism' **(Fig. 4)**. In this case, there is a backward fall with the weight of the skier on inner edge of the tail of the ski while the foot is planted on the ground, resulting in a twist of the leg that tears the ACL (21,24).

ACL tears can also be due to a contact mechanism such as road crashes or high falls and are produced by high-energy discharges that exceed ACL loading response (especially when the knee is hyperextended or valgus-forced) and are often associated with other ligament and meniscal injuries. Finally, in chronic ACL disruptions, the most frequent injury mechanism observed was the ligament impingement in narrow femoral intercondylar notches, which induce micro-tears over time, progressing slowly to macro-tears that weaken the ligament (21,25).

Figure 4. Phantom foot mechanism. There is a twist in the lower limb after a backward fall that produces an ACL disruption (21).

2.6 CLINICAL MANIFESTATIONS AND DIAGNOSIS OF ACL TEARS

Patients often describe a 'popping' sensation at the time of their ACL injury. It has been reported to be present in 33-90% of the cases and athletes are usually unable to continue their activities and to bear weight in the injured extremity, which lead patients to attend emergency room in the next few hours after the injury (23).

Severe pain is often described by the patient during the following hours, accompanied by a sensation of knee instability or 'giving way'. Loss of knee's range of motion (ROM) is usually told by the patient, both extension and flexion. 4-12 hours after the injury, knee effusion is developed. If there are further injuries, specific clinical symptoms may be present. A chronic

ACL-deficient knee often develops additional injuries with time, including meniscal tears, osteochondral injuries or other ligaments injuries that may set extra symptoms throughout the evolution of the initial ACL injury (26).

The combination of knee effusion, popping sensation and 'giving way' in a patient results in a positive predictive value of 83% and a negative predictive value of 81% of patients with ACL tear (23).

Diagnosis of these injuries in the following few hours is challenging as the physical examination is less reliable because of joint swelling and muscle guarding contraction. Nonetheless, a thorough history and physical examination are essential tools diagnosing an ACL injury (27). After assessing the characteristics of the injury (mechanism, time elapsed since injury, initial and current symptoms, reinjuries) and pathological and familial antecedents of the patient, a focused physical examination may be performed. The contralateral knee is examined first to allow a comparison. Initial evaluation should include inspection of skin and soft-tissue swelling along with palpation of the knee. Also, range of motion should be evaluated as it can be compromised by swelling, pain, and associated injuries (23,27).

After this, specific tests are performed to assess anterior knee instability: anterior draw, Lachman and pivot shift tests (16,27) **(Fig. 5)**.

- Anterior draw test: in supine and with the hip flexed to 45º, the knee flexed 90º and patient's foot stabilized by examiner's thigh, an anterior directed force is produced by both hands of the examiner placed in the posterior aspect of the proximal tibia. If there is an increased tibial displacement comparing to the uninjured knee, the test is positive, and is suggestive of an ACL tear (27).

- Lachman test: in supine and with the involved extremity on the side of the examiner. With the knee flexed between 20º and 30º, an anterior directed force is produced with one hand on the posterior aspect of the proximal tibia while the contralateral hand is stabilizing the distal femur. If there is an increased anterior tibial translation comparing to the contralateral leg, the test is considered as positive, being suggestive of an ACL tear (27).

- Pivot shift test: in supine, the injured leg is picked up in extension at the ankle with the examiner's ipsilateral hand. This hand internally rotates and flexes the knee while applying valgus stress with the contralateral hand on the lateral side of the proximal tibia. If the lateral tibial plateau is subluxed at extension and there is a reduction at nearly 30º of flexion, the pivot shift test is positive (27).
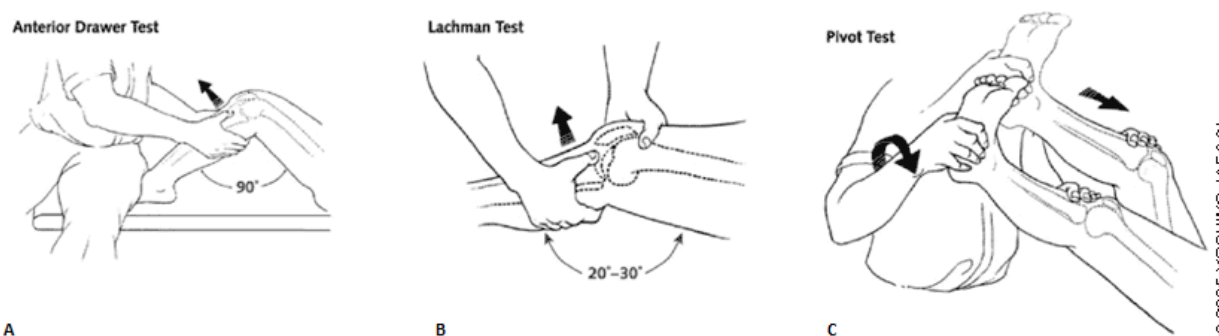
Figure 5. **Clinical tests to assess an ACL tear: the anterior drawer test (5A), Lachman test (5B) and pivot shift test (5C)** (28).

However, not all tests have the same power to predict an ACL tear, especially in acute moment. According to Benjaminse et al. (27), the most accurate is the Lachman test and the most specific one is the pivot shift test **(Table 4).**

Table 4. **Accuracy of clinical examinations for assessing ACL ruptures**. Adapted from (27)

	Sensibility	Specificity	LR +	LR -
Anterior draw test	49%	58%	1,4	0,7
Lachman test	86%	91%	9,4	0,1
Pivot shift test	32%	98%	1,3	1,0

In cases of questionable examination results, ligament laxity tests with arthrometers, such as the Knee Test 1000 (KT-1000), objectively document anterior tibial translation measured in millimetres. To evaluate the laxity, the anterior tibial translation is measured in the injured leg and, then, in the non-injured one. If there is >3 mm of difference between the anterior tibial displacement of both legs (*side-to-side difference*), an ACL tear is diagnosed (29). However, in clinical practice it is not common to use these instruments and they are more commonly used in clinical studies (27,30).

After clinical examination, and if there is an ACL disruption, a ligament injury classification may be performed **(Table 5)**. Grade I and II are considered to be partial disruptions and grade III is a total disruption of the ligament. Most of ACL injuries diagnosed are complete tears (approximately 80-90%) (30).

Table 5. **Classification of ligamentous injuries**. Adapted from (7)

	Amount of ligament fibres affected	Anterior tibial instability
Grade I	Minimum	<5 mm
Grade II	More ligamentous fibres	5-10 mm
Grade III	Complete ligament tear	>10 mm

2.7 RADIOLOGICAL DIAGNOSIS OF ACL TEARS

For the imaging diagnosis of an ACL tear, radiography and MRI are the most used tests. Radiographs are useful to rule out associated injuries, but the gold standard radiological test is MRI, which has been shown to have excellent sensitivity and specificity. Though, it is important to emphasize that the gold standard to diagnose an ACL tear is the arthroscopy (30).

Most of the ACL tears (approximately 80%) are complete, occurring in the middle third of the ACL (90%) or less frequently close to the femoral (7%) or tibial (3%) attachments. Less frequently (approximately 20%), ACL tears are incomplete with partial disruption of ACL fibres (31).

Radiography: findings of an ACL injury are indirect and limited to bone abnormalities. It is also used to screen associated osseous injuries and avulsion fractures. There are many indirect signs that raise the suspicion of an underlying ACL injury such as avulsion fractures at ACL insertion sites or avulsion fracture of lateral tibial capsule (*Segond fracture* which is pathognomonic, although not very common) (31).

Magnetic Resonance Imaging (MRI): MRI is the imaging modality of choice to diagnose an ACL tear, with sensitivity and specificity of more than 90% (32). The uninjured ACL is seen on MRI as a well-defined and continuous band. Unlike radiography, diagnosis of an ACL tear is usually based on direct signs. After an acute injury, MRI shows a loss of fibre continuity and a signal of haemorrhage and edema **(Fig. 6)**. Bone bruises are usually seen in the anterior aspect of the femoral condyles and the posterior aspect of the tibial plateaus, due to the impact between these surfaces after anterior tibial translation. Furthermore, MRI can reveal accompanying injuries such as meniscal or chondral injuries and other ligament disruption. Another described advantage is the fact that MRI is able to differentiate distinct grades of sprain of the ACL, which has implications in the treatment planning, since partial tears usually do not require surgery (30,31).

Figure 6. **Primary signs of ACL tear.** **6A: Typical appearance of ACL tear with fibre discontinuity of ACL (arrowheads). 6B: Chronic ACL tear with absence of normal ACL fibres compatible with complete resorption of fibres. 6C: Acute partial tear as characterized by thickening and edematous change of ACL fibres which show increased signal intensity (white arrows)** (31).

2.8 TREATMENT APPROACH IN COMPLETE ACL TEARS

Initial management of an ACL tear involves decreasing the patient's pain and swelling, followed by restoring range of motion with rest, ice, elevation and compression of the zone. Isometric and extension exercises will also help to restore normal motion of the joint. Returning to high-risk activities usually is not possible without sustaining additional episodes of giving way and additional treatment is required (30,33).

2.8.1 Non-operative versus operative treatment

There is not a unified treatment approach to ACL injuries. The key to appropriate treatment is based on patient's desire and motivation to recover sports activity at the same level as prior to knee injury. For individual patients, the risks of surgery must be weighed against the risks of sports disability, knee dysfunction and additional injuries that are associated with conservative management (30,33,34). In general, in patients over 50 years old who do not practice high-risk sports conservative treatment is offered, while in young active athletes surgical approach is the most common strategy (30,34).

Conservative treatment consists on providing functional stability to the knee regarding the ACL's deficiency. To achieve this objective, secondary stabilizers must be strengthened and neuromuscular control enhanced with physical therapy. Rehabilitation protocols should include muscle strengthening, proprioceptive training and regaining full ROM. However, the patient may be educated to avoid high-risk sports with cutting movements (34).

On the other hand, surgical treatment is often reserved for those who want to continue playing their sports. Reconstruction is carried out to prevent instability symptoms, additional articular injuries and to return patients to full activity (1). The main principles for successful ACL reconstruction are: use of a graft with biomechanical properties similar to those of the native ACL, precise placement of the osseous tunnels, and strong and rigid fixation of the graft under the correct tension (30).

Fithian et al. proposed a division in 2 groups of risk: low risk and moderate-high risk, based on number of hours per year practising high-risk sports and KT-1000 side-to-side differences reported in injured patients. In low-risk patients, non-conservative treatment showed good long-term results in terms of stability and additional meniscal injuries, while in moderate-high risk patients it seems that the surgical reconstruction is more appropriated (33).

The grafts[4] used to achieve good mechanical properties can be divided in autografts and allografts. Autografts can be harvested from the central third of the patellar tendon patient or from the isquiotibialis (specifically, semitendinosus and/or gracilis). Allografts are usually obtained from the patellar tendon or the tibialis anterior tendon. Another issue of the surgical approach is the fixation method applied to fix the graft to the bone (30). Nevertheless, it is not our interest to describe all the techniques, so this project will focus in the most used fixation technique (transtibial technique) and an emerging technique - the all-inside technique (AI).

2.8.2 Types of surgical techniques

2.8.2.1 Conventional Technique –Transtibial ACL Reconstruction (using Bio-TransFix®)

In this technique a full tunnel is made in the tibia, and the femoral socket[5] is performed through the tibial aperture. So, the tibial tunnel dictates the position of this femoral socket and it was observed that the graft is fixed in a more vertical and anterior position than the original ligament, which can affect its isometry during knee's motion (35,36). A brief explanation of the technique will be based on Arthrex's description using the Bio-transfix® and it is better described in **Annex 1** (37). The potential pitfalls of this technique are described later **(2.8.5 Clinical results)**, but in summary, in this technique (35):

- The creation of the tunnels is not independent. The tibial tunnel dictates the position of the femoral socket.
- Total perforation of the tibial bone what increases morbidity.
- The isometry of the graft can be affected during knee's ROM due to its vertical orientation.
- In the case that an autologous tissue is used as graft, it requires both semitendinosus and gracilis harvesting.

Firstly, the gracilis and the semitendinosus (isquiotibialis) are harvested to obtain a graft. This graft is prepared and tensioned on a special station to obtain a final length of 100-120mm. With an arthroscopic guide, we identify the footprints of the injured ACL, the remaining fibres are debrided and its zone of insertion marked **(Fig. 7).**

The tibial tunnel is created with a drill of the same diameter of the graft. It is performed in an outside-in way (from bone to knee joint) and crosses all the bone (complete tunnel). When this

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[4] A graft is the tissue that will be used as 'neo-ligament'. In our case, we will use autografts.
[5] A socket is also called a 'blind tunnel' and consists in a bone perforation that does not cross all the bone. Thus, the socket will have a bone entry without an exit.

tunnel is already performed, over-the-top position is identified in the femur and a drill of the same diameter of the graft performs the femoral socket with a length of 40mm.

To create the fixation of the graft on the femoral socket, a transverse femoral passage has to be performed. For that, a Tunnel Hook® is inserted on the top of the femoral socket and assembled in a system (Transfix Drill Guide®) that will allow us to drill the passage with a Guide Pin Sleeve® **(Fig. 8A).** Then, we introduce by the passage a Passing Wire® (made of nitinol) that will allow us to pull the graft **(Fig. 8B).**

Figure 7. A marking hook (green arrowhead) is locked on ACL tibial footprint and marked at 55-60º. Over the insertion of the pes anserinus, a small incision is done and a Guide Pin® (blue arrowhead) is inserted. After this, a drill performs the tunnel through the Guide Pin® and creates a complete tunnel. Adapted from (37)
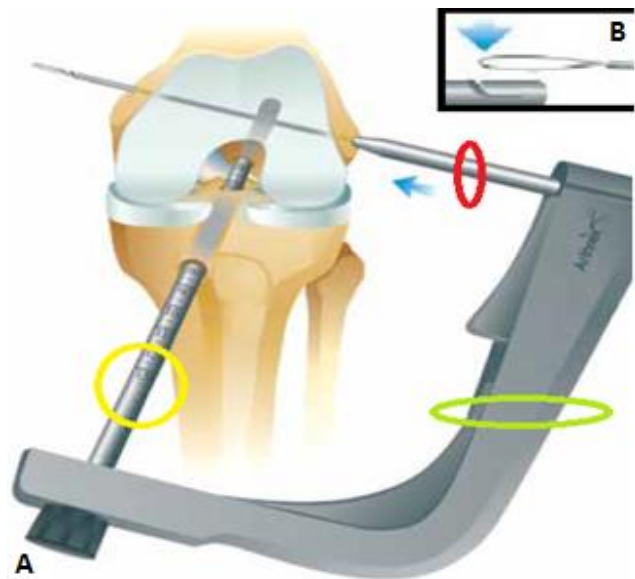
Figure 8. **8A:** A Transfix Tunnel Hook® (yellow) is assembled with a Transfix Drill Guide® (green) and is introduced from the tibia until the top of the femoral socket. A Guide Pin Sleeve® (red) of 3-mm of diameter is advanced to the bone exiting the femur medially. **8B:** Note that the Hook (yellow) has a little opening in its femoral end that will be useful to fix a Passing Wire®. Adapted from (37)

When the Passing Wire® is totally inserted, we retire the tunnel hook to drag the wire into the outside **(Fig. 9A).** The graft is then placed into this wire, and after that we will pull wire's free ends in order to insert the graft into the femur **(Fig. 9B).**

To fix the graft in the femur, a special implant (Transfix Implant®), similar to a screw, is inserted through the transverse femoral passage from lateral to medial. Finally, to fix the graft in the tibial tunnel, an interference screw is used and inserted over pressure. **(Fig. 10)**
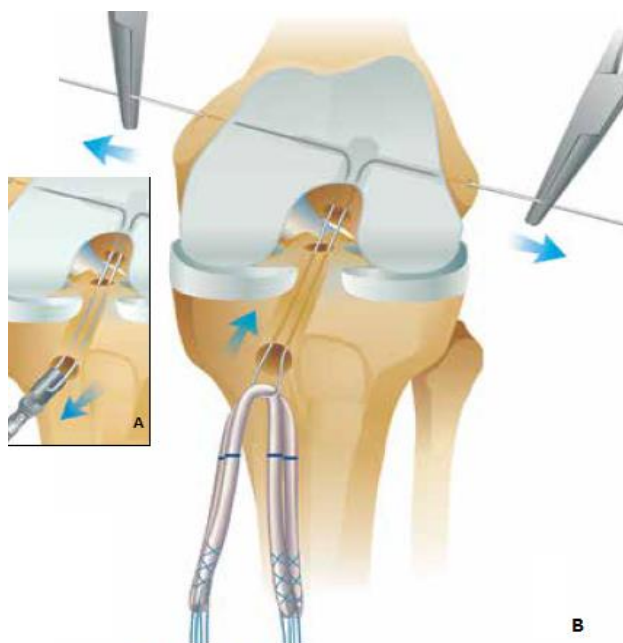
Figure 9. **9A: The hook is removed from the femur and drags the Passing Wire® with it. 9B: After placing the graft into the Passing Wire®, we can pull the graft by pushing up wire's free ends.** Adapted from (37)

Figure 10. **The TransFix Implant® (blue arrowhead) is inserted in the femur over the Passing Wire® (which is after retired). An interference screw (black arrowhead) is used to secure tibial fixation.** Adapted from (37)

2.8.2.2 All-inside technique

This technique presents three main characteristics: firstly, it uses sockets instead of full-tunnels to insert the graft. Secondly, the sockets are created independently using retrograde-drilling pins (FlipCutter®, Arthrex) and both femoral and tibial sockets are performed in an inside-out direction (from knee joint to bone). Thirdly, this technique uses cortical endobuttons as suspensory fixation devices that allow the tensioning of the graft even when it is already fixed (38).

