Original Article

Evaluating different closed loop graft preparation technique for tibial suspensory fixation in ACL reconstruction using TightRope™

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A B S T R A C T

In most anterior cruciate ligament (ACL) reconstructions, grafts are fixed to the femoral side first followed by the tibial side. Various techniques have been reported to achieve optimal tension on the grafts, but once the grafts are fixed it is difficult to adjust graft tension further. To enable post fixation tension control we have invented a new graft configuration using an adjustable loop-device (TightRope™, Arthrex, FL, USA) on the tibial side. In this paper, biomechanical properties of this configuration using soft tissue were examined in terms of graft diameter and various suture techniques (referred to as base suture) to make a closed circle to support TightRope™.

Two experiments were conducted under different conditions. In each experiment, cyclic load, followed by a pull-to-failure load, was applied to the grafts and elongation and failure mode were recorded. (1) To evaluate the effects of diameter, 5.0 or 6.0 mm grafts were prepared by a single locking loop stitch as the base suture (SLL5, SLL6). (2) To evaluate different base sutures, 5.0 mm tendons were used, and grafts were prepared using five kinds of base sutures (SLL, ZLL: zigzag locking loop, DZLL: double zigzag locking loop, DK: double Krackow, DK w/o TR: double Krackow without TightRope™). In the first experiment, tearing was observed in 2 of 6 cases in the SLL5 test group, whereas no tearing was observed with SLL6. In the second experiment, no tearing was observed with DZLL or DK. Elongation was smaller in these two groups compared to the other groups. Mechanical strength decreases with a smaller graft diameter. Biomechanical properties differed with different base sutures and, among them, the double-zigzag-suture stitch and double Krackow provided less elongation and higher ultimate load in this graft configuration.

Introduction

Several studies have reported the optimum tension required for graft fixation during anterior cruciate ligament (ACL) reconstruction.[1–4] However, in the clinical setting, there is no standard guideline for surgical techniques to achieve this appropriate tension. Fixation is frequently performed manually at maximum force. However, many surgeons also use a tensioner to ensure precise tension. Regardless, the tension exerted immediately before fixation may not be reproduced at the time of the final fixation, and it is also unclear at the time of surgery whether the planned tension has been achieved. Such a condition can be resolved by the use of a graft preparation technique with Tight-Rope™ on the tibial side as a fixation method (assuming the proximal end of the graft would already be fixed with another suspensory device such as Endobutton™ (Smith & Nephew, MA, USA) or TightRope™. This technique enables the adjustment of tension after initial graft fixation, even though only an increase of

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tension is allowed.[5] In double bundle ACL reconstruction using hamstrings as the graft material, several fixation methods, such as interference screws, suspensory devices, and post screw fixation, are available both on the femoral side and the tibial side depending on the surgeon's choice. But most reconstruction techniques fix the femoral side of the graft first followed by fixing the tibial side under graft tensioning.

In this paper we chose adjustable suspensory devices for the tibial side to accomplish tension adjustment. Specifically, after one end of the graft is passed through a loop-button device (Tight-Rope™) the graft is folded over. Then the two free ends of the graft are joined with sutures to make a closed end. Adding a TightRope™ for tibial fixation might be a mechanical concern because the sutures on the closed free ends of the graft have to support tension of the tibial TightRope™ (Fig. 1). This also may be a challenge when using small diameter grafts that are used in double bundle reconstruction. To our knowledge, biomechanical testing to optimize suspensory fixation on the tibial side under these single looped graft configurations does not exist, and thus we tried to address this.

In the present study, we used a doubled over graft diameter of 5.0–6.0 mm—generally applied in double-bundle reconstruction[6,7]—as a standard to observe the changes in the mechanical strength of these smaller graft samples by employing different suture techniques to join the two free ends of the graft (referred to as the base suture). We verified the appropriate graft preparation technique by using TightRope™ on the tibial side at the sutured graft tails connection.

The goal of this study is to evaluate several different methods of tibial side graft preparation to achieve the suspensory fixation goals. We hypothesize:

- When the same suture technique is applied, the strength at the suture site varies depending on the graft diameter.
- When a modified suture technique is applied, grafts with a small diameter are capable of maintaining sufficient strength.

