Anterior Laxity at 2 Years After Anterior Cruciate Ligament Reconstruction Is Comparable When Using Adjustable-Loop Suspensory Fixation and Interference Screw Fixation

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Background: Adjustable-loop suspensory fixation (ALSF) devices are commonly used in anterior cruciate ligament reconstruction (ACLR). However, concern exists regarding the potential for lengthening under cyclical loads.

Purpose: To compare the residual anterior laxity of 2 methods of femoral fixation, ALSF versus interference screw fixation, in patients undergoing isolated ACLR in the absence of meniscal injuries. To determine the preoperative risk factors associated with residual postoperative anterior laxity.

Study Design: Cohort study; Level of evidence, 3.

Methods: A retrospective analysis was performed comparing 2 groups of patients that underwent primary ACLR using ALSF versus bioabsorbable interference screw fixation. Anterior knee laxity was assessed with Telos stress radiography, while functional outcomes were evaluated with the Knee injury and Osteoarthritis Outcome Score (KOOS) and Tegner activity level scale at a minimum of 2 years postoperatively. A multivariate analysis was performed to identify factors associated with residual postoperative laxity >3 mm.

Results: Of the 1136 patients who underwent ACLR during the study period, 363 met the inclusion criteria. A total of 272 patients (75%) (mean age, 31.7 ± 10.7 years) with a mean follow-up of 25.7 ± 4.6 months (range, 24-36 months) consented to participate (screw group: n = 121; ALSF group: n = 151). The 2 groups were statistically comparable in terms of age, sex ratio, time from injury to surgery, graft diameter, preoperative laxity, preoperative objective International Knee Documentation Committee (IKDC) grade, and preoperative Tegner score. The mean postoperative laxity as a continuous variable was significantly different comparing the ALSF and screw groups (1.49 ± 1.98 mm and 2.32 ± 1.97 mm, respectively; $P < .001$). In the screw group, 76 patients (62.8%) had normal (<3 mm), 40 (33.1%) had nearly normal (3-6 mm), and 5 (4.1%) had abnormal (≥6 mm) postoperative knee laxity according to the IKDC grade, while in the ALSF group, 112 patients (74.2%) had normal, 37 (24.5%) had nearly normal, and 2 (1.3%) had abnormal laxity ($P = .0833$). No significant difference was found in KOOS or Tegner scores comparing the 2 femoral fixation methods: KOOS, 90.6 ± 7.5 (ALSF group) and 90.6 ± 7.4 (screw group) ($P = .7631$), versus Tegner, 6.5 ± 1.3 (ALSF group) and 6.3 ± 1.4 (screw group) ($P = .2992$). A negative correlation was found between postoperative laxity and final Tegner ($r_s = -0.303$, $P < .001$) and KOOS scores ($r_s = -0.168$, $P = .005$). The initial univariate analysis showed differences between groups of patients with residual knee laxity ≥3 mm and <3 mm on preoperative pivot shift, preoperative laxity, age, fixation type, and preoperative objective IKDC grade. The multivariate analysis on these factors showed that the pivot shift remained the only significant predictor for residual laxity ≥3 mm for pivot shift grade 2 compared with grade 1 (odds ratio, 4.689 [95% CI, 2.465-9.286]) and for pivot shift grade 3 compared with grade 1 (odds ratio, 58.025 [95% CI, 12.757-557.741]) ($P < .001$).

Conclusion: For primary ACLR, the use of an ALSF device for femoral fixation is associated with noninferior postoperative anterior knee laxity results compared with interference screw fixation at a minimum 2 years' follow-up. The preoperative pivot shift is the only significant risk factor for postoperative residual anterior knee laxity >3 mm.

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Anterior cruciate ligament (ACL) reconstruction is one of the most frequently performed knee operative procedures, which in general results in high rates of superior clinical outcomes and return to preinjury activities.[10,23] However, not all outcomes are positive, and the results may be affected by several factors including the choice of graft, the tunnel orientation, and the method of graft fixation.[6,16,17,34,47] Integration of the ACL graft into the tunnels is thought to be a key component to the success of the procedure.[25]

The hamstring tendon autograft is widely used for primary ACL reconstruction (ACLR); this graft type is popular because of its low donor site morbidity and clinical results, which are comparable with other types of grafts.[3,24] There are many methods described on the best configuration of the hamstring graft, with some authors advocating preserving the tibial insertion to maintain the vascularity of the tendons, which may enhance graft maturation, leading to ligamentization.[42]

Fixed-length cortical suspension devices are commonly used on the femoral side with hamstring grafts and have been shown to provide excellent biomechanical stability with high fixation strength.[1,21,38] However, because of their predetermined loop length, it may be difficult to adjust the graft length inside the femoral tunnel, especially when the hamstring tibial insertion is preserved.[1,2] As such, various adjustable-loop suspensory fixation (ALSF) devices have been developed to overcome any previous loop length calculation difficulties and to facilitate complete graft fill of the tunnels.[1,13,38,43,44,49]

However, concerns exist regarding the possibility of lengthening ALSF devices, which has been reported in biomechanical studies after the application of high cyclic forces.[1,30] This potential issue is of particular concern in the immediate postoperative period (6-12 weeks) when the graft's osseous integration relies on stable fixation.[1,30,38]

The purpose of the study was to compare residual anterior laxity in patients who underwent isolated ACLR with either an interference screw or an ALSF device for femoral fixation. A secondary aim was to identify preoperative risk factors that are associated with significant residual postoperative anterior knee laxity $\geq$3 mm.[39] The hypothesis was that the results of ALSF would be comparable with those of bioabsorbable interference screw fixation in terms of postoperative anterior laxity and clinical outcomes.

