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Anterior cruciate ligament reconstruction with semitendinosus graft, comparative study of two tibial fixation devices

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Many options are available concerning the graft fixation in ACL reconstruction, one of them being a suspensory device. Our study aimed to compare the strength of two different devices of fixation (suspensory device vs screw) on the tibia. We enrolled 80 patients older than 18 years with an isolated ACL tear confirmed at the MRI, divided into two comparative groups for a prospective study. The only factor which changed was the tibial fixation.
The surgical treatment, performed by a unique surgeon, used the same inside-out technique for the two groups, with a ST4-strand graft.
Various intraoperative parameters were studied like the time of the tourniquet, the diameter of the graft or an associated meniscus tear.
The AP knee laxity was evaluated at 6 months and 1 year after the surgery by a TELOS test. We also compared the two groups with subjective and objective surveys.
We can conclude that the suspensory device can offer the same strengthening.

Keywords: anterior cruciate ligament, tibial fixation, suspensory device, acl reconstruction, ST4-strand graft.

INTRODUCTION

Anterior cruciate ligament (ACL) ruptures are one of the most common afflictions for a knee orthopaedic surgeon. During the last decades, the surgical landscape has evolved. Many different surgical variants have emerged especially concerning implants fixation. Variability in surgical technique stem from choices in graft material, fixation device[2], and potential association of an anterolateral ligament (ALL) reconstruction, among other elements.

In our clinical practice, a prevalent technique involves the use of a four-strand hamstring graft, secured with a femoral fixed-loop device and a tibial screw fixation[3,4]. However, the fixation on the tibia tends to change with the advent of novel devices. This feature has been poorly discussed in the knee surgery literature, especially when compared to femoral fixation strategies[5-7]. Consequently, we led a study designed to compare the strengthening and the tightness between an adjustable suspensory fixation and an interference screw on the tibia[5-8]. Regarding femoral fixation, a fixed-loop suspensory fixation combined with the use of a quadrupled hamstring tendon (ST4) autograft is employed. With this method, we isolated a single variable in our investigation.

MATERIALS AND METHODS

Design of the study

We prospectively enrolled 80 patients with a primary ACL reconstruction for 2 years (accepted by Ethic Comity at Merignac, France – APE8610Z). This study is prospective and comparative, and the surgery has been performed by one single surgeon. Those patients were randomized and blindly divided into two groups of 40 members, without any interest in the side of the operated knee (65% of right knee for the screw group and 32% for the button group)[9]. The groups were not statistically different in terms of age, sex, or meniscus lesion (Table I).

For this study, the surgery was performed on 24 women and 41 men distributed randomly in the two groups with a mean age of 29,5 years. At the final follow-up, on our 80 patients, 5 patients were lost during the follow-up, 10 didn't fill in the questionnaires and 1 patient could not be evaluated until the end because he had a graft failure at 7 months after an inappropriate

Table I. — Data of the study.

		FIXATION	
Sexe		Screw	Pull-up
Woman (n) Men (n)		9 22	15 19
Delai (month) Age (year) Graft diameter (mm) Tourniquet time (min)	mean (SD) median mean (SD) mean (SD) mean (SD)	17,2 (43,8) 3 30 (12,7) 8,3 (0,5) 32,7 (4,1)	14,7 (39,1) 3 29,1 (10,8) 8,6 (0,5) 39,3 (5,4)
Side of the o erated knee			
Right (n) Left (n)		20 11	13 21
Internal meniscus			
Nothing (n) Resection (n) Suture (n)		23 3 5	26 3 5
External meniscus			
Nothing (n) Resection (n) Suture (n)		23 8 0	 6 4

rehabilitation. In total, we analysed the data of 65 patients at 6 months and 64 patients at 1 year (Fig 1). The evaluated parameters were the stability of the knee and the tightness of the tibial fixation with a TELOS TM (Telos GmbH, Laubscher, Holstein, Switzerland) (Fig. 2 & 3)[10]. We also assessed the satisfaction of a functional knee to each patient by asking them to answer different objective and subjective questionnaires (surveys).

Criteria of selection

The inclusive criteria were patients older than 18 years with a confirmed rupture of the ACL on the MRI

