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Mechanical properties of suspensory fixation devices for anterior cruciate ligament reconstruction: Comparison of the fixed-length loop device versus the adjustable-length loop device

Akio Eguchi [a,*], Mitsuo Ochi [a], Nobuo Adachi [a], Masataka Deie [a,b], Atsuo Nakamae [a], Muhammad Andry Usman [a]

[a] Department of Orthopaedic Surgery, Graduate School of Biomedical & Health Sciences, Hiroshima University, Hiroshima, Japan
[b] Department of Physical Therapy and Occupational Therapy Sciences, Graduate School of Biomedical & Health Sciences, Hiroshima University, Hiroshima, Japan

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ABSTRACT

Background: No definite consensus has been reached regarding the optimal technique for graft fixation to the femur in an anterior cruciate ligament reconstruction. The purpose of this study was to evaluate the mechanical strength of two cortical suspension devices which were the TightRope (TR), a new adjustable-length loop device, and the EndoButton (EB), a well-established fixed-length loop device.
Methods: The devices were tested under cyclic and pull-to-failure loading conditions in both an isolated device setup and a specimen setup using porcine femora and bovine flexor tendons. In particular, we examined the influence of tendon and device lengths, whereby the total length of the bone tunnel was fixed to 35 mm and an effective length of tendon in the bone tunnel was adjusted.
Results: In the isolated device testing, the EB showed significantly higher ultimate tensile strength than the TR. The displacement after preloading for the EB was statistically lower than that for the TR, and retained a significant difference after the cyclic load. In contrast, specimen testing showed no statistical difference in the displacement among the EB group and TR groups.
Conclusion: This study indicated that the EB provides greater mechanical strength than the TR. An important new finding was the measurement of initial displacement from the initiation of fixation until loading began using 50 N of tension. In isolated device testing, the TR induced significantly more displacement than the EB during preloading, which could reflect the TR loop's stretching capacity until a certain amount of tension is applied.

1. Introduction

An anterior cruciate ligament (ACL) injury is the most common major sports trauma to the knee. Typically, such an injury is treated by ACL reconstruction, which often involves using the hamstring tendon or bone–patellar tendon–bone as autogenous grafts [1,2]. Various techniques have been developed for graft fixation to the femur, the strength of which must be ensured to facilitate healing and return to normal function [1]. Several fixation devices are available for use in ACL reconstructions such as cortical suspension devices, transfixation devices, and interference screws; however, a definite consensus has not been reached regarding which fixation technique is optimal [3,4]. We currently use the EndoButton CL (EB), a cortical suspension device, and several studies have already demonstrated its mechanical strength [5–10]. A potential disadvantage of EB is the requirement for an additional 6-mm overdrilling of the femoral socket to flip the button. Because minimizing overdrilling is thought to produce a better clinical outcome in terms of bone preservation, stability of the tendon graft, and bone–tendon healing, a new device was recently developed, the TightRope RT (TR) [11]. TR has adjustable-length loops that can be tightened intraoperatively, thus avoiding the necessity for overdrilling and enhancing bone preservation by not leaving excess space in the bone tunnel. However, there are doubts as to whether the TR device could come loose and whether it provides adequate mechanical strength. Few studies have actually evaluated and compared mechanical strength among the fixation devices used for ACL reconstruction [12]. Therefore, we aimed to compare the mechanical strength of TR and EB devices under the same conditions by reproducing the actual clinical situation. Our hypothesis is that these two devices would provide similar mechanical strength regardless of the length of the bone tunnel and length of the device.

2. Materials & methods

The devices tested in this study were the Endobutton CL ultra with 20 mm Continuous Loop Suture (Smith & Nephew Inc., Andover, MA),

* Corresponding author at: Department of Orthopaedic Surgery, Graduate School of Biomedical & Health Sciences, Hiroshima University, 1-2-3 Kasumi, Minami-ku, Hiroshima 734-8551, Japan. Tel.: +81 82 257 5233; fax: +81 82 257 5234.
E-mail address: eguchi-ak@hiroshima-u.ac.jp (A. Eguchi).

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a fixed-length loop device, and the TightRope RT (Arthrex Inc., Naples, FL), an adjustable-length loop device (Fig. 1). Each device was tested in two separate protocols. First, the biomechanical properties of each device were tested in the absence of a specimen (isolated device testing). Second, each device was tested in an ACL femoral fixation model using a porcine femur and bovine flexor tendons for simulating a clinical ACL reconstruction (specimen testing).

2.1. Set up for isolated device testing

The biomechanical data of a fixation device during a reconstruction procedure are influenced by the properties of both bone and tendon. Thus, to determine the actual biomechanics of the device structures without influence from a biological environment, initial testing was done using a custom-made apparatus comprising a steel plate serving as the cortex and force applied to the loop with a steel hook. The cortical buttons were inserted through a tunnel in the steel plate, with the diameter of the tunnel corresponding to the manufacturer's recommendation for the femoral cortical diameter. Tunnel diameters were 3.6 mm for the TR, and 4.5 mm for the EB.

The TR was looped over a J-hook attached to the actuator of the MTS 858 Mini Bionix testing machine (MTS, Eden Prairie, MN), and the steel plate was clamped at a length of 20 mm into the vice on the 5-kN load cell. The loop was then tightened after ensuring a consistent loop diameter for each device. The EB was looped over a J-hook, and the steel plate was also clamped at 20 mm into the vice; there was no need to tighten with this fixed-length loop device (Fig. 2A). Ten devices from each group were tested in this fashion.