The potential advantages of this technique comparing to the transtibial one are described later **(2.8.5 Clinical Results)** but in summary (36):

- It is bone conserving, since it only requires sockets and not full-bone tunnels, which leads to less postoperative pain.

- Only requires the harvesting of the semitendinosus, decreasing the donor zone morbidity.

- The creation of the tunnels is independent, which results in a more anatomical position of the graft, mimicking better the characteristics of a non-injured ACL.

A brief explanation will be presented in this introduction based on the article of Lubowitz et al. (38). However, a more detailed description is presented on **Annex 2**.

Initially, the semitendinosus is harvested, sparing the gracilis (what decreases the morbidity and increases knee stability comparing to the transtibial technique). The graft is linked with TightRope® sutures, and then is prepared in a Graft Station®, obtaining a four-stranded graft[6] **(Fig. 11)**.

The graft is then tensioned in this Graft Station®, obtaining a final graft length of 75mm and 8mm of diameter. In this case, an exact graft length is important since the femoral and tibial socket lengths are predetermined, measuring 25mm and 30mm, respectively, and the intraarticular graft length measures 20mm.

The TightRope® sutures (that have an endobutton in its end) will be helpful to pull and tension the graft in the following steps **(Fig. 12)**.
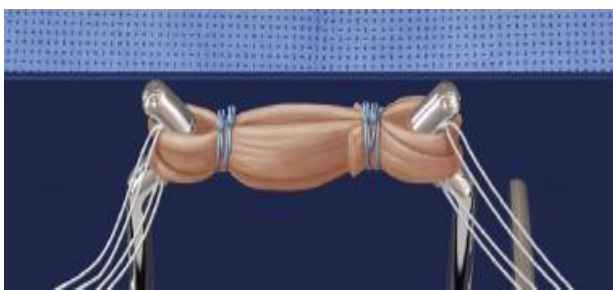
Figure 11. **Graft preparation: The semitendinosus is initially linked with TightRope® sutures (white). A four-stranded graft is created (with FiberWire® sutures, represented in blue) and loaded in a tensioning station (silver)** (38).
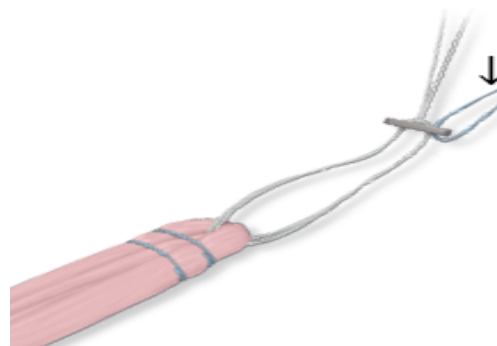
Figure 12: The TightRope® sutures (white) have an endobutton in its end that allows the assembly to the pulling sutures (arrowhead, blue).
This endobutton has another crucial function: it serves as the cortical fixation in bone. Adapted from (38).

With an arthroscopic guide, we identify the footprints of the injured ACL, the remaining fibres are debrided and its zone of insertion marked. A marking hook is fixed in the femoral footprint of the ACL and a guide pin is inserted in the femoral bone, advancing until the joint **(Fig. 13).** Then, pressing a button, the guide pin (with a diameter of 3mm) becomes a retrograde drill[7] (with a diameter of 8mm) that performs the femoral socket. Pressing the button one more time, it returns to be a guide pin and is removed from the bone. After the removal of the FlipCutter®, we leave a 25-mm femoral socket with a thin cortical bone-bridge **(Fig. 14).**

Pulling sutures are passed from the femoral socket until an anteromedial portal. This sutures will be helpful in the following steps.

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[6] A four-stranded graft is obtained from a 240-mm graft. Then, we give 4 turns to the Graft Station® obtaining a 'uniform' final graft with 60 mm of length (pre-tensioning length)
[7] The described guide pin that becomes a retrograde drill is a specific instrument called FlipCutter®

Figure 13. A marking hook (black arrowhead) is locked at 100-110º. The FlipCutter® (blue arrowhead) is assembled to the hook and enters in the femur. To pass the FlipCutter®, there is a cortical bone bridge, with 3mm of diameter, made through all the bone. Adapted from (38)

Figure 14. After the retrograde drilling, we can observe that the 25 mm wide socket (green arrowhead) is created and there is a cortical bone bridge (brown arrowhead) that was necessary to pass the FlipCutter®. Adapted from (38)

To create the tibial socket, we follow the same steps of the femoral socket creation.

After the creation of both sockets, we assemble both the TightRope® sutures and the pulling sutures (previously passed by the sockets) in the endobutton, creating a graft loop system. This system allows to pull the graft from the anteromedial portal until the femoral socket. The endobutton present in the end of the TightRope® suture will also serve as the cortical fixation.

When the button reaches the external surface of the femur it is flipped and with the TightRope® suture we can tension the graft to totally fill the socket **(Fig. 15).** *First, we drag (with the pulling sutures of the graft loop system), then we flip (the endobutton that serves as the cortical fixation) and finally we fill (with the TightRope® sutures).*

The same steps are followed for the tibial fixation, which means that we first track the pulling sutures, then we flip the endobutton and then we tension the graft **(Fig. 16).** Even after both buttons are flipped, the graft can be tensioned.
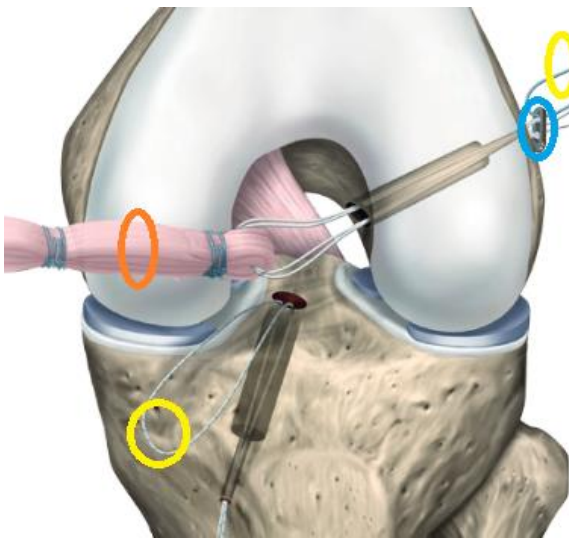
Figure 15. **The graft (orange) is pulled into the femoral socket by the graft loop system. The pulling sutures (yellow) are responsible to 'drag' the graft and the TightRope® system (white sutures, not circled) allows the tensioning of the graft to fill completely the socket. Note that the TightRope® sutures have an endobutton (blue) that will serve as the cortical fixation once it is flipped.** Adapted from (38).
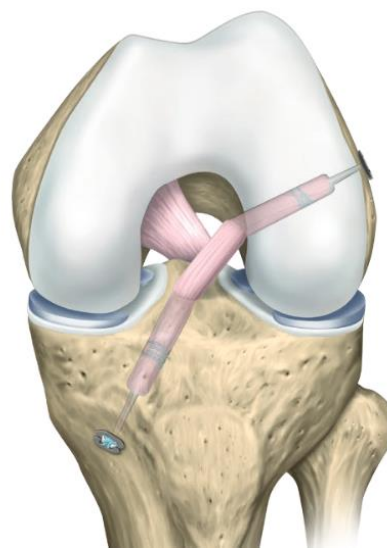
Figure 16. **The same steps are repeated in the tibial side and the tension of the graft can be adjusted even after both buttons are flipped. The final result of the procedure is shown** (38).

2.8.3 Surgical complications

Anterior cruciate ligament reconstruction is considered a safe procedure, with low complication rates. The most common reported complications include cellulitis, septic arthritis, wound infection, deep venous thrombosis, hemarthrosis (requiring arthrocentesis), stiffness (arthrofibrosis), anterior knee pain, loss of motion or persistent instability (39,40).

In this study, we will evaluate the ROM obtained after both procedures so we will provide detailed explanation about the loss of motion. The assessment of complications of this study will include septic arthritis and hemarthrosis, since these are the two most common reported complications (40).

2.8.3.1 Loss of motion

After an ACL reconstruction, loss of motion is a possible complication. Even though the IKDC defines as a complication a loss of at least 5º, studies have reported that less degrees are enough to have an impact on knee's functionality (41). Loss of knee extension is more important than loss of knee flexion, or in other words, the loss of 1º of extension has an increased impact on knee's function than the loss of 1º of flexion. However, after an ACL reconstruction, there is a tendency to lose more grades of flexion than extension (42).

Roaas et al. (43) estimated the normal range of motion (ROM) on general active population to be in a mean of 143,7º in flexion and -1,6º on extension, on a total ROM of 145,3º. The

preoperative ROM tend to be inferior due to swelling and pain while postoperative ROM usually returns to close to the preinjury levels, however, without achieving them (44).

Loss of full ROM at the knee can have detrimental effects on the function of the lower limb (41):
- Loss of extension has impact on gait, muscle activity and normal tibiofemoral arthrokinematics, inability to attain a stable position of the knee, and difficulty in running and jumping.
- Loss of flexion has been demonstrated to cause altered gait pattern as well as affecting other activities. A knee flexion less than 125º interferes in climbing stairs and sitting, and less than 135-137º can cause difficulties in running, landing and squatting (41,42).

Anteromedial placement of tunnels results in loss of flexion and extension due to intercondylar impingement. Also, vertically oriented graft does not reproduce the oblique orientation of a non-injured ACL, which could limit the ability of the reconstruction to restore the normal kinematics (45). The transtibial technique places the graft anterior to the anatomic center of the ACL, owing to constraints imposed by the tibial tunnel, which could affect normal knee motion (35,46). Improper bone tunnel positioning can result in abnormal graft tension, reduced ROM and postoperative instability. Also, deficient ROM, especially loss of extension, is associated to increased anterior knee pain, which also leads to decreased results in subjective scores (47).

Loss of motion after an ACL reconstruction is a described risk factor for developing osteoarthritis. Authors describe that only 1º of loss of extension or 3-5º of flexion is enough to develop early osteoarthritis and to have a significant impact on patient satisfaction (42,44,48). There are several factors that can affect the ROM after the surgery such as the preoperative ROM, surgery in the first 3 weeks after the injury (due to arthrofibrosis), vertical graft orientation (a non-anatomic position leads to impingement), concomitant ligament surgery or a rehabilitation program without emphasis on restoring motion (48,49).

2.8.3.2 Septic Arthritis and hemarthrosis

Septic arthritis rates are low (0.14%-1.7%) and are usually caused by *Staphylococcus Epidermidis* (41%) or *Staphylococcus Aureus* (35%). The most consistent findings include increased pain, inflammation, and moderate effusion, whereas fever and erythema are not always present (50).

The clinical diagnosis of septic arthritis can be difficult to make and laboratory data is crucial to establish the diagnosis. Laboratory values including erythrocyte sedimentation rate (ESR>30 mm/h) and C-reactive protein (CRP>1.0mg/dL) are recommended to confirm the diagnosis. Establishing the causative organism of the infection is crucial to start an appropriate treatment, whereby synovial fluid cultures are needed (39).

There is not a standard guideline for the treatment of septic arthritis after ACL reconstruction. The most frequent method applied is intravenous antibiotic therapy (considering surgical irrigation), and in case that it is not enough, the graft may be removed, what happens in 22% of patients. The clinical outcomes after treatment of infection seem to be satisfactory in terms of motion and KT-1000 values, however secondary complications such as pain, stiffness, cartilage degeneration and graft weakening were described (50).

Knee hemarthrosis is the extravasation of blood into the knee. After the surgical procedure, there is always a small amount of bleeding, what is considered normal and tends to disappear in the two first postoperative weeks. In literature, **hemarthrosis is referred as a complication** (0,23%-0,76%) **when** due to its excessive amount leads to severe pain which cannot be controlled with analgesia and **requires needle aspiration**. The diagnosis is clinical and based on patient's complaints and a ballotable patella or a tense knee can be observed (51).

2.8.4 Rehabilitation for patients following ACL reconstruction

Anterior cruciate ligament (ACL) reconstructions have to be combined with postoperative rehabilitation in order for patients to return to their pre-injury activity levels. The overall objectives before the return to sports activities are control of pain and swelling, a full range of motion and flexibility, elimination of muscle atrophy, a normal gait, restoration of proprioception and overcoming kinesiophobia (52,53).

Usually, the graft needs 2-3 months until it becomes incorporated into the bone, and 6 months before the remodelling process is sufficient to allow the graft to sustain vigorous loads, which carries to recommendations of 6-month rehabilitation protocols and return to sports activities only after 6-8 months. Strengthening exercises are started when the full range of motion has been recovered and swelling has disappeared (30,54).

A standard rehabilitation protocol based on Wright et al. (52,53) and Meara et al. (55) recommendations will be followed, as showed in **annex 3.**

2.8.5 Clinical results

The all-inside technique with TightRope® and a cortical endobutton fixation system was described in 2011, so there is not much evidence about this procedure (38).

There are only two clinical trials that compared this technique with the transtibial technique, reporting significantly less pain with the all-inside technique (56,57). However, in one of them there was an underestimation of sample size that led to an insufficient statistical power (57). The other existing literature only compared preoperative with postoperative status using this technique, showing excellent clinical outcomes (58–60).

The ultimate goal of ACL reconstruction is to stabilise the knee without restricting range of motion and prevent secondary damage. Transtibial technique remains a commonplace for the creation of the femoral tunnel and its position is dictated by tibial tunnel placement. This leads to a less anatomic position which results, consequently, in a vertical graft orientation that fails to restore normal kinematics (35,61).

One of the reported advantages of all-inside technique is that the socket drilling is performed independently over ACL footprints and this results in a more anatomic position, with increased stability of the knee (36,38,58). The cortical fixation method of this procedure, an adjustable-loop graft suspension (with an endobutton), has also been shown to be equivalent to other fixation methods in terms of graft failure or loosening (62).

Another difference of this technique is that it only requires the harvesting of the semitendinosus, leaving the gracilis available to be used for additional ligament reconstruction, minimising harvest morbidity and increasing lower limb's stability (57,60,63). Furthermore, the drilling of tibial and femoral sockets (instead of tunnels) over ACL footprints preserves the external cortex for the fixation, being less bony invasive, presenting less surgical trauma and being cosmetically more attractive (51,54).

In a histological study that compared the characteristics of grafts after all-inside cortical-button suspensory fixation in sockets versus interference screw fixation in tunnels in a canine model, there was superior graft healing to bone both in femoral and tibial sockets in the all-inside procedure. Also, the grafts showed direct attachment to bone with a four-zone integration, similar to the characteristics of the non-injured ligament. The authors hypothesize that this preclinical evidence could lead to improved clinical results comparing to screw fixation (used to fix the graft in transtibial technique) (64).

A summary of the published literature about all-inside technique is presented in **annex 4**.

3. JUSTIFICATION

ACL tear is one of the most frequent injuries seen in sports medicine. It usually affects young athletes and the return to high-risk activities generally is not possible without sustaining additional episodes of instability, whereby additional treatment is required. Operative treatment is the most common strategy in this kind of patients and there are several techniques described to reconstruct the ACL. An emerging and recently described procedure, the all-inside technique (AI), is bony conserving, needs less graft harvesting and is able to place the graft in a more anatomical position comparing to the conventional transtibial technique (35,36,38).

However, despite these theoretical advantages, low evidence is available about clinical and functional outcomes of the AI. Hence, the main reason for developing this project is to assess the outcomes comparing both procedures.

The most of the existing literature about AI only compared the preoperative with the postoperative status, concluding that it is a solid option (58–60). Nonetheless, there were only two clinical studies that directly compared this technique with the conventional procedure (transtibial technique), without assessing functional results. These studies concluded that AI has less postoperative pain than the transtibial technique without presenting more complications. This diminished pain could be due to less bone perforation and less graft harvesting (56,57). Furthermore, a histological study in canine models also showed higher graft healing to bone in grafts placed with a cortical endobutton fixation (used in AI) comparing to an interference screw fixation (used in transtibial technique), and although this is preclinical evidence it suggests that the recent procedure could also have potential clinical advantages due to the graft healing (64) **(2.8.5 Clinical Results)**.

In the conventional transtibial technique, the femoral socket position is dictated by the tibial tunnel placement. Due to this constraint, the femoral socket is placed anterior to the ACL's center. This less anatomic position of the femoral socket results in a vertical graft orientation that limits the ability to restore normal kinematics (35,46).
In AI, contrasting with the conventional procedure, the sockets are performed independently, being placed in a more anatomic position, closer to the center of the ACL which leads to a more anatomical (oblique) graft orientation (46,58). It has been described that an anterior femoral tunnel positioning could result in reduced ROM and postoperative

instability (47). Since the AI is able to place the tunnels in a more anatomic position, obtaining an oblique graft orientation, we expect to observe a better restoration of knee's kinematics and motion, expressed on higher values of total ROM (41,42,44) **(2.8.3.1 Loss of motion).**

In summary, our hypothesis is that apart from the described decrease in postoperative pain, the functional results obtained will also be significantly higher, because the graft mimics better the ACL orientation and, as a result, its functionality expressed as an increase on ROM.

We also expect to add high level evidence to the current literature in what respects to pain, ligament laxity, subjective knee's functionality and complications developed. To reach this objective a randomized, single-blind, controlled clinical trial is proposed.

4. **HYPOTHESIS**

All-inside technique will present better functional results (expressed as range of motion) than the conventional transtibial technique, in patients aged 18-50 years old undergoing ACL reconstruction.

