Biomechanical evaluation of four femoral fixation configurations in a simulated anterior cruciate ligament replacement using a new generation of Ligament Advanced Reinforcement System (LARS™ AC)

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Abstract

Background Recent improvements in manufacturing of biomaterials have made available a new generation of artificial ligaments with better biocompatibility and design that have led to a new interest in using them for ACL reconstructions.

Purpose To evaluate the biomechanical characteristics of four femoral fixations using a Ligament Advanced Reinforcement System (LARS™ AC; LARS, Arc sur Tille, France) for anterior cruciate ligament replacement.

Method Six femoral ACL fixations in four configurations using fresh calf femurs with an interference titanium screw inserted inside to outside, an interference titanium screw inserted outside to inside, an interference titanium screw inserted inside to outside with a staple and a new transversal cortical suspension device developed by LARS™ were compared in a static loading and failure test. Output values were ultimate strength, graft slippage, mode of failure, energy to failure and stiffness.

Results The transversal fixation performed with a significantly higher failure load than others (1804 N) ($p < 0.001$), whereas there were no significant differences between the three fixations with interference screws. There were no significant differences of stiffness between all fixations, and the transversal device had a significantly higher graft slippage (13.1 mm) than others (all $p < 0.01$).

Conclusions In this in vitro evaluation, the transversal fixation exhibited better biomechanical performance under static solicitations than others. The transversal device is expected to provide better clinical results than the well-established screw system fixations for femoral ACL fixation.

Clinical relevance Laboratory investigation (Level 2).

Keywords ACL · Fixation · Strength · Artificial ligament

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Introduction

Surgical techniques for reconstruction of anterior cruciate ligament (ACL) rupture are commonly based on autologous tissue graft. Despite its safety and efficacy, autograft suffers from several major drawbacks, such as extended post-operative recovery and graft harvest morbidity on the donor sites [1, 2]. When early rehabilitation is necessary or in case of multiple ligament injury or revision surgery, allografts are not very available in France in current practice and using an artificial ligament could appear as an interesting alternative strategy. Nevertheless, non-degradable artificial ligaments are not the first choice actually because of the bad history and results in the past with a high incidence of failure and clinical synovitis [1]. Recent improvements in manufacturing of biomaterials have made available a new generation of artificial ligaments with

better biocompatibility and design that have led to a new interest in using them for ACL and PCL reconstructions [3–5]. The Ligament Advanced Reinforcement System (LARS[TM] AC; LARS, Arc sur Tille, France) is a new generation of synthetic bioactive ligament made in polyethylene terephthalate (PET) that could mimic the natural ligamentous structure and control cellular responses [6–8] (Fig. 1). Reported short-term and midterm outcome scores between 2 and 5 years are good for this ligament and comparable to those for autograft techniques [3–5, 9]. These results may suggest that a full return to activity may be hastened by using the LARS[TM] artificial ligament rather than the conventional technique. It could represent a serious alternative to classic tendon autograft in the future. Nevertheless, for ACL reconstruction, a good fixation is important because it provides initial stability and allows integration of the graft. In the graft-fixation-bone construction, the fixation has been identified as the weakest link, providing lower strength and stiffness [10–12]. In literature, suspension devices using corticocancellous fixation seem to allow the least elongation and provide the greatest strength and stiffness. A new corticocancellous fixation has been introduced for the LARS[TM] on the femoral side. It consists of a metal screw introduced in the lateral metaphyseal cortex, crossing a ligament loop.

Fig. 1 The new generation of artificial ligament LARS

The purpose of this in vitro biomechanical study is to evaluate under static solicitations the elongation and failure performance of simulated femoral ACL fixation by comparing the new device to the performance of other interference system devices. We hypothesize that this new device will result in overall higher stiffness and failure load than the well-established screw system fixations for femoral ACL fixation.

