Anterior cruciate ligament reconstruction: Assessment of the hamstring autograft femoral fixation using the EndoButton CL®

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Summary The objective of this study was to evaluate the clinical and radiological results of a prospective, continuous series of 105 ACL reconstructions using the STG tendons fixed to the femur by an EndoButton CL®, with more than 4 years of follow-up.

Hypothesis: The subjective and objective clinical results as well as the radiological results (tunnel enlargement) obtained by a cortical, extra-anatomic femoral fixation are at least equivalent to the results obtained with other types of femoral fixation systems.

Material and methods: One hundred and five patients aged with a mean 26 years (range, 12–56 years) were operated on for an anterior cruciate ligament rupture using the same technique and by the same operator: four-strand STG fixed to the tibia by a double fixation — BioRCI-HA screw and staple — and on the femur by an EndoButton CL® (Smith and Nephew). The results were assessed at 6 months, 1 and 2 years and then at a mean follow-up of 51 months, both clinically (IKDC, Lysholm, KT-1000) and radiologically (Telos laximetry, tunnel position, and morphological analysis).

Results: No complications related to the use of the EndoButton® were observed. No additional interference screw was necessary. According to the IKDC laxity classification, 91.4% of the patients were classified in category A or B, nine knees (8.6%) were classified C or D. Four failures required revision with a patellar tendon graft. On the final IKDC score, 63 patients (60%) were classified grade A, 37 grade B (35.3%), four grade C (3.8%), and one grade D (0.9%). On the Telos laximetry, 62 patients (59%) had a differential laxity less than or equal to 2 mm. The mean value was 1.8 mm (range, 0–11). Tibial tunnel enlargement was constant;
The use of the semitendinosus and gracilis (STG) tendons is becoming the choice method in anterior cruciate ligament (ACL) reconstruction. This graft, with four strands of STG tightened identically, presents the advantage of having a mechanical resistance theoretically superior to the mechanical resistance of a tendon from the patellar ligament with a minimum width of 10 mm, having a minimum of iatrogenic complications, preserving the extensor apparatus and thus reducing anterior knee pain [1—8]. However, a wide variety of fixation solutions to attach the hamstring tendons have been proposed, a clear indication that the ideal fixation has not yet been found. For many authors, the unsatisfactory clinical results were related to the inadequate fixation methods for this graft. Steiner et al. [9] showed that the key to success required using a sufficiently rigid fixation system to obtain clinical results in terms of patient satisfaction, joint stability, and return to sports activities equivalent to the results obtained using the patellar ligament. The femoral fixation of the STG tendons using an EndoButton® (Smith and Nephew) appeared to be reliable. The femoral fixation of the STG tendons using an equivalent to the results obtained using the patellar ligament system to obtain clinical results in terms of patient satisfaction, joint stability, and return to sports activities equivalent to the results obtained using the patellar ligament. The EndoButton® of the STG tendons was chosen based on its mechanical resistance theoretically superior to the mechanical resistance of a tendon from the patellar ligament.

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Our working hypothesis was the following: the subjective and objective clinical results as well as the radiological results (tunnel enlargement) obtained with an extra-anatomic cortical femoral fixation are at least equivalent to those obtained with other femoral fixation systems.

Material and methods

This was a prospective study on a continuous series of 105 patients operated on for ACL rupture, using the same technique, by the same operator, from 1 September 2003 to 15 March 2004. The exclusion criteria were a previously operated knee, ligament reconstruction of the contralateral knee, associated lateral or medial ligament lesions, as well as observed chondral lesions that could modify the postoperative rehabilitation protocol (grade III or IV cartilaginous lesions). The minimum follow-up of the clinical assessment was 4 years, with a mean follow-up time of 51 months (range, 48—54 months). The mean time from injury to surgery was 3 months (range, 1—60 months). This series included 105 patients, with a mean age of 26 years (range, 12—56 years), with 62 men and 43 women. The right knee was involved in 58 cases and the left knee in 47 cases. Sports activity was the cause of rupture in all cases: skiing in 75%, soccer in 10%, rugby in 10%, and handball in 5%.

