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Can an adjustable-loop length suspensory fixation device reduce femoral tunnel enlargement in anterior cruciate ligament reconstruction? A prospective computer tomography study

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ABSTRACT

Background: The aim of this study was to compare bone femoral tunnel enlargement in patients who underwent anterior cruciate ligament (ACL) transtibial reconstruction using an adjustable-loop length suspensory fixation device and a fixed-loop length suspensory fixation device.
Methods: All patients treated for ACL reconstruction with an ipsilateral hamstring between March 2013 and March 2014 were evaluated. Subjects were assigned to Group A (TightRope™ (TR) femoral fixation) or Group B (EndoButton® (EB) femoral fixation). All patients were evaluated with the Lachman test, pivot-shift test, 2000 International Knee Documentation Committee (IKDC) knee examination and KT1000 arthrometer. The subjective evaluation was performed using the 2000 IKDC Subjective Knee score, the Lysholm knee score, and the Tegner activity scale.
CT examination was performed to evaluate femoral tunnel enlargement at four different levels. All patients were assessed at a 12 month follow-up visit. Power analysis was performed a priori in accordance with the femoral tunnel enlargement values from the CT scans. Differences with *P*-values of ≤0.05 were considered to be statistically significant.
Results: The groups were homogenous at baseline with regard to age, gender, BMI, dominance and disease duration. At the final follow-up, no statistically significant differences ($P > 0.05$) were found according to subjective and objective clinical outcome measures.
According to the femoral tunnel enlargement, no statistically significant difference was found between the two groups ($P > 0.05$).
Conclusion: In transtibial ACL reconstruction, the use of a fixed or adjustable-loop length device products, on the femoral side, led to similar clinical and radiological results.

1. Introduction

Successful anterior cruciate ligament (ACL) reconstruction depends on several factors, including stable initial fixation, biological bone-graft integration, and adequate graft strength. The graft fixation choice is critical for a good surgical result. It minimizes elongation and prevents failure at the graft attachment sites before integration is complete [1]. However, the method that produces the best result remains unknown.

In recent years, the EndoButton® (EB; Smith and Nephew) has become one of the most popular fixation devices. It is a suspensory fixation system, and several studies have already demonstrated its mechanical strength [2–4]. The literature reports that one of the disadvantages of the suspension system is the progressive enlargement of the femoral bone tunnel diameter [5]. In fact, it has been reported that suspensory fixation results in an increased rate of tunnel widening compared with aperture fixation [6].

Recently, a new fixation device, the TightRope™ (TR; Arthrex, Naples, FL, USA), was introduced; it is a second-generation adjustable-loop length suspensory fixation device that can be tightened intraoperatively. The adjustable graft loop has a four-point, knotless locking mechanism that relies on multiple points of friction to create resistance to cyclic displacement and slippage under tension.

Some authors also believe that the tensioning sutures at the button end reduce the loop length and tension on the graft strands in the same direction of graft advancement into the socket. This allows an

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optimal graft-to-socket fill, reducing longitudinal ('bungee-effect') graft motion within the bone tunnel and optimizing graft-to-bone healing [7].

In contrast, other authors [8,9] have demonstrated that the TR shows more slippage and less stiffness compared to the EB. Those mechanical proprieties can most likely facilitate tunnel widening.

The aim of this study was to compare bone femoral tunnel enlargement in patients who underwent ACL transtibial reconstruction using either an adjustable-loop length suspensory fixation device, the TR, or a fixed-loop length suspensory fixation device, the EB. The hypothesis is that there is no difference in outcome using either device. Our primary objective was to evaluate whether an ACL transtibial technique reconstruction with the TR produces a femoral tunnel enlargement equivalent to the EB system using a computer tomography (CT) scan after a follow-up period of 12 months. The secondary objective was to evaluate whether tunnel widening affects clinical outcomes and to compare the clinical outcomes of the TR and the EB.

2. Methods

2.1. Participants

All patients treated by the two senior authors for ACL reconstruction with ipsilateral semitendinosus (ST) and gracilis (G) between March 2013 and March 2014 were prospectively enrolled in this study.

The exclusion criteria for all patients were previous knee surgery, multi-ligament injury, marked rotatory instability (Jerk +++), or systemic or connective tissue disease. Patients with a graft size greater or less than 9 mm who required a femoral tunnel of greater or less than 9 mm were also excluded. Therefore, all patients had a graft size and femoral tunnel of 9 mm.

