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Current management of rotatory instability of the knee. Objective indications to perform an anterolateral extrarticular tenodesis

Simone Perelli

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PhD Program: Surgery and Morphological Science

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Barcelona 2023

Supera te stesso e supererai il mondo

Sant’Agostino

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CHAPTER 8. ANNEX MATERIAL OF THE THESIS (ARTICLE IN PRESS)

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AKNOWLEDGEMENTS

Since the beginning of my residency, I have been fascinated by knee surgery. For this reason, it is a great honor and pride for me to have become a knee surgeon and to have had the opportunity to write a doctoral thesis in this field. I would not have been able to achieve these goals without the help and support of some people. First of all, I would like to thank all my **family**, parents, brothers and sisters, who have supported and put up with me since the years of the medical school. Your silent help has been fundamental to never give up, to make the right decisions and to always set high goals in my life.

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Finally, I would like to thank all the **colleagues** of the knee unit of ICATME and of the Hospital del Mar, and all the foreign colleagues who contributed to the scientific research that had made this doctoral thesis possible. Any scientific work is never due to an individual, only teamwork can give results as good as those we achieved in the last years.

HYPOTHESIS AND OBJECTIVES OF THE THESIS

The hypothesis of this thesis is:

the anterolateral knee instability is one of the causes of persistence of symptoms and failure after an anterior cruciate ligament reconstruction. The objective evaluation of this kind of instability is currently complex and this makes it difficult to produce a therapeutic protocol and compare our data. Anterolateral extra-articular tenodesis may be a surgical technique that can reduce anterolateral instability and related failures. Despite the demonstrated advantages of this technique there may be disadvantages and complications in its use which need to be investigated adequately.

The objectives of this thesis are:

- To investigate by a literature review if the residual anterolateral instability is considered a cause of failure in ACL reconstruction in athletes and if the anterolateral tenodesis is proposed as a solution of this persistent instability
- To develop a new tool to evaluate objectively the anterolateral instability of the knee
- To study in a clinical setting possible intraoperative and postoperative complications and disadvantages of the anterolateral tenodesis
- To study in clinical setting the use of anterolateral tenodesis in patients with objective indications. It means in patients with objective rotational instability and patients with high risk of failure of the ACL reconstruction

SUMMARY OF PUBLICATIONS

This compendium of publication is mainly composed of 6 articles.

In three of the published papers, I appear as first author, in two as second authors and in one as the last author. All these articles have been published in peer-reviewed and indexed journals. One paper is still "in press" and has been added as an annex material of the thesis just to add this unpublished data to the discussion.

Perelli S, Morales-Avalos R, Formagnana M, Rojas-Castillo G, Serrancolí G, Monllau JC. Lateral extraarticular tenodesis improves stability in non-anatomic ACL reconstructed knees: in vivo kinematic analysis. *Knee Surg Sports Traumatol Arthrosc*. 2022;30(6):1958-1966. doi:10.1007/s00167-021-06854-8

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Rojas G, **Perelli S**, Ibanez M, Formagnana M, Ormazabal I, Monllau JC. Effect of Modified Lemaire Anterolateral Extra-articular Tenodesis on the Magnetic Resonance Imaging Maturity Signal of Anterior Cruciate Ligament Hamstring Graft. *Am J Sports Med*. 2021;49(9):2379-2386. doi:10.1177/03635465211018858

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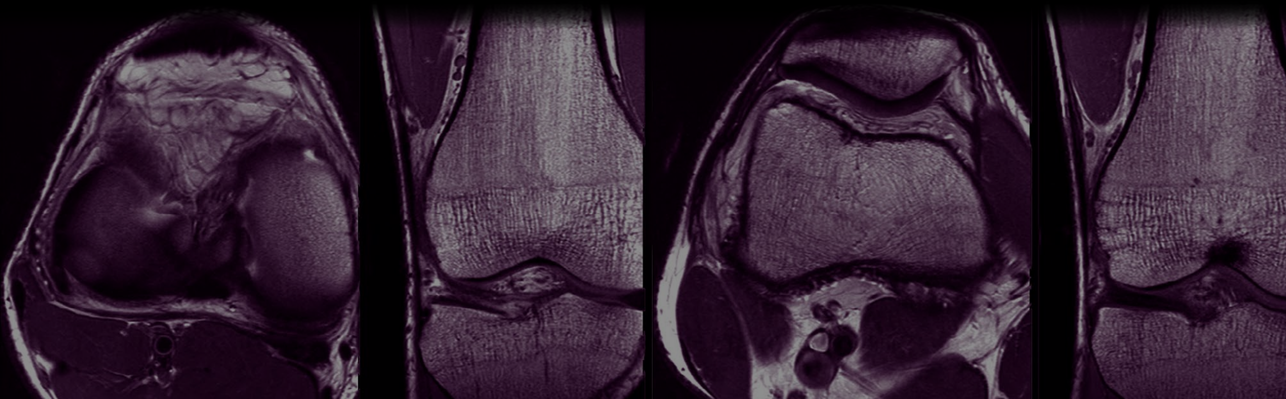
Serrancolí G, Bogatikov P, Tanyà Palacios G, Torner J, Monllau JC, **Perelli S**. An Open-Source Android Application to Measure Anterior–Posterior Knee Translation. *Applied Sciences*. 2020; 10(17):5896. https://doi.org/10.3390/app10175896

Perelli S, Gelber PE, Morales-Avalos R, Ronco S, Torres-Claramunt R, Espregueira-Mendes J, Monllau JC. Isolated lateral extra-articular tenodesis in ACL deficient knees: in-vivo knee kinematics and clinical outcomes. [***ARTICLE IN PRESS*** *Knee Surg Sports Traumatol Arthrosc*]

CHAPTER 1. INTRODUCTION

The anterolateral part of the knee: what is known



CHAPTER 1. INTRODUCTION

The anterolateral part of the knee: what is known

1.1 The Rationale of the thesis

In 2013, Steven Claes and Johan Bellemans published the quite famous article on the anatomy of the anterolateral ligament of the knee that every modern knee surgeon knows about. [1]

This turned attention back to the periphery of the knee after years of being focused only inside the notch. It was the beginning of the year 2016 when I arrive in Genk as fellow of Professor Bellemans. Anterolateral tenodesis at that time was not part of my daily practice and was not widely used the world of the knee. My time in Belgium presented me with the opportunity to learn more about this technique. Moreover, it led me to reflect on its use. The scientific literature of the last 10 years has partially quelled these doubts even though some aspects were still not entirely clear in my mind. My thesis was an opportunity to find answers to questions that were still unanswered, and it was an opportunity to deepen my understanding of rotational instability of the knee.

1.2 The anterolateral ligament

In 1879, years before the discovery of X-rays, Dr. Paul Segond described a remarkably constant avulsion fracture pattern on the anterolateral part of the proximal tibia as a result of forced internal rotation in the knee. [2] This eponymous Segond fracture was reported to occur in the tibial region "above and behind the tubercle of Gerdy." Furthermore, he designated the existence of "a pearly, resistant, fibrous band at this anatomical location, which invariably showed extreme amounts of tension during forced internal rotation of the knee." Despite Segond`s description, later literature has only rarely mentioned the presence of a ligamentous structure connecting the femur with the anterolateral tibia. These sporadic reports mention the 'anterior band of the lateral collateral ligament' [3], the 'mid-third lateral capsular ligament' [4-7], and the 'anterior oblique band'. [8] The different terms applied along with the vague descriptions and lack of detailed illustrations have led to much confusion about the precise anatomy and function of this structure up to the anatomical work of Claes et al. in 2013. [1] They performed a precise qualitative description of a ligament structure connecting the femur and the tibia on the lateral side of the knee. Its origin was identified as being on the prominence of the lateral femoral epicondyle, anterior to the socket from which the lateral collateral ligament (LCL) originated, and proximal and posterior to the insertion of the popliteus tendon. Furthermore, they stated that the body of this ligament ran an oblique course toward the anterolateral side of the proximal tibia, having a strong connection with the periphery of the middle third of the meniscal body of the lateral meniscus. Finally, they described the distal insertion of this ligament on the tibia just in the middle of the line connecting Gerdy's tubercle and the tip of the fibular head. They named this structure the anterolateral ligament (ALL). Actually, this name had already been coined by Vincent et al. [9] They reported their observations during total knee arthroplasty procedures when the authors noticed "a relatively consistent structure in the lateral knee, linking the lateral femoral condyle, the lateral meniscus, and the lateral tibial plateau." Although with the same name, the structure described by Claes et al. differs from the one described by Vincent et al. The first difference is because of the proximal insertion and the second is because of the connection with the iliotibial band (ITB). The Belgian authors described an insertion close to the origin of the LCL whereas Vincent et al. located the insertion close to the insertion of the popliteal tendon on the femur. Furthermore, the first authors underlined that the ALL has no connection with the ITB. It is unlike Vincent et al. that described important connections between the two structures. Several subsequent publications supported the findings of Claes et al.

1.3 Anterolateral instability

The interplay between the dynamic and static stabilizers of the knee joint is complex. The lateral side of the knee is especially reliant on these stabilizers due to its inherent bony instability of the opposing convex surfaces. Segond suggested that when an avulsion-fracture was present on the anterolateral part of the tibia after a knee trauma, it correlates with an injury of the antero-lateral stabilizers of the knee. After the observations of Segond, we had to wait one century before renewed attention was focused on the anterolateral structures. According to Hughston [4], this capsular ligament is "strong and supported superficially by the iliotibial band." It was thought to play an important role in the so-called 'anterolateral rotational instability' (ALRI) pattern of the knee [4,10], a clinical term which became obsolete with the advent of knee arthroscopy (and its inherent predominance in the diagnosis of intra-articular pathology) a few years later. Furthermore, Hughston introduced a classification system which included anteromedial instability, anterolateral instability, posterolateral instability, or combined rotational injury of the knee in 1976.

Inspired by the work of Dr. Hughston, the first correlation of the Segond fracture with the presence of significant knee instability was demonstrated by Woods et al. [11] In that study, all of the four acute cases with a positive 'lateral capsular sign' on X-ray, a concomitant rupture of the anterior cruciate ligament (ACL) was demonstrated. The same study, together with the work of Goldman et al. [12] and Hess et al. [13] were the basis the current belief that Segond fractures are pathognomonic for ACL tears. Since 2014, hundreds of papers have been published about the biomechanical definition of anterolateral instability and the role played by the anterolateral ligament. It is now known that, similar to the menisci, the anterolateral ligament is a secondary stabilizer of anterior translation and rotation of the lateral compartment. [14] Increased anterior translation in flexion as well as in extension and increased internal rotation at 90° of flexion has been shown to be consistent with combined injury to the anterior cruciate ligament and the anterolateral structures. [15] Moreover, cadaveric navigation studies showed an increase in the pivot shift grade after the sectioning of anterolateral structures when it was compared to an isolated ACL cut, suggesting its importance in the control of dynamic rotational laxity. [14] Therefore, these biomechanical studies support the need to restore the function of the anterolateral structures in the event of damage to them. For this reason, an important point of discussion is how to identify the lesions of the anterolateral structure properly. In other words, when is an anterolateral ligament reconstruction or an anterolateral tenodesis to restore the physiological anterolateral laxity indicated? Indeed, it has been shown that either an isolated ACL reconstruction or a combined ACL reconstruction and extra-articular tenodesis restored intact knee kinematics in an isolated ACL injury. However, an extra-articular tenodesis was necessary to restore intact kinematics when a lateral capsule lesion was present. [16,17]

The objective and quantitative measurement of anterolateral instability is still a point of debate, even more in the clinical setting where invasive devices are not indicated.

1.4 Measurement of anterolateral instability

To assess knee instability, the Lachman test, the anterior drawer test, and the Pivot Shift Test (PST) are widely used. The most specific clinical test for an ACL rupture is the PST, which was first described by Galway et al. in 1972 [18]

The pivot shift is a phenomenon observed in ACL-deficient knees where a primary anterior subluxation of the lateral tibial plateau occurs. As flexion increases, anterior translation converts into reduction of the tibia upon the femoral condyle and posterior tibial acceleration commences as the iliotibial band pulls the tibia posteriorly. Bull et al. determined the motion of the tibia during reduction to be a combination of external tibial rotation and posterior tibial translation [19].

Even though the Lachman's test has long been considered the gold standard in terms of establishing a diagnosis of an ACL rupture, the measured entity, being static anterior tibial translation, poorly correlates with patient satisfaction. Moreover, it has been shown that the PST better correlates with both clinical outcome [20] and the development of osteoarthritis (OA) [21]. As a matter of fact, PST is the only test used nowadays that can evaluate rotatory instability that is the main symptom complained of by patients with an ACL lesion. Anterolateral instability is based on the concept that some structures in the anterolateral part of the knee act as a secondary restraint limiting internal rotation. Therefore, PST also seems to be the most accurate test to evaluate anterolateral instability.

The problem is that, so far, the determination of rotatory laxity is mainly based on subjective grading using the pivot shift test. Even though a standardized pivot shift test has been proposed [22], the clinical grading and tibial translation still vary between examiners. A globally accepted standardized technique of performing the PST is an important step forward. However, the manual loading of the involved forces would still vary and bring about both intra- and inter-examiner variability. Therefore, we can define the PST as a qualitative evaluation of anterolateral instability. Even so, a proper analysis of rotational instability needs a quantitative analysis. A quantitative analysis of the pivot shift test does not only provide objective laxity parameters but more importantly provides side-by-side means of comparison of the healthy and injured knee. Additionally, a pre- and intraoperative quantification of knee kinematics during the PST can be used to create treatment algorithms.

Multiple devices for assessment of static or semi-dynamic rotational laxity have been developed in recent years. [23,24] However, it has been shown that the measurement of static rotational laxity is insufficient for the detection of rotational instability in ACL-deficient knees when compared with the PST.

Important measurement devices for the detection and quantification of the PST have been described in the literature, the most important being surgical navigation [25], electromagnetic sensor systems [26], and inertial sensors [27]. In addition, a new promising image analysis system has more recently been presented [28].

1.4.1 Computer assisted surgery

The first technique to measure dynamic rotational laxity was utilized as early as the 1990s when computer-aided surgery (CAS) was first reported as an adjunct in ACL reconstruction [29]. The original idea of CAS was to enhance tunnel placement to create better isometry and avoid graft elongation. However, the technique has also been implemented in the evaluation of knee laxity and kinematics [30]. Multiple studies have confirmed that navigation systems demonstrate good precision and reliability [31], but it is unfortunate that trackers and receivers must be invasively fastened to bone. This makes the technology only suitable for intraoperative evaluation and measures under anesthesia. Furthermore, assessment of the contralateral knee using navigation is uncommon due to ethical issues related to invasiveness. This limits the usefulness of this type of evaluation given that the degree and importance of rotatory instability of an ACL deficient knee is better understood by performing a comparison to the normal parameters of each subject. More recently, a promising alternative to the standard method of intra-osseous fixing of tracking devices has been described. In that instance, skin markers that are fixed on both ipsilateral and contralateral knees were used. The reliability of skin fixation with an ICC for internal rotation of 0.94 and for ATT of 0.89 was encouraging [32]. All in all, navigation systems have been utilized in multiple clinical studies and continue to provide important and precise information about dynamic knee laxity. The ability to measure knee kinematics intra-operatively with high precision without skin-artifacts is a major benefit. Moreover, the fact that patients are under anesthesia prevents muscular guarding. However, the disadvantages include invasiveness, a high cost, and risks associated with a prolonged surgical time.

1.4.2 Electromagnetic sensor systems

Electromagnetic sensor systems (EMS) have been utilized to assess rotational knee laxity since 2002 [33]. However, at the beginning, the tracking receivers were fixed using Kirschner wires. Consequently, an increased time under anesthesia was seen. Moreover, the invasive method limited use to the operating room only and entailed a potential risk for infection. The current devices can now provide non-invasive data, which can be extracted in both the operating room and the office setting. However, there are a few complications. Metallic objects can produce signal disturbances that call for the preparation of examination/operating rooms to eliminate ferromagnetic materials. Moreover, wireless systems are yet to be developed to facilitate examinations and the limited operational zone of the transmitter complicates the setup, primarily when used intra-operatively [34].

1.4.3 Inertial sensors

To my knowledge, Maeyama et al. was the first to document the use of a triaxial accelerometer in the evaluation of ACL deficiency in a porcine model [35]. Subsequently, Lopomo et al. have contributed to broadening our understanding of the use of accelerometers in patients with ACL tears by developing the first non-invasive triaxial accelerometer sensor (KiRA) that is currently used in clinical practice [36]. The same authors designed an additional study to validate the aforementioned accelerometer with a navigation system [27]. It works attached to the proximal tibia using a brace and it can be embedded in a protective plastic sheath for its intraoperative use if necessary. It should be positioned between the lateral aspect of the tibial tuberosity and the tubercle of Gerdy, aligned with the mechanical axis of the tibia and connected to a tablet or a mobile phone through a wireless connection. KiRA is able to detect both the anterior translation (measured in mm) during the Lachman test, and the acceleration of the tibia upon the femur during the pivot shift test (measured in m/s^2). The device is easy to use and versatile. It can be used in the outpatient clinic setting, and/or in the sterile setting of an operating room. It can even be used to evaluate the healthy contralateral knee in a non-invasive way. The great disadvantage of this technology is the cost. It makes the technology only suitable for use in highly specialized centers and, mainly, to carry out scientific research.

1.4.4 Optical motion capture technique

The advent of optical motion capture techniques using a camera to evaluate dynamic knee laxity is a relatively new technique. The first report on it was published in 2012 [28]. This system takes its cue from the simple concept that there is a correlation between the AP translation of the lateral compartment and the clinical grading of the PST. Therefore, using a simple digital camera to detect the movement of the 3 stickers during a PST can estimate the magnitude of the pivot shift. The round stickers are applied to three points on the lateral aspect of the knee: the tubercle of Gerdy, the fibular head, and the lateral epicondyle. Their relative two-dimensional movements are calculated using computer software and a graph is plotted showing the femoral AP position as a function of time. Preliminary validation of the technique was made in reference to an EMS device and the results showed a consistent lateral compartment translation. However, the magnitude observed was considerably smaller for the image analysis system when compared with the EMS system. Furthermore, no comparison to the healthy contralateral knee was made [28]. The image analysis system was further developed by Hoshino et al. They were the first to develop an app that makes it possible to detect and analyze the translation of the lateral compartment with an iPad [37]. However, the same developer described the low sensitivity of 59% of the system. The authors explain the large number of outlying values as being caused by three separate factors: marker movement outside the tracking field, faulty camera angle in relation to the lateral aspect of the knee joint, and the performance of the PST that is too fast for the frame rate of the camera. Even so, this application is still not available in the market. Therefore, subsequent studies in which it was used were all conducted in the Medical Institute of the developer.

Taken all together, we can say that we currently have different ways to evaluate rotational instability in an objective manner but all of them have intrinsic disadvantages. Regrettably, It is for that reason that none of these methods are presently available in the clinical setting

The future goal should be to develop a low-cost, easily reproducible and propagable technology so that it can be used in most hospitals in the world. In this way, we will have access to a huge amount of homogeneous data to analyze.

1.5 The anterolateral tenodesis

The idea of an extra-articular reconstruction was first popularized in the 1970s when open surgery with the patellar tendon graft was the gold-standard for ACL reconstruction. Lemaire in Europe, McIntosh in the USA, and others introduced extra-articular techniques with the aim of restoring the rotatory stability of the knee. With the establishment and advancement of arthroscopic ACL reconstruction, extra-articular procedures became less common. Critics cited the higher pressure on the lateral compartment and the restricted range-of-motion due to the anterior position of the femoral insertion as disadvantages of extra-articular tenodesis. Furthermore, in 2001, Anderson et al. [38] failed to show benefit of extraarticular tenodesis over intra-articular ACL reconstruction.

Nevertheless, in recent years, Neyret et al. and Marcacci et al. [39-40] were able to show excellent long-term results with high degrees of satisfaction and few signs of osteoarthritis. Additionally, Zaffagnini et al.[41] saw better clinical results and a faster return to sport at 5-year follow-up in a randomized study in patients treated with single bundle ACL reconstruction plus lateral plasty when compared to single-bundle four-strand hamstrings or patellar tendon types.

A combined intra- and extra-articular reconstruction may provide more normal restoration of knee kinematics after an ACL injury with concomitant anterolateral rotational laxity. Some authors advocate for it due to the longer lever arm of the lateral reconstruction, which may make for efficient control of tibial rotation [42]. Furthermore, tenodesis may provide a “backup” since it persists in cases of intra-articular graft failure [43]. Finally, extra-articular tenodesis has been found to decrease the stress on the intra-articular graft by more than 40 %, lending credence to the possible load-sharing role of the native structure [43,44].

The effects of extra-articular tenodesis have been extensively evaluated with navigation studies. Bignozzi et al. acquired in vivo knee kinematics before and after the execution of lateral tenodesis in combination with a single bundle “over the top” ACL reconstruction. They proved that the lateral plasty was able to reduce the anterior translation of the lateral compartment during the Lachman test when it was compared to isolated ACL reconstruction [45]. The same researchers also performed a randomized study aimed at comparing the single-bundle reconstruction plus a lateral plasty with the double-bundle reconstruction [46]. It showed that both techniques worked similarly for static knee laxity, while the lateral plasty technique better controlled tibial rotations and the displacement of the lateral compartment during the anterior drawer test. Similar biomechanical insights were also reported with different extra articular tenodesis techniques, suggesting that the lateral tenodesis as a key element to reduce the tibial rotation and control the pivot shift phenomenon [47,48]. Based on all these biomechanical findings, combined procedures were proposed to reduce forces transmitted to the ACL graft and protect it during ligamentization. There was an expectation that this would result in reduced graft rupture rates. Although these data confirmed the biomechanical usefulness of anterolateral tenodesis, by carrying out a literature review, (**Chapter 2**) we realized that one of the causes of the failure of the reconstruction of the ACL is still the lack of a treatment for anterolateral instability. At the same time, the literature survey we performed led us to conclude that we can reduce the cases of failure by resolving the anterolateral instability by means of a tenodesis or anterolateral ligament reconstruction. The most recent data published with a high level of evidence seems to confirm this hypothesis [49-50].

As discussed in paragraph 1.4, the crucial point is to be able to know when there is a lesion of the anterolateral structures associated with the injury of the anterior cruciate ligament. This could make it possible for us to objectively determine when an anterolateral tenodesis is indicated and when it is not. As previously stated, the tools and technology available today are invasive or have high costs. For this reason, in collaboration with the Engineering department and using the previously described technology as a basis, we have developed a completely free source application. The application along with only a mobile phone is capable of measuring knee instability to objectively evaluate the patients before, during and after surgery (**Chapter 3**).

Despite the continuous increasing attention given to extra articular tenodesis and the publication of hundreds of papers regarding this hot topic, poor attention has been paid to the safety of the procedure when performed at the same time as an ACL reconstruction. For this reason, we present the data we collected about the more frequent intraoperative complication linked to this specific technique in **Chapter 4**. Thanks to our investigation we were not only able to point out how frequent it is, but also to suggest how to avoid it.

In **Chapter 5**, we instead focused our attention on the biological consequences of using this technique on the knee joint. Even if this is not precisely considered a complication, it can indirectly generate serious complications such as re-rupture of the cruciate ligament if it is not taken into consideration during the postoperative rehabilitation phase. Thus, we were able to demonstrate how this technique is able to slow down the maturation of the ACL after its surgical reconstruction and we suggested how to adapt the postoperative phase based on our data.

In recent years, the use of anterolateral tenodesis has been studied not only in cases presenting injury to the anterolateral structures, but its effectiveness has also begun to be evaluated in patients with a high risk of ACL reconstruction failure. Indeed, anterolateral tenodesis was studied in high level athletes [51] and patients with hyperlaxity [52]. A reduction of the failure rate was seen when associating this technique at the same time as an ACL reconstruction. Inspired by these works, we also wanted to evaluate the biomechanical and clinical utility of anterolateral tenodesis in two other categories of patients with whom we deal daily in our clinical practice. Therefore, in **Chapter 6**, we investigate the use of anterolateral tenodesis in patients with persistent rotatory instability after ACL reconstruction. Then again, we compared the results of ACL reconstruction alone with ACL reconstruction and anterolateral tenodesis in skeletally immature patients in **Chapter 7**. We concluded that anterolateral tenodesis is able to improve the kinematics of the knee joint and also to decrease the re-rupture after a pediatric ACL reconstruction in both populations. Finally, in **Chapter 8**, we show unpublished data about the isolated use of anterolateral tenodesis. Indeed, nobody has evaluated it in the last 50 years even though numerous papers confirmed how its use in combination with ACL reconstruction can improve the outcomes of the surgery. Then again, isolated use of tenodesis may have some indication nowadays. In this interesting paper we showed how, even alone, anterolateral tenodesis can improve both the kinematic and the clinical symptoms in ACL deficient knees.

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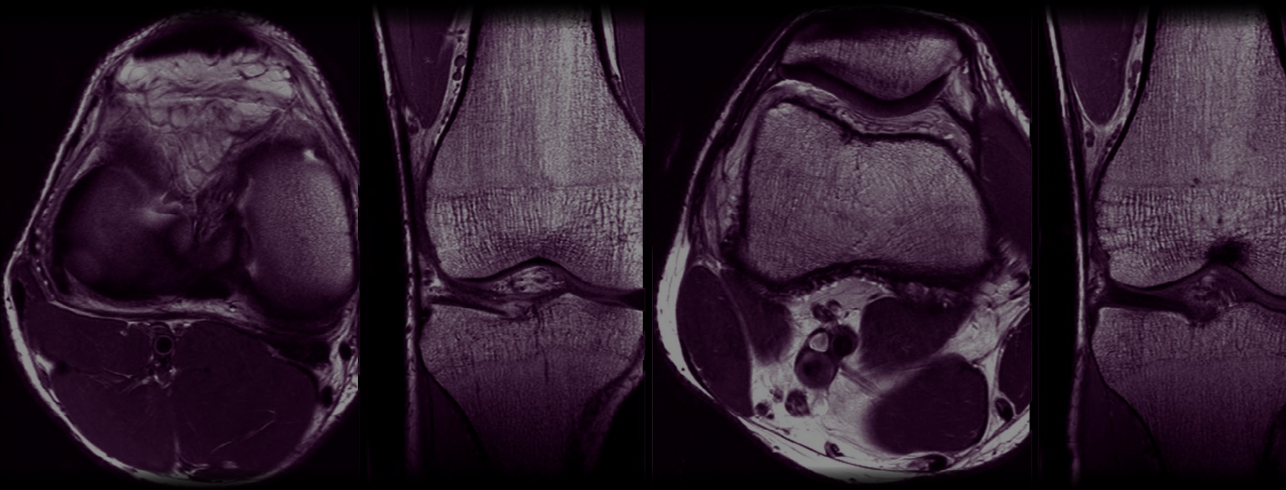
CHAPTER 2.

