



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



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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.

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## 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),

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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 pre-tensioned 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  $-15^{\circ}\text{C}$ , and tendon temperature between approximately 18 and  $19.5^{\circ}\text{C}$ , 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

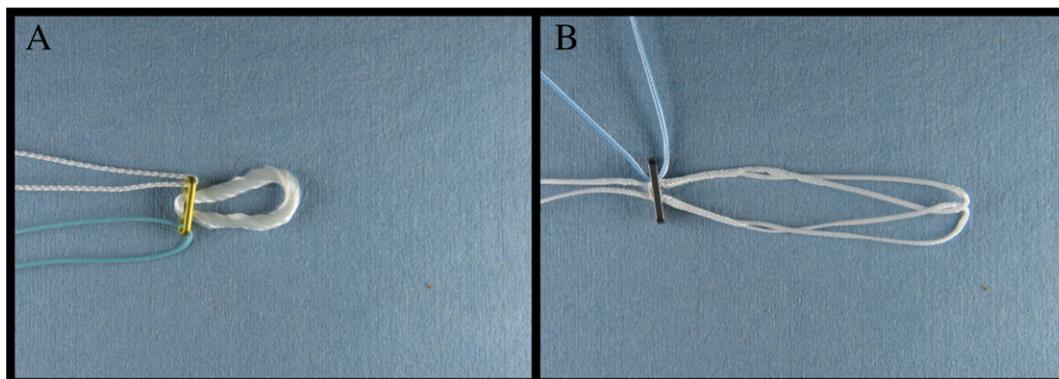


Fig. 1. (A) Endobutton CL ultra with 20 mm Continuous Loop Suture (Smith & Nephew Inc., Andover, MA). (B) TightRope RT (Arthrex Inc., Naples, FL).

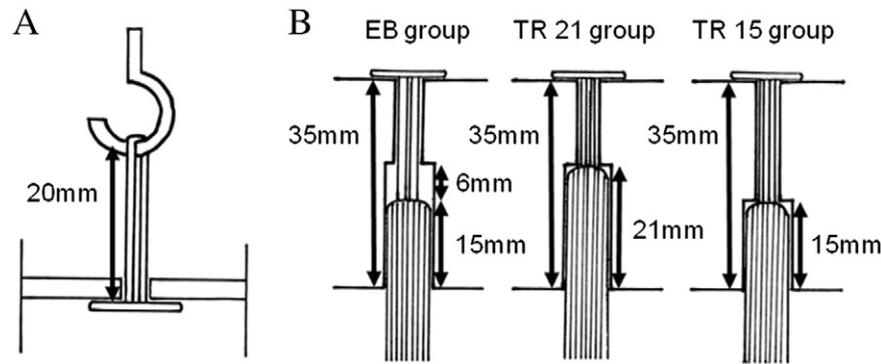


Fig. 2. (A) Set up for isolated device testing. (B) Definition of femoral tunnel length for specimen testing.

the maximum displacement after the 100, 500, 1000, and 2000 cycles, named the cyclic displacement. The load cell range was 0 to 10,000 N with a tolerance of  $\pm 1\%$  of applied load.

#### 2.4. Statistical analysis

Statistical analysis was performed using Statview 5.0 (SAS Institute, Cary, NC). The study compared data for isolated device testing using Student's *t*-test and for specimen testing using one-way analysis of variance (ANOVA). For ANOVA values that demonstrated a statistically significant difference, a post hoc Tukey HSD (honestly significant difference) test was conducted to assess the location of the means that were statistically significant between the groups. Significant difference was determined at  $P < 0.05$ .

### 3. Results

#### 3.1. Isolated device testing

All displacement values, after preload and at every time point of the cyclic loading, were significantly lower for the EB than for the TR (Table 1 and Fig. 4). In the EB group, the total displacement, which is the sum of preload displacement and cyclic load displacements, was also significantly lower than that in the TR group (Table 1). Additionally, the EB showed less displacement during the 50–2000 cycles than the TR, even after correcting for the early large displacement observed with the TR (Fig. 5). The ultimate tensile strength of

the EB device ( $1430 \pm 148$  N) was significantly higher than that of the TR ( $866 \pm 53$  N) as shown in Table 1. There were no differences in failure type between EB and TR.