After harvesting and calibrating the gracilis and semitendinosus tendons, the surgical technique consisted in passing them in the EndoButton® loop, placing direct traction on them, and then suturing them together at the two ends (Ethibon no. 3) over at least 20 mm, so that the compliance of the transplant in its intraosseous portion could be reduced. The EndoButton® length was chosen based on the femoral socket length. The tibial attachments of the remainder of the ACL were preserved. The anatomic femoral insertion zone was identified. The position of the tibial tunnels was as anterior as possible with no conflict with the femoral notch [17]. The femoral tunnel was drilled via the anteromedial portal approach, from inside to outside, with the knee flexed 120°. The femoral tunnel was calculated to within 0.5 mm. Once the graft was put in place, the graft was cycled with firm traction on the tibial extremity: the EndoButton® was thus held against the femoral cortex and the graft stretched as much as possible, avoiding possible secondary slackening. Then the graft was attached to the tibia using a BioRCl HA interference screw (Smith and Nephew) and a staple. No complementary fixation was placed on the femur.

The goal of this study was to prospectively evaluate the clinical and radiological results of a series of 105 patients who had undergone ACL ligament reconstruction using STG tendons attached to the femur by the EndoButton® CL, with a minimum follow-up of 4 years.
Rehabilitation was undertaken the day after surgery with walking and complete weightbearing using crutches but no brace. Only closed kinetic chain exercises were allowed during the first two postoperative months, then non-pivot, non-contact sports beginning at the 3rd postoperative month, pivot non-contact activity beginning at the 4th month, and return to competition at the 9th month.

All the patients were examined 3, 6, 12, and 24 months after surgery as well as at the latest follow-up. The clinical assessment involved the number of operative revisions and complications at the longest follow-up, the objective criteria of the International Knee Documentation Committee (IKDC 1999), the subjective score and functional signs (IKDC 1993), completed by the Lysholm score and an objective assessment based on laxity criteria (measured with the KT-1000). The radiographic work-up, done at the latest follow-up, was based on the laximetry assessed using the Telos device (150 and 200 N) and the position and enlargement of the tibial and femoral tunnels.

The diameter of the femoral tunnel was measured at its greatest width, perpendicular to the tunnel axis, on the AP images. Because of the obliquity of the femoral tunnel, attributable to the anteromedial portal approach, we were able to measure the diameter on the lateral views. We therefore did not measure the femoral tunnel area using the Clatworthy technique [13]. The original diameter of the tunnel was obtained from the operative report. The tibial tunnel diameter was calculated on the AP and lateral X-rays. The X-ray enlargement factor was determined by placing a metallic millimeter measuring device on the images.

To quantify the enlargement of the femoral and tibial bone tunnels, we used the four-stage Nebelung classification [21]: absent if less than 0.5 mm, slight between 0.5 and 2 mm, moderate between 2.5 and 4.5 mm, massive if greater than 4.5 mm. We only took into account the enlargements greater than or equal to 2 mm.

The results were statistically analyzed using the Statview® 4.5 software, with the Student t-test used to compare the continuous values and the correlation test for the nominal values. P < 0.5 was chosen as the significance threshold.

**Results**

In 75% of the cases, the EndoButton® length was 25 mm and 30 mm in the other cases. No additional interference screws were necessary. The mean graft diameter was 8.2 mm (range, 7—10 mm); the mean reaming diameter of the femoral tunnel was 8.3 mm (range, 7—10 mm). No intraoperative complication related to the EndoButton® was observed in this series.

Two patients presented a postoperative hematoma following transplant harvest, which required surgical revision with drainage but with no sequelae. One patient had a postoperative arthroscopy at 6 months for cyclops syndrome. After arthrolysis, this patient recovered full function and was included in revision at the latest follow-up. Two patients had a postoperative arthroscopy at 9 and 12 months for medial meniscectomy. These two patients had meniscal repair at the initial procedure. Four patients presented new injury to the same knee with iterative rupture of the ACL, occurring when resuming sports activity (at 7 months). These four patients had a second ligament reconstruction using a patellar ligament graft (BTB) (at 9, 12, 14, and 20 months after the first surgery). The EndoButton® was removed in these cases through the lateral femoral approach: it was whole and intact in both structure and length.