Minimizing the risk of graft failures after anterior cruciate ligament reconstruction in athletes. A narrative review of the current evidence



Chapter 2.

Minimizing the risk of graft failures after anterior cruciate ligament reconstruction in athletes. A narrative review of the current evidence

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ABSTRACT

Anterior cruciate ligament (ACL) tear is one of the most common sport-related injuries and the request for ACL reconstructions is increasing nowadays. Unfortunately, ACL graft failures are reported in up to 34.2% in athletes, representing a traumatic and career-threatening event. It can be convenient to understand the various risk factors for ACL failure in order to properly inform the patients about the expected outcomes and to minimize the chance of poor results. In literature, a multitude of studies have been performed on the failure risks after ACL reconstruction, but the huge amount of data may generate much confusion.

The aim of this review is to resume the data collected from literature on the risk of graft failure after ACL reconstruction in athletes, focusing on the following three key points: individuate the predisposing factors to ACL reconstruction failure, analyze surgical aspects which may have significant impact on outcomes, highlight the current criteria regarding safe return to sport after ACL reconstruction.

INTRODUCTION

Anterior cruciate ligament (ACL) tear is one of the most common sport-related injuries, involving about 3% of amateur athletes every year, and up to 15% of elite athletes per year. [1] The international literature unanimously agrees on the importance of performing surgical reconstruction in active patients, in order to properly restore the joint kinematics, preserve the intraarticular knee structures and increase the likelihood to resume preinjury sport activities [2 - 4].

Despite the recent advances in arthroscopic equipment, understanding knee biomechanics and surgical techniques, unfortunately ACL reconstruction is not always successful, but a significant number of patients (10% to 15%) [5] reports unsatisfactory outcomes. Previous systematic reviews reported that only 60% of amateur athletes [6] and 83% of elite athletes [7] returned to their preinjury sport level after ACL reconstruction. Graft failure is one of the main determinants of outcomes, representing a traumatic and career-threatening event in athletes. In a meta-analysis involving 1,272 elite athletes, the pooled failure rate was estimated in 5.2% (range 2.8% - 19.3%) [7], but this rate has been shown to grow up to 34.2% when including high-risk cohorts like younger athletes. [8] The outcomes after revision ACL reconstructions are shown not as good as primary reconstructions, in terms of functional scores, rotatory stability, and risk of developing knee osteoarthritis. [9, 10]

It can be convenient to understand the multiple risk factors for ACL graft failure, in order to properly inform the patients about the expected outcomes and to minimize the chance of poor results. In literature, a multitude of studies have been performed on the risk factors of failure after ACL reconstruction, but the huge amount of data may generate conflicting evidence. A comprehensive analysis of this information may support those who want to approach this issue with an evidence-based methodology.

The aim of the current review is to resume data collected from literature about the risk of graft failure after ACL reconstruction in athletes, focusing on the following three key points: (1) identify the predisposing factors to ACL reconstruction failure, (2) analyze surgical aspects which may have significant impact on outcomes, and (3) highlight the current criteria regarding safe return to sport after ACL reconstruction.

PREDISPOSING FACTORS

Identifying predisposing factors for graft failures can represent a successful approach for several reasons. First, patients can be better informed about the chances of failure after an ACL reconstruction. Secondly, this information can be used for developing strategies to modify manipulable factors and, therefore, reduce the risk of failure. For convenience, predisposing factors will be classified as demographic, anatomical and environmental factors.

Demographic factors

Age is universally recognized as independent factor affecting risk for ACL graft retear. In a recent systematic review including 33 studies from 4 different national registries [11], young age was reported as independent risk factor for revision ACL surgery in all registries. Patients aged under 20 years were found to have a risk three times higher than patients over 20 years old, four times higher when compared to patients over 30 years old and nearly eight times higher than patients aged 40 years or older. [11] In another prospective analysis of 2,488 primary ACL reconstructions, the authors found that the likelihood of retear decreased by 9% for each increasing year of patients' age. [12] One of the reasons may be the higher activity level in younger patients, which is shown to significantly affect the risk of reinjury. [12] In addition, Nakanishi et al. [13] evaluated the anteroposterior stability with arthrometric KT-2000 test of two groups of patients undergoing ACL reconstruction and found that younger group had a greater tendency for residual knee joint laxity. This joint laxity could alter dynamics of lower limbs motions and increase risk of graft failure. [14]

If the evidence for age can be defined as high, the same cannot be stated for patient gender as significant factor. Some registry studies demonstrated a higher risk for ACL revision in male patients [15, 16], whereas other registry data deny this finding, reporting a greater risk in female patients [17]. In addition, several other similar studies failed to demonstrate a statistically significant relationship between patient gender and ACL revision. [11, 12, 18]. A recent meta-analysis including 135 articles showed that graft failure rates did not differ significantly between sexes. [19] However, the inclusion of a such impressive number of studies is not immune from plausible confounders, such as differences in activity level or age distribution of the groups. The anthropometric sex-based differences, as well as sex hormonal influence deserve further investigation with higher methodological quality.

Anatomical factors

Several anatomical factors have been directly correlated with increased rate of ACL injury but there is poor evidence about the correlation of such anatomical patterns and risk of graft failure after ACL reconstruction. This is especially true for the body mass index (BMI). Two registry studies on 12,643 patients [20] and 21,304 patients [21], respectively, found a lower risk for ACL revision in patients with higher BMI. In contrast, a cohort study on 30,747 patients from the Norwegian and the Swedish National Knee Ligament Registries reported an increased risk for ACL revision within 2 years both in male and female patients with higher BMI. [22] However, this risk was higher especially for those patients with BMI between 25 and 30, whereas it significantly decreased in patients with a BMI > 30. The different neuromuscular control as well as the patients' level of participation in sport activity might affect the validity of this line of research, but on the other hand, can represent a convincing explanation of such findings. Another interesting chapter is the relationship between bony knee anatomy and risk for graft failure. Several anatomical features have been invoked over the years, including the lateral tibial slope, the intercondylar notch, the lateral femoral condylar offset, the alpha angle (that is the angle between the longitudinal axis of the femur and the Blumensaat line), the lateral femoral notch sign depth, the tibial eminence size, the lateral tibial plateau diameter, and many others. [23] All these bony morphologic features have been advocated as predisposing factors for native ACL rupture, but their effect on the risk of graft failure remains indefinite. [24] Among these, the lateral tibial slope has gained more attention among physicians in the last few years. A study on human cadavers reported that an increased lateral tibial slope was significantly associated with anterior tibial acceleration and ACL strain during simulated jump landing task. [25] Several studies found a significantly higher value of lateral tibial slope among patients with a failed ACL reconstruction, when compared to patients who did not experience graft failure after reconstruction. [24, 26 - 28] Considering this background, some authors advocated a combined closing-wedge anterior high tibial osteotomy in cases of multiple ACL reconstruction failures in the absence of technical errors and with a radiographic lateral tibial slope >12°. [29]

The evidence regarding the effect of the remaining anatomical variables on the risk of ACL graft failure is poor. This is also true for the intercondylar notch, discussed as early as 1980s. [23]. Theoretically, a small intercondylar notch could create wear of the graft on the lateral femoral condyle during knee extension and internal rotation movements. [30] However, some recent studies on human cadaveric knees [31] and post-operative imaging analysis [24, 32, 33] demonstrated that, if the graft is correctly placed, impingement should not occur, and therefore the risk for failure is not increased.

Environmental factors

Environmental factors include both extrinsic aspects to athlete (such as type of resumed sport, playing surface, footwear etc.) and biomechanical aspects of playing actions which may predispose to graft retear. Since all those are modifiable factors, large research efforts have been made to create preventive programs focused on these issues. [34]

Participation in pivoting and hard cutting sports is a well-known predictor of further graft tear after ACL reconstruction. It is estimated a four-times increased risk of knee reinjury among athletes of such sports activities. [35] However, modifying activity level is not always suitable, because intent to return to high level sports is often the main reason why a patient with an ACL tear undergoes arthroscopic reconstruction. Therefore, specific sessions including plyometric exercise, neuromuscular reeducation, balance and strength training have been advocated to prevent knee reinjuries. [35, 36] For instance, dynamic valgus collapse during weightbearing activities (such as cutting, landing or changing direction movements) was found to be a predictor of non-contact ACL injury. [37] This may be due to specific muscular weakness (hip abductors, knee flexors) as well as some predisposing anatomical features, such as increased femoral anteversion or external tibial torsion. [38] A proper balance between quadriceps and hamstring activation is critical to not overload the knee during the landing after a jump. Specifically, hamstring recruitment reduces ACL loads at landing [39] and may help to provide dynamic knee stability by resisting anterior tibial translation and rotations. [40] Based on this, several interventional studies describing specific neuromuscular and plyometric prevention programs demonstrated a significant reduction in the incidence of ACL injuries. [34 - 36]

SURGICAL PROCEDURE

Graft failure after ACL reconstruction may result from any combination of technical errors, biologic causes and traumatic events. Historically, technical errors have been considered the most important cause of graft failure. [41] A recent systematic review [41] conducted on 3,567 failures identified technical errors as one of the most common causes of failure, preceded only by traumatic events. Similarly, Karmath et al. [42] reviewed the literature regarding outcomes after ACL reconstruction and reported that technical errors (e.g., improper tunnel placement, inadequate ACL graft, insufficient graft tensioning and failure to recognize concomitant laxity) accounted for 22% to 79% of failure cases. Therefore, it should not be surprising that technical aspects of ACL reconstruction have always been a major focus for scientific investigation. With the aim to provide an exhaustive synthesis of the huge amount of data published in the literature, this section will focus on the proper management of concomitant lesions, the outcomes related to different graft types and the evidence about surgical technique.

Concomitant lesions management

When planning an ACL reconstruction, an assessment of the other ligaments as well as intra-articular structures of the knee should not be omitted. Associated lesions can compromise the graft function due to residual instability. It is estimated that about 15% of ACL reconstruction failures can be result of a missing diagnosis of associated ligament or meniscus lesion at time of surgery. [5, 43]

One of the most discussed issues about this topic is the protective effect of the anterolateral ligament (ALL) on the ACL graft function. This interest is fueled by the common finding of residual pivot-shift phenomenon after ACL reconstruction, which is estimated in up to 25% of cases regardless the chosen graft. [44] Furthermore, persisting rotational instability has been shown to be a risk factor for recurrent injuries and ACL failure. [44] Anterior translation, internal rotation, and pivot shift was found to be restored better with combined ACL/ALL reconstruction than with ACL reconstruction alone in several biomechanical studies.[45] Such biomechanical findings also result in clinical evidence of reduced risk of graft failure. [46] A recent meta-analysis of 20 randomized and nonrandomized controlled trials found that the rate of graft failure was two-to-four times lower in the ACL/ALL group than in the isolated ACLR group, regardless the adopted technique or the surgical timing. [46] Therefore, international literature supports the ALL reconstruction in high-risk patients. Indications include patients with high-grade pivot shift, concomitant Segond fractures, high-level athletes participating in pivoting sports and in ACL revision settings. [44]

Medial collateral ligament (MCL) injury is frequently associated to ACL tears [47], as a result of the valgus stress component of a typical ACL trauma. ACL and MCL play a concomitant role in maintaining anteromedial knee stability.

[48] Several cadaveric studies demonstrated that ACL strain is increased after sectioning MCL, when applying a valgus stress or an intra-rotation movement of the tibia. [48, 49]. In addition, combined MCL and ACL sectioning increases anterior knee laxity greater than isolated ACL sectioning. [50] Despite these findings, the treatment of combined ACL and MCL tears is still controversial. Most authors support the conservative management of the MCL injury, especially in acute settings and low-grade injuries. [47, 51] A "wait and see" approach is recommended by some authors also in high-grade MCL tears [47]. However, a recent study from the Swedish National Knee Ligament Registry highlighted a higher risk of ACL revision in patients with ACL reconstruction and non-surgically treated MCL injuries compared to isolated ACL reconstructions. When a repair or reconstruction of concomitant MCL injuries was performed, this risk was comparable to isolated ACL reconstructions. [52] These findings encourage the authors supporting early MCL repair or reconstruction [53] because ACL insufficiency might adversely affect the MCL process healing. [54] On the other hand, delayed ACL reconstructions have been related to better functional outcomes with earlier motion recovery. [55] MCL surgical treatment should be considered in patients with severe valgus alignment, entrapment over the pes anserinus tendon (Stener-like lesion), large bony avulsions and persistent instability after ACL reconstruction. [53, 55]

The posterolateral corner (PLC) of the knee is another important issue of academic interest, because of an evolving appreciation for its biomechanical relationship with the ACL. PLC injuries are commonly associated to cruciate ligaments tears, occurring in isolation in only 28% of cases. [56] Specifically, 7.4% - 13.9% of patients with ACL injury have a concomitant PLC injury. [57] Biomechanical data demonstrated a significant increase in force on the ACL in PLC-deficient knee, when applying a varus moment or a combined varus-internal rotation moment to the knee joint [58, 59], as well as during simulated gait and squatting. [60] In addition, Plaweski et al. [59] found that an ACL reconstruction was not enough to prevent varus and external rotation displacement in the setting of ACL-PLC deficient knee; a return to native kinematics was achieved only after adding a reconstruction of PLC static structures. Despite such promises, the role of PLC on the risk of ACL failure has not been adequately investigated. In one registry study, a concomitant PLC injury would appear to not affect the risk of ACL failure, whatever the treatment is. [52] However, this analysis was impaired by the small size of the study groups, which limits the relevance of such findings.

At last but not least, the biomechanical influence of the menisci on knee stability must not be overlooked. It is well known that the medial and lateral menisci contribute to knee stability, acting as secondary restraints for anterior and rotatory tibial displacement. [61 - 63] Meniscus repair would seem to restore knee stability comparable to ACL-reconstructed knees with intact menisci. [63] These findings also apply to meniscus posterior root lesions (MPRL) [64, 65] Lateral MPRLs were reported to increase anterior tibial subluxation of the lateral compartment in patients with ACL injuries. [64] Similarly, medial MPRLs were found to significantly increase ACL graft loads over the intact state, while root repair restored the function of the medial meniscus as a secondary stabilizer. [65] Finally, a ramp lesion in an ACL-deficient knee has also been shown to increase anterior tibial translation and external rotational laxities. [66, 67] This aberrant laxity cannot be completely restored after ACL reconstruction alone but with combined posterior menisco-capsular repair. [67] Nevertheless, there is no clinical evidence regarding increased risk of graft failure following meniscal loss, since several studies did not detect significant difference between isolated ACL reconstruction and ACL reconstruction combined with medial and/or lateral meniscectomy. [11, 68, 69] However, meniscectomy has been clearly recognized as a risk factor for delayed return to sport [69] and career shortening in athletes. [69 - 71] As a result, meniscus repair should be considered even in athletes.

Graft choice

Graft choice has always been one of the most critical topics for discussion. The “ideal graft” used for surgical ACL reconstruction should recreate, as far as possible, the biomechanical properties of the native ligament, providing rapid biological integration and reducing recovery.

Historically, autologous grafts have been considered as the first-choice graft. [72], since allografts and synthetic grafts have been proved to be inferior in terms of failure rates, clinical scores, and knee stability [11, 73 - 76], especially among younger patients. [75, 76] Actually, bone-patellar tendon-bone (BPTB) is the overwhelming favorite over hamstring grafts in athletic population, [77, 78] although quadriceps tendon (QT) has renewed interest among physicians as a potential alternative. [72]

The available evidence in literature is mixed on which graft type is associated with a higher risk of graft failure and revision ACL reconstruction. In a systematic review conducted in 2017 and including all available meta-analyses focused on comparison between BPTB and hamstring grafts [79], the authors found that 10 out of 13 meta-analyses failed to demonstrate statistically significance between the two groups regarding the graft failure rate. More recently, a systematic review exclusively involving athletic population [80] demonstrated similar failure rates between BPTB (2.2%) and hamstring autografts (2.5%), but a trend for higher return to sport rates was found in athletes with BPTB autografts (81%) when compared with HT autografts (70.6%). The association between graft choice and the rate of revision has also been investigated in several registry study. [11] In a systematic review collecting data from 11 registry studies [11], a statistically significant lower revision risk in favour of BPTB in comparison to hamstring grafts was reported in nine out of eleven studies. [11] Finally, a recent meta-analysis [81] pointed out a higher incidence of deep infections after ACL reconstruction with hamstring autografts compared with BPTB autografts. Although it is an unusual complication, it should deserve particular consideration because of the potentially deleterious effects on graft function, knee joint and athletes' career, taking into account that professional athletes are defined as a risk category. [82]

Outcomes of QT graft were evaluated in three recent meta-analyses. [83 - 85] Riaz et al. [83] firstly demonstrates comparable survival rates and joint stability when BPTB and QT grafts are used, but with fewer adverse donor site symptoms using QT grafts. Later, such findings were confirmed by Mouarbes et al. [84] in a systematic review of 2,856 patients, reporting QT grafts have comparable graft survival rate to BPTB and hamstring, with less harvest site pain than BPTB autograft and better functional outcome scores than hamstring autograft. Nyland et al. [85] found that QT autografts had lower failure rates than hamstring autografts, but difference was overturned when a suspensory femoral fixation was used in hamstring group. This led to the suggestion that graft fixation is also an important aspect of surgical failure. Surprisingly, a recent registry study from the Danish Knee Ligament Registry [86] reported a statistically significant higher risk of failure for QT graft (4.7%) in comparison to both BPTB (1.5%) and hamstrings graft (2.3%) at 2-year follow up. However, the smaller samples size, the lower patients' age and higher incidence of concomitant meniscus and cartilage injuries in the QT cohort represent a relevant bias. In addition to this, the same authors revealed the considerable influence of the learning curve on the outcomes of ACL reconstruction with QT, since revision rates dropped to 0.8–2.0% when low volume clinics with less than 100 procedures per years were excluded. [87]

From the foregoing, it is clear that each graft presents both advantages and issues that need to be considered. Therefore, it is feasible to make an individual graft choice, based on patient's expectation, body characteristics and kind of sport resumed.

Surgical technique

Proper positioning of the ACL graft has been proven to be of utmost importance to reduce risk of graft failure. [41, 88] Non-anatomic graft positions create not physiological intra-articular force vectors, which may affect graft longevity. For instance, a graft that is placed too posterior or too low in the femoral condyle edge is subjected to higher tension during knee extension [89] Conversely, a high and anterior position produces a longer and more "vertical" graft, which results in increased anterior tibial translation [90] and increased rotational laxity. [91, 92] In addition to the above, graft positioning also influences the risk of graft impingement. [93] This may impact not only knee motion, but also risk of graft failure. [94] According to the above, it is recommendable to place femoral and tibial tunnels as close to the native ACL footprints as possible, in order to reproduce more closely the biomechanical properties of the native ACL. [88, 92, 95]

The transtibial technique makes it more difficult to address accurately and reliably the femoral ACL footprint. [96] As a result, several physicians support tibial tunnel-independent methods for femoral tunnel placement, which have been proven to provide a more anatomic positioning of both the tibial and femoral tunnels. [96, 97] In accordance with such biomechanical evidence, international literature demonstrated that tibial tunnel-independent techniques result in better knee stability and functional outcomes. [97 - 100] Accordingly, these techniques should better protect the knee from further joint injuries [101] and osteoarthritis development [102]. This was confirmed by a recent meta-analysis including a total of 1546 patients [102], but such findings are affected by the lack of a more in-depth analysis of concomitant meniscal injuries, thus representing a relevant bias that may have influenced the observed rates of osteoarthritis development. Despite this, there is no evidence of lower subjective outcomes scores [98, 100] or increased graft failure rates [97, 99, 103] with the transtibial technique. In addition to this, there are several registry studies showing higher graft revision rates with the anteromedial portal technique. [11] Some authors argued that an anatomic reconstructed ACL graft is subjected to greater force than non-anatomic high placement of ACL graft. [104] Moreover, the tibial tunnel-independent techniques have shown to produce a higher graft bending angle than the transtibial technique. [105] This angle was demonstrated to significantly affect the graft signal and femoral tunnel diameter at 12 months [106], although the clinical relevance of such finding is unclear, because functional outcomes, arthrometric data and subjective scores seem to not be related. [106] Finally, the learning curve of the more demanding “tibial tunnel-independent” has been advocated as part of the explanation of such findings [107], although the anteromedial portal method has been reported as the most used technique for femoral tunnel drilling throughout the world. [108] With improved understanding of the anatomy and biomechanics of the ACL, the transtibial approach has been modified to achieve a more anatomic femoral tunnel placement. The modified transtibial technique showed superior outcomes than conventional transtibial approach and comparable with the anteromedial portal technique in terms of clinical scores, negative rates of the Lachman and the pivot-shift test, and return-to-sport level. [109] Future studies are needed to determine the long-term benefits with the modified transtibial in terms of graft failure rates.

In addition to the above, alternative techniques have been supported aiming to improve outcomes and graft survival. Further developing the concept of anatomical ACL reconstruction, the double-bundle reconstruction has been proposed to replicate the anteromedial and the posterolateral bundles. Several biomechanical studies supported this technique, demonstrating improved anteroposterior and rotational knee stability [110] However, this promising background resulted in a clinical small difference in terms of joint stability [111 - 116], but not in functional and subjective scores [110 - 115], as well as in terms of failure rate, [111, 113 -115] since only one meta-analysis demonstrated a lower risk of graft failures with double bundle ACL reconstruction. [116]

More recently, there is an increasing interest in replacing conventional round tunnels with tunnel shapes that resemble more closely the original ACL footprints. The basic principle of these techniques comes from some anatomic studies describing the ACL as a flat, “ribbon-like” structure, with a thin, oval-shaped insertion on the femur and a C-shaped tibial insertion. [117 - 119] The proposed advantages are both biomechanical with increased rotational stability [120], and biological due to increased bone-tendon contact and decreased distance to the central part of the graft. [121] Despite preliminary promising data, clinical benefits over conventional ACL reconstruction techniques have yet to be demonstrated with high quality methodology studies.

RETURN TO SPORT

One of the greatest challenges for clinicians is to return the injured athlete back to sport as quickly as possible, but at the same time not exposing the affected knee to excessively high reinjury risks. Unfortunately, the risk of sustaining a second ACL injury is highest during the early period after return to sport (RTS), especially during the first year after the index reconstruction. [35, 122] As a result, definition of rigorous and well-coded RTS criteria has always been a main research focus.

Time after ACL reconstruction is the most used criterion to assess RTS readiness. [123] In a recent scoping review of 209 studies [123], time to RTS was reported as criterion in 85% of included studies and represented the sole criterion to give athlete the all-clear to RTS in 42% of studies. It goes without saying that time is a crucial variable for proper graft integration and maturation. [124] Historically, six months for contact sports were considered a good compromise. [123] Recently, this axiom has been questioned. The Delaware-Oslo ACL cohort study found that delaying RTS at 9 months after ACL reconstruction may reduce reinjury risk by 84%. [35] Specifically, the reinjury rate was reduced by 51% for every month delay for up to 9 months, beyond which no further risk reduction was observed. Furthermore, some authors even supported delay of RTS until two years, calling into question biological and rehabilitative argumentations. [125]

However, it is obvious that time alone is not sufficient for determining readiness for sports resumption. [35, 123] Some authors proposed to focus instead on graft maturation and functionality. [126] Histologic analysis of biopsy graft specimens during second-look arthroscopy is considered the gold standard to determine graft maturity. [127] Nevertheless, this method is invasive and, therefore, not feasible for clinical follow-up. Magnetic resonance imaging (MRI) may be useful for indirect monitoring of graft “ligamentization” process, as incomplete graft maturation is related to a hyper-intense graft signal on MRI. [128] However, no evident correlation was found between signal intensity and knee stability outcome scores. [128] Therefore, a routine MRI assessment of graft maturity does not provide solid insights for RTS. Ideally, the information gained through MRI assessment should be combined with laxity measurements, to follow the graft evolution and early detect potential abnormalities (graft elongation, iterative rupture, contralateral rupture, etc.). Both anteroposterior and rotatory stability is required to safely RTS. Therefore, non-invasive devices for anteroposterior stability and pivot shift assessment have been developed in the last years, both to diagnose ACL injury and to detect residual laxity after ACL reconstruction. [129, 130] Such technologies could represent a potential aid in the follow-up evaluation of patients undergoing ACL reconstruction and in the RTS decision algorithm. An anteroposterior side-to-side difference < 5 mm is unanimously accepted as threshold for defining a knee as sufficiently stable. [126, 129]. On the other hand, a standardized quantification of knee rotatory laxity is still lacking. [130] The variability of the pivot shift outcome, for both displacements and accelerations, depends on how the tester is performing the maneuver itself, in terms of both the magnitudes of the applied loads and the speed with which the limb is moved. [130] Furthermore, clinical studies reported knee laxity measurements at a specific time point after ACL reconstruction. Thus, little is known about the evolution of knee laxity over the months. These conclusions are still difficult to generalize, due to the diversity of such variables as surgical techniques, graft types, fixations devices, associated injuries and measurement techniques.