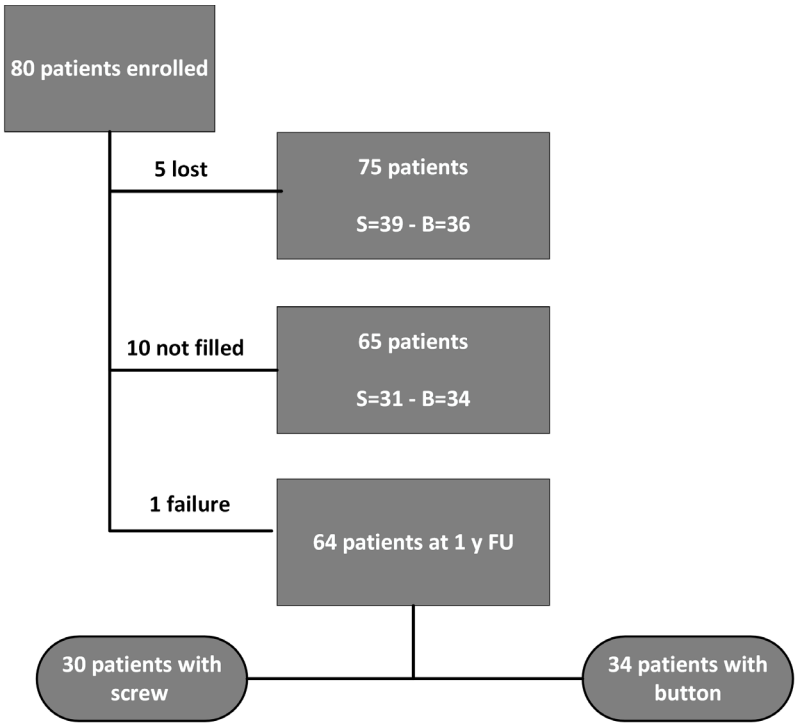

Fig. 1 — Flowchart of patient follow-up, s = screw group, b = button group).

Fig. 2 — Telos Test TM GmbH: Laubscher, Holstein, Switzerland,[10].

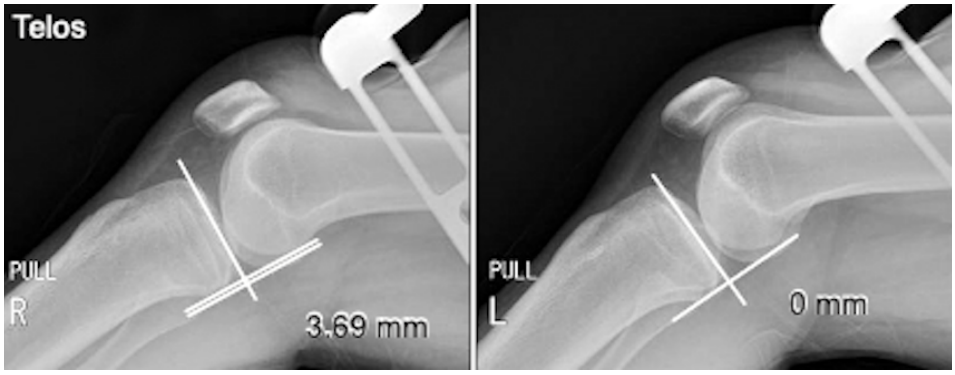

Fig. 3 — Example of Telos Test performed with 80N on a knee[10].

or on the CT-scan within two years, without any prior surgery on the concerned knee. We decided to include in the study patients in which the ACL reconstruction was sometimes associated with a meniscectomy or a meniscus repair.

Exclusion criteria

During this study, we excluded the following patients: minors ages (<18y), revisions of an ACL surgery or multi-ligament knee injuries.

All procedures using a different graft, or a different device of fixation were also excluded.

Surgical technique

Those ACL reconstructions were performed by one single surgeon and the same procedure was performed on all patients except for a different tibial implant fixation. We used the HT4 graft for all of them despite the sex, age or any other criteria[11].

The patient was put in the supine position with a pneumatic tourniquet. The surgery was performed under general anaesthesia combined with an ultrasound-guided femoral nerve block at the end of the procedure.

First, the semitendinosus was harvested, prepared into a "4l-loops graft" and stitched along its entire length using a resorbable suture[11]. The fixation on the femur was the same for patients in both groups. We used a fixed-loop device (Endo button TM, Smith & Nephew, MA 01810, USA) on the femur. Afterwards, we made the arthroscopic incision and made the owner's turn. We used a single-bundled anatomic technique for the ACL reconstruction. With a knee flexed at 120°, the femoral tunnel was drilled from inside-out through the anteromedial portal. We used the arthroscopic landmarks as described by Colombet et al.[1,12]

The tibial tunnel was drilled from outside-in on the centre of the anteromedial bundle footprint.

In the first group, we used the classical tibial fixation with an interference bioresorbable screw (Biosure TM, Smith & Nephew, MA 01810, USA). The tunnel was drilled on the entire length of the tibia to insert the screw and the graft. The insertion of the graft was made by an antegrade approach through the tibia and then the femur. We fixed first the cortical plate on the femur and after that, the graft was stretched in the tibial tunnel by pulling the resorbable stitches. Tensioning and fixation are achieved at 30° of flexion.