**Functional score**

On the IKDC subjective score, 97 patients (92.4 %) considered their knee to be normal or close to normal, four patients (3.8%) considered their knee to be abnormal, and four patients presented a new rupture (3.8%). The Lysholm score was a mean 72.1 (± 6.7) (range, 50—86) before surgery and 94.1 (± 3.7) (range, 71—99) at follow-up.

Sports activity was resumed at a mean 180 days (range, 90—295). Here we distinguished professional and high-level (national or international level) athletes: 65 out of 75 (86.6%) patients had resumed their teaching activity or their training level 1 year after surgery. For the others (recreational or occasional competitive athletes), out of 30 patients, seven (23.3%) had not resumed sports activity at 1 year.

**IKDC evaluation**

The IKDC evaluation is presented in Table 1.

According to the IKDC laxity, 70 knees (66.7%) were classified A, 26 (24.8%) B, nine (8.5%) C and D (Table 1). Eighty-five knees (80.9%) presented no pivot shift, 17 (16.3%) a glide...
Table 2  Femoral tunnel width (AP X-rays with corrected value).

<table>
<thead>
<tr>
<th>Femoral tunnel width</th>
<th>0.5—2 mm</th>
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<tr>
<td>At 1 year postoperative</td>
<td>( N = 86 ) (82%), mean = 1.2 mm</td>
<td>( N = 19 ) (18%), mean = 2.6 (range, 2—4)</td>
</tr>
<tr>
<td>At D + 4 years minimum</td>
<td>( N = 76 ) (72.3%), mean = 1.3 mm</td>
<td>( N = 29 ) (27.6%), mean = 2.4 (range, 2—4)</td>
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None of the patients presented hydrarthrosis. Seven knees showed a difference in mobility when flexed a mean 7° (range, 3—10°) compared to the other knee and four patients had a 5° extension deficit. Seven patients (6.7%) presented sensitivity at the hamstring harvest site, with a mean 15% (range, 10—30%) reduction in strength evaluated on isokinetic tests at 6 months after surgery. On the one-legged hop test, 90 patients were grade A, 13 patients grade B, and two patients grade C.

On the final IKDC evaluation, 63 patients (60%) were classified grade A, 37 grade B (35.3%), four grade C (3.8%), and one grade D (0.9%).

Radiographic assessment

A constant enlargement was observed in the tibial tunnel in all patients at 1 year and at the last follow-up. At 1 year of follow-up, femoral tunnel enlargement greater than 0.5 mm was observed in all patients and between 0.5 and 2 mm (mean, 1.2 mm) in 86 patients (82%). At more than 4 years of follow-up, 76 knees (72.3%) showed femoral tunnel expansion between 0.5 and 2 mm (mean, 1.3 mm) and 29 knees showed more than 2 mm (mean, 2.4 mm; range, 2—4 mm) (27.6%) (Table 2). The mean significant increase in the femoral tunnel diameter was 58% compared to the initial diameter of the drill (mean, 8.2 mm; range, 7—10 mm). No modification in the femoral tunnel diameter corresponding to the EndoButton® loop was found (5 mm-diameter tunnel). Expansion of the femoral tunnel was conical in shape in 60% of cases and linear in 40% of cases. No cavitory enlargement was found. As for the sagittal position of the femoral tunnel, the mean value was 85% according to the Staubli criteria and 90% were located in zone IV on the Blumensaat line and 10% in zone III (Fig. 1). No statistically significant correlation between femoral tunnel enlargement and laxity was observed.

Discussion

This study reports the clinical and radiological results of a consecutive, prospective series of 105 patients with isolated rupture of the ACL. All the patients were treated...
using the same technique, using the same operative procedure, with the same Tibial and femoral fixation performed by the same operator, and all underwent the same rehabilitation protocol. To date, no other study has been conducted concerning the ACL reconstruction technique using the STG attached to the femur with an EndoButton® continuous loop (EndoButton® CL; Smith and Nephew) with a minimum follow-up of 4 years.