According to the surgical technique, subjects were assigned to Group A (TR femoral fixation) or Group B (EB femoral fixation). A flow chart of participant enrolment is shown in Figure 1.

All patients agreed to participate in the study and signed an informed consent form in accordance with the Declaration of Helsinki. The study protocol was approved by the Local Ethics and Experimental Research Committee.

2.2. Surgical technique

In both groups, surgery was performed using an arthroscopic technique through a trans-patellar and anteromedial portal. Surgery was performed either with spinal or general anesthesia according to patient preference. We always prescribed prophylactic antibiotics and antithromboembolic medication both pre- and post-operatively. The patient was placed in the supine position. In all patients, we placed an ischemic band at the root of the lower limb.

Complete diagnostic arthroscopy was performed on every patient to confirm the ACL tear and to address any meniscal or chondral injuries. Gracilis and semitendinosus tendons were harvested through a small incision made over the pes anserinus and were prepared with bunnel sutures. Both tendons were pretensioned. The diameters of the grafts were measured in 0.5 mm steps, and the femoral tunnels were drilled according to the diameters of the grafts that were considered.

The extra-articular landmark of the tibial tunnel was always one centimeter above the insertion of the pes anserinus and 1.5 cm medial to the tibial tubercle. The tibial tunnel was drilled using a standard tibial guide. An impingement rod was used to prevent the femoral roof from impinging on the graft. In the coronal plane, the tibial drill guide was inclined to place one guide-wire at 60° relative to the medial joint line of the tibia. In the sagittal plane, drill guide inclination was 50°.

The intra-articular point of the tibial guide was placed at the center of the native tibial footprint of the ACL. After insertion of the guide pin, a tibial tunnel was created using a reamer of the same diameter as the graft. After the tibial tunnel was established, an offset guide was placed through the tibial tunnel. The femoral tunnel was drilled through the tibial tunnel with the knee flexed at 90° on a pin guide located in the center of the anatomical ACL insertion (at 10 o'clock for right knee and two o'clock for left knee), seven millimeter anterior to the posterior margin of the lateral femoral condyle.

The tunnel was drilled over the guide pin using a 3.5 mm drill in Group A and a 4.5 mm drill in Group B. The length of the tunnel was then measured, and a femoral tunnel of the necessary length was drilled to place the graft.

In Group A, the graft was pulled up to the ceiling of the femoral tunnel. In Group B, we set six to eight millimeters as the EB distance of the 'flip' movement.

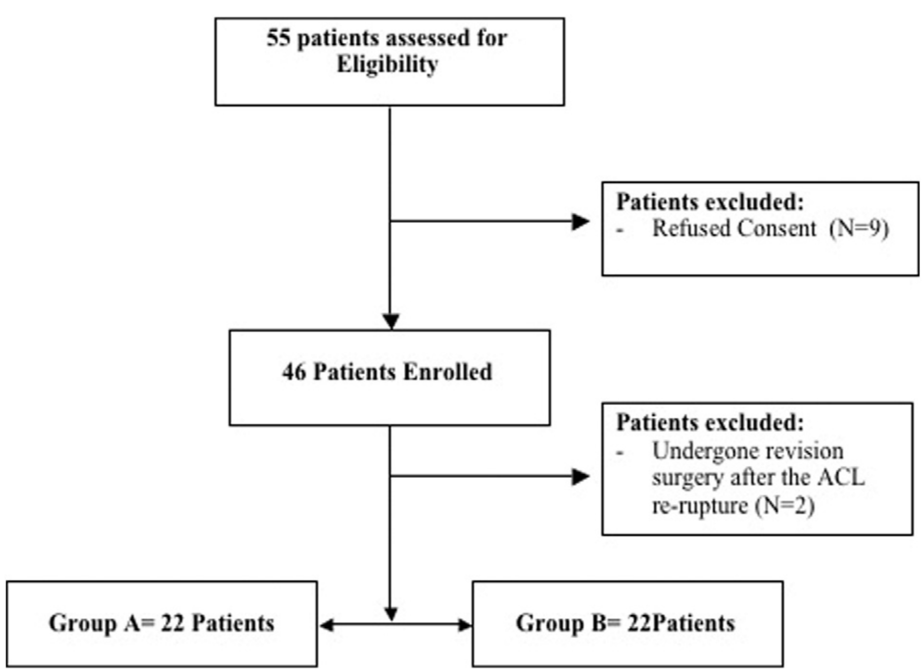

Figure 1. Participant flow chart.