Ultimate Load Measuring System for Fixation of Soft Tissue to Bone

ABSTRACT

Background: The initial ultimate load for graft fixation is one of the essential factors in the reconstruction of lateral ankle ligaments. Several anchoring devices have been developed to fix the substitute ligament into the bone. A fair comparison of these fixation methods warrant a reproducible examination system. The purpose of this study was to make an experimental animal model and to compare the initial ultimate loads of 3 graft fixation methods, including the use of EndoButton (EB), interference screw (IFS), and a novel socket anchoring (SA) technique.

Methods: Porcine calcaneus bones and 5-mm-wide split bovine Achilles tendons were used as fixation bases and graft materials, respectively. Both ends were firmly sutured side-by-side, using the circumferential ligation technique as a double strand substitute that was 45 mm in length. Porcine calcanei with similar characteristics to adult human calcanei were mounted on a tensile testing machine, and substitutes were fixed into bones using the 3 fixation methods. A polyester tape was passed through the tendon loop and connected to a crosshead jig of the testing machine. The initial ultimate loads were measured in 15 specimens for each fixation method to simulate a lateral ankle ligament (LAL) injury.

Results: The ultimate loads (ULs) were 223.6 ± 52.7 N for EB, 229.7 ± 39.7 N for SA, and 208.8 ± 65.3 N for IFS. No statistically significant difference was observed among the 3 groups (*P* = .571). All failures occurred at the bone–ligament substitute interface.

Conclusions: The initial ULs in all 3 fixation methods were sufficient for clinical usage. These values were larger than the UL of the anterior talofibular ligament; however, these were smaller than the UL of the calcaneofibular ligament.

Clinical Relevance: In an experimental animal model, ULs for SA, EB and IFS techniques showed no significant difference. All failures were observed in the fixation site of the calcaneus and were overwhelmingly related to suture fixation failure.

Keywords: Lateral Ligament, Ankle; Calcaneus; Achilles Tendon; Bone Screws; Ankle; Models, Animal

INTRODUCTION

Various repairs and reconstructions of lateral ankle ligaments have been developed for patients with chronic ankle instability.[4,6,7,9,12,15,21,25,26,28] The recurrence of instability after lateral ankle ligament reconstruction (LALR) has been reported to be between 2% and 18%.[19,24]

There are multiple factors that affect the treatment results of reconstruction procedures for chronic lateral ankle ligament (LAL) insufficiency. The insertion site of the graft, selection of a substitute ligament, and fixation methods are the most critical factors.[23] Because LALs are thin and short, it is not easy to maintain enough tension of the grafts until a complete biological integration of the bone–ligament interface is achieved to obtain ankle stability.

Many fixation methods have been developed in recent years to stabilize the soft tissue to the bone; however, few biomechanical studies have placed their focus on ankle ligament reconstruction.[16,18] Recently, the hamstring tendons were used as the graft materials [20]; however, obtaining human tendons for experimental usage can be challenging. A fair comparison of ultimate loads for several fixation methods may require a practical and reproducible system using constant materials similar to human hamstring. The mechanical properties of mammalian tendons have been reported in the literature,[10] and it appears reasonable to use a split bovine Achilles tendon as a graft substitute for the human tendon. [5,22]

The purpose of this study was to make a reproducible experimental system and to compare the initial ultimate loads of 3 tendon fixation methods—including EndoButton (EB), interference screw (IFS), and a novel socket anchoring (SA) fixation—which can be used for the reconstruction of lateral ankle ligaments to resist the inversion force in ankle sprains.

MATERIALS AND METHODS

Graft Preparation

Achilles tendons of 30-month-old bovine that were 150 mm in length were collected from the muscle-tendon junction to the calcaneal insertion. Five-millimeter-wide split tendon grafts were harvested using a scalpel from the flared proximal end up to 90 mm in length. Care was taken to avoid crossing the tendinous fibers, as they were twisting gently. Four grafts were obtained from 1 Achilles tendon.

Prior to the experiment, the mechanical properties of the graft were examined with a tensile testing machine (Autograph AG-1; Shimadzu Co., Kyoto, Japan). Both ends of the graft were augmented using a whipstitch to prevent slipping from grips. Ten grafts were used to confirm their applicability for the lateral ankle ligament reconstruction. The cross-sectional area was measured under 0.12-MPa compression force with a Cross-Section Meter (Meira Co., Nagoya, Japan). The mean and standard deviations of the cross-sectional area, ultimate load, and ultimate tensile strength were 15.56 ± 2.58 mm^2, 681.39 ± 106.82 N, and 45.3 ± 11.48 MPa, respectively (Table 1).

Both ends of the prepared split tendons each underwent a simple circumferential ligation 3 times using the manual max tension of the double strand substitute ligament of 45 mm in length. A 5-mm-wide polyester tape (Leeds-Keio artificial ligament) was passed through the tendon loop to be connected to the crosshead clamp (Figure 1).