METHODS

Study Design

The records of all patients who underwent ACLR between January 2013 and April 2015 by 2 surgeons (J.-C.P., J.B.) in our department were retrospectively reviewed. The operative technique and equipment used were consistent throughout this 2-year period and the same for both senior surgeons. Each patient enrolled gave written consent for his or her participation in this retrospective study. A retrospective evaluation protocol was established and approved by the institutional review board of Centre Osteoarticulaire des Cèdres (#2016-01).

The inclusion criteria were patients >18 years of age; a primary ACL rupture confirmed by a clinical examination, imaging assessment (magnetic resonance imaging), and comparative (with the contralateral side) anterior stress radiographic evaluation (anterior Telos under 15 kg and 20° of flexion); a hamstring tendon autograft with preservation of the tibial insertion; a bioabsorbable interference screw (screw group) or ALSF device (ALSF group) for femoral fixation; complete medical files including preoperative clinical examination results, objective International Knee Documentation Committee (IKDC) grades, and Tegner scores; and finally a minimum 24 months' follow-up. The type of fixation used during the study period reflected an evolution in implants over time, without any selection bias and without any changes in the surgical technique (concerning the creation of tunnels).

To compare the 2 fixation methods, other predisposing factors that could increase knee laxity and influence outcomes were excluded. For this reason, exclusion criteria were concomitant or previous meniscectomy or even meniscal repair at the time of ACLR,[29,48] surgery delayed more than 6 months,[29,33] and revision ACLR. Also, patients who had undergone surgery to the contralateral limb were excluded to make a postoperative comparison with the healthy knee. Patients who underwent extra-articular lateral tenodesis or had any other concomitant knee ligamentous injuries were also omitted. Finally, cases with chondral lesions greater than grade 2 (Outerbridge classification) were also excluded because of possible negative effects on the final functional evaluation.[15]

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Surgical Technique

The hamstring tendon grafts were harvested using an open tendon stripper without detaching them from their tibial insertion. An outside-in approach was employed to create the femoral tunnel using an ACL femoral drill guide (SBM), which was introduced through the anteromedial portal and positioned at the footprint of the ACL on the medial wall of the lateral femoral condyle (at the insertion of anteromedial fibers of the ACL).[9,13,35] After confirmation of an accurate intra-articular position of the guide pin, a full-length 6 mm–wide femoral tunnel was created.

The tibial tunnel was created using an ACL tibial drill guide (SBM) inserted through the anteromedial portal and positioned at the center of the ACL tibial stump.[26,43] Under direct visualization and using a low-speed drilling technique, an additional 6-mm tibial tunnel was created.

The whole ACL length was calculated by using a No. 2 white Vicryl suture (Johnson & Johnson) passed through both the femoral and tibial tunnels to the hamstring tibial insertion. After this, both the harvested tendons were retrieved from the pes anserinus and were marked accordingly based on the previous measurements. Normally and according to the patient's height, the necessary length from the hamstring tibial insertion was between 12 and 15 cm.[8]

Screw Group. In the cases in which a bioabsorbable screw was used for femoral stabilization, both the hamstring tendons were looped, at the measured length, over a nonabsorbable No. 3 Mersuture (Johnson & Johnson), and by keeping them in tension, they were secured with 2 figure-of-8 sutures[12] (nonabsorbable polyethylene fiber PowerTex; SBM) at each side of the graft (femoral and tibial). The middle of the graft was also secured with 2 or 3 figure-of-8 stitches using a Vicryl No. 2-0 suture. In this manner, a quadrupled graft with an 8- to 10-mm diameter was usually obtained. Finally, a nonabsorbable No. 3 Mersuture was placed at the tibial side of the graft that served as a traction suture.

According to the prepared graft diameter, the already made 6-mm femoral and tibial tunnels were drilled at their entire length to the desired width. Next, the graft was introduced, and with maximum tension maintained, the femoral side was secured first with an absorbable interference screw inserted from outside in (Ligafix; SBM) at 20° of knee flexion and under arthroscopic visualization. The graft was cycled through full range of motion, tensioned, and secured at the tibial side in 20° of knee flexion also with an interference screw (Figure 1).