#### 3.2. Specimen testing

There was no statistical difference in displacement after preload among the EB ( $1.06 \pm 0.30$  mm), TR21 ( $1.76 \pm 2.28$  mm), and TR15 ( $1.51 \pm 1.78$  mm) groups (Table 1) or at any time point of cyclic displacement (Fig. 6). However, our more detailed analysis of the mean displacement during 50 to 1000 cycles and 1000 to 2000 cycles revealed a significantly higher displacement in the second half of the 1000 to 2000 cycles for the TR21 group compared to the TR15 group (Fig. 7).

The ultimate tensile strength measurements were  $1115 \pm 274$  N for the EB group,  $880 \pm 60$  N for TR21, and  $860 \pm 70$  N for TR15. Thus, EB showed significantly higher apparent strength than either TR21 or TR15 (Table 1). The most frequently recorded failure type for the EB constructs was breakage of tendon (80%). For TR constructs, failure occurred mainly due to breakage of loop (90% in TR21, 70% in TR15) rather than breakage of tendon (10% in TR21, 20% in TR15).

### 4. Discussion

This study rejected the null hypothesis in showing significant differences between the EB and TR fixation devices. Although significant differences were not noted in the specimen testing, the preload displacement and cyclic displacement values recorded in the isolated device testing were significantly smaller with EB than with TR. The EB also had a greater ultimate tensile strength than the TR in both isolated device testing and specimen testing.

EB is currently the accepted standard fixation device for multi-stranded hamstring tendon grafts in ACL reconstructions, despite the potential disadvantage of EB that it requires additional overdrilling of the femoral socket to flip the button, possibly leading to graft motion within the tunnel. Rodeo et al. [13] reported that relative motion between the tendon and bone was highest and healing slowest at the intra-articular tunnel apertures. In addition, ingrowth of new bone around the tendon graft in the femoral tunnel was inversely proportional to the magnitude of graft-tunnel motion, with slower ingrowth and a wider tendon-bone interface at the tunnel aperture [14–16]. According to this, micromotion may influence the speed of graft ingrowth, and thus the time to final healing.

Recently, the adjustable-loop device was developed to avoid excessive overdrilling into the bone tunnel; however, few reports have been published evaluating these devices. Petre et al. [12] recently compared the mechanical properties of a fixed-length loop device with those of an adjustable-length loop device. However, the study report did not consider the tendon and device lengths as possible influence. Since the fixed-length loop device was examined at 15 mm in length, and the adjustable-length loop device was examined at 8 mm in length, the bone tunnel length was not a constant factor. It is critical that such testing for the mechanical strength of devices should be performed under consistent conditions. In addition, many similar studies only started measuring once preloading was complete, during which a certain amount of displacement is known to occur. The second problem with the study of Petre et al. [12] is that they did not measure the initial

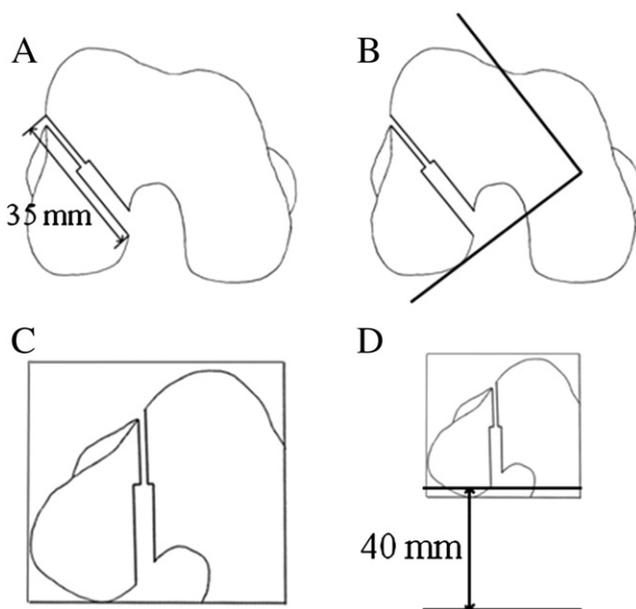


Fig. 3. (A) Total tunnel length for specimen testing. (B) Cut line of femur. (C) Fitting inside the slotted block that allowed force in line with the bone tunnel. (D) Secured position between the clamp edge and the exit of the femoral bone tunnel.