Muscular strength recovery is another fundamental requirement before RTS. Above all, isokinetic testing measures have been reported for proper evaluation of quadriceps and hamstring strength. [123, 131] In addition to this, functional and performance test have been supported to enhance their predictive value. [131] Among these, hop tests have become the mainstay of performance tests prior to returning the athlete to sport, with the numerous variations which have been added over the years. [123, 131] Limb symmetry index (LSI) has been widely adopted as a reliable measurement outcome. A LSI ≥ 90% is supported before RTS [123], although some authors recommended an LSI ≥ 100% for higher impact sports athletes. [132] However, there are some concerns regarding the use of the uninvolved limb as a reference for the involved limb. LSI may overestimate knee function since the resulting reduction in sports participation following ACL injury leads to bilateral muscle strength deficits. [133] Therefore, LSI could not be specific enough to indicate the athlete has reached the preinjury level. For this purpose, some authors proposed to consider the estimated pre-injury capacity (EPIC), that is obtained by comparing the involved-limb measures to uninvolved limb measures before ACL reconstruction. [134] Wellsandt et al. [134] demonstrated that 90% EPIC levels were more sensitive than 90% LSI levels at assessing the risk of ACL re-injuries. On the other hand, the preinjury level may be not sufficient for safe sports participation and performance. Furthermore, the outcome measure of hop tests and isokinetic tests is strictly quantitative in nature, while outcomes related to the quality of movement are not captured. [135] In order to solve those issues, Padua et al. [136] proposed a clinical assessment tool for qualitative analysis of aberrant movements during a standardized jump-landing test. Gokeler et al. [137] applied this score in a cohort of 28 patients who underwent ACL reconstruction. By doing so, the authors were able to detect 30% of patients with aberrant movements which may predispose to increased risk of ACL reinjury. [137] Moreover, the quality of movement is significantly affected by fatigue. [136, 137] Thus, repetitive testing is encouraged for proper evaluation of ACL-reconstructed knee kinematics. The evolving research has made available new technologies for more refined kinematics analysis, including gait analysis, force-plates, electromyography and virtual immersive analysis. [138] However preliminary findings need to be confirmed with high methodological quality studies.

Psychological aspect is another matter that should be considered before clear the athlete back to sport. The injury and time spent out of match can impair athletes' motivation, that has been shown to play a key role for returning to pre-injury sport level. [139] Patient's perception of symptoms, function and activity can be reliably estimated with various patient-reported outcome measures (PROMs). However, it is debated in literature whether PROMs may reliably predict risk of ACL reinjury. Granan et al. [140] observed an increased risk of graft failure in patients who had poor Quality of Life subscale of KOOS at 2 years after index ACL reconstruction. Similarly, Logerstedt et al. [141] reported that patients who scored poorly on the IKDC were over four times more likely to fail the RTS tests.

On the other hand, nearly 50% of the athletes with good scores overestimated their recovery. [141]

From the foregoing, it is clear that the decision to allow RTS after ACL reconstruction solely based on one single criterion (time, strength recovery, functional test, PROMs) cannot be adequate. An all-around evaluation including biological, kinematic and psychological aspects is strongly recommended. Therefore, battery of tests including multiple measurements should be performed, instead of one single assessment at the hypothetical end of rehabilitative process. A stepwise evaluation process during the entire rehabilitation process is thus indicated.

CONCLUSION

This review collected and summarized a large body of research addressing the risk of ACL failure. The current evidence available in literature shows that surgical technique represents a key factor, but this aspect alone is insufficient to ensure long-term graft survivorship. Instead, a careful preoperative evaluation is necessary, in order to detect any predisposing factor which may increase risk of graft failure, and therefore address it where possible. Similarly, the post-operative rehabilitation phase needs a global stepwise evaluation and should be managed by a specialized sport-traumatology team. Final RTS clearance decisions should positively balance the athlete's desire to savor the playing field with the risk of graft reinjury.

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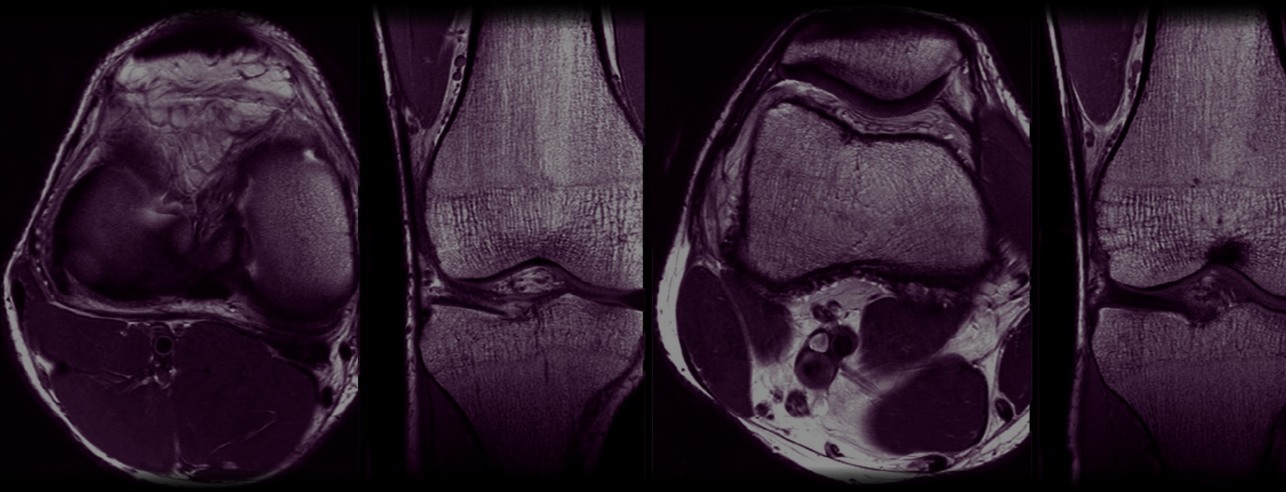
CHAPTER 3.

Open-source Android application to measure the anterior-posterior knee translation



Chapter 3.

Open-source Android application to measure the anterior-posterior knee translation

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ABSTRACT

Background and objectives: There are widely used standard clinical tests to estimate the instability of an anterior cruciate ligament (ACL) deficient knee by assessing the translation of the tibia with respect to the femur. However, the assessment of those tests could be quite subjective. The goal of this study is to present an open-source Android application universally affordable, easy and fast to use, that provide the possibility of a quantitative and objective analysis of that instability.

Methods: The anterior-posterior knee translation of seven subjects was assessed using the developed open-source Android application. A single Android smartphone and the placement of three green skin adhesives are required. The application was developed using the image-processing open-source libraries OpenCV.

Results: An open-source Android application was developed to measure the AP translation in ACL-deficient subjects. The application identified differences in the AP translation between the ipsilateral and the contralateral legs of five ACL-deficient subjects during Lachman and Pivot-Shift tests. Three out of five subjects were under anesthesia and were also the ones with significant differences.

Conclusions: The application detected differences in the AP translation between the ipsilateral and contralateral legs of subjects with ACL deficiency. The use of the application represents an easy, low-cost, reliable and fast method to assess quantitatively the knee instability.

INTRODUCTION

Injuries the anterior cruciate ligament (ACL) of the knee lead to negative consequences for the joint stability during sport and daily life [1]. There are studies which report that, either in USA or in Europe, around 30 people out of 100.000 inhabitants suffer this injury [2,3]. Standard clinical evaluation of an ACL deficient knee comprises specific tests like Pivot-Shift or Lachman tests [4]. Unfortunately they express instability only with a qualitative evaluation influenced by the technique employed by the surgeon and his expertise in grading the degree of instability [5]. A precise quantitative evaluation of the knee instability after an ACL rupture would be important both for the surgical planning and postoperative rehabilitation program.

Given that Lachman test simply consist in anterior tibial plateau translation in the knee close to the extension, the measure in millimeters of that translation provide a precise quantitative evaluation of that test. During the Pivot-Shift test firstly an anterior subluxation of the lateral tibial plateau is observed, then a spontaneous reduction occurs. Quantitative evaluation of Pivot Shift test then could be achieved measuring either anterior tibial translation or the acceleration of tibial reduction. Available systems for quantitative evaluation of the instability during the tests are not universally available, are mostly expensive and present some disadvantages. Commercial accelerometers (like KiRA [6]) can be used to quantify the instability during the Pivot-Shift or Lachman tests. However, it measures the absolute acceleration of the tibia with respect to the ground, which requires certain conditions to do the measurement, and it may not be easy to interpret during the Pivot-Shift test evaluation. Furthermore, the measurements by the arthrometers such as KT-1000 (one of the most popular) could present inadequate reliabilities (both intra- and inter-examiner) as shown in literature studies [7]. Fluoroscopy measurements would be the most reliable and accurate, though they are too invasive and expensive [8].

Image processing became a low-cost and non-invasive method to measure the anterior-posterior (AP) translation of the knee, during Lachman and Pivot-Shift tests. Nowadays the digital cameras used in the smartphones and tablet PCs can capture high quality videos. In addition, the algorithms and libraries for image analysis, such as the open-source library OpenCV [9], are available for everyone in different programming languages. Hoshino et al. [10] demonstrated the possibility of the non-invasive evaluation of lateral translation during Pivot-Shift test and Lachman test respectively. The same authors developed an iPad application to capture and process data during the Pivot-Shift test [11]. However, as far as the authors know, no application is freely available, and neither accessible for Android.

This article describes a developed Android application which can calculate the AP translation during the Lachman and Pivot-Shift tests using the video capture of the tests. The application uses the open-source library OpenCV and can be installed on any Android device such as smartphone or tablet PC. The results are presented for five subjects showing the differences between ipsilateral and contralateral legs. Since this method is noninvasive and does not require expensive instruments it can be easily included in the test routine both at the clinics and in the operating room.

The importance of being able to spread an objective, quantitative and open-source measurement method for knee instability is important in order to give everyone the opportunity to express their data with a single measurement parameter and thus be able to make effective global data comparison.

METHODS

This study has been approved by the ethical committee of ICATME with protocol number LCA-2017-01 and the subjects gave informed consent.

Experimental data

Lachman and Pivot-Shift tests were performed in both legs of seven subjects (six women, age: 33 ± 9.1 years old; one man, age: 40 years old) with one ACL-deficient knee, while they were being recorded by a regular smartphone camera. The measurements of three subjects were done also under anesthesia.

Three green round stickers of 13 mm of diameter were attached to the specific points of the subjects' knee: the Gerdy's tubercle, the lateral epicondyle and the center of the fibula head. The distance between point 1 and 3 was measured. The tests were performed always by the same experienced knee surgeon. The high-quality videos (resolution 1080p) were captured using a digital camera of a smartphone. After storing the videos in the gallery, they were used for the post processing within the developed Android application.

It is suggested that the videos are captured at a distance between half and one meter from the stickers. The plane of the camera should be as parallel as possible to the plane of the stickers during the Lachman tests and at the beginning of Pivot-Shift tests. Rounded green points in the background should be avoided to help the processing of the images and avoid confusion.

Image processing

The Android application was developed in Android Studio 3.1.3. The main algorithm included in the application to measure the AP knee translation consists of five steps. First, it loads the video requested by the user from the gallery storage of the smartphone. Second, it splits the video into single frames. Third, using the OpenCV 4.1.0 library (already used in other biomedical applications [12,13]), the algorithm converts the RGB (red green blue) image to an HSV (hue, saturation, value) image, and then, it identifies the green objects and creates the binary image of the current frame. Fourth, the Gaussian filter is applied to the binary image and the detection of the circle edges is performed by applying the Hough Transformation [14]. Fifth, once the three points are captured, the algorithm maps each point with the corresponding landmark. Then, the calculation of the AP translation is calculated from the detected XY coordinates of the three points. Third to fifth steps are performed for each frame.

Calculation of the AP translation

The AP translation is defined as the distance between the pivot point and the Gerdy's tubercle. The pivot point is defined as the intersection of the axis between Gerdy's tubercle and fibula head points, and the perpendicular of this axis crossing lateral epicondyle point. In order to determine the AP translation, the experimental distance between the Gerdy's tubercle point and the fibula head should be provided by the user. The location of the pivot point is determined for each frame. Then, the values of the AP translation are calculated for each frame. At the end of the processing the values of the AP translation are plotted on the screen .

User interface

The user interface, called "Funee" (from "Functional Knee"), consists of a main window where the user first introduces the experimental distance between the markers at the tibia (Gerdy's tubercle and fibula head). Then, the user picks the video from the gallery stored in the smartphone, and choose left or right leg. The video processing can be started and visualized on the screen. At the same time, a curve with the AP translation is shown in the plot. After that, the user can store the results in a .txt file.

Analysis

Mean and standard deviations of the range (difference between the max and min values) of AP translation during the Lachman and Pivot-Shift tests over five trials were calculated for both legs of the seven subjects. Additionally, we report the results for one subject before and after the ACL reconstruction surgery (with no anesthesia) for the injured leg. Significant differences are considered if the *p-value* < 0.05, when comparing the AP translations between ipsilateral and contralateral legs or the AP translation before and after the surgery.

RESULTS

The results show differences in the AP translation measured by the application between injured and non-injured legs. The range of AP translation was higher in the injured leg than in the contralateral leg for all seven subjects (S1 to S7), and significantly higher for five subjects during the Lachman tests ($p < 0.001$ for S2 and S3, $p = 0.005$ for S5, $p = 0.004$ for S6 and $p = 0.001$ for S7), and for three subjects during the Pivot-Shift tests ($p = 0.036$ for S5, $p = 0.045$ for S6 and $p = 0.02$ for S7). The three subjects who had significant differences consistently in both tests (S5, S6 and S7) were under anesthesia.

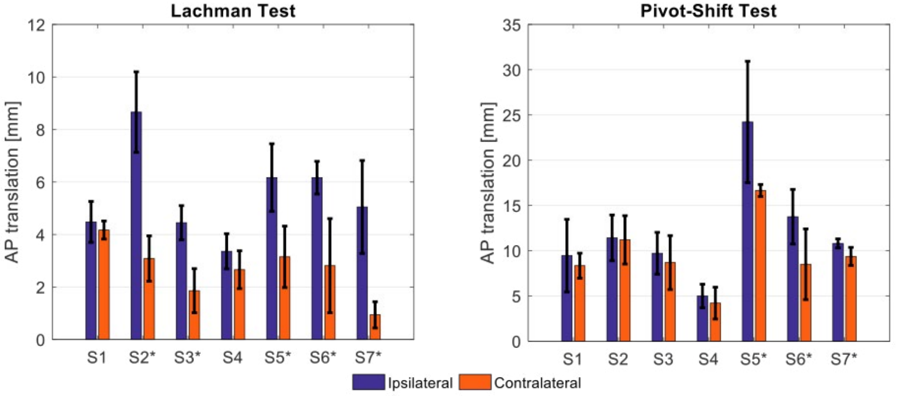

Figure 1. *Anterior-posterior translation values (mean ± standard deviation) in the ipsilateral and contralateral legs of seven ACL-deficient subjects during Lachman and Pivot-Shift tests. Note that the vertical axes do not have the same range of values. The star * indicates significant difference ($p < 0.05$).*

Additionally, we measured the AP translation in one subject (gender: woman, age: 28 years old) pre and post-surgery of an ACL reconstruction, when she was awake. The results show that there were significant differences in the AP translation of the injured knee before and after the surgery (Figure 2).

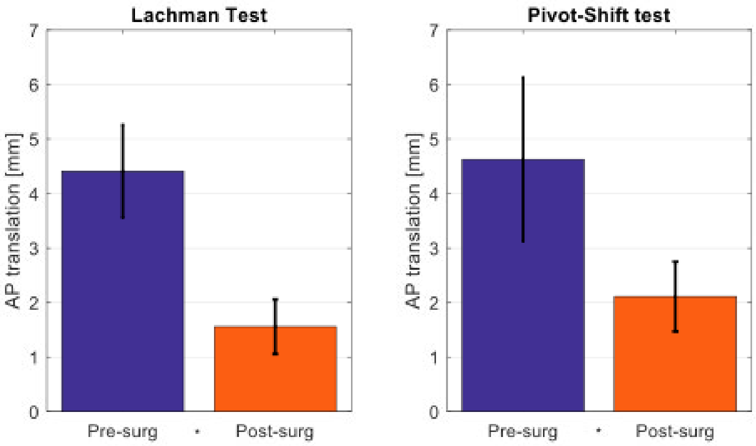

Figure 2. *Anterior-posterior translation values (mean ± standard deviation) in the ipsilateral leg of one ACL-deficient subject before and after the surgery. The star * indicates significant difference ($p < 0.05$).*

The processing of one video of about 10 s takes about 5 s to be processed. The results were obtained in a regular smartphone emulator (Nexus X5 Android 9.0, API 28).

DISCUSSION

This study aimed to present a new Android application able to measure knee instability by assessing AP tibial translation and show that differences can be observed between the injured and non-injured knee subjects before the surgery. It was also able to detect the difference in an injured knee between pre and post-surgery. This application is based on the open-source library OpenCV used to process images. Three out of the seven subjects were under anesthesia, and for those ones the results were significantly different between legs for both Lachman and Pivot-shift tests, which is in agreement with the conclusion of other studies [15].

The presented method represents an easy, affordable and fast way of assessing in a quantitative way the instability in ACL-deficient knees. It can be used in both the clinics and operating room, and it does not require to bring in the operating room bulky devices, such as KT-1000 usually used to assess Lachman tests. Only three adhesive stickers and a smartphone are required to use this method, not as other methods which require sophisticated and expensive devices [16]. The user obtains directly the AP translation, easy to interpret and to relate to instability of the knee. This is an advantage compared to the measurement with inertial systems [17,18], which usually reports the absolute acceleration with respect to the ground.

Despite these benefits, the results obtained with this application should be compared with the ones obtained with biplanar fluoroscopy, the current most reliable method, since it measures directly the instability between bones [19]. Only in this way could be validated the reliability of the application in assessing quantitatively the knee instability. Another limitation of the present work is that the given translation information is the projection on the camera plane. Therefore, when performing Pivot-Shift tests, the information provided by the application is not the actual value of the knee AP translation, since the tibia and femur are not completely parallel to the camera. However, Hoshino et al. [11] found that significant differences can also be observed for these tests. In our study, the number of analyzed ACL-deficient subjects was not high enough to have strong statistical conclusions, but the purpose is to present the application, and a clinical study with a larger sample size will be the scope of future works.

The fact that the application can be run in a standard Android smartphone with a short time of processing makes the use of this application suitable to assess the Lachman and Pivot-Shift tests with no extra training for any surgeon. The application is freely available, as well as its code (at https://github.com/gilserrancoli/funee_app).

CONCLUSION

An open-source Android application was developed to measure the knee instability in ACL-deficient subjects. Differences in the measurements were observed between the injured and non-injured knees, as well pre and post-operatively in a injured knee. The use of the application represents an easy, low-cost and fast method to assess the knee instability for the knee injured subjects.

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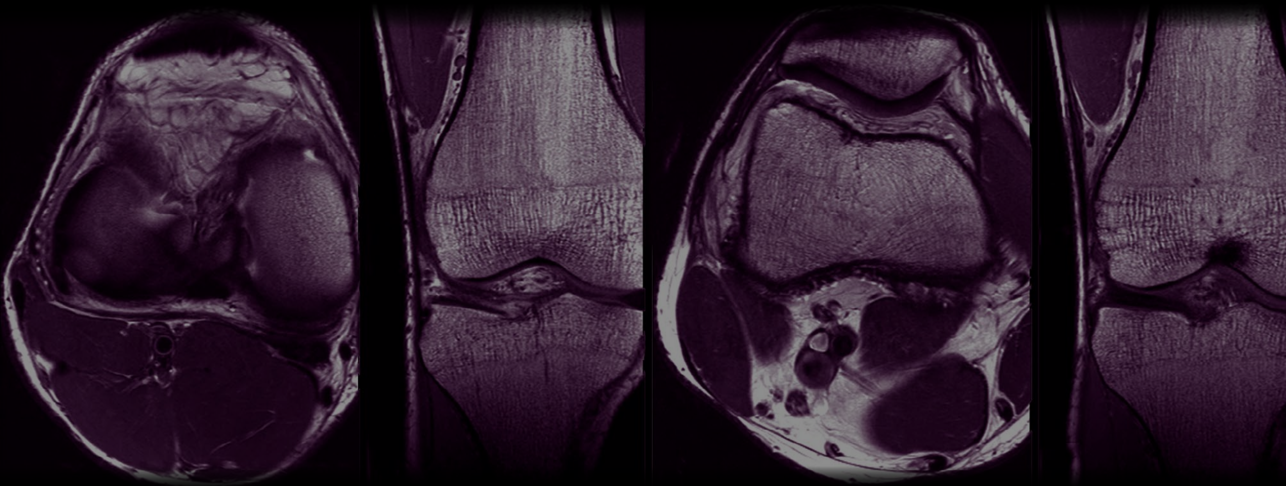
CHAPTER 4.

Evaluating for tunnel convergence in ACL reconstruction with modified Lemaire tenodesis: what is the best tunnel angle to decrease risk?



Chapter 4.

Evaluating for tunnel convergence in ACL reconstruction with modified Lemaire tenodesis: what is the best tunnel angle to decrease risk?

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ABSTRACT

Purpose: The purpose of the present study was to analyze post-operative CT scan evaluations of patients who had undergone a combined ACL reconstruction and modified Lemaire ALT with femoral fixation through a bony tunnel.

Methods: Postoperative CT scans of 52 patients who had undergone combined ACL and ALT were prospectively evaluated. ACL femoral tunnels were drilled through an anteromedial portal in the center of the native footprint. An ALT fixation tunnel was drilled 5mm proximal to the lateral epicondyle aiming at an inclination of 30° proximally and 30° anteriorly. Two independent observers evaluated the CT scans measuring any degree of collision, the shortest distance between the tunnels and the inclination of the ALT tunnels. Measurements were carried out both at the cortical level and on a plane passing 1 centimeter deeper in the lateral condyle.

Results*:* At the level of the cortex, no convergence of the tunnels was identified. In 14 out of 52 cases (26.9%), the shortest distance between the tunnels was less than 5mm. Tunnel collision occurred in 8 out of 52 cases (15,4%) and the bone bridge between the tunnels was less than 5mm in 11 cases (21,1%) when the measurements were made on the deeper plane. When the inclination on the axial plane was less than 15°, a collision always ($p<0.001$) occurs. When it was more than 20°, no collision occurred ($p<0.001$). No correlation between convergence and the inclination of the ALT tunnel on the coronal plane was detected.

Conclusions*:* In order to fix a modified Lemaire ALT through a femoral tunnel avoiding any interference with an anatomic femoral ACL tunnel, we recommend the femoral tunnel be drilled with an inclination of at least 20° anteriorly.

INTRODUCTION

Irrespective of the technique used for anterior cruciate ligament (ACL) reconstruction, some retrospective reviews highlighted that up to 34% of patients continue to have positive pivot shift postoperatively. (1) This may result in worse long-term outcomes and can influence the return to sport activities. (2-3) The anterolateral structures of the knee have been re-discovered in recent years. (4-5-6) Given that they appear to be involved in the rotational stabilizing process (7-8), antero-lateral tenodesis (ALT) has been suggested for use in combination with ACL reconstruction to increase rotational stability. (9) The results presented in clinical and cadaveric studies are not yet certain, but they seems to be promising when combining the two procedures. (10-11) No reconstruction technique has been proven to be the most effective but examining the different techniques in detail is not the purpose of this article. The vast majority of the techniques suggested for an anterolateral tenodesis involved a fixation point at the cortex of lateral femoral condyle. (12-13) The most used techniques require a femoral fixation independent from that of the ACL. Among many suggested femoral fixation methods, some require a bony tunnel. (14-15) This is why some authors later investigated the possible disadvantages of a tunnel creation in this anatomic region. In particular, the risk of damage to local structures has been taken in account. (16) Intuitively, the collision between extra-articular tenodesis and ACL femoral tunnels during an associated reconstruction represents a possible problem. This could therefore compromise either the integration or fixation of the graft. It might even cause possible condyle fractures if the tunnels´ collision occurs close to the lateral femoral cortex. These problems have been studied in the case of several tunnels for multi-ligament reconstructions. The results show that the multiple tunnels may increase the risk of femoral condyle osteonecrosis or fracture. (17-18) Different angles have been suggested in the literature to avoid collision of these two tunnels. However, those recommendations are only expert opinions and not based on scientific investigation. (19-20) To the best of our knowledge, there is only one study available in the literature on the likelihood of a femoral collision and the best orientation of the ALT tunnel to avoid collision with the

ACL femoral tunnel. (21) That was a cadaveric study. To date, there has been few reporting on this issue in the surgical context.

The purpose of the present study was to analyze post-operative CT scan evaluations of patients who had undergone a combined ACL reconstruction and modified Lemaire ALT with femoral fixation through a bony tunnel.

We hypothesize that there would not be any interference between the two femoral tunnels if the ALT tunnel was drilled proximally and anteriorly with an angulation of 30°. We also hypothesize that, between the two-drilled tunnels, there would be a residual bony bridge of at least 5mm if measured at the level of the lateral femoral cortex or 1cm deeper.

METHODS

This study was approved by the Ethics Committee of the authors' Institution. All patients gave valid consent to participate and no financial incentives were provided. The study was conducted between October 2017 and January 2018 at a single institution. All the patients' who had undergone a combined anatomic ACL reconstruction and ALT, performed by two senior surgeons (JCM, JIE), were prospectively included. In all cases autologous hamstring tendons and cortical suspension device (Endobutton, Smith and Nephew) were used.

The exclusion criteria were: 1) a revision ACL reconstruction, 2) congenital or post-traumatic femoral deformities, 3) intraoperative femoral blowout or a fracture of lateral femoral cortex, 4) patients not suitable for postoperative computer tomography (CT) evaluation (drop out, pregnant), 5) consensus denial for the present study. 58 patients were treated in that period with a combined anatomic ACL reconstruction and ALT, following the exclusion criteria the resultant study group included 52 patients.

ACL reconstruction

For each patient, the ACL reconstruction was performed as the first surgical step. Both semitendinous and gracilis tendons were harvested in all cases. Subsequently they were triplicated or quadruplicated, according to the length of the tendons and desired size of the graft, and then assembled on a 15-millimeter suspension device (Endobutton, Smith and Nephew). A 2.4 metal pin was inserted through a low anteromedial porta in the center of the native ACL. Aiming at the center of the native ACL, several intraarticular landmarks were taken into consideration. They were the native ACL remnant, lateral intercondylar ridge, lateral bifurcate ridge, antero-posterior length of the condyle like previously described. (22-23) When the native ACL stump as well as intercondylar and lateral ridge were clearly identifiable, the femoral tunnel was drilled in the center of the remnant using the bifurcate ridge as middle-point reference. If the remnant or bony landmark weren't clearly visible, the tunnel was positioned at 50% of anteroposterior length of the side wall of the notch measured with a 6mm metal ruler.