Materials and methods

To address the hypotheses, the study involved two different experiments.

Experiment

Evaluating the effect of tendon diameter

Using bovine extensor tendons, the mechanical strength and mode of failure in grafts with a different diameter were analyzed, wherein the base suture was prepared by employing a locking loop stitch technique.

Initial testing was performed with fresh frozen bovine extensor tendons (Advanced Tissue Concepts, LLC, Smithfield, UT, USA). Each sample was trimmed to a doubled-diameter of 5 mm (n = 6) or 6 mm (n = 6), and length of 60 mm, using a graft preparation station with the necessary attachments. Diameter was verified with a graft sizing block that was equipped with holes in 0.5 mm increments of diameter (AR-1886, Arthrex, Inc., Naples, FL, USA). Before suturing, one graft tail was passed through the TightRope™ABS loop (Arthrex, Inc., Naples, FL, USA), folded over in half and then sutured to the other graft tail end. A single locking loop stitch connecting the two graft tails was made starting at 20 mm from the distal tendon end with 3 locks at 5 mm intervals, distally to the tendon end using a #2-FiberLoop™ (Arthrex, Inc., Naples, FL, USA) (Fig. 2 SLL).[8]

Experiment

Evaluating the effect of different base suture

Using bovine extensor tendons, the mechanical strength of the four base suture techniques were analyzed in grafts with a diameter of 5 mm. In addition, a double Krakow locking stitch without TightRope™ABS was examined because this configuration was used in clinical settings to test unexpected adverse events that might occur with base suture plus TightRope™ABS configurations.

Bovine extensor tendons, similar to those used in Experiment (1), with a diameter of 5 mm, were used. Five suture techniques were examined (Fig. 2), and 6 samples were prepared in each of the following groups:

SLL: same as Experiment (1), single locking loop stitch with TightRope™ABS, involving 3 locks at 5 mm intervals, starting at 20 mm from the distal tendon end, moving distally using a #2-FiberLoop™.

ZLL: zigzag locking loop stitch with TightRope™ABS, involving suturing in zigzags and 3 locks at 5 mm intervals, starting at 20 mm from the distal tendon end, moving distally using a #2-
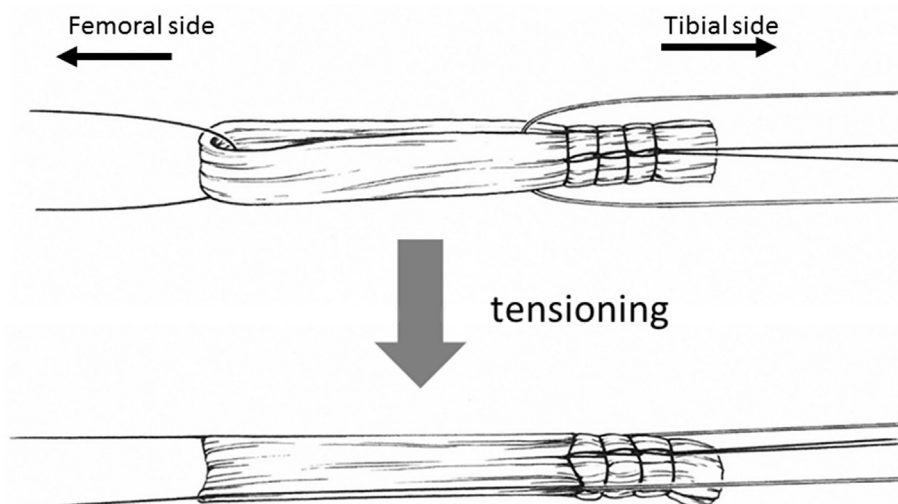