Calcanei of 6-month-old porcine were used because of their morphostructural similarity to human bone.[1] Bone mineral density (BMD) values were measured in 7 calcanei using dual-energy X-ray absorptiometry (DEXA) (Discovery A; Hologic, Inc. Marlborough, MA, USA). The mean BMD of the calcaneal bone of porcine was 0.74 ± 0.12 g/cm^2, which matches the BMD of premenopausal women.[30]

Tensile Test

The calcaneus bone was fixed to the tensile testing machine using a 120-mm Ilizarov ring with three 1.8-mm olive wires so that the lateral surface formed a vertical plane.

A bone tunnel with a diameter of 2.4 mm was drilled on the lateral surface of the bone at an inclination of 45 degrees, and a bone tunnel with a diameter of 5.5 mm and a depth of 15 mm shared the center of the hole.

In EB fixation, No. 2 FiberWire (Arthrex Inc, Naples, FL) suture was connected to the ligation site of the substitute graft tendon, pulled out to the medial cortex, and tied firmly in a knot after passing through the buttonholes.

In SA fixation, we modified the 5 mm TWINFIX Ti suture anchor (Smith & Nephew Inc, Mansfield, MA) to a looped ω shape (Figure 2). The anchor was inserted into the bottom of the socket, and the looped part of the No. 2 Ultrabraid was connected to the graft ligation site, pulled into the socket, and tied firmly in a knot (Figure 3).

In IFS fixation, the No. 2 FiberWire connected to the ligation site of the graft was pulled out to the medial side of the calcaneus, then a 4.75mm IFS was inserted into the gap between the wall of tunnel and the graft.

In the ultimate load examination, the calcaneus was fixed on the base grip using the Ilizarov ring fixator, and the loop end of the substitute graft was connected to a polyester tape; the tape was subsequently connected to the crosshead jigs. After setup, 10-N preloads were applied 10 times. To simulate an LAL injury, the graft was then subjected to a tensile test at a speed of 10 mm/s until material breakage to determine the ultimate loads (Figure 4). [2] The ATFL and CFL are attached to the surface of the bone at a sharp angle; therefore, we created the bone tunnel at an inclination of 45 degrees to simulate an LALR.

The ultimate load test was performed using the same calcaneus in EB, SA and IFS to minimize the effect of the previous test. The test was performed for 15 specimens using all 3 fixation methods, and a fixed order was used for the test. In the first test using EB fixation, the load was supported by the medial cortex. In the second test using SA, the pullout load was supported by the cancellous bone at the bottom of the socket. In the third test using IFS, the tunnel was deepened to 25mm to remove the cancellous bone used for SA fixation and allow space for IFS while keeping the wall intact. .

Statistical Analysis

Statistical analysis was performed using 1-way analysis of variance with JMP Pro, version 15.2.1, for Mac (SAS Institute Inc. Cary, NC). The statistical significance level was set at $P < .05$ for all tests. The sample size was 45 (P=.6646; β =0.8621; statistical power = 0.1379).

RESULTS

All breakages were observed in the fixation site of the calcaneus, not in the site of the looped tendon. The relation between the crosshead displacement and tensile load of a typical specimen of each fixation is presented in Figure 5. The sharpest rise of the tensile strength was observed in IFS, and the most gentle upward slope was shown in EB. There were typically 2 peaks in the EB.

The ultimate load of each fixation method was 223.6 ± 52.7 N for EB, 229.7 ± 39.7 N for SA, and 208.8 ± 65.3 N for IFS. The *P* value was .571 among the 3 groups, and no statistically significant difference was observed (Figure 6).

In EB fixation, 11 specimens were broken at the knots on EB, and 4 breakages were observed at the ligation site of the tendon ends. In SA, ligation breakage of the tendon ends occurred in 14 specimens, and the breakage of the knot was observed in 1 specimen. There was no screw anchor pull out from the bottom of the socket.

In IFS fixation, the substitutes were pulled out from the gap between the ISF and the wall of the bone tunnel in 13 specimens, and 2 breakages were observed at the ligation site of the tendon ends.

DISCUSSIONS

We focused on the ultimate load of the initial fixation in the present study. There was no statistically significant difference in the mean ultimate loads among the 3 fixation methods in this study; however, the type of breakage was different.

The ultimate load of each fixation method was 223.6 ± 52.7 N for EB, 229.7 ± 39.7 N for SA, and 208.8 ± 65.3 N for IFS. This is roughly comparable to the findings of Attarian et al.[3] who reported a mean maximum load of the ATFL and CFL of 138.9 N and 345.7 N, respectively. Thus, the mean maximum load of the 3 fixation methods in this study was greater than the ATFL and less than the CFL.

To make a reproducible experimental model, we used the bovine Achilles tendon and porcine calcaneus of similar age. The ultimate tensile strength of the split Achilles tendon was sufficient enough to serve as a mammalian model.[29] The BMD values of the porcine calcaneus used in our study were comparable to those reported for premenopausal adult women.[3,30] Previous studies have reported that the BMD correlates with the maximum force and mechanical property of cancellous bone.[8,13,14,31] The small Ilizarov fixation ring and appropriately tensioned olive wires provided sufficient stability for the small tarsal bone. The double-bundle substitute made from a split Achilles tendon was of similar width and thickness to normal lateral ankle ligaments, and the looped side provided reliable strength.