Materials and methods

The artificial ligament LARS[TM]

The LARS[TM] AC ligament implanted in this in vitro study consists of 40 fibres made of polyethylene terephthalate (PET) (5 mm of diameter) used for double-bundle ACL reconstruction. The intra-osseous segment is composed of longitudinal fibres bound together by a transverse knitted structure, while the intra-articular segment is composed of parallel longitudinal fibres twisted at 90°. This segment is positioned in the femoral bone tunnel and used as in a double-bundle ACL reconstruction (Fig. 1). The main innovation of this artificial ligament is its ability to mimic the natural ligamentous structure and reduce shearing forces by orientating the parallel fibres of the intra-articular portion of the graft clockwise or counterclockwise for use in right and left knees, respectively. Furthermore, the PET fibres of the intra-articular segment are designed to encourage tissue ingrowth due to the porosity of the material, allowing ingrowth from the surrounding osseous tunnels. Ideally, such tissue ingrowth between the ligament fibres would contribute to the viscoelasticity of the graft and protect against friction at the opening of the bony canal and between the fibres themselves [7, 8].

Specimen preparation

Four different devices and configurations for fixation of the femoral side of an ACL reconstruction were evaluated in this in vitro study (Fig. 2): a 6-mm titanium interference screw implanted inside-out (SIO group), a 6-mm titanium interference screw implanted outside-in (SOI group), a 6-mm-wide titanium interference screw (30 mm of length) implanted inside-out *and with* a chrome–cobalt staple of 8.0 × 20 mm on the metaphyseal lateral cortical (S group), and a new transversal cancellous fixation device developed by LARS[TM] (T group).

Twenty-four femoral bones came from calves aged between six and eight months old. The specimens were fresh-frozen at −20 °C and thawed overnight at room temperature before testing. All soft tissues were removed from the femur. Six specimens per group were tested.
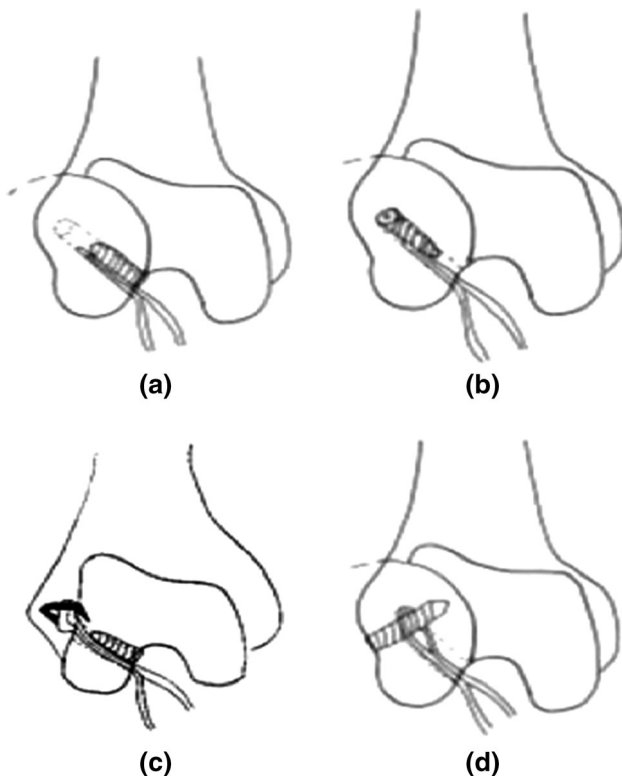
Fig. 2 Tested fixation devices: **a** SIO fixation **b** SOI fixation **c** S fixation and **d** T fixation

For each implantation, fixation of the LARS^{TM} ligament was performed according to the manufacture's guidelines using dedicated instruments in a double-bundle configuration. The artificial ligament was placed in the femoral bone through a 5.5-mm-wide femoral bone tunnel drilled from inside-out at the site of the femoral insertion of the ACL, like in a anatomic ACL reconstruction. The ligament was doubled and inserted into the femoral tunnel in order that its parallel longitudinal twisted portion remained in the bone tunnel, and the two knitted portions were together out of the bone as a double-bundle ACL reconstruction in the intra-articular side. For the SOI, SIO and S groups, the screw was inserted on a 2.4-mm guide wire placed into the femoral tunnel until it was flushed with the lateral cortical or the articular surface (Fig. 2a, b). For the S group, after insertion of a screw inside-out screw, a 20-mm-wide metallic staple was positioned on the lateral cortical bone crossing over the LARS^{TM} ligament (Fig. 2c). For the transversal device (T group), an additional transverse hole was drilled from the lateral side by using an associated drill guide. A femoral socket of 5.5 mm diameter and 35 mm depth was drilled, and a 4.5-mm-diameter lateral tunnel was drilled into the distal femur from lateral to medial. The artificial ligament was inserted into the femoral socket thanks to the femoral guide, and a 7-mm-diameter and

