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Can an expansion device be used in anterior cruciate ligament reconstruction? An in vitro study of soft tissue graft tibial fixation

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ABSTRACT

Background: The purpose of this study was to compare the mechanical properties of an interference screw with an expansion device in anterior cruciate ligament (ACL) reconstruction.
Methods: A total of 52 porcine tibia and 20 polyurethane foam blocks (0.16 g/cm^3) were used. Forty pullout tests were carried out to combine the two types of bones – surrogate and porcine – with the two fixation systems: interference screw and expansion device (n = 10 per group). Thirty-two cyclic tests (n = 8 per group) were carried out with both fixation devices in porcine bone at two different force amplitudes (100 N and 200 N).
Results: Stiffness and load values (mean ± SD) at six millimeters of displacement for the expansion device and the interference screw were 74 ± 33 N/mm, 318 ± 135 N, and 52 ± 28 N/mm, 205 ± 70 N, respectively, showing a difference in stiffness ($P = 0.016$) and load at six millimeters of displacement ($P = 0.001$). No correlation between insertion torque and the ultimate failure load was found for both fixation devices tested. In cyclic tests, significantly higher ($P < 0.001$) numbers of cycles (mean ± SD) were reached with the expansion device (81,014 ± 30,291 at 100 N; 13,462 ± 11,351 at 200 N) than with the interference screw (15,100 ± 8623 at 100 N; 343 ± 113 at 200 N) at six millimeters of displacement.
Conclusion: The use of an expansion device for ACL reconstructions seemed to be a promising alternative to an interference screw. Insertion torque alone was not a useful predictor of graft fixation strength in ACL reconstructions.

1. Introduction

In anterior cruciate ligament (ACL) reconstructions, fixation of the graft to the bone tunnels, especially on the tibial side, is the weakest link in the reconstructions, at least during the initial period of rehabilitation [1,2]. Thus, several fixation devices have been developed and tested. One of the most commonly used devices in ACL reconstruction is the interference screw, which is either metallic or bioabsorbable [3–5]. However, some researchers have reported problems using this device due to graft laceration with the screw threads during introduction [6], or the lack of parallelism (named divergence) between the bone tunnel and screw axis [7–9]. This divergence means that even when the surgeon applies a high insertion torque while introducing the device, the quality of the fixation is very poor. To maintain the advantages of the interference screw and overcome its drawbacks, many researchers have designed fixation devices based on the concept of radial expansion, sometimes using a sheath device [10–12]. Divergence is caused by lack of available space when inserting the screw into the bone tunnel, which is already occupied by the graft. Therefore, the screw thread makes its own hole in the bone. When using an expansion device, because the device is gently tapped into the tunnel, no divergence is expected.

In essence, radial expansion devices are placed into the bone tunnel without an insertion torque or with a very low one, avoiding graft laceration and screw divergence. Once inside the bone tunnel, the surgeon expands the device, generating compression forces that produce enough friction to resist the pullout force. As indicated by Smith et al., [13] the greater this radial force, the higher the pullout strength of the ACL reconstruction.

Therefore, the aim of this study was to compare the behavior of one of these expansion devices [14,15] with an interference screw. The main advantage of the studied expansion device is that it allows a final cylindrical shape, so the compression force along the graft is expected to be more uniform. The hypothesis was that the behavior of the two fixation systems was not statistically significantly different.

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2. Materials and methods

Fifty-two porcine tibiae and twenty artificial bone blocks were used. These were solid, rigid polyurethane foam blocks (Sawbones, Pacific Research Laboratories, Inc., WA, USA) of 10 lb./ft^3 (0.16 g/cm^3) laminated with a three-millimeter, solid, rigid foam sheet of 40 lb./ft^3 (0.64 g/cm^3), simulating a cortical shell. Foam blocks were cut into a block of 42 × 40 × 40 mm, which was considered sufficient to avoid edge effects. Bovine forelimb extensor digitorum tendons were obtained from a local slaughterhouse and were wrapped in gauze soaked in normal saline just after the killing of the animals, and stored at −20 °C until tested. Bovine tendons were used as a graft because they match the biomechanical properties of human double-looped semitendinosus and gracilis grafts [16]. The porcine tibiae, after removing all muscles and soft tissues, followed the same handling and storage protocol.

Two ACL fixation systems were tested: an interference screw (Propel, 9 × 30 mm, Linvatec, Largo, FL, USA) and a new fixation system based on radial expansion [14,15]. A nine-millimeter interference screw was used because it was found to have a significantly higher failure load than a seven-millimeter diameter screw [17]. The main dimensions of the radial expansion device were 31.8 mm length and an unexpanded nine millimeter diameter. Final diameter was 11.5 mm, which was achieved after inserting the 3.8 mm diameter interior screw (Figure 1).