**Table 1**  
Results of cyclic load testing and load-to-failure testing.

	Preload displacement (mm)	Cyclic displacement after 2000 cycles (mm)	Total displacement = preload + cyclic (mm)	Ultimate tensile strength (N)	Failure type
<b>Isolated device testing</b>					
Endobutton	1.09 (0.29)	0.94 (0.08)	2.03 (0.31)	1430 (148)	Loop broken (90%), Incomplete testing (10%)
TightRope	2.57 (1.19)	1.49 (0.17)	4.05 (1.16)	866 (53)	Loop broken (90%), Incomplete testing (10%)
P-value	0.0013	<0.0001	<0.0001	<0.0001	
<b>Specimen testing</b>					
Endobutton	1.06 (0.30)	4.82 (0.97)	5.88 (1.06)	1115 (274) ***	Tendon ruptured (80%), Button broken (10%), Loop broken (10%)
TightRope 21	1.76 (2.28)	5.98 (1.22)	7.74 (2.52)	880 (60) *	Tendon ruptured (10%), Loop broken (90%)
TightRope 15	1.51 (1.78)	5.43 (1.21)	6.39 (2.32)	860 (70) **	Tendon ruptured (20%), Loop broken (70%), Incomplete testing (10%)

All values shown are means with standard deviations in parentheses.

\* Significant difference ( $P < 0.05$ ) between EB and TR21.

\*\* Significant difference ( $P < 0.05$ ) between EB and TR15.

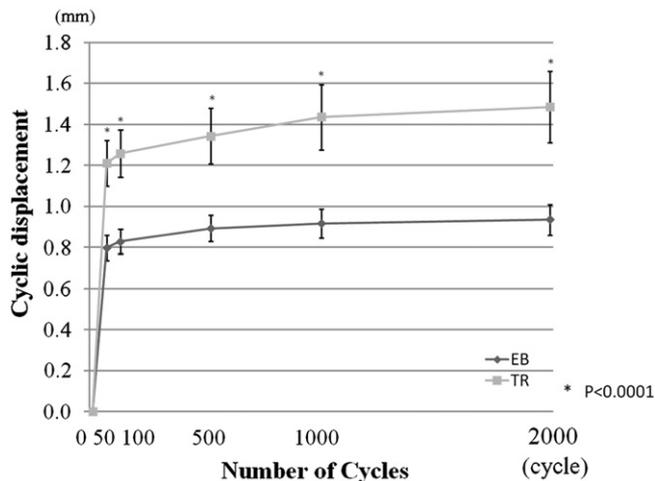
displacement; i.e., from unloaded to applying the preload. Due to the device structure, displacement might occur during the phase prior to preloading. Therefore, it is important to measure the initial displacement. Mechanical testing in the current study precisely defined the bone tunnel length and evaluated the displacement up to the preloaded state.

An important new finding from the current study was the measurement of preload displacement from the state of initial fixation until loading began and 50 N of preload tension was applied. In isolated device testing, the TR provided significantly more displacement than the EB during preloading, which could reflect the stiffness of the EB loops. In contrast, the TR's loops stretch until a certain amount of tension is applied; once tension exceeds that threshold, the Chinese finger trap design fixes the device. The current measurements indicated that the TR loop length setting of 20 mm stretched 2.57 mm until 50 N preload was applied. Although specimen testing did not reveal the same significant differences, large deviations were observed in the TR. Thus, substantial tension slackness was noted with some of the TR devices, while other TR devices showed no slackness before preloading. According to this testing, these failures tended to occur when the bone tunnel was too tight, with possible causes being slackness due to poor closing of the loop or too much play accompanying poor placement of the button and loop. In other words, the TR offers the advantage of being an adjustable-length loop device, but it includes elements of uncertainty