In several recent meta-analyses, no significant difference was found in terms of laxity between the use of hamstring tendons and the bone–patellar ligament–bone transplant. Blau [1], Goldblatt [22], and Yunes [23] et al. observe better stability control after patellar ligament graft, whereas Poolman [24] and Blau et al. [11], in more recent series, do not observe a difference. Concerning the objective IKDC score, although variations exist in the results of different comparative series within a single study, no significant difference is reported between the patellar and STG grafts. Nevertheless, no meta-analysis has taken into account the type of hamstring tendon fixation. Moreover, like Poolman et al. [25], we believe that a meta-analysis comparing the patellar ligament and the STG should take into account the type of hamstring fixation (former type of fixation versus EndoButton CL®) by conducting a sensitivity analysis (inferior behavior with old types of fixation).

Analysis of hamstring fixation

Biomechanical analysis

For the last 10 years, we have applied to all our ACL reconstructions with STG a nonaggressive rehabilitation protocol during the first 3 months after surgery to allow the graft to integrate with the bone in the tunnels without excessive solicitation of the fixation system. A single recent study by Milano et al. [26] involving the EndoButton CL® has compared the mechanical behaviour of different femoral fixation systems for hamstring tendons: the corticocancellous fixation systems seem to offer a better guarantee in terms of elongation and resistance to tearing (1469.7 N) and for the EndoButton CL® mechanical values with a sufficient safety margin for the rehabilitation phase of the first 3 months without going beyond the limit of resistance in traction (850 N), contrary to interference screws (392.5 N).

Clinical results

In a retrospective study, Charlton et al. [27] showed that the results of ligament reconstructions using STG tendons attached with bioabsorbable interference screws were comparable to the results of other ACL reconstruction methods in terms of satisfaction, knee stability, and function. With a mean clinical follow-up of 30.2 months, laxity as measured on the KT-1000 arthrometer was a mean 2.03 mm with a mean clinical follow-up of 30.2 months; laxity as measured on the KT-1000 arthrometer was a mean 2.03 mm with a median laxity of 1.3 mm. In this study, 74 systematic revision arthroscopies were performed after a mean 20.1 months (range, 9–32 months): the subjective analysis of graft tension showed that 52 knees had a graft considered to be tight, 22 knees were moderately tight, and none had ruptured. Harilainen et al. [30] conducted a prospective randomized study with 2 years of follow-up comparing the results of two series of STG tendons attached to the femur using cross-pins (Transfix® Arthrex) or metallic interference screws. On the IKDC score, no statistically significant difference was found between the two groups 1 and 2 years after surgery. In a prospective randomized study, Rose et al. [31] compared the clinical results of ACL reconstruction using hamstring tendons attached with a femoral fixation system, BIS, or a transfix system (Transfix). No statistically significant difference was observed between the two groups in terms of laxity measured with the Rollimeter: 90% of the patients in the entire series had a normal or nearly normal functional outcome; 94% of the patients were classified as grade A or B on the objective IKDC score for the Transfix® series and 84% for the Bioscrew® (Linvatec) series, similar to our clinical results (overall IKDC score grade A or B, 91.4%).

Tunnel enlargement

We observed significant enlarging of the femoral tunnel in 27.6% of our cases. These values from the various studies are difficult to compare because the measurement methods are often different and do not always take into account the radiological enlargement coefficient. With a 4-year minimum follow-up, in all cases our results appear to be equivalent or even superior to the results published for other fixation systems (Table 3) [32–38], in which the clinical follow-up was shorter except for Giron et al. [33], who, with 5 years of follow-up, noted a significant correlation between the length of the tibial screw and tunnel expansion: the longer the screw was, the greater the tibial tunnel expansion. In Jansson et al. [34], MRI analysis demonstrated an increase in contrast uptake, not at the ligament but surrounding the ligament. He suggested that this signal increase surrounding the ligaments is associated with tunnel enlargement. Fauno et al. [35] found the position of the fixation sites...
and the fixation methods were major factors in developing tunnel enlargement. In a prospective study with 2 years of follow-up, Buelow et al. [36] compared tunnel enlargement in relation to femoral fixation: the EndoButton® versus interference screws. These authors found the use of interference screws to be accompanied by a significant and immediate increase in tunnel diameter and a 6% increase of more than 50% of the diameter at 2 years, whereas for the extraarticular fixed, no immediate modification was observed with a 76% incidence of enlargement at 2 years. The only study analyzing the impact on femoral tunnel enlargement of an EndoButton CL® was published by Kuskucu et al. [38], who compared the short-term results of tunnel enlargement between two cohorts, one with an EndoButton CL® fixation and the other with crosspin fixation. Tibial fixation was identical to ours: interference screw and staple. At 12 months, enlargement was greater for the group with the EndoButton CL® femoral fixation (43.71% for the femur, 51.11% for the tibia) than for the cross-pin group (32.61% for the femur and 25.62% for the tibia), but with identical clinical results.