Fig. 1. Graft configuration.
A shearing load—due to traction by TightRope™—is directly applied on the tendon at the suture site, which leads to concerns regarding mechanical strength.
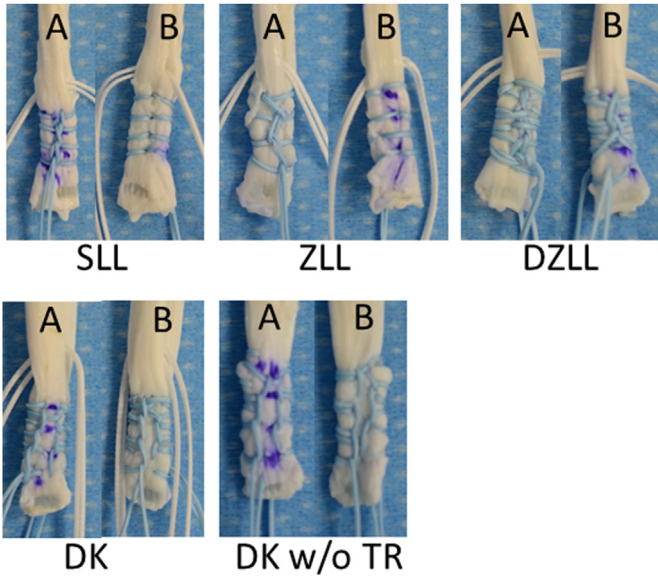
Fig. 2. Applied suture techniques.
A: locking side.
B: non-locking side.
SLL: Single locking loop stitch with TightRope™ABS.
ZLL: Zigzag locking loop stitch with TightRope™ABS.
DZLL: Double zigzag locking loop stitch with TightRope™ABS with locking loop stitches on both sides.
DK: Double Krackow locking stitch with TightRope™ABS with Krackow locking stitches on both sides.
DK w/o TR: double Krackow locking stitch without TightRope™ABS.

FiberLoop™.

DZLL: double zigzag locking loop stitch with TightRope™ABS, involving 3 locks at 5 mm intervals, starting at 20 mm from the distal tendon end, using two #2- FiberLoop™ and moving distally

while applying locking loop stitches on both sides.

DK: double Krackow locking stitch with TightRope™ABS involving 6 locks at 5 mm intervals, starting at 5 mm from the distal tendon end and turning down at 20 mm, using two #2-FiberWires (Arthrex, Inc., Naples, FL) and applying Krackow locking stitches on both sides.

DK w/o TR: double Krackow locking stitch without TightRope™ABS involving 6 locks at 5 mm intervals, starting at 5 mm from the distal tendon end and turning down at 20 mm, using two #2-FiberWires and applying Krackow locking stitches on both sides.

Biomechanical testing

Biomechanical testing was performed using Instron Materials Testing Machines (Instron Corp., Norwood, MA), which were calibrated and controlled with Instron WaveMatrix v1.8 software. A one-fourth-inch-thick metal hook was used to secure the proximal end of the doubled graft to the Instron cross-head because our focus was to examine the biomechanical properties of the tibial side. For constructs with a distal cortical button, the distal end of the graft with the TightRope™ button was secured to the testing surface with a metal box fixture and a metal plate with a 4.5 mm hole. Each sample was tensioned between 30 N and 40 N by pulling the TightRope tails. The base suture tails were then tied over the button using a six-throw surgeon's knot, as back-up fixation, and allowing for tension to be shared between the base sutures and the TightRope. The suture tails for samples without Tightrope™ (Group DK w/o TR) were secured to the testing surface with a pneumatic clamp, which was supplied with 100 psi of pressure. Examples of sample orientation within the testing machines are shown in Fig. 3.