In the second group, we also drilled an outside-in tunnel. When the tunnel was finished, we inserted the graft in the articulation by the tibial tunnel. We fixed first the femur side with the endo button and then the tibia with a suspensory device (Pull-Up, SBM, France). On the tibia, the device was fixed with a knee in full extension to avoid excessive tension and irreducible flessum deformity.

Ten times cycling at full range of motion is performed before every tibial fixation.

Wound was closed with stitches.

Rehabilitation

All patients received the same rehabilitation protocol concerning the ACL reconstruction during all the follow-ups. They immediately started a physiotherapist treatment to recover a full range of motion. They also immediately received the order of a full weight-bearing walk. All patient who benefited a meniscal suture received the order of a no weight-bearing support for 4 weeks.

We also applied an articular brace to all patients which was removed after 4 weeks. They started

cycling after 6 weeks, while jogging and swimming were permitted only after 3 months. Non-contact pivot sports were allowed only after 6 months, and the pivot and contact sports were permitted at the end of the rehabilitation at 9 months. However, the resumption of pivot sports should be postponed if there was a muscle deficit of more than 10% measured on the Isokinetic test compared to the contralateral side. These activities were permitted when good results were achieved.

Clinical outcomes

We followed the patients with a strictly clinical examination preoperatively and after 3 and 6 months and 1 year. A Telos TM (Telos GmbH, Laubscher, Holstein, Switzerland) test was performed at 6 months and 1 year after the surgery (Fig. 2 & 3)[10]. The patients have also filled various scores such as ACL-RSI, KOOS, IKDC subjective and objective. At the end of the 1-year rehabilitation, we asked the 2 groups to fill an assessment in the Tegner and Lysholm activity score.

Statistical analyses

Statistical analyses were used to summarize the data and were carried out using JMP software. After analysing all data and calculate the median, standard deviation, and standard error of the median (Table III and IV), we performed different tests.
First, the Shapiro-wilk test was used to determine the normality of our both groups. The distribution wasn't parametric, so we had to use the Kolmogorov-Smirnov to analyse the difference between the two groups. The p-value retained is 0.05.

We also measured the displacement (mm) of the knee on the TELOS test at 6 months and 1 year and a comparison for both devices were done by a student paired test depending on the normality of the distribution.

RESULTS

In this comparative study, we analysed the outcomes of ACL reconstructions performed using two different techniques (Table I). The mean time from injury to surgery was 14,6 months for the pull-up group, and 17,6 months for the group with the screw.
While the mean graft diameter was consistently 8.2 to 8.6 mm in both groups. A notable difference was observed in tourniquet times, probably attributed to the new technique of the pull-up. Despite these variations, the overall functional scores, as assessed by standardized questionnaires (Table II and III), the two groups follow normal distribution and didn't demonstrate significant difference (Kolmogorov-Smirnov test, p-value retained is 0.05). This suggests comparable levels of post-operative recovery and patient satisfaction.

The adjustable suspensory fixation, as evaluated using the TELOS TM device (Telos GmbH, Laubscher, Holstein, Switzerland), demonstrated a higher initial tension compared to the screw and the healthy knee at 6 months. This was followed by a secondary lengthening, leading to a comparable laxity to the screw fixation at 1 year (Table IV).

Our results indicated a mean difference of 0.5 mm (SD = 4.9) in knee laxity at 6 months post-operation when comparing the screw and pull-up techniques, with superior strengthening observed in the pull-up group. At 1 year, the mean difference narrowed to 0.2 mm (SD = 5.2), diminishing the disparity between the two groups. At this time point, no statistical significance was noted (p-value = 0.92).

Furthermore, within the pull-up group, we observed a significant change in laxity from 6 to 12 months ($p < 0.05$), with standard deviations indicating moderate variability (±5.0 at 6 months and ±4.7 at 12 months).

DISCUSSION

As Verhelst et al have noted, ACL reconstruction is of significant interest due to its impact on a young and active population[13]. For those reasons, the procedure is well-defined and received a lot of proves in the scientific literature[11,14]. Our study focuses on the tension between two tibial fixation options: the recently developed suspensory fixation device and the traditional interference screw. We aimed to determine if the former could be a viable and safe alternative[15,16].

In the scientific community, this topic is not well studied, and no consensus has been reached on the superior fixation device. Our findings suggest that the adjustable suspensory fixation device offers advantages in terms of intraoperative graft tension control and procedural end-point adjustability[5]. This tips, confirmed by Noonan et al., is important in order to avoid secondary lengthening[16-19]. However, it's crucial to balance these benefits against the risk of overtensioning the graft, which can lead to complications[20]. To avoid this pitfall, it's mandatory to tension the graft in full extension, thereby reducing the likelihood of post-operative flessum[19].

Moreover, the adjustable suspensory device allows for a 360° bone-graft contact in the tunnel, potentially

Table II. — Functional score at 6 months.