5. **OBJECTIVES**

5.1 MAIN OBJECTIVE

- Compare knee's passive range of motion, calculated as the difference between the maximum passive flexion and the maximum passive extension, after all-inside technique or conventional transtibial technique in patients undergoing arthroscopic ACL reconstruction.

5.2 SECONDARY OBJECTIVES

- Compare pain after all-inside technique or conventional transtibial technique in patients undergoing arthroscopic ACL reconstruction, using a VAS (Visual Analogue Scale).

- Compare subjective functional results after all-inside technique or conventional transtibial technique in patients undergoing arthroscopic ACL reconstruction, measured with IKDC (International Knee Documentation Committee) and Lysholm scores.

- Compare additional objective functional results after all-inside technique or conventional transtibial technique in patients undergoing arthroscopic ACL reconstruction, evaluating the anterior tibial translation with a KT-1000 arthrometer.

- Compare the complications after all-inside technique or conventional transtibial technique in patients undergoing arthroscopic ACL reconstruction.

6. **MATERIAL AND METHODS**

6.1 STUDY DESIGN

In order to obtain high level evidence a clinical trial is needed. This study has been designed as a non-placebo, single-blind, prospective, randomized, unicenter, controlled clinical trial. In patients undergoing ACL reconstruction, randomization will proceed and two groups will be formed, in a 1:1 ratio. One of the groups will receive the all-inside technique and the other one will receive the conventional transtibial technique. Patients will be followed up from the moment of the surgery until 24 months after the procedure.

It will be carried out by a multidisciplinary team integrating traumatologists and orthopaedic surgeons, nurses and physiotherapists. The center of reference will be Hospital Universitari Dr. Josep Trueta, in Girona, in which the patients will be selected.

6.2 POPULATION

The study population is based on patients aged 18 to 50 years old with an ACL tear grade III, diagnosed with a MRI and clinically unstable, who chose to have ACL reconstructive surgery.

Before being offered to enter the study, all patients will undergo clinical examination and imaging evaluations, including knee radiographs and knee magnetic resonance imaging, to assess the injury and its grade.

6.2.1 Inclusion criteria

- Grade III ACL tear diagnosis: defined by a clinically unstable knee (>1cm of anterior tibial translation in Lachman Test) and a MRI diagnosis of a complete ACL tear.
- Patients aged 18-50 years old.
- Surgery >21 days after the ACL injury.
- Informed consent.

6.2.2 Exclusion criteria

- ACL tear grade I or II.
- Chondral debridement.
- Tears of knee medial collateral ligament, posterior cruciate ligament, lateral collateral ligament or posteromedial corner injury.
- Radiologically documented knee osteoarthritis.

- High-level or high-performance athletes, according to the Spanish Royal Decree 971/2007. High-level athletes are those who belong to the 'high-level athletes list' that is annually published by the 'Consejo Superior de Deportes' in the BOE.
- Past surgeries on ipsilateral knee.
- Concomitant ACL tear on contralateral knee
- Medical contraindication to surgery.
- Medical condition limiting expectancy of life.

Age restrictions are due to the different range of motion patterns and functionality observed on past studies on people above 50 years old, due to osteoarthritis and degenerative changes. This fact could be a confounding factor for data analysis. Furthermore, it is not totally clear if patients above this age present better clinical results whether if they are submitted to a surgical reconstruction or treated with a conservative approach **(2.8.1 Non-operative versus operative treatment).** Patients under 18 years old will not be considered for this study since they are skeletally immature and a surgery could compromise their growth plates.

The surgery must be performed more than 21 days after the injury is produced because it has been described that ACL reconstructions performed before this time gap are associated with higher risk of arthrofibrosis and consequent loss of motion (42,65,66). We will schedule the surgery for two months after the injury (the usual time gap in our hospital due to administrative issues) so we will respect, in this way, the 21 days.

Concomitant ligamentous and posteromedial corner injuries with its respective surgery have also been associated with increased incidence of loss of motion (42,66).

High-performance athletes are excluded due to their special requirements and different rehabilitations protocols of the general population.

6.2.3 Withdrawal criteria

- Difficulty with maintaining follow-up: in the case that the patient misses one of the visits we will reschedule that visit to a week later and in case of missing this visit as well, the patient will be withdrawn.
- Incomplete ACL rehabilitation program: if the patient does not complete at least the estimated 24 weeks of rehabilitation program.

- Rupture of the graft within 2 years.
- Revocation of informed consent to not continue within the study.

An intention-to-treat analysis will be used in this study, so if a patient leaves during it or the follow-up is lost, data will not be excluded from the final analysis. Subjects withdrawn from the trial will not be replaced.

6.3 SAMPLE

6.3.1 Sample selection

The sample selection will be consecutive and non-probabilistic. Every patient seen on the emergency department of Hospital Universitari Dr. Josep Trueta, in Girona, or referred to us from Hospital Santa Caterina (in Salt), Hospital Comarcal de Blanes and Hospital d'Olot i Comarcal de la Garrotxa, meeting inclusion and not exclusion criteria will be offered to be enrolled in this trial. Interested patients will be informed about the study with an information sheet **(annex 5)**. Afterwards they will be contacted by a trial doctor who will review the study planning and will obtain the informed consent **(annex 6)**. The sample recruitment will take place in Orthopaedics and Trauma Surgery (OTS) unit of the Hospital Universitari Dr. Josep Trueta, in Girona, over three and a half years (42 months).

6.3.2 Sample size

Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 74 subjects are needed in the all-inside group and 74 are needed in the transtibial group to recognize as statistically significant a difference greater than or equal to 4,4 degrees (0,5 SD). The mean postoperative range of motion is estimated to be 135,6±8,8 (SD) degrees based on the studies of Watanabe et al. (58) and Seo et al. (67). Based on previous studies, a drop-out rate of 15% has been anticipated, considering future losses and withdrawals.
Sample size has been calculated with GRANMO:
https://www.imim.cat/ofertadeserveis/software-public/granmo/

6.3.3 Estimated time of recruitment and enrolment

Incidence of ACL reconstructions in Hospital Universitari Dr. Josep Trueta is estimated at 51 cases per year. By analysing the database of the Orthopaedics and Trauma Surgery Unit of the Hospital Universitari Dr. Josep Trueta, the number of patients who were submitted to

an ACL reconstruction last year that met the inclusion and not exclusion criteria for the study have been calculated, which is 42.

Using past studies data as reference, it has been anticipated a rate of 15% of patients lost during the follow-up. It has been estimated that 148 patients are needed for this study. Therefore three and a half years are needed at least to reach the sample size.

6.3.4 Randomization

A statistician expert will create a database containing ordered codes which will be randomly assigned to the participants. There will be as many codes as patients estimated on the sample size, 74 for each intervention, to ensure a 1:1 ratio randomization. These codes will designate if the patient receives treatment 1 or 2.
At the beginning of the study, main investigators will decide which intervention, A or B, corresponds to 1 or 2. So, the follow-up observer and the statistician will not know which intervention, A or B, is applied to treatment 1 and 2.
Randomization will be generated by the SPSS software by the statistician expert.

6.3.5 Masking techniques

Studies applying surgical techniques have a detection bias due to the impossibility of blinding the surgeon. In this study, patients will be blinded since the incisions needed to perform both techniques are similar and the patient will not be able to know which technique has been applied.

To minimize this type of bias an orthopaedic surgeon that has not participated in the surgery will assess the participants during the follow-up.
The statistical consultant will not know which intervention is assigned for each treatment group. Patient's name and technique assigned will not appear in examination records. In such wise, the detection bias will be reduced.

6.4 STUDY VARIABLES

In order to assess the proposed objectives, study variables are the following:

6.4.1 Independent variable

The independent variable of this study is the technique applied to reconstruct the ACL: the all-inside technique or the conventional transtibial technique.

6.4.2 Dependent variables

Primary dependent variable:

The main variable of the study will be the knee's passive range of motion (ROM), calculated as the difference between maximum degree of flexion and maximum degree of extension, measured by a goniometer and estimated in total unit degrees. This variable will be measured at 6 months (after the rehabilitation process), 12 months and 24 months. The collected data will be registered on the participant data sheet **(annex 9)**.

> ROM (º) = Maximum Flexion (º) – Maximum Extension (º)

Secondary variables:

In addition to the main dependent variable, during the follow-up, the following items will be assessed and registered on the participant data sheet:

- Flexion: measured in degrees with a goniometer **(Fig. 17)**. The patient is in supine, with the hip in 90º. The doctor applies a force to maximum flexion until reaching maximum knee stiffness. This variable will be measured at 6 months, 12 months and 24 months.
- Extension: measured in degrees with a goniometer. The patient is in supine, with the heel placed on a bolster to allow the knee to fully extend, and allowing a possible hyperextension **(Fig. 18).** It will be measured at 6 months, 12 months and 24 months.
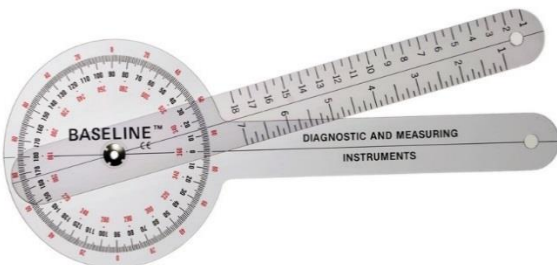
Figure 17. **A goniometer similar to the one that will be used in this clinical trial** (68).

Figure 18. **Measuring knee extension with a goniometer** (53).

▪ <u>Pain</u>: measured with a Visual Analogue Scale (VAS) **(annex 10)** at the postoperative day 1, day 15, 1st month, 6th month, 12th month and 24th month. We will express this variable in a range of 0-10.

The pain VAS is a continuous scale comprised of a horizontal line, of 10 centimetres (100 mm) in length, anchored by 2 verbal descriptors, one for each extreme symptom. The patient is asked to place a line perpendicular to the VAS line at the point that represents their pain intensity. Using a millimetre ruler, the score is determined by measuring the distance on the 100-mm line between the "no pain" anchor and the patient's mark, providing a range of scores from 0–100, or as more commonly reported, scores of 0-10 (conversion to cm). A higher score indicates greater pain intensity.

▪ <u>Subjective Functional results</u>: measured with IKDC score **(annex 11)** and Lysholm score **(annex 12)**. Patients will be asked to fulfil the 'IKDC SUBJECTIVE KNEE EVALUATION FORM' and the 'LYSHOLM KNEE QUESTIONNAIRE' and a score of knee functionality is obtained for each form. These forms will be assessed at 1 month, 6 months, 1 year and 2 years.

<u>The IKDC score</u> is a subjective scale that provides an overall score of knee's functionality. The questionnaire looks at 3 main categories: symptoms, sports activity and overall knee function, each one with subcategories. Scores are obtained by the sum of individual items and then transforming the crude total to a scaled number that ranges from 0 to 100. Higher scores indicate a better outcome with fewer symptoms.
The patient fulfils the form in a computer through the page: http://www.orthopaedicscore.com/scorepages/international_knee_documentation_comitee.html and the final score is automatically calculated.

<u>The Lysholm scale</u> consists of 8 items that assess pain (25 points), instability (25 points), locking (15 points), swelling (10 points), stair climbing (10 points), limp (5 points), squatting (5 points) and need for support (5 points). The total score is the sum of each response to the 8 questions and may range from 0-100. Depending on the final number obtained, the Lysholm score sets 4 grades: Excellent (>90); Good (84-90); Fair (65-83); Poor (<65).
The patient fulfils the questionnaire in a computer through the page: http://www.orthopaedicscore.com/scorepages/tegner_lysholm_knee.html and the final score is automatically calculated.

▪ <u>Anterior Tibial Translation:</u> measured with the KT-1000 arthrometer **(annex 13 contains the explanation of the instrument)** and calculated as the side-to-side difference, the difference between anterior tibial translations of both legs. This device measures the laxity of the ligament, applying a 134-N force in a 30º flexed knee, position where the secondary stabilizers have less function in anterior tibial translation and ACL's laxity can be better evaluated **(2.2 Biomechanics of the ACL).** Anterior tibial translation is expressed in millimetres and will be assessed at 6 months, 1 year and 2 years.

▪ <u>Complications</u>: we will measure separately the incidence of two complications: septic arthritis and hemarthrosis. These two complications were chosen as they are the most frequent, as described in literature. They will be evaluated at postoperative day 1, day 15, 1 month and 6 months. We will only assess complications until 6 months because we consider (by clinical experience) that from then on, complications may be related to other factors apart from the surgical procedures.

<u>Septic arthritis</u>: in a patient with a suspected diagnosis of septic arthritis due to pain, effusion, erythema and/or fever **(2.8.3.2 Septic Arthritis)**, we will perform a clinical examination, laboratory tests (values of ESR>30 mm/h and CRP>1.0 mg/dL are suggestive) and synovial fluid cultures. This variable will be assessed as 'yes', if present, or 'no', if not present.

<u>Hemarthrosis</u>: The presence of hemarthrosis requiring needle aspiration (significant hemarthrosis). The diagnosis is made by clinical examination **(2.8.3.2 Hemarthrosis).** This variable will be assessed as 'yes', if present, or 'no', if not.

<u>Other complications</u>: we will quantify and report other possible complications, such as deep venous thrombosis or loss of sensitivity (diagnosed by clinical protocol) that may be developed **(2.8.3 Surgical complications)**. This variable will be assessed as 'yes' or 'no' and, in writing, we will specify which was the complication developed.

6.4.3 Covariates

- <u>Age:</u> will be expressed in years.
- <u>Gender</u>: will be assessed as male or female.
- <u>Concomitant meniscal injuries:</u> any meniscal injury assessed as 'yes' or 'no'.
- <u>Body mass index (BMI):</u> will be expressed in kg/m².

- <u>Race</u>: will be assessed as white, black or other.
- <u>Sports activity per week:</u> will be registered in hours.
- <u>Preoperative total range of motion</u>: will be registered in degrees. It will be assessed because it is one factor that can affect postoperative ROM **(2.8.3.1 Loss of Motion).**
- <u>Patient knee's laxity:</u> measuring the preoperative side-to-side difference with KT-1000 arthrometer. Will be registered in millimetres.

<u>Table 6</u>. **Summary of the variables of the study**

	Variable	Type	Measurement	Units
Independent	All-inside technique or transtibial technique	CNV	-	-
Dependent	Total ROM	QCV	Goniometer	Degrees
	Flexion	QCV	Goniometer	Degrees
	Extension	QCV	Goniometer	Degrees
	IKDC score	QCV	IKDC score	Scale values
	Lysholm Score	COV	Lysholm score	Excellent, Good, Fair, Poor
	Pain	QCV	Visual analogue scale	VAS values in centimetres
	Ligament laxity	QCV	KT-1000	Millimetres
	Deep Infection	CNV	Clinical, analytical and microbiological signs	Yes or no
	Hemarthrosis	CNV	Clinical exploration	Yes or no
	Other complications	CNV	Clinical exploration	Yes or no
Covariates	Age	QCV	Clinical history	Years
	Gender	CNV	Clinical history	Male or female
	Race	CNV	Clinical history	White, black or other
	Concomitant meniscal injuries	CNV	Previous MRI	Yes or no
	Body Mass Index	QCV	Clinical Exploration	Kg/m^2
	Sports activity per week	QCV	Clinical history	Hours
	Preoperative ROM	QCV	Goniometer	Degrees
	Knee's laxity	QCV	KT-1000	Millimetres

ROM: Range of Motion; **CNV**: Categorical Nominal Variable; **COV**: Categorical Ordinal Variable; **QCV**: Quantitative Continuous Variable

6.5 STUDY INTERVENTIONS

The main objective of this study is to compare the postoperative range of motion in two different treatment options. One group will receive intervention A: All-inside ACL reconstruction technique and the other group will receive intervention B: Conventional transtibial ACL reconstruction technique.

Once the patient is diagnosed, meeting the inclusion and not exclusion criteria, he/she will be asked to take part in our study. An information sheet **(annex 5)** will be given to inform the patient. If the patient agrees, informed consent for the study **(annex 6)** will be given and

signed, and randomization will proceed. An informed consent for the surgery **(annex 8)** must also be signed.

The surgery will be scheduled to two months after the injury and it will be performed at the operating room of Hospital Universitari Dr. Josep Trueta by the knee surgical team, with Dra. María José Martínez (MJM) as the main surgeon.

6.5.1 Intervention A: All-inside technique

Preoperative care will consist of anaesthesiology assessment before the intervention. The patient is positioned supine with the knee flexed to 90° using a footrest and side support. General anaesthetics will be performed, a pneumatic tourniquet will be used and intravenous prophylactic antibiotics will be administered. If there is any concomitant meniscal injury, it will be repaired in the same surgery, before the ACL reconstruction. The standard surgical approach will consist of the following **(annex 2)**:

1. Skin incision over the insertion of the semitendinosus.
2. Harvesting, selection and preparation of the graft.
3. Skin incision in anteromedial and anterolateral zones of the patella.
4. Identification of the femoral ACL footprint, debridement of the remaining fibres and introduction of a marking hook.
5. After a small incision 1cm above and 2,5cm anterior to the lateral femoral epicondyle, introduction of a guide pin and creation of the femoral socket with a retrograde drill – FlipCutter® (Arthrex). Passing of a pulling suture from the recently created socket until the anteromedial portal.
6. Identification of the tibial ACL footprint, debridement of the remaining fibres and introduction of a marking hook.
7. Introduction of a guide pin sleeve through the incision previously made over the semitendinosus, and creation of the tibial socket with a retrograde drill – FlipCutter® (Arthrex). Passing of a pulling suture from the recently created socket until the anteromedial portal.
8. The pulling sutures are assembled to both ends of the graft, creating a graft loop suture.
9. Pull the graft into the femoral socket and flip the button to provide a cortical fixation. With the TightRope® system, completely fill the socket. *First we flip, then we fill.*

10. Pull the graft into the tibial socket and flip the button to provide a cortical fixation. With the TightRope® system, completely fill the socket. *First we flip, then we fill.*

11. Suture of skin incisions (subcutaneous and cutaneous plans).

12. Bandage of surgical wounds.

6.5.2 Intervention B: Transtibial Technique Using Transfix

Preoperative care will consist of anaesthesiology assessment before the intervention. The patient is positioned supine with the knee flexed to 90° using a footrest and side support. General anaesthetics will be performed, a pneumatic tourniquet will be used and intravenous prophylactic antibiotics will be administered. If there is any concomitant meniscal injury, it will be repaired in the same surgery, before the ACL reconstruction. The standard surgical approach will consist of the following **(annex 1)**:

1. Skin incision over the insertion of the pes anserinus.

2. Harvesting, selection and preparation of the graft.

3. Skin incision in anteromedial and anterolateral zones of the patella.

4. Identification of the tibial ACL footprint, debriding the remaining fibres and introduction of a marking hook.

5. Introduction of a guide pin through the incision previously made over the pes anserinus and creation of a tibial tunnel with a drill. Removal of the drill.