60-mm-length screw was inserted into the transverse hole from the lateral side by use of a dedicated passing guide until the screw had reached the lateral cortical (Fig. 2d).

Biomechanical testing

Each femur was sectioned in the diaphysis, 10 centimetres from the distal tunnel exit and embedded in a steel cylinder by using a low melting point alloy (MCP70). This steel cylinder was mounted in an experimental device that allowed a three-dimensional positioning and fixation of the femur. Using this configuration, the graft tunnel and the ligament were aligned with the traction axis (Fig. 3), which represented the "worst-case" tensile load. The two free ends of the ligament were fixed with a friction jaw on the moving TRAVERSE of the electromechanical testing machine (INSTRON5500-R, Instron Ltd, High Wycombe, UK) instrumented with a 2kN load cell. Tests were performed at room temperature. A standardized biomechanical testing set-up previously used was applied [7]. After a 5 N preload to simulate the intra operative graft tension device, the femurs were conditioned using 10 cycles between 5 and 50 N (5 mm/min) followed by 120-s relaxation at 100 N. Finally, a traction load with vector force in the axis of the
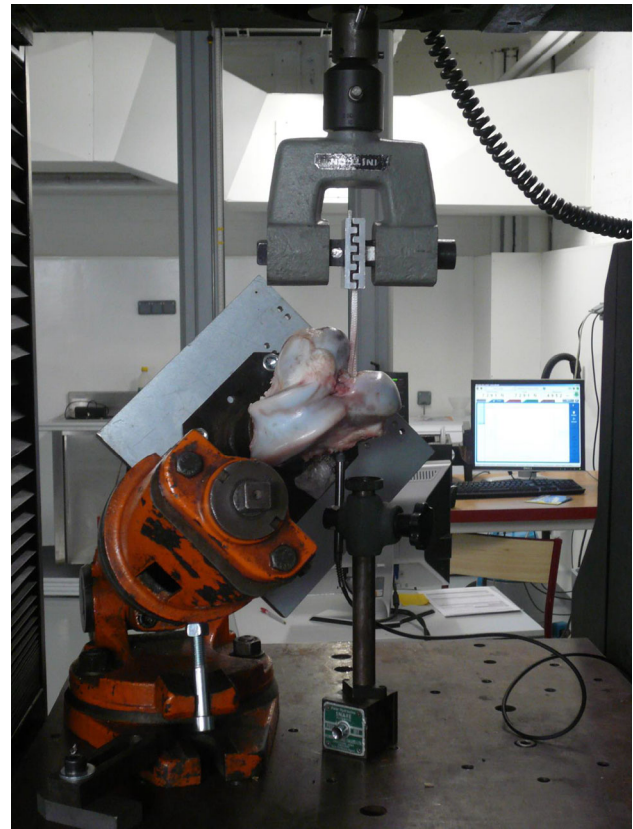
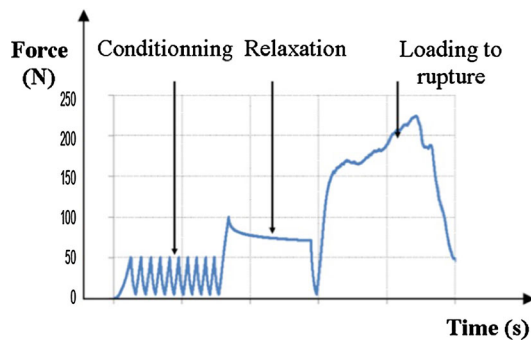**Fig. 3** ACLR loading experimental set-up
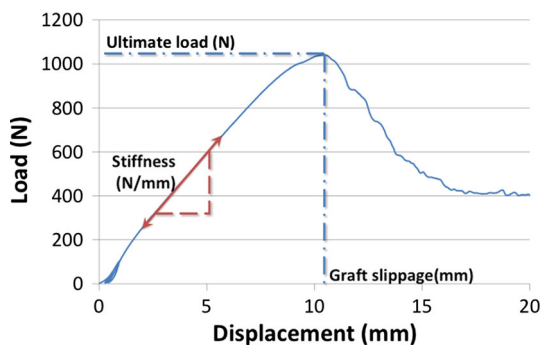
Fig. 4 Testing protocol