ALSF Group. In the cases in which an ALSF device was used for femoral stabilization, both the hamstring tendons were now looped, at the measured length, over a Pullup XL adjustable button device (SBM). The surgical steps of graft preparation were exactly the same as in the screw group. The button was flipped over the lateral femoral cortex, and at 20° of knee flexion and under arthroscopic control, the femoral side was initially fixed by securing the ALSF device. The graft was cycled through full range of motion, tensioned, and secured on the tibial side in 20° of knee flexion with an interference screw (Ligafix). Finally, the sutures on the ALSF device were retensioned. No additional securing knots over the button were performed (Figure 2).

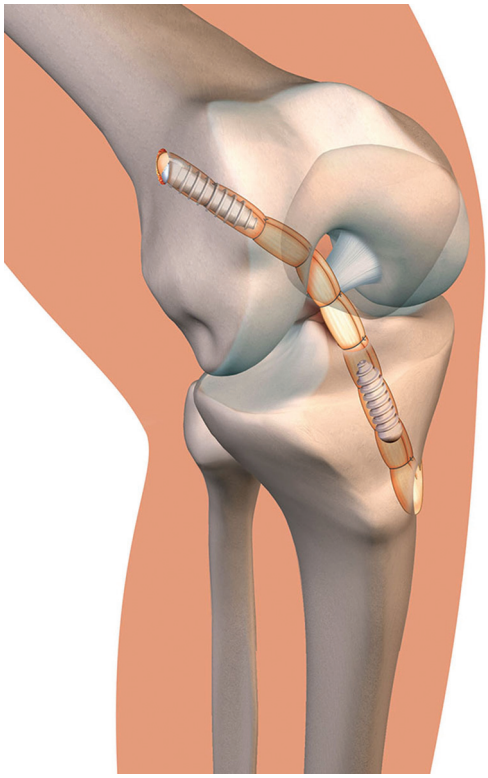

Figure 1. Drawing showing the final anterior cruciate ligament construct when an interference screw was used for both femoral- and tibial-side fixation. The hamstring tendon insertion is preserved.

Postoperative Rehabilitation

Both groups of patients followed the same rehabilitation protocol, including gradual full weightbearing (3 weeks' support with crutches because of pain) and progressive full range of motion exercises. Knee braces were not used. Swimming and cycling were permitted at 3 months postoperatively and jogging at 4 months. Return to noncontact sports and pivoting activities was decided at 6 months after an isokinetic muscle evaluation. Finally, contact pivoting sports were allowed 8 to 9 months postoperatively.

Postoperative Evaluation

At a minimum of 24 months postoperatively, the included patients were called for an evaluation. An independent orthopaedic surgeon (A.B.), blinded to the technique, performed the clinical examination and the calculation of the objective IKDC grade. Results of the Knee injury and Osteoarthritis Outcome Score (KOOS) and the postoperative Tegner activity level scale were also recorded.

Finally, a comparative anterior stress radiographic evaluation (anterior Telos under 15 kg and 20° of flexion) was also used to measure postoperative side-to-side knee laxity. All radiographic stress examinations (Telos) were performed with the same device and results evaluated by the same radiologist preoperatively and postoperatively.[18]

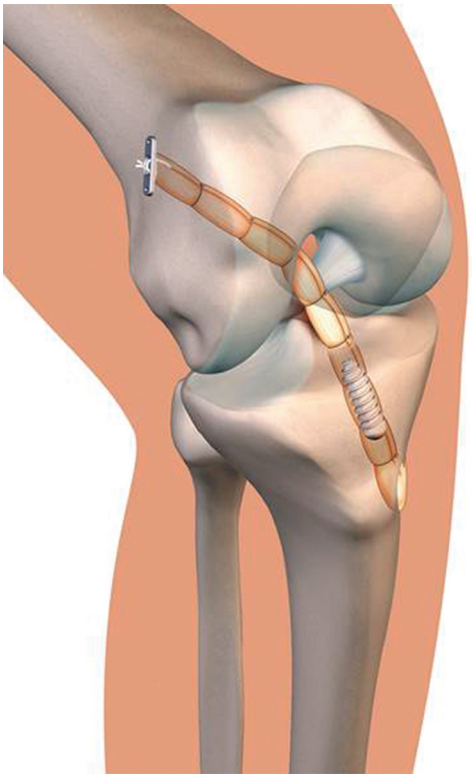

Figure 2. Drawing showing the final anterior cruciate ligament construct when adjustable-loop suspensory fixation was used for the femoral side and an interference screw for the tibial side, respectively. The hamstring tendon insertion is preserved.

Statistical Analysis

The sample size of the study was calculated as follows using G*Power software version 3.1 (Heinrich-Heine-Universität Düsseldorf). The α value was set at 0.05 and the power ($1 - \beta$ value) at 0.85. According to previously published data,[39,49] to detect a mean clinically significant side-to-side difference in anteroposterior knee laxity of 3 $\pm$ 3 mm, a minimum total sample size of 48 was required. Also, to detect a significant difference of 10 points in the KOOS, a minimum of 92 (46 in each group) was required.[50]

The characteristics of patients in each group were described as means, SDs, medians, quartiles, and ranges for continuous variables and as frequencies and percentages for discrete variables. These baseline characteristics were compared between the screw and ALSF groups using the Wilcoxon-Mann-Whitney test for non-Gaussian continuous variables, the Student *t* test for Gaussian continuous variables, and the chi-square test when conditions of application were verified; otherwise, the Fisher exact test for discrete variables was used. Normality was verified graphically.