6. A guide pin is inserted again through the tibial tunnel and over-the-top position in the femur is identified, near the ACL footprint. Following the position of the guide pin, the femoral socket is performed using a drill.

7. Removal of the drill and introduction of the Transfix Tunnel Hook® in the top of the femoral socket.

8. Assemble the Transfix Tunnel Hook® with Transfix Drill Guide® and Transfix Guide Pin Sleeve®. Advance the Guide Pin Sleeve® from the lateral until its exiting in the medial side of the femur.

9. Remove the Transfix Tunnel Hook® from the tibial tunnel. The Passing Wire® will also exit the tibia with the hook.

10. Pass the graft through the Passing Wire® with its end lengths equalized.

11. Pull away the Passing Wire® free ends until the graft fills the femoral socket.

12. Insert the Transfix Dilator® over the Passing Wire®, to create a pilot hole for the Transfix Implant®. Insert the Transfix Implant® from lateral to medial.

13. Insert the interference screw by the tibial tunnel.
14. Suture of skin incisions (subcutaneous and cutaneous plans).
15. Bandage of surgical wounds.

In both interventions, postoperative care will include the administration of analgesia during the first 7 days and crutches during the first 4 weeks. Patients will stay in the post-surgical unit until recovering from anaesthesia. After their recovery, patients will be transferred to the OTS unit for one day and analgesia will be provided. The rehabilitation process must be followed as previously explained **(2.8.4 Rehabilitation of ACL reconstruction).** The standard rehabilitation protocol will be performed in Centre d'Atenció Primària (CAP) Güell, in Girona, since it is the associated rehabilitation center of the Hospital Universitari Dr. Josep Trueta.

6.5.3 Safety

Patients will be informed about the benefits and the risks of the participation in the study. This information will be provided in an information sheet **(annex 5).** The informed consent for the surgery also provides information about the procedures and its risks **(annex 8).**

The benefits of the reconstruction of the anterior cruciate ligament are: increased knee stability, less pain, less development of additional articular injuries, increased range of motion and increased subjective sense of knee function. Recent studies have showed that all-inside technique has lower postoperative pain due to less morbidity.

The surgical steps of both procedures are in its essence comparable – drilling of two osseous tunnels fixing an autograft – so complications may be similar between the techniques and can be: wound infection, soft tissue infection, articular infection (septic arthritis), technical failure, muscle atrophy, bleeding (hemarthrosis), stiffness, loss of range of motion, deep vein thrombosis and pulmonary embolism. Vascular and nerve injury may also be presented and if this injury is irreversible, patient may be amputated. Every surgical intervention has implicit complications that can be potentially serious, and may require additional treatments (either surgical or medical) or progress, in a low percentage of cases, to death.

6.6 DATA COLLECTION

First visit

In a previous visit, a suspected diagnosis of an ACL tear is done and radiographs and a MRI are scheduled.

In the following visit (which will be considered as the <u>first visit of this study</u>), usually two weeks later, we already have the results of the MRI and we assess if the patient has a <u>confirmed diagnosis of an ACL tear grade III</u>.

Patient diagnosed with an ACL tear grade III by imaging diagnosis and with a clinically unstable knee, will be explored **(2.6 Clinical diagnosis)** to confirm the ACL tear. A thorough clinical history will also be assessed, asking for age, sex, profession, sports activity per week, date and mechanism of injury and about the desire to reconstruct the ACL tear.

If the patient meets the inclusion and not exclusion criteria, he/she will be proposed to participate in the study. We will give the trial's information sheet **(Annex 5)** and will be necessary to sign the informed consent for the study **(Annex 6)** as well as the surgical consent **(annex 8).**

After given the consent, we will schedule the surgery to two months since the injury. A code will be assigned to each patient to decide which treatment will be applied**.** A new Participant Data Sheet **(annex 9)** must be filled with patients' data.

Second visit – Surgical Intervention

<u>Hospital admission</u>

The patient will be admitted on OTS department in the day programmed and must fast 8h before the intervention. The nursing team will check vital signs before the hospitalization. Proceeding surgeons will explore and assess the patient during the hospitalization before the intervention.

<u>Preoperative assessment – Anaesthesiology</u>

The anaesthesiologist will assess the patient before the intervention, during the patient's hospitalization. American Society of Anaesthesiologists (ASA) Physical Status Classification System score will be used for surgical risk.

Preoperative assessment – OTS

An orthopaedic surgeon not involved in the surgery (OTS-N) will perform a preoperative examination that includes:

- Total range of motion: measuring with a goniometer, in the injured leg, the examiner will quantify the maximum values of passive flexion and extension and calculate the total range of motion.

- Knee's laxity: measuring with the KT-1000 arthrometer **(annex 13)**, with the patient in supine and his knees in 30º of flexion, the examiner will apply a 134-N force and measure the anterior tibial translation. This examination will be performed in both legs, recording the side-to-side difference, calculated as the difference between the anterior tibial translation in the injured and the non-injured knees.

This will be helpful to assess the covariates 'Preoperative range of motion' and 'Knee's Laxity' **(6.4 Study variables).**

Surgical procedure

Both surgical techniques are currently performed by the knee surgical team, so there is no need to train the surgeons before starting the study. Every patient will have a code that designs to treatment 1 or 2. The main investigators will decide which treatment, A or B, correspond to each number **(6.3.4 Randomization).**

The procedure will be performed by the main surgeon (Dra. Maria José Martínez), an associate surgeon (Dr. Didac Masvidal) and an OTS internship (OTS-I), an instrumentalist nurse and one anaesthesiologist.

The intervention will be performed in the operating room and time of surgery, from first skin incision to skin suture, and any complication during the procedure must be registered.

Postoperative care

Independently of which surgical technique is performed, the patient will stay in the post-surgical unit until he recovers from anaesthesia. After his recovery, the patient will be transferred to the OTS unit for one day and analgesia will be provided. The rehabilitation process must be followed as previously explained **(2.8.4 Rehabilitation of ACL reconstruction).**

In the OTS unit the nursing group will provide his primary care assistance. The OTS-N will assess the patient's pain level 24 hours after the surgery (using a VAS scale) as well as register any complication. This will be considered as the 1st assessment of the follow-up.

Nursing team will record all the incidences during the hospitalization and OTS doctor will discharge the patient after one day, if he/she is able to go home, providing analgesia until the 7th day. The patient will be scheduled to suture removing at the 15th postoperative day. If needed, additional appointments with an orthopaedic surgeon (extern to our study) will be done. Those appointments will not be related to our study.

Follow-up

The duration of the follow-up will be of 2 years. The results will be recorded during the follow-up visits in the outpatient service at 15th day and at 1st, 6th, 12th and 24th months. The information will be collected in the Participant Data Sheet **(annex 9)**. If any complication appears after the intervention, the patient is informed to come back as soon as possible.

The follow-up examination will be performed by an orthopaedic surgeon non-involved in the reconstruction (OTS-N) measuring ROM, pain level, ligament laxity and subjective scores of knee function along with assessing any complication.

Data collection steps are synthetized on a schedule of assessment **(Figure 19).** A study flow chart is also presented below **(Figure 20).**

Time since injury	0D	2W	2M	2M, 1D	2M, 15D	3M	8M	14M	26M
Patient diagnosis and enrolment									
Anamnesis	■	■							
Physical examination	■	■							
Clinical diagnosis	■	■							
Imaging diagnosis		■							
Information sheet		■							
Informed consent (study and surgery)		■							
Participant Data Sheet		■							
Assignation of numeric code		■							
Hospital admission									
Vital signs assessment			■						
Anaesthesiology assessment			■						
OTS preoperative assessment									
- Total ROM			■						
- Ligament laxity			■						
Surgical procedure									
- All-inside technique (A)			■						
- Transtibial technique (B)			■						
Postoperative care									
Recovering from anaesthesia			■						
Hospitalization			■	■					
Analgesia			■	Until 2M, 7D					
Physical Therapy				■	■	■	■		
Follow-up visits									
Suture removing					■				
Complications recording				■	■	■	■		
Pain level				■	■	■	■	■	■
ROM (total, flexion, extension)							■	■	■
Ligament laxity							■	■	■
Subjective scores						■	■	■	■

Figure 19. **Schedule of assessment. D**: Day; **W**: week; **M**: month; **ROM**: Range of Motion; **OTS**: Orthopaedic and Trauma Surgery
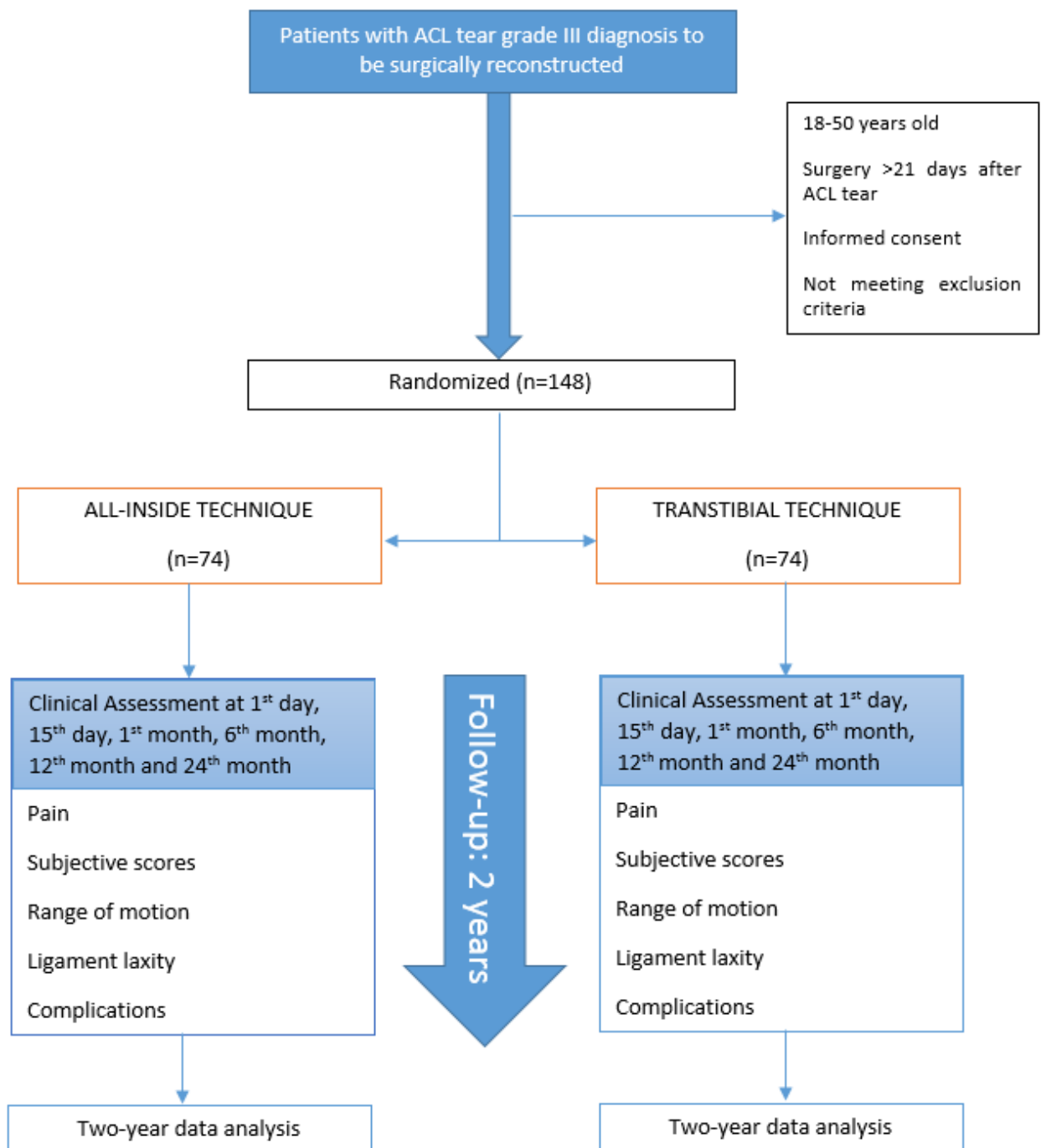
Figure 20. **Study Flow Chart. The follow-up is performed during two years and, after this time gap, the data analysis is made.**

6.7 STATISTICAL ANALYSIS

A detailed statistical analysis plan will be made on all randomized patients using an intention-to-treat analysis. This will be performed with the Statistical Package for the Social Science (SPSS) software for Windows®.

Univariate Analysis

Variables were defined as categorical nominal, categorical ordinal or quantitative continuous **(6.4 Study variables).** The results will be expressed as percentages for *categorical variables.* For *quantitative variables*, we will use the mean +/- standard deviation (SD) or median (with first and third quartile), depending on whether or not, they are normally distributed, respectively.

Bivariate Analysis

For the primary objective, the independent variable (all-inside or transtibial technique) was defined as a categorical nominal variable and the primary dependent variable, the range of motion, as a quantitative continuous variable. Therefore, T-student or U-Mann-Whitney test will be used, whether or not they are normally distributed, respectively.

For the secondary objectives, the pain level, the IKDC score and the ligament laxity were defined as quantitative continuous variables. Hence, to compare these outcomes between both procedures, we will use the T-student or U-Mann-Whitney test, whether or not they are normally distributed, respectively.

The Lysholm score was defined as a categorical ordinal variable. Thus, a Chi-Square test will be used.

The presence of complications (septic arthritis, hemarthrosis and other complications) reported after each technique was defined as a categorical nominal variable. Thereupon, a Chi-Square test will be used. A confidence interval of 95% will be assumed and $p<0.05$ will be considered statistically significant.

Multivariate analysis

A multivariate analysis will be performed to adjust our variables for covariates (age, gender, race, concomitant meniscal injuries, body mass index, sports activity per week, preoperative range of motion and knee's laxity), in order to avoid potential confounding that may modify the final results. Thus, we will use a multivariate logistic regression for *categorical variables* and a general lineal model for *quantitative continuous variables*.

A confidence interval of 95% will be assumed and $p<0.05$ will be considered statistically significant.

6.8 WORK PLAN AND CHRONOGRAM

6.8.1 Work Plan

Main researchers: Dra. Maria José Martínez (MJM), Alexandre Coelho Leal (AC)

Collaborators: Dr. Didac Masvidal (DM), OTS internship (OTS-I), Surgery Nursing staff (SNS), OTS doctor non-involved in surgery (OTS-N), Nursing staff (NS), Statistician (ST).

This study is expected to last a total of 79 months (approximately 6,5 years), from March 2017 until September 2023, divided in 4 months of pre-field work, 68 months of field work and data collection, plus 1 month for data analysis and 6 months for results publication. The activities carried out during this time will be organized in 5 phases which are detailed below and diagrammed **(6.8.2 Chronogram):**

0. Preparation phase – 3 months:
Conducted by: MJM, AC.

The study protocol must be accepted by the Clinical Research Ethics Committee of the Hospital Universitari Dr. Josep Trueta.

1. Coordination phase – 1 month:
Conducted by: MJM, AC, DM, OTS-I, SNS, OTS-N, NS, ST.

In this phase, the chronogram will be set up and each researchers' activity will be described, step by step. The protocol will be detailed to all members, explaining how the patient recruitment and the data collection will proceed. The hypothesis, objectives, variables and methods will be discussed.

2. Field work – 68 months
Conducted by: MJM, AC, DM, OTS-I, SNS, OTS-N, NS.

Sample recruitment (42 months - 3.5 years): patients who undergo to a reconstruction of an ACL tear grade III, meeting the inclusion and not exclusion criteria for the study will be collected and offered to participate in the study. The informed consents for the study **(annex 6)** and for the surgery **(annex 8)** must be signed. A code will be assigned **(6.3.4 Randomization)** and patients will be randomly distributed in two different groups (all-

inside technique or transtibial technique). There are 42 cases per year of ACL reconstructions that meet inclusion criteria and not exclusion in Hospital Universitari Dr. Josep Trueta. Thereby, it will take three and a half years to recruit all the 148 patients.

<u>Intervention and follow-up (5.5 years)</u>: patients included in the study will undergo through the assigned interventions, either all-inside technique or transtibial technique, *two months after the recruitment.* MJM, DM and OTS-I will perform the intervention. SNS will instrument the intervention.

NS working at OTS unit will attend the patients during its hospitalization and the OTS-N will realize the first assessment on the 1st postoperative day. The OTS surgeons will also visit the patients in the 1st postoperative day and discharge them to home.