2.2. Set up for specimen testing

Adult porcine rear limbs were obtained frozen from a nearby meat packing plant (Valley Brook Farm, Madison, GA) and all soft tissue was removed from the femur. Bovine flexor tendons (Farm to Pharm L.L.C., Warren, NJ) were used as the grafts, cut to 180 mm in length, and whip stitched with #2 Ultrabraid sutures at the ends with 5 to 6 throws. Two tendons were doubled over to make a single-bundle tendon graft of 8 mm in diameter after looping the graft around the cortical suspension device to be tested. All specimens were kept moist with physiological saline solution during specimen preparation, fixation procedures, and biomechanical testing.

The implants were placed according to the surgical guides accompanying each device and a manufacturer representative, unless otherwise indicated. The femoral tunnel was placed in the center of the porcine ACL footprint, and aimed with the 2.4-mm passing pin (Smith & Nephew) from the footprint to the lateral cortex using an Acufex femoral aimer guide (Smith & Nephew) to fix the tunnel length at 35 mm. The tunnel was drilled in 21 mm for the EB group and either 21 mm (TR21 group) or 15 mm (TR15 group) for the TR devices using an 8-mm acorn reamer (Smith & Nephew). This allowed an effective tendon length in the femoral tunnel of 15 mm for the EB and TR15 groups, and 21 mm for the TR21 group (Fig. 2B). Finally, the remaining tunnel was drilled with a 4.5-mm drill (Smith & Nephew) through the cortex for the EB group or a 3.5-mm RetroButton Drill Pin II (Arthrex) for the TR groups. The graft looping around the EB was inserted into the femoral tunnel using an eyelet pin loaded with the lead suture. The device was pulled through the femoral tunnel by applying tension to the lead suture and then flipped after being pulled through the cortex at the proximal end of the tunnel by applying tension to the trailing suture. The device was fixed with the button perpendicular to the outer femoral cortex while distal traction was applied to the graft. For the TR, the graft looping was passed through the femoral tunnel using passing suture and flipped on the lateral cortex. The graft was pulled into and seated fully in the tunnel by slowly pulling the tensioning sutures proximally.

The femur was cut to fit inside the slotted block that allowed force in line with the bone tunnel, and secured to prevent sliding during the mechanical testing using clay (Fig. 3A–C).

The MTS 858 with 5-kN load cell was set up on the bottom and the slotted block with femur on top, and attached using a CryoClamp with dry ice into the load cell. Thread sutures from the graft were pretensioned to 1 lb (0.45 kg) with weights for each tendon and secured by the CryoClamp with 40 mm between the clamp edge and the femur bone tunnel exit as measured with a standard metric ruler (Fig. 3D). Throughout the cyclic loading testing and the tensile failure testing, the clamp temperature was maintained at approximately −15 °C, and tendon temperature between approximately 18 and 19.5 °C, as monitored with a Professional 4-Volt Infrared Thermometer (Ryobi Tools, Anderson, SC) [6]. Ten specimens from each group were tested in this fashion.

2.3. Testing protocols

A constant preload of 50 N was applied to the device or the specimen for 30 s while the displacement, named preload displacement, reached a plateau that was manually recorded. Cyclic testing was performed by sinusoidal loading from 50 to 250 N at a frequency of 2 Hz for 2000 cycles. After cyclic loading, the devices and specimens were further displaced at 1 mm/s until failure. The first visible drop in load, named the ultimate tensile strength, was noted and the type of load failure was determined [5–9,12].

Data were collected with MTS FlexTest software (MTS) over the entire cycling protocol at a sampling frequency of 102.4 Hz. Data acquisition was force-driven, such that every time the increment level was crossed, the maximum force in that segment was recorded along with the corresponding displacement. The load and displacement data were collected at 50-N increments during cyclic loading and at 1-N increments during load to failure. The maximum displacement after the initial 50 cycles, named the initial displacement, was recorded, as was

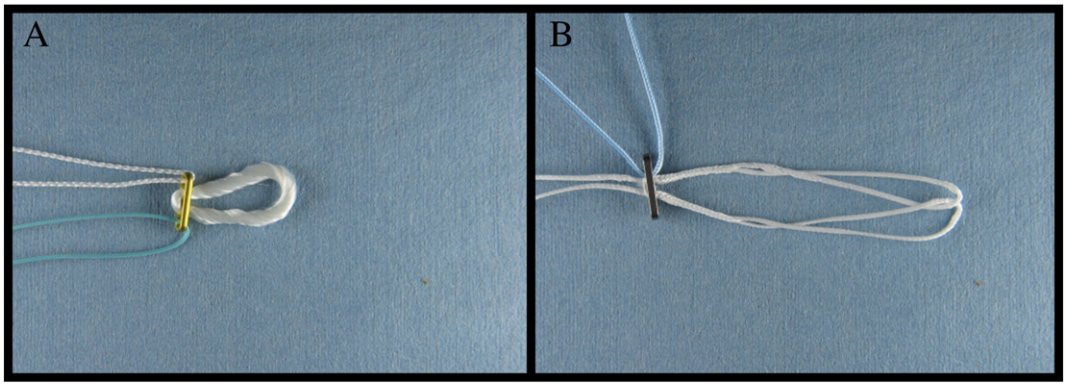

Fig. 1. (A) Endobutton CL ultra with 20 mm Continuous Loop Suture (Smith & Nephew Inc., Andover, MA). (B) TightRope RT (Arthrex Inc., Naples, FL).