To better achieve correct visualization of the femoral footprint, a third portal (central or high medial portal) was used for visualization and the working portal was the low anteromedial portal. A 4.5-millimeter tunnel was drilled over that pin all the way through the lateral condyle to its lateral cortex. Finally, the definitive ACL socket was drilled. The diameter was chosen according to the dimensions of the final graft, always leaving 5 millimeters of bone at the lateral cortex to avoid both a fracture at that level or slippage of the endo-button. All the tunnels were drilled with knee flexion at between 115 and 120°. The final diameters of the graft implanted were recorded.

Modified Lemaire ALT

An antero-lateral approach of about 4 to 5 centimeters was made between the lateral femoral epicondyle and Gerdy's tubercle. A 1cm x 8cm long strip from the central part of the *fascia lata* was harvested, leaving its distal attachment at the Gerdy´s tubercle intact.

In every case, a 5.5 x 20-millimeter tunnel was made starting 5 to 10 mm proximal from the lateral epicondyle being in line with the epicondyle. This tunnel was drilled aiming, in all cases, at an inclination of 30 degrees in both anterior and proximal direction. The proximal part of the graft was prepared with whipped stitches and subsequently passed beneath the lateral collateral ligament and secured in the tunnel with an interference screw (Biosure HA, Smith and Nephew) of 6 x 20 millimeters.

Imaging protocol

Postoperative CT scans were carried out on all 52 patients at the 15-day follow-up by a skilled musculoskeletal radiologist. All the knees were placed in full extension with the patella pointing straight up and imaged on multiple planes with a Siemens Somatom Sensation 64 spiral detectors to generate multiplanar reconstructions of axial-, sagittal-, and coronal-plane CT images. Slices of 1mm thickness and a recon increment of 0.7 mm with a dedicated algorithm and window (kernel B80S Ultra Sharp Window Osteo) were used. Volume-rendering 3-dimensional CT reconstructions were also performed. The analysis of the images was done using the Carestream Pacs system (Rochester, NY, USA). All measurements were carried out by 2 different observers (SP,GD), one orthopedic surgeon and one skilled musculoskeletal radiologist. For each case, measurements were taken twice while keeping the result of the first measurement blind.

First, the observers evaluated the angles of inclination of the ALT’s tunnels in both coronal and axial views. The orientation of the tunnels was expressed in terms of anterior and proximal inclination from the starting position with the anatomical transepicondylar line (the line connecting the center of the medial and lateral epicondyles) taken as a reference. Each measurement was performed from the distal (coronal plane) and dorsal (axial plane) border of the corresponding tunnel.

Then the shortest distance between each tunnel was measured at both the level of the cortex of the lateral femoral condyle and on a plane one centimeter deeper from the cortex itself. The latter location has been considered to evaluate the possibility of collision where the ACL femoral socket has the wider dimension. Any possible collision between the ACL femoral tunnel and ALT tunnel was also studied. Axial, coronal, and sagittal views were superimposed and only the shortest distance observed in any of the 3 different planes was the final measure considered for data purposes.

Tunnel convergence was defined as a distance of 0mm between the neighboring tunnels' circumferences without taking into consideration whether it was a major or minor collision.

A bone bridge of a minimum 5mm was considered as the minimum safe distance for this combined reconstruction.

Statistical Analysis

Statistical analysis was performed using the SPSS 19 software package (SPSS, Chicago, IL). A two-side $p < 0.05$ was considered statistically significant. Categorical variables are expressed as percentages and frequencies. Mean and standard deviations as well as medians, minima, and maxima were calculated for each continuous variable. Repeated-measures analysis of variance (ANOVA) was used for multiple comparisons of the mean values of the different drilling angles and the distance between the tunnels. The Pearson correlation was carried out to understand any correlation between continuous variables. The inter-observer agreement between two independent observers was assessed with Lin's concordance correlation coefficient and the 95% confidence interval (95% CI) for continuous measures. The Intraclass Correlation Coefficient (ICC) values were interpreted as follows: ICC\0.40 = poor agreement; 0.40\ ICC\ 0.75 = fair to good agreement; and ICC. 0.75 = excellent agreement. (24)

RESULTS

Tunnel collision and distance

When measures were taken at lateral cortical level, no collision was detected between the tunnels and the average distance between the two tunnels was 6.5 mm (SD 2.8). In 14 cases (26.9%), the distance between the 2 tunnels was less then 5mm.

The evaluation of the distance between the tunnels on a plane 1 centimeter deeper than the lateral femoral condyle cortex revealed 8 collisions out of the 52 cases (15.4%). No collisions were observed in 44 cases (84.6%). Of those 44, the bone bridge between the 2 tunnels was thinner than 5mm in 11 patients (21.1%). On this plane, average distance between the tunnels was 5.2mm (SD 3.14). A complete description of the distances is provided in table 1.

The ICC obtained was considered excellent (24) (0.93; 95% CI, 0.90 to 0.95), and the high calculated k coefficient (0.91; 95% CI, 0.88 to 0.95) showed excellent agreement between observers.

The dimensions of the ACL grafts had a diameter ranging from 8 to 9.5 mm (mean 8.6, SD 0.52) and no statistical correlation between diameter and collision was found.

Table 1. *Distances*

Measurement variable			
Cortical Distance	**Mean (SD)**	**ICC (95% CI) Intra – rater**	**ICC (95% CI) Inter – rater**
Rater 1			0.918 (0.884 – 0.955)
Measure 1	6.56 (2.89)	0.929 (0.907- 0.953)	
Measure 2	6.71 (2.73)		
Rater 2			
Measure 1	6.66 (2.93)	0.933 (0.913 – 0.948)	
Measure 2	6.74 (2.78)		
Cancelous Distance (mm)	**Mean (SD)**	**ICC (95% CI) Intra – rater**	**ICC (95% CI) Inter – rater**
Rater 1			0.915 (0.886-0.993)
Measure 1	5.28 (3.14)	0.929 (0.919-0.938)	
Measure 2	5.33 (3.17)		
Rater 2			
Measure 1	5.28 (3.09)	0.926 (0.922-0.929)	
Measure 2	5.25 (3.02)		

Orientation of ALT tunnels

The mean tunnel inclination on the axial plane was 20.6° (SD 6,19). The mean inclination on the coronal plane was 18.2° (SD 7.44). The ICC obtained was considered excellent (21) (0.91; 95% CI, 0.88 to 0.93), and the high calculated k coefficient (0.90; 95% CI, 0.88 to 0.92) showed excellent agreement between observers.

Tunnel inclination in correlation with the distance between the tunnels were then evaluated. The full results are shown in table 2.

Table 2. *Tunnel inclination in correlation with the distance between the tunnels*

Distance measurement	n (%)	Coronal Angle		Axial Angle	
		Mean (SD)	P-Value **	Mean (SD)	P-Value **
Cancellous distance					
Collision	8 (15.4)	17.7 (9.54)		9.58 (4.96)	< 0.001
< 5mm	11 (21.1)	18.7 (6.66)	0.965	17.7 (1.28)	
≥ 5mm	33 (63.5)	18.2 (7.37)		24.3 (2.84)	
Cortical distance*					< 0.001
< 5mm	14 (26.9)	18.3 (7.77)	0.967	14.3 (5.22)	
≥ 5mm	38 (73.1)	18.2 (7.37)		24.3 (2.84)	

* No collisions reported under cortical distance
** ANOVA for cancellous distance and Independent Student's T test for cortical distance

In relation to the measurements at the cortical level, the influence of the inclination of the tunnels on the possibility of collision at this level in both the coronal and axial direction was not identified (p = 0.989 and p = 0.915). Analyzing the tunnels at the level of the cancellous bone, in the event of a collision, the mean inclination detected on the coronal plane was 17.7° (SD 9.55) while it was 9.6° (SD 4.96) on the axial plane. When the bone bridge between the two tunnels was less than 5mm, the mean inclination detected on the coronal plane was 18.7° (SD 6.66) while it was 17.7° (SD 1.26) on the axial plane. When the bone bridge between the two tunnels was equal or more than 5mm, the mean inclination detected on the coronal plane was 18.2° (SD 7.37) while it was 24.3° (SD 2.84) on the axial plane. The The Anova analysis detected a statistical influence of the axial inclination on the possibility of collision ($p < 0.001$) whereas no statistical difference was detected for the inclination on the coronal plane (p= 0.965).

The analysis of the distribution of the distance between the tunnels in relation to the degrees of inclination did not detect any cut-off on the coronal plane. On the other hand, on the axial plane, we noticed that for an inclination less than

15° a collision always occurs and for inclinations of more than 20° no collisions occurred. When the tenodesis tunnels were drilled between 15 and 20 degrees, we found no collision, but the bone bridge was less than 5mm in 92% of the cases. Full data are summarized in table 3.

Table 3. *correlation between inclination and possibility of collision*

			Cancellous Distance	
Axial Angle	n (%)	Collision	<5	>5
< 15	8 (15.4)	8 (100%)	0	0
15 - 20	12 (23.1)	0	11 (92%)	1 (8%)
> 20	32 (61.5)	0	0	32 (100%)

All the diameters of the grafts were between 8 mm and 9.5 mm. The Pearson analysis between the final diameter of the graft and the distance between the tunnels (where collision was set in 0 mm distance) did not show any correlation.

DISCUSSION

The most important finding of the present study was that a risk of tunnel collision in the femur exists when combining ACL anatomic reconstruction with the Modified Lemaire ALT. The second finding was that this risk can be diminished almost completely by drilling the ALT tunnel with a minimum inclination of 20° anteriorly. This investigation also demonstrated certain tunnel collision when the axial inclination of the ALT tunnel was less than 15° and a 92% possibility an unsafe bone bridge (< 5mm) between the tunnels for an axial inclination between 15° and 20°. On one hand, the inclination on the axial plane seems to influence the possibility of collision, whereas the inclination on the coronal plane does not seem to have the same effect. All these data refer to an evaluation carried out on a plane passing through a point 1 centimeter medially to the lateral cortex of the femur at the anchor point of the cortical fixation system. When the same evaluation was carried out at the cortical level, no collisions were detected and no influence on the possibility of collision or on the distance between the two tunnels due to the direction of the drilling was found.

The possibility of tunnel collisions during multi-ligament reconstructions has been studied in recent years with regard to posteromedial and posterolateral peripheral structures. (25-26) Almost always, these studies have been carried out on cadavers or with computer simulations. (27-28) The present study is a prospective in-vivo evaluation. Even if our goal had been to drill with 30° of anterior and proximal inclination, only a few tunnels were drilled in this precise direction. This is because it is not always easy to find a precise bony landmark in an operative setting and free-hand drilling is usually carried out for the ALT tunnel. This prospective in-vivo simulation helps us in this respect. The 8 cases of collision all occurred in the first 20 cases of combined reconstruction. The mean tunnel inclination on the axial plane was 18.6° (SD 4.12) in the first 20 cases whereas was 22,7° (SD 4.71) in the other ones. The mean inclination on the coronal plane was 16.9° (SD 2.41) in the first 20 cases whereas was 19.6 (SD 4.37) in the other ones. This may lead us to think that by being able to see the collision directly in a postoperative CT control and understanding that the drilling inclination was not the one put forth intraoperatively, the surgeons are more aware and can improve their technique. Moreover, this leads us think that it might be useful to evaluate, through an intrarticular view, whether any collision is occurring before fixing the ACL graft.

To the best of our knowledge, there is only one study that evaluates the operative risks when a bony tunnel for an ALT is preferred. (21) However, the results of the present study differ from the ones in it. Indeed, Smeets et al described that the risk of convergence of the two tunnels is up to 87% and strongly correlates with an ALT tunnel drilled at a 20° angle the anterior direction in a cadaveric study. Some differences in the methods can explain these differences. First, the cadaveric setting is quite different from the clinical setting. The mean age of the specimen used was 74 years. That is the basis for speculating on there being diffuse osteophytosis and bone alteration that results in some difficulties looking for the anatomical femoral ACL footprint. That is even more so if the view portal is the anterolateral one like the authors used. In addition, they always drilled an 8x25mm femoral socket at 125° of knee flexion, systematically leaving 2mm of posterior condylar wall,which can not be the exact anatomic position in all the cases. Finally, in a cadaveric setting, the exact location of the ALT femoral tunnel is always achieved whereas in a surgical context there is some variability. Moreover, our goal for the positioning of the tunnel was just proximal to the epicondyle and not posterior. As a last consideration, they use as reference an axis perpendicular to the anatomical axis of the femur in the coronal plane assuming it was better for a surgical context reproducibility. We disagree with that considering without fluoroscopy only the trans-epicondylar axis is a reliable intraoperative landmark in operating setting. These points do not make the results of the two studies comparable. We assume that following the technique suggested here in the present study can decrease the rate of tunnel convergence with respect to the one suggested by Smeets et al.

Has been poorly shown what is considered the safe minimum distance between two tunnels and it has not been thoroughly assessed whether a tunnel collision can lead to long-term consequences such as failure of the reconstructed ligament. Nevertheless, it is intuitive to understand that a collision between 2 tunnels may lead to some problems such a poor graft integration, bone cracking and even damage to the suspension device used for ACL fixation. Therefore the findings of the present study have important clinical relevance. Firstly, it makes the surgeons who perform a combined procedure with ACL reconstruction and modified Lemaire ALT aware that the possibility of collision in between the 2 tunnels at femoral side is possible. Furthermore, the ALT should be drilled at least with 20° of anterior inclination or otherwise chose another fixation technique that does not require a bony tunnel at that level. Further comparative studies should be carried out to confirm the current preliminary data about the importance of the orientation in the coronal plane.

Limitations

We recognize that the present study has some limitations.

First, all the ACL reconstructions in the present study were performed with the most identical techniques possible. To reach the center of the anatomical femoral insertion of the ACL, other authors may use different techniques. They may be a different degree of knee flexion when performing the femoral tunnel, a different position for the anteromedial portal or the use of specific devices for drilling (e.g. flexible cutters). Moreover, some authors prefer not to place the femoral socket in the anatomical ACL footprint but in a more posterior and lower point. It is plausible to think that these modifications can vary, even slightly, the results in terms of the convergence of the tunnels presented in the present study. Therefore, we can conclude that the direction for the drilling of the femoral tunnel suggested in the present study is valid only when the technique is performed as previously described. Again about the technique we used, we always left 5mm of bone within the cortex of the lateral femoral condyle, we can speculate that using shorter tunnels could decrease the possibility of convergence.

Another limitation was that all coronal drilling values were positive, that means with a proximal orientation. In that way we can't know with certainty if a distal orientation of the tunnel may affect the possibility of collision. In addition, the size of the lateral femoral condyle was not taken into consideration, it could affect the possibility of collision between the 2 tunnels although the anthropometric parameters of the patients in the present study showed a wide range and their correlation with the possibility of collision was not observed. At any rate, the number of patients was relatively small and might not be generalizable to the entire population.

A further limitation is that even if no influence of the tunnel diameter on the possibility of collision was demonstrated, the grafts were homogeneous in our cohort. We cannot therefore exclude that grafts of larger diameters can lead to different possibilities of collision.

One last limitation is that the transepicondylar line was taken as a reference for evaluating the inclination of the tunnel. As is well known, that line has high inter-individual variability.

CONCLUSION

In order to fix a modified Lemaire ALT through a femoral tunnel avoiding any interference with an anatomic femoral ACL tunnel, we recommend the femoral tunnel be drilled with an inclination of at least 20° anteriorly.

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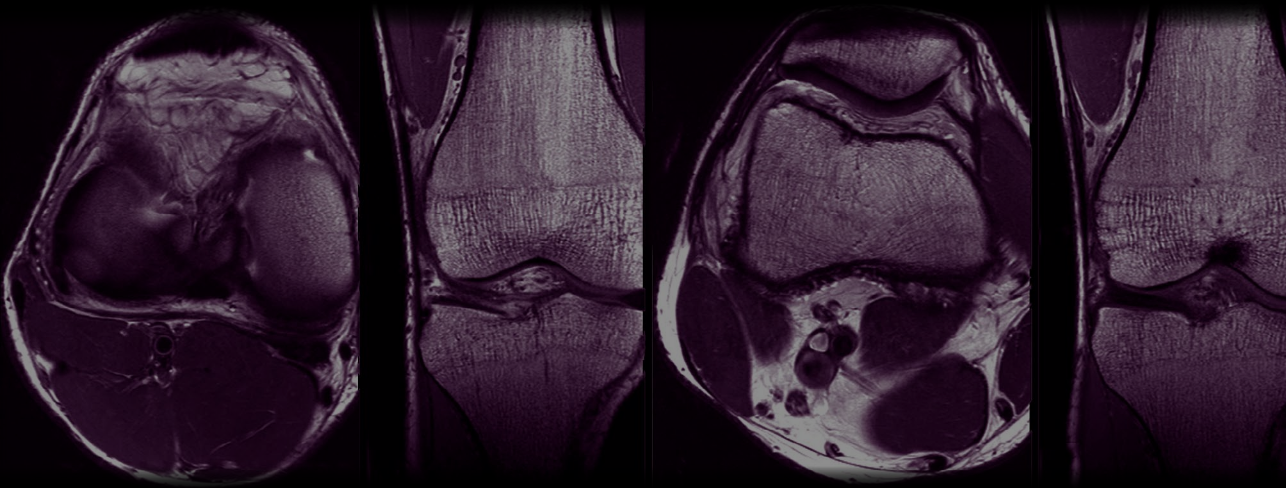
CHAPTER 5.

Modified Lemaire antero-lateral extra articular tenodesis alters the MRI maturity signal of ACL hamstring graft



Chapter 5.

Modified Lemaire antero-lateral extra articular tenodesis alters the MRI maturity signal of ACL hamstring graft.

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ABSTRACT

Background: One of the most widespread procedure to restore anterolateral stability is the lateral extra-articular tenodesis (LET). Clinical outcomes after association of a LET to ACL reconstruction (ACL-R) have been widely investigated, however potential influence of LET over the ACL ligamentization process have not been taken in account yet. **Purpose:** To compare on 10 months postoperatively MRI, the maturity of the grafts after ACL hamstring autograft reconstruction associated or not with a LET. The hypothesis was that when modified Lemaire lateral extraarticular tenodesis (MLLET) is performed, the MRI parameters of ACL graft maturity are modified. **Methods:** Patients who had undergone an anatomic three-stranded hamstring autograft ACL-R combined or not with MLLET and had had MRIs 10 months postoperatively from December 2017 to December 2018 were included. 30 isolated ACL-R and 22 ACL-R plus MLLET were included. The two groups were comparable based on all the criteria analyzed. To evaluate graft maturity, the signal-to-noise quotient (SNQ) was measured

in three regions of interest (ROIs) of the proximal, mid-substance and distal ACL graft. Lower SNQ ratios indicate less water content and theoretically better maturity and healing of the graft.

Results: The mean SNQ was 4.62 (SD 4.29; range 3.12-6.19) for the isolated ACL-R group and 7.59 (SD 4.68; range 4.38-8.04) in the ACL plus MLLET (P = 0.012).

Upon comparing the mean values of the three portions of one group to those of the other group, we found that only at the proximal and middle portions was there a significant difference between the 2 groups (p=0.007 and p=0.049, respectively) while no differences were identified (p=0.369) in the distal third. **Conclusion:** At the 10-month follow-up, hamstring tendon autografts for anatomic ACL reconstruction associated with MLLET do not show the same MR signal intensity compared to an isolated hamstring anatomic ACL reconstruction.

INTRODUCTION

Despite increased understanding of knee anatomy and the development of advanced Anterior Cruciate Ligament (ACL) reconstructive techniques, up to 34% of those patients may have persistent rotational Knee instability or residual pivot shift after ACL reconstruction (ACL-R).[27,4] In an attempt to prevent that happening, ACL-R have been increasingly combined with antero-lateral extra-articular procedures in the recent years. Lateral extra-articular tenodesis (LET) is the one that is most used. Indeed, numerous articles have already been published demonstrating a reduction in the postoperative pivot-shift phenomenon achieved by combining these techniques.[30,16] As we have already learned from the first published biomechanical studies in this field, LET could significantly decrease the stress forces on the ACL graft up to 43% in addition to improving the control on the rotational knee instability.[9]

If on the one hand this is a biomechanical advantage that might reduce the rate of failures, on the other it may have biological repercussions on the graft's maturation given that ACL graft undergoes histological rearrangement due to biomechanical action.[20]

To the best of our knowledge, no study has taken this possible effect of the LET on the ACL graft into consideration to date. Understanding whether the maturation and ligamentization of the ACL is modified when associating a LET would be of great contribution towards adapting rehabilitation protocols and the return to sport (RTS) in this subcategory of patients. According to Claes et al, ligamentization is the histological evolution of the graft.[6] As histological sections are impossible in humans, the best way to evaluate ligamentization is with MRI.[12,34,26] Previous animal studies have demonstrated a significant correlation between the graft signal intensity measured with MRI and ACL structural properties.[2,34] Therefore, graft signal intensity seems to be a non-invasive means that can provide us with excellent information about the biological state of the graft. More specifically, Weiler et al. compared the MRI signal intensity of the graft with its biomechanical and histological properties in animals to create the signal-to-noise quotient (SNQ). They demonstrated that the SNQ was inversely proportional to graft tensile strength.[20,34] Therefore, the purpose of this study is to analyze the potential differences associated with graft maturity measured with MRI between patients have undergone either an isolated anatomic ACL-R or an ACL-R associated with a modified Lemaire LET (MLLET). More specifically, the objective of the current study is to compare the signal-to-noise quotient (SNQ) of the hamstring tendon autograft of these two group of patients 10 months postoperatively. We hypothesized that when MLLET is performed, the MRI parameters of ACL graft maturity are modified.

METHODS

A retrospective comparative cohort study. This study adhered to the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines. It was conducted consisting of data collected for clinical purposes in patients who had undergone an anatomic ACL-R performed by a single surgeon (X.X.X.). Exempt IRB approval was obtained for this study to use data from an IRB-approved research registry (XXX Institutional Review Board, protocol LCA-2017-01). Informed consent was obtained to enroll subjects in this research registry, but additional informed consent was not required to include subjects in the current exempt study. Patients who had undergone an anatomic ACL-R combined or not with LET and had had postoperative MRIs 10 months after ACL reconstruction using a 3-Tesla magnet at our Institution from December 2017 to December 2018 have been included. The surgeon added an MMLET if the patient played pivoting sports, otherwise an isolated ACL reconstruction was performed. Typically, the ten-month postoperative MRIs have been taken at our institution to evaluate graft status before the return to play for non-professional athletes.

The following additional inclusion criteria were used: (1) ACL reconstruction using a three-stranded hamstring tendons autograft, (2) closed growth plates and less than 45 years of age at the time surgery. The following exclusion criteria were used: (1) previous surgery on the operated knee, (2) posterior cruciate ligament (PCL) lesion, lateral collateral ligament, or medial collateral ligament injuries superior to grade 2, (3) meniscal or cartilage injuries that requires treatment at the time of surgery, (4) any additional postoperative injury reported by the patients. Of the initial 122 patients, 47 patients did not meet the inclusion criteria. 8 patients with concomitant lesion of other ligaments were also excluded. Of the remaining 67 patients, 14 had undergone additional surgical treatment at the time of ACL-R and 1 patient suffered a postoperative knee injury. No patient was lost at 10 months follow up and all the patients had the follow-up MRI. Finally, 52 patients were included: 30 isolated ACL-R and 22 ACL-R plus MLLET. (Figure 1).

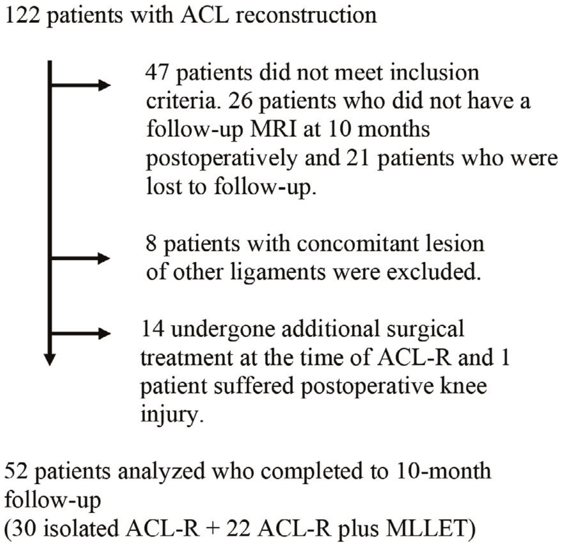

Figure 1: *Flow chart for follow-up. ACL, anterior cruciate ligament reconstruction; MLLET, modified Lemaire lateral extra-articular tenodesis.*

Medical and surgical reports were reviewed by an experienced knee-fellow to collect age, gender, time between surgery and MRI and the graft diameter of all the patients.

An analysis of the inclination of the ACL was carried out to assess the homogeneity between the two groups of this variable. This is extremely important since how the inclination of the ACL affects the forces that act on the graft and therefore might influence the state of maturation detected in the postoperative MRI has been described.[3]

Following previously described protocols, the inclination angles were measured in sagittal MRI views. The sagittal obliquity of the graft was defined by the intersection of two lines, one tangential to the anterior aspect of the graft and the other tangential to the anterior aspect of the intercondylar eminence and perpendicular to the long axis of the tibia. [25,28,19]

Surgical Procedure

ACL reconstruction

Both semitendinous and gracilis tendons were harvested in all cases. Subsequently, they were triplicated and assembled on a 15-millimeter suspension device (Endobutton, Smith & Nephew, Andover, MA, USA). Aiming at the center of the native ACL footprint, the femoral socket was drilled using a cannulated drill from the anteromedial portal. The diameter was chosen according to the dimensions of the final graft, always leaving 5 millimeters of bone at the lateral cortex to prevent both a fracture at that level or slippage of the endo-button. For the tibial tunnel, the tip of a standard tibial guide (Smith & Nephew Endoscopy, Andover, MA, USA) was placed at the center of the ACL footprint. A guidewire was over drilled with a conventional cannulated reamer that was 1mm smaller than the diameter of the graft. The soft trabeculae of the tibia were finally compressed with a dilator that matched the graft diameter. The graft was then passed through the tibial tunnel, across the joint, and into the femoral tunnel. After the graft was tensioned several times, fixation of the graft was achieved at between 20° and 30° of flexion by an absorbable interference screw (Biosure HA, Smith & Nephew, Andover, MA, USA) of the same diameter of the graft. [18]

Modified Lemaire LET

An antero-lateral approach of about 5 centimeters was made between the lateral femoral epicondyle and Gerdy's tubercle. A 1cm x 9cm long strip from the central part of the *fascia lata* was harvested, leaving its distal attachment at the Gerdy´s tubercle intact. In every case, a 5.5x20-millimeter tunnel was made starting 5 to 10mm proximal to the lateral epicondyle, the tunnel being 5mm posterior to the epicondyle in the sagittal plane. The proximal part of the graft was prepared with whipped stitches and subsequently passed beneath the lateral collateral ligament and secured in the tunnel with a 6x20 millimeter interference screw (Biosure HA, Smith & Nephew, Andover, MA, USA) The graft is then held taught but not overtensioned, with the knee at 30° of flexion and the foot in neutral rotation. [18]

All patients from the 2 groups participated in the same standardized postoperative rehabilitation protocol. Progression through each phase of rehabilitation considered each patient's status and the physician's guidance.