		FIXATION	
		Screw	Pull-up
ACL - RSI	median	65,83	62,91
	SD	20,4	19,23
	SEM	3,66	3,3
KOOS	median	85,71	89,29
	SD	12,08	13,89
	SEM	2,17	2,38
KOOS pain	median	88,89	92,71
	SD	9,65	10,79
	SEM	1,73	1,85
KOOS daily life	median	95,83	98,61
	SD	11,02	7,6
	SEM	1,98	1,3
KOOS sport	median	90	80
	SD	16,89	23,65
	SEM	3,03	4,06
KOOS qual of life	median	75	68,75
	SD	15,77	19,49
	SEM	2,83	3,34
Subjective IKDC	median	79,31	77,01
	SD	9,01	12,8
	SEM	1,62	2,19
Clinical IKDC			
A		2	15
B		17	15
C		12	4
Same ROM ?			
No		4	1
Yes		27	33

*SD = standard deviation, SEM = standard error of the mean.

Table IV. — Telos score at 6m and 1y, assessment of the laxity to the operated knee.

		FIXATION	
		Screw	Pull-up
Telos 6 monts	mean	0,8	0,3
	SD	3,0	3,6
Telos 1 year	mean	1,2	1
	SD	3,1	3,2

Table III. — Functional score at 1 year.

		FIXATION	
		Screw	Pull-up
ACL - RSI	median	67,92	75
	SD	21,39	20,28
	SEM	3,9	3,7
KOOS	median	85,71	89,29
	SD	15,46	10,09
	SEM	2,82	1,84
KOOS pain	median	93,06	94,44
	SD	12,71	10,93
	SEM	2,32	1,99
KOOS daily life	median	97,22	100
	SD	7,05	6,29
	SEM	1,29	1,15
KOOS sport	median	90	85
	SEM	16,56	19,78
		3,02	3,61
KOOS qual of life	median	75	75
	SD	19,81	15,49
	SEM	3,62	2,83
Subjective IKDC	median	86,21	85,06
	SD	12,85	12,75
	SEM	2,34	2,33
Lysholm	median	90	95
	SD	9,06	8,97
	SEM	1,65	1,64
Clinical IKDC			
A		9	13
B		17	16
C		3	5
D		1	0
Same ROM ?			
No		3	2
Yes		27	32
Same Tegner at 1 y ?			
No		15	14
Yes		15	20

enhancing the graft's integration[19,21]. This feature, coupled with the device's ability to use shorter grafts safely, offers a promising avenue for improving ACL reconstruction outcomes[8,18]. Mayr et al. further suggest that this technique might result in less tibial tunnel widening compared to screw fixation[5,22], even more for bioresorbable screw, a notable advantage in the long term and benefits in case of failure[1,8,23].

Despite these positives, concerns persist about bone tunnel widening and graft elongation with adjustable devices[24]. While laboratory studies have reported significant elongation, clinical studies, suggested by Singh et al. and Hyodo et al., have not found substantial differences in patient outcomes between adjustable and fixed devices[7,16,25-29].

Finally, while our study provides valuable outcomes into tibial fixation techniques, it does not account for potential differences based on the side of the operated knee, as indicated in the literature[9].

Furthermore, although our study is pioneering in comparing the tightness of two different tibial fixation options in ACL reconstruction, it's limited by a small cohort and a short follow-up period. Notably, the observed lengthening of the pull-out technique at 12 months compared to 6 months warrants further investigation as it might indicate a potential for progressive lengthening and secondary failure. Given

that this study was conducted over two years, no signs of failure were reported for different participants. But, it is well established that normally the graft is well integrated after several months[1,30]. Nonetheless, the phenomenon of secondary lengthening should not be solely imputed to the fixation device[19,21,30]. A comprehensive understanding of the postoperative graft's biological and mechanical behaviour is essential, as these may significantly influence secondary lengthening[31,32].

However, long-term assessments are imperative to substantiate the absence of statistical disparities observed between the two groups and to validate these findings in clinical practice. Subsequent research, completed by more comprehensive datasets are essential to fully understand the rehabilitation outcomes and the patients return to pre-injury activity levels.

CONCLUSION

We can state that the tibial fixation with a suspensory device gives the same properties in terms of tension and stability as an interference screw fixation. Those results were analysed with a subjective and objective measurement. This device can be a good and safe alternative with comparable results in terms of functional outcomes and stability with some advantages. It offers us the possibility of re-tensioning the graft after the fixation, the use of a short graft and a 360° bone-graft contact in the tunnel. However, certain precautions such as fixing in full extension or pre-tensioning the graft are advisable.

Good fixation device can help but do not replace a good surgical technique, with a sufficient graft diameter and correct tunnel positioning. It is important for each surgeon to use a technique that he knows and masters.

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