Each patient will be followed during two years after the surgical reconstruction. The follow-up will be performed by OTS-N as a blind investigator. Control visits will be programed at 15th day and 1, 6, 12 and 24 months after the surgery, assessing the range of motion, ligament laxity, subjective knee scores and pain level as well as reporting any complication.

3. Data collection – 66 months (5,5 years)
Conducted by: MJM, AC, OTS-N

All data collected during the follow-up will be recorded in a created database and reviewed every 3 months by the main investigators to control that the protocol is being followed and all data is properly registered.

4. Statistical analysis - 1 month
Conducted by: ST

After all the data is collected, it will be analysed using the appropriate statistical tests set in the protocol for each objective **(6.7 Statistical Analysis)**. This will be performed by the blinded ST.

5. Results interpretation and publication - 6 months
Conducted by: MJM, AC

Once statistical analysis is performed, principal investigators MJM and AC will interpret the results and draw conclusions. Principal investigators will also write and edit a scientific paper to publish.

6.8.2 Chronogram

Months	2017				2018	2019	2020	2021		2022	2023		
	3-5	6	7-8	9-12	1-12	1-12	1-12	1-2	3-12	1-12	1-2	3	4-9
Phase 0: Preparation – MJM, AC													
	▓												
Phase 1: Coordination – MJM, AC, DM, OTS-I, SNS, OTS-N, NS, ST													
		▓											
Phase 2: Field Work – MJM, AC, DM, OTS-I, SNS, OTS-N, NS													
Recruitment			▓	▓	▓	▓	▓						
Intervention				▓	▓	▓	▓	▓					
Follow-up				▓	▓	▓	▓	▓	▓	▓	▓		
Phase 3: Data Collection – MJM, AC, OTS-N													
				▓	▓	▓	▓	▓	▓	▓	▓		
Phase 4: Data Analysis – ST													
												▓	
Phase 5: Results interpretation and publication – MJM, AC													
													▓

Figure 21. Chronogram of the study

7. **ETHICAL AND LEGAL ASPECTS**

The Clinical Research Ethics Committee of the Hospital Universitari Dr. Josep Trueta will evaluate this study protocol and its methods, and it will not be applied unless it has its approval. Our ethical code is reflected on the great respect about all basic ethic principles according to the World Medical Association Declaration of Helsinki. The committee shall ensure that the study respects the ethical principles for medical research involving human subjects established by Helsinki's Declaration, and that the privacy of all the participants is protected and confidential as well as their personal information. Any further recommendation from the Committee will be taken into account in order to improve the procedure. This clinical trial will be registered in ClinicalTrials.gov.

Participants will be properly informed about the interventions and the clinical trial with an information sheet **(annex 5)**, where the risks, benefits and alternatives are reflected. If they are interested and accept to participate voluntarily, therefore, they must read, understand and sign the informed consent **(annex 6)** to enter the study and an informed consent for the surgical procedure **(annex 8)**. A revocation consent for the study will also be provided, if participants wish to leave the study **(annex 7).** Thus, the principle of autonomy will be respected.

This study includes an invasive procedure performed on the participants of both groups and the Spanish law 14/2007 of the 3rd of July about Biomedical Investigation must and will be respected. Specifically the section II details the basic principles, requirements, authorization and security of the studies in which a human being undergoes an invasive procedure.
According to the same law (14/2007), patients submitted to any procedure that may imply any physical or psychic risk, shall be insured. Thus, we will include in our study an insurance policy and all participants will be insured if any damage is caused.

Participants' data will be handled respecting Spanish organic law 15/1999 of the 13th of December about data protection, confidentiality and protection of personal data, and RD 1720/2007 of the 21st of December on personal data protection. Therefore, to maintain confidentially of personal data, a code number will serve as identification and will be used instead of the patient's name. This way again, the principle of autonomy will be respected.

Stated in the Spanish Constitution of 1978, article 43, the right of health protection is preserved on this trial.

Exclusion criteria could be contradictory to the principles of justice and beneficence. However, patients excluded (partial ACL tears, concomitant injuries) are treated with a different approach, either conservative treatment or different surgical techniques. Also, doctors and other medical workers who take part in it are accredited and well prepared for their assigned tasks, so the principle of non-maleficence will be respected.

8. <u>**STRENGTHS AND LIMITATIONS**</u>

The main limitation of this clinical trial is that it is based on a surgical procedure which disallow us to design a double-blind study, since the surgeons cannot be blinded, which can cause a detection bias. To overcome this limitation, the patients will be blinded to the surgical procedure, the follow-up examiner will be different to the surgeons who perform the procedure and the statistician will also be blinded when analysing the obtained data.

The second limitation is related to the method of the recruitment. The consecutive recruitment is non-probabilistic and may not obtain the best representative population, so a selection bias may be done. Nonetheless, to minimize this bias, rigorous inclusion and exclusion criteria have been set, and we estimate that the reference population to whom the protocol results are directed is very similar to our sample.

Inclusion and exclusion criteria are also designed to diminish the possible confounding factors. This study will not include patients older than fifty years old because the surgical approach may not be the most indicated. In addition, the outcomes such as the motion could be affected due to degenerative changes. Also, this study will not include patients younger than eighteen, because they are skeletally immature and their growth plates could be compromised with the surgery. The exposed facts may cause a selection bias.

We did not include high-performance athletes due to their special requirements and different rehabilitations protocols of the general population, so the conclusions of this study cannot be extrapolated to that special population.

Withdrawals during the follow-up can also cause a selection bias. An intention-to-treat analysis will be made to provide unbiased comparisons among groups. We are aware that in a follow-up of two years, patients may fail one of the visits due to different causes. For that reason, we will reschedule that visit to one week later in order to avoid withdrawals and no data collection of that period. We estimate that a 1-week time gap will not affect the results of the measurements. Withdrawals will be registered in the study and described in the results. Furthermore, losses during follow-up can also cause the same bias. These losses will be quantified.

However, to avoid this bias, we have already calculated the sample size with expectations of future losses and withdrawals, with base in previous studies of the same characteristics (comparison of techniques in a 2-year follow-up).

One of the strengths of the protocol is the experimental randomized blinded design. Randomization will help to distribute symmetrically the covariates on both groups to be able to extrapolate the future results on general population between 18 and 50 years. Besides, as previously commented **(3. Justification)**, there is a lack of this type of study in the literature, so it would be interesting to be able to extract conclusions once performed.

Pain and knee's functionality are subjective items. To overcome this limitation we will apply standardized, validated scales such as VAS, IKDC score and Lysholm score that obtain a final number, diminishing the subjectivity and allowing for comparisons.

We will perform a unicenter study and the surgical procedures will be performed by the same surgical team to avoid a procedure bias. Both procedures are detailed with the steps ordered to avoid interindividual surgical differences.
Nonetheless, this will lead to an increased time of patient enrolment. It would be interesting in a future to create a multicenter study in order to increase sample size for increasing statistical power and reduce time of recruiting. Also, long-term follow-up should be considered in future studies, especially to study the long-term incidence and progression to knee osteoarthritis in both techniques.

A large time of enrolment (3,5 years) will lead to a large time of field work (5,5 years). Our study is expected to last approximately 6,5 years from its beginning until its publication. We are aware that in 6,5 years, new studies including our objectives (and comparing these techniques) may be published and new techniques of ACL reconstruction may be described. However, we consider important that surgical procedures be performed by the same surgical team to avoid surgical differences which could cause a procedure bias. Also, the majority of the studies of the literature (comparison of 2 ACL reconstructive techniques with a follow-up of 2 years) last 4-8 years, and our study fits in that time gap.

Sample size and methods are designed to study the main objective, thus secondary objectives may not have a significant result. However, we estimate that almost all of the secondary objectives will reach significant clinical values except for the ligament laxity and complications.
In this case, the IKDC refers that only a side-to-side difference of >3mm is associated with instability, or in other words, is clinically relevant **(2.6 Clinical diagnosis).** The

conventional transtibial technique already presents side-to-side differences <3mm, as well as the all-inside technique results obtained in previous studies (preoperative versus postoperative status). We hypothesize that the all-inside technique will obtain lower laxity values which will show us a better ligament function, however without being clinically relevant.

The complications' rates and incidence in ACL reconstruction are low. For instance, septic arthritis is one of the most common complications and its rates are estimated to be in 0,14%-1,7%. In a sample size of 148 patients, we expect that a few number of patients will present complications and we will not be able to properly assess which technique presents lower complications' rates.

We will assess complications in 3 items: the two most frequent will be assessed separately and a third item will include all other possible complications. We are aware that not all of them have the same importance. However, since they are infrequent, we consider that assessing as 'other complications' and reporting which of them were developed is a suitable approach to encompass any complication that may appear. Complications will only be assessed until 6 months. This is explained because, by clinical experience, any complication that may appear since then can be related to other factors apart from the surgical procedures.

9. **FEASIBILITY**

This study will take place exclusively in Hospital Universitari Dr. Josep Trueta, in Girona, which has an OTS department with surgeons specialized in knee pathologies. The hospital will provide all the necessary means such as personnel salaries, surgeries, cures and additional procedures. Computer devices and programs to elaborate the database and to carry out the statistical analysis will also be provided.

The main investigators will be Dra. María José Martínez, OTS surgeon at Hospital Universitari Dr. Josep Trueta, and Alexandre Coelho Leal, Medical Student at Universitat de Girona. The medical team who will be part of this study, composed by knee surgeons and nursing staff, is familiar and well trained to the procedures performed, since both techniques are currently performed in this department. The examiner will also be a knee surgeon of the OTS department, despite that is not involved in the surgical procedures and rehabilitation team is also familiar to the standardized rehabilitation protocol. There are not specialized professionals in statistics, therefore an external statistician will be hired to perform the statistical analysis.

The operation room will be the orthopaedics operating room. As both procedures are already performed in this department, some of the resources are in stock and others will be requested, as they are currently. Patients will be hospitalized one day after the intervention, on OTS unit, so beds must be available.

Table 7. **Materials needed for the techniques**

ALL-INSIDE TECHNIQUE	TRANSTIBIAL TECHNIQUE
Graft Preparation Station	Graft Preparation Station
Guide Pin®	Guide Pin® and Drill
FlipCutter®	Transfix Tunnel Hook® and Drill Guide®
TightRope® with an endobutton	Passing Wire®
Pulling Sutures	Transfix Implant® and Interference Screw

In both techniques we will also need an arthroscopic equipment, surgical instruments, sterile gloves and sterile gowns, sterile compresses, sutures and sterile bandages. Follow-up material such as goniometers, KT-1000 arthrometer and an available computer to fulfil the subjective scores are currently in stock of the department.

It is estimated that in the Hospital Universitari Dr. Josep Trueta, around 51 patients per year undergo an ACL reconstruction and 42 of them meet the inclusion and not exclusion criteria. To find the main hypothesis relevant, we estimated that the sample size should be 74 patients per group, so we expect that in 79 months, starting in March 2017, of patient recruitment, follow-up and data collection, we will have the final results of the study.

10.   __BUDGET__

Performing this study do not suppose an increase of the costs of the surgical intervention, an increase in the number of the personnel or additional training processes and formation. This can be explained because both surgical techniques are currently performed in the OTS department. So, no additional cost for medical staff will be included in the budget.

After the surgical procedure, patients will be hospitalized during 1 day. Many hospitals of the country do not include hospitalization in their postoperative plan but our hospital does, so we will not take in account this cost. Currently, the hospitalization period is in charge of the National Health System.

This study will not suppose an increase on administrative costs related to the scheduling of the surgery or patients' visits, because we will follow the current practice.

The patients will follow a 6-month rehabilitation protocol in CAP Güell after the procedure. Rehabilitation is already part of the postoperative plan after ACL reconstructions performed in our hospital, so this will not suppose an increase of the costs.

It is necessary to hire a statistical expert for data analysis due to the lack of knowledge of the team in this area. It is estimated that 1 month will be needed for the data analysis, in a total duration of 160h of work payed at 25€/h. Total costs are 4000€.

In regard to the surgical materials **(9. Feasibility)**, the specific instruments needed for the techniques, such as the FlipCutter® or the Transfix Implant®, are provided by the National Health System. Some of the materials are currently in the stock of the department and the rest of the material needed will be requested, as it is currently.

The follow-up material will include a goniometer, a KT-1000 arthrometer and a computer to fulfil the questionnaires. The OTS department already have these materials in stock so there is no need to purchase any material to perform the follow-up.

We estimate that the cost of printing and material needed (for information sheets, informed consent sheets and participant data sheet) will be of 100€. Pens, paper, staplers and other office materials will be included in 'Office Supplies', with the estimated cost of 70€. As previously exposed **(7. Ethical and legal aspects),** patients will be insured for any possible damage due to the intervention. The insurance policy costs are budgeted on 6000€.

Once the study is finished, all collected data will be reflected on a scientific paper to be published and disseminated to the scientific community with the following costs:

a) Translation services: 200€.

b) Publication expenses in international scientific journals with an open access: 1500€

c) Attendance on national and international congresses for the broadcasting of the results in SECOT (Sociedad Española de Cirugía Ortopédica y Traumatología) and ESSKA (European Society of Sports Traumatology, Knee Surgery and Arthroscopy) congresses: 450€ and 750€ respectively. The date, duration and location of the congresses is still unknown, so the budget for travel, accommodation and food allowances can change. However, we estimate the costs in 400€ per person for the national congress and 500€ per person for the international and two people will attend to these congresses, in a total of 900€ per person.

d) Other expenses included in **table 8.**

Table 8. Budget

	Price	Quantity	Total Cost
STAFF AND SERVICES			
Medical staff	Provided by the National Health System (NHS)		
Hospitalization	Provided by the NHS		
Administrative costs	Provided by the NHS		
Rehabilitation staff	Provided by the NHS		
Statistical expert for data analysis	25€/h	160h	4.000€
Translation services	200€	1	200€
Insurance policy	6.000€	1	6.000€
MATERIAL			
Surgical Material	Provided by the NHS		
Follow-up material (goniometer, KT-1000 arthrometer and computers)	Already in stock		
Office Supplies	70€	1	70€
Printing and other materials	100€	1	100€
Data storage (pen-drives, hard-drives)	10€/unit	10	100€
PUBLICATION AND DISSEMINATION			
Publication expenses	1.500€	1	1.500€
Inscription to SECOT congress	450€	2	900€
Inscription to ESSKA congress	750€	2	1.500€
Travel, accommodation and food	900€	2	1.800€
TOTAL			16.170€

11.   **<u>IMPACT</u>**

The all-inside technique is an emerging procedure to reconstruct an ACL tear. The main aim of this project is to assess if there are better functional results using this technique than using the conventional (transtibial) technique, including the range of motion (ROM). Recent studies have shown that the postoperative pain is lower in this recent procedure. Other studies have also shown that after performing the all-inside technique better functional results (postoperative status) are obtained, comparing with the preoperative status.

However, functional results between both techniques were not assessed and further investigation is needed in order to make recommendations, and that is the reason why we propose this protocol.

If our hypothesis is confirmed and the results obtained are significant, the all-inside technique can be recommended as a preferable technique than the conventional transtibial one for the benefit of our patients. Firstly, because it mimics better the original ligament, demonstrated as presenting better functional results such as knee's ROM and ligament laxity. And secondly, because we can achieve this results with decreased morbidity, expressed as lower postoperative pain.

It was also observed that an increase in ROM and a decrease in pain lead to an increment of the sense of knee function **(2.8.3.1 Loss of motion),** therefore, if our hypothesis is confirmed, we expect to obtain higher values of subjective scores as well.

It is also expected that if our hypothesis is not confirmed or we find new relationships between the outcomes, this study will encourage other research teams to perform new studies about this technique.