Preconditioning of the graft involved sinusoidal loading of the sample, between 10 N and 50 N for 10 cycles at 1 Hz. After preconditioning, sinusoidal cyclic loading was performed between loads of 50 N and 250 N for 1000 cycles at 1 Hz, followed by a pull-
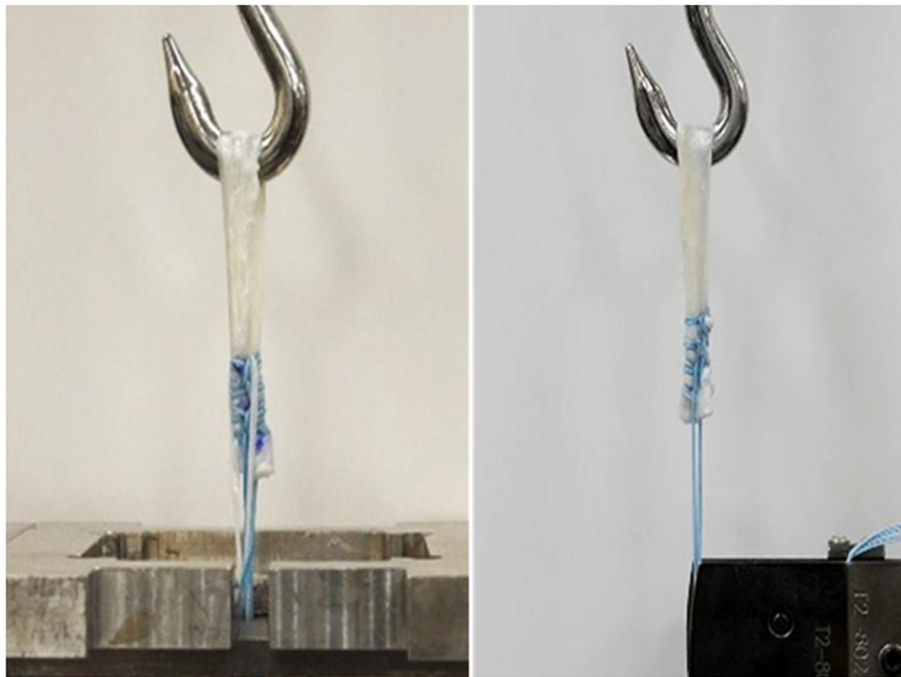

Fig. 3. Settings for biomechanical testing.
Left: A bovine extensor tendon sample, in which a suture button construct is secured to a metal plate with a 4.5-mm hole.
Right: A sutured bovine extensor tendon sample, in which suture tails are secured with a pneumatic clamp.

to-failure at 20 mm/min.[9,10] The elongation and load data were recorded for each sample at 500 Hz. The mode of failure was noted for each sample at the time of testing.

Statistical analysis

The mean elongation and ultimate load values of the bovine tendon sample groups were compared using a one-way analysis of variance ($\alpha = 0.05$), and pairwise multiple comparisons were made using the Holm-Sidek method. Because only 2 sample groups were included in Experiment (1), statistical analyses were performed using a two-sample *t*-test ($\alpha = 0.05$) using SPSS (software version 23.0, SPSS, IBM, Japan).

Results

Experiment

Cyclic loading test

In the SLL6 (single locking loop stitch with a diameter of 6 mm) group, no failure was noted following 1000 cycles, whereas 2 samples in the SLL5 (single locking loop stitch with a diameter of 5 mm) group demonstrated soft tissue tearing at cycle 59 and cycle 166. Elongation at 1000 cycles was 4.0 ± 0.8 mm in the SLL6 group and 7.8 ± 2.9 mm in the SLL5 group (excluding failed samples). Significant differences were noted between the groups (Table 1).

Pull-to-failure test

Ultimate load in the SLL6 and SLL5 groups was 590 ± 60.8 N and 394.5 ± 121.4 N, respectively; ultimate load was significantly higher in the SLL6 group ($P = 0.006$) (Table 1).

Failure mode

At the proximal suture site, the suture slipped toward the free end in all samples, and the stump tore at the sites where the needle passed through, which resulted in soft tissue tearing (indicated by ↔ in Fig. 4). The tear occurred on the non-locking side in 4 of 6 samples (66.7%) in the SLL6 group and 5 of 6 samples (83.3%) in the SLL5 group (Fig. 4).

Experiment

Cyclic loading test

Failure was observed in the SLL and ZLL groups, as 2 samples in

Table 1
Biomechanical properties due to graft diameter significant difference from SLL5.