We believe that these good results can be attributed to several factors: the EndoButton CL® is continuous and undergoes no secondary slackening (proof was also given by the absence of any structural modification in four EndoButton CL® removed at four revisions). The graft preparation technique reduces compliance of the intraosseous portion (suture of the four strands along a minimum of 20 mm). The graft is subjected to tension beforehand. Tunnel filling by the graft is optimum [39]. The knee is cycled once the graft is in place before placing the tibial fixation. We always applied a nonaggressive rehabilitation protocol respecting the biomechanical and biological steps for consolidation of the graft in the tunnels and ligamentization [40,41]. The femoral aiming zone sought should be the least anisometric, respecting the biomechanical behavior of the ACL [42]. For Segawa et al. [43], placing the femoral tunnel too far anterior is the source of a significant increase in the width of the femoral tunnel. All these actions result in minimizing the graft’s secondary relaxation and mobility in the tunnel. The anatomic fixation using the interference screw did not seem necessary. In Buelow et al.’s view [36], the presence of a screw may cause tunnel cavity enlargement (a form that was never observed in our series with the EndoButton®). Mixed corticocancellous fixation systems did not demonstrate any clinical or radiological advantages.

Chabra et al. [44] compared two femoral tunnel drilling techniques (medial portal vs transtibial approach): the increase in femoral tunnel diameter was a mean 38.20% on the AP view for the medial portal approach and 53.96% for the transtibial approach, and on the lateral view 23.80% for the medial portal approach and 50.07% for the transtibial approach. They concluded that femoral tunnel expansion was statistically significantly less with the anteromedial technique than for the transtibial approach. We showed that the anteromedial arthroscopic approach used for the EndoButton® allowed us to place the femoral tunnel in the proper position in 90% of the cases, without conflict, as shown by the radiographic criteria: like Iorio et al. [45], the search for the optimal femoral placement is a significant factor in favor of the absence of significant tunnel enlargement (71.2% of the cases in our series).

**Conclusion**

Today, this investigation is the only prospective study reporting the clinical and radiological results, with a 4-year minimum follow-up, of an ACL reconstruction technique using hamstring tendons attached to the femur with the continuous EndoButton®. With an objective IKDC score of 91.4% very good and good results (66.7% grade A and 24.8% grade B), our clinical results are comparable to other series and from a radiological point of view superior in terms of femoral tunnel enlargement, confirming our initial working hypothesis. Comparing the subjective and objective results between a patellar ligament (BTB) graft or a graft using the hamstrings (STG) in several meta-analyses, the current French National Authority for Health (HAS) [46] guidelines do not
allow us to define the superiority of one or the other of the two techniques. Which fixation method is best for the STG graft? The HAS considers that this femur fixation can call on an extra-anatomic system, an interference screw, or any other intracanal system. To date, no study provides sufficient evidence to recommend a double femoral fixation. We have shown that the EndoButton® CL is a reliable and reproducible means, with no iatrogenic complication, to obtain these clinical results. In addition, it did not appear useful to add a femoral interference screw to this system. The EndoButton CL© therefore seems to be a necessary and sufficient fixation system equal to the other femoral fixation systems.

Conflicts of interest

None.

References

Hamstring ACL reconstruction: femoral fixation with Endobutton (CL)