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13.   ANNEXES

ANNEX 1: TRANSTIBIAL TECHNIQUE

Table 1. **Summary of the steps performed in transtibial technique.** Based on (37)

Graft selection, length and preparation	The gracilis and the semitendinosus (isquiotibialis) are harvested and tensioned in a graft preparation station. The graft diameter shall be measured and the overall graft length after tensioning should be between 100-120mm **(Fig. 1)**. The graft tensioning is done to produce maximum stretching and to avoid the stretching of the graft once it is already fixed that would create laxity of the joint.
Creation of arthroscopic portals and identification of ACL footprint	Two arthroscopical portals are created, one in anteromedial side and another one in anterolateral side. After identifying the ACL tibial footprint, remaining fibres are debrided and this zone of insertion is marked.
Tibial tunnel creation	The marking hook is locked in the ACL tibial footprint and marked at 55-60º. In the external side of the tibia, the tibial guide is placed superior to the insertion of the pes anserinus. The guide pin is drilled to stablish the direction of the tunnel and after that a drill (with the same diameter of the graft) performs the tunnel. **(Fig. 2)**
Femoral Socket Creation	A guide pin is introduced by the tibial tunnel and over-the-top position is identified in the femur, next to the femoral ACL footprint. **(Fig. 3A)** After this, a drill equal to the graft diameter performs a socket with a depth of 40 mm. Afterward, the drill and the guide pin are removed. **(Fig. 3B)**
Creating a transverse femoral passage	A Transfix Tunnel Hook® (Arthrex) with the tunnel diameter is assembled with a Transfix Drill Guide® (Arthrex) and a Guide Pin Sleeve® (Arthrex). This Guide Pin is positioned on the skin of the lateral thigh. A small skin incision is done and the sleeve is advanced to the bone **(Fig. 4)**. After that, a 5-mm reamer drills a 'tunnel' over the guide pin that will be of importance to the placement of the Bio-TransFix® implant (see following steps). A Passing Wire (composed by Nitinol, a Niquel-Titanium alloy) is then passed through this recently created passage, and will be the mean of puling the graft into the femoral socket **(Fig. 5A)**.
Pulling the graft into the femoral socket	The tunnel Hook (with the Passing Wire engaged) is extracted from the tibia **(Fig. 5B)** dragging the Wire into the outside. The graft is then passed through the Passing Wire with the graft end lengths equalized. The wire free ends are then simultaneously pulled away and the graft advances from the tibial tunnel into the femoral socket. **(Fig. 6)**
Fixing the graft in the femur	When the graft fills the femoral socket, a TransFix Dilator® (Arthrex) is inserted over the wire to create a pilot hole for the implant and to further ensure proper graft positioning. After that, a Transfix Implant® (Arthrex) – an implant that could be compared with a screw, although it is not one – is inserted from lateral to medial to fix the graft. **(Fig. 7)**
Fixing the graft in the tibia	To fix the graft in the tibial tunnel, an interference screw is used and inserted over pressure. This screw has a 1,5mm variation in its diameter from proximal to distal (i.e: 8,5mm in proximal side and 10mm on the external side of the tunnel). The distal screw diameter shall measure 1mm more than the tunnel diameter to ensure proper fixation of the graft. Since the insertion of the screw is made on a spongy bone, it has some capacity of expansion and adapts to the screw form. **(Fig. 8)**
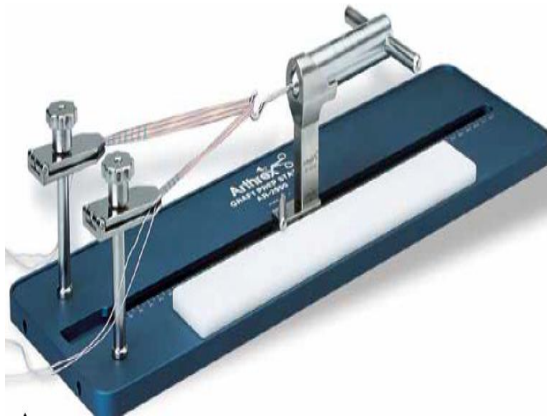
Figure 1. After the harvesting, the graft is prepared and tensioned in a graft station. A final graft length of 100-120mm should be obtained (37).

Figure 2. A marking hook is locked on ACL tibial footprint and marked at 55-60º. Over the insertion of the pes anserinus, a small incision is done and a Guide Pin® is inserted. After this, a drill performs the tunnel through the Guide Pin® and creates the tibial tunnel (37).
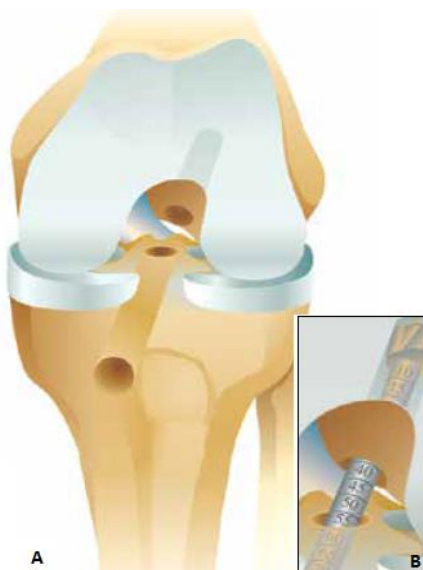
Figure 3. **3A:** The full-tunnel is performed on the tibia and the femoral socket is then performed through this recently created tunnel (transtibial). **3B:** Note that the drill has different length marks that allow us to know the depth that has been drilled. Adapted from (37)
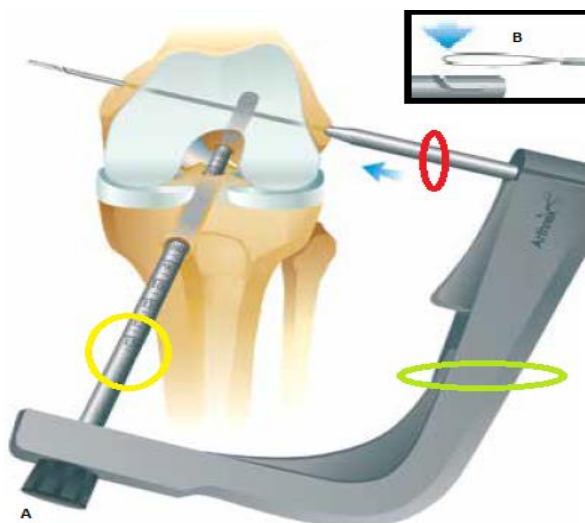
Figure 4. **4A:** A Transfix Tunnel Tunnel Hook (yellow) is assembled with a Transfix Drill Guide (green) and is introduced in tibia until the top of the femoral socket. A Guide Pin Sleeve (red) of 3-mm of diameter is advanced to the bone exiting the femur medially. **4B:** Note that the Tunnel Hook (yellow) has a little opening in its femoral end that will be useful to fix a Passing Wire, in the following steps of the surgery. Adapted from (37)
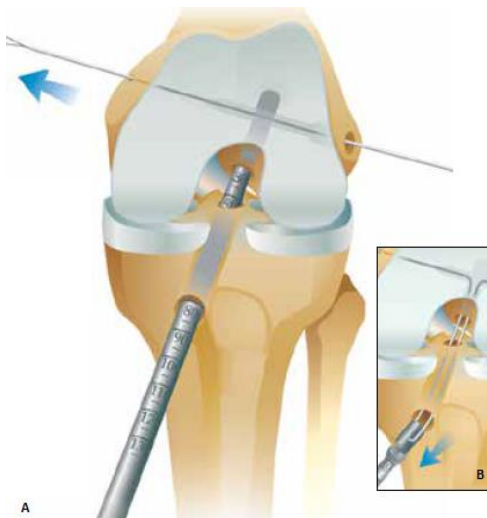
Figure 5. A Passing Wire is passed through the transverse femoral passage created (5A) and the Tunnel Hook Is then extracted dragging this wire with it (5B). Adapted from (37)
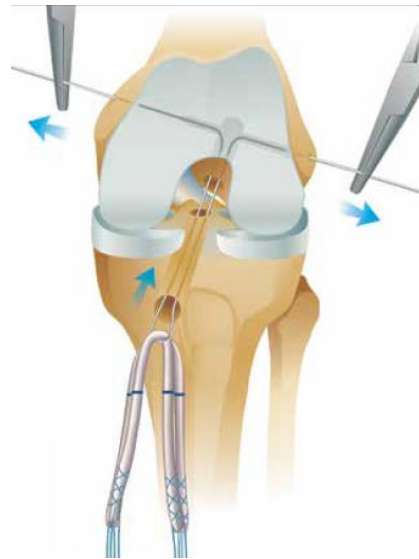
Figure 6. The midsection of the graft is the passed through the Passing Wire with graft ends length equalized. The ends of the Passing Wire are then pulled away and the graft advances from the tibial tunnel to the femoral socket (37).

Figure 7. The TransFix Implant® is inserted over the Nitinol wire as far medially as possible (37).

Figure 8: An Interference Screw is used to secure tibial fixation (37).

ANNEX 2: ALL-INSIDE TECHNIQUE

Table 1. **Summary of the steps performed in All-inside technique.** Based on (38)

|	
Graft selection, length and preparation	After the harvesting of the graft (the authors recommend a single semitendinosus harvesting, sparing the gracilis what provides increased knee stability and less morbidity), we shall consider that **the final length** of the graft may be **equal to the sum of femoral socket length plus tibial socket length plus intraarticular graft distance**. In general, the graft length previous its preparation should be of 240 millimetres (mm) in width. The preparation will allow us to obtain a **four-stranded graft** that measures 60-mm before its tensioning. After the tension, **a final graft length of 75 mm and 8 mm of diameter** is obtained. The graft tensioning is done to produce maximum stretching and to avoid the stretching of the graft once it is already fixed that would create laxity of the joint. **(Fig. 1)**
Creation of arthroscopic portals and identification of ACL footprint	Two arthroscopical portals are created, one in anteromedial side and another one in anterolateral side. In the anteromedial, a flexible silicone cannula is introduced to prevent soft-tissue interposition. After identifying the ACL footprints, remaining fibres are debrided and this zones of insertion are marked.
Socket length	Socket length is usually of 25 mm in femoral and of 30 mm on tibial side with 20 mm of intraarticular graft length. The diameter of the sockets depend on the graft, as it should be a snug fit to ensure graft biological incorporation but in general it measures 75 mm.
Femoral Socket Creation	A marking hook is locked in the femoral footprint of the ACL and marked at 110º. After that, a stab incision is done 1cm anterior and 2,5cm above the lateral femoral condyle. The guide pin is seeded and introduced in femoral bone and pressing a button it becomes a retrograde drill (Flipcutter®, Arthrex). This drill makes a 25-mm femoral socket with a thin cortical bone-bridge. **(Fig. 2)** Afterward, we reverse the drill to a guide pin again and remove it from the bone. We pass pulling sutures (FiberStick®, Arthrex) through the guide pin sleeve and remove them by the anteromedial portal, which will then allow us to pull the graft. After this procedure, only graft's pulling sutures remain in the cortical bone bridge and socket. **(Fig. 3)**
Tibial socket creation	The marking hook is locked in the ACL tibial footprint and marked at 55-60º. **(Fig. 4)** We introduce the FlipCutter® and the tibial socket is drilled (measuring 30 mm in length with a thin cortical-bone bridge), following the steps of the femoral socket creation. We pass the pulling sutures (FiberStick®, Arthrex) through the guide pin sleeve, which will allow us to pull the graft, and remove the guide pin sleeve. Only graft passing sutures remain in the cortical bone bridge and socket. **(Fig. 5)**
Graft passage and fixation	The graft is introduced in the knee by the anteromedial portal with the help of pulling sutures (FiberStick®, Arthrex). **(Fig. 6)** It is first introduced in the femoral socket and then in the tibial one. A graft loop is made through the endobutton (a loop between TightRope® and FiberStick®). **(Fig. 7)** This button also allows the cortical fixation of the graft, after it is flipped. The figure 6 explains the process of graft passage and fixation in tibia (when femoral introduction is already performed).
Graft tensioning	The femoral and tibial pull sutures tension the graft and we can adapt this tension with the TightRope system when the cortical suspensory button is already flipped. **(Fig. 8)**

Figure 1. Graft preparation: A four-stranded graft is created (with FiberWire sutures, represented in blue), loaded in a tensioning station (silver) and linked with TightRope sutures (white) (38).

Figure 2. A marking hook is locked at 100-110º and the FlipCutter enters in the femur. To pass the FlipCutter, there is a thin cortical bone bridge with 3mm of diameter (38).
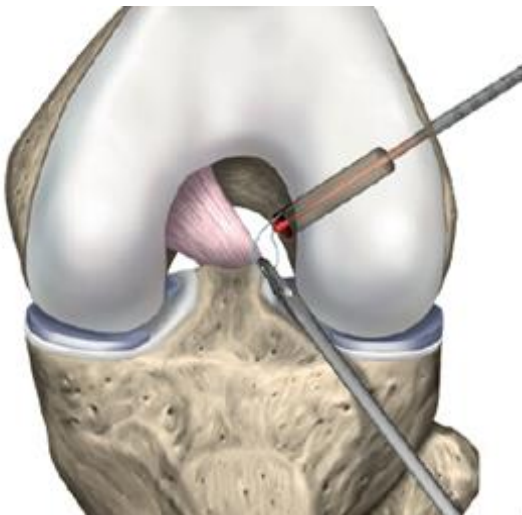
Figure 3. After "flipcutting", pass a FiberStick Suture through the drill sleeve and dock for later graft passing (38).

Figure 4. Drill the FlipCutter into the joint. Remove the marking hook (38).
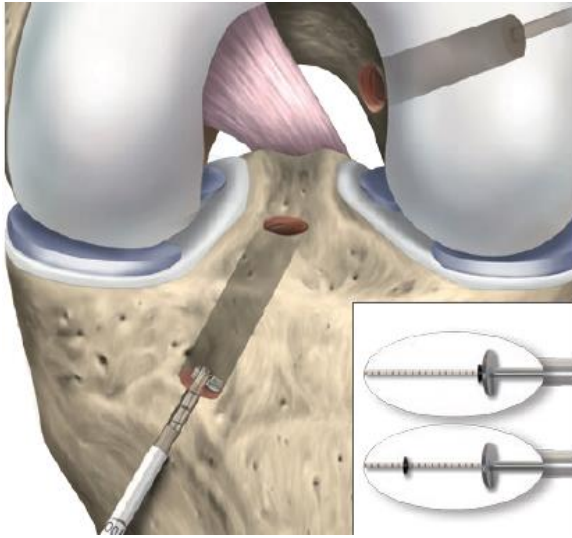
Figure 5. Flip the blade and lock into cutting position. Drill forward, with distal traction, to cut the socket (38).
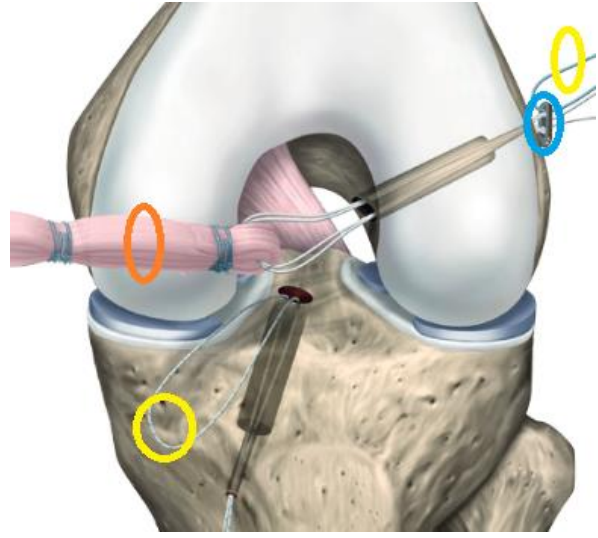
Figure 6. The graft (orange) is pulled into the femoral socket by the graft loop system. The pulling sutures (yellow) are responsible to 'drag' the graft and the TightRope system (white sutures, not circled) allows the tensioning of the graft to fill completely the socket. Note that the TightRope sutures have an endobutton (blue) that will serve as the cortical fixation once it is flipped. Adapted from (38)

Titanium Endobutton:
• Allows consistent cortical fixation
• Passes through small guide pin hole, preserving bone and decreasing surgical steps

Adjustable ACL TightRope technlogy:
• Facilitates complete filling of femoral socket with graft
• Locks securely and resists slippage due to four-point knotless fixation

Figure 7. The endobutton has two functions: it serves to assemble the TightRope® sutures with the pulling sutures (to create a graft loop) and allows the fixation of the graft in the bone. The TightRope® sutures allow the tensioning of the graft, what facilitates the complete filling of the socket (38).
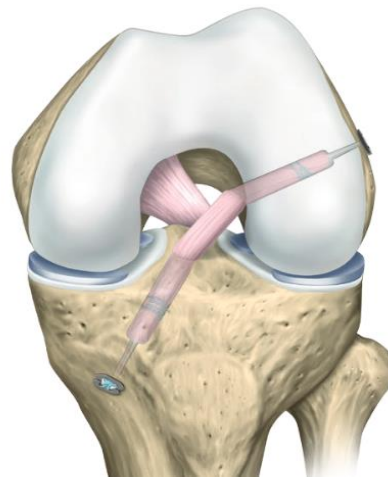
Figure 8. The final result of the all-inside technique. Note that there are two endobuttons, one in each bone. The independent drilling of the sockets allows the ACL to have an oblique orientation (38).