Twenty-four hours before pullout testing, the bones and tendons were thawed to room temperature. Throughout the handling and test periods, the specimens were kept damp by using a nebulizer with normal saline, and preparation and tests were carried out at room temperature. In the porcine bones, tunnels were created following a 45° angle with the longitudinal axis, entering at the lateral side of the tibial tuberosity and exiting from the upper part of the tibia, approximately at the natural insertion point of the ACL. In the artificial bone blocks, tunnels were made perpendicular to the laminated cortical shell, exiting from the opposite face. The tunnel diameter depended on the fixation system: nine millimeter (C-Reamer, Conmed Linvatec, Largo, FL, USA) was used for the interference screw, as usually used, whereas 10.5 mm (Badger, Conmed Linvatec, Largo, FL, USA) was employed for the radial expansion device because in previous tests, it was found that this tunnel diameter gave the best performance. Tendons were classified by diameter (measured with a custom-made tendon caliper); the 6.5-mm tendon was used for the interference screw reconstructions and the 6.0-mm tendon was used for the radial expansion device reconstructions. Tendons that were damaged due to cuts or lacerations were discarded.

For each test, a tendon was taken and its ends were sutured to make a double-looped graft that was inserted into the tunnel with the assistance of the sutures. Approximately four centimeters of the tendon was left extending out from the upper part of the tibia or the artificial bone block. The loop at this end of the tendon was used to hold the graft to a hook in the upper grip of the testing machine. The radial expansion device or interference screw was then inserted. The expansion device was gently tapped into the tunnel and the inner screw, which allows expansion, was inserted. The interference screw was inserted using a 3.5-mm Allen key. Maximum insertion torque during both fixation system insertions was recorded using a digital torque meter (DR-2453, Lorenz Messtechnik GmbH, Alfdorf, Germany) mounted on the Allen key.

Twenty pullout tests were carried out for each fixation method and two types of bone model (artificial and porcine) were used, resulting in $n = 10$ for each subgroup. Each bone model fixation system graft complex was subjected to a pullout test until failure, at a rate of 30 mm/min on a material-testing machine (EFH/5/FR, Microtest S.A., Madrid, Spain). The artificial bone blocks were placed directly in the lower machine jaw, whereas for the tibia, a custom-made jaw was used to hold it at an angle of 45° to the vertical axis of the testing machine (Figure 2). In both cases, the force was along the tunnel axis, representing the worst-case scenario for analyzing a fixation technique [18]. A small tension of 5 N was applied to all constructs for three seconds to establish the zero value for displacement [19]. The test ended when the graft was pulled out of the bone (either artificial or porcine) and could not take any more loading. The load was recorded using the 5 kN testing machine load cell (error ± 5 N) and displacement was recorded using the testing machine linear variable differential transformer (error ± 0.05 mm), so that the crosshead

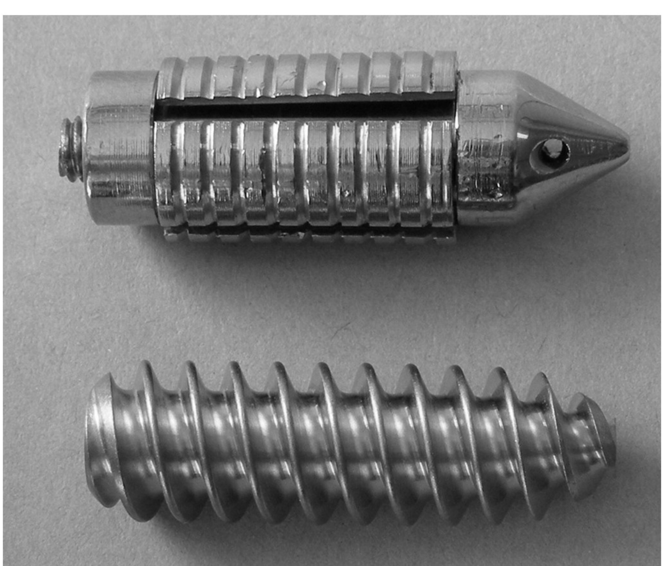

Figure 1. The two devices used in this study. Above: new radial expansion device. Below: interference screw.

Figure 2. Tibia specimen prepared for the test. The loop of tendon placed on the upper part is observed.