Postoperative laxity as a continuous variable was compared between fixation techniques using an analysis of covariance, after unadjusted comparison selection and a backward elimination procedure. Unadjusted comparisons on secondary endpoints were performed using the Fisher exact test for postoperative IKDC grades and the Wilcoxon-Mann-Whitney test for KOOS and postoperative Tegner scores. Correlations between postoperative laxity and KOOS and Tegner scores were performed with Spearman correlation coefficient estimation.

A secondary analysis was performed in which patients with postoperative laxity were categorized as normal (<3 mm), nearly normal (3-6 mm), or abnormal ($\geq$6 mm) and were compared using the Fisher exact test or Wilcoxon-Mann-Whitney test. Additionally, an adjusted comparison of fixation techniques on the probability of postoperative laxity according to the objective IKDC grade ($\geq$3 mm) was performed using a multivariate logistic model. Covariates were selected in a bivariate model with a threshold of 20%, and collinearity was graphically studied. Then, a backward elimination procedure was used. During this model, the linearity of preoperative laxity was not verified. For this reason, preoperative laxity was also categorized into 2 groups ($\leq$7 mm and >7 mm).[45] Interactions between the fixation type and each covariate were tested on the multivariate model.

Statistical significance was set at $P < .05$, and analyses were performed using SAS 9.4 (SAS Institute).

RESULTS

Characteristics

Of the 1136 patients who underwent ACLR during the study period, 363 met the inclusion criteria (screw group: n = 162; ALSF group: n = 201) (Figure 3). Finally, 272 patients consented to participate in the study and to undergo a final evaluation (screw group: n = 121; ALSF group: n = 151). The screw group consisted of 64 male and 57 female patients with a mean age of 32.6 $\pm$ 10.6 years, and the ALSF group consisted of 89 male and 62 female patients with a mean age of 31.0 $\pm$ 10.8 years.

The 2 groups of patients were statistically comparable in terms of age, sex ratio, time from injury to surgery, graft diameter, and follow-up period. Similarly, the preoperative clinical and radiographic examinations including the objective IKDC grade, pivot shift, Tegner score, and comparative anteroposterior knee laxity measured with the Telos showed no significant differences between them (Table 1).

During the latest follow-up, 10 patients in the screw group (6.2% of population) and 5 in the ALSF group (2.5% of population) had an iterative ACL tear of the same knee caused by a new sports injury and were excluded from the study. Also, 2 patients in each group underwent secondary meniscectomy and were also excluded. Finally, 5 patients (1 in the screw group and 4 in the ALSF group) reported a loss of extension caused by a cyclops lesion that was arthroscopically excised at a mean of 8 months postoperatively. No other complications were reported.

Objective Evaluation

Postoperative laxity as a continuous outcome was significantly lower (estimated difference, 0.75 $\pm$ 0.20 mm;