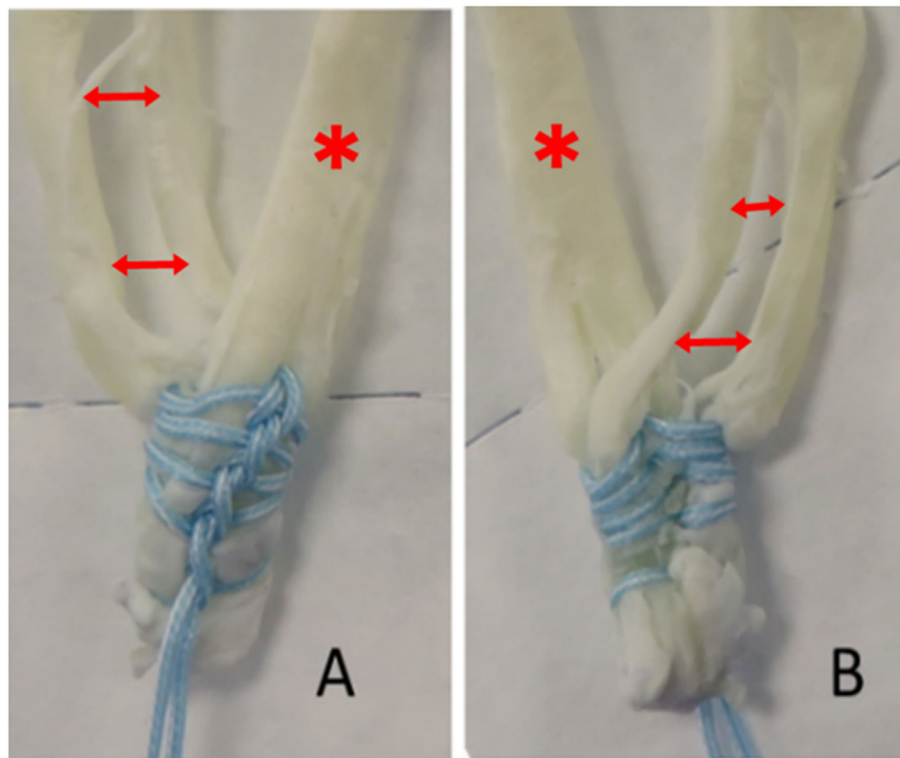| Sample	Cyclic Loading Test Number Of Failures/Cycles	Elongation (mm)	Ultimate Load (N)
SLL6 (n = 6)	0/-	4.0 ± 0.8[a]	590 ± 60.8[b]
SLL5 (n = 6)	2/59.166	7.8 ± 2.9	394.5 ± 121.4

[a] p < 0.1.
[b] p < 0.05.

Fig. 4. Tear pattern of the construct. Soft tissue tearing mainly occurred on the non-locking side, which included sites where the needle passed through (↔).
A: locking side (✳) .
B: non-locking side.

Table 2
Biomechanical properties due to suture configuration.

Sample	Cyclic Loading Test Number Of Failures/Cycles	Elongation (mm)	Ultimate Load (N)
SLL (n = 6)	2/59.166	7.8 ± 2.9	394.5 ± 121.4
ZLL (n = 6)	1/890	6.2 ± 2.7	456.5 ± 112.1
DZLL (n = 6)	0/-	5.2 ± 0.7[a]	558.7 ± 47.6
DK (n = 6)	0/-	4.3 ± 1.0[b]	505.5 ± 38.4
DK w/o RT (n = 6)	0/-	8.3 ± 1.3	549.7 ± 138.3

[a] Significant difference from DK w/o TR, $p < 0.05$.
[b] Significant difference from SLL and DK w/o TR, $p < 0.05$.

the SLL group demonstrated soft tissue tearing (at cycle 59 and cycle 166), as did 1 sample in the ZLL group (at cycle 890). In the DZLL, DK, and DK w/o TR groups, no failure was noted after 1000 cycles. Elongation at 1000 cycles was 5.2 ± 0.7 mm in the DZLL group and 4.3 ± 1.0 mm in the DK group. The values were not significantly different between the two groups. The value in the DZLL group was significantly smaller compared to the value in the DK w/o TR (8.3 ± 1.3 mm, P = 0.0400) group, and the value in the DK group was significantly smaller compared to the values in the SLL (7.8 ± 2.9 mm, p = 0.0392) and DK w/o TR (P = 0.0056) groups. Elongation in the DK w/o RT group was the largest of all groups (Table 2).

Pull-to-failure test

Ultimate load was the highest in the DZLL group (558.7 ± 47.6 N) but a statistical difference was not observed among the groups (Table 2). Note that two failure constructs from SLL and one from ZLL were excluded from the elongation and ultimate load tests.