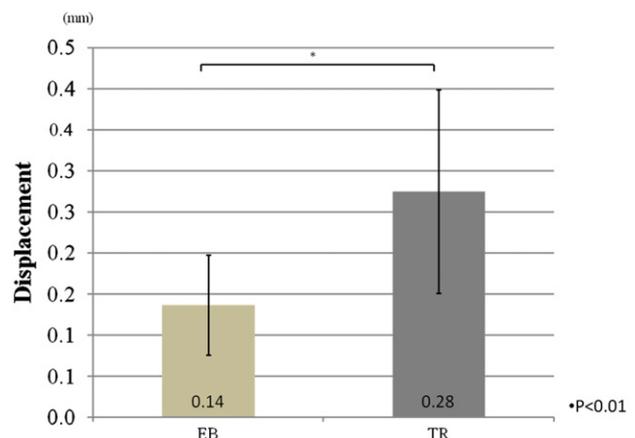
because of operating the device within the bone tunnel, such as the need to change the loop length inside the bone tunnel, difficulty in getting the flip response compared to the EB, and the potential for button floating due to drawing the button proximally when shortening the loop. Thus, adequate care must be taken when using these devices in actual clinical practice, especially when shortening strands for the graft seated fully in the tunnel and ensuring sufficient reverse tensioning by pulling back the graft distally.

In isolated device testing with a cyclic load of 50 cycles initially, displacement was significantly greater with the TR than with the EB, and the extent of gradual stretching with a load of 2000 cycles was significantly greater with the TR, although both of these displacements were minimal. In terms of total displacement, this difference was only 0.55 mm between the EB and the TR, which is probably not clinically significant, but achieving consistent fixation and greatly limiting micromotion are crucial for healing of the tendon graft.

In specimen testing, the EB had less displacement than the TR, which may facilitate healing. But in the cyclic displacement during 50 to 1000 cycles and 1000 to 2000 cycles, every displacement is less than 3 mm for both types of device, which is what has been reported as being necessary to ensure the graft healing. The clinical relevance is not obvious but needs to be clarified since there were very few differences. On the other hand, TR has the advantage of avoiding excessive



**Fig. 4.** The mean displacement after 50, 100, 500, 1000, and 2000 cycles for isolated device testing.



**Fig. 5.** The mean displacement during 50 to 2000 cycles for isolated device testing.

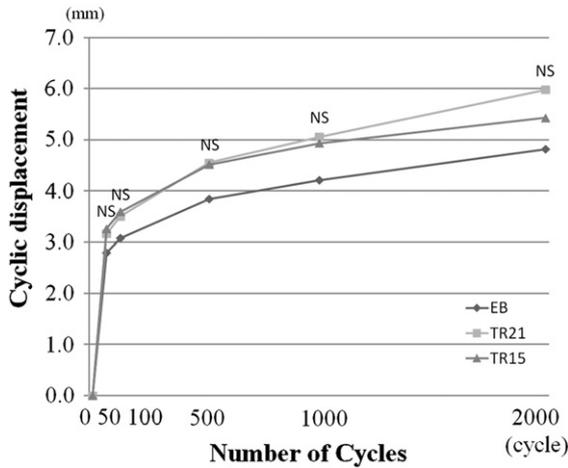


Fig. 6. The mean displacement after 50, 100, 500, 1000, and 2000 cycles for specimen testing.

drilling. Nevertheless, it is unclear how much the 6-mm excessive space influences the bone–tendon healing. This space may not be of clinical significance, especially if the ingrowth of new bone around the tendon graft occurs at the tunnel aperture. It is evident that the TR device is useful when the bone tunnel length is extremely short for overdrilling.