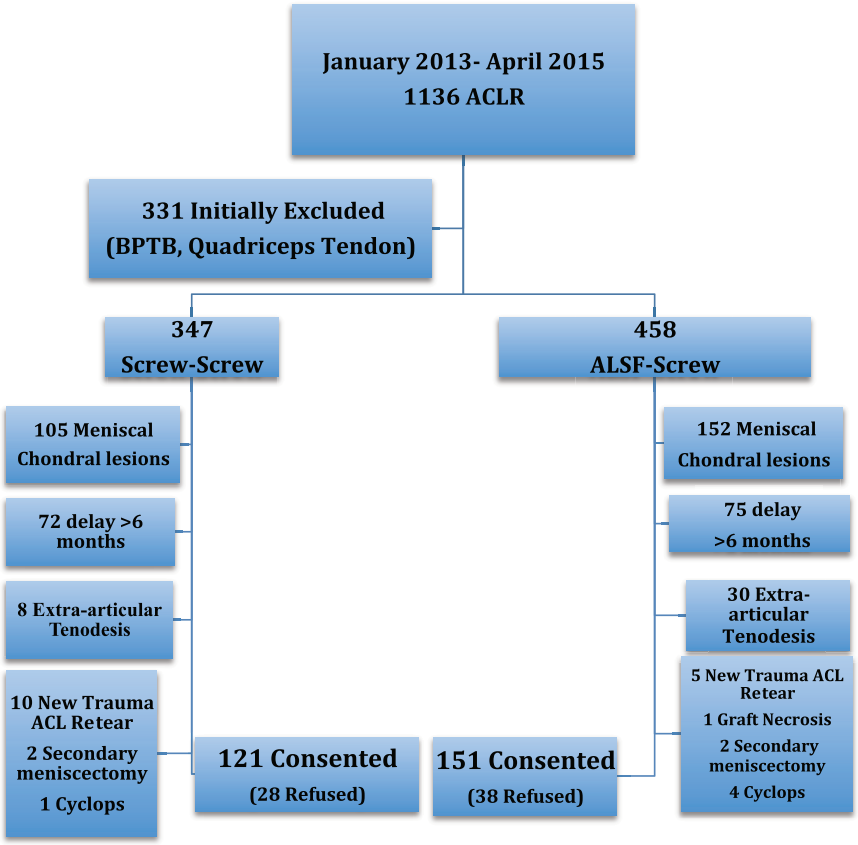

Figure 3. Flowchart of the study. ACL, anterior cruciate ligament; ACLR, anterior cruciate ligament reconstruction; ALSF, adjustable-loop suspensory fixation; BPTB, bone–patellar tendon–bone.

TABLE 1
Baseline Characteristics and Preoperative Results[a]

	All Patients (N = 272)	Screw Group (n = 121)	ALSF Group (n = 151)	*P* Value
Male sex, n (%)	153 (56.3)	64 (52.9)	89 (58.9)	.3177[b]
Age, y	31.7 ± 10.7	32.6 ± 10.6	31.0 ± 10.8	.2202[c]
Follow-up, mo	25.7 ± 4.6	25.6 ± 2.3	25.8 ± 4.3	.242[c]
Graft diameter, mm	8.7 ± 0.6	8.7 ± 0.6	8.7 ± 0.6	.5189[c]
Time from injury to surgery, mo	3.6 ± 1.5	3.4 ± 1.5	3.7 ± 1.6	.1888[c]
Preoperative IKDC grade, n (%)				.8339[d]
B	12 (4.4)	6 (5.0)	6 (4.0)	
C	214 (78.7)	96 (79.3)	118 (78.1)	
D	46 (16.9)	19 (15.7)	27 (17.9)	
Preoperative laxity, mm	6.2 ± 3.0	5.9 ± 2.9	6.4 ± 3.0	.1440[e]
Preoperative pivot shift, n (%)				.0965[d]
1 (+, glide)	149 (54.8)	58 (47.9)	91 (60.3)	
2 (++, clunk)	109 (40.1)	57 (47.1)	52 (34.4)	
3 (+++, gross)	14 (5.1)	6 (5.0)	8 (5.3)	
Preoperative Tegner score	6.9 ± 1.2	6.9 ± 1.2	6.9 ± 1.1	.8604[c]

[a]Values are presented as mean ± SD unless noted otherwise. ALSF, adjustable-loop suspensory fixation; IKDC, International Knee Documentation Committee.
[b]Chi-square test.
[c]Wilcoxon-Mann-Whitney test.
[d]Fisher exact test.
[e]Student *t* test.

TABLE 2
Postoperative Results[a]

	All Patients (N = 272)	Screw Group (n = 121)	ALSF Group (n = 151)	*P* Value
Postoperative laxity, mm	1.86 ± 2.01	2.32 ± 1.97	1.49 ± 1.98	**<.001**[b]
Postoperative IKDC grade, n (%)				**.0056**[c]
A	222 (81.6)	90 (74.4)	132 (87.4)	
B	47 (17.3)	28 (23.1)	19 (12.6)	
C	3 (1.1)	3 (2.5)	0 (0.0)	
Postoperative pivot shift, n (%)				**.0056**[c]
0 (equal)	222 (81.6)	90 (74.4)	132 (87.4)	
1 (+, glide)	47 (17.3)	28 (23.1)	19 (12.6)	
2 (++, clunk)	3 (1.1)	3 (2.5)	0 (0.0)	
KOOS score	90.61 ± 7.48	90.60 ± 7.44	90.62 ± 7.54	.7631[d]
Postoperative Tegner score	6.4 ± 1.3	6.3 ± 1.4	6.5 ± 1.3	.2992[d]

[a]Values are presented as mean ± SD unless noted otherwise. Bold values indicate statistical significance. ALSF, adjustable-loop suspensory fixation; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score.
[b]Analysis of covariance, adjusted for preoperative laxity and pivot shift.
[c]Fisher exact test.
[d]Wilcoxon-Mann-Whitney test.

analysis of covariance, $P < .001$) in the ALSF group compared with the screw group, after adjustments on preoperative laxity and pivot shift, with observed means of 1.49 ± 1.98 mm and 2.32 ± 1.97 mm, respectively (Table 2).

According to the objective IKDC grade, 90 patients (74.4%) of the screw group were rated as grade A, 28 (23.1%) as grade B, and 3 (2.5%) as grade C; 132 patients (87.4%) of the ALSF group were rated as grade A and 19 (12.6%) as grade B. The differences between the 2 groups were statistically significant (Fisher exact test, $P = .0056$). The same postoperative results were found regarding the pivot shift according to IKDC criteria (Table 2).