Discussion

The effect of suture configurations

The optimum tension required during graft fixation using the current ACL reconstruction techniques is controversial[1–4] and it is unclear whether the tension measured by a tensioner is reproduced after fixation. To enable the adjustment of graft tibial tension after initial fixation,[5] we used the modified graft wherein an adjustable loop-button device (TightRope™) is applied on the tibial side for double-bundle ACL reconstruction. As the weak point of this construct was where the looped graft sutured to itself, we then wanted to test different graft suturing techniques to optimize the strength of the overall graft construct.

The mechanical strength using various suture techniques has been assessed, and the usefulness of the Krackow locking stitch and locking loop stitch has been reported.[8,11,12] Based on the findings of these previous articles, we sought to examine and describe the mechanical strength of a single-looped graft wherein a combination of suture and TightRope™ is used on the tibial side of the graft to take advantage of the characteristics of TightRope™. The modification of the base suture helped to achieve strength against failure that was comparable to the recommended graft prepared by the double Krackow stitch.[13] Significantly superior elongation results also were demonstrated using this modification.

In previous studies, the strength at the tendon suture site against the traction of the suture thread was reported to be important. However, in the grafts used in the present study, the strength at the base against the shearing force due to the traction of TightRope™ is also important.

In Experiment (1), the single locking loop stitch technique showed significantly larger elongation and significantly lower strength against failure in grafts with a 5 mm diameter compared to

those with a 6 mm diameter. As the strength and elasticity properties of the tendon and suture thread and TightRope™ are similar, the main factor influencing failure and elongation is the degree of tendon tearing.

Hence, to reduce the degree of tearing, we focused on modifying the suture techniques. First, we adopted a zigzag locking loop stitch. In the conventional locking loop stitch, the insertion sites of the loop needle are arranged in a longitudinal row, and are consequently subjected to the linear traction load. In contrast, with the zigzag locking loop stitch, the insertion sites are arranged in a zigzag manner to shift the direction of the mechanical load away from the direction of tearing. Second, we used two pieces of suture. In a study of the Krackow locking stitch and non-locking loop stitch using porcine flexor digitorum tendons, Hahn et al. reported that there is no relationship between the increase in the number of loops and the decrease in elongation and increase in strength against failure when more than 4 loops were applied.[14] McKeon et al. and Hong CK et al. reported similar results.[13,15] The former reported that the number of locking loops was not associated with an increase in the strength against failure, but an increase in the number of sutures was associated with strength in a study of the Krackow locking stitch using porcine Achilles tendons.[13] Thus, increasing the number of sutures is more important than increasing the number of locking loops. Therefore, in the present study, we aimed to strengthen the base suture by using two pieces of suture, rather than by increasing the number of locking loops of a thread.

As a result, in Experiment (2), the grafts with a 5 mm diameter, prepared using a double-suture stitch, demonstrated a significant decrease in elongation and an increase in strength against failure. These results are similar to previous reports.[8,11] When using a zigzag locking loop stitch, although no significant difference was noted, a relatively stable mechanical strength than SLL was obtained. Hence, in terms of both elongation and strength against failure, this technique may be useful.