ANNEX 3: PHYSICAL THERAPY PROGRAM

Table 1. **Rehabilitation protocol after ACL reconstruction. Note that the protocol is only finished at 24 weeks**. Based on Wright et al. (52,53) and Meara et al. (55) recommendations

Postoperative time	Rehabilitation process	Frequency of sessions
0-2 weeks	Crutches with increasing weight bearing on injured leg after 7 days. In the first postoperative day, at the hospital, passive motion will be done. During the first 7 days, the rehabilitation will be done at home. Exercises of motion of the leg in a ROM of 0-75º will be recommended. Elevation and analgesia with ice 15 minutes per hour, what will be helpful to decrease pain and swelling. Initiation of physical therapy, at CAP Güell, in the 7th postoperative day with neuromuscular electrical stimulation, closed kinetic chain exercises, soft tissue and incisions treatments, posterior musculature exercising which will help to avoid fibrosis and range of motion exercises.	4 times/week
2-4 weeks	Total weight bearing using two crutches. Range of motion exercises (i.e. wall/heel slides, passive stretching), pain control, and continue with soft tissue treatments. Neuromuscular electrical stimulation Incorporate functional, closed-chain focused exercises and closed kinetic chain exercises. Balance and proprioception exercises	4 times/week
4-8 weeks	Removing of the crutches at 4th week, first remove one crutch and in the following week (5th week) remove the other one. Range of motion exercises, closed kinetic chain exercises until 6th week. Neuromuscular electrical stimulation, balance and proprioception exercises. From 6th week and since then, open kinetic chain exercises. Increase intensity of functional exercises. Single-leg workouts. Neuromuscular electrical stimulation. Balance and proprioception exercises. Stationary bike, leg-press and pool exercises	3 times/week
8-12 weeks	Lateral training exercises as able to demonstrate good mechanics and adequate strength. Swimming exercises with flutter kick only. Exercises for signs of diminished eccentric control, weakness, or poor ability to stabilize against varus / valgus moment with loading exercises. Proprioceptive gaining with specific exercises.	2 times/week
12-24 weeks	Begin jogging in a plan surface, preferably a treadmill. Continue and progress strengthening. Proprioceptive gaining with specific exercises. Increased intensity in jogging and combining with lateral and pivoting exercises. In the final 6 weeks (18-24 weeks), start outdoor exercises, increasing progressively the intensity. Controlled, pivoting manoeuvres.	1 time/week

ANNEX 4: CLINICAL RESULTS OF ALL-INSIDE TECHNIQUE

Table 1. Clinical results of all-inside technique

STUDY	Lubowitz et al. 2013 (56)	Benea et al. 2013 (57)	Watanabe et al. 2015 (58)	Schurz et al. 2015 (59)	Yasen et al. 2016 (60)
Treatment A	All-inside reconstruction	All-inside reconstruction	All-inside reconstruction	All-inside reconstruction	All-inside reconstruction
Treatment B	Endoscopic transtibial technique	Endoscopic transtibial technique	-	-	-
Comparison	Treatment A vs Treatment B	Treatment A vs Treatment B	Preoperative status (PR) vs postoperative status (PO)	PR status vs PO status	PR status vs PO status
Design and setting	Prospective, randomized clinical trial. Not blinded	Prospective. Randomized clinical trial. Single-blind	Prospective case series.	Retrospective case series.	Prospective case series.
Number of participants (n)	144 (73M: 71F)	46 (29M:17F)	24 (13M:11F)	79 (53M:26F)	108 (81M:27F)
Age	39,3 (A) / 41,1(B)	29,3 years	31 years	29 years	30,9 years
Follow-up	2 years	6 months	2 years	2 years	2 years
CLINICAL OUTCOMES					
Pain	PR: 2.6(A)/ 1.6(B) 1st day: 2,5(A)/ 3,8(B) 7th day: -0,1(A)/ 0,9(B) 10th day: -1,1(A)/ 0,0(B) 6 wk: -1,8(A)/ -1,2(B) 12m: -2,3(A)/ -1,2(B) 24m: -2,5(A)/ -1,7(B) NOTE. Pain scores were compared with baseline values (a negative value represents less pain). **Significant differences (S) found at 1st, 7th and 10th days and 2 years in pain level compared with baseline. All-inside (A) had significantly lower pain than endoscopic transtibial technique (B).**	In this study, the VAS used had a range of 0-100 PR: 30,9 (A)/ 28 (B) 10th day: 17,9 (A)/ 17,2 (B) 1 m: 3,2 (A)/ 8,6 (B) 6 m: 0,9 (A)/ 4,1 (B) No significant (NS) differences between groups at PR and 10th day. Significant differences at 1m and 6m. **The authors affirm that there was an underestimation of the sample size, which led to a statistical power of 0,6.**	-	PR: 5 3m: 2 6m:0,3 12m: 0,2 24m: 0,14 All-inside showed better pain levels than baseline	-
Ligament laxity using KT-1000 arthrometer (side-to-side difference measured in mm)	-	PR: 4,2 (A)/3,1 (B) 6m: 1,2 (A)/0,8 (B) NS between groups	PR: 5.36 2y: 0,05	PR: NA 2y: 1,7 mm	PR: 4,60mm 6m: 2,4 mm 1y: 1,8 mm 2y: 2,2 mm

				Significant difference respect to baseline		Significant difference respect to baseline
Range of motion (ROM)	Mean ROM	-	-	PR: 137º 2y: 143,5º	-	PR: 131,6º 6m: 136,4º 1y: 139, 3º 2y: 140,2º
	Extension	-	-	PR: -3,0º 2y: -0,87º	-	PR: -1,2º 6m: 0,04º 1y: -1,4º 2y: -1,2º No differences respect to baseline.
	Flexion	-	PR: 131,4º(A)/135º(B) 6m: 133,6º (A)/130,9º (B) Significant differences were found at 6months	PR: 134,0º 2y: 142,6º Significant difference respect to baseline	-	PR: 130,4º 6m: 136,3º 1y: 137,9º 2y: 139º Significant difference respect to baseline
Subjective scores	IKDC	PR: 47,4(A)/ 49,6(B) 3m: 60,0(A)/59,6(B) 1y: 83,3(A)/ 80,8(B) 2y:86,5(A)/ 84(B) NS differences	PR: 60,6 (A) / 62,5 (B) 6m: 81,3 (A)/ 81,1 (B) NS differences	-	PR: 44,6 3m: 70,3 6m: 88,6 1y: 89,5 2y: 89,7 Significant difference respect to baseline	-
	Lysholm	-	-	PR: 56.3 2y: 95.3	PR: 53,4 3m: 81,6 6m: 88,4 1y: 91,1 2y: 93,1	PR: 54,9 6m: 81,4 1y: 86,3 2y: 88,1
Radiological Outcomes		No significant differences were found in tibial and tunnel widening in 2-year radiographs obtained.	Tunnel positioning measured with X-Ray: Tibial and femoral tunnels significantly better in group A.	CT scans obtained 2 weeks after surgery showed that tunnels are done in an anatomically appropriate position.	-	-
Complications		No complications reported	1 septic arthritis and 1 persistent hemarthrosis.	No complications reported	No complications reported	1 superficial infection, 1 hemarthrosis and 1 hematoma were reported.

ANNEX 5: INFORMATION SHEET

Hospital Universitari
Dr. Josep Trueta,
Av. França s/n 17007
Girona

INFORMATION SHEET

TITLE: ALL-INSIDE VERSUS CONVENTIONAL TECHNIQUE IN ACL RECONSTRUCTION: A RANDOMIZED CLINICAL TRIAL

INVESTIGATORS: Dra. María José Martínez, Alexandre Coelho Leal

LOCATION: Hospital Universitari Dr. Josep Trueta, Girona

We would like to provide you with the information about a research project that is being carried out in our center, which you are invited to participate. We would like you to consider this research project and then decide whether or not you wish to take part in it. Please read carefully the following information before making a decision.

DESCRIPTION OF THE STUDY

The main objective of this study is to compare the range of motion obtained after the anterior cruciate ligament (ACL) reconstruction with two different techniques: all-inside technique or transtibial technique. Half of the patients will be operated with the all-inside technique. The other half of the patients will have their ACL reconstructed by the transtibial technique. After both procedures, the patient will be transferred to the orthopaedics and traumatology surgery unit during one day. Both techniques will require 24 weeks of rehabilitation programme to recover knee function, normal gait and sports activity ability.

After the treatment you will be visited by an Orthopaedics and Traumatology Surgeon for 24 months. In the day after the surgery, you will be evaluated by a surgeon as well as the nursing service. A surgeon will discharge you from the hospital if you are able to. Visits will be scheduled in the outpatient service for 15th day (which includes sutures removing) and 1, 6, 12 and 24 months after the surgery.

If you need extra visits due to any complication an appointment can be scheduled at any time. Also, if you are not able to attend to a visit, we will reschedule that visit to a week later.

WHY HAVE YOU BEEN INVITED?

You have been diagnosed of an anterior cruciate ligament tear grade III meeting inclusion and not exclusion criteria.

VOLUNTEER PARTICIPATION:

Your participation in the study is totally voluntary. You are free to decide whether to participate or not and you are able to withdraw the study at any time without any reason. The decision will not affect the treatment or healthcare assistance you deserve. If you decide to take part, after reading this information sheet, you will be asked to sign the informed consent. You should also be informed that you can be excluded from the study if investigators or the sponsor of the study considers it necessary, if you are not complying with the established procedures or if you meet exclusion criteria. If you miss one of the visits, we will call you and reschedule that visit to a week later, and if you miss that visit as well, you will be withdrawn of the study. In the case that you have been withdrawn, that will not affect the healthcare you deserve. In any case you will receive a proper explanation why have you been withdrawn from the study.

BENEFITS AND RISKS OF PARTICIPATION ON THE STUDY:

You chose to have an ACL surgical reconstruction. The current techniques to reconstruct the ligament include the all-inside technique (recently described and with an emergent importance) and the transtibial technique (the conventional and most used one). The surgical steps are in its essence similar so complications may be similar between both techniques and can be: wound infection, soft tissue infection, articular infection (septic arthritis), technical failure, muscle atrophy, bleeding (hemarthrosis), stiffness, loss of range of motion, deep vein thrombosis and pulmonary embolism. Vascular and nerve injury may also be presented and if this injury is irreversible, patient may be amputated. Every surgical intervention has implicit complications that can be potentially serious, and may require additional treatments (either surgical or medical) or progress, in a low percentage of cases, to death.

The benefits of reconstruction of the anterior cruciate ligament are: increased knee stability, less pain, less development of additional articular injuries, increased range of motion and increased subjective sense of knee function.

It is reported that all-inside technique presents less postoperative pain than the transtibial one. The aim of our study is to report if the range of motion after the all-inside technique is greater than the range of motion after the transtibial technique.

RESPONSIBILITY AND INSURANCE:

You are insured for any damage you may suffer as a result of your participation on this trial, in accordance with the law (Spanish law 14/2007 about Biomedical Investigation).

CONFIDENTIALITY:

All patient data is recorded on a password protected computer database. The information will be confidential according to the Spanish Organic law (15/1999) on personal data protection. Data collected during the study will be identified by a numeric code and only the researchers and collaborators will be able to access this information. Your personal identification will not be disclosed.

ECONOMIC COMPENSATION:

Your participation in the study will not include any additional cost and you will not pay the treatments received during this study.

CONTACT:

If any doubt or problem during the trial occurring during period please contact the researchers:

Dra. Maria José Martínez and Alexandre Coelho Leal

Hospital Universitari Dr. Josep Trueta

Av/ de França, s/n. 17007 – Girona

Thank you for reading this. Try to keep this information sheet until your participation in the study is finished. If you have any queries, questions or doubts do not hesitate to ask us.

If you agree to participate in the study, please sign the consent below.

Note: A Spanish version of the information sheet will also be available.

ANNEX 6: INFORMED CONSENT TO THE STUDY

Hospital Universitari de Girona Doctor Josep Trueta

Hospital Universitari
Dr. Josep Trueta,
Av. França s/n 17007
Girona

INFORMED CONSENT TO THE STUDY

WRITTEN INFORMED CONSENT FOR THE PATIENT

TITLE OF THE STUDY: ALL-INSIDE VERSUS CONVENTIONAL TECHNIQUE IN ACL RECONSTRUCTION: A RANDOMIZED CLINICAL TRIAL

INVESTIGATORS: Dra. Maria José Martinez, Alexandre Coelho Leal.

I, Mr. /Mrs. _____, confirm

that I have been informed by the investigator about the purpose of the study:

- I have read and understood the information sheet

- I have had time to think and consider this information

- I have had the opportunity to ask any questions and be answered

- I understand that my participation is entirely voluntary and I can withdraw this study any moment I wish, for any reason and without any consequences for the healthcare I receive.

- I give permission to collect my data and analyse it. I have been informed that all my data will be kept confidential.

I have spoken with (name of the investigator / Orthopaedic surgeon):

In consequence,

I give my conformity to enter this study.

Yes ☐   No ☐

I allow the personnel of this study to consult my clinical history with the aim of verification of the data.

Yes ☐   No ☐

I allow the use of the gathered data for further investigation in the Traumatology and Orthopaedic Surgery department.

Yes ☐   No ☐

Name of the participant   Name of Doctor taking consent

_____   _____

DNI   DNI

_____   _____

Signature   Signature

_____   _____

Girona, _____ (month) _____ (day), 20____ (year)

Note: A Spanish version of the informed consent for the study will also be available.

ANNEX 7: REVOCATION CONSENT

Hospital Universitari de Girona Doctor Josep Trueta

Hospital   Universitari
Dr. Josep Trueta,
Av. França s/n 17007
Girona

REVOCATION CONSENT

TITLE OF THE STUDY: ALL-INSIDE VERSUS CONVENTIONAL TECHNIQUE IN ACL RECONSTRUCTION: A RANDOMIZED CLINICAL TRIAL

INVESTIGATORS: Dra. Maria José Martinez, Alexandre Coelho Leal.

I, Mr. /Mrs. (Name and Surname) _____

_____, with DNI _____,
REVOKE the informed consent signed in ___/ ____/ ____ and it's my desire to finish my participation
in this clinical trial.

_____   _____
Signature of the participant   Signature of the Doctor

Girona, _____ (month) _____ (day), 20___ (year)

Note: A Spanish version of the informed consent for the study will also be available.

ANNEX 8: INFORMED CONSENT TO SURGICAL PROCEDURE

Hospital Universitari Dr. Josep Trueta,
Av. França s/n 17007 Girona

INFORMED CONSENT TO SURGICAL PROCEDURE

DOCUMENTO DE CONSENTIMIENTO INFORMADO PARA RECONSTRUCCIÓN DEL LIGAMENTO CRUZADO ANTERIOR

Usted tiene derecho a conocer el procedimiento al que va a ser sometido y las complicaciones más frecuentes que ocurren. Este documento intenta explicarle todas estas cuestiones; léalo atentamente y consulte con su médico todas las dudas que se le planteen.

Le recordamos que, por imperativo legal, tendrá que firmar, usted o su representante legal, familiar o persona vinculada de hecho, el Consentimiento Informado para que podamos realizarle dicho procedimiento/tratamiento.

PACIENTE

Yo, D./Dña...de.............años de edad,
(Nombre y dos apellidos del paciente)

Historia Clínica n.º...DNI n.º...,

con domicilio en...

REPRESENTANTE LEGAL, FAMILIAR O PERSONA VINCULADA DE HECHO

Yo, D./Dña. ....de.............años de edad,
(Nombre y dos apellidos del representante legal, familiar o persona vinculada de hecho)

con domicilio en...

DNI n.º....................................., en calidad de..del paciente.
(Representante legal, familiar o persona vinculada de hecho)

DECLARO

Que el Dr./la Dra..
(Nombre y dos apellidos del Dr./Dra.)

N.º de Colegiado...me ha explicado que es conveniente proceder, en mi situación, a realizar el procedimiento/tratamiento quirúrgico de **RECONSTRUCCIÓN DEL LIGAMENTO CRUZADO ANTE-RIOR**. He leído esta información que me ha entregado y que se reproduce a continuación.

1. PREOPERATORIO
Antes de la cirugía será necesario realizarle algunas pruebas diagnósticas, como analítica, radiografías o electrocardiograma. También le indicaremos desde qué hora debe permanecer en ayunas.

2. PROCEDIMIENTO
La rodilla es la articulación donde encaja el hueso del muslo (fémur) con el hueso de la pierna (tibia). El ligamento cruzado anterior se encuentra situado en el centro de la articulación y tiene la función de estabilizar la rodilla junto con otras estructuras. Su rotura puede producir episodios repetidos de "fallo" que cursan con dolor y, a veces, con derrame de la rodilla y que, a medio o largo plazo, suele provocar una degeneración de la articulación. Muy frecuentemente la rotura del ligamento cruzado anterior se acompaña de otras lesiones en la rodilla: de los meniscos, del cartílago o de los ligamentos.

La intervención consiste en la reconstrucción del ligamento, ya sea con otro tendón de la rodilla, con un ligamento de un donante o con otro artificial sintético. Para su anclaje es necesario realizar unos túneles a través del hueso y fijarlo con implantes metálicos.

El objetivo del procedimiento es el de mejorar la función de la rodilla, dotar a la articulación de una mayor estabilidad y retrasar la progresión de las lesiones.

La intervención precisa de anestesia general o bien de anestesia raquídea (de cintura para abajo). El Servicio de Anestesia y Reanimación estudiará sus características personales, informándole en su caso de cuál es la más adecuada.

Para reducir la incidencia de dos de las complicaciones principales: aparición de trombosis en las venas o infección después de la operación, se le administrará la medicación oportuna.

3. CONSECUENCIAS SEGURAS
Después de la intervención presentará dolor en la zona de la rodilla, debidos a la cirugía y a la adaptación de los músculos de la zona. Estas molestias pueden prolongarse durante algunas semanas o meses, o bien hacerse continuas.

Precisará guardar reposo en cama unos días y posteriormente recibirá instrucciones sobre la rehabilitación a realizar y sobre cómo utilizar las muletas. Además, puede necesitar una rodillera o escayola durante algún tiem-

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po. En algunos casos es necesaria una segunda operación para retirar los implantes metálicos colocados, cuando provoquen algún tipo de molestias y una vez que hayan cumplido su función.

4. DESCRIPCIÓN DE LOS RIESGOS TÍPICOS

La cirugía de RECONSTRUCCIÓN DEL LIGAMENTO CRUZADO ANTERIOR puede presentar complicaciones:

a) Toda intervención quirúrgica, tanto por la propia técnica operatoria como por la situación vital de cada paciente (diabetes, cardiopatía, hipertensión, edad avanzada, anemia, obesidad...), lleva implícitas una serie de complicaciones, comunes y potencialmente serias, que podrían requerir tratamientos complementarios, tanto médicos como quirúrgicos y que, en un mínimo porcentaje de casos, pueden ser causa de muerte.

b) Obstrucción venosa con formación de trombos e hinchazón de la pierna correspondiente que, en raras ocasiones, se complica con dolor torácico y dificultad respiratoria (embolia pulmonar) y que puede conducir incluso a la muerte.

c) Infección: ésta puede ser superficial (se puede resolver con limpieza local y antibióticos) o profunda (generalmente hay que retirar el implante). Dicha complicación puede aparecer incluso meses después de la intervención.

d) Lesión de los vasos de la pierna. Si la lesión es irreversible puede requerir la amputación de la extremidad.

e) Lesión de los nervios de la pierna que puede condicionar una disminución de la sensibilidad o una parálisis. Dicha lesión puede ser temporal o definitiva.

f) Rigidez de la rodilla por la formación de una cicatriz adherente que puede requerir una movilización bajo anestesia. Esta rigidez puede aparecer aislada o acompañada de inflamación importante y descalcificación de la zona (atrofia ósea).

g) Persistencia o reaparición de inestabilidad en la rodilla, habitualmente por desinserción o rotura del nuevo ligamento.

h) Aparición de fracturas en las zonas donde se extrae el tendón que sirve como injerto o por los túneles óseos donde se ancla el nuevo ligamento.

i) Atrofia muscular importante.

j) Derrames de repetición en la rodilla.

k) Aparición de artrosis de rodilla.

l) Rechazo del implante cuando éste proviene de un donante o bien es uno sintético/artificial.