Furthermore, preoperative laxity and pivot shift were significantly associated with an increase in postoperative laxity, with an estimated additional 0.10 ± 0.04 mm ($P = .0013$) per additional millimeter on preoperative laxity and 1.38 ± 0.22 mm ($P < .0001$) for pivot shift grade 2 (++, clunk) compared with grade 1 (+, glide) and 4.03 ± 0.47 mm ($P < .0001$) for pivot shift grade 3 (+++, gross) compared with grade 1 (+, glide) (Appendix Figure A1, available in the online version of this article).

Subjective Functional Evaluation

The final functional evaluation showed no differences in the overall KOOS score or in the Tegner score between the 2 groups of patients. At the latest follow-up, the mean KOOS score was 90.60 ± 7.44 for the screw group and 90.62 ± 7.54 for the ALSF group ($P = .7631$) (Table 2). Also, the mean Tegner score was 6.3 ± 1.4 for the screw group and 6.5 ± 1.3 for the ALSF group ($P = .2992$) (Table 2). However, there was a significant decrease in the Tegner score after surgery ($P < .001$).

In the screw group, there were 89 patients (73.6%) who returned to the same activity level and 32 (26.4%) who returned to a lower level (7 for reasons unrelated to the injured knee, 10 because of apprehension, 11 because of anterior knee pain, and 4 because of a painful tibial tunnel). In the ALSF group, there were 124 patients (82.1%) who returned to the same activity level and 27 (17.9%) who returned to a lower level (8 for reasons unrelated to the injured knee, 7 because of apprehension, 10 because of anterior knee pain, and 2 because of a painful tibial tunnel). The comparison between the groups was not significant ($P = .104$).

As regards radiographic laxity measures using Telos, there was a statistically significant negative correlation between postoperative knee laxity and the final Tegner score ($r_s = -0.303$, $P < .001$). The same but less strong correlation was found also for the KOOS score ($r_s = -0.168$, $P = .005$).

Predictors of Increased Postoperative Laxity (Objective IKDC Grade)

One hundred eighty-eight patients (69.1%) had grade A (normal), 77 (28.3%) had grade B (nearly normal), and 7 (2.6%) had grade C (abnormal) postoperative laxity according to the IKDC grade. No patients showed severely abnormal (grade D, >10 mm) laxity at the latest follow-up. In the screw group, 76 patients (62.8%) had normal, 40 (33.1%) had nearly normal, and 5 (4.1%) had abnormal postoperative knee laxity, while in the ALSF group, 112 patients (74.2%) had normal, 37 (24.5%) had nearly normal, and 2 (1.3%) had abnormal laxity. The initial bivariate model showed no statistically significant differences between the 2 fixation methods ($P = .0833$) (Table 3).

All patients with preoperative pivot shift grade 3 (+++, gross) had postoperative laxity ≥3 mm (8 grade B and 6 grade C). Furthermore, 85.7% of the patients with abnormal postoperative laxity (IKDC grade C) had preoperative pivot shift grade 3 (+++, gross) ($P < .001$) (Table 3 and Appendix Figure A2, available online).

Patients with postoperative laxity grade A (normal) had preoperative mean values of 5.7 ± 2.9 mm, those with

TABLE 3
Unadjusted Effect of Covariates on the Probability for Postoperative Knee Laxity According to IKDC Grade[a]

	All Patients (N = 272)	A: Normal (n = 188)	B: Nearly Normal (n = 77)	C: Abnormal (n = 7)	*P* Value
Fixation type, n (%)					.0833
Screw	121 (44.5)	76 (40.4)	40 (51.9)	5 (71.4)	
ALSF	151 (55.5)	112 (59.6)	37 (48.1)	2 (28.6)	
Sex, n (%)					.6157
Male	153 (56.3)	107 (56.9)	41 (53.2)	5 (71.4)	
Female	119 (43.8)	81 (43.1)	36 (46.8)	2 (28.6)	
Age, y	31.7 ± 10.7	32.8 ± 10.5	30.1 ± 11.1	20.9 ± 6.8	**.0030**
Graft diameter, mm	8.7 ± 0.6	8.7 ± 0.6	8.7 ± 0.6	8.6 ± 0.5	.6686
Time from injury to surgery, mo	3.6 ± 1.5	3.6 ± 1.6	3.5 ± 1.5	3.1 ± 1.7	.7148
Preoperative IKDC grade, n (%)					**<.0001**
B	12 (4.4)	12 (6.4)	0 (0.0)	0 (0.0)	
C	214 (78.7)	157 (83.5)	56 (72.7)	1 (14.3)	
D	46 (16.9)	19 (10.1)	21 (27.3)	6 (85.7)	
Preoperative laxity, mm	6.2 ± 3.0	5.7 ± 2.9	7.0 ± 2.9	7.7 ± 3.3	**.0043**
Preoperative laxity, n (%)					**.0200**
0 (≤7 mm)	186 (68.4)	138 (73.4)	45 (58.4)	3 (42.9)	
1 (>7 mm	86 (31.6)	50 (26.6)	32 (41.6)	4 (57.1)	
Preoperative pivot shift, n (%)					**<.0001**
1	149 (54.8)	125 (66.5)	24 (31.2)	0 (0.0)	
2	109 (40.1)	63 (33.5)	45 (58.4)	1 (14.3)	
3	14 (5.1)	0 (0.0)	8 (10.4)	6 (85.7)	