Fig. 5 Output values obtained from the load displacement curve

femoral tunnel until total failure was applied to the specimen using a displacement rate of 5 mm/min (Fig. 4).

Data analysis

The experimental load elongation curves were recorded. Stiffness was determined as the most linear region of the load elongation curve. Failure mode (by fixation failure, bone plug fracture or tendon disruption), graft slippage and ultimate failure load were also documented (Fig. 5). Maximum load to failure was calculated from the load displacement curve at the ultimate strength. Graft slippage was determined from displacement and corresponded to the difference in position from the end of the relaxation period to the final position before failure. The failure modalities were analysed and described.

Numerical data were expressed as median and the range. The confidence interval at 95 % was calculated. Maximum load to failure, graft slippage and stiffness were tested for significant differences across the four implant types. Statistical analyses were performed using the software Statplus: Mac (AnalystSoft Inc., StatPlus:mac. 2009. http://www.analystsoft.com/fr/). These values were compared using one-way analysis of variance (ANOVA) followed by Newman–Keuls and Tukey's multiple comparison test. The significance level was set at $p = 0.0125$, as was Coleridge

et al. [13], whose protocol was similar to the one used in the current study.

Results

Results of the pull-out tests are presented in Table 1. The mean ultimate failure load for the T group was 1804 N, which is significantly higher than the ultimate strengths of the three others fixations (all $p < 0.001$). The differences of ultimate failure load between the three groups with an interference screw (SIO, SOI, S) were not significant (all $p > 0.2$) (Fig. 6). No significant difference was found between the four groups concerning the stiffness of the fixation (all $p > 0.6$) (Fig. 7). In the T group, the mean graft slippage at failure was 13.11 mm and was significantly higher than the three other groups (all $p < 0.01$) (Fig. 5). Among the groups with an interference screw (SIO, SOI and S), the differences of mean graft slippage at failure were not significant (all $p > 0.8$). Different modes of failure were observed among the four groups (Table 2). In the group T, the screw was pulled out in three specimens, a bone block fracture occurred twice and a screw failure once. In the SOI group, the ligament slipped through the hole between the screw and the bone tunnel wall in all specimens. In the VIO group with or without a staple, either the screw was pulled out or the ligament slipped through the hole between the screw and the bone tunnel wall.

Discussion

Currently, ACL reconstruction used autologous tissue graft but autograft suffers from several major drawbacks, such as extended post-operative recovery and graft harvest morbidity on the donor sites [1, 2]. Moreover, in case of multiple ligament injury or revision surgery, allografts may be not easily available and using an artificial ligament could appear as an interesting alternative strategy. Furthermore, the use of allograft may result in disease transmission and immunologic rejection response. Actually, in our country, LARS is most of the time used for posterior cruciate ligament reconstruction in acute multi-ligament injuries with a good efficacy and safety. These results have focused the attention of orthopaedic sports medicine surgeons, and some surgeons have been try to use it for ACLR [3, 4]. In literature, preliminary investigations into the use of the LARS artificial ligament have been encouraging. Lavoie et al. [4] on 47 patients at a mean follow-up of 21.9 months had a patient satisfaction KOOS score ranged from 73.5 to 93.0 % without patients presenting symptoms of synovitis. Another recent study by Nau et al. [3] in a 2-year follow-up randomized controlled trial that compared

Table 1 Results of failure strength (N), graft slippage (mm), stiffness (N/mm) of each device after static loading (median, range and confidence interval at 95 %)