MRI evaluation

All subjects underwent a knee MRI on average at 10 months postoperatively using a 3-tesla magnet (Signa HDxt, GE Healthcare, USA) running software version HD 23 equipped with a 4-channel transmit receive knee coil. Standard oblique sagittal T1- proton density-weighted images with a 3 mm slice thickness were used for the analysis of graft maturity maintaining the obliquity in line with the ACL. The protocol was set up as follow: the field of view was 160x160mm, matrix size was 512x512 pixels, slice thickness was 3mm with slice separation of 0.75 mm acquiring 31 slices. The repetition time (TR) was 600.2 ms and echo time (TE) was 16 ms. The best single slice that demonstrated the full length of the ACL was selected for analysis. To compare the maturity difference between the two groups, their signal intensity was measured with the freehand region-of-interest (ROI) function. The graft signal values were averaged as described by Weiler et al.[34] Circular ROIs, 5mm in diameter, were evaluated for measuring the signal of the ACL, PCL and the background. Graft signal intensity was measured for three regions, the proximal, mid-substance and distal. The midpoint of the central ROI was located at the midpoint between those of the proximal and distal ROIs. Finally, the average of the three was calculated. The background ROI was placed approximately 2cm anterior to the patellar tendon. Mean signal intensity and standard deviations were recorded based of image pixels as absolute signal intensity with a measurement accuracy of one decimal.

The SNQ for each graft was calculated with the following formula:

$$\text{SNQ} = \frac{\text{Graft signal} - \text{PCL signal}}{\text{background signal}}$$

Lower SNQ ratios indicate less water content and theoretically better maturity and healing of the graft. To assess inter-observer reliability, the images were independently measured by one orthopedic surgeon (X.X.) and one orthopedic radiologist (X.X.). To assess intra-observer reliability, for each case, measurements were taken once and four weeks later by X.X. while keeping the result of the first measurement blind. The measurements were done in a double-blind manner. Neither rater knew the SNQ score assigned by the other rater for the same examination. Neither were the raters informed about which group the patient belonged to. The analysis was performed using a PACS workstation (Horizon Rad Station; McKesson).

Statistical Analysis

Continuous variables are expressed as mean and standard deviations (SD). Categorical variables are presented as percentages. The Chi-squared test was used to analyze the categorical variables. The Student T-test and the Mann-Whitney *U* test were used to assess the differences between the two groups relative to the SNQ values and ACL angle.

The inter-observer agreement between the two independent observers was assessed with Lin's concordance correlation coefficient and the 95% confidence interval (95% CI) for continuous measures. The Intraclass Correlation Coefficient (ICC) values were interpreted as follows: ICC\0.40 = poor agreement; 0.40\ ICC\0.75 = fair to good agreement; and ICC. 0.75 = excellent agreement.[15]

A two-side $p <0.05$ was considered statistically significant.

It was assumed that a standardized difference of 0.5 SD in the SNQ signal is considered acceptable when comparing different ACL reconstruction techniques with hamstrings. [31,7] With a power of = 0.80 and alpha of 0.05, 21 subjects were necessary in each group to recognize a difference consisting of 1 standardized difference in the SNQ signal. The statistical analysis was performed using the SPSS 19 package. (SPSS Inc, Chicago, Illinois).

RESULTS

Of the 52 patients included, 30 were isolated ACL-R (ACLI group) and 22 ACL-R plus MLLET (ACLT group). The two groups were comparable based on all the criteria analyzed. Detailed data are shown in Table 1.

Table 1. *characteristics for ACLI and ACLT groups*[*]

Parameter	ACLI	ACLT	*P* Value
Male/Female, n (%)	13/17 (43.3/56.7)	10/12 (45.4/54.6)	0.904
Age, y	29.7 ± 8.2	31.1 ± 6.1	0.068
Affected side (Right/Left)	15/15	12/10	0.784
Time between injury and surgery, d	89 ± 49	101 ± 27	0.882
Graft diameter, mm	8.6 ± 0.4	8.5 ± 0.5	0.287
ACL graft inclination, °	48.3 ± 4.1	51.1 ± 2.7	0.687

[*] Values are shown as mean ± SD unless otherwise indicated. ACLI: Isolated ACL Reconstruction; ACLT: ACL reconstruction + . Modified Lemaire Tenodesis.

The mean SNQ was 4.62 (SD 4.29) in the ACLI group and 7.59 (SD 4.68) in the ACLT group (p= 0.012). Upon analyzing the values relating to the three portions of the ligament, the SNQ of the ACLI group was found to be homogeneous among the three portions, with lower values at the distal part but without any significant difference (p = 0.082 distal vs middle; p = 0.278 middle vs proximal; p = 0.054, proximal vs. distal). The distal region of the ACLT group showed a significantly lower mean SNQ value compared with middle region and the mean SNQ value in the proximal region was the highest (p = 0.032 distal vs. middle; p = 0.009 middle vs. proximal; p < 0.001 proximal vs. distal). Upon comparing the mean values of the three portions of one group to those of the other group, it was found that there was only a significant different between the 2 groups at the proximal and middle portions (p=0.007 and p=0.049, respectively) while no differences were identified (p=0.369) in the distal third.

A complete summary of the SNQ values is presented in Table 2.

Table 2. *Description of SNQ values*[*]

SNQ	ACLI	ACLT	*P* Value
Proximal (A)	4.99 ± 2.32	8.95 ± 1.91	0.007
Middle Portion (B)	4.22 ± 3.59	6.11 ± 2.37	0.049
Distal (C)	2.81 ± 2.34	3.91 ± 1.60	0.369
Mean	4.62 ± 4.29	7.59 ± 4.68	0.012
***P* Value**	AvsB = 0.278 BvsC = 0.102 CvsA = 0.064	AvsB = 0.009 BvsC = 0.032 CvsA < 0.001	

* Values are shown as mean ± SD. ACLI: Isolated ACL Reconstruction; ACLT: ACL reconstruction + Modified Lemaire Tenodesis.

There was no significant difference of the ACL graft angle measurement between ACLI and ACLT group, them being 48.3° (SD 4.1) and 50.1° (SD 3.7), respectively (p=0.687).

The ICC obtained was considered excellent (0.92; 95% CI, 0.90 to 0.95), and the high calculated k coefficient (0.90; 95% CI, 0.88 to 0.95) showed excellent agreement between the observers.[15]

DISCUSSION

The most important finding of the present study is the significant difference between the isolated reconstructed ACL hamstring graft and the group of ACL-R associated with MLLET in the SNQ values in the proximal and mid-substance regions at the 10-month follow-up. Hence, the hypothesis has been confirmed. More specifically, the association of MLLET with increased mean SNQ values was detected, particularly at the proximal third of the ACL. It means inferior MRI-based maturity of the graft.

Previous studies have shown that, at the 6-month follow-up, the SNQ values of the ACL graft in the proximal and mid-portion regions are significantly higher than in the distal regions but these high SNQ usually decrease over time. [24,17] Like in the data presented here, the highest SNQ values are always located at proximal third. Some authors have suggested that the steeper graft bending angle (GBA) on the femoral side may contribute to increased ACL graft signals in the proximal regions. [5,32] The GBA is defined as the angle between the femoral bone tunnel and the line connecting the femoral and tibial tunnel apertures. Moreover, it has been demonstrated that the graft inclination varies depending on femoral tunnel reaming technique, and that obliquity influences the in-situ graft force.[3,19] At 10 months postoperatively, homogeneous SNQ values were detected in the ACLI group whereas the proximal third of the graft still showed remarkably high SNQ values in comparison with the mid-substance and distal third in the ACLT group. To avoid any BIAS due to the direction of the graft, only anatomical trans antero-medial portal ACL reconstructions were included and the values of the ACL inclination angle were analyzed, individuating homogeneity among the 2 groups. Thus, with all the possible biases minimized, it seems that it is the association with MLLET that slows down the healing process of the hamstring ACL graft at its proximal third.

Weiler et al. first observed that a higher signal intensity in the MRI corresponded to lower mechanical strength of the graft during the early remodeling phase. Hence, the SNQ is inversely proportional to the graft's tensile strength.[34] Subsequently, Fleming et al. describes MR signal intensity as a predictor of ACL graft structural properties.[11] Therefore, it might be surmised that associating MLLET with ACL reconstruction leads to an increase in the failure rate due to a worse mechanical strength of the graft. Actually, numerous recent studies that have prospectively evaluated the clinical results at short-term follow up after combined reconstruction of the ACL and LET have shown excellent results and a reduction in the failure rate,[13] even in professional athletes.[29] Unfortunately, all those studies have a short follow-up and did not describe any MR evaluation at the last follow-up. Therefore, we cannot know if some of the patients who had a failure in these cohorts had high SNQ values before return to sport activities, nor if a low SNQ value before return to sport have any long-term repercussion.

The SNQ values found in the literature related to hamstring anatomic ACL grafts have a wide range both at 6 months (from 0.78 ± 0.62 to 26.5 ± 11.7)[8,23] and 12 months (from 5.2 ± 4.5 to 18.6 ± 7.6),[7,23] postoperatively. Herein, mean SNQ values of 4.62 ± 4.29 in the ACLI group and 7.59 ± 4.68 in ACLT group were found. The wide differences in SNQ values in the literature are due to different factors. First, several variations in measuring the SNQ have been described: employing gadolinium or not [14,34,26] and using the quadriceps tendon signal instead of the PCL signal for comparison.[12,1] In the current investigation, the methodology proposed by Weiler et al.[34] was used. The fact that they developed the SNQ measurements in MRI, comparing the signal with histological evaluations of the grafts, led to considering it a reliable method to have a clear idea about the mechanical properties of the graft. The data obtained in the present study came from a retrospective cohort. Therefore, the MRI was always performed without intraarticular gadolinium. Despite that, the same Weiler et al.,[34] and Fleming BC et al.[11] have shown that there are no alterations in the signal of the graft even without gadolinium.

Other possible influencers on the wide range of SNQ values found in the current literature are: the evaluation of different ACL-R techniques,[31] MRI analysis with different magnets (mostly 1.5 or 3 tesla) [7,17] or on different MRI images (sagittal or coronal oblique).[7,24] For the present study, only patients operated by the same surgeon always using the same technique and the same fixation devices were included. Moreover, the patients underwent an MRI evaluation always using the same magnet and following the same MRI protocol under the supervision of a skilled musculoskeletal radiologist. Finally, the SNQ values of the ACLT group were compared with those of a group of isolated hamstring ACL-R to avoid any comparison of our data with the wide-ranging values in the current literature.

The graft healing process might be influenced by multiple variables including the anatomy of the patient, the type of graft, the surgical technique and the rehabilitation protocol.[33]

However, postoperatively, the only modifiable variable among them is rehabilitation.

Knee arthrometry, hop testing, and patient-oriented outcome questionnaires have been useful for many clinical studies as a standardized way to evaluate overall patient knee outcomes following ACL treatment and to guide the return to sport. However, these evaluation techniques are knee specific measures of joint and patient health but may lack the sensitivity to determine the biomechanical properties of the graft.[10,23] Measurement of graft maturity by SNQ could then provide an opportunity to identify patients with a lower mechanical graft strength who might have a worse clinical outcome. In these cases, an attempt to properly change the rehabilitation therapy to improve patient's outcome can be carried out. Therefore, it may be advisable to slow the progression of activities in individuals with ACL-R associated with MLLET if postoperative MRI evaluation is not available or a high signal intensity of the graft is seen, especially in athletes ready for return to play (RTP) for which the graft may not be mature enough.

The current study had several limitations that should be acknowledged. Firstly, there was no randomization of the patients. However, we compared the 2 group on several variable that can influence the graft maturation and the 2 groups resulted comparable. The SNQ is a variable parameter with a peak between 5 and 7 months and then decreases over time until 60 months postoperatively.[26] This means that our 10-months evaluation can only provide a snapshot of what the evolution of graft maturation is. However, both the return to play after ACL-R and most of the failures of ACL reconstruction occur at between 6 and 12 months. Then, the graft status at 10 months postoperatively can be considered a useful information. The sample size does not allow for an adequate statistical evaluation between the subgroups. It would be interesting to evaluate the possible differences between genders and among the different graft diameters. In terms of gender, the interest is based on the differences in hormonal levels that have been shown as possibly influencing graft maturity.[21] Furthermore, an evaluation of the differences in diameters would be worthwhile as it is known that it can influence graft tensile force. Nevertheless, the two groups were comparable based on both these variables. Finally, the SNQ was not correlated with the clinical and functional evaluation of the patients. This was not the goal of the study, but prospective studies that correlate SNQ with clinical outcomes are needed to confirm whether there are relationships.

Despite these limitations, the results of the present study may be clinically relevant for the casual reader. Understanding that an extra-articular tenodesis may influence the maturation process of the intraarticular graft may allow for the modification of postoperative rehabilitation programs or a more thorough MRI analysis before return to sport.

CONCLUSION

At the 10-month follow-up, hamstring tendon autografts for anatomic ACL reconstruction associated with MLLET do not show the same MR signal intensity compared to an isolated hamstring anatomic ACL reconstruction. Therefore, a slow-down effect on the maturation of the intraarticular graft should be considered when a MLLET is associated, thereby modifying the individual rehabilitation accordingly, particularly in the early stages after ACL reconstruction.

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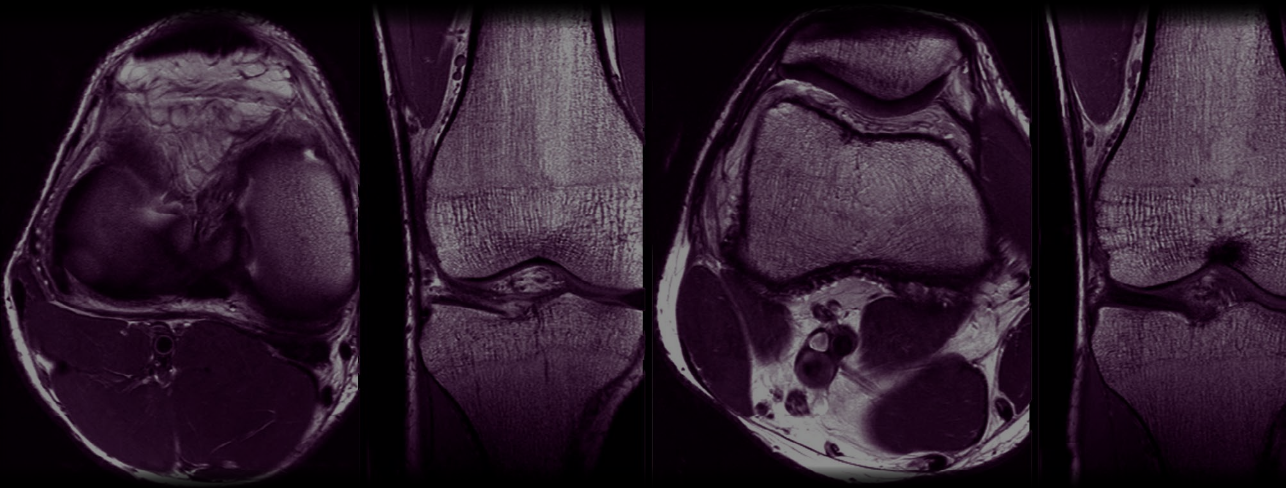
CHAPTER 6.

Lateral extra-articular tenodesis improves stability in non-anatomic ACL reconstructed knees. *In vivo* kinematic analysis



Chapter 6.

Lateral extra-articular tenodesis improves stability in non-anatomic ACL reconstructed knees. *In vivo* kinematic analysis

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ABSTRACT

Purpose: To carry out an *in vivo* kinematic analysis to determine whether adding a lateral extraarticular tenodesis (LET) for those patients with subjective instability and objective residual laxity after a trans tibial (TT) anterior cruciate ligament reconstruction (ACLR) reduces anteroposterior and rotational laxity and to evaluate the 2-year follow-up clinical outcomes to analyze whether biomechanical changes determine clinical improvement or not.

Methods: A total of 19 patients with residual knee instability after TT ACLR who underwent a modified Lemaire LET were prospectively evaluated for at least 2 years follow up. Preoperative, intraoperative, 6 and 24-month postoperative kinematic analyses were carried out using the KiRA accelerometer and KT1000 arthrometer to look

for residual anterolateral rotational instability and residual anteroposterior instability. Functional outcomes were measured with the single-leg vertical jump test and the single-leg hop test. Clinical outcomes were evaluated using the IKDC 2000, Lysholm and Tegner scores.

Results: A significant reduction in anterolateral rotational instability was detected with the patient under anesthesia (from 3 ± 1.2 to 1.1 ± 1.1m/s^2; $p < 0.05$) as well as with the patient awake (from 2.1 ± 0.8 to 0.7 ± 1.4m/s^2; $p < 0.05$). A significant reduction in anteroposterior instability was only present under anesthesia (from 3.4 ± 1.9 to 2.1 ± 1.1mm; $p < 0.05$) while no difference was present without anesthesia (from 2.3 ± 1.1 to 1.6 ± 1mm; n.s.). Postoperative analysis of knee laxity did not show any significant variation from the first to the last follow up. Both the single-leg vertical jump test and single-leg hop test improved significantly at the last follow up (both $p < 0.05$). The mean values of both the IKDC and Tegner scores showed an improvement ($p < 0.05$ and $p < 0.05$ respectively) whereas that was not the case with the Lysholm score (n.s.).

Conclusions: The modified Lemaire LET can improve the kinematics of a non-anatomic ACL reconstructed knee with residual subjective and objective instability. These kinematic changes were able to lead to an improvement in subjective stability as well as the function of the knee in a small cohort of recreationally active patients. At two years follow-up, the kinematic changes as well as the level of activity of the patients and the IKDC score show their improvement sustained.

INTRODUCTION

For many patients with an anterior cruciate ligament (ACL) lesion, an isolated intra-articular ACL reconstruction (ACLR) is sufficient to achieve an excellent functional outcome. However, the ACLR does not lead to a complete recovery for some patients (up to 30%) in terms of patient-reported outcomes (PROs), knee kinematics, and return to sports [2, 37, 48, 53].

In that group of patients, residual rotational instability remains an important post-operative clinical issue given that a positive pivot shift (PS) after an ACLR is one factor associated with poor functional outcomes [3, 45]. The severity of the PS has been correlated with functional instability, patient dissatisfaction, activity limitation, poor knee function, limited sports participation, and lower functional knee scores [26]. Regardless of the technique used to perform the ACL reconstruction, a non-anatomical reconstruction has been shown to lead to a higher failure rate [22]. Choosing the transtibial technique (TT) for ACLR makes it more difficult to place the femoral tunnel in the anatomical footprint, thus setting up a non-anatomical inclination of the neo-ligament [23]. Therefore, it is more frequent to find postoperative residual instability, in particular rotatory instability in patients who have had a reconstruction of the ACL with the TT [31, 33]. The pathophysiology of this persistent instability is multifactorial. However, after the recent revival of the interest on the anterolateral structures of the knee, it has been suggested that a lateral extraarticular procedure (LEP) would help in controlling anterolateral rotatory instability (ALRI). The rationale for considering a concomitant LEP is based on its biomechanical peculiarity. It provides an increased lever arm for controlling rotation than an isolated intra-articular reconstruction since it moves away from the center of rotation of the knee [11, 44]. Several studies have evaluated in cadaveric setting the kinematical changes provided by adding a LEP to an ACL reconstruction [25, 29, 50] and some studies tried to explain also the *in vivo* kinematic of combined ACL and LEP [8, 38, 39, 52]. Few studies finally tried to analyze the biomechanical effects of the LEP separately from the ACL ones [6, 32, 41, 43]. All the investigations reported, were carried out by associating the LET with an anatomical ACLR. Thus, as far as we know, no *in vivo* data is available on the LET in association with a non-anatomic reconstruction. The purpose of this study was to carry out an *in vivo* kinematic analysis to determine whether adding a LET for those patients with subjective and objective residual instability after a TT ACLR reduces anteroposterior and rotational laxity. The secondary aim was to look at the 2-year follow-up clinical outcomes to analyze whether biomechanical changes determine clinical improvement or not. Our hypothesis was that the rotatory stability would increase and thereby the clinical outcomes would improve in this group of patients if a LET were added to a non-anatomic ACL reconstructed knee.

MATERIALS AND METHODS

A prospective observational single-center study was carried out adhering to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [13]. All the procedures described in this study were performed in accordance with the ethical standards of the 1964 Declaration of Helsinki and its later amendments [49] and ethics committee approval was obtained (Protocol No. LCA-2017-01, Hospital Universitari Dexeus). All patients signed an informed consent form before recruitment. No external funding was received for the initiation or completion of this study. During the period from 2017 to 2019, all patients presenting to the two senior authors (S.P., J.C.M.) with residual subjective instability after an ACLR were considered for enrollment in the study. Subjective instability was described as the feeling of giving way during daily life and/or sport and work activities and the lack of confidence in the knee joint. Only patients who persisted with subjective instability despite at least one year of proper rehabilitation through muscle strengthening and proprioceptive training were considered for the study. In every patients, the subjective instability of the patients was confirmed by a quantitative evaluation of the degree of anteroposterior and rotational laxity. The surgical protocol of the index surgery was revised and only the patients that had had a TT ACLR were asked to take part in the study.

A knee MRI was obtained in every patients to evaluate possible ACL graft rupture and to confirm non-anatomic positioning of the graft by measuring the ACL inclination angle as previously described [18, 23]. All the patients came from other institutions given that the TT ACLR is not performed at the authors' institution. All the patients who satisfied the additional study criteria in Table 1 were finally asked to take part in the study and a lateral extraarticular tenodesis (LET) was proposed for them.

Table 1. *Inclusion and exclusion criteria*

Inclusion Criteria	Exclusion Criteria
Previous ACL reconstruction with TT	Previous multiligament reconstruction
Skeletally mature	Not fit for a surgery
Subjective instability with giving-way sensation	Not willing to carry out the study
Able to provide written informed consent	Meniscal repair at the time of LET surgery
	MR or intraoperative signs of ACL rupture
	Knee osteoarthritis

ACL: anterior cruciate ligament; TT: transtibial technique; LET: lateral extra-articular tenodesis; MR: magnetic resonance.

All the surgical procedures were performed by the two senior authors. Twenty-three patients with residual functional instability after a TT ACLR were evaluated. Two patients were excluded because a lateral meniscal lesion was repaired at the same time as the LET surgery. Meniscal suture was considered as an exclusion criteria given that it has been recently shown that both lateral and medial meniscal suturing can reduce rotatory instability [24]. In that sense a source of bias did not want to be introduced. Two more were excluded due to the absence of the ACL graft in the MRI evaluation. The remaining 19 patients were prospectively included in the study.

Lateral Extrarticular Tenodesis

Before starting with the LET, an arthroscopic review of all the joint compartments was always done to check on the integrity of the ACL graft and to look for cartilage or meniscal injuries. A modified Lemaire tenodesis was performed in every patients, as previously described [40]. An antero-lateral approach of about 4 to 5cm was made between the lateral femoral epicondyle and Gerdy s tubercle. A 1cm × 8cm long strip from the central part of the fascia lata was harvested, leaving its distal attachment at the Gerdy´s tubercle intact. In every case, a 5.5 × 20 mm tunnel was made starting 5 to 10 mm proximal and 5 mm posterior from the lateral epicondyle. The proximal part of the graft was passed beneath the lateral collateral ligament and secured in the tunnel with a 6 × 20 mm interference screw (Biosure HA, Smith and Nephew) maintaining the foot in neutral rotation. During fixation, care was taken to avoid extreme tensioning on the graft given that previous biomechanical studies have suggested that tension over 20N may overconstrain knee kinematics [15].

Clinical assessments and follow-up

For all patients, age, sex, body mass index (BMI), type of graft used for index ACL surgery as well as the time between index ACL surgery and LET were recorded. The same preoperative MRI and radiographs protocols were used in every case to detect ACL graft rupture, cartilage and meniscal injuries, lower limb malalignment and radiological signs of osteoarthritis. During the outpatient clinic visit, anteroposterior knee laxity was measured using the Kinematic Rapid Assessment (KiRA) triaxial accelerometer (Orthokey Italia Srl, Firenze, Italy), and the KT-1000 arthrometer (MEDmetric San Diego, California) while performing the manual maximum test as previously described. The difference between the injured and uninjured legs was expressed in 0.5mm increments [10, 42].

Quantitative assessment of the pivot shift (QPS) phenomenon, detecting the values of rotational acceleration, was performed using the KiRA accelerometer.

All the measurements were recorded following the indications previously described [28, 42]. Each measurement was performed five times. Then, the maximum and minimum values were excluded, and the three remaining values were averaged and used for the analyses. Both knees were evaluated to analyze the difference in rotational acceleration. It is defined as residual anterolateral rotational instability (ALRI). ALRI was calculated by subtracting the value of laxity of the healthy joint from the one acquired on the involved joint [24]. In the same way, the residual anteroposterior instability (API) was calculated with both the KT1000 and KiRA.

Preoperative and postoperative assessments were always performed by the same senior surgeon (M.F.) trained with the KiRA system and KT1000 arthrometer to avoid a technical bias. A single trained observer approach was adopted to mitigate the broad inter-observer reliability of the test. The examiner was not blinded to the state of the knee but was blinded to the results of the KiRA analyses during the execution of the tests. The observer was not one of the treating surgeons.

To evaluate knee function and subjective instability, the Single-leg vertical jump test (SLVJT) and the Single-leg hop test (SLHT) were used, as originally described. For the SLVJT, the subject starts with the foot of the test leg on a 75 × 50cm rectangular mat, begins to sink and holds a knee position (at an approximately 120° knee angle). On the count of four, the subject jumps as high as possible. A successful trial was one where there was no sinking or counter- movement prior to the execution of the jump. The test was performed correctly when one foot landed on the mat with elbows clasped behind the back throughout [51].