[a]Values are presented as mean ± SD unless noted otherwise. Bold values indicate statistical significance. ALSF, adjustable-loop suspensory fixation; IKDC, International Knee Documentation Committee.

grade B (nearly normal) of 7.0 ± 2.9 mm, and those with grade C (abnormal) of 7.7 ± 3.3 mm (P = .0043) (Table 3). Thirty-six patients (42.9%) with preoperative laxity >7 mm showed postoperative laxity ≥3 mm (P = .0200). Also, 58.7% of the patients (27/46) with preoperative IKDC grade D had postoperative laxity ≥3 mm (P < .0001) (Table 3 and Appendix Figure A2, available online).

In this study population, the bivariate model showed that younger age was also a negative prognostic factor for increased postoperative laxity. The mean age for patients with abnormal (grade C) postoperative laxity was 20.9 ± 6.8 years, with nearly normal (grade B) laxity was 30.1 ± 11.1 years, and with normal (grade A) laxity was 32.8 ± 10.5 years (P = .0030) (Table 3).

However, the final multivariate logistic model showed that preoperative rotational knee instability expressed by the pivot shift grades remained the only highly statistically significant prognostic factor of postoperative anteroposterior laxity ≥3 mm (P < .001) (Table 4).

TABLE 4
Multivariate Logistic Model Predicting the Probability for Postoperative Anteroposterior Knee Laxity ≥3 mm[a]

	Odds Ratio (95% CI)	*P* Value
Fixation type: screw vs ALSF	1.628 (0.883-3.022)	.120
Preoperative laxity: >7 mm vs ≤7 mm	1.828 (0.921-3.626)	.084
Preoperative pivot shift		**<.001**
2 vs 1	4.689 (2.465-9.286)	
3 vs 1	58.025 (12.757-557.741)	

[a]Bold values indicate statistical significance. ALSF, adjustable-loop suspensory fixation.

DISCUSSION

The main finding of our study was that the use of an ALSF device for femoral fixation resulted in noninferior anterior knee laxity compared with interference screw fixation at 2 years after primary ACLR. In addition, no difference was found between subjective outcomes and rates of return to same activity levels between the 2 femoral fixation methods. These results confirmed the hypothesis of clinical comparability between femoral fixation methods using ALSF and screw fixation. These results were found in 2 homogeneous groups with similar preoperative activity levels and with the exclusion of all possible factors that might increase postoperative knee laxity such as meniscal injuries or increased chronicity of the ACL tear.[29,33]

The measurement of clinical laxity in the current study, using Telos stress radiography, differed somewhat from the findings of several recent biomechanical studies performed in the laboratory using a variety of ALSF devices.[1,19,30,37,38] Specifically, Petre et al[38] reported that all tested ALSF devices showed increased initial and cyclic displacement compared with fixed-loop devices. In some cases, this displacement exceeded the clinical failure threshold of 3 mm.[38] The authors proposed that retensioning of the ALSF device after cycling the knee may improve undesired lengthening.[38] Despite this suggestion, the importance of retensioning has not always been verified

in subsequent biomechanical studies.[19] However, the current authors in clinical practice use this retensioning technique routinely. In an effort to verify the initial results of Petre et al,[38] further biomechanical experiments have been performed in an attempt to precisely measure possible slippage of the ALSF device. A number of studies have found that loop lengthening occurs, which has been reported of up to 45 mm in some cases.[1,19,30,37] However, this remains a source of ongoing controversy. In a recent study, Born et al[4] proposed a computed tomography–based 3-dimensional metric protocol to directly visualize possible loosening of ALSF devices. Contrary to the previously published results, the authors concluded that ALSF may lead to acceptable displacement and laxity measurements with no detrimental effects.[4] Nevertheless, it is not clear whether these conflicting findings are a result of different experimental protocols. Further, it is important to consider what the effect that this potential displacement has in the clinical setting and on functional outcomes.