	SIO	SOI	S	T
Median failure strength (N)	957	1,058	1,199	1,804**
Range (min–max)	552–1,552	920–1,207	801–1,528	1,237–1,933
Confidence interval 95 %	726–1,188	827–1,289	974–1,424	1,573–2,035
Median graft slippage (mm)	8.6	7.4	8.5	13.1*
Range (min–max)	6.9–12.6	5.2–10.4	5.7–16.4	9.6–15.4
Confidence interval 95 %	6.9–10.3	5.7–9.1	6.3–0.7	11.4–14.8
Median stiffness (N/mm)	175.7	189.5	200.4	163.4
Range (min–max)	76.8–302.9	157.8–227.7	135.4–279.0	153.1–191.4
Confidence interval 95 %	130.1–243.6	143.6–235.4	155.8–244.9	117.5– 209.3

$* p < 0.01$; $** p < 0.001$
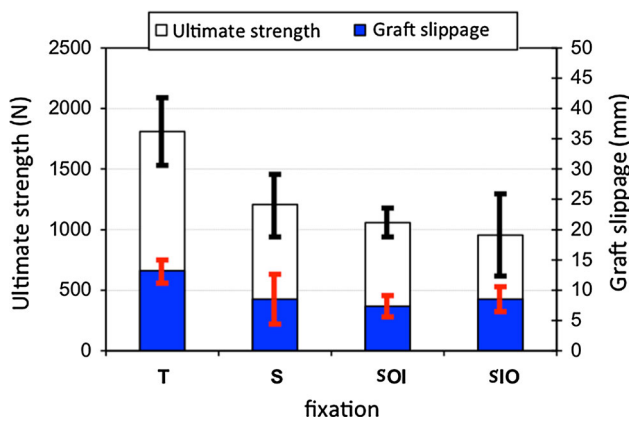
Fig. 6 Mean ultimate strengths and graft slippages, and standard deviation, as a function of type of configuration
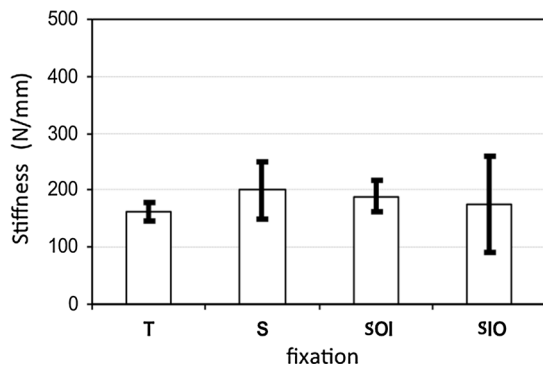
Fig. 7 Mean stiffness, and standard deviation, as a function of type of configuration

the bone-patellar tendon bone autograft with the LARS in 53 patients reported similar overall results obtained for both groups. Therefore, in vitro studies to explore biomechanical behaviour of the LARS are necessary to improve ACL reconstruction surgical technique.

The aim of this work was to evaluate the biomechanical behaviour of a transversal femoral ACL fixation device build for a new generation of biocompatible artificial ligament LARS[TM] and to compare it with three other femoral

devices commonly used. Scheffler et al. [14] showed that the tibial fixation site is the weakest link in an ACLR. This fact led many searchers to perform solicitations on the tibia, resulting in a lack of interest for the femoral fixation site. Our study shows that the new transversal device had significantly better ultimate strength and graft slippage at failure than the other fixations. Greater slippage at failure in the T group is the result of the failure mode with observed pull-out and screw failure, contrary to other device. Bone fracture is only observed in the T group because of a better ultimate strength. Other device failed before bone or screws were solicited with a slippage of the LARS. In fact, the stiffness in all groups was similar. So, our hypothesis was affirmed: in this in vitro evaluation, the new transversal device for femoral fixation in ACL reconstruction developed by LARS[TM] exhibited better biomechanical performance under static solicitations than other conventional interference screw fixations.