5. ALTERNATIVAS DE TRATAMIENTO

Como alternativa al procedimiento propuesto podrá seguir con tratamiento analgésico y antiinflamatorio durante un tiempo y efectuar reposo relativo, evitando la actividad intensa y deportiva. Precisará de fisioterapia intensiva. La rodilla puede protegerse con la utilización de una rodillera con unos ejes metálicos laterales, de forma continua o durante la actividad deportiva. Dicho tratamiento solamente mejora los síntomas pero puede que no evite los fallos de dicha rodilla o que no detenga el desgaste progresivo de la articulación que le hagan necesario una intervención posterior.

He comprendido las explicaciones que se me han facilitado en un lenguaje claro y sencillo y el médico que me ha atendido me ha permitido realizar todas las observaciones y me ha aclarado todas las dudas y preguntas que le he planteado respecto a los fines, alternativas, métodos, ventajas, inconvenientes y pronóstico de la misma, así como de los riesgos y complicaciones que por mi situación actual pueden surgir tales como:

Si en el momento del acto quirúrgico surgiera algún imprevisto, el equipo médico podrá variar la técnica quirúrgica programada. Asimismo, he entendido y acepto que durante el procedimiento/tratamiento se podrán realizar fotografías o grabar imágenes que luego se conservarán y se podrán transmitir con fines científicos y/o de docencia y utilizar en sesiones clínicas, juntas facultativas, conferencias, congresos, publicaciones médicas y actos científicos, sin que en las mismas figure identidad alguna del paciente. También comprendo que, en cualquier momento y sin necesidad de dar ninguna explicación, puedo revocar el Consentimiento que ahora presto. Por ello, manifiesto que me considero satisfecho/a con la información recibida y que comprendo la indicación y los riesgos de este procedimiento/tratamiento.

CONSENTIMIENTO INFORMADO
de la Sociedad Española de Cirugía Ortopédica y Traumatología. SECOT

2 de 3

Alexandre Coelho Leal

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Y en tales condiciones, libre y voluntariamente, **DOY MI CONSENTIMIENTO** para que se me realice/realice al paciente el procedimiento/tratamiento quirúrgico de **RECONSTRUCCIÓN DEL LIGAMENTO CRUZADO ANTERIOR:**

....

En.., a .... de...de...................

Fdo. EL DR./LA DRA.   Fdo. EL/LA PACIENTE   Fdo. EL REPRESENTANTE LEGAL,
                                                        FAMILIAR O PERSONA VINCULADA DE HECHO

TESTIGO

Yo, D./Dña...
(Nombre y dos apellidos del testigo)

con DNI n.º...declaro bajo mi responsabilidad que el paciente

D./Dña...ha recibido la hoja de información
(Nombre y dos apellidos del paciente)

que le ha entregado el Dr./la Dra..
(Nombre y dos apellidos del Dr./Dra.)

Ha comprendido las explicaciones que se le han facilitado en un lenguaje claro y sencillo y el médico que le ha atendido le ha permitido realizar todas las observaciones y le ha aclarado todas las dudas y preguntas que le ha planteado respecto a los fines, alternativas, métodos, ventajas, inconvenientes y pronóstico de la misma, así como de los riesgos y complicaciones que por su situación actual pueden surgir. Si en el momento del acto quirúrgico surgiera algún imprevisto, el equipo médico podrá variar la técnica quirúrgica programada. Asimismo, ha entendido y acepta que durante el procedimiento/tratamiento se podrán realizar fotografías o grabar imágenes que luego se conservarán y se podrán transmitir con fines científicos y/o de docencia y utilizar en sesiones clínicas, juntas facultativas, conferencias, congresos, publicaciones médicas y actos científicos sin que en las mismas figure identidad alguna del paciente. También comprende que, en cualquier momento y sin necesidad de dar ninguna explicación, puede revocar el Consentimiento que ahora presta. Se considera satisfecho/a con la información recibida y comprende la indicación y los riesgos de este procedimiento/tratamiento.

Y en tales condiciones, libre y voluntariamente, **HA DADO SU CONSENTIMIENTO** para que se le realice el procedimiento/tratamiento quirúrgico de **RECONSTRUCCIÓN DEL LIGAMENTO CRUZADO ANTERIOR:**

....

En.., a .... de...de...................

Fdo. EL DR./LA DRA.   Fdo. EL/LA TESTIGO

REVOCACIÓN DEL CONSENTIMIENTO INFORMADO

Yo, D./Dña...
(Nombre y dos apellidos del paciente)

Yo, D./Dña...
(Nombre y dos apellidos del representante legal, familiar o persona vinculada de hecho))

Yo, D./Dña...
(Nombre y dos apellidos del testigo)

REVOCO el Consentimiento prestado en fecha......................................., y no deseo proseguir el procedimiento/tratamiento, que doy con esta fecha por finalizado.

En.., a .... de...de...................

Fdo. EL DR./LA DRA.   Fdo. EL/LA PACIENTE   Fdo. EL REPRESENTANTE LEGAL   Fdo. EL/LA TESTIGO
                                              FAMILIAR O PERSONA VINCULADA DE HECHO

CONSENTIMIENTO INFORMADO
de la Sociedad Española de Cirugía Ortopédica y Traumatología. SECOT   *3 de 3*

Source: Sociedad Española de Cirugía Ortopédica y Traumatología (SECOT)

ANNEX 9: PARTICIPANT DATA SHEET

	Hospital Universitari Dr. Josep Trueta, Av. França s/n 17007 Girona	**PARTICIPANT DATA SHEET – MAIN INVESTIGATORS**
Hospital Universitari de Girona Doctor Josep Trueta		

TITLE OF THE STUDY: ALL-INSIDE VERSUS CONVENTIONAL TECHNIQUE IN ACL RECONSTRUCTION: A RANDOMIZED CLINICAL TRIAL

PARTICIPANT
Name:
DNI:
Date of birth: ___/___/___
Telephone:
Email:
Address:
Sex: M □   F □
Patient's code number:

CLINICAL HISTORY

ALLERGIES:
SIDE OF THE INJURY: LEFT □   RIGHT □
MEDICATION:
MECHANISM OF INJURY:
DATE OF THE INJURY: /   /
PHYSICAL ACTIVITY (hours per week):
BMI:
PROFESSION:

CURRENT DIAGNOSIS

MRI

ACL tear grade III: Yes □   No □

Concomitant meniscal injury: Yes □   No □

Other findings: _____

Hospital Universitari Dr. Josep Trueta, Av. França s/n 17007 Girona	**PARTICIPANT DATA SHEET – FOLLOW-UP**

TITLE OF THE STUDY: ALL-INSIDE VERSUS CONVENTIONAL TECHNIQUE IN ACL RECONSTRUCTION: A RANDOMIZED CLINICAL TRIAL

PARTICIPANT

PATIENT'S NUMBER CODE:

		Pre operative	1st Day	15th Day	1 month	6 months	12 months	24 months
ROM	Total ROM (º)							
	Flexion (º)							
	Extension (º)							
Pain	VAS							
Subjective outcomes	IKDC score							
	Lysholm score							
Ligament laxity	KT-1000 (mm)							

COMPLICATIONS REPORTED	
Day 1	
Day 15	
1 month	
6 months	

TITLE OF THE STUDY: ALL-INSIDE VERSUS CONVENTIONAL TECHNIQUE IN ACL RECONSTRUCTION: A RANDOMIZED CLINICAL TRIAL

PARTICIPANT
PATIENT'S NUMBER CODE:

DATE: Preoperative assessment

EVALUATION	
TOTAL ROM	
KT-1000	

DATE: 1st EVALUATION: Day 1

EVALUATION	
PAIN LEVEL (VAS)	
COMPLICATIONS	

DATE: 2nd EVALUATION: Day 15

EVALUATION	
PAIN LEVEL (VAS)	
COMPLICATIONS	

DATE: 3rd EVALUATION: 1 month

EVALUATION	
PAIN LEVEL (VAS)	
IKDC SCORE	
LYSHOLM SCORE	
COMPLICATIONS	

DATE:
4th EVALUATION: 6 months

EVALUATION

TOTAL ROM	
FLEXION	
EXTENSION	
PAIN LEVEL	
IKDC SCORE	
LYSHOLM SCORE	
KT-1000	
COMPLICATIONS	

DATE:
5th EVALUATION: 12 months

EVALUATION

TOTAL ROM	
FLEXION	
EXTENSION	
PAIN LEVEL	
IKDC SCORE	
LYSHOLM SCORE	
KT-1000	

DATE:
6th EVALUATION: 24 months

EVALUATION

TOTAL ROM	
FLEXION	
EXTENSION	
PAIN LEVEL	
IKDC SCORE	
LYSHOLM SCORE	
KT-1000	

ANNEX 10: VISUAL ANALOGUE SCALE (VAS)

Visual Analog Scale

No
pain

Worst
possible
pain

Source: Aesthetic Surgery Journal

ANNEX 11: IKDC SCORE

2000 IKDC SUBJECTIVE KNEE EVALUATION FORM

Name: _____ _____ **Date:** _____
       First   Last

Physician: _____ **Date of Injury:** _____

SYMPTOMS*:

*Grade symptoms at the highest activity level at which you think you could function without significant symptoms, even if you are not actually performing activities at this level.

1. What is the highest level of activity that you can perform without significant knee pain?
   - ○ Very strenuous activities like jumping or pivoting as in basketball or soccer
   - ○ Strenuous activities like heavy physical work, skiing or tennis
   - ○ Moderate activities like moderate physical work, running or jogging
   - ○ Light activities like walking, housework or yard work
   - ○ Unable to perform any of the above activities due to knee pain

2. During the past 4 weeks, or since your injury, how often have you had pain?

	0	1	2	3	4	5	6	7	8	9	10	
Never	○	○	○	○	○	○	○	○	○	○	○	Constant

3. If you have pain, how severe is it?

	0	1	2	3	4	5	6	7	8	9	10	
No pain	○	○	○	○	○	○	○	○	○	○	○	Worst pain imaginable

4. During the past 4 weeks, or since your injury, how stiff or swollen was your knee?
   - ○ Not at all
   - ○ Mildly
   - ○ Moderately
   - ○ Very
   - ○ Extremely

5. What is the highest level of activity you can perform without significant swelling in your knee?
   - ○ Very strenuous activities like jumping or pivoting as in basketball or soccer
   - ○ Strenuous activities like heavy physical work, skiing or tennis
   - ○ Moderate activities like moderate physical work, running or jogging
   - ○ Light activities like walking, housework or yard work
   - ○ Unable to perform any of the above activities due to knee swelling

6. During the past 4 weeks, or since your injury, did your knee lock or catch?
   - ○ Yes   ○ No

7. What is the highest level of activity you can perform without significant giving way in your knee?
   - ○ Very strenuous activities like jumping or pivoting as in basketball or soccer
   - ○ Strenuous activities like heavy physical work, skiing or tennis
   - ○ Moderate activities like moderate physical work, running or jogging
   - ○ Light activities like walking, housework or yard work
   - ○ Unable to perform any of the above activities due to giving way of the knee

Page 2 – 2000 IKDC SUBJECTIVE KNEE EVALUATION FORM

SPORTS ACTIVITIES:

8. What is the highest level of activity you can participate in on a regular basis?

- ○ Very strenuous activities like jumping or pivoting as in basketball or soccer
- ○ Strenuous activities like heavy physical work, skiing or tennis
- ○ Moderate activities like moderate physical work, running or jogging
- ○ Light activities like walking, housework or yard work
- ○ Unable to perform any of the above activities due to knee

9. How does your knee affect your ability to:

		Not difficult at all	Minimally difficult	Moderately Difficult	Extremely difficult	Unable to do
a.	Go up stairs	○	○	○	○	○
b.	Go down stairs	○	○	○	○	○
c.	Kneel on the front of your knee	○	○	○	○	○
d.	Squat	○	○	○	○	○
e.	Sit with your knee bent	○	○	○	○	○
f.	Rise from a chair	○	○	○	○	○
g.	Run straight ahead	○	○	○	○	○
h.	Jump and land on your involved leg	○	○	○	○	○
i.	Stop and start quickly	○	○	○	○	○

FUNCTION:

10. How would you rate the function of your knee on a scale of 0 to 10 with 10 being normal, excellent function and 0 being the inability to perform any of your usual daily activities which may include sports?

FUNCTION PRIOR TO YOUR KNEE INJURY:

	0	1	2	3	4	5	6	7	8	9	10	
Couldn't perform daily activities	○	○	○	○	○	○	○	○	○	○	○	No limitation in daily activities

CURRENT FUNCTION OF YOUR KNEE:

	0	1	2	3	4	5	6	7	8	9	10	
Cannot perform daily activities	○	○	○	○	○	○	○	○	○	○	○	No limitation in daily activities

[Print Form]

| 0 | IKDC Score

[Submit]

Source: Orthopaedic Scores

ANNEX 12. LYSHOLM SCORE

Lysholm Knee Questionnaire

Name: [_____] [_____] **Date:** [_____]
  First   Last

Physician: [_____ ▾]

1. Limp:
- ○ a) None
- ○ b) Slight or periodical
- ○ c) Severe and constant

2. Support:
- ○ a) None
- ○ b) Stick or crutch
- ○ c) Weight-bearing impossible

3. Locking:
- ○ a) No locking and no catching sensations
- ○ b) Catching sensation but no locking
- ○ c) Locking occasionally
- ○ d) Locking frequently
- ○ e) Locked joint on examination

4. Instability:
- ○ a) Never giving way
- ○ b) Rarely during athletics or other severe exertion
- ○ c) Frequently during athletics or other severe exertion (or incapable of participation)
- ○ d) Occasionally in daily activities
- ○ e) Often in daily activities
- ○ f) Every step

5. Pain:
- ○ a) None
- ○ b) Inconstant and slight during severe exertion
- ○ c) Marked during severe exertion
- ○ d) Marked on or after walking more than 2 km
- ○ e) Marked on or after walking less than 2 km
- ○ f) Constant

6. Swelling:
- ○ a) None
- ○ b) On severe exertion
- ○ c) On ordinary exertion
- ○ d) Constant

7. Stair-climbing:
- ○ a) No problems
- ○ b) Slightly impaired
- ○ c) One step at a time
- ○ d) Impossible

8. Squatting:
- ○ a) No problems
- ○ b) Slightly impaired
- ○ c) Not beyond 90°
- ○ d) Impossible

Lysholm Score: [_____]   [Print Form] [Submit]

Source: Orthopaedic Scores

ANNEX 13: KT-1000 ARTHROMETER

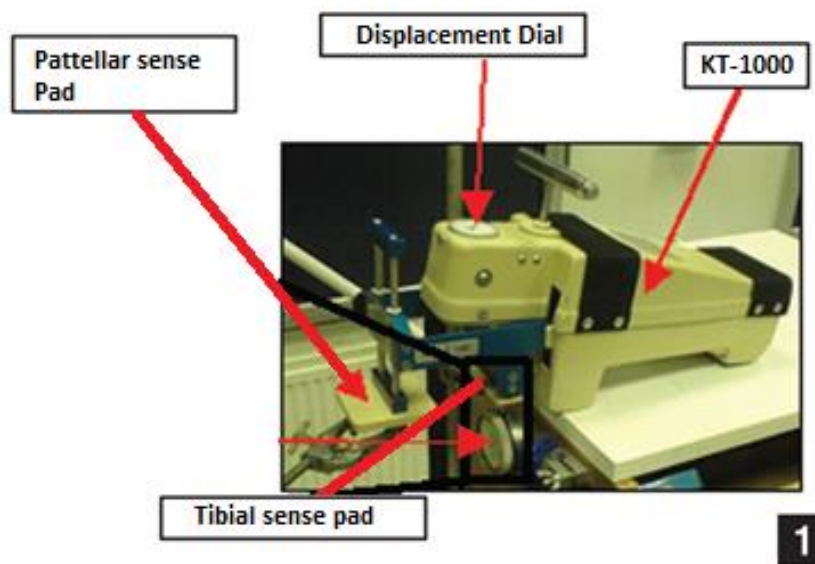**Figure 1**. **The KT-1000 arthrometer** (69).

Figure 2. **The KT-1000 and its parts. Only the sense pads and the displacement dial are
identified in order to simplify the figure.** Adapted from (69)

How does it works?
The patient is in a supine position with his thigh on a bolster, what keeps the knee in approximately 30º of flexion. The arthrometer has 2 sensing pads: one is positioned on the patella, the other is placed on the tibial tubercle. The sensor pads are freely moveable so that the difference in the AP displacement is determined by the distance or relative motion between the 2 pads and the minimum amount of displacement determined is 0,5mm. As the examiner applies an anterior force through the handle a tone is heard at 67-N of force. A second tone is heard as the force reaches 89-N and a third tone is heard a 134-N. The readings are all recorded, but for the analysis only 134-N will be taken in account, since it will give us the greatest value. After an ACL tear, the side to side difference is increased **(2.6 Clinical diagnosis)** and this should decrease to within normal range post-operatively. This test gives us information about the ligament laxity and lower values indicate a better ligament function.