The comparison of TR21 and TR15 indicated that TR21 had a significantly larger rate of stretching with a cyclic load from 1000 to 2000 cycles. In the current study, specimen testing indicated that the length of tendon in the bone tunnel was a major factor affecting displacement rather than the stretch of the device. Specifically, the current study performed reconstruction by adjusting the length of the device so that the usual length of tendon inside the bone tunnel would be about 15 mm. Having a length of tendon >15 mm inside the bone tunnel may therefore be inappropriate in terms of facilitating healing of the tendon graft, although conversely, it may introduce the disadvantage of reduced mechanical strength [17].

Petre et al. [12] noted that the ultimate failure strength was 1456 N for the EB and 841 N for the TR in isolated device testing, and this supports the current results. However, the true maximum tensile strength of the EB could not be accurately measured by the current specimen testing, because the tendon had previously torn in most of the EB group cases and the loops of the TR had already ruptured under the same conditions. Under clinical conditions, although the forces on the

ACL graft during the postoperative period are not accurately known [18–21], Serpas et al. [22] reported the ACL force in normal walking to be 590 N. Thus, the adequacy of mechanical strength of these cortical suspension devices remains uncertain and further examination is required in the future.

There are several limitations to the current study. First, although this study involved a model simulating ACL reconstruction under actual clinical conditions, the strength of porcine bone and the elasticity of bovine tendons could differ from the equivalent factors in human. However, this model has already been used in similar biomechanical studies. Second, mechanical loading was in line with the bone tunnel, so accurate reproduction of the flexion and extension of the knee and load bearing was not possible. Third, healing of the bone tunnel and tendon is considered to take 8–12 weeks, but the current study was merely a mechanical study conducted at time zero. Thus, the extent to which this study was able to draw any conclusions on healing differences between devices is unclear. The model in the current study is effective for comparing device strength.

### 5. Conclusion

The EB has some advantages over the TR with respect to biomechanical properties and handling, although the design adopted to avoid excessive overdrilling is currently inferior to that used in the adjustable-length loop devices. According to our results, the observed displacement might actually be diminished by meticulous preconditioning of the graft–implant complex before fixation; thus, both the EB and the TR should be used effectively in clinical practice until we can ascertain better ways to prevent clinical failure.

### Conflict of interest

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

### Acknowledgments

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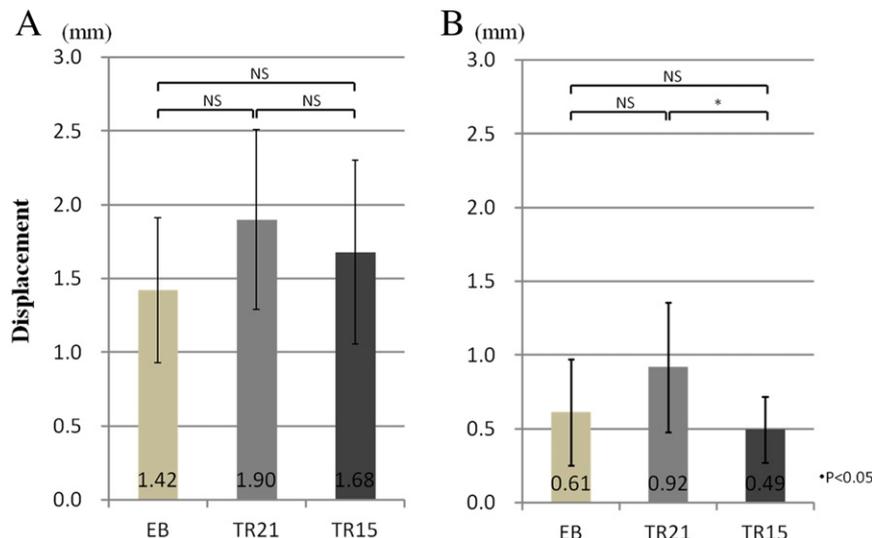


Fig. 7. The mean displacement during 50 to 1000 cycles (A) and 1000 to 2000 cycles (B) for specimen testing.

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