To perform the SLHT, each participant stands on one leg with the heel on a predetermined mark on the floor. Then, the subject hops forward as far as possible while landing on the same leg. The investigator uses a standard tape-measure to record the horizontal displacement in centimeters from the heel starting position to the heel landing mark. This test was performed three times, and the greatest distances for the involved and uninvolved limbs were measured [57]. Subjective outcomes were assessed using the IKDC 2000 subjective knee evaluation form and the Lysholm score [7, 21]. Finally, patients were asked to complete the Tegner activity scale [7]. The Patients Reported Outcomes (PRO) measures, SLVJT and SLHT, KT-1000 and KiRA evaluations were collected before surgery, at 6 months and 2 years after surgery. Patients were prospectively followed up, and the occurrence of any complications, further surgery and/or recurrence of ACL ruptures or meniscal lesions were noted.

Time Zero Kinematic Assessment

On the day of surgery, the patient was evaluated to obtain quantitative anterior and rotational laxity values using the KiRA system. Both the knees were evaluated on two occasions following the same preoperative protocol, 1) after the administration of general anesthesia but before the application of the tourniquet and 2) just after the end of the surgery after the removal of the tourniquet (still under anesthesia).

Statistical analysis

Continuous variables are presented as mean and standard deviations (SD). Categorical variables are presented as percentages and frequencies. The Shapiro Wilk test was used to confirm the normality of the variables. The inference in continuous variables was calculated with the paired-samples T-test and their results are presented with their 95% confidence interval (95% CI). The inference for categorical variables was studied with the Chi-squared test or Fisher's exact test, depending on what corresponded. To compare repetitive variables, the ANOVA test was used. The Wilcoxon signed-rank test and the Spearman Rank correlation coefficient were used to assess any association between the side-to-side difference in laxity and the baseline characteristics (age, sex, type of ACL graft, BMI, additional procedure). The level of significance was set at 5% ($\alpha = 0.05$), the bilateral approximation. The sample size calculation was based on the primary outcome: the difference in rotational acceleration. The calculation took in account previous published data [24, 36] that showed as a reduction of the side-to-side difference under anesthesia of $1.5 \pm 0.4 m/s^2$ in rotational acceleration was considered clinically relevant. Based on these data, the estimated effect size was calculated using Cohen's D statistic, resulting in $d = 3.00$. Thus, using a two-sided alpha value of 0.05 in a formula for the difference of means in two dependent populations, a total of 15 participants would give us 80% of power with 95% of confidence. All the analyses were performed with the SPSS version 19 (SPSS Inc., Chicago, Illinois).

RESULTS

A total of 7 females and 12 males were prospectively followed up. The mean age in the cohort was 24.5 ± 7.5 years (range, 17-34 years). The mean value of the graft sagittal inclination angle was 60.2 ± 4.3º. The baseline characteristics of the patients are summarized in Table 2.

A meniscal procedure was undertaken on 5 patients during the index ACL reconstruction surgery and 5 patients underwent a partial meniscectomy during LET. No associations have been detected between the side-to-side difference in laxity and the baseline characteristics.

Table 2. *Baseline characteristics and additional procedures during ACL reconstruction or LET*

Patient	AGE (years)	SEX	BMI (Kg/ m^2)	Time between ACL and LET (months)	ACL graft
1	18	Male	23,2	25	BTB
2	33	Male	24,1	21	Hamstring
3	31	Male	21,7	24	BTB
4	30	Male	22,3	15	BTB
5	22	Female	20,1	28	Hamstring
6	20	Male	21,9	31	BTB
7	19	Male	24,1	23	Hamstring
8	25	Female	23,1	18	BTB
9	23	Female	22,8	25	Hamstring
10	24	Female	19,9	21	Hamstring
11	21	Male	24,6	19	BTB
12	34	Male	21,3	19	Allograft
13	17	Female	20,7	17	BTB
14	26	Male	25,1	21	Hamstring
15	24	Male	22,5	25	Hamstring
16	20	Female	23,8	27	Hamstring
17	20	Male	26,1	29	Hamstring
18	18	Male	22,4	34	BTB
19	21	Female	20,5	24	Hamstring

BMI: body mass index; BTB: Bone-Tendon-Bone; M: medial; L: lateral; ACL: anterior cruciate ligament; LET: lateral extraarticular tenodesis.

Additional Procedure during ACL	Additional Procedure during LET
None	None
Meniscal suture (M)	Partial meniscectomy (M)
None	None
None	Partial meniscectomy (L)
None	None
Meniscal suture (L)	None
Partial meniscectomy (L)	None
None	None
None	None
None	None
None	Partial meniscectomy (M)
None	None
Meniscal suture (M)	None
None	None
None	None
Partial meniscectomy (M)	Partial meniscectomy (M)
None	None
None	None
None	Partial meniscectomy (L)

Kinematic analysis

The side-to-side difference in dynamic rotational acceleration of the tibia during the pivot shift test, as measured with KiRA, decreased significantly under both anesthesia and without the effect of the anesthesia. The side-to-side difference in anterior tibial translation measured in millimeters with KiRA decreased significantly only under anesthesia. The side-to-side difference in anterior tibial translation measured without anesthesia with both KiRA and KT1000 didn't show a significative variation (n.s. in both measurements). Postoperative analysis of knee laxity did not show any significant variation from the first to the last FU. A complete summary of the kinematic values is presented in Tables 3 and 4.

Table 3. *Summary of the mean kinematic values under anaesthesia*

	Preoperative	Postoperative	*P* value
AP TRANSLATION (KiRA)	8,6 ± 1,4	7,2 ± 1,8	**0,019**
QPS	5,9 ± 1,5	4,3 ± 0,8	**0,007**
Residual API	3,4 ± 1,9	2,1 ± 1,1	**0,019**
Residual ALRI	2,2 ± 1,2	0,5 ± 1,1	**0,003**

AP translation: antero-posterior translation of the involved limb (mm); QPS: quantitative Pivot Shift of the involved limb (m/s^2); API: antero-posterior instability (mm); ALRI: anterolateral rotational instability (m/s^2).

Table 4. *Summary of the mean kinematic values without anaesthesia*

	Preoperative	6 months FU	2 years FU	*P* Value
AP TRANSLATION (KiRA)	6,8 ± 2,1	6,1 ± 1,6	6 ± 1,5	0,064
AP TRANSLATION (KT1000)	8,3 ± 2,4	7,5 ± 1,4	7,3 ± 1,6	0,071
QPS	3,7 ± 3,2	2,4 ± 2,8	2,3 ± 2,5	**0,022**
Residual API (KiRA)	2,3 ± 1,1	1,6 ± 1	1,5 ± 1,2	0,057
Residual ALRI	1,4 ± 1,8	0,2 ± 1,4	0,3 ± 1,3	**0,018**

AP translation: antero-posterior translation of the involved limb (mm); QPS: quantitative Pivot Shift of the involved limb (m/s^2); API: antero-posterior instability (mm); ALRI: anterolateral rotational instability (m/s^2); FU: follow up.

Clinical and functional findings

All 19 patients complained of subjective instability, preoperatively. At the 6 months follow up only one patient was still complaining of instability during sport activities (tennis, skying). Anyway, this patient reported an increasing in the stability of the knee during heavy work activities improving his Tegner activity level from 4 to 5. Two patients suffered a knee sprain during sport activities at 13 and 15 months postoperatively that led to a complete rupture of the ACL. Both these patients increased their level of activities after the surgery (from 4 to 6 in the Tegner Activity scale in both cases). After the new injury they decreased their level of activity to 3 of Tegner activity scale requiring a revision ACL surgery. Finally in 16 patients (84.2%), the subjective feeling of instability disappeared at the last follow-up.

The mean inclination angle value of the ACL measured on MRI was 60.2 ± 4.3° and all the grafts had a sagittal inclination angle > 55°. The mean inclination angle of a native ACL measured in a sagittal MRI is 49.3 ± 4.2° [23] and an inclination > 55° falls outside the anatomical range previously described [18]. Thus, it was confirmed that the TT ACLR was not anatomical in the patients of our cohort.

Eight patients (42.1%) were able to perform the SLVJT before the operation, 17 (89.5%) were able at 6 months and 16 (84.2%) at the 2-year FU ($p < 0.05$).

Also for the SLHT a significative improvement was found in the postoperative evaluation (Table 5).

The mean value of subjective IKDC showed a significant improvement ($p < 0.05$), on the contrary, no significant improvement was detected for the Lysholm score (Table 6).

Table 5. *Single leg hop test results*

SLHT	Preoperative	6 months FU	2 years FU	*p* Value
length	128.2 ± 28.9 cm	138.7 ± 32.3cm	141.8 ± 21.1cm	0.009
Limb symmetry index	78.6 ± 9.9%	85.9 ± 15.5%	89.7 ± 11.2%	0.017

Table 6. *Summary of clinical scores. No significative variation was showed from the first to the last follow up.*

	Preoperative	6 months FU	2 years FU	*p* Value
IKDC	80.4 ± 10.3	92.9 ± 10.9	91.1 ± 12.2	0.009
LYSHOLM	84.8	93.2	91.7	0.051

FU: follow up

DISCUSSION

The main finding of the present study was that LET can improve the kinematics of a non-anatomic ACL reconstructed knee with residual laxity. More specifically, it can significantly reduce both rotatory and anteroposterior laxity. The latter shows less significant improvement, which can only be detected with the patients under anesthesia. The improvement in rotational laxity was still present at the last follow-up without changes from the first follow-up. Those who support the use of an associated LET do so based upon the results of biomechanical studies and a few recent clinical studies with short follow-ups. All these studies have been done performing the ACLR with an anatomical trans anteromedial portal technique [14, 16, 35, 46]. As far as we know, this is the first data available on the *in vivo* kinematics of an LET associated with a non-anatomic ACLR technique. For an *in vivo* assessment of rotational instability of the knee, the Pivot-shift test remains the most practical tool available [36] but considerable variations in interobserver reliability have been reported and the diagnostic accuracy of the test remains somewhat limited [4]. For these reasons, a triaxial accelerometer was used for an accurate quantitative analysis of laxity in the present study. The use of the triaxial accelerometer has been widely validated and found to be useful and easy to perform a kinematic analysis, even intraoperatively [24, 36, 42].

The kinematic data of the present study does not only have statistical significance. Indeed, according to the data from some previous studies, one clinically relevant grading difference in pivot-shift acceleration under anesthesia was 1.5 (± 0.4m/s^2) [24, 36]. This suggests that the mean tibial acceleration reduction by the LET in TT ACLR knees in the present study ($> 1.5 \pm 0.4\text{m/s}^2$) was clinically significant.

Furthermore a 1.9m/s^2 side-to-side difference in tibial acceleration as well as 3mm side-to-side difference in tibial anterior translation have been demonstrated to be pathological [5]. In 4 patients (21%), preoperative pathological anterior translation was detected whereas the side-to-side tibial acceleration was $\geq 1.9\text{m/s}^2$ in 16 subjects (84.2%). This data is in line with previous studies that showed that a non-anatomic position of a femoral ACL tunnel can frequently lead to persistent rotational instability [31, 33].

The second important finding of the present study is that the kinematic changes provoked by the LET results in an improvement in subjective stability and the functional and clinical outcomes in this small cohort of recreationally active patients.

The SLHT was designed to assess both the strength and confidence in the involved limb in an easy way while performing it in outpatient clinics [47]. The SLVJT has been reported to provide an assessment of strength, power and patient willingness to accept weight on the involved side. Specifically, the latter was the objective of the present study in which the simplest SLVJT variation was used [27, 30].

In 84.2% of the patients, the LET was useful in resolving the functional instability. Moreover, an improvement in both the SLVJT and SLHT was seen. This results in a significative improvement in both the Tegner activity score and IKDC score.

Given that it was a secondary outcome of the study, no power analysis relative to clinical outcome changes was carried out. This is one of the reasons why we cannot state with certainty whether the statistical difference of IKDC would correspond to a clinical improvement or to a random error [19]. The lowest minimal detectable change (MDC) previously published for IKDC is 8,8 points in cohort of a mixed knee pathology [9] and in the cohort of the present study the mean improvement was 10.7 points. The patient acceptable symptom state (PASS) previously described for the IKDC after ACL reconstruction is 75.9 [34] and the normative mean value for the IKDC described for patients ranging in age between 18 and 50 years was 87.6 [1]. The cohort in the present study showed a mean improvement that went from 80.4 to 91.1. It means that the preoperatively IKDC value was already in the PASS range but not in the normative value range. Moreover after the surgery the IKDC value reached the normative value previously described. Finally, the minimal clinically significant difference (MCID) for the IKDC is reported in literature as 6.3 and 16.7 for chondral injuries (6 and 12 months respectively), and from 11.5 to 20.5 for other mixed knee pathologies [9,17]. If theses MCID values are followed the statistical difference we found in the present study might not correspond to a clinical improvement.

This study has several limitations. The first limitation is the small cohort size. Thus, this study was not powered to detect differences between the baseline characteristics of the patients (i.e., BMI, sex, type of graft). Similar studies with a larger cohort will be better able investigate whether baseline characteristics can influence the biomechanical changes brought on by LET.

The second limitation is the lack of a control group for the clinical part of the study. A group of patients with the same pathology treated with a different technique or approach would make the results more consistent. Both from an ethical and a practical point of view, it did not seem appropriate to offer patients a different treatment from the one we proposed to them. Patients could not tolerate continuing conservative treatment due to lack of results and a revision ACL reconstruction in recreationally patients with intermediate objective instability and intact ACL graft on MRI was considered a too aggressive solution.

A further limitation is the single evaluator methodology. This obviously has an inherent weakness but it was specifically adopted to minimize the error that would be introduced as a result of multiple observers. Nevertheless, previous studies have already demonstrated that the KiRA is both accurate and reliable at quantifying rotational acceleration and antero-posterior laxity [20, 24, 42]. At the same time, it has been shown that the reliability of the KiRA device is proportional to the experience of the user [5]. For these reasons, an observer who was well-experienced in knee surgery and had more than three years of experience using this triaxial accelerometer was chosen.

Finally, some could claim that the detected lower value of laxity for the involved knee collected at time zero may also be related to the required prudence in postoperative measurements. For this reason, the decision was taken to re-evaluate the patients in the outpatient clinic up to 2 years postoperatively to mitigate the influence of this bias.

CONCLUSIONS

The modified Lemaire LET can improve the kinematics of a non-anatomic ACL reconstructed knee with residual subjective and objective instability. These kinematic changes were able to lead to an improvement in subjective stability as well as the function of the knee in a small cohort of recreationally active patients. At two years follow-up, the kinematic changes as well as the level of activity of the patients and the IKDC score show their improvement sustained.

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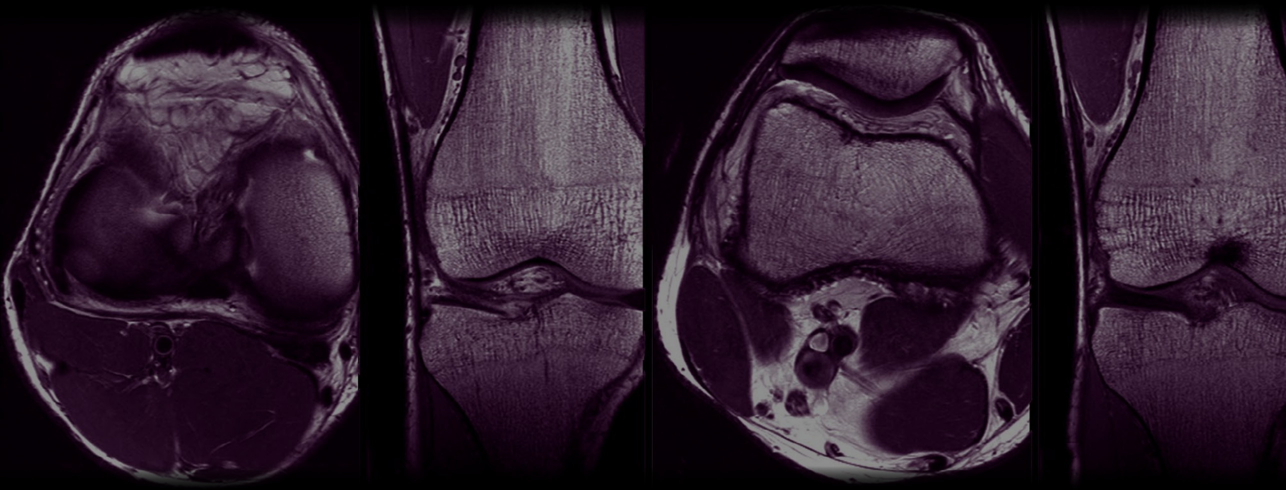
CHAPTER 7.

Combined Anterior Cruciate Ligament Reconstruction and Modified Lemaire Lateral Extra-Articular Tenodesis better restores Knee Stability and reduces Failure Rates than Isolated Anterior Cruciate Ligament reconstruction in Skeletally Immature Patients



Chapter 7.

Combined Anterior Cruciate Ligament Reconstruction and Modified Lemaire Lateral Extra-Articular Tenodesis better restores Knee Stability and reduces Failure Rates than Isolated Anterior Cruciate Ligament reconstruction in Skeletally Immature Patients

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ABSTRACT

Background: The increase in anterior cruciate ligament (ACL) injuries in pediatric patients and the high failure rate reported in the literature in this population are driving surgeons to search for specific techniques to better restore knee stability. Recent literature has reported that the combination of lateral extra-articular tenodesis (LET) and ACL reconstruction improves outcomes in high-risk patients. However, such advantages in pediatric patients have been infrequently evaluated.

Purpose: The aim of this multicenter study is to assess whether adding LET to ACL reconstruction can significantly improve knee stability, clinical outcomes, and failure rates in pediatric patients.

Methods: A multicentric study involving three orthopedics teaching centers was conducted to evaluate pediatric patients aged between 12-16

years who have undergone primary ACL reconstruction using a physeal sparing femoral tunnel drilling technique. A minimum 2-year follow-up evaluation was required. Based on the surgical technique performed, the patients were divided into 2 group. The patients in group 1 underwent an isolated arthroscopic ACL reconstruction, while the patients included in group 2 had an arthroscopic ACL reconstruction in combination with a modified Lemaire LET procedure. Group 1 was a historical control cohort of patients, whereas group 2 was prospectively enrolled. All the patients included in the present study were clinically evaluated using the Pedi-IKDC subjective score and the Pedi-FABS score. Anteroposterior knee stability was measured using the KT-1000 knee ligament arthrometer and the objective pivot shift evaluation was documented with a triaxial accelerometer. The included patients also underwent a standardized radiological protocol to evaluate leg-length-discrepancies, axial deviation and degenerative signs preoperatively and at last follow-up.

Results: This study included 66 pediatric patients with an anatomic hybrid ACL reconstruction using an autologous four-strand hamstring graft. In group 1 there were 34 patients (mean bone age 13.5 ± 1.2 years), while 32 patients (mean bone age 13.8 ± 1.4 years) were included in group 2. The clinical outcome scores showed no difference between the two groups (Pedi-IKDC, p= .072; Pedi-FABS, p= .180). Nevertheless, the patients in group 2 had better anteroposterior stability measured with a KT-1000 arthrometer (1.9 ± 1.1 in group 1 vs 0.8 ± 0.8 in group 2, p= .031), as well as better rotational stability measured with KIRA (–0.59 ± 1.05 in group 1 vs 0.98 ± 1.12 in group 2, p= .012). The patients in group 1 returned to sport at the same competitive level at a rate of 82.4%, while patients included in group 2 returned at the same competitive level in 90.6% of the cases without significant difference between the two groups (p= .059). No leg-length-discrepancies were found between the 2 groups at last follow-up (p= .881). Three patients displayed an increased valgus deformity of 3º on the operated limb at last follow-up (two in group 1 and one in group 2). Group 1 had a significatively higher cumulative failure rate (14.7% vs 6.3%; p = .021). No difference in intra o postoperative complication was observed between the two groups.

Conclusions: performing a modified Lemaire LET along with an ACL reconstruction with hamstrings in pediatric patients reduces the cumulative failure rate and improves objective stability with no increase in intra- or postoperative complications. No significant difference was found between the two groups in terms of patient-reported outcomes or in the return to sport activity. Further studies of greater methodological quality are welcomed to confirm the safety and efficacy of the combined ACL/LET procedure in the pediatric population with long term follow up.

INTRODUCTION

Anterior cruciate ligament (ACL) ruptures in pediatric patients are becoming increasingly common as more children engage in competitive sports and physical activities. [13] These injuries account for 21.5% of all knee injuries in the pediatric population. They mostly turn out to be high-pivoting sport-related injuries. [44] The proper management of ACL ruptures in this population has been a matter of debate for many years. Advocates of non-surgical or delayed surgical treatment have pointed out the risk of growth disorders related to physeal damage. [47] However, subsequent reports have indicated that non-operative management leads to higher rates of sport dropouts [37], recurrent knee instability [37], progressive meniscal and cartilage damage, and arthritic changes in about 61% of knees. [1,34] Then again, there is controversy about the best reconstruction technique, the most suitable graft choice and the fixation methods. [3,25,37] One of the great concerns raised when facing an ACL reconstruction in this population is the high risk of graft failure, which is estimated in 8.3%-25.5% of the cases regardless of the technique and graft used. [7, 25, 49] This failure rate has been described as 2 to 3 times higher when compared to adult patients. [2,16,43]

Recently, combining a lateral extra-articular tenodesis (LET) with ACL reconstruction has been reported to significantly decrease failure rates while improving objective rotatory stability and the postoperative activity level. [32] As a result, LET has been strongly recommended for patients at high risk of failure. Indications include patients younger than 25 years of age, patients practicing pivoting sports, patients with joint hyperlaxity and patients with a high-grade preoperative instability. [29, 42] Since such features are quite common in the pediatric population, LET might be quite convenient in this context. However, to date, the advantages of combining LET with ACL reconstruction in pediatric patients have been infrequently evaluated. Moreover, there are some unsolved issues raised in recent studies reporting the theoretical risk of knee overconstraint and the increase in lateral compartment pressures [21,33,48], which can accelerate degenerative joint changes. It remains unclear whether such findings result in alterations in bone growth in patients that are still developing.

The aim of the present study was to assess whether performing a LET in combination with ACL reconstruction can improve knee objective stability and clinical outcomes and decrease the failure rate in the pediatric population. The hypothesis was that combining modified Lemaire LET to ACL reconstruction improves knee stability, clinical outcomes and reduces the failure rate in comparison with isolated ACL reconstruction in a skeletally immature population.

METHODS

A multicentric study involving three orthopedics teaching centers was conducted to evaluate skeletally immature patients who have undergone ACL reconstruction with a minimum 2-year follow-up. The study was conducted in conformity with the principles of the 1964 Helsinki Declaration and its later amendments [18], and in accordance with the ethical standards of the institutional research committee (protocol LCA-2017-01). All patients were informed of the study procedure, purpose, and known risks. Both the patients and parents gave written informed consent.

The included patients were skeletally immature individuals with a maximum bone age of 16 years in males and 14 years in females. There had to be evidence of both tibial and femoral open epiphyseal growth plates in magnetic resonance imaging (MRI) and a diagnosis of a primary ACL rupture. In addition, only patients willing to return to sports activities after the rehabilitation process were included. Only patients that undergone an autologous hamstring ACL reconstruction were considered for the enrollment. Patients were excluded if one of the following criteria was met: (1) a follow-up period less than 24 months after the index ACL reconstruction; (2) a concomitant grade 2 or more tear of any other knee ligament (medial collateral ligament, lateral collateral ligament, posterior cruciate ligament); (3) cartilage injuries requiring surgical treatment at the time of the ACL reconstruction; (4) previous surgery on the affected knee.

Patient information

Demographics, patient characteristics, and the mechanism of injury were collected in an institutional database. Additional data were collected for each patient relative to intra- and postoperative complications, time to return to sports activity, the level of resumed sports activity and any further reoperation required in the follow-up period.

The surgical data were abstracted to include details surrounding the operative procedure like the size of the ACL graft, concomitant injuries and respective treatments. Physical examination findings were noted by the treating surgeon, including the preoperative range-of-motion to evaluate hyperextension and the objective anteroposterior and rotational instability. The anteroposterior knee stability was measured using the KT-1000 knee ligament arthrometer (MEDmetric Corp, San Diego, CA, USA). The test was performed on both knees applying a 134 N force, and the side-to-side difference was recorded. The quantitative objective pivot shift evaluation was documented with a triaxial accelerometer (KiRA; Orthokey LTD). Also in this case, the test was performed bilaterally to calculate the side-to-side difference. Each measurement was performed five times. Then, the maximum and minimum values were excluded, and the three remaining values were averaged and used for the analyses. Both instrumental evaluations were performed preoperatively and at last follow-up. These evaluations were performed following previously published protocols by a trained knee-surgeon.[8,30] Preoperative and postoperative assessments were always performed by the same senior surgeon trained with the KiRA system and KT1000 arthrometer to avoid a technical bias. A single trained observer approach was adopted to mitigate the broad interobserver reliability of the test. The examiner was not blinded to the state of the knee but was blinded to the results of the KiRA analyses during the execution of the tests. The evaluator was not one of the treating surgeons.

Based on the surgical technique employed, patients were divided into 2 groups. The patients in group 1 underwent an isolated arthroscopic ACL reconstruction, while the patients included in group 2 underwent an arthroscopic ACL reconstruction in combination with a modified Lemaire LET procedure. Group 1 was a historical control cohort of patients that had undergone surgery from September 2015 to September 2017 and that was clinically evaluated from October 2017 to October 2019. Participant enrollment in this group and the duration of follow-up was retrospective, but the clinical outcomes and radiographic measures were prospectively collected. The 2 years follow up evaluation of this group of patients was done after the beginning of the present study. A historical control group was used because all the surgeons involved in the study had routinely performed the ACL-LET procedure on pediatric patients since 2017. Group 2 was evaluated prospectively, recruiting patients that fulfilled the inclusion criteria between October 2017 and October 2019 and followed up until October 2021. The demographic data of the 2 groups were compared to evaluate the similarities between them. (Table 1)

Table 1. *Baseline characteristics of the groups. Age, bone age and BMI are expressed as mean and standard deviations. () indicate the range.*

	Group 1	Group 2	*P value*
Male	23	20	.191
Female	11	12	.434
Age (years)	13.5 ± 1.2 (12-16)	13.8 ± 1.4 (12-16)	.792
Bone age (years)	14.0 ± 0.9	14.1 ± 1.0	.897
Hyperextension (degrees)	8	9	.901
BMI	21.3 ± 1.6	20.9 ± 2.4	.486
Meniscal tears	18	22	.251
Partial meniscectomy	6	6	1
Posterolateral tibial slope (degrees)	6.8 (4-11)	7.3 (2-12)	.891
Posterolateral tibial slope > 8 degrees	8	8	.937
Graft diameter (mm)	8.2 ± 0.8	8.3 ± 1.1	.879

BMI= Body Mass Index. Hyperextension: only patients with more than 5 degrees of hyperextension measured by goniometer were considered.