Other studies [13–25] have investigated biomechanical behaviour of different ACL reconstruction femoral fixations and of other transversal devices. Milano et al. [22] compared the Transfix (Arthrex; Naples, FL) and the Rigidfix (Mitek; Norwood, MA), which are transcondylar devices like the new device developed by LARS[TM], against conventional screw fixations. Even if the protocol of solicitation was different from the one used in this study, the ultimate strength at failure of these devices was significantly greater than with an interference screw fixation. Espejo-Baena et al. [23] compared, with a protocol similar to the one used by Milano et al. [22], the strength of a Bio-Transfix Cross-pin (Arthrex; naples, FL) with a classic screw fixation and had the same conclusion. In our study, there is no significant difference in biomechanical behaviour between each interference screw fixation. Bryan et al. [26] in an in vitro study with calf bones analysed the influence of femoral fixation with cannulated interference 7×25 mm (Concept Inc., Largo, FL) screws inserted "inside-out" and "outside-in" and found no significant difference in mean ultimate strength between those two fixations, as in our study. Considering graft slippage,

Table 2 Failure mode for each type of fixation group

Group	Number of specimens				
	Ligament slippage	Pull-out	slippage + pull-out	Bone fracture	Screw failure
SIO	3		3		
SOI	6				
S	4		2		
T		3		2	1

ultimate strength or stiffness, the fixation configuration with a staple in addition to an interference screw presented a mechanical behaviour similar to the same configuration without staple. This finding calls into question the utility of staples in addition to interference screws for femoral fixations, particularly if, as described by Gillquist [27], the staple removal may induce severe complications. At last, as the ACL injuries often occur during landing or deceleration prior to a change of direction [24], we compared the forces during sport activities that acted in ACL and the values we found for each fixation. Shin et al. [25] established that the peak force during landing during participation in sports (as football or basketball) on ACL is 1294 N. This value is greater than ultimate strengths of screw system fixations (SIO = 957 N, SOI = 1054 N and S = 1199 N) whereas is lower than the ultimate strength of the transversal fixation developed by LARS^{TM} (1804 N). This comparison suggests that the transversal fixation developed by LARS^{TM} would be more adapted to perform ACLR on athletes, particularly the professionals who need a fast recovery and return to their sport.

Our study has some limitations. It was an in vitro simulation of a complex in vivo situation, and some limitations must be underlined. First of all, the choice of the bone used for testing was some fresh-frozen femoral bones coming from calves 6 and 8 months old rather than humans. A lot of studies [15–17] related to the evaluation of anchorages for ACLR used elderly human bones because they could not have access to young human bones. However, Brown et al. [18] showed that young bovine has similar bone density to young humans, and comparative tests [19] showed that bone density from calf bone is closer to young humans than elderly human bone. So, it is more accurate, for the evaluation of anchorages to choose calf bone instead of elderly human bone. Secondly, the traction axis was aligned with the bone tunnel axis. In this configuration, load is directly transmitted to the fixation, with no friction effects due to angulations. This case represented the mechanical worst-case scenario, which is rarely encountered in practice but often studied in literature [20, 21]. Moreover, this method allowed us to be free from the differences of angulations of the drilled shaft between one implantation and another. Moreover, it also permitted a real measurement of graft slippage, which is an essential value

when evaluating the security of a fixation. Static solicitations have been chosen instead of cyclic solicitations, which reproduce the situation beyond a few days after operation, but in clinical situations, the quality of the fixation would have changed because of bone remodelling and bone integration. The protocol consisted of the evaluation of fixations quality during the first loading, aiming to reproduce the immediate post-operative clinical situation. The protocol simulates an immediate loading on ACL after surgery. Finally, graft elongation was measured by displacement of the machine cross-head and therefore represents the overall compliance of the system. However, grafts were rigidly fixed, and the length of the exposed femur was standardized, so between-group differences are mostly due to the differences in graft fixation.

Conclusion

This study tested the hypothesis that some fixations would show a better mechanical resistance than others. The new LARS^{TM} transversal fixation showed a greater ultimate strength than others, whereas no significant differences have been found among the screw system fixations. These results encourage choosing a transversal fixation developed by LARS^{TM} instead of a conventional ITS fixation for a femoral fixation of an ACLR.

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