There was no statistically significant difference in the mean ultimate loads among the 3 fixation methods in this study; however, the type of breakage was different. In EB fixation, the circumferential ligation site and the knot of the No. 2 FiberWire were weaker than the tendon and polyester tape. During the preloading, the knot of FiberWire on the EB became tighter. The FiberWire also dug into the tendon and subsequently into the suture of the graft during the first peak, which may have prevented a complete rupture as the tensile force decreased. Eventually, a bimodal failure was caused as a result of the breakage at the knot over the EB. We believe that the elongation of the total length of the grafted substitute is inevitable. Moreover, the bungee effect of the FiberWire between knots and the connection site to the tendon end cannot be avoided. [11] Therefore, a preloading maneuver is essential for EB fixation.

In SA fixation, the No. 2 Ultrabraid length was minimal and the weakest part of the substitute was the side-by-side sutured part of the grafted tendon. Secure circumferential ligation contributes to improving the initial strength. Because this fixation requires a minimum depth of the socket, the requisite graft length could be short.

In IFS fixation, the ultimate load was dependent on the friction between the tendon and tunnel wall and the friction between the tendon and the screw threads. Our study revealed that the friction between the screw and the wall of the bone tunnel was larger than the tendon side. An adequate gap control between the graft and the bone tunnel is essential to obtain suitable friction. Tomita et al.[27] showed that the collagen fibers resembling Sharpey's fibers were grown in the distraction side gap but not in the compression side in a canine ACL model and recommend IFS should be inserted in the compressive side of the bone tunnel.

There were several limitations to this study. First, this was not a cyclic loading test but a single ultimate load test. We did not clarify the effect of loosening at the fixation site. In the reconstruction of short ligaments such as lateral ankle ligaments, maintaining the graft length is important. During the dorsiplantar flexion of the ankle, the grafted ankle ligaments require some length strain even if they are in their anatomical position. The effect of these small length strain changes remains unclear. Second, we used an Ilizarov ring fixator with olive wires to stabilize the small calcaneus bone to the base of a tensile testing machine. Although this fixation technique can prevent fractures at the junction between the fixation metal and bone, we cannot account for the stiffness of the grafted ligaments owing to the elasticity of the wires. Third, we used the same calcaneus for three fixation tests. Therefore, we had to adjust the testing order to minimize the effects of the previous test. Fourth, this study may not reflect the initial fixation of the graft because both sides of the graft require fixation in actual reconstruction procedures. After the aforementioned fixation methods are performed, additional fixation is applied with an appropriate tension using a double stapler. Since 1991, we have been using a double stapling technique to maintain the initial graft tension for polyester mesh tape used as a leader for substitute. Although the double-stapling method on the lateral malleolus is strong enough for clinical applications, we did not quantitatively measure its strength in this study.

Biological union between the grafted tendon and bone has been reported to take 8 weeks to complete.[17] The role of substitute fixation is to maintain the grafted tendon in place until biological integration is achieved,[14] and the 3 methods in this study showed equivalent initial fixation for lateral ankle ligament reconstruction.

CONCLUSION

In LALR, we confirmed that the EB, IFS, and SA all demonstrated sufficient initial strength. The breaking pattern of each method showed the importance of substitute preparation. To avoid early fixation failure, repeating a small loading procedure may help achieve secure initial fixation. Care must also be taken in any fixation method until the implanted tendon achieves biological union.

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LEGENDS

Figure 1. Substitute ligament

Split bovine Achilles tendons were firmly sutured side-by-side, using the circumferential ligation technique with a double strand substitute ligament, and polyester tape was passed through the tendon loop.

Figure 2. Modified suture anchor

The TWINFIX Ti suture anchor® was modified to a looped ω shape.

Figure 3. Socket anchoring fixation

The anchor was inserted into the bottom of the socket, and the graft ligation pulled into the socket without exposing opposite side.

Figure 4. Ultimate load examination

The calcaneus was fixed on the base grip using the Ilizarov ring fixator, and the loop end of the substitute graft was subsequently connected to the crosshead jigs.

Figure 5. Load-displacement curve

An example of the ultimate load for crosshead migration length (EB: EndoButton, SA: socket anchoring, IFS: interference screw).

Figure 6. The ultimate load of each fixation method

The dots present the ultimate loads of each specimen, the two parallel transverse lines present + and - standard deviations. The central transverse lines of the diamonds indicate mean values, and the height of the diamonds indicates the 95% confidence interval. The mean ultimate load in each fixation method was 223.6 ± 52.7 N for EB, 229.7 ± 39.7 N for SA, and 208.8 ± 65.3 N for IFS. The *P*-value was .571 among the three groups, and no statistically significant difference was observed (EB: EndoButton, SA: socket anchoring, IFS: interference screw).

Table 1. Mechanical properties of the graft

The mean and standard deviations of the cross sectional area, ultimate load, and ultimate tensile strength were 15.56 ± 2.58 mm^2, 681.39 ± 106.82 N, and 45.3 ± 11.48 MPa, respectively.