Graft diameter

The graft diameter examined in Experiment 2 was 5 mm, and this seems to be the smallest used in such studies as reported by previous work in this field. Some papers dealt with tendons more than 7 mm in diameter,[9,16,17] and others reported a cross sectional area of more than 40 mm.[2,8,15] Sakaguchi et al. conducted their study with porcine flexor tendon with cross sectional area of 17 mm^2 that seemed to be the smallest based on the previous literature,[18] and that was more than 6 mm in diameter when doubled over. To examine the mechanical properties of the grafts for double bundle ACL reconstruction, grafts 5 mm in diameter might be better examined because they are commonly used clinically.[6,7] Greater diameter is the important parameter to determine strength and failure risk, as shown in Experiment 1 of the present study.
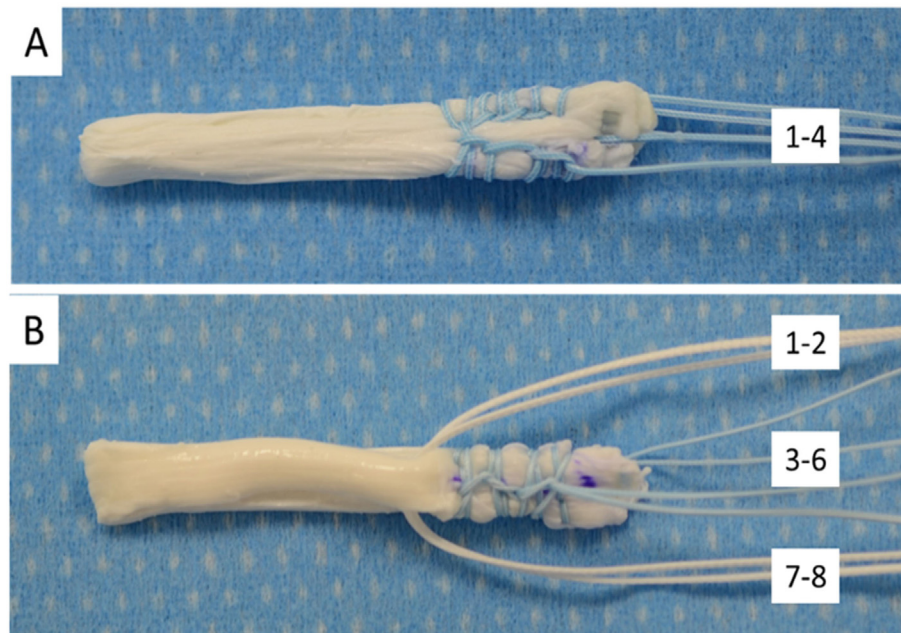
Fig. 5. Graft configuration with or without TightRope™.
A: In the groups without TightRope™, the number of traction threads is 4.
B: In the groups with TightRope™, the number of traction threads is 8.

Load on the ACL

Yanke et al. estimated that the load on the ACL in vivo is 303–445 N.[19] In the present study, ultimate load was 558.7 ± 112.1 N using a double zigzag locking loop stitch, even in grafts with a 5 mm diameter (we assumed this as one bundle of a double bundle ACL reconstruction). Therefore, these grafts are expected to be capable of withstanding the load experienced in daily life. When using a double-suture stitch, grafts with a small diameter can show adequate strength not only against traction, but also shearing force.

Importance of two sutures and function of TightRope™

In Experiment 1, we assessed mode of failure and found that tendon graft failure frequently occurs on the non-locking side. The usefulness of locking on both sides was demonstrated in Experiment (2). By using double-suture stitches, the tendon was tightly gripped from both sides and strengthened. The DK w/o TR group demonstrated greater strength against failure, similar to previous reports,[13] although larger elongation was observed. In the groups with TightRope™, given that a loop of TightRope™ corresponds to 4 pieces of traction thread, the traction load per thread might have been reduced because the number of traction threads increased from 4 to 8 (Fig. 5). Furthermore, in the groups with TightRope™, the loosening of the thread by contraction should not occur due to the absence of locking elements in TightRope™. However, in the DK w/o TR group, suturing threads would be loosened by contraction. This is a possible explanation for why the DK w/o TR group demonstrated larger elongation.

This study demonstrated a clinically safe and useable graft preparation technique for double-bundle reconstruction using TightRope™ on the tibial side. With the use of this graft, dispersion of the final fixation tension will be reduced. This may lead to further research into more appropriate fixation strength/techniques by combining a modification such as digitizing final fixation tension.

Limitations

First, we used bovine extensor tendons for the study. Human material would be ideal but almost identical biomechanical properties have been reported between bovine extensor tendons and human semitendinosus tendons.[20] Second, living tendons might be ideal for the study but due to the availability, we used frozen and thawed tendon, as did most previous studies. Third, we conducted mechanical tests under a condition of linear loading, which may be very different from the loads generated in the knees from flexion, extension, rotation, and antero-posterior sliding. Fourth, due to the large number of loops (locks), there are concerns regarding ischemia and fraying caused by strangulation of the graft configuration. A small part of the tendon is exposed at a suture site, which is unfavorable for tendon-to-bone healing.

Conclusions

We examined different graft preparation techniques using TightRope™ on the tibial side to verify an appropriately strong construct. The mechanical strength at the suture site decreases in grafts with a smaller diameter, when the same suture technique is applied. However, the double-zigzag-suture stitch technique provided the grafts with the strongest mechanical strength for double-bundle ACL reconstruction.

Conflicts of interest

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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