In an attempt to answer this question, a few studies have evaluated the postoperative laxity and clinical outcomes of patients who underwent ACLR with ALSF devices. Boyle et al[5] studied 188 consecutive patients who had undergone ACLR with either the adjustable TightRope (Arthrex) or the fixed RetroButton (Arthrex), and they found no differences in KT-1000 arthrometer measurements or in the overall incidence of graft failure. Similarly, Choi et al,[11] with a cohort of 117 patients, compared outcomes using an Endobutton (Smith & Nephew) or TightRope and reported no significant differences with respect to KT-1000 arthrometer laxity measurements (1.5 ± 1.8 mm in the fixed-loop group vs 1.2 ± 2.3 mm in the adjustable-loop group; $P = .530$). However, the authors observed better rotational stability during the pivot-shift examination in the fixed-loop group of patients.[11] In the current study, objective measures using a comparative radiographic stress examination (Telos) demonstrated similar results to the aforementioned clinical studies, and any possible undesired loop displacement did not affect the final results at a minimum 2 years' follow-up. It is important to note that an ALSF device was compared with an interference screw and not with a fixed-loop device as in previous studies. This is because an outside-in femoral drilling technique is preferred by the authors to maximize graft integration in the femoral tunnel and to preserve the hamstring tibial insertion. Notably, the laxity measurements found using ALSF are also in accordance with several biomechanical and experimental studies that have shown the superiority of cortical fixation methods compared with cancellous devices in terms of elongation, fixation strength, and stiffness.[14,20,31]

Another interesting finding of the current study was that regardless of the fixation method used and in the absence of any meniscal injury or excessive surgical delay, clinically significant (≥3 mm) residual anterior knee laxity was found in approximately 30.8% of the cases. This residual laxity also had a direct negative effect on the final functional outcomes (KOOS score) and on the rates of return to the same activity level (Tegner score). Interestingly, ALSF tended to control this phenomenon better than screw fixation (25.8% and 37.2%, respectively, of the patients had residual laxity ≥3 mm). However, the difference was not statistically significant between the 2 groups of patients ($P = .0833$). The importance of this observation is enhanced by the conclusion of Pinczewski et al,[39] who demonstrated that the absolute decrease in graft failure and revision surgery is correlated with laxity <3 mm. Careful interpretation of the many published studies shows that the limit of 3 mm has also been exceeded in some of their patients.[7,22,27,32] In a recent large randomized clinical trial, Mohtadi et al[32] compared the results of ACLR by using single-bundle and double-bundle hamstring autografts and patellar tendon autografts. In all cases, a fixed-loop Endobutton was used for femoral fixation. At the final follow-up, despite the good functional outcomes, only 56% of the patients with a patellar tendon graft, 44% with a single-bundle quadrupled hamstring autograft, and 58% with a double-bundle hamstring autograft reached normal knee laxity values according to IKDC criteria.[32]

In our study population with isolated acute ACL tears, the initial bivariate model showed that the most important risk factors leading to laxity ≥3 mm were younger age at the time of surgery (~21 years), increased preoperative laxity, and preoperative rotational instability expressed by the pivot shift. Regarding the age and the high grade of preconstruction laxity, newer studies have confirmed their association with significantly increased odds of ACL graft revision.[28,41,51] However, our multivariate logistic model showed that the only significant predictor of increased laxity according to the IKDC criteria was the pivot shift. Forty-six patients (42%) with preoperative pivot shift grade 2 (++, clunk) and 100% with pivot shift grade 3 (+++, gross) had residual knee laxity ≥3 mm. Furthermore, pivot shift grade 2 (++, clunk) has an almost 5 times (odds ratio, 4.689) and grade 3 (+++, gross) has an almost 58 times (odds ratio, 58.025) higher risk for postoperative laxity ≥3 mm compared with patients with limited rotation instability (+, glide) ($P < .001$). Our results show that in these cases of increased preoperative pivot shift, additional procedures could probably be necessary.[45,46]

This study provides 2 large, homogeneous closely matched groups for comparison, which were chosen using strict inclusion and exclusion criteria. Furthermore, all patients with concomitant or previous meniscal lesions and a delay in surgery greater than 6 months were excluded. Two experienced surgeons operated on all patients, following the same surgical technique, without any selection bias of one fixation method over the other. In addition, an independent assessor blinded to the operative technique used analyzed the patients clinically. However, the authors acknowledge that there are limitations to this study. This is a nonrandomized, retrospective case control study. As mentioned above, because of the surgical technique preferred in our department, we compared ALSF to intratunnel fixation and not to a fixed-loop device. No radiographic assessment was included in this follow-up, as the method used for tunnel positioning was the same in each group. As a result, no assessment of tunnel widening was carried out. The authors also acknowledge that the assessment of pivot shift was performed manually without the use of an objective tool. However, this was performed consistently by the 2 senior surgeons preoperatively in each case

and by the blinded, independent surgeon at final follow-up. Finally, the optimal method to measure instrumented knee laxity is a source of ongoing debate.[18,36,40] In this study, Telos stress radiography was performed in the same department following a strict reproducible protocol. Also, the same experienced radiologist interpreted all preoperative and postoperative images.

CONCLUSION

For primary ACLR, the use of an ALSF device for femoral fixation is associated with noninferior postoperative anterior knee laxity results compared with interference screw fixation at a minimum 2 years' follow-up. In addition, no difference was found between subjective outcome measures and return to same activity levels between the 2 femoral fixation methods. Finally, preoperative pivot shift is the only significant risk factor for residual postoperative anterior knee laxity >3 mm.

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