Radiographic data

Preoperatively, the patients underwent a standardized radiological protocol that included a left wrist view to evaluate skeletal age in accordance with the Greulich and Pyle method. [23] A bilateral anteroposterior full-length weightbearing view was obtained preoperatively and at last follow up to calculate any coronal alignment changes and leg-length discrepancies. Total limb-length and segmental femoral and tibial lengths were measured with an institutional picture archiving and communication system (PACS; Sectra Imaging, Sectra Medical). A Rosemberg view, Merchant view and lateral view were obtained preoperatively and at last follow up to assess the development of early degenerative changes using the Kellgren-Lawrence scale. [26] Special attention was placed on evaluating the lateral tibiofemoral compartment where degenerative signs can come from either subchondral impaction or overconstraint secondary to the LET. Posterolateral tibial slopes were measured since has been demonstrated in previous sudies that a slope > 8 degrees is a risk factor for reinjury in this population.[9,22] Measurements have been made with the technique described by Hudek et al [22] as validated by MRI in a pediatric population.[9] Finally, a 1.5 T MRI was obtained in all cases at the 10-month follow-up before allowing patients to return to sport.

Surgical technique and rehabilitative protocol

All the patients underwent an arthroscopic anatomic ACL reconstruction with autologous four-strand hamstring graft (semitendinosus and gracilis tendons). The femoral tunnel was done using a physeal-sparing technique with a retrodrill system, using an adjustable cortical suspension system (Ultrabutton, Smith & Nephew Endoscopy, Andover, MA, USA) for the femoral fixation. The tibial tunnel was executed in an out-in manner. Using a compass tibial guide at 60°-65º, it was placed as centered as possible on the anterior tibial cortex. By doing so, the tunnel was made as vertical as possible when trespassing the physeal growth plate. Thereby, the damage caused to this growth plate was minimized. [36] The graft was then fixed at 20° of knee flexion using a bioabsorbable interference screw (Biosure HA, Smith and Nephew, Memphis, USA).

A modified Lemaire anterolateral tenodesis was performed only in the patients in group 2. A 4 to 5 cm anterolateral approach was made between Gerdy's tubercle and the lateral femoral epicondyle. A 1cm wide x 8 cm long strip was harvested from the middle third of the fascia lata, preserving its distal insertion in Gerdy's tubercle intact. The proximal part of the graft was secured with whipped stitches and subsequently slipped deep under the lateral collateral ligament. A blind femoral tunnel of 5.5 mm wide x 20 mm long was drilled and subsequently dilated with a 6 mm dilator. Finally, the graft was driven through the femoral tunnel and secured using a 6 mm x 20 mm bioabsorbable interference screw (Biosure HA, Smith and Nephew, Memphis, USA) while the knee was maintained at 30° of flexion and in neutral rotation. The femoral tunnel was not placed in the position suggested by Katakura et al. [24] (5 to 10 mm proximal and 4 mm posterior from the lateral epicondyle) but approximately 1 cm proximal to this area to prevent injuring the physeal growth plate. Both the femoral ACL tunnel and the LET tunnel were drilled under fluoroscopic control to confirm physeal sparing.

All patients from the two groups participated in the same standardized postoperative rehabilitation protocol. Progression through each phase of rehabilitation was based on each patient's status and the physician's guidance. Full weightbearing and full range-of-motion was encouraged from day 1 unless concomitant meniscal suturing was done. In case of concomitant meniscus repairs, full weightbearing was delayed until week 2 to 4, according to the tear location and repair configuration. Isometric quadriceps strengthen was encouraged as soon as possible. During the first 12 weeks, quadriceps-strengthening exercises were restricted to closed kinetic chain exercises. Sport-specific training was started and gradually progressed after 6 months. A complete return to sports (including cutting sports) was allowed between 10 and 12 months when the physical examination, muscular strength and the MRI aspect of the graft were favorable.

Outcomes

Four primary clinical outcomes were evaluated in the present study. They were cumulative graft failure, objective knee stability, return to sports and patient-reported outcome measures. The cumulative failure was defined by the presence of clinical failure and/or graft rupture, as previously reported by Crawford et al. [6]. Clinical failure was defined as the presence of a patient-reported feeling of giving-way and an abnormal KT-1000 side-to-side difference > 5 mm or an abnormal KIRA side-to-side difference > 1.9 m/s^2, as previously described. [4,31] A graft rupture was defined by MRI evidence of graft discontinuity. Patients with clinical failures and/or MRI evidence of graft ruptures were singularly included in the cumulative failure. In presence of both clinical failure and graft rupture in the same patient, this individual was counted only once.

Return to sport activities was evaluated and recorded. The time passed from the surgery was also noted down. Return to sport was determined by asking the patient if they had returned to the desired level of sports. If "no" was the answer, the patients were questioned as to why she or he did not return to sport.

Patient-reported outcomes were collected preoperatively and at annual intervals. The Pedi- International Knee Documentation Committee (IKDC) subjective score [27] and the Pedi- Functional Activity Brief Scale (FABS) score [15] were employed in the present study. Preoperative Pedi-FABS was used to detect pre-injury activity level of the patients.

Furthermore, all the following complications were collected for both group: infection, deep vein thrombosis and pulmonary embolism, range-of-motion loss and persistent knee pain.

Statistical analysis

Continuous variables are presented as mean and standard deviations (SD). Categorical variables are presented as percentages and frequencies. The Shapiro Wilk test was used to confirm the normality of the variables. The inference in continuous variables was calculated with the paired-samples T-test and their results are presented with their 95% confidence interval (CI). The inference for categorical variables was studied with the Chi-squared test or Fisher's exact test, depending on what corresponded. To compare repetitive variables, the ANOVA test was used. The level of significance was set at 5% (α = 0.05), the bilateral approximation. All the analyses were performed with the SPSS 19 (SPSS Inc., Chicago, Illinois). No sample size estimation was performed because all patients in the database who met the inclusion criteria for group 1 were analyzed, and the group 2 was matched to similar size of group 1. A post-hoc calculation achieved a power of 82.6% for the KT-1000, 88.3% for the KiRA evaluation and 85.1% relative to the subjective IKDC at the two-year follow-up.

RESULTS

Patient information

Seventy-three patients were initially included in this study. However, seven (three in group 1, four in group 2) were excluded. In three cases there was no two-year follow-up (dropouts: one in group 1, three in group 2), in one case a cartilage lesion that required surgery was observed and the remaining three cases had a knee multiligament reconstruction. In the end, a total of 66 skeletally immature patients were evaluated, being 34 patients included in group 1 and 32 in group 2. The mean age was homogeneous across groups (p= .792). The injury mechanism was predominately non-contact (70.1%), and the injuries were sustained during pivoting sports (soccer, 36.2%; basketball, 16.8%; sky, 11.8%) in most of the cases.

The mean graft diameter was 8.2 ± 0.8 mm (range, 7-9; median 8) in group 1 and 8.3 ± 1.1 mm (range, 7-9; median 8) in group 2 (p= .879). In 8 cases of group 1 and 9 cases of group 2 the graft diameter was 7mm (p=.912). The mean follow-up was 26.6 ± 4.2 months for group 1 and 25.1 ± 2.2 months for group 2 (p = .591). In 60.6% of the cases (40 patients: 18 in group 1, 22 in group 2), meniscal lesions were detected: lateral isolated, 23.5%; medial isolated, 51%; and lateral and medial, 25.5%. A ramp lesion was observed in 16,7% of the cases, a posterolateral root tear was observed in 13,6% of the cases, the combination of both these lesions was observed in 3% of the cases. A medial partial meniscectomy was performed in 6 cases in each group. In all the rest of the lesions, meniscal sutures were done. No significant differences were found between the two groups in terms of age, body max index (BMI), gender distribution, preoperative instability, hyperextension, posterolateral tibial slope, associated meniscal tears or partial meniscectomy. A complete description of the data is available in Table 1.

No intraoperative complications were detected. Two patients from group 2 developed a postoperative hematoma in the area of the lateral approach. Surgical debridement was called for in one of those cases. Two patients in group 1 and one in the group 2 underwent to arthroscopic arthrolysis for flexion or extension deficit at 3 months follow up. No infection, deep vein thrombosis and pulmonary embolism, deficit in range-of-motion, or persistent knee pain were noted at the 2 years follow up.

Radiographic Outcomes

The bone age of the group 1 averaged 14.0 ± 0.9 years (range, 12-16 years; male, mean 14.5 years; female, mean 13.0 years). It was 14.1 ± 1.0 years (range, 12-16 years; male, mean 14.7 years; female, mean 13.2 years) in the group 2 ($p = .897$). In all 66 patients, the preoperative MRI showed both the femoral and tibial physis open. No leg-length discrepancies were found at last follow-up. ($p= .881$). Two patients developed increased valgus deformity of 3° on the operated limb in the last medical follow-up, one from group 1 and one from group 2. No patients showed degenerative changes in the joint based on the Kellgren-Lawrence classification. Specifically, no changes were detected at the lateral compartment at the last follow up.

Clinical Outcomes

Four patients (11.8%) in group 1 and one patient (3.1%) in group 2 sustained a complete graft tear (confirmed by MRI and pathological instrumental evaluation) during sport activities. In addition to the above, one patient from group 1 (2.9%)

and one patient from group 2 (3.1%) presented clinical failure, complaining of postoperative subjective giving way associated with pathological KT-1000 and/or KiRA values. The cumulative failure was defined by the presence of clinical failure and/or graft rupture: it was 14.7% group 1 vs 6.3% group 2 (p = .021). All data is presented in Table 2.

Table 2. *Clinical failures and graft ruptures. Data are presented as absolute number and relative rate between brackets.*

	Group 1	Group 2	*P value*
Clinical failure	1 (2.9%)	1 (3.1%)	.875
Graft rupture	4 (11.8%)	1 (3.1%)	.017
Cumulative failure	5 (14.7%)	2 (6.3%)	**.021**

In the subgroup of patients with graft diameter of 7 mm we observed only a graft tear in the group 2 and no clinical failures.

At the last follow up, the patients in group 2 had better anteroposterior stability measured with a KT-1000 arthrometer (p= .031), as well as better rotational stability measured with a KIRA triaxial accelerometer (p= .012). A detailed description of the values is provided in Table 3.

Table 3. *Preoperative and postoperative knee laxity. Values are expressed as mean and standard deviations. Both for KT1000 and for KiRA side-to-side difference was calculated.*

	Group 1	Group 2	*P value*
KT1000 preoperative (mm)	4.2 ± 1.3	4.6 ± 1.4	.565
KT1000 postoperative (mm)	1.9 ± 1.1	0.8 ± 0.8	.031
KiRA preoperative (m/s^2)	2.51 ± 3.24	2.62 ± 4.00	.574
KiRA postoperative (m/s^2)	0.98 ± 1.12	−0.59 ± 1.05	.012

The return to sports rate at the same competitive level was 82.4% for group 1, while this rate was of 90.6% in group 2, without significant difference between the groups (p= .059). Of those not returning to sport, five (three in group 1 and two in group 2) stopped playing sport for reasons unrelated to the knee, and four (three in group 1 and one in group 2) stopped playing as a result of lack of confidence in their knee. No difference was detected in the average time to return to sports of 10.3 ± 1.9 (range, 8.9-12.4) months after surgery in group 1 and 10.8 ± 1.4 (range, 10.2-12.1) months in group 2 (p= .236). The Pedi-IKDC subjective knee evaluation recorded for both groups showed no difference (p = .072) and neither did the activity level of the groups evaluated by means of the Pedi-FABS (p= .180). (Table 4)

Table 4. *Patients reported outcomes*

	Group 1	Group 2	*P value*
Pedi-IKDC preoperative	55.4 ± 5.1	53.9 ± 2.5	.441
Pedi-IKDC postoperative	86.4 ± 8.4	90.5 ± 9.6	.072
Pedi-FABS Pre-injury	18.9 ± 4.3	19.2 ± 3.6	.593
Pedi-FABS postoperative	17.8 ± 3.2	18.5 ± 4.0	.180

DISCUSSION

The main finding of the present study is that a concomitant LET procedure during ACL reconstruction significantly reduces the failure rate when compared to isolated ACL reconstruction. A similar finding was recently described in an adult population in a recent meta-analysis of 1.010 ACL cases. It demonstrated that concomitant LET results in a three-fold lower risk of graft failure. [32] The second relevant finding of the present study is that combining LET with ACL reconstruction significantly improves both anteroposterior and rotatory knee stability in this skeletally immature cohort without increasing the risk of complications. This is in accordance with biomechanical evidence that demonstrates that LET in combination with ACL reconstruction significantly reduces both anterior tibial translation and tibial internal rotation as compared to isolated ACL reconstructions. [11, 17, 41]

To our knowledge, this is the first comparative study on this topic conducted on a pediatric cohort. Previous case series of combined ACL reconstruction and LET in skeletally immature patients showed failure rates ranging from 0% to 5.3%. [28,39,46] The failure rate of the combined technique in the present study (6.3%) approaches this range and is lower than that previously reported in this age group. [25] It is well known that an earlier return to sport represents a relevant risk for graft failure. [10] The low failure rate in our series may be partially related to the mean time to return to sport of 10.8 months. However, this figure does not explain the statistically significant intergroup difference in the failure rates, since neither the time to return to sport nor the rate of return at the same competitive level was significantly different between the two study groups. Furthermore, the present rate of return at the same competitive level with the ACL-LET reconstruction, seems to be higher than the range of 71% - 86% reported in the literature for isolated ACL reconstruction. [25] Even if objective knee laxity was significantly lower in group 2, the groups had Pedi-IKDC that were not statistically significantly different. This finding may suggest that, in this specific population, a minor degree of residual instability does not significantly influence the clinical outcomes for patients that do not present graft failure. Similar findings have been previously described in a cohort of patients with hyperlaxity and an ACL rupture. [20]

Another finding from this study was the low rate of growth disorders, with no significant difference between the two groups. Physeal damage is one of the main concerns in ACL reconstructions in skeletally immature individuals [35] because it may cause growth disturbances in some 13% of cases. [5] Interestingly, this complication is also common after physeal-sparing techniques. [5, 38] The risk of damage of the tibial physis should be minimized by creating a tibial tunnel as vertical as possible. [36] As a confirmation of this, no significant limb length discrepancy was reported in our study. In addition, the risk of violating the femoral physeal growth plate is overcome with the present modified Lemaire

LET technique, because of the more proximal location of the femoral tunnel. The concomitant LET procedure did not significantly increase valgus deviations as expected. This finding is shared with previous reports where the rate of growth disturbance and axial deviation after LET procedures is low. [28,39,46] Therefore, the concern about generating compressive forces resulting in growth inhibition due to graft over-tensioning [14] is questionable. In addition to the safe completion of growth, concern regarding overconstraint of the lateral compartment may be a consideration. However, the absence of degenerative changes in this study as well as in similar previous case series [28,39,46] would appear to confirm safety of LET procedures within at least a short-term follow-up of 2 years, which has already been demonstrated in adult patients in the literature. [12] Regardless, longer follow-up evaluations are needed to confirm our preliminary data.

The present study is not without limitations. The first limitation is inherent to the study design. Its design consists of retrospective participant enrollment (historical cohort) even though the clinical results, patient-reported outcomes, and radiographic measures were prospectively collected. Secondly, this is a multicentric study, involving different experienced surgeons. However, a uniform technique was used, and strict inclusion criteria were adopted to generate a narrowly defined study population. On the other hand, the idea of involving more centers allowed us to enlarge the cohort size. Collecting data from vast cohorts in this context is difficult because the incidence of ACL injuries in children remains low and conservative treatment until skeletal maturity is still common. Thirdly, a longer follow-up would be desirable to better determine the definitive graft failure rate with this procedure, as well as to evaluate the long-term radiological outcomes. Although our follow-up was limited to the short term, ACL graft failure has been reported to occur in 74% of the cases within the first 24 months. [45] Lastly, all the measures were recorded singularly. Therefore, the intraclass correlation coefficient was not calculated. However, intra- and inter-observer reliability tests for radiologic measures (the lower-limb length measurement and tibiofemoral angle calculation) has already been proven excellent in skeletally immature patients. [40] Furthermore, the single evaluator methodology was specifically adopted to minimize the error that would be introduced as a result of multiple observers using the KT1000 and KiRA. Moreover, previous studies have already demonstrated that the KiRA is both accurate and reliable at quantifying rotational acceleration and antero-posterior laxity. [19] At the same time, it has been shown that the reliability of the KiRA device is proportional to the experience of the user. [4] For these reasons, an observer who was well-experienced in knee surgery and had more than three years of experience using this triaxial accelerometer was chosen.

CONCLUSIONS

Based on these findings, performing a modified Lemaire LET along with an ACL reconstruction with hamstrings in pediatric patients reduces the cumulative failure rate and improves objective stability with no increase in intra- or postoperative complications. No significant difference was found between the two groups in terms of patient-reported outcomes or in the return to sport activity.

Further studies of greater methodological quality are welcomed to confirm the safety and efficacy of the ACL-LET procedure in the pediatric population with long term follow up.

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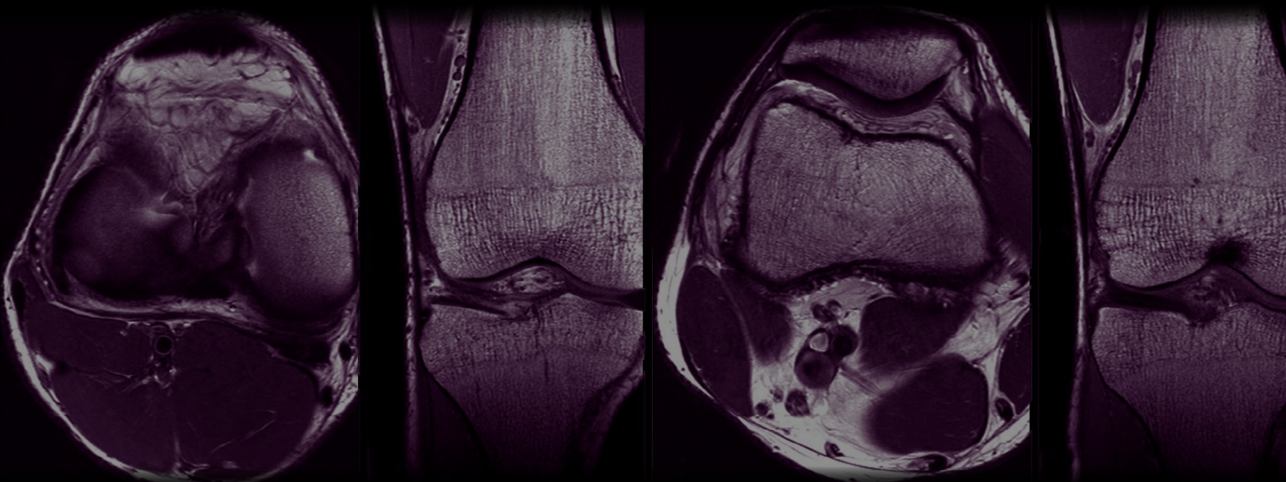
CHAPTER 8. ANNEX MATERIAL OF THE THESIS (ARTICLE IN PRESS)

Isolated lateral extra-articular tenodesis in ACL deficient knees: in-vivo knee kinematics and clinical outcomes



Chapter 8. Annex material of the thesis (article in press)

Isolated lateral extra-articular tenodesis in ACL deficient knees: in-vivo knee kinematics and clinical outcomes

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ABSTRACT

Purpose: to carry out an *in vivo* kinematic analysis of isolated modified Lemaire lateral extraarticular tenodesis (LET) to explore its ability to modify the stability of anterior cruciate ligament (ACL) deficient knees. The secondary aim was to look at the clinical outcomes of the isolated LET to analyze whether biomechanical changes have an influence on clinical improvement or not.

Methods: a total of 52 patients who underwent an isolated modified Lemaire LET were prospectively studied. Twenty-two were over 55 years old patients with ACL rupture and subjective instability (group 1). They were followed up for 2 years postoperatively. Thirty were patients who underwent a two-stage ACL revision (group 2). They were followed up for 4 months postoperatively (up to the second stage of the ACL revision). Preoperative, intraoperative, and post-

operative kinematic analyses were carried out using the KiRA accelerometer and KT1000 arthrometer to look for residual anterolateral rotational instability and residual anteroposterior instability. Functional outcomes were measured with the single-leg vertical jump test (SLVJT) and the single-leg hop test (SLHT). Clinical outcomes were evaluated using the IKDC 2000, Lysholm, and Tegner scores.

Results*:* A significant reduction of both rotational and anteroposterior instability was detected. It was present both with the patient under anesthesia ($p<0.001$ and $p=0.007$ respectively) as well as with the patient awake ($p=0.008$ and $p=0.018$ respectively). Postoperative analysis of knee laxity did not show any significant variation from the first to the last follow-up. Both the SLVJT and SLHT improved significantly at the last follow-up ($p<0.001$ and $p=0.011$ respectively). The mean values of both the IKDC, Lysholm and Tegner scores showed an improvement ($p=0.008$; $p=0.012$; $p<0.001$).

Conclusion*:* The modified Lemaire LET improves the kinematics of ACL deficient knees. The improvement in the kinematics leads to an improvement in subjective stability as well as in the function of the knee and in the clinical outcomes. At the 2-year follow-up, these improvements were maintained in a cohort of patients over 55 years.

INTRODUCTION

The use of lateral extraarticular procedures in association with anterior cruciate ligament (ACL) reconstruction has increased over recent years. Biomechanical, cadaveric, and clinical studies have investigated the advantages, disadvantages, and clinical results of these combined procedures [31,27,40,47]. Some studies have analyzed the kinematic effect of lateral extraarticular tenodesis (LET) *in vivo* [6,34,42,49]. All those investigations were carried out with a focus on the effects of the combined LET and ACL procedures and described contrary results. Thus, little *in vivo* data are available on the role of an isolated anterolateral procedure in ACL deficient knees from a biomechanical point of view.

Extra-articular techniques were originally thought to mechanically act on the lateral periphery of the joint to prevent subluxation of the tibial plateau and thereby reduce rotational instability of the knee [12,14]. Therefore, its use can be theoretically indicated in case of subjective instability of ACL deficient knees when it is not indicated to carry out an intra-articular ACL reconstruction even though isolated extra-articular reconstructions are rarely performed in contemporary practice [50].

The most recent clinical reports on the use of an isolated LET were published more than 25 years ago. They were small retrospective non-controlled studies mostly using the MacIntosh procedure [1,2,39,52,3,11,13,15,21,25,30,32].

Most of those studies described good outcomes in terms of patient-reported outcome measures and the ability of LET to provide rotational control. However, they reported persistent anterior laxity in the operated knees and early degenerative changes in the lateral compartment [39,52,13,21,30]. Many authors have attributed these problems to numerous factors including the non-anatomic nature of the techniques used and the slow rehabilitation with a prolonged period of cast immobilization [8,10,35,43,44]. For those reasons and due to the spread of intra-articular reconstruction of the ACL, the use of isolated extra-articular tenodesis has been abandoned over time and no recent clinical data about isolated use of LET are available.

The purpose of the present study was to carry out an *in vivo* kinematic analysis of isolated modified Lemaire LET to explore its ability to modify the stability of ACL deficient knees. The secondary aim was to look at the clinical outcomes of the isolated LET to analyze whether biomechanical changes have an influence on clinical improvement or not. Our hypothesis was that both knee instability and clinical outcomes can be improved performing isolated LET in ACL deficient knees.

MATERIALS AND METHODS

A prospective observational single-center study that adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines was carried out [53]. All the procedures described in this study were performed in accordance with the ethical standards of the 1964 Declaration of Helsinki and its later amendments [54] and ethics committee approval was obtained (Protocol LCA-2017-01, Approved by ethics committee of Grupo Hospitalario Quiron en Barcelona). All the patients signed an informed consent form before recruitment. No external funding was received for the initiation or completion of this study.

All the patients who had undergone an isolated LET to treat instability of an ACL deficient knee were considered for the study. Patients were recruited between November 2017 and February 2020 and prospectively followed up for two years. The isolated LET was considered an indication for two groups of patients: 1) complete ACL rupture in active patients over 55 years old, 2) patients undergoing the first step of two-stage revision ACL reconstruction.

Exclusion criteria for both groups were skeletally immature patients, knee osteoarthritis superior to stage 2 of the Kellgren-Lawrence classification, a multiligament knee injury or previous ligament reconstruction, the need for cartilage lesion surgery at the time of LET, patients with contralateral ACL injuries, those with excessive (> 5°) varus/valgus deformity, excessive (>12º) tibial slope or associated severe meniscal damage (root tears, ramp lesions, bucket handle tears). Finally, patients not willing to participate in the study or unable to sign written informed consent were excluded.

All the surgical procedures were performed by two of the senior authors.

Sixty-seven patients were assessed for eligibility. After application of the exclusion criteria, fifty-two patients were prospectively included in the study. Three patients were excluded because of a medial collateral ligament lesion and 2 other patients because of the presence of advanced medial compartment osteoarthritis. 4 were excluded because of a root tear, 4 because of a ramp lesion and 2 underwent a bucket handle suture of the medial meniscus.

The patients in group 1 were encouraged to go through a 6-month rehabilitation and strengthening program before they would be considered suitable for the surgical approach. Only patients who presented instability that limited their activity level at the end of this program were proposed for an isolated LET. Subjective instability was described as the feeling of giving way during daily life and/or sport and work activities and the lack of confidence in the knee joint. In all cases, the subjective instability of the patients was confirmed by a quantitative evaluation of the degree of anteroposterior and rotational laxity. Only patients with both objective and subjective instability were included.

The patients in group 2 were treated with 2-stage revision ACL surgery when either the position or the enlargement of the tunnels used for previous ACL reconstruction prevented a revision in one-stage. Subsequently, the patients underwent the second step of the revision at 4 months after the first step. We usually perform LET during the first step of the two-stage approach to prevent the patient from excessive instability during the months between the first and second step of the revision.

Lateral Extrarticular Tenodesis

Before starting the LET, an arthroscopic review of all the joint compartments was always done to confirm the presence of an ACL lesion and to rule out associated injuries. All meniscal procedures were performed before the LET. In all cases in group 2, debridement of the ACL graft remnant was performed in association with allogenic bone impaction grafting in the previously used tunnels. A modified Lemaire tenodesis was carried out in all cases using an interference screw to fix the fascia lata into the femur as previously described [41]. During fixation, care was taken to avoid extreme graft tensioning given that previous biomechanical studies have suggested that tension over 20N may overconstrain knee kinematics [16].

Starting from the first postoperative day, the patients were encouraged to perform active motion and weightbearing as tolerated. Progressive strengthening of the lower limb was encouraged from the beginning. The crutches are usually completely abandoned at between 2 and 3 weeks and soft treadmill running was performed between 4 and 6 weeks postoperatively.

Clinical assessments and follow-up

The same preoperative magnetic resonance imaging (MRI) and X-ray protocols were used in every case to detect ACL graft rupture, cartilage and meniscal injuries, lower limb malalignment and radiological signs of osteoarthritis.

During the outpatient clinic visit, anteroposterior knee laxity was measured using the Kinematic Rapid Assessment (KiRA) triaxial accelerometer (Orthokey, Italia Srl, Firenze, Italy) and the KT-1000 arthrometer (MEDmetric, San Diego, California) while performing the manual maximum test at 30° of flexion as previously described [9,45]. Quantitative assessment of the pivot shift (QPS) phenomenon to detect the values of rotational acceleration was performed using the KiRA accelerometer. All the measurements were recorded following the indications previously described, allowing 2 decimals [29,45]. Each measurement was performed five times. Then, the maximum and minimum values were excluded, and the three remaining values were averaged and used for the analyses. Both knees were evaluated to analyze the difference in rotational acceleration. It is defined as residual anterolateral rotational instability (ALRI). ALRI was calculated by subtracting the value of the laxity of the healthy joint from the one acquired on the involved joint. In the same way, the residual anteroposterior instability (API) was calculated with both the KT1000 and KiRA.

To prevent a technical bias, preoperative and postoperative assessments were always performed by the same senior surgeon trained on the KiRA system and KT1000 arthrometer. A single trained observer approach was adopted to mitigate the broad inter-observer reliability of the test. The examiner was not blinded to the state of the knee but was blinded to the results of the KiRA analyses during the execution of the tests. The observer was not one of the treating surgeons.

To evaluate knee function and subjective instability, the Single-leg vertical jump test (SLVJT) and the Single-leg hop test (SLHT) were used, as originally described [28,33,46].

Subjective outcomes were assessed using the IKDC 2000 subjective knee evaluation form and the Lysholm score [5,22]. Finally, the patients from group 1 were asked to complete the Tegner activity scale [5]. None of the patients from group 2 were asked to complete Tegner scale since they were not allowed to participate in sport activities before the second step of the ACL revision.

The Patient Reported Outcomes (PRO) measures, SLHT, SLVJT, KT-1000 and KiRA evaluations were collected during the last visit before surgery and at 4 months. At 2 years after surgery, the collection was only carried out with group 1. Furthermore, the SLVJT was also evaluated at 6 weeks postoperatively. Patients were prospectively followed up, and the occurrence of any complications, further surgery, persisting symptoms of instability or meniscal lesions were noted.

Time Zero Kinematic Assessment

On the day of surgery, the patient was evaluated to obtain quantitative anterior and rotational laxity values using the KiRA system. Both knees were evaluated on two occasions following the same preoperative protocol: 1) after the administration of general anesthesia but before the application of the tourniquet and 2) just after the end of the surgery after the removal of the tourniquet (still under anesthesia).

Statistical analysis

Continuous variables are presented as mean and standard deviations (SD). Categorical variables are presented as percentages and frequencies. The Shapiro Wilk test was used to confirm the normality of the variables. The inference in continuous variables was calculated with the Paired-Samples t-Test and the results are presented with their 95% confidence interval (95% CI). The inference for categorical variables was studied with the Chi-squared test or Fisher's exact test, depending on what corresponded. To compare repetitive variables, the ANOVA test was used. The level of significance was set at 5% ($\alpha = 0.05$), the bilateral approximation. The sample size calculation was carried out both for the kinematic and the clinical part of the study. The difference in rotational acceleration was considered for the kinematic evaluation. The calculation factored in previous published data [24,38] that showed that a reduction of the side-to-side difference under anesthesia of $1.5 \pm 0.4 m/s^2$ in rotational acceleration was considered clinically relevant. Based on these data, the estimated effect size was calculated using Cohen's D statistic, resulting in $d = 3.00$. Thus, using a two-sided alpha value of 0.05 in a formula for the difference of means in two dependent populations, a total of 15 participants would give us 80% power with 95% confidence. Using the same formula, the power analysis was performed with the IKDC. The minimal clinically significant difference (MCID) was used to identify true clinically meaningful changes in the measures that were not the result of measurement error. The MCID for the IKDC has been reported as 11.5 point [7,18,22,23]. Then, it was used to identify a meaningful difference. A minimum of 20 patients was determined to be necessary to adequately identify a clinically meaningful difference. Considering a possible 10% drop out rate, a minimum of 22 patients was considered adequate. All the analyses were performed with the SPSS version 19 (SPSS Inc., Chicago, Illinois).

RESULTS

Twenty-two subjects were included in group 1 and 30 subjects were included in group 2.

The baseline characteristics of the patients are summarized in Table 1. A meniscal procedure was undertaken on 11 patients during the LET surgery. (Table 1)

Table 1. *Baseline characteristics of the cohort and meniscal surgery at the time of LET. Age is expressed as mean and standard deviations.*

	Age (years)	Male	Female	Meniscectomy	Meniscal suture
Group 1	57.7 ± 1.4	13	9	4 (M)	0
Group 2	25.4 ± 6.9	16	14	2 (M), 1 (L)	2 (M), 2(L)

[M=medial; L=lateral.]

Kinematic analysis

The mean side-to-side difference in rotational acceleration of the tibia during pivot shift test measured with KiRA (ALRI) decreased significantly under anaesthesia ($p<0.001$) as well as without the effect of the anaesthesia at last FU ($p=0.008$). The mean side-to-side difference in anterior tibial translation measured with KiRA (API) decreased significantly under anaesthesia ($p=0.007$) and without the effect of the anaesthesia at last follow up ($p=0.018$). The mean side-to-side difference measured with KT1000 turned out to be significant at last follow up ($p=0.024$). All the postoperative analyses made from the first to the last FU showed no significant variation in neither rotational acceleration or anterior tibial translation (p=0.002 and p=0.004, respectively). A summary of the mean kinematic values is presented in Tables 2 and 3.

Table 2. *Summary of the mean kinematic values under anaesthesia measured with KiRA. Measures are expressed as mean and standard deviations.*

	Pre API	Post API	P value	Pre ALRI	Post ALRI	P value
Group 1	3.72 ± 1.93	2.56 ± 1.84	0.008	3.25 ± 2.50	1.61 ± 1.66	0.004
Group 2	4.60 ± 2.25	3.12 ± 2.14	0.003	3.91 ± 3.14	1.94 ± 2.12	<0.001
Group 1+2	3.98 ± 2.87	2.61 ± 2.19	0.007	3.63 ± 3.81	1.87 ± 2.89	<0.001

[Pre=preoperative; Post=postoperative; API=anteroposterior instability (mm); ALRI=anterolateral rotational instability (m/s^2).]

Table 3. *Summary of the mean kinematic values without anaesthesia measured with KiRA. Measures are expressed as mean and standard deviation.*

	Pre API	4M API	2Y API	P value	Pre ALRI	4M ALRI	2Y ALRI	P value
Group 1	3.03 ± 3.95	1.98 ± 1.79	1.89 ± 2.15	0.021	2.39 ± 3.68	0.82 ± 1.95	0.91 ± 2.11	0.009
Group 2	3.84 ± 3.67	2.68 ± 2.52		0.008	2.65 ± 4.02	0.86 ± 1.87		0.008
Group 1+2	3.49 ± 3.39	2.41 ± 1.96		0.018	2.51 ± 3.98	0.87 ± 2.13		0.008

[Pre=preoperative; 4 M= 4 months follow up; 2 Y= 2 years follow up; API=anteroposterior instability (mm); ALRI=anterolateral rotational instability (m/s^2).]

Clinical and functional findings

All 52 patients complained of subjective instability preoperatively. At the 4-month follow-up, this feeling disappeared in all cases from group 1 (n=22), and in 76.7% of the patients from group 2 (n=23). A significant improvement was detected in the SLVJT (p=<0.001) as 21.1% (n=11) of all the patients were able to perform SLVJT before the operation, 55.7% (n=29) were able at 6 weeks postoperatively, 71.1% (n=37) at 4 months FU, 100% of the patients evaluated at the 2-year FU (22 patients from group 1). Moreover, a significative improvement was found for the SLHT in the postoperative evaluation (Table 4).

Table 4. *Measurements of Single Leg Hop Test. Measures are expressed as mean and standard deviation.*

SLHT	Preoperative	4 M	2 Y (only group 1)	p Value
Length	103.2 ± 38.9 cm	117.4 ± 25.3 cm	123.8 ± 20.2 cm	0.011
Limb symmetry index	64.7 ± 11.8%	75.5 ± 29.5%	77.9 ± 23.6%	0.017

[SLHT=Single Leg Hop Test; M= 4 months follow up; 2 Y= 2 years follow up]

For both IKDC and Lysholm score, we detected a significant improvement (*p*=0.008 and *p*=0.012, respectively) between the pre and postoperative evaluations (Table 5).

Table 5. *Summary of clinical scores.*

	Preoperative	4 M	2 Y (only group 1)	p Value
IKDC	60.1 ± 14.3	76.9 ± 10.8	79.6 ± 11.2	0.008
LYSHOLM	65.8 ± 12.7	79.4 ± 14.7	80.8 ± 13.7	0.012

No significant variation was seen from the first to the last follow up (p<0,001)**.** The median preinjury Tegner activity score in group 1 was 6 (range 4-6). That median dropped to 3 (range 1-4) preoperatively (post injury), and the postoperative median at the last follow up rose to 6 (range 3-6, $p < 0.001$).

No postoperative complications or deficits in range-of-motion of the operated knees were observed.

DISCUSSION

The main finding of the present study was that isolated LET procedure improved the kinematics of ACL deficient knees. More specifically, it reduced both rotatory and anteroposterior laxity. This improvement in kinematics did not decrease at the 2-year follow-up. Several biomechanical and clinical studies have shown that LET can improve both the kinematics and the clinical results when associated with an ACL reconstruction [20,16,37,55]. Nevertheless, few of them have evaluated the capacity of LET itself to modify the mechanics of an ACL deficient knee. Monaco et al. [34] tested 10 knees with navigation during a combined ACL and LET reconstruction performing the extraarticular procedure first. They concluded that LET itself can decrease the rotational instability but has little effect on reducing the anterior displacement of the tibia at 30° of flexion. In a cadaveric study, Tavlo et al. [51] stated that LET has only the capacity to reduce rotational laxity when the ACL is intact. Then again, it can bring about a descrease in both rotational and anterior tibial translation when the ACL is lacking. The present study confirmed these latter findings in an *in vivo* evaluation with the patient under anesthesia as well as with the patient awake. A triaxial accelerometer was used for an accurate quantitative analysis of laxity in the present study. The use of the triaxial accelerometer has been widely validated and found to be useful and easy to use to perform a kinematic analysis [28,45]. According to the data from some previous studies, one clinically relevant grading difference in pivot-shift acceleration under anesthesia was 1.5 ($\pm$ 0.4m/s^2) [24,38]. This suggests that the mean tibial acceleration reduction via LET in ACL deficient knees in the present study ($> 1.5 \pm 0.4$m/s^2) was both clinically and statistically significant. The second finding of the present study is that subjective stability, the functional and the clinical outcomes can be improved with an isolated LET in ACL deficient knees even few months postoperatively. The primary complaint of a patient with ACL insufficiency after an injury is instability. These patients complain particularly of subjective rotational instability with pivoting or cutting activities [26]. In 86.5% of the patients in the present study, the LET was useful in resolving the subjective instability as early as at the 4-month follow-up. Moreover, an improvement in both the SLVJT and SLHT was seen, pointing to an improvement in terms of stability during functional tests, as well. The SLVJT has been reported to provide an assessment of strength, power and patient willingness and confidence to accept weight on the involved side [28,33,46]. Only 21.1% of the patients were able to perform a SLVJT correctly preoperatively and 55.7% of the patients were able at 6 weeks postoperatively ($p<0.001$). The improvement in subjective instability and in the functional test may explain the improvement seen in the patient reported outcomes. The mean improvement in the IKDC values was of 17.1 ± 8.3 points at the 4-month follow-up ($p=0.008$). Considering that the MCID for the IKDC have been reported as 11.5 points [7,18,22,23], we can state that the difference is clinically significant. Furthermore, the patient acceptable symptom state (PASS) previously described for the IKDC after ACL reconstruction is 75.9 points [36]. All the patients in this study were out of the PASS range preoperatively, whereas 73% ($n=38$) of the patients were in the PASS range at the 4-month follow-up. Those that were in the PASS at the 2-year follow-up came to 95.5% of the patients ($n=21$) from group 1. That number confirmed the clinical significance of our results. Our data can confirm it only in a population over 55 years.

We recognize that there are several limitations in the present study. The first limitation is the small cohort size. Thus, this study was not powered to detect differences between the baseline characteristics of the patients (i.e., Body Mass Index, sex, meniscal lesions). Similar studies with a larger cohort would be better able to investigate whether baseline characteristics can influence the biomechanical changes brought on by the LET. The second limitation is the lack of a control group for the clinical part of the study. A second group of patients over 55 years treated by an ACL reconstruction would make the results more consistent about the capacity of LET surgery to improve the clinical outcomes. In the day practice of our health system most of these patients are reluctant or unable to undergo a long and hard rehabilitation protocol as is required in the case of an ACL reconstruction. For this reason, we started to look for an alternative to ACL reconstruction, in this specific kind of patients, in the case of persistent instability after an adequate rehabilitation protocol. Therefore, we couldn't provide a control group for the clinical part of the study. Finally, our aim wasn't to demonstrate the superiority of LET surgery to the ACL reconstruction that, when possible, remain the gold standard in healthy and fit patients over 50 years. For the kinematic part of the study, which was the primary aim, the contralateral knee was considered the control group.

A further limitation is the single evaluator methodology. This obviously has an inherent weakness, but it was specifically adopted to minimize the error that would be introduced as a result of multiple observers as some authors claimed about the inter-rate reliability of KiRA, mainly in evaluate the anteroposterior stability [48]. Nevertheless, numerous studies have demonstrated that the KiRA device is both accurate and reliable at quantifying rotational acceleration and antero-posterior laxity [4,19,24]. At the same time, it has been shown that the reliability of the KiRA device is proportional to the experience of the user [4]. Finally, some could claim that the detected lower value for laxity of the involved knee collected at time-zero may also be related to the prudence required in postoperative measurements. For this reason, the decision was taken to re-evaluate the patients in the outpatient clinic for up to 2 years postoperatively to mitigate the influence of this bias.

CONCLUSIONS

The modified Lemaire LET improves the kinematics of ACL deficient knees. The improvement in the kinematics leads to an improvement in subjective stability as well as in the function of the knee and in the clinical outcomes. At the 2-year follow-up, these improvements were maintained in a cohort of patients over 55 years.

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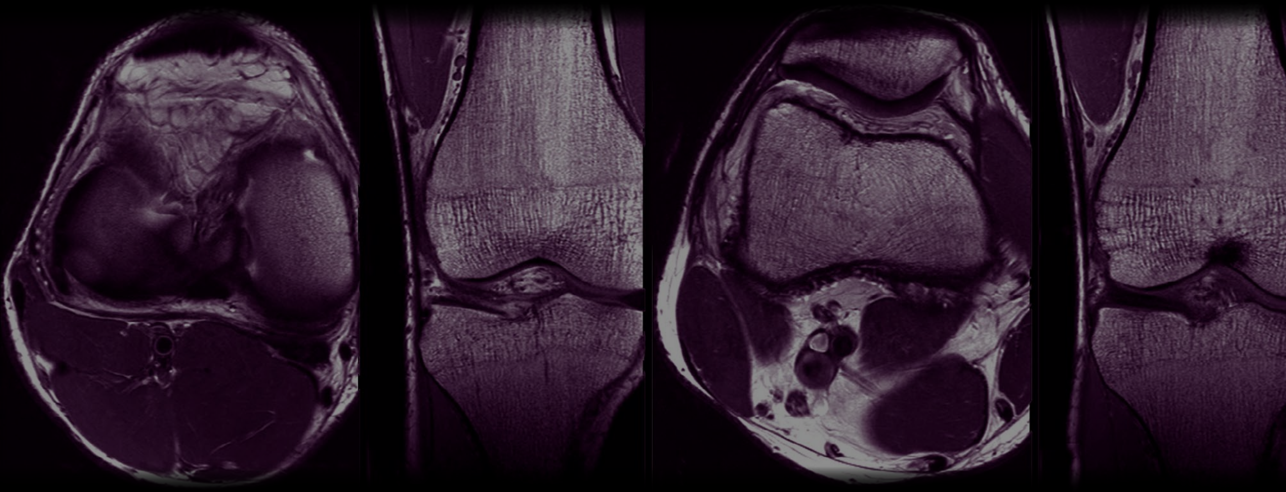
CHAPTER 9.

Summary of the results, general discussion and future research



Chapter 9.

Summary of the results, general discussion and future research

A detailed presentation of the results and a complete discussion of each article is present in the corresponding chapter.

This thesis describes the importance of the anterolateral rotational instability, the power of the anterolateral tenodesis in control the anterolateral instability and the possible complications and secondary effects of the anterolateral extraarticular tenodesis. The literature was reviewed (**Chapter 2**) looking for the causes of ACL failure. Anterolateral instability has been listed as one of the causes of ACL failure when it is not addressed. At the same time, adding an anterolateral tenodesis or performing an anterolateral ligament reconstruction at the same time of the ACL reconstruction seem to restore normal knee kinematics and bring the failure rate down.

The topic of rotational instability was analysed starting from the ground up. One of the current points of debate is the way to measure this instability in an objective way. Since the clinical test can only produce a subjective evaluation, an objective evaluation would help in the treatment algorithm as well as in the interpretation of the postoperative results. All the objective methods of measuring anterolateral instability now available present some drawbacks. For this reason, we present a new open-source technology in **Chapter 3** that will help the clinician to objectively evaluate the stability of the knee.

In **Chapter 4** we analysed one of the possible intraoperative complications performing an anterolateral extraarticular tenodesis. The data on the collision of the ACL femoral tunnel and anterolateral tenodesis tunnel are shown. We performed a postoperative CT scan analysis looking for any kind of collision between the two tunnels. Our conclusion was that the collision between the tunnels is a quite frequent intraoperative complication when this combined technique is used. Furthermore, thanks to an accurate analysis of the inclination of the tunnels, we were able to describe how to avoid this kind of intraoperative complication in the same paper. This was the first in-vivo study of the collision of the two tunnels during a combined ACL-tenodesis procedure, and it was able to introduce a new clinically relevant indication about how to perform in a safe way this combined technique.

Chapter 5 was dedicated to analysing whether the kinematic changes made by the tenodesis were able to cause a biological alteration in the maturation of the ACL. The idea was to evaluate whether there were any advantages or disadvantages from the LCA integration point of view when carrying out this combined technique. Surprisingly, we observed, from a radiological point of view, that the ligament maturation slows down when an anterolateral tenodesis is associated to ACL reconstruction. This finding implies that the rehabilitation protocol and the return to sport activities should be slower in these subjects to avoid biological failure due to the ACL mis-integration. Our work was the first published describing this biological effect of the anterolateral tenodesis and provided an important clinically relevant indication about maturation of the ACL when this combined technique is performed. Chapters 6, 7 and 8 were focused on the possible indications of the anterolateral tenodesis. The data described in these studies present clinical and kinematic results of the use of the anterolateral tenodesis in a particular population of patients. In **Chapter 6,** the tenodesis was used in patients with persistent rotational instability after ACL reconstruction. All those patients underwent ACL reconstruction with the transtibial technique. It is not so uncommon that the patients continue to perceive some degree of instability when this technique is employed. Our work showed how the patients improve, from both the kinematic and clinical point of view, by adding an anterolateral tenodesis. Therefore, this research has important clinical usefulness given that it suggests an easy way to reduce symptoms of instability in the knee in this population of patients. In **Chapter 7**, we performed a comparative study in skeletally immature patients with an ACL lesion. In one group, the lesion was addressed with an isolated ACL reconstruction. In the control group, an anterolateral tenodesis was associated to the ACL reconstruction. The first finding of the study was that the tenodesis is also a safe procedure in the paediatric population. The second important finding was that we observed less ACL failure at 2 years follow up in the control group. This confirms the utility of this technique to reduce the clinical failure after ACL reconstruction also in skeletally immature patients.

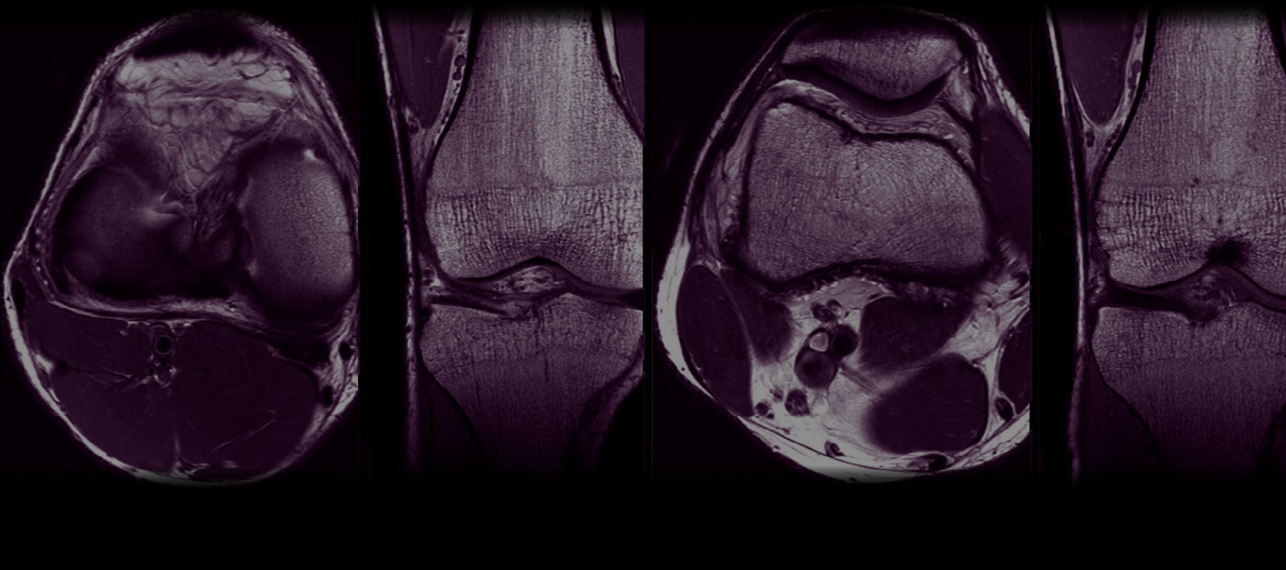
The **Chapter 8** present data still in press. The idea of this study was to evaluate the utility of an isolated anterolateral tenodesis performed in patients in which an ACL reconstruction was not possible. The kinematic analysis of this patients showed how the tenodesis, even when performed alone, has the power to reduce anteroposterior and rotational instability. Furthermore, the patients improved both from a clinical and functional point of view due to these kinematic changes.

The anterolateral instability and its treatment remain an important topic that needs further investigation to achieve a more comprehensive understanding of it. In this thesis, we have tried to assuage some doubts about the safety of tenodesis and suggest alternative indications for this procedure. After this thesis, interesting areas for further study remain. Specific purposes of further study could be:

- Develop different and less invasive anterolateral tenodesis techniques with less risk of intraoperative complications.
- A long-term evaluation of anterolateral tenodesis to assess possible long-term side effects, which could possibly be osteoarthritis of the lateral tibio-femoral compartment.
- A mid- and long-term evaluation of anterolateral tenodesis performed in skeletally immature patients to assess any growth disturbance.

CHAPTER 10.

Conclusions of the thesis



Chapter 10 .

Conclusions of the thesis

- Anterolateral instability is considered one of the causes of the failure of an ACL reconstruction and the anterolateral extraarticular tenodesis is a possible solution in the general population and in athletes. That is especially useful when an high degree of rotational instability is found or when a diagnose of anterolateral structure injury is made

- The objective evaluation of the rotatory instability is difficult, and the available methods have several disadvantages. The use of an open-source tool using a simple mobile phone App could be a solution.

- During the combined use of anterolateral tenodesis and anterior cruciate ligament reconstruction a collision between the two femoral tunnels of the combined technique may occur. Performing the drilling of the tunnel of the anterolateral tenodesis with an inclination of at least 20° anteriorly reduces this risk

- When an anterolateral tenodesis is added to an ACL reconstruction, it slows down the maturation of the ACL when evaluated by an MRI. That must be taken in account changing the rehabilitation protocol according to this finding

- In the case of a persistent rotatory instability after an ACL reconstruction with transtibial technique, the anterolateral tenodesis can improve the knee kinematic and improve subjective stability as well as the function of the knee.

- Adding an anterolateral tenodesis to ACL reconstruction in skeletally immature patients can improve the knee stability and decrease the failure rate in this specific population. That support the use of this combined technique in the case of ACL paediatric reconstruction.

- The anterolateral tenodesis even when performed in an isolated fashion can improve an ACL deficient knee. More specifically, it can improve the knee kinematic, the function and also the clinical scores of patients with ACL rupture.

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